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Original Article

Evaluation of Safety and Effectiveness of the LISTENT LCI-20PI Cochlear Implant in Post-Lingually Deafened Individuals

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BACKGROUND: Cochlear implantation is safe and effective in restoring hearing and speech recognition abilities for individuals with severe to profound sensorineural hearing loss. This prospective multicenter clinical trial was conducted to evaluate the safety and effectiveness of a novel cochlear implant (CI) system, the LISTENT LCI-20PI device, in post-lingually deafened individuals.

METHODS: The LCI-20PI CI system was implanted in 70 individuals 6-68 (27.7 ± 14.0) years old. The safety and effectiveness of the devices were evaluated during a 1-year follow-up.

RESULTS: Electrically evoked compound action potential were successfully measured in 98.6% (69/70) of subjects. Electrode impedance was within normal limits of 0.7-20 kOhm in 99.8% of cases. All subjective T/C levels were successfully measured on the selected 12 electrodes of the LCI-20PI recipients at device activation and 1 month, 3 months, 6 months, and 12 months post-activation. The mean open-set monosyllabic-word recognition score (MRS), disyllabic-word recognition score (DRS), and sentence recognition score (SRS) were 28.9 ± 21.0%, 30.3 ± 25.8%, and 36.3 ± 36.3% at 6 months post-activation, and 57.1 ± 21.1%, 69.1 ± 24.4%, and 89.7 ± 21.5% at 12 months post-activation, respectively. Sex, side of the ear implanted, residual hearing, duration of deafness, etiology of deafness, and surgeon did not influence postoperative speech recognition performance.

CONCLUSION: The novel LCI-20PI CI device is safe and effective in post-lingually deafened recipients.

KEYWORDS: Safety, effectiveness, cochlear implant, speech recognition, LCI-20PI

INTRODUCTION

Hearing loss is a significant global health burden. According to the World Health Organization (WHO), 430 million people had moderate or more severe hearing loss in the better hearing ear around the globe. Since China accounts for approximately 20% of the world's population, the social and economic impact of hearing impairment is magnified by this large population. The China Disabled Persons' Federation reported in 2006 that the number of persons with hearing disabilities was 27.8 million in China. In addition, the number of deaf newborns is 10 000-30 000 every year in China.

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Cochlear implantation is safe and effective in restoring hearing and speech recognition abilities for individuals with severe to profound sensorineural hearing loss. All cochlear implant (CI) products used in China before 2010 were imported. Chinese doctors and engineers have made great efforts to design and produce domestic CI devices, providing an alternative for individuals with profound sensorineural hearing loss.[1] At present, 2 Chinese CI manufacturers have received state FDA approval, including Nurotron and LISTENT, the device presented here.[2] LISTENT Company (Shanghai, China) was established in 2004 after CI technology was transferred from Fudan University.[1] LISTENT is dedicated to developing low-cost and high-performance CI systems to benefit individuals with profound hearing loss in developing countries. The LCI-20PI device is a novel CI system consisting of the LCI-20PI implant and the LSP-20A sound processor. It is a 22-channel device housed in a titanium case with a 17.6-mm electrode array. A clinical trial was designed and conducted to assess whether the LCI-20PI device met the National CI standard during a 2-year period since 2016. In this prospective clinical trial, 70 post-lingually deafened individuals received LCI-20PI CIs in 4 medical centers and a 1-year follow-up was completed. In this study, all clinical data associated with the safety and effectiveness of LCI-20PI CIs in all 70 recipients were presented. The clinical trial registration number is ChiCTR2200067091.

METHODS

Study Design

This was a prospective, single-arm, multicenter clinical trial to evaluate the safety and effectiveness of LCI-20PI CIs in post-lingually deafened individuals. This trial was conducted at Eye & ENT Hospital of Fudan University, Union Hospital of Tongji Medical College, Shanghai Ninth People's Hospital, and Shanghai Xinhua Hospital. The protocol was in accordance with the Helsinki Declaration and was approved by the local ethics committee at each clinical site. The Ethics Committee of Fudan University Eye & ENT Hospital approved the study (approval No.: 2015043, date: 2016/1/12). All individuals or their guardians provided written informed consent. Enrollment started in January 2016 and finished in October 2016. The last follow-up was completed in December 2017.

The sample size was calculated by the following formula[3]

$$n=\frac{\left[\mu_{1-\alpha}\sqrt{p_0\left(1-p_0\right)}+\mu_{1-\beta}\sqrt{p_T\left(1-p_T\right)}\right]^2}{\left(p_T-p_0\right)^2},$$

where p_0 was the expected proportion of 70% according to CI effectiveness criteria of the Chinese National Medical Products Administration (CNMPA).[4] P_T was the pre-study estimate of the proportion to be measured. Based on pre-study estimates, p_T was set at 85%. Type I error rate (α) was set at 0.05 using 2-sided tests, therefore $\mu_{1-\alpha}$ was 1.96. Type II error rate (β) was set at 0.2, therefore the statistical power was 0.8 and $\mu_{1-\beta}$ was 0.842.

$$N=\frac{\left[1.96\times\sqrt{0.7\times\left(1-0.7\right)}+0.842\times\sqrt{0.85\times\left(1-0.85\right)}\right]^2}{\left(0.85-0.7\right)^2}=63.88\approx 64$$

The loss-to-follow-up quotient was estimated to be 10%. Therefore, the sample size in this clinical trial was determined to be 70.

The LCI-20PI Device

The parameters of the LCI-20PI electrode array were described in a previous study.[5] The LCI-20PI electrode array is precurved with 19 half-ring contacts facing the modiolus. The surface area of the apical 1-8, middle 9-19, and basal 20-22 contacts is 0.21, 0.28, and 0.56 mm,[2] respectively. The LCI-20PI implant has 2 extracochlear common electrodes. The LCI-20PI CI system can perform electrically evoked compound action potential (ECAP) testing through neural response detection (NRD) software. Electrically evoked compound action potential is a measure of synchronous VIII nerve activity elicited by electrical stimulation.

The LCI-20PI CI system adopts the LISTENT continuous interleaved sampling (L-CIS) strategy, which is based on the continuous interleaved sampling (CIS) strategy.[6] The process of the L-CIS strategy is as follows: the digital audio signal first passes through a set of bandpass filters, and the envelope is extracted through full-wave rectification and low-pass filtering. Secondly, the output signal from low-pass filtering is decimated and gained. Finally, the signal is non-linearly compressed and mapped to an acceptable amplitude range, and then it can be encoded and sent out through the transmitting coil. The L-CIS strategy recognizes the Mandarin Chinese 4-tone as follows: the highest single- and total-channel stimulation rates are 2K Hz and 15K Hz, respectively. The minimal stimulation pulse widths are 32 μs. Stimulation pulse amplitude is 18~1750 μA. Stimulation amplitude is expressed in the current level (CL). The following conversion was used, where *I* is the current in μA: $I=17.5\times 100^{CL/255}$. The CL ranges from 1 to 255 current units, which corresponds to electrical currents from 18 μA to 1.75 mA.

Participants

Seventy post-lingually deafened individuals, 6-68 (27.7 ± 14.0) years old, received the LCI-20PI CI system. Enrollment was limited to individuals who met the following inclusion criteria: 6 years of age or older; post-lingual deafness; bilateral severe-to-profound sensorineural hearing loss with an average hearing threshold >80 dB at 0.5, 1, 2, and 4 KHz; no improvement or poor speech recognition ability after 3 months of hearing rehabilitation with hearing aids; no history of cochlear implantation; native mandarin language speech ability before deafness; no history of cognitive impairment; open-set speech recognition score with bilateral hearing aids less than 50%; no abnormal findings on temporal bone computerized tomography (CT); and magnetic resonance imaging (MRI) except large vestibular aqueducts. Individuals were excluded from the study if they met any of the following exclusion criteria: conductive or retrocochlear auditory disorders; cochlear anomaly; active middle ear infection;

MAIN POINTS

- A novel LISTENT LCI-20PI cochlear implant device was implanted in 70 post-lingually deafened recipients in this prospective clinical trial.
- The novel LCI-20PI cochlear implant device proved to be safe and effective in post-lingually deafened recipients.

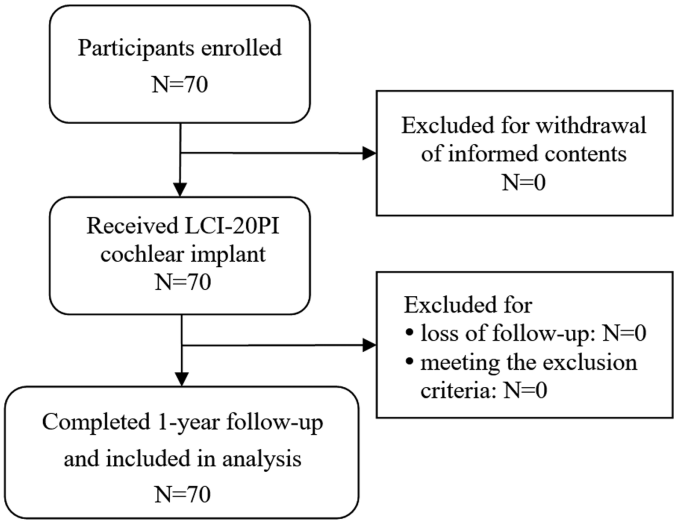

Figure 1. Flow diagram.

intolerance of the materials used in the implant (medical-grade silicone, platinum); organic brain dysfunction; unrealistic expectations on the possible benefits of CI devices; any physical, psychological, or emotional disorder that interferes with surgery or the ability to perform on test and rehabilitation procedures. Medical data of the subjects were acquired, including clinical manifestations, radiological image findings, preoperative and postoperative audiological evaluations, surgical procedure, adverse events related to surgery, or CI devices. Figure 1 provides the study flowchart.

Evaluation of Safety of the LCI-20PI Device

According to CI safety criteria of CNMPA,[4] evaluation of the safety of LCI-20PI devices was conducted. (1) Location of the electrode array was assessed by postoperative cochlear view radiography.[7] (2) All the subjects underwent routine blood tests, liver function tests, and kidney function tests to confirm normal functions of the liver and kidney preoperatively and postoperatively. (3) All adverse events related to CI devices or surgery were described. The primary safety endpoint was the number and proportion of individuals experiencing an adverse event, defined as any surgical and/or device-related event. The adverse events include vertigo, dizziness, tinnitus, or balance problems that did not exist preoperatively or worsened postoperatively, facial nerve problems including injury and unintended stimulation, meningitis, perilymphatic fistulae, skin flap problems, implant migration/extrusion, and device-related/programming problems.

Evaluation of the Status of the LCI-20PI Devices: CI Device Testing and Fitting

To evaluate the status of the LCI-20PI devices, CI device testing and fitting, including measuring electrode impedances, electrically evoked compound action potential (ECAP), subjective thresholds (T levels), and subjective comfort levels (C levels), were conducted. (1) Electrode impedance was recorded in kOhm (kΩ) for each electrode along the array from apical electrode 1 (E1) to basal electrode 22 (E22) with monopolar 1+2 (MP 1+2) stimulation mode intraoperatively, at device activation and 1 month, 3 months, 6 months, and 12 months post-activation. Monopolar 1+2 stimulation mode measured the impedances between each intracochlear electrode and the 2 extracochlear electrodes. The normal range of electrode impedance was 0.7-20 kOhm. A short circuit was defined as low impedance (<0.7 kOhm), and an open circuit was defined as high impedance (>20 kOhm). (2) ECAP testing was conducted through NRD software intraoperatively in all the subjects. (3) Subjective T/C levels of behavioral responses elicited by electrical stimulation with LCI-20PI devices were recorded along the array from apical electrode 1 (E1) to basal electrode 19 (E19) at 12 selected electrodes (E1, E3, E4, E5, E7, E8, E9, E11, E13, E15, E16, and E19) at device activation, and 1 month, 3 months, 6 months, and 12 months post-activation. Dynamic range was between T and C level.

Evaluation of Effectiveness of the LCI-20PI Devices: Audiological Evaluation

The audiological evaluation includes average hearing thresholds at 0.5, 1, 2, and 4 KHz and speech recognition scores. Monosyllabic-word recognition score (MRS), disyllabic-word recognition score (DRS), and sentence recognition score (SRS) were evaluated with Mandarin speech test materials (MSTMs) in quiet.[8] Each list of the MRS test contains 50 monosyllables. Each list of the DRS test contains 50 disyllables. Each list of the SRS test contains 10 sentences with 50 key words. Mandarin speech test materials contain 10 equivalent lists of MRS and DRS tests and 15 equivalent lists of the SRS test.

Preoperative speech recognition scores were obtained under quiet conditions with hearing aids. The CI device was activated 4-6 weeks postoperatively. Postoperative speech recognition scores under quiet conditions were obtained at 6- and 12 months post-activation. The MSTMs were presented to the implanted ear with CI aiding via a loudspeaker. An ear plug was placed in the contralateral ear, and masking was used when appropriate. To avoid the influence of memory, different equivalent lists of MRS, DRS, and SRS tests were used at different time points.

Evaluation of Possible Influencing Factors of Postoperative Speech Recognition Performance

To evaluate the possible influencing factors of postoperative speech recognition performance, MRS, DRS, and SRS at 12 months post-activation were compared between male and female individuals, between left-ear-implanted and right-ear-implanted individuals, between individuals with preoperative average hearing threshold ≤100 dB and those with preoperative average hearing threshold >100 dB without hearing aids, between individuals with preoperative average hearing threshold ≤80 dB and those with preoperative average hearing threshold >80 dB with hearing aids, between individuals with a short duration of deafness (<10 years) and those with a long duration of deafness (≥10 years), among individuals with different etiology (genetic, sudden hearing loss, ototoxic, infectious disease, or unknown), and among individuals in the 4 medical centers.

Statistical Analyses

Nonparametric tests were chosen because of the non-normal distribution of all speech recognition data, most of the impedance data, and some T/C level and dynamic range data among the subjects (Kolmogorov–smirnov test, $P < .05$). Mann–Whitney *U*-test was used to compare 2 groups. Kruskal–Wallis test was used to compare 3 or more groups. Statistical significance was accepted at the level of $P < .05$. SPSS version 26 software (IBM Corp., Armonk, NY, USA) was used for the statistical analyses.

Table 1. Individuals' Characteristics

Total	**70 (100%)**
Sex	
Male	39 (55.7%)
Female	31 (44.3%)
Age (years old)	
8-17	21 (30%)
18-29	22 (31.4%)
30-39	9 (12.9%)
40-49	13 (18.6%)
50-59	4 (5.7%)
60-69	1 (1.4%)
Ear implanted	
Left	25 (35.7%)
Right	45 (64.3%)
Duration of deafness	
<10 years	36 (51.4%)
>10 years	29 (41.4%)
unknown	5 (7.1%)
Etiology of hearing loss	
Genetic	14 (20%)
Sudden hearing loss	5 (7.1%)
Ototoxicity	9 (12.9%)
Infectious disease	3 (4.3%)
Unknown	39 (55.7%)

RESULTS

All 70 subjects underwent LCI-20PI implantation and completed assessment for safety and effectiveness of CI devices preoperatively and during 1-year postoperative follow-up. The individuals' characteristics are illustrated in Table 1.

Evaluation of Safety of the LCI-20PI Device

The cochlear view radiographs showed that the electrode arrays were inserted into the cochleae of all recipients, and no migration or extrusion of implants was observed (Figure 2). No damage to the liver and kidney was revealed based on the blood tests. No major adverse events such as meningitis, perilymphatic fistula, facial nerve palsy, or stimulation were demonstrated. A total of 15 adverse events were reported (Table 2) to be related to the device or surgical procedure.

Evaluation of the Status of the LCI-20PI Devices: Cochlear Implant Device Testing and Fitting

Electrically evoked compound action potentials were successfully measured in 98.6% (69/70) of recipients intraoperatively. In all 70 subjects, 9240 electrode impedance measurements were obtained on the intracochlear 22 electrodes of the LCI-20PI CI intraoperatively, at device activation and at 1 month, 3 months, 6 months, and 12 months post-activation. Among the impedance measurements, 99.8% (9222/9240) were within normal limits of 0.7-20 kOhm. The impedances of 3 electrodes (E22 in No. 18 patient, E10 in No. 32 patient, and E22 in No. 38 individual) exceeded 20 kOhm intraoperatively, at device activation and at 1 month, 3 months, 6 months, and 12 months post-activation. The incidence of the LCI-20PI CI device having at least one short or open circuit was 4.3% (3/70). The average electrode impedances were 3.62 ± 1.48, 7.59 ± 1.58, 7.42 ± 1.64, 8.02 ± 2.68, 8.02 ± 2.68, and 8.12 ± 2.27 kOhm intraoperatively, at device activation and at 1 month, 3 months, 6 months, and 12 months post-activation, respectively. The electrode impedances increased rapidly during the first 4-6 weeks following cochlear implantation and then gradually stabilized (Figure 3).

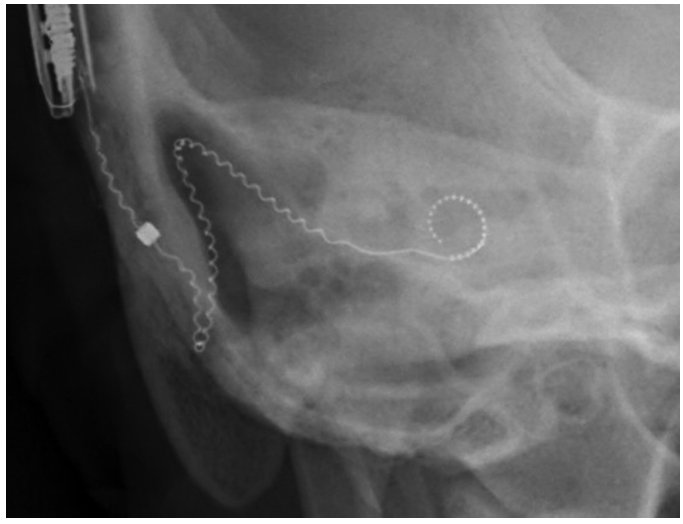

Figure 2. The cochlear view after cochlear implantation (male, 11 years old, left), completed electrode insertion was achieved.

The subjective T/C levels were successfully measured on intracochlear electrodes 1, 3, 4, 5, 7, 8, 9, 11, 13, 15, 16, and 19 in all 70 recipients at device activation and at 1 month, 3 months, 6 months, and 12 months post-activation. The T/C levels increased rapidly in the first 3 months post-activation and then gradually stabilized (Figures 4 and 5). Dynamic ranges increased rapidly in the first month post-activation (Figure 6).

Evaluation of Effectiveness of the LCI-20PI Devices: Audiological Evaluation

The individuals' average hearing threshold at 4 frequencies (0.5, 1, 2, and 4 kHz) were 106.8 ± 7.9 dB, 41.9 ± 7.1 dB, and 37.3 ± 5.4 dB at preoperative and 6- and 12 months post-activation testing, respectively. In 98.6% (69/70) of individuals, the average hearing threshold was less than 50 dB at 6- and 12 months post-activation.

Table 2. Number and Percentage of Adverse Events Observed for LCI-20-PI Recipients

Event	**Number of Events**	**Number of Subjects with Events**	**Percent of Subjects**	**Percent Resolved**
Ear pain	1	1	1.4%	100%
Dizziness	6	6	8.6%	100%
Vertigo	2	2	2.9%	100%
Wound infection	4	4	5.7%	100%
Poor wound healing	1	1	1.4%	100%
Wound pain	1	1	1.4%	100%
Total	15	15	27.1%	100%

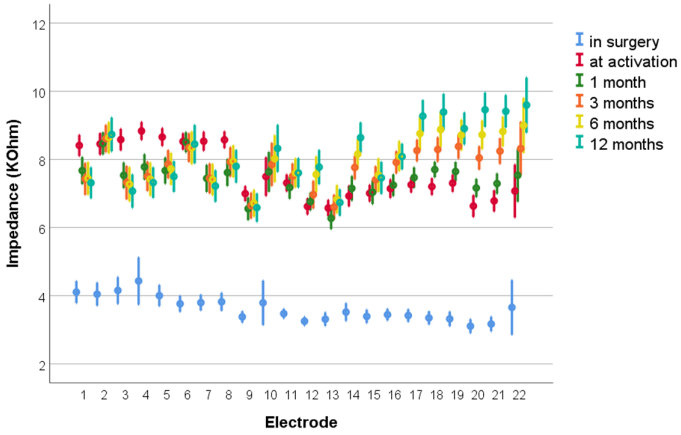

Figure 3. Average electrode impedance measurement values in kOhm (±SD) in surgery, at device activation and at 1 month, 3 months, 6 months, and 12 months post-activation. The electrode impedance was measured in each intracochlear electrode in all the LCI-20PI recipients using MP1+2 mode. Data are displayed for the 22 electrodes.

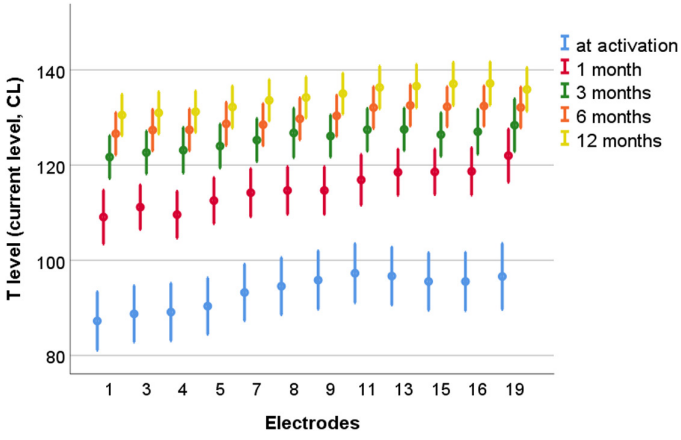

Figure 4. Average T levels at device activation, and at 1 month, 3 months, 6 months, and 12 months post-activation. T levels at the 12 electrodes increased rapidly in the first 3 months post-activation and then stabilized in LCI-20PI CI recipients.

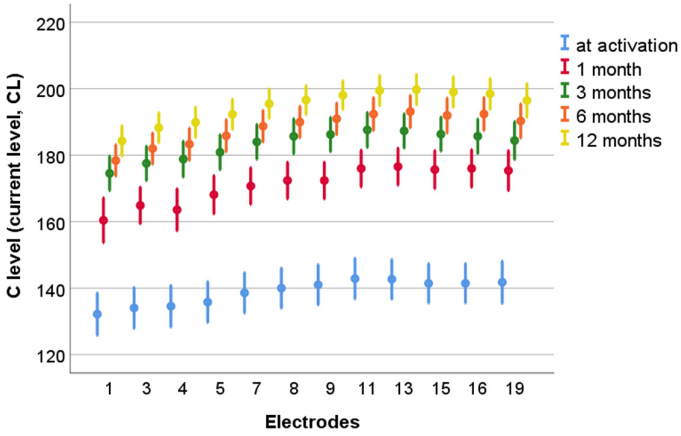

Figure 5. Average C levels at device activation and at 1 month, 3 months, 6 months, and 12 months post-activation. C levels at the 12 electrodes increased rapidly in the first 3 months post-activation and then stabilized in LCI-20PI CI recipients.

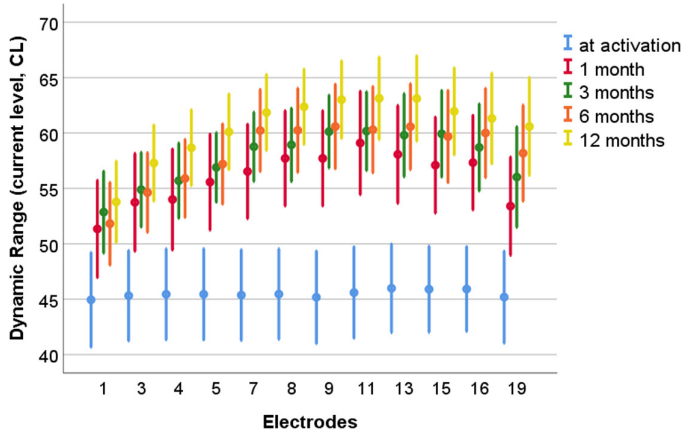

Figure 6. Changes of average dynamic ranges over time. Average dynamic ranges at the 12 electrodes increased rapidly in the first month post-activation and then stabilized in LCI-20PI CI recipients.

Mean MRS in the implanted ear were 6.3 ± 11.7%, 28.9 ± 21.0%, and 57.1 ± 21.1% at preoperative and 6- and 12 months post-activation testing, respectively (Kruskal–Wallis test, $P < .001$, Figure 7). Compared with the preoperative mean MRS, statistically significant improvements in mean MRS at 6- and 12 months post-activation were observed (Mann–Whitney *U*-test, $P < .001$, Figure 7). Compared with the mean MRS at 6 months post-activation, there was a statistically significant improvement in mean MRS at 12 months post-activation (Mann–Whitney *U*-test, $P < .001$, Figure 7).

Mean DRS in the implanted ear was 5.1 ± 11.0%, 30.3 ± 25.8% and 69.1 ± 24.4% at preoperative and 6- and 12 months post-activation testing, respectively (Kruskal–Wallis test, $P < .001$, Figure 7). Compared with the preoperative mean DRS, statistically significant improvements at 6- and 12 months post-activation were observed (Mann–Whitney *U*-test, $P < .001$, Figure 7). Compared with the mean DRS at 6 months post-activation, there was a statistically significant improvement at 12 months post-activation (Mann–Whitney *U*-test, $P < .001$, Figure 7).

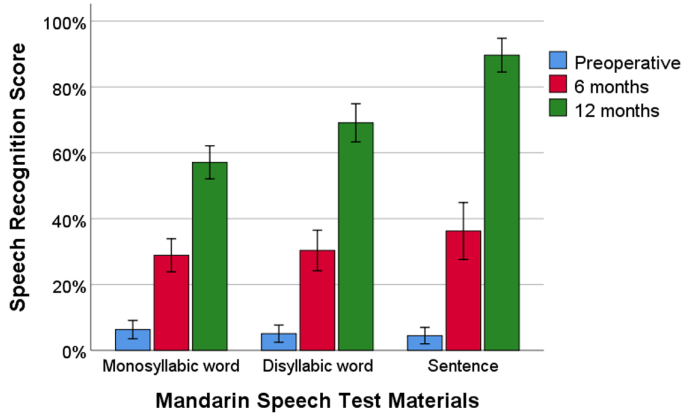

Figure 7. Speech recognition scores of LCI-20PI CI recipients at preoperative and 6- and 12 months post-activation testing. Compared with preoperative average speech recognition scores, statistically significant improvements in average MRS, DRS, and SRS at 6- and 12 months post-activation were observed (Mann–Whitney *U*-test, $P < .001$). MRS, monosyllabic-word recognition score; DRS, disyllabic-word recognition score; SRS, sentence recognition score.

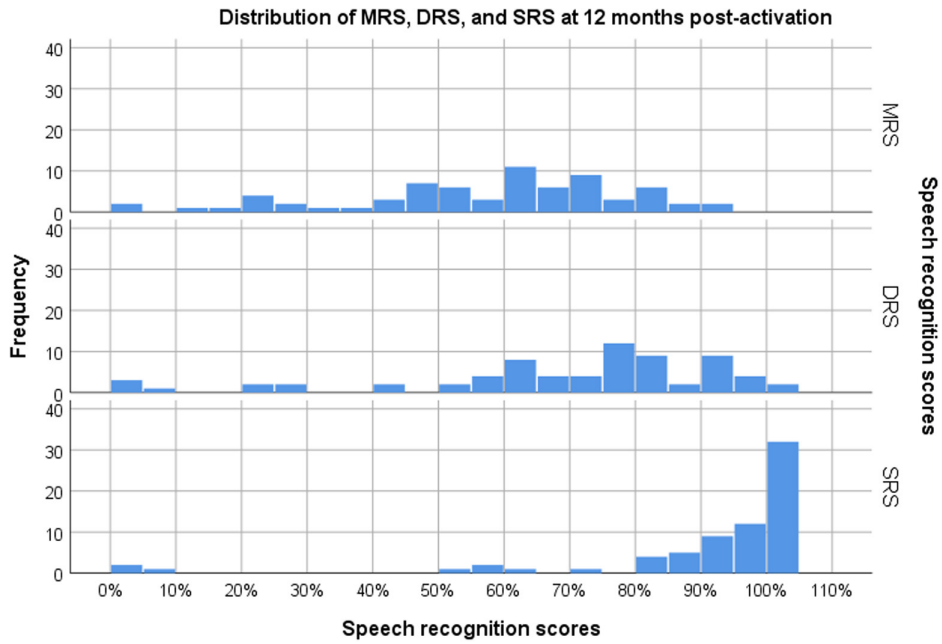

Figure 8. Distribution of MRS, DRS, and SRS in the LCI-20PI CI recipients at 12 months post-activation. MRS, monosyllabic-word recognition score; DRS, disyllabic-word recognition score; SRS, sentence recognition score.

Mean SRS in the implanted ear was 4.5 ± 10.5%, 36.3 ± 36.3%, and 89.7 ± 21.5% at preoperative and 6- and 12 months post-activation testing, respectively (Kruskal–Wallis test, $P < .001$, Figure 7). Compared with the preoperative mean SRS, statistically significant improvements at 6- and 12 months post-activation were observed (Mann–Whitney *U*-test, $P < .001$, Figure 7). Compared with the mean SRS at 6 months post-activation, there was a statistically significant improvement at 12 months post-activation (Mann–Whitney *U*-test, $P < .001$, Figure 7).

The distribution and variation of MRS, DRS, and SRS among the 70 recipients at 12 months post-activation are illustrated in Figure 8.

Evaluation of Possible Influencing Factors on Postoperative Speech Recognition Performance

There was no statistically significant difference in the MRS, DRS, and SRS at 12 months post-activation between the male and female individuals, between the left and right ear implantation, between the hearing threshold ≤100 dB and hearing threshold >100 dB individuals, between the hearing threshold ≤80 dB and hearing threshold >80 dB individuals, between individuals with a short duration of deafness (≤10 years) and the individuals with long duration of deafness (>10 years) (Mann–Whitney *U*-test, $P > .05$, Table 3), among the individuals with different causes (Kruskal–Wallis test, $P > .05$, Table 3) and among the 4 medical centers (Kruskal–Wallis test, $P \geq .05$, Table 3).

DISCUSSION

This prospective clinical trial demonstrated that the LCI-20PI CI device is safe and effective.

Cochlear implant device testing and fitting are important for the evaluation of the status of CI devices. The successful ECAP measurements in LCI-20PI CI recipients were similar to those in Nucleus 24 CI recipients.[9-11] Several possible factors may be associated with unsuccessful ECAP measurement: poor contact of test equipment, inexact alignment of the external transmitter coil over the receiver coil, misplacement of the intracochlear electrode, reference electrode, or common electrode.

The result of electrode impedances, T/C levels in LCI-20PI recipients, was similar to other CI recipients. The incidence of the LCI-20PI CI devices having at least one open or short circuit was 4.3% (3/70). Goehring et al[12] reviewed the impedances measured in 194 CI recipients and showed that the incidence of CI devices having at least one open or short circuit was 12.4% (24/194) intraoperatively and decreased to 8.2% (16/194) postoperatively. The impedances measured in LCI-20PI recipients were in the same range as in Nucleus CI and MEL-DL recipients.[13, 14]

It is widely accepted that electrode impedance increases following cochlear implantation.[13,15] The electrode impedance increases following cochlear implantation were also observed in LCI-20PI recipients. This increase in impedance is a result of fibrous tissue growth encapsulating the electrode array due to a foreign body immune response.[16,17]

Measurement of subjective T/C levels is an important part of CI testing and fitting. The subjective T/C levels increased rapidly during the first 3 months post-activation and then gradually stabilized. Similar results were also reported in Nucleus CI recipients.[18-20]

Improvement in speech recognition score is the most important endpoint for evaluating CI effectiveness. The open-set MRS, DRS, and SRS in the LCI-20PI CI recipients were 57.1 ± 21.1%, 69.1 ± 24.4%, and 89.7 ± 21.5% at 12 months post-activation, respectively. LCI-20PI CI proved to be effective in post-lingually deafened recipients. Zhu et al[21] reported that the open-set DRS and SRS in Mandarin-speaking

Table 3. Average Open-Set Speech Recognition Scores (and SDs) 1 Year After Device Activation and Results of Mann–Whitney *U*-Test or Kruskal–Wallis Test Examining Factor Effects on Outcomes (n = 70)

	Monosyllables (%)	*P*	Disyllables (%)	*P*	Sentences (%)	*P*
Sex						
Male (n = 39)	61.2 (19.2)	.059	73.0 (22.3)	.068	91.2 (18.6)	.891
Female (n = 31)	52.0 (22.5)		64.3 (26.3)		87.7 (24.7)	
Ear implanted						
Left (n = 25)	56.1 (17.0)	.516	69.4 (20.9)	.690	90.8 (21.0)	.718
Right (n = 45)	57.7 (23.2)		69.0 (26.3)		89.0 (21.9)	
Preoperative average hearing threshold						
≤100 dB HL (n = 15)	58.0 (13.2)	.841	73.2 (17.3)	.704	90.8 (13.0)	.512
>100 dB HL (n = 55)	56.9 (22.9)		68.0 (26.0)		89.3 (23.3)	
Preoperative average hearing threshold with hearing aids						
≤80 dB HL (n = 38)	58.3 (16.8)	.883	72.1 (18.8)	.654	92.8 (11.9)	.970
>80 dB HL (n = 32)	55.8 (25.5)		65.6 (29.6)		85.9 (28.8)	
Duration of deafness						
≤10 years (n = 36)	60.9 (18.9)	.383	71.0 (22.2)	.869	90.7 (19.3)	.916
>10 years (n = 29)	55.2 (22.4)		68.8 (25.7)		90.5 (19.3)	
Etiology of hearing loss						
Genetic (n = 14)	64.6 (12.4)	.472	73.9 (15.0)	.677	97.6 (4.0)	.341
Sudden hearing loss (n = 5)	55.2 (11.5)		74.0 (16.0)		91.2 (7.0)	
Ototoxicity (n = 9)	50.4 (23.7)		64.7 (23.2)		89.6 (12.4)	
Infectious disease (n = 3)	67.3 (11.4)		83.3 (14.0)		98.0 (2.0)	
Unknown (n = 39)	55.4 (24.0)		66.7 (28.5)		86.0 (27.4)	
Medical centers						
Union hospital of Tongji medical college (n = 18)	64.4 (19.0)	.050	73.9 (20.7)	.085	90.0 (13.7)	.094
Eye and ENT hospital of Fudan University (n = 22)	61.1 (18.3)		75.5 (23.0)		92.3 (21.7)	
Shanghai Xinhua hospital (n = 10)	43.2 (22.0)		61.8 (28.3)		82.0 (31.5)	
Shanghai ninth people's hospital (n = 20)	53.1 (22.5)		61.4 (25.5)		90.3 (21.7)	

post-lingually deafened Nucleus-24 (n = 8) and HiRes 90K (n = 2) recipients achieved 76.6% and 84.4%, respectively. Li et al[2] revealed that the open-set MRS and SRS at 2 years after device activation in Mandarin-speaking post-lingually deafened Nurotron CI recipients were 56.67 ± 9.77% and 82.88 ± 21.40%, respectively, while the average scores among Cochlear Nucleus CI24 recipients were 52.8 ± 12.76% and 87.33 ± 14.44%, respectively. The improvement in Mandarin speech recognition in LCI-20PI CI recipients was comparable to Nucleus-24, HiRes 90K, and Nurotron CI recipients.

There are several limitations in this study. Firstly, there was no control group in this study. Secondly, this was not a blind study. Thirdly, there was no predictable criterion to exclude those individuals preoperatively who had poor speech learning ability or were not cooperative in postoperative speech rehabilitation.

CONCLUSION

The novel LCI-20PI CI device is safe and effective in post-lingually deafened recipients.

Availability of Data and Materials: The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restricitions.

Ethics Committee Approval: This study was approved by the Ethics Committee of Fudan University Eye & ENT Hospital (approval no: 2015043, date: January 12, 2015), Huazhong University of Science and Technology Tongji Medical College, Union Hospital (approval no: 2015-167, date: October 28, 2015), Shanghai Jiaotong University School of Medicine, Shanghai Ninth Hospital (approval no: 2016-31, date: April 15, 2016), Shanghai Jiaotong University School of Medicine, Shanghai Xinhua Hospital (approval no: XHEC-2016-002-2, date: March 15, 2016).

Informed Consent: Written informed consent was obtained from the patients or their guardians who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – C.D.; Design – C.D.; Supervision – C.D.; Resources – Z.S.; Materials – Z.S.; Data Collection and/or Processing – C.D., Q.H., H.W., Y.L., W.K.; Analysis and/or Interpretation – Q.D., C.D.; Literature Search – Q.D.; Writing – Q.D.; Critical Review – C.D.

Declaration of Interests: The authors have no conflicts of interest to declare.

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