Comparison between new and old generation RetroX® auditory implants

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Key-words. RetroX®; high-frequency hearing loss; implantable hearing aid; open ear canal hearing aid; acoustic feedback

Abstract. Comparison between new and old generation RetroX® auditory implants. Objective: To compare post aural soft tissues tolerance of the old and new titanium RetroX® (Auric GmbH, Rheine, Germany) tube, and to compare the hearing improvements between the old (DSP-pro®) and the new (Concertino®) hearing aid units of the RetroX. Methodology: Retrospective case review of 46 patients with high-frequency sensorineural hearing loss, fitted with DSP-pro or Concertino, and who received 51 implantations (with the old or new generation titanium tube) in a tertiary referral center at a university hospital. The RetroX consists of an electronic unit situated in the postaural sulcus connected to a titanium tube implanted under the auricle between the sulcus and the external auditory meatus. Implanting requires minor surgery (10 minutes under local anaesthesia). Three months after their implantation, patients were asked to fill out a questionnaire to evaluate acoustic feedback annoyance and to undergo 3 audiometric tests: pure-tone audiometry in silence, speech audiometry in silence, and speech audiometry in noise. Results: The new tube is more reliable (12 explantations from patients who received 26 older tubes compared with 1 explantation in 25 who received new tubes) even if the size must be adjusted more often (2/26 for the old model and 5/25 for the new one). Concertino allows a higher amplification before feedback appears, which improves hearing gain. Conclusions: The new RetroX is better tolerated than the older one, and improves hearing ability.

Introduction

In our previous publications on the first-generation RetroX® implant,1,2 we reported that several patients experienced a chronic granulomatous inflammatory reaction around the titanium tube requiring 16% (4/25) of patients to be explanted. Such high rejection rates, the expensive purchase price (2650 €) which was only partially covered by Belgium’s health insurance, and necessity of daily maintenance (brushing) obliged us to advise against using the RetroX. However, the device has many advantages compared with conventional air-conduction hearing aids, including the following:
- The external auditory canal is not occluded (Figure 1) offering the advantages of an open ear-mold hearing aid1-2
- Discrete, cosmetic hearing aid (Figure 1)
- Minor surgery requirement
- Trial before implantation extremely important
- Titanium does not contraindicate MRI

For these reasons, we decided to use a new generation titanium tube. To solve the tube rejection problem, the manufacturer (Auric GmbH, Rheine, Germany) modified several technical parameters of the titanium tube (Table 1).9 Simultaneously, the manufacturer proposed a new type of hearing aid unit to improve the fitting for patients with “ski-slope hearing loss” (Table 2),10 i.e. high-frequency sensorineural hearing loss with normal hearing at the low and middle frequencies, which is difficult to compensate for with conventional hearing aids11 due to the so called “occlusion effect.”12,13 With the first generation RetroX implant,2 we found a statistically significant and audiometrically relevant...
improvement of thresholds in a quiet environment at 1, 2, 4 and 8 kHz, and a mean 15% increase in speech intelligibility in an environment including cocktail-party noise (with a signal-to-noise ratio ranging from −5 to +5 dB).14

According to Barbara et al.,10 RetroX provides a greater audiological benefit than a standard digital CIC hearing aid for speech comprehension in a noisy environment. We evaluated whether or not these two modifications improved the anatomical and functional results of the implant.

It must be emphasized that our team has no commercial or financial relationship with the manufacturer, and our work was not sponsored by Auric GmbH.

**Materials and methods**

**Patients and audiology**

Between July 2001 and December 2005, 46 patients (9 women and 37 men) were implanted at the ENT Department of the Université Catholique de Louvain at Mont-Godinne (Belgium) and were followed until December 2006. Their ages ranged from 21 to 75 years (mean age, 53 years). Including reimplantations and bilateral implantations, 51 implantations were included in the study. To be included in the study, the patient’s deafness had to correspond to the RetroX application range (Figure 2) without malformation of the pinna, external ear meatus, or canal. They also had to experience hearing improvement during pre-implantation testing, and to accept and be able to complete the questionnaires and pass several audiological tests. The unaided, mean sensory-neural hearing loss for the 46 enrolled patients was 28 dB (SD = 10 dB) for the speech reception threshold for speech audiology in quiet environments, 44 dB (SD = 12 dB) for the comprehension threshold, 4000 Hz/52 dB (SD = 17 dB) for pure-tone audiology in a quiet environment, 6000 Hz/58 dB (SD = 19 dB), 8000 Hz/69 dB (SD = 22 dB). All patients used their implant everyday for 3 months before they underwent audiological testing in a soundproof booth under 2 conditions; unaided, or with the implant set at the patient’s usual level with the contralateral ear remaining free (i.e., neither obstructed by a plug nor masked by noise), thus reproducing the patient’s real-life conditions.

We conducted three series of tests: (1) pure-tone audiology in a quiet environment where we measured the pure-tone thresholds at 4 KHz, 6 KHz and 8 KHz; (2) speech audiology in a quiet environment without lip reading (lists of disyllabic words, phonetically balanced for the French language) where we measured the patient’s speech reception threshold (i.e., the sound intensity required to repeat 50% of words correctly) and the comprehension threshold (i.e., the sound intensity required to repeat 100% of words correctly); and (3) speech audiology in a noisy environment without lip reading where disyllabic word lists were delivered at 50, 55, and 60 dB SPL, and combined with a cocktail party background noise at
**Table 1**
Comparison of old and new titanium tubes

<table>
<thead>
<tr>
<th>Component</th>
<th>Old tube</th>
<th>New tube</th>
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| I. Components      | 3 Pieces: 1. connector  
                    | 2. old titanium tube  
                    | 3. cone  |
|                    | 2 Pieces: 1. connector and new titanium tube  
                    | in one piece  
                    | 2. new cone  |
| II. Outer diameter | 4.4 mm² | 2.5 mm²          |
| III. Inner diameter| –       | No change        |
| IV. Cone           | Cut in the shape of a vase with a wide opening | Flat with a countersunk extremity |
| V. Price           | 1000 €  | 1000 €           |
| VI. Surgical Procedure  | The three parts must be screwed together during the surgical implantation, under the pinna | Titanium tube is punched straight forward in the soft tissues under the conchal cartilage, in one action (Figure 1 and Figure 4) |
| VII. Incision      | 4-mm incision in postaural sulcus | 2-mm incision |
| VIII. Duration of procedure | 20 min | 10 min |

* To reduce the contact area between the titanium and the patient’s tissues.
* To avoid alterations of the previous acoustic properties, which were good with the old tube, and to allow the possibility for the patient to change the old tube for a new one without having to change the hearing-aid unit.
* Easily obstructed by earwax and difficult to clean by the patient himself. Moreover, this shape allows excessive mobility of the entire tube, sliding in place when the patient connects the hearing-aid unit.
* Local anesthesia (infiltration with a 2% lidocaine, 1:100,000 adrenaline solution) in an outpatient surgery setting. For post-operative care, oral antibiotics (ciprofloxacin 500 mg twice daily) are prescribed for 5 days and the RetroX external unit is usually connected 4-6 weeks after surgery.
* There was a risk of pinching the soft tissues during these manipulations, resulting in a post-operative inflammatory reaction in the area.
* The final step is to screw the new cone onto the tube into the external auditory canal (Figure 1). There are choices between different standard sizes (16, 19, 21 or 23 mm), although custom-made lengths can be provided by the manufacturer. The perfectly smooth external surface of the tube prevents chronic sliding friction and serious scarring of soft tissues.

**Table 2**
Comparison of old and new hearing-aid units

<table>
<thead>
<tr>
<th>Old generation: DSP-pro®</th>
<th>New generation: Concertino®</th>
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<tbody>
<tr>
<td>Analogue</td>
<td>Numeric</td>
</tr>
<tr>
<td>–</td>
<td>More efficient anti-feedback system</td>
</tr>
<tr>
<td>1650 E</td>
<td>1650 E</td>
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</table>

* According to the manufacturer, the new system should allow an extra 5-dB amplification before reaching the feedback threshold.

a constant intensity of 55 dB SPL. We measured the percentage of words correctly repeated for a signal-to-noise ratio of –5 dB, 0 dB, and +5 dB.

Results were compared between two groups: the ANA group of patients using the RetroX (DSP-pro) analogue hearing-aid unit and the NUM group of patients using the new digital Concertino hearing-aid unit.

Because the inner diameter of the new titanium tube is the same as the old one (only the outer diameter had changed), we did not compare the audiometric results between patients fitted with old and new titanium tubes.

**Patient satisfaction**

To investigate the subjective level of patient satisfaction, the patients were interviewed and asked to complete a questionnaire regarding the improvement they noticed with their implant in various daily life situations. The ability to understand conversations in noisy environments and acoustic feedback annoyance were of particular interest.

**Statistical analysis**

The Chi-square test was used to compare Larsen onsets. Numerical variables were compared between groups and between times by the Wilcoxon rank sum test and Wilcoxon signed rank test, respectively. Explant curves were estimated using the Kaplan-Meier method and compared by log rank test.
Results

Of the 51 implantations in 46 patients, 26 were with the older generation titanium tubes and 25 were with the newer ones (Figures 3,4). Only one patient received bilateral implants. The remaining patients felt no need, deciding that one implant was sufficient to improve their hearing. Of the 46 patients, 36 were fitted with the DSP-pro and 11 with the Concertino (one patient was fitted with a DSP-pro and an older titanium tube and, after explantation, was reimplanted with a new tube and fitted with Concertino).

Local tolerance of the tube in the soft tissues

Twelve of 26 (46%) patients with the old generation titanium tube had to be explanted because of localised chronic inflammation with pyogenic granuloma causing pain, repeated bleeding, and no remission despite intensive local care and several courses of antibiotics.

The first explantation occurred one month after and the last after two years and three months after implantation. As for the size of the implant, 2 had to be changed; the first after 2 months and the second after 29 months. In contrast, only one of 25 (4%) patients who received the new model titanium tube had to have the implant removed. This occurred 5 months after implantation. The reason for this explantation was not granulation tissue or a poor audiological result, but a permanent retroauricular discomfort and the patient’s reluctance to carry out daily local care. The tube size had to be changed in 5 patients, generally after 1 month, when the length chosen during surgery appeared to be too short or too long after the post-operative swelling of the postaural sulcus resolved.

The follow-up time was 3 years for the new tube compared with 5½ years for the older one. Figure 5 shows the Kaplan-Meier estimated explantation rates for the 2 types of implants. The curves separate with a statistically significant difference between them (p = 0.025).

Hearing improvement with the implant

Pure-tone audiometry in a quiet environment

Figure 6 shows the mean pure-tone hearing thresholds at 4000, 6000, and 8000 Hz attained during soundfield testing in a quiet environment with and without Dsp-pro® or Concertino®.

The hearing thresholds improvement compared with no hearing aid was:
New and old RetroX® auditory implant

– 13 dB for Dsp-pro (p < 0.001) and 17 dB for Concertino (p = 0.007) at 4 kHz
– 6 dB for Dsp-pro (p < 0.001) and 12 dB for Concertino (p = 0.002) at 6 kHz
– 9 dB for Dsp-pro (p < 0.001) and 1 dB for Concertino (p = ns) at 8 kHz

The difference between the Dsp-pro® and the Concertino® was not statistically significant.

Speech audiometry in a quiet environment

The improvement in the speech reception threshold with Concertino and Dsp-pro is 8 dB (both are statistically significant compared with no hearing aid unit) (Table 3). For the comprehension threshold, the improvement is 11 dB (mean voice intensity of 45 dB when unaided and 34 dB when monaurally aided) for Dsp-pro and 14 dB (54 dB unaided and 40 dB monaurally aided) for Concertino. Both improvements were statistically significant compared with no hearing aid unit, but the difference between the Concertino and the Dsp-pro was not significant.

Speech audiometry in a noisy environment

For a signal-to-noise ratio of −5 dB, the intelligibility improved 21% with Dsp-pro and 4% with Concertino, but the result is not statistically significant for Concertino (Table 4). For a signal-to-noise ratio of 0 dB, the intelligibility improved 20% with Dsp-pro and 26% with Concertino. Both improvements are statistically significant but the difference between Concertino and Dsp-pro was not significant.
Subjective satisfaction and acoustic feedback

Thirty-nine questionnaires were completed. Of these, 28 concerned the older implant and 11 the newer one. On the 28 questionnaires answered by patients who were users of the DSP-pro, 10 acoustic feedback complaints were recorded and 4 patients (14%) said that they often experienced discomfort because of it. On the 11 questionnaires completed by patients who used Concertino, 5 acoustic feedback complaints were recorded and one (9%) patient said that this was a real problem causing discomfort (9% vs. 14%: difference not statistically significant).

Discussion

Local tolerance of the tube in the soft tissues

With the changes made to the titanium tube, the tolerance significantly improved with 96% of patients tolerating it well compared with 54% of patients who received the older, first generation tube. These results agree with those reported by Wesendahl showing 82% (9/11) of patients implanted with the older tube experienced irritation. Of these patients, 9% (1/11) had granulation tissue and 9% (1/11) required removal of the implant. With the new tube, 19% (4/21) experienced irritations and only 5% (1/21) had granulation tissue without requiring explantation (after a 4-month investigation of the new tube).

We believe this improvement is due to the less aggressive surgical procedure for implantation, the smoothness of the external surface of the tube, and the reduced external diameter that reduces the amount of surface contact between the titanium and the patient’s tissues.

We present a series of patients with 3 years of follow-up to assess the long-term tolerance of the implant. However, we will continue to follow these patients, since granulation tissue can appear around the tube long after implantation (although, in our experience, the maximum interval with the older model was 2 years and 3 months).

The new tube has one minor disadvantage; it is more difficult to estimate the correct size of the tube (in order to obtain a perfect application of both ends to the skin of the external ear canal and in the postaural sulcus) because of the two-part structure and the need to choose the correct titanium tube during surgery with local anaesthesia, whereas the three separate components of the older tube was easier to adjust. This difference explains why only 2 of 26 old tubes vs 5 of 25 new tubes required a size adjustment. However, when needed, the size modification can be performed without difficulty under local anaesthesia at the office.

Hearing improvement with the implant

Both the Concertino® and DSP-pro® provide significant hearing gains on a whole range of audiometric tests, and this study was performed in a larger population than in our previous studies. Interestingly, the new Concertino hearing aid is able to compensate for hearing losses in the higher frequencies, as shown in Figure 4. The figure shows:

- The mean hearing loss in patients using the DSP-pro was 48.5 dB at 4 KHz, 56.5 dB at 6 KHz, and 68.5 dB at 8 KHz, respectively (unaided); on the other hand, the hearing loss in patients using the new Concertino was measured at 59.5 dB, 63 dB, and 70 dB at 6 KHz, and 68.5 dB at 8 KHz, respectively (unaided).

- For unaided speech audiometry in a quiet environment, candidates for the DSP-pro® needed 26.5 dB to understand 50% of the words, and 45 dB to reach 100% intelligibility, where as these values were 35 dB and 54.5 dB, respectively, in candidates for the Concertino.
Figure 2 shows the theoretical limits of implantation advised by the manufacturer.

Subjective satisfaction and acoustic feed-back

The two groups of patients reported a relatively large number of acoustic feedback complaints; however, upon investigation into their complaints, few were retained. For example, patients reported that “the device hisses when I pass my hand through my hair,” “it whistles more easily when I am in the car,” etc. Genuine complaints are those which cause a frequent annoyance to the patient which is often highlighted on our feedback evaluation questionnaire. We noted that 9% of patients wearing Concertino® complained compared with 14% wearing the DSP-pro®. However, this difference was not statistically significant, showing that Concertino® allows compensation of more advanced deafness without more feedback problems, which is always a challenge for any kind of open ear-mold hearing aid. In further studies, it would be interesting to evaluate the subjective patient satisfaction with pre-implantation, extended high-frequency audiometry.15

RetroX and open ear-mold hearing aids

It is impossible to talk about RetroX without addressing the question of open ear-mold hearing aids. The continuous progress with these devices and the high satisfaction rate of patients who choose this option explains why the open ear-mold solution cannot be ignored in cases of “ski-slope hearing loss.”16,17 Presently, there is only one study comparing the open ear-mold and conventional air conduction devices.18 Lenarz et al showed that RetroX provided better speech perception in noisy environments and better wearing comfort compared with conventional open ear-mold hearing aids. Regarding these results, we were obliged to speak about these two solutions for patients with mild to moderate high frequency sensorineural hearing loss. A great advantage is that a patient can try the two different devices before buying an open ear-mold hearing aid and before being implanted with RetroX giving to the patient the opportunity to choose the hearing aid which is best suited for him or her from a hearing and cosmetic point of view.

Conclusions

The new model RetroX® auditory implant offers two advantages compared with the first generation: the titanium tube is much better tolerated by the soft tissues of the postaural sulcus and the digital processor allows compensation for slightly more pronounced deafness without Larsen’s phenomenon.

References


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