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Three-Year Clinical and Audiological Outcomes of Percutaneous Implants for Bone Conduction Devices: Comparison Between Tissue Preservation Technique and Tissue Reduction Technique

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Objectives: To evaluate the three-year clinical and audiological outcomes of soft-tissue preservation compared to soft-tissue reduction in linear incision surgery for percutaneous implant for bone conduction (BC) devices.
Methods: Twenty-five patients (25 implants) were enrolled in a prospective cohort for implant surgery with linear incision and tissue preservation. The control group consisted of 25 patients (25 implants) from a previous randomized controlled trial in which a linear incision with soft-tissue reduction was applied. Follow-up visits were scheduled at 7 and 21 days (fitting of sound processor); 12 weeks; 6 months; and at 1, 2, and 3 years after implantation. Main outcome measures were skin sensibility, soft-tissue status, Implant Stability Quotient (ISQ), skin height, implant survival, revision surgery, scar assessment, and hearing thresholds (BC in-situ between 250 Hz and 8 kHz with BC device on testband and abutment, and BC thresholds at 250Hz–4 kHz with a B71 bone conductor).
Results: Tissue preservation resulted in superior sensibility (mean percentage correct responses 99.7% [SD 1.7] vs 92.0% [SD 9.2], $p = 0.0001$). No spontaneous implant loss occurred in either group. The abutment was removed in two tests and in one control patient. Two control patients needed skin revision surgery. Although not statistically significant, more adverse soft-tissue reactions (Holgers ≥ 2) were observed in the test-group (n = 9 [36%] vs n = 3 [12%], $p = 0.095$). ISQ increased significantly more in the test group compared to the control group (7.64 [SD 4.05] vs 4.29 [SD 3.93]). Skin thickening, scar assessment, and hearing outcomes were comparable.
Conclusion: Tissue preservation demonstrated superior skin sensibility compared to tissue reduction while other clinical outcomes were comparably excellent. **Abbrevia-Abbreviations:** AUC, area under the curve.—BC, bone conduction.—BCD, bone conduction device.—ISQ, implant stability quotient.—RFA, resonance frequency analysis.—SD, standard deviation.

Key Words: BAHA—Bone conduction—Bone-anchored hearing—Hearing loss—Holgers—Implant loss—implant stability—ISQ—Soft tissue reactions—Tissue preservation—Tissue reduction—Wide-diameter implant.

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Over the last decades, the surgical technique for inserting percutaneous titanium implants in the temporal bone, onto which bone conduction devices (BCDs) can be coupled, has evolved, driven by the aim to reduce postoperative complications, for example, adverse skin reactions and implant loss. Until 2011, surgical implantation was always combined with peri-implant soft-tissue reduction, called skin thinning. The rationale behind skin thinning was that by reducing the skin mobility around the implant, the risk of inflammation and implant loss is reduced, and skin overgrowing the abutment is avoided (1–3). At the same time, however, skin thinning inflicts more surgical trauma and compromises both blood flow, thus hampering an optimal immune response during an infection, and neural structures around the implant,

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causing numbness (4). In addition, skin thinning prolongs the surgical procedure. In the past, different incision techniques with skin thinning have been described, such as the U-shaped flap, dermatome, and linear incision technique (5–7). Although several studies indicate the linear incision to be superior regarding clinical outcomes (8,9), adverse skin reactions, osseointegration failure, and the need for skin revision surgery still occur (10).

In 2011, after the introduction of wider diameter implants and longer abutments, Hultcrantz (11) described a modified linear incision technique without soft-tissue reduction. By preserving the soft tissue, hence inflicting less surgical trauma, it was hypothesized that this technique would result in less scar tissue formation and numbness, cosmetic advantages, shorter surgery times, faster wound healing, and possibly fewer skin infections. A recent systematic review concluded that surgical techniques with soft tissue preservation indeed have limited postoperative skin complication rates and require less surgical time compared to the skin-thinning techniques. However, because different surgical techniques were used in most comparative studies, no conclusions could be drawn on which technique, that is, skin preservation or skin reduction, is superior (12). The current study, a continuation of the previously published 6-month follow-up study, wherein short term and other data, such as surgery duration, is reported (13), investigated the 3-year clinical and audiological outcomes of the linear incision surgical technique with soft-tissue preservation compared to soft-tissue reduction.

MATERIALS AND METHODS

Ethical Considerations

The current study was performed in accordance with the guidelines established in the Declaration of Helsinki (Washington 2002, ISO 14155), Good Clinical Practice (International Conference on Harmonization Good Clinical Practice), and was approved by the local ethical committee. The current study was registered as NCT02064478 at www.Clinical-Trials.gov.

Study Design and Patients

The current study was designed as a prospective clinical trial on soft-tissue preservation in implant surgery for BCDs (test population) compared to a historical control population in which soft-tissue reduction was performed. To be eligible for participation, patients indicated for a percutaneous BCD in our tertiary referral centre had to be $\geq$18 years and provide written informed consent. Exclusion criteria were (i) bone thickness of $<$4 mm at the implant site; (ii) skin thickness of $>$10 mm; (iii) inability to participate in follow-up visits; (iv.) history of psychiatric diseases or mental disabilities; and (v) having a disease or treatment known to compromise bone quality at the implant site (e.g., diabetes mellitus, radiation therapy, osteoporosis). These eligibility criteria were identical for test and control group, except for the exclusion criteria skin thickness of $>$10 mm (in the test group) and the need for $>$6 mm abutment (in the control group).

The primary outcome of this study, skin sensibility around the implant, was used as an outcome in a study on these implants for the first time; therefore, no data were available for statistical sample size calculations. Sample size was instead determined pragmatically by the investigators' experience, as well as on practical feasibility. Twenty-five patients consented and were consecutively included in the test group between February and September 2014. The historical control group consisted of the last 25 patients (having received 25 implants) of a previously published randomized controlled clinical study implanted between March 2013 and January 2014. These patients received the same implant, placed using the same incision technique, but with soft-tissue reduction instead of tissue preservation (14). Two senior surgeons (EM and MH) performed all surgeries in both groups.

Surgical Techniques, Implants, and Follow-Up

The same type of Wide Ponto implant (diameter 4.5 mm, length 4 mm) with selected abutment was placed in a single-staged surgical procedure using a standard linear incision technique, with either soft-tissue preservation (test), as originally described by Hultcrantz (11), or soft-tissue reduction (control), as described by De Wolf et al (7). In both techniques, a linear incision of approximately 30 mm is made, followed by exposing and mobilization of the periosteum. After the standard drilling procedure, the implant is inserted in the mastoid bone. In the reduction technique, subcutaneous tissue is then removed over an area of approximately 2 cm around the incision. In contrast, subcutaneous tissue is retained in the preservation technique. In both techniques, the skin is then closed with sutures and punctured at the implant location for the abutment to penetrate the skin. In the test group, abutment length was determined based on skin thickness measured at the start of surgery before injection of local anesthetics (0.5–3 mm skin thickness = 6 mm abutment; 3–6 mm = 9 mm; 6–10 mm = 12 mm). In the control group, all patients underwent soft-tissue reduction with placement of a 6 mm abutment (14). All implants and abutments were developed by Oticon Medical AB (Askim, Sweden).

Follow-up visits in test group were scheduled at 7 and 21 days (fitting of sound processor); 12 weeks; 6 months; and at 1, 2, and 3 years after implantation. Follow-up visits in the control group were scheduled at identical time points, with additional visits at 14 and 28 days, and 6 weeks. Additional assessments, intended for the current study, were included at the 12-month follow-up visit and onward for control patients.

Outcome Measures

The primary objective of this study was to compare skin sensibility around the abutment in the test group compared to the control group. Sensibility was determined at six standardized locations (Fig. 1A) using a broken wooden cotton swab to determine gnostic (cotton side) and vital (sharp wooden side) sensibility, and was reported as a percentage of correct answers. In addition, subjective numbness was measured on a visual analog scale (VAS)—from 0 (no numbness) to 10 (complete numbness)—and by the patient reported diameter (centimeters) of the numb area.

The secondary objectives were to investigate implant stability over time (measured as Implant Stability Quotient, ISQ) and to compare soft-tissue tolerability, skin height, implant survival, the need for revision surgery, and scar assessment. ISQ was objectively measured by means of resonance frequency analysis (RFA), using a handheld Osstell ISQ device (Ostell AB, Göteborg, Sweden) and a SmartPeg (type 55) attached to the abutment. Perpendicular measurements result in two values, recorded as an ISQ-low value and an ISQ-high value, respectively. Soft-tissue tolerability was assessed according to Holgers' classification (15), in which a Holgers grade 2 or

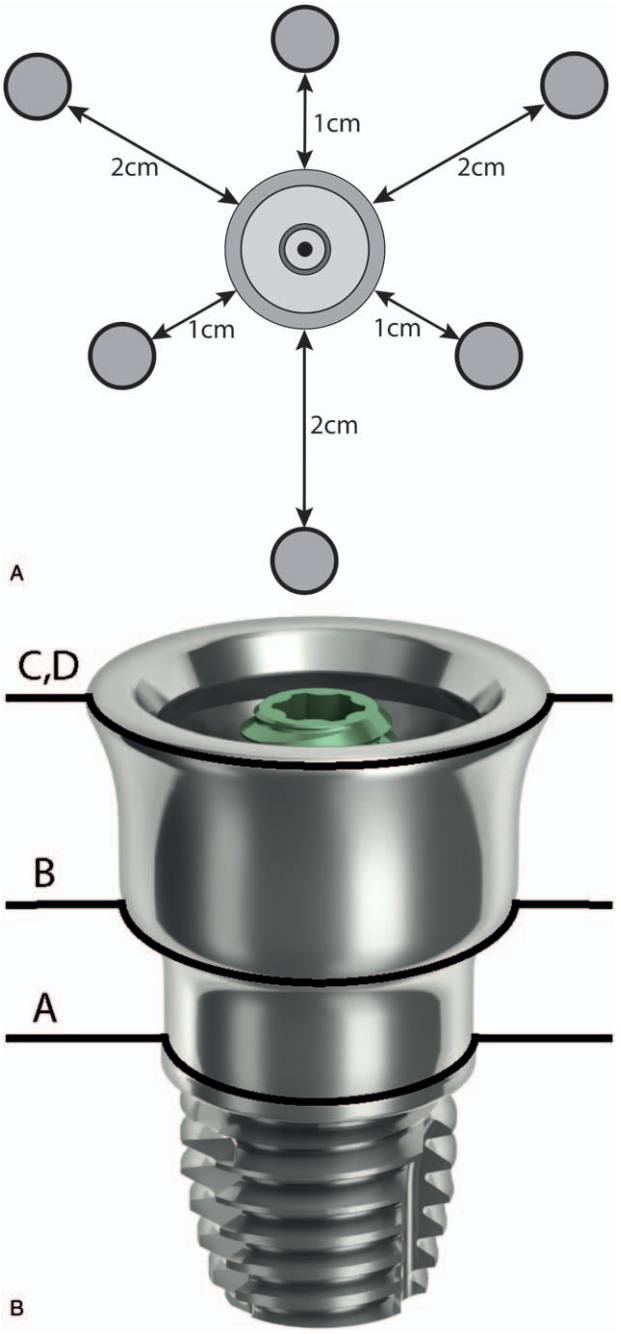

FIG. 1. (*A*) Sensibility test locations: at all locations both vital (broken, sharp wooden side) and gnostic (cotton side of wooden cotton swab) sensibility were tested in a random fashion. (*B*) Skin height relative to abutment (A—under the shoulder of the abutment; B—above the shoulder of the abutment; C—partial overgrowth; D—complete overgrowth).

higher was considered an adverse skin reaction. Skin height was evaluated in relation to the abutment (Fig. 1B). Scar assessment was performed by means of the Patient and Observer Scar Assessment Scale (POSAS) v2.0 (16). The POSAS consists of a patient and an observer scale, containing six categories with response options from 1 (normal skin) to 10 (worst imaginable). The total score ranges from 6 to 60 for both scales. The patient and the observer additionally score their overall opinion (not included in the total scores).

To investigate a potential sound dampening effect of the preserved soft tissue surrounding the abutment, BC in situ thresholds were measured both with the patients' sound processor on abutment and on a testband. Furthermore, audiometric BC thresholds (Interacoustics Equinox audiometer fitted with a B71 transducer, Interacoustics, Assens, Denmark) were used to check stability of the BC thresholds over time.

Data Analysis

Data management and statistical analyses were performed by independent external data managers and biostatisticians (Statistiska Konsultgruppen, Göteborg, Sweden) and executed according to a predefined statistical analysis plan.

For comparisons between groups, Fishers nonparametric permutation test was used for numbness variables, Mantel–Haenszel chi-square tests were used for all ordered categorical variables, Fisher's exact test was used for all dichotomous variables, and Mann–Whitney *U* tests were used for all continuous variables. Implant survival was analyzed with the log-rank survival test between the two groups. Repeated measures analyses were done for changes over time, using the Wilcoxon signed rank tests for continuous variables and Sign test for categorical and dichotomous variables. Due to differences in abutment length in the test group, for ISQ values and functions of ISQ values the adjusted analyses between the two groups was performed with analysis of covariance (ANCOVA). Groups were compared according to the intention-to-treat principle. The number of visits varied between test and control groups. Therefore, only data from follow-up visits available for both groups were included in the analysis of visit-based data; for cumulative variables all visits, including extra visits, were included. All tests, performed by using SAS v9.4 (Cary, NC), were two tailed and conducted at 0.05 significance level.

RESULTS

Patients and Follow-Up

The test population consisted of 25 patients with the same number of implants. The historical control population consisted of 25 patients with 25 implants. Demographics and baseline characteristics showed no statistically significant differences between these study groups (Table 1). No major perioperative complications were observed in either group. In total, 45 patients (46 implants) completed the 3-year follow-up. Three patients were withdrawn from the test group. The first patient had his abutment electively removed after 30 months due to persisting pain and minimal bleeding at the implant site despite extensive antibiotic treatment and pain medication. The second patient wanted his abutment removed after 26 months due to the burden of fast progressing Lewy-body dementia. The third patient was lost to follow-up, after missing multiple scheduled visits. His last visit was performed 6 months after surgery, during which he stated to only use the sound processor a few hours per month. In the control group, one patient had his abutment electively removed after 24 months in another hospital due to disabling tinnitus, which was hoped to improve by performing a stapedotomy combined with a

TABLE 1. *Baseline characteristics*

Variable	Tissue Preservation group (n = 25)	Tissue reduction group (n = 25)	*p*-value
Gender			
Male	15 (60.0%)	10 (40.0%)	
Female	10 (40.0%)	15 (60.0%)	0.26
Age	51.5 (SD 13.4; range, 18.0; 73.0)	53.9 (SD 12.2; range, 30.0; 83.0)	0.55
Smoking	4 (16.0%)	4 (16.0%)	1.00
Indication			
Acquired cond./mixed	21 (84.0%)	18 (72.0%)	0.50
Congenital conductive	1 (4.0%)	0 (0.0%)	1.00
Single-sided deafness	3 (12.0%)	7 (28.0%)	0.29

normal air-conduction hearing aid (14). For all these patients, data were included in the analysis up until the moment of withdrawal.

Besides these withdrawn patients, only four follow-up visits, in four different patients (two test patients and two control patients), were missed or performed outside the predefined visit window.

Skin Sensibility

The cotton swab sensibility test showed a significant difference in median total sensibility (percentage of correct answers): 99.7% (range 91.7–100%) in the test group vs 92.0% (range 66.7–100%) in the control group ($p = 0.012$) 36 months after surgery (see table, supplemental digital content 1, http://links.lww.com/MAO/A725, which reports sensibility scores for each group per visit). Moreover, 4% of the test patients experienced numbness to some extent, compared to 52% of the control patients. In line with this, subjective numbness (VAS 0 [SD 0] vs VAS 0.9 [SD 1.6]) and patient reported diameter of the numb area (0 cm [SD 0] vs 0.4 cm [SD 0.7]) also differed significantly in favor of the test group. Skin sensibility at 12 and 36 months is displayed in Figure 2.

Soft Tissue Tolerability and Complications

Figure 3 presents an overview of soft tissue reactions per planned visit and all visits combined (including extra visits). Across all visits, adverse skin reactions (Holgers 2–4) were observed in 36.0% of the test patients and in 12.0% of the control patients, which were all successfully treated with locally applied ointment for 14 days. Neither

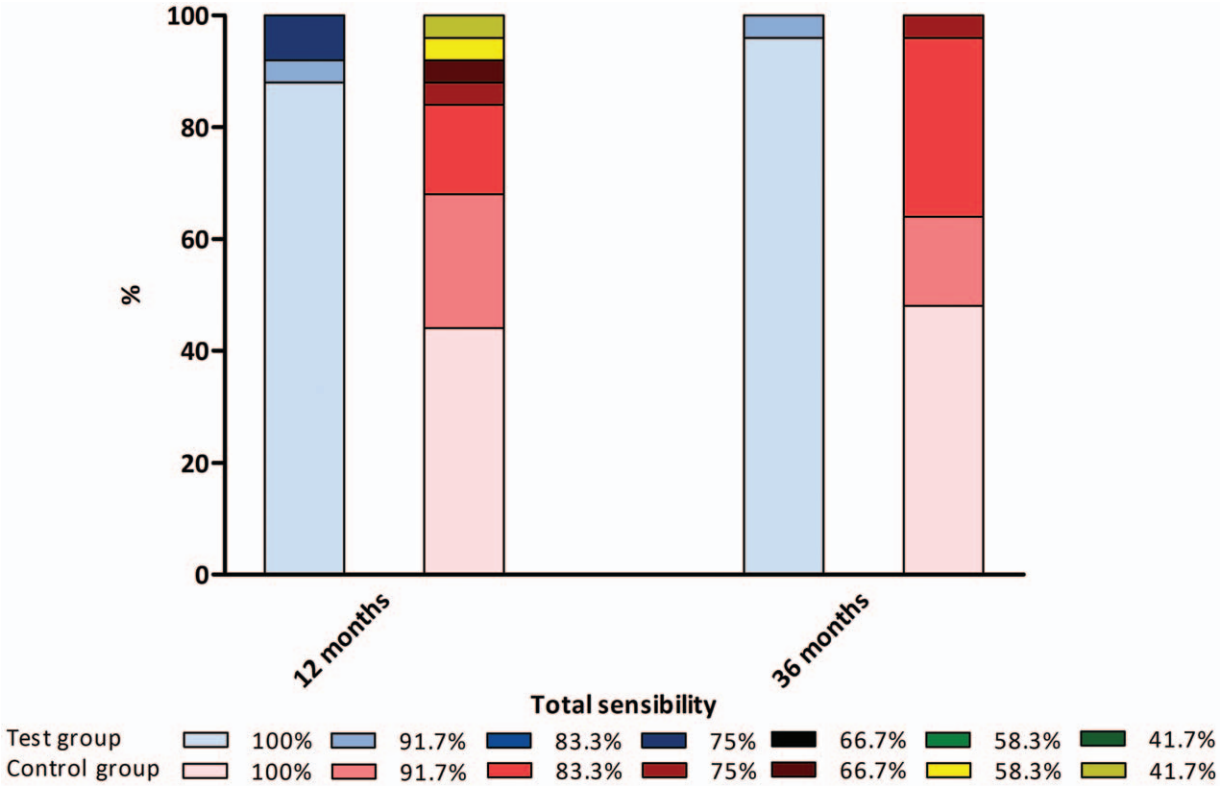

FIG. 2. Total skin sensibility test results at 12 and 36 months.

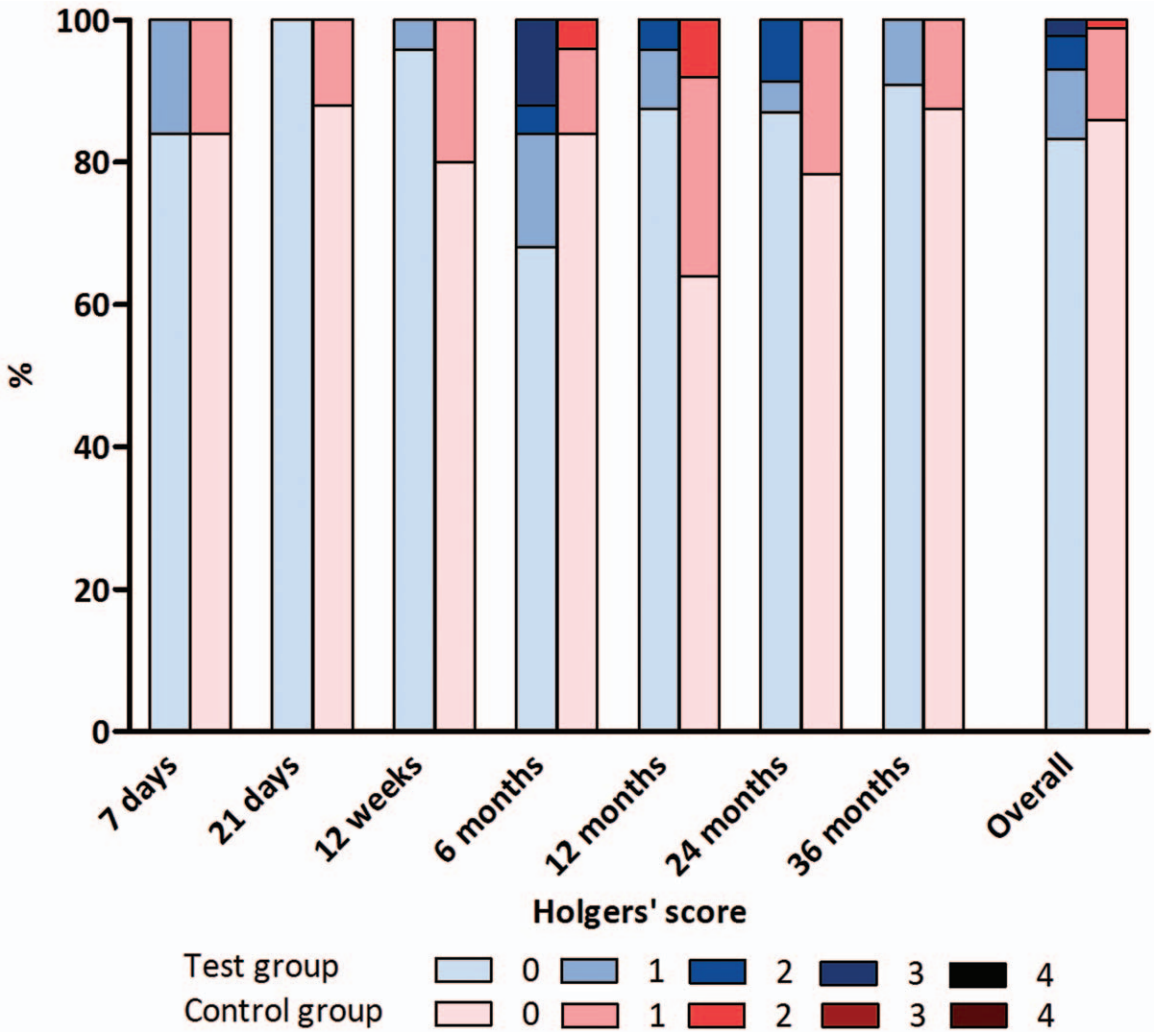

FIG. 3. Skin reactions (Holgers grade) at each visit and overall. The overall data also contain observations during unplanned extra visits.

adverse skin reactions ($p = 0.10$) nor other postoperative complications were significantly different between groups: bleeding or hematoma (0% vs 0%; ($p = 1.0$); and skin dehiscence (0% vs 8% (all healed 3 weeks after surgery); $p = 0.49$).

Thickening of the skin was observed in 56% (test) and 64% (control) of the patients, not statistically correlating with the presence of an adverse skin reaction (Holgers grade 2–4). Neither the maximum skin height observed at all visits, nor skin height during any of the follow-up visits differed between groups. Skin height per visit is displayed in Figure 4. Only two control patients needed revision surgery (6 weeks and 9 months after surgery, respectively), both due to thickened skin (level B) around the abutment without inflammation, resulting in feedback issues (14).

POSAS

At 1-year follow-up, none of the categories on the patient and observer scale exceeded scores of 4. The patient categories thickness ($p = 0.031$), irregularity ($p = 0.03$), mean total patient score ($p = 0.01$), and overall opinion ($p = 0.003$) differed significantly in favor of the test group. The observer categories vascularity ($p = 0.012$), relief ($p = 0.004$), surface area ($p < 0.0001$), mean total observer score ($p = 0.0025$), and overall opinion ($p = 0.0004$) differed significantly in favor of the test group.

At 3-year follow-up, none of the categories on the patient and observer scale exceeded scores of 3. The patient category stiffness significantly ($p = 0.041$) differed in favor of the control group. The observer categories relief ($p = 0.0037$), and overall opinion ($p = 0.027$), differed significantly in favor of the test-group (see table, supplemental digital content 1, http://links.lww.com/MAO/A725, which reports the POSAS data per visit).

Implant and Abutment Survival

No implants were lost in either group. No statistically significant difference in 3-year abutment survival was observed between groups (test 92% vs control 96%): two abutments were electively removed in the test group and

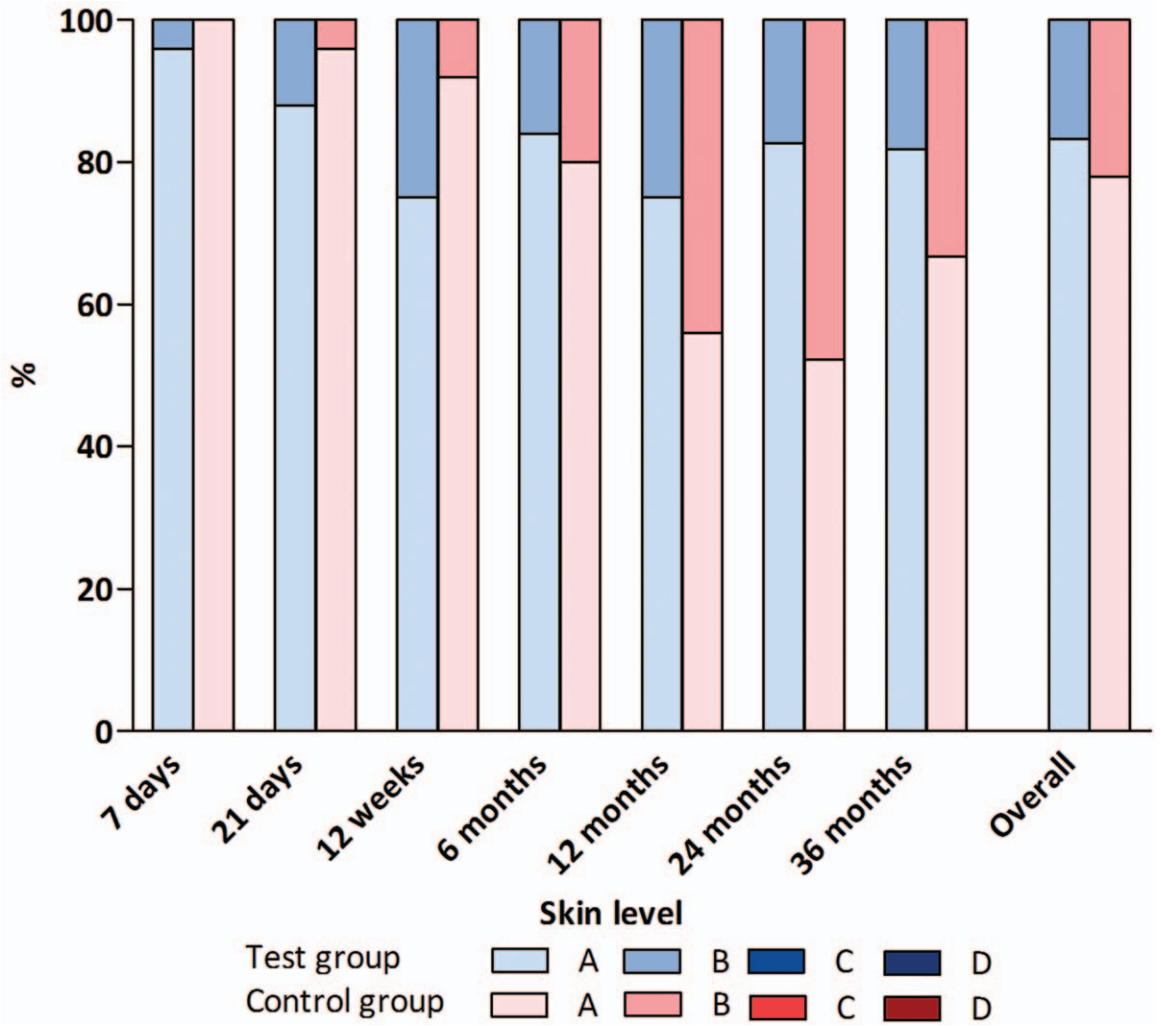

FIG. 4. Skin height relative to abutment by visit and overall per group. The overall data also contain observations during unplanned extra visits.

one in the control group (see section 'patients and follow-up'). The implant itself remained seated in all three patients.

ISQ

As expected with differences in abutment length, the mean 36-month AUC for ISQ-low was significantly higher in the control group compared to the test-group ($p < 0.001$). In both groups a significant increase in ISQ low is observed over time ($p < 0.001$), however, this increase is significantly higher in the test group compared to the control group (7.64 (SD4.1) vs 4.29 (SD3.9); $p = 0.0068$) For ISQ high, similar results were observed, with absolute numbers 1 to 2 points higher on average and slightly less increase over time. ISQ data are displayed in Figure 5.

Audiology

After 36 months, no significant differences ($p>5\%$) were seen for thresholds measured with testband and B-71 audiometric bone conductor when averaged across all frequencies, indicating essentially similar hearing thresholds. Also, BC-in-situ (i.e., on abutment) thresholds averaged across 250Hz-8 kHz showed no difference between test and control group (mean, 27.5 dB [SD 12.3] vs 27.1 dB [SD 14.0] $p = 0.81$). However, the 1000-Hz thresholds on testband were statistically significantly different (mean 34.5 dB [SD 13.8] vs 25.0 dB [SD 14.4] $p = 0.015$). When comparing individual thresholds on testband, abutment, and B71 between test and control group *B71* and abutment were not significantly different, but at 1000 Hz, a significant group effect was observed for the differences between abutment and testband thresholds (mean, -17.6 dB [SD 10.2] vs -9.0 dB [SD 6.1] $p = 0.0016$).

DISCUSSION

Synopsis of Key/New Findings

In current study, we compared the long-term clinical outcomes of two different surgical techniques for

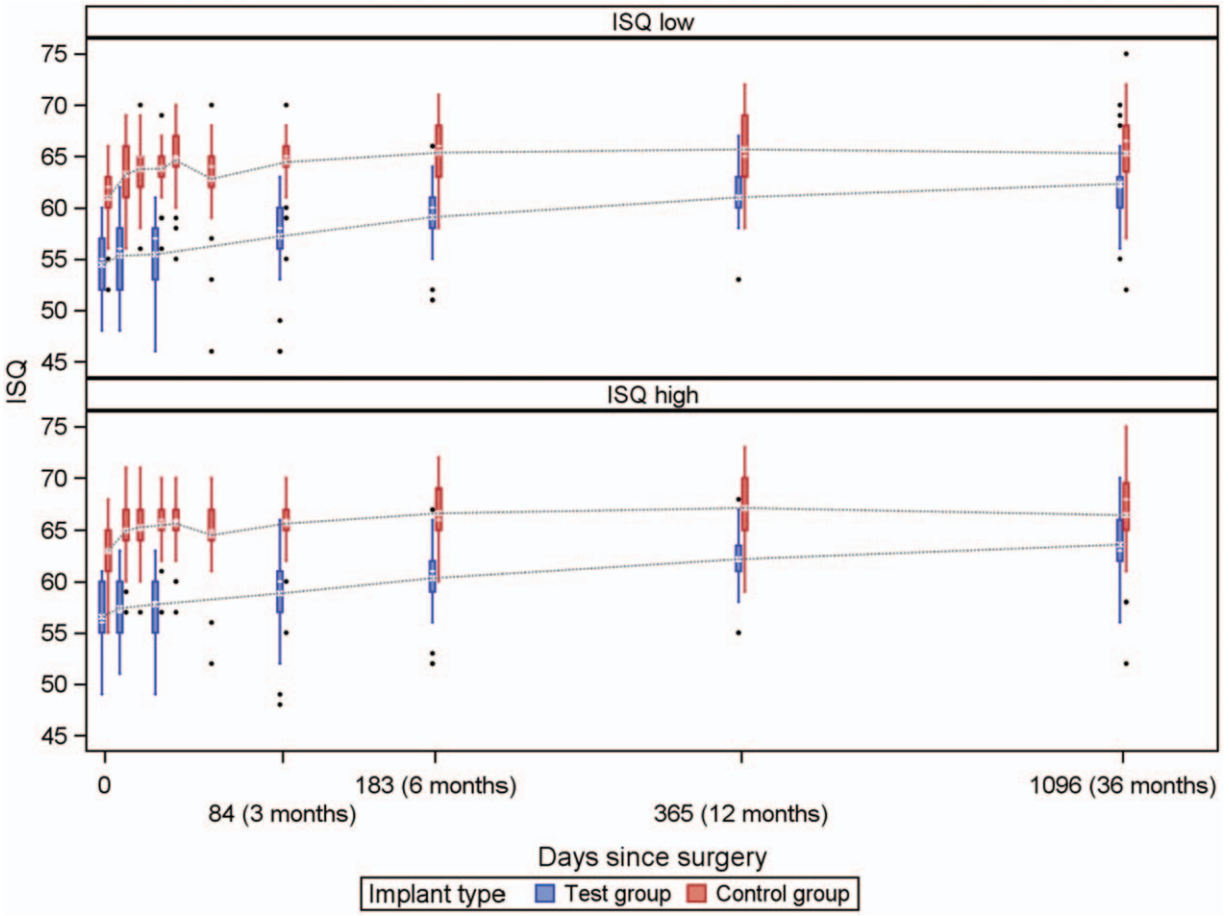

FIG. 5. Boxplot of ISQ low and ISQ high over time. ISQ indicates Implant Stability Quotient.

placing a percutaneous titanium implant for BCDs in the temporal bone: the linear incision with soft tissue reduction and the linear incision with soft tissue preservation. Based on our primary outcome measure, that is, skin sensibility 3 years after surgery, patients operated with tissue preservation experienced significantly less numbness at the implant site compared to the tissue reduction group. No differences were observed in the total POSAS-scores, soft tissue tolerability, skin height around the abutment, implant survival, and audiological performance.

Strengths and Limitations of the Study

The current study is the first to compare long-term clinical outcomes of two groups with tissue preservation or reduction as the only variable. In addition, data quality is considered very high, with only one patient lost-to-follow-up and four visits outside the predefined visit window.

At the study's inception, skin sensibility was measured for the first time in relationship to these surgical techniques. A sample size could therefore not be calculated, thus, was empirically chosen. In addition, by using a historical control group randomization was not possible. However, for both groups the same eligibility criteria were applied, baseline characteristics were comparable, and all data were gathered prospectively. Blinded follow-up was not feasible, since the implant site appearance differs between surgical techniques and longer abutments were used in the test group.

Another limitation could be the difference in follow-up visits. In the first 6 months of follow-up, patients in the control group had three additional visits compared to the test group. This might have influenced the quality of the soft-tissue care, since more than half of adverse soft-tissue reactions in the test group were observed at the 6-month visit, and 77% of all reactions occurred in the first 6 months after surgery. Nonetheless, no difference in soft tissue reactions was observed at the 1-year interim analysis and over the entire follow-up.

Comparisons with Other Studies

Postoperative numbness is evaluated in only two other studies (17,18). In these studies, the linear incision technique with tissue preservation is compared to the dermatome technique with tissue reduction. In line with our observations, both studies reported significantly less numbness at the implant site for the tissue preservation

group. However, caution is needed since a different skin thinning technique was used (17,18).

A recent systematic review on soft tissue preservation techniques concluded that postoperative skin complication rates were low and that overall complication rates were comparable with skin-thinning techniques, while the duration of the surgery was significantly shorter (12). However, in only one comparative study, the same incision technique, i.e. linear incision, was applied in both skin-thinning group and tissue preservation group (18). Despite the relatively high incidence of Holgers$\geq$2 at 1 week (64% vs 67%), no significant differences in cutaneous reactions after 1 year of follow-up were found between groups (18), which is in line with the observations in the current study.

Clinical Applicability of the Study

The primary outcome, that is, skin sensibility, differed significantly in favor of the tissue preservation technique. However, also patients operated with the reduction technique reported good sensibility scores and low subjective numbness scores (VAS) in small corresponding areas, which all improved over time. In addition, no difference in subjective numbness was observed at 12 months despite significantly differing sensibility scores. The significant differences on the POSAS after 12 months, in favor of the tissue preservation technique, were overcome at the 3-year follow-up; especially the total patient score in the control group improved (from 18.9 to 9.1). It is worth noting, however, that many patients reported difficulties answering the POSAS questions because of limited visibility and the lack of interest in the appearance of the scar. Due to the position of the implant, sensibility and appearance seem to be of limited importance to patients, especially in the long-term.

In the previous 6-month evaluation, significantly more soft tissue reactions were observed in the tissue preservation group (13). At the following visits, however, no differences in soft tissue reactions were observed. As such, over the entire follow-up, no significant difference in adverse skin reactions were noticed between surgical techniques.

Skin thickened in more than half of the patients, regardless of the surgical technique. The skin height per visit did not differ between groups. At the 36-month follow-up skin thickening was observed in 18.2% (test) and 33.3% (control) patients. This suggests that skin thickening is often only temporary. The previous hypothesis that thickening of the skin reflects the restoration of normal soft tissue after soft tissue reduction seems unlikely since skin thickening is also observed after tissue preservation surgery (14). The hypothesis that skin thickening could be the result of more active immunological mechanisms to compensate for the continuous breach of the skin implied by the skin-penetrating implant, seems more likely. However, we did not observe any correlation with adverse skin reactions. Future research, therefore, remains needed.

The difference in absolute ISQ scores (both low and high) between groups was expected, since longer abutments were used in the test group. Interestingly, the ISQ-scores over time increased significantly more in the tissue preservation group compared to the tissue reduction group. Although this observation could suggest that tissue preservation leads to a more rigid bone-implant interface, we deem it unlikely that soft tissue handling significantly influences osseointegration. Perhaps, the stronger increase in ISQ could be assigned to measurement error caused by the difference in abutment length, which emphasizes the importance of not comparing ISQ values of implants with different abutment lengths (19). These results should be repeated by future studies with similar protocols to affirm these assumptions.

The two statistically significant differences in frequency specific BC thresholds between groups (BC-in-situ threshold for 1000 Hz on testband and the difference between the BC-in-situ threshold on abutment and testband) were also, and to the same extent, observed in the 6-month evaluation (13). These differences can be most likely attributed to differences in resonance frequency of the sound processor in the transcutaneous conditions (13,20). Nonetheless, since no differences were observed between groups on the average thresholds measured on testband, B71, and abutment, these indicate that the preservation of soft tissue around the abutment has no sound dampening effect.

CONCLUSION

A linear incision with soft-tissue preservation for the implantation of percutaneous implants for BCDs is superior in terms of skin sensibility and scar appearance, without influencing audiological outcomes, compared to soft-tissue reduction. Both surgical techniques have comparable implant survival and soft tissue tolerability. Also taking into account the shorter surgery time, we advocate using the soft-tissue preservation technique.

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