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OTOLOGY

Scar evaluation in subperiosteal temporal pocket versus the one-layer flap technique in cochlear implantation using the Patient and Observer Scar Assessment Scale

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Abstract

Purpose To compare the local and intracranial complications, migration of the IRS, surgical duration, and quality of life with the subperiosteal pocket technique and the one-layer flap (OLF) technique using the Patient and Observer Scar Assessment Scale (POSAS).

Methods Eight patients who underwent cochlear implantation. The patients were applied subscales of the POSAS and were asked to respond to the questionnaire items via a telephone conservation conducted by a physician. Another researcher evaluated the patients' photographs using OSAS. POSAS was applied to the patients to compare the differences of scar assessment in subperiosteal pocket technique and the OLF technique.

Results The surgical duration was 72.7 ± 12.3 min in the OLF group and 51.3 ± 11.7 min in the subperiosteal pocket group. The difference was statistically significant. No migration or intracranial complications were observed in either group. Patients in group 1 who underwent the subperiosteal technique were more satisfied than patients who received the OLF technique. However, there was no superiority between the two methods for the observer in scar assessment.

Conclusion Although the surgical time is longer, the lack of difference in terms of scar formation from smaller incisions, and few intra- and post-operative complications in experienced hands ensure that the OLF technique is a safe and reliable method in cochlear implantation surgery.

Keywords Cochlear implantation · Hearing loss · One-layer flap technique · Lazy-S incision · Patient and Observer Scar Assessment Scale

Introduction

Cochlear implantation (CI) has become a routine procedure worldwide for the management of sensorineural hearing loss (SNHL). Some complications can be seen after CI surgery after each operation. CI surgery has evolved through various techniques to reduce post-operative complications, the early surgical technique for CI included large skin incisions. These extended incisions and large soft tissue flaps were accompanied by post-operative problems associated with hematoma and seroma, resulting in flap necrosis and infection. The tendency to minimal incision by otolaryngologists has gradually increased because the majority of CI complications have been associated with the skin incision and soft tissue flaps [1, 2]. In addition to the change in incision size, post-operative scar satisfaction has become important. Although scar evaluation is mostly focused on burns scars, there is increasing interest in surgical scars [3]. The purpose of this study was to compare the differences of scar assessments in the subperiosteal pocket technique versus the OLF technique in cochlear implant surgery (Table 1).

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Table 1 Patients' demographics

	Group 1 (one-layer flap technique)	Group 2 (subperiosteal pocket technique	*p*
Sex *n* (%)			0.501[a]
Male	17 (42.5)	20 (50)	
Female	23 (57.5)	20 (50)	
Age			0.087[b]
Mean ± SD	38.6 ± 16.0	31.7 ± 17.5	
Med (min–max)	35 (28–91)	24 (3–70)	
Type of hearing loss, *n*			
Prelingual	6	3	
Postlingual	34	37	
Implant site, *n*			
Right	34	33	
Left	6	7	
Brand of cochlear implant, *n*			
MED-EL medium	18	26	
MED-EL standard	10	5	
Nucleus contour advance	7	8	
Digisonic	5	1	

[a]Chi-square test

[b]Mann–Whitney *U* test

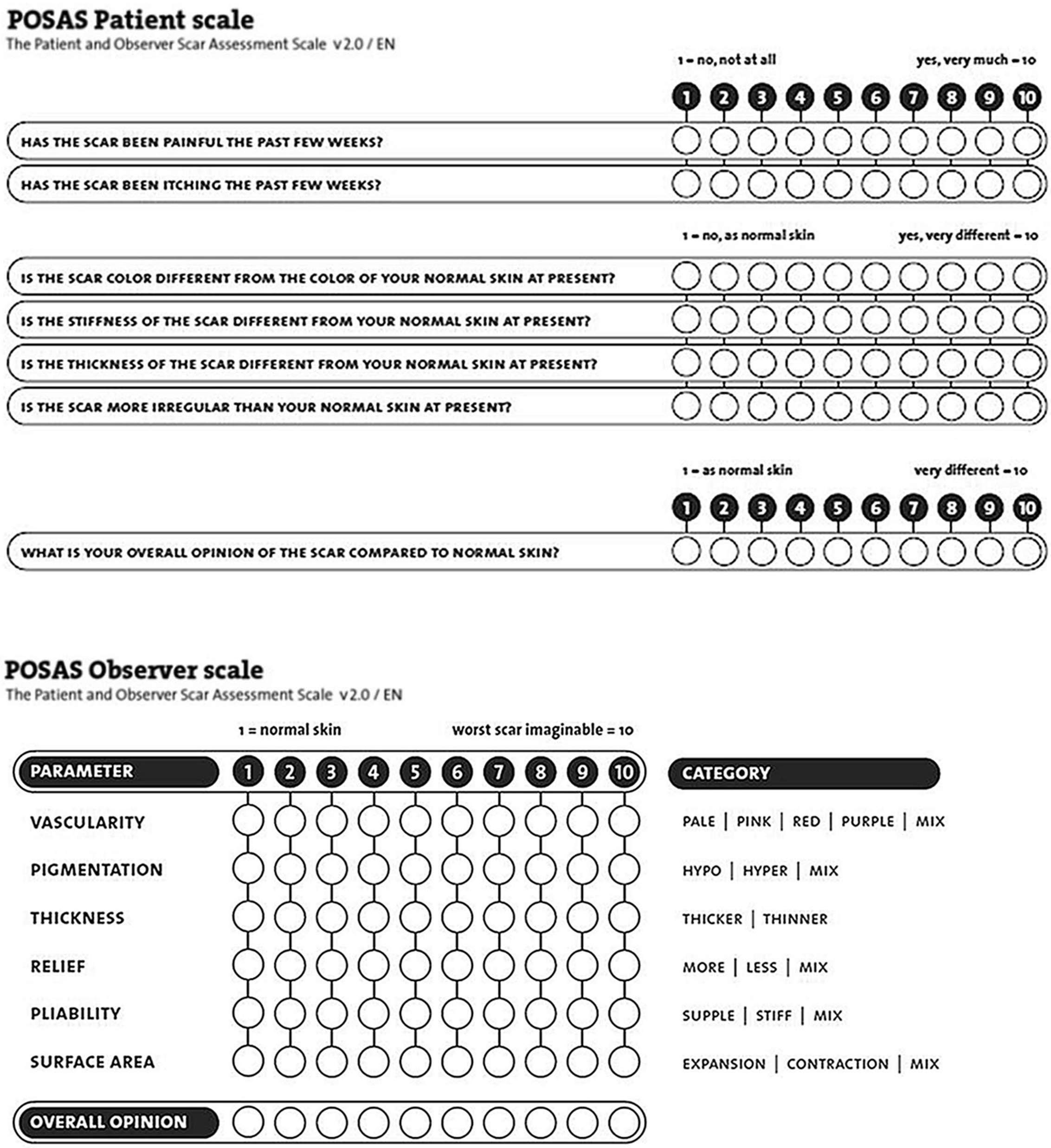
Materials and methods

A retrospective review was performed of all patients who underwent CI between January 2014 and June 2016. The study protocol was approved by the Ethics Review Board of our university. The Patient and Observer Scar Assessment Scale (POSAS), which consists of patient (PSAS) and observer (OSAS) subscales, was used to evaluate the scars in the subperiosteal pocket technique (group 1) versus the OLF technique (group 2) in cochlear implant surgery. Patients older than 18 years, patients who underwent at least 2 years after CI surgery, and patients undergoing primary surgery were included in the study. Participation was voluntary. Forty patients from group 1 and 40 patients from group 2 who met these criteria were selected. Patients aged under 18 years, and patients undergoing revision surgery were excluded from the study. The patients were applied subscales of POSAS and were asked to respond to the questionnaire items via a telephone conservation conducted with a physician. Another researcher evaluated the patients' photographs with OSAS. Both PSAS and OSAS consist of two scales: a six-item 'total score' scale and a single-item 'overall opinion' scale (Fig. 1). The sub-items are scored on a ten-point scale comparing the patient's skin with normal skin. The lowest score, one point, reflects normal skin, whereas the highest score, ten points, reflects the worst imaginable scar (Table 2).

Surgical technique

General anesthesia was used in all patients. CI surgery was performed in group 1 using the subperiosteal pocket technique with a C-incision, and OLF technique in group 2 using a lazy-S incision. Mastoidectomy, posterior tympanotomy, and oval window or cochleostomy approach under general anesthesia were performed for all groups. After a retroauricular incision was made, either a lazy-S incision or C-shape incision was performed, then the temporal occipital periosteum was elevated. The skin overlaying the temporalis muscle fascia was raised to form the first flap (skin flap) in group 2. The muscle and periosteum were incised in a straight line and in a different plane from the first incision with no contact, this is called a second flap in the OLF technique. A second incision was made through the muscle and periosteum to reach the bone and was directed obliquely from the superior posterior zone to the inferior anterior zone to ease bone drilling in the OLF technique (Table 3).

The CI technique in group 1 requires a small postauricular incision, minimal soft tissue flaps, and a tight subperiosteal pocket for the device. A bone recess with suture fixation was used in group 2. Subsequent to cortical mastoidectomy and visualization of the short process of the incus, the facial recess was detected and enlarged to approach the round window niche. Cochleostomy was chosen in patients whose round window was not fully visible. Electrodes were


POSAS Patient scale
The Patient and Observer Scar Assessment Scale v2.0 / EN
1 = no, not at all   yes, very much = 10
1 2 3 4 5 6 7 8 9 10
HAS THE SCAR BEEN PAINFUL THE PAST FEW WEEKS?
HAS THE SCAR BEEN ITCHING THE PAST FEW WEEKS?
1 = no, as normal skin   yes, very different = 10
IS THE SCAR COLOR DIFFERENT FROM THE COLOR OF YOUR NORMAL SKIN AT PRESENT?
IS THE STIFFNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?
IS THE THICKNESS OF THE SCAR DIFFERENT FROM YOUR NORMAL SKIN AT PRESENT?
IS THE SCAR MORE IRREGULAR THAN YOUR NORMAL SKIN AT PRESENT?
1 = as normal skin   very different = 10
1 2 3 4 5 6 7 8 9 10
WHAT IS YOUR OVERALL OPINION OF THE SCAR COMPARED TO NORMAL SKIN?

POSAS Observer scale
The Patient and Observer Scar Assessment Scale v2.0 / EN
1 = normal skin   worst scar imaginable = 10
PARAMETER 1 2 3 4 5 6 7 8 9 10   CATEGORY
VASCULARITY   PALE | PINK | RED | PURPLE | MIX
PIGMENTATION   HYPO | HYPER | MIX
THICKNESS   THICKER | THINNER
RELIEF   MORE | LESS | MIX
PLIABILITY   SUPPLE | STIFF | MIX
SURFACE AREA   EXPANSION | CONTRACTION | MIX
OVERALL OPINION

Fig. 1 The Patient and Observer Scar Assessment Scale (POSAS)

Table 2 Observer questionnaire

	Group 1		Group 2		p^a
	Mean ± SD	Med (min–max)	Mean ± SD	Med (min–max)	
Vascularity	1.0 ± 0.0	1.0 (1–1)	1.8 ± 0.9	1.5 (1–4)	< 0.001
Pigmentation	2.0 ± 1.1	2.0 (1–4)	2.2 ± 1.2	2 (1–4)	0.441
Thickness	1.6 ± 0.8	1 (1–4)	2.1 ± 0.8	2 (1–3)	0.004
Relief	2.1 ± 1.4	2 (1–6)	2.4 ± 0.8	2 (1–4)	0.057
Pliability	2.1 ± 1.4	1 (1–5)	1.8 ± 1.0	1 (1–4)	0.365
Surface area	1.8 ± 0.9	1 (1–9)	1.8 ± 0.9	1 (1–4)	0.971
Overall	1.6 ± 0.7	1.5 (1–3)	1.9 ± 0.8	2 (1–3)	0.131

[a]Mann–Whitney *U* test

Table 3 Patient questionnaire

	Group 1		Group 2		p
	Mean ± SD	Med (min–max)	Mean ± SD	Med (min–max)	
S1	1.8 ± 1.9	1.0 (1–8)	1.2 ± 0.9	1 (1–5)	0.076
S2	1.7 ± 1.7	1 (1–7)	1.4 ± 1.2	1 (1–5)	0.335
S3	1.9 ± 1.2	1 (1–5)	1.5 ± 1.1	1 (1–5)	0.176
S4	2.3 ± 2.1	1 (1–7)	1.8 ± 1.9	1 (1–9)	0.185
S5	2.1 ± 1.5	1 (1–5)	2.1 ± 1.4	1.5 (1–7)	0.726
S6	2.6 ± 1.9	1 (1–6)	1.7 ± 1.4	1 (1–6)	0.021
Overall	2.1 ± 1.4	1 (1–5)	1.3 ± 0.8	1 (1–4)	0.001

implanted in the scala tympani. The facial recess was sealed with small pieces of muscle to keep the electrodes away from the external auditory canal to provide the original anatomy. Complete insertion depth was accomplished in all cases. The processor of the cochlear implant was placed into its bed on the temporal bone and fixed with 0 Prolene in group 2. The ball electrode in the cochlear implants (Cochlear Ltd., Lane Cove NSW, Australia) was placed under the temporal muscle. The whole periosteal flap was closed using absorbable sutures and the skin was closed with Prolene sutures. Electrical compound action potential (ECAP) was measured intra-operatively after insertion. Stenvers and transorbital petrous skiagram were acquired during early post-operative period to define and record the appropriate placement of the implants.

Statistical analyses

Statistical analysis was performed using the MedCalc Statistical Software version 12.7.7 (MedCalc Software bvba, Ostend, Belgium; https://www.medcalc.org; 2013). The normality of continuous variables was investigated using the Shapiro–Wilk test. Descriptive statistics are presented using mean and standard deviation for normally distributed variables and median (and minimum–maximum) for non-normally distributed variables. For the comparison of two non-normally distributed independent groups, the Mann–Whitney *U* test and Wilcoxon signed-rank test were used. Categorical variables were compared using the chi-square test. Statistical significance was accepted when two-sided *p* values were lower than 0.05.

Results

There were 17 (42.5%) males and 23 (57.5%) females in group 1, and 20 (50%) males and 20 (50%) females in group 2. The mean age of group 1 and group 2 was 35 (range 28–91) years and 24 (range 18–70) years, respectively. There were no statistically significant differences in age and sex distribution between the two groups. Postlingual hearing loss was observed in 71 patients; only 9 patients were diagnosed as having prelingual hearing loss. The follow-up period ranged from 28 to 36 (mean 30.8) months. The right ear was the operated side in 67 patients, and 13 patients underwent surgery on the left ear. The surgical duration was 72.7 ± 12.3 min in the OLF group and 51.3 ± 11.7 min in the subperiosteal pocket group. The mean surgical time was 22 min shorter in the subperiosteal pocket group than in the OLF group, and the difference was statistically significant ($p < 0.001$).

In group 1, 18 patients were implanted with Med-El standard (Medel Medical Electronics, Innsbruck, Austria), 10 patients with Med-El medium (Medel Medical Electronics, Innsbruck, Austria), 7 patients with Nucleus Freedom Contour® Advance (Cochlear Ltd., Lane Cove NSW, Australia), and 5 patients with Digisonic devices (Neurelec, Vallauris, France).

In group 2, Med-El standard (Medel Medical Electronics, Innsbruck, Austria) was used in 26 patients, Nucleus Freedom Contour® Advance (Cochlear Ltd., Lane Cove NSW, Australia) was used in 8 patients, Med-El medium (Medel Medical Electronics, Innsbruck, Austria) was used 5 patients, and a Digisonic device (Neurelec, Vallauris, France) was used in 1 patient.

No intra-operative complications were observed in either group. No CSF gushing or oozing was observed. Transient facial paresis after surgery was seen in one patient in group 2. This complication is thought to have arisen from heating by the drill. The patient had an anatomically narrow posterior tympanotomy. Facial paresis was seen as a result of the effect of heat on the facial nerve in the narrow area. The patient was fully recovered after 6 months.

Vascularity and thickness showed a statistically significant difference between the two groups in the observer questionnaire (Mann–Whitney *U*; $p < 0.001$, $p = 0.004$). The scores of vascularity and thickness in group 2 were higher for the observer. The sixth question and overall scores in the patient questionnaire showed statistically significant differences between the two groups (Mann–Whitney *U*; $p = 0.021$, $p = 0.001$). The scores in group 2 were higher. Patients in group were more satisfied with their scars.

Discussion

Cohen and Hoffman's classification of cochlear implant complications is the most accepted classification [1, 2]. The most commonly reported CI complications after electrode failure are associated with the skin incision and soft tissue flaps [1, 2]. Many incision techniques have been described to minimize these complications. Telian et al. and O'Donoghue and Nikolopoulos used a small incision for this purpose and reported that this technique reduced wound and flap problems [3, 4]. The shape of the incision is identified by the internal receiver/stimulator (IRS) fixation technique, and it also helps to avoid skin and flap complications. Besides, there is no agreement on the optimal method for fixing the IRS.

Balkany et al. were the first to describe the temporalis pocket (T-pocket) technique anatomically and clinically [5]. Anatomically, they defined the intensive fibrous attachments of the pericranium to suture lines in the cranium. In the clinical study, 227 patients were examined retrospectively. They reported that IRS migration or intracranial complications did not occur in either group. Prager noted that the surgical duration was shorter in the minimal access technique, but they found no significant difference between the two techniques in terms of complications [6]. Güldiken et al. also stated that the surgical time was less than the classic technique and they found no significant difference between the two techniques regarding complications [7]. In our study, the duration of the minimum access technique was significantly shorter than the OLF technique. We also accomplished the same results in our study. Neither migration nor intracranial complications were observed in either group.

The lazy-S incision is a modification of the straight incision, which results in requiring less tissue elevation and better cosmetic results by supplying a tight pocket for the implant. Low minor 0.7–18% and major complication rates of 0–3.2% have been seen using this incision type [3, 8]. In the OLF technique, the incisions overlap but the deeper incision is made more reliable with tight periosteal sutures and is protected from the complications of the superficial incisions. As a result of the healing processes of the two layers, the periosteum and skin, non-permanent, relatively weak, scar tissue forms between the superficial skin and deeper layers. Unfortunately, this claim has yet to be proven [9]. Alzoubi et al. used a modified double-flap technique and reported minor wound-related complications with a very low rate of 1.2%; all of which were treated conservatively without requiring surgical intervention [9]. We used the OLF technique but the periosteum was tightly sutured. Our experience showed that, no matter what the flap technique, tightening of the periosteum can minimize the complications related to the incision.

During the preparation of the implant bed in the standard technique, the dura mater may become visible and this poses a number of risks including dural tear and CSF leak for all age groups, but especially children [6, 7]. If a minimal access technique is used, these complications are not seen. We believe that there will be no such intracranial complications in an experienced team. We open small holes for fixing to the head and we use a diamond bur in this process.

The greatest criticism against minimum access cochlear implant techniques is that they cannot prevent migration when they do not use rigid fixation. This situation creates concern for high rates of migration. We recommend the OLF technique including drilling with suture fixation. Fixation in pediatric patients is more important than in adults due to the fact that children have thinner soft tissue than adults and are more likely to experience trauma. Davids et al. supported this issue in their publication [10]. In this study, all of our patients were selected as adults to respond to a questionnaire. This is one of the reasons why we do not experience exposures of the cochlear implantation. Regardless of the incision, we found more skin and flap complications in pediatric patients with the subperiosteal pocket technique. Therefore, we think that it is not enough to prepare the bone implant bed, and IRS should be also fixed using suture-retaining holes on the temporal bone. Although Vicryl® or Prolene® could be used, we use 0 Prolene® for fixation.

Scar formation occurs as the last phase of wound healing by the temporary overlap of inflammatory, proliferative, and remodeling phases. The maturation of scars takes 1–2 years [11]. Therefore, at least 1 year is required to assess scar formation. The follow-up period ranged from 28 to 36 (mean 30.8) months in our study. POSAS presents an applicable modality for measuring both patient- and observer-reported quality of cochlear implantation scars. No relation between the total score and overall opinion for both the PSAS and OSAS was obtained. Besides, the inter-rater reliability was poor. This may be due to the fact that the patients and observers had different expectations from the scar result. Güldiken et al. reported on subperiosteal temporal pocket versus the standard technique in CI with using a visual analog scale (VAS) [7]. The evaluation of the VAS scoring was done by parents because some of the patients were children [7]. In our study, we removed factors that would make additional illusions such as parental interpretation by selecting adult patients. Also, both the patient and the observer participate in POSAS and this provides superiority to other scar assessment tools. The patients who underwent the OLF technique with lazy-S incision were found to be more irregular in terms of scar than normal skin. Furthermore, the patients in group 1, who received the subperiosteal technique, were more satisfied than those who underwent the OLF technique. However, there was no superiority between the two methods for the observer in scar assessment except vascularity and thickness. We think that the presence of subjective things such as itching and pain in the patient evaluation was effective in this result. The poor inter-rater reliability could also be expressed by the psychological perspective of the patients.

Although the surgical time is longer, the lack of difference in terms of scar formation from smaller incisions, and few intra- and post-operative complications in experienced hands ensure that the OLF technique is a safe and reliable method in cochlear implantation surgery.

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Compliance with ethical standards

Conflict of interest No potential conflict of interest was reported by the authors.

Ethical approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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