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Insertion Procedure, Aftercare, and Soft-Tissue Reaction of the 2.5-mm Titanium Tube System for a Transcutaneous Air Conduction Hearing Aid System

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Abstract: The term *transcutaneous air conduction hearing aid system* designates a new category of hearing devices established by the U.S Food and Drug Administration in 2002. The only product included in this category is the RetroX device manufactured by Auric Hearing Systems, Rheine, Germany. This device consists of two components: a titanium tube system for sound conduction and a hearing processor. The component implanted in the soft tissue of the outer ear is the titanium tube system, for which the outer diameter of the central part has recently been reduced. Both the implantation tools and the tube system itself have been optimized over the last few years with regard to shape and function, thus effectively reducing the surgery involved to a kind of "functional body piercing" procedure. As a result of this, the time required for implantation has been minimized, as has the duration and severity of postoperative soft-tissue reaction. Complications may be avoided by correct positioning and proper mounting of the tube system in the outer ear, comprehensive patient counseling, and scheduled aftercare. One key objective is to ensure that the soft-tissue channel in which the titanium tube is implanted heals without any inflammatory reaction.

Key Words: high-frequency hearing loss; implantable hearing aid; RetroX; transcutaneous air conduction hearing aid system

Only some 22% of the 28 million hearing-aid candidates in the United States wear hearing aids [1]. Among the many factors dissuading people from buying or using these devices is the acoustical and mechanical or physical blocking of the ear canal, which may give rise to audiological and medical problems.

The RetroX, manufactured by Auric Hearing Systems, Rheine, Germany, [2–6] is a semi-implantable hearing system that allows keeping the outer ear canal fully open, thereby avoiding the aforementioned problems arising from use of conventional hearing aids. In particular, the recipient no longer has the feeling of "fullness" (irritation of the vagus nerve) and blockage caused by inserting a plug [such as the mould of a behind-the-ear (BTE) device or the shell of an in-the-ear (ITE) hearing aid] in the outer ear canal.

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For the RetroX, the U.S. Food and Drug Administration has established a new category called the *transcutaneous air conduction hearing aid system* (TACHAS). This hearing system consists of a titanium tube system for implantation into the lateral part of the outer ear and a digital hearing processor, which is connected to the tube system retro-auricularly. The RetroX preserves all outer-ear effects, especially directional effects and the ear canal resonance effect.

The fitting range, which is a consequence of possible gain provided by the processor and the physical properties of a fully open ear canal, is shown in Figure 1 (shaded area). The device is especially suitable for compensating mild to moderate high-frequency hearing loss.

MATERIALS AND METHODS

The first titanium tube system, which became commercially available in Europe in 2000, consists of three components: a central part, a sound inlet head, and a

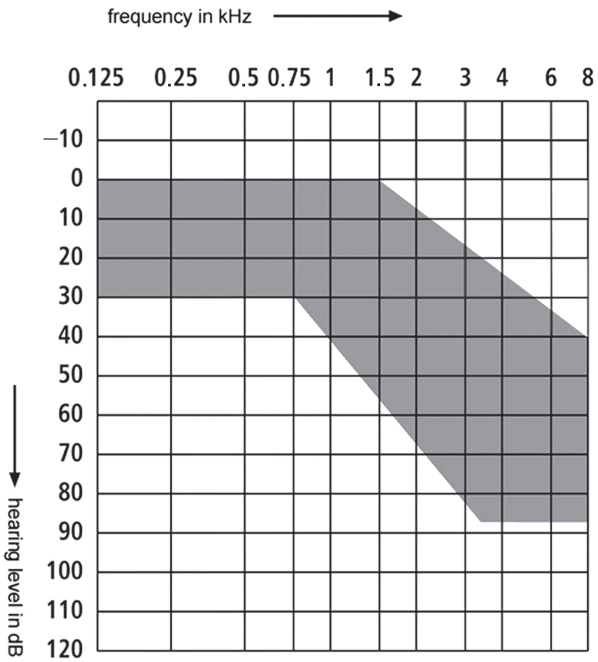


Figure 1. Fitting range of the RetroX (shaded area).

sound outlet head [2]. This tube system has a central diameter of 4.4 mm (Fig. 2A, B). To reduce mechanical irritation of the soft tissue, the outer diameter of the central part of the implant has been reduced from 4.4 mm to 2.5 mm (see Fig. 2C, D), although the basic design of the tube has not been changed.

The inner diameter of both tubes is nearly identical, so that the acoustical properties are similar. The smaller central diameter and the shape of the tube render implantation much easier and allow the device to be implanted in little more than half of the time taken to implant the 4.4-mm tube. This occurs because only two pieces have to be mounted and forming the implantation channel by using scissors is not required. The tube can be implanted by pushing the trocar-like instrument forward through the soft tissue until its tip reaches the outer-ear canal. One feature of the new system is a higher ratio between the outer diameter of the sound inlet head and the diameter of the central part. Consequently, although it is (to a limited extent) floating, the tube is secured more effectively within the soft-tissue channel. Soft-tissue integration of the tube still does not occur.

The three-part tube system was changed to a two-component system. In addition, the groove that ran between the individual parts of the implant in the three-part system, constituting a potential irritant to soft tissue [5], is no longer present.

A sensitive part of the TACHAS tube system is the rubber-ring coupling between the stud of the hearing processor and the titanium tube system. Figure 3 shows the sound inlet head of the 4.4-mm tube and the 2.5-mm tube systems, respectively. The fitting between the stud of the hearing processor and the rubber ring in the sound inlet head depends on the diameter of the stud, the dimensions of the rubber ring, and the height and depth of the nut for the ring. Minimum differences in the manufacturing process for these parts may influence the quality of the fitting and cause mechanical stress, potentially leading to an inflammatory reaction of the soft tissue. The design of the sound inlet head has been improved: By means of a screw (see Fig. 3C), the height of the nut and, consequently, the pressure on the rubber ring can be varied. In this way, the quality of the coupling is less dependent on the manufacturing process and the dimensions involved. Furthermore, in the case of mechanical, thermal, or chemical damage, the rubber ring can easily be removed.

To research long-term reactions, light-microscopy investigations of the soft tissue around the tube were carried out. The samples for these histological studies were fixed by immersion fixation with phosphate-buffered 2.3% glutaraldehyde solution (pH 7.4) and, after dehydration with alcohol, were postfixed with 2% phosphotungstic acid. The tissue was subsequently immersed in glycidil ether (EPON).

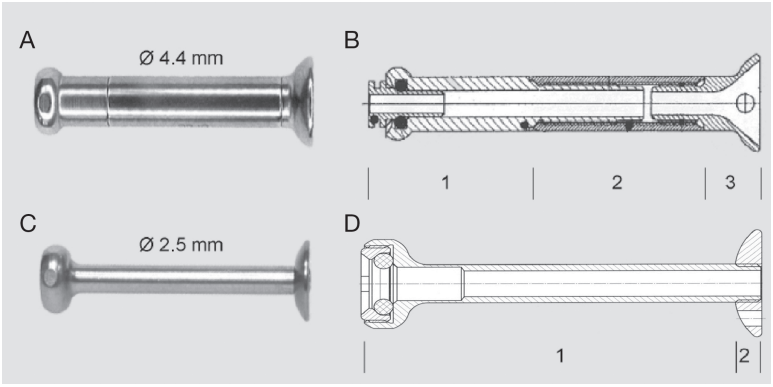


Figure 2. (A) Photograph and (B) longitudinal section of the 4.4-mm tube system. (*1* = sound inlet head; *2* = central part; *3* = sound outlet head.) (C) Photograph and (D) longitudinal section of the 2.5-mm tube system. (*1* = implant; *2* = sound outlet head.)

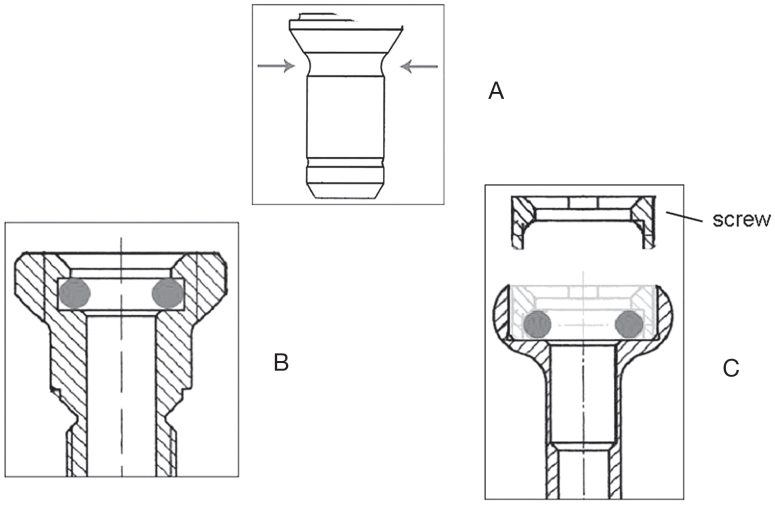


Figure 3. Coupling between (A) the stud of the hearing processor and the sound inlet head of (B) the 4.4-mm and (C) the 2.5-mm tube system.

INSERTION PROCEDURE

The smaller 2.5-mm implant effectively reduces the implantation surgery to a kind of functional body piercing procedure (Fig. 4). The titanium tube has to be mounted onto a handle using a guide and a special cutting tip, a procedure normally performed under local anesthetic. After a small skin incision has been made retroauricularly in the mould between the skin of the pinna and the mastoid, the trocar-like instrument is inserted and pushed forward horizontally until the tip has reached the outer-ear canal (Fig. 5).

Its position should be between the entrance of the outer-ear canal and the near boundary of the bony part of the outer-ear canal in the posterior wall. Owing to the anatomical shape of the cartilage skeleton [7], this positioning does not entail any perforation of the cartilage. After the cutting tip has been removed, the sound outlet head is mounted in the outer-ear canal (Fig. 6).

The tube system has to be implanted in a more or less horizontal plane (middle position in Fig. 7). If the tube were in the lower position (see Fig. 7), it might come into contact with the cartilage skeleton and cause pain. Furthermore, the microphone position would be more problematic with regard to feedback and wind noise. If, however, the tube is in a higher position (see Fig. 7), the implantation channel will be longer, and the healing time will be extended. If the sound outlet head is unfavorably positioned in the outer-ear canal, it may exert pressure on its wall.

A torque wrench can be used to attach the implant to the sound outlet head. It controls the torque, so that on one side, the two parts are securely fixed in place and, on the other side, the sound outlet head can be unscrewed without any difficulties.

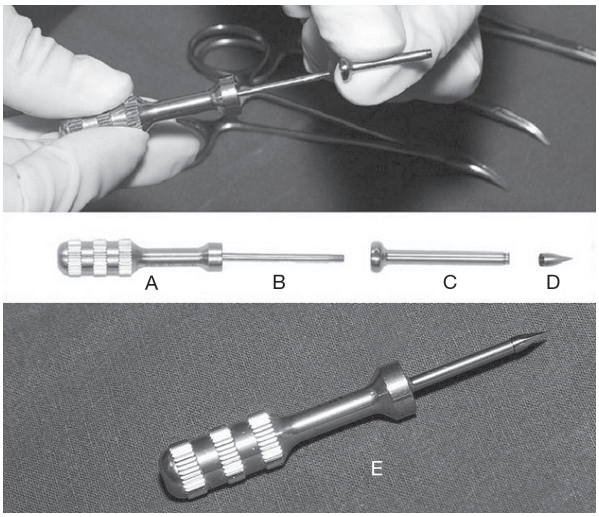


Figure 4. Tube and tools for implantation: (A) handle; (B) guide; (C) titanium tube; (D) cutting tip; (E) trocar-like instrument.

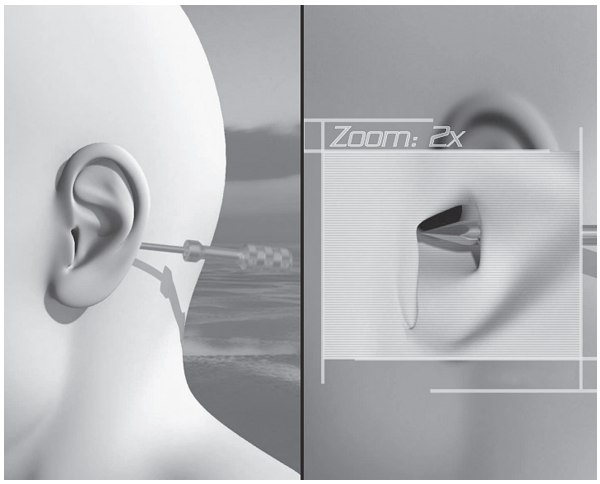


Figure 5. Trocar-like instrument in the soft tissue of the outer ear.

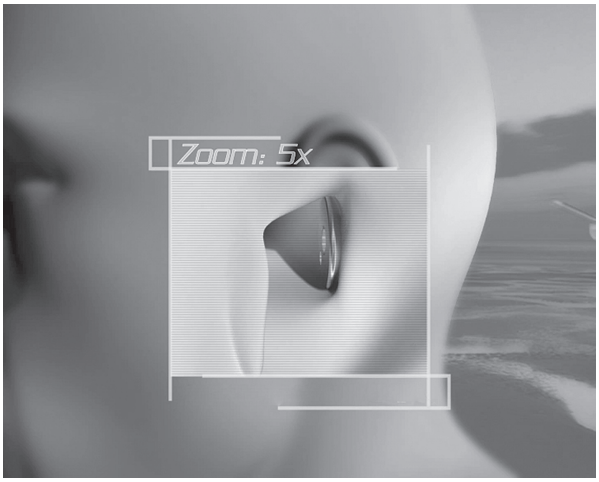


Figure 6. Sound outlet head in the outer-ear canal.

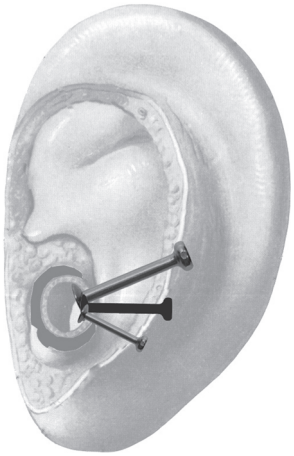


Figure 7. Different positions of the tube system in the outer ear.

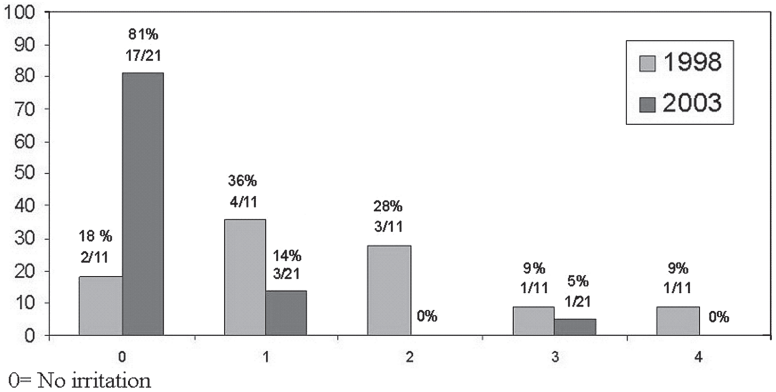
After the surgical procedure, several follow-up appointments (approximately eight in the first 4 months) must be made with affected patients for cleaning and checking both the implant itself and the area around it. The hearing processor then is fitted 3–6 weeks after implantation. This time interval is a compromise between the time required for primary healing—perhaps 3 months—and patients' desire to receive the hearing processor as soon as possible.

COMPLICATIONS

Affected patients should receive comprehensive counseling during the first 4–6 weeks so that they can be advised about hygiene and mechanical stress. Recipients should refrain from interfering with the ear canal (e.g., by inserting cotton buds), swimming without suitable ear protection, physical exertion, the use of saunas, and manipulating the tube in any way, as all of these activities may provoke an inflammatory soft-tissue reaction.

Such complications as mild bleeding may arise during the implantation procedure. Pain occurs mainly on the day of implantation, when the effects of local anesthesia wear off. To evaluate the risk of complications (e.g., granulation or infection), the implantation must be followed by a series of follow-up checks.

Complications have been classified according to a scale based on experience with the procedure, its potential for inflammatory complications, and earlier experience of soft-tissue reaction in the vicinity of skin-penetrating titanium implants [8]. *Category 0* indicates no irritation. Slight reddening, requiring local therapy but no additional control, is assigned *category 1*. In *category 2* complications, the tissue is reddened and moist around the tube, but no granulation occurs. Local therapy and additional control are necessary. Severely



0= No irritation
1= Slight reddening, local therapy, no additional control
2= Tissue reddened and moist, no granulations, additional control
3= Severely reddened, very moist, granulation tissue
4= Removal of the titanium tube due to infection

Figure 8. Classification of complications.

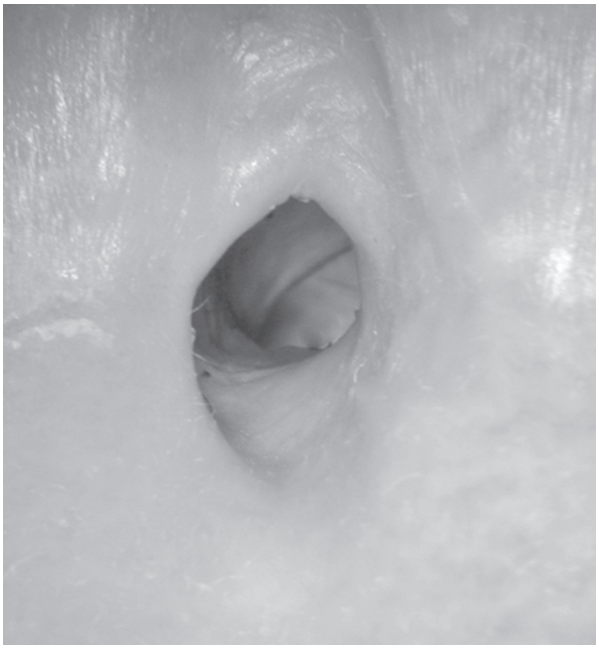


Figure 9. Endoscopic view into the implantation channel of a patient's ear implanted with a tube system in 1998.

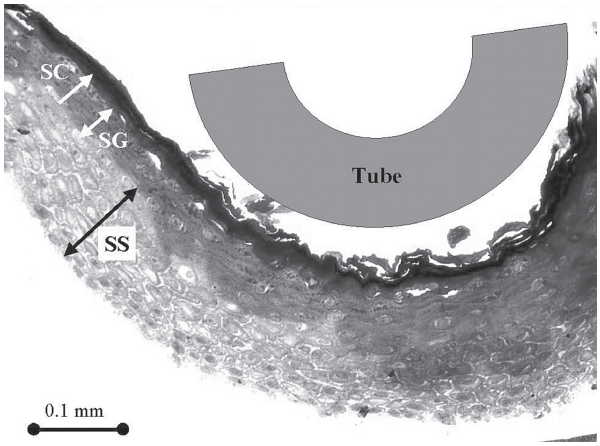


Figure 10. Semithin section of the tissue in the implantation channel (same patient as depicted in Figure 9) as seen on light microscopy. [*SS* = stratum spinosum (spinous layer of epidermis); *SG* = stratum granulosum (granular layer of epidermis); *SC* = stratum corneum (horny layer of epidermis) including stratum lucidum (clear layer of epidermis).]

reddened, very moist, and granulated tissue are designated *category 3*. A *category 4* complication necessitates removal of the titanium tube owing to infection.

Figure 8 shows the results of a 4-month investigation of the 2.5-mm tube system in 2003 (dark bars) compared with those for the 4.4-mm tube system in 1998 (light bars). Eleven patients underwent monitoring in 1998, and 21 were monitored in 2003. With the 4.4-mm tube and the 2.5-mm tube, no irritation was observed in 18% and in approximately 80% of cases, respectively. The incidence of slight reddening was 14% with the narrower tube but 36% with the wider tube. When the new system was used, no titanium tubes had to be removed during the study period owing to infection, and only one case of granulated tissue occurred.

LONG-TERM RESULTS

Figure 9 depicts the ear of a patient that was implanted with the titanium tube in 1998. The implantation channel is coated with an epithelial layer. The channel is some 20 mm long. At the end of the channel, the anterior wall of the outer-ear canal can be seen.

Histological investigations[1] of the tissue around the tube in this same patient were made (Fig. 10). The superficial stratum corneum (horny epithelial) layer is partially coming off as a result of having removed the tube. The light-microscope results show that, in the long term, the implanted tubes become lined by typical epidermal cornified tissue shown to be differentiated into spinous, granular, and horny layers. It is, to an extent, comparable with the epithelium of the lips.

CONCLUSIONS

The RetroX provides a hearing solution that keeps the ear canal fully open. It has proved to be an effective hearing system for patients suffering from mild to moderate high-frequency hearing loss. The audiological fitting range could be extended in the future using improved feedback- management systems; a tinnitus instrument will also be available soon. It has further audiological and medical advantages because no plug has to be inserted in the ear canal.

The incidence of complications, especially the incidence of granulation tissue seen in the 4.4-mm tube system, is diminished as a result of improved coupling between the tube and the stud of the hearing processor and by reducing the diameter of the central part of the tube system to 2.5 mm. The smaller tube facilitates a less traumatic operation, with surgery effectively reduced to a functional body piercing procedure. The postsurgical healing process is more rapid, with less mechanical irritation of soft tissue and, in turn, fewer complications.

Compliance on the part of the patient, sensitive counseling, and scheduled aftercare are important to

[1] The light-microscopical investigations were carried out by Dr. Uwe Hiller, Institute of Anatomy at the Westfälische Wilhelms–Universität, Münster, Germany.

guarantee a safe healing process. Long-term results show that the tissue around the tube develops an epithelium similar to that of the lips.

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