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Surgical Technique for Implantation of the MED-EL SONATATI[100]

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Key Words
Cochlear implant · MED-EL SONATATI[100] · Surgical technique · Complication · Fixation · Implant bed

Abstract
Aims: The objective of this study was to describe our surgical techniques following the general principles of cochlear implantation focusing on the small and thin design of the SONATATI[100] implant device. ***Methods:*** From May 2007 to December 2010, 97 patients were implanted with the SONATATI[100] device. Due to the titanium housing, a bony bed and a muscle-periost pocket were created to host the biggest part of the device with its magnet. For device fixation, suture-retaining holes were drilled at the end of the bed, and the electrode array was inserted deeply into the scala tympani via the round window or a cochleostomy. ***Results:*** Up to now, no case of device failure, migration or intracranial complication has been reported. However, one minor wound healing complication has occurred. ***Conclusion:*** Following the principal rules of cochlear implantation using a 2-bed technique combined with sutures allows safe fixation of the SONATATI[100] device.

Introduction

Over the last few decades, growing experience in cochlear implantation and changes in implant design have influenced the general principles of cochlear implantation surgery and allowed for variations in surgical techniques [1–5]. Consequently, a tendency towards smaller incisions, no drilling of the implant bed and no additional fixation with sutures, and away from these principles has evolved to minimize anesthetic time, for example, and to benefit from the further development of implant device technology, such as the steadily decreasing size and width of the devices [6–8]. However, despite the positive aspects of these surgical changes, several general principles seem to remain crucial for a safe implantation – even in the smaller and thinner implant devices currently on the market or in development [8].

The SONATATI[100] is a device of this newer generation and was introduced to the market in 2007 by MED-EL (Innsbruck, Austria). Multiple studies report on the beneficial outcomes of the new device in speech recognition, noise and music perception due to its fine structure processing speech coding strategy [9, 10]. To our knowledge, however, no reports on surgical techniques for a safe use of this device exist.

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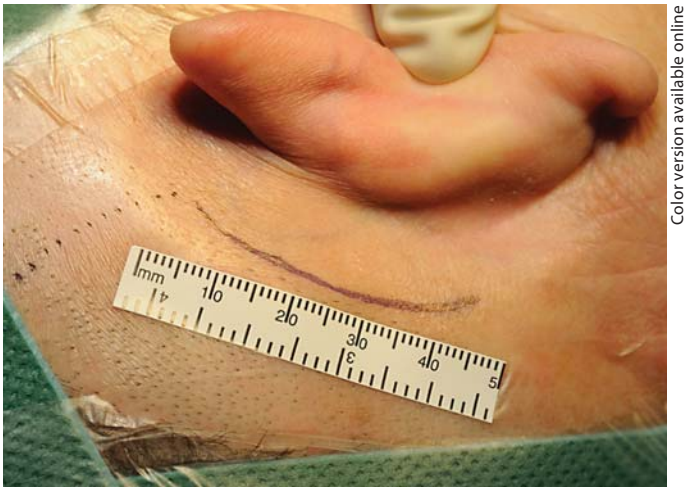

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Fig. 1. Postaural incision.

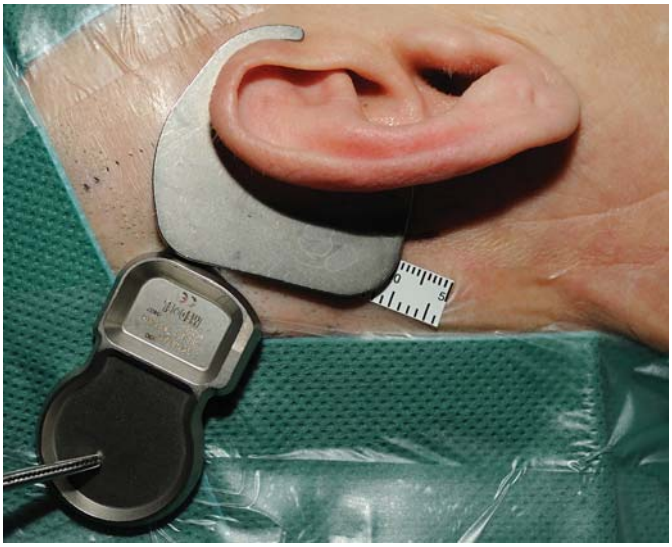

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Fig. 2. Planning the implant bed for the receiver with sufficient distance to the behind-the-ear processor (dummy).

The objective of this study was to describe our surgical techniques following the general principles of cochlear implantation, focusing on the small and thin design of the SONATATI[100] implant device, as well as on intraoperative problems, postoperative complications and data in the literature.

Patients and Methods

Patients

Ninety-seven patients with a profound sensorineural hearing loss were implanted with the SONATATI[100] device between May 2007 and December 2010. Careful diagnostic procedures were routinely carried out during preoperative evaluation.

Surgical Technique

After preparation, including shaving and injection of local anesthetics (Carbostesin 0.5% with adrenalin 1:200,000), a postaural incision was performed which could have been easily extended if required (fig. 1). The incision, which was as small as possible to minimize the risk of wound infection, was done with a distance to the implant bed to avoid that the scar would lie directly over the implant. Subsequently, a muscle-periost pocket was created to host the biggest part of the device with its magnet. Due to the titanium housing, a bony bed was drilled allowing increased stability, a lower profile and a decreased risk of trauma. The bed was positioned distantly to the mastoidectomy to avoid possible bacterial contamination of the device during acute otitis media. Another reason for this distant placement was the fact that the receiver would need sufficient distance to the behind-the-ear processor to avoid interference of the magnet with the batteries of the behind-the-ear processor (fig. 2). In very small children with thin skulls, it was sometimes necessary to expose the dura. To stabilize the implant and to avoid any movement, 2 bony holes for sutures were drilled next to the implant bed and at the beginning of the muscle-periost pocket.

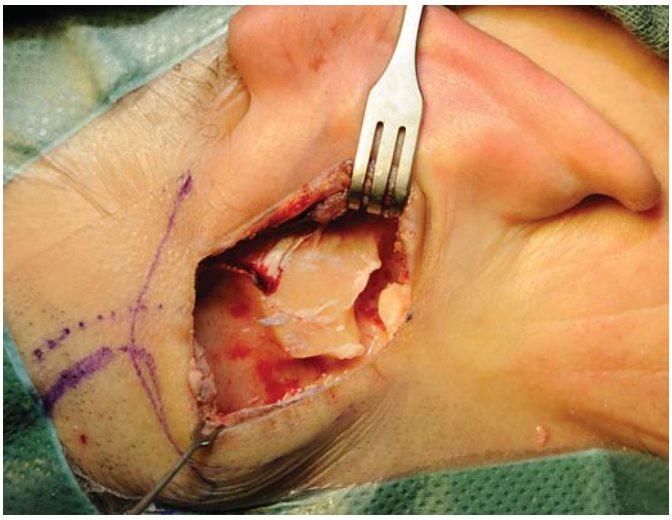

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Fig. 3. Intraoperative view: bony implant bed, channel with bony overhang, mastoidectomy.

To be able to access the cochlea, a canal wall-up mastoidectomy with a clear identification of the anatomical landmarks to avoid complications and a posterior tympanotomy were performed. To capture the proximal electrode lead, a bony overhang was left in the posterior and superior part of the mastoidectomy. In addition, a channel was drilled to connect the implant bed to

the mastoid (fig. 3). Special attention was given to avoid sharp edges that could damage the electrode.

The extended facial recess approach allowed access to the middle ear space. With cutting and diamond burrs, a triangularly shaped access with 3 borders was created: inferior to the incus bar, posterior to the chorda tympani and anterior to the facial nerve. First, the posterior wall of the external ear canal was thinned sufficiently without perforating the bony wall or destroying the chorda tympani. The facial nerve was identified and left covered by bone. If orientation is difficult the incus bar can be removed, but this was not necessary in these cases.

For insertion of the electrode we used a cochleostomy as well as the round window itself. The cochleostomy was placed anteriorly to the bony niche of the round window. The stapedial head was used for orientation: the cochleostomy was positioned at a distance double the width of its diameter inferior to the oval membrane. When opening the cochlea, special attention was paid to prevent bone dust from entering. Recently we began to prefer electrode insertion via the round window. Compared with a cochleostomy, the round window approach required less drilling for accurate electrode insertion. If the anatomical situation was narrow and the position of the round window was unfavorable, a standard cochleostomy was drilled through the promontory as described above.

Full insertion of the electrode array was performed. The standard electrode (MED-EL) was inserted gently, without force, up to the marker ring. The marker ring usually sealed the opening of the cochlea and was additionally covered with soft tissue.

The implant itself was placed in its bony bed and fixed by sutures. We used bone paté at its sides to stabilize the receiver. The electrode in the canal was sometimes covered by bone paté as well. Resorbable intracuteanous sutures, 4-0 skin sutures in adults or topical skin adhesives in children, and tapes were used for wound closure. A standard head bandage, which allowed elastic compression, covered the wound. The pressure of the bandage prevented the formation of hematoma so that no drainage was necessary.

Results

Twenty-nine (28%) of the 97 patients were children and 68 (66%) were adults. The mean age at implantation was 4.8 years in the pediatric group and 54.1 years in the adult group (range: 8 months to 87 years). All patients were successfully implanted using the standard surgical procedure described above. None of the patients showed a malformation of the cochlea. No cochlear ossification occurred in the postmeningitic patients (n = 9). Insertion of the electrode array was achieved in all 97 cases; 46% were implanted via the round window and 54% via a cochleostomy. The mean surgical time was 78 min (range: 52–137 min).

During surgery, no major complications occurred. Postoperatively, no intracranial complications, severe wound infections, flap necrosis, extrusion or migration of the implant at the follow-up assessment (mean: 1.9 years, range: 0.2–3.7 years) occurred. One patient showed minor wound healing complications which could be treated locally. All patients became full-time users of the implant device.

Discussion

In this study, we described a safe and reproducible surgical technique for implantation of the SONATATI[100] device. It is important to point out that we used well-approved techniques even though the reduced size of the device may allow for quicker techniques such as not drilling an implant bed at all [6]. All surgeries were carried out in a reproducible, standardized manner by experienced surgeons. As a result, the mean surgical time was 78 min. For academic settings with the obligation to teach residents and fellows, Majdani et al. [11] report on a mean surgical time of 145 min with a significant correlation between surgeon experience and surgical duration.

Although shaving the surgical field is not necessary to avoid wound infection, it may be helpful [12]. As we use a small retroauricular incision of about 4 cm, which can be easily extended to 6–7 cm to an inverted J-shape, spacious shaving is never required. This incision allows a good view so that drilling of the implant bed in the skull as well as the mastoidectomy are safe. The special surgical anatomy and possible variations in the temporal bones of children make implantation more difficult and may result in a higher risk of complications. Therefore, a good view is essential, and special attention has to be paid to the thin bone of the skull and adaptation for head growth. In addition, the surgeon has to deal with a small, flat mastoid, whose pneumatization is incomplete [3]. In this narrow anatomical situation, the sinus is more anterior and, due to the small mastoid, the facial nerve seems to be more lateral [3]. Smaller incisions are technically possible but not always more feasible as the exposure of the surgical field is limited. In our experience patients do not complain about the scar after cochlear implant surgery.

The small size and flat design of the new devices allow smaller incisions but should not provoke surgeons to abandon the option for safe fixation of the implant device. Although the need of an implant bed and the fixation of the implant device are controversial we recommend both, to drill an implant bed as well as to fix the SONATATI[100] implant with sutures as a bony bed for the titanium housing increases stability, lowers the profile and decreases the risk of trauma [3]. Although multiple

studies exist describing different surgical techniques focusing on incision, implant bed and fixation of the device, none has so far used the SONATATI100 implant [6–8, 12–14]. In a retrospective, anonymized, cross-sectional survey, Yoshikawa et al. [13] report on the current common practices and techniques used to fix and stabilize internal receivers. According to their results, about 80% of the surgeons always drill a bony well for the internal receiver, whereas 56% of the surgeons use diverse techniques for securing the device in adults and 50% in children. Up to 18% never secure the device. To create bone holes, most respondents rarely or never drill down to the dura.

Safe fixation of the device is recommended by several authors, even in small incision surgery [8, 14]. This is reasonable as we know the risk for electrode migration and receiver/stimulator migration from revision surgery [15]. Cohen [16] advises to use a bony bed and to drill bony holes for sutures. Adunka and Buchman [17] describe a technique for implant device fixation that uses a seat for the device and suture fixation through the native cranial periosteum without complication in 160 pediatric cochlear implant recipients. Also, Molony et al. [7] favor a periosteal tie-down technique. Cuda [18] reports on a small incision technique drilling a bony bed for MED-EL's PULSARCI100 device. In 14 patients, the implant was fixed with sutures; in 16 patients, it was placed in a periosteum pocket without additional sutures. At the follow-up (mean 3.2 years), no migration of the device was observed in either group [18]. Furthermore there are less frequently used techniques such as the fixation of the device using polypropylene mesh and titanium screws [19]. Balkany et al. [6] describe a technique for securing the receiver without drilling bone by creating a subpericranial pocket. In this study with a minimum follow-up of 12 months, no cases of migration or intracranial complication occurred [6]. There are a few reports on intracranial complications and cerebrospinal fluid leak followed by accidental damage of the dura or blood vessels. Gosepath et al. [20] report a case of an epidural hematoma after cochlear implantation in a 2.5-year-old boy. Dodson et al. [21] describe 2 patients with minor dural defects with cerebrospinal fluid leak at the site of the receiver recess and 1 elderly patient with an acute extensive subdural hematoma (0.86%, n = 345). In a retrospective analysis over a decade, Ding et al. [22] review 1,237 patient records and describe no cerebrospinal fluid leakage or intracranial complications after cochlear implantation. In cochlear implantation, intracranial complications have to be considered as extremely rare, but serious, complications.

Surgical principles for cochleostomy are well established and allow a full insertion of the electrode array into the scala tympani [23]. For years we used this standard cochleostomy routinely in cochlear implant surgery [3]. With regard to preservation of residual hearing, increased emphasis has recently been placed on the need to minimize insertional trauma. Thus, electrode insertion via the round window has regained its status and popularity. Round window insertion is discussed to be potentially less traumatic than the standard cochleostomy insertion, but it may be challenging [5]. Particularly with regard to hearing preservation, the recommended location of a cochleostomy has ranged from different sites in the promontory. Adunka et al. [24] describe a cochleostomy located more inferiorly and only slightly anteriorly to the round window. This technique leads to a safe insertion into the scala tympani without any basal cochlear traumatization, but it might be even more challenging than the round window approach. Anatomical variations in the round window area may make insertion via the round window membrane or an inferiorly located cochleostomy difficult. To avoid damage of the facial nerve and the chorda tympani, a standard cochleostomy is still feasible for electrode insertion [25].

Since 2008, the round window approach has more and more replaced standard cochleostomy in our group of patients. We performed a full insertion of the electrode array via the round window in 45 cases and through a standard cochleostomy in 52. All patients demonstrated successful results relating to speech perception. This is consistent with the literature [26].

Conclusion

Following the general principles of cochlear implant surgery, we adapted the surgical techniques to the characteristics of the SONATATI100 device as described above. This surgical technique is fast, safe and easy to handle as it allows (i) a reduction in surgery time, (ii) a stable fixation of the device and (iii) a good intraoperative view.

Disclosure Statement

The authors have no conflicts of interest to declare.

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