

诺尔康白皮书

二零一八年

浙江诺尔康神经电子科技股份有限公司
NUROTRON BIOTECHNOLOGY., Ltd.



诺尔康白皮书

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16例诺尔康人工耳蜗 植入术后听觉言语康复效果分析

Treatment Outcome of Nurotron Cochlear Implants in 16 Cases

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【摘要】目的 分析国产诺尔康人工耳蜗植入术后患者的听觉言语康复效果。**方法** 回顾分析我院2010年5月~2015年11月植入诺尔康人工耳蜗,并完成10月~5.5年随访的患者16例,采用电话随访患者本人及其家属,使用听觉行为分级标准(categories of auditory performance, CAP)和言语可懂度分级标准(speech intelligibility rating, SIR)评价其听觉言语康复效果。**结果** 16例(16耳)电极全部顺利植入耳蜗内;术后无脑膜炎、面瘫、脑脊液漏等并发症;随访46月后, CAP得分较术前显著提高($P < 0.05$), SIR得分差异无显著性意义($P > 0.05$)。④语后聋患者的听觉能力改善显著,语前聋患者效果不明显。**结论** 诺尔康人工耳蜗植入后可有效提高患者听觉言语能力,但应尽早植入。

【关键词】人工耳蜗;手术;治疗结果

【Abstract】Objective To summarize the treatment outcome of Nurotron cochlear implants in patients with profound sensorineural hearing loss(SNHL). **Methods** Twenty-two patients with profound SNHL received Nurotron cochlear implants from May 2010 to Nov. 2015. After 10 months to 5.5 years(45.75 ± 23.67 months) follow up, 16 patients were interviewed by telephone. The outcome of auditory and speech rehabilitation was evaluated with Categories of Auditory Performance (CAP) and Speech Intelligibility Rating (SIR). **Results** 1) All electrodes were successfully inserted into cochlea. 2) No serious postoperative complications occurred. 3) Compared to preoperative value, there was a significant improvement in postoperative CAP($P < 0.05$), and no obvious improvement in postoperative SIR($P > 0.05$). 4) The improvement of CAP of patients with postlingual deafness was significant, while that of patients with prelingual deafness was not evident. **Conclusions** Nurotron cochlear implant is safe and effective in improving the auditory and speech rehabilitation for patients with profound SNHL. The earlier it is implanted, the better the outcome is.

【Key words】Cochlear implant; Surgery; Treatment outcome

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人工耳蜗植入是目前治疗重度和极重度感音神经性聋最为有效的方法。目前国内市场使用的人工耳蜗主要来自国外三家公司,由于其价格昂贵,使得很多患者无法受益。近年来随着科技和民族工业的发展,国内由浙江诺尔康神经电子科技股份有限公司研发出诺尔康人工耳蜗,逐渐在国内获得应用^[1,2]。我科已成功植入22例患者,电话随访其听觉言语康复后的效果,6例失访,现将随访的16患者的结果报道如下。

1 资料和方法

1.1 患者基本资料

16例(16耳)患者均为极重度感音神经性聋,男11例,女5例,年龄6~51岁,平均年龄 25.10 ± 11.10 岁。语前聋6例,语后聋10例。其中1例合并双侧前庭导水管扩大,2例有头部外伤史。

1.2 术前检查结果

1.2.1 听力检查结果 16例患者术前纯音测听均为极重度感音神经性耳聋,平均听阈大于95 dB HL。听觉脑干诱发电位双侧100 dB nHL均未引出。耳声发射双侧均未引出。

1.2.2 影像学检查结果 行颞骨薄层CT及头颅MRI,除1例合并双侧前庭导水管扩大,其余患者内耳及内听道、颅脑均无明显异常。

1.3 手术及听力言语康复训练

手术均经乳突后鼓室面神经隐窝入路行人工耳蜗植入,均为单耳,其中右耳9例,左耳7例,植入CS-10型诺尔康人工耳蜗。术后于重庆市残疾人综合服务中心康复训练。随访10月~6年,平均 45.75 ± 23.67 月。

1.4 术后听觉言语能力评估

患者经正规康复训练后,电话随访其CAP和SIR评分^[3,4]。

1.5 统计分析

采用SPSS 20.0进行统计分析, $P < 0.05$ 为差异有显著性意义。

2 结果

2.1 手术及开机调试结果

16例患儿人工耳蜗电极均成功植入,术后切口均1期愈合,无脑膜炎、面瘫、脑脊液漏等并发症。术后第3天行头颅正位片,确定电极放置正确,术后约1个月开机调试正常。

2.2 听力言语康复情况

2.2.1 所有患者的详细病例资料 术前CAP平均得分 3.00 ± 1.86 ,术后CAP平均得分为 5.13 ± 2.19 。术后得分较术前得分差异有显著性意义($P < 0.05$),见表1。

SIR分级术前平均得分 3.75 ± 1.57 。术后平均得分 4.00 ± 1.14 。术后得分较术前得分差异没有显著性意义($P > 0.05$),见表1。

2.2.2 患者的听觉言语康复效果 从表2可以看出,在所有患者中,术后CAP值与术前相比有差异有显著性意义($P < 0.05$),术后SIR值与术前相比差异无显著性意义($P > 0.05$)。分别分析语前聋和语后聋患者的听觉言语康复效果,可见语前聋患者的术后CAP值和SIR值与术前相比差异均无显著性差异($P > 0.05$),语后聋患者的术后CAP值与术前相比差异有显著性意义($P < 0.05$),即术后较术前有显著提高,而术后SIR值与术前相比差异无显著性意义($P > 0.05$)。

3 讨论

诺尔康人工耳蜗于2011年8月获得国家食品药品监督管理局颁发的产品注册证,填补了国产人工耳蜗的空白。截止2015年12月,已有近3000名听障植入者。诺尔康人工耳蜗由植入体部分和体外言语处理器部分组成。植入体部分的壳体采用钛金外壳外裹硅胶材料,电极单向C型(马鞍型)设计,保证电极触点面向蜗轴。电极采用铂铱合金材料,蜗内24个电极,蜗外2个,电极长度为20.5 mm,电极间隔0.85 mm,壳体体积12.8 cc(56.4 mm × 33.0 mm × 6.9 mm)。植入体采用多电流源技术,可以实现虚拟通道,钛金壳体,抗撞击能力强,软性导向电极,有保留采残余听力的可能性。该产品同样适用于耳蜗骨化、耳蜗畸形、共腔畸形的情况。

在使用诺尔康人工耳蜗的工作中,体会到该产品体积较小,不需磨除过多的骨质,电极柔韧度适中,植入时阻力不大。植入后没有发生感染、异常电刺激、排异反应等,也没有发生脑膜炎、面瘫、脑脊液漏等并发症,表明其安全可靠。

资料显示,植入后经过正规的言语康复训练,全部患者的CAP值较术前显著提高,表明患者的听觉能力显著改善,不借助唇读也能辨别言语声。所有患者SIR值的术后与术前差异无显著性意义。分

表1 16例患者的详细病例资料

患者编号	年龄	手术侧	随访时间	术前CAP评分	术后CAP评分	CAP差	术前SIR评分	术后SIR评分	SIR差	语前聋/语后聋
1	36	左	76	1	8	7	4	4	0	语后聋
2	16	左	76	6	8	2	5	5	0	语后聋
3	26	右	76	6	7	1	5	5	0	语后聋
4	21	左	70	4	5	1	3	5	2	语后聋
5	34	左	76	6	7	1	5	5	0	语后聋
6	25	右	55	2	7	5	5	5	0	语后聋
7	15	左	54	2	2	0	5	5	0	语后聋
8	18	右	40	1	2	1	1	1	0	语前聋
9	21	左	39	1	2	1	5	5	0	语后聋
10	39	右	39	3	6	3	5	5	0	语后聋
11	6	右	38	2	7	5	1	3	2	语前聋
12	20	右	24	5	5	0	4	4	0	语前聋
13	51	左	23	1	5	4	5	5	0	语后聋
14	33	右	20	2	2	0	1	1	0	语前聋
15	22	右	16	3	5	2	3	3	0	语前聋
16	18	右	10	3	4	1	3	3	0	语前聋

表2 16例患者听觉言语康复效果

	分组	术前	术后	P
全部患者	CAP	3.0±1.9	5.1±2.2	<0.001
	SIR	3.8±1.6	4.0±1.4	0.16
语前聋	CAP	2.7±1.4	4.2±1.9	0.15
	SIR	2.2±1.3	2.5±1.2	0.66
语后聋	CAP	3.2±2.1	5.7±2.2	0.02
	SIR	4.7±0.7	4.9±0.3	0.41

析其原因,可能因多数患者为语后聋(10/16),其语言并未受太大影响,术前SIR分值即较高(4.7分),而语前聋患者SIR为2.2分。为此,我们进一步分别分析语前聋和语后聋患者,发现语后聋患者的CAP值由3.2提高至5.7,术前术后比较差异有显著性意义($P<0.05$),SIR值由4.7提高至4.9,差异没有显著性意义($P>0.05$),表明这些患者的听觉能力改善显著,但SIR提高并不显著。病例4为突聋后1年植入CI,其病程在所有语后聋患者中为最短的,其SIR由术前的3分提高至术后的5分,目前尚不能确定病程与SIR间是否有相关性。郭思荃等^[5]的研究表明,语后聋患者人工耳蜗植入后CAP与听力下降时间、植入时间、术前助听器使用情况无相关性。

而植入CI后的时间越长,患者的言语识别能力越强,这可能是由于听觉可塑性机制的存在,引起听觉皮层区域和负责语言处理的相关皮层被激活,进而从听觉剥夺引起的损伤中恢复^[6]。语后聋患者由于听觉皮层发育完全,术前语言能力受影响不大,其言语几乎都为聆听者听懂,因此绝大部分患者的SIR在术前术后无明显变化。

语前聋患者的CAP值由2.7提高至4.2,术前术后比较差异没有显著性意义($P>0.05$),SIR由2.2提高至2.5,差异没有显著性意义($P>0.05$),表明这些患者的听觉言语康复效果均不佳。详细分析其病史可以发现,病例8、14、15、16为语前聋,植入时已成年,植入后的CAP仅提高1~2分,而SIR均无变

化,仅为1~3分,显示这些患者的康复效果不佳。病例11虽亦为语前聋,但植入时仅为6岁,经过3年多的康复,其CAP提高2分提高至7分,SIR提高1分提高至3分,显示康复效果好。病例12亦为语前聋,但在听力下降后及时配戴助听器,并进行了康复训练,因此术前的CAP值为5,SIR值为4。现有研究表明,对于语前聋患者,人工耳蜗植入的年龄越小,听力及言语水平恢复越快,而术前平均残余听力、术前使用助听器时间、术前语训时间、康复训练时间与术后听力言语康复效果密切相关^[7-9]。随着随访时间的增加,患者的听觉言语能力可能还会进一步提高。

上述结果表明,植入诺尔康人工耳蜗后,对于语后聋患者,可显著提高其听觉能力,而对于语前聋患者,应尽早植入,以利于听觉言语康复,成年后再植入则听觉言语康复效果差,即使未植入人工耳蜗,也应该早期干预(如配戴助听器),将有利于听觉言语康复。本组病例较少,还需积累更多病例观察疗效。

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人工耳蜗开机与调试 ——特殊问题探讨

Analysis of Related Special Issues of Switch-on
and Mapping for Cochlear Implant Recipients

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【摘要】按照常规方法可以顺利完成大部分人工耳蜗植入者的程序调试,但遇有植入者患有耳蜗畸形、骨化,调试欠配合及出现蜗外电极等特殊情况下,需要调试者掌握一些特殊技巧才有可能做到人工耳蜗调试效果最大化。本文作者根据多年调试经验进行总结,希望可以对人工耳蜗调试工作者提供参考借鉴。

【关键词】人工耳蜗;开机;调试

【Abstract】Routing mapping can help most of cochlear implant recipients hear, but special mapping tactics should be applied for some special cases such as recipients suffered from cochlear malformation, ossification, less cooperation with mapping and unusual ex-cochlear electrodes to maximize cochlear implant mapping outcomes. Authors reviewed their very rich mapping experience and summarized in this paper. The purpose is to provide a reference for clinical audiologists who are dedicate in cochlear implant recipients' mapping work.

【Key words】Cochlear implant; Switchon; Mapping

人工耳蜗开机和调试工作是人工耳蜗系统工作的重要环节,开机和调试是否成功直接影响人工耳蜗植入者的听声效果。如果植入者耳蜗结构无异常,对开机后预期效果有正确的期望值,植入手术顺利且达到了产品设计的插入深度和插入部位,产品各参数均正常工作和植入者能配合的前提下,则开机和调试工作一般耗时较短,非常顺利。但反之则开机和调试工作会面临较大挑战,如果掌握了一定规律和技巧依然可以最大化植入者听声效果。

1 人工耳蜗调试定义

调试的英文原文是mapping,可以译为调机或编程。其本意是模式匹配的过程,即将耳蜗内电刺激所产生的心理响度和音调与大脑听中枢相应区域做出映射匹配从而得以识别的过程。

人工耳蜗调试分为开机调试和随访调试两种类型,开机调试是指人工耳蜗术后一段时间内,听力师将植入者体外和体内设备物理性(磁铁吸附)连接并检查植入体状态和设置、测试和保存程序发出刺激,植入者开始听到声音的过程。随访调试是指开机后特定的时间段,对植入者的植入体进行检测和程序调整,以及咨询,解决植入者的听声问题和确保在调试后一段时期内达到最佳聆听的过程。

2 人工耳蜗开机和调试的一般流程

通常在人工耳蜗植入术后4周左右开机。开机时,要确保植入者皮瓣正常,切口愈合良好。听力师要充分了解植入者对植入效果的期望值以及术前、手术情况和查看术后植入体X-线片和/或CT片(如有)并进行相应咨询。将植入者体外设备的处理器与编程器

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通过编程导线相连,将外传输线圈(也称为头件)隔头皮与头皮下内传输线圈通过磁铁相吸附物理连接。打开调试软件,建立植入者档案,测试阻抗,选择刺激参数(一般为默认值),测试通道T和C值,建立和保存程序,在实景听声模式下,进行林氏六音等测试。指导植入者使用设备,康复安排,预约下次调试时间等。随访调试时,要了解植入者听声情况并进行听力评估,根据了解到的植入者听声情况和评估结果调整程序,操作过程与开机调试相仿,不再赘述。

3 对特殊案例的调试

3.1 异常电极的调试处理

3.1.1 蜗外电极的调试处理:此处蜗外电极是指位于本应插入耳蜗的电极系列的电极或触点位于蜗外(如中耳腔)的情形,要与植入体自身的蜗外参考电极(如MP1和MP2)区分开来。判断蜗外电极的方法包括查看医生手术记录,阅读植入者植入术后拍摄的特定体位X线片,CT片^[12],以及调试时查看植入者对单一电极特别是位于蜗底的电极主观反应、客观反应(如NRT等)和蜗底电极与相邻电极是否呈现出“翘尾巴”的图形。通过电极阻抗值判断电极是否位于蜗外是不准确的,这是由于蜗外电极只要与中耳组织或体液接触其阻抗值可以表现为正常。遇有确切的蜗外的电极应予以关闭,被关闭电极所承担的刺激频段会由相邻可用电极承担刺激。

3.1.2 超容顺电极/通道的调试处理:电极/通道超容顺是指由于单个或多个电极阻抗值过高,造成受累电极电压不足以提供相应的电流获得植入者T和/或C值(C值常见),从而造成植入者心理响度不能随刺激量的增加而变化。即发生超容顺时,虽然电流值可以人为上升,但植入者的心理响度不会随着超过容顺的电流值增加而变响,且会增加耗电量以及“低效占用频段”。因此必须处理超容顺的通道。视超容顺通道数目多寡,采用增加单一通道或所有通道的脉宽,从而降低刺激幅度。必要时可以暂时关闭超容顺通道。

3.2 特殊的调试值

所谓特殊的调试值是指由于电极或植入者自身因素导致的一些“特殊值”,听力师遇有这些“特殊值”时需要做出准确判断,并巧加利用,不但处理好植入者的症状,也借“特殊值”加速设定调试程序。常见的“特殊值”包括:

3.2.1 T尾巴值:所谓T尾巴是指将植入者刚听到声音时的电流值初步判断为T值,但随着电流刺激

的增长,植入者反馈的心理响度并未随之增加,直至到一个“拐点”植入者方才指出声音较上一个刺激级大一些。这种从刚听到响度增加的“拐点”数值,可以称之为T尾巴。此时的T值应设定在T尾巴的“拐点”处的电流值。

3.2.2 “(面)抽值”:指给声(电)时发生面部(常见植入侧眼睑和口角)抽搐症状的电刺激量。人工耳蜗植入者发生的面抽往往是由于电刺激面神经所致,原因可能是面神经走行的骨壁对刺激电流的通透性高(如患有耳硬化症人工耳蜗植入者),骨壁有裂隙或缺失和/或刺激电流过大导致。如果是单通道刺激引起的面抽,可以尝试增加该通道的脉宽,从而降低刺激幅度,或者直接关闭该通道。通过以C值扫描或实景听声时发出林氏六音观察引起面抽的通道(频率)所在,如果引起面抽的通道较多,可以采用逐次关掉2~3个通道的方法,仔细查找问题通道。找到问题通道后即可通过上述增加脉宽或关闭通道的方法解决问题。如果关掉可用通道25%,面抽仍然存在时,可改变电流刺激的模式(如:Monopolar或Bipolar等)。此外还要结合“抽值”是否达到了C值,也即要结合抽值和容顺值设定C值。建议对于有面抽的植入者,可以先查“抽值”是否低于C值,如果“抽值”低于C值时就需要增加脉宽。假设为通道设定T值后发现因为面抽无法设定该通道C值而增加脉宽,就需要重测该通道的T值,从而会造成调试时间的延长。

3.2.3 “哭值”:部分年幼小儿调试时,不能很好配合,致使可能在某一刺激量时发生哭闹,打砸玩具,拿掉或蹭掉线圈的现象。可以根据孩子的年龄采用适宜的小儿行为测听法或客观法(如NRT)进行程序设定。如依然无法配合或没有获取客观阈值。则参考其“哭值”,在“哭值”基础上降低10个左右电流级作为C值,设定30电流级的动态范围,即T值等于C值减30电流级。并在此基础上实景听声和整体调整T和C值。如果可以耐受,则嘱咐家长或老师进行听声放物反应训练,并缩短下次来调试时间,从而进一步按照标准手段进行调试。

3.3 电池使用寿命短的处理

影响电池使用寿命的因素众多,包括电池品牌、使用方法、使用环境(温湿度、背景噪音程度等)、植入体部位皮瓣厚度、电极性能(阻抗值等)、程序设置(功率、刺激率、C值、T值、脉宽、超容顺通道数、每刺激通道数等)。遇有植入者抱怨其电池使用寿命短时,应首先要明确植入者的以上电池寿命相关因素情况如何,从而判断其电池寿命是否为异常。如果“正常”则予以

说明是由于其自身因素(如皮瓣过厚)或已经最优化的程序因素导致,这时要考虑使用充电电池以减少电池花费。其次还要排除植入者使用不当的情形,包括用线圈套缠绕线圈、将线圈从头皮取下时不关机、经常在吵闹环境下听声以及使用环境的温湿度不恰当和其它电池使用方法不当等情形。排除以上因素后,就要从程序入手解决。推荐按照以下步骤操作,a)降低功率(Power Lever);降低功率是最有效的省电手段,但要求植入者可以配合说出当功率降低时,其听声有无改变。常见功率降到某一数值时,植入者反映发生声音断续的情况,要避免此情况的发生。b)降低刺激率,改变刺激率后要重新设定T和C值。c)整体降低C值。d)处理超容顺通道,使其回归到容顺值内。e)降低脉宽,改变脉宽后要重新设定T和C值。f)减少每刺激通道数,改变每刺激通道数后要重新设定T和C值。以上手段应逐一尝试,且以不影响植入者听声为原则。如果通过调试改善了电池使用寿命,但影响了植入者听声效果时,则要与植入者或家人商量取舍。对于有多种电池供电方式的设备,可以推荐使用大电能的供电方式(如体佩式供电系统)。

3.4 听声质量不佳的处理

大部分成人语后聋植入者虽然最终效果优良,但他们在开机及早期随访调试时往往有较多的反映听声质量不佳的主观症状。听力师在处理听声质量不佳等植入者或其家人反映的主观症状时,要遵循以下原则处理:(1)高度重视植入者的症状,向植入者和家人了解影响植入者听声的社会、心理等因素。(2)进行相应测试,最简单的是林氏六音测试,进而可以实施声场、言语测试及问卷评估等。(3)先简后繁原则,即先检查植入者对设备的设置(如选取的程序位置、音量和敏感度设置等)是否恰当。(4)先外后内的原则,即先对植入者体外设备进行排查,常用监听耳机和信号检测仪检查,有些型号的人工耳蜗系统自带故障检测提示,观察有无提示及提示内容,如确认体外机无障碍才进行植入体检查,调试乃至实施植入体整合测试。(5)根据阻抗测试结果处理故障电极。(6)根据植入者症状对程序做出相应调整,如低频症状,主要调整低频段电极的T和C值,增益等,为了排除植入者的心理暗示效应,可以进行“假动作”试验,即调试者可以做“假动作”(如假意操作键盘,实际上未改变任何数值)后实景听声,如果植入者反映音质发生了变化,则认为植入者反映的听声问题,可能是心理因素导致。(7)注重“话聊”,耐心解答植入者和家人提出的问题,做出权威正确的解释,指导植入者接受适宜的康

复训练,强调最重要的是要坚持佩戴,通过坚持佩戴植入者才能最终适应和喜爱人工耳蜗刺激声。

3.5 对患有耳蜗畸形、耳蜗骨化、听神经病、耳鸣等病症的植入者的调试

首先要了解术前咨询是否到位,开机前还要进一步的调整期望值,要了解手术情况,了解有无并发症,对耳蜗畸形和耳蜗骨化的案例强调必须阅读电极位置平片和CT片,耳蜗畸形、骨化时残存螺旋神经节细胞较少,往往要加大刺激电流脉宽。为听神经病病例调试时,Stanley P.等人发现,为那些哪怕使用多年人工耳蜗效果不佳的听神经病植入者调试时选用低刺激率可以提高他们的闭合式言语识别率^[3]。人工耳蜗电刺激往往可以抑制耳鸣,且刺激量越大抑制耳鸣效果越好^[4,5]。此外,由于耳蜗畸形儿童植入人工耳蜗后罹患脑膜炎的风险高,故应告诫家长为孩子进行脑膜炎预防接种。

总结:调试是人工耳蜗系统工作中的重要环节。调试人员应不但能胜任正常情况下的调试工作,也应该具有对特殊情况下的耳蜗调试技巧,这样才能做好调试工作,确保植入者能最大化地使用人工耳蜗听声。

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诺尔康人工耳蜗术后 电诱发镫骨肌反射测试及临床应用

Electrically Evoked Stapedius Reflex and Clinical Trials in Post-Cochlear Implant Patients of Nurotron

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【摘要】目的 探讨电诱发镫骨肌反射(Electrically evoked Stapedius Reflex, ESR)的特性及其反应阈(Electrically evoked Stapedius Reflex Threshold, ESRT)与心理物理测量数值(T和C值)之间的关系,为人工耳蜗调试刺激参数的设定提供参考。**方法** 选取植入诺尔康晨星人工耳蜗系统(CS-10A植入体),能配合行为调试并可以准确反映其听声感受的植入者19例,采用心理物理方法测量其T值(Threshold Level)、C值(Comfortable Level)及相应电极的ESRT值,并对数据进行分析比较。**结果** ESRT阈与植入者反映的C值具有良好的相关性,其关系为 $C=1.022 \times ESRT - 15.143$,而T值与C值、ESRT值之间均无相关性($P>0.05$)。**结论** 诺尔康晨星人工耳蜗系统调试中,可通过测量ESRT值以帮助设定难测者的C值,并有助于动态观察植入者听神经功能。

【关键词】诺尔康;晨星人工耳蜗系统;ESRT

【Abstract】Objective The aim of this study was to explore the characteristics of the electrically evoked stapedius reflex (ESR) and the electrically evoked stapedius reflex threshold (ESRT), and its relation with the threshold level (TL) and comfort level (CL), so that it can provide information for the parameter setting of cochlear implant (CI) mapping (programming). **Methods** 19 Nurotron Venus cochlear implant recipients, who could cooperate with mapping and who could well reflect the hearing perception, participated in this study. The TL and CL were obtained psychophysically. The results of TLs and CLs were statistically compared to the ESRT results. **Results** ESRT value had a significant correlation with CL, which was concluded as $CL=1.022 \times ESRT - 15.143$, but TL had no significant correlation with ESRT and CL ($P>0.05$). **Conclusion** ESRT can be used to estimate the CL in Nurotron Venus cochlear implant users who cannot well cooperate with the mapping, and also can be used to evaluate the nerve function.

【Key words】Nurotron;Morning-star cochlear system;ESRT

人工耳蜗调试是影响人工耳蜗术后效果的重要因素之一,调试中常采用心理物理方法设定T值和C值。对于配合度高的植入者,一般能够快速、准确地完成心理物理测试,但对低龄儿童、不能配合或多重残疾者,则较难设定,可以通过客观测试的神经遥测反应阈值估算和设置C值和/或T值^[1,2]。

正常情况下无论声音到达任一耳,只要达到一定强度即可引起双耳的镫骨肌反射。而通过人工耳蜗系统电刺激耳蜗残存的神经所诱发的反射为电诱发镫骨肌反射(ESR),其阈值为电诱发的镫骨肌反射阈值(ESRT)。本研究旨在探讨诺尔康晨星人工耳蜗系统植入者通过ESRT设定T值和C值的可行性。

1 研究对象及方法

1.1 研究对象

诺尔康晨星人工耳蜗系统植入者19例,其中女11例,男8例,年龄12—66岁,平均 29.79 ± 18.50 岁,其中语前聋6例均为先天性聋,语后聋13例包括药物性聋6例,遗传性聋4例,突发性聋3例,术前除1例突发性聋导致听力损失,听觉剥夺时间为1年,没有助听器佩戴史外,其余患者均佩戴助听器,但助听效果不佳;患者均为双侧极重度聋,单侧植入人工耳蜗。所有受试者的双耳鼓室导抗图均为A型,并有一定的交流能力和对声音响度的辨别能力,见表1。

1.2 研究方法

使用诺尔声调试系统(V 1.0),电刺激信号为脉冲波,脉宽为 $50 \mu s$,电极刺激频率为680 Hz,刺激时间为1 s,刺激间隔为1 s,每1电极刺激8次。以GS1中耳分析仪作为ESR记录装置。

实验方法:①可以从1号电极(对应的是诺尔康

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#并列第一作者

表1 受试者术前情况

案例	性别	术前年龄	病因	听剥时长	语前/语后	助听器验配史	中耳病史	手术情况	植入侧别
1	女	40岁	药物性聋	28年	语后聋	是	无	正常	右
2	女	43岁	药物性聋	31年	语后聋	是	无	正常	右
3	男	10岁	先天性聋	10年	语前聋	是	无	正常	左
4	女	17岁	LVAS	15年	语前聋	是	无	正常	左
5	男	8岁	突发性聋	1年	语后聋	否	无	正常	右
6	男	13岁	先天性聋	13年	语前聋	是	无	正常	左
7	女	18岁	原因不明	16年	语后聋	是	无	正常	左
8	男	19岁	LVAS	16年	语后聋	是	无	正常	右
9	男	10岁	遗传性聋	10年	语前聋	是	无	正常	左
10	女	50岁	多发神经衰弱	2年	语后聋	是	无	正常	右
11	女	41岁	遗传性聋	1年	语后聋	是	无	正常	左
12	男	34岁	药物性聋	27年	语后聋	是	无	正常	右
13	女	66岁	突发性聋	2年	语后聋	是	无	正常	左
14	女	29岁	先天性聋	29年	语后聋	是	无	正常	右
15	男	10岁	先天性聋	10年	语前聋	是	无	正常	左
16	女	11岁	先天性聋	11年	语前聋	是	无	正常	左
17	男	34岁	药物性聋	27年	语后聋	是	无	正常	右
18	女	66岁	突发性聋	2年	语后聋	是	无	正常	左
19	女	28岁	突发性聋	1年	语后聋	是	无	正常	左

蜗顶电极)开始选择,也可以中间向两端或蜗底到蜗顶,没有特定要求方向。该实验中,先对植入者进行心理物理的T、C值测量。T值为受试者刚刚能听到的最小电流值,以举手方式取得。C值为受试者能承受的最大电流值,听着大声且舒适,由植入者从“声音小”、“声音适合、中等”、“声音大、但是舒服”、“声音太大、不舒服、头疼”这四个级别中选择。②以植入耳的对侧耳为记录耳,将中耳分析仪探头塞入并密封外耳道,测试鼓室导抗图。③将中耳分析仪置于声衰模式。分别测试1、4、9、13、17、21、24号电极,分别对应的是从低频到高频。电刺激强度从对应测试电极的C值开始,将电刺激与声反射记录按键同时按下,记录反应。将能够记录到ESR的可重复的、最小的电流单位记为ESR阈值。ESR测试示意图见图1。



图1 ESR测试示意图

1.3 统计分析

使用SPSS 18.0进行统计分析,相关性分析采用spearman相关性检验, $P < 0.05$ 具有统计学意义。

2 结果

ESR总引出率为81.6%,采用对侧的镫骨肌反射记录。所有受试者均能引出镫骨肌反射,相关性分析表明C值和ESRT值具有良好的相关性($r=0.833, P < 0.001$),其关系为 $C=1.022 \times ESRT - 15.143$,但是T值与C值、ESRT值之间均无相关性($P > 0.05$)。此外,通过表1进行ESR引出率与年龄、性别、耳聋病因、听剥时长、语前/语后、助听器验配、手术情况、植入侧别及CAP因素的相关性分析,结果显示均无显著相关性($n=19, P > 0.05$)。

3 讨论

ESR通过电极刺激听神经,神经冲动传导至耳蜗核、面神经核,并支配面神经引起镫骨肌收缩,牵拉镫骨向后运动,引起中耳声顺的变化,通过中耳分析仪可以监测是否引起镫骨肌的收缩。与声反射

一样,ESR能够引出的前提是非测试耳(声导抗探头所在耳)的中耳功能正常,可以通过使用鼓室导抗图来鉴别。通过ESR的传导路径可知,如果能够引出ESR,表明脑干以下的听觉通路传导通畅,植入装置工作正常;然而未引出ESR,既不能说明植入者听神经功能不良,也不能够说明植入装置工作不正常。

目前报道的关于ESR无法引出的原因有两个^[3]:①刺激强度为ESRT时已经达到植入者的不舒适阈,无法再增加刺激强度;②可能与植入者的耳蜗及听神经的残存神经纤维数量有关,但是目前还无法验证这个假设。本研究植入者的低、中频电极ESR的引出率高于高频电极,且阈值呈蜗顶向蜗底升高的趋势,该结果与Battmer^[4]等一致,其研究也认为蜗顶电极ESR阈值较耳蜗中部及蜗底电极低,且ESR的引出在蜗顶电极相对容易记录到。当电流值达到容顺值,还没有引出声反射,可以对该电极增加脉宽,再测试。

本研究诺尔康人工耳蜗植入者的动态范围,与文献报道的其它厂牌人工耳蜗产品的ESRT高于T值,而低于C/M值,并位于两者动态范围之间^[3],这一结果存在较大差异,但与高娜等^[6]报道的诺尔康人工耳蜗ESRT和C值的关系一致。已有文献关于ESR的引出率报道并不一致,大致在70%左右^[4],本研究的引出率为81.6%。

已有研究报道T值远低于ESRT,ESRT在行为阈值和舒适阈的动态范围间70%~80%,因此对于无法用行为测试得到其C值的植入者,可以使用ESRT的结果作为参考^[7]。但是也有报道认为ESRT与C值的关系不确定,以ESRT作为C值是不准确的^[8]。本研究受试者所测试的电极中,很多都超出C值,且差异变化很大(2~65不等的电流级)。分析存在较大差异原因主要是C值是一个心理物理测量值,特别是语前聋患者,由于听觉经验不足,听觉剥夺时间长短不同,其个体差异更大。尽管本研究中ESRT的值高于C值,但在测试过程中,受试者没有出现由于声音过大而感觉不舒服的情况,因此C值是可以再调整的。ESRT可以用来验证和纠正人工耳蜗调试过程中植入者对声音响度的概念。

通过使用诺尔康晨星人工耳蜗系统可以引出ESR波形并判定ESRT,为无法配合完成行为测试的植入者进行调试,辅助设定其T值和C值,从而设

定或优化行为法设定的调试程序。ESR的测试也有助于动态观察植入者听神经功能的变化,是一项有价值和应用前景的电刺激诱发神经反应的生理试验方法。

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综述

单侧聋患者人工耳蜗植入的进展

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既往未将双耳非对称性听力损失(asymmetric hearing loss, AHL)的极端案例—单侧听力损失(unilateral hearing loss, UHL)或单侧聋(single side deafness, SSD)纳入人工耳蜗植入的适应症。近年来有人开始尝试为单侧聋伴有严重耳鸣的患者患耳植入人工耳蜗,结果发现不但可以有效地减轻甚至消除耳鸣,而且还发现适应后可以与健耳听力很好地整合,从而达到双耳聆听的效果。

非对称性听力损失(AHL)是指双耳间听力存在差距,泛指双耳听敏度存在一定程度的不对称,极端例子是差耳为全聋,而对侧耳听力正常或仅有轻度听力损失,一般将这种极端例子称为单侧听力损失(UHL)或单侧聋(SSD),此时,双耳0.5、1、2、4 kHz频率的平均纯音阈值(PTA4)差值(差耳PTA4—好耳PTA4)达到30 dB或更多,同时差耳听阈为重度到极重度听力损失,达到传统的人工耳蜗植入标准。另一个得到公认的UHL还需满足的附加条件是好耳平均听阈应好于60 dB HL,这样就明确了好耳不适合植入人工耳蜗¹。表1是以上定义的总结。

表1 基于纯音平均听阈的SSD、AHL、双耳听力不对称的差耳及好耳听阈

听力损失特征	差耳听阈	好耳听阈
SSD	重度到极重度听力损失	≤30 dB HL
AHL	重度到极重度听力损失	≥30 dB HL
双耳听力不对称	差耳PTA4—好耳PTA4	≥30 dB

根据普遍新生儿听力筛查数据估算,儿童单侧聋的发病率为1%~3%¹¹,成人单侧聋发病率较高,特别是老年人的发病率可以高达18%¹²。现在一些国家的医疗机构和医生已将单侧聋纳入人工耳

蜗植入的适应症。虽然单侧聋植入人工耳蜗效果满意,但中国同类案例较少,而且尚未正式纳入人工耳蜗植入的适应症,也未得到广大单侧聋患者的接受,因此,应当谨慎推荐。本文总结近年来对单侧聋的干预,特别是单侧聋人工耳蜗植入的情况,对单侧聋的病因、危害、干预及效果进行综述。

1 单侧聋的病因

造成单侧聋的原因可以是遗传性、先天性和获得性,如:单侧蜗神经发育异常(cochlear nerve deficiency CND),先天性小耳畸形、大前庭水管综合征、听神经病、病毒或细菌感染性耳聋、单侧突发性聋、噪声性聋、梅尼埃病、头部外伤、单侧听神经瘤等^{3,4}。

2 单侧聋的危害

非对称性听力损失和单侧聋患者对听到的言语信号中的语音线索,如:音调等的辨别能力弱^{5,6},造成言语识别率低⁷,但一般不会严重影响患者的言语和语言发育,且由于部分患者学习成绩没有受到直接影响,因此,许多单侧聋患者终生没有接受任何干预⁸。有研究(Lee DS1, 2001; Sharma et al, 2005)表明,如果在言语发育关键期发生耳聋,由于此时听觉功能未能建立,会导致中枢功能重塑,而这种重塑会降低植入人工耳蜗的预期效果。患者在人工耳蜗植入前,由于缺乏声刺激,其大脑易于发生交叉知觉模式重组(补偿)⁹(CROSS—MODAL recruitment),即大脑通过视觉和体感系统补充缺失的声信号刺激^{10~12}。发生单侧聋时,大脑会牺牲双侧声源定位能力,以强化单侧听力,这种效应导致高级听觉处理过程中获取语言的通路及听觉定位出现问题,即:这种中枢适应性的优化改变会对以后恢复聋侧听力和双耳声源定位功能不利¹³。单侧聋患者常常会反映其聋耳难以听懂谈话声,无法辨别声音来源以及在有背景噪声时难以理解语言(Giolas T, 1994)。有文献报道^{14,15},患有永久性单侧聋的儿童中有35%患儿无法跟上班级课程;单侧聋患者

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与他人交流或参加会议时往往要选择好耳朝向声源,从而造成尴尬和不便;单侧聋患者择业时也会受到一定限制,他们很难选择那些对听力要求高的职业;单侧聋的另一个危害是耳聋往往伴有严重的耳鸣。据估算突发性单侧聋的发病率为 1/10 000,其中 40% 患者伴有严重耳鸣,且每年每百万人口会新发 20~25 例¹。

3 单侧聋的干预

建议对非对称性听力损失和单侧聋进行干预。目前对单侧聋一般不治疗,可验配环绕信号(contralateral routing of signal, CROS)助听器(通过患侧耳放置的麦克风接收声音并无线传送到对侧耳助听设备)和应用骨导助听系统(BCHS),即:在患侧通过佩戴软带(softband)固定骨导助听器或通过手术植入钛钉(BAHA)或磁力钛板(sophono 等)外佩体外机,利用双耳骨导衰减小的原理获得“双耳”听力,但收效不大^{16,17}。这些干预方式并不能给患者带来真正的双侧听力,因为大脑仅接收和处理了来自单侧的声输入,因此,人工耳蜗植入是唯一能帮助单侧极重度聋患者恢复听力的选择¹⁸。另外有研究表明在某些情形下,个体可以将一耳的声刺激与另一耳的电刺激相结合从而获得双侧听力的益处^{19,20}。根据已知的人类言语发育关键期(3.5 岁)推算,应该在 3.5 岁前对单侧聋患者进行干预;因为 3.5 岁时聋耳与皮层间尚保持有残存的连接,也只能通过对弱势耳(weaker ear)的输入刺激才能加以补偿。确诊单侧聋后即便只是对弱势耳进行短期的训练,如:聆听睡前故事,都有可能进一步帮助患耳克服已经存在的对侧优势耳的趋势²¹。

4 单侧聋患者选择人工耳蜗植入的原因

为了解决单侧聋患者的难治性耳鸣症状,比利时的 Heyning 等为患有单侧聋合并耳鸣、而对侧耳听力正常或轻度听力损失的患者植入了人工耳蜗,尝试是否可以用电刺激的方式来抑制耳鸣,初步结果非常满意²²。此后,不断有医生尝试为伴有严重耳鸣的单侧聋患者植入人工耳蜗并逐渐将人工耳蜗植入适应症拓展到那些没有(严重)耳鸣的单侧聋患者,其后的研究结果表明^{24~25},单侧聋人工耳蜗植入者在使用人工耳蜗一段时间后可以整合双耳不同的刺激源(声和电)并获得了双耳听力的益处,比如:可以定位声音来源、听声“音量”变大、噪声环境下不必努力寻求健耳朝向发声源等。有单侧聋患者在发现其健侧耳听力开始下降,即将或已经成为双侧聋时,为了避免因双侧耳聋造成的听觉剥夺,而在原耳聋侧植入人工耳蜗,同期或之后又在新发耳聋侧植入人工耳蜗²⁶;单侧聋患者选择植入人工耳蜗的原

因还包括医患达成共识,给患耳植入人工耳蜗没有“失去”什么²⁷。现在有更多的单侧聋患者意识到了双耳听力在社会交往中所发挥的作用,因此,开始寻求对患耳进行干预²⁸。此外,尚有由于工伤导致单侧聋得到赔偿而植入诺尔康人工耳蜗的案例。

5 单侧聋患者人工耳蜗植入前后的测试方法

5.1 术前试用设备 除非有禁忌症,否则在评估方案中应包括其它干预方式(如传统的 CROS 及 BI-CROS 和骨导设备),对单侧聋患者试用软带骨导助听装置时应注意不要故意堵塞健耳,这样虽然会得到较好的试用效果,但与骨导助听设备植入后实际情况相差较大,会造成植入者的失望。

5.2 术前和术后测试手段 日常生活中需要通过双耳聆听进行声源定位,无法定位声源是非对称性听力损失患者术前的最大缺陷,而可以定位声源是单侧聋患者植入人工耳蜗后比较显著的收益。由于声源定位试验需要高度的认知能力的发育,所以年幼儿童特别是 4~6 岁以下的儿童不易配合;对头影效应的评估可能是一种相关的替代方法,该法可以显示双耳刺激的益处。目前尚无一种理想的疾病相关生活质量问卷表,推荐采用测试声源定位和疾病特定的生活质量问卷,例如言语、空间和听觉质量量表(speech, spatial and qualities of hearing, SSQ)^{29,30},该量表可以反映非对称性听力损失或单侧聋患者日常听觉能力和遇到困难的情境。由于无双侧听力的患者在噪声下听声比较困难,因此,也将噪声下测听纳入评估项目³¹。目前对非对称性听力损失的常用的言语测听方法包括:言语理解阈(speech reception threshold, SRT)测试、三维空间构型(three spatial speech-in-noise configurations)测试等。单侧聋患者人工耳蜗植入后,另外一个比较显著的收益是电刺激对耳鸣的抑制;评估耳鸣程度及对耳鸣抑制效果的测试量表包括:耳鸣残疾评估量表(tinnitus handicap inventory, THI)、耳鸣问卷(tinnitus questionnaire, TQ)和视觉比拟量表(visual analogue scale, VAS)^{21,34}。

5.3 测试方法细节 ①三维空间构型测试方法为:言语和噪声均自前方(0°方位)给出(S₀N₀),以测试双耳整合(binaural summation)效应;言语自前方(0°方位)给出而噪声从人工耳蜗植入侧(90°方位)给出(S₀N₉₀),以测试双耳抑噪(binaural squelch)效应;言语在人工耳蜗植入侧(90°方位)给出而噪声自正常听力侧(270°方位)给出(S₉₀N₂₇₀),以测试头影和噪声抑制的结合效应。测试时采用关闭人工耳蜗(CL_{off})和开启人工耳蜗(CL_{on})两种测试条件。平常佩戴助听器的患者在接受测试时应继续佩戴原有助

听器。

②SSQ 包含有 50 个问题,分为三组题,分别为言语、空间和声音质量评分;SSQ 得分有助于判断听障者每日生活的表现。测试要求受试者分别于术前及人工耳蜗术后 12 和 36 个月完成问卷³⁶⁾。另外单侧聋患者人工耳蜗植入后的效益还可以采用工

作表现问卷表(表 2),评估时间可以选取植入后的一定阶段,如:开机 6 个月、12 个月、24 个月等¹³⁾。除了上述主观测试方法外,还有客观测试方法,如:测试双侧皮层反应³⁸⁾以及磁共振弥散张量成像(diffusion tensor imaging,DTI)以评估双侧听中枢功能及形态²¹⁾。

表 2 工作表现问卷表

1. 人工耳蜗对你的工作帮助有多大? How much has the CI helped you to do your work?
(a) 很大 (b) 中等 (c) 不大 (d) 无变化 (e) 变差
2. 人工耳蜗对你的职业生涯发展帮助有多大? How much has the CI positively influenced your career development or planning?
(a) 很大 (b) 中等 (c) 不大 (d) 无变化 (e) 变差
3. 植入人工耳蜗后你工作的主动性变化有多大? How much more active have you been in your working environment after the CI?
(a) 很大 (b) 中等 (c) 不大 (d) 无变化 (e) 变差
4. 佩戴人工耳蜗工作后是否会降低你的疲劳感? Has the CI decreased your fatigue after the working day?
(a) 很大 (b) 中等 (c) 不大 (d) 无变化 (e) 变差
5. 佩戴人工耳蜗是否有助于你与客户的交流? Is it easier to communicate with your co-workers after the CI?
(a) 很大 (b) 中等 (c) 不大 (d) 无变化 (e) 变差
6. 人工耳蜗是否有助于你通过电话交流? Is it easier to speak on the phone after the CI?
(a) 很大 (b) 中等 (c) 不大 (d) 无变化 (e) 变差

6 单侧聋患者人工耳蜗植入的手术指征

设立单侧聋人工耳蜗植入手术指征的初衷是尽可能地缩短由单侧聋造成的听觉剥夺时间,从而避免听觉中枢重组。当非对称性听力损失达到单侧聋的程度,即单侧耳听力损失达到重度或极重度感音神经性聋且助听效果不佳时,就可以考虑在听力较差耳植入人工耳蜗。儿童和成人单侧聋人工耳蜗植入指征不同,单侧聋儿童的人工耳蜗植入应在耳聋后尽早实施。目前虽然对于先天性或早发的单侧聋患者人工耳蜗植入时机尚无定论,但如果听觉剥夺时长超过 4 年则需谨慎考虑。对于大龄儿童和成人确诊单侧聋后也应推荐尽早人工耳蜗植入,这对于那些好耳有发展成显著性听力下降风险的患者尤为重要¹⁾。术前对所有潜在适应症患者均应进行头部 MRI 检查以排除听神经异常,因为有超过 50% 的单侧聋儿童耳蜗神经发育不良,而蜗神经异常往往是人工耳蜗植入的禁忌症¹¹⁾。对于人工耳蜗植入目的主要是为了缓解耳鸣的患者,要求他们术前 THI 得分至少要达到 38 分和/或耳鸣问卷(TQ)得分至少要达到 42 分,视觉比拟量表(VAS)至少达到 7.0 分^{71, 82)}。

7 单侧聋患者人工耳蜗植入的效果分析

多项研究表明人工耳蜗植入可以改善单侧聋患者的生活质量,提高其言语识别率¹³⁾和声源定位能力³⁶⁻⁴¹⁾,且较传统的单侧聋干预方法(如使用骨导助听设备和 CROS)效果好⁴⁰⁾。单侧聋患者人工耳蜗植入后可以获得双耳听力,双耳聆听可以利用头影效应、¹⁾ 双侧抑制效应和双侧整合效应改善听力和

提高声源辨别能力。头影效应是由头颅对声波造成衍射的物理效应(Dillon CM, 2001),对于空间分割源而言,每侧耳的信噪比由于头影效应而不同,如果通过信噪比较好一侧耳聆听,可改善言语理解力;如果单侧聋患者有功能的一侧耳朝向信噪比较差的方向时,言语理解力会降低(Dillon CM, 2001; Bronkhorst AW, 1988)。双侧抑制效应(binaural squelch effect)是通过在信噪比较差的对侧耳增加额外的声音输入改善噪声下的言语理解力。空间分割信号(spatially separated signals)是指在双耳间声信号的时间和强度差,有利于改善言语理解力¹²⁾。双侧整合效应(binaural summation)是言语和噪声均来自同一方位以及同一信号同步抵达双耳,双侧整合可以改善正常听力者言语理解阈(SRT)0.5~2 dB¹³⁾。需要双耳输入信号的中枢神经整合才能达到双耳整合与双耳抑制效应同时发挥作用。Hörkönen 等³⁸⁾研究单侧聋患者人工耳蜗植入后对工作效率的影响发现,单侧聋人工耳蜗植入者较易应对工作,工作一天后较少产生疲劳感;而且由于与同事或客户的沟通变得容易,其工作时变得更主动;双耳聆听降低了植入者产生倦怠或从事对听力要求较高职业时常请病假的风险。

1976 年首次有作者提出人工耳蜗植入对抑制耳鸣有帮助(House WF, 1976),其后不断有人工耳蜗植入抑制耳鸣的文章发表¹⁴⁾,近来的研究依然支持既往的观点^{15, 16)},发现且伴有无法忍受的耳鸣的单侧聋患者通过在患耳植入人工耳蜗不但恢复了听力,而且有 90% 的患者耳鸣的响度和严重程度显著

降低^[35,47,48]。研究者对耳鸣成因的共识是耳鸣是由于听觉剥夺导致中枢听觉通路的不良适应塑形(maladaptive plasticity)导致的^[25]。对耳鸣抑制是基于对假定的神经不良适应塑形反转或通过引入环境声转移对耳鸣的注意力,从而减轻人工耳蜗植入者对耳鸣的感知,可以通过圈内电刺激(looped electrical stimulation)甚至有时可以采用非听性刺激减轻耳鸣。因此,推测可能不需要引入外界声音信号而仅通过蜗(圈)内电刺激治疗耳鸣,这种不依赖于外部声信号的蜗内电刺激法是潜在的耳鸣治疗手段。既往研究未发现手术自身可以造成耳鸣,长期使用人工耳蜗可以进一步优化对耳鸣的抑制作用^[47-53];要设置对耳鸣抑制理想的刺激参数,中等及大的刺激量较小刺激量抑制耳鸣的效果更明显,这与掩蔽效应有关^[54];与耳鸣音调相匹配的电极发出的刺激其耳鸣抑制效果与所有可用电极发出刺激产生的效果无显著差异^[55];刺激幅度调制对耳鸣抑制没有显著效果^[41],不同的刺激率对耳鸣的抑制作用没有显著差异^[32,56]。虽然单侧聋患者使用人工耳蜗可以显著受益,然而与双侧人工耳蜗植入者相比他们的双耳整合效应发展缓慢,这与单侧聋植入人工耳蜗植入者较难整合电和声刺激有关^[56]。为此,术前应调整好他们的期望值,并鼓励他们坚持使用人工耳蜗设备。

8 结论

由于非对称性听力损失特别是单侧聋会造成患者声源定位能力缺失、噪声下言语理解能力下降,并往往伴有严重耳鸣,从而对患者的学习和生活均造成困扰。如果不及时干预,大脑听中枢的不良重塑会造成不可逆的损害,因此,对非对称性听力损失特别是单侧聋患者应积极干预。迄今为止,人工耳蜗植入是可以恢复单侧聋患者功能性听力并可能恢复双侧听力的唯一方法,如果没有禁忌症应积极考虑尽早在患耳植入人工耳蜗;一侧已经植入人工耳蜗的双侧聋患者经过评估符合植入标准的也要积极考虑尽早在对侧耳植入人工耳蜗。但必须说明的是,中国尚未正式将单侧聋纳入人工耳蜗植入适应症,故应谨慎实施。

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病例报告

一例引出短潜伏期负反应的前庭水管扩大患儿的追踪报告

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大前庭水管综合征(LVAS)是一种先天性内耳畸形,属常染色体隐性遗传性疾病,是儿童感音神经性听力损失的常见原因,如能早发现、早诊断、及早治疗,可有助于延缓此类患者听力下降,提高听力和言语康复的效果¹。日前诊断LVAS的金标准是影像学检查,婴幼儿由于年龄因素,在尚不能进行影像学检查时,声诱发短潜伏期负反应(ASNR)的出现,可作为此类患者听力学特征指标。浙江省台州医院耳鼻喉科近几年在新生儿听力诊断工作中,对初诊时出现短潜伏期负反应但尚不能确诊的患者

均进行跟踪随访,发现有1例患儿复诊时听力损失明显加重,经影像学检查后确诊为大前庭水管综合征。现将该患儿跟踪随访情况报告如下。

1 临床资料

患者,男,初诊年龄6月龄,家长反映其对声音不敏感。来院后行听性脑干反应,耳声发射,声导抗检测,气导ABR反应阈双侧70 dB nHL(图1),骨导ABR未完成测试,耳声发射双侧未通过,声导抗检查双侧鼓室导抗图均为A型。气导ABR检测时发现双侧在3 ms左右均出现宽大的负波,考虑患儿

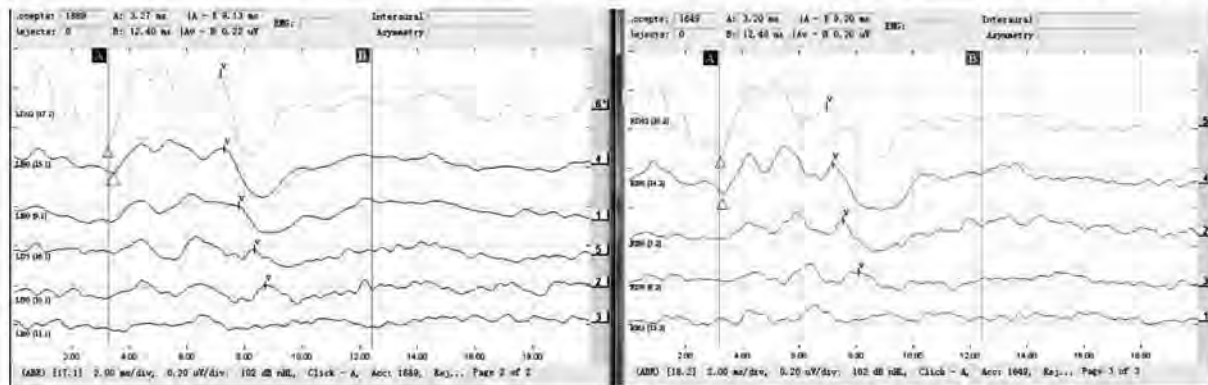


图1 患儿初诊时 ABR 波形

图中△表示负反应波;双侧在高声强时出现大负波,102 dB nHL 刺激下,左侧负波在 3.27 ms 出现,右侧负波在 3.2 ms 出现;随着刺激强度降低,负波潜伏期延长;双侧 80 dB nHL 刺激时,负波消失。

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6月龄,暂未行影像学检查,告知3个月后复查。之后患者感冒引发肺炎,经治疗康复后来复诊,复诊年

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大龄语前聋诺尔康人工耳蜗 植入康复效果分析

An Analysis of the Habilitation Efficacy on Older Pre-lingual Deafness with Cochlear Implantation

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【摘要】目的 观察并分析大龄语前聋患者植入诺尔康人工耳蜗后1年的听觉、言语康复效果。**方法** 对18例接受国产诺尔康人工耳蜗植入手术的大龄语前聋患者,分别于术前和开机后2个月、6个月、12个月,采用《听觉能力评估标准及方法》和听觉行为分级标准(CAP),言语可懂度分级标准(SIR),有意义听觉整合量表(MAIS)及有意义使用言语量表(MUSS)问卷行听觉言语评估,并对数据进行统计分析。**结果** 声母、韵母和短句识别率,听话识图、主题对话和SIR分级在人工耳蜗植入术前和开机后各时间点之间的差异均无统计学意义($P>0.05$)。双音节识别率开机后12个月与术前,开机后6个月差异有统计学意义($P<0.05$)。CAP分级较术前及开机后各时间点之间的差异均有显著统计学意义($P<0.05$)。MAIS得分较术前差异均有统计学意义($P<0.05$),且开机后6个月的得分最高(P 均 <0.05)。MUSS得分除开机后2个月与术前差异无统计学意义外,其它各时间点之间差异均有统计学意义($P<0.05$)。**结论** 大龄语前聋患者开机后经1年康复训练,听觉能力均有不同程度的提高,尤其是在基本声音的感知、识别方面,言语能力虽没有提高,但在语言的使用意识、应用技巧上仍有进步。

【关键词】人工耳蜗植入;语前聋;大龄;康复效果;诺尔康

【Abstract】Objective To analyze the rehabilitation outcomes of auditory and speech ability for older pre-lingual hearing-impaired patients at one year after Nurotron cochlear implantation. **Methods** 18 pre-lingual hearing-impaired patients who underwent Nurotron cochlear implantation participated in this study. Auditory and speech abilities were evaluated by the Auditory Ability Assessment Criteria and Methods, the Categories of Auditory Performance(CAP), the Meaningful Auditory Integration Scale(MAIS), the Speech Intelligibility Rating(SIR) and the Meaningful Use of Speech Scale (MUSS) at pre-operation, 2 months, 6 months and 12 months after operation. The results were statistically analyzed. **Results** There were no significant differences in Vowels, consonants, short sentence recognition rate, listen and find the associated picture, thematic dialogue and the Speech Intelligibility Rating(SIR) between pre-cochlear implantation and after cochlear implantation at all time points, there was a significant difference in two-syllable recognition between 12 months after operation and pre-operation and 6 months after operation ($P<0.05$). The CAP questionnaire showed there were significant differences between preoperative and each postoperative time point ($P<0.05$). MAIS scores showed there were significant differences ($P<0.05$) between preoperative and each postoperative time point, and MUSS scores showed significant differences ($P<0.05$) except for 2 months after operation and got the highest score in 6 months after operation. **Conclusion** The auditory ability of the pre-lingual hearing-impaired patients was improved to different degrees after one year of rehabilitation, especially in the basic sound perception and recognition. Although their speech abilities did not improve substantially, their awareness and skills of language application were still better.

【Key words】Cochlear implantation; Pre-lingual deafness; Older; Rehabilitation outcome; Nurotron

人工耳蜗植入(cochlear implantation, CI)是目前公认的对重度和极重度感音神经性耳聋治疗最有效的方法。我国耳聋患者众多,但长期以来,人工耳蜗多为进口产品,价格高,无法满足大部分聋人家庭的需求^[1]。诺尔康国产人工耳蜗的问世,为患者提供了更多选择,目前国内植入达3500例,国外植入超过120例。随着相关技术的进步、社会经济的发展,康复意识的提高,大龄语前聋患者对CI的需求日益增长,然而此类患者能否通过CI获益还存在很大争议^[2]。鉴于国

产人工耳蜗的价格优势,一般家庭基本能承受,加之全国慈善机构和个人捐赠项目的增多,使诺尔康人工耳蜗植入项目的普遍开展成为可能,为大龄语前聋患者接受人工耳蜗植入提供了条件。本文旨在探讨大龄语前聋患者植入诺尔康人工耳蜗后的康复效果。

1 资料与方法

1.1 研究对象

选择2014年12月至2015年1月在第四军医大学

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第一附属医院耳鼻咽喉头颈外科成功植入国产诺尔康人工耳蜗大龄语前聋患者18例,其中男10例,女8例;植入年龄8~18岁,平均 12.49 ± 3.17 岁;所有患者均符合人工耳蜗植入适应症;双侧重度或极重度感音神经性聋,除4例前庭导水管扩大,其余均无中耳和内耳畸形;无其他人工耳蜗植入禁忌证;精神智力发育正常,无其他全身疾病。其中,有助听器佩戴史患者15例,佩戴时间11月~12年,平均 4.66 ± 3.66 年。术前17例患者在康复机构训练,1例助听器佩戴者在普校就读;康复时间2~11年,平均 5.28 ± 2.65 年;术前助听效果:最适1例,较适1例,看话16例,均有一定语言基础,其中11例以口语表达为主,7例以手语、唇读、书写为主,可配合口语表达。本组患者均为右耳植入,术中检测电极阻抗正常,术后X线检查示电极位置正常,无感染、面瘫等并发症,均在康复机构进行康复训练。

1.2 方法

分别于患者术前和术后进行听觉言语能力测试和问卷评估,随访时间为开机后2个月 \pm 1周、开机后6个月 \pm 1周、开机后12个月 \pm 2周,随访内容如下:

1.2.1 听觉言语能力测试及问卷评估 采用中国聋儿康复研究中心修订的《听觉能力评估标准及方法》^[3]对受试患者进行韵母、声母、双音节、短句识别、听话识图及主题对话的测试^[4]。测试时,测试者与受试者相距1 m,于受试者人工耳蜗植入侧成 45° 角;测试者遮挡口型进行口语发声,声级控制声压级为65~75 dB(A)。测试按照《听觉能力评估标准及方法》进行并计算正确识别率得分。

采用听觉行为分级标准(Categories of Auditory Performance, CAP)及有意义听觉整合量表(Meaningful Auditory Integration Scale, MAIS)进行听觉能力问卷调查;采用言语可懂度分级标准(Speech Intelligibility Rating, SIR)及有意义使用言语量表(Meaningful Use of Speech Scale, MUSS)进行言语能力调查。

以上测试均由专业测评人员完成。所有问卷均固定专人负责,由最熟悉患者情况的家属对患者进行听觉和言语的分级评价。

1.2.2 统计方法 采用SPSS 17.0统计学软件进行数据处理,所有数据以均值 \pm 标准差($\bar{x} \pm s$)表示,计量资料比较采用非参数 t 检验, $P < 0.05$ 差异具有统计学意义。

2 结果

2.1 听觉能力测试

声母、韵母和短句识别率在人工耳蜗植入(CI)开机后2个月测试时较术前有所下降,在开机后6个月、12个月时有所提高,但与术前差异均无统计学意义($P > 0.05$),且开机后各时间点之间的差异均无统计学意义($P > 0.05$);CI开机后双音节识别率逐渐提高,且开机后12个月与术前、开机后6个月差异均具有统计学意义($P < 0.05$),见表1。

2.2 言语能力测试

听话识图、主题对话测试结果在CI术前与开机后3次随访呈增高的趋势,但各时间点之间的差异均无统计学意义($P > 0.05$),见表1。

2.3 CAP、SIR问卷

CAP、SIR分级在CI开机后2个月、6个月、12个月均较术前有不同程度提高。CAP分级在术前及开机后各时间点之间的差异均有显著统计学意义($P < 0.05$);而SIR分级在术前及开机后各时间点之间差异均无统计学意义($P > 0.05$),见表1。

2.4 MAIS、MUSS问卷

MAIS、MUSS得分在CI开机后2个月、6个月、12个月均较术前有不同程度提高。MAIS问卷得分在开机后3次随访与术前差异均具有统计学意义($P < 0.05$),且开机后6个月的得分最高,与术前得分差异具有显著统计学意义($P < 0.01$),与开机后2个月和12个月的得分差异均具有统计学意义($P < 0.05$);此外,开机后2个月和12个月的MAIS得分与术前相比,差异均具有统计学意义($P < 0.05$)。MUSS问卷得分呈逐渐增高的趋势,除开机后2个月与术前差异无统计学意义外,其它各时间点之间差异均具有显著统计学意义($P < 0.05$),见表1。

3 讨论

中华医学会耳鼻咽喉科分会在2013年制定的《人工耳蜗植入工作指南(2013)》^[5]中,对语前聋患者CI的最佳年龄定为12个月~6岁。7岁以上患者大脑的可塑性明显降低,冯永^[6]等将“大龄”语前聋的概念定在7岁及以上。而Teoh等^[7]发现听觉中枢皮层被其他感觉功能区定植占据是大龄语前聋植入后康复效果受限的主要原因,通过以听觉为基础的训练可以减少皮层定植现象,从而改善大龄语前聋植入后的康复效果。

表1 听觉言语能力测试及评估结果($\bar{x} \pm s$)

测试项目	术前	开机2个月	开机6个月	开机12个月
韵母识别率	15.11 ± 26.05	7.78 ± 22.89	16.67 ± 32.27	19.56 ± 37.77
声母识别率	11.11 ± 23.75	7.78 ± 22.90	14.22 ± 27.79	16.40 ± 32.30
双音节识别率	14.67 ± 25.99	23.11 ± 36.17	37.39 ± 40.28	42.56 ± 42.83 [⊙]
短句识别率	15.56 ± 25.89	10.28 ± 30.02	16.67 ± 34.30	20.83 ± 40.45
听话识图	1.89 ± 1.32	1.89 ± 1.32	2.11 ± 2.17	2.33 ± 1.37
主题对话	1.83 ± 1.29	1.89 ± 1.28	2.17 ± 1.25	2.33 ± 1.189
CAP	2.17 ± 2.01	3.39 ± 1.54 [*]	4.33 ± 1.14 ^{**}	4.50 ± 0.98 ^{**⊙}
SIR	2.00 ± 1.09	2.06 ± 1.11	2.17 ± 1.04	2.28 ± 0.89
MAIS	27.78 ± 25.62	60.56 ± 16.35 [*]	72.64 ± 14.28 ^{**}	66.67 ± 14.93 [⊙]
MUSS	26.39 ± 22.03	30.69 ± 22.65	40.42 ± 22.07 ^{**}	41.81 ± 18.98 ^{**⊙}

注:与术前比较,^{*} $P < 0.05$,^{**} $P < 0.01$;与开机后2个月比较,^{*} $P < 0.05$,^{**} $P < 0.01$;与开机后6个月比较,[⊙] $P < 0.05$,^{⊙⊙} $P < 0.01$ 。

本研究中18例语前聋患者均在3岁以上发现听力异常,9例在6~7岁上学后才配戴助听器进行干预,佩戴时间少于5年,还有3例无助听器佩戴史;2例自行选配助听器,其他均为残联捐赠。术前康复时间最长的11年,最短2年;术前助听效果为最适1例、较适1例、看话16例;除1例术前在正常学校上学,辅助读唇后能与人正常交流,CAP达到6级,SIR达到4级外,其余均在康复中心学习口语或手语,书写交流。术前CAP最高4级,SIR最高3级,均不能达到日常交流目的。患者术前普遍存在康复训练时间短、听觉补偿不足、助听效果不佳等问题。

刘莎^[3]等研究发现,虽然多数涉及到人工耳蜗植入效果评估的研究均认为语前聋青少年术后语言能力无明显改善,不宜选择人工耳蜗^[9],但术后所有大龄语前聋耳蜗使用者均可感知音节和有意义的的环境声,虽然语言的辨识、理解能力在术后一年内无显著改善,但术后利用唇读理解语言的能力、交流意识、交流方式均有提高。本研究也得到同样的结果,多数患者可以逐渐学习并掌握如何利用听觉信息识别出部分环境声、理解自己的名字、提高听反应敏感性等,并可以有意识地在日常生活中尽量应用口语或从以手语为主过渡到以口语为主的交流方式。大部分患者对人工耳蜗的依赖度也高于助听器,认为人工耳蜗佩戴更舒适。这些,都是得益于人工耳蜗的植入。

本研究患者经术前和开机后1年随访可知:听觉能力在开机后2个月时,声母识别、韵母识别、短句识别均有所下降,双音节识别虽有提高,但与术前无明显差异。此结果可能与耳蜗开机时间短,未能适应有关。而在开机后6个月、12个月,仅有双音节识别提高较明显。从而提示,在语言的辨识、理解方面,术后无明显进步。在CAP、SIR问卷调查中,与上述结果相同。CAP分级在术后不同时间点均有提升,除1例术前基础较好、术后达到CAP 7级、可以用电话与家人进行交流外,其他患者平均CAP 4级,只能达到不读唇听懂常用词组的程度,无法听懂短语、句子,而SIR分级在术后无明显进步,大部分不能说出连贯的句子,只能说一些可以根据唇读或上下文理解的词组。而在MAIS、MUSS问卷调查中,MAIS得分在术后有较大提高,但提高集中在听辅设备的使用,基本声音的察知,对自己名字的反应等基本听能方面,而在声音的辨识、理解等方面,均没有太大进步。另外,MAIS得分在术后12个月时有一定下降,提示可能因辨识、理解困难,部分患者出现听觉能力的倒退;MUSS得分从术后6个月开始提升,主要集中在主动发声、在家中或与认识的人语言交流增多、可以更多的用语言进行解释等方面,提示交流意识、交流方式均有不同程度提高。即开机后经过1年康复,虽然在声音的辨识、理解,以及高级听能等方面没有太大帮助,但在基本声音的感知、识

别方面均有提高。因此提示,大龄患者可以通过植入耳蜗恢复听觉,但如果要在人工耳蜗术后取得较好的效果,需要尽早佩戴助听器并进行听觉言语康复练习^[5]。

青少年因处于各种能力迅速发展的时期,有强烈的学习和交往需求^[8]。而大龄语前聋患者,因听力言语发育滞后,在交流和沟通上存在较多局限性,较听力正常的青少年更容易出现心理问题^[10]。同时,由于各方面原因,植入者家庭对人工耳蜗期望值过高,会导致大龄耳蜗植入者术后产生失望情绪,弃之不用^[11]。刘莎等^[8]研究表明期望值不恰当的程度与术后对人工耳蜗植入满意度呈负相关,李原等^[12]建议家长术前应充分了解人工耳蜗相关知识及患者的具体情况,以建立适当的期望值。

本研究入组患者在开机后2个月及6个月时,家属反映进步明显,听反应明显增加,也愿意主动说话。但在开机后12月时,患者的听觉及言语方面均有不同程度的降低,部分患者的学习热情明显下降,主动交流减少,有的甚至拒绝进行康复训练,与家人之间的矛盾也日益增加。因此,术前应帮助患者及家属建立合适的期望值,除非本人有强烈的听、说愿望,家庭能提供全面、持续的支持。否则,建议采取其他渠道沟通与生活。同时,呼吁相关部门构建、完善不同能力听障人士的学习、就业渠道,使多种选择的生活方式成为可能。

研究显示,除了年龄因素外,术前的助听时间、植入后时间、康复模式、家庭支持、经济状况、遗传等都对术后听觉言语能力康复有很大影响^[13-15]。因此,对于大龄语前聋患者,植入效果需要多方面综合考量。

本次选择的病例均是陕西省项目资助患者,手术、调机、术后康复比较集中,便于统计对比。但因资助名额限制,观察到的病例数较少,术后1年的观察期也较短。因此,需要更多病例、更长期的观察才能更准确地了解大龄耳蜗植入者的康复效果,从而更有效的指导临床。同时,虽然本次研究均采用诺尔康人工耳蜗植入患者的听觉言语效果的评价,但因所选取的都是大龄语前聋患者,术前基础欠佳,不能单方面认定为耳蜗产品效果的评价,还需要有更多、更长期的病例比较才能探讨不同产品之间的差异。

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诺尔康人工耳蜗语前聋效果配对研究初步报告

Preliminary report of a matched case-control study of Nurotron cochlear implants

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【摘要】目的 评价极重度语前聋患者植入国产诺尔康人工耳蜗与进口人工耳蜗后的听觉语言康复效果。**方法** 回顾性纳入2011年6月~2015年12月在华西医院人工耳蜗植入中心植入诺尔康人工耳蜗并随访半年以上的26例患者为研究组(诺尔康组),对照组选择同期接受进口人工耳蜗植入的患者(进口耳蜗组),按照性别、年龄、病史、术前语言基础等进行配对研究,比较两组的听觉行为分级标准(categories of auditory performance, CAP)和言语可懂度分级标准(speech intelligibility rating, SIR)得分,评价其听觉语言康复效果。**结果** 诺尔康组CAP得分均值 4.31 ± 1.12 分, SIR得分均值 2.54 ± 0.71 分;进口耳蜗组CAP均值 4.85 ± 1.19 分, SIR均值 2.88 ± 1.07 分。两组CAP和SIR得分分别比较,差异均无统计学意义($P > 0.05$)。两组均有84.6%(22/26)的患者CAP评分 ≥ 4 分、能分辨言语, SIR ≥ 3 分,具备一定言语可懂度者诺尔康组有57.7%(15/26),进口耳蜗组为69.2%(18/26)。**结论** 语前聋患者使用诺尔康人工耳蜗在听觉语言效果上与进口产品无差异,能为极重度聋患者提供有效帮助。

【关键词】诺尔康人工耳蜗;配对研究;语前聋;CAP;SIR

【Abstract】Objective To evaluate and compare the rehabilitation of the prelingually profound deaf patients using domestic Nurotron cochlear implant and the imported cochlear implant. **Methods** 26 pairs of patients were retrospectively included who had the cochlear implantations during Jun 2012 to Nov 2015 with a six-months-follow-up at least. 26 patients with Nurotron cochlear implants were divided into the research group, while the 26 patients with the imported implants as the control group, whom were matched by the date of surgery, gender, age, medical history, preoperative language ability, et al. CAP and SIR were assessed to evaluate the effect of the implants. **Results** The average CAP and SIR score of the research group were 4.31 ± 1.12 and 2.54 ± 0.71 , while of the control group were 4.85 ± 1.19 and 2.88 ± 1.07 . There was no statistically significant difference ($P > 0.05$) between neither the CAP nor the SIR scores of the two groups. 84.6%(22/26) patients of both group had CAP score ≥ 4 , who were able to distinguish the speech. 57.7%(15/26) patients of the research group and 69.2%(18/26) of the control group with SIR score ≥ 3 had a degree of speech intelligibility. **Conclusion** There was no significant difference of the effects between the domestic Nurotron cochlear implants and the imported implants, and the domestic Nurotron cochlear implants can help the deafened patients effectively.

【Key words】Nurotron cochlear implant; Matched case-control study; Prelingually deaf; CAP; SIR

人工耳蜗植入(Cochlear Implantation, CI)在我国开展已有20余年,选择安全、有效、低廉的植入体是广大听障患者最关注的问题之一。相较于进口产品,国产诺尔康人工耳蜗虽然上市时间短,但价格经济,安全性较高^[1-2]。为对比其与进口产品是否存在差异,本文采用回顾性研究,纳入在我科CI术后开机半年以上、临床资料和随访记录完整的26对语前聋人工耳蜗植入患者并比较其术后的康复情况,为人工耳蜗产品选择提供参考。

1 资料和方法

1.1 临床资料

纳入2011年6月~2015年12月在我院由通讯作者

完成、使用诺尔康人工耳蜗植入,随访半年以上、资料完整的极重度语前聋患者26例为研究组(诺尔康组),与同期同一术者完成、使用进口耳蜗的语前聋患者26例为对照组(进口耳蜗组),进行配对病例研究。

1.2 配对方法

①在使用进口人工耳蜗的CI患者中按照研究对象首先逐一筛选手术时间相近(± 3 月)、相同性别的病例;②二次筛选出与目标病例年龄相近(± 3 月)、术前语言基础类似(能否开口说话、能说词句长短及清晰度等)、影像学检查结果类似(有无内耳畸形、脑白质异常等)的病例;③再次筛选出与目标病例术前病史相似(有无语训、有无佩戴助听器及佩戴时间相近(± 6 月))的病例;④若有多例,将病例编号,按随机

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数字表抽取;⑤若无配对病例,则扩大年龄范围(±6月)及助听器佩戴史(±1年)进行筛选。在配对组中无配对病例的研究组病例予以排除。

1.3 研究方法

对患者和/或了解患者情况的家属电话或面谈,应用诺丁汉人工耳蜗中心Nikolopoulos等^[1]提出的听觉行为分级标准(categories of auditory performance, CAP)和言语可懂度分级标准(speech intelligibility rating, SIR),评估患者CI术后的听觉言语能力。CAP根据患者对外界环境声音及言语声音的行为反应能力划分0~9级共10级。SIR是根据患者自发言语可被理解的程度分为1~5级共5级。同时随访患者及其家庭对CI术后效果的满意度,分为非常满意(效果优于预期)、基本满意(效果与预期相当)及不满意(效果差于预期)三级。

1.4 统计学分析

采用SPSS 19.0统计软件对两组患者CAP和SIR得分进行两配对样本的t检验,结果以P<0.05表示有统计学差异。

2 结果

2.1 手术及开机情况

两组患者均手术顺利,术后无面瘫,切口愈合好,随访期内无感染,无排异表现。所有患者均术后1月开机,开机后1月、3月、6月、1年调机,此后每年定期调机。

2.2 术后康复情况

两组语前聋患者术后均参加正规康复学校语训,3岁及以下患者多为亲子同训言语康复,3岁以上患者多数为全日制康复教育训练,同时辅以家庭语训。

2.3 基本资料配对

符合纳入标准、使用诺尔康人工耳蜗的病例共26例,经配对方法①-③逐一配对,成功筛选出26例对照组,对照组植入体类别包括:澳大利亚科利尔10例,美国AB3例,奥地利Medel13例。

两组语前聋患者共52例,一般资料见表1。两组病例中,2~3岁患者各4例(15.4%),3~6岁患者各3

例(11.5%),6~18岁患者各17例(65.4%),18岁以上各2例(7.7%),两组最大年龄均为27岁。6岁以下植入者仅占26.9%(7/26),并且其中有脑白质异常及内耳畸形的比例达57.1%(8/14);6岁及以上植入者占73.1%(34/52),其中有脑白质异常及内耳畸形的占31.6%(12/38)。两组18岁以下患者术前仅能发2~3字单音节词,语言清晰度差;两组18岁以上的4例患者术前能讲5~8字短句,语言清晰度差。两组患者中,人工耳蜗使用时间0.6~1年的占15.4%(4/26),1~2年的占30.8%(8/26),2~3年的占26.9%(7/26),3~4年的占26.9%(7/26)。

2.4 CAP得分

诺尔康组患者CAP得分均值4.31±1.12分,能分辨言语;最低为1分(1例)者为脑白质异常患儿,并曾于2岁前诊断为运动发育迟缓,2岁时接受CI,目前使用人工耳蜗18月,对纯音有反应,正在学习理解短语含义,尚不能排除是否合并言语发育迟缓;3分3例,尚不能分辨言语;4分12例;5分6例,最高分6分4例。对照组CAP均值4.85±1.19分;CAP≤3分者4例,尚不能分辨言语,最低2分;4分3例;≥5分19例,最高7分。两组患者CAP得分分布情况见图1。在人工耳蜗开机后半年至3年的随访中,诺尔康组与进口耳蜗组均有84.6%(22/26)的患者CAP评分≥4,能分辨言语。

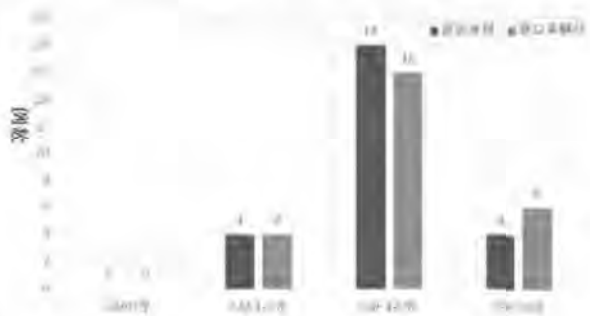


图1 CI诺尔康组与进口耳蜗组CAP得分分布

2.5 SIR得分

两组患者SIR得分分布情况见图2。诺尔康组患者SIR得分均值2.54±0.71分,听者能借助唇读及语

表1 语前聋患者CI诺尔康组与进口耳蜗组一般资料对比(n=26)

组别	病例数	平均年龄(岁)	年龄分布				人工耳蜗使用时间(月)	
			<6岁(2~5岁)		≥6岁(6~27岁)		使用时间	平均使用时间
			例数	平均值(岁)	例数	平均值(岁)		
诺尔康组	26	9.16±6.28	7	3.25±1.36	19	11.34±5.96	6~46	26.58±12.26
进口耳蜗组	26	9.68±6.97	7	3.65±1.44	19	12.53±5.67	6~47	27.11±11.20

境听懂患者单个词汇;最低1分2例,2分9例,3分14例,最高4分1例。进口耳蜗组SIR得分均值 2.88 ± 1.07 分,最低1分3例,2分5例,3分12例,4分4例,最高5分2例。SIR ≥ 3 分,具备一定言语可懂度的患者诺尔康组有57.7%(15/26),进口耳蜗组有69.2%(18/26)。

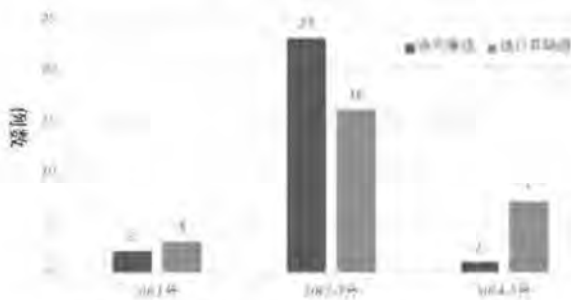


图2 CI诺尔康组与进口耳蜗组SIR得分分布

2.6 两组比较

诺尔康组及进口耳蜗组植入者各年龄段的耳蜗平均使用时间见图3,各年龄段CAP及SIR得分均值分别见图4及图5。

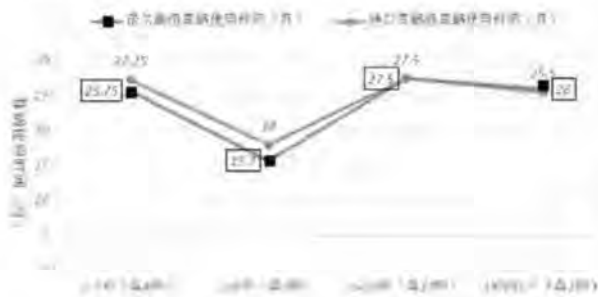


图3 CI诺尔康组与进口耳蜗组各年龄段耳蜗平均使用时间

根据对照组使用进口耳蜗品牌不同,将其中使用例数较多的澳大利亚科利尔(10例)及奥地利Medel(13例)分为两亚组,与逐一配对的研究组病例进行组内比较,其CAP和SIR得分结果见表2。诺尔康1组与与之配对全部使用科利尔的植入者相比,CAP及SIR得分无统计学差异($P>0.05$);诺尔康2组与与之配对

表2 CI诺尔康组与不同品牌进口耳蜗CAP与SIR得分组内比较($\bar{x} \pm s$)

例数	诺尔康1组	科利尔	诺尔康2组	MEDEL
	10	10	13	13
CAP平均值	4.33 ± 0.32	4.88 ± 1.56	4.30 ± 1.44	4.83 ± 1.20
SIR平均值	2.61 ± 0.57	2.91 ± 1.17	2.47 ± 0.86	2.84 ± 0.99

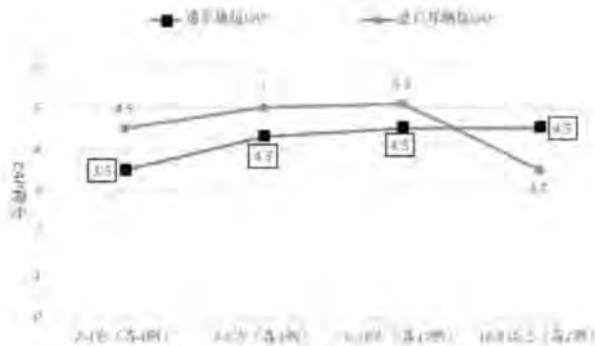


图4 CI诺尔康组与进口耳蜗组各年龄段CAP得分

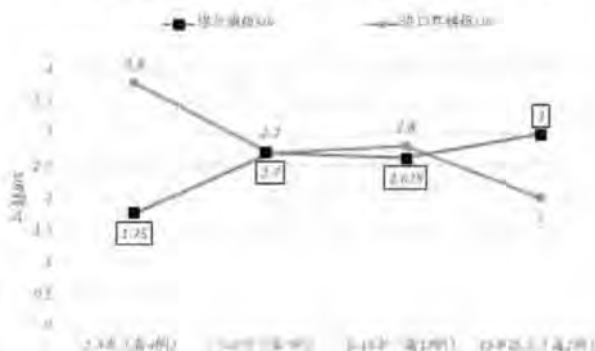


图5 CI诺尔康组与进口耳蜗组各年龄段SIR得分

全部使用Medel的植入者相比,两组CAP及SIR得分无统计学差异($P>0.05$)。

综合两组各26例病例,CAP及SIR平均得分结果见表3。两组间CAP得分配对t检验 $P=0.771$,SIR得分配对t检验 $P=0.566$,均无明显统计学差异($P>0.05$)。

表3 CI诺尔康组与进口耳蜗组CAP及SIR得分($\bar{x} \pm s, n=26$)

组别	CAP	SIR
诺尔康组	4.31 ± 1.12	2.54 ± 0.71
进口组	4.85 ± 1.19	2.88 ± 1.07

2.7 满意度调查

在随访中,两组患者及其家庭均对选择使用人工耳蜗感到满意(效果等于或优于预期);其中诺尔康组有46.2%(12/26)的患者及家庭非常满意,53.8%(14/26)基本满意;进口耳蜗组非常满意及基本满意各占50.0%(13/26)。

3 讨论

CI患者术后听力及言语康复效果受诸多因素影响。对话前聋患者,尽管语言发育能力有较大的个体差异,但植入年龄越小,植入后言语康复效果越好^[4,5]。听觉剥夺会改变听障患者的大脑分区,越早植入人工耳蜗,越有利于尽早建立神经元联系、促进神经结构生理性成熟,促进听觉中枢的发育^[6,7],利于听力及言语康复。而不论语前聋、语后聋患者,使用人工耳蜗时间越长,听力及语言能力均呈进步趋势^[5,8-9],这可能是由于听觉中枢具有可塑性,在听觉剥夺后重新获得听觉刺激,仍能激活皮层并逐步恢复功能,时间越长,越有利于耳蜗与脑功能区建立有效联系^[7,10]。在本文的两组病例中,绝大多数患者(84.6%)使用人工耳蜗后能分辨言语;同时,大部分植入者(诺尔康组57.7%、进口组69.2%)发展了一定的语言交流能力,能被听者理解一部分言语内容。报道其他影响效果较多的因素包括:术前是否使用助听器、是否语训、康复模式、家庭收入等^[5,8,11]。

本文在配对选择时尽量匹配了可能影响效果的观察组与对照组病例的年龄、性别、术前语言基础、助听器使用时间、语训、其他如脑白质异常、耳蜗发育畸形等,术后人工耳蜗使用时间,结果显示使用国产诺尔康耳蜗的研究组与使用进口人工耳蜗的对照组相比,CAP、SIR均无明显统计学差异。诺尔康国产人工耳蜗能为语前聋患者术后听力及言语康复提供有效帮助。尽管其正式临床应用仅有3年(6岁以下)至5年(6岁及以上),未发现与进口产品的使用效果有明显差异。在本研究26例语前聋患者中,CAP及SIR评分均值不高,可能与6岁以上大龄植入且语言基础差者占比较高(73.1%)有关。在本组随访中所有患者及家庭均表示使用国产人工耳蜗后受益,88.5%的患者能分辨言语,57.7%的患者能通过言语与他人进行不同程度的交流,其社会生活有了巨大的良性变化。国产产品的价格让更多家庭可以承受,能有效帮助听障患者重返有声世界。

本研究语前聋患者术后主要选择接受各康复机构的听觉康复及语言训练,少数患者(特别是大龄语前聋患者)则主要为家庭训练,两组间两种模式的训练方式、水平目前难以量化评估。另有研究显示,家庭经济水平越高、家庭成员文化水平越高、家庭与专业机构相结合的模式、交流语言为普通话的家庭更有利于患者术后听觉及言语康复^[11-13]。本研究因系回顾性研究,样本量有限,有待论证。

综上,诺尔康国产人工耳蜗为广大重度、极重度

听障患者及家庭带来了同样有效并更经济的选择。我国听障患者基数巨大,各地区、各人群经济条件差别大,人工耳蜗产品的多样化及良性竞争有利于行业整体水平进步,为患者带来多样选择及有效帮助。

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· 听力康复 ·

语前聋患儿国产人工耳蜗植入效果分析

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【摘要】 目的 观察语前聋患儿植入诺尔康—晨星人工耳蜗(Nurotron-Venus cochlear implant, Nurotron-Venus CI)后的听觉言语发育情况及其安全性和稳定性。方法 回顾性分析郑州大学第一附属医院行 Nurotron-Venus CI 植入的 78 例语前聋患儿的临床资料, 患儿植入年龄为 13~96 月, 按植入年龄将患儿分为 A 组(13~24 月, 16 例)、B 组(25~36 月, 13 例)、C 组(37~48 月, 16 例)、D 组(49~72 月, 18 例)、E 组(73~96 月, 15 例); 在患儿术前及开机后 1、3、6、12 个月采用有意义听觉整合量表(meaningful auditory integration scale, MAIS)(C、D、E 组)、婴幼儿有意义听觉整合量表(infant-toddler meaningful auditory integration scale, IT-MAIS)(A、B 组)进行听觉能力评估。开机后 1、3、6、12 个月使用有意义言语使用量表(meaningful use of speech scale, MUSS)进行言语能力评估。术后行 X 线耳蜗平片检查明确电极位置及形态, 定期随访了解术后相关并发症及佩戴人工耳蜗时间和使用情况。结果 所有患儿术前及开机后 1、3、6、12 月 IT-MAIS 或 MAIS 得分分别为 1.67±1.19、6.60±5.12、11.86±5.44、17.41±5.04、22.87±5.46 分, 术后 1、3、6、12 月 MUSS 得分分别为 5.01±3.26、8.38±3.58、11.88±3.88、16.58±4.95 分, 随着植入时间延长得分不断上升(均 $P < 0.05$); 不同年龄组 IT-MAIS 或 MAIS 得分比较: 术前 A 组低于 C、D、E 组, 开机后 1、3 月 A、B 组低于 E 组, 开机后 6 月 A 组低于 C、D、E 组, B 组低于 E 组(均为 $P < 0.05$); 不同年龄组 MUSS 得分比较: 开机后 1 月 B 组低于 E 组, 开机后 3 月 A、B、C 组低于 E 组, 开机后 6 月 A 组低于 C、D、E 组, B 组低于 E 组, 开机后 1 年 A 组低于 C、D、E 组(均为 $P < 0.05$)。所有患儿在开机后 1、3、6、12 月 MUSS 与 IT-MAIS 或 MAIS 得分相关系数分别为 0.918、0.808、0.881、0.756(均为 $P < 0.05$), 两者呈正相关。78 例患儿术后耳蜗位 X 线平片均显示电极位置正常, 形态良好; 2 例患儿出现处理器故障, 其余 CI 整体工作状态良好。结论 语前聋患儿国产人工耳蜗植入后 1 年内, 所有患儿的听觉言语能力随时间延长不断提高; 小龄组患儿听觉言语得分在术后早期低于大龄患儿; 听觉能力在开机后 12 月时已无差异, 但小龄组患儿的言语能力仍低于大龄患儿; 听觉整合能力越强, 言语使用能力越强; Nurotron-Venus CI 安全、效果可靠。

【关键词】 语前聋; 人工耳蜗, 国产; 有意义听觉整合量表; 婴幼儿有意义听觉整合量表; 有意义言语使用量表

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The Outcomes of Domestic Cochlear Implants In Prelingually Deaf Children

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【Abstract】 Objective To investigate the development of auditory and speech skills and the safety and stability among the prelingually deaf children with Nurotron Venus cochlear implants. Methods A total of 78 cochlear implant subjects were recruited from the first of affiliated hospital of Zhengzhou university. They were divided into 5 groups according to the ages at the time of implantation: group A (between 13 and 24 months), group B (between 25 and 36 months), group C (between 37 and 48 months), group D (between 49 and 72 months), group E (between 73 and 96 months). Children were evaluated by IT-MAIS (group A and B) and MAIS (group C, D and E) before the surgery and 1 month, 3 months, 6 months, and 12 months after surgery. All children were evaluated by MUSS

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questionnaires 1 months, 3 months, 6 months, and 12 months after surgery. Post-operative cochlear radiographs determine the position of the CIs. The complications and usage of The CIs were followed up. **Results** The auditory and speech ability of children with CIs improved constantly. The auditory and speech of different groups were statistically significant. All the surgeries of 78 cases Nurotron-Venus cochlear implants were successful. Post-operative cochlear radiographs showed electrodes in the normal position. 2 cases had processor failures. The remaining CIs were implanted completely. **Conclusion** Within 1 year, the ability of auditory and speech improved gradually. The scores of auditory and speech about the small age groups are lower than older children in the early days. There is no influence on the audition in 12 months. Small children's scores of speech are lower than older children in 12 months. The better ability to integrate auditory information is, the better the ability to speak is. The Nurotron CIs work safety and effectively.

【Key words】 Prelingual deafness; Domestic cochlear implant; MAIS; IT-MAIS; MUSS

我国听障患儿较多,且数量持续增加^[1],人工耳蜗植入给重度或极重度感音神经性聋患儿带来了福音,但是,由于进口人工耳蜗产品价格昂贵和传统观念的局限等许多因素,仍有不少患儿无法解决听障问题。国产人工耳蜗的问世有助于解决这一问题,2006 年国产诺尔康人工耳蜗开始研发并经过临床试验,设计了 2 个参考电极和 24 个工作电极,2011 年获得了市场准入,2012 年获得了欧盟认证,并应用于临床^[2]。为评价诺尔康-晨星人工耳蜗植入(Nurotron-Venus cochlear implant, Nurotron-Venus CI)的临床效果和安全性,本研究拟通过观察语前聋儿童植入 Nurotron-Venus 人工耳蜗后的听力言语康复效果,探讨植入年龄对术后听觉言语康复效果的影响,听觉功能和言语康复的关系及其使用的安全性、稳定性。

1 资料与方法

1.1 研究对象及分组 选择 2013 年 12 月至 2015 年 9 月在郑州大学第一附属医院接受 Nurotron-Venus 人工耳蜗植入术的河南省“农村儿童大病救助项目”的听障儿童 78 例为研究对象,其中,男 37 例,女 41 例,年龄 13~96 月,平均 47.42±2.64 月。入选标准为:植入年龄在 13~96 个月的双耳重度或者极重度感音神经性聋的患儿,影像学排除严重先天性耳蜗畸形(耳蜗未发育, Mondini 畸形,共同腔畸形、大前庭水管综合征等)、脑白质异常、听神经病等,其父母能够配合完成婴幼儿有意义听觉整合量表(infant-toddler meaningful auditory integration scale, IT-MAIS)、有意义听觉整合量表(meaningful auditory integration scale MAIS)、有意义言语使用量表(meaningful use of speech scale, MUSS)问卷评估。患儿按植入年龄分为 A 组 16 例(13~24 月,平均 18.69±0.88 月)、B 组 13 例(25~36 月,平均 29.62±1.00 月)、C 组 16 例(37~48 月,平均 43.69±0.73 月)、D 组 18 例(49~72 月,平均 58.01±1.52 月)、E 组 15 例(73~96 月,平均 84.73

±1.26 月),其中 A 组 3 例、B 组 6 例、C 组 6 例、D 组 8 例、E 组 15 例有助听器佩戴史,佩戴助听器的平均时间分别为 4、9、21、35、53 个月,均进行过言语康复训练,但效果欠佳,言语发育能力较差。

1.2 听觉及言语能力评估 各组患儿在术前、开机后 1、3、6、12 月进行听觉能力评估,测试在安静的房间进行,A 组和 B 组用 IT-MAIS 进行评估,C、D、E 组使用 MAIS 进行评估,量表含 10 个问题,包括 3 方面内容:人工耳蜗使用情况(问题 1、2)、对声音的察觉能力(问题 3~6)及对声音的理解能力(问题 7~10),每个问题 0~4 分;该情况从不发生(0 分)、该情况很少发生(1 分)、该情况偶尔发生(2 分)、该情况经常发生(3 分)、该情况总是发生(4 分);满分 40 分,得分越高表明患儿相应的听觉能力越好。由于大部分听障儿童术前无言语能力,因此,在开机后 1、3、6、12 月采用 MUSS 进行言语能力评估,评估人员逐一询问该量表中的 10 个问题,由家长或监护人对患儿在日常生活中言语发生行为进行详细的描述,根据其言语行为发生的频率进行评分,每个问题分为 0 至 4 分,共 5 个级别,每个级别间言语行为发生的频率相差 25%,满分为 40 分,得分越高表明言语产出能力越强。

1.3 安全性及稳定性评估 所有患儿术后 2 天行耳蜗 X 线平片检查,明确电极位置及形态;术后 5 天、14 天、1 月、3 月、6 月、12 月随访了解 CI 植入术后相关并发症(皮下血肿、术后感染、植入体脱出等),并随访家长了解患儿佩戴 CI 时间及使用情况(佩戴时间、有无主动要求佩戴)。

1.4 统计学方法 采用 SPSS17.0 统计软件包,采用单因素方差分析时间效应对患儿得分的影响;采用 Pearson 相关分析 IT-MAIS 或 MAIS, MUSS 各个时间点的得分相关性, $P < 0.05$ 为差异有统计学意义。

2 结果

2.1 不同时间患儿 IT-MAIS 或 MAIS 及 MAIS

评估结果 78 例患儿术前及开机后不同时间 IT-MAIS 或 MAIS 与 MUSS 得分见表 1, 可见, 随着人工耳蜗植入时间延长, 得分不断增加, 开机后不同时间点的 IT-MAIS 或 MAIS 及 MUSS 得分差异均有统计学意义(均为 $P < 0.05$)。

表 1 78 例患儿术前及开机后不同时间的 IT-MAIS 或 MAIS 与 MUSS 得分(分, $\bar{x} \pm s$)

测试时间	IT-MAIS 或 MAIS	MUSS
术前	1.67 ± 1.19	-
开机后 1 月	6.60 ± 5.12	5.01 ± 3.26
开机后 3 月	11.86 ± 5.44	8.38 ± 3.58
开机后 6 月	17.41 ± 5.04	11.86 ± 3.88
开机后 12 月	22.87 ± 5.46	16.58 ± 4.95

2.2 不同年龄组不同时期 IT-MAIS 或 MAIS 及 MUSS 得分 术前及术后 1、3、6、12 月各组 IT-

表 2 不同年龄组不同时间的 IT-MAIS 或 MAIS 得分(分, $\bar{x} \pm s$)

组别	例数(例)	术前	开机后 1 月	开机后 3 月	开机后 6 月	开机后 12 月
A	16	0.94 ± 0.76	5.50 ± 5.83	9.75 ± 5.94	14.38 ± 5.58	20.93 ± 4.58
B	13	1.30 ± 0.86	4.85 ± 2.44	9.53 ± 3.93	15.92 ± 3.04	22.85 ± 3.02
C	16	1.88 ± 1.08	6.13 ± 2.85	13.12 ± 4.19	18.06 ± 5.46	22.87 ± 6.28
D	16	2.06 ± 1.64	7.50 ± 5.57	11.67 ± 5.83	17.94 ± 4.28	23.61 ± 4.31
E	15	2.13 ± 0.50	8.73 ± 6.76	15.00 ± 5.37	20.60 ± 4.47	24.07 ± 4.18

表 3 不同年龄组不同时间的 MUSS 得分(分, $\bar{x} \pm s$)

组别	例数(例)	开机后 1 月	开机后 3 月	开机后 6 月	开机后 12 月
A	16	4.44 ± 4.00	7.50 ± 4.15	9.62 ± 4.23	13.38 ± 4.80
B	13	3.77 ± 2.17	6.77 ± 3.47	10.85 ± 3.56	15.02 ± 3.82
C	16	4.87 ± 4.31	7.62 ± 4.90	12.44 ± 3.69	17.17 ± 5.93
D	16	5.11 ± 3.17	9.00 ± 3.31	12.35 ± 3.14	17.88 ± 4.02
E	15	6.33 ± 4.16	10.69 ± 3.95	13.94 ± 3.45	18.35 ± 4.33

2.3 开机后不同时期 MUSS 与 IT-MAIS 或 MAIS 得分相关性分析 开机后 1、3、6、12 月时 MUSS 得分与 IT-MAIS 或 MAIS 得分的相关系数分别为 0.918、0.808、0.881、0.756(均为 $P < 0.05$), 说明两种量表的评估结果显示出较好的一致性, IT-MAIS 或 MAIS 得分越高, MUSS 得分就越高。

2.4 Nurotron-Venus CI 的安全性及稳定性分析

78 例患儿 CI 术中进展顺利, 其中 4 例患儿电极未完全植入, 存在 2~4 个蜗外电极, 已于开机时关闭, 其余患儿人工耳蜗电极均完全植入, 术后切口愈合良好; 耳蜗 X 线平片检查均显示电极位置正常, 形态良好; 3 例患儿因外伤后, 出现植入体故障, 行二次手术; 2 例患儿出现处理器故障, 其余患儿植入的人工耳蜗整体工作状态良好, 生物相容性良好, 随访 12 个月均未出现排异反应及过敏反应。

3 讨论

Robbins 等在 1991 年将 MAIS 及 MUSS 用于儿童听觉言语能力的评估, 1997 年根据婴幼儿的特点在 MAIS 的基础上进行修订, 提出了 IT-MAIS,

MAIS 或 MAIS 得分见表 2, 经单因素方差分析, 可见术前 A 组得分明显低于 C、D、E 组(均为 $P < 0.05$); 开机后 1、3 个月, A、B 组得分低于 E 组(均为 $P < 0.05$); 开机后 6 个月, A 组得分低于 C、D、E 组(均为 $P < 0.05$), B 组得分低于 E 组($P < 0.05$), 其余各组间得分差异均无统计学意义($P > 0.05$)。不同年龄组术后 1、3、6、12 月 MUSS 得分见表 3, 经单因素方差分析, 可见开机后 1 个月, B 组得分低于 E 组($P < 0.05$); 开机后 3 个月, A、B、C 组得分低于 E 组(均为 $P < 0.05$); 开机后 6 个月, A 组得分低于 C、D、E 组(均为 $P < 0.05$), B 组得分低于 E 组($P < 0.05$); 开机后 1 年, A 组得分低于 C、D、E 组(均为 $P < 0.05$); 其余各组间得分差异均无统计学意义($P > 0.05$)。

用于婴幼儿的听觉能力评估。目前这两种量表已译为中文, 在国内被应用于评价人工耳蜗植入术后患者的言语康复效果评估^[1-3]。从本研究结果看, 在 Nurotron-Venus CI 术后 1 年内本组患儿 IT-MAIS 或 MAIS 及 MUSS 得分随着开机时间延长而升高, 说明其听觉言语能力随着人工耳蜗使用时间延长而提高, 与李刚等^[1]观察的 18 个月前的语前聋患儿植入 CI 后的听觉能力随时间延长而提高结果相近。

IT-MAIS 或 MAIS 得分主要用于评估听觉能力, 本研究结果显示, 术前植入年龄为 13~24 月组(A 组)得分低于 37~96 月组(C、D、E 组), 开机后 1、3 月时, A 组与 C、D 组得分已无差异, 开机后 6 月时, A 组得分低于 C、D 组, 在开机 12 月时各年龄段的听觉能力得分均趋势于相近。而 MUSS 得分主要评估言语能力, 从文中结果看, 在开机后 1 月 B 组得分低于 E 组, 开机后 3 月时 A、B、C 组得分低于 E 组, 开机后 6 月时 B、C 组得分低于 E 组, 开机 12 月时, 只有 A 组的得分低于 C、D、E 组的儿童, 其余年龄段的患儿得分已无差异。这一特点与陈雪清

等学者发现的 CI 儿童听觉言语发育并不是匀速的,而是表现出快速、缓慢及相对稳定发展的特点相似^[6,7];有研究表明获得早期干预的耳聋患儿在获得听觉能力的基础上,语言和交流的能力得分均较高^[7],且本组对象中年龄较大组患儿(D、E 组)术前佩戴助听器者较多,且佩戴时间较长,对听觉辅助的使用优于年龄小的儿童,并在开机后对声音的察觉和感知好于年龄小的儿童,且理解能力也有明显优势,配合能力和主动学习的能力较强,所以早期的听觉言语得分高于年龄小的儿童;由于婴幼儿的神经系统快速发育,且随着小几年龄增长逐渐完善,故术后 12 月时儿童各项的听觉言语得分均达到比较高的水平,而评估材料会出现天花板效应^[8],故在更长期的随访中应考虑增加测试难度,所以语前聋儿童 Neurotron-Venus CI 术后更长时间的听觉言语发育情况有待今后更长时间观察随访研究。

河南省新农合大病救助项目将 8 岁以下的重度或极重度感音神经性聋患儿人工耳蜗植入纳入救助计划,大龄语前聋患儿的需求越来越多,本组对象中 E 组的 15 例大龄儿童,术前均有长期助听器佩戴史,有一定的听觉基础,且个别患儿有语言基础,符合大龄聋儿人工耳蜗植入的适应症^[9]。从文中结果看,本组患儿听觉言语能力评估平均分数较高,对于该组患儿术后长期的听觉言语发育情况及康复效果仍需长期跟踪随访。值得注意的是大龄儿童术后多存在社会心理问题,会出现“期待”、“欣喜”、“困惑”、“失望甚至绝望”的心理变化^[9],因此,在以后的随访中,应缩短这类患儿每次评估的间隔时间,密切关注其心理变化,帮助他们逐步适应并融入有声世界。

吕静等^[10]认为语前聋婴幼儿助听后听觉与言语能力关系密切,本研究结果也表明,随着 CI 术后康复时间的延长,IT-MAIS 或 MAIS 得分与 MUSS 得分始终呈正相关,说明患儿整合听觉能力越好,言语发育能力越强。

诺尔康人工耳蜗系统是我国研发团队从美国加州大学和 House 耳研究所引进技术,在美国研发,

在中国制造的多导人工耳蜗,从本研究 78 例植入诺尔康人工耳蜗儿童的听觉及言语康复效果看,经过 1~3 年的跟踪随访,尽管个别患儿植入装置出现故障,但发生率与国内外品牌整体发生率^[11]并无明显差异,6 岁内重度或极重度感音神经性聋患儿在术后 1 年内的安全性及可靠性得到了验证,在提高听觉及言语能力方面效果满意。

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诺尔康人工耳蜗在特殊病例中的应用及疗效分析

An Analysis of Special Applications and Effects of Nurotron Cochlear Implants

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【摘要】目的 通过总结诺尔康人工耳蜗在特殊病例中的应用情况,客观评价诺尔康人工耳蜗在特殊类型感音神经性耳聋患者中的有效性及安全性,为相关患者人工耳蜗植入提供参考。**方法** 对大前庭导水管综合征、脑白质营养不良、耳硬化症、慢性化脓性中耳炎、双侧植入、再次植入等特殊病例患者,比较分析接受诺尔康人工耳蜗植入过程与类似病例在其他人工耳蜗植入过程中的异同点,术后定期调试及听觉言语测试评价其安全性及听觉言语康复效果,总结诺尔康人工耳蜗在特殊病例人工耳蜗植入中的特点并进行疗效分析。**结果** 13例14耳特殊病例患者均成功植入诺尔康人工耳蜗且无并发症。诺尔康人工耳蜗特殊病例组患者术后声场测听平均听阈为25~35 dB HL,均达到日常生活实用听力水平。术后开机3个月声母、韵母、单音节词言语识别率分别为 $52.33 \pm 10.95\%$ 、 $62.32 \pm 11.01\%$ 及 $40.11 \pm 9.43\%$,与诺尔康普通病例组及某国外品牌对照组术后言语识别率无统计学差异($P > 0.05$)。**结论** 诺尔康人工耳蜗在产品安全性及有效性方面和国外产品并无显著差别,可常规应用于特殊病例的人工耳蜗植入手术。

【关键词】人工耳蜗;大前庭导水管综合征;脑白质营养不良;耳硬化;双侧植入

【Abstract】Objective To make an objective evaluation of the reliability and effectiveness of Nurotron Cochlear Implant in special cases of sensorineural deafness and offer reference to patients with similar diseases. **Methods** Among the patients receiving cochlear implant, we chose patients of special complication or other abnormalities as the target for the study in this paper. The special complication included Large Vestibular Aqueduct Syndrome(LVAS), Hypertensive leukoencephalopathy, Otosclerosis, and Chronic suppurative otitis media. The abnormalities included bilateral implants and re-implantation. We made a study of the surgery of these cases and assessed the hearing speech rehabilitation effects after implants and finally drawn a conclusion of Nurotron Cochlear Implant. **Results** 14 Nurotron Cochlear Implants were successfully implanted in 13 patients of special complication or other abnormalities and no complications occurred. The results of intra-operative impedance tests were in the normal range. The pure tone average in sound field of patients in special cases group who received Nurotron Cochlear Implant was among 25 to 35dB. The speech discrimination scores of initials and finals and single-syllable words after 3 months after the first use of cochlear implants were $52.33 \pm 10.95\%$ and $62.32 \pm 11.01\%$ and $40.11 \pm 9.43\%$. There was no significant difference among the special cases group with Nurotron Cochlear Implants and normal cases group with Nurotron Cochlear Implants and other group with Cochlear Implants of foreign brands. **Conclusion** Nurotron Cochlear Implants can be used routinely in special cases of cochlear implantation and there are no significant differences between the Nurotron Cochlear Implants and those similar products at abroad in safety and effectiveness.

【Key words】Cochlear implant; Large vestibular aqueduct syndrome; Hypertensive leukoencephalopathy; Otosclerosis; Bilateral implant

人工耳蜗植入是公认治疗重度、极重度感音神经性耳聋最有效的治疗手段。国产诺尔康人工耳蜗目前在临床应用越来越广泛,为更全面的认识和评价诺尔康人工耳蜗,现将我院实施诺尔康人工耳蜗植入手术以来,在一些特殊病例中的效果予以总结,为类似病人的人工耳蜗植入提供参考。

1 资料和方法

1.1 临床资料

病例为中南大学湘雅医院收治的特殊病例且实施诺尔康人工耳蜗植入者共13例。其中男4例,女9例,语前聋6例,语后聋7例,平均失聪时间为4.7年,手术时年龄从1岁8个月至38岁不等。包括大前庭导水管5例、脑白质营养不良4例、慢性化脓性中耳炎1例、耳硬化症1例、双侧植入1例、再次植入1例。所有患者听力学检查均为重度或极重度感音神经性耳聋,佩戴助听器无效,选择接受诺尔康CS-10A型人工耳蜗植入。

13例患者中,左侧植入3例,右侧植入9例,双侧植

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入1例。单侧植入者中1例行左耳人工耳蜗植入的同时实施了左耳鼓室成形术；1例患者1岁半时在外院右耳植入人工耳蜗半年后发现耳蜗故障，来我院二次手术。

1.2 术中情况

手术选用术侧耳后小“C”形切口，常规经面隐窝入路暴露圆窗龛，经圆窗膜入路将耳蜗电极插入鼓阶，电极阻抗测试正常后，缝合切口结束手术。伴前庭导水管扩大患者术中开放圆窗后出现“井喷”，并不影响耳蜗电极插入，电极插入后取少许肌肉封闭电极周围间隙避免外淋巴液持续涌出；伴脑白质营养不良患者耳蜗植入过程与普通患者手术过程并无特殊；耳硬化症患者鼓阶内发现部分骨质增生病变，予以清除后顺利插入耳蜗电极；双侧耳蜗植入者再次消毒后行对侧人工耳蜗植入，对侧耳蜗植入手术过程中避免使用单极电刀；伴中耳炎患者植入人工耳蜗前取同侧颞筋膜备用，清除鼓室病变后，沿残余鼓膜边缘准备移植床，待耳蜗电极插入后一期行同侧鼓室成形术；再次植入患者在将前次植入耳蜗电极取出后在同侧耳随即植入新的耳蜗电极，电极插入过程顺利，术中阻抗测试正常。

1.3 术后调试及听觉言语评估

术后2天常规耳蜗位片检查耳蜗电极植入情况。术后1月开机，使用诺尔声软件测试植入耳蜗电极阻抗值、各电极反应阈值及最大舒适阈值，采用峰值提取处理策略(m-n)行言语编程，双侧植入者采用左右耳同步调试，此后3月内每月调试1次，再隔3月调试1次，隔6月调试1次，程序稳定后每半年或1年调试1次。术前及术后开机后3月声场测听进行听力评估，《聋儿康复听觉言语评估词表》进行闭合式语言测试，并随机选取同期在我院手术的行诺尔康人工耳蜗植入普通病例15例及某国外品牌人工耳蜗植入病例15例对比测试。

1.4 数据统计

测试结果采用SPSS 14.0 for Windows统计学软件行单因素方差分析， $P < 0.05$ 具有统计学意义。

2 结果

共对13例特殊病例患者14侧耳顺利实施诺尔康人

工耳蜗植入，电极均能全部植入，术中电极阻抗测试全部正常，伤口均I级愈合，无并发症发生，术后耳蜗位片检查显示电极在耳蜗内位置正常。同期行鼓室成形术患者术后复查鼓膜修复成功。

术后特殊病例组声场测听听阈平均为25~35 dB HL，均达到日常生活实用听力水平，诺尔康特殊病例组术后开机3个月声母、韵母、单音节词言语识别率分别为 $52.33 \pm 10.95\%$ 、 $62.32 \pm 11.01\%$ 及 $40.11 \pm 9.43\%$ ，测试结果显示患者人工耳蜗植入后言语识别率均得到明确改善，与诺尔康普通病例组及某国外品牌耳蜗植入病例组术后言语识别率改善情况均无显著差别(见表1)。

3 讨论

自多通道人工耳蜗问世以来，以往临床医师束手无策的重度、极重度感音神经性耳聋的治疗得到了彻底的改观^[1]，经过多年来不断的实践，人工耳蜗的手术适应症不断扩大^[2]，由极重度聋扩展到部分重度聋，手术最低年龄限制不断下降，从开始的2岁到现在的1岁甚至更小^[3]。但是，对一些特殊病例的人工耳蜗植入，如合并大前庭导水管综合征、脑白质营养不良、慢性化脓性中耳炎、耳硬化症等情况的特殊病例，人工耳蜗植入的可行性及有效性还在探讨之中^[4-6]。根据国内外文献报道及我科开展人工耳蜗植入工作以来的经验，大前庭导水管综合征是临床上最常见的一种内耳畸形，其表现为波动性听力下降，既可表现为先天性极重度感音神经性耳聋，又可表现为迟发型感音神经性耳聋，合并该内耳畸形患者进行人工耳蜗植入后均能得到较好的听觉言语康复^[7]。

脑白质营养不良的患者近年来随磁共振检查的应用检出率明显增高^[8]，严重时可能出现运动发育迟缓及精神智力障碍，所以曾经是人工耳蜗植入的禁忌症，但其临床症状差异很大，相当一部分患者并无明显症状，对脑白质营养不良患者一概不予人工耳蜗植入可能导致这部分患者错过听觉言语康复的机会^[9]，中华医学会耳鼻咽喉头颈外科分会2013年人工耳蜗

表1 不同人工耳蜗植入病例组术前术后言语识别率(%)

	声母		韵母		单音节词	
	术前	开机3月	术前	开机3月	术前	开机3月
诺尔康特殊病例组	9.25 ± 2.34	52.33 ± 10.95	10.11 ± 2.67	62.32 ± 11.01	6.28 ± 1.03	40.11 ± 9.43
诺尔康普通病例组	11.02 ± 1.82	51.42 ± 9.17	9.53 ± 3.21	65.65 ± 10.17	12.16 ± 4.02	41.15 ± 9.13
其他品牌病例组	10.65 ± 3.01	53.05 ± 13.36	11.28 ± 2.54	65.18 ± 15.54	10.98 ± 5.19	47.54 ± 16.06
F值	3.216	1.894	2.572	2.274	1.299	1.611
P	>0.05	>0.05	>0.05	>0.05	>0.05	>0.05

植入工作指南对此做出了专门说明^[10],指出合并脑白质营养不良的患者,术前经智力测试在正常范围,未合并癫痫频繁发作不能控制,无内耳严重畸形即可行人工耳蜗植入术,根据我科对该类患者人工耳蜗植入的情况表明,该类患者均能从人工耳蜗中获益,得到不同程度的听觉言语康复效果。

随着人们生活水平的提高,慢性化脓性中耳炎患者对人工耳蜗的需求也逐渐上升^[11],该类患者行人工耳蜗手术有可能导致迷路炎、脑膜炎等并发症,化脓性炎症长期不愈时可能导致植入耳蜗取出的严重后果,因此对慢性化脓性中耳炎患者实施人工耳蜗植入均持谨慎态度,根据同类病例报道及我科经验,在做好预防感染、清除病灶的基础上同期实施人工耳蜗植入和鼓室成形术是可行的,人工耳蜗植入后患者的听觉康复效果也是显而易见的。

另外,双侧人工耳蜗植入及人工耳蜗再植入等特殊情况都对耳蜗的安全性、技术指标都提出了更高的要求。诺尔康人工耳蜗在普通的重度、极重度感音神经性耳聋患者中的应用已经非常广泛,其有效性和安全性也已经得到验证^[12],通过对上述特殊病例实施人工耳蜗植入的实践说明诺尔康人工耳蜗在特殊病例中的有效性和可行性也是有保证的。

我国是一个人口大国,需要接受人工耳蜗植入的重度、极重度耳聋人群数量巨大,但现阶段我国基本国情下广大人民群众的经济能力与进口耳蜗较高的价格之间仍有较大的差距,因此发展我国自主品牌的多通道人工耳蜗产品非常必要。诺尔康人工耳蜗作为最早的国产耳蜗品牌在我院已经应用了5年时间,在普通病例和特殊病例中的应用情况均证实了其安全性和有效性,当然,我们仍然需要继续扩大应用的病例数、延长术后效果观察时间来对其做出更全面、准确的评估。

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中国听障儿童服务网开通助听器免费借用服务

(本刊讯)为保障各类人工耳蜗救助项目顺利实施,切实减轻贫困儿童手术前需购买助听器进行适应性训练的负担,中国聋儿康复研究中心通过中国听障儿童服务网(<http://www.hearingkids.org.cn/>)面向全国开通助听器免费借用服务。具体网址:<http://bbs.hearingkids.org.cn/borrowhearingaid/introborrow.php>

鼻中隔偏曲伴下鼻甲肥大的经鼻内镜术治疗

金国君

(横店文荣医院耳鼻喉科)

【中图分类号】R76

【文献标识码】B

鼻中隔偏曲伴下鼻甲肥大在临床上比较普遍,是鼻科的常见病。传统的鼻中隔矫正术对鼻中隔高位、后段的偏曲较难彻底矫正,且常规的下鼻甲处理方式较难完全保留粘膜的功能,致临床疗效不理想。为解决该难题,本科自2002年3月至2007年4月采用鼻内镜下行鼻中隔偏曲矫正术,同时用低温等离子射频治疗肥大的下鼻甲,疗效满意,报告如下。

1 临床资料

1.1 一般资料 本组108例患者中男60例,女48例;年龄18~55岁,平均35岁;病程2~30年,平均10年。主要临床表现为鼻塞、头痛、鼻出血、涕多等。所有病例术前均经鼻内镜和鼻窦冠状位CT扫描检查;鼻中隔偏曲呈“C”型38例,“S”型30例,“棘”型25例,“嵴”型15例。所有病例均伴有下鼻甲肥大,且对麻黄碱不敏感。伴鼻窦炎,鼻息肉患者不记入本组。

1.2 手术方法 应用WOLF公司生产的0°鼻内镜,内窥镜手术系统及电视监视设备。患者取仰卧位,1%地卡因加1:1000肾上腺素棉片收缩麻醉鼻腔2次后,取1%利多卡因加1:1000肾上腺素溶液作鼻中隔切口及肥大下鼻甲的浸润麻醉。于鼻中隔偏曲明显侧作Kilian术式切口,取特制的粘骨膜剥离器,边吸引,边清晰的分离该侧的粘(软)骨膜,向后达筛骨及犁骨后分至偏曲骨全暴露,再剥离对侧粘(软)骨膜,直视下对偏曲的软骨及骨质予切除或行骨折复位位于正中位;如鼻中隔软骨偏曲不明显,可在鼻中隔软骨与垂直板、犁骨交接处游离,再剥离对侧粘骨膜,咬除骨折样折偏曲骨质,复位粘骨膜[1],缝合或不缝合切口。肥大的下鼻甲用美国Arthrocare公司制造的ENTec-Coblator等离子手术系统治疗仪,选择Reflex-45型等离子刀,组织间电解质选用生理盐水。主机输出功率设定为4级。在0°鼻内镜的引导下,于下鼻甲前缘下部或外下部进入,开启工作开关,沿下鼻甲背缘向后推进,深度为1~2cm,持续工作10s后,开启凝血开关,并退出等离子刀。根据下鼻甲收缩情况,上述操作可重复2~3次,但穿刺部位不能重复,以免造成过度消融。术后双侧鼻腔均填塞Merocel高膨胀止血海绵。术后48~72h抽除鼻腔填塞,常规予抗生素及止血药物治疗,缝线者术后5~7d拆线。

2 结果

术后3个月复查,鼻中隔均获得一次性彻底矫正,疗效满意。相关症状基本消失,无再度偏曲,鼻梁塌陷,鼻腔粘连,鼻中隔血肿,脓肿,脑脊液鼻漏,鞍鼻等严重并发症。下鼻甲色泽红润,光滑,体积明显缩小,与鼻中隔距离>3mm。

3 讨论

传统经鼻下鼻甲偏曲矫正术,患者取半卧位,一般仅能暴露鼻中隔前1/3区域,且经鼻的照明度有限视野小,高位及后段部的偏曲难以充分暴露,对该区域的操作有盲目性,切除少了矫正不满意,切除多了会破坏中隔支架,造成鼻梁塌陷、鼻中隔穿孔等并发症。随着鼻内镜技术的发展,传统的手术方式将逐渐被淘汰,为鼻内镜电视显示系统下的微创手术所替代,鼻内镜多种角度,照明度好,术野清晰,操作方便,剥离准确,损伤小[2],能清晰的看到鼻

中隔软骨与筛骨垂直板的结合处,及犁骨、上颌骨鼻嵴与鼻中隔软骨下部的错接交接和纤维粘连带[3],使操作更加准确,尤其对较高、较后的偏曲骨切除时可看到切除的范围,最大限度的保留中隔的骨性支架,防止鼻梁塌陷,鼻中隔穿孔等并发症的发生。

鼻中隔偏曲伴下鼻甲肥大在临床上较常见,在进行鼻中隔矫正术时,必须同时行肥大的下鼻甲手术,才能成功的改善鼻塞及头痛[4]。文献报道[5]:作鼻中隔矫正术而未行鼻甲减容术的结果是71%~80%的患者鼻塞无减轻。故行鼻中隔偏曲矫正的同时行肥大的下鼻甲减容术,既保证了手术的效果,又免除了患者二次手术的痛苦,减轻了患者的经济负担。

下鼻甲是鼻腔重要的解剖结构,具有重要的生理功能。下鼻甲黏膜上的纤毛运动能将粘附于粘液毯中的灰尘颗粒运送至咽部咽下或吐出。故下鼻甲肥厚的理想治疗方法应是在保证下鼻甲粘膜完整的前提下缩小下鼻甲体积,以恢复正常的鼻腔通气而不破坏下鼻甲的生理功能。目前治疗手段中的微波、激光、冷冻、手术部分切除均不可避免的破坏下鼻甲黏膜的纤毛功能。再者由于操作和视野方面的局限性,仅解决了鼻腔通气道的前中部分。对于下鼻甲后端增殖性病变患者,其疗效欠佳,且由于下鼻甲血供丰富,常规下鼻甲部分切除术极易出血。低温等离子射频治疗的作用机制主要是通过等离子刀和组织间的电解质液形成等离子薄膜,使靶组织中的细胞凝固坏死脱落,后期疤痕收缩,获得减容效果。其在粘膜下低温消除对周围组织作用局限,表面创伤小,可最大限度地保留正常生理结构及组织正常功能。通过下鼻甲粘膜下组织减容,疤痕收缩等,使气道腔径扩大,改善了症状,并最大限度地保护了下鼻甲表面黏膜的纤毛功能,且康复时间短,可重复治疗。

鼻内镜下治疗鼻中隔偏曲伴下鼻甲肥大与传统的鼻中隔矫正及下鼻甲手术比较,更加安全有效,减少术中创伤,使患者尽快恢复健康,具有较好的临床应用价值。

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国产诺尔康人工耳蜗植入临床探析

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【摘要】目的:探讨国产诺尔康人工耳蜗植入临床效果。方法:选取感音神经性耳聋重度或极重度的语后聋患者30例,均为我院耳鼻喉科在2015年8月至2015年12月收治,采用国产诺尔康人工耳蜗植入治疗,对比应用前后言语可懂度标准(SIR)分级量表及Nijmegen中文版人工耳蜗植入量表(NCIQ)评分。结果:相较植入前,植入后患者SIR评分明显提高。相较植入后3个月,植入后6个月患者NCIQ评分各因子及总分均明显提高,差异均具统计学意义(P<0.05)。结论:采用国产诺尔康人工耳蜗对感音神经性耳聋重度或极重度患者治疗,可明显改善其听力状况,增强生活质量,具有重要的实施价值。

【关键词】国产诺尔康人工耳蜗植入;感音神经性聋;效果

【中图分类号】R563

【文献标识码】B

人工耳蜗植入(CI)是现阶段对感音神经性聋重度和极重度患者治疗的最有效手段。但因人工耳蜗产品长期以来多为进口,大部分家庭对高昂的费用较难承受,使患者无法得到有效及时的救治。国产诺尔康人工耳蜗的研制,使上述问题得以解决,已让国内耳聋患者受益[1]。本次研究就语后聋患者植入国产诺尔康人工耳蜗后的效果展开探讨,现回顾如下。

1 资料与方法

1.1 一般资料 选取30例感音神经性聋重度或极重度的语后聋患者,男16例,女14例,年龄10~62岁,平均22.8±3.1岁,失聪时间平均16.2±1.3年。耳聋原因:大前庭导水管综合征14例,高热致聋4例,突发性耳聋致聋6例,不明原因6例。均为耳后聋,曾配戴助听器效果不佳,对本次研究知情同意。

1.2 方法 30例患者均采用国产诺尔康人工耳蜗植入治疗,24例为右侧植入,6例为左侧植入。步骤:手术切口于术侧耳后选取,准确定位耳蜗模具后,

子以美兰标记,再将皮肤、皮下组织依次切开至乳突骨膜,依据亚甲蓝标记位置将植入床磨出,后对乳突腔行开放处理,经面神经隐窝将蜗窗呈暴露状态,鼓阶蜗窗径路予以开放,后对植入体进行固定,于鼓阶处插入电极,采用颞肌封闭耳蜗造口,对电极进行测试,结果呈正常显示后,对切口缝合,完毕。

1.3 指标观察 (1) 采用言语可懂度分级标准 (SIR) 评估患者治疗前后听力状况,依据其理解言语的程度按 1-5 级划分,分别为 1-5 分,分值越高,效果越好。(2) 生活质量评估:采用 Nijmegen 中文版人工耳蜗植入量表 (NCIQ) 评估植入后 3 个月与植入后 6 个月生活质量情况,包括基本声音感知、高级声音感知、言语能力、自信心、活动能力、社会交流各因子以及总分平均分,分值越高,效果越好。

1.4 统计学分析文中数据均输入 SPSS13.0,组间计量数据采用 $(\bar{x} \pm s)$ 表示,行 t 检验, $P < 0.05$ 差异有统计学意义。

2 结果

2.1 SIR 评分对比相较植入前,植入后患者 SIR 评分明显升高,差异具统计学意义 ($P < 0.05$) 见表 1。

表 1 植入前后 SIR 评分对比 ($\bar{x} \pm s$, 分)

时间	n	SIR 评分
植入前	30	3.16 ± 1.03
植入后	30	4.79 ± 0.56*

注: * 与植入前对比具统计学差异 ($P < 0.05$)。

2.2 NCIQ 评分对比相较植入后 3 个月,植入后 6 个月患者 NCIQ 评分各因子及总分均明显提高,差异均具统计学意义 ($P < 0.05$) 见表 2。

表 2 植入后不同时间段 NCIQ 评分对比 ($\bar{x} \pm s$, 分)

项目	植入后 3 个月	植入后 6 个月
基本声音感知	45.71 ± 14.24	72.31 ± 15.56*
高级声音感知	43.89 ± 13.27	62.92 ± 20.31*
言语能力	42.71 ± 12.92	73.42 ± 12.85*
自信心	42.73 ± 12.81	49.23 ± 13.53*
活动能力	45.34 ± 10.45	52.48 ± 17.27*

社会交流	41.02 ± 9.34	49.42 ± 11.54*
总分	41.2 ± 9.71	59.91 ± 10.74*

注: * 与植入后 3 个月对比均具统计学差异 ($P < 0.05$)。

3 讨论

现阶段,我国聋病患者对人工耳蜗的需求巨大,但人工耳蜗产品多自国外购得,价格昂贵,大部分家庭较难承受,对我国新型多道人工耳蜗进行研制,是改善上述状况,使更多患者得到有效及时治疗的关键 [2-3]。诺尔康人工耳蜗即属新型研制的产品之一,实践表明,采用诺尔康人工耳蜗植入对耳聋患者治疗,术后无排斥反应,异常电刺激,感染等并发症,均可完全植入电极,且相较其他产品,植人体较薄,明显减少了术中磨骨面积,缩短了手术用时 [4-5]。术后患者听力状况,生活质量均明显改善,与本次研究结果一致。

综上,采用国产诺尔康人工耳蜗对感音神经性聋重度或极重度语后聋患者治疗,可明显改善其听力状况,增强生活质量,具有重要的实施价值。

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紫甘蓝色素提取条件的研究

陈颖

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【摘要】 本文采用不同的条件提取紫甘蓝的色素, 采用在 525nm 处最大吸收度下比较色素提取效果进行分析, 研究其最佳提取方法。

【关键词】 紫甘蓝; 色素; 提取

【中图分类号】 R318.52

【文献标识码】 B

The study on Extraction of Pigment form Purple Cabbage

【Abstract】: Different methods were used in extracting anthocyanins form purple cabbage and the samples were also analyzed for physicochemical activity using the spectrophotometer methods.

【Keywords】: purple cabbage; Pigment; abstraction

1 前言

紫甘蓝色素是一种重要的天然色素物质, 从化学结构来看, 是花色苷类物质, 具有重要的生理活性功能, 可以清除体内自由基, 具有抗氧化、抗衰老功能, 可以作为重要的功能性食品添加剂开发 [1]。

本文以紫甘蓝色素为原材料, 就提取剂、温度、固液比及提取时间等因素, 研究紫甘蓝色素提取的最佳条件, 得出一些结论, 为食品生产过程提供一些依据。

2 材料与方法

2.1 实验器材与材料

主要仪器: RE-52A 旋转蒸发器; 722 型光栅分光光度计; HH-2 型电热恒温水浴锅; SH2-D 型循环水式真空泵

实验材料: 食用紫甘蓝; 乙醇; 蒸馏水; 盐酸。

2.2 实验原理

紫甘蓝色素在结构上属于花青素类, 它在稀酸溶液中更易溶解, 其提取工艺流程如下: 紫甘蓝洗净晾干→粉碎→提取剂中浸提→减压抽滤→滤液蒸发→冷冻干燥→色素胶质。

用分光光度计检测紫甘蓝色素时, 其在波长 520nm-530nm 间存在一个波峰, 最大吸收值为 525nm。本实验选择以 525nm 吸光度为指标, 以提取剂、固液比、提取时间、提取温度四个因素为对象, 分别研究各个因素对色素提取的影响, 选择最佳提取条件。

2.3 试验方法

紫甘蓝中色素的定量分析, 采用 PH 示差法。

称取紫甘蓝 5000g, 将其切碎, 研磨至组织细胞破碎, 放入大烧杯, 向其中加入适量已配好浓度提取剂, 在恒温水浴中进行连续浸提, 直至滤液吸光度接近零。将得到的提取液浓缩后, 进行冷冻干燥, 获取紫甘蓝色素样品, 用蒸馏水定容, PH 示差法吸收光谱测定。

3 实验结果

3.1 提取剂的选择

准确称取 6 份洗净、晾干、切碎的紫甘蓝, 每份 5000g, 分别称在干净的锥形瓶中, 分别加入 20% 无水乙醇、PH=2 蒸馏水、50% 乙醇、95% 乙醇、PH=2

50% 乙醇、1% HCl 及蒸馏水各 50mL, 室温浸提 4h, 采用浸提法提取紫甘蓝色素, 测定吸光度结果如下表 1

溶剂	20% 乙醇	PH=2 蒸馏水	50% 乙醇	95% 乙醇	PH=2 50% 乙醇	1% HCl
吸光度	0.491	0.545	0.458	0.219	0.939	0.678

表 1 各提取剂对应吸光度

观察实验结果可发现, 紫甘蓝色素在 50% 乙醇 PH=2 条件下提取, 吸光度最大, 提取效果最佳。

3.2 选择最佳提取时间

在室温下, 准确称取 6 份洗净、晾干、切碎的紫甘蓝, 每份 5000g, 分别称在干净的锥形瓶中, 分别浸提色素 1h, 1.5h, 2h, 3h, 4h, 测定吸光度结果如表 2:

时间	1h	1.5h	2h	3h	4h
吸光度	0.938	0.947	0.952	0.965	0.989

表 2 提取时间

结果说明色素提取时间越长, 效果越好, 因此选择提取 4h。

3.3 选择最佳固液比

在室温下, 准确称取 6 份洗净、晾干、切碎的紫甘蓝, 每份 5000g, 以

用爱托起一片属于你的蓝天

——大龄听障儿童植入国产诺尔康人工耳蜗产品访谈实录

■本刊记者 薛静 于丽纹 孙金忠

我国有听力残疾人2780万,每年新生听障儿童约2.3万人。目前,针对听障儿童的有效干预措施主要为配戴助听器进行听力补偿或植入人工耳蜗进行听觉重建。人工耳蜗是一种为重度、极重度听力障碍成人和儿童恢复听觉、重建听力的有效装置,它把声音信号转变为电信号直接刺激残余听神经纤维末梢,从而产生听觉,听障人士可通过人工耳蜗植入重建听力,实现正常的聆听与交流。对于重度和极重度听障儿童,助听器验配不能达到良好效果者,人工耳蜗植入是其获得听力重建、进行听力语言康复的有效手段。近年来,人工耳蜗技术不断完善与发展,越来越多的听障患者得到了听力重建与康复的机会。但是,人工耳蜗产品多为国外进口、价格昂贵,使得一些患者无法得到及时有效地干预。国产人工耳蜗以其价格优势及基于中国汉语四声研发的特点进入中国市场。

国产人工耳蜗产品的相继问世,打破了进口人工耳蜗在国内市场的垄断局面。目前市场上各年龄段广泛使用的国产人工耳蜗主要为浙江诺尔康公司的24通道晨星(CS-10A型)人工耳蜗。诺尔康致力于研发针对国人听力言语特点的人工耳蜗产品,且能够满足不同经济收入群体。截至2016年6月,有近5000例中外听障患者选择了诺尔康人工耳蜗。2016年,诺尔康成

为国家人工耳蜗救助项目的中标产品之一,项目救助对象年龄范围以小龄听障儿童为主。

自2009年国家人工耳蜗项目启动以来,共有18000余名0~6岁小龄听障儿童得到了项目救助,使他们在语言康复的关键期得到了有效的干预,但对于6岁以上的大龄青少年则鲜有关注。为帮助大龄听障儿童重获新声,使各年龄段听障人群得到救助与帮扶,部分省市政府出资自主开展了针对不同年龄群体的国产诺尔康人工耳蜗救助项目,项目受助人年龄范围多为7~18岁大龄青少年。为了解国产诺尔康人工耳蜗的有效性和安全性,推动国产人工耳蜗的优化和普及,同时,总结大龄人工耳蜗植入的康复特点与经验,本刊编辑部随机选取省内自主开展国产诺尔康人工耳蜗资助的陕西、海南两省,对大龄人工耳蜗植入项目的管理人员、手术医生、调机师、康复教师及听障儿童家长进行了访谈,分享了项目实施过程中的经验与方法,提出了目前存在的问题,为国产人工耳蜗项目更好地开展提供借鉴与参考。

陕西篇

阳春三月,古都西安洋溢着种种生机,编辑部一



薛静,副研究员,毕业于北京师范大学学前教育专业,教育学学士,就职于中国聋儿康复研究中心编辑部,从事专业期刊编辑、审稿、听障儿童康复教育研究工作十余年。作为责任编辑,先后策划了多个学科焦点重点号专题,使杂志的稿件质量不断提升。同时担任增刊执行主编,为基层康复教师及听障儿童家长提供了实用的康复技巧与经验。参与国家“十二五”科技支撑计划课题研究工作,在国家级学术期刊发表论文10余篇,参与编写论著1部。

行三人来到陕西省听力语言康复中心,对陕西省国产诺尔康人工耳蜗项目进行了深度采访。

项目组织实施机构管理者:陕西省听力语言康复中心项目办负责人

●请介绍一下陕西省国产诺尔康人工耳蜗项目的概况?

在陕西省残联、陕西省听力语言康复中心的精心组织与实施下,截止2016年3月,陕西省民生康复项目共计有45例大龄青少年进行了国产诺尔康人工耳蜗植入手术,年龄7-18岁,平均年龄11岁,植入者术后均进行了机构及家庭言语康复训练。

●项目的术前筛查与评估情况如何?

项目实施前,陕西省听力语言康复中心参照项目实施规范对受助者进行了术前筛查与评估,其中包括年龄、听觉、言语评估等,并对家长说明了项目知情事项,帮助家长建立了正确的期望值,对合格者给予公示后实施人工耳蜗植入手术。

●术后是否达到了预期效果?家长满意度如何?

在参与回访的32例家长中,29例表示对康复效果满意,占91%,3例因产品导线等客观原因及植入者主观原因表示康复效果不满意,占9%。总体来说,受助家庭对康复效果较满意,且听障儿童在日常生活中提高了交流与沟通能力。

●您对诺尔康产品了解吗?其针对国人有何特点?从机构角度您对诺尔康人工耳蜗产品评价如何?

国产诺尔康人工耳蜗是专门针对汉语语音发音特点而设计的助听产品,其价格与同规格进口植入体相比具有明显优势,使用性能良好,能够满足听障患者对听声的需求,我认为它是中低收入家庭的较好选择。

●贵单位对家长培训及宣教工作开展情况如何?

我们在人工耳蜗植入术前会召开专门的术前家长会,让家长了解植入手术的安全性与注意事项,并对孩子的生理、病理变化进行详细介绍与讲解;术后开机时,人工耳蜗公司会进行专门的培训,讲解人工耳蜗开机、调机及使用要点,同时每年举办2次家长培训,以便让家长间互助交流,共享经验。

●项目开展过程中有何困难?希望得到哪方面的支持?

项目的实施得益于国家、政府对残疾儿童的关爱与扶助,得益于中残联、省残联对项目的领导与重视,同时离不开相关专业人员、人工耳蜗公司及患儿家长的支持与合作,我们希望能够加强各方联系,并在陕西省增设产品维护服务点,以方便受助家庭的产品使用、

调试及升级等服务。

国产人工耳蜗手术医生:西安交通大学附属第二医院耳鼻咽喉科主任医师

●请介绍一下国产诺尔康人工耳蜗的产品性能与特点及适应证选择?

国产诺尔康人工耳蜗是我国与国外相关科技人员共同研发的自有品牌人工耳蜗产品,其与进口许多品牌一样,拥有良好的产品性能,能够满足听障患者的听力重建需求,它对植入者没有特殊的要求,只要符合人工耳蜗植入手术条件即可进行植入手术。

●诺尔康人工耳蜗植入手术时有何技巧?对残余听力的保留如何?

诺尔康人工耳蜗的植入体磨骨体积小,对内耳的破坏性较小,对基底膜无损伤,能够较好地保留残余听力。

●诺尔康人工耳蜗植入手术成功率如何?

截止目前,我院累计植入国产诺尔康人工耳蜗80余例,手术成功率为100%,没有因产品性能问题而产生负面影响。

●手术过程中有何困难?产品性能有何需要改进的地方?

个人认为其产品的体外机外观、电极、配戴舒适性等方面有提升空间。

●诺尔康人工耳蜗术后效果评价如何?

目前,随着国家及各地区救助项目的开展,国产诺尔康人工耳蜗的市场占有率越来越多,其产品频率覆盖范围较大,能够较好地帮助听障患者听到各种声音,是适合我国中低收入家庭的听力辅具。

陕西省听力语言康复中心语言训练部康复教师、听力门诊部调机师

●诺尔康人工耳蜗术后整体康复效果如何?

诺尔康人工耳蜗植入后的助听听阈在香蕉图内,因项目受助儿童的年龄较大,80%在学龄就读,在机构内进行语言康复主要以一对一的个别化康复训练方式为主,辅以家庭康复训练。训练1个月后,有康复经历的听障儿童康复效果较明显,没有康复经历的听障儿童需要更长时间的康复才能达到满意效果,但总体康复效果较好。诺尔康人工耳蜗与其它品牌人工耳蜗的听力补偿效果与康复效果没有明显差异。

●大龄人工耳蜗植入儿童的康复方法及评估方法有哪些特点?

我中心对大龄人工耳蜗植入儿童的康复训练方法以听觉口语法为主,包括对声音的察知、理解、分辨训练等,因受助儿童年龄偏大,已经具备一定认知能力,因此,康复训练以听觉训练、心理健康教育为侧重,而不是以认知训练为主。调机前及调机后的评估很重要,应按时完成。

●您是否与植入者家长经常沟通儿童的康复情况?

家长对听障儿童的期望值很重要,直接影响康复效果的成败,因此,我们会定期举办家长培训班,沟通儿童康复情况,传授康复技巧,共享康复经验,为家长树立信心、建立正确的期望值提供帮助与指导。同时,我中心确立每周四下午为家长访谈日,集中解决患者的相关问题。

●项目实施过程中有何困难?

希望人工耳蜗公司能够举办针对康复教师的产品使用培训,以帮助教师掌握康复训练中遇到的故障检测与排除等问题。



陕西省研讨会现场



采访陕西省项目办专员

海南篇

爱就像一粒种子,播种了就会发芽。人工耳蜗康复项目已成为海南省残联的品牌形象,2016年4月,我们带着这粒种子来到了我国的最南端,走进了美丽的

海岛——海南省残疾人康复指导中心。

项目组织实施机构管理者:海南省残疾人康复指导中心项目办负责人

●请介绍一下诺尔康人工耳蜗项目的概况与背景?

为帮助更多的贫困听障儿童植入人工耳蜗,让他们重返有声世界,海南省残疾人联合会、海南省残疾人基金会、海南广播电视总台联合开展了“2015助梦启航—关爱听障儿童”大型公益活动,活动旨在帮助100名听力语言障碍残疾人免费植入国产诺尔康人工耳蜗。

●贵单位目前诺尔康人工耳蜗植入者大致情况如何?

截止2016年7月,共植入诺尔康人工耳蜗98例,年龄7~20周岁。植入者均进行了不同程度的康复训练,并定期进行回访与评估,评估结果显示,受助儿童的听力语言能力均得到不同程度的改善。

●您对诺尔康产品的了解如何?

诺尔康人工耳蜗与其它进口人工耳蜗产品没有太大差别,其价格适宜,贫困残疾人家庭依然可以承受。

●诺尔康人工耳蜗的术前筛查与评估情况如何?

我省“助梦启航”项目受助对象主要为7岁以上听障患者,因此,术前筛查条件比国家项目标准相对放宽。

●术后是否达到了预期效果?家长满意度如何?

患者术后听觉言语评估均较术前有一定程度提升。大龄听障儿童的术后康复效果与小龄儿童不同,他们因为错过了言语的最佳发展期,因此,家长的期望值应建立在孩子自身情况的基础上,适当调整心态,把孩子每一个小小的进步及变化视为成果,一步步使孩子适应有声的语言环境。

●贵单位对家长培训及宣教工作开展情况如何?

我中心术前、术后均开展家长培训,同时利用报刊、电视等媒体对家长进行宣传教育,以使家长正确看待人工耳蜗植入后的康复效果。

●项目开展过程中有何困难?希望得到哪方面的支持?

基层针对大龄听障儿童的康复训练、评估方法等

缺乏经验,希望得到康复技术指导与支持。

国产人工耳蜗手术医生:解放军总医院海南分院耳鼻喉科主任医师

●请介绍一下国产诺尔康人工耳蜗的产品性能特点及适应证选择?

我院开展国产诺尔康人工耳蜗植入手术已近20余例,该产品是经欧盟认证的安全可靠的人工耳蜗产品,与进口人工耳蜗产品相差无几。诺尔康公司的研发团队在美国,有较强大的研发与技术力量,其性价比很高,推荐国人使用。

●诺尔康人工耳蜗植入时有何手术技巧?对残余听力的保留如何?

诺尔康人工耳蜗的电极软硬度适宜,开窗的路径、角度与进口产品略有差别。植入过程中磨骨体积小,符合微创手术要求。临床结果表明,其使用功能与进口人工耳蜗效果相同,并且可以保留残余听力。

●诺尔康人工耳蜗植入手术成功率如何?

国产诺尔康人工耳蜗植入手术成功率为100%,人工耳蜗设备工作状态稳定,生物相容性好,无手术相关的严重并发症发生。

●诺尔康人工耳蜗术后效果评价如何?

诺尔康人工耳蜗植入术后3个月的助听听阈均值较术前术侧裸耳听阈均值显著降低。

海南省残疾人康复指导中心语言训练部康复教师、听力门诊部调机师

●诺尔康人工耳蜗术后整体康复效果如何?

诺尔康人工耳蜗植入项目植入者大多为大龄听障儿童,其平均训练5-6个月后,可取得显著效果。植入者的韵母、声母、单音节和双音节识别测试,林氏六音测试,IT-MAIS问卷评估结果较术前均显著提高,能够与老师、家长进行正常沟通与交流。

●大龄人工耳蜗植入者的康复方法有何特点?

大龄人工耳蜗植入者的康复训练以AVT个别化训练为主,每天半小时,辅以家庭指导。我中心主要采用情景教学与区角活动相结合的方式开展康复训练,让儿童在自然的交际情景中完成听力语言康复学习,寓教于乐,效果显著。

●您是否与植入者家长经常沟通儿童情况?

家长如何看待孩子的康复效果是孩子成功康复的关键。有的家长期望值较高,如果达不到目标,便很

失落,建议家长应建立正确合理的期望值。因此,我中心于每周五下午举办家长培训,解决家长在家庭康复中遇到的问题。

●项目实施过程中有何困难?

希望人工耳蜗公司能够提高产品的操作性及人机软件界面设计问题,同时国家相关部门能够建立并规范大龄人工耳蜗植入儿童的评估工具与方法,以便于基层开展工作。

听障儿童家长代表

●您的孩子听力损失情况如何?

我有两个孩子,先后被诊断为感音神经性耳聋,他们是幸运的,先后植入了诺尔康人工耳蜗,为生活带来了转变的可能。我的孩子13岁,3岁时发现耳聋,6岁开始配戴助听器并进行康复训练,但效果欠佳,孩子还是吐字不清。2014年,我们有幸成为国产诺尔康人工耳蜗项目的受助家庭,植入了诺尔康人工耳蜗,为生活带来了新的期待与希望。

●您是否了解相关人工耳蜗品牌的特性?什么原因让您选择了诺尔康人工耳蜗?

植入人工耳蜗前,我们了解了一些关于人工耳蜗的资料,我们相信国产的自有品牌,并且认为它更适合于中国人的汉语发音,我们愿意选择一款适合中国人的自有产品。

●您认为诺尔康人工耳蜗适合孩子吗?与植入前相比,孩子有什么变化和进步?

孩子经过开机后的适应,在半个月后就能够辨别声音,1个月后能够听懂较长的句子,远距离的交流也比以前更顺畅,孩子说话的语句比以前有所增长。在一次放学后,孩子看到我正在做饭,主动问我:“妈妈,累不累?”我感动的哭了,终于感受到了孩子的成长与康复成效。

●您是否参加过诺尔康人工耳蜗产品相关介绍培训?有什么收获?

人工耳蜗公司会定期举办产品培训与交流,对产品作详细介绍及相关售后维护等培训,我们非常需要这样的培训。

●您认为选择诺尔康人工耳蜗对您的经济支出是否有压力?

人工耳蜗是价格昂贵的助听辅具,对于我们来说压力是有的,但通过国人的开发与研制,国产人工耳蜗面世,为我们提供了更多的选择,使中低收入家庭看到了康复的希望。

●您对诺尔康人工耳蜗有什么意见和建议?

希望产品的外观能够更加小巧、美观,实现24小时售后服务。



海南省访谈现场

会,重获新“声”。但是,针对这些大龄听障儿童植入人工耳蜗后的听觉言语康复需要康复机构及家长们树立正确的期望值,进行坚持不懈的康复训练,才能达到预期的康复效果。

编辑部一行通过实地访谈陕西、海南两省国产诺尔康人工耳蜗项目的实施情况,客观、真实地反映了民族自有品牌——诺尔康人工耳蜗在基层康复机构及听障人群中的应用情况,同时也看到了大龄人工耳蜗植入儿童的可喜康复成果,他们的家庭、父母终于在黑暗中看到了希望与光明。国产诺尔康人工耳蜗项目的实施,为大龄听障孩子重获听力托起了一片天,走近他们之后,才越发觉得生命的不易与亲情的爱与感动。让我们用心去聆听这爱与责任的乐章,希望他们在未来的路上越走越好。

后记

随着国家、地方加大财政投入用于改善残疾人现状,很多大龄听障儿童也享有人工耳蜗免费植入机

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实习编辑 李晔

欢迎订阅《中国听力语言康复科学杂志》 2016年增刊(家长版)

经过广泛调研,为满足广大读者的需求,使杂志更具指导性与大众性,让更多听障儿童回到有声世界,杂志社于2016年8月出版发行了2016年增刊(家长版)。

增刊内容围绕家庭在听障儿童康复中的重要性为主题,对《“十三五”残疾人精准康复服务行动实施方案》进行了解读,并以家庭环境、家长角色、家庭教养方式、家长心理为线索,内容涵盖耳聋基因遗传咨询、深度解读人工耳蜗、听障儿童全面康复及相关康复新理念、康复环境的创设,以及成功康复听障儿童家长的心得体会分享。希望给予家长及基层康复教师切实可行的帮助与指导。欢迎广大基层康复教师及听障儿童家长订阅。单价16元/本(含邮资)。

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区角环境的创设与运用

■邢文婷

随着国家及地方人工耳蜗项目的不断推进,越来越多的人工耳蜗植入儿童需要得到安置与康复。海南省残联2015年开展了“助梦启航—关爱听障儿童”大型公益活动,帮助100名听力语言障碍残疾人免费植入国产诺尔康人工耳蜗。利用区角活动对人工耳蜗术后听障儿童进行听觉言语康复训练效果显著,本文以作者工作实践出发,探讨了人工耳蜗植入儿童术后康复区角环境的创设与运用。

1 区角活动在人工耳蜗植入后儿童康复训练中的重要性

区角活动需要教师从多方面考虑,从幼儿的实际生活经验出发,在与环境的相互作用中,让幼儿通过互相交往、合作、共同商讨的过程中学习和积累、修正和表达自己的经验和感受,在获得游戏般体验的同时,获得认知、情感、社会性、语言及动作技能等方面的发展。

2 区角活动的局限性

在幼教课程改革的大背景下,区角活动无疑是一种以儿童发展为指导的学习活动,它对推动幼儿的自主学习和经验提升具有重要价值。但是,在区角创设和运用过程中,由于出现种种问题导致区角活动的价值难以体现,具体表现在以下方面。

●投放材料数量少、种类少、长期没有变化。教师投放材料数量少、种类单一、有些材料投放盲目,缺乏

层次性且没有及时更新材料,材料的选择不符合幼儿的能力发展。

●幼儿参与率低,设置形式化。教师没有根据幼儿的个性特点投放动手操作和动脑思考的材料,幼儿的参与率低,导致区角环境形如虚设。

●区角设置没有从幼儿的兴趣和需要出发。教师对区角活动的目标、形式、指导等理解认识笼统,对不同年龄幼儿的生理、心理特点与发展水平等把握不够,难以满足幼儿的发展需求,无法体现区角的价值。

●教师盲目跟从,没有突出教学目标。在区角活动中,教师常常心中没数,人云亦云,无法实现区角活动的教育功能。

3 怎样创设区角活动

根据目前区角活动存在的问题,本中心结合在训儿童年龄与心理特点,利用情景教室区角环境开展多种教学形式,使区角活动的价值发挥到最大化,更深层次地挖掘区角的功能。

第一,在学前教育方面,区角活动主要体现幼儿之间的交往与探索。每个孩子在学习性区角环境中能按照自己的意愿和需求进行活动,在自由、宽松的心理环境下幼儿的个性得到了满足,学习动力得到了激发,在活动中满足了自身的心理需求,锻炼了各种能力,如动手操作能力、语言交往能力、社会性培养等。

例如,集体课教师利用麦当劳情境教室开展区角活动。幼儿运用模仿和想象,通过角色扮演创造性地



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反映了现实生活,在区角活动中,教师分别设置了等待区、点餐区和用餐区等,在各个领域里,教师分别为幼儿准备了可乐杯、冰激凌杯、薯条、牛排、汉堡包等材料,这些材料的投放,不仅有利于发展幼儿的动手能力,更有利于幼儿想象力的发展。在真实的情境中,幼儿的交往与探索能力得到了很好地发展(见图1)。



图1 麦当劳情景教室中,孩子们在排队点餐

第二,在个别化教学方面,区角活动能很好地帮助个别化教师与幼儿之间的互动。课堂教学不能局限于教室,在区角环境中以实际操作培养孩子的各种能力,解决了教师授课模式单一化的问题。

例如,个别化教师利用娃娃家和麦当劳情景教室给幼儿上个训课。根据幼儿需求与认知发展特点,为幼儿创设贴近生活、有学习价值与意义背景的区域情境,激发幼儿的兴趣,丰富幼儿的个别化经验,促进幼儿个别化学习能力的发展。让幼儿在情境中学习、游戏、锻炼、生活。开放的区角环境让孩子把已有的知识经验与理解的知识运用起来,让幼儿想说、敢说、喜欢说、有机会说(见图2)。

第三,在家庭指导方面,针对性地对个别幼儿家庭进行指导。在家庭指导中,教师希望家长能把课堂中所学的技巧运用于日常生活中,可是,往往课堂上老师怎样示范,回家后家长也将课堂模式死板地用于日常生活中,结果导致幼儿没有学习兴趣,严重挫败了幼儿的主动性与积极性。针对这个问题,我们结合



图2 利用情景教学进行个别化训练

区角环境中的运用,在自然情境中教学,并将老师指导的技巧运用于情景康复中。

例如,个别化教师利用麦当劳情境教室给幼儿家庭上AV课。教师通过情景教学中示范、家长参与,让家长理解老师在课堂中教授的技能技巧,在日常生活中如何运用,使孩子更有针对性地学习。更重要的是,教师借助区角环境把教学目标展现出来,由于区角环境的真实性,使教学目标更有目的性和操作性,解决了教师不再盲目跟从,无法着手教学目标的问题(见图3)。



图3 利用情景教学开展家长指导

第四,家长培训方面,教师利用情境教室给家长示范。在情景中自然宽松的培训氛围使家长能通俗易懂地接受康复技巧。在家长培训中,采用理论和实践相结合的方式,集中理论培训后,家长根据理论培训的知识在情境教室分组实践,教师根据家长存在的问题给予指导。由于家长、教师和幼儿的充分参与,使得区角环境的创设不再形式化,它的功能和价值更丰富和多样化(见图4)。



图4 教师在情景教室中给家长示范指导

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陕西省45名大龄听障儿童 植入诺尔康人工耳蜗后1年康复效果分析

■王晓平 蔡砾洋 宋■ 任利敏

随着人工耳蜗技术的发展与成熟,人工耳蜗成为重度/极重度感音神经性耳聋患者重建听觉系统的唯一途径。近年来,国家政策对残疾人的帮扶力度越来越大,人工耳蜗的植入年龄逐步拓宽,大龄听障儿童在错过最佳植入年龄的情况下也能顺利植入人工耳蜗。本文通过对陕西省45名植入诺尔康人工耳蜗的大龄听障儿童康复1年后听觉语言能力、听觉行为分级标准(categories of auditory performance, CAP)和言语可懂度分级标准(speech intelligibility rating, SIR)的评估结果进行分析对比,为其康复训练提供参考。

1 研究对象

选择2014年陕西省民生工程项目45名诺尔康人工耳蜗植入听障儿童,其中男27例,女18例;年龄9~21岁,平均年龄14岁。有助听器配戴史41例,最短配戴时间6个月,最长配戴时间15年。

2 研究方法

2.1 评估材料

采用《听障儿童听觉语言能力评估标准及方法》、CAP及SIR进行评估。

2.1.1 《听障儿童听觉语言能力评估标准及方法》包含听觉能力和语言能力评估两部分。听觉能力评估选取声母识别、韵母识别、声调识别、单音节识别、双音节词识别和短句识别6项测试。语言能力评估选取语音清晰度、语法能力、理解能力、表达能力和交往能力5项测试。测试时在安静的房间里,被试坐在测试参考位置,评估人员为专业康复教师。

根据听障儿童实际言语能力选用听说复述法或听话识图法进行测试。韵母识别、声母识别测试时依次以组为单位出示图片,同时发出词表中的目标音,被试从3幅图片中指出所听到的测试词,25组图片循环出示1次即完成测试。单音节声调识别测试时出示4张有声调符号的图片,测试者依据此词表发声,分别读出5组测试音,被试根据发声词分别选出图片。单音节识别、双音节识别、短句识别测试时以每组为单位出示图片分别随机读两张图片让被试识别,依次测试,循环两次。

2.1.2 CAP是全球通用的评估听觉感知能力的



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方法,主要反映受试者日常生活中的听力表现,包括对自然环境声、言语声的感知及识别的等级评价,将听觉能力分为1~8级,由受试者生活环境中的密切接触者根据患者对于所有外界声音(包括环境声音和言语声)的行为反应程度对其进行直观分级评价。SIR用于评估受试者的言语产生能力,根据受试者自发言语的受众理解程度将患者言语可懂度分为1~5级,同样由患者生活环境中的密切接触者进行直观分级评价。

2.2 统计方法

使用SPSS 20.0软件进行统计分析,计量资料使用(平均值±标准差)表示, $P<0.05$ 表明差异有统计学意义。

3 结果

3.1 大龄听障儿童植入诺尔康人工耳蜗开机1个月内和康复1年后的CAP和SIR的值有明显提高,差异有统计学意义($P<0.05$),见表1。

3.2 随着康复时间的增长,大龄听障儿童听觉语言能力评估成绩总体呈向上发展趋势,平均提高幅度很大,见表1。

表1 CAP、SIR以及听觉语言能力1个月内和1年后的比较($\bar{x}\pm s$)

评估内容	时间	均值	<i>P</i>	<i>t</i>
CAP	1个月内	0.78±0.64	0.000*	-48.103
	1年后	4.47±0.73		
SIR	1个月内	1.67±0.83	0.000*	-8.482
	1年后	2.40±0.92		
听觉能力	1个月内	0.23±0.25	0.000*	-18.267
	1年后	0.72±0.15		
语言能力	1个月内	1.67±0.92	0.000*	-13.338
	1年后	2.81±0.83		

注:* $P<0.05$

4 讨论

大龄听障儿童植入诺尔康人工耳蜗后听觉语言能力、CAP和SIR受开机后康复训练时间的影响显著。听觉语言能力评估结果显示,康复时间是影响听障儿童康复效果的重要因素。本研究发现,大龄听障儿童开机1个月和1年的听觉言语能力存在显著性差异($P<0.05$)。因此,对于大龄听障儿童而言,开机后1年仍然是康复训练的关键期。随着康复时间的延长,其听觉适应能力和言语技巧不断进步,听觉言

语能力也不断提高。被试CAP和SIR都有显著提高($P<0.05$)。但是CAP能达到6级的寥寥无几,SIR也没有能达到5级的,虽然听觉言语能力有所提高,但在分级标准中都在偏低的位置。这说明大龄听障儿童植入人工耳蜗康复1年后,还不能完全依赖听觉能力达到生活交流的需求,在遇到复杂的语句时会听不懂,仍然需要借助放慢语速、突出关键词、停顿、分解语句等方式帮助其理解。同样,大龄听障儿童的言语也不能被太多没有听过被试说话的人听懂,在康复1年的这个阶段,他们还在语音、语调、构音、语法等方面存在问题,没有完全改变自己长期固有的语言思维模式和发音模式,仍然需要继续康复。

大龄听障儿童家长要本着听障儿童听力语言康复的“三早”原则,更好的克服和减轻听障带来的不良后果。人的言语获得1~3岁最为旺盛,6岁以前为获得最佳时期,7~12岁大脑的可塑性明显减弱,12岁以后就逐渐接近成人。本文针对大龄听障儿童术后康复1年的效果来看,术前是否配戴助听器及康复时间的长短是影响患者术后康复效果的关键因素。对于大龄听障儿童不仅要关注他的听觉语言能力发展,更重要的是关注其个体的社会参与能力、情绪情感交流能力及自信心的建立等。

作为大龄植入诺尔康人工耳蜗听障儿童家长,孩子本身已经错过了最佳的康复期,如果对子女的期望值过高,在期望中带着极大地盲目性,忽视了孩子自身的听觉语言能力,反而会让孩子丧失康复信心。同时,家长期望值过高,也会产生急躁情绪,在家庭康复训练中缺乏理智和耐心。反之,如果家长的期望值过低,便会影响孩子的自信心,从而影晌应有的康复效果。因此,对于植入诺尔康人工耳蜗的大龄听障儿童家长而言,需要坚持做到以下几点:第一,在康复之路上建立合理的期望值,避免和其他植入者横向比较;第二,重视孩子的本身的特点,擅于发现孩子的特长;第三,学会调控自我情绪,促进家庭和谐;第四,坚持康复,定期调试助听设备。

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人工耳蜗非实时研究平台开发与验证

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摘要: 人工耳蜗帮助超过 40 万人恢复了部分听力, 但其性能仍有较大提升空间, 且电听觉机理仍有待进一步揭示。针对诺尔康人工耳蜗系统开发了非实时研究平台。为了验证平台的有效性, 对成年植入者开展了电听觉基础心理物理实验(位置音高和包络音高)和噪声中的言语接受阈测量实验。心理物理结果显示, 被试者可以按照电极位置从蜗尖到蜗底或按照幅度调制频率从 50~200 Hz, 产生音高上升的感觉。言语测试显示, 基于该平台实现的策略, 能提供与临床处理器相当水平的噪声中言语接受阈。该平台可以帮助研究者快速开展电听觉心理物理和信号处理策略方面的研究。

关键词: 人工耳蜗; 电听觉; 音高; 言语接受阈

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Development and validation of an offline research interface for cochlear implants

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Abstract: Cochlear Implants (CIs) have been used to restore hearing for more than 400,000 people. However, the performance of CIs is still limited comparing with the normal hearing and the underlying mechanisms of electric hearing are not fully revealed. An offline research interface of Nurotron CI system is introduced in this paper. Two versions of the interface were developed in the past five years. To validate the interface, basic psychophysical experiments (place-pitch and envelope-pitch ranking) and speech recognition thresholds test were performed on totally 13 adult Nurotron CI users (4 for place-pitch, 7 for envelope-pitch, and 2 for speech test). The basic psychophysical results show that pitch could be ranked from low to high according to tonotopic place (from apex to base) and amplitude modulation rate (from 50 to 200 Hz), and the data conform to the data in other literatures. The speech test results show that the experimental strategy, which is implemented through the interface, derives comparable speech reception thresholds in noise to the subjects' clinical processors. The research interface is crucial for CI researchers to perform electric hearing psychophysical study and CI signal processing study in China.

Key words: cochlear implant; electric hearing; pitch; speech reception threshold

0 引言

人工耳蜗(Cochlear Implant, CI)通过植入耳蜗内的电极直接刺激听神经来帮助重度以上听力损失者恢复部分听觉能力。CI 作为目前最成功的神经假

体, 全球已经有超过 40 万植入者。在上世纪 90 年代初以后, 由于信号处理策略等方面的改进, 大多数植入者, 尤其是在幼年植入的先天性耳聋者, 能够获得一定的开放式言语交流能力, 进而融入正常的社会活动中。

虽然 CI 已经取得了巨大的成功, 但是 CI 植入者的声音感知效果与正常听力者仍有较大差距。即便在安静环境下的一对一交谈中, 较快的语速、吐字发音不准确、小声说话或耳语等都会对植入者的言语理解产生障碍。CI 植入者对于音高的分辨(影响到音乐旋律识别、声调识别)、音色和环境声的识别、声源方向的辨别都明显弱于正常听力者。还有

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一个经常困扰他们的问题是，噪声环境下的言语识别能力较差。这些都说明在电听觉技术方面还有许多工作需要做。

CI 除了是一种有效的听觉辅助设备，它也是最成功的脑机接口^[1]，为研究听觉机理提供了全新的平台^[2-12]。在常规的声刺激听觉研究中，声信号在耳蜗中是从蜗底向蜗尖传播的，CI 电刺激模式则完全不同。时间信息和位置信息在 CI 电刺激中可以实现独立编码^[3]。通过 CI 可以明确地对基底膜上不同位置附近的听神经细胞群产生刺激，且可以人为精确控制每个电极位置上的电信号时域形式。图 1 展示了现代 CI 电脉冲序列的基本刺激形式，其中每根竖线代表一个电脉冲。对于单个脉冲，幅度越大，产生的有效电流扩展可能越广，进而可能刺激到更多的听神经细胞。对于电脉冲串，以音高感知为例进行分析，包括位置音高、速率音高和包络音高。位置音高是指，刺激不同的位置产生不同的音高感知，通常音高从蜗底向蜗尖逐渐降低。速率音高是指，单个电极位置上，更高的刺激速率可能产生更高的音高感知。包络音高是指，单个电极位置上脉冲幅度的时域包络的波动越快可能产生更高的音高感知。其中，速率音高和包络音高被认为是时域音高。现代 CI 中，位置音高和时域音高都起着作用。位置音高的音高跨度更大，时域音高的跨度较小。

图 1 中每个抽象电脉冲的最常见的实际波形形式是正负双相电流脉冲，如图 2 所示。以上提到的

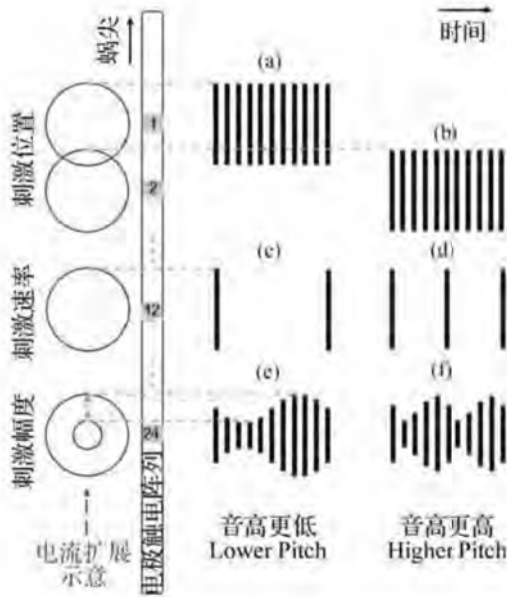


图 1 人工耳蜗电脉冲序列的基本刺激形式 (a)-(f) 脉冲序列的横坐标是时间，纵坐标是电流。
Fig.1 Basic patterns of the electric pulse trains in cochlear implants. The abscissa and ordinate of the pulse train in each of (a)-(f) is time and current respectively.

这些电刺激参数的变化与感知，都已经得到了很多的研究，例如文献[2]和[7]。但是仍有很多未知的领域有待探索。

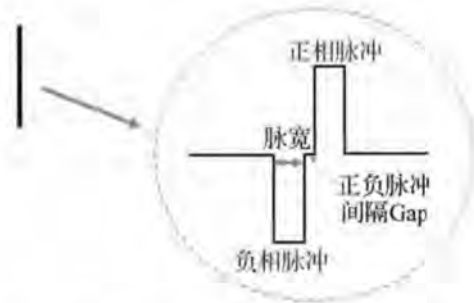


图 2 人工耳蜗采用的最典型的脉冲波形形式：双相电流脉冲
Fig.2 A biphasic electric current pulse: the typical waveform of the electric pulses in cochlear implant.

综上，CI 声音感知性能亟待提升，电听觉机理仍有大量可探索领域，另外还考虑到中国语言与西方语言的差异，有必要在中国开展更多基础电刺激听觉研究。本研究开发了一套基于国产诺尔康 CI 系统的非实时研究平台。利用这个平台，可以对新的信号处理算法进行快速的实验验证，也可以高效地开展电听觉心理物理实验研究。

1 植入体基本参数和性能

根据研究需要，我们选择了国产诺尔康人工耳蜗系统作为平台连接对象。主要原因是国产人工耳蜗公司对我们的技术开放程度更高，且诺尔康系统已经有了较多植入者(截止 2015 年 7 月已有超过 2000 名)。诺尔康 CS10-A 型植入体有一个板状铂参考电极、一个环状铂参考电极和 24 个(蜗内)电极触点。植入体中的刺激芯片包含 4 个独立电流源，能够让两个电极同时刺激以构建虚拟通道，也可以实现更为复杂的电脉冲波形形式。单通道刺激速率上限为 20 kpps(pulse-per-second, 每秒脉冲数)。刺激电流 I 的范围是 0~1904 μ A，按照公式(1)进行 256 级编码(用 Y 表示，称为电流单位 CU)。根据最早 60 例临床成年植入者的测试数据(包括客观阻抗测量、主观阈值 T 和舒适阈测量 C 、主观言语评估)，该系统显示出了与市场其他产品相当的性能^[4]。这说明该系统工作正常，可以参考基于其他产品系统的已有成果进一步开展研究工作。

$$I = \begin{cases} 2Y, & 0 \leq Y < 64 \\ 4(Y-64)+128, & 64 \leq Y < 128 \\ 8(Y-128)+384, & 128 \leq Y < 192 \\ 16(Y-192)+896, & 192 \leq Y < 255 \end{cases} \quad (1)$$

2 非实时研究平台开发

非实时研究平台的框图如图 3 所示。通过计算机将某个有限长度的声音进行处理,并编码为电极放电参数数据,然后将这些数据通过调试盒发送到实验用言语处理器,最后由实验用言语处理器将数据通过射频通信发送到植入体中,由植入体生成指定的电流脉冲刺激。在临床使用的言语处理器中,DSP 算法是用汇编语言编写的,并且可利用的计算和存储资源极其有限。相比而言,利用非实时研究平台的优点是,研究者可以快速验证采用高级编程语言(MATLAB、C 等)实现的信号处理算法的效果,不受编程语言、硬件资源的限制^[5]。在过去五年多的时间,我们开发了两个版本的非实时研究平台。

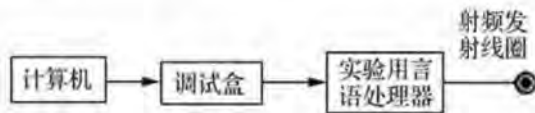


图 3 非实时研究平台框图

Fig.3 The diagram of this offline research interface

版本 1: 用于基础心理物理测试,可以实现对 1 个通道的电脉冲信号进行精确控制,也可以对 2 个通道进行同步脉冲刺激以实现虚拟通道。可以调节的电刺激参数包括:电极通道号、刺激模式(根据回收电流的参考电极的不同划分,包括双极模式 BP,单极模式 MP1、MP2 和 MP1+2。BP 和 MP 的示意图见文献[6]的图 1。MP 后面的数字,1 代表使用板状参考电极,2 代表使用环状参考电极)、刺激速率(10 pps ~10 kpps)、双相脉冲的正负脉冲先后顺序、每个脉冲的电流幅度(0~255 个 CU)、脉冲宽度(0~512 μ s)、正负脉冲间隔(0~32 μ s)。

版本 2: 主要用于信号处理策略研究,也可以用于进行幅度调制(即时域包络)方面的基础心理物理测试。每个电极通道的相邻脉冲间刺激间隔固定为 960 μ s(对应刺激率为约 1042 pps),脉冲宽度为 25 μ s,正负脉冲间隔为 5 μ s,刺激模式固定为单极模式 MP1+2。每隔 960 μ s 从植入者的全部可用的 m 个通道(至多为 24 个)中按照一定规则选择 n 个通道(不多于 8 个)产生刺激,不同通道间以间隔刺激的模式避免通道间干扰。每 960 μ s 中的 n 个通道的数据被称为“一帧”数据。在不同帧中可以选择不同的 n 通道产生幅度在 0~255 CU 的双相脉冲。利用这些特性可以实现经典的 n -of- m 策略。例如,澳大利亚科利尔公司的高级混合编码(Advanced Com-

bination Encoder, ACE)策略和浙江诺尔康公司的高级峰值选取(Advanced Peak Selection, APS)策略都属于 n -of- m 策略。

通过对植入体测试板上电极的实际电流输出进行测量,验证了输出的电流脉冲参数符合预期。其中植入体测试板的作用是将某个合格植入体的电极信号人为引出,可以用示波器或数据采集卡观察每个电极的放电情况。

3 实验验证

进一步通过主观实验验证平台的有效性。3.1 和 3.2 节的基础心理物理实验,在之前已有文献对其过程进行了详细记载^[7-9],这里仅作与本文有关的简要介绍。3.3 节中为本研究中刚刚开展的策略评估工作,做了详细介绍。以下实验中的 CI 植入者在双侧耳均无可用残余听力。

3.1 基于版本 1 的基础电听觉心理物理实验

平利川等人^[7]对 4 位言语表达能力良好的成人语后聋植入者开展了位置音高排序实验,即让被试者比较相邻电极间的音高高低,通过测量音高灵敏度(d')的心理物理方法来进行度量。结果发现从蜗尖到蜗底,随着刺激位置的变化,4 位被试者均可获得从低到高的音高感知变化,但灵敏度的个体间差异较大(见文献[7]的图 1)。随后,平利川^[8]还对 6 位植入者开展了速率音高和虚拟通道音高的测量,初步发现,诺尔康系统能够提供一定的速率音高分辨和虚拟通道音高分辨,相比于位置音高,这两方面的灵敏度较弱。平利川^[8]提到测量时需要严格控制响度等因素的影响。

3.2 基于版本 2 的基础电听觉心理物理实验

采用版本 2 平台开展的第一组实验是,对 7 位植入者(s1~s7)进行包络音高排序测量。其中 s1、s5、s7 是“明星”植入者,即他们的言语交流能力明显高于平均水平。测量方法是,对每位被试者在蜗底、蜗中、蜗尖区域分别选择一个电极,在每个电极上让其比较两个正弦幅度调制信号的音高高低,其中两个正弦幅度调制信号的调制频率为 50、80、100、200 Hz 中的相邻配对。最后通过累积音高敏感度来表达结果,如图 4 所示。图中 r_1 、 r_2 、 r_3 分别代表蜗尖、蜗中、蜗底三个电极位置上各自得到的回归曲线的斜率。单位是 $10^{-2}/\text{Hz}$ 。注意:每条回归线的截距是实验时我们将 50 Hz 点与 10 Hz 点比较后得到的一个敏感度值,在此处不表达任何含义,读者只需关心斜率的差别。图 4 结果显示,“明

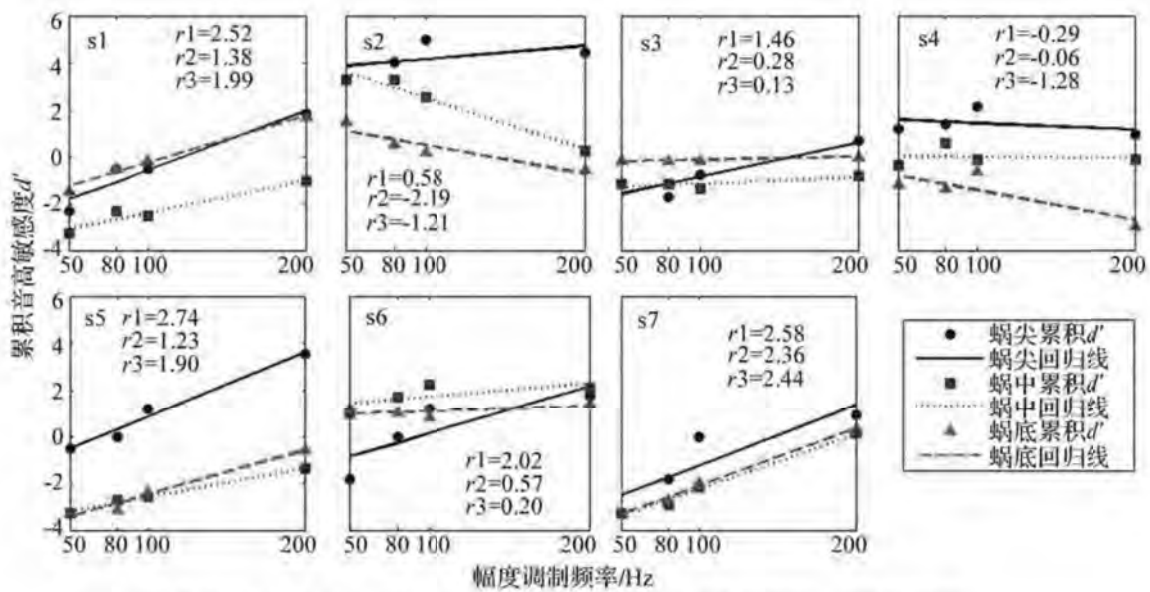


图4 七位被试者(s1-s7)的包络音高排序结果: 累积音高敏感度 d' 和相应的线性回归直线。

Fig 4 Envelope-pitch raking results for the seven cochlear implant subjects (s1-s7): cumulative pitch sensitivity measure d' and the corresponding linear regression line.

星”植入者可以在三个电极位置上都获得一致的包络音高排序能力,即调制频率越高对应的音高越高。另外,对于大部分植入者(除了s4)都可以在蜗尖位置获得一致的音高排序能力。更多细节可以参阅文献[9]的第三章。3.1和3.2的两个实验说明本研究平台可以用于开展人工耳蜗电听觉心理物理研究。

3.3 基于版本2的信号处理策略验证实验

信号处理: 诺尔康的默认临床策略 APS 策略,按照前述的 n -of- m 策略的方式工作,其中 $m \leq 24$,且通常 $n = 8, 7$ 或 6 。APS 中提取 m 个通道的时域包络的方法是,对声音信号(16 kHz 采样)进行分帧加窗(窗长 256 点,帧间重叠 50%)后计算 FFT,然后将幅度谱的低频段进行线性划分,对高频段进行非线性类似对数划分,总计划分 m 个通道,将每个通道内的频域能量作为当前帧该通道的时域包络采样点。本研究中通过时域的方式实现了时域包络提取,具体做法是按照与 APS 相同的方式进行频带划分得到 $m+1$ 个截止频率,设计 m 个 6 阶巴特沃斯带通滤波器对声音信号进行带通处理,然后再用全波整流加低通滤波器(250 Hz 截止频率)的方式提取每个通道的时域包络。在这里我们将这种时域实现的 APS 标记为 APS_t,以示区分(APS 的时域包络提取是在 FFT 后的频域完成的)。APS_t 和 APS 后续采用了相同的非线性压缩参数。APS_t 和 APS 采用的脉宽不同,前者是 25 μ s,后者是 50 μ s。被试者采用自己的言语处理器中的 APS,在隔音室内听扬声器(Yamaha HS50M + TASCAM US-144MKII)播放

的声音。APSt 用版本 2 平台实现,通过计算机直接发送数据。

目的: 初步评估基于版本 2 是否能实现一个性能与 APS 相当的策略。我们假设 APSt 和 APS 能够提供水平相当的言语可懂度。

被试者: 两位 CI 被试者均为语后聋女性成人植入者,安静环境下面对面都可以进行有效的言语交流,其他信息见表 1。另外,还招募了两位正常听力的年轻人(25 岁)作为正常听力组(编号为 NH1 和 NH2)。正常听力组的结果仅用于初步观察 CI 和正常听力者的差距。

表1 CI 植入者信息
Table 1 The information about the cochlea implant users

编号	年龄	致聋原因	植入侧	重度 聋年数	使用 CI 月数
C7	31	不明	左	4	15.5
C11	45	不明	右	10	8.5

(伴耳鸣)

3.3.1 材料和方法

言语材料为中文言语评估测试短句(Mandarin Speech Perception test, MSP^[10])和噪声下的普通话聆听听库(Mandarin Hearing In Noise Test, MHINT^[11])。MSP 包含 10 个句表,每个句表中有 10 句话,每句有 7 个字。MHINT 包含 12 个实验用句表和 2 个练习用句表,每个句表中有 20 句话,每句有 10 个字。本研究测量了两位被试者在采用 APS 和 APS_t 时,对噪声中的 MSP 句子和 MHINT 句子的 50% 言语接

受阈(Speech Reception Thresholds, SRTs)。对于正常听力组, 测量了相同的项目, 但测试材料无需经过策略处理。

其中对 MSP 采用了“5-talker babble”噪声, 对 MHINT 采用了“5-talker babble”和语谱噪声(Speech-Shaped Noise, SSN)。对每位被试者的 MSP 或 MHINT 测试, 5-talker babble 噪声的生成方法是, 从相应的库中随机选取一个句表, 从该句表中随机选出 5 句话的信号直接相加(注意: 此句表后续不再被使用)。因此对于每个策略(APS 和 APS_t)都会有先后有三组测试: MSP-babble、MHINT-babble 和 MHINT-SSN。每组测试采用的材料是随机从 MSP 中挑选 3 个句表(30 句话)或从 MHINT 中挑选 2 个句表(40 句话)。其中, 对于一位被试者来说每个句表不会被重复使用。

SRT 的测量方法是, 在每个策略的每组测试中采用一上一下自适应调整信噪比(Signal-to-Noise Ratio, SNR)的方法。初始 SNR 为 10 dB, 在第二个反转点前, 调整步长为 8 dB, 在第四个反转点前步长为 4 dB, 反转点之后为 2 dB, 直至当前组全部句子测试完毕。其中, 在每个试次中(即播放每个句子时), 听者可以要求至多再重听两次, 主试者在软件界面上勾选被试者复述对的字, 被试者复述出多于半数的字时, 软件判定为答题正确, 否则为答题错误。每组中最后 10 句话的 SNR 的算数平均值记为当前条件下的 SRT。正式实验开始前会对被试者进行训练和指导。对于每种材料, 先进行 APS 测试, 再进行 APS_t 测试。实验中, 信号响度被控制在舒适范围。

其他准备工作: 植入者到来前, 根据其临床程序的参数提前设定好参数文件, 并通过示波器或采集卡检查信号输出, 保证与预期相符合。言语测试前, 先对植入者在单个电极上的 T 值和 C 值进行测量。测量软件为基于版本 2 平台开发的专用软件。在 APS_t 实际言语测听训练开始时, 先将电流单位控制在 C/2 以下, 然后根据被试者的反应, 逐渐上升, 直至舒适。

3.3.2 结果和分析

SRT 如图 5 所示。如两位植入者的 SRT 在 4.6~17.8 dB 之间, 远高于正常听力对照组的 -8.6~-2.2 dB。说明两位植入者在抗噪声干扰方面的能力远弱于正常听力者。比较 APS 和 APS_t 发现, 在多数情况下, 两位植入者在使用 APS_t 时获得了更好(更低)的 SRT 值。

注意, 这并不能直接证明 APS_t 的时域包络提

取方式能比 APS 的频域包络提取方式提供更好的言语识别能力。因为在实验中, 在每组材料条件下都是先做 APS 再做 APS_t, 这可能导致后做 APS_t 时被试者已经得到了更充分的训练, 更熟悉声音材料的特点。另外, APS 是在声场中进行测量, 而 APS_t 是从计算机通过版本 2 研究平台直接发送数据到植入体, 前者听到的声音经过了电声转换、房间反射、声电转换等环节可能带来干扰, 后者不存在这些问题。

但是, 这个结果已经说明 APS_t 提供了与植入者日常言语识别效果相当的言语可懂度, 进而说明利用版本 2 研究平台可以进行 CI 信号处理策略研究。

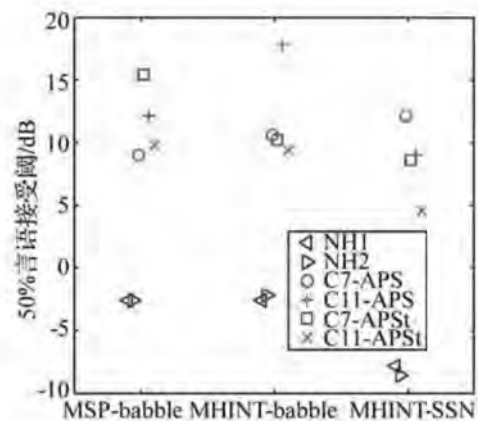


图 5 噪声中的 50% 言语接受阈
Fig.5 50% speech reception thresholds in noise

4 总结和展望

人工耳蜗的性能仍有很大提升空间, 然而开展这方面研究对公司的依赖较大。由于一些原因, 垄断此行业的三家国外公司不向中国大陆的研究者提供研究平台。受此限制, 目前国内的人工耳蜗研究主要局限于听力学临床评估与康复、基于声码器仿真模型的信号处理策略研究。由国内研究机构独立完成的, 基础电听觉心理物理研究和直接招募人工耳蜗植入者作为被试者进行全新信号处理策略开发的研究非常少。为了进一步促进和推动我们在人工耳蜗电听觉方面的研究, 在过去五年多里, 我们针对国产诺尔康人工耳蜗开发了一套非实时研究平台。本文对此平台的两个版本进行了介绍, 并通过主观实验证明了该平台可以用于电听觉心理物理实验研究和信号处理策略研究。

未来需要做的工作是: (1) 利用该平台研究信号处理算法(包括编码策略和预处理方面)的改进, 找到提升人工耳蜗电听觉性能的方法; (2) 利用该

平台开展更多、更深入的心理物理研究,探究电听觉感音机理;(3)进一步完善和扩展平台功能,让中国的研究者能更方便快速地开展相关研究工作。**致谢:** 特别感谢所有参与实验的被试者。感谢孙晋和张晓薇协助完成实验。感谢原猛和王生在平台开发中提供的帮助。本研究得到了诺尔康公司的技术支持,但未受到该公司的直接经费资助。

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· 论著 ·

先天性聋人工耳蜗植入儿童皮层听觉诱发电位的研究

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【摘要】 目的 通过对先天性聋人工耳蜗植入儿童皮层听觉诱发电位(cortical auditory evoked potential, CAEP)的研究,探讨中枢听觉发育与人工耳蜗植入年龄之间的关系。方法 5岁前植入人工耳蜗的先天性聋患儿110例,测试时年龄12~80个月,其人工耳蜗使用时间从刚开机到48个月。声场下以65 dB SPL的/m/、/l/、/g/为测试声,进行CAEP测试,记录其P1、N1及P2波。分析各波的引出率、人工耳蜗植入年龄以及使用时间与P1波潜伏期的关系。结果 P1波的总体引出率为66.4%,N1波为15.5%,P2波为12.7%;P1波的引出率明显高于N1波($\chi^2=228.542, P=0.00$)和P2波($\chi^2=257.438, P=0.00$),差异具有统计学意义。/m/、/l/、/g/等三种刺激声的P1波引出率分别为64.1%、66.9%和68.3%,差异无统计学意义($\chi^2=0.589, P=0.75$);三种刺激声之间P1的潜伏期($P=0.22$)和幅度($P=0.09$),差异均无统计学意义。植入年龄 ≤ 42 月龄组P1潜伏期进入与年龄相当的正常值范围的百分比(95.3%)明显高于 > 42 月龄组(66.7%),差异具有统计学意义($P=0.02$)。在42月龄前植入人工耳蜗的儿童中,耳蜗使用时间分别为1年、2年、3年和4年的各组之间,在进入年龄相当的正常P1潜伏期范围的百分比上,差异无统计学意义($P=1.00$)。结论 先天性聋患儿42月龄前植入人工耳蜗,其听觉中枢更有可能实现正常发育,而且一经植入使用,即可迅速发育达到正常听力的水平。

【关键词】 听觉丧失; 诱发电位, 听觉; 耳蜗植入术; 儿童

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Cortical auditory evoked potentials in congenital hearing impaired children with cochlear implants

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【Abstract】 Objective By investigating the auditory cortical evoked potential in congenital hearing impaired children with cochlear implants, the association between central auditory development and the age of implantation was studied. **Methods** P1-N1-P2 were recorded in 110 profound hearing impaired children, aged from 12 to 80 months old and being implanted with cochlear implants before the age of 5 years. Their implant using time ranged from just at the switch-on to 48 months. The stimuli were /m/, /l/, /g/, presented at 65 dB SPL in sound field. The presence rate of each wave was obtained and the relationship between P1 latency and implant age, the time of speech processor switch-on were analyzed. **Results** The

presence rate of P1, N1 and P2 was 66.4%, 15.5% and 12.7%, respectively. The presence of P1 was significantly higher than that of N1 ($\chi^2 = 228.542, P = 0.00$) and P2 ($\chi^2 = 257.438, P = 0.00$). There was no significant difference of P1 presence rate elicited by /m/, /l/ and /g/ (64.1%, 66.9% and 68.3%, $\chi^2 = 0.589, P = 0.75$). There existed no significant difference either among P1 latency ($P = 0.22$) or amplitude ($P = 0.09$) elicited by /m/, /l/ and /g/. There was significant difference between the implant age before and after 42-month-old regarding the proportion that entered the age-appropriate normal P1 latency range ($P = 0.02$). No significant difference was found among groups of implant using time of 1, 2, 3 and 4 years in aspect of the proportion that entered the age-appropriate normal P1 latency range ($P = 1.00$).

Conclusions Compared with implanted after the age of 42-month-old children with prelingual hearing impairment younger than 5 years old, the ones implanted before 42-month-old have more chance for normal development for central auditory system. Once implanted before 42-month-old, the cortical auditory system restored its normal development as early as 1 year after implantation.

【Key words】 Hearing Loss; Evoked potentials, auditory; Cochlear implantation; Child

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随着新生儿听力筛查的普遍开展,越来越多的重度或极重度聋患儿需要及时确诊并得到准确的治疗和干预,而各种听觉辅助设备如助听器、人工耳蜗、振动声桥、骨锚式助听器(bone anchored hearing aid, BAHA)等的不断出现与改进,使得听觉言语康复效果的评估越来越重要。近年来应用于儿童的听觉言语评估方法主要有儿童言语测听和问卷法,如听觉整合量表(meaningful auditory integration scale, MAIS)等^[1]。众所周知,儿童言语测听的最大问题是其只适用于主动配合的、年龄较大的受试儿童,不适用于低龄儿童。此外,受试儿童的认知水平、词汇量、方言和语言等因素都会影响测试结果的准确性。问卷法需要检查者具备一定的技巧,即使这样也难以避免检查者之间的主观因素带来的差异。因此在儿童,特别是婴幼儿迫切需要建立一种无需受试者配合的客观测试方法,以满足日益增长的听觉康复效果评估的需要。

皮层听觉诱发电位(cortical auditory evoked potential, CAEP)是指大脑在对声音信号进行感觉、认知、记忆过程中产生的电位,其潜伏期为 50 ~ 500 ms。CAEP 分为外源性成分和内源性成分, P1-N1-P2 属于 CAEP 的外源性成分,它与听觉识别和感知密切相关^[2]。儿童 CAEP 的 P1 波潜伏期随着年龄的增长逐渐缩短,直到 20 岁才达到成人水平^[3]。因此,CAEP 有望成为评估听觉中枢重塑和发育水平的重要工具^[3,5]。

本研究通过采集 110 例手术年龄在 5 岁以前的人工耳蜗植入先天性聋患儿 CAEP 的 P1-N1-P2 成分,分析其引出率和潜伏期等特点,探讨人工耳蜗植入儿童中枢听觉发育与植入年龄之间的关系。

资料与方法

一、研究对象

研究对象为 2011 年 5 月至 2012 年 12 月在首都医科大学附属北京同仁医院接受人工耳蜗植入手术及随访调试的 217 例患儿。排除标准为:(1)植入时年龄大于 5 岁者或者人工耳蜗使用时间超过 4 年(因为之前为本单位开展人工耳蜗工作初期,存在诊断流程不完善以及数据录入不完整的情况);(2)颞骨 CT 和内耳 MRI 显示内耳严重畸形,如 Michel 畸形者;(3)内耳 MRI 显示蜗神经发育不全或细小者;(4)头部 CT 或者 MRI 显示有中枢发育异常者;(5)术前听力学资料显示耳蜗功能存在者,如畸变产物耳声发射或耳蜗微音电位能够引出而 ABR 严重异常者;(6)因耳蜗畸形、骨化或其他原因导致植入电极数量不满意者。

最终入选患儿 110 例,其中男性 66 例,女性 44 例;测试时年龄 12 ~ 80 个月,中位年龄 46 个月;手术时年龄 6 ~ 59 个月,中位年龄 32 个月;人工耳蜗开机时间,最短为刚开机,最长为 46 个月,中位时间为 12 个月。受试患儿均为先天性聋,术前未使用过助听器;绝大多数都在进行听觉言语康复训练,每天至少 1 h。人工耳蜗植入装置包括澳大利亚 Neucleus 40 例,奥地利 Medel 36 例,美国 Advanced Bionics 16 例,国产诺尔康 18 例。

二、测试方法

1. 仪器设备及测试环境:CAEP 的记录采用 Hearlab 测试系统(Frye Electronics, 澳大利亚),测试地点为背景噪声小于 30 dB(A)的隔声室,扬声器在受试儿两侧相距 1 m 处,高度大致与双耳平齐。

2. 刺激声信号的录制与校准:应用系统自带的辅助皮层测试模式(aided cortical assessment, ACA)进行测试,刺激声为澳大利亚 NAL (National Acoustics Laboratory of Australia) 实验室所录制的 /m/、/t/ 和 /g/, 其主要频率分别为 200 ~ 500 Hz、800 ~ 1 600 Hz 和 2 000 ~ 8 000 Hz, 持续时间分别为 30 ms、30 ms 和 20 ms, 给声强度均为 65 dB SPL (受试患儿耳蜗麦克风处的声强)。

3. 测试步骤:记录电极置于颅顶,参考电极置于非术耳乳突侧,地极置于鼻根部,电极阻抗低于 3 kΩ。受试儿童佩戴好电极后,通过观看无声动画片来保持清醒、安静状态。CAEP 记录的开窗时间为 700 ms, 包括刺激声前 100 ms 和刺激声后 600 ms, 重复周期为 1 125 ms, 叠加次数 2 次/s, 伪迹拒绝范围为 -150 ~ +150 μV。刺激声强度为 65 dB SPL, 记录 P1、N1 及 P2 波, 每个波形重复记录两次加以确认。

受试儿童正常配戴人工耳蜗体外装置, 打开言语处理器, 并使之处于日常使用程序。受试儿童的开机或调试在首都医科大学附属同仁医院或者北京通州区人工耳蜗康复训练中心, 由两名听力师配合完成, 其中一名边观察受试儿童状态边调试言语处理器程序, 另一名负责控制受试儿童状态。所有受试患儿在 CAEP 测试前均进行了听觉评估, 如助听听阈、听觉发育量表等测试, 以确保所使用程序和设置处于最佳状态。

三、统计学处理

使用 SPSS 17.0 统计学软件进行数据处理和分析。应用卡方检验分析不同刺激声 /m/、/t/、/g/ 之间的 P1、N1、P2 各波引出率的差异; 秩和检验分析 /m/、/t/、/g/ 的 P1 潜伏期和幅度之间的差异; Fisher 检验 (卡方检验) 分析不同植入年龄组间以及不同使用时间组间进入正常 P1 潜伏期范围的百分比的差异。本研究中与儿童生理年龄相当的 P1 波潜伏期的正常范围参考 Sharma 等^[6] 的研究 (表 1)。P < 0.05 为差异具有统计学意义。

表 1 正常听力儿童不同生理年龄皮层听觉诱发电位 P1 波潜伏期的正常值范围^[6]

年龄 (月)	P1 波潜伏期 95% 置信区间 (ms)
12	120 ~ 180
24	100 ~ 170
36	85 ~ 155
48	75 ~ 145
60	70 ~ 140

结 果

一、P1、N1、P2 波的引出率

110 例受试儿童中 73 例可记录到 CAEP 反应 (图 1), 共有 37 例患儿未记录到任何 CAEP 反应, 分散于各个品牌的使用者中。在这 37 例未记录到反应者中, 人工耳蜗使用时间 < 6 个月者 13 例 (35.1%), 而人工耳蜗使用时间 < 6 个月者共 38 例, 未引出者占 34.2% (13/38)。

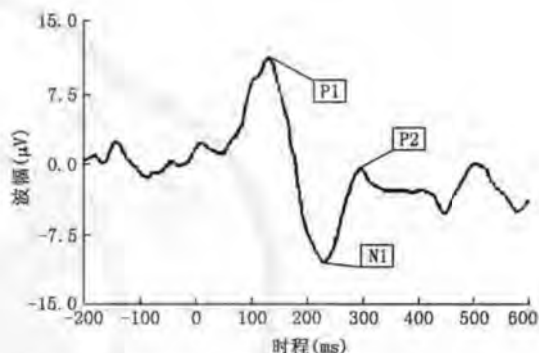


图 1 典型皮层听觉诱发电位 (CAEP) 波形 受试儿童 5 岁 (1 岁时植入人工耳蜗), 刺激声为 /m/, 强度为 65 dB SPL

不同刺激声 P1、N1、P2 波的引出率如图 2 所示。P1 波的总体引出率为 66.4% (283/426), N1 波为 15.5% (66/426), P2 波为 12.7% (54/426)。P1 波的引出率显著高于 N1 波 ($\chi^2 \approx 228.542, P = 0.00$) 和 P2 波 ($\chi^2 = 257.438, P = 0.00$), 差异具有统计学意义。三种刺激声 (/m/、/t/、/g/) 的 P1 波引出率分别为 64.1% (91/142)、66.9% (95/142) 和 68.3% (97/142), 三者之间差异无统计学意义 ($\chi^2 = 0.589, P = 0.75$)。

二、P1 波的潜伏期和幅值

三种刺激声 /m/、/t/、/g/ 对应的 P1 潜伏期 (均

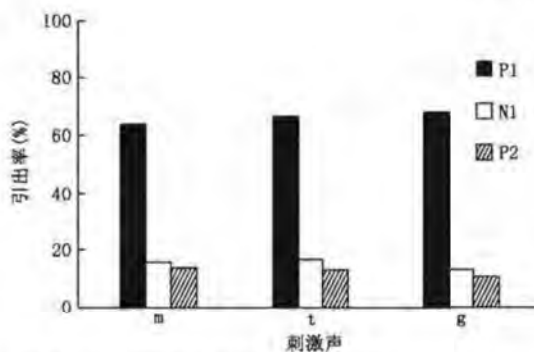


图 2 人工耳蜗植入患儿不同刺激声 /m/、/t/、/g/ 的 P1、N1、P2 波引出率

值±标准差,下同)分别为:(120±28)ms、(118±30)ms和(118±29)ms;P1波的幅值分别为(6.0±4.2) μ V、(5.7±4.1) μ V和(7.0±4.3) μ V。秩和检验结果显示,三种刺激声的P1潜伏期($P=0.22$)和幅值($P=0.09$)差异均无统计学意义。

三、人工耳蜗植入年龄对P1波潜伏期的影响

除去未引出反应病例后,共有73例患儿纳入数据分析,以植入年龄42个月(3.5岁)为界,分为≤42月龄组(64例)和>42月龄组(9例)。二者进入与生理年龄相当的P1波潜伏期正常值范围的百分比分别为95.3%(61/64)及66.7%(6/9),Fisher检验显示二者差异具有统计学意义($P=0.02$)。

四、人工耳蜗使用时间对P1波潜伏期的影响
在植入年龄≤42月龄组中,按人工耳蜗使用时间进一步分为1年组(开机12个月以内)30例、2年组(13~24个月)17例、3年组(25~36个月)11例和4年组(37~48个月)6例。各组进入与其生理年龄相当的P1波潜伏期正常值范围的百分比分别为93.3%(28/30)、94.1%(16/17)、100%(11/11)和100%(6/6),Fisher检验显示四者之间差异没有统计学意义($P=1.00$)。

讨 论

一、CAEP各波的引出率

P1-N1-P2属于CAEP的一种,在正常听力成人头皮正中记录到的P1-N1-P2波形由位于刺激后大约50ms的正波P1、80~100ms的负波N1以及180~200ms的正波P2组成^[2]。P1-N1-P2的产生部位目前还有争议,通常认为其来源于双侧颞叶上份的初级听觉皮层^[7]。正常听力儿童的P1-N1-P2波主要是由大的正波P1组成^[8],其潜伏期略短于成人的N1波,其后约180ms为一负波,早于成人的P2波。这些波的潜伏期随着年龄增长不断缩短,直至18、19岁时,才达到成人水平^[9,40]。正常听力婴儿的P1波潜伏期大约为300ms,随后随着年龄的增长迅速下降,到3岁时缩短为125ms,此后下降速率渐缓,15岁时达95ms,逐渐接近正常听力成人(60ms)^[6,10~11]。由于P1波的潜伏期与年龄发育之间有着显著的相关趋势,故已成为听觉中枢发育的指标之一^[4,12-14]。

本研究的受试者为110例在5岁以前植入人工耳蜗、使用时间4年以内的儿童,以刺激声/m/、/l/、/g/分别代表低、中、高频信号,记录和分析了其P1-N1-P2各波的引出率和潜伏期等指标。其中,P1

波的引出率显著高于N1和P2波,接近70%。以往相关研究的受试者均至少开机半年以上^[8],但没有关于P1-N1-P2引出率的报道。本研究发现,开机时间并不是波形引出与否的关键因素,因为本研究中开机时间少于半年者有38例,引出反应波形者25例(65.8%),未引出者13例(34.2%),而在所有未引出波形的37例中,还另有24例开机时间超过半年。我们认为波形引出率的影响因素包括术前、术中及术后三个方面。在成人人工耳蜗植入者,听觉剥夺时间是波形引出与否的重要因素^[15],但本研究所有受试者均于5岁前植入耳蜗,与成人相比,听觉剥夺时间相对较短,因此暂不考虑该因素的影响。术前因素还有耳蜗畸形以及其他尚未明确的病因等。术中因素有电极植入的数量和状态,尽管本研究入选病例绝大多数电极都顺利植入,但电极植入后的细微状态差别可能会影响波形的引出。术后因素包括耳蜗装置使用状态、是否进行了必要的康复训练等。此外,由于不同耳蜗中心听力师调试经验和方法的差异,言语处理器参数设置的不同也会影响波形的记录。为避免这个问题,本组患儿在CAEP测试前需进行听觉评估,尽可能使人工耳蜗装置处于最佳工作状态。

二、P1潜伏期及其影响因素

P1波潜伏期反映了听觉通路上从周围到中枢的突触传导时间的总和^[12]。P1波的潜伏期和形态因听觉剥夺的年限而不同。动物和人的研究都表明听觉中枢在发育早期,存在着一个关键时期。也就是说,如果发生听觉剥夺,在这一关键时期重新获得听觉刺激(如人工耳蜗植入)后,听觉中枢的发育不受影响。而如果听觉剥夺的持续时间过长,超过这一时期,则听觉中枢的发育将会延迟甚至停滞^[14]。先天性聋的猫、大鼠和小鼠等不同种类的动物实验均表明听觉系统确实存在这样一个关键时期,如果在这一时期植入人工耳蜗,会在听觉中枢功能方面产生很好的效果^[16-19]。人类听觉研究的结果也是如此,先天性聋患儿在关键时期内植入人工耳蜗,其P1波潜伏期会进入同龄正常听力儿童的范围,最终可获得较好的听力言语水平^[3,20,21]。而如果听觉剥夺时间过长,即便植入人工耳蜗,P1波的潜伏期仍会持续异常,最终植入效果也不理想。

为何先天性聋患儿在听觉剥夺达3~4年后植入人工耳蜗,其听觉中枢仍然获得了正常的发育?我们推测可能原因有二:第一,听觉中枢系统在听觉剥夺短于3~4年的情况下,即使没有声音信号的输

人,仍然能正常发育,因为此时该部位没有或只有很少的退行性变。Huttenlocher 和 Dabholkar^[22]关于正常听力者出生后听觉皮层突触密度的研究为这一假说提供了依据,突触形成开始于胎儿期,持续至 4 岁,4 岁以后听觉通路主要通过去除无用突触开始进一步精细发育,而且最重要的是突触形成是自身调节的,很大程度上并不依赖于听觉经验。因此推测儿童早期的听觉通路的发育在一定程度上并不依赖于声音的刺激。第二,与前一假说相反,在 3~4 岁前听觉刺激能够改变听觉通路的发育,但此时听觉中枢在这一时期具有很强的可塑性,以致声音信号的重新刺激能够克服听觉剥夺所造成的影响。这一假说首先在视觉的发育中得到证实, Maurer 等^[23]发现白内障儿童在手术后短短的 1 h 内视觉就有显著的提高,与同龄儿童相比,其视觉发育的速度明显加快。后来研究发现,听觉发育也存在着类似的现象。Sharma 等^[24]报道早期植入人工耳蜗的先天性聋患儿,其 P1 波的形态在植入后的 6~8 个月会发生迅速改变,其潜伏期迅速下降,这一下降速率显著高于正常听力对照组,最后可进入与生理年龄相当的正常范围。

由于听觉中枢的发育存在着关键时期,因此对于先天性聋儿童,就存在人工耳蜗最佳植入年龄的问题。通常的观点认为,植入年龄越早越好,但是关键的年龄节点是多少,目前还不十分明确。Sharma 等^[6]报道,人工耳蜗植入半年后,早植入组(早于 3.5 岁,即 42 月龄)进入年龄相当的 P1 波潜伏期正常范围的百分比显著高于晚植入组(晚于 7 岁,即 84 月龄)和中植入组(3.6~6.5 岁,即 43~78 月龄);中植入组(3.6~6.5 岁)P1 波潜伏期分布范围较广,有 2/3 的受试者 P1 波潜伏期落在正常范围之外,1/3 在正常范围之内。本研究比较了 5 岁以内先天性聋儿童 42 月龄前后植入的差异,结果显示在二者在进入年龄相当的 P1 波潜伏期正常范围的百分比存在差异($P=0.02$),42 月龄前植入人工耳蜗的儿童显著高于 42 月龄之后植入者。因此,先天性聋患儿在 42 月龄前植入人工耳蜗,听觉中枢有更大的几率达到正常发育水平。该结果与 Sharma 等^[6]的报道一致,进一步验证了植入人工耳蜗的最佳年龄确实是在 42 月龄以前。

为了探讨人工耳蜗使用时间对于先天性聋儿童听觉中枢的影响,本研究进一步将 42 月龄前植入的患儿按照使用时间分为 1 年组、2 年组、3 年组和 4 年组,各组进入与生理年龄相当的 P1 波潜伏期正

常值范围的百分比分别为 93.3%、94.1%、100% 和 100%,组间差异无统计学意义。这一结果并没有像预想的那样,随着使用时间的增加,进入年龄相当正常范围的百分比逐渐增加,而是在人工耳蜗开机后的第一年内,P1 潜伏期就快速缩短而进入正常范围,并且此后一直保持在正常范围内。该结果说明在 42 月龄前听觉中枢存在非常大的可塑性,先天性聋儿童 42 月龄前一经植入人工耳蜗重新获得声音刺激,听觉剥夺所带来的不利影响迅速被消除,听觉中枢的发育在开机 1 年后立即进入正常水平。

由于近年来家长对儿童听力保护意识的提高,绝大多数先天性聋儿童在 1~2 岁时植入人工耳蜗,3 岁以后植入的病例已经比较少见。本研究因病例数的限制,只能粗略地根据植入年龄以 42 月龄为界分为两组,然后再分别按使用时间分组。今后还需要增加样本量,通过 CAEP 进一步细化植入年龄与人工耳蜗植入效果之间的关系,以期获得更精确的语前聋儿童植入最佳年龄。

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编辑导读

本期设有重点号。《先天性聋人工耳蜗植入儿童皮层听觉诱发电位的研究》通过记录分析 110 例先天性聋人工耳蜗植入儿童皮层听觉诱发电位,证实先天性聋患儿 42 月龄前植入人工耳蜗,其听觉中枢更有可能实现正常发育,而且一经植入使用人工耳蜗,听觉中枢即可迅速发育达到正常听力的水平。《不同听力损失类型青年人言语声诱发听性脑干反应与最大言语识别率关系的探讨》发现不同听力损失类型青年人的言语声诱发听性脑干反应与最大言语识别率之间有着稳定、密切的相关关系,言语声诱发听性脑干反应有望成为辅助评估言语识别功能的电生理方法。《重复滚转试验对水平半规管管石症定位的必要性探讨》对 51 例水平半规管管石症患者进行了 2 个循环的滚转试验测试,总结分析后建议可疑水平半规管管石症的患者在进行滚转试验时至少行 2 个循环重复测试,并主要以第 2 个循环判定责任半规管。《慢性侵袭性真菌性鼻-鼻窦炎临床分析》回顾性分析了 7 例慢性侵袭性真菌性鼻-鼻窦炎患者的临床资料,认为该病多发生于免疫功能正常患者,单窦发病为主,上颌窦最多见,病程缓慢进展,多以周围组织结构受侵犯症状为主,曲霉菌多见;临床表现及早期鼻窦 CT 缺乏特异性,晚期鼻窦 CT 可见骨质破坏;治疗以手术联合足量足程抗真菌药物为主。《组织嗜酸粒细胞增多对于慢性鼻-鼻窦炎伴息肉复发的预测价值研究》分析了 248 例慢性鼻-鼻窦炎患者临床指标与鼻息肉复发的相关性,发现鼻息肉组织嗜酸粒细胞增多对于鼻息肉术后复发具有预测价值,组织嗜酸粒细胞百分比 > 27%,可作为预测鼻息肉术后复发的标准。《内镜下球囊扩张治疗儿童声门下狭窄》回顾性分析了 9 例儿童声门下狭窄患者的临床资料,发现对于程度较轻的声门下狭窄,内镜下球囊扩张是一种相对安全有效和微创的手术方法。《原发性甲状旁腺功能亢进症合并甲状腺癌病例分析》总结分析了 27 例原发性甲状旁腺功能亢进合并分化型甲状腺癌患者的诊疗结果及其影响因素,研究表明原发性甲状旁腺功能亢进症合并甲状腺癌患者一期手术可降低术后长期性甲状旁腺功能低下风险,甲状腺癌患者术前应尽可能检查血钙和甲状旁腺激素。继续教育园地《咽部手术治疗阻塞性睡眠呼吸暂停低通气综合征疗效的预测》对体检类(BMI 和扁桃体大小)、睡眠监测类(呼吸暂停低通气指数和血氧类指标)、影像学和其他检查类(评估阻塞平面)参数分别进行阐述,最后介绍了建立于多项因子基础上的预测系统,供临床医生决策时参考。

语后聋患者国产人工耳蜗植入后听力初步评估报告

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内容提要: 目的: 应用听觉行为分级 (CAP) 和诺尔训听能综合康复系统 5.01.01 中的字词测试表进行 1-4 个音节字/词组测试) 评估植入国产人工耳蜗的语后聋患者手术后听觉恢复状况。方法: 回顾分析 13 例语后聋国产人工耳蜗植入者的临床资料, 应用 CAP 和字词测试表评估术前、术后 3 个月和术后 6 个月的听觉能力, 采用 SPSS 16.0 软件进行统计描述及结果分析。结果: 13 例植入者开机使用 6 周后声场测听结果显示补偿后平均听阈介于 25-45dB SPL 之间; 术前 CAP 平均得分为 0.31 ± 0.48 分, 术后 3 个月时平均得分为 4.69 ± 1.03 分, 术后 6 个月时平均得分为 6.23 ± 1.23 分, 三个时间段的 CAP 得分差异有显著性意义; 1-4 个音节字/词组测试的术前得分 10.12 ± 3.23 分, 术后 3 个月平均得分 73.69 ± 7.72 分, 术后 6 个月平均得分 86.69 ± 8.34 分, 术前、术后 3 个月与 6 个月得分差异有显著性意义。结论: 语后聋患者植入国产人工耳蜗后经过康复训练听觉能力逐渐提高, 值得推广使用。

关键词: 耳蜗植入 语后聋 听觉行为

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Study of auditory Rehabilitation Performance of Post-lingual Cochlear Implantees with Nurotron Cochlear

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Abstract: *Objective:* To evaluate the auditory rehabilitation effect of post-lingual deafness cochlear implantees with domestic Nurotron cochlear using categories of auditory performance (CAP) and 1-4 syllable word/phrase test of Nurotron comprehensive training rehabilitation system 5.01.01 after surgery. *Methods:* A retrospective analysis was conducted on 13 cases of post-lingual with domestic Nurotron cochlear implantation. CAP and 1-4 syllable word/phrase test were applied in the evaluation of verbal communication skills before surgery and postoperative 3 months and 6 months; the general clinical related information collection, application of CAP and word test table to assess preoperative and postoperative 3 months and 6 months after hearing ability. SPSS Statistics 16.0 was used in statistical analysis. *Results:* The compensation hearing threshold of 13 patients using sound field audiometry was 25-45 dBHL after surgery 6 weeks. CAP scored an average of 0.31 ± 0.48 points preoperatively and postoperatively 3 months scored an average of 4.69 ± 1.03 points, and postoperatively 6 months scored an average of 6.23 ± 1.23 points, these difference had significance. 1-4 syllable word/phrase tests score 10.12 ± 3.23 points preoperatively, and postoperatively scored an average of 73.69 ± 7.72 3 months, 6 months after surgery scored an average of 86.69 ± 8.34 points, these difference has significant. *Conclusion:* Post-lingual deafness cochlear implantees with domestic Nurotron cochlear gradually improved their hearing ability after rehabilitation training.

Key words: cochlear implantation, post-lingual deafness, categories of auditory performance

人工耳蜗植入 (cochlear implantation, CI) 是治疗重度和极重度感音神经性聋的最佳治疗手

段,我国以往均采用国外进口品牌的人工耳蜗并取得很好的治疗效果,但其昂贵的价格是该技术未能被普遍使用的主要原因之一。随着近十几年来国产人工耳蜗技术的逐步发展,已有我国自主

品牌人工耳蜗问世,并已开始造福越来越多的耳聋患者。本文对在我院进行国产诺尔康 CI 的患者进行初步的回顾性研究,目的是为未来的应用提供临床经验和参考。

1. 资料和方法

1.1 临床资料:2012年8月~2014年4月在中山大学附属第一医院就诊手术的重度或极重度感音神经性聋患者13例,男6例,女7例,均为语后聋,年龄9~54岁,中位数年龄26.1岁;耳聋时间介于1~23年,其中耳聋<1年的有3例,耳聋1~2年的有2例,耳聋2~5年的有5例,耳聋5~10年的有2例,耳聋>10年的有1例,平均失聪时间17.2年。耳聋原因:大前庭导水管综合征3例,可疑药物性聋3例,原因不明7例。所有患者均无严重内耳畸形。所有患者均曾有佩戴助听器史,手术前检查显示符合《人工耳蜗植入工作指南(2003年,长沙)》所规定的人选标准^[1]。左侧植入4例,右侧植入9例。均采用诺尔康CS-10A型人工耳蜗。

1.2 方法:

1.2.1 将耳蜗模具定位后美兰标记,采用耳后小“C”形切口,开放乳突腔,经面神经隐窝径路暴露蜗窗,开放鼓阶,固定植入体后将电极插入鼓阶,封闭耳蜗造口后依层缝合切口,采用诺尔康1.0软件测试植入的人工耳蜗电极阻抗值,无异常后加压棉垫包扎手术结束。

1.2.2 所有患者均无出现手术并发症,并于术后1周~1个月开机。采用诺尔康1.0软件进行言语处理器调试。调试前首先测试植入耳蜗的电极阻抗值,采用峰值提取处理策略进行编程,所有植入者均能主动行为配合调试各电极反应阈和最大舒适阈,开机后2周、3周、1个月、3个月序贯进行调试,之后再根据植入者主观反映择期进行调试。所有患者在开机后即进行听力言语康复训练。

1.3 听觉能力测试:

1.3.1 采用Nikolopoulos等提出的CAP问卷进行调查,CAP能反映患者日常生活环境中的听觉水平。根据患者听觉水平的高低,将患者的听觉能力分为0~9级共十个级别,依次从环境声的识别到言语声的分辨^[2]。通过询问患者本人和熟悉患者日常生活状况的家属进行计分,详见表1。

1.3.2 开机后3个月在隔声室内进行助听听阈测听,了解人工耳蜗听力补偿情况;术后3个月和6个月调试时采用听觉行为分级(CAP)表询问听力康复情况并记分;采用诺尔康综合康复系统5.01.01中的字词测试表在隔声室内进行1~4个音节字/词组测试,测试字词采用常用的家庭称谓、中国地理位置名称、食品名称和动物名称,测试时电脑屏幕呈现4~8张字词卡片给患者,测试人员与患者面对面坐,声场给声,使用USB音频转换接头连接测试电脑、Madsen纯音听力计和标配扬声器进行测试。测试时扬声器置于受试者前方1m处,高度与受试者外耳道外口中点齐平,测试声以45°角入射,要求患者复述所听到的字词,最后以计算字词正确率进行统计。

1.3.3 采用SPSS 16.0统计软件进行分析,显著性水准 $\alpha=0.05$ 。

表 1. CAP 分级标准

分级	判断标准
0	对环境声或说话声没有注意
1	可注意环境声
2	可对言语声做出反应
3	可鉴别环境声
4	无需借助唇读可分辨言语声
5	无需借助唇读可理解常用短语
6	无需借助唇读可理解交谈内容
7	可以和认识的人打电话
8	在有回声或干扰噪声的房间(如教室或餐厅)里可与一组人员交谈
9	在不知话题时可以和陌生人打电话

2. 结果

2.1 13例患者手术均顺利完成,伤口Ⅰ级愈合,未出现面瘫、感染和眩晕症状及体征,术后开机也未出现面神经刺激抽搐和其他不适症状。所有患者开机使用6周后进行声场测听,补偿后平均听阈介于25~45dB SPL之间。所有患者使用至今植入体未出现任何异常,植入电极的阻抗值测试均在正常范围。

2.2 术前及术后开机3个月、6个月时分别进行CAP表询问计分:本组患者术前平均得分为 0.31 ± 0.48 ,术后3个月时平均得分为 4.69 ± 1.03 ,术后6个月时平均得分为 6.23 ± 1.23 。经配对t检

验,术后3个月与6个月得分差异经检验 $t=10.69$, $p<0.05$;术前与术后3个月得分差异经检验 $t=15.14$, $p<0.05$ 。

2.3 采用诺尔训听能综合康复系统5.01.01中的字词测试表进行1~4个音节字/词组测试结果:术前得分 10.12 ± 3.23 分,术后3个月平均得分 73.69 ± 7.72 ,术后6个月平均得分 86.69 ± 8.34 ,术前与术后3个月得分差异经检验 $t=6.45$, $p<0.05$ 术后3个月与6个月得分差异经检验 $t=4.20$, $p<0.05$ 。

3. 讨论

据2006年第二次全国残疾人抽样调查显示,我国现有耳聋患者约2780万,每年还有约2~3万新生聋儿,重度及极重度听力障碍患者人数众多。因此,人工耳蜗在我国广大聋病患者中有着广泛的使用前景,需求量巨大,但目前使用的大部分人工耳蜗产品均为国外进口品牌,众所周知进口人工耳蜗的费用昂贵,虽然国家和地方财政、地方医保和慈善团体等机构有各种补助项目或完全免费提供,但并不能涵盖所有重度和极重度感音神经性聋患者,国内仍有大部分患者需要自费承担人工耳蜗费用,对大部分需要自费的而言较难负担,因此近年来一些国产人工耳蜗的上市就为我国重度和极重度听障患者的治疗提供了新的选择和康复的希望。

13例在我院进行国产人工耳蜗植入的患者手术中和手术后均未出现各种并发症,植入电极数符合产品要求,伤口Ⅰ级愈合,电极阻抗值测量均在正常范围,使用至今未出现植入体任何异常。植入电极的阻抗值测试均在正常范围,说明国产人工耳蜗产品的设计、封装工艺和质量在近3年内使用期间是可靠的。

所有患者开机使用6周后的声场测听结果显

示补偿后的平均听阈介于25~45dB HL之间,这一方面提示患者的人工耳蜗植入体与言语处理器的工作状态正常,因此听力补偿情况良好,这将为下一步的听觉言语康复打下良好的基础;另一方面也可能与这些患者均为语后聋,有较好的听觉经验有关,因此对仅需要听觉察觉经验的声场纯音信号反应较好。

Nikolopoulos等提出的CAP问卷目前已有汉化版,专业及无听觉言语评估经验的非专业人士均可很快掌握评价基本要领,因此是一种简便、快速的评估听觉能力的方式,适合在临床工作中推广^[4]。本组患者术前平均得分为 0.31 ± 0.48 ,术后3个月时听觉能力已有明显的改善,评分上升为 4.69 ± 1.03 ,康复效果介于“无需借助唇读可分辨言语声”和“无需借助唇读可理解常用短语”之间;术后6个月时平均得分继续上升为 6.23 ± 1.23 ,康复效果已达到“无需借助唇读可理解交谈内容”至“可以和认识的人打电话”之间。由此可以看出本组语后聋患者在植入国产人工耳蜗之后听力康复效果一直呈现持续进步趋势,在术后6个月时的进步程度是令人较为满意的。

(下转第34页)

理体系的充分性、有效性和适宜性。在贯彻 YY/T0287/ISO13485 标准第三个十年, 医疗器械组织的质量管理需要从规范性管理向精益性管理转变, 向着卓越绩效管理迈进; 实施标准要从机械条款式符合标准要求向科学系统式符合标准要求转变, 向着由形似标准到神似标准的迈进; 医疗器械组织的自身质量管理向医疗器械产业链质量管理转变, 向着医疗器械全生命周期的管理迈进。贯彻新版标准不是从标准的条款和概念出发, 而

是要从组织的质量管理体系输入、过程运行的控制和管理以及质量管理输出的实际出发, 应用标准的管理理念和要求系统地解决组织质量管理体系实际问题, 创造价值, 促使顾客和相关方满意。质量管理体系的运行是动态的, 因此要不断地改进质量管理体系, 建立有生命力的质量管理体系, 提升组织的核心竞争力, 打造组织品牌, 实现医疗器械组织的战略和目标。

(上接第 17 页)

我们在术前、术后 3 个月和术后 6 个月时分别使用诺尔训听能综合康复系统软件进行了常用字词的测试, 结果显示本组植入者听力损害严重导致术前得分为 10.12 ± 3.23 分, 经过术后 3 个月的康复后测试得分快速上升, 使用字词测试表进行 1-4 个音节字/词组测试的平均得分达 73.69 ± 7.72 , 继续进行康复训练后可见患者的听觉能力也进一步提高, 由结果可见术后 6 个月平均得分达到 86.69, 得分的差异经检验均有显著性, 说明术后植入者的听觉能力有逐步持续的提高, 术后 6 个月时的听觉能力令人满意。我们分析后认为有以下五点原因: ①本组植入者均为语后聋患者, 有听力言语能力的基础, 并且术前保留有不同程度的听觉经验; ②大部分植入者失聪时间并不长, 失聪 <5 年的就有 10 例, 听觉剥夺

的时间较短, 有研究显示, 术后听觉皮层区域和负责语言处理的相关皮层仍有可塑性, 可在植入手术后随着时间增长而发生进展性的激活^[9], 从而帮助植入者从听觉剥夺引起的损伤中恢复; ③大部分患者手术植入时年龄较轻, 植入手术的中位年龄仅为 26.1 岁, 学习主动性和学习能力仍较好, 也较易从听觉剥夺引起的听觉言语功能下降中恢复^[10]; ④所有植入者在失聪后有配戴助听器史, 这可帮助患者保留部分的听觉经验; ⑤术后公司提供康复训练软件并指导本组植入者进行积极的康复训练。

综上所述, 语后聋患者植入国产人工耳蜗后听觉能力逐步康复, 术后 6 个月时 CAP 问卷得分和字词测试得分均较术前明显提高, 未见有短期并发症发生, 是语后聋患者的健康福音。

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The relationship between cortical auditory evoked potentials (CAEPs) and speech perception in children with Nurotron[®] cochlear implants during four years of follow-up



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ABSTRACT

Objective: The purpose of the current study was to evaluate the relationship between the presence or absence of cortical auditory evoked potentials (CAEPs) to speech stimuli and the performance of speech perception in Chinese pediatric recipients of the Nurotron[®] cochlear implant (CI). We also wanted to determine how the CAEPs might be used as an indicator for predicting early speech perception and could provide objective evidence for clinical applications of CAEPs.

Methods: 23 pediatric unilateral CI recipients participated in this study. 15 males 8 females, and their ages at implantation ranged from 13 to 68 months, with a mean age of 36 months. CAEPs and Mandarin Early Speech Perception (MESP) tests were used to evaluate the audibility and speech perception of these CI users. The tests were administered at the first, second, third, and fourth year after the CI surgery.

Results: All the subjects demonstrated improvements in detection of speech sounds with CI. The percentages of participants who could detect all three stimuli were 26% (6/23) at first year, to 100% (23/23) at the fourth year post-implantation. The percentages of participants who passed the Category 6 of MESP were from 9% (2/23) at first year, to 91% (21/23) at the fourth year post-implantation. Significant correlations ($p < 0.05$) were found between CAEP scores and MESP at the first, second, third year after the CI surgery. The multiple regression equation for prediction of MESP categories from CAEP scores and hearing ages was $MESP = 1.088 + (0.504 \times CAEP \text{ score}) + (0.964 \times \text{hearing ages})$ ($F = 72.919, p < 0.001, R^2 = 0.621$).

Conclusion: The results of this study suggested that aided cortical assessment was a useful tool to evaluate the outcomes of cochlear implantation. Cortical outcomes had a significant positive relationship with the MESP, which predicted the early speech perception of CI recipients.

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1. Introduction

In China, there are about 27.8 million individuals with hearing loss. Hearing loss is a common, disabling disease, particularly for

children where it causes delayed speech and language development, scholastic underachievement and social difficulties [1–6]. However, with the introduction of newborn hearing screening, it is possible to make an early diagnosis of children's hearing loss, and then recommend appropriate interventions which may include hearing aids or cochlear implants (CI) [7,8].

For children with profound sensorineural hearing loss, CI may be the best solution for them. When hearing loss is detected with infants or young children, they are unable to respond to behavioral threshold measurements, and aided outcome hearing threshold estimations are hard to obtain [9,10]. In clinical practice, parental questionnaires have been extensively used in assessing the effectiveness of CI use, but they are restricted by many factors like parents' attention to details of their child's auditory

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behaviors, the abilities of the researchers to extract relevant information from what the parents say, and the lifestyle of the children. [11]. Audiologists usually use simple Ling6 to elicit responses or a drum to test the children's audibility and tolerance after they receive their cochlear implantation. Unfortunately, the accuracies of these approaches are affected by the infants' awareness, and the audiologists' control of their own voice intensity [12]. Therefore, objective methods to verify the outcomes and effectiveness of the cochlear implant are of great importance.

There are about 40,000 CI recipients in China, and accurate, objective, and convenient clinical tools to evaluate the success of cochlear implantation are critical. Electrophysiological methods are useful measurements to understand infants' CI performance. For example, cortical auditory evoked potentials (CAEPs) generated from primary auditory cortex and associative cortical areas can provide objective sensation, cognition, memory, speech perception and other information of the central auditory nervous system [13,14]. CAEP was first put forward by Davis in 1939 [15], and progressed through 1960s and early 1970s [16], then as the appearance of ABR [17] and the difficulty of judging the CAEP waveforms, CAEP seldom used for a period. But in the mid-1990s, CAEPs was revived for indicating sound discrimination abilities [18]. CAEP waveforms can now be judged by automated statistical detection techniques (e.g. Hotelling's T^2) [19,20], and gradually can be used in clinical work.

Speech language perception tests are also useful measurements to assess the outcomes of CI. Several speech language perception test materials exist for children, including the early speech perception (ESP) test [21]; the Pediatric Speech Intelligibility (PSI) test [22], the Lexical Neighbor Test (LNT) [23] and pediatric Hearing In Noise Test (HINT) [24]. For young children in China, the Mandarin Early Speech Perception (MESP) test was developed by Zheng and her colleagues for normal developmentally 2–5 years old Mandarin-speaking children to evaluate early speech perception based on the English version [25].

Several studies have demonstrated the relationship between CAEP components and speech perception. Alvarenga et al. [26] used a Smart EP USB Jr. system to record CAEPs and the tests 5 and 6 of the Glendonald Auditor Screening Procedure (GASP) to evaluate speech perception respectively in 14 pediatric (4–11 years of age) CI users with ANSD, results revealed that P1 component correlated with speech perception and can be a predictor of the speech perception outcome in implanted children. Raince et al. [27] also investigated 18 children with ANSD ranging in age from 6 to 92 months, found that the occurrence of cortical potentials was closely related to PBK open-set speech perception assessment in subjects with hearing aids. The study by Narne [28] showed that speech identification scores had a good relationship with the amplitude of cortical potentials in ANSD subjects and might offer a way for predicting perceptual skills in these individuals. Maryanne's [11] research indicated the presence of cortical responses had a good relationship with functional measures of real-world listening behaviors with hearing aids. In addition, many previous studies revealed P1 parameters (latency and amplitude) correlated with speech perception performance in children and adults [29–33]. But the previous researches tested the relationship between cortical responses and speech perception for just one time, not a long period. In our study, in light of the difference of CAEPs recording equipment and characteristics of the mandarin Chinese, we examined the relationship between the occurrence of CAEPs and MESP performances in CI users with profound sensorineural hearing loss during four years of follow-up.

The goal of the current study was to examine the clinical applications of CAEPs. We would investigate the relationship between CAEPs and outcomes of speech language perception tests in children with CI.

2. Materials and methods

2.1. Subjects

23 unilateral CI recipients participated in this study, 15 males 8 females; they had their CI surgery at Beijing Tongren Hospital, Capital Medical University. Their ages at implantation ranged from 13 to 68 months with a mean of 36 months. The tests were administered at the first, second, third, and fourth year after the CI surgery. All subjects were diagnosed with bilateral profound sensorineural hearing loss prelingually by audiological tests like paediatric behavioral audiometry, tympanometry, distortion-product otoacoustic emissions (DPOAEs), auditory brainstem response (ABR) and auditory steady-state response (ASSR). They were all without inner ear malformation and other physical and mental diseases.

All the participants were fitted with Nurotron[®] Venus[™] (NSP-60B strategy) CI. A summary of the subject characteristics, including gender, etiology, age at implantation and other information, are presented in Table 1.

2.2. Procedures

The parents of the participants were informed of the test protocol and agreed to participate in the research. The study received approval by the Beijing Tongren Hospital Institutional Research Ethics Board. The children were fitted with their CI before test protocol began, with their threshold (T) levels being measured by visual reinforcement audiometry (VRA), play audiometry (PA), or conventional audiometry according to their ages. Comfort (C) levels were measured by picture pointing tasks or behavioral observation methods during the CI mapping process. The assessment procedure included objective recording of CAEPs as well as subjective speech perception measurements with the Mandarin Early Speech Perception (MESP) test. All the measurements were tested in a free sound field with ambient noise level below 30 dB (A).

2.3. Measures

2.3.1. Measurement of cortical auditory evoked potentials (CAEPs)

The cortical auditory evoked potentials (CAEPs) were recorded using the HEARLab[™] system (Frye Electronics) [34] with the active electrode attached to the vertex position (Cz), referenced to the non-surgical ear mastoid (Ref), and the forehead as ground (Gnd). The test stimuli /m/, /g/, /t/ were extracted from a running speech of a female. They had little vowel transition and represented a spectral emphasis in the low-, mid-, high-frequency regions respectively and closely equaled to the International Long-Term Average Speech Spectrum (ILTASS). Their durations were 30, 30, 20 ms, separately, the interstimulus interval was 1125 ms.

Speech stimuli were presented from a loudspeaker positioned at 0° azimuth, approximately 1.5 m from the test position, and the child sitting in a reclining chair and watching a silent cartoon. Prior to testing, CAEP equipment had been calibrated, and both Ref and Cz electrodes had an impedance of <5 k Ω . The recording window contained a 200 ms pre-stimulus baseline, and a 600 ms post-stimulus, and artifact reject level was $\pm 150 \mu\text{V}$. Online EEG band pass filter settings were 0.2–30 Hz. The speech stimuli were presented at 65 dB SPL, and at least 200 artifact-free epochs were accepted for each stimulus. The probability of detecting the cortical response was automatically analyzed by the statistical procedure (Hotelling's T^2) on the HEARLab[™] system, with a system-generated significance level (*p*-value), a *p*-value ≤ 0.05 indicating a significant result.

Table 1
Audiological and demographic characteristics of the subject sample.

Nr	Gender	Etiology	AAI (years)	Pre-implant use of hearing aids	Bimodal stimulation	Implant side	Year of reaching max level of CAEP	Year of reaching max level of MESP
1	F	Family history	2.6	No	No	L	First	Second
2	F	Unknown	1.8	No	No	L	Second	Third
3	F	Unknown	3.1	No	No	L	Third	Third
4	M	Unknown	2.2	No	No	L	Third	Third
5	M	Rubella	2.6	No	No	L	First	Second
6	F	Rubella	2.4	No	No	L	Second	Second
7	M	Unknown	2.2	No	No	L	First	Fourth
8	M	Unknown	1.4	Yes	No	L	Second	Third
9	M	Family history	3.2	No	No	L	Fourth	Fourth
10	M	Unknown	2.4	No	No	L	Third	Third
11	M	Unknown	2.5	No	No	R	Third	Fourth
12	F	Unknown	2.1	Yes	No	L	Second	–
13	M	Unknown	5.3	Yes	No	L	Third	Third
14	M	Unknown	1.5	Yes	No	L	Fourth	Fourth
15	M	Unknown	5.4	Yes	No	L	Second	Third
16	F	Unknown	4.6	No	No	L	First	First
17	M	Unknown	1.4	No	No	L	Fourth	–
18	M	Unknown	2.8	No	No	L	Third	Fourth
19	F	Unknown	3.8	Yes	Yes	L	Second	Second
20	M	Unknown	5.6	No	No	L	First	First
21	M	Hypoxia Rubella	2.6	Yes	No	L	First	Fourth
22	F	Unknown	1.1	No	Yes	L	Fourth	Fourth
23	M	Unknown	3.5	No	No	L	Second	Third

Abbreviations: F = Female, M = Male, AAI = Age at implantation, L = left, R = right. "First" means the first year after CI implantation; "Second" means the second year after CI implantation; "Third" means the third year after CI implantation; "Fourth" means the fourth year after CI implantation. "–" means the subject did not reach the max level of MESP at the last test time.

The recording of CAEPs was taken as objective evidence of the detection of speech stimuli at average conversational level (65 dB SPL). In this study, the presence or absence of P1 wave represented the presence or absence of cortical auditory evoked potentials. The scores of CAEPs were ranged from 0 to 3 for each child; a score of "0" was obtained when no CAEPs was elicited to any of the speech stimuli, while "3" was considered as evidence of CAEPs to all three speech stimuli presented at 65 dB SPL [11].

2.3.2. Mandarin Early Speech Perception (MESP) test

The MESP test was a closed-set evaluation measure of early speech perception abilities using picturable words as stimuli for children 2 or more years of age. It paralleled the English version early speech perception (ESP) but was not exactly the same as ESP. MESP included two additional subtests. The first three items (Speech Detection, Pattern Perception, Spondee Perception) of MESP were as same as the ESP, the fourth category Monosyllable Perception of ESP was split into the later three categories Vowel Perception, Consonant Perception, and Tone Perception in the MESP test. According to the characteristics of the mandarin Chinese, the six subtests were with increasing difficulty, only when the subject reached a threshold percentage, could he/she pass the category, and then went on the next subtest. Threshold percentage were referred as the lowest percentage for a category that was obviously higher than chance performance which were 54.5%, 30.3%, 63.6%, 63.6%, and 63.8% for Category 2, 3, 4, 5, and 6 respectively [25].

In our study, we used the standard version of MESP test. If the subject could not meet Category 1 (speech detection) criterion, the test was stopped; otherwise, the next category Pattern Perception, Spondee Perception, Vowel Perception, Consonant Perception, and Tone Perception was administered until the child did not reach the threshold scores of the testing category, the final passed category was written down. The result of MESP for a certain subject was displayed by the highest category that he/she finally passed. The Comparison of ESP and MESP test structures are shown in Table 2 [25].

2.4. Statistical analysis

The relationship between the CAEP scores and MESP categories was analyzed by the Spearman correlation test. Multiple linear regression analysis was performed to investigate the relationship among CAEP scores, hearing ages and MESP categories. Statistical calculations were performed with SPSS 16.0 version. Two-sided *p*-values ≤ 0.05 were considered to indicate statistical significance in all tests.

3. Results

3.1. The progress of cortical responses and speech perception

Table 3 shows the numbers of subjects detecting the stimuli of CAEPs at different test intervals. The percentages of participants who could detect all three stimuli were from 26% (6/23) at first year to 100% (23/23) at fourth year post-implantation. From the scores of CAEP in Table 3, we also found that only 4 subjects could not detect speech sounds after 1 year of CI use, but all subjects demonstrated improvements throughout 2 years of observation post-implantation, and at the fourth year post-implantation, all children obtained the highest score 3. The category scores of MESP are shown in Table 4. The percentages of participants who passed the Category 6 were from 9% (2/23) at first year to 91% (21/23) at the fourth year post-implantation. Table 5 shows the detail scores of CAEP and MESP at different test intervals.

3.2. The changes of P1 latency

Table 6 shows the changes of P1 latency during the test procedure. From the table we could see that there was no significant difference of P1 latency between the children who were fitted with cochlear implants before age 3.5 years and after age 3.5 years but before 7 years.

Table 2
Comparison of ESP and MESP test structures.

	ESP	MESP
Category 1 Description	Speech Sound Detection Live voice determination of detection and awareness of speech	Speech Sound Detection Same as ESP
Category 2 Description	Speech Pattern Perception 12 words in four different syllable and stress patterns: three each of monosyllables, disyllable trochees, disyllable spondees, and trisyllables	Speech Pattern Perception Similar to ESP, Mandarin spondees have same tone in each syllable, and tone 3 is excluded
Category 3 Description	Spondee Identification 12 disyllabic spondees with widely differing consonants and vowels	Spondee Perception Similar to ESP, Mandarin spondees have the same tone in each syllable
Category 4 Description	Monosyllabic Word Identification 12 monosyllabic words that begin with/b/and vary in medial vowel and final consonant	Vowel Perception 4 groups of 3 monosyllabic words with same consonant and tone but different vowels
Category 5 Description		Consonant Perception 4 groups of 3 monosyllabic word with same vowel and tone but different consonants
Category 6 Description		Tone Perception 6 subsets consisting of 4 pairs of monosyllabic words with same consonant and vowel but different tones

ESP: early speech perception; MESP: Mandarin Early Speech Perception.

3.3. The relationship between CAEP and MESP

Fig. 1 shows the categories of MESP as a function of CAEP outcomes over four years post-implantation for all participants combined. A significant relationship was found between the categories of MESP and CAEP scores ($r_s = 0.757$; $n = 23$; $p = 0.000$). The detailed relationships between the categories of MESP and the CAEP scores for the first, second and third year post-implantation are shown in Fig. 2 ($r_s = 0.622$; $n = 23$; $p = 0.002$), 3 ($r_s = 0.701$; $n = 23$; $p = 0.000$), and 4 ($r_s = 0.437$; $n = 23$; $p = 0.037$), respectively. The fourth year post-implantation, the scores of CAEP presented a ceiling effect that all the participants got the highest CAEP score 3, so the relationship between CAEP and MESP at this year was not shown (Figs. 3 and 4).

The relationship between the CAEP scores at the first year and MESP categories at the second, third year after surgery was shown

in Fig. 5 ($r_s = 0.747$; $n = 23$; $p = 0.000$), and 6 ($r_s = 0.552$; $n = 23$; $p = 0.006$). The relationship between the CAEP scores at the first year and MESP categories at the fourth year after surgery was not significant ($r_s = 0.320$; $n = 23$; $p = 0.136$).

A multiple linear regression was used to analyze the CAEPs that could reflect early speech perception. The MESP outcomes were the dependent variable, and the two independent variables were CAEP scores and years. The statistical test of regression equation was performed by ANOVA ($F = 91.808$, $p < 0.001$), so the multiple regression equation was obtained, the categories of MESP = $0.915 + (1.104 \times \text{CAEP score}) + (0.424 \times \text{years post-implantation})$ ($R^2 = 0.674$) (Fig. 6).

Table 3
Numbers of children in each CAEP scores at different test intervals.

Score	Pre-operation	1 year	2 years	3 years	4 years
0	23	4			
1		8	5		
2		5	5	4	
3		6	13	19	23
Total	23	23	23	23	23

Table 4
Numbers of children in each MESP category at different test intervals.

Category	Pre-operation	1 year	2 years	3 years	4 years
0	17				
1	6	5	1		
2		4	2		
3		7	2	2	1
4		3	4	1	
5		2	8	6	1
6		2	6	14	21
Total	23	23	23	23	23

Table 5
The score of CAEP and MESP at every test year.

Nr	Gender	First year post-implantation		Second year post-implantation		Third year post-implantation		Fourth year post-implantation	
		CAEP	MESP	CAEP	MESP	CAEP	MESP	CAEP	MESP
1	F	3	3	3	6	3	6	3	6
2	F	2	1	3	5	3	6	3	6
3	F	2	2	2	5	2	6	3	6
4	M	0	1	1	2	3	4	3	6
5	M	3	3	3	6	3	6	3	6
6	F	1	3	3	6	3	6	3	6
7	M	2	4	2	5	3	6	3	6
8	M	3	5	3	5	3	5	3	6
9	M	1	3	1	4	2	5	3	6
10	M	1	3	2	5	3	6	3	6
11	M	0	3	2	3	3	5	3	6
12	F	1	2	3	5	3	5	3	5
13	M	1	4	1	4	3	6	3	6
14	M	0	2	3	3	3	5	3	6
15	M	1	2	3	5	3	6	3	6
16	F	3	6	3	6	3	6	3	6
17	M	0	1	1	2	2	3	3	3
18	M	2	3	2	4	3	5	3	6
19	F	2	5	3	6	3	6	3	6
20	M	3	6	3	6	3	6	3	6
21	M	3	4	3	5	3	6	3	6
22	F	1	1	1	1	2	3	3	6
23	M	1	1	3	4	3	6	3	6

Table 6
Mean P1 latencies (ms) are shown for different age-implemented children.

Stimuli	First year post-implantation		Second year post-implantation		Third year post-implantation		Fourth year post-implantation	
	AI < 3.5	3.5 < AI < 7	AI < 3.5	3.5 < AI < 7	AI < 3.5	3.5 < AI < 7	AI < 3.5	3.5 < AI < 7
M	132.1	137.7	126.6	125.3	116.5	116.2	105.0	102.6
G	125.1	125.3	119.2	124.4	115.3	118.4	106.1	108.9
T	123.0	129.3	121.4	128.8	117.2	117.3	112.9	108.6

Abbreviations: AI = age at implantation; AI < 3.5 means the age at implantation was younger than 3.5 years old; 3.5 < AI < 7 means the age at implantation was between 3.5 and 7 years old.

4. Discussion

The main purpose of pediatric cochlear implantation is to provide hearing that will promote the development of speech and language like their normal hearing peers, allowing them to participate in the mainstream of society. Therefore the evaluation of the outcomes of CI is of great importance. Cortical response is an objective method that can provide information on the functioning of the central auditory nervous system [35]. This study aimed to evaluate the relationship between CAEP outcomes and speech perception over 4 years observations in pediatric users of the Nurotron[®] cochlear implant system and to determine if the CAEPs could be used as an index for predicting outcomes of speech perception.

From our results the majority of subjects demonstrated improvements in audibility skills throughout 2 years of observation post-implantation, and at the fourth year post-implantation, the subjects wholly obtained highest CAEP scores. While the presence of CAEPs to speech stimuli could provide early objective indications of the aided child’s ability to access speech by audition [11], the absence of cortical responses suggested that the speech sounds may have not been detected, or might be related to insufficient sensation level of the amplified sounds [36], or the immaturity of the central auditory system. Only four subjects could not detect speech sounds after 1 year of CI use. These four subjects who were insensitive to speech sounds may have not been behaviorally ready for this testing. Because the audiologists also kept the amplified sounds conservative when they adjusted the CI mapping, this may have contributed to the inadequate sensation levels needed to elicit cortical responses. CAEPs also might not be

detectable in some individuals at low to medium sensation levels [37]. The findings of the current study suggested that cortical assessment was a useful objective tool to assess the effectiveness of amplification for sound detection and guide the CI mapping, rehabilitation training in the future.

There were also many other factors that affected P1 wave. There was a sensitive period that influenced the central auditory development in CI children, the age cut-offs were set at 3.5 and 7.0 years (<3.5 years for early-implanted group and >7.0 years for late-implanted group). Many researches revealed that early-implanted children showed rapid development in CAEP waveform and P1 latency, but late-implanted children showed aberrant waveform morphology and slower decrease P1 latency after the surgery [38]. Dorman et al. found that if children experienced less than 3.5 years of auditory deprivation, P1 latency fell into the range of normal following 3–6 months stimulation; but if the auditory deprivation was longer than 7 years, P1 waveform would not develop into normal latency [39]. Therefore, the age at implantation was very important to the development of P1 latency, this told us that cochlear implantation should be performed as early as possible. In this study, there were only 7 children accepted their CI surgery after 3.5 years old but younger than 7 years old, and there was no significant difference between these two groups in P1 latency but the P1 latency of all the subjects decreased as their ages increased. Rehabilitation was also a factor that influenced P1 latency. Thabet’s [11] study revealed that prolonged P1 latencies would be recorded in hearing impaired children with inadequate rehabilitation. In our study, most children came from countryside;

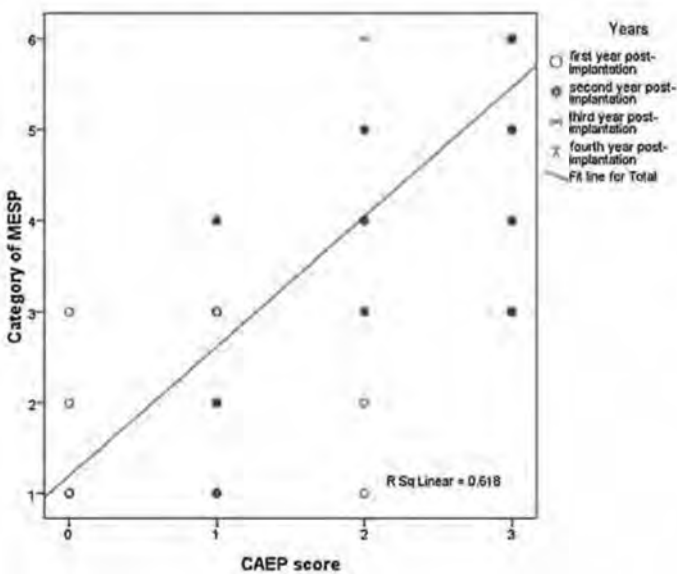


Fig. 1. Horizontal axis shows the CAEP scores from 0 to 3, vertical axis shows the Category of MESP from 1 to 6. The line reveals MESP outcomes as a function of the overall CAEP scores for all participants over 4 years combined.

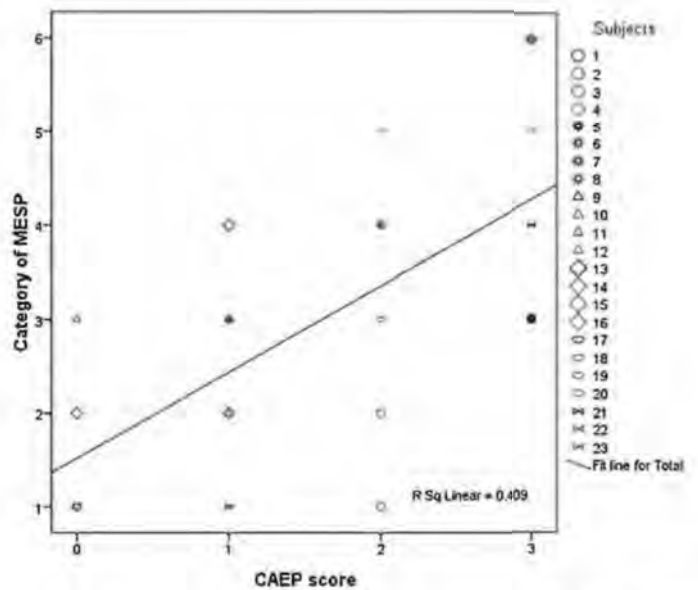


Fig. 2. Horizontal axis shows the CAEP scores from 0 to 3, vertical axis shows the Category of MESP from 1 to 6. The line reveals the CAEP scores in relation to the MESP category for all participants at the first year post-implantation.

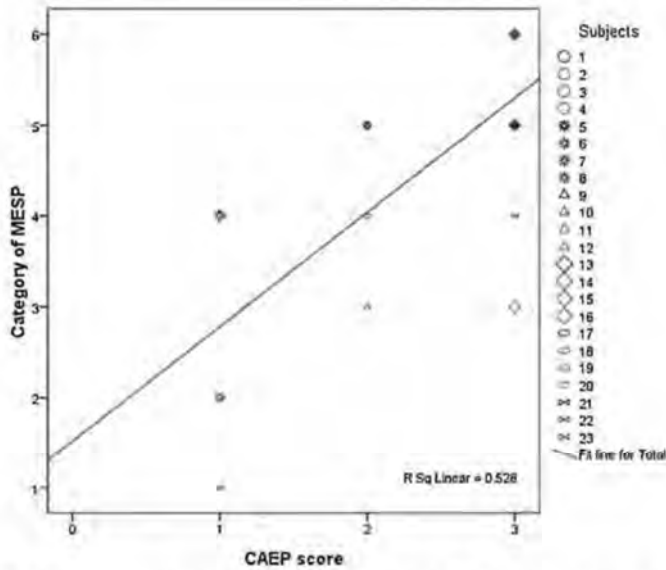


Fig. 3. Horizontal axis shows the CAEP scores from 0 to 3, vertical axis shows the Category of MESP from 1 to 6. The line reveals the CAEP scores in relation to the MESP category for all participants at the second year post-implantation.

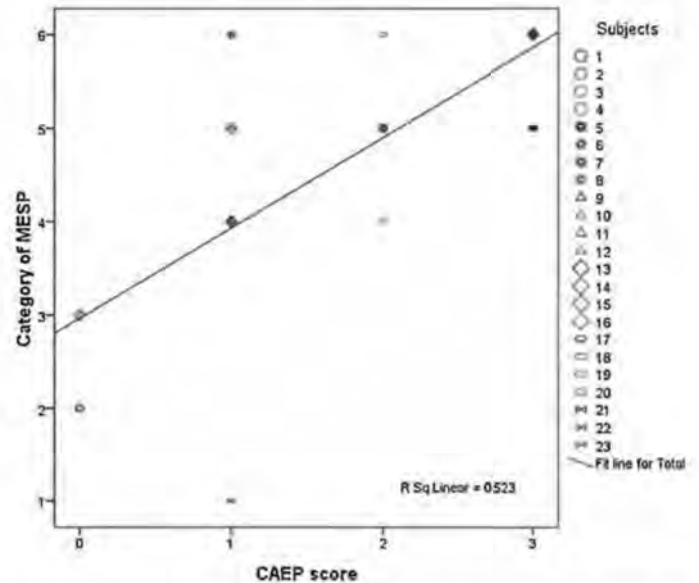


Fig. 5. Horizontal axis shows the CAEP scores from 0 to 3, vertical axis shows the Category of MESP from 1 to 6. The line reveals the CAEP scores at the first year in relation to the MESP category at the second year post-implantation for all participants.

their parents did not have enough money to send them to rehabilitation institute, so it was not discussed in this study.

Zheng and her colleagues created the MESP for developmentally normal 2–5 years old Mandarin-speaking children to evaluate early speech perception. Zheng demonstrated that all children aged 4–5 years old could reach all MESP categories successfully [25]. She also successfully used the MESP as subjective outcome assessment of speech perception and discrimination in pediatric CI recipients, and that after 4 years CI use, most Mandarin-speaking CI recipients had reached the highest MESP category 6 [40]. The MESP outcomes of the participants in present study showed a delayed speech language development compared with normal children at the same chronological age. Nearly all the recipients eventually reached level 6, the most difficult category in MESP, if the participant could pass this category, he/she might develop the

ability of Monosyllabic Word Identification which was also the most difficult category in ESP. There was a common developmental trajectory in relation to hearing age, which proved that the earlier cochlear implantation was done, the better the results were.

The relationship between the categories of MESP and CAEP scores was examined for all participants over 4 years post-implantation and a significant positive correlation was found. There was significant correlation between the categories of MESP and CAEP scores for the first, second, and third year post-implantation. At the fourth year after surgery, the correlation between these two variables was not presented, because at that time the MESP categories and CAEP scores varied little as the audibility skills of all children in this study developed appropriately. While there was significant relationship between MESP

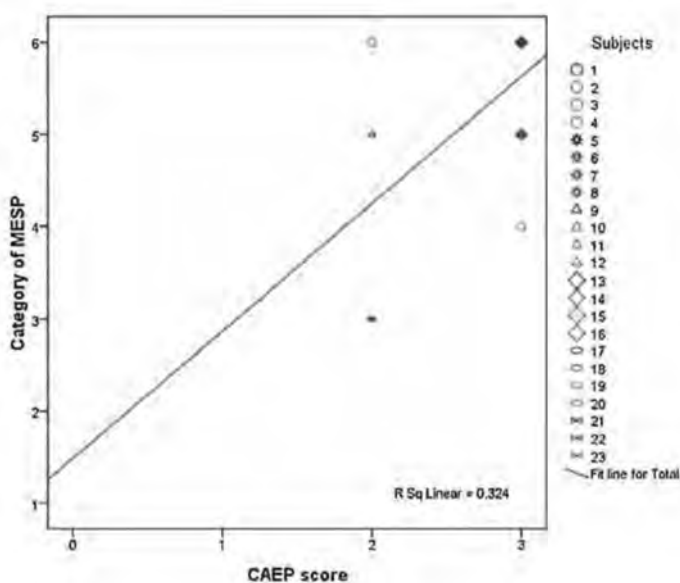


Fig. 4. Horizontal axis shows the CAEP scores from 0 to 3, vertical axis shows the Category of MESP from 1 to 6. The line reveals the CAEP scores in relation to the MESP category for all participants at the third year post-implantation.

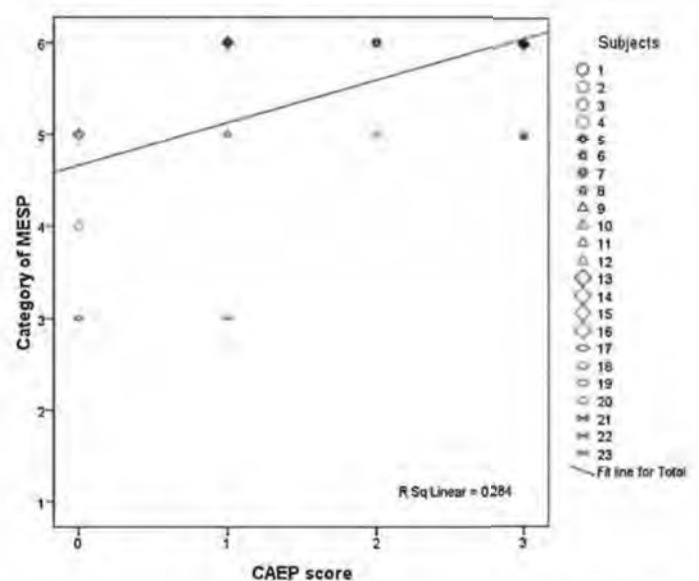


Fig. 6. Horizontal axis shows the CAEP scores from 0 to 3, vertical axis shows the Category of MESP from 1 to 6. The line reveals the CAEP scores at the first year in relation to the MESP category at the third year post-implantation for all participants.

categories and CAEP scores in children who used CI, but the amount of variance in MESP categories that was explained by CAEP was not very high suggesting that there were other factors that impact on the outcomes of MESP test. This could be the result of the abilities of the children improved as they got older individual differences, ages at implantation, duration of deafness, wellness of the family, the language used in daily life, and the education of their parents [41,42]. Therefore, the outcomes of MESP varied a lot. We believe this does not change the importance of CAEP outcomes to speech stimuli and their relationship to speech perception in children. Because the presence of CAEP and progress of speech perception using MESP were both reliant on the audibility of speech, our results were not amazing. For future research, we will consider extending the numbers of subjects, and discuss the relationship to different ages at implantation, different rehabilitation intensity, separately.

This study also showed that the CAEP scores at the first year have relationships with the categories of MESP at the second and third year. CAEP could be a predictor of speech perception. For children with CI, better audibility skills were not correlated to excellent speech language performance in the future. However, poor audibility skills indicated low speech language performance.

Clinical uses of auditory evoked potentials include threshold estimation and auditory discrimination, and many researchers focused their attention on the obligatory component of CAEPs, which was generally considered as the P1-N1-P2 complex [35]. Previous studies usually used P1 component to evaluate the benefits from cochlear implantation, auditory training, or amplification and the maturation process, plasticity of central nervous system in congenitally hearing-impaired children after they have been fitted with CI. [1,10,39,43–45]. Recently, research has revealed that CAEPs are also a valid tool for assessment of the effectiveness of hearing aids for young children. Maryanne's [11] research results indicated the presence of cortical responses had a good relationship with functional measures of real-world listening behaviors. Recording CAEPs to speech stimuli could provide objective evidence that these amplified stimuli had reached the cortex and they were potentially audible to the individual with CI. Our findings revealed that significant positive correlation between CAEP scores and the categories of MESP, as for infants and young CI children, they were not able to provide feedback of reliable behavioral responses and could not cooperate with speech language tests, so cortical assessment was an objective method to evaluate the outcomes of cochlear implant, and could be used to assess the early speech perception as time went on.

In summary, results from present study suggest that CAEP is a good way to evaluate the outcomes of CI, and a significant correlation exists between CAEP and MESP. CAEP can be used as a predictor of early speech perception in young children.

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Research Article

Induced Loudness Reduction and Enhancement in Acoustic and Electric Hearing

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ABSTRACT

The loudness of a tone can be reduced by preceding it with a more intense tone. This effect, known as induced loudness reduction (ILR), has been reported to last for several seconds. The underlying neural mechanisms are unknown. One possible contributor to the effect involves changes in cochlear gain via the medial olivocochlear (MOC) efferents. Since cochlear implants (CIs) bypass the cochlea, investigating whether and how CI users experience ILR should help provide a better understanding of the underlying mechanisms. In the present study, ILR was examined in both normal-hearing listeners and CI users by examining the effects of an intense precursor (50 or 500 ms) on the loudness of a 50-ms target, as judged by comparing it to a spectrally remote 50-ms comparison sound. The interstimulus interval (ISI) between the precursor and the target was varied between 10 and 1000 ms to estimate the time course of ILR. In general, the patterns of results from the CI users were similar to those found in the normal-hearing listeners. However, in the short-precursor short-ISI condition, an enhancement in the loudness of target was observed in CI subjects that was not present in the normal-hearing listeners, consistent with the effects of an additional attenuation present in the normal-hearing listeners but not in the CI users. The results suggest that the MOC may play a role but that it is not the only source of these loudness context effects.

Keywords: auditory context effects, loudness, loudness recalibration, cochlear implants

INTRODUCTION

As with many other aspects of perception, the loudness of a sound depends not only on its physical properties but also on the context in which the sound is presented. One loudness context effect that received early attention was termed “loudness enhancement.” This effect was demonstrated by presenting three successive tones at the same frequency: a precursor, a target tone, and a comparison tone. Listeners were instructed to adjust the level of the comparison tone until its loudness matched that of the target. When the precursor was more intense than the target, the listeners often adjusted the level of the comparison tone to be higher than that of the target at equal loudness, leading to the conclusion that the precursor had enhanced the loudness of the target tone (Zwislocki and Sokolich 1974; Elmasian and Galambos 1975). These effects declined as the spectral distance between the precursor and the target increased and tended to disappear completely at large spectral distances (Marks 1994; Wang et al. 2015).

The effects of loudness recalibration (LR; e.g., Arieh and Marks 2003) or induced loudness reduction (ILR; e.g., Nieder et al. 2003) are also measured by using a precursor at the same frequency as the target, but the comparison tone is at a frequency remote from that of the target and precursor. Using this paradigm, the opposite effect is usually reported: a precursor that is

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more intense than the subsequent target tone can reduce the target's loudness (Marks 1994). Mapes-Riordan and Yost (1999) found that the effect was strongest when the precursor was 10–20 dB higher than the target and that the effect was smaller or non-existent when the level difference exceeded 40 dB or when the target was presented at or near its detection threshold.

Scharf et al. (2002) suggested that the results from earlier loudness enhancement studies should be reinterpreted in light of the ILR findings. They noted that when all three tones were presented at the same frequency (as in the traditional enhancement studies), the precursor may have reduced the loudness of the comparison tone rather than enhancing the loudness of the target tone. This reinterpretation was supported by Arieh and Marks (2003), who found that ILR did not occur immediately after a precursor, but reached a maximum at a delay of around 1 s, and lasted for at least 3 s (Arieh and Marks 2003), which was longer than the gaps between precursor and comparison in the previous loudness enhancement studies.

To further test this interpretation, Oberfeld (2007) measured loudness context effects with the traditional three-tone paradigm where all tones were presented at the same frequency, along with a novel four-tone paradigm, in which a fourth tone was presented at a different frequency to measure more directly the perceived loudness of the third (comparison) tone. Results from Oberfeld (2007) showed that not only was the target tone enhanced in loudness, but the loudness of the comparison was reduced, in line with a “dual-process” model proposed by Arieh and Marks (2003). In this model, a fast-onset and fast-decay “enhancement” process, accompanied by a fast-onset and slow-decay reduction process, contribute to the “loudness enhancement” of the target.

One way in which the rapid enhancement process could occur is through “assimilation” or “over-integration” of the loudness of the precursor with that of the target (Plack 1996). This is thought to occur only when the precursor and target are perceptually similar (Oberfeld 2008). Some evidence in favor of the assimilation hypothesis is that a decrement in the judged loudness of the target can occur when the precursor is lower in level than the target (Elmasian et al. 1980). In addition, the assimilation hypothesis can explain why enhancement is sometimes observed even when the enhancer follows the target in time (Elmasian et al. 1980). One potential mechanism of ILR involves the medial olivocochlear (MOC) efferent system (e.g., Nieder et al. 2003), which can reduce cochlear gain by controlling the action of the outer hair cells (Stankovic and Guinan 1999; Guinan 2006). This in turn reduces neural firing and could reduce loudness. Although the time constants associated with the MOC fast effect are not thought to extend to several seconds, the MOC slow

effect may potentially contribute to loudness changes (Cooper and Guinan 2003).

Cochlear implants (CI) may provide a way to examine the role of the MOC efferents in ILR. If the MOC system is the sole source of ILR, then ILR should not be observed in CI users. A recent study by Wang et al. (2015) investigated loudness context effects in CI users using the traditional three-stimulus technique, with all three stimuli presented to the same electrode. Wang et al. (2015) found both similarities and differences between the results from CI users and those from normal-hearing listeners. In particular, in both normal-hearing and CI groups, a more intense precursor resulted in the target sound being judged louder than the comparison signal when they were presented at equal levels, and frequency selectivity was observed in this effect. In contrast, an increase in precursor level led to an increase in the effect for the normal-hearing listeners but not for the CI users. Because the target and the comparison tone were presented to the same electrode, it was not possible to separate potential loudness enhancement from ILR effects.

In the present study, we measured ILR in both normal-hearing listeners and CI users, with a moderately intense precursor and a fixed-level target, presented at the same frequency (or same electrode), and a varying-level comparison, presented at a spectrally remote frequency (or electrode) from the precursor and the target. Listeners were asked to compare the loudness of the comparison with that of the target. Pure tones were used as stimuli for the normal-hearing listeners, whereas fixed-rate electrical pulse trains were presented directly to the CI users. Our targets were always 50 ms in duration. The precursor duration was either 50 or 500 ms. If enhancement is due to a higher-level assimilation process, then both normal-hearing listeners and CI users should exhibit the effect, which should be maximal when the precursor and target are of similar duration (and therefore are most perceptually similar). If ILR is governed by the MOC system, it should be present only for the normal-hearing listeners, and should be greater for longer-duration precursor, which allows for more build-up of the MOC effect (Guinan 2006).

METHODS

Subjects

Normal-Hearing Listeners

Ten listeners (3 males, 7 females) participated in this experiment and were compensated for their time. Their ages ranged from 19 to 63 years (mean age 25.3 years, with only one subject older than 45). All

listeners had audiometric thresholds below 20 dB HL at octave frequencies between 0.25 and 8 kHz.

Cochlear-Implant Users

Seven post-lingually deafened CI users participated in this study and were compensated for their time. Their ages ranged from 54.1 to 74.4 years (mean age 62.0 years). Information regarding the individual CI users is provided in Table 1.

Stimuli

Normal-Hearing Listeners

Figure 1 provides a schematic diagram of the stimuli used in this experiment. In each trial, three pure tones, a precursor at 1278 Hz, a target also at 1278 Hz, and a comparison at 455 Hz, were presented in sequence. The spectral distance between the precursor and comparison was selected to be large enough to avoid any effects of the precursor on the comparison (e.g., Marks 1994). The frequencies of the test tones were selected from the standard Advanced Bionics 16-channel map for CIs, corresponding to the center frequencies of the channels mapped to electrodes E8 and E2, respectively. For reasons outlined in the introduction, two precursor durations, 50 and 500 ms, were tested. The durations of both the target and the comparison were always 50 ms. All the stimuli were gated on and off with 10-ms raised-cosine ramps. The interstimulus interval (ISI) between the precursor and the target was 50, 250, or 1000 ms, and the ISI from the target to the comparison was fixed at 1000 ms. The six precursor conditions (two durations and three ISIs) were tested along with a reference

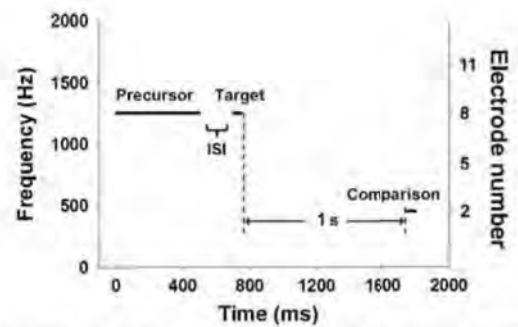


FIG. 1. Schematic diagram of the stimuli used for both the normal-hearing listeners and CI users. For the normal-hearing listeners, the precursor was a pure tone at 1278 Hz and 75 dB SPL, presented for either 50 or 500 ms. A 50-ms target tone at the same frequency and 60 dB SPL followed it after a gap of 50, 250, or 1000 ms. After a further 1000-ms gap, a 50-ms comparison tone with adjustable level was presented at 455 Hz. For the CI users, the stimuli had the same overall durations, but were presented as pulse trains to different electrodes. The precursor and target were presented to a middle electrode (E8), whereas the comparison was presented to a more apical electrode (E2). The level of the precursor was set to the most comfortable level (MCL) and the target was set to 70 % of each subject's dynamic range.

condition with no precursor, giving a total of seven conditions. The levels of the precursor (when present) and the target were always 75 and 60 dB SPL, respectively. The level of comparison tone was modified according to subjects' responses in an adaptive procedure, described below. The stimuli were generated digitally and played out diotically from a LynxStudio L22 24-bit soundcard at a sampling rate of 48 kHz via Sennheiser HD650 headphones to listeners seated in a double-walled sound-attenuating chamber.

TABLE 1

Subject code	Gender	Age (years)	CI user information				
			CI use (years)	Etiology	Duration of hearing loss prior to implant (years)	Absolute threshold (μ A)	MCL (μ A)
D02 (★)	F	63.9	12.1	Unknown	1	73	356
D10 (◊)	F	59.4	10.8	Unknown	8	68	509
D19 (□)	F	54.1	9.4	Unknown	11	85	475
D24 (△)	M	63.3	5.9	Unknown	27	91	413
D28 (○)	F	64.6	10.6	progressive Familial	27	186	766
D33 (▽)	M	74.4	1.0	progressive SNHL	<1	55	637
D36 (○)	F	54.5	1.5	Noise exposure; trauma	Unknown	173	863
				High fever			

MCL denotes maximum comfortable loudness.

Cochlear-Implant Users

The stimuli were similar to those used for normal-hearing listeners (Fig. 1). All the stimuli were delivered directly to the Internal Cochlear Stimulator (ICS) system based on a clinical research platform, BEDCS, provided by Advanced Bionics (Valencia, CA). The durations of all the signals and gaps were the same as those used with the normal-hearing listeners, with the exception that no onset and offset ramps were used. The stimuli were all pulse trains, consisting of 32 μ s/phase, cathodic-first biphasic pulses, presented in monopolar mode at a rate of 2000 pulses per second (pps). Electrode 8 was selected to present the precursor and target, and the comparison was presented from electrode 2. These electrodes correspond to frequencies of 1278 and 455 Hz, respectively, according to the standard Advanced Bionics 16-channel map. Presentation levels were determined for each subject individually by setting the target level at 70 % of the dynamic range (DR), defined as the range from absolute threshold (THS) to most comfortable level (MCL) in microamperes (μ A), and by setting the precursor level at MCL. The level of the comparison stimulus was varied using the same adaptive procedure as for the normal-hearing listeners in units of percent in DR.

Procedure

Normal-Hearing Listeners

Listeners were instructed to ignore the first stimulus, the precursor (if present), and to judge whether the comparison was louder or quieter than the target. An interleaved tracking procedure (Jesteadt 1980), consisting of a two-down one-up track and a two-up one-down track, was employed to estimate to the point of subjective equality (PSE) in loudness between the target and comparison tones. The two adaptive procedures track the 70.7 and 29.3 % points on the psychometric function, so that the mean of the two tracks approximates the 50 % point on the psychometric function, i.e., the point at which the target and comparison were judged to be equally loud. Each trial was selected at random with equal priori probability from one of the two tracks. Each condition was repeated four times in random order, with a different random order selected for each subject and each repetition. However, for each repetition, a different pair of starting points was selected for the tracking procedure (51/60, 54/63, 57/66, and 60/69 dB SPL), to reduce and control for any potential response bias generated by the starting points (e.g., Marks 1994). In each track, the initial step size was 5 dB. The step size was reduced to 3 dB after the first two reversals, and to 2 dB after the fourth reversal. A block of trials ended

when four reversals at the final step size occurred in both tracks. If the stopping rule for one track was met before the other, the "completed" track would continue, but the levels were not incorporated into the PSE estimates. The final measured PSE (i.e., the level at which the comparison was judged louder than the target 50 % of the time) was the mean of the last four reversal points from both tracks. The seven conditions with four starting values resulted in a total of 28 runs per subject.

Cochlear-Implant Users

The experimental procedures for the CI users were the same as those used for the normal-hearing listeners, with the following exceptions. First, the THS and MCL levels were determined for each subject individually using 200-ms pulse trains on each of the test electrodes (E2 and E8), as described in Wang et al. (2015). Second, the different pairs of starting points for each of the four repetitions of the adaptive tracking procedure were 55/70, 60/75, 65/80, and 70/85 % DR. Third, the initial step size in the adaptive procedure was 5 % DR, which was reduced to 3 % DR after two reversals and to 2 % DR after four reversals.

RESULTS

Normal-Hearing Listeners

A one-way within-subjects ANOVA revealed no significant main effect of starting point in the adaptive procedure [$F(3,27)=1.13$, $p=0.353$], suggesting that the starting points did not affect the actual matches of subjects. Therefore, the results were averaged across the four runs with different starting points for the remainder of the analysis. The mean results are presented in the left panel of Figure 2. The black bar at the left represents the results from the baseline condition with no precursor. The mean level of the 455-Hz comparison tone was 58.3 dB SPL, which was not significantly lower than the 60-dB SPL of the 1278-Hz target tone [paired-samples t test: $t(9)=-1.08$, $p=0.307$]. The lack of a level difference is expected, given the relatively similar expected loudness of 455-Hz and 1278-Hz tones, based on the 60-phon curve from current iso-loudness contours (ISO:226 2003). The presence of the precursor generally reduced the level of the comparison tone at the PSE, indicating a reduction in the loudness of the target tone, as expected. The right panel of Figure 2 displays the amount of loudness reduction, calculated simply by subtracting the level of the comparison in the presence of the precursor from its level in the absence of the precursor. The maximum ILR of about 7 dB

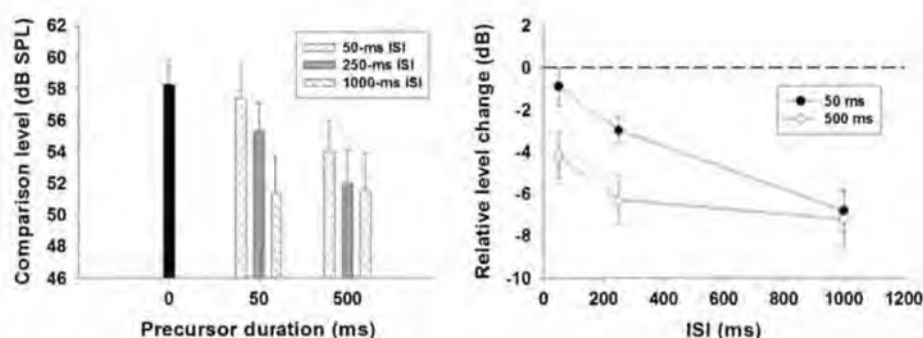


FIG. 2. Mean results from normal-hearing listeners. In the left panel, from left to right, the matched levels of comparison tone in no-precursor (baseline), short-precursor (50 ms), and long-precursor (500 ms) conditions are displayed. In the right panel, the levels in each condition are shown, relative to baseline. The

filled and open circles represent results from conditions with the 50-ms and 500-ms precursor, respectively. The dashed line indicates the baseline. Error bars represent 1 s.e. of the mean across subjects.

was found for ISIs of 1 s for both the 50-ms and the 500-ms precursor. At shorter ISIs, the longer precursor continued to produce ILR, whereas the amount of ILR produced by the shorter (50-ms) precursor decreased with decreasing ISI, reaching an average of less than 1 dB at the shortest ISI of 50 ms.

The increase in ILR with increasing ISI out to 1 s is consistent with the results from previous studies (Arieh and Marks 2003; Nieder et al. 2003). The maximum effect of 7 dB is somewhat less than that reported in earlier studies (around 10 dB), although this may be due to the relatively small level difference we used between the 60-dB target and the 75-dB precursor. Most previous studies have used precursor levels of 80 dB SPL, with level differences between the precursor and target of 20 dB or more. The amount of ILR has generally been found to reach a maximum with a level difference of around 20–30 dB between the precursor and target (Mapes-Riordan and Yost 1999; Oberfeld 2007). A two-way within-subjects ANOVA was conducted, with the change in level (relative to the no-precursor condition) as the dependent variable and precursor duration and ISI as the two factors. A significant main effect was found for precursor duration [$F(1,9)=9.59$, $p=0.013$], in line with the observation that the longer precursor induced a larger effect overall. The main effect of ISI was also significant [$F(2,18)=16.38$, $p<0.001$], as was the interaction between precursor duration and ISI [$F(2,18)=4.74$, $p=0.022$], reflecting the observation that the effect of precursor duration was greatest at the smallest ISI and became much smaller at the longest ISI.

According to the two-component model of Arieh and Marks (2003), the effects of a precursor are a combination of a short-lived enhancement process, which lasts no more than about 100 ms, superimposed on a longer-lasting ILR, which reaches a maximum after about 1 s. If we assume that only ILR remains at an ISI of 1 s, then the magnitude of the enhancement

component can be defined as the difference between the level of the comparison in the 1000-ms ISI condition and its level at shorter ISIs as suggested in Oberfeld (2007). According to this approach, the maximum ILR is about 7 dB for both the 50-ms and 500-ms precursors, and the maximum amount of enhancement (observed at an ISI of 50 ms) is about 6 dB for the 50-ms precursor and 3 dB for the 500-ms precursor. Thus, for the normal-hearing listeners, the prediction of greater enhancement for the shorter precursor was confirmed; however, the prediction of greater ILR for the longer precursor was not supported.

Cochlear-Implant Users

The individual matched levels of the comparison tone were converted into dB re. 1 μ A and were then averaged. As in experiment 1, a one-way within-subjects ANOVA revealed no significant difference in the response level with different starting points of the adaptive tracking procedure [$F(3,18)=1.46$, $p=0.26$], so the results were averaged across the four different starting levels.

The mean results from CI users are shown in Figure 3. In the left panel, the baseline condition with no precursor is shown with the black bar. It is not informative to compare the current levels of the comparison and target in the baseline condition, as they were presented to different electrodes, and so likely have different loudness-level relationships. In general, the effects of the precursor seem greater for the 50-ms precursor than for the 500-ms precursor. There was a trend for a decreasing PSE with an increasing ISI for the 50-ms precursor, but the trend was less apparent for the 500-ms precursor. The effect of the precursor was again calculated by subtracting the comparison level at the PSE in the no-precursor condition from the comparison level at the PSE in the with-precursor conditions (right panel of Fig. 3). In

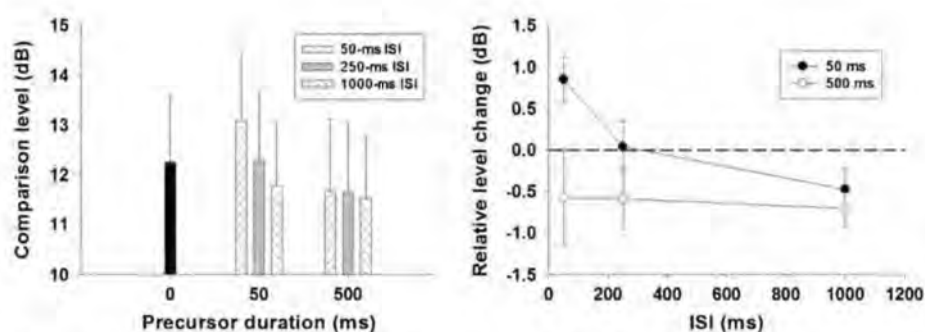


FIG. 3. Mean results from CI users. In the left panel, the individual matched levels of comparison tone were converted into decibel re. $1 \mu\text{A}$, and averaged to the mean matched levels. From left to right, the matched levels of comparison tone in no-precursor (baseline), short-precursor (50 ms), and long-precursor (500 ms) conditions are displayed. In the right

panel, the levels in each condition are shown, relative to baseline. The filled and open circles represent results from conditions with the 50-ms and 500-ms precursor, respectively. The dashed line indicates the baseline. Error bars represent 1 s.e. of the mean across subjects.

one case (50-ms precursor and 50-ms ISI), the comparison level was higher in the presence of the precursor. In all other cases, the mean PSE with the precursor were the same as, or lower than, the levels without the precursor, as was also found for the normal-hearing listeners under all conditions.

A two-way within-subjects ANOVA was performed with the change in level (in dB, relative to the no-precursor condition) as the dependent variable, and precursor duration and ISI as the two factors. A significant main effect was obtained for precursor duration [$F(1,6)=12.3$, $p=0.013$]. The main effect of ISI failed to reach significance [$F(2,12)=3.52$, $p=0.063$], but the interaction was significant [$F(2,12)=4.71$, $p=0.031$], reflecting the greater effect of ISI for the 50-ms precursor than for the 500-ms precursor.

Comparison of Results from Normal-Hearing and Cochlear-Implant Subjects

When considered in isolation, the patterns of results from the CI group with each of the two precursors look reasonably similar to those found in the normal-hearing subjects: with the 50-ms precursor, the matched comparison level decreased with increasing ISI, and with the 500-ms precursor the effect of ISI was reduced. However, when comparing the absolute effects of the presence of the precursor, some differences between the data from the CI users and the normal-hearing subjects emerge. As shown in the right panel of Figure 3, the mean difference between the precursor and no-precursor PSE levels is positive for the 50-ms precursor and 50-ms ISI, implying that the enhancement effect was greater than the ILR for the CI users. In contrast, as shown in the right panel of Figure 2, the normal-hearing listeners showed no overall enhancement in any of the conditions tested.

A more direct or quantitative comparison of the data from the normal-hearing and CI groups is

hampered by the differences in overall dynamic range, and by uncertainty regarding the appropriate units in which to compare the data. One way to provide such a comparison is to convert the amount of change in the matching stimulus into a proportion of the overall dynamic range (Wang et al. 2015). We calculated these normalized values by considering the dynamic range of the CI users to be the difference between MCL and THS (in dB) for each subject individually, and then converting any changes in level into a proportion of the dynamic range. For instance, if the overall dynamic range was 10 dB, then a change in the comparison level of 1 dB was considered a 10% change. For the normal-hearing listeners, the total dynamic range was assumed to be 100 dB. Using these conversions, the individual normalized effects of the precursors are shown in Figure 4, with the normal-hearing listeners on the left and the CI users on the right.

For the normal-hearing listeners, only 3 out of 10 subjects showed a positive overall effect of the precursor, and the average proportion of level change is slightly below the baseline as shown in Figure 2. In other conditions, the overall effect is even more clearly negative, indicating that ILR dominated any potential enhancement effects. In contrast, for the CI users in the 50-ms ISI and 50-ms precursor condition, six out of seven subjects showed more enhancement than ILR, resulting in a significant overall enhancement effect, as confirmed by a one-sample t test between the normalized level change and 0% [$t(6)=2.85$, $p=0.029$]. In the 50-ms ISI and 500-ms precursor condition, more inter-subject variability was observed, with no clear trend for overall enhancement.

Despite the slightly different number of subjects in each group (7 vs. 10), a mixed-model ANOVA using type-III sums of squares (Keppel and Wickens 2004) on the normalized proportion of level change with group (normal-hearing or CI) as a between-subjects

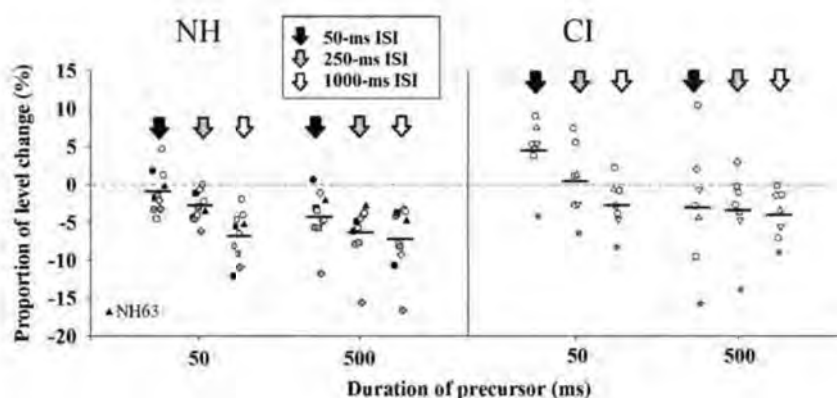


FIG. 4. Individual normalized proportion of level change in normal-hearing listeners and CI users. In the *left panel*, *black, gray, and unfilled arrows* indicate results from 50, 250, and 1000-ms ISI conditions, respectively. Each symbol represents the normalized effect of precursor of an individual subject. The *black lines* indicate

the mean results of each condition. The *triangles* (NH63) indicate the results of the oldest (63-year-old) NH subject. The *right panel* shows individual results of CI users. The corresponding symbols of CI users are indicated in Table 1. The *dashed line* indicates the baseline.

factor, and ISI and precursor duration as two within-subjects factors revealed a significant effect of group [$F(1,15)=4.69$; $p=0.047$], a significant effect of ISI [$F(2,30)=14.6$; $p<0.001$], and a significant effect of precursor duration [$F(1,15)=23.7$; $p<0.001$]. A significant interaction between ISI and precursor duration was also found [$F(2,30)=9.24$; $p=0.001$], whereas no significant interactions with subject group were found. The main effect of group, and lack of significant interactions with group, support the observation that the effect of the precursors in the CI group was vertically shifted up relative to the effect found in normal-hearing listeners.

DISCUSSION

In the present study, we investigated potential interactions between ILR and enhancement in both normal-hearing listeners and CI users. When considering the two precursor conditions in isolation, the patterns of results from the CI users look reasonably similar to those found in the normal-hearing listeners: with the 50-ms precursor, the matched comparison level decreased with increasing ISI, and with the 500-ms precursor the effect of ISI was reduced. However, when comparing the results with and without a precursor, some differences between the results from the CI users and the normal-hearing subjects emerge. For the CI users, in the 50-ms precursor and 50-ms ISI condition, the mean difference between the precursor and no-precursor PSE levels was positive, implying more enhancement than ILR. In contrast, there were no conditions with the normal-hearing listeners that showed an overall enhancement in the loudness of the target.

The ability to distinguish between an enhancement of the loudness of the target and a reduction in the loudness of the comparison is only possible through the use of a different frequency (or electrode) for the comparison. The assumption is that any effects of the precursor will be frequency selective, and so will not extend to the frequency of the comparison stimulus. This assumption is generally well supported by the work of Marks and colleagues, who have shown that the effects of ILR, or loudness recalibration, are highly frequency selective and are reduced or absent once the two frequencies differ by more than about 15 %, or a “critical band” (e.g., Marks 1994). It is known that CI users generally exhibit much poorer frequency selectivity than normal-hearing listeners (e.g., Zeng 2004). An earlier study of spectral enhancement of vowels (Wang et al. 2012) found that CI users showed generally less enhancement than normal-hearing listeners, but that the difference was reduced once poorer spectral resolution was simulated in normal-hearing listeners using vocoder techniques. It is therefore possible that the differences observed in the present study between normal-hearing listeners and CI users may be due to the CI users’ poorer spectral resolution. This explanation seems unlikely to account for the whole effect, however, given the earlier results of Wang et al. (2015). They found that loudness context effects in CI users decreased with increasing electrode distance between the precursor and target, and were generally negligible when the precursor was presented to electrode 8 and the target was presented to electrode 2. Thus, the reduction in spectral resolution in CI users is unlikely to account fully for the differences in ILR observed here.

Another difference between normal-hearing listeners and CI users is the presence of the MOC

fferent system in the normal auditory system (e.g., Liberman 1988; Stankovic and Guinan 1999). The amount of enhancement (defined as the difference in comparison level between the 50- and 500-ms ISI with the 50-ms precursor) was very similar for both the normal-hearing listeners and the CI users—in both cases it amounted to about 6 % of the respective dynamic range on average. However, the CI results suggest less reduction in initial gain, relative to the normal-hearing listeners, leading to somewhat less ILR at the longest ISI. It is possible that the gain reduction “missing” from the CI data may reflect the absence of the MOC-induced gain reduction, which in this case led to some initial overall loudness enhancement for the CI users. However, the fact that ILR was observed at all in CI users is consistent with previous findings suggesting that loudness context effects (Wang et al. 2015) as well as auditory enhancement effects (Goupell and Mostardi 2012; Wang et al. 2012) cannot be mediated solely by the MOC efferent system. An alternative candidate is neural adaptation, which occurs at many levels of the auditory system, beginning in the auditory nerve (Pickles 2013).

A final consideration is the potential effect of age. Our CI users were on average considerably older than our normal-hearing listeners. Any MOC effects may decrease with age (Kim et al. 2002; Jacobson et al. 2003). However, as shown by the triangles in the left panel of Figure 4, our oldest normal-hearing listener (NH63) performed very similarly to the younger normal-hearing listeners. Thus, although we cannot rule out the possibility that age differences affected our results, it does not appear to have played a critical role.

In summary, the predictions outlined in the introduction were partially supported. Both normal-hearing listeners and CI users exhibited similar amounts of enhancement (defined as the difference in the comparison level between the 50- and 1000-ms ISI with a 50-ms precursor), consistent with expectations of a centrally located assimilation effect. The effect of ILR (defined as the difference in comparison level between the condition without a precursor and the condition with a precursor separated by a 1000-ms ISI) was somewhat reduced, but not eliminated, in the CI users; in addition, ILR was not greater with the 500-ms precursor than with the 50-ms precursor. Neither of these findings is consistent with predictions based on a completely peripheral (i.e., MOC) locus for ILR. However, the fact that ILR was somewhat reduced in the CI users suggests that peripheral processes may contribute to the overall effect.

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儿童诺尔康人工耳蜗植入者术后长期 康复效果分析

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【摘要】 目的 观察儿童诺尔康人工耳蜗植入患者术后 3 年的康复效果,评价该国产人工耳蜗的安全性和有效性。方法 2011 年 4 月至 6 月植入诺尔康晨星人工耳蜗系统的双侧重度或极重度感音神经性聋患儿 60 例,植入年龄 12~71 个月,平均(39.6±18.9)个月。所有植入患儿术后 3~4 周开机,并在开机后 3 个月、1 年、2 年和 3 年定期随访,对人工耳蜗装置的使用情况和工作状态进行跟踪,同时对其听觉康复效果进行评估,并应用 SAS 9.13 统计软件进行数据分析。结果 60 例患儿均手术成功,开机后能坚持每日佩戴使用人工耳蜗,随访期间无与人工耳蜗植入相关的并发症发生,人工耳蜗装置整体工作状态良好。患儿声场言语频率的助听听阈测试,韵母、声母、单音节词和双音节词测试,Ling 氏六音测试,婴幼儿有意义听觉整合量表(Infant-Toddler Meaningful Auditory Integration Scale, IT-MAIS)得分均较术前明显提高,并随着人工耳蜗使用时间延长而逐渐改善。植入儿童的语法能力、理解能力、交往能力和表达能力测试结果也随着耳蜗使用时间的延长有明显提高。结论 随着人工耳蜗使用时间的延长,儿童植入者的听觉和语言评估测试结果显著提高,诺尔康晨星人工耳蜗系统具有良好的安全性和有效性。

【关键词】 耳蜗植入术; 测听法; 治疗结果; 儿童

Long-term results of Nurotron Cochlear Implant System in deaf children Yu Limei*, Li Jianan*, Wang Liyan*, Wang Qian*, Miao Yan*, Zhang Yang*, Shen Min*, Xue Jing*, Wei Peifang*, Han Rui*, Yang Shiming*. *China Rehabilitation Research Center for Deaf Children, Beijing 100029, China; *Department of Otorhinolaryngology Head and Neck Surgery, Institute of Otorhinolaryngology, General Hospital of People's Liberation Army, Beijing 100853, China

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【Abstract】 Objective To observe the long-term safety and performance of Nurotron cochlear implant system. To analyze the auditory and speech rehabilitation characteristic of pediatric deafened patients after cochlear implantation. **Methods** To analyze 3 years results of pediatric deafened patients with Nurotron® Venus™ cochlear implants. From April to June 2011, sixty deaf children received domestic cochlear implant. All subjects were switched on after 3 to 4 weeks of surgery, and were assessed the auditory rehabilitation on 3 months, 12 months, 24 months and 36 months after switching on. To evaluate the rehabilitation results by Aided Hearing Thresholds, Auditory & Verbal Ability Test and IT-MAIS Questionnaire. Meanwhile, the safety and performance of cochlear implant system were followed-up. Before surgery, all the recipients in this study were 12 to 71 months of age with the average hearing threshold higher than 90 dBHL. **Results** Sixty cases of deaf children were implanted successfully. All the recipients used their devices every day, and all of their devices worked well. No complication or side effect related to implantation were found. The sound field aided hearing thresholds, vowels, consonants, monosyllabic words and two-syllable words test, as well as Ling's test, and IT-MAIS Questionnaire of all recipients were improved significantly with prolonged use of CI device. The results of grammatical competence,

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understanding, communication and presentation skills tests also get significantly promotion in 3 years follow up. **Conclusions** With prolonged use of CI device, the hearing and language tests of children recipients could obtain significantly improvement. The Nurotron[®] Venus[™] CI system works safely and effectively.

【Key words】 Cochlear implantation; Audiometry; Treatment outcome; Child

根据 2006 年第二次全国残疾人抽样调查数据,我国有听力残疾人 2 870 万,其中 6 岁以下听力残疾儿童有 13.7 万^[1]。听力障碍不但影响患儿接受外界信息,还会延误其语言学习、心理及智力的正常发展,同时也给社会和家庭带来沉重的经济和精神负担。人工耳蜗是帮助重度以上感音神经性聋患者恢复听觉的高科技电子产品。在中国,从 30 多年前单通道人工耳蜗的研发,到近些年日趋成熟的多导人工耳蜗正式用于临床,围绕人工耳蜗技术,国产人工耳蜗的研究探索从未停止。

本研究通过对植入国产诺尔康人工耳蜗系统的 60 例聋儿进行跟踪随访,探讨该人工耳蜗系统对于儿童植入者的安全性和有效性。

资料与方法

一、受试者资料

研究对象为 2011 年 4—6 月植入 26 导诺尔康晨星人工耳蜗系统的 60 例双侧重度或极重度感音神经性聋患儿,其中男性 39 例,女性 21 例;手术年龄 12~71 个月,平均(39.6±18.9)个月,其中<36 月龄和≥36 月龄的患儿均为 30 例。全部受试者均无严重中耳和内耳畸形,无人工耳蜗植入的禁忌证,精神智力发育正常,无其他全身疾病;35 例术前曾有助听器佩戴经验,19 例术前曾在当地康复机构接受康复训练。

二、评估方法

所有植入患儿均在术后 3~4 周开机,分别在开机后 3 个月(±1 周)、开机后 1 年(±2 周)、开机后 2 年(±2 周)和开机后 3 年(±2 周)进行随访和听觉康复效果评估。

1. 人工耳蜗装置安全性和稳定性的评估:①术后头颅侧位 X 线片复查耳蜗电极位置;②开机后 3 个月和 1 年时复查血常规、尿常规、血生化和心电图检查,监测受试者全身情况;③随访与耳蜗植入相关并发症的发生情况;④询问受试者耳蜗每天佩戴时间及使用情况。

2. 人工耳蜗有效性的评估:①声场语言频率助听听阈测试:采用美国 GSI 61 型听力计,由专人在隔声室内进行测试,测试手术耳 500、1 000、2 000 和 4 000 Hz 的啜音听阈(因对侧耳听力损失均为重度

以上,故不需堵耳掩蔽),测试时患者言语处理器的设置与日常使用一致。②听觉能力测试:采用中国聋儿康复研究中心修订的《听觉·语言能力评估标准及方法》^[2],对受试者在开机后 3 个月、1 年、2 年和 3 年时分别行韵母、声母、单音节词和双音节词识别测试^[3]。③语言能力测试:同样采用《听觉·语言能力评估标准及方法》^[2],对受试儿童在术前、开机后 9 个月、2 年和 3 年分别进行语法能力、理解能力和交往能力测试,在 2 年和 3 年时增加表达能力测试,该测试结果以语言年龄(岁)表示,范围 0~4 岁。④Ling 氏六音测试:对受试儿童在开机后 3 个月、1 年、2 年和 3 年时进行/m/、/w/、/ɑ/、/i/、/sh/、/s/识别测试。⑤婴幼儿有意义听觉整合量表(Infant-Toddler Meaningful Auditory Integration Scale, IT-MAIS)测试^[4,5]:对受试儿童在开机后 3 个月、1 年、2 年和 3 年行 IT-MAIS 评估。

三、统计学分析

数据管理使用的录入软件为 EPI DATA 3.0,统计分析软件为 SAS[®] 9.13。正态分布计量资料以 $\bar{x} \pm s$ 表示,非正态分布计量资料以中位数、25 分位数(Q_1)及 75 分位数(Q_3)表示。 $P < 0.05$ 为差异具有统计学意义。

结 果

一、人工耳蜗装置的安全性和稳定性

全部 60 例植入诺尔康晨星人工耳蜗系统的儿童受试者均手术成功,切口愈合良好,生物相容性良好(全身无感染,植入部位无肿胀、疼痛),人工耳蜗整体工作状态良好(耦合良好且系统工作正常)。开机后 3 个月和 1 年时复查血常规、尿常规、血生化和心电图检查等均正常,无与人工耳蜗植入相关的并发症发生。所有受试者均每天坚持佩戴耳蜗装置 8 h 以上,在术后 2 年和 3 年的持续随访观察中发现,所有参加随访者均获益良好。

失访情况:开机后 3 个月随访时,2 例受试者因联系方式发生变化错过随访;开机后 2 年、3 年时,分别有 4 例、8 例受试者因家中有事无法参加随访。

二、声场语言频率听阈测试结果

术前患儿裸耳行为测听和植入人工耳蜗开机后声场内助听听阈测试结果见表 1。术前左耳语言频

率平均听阈为(111.1 ± 8.3) dBHL, 右耳平均听阈为(111.0 ± 9.8) dB HL; 开机后 3 个月声场内平均助听听阈为(44.8 ± 10.3) dBHL; 开机后 1 年声场内平均助听听阈为(39.3 ± 5.4) dBHL; 开机后 2 年声场内平均助听听阈为(39.9 ± 5.4) dBHL; 开机后 3 年声场内平均助听听阈为(37.3 ± 6.3) dBHL。

重复测量方差分析结果显示, 术后 3 个月声场助听听阈即较术前术侧裸耳听阈有显著提高, 差异具有统计学意义($P = 0.000$), 而开机后 3 个月、1 年、2 年和 3 年声场下助听听阈基本保持在 40 dBHL 的平均水平, 差异无统计学意义($P > 0.05$)。

三、听觉能力测试结果

术前韵母、声母、单音节词、双音节词识别测试: 39 例受试患儿可以配合完成测试, 测试结果均呈非正态分布, 四项得分的中位数、25 分位数(Q_1)、75 分位数(Q_3)均为 0%; 另外的 21 例 < 36 月龄的患儿因无法配合未做评估。

开机后 3 个月韵母、声母、单音节词、双音节词识别测试: 36 例受试者配合完成测试, 测试结果亦均呈非正态分布, 其中韵母识别得分中位数为 0.00%, Q_1 为 0.00%, Q_3 为 84.00%; 声母识别得分中位数为 24.00%, Q_1 为 0.00%, Q_3 为 60.00%; 双音节识别得分中位数为 3.33%, Q_1 为 0.00%, Q_3 为 88.33%; 单音节识别得分中位数为 4.29%, Q_1 为 0.00%, Q_3 为 84.29%。

开机后 1 年韵母、声母、单音节词、双音节词识别测试: 45 例受试者配合完成测试, 得分呈正态分布, 分别为(86.80 ± 14.09)%, (77.24 ± 15.35)%, (86.23 ± 19.67)% 和(87.36 ± 18.18)%。

开机后 2 年韵母、声母、单音节词、双音节词识别测试: 50 例受试者配合完成测试, 得分分别为(90.82 ± 8.78)%, (81.70 ± 12.83)%, (95.79 ± 8.99)%, (95.93 ± 7.56)%。

开机后 3 年韵母、声母、单音节词、双音节词识

别测试: 46 例受试者配合完成测试, 得分分别为(94.52 ± 7.98)%, (86.04 ± 13.66)%, (95.83 ± 12.42)%, (94.05 ± 15.67)%。

上述结果显示, 术后 3 个月韵母、声母、单音节词、双音节词识别测试结果较术前均显著提升, 但个体间差异较大, 呈非正态分布。随着耳蜗使用时间的延长听觉能力 4 项测试得分逐步提升, 从 3 个月时平均 40% 左右的得分迅速上升到开机后 1 年的 80% 得分, 之后提升速度变缓, 并且个体间差异缩小, 得分呈正态分布。

四、语言能力测试结果

受试儿童术前言语能力测试结果呈非正态分布: 其中语法能力中位数为 0.0 岁, Q_1 为 0.0 岁, Q_3 为 1.0 岁; 理解能力的中位数、 Q_1 、 Q_3 均为 0.0 岁; 交往能力的中位数、 Q_1 、 Q_3 均为 0.0 岁。开机后不同时间点的言语能力测试结果见表 2, 其语法能力年龄、理解能力年龄、交往能力年龄和表达能力年龄均随人工耳蜗使用时间延长而增长。结果反映了聋儿佩戴人工耳蜗后的语言能力发展基本符合人工耳蜗使用时间, 但仍低于其生理年龄[本组受试者手术年龄平均为(3.3 ± 1.6)岁]。在开机后最初 9 个月, 语法能力、理解能力和交往能力进步比较快, 可达到 2 岁左右的水平, 表达能力进步较缓, 无法进行测试。开机后 2 年和 3 年语言能力测试结果较 9 个月时有所提高, 表达能力也逐步显现, 语法能力和理解能力仍优于交往能力和表达能力, 这也符合正常听力年龄的发展规律。但开机后 2~3 年间语言能力发展情况总体而言进步较慢, 仍低于受试儿童生理年龄水平。

五、Ling 氏六音识别测试

受试儿童在不同时间点 Ling 氏六音识别测试结果(/m/、/u/、/a/、/i/、/sh/、/s/ 6 个音的平均得分), 术前($n = 60$)得分呈非正态分布, 中位数、 Q_1 、 Q_3 均为 0.00%, 开机后 3 个月($n = 56$)得分为

表 1 儿童诺尔康人工耳蜗植入者术前及术后不同随访时间语言频率行为测听结果(dBHL, $\bar{x} \pm s$)

测试时间	例数	500 Hz	1 000 Hz	2 000 Hz	4 000 Hz
术前					
左耳	60	105.8 ± 11.5	109.5 ± 10.2	113.3 ± 8.5	115.9 ± 7.5
右耳	60	105.6 ± 13.9	109.8 ± 10.9	113.5 ± 8.9	115.0 ± 8.6
开机后 3 个月	56	43.9 ± 9.9	44.6 ± 11.7	46.1 ± 11.2	44.8 ± 13.5
开机后 1 年	60	42.3 ± 5.9	37.0 ± 7.4	38.8 ± 5.9	39.3 ± 6.4
开机后 2 年	56	41.3 ± 5.7	41.8 ± 6.2	41.2 ± 5.6	36.0 ± 8.3
开机后 3 年	50	38.5 ± 6.0	36.7 ± 7.3	35.9 ± 7.3	37.7 ± 7.4

注: 术前裸耳行为测试听力计最大声输出为 120 dBHL, 对最大给声强度仍无反应的患儿, 统计时听阈按 120 dBHL 计算; 术后为声场内人工耳蜗助听听阈

(69.15 ± 35.92)%, 开机后 1 年 ($n = 60$)、开机后 2 年 ($n = 56$) 和开机后 3 年 ($n = 51$) 的得分均为 100.0%。

表 2 儿童诺尔康人工耳蜗植入者不同时间点语言能力测试结果(岁, $\bar{x} \pm s$)

测试时间	例数	语法能力	理解能力	交往能力	表达能力
开机后 9 个月	39	2.2 ± 1.4	2.4 ± 1.7	1.8 ± 1.4	-
开机后 2 年	50	3.0 ± 0.9	3.7 ± 0.6	2.7 ± 1.0	2.5 ± 1.0
开机后 3 年	49	3.3 ± 0.8	3.9 ± 0.5	3.0 ± 1.2	2.5 ± 0.9

注: - 为无法完成测试

六、IT-MAIS 量表得分

受试儿童术前 ($n = 60$) IT-MAIS 得分呈非正态分布, 中位数、 Q_1 、 Q_3 均为 0.00%, 开机后 3 个月 ($n = 56$) IT-MAIS 得分为 (25.05 ± 5.29) 分, 开机后 1 年 ($n = 60$) IT-MAIS 得分为 (36.98 ± 2.99) 分, 开机后 2 年 ($n = 56$ 例) IT-MAIS 得分为 (38.26 ± 2.71) 分, 开机后 3 年 ($n = 52$) IT-MAIS 得分均为满分 40 分。随着时间的推移, 从术前到术后 3 个月、1 年 IT-MAIS 成绩逐步显著提升, 而开机 1 年、2 年和 3 年, 量表得分无明显变化, 差异无统计学意义 ($P > 0.05$), 并且 3 年时均可达到满分。

讨 论

人工耳蜗被认为是目前最成功的神经植入假体, 是治疗重度以上感音神经性聋的唯一选择。近些年随着听觉植入相关研究大量开展, 更优化的植入体设计、小型化体外机、电极阵列设计、刺激模式和编码策略的更新等都被运用到新的听觉植入产品中, 人工耳蜗技术取得了突破性进展^[6-7]。目前世界上三家主要的人工耳蜗制造公司(包括澳大利亚 Cochlear 公司、奥地利 Med-EL 公司和美国 Advanced Bionics 公司)控制了全球主要市场。临床研究表明, 在植入者各方面条件相当的情况下, 不同人工耳蜗系统植入后的听觉水平和言语可懂度等康复效果差异无统计学意义^[8]。当前, 人工耳蜗价格仍然昂贵, 即使在发达国家, 价格问题也制约了很多耳聋患者从中获益。

回顾人工耳蜗在中国的发展历史, 从 1980 年北京协和医院研发成功的单导人工耳蜗, 到 1987 年的 3 导人工耳蜗, 再到近些年几家科研团队和企业投入巨大精力财力研发的新型多导人工耳蜗产品, 围绕了人工耳蜗的研究探索在中国从未停止。目前中

国的多导人工耳蜗技术已经日趋成熟和完善, 并成功应用于临床。本研究所选用的国产诺尔康晨星人工耳蜗系统是 26 导人工耳蜗产品, 包括 24 个刺激电极和 2 个参考电极, 材料为铂铱合金, 电极有效植入长度为 20.5 mm, 其植入体壳体采用钛金外壳外裹硅胶。系统参数: 传输频率 16 MHz、数据传输率 1 MB/s、刺激速率 40 kHz, 具有 4 个电流源, 具备虚拟通道能力^[9]。该产品在 2011 年和 2013 年分别通过了中国食品药品监督管理局 (SFDA) 审批和欧盟 CE 认证, 已开始在临床上应用。本研究对在同一时期内植入诺尔康人工耳蜗的 60 例儿童患者进行了 3 年长期随访, 从各项安全指标和疗效来看, 都达到了较满意效果。患儿佩戴耳蜗后能够满足日常听声需求, 并且随着人工耳蜗使用时间的延长, 其听声反应、感知能力、表达能力等均获得了显著提高, 从而为患儿提供了良好的学习交流机会, 这与国外很多关于听障儿童人工耳蜗植入的研究结果相同^[10-11]。

本研究儿童植入者听觉康复效果评估包括声场内助听听阈、言语识别测试(包括音素、单音节词、双音节词)、问卷评估等多种方式; 语言康复效果评估则从语法能力、理解能力、表达能力、交往能力等方面进行测试, 能较全面、真实地反映儿童的听觉语言能力。结果显示, 随着人工耳蜗使用时间的延长, 患儿各项听觉评估成绩均稳步提高。其中, 助听听阈在术后 3 个月即达到比较理想的状态, 随着时间的推移一直保持稳定状态; 言语识别测试和问卷评估的分数术后 3 个月即比术前有大幅提升, 术后 3 个月至 1 年间进步仍非常明显, 术后 1 年时各项分数均达到比较高的水平, 之后发展速度减缓, 这同时也反映出听觉评估材料出现了天花板效应, 在更长期的随访中应考虑增加测试难度, 如增加噪声下的言语识别测试等^[12-13]。本组受试儿童的听觉发展特点与使用其他品牌人工耳蜗的患儿相似^[14-18]。语言评估结果表明, 该组受试儿童各项语言能力均随着人工耳蜗植入时间的延长有所提升, 但术后 3 年的语言年龄和生理年龄相差仍较大, 表明其语言能力和同龄健听儿童相比仍有较大差距; 进一步分析发现, 各项语言能力中, 受试儿童的理解能力表现最优, 表达能力相对较弱, 这和儿童语言的发展规律相吻合, 也与其他听障儿童相关研究结果类似^[19-20], 提示后续康复应加强训练受试儿童的表达能力。鉴于儿童成长发育的特殊性, 更长期的随访仍是必要的, 患儿上学后的情况、在学校和社会生活中的融入度, 乃至将来的工作生活情况, 都将是下一

步的随访重点。

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· 学术动态 ·

2015 年第 I、II 期协和颞骨显微外科技术讲习班通知

良好的外科技术是保证手术成功的基本条件。由北京协和医院耳鼻咽喉科主办的国家医学继续教育项目、国家临床重点专科项目、卫生部行业基金项目、Fisch 国际显微外科基金会支持项目——协和颞骨显微外科技术讲习班 2015 年将继续在北京协和医院耳鼻咽喉微创外科技术实验室举办。授课内容:外耳道皮瓣、外耳道成形术、上鼓室探查术、完璧式乳突根治术、人工耳蜗植入术、VSB 植入术(分别固定于砧骨长脚和圆窗)、自体砧骨听骨链重建术、开放式乳突根治术、颞骨次全切除术、颞下窝进路 Type B(仅限颞骨内步骤)、颞下窝进路 Type A(仅限颞骨内步骤)、经耳囊(全迷路)入路。

2015 年讲习班将举办二期:第 I 期,2015 年 6 月 7—10 日,语言:中文;第 II 期,2015 年 10 月 10—13 日,语言:英文。讲习班以传授经协和验证过的颞骨外科技术为目的,每期拟招收操作学员 12 名,为每一名学员提供颞骨、人工耳蜗和 VSB 训练用假体。采取“step by step”的授课方式,教员全程指导,注重手术操作技术的交流和掌握,务求实效。讲习班食宿费用自理,培训费 5 000 元/人,同时招收参观学员(可参与讨论,获得学分),费用 1 000 元/人,限 5 人以内。

详细课程表和报名回执可从北京协和医院耳鼻咽喉科网站下载,网址: <http://www.pumch.cn/Item/12599.aspx>。

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儿童患者植入诺尔康-晨星人工耳蜗术后听觉康复效果分析

The Hearing Rehabilitation Results of Deaf Children with Nurotron Venus Cochlear Implantation

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【摘要】目的 观察及分析听障儿童植入国产诺尔康-晨星人工耳蜗术后的听觉康复效果及人工耳蜗产品性能。**方法** 选择2011年4月-6月植入诺尔康-晨星人工耳蜗系统的听障儿童60例,在开机后3个月、6个月、9个月、12个月进行听觉康复效果评估,同时对人工耳蜗产品的使用情况和工作状态随访。使用SPSS统计软件进行数据分析。**结果** 60例患儿的人工耳蜗植入手术成功,产品的生物相容性和整体工作状态良好,受试者术后1个月开机后均能坚持每日配戴人工耳蜗,无与人工耳蜗植入相关的并发症。受试者声场言语频率的助听阈测试,韵母、声母、单音节和双音节识别测试,林氏六音测试,IT-MAIS问卷评估结果较术前均显著提高。随着人工耳蜗使用时间的延长,受试者听觉能力逐渐提高。**结论** 诺尔康-晨星人工耳蜗系统安全可靠,在恢复听觉、提高言语和声音感知与识别能力等方面效果良好。植入体纤薄,适合儿童植入。远期效果有待进一步观察。

【关键词】 儿童人工耳蜗植入;听觉康复;诺尔康人工耳蜗

【Abstract】Objective The aim of this study is to observe and analyze the auditory and speech rehabilitation outcomes as well as the performance of Nurotron Venus cochlear implant (CI) made in China among deaf children. **Methods** From April to June 2011, 60 deaf children received Nurotron Venus cochlear implantations. All CI systems of subjects were switched on 3 to 4 weeks after surgery, and the auditory rehabilitation outcomes were assessed 3 months, 6 months, 9 months and 12 months after being switched on. The effectiveness of Nurotron Venus CI system was evaluated using SPSS statistical software. Meanwhile, the safety and performance of Nurotron Venus CI system were followed-up. All pediatric recipients in this study have severe to profound hearing loss, aged from 12 to 71 months with an average age of 39.6 ± 18.9 months. **Results** 60 deaf children were implanted with the Nurotron cochlear implants successfully. All the Nurotron recipients regularly used their devices which worked effectively. No complication or side effects related to implantation was found. The postoperative results of the aided hearing threshold test, consonants, vowels, monosyllable, disyllable, Ling Six Sound and IT-MAIS test improved significantly compared with the preoperative results. After a period of use, the auditory ability of those pediatric recipients progressed considerably. **Conclusion** The Nurotron Venus CI system made in China worked safely and effectively. The slim design of implant is suitable for pediatric implantation. However, further observation is still needed.

【Key words】 Cochlear implantation in deaf children; Auditory rehabilitation; Nurotron cochlear implant

听力障碍不但影响儿童接受外界信息,延误其语言学习、心理及智力的正常发展,同时给社会和家庭带来沉重的经济和精神负担。人工耳蜗是帮助重度/极重度感音神经性耳聋患者恢复听觉的高科技电子产品,目前中国市场主要被进口人工耳蜗占据,其昂贵的价格使许多听障患者望而却步。近些年,国内

数家科研团队正在研发高性能低价位的国产人工耳蜗产品,其中诺尔康-晨星人工耳蜗系统经过临床试验,已通过中国食品药品监督管理局审批,是目前技术较成熟的国产人工耳蜗产品。

本研究通过对60例植入诺尔康-晨星人工耳蜗系统的听障儿童进行跟踪随访,分析观察该产品对儿

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童植入者的安全性和有效性,在开机后3个月、6个月、9个月、12个月进行听觉康复效果评估,探寻听障儿童人工耳蜗植入后听觉康复规律。

1 材料和方法

1.1 受试者资料

选择2011年4月~6月植入诺尔康-晨星人工耳蜗系统的听障患儿60例,所有受试者均为双侧重度或极重度感音神经性聋,除4例为前庭导水管扩大外,无严重中耳和内耳畸形,无其他人工耳蜗植入禁忌证,精神智力发育正常,无其他全身疾病。其中35例受试者术前曾有助听器配戴经验;19例受试者曾在当地康复机构接受康复训练。60例受试者在年龄和性别方面分布均匀,男性39例,女性21例。手术年龄12~71月龄,平均 39.61 ± 18.87 月龄,其中 < 36 月龄和 ≥ 36 月龄的受试者均为30例。60例患儿均在各地康复中心接受听力语言康复训练。

1.2 方法

随访时间:开机当天、开机后3个月 ± 1 周、开机后6个月 ± 2 周、开机后9个月 ± 2 周、开机后12个月 ± 2 周进行随访,随访内容如下。

1.2.1 安全性和稳定性评价 ①术后头颅侧位X线片复查耳蜗电极位置;②复查血常规、尿常规、血生化和心电图,检查监测受试者全身情况(开机后3个月和12个月);③随访与人工耳蜗植入相关并发症发生情况;④询问受试者每天配戴人工耳蜗时间及产品使用情况。

1.2.2 有效性评价 ①听阈测试:术前采用耳机测试双侧裸耳听阈,术后在声场条件下测试言语频率的助听听阈。采用美国GSI 61型听力计,由专人在隔声室内进行测试。用啜音测试手术耳500、1000、2000和4000 Hz的助听听阈(因对侧耳均为重度以上耳聋,故不堵耳掩蔽)。测试时患者言语处理器的设置与日常使用一致。②听觉能力测试:采用中国聋儿康复研究中心修订的《听觉能力评估标准及方法》^[1]对受试儿

童行韵母、声母、单音节和双音节识别测试^[2]。③林氏六音/m/、/u/、/a/、/i/、/sh/、/s/测试。④婴幼儿有意义听觉整合量表IT-MAIS测试^[3,4]。以上测试均由专业测评人员完成。

失访情况:开机后3个月随访时,4例受试者因联系方式变化未及时通知研究者而错过随访;开机后6个月随访时,1例受试者因家中有事未参加随访;开机后9个月和12个月所有受试者均按时随访。

1.2.3 统计方法 所有统计分析在0.05显著性水平下进行。数据管理使用EPI DATA 3.0软件,统计分析软件为SPSS。①描述性分析:采用均数、标准差、中位数、最大值、最小值、第25及75分位数描述。②疗效分析:正态分布的计量资料研究前后比较采用重复测量方差分析。

2 结果

2.1 安全性和稳定性结果

60例植入诺尔康-晨星人工耳蜗系统的儿童受试者植入手术成功,切口愈合良好,生物相容性良好(全身无感染,植入部位无肿胀疼痛)。术后X线片观察显示,所有植入者的电极均正确植入耳蜗鼓阶内;12例患者存在1~5个蜗外电极,已于开机时关闭;其余植入者的电极均为完全植入,且人工耳蜗整体工作状态良好(耦合良好且系统工作)。开机后3个月和12个月复查血常规、尿常规、血生化及心电图检查均正常,无与人工耳蜗植入相关的并发症发生。所有受试者均每天坚持配戴人工耳蜗8小时以上,获益良好。

2.2 言语频率听阈测试结果

手术前后言语频率听阈测试结果见表1和图1。重复测量方差分析结果显示,术后3个月助听听阈均值较术前术侧裸耳听阈均值显著降低($P=0.000$),而开机3、6、9、12个月之间均无显著性差异($P>0.05$),即保持接近40 dB HL的平均水平。

2.3 听觉能力测试

听觉能力测试结果见表2和图2。统计分析显示,

表1 手术前后言语频率听阈测试结果(dB HL)

听阈	测试例数	500 Hz	1000 Hz	2000 Hz	4000 Hz	平均值
术前左耳裸耳	60	105.8 \pm 11.5	109.5 \pm 10.2	113.3 \pm 8.5	115.9 \pm 7.5	111.1 \pm 8.3
术前右耳裸耳	60	111.0 \pm 9.8	105.6 \pm 13.9	109.8 \pm 10.9	113.5 \pm 8.9	115.0 \pm 8.6
开机3个月助听	56	43.9 \pm 9.9	44.6 \pm 11.7	46.1 \pm 11.2	44.8 \pm 13.5	44.8 \pm 10.3
开机6个月助听	59	41.0 \pm 5.7	40.3 \pm 8.4	44.4 \pm 8.4	43.6 \pm 10.3	42.4 \pm 7.0
开机9个月助听	60	40.7 \pm 6.0	38.7 \pm 6.6	38.4 \pm 6.7	38.4 \pm 8.1	39.0 \pm 6.1
开机12个月助听	60	42.3 \pm 6.0	37.00 \pm 7.4	38.8 \pm 5.9	39.2 \pm 6.4	39.3 \pm 5.4

注:术前裸耳听阈测试中,部分受试者的部分频率在听力计最大声输出强度仍无反应,统计分析时以仪器最大标记可测值,即120 dB HL为计算依据

表2 听觉能力测试结果($\bar{x} \pm s, \%$)

测试时间	测试例数	韵母识别率	声母识别率	单音节识别率	双音节识别率
术前	39	2.3 ± 14.1	2.4 ± 14.7	0.5 ± 3.2	1.1 ± 7.0
开机3个月	36	40.1 ± 41.0	31.7 ± 34.0	36.2 ± 42.6	37.7 ± 43.2
开机6个月	38	57.8 ± 38.7	48.1 ± 35.0	56.8 ± 42.2	57.0 ± 44.1
开机9个月	39	66.6 ± 36.4	59.0 ± 32.7	61.9 ± 41.1	62.0 ± 41.1
开机12个月	30	85.3 ± 17.5	77.7 ± 17.0	85.4 ± 22.7	87.3 ± 20.7

注:由于许多年龄小于3周岁的植入者无法配合完成该测试,因此仅对配合患儿的测试结果进行统计

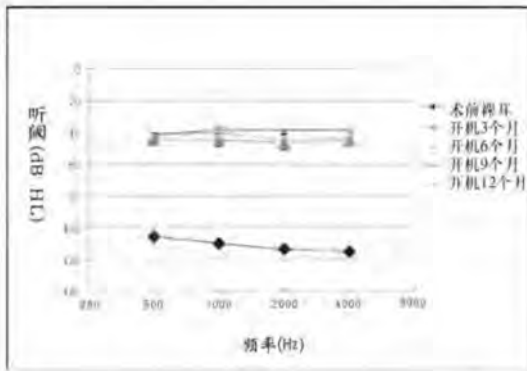


图1 声场言语频率听阈测试结果

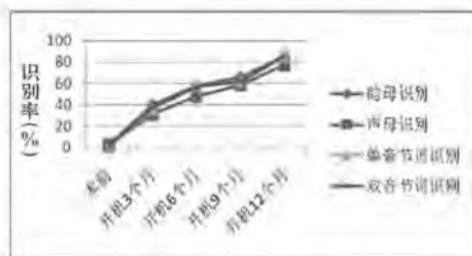


图2 听觉能力测试结果

术后3个月听觉能力4项测试结果较术前均显著提升($P=0.000$),其后平均得分逐步提升,即从3个月时40%左右的水平逐步上升到12个月80%左右的水平。成对比较结果显示,除6个月、9个月的韵母识别、单音节识别得分之间无显著差异(P 值分别为0.089和0.213)外,其它3、6、9、12个月之间的成对比较均有显著性差异($P<0.05$)。

2.4 林氏六音测试

林氏六音/m/、/u/、/a/、/i/、/sh/、/s/测试结果见图3。术前林氏六音测试得分为9.6%($n=60$ 例);开机后3个月、6个月、9个月、12个月林氏六音测试得分分别为69.2%($n=56$ 例)、86.4%($n=59$ 例)、95.0%($n=60$ 例)、100.0%($n=60$ 例)。统计结果显示,从术前到开机3个月、6个月,林氏六音结果显著提升(P 值分别为0.000和0.001);该项测试结果在6个月左右

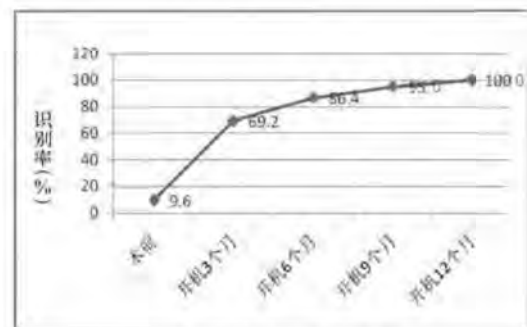


图3 林氏六音测试结果

达到平台期,12个月时达到最高值,其中6个月的得分与9、12个月之间无显著差异(P 值分别为0.148和0.006)。

2.5 IT-MAIS测试

IT-MAIS测试结果见图4。术前儿童听觉意义整合量表IT-MAIS测试得分为2.3 ± 7.0($n=60$ 例);开机后3个月、6个月、9个月、12个月儿童听觉意义整合量表IT-MAIS测试得分分别为25.1 ± 5.3($n=56$ 例)、29.5 ± 6.0($n=59$ 例)、34.6 ± 3.8($n=60$ 例)、37.0 ± 3.0($n=60$ 例)。统计结果显示,随着时间的推移,从术前到术后3个月、6个月、9个月、12个月的结果逐步显著提升,差异有统计学意义($P=0.000$)。

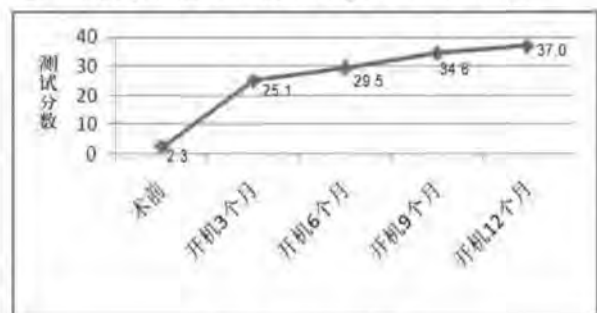


图4 IT-MAIS测试结果

3 讨论

3.1 儿童人工耳蜗植入后听觉康复效果分析
植入人工耳蜗系统可使听障儿童重建听力,避免

生理心理障碍的产生,并使患儿不错失学习语言的最佳时机。为使听障儿童人工耳蜗植入后获得最佳效果和最大收益,要坚持长期进行语言康复训练,遵循声音察觉、分辨、识别、理解的程序,指导患儿逐步适应有声环境,进而掌握语言交流能力。本研究的60例植入者均遵照此原则,在康复中心接受正规的语言康复训练。

通过对60例受试听障儿童进行12个月的追踪评估,可以发现患儿使用诺尔康-晨星人工耳蜗系统后,听觉能力得到显著提高,具体结果分析如下。

3.1.1 助听听阈 术后助听结果显示,开机后患儿听力得到显著提升,能够满足日常听声需求。

3.1.2 听觉能力评估 开机12个月的评估结果显示,患儿韵母、声母、双音节、单音节词识别率平均为80%及以上,其中声母识别得分相对较低,而术前以上各项检查的识别率均<3%。术后较术前的听觉能力有显著提高,这表明通过植入人工耳蜗及术后康复训练,患儿不仅获得了听觉,并能够达到对声音的感知、理解。通过分析3个月、6个月、9个月、12个月的测试结果,患儿的康复效果随着人工耳蜗使用时间的延长逐渐提高,目前虽已取得较好成绩,但尚未到达平台期,最终效果有待进一步随访。

3.1.3 林氏六音 患儿术前林氏六音识别率低于10%,开机12个月时提升至100.0%,该结果提示患儿在使用人工耳蜗后能够较好地感知各频段的声音,并对声音有良好辨识。

3.1.4 IT-MAIS 术前、术后IT-MAIS得分变化提示,患儿使用人工耳蜗后日常生活中的听觉能力得到了显著提高。

3.2 诺尔康-晨星人工耳蜗系统的产品性能

从1970年第一个用于临床的单通道人工耳蜗植入装置研制成功,到80年代初澳大利亚墨尔本大学研究小组开发了第一个多通道人工耳蜗植入体,经过多年的临床效果观察,人工耳蜗已成为帮助重度、极重度感音神经性聋患者恢复听觉的可靠手段,尤其是近10多年来,国际上人工耳蜗技术取得了突破性进展^[5,6],进口人工耳蜗引进中国已近20年,帮助数万例中国听障患者获得听说能力,回归有声世界。在植入者各方面条件相当的情况下,不同植入电极术后的听觉水平和言语可懂度等康复效果无明显差异^[7]。国产诺尔康-晨星人工耳蜗系统是我国研发团队从美国加州大学和House耳研所引进技术,在美国研发、中国生产制造的多导人工耳蜗产品,经过临床试验,已通过中国食品药品监督管理局的审批,可用于临床^[8]。

此前,笔者曾对15例植入诺尔康人工耳蜗的成年语后聋患者与15例植入进口人工耳蜗的语后聋患者开

机后2年的听觉言语康复情况进行对比发现,言语识别率无显著差异^[9]。本研究60例儿童受试者均植入诺尔康-晨星人工耳蜗系统,经过1年的跟踪随访,目前从各项评估指标来看,该人工耳蜗系统安全可靠,患者使用后能够满足日常听声需求,并能够显著提升听觉能力,为患儿提供了良好的学习交流机会。

综上所述,诺尔康-晨星人工耳蜗系统在12~71月龄双耳重度或极重度感音神经性聋患者术后1年的安全性可靠性得到了验证。在恢复听觉、提高言语、声音感知和识别能力等方面效果满意。该系统植入体纤薄,适合儿童植入。人工耳蜗植入不仅有利于提高听力障碍儿童的言语感知能力,对听障儿童的语言发展、言语可懂度的提高亦有巨大贡献^[10-12],但考虑到儿童的听觉言语能力建立发展的规律,本研究的远期效果还有待进一步随访和总结。

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诺尔康人工耳蜗技术 在中国的应用与前景

The Application and the Future: Nurotron Cochlear Technology in China

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YANG Shi-ming, LI Jia-nan

【摘要】人工耳蜗是目前应用最成功的神经植入假体技术,世界范围内已有30余万重度以上听障患者通过人工耳蜗植入重获听觉功能。但是相对于庞大的耳聋人口基数,仅有少部分候选人群获得了人工耳蜗植入的机会,人工耳蜗价格昂贵是原因之一。30年来中国也一直在研发人工耳蜗产品,但一直未广泛用于临床。直到近年一种新型的26电极诺尔康人工耳蜗研发成功,在全国5家医院完成了临床验证并取得较满意效果,2011年通过了中国食品药品监督管理局(CFDA)审批,2012年获得了欧盟CE认证。诺尔康人工耳蜗的成功研发和应用,降低了人工耳蜗植入的费用,并有望推动人工耳蜗在世界其它国家的广泛应用。本文将介绍诺尔康人工耳蜗装置的研发背景、产品特点、临床验证及应用前景等,从侧面展现中国人工耳蜗发展的脉络与历程。未来人工耳蜗产品的发展方向是更加小巧、人性化,进一步融合相关领域的新技术,随着电子技术的发展和生物治疗技术的新发现,最终可能实现植入体全植入和听觉通路全覆盖。

【关键词】诺尔康人工耳蜗;产品性能;评估;应用前景

【Abstract】Cochlear implants (CIs) have been widely acknowledged that the most successful neural prosthesis used in deafness. More than 300,000 deaf patients in the world received this kind of prosthesis. Although the huge number of deaf people, the amount of CI beneficiaries is still limited. It's still too expensive to afford for most of the candidates. During the past 30 years, there is nonstop exploration in cochlear technology development in China. A 26-electrode cochlear implant Nurotron was devised and conducted in recent years. It has received China's Food and Drug Administration (CFDA) approval in 2011 and European Commission (CE) marking in 2012. It's helpful to lower the cost of CI in China. And it may also be widely used in other countries in the future. This comment will introduce the background of Nurotron, device specification, clinical test, and future prospects. It also reflects the history of CI evolution in China. The future tendency of CI device is more miniaturization and smarter, even move forward to full implantation, combined with new technology and new material.

【Key words】Nurotron CI; Property and performance; Evaluation; the Future

1 诺尔康人工耳蜗研发背景

人工耳蜗是目前应用最成功的神经植入假体技术,世界范围内已有30余万重度以上听障患者通

过人工耳蜗重获听觉功能。目前,三大人工耳蜗公司——澳大利亚Cochlear公司,奥地利Med-EL公司及美国Advanced Bionics公司——基本主导了



杨仕明,主任医师,教授,博士生及博士后导师,听觉植入、耳聋临床和基础研究领域著名专家,国家重点学科带头人,国家973项目首席科学家,现任中国人民解放军总医院耳鼻咽喉头颈外科主任,中国人民解放军总医院听觉植入中心主任,耳聋教育部重点实验室主任,全军声损伤防护重点实验室主任,中华医学会耳鼻咽喉头颈外科分会秘书长,中国医师协会耳鼻咽喉科医师分会副会长,北京医师协会耳鼻咽喉专科分会会长,北京医学会耳鼻咽喉头颈外科学分会副主任委员,中国残疾人康复协会第五届理事会理事,国家人工耳蜗救助项目指导专家,《中华耳科学杂志》主编,《Journal of Otology》主编,《Acta Oto-Laryngologica》国际编委,《Chinese Medical Journal(English)》,《中华耳鼻咽喉头颈外科杂志》等9家杂志编委。主持国家973项目,863项目和国家自然科学基金重点项目等课题。

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全球人工耳蜗市场。但是相对于庞大的耳聋人口基数,仅有少部分候选人群获得了人工耳蜗植入的机会,主要是植入体比较昂贵、传统观念的局限及手术医生技术有限等诸多因素造成的^[1]。为了解决植入体昂贵的问题,中国一直在研发国产人工耳蜗产品。

回顾人工耳蜗技术在中国的发展历史,从1980年北京协和医院研发单导人工耳蜗到多导人工耳蜗研发验证,解放军总医院、北京同仁医院、复旦大学附属耳鼻喉科医院等国内医疗中心先后进行尝试,但国产人工耳蜗相当长时间内都没有在临床上得到广泛应用。尽管如此,围绕人工耳蜗的探索在中国从未停止。近些年,浙江诺尔康、上海力声特、沈阳爱益声等国产人工耳蜗产品相继问世,开始打破进口人工耳蜗在中国的垄断局面^[2]。本文将重点介绍诺尔康人工耳蜗装置的产品特点、临床验证及应用前景等,希望从侧面展现中国人工耳蜗发展的脉络与历程。诺尔康人工耳蜗2006年开始研发并经过临床试验,2011年获得了中国食品药品监督管理局(CFDA)市场准入,2012年获得了欧盟(CE)认证。截至2014年12月,已有1500名中国、2名哥伦比亚、2名土耳其和12名印度听障患者成功植入了诺尔康人工耳蜗装置并取得满意效果。

2 诺尔康人工耳蜗产品的特点

在过去的30年中,人工耳蜗技术已由单电极模拟电信号刺激发展到多电极交互脉冲刺激^[3,4]。现代人工耳蜗系统功能模块的基本组成包括外部部件、跨皮射频传输单元、内部部件和调试部件(临床医生用于调整最佳参数)。诺尔康人工耳蜗的研发理念遵循了现代人工耳蜗系统的要求^[5]。首先,装置遵循欧洲EN 45502-2-3(2010)标准及附加的通用惯例以满足安全性要求。其次,它采用多通道、多刺激策略模式以满足高性能需求。诺尔康人工耳蜗装置具备灵活构架以满足未来需求,设计了2个参考电极和24个工作电极,并且可以产生47个或更多频谱的虚拟通道和精细结构编码,以改善噪声中的言语识别、声调语言理解和音乐理解。此外,装置能支持未来技术水平的延伸,比如其他神经假体的应用,如听神经植入、听性脑干植入、视网膜植入、深部脑刺激等。

诺尔康人工耳蜗的组成是现代人工耳蜗系统的体现,耳背式声音处理器包含双向麦克风、控制

按钮、指示灯、电池盒及射频传输线圈。人工耳蜗在过去10年的进展主要集中在声音预处理和外观上,言语编码策略、射频传输、接收器和电极序列改变则很少。目前所有的人工耳蜗装置,包括诺尔康装置,在外部部件方面都有相似的技术参数。诺尔康射频及内部部件最关键的技术参数^[5]基本介于当前其它可用装置的参数之间。诺尔康电极包含24个蜗内刺激触点和2个蜗外参考电极,其电极阵列具有以下特点:①硬度适宜的直电极无需插入工具或抽离内芯;②刺激电极触点的暴露面积为 0.2 mm^2 ,以 0.8 mm 的间隔分布在电极内侧,电极植入时触点需朝向蜗轴;③初步的颞骨研究及术后临床影像学评估显示,诺尔康电极阵列能够顺利插入 22 mm 深度同时不造成显著损伤;④电极阵列与植入刺激器的连接测试和最大的放电强度均达到欧洲标准EN 45502-2-3(2010)。诺尔康人工耳蜗拥有汉语特色的言语编码策略。声调信息对于有声调语言(如汉语普通话)的识别至关重要,而汉语四声具有各自不同的基频轮廓,诺尔康目前正在开发的E-Tone算法,通过与APS策略共同作用,根据言语基频轮廓来调整振幅包络,从而提高声调识别能力。这将更适应以汉语为母语的中国耳聋人群。

3 诺尔康人工耳蜗临床应用与评价

2009年11月~2010年10月,诺尔康人工耳蜗在中国人民解放军总医院、复旦大学附属耳鼻喉科医院、北京同仁医院、浙江大学医学院附属第二医院、重庆医科大学附属第一医院5家医院完成了60例语后聋受试者(平均年龄 26 ± 12 岁,年龄范围为6~59岁)的临床验证。受试者的平均耳聋持续时间为 7 ± 5 年(时间范围为0.3~15年),术前平均纯音听阈为 $107\pm 11\text{ dB HL}$ 。耳聋原因:耳毒性药物致聋31例、大前庭水管综合征7例、突发性聋5例、脑膜炎2例、噪声性聋2例、未知原因13例。随访情况:60例受试者中,58例完成了1年的随访评估,52例完成了2年的随访评估,48例完成了3年的随访评估。

手术方式与入路和目前常规微创人工耳蜗植入手术相同,耳后做小切口,乳突进路打开面神经隐窝,进入鼓阶前磨出放置接受刺激器的骨床,充分暴露圆窗龛,经圆窗膜或圆窗前下鼓阶开窗植入电极。术后X线或颞骨CT检查植入电极的位置及深度。

临床试验听觉康复效果评估结果显示,人工耳蜗植入前开放式语句识别率平均为0.03%,在开机1、2、4个月测试时分别达到了27%、41%、68%,6个月时达到平台期,36个月测试时识别率达到89%(测试材料为HOPE测试语句^[6]和House测试语句^[7])。语句识别率在不同受试者之间有差别,但在开机之后36个月内个体间差异缩小,均达到较好水平。

在一项严格控制入组条件的研究中,比较了诺尔康人工耳蜗装置和其它进口人工耳蜗装置的术后表现^[8],两组各15例样本在手术年龄(29 ± 13 岁和 25 ± 9 岁)、重度耳聋持续时间(7 ± 5 年和 7 ± 4 年)、性别(9男6女和10男5女)及其他听力学和病因学因素方面做了严格匹配,两组使用同样的手术和评价方案。结果显示,两组患者植入不同人工耳蜗装置后听觉言语康复效果无统计学差异。

诺尔康人工耳蜗60例语后聋受试者的临床验证数据提交中国食品药品监督管理局(CFDA)后获批继续儿童试验。2011年4月~2011年6月,60例双耳重度或极重度感音神经性耳聋患儿(平均年龄 39.61 ± 18.87 月,年龄范围12~71月)在中国人民解放军总医院、北京同仁医院、复旦大学附属耳鼻喉科医院植入了诺尔康人工耳蜗系统。中国聋儿康复研究中心和解放军总医院合作对这60例聋儿人工耳蜗植入后情况进行随访,结果显示60例受试者随着人工耳蜗使用时间的延长,听觉能力逐渐提高;术后1年声场言语频率的助听听阈测试,韵母、声母、单音节和双音节识别测试,林氏六音测试,IT-MAIS问卷评估结果较术前均显著提高;人工耳蜗设备工作状态稳定,生物相容性好,无与手术相关的严重并发症发生。具体情况在本期“儿童患者植入诺尔康-晨星人工耳蜗术后听觉康复效果分析”一文及后续文章中报道。

解放军总医院耳鼻咽喉头颈外科听觉植入中心自1996年开展多导人工耳蜗植入工作以来,至今已为2000余例重度以上耳聋患者成功植入人工耳蜗,并以每年200~300例的速度增长^[9]。我们对不同电极人工耳蜗植入患者^[10]、语后聋患者^[11-13]、老年聋患者^[14-16]、各种综合征型耳聋患者^[17]、复杂病例的人工耳蜗选择^[18,19]等做了大量探讨和研究。19年的临床观察显示,早期植入人工耳蜗的患者99%以上设备仍工作正常,配戴者获益良

好。不同电极人工耳蜗植入虽然言语识别率差异没有统计学意义,但产品更新换代对患者佩戴的舒适性、美观性、附加功能和声音处理细节仍有很大改善。植入时机和适应证选择对后期康复效果至关重要,近些年人工耳蜗植入开始向小龄化发展,1岁以内的人工耳蜗植入病例康复效果更佳。而在前些年存在争议的老年聋患者,研究结果显示人工耳蜗能有效帮助他们提高听力和言语交流能力,显著改善老年人的生活质量。随着人工耳蜗植入适应证范围扩大,各类综合征型耳聋患者、听神经病患者、复杂病例耳聋患者在术前和术中充分评估和准备的前提下,在新的手术技术的帮助下(如术中CT引导电极植入),人工耳蜗成功植入均能不同程度地帮助其重建听力。自2010年3月~2014年12月,解放军总医院共有139例诺尔康人工耳蜗植入者,我们针对这些患者做了一系列随访研究。目前来看,除1例因过敏导致二次手术外,其余患者植入设备及体外机工作正常,听觉言语康复效果存在个体差异,但整体效果满意。对于植入诺尔康人工耳蜗后耳鸣的研究,可见本期“诺尔康人工耳蜗植入对耳鸣的影响研究”一文。另外,我们也发现诺尔康体外设备带电时间稍短,能耗问题有进一步改进、提升的空间。

4 展望

中国人工耳蜗技术的发展和进步是对发展中国家乃至全世界听觉植入技术进步的重要贡献。以诺尔康为代表的国产人工耳蜗逐步成为较成熟的产品,其成功研发不但打破了技术壁垒,也因其价格低有望使更多听障人士从中获益。同时,汉语音调编码策略的研发应用,使国产人工耳蜗与基于英语和德语为母语者设计的进口人工耳蜗相比,更加适用于中国市场。国产人工耳蜗的高性能和低价位,有望推动国内人工耳蜗植入新格局的形成。今年2月在美国迈阿密大学耳鼻咽喉头颈外科系举办的“第二届高级颞骨研修班”即指定诺尔康人工耳蜗产品电极为研修班学员的训练电极,并拟对诺尔康电极特性进行更加深入的研究。国际同行的认可使诺尔康人工耳蜗向国际市场又迈进了一步。未来的人工耳蜗产品发展方向是更加小巧、人性化,进一步融合相关领域的新技术,特别是随着电子技术的发展和生物治疗技术的新发现,人工耳蜗植入将更加多元化,最终可能实现人工耳蜗全植入和听觉通路全覆盖。

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《中国听力语言康复科学杂志》征稿启事

《中国听力语言康复科学杂志》是由中国残疾人联合会主管, 中国聋儿康复研究中心主办的国家级学术期刊。2006年, 本刊被评为中国科技论文统计源期刊及中国科技核心期刊。本刊宗旨为传播听力语言康复科学的新理念、新技术、新方法, 使读者及时了解听力语言康复科学领域内的基础理论、临床实践、康复教育及相关学科的最新动态与进展。本刊于2003年11月创刊, 为双月刊, 大16开, 每期80页, 设有专家笔谈、基础研究、临床研究、康复教育、康复论坛、综述、个案研究、新技术与新进展、经验交流等有特色的栏目。

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人工耳蜗对语后聋患者双侧耳鸣的影响

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【摘要】 目的 观察人工耳蜗植入对语后聋患者双侧耳鸣的影响,探讨人工耳蜗植入治疗耳鸣的可行性。方法 对 32 例(64 耳)术前双侧耳鸣语后聋人工耳蜗植入者(男 13 例,女 19 例;31 例单侧植入,1 例双侧植入)进行术前、术后耳鸣问卷调查评估。测试材料采用耳鸣残疾评估量表(Tinnitus Handicap Inventory, THI),同时记录患者耳鸣的特征,分析植入同侧及对侧耳鸣术前术后响度的变化情况,并观察人工耳蜗开机工作和关机两种状态对耳鸣响度的影响。采用 SPSS18.0 软件进行数据统计分析。结果 22 例患者(71.0%)术后 THI 得分比术前下降 ≥ 20 分。术前 THI 总分平均为(56.4 \pm 18.1)分,术后 THI 总分平均为(24.7 \pm 22.7)分,经配对 *t* 检验分析,得分手术前后差异具有统计学意义($t=8.037, P<0.05$)。患者术后未开机情况下,同侧耳鸣 81.9%(27/33)减弱或消失,18.2%(6/33)响度未变,无响度加重情况出现;对侧耳鸣 71.0%(22/31)术后减弱或消失,16.1%(5/31)响度未变,12.9%(4/31)响度加重。在开机状态下,同侧耳鸣 97.0%(32/33)减弱或消失,对侧耳鸣 83.9%(26/31)减弱或消失。结论 人工耳蜗植入对语后聋患者的耳鸣症状具有较好的抑制作用,但也存在耳鸣加重的风险。

【关键词】 耳蜗植入术; 耳鸣; 问卷调查

Effect of cochlear implantation on bilateral perceived tinnitus of postlingually deafened patients
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【Abstract】 Objective The aim of the study was to evaluate the effects of cochlear implantation on bilateral perceived tinnitus of postlingually deafened patients. **Method** Total of 32 postlingually deafened cochlear implant recipients (13 males, 19 females; 31 unilateral, 1 bilateral cochlear implantation) with bilateral tinnitus were assessed by Tinnitus Handicap Inventory (THI) before and after implantation. Furthermore, characteristics information of tinnitus were recorded to analyze the variety of tinnitus. Intensity of tinnitus in ipsilateral and contralateral ears was investigated when cochlear implant was switched on and off. Statistical analysis was performed by SPSS 18.0. **Results** Twenty-two patients (71.0%) got a decreased THI score of more than 20 points after the operation. The average THI score of pre-operation was 56.4 \pm 18.1, and post-operation score was 24.7 \pm 22.7. A paired-samples *t* test analysis showed a significant difference of the THI total scores ($t=8.037, P<0.05$). Tinnitus in the ipsilateral ear improved in 81.9% (27/33) patients and 18.2% (6/33) unchanged. Tinnitus in the contralateral ear improved in 71.0% (22/31) patients, 16.1% (5/31) unchanged and 12.9% (4/31) worsen. Tinnitus of ipsilateral ears improved or abolished in 97.0% (32/33) patients, while 83.9% (26/31) of contralateral ear got reduction or absence of loudness when cochlear implant was switched on. **Conclusions** As an electrical stimulation treatment method, cochlear implant has the inhibitory effect on tinnitus. However, cases of tinnitus aggravation were found, further data is still necessary before considering CI as a treatment of tinnitus.

【Key words】 Cochlear implantation; Tinnitus; Questionnaires

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耳鸣是指在无外源性声音或电刺激的情况下,人的耳内或颅内产生的一种声音感觉^[1]。作为一种常见的临床症状,耳鸣在人群中的发生率可达 10%~15%^[2]。目前对耳鸣的治疗方法有很多种,如使用扩张血管、改善微循环的药物治疗,掩蔽治疗,习服治疗,心理治疗等^[3]。但由于耳鸣不是一种独立的疾病,其发病原因多种多样,且发病机制尚未明确,因此目前对耳鸣还没有统一且完全有效的治疗方法。

耳鸣的发生常与耳聋相伴,人工耳蜗植入的人群是重度以上感音神经性聋的患者,因此耳鸣在这个群体中更为常见,其发生比例可达 67%~100%^[4]。国外已有学者开始研究多导人工耳蜗植入对耳鸣的抑制作用,综合文献发现,在单侧人工耳蜗植入者中,33%~66% 术后耳鸣完全消失,25%~39% 耳鸣减轻或缓解,但也有 5%~8% 的患者在术后出现耳鸣或耳鸣加重^[5]。早在 1998 年 Aschendorff 等^[6]与 Demajumdar 等^[7]学者就提出优先选择有耳鸣一侧作为人工耳蜗植入侧,以达到同时治疗耳聋与耳鸣的目的。更有学者认为,对于听力正常或轻度下降但伴有重度耳鸣的患者可以考虑选择人工耳蜗植入治疗耳鸣^[8]。目前,国内对此方面的研究报道较少,适用于评价我国人工耳蜗植入对耳鸣影响的调查问卷也有待开发。本研究针对双侧重度与极重度语后聋这一耳鸣发生率较高的人群,通过耳鸣残疾评估量表(Tinnitus Handicap Inventory, THI)对人工耳蜗植入术前和术后的耳鸣情况进行调查评估,探讨人工耳蜗治疗耳鸣的可行性。

资料与方法

一、研究对象

2009 年 8 月至 2014 年 2 月期间在解放军总医院听觉植入中心接受人工耳蜗植入的双侧重度-极重度语后聋患者 32 例(64 耳),术前均自述有双侧耳鸣,术后开机在半年以上。其中男性 13 例,女性 19 例;年龄 14~67 岁,平均(37.7±17.2)岁。就医时均以耳聋为主诉,耳聋时间 1~46 年,平均(14.5±12.9)年;人工耳蜗植入前耳鸣持续病程 1~46 年,平均(11.7±11.0)年。单侧植入 31 例,双侧植入 1 例。患者耳聋病因、植入侧别及人工耳蜗产品型号见表 1。其中患者 S14 患有抑郁症,自述术前有双侧耳鸣,现术后耳鸣消失,但因服用抗抑郁药物影响记忆,无法准确填写问卷,故仅收集到其基本信息及对耳鸣强度的主观评价,其余问卷项目均未填

写。本研究为回顾性研究,患者在进行人工耳蜗术后调试时自愿参与并填写术前及术后耳鸣的问卷调查。调查评估工作由听觉植入中心的调机师完成。

二、耳鸣评估方法

1. 中文版 THI 量表:我们采用的 THI 量表最初由 Newman 在 1996 年开发,主要用于评估耳鸣患者的主观感受^[9]。2007 年,石秋兰等^[10]研译了中文版 THI 问卷,通过对 199 例耳鸣患者的调查,对量表进行了信度、效度等方面的评价,现中文版已被普遍应用于国内对耳鸣严重程度评估的工作中。与英文版 THI 一致,中文版量表共含 25 个问题,受试者要求在“是(Yes)”、“有时(Sometimes)”、“没有(No)”3 个备选答案中进行选择。这三个选项的分值分别为 4 分、2 分和 0 分。量表从三个维度对耳鸣进行定量评价,第一个维度是功能性维度(functional subscale),共 11 个问题,主要评估耳鸣患者的精神功能、社会/职业功能和身体功能;第二个维度为情感性维度(emotional subscale),共 9 个问题,主要评估患者对耳鸣的情感反应;最后一个维度为灾难性维度(catastrophic subscale),共 5 个问题,主要评估耳鸣对患者所造成的影响的严重程度。

2. 人工耳蜗患者耳鸣特征调查:收集人工耳蜗植入者耳鸣的特征情况,对耳鸣类型、耳鸣困扰及左右耳的耳鸣响度进行详细记录^[11]。其中耳鸣的响度由人工耳蜗植入者主观评判,分为 7 个等级:0 级,无耳鸣;1 级,耳鸣轻微响,似有似无;2 级,耳鸣轻微响,但肯定可以听到;3 级,耳鸣中度响;4 级,耳鸣很响;5 级,耳鸣很响,有吵闹感;6 级,耳鸣极响,难以忍受。对于开机半年以上耳鸣未消失的患者,记录其人工耳蜗开机工作和关机两种情况下耳鸣响度的变化。由于人工耳蜗对耳鸣存在残余抑制(residual inhibition),本研究在患者关闭人工耳蜗 1 h 后,记录关闭耳蜗状态下的耳鸣响度。

三、统计学方法

使用 SPSS 18.0 软件进行数据统计分析。患者术前、术后 THI 量表总分、三个维度得分及耳鸣特征信息数据(耳聋时长、耳鸣病程、同对侧响度等)均呈正态分布。采用配对 *t* 检验分析手术前后的差异, $P < 0.05$ 为差异有统计学意义。相关性分析采用双侧 Pearson 二元变量相关分析, $P < 0.01$ 为差异具有统计学意义。

结 果

一、THI 量表结果

表 1 32 例双侧耳鸣语后聋人工耳蜗植入者的一般信息

植人者	年龄(岁)	耳鸣病程(年)	耳聋病因	植人侧别	植人体型号	处理器型号
S1	28	10	药物中毒(链霉素)	右	奥地利 Sonata	Opus1
S2	39	30	药物中毒	右	美国 Hilex90k	Hamony
S3	63	31	突发性聋	左	澳大利亚 CI24RCA	Esprint3G
S4	19	8	大前庭导水管综合征	左	澳大利亚 CI24RE	Freedom
S5	61	20	右耳突发性聋,左耳不明原因	左	奥地利 Sonata	Opus1
S6	28	13	不明原因	右	奥地利 Sonata	Opus1
S7	60	6	老年性聋	右	奥地利 Sonata	Opus1
S8	16	6	不明原因	右	诺尔康 CS10A	NSP-60B
S9	24	4	不明原因	右	美国 Hilex90k	Hamony
S10	29	6	药物中毒	右	美国 Hilex90k	Hamony
S11	67	30	药物中毒(链霉素)	右	澳大利亚 CI24RCA	Esprint3G
S12	27	5	药物中毒(庆大霉素)	右	奥地利 C40+	Opus1
S13	27	10	发热后听力下降	左	澳大利亚 CI24RCA	Esprint3G
S14	24	2	不明原因	右	澳大利亚 CI24RE	Freedom
S15	35	9	多发性神经纤维瘤病,γ刀术后	右	诺尔康 CS10A	NSP-60B
S16	17	15	大前庭导水管综合征	右	澳大利亚 CI24RE	Freedom
S17	57	12	老年性聋	右	澳大利亚 CI24RCA	Esprint3G
S18	58	3	外伤	右	美国 Hilex90k	Hamony
S19	14	1	突发性聋,耳蜗有少许纤维化	双	奥地利 Sonata	Opus1
S20	59	20	遗传性因素	右	澳大利亚 CI24RCA	Freedom
S21	30	4	药物中毒	左	奥地利 Concerto	Opus2
S22	51	32	双耳中耳炎病史,乙状窦前移	右	美国 Hilex90k	Hamony
S23	59	12	右侧听神经瘤γ刀术后,左侧突发性聋	左	诺尔康 CS10A	NSP-60B
S24	25	3	突发性聋	右	奥地利 Sonata	Opus1
S25	21	1.5	头外伤后听力下降,术中发现有迷路炎	右	奥地利 Sonata	Opus1
S26	55	46	9岁时脑膜炎病史,内听道略窄,锤砧骨融合	左	诺尔康 CS10A	NSP-60B
S27	25	5	大前庭导水管综合征	右	奥地利 Pulsar	Opus1
S28	44	10	突发性聋	左	澳大利亚 CI24RCA	Esprint3G
S29	44	7	药物中毒	右	澳大利亚 CI24RCA	Esprint3G
S30	21	3	大前庭导水管综合征	右	澳大利亚 CI24RE	Freedom
S31	21	1	突发性聋	右	澳大利亚 CI24RE	Freedom
S32	59	10	感音神经性聋	左	奥地利 C40+	Opus1

1. THI 总分及三个维度得分:THI 量表根据患者的回答计分,得分越高耳鸣的程度越重。耳鸣程度 I 级(轻微,THI 得分 0~16 分), II 级(轻度,THI 得分 18~36 分), III 级(中度,THI 得分 38~56 分), IV 级(重度,THI 得分 58~76 分), V 级(灾难性,THI 得分 78~100 分)。根据 Newman 等^[12]研究,治疗后 THI 得分比治疗前减少≥20 分时表明治疗有效。本研究共收集到 31 例患者的 THI 量表结果,其术前耳鸣程度分布及术后耳鸣程度分布见图 1。术前 V 级灾难性耳鸣 3 例(9.7%)、IV 级重度耳鸣 13 例(41.9%)、III 级中度耳鸣 11 例(35.5%)、II 级轻度耳鸣 4 例

(12.9%)。人工耳蜗植入术后 31 例受试者中 THI 得分比术前下降≥20 分者有 22 例,占总体的

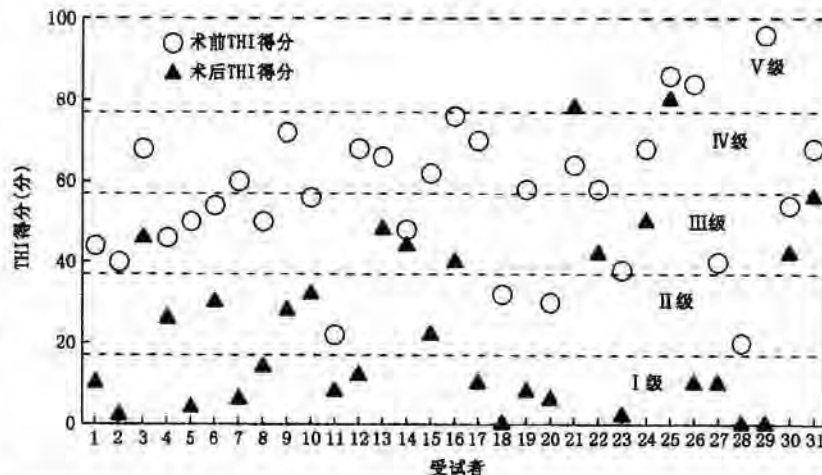


图 1 31 例语后聋耳鸣人工耳蜗植入者术前及术后耳鸣残疾评估量表(THI)得分情况

71.0%。术前 THI 总分平均为(56.4 ± 18.1)分,术后平均为(24.7 ± 22.7)分,经配对 *t* 检验, *t* = 8.037, *P* < 0.05, 差异具有统计学意义, 即人工耳蜗对植入者的耳鸣具有明显的改善作用。

对 THI 量表的三个子维度进行统计, 配对 *t* 检验显示, 31 例患者术前术后的功能性得分 (*t* = 6.641, *P* = 0.000)、情感性得分 (*t* = 6.979, *P* = 0.000)、灾难性得分 (*t* = 8.905, *P* = 0.000), 差异均具有统计学意义(图 2)。该结果提示人工耳蜗植入人对耳鸣患者的功能性、情感性及耳鸣灾难性改善均具有显著效果。

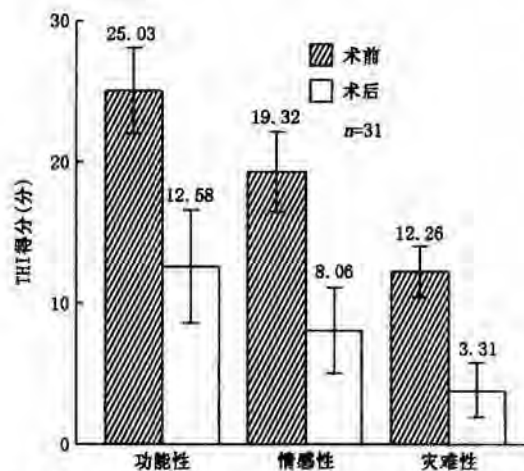


图 2 31 例术后聋耳鸣人工耳蜗植入者耳鸣残疾评估量表 (THI) 中功能性、情感性及灾难性得分的改善情况

2. 术前术后 THI 总分变化与三个维度变化的相关性分析: 将术后 THI 总分的变化值记为 Δ THI, 三个维度得分的变化值分别记为 Δ 功能性、 Δ 情感性、 Δ 灾难性, 分析 Δ THI 与三个维度得分变化的相关性。经双侧 Pearson 检验, *P* 值均 < 0.01, 具有统计学意义(表 2), Δ THI 与三个维度得分的变化均高度相关。

表 2 THI 量表总分与三个维度得分的相关性分析 (*n* = 31)

量表维度	<i>r</i> 值	<i>P</i> 值
Δ 功能性	0.928	0.000
Δ 情感性	0.904	0.000
Δ 灾难性	0.793	0.000

二、人工耳蜗患者耳鸣特征调查结果

经调查, 只有少数患者(4 例)在术前接受过耳鸣治疗, 但效果均不理想。31 例患者中有 21 例为不明原因的耳鸣, 6 例在情绪不佳时会引起耳鸣, 2 例听神经瘤患者术前伴有较重的耳鸣, 1 例患者外伤后产生耳鸣, 1 例突发性聋后产生耳鸣。31 例患

者术前大部分为听力逐渐下降, 其中 24 例反映耳鸣影响了聆听质量。12 例表述耳鸣引发失落、焦虑等情绪影响。其他患者指出耳鸣对工作、睡眠和记忆力也造成了一定困扰。

患者术前的耳聋时间及耳鸣病程各不相同, 为探讨二者是否存在关联, 我们对患者术前耳聋时间及耳鸣病程进行了相关性分析。结果表明, 相关系数 *r* = 0.627, 双侧 Pearson 检验 *P* = 0.000, 有统计学意义, 即耳聋时长与耳鸣病程具有相关性。

同时本研究也探讨了术前耳聋时间、耳鸣病程与耳鸣总体改善 (Δ THI) 的相关性。经统计, 植入前耳聋时间与 Δ THI 之间, *r* = 0.143, *P* = 0.443, 无统计学意义, 即两者无相关性。植入前耳鸣病程与 Δ THI 之间, *r* = 0.380, *P* = 0.035, 无统计学意义, 同属非相关。即耳聋时间、耳鸣病程均与耳鸣总体改善 (Δ THI) 无统计学相关性。

32 例患者的双侧耳鸣在植入人工耳蜗后均有不同程度的改善。耳鸣在手术侧记为同侧耳鸣, 在非植入侧为对侧耳鸣, 本研究同侧耳鸣 33 耳, 对侧耳鸣 31 耳。对患者耳蜗开机和关机两种情况下的同侧及对侧耳鸣的状况进行主观等级评分, 术后同侧及对侧耳鸣的改变情况见表 3。

表 3 32 例双侧耳鸣人工耳蜗植入者术后同侧与对侧耳鸣的变化 [耳 (%)]

耳鸣改变情况	同侧耳鸣		对侧耳鸣	
	耳蜗关机	耳蜗开机	耳蜗关机	耳蜗开机
消失	15 (45.5)	23 (69.7)	10 (32.3)	19 (61.3)
响度减轻	12 (36.4)	9 (27.3)	12 (38.7)	7 (22.6)
响度未变	6 (18.2)	1 (3.0)	5 (16.1)	4 (12.9)
响度加重	0 (0.0)	0 (0.0)	4 (12.9)	1 (3.0)

手术后 THI 总分变化 (Δ THI) 与手术同侧及对侧耳鸣的变化也是我们需要探讨的问题。除患者 S14 未参与 THI 测试, 我们对其余 31 例患者的同侧对侧耳鸣变化情况与耳鸣 Δ THI 得分进行了相关性的分析。耳鸣的响度分为 0~6 个等级, 耳鸣的变化记为术前到术后耳蜗开机状态下的变化级。将同侧及对侧耳鸣等级的变化分别与 Δ THI 进行相关性分析, 结果显示, 同侧与 Δ THI 的相关系数 *r* = 0.494, *P* = 0.005; 对侧与 Δ THI 的相关系数 *r* = 0.550, *P* = 0.001。

讨 论

越来越多的研究发现, 人工耳蜗在一定程度上可以对耳鸣产生抑制作用。本研究调查的患者大多

数术后耳鸣消失或响度减弱,但同时也观察到耳鸣持续或加剧的情况。在调查中发现,耳鸣情况得到缓解的患者表述人工耳蜗聆听的效果也更好,而耳鸣未变或加剧的患者感到使用人工耳蜗受到干扰而聆听不清晰。耳聋伴有耳鸣的患者术前大多为听力逐渐下降,且耳聋时间与耳鸣病程具有一定的相关性,患者已经有过长时间被耳鸣干扰听力的经历。配戴耳蜗后植入者的听力得到改善,但同时对耳鸣的存在也较术前更为关注,术后耳鸣会成为评价耳蜗聆听效果的重要因素。因此人工耳蜗对于耳鸣的治疗作用也更加具有实际意义。耳鸣对患者的影响不仅仅表现在聆听效果上,在以往研究报道中,耳鸣对患者日常活动功能情况及心理状态均会产生极其严重的干扰^[13]。本研究发现人工耳蜗对耳鸣患者的功能得分及情感得分均具有较大的影响。功能性维度的变化提示,患者在配戴耳蜗后在精神功能、社会/职业功能和身体功能方面有着整体的改善。而情感反应同样是评价耳鸣治疗效果的必要项目,同时也是影响耳鸣变化的重要因素,二者相互作用。耳鸣可使患者产生焦虑、痛苦、愤怒、烦躁等情绪,严重者可使患者抑郁甚至产生自杀的念头^[14],而不良情绪同时可加剧耳鸣的存在和影响。在问卷调查时发现,62.5%的患者自述当情绪不佳时会引起耳鸣的加剧。THI 情感得分的变化提示,人工耳蜗对耳鸣患者的情感反应同样具有改善作用。

本研究在耳鸣特征调查问卷中也对患者的同、对侧耳鸣的变化情况进行了收集。手术后 THI 总分变化(Δ THI)与手术同侧及对侧耳鸣的变化也是我们需要探讨的问题。从计算结果看,同侧及对侧耳鸣的变化与 Δ THI 具有正相关关系,结果虽然具有统计意义,但相关系数 r 值并不高。逐个分析患者手术侧与对侧的变化情况可发现,有些患者尽管 THI 总分有所下降,但双侧耳鸣仅表现为一侧下降,另一侧情况未变;患者 S2I 的 THI 总分在术后增加,而患者仅表述对侧耳鸣加重,同侧耳鸣反而有所减缓。可见 THI 总分的变化是同侧与对侧耳鸣共同作用的最终结果,不能仅凭 THI 的变化情况得出双侧耳鸣各自的变化情况。同侧与对侧耳鸣虽与 Δ THI 具有一定相关性,但在评价人工耳蜗治疗耳鸣时也要分别记录和说明,以保证研究的严谨性。

目前人工耳蜗对耳鸣的作用机制有多种解释。2002 年, Mirz 等^[15]借助正电子发射断层扫描(PET)这一功能影像学手段,观察到人工耳蜗可以影响初级听觉皮层及相关区域的耳鸣相关代谢活动,从而

对耳鸣起到抑制作用。Quaranta 等^[16]研究了 41 例患者单侧人工耳蜗后植入后对双侧耳鸣的影响,指出中枢听觉系统可塑性重组作用(plastic reorganization)可能是影响因素之一,即人的中枢听觉系统具有可塑性,中枢神经系统在适应各种听觉感受体验时会相应发生生理性改变。2011 年, Bovo 等^[17]对 51 例语后聋伴严重耳鸣患者进行了研究,进一步推测,耳鸣在术后半年以上较术前有所减轻的机制可能与中枢听觉系统可塑性重组有关。由此可见,对人工耳蜗植入后的耳鸣患者进行长期的跟踪研究是非常有意义的。本研究在收集受试者数据 1 个月,后又对患者的耳鸣情况进行了回访。通过了解,有少部分耳鸣消失的患者仍可存在短暂的耳鸣复发的情况。我们考虑短时间的耳鸣抑制可能是由电刺激或掩蔽作用所引起,如果耳鸣抑制是经过较长时间后逐渐出现,则考虑听觉中枢系统重组的原因。对于人工耳蜗抑制耳鸣随时间变化的过程,我们还需要更长期的观察。

近几年来,相对单侧耳蜗植入,双侧植入因具有增强声源定位、防止听觉剥夺及提高噪声下言语识别等优势,而越来越被提倡。本研究中仅有一例双侧耳蜗植入者,其双侧耳鸣均在术后消失。是否双侧植入对耳鸣治疗也会优于单侧,目前尚无法定论,还应对双侧人工耳蜗植入的耳鸣患者做更多的数据收集及研究。国外 Summerfield 等^[18]对 16 例行对侧人工耳蜗植入术的耳鸣患者进行研究,结果发现 44% 的患者耳鸣加重,8 例术前无耳鸣患者有 50% 在第二次耳蜗植入后出现了耳鸣。此结果显示双侧耳蜗植入的耳鸣发生率反而高于单侧人工耳蜗。目前国内成人双侧人工耳蜗植入患者的数量也在逐渐增加,只有收集足够多的样本量,才能更有利于说明双侧植入对耳鸣治疗的影响。

总之,本研究通过对成人语后聋双侧耳鸣人工耳蜗植入患者进行研究,发现人工耳蜗可对患者耳鸣起到抑制作用,但也发现有耳鸣加重的现象。这说明,人工耳蜗作为一种耳鸣治疗的方法有其积极作用,但为了单纯治疗耳鸣而选择人工耳蜗植入也存在一定的风险性。

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· 海外撷英 ·

不伴有颈部淋巴结转移的口腔鳞状细胞癌患者发生肿瘤区域复发的原因分析

(北京大学第三医院 曾进摘译) 口腔鳞状细胞癌(oral squamous cell cancer, OSCC)是世界范围内一种常见的恶性肿瘤。该研究试图证实不伴有颈部淋巴结转移的 OSCC 患者出现肿瘤区域复发是否由于术中不完善的抽样送检过程造成的。

研究团队回顾了世界范围内 11 家癌症治疗中心从 1990 年至 2011 年诊断为 OSCC 的 2 258 例患者的病历记录。这些患者通过组织病理学检查证实没有出现淋巴结转移(pN-)但接受了颈淋巴结清扫手术。这些患者中,345 例在影像学检查中怀疑有淋巴结转移。有 193 例患者的颈部标本可以供重新分析。使用 Kaplan-Meier 曲线和多因素分析来计算生存率。主要观察指标包括 5 年总生存率(OS), 疾病特定存活率(DSS)和无病存活率(DFS)。

对临床怀疑有淋巴结转移(cN+)而病理结果证实没有淋巴结转移(pN-)的颈清扫标本进行分析,结果显示,在 193 例患者中,假阴性的例数为 29 例(15%)。初次病理诊断的阴性预测值为 85%。临床认为无淋巴结转移(cN-)且病理结果证实无淋巴结转移(pN-)的病例组,5 年的总生存率为 77.6%, 疾病特定存活率为 87.2%。临床怀疑有淋巴结转移(cN+)而病理结果证实没有淋巴结转移(pN-)的病例组,5 年的总生存率为 62.6%, 疾病特异存活率为 78.5% ($P < 0.001$)。在多因素分析中,临床怀疑有淋巴结转移(cN+)与较低的 5 年总生存率($HR = 1.7, 95\% CI$ 为 1.1 ~ 3.8, $P = 0.03$)和较低的疾病特定存活率($HR = 1.46, 95\% CI$ 为 1.1 ~ 4.1, $P = 0.04$)密切相关。临床怀疑有淋巴结转移(cN+)也和较低的无病存活率(66.3% vs 76.2%, $P = 0.05$)以及较低的局部区域无复发生存率(68.6% vs 78.8%, $P = 0.02$)相关,但是与局部或远处转移无关。

因此研究认为,病理学分期低估了 cN+ 患者发生淋巴结转移的概率。在对病理诊断遗漏淋巴结转移的情况进行修正后,可以推断出颈部淋巴结的影像学证据是一个独立的预测指标,说明术中传统的取样方法可能遗漏转移的病变,这就可以解释这些患者为什么治疗失败。

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诺尔康人工耳蜗植入对耳鸣的影响研究

The Results of Nurotron Cochlear Implant on Tinnitus Patients

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【摘要】目的 研究诺尔康人工耳蜗对耳鸣的治疗效果。**方法** 对26例语后聋患者植入诺尔康人工耳蜗前后进行耳鸣问卷评估,评估材料采用耳鸣残疾评估量表(Tinnitus Handicap Inventory, THI)。**结果** 21例(80.8%)患者自觉耳鸣消失或减弱,其中20例(76.9%)患者耳鸣治疗有效,THI得分与植入人工耳蜗前相比下降 ≥ 20 分,3例患者自觉耳鸣无改善,1例患者自述耳鸣加重,1例患者术前无耳鸣,术后出现中度耳鸣,26例患者人工耳蜗植入术前THI总分平均分 56.5 ± 20.6 ,术后THI总分平均分 20.2 ± 20.9 。经过配对 t 检验分析,配戴人工耳蜗前后的总分及功能性、情感性、严重性3个维度的得分具有显著差异($P=0.000 < 0.05$)。**结论** 人工耳蜗植入对耳鸣有一定程度的改善作用,但仍存在一定风险。

【关键词】 耳鸣;人工耳蜗;耳鸣残疾评估量表

【Abstract】Objective To study the changes of tinnitus after Nurotron cochlear implantation and to evaluate the therapeutic evolution on tinnitus patients. **Methods** 26 Nurotron[®] Venus[™] cochlear implant recipients received the Tinnitus Handicap Inventory investigation before and after wearing the cochlear implant device. **Results** 20 patients (76.9%) got the THI score decreased more than 20 points after the implantation. Three patients had tinnitus intensity unchanged and one patient felt worsen. Furthermore, one patient without tinnitus had it occurred post-operation. The average THI score of pre-operation was 56.5 ± 20.6 , and post-operation score was 20.2 ± 20.9 . Statistical analysis showed a significant difference of the THI total and subscale scores ($P=0.000 < 0.05$). **Conclusion** As an electrical stimulation treatment method, cochlear implant has the inhibitory effect on tinnitus. In order to avoid the bad risk, we need to do more in-depth research on it.

【Key words】 Tinnitus; Cochlear implant; Tinnitus Handicap Inventory (THI)

自20世纪90年代以来,人们越来越重视耳鸣(Tinnitus)对生活质量的影 响。耳鸣虽不致命,却给患者带来焦虑、痛苦、愤怒等烦恼,使患者难以正常入睡,造成失眠、注意力难以集中、记忆力下降等问题^[1],令患者苦不堪言。已有文献报道,人工耳蜗植入患者术前常伴有耳鸣症状,平均可达80%^[2]。值得关注的是,有研究显示人工耳蜗植入能对患者耳鸣产生积极影响^[3,4]。

目前,我国国产人工耳蜗的研发和生产技术已日趋成熟,其中诺尔康人工耳蜗已正式用于临床治疗,并已拥有千余例植入者。本研究拟考察诺尔康人工耳蜗植入对耳鸣的影响。

1 资料与方法

1.1 研究对象

本研究对象为26例国产诺尔康人工耳蜗植入的语后聋患者。植人体型号CS-10A,处理器型号NSP_60B。开机时间大于半年。男性11例,女性15例。年龄13~82岁(平均 37.2 ± 17.1 岁)。术前因耳聋就医,耳聋病程0.5~46年(平均 12.5 ± 11.0 年)。24例术前伴有耳鸣症状,耳鸣病程0~46年(平均 11.1 ± 10.0 年);1例患者忘记术前耳鸣病程时长,1例患者术前无耳鸣。患者基本信息见表1。

1.2 耳鸣评估问卷

本研究采用国际广泛认可的耳鸣残疾评估量表

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(Tinnitus Handicap Inventory, THI)^[5-6]分别对受试者人工耳蜗植入前后的耳鸣程度进行评估。此量表共包含25个问题,测试者要求在“是(Yes)、有时(Sometimes)、没有(No)”3个答案中选择,分值分别为4分、2分和0分。THI问卷根据患者的回答计分,分数越高,代表耳鸣程度越重。

THI问卷25道题目的总分值划分为5个等级,代表耳鸣的不同程度,I级(轻微,0~16分),II级(轻度,18~36分),III级(中度,38~56分),IV级(重度,58~76分),V级(灾难性,78~100分)。根据Newman等研究,治疗后THI得分比治疗前减少 ≥ 20 分时表明治疗有效^[7]。

1.3 统计方法

本研究采用SPSS 18.0软件进行数据分析。使用One-sample Kolmogorov-Smirnov检验分析受试者术前及植入人工耳蜗后THI得分的正态分布情况。若结果显示呈正态分布,则进一步对数据进行配对t检验。

2 结果

2.1 THI总体得分情况

26例患者植入人工耳蜗前后的耳鸣程度分布如图1。

表1 植入者基本信息

患者	人工耳蜗 开机时间(月)	性别	年龄(岁)	耳聋原因	耳聋时长(年)	耳鸣病程(年)	植入耳
S1	56	女	32	药物性聋	10	16	右
S2	56	男	41	突发性聋	5	20	右
S3	56	女	27	药物性聋	3	4	左
S4	32	女	43	药物性聋	17	2	左
S5	59	女	47	突发性聋	8	2	右
S6	55	女	45	药物性聋	12	28	右
S7	56	男	36	药物性聋	8	10	右
S8	56	男	36	不明原因	11	10	右
S9	32	男	29	外伤	8	9	右
S10	56	男	25	不明原因	14	6	左
S11	27	女	44	药物中毒	31	10	右
S12	25	女	31	听神经病	16	16	左
S13	17	女	39	药物中毒	29	不详	右
S14	11	男	82	老年性聋	2	2	左
S15	8	女	77	感音神经性聋	1	10	左
S16	8	男	63	中耳炎	13	13	右
S17	22	女	34	药物中毒	32	22	双
S18	12	男	16	不明原因	14	14	右
S19	10	女	16	不明原因	5	6	右
S20	16	女	24	怀孕时突聋	1	6	左
S21	21	男	35	多发性神经瘤 病,听瘤r刀术后	7	9	右
S22	9	女	13	大前庭导水管 综合症	6	6	右
S23	6	男	28	胆脂瘤术后	0.5	7	左
S24	24	女	55	9岁时脑膜炎史, 内听道略窄, 砧骨融合	46	46	左
S25	16	女	24	发烧打针后 听力下降	15	0	左
S26	12	男	24	中耳炎鼻炎	10	10	右

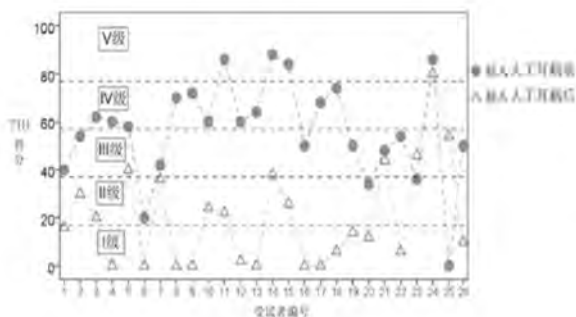


图1 人工耳蜗植入前后THI得分

图1以虚线分割了5个耳鸣程度。术前V级灾难性耳鸣4例(15.4%)、IV级重度耳鸣10例(38.5%)、III级中度耳鸣8例(30.8%)、II级轻度耳鸣3例(11.5%)、无耳鸣1例。植入人工耳蜗后,7例(26.9%)耳鸣消失,14例(53.8%)耳鸣程度减缓。另有3例患者自觉耳鸣无改善;1例患者自述耳鸣加重;1例患者术前无耳鸣,术后出现中度耳鸣。以THI计分标准,治疗有效的人数为20人,占总体的76.9%;

26例患者植入人工耳蜗前THI总分平均为 56.5 ± 20.6 , 术后THI总分平均为 20.2 ± 20.9 , 经配对 *t* 检验, 两者比较具有显著性差异 ($P=0.000 < 0.05$)。

2.2 THI各维度得分

THI量表将耳鸣患者的改善情况以3个维度进行定量评价。第一个维度功能性维度(functional subscale), 共11题, 主要评估耳鸣患者精神功能、社会/职业功能和身体功能; 第二个维度情感性维度(emotional subscale), 共9题, 主要评估患者对耳鸣的情感反应; 第三个维度严重性维度(catastrophic subscale), 共5题, 主要评估耳鸣对患者的影响程度。以此评价耳鸣对患者术前及植入人工耳蜗后生活质量的影响。对26例耳鸣患者植入人工耳蜗前后3个维度的得分进行配对 *t* 检验, 结果如图2所示。

植入人工耳蜗前患者功能性得分为 25.8 ± 10.2 , 情感性得分为 19.2 ± 7.6 , 严重性得分为 11.4 ± 5.6 分; 植入人工耳蜗后患者功能性得分为 9.2 ± 9.2 , 情感性得分为 7.0 ± 7.7 , 严重性得分为 3.9 ± 4.6 分。植入人工耳蜗前后患者功能性、情感性、严重性得分具有显著性差异 ($P < 0.05$), 提示人工耳蜗对受试者耳鸣3个维度均有显著改善效果。

2.3 严重耳鸣患者植入人工耳蜗后的改善情况

本研究26名患者中, 术前THI得分为灾难级

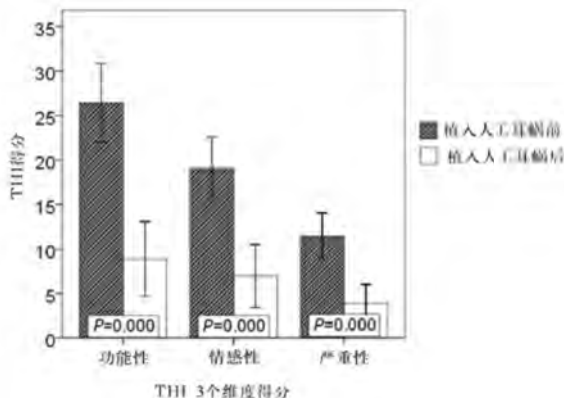


图2 人工耳蜗植入前后3个维度的得分

(IV级)、重度级(V级)的患者占总体的53.8%(14/26)。这部分患者就医时自述耳鸣对主观感受及生活质量有严重影响。植入人工耳蜗后, 14例严重耳鸣患者中7人THI得分降至I级, 4例降至II级, 2例降至III级, 1例患者仍在V级未改善。同时, 本研究将严重耳鸣患者与其余12名患者术后耳鸣变化进行比对, 结果如表2所示。

表2 严重耳鸣患者与其他患者术后耳鸣变化情况

耳鸣变化	严重耳鸣患者		中轻度或无耳鸣患者	
	人数(例)	百分比(%)	人数(例)	百分比(%)
耳鸣消失	5	35.7	2	16.7
耳鸣减弱	8	57.1	6	50.0
耳鸣未变	1	7.1	2	16.7
耳鸣加重	0	0.0	2	16.7

严重耳鸣患者耳鸣消失减弱的比例较中轻度耳鸣患者高; 严重耳鸣患者术后耳鸣未变或加重的比例较中轻度耳鸣患者低。可见, 植入人工耳蜗后严重耳鸣患者的改善效果较好, 且出现耳鸣加重的风险较低。

3 讨论

耳鸣是在无任何外界声源或电刺激时耳内或头部产生的声音感觉, 是一种与外界真实声音无关的声音感知^[8]。其发生的病理生理机制仍不明确, 且尚无一种普遍有效的治疗方法^[9]。本研究26例国产人工耳蜗植入者中, 术前耳鸣在中度以上的患者占53.8%(14/26)。随着患者对耳鸣的逐渐重视, 人工耳蜗术后的效果评价已不仅

局限于对听力及言语识别能力的考查。2009年, Vermeire^[13]等通过对20名受试者的分析,证实了人工耳蜗在提高听力的同时,对耳鸣也起到了良好的抑制作用。Bovo等^[14]通过对语后聋伴严重耳鸣患者进行系统的回顾性研究,证实了人工耳蜗对耳鸣有着确切的治疗作用。

目前,国际上有很多评估耳鸣的量表。2005年, Henry等^[10]在听力学耳鸣处理临床指南中推荐3个量表用于评价耳鸣的严重程度和治疗效果,由Neman等发展的耳鸣残疾评估量表(THI)为其中之一。因其具有良好的信度、效度而被广泛应用于临床评估中^[11,12]。THI量表能从多角度了解耳鸣的严重程度和患者的心理状态,对疗效评估及指导治疗具有一定帮助。有研究发现,人工耳蜗对耳鸣的影响程度与患者的情绪状态有一定相关性。受耳鸣困扰的患者植入人工耳蜗后,30%以上比未有困扰的患者感觉耳鸣治疗效果差^[13]。在本研究的调查过程中,患者往往自述耳鸣与烦躁情绪互为诱发原因。焦虑、烦躁等情绪可引起耳鸣加重,同时耳鸣又可引发患者的负面情绪。通过THI问卷调查可使听力师及时了解患者心理变化,从而给患者积极的心理疏导及建立合理的期望。

行人工耳蜗植入术前就医的患者以耳聋为主诉。伴严重耳鸣的患者会在就诊时主动表述所受耳鸣的困扰,部分患者经药物治疗无效。耳鸣较轻的患者往往只关注对耳聋的治疗,严重耳鸣患者对耳鸣能否改善更加关注,对于这一群体术后的耳鸣情况也应加以重视。在已有文献中显示,严重耳鸣患者可以考虑选择人工耳蜗植入进行治疗^[14]。在国外已有研究中,人工耳蜗术后出现耳鸣或耳鸣加重的情况约占5%~8%^[15]。本研究严重耳鸣患者中未见这一状况,其他患者中这一比例占7.7%,可见采用人工耳蜗治疗耳鸣仍存在一定风险。对于适应证的条件应严格把关,其可行性也应密切结合患者的具体病情。对于严重耳鸣伴轻度听力损失或听力正常的患者,要为其建立合理的期望值并告知治疗风险。

4 结论

本研究结果表明,通过植入人工耳蜗可对患者的耳鸣产生一定的缓解作用,甚至可使耳鸣消失。但仍有部分患者耳鸣未得到改善甚至加重。由此可见,通过实施人工耳蜗植入方法治疗耳

鸣具有一定的风险。何种耳鸣适用于通过人工耳蜗治疗,仍需进行更深入的研究以提供充分的理论依据。本研究样本量较小,可考虑在未来的研究中增加调查对象的数量,进一步验证和探讨人工耳蜗对严重耳鸣患者的影响。

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人工耳蜗：中国深度耳聋患者的新未来

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内容摘要：自20世纪80年代人工耳蜗问世以来，人工耳蜗已经成为了世界多地重度和深度耳聋患者的常规治疗手段。本文描述了人工耳蜗系统的基本设计，包括一个外部声音处理器，植入接收/刺激器以及耳蜗内刺激电极阵列。此外，本文还对现今临床和实验室研究领域以及关键挑战等进行了阐述，这些研究将对人工耳蜗技术在中国的广泛应用产生影响。

关键词：人工耳蜗 电极设计 诺尔康

Cochlear Implants: a New Future for Children and Adults with Profound Hearing Loss in China

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Abstract: Cochlear implants have become the standard of care for the treatment of severe and profound hearing loss in many parts of the world since their introduction in the 1980's. This article describes the basic design of cochlear implant systems which include an external sound processor, implanted receiver/stimulator and a stimulating electrode array which is located in the cochlea. Current areas of clinical and laboratory research and critical challenges that impact the broad application of this technology in China are also presented.

Key words: cochlear implant, electrode design, Nurotron

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0. 引言

宸宸（见图1）于2010年生于河北省。他的父母最初发现他对于周围的声音没有反应，于是到当地的医院检查证实宸宸患有耳聋。父母经过多方努力，终于宸宸于2011年在上海五官科医院接受了人工耳蜗植入。现在，他的言语和听觉能力使得他能够和其他小朋友一样参加正常学习并和他人顺畅地交流。

当人们发现耳聋对于一个像宸宸这样的小孩来说比失明更具有挑战性时，通常都会感到吃惊。

研究表明，听障儿童比失明的儿童更少完成教育，雇佣率和终身所得更低。对于正常听力的成年人，听力损失的发生率随着年龄的增长显著增加。在美国，年龄在45岁到54岁之间的人群中约有2%患有听力障碍。而在55~64岁这一年龄段，这一比例增加到了8.5%；在65~74岁年龄段，这一比例为25%；在年龄超过75岁的人群中，这一比例高达50%。直到20世纪80年代中期，仍没有很好的办法来治疗这些人群。



图1. 宸宸目前已经4岁了。他于2010年在河北省出生，患有先天性深度聋。2011年，他在上海复旦大学附属眼耳鼻喉科医院接受了人工耳蜗植入手术。现在宸宸的人工耳蜗效果很好，已经到正常学校上学了。

在20世纪70年代和80年代早期，澳大利亚、奥地利、美国的研究团队致力于更好地了解耳聋治疗所需要的生理处理过程和工程技术，即“人工耳”。这些现代人工耳蜗的先驱者们发现，从耳蜗传出至大脑的神经元在聋人中大多都是可用

的，如果将一个电极或电极序列植入内耳正确位置，信号就能被传递至中枢神经系统。由于听神经的周边神经元是沿着螺旋状的耳蜗有序排列的，电极阵列的有序刺激能够重新产生多重音高感知，因此，患者能够感知和识别环境声及言语声所需要的声音的复杂形态。确实，早期的研究证实，在靠近蜗底的位置由单个电极刺激产生的电信号被感知为较高的音高，而在电极阵列顶部深插入耳蜗的刺激位点，感知到了较低的音高。言语声通过信号处理技术被划分为一系列的频带，而每一个频带的能量被指定至鼓阶中相应的电极列位点，早期人工耳蜗植入者被证实能够理解言语。现在的人工耳蜗的原理与此相同，而声音处理、封装、电极设计以及整个系统的效能则更先进了，从而提升了效果、可靠性以及患者使用的方便性。由于这些技术的成功，全世界范围内约有400,000人植入了人工耳蜗。

1. 人工耳蜗装置

目前中国市场上的人工耳蜗系统主要有四家制造商生产：美国的Advanced Bionics (<http://www.bionicear.com.cn>)，澳大利亚的Cochlear (<http://www.cochlear.com>)，奥地利的Med El (<http://www.medel.com.cn>)，中国的诺尔康 (<http://www.nurotron.com>)。这些制造商的基本系统设计都非常简单。所有的人工耳蜗包含两个主要部分，一个体外部分和一个体内部分。体外声音处理器通过单个或多个麦克风接收环境声，声音信号的声学频谱被分为多个频带，可以调节每个频带的声音动态范围和水平来满足患者各自的需求，这些信息经编码后被传输至植入体。图2显示了典型人工耳蜗系统的示意图。植入装置包括一个射频天线，一个封装的接收器/刺激器以及刺激电极。天线和刺激器被放置在耳后的皮肤下，而传送来自接收器/刺激器刺激信号的刺激电极则通过从乳突磨骨、开孔插入耳蜗内（见图3）。

人的耳蜗包括横截面上一个大致的螺旋腔，它由三个阶组成。图4显示了三个阶：前庭阶、中阶和鼓阶。对于一个正常听力个体来说，声能震动鼓膜并引起三块听小骨组成的听骨链运动，伴随每一次的声振动，位于最后的听小骨推动牵

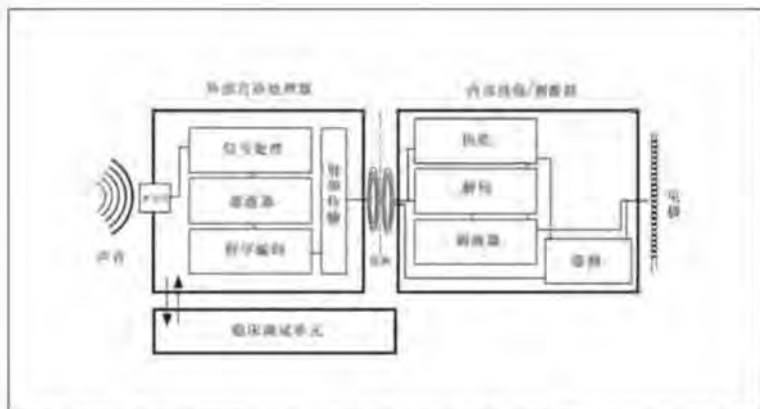


图2. 目前的人工耳蜗系统包含了一个外部的言语处理器，射频发射线圈以及一个内部植入的接受刺激器来刺激耳蜗内的电极阵列。滤波器将输入声滤波成多个频带，以提取理解言语所需要的最重要的信息。使用临床调试界面来调整这些数据流以满足用户个体需要。这些数据通过皮肤传输至体内植入体，进行解码后以脉冲波序列的形式对多通道电极进行刺激。电极的遥测反馈数据以及使用者的神经信号被传输回外部处理器。



图3 图中显示了目前人工耳蜗系统的一部分。戴于耳后的小装置就像传统的助听器，其中包含了外部言语处理器及麦克风。外部的传输线圈通过磁铁与内部接收器的植入线圈相匹配。接收器对信号进行解码并将刺激脉冲发送至耳蜗内的每一个电极位点。

拉前庭阶开口处的卵圆窗膜，并将这些声能通过充满淋巴液的各阶传递。这些声能触发了位于中阶内的毛细胞，这些毛细胞发生反应并通过听神经向中枢神经系统发出动作电位。鼓阶连同大活动度的圆窗膜与中耳腔相隔断，便于声能在耳蜗内的行波衰减过程。

如此看来，耳蜗是声能的感觉指示器，根据声音的不同响度作出响应。然而耳蜗的解剖功能使得它能够对声音进行更复杂的估算工作。中阶内的感音细胞，即毛细胞，位于前庭阶和鼓阶之间的一层膜上。这层基底膜机械地进行“调音”来达到最佳震动，实现从耳蜗近基底处（在卵圆窗和圆窗位置）的高频到近蜗尖部低频的连续频率梯度。这样，通过毛细胞上的精细感知纤毛探测震动的位置和强度，周围声音的频谱信息便被沿着基底膜转换为一个空间频率梯度，或者音质序列。毛细胞上的纤毛弯曲并释放神经冲动，引发动作电位，通过与神经元的连接将动作电位传

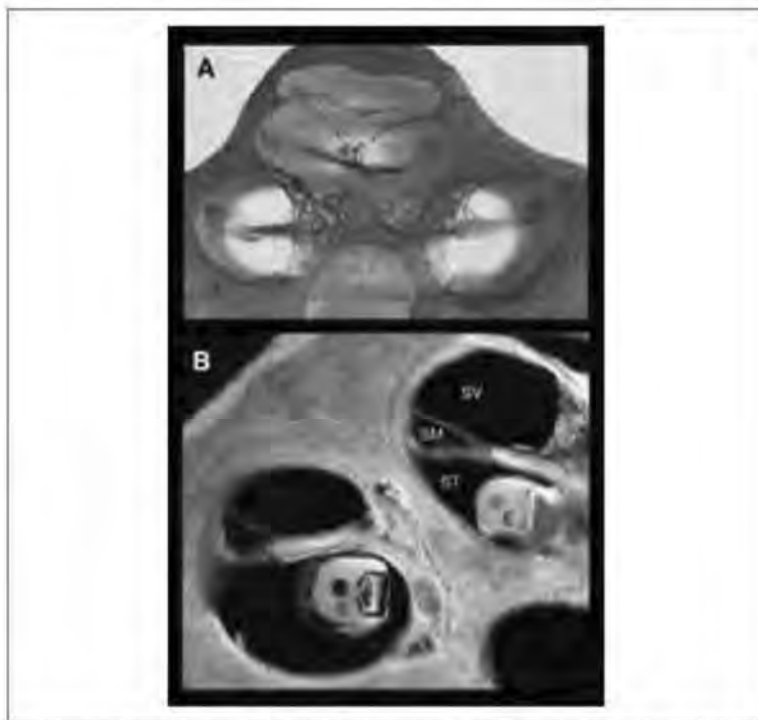


图4 图中显示了人体耳蜗中部 1.5 mm 厚的部分。上图 A 显示了耳蜗的第一、第二和第三转，正常听力耳，骨螺旋板将液体腔隙隔开，基底膜感知声音震动。下图 B 为高倍放大，耳蜗的结构清晰可见。SV 指的是前庭阶，SM 指的是中阶，ST 指的是鼓阶。感音器位于中阶的下缘以及鼓阶。在耳聋患者中，人工耳蜗电极被插入鼓阶内。电极发出的电脉冲刺激耳蜗的核心神经元。这些听神经的神经元将信息传递至大脑。

递至中枢神经系统。在那里，相应的频率梯度被重新建立。

大部分听力损失的真正原因是由于听觉退行性病变使得感音毛细胞丧失，或者这些细胞的先天缺失。幸运的是，在大多数听力损失患者中，从耳蜗传导信号至中枢神经系统的神经元功能尚在。这些传输神经元的存在使得人工耳蜗成为可行的假体装置，其通过附载这些频率编码信息将信号从人工耳蜗传递至大脑，这些信号被转换为类似神经冲动的信号并被中枢神经系统就像听力正常个体一样的方式接收。

2. 人工耳蜗的言语处理方式

根据以上描述，人工耳蜗系统成功的关键为中枢神经系统相应位置进行言语识别所需要的声音信号的关键成分呈现。为了实现这一点，声

音被麦克风拾取后被传递至人工耳蜗处理器，并使用数字带通滤波器将其分为多个频率带。频率带的数量与耳蜗内可用电极数通常保持一致。目

前,各系统的可用滤波通道的数量范围为12到24。如果平衡或操控2到3个位点之间的刺激场产生虚拟通道,那么某些患者感知到的滤波通道数量就可以达到100个以上^[10]。

采用一些策略来分析这些输入的能量带,并将这些处理后的信号分配至耳蜗内正确的刺激位点。最早的多通道言语处理器使用了模拟策略,这种策略简单地对输入声进行滤波,生成与可用通道数相匹配的频带,并压缩每一通道的动态范围来匹配个体患者中每一刺激位点有限的动态范围,且使用这种压缩后的模拟信号来刺激每一个电极位点。研究者很快发现由于每个电极对以不可预知的方式互相干扰,使得最终用于刺激听神经的相互作用的电压梯度被放大或者抵消,进而导致了很多人受试者感受到了相邻通道间非常大的干扰。

为了减轻这种相互干扰,连续的短脉冲序列被及时抵消,这些脉冲序列的间隔通常为10微秒,是由相邻电极位点传递的。20世纪80年代早期,第一次成功实施的这种策略被命名为连续交叉采样(CIS)^[11]。在CIS中,所有刺激通道的数量是基于个体受试者的有效电极位点的数量来设定的。采用全波整流和低通滤波的方式,提取每一个频带的包络。在一个清晰的,没有重叠的伴有每一频带中信号的相应包络的序列中,对电极进行刺激。

在另外的一些策略中,伴随刺激器每一次循环,对较少数量的电极进行选择并刺激。SPEAK、ACE及APS策略是“n of m”处理器架构的典型例子,其中m为带通滤波通道,而n为刺激的通道数。一般来说,“n of m”策略采用6~10个频率带,拥有最大的刺激振幅,这些信号被传送至这些频带的相应电极位点。

对于一些语言来说,受试者的言语识别大量

依赖声调识别。比如汉语,如果言语时相精细结构能够在处理器的输出中表现出来,那么言语识别可以相应地得到提升。FSP和APS即为整合这些快速信号成分的策略,而之前的其他策略,这些快速成分中通常在提取慢速包络后被丢弃。

在虚拟通道刺激中,对相邻电极触点之间的电流级进行平衡,来产生任一电极位点刺激产生的音高间的中间音高。在Advanced Bionics HiRes 120™和诺尔康的系统中,完整的频谱被带通滤波器分割,提取每一个频带的包络,且使用FFT(快速傅里叶变换)分析每一个包络的主要频率。这些频谱峰被用来确定这一频带的虚拟刺激的最佳位点,在耳蜗中最高可分配120个频率位点。

在所有设备中,这些处理后的信号通过皮肤被传输至接收器,并在接收器中被解码,而传输信号中的射频能量则被用来作为植入体的能源。刺激器包含了一个或多个电流源,它们可以被快速转换至每一个蜗内电极触点或者一个远程的参考地级。多电流源(比如Advanced Bionics和诺尔康的系统)允许多电极位点的同时刺激。这些电流源控制通过每个电极组合传递的电流,以补偿个体刺激位点的不同阻抗,并保证每一刺激脉冲的正相位和负相位平衡,来避免对电极阵列周围组织的损伤或者对刺激位点本身的腐蚀效应。

目前的植入的接收刺激器也包括预留遥感线圈,使得信号处理单元能够将数据传输回外部的言语处理器。在大部分情况下,这种遥测能够进行电极功能的基本分析,包括各个电极触点的阻抗测量,从耳蜗中采集神经信号。这些神经反应能够被用来调节婴儿的言语处理器设置水平,因为婴儿通常不能对听力测试进行反馈。另一方面,神经反应也可以被用来评估耳蜗内各个刺激位点的兴奋传播。

3. 接收/刺激器

接收/刺激器包含了一个射频天线以及一个封装的壳体(如图5所示)。目前人工耳蜗系统采

用钛金来封装植入体电子元器件部分,因为钛金具有较高的耐撞击性和生物兼容性。封装的引针

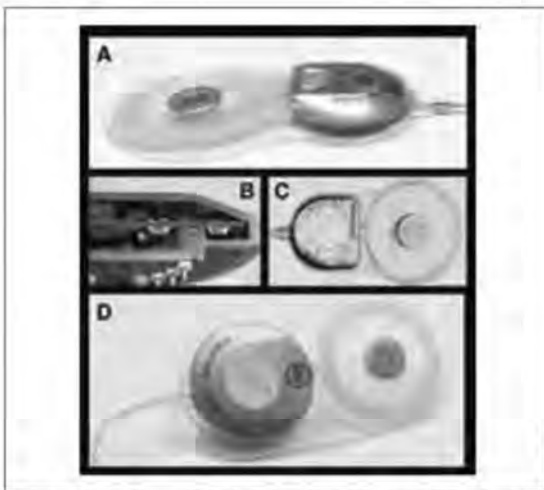


图 5. 置于人工耳蜗系统钛金壳体中的射频接收器和神经刺激器。图中显示了诺尔康 (A), Cochlear (C) 以及 Advanced Bionics (D) 公司的接受刺激器。图 B 显示了诺尔康刺激器的内部结构。

包括外裹绝缘硅胶的铂依合金针, 硅胶陶瓷或铜焊金陶瓷, 用以提供输入天线、内部电子元器件以及电极导线和参考地电极之间的内部连接。比起其他电子植入设备, 人工耳蜗的这些封装显得尤为重要, 因为人工耳蜗引针连接更多, 内容量则更小。如果进行合理的设计和制造, 这些封装技术能够可靠地保持小于 1×10^{-9} atm cc/ 秒的氦气泄漏, 并能保证平均几十年的使用寿命。

封装的接收/刺激器的部件包含来自各个制造商的特有 VLSIC 芯片, 这些芯片被放置在单面或双面的印刷电路板上, 并直接与输入和输出的引针相连接。射频连接提供了运行刺激器的能量, 将数据从外部声音处理器传至各个刺激位点, 并将遥测的数据传输回外部的处理器。这一返还的遥测数据包括对电极阻抗的不间断的检查以及对电刺激反应产生的神经信号的实时监测。目前人工耳蜗系统的数据传输频率范围为 5 MHz 到 49

4. 电极

当今的人工耳蜗电极采用液体或弹性硅胶进行注塑。这些橡胶成分提高了耐撕裂能力以及与内耳环境的兼容性。硅胶载体将刺激触点放置

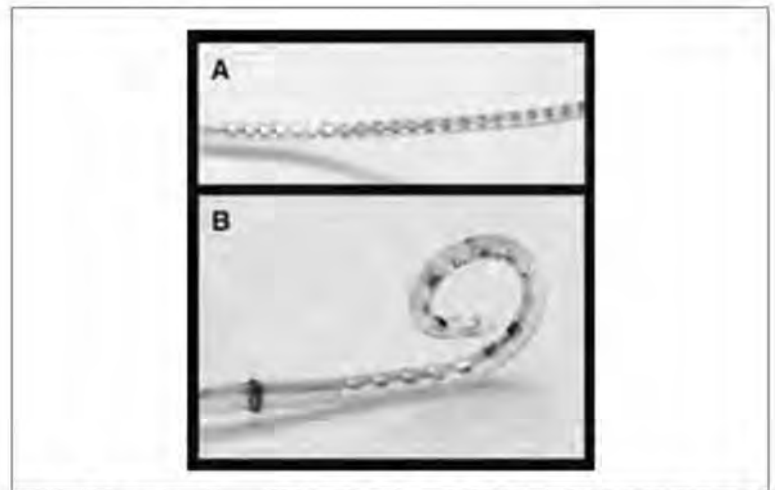


图 6. 图中显示了两种不同的刺激电极。上图 (A) 为诺尔康的 24 导直电极阵列。下图 (B) 为 Advanced Bionics 的 16 导 HiFocus Mid-Scale™ 电极阵列。两种电极均由液体硅胶注塑并采用铂依合金材料作为刺激触点。

MHz, 而运行的刺激速率最高可达 83 KHz。

在植入刺激器中, 对刺激时间, 电极位点指派, 以及刺激水平进行编码来控制每一个刺激位点的固定电流。据上所述, 在言语处理器中, 将处理后的环境声过滤成多个频率带, 将每一个频带对应至一个位点, 而响度范围则根据术后的初始测试进行设定。受试者通常对每个刺激电极位点具有不同的音高感知, 这些感知遵循耳蜗底部音高较高, 蜗尖部 (或植入电极的顶端) 音高较低这一频率分布的自然规律。从刺激器通向电极阵列的细线被焊接在从刺激器输出的封装引线上, 这些引线覆盖有金属保护盖或者环氧树脂密封, 并进行螺旋卷曲处理以减少破损。对每一根引线的顶端触点进行放大, 以减小电极阻抗和在电刺激过程中可能出现的腐蚀。目前的电极和触点设计见图 6。

在正确的位置上, 并保证了插入耳蜗时的正确朝向, 在刺激位点和导线间提供了绝缘层, 并对从植入刺激器到电极尖部的整条导线束进行了保护。

刺激触点以及相连的导线采用的是铂依合金，铂依的比例通常为 90% : 10%，并采用聚四氟乙烯 (Teflon™) 进行绝缘。

目前在中国销售的四家人工耳蜗制造商所制造的蜗内电极的横截面大小、长度、总体的形状以及机械性能差异较大。总的来说，在过去的十年中电极阵列的横截面逐步减小，因为实验室研究以及手术经验表明，较大的电极会增加损伤耳蜗的风险。目前的电极阵列近耳蜗基底部的直径通常为 1.0mm 或更小，而尖部则只有 0.5 mm 或更小。电极阵列的长度范围从 15.0 mm (专门针对耳蜗近基部高频部位进行刺激的短电极) 到 31.5 mm (专门为深插入以及较低频刺激设计的长电极) 不等。

其他影响电极的安全性和频率分布的因素

为：每一个电极的形状以及在鼓阶内植入电极的位置。如果将弯电极 (以 Advanced Bionics HiFocus™ Mid-Scala™, Helix™ 以及 Cochlear Contour Advance™ 电极为例) 置于靠近鼓阶内壁的位置，大约 18mm 的长度就能够覆盖蜗轴内螺旋神经节束的全长^[3]。而直电极阵列 (以 MedEl 和诺尔康的电极为例) 由于较大的耳蜗壁周长，需要更长的长度来产生相似频率位置范围的刺激。除了电极在鼓阶内植入的位置外，电极阵列的形状 (直电极或者弯电极) 也可显著影响耳蜗损伤的可能性。近期的研究显示，与之前的任何一种电极设计相比，一种新型的优化形状和机械性能的弯电极能够减少与鼓阶内壁的接触，从而减少损伤^[4]。而一些直电极优化后的硬度设计也可以减轻损伤，且这些直电极的优势在于易于插入^[5]。

5. 人工耳蜗使用者听到了什么

几乎所有的中文人工耳蜗使用者不依靠唇读，而是靠听随机句子中的关键词来进行言语识别。通过术后调试程序 (调试每个电极通道所需要的响度以及受试者每一个位点的音高感知)，部分受试者可以立刻获得言语感知。很多表现卓越的人工耳蜗使用者能够在仅仅一两个月的康复之后达到最佳的言语识别，他们的测试得分能够达到 100%。部分人工耳蜗使用者的听能恢复较慢，可能需要 36 个月的时间来达到他们的最佳表现。尽管表现差异较大 (尤其对于那些术前耳聋时间

较长的人工耳蜗使用者)，在没有唇读辅助的情况下，大部分人工耳蜗使用者能够达到 75% 以上的句子材料识别。当来自人工耳蜗的言语信号与唇读信息和其他听觉输入相结合时，在日常生活中很难将部分人工耳蜗使用者与正常听力人群区分开。有趣的是，在中国尽管来自 4 家制造商的人工耳蜗系统的言语编码策略不同，策略运行的方式不同以及电极配置不同，但不同人工耳蜗设备使用者的总体表现却没有显著差异^[6]。

6. 人工耳蜗未来的方向

作为重度及深度耳聋患者的常规治疗方式，人工耳蜗已被广泛接受，加之市场竞争日益激烈，加速了对于发展这些装置的研究。第一代人工耳蜗基础科学和工程研究的经济资助主要来源于政府或私人捐助者，而如今这些装置的商业化制造对这方面研究的作用已经变得越来越重要了。目前研究项目的目的主要包括：提高人工耳蜗植入

者听声表现，提高可靠性和使用的方便性，保护甚至支持听力损失患者残存的听神经再生 (这对于假体的长期运行而言至关重要)。

综上所述，人工耳蜗的功能是直接刺激听力损失后耳蜗内的残存神经。因此我们直观地假设比起那些残存神经元较少、排列分散的人工耳蜗使用者来说，有更多残存神经元集中分布在蜗轴

上的患者的人工耳蜗植入效果会更好。动物试验已经证实了这一假设，并显示周围神经元和细胞体的丧失会导致对电极敏感度的下降。伴随着神经元的丧失，分辨耳蜗内刺激位点的能力以及中枢神经系统解码来自耳蜗的高频信号的能力也会随之下降。也就是说，听力损失的时间越长，神经元损失越多，越会造成中枢神经系统频谱分辨能力的下降。伴随听力损失产生的神经元的丧失是不可避免的，然而人工耳蜗手术对患者造成的额外的神经元破坏是可以通过优化电极的机械性能来避免。一些研究已表明，在垂直弯曲设计比水平设计硬度更大时，可以减少从鼓阶向上通过敏感的中阶偏转至前庭阶的可能性。这种类型的手术损伤是在实验室和临床患者身上观察到的最常见的对耳蜗的损伤。Advanced Bionics 和诺尔康已在电极设计制造中融入了这一考虑。

人工耳蜗电极通过鼓阶的轨迹取决于电极阵列本身的曲度以及电极尖部与腔隙边缘的相互作用。Contour Advance™ (Cochlear 公司), HiFocus Mid-Scala™ 和 Helix™ (Advanced Bionics 公司) 的几款弯电极的设计能够在插入阵列过程中减少与鼓阶壁的接触。为减少电极尖部对鼓阶边缘产生压力可能造成的损伤，Contour Advance™ 阵列采用了一种特殊设计的软尖部 (Softip™)。为防止插入中和插入后的接触，HiFocus Mid-Scala™ 电极置于鼓阶的中央，据报道显示，这是接受测试的几款电极中与鼓阶壁接触最少的一款。另一种维持或者提升人工耳蜗植入者神经数量的途径，是通过替换一种或多种自然生长因子来直接支持这些细胞的生物活性，这些因子在正常耳中存在，却随着听力的损失减退了。脑源性神经生长因子 (BDNF) 以及胶质细胞源性神经因子 (GDNF) 是有望用来治疗人类神经退化疾病的两种蛋白质 (ALS 和 Parkinson 这两种疾病就是典型的例子)。这些治疗能够支持耳蜗内听神经的存活并提高人工耳蜗的效果吗？研究已经表明，控制耳聋动物的神经生长因子能够提升耳蜗内神经细胞体的存活，并且在给药提供营养神经因子期间同时通过

人工耳蜗给电刺激可以增加这种效应^[7]。在这些研究中，通过植入毗邻耳蜗位置的微纤渗透管将营养神经因子注射进耳蜗。不幸的是，在停止给药后这些神经元的存活无法持续，而且将这种方法用于长期治疗人类受试者是不现实的。

为了解决这一问题，近期研究正在验证采用基因治疗来刺激内耳神经生长因子的自然产物这一方法。在这一方案中，标记营养神经因子产物的基因编码片段被叠加成活性衰减病毒的基因序列，然后注射进鼓阶内。理论上，内耳细胞会被病毒感染，有用的基因编码就可以被传递至这些细胞，并不限定地复制神经生长因子。数据显示，元踪蛋白的基因编码已在动物内耳细胞中成功转导。下一步工作是要证实神经生长因子基因编码的有效编入，并观察到这些动物中神经存活的增加。如果这些项目成功了，基于基因的治疗联合人工耳蜗这一手段有望提升这些患者的总体表现。

除了这些为保证更好的生物环境以提升人工耳蜗效果所做的努力之外，其他科学工作组正在试图通过在现有设备基础上进行微调、优化的方式来使现有的和将来的使用者受益。正如之前提到过的，通过偏转或集中电场的方式在两个或多个电极间产生虚拟通道，可使得对一些植入者的频谱信息传递得到优化。此外，特定的处理器参数设置可以使系统优化对某些特定言语的识别。以汉语为例，作为声调语言，与欧洲语言的识别不同，声调的识别对汉语来说至关重要。往后的言语处理算法会更好适应不同的语言。

很多人工耳蜗植入者报告双侧植入后言语识别的显著提升。双侧人工耳蜗帮助患者更好地进行声源定位并在噪声较大的环境下提取需要听取的声音。

先进的材料及电子技术也正在促进人工耳蜗植入体的设计和发展。下一代植入接收刺激器将变得更小，使得手术植入更容易、更隐形、更牢固。缩小体积以及增加易用性的终极目标则是全植入式的人工耳蜗系统。将麦克风、言语处理器、刺激器整合至一个植入单元可以摒弃目前暴露在体

外且需要经常维护的体外部分。目前,全植入式人工耳蜗的制造最大的挑战是能源问题。长期可充电电池作为植入系统的一部分可能是解决这一

问题的方法之一。最终,一种能够从机体富有电荷的细胞中或者从肌肉运动中持续产生能量的真正的生物电池可使得人工耳蜗不再需要外部供给。

7. 中国人工耳蜗应用的挑战

过去五年中,人工耳蜗在中国的植入已变得更加普及,并且中国即将将人工耳蜗纳入用于新生深度聋婴儿治疗的常规手段。由于目前中国医疗和技术方面正高速发展,一些挑战将是不可避免的。

第一大挑战为长期的资金支持。中国每年有近 17 万新生儿,新生儿耳聋比率是美国和欧洲的两倍,预计每年有超过 3 万的新生儿适合人工耳蜗植入。此外,中国目前已有大量的人工耳蜗适应证人群,且由于退行性耳聋病变加入使这一行列的人群呈上升趋势。价格最低的诺尔康人工耳蜗系统包括手术费以及一年的康复费用总计大约需要花费 13 万,而其他人工耳蜗品牌则平均需要超过 20 万的费用,这些数字是惊人的。然而,

相比于聋人专项教育的花费以及生活能力的丧失,美国和欧洲的调查证实这些儿童和成人从人工耳蜗获得的收益远大于支出。

第二大挑战为:随着人工耳蜗在中国市场的普及,需要发展大量的专业支持。在未来的几十年内,手术医生、听力师以及康复老师的需求增长会对医院及大学教育体系造成压力。因中国农村的庞大人口,且这些人群与大城市以及先进医疗机构之间的距离远,这一挑战会进一步加深。然而,与这种负担相比,对中国人工耳蜗制造业的发展来说这是独一无二的契机。如果目前人工耳蜗专业人士小群体能够被进一步组织并训练到更高的水平,他们将能够成为一代高效的从业者,并建立一套可以支持人工耳蜗未来庞大需求的临床体系。

8. 结论

人工耳蜗为先天性耳聋儿童和渐进性重度及深度聋成人患者提供了显著的收益。在很多国家,尤其是北欧,人工耳蜗的接受和应用率非常高,90%的全聋儿童在学前就植入了人工耳蜗。从几十年的经验来看,这些年轻的人群已经完全融入了主流社会中,他们进入了主流学校并找到了工作。2013年,中国超过 1 万名成人和儿童植入了人工耳蜗,政府承诺未来将资助更多的儿童植入人工耳蜗^[1]。尽管人工耳蜗初始花费较高,从长期对个人生活能力和生活质量的提升来看,这

些支出是非常值得的。提高长期的资助,生产性价比更高的人工耳蜗以及人工耳蜗专业团队的持续发展,可以使得成千上万的深度聋患者从人工耳蜗技术中受益,和宸宸一起分享有声世界。

致谢:感谢美国加州大学欧文分校的曾凡刚博士以及浙江诺尔康神经电子科技股份有限公司的银力先生协助这篇文章的信息收集。作者本人为加州大学旧金山分校的研究员,并兼任 Advanced Bionics 和诺尔康公司的咨询顾问。

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· 临床研究 ·

诺尔康人工耳蜗使用情况调查及效果分析

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解放军总医院耳鼻咽喉头颈外科

【摘要】目的 探讨诺尔康人工耳蜗植入术后效果。**方法** 2010年3月至2014年12月我科听觉植入中心共有139例重度以上耳聋患者接受了诺尔康人工耳蜗(CS-10A)植入,其中40例植入耳蜗1年以上的患者接受了此次电话随访,回顾性分析这40例植入者的产品日常使用情况和康复效果。将这些患者分成术后聋植入组和术前聋植入组,对患者本人或其家属进行电话随访及问卷调查。随访内容包括CI植入后产品日常使用情况、生活质量改善状况,并使用听觉行为分级标准(CAP)和言语可懂度分级标准(SIR)评价植入者听觉及言语康复情况。**结果** 本研究40例受试者人工耳蜗设备工作正常,每天均日常佩戴,所有受试者评价术后的生活水平较术前改善,对效果满意,CAP和SIR得分较术前显著提高。**结论** 诺尔康人工耳蜗性能稳定,术后听力及言语康复效果满意,能有效提高耳聋患者的生活质量。鉴于人工耳蜗是患者需要终身使用的电子产品,长期结果仍需要进一步随访观察。

【关键词】诺尔康;人工耳蜗;效果分析

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An Analysis of Usage and Outcomes of Nurotron Cochlear Implants

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【Abstract】Objective To report outcomes and safety of usage of Nurotron Cochlear implants over one year. **Methods** One hundred thirty nine patients with severe deafness received Nurotron Cochlear Implantation (CS-10A) from Mar. 2010 to Dec. 2014. Of these patients, 40 took part in follow-ups by telephone. Their daily-use of the Nurotron products, improvement of quality of life, and auditory rehabilitation (evaluated by Categories of Auditory Performance [CAP] and Speech Intelligibility Rating [SIR]) were analyzed. **Results** All of the Nurotron bionic cochlear implants worked well in the 40 interviewed patients. The recipients reported improvement in quality of life and were satisfied with the product. Their CAP and SIR scores significantly improved after operation. **Conclusions** The Nurotron bionic cochlear implants are reliable and helpful in auditory and speech rehabilitation and help improving patients quality of life. In regards of lifelong use of the bionic cochlear implant, long-term observation is needed.

【Key words】Nurotron; Cochlear implant; clinical analysis

人工耳蜗植入(cochlear implantation,CI)是目前公认的对重度和极重度感音神经性耳聋治疗最有效的方法,在中国也已有3万余例耳聋患者接受了人工

耳蜗植入手术。目前中国的人工耳蜗植入设备95%来自于进口,平均费用都在20万元以上,昂贵的费用是我国众多耳聋患者无法获益于人工耳蜗的重要原因。直到20世纪80年代由王正敏院士团队研制的国产感应式单通道人工耳蜗的试用,近些年继而出现的杭州诺尔康、沈阳爱益声、上海力声特等人工耳蜗产品的问世,才慢慢的打破了这一局面^①。

我自2010年起参与了多家国产人工耳蜗的临床试验和疗效研究,其中诺尔康人工耳蜗是我们观察时间较长的植入设备,也是目前国产人工耳蜗中比较成熟的产品,到目前为止我科成功开展了139

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台,本研究通过电话随访到了开机满一年的40例诺尔康人工耳蜗植入患者,随访内容和结果如下:

1 资料和方法

1.1 受调查者资料

我科自2010年3月至2014年12月植入杭州诺尔康人工耳蜗(CS-10A)患者139例,本研究范围内患者53例患者,随访到的开机满一年的患者40例,术前均为重度或极重度感音神经性耳聋,其中语后聋患者18例,语前聋患者22例。所有植入者手术顺利,术中测试电极阻抗均在正常范围内,术中及术后未见其他异常状况。将40例受试者按照CI植入之前的言语情况分为语后聋植入组和语前聋植入组,具体情况如下:

语后聋植入组:参加测试患者共计18例,其中男9例,女9例,平均手术年龄 23.0 ± 14.5 岁(年龄范围6.8~60.2岁),重度耳聋病程平均 8.84 ± 7.20 年(耳聋病程范围0.7~26年)。

语前聋植入组:参加测试患者共计22例,其中男16例,女6例,平均手术年龄 6.60 ± 3.37 岁(年龄范围1.5~11.7岁),耳聋时间 5.6 ± 3.19 年(耳聋病程范围0.5~11.5年)。

对听觉行为能力和言语可懂度的调查评估采用诺丁汉大学Nikolopoulo等提出的听觉行为分级标准(CAP)和言语可懂度分级标准(SIR)。CAP:可用于反应患者日常生活环境中的听觉水平,将患者的听觉能力分为1-8级(表1),分别得分为1-8分^[10]。SIR:用于评估患者的言语产生能力,根据患者的言语可被理解的程度分为1-5级(表2),分别得分为1-5分^[11]。得分均由患者本人或家属对患者日常生活中的听觉及言语情况进行描述,由随访的同一位听力师根据患者或家属描述进行分级打分,尽量做到客观准确。

表1 听觉行为分级标准(CAP)

分级	听觉行为能力
8	使用电话与熟悉的人进行交流
7	不借助唇读即可与人交谈
6	不借助唇读即可理解常用的短句
5	不借助唇读,能够辨别一些言语声
4	能够辨认环境声音
3	对言语声(例如“走”等)能够做出反应
2	能够感知环境声音
1	不能感知环境声音

表2 言语可懂度分级标准(SIR)

分级	言语可懂度
5	连贯言语可被所有人听懂,在日常语境下儿童可以轻易听懂
4	连贯言语可被不具备聆听聋人言语经验的人听懂
3	连贯言语需要听者集中注意力并结合唇读方可被听懂
2	连贯言语可懂,但听者主要是通过个别词语并借助语境和唇读提示理解其言语
1	连贯言语不可懂,口语中的单词只有手术之前可懂的单词能被识别,主要交流方式为手语或手势

另外,同样通过电话随访的方式,对术后并发症以及术后的生活质量改善情况进行CI术后生活质量问卷,内容如下:

1人工耳蜗每天佩戴时间,是否主动要求;2佩戴过程中遇到的问题,是否影响外观及情绪;3装置是否一直正常工作,以哪些部件为主,每年几次;4是否参加了语训,时间有多久,以哪种形式为主,效果如何;5是否植入双侧人工耳蜗,两侧植入间隔时间;6对侧耳是否佩戴助听器,助听效果如何;7语言发育是否正常(不正常/基本正常/完全正常);8在嘈杂环境下是否可以交流;9现在工作或学习状况;10同学同事关系是否融洽(人际关系),较术前是否有进步;11是否喜欢参加社会活动;12是否喜欢看电视(是否看字幕),哪种类型的,是否听广播;13是否喜欢听音乐,是否愿意模仿,模仿时是否有“变调”;14独立生活能力;15术后是否出现过并发症,如伤口感染、头皮血肿、线圈下毛囊稀疏等;16对人工耳蜗植入手术是否满意;17对植入人工耳蜗后的生活是否满意;18对该耳蜗产品是否满意,有哪些需要改进的地方。

1.3 统计方法

本研究使用SPSS 17.0软件进行数据统计分析。

2 结果

2.1 听觉能力CAP分级得分情况(满分8分)

语后聋植入组术前平均得分 3.83 ± 0.92 ,术后平均得分 7.61 ± 0.50 ($P=0.000 < 0.05$)。表明语后聋植入组术前仅能够辨别环境声音,术后全部可以不借助唇读与人交谈,大部分可使用电话与熟悉的人进行交流,已基本接近正常人听力水平。语前聋植入组术前平均得分 1.64 ± 1.13 ,术后平均得分 6.45 ± 1.65 ($P=0.000 < 0.05$)。表明语前聋植入组术前仅能够感知环境声音,术后不借助唇读即可与人交谈,可见CI

术后患者的听觉能力明显提高。(图1)

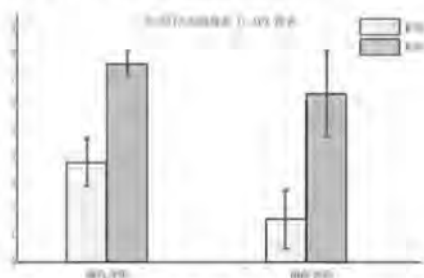


图1 语前聋组和语后聋组术前术后CAP得分情况

2.2 言语可懂度分级(SIR)得分情况

语后聋植入组术前平均得分 3.17 ± 1.04 , 术后平均得分 4.78 ± 0.55 ($P < 0.05$); 表明语后聋植入组术前连贯言语需要听者集中注意力并结合唇读方可被听懂, 术后连贯言语可被所有人听懂, 在日常语境下儿童可以轻易听懂, 已基本接近正常人言语水平。语前聋植入组术前平均得分 1.43 ± 0.93 , 术后平均得分 3.43 ± 1.38 ($P < 0.05$); 表明语前聋植入组术前连贯言语可懂, 但听者主要是通过个别词语并借助语境和唇读提示理解其言语, 术后连贯言语可被不具备聆听聋人言语经验的人听懂。(图2)

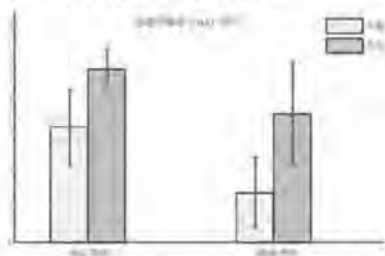


图2 语前聋和语后聋的术前术后SIR得分比较

2.3 人工耳蜗植入后生活改善情况

各组患者的每天平均佩戴时间均 >11 小时, 83.3%的患者进入正常的学校或者工作岗位学习工作, 79.2%的患者的发音被周围的人认定为正常或基本正常, 81.3%的患者较手术之前更加愿意和别人交流, 参与到社会活动中去, 有62.5%的患者表示带上人工耳蜗后愿意或基本愿意尝试听音乐。但是我们也发现有一例声音大时眼睛跳动的病例, 但经过重新调机编程之后症状消失; 一例前期带上线圈后头皮发红的病例, 减小线圈磁铁磁力后症状好转。另外也发现诺尔康人工耳蜗的外机导线毁损率偏高。

3 讨论

本研究主要是探讨诺尔康人工耳蜗植入后的听觉言语康复效果, 随访人工耳蜗植入对患者生活质量的影响。观察发现患者的听觉行为分级标准(CAP)、言语可懂度分级标准(SIR)均随着植入时间的延长而得到更理想的结果, 相比之下语后聋患者能在更短的时间内达到这样的效果, 甚至是接近正常人的水平。但是我们也发现满意度问卷的得分和患者本人及家

属的期望值关系相当大, 提示临床医生应该在手术之前应与患者及家属充分沟通。另外对于手术之前有助听器佩戴史的一部分患者, 在刚植入的一段时间内可能没有术前佩戴助听器的效果好, 需要一段时间适应CI之后方可得到满意效果, 这也需提前沟通, 只有术前妥善沟通才能帮助患者及家属建立一个合理的期望值, 提高术后满意度。

再者, 有些语前聋患者手术完成之后没有参加言语康复训练, 或者是参加的全托管形式的言语康复班, 平时没有家长或者亲属的陪伴学习, 这些患者之后的言语效果大部分欠理想。关于术后言语康复训练的重要性仍然是耳科医生和听力师术前应该强调的重要问题。

最后, 语前聋患者由于有不同程度的听觉剥夺史, 中枢听觉系统对声刺激电信号的处理也会受到影响^[5]。另外, 人工耳蜗植入时间的长短也是影响术后效果的重要因素, 植入时间越长, 患者言语识别能力越强^[6]。上述两因素共同影响了语前聋患者的评估结果, 1年的术后康复时间可能并不能达到最好的效果。所以在本次研究中, 各项测评结果都低于语后聋组, 下一步需要继续对患者进行随访, 观察更长时间的术后言语康复情况。

国产人工耳蜗的出现和日臻成熟的技术打破了进口人工耳蜗在中国的垄断现状, 以更加合理和低廉的价格造福了一大批普通家庭和贫困家庭的耳聋患者, 在2014年年初的时候诺尔康人工耳蜗(CS-10A)的使用者已超过千名, 并且这个数字以很快的速度增长, 随之问题也呈现出来, 比如: 售后服务的压力会越来越大, 但是同时还要要求服务质量; 诺尔康人工耳蜗产品的安全性、稳定性及远期疗效还需要更有力的数据来进行说明; 另外随着患者的增多, 要满足不同人群及消费个体的各种需求, 产品需要不断的推陈出新^[7]; 最关键的是, 人工耳蜗作为人体需要终身使用的电子产品, 要保证产品质量和工艺的精益求精。

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诺尔康人工耳蜗植入者康复方法探析

(附6例报告)

The Essence of Rehabilitation Methods for 6 Nurotron Cochlear Implant Users

■季艳

Ji Yan

【摘要】目的 以6例诺尔康人工耳蜗植入者的康复效果为基础,探讨针对国产人工耳蜗植入患者康复方法的有效性。**方法** 针对人工耳蜗植入者不同的个体情况制定康复计划,采用个别化教学和小班教学的方法进行康复训练。**结果** 国产诺尔康人工耳蜗植入者均获得较好的康复效果。**结论** 诺尔康人工耳蜗植入后,配合个别化教学和小班教学相结合的康复方法,能够提高听障患者的听觉言语水平。

【关键词】 康复方法;个别化教学;人工耳蜗植入

【Abstract】 The purpose of the article is to study the effectiveness of Nurotron cochlear implant used for hearing rehabilitation by 6 recipients. The study is to design an individualized diagnosis and rehabilitation program for each cochlear implantee so that achieved was a better understanding of individualized listening teaching and small-class education. The study shows that Nurotron cochlear implant users have recovered well. Therefore, it can be concluded that Nurotron cochlear implants can be used for children for their rehabilitation combined with individualized listening teaching and small-class education.

【Key words】 Rehabilitation method; Individualized teaching; Cochlear implant

1 引言

2010年4月,我中心接收了6名国产诺尔康人工耳蜗听障儿童及成人,通过听觉和言语康复,患者从对声音的察觉、分辨、识别、理解,逐步体会到了人工耳蜗植入带来的听觉体验。本文探讨、总结了6名国产诺尔康人工耳蜗植入者的康复方法及康复效果,验证国产人工耳蜗植入与符合本质规律的康复方法相结合能够取得较好的康复效果。

2 康复方法

2.1 被试基本情况

本研究被试基本情况见表1,年龄4~33岁,2例为有一定语言基础的语后聋患者,4例为语前聋者。其共同特点是生活在健听家庭,有良好的语言氛围,其中赵某的弟弟也是听障儿童。从医院的检查报告看,韩某内听道狭窄,蜗神经细;陈某为双侧Mondini畸形,其他患者基本正常。患者家庭对康复的重视度较高,开机后即开始接受听觉言语康复训练。

患者初始能力评估见表2。评估方法参照听障儿童听觉语言能力评估标准及方法^[1]及听觉口语法听能与语言评估方法^[2]。

2.2 康复方法

根据患者的不同情况和康复需求,笔者制订了个性化的康复计划,包括短程计划、强化计划、学期计划、长程计划^[2]。短程计划为10天~3个月不等的短期康复计划,其中有针对性较强的强化计划和学期计划。短程计划完成并通过评估验证后,根据患者不同的康复程度,再次对患者进行后续康复训练计划。

本研究被试张某是语后聋患者,生活经验较丰富,平时工作中能通过看口型、辅助手势和笔录进行沟通。植入人工耳蜗后需改善听觉能力,以实现分辨声音、听取外界信息、排除噪音进行跨听的目标。笔者采取了为期10天的短程计划,训练内容主要为林氏六音辨识、词组辨识、听觉记忆、听觉指令、听觉描述、叙事提问、主题讨论、录音电话。侧重进行大量听练习,包括音素中的声调、语气等细微变化以及在嘈杂环境声中的倾听。

郭某是初中生,语言基础较好,言语清晰度和跨听能力不足。为了不耽误学业,笔者采取了为期1个月的强化计划,利用大量听练习提高患者的听反应速度,以增强患者听的信心。训练内容主要为词组辨识、听觉记忆、日常指令、听觉描述、录音听辨、组词造句、看图讲述、叙事表达、认知扩展、话题讨论。侧重听回应的反应能力,利用个别化教学与集体教学相结合的

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表1 被试基本情况

姓名	性别	年龄(岁)	开机时间	康复起始时间	发现耳聋时间	性格,兴趣	耳聋原因
张某	女	33	2010.03.12	2010.04.01	语后聋	外向,喜欢旅游	药物性
郭某	女	16	2010.02.03	2010.04.01	语后聋(2岁)	内敛,喜欢手工	不详
赵某	女	6	2011.08.18	2011.09.01	1岁左右	外向,喜欢看书	遗传性
韩某	男	4	2011.07.07	2013.11.01	1岁左右	乖巧,喜欢启智	不详
王某	男	6	2014.05.07	2014.05.02	3岁	好动,喜欢动手	不详
陈某	男	17	2014.09.18	2014.09.18	6岁	内向,喜欢笔谈	不详

表2 被试初始能力评估结果

姓名	听觉能力	语言能力	听觉口语评估				
			听能	语言	认知	说话	沟通
张某	/	/	三项	句式颠倒	与同龄健听人相比略有差距	第4阶段音素不够完善	看口型较多,辅助写字进行沟通
郭某	/	/	四项	语汇丰富,接近正常	与同龄健听人相比心理上略有差距	有鼻音,平翘舌音分辨不清	能正常沟通,但缺乏信心
赵某	无法测得	无法测得	对声音有反应	能模仿发音	会简单配对操作	会模仿看口型发声,假声较严重	有眼神的注视,不会等待
韩某	四级	一级	两项	能表达词语	对数字感兴趣,形状、颜色能分类	能在情境中表达短语	眼神专注力很好,明确等待要求,会简单互动
王某	无法测得	无法测得	不会察觉声音	能模仿发音	会简单配对操作	能模仿发声,但没有音节	缺乏眼神专注力,不会轮替、等待
陈某	/	/	对声音有反应	能模仿发音	能观察比较区分不同	能模仿发音,不会连到音节中	不会看口型,用写字辅助简单沟通

方式建立跨听能力。

其他4名患者采取系统的康复练习,分别制订了为期3个月的短程计划,通过个别化训练和小班化集体教学,注重先听后说的原则,以达到自然交流。训练内容主要为林氏六音察觉、辨识,听觉记忆,听觉指令,描述等听能训练,另外,根据患者的认知水平进行语言表达训练,训练时侧重自然、互动。

3 结果

被试短程计划完成后的听觉、言语、认知能力均有较大提高,评估结果见表3。

根据短程计划评估结果,笔者对被试进行了2个月-4年7个月的后续康复训练。实施后的康复评估情况见表4。

由表3、4可知,经过短程计划及后续康复,6名患者的听觉、语言、言语、沟通等方面均获得了很大进步。其中,张某回到工作岗位,郭某、赵某进入普通学

校就读。随着康复时间的延长,6名被试言语清晰度、沟通与表达意识明显提高,康复效果良好。

4 讨论

4.1 通过个别化教学帮助患者在互动中理解听的意义,形成听的习惯

本文6例人工耳蜗植入患者的康复过程以短程计划、长程计划,辅以强化计划,较集中地进行了听觉记忆4个阶段的训练,目标有针对性,康复效果有效。植入人工耳蜗后,首先是察觉声音,其次是意义联结,即将声音和相关物品联结。当患者具有分辨能力时,就开始发展听觉记忆。为了明确听觉记忆的要求,侧重词汇量的积累及概念扩展,听觉记忆可分为4个阶段。第一阶段:听懂了会操作。听觉程度达到0~1项时,引导患者听懂后进行操作,侧重听反应能力,建立听的意识。第二阶段:操作及表达,即听觉程度达到2~3项时,引导患者听懂操作后进行语言表述,侧重词汇量

表3 被试阶段能力评估结果

姓名	听觉能力	语言能力	听觉口语评估				
			听能	语言	认知	说话	沟通
张某	✓	✓	四项	句式能稳定表达	可以通过听积累认知经验	会监听自己说话,有自我修正的意识,说话清晰度提高	能有意识地听,开始用听进行简单沟通
郭某	✓	✓	五项	能用较完整的语言讲述事件	自信心增强	能有意识地发平翘舌音,可以做到自我修正	主动说话意识明显增强,能大胆开启话题,可以接听免提电话
赵某	四级	一级	两项	可以表达2~3字词语	在情景互动中可以简单回应	假声有所改善,能说出第一、第二阶段声母	建立了听等待的习惯
韩某	三级	二级	三项	能表达5~6字短句,连贯性提高	在认知操作中,能用语言进行表达	互动表达时,能有意地说好声母	在情景互动中,能用语言及时回应
王某	四级	一级	稳定辨识六音,一项稳定	能说词语	在情景中能回应对错	第一阶段声母稳定	会眼神的注视,有听等待的习惯
陈某	✓	✓	稳定辨识六音,两项发展	会表达4~5字短语	在观察比较中能用短语表达	能进行声韵母的轮替结合,说话声音有所改善	在日常互动中能主动问好,并简单回应

表4 被试康复评估情况

姓名	康复时间	听觉能力	表达能力	沟通意识	言语清晰度
张某	4年7个月	能进行简单的电话交流;可以在小团体中交流	能用概述的语言讲述事件	在工作中能主动发表自己的观点	发音比较稳定,能进行自我纠正
郭某	4年6个月	可自然接听电话;能在嘈杂环境中进行讨论交流	能用自然地语言进行自信的表达,发表自己的不同见解	在同伴集体交流中,可以进行反驳,说出自己的理由	说话的语气、语调比较自然,发音稳定
赵某	3年2个月	在课堂上能听懂老师的授课过程;可以听懂录音磁带	语言表达自然、连贯,可以完整讲述	在学习中遇到困难时,会主动请求老师、同伴的帮助	能和小伙伴自然交流,发音基本稳定
韩某	1年	听觉记忆4项,开放式指令操作2~3项	能表达完整的句子	有主动沟通语言的意识,自发性语言较多	声母较稳定,语气较自然,有四声调的变化
王某	5个月	听觉记忆1项稳定,发展2项	在生活情境中,能引导表达短语	有眼神的注视,有听等待的习惯	第一阶段的声母能与韵母结合,连到词语中表达
陈某	2个月	听觉记忆2项,发展半开放式的听仿	在老师的要求下,能表达5~6个字的短语	在情景中能主动问好	声韵母结合已稳定,但大小声不会变化

的积累,针对不同句式进行完整表达。第三阶段:听懂后边说边做。当听觉程度达到3~4项时,可要求患者听懂后进行表达,侧重不同词性的理解及表达。第四阶段:讲述做的过程。当听觉程度达到4项以上时,要求患者讲述操作过程,侧重表达时的完整性,要求患者用自己的语言表达。理解听的意义和形成听的习惯需要教师利用日常生活情景与突发事件进行个别化随机教学实现。

4.2 通过小班教学让患者在课程中获得发展,并在“家庭教室”中全面理解语言的意义

对于儿童患者,小班教学的目标一是为其提供共性的幼儿教育需求;二是在家庭教室中进行听语课程,帮助孩子获得生活语言。幼儿教育包含健康、语言、社会、科学、艺术5个领域,其实现方法是通过集体互动的游戏^[3,4]。这样的教育有利于孩子性格的塑造、集体意识的形成和语言能力的提升。笔者设定了家庭情景教室作为听语课堂的一部分(客厅、卧室、厨房等),安排听障儿童在互动过程中学习语言^[2],此教学

方式较易被听障儿童所接受。笔者强调了强化训练对人工耳蜗植入儿童康复训练的重要性,以家庭情景教室作为康复训练方法,效果良好。

本研究6名诺尔康人工耳蜗植入者通过人工耳蜗植入重建了听觉能力,同时他们所接受的个别化教学和小班教学相结合的康复方法也是行之有效的^[5]。

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诺尔康人工耳蜗临床效果分析

A Report of Nurotron Cochlear Implant Clinical Trial

■高娜¹ 迟放鲁¹ 银力²

GAO Na, CHI Fang-lu, YIN Li

【摘要】目的 了解诺尔康人工耳蜗的临床效果。**方法** 对60名6~59周岁的语后聋患者进行诺尔康人工耳蜗植入术前评估、植入手术、术后开机调试及评估。术后随访4年,受访植入者完成了开放式、封闭式言语测试和残余听力检测。**结果** 所有植入者均未发生任何人工耳蜗术后并发症;所有植入者的评估结果均逐步提升,开放式和封闭式言语测试平均得分分别从术前的0%和20%以下水平逐步提升到了术后4年的80%以上水平;术后1个月52.94%的植入者保留了残余听力,术后24个月45.83%的植入者保留了残余听力。**结论** 经过4年连续观察,证明诺尔康人工耳蜗设备安全、有效。

【关键词】诺尔康人工耳蜗;临床验证;语后聋;残余听力

【Abstract】Objective To study the clinical effect of the Nurotron Cochlear Implant. **Methods** Totally 60 recipients from China joined in this clinical trial, ranged from 6 to 59 years old. All the recipients were postlingual deafness, with various etiologies. They all underwent pre-operative assessment, cochlear implant surgery, switch-on after surgery, mapping and evaluation. Both closed- and open-set speech recognition tests were conducted among recipients 1 month, 2 months, 4 months, 6 months, 1 year, 2 year and 4 year after switch-on, respectively. **Results** During four years of assessment after switch-on, we found that all the recipients had no complication related to implant or implantation surgery. All recipients' speech performance had improved gradually. The average scores of open-set and closed-set speech tests improved respectively from 0% and below 20% level to above 80% level. Some of recipients still retained residual hearing, 52.94% recipients retained residual hearing after 1 month of operation, with 45.83% after 24 months. **Conclusion** With four years of continuous observation, Nurotron cochlear implant system is proved to be safe and effective.

【Key words】Nurotron cochlear implant system; Clinical trial; Postlingual deafness; Residual hearing

人工耳蜗是目前重度和极重度听障患者有效重建听觉功能的电子装置。由于进口人工耳蜗高昂的价格及患者认知局限性等原因,目前仅有一小部分极重度听障患者受益于人工耳蜗。为了更好地造福于广大听障患者,诺尔康人工耳蜗作为国产人工耳蜗品牌经过临床验证,于2011年顺利获得国家药监局批准,凭借价格优势及显著的疗效应用于听障患者。诺尔康临床验证试验自2009年12月23日开始实施第1例植入手术以来,截止2014年,植入者已完成了4年的调试和相关评估。

1 方法

1.1 术前病例筛查

1.1.1 基本情况 参照2003年中华医学会制订的人工耳蜗植入工作指南^[1],以临床试验方案为准则,通过医学、听力学、心理学等指标的筛查,最终确定了60名候选人接受了手术。

60名植入者中男性34人,女性26人。术时年龄最小6岁,最大59岁,中位数年龄23.5岁;右耳植入35例,左耳植入25例。

1.1.2 耳聋病史情况 60例植入者中,药物性聋31例,大前庭导水管综合征7例,噪声性聋2例,突发性耳聋5例,脑膜炎2例,不明原因聋13例。所有植入者耳聋进程均为语后聋,渐进性;术前极重度耳聋最短6个月,最长15年,中位数6.0年,发生极重度耳聋的时长为0~12月12例,13~60月14例,61~120月17例,121~180月17例。术前63.33%的植入者配戴助听器,其中双侧配戴12例,配戴时长平均为5.98年。

1.2 植入手术

1.2.1 手术医院 手术在5家医院开展,其中复旦大学附属眼耳鼻喉科医院23例,中国人民解放军总医院15例,首都医科大学附属北京同仁医院10例,浙江大学医学院附属第二医院7例,重庆医科大学附属第一医院5例。

1.2.2 手术 采用柔手术技巧,耳后切口,完整式鼓室进路,通过面隐窝,从圆窗龛前下方打开耳蜗,开孔直径为1 mm;手术过程一般为2~3小时。术中对全部病例进行了电极阻抗检查。

1.3 术后调试及康复

1.3.1 术后恢复 所有病例均在术后1周左右拆

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除缝线, I/甲愈合;于开机当天,开机后4个月、6个月做相关检查以进行全身功能安全性观测,拍摄术后X线片以了解电极植入情况。所有病例未见面瘫、血肿、皮瓣问题以及植入部位不适等并发症,2例术后当天发生植入体部位水肿,3天内水肿自行消退。医生、植入者及其家人普遍反映植入体所在头皮区域无明显隆起。

1.3.2 开机及调试 所有植入者均在术后4周左右开机,采用MP1+2的刺激模式和峰值提取编码策略;植入者对所有可用通道均有行为反应^[2]。

1.3.3 康复 21名植入者在全国多家康复机构进行了为期1~2个月的集中康复训练,上课形式主要为教授语训方法并结合软件进行康复,其余植入者在家使用天使语训软件TM进行康复训练。

1.4 术后效果评估

对60例受试者分别在术后1个月、2个月、4个月、6个月、1年、2年、3年、4年进行言语测听,残余听力测试,并记录主观听声情况。言语测听以电脑软件操作的形式进行评估,材料选用HOUSE耳研所付前杰教授研发的捷星评估系统(<http://www.tigerspeech.com>)^[3],给声强度为65 dB SPL。言语测听材料包括闭合式和开放式两类,其中闭合式言语评估包括环境声音检测、声母识别、韵母识别、声调识别、字词辨识、双字辨识和数字辨识7项内容,要求受试者在4个选项中选1个,记录各项测试得分,取均值作为闭合式评估的成绩;开放式言语评估包括HOUSE短句识别、301短句识别及301双字词识别3项内容,要求受试者复述听到的内容,记录各项测试得分(短句以关键词的识别率计算),取均值作为开放式评估的成绩。

由于学业、工作、身体状况等原因,60例植入者中58例参加了1年的评估,52例参加了2年的评估,48例参加了3年的评估,40例参加了4年的评估。

2 结果

2.1 诺尔康人工耳蜗系统安全性观察

在人工耳蜗植入过程中,所有60名植入者未发生磨穿颅骨、扩大面隐窝、扩大口径开放耳蜗、面神经损伤、鼓索神经损伤等情况。术后除个别术前庭导水管综合征植入者(2例)发生预期的眩晕外,未发现其它并发症。通过术后4年的观察,所有植入者均未发生与植入体相关的并发症和身体异常情况;身体各项生化检查提示重要脏器无损害。

2.2 诺尔康人工耳蜗系统效果评估

2.2.1 言语测试结果 植入者开机至4年的闭合

式和开放式言语评估结果见图1。由图可知,植入者的言语测试得分随着时间的推移逐步提升。

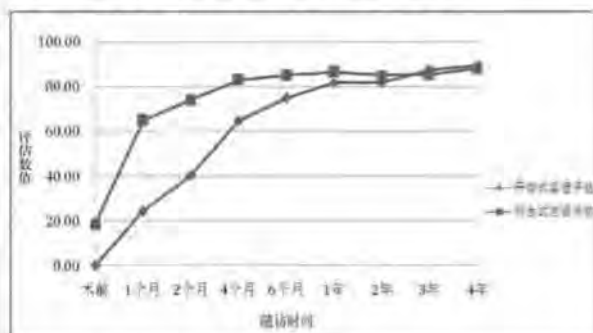


图1 植入者开机至开机4年的闭合式、开放式言语测试结果

2.2.2 耳聋时长与植入效果关系 根据重度耳聋的时长,将58名患者分为耳聋时长 ≤ 10 年($n=40$)和耳聋时长 > 10 年($n=18$)两组。对两组开机1年的言语评估结果进行分析,结果显示,开机1年时,耳聋时长 ≤ 10 年组的开放式和闭合式言语评估平均得分分别为 $78.99\% \pm 17.13\%$ 和 $84.98\% \pm 8.63\%$;耳聋时长 > 10 年组的开放式和闭合式言语评估平均得分分别为 $64.78\% \pm 14.97\%$ 和 $83.75\% \pm 5.73\%$ 。采用SPSS 13.0相关性统计分析,发现耳聋时长与开放式言语评估得分具有一定相关性($P < 0.05$),而与闭合式言语评估得分无显著相关,表明耳聋时长越短,开放式言语评估成绩越好。

此外,分别以重度聋时长1年、5年及15年为临界点,将植入者分组进行比对,发现闭合式及开放式言语评估得分均无显著差异($P > 0.05$)。

2.2.3 术前助听器配戴与植入效果的关系 将58名植入者按照助听器配戴时长分成配戴助听器组(配戴助听器 ≥ 1 年, $n=36$)和未配戴助听器组(配戴助听器 < 1 年, $n=22$),对两组开机1年时的言语评估得分进行比较。配戴助听器组的开放式和闭合式言语评估平均得分分别为 $77.87\% \pm 17.59\%$ 和 $85.28\% \pm 8.37\%$;未配戴助听器组的开放式和闭合式平均得分分别为 $69.21\% \pm 16.77\%$ 和 $83.49\% \pm 6.83\%$ 。SPSS 13.0分析显示,两组的评估得分结果无显著差异($P > 0.05$)。

2.2.4 残余听力保留情况 对60例患者的残余听力进行了统计,术前有残余听力的共计34人(250, 500, 1000 Hz处的残余听力均 ≤ 115 dB HL)。术后1个月保留残余听力18人(52.94%),其中完全保留3人(250, 500, 1000 Hz处的残余听力下降均 ≤ 10 dB HL),占8.82%;部分保留15人(250, 500, 1000 Hz处的残余听力中至少有1处保留,下降区间为10

~40 dB HL)。术后24个月:24名术前有残余听力的患者参加了测试,11人(45.83%)仍保留了残余听力,其中3人(12.5%)为完全保留,其余为部分保留;13人(54.17%)残余听力消失。

2.2.5 使用电话交流情况 随着时间的推移,能够使用电话与熟人简单交流的植入者由5人(开机1月时)增长到31人(开机1年时)。

3 讨论

近年来人工耳蜗发展的热点包括声电联合刺激(Electric-Acoustic-stimulation, EAS)、微创(柔)手术、双模式听力等,这些努力的目的在于最大程度地保留植入者的残余听力。诺尔康人工耳蜗采用软性导向电极,可减少耳蜗损伤。植入过程中,手术医生反映诺尔康植入体的优点为磨骨体积小、电极硬度适中,符合微创手术要求。同时研究表明,植入者的残余听力保留率与国外报道相近^[2-6]。

诺尔康人工耳蜗采用24个电极和通道(耳蜗内),与澳大利亚的Nucleus Freedom耳蜗(22个电极)、美国AB公司的HiRes 90K(16个电极)、奥地利Med-EL耳蜗(12个电极)相比,具有最多的刺激通道^[7,8]。文献表明,术后2年时,采用HOPE测试,诺尔康人工耳蜗与澳大利亚Nucleus CI24人工耳蜗植入者在言语分辨方面无显著差异^[9]。

本文进一步研究诺尔康人工耳蜗植入者开机4年时的言语识别率,结果表明植入者的开放式言语评估均达标(有效指标为开放式言语识别率术前术后对比提高 $\geq 20\%$),且随着时间的推移,言语评估得分不断提高,表明植入者通过诺尔康人工耳蜗重新获得了听觉,达到了对声音的感知和理解。此外,闭合式言语评估在开机前2年有显著提高,开机2~4年的评估结果略有波动,经统计学分析并无显著差异。其中,大前庭水管综合征植入者的言语评估成绩优异,与国内外相关报道结果相印证^[10]。同时,诺尔康人工耳蜗植入者在使用电话方面与国内研究结果也具有一定的可比性^[11]。

本研究对植入者的重度聋时长与言语评估结果之间的关系进行分析,显示重度聋时长 ≤ 10 年组开放式得分明显超过重度聋时长 > 10 年组,而闭合式得分两组无显著差异,表明重度聋时长 ≤ 10 年的植入者在声音感知、理解方面表现得更好。将植入者以重度聋时长1年、5年、15年为临界点进行分组对比,发现各组评估成绩无显著差异。因此,耳聋时长10年对于成年语后聋患者来说可能是一个分水岭,这对于成年语后聋患者植入人工耳蜗及术后康复有一定借鉴意义。

4 结论

通过60例6~59岁语后聋患者植入诺尔康人工耳蜗术后4年的临床观察,所有植入者的设备均是安全的,植入体对人体各重要脏器未造成损害,人体对植入体无排斥反应;所有植入者通过使用设备均获得了不同程度的收益,达到了理解声音及简单对话交流能力,部分植入者可以使用电话与人交流;部分植入者甚至达到了国际人工耳蜗植入效果指标,即残余听力得到了保留。

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诺尔康26电极人工耳蜗 植入系统的开发及评估

Development and Evaluation of the Nurotron 26-electrode Cochlear Implant System

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【摘要】本文阐述了诺尔康26电极人工耳蜗的设计理念、系统特点及技术验证。该人工耳蜗具有先进的数字信号处理技术和多精度的4个电流源, 不仅与感知能力匹配, 而且可进行间隔或同时刺激。此外, 本文描述了60例诺尔康人工耳蜗植入者3年的评估数据。客观测试显示, 电极阻抗值在使用设备1个月后会降低, 此后持续保持稳定, 直到2年时略有上升。主观响度测试显示, 电刺激阈值相对稳定, 最大舒适阈在3年中逐渐提高。汉语句子识别率从术前的0%增长至开机6个月时约80%的水平。间接和直接对比研究均显示诺尔康人工耳蜗与其他同类人工耳蜗产品使用效果相当。

【关键词】人工耳蜗; 诺尔康; 开发; 评估

【Abstract】The article describes design philosophy, system specification, and technical verification of the Nurotron device, which includes advanced digital signal processing and 4 current sources with multiple amplitude resolutions that not only are compatible with perceptual capability but also allow interleaved or simultaneous stimulation. The article also presents 3-year longitudinal evaluation data from 60 human subjects who have received the Nurotron device. The objective measures show that electrode impedance decreased within the first month of device use, but was stable until a slight increase at the end of two years. The subjective loudness measures show that electric stimulation threshold was stable while the maximal comfort level increased over the 3 years. Mandarin sentence recognition increased from the pre-surgical 0%-correct score to a plateau of about 80% correct with 6-month use of the device. Both indirect and direct comparisons indicate indistinguishable performance differences between the Nurotron system and other commercially available devices.

【Key words】Cochlear implant; Nurotron; Design philosophy; Evaluation

自1984年美国国家食品药品监督管理局(FDA)通过了第一个人工耳蜗产品的认证, 至今全世界超过30万听力损失人群通过电刺激听神经的方式重建听力和发展言语。尽管数据明确显示了人工耳蜗的益处, 在发达国家仍只有将近10%的潜在候选人植入了人工耳蜗, 在发展中国家则更少^[1]。虽然近30年人工耳蜗植入数量不断上升, 但其价格却居高不下, 极大地限制了人工耳蜗的市场普及。开发一款低价、高性能

的人工耳蜗一直被认为是通过竞争实现市场普及的唯一有效途径, 尤其对发展中国家^[2,3]。

2006年中国开始研发诺尔康26电极人工耳蜗系统, 2008年投入生产, 2009年开始进行临床试验。截止2014年12月, 已有1500名中国患者、2名哥伦比亚患者、2名土耳其患者和12名印度患者植入诺尔康人工耳蜗。本文阐述了诺尔康26电极人工耳蜗系统的总体设计和开发理念; 其次, 描述了具体系统部件的设计

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和验证,包括体外声音处理器、无线频率传输,体内接收器、刺激器和蜗内电极;另外,通过对参加中国国家食品药品监督管理局(CFDA)临床试验60例受试者的客观和主观功能测试,呈现总体系统的评估结果。

1 系统指标

近30年人工耳蜗技术已从最初单电极模拟刺激发展到多电极间隔刺激^[4,5]。图1为诺尔康人工耳蜗系统的原理图,其中包括了体外部分、经皮射频(radio-frequency, RF)传输部分、体内部分及调试部分。体外部分通常被称为言语或声音处理器,其主要作用是通过数字信号处理(digital signal processor, DSP)的办法把采集到的环境声转换成射频发射信号。体内部分包含一块专用集成电路(application-specific-integrated-circuit, ASIC)芯片,用于接收及解码RF信号,并将电刺激传递至相应电极,再从电极中读取反馈信号,通过反向回传电路发射至声音处理器或临床调试系统。

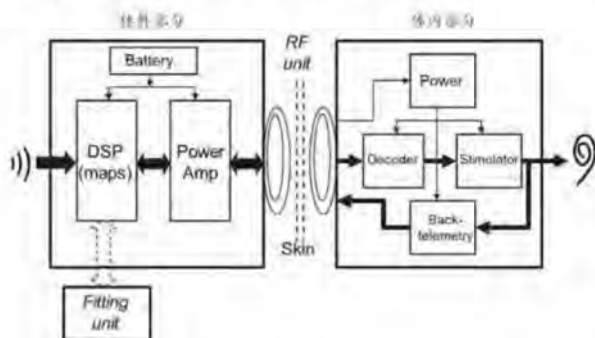


图1 诺尔康26电极人工耳蜗功能示意图

诺尔康人工耳蜗系统的设计基于以下原则。第一,设备必须达到现代人工耳蜗安全有效的关键性技术指标。本设计遵照欧标EN 45502-2-3(2010)^[6]及其他的实际验证保证安全;采用多通道、多刺激策略满足听声需求;第二,设备需要有灵活的设计满足未来的需求。比如能够用于提高噪声下言语识别、声调语言识别和音乐欣赏的虚拟通道、精细结构编码等。遵照这一原则,ASIC包含了4个电流源提供2或3个电极的同时刺激,或在频谱上产生47个或更多的虚拟通道;第三,设备具有支持其他神经假体的潜能。如听觉神经假体、听觉脑干神经假体、人工视网膜或深脑刺激。为了支持这些神经假体,设计了包含2个参考电极及24个主动刺激输出,可配置为2×12、3×8或4×6的表面或穿透式电极。



图2 诺尔康人工耳蜗系统:言语处理器(A)及体内部分(B),包括接收器、刺激器和电极阵列

诺尔康人工耳蜗系统实物图见图2。图2A为耳背式声音处理器,包含双麦克风、控制按钮、指示灯、电池仓及射频发射线圈。另有体配式声音处理器可供选择,可用于延长电池使用时间或对此有偏好的人群。图2B为系统的体内部分,包含黄金RF接收线圈,可取出的磁铁、一个钛金壳体、一个板状铂参考电极、一个环状铂参考电极及24触点直电极阵列。

2 设计和验证

2.1 声音处理技术

先进的声音处理技术对人工耳蜗效果至关重要。首先,需要对声音进行预处理以保证言语声的可听度及清晰度。诺尔康标准预处理包括敏感度控制、自动增益控制、单麦克风降噪及混合输入选择。其次,声音处理需要将模拟声转换成电脉冲。诺尔康DSP拥有连续交叉采样(CIS)、智能峰值提取(APS)及虚拟通道(Symphony)3种处理策略。CIS策略对固定数量的通道进行分析和刺激,实际数量由植入者的可用电极数决定,最多为24个。APS策略与“n-of-m”策略接近,最多分析通道数为24,而刺激通道数通常为6~8,取决于输入声的能量分布及可用电极数。APS策略增加了刺激速率从而提升了对时域中精细结构的表达。Symphony策略结合了虚拟通道和峰值提取策略。在这一策略中,通过同时刺激两个物理电极而产生处于两个电极间一种额外的音高感知,从而提升频域内的精细结构。图3显示了汉语句子“今天去哪里?”的频谱图和电极图。在该例中,电极图由APS策略产生输出,它将从100~8000 Hz的连续频带分为128个线性分布的频段。之后基于格林伍德映射(Greenwood map spacing)将128个FFT频段整合进24个分析频段,在24个频段中选择8个能量最大的通道将电刺激传递至相应的电极位点。本文受试者效果数据来自APS策略。

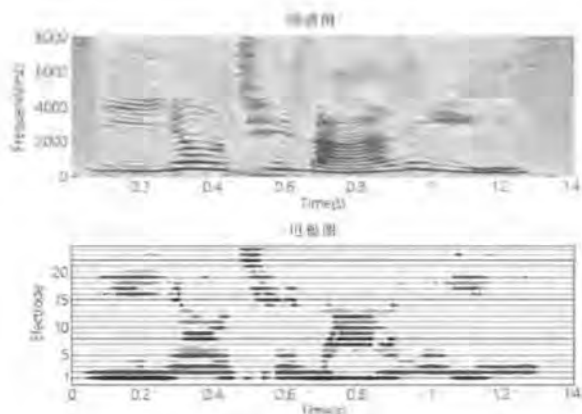


图3 汉语句“今天你哪里?”的频谱图(上图)及对应的电极图(下图)

2.2 无线频率传输

RF单元具有4大功能:①以相应的传输频率为植入单元提供能量;②可靠地向植入单元传输数据;③使外部处理和植入单元同步,并为后者提供时序信息;④提供反馈信号以监控植入单元的能量和状态,测量电极阻抗和实现神经遥测技术。为了实现这些功能,诺尔康外部处理器通过脉冲宽度调制(pulse width modulation, PWM)编码数字信号,以及幅移键控调制方法平衡传输的效率和可靠度。系统选择16 MHz正弦波作为载波频率,采用Class-E放大电路,并通过调整负载、电路的最佳谐振点实现高效。

图4A显示了用脉冲宽度调制编码“0”和“1”,其中比特“0”由5个周期长度的载波编码,而比特“1”则被10个周期长度的载波编码。图4B显示了植入单元中实际所得的16 MHz RF波形。由于Class-E放大器的谐振效应,上升斜坡及调制后回响在接收的波形中很明显。另外,环境干扰、头皮厚度的差异、外部线圈和内部线圈的相对位移都会使RF信号失真。因此需要一个稳固的解码器可靠地收集数字信息。系统采用迟滞触发器,使得3~7个RF周期均被解码为比特“0”,而8~12个周期则被编码为比特“1”。图4B为PWM编码“0”和“1”的恢复包络。这种PWM编码比特信号(1 MHz)为植入单元提供了运行时钟。系统反向传输采用在RFID中经常使用的一种负载调制方式。通过这种方法,可使用同样的一对线圈实现前向和反向的数据传输。植入体反向传输数据包括ASIC芯片的内部状况、恒流源的输出电压、刺激波形、阻抗及神经反应等。

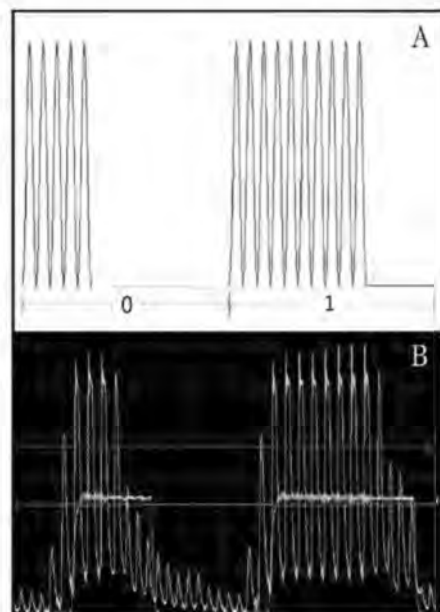


图4 诺尔康射频编码方案:图A显示了使用脉宽调制来编码“0s”和“1s”,图B显示了实际接收的16 MHz射频波形及复原后的“0”和“1”时相包络

2.3 接收器和刺激器

植入体线圈接收RF信号产生能量,然后解码数据和发出指令产生电刺激。为了保证传输数据的正确性,系统采用了一系列的验证方法,包括奇偶校验检查、循环冗余核对、数据范围检查及传输握手确认等常规技术。图5A显示了Nurotron ASIC接收器和刺激器的芯片布线图。芯片裸片的大小为 $3594 \times 2499 \mu\text{m}^2$,是一个含模拟电路和数字电路的混合COMS芯片。芯片包含4个电流源,保证可靠性并实现间隔和同时刺激,支持多种刺激方式,如蜗内双电极的同极性、反极性刺激或包含3个蜗内电极的三极性刺激等。

图5B显示了两通道之间的间隔双相脉冲序列。图5C显示了一个 $25\text{-}\mu\text{s}$ 脉宽和 $2\text{-}\mu\text{s}$ 相位间隔,负相位在前的双相脉冲。图5D显示了电流单位(X轴)和相应的电流级(Y轴),以及预期值(线条)和测得值(圆点,从7个芯片选择14个电流源或者每个芯片随机选择2个电流源)。为了使刺激符合电刺激的感知幅度编码,4种不同的电流分辨率($2, 4, 8$ 和 $16 \mu\text{A}$)被用来将实际电流($I = 0 - 1904 \mu\text{A}$)编码成256个临床电流单位(CU)。采用实际电流产生的响度和临床电流单位产生的响度在感知上大致相当^[7]。

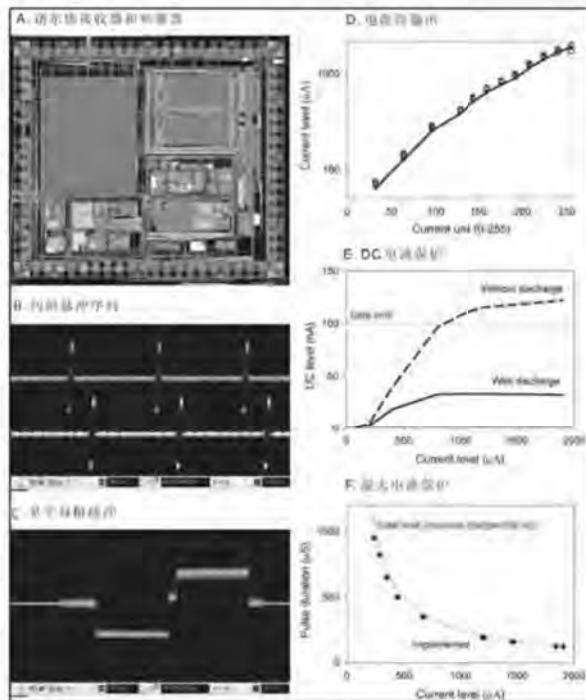


图5 诺尔康接收器和刺激器

根据指定和实测电流值之间的百分比差异, 电流源的精度为 $8.0\% \pm 2.6\%$ 。计算14个电流源的标准差和均值之间的比率, 电流源的公差为 $3.0\% \pm 1.3\%$ 。这两种验证方法表明诺尔康产品在调试时没有必要对单个电流源幅度进行校正。

ASIC采用了多重措施保证电刺激的安全性。第一, 双向脉冲刺激产生的静电荷量应该平衡, 积累的直流偏置电流应小于100 nA (EN 45502-2-3: 2010)^[6]。图5E显示了积累的直流偏置电流和刺激强度之间的关系。如果没有ASIC的主动放电回路, 积累的直流电流会超过100-nA的安全限值, 达到800- μ A电流级或更高。有了放电回路, 累计直流电流为33 nA, 远小于刺激脉冲的电量。第二, 为了进一步平衡可能作用于组织的剩余电荷, 在每个电极上串联一个隔直电容。第三, 为避免过度刺激造成组织损伤, 在硬件上限制每个相位的最大输出电荷为250 nC^[8]。图5F显示了过度刺激保护模式(虚线)及不同脉宽和刺激幅度下(圆点)实际测得的最大电荷。在任何情况下, 刺激的最大电荷都不超过250 nC。

ASIC芯片的反向遥测电路采用最大增益为60 dB可编程增益放大器和12-bit模拟-数字信号转换器。采用这样的电路后, 神经信号记录的最小的有效电位是10 μ V, 阻抗测量误差为5%。

2.4 电极(24+2)

诺尔康人工耳蜗通过一个24触点的蜗内电极阵

列刺激听神经产生听觉。现有的电极设计既能最大程度地避免和减少插入造成的损伤, 保证病人较好的听声效果, 又能保证电极在人体内的长期稳定性。在尸头颞骨中所做的研究表明, 人工耳蜗电极设计特性与蜗内损伤显著相关, 且蜗内损伤可显著影响听声效果^[9-14]。基于这些研究, 诺尔康电极阵列足够小以适应个体间的鼓阶大小变化。此外, 诺尔康的电极阵列具有以下特点: 电极的垂直面硬度大于水平面硬度, 这一设计可以最大程度地减少电极插入时在垂直方向偏移以致进入中阶或前庭阶的几率。

诺尔康电极由一个硅胶注塑的载体, 24个蜗内刺激触点和2个蜗外参考电极组成。图6A显示了电极柔软灵活的尖部及7个位于末端的电极触点。刺激电极触点的暴露面积为 0.2 mm^2 , 以 0.8 mm 的间隔分布在电极内侧, 这一侧在植入时需朝向蜗轴, 以保证电极触点更靠近听神经。刺激时, 最大的电荷密度为 $1.25 \mu\text{C}/\text{mm}^2 (=250 \text{ nC}/0.2 \text{ mm}^2)$ 。考虑到实际的铂金触点表面具有1.4的粗糙系数, 实际电荷密度约为 $0.9 \mu\text{C}/\text{mm}^2$, 远低于文献规定的最大安全电流限制^[15]。图6B显示了电极阵列反面的触点位置及连接触点的电极导线, 图6C显示了尾部旋绕的电极导线。建议电极阵列插入全长为 22.0 mm , 相当于在正常形态耳蜗中插入直电极时 400° 左右的深度^[16]。24个刺激电极触点及相对较深的插入保证了良好的听声效果, 详见后面的报告。为了适应人类鼓阶的尺寸, 诺尔康电极阵列顶部尺寸为 0.70 mm (高) \times 0.56 mm (宽), 而基部则为 0.93 mm (高) \times 0.68 mm (宽), 这种设计适用于所有已报告的人类鼓阶的横截面^[9]。图6D显示了基部 90° 及电极顶部 360° 位点, 诺尔康电极阵列在任意挑选的人类鼓阶横截面的轮廓和位置。

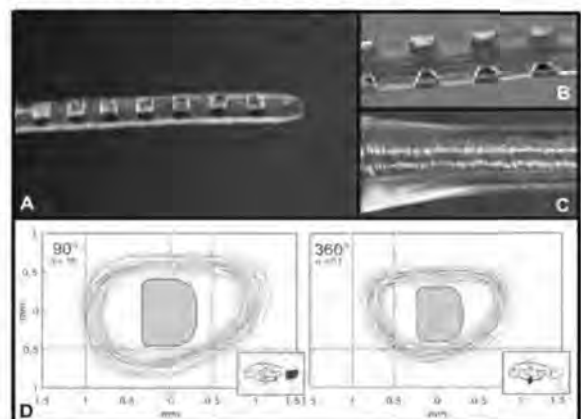


图6 诺尔康24通道蜗内电极阵列

为了减少电极尖部垂直位移造成的损伤几率, 诺尔康电极增加了垂直面上的机械硬度。电极阵列

的物理性能测试显示垂直硬度和水平硬度的比率为2.5/3.0。实验数据显示,采用了类似比例的其他电极设计能显著减少电极插入过程中造成的损伤^[9,10]。初步的颞骨研究及术后临床影像学评估已经证实诺尔康电极阵列能够顺利地插入22 mm推荐深度同时不造成显著的损伤。在电极和线圈的可靠性实验中,电极阵列与植入刺激器相连,通过对植入体线圈和电极的反复弯折测试表明,诺尔康的电极抗弯折性符合欧洲标准(EN 45502-2-3;2010)^[6]。为了减少与耳蜗开孔位置、鼓阶基部视野暴露不足、电极尖部的角度方向错误或这些因素共同造成的插入损伤,电极设计的另一个要求是简化手术时电极插入方法。诺尔康电极是一款硬度适宜的直电极,没有内芯,无需手术插入工具,大大降低了手术难度。

2.5 封装及磁共振兼容性

在植入体壳体中,25根铂金引针被放置在钛金壳体的底部,一端与壳体内部的PCB相连接,另一端则与24个蜗内电极以及环状参考电极相连接。钛金壳体的体积为12.8 ml(36.4×33.0×6.9 mm³),而位于皮肤和乳突表面的部分厚度仅为3.9 mm,另外的3 mm被置于骨槽中以固定植入体减少位移。另有3根引针在植入体壳体侧面,分别与射频(RF)线圈及板状参考电极相连。壳体和电极焊接后,植入体的最后工序是植入体整体的硅胶注塑。植入体完成后需要进行生物兼容性测试,并于临床试验前得到了CFDA指定测试机构的认证。植入体的密封性主要是通过氦气泄漏实验来验证的,诺尔康植入体壳体的泄漏率小于 1×10^{-9} 大气压·立方厘米/秒,达到欧洲标准要求(EN 45502-2-3;2010)^[6]。

诺尔康人工耳蜗在1.5 T下的MRI兼容性已得到了验证。在热发生测试中,不含磁铁的植入体被置于充满15 ml浓度为9 g/l盐水的容器中,另一同样但不含植入体的容器作为对照组。15分钟的MRI扫描没有对两个容器的温度造成显著差异,植入体壳体或电极尖部的温度上升小于2℃。此外,MRI扫描产生了0.06 nC的电流,低于10 nC的安全范围(EN 45502-2-3;2010)^[6]。另外,15分钟的MRI操作没有对植入体装置的功能和效果产生显著影响。

3 系统评价

3.1 方法

3.1.1 受试者 2009年11月~2010年10月,60例语后聋受试者参加了诺尔康人工耳蜗临床试验。其中男性34名,女性26名,平均年龄为 26 ± 12 岁(范围6~59岁)。人工耳蜗入选遵照卫生部颁发的标准^[17]。对受

试者进行随访,其中48例患者参加了3年的随访。

3.1.2 手术 对60例受试者进行了乳突切开和耳蜗开孔。在耳缘后切口,在进入中耳之前先磨骨0.44 mL或440 mm³以固定接收器和刺激器壳体。打开面隐窝后磨骨以尽量暴露圆窗龛。使用1.0或0.5 mm金刚钻从圆窗龛前下方开一小孔,耳蜗开孔直到骨内膜的蓝线清晰可见。往鼓阶注射小剂量的透明质酸钠以防止液体流出及骨粉进入,在这个步骤中禁止吸引以避免外淋巴液的流失,随后将电极阵列插入鼓阶,完成后使用小块肌肉填充耳蜗开孔。人工耳蜗植入后,测量电极阻抗以及电蹬骨肌反射以验证设备的工作状况。植入时间为30~120分钟。

为了估计电极的位置及插入深度,48名患者进行了术后X光片拍摄,平均插入深度为449°,标准差为79°,比设计插入长度440°稍深^[18,19]。在这48例受试者中,37例患者的24个电极全部插入耳蜗,11例存在电极轻微弯折或错位现象(尤其是靠近圆窗的位置,见图7),提示需要对电极设计和手术过程进一步评价。电极阵列弯折或错位的影响将在后文进行讨论。

3.1.3 刺激 采用House句子识别测试^[20]和301句子识别测试^[21]对诺尔康人工耳蜗的效果进行评价。采用关键词的正确识别率作为上述两项开放式测试的得分。因两项测试未发现显著差异,故采用平均得分进行数据统计。另外进行了声母、韵母、声调识别3项闭合式测试(<http://www.tigerspeech.com>)。

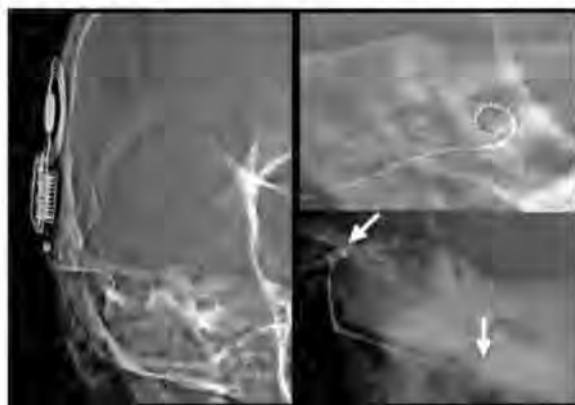


图7 诺尔康人工耳蜗设备的高分辨率X线片

默认的语言识别采用APS策略,默认刺激模式为单极模式,即同时使用2个参考电极(MP1+2)。电极阻抗通过40 ms的脉冲间隔的双向脉冲波进行估计。采用500 ms、1000 Hz的双向脉冲序列对阈值和舒适阈进行估计,脉冲间隔为25或50 ms/相位。在声场中以65 dB SPL的强度给言语信号。

3.1.4 步骤 作为知情同意的一部分,所有受试

者同意参加术前测试及术后1、2、4、6、12个月测试。24个月和36个月的测试为自愿参加。在每次测试中,受试者接受气导纯音听阈测试、电阻抗测试、各通道阈值和舒适阈测试,闭合式言语测试和开放式句子识别测试。另外,受试者均接受全面的生理检查,包括生命体征、血常规、血生化、心电图、胸片及手术并发症(如肿胀、感染、面瘫、血肿)检查。

3.2 结果I:客观测试

在1年的临床试验期间,发生了6例不良事件,2例可能与手术有关(植入体部位肿胀、手术部位肿胀,后自行消退),4例与手术或设备无关(2例脂肪肝,1例急性肾炎及1例上呼吸道感染)。手术医生确认这些事件均与诺尔康设备无直接联系。

图8分别显示了以设备开机时电极位置和设备使用时间为横坐标的电极阻抗值。在开机时,电极阻抗为 $13 \pm 3 \text{ k}\Omega$,电极位置之间没有显著差异 [$F(23, 771) = 0.7, P > 0.05$]。然而,随着植入时间的推移,所有电极的平均阻抗值发生显著变化 [$F(23, 242) = 20.2, P < 0.01$]。从开机到开机1个月,平均阻抗降低了6 $\text{k}\Omega$,在12个月时保持稳定 ($P > 0.05$),在24个月时显著提高了2 $\text{k}\Omega$ ($P < 0.05$)。

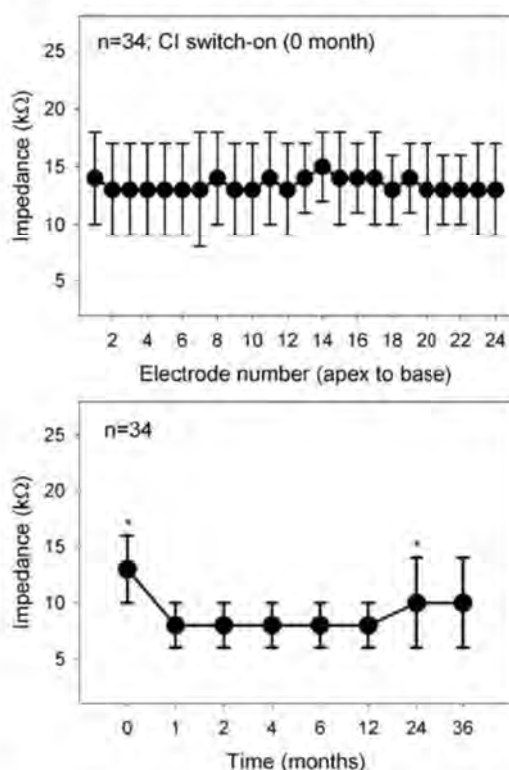


图8 开机时的平均阻抗,上图以电极位置为横坐标,下图以设备使用时间为横坐标。*号表示 $P < 0.05$

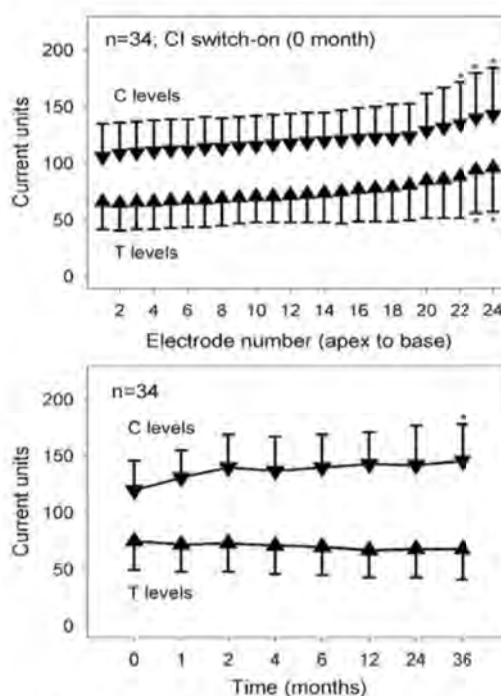


图9 开机时的平均T值和C值,上图以电极位置为横坐标,下图以设备使用时间为横坐标。*号表示 $P < 0.05$

3.3 结果II:心理声学测试

图9上图显示,开机时T值和C值均出现随着电极号增大而显著上升的趋势[T值和C值分别为 $F(23, 711) = 3.1, P < 0.01$; $F(23, 717) = 3.3, P < 0.01$]。与最蜗尖电极(#1)相比,post-hoc分析显示23和24号电极的T值显著较高,而对于C值来说,22、23和24号电极显著较高 ($P < 0.05$)。值得注意的是,这些T值和C值的不同和电极阻抗无关,因为不同电极之间的阻抗没有显著差异。

图9下图显示,T值在36个月时保持稳定 [$F(7, 226) = 0.4, P > 0.05$];C值随着时间的推移逐步提升 [$F(7, 226) = 2.3, P < 0.05$],36个月的C值显著比开机时要高 ($P < 0.05$)。C值的提高可能反映了听神经对电刺激耐受的增强^[22]。

3.4 结果III:功能测试

图10虚线显示,受试者之间的句子识别率差异较大;随着时间的推移受试者平均得分显著提升 [$F(7, 426) = 132, P < 0.01$],即从术前的0%、分别提升到了开机1、2、4个月时的27%、41%和68% ($P < 0.05$)。人工耳蜗效果在6个月时达到平台期,36个月时达到最高值(89%)。

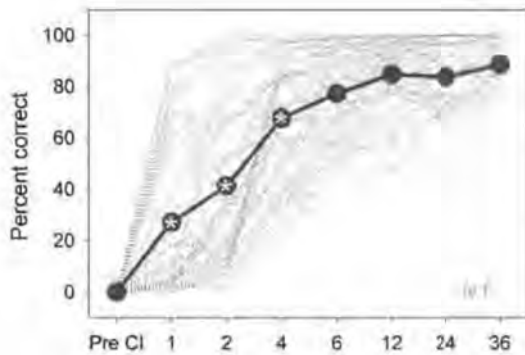


图10 个人(虚线)及平均(实线连接的点)句子识别得分,以设备使用时间为横坐标。点中带*号表示与之前的测试时间有显著差异

图11显示了声母识别、韵母识别及声调识别正确率。总体而言,这几项言语识别与句子识别结果接近,而受试者之间差异较大(虚线部分),识别结果随着时间的推移逐步提升[$F(7,426) > 45, P < 0.01$]。声母和韵母识别在使用4个月时即达到平台,而声调识别在使用6个月时才达到平台,提示声调识别对于汉语识别的重要性^[23]。

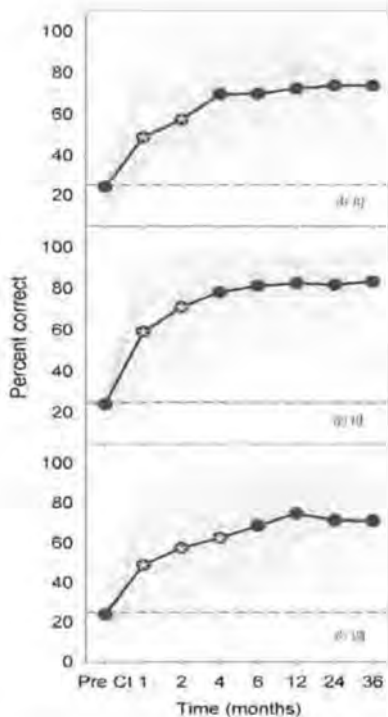


图11 个人(虚线)及平均(实线连接的点)声母识别(上图)、韵母识别(中图)和声调识别(下图)得分。点中带*号表示与之前的测试时间有显著差异

4 讨论

4.1 技术对比

表1比较了诺尔康和其他3种人工耳蜗产品。就体外部分而言,诺尔康与其他品牌的设备具有相似的技术参数:相对较宽的输入动态范围(75~80 dB),默认编码策略(如CIS)的频率范围(~8000 Hz),处理器中的程序数量(4~5)。但诺尔康言语处理器缺少无线通讯功能,这一点在2005年的设计中没有考虑到。目前诺尔康产品正在处理能耗和连接的问题。

尽管尚无生产厂家给出关于人工耳蜗电极阵列在人体内状态的系统报告,但人工耳蜗系统电极弯折和放错位置的情况时有发生,例如有报道称电极阵列在某些病例错误插到前庭阶的几率高达40%^[10,11,25-27]。术后分析发现,本文报告的11例患者由于电极弯折或放错位置导致的不可用电极数目平均为4个(范围0~13个),而其他患者平均只有1个(范围0~10个)。有电极问题患者的平均言语识别率是70%±18%,无电极问题患者的平均识别率为79%±19%。两组患者不可用电极数目及句子识别得分均无显著差异($P > 0.05$),这或许与样本量较小有关。受试者与设备之间的关系很复杂,例如,有最多不可用电极(13个)的受试者,却获得了较高的言语识别率得分(92%)。

除了拥有数量最多的蜗内电极,诺尔康的射频和内部装置的关键技术参数大都处于现有产品的中间水平。例如,16 MHz的载波较AB的49 MHz低,但高于科利耳的5 MHz和Med-El的12 MHz;其40 KHz的总刺激速率比科利耳的32 KHz高,但低于AB的83 KHz和Med-El的51 KHz;4个电流源比科利耳的1个电流源多,但少于AB的16个和Med-El的24个。总之,这些技术参数的差异反映了设计理念的差别,但并未产生实际效果的差异。

4.2 效果比较

本文报告的电极阻抗(图8)和刺激级(图9)结果与其它品牌人工耳蜗产品的大样本研究一致^[28-33]。除了较大样本量和较长观察期(3年和1~2年),本研究以如下方式延伸了既往的研究:首先,电极阻抗与电极位置无关(图8A)提示电极阻抗主要反映了电极的物理特性,如面积以及电极与周边组织的动态关系^[34],而响度与电极位置有关(图9A)则提示行为测试更多地反映了包括电场特性、存活神经数量和分布及中枢因素的总和^[33]。阻抗与时间的非单调函数关系(图8B)以及响度与时间的单调函数关系(图9B)进一步证明

表1 诺尔康26电极人工耳蜗系统与其它3种人工耳蜗系统对比表

系统单元	参数	诺尔康晨星	Nucleus N6	AB HiRes 90K	Med-EI MAESTRO
体外单元	名称及关键特性	晨星:全向或方向性麦克风	N6:全向或方向性麦克风	Harmony: T-mic	OPUS2: 全向性麦克风
	输入动态范围	输入动态范围(75 dB)	输入动态范围(-75 dB)	Dual-loop AGC, 输入动态范围(20-80 dB)	Dual-loop AGC, 输入动态范围(-75 dB)
	频率范围	100 ~ 8000 Hz	100 ~ 8000 Hz	150 ~ 8000 Hz	70 ~ 8500 Hz
	锂电池或3粒锌空气电池(8-24小时)	锂电池或3粒锌空气电池(8-24小时)	2粒锌空气电池或可充电电池(18-60小时)	锂电池(12-56小时)	3粒锌空气电池(12-90小时)
	编码策略	CIS APS Symphony	SPEAK ACEMPS Hi-ACE	CIS HD HiRes Fidelity 120	CIS+ CIS FSP
	程序数量	4	4	5	4
	设备连接	直接音频输入	直接音频输入	直接音频输入	直接音频输入
射频单元	射频传输	16 MHz	5 MHz	49 MHz	12 MHz
	数据传输	0.9 MB/秒	0.5 MB/秒	1 MB/秒	0.6 MB/秒
体内单元	总刺激速率	40 KHz	32 KHz	83 KHz	51 KHz
	电流源数	4	1	16	24
	最大电流值	1.9 mA	1.75 mA	1.9 mA	1.2 mA
	蜗内电极数	24	22	16	12
	参考电极数	2	2	2	2
	同时刺激	是	否	是	是
调试单元	阻抗测量	是	是	是	是
	中文界面	是	否	否	否

注:该表数据来源: Cochlear N6来自www.cochlear.com用户指南和技术规格; Clarion HiRes 90K来自www.bionicear.com; Med-EI Maestro来自参考文献[24]。其它信息来自http://cochlearimplantonline.com

长期电流刺激增加了病人对响度的耐受力,这一变化反映了中枢增益的降低,而非耳蜗内电极特性的改变^[22]。较之成人,这一响度变化在儿童植入者中更为显著,这与发育中的大脑具有更大的可塑性有关^[28-31]。

言语测试结果显示诺尔康产品使用效果与其它品牌人工耳蜗产品无差异。图12A是4家人工耳蜗产品句子识别测试结果对比。美国Advanced Bionics (AB)的数据为51位植入者在使用HiRes处理策略3个月后得到的结果(在这之前已有3个月使用传统策略如CIS或SAS的经历)^[36];奥地利Med-EI的数据为14名植入者使用精细结构处理策略得到的结果(在这之前已使用了平均1年的CIS编码策略)^[37];澳大利亚科利耳的数据为55名植入者参加Nucleus Freedom北美临床试验期间使用Freedom设备6个月后得到的

结果^[38]。诺尔康植入者3个月、6个月及1年的数据对比,发现6个月显著高于3个月,1年高于6个月但差异不显著(图10)。尽管AB和科利耳采用的是英文句子,Med-EI用的是德语句子,而诺尔康用的是中文句子材料,而且这些临床试验是通过不同的研究者采用不同的方案实施的,但最终4种产品在安静环境下测试均获得了60%~80%的句子识别率,表明4种产品的效果相当。

在一项严格控制的研究^[39]中,对比了科利耳和诺尔康人工耳蜗产品的使用情况。两家产品植入者的年龄、耳聋时长、性别、听力学及耳聋病因等因素均进行了匹配。采用相同的手术和评估方案(中文言语测试材料)进行评估,发现两种设备植入者使用效果无显著差异。图12B显示了使用2年后两种品牌植入者的句子识别得分情况,科利耳植入者得分为87%±14%,

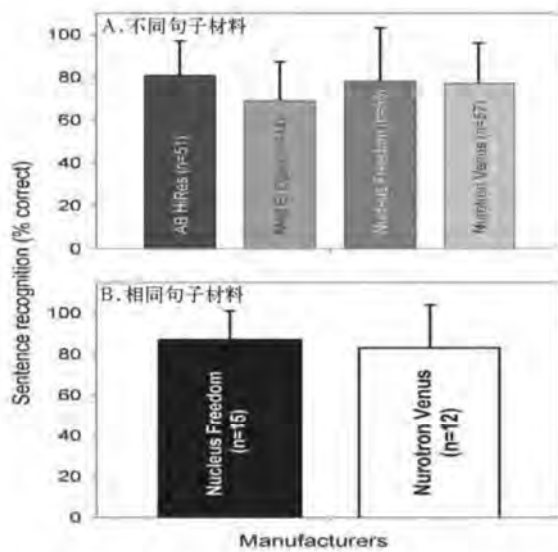


图12 上图为采用不同测试材料和方案得到的诺尔康产品与其它3家产品句子识别得分;下图为采用相同测试材料和方案得到的诺尔康产品与科利耳产品句子识别得分

诺尔康植入者得分为 $83\% \pm 21\%$ 。其它独立研究^[40,41]也表明,诺尔康植入者具有高言语识别得分,植入后生活质量得以改善。

5 小结

诺尔康人工耳蜗系统包括体外言语处理器、射频传输线圈、体内天线、接收器和刺激器。系统默认的编码策略为多峰间隔刺激策略,默认刺激模式为单极刺激,即24个电极中1个作为刺激电极而2个蜗外电极作为参考电极。60名重度至极重度听障受试者参加了为期一年的临床试验,其中大多数人参与了3年的评估。与其它人工耳蜗品牌相似,诺尔康产品也具有开机后一个月阻抗值下降,3年内T值稳定和C值渐升的特点。中文言语识别测试结果显示,诺尔康人工耳蜗植入者言语识别率从术前到使用4个月期间显著提升;使用6个月后达到80%的正确率。直接和间接的比较研究表明,诺尔康26电极人工耳蜗与其它人工耳蜗品牌使用效果相当。

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Review

Development and evaluation of the Neurotron 26-electrode cochlear implant system



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ABSTRACT

Although the cochlear implant has been widely acknowledged as the most successful neural prosthesis, only a fraction of hearing-impaired people who can potentially benefit from a cochlear implant have actually received one due to its limited awareness, accessibility, and affordability. To help overcome these limitations, a 26-electrode cochlear implant has been developed to receive China's Food and Drug Administration (CFDA) approval in 2011 and *Conformité Européenne* (CE) Marking in 2012. The present article describes design philosophy, system specification, and technical verification of the Neurotron device, which includes advanced digital signal processing and 4 current sources with multiple amplitude resolutions that not only are compatible with perceptual capability but also allow interleaved or simultaneous stimulation. The article also presents 3-year longitudinal evaluation data from 60 human subjects who have received the Neurotron device. The objective measures show that electrode impedance decreased within the first month of device use, but was stable until a slight increase at the end of two years. The subjective loudness measures show that electric stimulation threshold was stable while the maximal comfort level increased over the 3 years. Mandarin sentence recognition increased from the pre-surgical 0%-correct score to a plateau of about 80% correct with 6-month use of the device. Both indirect and direct comparisons indicate indistinguishable performance differences between the Neurotron system and other commercially available devices. The present 26-electrode cochlear implant has already helped to lower the price of cochlear implantation in China and will likely contribute to increased cochlear implant access and success in the rest of the world.

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1. Introduction

Since the United States Food and Drug Administration (FDA) approved the first cochlear implant in 1984, more than 300,000 hearing-impaired people worldwide have used electric stimulation of the auditory nerve to derive benefits from restoring speech perception in post-lingually deafened adults to developing language in pre-lingually deafened children Clark, 2015, Hochmair,

2015, Wilson, 2015, Eisenberg, 2015, Chouard, 2015, Merzenich, 2015. Cochlear implant technology has evolved from a single-electrode analog device to multi-electrode devices with interleaved stimulation and *in vivo* neural recording. Three major companies, Cochlear Corporation in Australia, Med El in Austria and Advanced Bionics LLC in the United States, control essentially the entire market, with Cochlear Corporation being the dominating player. Despite clearly documented benefits, technological advances and commercial success, the cochlear implant is still limited to about 10% of potential candidates in developed countries and much less in developing countries (Zeng, 2007). The high cost of the cochlear implants has not changed in the last 30 years despite the increased volume and is still a major factor limiting market access. Developing a low-cost, high-performance cochlear implant system has long been recognized as an effective, perhaps the only means to increase competition and hopefully market access, particularly in developing countries (An et al., 2007; Wilson et al., 1998; Zeng, 1995).

The present article describes the conceptualization and process in developing and evaluating the Nurotron 26-electrode cochlear implant system, which started with a technology transfer from the University of California in 2006, received CFDA market approval in 2011 and CE Mark in 2012. As of July 2014, the Nurotron device has been implanted in 1500 deaf subjects in China, 2 in Columbia and 2 in India. First, the philosophy is presented on the design and development of the overall system specification. Second, specific design and verification of the system components are laid out from the external sound processor and radio frequency transmission to the internal receiver, stimulator and intracochlear electrode array. Third, systematic evaluation results are presented from objective measures to subjective functional assessments in 60 human subjects who participated in the initial CFDA clinical trial. Finally, relevant research and socio-economical impact are discussed.

2. System specifications

Cochlear implant technologies have converged in the last 30 years – from single-electrode analog stimulation to multi-electrode interleaved stimulation (e.g., Wilson et al., 2008; Zeng et al., 2008). Fig. 1 presents the functional block diagram of a contemporary cochlear implant system, consisting of an external unit, a transcutaneous radio-frequency (RF) transmission unit, an internal unit, and a fitting unit that is not worn by the user but

used only by clinicians to adjust connection and stimulation parameters for optimal performance. The external unit is often called a speech or sound processor and contains a digital signal processor (DSP) to control signal flow from environmental sounds to RF transmission. The internal unit includes a hermetically sealed application-specific-integrated-circuit (ASIC) that derives power and decodes information from the RF signal, while delivering electrical stimulation to the electrodes, measuring feedback signals from the electrodes and transmitting these measurements back to the sound processor or the clinical fitting system.

The Nurotron cochlear implant system was developed based on the following design philosophy. First, the device should meet technical specifications that are critical to safety and performance of a contemporary cochlear implant. The European standard EN 45502-2-3 (2010) and additional modern practices were followed to conform to safety considerations; multi-channel, multi-stimulation strategies were employed to meet performance needs. Second, the device should have a flexible architecture to meet future needs such as virtual channels or fine structure encoding that could improve speech recognition in noise, tonal language understanding and music appreciation. With this philosophy in mind, the ASIC contained 4 current sources to provide simultaneous stimulation of 2 or 3 electrodes to potentially produce 47 or more spectral channels. Third, the device should have the capacity to support other neural prosthetics applications such as auditory nerve implants, auditory brainstem implants, retinal implants, or deep brain stimulation. To provide this level of expandability, the design included 2 reference electrodes and 24 active stimulating outputs that could be configured as 2×12 , 3×8 , or 4×6 surface electrodes or penetrating bundles.

Fig. 2 illustrates the Nurotron cochlear implant system. Panel A shows the behind-the-ear sound processor that contains dual microphones, control buttons, display lights, battery case, and an RF transmission coil. A body-worn sound processor (not shown) is also available for extended battery life or as preferred by some user groups. Panel B shows the internal components of the system that contains a gold RF receiving coil, a removable magnet (with "X" sign in the middle of the coil to designate polarity), a titanium case, a plate platinum reference electrode (beside the logo in the case), a ring platinum reference electrode (at the exit of the electrode array), and a straight 24-contact electrode array. The following section describes specific design and verification for the Nurotron cochlear implant system.

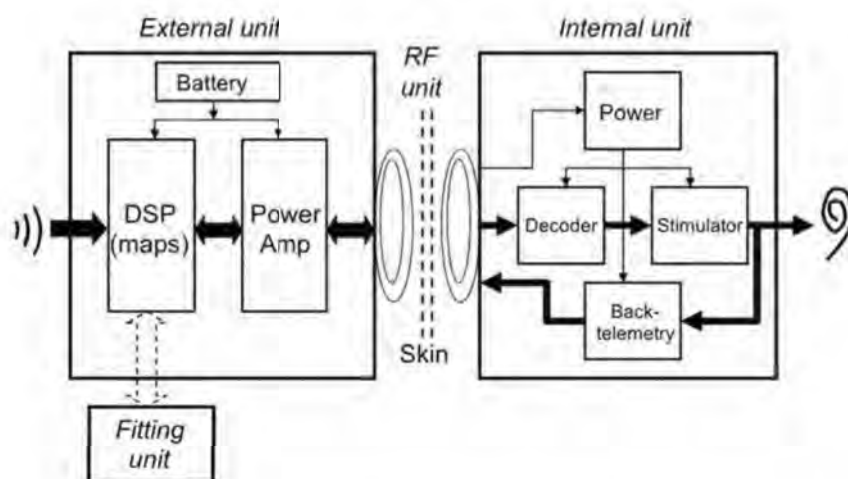


Fig. 1. A functional block diagram of the Nurotron 26-electrode cochlear implant.

A. Nurotron Sound processor

B. Nurotron cochlear implant



Fig. 2. The Nurotron cochlear implant system: The sound processor (A) and the internal unit containing the receiver, stimulator and electrode array (B).

3. Design and verification

3.1. Sound processing

Advanced sound processing is critical to cochlear implant performance. First, sound pre-processing is needed to ensure audibility and clarity of speech sounds. The Nurotron standard pre-processing includes sensitivity control, automatic gain control, single microphone noise reduction, and mixed input selection. Second, sound processing needs to convert analog sound into electrical pulses. The Nurotron DSP employs 3 processing strategies, including continuous-interleaved-sampling (CIS), advanced peak selection (APS) and virtual channel (Symphony) strategies. The CIS strategy employs a fixed number of analysis and stimulation channels, with the actual number being determined by the number of a subject's usable electrodes up to 24. The APS strategy is similar to an "n-of-m" strategy, with the maximum number of analysis channels being 24 while the number of stimulation channels being typically 6 to 8, dependent on the energy distribution of the input sound and the number of available electrodes. The APS strategy increases stimulation rate for improved representation of temporal fine structure. The Symphony strategy combines virtual channel and peak selection strategies to additionally improve the spectral fine structure, in which simultaneous stimulation of two electrodes is used to generate intermediate pitch percepts between two these two electrodes.

Fig. 3 shows the spectrum (upper panel) and electrodogram (lower panel) of a Mandarin sentence of "今天你去那里?(Where are you going today?)". In this example, the electrodogram shown is the output generated by the APS strategy, which divides a continuous frequency band between 100 and 8000 Hz into 128 linearly-spaced frequency bands. The 128 frequency bands are then combined into 24 analysis bands based on the Greenwood map spacing, of which 8 channels with peak energy are selected to deliver electrical stimulation to the appropriate electrode sites. The APS was the default strategy used to produce performance data reported in the user performance result section of this study.

3.2. Radio frequency transmission

The RF unit serves 4 functions, including (1) providing power to the implant circuit with reasonable transmission efficiency, (2) transmitting data to the implant circuit with high reliability, (3) synchronizing between the external processor and the implant circuit while providing timing for the latter, and (4) transmitting

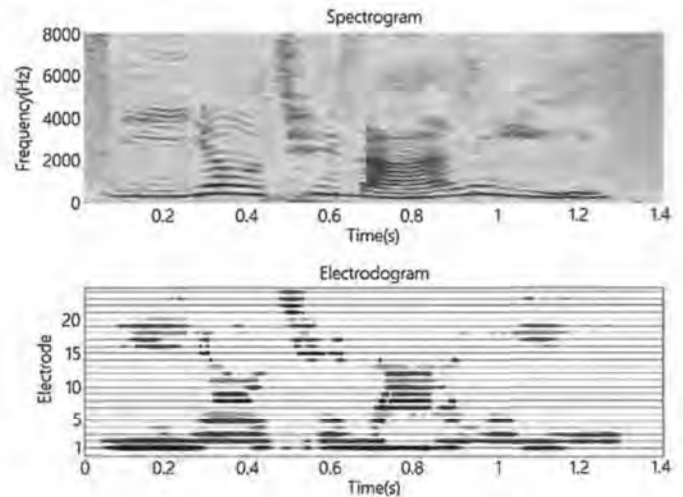


Fig. 3. The spectrogram (upper panel) and its corresponding electrodogram of the Nurotron device (lower panel) for a Mandarin sentence "今天你去那里?(Where are you going today?)".

feedback signals to monitor the implant circuit power and status and to measure electrode impedance and neural responses to electric stimulation. To accomplish these functions, the Nurotron external processor employs Pulse Width Modulation (PWM) to encode digital signals and Amplitude Shift Keying (ASK), a method of amplitude modulation, to balance transmission efficiency and reliability. A 16-MHz sinusoid is chosen as the carrier frequency. A Class-E amplifier is employed to achieve high efficiency by maintaining the loaded RF circuit in a quasi-resonant status.

Fig. 4A shows the use of pulse width modulation to encode "0s" and "1s", in which bit "0" is coded by 5 RF cycles whereas bit "1" by 10 RF cycles. Fig. 4B shows the actually received 16-MHz RF waveform (yellow traces) in the implant circuit. Due to the Class-E amplifier's resonance status, rising ramps and post-modulation ringing are apparent in the received waveform. In addition, environmental interferences, variations in scalp thickness, and relative movement between the external and internal coils all distort the received RF signal. Therefore, a robust decoder is needed to reliably retrieve the digital information. Hysteresis trigger levels are employed so that signal patterns with 3–7 RF cycles are all decoded as bit "0", whereas that with 8–12 cycles as bit "1". Fig. 4B shows the recovered envelope of the PWM-coded "0" and "1" (green traces). This PWM-coded bit signal also provides a 1-MHz clock for the implant circuit. For back telemetry, a load modulation method, as commonly used in RFID, uses the same pair of coils to transmit the implant related data to the external processor. The implant related data include internal status of the ASIC, compliance voltage, stimulation waveform, impedance and neural responses.

3.3. Receiver and stimulator

The implant circuit receives RF signals to derive power, then to decode data and command frames to produce electric stimulation. Common techniques such as parity check, cyclic redundancy check, data boundary check, and handshaking protocols are used to validate data transmission integrity. Fig. 5A shows the layout of the Nurotron ASIC receiver and stimulator. The die size is $3594 \times 2499 \mu\text{m}^2$. The core is a hybrid CMOS chip with mixed digital and analog circuit. The chip contains 4 current sources, ensuring reliability and enabling both interleaved and simultaneous stimulation, including two-intracochlear-electrode

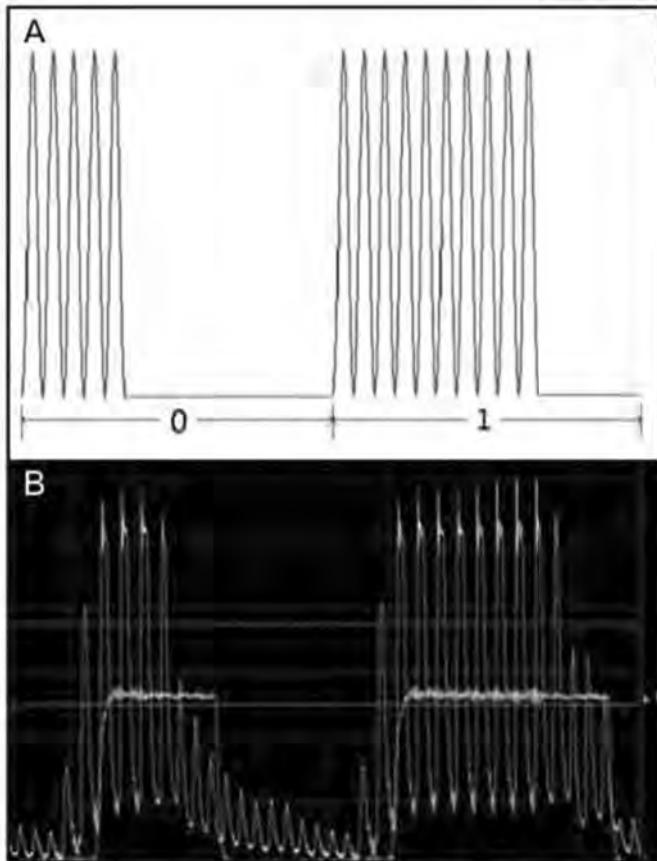


Fig. 4. The Nurotron RF encoding scheme: Panel A shows the use of pulse width modulation to encode “0s” and “1s” (Panel A) and Panel B shows the actually received 16-MHz RF waveform (yellow traces) and the recovered “0” and “1” temporal envelopes (green traces).

stimulation with the same or opposite polarity at the same time as well as tripolar stimulation involving three intracochlear electrodes.

Fig. 5B shows two biphasic pulse trains interleaved between two channels. Fig. 5C shows detailed waveform of a cathodic-leading biphasic pulse, with 25- μ s phase duration and 2- μ s inter-phase gap. Fig. 5D shows current units (x coordinates) and their corresponding current levels (y coordinates) in term of predicted values (line) and measured values (circles; from 14 current sources in 7 chips or 2 arbitrarily selected sources per chip). To take advantage of perceptual electric amplitude coding (Zeng et al., 1994), 4 different current resolutions (2, 4, 8, and 16 μ A) are used to encode the actual current ($I = 0\text{--}1904 \mu\text{A}$) into 256 clinically used Current Units (CU) that are roughly perceptually equal.

$$I(\mu\text{A}) = \begin{cases} 2CU & 0 \leq CU < 64 \\ 4(CU - 64) + 128 & 64 \leq CU < 128 \\ 8(CU - 128) + 384 & 128 \leq CU < 192 \\ 16(CU - 192) + 896 & 192 \leq CU < 255 \end{cases} \quad (1)$$

The accuracy of the current sources is estimated to be $8.0 \pm 2.6\%$ as the percent difference between the specified and measured current levels. The tolerance of the current sources is estimated to be $3.0 \pm 1.3\%$ as the ratio between the standard deviation and the mean of the measured 14 current sources. These two verification measures suggest that no individual calibration be needed in the amplitude-fitting program.

Several measures have been implemented in the ASIC to ensure safe electric stimulation. First, biphasic pulse stimulation should be charge balanced, resulting in less than 100 nA DC bias current (EN 45502-2-3: 2010). Fig. 5E shows accumulated DC current level as a function of biphasic pulse current level. Without an active discharge circuit in the ASIC, the DC level exceeds the 100-nA safe limit at 800- μ A current level and above. With the discharge circuit, the DC level was at 33 nA or less over the entire pulse current level. Second, to further balance residual charge that may be applied to tissues, a capacitor is serially connected to each of the electrodes. Third, to avoid overstimulation causing tissue damage, maximal charge of any phase is hardware limited to 250 nC (Shannon, 1992). Fig. 5F shows overstimulation protection model (dashed line) and actually measured maximal charges under different pulse duration and current level combinations (circles). Under no circumstance, does the implemented maximal charge exceed 250 nC.

Implemented on the ASIC chip is a programmable gain amplifier with a maximal gain of 60 dB and a 12-bit analog-to-digital convertor for back telemetry. As a result, a 10 μ V change can be detected to support recording of neural responses. Electrode impedance can be measured with 5% tolerance.

3.4. Electrodes (24 + 2)

A final step towards cochlear implant hearing is electric stimulation of the auditory nerve via a 24-intracochlear-electrode array. Optimally, this electrode-nerve interface should support high levels of subject performance, minimize the occurrence and severity of insertion related trauma, and demonstrate excellent long-term reliability. The physical characteristics of individual cochlear implant electrode designs have been clearly associated with the incidence of intracochlear trauma in studies using human cadaver temporal bones (Rebscher et al., 2008, 1999; Wardrop et al., 2005a; Wardrop et al., 2005b) and intracochlear trauma has been correlated with significant reductions in subject performance (Aschendorff et al., 2007; Carlson et al., 2011; Finley et al., 2008). Based on these studies, it is important for the electrode array to be sufficiently small to fit within the wide variety of scala tympani dimensions. Additionally, the Nurotron electrode array incorporates greater stiffness in the vertical plane of the cochlear spiral than in the horizontal plane which has been shown to be one successful strategy to minimize the occurrence of vertical deviation into the scala media or scala vestibuli.

The Nurotron electrode consists of an injection molded silicone elastomer carrier supporting 24 intracochlear stimulating contacts and 2 extracochlear reference electrodes. Fig. 6A shows the flexible tip and 7 most distal electrode contacts. The active contacts have an exposed surface area of 0.2 mm^2 and are located at intervals of 0.8 mm on the inner surface of the electrode to be oriented toward target neurons in the modiulus. The maximum charge density is 1.25 $\mu\text{C}/\text{mm}^2$ ($=250 \text{ nC}/0.2 \text{ mm}^2$). Taking into account that a platinum contact with smooth surface has a roughness factor of 1.4, the actual maximum charge density is more likely 0.9 $\mu\text{C}/\text{mm}^2$, well below the safety limit of electric stimulation (Brummer et al., 1983). Fig. 6B shows the contact sites and leads from the opposite side of the array. The tapered ends of each contact are securely embedded in the silicone carrier. Fig. 6C illustrates the coiled wire lead cable. The total recommended insertion length of the array is 22.0 mm, corresponding to an insertion depth of roughly 400 $^\circ$ by a straight electrode array in an average-sized cochlea (e.g., Franke-Triegeer et al., 2014). These 24 active intracochlear contacts and the relatively deep insertion support high levels of subject performance as reported below. To accommodate the size of the human scala tympani, the Nurotron electrode array is 0.70(H) \times 0.56 mm(W) at

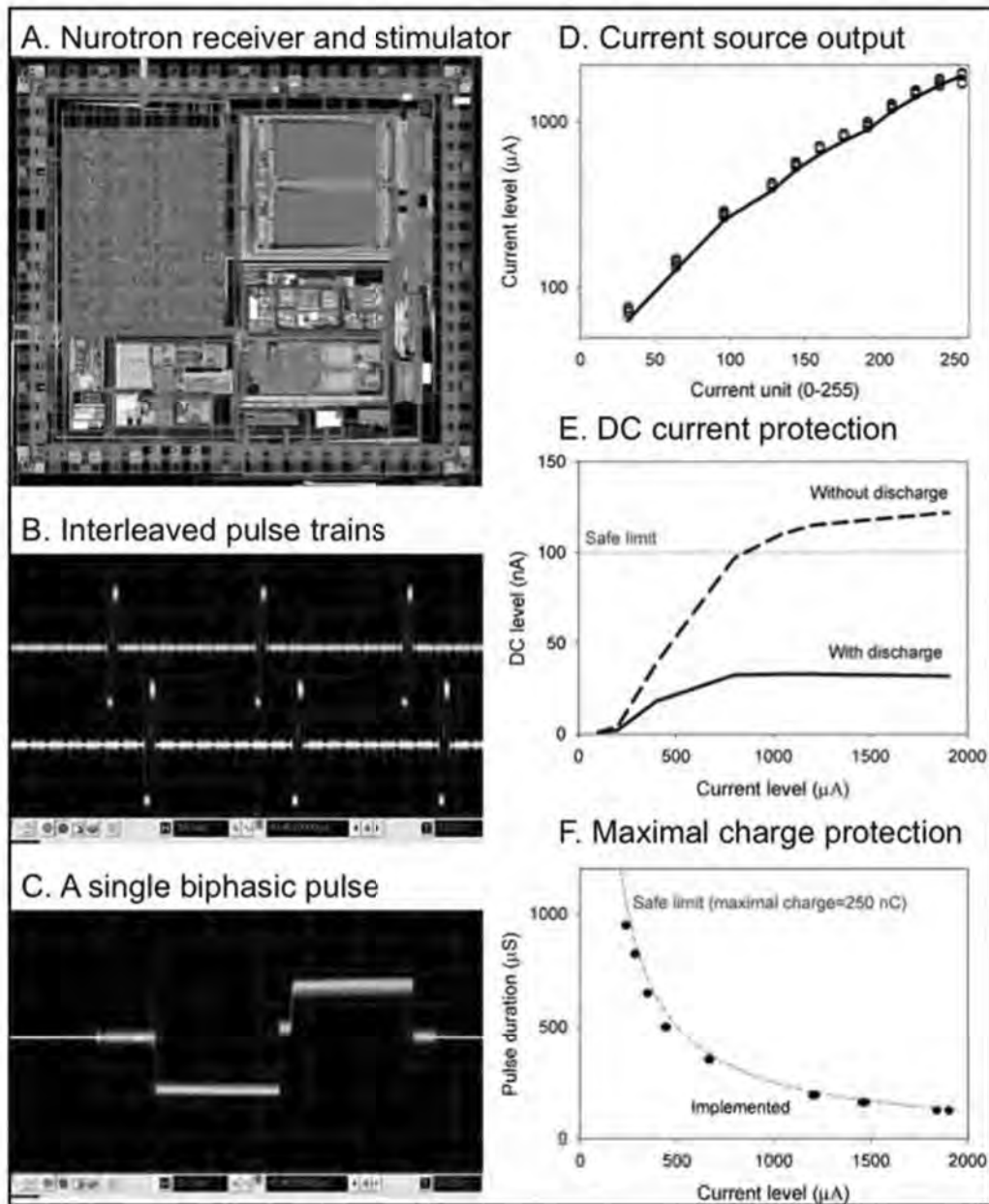


Fig. 5. The Nurotron receiver and stimulator. Panel A shows the ASIC die configuration. Panel B shows two interleaved biphasic pulse trains. Panel C shows detailed waveform of a cathodic-leading biphasic pulse, with 25- μ s phase duration and 2- μ s inter-phase gap. Panel D shows current units as a function of current levels in term of predicted values (line) and measured values (circles; from 14 current sources in 7 chips). Panel E shows accumulated DC current level as a function of biphasic pulse current level, with (solid line) and without (dashed line) an active discharge circuit. Panel F shows overstimulation protection implementation suggested by the model (dashed line) and measured by different pulse duration and current level combinations (circles).

the tip and 0.93 mm(H) \times 0.68 mm(W) at the base, which fits within all documented human scala tympani cross sections (Rebscher et al., 2008). Fig. 6D shows that the Nurotron electrode array fits within the outlines of a set of randomly selected human scala tympani cross sections in the base (90°) and near the electrode tip at 360°.

As described above, the Nurotron electrode is mechanically stiffened in the vertical plane as a strategy to reduce the incidence of damage resulting from vertical deviation of the electrode tip. Physical measurements of the array indicate a ratio of 2.5–3.0 between vertical stiffness and horizontal stiffness, similar to that reported for other electrode designs which have demonstrated significant reduction in insertion associated trauma (Rebscher et al., 2008; Wardrop et al., 2005a). Preliminary temporal bone

studies, and post-surgical clinical radiography, have confirmed that the Nurotron array can be reliably inserted to the 22 mm recommended insertion depth without significant trauma. To validate reliability, connection of the electrode array to the implanted stimulator, repetitive flex testing of the spiral coiled interconnect cable and the intracochlear electrode itself have been conducted to meet the European standard (EN 45502-2-3: 2010). A final design consideration in reducing traumatic insertions, which have been associated with poor cochleostomy placement, incomplete visualization of the basal scala tympani, angular misdirection of the electrode tip or a combination of these three factors, is to facilitate a simplified insertion technique. The Nurotron electrode is shaped as a straight array with moderate overall

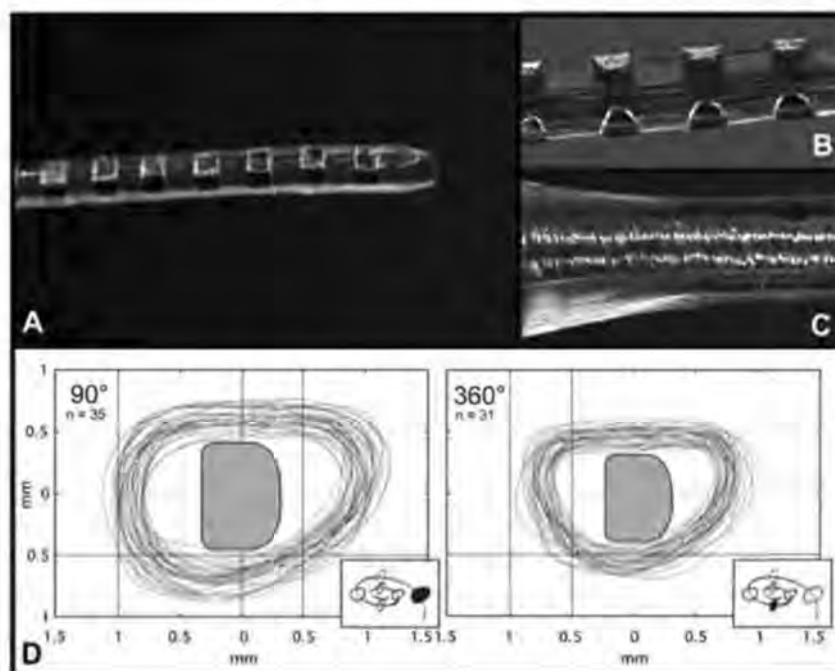


Fig. 6. The Nurotron 24 channel intracochlear electrode array. Fig. 6A shows the flexible tip of the electrode array and 7 distal sites of the 24 stimulating contacts, being equally distributed with a pitch of 0.8 mm along the 22.0 mm array and with each contact having a surface area of 0.2 mm². Fig. 6B shows the contact sites and leads from the opposite side of the array. The tapered ends of each contact are securely embedded in the silicone carrier. The organized vertical arrangement of the wire leads is also visible in this image. Fig. 6C illustrates the coiled wire lead cable. A critical factor in minimizing insertion related trauma is the fit of the electrode array within the confined cavity of the scala tympani. To ensure that the Nurotron array would safely fit in the range of cochlear dimensions observed across the subject population, the design was modeled in a series of cochlear cross section outlines (Fig. 6D) measured at 90° (35 bones) and 360° (31 bones) intervals (Rebscher et al., 2008). These measurements indicate that the Nurotron array occupies approximately 25–30% of the cross sectional area of the scala tympani at each location evaluated and fit within all scala tympani profiles previously documented.

stiffness to allow uncomplicated insertion without the need for an insertion tool or stylet.

3.5. Packaging and MRI compatibility

Twenty-five platinum feedthroughs are placed in the bottom of the titanium case and connected to an internal PCB on one end, the 24-intracochlear electrodes and the ring reference electrode on the other. The titanium case has a volume of 12.8 ml (36.4 × 33.0 × 6.9 mm³), but with only 3.9-mm spacing being expected between the skin and the mastoid surface because a 3-mm deep recess is routinely drilled in the bone to securely house the implant and minimize its movement. Three additional platinum feedthroughs on the sidewall of the case are connected to the two ends of the RF coil and the plate reference electrode, respectively. Silicone coating and molding form and shape the final package of the implant. Biocompatibility tests were performed and approved by the CFDA testing facility before human clinical trial. Hermetic seal, measured by the helium-gas leakage rate, is less than 1×10^{-9} atm cm³/second (EN 45502-2-3: 2010).

MRI compatibility at 1.5T has been verified for the Nurotron cochlear implant. In the heat generation test, the implant without the magnet, was placed into a 15-ml container filled with 9 g/l saline. An identical container without the implant served as control. 15-min MRI scan produced no significant difference in temperature between the two containers, with a temperature rise in the implant case or at the electrode tip being less than 2 °C. In addition, the MRI scan produced a charge of 0.06 nC, less than the 10-nC safe limit (EN 45502-2-3: 2010). Finally, the 15-min MRI operation produced no noticeable change in function and performance of the implant device.

4. System evaluation

4.1. Methods

4.1.1. Subjects

Sixty subjects participated in the Nurotron cochlear implant clinical trial from December 2009 to October 2010. They were 34 males and 26 females, with a mean age of 26 ± 12 years old (range = 6–59 years old). The cochlear implantation candidacy criteria followed the standard issued by Chinese Ministry of Health (Chinese Ministry of Health, 2007). The mean duration of deafness, defined as bilateral pure-tone-average thresholds (0.5, 1, 2 and 4 kHz) greater than 85 dB HL, was 7 ± 5 years (range = 0.3–15 years). The actual pre-surgical pure-tone-average thresholds were 107 ± 11 dB HL. The etiologies included ototoxicity ($n = 31$), enlarged vestibular aqueduct syndrome (7), sudden onset hearing loss (5), meningitis (2), noise exposure (2), and unknown causes (13). These subjects were from 18 provinces in China. Each subject and his or her family consented to participate in the clinical trial, with a protocol that was approved by the local Human Research Ethics Committee of each of the five participating hospitals, including Shanghai Fudan University ($n = 23$), Beijing PLA General Hospital (15), Beijing Tongren Hospital (10), Zhejiang University (7), and Chongqing Medical University (5). At the end of the first year, 3 subjects dropped out the clinical trial, with 2 being unable to be tested at the 4- and 6-month periods and 1 being disqualified for having a pre-surgical pure-tone-average threshold that was 5 dB lower than the 85 dB HL inclusion criterion. The one-year clinical trial data were submitted to Chinese FDA and received its approval on August 19, 2011. However, follow-up continued with data being collected in 48 subjects until the end of the third year; the additional 9 subjects dropped out due to their inability or unwillingness to be tested at the specified times.

4.1.2. Surgery

Twelve neurotologists, who all had prior experience in cochlear implant surgery, used a soft surgical approach to perform mastoidectomy and cochleostomy in the 60 participants. An incision was made in the skin behind the ear. A 0.44-mL, or 440-mm³, bed was created to securely house the receiver and stimulator case before entry into the middle ear. The facial recess was opened, and the bone anterior to the facial nerve was removed to provide wide exposure of the round window niche. A small cochleostomy hole was made in a position inferior and anterior to the round window niche with a 1.0- or 0.5-mm diamond burr. The cochleostomy hole was drilled until the blue lining of the endosteum became visible. A small amount of sodium hyaluronate was gently injected into the scala tympani to prevent fluid leak and entry of foreign bodies such as bone dust. Suction was prohibited at this stage to avoid loss of perilymphatic fluid. The electrode array was then inserted into the scala tympani. The cochleostomy was then sealed with a small amount of connective tissue. After implantation, electrode impedance and electrically evoked stapedius reflex were typically measured to verify device integrity and functionality. The total time of implantation ranged from 30 to 120 min, dependent on surgeon's experience and subject's condition. Although all 12 surgeons encountered no significant difficulty in inserting the electrode array, 4 recommended an insertion tool be used in the future.

To estimate the electrode position and insertion depth (Verbist et al., 2010; Xu et al., 2000), 48 subjects had X-ray of the cochlear implant after their surgeries. The average insertion depth was 449°, with a standard deviation of 79°, which was slightly deeper than the designed insertion depth of 400°. Of these 48 subjects, 37 had all of the 24 electrodes properly placed in the cochlea (e.g., Fig. 7A), whereas 11 had a buckled or mislocated electrode array, especially near the round window (e.g., Fig. 7B), indicating the need for further evaluation of the electrode design and surgical procedure. The effect of a buckled or mislocated electrode array will be addressed in the discussion section.

4.1.3. Stimuli

Two open-set tests of Mandarin sentence recognition were used for evaluation of the Nurotron cochlear implant performance. The House sentence recognition test included 10 lists of 10 phonetically-balanced sentences with each containing 7 key words (Fu et al., 2011). The 301 sentence recognition test included 12 lists of 11 sentences with each containing 6–8 key words, for a total of 57 words (Xi et al., 2012). Percentage of correctly identified words was used as the open-set sentence recognition score. Because no statistical difference was found between the two tests, the averaged scores were used in data analysis and reported here. In addition, 3 closed-set tests of Mandarin consonants, vowels, and tones were used, in which each test had four alternatives and the subject had to choose one of them (<http://www.tigerspeech.com>).

The default speech processing was the multi-peak APS strategy. The default stimulation was monopolar mode using both reference electrodes (MP1 + 2). Electrode impedance was estimated by a single biphasic pulse with a 40- μ s pulse duration. The threshold and comfort loudness levels were estimated by a 500-ms, 1000-Hz biphasic pulse train. The pulse duration was either 25 or 50 μ s/phase. Speech stimuli were presented to the subject at 65 dB SPL in a sound field condition.

4.1.4. Procedures

As part of the informed consent, all subjects agreed to participate in a pre-surgical test and 5 post-surgical tests at 1, 2, 4, 6 and 12 months. The additional tests at 24 and 36 months were voluntary. During each test, the subject went through a full battery of audiometric tests including air-conducted pure-tone thresholds, electric impedance, threshold (T) and comfortable (C) levels for each electrode, and both closed-set phoneme and open-set sentence recognition. In addition, the subject went through a full physical examination, including vital signs, blood and urine tests, electrocardiogram, thoracic roentgenoscopy, visual examination for surgical complications such as swelling, infection, facial paralysis, and hematoma. All tests were performed independently by

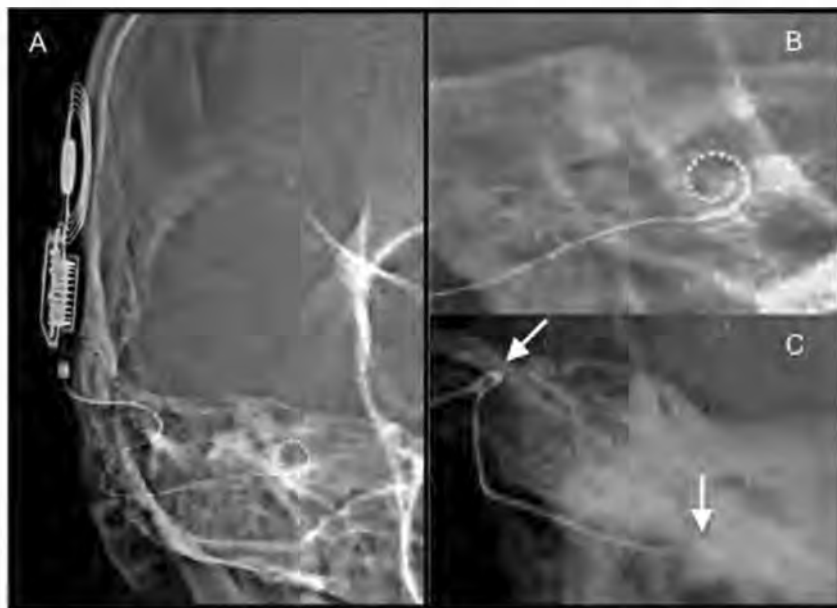


Fig. 7. *In vivo* high-resolution X-ray pictures of the Nurotron cochlear implant device. A. A user with a proper placement of the receiver, stimulator and in-ra-cochlear electrode array. The profile of the receiving coil, magnet, case, and feedthroughs are seen on the left side of the picture, while the electrode cable ("Z" shaped in the picture) and the coiled 24-electrode contacts are seen in the lower part of the picture. B. A user with a smooth electrode cable and electrode contacts near round window. C. A user with a buckled electrode cable (upper arrow) and knotted electrode contacts near round window (lower arrow). The buckled cable was likely due to improper pinch by surgical tweezers while the knotted contacts were due to forceful insertion. This subject had 6 unusable electrode contacts and a 73% correct sentence recognition score.

audiologists and physicians, under supervision of a certified contract research organization.

4.2. Results I: objective measures

During the first year clinical trial period, 6 adverse events were noted, including 2 possibly related to surgery (swelling in the eyelid and swelling in the surgery area) and 4 unrelated to the surgery or the device (2 mild fatty liver cases, 1 acute nephritis, and 1 upper respiratory tract infection). The physicians determined that none of these adverse events was directly related to the Nurotron device.

Fig. 8 shows impedance as a function of electrode position at the device switch-on time (upper panel) and as a function of the implant usage time (lower panel). At the time of switch on, electrode impedance was 13 ± 3 k Ω , which was not significantly different as a function of electrode position [$F(23,771) = 0.7$, $p > 0.05$; univariate ANOVA]. However, the impedance averaged over the entire electrode array changed significantly with implant use [$F(23,242) = 20.2$, $p < 0.01$]. The average impedance decreased significantly by 6 k Ω from switch on to 1 month, stayed unchanged over the 12-month period ($p > 0.05$), and increased significantly by 2 k Ω at the 24-month evaluation ($p < 0.05$; *Post Hoc* tests with Bonferroni correction for these and other comparisons in the remainder of the results section).

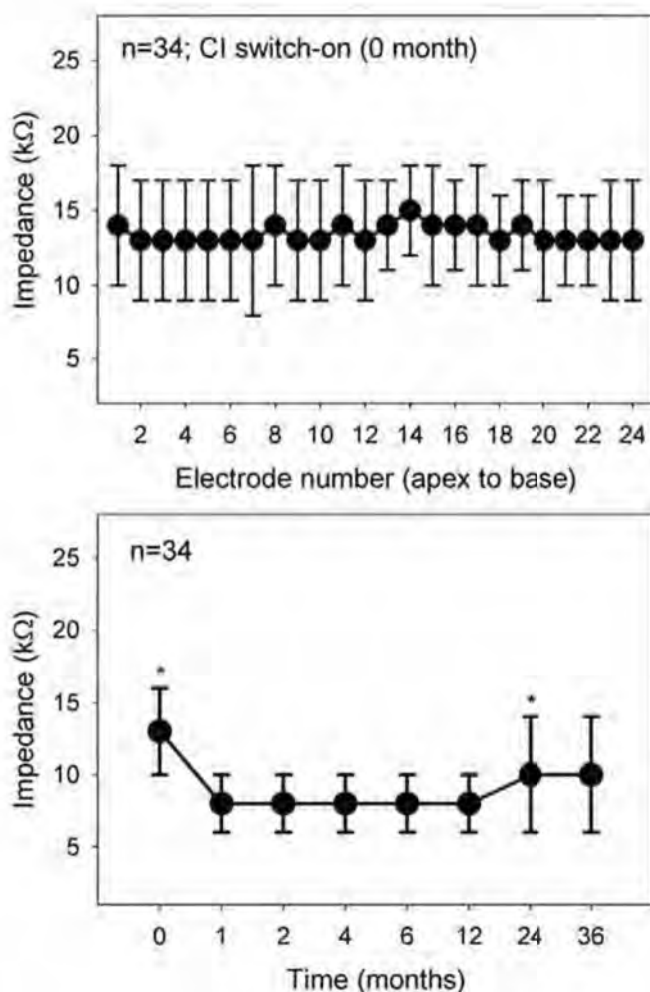


Fig. 8. Average electrode impedance as a function of electrode position at the device switch-on time (upper panel) and as a function of device usage time (lower panel). The "*" symbol indicates significance at $p < 0.05$ level.

4.3. Results II: psychophysical measures

The upper panel of Fig. 9 shows threshold (T) and comfortable (C) levels as a function of electrode position at the device switch-on time. Both T and C levels showed a significantly increasing trend as a function of electrode position at the time of switch on [$F(23,711) = 3.1$, $p < 0.01$, $F(23,717) = 3.3$, $p < 0.01$, for T and C levels respectively]. Compared with the most apical electrode (#1), post-hoc analysis revealed significant higher T levels for electrode 23 and 24 and higher C levels for electrodes 22, 23 and 24 ($p < 0.05$). Note that these different T and C levels cannot be attributed to electrode impedance, which was not significantly different between electrodes (Fig. 8).

The lower panel of Fig. 9 shows the averaged T and C levels over the entire electrode array as a function of the implant usage time. The T level had been stable over the 36 month period [$F(7,226) = 0.4$, $p > 0.05$]. Interestingly, the C level increased over time [$F(7,226) = 2.3$, $p < 0.05$], with the C level at 36 months being significantly greater than that at the time of switch on [$p < 0.05$]. This increased C level possibly reflects the increased tolerance to electric stimulation of the auditory nerve (Zeng, 2013).

4.4. Results III: functional measures

Fig. 10 shows that sentence recognition varied greatly among subjects (dotted lines) but improved significantly as a function of implant usage over the 36-month period [$F(7,426) = 132$, $p < 0.01$].

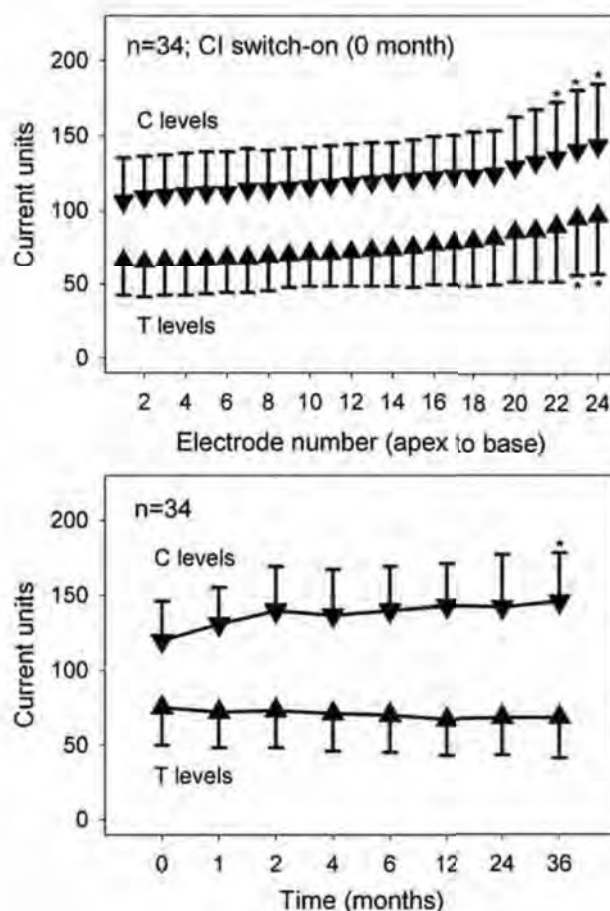


Fig. 9. Average T and C levels as a function of electrode position at the device switch-on time (upper panel) and as a function of device usage time (lower panel). The "*" symbol indicates significance at $p < 0.05$ level.

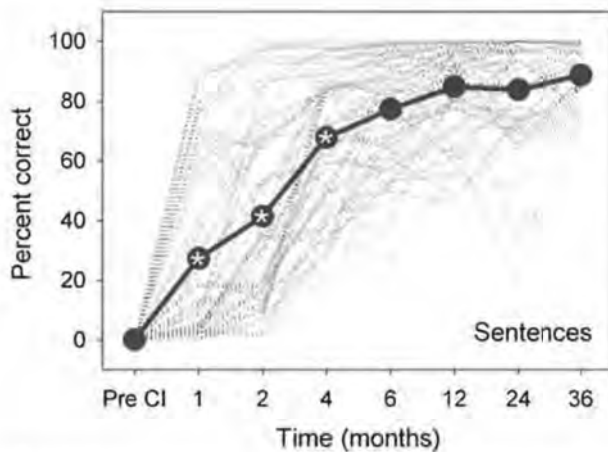


Fig. 10. Individual (dotted lines) and average (circles connected by a solid line) sentence recognition scores as a function of device usage time. The "*" within the circle represents a significant difference over the previous test time.

Post-hoc analysis revealed significant improvement from an average score of 0.03% correct before cochlear implantation to 27%, 41% and 68% correct at the 1-, 2- and 4-month test time, respectively ($p < 0.05$). The cochlear implant performance reached a plateau after 6 months, with the highest recognition of 89% at the 36-month evaluation.

Using the same format, Fig. 11 shows percent correct recognition as functions of time for consonants (upper panel), vowels (middle panel) or tones (lower panel). Overall, phoneme recognition was similar to sentence recognition (Fig. 11), varying greatly among subjects (dotted lines) and improved significantly as a function of time [$F(7,426) > 45$, $p < 0.01$]. Different from sentence recognition, consonant and vowel recognition reached a plateau after only 4-month usage. Similar to sentence recognition, tone recognition reached a plateau after 6-month usage, reinforcing the importance of tone recognition in Mandarin speech recognition (Fu et al., 1998).

5. Discussion

In this section, the Nurotron device is compared against other devices from both technical and performance perspectives. Several relevant studies using the Nurotron device are also summarized and discussed. Finally, the socio-economical impact of the present developmental effort is discussed.

5.1. Technical comparison

Table 1 compares key technical parameters of the Nurotron cochlear implant against presently available devices by the three major cochlear implant manufacturers. Although the Nurotron device was conceived in 2005 and developed into a product in 2008, it is still technically comparable by today's standards. A reason for this comparability is that cochlear implant advances in the last decade have been mostly in pre-processing and cosmetics, with little changes in speech processing strategies, RF transmission and receiver and electrode arrays.

In terms of the external unit, all devices, including the Nurotron device, have similar technical parameters from a relatively wide input dynamic range (75–80 dB) and a frequency range (~8000 Hz) to the default processing strategy (CIS-like) and the number of maps in the processor (4–5). Note that the Nurotron processor has the shortest battery life, reflecting a lack of design consideration for optimal power consumption. Also note that the Nurotron processor

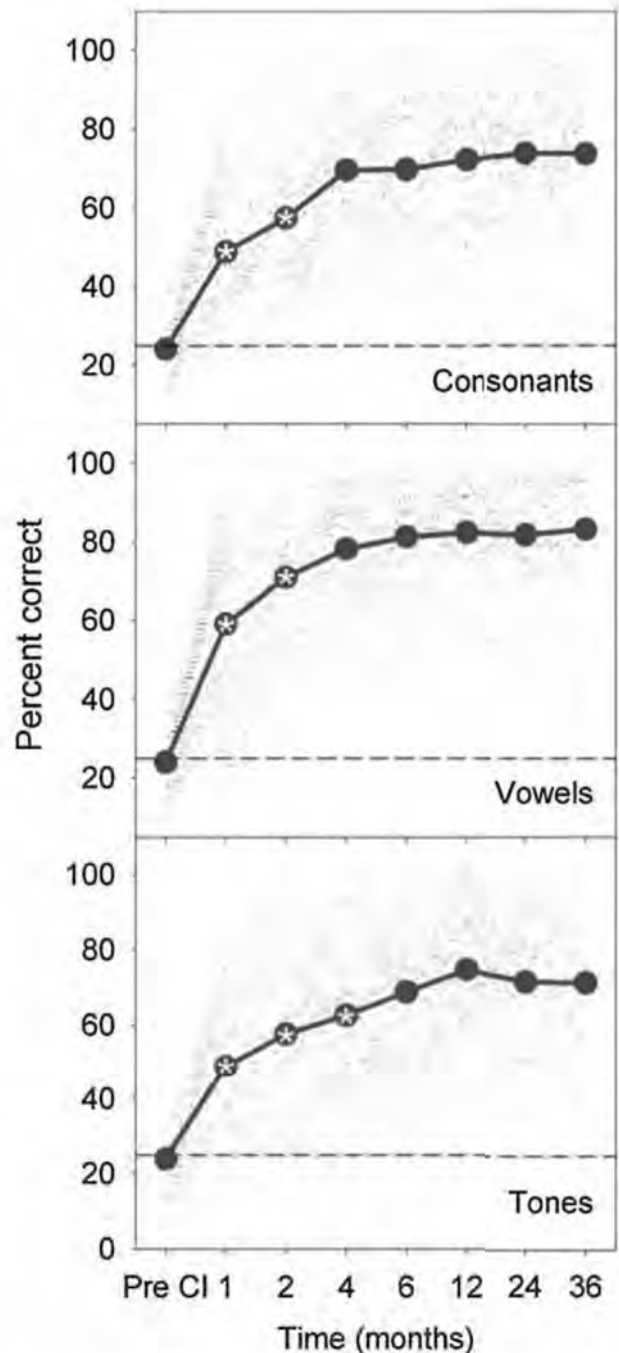


Fig. 11. Individual (dotted lines) and average (circles connected by a solid line) recognition scores as a function of device usage time for consonants (upper panel), vowels (middle panel) and tones (lower panel). The "*" within the circle represents a significant difference over the previous test time.

lacks wireless connectivity, reflecting design priority considerations in 2005. Both power consumption and connectivity problems are being addressed by Nurotron, but are beyond the scope of discussion for the present study.

Although there is no manufacturer-specific systematic report on *in vivo* electrode array status, buckled or mislocated electrode arrays are believed to be present in all devices, e.g., as high as 40% electrodes mislocated in scala vestibuli in some cases (Holden et al., 2013; Kong et al., 2012; Skinner et al., 2007; Wardrop et al., 2005a, 2005b). It is unclear whether the incidence of the presently

Table 1

System specifications of the Nurotron 26-electrode cochlear implant compared with other three major cochlear implant systems. Data Sources: Cochlear N6 (User Guide and Technical Specifications from www.cochlear.com); Clarion HiRes 90 K (www.bionicear.com); Med El Maestro implant system (Hochmair et al., 2006). Additional information from <http://cochlearimplantonline.com>

System units	Parameters	Nurotron Venus	Nucleus N6	AB HiRes 90 K	Med-El MAESTRO
External unit	Name and key features	Venus: Omni or directional mics IDR (75 dB) Freq range: 100–8000 Hz Li-Ion or 3 Zinc Air batteries (8–24 h)	N6: Omni or directional mics IDR (–75 dB) Freq range: 100–8000 Hz 2 Zinc Air or recharge. batteries (18–60 h)	Harmony: T-mic Dual-loop AGC IDR (20–80 dB) Freq range: 150–8000 Hz Li-Ion batteries (12–56 h)	OPUS2: Omni mic Dual-loop AGC IDR (–75 dB) Freq range: 70–8500 Hz 3 zinc-air batteries (12–90 h)
	Processing strategies	CIS APS Virtual channel	SPEAK ACE Hi-ACE	CIS MPS HiRes Fidelity 120	CIS+ HD CIS FSP
	Number of maps	4	4	5	4
	Connectivity	Direct Audio Input	Direct Audio Input	Direct Audio Input	Direct Audio Input
RF unit	RF carrier	16 MHz	5 MHz	49 MHz	12 MHz
	Data rate	0.9 MB/Sec	0.5 MB/Sec	1 MB/Sec	0.6 MB/Sec
Internal unit	Total stimulation rate	40 KHz	32 KHz	83 KHz	51 KHz
	Number of current sources	4	1	16	24
	Max current	1.9 mA	1.75 mA	1.9 mA	1.2 mA
	Number of intracochlear electrodes	24	22	16	12
	Number of reference electrodes	2	2	2	2
	Simultaneous stimulation	Yes	No	Yes	Yes
	Fitting unit	Impedance measure	Yes	Yes	Yes
	Chinese Interface	Yes	No	No	No

reported 11 cases of buckled electrodes is comparable to other devices, and whether these cases are due to the inexperience of some of the surgeons themselves, or their unfamiliarity with a new device. Nevertheless, post-surgical analysis showed that the average number of unusable electrodes is 4 (range = 0–13) in subjects with buckled or mislocated arrays, compared with 1 (range = 0–10) in other subjects. The corresponding average sentence recognition score was $70 \pm 18\%$, compared with $79 \pm 19\%$ correct. Neither the difference in the number of unusable electrodes nor that in the sentence recognition score reaches a statistically significant level ($p > 0.05$), possibly due to the relatively small sample size. To highlight the complicated subject and device interactions, the subject with the most unusable electrodes (=13) actually had one of the highest sentence recognition score (=92%).

Except for having the most intracochlear electrodes, the key technical parameters for the Nurotron RF and internal units are roughly in the middle of other currently available devices. For example, the 16-MHz RF carrier is lower than the 49-MHz AB device but higher than the 5-MHz Nucleus and 12-MHz Med El devices; the 40-KHz total stimulation rate is higher than the 32-KHz Nucleus device but lower than the 83-KHz AB and 51-KHz Med El devices; the 4 current sources are more than the 1-source Nucleus device but less than the 16-source AB and 24-source Med El devices. As can be seen from the remainder of the discussion, these differences in technical parameters reflect philosophical differences in design but have not produced any measurable differences in performance.

5.2. Performance comparison

The Nurotron device has produced similar performance to other devices in terms of basic objective and subjective measures. The present electrode impedance (Fig. 8) and stimulation level (Fig. 9) effects are generally consistent with a large body of existing studies from other cochlear implant devices (e.g., Henkin et al., 2003, 2005, 2006; Hughes et al., 2001; Mosca et al., 2014; van Wermeskerken et al., 2006). In addition to a larger sample size and longer

observation time (3 years vs. 1–2 years), the present study extends previous studies in the following ways. First, the absence of electrode position effect on impedance (Fig. 8A) suggests that electrode impedance reflects mostly the electrode physical properties such as area and the dynamic interplay between electrode and nearby tissues in electric stimulation (e.g., Clark et al., 1995), whereas the presence of electrode position effect on loudness levels (Fig. 9A) suggests that behavioral measures reflect more the overall electric field property, the survival nerve extent and distribution, and central factors (e.g., Tang et al., 2011). The non-monotonic function of impedance versus time (Fig. 8B) and the monotonic function of loudness versus time (Fig. 9B) lend further support for the idea that increased loudness tolerance with prolonged electric stimulation reflects more a decreased central gain in the brain rather than changes in electric properties in the cochlea (Zeng, 2013). The greater amount of this loudness change in children than in adults (e.g., Henkin et al., 2003, 2005, 2006; Hughes et al., 2001) is consistent with greater plasticity in the developing brain.

The Nurotron device has produced functionally indistinguishable performance from other devices in speech recognition measures. Fig. 12A shows comparison in sentence recognition between 4 cochlear implants. The Advanced Bionics data were from 51 subjects who had used the HiRes processing strategy for 3 months after prior 3-month experience with conventional strategies, CIS or SAS (Koch et al., 2004). The Med El data were 14 subjects who had used the fine structure processing strategy after an average 1-year experience with the CIS strategy (Arnoldner et al., 2007). The Cochlear data were from 55 subjects who participated in the Nucleus Freedom North America clinical trial and had used the Freedom device for 6 months (Balkany et al., 2007). As a comparison, the Nurotron data were from the 6-month performance, which was significantly higher than the 3-month performance but lower than, although not significantly different from, the 1-year performance (Fig. 10). Despite the fact that Advanced Bionics and Cochlear used English sentences, Med El used German sentences and Nurotron used Mandarin sentences, and additionally these clinical trials were conducted by different researchers and under

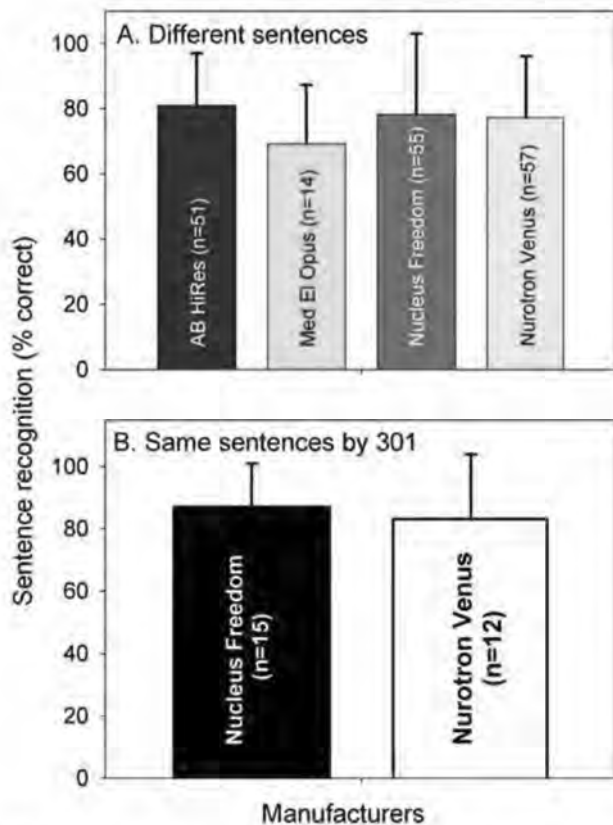


Fig. 12. Sentence recognition between the Nurotron device and the other three devices using different test materials and protocols (upper panel) and sentence recognition between the Nurotron and Cochlear devices using the same test materials and protocols (lower panel).

different protocols, all 4 devices produced functionally equivalent performance between 60 and 80% correct for sentence recognition in quiet.

In a more tightly controlled study, researchers at Beijing 301 Hospital (Li et al., 2014) directly compared performance between Nucleus and Nurotron devices by recruiting two groups of subjects who were matched in age (29 ± 13 vs. 25 ± 9 years old), duration of deafness (7 ± 5 vs. 7 ± 4 years), gender (9 males and 6 females vs. 10 males and 5 females), and other audiological and etiological factors. Using the same surgical and evaluation protocols including the same Mandarin speech test materials, they found no statistically difference in performance between these two devices. Fig. 12B replots the subjects' sentence recognition data after 2-year usage of their respective Nucleus and Nurotron devices. The Nucleus users produced $87 \pm 14\%$ correct score while the Nurotron users produced $83 \pm 21\%$ score. The high level of speech performance by the Nurotron device as well as its ability to improve quality of life has been independently verified by other researchers at Beijing Tongren Hospital (Liu et al., 2014), Central South University Xiangya Hospital (Yu, 2013), and China Rehabilitation Research Center for Deaf Children (Yu, 2013).

5.3. Socio-economical impact

Thanks to pioneers such as William House, Blair Simmons, Robin Michelson (Eisenberg ref and Merzenich ref in this issue), as well as the three 2013 Lasker Award winners: Graeme Clark, Ingeborg Hochmair and Blake Wilson, the cochlear implant has helped restored partial hearing to more than 300,000 adults and

children worldwide. Unfortunately, only a fraction of the current cochlear implant users reside in developing countries, despite the fact that these countries boast more than 80% of the world population. While a lack of competition, a lack of awareness and a lack of access all contribute to some extent, high price is the prohibitive factor limiting the widespread use of the cochlear implant (Zeng, 2007).

To our knowledge, the Nurotron cochlear implant represents the first time an implantable, active medical device has ever been developed and manufactured in a developing country. Although the commercial operation is still in infancy, the successful development of the Nurotron device, as shown here, has not only broken technical barriers, but also produced a significant socio-economical impact. Thanks to this emerging product and the competition it has brought about, at present, 3 deaf children in China can benefit from the cochlear implant for the price that would allow only child to receive a device several years ago. It is expected that the cochlear implant will continue to drop in cost while improving performance, benefitting hearing-impaired people living in both developed and developing countries.

6. Summary

The present article describes the development and evaluation of a 26-electrode Nurotron cochlear implant that is comprised of an external sound processor, a radio-frequency transmission link and an internal receiver and stimulator. The default sound processing strategy uses multi-peak interleaved stimulation, while the default mode is monopolar stimulation with an active electrode being one of the 24 intracochlear electrodes and both extra-cochlear electrodes being the reference. Sixty severe-to-profoundly hearing-impaired subjects had participated in a 1-year clinical trial with some of them being continuously followed up for 3 years. Similar to other commercially available cochlear implants, the Nurotron device showed a decrease in electrode impedance within the first month implant use, a stable threshold level, and an increased comfort level over the 3-year period. Mandarin speech recognition significantly improved from the pre-implantation level to 4-month usage, reaching a plateau high-level performance of about 80% correct after 6-month usage. Both indirect and direct comparisons indicated that the Nurotron 26-electrode cochlear implant and other commercially available devices produced indistinguishable performance.

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Speech performance in pediatric users of Nurotron[®] Venus[™] cochlear implants



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ABSTRACT

Objectives: The primary purpose of this study was to investigate the longitudinal speech performance over 3 years in pediatric users of the Nurotron[®] cochlear implant system. The secondary purpose was to compare the speech performances of younger and older children with cochlear implants (CIs).

Methods: The Mandarin Early Speech Perception (MESP), Meaningful Use of Speech Scale (MUSS), and Putonghua Chinese Communicative Development Inventory (PCDI) were used to evaluate speech performance of 22 Mandarin-speaking pediatric CI users throughout the first 36 months post-implantation. The subjects were grouped according to the age at implantation, i.e., younger CI group (<3 years) and older CI group (>3 years).

Results: All the subjects demonstrated improvement in speech performance throughout the first 3 years of implant use with mean scores reaching the maximum performance at 36 months post-implantation. The median categories of MESP increased from 0.23 pre-implantation to 5.57 three years post-implantation. Likewise, the median percentage of MUSS was 5.57% to 73.75%; the median performance of PCDI was 55 to 400 for PCDI-comprehension and 32 to 384 for PCDI-production at the same interval. At nearly all test intervals, the older group performed better than the younger group except 24 months post-implantation, at which the MUSS score of the younger CI group was higher than that of the older CI group.

Conclusion: The children with Nurotron[®] Venus[™] CI system showed considerable gains in speech and language development including tone performance which improved with hearing age. Earlier implantations haven't presented significantly positive performances until 24 months post-implantation in all the tests.

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1. Introduction

The commercialized cochlear implantation for children in the United States was initiated in the 1980s [1]. The main purpose of pediatric cochlear implantation is to improve the development of speech, prompting patients to return to the mainstream of society. The ability to perceive speech could be considered the single most

important primary outcome measure of cochlear implantation [2]. Along with the increased population of young children receiving cochlear implants (CIs) every year, a series of studies assessing early speech ability had been carried out, and children in nearly all the studies presented a progressive auditory and speech improvement following implantation [3–5]. Robbins et al. [6] showed rapid improvement in auditory skills in children over the first year post-implantation as assessed with the IT-MAIS (Infant-Toddler Meaningful Auditory Integration Scale) parental questionnaire. Tyler et al. [7] indicated that gains were obtained in the perception of stress and words in a closed-set context within 1 year of implant use and information on vowel and consonant features showed an increase after 2 years of implant use. O'Donoghue et al. [8] found that the median score of the Iowa Matrix Closed Set Sentence Test

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reached a plateau of 99% at 3 years post-implantation. Calmels et al. [2] showed that after 5 years of implantation, the median percentage of closed-words speech perception (CSW) was 95.5–93.67% correct for closed-sentence speech perception (CSS) and 76.3% correct for open-sentence speech perception (OSS). Speech production skills, evaluated by means of questionnaire batteries, i.e., Meaningful Use of Speech Scale (MUSS), developed slowly and took over 3 years to reach the given level [9].

As previous studies noted above, the speech processors of CI had proven to be effective for speech recognition. However, CI devices are ineffective in encoding voice pitch information required for tone recognition. Wilson et al. pointed out that the relatively poor resolution of pitch should have a significant impact on CI patients who speak a tone language, i.e., a language in which pitch is used to signal a difference in meaning among words [10]. Wei et al. showed that current CI users produced significantly lower performance than that by the normal-hearing subjects listening to acoustic simulations of CIs using the vocoder technique [11]. As a tonal language, Chinese–Mandarin differs from English in that the pitch pattern of a single-syllable word conveys lexical meaning [12]. One syllable can be expressed in four tones, representing different words, for example: 妈 mā (mom), 麻 mā (hemp), 马 mǎ (horse), 骂 mǎ (scold). The new Nurotron[®] implant system, developed by Nurotron Biotechnology Inc. (USA) and manufactured by its facility in Hangzhou Nurotron Biotechnology Co., Ltd in China, employed three processing strategies, including continuous-interleaved-sampling (CIS), advanced peak selection (APS) and virtual channel (Symphony) strategies; the Symphony strategy combines virtual channel and peak selection strategies to additionally improve the spectral fine structure, in which simultaneous stimulation of two electrodes is used to generate intermediate pitch percepts between two these two electrodes [13].

In addition, age of the children at implantation was regarded as one of the most important factors which affected the acquisition of speech with young prelingually-deafened children [14]. Age at implantation negatively correlates with improved speech perception post-implantation. Improvement was shown to occur at a faster rate than for children implanted at an older age [15–17]. Age of implantation was also found to contribute to tone perception and production development in prelingually-deafened, Mandarin-speaking children with CIs [18–20]. More recently, it has been shown that some children who receive CIs between 2 and 4 years have the capacity to approximate the language and reading skills of their earlier-implanted peers (i.e., implanted <2 years of age) [21]. Another recent study showed that prelingually-deafened children who receive a CI before their 5th birthday have better outcomes than those who receive a CI later in the form of better auditory skills, speech perception abilities, and better language levels, although such advantages became less obvious at the end of the 2-year study period [22].

In light of the literature as reviewed above, the research question that we are trying to address in the present study is that whether the new Nurotron[®] implant system produces similar outcome results in its users. The two primary goals for this study are: (1) to document the speech performance of pediatric users with the Nurotron[®] implant system; and (2) to compare the outcomes of the younger and older implanted groups.

2. Methods

2.1. Subjects

This study consisted of 22 prelingually deaf pediatric unilateral CI users. All users were consecutively implanted at Beijing Tongren Hospital, Capital Medical University. There were no post-operative

complications. Subject inclusion criteria consisted of bilateral profound sensorineural hearing loss, no evidence of mental retardation, at least 1 year of age and Mandarin Chinese as their native language. The subjects included 14 males and 8 females. The age at implantation ranged from 13 to 68 months, with a mean of 35 months. Preoperative audiological evaluation included behavioral audiometry, impedance audiometry test, auditory brainstem response (ABR), and distortion-product otoacoustic emissions (DPOAEs). All subjects had a profound hearing loss as confirmed by the ABR thresholds. No inner ear malformations were indicated using computer tomography (CT). They all received speech and language habilitation since their first CI programming about four weeks post-implantation. This study obtained approval from the Institutional Review Board of Beijing Tongren Hospital.

The demographic data for all children are presented in Table 1. All the subjects were implanted with Nurotron[®] (NSP-60B strategy), a new CI system developed in China. Twenty subjects were implanted in the left ear; two subjects were implanted in the right ear.

The subjects were divided into two groups, younger and older, according to their age at implantation. The younger group enrolled 14 subjects whose age at implantation was less than 36 months with the mean age of 25 months. The older group consisted of eight subjects whose age at implantation was greater than 36 months with the mean age of 50 months.

2.2. Test materials

Speech perception was assessed by the Mandarin Early Speech Perception (MESP) test and speech production skills were evaluated using two questionnaires: Meaningful Use of Speech Scale (MUSS) and Putonghua Chinese Communicative Development Inventory (PCDI).

We focused on the Early Speech Perception (ESP) test since it can be applied to younger children as early as 2 years old. The ESP test was developed by Moog and Geers to assess speech perception in normal developing children and those with CI or hearing aid intervention [23]. The ESP test had been translated into many languages (Italian, Arabia, Spanish, and Chinese). Zheng and colleagues created MESP and established the threshold score for

Table 1

Demographics of the CI users. All the subjects had no ABR responses at 100 dB nHL (maximum intensity level). Abbreviations: F = Female, M = Male, AAI = Age at implantation.

No.	Gender	Pre-implant use of hearing aids	AAI (months)	Bimodal stimulation
1	M	No	13	Yes
2	F	No	17	No
3	M	Yes	18	No
4	M	No	18	No
5	F	No	20	No
6	M	Yes	25	No
7	M	No	25	No
8	F	No	25	No
9	F	No	29	No
10	F	No	31	No
11	M	Yes	31	No
12	F	No	32	No
13	M	No	32	No
14	M	No	35	No
15	F	No	37	No
16	M	No	38	No
17	M	No	43	No
18	M	Yes	46	Yes
19	M	Yes	52	No
20	F	Yes	64	No
21	M	Yes	65	No
22	M	No	68	No

every category in 92 developmentally normal children between the ages of 2 and 5 years old [24]. MESP had also been evaluated for its practicability by assessing speech recognition in Mandarin-speaking pediatric CIs [25,26]. The English ESP contains four speech perception categories: Category 1 (Detection of Speech), Category 2 (Speech Pattern Perception), Category 3 (Some Word Identification), and Category 4 (Consistent Word Identification) [23]. Because of the special characteristics in phonemics and tone of Chinese Language, The MESP does not have a strong consistency with ESP. Instead, the MESP consists of 6 subtests which increase in difficulty: Category 1 (Speech Detection), Category 2 (Pattern Perception), Category 3 (Spondee Perception), Category 4 (Vowel Perception), Category 5 (Consonant Perception), and Category 6 (Tone Perception) [24]. The first three categories in MESP parallel the English subtests, with categories 4–6 representing Chinese features in vowels, consonants, and tones. To facilitate its use in the clinic and for research, the MESP was recorded with Mandarin and a software program was written to automatically score speech recognition performance. Although the MESP has a low verbal version, we chose a standard version with recorded test materials because it would be easier to compare performance in a longitudinal follow-up study.

Robins and Osberger [27] created the Meaningful Use of Speech Scale (MUSS) questionnaire which intended to evaluate the child's ability to use speech and language meaningfully to evaluate speech production. MUSS contains 10 questions divided into 3 subscales: evaluation of the vocalization efforts, communicative interactions, and the use of oral language. Each of the 10 questions is scored on a five-rung scale from 0 (lowest) to 4 (highest): 0 = never (0%), 1 = rarely (25%), 2 = occasionally (50%), 3 = frequently (75%), and 4 = always (100%). The maximum score for MUSS is 40. The total score of the subjects is then transformed into percentage (total score/40 × 100%) with the higher the percentage representing high speech and language ability. Face to face interviews were carried out with the subjects' parents or other guardians while their response to each question in MUSS was recorded.

MacArthur-Bates Infant and Toddler Communication Development Inventories (CDI) invented by Fenson and colleagues [28], focuses on assessing language and communication skills of infants and toddlers. The CDI forms are valid tools to use with children with CIs in the early stages of language development. Chinese Communicative Development Inventory compiled mainly by Tardif and colleagues was based on MacArthur-Bates CDI and included two versions, Putonghua (PCDI) and Cantonese (CCDI) [29]. Similar to CDI, PCDI consists of infant and toddler forms. The infant form (Words and Gestures) designed for 8 to 16 months in normally developing children consists of two parts. Part I includes a checklist of 411 words that evaluate word comprehension and production while Part II elicits information about the development of 43 communicative and symbolic gestures. The toddler form (Words and Sentences) designed for 16 to 30 months in normally developing children also consists of two parts. Part I is a checklist of 799 words that evaluate word production only, whereas Part II assesses several different grammar aspects. Both Infant and

Toddler forms have established the normative database. Based on the language ability of the subjects, the Words and Gestures form was used in this study. This questionnaire was completed by a face-to-face parental interview based on the everyday performance of their children. We counted the words of the subject's comprehension and production as their performance.

2.3. Procedures

All tests were administered during preoperative evaluation and CI programming in the hospital. Hand raising method, visual reinforcement, and play audiometry were used according to the age or cognition ability of the child during the mapping process to measure the threshold (T) and comfort (C) level of each individual electrode. The assessment protocol in this study for the pediatric CI users included pre-implantation and post-implantation (1, 3, 6, 9, 12, 24 and 36 months) over a 36 months follow-up period. Some children were unable to be tested at each interval for health issues, time constraints, or other reasons. MESP was tested in a free sound field with ambient noise levels below 30 dB (A). The stimulus presentation level from the front was 65 dB (A). The volume and sensitivity settings for CI devices were adjusted to typical use setting. Before formal testing, the subjects had a practice battery to familiarize themselves with the test procedure. The subjects were required to point at the picture of the word that they had heard from the loudspeaker. Formal test performance was scored according to the percent of words correctly identified in each category. If the score reaches or exceeds the threshold score, we would consider this category achieved. Threshold scores are defined as the lowest score for a category that is significantly greater than chance performance which are 54.5%, 30.3%, 63.6%, 63.6%, and 63.8% for Categories 2–6, respectively [30]. Category 1 was needed to determine if the subjects could detect speech. We recorded the highest category achieved by the children as results.

The performances of MUSS and PCDI were collected by means of face-to-face parental interview regarding the everyday performance of the CI children.

3. Results

All subjects demonstrated improvement throughout the 3 years of observation post-implantation. The median categories of MESP increased from 0.23 at pre-implantation to 5.57 three years post-implantation. Likewise, the median percentage of MUSS was 5.57 to 73.75%; the median performances of PCDI were 55 to 400 for PCDI-comprehension and 32 to 384 for PCDI-production. The mean score was at or close to the maximum performance at 36 months post-implantation. From the category scores of MESP in Table 2 we found that all the subjects could achieve Speech Detection (Category 1) at 3 months post-implantation and the average score at 9 months was 2.05, which is equal to Category 2 pattern perception (differentiation of syllable number and stress pattern).

Results from MESP, MUSS and PCDI showed that the development of speech production was slower than that of speech

Table 2
Numbers of children in each MESP category at different test intervals.

Category	Pre-operation	1 month	3 months	6 months	9 months	12 months	24 months	36 months
0	17	9						
1	5	12	19	13	9	5	1	
2		1	1	6	5	3	2	
3			2	3	4	7	2	2
4					2			
5						3	8	
6						2	7	12
Total	22	22	22	22	20	20	20	14

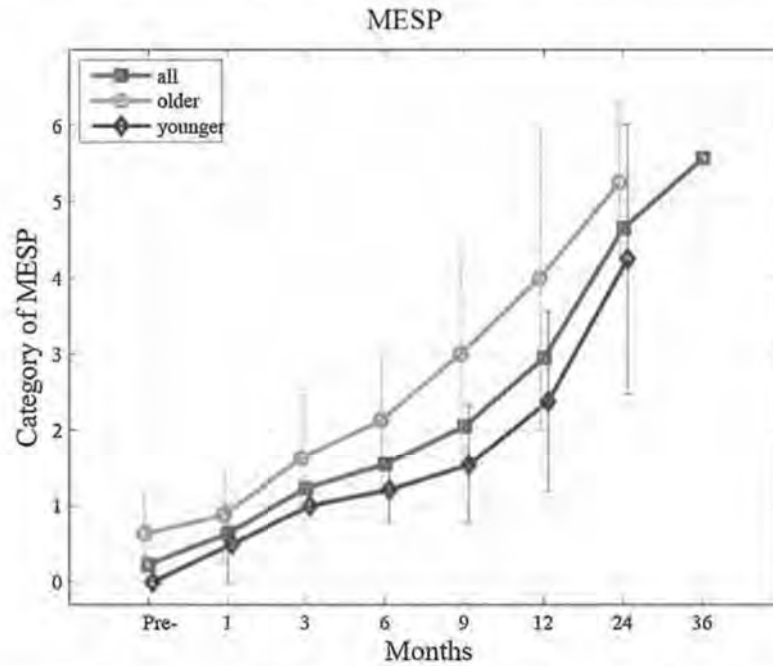


Fig. 1. The mean speech perception using MESP test for all subjects and for the younger and older CI groups over time.

perception. Score of PCDI-production was smaller than that of PCDI-comprehension at each test interval. There was no significant progress in MUSS for the first few months (speech production) post-implantation. From 1 month to 12 months post-implantation, all speech perception and production results showed the fastest growth when compared with 24 and 36 months post-implantation.

3.1. Evolution of speech perception after cochlear implantation

The median categories of MESP for every test interval are shown in Fig. 1. There was a significant improvement of these performances in all adjacent test intervals ($P < 0.05$).

Table 2 shows the number of subjects who can pass each category of MESP at different test intervals. From 10% (2/20) at 12 months to 86% (12/14) at 36 months post-implantation, nearly all the subjects accomplished category 6 (tone test) in the last test.

The MESP results from the current study can be compared with that reported by Eisenberg et al. and Zheng et al. Table 3 summarizes the first-year results from the present study and those from Eisenberg et al. [31] and Zheng et al. [26]. Note, however, the stimuli in Eisenberg et al. study were delivered by a live voice. The percentage of children that could be evaluated with the standard version at baseline was very small in all the three studies. At 6 and 12 months, the percentage of children that could be evaluated with standard MESP was highest in the current study, by contrast,

Table 3

Comparison of Mandarin and English results for the standard version of ESP from the current study, Zheng et al., and Eisenberg et al. The columns labeled "Percent" report the percent of subjects who passed Category 1 in the MESP at each evaluation interval. The columns labeled "Average" report the average score (category) the subjects could achieve.

	Eisenberg (N = 42)		Zheng Yun (N = 39)		Current study (N = 22)	
	Percent	Average	Percent	Average	Percent	Average
Baseline	2.4	3.0	0.0	-	0.0	-
6 months	14.3	3.8	10.3	3.0	40.9	2.3
12 months	28.6	3.9	53.8	4.8	75.0	3.6

with the average score being the lowest. At 12 months 5 of the 22 subjects could not reach Category 2, however, a separate 5 of the 22 subjects were able to achieve Category 5 or 6 which is more difficult. Thus, our results demonstrated a very large variation in performance.

3.2. Evaluation of speech production after cochlear implantation

The performance of MUSS is presented in Fig. 2. The PCDI-comprehension and PCDI-production are shown in Figs. 3 and 4, respectively.

The median percentages of speech production (MUSS) in pre-implantation, 1, 3, 6, 9, 12, 24, and 36 months post-implantation were 5.57%, 11.02%, 11.19%, 14.55%, 18.88%, 38.75%, 60.36%, and 73.75%, respectively. There were significant improvements of these performances between pre-implantation and 1 month, 9 and 12 months, 12 and 24 months, and 24 and 36 months post-implantation ($P < 0.05$).

The median numbers of words about PCDI-comprehension in pre-implantation, 1, 3, 6, 9, 12, 24, and 36 months post-implantation were 55, 73, 86, 201, 293, 337, 384, and 400, respectively. There was a significant improvement of these performances between pre-implantation and 1 month, 3 and 6 months, 6 and 9 months, 9 and 12 months, and 12 and 24 months post-implantation ($P < 0.05$).

The median numbers of words for PCDI-production in pre-implantation and 1, 3, 6, 9, 12, 24, and 36 months post-implantation are 32, 35, 41, 103, 200, 261, 347 and 384, respectively. There were significant improvements with these performances between 3 and 6 months, 6 and 9 months, 9 and 12 months, 12 and 24 months, and 24 and 36 months post-implantation ($P < 0.05$).

3.3. Effects of age at implantation on speech and language outcomes

A repeated-measure ANOVA was used to compare different implanted age groups with the criterion of statistical significance set at $P < 0.05$. The results 36 months post-implantation had not been calculated because the number of subjects between younger

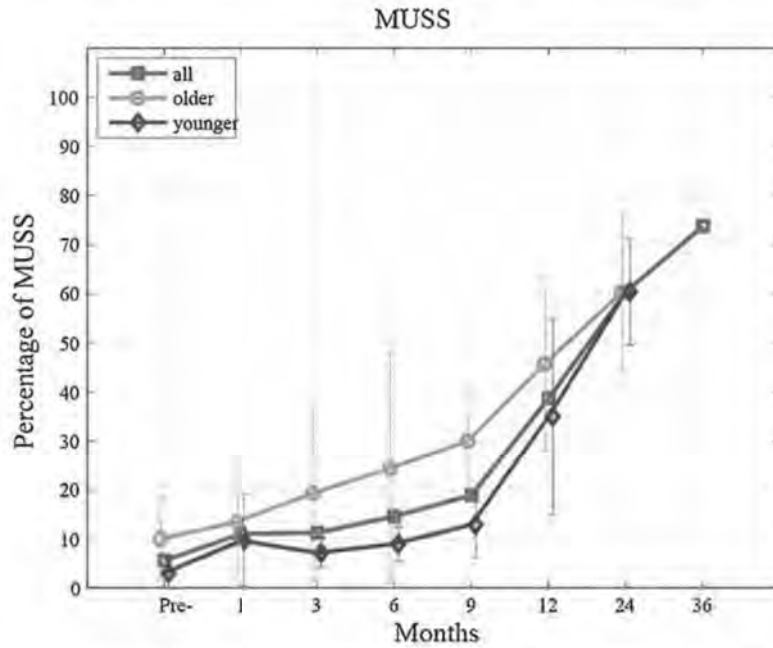


Fig. 2. Mean score of MUSS for all subjects and the average performance of this test between younger and older cochlear implanted groups over time.

(12 subjects) and older (2 subjects) cochlear implanted groups differed greatly.

At nearly all test intervals, the older group performed better than the younger group (the differences were not statistically significant at each test interval) except 24 months post-implantation at which the MUSS score of the younger cochlear implanted subjects was higher than that of the older (Fig. 2). As time went on, the performance of the younger group became more and more close to that of the older group.

4. Discussion

This study demonstrated a significant improvement in speech and language with Nurotron® Venus™ CIs. Comparing with the

results from other similar studies or the normal-hearing peers, the subjects in this study showed language delay. However, the speech and language development was similar to the normal developmental trajectory when hearing age in the CI recipients of this study and the chronological age in the normal-hearing children were equated.

At 6 and 12 months post-implantation, the percentage of children evaluated with the standard MESP in the current study was significantly higher than that of Zheng et al. and Eisenberg et al.; the highest percent of subjects conducting the standard test (with a low score) were possibly contributed to the lowest average score. Note that the stimuli in Eisenberg et al. study were delivered by a live voice which might lead to a higher performance in their study. When Zheng and colleagues [24] established MESP through

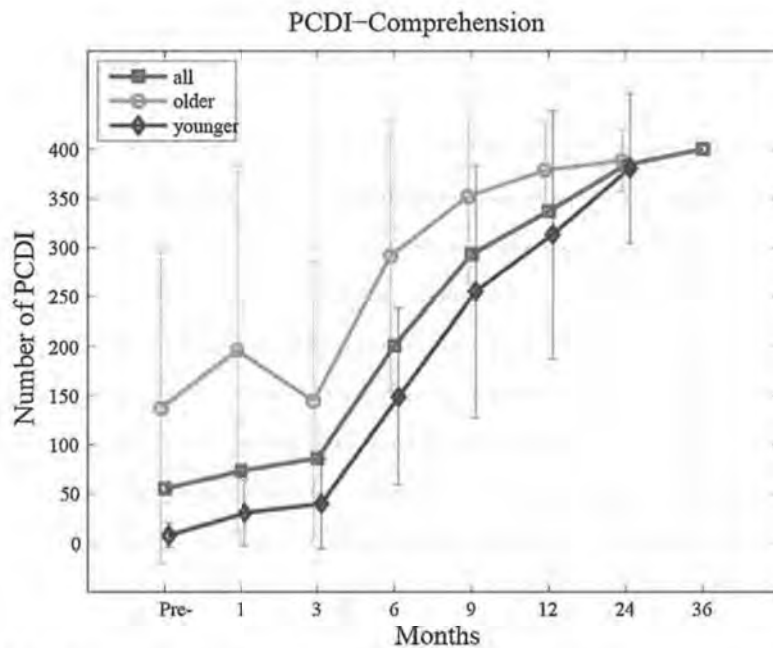


Fig. 3. The average number of words all the subjects could comprehend and the average performances of this test between younger and older cochlear implanted groups over time.

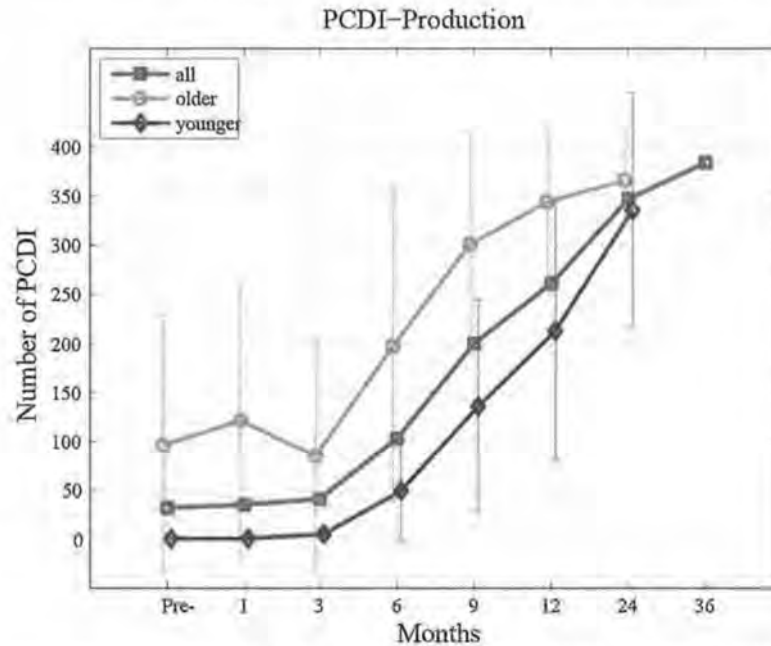


Fig. 4. The average number of words all the subjects could speak and the average performances of this test between younger and older cochlear implanted groups over time.

the investigation of 2 to 5 year old ($N = 92$) normal developing children, they had demonstrated that all subjects 4–5 years old could reach all MESP categories successfully. In relation to chronological age, the speech perception of MESP was delayed in this study. However, considering the duration of hearing experience, most CI participants showed similar (mean categories of MESP was 5.57 three years post-implantation) speech perception performance in comparison with typically developing children.

MUSS designed as a time-effective global outcome measure of speech production in real-life situations had been translated into Chinese. Scores of 3, 6 and 12 months post-implantation in current study were significant higher than that of Martines et al. [32]. Direct comparison between the studies, however, is difficult considering the difference in age of implantation.

The Infant form (Words and Gestures) of PCDI designed for 8 to 16 months in normally developing children in China provided the normal reference range however, there were some differences in the details from the original version because of the characteristic of Chinese. In relation to chronological age, the acquisition of speech was delayed in this study. However, considering the duration of hearing experience, CI participants exceeded 95% of the typically developing children in 6 and 9 months post-implantation.

The studies investigating factors influencing outcomes of pediatric CIs demonstrated that age at implantation, parental education, family income, duration of deafness, communication mode, expectations of parents, experience of the therapists and the participation and support of the child's family during rehabilitation are essential factors that determine linguistic improvement [33,34]. In this study, close to 90% of the subjects' came from the countryside with only 9% of their parents having a high school education while the remaining parents had poorer level of education. Approximately 9% of the subjects' families were from middle income (5000–10,000 yuan/month) families and the rest (91%) were from low income (1000–5000 yuan/month) families. The children with CIs might have obtained limited support from their family during the rehabilitation. Most of the language training for the deaf children used Mandarin Chinese in the rehabilitation center, however, when they communicated with their families at home they might use a local dialect. For comparison with other studies, we adopted a Standard Version of MESP in spite that the subjects might be more

sensitive to live voice that was employed in the study of Eisenberg et al. These may all be important causes of poorer speech performance in this study.

The four Mandarin tones were combined in six different ways in Category 6 (Tone Perception) of MESP: tones 1–2, 1–3, 1–4, 2–3, 2–4, and 3–4. Four pairs of minimally contrastive words were selected for each tone combination [24]. At 36 months post-implantation, nearly all the subjects (12/14) could accomplish category 6 (tone test) and the average score was 79.94% correct which is higher than the scores from Zhou et al. [20] and Peng et al. [35]. This demonstrated that the new Nurotron[®] implant system might have a more positive effect on tone performance. However, we must note the sample size was small and the data were from a single site in this study. We also caution not to interpret the results as an overall representative of the tone performance level in China. A future multicenter study with more subjects is warranted.

O'Donoghue et al. emphasized that the age at implantation is one of the most important known determinants of subsequent speech perception in pediatric cochlear implantation [8] and several studies also demonstrated that children who were implanted earlier performed better than the older ones. Although nearly all testing outcomes from subjects under the age of three achieved lower levels of speech performance than that of the older group, they did improve at a faster rate and caught up with the older group eventually. The initial delay in language development might be associated with the chronological age resulting in differences in physiological development and cognition and comprehension development between the two groups. It might take 12–24 months of implant experience for the auditory system and central processing to mature to some level [36]. Factors influencing outcomes of pediatric CIs, such as age at implantation, parental education, family income, duration of deafness and so on could be not exactly matched in the two groups. A longer follow-up and more carefully designed study is necessary to further explore the effects of age of implantation on language development in children with CIs.

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RESEARCH ARTICLE

Objective and subjective evaluations of the Nurotron Venus cochlear implant system via animal experiments and clinical trials

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ABSTRACT

Conclusion: This study described objective and subjective evaluations of the Nurotron[®] Venus[™] Cochlear Implant System and indicated that this system produced a satisfactory performance. **Objective:** To observe the performance of the Nurotron[®] Venus[™] cochlear implant (CI) system via electrophysiological and psychophysical evaluations. **Methods:** A 26-electrode CI system was specially designed. The performance of MRI in animal and cadaveric head experiments, EABR in cats experiment, the correlation between ESRT and C level, and psychophysics evaluations in clinical trials were observed. **Results:** In the animal and cadaveric head experiments, magnet dislocation could not be prevented in the 1.5 T MRI without removal of the internal magnet. The EABR was clearly elicited in cat experiment. In the clinical trial, the ESRT was strongly correlated with C level ($p < 0.001$). The human clinical trial involving 57 post-lingually deafened native Mandarin-speaking patients was performed. Residual hearing protection in the implanted ear at each audiometric frequency was observed in 27.5–46.3% patients post-operatively. A pitch ranking test revealed that place pitches were generally ordered from apical to basal electrodes. The recognitions of the perceptions of 301 disyllabic words, environment sounds, disyllabic words, and numerals were significantly better than the pre-operative performance and reached plateaus.

KEYWORDS

Cochlear implant, electrically evoked auditory brainstem responses (EABR), electrically evoked stapedius reflex threshold (ESRT), MRI, Nurotron, pitch ranking, speech perception

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Introduction

A number of cochlear implant systems have been developed for people with profound hearing loss. Generally, it is believed that a greater number of intracochlear electrodes improve the user's resolution and provide greater sound detail [1,2]. Electrode array placement has been recognized as a potentially important factor in the efficacy of the responses of the residual nerve-fibers within the cochlea to electrical stimulation [3]. To restore hearing to people with severe-to-profound deafness, a 26-electrode auditory prosthesis—Nurotron[®] Venus[™] cochlear implant system was specially designed. This system included a flexible electrode array to reduce the damage to the cochlea and preserve the residual hearing to the greatest extent possible.

In August 2011, the Food and Drug Administration of China approved the commercial release of the

Nurotron[®] Venus[™] Cochlear Implant System. A group of 57 post-lingually deafened, native Mandarin-speaking patients using the Nurotron[®] Venus[™] Cochlear Implant System completed their 36-month experiences. The purpose of this study was to present the results of electrophysiological and psychophysical evaluations of these cochlear implant recipients [4].

Materials and methods

Study design

A 26-electrode auditory prosthesis, i.e. the Nurotron[®] Venus[™] cochlear implant system, was specially designed and approved for commercial release by the Food and Drug Administration in China. The authors present assessments of this system's performance based on 1.5-Tesla (T) MRI experiments with animals and cadaveric heads, electrically evoked auditory brainstem responses (EABRs) observed in cats, the correlation

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Figure 1. Before the MRI scan, a crepe bandage was firmly wrapped around the head of the cat. (A) Dashed area shows the Nurotron Venus™ Cochlear Implant System implanted between the skull and skin of the cat. (B–D) The crepe bandage was wrapped around the head of the cat firmly.

between the electrically evoked stapedius reflex threshold (ESRT) and the maximum comfort level (C level), and psychophysical evaluations in a clinical trial.

MRI compatibility in cat and cadaveric head experiments

The Nurotron® device's magnetic resonance imaging (MRI) compatibility was tested and found to meet the international EN45502 safety standards for static magnetic fields up to 1.5 T. The major concerns of imaging with the magnet *in situ* are the forces generated by the magnet and the MRI equipment and the risk of magnet displacement and associated discomfort.

To evaluate the effects of the 1.5 T MRI on the Nurotron® Venus™ Cochlear Implant System, the

prosthesis, including the internal magnet, was implanted into a cat and maintained for a period of 6 weeks. During the MRI experiment, the animal was anesthetized, and all of the external components were removed. A crepe bandage was firmly wrapped around the animal's head prior to the MRI scan (Figure 1). The cat was then transported to a SIEMENS SONATA 1.5 T MRI scanner and placed on the table of the scanner in a position in which the implanted ear was facing up.

To evaluate the effect of the 1.5 T MRI on the internal magnet, a fresh-frozen cadaveric head was unilaterally implanted with a Nurotron® Venus™ Cochlear Implant that included the internal magnet. All external components were removed, and a crepe bandage was firmly wrapped around the head prior to the MRI scan. The fresh-frozen cadaveric head was then transported

to the SIEMENS SONATA 1.5 T MRI scanner and placed onto the table of the scanner with the implanted ear facing up.

To examine the displacement caused by the MRI scan, X-ray scans were performed before and after the MRI experiment. The phenomenon that the internal magnet was totally moved out of the shell was defined as complete displacement. If the internal magnet was moved out partly, the angle between the magnet and the plane of the coil was recorded.

Electrophysiological evaluation in cat experiments and clinical trials

Cat experiments

Prior to the human clinical trial, Nurotron[®] Venus[™] Cochlear Implant Systems were implanted into two normal-hearing cats. The EABRs of the cats were recorded. A 200- μ s/phase biphasic current pulse was applied, and the potential difference between the scalp electrodes was averaged over 1000 repetitions.

Clinical trials

To evaluate the performances of the cochlear implants [5] and the functions of the auditory systems of cochlear implant users and to assess the relationship between the ESRTs and C levels, post-lingually deafened patients were recruited.

The inclusion criteria were as follows: (1) 6–65 years of age; (2) bilateral post-linguistic severe-to-profound sensorineural hearing loss (≥ 85 dB HL average hearing thresholded of 0.5, 1, 2, and 4 kHz); (3) $\leq 30\%$ average open-set sentence recognition in the ear to be implanted and $\leq 50\%$ average closed-set recognition (<http://www.tigerspeech.com>) [6]; and (4) the patients satisfied the standard cochlear implantation candidacy criteria issued by the Chinese Ministry of Health [7].

The exclusion criteria were the following: (1) inner ear malformations and/or auditory nerve absences; (2) otitis media; (3) serious mental diseases; (4) patients who did not understand or refused the clinical evaluation; and (5) patients who did not satisfy the standard cochlear implantation candidacy criteria issued by the Chinese Ministry of Health [7].

Twenty-three volunteer patients (outpatients of the Eye Ear Nose & Throat Hospital of Shanghai Fudan University) with post-lingual deafness were recruited and were implanted with Nurotron[®] Venus[™] Cochlear Implant Systems. Sixteen of these patients (female/male ratio = 7/9, 20 ± 9 years old, range = 7–35 years) agreed to participate in and ultimately completed this part of

the research. All 16 patients with the Nurotron[®] Venus[™] Cochlear Implant System were evaluated 1 month after cochlear implantation surgery with full insertion of the electrode array. The causes of deafness included head trauma, familial progressive disease, and deafness of unknown cause. All subjects were stimulated using the m-n strategy. Prior to the measurement of the ESRT, the C levels were tested. The ESRTs were assessed with the acoustic impedance electro-audiometer (Madsen Electronics ZODIAC 091) and the programming station of the Nurotron[®] system. The C levels were obtained via standard procedures. The audiologist had access to the ESRTs during programming. Nine cochlear electrodes (electrodes 1, 2, 3, 11, 12, 13, 21, 22, and 23) were stimulated as the tested electrodes.

Psychophysical evaluation in clinical trials

Regarding its application in humans, the Food and Drug Administration in China approved human clinical trials of the Nurotron[®] Venus[™] Cochlear Implant System in October 2009, and the commercial release of this system in August 2011.

Post-lingually deafened patients were recruited. The inclusion criteria and exclusion criteria are described above. Sixty post-lingually deafened patients (female/male ratio = 34/26, 26 ± 12 years old, range = 6–59 years; implantation age = 25.94 ± 12.38 years old) participated in the Nurotron[®] cochlear implant clinical trial from December 2009 to October 2010. The investigation was conducted at the following five cochlear implant clinics in China: Shanghai Fudan University ($n = 23$); Beijing People's Liberation Army General Hospital (PLA General Hospital, $n = 15$); Beijing Tongren Hospital ($n = 10$); Zhejiang University ($n = 7$); and Chongqing Medical University ($n = 5$). At the end of the first year, 57 of the 60 participants completed their 12-month evaluations, and the remaining three participants were lost to follow-up. Forty-eight of the 60 participants completed their 36-month evaluations. At the 36-month follow-up, no acute adverse events caused by the medical devices were observed. Twelve participants were lost to follow-up for reasons that included distance, time problems, and phone number and address changes.

The speech recognition tests included the House sentence recognition test, the 301 (PLA General Hospital) sentence recognition test, the environment sounds, vowels, consonants, numerals, disyllabic words, and multi-word recognition (<http://www.tigerspeech.com>) [6].

Residual hearing of pure tone audiometry

To establish a baseline auditory function, the patients were pre-operatively evaluated under unaided conditions [8]. The unaided hearing thresholds of each ear were measured with headphones. The thresholds were measured at 250, 500, 1000, 2000, and 4000 Hz. The responses that were perceived as auditory were recorded. The data from the patients who exhibited hesitancy in the testing process were not included. To categorize the PTA threshold changes at each frequency, the changes in the threshold values for each participant were subdivided. We adopted the schema proposed by James et al. [9] and adapted by Garcia-Ibanez et al. [10] as follows: ≤ 10 dB (clinically insignificant/gold standard); 11–20 dB (clinically significant with moderate preservation); 21–40 dB (clinically significant with marginal preservation); and > 40 dB or no measurable response (no preservation).

Pitch ranking

Six subjects (S1, S2, S3, S4, S5, and S6) among the 57 Nurotron[®] CI users (6 month experience with CI) performed the speech recognition and electrode pitch ranking tests. The electrode pitch ranking test was performed to evaluate the place–pitch perception abilities of CI users.

The testing methods of the electrode pitch ranking tests were similar to those employed in the studies of Townshend et al. [11] and Nelson et al. [12]. The stimulus was composed of 50- μ s/phase biphasic current pulses, 890 pps, 500 ms pulse train, and presented in monopolar mode (MP1 + 2). The subjects reported that all electrodes were in tonotopic order based on the subjective pitch of the stimuli that was swept across the array. The parameters were chosen according to each subject's clinical map. Once the subject's active electrodes had been selected, the initial current level of each electrode was set at 75% of the patients' clinical maximum comfort level. In the pitch ranking step, all of the adjacent electrode pairs were selected. For S1, S2, and S4, a total of 23 pairs of stimuli ($\{E1, E2\}, \{E2, E3\}, \dots, \{E23, E24\}$) were chosen. The sensitivity index or d' was calculated from the percentage of correct scores obtained from the subject's response. The sensitivity index d' can be considered to be a measure of the perceptual difference between the two intervals. In this study, d' provided a measure of the discriminability between pairs of electrodes. If the place–pitch represented a single perceptual dimension, the d' sensitivity should be accumulated; e.g. the sum of d' for the ranking of electrodes E1–E2 and E2–E3 should equal d'

for the ranking of electrodes E1–E3. A graphical user interface was developed to control the presentation of the test stimuli and collect the responses from the subjects [13].

Speech/word perception

The close-set tests (environment sounds, numerals, and disyllabic words) were evaluated. Each test had eight alternatives, and the subject had to choose one of them (<http://www.tigerspeech.com>). The open-set test (PLA General Hospital disyllabic words) was also performed.

Institutional Review Board approval

The experimental protocols were reviewed and approved by the Animal Care and Use Committee and the Institutional Review Board. Each patient signed an informed consent form prior to participation.

Statistical analysis

Data were analyzed using SPSS Statistics 16, and $p < 0.05$ was adopted as indicative of statistical significance.

Results

MRI compatibility in cat and cadaveric head experiments

An X-ray was taken prior to the MRI scan. Fifteen minutes after the axial and coronal plane MRI scan, an X-ray was acquired and compared to the X-ray that was acquired prior to the MRI scan. Displacement of the internal magnet occurred in the live cat (complete displacement) and the cadaveric head (the angle between the magnet and the plane of the coil was 67.6°) (Figure 2A–D).

Following the removal of the internal magnet, one fresh-frozen cadaveric head was implanted unilaterally with a Nurotron[®] Venus[™] Cochlear Implant System. The fresh-frozen cadaveric head with a crepe bandage wrapped firmly around it was subjected to an MRI in the same scan condition. After the scan, no displacement of the internal device occurred following internal magnet removal (Figure 2E).

Electrophysiological evaluation in cat experiments and clinical trials

Cat experiments

The Nurotron[®] Venus[™] Cochlear Implant System was implanted into two normal-hearing cats. The EABRs of

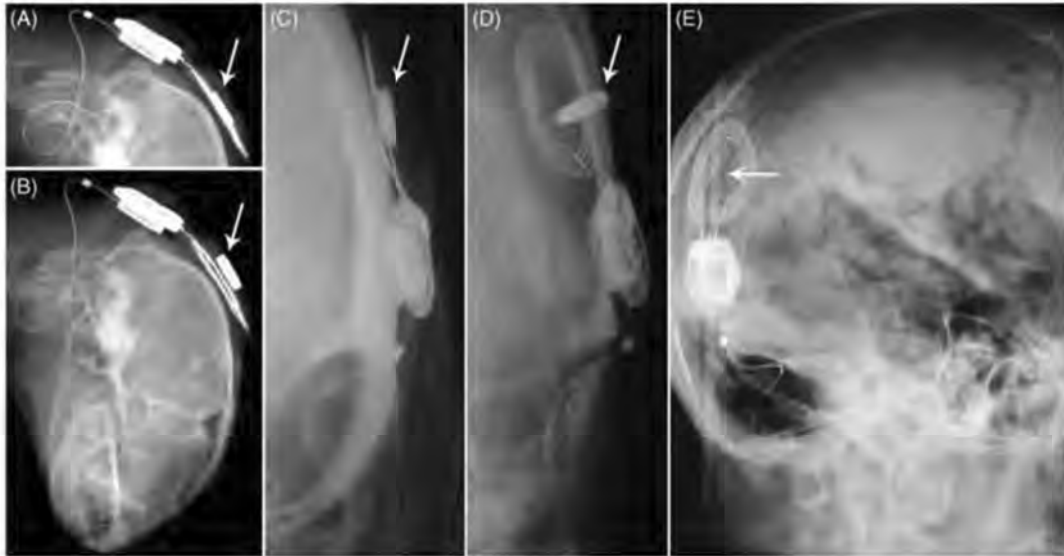


Figure 2. The X-ray of Nurotron cochlear implant after 1.5 T MRI. (A) Before MRI, the internal magnet was in normal position in the cat (see arrow). (B) After MRI, the internal magnet was separated from the housing without internal magnet removal (see arrow). (C) Before MRI, the internal magnet was in normal position in the cadaveric head (see arrow). (D) After MRI, the internal magnet in the

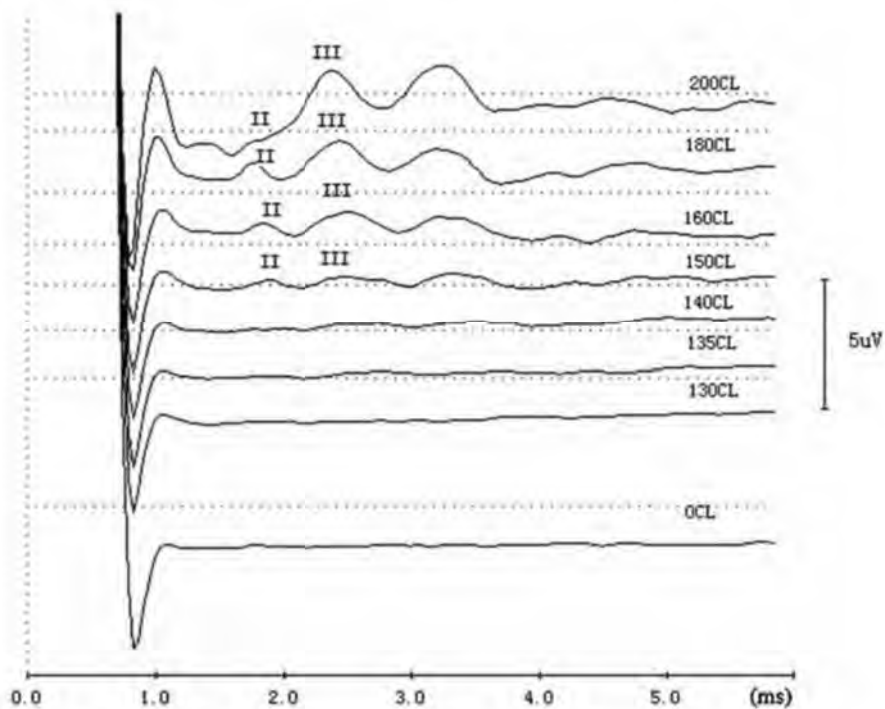


Figure 3. The typical EABR waveforms recorded in one of the cat animals. The positive peaks were clearly evident following. The threshold of this animal was 150 CL.

the cats were recorded. Figure 3 illustrates typical EABR waveforms that were recorded in one of the cats. The positive peaks (II, III) were clearly observed, and the latencies were 1.78- and 2.45-*ms*, respectively [14]. The threshold EABR of this animal was 150 CL.

Clinical trials

Sixteen post-lingually deafened CI users with Nurotron[®] Venus[™] Cochlear Implant Systems were evaluated at 1 month after cochlear implantation surgery. The ESRT and C levels were tested in all subjects, and the results

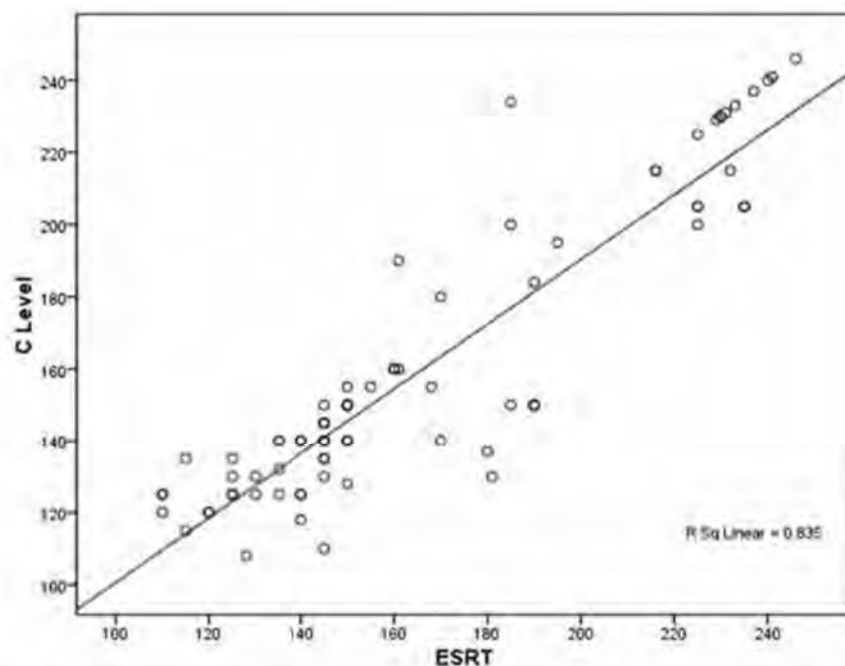


Figure 4. The correlation between the ESRT and C level. The correlation between the ESRT and C level, with the R^2 linear = 0.835 ($R = 0.91$, $p < 0.001$), indicating that the ESRT is highly correlated with C level obtained through subjective judgments.

Table I. Summary of the pre-operative residual hearing at each frequency and the unaided acoustic hearing thresholds at each frequency on the implanted side at the 1-month post-operative evaluation.

Increase in HTL (dB)	Pure-tone test frequency (Hz)				
	250 Hz	500 Hz	1000 Hz	2000 Hz	4000 Hz
Pre-operation (n)	41	54	49	40	25
Post-operation					
0–10 dB (n)	13 (31.7%)	12 (22.22%)	11 (22.45%)	11 (27.5%)	6 (24%)
11–20 dB (n)	3 (7.31%)	4 (7.41%)	4 (8.16%)	0 (0%)	0 (0%)
21–40 dB (n)	3 (7.31%)	3 (5.56%)	0 (0%)	0 (0%)	1 (4%)
> 40 dB or no measurable (n)	22 (53.7%)	35 (64.81%)	34 (69.39%)	29 (72.5%)	18 (72%)

The percentage of patients for whom the threshold changes were within each decibel range are indicated for each frequency.

were observed by the audiologist. ESRTs were detected in 91 out of the 144 tested electrodes (63.2%). Figure 4 shows the correlation between the ESRT and the C level, and the R^2 linear = 0.835 ($R = 0.91$, $p < 0.001$).

Psychophysical evaluation in clinical trials

Residual hearing of pure tone audiometry

Fifty-four (94.7%) of 57 patients exhibited measurable hearing pre-operatively at two or more audiometric frequencies in the implanted ear. Post-operatively, the unaided acoustic hearing thresholds were re-measured in the implanted ear at the 1-month post-surgery evaluation. The threshold changes at each frequency are shown in Table I.

Pitch ranking

Six subjects (S1, S2, S3, S4, S5, and S6) of the 57 Nurotron[®] CI users (6 month experience with CI) performed speech recognition, and electrode pitch ranking tests. Table II illustrates the information for the six subjects. Figure 5 demonstrates the findings of the electrode tone sequencing tests for these six subjects. The horizontal co-ordinate represents cochlear electrodes #1–24 (from the cochlear apical electrode to the basal electrode), and the vertical co-ordinate represents their corresponding tone sensitivities (d'). All of the subjects acquired the tone perception from 'low' to 'high' as expected.

The results indicated that the place pitch was generally ordered from the apical to basal electrodes. The apical

Table II. Subject information from the CI users who participated in the electrode pitch ranking tests.

Subjects	Gender	Age (years)	Etiology	Numbers of active electrode	Speech perception (close)
S1	Male	23	Sudden deafness	24	92.9%
S2	Female	35	Ototoxic deafness	24	100%
S3	Male	26	Ototoxic deafness	23	100%
S4	Male	20	Ototoxic deafness	22	97.1%
S5	Male	36	Noise-induced deafness	24	100%
S6	Female	20	Ototoxic deafness	19	92.9%

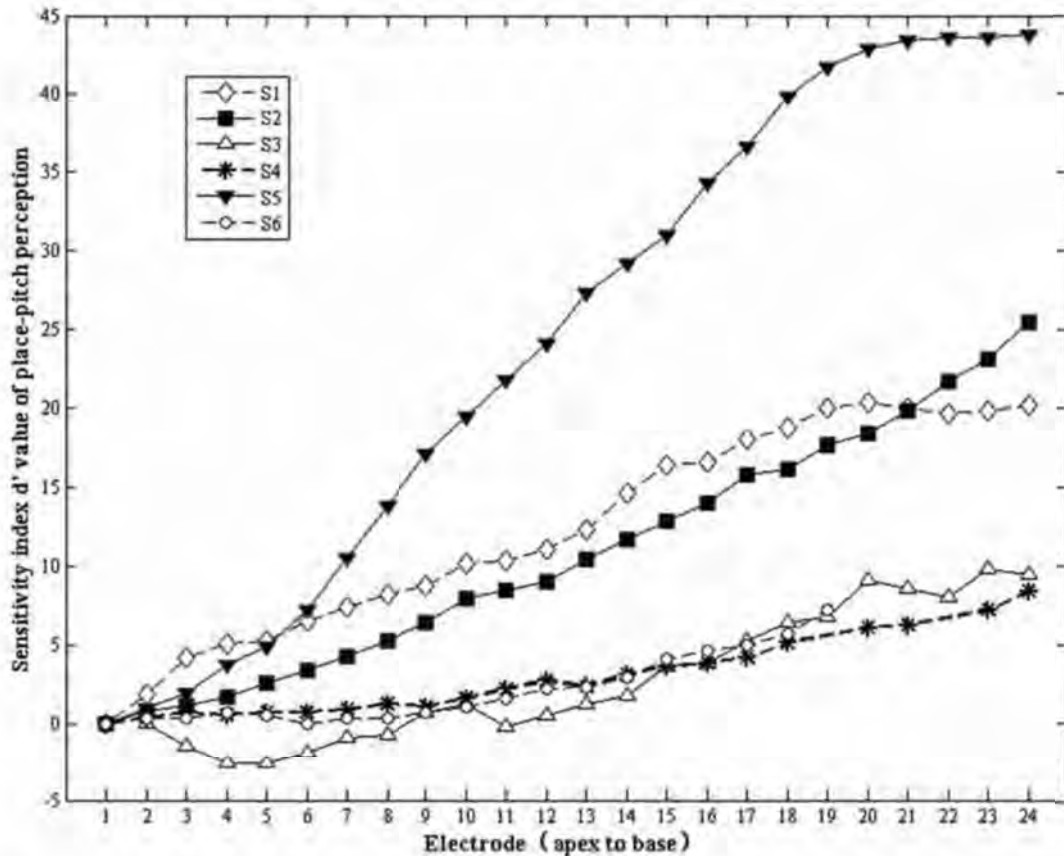


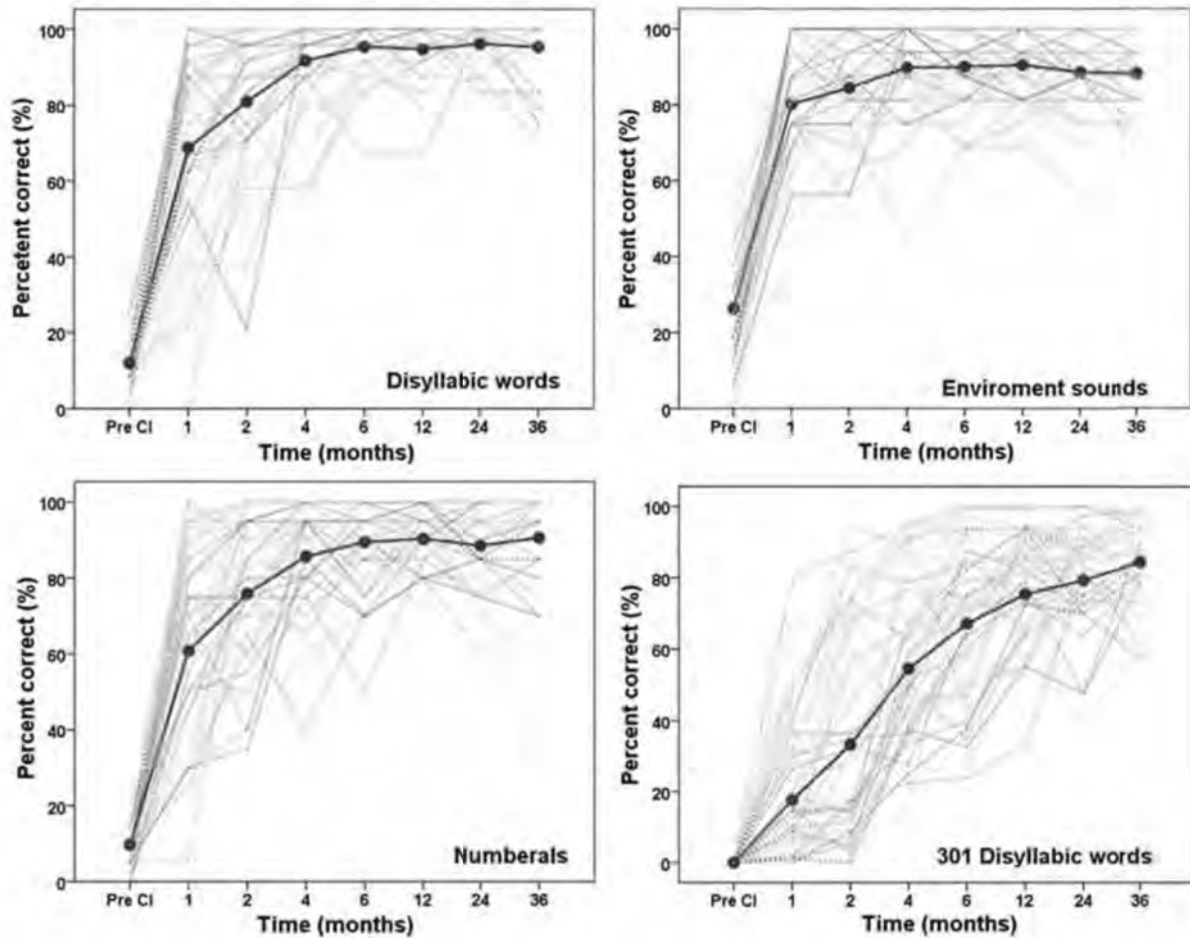
Figure 5. The electrode pitch ranking results of six CI subjects. The horizontal axis shows the 24 electrodes ordered from apical (bottom) to basal (top). Place-pitch were generally ordered from apical to basal electrodes. The apical electrodes were judged lower in pitch than basal electrodes. Large individual difference was found, maybe due to the different conditions of nerve survival in the cochlea.

electrodes were judged to be lower in pitch than the basal electrodes. Large individual differences were found. A comparison of the pitch and speech performances revealed that the speech recognition results were related to the place-pitch perception abilities of the CI users; however, this relationship was limited by ceiling effects.

Speech/word perception

The close-set tests (environment sounds, numerals, and disyllabic words) were evaluated. Each test involved eight alternatives, and the subject was required to choose one

of these alternatives (<http://www.tigerspeech.com>). The open-set test (PLA General Hospital disyllabic words) was also performed. Figure 6 illustrates the percentages of correct recognition as functions of time for the environment sounds, disyllabic words, and numerals. Overall, the results of the environment sound recognition were similar to those of the sentence recognition. Although variations across subjects were substantial (1-month), recognition improved significantly as a function of time [$F(7,426) = 199, p < 0.01$] to reach a plateau after only 2-months of use. The disyllabic words and numerals recognitions varied widely among the



subjects (1- and 2-month) and significantly improved as a function of time [$F(7,426) = 206, p < 0.01$; $F(7,426) = 194, p < 0.01$] to reach a plateau after only 4-months of use. This result is similar to those of previous studies of consonant and vowel recognition.

Figure 6 also illustrates that the open-set test results on the PLA General Hospital disyllabic words recognition task varied widely among the subjects (1, 2, 4, 6), but improved significantly as a function of implant usage over the 36-month period [$F(7,426) = 166, p < 0.01$]. Post-hoc analysis revealed significant improvements from an average score of 5% correct prior to cochlear implantation to 18%, 33%, 54%, and 67% correct at the 1-, 2-, 4-, and 6-month testing times, respectively ($p < 0.05$). The cochlear implant performance reached a plateau after 12 months, with a peak recognition rate of 85% at the 36-month evaluation.

Discussion

The Nurotron[®] Venus[™] array has 26 pure-platinum contacts, which is more than any other electrode array in

the world (the Nucleus has 22 electrodes, the MED-EL has 12, and the Advanced bionics has 16) and is capable of spanning the speech frequency range within the cochlea.

Devices from three major manufacturers, including the Nucleus CI24, MED-EL Pulsar CI100, and Advanced Bionics HiRes 90k [15], were examined by Tam et al. [15], who performed a series of *in vitro* tests that revealed that no alterations in device function following the acquisition of images of sufficient quality via MRI scanning in a 1.5-T machine. The present study in the cat and cadaveric head found that MRI examinations involving the Nurotron[®] Venus[™] cochlear implant should only be performed when there is a strong medical indication, and surgical removal of the internal magnet should be performed before scanning in 1.5-T MRI machines.

The positive peaks of the EABRs in the cat experience were similar to those reported in a study by Kretzmer et al. [16] in which Clarion II high-focus implants from the Advanced Bionics Corporation CI that were manufactured with smaller 6-electrode arrays for use

in cats were examined. The waveforms of the EABR revealed that the Nurotron[®] Venus[™] Cochlear Implant System was able to effectively stimulate the feline auditory system.

In clinical trials, ESRTs were detected in 91 of the 144 tested electrodes (63.2%), and this result is similar to that reported in Battmer's research (70%) [17]. ESRT programs and behavioral testing programs are strongly correlated, and the use of the ESRT has been suggested to be a useful means for creating a cochlear implant speech processor program [18]. The threshold of the ESRT might be an important parameter for helping doctors and audiologists estimate the C level during the tuning of cochlear devices. Similar to the results of Hodges with the Nucleus cochlear implants [19], in the present study of the Nurotron[®] Venus[™] Cochlear Implant System, the correlation between the ESRT and C level indicated that the ESRT was highly correlated with C level, as assessed through subjective judgments.

Post-operatively, the unaided acoustic hearing thresholds were re-measured only in the implanted ears only at the 1-month post-surgery evaluation to assess the residual hearing following surgery [20,21]. In a study of Nucleus 24 Contour array [22], clinically insignificant (change in 250 Hz PTA \leq 10 dB) was observed in 7% patients, and clinically significant with moderate preservation (change in 250 Hz between 11–20 dB) was observed in 19% patients. In this study, clinically insignificant (change in 250 Hz, PTA \leq 10 dB) was observed in 31.7% patients, and clinically significant with moderate preservation (change in 250 Hz between 11–20 dB) was observed in 7.31% patients. This success rate can be ascribed to the atraumatic insertion of the Nurotron[®] Venus[™] electrode array and indicates that the Nurotron[®] Venus[™] cochlear implant system exhibited a satisfactory performance in terms of residual hearing protection.

The pitch ranking test was used to systematically investigate the place-pitch perceptions based on the electrical hearing and revealed that the place pitch was generally tonotopic from the apical to the basal electrodes. Large individual differences were observed, and these differences indicate that the current signal processing functions of the CI system can provide sufficient information to understand speech. Kong and Zeng [23] and Xu et al. [24] observed that much finer spectral information (8–12 channels) is needed for tone recognition in spoken Mandarin and Cantonese. Previous clinical trial research has demonstrated that the sound signal characteristics transmitted by the sound coding strategy of the Nurotron[®] cochlear implant can provide excellent speech recognition effects.

When a CI user recognizes complicated signals such as music, his/her tone perception ability at the electrical

stimulation hearing site determines the auditory effect to a certain extent. Previous studies [4,25] of this 26-electrode cochlear implant system revealed that all of the subjects exhibited significant improvements in quiet and reached the level of ceiling effects in close-set tests (Mandarin consonants, vowels, and tones) and open-set tests (House sentence recognition and PLA General Hospital sentence recognition) of Mandarin. Our findings are consistent with those of previous research. In the present study, the results of close-set tests that included the recognition of environment sounds, disyllabic words, and numerals exhibited improvements and plateaued after 2–4 months of usage. In the open-set test of the present study, the PLA General Hospital disyllabic words recognition significantly improved, and the greater recognition was 85%, which was observed at the 36-month evaluation. Both the close-set and open-set evaluations indicated that the Nurotron[®] Venus[™] cochlear implant system exhibited a satisfactory performance in this study.

Using a large sample size and a long observation time (3 years), this study demonstrated significant improvements in the perceptual recognition. A clear trend of progress with the time of the implant usage was also observed.

Conclusion

This study describes objective and subjective evaluations of the Nurotron[®] Venus[™] Cochlear Implant System based on animal experiments and clinical trials. The Nurotron[®] Venus[™] array has 26 pure-platinum contacts. The studies of MRI compatibility in cat and cadaveric head experiments, EABR in cats experiment, ESRT and C level, and residual hearing of pure tone audiometry in clinical trials revealed the steady performance of this system. The results of the pitch ranking test in clinical trials suggested that this system can provide sufficient information for the understanding of speech. The large sample size and long observation time of this clinical study demonstrated that the Mandarin speech recognition significantly improved from the pre-implantation level to reach a plateau of high-level performance following a maximum of 12 months of usage. The results of this study indicate that the Nurotron[®] Venus[™] cochlear implant system exhibits a satisfactory performance for patients.

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儿童人工耳蜗植入术后音乐能力发育研究*

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[摘要] 目的:探讨儿童人工耳蜗植入术后音乐能力的发展趋势,为人工耳蜗植入儿童音乐能力评估提供临床资料。方法:26例人工耳蜗植入儿童,手术年龄为11~68个月,平均35.6个月;以76例1~24月龄的听力正常婴幼儿作为对照组,平均月龄6.1个月。使用小龄人工耳蜗儿童音乐能力等级量表进行评估。人工耳蜗植入儿童评估分别在开机时、开机后1、3、6、9、12及24个月时进行;听力正常婴幼儿评估分别在1、3、6、9、12及24月龄时进行。结果:人工耳蜗植入儿童的音乐能力得分随人工耳蜗使用时间的延长而显著提高($P < 0.05$),听力正常婴幼儿的音乐能力得分亦随年龄的增长而显著提高($P < 0.05$)。经两样本比较的秩和检验,人工耳蜗植入儿童与听力正常婴幼儿在听力年龄为1、3、6、9、12个月时音乐能力得分的差异无统计学意义($P > 0.05$),在听力年龄为24个月时音乐能力得分的差异有统计学意义($P < 0.05$)。结论:人工耳蜗植入儿童开机后音乐能力随人工耳蜗使用时间的延长而显著提高,并在开机12个月内呈现快速增长趋势。

[关键词] 儿童;耳蜗植入术;小龄人工耳蜗儿童音乐能力等级量表

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The development of musicality in children after cochlear implantation

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Abstract Objective: The purpose of this study is to analyze the development of musicality in children after cochlear implantation, and provide a clinical database for the evaluation of their musicality. **Method:** Twenty-six children with cochlear implants (CI group) participated in this research. They received cochlear implants at the age of 11 to 68 months with a mean of 35.6 months. Seventy-six infants as a control group aged from 1 to 24 months with a mean of 6.1 months participated in this study, whose hearing were considered normal by passing the case history collection, high-risk registers for hearing loss and hearing screening using DPOAE. The music and young children with CIs; Musicality Rating Scale was used to evaluate their musicality. The evaluation was performed before cochlear implantation and 1, 3, 6, 9, 12, 24 months after cochlear implantation for children with cochlear implants. The evaluation was also performed at 1, 3, 6, 9, 12, 24 months for children with normal hearing. **Result:** The mean scores of musicality showed significant improvements with time of CI use for CI group ($P < 0.05$). The mean scores of musicality also showed significant improvements with time for control group ($P < 0.05$). There were no significant differences in mean scores between CI group and control group at 1, 3, 6, 9, 12 months of hearing age by rank sum test ($P > 0.05$). Significant difference was noted between the two groups at 24 months ($P < 0.05$). **Conclusion:** The musicality of children with cochlear implants improved significantly with time after cochlear implantation. The most rapid growth was found in the first year after cochlear implantation.

Key words infants; cochlear implantation; music and young children with CIs; musicality rating scale

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随着新生儿听力筛查的普及和听力诊断技术的提高,越来越多的耳聋患儿在出生后较短时间内即可明确诊断,使早期干预成为可能。近年来,人工耳蜗技术不断进步,有越来越多的重度 and 极重度耳聋患儿通过人工耳蜗植入手术实现早期干预并获得良好的听觉和言语能力。与此同时,随着人们对健康需求的不断提高,耳聋患儿及家属对术后欣

赏音乐的期望值也在不断提高。因此,如何评估耳聋患儿植入人工耳蜗后的音乐能力,人工耳蜗术后音乐能力的发育规律及与听力正常儿童的差异究竟如何,成为迫在眉睫的研究课题。临床上常用的评估人工耳蜗术后音乐能力的方法有音乐感知能力测试和音乐能力评估量表等。音乐感知能力测试需要患者配合,常用于成人及较大儿童^[1],小龄儿童因难以配合测试而无法完成。音乐能力评估量表是通过询问家长而获得儿童音乐能力方面的信息,不需儿童配合,因此成为临床上常用的评估儿童尤其是小龄儿童音乐能力的主要方法。

小龄人工耳蜗儿童音乐能力等级量表(music and young children with CIs; musicality rating scale)是由 Julie Kosaner 在 2007 年设计完成的,用于评估小龄儿童人工耳蜗术后的音乐能力。本研究使用该量表对儿童人工耳蜗植入术后的音乐能力发展规律进行分析,并与听力正常儿童的音乐能力进行对照,为人工耳蜗植入患儿音乐能力评估提供临床资料。

1 材料与方法

1.1 临床资料

本研究对 26 例单侧人工耳蜗植入儿童(人工耳蜗组)进行音乐能力评估,分别在开机时,开机后 1、3、6、9、12 及 24 个月时进行。26 例中,男 18 例,女 8 例;人工耳蜗植入时年龄为 11~68 个月,平均植入年龄为 35.6 个月。所有患儿均使用诺尔康晨星人工耳蜗系统(包括 CS-10A 型人工耳蜗植入体、NSP-60B 型人工耳蜗言语处理器)。

听力正常对照组所有儿童均进行病史采集、耳聋高危因素排查及听力筛查。首先,由听力学专业人员向家属询问小儿病史,若存在任何一项与耳聋相关的病史,则予以排除。其次,由家属填写耳聋高危因素表,若存在 10 条高危因素中的任何一条,则予以排除。最后,进行听力筛查。使用德国 MAICO 公司 ERO SCAN Pro 仪器,选择畸变产物耳声发射的快速筛查模式进行听力筛查。筛查标准为:①信噪比 ≥ 6 dB;②全部 4 个频率中至少有 3 个频率通过。听力筛查未通过者,则予以排除。以上所有项目均通过者,其音乐能力评估结果纳入最

终统计范围。共有 76 名听力正常婴幼儿作为对照组进行音乐能力评估。其中男 42 例,女 34 例;年龄 1~24 个月,平均 6.1 个月。评估分别在 1、3、6、9、12 及 24 月龄时进行。

1.2 评估方法

本研究使用小龄人工耳蜗儿童音乐能力等级量表对植入人工耳蜗儿童和听力正常儿童进行音乐能力评估。量表共有 25 个问题,涉及儿童对音乐的反应及对音乐的节奏、音色和旋律的感知等行为。每个问题设 0~2 分,满分为 50 分。0 分为没有反应,1 分为有时有反应,2 分为总是有反应。评估由测试人员指导家长,由家长进行打分。

1.3 统计学处理

采用 IBM SPSS Statistics20 软件对数据进行统计学分析。

2 结果

2.1 人工耳蜗植入儿童的音乐能力发展随人工耳蜗使用时间而变化

经单因素方差分析,人工耳蜗植入儿童的音乐能力得分随人工耳蜗开机时间的延长而显著提高($P < 0.05$),见图 1。经均数的两两比较,人工耳蜗植入儿童除在开机后 1 个月与 3 个月,6 个月与 9 个月,9 个月与 12 个月,12 个月与 24 个月的音乐能力得分的差异无统计学意义外($P > 0.05$),在其余各评估阶段音乐能力得分的差异均有统计学意义($P < 0.05$),如表 1 所示。

2.2 听力正常婴幼儿的音乐能力发展随年龄的变化

经单因素方差分析,听力正常婴幼儿的音乐能力得分随年龄的增长而显著提高($P < 0.05$),见图 1。经均数两两比较,听力正常婴幼儿除在出生后 1 个月与 3 个月、9 个月与 12 个月的音乐能力得分的差异无统计学意义外($P > 0.05$),在其余各评估阶段音乐能力得分的差异均有统计学意义($P < 0.05$),如表 2 所示。

2.3 人工耳蜗植入儿童与听力正常婴幼儿相同听力年龄音乐能力的差异

听力正常婴幼儿听力年龄从出生后开始计算,即出生后 1 个月为听力年龄 1 个月,出生后 3 个月

表 1 人工耳蜗植入儿童音乐能力得分在不同评估阶段两两比较结果

开机时间	1 个月	3 个月	6 个月	9 个月	12 个月	24 个月
开机时	$P=0.026$	$P=0.001$	$P=0.000$	$P=0.000$	$P=0.000$	$P=0.000$
1 个月		$P=0.221$	$P=0.000$	$P=0.000$	$P=0.000$	$P=0.000$
3 个月			$P=0.000$	$P=0.000$	$P=0.000$	$P=0.000$
6 个月				$P=0.210$	$P=0.003$	$P=0.000$
9 个月					$P=0.081$	$P=0.012$
12 个月						$P=0.479$

表 2 听力正常婴幼儿音乐能力得分在不同评估阶段两两比较结果

年龄	3 个月	6 个月	9 个月	12 个月	24 个月
1 个月	$P=0.859$	$P=0.000$	$P=0.000$	$P=0.000$	$P=0.000$
3 个月		$P=0.001$	$P=0.000$	$P=0.000$	$P=0.000$
6 个月			$P=0.020$	$P=0.028$	$P=0.000$
9 个月				$P=0.929$	$P=0.012$
12 个月					$P=0.000$

为听力年龄 3 个月,依此类推。人工耳蜗植入儿童听力年龄从人工耳蜗开机后开始计算,即开机后 1 个月为听力年龄 1 个月,开机后 3 个月为听力年龄 3 个月,依此类推。经两样本比较的秩和检验,人工耳蜗植入儿童与听力正常婴幼儿在听力年龄为 1、3、6、9、12 个月时音乐能力得分的差异无统计学意义($P>0.05$),在听力年龄为 24 个月时音乐能力得分的差异有统计学意义($P<0.05$)。如图 1 所示。

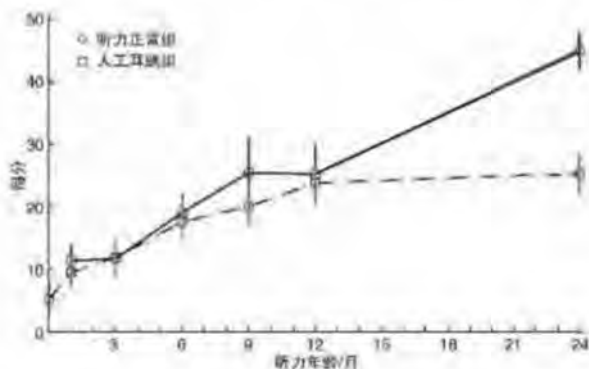


图 1 两组儿童音乐能力得分随年龄的变化

3 讨论

3.1 人工耳蜗植入儿童音乐能力发展趋势

人工耳蜗植入儿童音乐能力得分随着人工耳蜗使用时间的延长而逐渐增加,表明人工耳蜗植入儿童的音乐能力随着听力年龄的增长而逐渐提高。统计学分析显示,在开机后的 12 个月内人工耳蜗植入儿童音乐能力增长速度较快,在 12 个月以后增长速度逐渐减慢。国外学者也有相似的研究报道。Scorpecci 等^[3]的实验证实植入耳蜗儿童音乐能力得分明显低于听力正常受试者;在人工耳蜗植入组,音乐的识别能力和人工耳蜗的使用年限以及歌曲的识别技术显著相关。王硕等^[4]对人工耳蜗使用者的音乐感知能力进行了一系列的研究。使用慕尼黑音乐经验问卷(Munich music questionnaire, MUMU)评估 12 例听力正常受试者与 12 例人工耳蜗使用者的年龄与音乐经验的匹配程度,使用 Fitzgerald 等开发的人工耳蜗音乐评估软件(MuSIC)中的旋律辨别与和弦辨别测试评估人工耳蜗使用者的音乐音调感知能力,实验证实语后聋

成人人工耳蜗使用者的音乐音调感知能力与人工耳蜗植入前助听器佩戴时间以及植入后聆听音乐的经验相关。

3.2 人工耳蜗植入儿童与听力正常儿童音乐能力发展趋势对比

由于助听设备的限制,有人推测人工耳蜗植入儿童在音乐感知方面的发展也异常于听力正常儿童。Hopyan 等^[5]通过实验证明人工耳蜗植入儿童与听力正常儿童一样,也具有辨别节奏变化、记住乐曲的能力。国外研究均证实人工耳蜗植入儿童的音乐能力低于听力正常儿童。Hopyan 等^[5]的另一项实验表明一组 7~13 岁人工耳蜗植入儿童拥有感知音乐内情感内容的能力,但其能力低于健听儿童。Vecchiato 等^[6]的实验也证明了这一点。在国内对成人人工耳蜗植入研究方面也有相似结果。刘子夜等^[7]对 13 例成人人工耳蜗植入者分别进行音乐聆听行为评估和旋律辨别、乐器辨别测试,并与正常对照组比较,结果证实成人人工耳蜗植入者的旋律感知能力和音色感知能力明显落后于听力正常者。本研究结果与国外学者研究相似。听力正常婴幼儿音乐能力得分随着年龄的增长而逐渐增加。人工耳蜗儿童音乐能力发展趋势与正常儿童发展趋势基本一致。在听力年龄 1 年内,人工耳蜗儿童与听力正常婴幼儿音乐能力得分比较无显著差异。而在听力年龄为 2 年时,两组儿童存在显著差异。由于问卷包含音乐的节奏、音色和旋律的感知等多方面内容,这些能力的发展在听力正常儿童中也需要一个过程,因此在开机后的 12 个月内,人工耳蜗植入儿童对于音乐的节奏、旋律等基本音乐要素的感知发展速度与听力正常儿童相似。但由于人工耳蜗对于音乐精细结构的处理存在不足^[1],因此在其后的 1 年内,人工耳蜗植入儿童的音乐能力发展处于相对缓慢的水平;而听力正常儿童的音乐能力继续发展,在年龄为 24 个月时得分接近满分,从而造成两组儿童在听力年龄为 24 个月时音乐能力得分出现统计学差异。

3.3 音乐康复训练对植入耳蜗儿童音乐能力发展的促进作用

Gfeller 等^[8-11]于 2000-2006 年进行了一系列的成人人工耳蜗植入者的音乐能力与音乐康复训练的研究。研究对成人人工耳蜗植入者在音高感知、音色识别、旋律识别及包含音乐问题的生活质量问卷等多方面与正常人进行比较,从多方面证实成人人工耳蜗植入者在音乐能力上低于听力正常成年人。因此他们开发了一套供成人人工耳蜗植入者在家进行多种音乐训练的康复工具,除上述测试内容包含的因素外还融入了音色欣赏、音乐风格欣赏等多项内容,供 11 例成年植入者完成训练项目。通过再次测试发现,他们在复杂歌曲测试中的

旋律识别得到明显提高,同时他们对康复工具的整体满意度也很高。由此可见人工耳蜗植入者的音乐能力可通过音乐康复训练得到提高。

近年来,国外也有多项研究对人工耳蜗植入儿童音乐康复训练的必要性进行探讨。Dastgheib等^[12]的研究证实根据神经可塑性的原则,音乐可以通过激活相同的处理语言的大脑区域来提高语言技能。众所周知,越大范围的大脑区域被激活,就有越多的学习和可塑性突触变化发生在特定的区域。因此,即使耳蜗植入儿童不能像健听儿童一样习得语言的细节,也可以通过音乐康复训练补偿这种发展迟缓。Gfeller等^[18-19]也在相关研究中描述了典型的音乐疗法及对学龄前儿童进行合适的干预计划。van Besouw等^[18-19]的相关研究表明,父母经常在家唱歌、演奏乐器,接受较大音乐刺激量的人工耳蜗植入儿童对音乐的刺激更加敏感。所以家长在平时也应尽可能增加音乐刺激量。Stordahl^[13]通过歌曲识别测试及音乐背景问卷等一系列研究表明,尽管耳蜗植入者和听力正常儿童之间存在部分差异,但在喜欢听的音乐方面非常接近。所以家长在平时也应尽可能增加音乐刺激量,以促进人工耳蜗植入儿童音乐能力的发展,进而促进语言的进步。

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语前聋儿童人工耳蜗植入术后前 语言交流能力发展[△]

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【摘要】 目的 分析人工耳蜗植入后儿童前语言交流能力的发展规律,探讨其与其它听觉及言语评价指标的相关性,为早期听觉言语康复评估提供依据。方法 对 23 例接受国产人工耳蜗植入术的语前聋儿童进行一年的随访,手术月龄 12~66 个月,平均 35±8 个月。分别于开机时及开机后 1、3、6、9、12 个月使用录像分析法对患儿的轮流交流、主动交流、视觉交流及听觉注意 4 项前语言交流能力进行分析和评估;同时使用听觉行为分级(CAP)、言语可懂度分级(SIR)问卷对其听觉和言语能力进行评估。结果 随术后开机时间延长,患儿的轮流交流和听觉注意能力呈显著增长趋势($P<0.05$),前 6 个月增长较快($P<0.05$),后 6 个月缓慢增长($P>0.05$);患儿主动交流和适时的视觉交流能力得分较低,两者差异无统计学意义($P>0.05$);患儿 CAP 和 SIR 得分与轮流交流和听觉注意能力相关。结论 随着人工耳蜗使用时间的延长,患儿逐步建立了听/说的交流模式;前语言能力评估结果与 CAP 和 SIR 得分有相关性,三者结合可相互印证并能更全面准确地对人工耳蜗植入术后儿童早期听觉、语言和交流能力进行评估。

【关键词】 录像分析法; 前语言交流能力; 儿童; 人工耳蜗

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The Development of Preverbal Communication Skills in Prelingually Deaf Children with Cochlear Implants

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【Abstract】 Objective The aim of this study is to summarize preverbal communication skills in children with cochlear implants, and to provide a clinical baseline of assessment in early stage after cochlear implantation. Methods 23 prelingually deaf children with homebred cochlear implants participated in this study. The age at cochlear implantation ranged from 12 to 66 months with a mean of 35 months. The evaluation was performed at switch-on session and 1, 3, 6, 9 and 12 months after the first programming session. Tait video analysis was used to assess the preverbal communication skills including turn-taking, autonomy, eye contact and auditory awareness. CAP and SIR were used to evaluate the auditory and speech abilities. Results The skills of turn-taking and auditory awareness increased significantly, especially in the first six months after switch-on session ($P<0.05$). The scores of autonomy

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and eye contact were relative low and there were no significant differences during the first year after surgery ($P > 0.05$). There was a correlation between the score of CAP/SIR and turn-taking or auditory awareness. **Conclusion** Children with cochlear implants established vocal-auditory mode of early communicative behavior over time. Pre-verbal communication skills CAP and SIR have relativity and can comprehensively evaluate the auditory, speech and communication skills of children with cochlear implants.

【Key words】 Tait video-analysis; Preverbal communicative skill; Children; Cochlear implant

目前,对于低龄耳聋儿童,其助听后的听觉言语康复水平评估的方法较少,虽然婴幼儿有意义听觉整合量表(infant-toddler meaningful auditory integration scale, It-Mais)、有意义听觉整合量表(meaningful auditory integration scale, Mais)、有意义言语使用量表(meaningful use of speech scal, MUSS)、听觉能力分级(categories of auditory performance, CAP)和言语可懂度分级(speech intelligibility rating, SIR)已用于助听后儿童听觉言语康复的早期评估,但对于助听后耳聋儿童早期交流能力的评估还不够全面。

“前语言时期”是指儿童掌握语言之前语言发生的准备阶段,通常指从出生到第1个有真正意义的词产生(10~14个月)之间的时期^[1],这一时期儿童是通过一些特定的语音、表情和动作代替语言进行交流^[2-4]。前语言交流能力是指前语言时期儿童的交流能力,研究证实,聋儿助听后前语言交流能力可预示其后言语感知能力和语言能力的发展情况,前语言交流能力越高,言语感知和语言能力的发展越快,康复效果越好^[5,6]。因此,可将聋儿助听后的前语言交流能力高低作为早期评估其听觉言语康复效果好坏的指标。Tait最早设计出录像分析法^[7-9]用于人工耳蜗植入患儿前语言交流能力的评估,录像分析法是录制一段患儿与他所熟悉的成人之间交流情况的录像,根据录像分析患儿所运用的交流技巧,交流技巧分为轮流交流(turn-taking)、主动交流(autonomy)、视觉交流(eye contact)、听觉注意(auditory awareness)等,利用这几项指标来评价患儿的前语言交流能力^[10]。本研究使用录像分析法总结使用国产人工耳蜗后听障儿童前语言交流能力的发展规律,并探讨其与助听后CAP、SIR的关系,为这类患儿早期康复效果的评估提供参考依据。

1 资料与方法

1.1 研究对象 选取23例接受国产人工耳蜗(诺尔康,体外机型号为NSP-60,植入体型号为CS-10A)植入术的语前聋儿童为研究对象,进行一年的跟踪研究,其中男14例,女9例。手术月龄12~66个月,平均 35 ± 3 个月,其中 >2 岁者19例(82.61%)。患儿术前均为极重度感音神经性聋,其中9

例有术前助听器使用史。术中电极全部植入,术后均无手术并发症,开机时0.5、1、2、4 kHz平均助听听阈为25~40 dB HL,2例术后非植入耳佩戴助听器,全部对象均进行为期一年的听觉言语康复训练,训练时间为20~40小时/周。无其他医学禁忌证,耳科疾病及影响智力、心理或身体发育的疾病。

1.2 听觉及言语能力评估方法 全部对象于人工耳蜗植入后开机时,开机后1、3、6、9、12个月分别进行前语言交流能力、CAP、SIR评估。由经过培训的人员使用CAP和SIR量表对患儿进行问卷评估。评估人员按由低到高的等级逐一询问量表中的问题,家长根据患儿在日常生活中的反应做出详细的描述,评估人员按家长的回答进行评分。

1.2.1 前语言交流能力评估 前语言交流能力使用录像方式(使用SONY高清数码摄像机)进行采集。每次录像采集时间为5分钟,选取其最具代表性的2分钟录像片段作为分析材料。拍摄时患儿坐在靠近窗户的位置,以便光源可以照到其身上,摄像机放在远离光源处,主要给予患儿全镜头,参与测试的监护人也应出现在镜头范围内。摄录内容包括患儿面部表情、语言、手势或肢体动作,监护人使用语言与患儿进行交流,尽量不给患儿肢体动作提示,交流时要求在每句话后有少许停顿,以便于患儿有时间使用前语言交流技巧对监护人的每一句话做出反应^[11]。由2名经过正规培训的测试者参与分析以确保分析结果的可靠性^[12]。前语言交流能力评估指标包括轮流交流、主动交流、视觉交流及听觉注意^[13]。

①轮流交流 将患儿回应监护人讲话后的停顿,或是患儿打断监护人的谈话,视为“一轮”。轮流交流可以是有声回应(轮流交流V),也可以是肢体回应(轮流交流G),若两种反应均没有,则记为无反应(NR)。以所分析录像资料中的总轮数作分母,分别计算上述各种回应方式占总轮数的百分比。

②主动交流 如果患儿在交流时所提供的信息不能从监护人的谈话中预测,即交流是由患儿主动发起的,那么此轮可称为主动交流。主动交流可为有声回应(主动交流V)或肢体回应(主动交流G),若两种反应均没有,则记为无反应(NR)。同样计算

上述各交流方式占总轮数的百分比。

③视觉交流 在监护人说话时,患儿目光适时地注视监护人,称为视觉交流。以录像资料中监护人讲话的总字数作分母,患儿表现为视觉交流的字数作分子,以计算所得的百分比表示视觉交流能力。

④听觉注意 若患儿在一轮对话中出现了有声回应而未表现出视觉交流,则这一轮出现了听觉注意。以无视觉交流的有声回应(non-lookng vocal turn)做为评估指标。以所分析录像资料中的总轮数作分母,计算有声回应方式占总轮数的百分比。

1.2.2 CAP 问卷评估 CAP 将患儿的听觉能力分为 8 个等级,得分为 0 至 7 分,其中 0 分为不能觉察环境声或说话声,1 分为可觉察环境声,2 分为可对言语声做出反应,3 分为可鉴别环境声,4 分为无需唇读可分辨言语声,5 分为无需借助唇读可理解常用短语,6 分为无需借助唇读可理解交谈内容,7 分为可以和认识的人打电话^[10];得分越高,听觉能力越好。

1.2.3 SIR 问卷评估 SIR 将患儿的言语可懂度分为 5 个等级,得分为 1 至 5 分,其中 1 分为连贯的言语无法被听懂,口语中的词汇不能被识别,患者日常交流的主要方式为手势;2 分为连贯的言语无法被听懂,当结合谈话情境和唇读线索时,可听懂言语中的单个词汇;3 分为连贯的言语可被某位聆听者

听懂,但需聆听者了解谈话主题,集中注意力并结合唇读;4 分为连贯的言语可被某位聆听者听懂,如果聆听者不熟悉聋人言语,不需费力倾听;5 分为连贯的言语可被所有聆听者听懂,在日常语境中孩子的语言很容易被理解^[11-12]。得分越高,言语清晰度越佳。

1.3 统计学方法 采用 SPSS17.0 统计软件包对研究资料进行统计分析。对于方差齐性的数据采用 Bonferroni 进行多组均数两两比较,对于方差不齐的数据采用 Tamhane's T2 进行多组均数两两比较;运用 spearman 秩相关进行相关性分析,显著性标准均为 $P < 0.05$ 。

2 结果

2.1 前语言交流能力评估结果

2.1.1 轮流交流能力(表 1) 随术后开机时间延长,患儿轮流交流(V+G)能力呈显著增长趋势($P < 0.05$),其中有声回应(轮流交流 V)能力也显著增长($P < 0.05$),肢体回应(轮流交流 G)能力无显著变化($P > 0.05$)。轮流交流(V+G)和有声回应(轮流交流 V)各评估阶段得分均值两两比较结果见表 2。

2.1.2 主动交流能力 随术后开机时间延长,患儿各评估时段主动交流能力(V+G)、有声回应(主动交流 V)能力、肢体回应(主动交流 G)能力差异均无统计学意义($P > 0.05$)(表 3)。

2.1.3 听觉注意能力 23 例人工耳蜗植入术后儿童听觉注意能力随术后开机时间的变化见表 4 和表 5。

表 1 23 例人工耳蜗植入术后儿童各评估阶段轮流交流能力得分(%, $\bar{x} \pm s$)

评估时间	例数(例)	轮流交流(V+G)	轮流交流 V	轮流交流 G
开机时	22	11.117±11.457	5.129±11.222	5.987±6.047
开机后 1 月	23	15.400±12.874	7.978±9.932	7.423±7.003
开机后 3 月	21	33.420±26.583	25.737±28.601	7.683±7.042
开机后 6 月	21	45.904±27.963	38.499±30.127	7.405±6.835
开机后 9 月	19	56.627±29.771	49.416±33.816	7.211±9.694
开机后 12 月	19	61.623±23.663	51.053±26.101	10.570±14.317

表 2 开机后不同时间轮流交流能力(V+G)、轮流交流 V 均值两两比较结果

开机后时间(月)	轮流交流能力(V+G)					轮流交流 V				
	0	1	3	6	9	0	1	3	6	9
1	0.985	-	-	-	-	0.999	-	-	-	-
3	0.022	0.123	-	-	-	0.070	0.171	-	-	-
6	0.000	0.001	0.900	-	-	0.001	0.003	0.935	-	-
9	0.000	0.000	0.187	0.986	-	0.000	0.001	0.294	0.994	-
12	0.000	0.000	0.016	0.616	1.000	0.000	0.000	0.083	0.934	1.000

表 3 23 例人工耳蜗植入术后儿童各评估阶段主动交流能力得分(%, $\bar{x} \pm s$)

评估时间	例数(例)	主动交流(V+G)	主动交流 V	主动交流 G
开机时	22	4.305±5.452	2.687±4.863	1.618±2.649
开机后 1 月	23	5.381±5.677	2.934±4.051	2.448±4.345
开机后 3 月	21	6.066±5.821	4.144±4.273	1.922±3.428
开机后 6 月	21	5.434±5.506	3.978±5.056	1.437±2.561
开机后 9 月	19	6.167±7.444	4.616±7.404	1.550±2.472
开机后 12 月	19	6.753±9.782	6.753±9.782	0.000±0.000

表 1 各评估阶段听觉注意能力和视觉交流能力得分(%, $\bar{x}\pm s$)

评估时间	例数(例)	听觉注意能力	视觉交流能力
开机前	22	1.455±3.759	7.259±14.522
开机后 1 月	23	3.463±7.607	9.842±12.931
开机后 3 月	21	17.601±23.368	9.026±11.759
开机后 6 月	21	28.251±25.599	11.722±14.008
开机后 9 月	19	40.913±30.925	6.775±11.068
开机后 12 月	19	38.867±23.517	7.558±10.864

表 5 开机后不同时间听觉注意能力均值两两比较结果

开机后时间(月)	0	1	3	6	9
1	0.990	-	-	-	-
3	0.074	0.192	-	-	-
6	0.002	0.004	0.935	-	-
9	0.000	0.001	0.102	0.958	-
12	0.000	0.000	0.097	0.949	1.000

随使用人工耳蜗时间延长,患儿听觉注意能力呈显著增长趋势($P<0.05$)。

表 7 开机后不同时间 CAP 和 SIR 得分均值两两比较

开机后时间(月)	CAP					SIR				
	0	1	3	6	9	0	1	3	6	9
1	0.021	-	-	-	-	1.000	-	-	-	-
3	0.002	0.578	-	-	-	1.000	1.000	-	-	-
6	0.000	0.001	0.058	-	-	0.003	0.002	0.109	-	-
9	0.000	0.000	0.000	0.991	-	0.000	0.000	0.012	1.000	-
12	0.000	0.000	0.000	0.162	0.988	0.000	0.000	0.000	0.300	0.345

2.3 CAP 与前语言能力各项评估得分的相关性(图 1) 用 spearman 秩相关对其相关性进行检验,可见,CAP 与轮流交流和听觉注意得分的相关性有统计学意义($P<0.001$);CAP 与主动交流和视觉交流得分的相关性无统计学意义($P>0.05$)。说明随着 CAP 得分的提高,轮流交流和听觉注意的得分也逐步提高。

2.4 SIR 与前语言能力各项评估得分的相关性(图 2) 用 spearman 秩相关对其相关性进行检验,可见,SIR 与轮流交流和听觉注意得分相关性有统计学意义($P<0.001$),SIR 与主动交流和视觉交流得分相关性无统计学意义($P>0.05$),说明随着轮流交流和听觉注意得分的提高,SIR 得分也逐步提高。

3 讨论

本研究显示,开机后 1 年内人工耳蜗植入患儿的轮流交流和听觉注意能力呈显著增长趋势,且在前 6 个月增长较快,6~12 个月增长缓慢并逐步进入平台期。这可能是由于参与本研究患儿手术年龄多数较大(82.61% 超过 2 岁),理解和学习能力较好,能较快达到“平台期”,这与国外研究结果相似^[7,11];其中轮流交流和听觉注意的有声回应能力也以相同的方式增长,而肢体动作回应能力基本无变化,表明人工耳蜗植入患儿在前语言期逐渐学会了以轮流交流的方式与人进行交流,且更多地以发声的方式回应;同时患儿对运用听觉获得信息的能

2.1.4 视觉交流能力(表 4) 可见,随术后开机时间延长,患儿各阶段视觉交流能力差异无统计学意义($P>0.05$)。

2.2 CAP 和 SIR 评估结果 23 例人工耳蜗术后儿童听觉能力和言语可懂度随术后开机时间的变化见表 6 和表 7。随术后开机时间延长,患儿 CAP 和 SIR 得分呈显著增长趋势($P<0.05$)。

表 6 开机后不同时间 CAP 和 SIR 得分(分, $\bar{x}\pm s$)

开机时间(月)	例数(例)	CAP	SIR
开机前	22	0.91±0.971	1.27±0.550
开机后 1 月	22	1.68±0.716	1.18±0.395
开机后 3 月	19	2.37±1.257	1.12±0.607
开机后 6 月	21	3.90±1.758	1.35±0.740
开机后 9 月	19	4.42±1.387	2.11±0.809
开机后 12 月	19	5.16±1.119	2.14±0.805

力也有提高,初步建立起了“听/说”的交流模式。

国外研究显示^[12],不同手术年龄组的患儿前语言交流模式存在较大差异,1~2 岁手术的患儿较 2 岁后手术的患儿更易形成发声、主动的交流模式;1~2 岁手术的患儿随着术后开机时间的延长,患儿的主动交流能力呈逐步增长的趋势;2 岁后手术的患儿其主动交流能力无明显增长趋势。本研究患儿手术平均年龄将近 3 岁,在开机后 1 年内患儿的主动交流能力得分较低且无显著增长,与国外研究相似,这可能是由于患儿手术年龄偏大,较难在短期内形成主动交流的模式;同时,由于患儿术前听觉及语言能力较差,与外界主动交流少,较难改变以前的交流习惯。另外,国内外社会和文化背景的差异,中国父母更强调孩子的服从,并倾向于控制孩子的冲动行为,同西方儿童相比中国儿童较少进行主动的活动^[13,14],主动交流意愿低,这也可能是造成主动交流能力得分较低的原因。

国外研究^[15]也发现患儿视觉交流一致性较差,而本组对象开机一年内视觉交流能力得分基本无变化,且个体间变化较大。这主要是由于视觉交流除了与患儿听觉、语言能力有关外,录像时的环境等对其也有较大的影响。因此,建议在评估这类患儿前语言交流能力时视觉交流可不作为主要指标,只作为次要指标,若听觉注意得分过低时,可用于观察是否由于视觉交流得分过高所致。

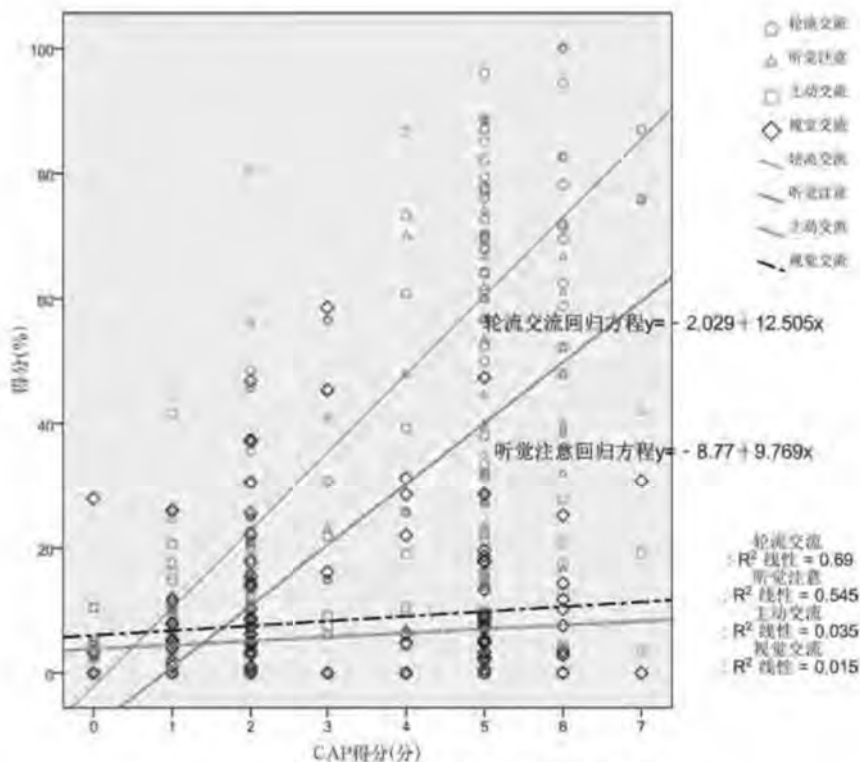


图 1 CAP 得分与前语言能力各项评分指标的相关性

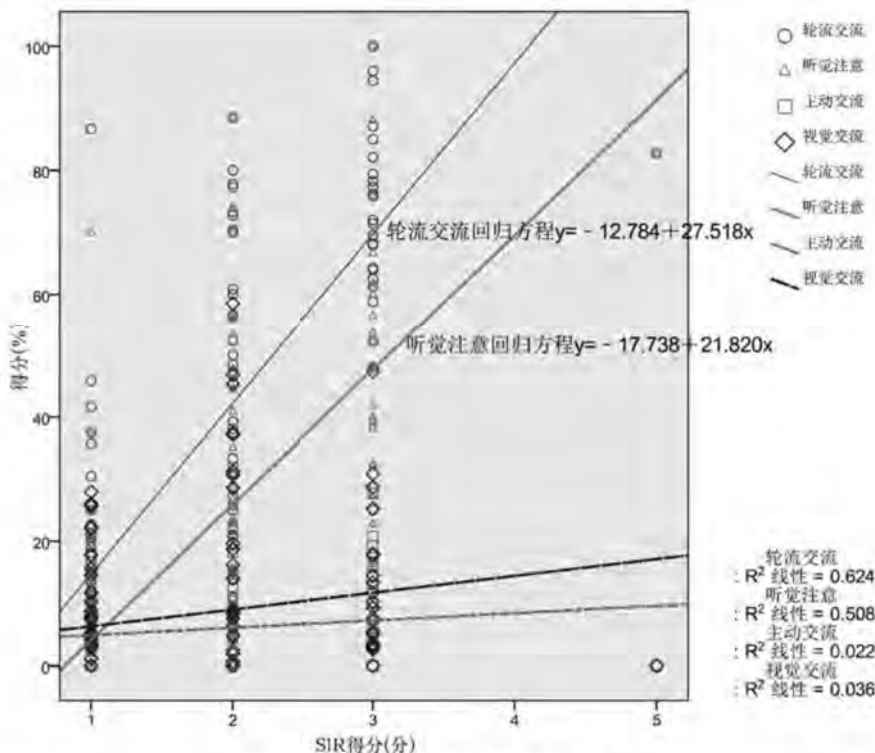


图 2 SIR 得分与各项评分指标的相关性

CAP 是对人工耳蜗植入术后儿童听觉能力的评估, SIR 是对患儿言语能力的评估。文中结果显示开机一年内患儿 CAP 和 SIR 得分呈逐步上升趋势, 说明本组患儿在人工耳蜗植入术后一年内其听觉及言语能力逐渐提高; 但 CAP 得分增长较 SIR 得分增长快, 说明患儿听觉能力的发育在先, 当有一定听觉积累后, 言语能力随之发育。轮流交流和听

觉注意反映患儿听到语言声后的动作和发声等表现, 从文中结果看, 患儿 CAP 得分与轮流交流和听觉注意能力得分都呈上升趋势, 且相关性具有统计学意义, 说明随着听觉能力的提高, 患儿更愿意与他人进行听/说交流; 同时, 随着患儿轮流交流和听觉注意能力的提高, 患儿言语能力即 SIR 得分也逐步提高, 且相关性具有统计学意义, 说明语言表达能力

好的患儿更愿意与他人进行听说交流。综合前语言交流能力、CAP、SIR 三项得分,可以相互印证评估结果的准确性,且既能反映患儿术后听、说能力如何,还能反映听与说的联系,从而可更全面评估患儿的听觉言语交流能力。此外,CAP 和 SIR 用于对患儿听觉能力进行评估已得到国内外广泛的认同,前语言交流能力评估指标中的轮流交流和听觉注意与其具有良好的相关性,进一步说明这两项指标适用于人工耳蜗植入术后儿童听觉言语早期康复效果的评估。由于本研究样本量较少,某些评估阶段的 CAP 和 SIR 得分数据量较少,造成变异度较大,可能会对该二种方法得分与前语言交流能力得分相关性分析造成影响。此外,轮流交流和听觉注意两项指标可同时反映听、说或听、肢体反应等的表现,而 CAP 和 SIR 只反映听或说的一方面,因此未来对于轮流交流和听觉注意的回归方程的建立可进一步由单因素(CAP 或 SIR)转变为多因素,以获得更准确的回归方程。

用于儿童前语言能力评估的录像分析法与其它早期评估聋儿康复效果的方法相比有以下优点:①可直接观察患儿在交流过程中所运用的技巧及其变化,较问卷形式减少了家长主观因素的影响;②以日常交流最重要的感知对象——语言为媒介,评价结果更具有实际意义;③对人工耳蜗植入术后儿童听觉、肢体语言、发音、主动交流意愿等多方面进行综合评估,而不是独立的评估某一方面;④对人工耳蜗植入术后儿童的生理年龄和手术年龄没有严格要求。该方法较适用于人工耳蜗植入术后早期患儿和年龄较小患儿的听觉言语交流能力的评估。此外,录像分析法对设备和环境的要求不高,分析人员进行系统的培训后可保证分析结果的准确性,但由于数据的采集是否规范对结果有较大影响,因此录像前要对家长进行相关注意事项的讲解,以取得家长的配合。

研究表明,中枢神经系统对于语言的形成有一个敏感期,这一时期若没有足够的声音刺激则会影响语言和交流能力的发展^[15,16]。同样,人工耳蜗植入年龄对助听后耳聋儿童的前语言交流能力也有影响^[15,17]。本研究仅观察了部分手术年龄较大的语前聋患儿人工耳蜗植入术后前语言交流能力的发展情况,今后还应进一步对手术年龄较小的患儿前语言期交流能力进行研究,获得不同年龄植入人工耳蜗儿童术后前语言交流能力的发展规律,并探讨不同助听模式下患儿前语言交流能力是否存在不同,从而指导患儿使用最佳的助听模式。

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· 临床研究 ·

诺尔康人工耳蜗植入者的声调识别与生活质量评价*

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[摘要] 目的:评估诺尔康人工耳蜗植入者对普通话的声调识别能力和术后生活质量。方法:49例植入诺尔康人工耳蜗1年的受试者,使用课题组前期编制的声调识别测试软件,评估植入者的声调识别能力;使用Nijmegen人工耳蜗植量表(NCIQ),评估植入者术后生活质量。结果:①安静条件下声调识别率平均为67.26%,全部高于机会水平;②噪声条件下声调识别率平均为51.92%,除2例植入者的声调识别率低于机会水平外,其余均高于机会水平;③声调识别混淆矩阵结果显示,三声为较容易辨别的声调;④术后NCIQ总分及基本声音感知、高级声音感知、言语能力、自信心、活动能力和交流能力均获得改善,分别为35.4、72.4、54.0、63.4、50.7、47.3和44.7分。结论:诺尔康人工耳蜗植入者术后具有声调识别能力并可获得生活质量的改善。

[关键词] 耳蜗植入;声调识别;生活质量;术后聋

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Lexical tone perception and quality of life in Nurotron cochlear implant users

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Abstract Objective: To investigate the lexical tone perception and quality of life of Nurotron cochlear implant users. **Method:** Forty-nine adult cochlear implant users participated in this study. Mandarin tone identification test developed by Beijing Institute of Otolaryngology was used to evaluate the tone perception. Nijmegen cochlear implantation questionnaire (NCIQ) was administered to quantify the quality of life. **Result:** ① The average scores of tone perception in quiet was 67.26%. The tone perception rates under quiet condition for all cochlear implant recipients were higher than the opportunity level. ② The average scores of tone perception under noisy condition was 51.92%. Except for two recipients, the tone perception rates under noise condition for the rest recipients were

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better than chance. ③The confusion patterns of tone recognition showed that Tone 3 was the easiest tone to perceive. ④The postimplant scores for the total, basic sound perception, advanced sound perception, speech production, self-esteem, activity and social interactions of NCIQ were 55.4, 72.4, 54.0, 63.1, 50.7, 47.3 and 44.7, respectively. **Conclusion:** The Nurotron cochlear implant users had the ability for lexical tone perception and had an improvement in quality of life after cochlear implantation.

Key words cochlear implant; tone perception; quality of life; postlingually deafness

众所周知,人工耳蜗是一种为重度 and 极重度听力损失患者提供听觉言语康复的有效手段。随着人工耳蜗技术的完善和提高,植入者的言语识别能力和言语发育均获得了明显的进步。然而对基于西方语系开发的人工耳蜗系统以及所采用的言语编码策略是否能准确地反映汉语言的特点和有效地识别普通话的声调已成为众多学者关注和研究的重点。本研究针对使用诺尔康人工耳蜗的受试者进行了前瞻性随访设计,探究其声调识别能力和术后生活质量的变化趋势。

1 资料与方法

1.1 临床资料

行植入手术 1 年的诺尔康人工耳蜗植入者 49 例,其中男 30 例,女 19 例;年龄 16~60 岁,平均(26.8±11.7)岁;均为双侧重度或极重度感音神经性听力损失患者,无手术禁忌证,无术后并发症;均使用峰值提取编码策略(m-n),每天人工耳蜗使用时间平均为(11.80±2.35)h。

49 例植入者均接受了生活质量问卷调查,其中 21 例接受了声调识别测试。

1.2 研究方法

1.2.1 测试材料 ①声调识别测试材料:使用北京市耳鼻咽喉科研究所编制的声调识别测试软件^[1],所有测试词均为日常生活常用词,男生朗读。在安静和噪声 2 种测试条件下采用封闭项测试方法,随机选取 80 个词(20 个音节×4 个声调)完成测试,机会水平为 25%。②生活质量评价问卷:使用中文版 Nijmegen 人工耳蜗植入量表(Nijmegen cochlear implantation questionnaire, NCIQ)进行生活质量评价,该量表由 Hinderink 等^[2-3]于 2000 年研制开发,量表从生理功能、社会功能和心理功能 3 个方面对植入者进行综合评价,生理功能包括基本声音感知(basic sound perception)、高级声音感知(advanced sound perception)和言语能力(speech production)3 个子维度,心理功能包括自信心(self-esteem)1 个子维度,社会功能包括活动能力(activities)和交流能力(social interactions)2 个子维度。分数评定依次为 1~5 分 5 个等级。将每个子维度中的问题得分相加再除以完成的问题数目即为该子维度得分,并将其得分转化为百分制,满分为 100 分。

1.2.2 测试方法 测试环境和设备:测试前让受

试者先熟悉测试要求并给予受试者充分的指导和练习,在受试者能够完全理解、配合测试后开始正式测试。测试时环境噪声<35 dB A,受试者安静放松,保持言语处理器各项参数与日常使用时的设置相同。扬声器置于受试者前方 1 m 并与受试者耳部齐平,信号声和(或)噪声均以 0°正面入射。声调识别测试条件:包括安静条件和噪声条件。安静条件下的信号强度为 65 dB A;噪声条件下信号强度为 65 dB A,噪声强度为 60 dB A。受试者根据所听到的声音通过用户界面选择相应的测试词,当受试者选择结果后,进入下一组测试,每组测试仅播放一遍。

2 结果

2.1 声调识别率

安静条件下全部 21 例植入者声调识别得分均高于机会水平,噪声条件下有 2 例植入者声调识别率低于机会水平,其余 13 例植入者声调识别率均高于机会水平。各项测试得分情况见表 1。

表 1 声调识别率

项目	安静条件	噪声条件
受试人数/例	21	15
平均分/%	67.26	51.92
标准差/%	15.33	21.54
最低分/%	33.75	15.00
最高分/%	96.25	95.00

2.2 声调识别混淆矩阵分析

声调识别混淆矩阵结果(表 2、3)显示,三声是较为容易辨别的声调,不容易与其他声调相混淆。

表 2 安静条件下声调识别混淆矩阵

	一声	二声	三声	四声
一声	0.58±0.24	0.16±0.12	0.05±0.08	0.20±0.17
二声	0.23±0.15	0.54±0.19	0.15±0.10	0.08±0.11
三声	0.06±0.08	0.11±0.14	0.80±0.20	0.04±0.07
四声	0.09±0.09	0.07±0.08	0.07±0.10	0.77±0.21

2.3 人工耳蜗植入者生活质量分析

对 49 例人工耳蜗植入者进行与健康相关生活质量评价(图 1),所有植入者对基本声音的感知较好(满分为 100 分)。

表 3 噪声条件下声调识别混淆矩阵

	一声	二声	三声	四声
一声	0.41±0.22	0.19±0.11	0.19±0.14	0.20±0.17
二声	0.21±0.16	0.49±0.26	0.15±0.13	0.15±0.16
三声	0.07±0.10	0.15±0.16	0.73±0.25	0.05±0.07
四声	0.12±0.11	0.14±0.15	0.30±0.24	0.45±0.31

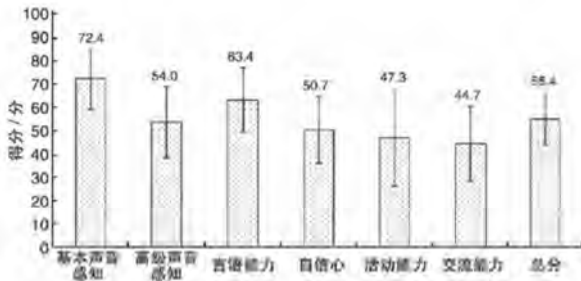


图 1 NCIQ 各维度计分图

3 讨论

声调语言是超过世界 1/4 人口的主要交流方式,汉语作为声调语言的典型代表,与无声调语言在语音学、声学以及心理声学等层次上均存在显著差异,而声调作为汉语的重要语音学特征之一,具有区分语意的重要属性^[1]。然而人工耳蜗植入者普遍存在着声调缺失现象,这势必影响植入者的言语理解和构成,影响植入者进入主流社会的效能;另外目前国内评价人工耳蜗效果的指标常局限于对植入者听觉能力的评价以及对言语能力改善的关注,鲜有对植入者日常生活实际使用情况的评估和植入者在社会活动中与听力正常者交往的评价。本研究以切合植入者生活质量提高的需求为出发点,通过声调识别能力和生活质量 2 个方面对诺尔康人工耳蜗植入者进行评估,探讨其术后生活的自然声音效果。

声调作为汉语的重要语音学构成要素,除了具有别义功能之外,还具有许多其他功能,如构形功能、分解功能、抗干扰功能和修辞功能等,人工耳蜗植入者的声调识别能力会直接影响其言语分辨能力和理解能力,因此关于声调识别的研究对于言语评估与康复技巧的改进都具有重要意义。本研究发现所有植入者在安静条件下的普通话声调识别率均高于机会水平,其中 3 例可以达到 90% 以上;噪声条件下有 2 例植入者的声调识别率低于机会水平,其余 13 例均高于机会水平。

言语信号从声学处理的角度可以分为频域信息和时域信息,频域信息和时域信息又分别包含其包络和精细结构。国内外早期研究表明汉语声调识别主要依靠频率,梁之安(1963)指出汉语声调识别的语音学特性主要存在于频率,声调信息较广泛地分布于音节的各个频带成分中,基频及其各次谐

波中承载着声调的主要信息。后续研究发现,当基音频率起作用时,音长、音高和音强等都仅是可有可无的辅助信息,当频域信息不足时,时域信息可补偿基频信息的缺失,音长对声调识别也有影响^[2],特别是当基频不起作用时,这些则可能成为声调感知的重要依据^[3]。本研究声调识别混淆矩阵显示,三声比较有特点,不容易与其他声调相混淆。普通话四个声调中,四声音长最短、音强最强,三声音长最长、音强最弱,一声和二声居中^[4],三声与其他声调在音长方面的差异最大,对植入者而言最容易分辨,因此混淆概率较低;而一声和二声之间音长和音强方面的差异较小,因此较易混淆。

世界卫生组织(1993)提出健康不仅是免于疾病和衰弱,而且是保持体格、精神和社会方面的完美状态,并将这种健康的评价称之为生活质量,即“不同文化和价值体系的个体对于他们的目标、期望、标准以及所关心的事情有关的生活或状态的体验”。实际上无论是从医学还是从社会学的角度,评价的最终目的都是为了全面提高人们的生活质量,因此全面评价人工耳蜗植入者日常生活实际情况及在社会活动中与听力正常者交往时的心理情况已经成为听力学工作者必须要面对的责任和任务。NCIQ 作为一种具有一定影响力的人工耳蜗植入者生活质量评价的特异性量表,目前较为广泛地应用于临床,已被荷兰、德国和美国等越来越多的人工耳蜗中心采用^[5-10]。本课题组的研究结果显示 NCIQ 中文版基本满足生活质量量表所需的心理测量学特性标准,可以用来评估人工耳蜗植入者的术后效果^[5]。本研究发现诺尔康植入者术后对基本声音的感知较好,可以参加社会活动,部分植入者有一定的高级声音(如电话和音乐)感知能力,10 例植入者能够较好地进行简单的电话交流,2 例植入者能够很好地进行电话交流。本课题组曾使用 NCIQ 量表对 32 例语后聋成年人人工耳蜗植入者进行研究,发现植入者独立生活性和自信心均有明显提高,听觉能力和情感交流能力提高^[11]。Klop 等(2008)对 14 例语后聋人工耳蜗植入者进行随访发现,开机 4 个月后植入者 NCIQ 所有方面的得分均较术前显著提高,以上研究均表明语后聋人工耳蜗植入者术后生活质量获得了显著改善。

综上所述,本研究以切合植入者健康水平提高的需要为出发点,通过声调识别测试和生活质量自我评价 2 个方面对植入诺尔康人工耳蜗系统的语后聋患者术后效果进行评价,发现术后 1 年的植入者已经获得声调识别能力和生活质量的改善,后期将继续对该组植入者进行更长期的跟踪效果评估。

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管不及而出现窒息死亡。造成脱管的原因很多,如套管大小不合、皮下气肿、护理人员操作不熟不慎、外套管系带过松等都会引起外套管脱落。外套管脱落直接引起喉梗阻,将危及患者的生命^[7]。临床中要密切观察脱管现象,及时采取救治措施,保证患者生命安全。

有 6 例患者气管切开后给予吸氧过程中出现呼吸频率及呼吸幅度和血氧下降,出现呼吸衰竭征象,应用呼吸机辅助呼吸后好转。6 例患者均是 III 度或 IV 度呼吸困难,更主要的是梗阻时间长,高二氧化碳分压使呼吸系统兴奋,呼吸频率加快;当气管切开后,骤然间氧气吸入,相对的二氧化碳骤减,没有足够量的二氧化碳刺激呼吸中枢,致使中枢性呼吸骤停。这时,有条件可应用呼吸机辅助呼吸,也可采取在套管口连接简易呼吸囊给予正压呼吸,同时给予氧气和二氧化碳混合气体吸入,患者多在短时间内恢复。我们在临床上观察到,所有行紧急气管切开的患者,特别是梗阻时间较长的患者,气管切开并给予吸氧后,即便不出现呼吸骤停,氧分压也不能马上改善,可能都与出现呼吸抑制有关。

有资料表明,环甲膜切开术开放气道对于需要紧急建立气道的患者是相对安全的^[8],但由于担心气道狭窄等原因,临床上耳鼻喉科医师仍更倾向于避免施行环甲膜切开术。因而紧急气管切开在临床上仍是部分患者开放气道的重要手段,也是抢救急危重患者最有效的急救方法之一。但紧急气管切开患者并发症的发生率高于常规气管切开者,因此,手术时机与并发症发生有很大的关系^[1],对于呼吸困难患者,特别是已出现 III 度呼吸困难的患

者,要综合判断病情的发展情况,短期内不能缓解且有发展趋势的,宜及时果断地实施气管切开,如因犹豫不决或其他原因使病情恶化而迫不得已实施紧急气管切开术,将大大增加手术风险及并发症的发生。

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一例神经纤维瘤患者 植入人工耳蜗的效果观察

Outcome of Cochlear Implantation in a Patient with Acoustic Neuroma

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【摘要】目的 探讨神经纤维瘤听力下降患者人工耳蜗植入手术可行性及疗效。**方法** 对一例多发性神经纤维瘤伽马刀术后患者带瘤行CS-10A人工耳蜗植入,术前和术后3个月分别进行裸耳/助听听阈评估、单音节和双音节言语识别测试。**结果** 患者术前右侧重度、左侧极重度感音神经性聋,术前言语识别率左耳最大声输出患者无反应,右耳最大单音节词言语识别率为12%,双耳双音节词言语识别率均为0%。听觉行为分级量表为2级。患者右侧成功植入人工耳蜗。术后3个月助听后声场评估右耳(人工耳蜗植入耳)平均听力42.5 dB HL,单音节词最大言语识别率为64%,双音节词最大言语识别率为47%,听觉行为分级量表为7级。**结论** 在影像学证明神经完整的情况下,神经纤维瘤伽马刀术后重度聋患者可植入人工耳蜗,以提升听力水平。

【关键词】人工耳蜗;神经纤维瘤

【Abstract】Objective To explore the safety and efficacy of cochlear implantation in a neuroma resection patient with hearing loss. **Methods** One patient after bilateral acoustic neuroma resection by Gamma knife surgery received a CS-10A cochlear implant in right ear. Postoperative performance including unaided/aided hearing thresholds and monosyllable and disyllable recognition rates was evaluated and compared with the preoperative performance. **Results** The patient suffered a severe hearing loss in the right ear and a profound hearing loss in the left ear. The preoperative monosyllable recognition rates were 0% and 12% for the left and right ear, respectively. The preoperative disyllable recognition rates were 0% for both ears. The preoperative CAP score was 2. Three months after cochlear implantation, the average aided hearing threshold of the right ear (implanted ear) was 42.5 dB HL. The postoperative monosyllable recognition rate was 64% and disyllable recognition rate was 47%. The postoperative CAP score was 7. **Conclusion** Cochlear implantation is a safe and effective approach to improve the hearing of patients after acoustic neuroma resection by Gamma knife surgery if the acoustic nerve is intact according to the preoperative imaging tests.

【Key words】Cochlear implant; Acoustic neuroma

人工耳蜗重建双侧重度、极重度感音神经性耳聋患者的听力及言语识别率的效果已经被人们所认同。人工耳蜗植入是通过将电极系列放置在患者耳蜗的鼓阶中,外界声音经由体外言语处理器收集处理后发送给植入耳蜗中的电极,刺激螺旋神经节,通过听神经传递至听觉中枢^[1]。然而人工耳蜗的疗效对于不同患者的收益程度是因人而异的。影响患者效果的因素中,患者本身的听力基础、听神经功能尤为关键。神经纤维瘤患者经伽马刀切除后可能造成听神经损伤,植入人工耳蜗效果尚无确切报道。本文报道1例多发性神经纤维瘤患者在神经纤维瘤伽马刀术后行人工耳蜗植入的疗效评估观察。

1 临床资料

患者,男,33岁,2006年底无明显诱因出现双耳“吹风样”持续性耳鸣,伴双侧听力下降、眩晕,对症治疗无效,3个月后耳鸣进一步加重,呈“隆隆声”,

且自觉听力下降。2007年来院就诊,右耳纯音测听平均听力损失60 dB HL,左耳全聋。颅脑磁共振平扫提示多发性神经纤维瘤。双耳先后2次接受伽马刀治疗。第一次伽马刀治疗:病灶位置为左小脑桥脑角区,肿瘤大小为 $17.4 \times 21.1 \times 25.3$ mm,体积为 4.8 cm³,准直器为14 mm,射点为3,靶中心剂量为27 Gy,靶周边剂量为15 Gy,局部等剂量曲线55%。第二次伽马刀治疗:病灶位置为左小脑,肿瘤体积为 $20.2 \times 12.6 \times 14.2$ mm,体积为 2 cm³,准直器为14 mm,射点为2,靶中心剂量为24 Gy,靶周边剂量为15 Gy,局部等剂量曲线63%。2009年听力进一步下降,且呈波动性,伴右耳耳鸣加重。试配助听器,助听效果因听力波动较大而时好时差,患者未坚持佩戴。2012年患者及其家属迫切希望通过人工耳蜗改善听力和言语交流水平。医生向患者及其家属交代了人工耳蜗手术的风险,并充分沟通了伽马刀术后可能损害听神经的情况。人工耳蜗术前颅脑MRI示:神经

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纤维瘤病术后, 双侧桥小脑角区、内听道见不均匀短T1、长T2异常信号, 增强扫描后T1信号明显强化, 右侧小脑局部脑实质受压改变。左侧小脑半球实质内见不均匀长T1、长T2信号, 周围见水肿信号, 增强扫描病变内部可见结节状强化。脑沟、裂、池及幕上脑室系统无扩大, 中线结构居中。右侧上颌窦, 右侧乳突气房内可见不均匀长T2信号影。神经纤维瘤病术后复查, 与6个月前MIR片比较, 双侧桥小脑角区及左侧小脑半球病变无明显变化。右侧上颌窦黏膜下囊肿, 右侧乳突炎。

2 方法

2.1 术前评估

术前纯音测听结果见表1, 右耳(植入耳)500、1000、2000、4000 Hz(4FA)平均听力81.25 dB HL, 左耳各频率最大声输出无反应。声导抗测试显示, 双侧226 Hz鼓室曲线为“A”型, 双侧声反射未引出。听性脑干反应阈值为: 右侧90 dB nHL、左侧100 dB nHL未引出反应。40 Hz听觉相关电位结果: 右侧90 dB nHL、左侧120 dB nHL未引出反应。畸变产物耳声发射双侧各频率均未引出有意义的DPOAE。CT和MRI评估排除患者耳蜗骨化及钙化, 患者虽经过伽马刀神经纤维瘤手术, 但是通过各项听力测试(表1)和神经功能评估, 初步判断患者的听神经功能表现尚可。患者术前右侧重度、左侧极重度感音神经性聋。

利用心爱飞扬言语测听材料^[2]测试单音节词和双音节词言语识别率, 左耳单音节词识别率最大声输出患者无反应。右耳单音节词识别率在101 dB HL刺激声强度下为12%。术前双音节词言语识别率测试左、右两侧均为0%。听觉行为分级问卷(Categories of Auditory Performance, CAP)为2级, 能够感知环境声音。建议患者可带瘤右耳行人工耳蜗植入术, 术前向患者和家属交待病情, 详细介绍人工耳蜗术后的疗效及风险。

2.2 手术

常规耳后切口(右侧), 切开皮肤、皮下至乳突及

顶枕部骨皮质表面, 用电钻切除乳突气房, 暴露鼓窦入口和砧骨短突。见乙状窦前内侧后颅窝脑板部分吸收, 裸露的硬脑膜表面增厚。在手术显微镜下, 以砧骨短突为标志, 确定面神经隐窝的位置, 在面神经垂直段起始部外侧、砧骨窝下方、鼓索神经内侧交替使用密纹钻头和钻石钻头磨除骨壁, 经面神经隐窝进入鼓室, 看到圆窗龛, 标志清楚。磨除圆窗龛上缘部分骨质完全裸露圆窗膜。在顶切迹后上方磨除约2×2 cm的顶枕部皮质骨直至硬脑膜, 放置言语接收刺激器。然后划开圆窗膜, 立即滴入地塞米松液和透明纸酸钠, 将(诺尔康)24导人工耳蜗CS-10A的作用电极自面神经隐窝、圆窗膜洞口缓慢顺利插入鼓阶内, 洞口外无剩余电极。自切口取小块肌肉填塞放入电极的洞口以固定电极。取小块明胶海绵填塞面神经隐窝。耳后切口以可吸收线作皮下间断缝合, 以5个零尼龙收线皮内缝合。计算机检测示各植入电极阻抗正常。

2.3 术后听力语言评估

术后1个月开机, 开机后1个月、2个月、3个月随诊调试。采用心理物理测试, 调试参数脉宽50 us、频率680 Hz、T值50~80 CL、M值150~180 CL。术后3个月行声场下助听阈测试, 利用心爱飞扬言语测听材料测试单音节词和双音节词言语识别率, 同时采用听觉行为分级问卷(Categories of Auditory Performance, CAP)对听觉行为进行疗效分析, 观察听力言语康复效果。

3 结果

术后5天右耳耳蜗史氏位X光片显示患者成功植入人工耳蜗。术中阻抗测试阻值正常。无术后并发症及不良反应。术后1个月开机测试电极阻抗正常。开机调试心理物理测试反应良好。开机当天患者可听到模糊言语声, 并听清自己的名字; 开机1个月后可与家人简单交谈。术后3个月患者全天配戴人工耳蜗可以基本正常工作和生活。助听后声场评估右耳(植入耳)500、1000、2000、4000 Hz(4FA)平均听力42.5 dB HL(见表1)。言语识别率测试结果为: 在60 dB HL

表1 患者术前纯音气导听阈及术后声场助听阈(dB HL)

	125 Hz		250 Hz		500 Hz		1000 Hz		2000 Hz		4000 Hz		8000 Hz	
	左耳	右耳	左耳	右耳	左耳	右耳	左耳	右耳	左耳	右耳	左耳	右耳	左耳	右耳
术前	—	—	—	90	—	85	—	85	—	75	—	80	—	65
术后	—	—	—	45	—	45	—	40	—	45	—	40	—	30

注: “—”代表该频率最大声输出无反应

刺激声强度下单音节最大识别率为64%，双音节词最大识别率为47%。听觉行为分级问卷(CAP)听觉行为分级为7级(不借助唇读可以与人交谈)。该患者对人工耳蜗植入效果非常满意。手术后重建了听力，听觉及言语识别能力均有明显提高。

4 讨论

神经纤维瘤患者行人工耳蜗手术前应谨慎评估患者听神经的结构和功能。该患者为NF-II型神经纤维瘤病，是一种常染色体显性遗传病，该类型比较罕见，特点为双侧听神经纤维瘤或单侧神经纤维瘤伴有其它部位神经纤维瘤脑膜瘤或胶质瘤，主要临床表现双侧或单侧听力障碍，偶可发现奶油咖啡斑皮下结节，常见病史数月或数年^[1]。神经纤维瘤伽马刀术后的全聋患者应结合听力检查，CT、MRI影像学结果全面评估判断患者的听神经是否由于伽马刀手术而受损。术前高分辨率CT或MRI提供了确定听神经通路通畅与否的最好方法^[4]。本例患者右侧植入耳虽然接受伽马刀手术治疗，但CT、颅脑MRI和内听道水成像MRI均显示内耳结构正常，耳蜗骨化及钙化可能性较小。术中证实电极可以顺利插入耳蜗。

CT及MRI一般仅提供耳蜗结构正常依据，对于耳蜗听神经功能的评估还要结合听力学评估结果。研究表明，先天性神经孔缺如以及神经纤维瘤所致的极重度感音神经性聋，因缺乏足够的神经支配，是两种非常罕见但必须排除的耳蜗植入禁忌证^[5]。本例患者术前纯音测听检查结果左侧全聋，右侧气导平均听力损失(500、1000、2000、4000Hz 4个频率的平均值)为81.25 dB HL。且各频率均有残余听力，其他听力检查结果与纯音测听结果相印证。听力检查结果提示右耳听神经功能尚可，可进行人工耳蜗植入手术。术后开机调试证实患者各电极通道均有明确可重复的听性反应，患者的言语分辨能力有很大提高。对于神经纤维瘤患者必要时可行鼓岬电刺激或术中EABR测试^[6,7]。这些检查结果为判断患者是否适合接受人工耳蜗手术提供依据。对于不能判断听神经功能或耳蜗骨化钙化的双侧神经纤维瘤患者，人工耳蜗植入是不适合的治疗方式，听觉脑干植入可提供切实可行的恢复听觉传导通路的选择^[8]。

本例患者2007年伽马刀术前右耳开始听力下降，至人工耳蜗术前2个月听力下降至平均听力损失80 dB HL，听力下降至重度聋水平时间较短。在人工耳蜗开机3个月时，单音节词最大言语识别率为64%，双音节词最大言语识别率为47%。听觉行为分级量表为

7级(不借助唇读可以与人交谈)。该患者听力下降时间较短，人工耳蜗植入效果较好。这与其他研究人员的研究结果相符^[9]。Gantz采用了广泛的测试方法包括术前听力评估、言语感知测试、电生理学测试、心理物理学测试等得出的结果为言语感知能力的表现与人工耳蜗植入术前患者的年龄和耳聋时间呈反比^[10]，也就是说人工耳蜗植入术前的极重度耳聋时间越短，人工耳蜗植入后能获得较好言语感知能力的可能性越大。但是这些只能解释人工耳蜗植入术后患者表现的部分差异。其他影响人工耳蜗预后的因素也起重要作用。尤其对于复杂病例应该具体问题具体分析。同时对于本例高风险人工耳蜗植入患者，术前根据患者特点与患者及家属充分讲解沟通，使患者及家属对手术及术后效果有正确期望值同样重要和关键。

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ORIGINAL ARTICLE

Analysis of the performance of post-lingually deafened patients with Nurotron® Venus™ cochlear implants

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Abstract

Objective: The aim of this study was to analyze the safety and effectiveness of a new cochlear implant (CI) system developed in China, the Nurotron Venus device. **Material and methods:** Fifteen post-lingually deafened patients received Nurotron Venus CIs in our hospital. The safety and effectiveness of the devices were evaluated within 2 years after implantation. Patients' hearing thresholds were assessed. In addition, the speech perception performance of Nurotron Venus CI recipients was compared with that of 15 Cochlear Nucleus CI24 recipients. **Results and conclusion:** During 2 years of observation, all the Nurotron recipients used their devices regularly and effectively. The aided hearing thresholds of all the recipients were within the speech spectrum. The average scores of HOPE sentences and HOPE monosyllable words tests among Nurotron CI recipients were $82.88 \pm 21.40\%$ and $56.67 \pm 9.77\%$, respectively. The average scores among Cochlear Nucleus CI24 recipients were $87.33 \pm 14.44\%$ and $52.8 \pm 12.76\%$, respectively. There was no statistically significant difference in the speech test scores between these two groups when assessed using the t test. The Nurotron Venus cochlear implant system worked safely and effectively. The speech perception of Nurotron recipients was similar to that of the other CI system recipients.

Keywords: Safety, effectiveness, auditory performance, speech perception

Introduction

Multi-channel cochlear implants (CIs) are high-tech electronic products that can help severe to profoundly deafened patients restore or gain their hearing perception. During the last 40 years of clinical application and development, more than 380 000 deaf patients in the world have received CIs. According to the ear and hearing disorder survey protocol of WHO, Xingquan Pu, et al. [1] conducted a relevant survey in China in 2005. The results showed that there were about 48 million hearing-impaired Chinese people, and the number of deaf newborns in China is about 20 000–30 000 per year. The technology of cochlear implantation was introduced to China about 20 years ago, and more than 20 000 Chinese people have benefited from it. For those

who suffer from severe to profound sensorineural hearing loss, cochlear implantation is an effective approach for hearing rehabilitation. However, most of the CI products used in China are imported, and they are too expensive for most Chinese people to afford. The Nurotron Venus CI system, originally developed in the University of California Irvine and House Research Institute by Dr Fangang Zeng et al. [2–4], was introduced to China by Hangzhou Nurotron Biotechnology Co. Ltd in 2006. The research and development center of Nurotron is located in California, and the CI devices are manufactured in China. The Nurotron Venus CI system (Figure 1) produced in China is a relatively new device that has 24 intracochlear electrodes and two extracochlear electrodes, high stimulation rates (40 kHz), high data transmission rates (1 MB/s), multiple stimulation

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Figure 1. Nurotron Venus CI system.

modes, and four independent current sources. The major parameters of the CS-10A implant and the NSP-60B speech processor, which indicate the characteristics of Nurotron Venus CI system, are shown in Tables I and II. After several years of careful and successful verification both in the laboratory and in animals, this device was finally approved by the State Food and Drug Administration for application in post-lingually deafened volunteers. According to the clinical trial protocol, a total of 60 subjects all over China participated in this clinical trial from December 2009. They were all native Mandarin speakers and post-lingually deafened, and their ages were not younger than 6 years old.

As part of the clinical trial for this new device, 15 hearing-impaired patients received Nurotron Venus CIs in the Department of Otolaryngology-Head and Neck Surgery of our hospital. The safety and effectiveness of the device were evaluated in this

Table I. Parameters of the Nurotron CS-10A implant.

Implant characteristics	Parameters
Material	Platinum, titanium, silicon
Electrodes	24 intracochlear electrodes and 2 extracochlear electrodes
Length of electrode array	20.5 mm
Interval of electrodes	0.85 mm
Volume of titanium housing	12.8 ml (56.4 × 33.0 × 6.0)
Bone-excavation volume	0.44 ml
Number of channels	24
Number of current sources	4
Wireless transmission frequency	16 MHz
Data transmission rate	1 MB/s
Total stimulation rate	40 kHz
Maximum current output	1.7 mA
Virtual channel capability	Yes
Telemetry capability	Yes

Table II. Parameters of the Nurotron NSP-60B speech processor.

Speech processor characteristics	Parameters
Wearing styles	Body-worn and ear-level
Audio input dynamic range	75 dB
Speech processing strategies	APS, CIS, VC (virtual channel)
Display mode of the volume and programs	LED lights
Water splash-proof	IP44
Battery	Rechargeable battery for both body-worn and ear-level, or two disposable AAA batteries for body-worn and three disposable zinc-air power batteries for ear-level

study. In addition, the speech perception of Nurotron Venus CI recipients was compared with that of Cochlear Nucleus CI24 recipients.

Materials and methods

Subjects

In the Nurotron group of the clinical trial, 15 post-lingually deafened patients, including 10 males and 5 females, received Nurotron Venus CI systems (including the CS-10A implant and the NSP-60B speech processor) in our hospital from March to April 2010 (Table III). Their average age was 25.4 ± 8.97 years, within the range 12–43 years. The duration of severe to profound hearing loss in these subjects was 7.27 ± 4.43 years on average. Their average preoperative hearing thresholds at four frequencies (0.5, 1, 2, 4 kHz) were 117.67 ± 6.23 dB HL, 117.33 ± 5.63 dB HL, 118.00 ± 3.68 dB HL, and 119.00 ± 3.87 dB HL, respectively. Among them, one subject had large vestibular aqueduct syndrome (LVAS), and the others had normal inner ear structure under imaging examination. In the Cochlear group, 15 post-lingually deafened patients, including 9 males and 6 females, underwent Cochlear Nucleus CI24 implantation in our hospital from March to December 2009 (Table IV). Their ages ranged from 18 to 56 years, with an average of 28.93 ± 13.07 years. The duration of severe to profound hearing loss was 7.47 ± 4.52 years on average. Among them, four subjects had LVAS, and the others had normal inner ear structure under imaging examination.

Methods

Observation of safety and stability of Nurotron Venus CI system. (1) For all the subjects, the location of the electrode array was investigated using cochlear view

Table III. Basic information for 15 Nurotron Venus CI recipients.

Recipient no.	Gender	Age at implantation (years)	Date of surgery	Duration of severe deafness (years)
1	Female	27	03.01.2010	7
2	Female	12	03.01.2010	9
3	Male	14	03.10.2010	3
4	Male	21	03.10.2010	7
5	Female	22	03.10.2010	3
6	Male	16	03.11.2010	10
7	Male	36	03.12.2010	15
8	Male	34	03.16.2010	2
9	Male	43	03.16.2010	3
10	Male	31	03.19.2010	1
11	Male	31	03.19.2010	11
12	Female	24	03.23.2010	13
13	Male	21	03.24.2010	9
14	Male	32	03.30.2010	4
15	Female	17	04.01.2010	12

X-ray examination after surgery. (2) To check the functions of their major organs, all the Nurotron recipients underwent blood tests and electrocardiograms at the approximate time points of 6 months, 1 year, and 2 years after surgery, which was required by the regulation of the State Food and Drug Administration. (3) All the Nurotron recipients were observed to see if there were any complications and side effects related to CIs or CI implantations.

(4) The average duration that the Nurotron recipients used their CI devices each day was recorded.

Effectiveness of the Nurotron Venus CI system. (1) Aided hearing threshold test. The test was conducted in free field by using GSI 61 audiometer in a standard sound-proof booth. The aided thresholds at 0.5, 1, 2, and 4 kHz were assessed by using warble tones, and the

Table IV. Basic information for 15 Cochlear Nucleus CI24 recipients.

Recipient no.	Gender	Age at implantation (years)	Date of surgery	Duration of severe deafness (years)
1	Male	42	08.08.2009	15
2	Female	24	05.18.2009	10
3	Male	35	08.25.2009	3
4	Male	56	09.10.2009	2
5	Female	20	08.06.2009	10
6	Male	18	05.12.2009	1
7	Female	21	12.21.2009	8
8	Male	27	05.13.2009	8
9	Female	18	07.10.2009	3
10	Female	27	05.23.2009	13
11	Female	24	12.04.2009	4
12	Male	22	08.08.2009	7
13	Male	20	07.24.2009	4
14	Male	41	10.28.2009	10
15	Male	19	12.09.2009	14

settings of their speech processors were the same as those used daily.

(2) Open-set speech perception test. In this study 12 Nurotron Venus CI users performed the tests of sentences and monosyllable words 2 years after surgery. The results were compared with the scores achieved by Cochlear Nucleus CI24 users. Specifically, the speech processing strategy used by all the Nurotron recipients in this study was APS, i.e. advanced peak selection, a peak extraction strategy that select the largest outputs of filter bank. All the Cochlear recipients used ACE strategy in this study. The Mandarin speech test material, HOPE, was developed by the Auditory Implantation Center of the Department of Otolaryngology & Head and Neck Surgery of PLA General Hospital [5,6]. Each list of HOPE monosyllable words contains 25 monosyllable words and each list of HOPE sentence tests contains 10 sentences and 50 key words. All the tests were conducted by an open-set approach. The *t* test with SPSS software was used to analyze the results.

Satisfaction surveys. Satisfaction surveys on sound perception, communication skills, and the quality of life were conducted 2 years after implantation among Nurotron CI recipients.

Results

Safety of Nurotron Venus CI system

The post-surgery radiological results (Figure 2) showed that the electrode arrays in 15 Nurotron Venus CI recipients were all inserted inside the cochlea. No electrode migration, prolapse or displacement was observed. The results of the blood tests and electrocardiograms were in the normal range. No infection or rejection of the implants was reported. No complication related to the Nurotron Venus CI system occurred. Three of 15 recipients dropped out of the clinical trial program for personal reasons. The CI system worked well for all the remaining 12 implantees, and they used their devices during all their waking hours.

Aided hearing thresholds

The mean aided hearing thresholds of the 12 recipients ranged from 25 to 50 dB HL. The average thresholds at four frequencies (at 0.5, 1, 2 and 4 kHz) were 42.50 ± 3.37 dB HL, 40.00 ± 3.69 dB HL, 42.50 ± 3.99 dB HL, and 43.33 ± 4.92 dB HL, respectively. They were all within the range of speech spectrum.



Figure 2. X-ray result after cochlear implantation (Zhang, female, left ear).

Results of open-set speech perception tests (Figure 3)

Two years after CI surgery, the average scores for HOPE sentence tests and monosyllable words tests among 12 Nurotron recipients were $82.88 \pm 21.40\%$ and $56.67 \pm 9.77\%$, respectively.

The average scores for HOPE sentence tests and monosyllable words tests among 15 Cochlear recipients were 87.33 ± 14.44 and $52.8 \pm 12.76\%$,

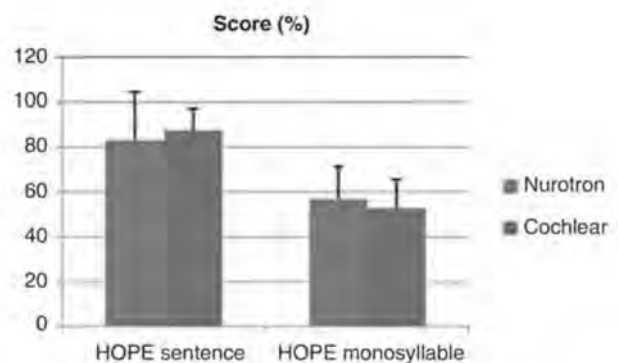


Figure 3. Speech perception scores of Nurotron Venus CI users and Cochlear Nucleus CI24 users. No statistically significant difference could be found between the two groups ($p > 0.05$).

respectively. The scores of the above tests from the two groups were in accordance with normal distribution. There were no statistically significant differences ($p > 0.05$, t test) in the scores for the speech tests between the two groups.

Satisfaction surveys

Of the 12 recipients who participated in the 2-year assessment, 10 recipients (83.34%) were satisfied with their outcomes, and the other two felt 'normal' with their outcomes. Their relationships with their families and friends were improved. Nine of them found new jobs or had better performance in their daily work since they could benefit from CIs. Two of them had significant improvement in their studies. Three of them were married to normal-hearing men, as they could communicate with their husbands with CIs. They felt much safer than before and it was more convenient for them to go shopping or go on a trip. Eight recipients could even use the telephone to simply communicate with others.

Cases lost during follow-up

During the 2-year follow-up of Nurotron Venus CI users, we lost contact with one recipient and two dropped out. Their circumstances were as follows. (1) Wu, male, 36 years old, received a CI on March 12, 2010. We failed to make contact with him 1 year after CI surgery. (2) Zang, male, 20 years old, received a CI on March 10, 2010. He declined to participate in clinical assessment from August 5, 2010 for family reasons. (3) Tong, male, 14 years old, received a CI on March 10, 2010. He did not participate in the 2-year assessment for personal reasons.

Discussion

After several decades of development, CI technology has been maturing. In fact, the outcomes of CIs were well documented in the last century [7-9]. Undoubtedly, the demand for CIs in China is extensive. However, the prices of imported CI devices are not affordable, and the choices left to those people suffering from severe hearing loss are relatively limited. Similar to other products, the Nurotron Venus CI system consists of two parts, the implant and the speech processor, which are programmed using NuroSound software. The parameters and the functions of this product seem to be comparable to others. If the long-term safety and outcomes could be tested and verified, the emergence of this product may have

some significance for the local deaf patients and even for the whole CI industry.

The objective of this study was to analyze the safety and effectiveness of the Nurotron Venus CI system. For the sake of collecting information precisely and efficiently, post-lingually deafened adults are ideal subjects. They experienced aural and verbal communications before they were profoundly deafened. Therefore, they could benefit from CIs soon after the surgery and could communicate with clinicians more easily [10]. In addition, the duration of severe to profound deafness is an important factor as regards the outcome of cochlear implantation [11,12]. The duration of severe to profound deafness of all the patients in this study was less than 15 years.

During the 2 years of follow-up of Nurotron Venus CI system users, no complications related to the device were observed and all the CI systems worked well. The aided hearing thresholds were within the speech spectrum, indicating that the recipients were able to detect most of the speech sounds in daily life. There was no statistically significant difference in the speech perception scores between Nurotron CI users and Cochlear CI users.

Basically, the Nurotron CI recipients were satisfied with the outcomes of CI surgery. The improvements in hearing detection and speech perception are of great significance, and the most important goal of cochlear implantation is to help those deaf people return to the normal hearing world. According to surveys among Nurotron CI implantees, their quality of life improved significantly, including their daily life, study, and careers. In the present study, we found that post-lingually deaf CI users usually have high expectations for the outcomes, since they used to hear natural sounds before their deafness. Therefore, we should help post-lingually deafened people to understand the benefits and limitations of CIs and establish appropriate expectations for the outcomes.

Conclusions

During the 2-year observation period, the Nurotron Venus CI system produced in China worked safely and effectively. After implantation, all the recipients had better auditory performance and their quality of life was significantly improved. They all enjoyed the pleasant communication and the convenience obtained from their CI devices. According to the test results, the speech perception of Nurotron recipients was similar to that of the other system CI recipients. However, further long-term observations are needed.

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国产人工耳蜗植入技术临床使用的评价

张道行

【关键词】 耳蜗植入术 (Cochlear Implantation); 电极, 植入 (Electrodes, Implanted); 结果评价 (卫生保健) [Outcome Assessment (Health Care)]

1 国产人工耳蜗技术发展背景

人工耳蜗植入 (cochlear implantation, CI) 是现代高科技在医学领域应用最成功的典范, 经过近30年的实践和完善, 已经达到了几乎完美的程度。其使完全失聪者重新建立了接近生理状态的听觉功能。大部分CI患者已经重新建立了人工耳蜗的听觉, 进入了听觉语言的主流社会^[1]。

曾经CI产品均来自国外, 以AB公司的高分辨生物耳植入体HiRes 90K, 科利耳公司配备薄型自弯电极CI24RE (CA) 的Nucleus Freedom植入体, Med-EL公司的PulsarCI100植入体和SonataTI100植入体等为代表。3种产品在我国的临床中应用的最大问题是价格昂贵, 均在100 000~200 000元, 使得大多数听力障碍患者由于经济问题而无法接受治疗。即便几年后积攒足够的费用, 患儿却已经错过了最佳治疗时间。

近十几年来国产人工耳蜗技术逐步发展。诺尔康24道人工耳蜗由杭州诺尔康神经电子科技有限公司自主开发和研制。其外形及技术参数与美国AB公司的高分辨HiRes 90K产品相近, 但植入体磨骨槽部分更加小型化。临床试验成人组60例, 年龄6~65岁。2009年12月~2012年6月进行临床评估; 临床试验儿童组60例, 年龄12~71月龄, 2011年4月~2012年7月进行临床观察。通过对这120例植入手术、开机、调试及随访观察, 未发现与植入体及植入手术相关的任何并发症和严重不良反应。连续观察成人组2年, 患者均通过反映听觉敏感度的助听阈测试, 语频区听阈平均在10~45 dB, 接近正常听力水平; 通过反映听功能的开放式及闭合式言语测试, 得分逐年提高。连续观察儿童组1年, 所有植入者都通过了助听阈、IT-MAIS和/或中国聋儿康复研究中心编制的言语评估。经过解放军总医院、首都医科大学附属北京同仁医院、中国科学院等第三方机构的对比研究发现, 诺尔康CI效果与其他进口产品的效果相近, 且所有植入者的效果均随着时间的推移而不断进步。产品通过国家药品食品监督管理局的审查鉴定, 于2013

年6月开始享受国外三家产品同等年龄要求, 在各年龄组的听力障碍患者中使用。到目前该产品已经在临床上完成了700余例CI, 获得比较满意的听力和言语识别效果, 但仍需经过一长期的观察来评价效果的高峰值。下一代的产品也正在研制中。

上海力声特人工耳蜗经过几年临床实验达到预期效果, 获得国家药品食品监督管理局批准, 从2011年2月始临床应用于18岁以上的听力障碍患者, 到目前完成了约200例CI。其下一代产品的研制已经基本成型, 一些重要参数指标基本与国外品牌相近。

沈阳IES公司研发的蜗内中央电极刺激式人工耳蜗正在进行临床观察和申请国家药品食品监督管理局的临床应用许可。

2 对国产人工耳蜗技术目前临床使用的评价

目前在临床上使用的两种国产人工耳蜗诺尔康24道人工耳蜗和力声特22道人工耳蜗共同特点是价格便宜, 约70 000~90 000元人民币, 相对进口产品在价格上有明显优势, 一些经济条件差的患者家庭可勉强承受。

笔者在临床上开展并行CI已有15年, 患者超过3000例。曾经全部使用国外三大人工耳蜗公司产品。近1、2年开始在临床上使用国产人工耳蜗产品, 到目前超过百例。尤其是2013年6月开始, 诺尔康24道人工耳蜗可以应用于1岁患儿, 国产人工耳蜗的手术数量与进口产品比较, 已经近平分秋色的状态。

如何评价国产人工耳蜗在临床上使用的效果? 笔者认为主要应从产品的3个方面考虑, 即有效性、安全性、稳定性。这是医学人体植入产品临床使用前国家进行医学把关、是否准入的最重要考核指标。人工耳蜗产品的有效性和安全性, 因为有严格的准入、把关, 在临床上使用中不容易出现问题。若有效性出现问题, 大多不在产品, 而是临床医师的病例选择问题, 即患者自身存在问题或医师手术问题, 如耳蜗神经缺如、严重听神经病、耳蜗严重畸形、手术不到位、术中耳蜗的损伤

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等问题。在安全性方面亦然,人工耳蜗产品对人体的排斥现象是非常少见的,这一问题也是在产品临床使用准入以前,需要进行反复的实验和观察的重要指标,因此,主要原因是患者存在的各种问题及医师在适应证选择上的经验不足或疏漏。如一些全身性疾病不能耐受CI等;因手术医师经验不足和/或技术水平不高而使手术失败或周围损伤,甚至导致患者生命危险或功能障碍等。产品稳定性是考验产品信誉和推广前景的重要因素。由于产品稳定性是按终生设计的,需要在长期使用过程中进行总结性评价。新产品被批准临床使用之前的审批,在时间上是有局限性的,因此国外三大人工耳蜗产品在临床使用中都有召回的经历,在长期的临床使用中发现问题是不可避免的,重要的是发现了问题有及时纠正的机制。目前两家国产人工耳蜗产品,在临床使用中尚未发现“有效性、安全性、稳定性”问题的发生,也未发生召回事件,但仍然需要进行严格的临床随访,一旦发生问题,应该及时主动启动召回的程序,避免不良后果的扩大。所有的人工耳蜗产品,应经得起时间的考验,无论在产品的召回问题上或产品技术跟踪和服务及产品的升级换代上,都是一长期的过程。

除了要对人工耳蜗在临床使用上的“有效性、安全性、稳定性”的考虑外,还应该进行几个方面的考虑:①设计的小型化程度;②生产工艺的精度;③产品的抗不利环境的能力,如对热、磁、电、水、辐射、外力的抵御能力等,尤其是手术医师在电极植入时电极的依从性和抗暴力的能力及对体内组织的损伤的大小等。

另外,人工耳蜗产品的几个辅助功能,如使用的安全性和有效性的几个重要检测手段也不可或缺。如检测产品植入后的工作状态的稳定性目前是通过“阻抗”检测;CI患者术后对人工耳蜗反应效果的存在是通过3个方面的综合评估:蜗神经的神经反应遥测、听神经传导状态检测电诱发听性脑干反应(electrically auditory brainstem responses, EABR)、主观电听行为反应。前者是检测人工耳蜗在人体的工作状态是否正常,后三者是评价患者对人工耳蜗电信号接受的状态,对人工耳蜗电刺激强度的适应范围,这些检测的结果的好与否,完全

是患者的自身残留听觉条件相关的,和耳蜗产品无关。

如何评价人工耳蜗对听力障碍患者听觉开发的效果?对人工耳蜗本身技术水平高低的评价,只能在得分最高或使用效果最好的患者之间进行评价,即尽量排除残留听觉功能不好的患者,才能比较真实的反应CI效果。除外患者自身条件因素,CI效果越接近生理性听觉效果,人工耳蜗的技术水平越高。目前临床上使用的国产人工耳蜗对正常言语交流是可以胜任的。人工耳蜗对音乐韵律及感情欣赏要求很高,目前的人工耳蜗技术是否能将乐曲的感情信息输入患者耳中达到正常的生理状态、国产人工耳蜗与进口人工耳蜗是否存在信息量输入上的差异等问题目前尚未进行过研究和比较。在人工耳蜗技术参数中,电子编程方法、刺激速率、电极或通道数量是否能成为评价人工耳蜗产品效果的指标是今后要明确的问题。笔者认为提取最大共振峰的编程方法,由于丢失的声音信息量较多,患者对听觉效果并不满意,新一代人工耳蜗已不将此作为主要编程方法。人工耳蜗的刺激速率并不是越快越好,最佳速度目前尚无定论。人工耳蜗电极通道数也未必越多越好,国产人工耳蜗可不必将此作为追求的方向。为强化对生理的语言频率区作用的发挥,目前大部分人工耳蜗的刺激频率设定在100~8000 Hz,按生理性基底膜的共振频率特性,人工耳蜗电极长度以25 mm最佳,如果手术医师将最末端电极再向耳蜗内多推入5 mm,具有8000 Hz刺激效果的末端电极正好落在耳蜗基底膜生理性8000 Hz的频率特性上,末端电极正好落在100 Hz频率的基底膜位置。

对耳蜗发育正常患者行CI,方向性电极较环形电极更具有优势性。其一是方向性电极可减少无效刺激,其二是对耳蜗鼓阶内部的术中损伤小。诺尔康和力声特新一代产品均为方向性电极。

人工耳蜗在发挥相同对耳蜗电刺激效果的条件下,电池的耗电率是评价人工耳蜗技术水平的重要指标,耗电量映每一工作环节发挥了最大的工作效率。电极设计、刺激方案和刺激速率的选择与适应程度等,应该是今后国产人工耳蜗需要努力提高的重点。■

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诺尔康人工耳蜗儿童组康复效果

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[关键词] 耳蜗植入物 (Cochlear Implant) ; 临床试验 (Clinical Trials) ; 治疗结果 (Treatment Outcome)

杭州诺尔康神经电子科技有限公司研制的晨星人工耳蜗系统由体内部分植入体CS-10A和体外部分处理器NSP-60B组成; 诺尔康晨星人工耳蜗系统自2009年12月起开始成人组(6~65岁)临床验证试验, 证实了该系统在成人组的安全性和可靠性。中国国家食品药品监督管理局于2011年8月向诺尔康公司颁发了进入市场许可证。2011年3月晨星系统人工耳蜗儿童组(12~71个月龄)进行临床验证, 按照试验设计, 植入9个月为临床试验终点, 通过医学观察和听力及言语评估, 证实晨星人工耳蜗系统在儿童组同样有效。

1 诺尔康儿童临床试验研究者及分工

2011年1月经专家会讨论最终确立诺尔康人工耳蜗系统小儿临床验证方案, 并开始进行病例筛查工作。以首都医科大学附属北京同仁医院为首席研究单位, 中国人民解放军总医院、复旦大学眼耳鼻喉科医院共同执行植入手术, 由中国聋儿康复研究中心对在北京接受手术的诺尔康晨星人工耳蜗系统有效性进行评估, 2011年6月中国聋儿康复研究中心委托上海市聋儿康复中心对复旦大学附属眼耳鼻喉科医院的诺尔康儿童植入者进行评估

2 术前评估项目

诺尔康人工耳蜗儿童临床试验术前验证项目包括: ①客观听力学检查, 多频稳态诱发电位(或听性脑干诱发电位)、声导抗及耳声发射(OAE); ②主观听力检查, 小儿行为测听、助听测听及聆氏六音测试; ③家长问卷表, IT-MAIS表; ④医学及医学影像学评估, 耳科学检查、内耳CT和MRI; ⑤心理智力评估, 希-内/格雷费斯、CONNER多动症评价量表、RUTTER儿童行为问卷评估及

克式孤独症行为量表。

3 术前一般情况

通过医学、听力学、康复学和心理学筛查咨询最终确定了60例候选人接受了手术, 其中男29例、女31例。术时年龄最小12月龄, 最大71月龄(平均40.48月龄), 3岁上下各有30例; 植入右耳34耳、左耳26耳、双耳0; 耳聋原因包括药物性聋、大前庭导水管综合征、遗传性聋及不明原因聋等。

4 术后开机及随访周期及测试手段

植入术后(3±1)周开机; 随访时间为开机当天、开机后1个月±1周、开机后3个月±1周、开机后第6个月±2周、开机后9个月±2周(临床试验终点); 开机后12个月±2周继续随访。随访内容为≥36月龄(30例)行听觉能力评估、IT-MAIS、声场测听、聆氏六音、希-内及言语能力评估, <36月龄(30例)行IT-MAIS、声场测听、聆氏六音及格雷费斯测试。评估有效的指标为, ≥36月龄组: ①听觉识别率≥Δ20%, ②IT-MAIS>24分, ③声场测听平均值<60 dB HL; <36月龄组: ①IT-MAIS>24分, ②声场测听平均值<60 dB HL。

5 术后康复

60例小儿植入者均接受了系统的听觉语言康复训练, 康复地点分别在位于北京、浙江、上海、安徽、山东、河北等地的共计20余所康复学校。

6 开机9个月评估效果分析

按照临床方案规定, 开机9个月为临床评估终点, 通

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过开机9个月的评估,观察到所有植入者通过使用诺尔康晨星-人工耳蜗系统,听觉、语言能力得到显著提高。

6.1 助听听阈。60例植入者术前听阈右耳平均为 (110.98 ± 9.77) dB HL,左耳平均为 (111.13 ± 8.30) dB HL,开机9个月的助听听阈平均为 (39.04 ± 6.05) dB HL。结果提示植入者开机后听力得到显著提升,能够满足日常听声需求。

6.2 聆氏六音。60例植入者聆氏六音识别率从术前的 9.63 ± 24.84 提升至开机9个月的 95.00 ± 16.61 ,提示植入者在使用诺尔康人工耳蜗后能够较好地感知各频率段的声音,并达到了声音的良好辨识。

6.3 言语能力评估。60例植入者开机9个月的评估结果显示,植入者语法能力言语年龄平均为 2.15 ± 1.42 ,交往能力言语年龄平均为 1.82 ± 1.39 ,理解能力言语年龄平均为 2.38 ± 1.65 ,而术前以上各项检查的识别率均 < 1 。这表明植入者经使用诺尔康人工耳蜗及经过术后康复后,言语能力得到了显著提升,语法、交往、理解等都得到了发展,这将有利于将来语言的进一步发育。

6.4 学习能力。60例植入者希内测试的术前平均得分为 96.21 ± 9.53 ,开机9个月时平均为 102.77 ± 17.91 ;格雷费斯测试的术前平均得分 103.14 ± 8.59 ,开机后9个月时平均为 99.55 ± 11.12 。由此可以看出学习能力得分出现不稳定的现象,这可能与患儿当时的配合程度有关。

6.5 IT-MAIS问卷。通过对60例患儿家长的问卷了解12~71月龄患儿的听声情况,随着时间的推移,问卷平均得分呈上升趋势,表明小儿的听声效果逐步提升(图1)。

6.6 听觉能力评估。材料由中国聋儿康复研究中心编制,测试项目包括声母、韵母、单音节词、双音节词识别测试。 ≥ 36 月龄的植入者术后结果比术前结果显著提高,且开机3~12个月评估结果呈逐步上升趋势(图2)。

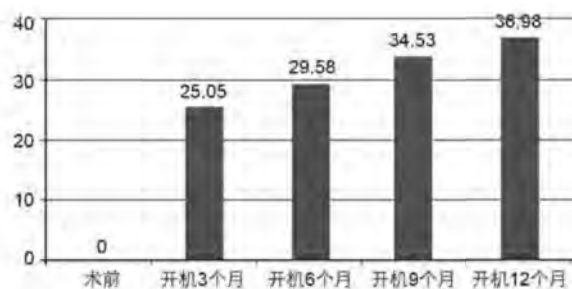


图1 60例小儿植入者 IT-MAIS家长问卷

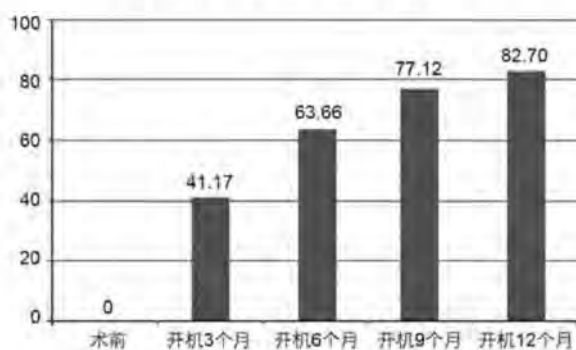


图2 ≥ 36 月龄组共计30例听觉能力评估测试得分

7 总结

60例12~71月龄双耳重度或极重度感音神经性聋患儿行诺尔康人工耳蜗植入,在安全可靠方面得到了验证,植入体纤薄,适合儿童植入。在恢复听觉、提高言语和声音感知和识别等有效性方面效果良好。植入耳蜗后听力得到显著提升,能够较好地感知各频率段的声音,能够满足日常听声需求。术后言语能力得到了显著提升,语法、交往、理解等都得到了发展。听觉及言语能力随着时间的推移逐步改善,这将有利于将来语言的进一步发育。因此认为诺尔康人工耳蜗同样适宜于听障儿童使用。考虑到儿童的听觉言语能力建立发展的规律,本研究人工耳蜗植入后随访时间尚短,产品性能还有待进一步做远期观察随访。■

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编辑 胡丹



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中国自有品牌人工耳蜗的研发和应用

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[关键词] 耳蜗植入物 (Cochlear Implant); 植入手术 (Implantation Surgery); 临床应用 (Clinical application); 使用效果 (outcomes)

1 引言

近20年, 中国人不断探索研发生产高价值低价格的自主品牌人工耳蜗产品, 以确保广大的中国聋人不但可以买得起, 也可以承受得起长期使用费用, 目前中国制造人工耳蜗品牌中技术和制造最成熟、临床适应证范围最广及市场占有率和被市场接受程度最高的, 当属杭州诺尔康神经电子科技有限公司生产的晨星人工耳蜗系统。

2 诺尔康人工耳蜗研发

诺尔康人工耳蜗系统包括体内装置, 体外言语处理器以及用于测量和调节植入者设备参数的调试系统 (图1)。系统总结国际上主要耳蜗产品的优缺点, 提出了一套完整的独立的系统解决方案, 包括言语编码策略、言语处理器和射频编码、植入体芯片、电极设计以及调试系统的设计。

2.1 言语处理策略。虽然几家公司之间具体的处理采用的方式互有差异, 如多通道连续间隔采样编码策略 (简称 CIS)^[1], ACE, HiRes Fidelity 120等, 但是究其本源都是提取声音信号中不同通道下的时域包络信息编码, 舍弃了单个通道中的信号的细节相位关系。诺尔康人工耳蜗系统中支持

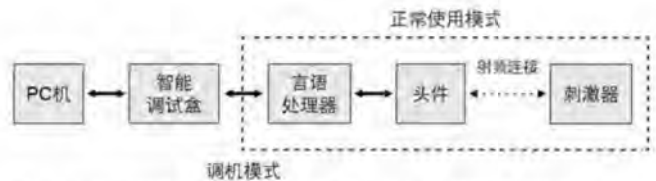


图1 系统模式图。为系统在不同模式下的工作状态, 虚线外是调试系统时的模式, 图中虚线内为正常使用模式下的工作状态

3种言语处理策略: 连续间隔采样处理策略 (CIS)、峰值提取处理策略 (APS) 和美音策略 (Symphony)。美音策略是一种峰值选取虚拟通道策略, 最多可达120个虚拟通道, 峰值数目可选, 最大可达24, 这个策略提供较高的频率分辨率, 表达更多声音的细节, 提高用户的音乐欣赏和声调语言识别^[2]。在实现方面, 算法利用了专用语音芯片中的FFT硬件引擎, 在瞬间完成128通道上的能量提取, 通道合并和声电压压缩的转换 (图2), 从而提供较高的时域包络的分辨率。诺尔康公司与美国HOUSE研究所合作开发加强音调语言识别的编码策略ETONE, 初步研究表明, 该编码策略对于汉语四声的辨识有帮助, 公司预计在短期内推出使用。

2.3 言语处理器的主要功能。主要有声音获取和策略编码、射频信号编码、发射和接收、用户接口控制几部分。言



图2 基于FFT滤波器组的实时处理方式

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语处理器设计的一大难点就是体积、功耗和功能的兼顾。诺尔康的体外机选择专用超低功耗的语音芯片和ASIC芯片相结合的方式，保证了体外机低功耗的同时，增加系统的灵活性，同时为将来的技术升级预留了充分的空间。这样的方式从产品设计的成本角度考虑也是比较低的。诺尔康系统采用可以支持4电流源设计的高灵活度数据编码方案和基于幅度调制的位编码方案进行射频通讯。每一个电流源的信息可以被模块化，支持多种的刺激模式，刺激策略，随意的相位极性，随意的刺激波形，和不同相位宽度和相位间歇（图3）。

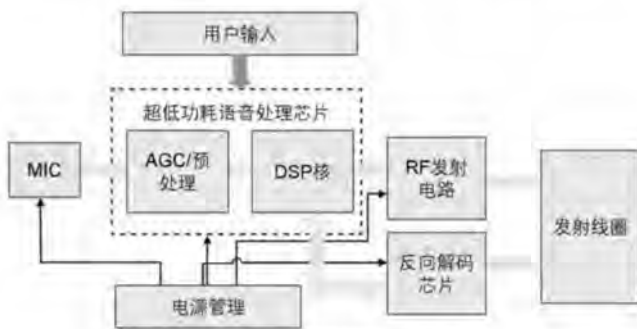


图3 体外机功能结构框图

2.3 植入体芯片方面。诺尔康采用自行设计研发的专用解码刺激芯片。主要功能包括接收体外言语处理器发射的无线电波，从中提取所需的能量、数据；根据所接收到的数据产生相应的刺激脉冲，刺激患者的残存听神经恢复听觉；向体外言语处理器传输体内电路的静态参数。为了达到抗干扰，低噪声，安全可靠要求，内芯片还包括防过量刺激和防静电等众多保护电路（图4）。

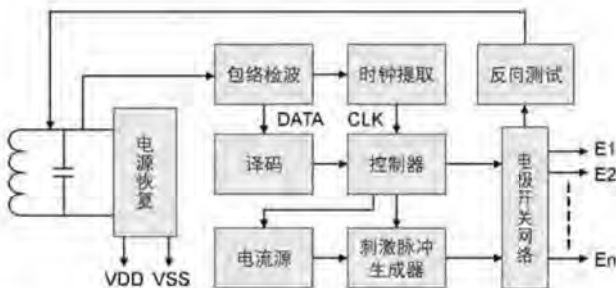


图4 刺激解码器功能结构框图

2.4 电极。诺尔康刺激器CS-10A电极阵列总长102.4 mm，蜗内电极阵列长度为20.5 mm，电极的触点的暴露表面积为0.2 mm²。蜗内刺激电极的刺激触体和电导线都采用铂铱合金材料，所有的铂电极都采用硅胶固化的模塑载体来支撑电极触体等。刺激电极的形状是呈马鞍形的，使得电极系列进入耳蜗时电极朝向蜗轴。在电极阵列末端有一些凹

点，用于指示电极的朝向，在植入手术时可以以此确认电极的朝向是否正确（图5）。



图5 诺尔康人工耳蜗电极

2.5 诺尔康调试系统包括调试软件和调试盒。调试软件在电脑上运行，调试盒负责电脑和言语处理器之间的通讯。听力师操作该软件，根据植入者的主观反应为其言语处理器设置最佳工作参数，达到最佳聆听效果。软件主要包括2部分的功能，即植入者资料的录入与查询以及言语处理器工作参数调整及编程。该调试系统主要特点是：方便易用的双模式运行状态（正常模式和训练模式），基于SQL数据服务器的多功能患者资料管理，自动电极阻抗测量以及电极状态显示，处理器程序管理，快速智能程序参数设置等。

3 诺尔康人工耳蜗手术开展情况

迄今为止，中国大陆共有67家医院，66名医师开展和实施了诺尔康人工耳蜗植入手术。手术总例数已经接近700例，植入者中年龄最小是12月龄（儿童临床试验者），最大为76岁，所有手术均顺利进行，部分医师采用了柔手术、蜗窗入路等手术技巧。

多位手术医师对诺尔康人工耳蜗的植入体会是：①植人体积较小，磨骨体积小，电极直径小于1 cm，软硬适中，适宜微创手术；②植人体较薄，内侧面稍具弧度的设计，可以更加贴合颅骨的曲度，植入部位隆起不明显，美观；③软性电极，对蜗内结构的创伤轻，可以通过圆窗入路插入耳蜗，可以保存残存听力；④电极单向弯曲、电极基部凹点设计，可保证电极触点面向蜗轴；⑤电极尾部两个环形标记，保证电极插入深度（一圈至一圈半）；⑥可以用于畸形和骨化耳蜗植入。不足之处是电缆柔韧性稍欠佳，在乳突腔弯曲时较僵硬。

4 诺尔康人工耳蜗使用效果观察

诺尔康人工耳蜗成人临床试验（定义为6~65岁年龄组）从2009年12月开始，到2012年6月为止已经完成了2年评估；儿童临床试验（定义为12至71月龄组）从2011年4月开始，到2012年7月为止已经完成了1年评估；所有植入者均通过了制定的各项评估测试。全国范围内招募了120名试验志愿者，其中成人临床组60名，年龄分布在6~59周岁；儿童临床组60名，年龄分布在12~71月龄，致聋原因多样，以

药物性和先天性聋居多,其中成人临床组,耳聋进程均为语后聋,所有植入者均经过了术前评估、植入手术、术后开机调试、评估过程,部分植入者接受了康复训练等过程。通过对这120例植入手术和开机、调试及随访观察,未发现与植入体及植入手术相关的任何并发症和严重不良反应。连续观察成人临床组2年,参与者均通过了反映听觉敏感度的助听阈测试,助听阈值均位于香蕉图内;通过了反映听功能的开放式及封闭式言语测试,得分逐年提高(图6)。连续观察儿童临床组1年,所有植入者都通过了助听阈、IT-MAIS和/或中聋编制的言语评估(图7,图8);经过中国人民解放



图6 诺尔康成人临床试验言语测试得分趋势图,测试材料为House Ear Institute编制的言语测试评估系统speech perception test (both open and close set) result with House Ear Institute Speech Perception Test System

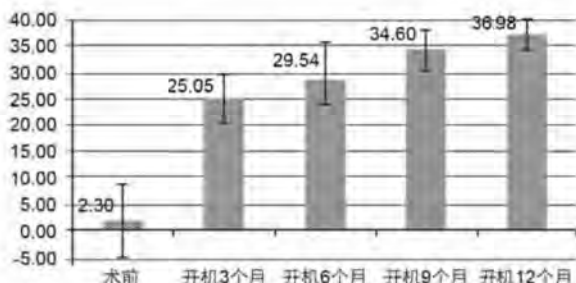


图7 诺尔康儿童临床试验60例植入者IT-MAIS平均分趋势图

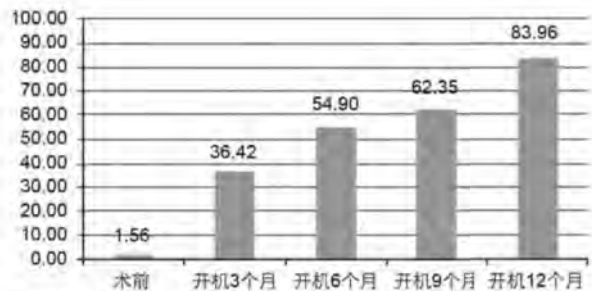


图8 诺尔康儿童临床试验36月龄以上组言语测试平均分趋势图,言语测试材料为中聋编制,包含声母、韵母、单音节、双音节共4项测试

军总医院、首都医科大学附属北京同仁医院、中科院等第三方机构的对比研究发现,诺尔康人工耳蜗植入效果与其他进口产品的效果相当,且所有植入者的效果均随着时间的推移而不断进步。两组临床试验的结论均为,听障者可以通过使用诺尔康人工耳蜗获得了听觉、语言康复的预期目标,且设备使用安全可靠。

研究发现植入者生活质量获得显著改善,其自我主观评价明显由于言语识别能力评价^[3];植入者开机后视听结合及单一听觉模式下的言语感知能力不断提高^[4]。中科院声学所平利川等对10位诺尔康的植入者进行了音乐感知测试。听辨测试结果表明,植入者的音高方向辨别差阈在1~20个半音之间,旋律轮廓识别结果在25%~95%之间。音色与频率范围对测试结果亦有显著影响($P < 0.05$)。问卷调查结果显示,植入者的满意度和享受程度在7分左右。植入者之间个体差异显著^[5]。另外初步观察植入者术后残余听力完全保留率达到了33%,这与其它品牌人工耳蜗残余听力保留比例相当^[6-8]。

中国聋人数目巨大,中国经济尚处于发展阶段,通过使用高价值低价格的人工耳蜗产品可以解决中国聋人的听声需求,诺尔康人工耳蜗产品可以满足这一需求。■

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方兴未艾的国产人工耳蜗——诺尔康人工耳蜗

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[关键词] 耳蜗植入物 (Cochlear Implant) ; 临床方案 (Clinical Protocols)

耳聋一直是困扰人类的常见疾病, 给社会和家庭带来了困扰, 同时耳聋的康复治疗消耗了大量的人力和物力。据世界卫生组织估计, 全世界有2亿多人患有中度以上听力损失。2006年第二次我国残疾人抽样调查推算, 全国各类残疾人的总数为8296万人, 其中听力残疾2004万人、言语残疾127万人, 占各种残疾的首位, 并以每年2~3万新生聋儿的速度增长。初步估算目前我国0~6岁听力障碍患儿约13.7万, 重度聋以上听力障碍者占80%多。目前人工耳蜗植入 (cochlear implantation, CI) 是重度或极重度感音性聋的有效治疗和康复方法。自20世纪90年代以来越来越多的患者接受CI, 全世界行CI患者已逾20万。我国1995年完成首例成人澳大利亚22道CI, 1997年完成首例儿童澳大利亚22道CI, 目前行CI患者已逾2万例。我科自1996年开展多道CI, 1998年初完成第1例儿童CI, 迄今完成各种CI术近2000例, 并以每年200~300例的速度增长^[1]。绝大多数的耳聋患者行CI后的听觉和言语康复取得较好疗效, 多数语后聋CI患者可以较自如的使用电话, 许多年龄较小的语前聋患儿行CI后可适应正常幼儿园、学校学习和日常生活。

20世纪60年代初美国House等开展CI临床实践, 即单道CI, 并对术后听觉康复效果进行了评价, 重度-极重度耳聋患者行单道CI后可恢复一定的听觉功能, 如可听到环境声, 利于患者提高唇读能力, 增加患者对外界的警觉, 增加安全感如紧急避险等。单道CI患者仅可听到声音, 因为单道无频率特性, 无法提高语言分析能力, 所以在言语康复方面收益不大。20世纪80年代初随着电子工业尤其是电

子计算机的进步, 人工耳蜗已由单道发展到多道, 从而提高语言的识别能力成为可能。1984年获得了由美国FDA颁发的成人人工耳蜗注册证, 1990年美国FDA批准了儿童CI。我国耳鼻咽喉科工作者也长期从事人工耳蜗的研究, 但与澳大利亚、奥地利和美国人工耳蜗技术发达的国家相比还有很大差距, 1995~2009年我国人工耳蜗市场还是上述3个国家的人工耳蜗公司垄断。20世纪70年代末中国医学科学院北京协和医院才开展单道人工耳蜗的动物实验研究, 并首先应用穿皮插座式人工耳蜗试用于临床, 因为存在易感染等不利因素, 80年代复旦大学附属眼耳鼻喉科医院王正敏院士开始应用国产感应式单道人工耳蜗^[2]。经过相关人员不懈的努力, 我国数家科研团队陆续研发了国产的新一代人工耳蜗产品, 包括杭州诺尔康人工耳蜗^[3]、沈阳爱益声人工耳蜗^[4]、上海力声特REZ-I人工耳蜗^[5, 6]等, 目前已相继通过临床试验上市或准备上市。我科也积极参与了人工耳蜗的基础和临床研究, 2009~2010年参与诺尔康人工耳蜗的临床疗效及安全性临床试验研究, 随着诺尔康人工耳蜗正式获得了由中国食品药品监督管理局颁发的注册证上市, 我科也正式开展了诺尔康CI临床工作, 目前已完成101例, 取得了不错的疗效。

诺尔康晨星人工耳蜗系统由杭州诺尔康神经电子科技有限公司研发, 该公司成立于2006年, 是致力于研制神经电子的高科技企业, 该公司开创性地采取专利买断、境外研发、境内制造与销售的模式, 主要依托于美国加州大学和耳科研究所汇集的华人神经电子领域中一些杰出的科学

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家和工程师，他们的专业领域覆盖了神经电子技术所必需的相关学科，包括神经电子学、声学、光学、神经医学、信号处理、集成电路、电极设计、激光封装等。该公司联合国内知名医院、科研机构、高等院校，包括解放军总医院、中国科学院、清华大学、中国聋儿康复研究中心、首都医科大学附属北京同仁医院、首都医科大学附属北京天坛医院、北京市神经外科研究所等单位，共同组建研发团队，并参与“十一五”国家科技支撑计划项目、国家“十二五”科技支撑计划和中国科学院科技助残计划项目等国家项目，共同完成了国内人工耳蜗国产化。经过多年努力，诺尔康拥有十几项国际国内完全自主知识产权的专利技术。由公司自主研发、全独立自主知识产权的人工耳蜗系统于2011年8月和2013年7月分别获得了由中国食品药品监督管理局颁发的针对6岁以上及6岁以下患者的注册证。

下面简单介绍一下诺尔康人工耳蜗产品技术特点（以下图片和数据表由诺尔康公司提供）。人工耳蜗由植入体部分和体外言语处理器部分组成。植入体部分的壳体采用钛金外壳外裹硅胶材料（图1），电极单向C型（马鞍型）设计（图2），保证电极触点面向蜗轴，电极采用铂铱合金材料，蜗内24个电极，蜗外2个，电极长度为20.5 mm，电极间隔0.85 mm，壳体体积12.8 cc（56.4 mm x 33.0 mm x 6.9 mm）。体外部分（言语处理器）分耳背式和体佩式（图3，图4）。与国外人工耳蜗产品言语处理器主要指标相近（表1）。

从2009年12月23日诺尔康人工耳蜗系统在复旦大学附属眼耳鼻喉科医院植入第1例开始，目前已在全国开展CI

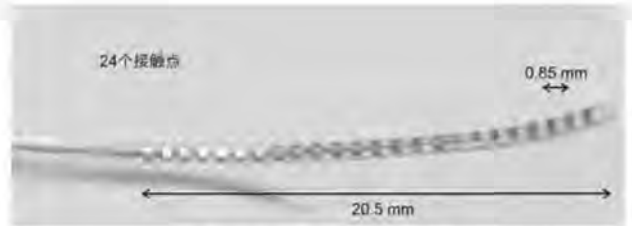


图2 诺尔康CS-10A电极参数



图3 诺尔康-晨星人工耳蜗系统体外部分（耳背式言语处理器）



图4 诺尔康-晨星人工耳蜗系统体外部分（体佩式言语处理器）



图1 诺尔康-晨星人工耳蜗系统体内部分（植入体）

近千例，手术成功率比较高，没有严重的并发症发生^[7]。我科从2010年2月开始参与了诺尔康人工耳蜗的研发、疗效和安全性验证工作，截至2013年8月共完成101例CI，其中男76例，女25例，年龄1~75岁，平均年龄16.6岁，植入的平均年龄较进口CI平均年龄（平均3岁）大，考虑2013年7月才取得中国食品药品监督管理局颁发的针对6岁以下患者的注册证，入选大部分患者为6岁以上。所有人

表1 与国外人工耳蜗产品言语处理器主要指标对比

言语处理器参数	诺尔康NSP-60	科利耳EREEDOM	AB AURIA	Med E1 OPUS
言语处理器佩戴方式	体佩式、耳背式	体佩式、耳背式	耳背式	耳背式
音频动态范围	65 dB	50 dB	60 dB	60 dB
编码策略	m-n、CIS、VC	ACE、CIS、SPEAK	CIS	CIS、CIS+
LED灯显示	有	有	有	有
防潮功能	有	有	有	不详
电池	3节锌空电池/AAA电池	3节锌空电池	锂离子充电电池	3节锌空电池

选的患者按照中华医学会耳鼻咽喉科学分会和中华医学会耳鼻咽喉科杂志编辑委员会的《人工耳蜗植入工作指南》(2003年,长沙)^[7]进行筛查,筛查包括听力学检查、影像学评估和心理、智力及学习能力评估等^[8~11]。听力学检查包括:①主观听阈测定:6岁以下患儿可采用小儿行为测听法;②声导抗测定:包括鼓室压曲线和镫骨肌反射;③听性脑干反应(ABR),40 Hz相关电位;④耳声发射;⑤多频稳态诱发;⑥助听听阈和言语识别测试;⑦言语测听。若疑有听神经病还需加做耳蜗电图耳蜗微音电位^[12]。影像学评估:颞骨薄层CT扫描和颅脑磁共振、内听道水成像和内耳道断面扫描。鼓膜穿孔者修补鼓膜愈合后6个月行CI,6岁以上语前聋患者均有配戴助听器和言语基础。所有患者均符合CI工作指南的患者选择标准,无手术禁忌证。手术采用耳后小切口、面神经隐窝经路,蜗窗或耳蜗开窗植入电极。手术疗效术中未发生任何并发症,通过术后24个月观察,所有植入者均未发生并发症^[9]和身体异常情况,身体各项生化检查均正常,提示植入体对身体重要脏器无损害。术后从开机后1~24个月时患者的闭合

式、开放式言语测试得分呈上升趋势^[2]。

CI需要关注和改进的技术要点:诺尔康电极单向C型(马鞍型)设计,保证电极触点面向蜗轴,但电极触点地金属片牢固程度需要进一步改进;人工耳蜗品种较单一,针对特殊人群的特殊电极尚待开发,如有耳蜗部分纤维化和骨化、耳蜗畸形等人群,另外需要扩大植入者的适应证选择,如听神经病、老年CI、成人CI等^[12~18];国产耳蜗由于上市时间短,国人认知度低,需加强宣传,疗效和安全性等需要进一步观察^[19],需要研发更好的术后影像学评估手段^[20]。

总之,国产人工耳蜗的上市是广大中国聋人的重大利好消息,国产诺尔康人工耳蜗有以下特点:安全、有效、自主知识产权、相对经济有价格优势及植入候选人群数目巨大,但就产品类型和工艺需要进一步改进,需扩大国产耳蜗研发和宣传力度,争取或利用国家优惠政策,增加研发投入。也希望更多的耳鼻咽喉头颈外科的同仁关注和支持国产耳蜗的发展,国产人工耳蜗方兴未艾,希望能让中国聋人终身享受买得起而且用得好的好的人工耳蜗。■

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本专题由
杭州诺尔康神经电子科技有限公司
协办

15 例国产电子耳蜗植入体会

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摘要:目的 对耳聋患者行国产耳蜗植入的相关问题进行探讨。方法 对 15 例年龄不等的耳聋患者行国产 CS-10A 型电子耳蜗植入。结果 1 例进行两次手术,其余 14 例患者手术顺利,均无手术并发症,15 例都术后 1 月开机调试,效果良好。结论 国产电子耳蜗植入是安全有效的。

关键词:人工耳蜗植入;耳聋

人工耳蜗植入技术已越来越成熟,也越来越被许多家长及患者所接受,我科于 2011 年 11 月开展诺尔康公司 CS-10A 电子耳蜗植入,至今共对 15 例语聋患者植入,现报道如下。

1 资料与方法

1.1 临床资料 2010 年 7 月至 2012 年 2 月收治我科 15 例行国产人工耳蜗植入患者,其中男 9 例,女 6 例,年龄 6~47 岁,1~10 岁 10 例,11~20 岁 2 例,21~30 岁 2 例,41~50 岁 1 例,13 例语前聋,无言语表达能力,仅能发单音,全部患者对大声无反应,其中母亲在妊娠期间无氨基糖苷类抗生素使用史,无耳聋家族史,其中 6 例曾佩戴合适的助听器,经过听力康复训练半年后听觉言语能力无明显改善。2 例语后聋患者,其中 1 例系突发性耳聋收住我科经扩血管等对症处理无效后行人工耳蜗植入,1 例系慢性中耳炎史二十余年,听力丧失,共行两次人工耳蜗植入。

1.2 材料 本组病例全部采用诺尔康公司生产的 CS-10A 电子耳蜗,埋置部分:接受刺激器,蜗内电极阵列 24 个电极和蜗外 2 个电极。壳体是钛金外壳外裹硅胶,电极是铂铱合金,电极总长度 102.4 mm,电极阵列长度 20.5 mm,电极间隔 0.85 mm,壳体体积 12.8 cc(56.4 mm×33.0 mm×6.9 mm),磨骨体积 0.44 cc。

1.3 手术方法 在全麻下做耳后倒“S”形小切口,切开皮肤,皮下组织,在离耳后约 3 cm 处颞骨表面磨深约 0.5 cm 植人体骨槽,分离颞枕部骨膜,磨开乳突,收集骨粉,乳突轮廓化暴露砧骨短脚,砧骨窝,在其下方 1 mm 开放面神经隐窝,见镫骨肌,圆窗窝,在圆窗窝前下缘 1.5 mm 处磨开约 1 mm 窗孔,进入耳蜗鼓阶,此时有微量清亮淋巴液溢出,用明胶海绵填塞窗孔,彻底止血,冲洗术腔,接收器小心放入骨槽,用骨粉加入耳胶固定,取出明胶海绵,在显微镜下小心植入刺激电极从开窗孔到耳蜗鼓阶内,并剪小块肌肉填塞电极周围封闭,抗生素冲洗术腔,分层缝合切口,加压包扎。

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1.4 术中情况 15 例患者中 5 例行左耳植入,10 例行右耳植入,14 例手术顺利,术中测阻抗正常,1 例慢性中耳炎术后聋患者,右耳乳突根治术后改变,左耳慢性中耳炎,首先清理病灶,后行左侧人工耳蜗植入,由于术中标志不清,病变严重,手术后病人眩晕明显,复查 CT 电极植入上半规管,后行二次手术,电极完全植入,术中阻抗正常,术后抗生素预防感染。

2 结果

15 例患者术后切口愈合较好,无血肿等并发症,术后 6 d 出院,术后 1 个月开机调试,均有听觉反应,13 例语前聋患者经半年时间听力康复培训,听觉言语能力明显高于术前,能进行交流,2 例语后聋患者经 3 个月训练适应后效果很好。

3 讨论

3.1 人工耳蜗植入适应证 我国中华医学会耳鼻咽喉科学会 2003 年长沙制定的《人工耳蜗植入指南》提出了人工耳蜗植入的选择标准,对语前聋患者的标准:(1) 双耳重度或极重度感音神经聋;(2) 最佳年龄应为 12 个月至 5 岁;(3) 佩戴合适的助听器,经过听力康复训练 3 到 6 个月后听觉言语能力无明显改善;(4) 无手术禁忌证;(5) 家庭和(或)植入者本人对人工耳蜗有正确认识 and 适当的期望值;(6) 有听力言语康复教育的条件。语后聋患者的选择标准:(1) 各年龄段的语后聋患者;(2) 双侧重度或极重度感音神经性聋;(3) 助听器无效或效果很差,开放短句识别率 ≤ 30%;(4) 无手术禁忌证;(5) 有良好的心理素质 and 主观能动性,对人工耳蜗有正确认识 and 适当的期望值;(6) 有家庭的支持。近年来,随着人工耳蜗植入手术越来越成熟,患者植入的年龄也扩大,研究表明^[1],早期手术可刺激听神经,促进听觉语言中枢的发育。低于 1 岁的患儿接受 CI 手术的报道也越来越多,我科曾对 1 例 8 月龄的患儿和 1 例 47 岁行 CI^[2],术中术后无明显并发症,术后康复都达到家庭或患者满意。但婴幼儿自身的发育情况及全麻风险,手术及其效果有待观察,同时,随着术前评估技术的完善、手术技巧的提高及植入装置的进步、术中影像学 and 电生理监测技术的应用,以前的禁忌证及相对禁忌证也逐渐手术治疗。有关大前庭水管综合征^[3]、听神经病^[4]、耳蜗硬化、内耳畸形成功植入 CI^[5]的报道不断增多,我科目前已对 23 例脑白质病,16 例耳蜗骨化、16 例耳蜗畸形患者行人工耳蜗植入,手术均成功植入,术中测试和术后开机均正常,随访半年听觉语言恢复良好,耳蜗硬化曾经是人工耳蜗植入术的禁忌证,现在可根据耳聋患者耳蜗骨化情况,告诉患者手术可能风险,可以手术。耳蜗骨化后行手术成功植入者 16 例中有 3 例最后个电极平圆窗,未完全植入,术后随访半年听觉均有所提高,无明显差异,对于耳蜗骨化术前影像学检查特别重要,其中 MRI^[6]三维重建起到至关重要作用。耳蜗发育异常植入者主要有 Mondini 畸形 11 例,共腔畸形 5 例。术前有残余听力可以行手术治疗,Michel 畸形是手术禁忌证,内听道狭窄患者应慎重考虑。但耳蜗完全未发育、听神经病患儿除外。

3.2 成人人工耳蜗植入^[7] 随着人的寿命延长和对生存质量要求的提高,老年人^[8]的听力下降问题越来越得到重视,据统计,听力下降是影响老年人生活的重要因素之一,同时,成人因患慢性中耳炎、药物引起、突发性耳聋等原因导致听力丧失的语后聋患者也越来越多,由于助听器往往无法达到听力恢复水平,而行耳蜗植入手术也不少见,我科至今给 4 例成人行

手术治疗,1 例长期患中耳炎导致听力重度丧失,三例系突发性耳聋因治疗无效导致听力丧失,手术均成功植入,术后开机随访半年均无不适,研究表明^[9],老年人和年轻人 CI 与儿童的效果近似,并不受器官退化的影响,并且老年人 CI 术后生活质量将提高。由于老年人因费用等问题使得手术有所受限,但国产耳蜗价格较低能满足其需求,对老年人等群体听力恢复将起到重要作用。

3.3 诺尔康 CS-10A 特点 国产人工耳蜗的研制工作始于 20 世纪 90 年代,王正敏教授^[10]主持的人工耳蜗研究小组设计的单道隔皮射频载波向耳蜗输入模拟语言波形的电信号,当年在全国应用和推广植入者 800 例,2005 年国产第 1 代 REZ-I^[11]型人工耳蜗成功研制,经过 2009 年 6 月至 2010 年 3 月临床验证,REZ-I 型人工耳蜗具有良好的生物相容型,安全性。诺尔康神经电子科技有限公司成立于 2006 年,从美国加州大学和 House 耳科研究所引进技术,成功开发出新一代国产人工耳蜗,CS-10A 具有 24 道电极阵列,采用多电流源技术实现了虚拟通道和多电极同时刺激功能,让声音更自然、清晰。并且采用陶瓷与铂铱合金设计,壳体纤薄,电极弧度设计,更易贴近蜗轴。电极仅有植入电极,电极序列在一侧,植入时应注意方向,电极质地比美国耳蜗较硬,植入后有可能旋转移位,在填塞肌肉前一定要检查电极方向是否贴近蜗轴。我科进行了 15 例患者成功植入,术后一年随访,语言康复效果较好,能明显改善听力,所有患者可达到辨识言语的水平,植入效果是肯定的,国产人工耳蜗具有自己独特的优势,其产品化在不久的将来是必然趋势,会使更多的耳聋患者有机会选择优质且价格较低的国产人工耳蜗产品。但其起步较晚,并且主要模仿国外,工艺较国外还有差距,电极较硬,材料要进一步改进。

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成人人工耳蜗植入临床资料分析

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【关键词】 耳蜗植入术 (Cochlear Implantation); 临床方案 (Clinical Protocols); 治疗应用 (Therapeutic Uses); 治疗结果 (Treatment Outcome)

人工耳蜗植入 (cochlear implantation, CI) 给重度、极重度听力损失患者带来了福音, 患者通过行CI可以实现听力重建。而术后通过对阶段性听觉言语康复的效果进行评定, 可以观察CI疗效及言语康复效果。

1 耳蜗成人组的临床验证

2010年3月17日~4月7日在首都医科大学附属北京同仁医院进行了10例成人CI临床验证, 植入的耳蜗为诺尔康晨星人工耳蜗系统, 由体内部分植入体CS-10A和体外部分处理器NSP-60B组成。

1.1 术前一般资料。 男性7例, 女性3例, 年龄最小19岁, 最大36岁。10例均为语后聋。术前行常规CT等影像学评估, 10例患者耳聋原因有药物性聋5例、突聋1例、前庭导水管扩大1例、脑膜炎1例、耳硬化症1例及不明原因1例, 其中1例存在耳蜗骨化。

1.2 术前听力学资料。 植入耳术前裸耳残余听力4FA (0.5、1、2及4 kHz) ≥ 75 dBHL (表1)。植入侧鼓室图为A或As或Ad型; 耳声发射 (OAE) -畸变产物耳声发射 (DPOAE) 双侧均未引出; 听性脑干反应 (ABR) 和多频稳态诱发反应 (multiple auditory steady-state evoked

responses, ASSR) 结果达到重度聋或极重度聋。

1.3 术前言语评估资料。 裸耳闭合式听能评估测试 (19.16 \pm 3.03)%; 裸耳开放式听能评估测试值0.00 \pm 0.00。其中, 开放式听能评估测试材料包括house短句、301短句、301中文双音节词识别共3项; 闭合式听能评估材料包括单音节辨识、双音节辨识、数字辨识、环境声音、声母识别、韵母识别及声调识别共7项, 给声强度为65 dB A。

1.4 开机调试及随访时间。 术后 (3 \pm 1) 周开机。临床随访时间为植入耳蜗当天、开机当天, 开机后1个月 \pm 1周、开机后2个月 \pm 1周、开机后4个月 \pm 1周及开机后6个月 \pm 2周, 预计开机5年内1年随访1次。

1.5 开机后随访结果。 ①开机1年内助听听阈结果。10例植入者中有9例参与了本次评估, 其中1例因无法配合评估测试记为脱落。助听听阈结果显示人工耳蜗能够满足植入者日常生活中各频率的听声需求 (表2)。②开机1年内听能评估结果。开机1、2、4、8及12个月言语测试结果: 闭合式平均得分73.83%、78.18%、87.97%、88.40%及94.80%; 开放式平均得分41.28%、50.55%、68.78%、81.32%及89.58% (图1)。10例植入者中有9例参与了评估, 其中1例因未配合随访测试记为脱落。测试材料与术

表1 CI患者植入耳术前裸耳残余听力 ($\bar{x} \pm s$, n=10)

检测频率 (kHz)	0.5	1	2	4	平均值
裸耳听阈 (dB HL)	97.5 \pm 14.19	112 \pm 9.78	114 \pm 9.37	115.5 \pm 11.17	109.75 \pm 8.72

表2 CI患者开机1年内助听听阈 ($\bar{x} \pm s$, n=9)

检测频率 (kHz)	0.5	1	2	4	平均值
裸耳听阈 (dB HL)	39.44 \pm 1.66	35.11 \pm 2.20	36.11 \pm 2.33	39.44 \pm 1.67	37.77 \pm 1.37

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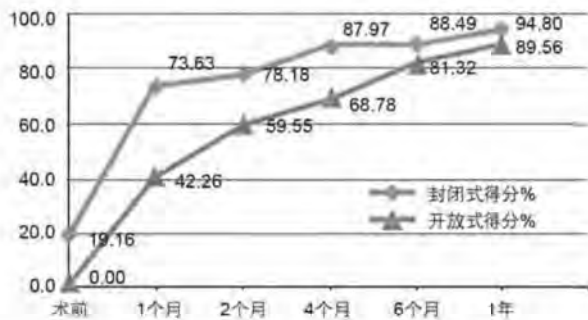


图1 CI患者开机1年内听能评估 ($\bar{x} \pm s, n=9$)

前的言语评估材料相同。从图中可看出,人工耳蜗植入后言语评估测试结果显著提高,且随着时间的推移,测试得分逐步上升。

2 成人中的临床应用

首都医科大学附属北京同仁医院于2012年正式开始将诺尔康耳蜗应用于成人CI。2012年共行175例CI,其中25例为诺尔康;2013年截止到发稿成人植入诺尔康耳蜗2例。

27例诺尔康CI中,10例CT等影像学评估未见异常;8

例内耳畸形;4例骨化性迷路炎;1例内听道狭窄;1例前庭导水管扩大;3例中耳乳突炎。术后常规行X片观察其植入体位置,其中1例因磁铁移位行二次手术,10例患者术后恢复均良好。

对这些患者进行了术后开机之后助听听阈的评估,声场下的助听听阈在4FA (0.5、1、2及4 kHz) ≤ 45 dB HL,术后定期随访对听力进行了定性评估,表明听力状况均有不同程度的提高。

3 总结

10例成人双耳重度或极重度感音神经性聋于首都医科大学附属北京同仁医院行诺尔康晨星人工耳蜗系统植入,在安全可靠性方面得到了验证,在恢复听觉、提高言语和声音感知和识别等有效性方面效果良好。2012年起诺尔康耳蜗在北京同仁医院正式用于成人CI,患者术后听力均得到了显著提升,能够较好地感知各频率的声音,能够满足日常生活中的听声需求,并且术后言语能力得到了显著提升,在日常交往、理解能力等各方面都得到了提高,并且听觉及言语能力随着时间的推移有逐步改善。■

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协办



国产诺尔康人工耳蜗植入临床分析

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【关键词】 耳蜗植入术 (Cochlear Implantation); 电极, 植入 (Electrodes, Implanted); 中耳炎 (Otitis Media); 数据说明, 统计 (Data Interpretation, Statistical)

人工耳蜗植入 (cochlear implantation, CI) 是目前临床上针对重度和极重度感音神经性聋的最佳治疗手段。但长期以来由于人工耳蜗产品依赖进口, 价格居高不下, 很多家庭难以承受, 使众多需要行CI的患者不能得到及时有效的治疗。而中国自主品牌诺尔康人工耳蜗的问世, 无疑为解决这一问题提供了新选择, 并造福更多的国内耳聋患者。本文将对我科诺尔康CI患者进行初步的回顾性研究, 为更大范围国产人工的应用提供临床参考。

1 资料和方法

1.1 临床资料。2012年11月~2013年3月在中南大学湘雅医院就诊的重度或极重度感音神经性聋患者13例, 男5例, 女8例; 语前聋6例, 语后聋7例, 年龄7~41岁。平均失聪时间为16.1年。耳聋原因: 先天性聋6例, 高热致聋2例, 中耳炎后耳聋1例, 溺水后耳聋1例, 原因不明3例。均曾配戴助听器无效, 接受诺尔康CS-10A型人工耳蜗植入。13例患者中, 左侧植入2例, 右侧植入10例, 双侧植入1例。其中12例患者除重度或极重度感音神经性聋外不伴其他耳部病变, 11例单侧植入, 1例双侧植入。另有1例患者除极重度感音神经性聋外伴双侧中耳炎, 右耳曾行乳突根治术, 左耳鼓膜紧张部大穿孔, 但已于耳10余年, 左耳行CI并鼓室成形术。

1.2 方法。手术选用术侧耳后小“S”形切口, 将耳蜗模具定位后美兰标记, 再依次切开皮肤、皮下组织直至乳突骨膜, 按亚甲蓝标记位置磨出植入床, 然后开放乳突腔, 经面神经隐窝径路暴露蜗窗, 经蜗窗膜径路开放鼓阶, 然后固定植入体, 将电极插入鼓阶, 使用颞肌封闭耳蜗造

口, 测试电极正常后, 缝合切口, 伤口包扎结束手术。双侧CI患者再次消毒后同法行对侧CI。伴中耳炎患者行CI前取同侧颞筋膜备用, 清除鼓室病变后, 沿残余鼓膜边缘准备移植床, 待耳蜗电极插入后行同侧鼓室成形术。术后2 d行耳蜗位片检查耳蜗电极植入情况。术后1个月开机, 使用诺尔声1.0软件测试植入耳蜗电极阻抗值、各电极反应阈值及最大舒适阈值, 采用峰值提取处理策略(m-n)行言语编程, 双侧CI患者采用左右耳同步调试, 此后3个月每月调试1次, 再隔3个月调试1次, 隔6个月调试1次, 程序稳定后每半年或1年调试1次。

1.3 听觉言语测试。术前及术后开机后3个月听力测试采用声场测听, 言语测试采用全国聋康系统普遍采用的《聋儿康复听觉言语评估词表》进行闭合式语言测试, 分别行声母、韵母、单音节词及短句测试, 使用有意义听觉整合量表(MAIS)进行CI效果评估。

2 结果

13例患者14耳行CI均成功, 伤口均I级愈合, 无面瘫、感染、眩晕等并发症发生, 无排异反应发生, 术后耳蜗位片显示电极完全植入, 术后调试时无异常放电导致面神经刺激及其他不适发生。伴中耳炎行鼓室成形术后鼓膜修复成功。术后声场测听平均听阈为25~50 dB, 均达到日常生活实用听力水平。术后有意义听觉整合量表调查得分 32.15 ± 10.12 , 显示所有患者行CI后听觉康复效果满意, 生活质量得到明显改善。患者术前及术后开机3个月声母、韵母、单音节词测试结果提示术后言语识别率得到明确改善(表1)。双侧CI患者声母、韵母及单音节词测

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表1 人工耳蜗植入患者术前术后言语识别率 (%)

	声母		韵母		单音节词	
	术前	开机3个月	术前	开机3个月	术前	开机3个月
语前聋	0.31±1.28	40.15±13.21	0.27±2.16	52.18±10.56	0.15±2.54	38.21±9.52
语后聋	15.72±3.15	63.42±18.53	16.21±5.31	71.65±13.84	10.76±3.55	41.65±10.15

试结果分别为55.12%、65.61%、45.33%，均明显高于单侧植入语前聋组患者。

3 讨论

1972年House 3M型单道人工耳蜗成为世界上第1个进入市场并得到FDA批准使用的人工耳蜗，但由于其局限性，听觉言语康复效果有限，一直未能得到大量应用。1984年多道人工耳蜗的问世，使得人工耳蜗具备了更好的频谱感知和言语识别能力，这种人工耳蜗先后被批准在成人和儿童中使用。随着多道人工耳蜗相关技术的发展，电极数量不断增多，电极形状得到改善，耗电减少，语言信息提取方式不断优化，言语编码策略多样化发展，言语处理器微型化，手术技巧不断改进，残余听力得到保护，术后听觉、言语训练效果得到提高，多道人工耳蜗得到了大范围应用。目前人工耳蜗的手术适应证不断扩大，由极重度聋扩展到部分重度聋，手术最小年龄不断下降，从开始的2岁到现在的1岁甚至更小。人工耳蜗已经被公认为目前为重度、极重度聋患者恢复或获得听力的最有效装置。

我国的人工耳蜗起始于20世纪70年代末和80年代初，当时研制出一系列单道人工耳蜗，由于效果不理想及感染问题，逐渐停止使用。我国的重度及极重度听力障碍患者人数众多，据2006年第二次全国残疾人抽样调查显示，我国现有耳聋患者约2004万，其中聋哑人200多万，每年还有约3万新生聋儿，因此人工耳蜗在我国广大聋病患者中需求巨大。但实际情况是，目前使用的大部分人工耳蜗产

品均来自国外三大人工耳蜗公司，价格相对昂贵，很多家庭难以负担，虽然国家和各级政府、慈善团体及个人采用了各种方法免费提供耳蜗，或减免部分费用，但对巨大的需求基数来说仍是杯水车薪。因此，研制我国自己的新型多道人工耳蜗就显得尤为重要。目前我国已经有数家机构开展相关研究，诺尔康人工耳蜗就是其中之一，通过临床分析，在我院接受诺尔康CI的耳聋患者，术后并无感染、异常电刺激、排异反应等并发症的发生，电极均能完全植入，且植人体较其他产品薄，使得手术中磨骨面积减小，节省了手术时间。术后效果评估满意，听觉及言语识别率等均得到满意康复，目前由于我们只总结了术后开机3个月的言语识别率的数据，与文献报道的国外品牌人工耳蜗同时期的言语识别率数据比较并没有显著差异，充分说明了诺尔康CS-10A型人工耳蜗能成功有效的帮助重度、极重度聋患者恢复或获得听力，从而促进其言语康复，因为价格相对进口产品显著降低，因此为我国及广大发展中国家重度、极重度聋患者提供更佳选择。

另外，目前我国人工耳蜗工作指南推荐的语前聋患者最佳植入年龄为12月龄~5岁，国家及各级政府提供的优惠政策也主要向6岁以下患者倾斜。但是我们在实际临床工作中经常可以见到很多6岁以上的重度、极重度感音神经性聋患儿无法通过助听器取得帮助，人工耳蜗对于他们来说仍然是最好的选择。我们的临床研究中的语前聋6例患者均超过6岁，但行CI后仍然能获得较好的听觉言语康复，因此，大龄语前聋患者行CI也应该得到重视。■

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语后聋人工耳蜗使用者视听言语感知能力研究*

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【摘要】 目的 观察语后聋人工耳蜗植入者开机后安静环境中视听言语感知能力的变化情况,分析视觉言语信息在言语感知中的作用。**方法** 评估 12 名(12~13 岁)语后聋国产诺尔康人工耳蜗使用者开机后 1、2、4、6 个月时在安静环境中单一视觉、单一听觉和视听结合三种模式下的语句识别率。**结果** 在开机后半年内,随着开机时间的延长,12 名受试者在视听结合和单一听觉模式下,安静环境中语句识别率呈上升趋势,使用重复测量方差分析,两种模式下不同时间点测试结果之间的差异均有统计学意义($P < 0.05$),其中视听结合模式下开机后 2 月和 4 月时的测试平均分差异无统计学意义,单一听觉模式下,开机后 4 月和 6 月时测试平均分差异无统计学意义。单一视觉模式下,各个时间点的测试结果无明显变化,经重复测量方差分析,各个时间点测试结果的差异无统计学意义($P > 0.05$)。视听结合模式下各个时间点语句识别平均得分均明显高于单一视觉、单一听觉两种模式。**结论** 语后聋人工耳蜗植入者在开机后半年内视听结合和单一听觉模式下的言语感知能力不断提高,单一视觉模式下的言语感知能力无明显变化,视觉言语信息对安静环境中的言语感知有较大帮助。

【关键词】 人工耳蜗; 视听整合; 言语感知

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Audiovisual Speech Perception of Postlingually Deaf Patients with Cochlear Implants
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【Abstract】 Objective To investigate the development of audiovisual speech perception ability in postlingually deaf patients with cochlear implants, to analyse the role of speechreading in audiovisual interactions during the recovery of speech comprehension in cochlear implant users. **Methods** Twelve postlingually deaf patients with the Nurotron cochlear implant system were involved in this study. Auditory-only, visual-only, and auditory-visual speech perception in quiet were examined during 1, 2, 4, 6 month after switch-on. **Results** The results revealed that postlingually deaf patients with cochlear implants performed better under audiovisual presentation compared with auditory-only or visual-only conditions. The scores under the auditory-only and auditory-visual conditions were both progressive during the six months post-implantation, while the speechreading performances were stable. **Conclusion** Postlingually deaf cochlear implant users benefited from the use of visual cues for speech perception in quiet.

【Key words】 Cochlear implant; Audiovisual integration; Speech perception

言语交流过程中的视觉信号承载着重要的语言信息,人会不同程度的利用这些信息提高言语识别的效率,尤其是耳聋患者,在通过单纯的听觉信息不足以达到满意的言语识别的情况下,从唇读或手语等视觉信息中可以获得部分补偿。

重度和极重度感音神经性聋患者可以通过人工耳蜗植入获得听觉康复的机会,然而由于人工耳蜗装置进行声电转换的过程中部分声信号丢失和患者听觉系统接收处理能力有限等因素,植入者的聆听效果和正常人尚有较大差距^[1],因此,人工耳蜗使用者整合视觉信息和电听觉信息成为其日常交流的重要言语识别模式。本研究旨在通过观察语后聋国产人工耳蜗植入者在安静环境中单一视觉、单一听觉和视听结合三种模式下的言语感知变化情况,探索言语交流中视觉信息对话后聋人工耳蜗使用者言语识别的影响。

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1 资料与方法

1.1 研究对象 受试对象为2010年在解放军总医院接受国产诺尔康人工耳蜗植入的12例语后聋患者,其中男性7例,女性5例,年龄12~43岁,均为双耳极重度感音神经性聋,影像学检查无明显内耳畸形,无手术禁忌证。受试者均于右耳植入国产诺尔康一晨星人工耳蜗,植人体型号为CS-10A(24个蜗内刺激电极,2个蜗外参考电极),所有受试者术后头颅侧位片显示电极位置良好。受试者详细资料见表1。

表1 12例受试者耳聋原因、病程及助听器佩戴史

受试者编号	年龄(岁)	性别	耳聋原因	耳聋时间(年)	助听器佩戴史
1	27	女	药物性聋	23	有
2	12	女	药物性聋	3	有
3	22	女	药物性聋	3	有
4	16	男	大前庭水管综合征	13	有
5	31	男	突发性聋	30	有
6	43	男	药物性聋	8	无
7	31	男	突发性聋	8	无
8	31	男	不明原因	18	无
9	21	女	脑膜炎	18	无
10	21	男	不明原因	13	无
11	32	男	药物性聋	10	有
12	17	女	药物性聋	11	有

1.2 测试材料和方法 使用解放军总医院编制的安静环境中语句识别句表,共12张表,每张表含10个短句,50个关键词。句表内容以音频、视频及音频结合视频三种文件形式集成到心爱飞扬言语测听软件^[2]中。测试在经校准满足准自由场条件的隔声室进行,本底噪声在20 dB A以下。使用UA-1X型USB音频转接头连接笔记本电脑和经校准的GSI61听力计,通过高精度扬声器播放语句,给声强度为50 dB言语听力级。受试者面对视频显示屏,扬声器位于其植入侧45°前方1 m处,与患者坐姿时耳部高度齐平。

受试者分别在开机后第1、2、4、6月时进行单一视觉、单一听觉和视听结合三种模式下安静环境中语句识别率测试。每次测试前均进行练习,确保受试者熟悉测试流程并能配合测试之后,再选取测试句表正式测试并计分。受试者在练习和测试过程中不使用重复的句表,测试人员根据受试者复述的内容以关键词为单位记录结果,软件自动计算语句识别率,识别率=正确回答关键词数/测试内容总关键词数×100%,去除百分号为言语识别得分。

1.3 统计学方法 使用SPSS18.0统计软件对视、听和视听结合三种模式下开机后不同时间点测试结果分别进行重复测量方差分析。

2 结果

开机后1、2、4、6个月时受试者单一视觉、单一听觉和视听结合三种模式下安静环境中语句识别率见表2,变化趋势见图1。

12例受试者在单一视觉模式下不同时间点语句识别率之间的差异无统计学意义($P>0.05$),由图1可见,开机后半年来受试者在单一视觉模式下语句识别平均得分无明显上升或下降趋势;开机后1月到6月,单一听觉模式下不同时间点语句识别平均得分之间的差异有统计学意义($P<0.05$),随着开机时间的延长,受试者在单一听觉模式下语句识别得分有逐渐增加的趋势,开机后4月与开机后6月的语句识别平均得分差异不显著;视听结合模式下开机后不同时间点受试者的语句识别平均得分呈增加趋势,各时间点得分之间的差异有统计学意义($P<0.05$),开机后2月与开机后4月时测试平均得分差异不显著。视听结合模式下各个时间点语句识别得分均显著高于单一视觉和单一听觉模式。

表2 不同测试模式下不同测试时间受试者语句识别率比较(%, $\bar{x}\pm s$)($n=12$)

测试模式	开机后1月	开机后2月	开机后4月	开机后6月
单一视觉	23.83±15.92	32.17±22.87	31.67±17.37	31.17±17.78
单一听觉	10.83±9.93	21.67±16.50	39.83±23.30	37.67±21.51
视听结合	47.83±20.83	55.17±18.52	55.00±22.59	71.67±16.88

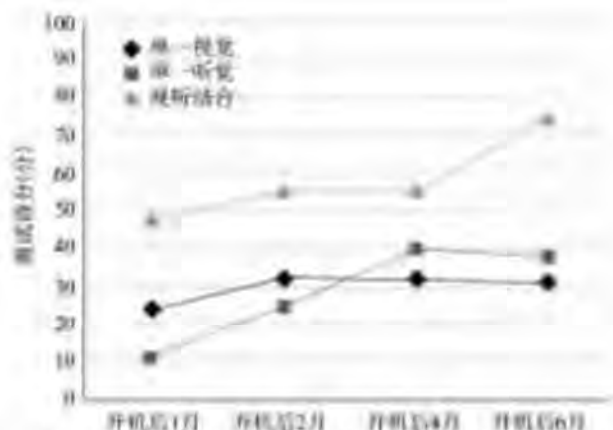


图1 开机后1、2、4、6个月受试者视听言语识别得分趋势图

3 讨论

言语感知本质上是对多种感觉进行整合的过程,主要通过听觉和视觉感官收集言语信息,信息传至大脑后经相关皮层整合加工最终形成对言语信息的识别。视觉信号承载的语音信息对听力正常人和耳聋患者的言语感知均有重要影响。Sumby等^[3]发现对于正常听力的受试者在较低的信噪比下增加视觉信息可以显著提高言语识别率。视觉信息对言语识别的影响在McGurk效应^[4]中也有体现,即受试者同时接收内容不一致的听觉和视觉信息,经大脑整合最终会得出异于二者内容的识别结果。在日常

环境中,言语识别在视听模式下完成,听者收集与听觉信息相匹配的视觉信息有利于及时感知声音信号的内容时程以及讲话者传递的情感等信息,增加了言语感知的精确度,尤其是在噪声环境或者声音清晰度较差的情况下。对于语后聋患者,感知言语时主要通过唇读来弥补听觉的不足,尽管个体的唇读能力有较大差异,根据以往的研究数据显示,耳聋患者整体的唇读能力较正常人高^[10]。语后聋患者在植入人工耳蜗的初期需要一段时间适应和学习人工耳蜗提供的缺乏精细时域信息的电听觉信号,在此过程中唇读能力可能随着听觉处理能力的提高而下降,也可能保持植入前的水平,或者为了协助理解人工耳蜗提供的电听觉信息而变得更加重要。视听相关研究的结果对于是否选择为人工耳蜗植入者提供利用视觉捕捉言语信息相关的康复训练有重要参考价值。本研究结果表明在受试者植入人工耳蜗之后的半年内,唇读能力变化不大,然而唇读结合听觉后,受试者整体的言语感知水平明显高于单一听觉模式,这意味着在人工耳蜗植入者的康复初期,唇读在言语感知过程中起着非常重要的作用。

人工耳蜗植入已成为治疗重度和极重度感音神经性聋的常规方法,本研究结果显示语后聋患者植人工耳蜗后的半年内听觉处理能力呈明显提高的趋势,根据有关听觉皮层正电子发射断层扫描(positron emission tomography, PET)的研究报道^[6],在人工耳蜗植入后听觉皮层区域和负责语言处理的相关皮层发生进展性的激活,这可能是患者植人工耳蜗后一段时期内听觉处理能力不断提高的原因。患者耳聋期间通过唇读信息补偿有限的听觉信息来协助日常语言交流,理论上随着植人工耳蜗后听觉能力的提高,其对视觉信息的需求降低,唇读能力会逐渐下降。然而,关于人工耳蜗植入者开机后唇读能力的变化,各项研究结果有较大差异,Giraud 等^[7]报道植人工耳蜗后一年内患者唇读能力呈不断提高的趋势,而 Bergeson 等^[8]的研究结果显示植人工耳蜗后患者的唇读能力只有非常小幅的提高,Gray 等^[9]则未观察到显著变化。Strelnikov 等^[10]对 100 例语后聋人工耳蜗使用者长达 8 年的观察结果显示其唇读能力在人工耳蜗植入后各个时期没有显著变化,与本研究观察到的结果一致。虽然随着人工耳蜗植入时间的延长,患者安静下的言语交流能力明显提高,然而在噪声环境下及多人对话模式下的言语识别仍较差^[11],对视觉信息的依赖并没有减少,这可能是唇读能力变化不大的原因之

正常人的听觉皮层位于颞叶,主要负责听觉信号的处理,耳聋患者的功能性 MRI 显示非听觉刺激如视觉和躯体感觉也可以使颞叶听觉皮层活化,这种其他感觉对听觉皮层的占领主要是由于听觉刺激的缺乏^[11]。语后聋患者植人工耳蜗前多有数月甚至数年听觉剥夺的经历,植人工耳蜗后听觉刺激的重新传入会使颞叶皮层功能分区如何变化尚有待进一步研究。

总之,本研究结果显示视听结合模式下,语后聋人工耳蜗植入者可以获得最佳的言语识别效果,因此,充分利用视觉信息协助听力语言康复可能是加快语后聋人工耳蜗使用者康复进程的有效手段。

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国产人工耳蜗，任重道远

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【关键词】 耳蜗植入物 (Cochlear Implant)；听觉丧失，感音神经性 (Hearing Loss, Sensorineural)

对于重度和极重度感音神经性听力下降 (sensorineural hearing loss, SNHL) 患者，人工耳蜗植入 (cochlear implantation, CI) 是目前能帮助他们改善听力的唯一方法^[1]。对话前聋SNHL婴幼儿，早期CI可帮助他们发展听力和言语，几乎获得和听力正常同龄儿童一样进入正规教育的机会^[2-3]。而对于语后聋SNHL青少年和成人，CI能帮助他们参与社会交流和工作，重返主流社会，显著提高生活质量^[4]。20世纪90年代初国外人工耳蜗逐渐引入我国，人工耳蜗市场被3家国外公司占据，国外人工耳蜗价格昂贵，非普通家庭能够承受，尽管国家政府和民间慈善家对听力障碍人群进行了很大力度的资助，但仍有大量的重度和极重度SNHL患者在漫长的等待之中，无法得到救助。

1 历史

为解决进口人工耳蜗技术垄断和市场垄断，几代中国耳科学和听力学专家致力于开发国产人工耳蜗。我国自主研发人工耳蜗的工作始于20世纪70年代后期，由邹路得等首先研制了插座式单道人工耳蜗，随后有高荫藻、陈成、王正敏等先后开发出单道及三道感应式人工耳蜗植入体，至80年代初期，国内共完成了约300余例植入手术。但是由于电子技术、材料与工艺的落后，使国内“热潮”急剧冷却^[5]。我国国产人工耳蜗的关键技术研究开始于20世纪80年代，复旦大学附属眼耳鼻喉科医院王正敏院士带领国产人工耳蜗项目组先后研制成功单道脉冲式人工耳蜗和单道连续式人工耳蜗，在全国应用和推广单道人工耳蜗达800余例。他们又经过多年努力成功研制出数字人工耳蜗（原型），于1997年申请并获批“多道程控人工耳蜗”专

利^[6]。但由于同时期国外多道人工耳蜗产品进入中国大陆市场，国产单道人工耳蜗和数字人工耳蜗（原型）并未真正被广泛应用。自2004年复旦大学与上海力声特医学科技有限公司合作开展国产人工电子耳蜗关键技术研究，先后突破语音编码、听神经刺激电极序列设计、刺激信号/能量透皮传输等关键技术，并于2005年研制出达临床应用水平的多道人工人工耳蜗，形成了具有自主知识产权的MTone语音信号编码策略和LST-MAP management调试软件，2007~2010年先后完成48例成人临床试验，2011年2月获得中国本土的第1个人工耳蜗医疗器械产品注册证，成为具有自主知识产权的第1个国产人工耳蜗，获批19项国内专利，其中发明专利5项。

几乎与此同时，杭州诺尔康神经电子科技有限公司也自主研发出了适合国人的晨星人工耳蜗系统。诺尔康公司由美国加州大学和House耳研所一批杰出的华人科学家和工程师倡导、于2006年正式成立，总部和生产基地位于中国杭州，研发中心位于美国加州，汇聚了国内外耳科学、听力学、生物工程学、神经电子学各个领域专家。杭州诺尔康公司联合中国科学院声学研究所、清华大学深圳研究生院、解放军总医院、中国聋儿康复研究中心和首都医科大学附属北京同仁医院获得了国家“十一五”国家科技支撑计划资助，随后又获得国家“十二五”科技支撑计划和中国科学院科技助残计划项目等国家项目。2009年9月临床试验启动会在杭州召开，诺尔康公司在全国5所三级甲等医院（复旦大学附属眼耳鼻喉科医院、首都医科大学附属北京同仁医院、解放军总医院、浙江大学医学院附属第二医院和重庆医科大学附属第一医院）开展120例成人和儿童的临床验证工作，评估该公司自主研发的人工耳蜗晨

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星系统在我国成人和儿童重度/极重度SNHL患者中使用的安全性和有效性。2011年6月和8月诺尔康人工耳蜗言语处理器和植入体先后获得国家食品药品监督管理局颁发的医疗器械注册证。在获得政府大力扶持后，该公司不忘回馈社会，2011年向中国残疾人福利基金会“集善工程—助听行动”捐赠100套人工耳蜗系统及100万元项目配套资金，向浙江省残联“爱心助听行动”捐赠100套人工耳蜗系统，以及向中国残疾人服务网“网络春晚”捐赠3套人工耳蜗系统。同期，上海力声特公司也已经向中国残疾人福利基金会完成捐赠100套，向复旦大学附属耳鼻喉科医院捐赠50套，并由大连慈善总会采购300套。由此，国产人工耳蜗迅速在国内超过60家临床医院展开应用。

沈阳弘鼎康医疗器械有限公司为中美合作企业，成功研制的爱益声单道人工耳蜗产品于2009年进行临床试验，临床验证工作由首都医科大学附属北京同仁医院、解放军总医院，中国医学科学院北京协和医院及中国医科大学附属盛京医院等共同完成，现处于疗效观察和随访阶段。

国内其他科研院所，包括北京大学、清华大学、重庆大学、首都医科大学附属北京同仁医院、中国医学科学院北京协和医院等单位均开展了国产人工耳蜗相应技术研发

工作，在一些关键技术方面取得了成果，并形成了相应的知识产权，如清华大学的语音编码算法设计研究、重庆大学的耳蜗柔性微电极研制等，但都没有形成商业化产品。

2 现状

目前应用于临床的国产人工耳蜗主要是来自杭州诺尔康公司的晨星系统和上海力声特公司的REZ-I型系统。晨星系统大体分为体内部分（植入体，CS-10A型）、体外部分（处理器）和智能调试系统（诺尔声）3部分。REZ-I型系统构成与此类似（表1）。

晨星系统先后对重度/极重度SNHL成人和儿童进行了临床验证，2009年12月~2012年6月完成了为期2年的成人临床验证，2011年4月~2012年7月完成了为期1年的儿童评估。全国范围内共招募120例试验志愿者。致聋原因多样，以药物性和先天性聋居多，成人组和儿童组各60例，其中成人组均为语后聋。通过对120例植入手术、开机、调试及随访观察，未发现与植入体及植入手术相关的任何并发症和严重不良反应。成人组参与者均通过了反映听觉敏感度的助听听阈测试，助听听阈均位于香蕉图内，通过了反映听功能的开放式及封闭式言语测试，

表1 国产与进口人工耳蜗同类产品体内部分和体外部分相关技术参数比较

公司	澳大利亚 Cochlear公司	美国 Advanced Bionics公司	奥地利 MED-EL公司	杭州 诺尔康公司	上海 力声特公司
产品型号	Nucleus 24Contour	CII、HiRes 90K	COMBI 40 ⁺	CS-10A	REZ-I
电极通道数	22	16	12	24	22
电极形状	圆环 锥形0.5~0.8 mm、 直/预弯电极	平板电极 预弯电极	圆环、 锥形0.5~1.3 mm	马鞍形 预弯电极 直电极	圆环 0.6 mm 直电极
电极形式	单电极、双电极	单电极	单电极、双电极	双电极	单电极
电极有效长度	15 mm	-	27.4 mm	20.5 mm	18.1 mm
植入装置厚度	6.9 mm	5.5 mm (90 K)	4 mm	6.9 mm	5.5 mm
植入装置重量	9.5 g	-	-	-	8.8 g
植入装置外壳	钛	陶瓷 (CII)、合金	陶瓷	钛金外壳外裹硅胶	钛
遥测功能	有	-	-	有	有
言语处理器	体佩式、耳挂式	体佩式、耳挂式	体佩式 CIS PRO ⁺	体佩式、耳挂式 耳挂式TEMPO ⁺	体佩式
言语编码策略	SPEAK、 CIS及ACE	Hires-S、Hires-P、 CIS、MPS	CIS	CIS、APS、 Symphony、 (E-Tone研发中)	MTone
汉语音调编码	无	无	无	研发中	有
刺激速率	14400 Hz	83000 Hz	18000 Hz	-	20000 Hz
音频动态范围	60 dB	80 dB	-	65 dB	60 dB
电池技术	3颗纽扣电池 可维持30 h	锂离子充电电池， 持续10~17 h	TEMPO ⁺ ： 3颗纽扣电池 可维持30 h	3节锌空电池/ AAA电池：-	2节5号电池， 持续工作 > 10 h

得分逐年提高。连续观察儿童组1年,所有植入者都通过了助听听阈、婴幼儿有意义听觉整合量表(infant-toddler meaningful auditory integration scale, IT-MAIS)和/或中聋编制的言语评估。对比研究发现植入效果与其他进口产品的效果相当,可获得听觉、语言康复的预期目标,且设备使用安全可靠^[7]。自从2009年12月23日在复旦大学附属眼耳鼻喉科医院植入第1例开始,目前已经在中国大陆67家医院对近1000例12月龄~78岁的患者行CI,所有手术均顺利进行,临床应用最长已达4年。多位手术医师认为诺尔康人工耳蜗的置入优点有:①植入人体积较小(12.8 cc, 56.4 mm x 33.0 mm x 6.9 mm),磨骨体积小(0.44 cc),电极直径<1 mm,软硬适中,适宜微创手术;②植入体较薄,内侧面稍具弧度的设计更加贴合颅骨的曲度,置入部位隆起不明显,美观。③软性电极,对蜗内结构的创伤轻,可通过蜗窗径路插入耳蜗,可保留残余听力;④电极单向弯曲,电极基部凹点设计,可保证电极触点面向蜗轴;⑤电极尾部2个环形标记,保证电极插入深度(1~1.5圈);⑥可用于部分畸形和骨化耳蜗插入。不足之处是电缆柔韧性稍欠佳,在乳突腔弯曲时较僵硬^[7]。

我科自2010年3月17日完成第1例国产CI以来,手术数目逐年攀升,对成人重度/极重度SNHL患者植入诺尔康晨星人工耳蜗系统术后随访1年,不仅声场助听听阈在各频率均显著提高,而且通过闭合式和开放式听功能测试,术后听觉言语能力显著提升,且表现出明显的学习效应,即随着时间推移逐步改善并趋于饱和^[6]。冯永等^[9]对13例7~14岁的重度/极重度SNHL患者(包括语前聋和语后聋)行诺尔康CI,术后3个月通过声场测听和言语功能测试发现术后听觉言语康复效果满意,提出需重视超过6岁的大龄语前聋儿童CI。且其中1例双侧CI患者的声母、韵母及单音节词测试结果均明显高于单侧植入语前聋组患者,提示双耳有效听力对提高言语识别能力的重要性。戴朴等^[10-12]报道采用柔手术技术和经蜗窗膜径路等手术技巧,能较好保留低频区听力,这与其他研究报告的国外人工耳蜗植入后残余听力保留相当。但听力保留随着时间的推移逐步下降的现象也值得注意。另外,辜萍等^[13]研究表明诺尔康人工耳蜗植入者开机后视听结合及单一听觉模式下的言语感知能力不断提高。

上海力声特公司的REZ-I型人工耳蜗于2009年6月~2010年3月在全国5家医院进行临床试验,对48例重度/极重度SNHL患者(成年语后聋)进行了国产CI有效性、安全性及可靠性评估等工作。通过定期观察和随访(随访

期>1年),临床验证结果表明REZ-I型人工耳蜗显著改善成人语后聋患者听力,80%以上患者基本上可达到辨识言语的水平;其具有良好的生物相容性,安全性良好,手术方便安全,可较好保留部分患者术耳残余听力^[14];植入人体后性能在观察期内基本稳定,未发生与植入的人工耳蜗有关的毒副反应和不良事件。以上结果表明REZ-I型人工耳蜗临床使用于成人患者安全有效^[6]。目前力声特公司REZ-I型人工耳蜗尚未获准使用于儿童患者。

3 未来

我国自主研发人工耳蜗的初衷主要是打破进口人工耳蜗的价格垄断,以合理的价格惠及更多中国普通家庭的重度/极重度SNHL患者,目前晨星人工耳蜗系统和REZ-I型人工耳蜗市售价都在8万元人民币左右,再加上手术和术后开机调机、康复、电池和维护费用,单侧CI前后的花费仍在10万元以上,对于工薪家庭,特别是广大中小城市、城镇和农村的患者家庭而言是一笔不菲支出。随着国产人工耳蜗批量化生产能力逐步提高,期望国产人工耳蜗裸机单价有所下降,能在兼顾经济效益的同时惠及更多需要行CI的患者,并让一部分双耳重度/极重度SNHL患者有机会接受双耳CI,获得真正的双耳有效听力。

国产人工耳蜗除打破国外产品的价格垄断外,更需要打破技术垄断,首先亟需提高国产人工耳蜗产品质量。目前国产人工耳蜗投入临床使用时间尚短,其远期有效性、安全性和可靠性还有待评价。截止到2010年12月全球行CI患者总数已达20万例^[8]。我国两家自主研发的国产人工耳蜗均在2009年各自进行了第1台植入手术,迄今最长使用时间4年,使用者人数总和仅为千余例,悬殊的样本量和相对短的临床观察时间使得目前对国产人工耳蜗的评估尚显单薄。国产人工耳蜗产品的安全性和可靠性需要大样本、长时间的观察,还需对其近、远期有效性即疗效进行评估,因此我们倡议在全国范围内进行多中心、大样本、对照临床研究,将国产人工耳蜗与进口人工耳蜗同类产品进行比较,了解其优势及不足。目前,两家公司目前各自只有1种型号产品投入临床使用,种类单一,和国外人工耳蜗公司多规格、甚至个体化定制的产品还有相当的差距。今后应根据不同的听力下降特点和用户需求,提供多种选择,并预留产品升级可能,如适合以高频听力下降为主的短电极、适合耳蜗骨化患者的分离电极、自由选择体佩式或耳挂式言语处理器等。寻找和尝试新的生物材料,提高生物相容性,改善电极理化特性及实现电极载药等是

国内外生物工程学、材料学和耳科学目前研究的热点。

声调识别是国产人工耳蜗面临最需突破的关键技术。相关研究结果显示中国人使用进口人工耳蜗普遍存在声调感知障碍^[15, 16]和发声无音调^[17, 18]缺陷。进口人工耳蜗是基于英语和德语母语者设计研发的,而国产人工耳蜗的最大目标人群是中国聋病患者,他们日常使用的汉语是有声调语言,声调在语词中具有辨义作用^[19]。英语属于重音语言,两者在声学 and 语音学层次上有着明显的不同,心理声学的研究表明两者在听感知上也存在差异,当目标言语为汉语时,在嘈杂环境下更容易出现能量掩蔽(energetic masking)和信息掩蔽(informational masking)^[20]。声调是调式语言所特有的言语特征。汉语声调具有能区别意义的音高特征,主要取决于基音的频率。从声调最低音到最高音是“调域”,即基频(F0)的变化范围,一般占1个倍频程(octave)。汉语普通话的声调音位(phoneme)有4个,其中每个调位均含轻声作为变体(allophone)^[21]。影响声调感知的声学特征主要包括F0、时长和音高,其中以F0信息最为重要。声调感知的基础主要取决于F0,同时兼顾其他冗余信息,就语言学概念而言,声调变化就是在极短时间内F0的微小变化。由于人工耳蜗电极数目有限,每个电极承载的频域信息广泛、频率特异性较差,而时域信息和频域信息对汉语普通话声调识别具有协同作用^[22],因此需要提高刺激率以捕获更多时间信息,才能具有提高辨别频域微小变化的能力进而有利于识别声调。

人工耳蜗言语处理方案也称言语编码策略,是将声波转换成点脉冲信号的编码规则,是决定如何分析言语信号并如何刺激电极的操作程序,对提高人工耳蜗者言语识别能力起着决定性的作用^[23]。目前普遍采用的人工耳蜗连续相间采样(continuous interleaved sampling, CIS)语音处理策略算法能够使说英语和德语的患者获得较高的言语可懂度,但是对于母语为汉语的患者,其言语可懂度明显不及前者,特别是在声调识别方面,大部分CI者在安静的环境中基本具备健听者的言语识别能力,但进入嘈杂的环境,他们的言语识别能力远不及健听者^[20]。为了增强声调感知,目前杭州诺尔康公司正在由美国House研究所付前杰教授研发新的言语编码策略E-Tone,通过强调F0来增强对音调的感知,尚未市场化。REZ-1人工耳蜗采用了自主研发的M-Tone,临床研究表明成人聋患者术后90 d平均声调正确识别率达69.41%,且随着开机时间的增加,言语识别和声调识别能力均逐步提高^[24]。

为了开发更适用于声调语言的人工耳蜗言语处理方案,首先需要了解不同特征的声学信息在声调识别中所起的作用。言语信号从声学处理的角度可以划分为频域信息和时域信息;频域和时域信息内又各自包括其包络和精细结构。其中频域包络是指频谱中由共振峰组成的结构,频域精细结构是指频谱中的详细的频率信息,包括F0及其各次谐波^[25]。时域包络是指500 Hz以下时域信息,包含言语信号的时长信息、幅值包络及其周期性信息;时域精细结构(temporal fine structure, TFS)是指0.5~10.0 kHz的时域信息,体现了言语信号中瞬时的相位信息^[26]。近年来利用声嵌合技术研究发现,声调识别主要取决于细微结构,这一点与音乐感知的结果类似,而不象言语识别,后者主要依赖于时域包络信息。因此,增加人工耳蜗系统中有效的频道数将有助于尤其是噪声环境下的言语识别,而将人工耳蜗刺激中提供更多的细微结构信息可能会提高患者声调识别的成绩^[27]。于是,研究人员开始致力于开发能传递声音精细结构信息的人工耳蜗编码策略。2007年奥地利研究人员开发出精细结构编码策略(fine structure processing, FSP),也称为FS编码策略。该方案以现行的CIS为基础,将TFS信息引入人工耳蜗最顶部的1~3个通道,通过同时传输包络信息和快速变化的音调细节,更好地模拟声信号的自然处理过程。Riss等^[28]和Vermeire等^[29]跟踪性研究发现,引入精细结构信息的人工耳蜗编码策略有利于提高人工耳蜗使用者的言语识别成绩,这种作用在言语识别环境变差、难度增大的困难条件下尤为突出;但是人工耳蜗使用者需要一定时间逐渐学会,有效利用低频区域增加精细结构信息进行言语识别。且使用旧CI系统的患儿不需要进行再次手术,也可以通过选用新的言语处理器和人工耳蜗编码策略来获益^[30]。但是,另一些研究结果提示FSP对改善人工耳蜗使用者的言语识别能力没有太大帮助,特别是对于声调识别的改善程度不明显。Schatzer等^[31]评估FSP对讲广东话CI患者言语识别能力的影响,12例受试者的急性言语识别测试结果显示,声调识别平均成绩、噪声下言语识别测试平均成绩与使用CIS'编码策略时获得成绩无显著差异。辜萍等^[32]对汉语普通话成人CI患者研究发现,使用FS4编码策略对人工耳蜗植入者的音乐音高感知有较大帮助,而在汉语声调、声母和韵母识别方面,FS4和HDCIS编码策略的使用效果差异不大。Chen等^[33]对采用FSP的10例汉语普通话成人CI患者在开机后6个月进行研究发现,噪声环境下言语识别和声调感知有显著改善。由于前人在研究中均发现升级至FSP后的急性测试结

果先呈现下降趋势,因此,不能仅根据急性言语测试成绩推断出引入TFS信息的编码策略对改善声调识别能力没有帮助,有待对较大群体进行长时跟踪性研究后,最终获得FSP将对人工耳蜗使用者识别声调能力产生的影响作用和程度。

需要补充指出的是,在国产人工耳蜗效果评价中测试方法和材料的选择。对汉语普通话人工耳蜗植入者的评价中十分重要的项目就是普通话言语测试和生母、韵母和声调测试。郝昕^[34, 35]于2011年发表了《言语测听的基本操作规范》,但尚未形成全国施行的临床指南。目前各医院、研究所和康复机构并未采用统一的测试材料。言语测听材料的信度(可行性)、效度(可靠性)和敏感度(效能)是3项主要评价指标^[36]。张华等^[37]继续编制了一系列普通话言语测听材料(mandarin speech test materials, MSTMs)并对其进行计算机智能化以便更适用于临床应用。针对我国接受人工耳蜗者以儿童居多的特点,2008年张宁等^[38]参考美国印第安纳大学开发的英文版儿童词汇相邻性测试(lexical neighborhood tests, LNT)编制了汉语普通话儿童词汇相邻性单音节词表和双音节词表。这是一

种开放式的儿童言语测听方法,可用于CI患儿听觉言语评估。同年,曹永茂等^[39]编制了幼儿普通话声调辨别词表。同期,徐立等对讲汉语的CI患儿在声调构成与评价方法方面进行了系统的研究,提出了一套适宜的评价方法^[40]。制定并采用统一规范的言语和声调测试材料对进行大规模、多中心、对照临床研究是必要的。

4 总结

国产人工耳蜗的问世和推广使用打破了进口人工耳蜗20多年来在中国的价格垄断和技术垄断,造福了我国广大重度/极重度SNHL患者。但我们还任重道远,需要进行大规模、多中心、对照临床研究,对产品的安全性、可靠性和有效性进行近期和远期观察。并积极提高产品质量、增加产品种类来满足不同个体需求,关键是研发出适合于中国人汉语普通话的言语编码策略和配套产品,这将大大提高中国人的声调感知和言语识别,也可对音乐感知大幅提高。在国内同道、国外华人学者和民族企业的共同努力以及政府支持下,国产人工耳蜗必将日臻完善,与国外人工耳蜗媲美,并青出于蓝而胜于蓝。■

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学习班

深港合作颞骨解剖及耳显微外科培训班通知

为促进国内耳鼻咽喉—头颈外科学科的发展, 提高耳鼻咽喉科临床水平, 规范耳鼻咽喉科学相关诊疗技术, 传递最新的技术理念及基础理论, 香港中文大学-深圳市耳鼻咽喉研究所联合研究中心、深圳市龙岗中心医院耳鼻咽喉科医院将于2013年10月、12月分别举办第四届和第五届“颞骨解剖及耳显微外科”培训班; 届时将邀请国内知名耳科专家进行专题讲座、手术示教、一对一尸头解剖培训等。并对相关领域新进展进行广泛而深入的探讨。

本联合研究中心的颞骨解剖实验室配备国际先进的德国Leica M400E手术显微镜和美国Medtronic XPS3000耳鼻咽喉科动力系统及高清视频教学系统等设备, 并有充足的颞骨标本来源。此培训项目已连续举办三期, 深受广大学员的好评, 欢迎有一定耳显微外科基础的同道参加。详情请登录研究所网址: <http://www.szwghos.com>。可电话或Email索取纸质版通知。联系人: 马世博; 电话: 0755-28989999转6609, 15817469881; 传真: 0755-28981811; QQ: 1620582675; Email: 1620582675@qq.com。



诺尔康人工耳蜗残余听力保留技术和术后效果

戴朴, 王翠翠

【关键词】 耳蜗植入术 (Cochlear Implantation); 电极, 植入 (Electrodes, Implanted); 治疗结果 (Treatment Outcome)

人工耳蜗自应用以来已成为治疗重度-极重度感音神经性聋的有效方法。随着言语编码技术的进步、手术技术的不断完善及声电联合刺激模式下言语功能优势的体现,人们对人工耳蜗植入 (cochlear implantation, CI) 的有效性、安全性认识不断提高, CI 患者的选择标准也发生着变化,有残余听力的患者亦被列为CI 候选者。随着对CI 术后原有残余听力损失机制的不断认识及研究,研究者提出了一系列保护残余听力的措施及手术技巧,如蜗窗膜径路或蜗窗膜前下径路应用、柔手术技术 (soft surgery technique) 应用、糖皮质激素应用等,术后残余听力的保留率显著提高。

1 国外品牌人工耳蜗植入术后效果

人工耳蜗制造商致力于细小而柔软、弯曲性能好、对耳蜗结构创伤小的电极研发,即所谓的微创电极。澳大利亚Cochlear公司的Hybrid电极以浅植入为特征,电极长度为10 mm (Hybrid S) 或16 mm (Hybrid L),旨在保护耳蜗内的低频区。Iowa人工耳蜗临床研究中心的初步研究报告显示87例患者植入Hybrid S电极,98% (85/87) 术后即刻残余听力保留,随访3~60个月,91%患者残余听力不同程度保留,75%患者低频听力 (125~750 Hz) 平均阈值升高 < 30 dB^[1]。Poznan大学医学中心报道Hybrid-L的残余听力保留率为80.95% (17/21)^[2]。Advance Contour电极有22个刺激电极,植入后电极靠近蜗轴,植入深度17 mm,可避免电极植入过深,采用进极止芯技术 (advance off stylet technique, AOS) 可减少植入过程

对耳蜗内结构的损伤。Garcia-Ibanez等^[3]研究28例患者植入Advance Contour电极,术后6个月71%~86%患者低频 (125~1000 Hz) 残余听力保留,36%患者各频率阈值升高 < 10 dB。奥地利MED-EL公司研发的Flex soft系列电极,应用独特的Zigzag技术增加电极顶端的柔软性,在电极植入过程中减少推进力,降低对耳蜗内结构的损伤,以达到保护听力的目的。Flex Soft电极与该公司标准电极类似可植入蜗顶区域,实现耳蜗全覆盖,为患者提供更高质量的听觉效果。Bruce等^[4]研究14例患者植入Med-El Flex soft电极,术后随访1周~23个月,12例患者成功保留残余听力。Baumgartner等^[5]报道16例患者术前有残余听力, Flex soft电极植入后1个月,10例患者残余听力保留。Helbig等^[6]则报道77.3% (17/22) 患者术后4~33个月残余听力不同程度保留,其中18.2% (4/22) 患者低频残余听力阈值升高 < 10 dB, 40.9%患者阈值升高11~30 dB, 18.2% (4/22) 升高 > 30 dB。Flex EAS电极是MED-EL公司专为声电联合刺激 (electric acoustic stimulation, EAS) 模式植入设计,其植入深度不超过耳蜗底回。Arnoldner等^[7]报道11例患者植入Flex EAS电极后,所有患者的残余听力均保留,其中5例 (45.4%) 患者残余听力完全性保留 (低频听力平均阈值升高 < 10 dB), 6例 (54.5%) 部分保留 (有反应,但低频听力平均阈值升高 > 10 dB)。而Santa Maria等^[8]的研究中Flex EAS电极植入术后即刻残余听力 (250、500、1000、2000 Hz) 保留率为100%, 24个月后完全保留率为25%,部分保留率为12.5%,微保留率为37.5%,12.5%的患者残余听力完全丧失 (注:24个月时

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共随访8例患者，其中1例患者因其他原因死亡)。

但并非只有采用上述电极类型方可保留残余听力，也有研究表明应用标准电极亦可保留患者的残余听力。Brown等^[9]报道31例术前有残余听力的患儿采用柔手术技术植入HiFocus Helix或HiFocus Ij电极、Med-El Pulsar标准电极等，术后随访1~30个月，低频听力(250、500、1000 Hz)平均阈值升高18.5 dB，其中90.3%患者残余听力保留(低频听力平均阈值升高≤40 dB)，其中45.2%(14/31)的患者低频听力完全保留(低频听力平均阈值升高≤10 dB)，仅9.7%(3/31)患者残余听力未保留(低频听力平均阈值升高>40 dB或最大刺激无反应)，Kiefer等^[10]报道14例患者植入Med-El Combi 40+/40°M电极，术后85.7%(12/14)患者保留残余听力(平均阈值升高≤20 dB)，64.3%(9/14)患者残余听力完全保留(平均阈值升高≤10 dB)，中位阈值在250、500及1000 Hz分别升高15、17.5及5 dB。而Gstoettner等^[11]则报道植入Med-El Combi 40+电极的患者90.0%(9/10)低频听力保留(任一低频听力有反应)。Derinsu等^[12]的研究中31例患者经蜗窗膜径路植入标准电极(Med El Pulsar或Nucleus Freedom)，随访6~26个月后，27例(87%)患者低频残余听力(250、750 Hz)得以保留，11例(35.48%)患者所有频率听力均得以保留。

由于各研究之间样本量、植入电极类型、手术技巧、残余听力保留评定标准等方面存在着差异，故无法将他们进行比较，却给我们提供一个重要的信息：无论微创电极或标准电极均可实现残余听力的保留，保留率可达到50%以上。

2 国有自主品牌人工耳蜗

2.1 CI术后残余听力保留效果。诺尔康是目前应用最多的国有自主品牌人工耳蜗，其电极包括CS-10A电极和参考电极，前者长约23.0 mm，直径0.85 mm，包含24个接触点。其临床试验以2009年12月23日第1例植入术为起点，手术在5家医院开展。120例成人和儿童临床试验植入者中，53例术前具有残余听力(250、500及1000 Hz处的残余听力均≤115 dB)，术后1个月36例(68%)保留残余听力，术后24个月(26例成人接受了测试)，46.15%(12/26)患者保留残余听力，提示诺尔康CS-10A植入体具有保留植入者残余听力可能。

2.2 解放军总医院海南分院行CI术后效果。作为国内重要的CI中心之一，解放军总医院海南分院自2012年2月14

日起开始CI工作，共植入14例诺尔康人工耳蜗，其中7例患者术前具有的较好低频残余听力。手术由同一术者完成，术中遵循柔手术技术原则，采用4 cm左右微创切口，肌筋膜瓣切口与皮肤切口相错1 cm以上，根据需要开放乳突腔，开放面神经隐窝，保证蜗窗龛全部或大部分暴露，磨去蜗窗龛前、上缘，经蜗窗膜径路(4例)或蜗窗膜前下(3例)耳蜗开窗技术植入电极，过程顺利，电极植入完全，植入过程中鼓室内应用激素和透明质酸凝胶，未发生任何并发症。7例患者术前125、250、500及1000 Hz阈值平均值分别为54.1、67.8、85及96.4 dB，中位数分别为45、70、85及95 dB，术后1~4周测试患者术侧裸耳听力，7例患者均有不同程度残余听力保留，其中5例患者术侧低频残余听力完全保留(低频PTA升高≤10 dB)，2例部分保留(低频PTA升高>10 dB)，无患者低频残余听力完全丧失(表1，图1)。残余听力的保留率与既往报道一致。提示在柔手术技术等微创CI技巧的基础上，诺尔康CS-10A植入体具有保留植入者残余听力可能。本组3例患者术前高频区(2000、4000、8000 Hz)听力水平尚可(高频听阈平均值81.7、100及76.7 dB)，电极植入后高频区对最大声刺激无反应，而低频区听力能够很好的保留，这与其他研究中心的报道一致。

诺尔康人工耳蜗作为目前应用最多的国产品牌人工耳蜗，具有保护患者残余听力的能力。其植入体适合做微创径路手术，耳蜗电极较为柔软。电极植入时经耳蜗开窗或蜗窗径路均可，经初步观察，经蜗窗径路的诺尔康人工

表1 7例患者各频率阈值变化情况

	< 10 dB	11~20 dB	21~40 dB	≥41 dB或最大刺激未引出
125 Hz	4	1	2	0
250 Hz	6	1	0	0
500 Hz	5	0	0	2
1000 Hz	2	1	1	3
2000 Hz	3	0	0	4
4000 Hz	3	0	0	4
8000 Hz*	0	0	0	4
PTA (125、250及500 Hz)	5	**	**	**
PTA (125、250、500及1000 Hz)	4	1	**	**

*：7例患者术前有3例在8000 Hz处最大输出无反应。

**：7例患者中有2例术前在500及1000 Hz处对声刺激有反应，术后最大输出无反应。

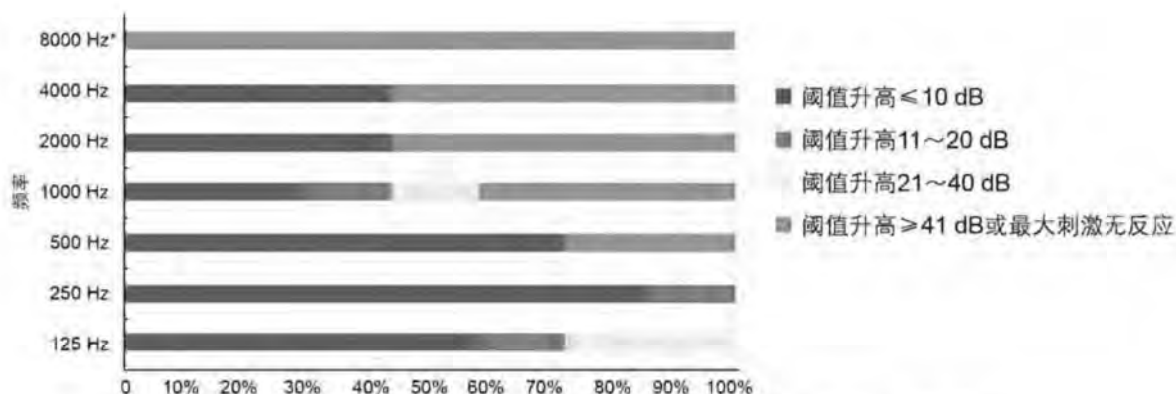


图1 各频率残余听力保留情况 (n=7)。*: n=4, 7例患者中3例术前在8000 Hz处最大输出无反应

耳蜗电极植入更为顺利。本项观察将有利于国产人工耳蜗在具有较好残余听力的患者中使用,特别是在高频陡降型耳聋患者、老年性聋患者、听神经病及需要双侧植入的耳

聋患者群体中,应用微创手术技术植入国产诺尔康耳蜗电极,对于保护耳蜗内残余正常结构有重要意义,对于患者远期效果、术后康复、言语功能的提高有潜在益处。■

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创造中国品牌人工耳蜗的千里之行

曾凡钢

[关键词] 耳蜗植入物 (Cochlear Implants); 神经电子 (neural prostheses)

从1984年美国食品药品监督管理局批准世界第1个商业装置起,人工耳蜗已让三十多万聋人走出无声世界,其中一半聋儿不仅能听会说,而且成功进入主流社会,但对其工作和贡献的认同却姗姗来迟,最值得褒奖的人工耳蜗加州三剑客(洛杉矶的House,斯坦福的Simmons和旧金山的Michelson)已过世。2013年才把有“美国诺贝尔”之称的拉斯克奖授予了还在世的另外3位人工耳蜗研究者(澳大利亚的Clark,奥地利的Hochmair和美国的Wilson)。人工耳蜗得诺贝尔奖的呼声很高,或许就在2013年。

中国的人工耳蜗研发始于20世纪70年代末,几乎与国际同步^[1]。中国医学科学院北京协和医院的邹路德、王直中和曹克利等研发的单道人工耳蜗有近300人使用。复旦大学附属眼耳鼻喉科医院王正敏等也研制出单、多道装置,使用人数上百。另外兰州空军医院雷汉飞,陕西省人民医院高荫藻,湛江中心人民医院陈成伟等先后开发出国产人工耳蜗,进行了临床人体实验。这些早期的研发和临床工作虽然没有在商业上获得成功,但为人工耳蜗造了势,让医师、患者和公众了解并熟悉这项新技术,做出极有价值的贡献。21世纪初国产人工耳蜗的商业化进入高潮,从南到北近10家企业在开发产品。至今为止已有上海力声特和杭州诺尔康在2011年获得中国食品药品监督管理局的成人植入许可证;诺尔康更是于2012年获得欧盟认证及2013年获得中国药监局的1~6岁儿童植入许可证。

笔者从事人工耳蜗的研究工作时间较长,与国内外的学术界、工业界、患者及投资界交往甚多。承蒙《中国医学文摘耳鼻咽喉科学》邀请,特作此文,一是回顾自己的心路历程;二是总结经验教训,供同行参考借鉴。

笔者1978年进入中国科技大学电机工程系学习,受张作生教授“生物电子学”课程的影响很深,他说“下个

世纪是生物学的世纪”,所以在报考硕士研究生时更改了专业方向。1982年进入中国科学院上海生理所师从秦治纯、陈俊强和梁之安3位教授,硕士论文研究汉语识别的时间因素,就此与人工耳蜗结缘。1987年在纽约雪城大学读博士,师从Turner教授,主修听觉生理和心理。1990年在洛杉矶House耳科研究所做Shannon教授的博士后,正式从事人工耳蜗研究。那时人工耳蜗研究并非主流,名声(指研究质量)不佳,听力学权威Zwislocki曾告诫“凡钢,人工耳蜗可是黑洞,进去可能就出不来了”。多年以后,人工耳蜗不仅商业成功而且成为研究热点,Turner和Zwislocki自己也都陷进了这个“黑洞”。

20世纪90年代初的House耳科研究所是钱多人少,资源丰富(成文之际,惊闻1946年成立的洛杉矶House耳科研究所宣告破产,真可谓创业难,守业更难),Shannon又是无为而治的高手,所以我进步很快,在迅速对人工耳蜗从基础到临床有了比较全面和深入的了解后,即刻做出一些创新工作,获得研究经费并建立自己的实验室。

那时国内到House耳科进修来访的学者也比较多,如姜泗长、杨伟炎、方耀云、韩德民等。1993年郑州医科大学附属第一医院耳鼻咽喉头颈外科的董明敏在House耳科研究所进修,我向她提起做国产耳蜗的念头,计划先举办会议,她爽快的提出在郑州举办并给予支持。于是,我们立即邀请了连续相间采样(continuous interleaved sampling, CIS)发明人杜克大学Wilson,电极专家加州大学Rebcher和Shannon(图1),科利耳技术总监Patrick,澳洲听力服务处Higgins和刚成立的AB公司首席科学家Loeb及夫人(他们都是第1次到中国,不敢喝水,整天啤酒解渴)。他们还到上海拜访生理所和复旦大学附属眼耳鼻喉科医院(图2),到北京参观协和医院和解放

曾凡钢

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图1 1993年曾凡钢、Rebcher、Shannon和Wilson（从左到右）在中国西安
 图2 1993年参观复旦大学附属眼耳鼻喉科医院，自左至右为江畔、Shannon、王正敏和曾凡钢
 图3 1993年参观解放军总医院并与科室人员合影。自左至右为瞿所强、方耀云、Shannon夫人、姜泗长、Shannon、黄德亮、张素云、曾凡钢、于宁
 图4 1993年郑州国际电子耳蜗听力语言学研讨会开幕式
 图5 1996年House耳研所和AB公司共同开发出的4道、模拟CIS人工耳蜗样机
 图6 1996年曾凡钢和邓元诚（右）在广东新会考察

军总医院（图3）。他们与参加郑州会议的近百人，包括董民声、吴展元、曹克利、李华伟等会上会下均进行了充分的交流（图4）。那次郑州会议至少让3家公司受益，推动了人工耳蜗在中国的进程和发展。

首先，科利耳对中国市场的潜力和存在的障碍作出了正确的判断和决策。他们意识到开发中国市场的瓶颈不是耳科医师，而是听力学基础建设的缺乏。这才有了日后与首都医科大学附属北京同仁医院、华西医科大学共办听力学学习班之举。从1995年植入第1支产品起，科利耳通过捐赠和国家项目，占据了中国市场大半江山。现在中国市场对科利耳全局和未来发展至关重要：就去年来讲，如果没有中国贡献的话，其市场增长率就会从16%降至4%。

其次，1993年刚成立的AB公司也获益良多。在郑州会议上，大家达成一个共识，应尽快开发一个符合中国市场价格和生产能力方面的需求的人工耳蜗^[2]。回美后，AB公司和House耳科研究所签了共同研发一个低价高效人工耳蜗的合同，由笔者担任项目负责人。历时3年耗资百万

美元之后，于1996年完成样机（图5），并获得2项专利（US 05549658和US 05749912），由AB和House耳科研究所共同拥有。笔者兴致冲冲与国内联系，希望在国内生产制造。因为科利耳和AB的基本生产技术都来自于心脏起搏器，通过首都医科大学附属北京同仁医院的邓元诚和卫生部医疗器械司找到了宝鸡和新会两家起搏器厂家。邓元诚还特地陪我在1996年底去新会的康明生物医学工程公司考察（图6），并协助开展中国聋人市场调查工作。中国方面十分积极和配合，就在万事俱备只欠东风时，AB公司却给康明开出非常苛刻的转让条件力图让其知难而退，但康明出乎意料接受了条件，最后AB公司只能表明该技术坚决不会转让，公司成本、技术和市场分析的负责人认为这款产品如果转给中国将会对公司自己开发的产品不利，甚至造成日后竞争。之所以说AB受益，是因为通过这个合作项目，我们发现并帮助修改了AB有缺陷的电流源，改进言语处理器，使其舍弃很难生产但又作用不大的“蘑菇状”电极。

令人失望的是在技术转让过程中，House研究所管理层始终倾向于AB公司。于是1998年笔者离开House耳研所到了东岸的马里兰大学。2年后又回到西岸，出任尔湾加州大学耳鼻咽喉头颈外科研究主任。一方面研究增进人工耳蜗使用者的汉语声调识别，另一方面积极寻找新的合作伙伴。接触了20余家中外投资者后选定与浙江李方平和加拿大梁涛合作，2006年成立诺尔康公司。研发中心在加州，以便和世界水平接轨；而生产基地在杭州，希望能充分利用国内政策、土地和劳动力等资源优势。创始之时，研发中心有孙小安、陈洪斌、付前杰和笔者，还有1位电极专家和1位芯片专家及李方平之子李楚。从前同AB公司的合作虽然以失败告终，却给这次创业留下了宝贵财富，其中最重要的是人脉关系。在笔者负责诺尔康研发到获得许可证的5年里，邀请的顾问有四、五十人之多，他们来自各行各业，其中许多可称得上“身怀绝技”独一无二的专业人士。一位前耳蜗公司的顾问对我们当时的设计 requirements 是“既然耳蜗市场已趋成熟，你们的产品出手的时候就要做到十全十美”。我们力争完美，但由于人力、物力、财力和时间所限，只能尽全力做到足够好。正因为很多关系和人脉是直接或间接在郑州会议建立的，所以从这个意义上讲诺尔康是郑州会议第3个也是最大的受益者。

目前国产耳蜗与国际水平主要差距是“国内电子技术、材料和工艺的落后”^[3]。美酒长1993年4月10日给我

来信对早期国产耳蜗也作出类似评价“手术不难，而器械不好”。对于国内材料和工艺的落后我自己也有切身体会。2005年一位朋友告之北京有家公司可以做防湿激光封装，其产品都上了神舟飞船。联系到该公司负责人，叫上曹克利和王秋菊一起去实地考察。这位负责人带着我们在北京城郊转悠半天后，最后进了一家餐馆。秋菊心直口快“我们想看你的技术，不稀罕你这顿饭”。我们猜测其实他们没有这技术，走的是进口组装这条路。否则怎么到现在国产心脏起搏器还未现身呢？

人工耳蜗进入欧美市场30年，价格只升未降，但为什么最近仅在中国市场大幅降价？因为有了中国自主品牌的人工耳蜗。虽然目前没有一家国产耳蜗公司在赢利，投资人也没有获利，但国产人工耳蜗初步成功已经让中国聋儿间接受益：同样价钱在3年前只能买1个耳蜗，如今可买3个。这就是对创建中国品牌人工耳蜗的工作最好回报。所以创建中国品牌人工耳蜗的工作一定要坚持，更需要大家支持，否则耳蜗价钱降了还会再升回来。

放眼世界，人工耳蜗如今是神经电子行业的领头羊。中国已有非常好的临床基础和科研资源，国产人工耳蜗已经有了一个良好开始，正在步入正轨，肯定会有一个美好的未来。我希望国产人工耳蜗不断完善，提高可靠性，增强稳定性，提升术前、术中和术后服务水平，以便尽快直接为中国乃至世界聋人服务。这迢迢千里才刚刚走完第一步，大家仍需努力。■

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杭州诺尔康神经电子科技有限公司
协办



补，切取耳垂脂肪粒，在视频耳内镜直视下制作鼓膜穿孔边缘移植床，将修剪成合适大小的脂肪粒塞入穿孔处，尽量呈哑铃状嵌于穿孔处。随访6-12月。结果 17例用该方法进行鼓膜修补的患者，有一例患者脂肪粒掉入鼓室，穿孔未愈合，两例患者术后半年愈合鼓膜变薄，其中一例重新用脂肪粒修补已随访3月，愈合佳。穿孔愈合率达到945%。结论 视频耳内镜下脂肪修补鼓膜，对穿孔面积小于25%的鼓膜穿孔，在严格掌握手术适应症的情况下，是一种简单、安全、有效的方法。

四种品牌人工耳蜗植入的临床体会

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目前人工耳蜗有四种品牌，十年前还有法国人工耳蜗，因为产品技术原因，于2002年退出市场，现有国外品牌三种，分别为澳大利亚科利耳公司的人工耳蜗、奥地利MED公司的人工耳蜗、美国ADVANCED BIONICS公司的人工耳蜗，国内已推向市场的诺尔康公司的人工耳蜗，我院对不同需求的患者进行各个品牌的人工耳蜗植入，均受到较好疗效。对于不同品牌的产品其手术的临床体会有所不同，特提出与大家分享。

我们在250多例患者人工耳蜗的手术中，选择澳大利亚产品的最多；奥地利产品次之；美国产品较少，诺尔康公司的产品最少，究其原因有如下几点，（1）销售能力：澳大利亚科利耳公司销售能力较强，奥地利MED公司次之……；（2）累加病人数：这与购买普通商品一样，有个群集效应，买的人多，货物一定不会差；（3）售后服务能力：这跟售出数量有一定关系，同时与公司售后服务理念关系密切；（4）与产品在手术中的难易度有关：澳大利亚科利耳公司的主导产品手术极其方便，插入人工耳蜗电极简便、安放植入体容易，可以大大缩短手术时间，有好多时候，完成整个手术过程大约半个小时，美国ADVANCED BIONICS公司的次之，诺尔康还行，奥地利稍慢，但最新奥地利产品吸取他家优点，改进后新产品基本与美国相似；（5）与医生的偏好有关：其实奥地利产品也是很有特色的产品，常常在医生熟练后会偏好她，MED+10电极长度为31MM，人类耳蜗两圈半总长度为32毫米，有一定的挑战性，医生需要有一个相当时间的磨合掌握过程，才能达到全植入。而一般医生大多数喜欢澳大利亚耳蜗，除了电极插入方便、植入体安放容易外，其电极更靠近蜗轴的螺旋神经节；（6）术中检测的把握度也是医生考虑产品的另一个原因：至今为止，澳大利亚科利耳公司的术中NRT检测应用最早，已有8年历史，只要术中能引出NRT，该患者术后一定能听到，而且术中NRT的阈值越低，患者术后听觉效果越好，有些软件却显示术中、术后不稳定状态，我国诺尔康还没有NRT技术，术中无法知晓术后听觉效果；（7）价格因素：国际上三家品牌的价格极为相近，国产诺尔康价位最便宜，只有进口的一半，现在卖价是七万多，有些患者基于家庭经济承受力，会越来越多考虑国产品牌。

对于每家品牌人工耳蜗术后的效果，也是多数医生较为关注的事，遗憾的是：至今为止还没有可靠的数据证明国外三家公司的效果排序，原因是影响听觉效果的因素十分繁多，采用单一因素对照意义不大，而且手术要达到标准化也有一定困难。最重要的是患者基础听力与年龄相同的配比研究机会太少。但，根据我们10多年来观察，孩子在语言交流方面，目前国际上的三家耳蜗品牌都能达到较为满意的交流能力，国产诺尔康耳蜗术后康复时间未达到五年，其效果还有待于观察。

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