



ORIGINAL ARTICLE

Findings from the experience with the punch technique for auditory osseointegrated implants: A retrospective single center comparative study

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Abstract

Objective: To compare the punch technique and linear incision with soft tissue reduction for the placement of auditory osseointegrated implants (AOI) and analyze results of osseointegration obtained with the punch technique as measured with the Implant Stability Quotient (ISQ). **Methods:** Case review of 34 patients who received auditory osseointegrated implants between January 2010 and July 2015 and were divided into two groups according to the surgical technique: 18 with the punch technique (PT) and 16 with the linear incision technique (LI). Minimum follow-up was four months (mean: 24 months; range 4--64 months). Included in the analysis were patient profiles and records of the demographic data, surgical indications, surgical technique, implant placement, surgical time, intraoperative complications, as well as postsurgical complications (Holgers classification) and implant stability quotients (ISQ).

Results: Use of larger abutments was significantly greater in the PT group (PT, 10 mm; LI, 6 mm, $p < 0.001$). The PT technique resulted in a shorter procedure than the LI (PT, 20 min; LI, 45 min, $p < 0.001$). Holgers classification scores identified significantly fewer skin complications one week after surgery for the PT group; however, only small differences were seen between the two groups at the one- and three-month control visits.

Conclusions: As shown for our cohort, the punch technique for surgical placement of AOI is faster and presents fewer immediate postoperative complications when compared to the linear incision technique. The clinical application of the ISQ is a useful, easy method to demonstrate the status of osseointegration and, thus, the stability of the device.

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PALABRAS CLAVE

Conducción ósea;
Prótesis auditivas;
Hipoacusia de
conducción;
Estudio
retrospectivo;
Complicaciones
postoperatorias

Resultados de la experiencia con la técnica de perforación para implantes auditivos osteointegrados: estudio comparativo retrospectivo de nuestro centro hospitalario

Resumen

Objetivo: Comparar la técnica de perforación con la de incisión lineal con reducción de tejidos blandos en la colocación de implantes osteointegrados y analizar los resultados de la osteointegración obtenidos con la técnica de perforación (PT) medidos con el coeficiente de estabilidad del implante (Implant Stability Quotient [ISQ]).

Métodos: Treinta y cuatro pacientes recibieron implantes osteointegrados entre enero 2010 y julio 2015, dividiéndolos en 2 grupos: 18 con PT y 16 con técnica de incisión lineal (LI). El seguimiento mínimo fue de 4 meses (media: 24 meses; rango 4-64 meses). Analizamos los perfiles de los pacientes, datos demográficos, indicaciones quirúrgicas, técnica quirúrgica, colocación del implante, tiempo de cirugía, complicaciones intraoperatorias y postoperatorias (clasificación de Holgers) y el ISQ.

Resultados: El uso de pilares más largos fue significativamente mayor en el grupo PT (PT: 10 mm; LI: 6 mm, $p < 0,001$). La PT fue más corta que la LI (PT: 20 min; LI: 45 min, $p < 0,001$). La clasificación Holgers identificó menos complicaciones cutáneas a la semana poscirugía en el grupo PT de forma significativa; de hecho, solo se apreciaron pequeñas diferencias entre los 2 grupos en las visitas a los 3 meses.

Conclusiones: Como se muestra en nuestro estudio, la PT para la colocación de implantes osteointegrados es más rápida y presenta menos complicaciones cutáneas postoperatorias inmediatas cuando se compara con la técnica LI. La aplicación clínica del ISQ es útil y fácil para objetivar la osteointegración y así la estabilidad del implante.

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Introduction

An auditory osseointegrated implant (AOI) provides an effective solution with predictable

results for auditory rehabilitation of patients with conductive, mixed or unilateral neurosensory hearing loss. The implant transmits sound received in the device directly to the bone of the skull, improving the sound perception by more than 25 dB, compared with other traditional bone-conduction auditory prostheses.¹ Since its introduction in 1977, AOI surgical tech-

niques have undergone constant improvements, becoming less invasive, with fewer intraoperative and postoperative complications, shorter surgical time, and lower incidence of extrusion cases and implant failure.^{2,3} With time, AOI appli-

cation has increased due to the wide acceptance amongst patients, the good levels of auditory performance achieved, and the lower incidence of skin complications. Further, the option of performing the surgical procedure under local anesthesia is becoming more frequent, reducing surgical time, minimizing surgical costs and lessening the incidence of possible complications from general anesthesia.

It was Tjellström^{1,4} who initially described the surgical

technique for these devices with the creation of a cutaneous flap by means of a dermatome with additional soft tissue

reduction before placing the implant. That technique was not without postoperative cutaneous complications as defined by the Holgers classification,^{5,6} making postopera-

tive management more challenging and delaying device use. Consequently, a new technique variant was developed, the U flap, described by Woolford et al.,⁷ that included reduction of soft tissues at the implant site. Several authors have compared the classical dermatome and the U-flap techniques, and described their respective cutaneous complications.⁸⁻¹⁰

The linear incision (LI) with cutaneous flap technique was later adapted in 2007 by Tjellström et al.,² reducing the

cutaneous complications around the implant and improving esthetics. Since its introduction, the LI approach has undergone improvements by various authors.¹¹⁻¹⁴ Studies on

complications followed, some reporting few, such as the work of Van de Berg et al.,¹⁵ and others, such as that pub-

lished by De Wolf et al.,¹⁶ reporting high index scores of

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Findings from the experience with the punch technique for implants severe cutaneous alterations according to Holgers classification (16.9%). Current literature reports fewer cases of adverse skin reactions, flap necrosis problems, cutaneous growth on the abutment, osseointegration failure and ultimate extrusion of the implant.^{11,13,17--22}

An important change in the LI surgical technique was proposed by the Radboud University Nijmegen Medical Centre group, at the beginning of the 90s, resulting in a reduction in flap failures.^{14,17} Further, the arrival of longer abutments,

designed by the manufacturers (Cochlear and Oticon), led to the development of less invasive techniques to the subcutaneous soft tissues. With the appearance of these longer abutments, studies appeared that defended their use in order to avoid cutaneous overgrowth, which was seen on occasion with the 6 mm abutment, confirmed by the studies of Pelosi and Chandrasekhar.²³ Similarly, reports

have supported the concept that longer abutments did not have a greater extrusion index, such as that published by D'Eredita et al.¹ Research by Hultcrantz¹⁷ and Hultcrantz and Lanis¹⁸ concluded that avoiding soft tissue reduction

did not affect the stability of the implant. A prospective study with results of LI with no soft tissue reduction in 34 patients was published by Altuna et al.²⁴ with reduction in

postsurgical complications. Thus the current trend is toward an evolving less surgical invasive procedure, which has led to an increased rate of treatment in less experienced medical centers.^{25,26}

The least invasive technique described, to date, is the punch technique. According to Gordon and Coelho²¹ it was

used for the first time by Novak in 2009. At this point, it must be said that this trend toward a less invasive surgery technique has guided to Oticon Medical AB to develop a device called MIPS (Minimally Invasive Ponto System). A criticism toward the punch technique has been potentially slow osseointegration, due to low visibility during implant insertion. Different published works consider the Implant Stability Quotient (ISQ) as an objective measure of osseointegration, such as by D'Eredita et al.,¹ where the linear

incision technique with tissue reduction was used, or the paper by Høgsbro²⁰ that compared the ISQ obtained with

skin flap with dermatome versus linear incision with little or no soft tissue reduction. In both works, the ISQ measured the degree of osseointegration of the implant, in order to obtain the earliest charge of the processor. Other

published papers relating to the Pontosystem (Oticon Medical AB, Askim, Sweden) showing osseointegration measurements via ISQ and linear incision technique have also been reported (Hultcrantz²⁷; Dun et al.²⁸; Foghsgaard and

Caye-Thomasen²⁹) and more recently by Nelissen et al.³⁰

The objective of this study was to assess and compare the clinical outcomes and issues with the two surgical techniques in a successive cohort of AOI recipients, using the punch technique and the linear technique. In addition, the level and rate of osseointegration, recorded via ISQ was compared. To our knowledge, this is the first published work on the Punch Technique describing the osseointegration measurements obtained with the ISQ in detail.

Materials and methods

Patients

This retrospective study was carried out on all patients undergoing AOI surgery treatment between January 2010 and July 2015 in our ENT department. Revision cases were excluded. Review and summary of the clinical histories were performed for patients' demographic data (age, sex), rationale for AOI indication, ear implanted, surgical technique used, details of implant and abutments used, skin thickness (where available for the PT group), surgical time and registered complications. As skin thickness was not available for the entire LI group, this variable was not included in the comparative analysis.

Subjective and objective measurements

Skin complications were confirmed in accordance with the Holgers classification (Table 1), as well as the ISQ in the follow-up visits at one week, one month and three months after surgery. The measurement of the ISQ was carried

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Table 1 Holgers classification of skin reactions at the implant site.

Degree	Description
0	Skin without reaction around abutment
1	Redness with slight swelling around the abutment
2	Redness, moistness and moderate swelling
3	Redness, moistness, moderate swelling with tissue granulation around the abutment
4	Overt signs of infection resulting in removal of the implant

out by screwing the magnetic Smartpeg#55 (Osstell, Göteborg, Sweden) to the abutment, and with the Osstell

ISQ measurement device (Osstell, Göteborg, Sweden). This device measures the stability of the implant by using resonance-frequency analysis of the vibrations of the mag-

netic Smartpeg screwed to the abutment. Measurements were made in all axes, placing the perpendicular probe to the abutment, without contact to it, to obtain different perpendicular measurements. In this way, objective, comparable information with respect to the stability was obtained and then related to the options for mounting the device when osseointegration is adequate. This technique is noninvasive and takes less than five seconds. For each patient, the median between the highest and the lowest recorded values was calculated and stored.

Surgical techniques

Three surgeons performed all the interventions. In all cases, the Baha system was implanted (Cochlear Corp., Australia). All the operations were performed as a single procedure. The Punch technique was carried out under local anesthesia, except for pediatric cases, while the LI patients received general anesthesia. All patients were discharged on the same day with no immediate complications from the procedure.

Linear incision technique (LI) (Fig. 1)

Our approach is similar to that described in the Nijmegen Medical Centre.^{17,18} After preparing the surgical area by

means of shaving, cleaning and sterilizing the area with iodine solution, the anesthetic solution of articaine with

epinefrin (Ultracain, Normon Spain, S.A.) is administered. Then, an incision of 3 cm is drawn, at a distance of 6 cm posterior to the external auditory canal. Using a no. 15 scalpel, the skin is thinned 2 cm in all directions around the implant site and the subcutaneous tissue is extracted down to the periosteum. A cross on the periosteum is drawn to

indicate the point of drilling to position the implant and to permit screwing of the abutment in the normal direction. Next, an anterior opening is carried out anterior to the incision with a surgical punch of 6 mm, to allow the abutment to pass through the skin. We used BI300 implants in the first ten patients and in the last six patients we implanted the BI400, measuring skin thickness and using abutments 3 mm longer than the measurement obtained. In this last group of

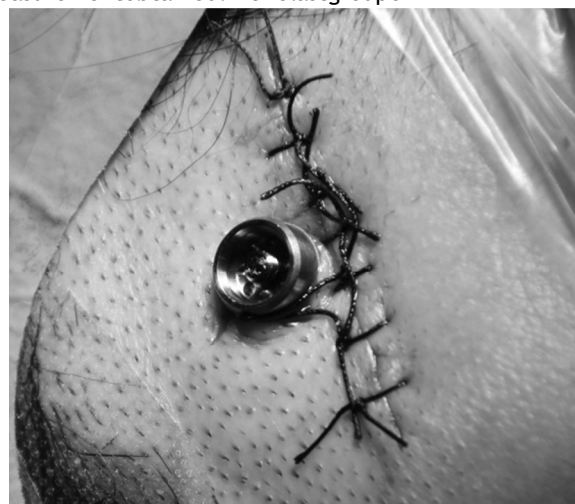


Figure 1 Linear incision technique.

patients, the LI technique with soft tissue preservation was employed. The incision is closed with loose silk stitches 4-0 and a healing cap is placed in position with antibiotic and corticoid solution embedded gauze (Cuatroderm).

Punch technique (PT) (Figs. 2 and 3)

In all cases, after the preparation of the area, measurements for the placement BI400 are taken at 6 cm from the external auditory canal using a dummy implant provided by the manufacturer. The implant position is marked with a surgical pen. At this point, a needle is introduced through the skin until reaching the bone to measure the thickness of the skin before infiltrating with local anesthesia. An implant 3 mm longer than the measurement obtained is placed, which is determined by catching the needle with a clamp and measuring the distance between the clamp and the point of the needle. After proceeding to infiltration of the anesthetic solution with articaine and epinefrin and waiting for the necessary time to achieve vasoconstriction, a dermatological punch of 6 mm is used to obtain a cutaneous cylinder that reaches to the periosteum. The tissue is removed through this small orifice, without reduction of the soft tissue, followed by drilling and screwing of the abutment-implant in position. During drilling, profuse irrigation with saline solution is provided via a curved needle through the punch hole. Finally, a healing cap is placed

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Findings from the experience with the punch technique for implants over the implant with antibiotic and corticoid solution embedded gauze.

Statistical analysis

Statistical analyses were performed by an independent statistician. For comparisons between categorical variables, Fisher's exact test or the Chi-square test were used. We used the non-parametric Mann-Whitney U test between the quantitative variables and categorical binary variables. All p values reported were two-sided and statistical significance was defined at $p < 0.005$.



Figure 2 Punch technique.



Figure 3 Punch technique-final result.

Results

Of the 34 patients operated on for AOI, 18 were intervened by means of the punch technique and 16 with the linear incision technique.

The descriptive analysis of age, sex, surgical indication, ear operated on and intraoperative complications are shown in Table 2. The median age in the PT group was lower than in the LI group. It is noteworthy that the four children were implanted with the punch technique, with three receiving the 3 mm implant (Fig. 4); in the fourth, the 4 mm implant was used. All other cases, both PT and LI groups, received

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Figure 4 BAHA5 in position.

4 mm implants. There were no intraoperative complications with the punch technique; in the linear incision group, there was only one case of CSF leakage, which was resolved by placing the implant.

The implant abutment lengths most frequently used for the linear incision group (14 cases, 87.5%) were 6 and 8 mm abutments. This had a direct influence on the ISQ measurement, described later. In the punch technique group, 12 cases (66.7%) received a 10 mm abutment and five cases (27.8%) received the 8 mm; i.e. 100% had abutments that were 8 mm or longer (Table 3). The median abutment size used was significantly different

between the two groups ($p < 0.001$) being 10 mm for the punch technique and 6 mm for the linear incision technique (Table 3).

For the ISQ values, the higher the number, the richer the integration. The ISQ values were significantly different at each time point of measurement ($p < 0.001$). At one week, median ISQ values were 50.5 (43---56) for the PT group and 57 (49---60) for the LI group; at one month were 52 (43---57) for the PT and 60 (51---62) for the LI, and at 3-month visit 54.5 (45---60) for the PT and 61 (51---64) for the LI group.

The surgical duration time (Table 3) for the two groups was statistically different ($p < 0.001$), 45 min (20---100 min) for the LI group and 20 min (10---30 min) for the PT group.

Table 3 Comparison of length of abutment and surgical time between the two techniques.

Abutment length (mm)	PT, n (%)	LI, n (%)	
6	0	11 (68.75%)	
8	5 (27.8%)	3 (18.75%)	
10	12 (66.7%)	1 (6.25%)	
12	1 (5.5%)	1 (6.25%)	
Total	18	16	
Mean abutment (range) (mm)	10 (8---12)	6 (6---12)	$p < 0.001$
Mean surgical (range) (min)	20 (10---30)	45 (20---100)	$p < 0.001$

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Table 2 Comparison of patients operated on for AOI.

	PT (n=18)	LI (n=16)	p
Median age (range)	52 (9---65)	58 (33---78)	0.037
Sex (M/F)	7 (39%) / 11 (61%)	8 (50%) / 8 (50%)	NS
Diagnosis			NS
Mixed HL	4 (22%)	6 (37%)	
Conductive HL	4 (22%)	6 (37%)	
Single-sided Deafness	10 (56%)	4 (25%)	
Ear (R/L)	6 (33%) / 12 (67%)	8 (50%) / 8 (50%)	NS

HL=hearing loss;; PT=punch technique; LI=linear incision.

Table 4 Postsurgical skin complications according to surgical technique and in accordance with Holgers classification.

Holgers class.	Post-surgical follow up interval					
	One week p=0.007		One month p=0.007		Three months p=0.77	
	PT	LI	PT	LI	PT	LI
0	10 (55.55%)	3 (18.75%)	7 (38.88%)	7 (43.75%)	16 (88.88%)	13 (81.25%)
1	3 (16.66%)	10 (62.5%)	9 (50%)	5 (31.25%)	1 (5.55%)	1 (6.25%)
2	5 (27.77%)	1 (6.25%)	1 (5.55%)	3 (18.75%)	1 (5.55%)	2 (12.5%)
3	0	2 (12.5%)	1 (5.55%)	1 (6.25%)	0	0
4	0	0	0	0	0	0

p: the probability value.

Three surgeons performed the interventions: one, 18 interventions; another, 12 and the third, 4.

With respect to the postsurgical cutaneous complications reported according to Holgers classification at one week, one month, and three months, the LI group showed a significantly greater number of patients classified with complications at one week that were greater than "0" -- 13/16 patients (81.3%) compared to the PT group, 8/18 patients (44.4%) ($p=0.007$). The differences between the two groups at the one-month and three-month postsurgical visits were not statistically significant (Table 4).

Extrusions were not reported in any of the patients from either group. On writing this article, all the patients were satisfied, consistent daily device users.

Discussion

According to Wróbel et al.,¹⁹ the implant stability can be

affected by different factors: 1) system height, 2) implant diameter, 3) the properties of the implant material 4) the technical factors of the fixation procedures, and 5) the quality

of the bony substrate. The arrival of longer abutments was a very important milestone, because they increased the system height, but did not increase the extrusion index, as D'Eredita et al.¹ defended in their paper. In their work, they

concluded that longer abutments did not increase the incidence of implant extrusions. Our findings are consistent with this report, as no extrusions occurred in any patient of the PT group, where we used abutments longer than 8 mm in 100% of the patients. The diameter of the implant, in our study, was 4 mm in all adult cases; in pediatric cases, we used 3 mm implants, as previously mentioned. Implant diameter had no influence on implant stability according to our data.

Goldman et al.²² carried out a pilot study on 15 patients

where they used the punch technique of 12 mm with an average surgical time of 15 min. They collected no cases of Holgers grade 2 or higher. Wilson and Kim,²⁵ compared

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the results obtained between the skin flap technique with dermatome and reduction of soft tissues versus punch technique. In their work, a 4 mm punch was used, carrying out a conical subcutaneous soft tissue reduction under microscope to allow good visualization of the implant area. The skin thickness was measured after creating an opening with the punch, and an abutment 3 mm longer than the measure obtained was placed. The surgical time was shorter in the punch group (32.3 min vs 56.1 min).

Gordon and Coelho²¹ compared two groups of patients,

punch technique versus linear incision with soft tissue reduction, in 51 patients. They found that the operating time was less in the punch technique group (13.4 min vs 49.2 min), with no significant differences between the two groups with respect to Holgers degrees at the first or last control visit. The punch used in the Gordon et al. work was 6 mm, and all the patients received 4 mm implants and 9 mm abutments. Finally, Dumon et al.²⁶ published their results comparing two

groups, skin flap with dermatome and soft tissue reduction versus punch technique, in a total of 40 patients. In the punch technique group, the skin thickness was measured and they used a 5 mm punch. The implant was 4 mm and the abutment was 3 mm taller than the skin thickness, measured with a hypodermic needle. In their study, general anesthesia was used on all the patients. The median surgical time was significantly shorter in the punch technique (15 min) compared to the skin flap group (30 min). There were no differences in terms of Holgers between the groups, and no

® differences between Baha (Cochlear) versus Ponto (Oticon) systems. PT group median surgical time reported in our study (20 min) is consistent with previously published data (Gordon and Coelho,²¹ 13.4 min; Goldman et al.,²² 15 min;

Dumon et al.,²⁶ 15 min and Wilson and Kim,²⁵ 32.3 min).

The punch technique used in this current work is a compendium of that published to date, as we use local anesthesia on all our adult patients as opposed to Wilson and Kim²⁵ and Dumon et al.²⁶ In our opinion, the use of

local anesthesia helps to reduce surgical time and reduces procedure-related costs. The procedure is extremely well tolerated by patients. There were only three cases given general anesthesia, and all were pediatric patients.

We measured skin thickness, before the anesthetic infiltration by means of the hypodermic needle, a simple and reliable maneuver, and our skin thickness median was 7 mm

with a range of 5---8 mm. We added 3 mm to the measurement obtained in this way. In Dumon et al.,²⁶ they obtained

skin thickness median of 7 mm with a range of 4---8 mm, but in Gordon and Coelho²¹ they did not use skin thickness

as a parameter to fit the length of the abutment; they used a 9 mm abutment in all their patients. They had to do a revision surgery to change an abutment that was too short. The most frequent abutment size in our cases for punch group was 10 mm, while in the linear incision group it was 6 mm, with this difference being significant. It is important to note that we began using BI400 implants in December 2012, which means that in the last six patients of LI group no soft tissue reduction was performed. This explains why there are some patients in the LI group with 8 and 10 mm abutments. All patients receiving the BI400 had skin thickness measured; however, since there were only six patients, the parameter of skin thickness was not taken into consideration for comparison to the PT group.

A punch of 6 mm was used, which in our experience is the easiest measurement to work without the help of a microscope.²⁵

In our cohort, through the punch hole created, we experienced no difficulties with visibility and observed that the irrigation procedure via the curved needle was very effective to clear debris. In our opinion, using a microscope adds to the complexity of the procedure and the expense. Furthermore, we did not perform tissue reduction for any recipient in this group. Subsequently, the PT procedure was considerably shorter to perform, with a median operative time of 20 min, in comparison to 45 min for the linear incision technique. In comparison to that reported in the literature. The longest surgical time we experienced using the punch technique is the same time as the shortest surgery time reported for the linear incision technique by researchers Gordon and Coelho.²¹ This suggests a significant difference

between the time involved in both techniques which has implications for expense of each procedure ultimately.

From our study, it is important to highlight the significant difference in Holgers degrees between the first postsurgical checkups carried out at one week where the punch group yielded more degrees 0 and 1, while the linear incision group yielded more 1, 2 and 3 degrees. This corresponds with our initial impression that there is a decrease in skin reactions immediately after surgery, with less need for dressings. Although both techniques are described as minimally invasive, the punch technique presents less of an assault on the skin because of the punch device compared with soft tissue reduction done in linear incision technique. To our knowledge, this is the first time that such a comparison has been made between the two techniques with respect to initial

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Findings from the experience with the punch technique for implants after care.^{21,22,25,26} The subsequent reviews at one and three

months revealed that there were no differences between the Holgers classifications assigned to each surgical group.

An important aspect of our study was the measurement of osseointegration using the implant stability quotient in association with the punch technique. We decided to include the ISQ to address earlier criticism of the punch procedure. That is, the difficulty in performing the PT reportedly may result in the possibility of periosteum remaining at the implant site and, therefore, reduce the degree of osseointegration. Our data on 34 patients, regardless of technique, revealed that there were no cases of extrusion after a minimum follow-up of four months post-implant. The highest ISQ were found in the LI group, at all the follow-up visits. This finding has an explanation: in the LI group, we used shorter abutments than in PT group. The ISQ measures have a direct relationship to abutment length, as reported in previous papers,^{19,20,27-30}

where it was shown that the longer the abutment the lower the ISQ. It was not possible to compare the absolute ISQ values obtained for the IL and PT groups because of the different abutment lengths; however, we can evaluate relative ISQ values as they change over time. Our data show that the PT group ISQ mean increases at each follow-up visit in a similar progression to that seen to the IL group ISQ mean (Table 4). These findings indicate good osseointegration independent of the surgical technique used for both techniques, thus confirming that PT has an osseointegration index similar to that of the LI. There were no ISQ differences between adults and pediatric cases in PT group, with similar ISQ measures. Sound processors were loaded four weeks after the surgery with no problems encountered in any case. The argument that the PT has the potential to reduce osseointegration can be rejected. In light of reduced surgical time and fewer skin complications, the PT is a valid alternative to LI. In measuring the ISQ, we were able to obtain objective feedback about the progression of osseointegration and gain valuable information that aids in the decision for the best timing for sound processor loading or when an implant loss is a risk²⁷. ISQ measures are performed effi-

ciently in less than five seconds, are noninvasive and present no audible sensation to the patient,²⁸ which allow them to

be integrated easily into clinical routine and for evaluations of outcomes as reported here.

Conclusions

In light of reduced surgical time and fewer skin complications, we conclude that the PT is a valid alternative to LI, with comparable osseointegration as demonstrated with ISQ measurement outcomes. Preliminary evidence suggests that early complications, as identified through reported Holgers degrees, are significantly reduced when using the punch technique. Further studies are needed to confirm these results.

Author contribution

Alfonso Bonilla, M.D. designed the work, wrote the paper, collected data, interpreted data; Carlos Magri, M.D. collected data, designed the work, revised the paper; Eulalia Juan, collected data, revised the paper.

Conflict of interests

Alfonso Bonilla, M.D.: none.

Carlos Magri, M.D.: none.

Eulalia Juan: Cochlear Rehabilitation Consultant. Dpt. Cochlear Academy.

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