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OTOLOGY

Wide diameter bone-anchored hearing system implants: a comparison of long-term follow-up data between tissue reduction and tissue preservation techniques

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Abstract

Objective To present long-term data on the Wide Ponto implant bone-anchored hearing system (BAHS) in regards to implant stability, soft tissue reaction and implant loss for two case series undergone either the tissue reduction- or the tissue preservation surgical technique.

Methods Comparison of two consecutive, prospective case series. Each case series enrolled 24 patients. The case series underwent one-stage implantation of the Wide Ponto implant BAHS using either a linear incision technique with subcutaneous reduction or a linear incision technique without subcutaneous reduction. Implant stability quotient (ISQ) values were measured using resonance frequency analysis and soft tissue reactions were graded according to Holgers' classification system. Follow-up visits were performed at 10 days, 6 weeks, 6 months, 12 months and annually up to 4 years (tissue preservation) or 5 years (tissue reduction) postoperatively.

Results The two case series had homogenous patient populations and followed an identical postoperative scheme. The ISQ values increased consistently the first 12 months for both groups ($p \leq 0.001$), and were higher in the tissue preservation case series, ($p = 0.04$, 9 mm abutment). More than 91% of the soft tissue observations were assessed as Holgers' grade 0 or 1. One implant (2.1%) was lost due to trauma.

Conclusion In both case series, the Wide Ponto implant showed increasing implant stability during the follow-up period from the time of surgery, irrespective of surgical technique, indicating good osseointegration. Soft tissue reactions were rare and of minor severity. Implant survival was high.

Keywords Bone-anchored hearing systems · Wide implant · Osseointegration · Implant stability quotient · Soft tissue and skin reaction · Tissue reduction/preservation surgery

Introduction

Bone-anchored hearing systems (BAHS) have been used clinically for 40 years since Tjellström and co. published the results of 14 patients receiving Bone-Anchored Hearing Aids (BAHA) in 1981 [1]. Since then, thousands of patients have been implanted successfully with complications of minor nature, typically related to the skin and soft tissue around the abutment [2]. Several studies have shown excellent outcomes in regard to hearing, quality of life and overall implant survival rates exceeding 90% [3–5] albeit lower in pediatric cases [6, 7] and irradiated patients [8].

Prior to osseointegrated implants, patients had to wear bone conducting hearing aids via e.g. headband or other methods of fixation causing discomfort, poor sound quality and aesthetic dissatisfaction. The patients benefitting from

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BAHS suffer either from anatomical abnormalities, conductive or mixed hearing loss, single-sided deafness (SSD) or simply inability to wear conventional hearing aids due to unwanted side effects.

The BAHS work by processing the acoustic sound in an external device, i.e. a sound processor, causing vibrations in the percutaneous abutment that are transmitted via the osseointegrated implant and the temporal bone to both cochleas. During the last years, wider diameter implants, Ø 4.5 mm, have replaced the previous generation of implants, Ø 3.75 mm. The wider diameter provides larger initial surface to bone contact which leads to higher initial stability, enabling the possibility of loading the implant at an earlier stage without compromising the long-term result [9–11]. As the soft tissue preservation technique develops, studies in recent years indicate an advantage over tissue reduction surgery in regard to extent, cost, postoperative sequelae and long-term results [12–17]. In this paper, the tissue reduction (TR) procedure refers to the one-stage, simplified linear incision technique initially described by van der Pouw from the Nijmegen group [18]; also known as a two broad pedicled, local epidermal skin flaps technique [19], in which the 4-cm incision is followed by an extensive reduction of the subcutaneous tissue whilst palpating the thickness of the skin to thin it maximally. In contrast to the tissue preservation (TP) procedure described by Hultcrantz from Karolinska [20], where no subcutaneous tissue is removed but the thickness of the skin is measured enabling an appropriate abutment length to be chosen, prior to a similar linear incision and drilling.

Even though several papers on this subject have shown good implant stability and survival, to our knowledge, the combination and long-term follow-up results presented in this paper are unreported, hence objectively measured implant stability might change. This paper presents long-term follow-up (F/U) data comparing results on implant stability initially and over time, i.e. survival, and soft tissue reaction for the Wide Ponto implant between a case series undergone TR and TP surgery.

Materials and methods

Two separate, non-randomized, consecutive and prospective case series were compared on the basis of the 12-month studies by Foghsgaard and Cayé-Thomasen; Mowinckel et al., [4, 9] with additional annual follow-ups (F/U). A total number of 48 patients, 24 patients in each series, underwent BAHS-surgery at our tertiary referral center (Rigshospitalet, Copenhagen University Hospital). The first case series underwent the tissue reduction (TR) procedure from 2011 to 2012, whereas the second case series underwent tissue preservation (TP) procedure from 2013 to 2014. All patients received the Wide Ponto implant (Oticon Medical AB, Askim, Sweden; diameter 4.5 mm; length, 4 mm) with the traditional Brånemark-type machined titanium implant surface. Depending on skin thickness, (titanium) abutments of lengths 6, 9, and 12 mm were used. Both studies had the same inclusion criteria; age over 18, eligibility for bone conduction implant surgery and no known bone quality disorder. The second study excluded cases with skin disease in the surgical field or those with an inability to participate in F/U, whereas no exclusion criteria were set for the first study. Both studies were reviewed by the regional ethical committee (H-4-2013-FSP).

Surgical procedures and F/U

All procedures were performed in one-stage under local anesthesia. TR procedures were all performed by one surgeon (last author) using the simplified linear incision technique with subcutaneous reduction [18].

The skin incision length was approximately 4 cm including all layers to the periosteum. A hole was drilled, under constant saline irrigation, and subsequently widened with a 3.8-mm diameter counter-sink after removal of periosteum. The implant was installed (in a single stage) by application of 50 Ncm torque followed by removal of subcutaneous tissue and suturing of the incision. A biopsy punch was used to create a separate hole for the abutment to penetrate the skin and thread over the abutment next to the incision.

The TP procedures were performed by two surgeons (last author and colleague) according to the one-stage, linear incision technique without subcutaneous reduction [20]. The implant placement was measured and the skin thickness assessed with a thin needle and a ruler to select the appropriate abutment length. A 4 cm linear skin incision going through all soft tissue layers down to the periosteum, which was subsequently removed, was performed. The drilled and saline-cooled hole was also widened with a 3.8-mm diameter countersink and the implant was installed (in a single stage) by applying 50 Ncm torque, followed by suturing the epidermal skin layer. A biopsy punch was used to create the separate hole for the abutment approximately 1 cm from the incision line.

At the end of both procedures, the implant stability quotient (ISQ) was measured and a healing cap was fixed to the abutment with gauze covered in steroid–antibiotic (hydrocortisone 10 mg/g with oxytetracycline 30 mg/g) ointment circulated around the abutment under the healing cap. A compressive head dressing was applied during the first postoperative night to prevent hematoma and the healing cap and gauze were removed after 10 days. The sound processor was fitted from 6 weeks postoperatively.

Both groups had similar F/U appointment schemes in the outpatient clinic; after 10 days, 6 weeks, 6 months,

12 months and annually subsequently. The TR group was followed for 5 years and the TP group for 4 years.

Outcome measures

Implant stability was measured non-invasively using resonance frequency analysis (RFA) obtained by Osstell ISQ (Osstell, Göteborg, Sweden). This is a portable, handheld instrument that includes the use of a magnetic SmartPeg (Osstell) attached to the abutment. The SmartPeg is excited by a magnetic pulse from the measurement probe on the handheld instrument. The resonance frequency is calculated from the response signal and the result is displayed as ISQ, which is scaled from 1 to 100 (latter value being the greatest possible stability). The Osstell ISQ instrument has an accuracy of ± 2 ISQ points. The measurements were performed manually in two perpendicular directions, which resulted in two different ISQ values: ISQ high and ISQ low. In this study, the ISQ measurements presented are the ISQ low values. ISQ low is the most conservative measurement and was also chosen for transparency. The same SmartPeg was used on the individual patient throughout the study to minimize the measurement variability. Due to the principle of RFA, longer abutments prompt lower ISQ values.

At every F/U appointment, any postoperative complications were assessed, ISQ measurements were performed and soft tissue reactions around the abutment were graded according to Holgers' classification system [2].

Statistics

For statistical comparisons of implant stability over time, the Wilcoxon signed rank test was used. Additionally, the Mann–Whitney *U* test was used for comparison of the surgical techniques. A significance level of 0.05 was adopted.

Results

Patient characteristics of the TR and TP group are presented in Table 1.

The age and sex distribution is fairly similar as well as the indications, which were conductive or mixed hearing loss and SSD. There is a slightly greater proportion of the patients in the TR group who smoked.

Patients treated with oral steroids suffered from Crohn's disease in the TR group and Addison's disease and nasal polyps in the TP group, respectively. Two patients in the TP group had received radiation therapy, for tonsillar and parotid gland cancer, respectively.

All patients received the 4-mm long, 4.5-mm diameter Wide Ponto titanium implant, whereas the abutment length differed depending on skin thickness and surgical technique.

Three of the patients receiving a 9-mm abutment in the TR group had thick subcutaneous tissue despite reduction and had a BMI of 31, 32 and 28, respectively. The majority in the TP group received the 9-mm abutment and all had skin thickness around 5–6 mm. The three patients receiving the 12-mm abutment had skin thickness around 8–9 mm.

Apart from a minor bleeding in one patient due to drilling into a vein, there were no surgical complications to any of the procedures.

After implantation, the patients were followed for five (TR) and four (TP) years.

The patients in the TR group were fitted with sound processors after 7.2 weeks on average (range 5.7–9.1 weeks; one patient was fitted after 30 weeks at the only F/U visit,

Table 1 Baseline patient characteristics of the case series

Study	Tissue reduction	Tissue preservation
No. of patients	$n=24$	$n=24$
Gender	71% women; 29% men	58% women; 42% men
Age	54.6 years (25–71)	58.2 (27–75)
Indication	Acquired cond/mixed: 40%	Acquired cond/mixed: 54%
	Congenital cond/mixed: 0%	Congenital cond/mixed: 0%
	SSD: 60%	SSD: 46%
Smokers	35%	14%
Relevant diseases/ treatments	Chronic steroid use: 8% ($n=2$); Diabetes: 8% ($n=2$); Irradiated: 0%; Other conditions known to compromise the bone: 0%	Chronic steroid use: 8% ($n=2$); Diabetes: 4% ($n=1$); Irradiated: 8% ($n=2$); Other conditions known to compromise the bone: 0%
Implant	4 mm: 100%	4 mm: 100%
Abutment	6 mm: 83.3% ($n=20$)	6 mm: 8.3% ($n=2$)
	9 mm: 16.7% ($n=4$)	9 mm: 79.2% ($n=19$)
		12 mm: 12.5% ($n=3$)

increasing the average to 8.5 weeks, and excluded from the ISQ analysis due to drop-out). In the TP group, the sound processor was fitted after 8.3 weeks (range 4.0–14.6 weeks).

In the TR group, one patient had the 6-mm abutment changed to 9 mm at 6 months F/U and to a 12 mm at 12 months F/U due to contact between the skin and external processor (BMI was 29). Two other patients also changed to a 9-mm abutment, although considerably later, at 46 months and just before the 60 months F/U due to skin overgrowth and several incidents of processor detachment.

In the TP group, one patient had 7 mm skin thickness and was changed to a 12-mm abutment due to contact between the skin and external processor. One of the patients with the 6-mm abutment changed to 9 mm just after 24 months F/U due to skin overgrowth.

Two patients, one in each group, did not wish to attend further F/U after 6 months.

In the TP group, one patient did not attend F/U after 24 months and several attempts of contact were unsuccessful. One patient had the implant removed due to deterioration of hearing necessitating a Cochlear Implant. Two patients deceased during the F/U period. One patient lost the implant in the TR group after 3.5 years. The patient, unfortunately, walked into a glass door and suffered a head trauma, approximately 2 months prior to implant loss.

The patients lost to drop-out were excluded from ISQ analysis but otherwise included in the dataset. The drop-out is summarized in Table 2.

ISQ measurements were performed at surgery and up to 5 years postoperatively, see Fig. 1. As expected, shorter abutment lengths resulted in higher ISQ levels, irrespective of the surgical technique used. In general, the implant stability increased significantly over time up to 12 months for both surgical techniques. After 12 months F/U stable or slightly decreasing ISQ values were measured. Comparing ISQ values from the time of surgery to F/U measurements, significant increase is observed in both groups up to 2 years, see Table 3. This continues for the TP group during the entire F/U. All the patients (except TR 9 mm, $n=4$, and TP 6 mm, $n=1$) had higher ISQ values at the last measurement compared to the time of surgery.

All abutment lengths in both groups had increasing ISQ values during the first 10 days after implantation. An ISQ dip was measured at the subsequent F/U in the TR group and one patient in the TP group followed by increasing ISQ values at 6 months F/U in all patients.

For the TR group, the ISQ values generally increased for both the 6 mm and 9 mm abutment, but only significantly for the 6 mm abutment (Table 3a). Collectively the TR group had a statistically significant increase in ISQ value from the time of surgery to first F/U and between every F/U until 12 months ($p=0.034$). This included a significant ISQ decrease from first to second F/U in accordance to the ISQ dip in Fig. 1. From 12 months to 5 year F/U the ISQ values decreased but not statistically significant. ISQ values increased from the time of surgery

Table 2 Drop-out specifications in the case series

	Tissue reduction	Tissue preservation
Included in ISQ analysis	$n=19$	$n=17$
Included in Holgers' grading	$n=24$	$n=24$
Did not attend follow-up	$n=1$	$n=2$
Abutment changed	$n=3$	$n=2$
Deceased	$n=0$	$n=2$
Implant removed	$n=0$	$n=1$
Implant loss	$n=1$	$n=0$

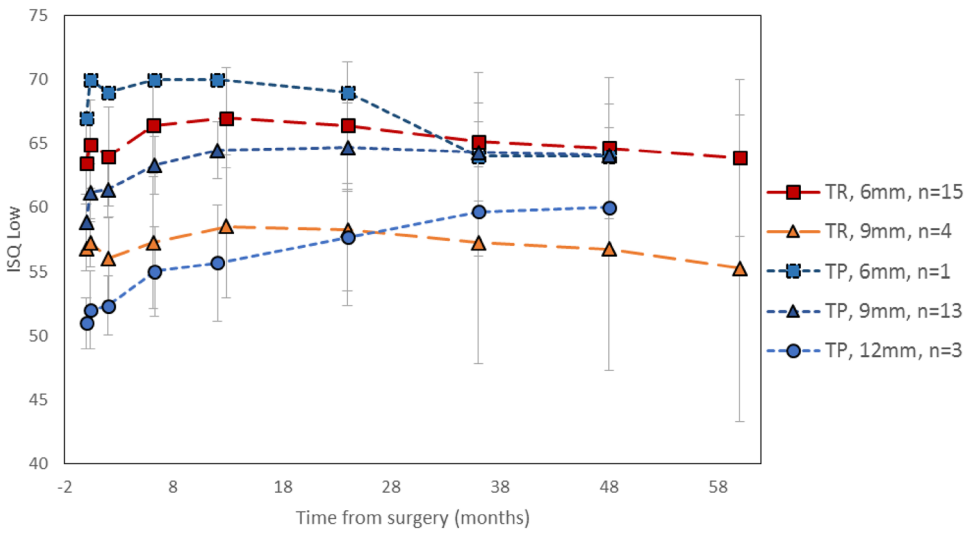

Fig. 1 ISQ development: tissue reduction (TR) group ($n=19$) vs tissue preservation (TP) group ($n=17$). Especially the first 12 months both groups showed a tendency of increased overall ISQ values over time across different abutment lengths

Table 3 ISQ low comparisons over time for tissue reduction and tissue preservation procedures

Abutment length	6 mm		9 mm		12 mm		All (6, 9, 12 mm)	
	p value*	*n*	*p* value	*n*	*p* value	*n*	*p* value	*n*
a. Tissue reduction								
Surgery—2 weeks	*0.003*	15 vs. 15	0.317	4 vs. 4	–	–	*0.002*	19 vs. 19
Surgery—6 weeks	0.434	15 vs. 15	0.705	4 vs. 4	–	–	0.606	19 vs. 19
Surgery—6 months	*0.003*	15 vs. 15	0.593	4 vs. 4	–	–	*0.006*	19 vs. 19
Surgery—12 months	*0.002*	15 vs. 15	0.465	4 vs. 4	–	–	*0.001*	19 vs. 19
Surgery—24 months	*0.02*	15 vs. 15	0.465	4 vs. 4	–	–	*0.017*	19 vs. 19
Surgery—36 months	0.248	15 vs. 15	0.577	4 vs. 4	–	–	0.264	19 vs. 19
Surgery—48 months	0.393	15 vs. 15	1	4 vs. 4	–	–	0.491	19 vs. 19
Surgery—60 months	0.609	15 vs. 15	0.593	4 vs. 4	–	–	0.777	19 vs. 19
b. Tissue preservation								
Surgery—2 weeks	–	1 vs. 1	*0.004*	13 vs. 13	0.18	3 vs. 3	*0.001*	17 vs. 17
Surgery—6 weeks	–	1 vs. 1	*0.003*	13 vs. 13	0.157	3 vs. 3	*0.001*	17 vs. 17
Surgery—6 months	–	1 vs. 1	*0.001*	13 vs. 13	0.109	3 vs. 3	*0.000283*	17 vs. 17
Surgery—12 months	–	1 vs. 1	*0.001*	13 vs. 13	0.157	3 vs. 3	*0.000411*	17 vs. 17
Surgery—24 months	–	1 vs. 1	*0.001*	13 vs. 13	0.109	3 vs. 3	*0.000277*	17 vs. 17
Surgery—36 months	–	1 vs. 1	*0.003*	13 vs. 13	0.109	3 vs. 3	*0.001*	17 vs. 17
Surgery—48 months	–	1 vs. 1	*0.005*	13 vs. 13	0.109	3 vs. 3	*0.002*	17 vs. 17
c. Comparisons between TR and TP procedure								
Surgery	0.188	15 vs. 1	0.103	4 vs. 13	–	0 vs. 3	*0.013*	19 vs. 17
2 weeks	0.126	15 vs. 1	*0.014*	4 vs. 13	–	0 vs. 3	0.057	19 vs. 17
6 weeks	0.126	15 vs. 1	*0.014*	4 vs. 13	–	0 vs. 3	0.176	19 vs. 17
6 months	0.275	15 vs. 1	*0.046*	4 vs. 13	–	0 vs. 3	0.127	19 vs. 17
12 months	0.327	15 vs. 1	0.058	4 vs. 13	–	0 vs. 3	0.166	19 vs. 17
24 months	0.663	15 vs. 1	*0.04*	4 vs. 13	–	0 vs. 3	0.494	19 vs. 17
36 months	0.585	15 vs. 1	0.098	4 vs. 13	–	0 vs. 3	0.715	19 vs. 17
48 months	0.586	15 vs. 1	0.125	4 vs. 13	–	0 vs. 3	0.937	19 vs. 17

*Asymp. Sig. (2-tailed), Mann–Whitney *U* test (IBM® SPSS® Statistics, version 24). Statistically significant in italicized

compared to all F/U measurements but not significantly after the 2-year F/U or at the second F/U.

The TP group had a consistent increase in ISQ values for the 9- and 12-mm abutment lengths during the entire F/U period, but apparently only significant for the 9-mm abutment (Table 3b). Collectively the TP group had a statistically significant increase in ISQ value from the time of surgery and between F/U's lastly at 12 months ($p = 0.047$). Unlike the TR group an ISQ increase was measured between first and second F/U but not significant. From 12 months to 4 year F/U the ISQ values were stable. ISQ values increased from the time of surgery compared to all F/U measurements with all *p* values highly significant ($p \leq 0.001$).

Inherent to the surgical technique, the number of patients with specific abutment length vary substantially, making statistical comparisons difficult. Yet, the TP group generally had higher ISQ values and comparing the 9-mm abutment (Table 3c), a significant difference was found with higher ISQ values in the TP group at several F/U measurements.

Soft tissue reactions were assessed according to Holgers' classification system [2] and are shown in Fig. 2. Irrespective of the surgical technique, the majority of patients showed no or minor skin reactions. One out of the five patients who had their abutment lengths changed were due to infection (Holgers' grade 3, TP group). The rest due to contact between processor and skin and/or skin overgrowth and subsequent processor detachment, but not infection.

Out of a total of 326 visits in both studies, 91–92% of the visits showed no skin reactions or irritation (Holgers' grade 0) and 4–4.5% showed slight redness (grade 1).

Adverse soft tissue reaction (grade ≥ 2) was seen in six visits (3.4%) in the TR group and in eight visits (5.3%) in the TP group.

In the TR group, six patients accounted for the soft tissue reactions (Holgers' ≥ 1), of which four of the patients had Holgers' grade ≥ 2. Two of these patients had diabetes and Crohn's disease in their medical record. Similarly, in the TP group seven patients had Holgers' ≥ 1, out of which five patients had Holgers' grade ≥ 2. One of these patients suffered

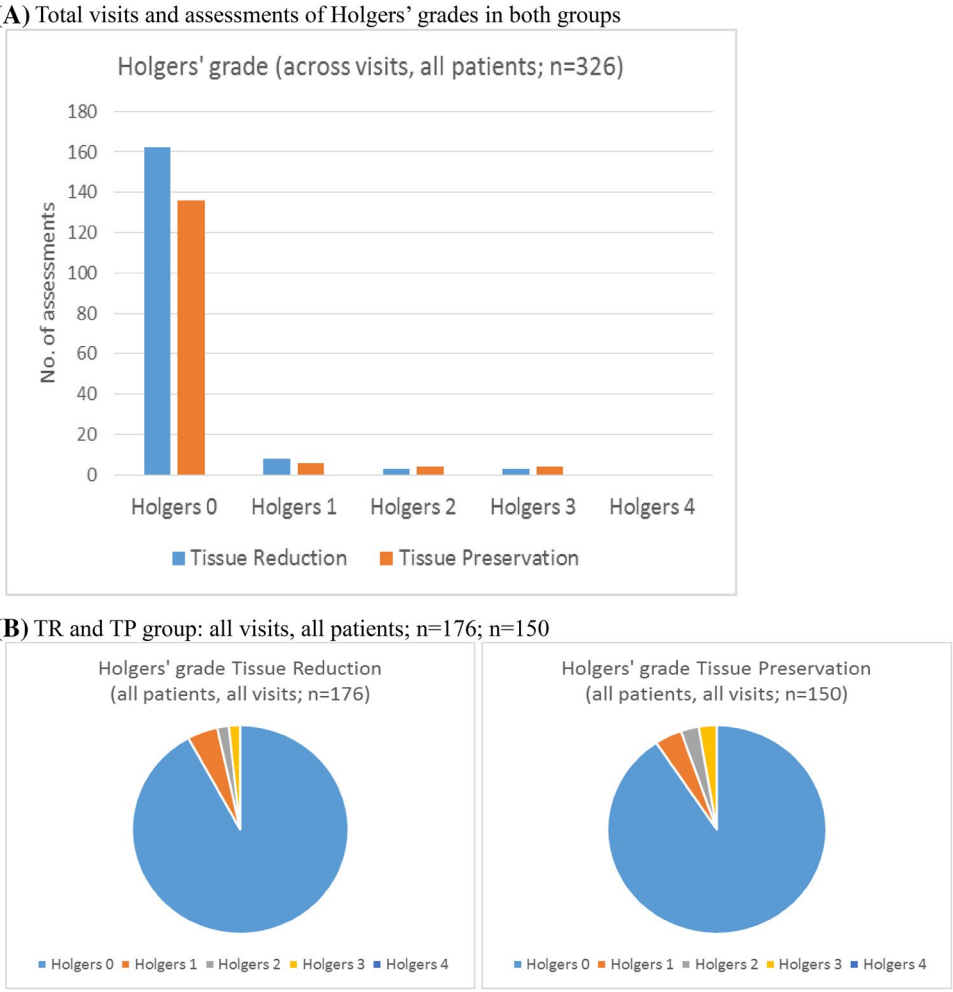

Fig. 2 Soft tissue reactions according to Holgers' classification. **a** Holgers' grade for all patients through all visits in the TR group, a total of 176 assessments, and in the TP group, a total of 150 assessments. **b** Holgers' grade distribution within each group

from Waldenströms macroglobulinemia (potentially reducing blood flow due to hyperviscosity) and had three grade ≥ 2 reactions which were all successfully treated with antibiotic ointment and lapis 50%, as well as oral antibiotic.

Interestingly, both of the previously irradiated patients showed no tissue reactions during 4 years of F/U. None of the Holgers' grade 3 observations needed surgery, nor did the three observations of skin overgrowth (two in TR group, one in TP group) which instead were solved by a change of abutment. No observations of Holgers' grade 4 were noted in either group.

The observed soft tissue reactions were not associated to any particular period during the F/U. The assessments of Holgers' grade ≥ 1 were evenly distributed over 4 and 5 years, respectively.

Discussion

This is the first paper presenting long-term (4–5 years) F/U results on the Wide Ponto titanium implant BAHS, comparing the two surgical techniques of TR and TP, respectively.

The use of wide implants is not a novelty and was primarily introduced to improve implant stability, osseointegration capabilities and thereby reduce the risk of implant loss and several studies have been published about osseointegration [9–11]. Non-invasive assessment of implant stability is done by ISQ measurements based on the RFA technique. The method relies on a great number of factors originally studied from dental implantation;

including implant width, length of implant and abutment alike, geometry, coating, threading, insertion torque, bone quality, soft tissue and eventually osseointegration [4, 10, 16]. The ISQ values may, therefore, differ in the same patient depending on, e.g. manufacturer, implant type and surgical technique.

The latter has evolved since the first surgical technique was described by Tjellström [1]. Several studies describe different flaps and TR in various ways, both with and without the use of dermatomes, and in recent years preserving the subcutaneous tissue by making a linear incision combined with a skin punch or even Minimal Invasive Ponto Surgery (MIPS) [19, 21, 22]. TR surgery has a number of drawbacks such as scar tissue formation, numbness in the area around the abutment and for many patients an unpleasant aesthetic appeal. TR procedures incur longer surgical time, are arduous and meticulous in dealing with removal of hair follicles and keeping an antiseptic environment around the abutment. TP procedures are comparatively more swift and hence less costly. The soft tissue around the abutment shows less tendency to get infected and patients report less pain and numbness [20].

In the presented case series the majority of the abutments placed using the TR technique were 6 mm, whereas 9-mm abutments were most frequently placed using the TP technique, as shown in Table 1 and Fig. 1. Both groups receiving these abutments have increasing ISQ measurements during the first 12 or 24 months and relatively narrow 95% confidence intervals, although the TR group had an ISQ dip at 6 weeks F/U. In contrast, ISQ values of other abutment lengths have larger intervals due to the small number of patients.

Nevertheless, after the first year, it appears that the ISQ values continue to increase only in the TP group, whereas a slight non-significant decrease in ISQ is observed for the TR group. This might suggest that the soft tissue around the abutment has a stabilizing effect. The ISQ decrease in year 3 for the TP group, 6 mm abutment, is based on one single patient, since an abutment change excluded the other patient in this group from the ISQ analysis. This exposes a weakness of the study in terms of patient numbers in each group and different abutment lengths.

Noticeably the TP group ISQ measurements are consistently higher, both at the primary implant time and during the F/U period. The TP group has higher ISQ values at most observations compared to the equivalent abutment size in the TR group. There is no obvious explanation for higher ISQ values in the TP group and one could hypothesize that it might signify that the soft tissue alone increases the stability. This is supported by the statistical analysis showing a significantly higher mean ISQ low in the TP group, 9 mm abutment, during the first 6 months ($p = 0.046$). Even though this could seem obvious, the primary implant stability is less affected by soft tissue compared to the bone quality and bone quantity [4].

Previous studies have shown ISQ dips after implantation or following loading of the sound processor [11, 16], which is also seen in our observations. Although the only statistically significant decrease is measured for the TR group receiving 6-mm abutments from 10 days to 6 weeks ($p = 0.045$). One can speculate if it is correlated to the processor loading as the TR group on average has the processor loaded one week earlier than the TP group and some of the 6 weeks F/U would have been done after this.

Although still not utilized as a standardized assessing instrument in clinic, the ISQ measurement in our experience has a motivating ability and encourages the patients to attend F/U appointments. ISQ measurements of implants are, therefore, still used for research purposes only until the day a specific cut-off value is established.

With regard to successful F/U, the TR group had a higher proportion of missed appointments at the second year compared to the subsequent annual F/U appointments, which is probably attributable to an increased awareness from the department. Interestingly, the number of completed F/U appointments were considerably higher in the TP group, when nurse-led appointments was introduced. In cases of patients not attending, the nurses telephoned the patients reminding them of the appointment and rescheduled for a successful F/U.

Overall, the majority of patients in both case series had no skin reactions around the abutments. The patients who suffered minor skin reactions (Holgers' grade 1) were treated with topical antibiotic or, in the more severe cases (grade ≥ 2), with application of lapis. As previously mentioned, several of the patients represented in this category have conditions that might play a part. The percentage of soft tissue reactions is comparable with other studies [14], as well as no difference in soft tissue reactions between the two surgical techniques [15].

The strength of this study is the combination of long-term prospective results of the newest type of implants, in a homogenous group of patients, undergoing the linear incision tissue reducing and tissue preserving technique.

In conclusion; the survival rate of the Wide Ponto implant is high during long-term follow-up. The two different surgical techniques with and without tissue preservation both shows long-term stable ISQ values and significant ISQ increase during the first 12 months. Higher ISQ values are noted in the group with tissue preservation compared with tissue reduction and there is no difference in adverse skin reactions comparing the two surgical techniques. This advocates to opt for the tissue preservation procedure for future patients.

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Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

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.

Informed consent Informed consent was obtained from all individual participants included in the study.

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