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Original Article

Comparison of Conventional Technique with Suture Fixation and Subperiosteal Tight Pocket Technique on Revision Cochlear Implantation Rate

Mehmet Emrah Ceylan[1], Mehmet Ekrem Zorlu[2], Onur Çorakçı[2], Ecem Sevim Akı[2], Gökçe Aksoy Yıldırım[2], Abdullah Dalgic[2]

[1]Private ENT Clinic, Isparta, Türkiye
[2]Department of Otolaryngology-Head and Neck Surgery, Izmir Bozyaka Education and Research Hospital, University of Health Sciences, İzmir, Türkiye

ORCID iDs of the authors: M.E.C. 0000-0001-7330-9306, M.E.Z. 0000-0003-0474-8094, O.Ç. 0000-0001-7758-6298, E.S.A. 0000-0001-6256-2015, G.A.Y. 0000-0002-4330-0164, A.D. 0000-0002-6958-4169.

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BACKGROUND: Several fixation methods have been described to secure the cochlear implant's receiver/stimulator, but the optimal stabilization technique is still being debated. The aim of this study was to compare the conventional technique with suture fixation to the subperiosteal tight pocket technique in terms of revision cochlear implantation rate.

METHODS: A retrospective review was conducted on the medical records of 649 patients who underwent cochlear implantation. The study participants were divided into different groups regarding the applied surgery technique. The relationship between the fixation technique, revision rates, and the cause of revisions related to techniques was investigated.

RESULTS: The overall revision rate was 2.9% (19 out of 649). There were 14 (3.5%) and 5 (2%) revision implantations in the subperiosteal tight pocket and conventional technique groups, respectively. The incidence of device failure was 2.5%, and it constituted the primary cause for revision surgery in both groups. Even though patients who had the subperiosteal tight pocket technique had a much higher rate of device failure, the results indicate that there was no significant difference between the groups, as evidenced by a *P*-value of .12.

CONCLUSION: The conventional and subperiosteal tight pocket techniques can both be safely preferred with low revision rates in patients undergoing cochlear implantation.

KEYWORDS: Cochlear implantation, ear, inner, hearing loss, mastoidectomy

INTRODUCTION

The practice of utilizing cochlear implantation is a prevalent method for the purpose of rehabilitating individuals who suffer from significant sensorineural hearing loss. The transmastoid facial recess approach and cochleostomy are generally well-defined standard techniques during cochlear implantation. Various techniques have been reported to secure the receiver/stimulator (R/S), such as the subperiosteal tight pocket method and the conventional approach of drilling the bone implant bed with or without utilizing stabilization aids.[1] In the conventional technique, a bone bed is created on the calvarium for R/S stabilization. However, the calvarium may be very thin, especially in children, which can result in unfavorable intracranial complications. On the other hand, improper fixation can cause R/S migration, which can lead to implant failure. The optimal stabilization technique is still being debated among patients with cochlear implantation.

The aim of this study was to compare the conventional technique with suture fixation to the subperiosteal tight pocket technique in terms of the preferred technique-related revision cochlear implantation rate.

Corresponding author: Mehmet Emrah Ceylan, e-mail: mrhcyln@gmail.com
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MATERIAL AND METHODS

The research was carried out at the Department of Otolaryngology, Head and Neck Surgery at University of Health Sciences Türkiye Izmir Bozyaka Research and Education Hospital. A retrospective review was conducted on the medical records of patients who underwent cochlear implantation within the time frame of January 2008 to January 2012.

Ethical Considerations

The study was granted approval by the Ethics Committee of University of Health Sciences Türkiye Izmir Bozyaka Research and Education Hospital. (Date: January 12, 2022; Approval No: 2022/11). Prior to all diagnostic and therapeutic procedures, written informed consent was procured. The research was carried out in adherence to the guidelines outlined in the 1964 Declaration of Helsinki and its subsequent revisions.

Study Design and Population

The main inclusion criteria were: (1) primary cochlear implantation in a male or female patient; and (2) revision cochlear implantation in a patient who had the primary intervention in our clinic. The individuals who received surgical revision procedures, had their initial surgery at a different center, and had a history of trauma were excluded. Also, the patients with complications that were not related to the preferred fixation technique, like cholesteatoma and covering the electrode with bone tissue, were excluded. According to the inclusion and exclusion criteria, 649 patients were included in the study. While the conventional technique with suture fixation was preferred by a senior surgeon between 2008 and 2012 until he left the clinic, the subperiosteal tight pocket technique was preferred by another senior surgeon, and the frequency of its application has gradually increased. The demographic characteristics of the patients, the reason for the revision surgery, and the R/S fixation technique were documented. The participants were divided into 2 groups based on the method of fixation employed. The patients who underwent subperiosteal tight pocket technique were named group 1, and the patients who underwent conventional technique were named group 2. A transmastoid facial recess approach and cochleostomy were applied to all patients. There were no other additional fixation techniques, like using meshes, screws, sutures, pins, ligatures, or creating bone grooves, in the patients included in the study.

According to the consensus development conference statement, the reasons for device failure were classified as hard or soft failure.[2] Hard failure was described as the loss of audio input with an abnormal integrity test. Soft failure was described as when a patient showed poor progress and/or symptoms that could indicate cochlear implant failure, such as a persistent headache, dizziness, tinnitus, facial stimulation, or refusal to use the device, even though integrity tests were normal. The medical records of the patients were reviewed retrospectively, and the relationship between R/S fixation technique, revision rates, and the cause of revisions was investigated.

MAIN POINTS

- Various techniques have been reported to secure the receiver/stimulator (R/S) in cochlear implantation.
- The optimal stabilization technique is still being debated in patients with cochlear implantation.
- The subperiostal tight pocket method has a similar revision rate compared to the conventional technique with suture fixation.
- The conventional and subperiostal tight pocket techniques can both be safely preferred with low revision rates in patients undergoing cochlear implantation.

Surgery Techniques

Subperiosteal Tight Pocket Technique

The skin incision is made approximately 2 centimeters from the post-auricular sulcus. The flap is lifted forward towards the external ear canal. Incisions made from the superior linea temporalis and mastoid tips are joined away from the skin incision. The Palva flap, which is based on the anterior region, is elevated towards the external auditory canal. A subperiosteal pocket is created between the linea temporalis and the lamboidal suture in the parietal region. By utilizing a silicone rubber model as a prototype, the pocket is progressively expanded until the model can be accommodated without witnessing lateral buckling exceeding 1 mm. Subsequently, a conventional cortical mastoidectomy and posterior tympanotomy approach are executed, followed by a cochleostomy through the round window. The implant body is inserted into the subperiosteal pocket that has been prepared, and the electrodes are subsequently positioned within the cochlea. The drilling of an implant bed and the use of sutures were not implemented. If there is a ground electrode, it is placed in the subperiosteal plane. Then, the periosteal flap and skin incisions are closed.

Conventional Techniques with Suture Fixation

A modified hockey stick incision[3] is made approximately 2 centimeters from the post-auricular sulcus. The flap is lifted forward towards the external ear canal. Incisions made from the superior linea temporalis and mastoid tips are joined away from the skin incision. The Palva flap, which is based on the anterior region, is elevated towards the external auditory canal. Following cortical mastoidectomy, the outer edge of the mimicked implant is inscribed on the calvarium. A diamond burr was used to prepare the bone implant bed. After the dummy implant was fully placed, the diamond burr was used to create a groove that connects the mastoidectomy cavity to the implant bed. Next, 4 holes were drilled in the side of the implant bed for receiver/stimulator fixation. The cochleostomy procedure was carried out after the facial recess was opened. Two anchoring absorbable stitches were inserted before the implant R/S was positioned in the bone bed. The ground electrode was then positioned subperiosteally after the electrode had been implanted in the cochlea. Periosteum and skin incisions were closed multilayer in a watertight manner.

Statistical Analysis

The software Statistical Package for the Social Sciences Statistics version 25.0 (IBM SPSS Corp.; Armonk, NY, USA), was used for the statistical analysis. Categorical data were shown in n and frequency, while continuous variables were shown in mean and standard deviation (SD). The Kolmogorov–Smirnov and Shapiro–Wilk tests were applied for normality checks. The Mann–Whitney *U*-test was utilized for group differences in continuous data, and the Fisher exact test was used for categorical variables. A .05 *P*-value was regarded as statistically significant.

RESULTS

Three hundred ninety-six patients comprised group 1, and 253 patients comprised group 2. In Table 1, the demographic data of the patients who underwent cochlear implantation is given. Operation time was 145.02 ± 13.51 and 150.65 ± 20.95 minutes in groups 1 and 2, respectively ($P = .00$). The mean follow-up time was 150.66 ± 20.98 and 149.00 ± 22.04 months in groups 1 and 2, respectively ($P = .405$). No statistically significant difference was found regarding the demographic characteristics of the groups. Table 2 displays the distribution of cochlear implants among the device manufacturers.

In Table 3, the revision causes and rates for the groups are given. The overall revision rate was 2.9% (19 of 649). There were 14 (3.5%) and 5 (2%) revision implantations in groups 1 and 2, respectively ($P = .341$). The mean time to revision (months) was 29.14 ± 17.31 and 22.00 ± 14.97 in groups 1 and 2, respectively ($P = .336$). Device failure was the most frequent cause of revision surgery in both groups, with a device failure incidence of 2.5%. It was 3.3% and 1.2% in patients who underwent subperiosteal tight pocket and conventional techniques, respectively ($P = .120$). No statistically significant differences were found regarding device failure and revision rates between groups.

In patients with hard failure, revision was performed due to electrode dislocation in 5 of 9 patients in group 1, obvious implant migration in 2, and a magnet coming out of the socket in 2 patients. In group 2, revision was performed due to the dislocation of the electrode in 1 patient and the magnet in 1 patient. In Table 4, the etiology of the revisions and the details of the cochlear implants are given.

Recurrent hematoma was the cause of the revision in 3 patients. There were no skin flap failures or infections requiring revision surgery in either group. In all cases, complete electrode insertion was achieved during revision, except for 2 patients with partial insertion in group 1. In any of the revision cases, there were no intraoperative complications, except for 1 patient who had a gusher.

In Table 5, demographic data for the patients who underwent revision surgery is given. No statistically significant differences were found regarding the demographic characteristics of the groups. While there were 5 patients younger than 2 years old with hard failure in group 1,

Table 1. Demographic Data of the Patients

(n/%)	Group 1 (n = 396)	Group 2 (n = 253)	P
Gender			
Male	211 (53.3)	133 (52.6)	.937
Female	185 (46.7)	120 (47.4)	.937
Age			
<2 years	53 (13.4)	24 (9.5)	.134
2-18 years	189 (47.7)	135 (53.4)	.162
>18 years	154 (38.9)	94 (37.1)	.657
Age (mean±sd)	19.69 ± 20.97	18.13 ± 20.00	.347
Side			
Bilateral	12 (3.0)	4 (1.6)	.306
Right	288 (72.7)	192 (75.9)	.409
Left	96 (24.3)	57 (22.5)	.637
Operating time (minute/mean ± SD)	145.02±13.51	150.65 ± 20.95	.000
Follow-up (months/ mean ± SD)	150.66±20.98	149.00±22.04	.405

Table 2. Distribution of Cochlear Implants Among the Device Manufacturers

(n)	Group 1 (n = 396)	Group 2 (n = 253)	P
Advanced Bionics	36	43	.003
Cochlear	101	40	.005
Medel	228	153	.513
Oticon	31	17	.647

Table 3. Revision Causes and Rates for the Groups

(n/%)	Group 1 (n = 396)	Group 2 (n = 253)	P
Device failure	13 (3.3)	3 (1.2)	.120
Hard failure	9 (2.3)	2 (0.8)	.330[a]
Soft failure	4 (1.0)	1 (0.4)	.653[a]
Recurrent hematoma	1 (0.3)	2 (0.8)	.564[a]
Total	14 (3.5)	5 (2.0)	.341

[a]Fisher's exact test.

Table 4. Etiology of the Revision and the Manufacturer of the Implants

	Manufacturer	Model	Etiology
Group 1			
Case 1	Medel	Sonata	Electrode dislocation
Case 2	Medel	Concerto 2	Electrode dislocation
Case 3	Cochlear	CI24RE	Electrode dislocation
Case 4	Medel	Concerto 2	Electrode dislocation
Case 5	Cochlear	CI422	Electrode dislocation
Case 6	Advanced Bionics	Hires 90K	Obvious implant migration
Case 7	Medel	Sonata	Obvious implant migration
Case 8	Cochlear	CI24RE	Magnet coming out of the socket
Case 9	Cochlear	CI422	Magnet coming out of the socket
Case 10	Medel	Synchrony	Recurrent hematoma
Case 11	Cochlear	CI422	Soft failure
Case 12	Medel	Concerto 2	Soft failure
Case 13	Cochlear	CI422	Soft failure
Case 14	Medel	Concerto 2	Soft failure
Group 2			
Case 1	Medel	Concerto 2	Electrode dislocation
Case 2	Advanced Bionics	Hires 90K	Magnet coming out of the socket
Case 3	Medel	Pulsar	Recurrent hematoma
Case 4	Cochlear	CI422	Recurrent hematoma
Case 5	Cochlear	CI422	Soft failure

Table 5. Demographic Characteristics of the Patients in the Groups who Underwent Revision Surgery

(n/%)	Group 1 (n = 14)	Group 2 (n = 5)	*P*
Gender			
Male	4 (28.6)	1 (20.0)	.603[a]
Female	10 (71.4)	4 (80.0)	.603[a]
Age			
<2 years	5 (35.7)	-	.257[a]
2-18 years	5 (35.7)	3 (60.0)	.603[a]
>18 years	4 (28.6)	2 (40.0)	.520[a]
Age (mean ± sd)	14.64 ± 20.84	13.80 ± 13.95	.935

[a]Fisher's exact test.

there were no patients younger than 2 years old in group 2, but there was not a statistically significant difference.

DISCUSSION

The revision rate in the current study was 3.5% and 2% in patients with the subperiosteal tight pocket technique and conventional technique, respectively. No statistically significant difference was found between groups. Similar to the literature, the most frequent reason for re-implantation in both groups was device failure.[4,5] The overall revision rate was 2.9%, which was comparable to previous reports. Aldhaferei et al[4] stated that out of 922 participants, 37 (4%) underwent revision surgery. While Sunde et al[6] mentioned a rate of 4.1%, Pamuk et al[7] observed a similar rate of 3.43% for 1516 cochlear implantations performed from 2002 to 2016. The reason for the low overall revision rate in the present study may be that only complications related to the fixation method were evaluated. Other complications causing revision surgery, such as bone coverage of the electrode, cholesteatoma, and infection, were not taken into account.

The majority of fixation methods are based on 2 fundamental approaches. The drilling of a bone well and holes for sutures are necessary for the traditional fixing technique. In the event of seroma, hematoma, and infection, it offers a better direct view, a reduced profile of the device, simpler drilling, and better fixation.[1] Pamuk et al[7] reported that the conventional technique is associated with a lower revision rate than the subperiosteal pocket technique regarding device failure rate and mentioned that the conventional technique should be the preferred method of R/S fixation.

The other methods involve using "minimally invasive" techniques to create a small sub-periosteal pocket in which the R/S is placed and periodically held in place by periosteal sutures. These methods involve using "minimally invasive" techniques. Meshes, screws, sutures, pins, ligatures, bone grooves, and other minimally invasive techniques can be used to provide additional fixation. In a prospective clinical study, it was reported that implant migration was found to be a rare complication of the subperiosteal pocket technique.[8] Also, it is reported that using only the subperiosteal pocket technique without additional fixation techniques results in enough stabilization of the R/S via spontaneous bone bed formation.[9] In addition, Jethanamest et al[10] reported similar findings and added that using the solely subperiosteal tight pocket technique without suture fixation or bone recess is an efficient and minimally invasive technique without compromising patient safety or device performance. With minimally invasive techniques, lower infection risk, faster recovery after surgery, shorter hospital stays, earlier device activation, and fewer foreign body reactions are provided.[1] In addition, similar to the present study, Sweeney et al[11] reported that the subperiosteal tight pocket technique led to a statistically significant reduction in operative time and mentioned that it is a safe and efficient technique in patients undergoing cochlear implantation. We believe that a shorter operation time is an important advantage and provides less morbidity.

More robust stabilization of the R/S is mainly attempted to prevent R/S migration and electrode dislocation. R/S migration may be in the form of a micro-movement that can cause wire fatigue, degrading the performance of the implant, or may be so pronounced that it completely inhibits the use of the external unit and may result in revision surgery.[12]

Between 20% and 25% of adult and pediatric patients receiving the subperiosteal pocket method exhibited objective RS migration, although none of these patients encountered device failure, according to Maxwell et al[13] In the present study, with a lack of a statistically significant difference between groups, 7 of the 8 patients with migration requiring revision used the subperiosteal pocket technique. An electrode dislocation that resulted in reimplantation could be considered one of the valid criteria for implant migration. The rate of electrode dislocation in the current study was 1.2 percent (8/649). This is consistent with the findings reported in the review by Alenzi et al.[14] In a recent review, Markodimitraki et al[15] reported that no evidence has been reported of a difference between the conventional and tight pocket techniques concerning the R/S device or electrode array migration in adults. In a recent review, Goh X and et al[16] reported that surgeon seniority, preferred surgical technique, and electrode type did not influence the risk of electrode migration in the early healing period. However, it is important to keep in mind that implant material and thickness may influence revision rates in the long-term follow-up. In our opinion, the lack of consensus in the evaluation of electrodes and R/S migration causes different opinions to be reported in the literature. Further prospective large-scale studies with objective R/S migration and electrode dislocation measurement methods are needed to achieve more reliable results.

In this study, the relationship between the reasons for revision and age was not investigated, but it was remarkable that 13 of 19 (68%) patients who underwent revision were in the pediatric age group. Gümüş B et al[17] reported that the most common reason for revision in children is device failure. In the present study, the causes of device failure in the subperiosteal tight pocket group under 2 years of age may be early implantation, frequent falls while learning to walk, or vestibular immaturity, as stated by Gümüş B et al.[17]

According to O'Neill et al[18] over 10 years, the cumulative survival probability for all-cause revision surgery is 0.71%. Nearly 30% of children with unilateral implants will have revision surgery 10 years after implantation. They mentioned that this figure is much higher than overall revision rates, illustrating the importance of interpreting results in context. Receiver/stimulator fixation is an essential surgical step of cochlear implantation and should be done with meticulous care to avoid possible complications.

It was seen that the implant manufacturers of the revision cases are distributed homogeneously. In addition, Concerto 2 is included in both groups 1 and 2 in electrode dislocation cases. This may indicate that the implant model is not the main cause of electrode dislocation. However, this study did not examine the relationship between the distribution of cochlear implants among device manufacturers and revision rates. Further prospective, large-scale studies are needed to achieve more reliable results on this topic.

The most important limitation of the study is its retrospective nature. Another weakness of the study is that the micro-movement of the R/S, which did not result in revision, was not taken into account. Further prospective, large-scale studies are needed to achieve more reliable results on this topic.

According to the current research, the subperiosteal tight pocket method has a similar revision rate compared to the conventional technique with suture fixation. In other words, safety in both groups is equivalent. High-level data suggests that anesthetics lasting up to an hour do not have long-term negative effects on neurodevelopment in infants. However, it is not as clear what effects longer durations of general anesthesia have.[19] The equivalent safety with a shorter operation time is the main benefit for patients with the subperiosteal tight pocket technique. Therefore, we believe that conventional and subperiosteal tight pocket techniques can both be safely preferred with low revision rates in patients undergoing cochlear implantation.

Ethics Committee Approval: This study was approved by the University of Health Sciences Türkiye Izmir Bozyaka Research and Education Hospital. Ethics Committee (Approval No: 2022/11; Date: January 12, 2022).

Informed Consent: Informed consent was obtained from the patients who agreed to take part in the study.

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