

OTOLOGY

Cochlear implantation with Pulsar[®] Med El: a novel small incision technique

Impianto cocleare Pulsar[®] Med-El: tecnica chirurgica mininvasiva

D. CUDA

Department of Otolaryngology, "Guglielmo da Saliceto" Hospital, Piacenza, Italy

SUMMARY

Although still widely implanted, Pulsar[®] Med-El is rarely considered for small incision approach. Overall, 30 teen-age and adult patients were operated upon with a novel small incision (4-5 cm). Full insertion of the electrode array was achieved in all cases. No major intra-operative complications occurred. At follow-up, no flap-related complications and no migration of the receiver-stimulator were observed in the "device suture" (14 patients) or "no device suture" groups (16 patients). All patients are full-time users of the device. In conclusion, a small incision for the Pulsar[®] Med-El cochlear implant is feasible, safe and reproducible. Ligature fixation of the device is not critical with this operation. Also with this device, in adult and teen-age patients, it is, therefore, possible to retain several typical advantages of small incision approaches.

KEY WORDS: Deafness • Cochlear implant • Pulsar[®] • Surgical technique • Small incision

RIASSUNTO

Sebbene sia ancora diffusamente utilizzato, l'impianto cocleare Pulsar[®] viene raramente considerato adatto agli approcci chirurgici mininvasivi con incisione piccola. Il presente lavoro descrive l'esperienza clinica condotta su un gruppo di trenta pazienti adolescenti ed adulti con una nuova incisione di 4-5 cm. In tutti i casi operati si otteneva l'inserzione completa del multielettrodo. Non si registravano eventi avversi intraoperatori. Al follow-up non si osservavano complicanze a carico del lembo cutaneo né migrazioni dell'impianto sia nel gruppo in cui questi veniva suturato (16 pazienti) che in quelli senza sutura del dispositivo alla teca cranica (14 pazienti). Tutti i pazienti utilizzano con regolarità l'impianto cocleare. In conclusione una incisione piccola con impianto Pulsar[®] Med El risulta fattibile, sicura e riproducibile anche senza sutura del dispositivo. Anche con questo dispositivo pertanto pazienti adolescenti ed adulti possono sfruttare i molteplici vantaggi delle procedure mininvasive con incisione piccola.

PAROLE CHIAVE: Sordità profonda • Impianto cocleare • Pulsar[®] • Tecnica chirurgica • Incisione piccola

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Introduction

It is now well known that small incision cochlear implant (CI) surgery reduces morbidity¹⁻² and improves patient and parent satisfaction³ as compared to wider access operations. In fact, several operations have been proposed in various populations and with different devices¹⁻⁶. Although still widely used, the Pulsar[®] Med-El CI (Med-El GmbH, Innsbruck, Austria) is rarely considered for minimally invasive surgery. In order to correctly wear the speech processor, in fact, the receiver-stimulator (RS) must be placed in a more posterior position than with other devices such as the new Sonata[®] Med-El. In other words, due to their distance, the bony bed for the RS and the mastoidectomy are not easily drilled through a small incision. The present report refers to clinical experience with a new small incision operation with the Pulsar[®] cochlear implant.

Materials and methods

Surgical technique

All procedures were performed in a hospital setting under general anaesthesia. Initially a minimal trichotomy was carried out around the hair-line on the retro-auricular area. A small incision (4-5 cm) was made behind the ear just posterior to the retro-auricular speech-processor template mark. Below, the incision began at the posterior extension of the cantho-meatal line (Fig. 1). The skin was raised from the underlying tissues, al-



Fig. 1. Incision (4-5 cm) is traced behind retro-auricular template framework mark (T), starting below posterior extension of cantho-meatal line (CML).

lowing the *pericranium*, *temporalis fascia* and post-auricular muscles to remain in place. A second layer, *fibroperiosteum*, was then incised, avoiding the area with the skin incision. Using a dissector, a periosteum flap was then carefully elevated to the mastoid tip, to the posterior border of the external auditory canal and to the zygomatic root. The postero-superior flap was elevated to make a sub-pericranial pocket to accommodate the RS. The size of this pocket was about 3 cm wider than the RS; this was checked with the implant template. In order to stabilize the surgical field and to prevent trauma to soft tissues, the edges of the skin and periosteum flaps were sutured together with surgical drapes. Self-retaining retractors were used and a cortical mastoidectomy was carried out, as usual, under gross vision. A metallic shell was then used to lift the posterior flap, to protect soft tissues and to facilitate drilling of the RS bed on the skull below the fibroperiosteum pocket. The shell was cut in half from a common steel surgical bowl; the edges were smooth and dimensions were: 3 cm (antero-posterior) x 6 cm (lateral) x 4 cm (depth) (Fig. 2). The upper wing of the metallic shell was first inserted under the periosteum through the superior aspect of the incision. The shell was then fully inserted with a slow postero-inferior movement. In this way, the inferior wing of the shell rested under the periosteum and extended to the inferior aspect of the incision. At this point, the operating bed was rotated towards the surgeon in order to better expose the skull. The shell allows visualization, protection of the overlying tissues and, at the same time, avoids the need of assistance with retraction. The RS bed was then drilled under gross vision with the anterior border located behind the skin incision line. Once again, the correct size of the bed was frequently checked by means of a surgical template and by previously prepared aluminium strips. In the first 16 patients, tie-down holes were drilled on the lateral wall of the RS bed in order to fix the device to the skull with non-resorbable sutures (Fig. 3). In the remaining 14 patients, no suturing of the device was performed; in these non-sutured cases, stability of the device was provided by the pressure of the periosteum pocket on the skull bed.

Thereafter, the metallic shell was removed, with tooth forceps, rotating it in the opposite direction to that of insertion.



Fig. 2. A metallic shell (SMS) is used to lift posterior sub-periosteal pocket and to protect soft tissues during drilling.



Fig. 3. Oblique-surgical view of Pulsar® receiver stimulator bed (B). Pericranium flap is elevated by SMS. Holes (H) for tying down RS have been drilled on lateral wall of bed.

A curvilinear groove between the RS bed and mastoidectomy was then drilled in order to accommodate the implant cables (Fig. 4). The other surgical steps (posterior tympanotomy, cochleostomy or round window preparation) were performed in the usual manner before implanting the device. Soft tissues were sutured in layers. In some cases, a histoacrylic glue was used to close the skin. A head dressing was routinely used in order to prevent any haematoma and stabilize the position of the device.

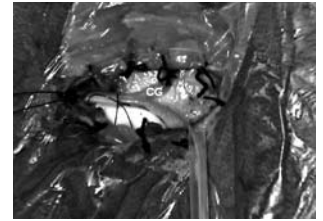


Fig. 4. Pulsar® receiver stimulator is placed on bony bed before suture is completed. A curvilinear groove (CG) accommodates cables towards the mastoidectomy.

Patients

The operation was performed on a consecutive series of 30 adult and teenage patients (12 male, 18 female). Age ranged from 12 to 72 years (mean = 43). The cause of hearing loss was non-syndromic hereditary loss in 9 cases, otosclerosis in 4 cases, autoimmune hearing loss in 2 cases and a Mondini-like cochlear abnormality in one case. The cause of hearing loss was unknown in 14 cases. Prospectively recorded surgical data, which included duration of surgery, length of hospital stay and complications, were reviewed.

Results

All patients were successfully implanted using a 4-5 cm incision. Full insertion of the electrode array was achieved in all cases. The small incision was never extended, not even in two particularly difficult cases. In the first, we effectively managed an anteriorly placed sigmoid sinus by its posterior partial displacement. In the second (a Mondini-like cochlear malformation), a complete middle ear and external meatus obliteration was performed on account of a relevant gusher.

A mastoid emissary vein bleeding occurred in 3 cases. It was easily controlled by a diamond burr, bipolar coagulation, bone wax or a combination of these. No major intra-operative complications occurred. All patients were discharged on the second post-operative day without requiring readmission. At follow-up (mean 3.2 years, range = 3-5) no flap-related complications and no migration of the RS were observed in either the “device suture” or “no device suture” patients. No significant alopecia was observed around the incision line. All recipients are full-time users of the device.

Discussion

In the present report, a novel small incision for Pulsar® device is described. This operation appears to be safe and reproducible. An important issue with this technique is

that the incision line is more posterior than usual; it is placed just behind the post-auricular area of the speech-processor template. This ensures that the receiver-stimulator does not lie directly below the speech processor. The pressure of the external component on the skin over the device can be painful and even cause flap necrosis or contribute to metal fatigue of the array⁷.

The incision line is considered here as a sort of watershed between the two main drilling areas, i.e., the mastoidectomy, anteriorly, and the RS well, posteriorly. The anterior drill is relatively easy, while the posterior drill is a slightly more difficult. It requires expansion of soft tissues and, at the same time, a tool to protect these tissues. The elevator we used is easily made, in a reproducible way, from a standard surgical steel bowl. It is inexpensive, safe, reusable and easily inserted and removed from the surgical field. The surgeon does not have to change position but, instead, has only to work in a more oblique way under soft tissues. The preparation of the RS bed takes a little longer than the “open” procedure proposed by the manufacturer⁸ on account of the oblique direction of drilling and the frequent checks of bed size. Our experience demonstrated that the learning time is short, and this technique is now routine in our Institution when a Pulsar[®] device is employed. Difficult anatomical situations like anteriorly placed sigmoid sinuses or the need to obliterate the middle ear or the external auditory meatus have been successfully managed by this small incision which could be enlarged, at any time, if necessary.

References

- ¹ Gibson WP, Harrison HC, Prowse C. *A new incision for placement of cochlear implants*. J Laryngol Otol 1995;109:821-5.
- ² O'Donoghue GM, Nikolopoulos TP. *Minimal access surgery for pediatric cochlear implantation*. Otol Neurotol 2002;6:891-4.
- ³ Eshraghi A, Balkany TJ, Telischi FF, Ahsan S, Ardic FN, Angeli SI. *Minimal incision technique for cochlear implantation*. Annual meeting of the American Academy of Otolaryngology-Head & Neck Surgery, September 22-25, 2002, San Diego, CA.
- ⁴ Jiang D, Bibas A, Fitzgerald O'Connor A. *Minimally invasive approach and fixation of cochlear and middle ear implants*. Clin Otolaryngol 2004; 29:618-20.

Ligature fixation of devices has been considered a basic principle of cochlear implant surgery⁹ because of the risk of displacement. The surgical experience with small incisions demonstrated that the periosteal closure is sufficient to hold the device in place in its bone bed², although some Authors^{6,7} continue to tie down the device in children. Since no difference was observed between the “device suture” and “no device suture” group, in terms of late migration of the device, we no longer tie it down on the skull. A properly prepared head dressing is sufficient to stabilize the operating field and prevent early migration. In fact, stability of the device is ensured by the pressure of the pericranium on the skull bed and also by the lateral vertical wall of the bed. The next step for validation of this approach is to use it in children where the need for minimal access surgery is greater.

Conclusions

A reliable “small incision” (4-5 cm) operation with Pulsar[®] CI has been developed for adult and teenage patients. The operation does not require expensive instrumentation or surgeon sitting variation compared to standard otologic surgery. It is also possible with this device to take advantage of the well-known benefits of small incision approaches, such as, for example, fewer post-operative flap complications, reduced risk of infection, less post-operative pain, faster operation and recovery times, less or no shaving and better psychological acceptance.

- ⁵ Obholzer RJ, Graham JM. *A novel retractor for use in cochlear implantation*. Otol Neurotol 2004;25:83-5.
- ⁶ James AL, Papsin BC. *Cochlear implant surgery at 12 months of age or younger*. Laryngoscope 2004;114:2191-5.
- ⁷ James AL, Papsin BC. *Device fixation and small incision access for pediatric cochlear implants*. Int J Ped Otorhinolaryngol 2004; 68:1017-22.
- ⁸ MED-EL Pulsar[®] *Surgical manual*. Innsbruck. MedEl GmbH. 2006.
- ⁹ Webb RL, Lehnhardt E, Clark GM, Laszig R, Pyman BC, Franz BK. *Surgical complications with the cochlear multiple-channel intracochlear implant: experience at Hannover and Melbourne*. Ann Otol Rhinol Laryngol 1991;100:131-6.

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Conflict of interest

No financial relationships exist with the organizations mentioned in the present report.

Address for correspondence: Dr. D. Cuda, Divisione di Otorinolaringoiatria, Ospedale “Guglielmo da Saliceto”, Via Cantone del Cristo, 40, 29100 Piacenza, Italy. Fax : +39 0523 303273. E-mail: d.cuda@ausl.pc.it