Rehabilitation of high-frequency hearing loss with the RetroX® auditory implant

P. Garin*,**, F. Genard*,**, C. Galle*, M. H. Fameree**, J. Jamart* and M. Gersdorff**

*Cliniques Universitaires U.C.L., Université Catholique de Louvain, Mont-Godinne, Belgium; **Cliniques Universitaires Saint Luc, Université Catholique de Louvain, Brussels, Belgium

Key-words. Implantable hearing aids; hearing in noise; acoustic feedback; acoustic occlusion effect; open earmold

Abstract. Rehabilitation of high-frequency hearing loss with the RetroX® auditory implant. The RetroX® is a new semi-implantable hearing aid which does not occlude the external ear canal. It consists of an electronic unit that plugs into a titanium tube which is implanted under the pinna so as to connect the retroauricular sulcus with the inside lumen of the external ear canal. Implantation requires minor surgery which can be performed under local anesthesia. Moreover, a pre-implant simulator exists and allows patients to try the device before deciding on definite implantation.

The RetroX® auditory implant is indicated in case of high-frequency sensorineural hearing loss with a steep slope (ski-slope audiogram). We implanted 25 adults suffering from such a hearing loss, and we report their hearing measured after 2.5 to 15 months of use.

Four patients developed a persistent granulomatous reaction which disappeared after explantation. Two patients complained of acoustic feedback and needed supplementary fitting. Twenty three of our 25 subjects are satisfied or even extremely satisfied with the hearing improvement provided by the RetroX®; they wear the implant daily, from morning until evening.

Audiometrically, we observed a statistically significant improvement of the pure-tone thresholds at 1, 2, 4 and 8 kHz. In quiet, the speech reception thresholds decreased by 10 dB SPL and in noise, speech intelligibility increased by 15% for signal-to-noise ratios between -5 dB and +5 dB.

Up till now, our patients were implanted monaurally because of financial considerations and our initial inexperience with this new implant. The overall results, however, are promising and nowadays, we advise bilateral implantation for patients who tolerate the first implant. By doing so, we hope to improve hearing in noise and spatial sound perception.

Introduction

The RetroX® (Auric GmbH, Rheine, Germany) is a new semi-implantable hearing aid indicated for patients with a “ski-slope audiogram”: an audiometric threshold curve characterized by normal thresholds at low- and mid-frequencies and steeply increasing thresholds at high frequencies.

This type of hearing loss creates limited discomfort in quiet, but in noise, speech comprehension is severely reduced, mainly because of confusion between consonants.² Smoorenburg demonstrated that pure-tone threshold shifts of 30 dB HL at 2 and 4 kHz are associated with a 45% decrease of sentence recognition in noise and Horwitz et al. recently found that speech comprehension of subjects with high-frequency hearing loss is 20% less than would be expected from the mere loss of audible high-frequency speech information.

Compensating ski-slope hearing loss with conventional (closed earmolds) hearing aids is difficult because the frequency profile of amplification cannot match the steep frequency profile of the hearing loss. Lack of frequency selectivity of amplification is partly due to occlusion of the external ear canal which shifts the ear canal’s resonance frequency to low frequencies. Boosting the amplitude of low frequencies results in the so called “occlusion effect”:

– a sensation of occlusion, a feeling of aural pressure;
– unnatural quality and loudness to the user’s own voice;
– amplification of swallowing or chewing.

In the closed ear canal, thus, low-frequency sounds are too intense for patients with ski-slope hearing loss, and this is experienced as especially discomforting. Until recently, the best solution for high-frequency hearing loss was a hearing aid with open earmold. Opening or venting an earmold offers several advantages:

– it reduces boosting the amplitude of low-frequency sounds;
– direct transmission of non-amplified sounds to the ear-drum;
— it improves wearing comfort by eliminating an occluded sensation;
— it alleviates chronic suppurative otitis externa, especially in patients with tympanic membrane perforations or chronic eczema of the external ear canal;
— it restores azimuthal sound localization which relies on undistorted low-frequency sound.

A possible problem with venting is acoustic feedback which mostly occurs at the natural resonance frequency of the ear canal (around 3 kHz). Acoustic feedback can be avoided by limiting the gain of the hearing aid, but reduces the application range of open earmold devices to mild and moderate hearing losses.7

Because of feedback and other problems, reported patient satisfaction is sometimes low. Beamer et al.13 fitted 134 US male military patients suffering from high-frequency hearing loss with open earmold hearing aids. After six months, their satisfaction was evaluated with the Profile of Hearing Aid Benefit (PHAB) questionnaire. Despite regular use of the hearing aid, dissatisfaction was quiet frequent: 53% under reverberant conditions, 55% with reduced cues and 54% in background noise.

Other devices that keep the external ear canal open, have been suggested. Stenfet et al.14 studied the effectiveness of bone-anchored hearing aids (BAHA) in remediating high-frequency sensorineural hearing loss. The initial results of 8 patients, however, were disappointing and the idea seems currently discarded.

Semi-implantable middle ear hearing aids, such as the Vibrant Soundbridge® (Vibrant MED-el Corp, Innsbruck, Austria), are capable of effectively amplifying frequencies above 4 kHz whilst providing a sound described as extremely natural.15,16 These implants, however, require more invasive surgery which cannot be performed under local anesthesia. The surgery also involves risks such as hearing-loss aggravation, ossicular dislocation, and possible facial nerve paralysis. Moreover, a pre-implantation trial of this type of middle ear implant is currently not available. The RetroX® external ear implant might therefore offer an interesting alternative.

**Presenting the RetroX®**

**Operating Principle**

The RetroX® consists of two parts:

The first part is a small titanium tube, with a length of 3 cm and a diameter of 0.4 cm. It is implanted under the auricle; one end fits in the external ear canal and the other end in the postaural sulcus (photograph 1). The other element is the hearing-aid unit which reversibly connects to the titanium tube via which amplified sound is projected in the ear canal (photograph 2).

The hearing aid unit has an omnidirectional microphone at its upper pole and a dual-band numeric processor (Digital Sound Processor, DSP). The unit can be connected to a computer which enables an audiologist to load amplification parameters in the DSP so as to fit each patient individually. To avoid acoustic feedback, the audiologist can activate a notch filter which suppresses the frequencies likely to evoke feedback. The device has a class D amplifier.
High-frequency hearing loss

Because the external auditory canal is not occluded, the RetroX® provides selective amplification of high-frequency sounds.

**Simulation test before RetroX® implantation**

Figure 1 illustrates the application range of the RetroX® as suggested by the manufacturer.

When a patient’s audiometric curve falls within the application range of the RetroX®, we propose a trial with the implant simulator. This simulator is an open earmold hearing aid similar to the RetroX®. The patient wears the simulator for 3 to 4 hours during which he/she is free to test the implant under real conditions, including in noise (the clinic’s restaurant for example). For practical reasons, we cannot allow the patients to take the simulator out of the hospital. We then carry out a series of audiometric tests with and without the simulator: sound-field pure-tone audiometry in quiet, sound-field speech audiometry in quiet, and speech audiometry in noise.

The decision to implant is based on the simulator-aided audiological results and on the patient’s subjective appreciation. The patient is informed about the cost, advantages and disadvantages of the RetroX®. We also offer the alternative of an open earmold hearing aid.

**Surgical Technique**

The operation is performed under local anesthesia (infiltration with a 2% lidocaine-1:100,000 adrenaline solution), in an outpatient surgery setting.

A 4-mm skin incision is made in the postaural sulcus. Blunt dissection under the concha is performed until the posterior wall skin of the external auditory canal is incised. The dissection is performed under the cartilage of the concha, without incision in it.

The titanium tube is then inserted; it consists of three screwable elements: a cone, open in the external ear canal; a tube that represents the middle third; and a connector, open in the postaural sulcus.

The sizes of the various elements are chosen so that the opening of the connector overshoots the surface by 2-3 mm, thus preventing skin closure during the healing phase.

The surgery resembles placing of an ornamental piercing, and takes about 20 minutes.

Antibiotics (cefuroxime axetil 500 mg twice a day; or ciprofloxacin 500 mg twice a day) are prescribed for 5 days. The RetroX® external unit is mostly connected 4 to 6 weeks after surgery.

**Materials and methods**

**Subjects**

We implanted 25 patients (6 women and 19 men) between April 2001 and August 2003 at the ENT Department of the Université Catholique de Louvain (UCL, Belgium). Their age ranged from 24 to 77 years (on average 56 years).

Our patients sought medical advice for because of reduced hearing in noisy environments. The hearing loss was unilateral in two cases; the etiology was cochlear otosclerosis in 1 case; and unknown in the other case. The etiology of the bilateral hearing losses was presbyacusis in 16 cases, and noise-induced in 7 cases.

All patients were implanted monaurally, because the cost of the implant and our fear of rejection.

Post-implantation follow-up ranged from 2.5 to 15 months (mean: 6.5 months).

Although 92 patients tried the simulator in the hospital, only 25 of them opted for an implant. Various reasons motivated the
remaining 67 patients to refuse the implant: insufficient subjective improvement; permanent or frequent acoustic feedback; absence of tinnitus relief.

**Test Method**

All patients underwent audiometric testing in a soundproof booth before and after fitting with the RetroX: under 2 conditions:

- both ears free (i.e., neither obstructed by a plug nor masked by noise) and unaided;
- both ears free, and the implanted side aided by the RetroX® (thus reproducing the patient’s real life conditions).

We conducted 4 series of tests:

- pure-tone audiometry in quiet;
- speech audiometry in quiet (Fournier’s disyllabic word lists);
- speech audiometry in noise (in 17 patients): Fournier’s disyllabic word lists were delivered at 50, 55 and 60 dB SPL, and combined with cocktail party background noise at a constant intensity of 55 dB SPL;
- head shadow testing (in 17 patients): this soundfield test was performed in quiet; the patient, with immobilized head, was encircled by 12 equally spaced (30°) loudspeakers in a horizontal plane at ear level. The hearing thresholds for a 4 kHz warble tone were obtained for the two opposite directions parallel to the interaural axis. Speech audiometry in noise and establishing the head shadow required a special audiometric booth that was only available in one of both hospitals participating in the study; that is the reason why such data are available for only 17 of the 25 patients.

To assess satisfaction, ten patients were asked:

- to fill in the APHAB questionnaire;¹⁸
- to grade global satisfaction with the RetroX® on a visual analog scale (deep disappointment 0/10 and full satisfaction 10/10).

In our first ten patients,¹ we observed a strong correlation between the patient’s appreciation and his audiometric results, therefore we no longer assessed satisfaction of the last 15 patients.

**Statistical analysis**

Audiometrical data were analyzed with a two-way ANOVA for repeated measurements, or a paired Student t-test. Satisfaction questionnaires were analyzed with the Wilcoxon signed rank test. All statistical tests were two-tailed.

**Results**

**Postoperative progress**

At three months after implantation and following normal initial healing, four patients developed a pyogenic granuloma around the tube opening in the external auditory canal. Despite intensive local care and several courses of antibiotic therapy, this granuloma persisted, caused pain, and bled repetitively. Although the implant provided good hearing, we had to remove the titanium tube in all cases. Following extraction, healing was complete after 10 days and without sequelae.

In one female patient, the RetroX® implant caused intracanal acoustic feedback despite efforts of fine tuning the amplification settings and use of the notch filter. We removed the titanium tube and allowed the area to heal for 4 months. We then re-implanted a shorter titanium tube so that the internal tube opening was further from the anterior wall of the external ear canal and we positioned the tube so that the internal opening was oriented more towards the eardrum. Re-implantation was straightforward and without any particular surgical problem (e.g., fibrosis or bleeding). With the tube in a new position, the final audiological result was good and acoustic feedback did not occur.

Another patient complained about acoustic feedback that was solved by fine tuning of the DSP and activation of the notch filter.

The remaining 19 implantees did not encounter particular postoperative problems. Small granulomas around the tube frequently occurred during the three first postoperative months; careful medical management remediated such episodes.

**Pure-tone audiometry in quiet** (Figure 2)

Pure-tone thresholds in quiet, before and after fitting, reveal statistically significant and audiometrically relevant improvement of hearing with the RetroX:

- 6.2 dB at 1 kHz (average threshold of 22.4 dB HL without implant and 16.1 dB HL with RetroX), p = 0.003
- 10.7 dB at 2 kHz (average threshold of 30.9 dB HL without implant and 20.2 dB HL with RetroX), p < 0.001
- 13.6 dB at 4 kHz (average threshold of 51.8 dB HL without implant and 38.2 dB HL with RetroX), p < 0.001
High-frequency hearing loss

- 6.6 dB at 8 KHz (average threshold of 64.4 dB HL without implant and 57.8 dB HL with RetroX®), p = 0.002
- At lower frequencies, the RetroX® did not provide a statistically significant gain.

Speech audiometry in quiet

We performed soundfield speech audiometry in quiet, with and without the RetroX®.

The Speech Reception Threshold (i.e., the sound intensity required to repeat 50% of words correctly) improved 10 dB SPL from 31 to 21 dB SPL with the RetroX® (p < 0.001).

The average intensity at which the score was 100%, improved with 14 dB SPL from 50 to 36 dB SPL (p < 0.001).

Speech audiometry in noise

Figure 3 shows the results of soundfield speech audiometry in noise, with and without the RetroX®.

- For the -5 dB SNR (signal 5 dB less intense than the noise), intelligibility improved from 49% unaided to 68% monaurally aided, i.e., 19% improvement (p < 0.001).
- for a signal-to-noise ratio of 0 dB: intelligibility improved from 70% unaided to 88% monaurally aided, i.e., 18% improvement (p < 0.001); and
- for a signal-to-noise ratio of +5 dB (signal 5 dB more intense than the noise): intelligibility improved from 89% unaided to 97% monaurally aided, i.e., 8% improvement (p < 0.001).
- the mean intelligibility improvement for SNRs between -5 and +5 dB is thus 15%

Head shadow effect

We determined the hearing threshold of a 4 kHz warble tone with and without the RetroX® for the two directions on the interaural axis. When the warble was emitted by the ipsilateral loudspeaker (i.e. the side of implantation) thresholds decreased with 16 dB when the RetroX® was connected. With sound coming from the contralateral speaker, thresholds decreased with 9 dB when the RetroX® was connected. These results suggest that, also with the RetroX®, the head shadow persists as a localization cue for high frequency sound.

Satisfaction questionnaire

- All but the explanted patients wear the device daily, the mean appreciation score on the visual analog scale was: 8/10.
- Table 1 shows the difficulties reported in the everyday life, based on the APHAB questionnaire:
The patients reported a significant improvement of their hearing in background noise and in reverberant conditions. They experienced improved ease of communication with other people. Some patients experienced high pitched sounds as more aggressive when the RetroX was plugged.

**Discussion**

*Advantages of the RetroX®*

1) The external ear canal is not occluded which conveys the advantages of an open earmold.

2) The small size and postaural position of the sound processing unit appeals to patients with cosmetic considerations. The RetroX®, although not fully concealed, is extremely discrete.

3) Contrary to middle ear implants, no contraindication to radiological imaging or nuclear magnetic resonance exists because titanium does not have ferromagnetic properties.

4) The surgery is performed under local anesthesia, on the skull surface, and is minor when compared to that for middle ear implants which involves the risk of damaging the eardrum, middle ear, inner ear, or facial nerve.

5) Prior to deciding on implantation, a trial with the RetroX® simulator is possible. This is extremely important, as only 25 of the 92 patients who tried the simulator decided in favour of implantation. The others were disappointed by permanent or frequent acoustic feedback; absence of tinnitus relief, or insufficient subjective hearing improvement (this might be due to cochlear dead regions or severe auditory distortions, such as recruitment). We observed no significant difference between the hearing tests performed with the RetroX simulator and the postoperative results with the real implant. Moreover, all the patients who were satisfied with the simulator and who opted for implantation, were satisfied with the real implant.

*Disadvantages of the RetroX®*

1) As for any open earmold hearing aid, the amount of amplification is limited due to the risk of acoustic feedback. In one case, permanent acoustic feedback occurred but could be controlled by electronic tuning; in another case, repositioning of the tube eliminated permanent acoustic feedback.

2) The RetroX® requires daily attentive and conscientious care (brushing) as well as avoidance of water entering the external ear canal (shower, bath, swimming pool). Cleaning the ear with a cotton-bud or wearing anti-noise protective ear plugs can be problematic because the titanium tube partially obstructs the entrance of the ear canal.

3) The purchase price (3,000 €) is high and only partially covered by Belgium’s health insurance. Some patients can get the same reimbursement than for a conventional hearing aid, depending on the severity of the hearing loss. The RetroX® uses a small Zinc-Air type 10 battery which has a short lifetime (70 hours; an average 5-day use); battery costs are therefore to be considered.

4) As with any implanted foreign body, the risk of local infection and rejection of the tube exists. In our series of 25 patients, this happened in four cases. In our previous publication with the first ten patients, we reported only one case of explantation due to a chronic granulation problem. It appears now, with a larger experience, that this problem is more frequent than we initially thought. To reduce the risk of a pyogenic granuloma, the manufacturer now proposes a titanium tube with a smaller outer diameter, and thus, with reduced contact surface. This new model of the titanium tube is currently under evaluation in our center.

*Results with the RetroX®*

It must be emphasized that we report the short term results of a limited number of patients. Our patients choose the implant mainly for cosmetic reasons; in fact one may expect similar hearing improvement with a behind-the-ear hearing aid using an open earmold and a notch filter to avoid acoustic feedback.
Anamnesis and standardized questionnaires clearly show that our patients are satisfied or even extremely satisfied with RetroX. On average, patients attribute a score of 8/10 to the implant and wear it daily from morning until evening which, according to Schum,\textsuperscript{20} is a very good satisfaction index for hearing aid users.

The audiometrical investigations were performed with a free non-implanted ear (no earwax, no masking) in order to evaluate hearing under more or less realistic conditions.

Pure-tone audiometry shows a small (6,2 to 13,6 dB SPL) but significant improvement of hearing threshold at 1, 2, 4 and 8 kHz. Those are the frequencies at which amplification compensates for a high-frequency hearing loss.

The RetroX\textsuperscript{®} also yields improved speech intelligibility: the Speech Reception Threshold shifts on average 10 dB SPL down whilst the intensity required for reaching 100% intelligibility decreases by 14 dB SPL. Speech intelligibility in noise for a SNRs between -5 dB and +5 dB improved on average 15%.

In the future, we’ll consider bilateral RetroX\textsuperscript{®} implantation in order to further improve spatial hearing:

- with monaural RetroX\textsuperscript{®} use, a patient’s speech understanding in noise nearly but not fully approximated that of healthy subjects\textsuperscript{2};
- Azimuth audiometry at 4kHz reveals a head shadow: thresholds are significantly lower when the sound source is located ipsilateral to the implant compared to contralateral.

References


Dr. P. Garin
Service ORL des Cliniques Universitaires U.C.L.
Avenue Thérasse 1
B-5530 Mont-Godinne, Belgium
Fax: +32.81.42.37.03
E-mail: pierre.garin@orlo.ucl.ac.be