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Clinical Evaluation of a Novel Laser-Ablated Titanium Implant System for Bone Anchored Hearing Systems in a Pediatric Population and the Relationship of Resonance Frequency Analysis With Implant Survival

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Objective: To evaluate the clinical outcomes of pediatric patients implanted a novel 4.5 mm wide laser ablated titanium bone anchored implant system and to evaluate the implant stability over the first 12-month period.
Study Design: A prospective, single-subject, repeated measure, cohort study. Participants served as their own controls.
Setting: Community and tertiary referral hospital pediatric assessment center.
Patients: A total of 115 consecutive pediatric patients aged 4 to 15 years were implanted with 176 laser ablated titanium bone anchored implants from January 2016 to January 2019.
Main Outcome Measure: Clinical outcomes, implant failure rates, and post implantation implant stability quotient (ISQ) scores were studied over the first 12-month period. Data were analyzed for statistical significance through mixed effect modeling, with the significance level $p = 0.01$.
Results: A median 12-month survival of 96.6% was observed. Six implants (3.5%) were lost in total, one of these (0.6%) was lost due to trauma. Adverse skin reactions (Holgers grade 2–4) were observed in 4.4% of all postoperative visits, occurring in 22 individuals (19.1%). Neither the ISQ high (ISQH) nor ISQ low (ISQL) values increased significantly between the stage 1 and 2 surgeries. In contrast, the ISQ results, irrespective of abutment size, demonstrated an increasing trend from 49.1 to 57 over the 12 months review period. A statistically significant change was only demonstrated from the 3 months follow up onwards.
Conclusion: The use of 4.5 mm wide laser-ablated titanium bone anchored hearing implants resulted in superior survival rates and excellent clinical outcomes compared with previous implant systems. **Key Words:** Bone conduction hearing—Bone-anchored hearing aid—Dental implants osseointegration—Resonance frequency analysis.

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Since 1977, bone anchored titanium implants have been utilized for the attachment of percutaneous abutments allowing for fixation of sound processors for bone conduction hearing (1). Successful implantation is dependent on osseointegration with the surrounding bone during healing of the implant (2). Osseointegration is in turn influenced by implant geometry (macro, micro, and nanoscale), surface and material properties, drilling protocol, osteotomy configuration, surrounding bone quality, and systemic and local host characteristics (3,4).

It has been reported that the pediatric population has either lower or equal implant survival rates compared with adult populations (5) despite fewer patient-related conditions such as high body mass index (BMI), smoking, diabetes, previous local radiotherapy (6). Furthermore, some centers advocate early and immediate loading of processors in adults (7–11) and at 6 weeks in children (12). These factors underscore the need for accelerated osseointegration, increased stability, and higher survival rates of bone conduction hearing devices in children. One strategy is to increase the diameter and therefore the implant-to-bone contact, which is reported to reduce failure rates in oral implantations (10,13). Compared with the 3.75 mm previous generation implants 4.5 mm diameter wide bone anchored hearing implants (BAHIs) provided similar improvement in survival rates (8,14–16).

In the adult population, a recent systematic review of 1,166 BAHIs of various designs reported an overall survival rate of 97.7% over an average follow-up time of 17 months (17), supporting previous findings of failure rates between 2.6 and 4.2% in the adult population (8,10,16,18). In the pediatric population, wide diameter implants demonstrated a 5.9% implant loss compared with a 17.1% loss with narrow diameter implants (19), irrespective of any other design variation. Previous small-diameter generations of BAHI were also associated with higher peri-abutment soft tissue complications in pediatric populations resulting in requirements of longer abutments (5,20).

In dental applications, surface modifications techniques were developed that increased the roughness of the surface of the implant and demonstrated a stronger bone response and better clinical results compared with non-modified implants (3,21). Based on these findings the 4.5 mm wide diameter laser ablated titanium bone anchored implant system, was introduced in 2015. Using laser ablation, a distinct hierarchical structure is created with a combined macro- and microtopography. In addition, a superimposed nanotexture is confined to the valleys of the implant threads. This laser-ablation was designed to promoted stronger bone anchorage during the early healing period of osseointegration than a standard machined implant (22). A recent study evaluating this surface modified implant in adults reported an implant survival of 97% together with good soft tissue tolerability (23). The potential advantages or disadvantages of this new generation of BAHIs have not yet been evaluated in children.

Resonance frequency analysis (RFA) was introduced as a non-invasive, in situ method to assess the stability of BAHI in patients. The RFA of a small transducer rod (smartpeg) attached to the implant is converted into an implant stability quotient (ISQ) (between 1 and 100), where a higher number indicates higher stability. Two ISQ recordings are taken in perpendicular directions ISQ high (ISQH) and ISQ low (ISQL) which are generated due to the different bone characteristics in each direction (24). The ISQ of attached abutments is measured in an identical manner by placement of the smartpeg into the abutment center. ISQ values for BAHI demonstrate trends in stability in individual patients or cohorts over time, and clinical conclusions cannot be drawn from single ISQ values according to a review of 17 studies using ISQ (25). The role of stability measurement in children is still debated but has been used by some centers to help guide early loading in single-stage procedures (12,25).

The objectives of this study were to determine implant stability using ISQ at the fixture and abutment levels and implant survival over the first 12-month period in a cohort of 115 consecutive children fitted with the laser ablated Ponto BHX implant system.

MATERIALS AND METHODS

Study Population and Surgery

This was a prospective, single-subject, repeated measure, cohort study in which each participant served as their own control. Ethical approval was granted by the research and development committee (REC ref 11/WM/1054, IRAS project ID 145812). Participants aged between 4 and 15 years with unilateral or bilateral, conductive hearing loss eligible for BAHI were recruited at Birmingham Children's Hospital (Birmingham, England). Following a formal consent process, 115 consecutive children were offered a place in the study. Patient demographics, underlying etiological indications for implantation and surgical techniques were recorded.

This center preferred two stage implantations in younger children. Single stage procedures were performed in seven patients (total nine implants). In all but five cases, two fixtures were placed on the indicated side, one acting as a ''sleeper.'' Typically, a two-stage procedure consisting of a 3-month healing period between surgeries was used. All surgeries were performed by three consultant surgeons between January 2016 and January 2019. The following three surgical techniques were used: 1) linear incision for implant placement followed by a linear incision without skin reduction for second stage; 2) a ''U'' shaped incision for implant placement followed by a 4-mm skin punch with no skin reduction for the second stage; 3) ''S'' shaped skin incision for stage one with no skin reduction followed by a 4-mm skin punch with minimal skin reduction for the second stage. Single-stage procedures were performed in an identical fashion.

Implant and Abutment

The implant was the laser ablated titanium bone anchored implant system Ponto Biohelix (BHX) (diameter, 4.5 mm; length 3 or 4 mm) (Oticon Medical AB Askim, Sweden). Ponto BHX with premounted abutments of lengths 6, 9, and 12 mm were used for single stage surgeries. Abutment lengths of 6, 9,

and 12 mm were used at the second stage surgeries for all other children.

Follow Up and Review

Second-stage surgery for abutment placement occurred following a minimum 3-month period. Reviews then occurred at weeks 1 and 2 and then at 3, 6, 9, and 12 months. Complications, revision rates, skin reactions according to the Holger Classification (26), loss of abutment, implant failures, and abutment level ISQs (Osstell ISQ, Osstell AB, Gothenburg, Sweden) were documented at each review. Holgers more than or equal to two were considered adverse skin reactions. Fixture- and abutment-level ISQs were recorded at each surgical stage and subsequently, only abutment-level ISQs were recorded. Two recordings were taken in perpendicular directions (ISQH and ISQL).

Statistics

All data were analyzed using Stata 16 version 16.1 (StataCorp LLC, TX). Categorical data are presented as n (%) and numeric data are presented as the mean (SD) and range or mean (95% CI). To assess the effect of time from surgery on the ISQ, a mixed effect model was applied, and comparisons were performed using the data from the time of surgery as the baseline. The results are presented as coefficients or means with the appropriate confidence interval, and the level of significance was set at $p = 0.01$.

RESULTS

A total of 115 consecutive pediatric patients were implanted with the laser ablated titanium bone anchored implant system. The mean age was 8.8 years, with a slight female predominance (52%). Sixty-one children had bilateral implants and 54 had unilateral implants giving a total of 176 implants (3 mm implants n = 124, 4 mm n = 52). A two-stage implantation was performed in 108 patients (167 implants) whereas a single-stage procedure was performed in seven patients (nine implants). In all but five cases, two fixtures were placed on the indicated side, one acting as a ''sleeper.'' One implant was lost before the second-stage surgery; therefore, 175 implant systems were fitted with abutments and followed from this point. Patient demographics and systems implanted by each surgical technique are provided in Table 1 for direct comparison.

Second Stage Interval Analysis

The mean healing period between stage one and stage two was 14.3 weeks (SD 3.25; range, 9–24). The longer healing periods were used for patients with very thin bone (<2 mm) or due to social factors such as medical or school commitments.

Implant Survival

For the entire cohort, a median 12-month implant survival of 96.6% (n = 169), implant failure rate of 2.8% (n = 5), and traumatic loss rate of 0.6% (n = 1) were determined (Table 1). All but one implant loss occurred before the 6-month review, the exception being traumatic loss, which occurred between the 6 and

TABLE 1. *Demographics and implant loss rates for all included patients and surgical approach subgroups*

	Total	Surgery Method		
	n = 115	'U' Shape (n = 36)	'S' Shape +SR (n = 21)	Linear +SR (n = 58)
Sex, n (%)				
Male	55 (47.83)	16 (44.44)	10 (47.62)	29 (50.00)
Female	60 (52.17)	20 (55.56)	11 (52.38)	29 (50.00)
Side of surgery n (%)				
Bilateral	61 (53.04)	16 (44.44)	10 (47.62)	35 (60.34)
Left	21 (18.26)	6 (16.67)	6 (28.57)	9 (15.52)
Right	33 (28.70)	14 (38.89)	5 (23.81)	14 (24.14)
Age: mean (SD)	8.8 (3.5)	9.1 (3.7)	9.0 (3.8)	8.4 (3.3)
(range)	(4, 15)	(4, 15)	(4, 15)	(4, 15)
Mean BMI centile (SD)	23.2 (13.3)	21.4 (11.2)	21.6 (9.9)	24.9 (15.4)
Implant length n (%)				
3 mm	124 (70.5)			
4 mm	52 (29.5)			
Abutment length n (%)				
6 mm	29 (16.5)			
9 mm	141 (80.5)			
12 mm	5 (3%)			
Total number of implants	176	52	31	93
Total number of abutments Fitted	175	52	30	93
Implant failure n (%)	5 (2.8)	1 (1.9)	1 (3.2)	3 (3.2)
Traumatic failure n (%)	1 (0.6)	1 (1.9)	0	0
Total implant failures	6 (3.4)	2 (3.8)	1 (3.2)	3 (3.2)

Linear +SR = linear incision for implant placement followed by a linear incision with minimal skin reduction for the second stage. ''U'' shaped = U-shape incision of the first stage, followed by a 4-mm skin punch without skin reduction. ''S''-shaped + SR = S shaped skin incision for the first stage with no skin reduction, followed by a 4-mm skin punch with slight skin reduction for stage two.

12 months reviews. Lost implant systems were replaced outside this study. All data from the patients up to the point of implant loss were included in the analysis.

There was no statistically significant difference in the implant survival rate for the group of implants installed with minor soft tissue reduction (31 implants) compared with those that had no soft tissue reduction (145 implants) (failure rates of 3.2 and 3.8%, respectively). Most implants were 3 mm long (n = 124, 70.5%) and considered the fixture of choice when the thickness of calvarial bone was less than or equal to 2 mm. These fixtures were placed with a low torque of 25 to 30 Nm^2 and where possible positioned flush with the calvarial bone.

Spontaneous implant loss occurred in four female patients and one male patient aged 4 to 15 years (median 7). One 3-mm implant failed before the second stage of surgery, two implants (3 and 4 mm) failed by the 3-month review, and the remaining two (3 mm) failed by 6 months. Two patients within this group had undergone single stage procedures performed by two different operating surgeons which were recorded at the 3 and 6 month review points.

Soft Tissue Outcomes

Holgers Grade 0 was recorded in 54.7% of visits across the entire study group. During the 12-month follow-up, adverse skin reactions (Holgers grade 2–4) were observed in 4.4% of all postoperative visits, occurring in 22 individuals (19.1%). No association with surgical technique, age, sex, or BMI was identified. Pain was reported by one individual at the second postoperative review. Keloid scarring and scar overgrowth occurred in four (2.2%) implant systems; however no revision surgery was required for any implant.

Implant Stability Quotient

Three implants had missing ISQ recordings from the time of implantation and 63 implants were missing ISQ data at the second stage surgery (Table 2). Single-stage procedures (n = 9) did not have implant-level ISQ recorded at either surgical stage. Therefore, ISQ was measured in 164 implants at the implant level, i.e., first-stage surgery and 101 implants at the second stage surgery before abutment placement. Irrespective of the implant length the mean ISQH and ISQL demonstrated a nonsignificant increase between the first and second stages of 2 and 3.1 points, respectively (Table 2).

With respect to the abutment ISQ, the mean ISQH increased for the 6-, 9-, and 12-mm abutments by 2.5, 9.5, and 10.8, respectively (Fig. 1/Table 3). However, this increase was only statistically significant within the 9-mm cohort and from the 3 month review onwards. Combining the entire cohort of abutment length with an overall increase in ISQH of 8.43, statistical significance was reached at 3 months.

The mean ISQL increased by 5.2 and 10.1 for the 6- and 9-mm abutments, respectively, whereas it decreased by 3.9 in the 12-mm group. These changes were only statistically significant in the 9-mm group. Overall, an increase in ISQL of 9.03 was observed (Fig. 1/ Table 3).

TABLE 2. *Mean ISQ at implant level, SD, and range with p-value of change between these two measurement points irrespective of implant size*

	First Stage	Second Stage		
n=	164	101		
ISQ L			Change	*p*-Value
Mean	62	65.1	3.1	0.06
SD	14.2	11		
Range	20–96	39–90		
ISQ H				
Mean	68	70	2	0.23
SD	14.4	11.2		
Range	9–98	44–90		

ISQ indicates implant stability quotient.

Relationship Between Fixture Failure, BMI, and ISQ

The mean BMI centile of the fixture failure patients (22.7th centile SD, 7.9) did not differ from the mean for the entire cohort (23rd centile, SD 13.3). Statistical analysis of the relationship between atraumatic fixture failure and the ISQ was not performed due to the small sample size (n = 5). However, no obvious correlation or relationship could be identified between ISQ at either fixture of abutment level and subsequent failure, the ISQ at all visits for each of these implants as demonstrated in Table 4.

DISCUSSION

To our knowledge, the current study is the largest published evaluation of wide implants BAHIs in pediatrics and the first study evaluating the clinical outcomes of the new Ponto BHX in children.

The present study revealed an implant loss rate of 3.4% in a pediatric population. A previous study on 182 children from BCH using two-stage surgery in 95% of the cases, demonstrated implant failures in 14% of loaded implants (27). In contrast to the present study, 3.75 mm machined implants were used and installed using a split skin graft technique. Moreover, the follow-up time was 15 years. However, the majority of implants were lost during the first 2 years and associated with wound breakdown and significant skin reaction, indicating the influence of implant design and surgical technique on the survival rate. In comparison to other results at our center, outcomes using the previous Ponto wide implant (without a laser ablated surface) showed a 10% implant failure rate in 75 implanted systems (28), indicating a benefit in terms of survival rate using the present implant surface with micro- and nanoscale features. The results from the present study can also be compared with the use of a wide blasted implant (BIA300, Cochlear Nordic AB, Mölnlycke,

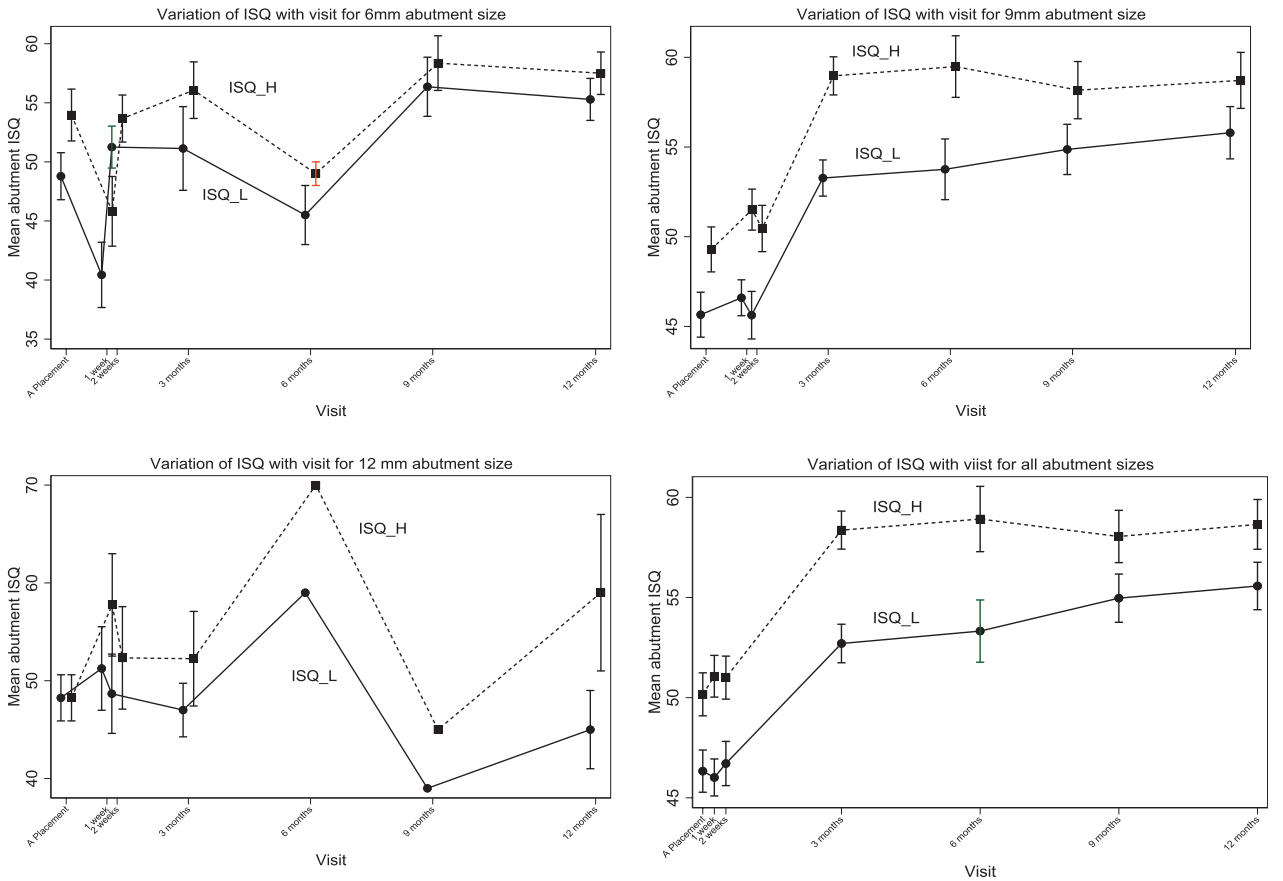

FIG. 1. Change in Mean ISQ H and ISQ L at each review point according to abutment size. ISQ indicates implant stability quotient.

Sweden) demonstrating 5% implant loss at our center (29). A recent meta-analysis of wide diameter implant systems in the pediatric population demonstrated a 5.9% fixture loss, whereas the corresponding result for the previous narrow BAHI implant was 17.1%, corroborating our findings (19).

The reduced revision surgery rate in the present study in comparison with previous results in our center using the small diameter implant, 0% versus 8% (27), is in line with the results in a recent systematic review (19) and far exceeds this center's experience with the Cochlear BIA300 implant, which demonstrated a significant 77% skin reaction rate and 35% revision rate (29). Taken together, the present study therefore demonstrates significant improvement in the implant loss and revision surgery rates (2.8 and 8.3%) as well as comparable soft tissue complications, compared with previous implant systems utilized.

Peri-abutment adverse skin responses are well-known side-effects in pediatric patients (19,27,28). These responses have been linked to hygiene, puberty, skin movement, and medical comorbidities, making children more prone to adverse soft-tissue complications compared with adults (19). In children under 5 years old, there is a disproportionate soft tissue complication rate of 15 to 42%, with an associated 10 to 25% revision rate reported (30,31). In our present cohort of 26 children under the age of 5 implanted with 40 BAHIs, two fixture losses were observed (5%) with soft tissue complications (Holgers 2–4) observed in three patents (11.5%). Taken together, the 4.5 mm wide laser ablated titanium bone anchored implant system appears to promote favorable results in this at-risk subgroup compared with the previous Oticon wide implant. Overall adverse soft tissue reaction was noted in 19% of the patients and no revision surgery was required over the 12 months follow up. They only comprised 4.4% of all postoperative visits recorded indicating the transient nature of these reactions. In comparison with previous reports of adverse skin reactions in 17% of patients and revision surgery in 8% of patients (using similar implant widths but non-laser ablated surfaces), it is suggested that implant diameter does not influence the soft tissue outcome (27). Similar conclusions were reached in a review, demonstrating an equal incidence of adverse reactions (28%) in wide- and small-diameter implants (19).

The reduced revision surgery rate in the present study in comparison with previous results in our center using the small diameter implant, 0% versus 8% (32), is in line with the results in the review (19). In contrast, this

TABLE 3. *Mixed effect modeling to estimate the magnitude of the change in ISQ according to visit and abutment size*

	ISQ_Low		ISQ_High	
	Mean Change (95% CI)	*p* Value	Mean Change (95% CI)	*p* Value
6 mm				
Post op visit Week 1	**−8.5 (−13.4, 3.6)**	0.001	**−8.2 (−13.0, −3.5)**	0.001
Post op visit Week 2	2.2 (−3.3, 7.6)	0.44	0.3 (−5.0, 5.6)	0.92
3 months	3.2 (−1.8, 8.2)	0.21	3.5 (−1.3, 8.4)	0.16
6 months	−1.4 (−13.1, 10.4)	0.82	−1.4 (−12.9, 10.1)	0.82
9 months	6.3 (1.2, 11.4)	0.015	3.2 (−1.8, 8.1)	0.21
12 months	5.2 (0.1, 10.3)	0.045	2.5 (−2.4, 7.5)	0.32
9 mm				
Post op visit Week 1	1.1 (−1.6, 3.8)	0.43	2.4 (−0.4, 5.2)	0.1
Post op visit Week 2	−0.3 (−3.5, 2.9)	0.86	1.0 (−2.5, 4.4)	0.58
3 months	**7.7 (4.8, 10.5)**	<0.0001	**9.8 (6.8, 12.8)**	<0.0001
6 months	**8.0 (4.0, 12.0)**	<0.0001	**10.1 (5.8, 14.3)**	<0.0001
9 months	**9.7 (6.1, 13.2)**	<0.0001	**9.4 (5.7, 13.1)**	<0.0001
12 months	**10.1 (6.6, 13.4)**	<0.0001	**9.5 (5.8, 13.1)**	<0.0001
12 mm				
Post op visit Week 1	1.2 (−3.8, 6.2)	0.63	9.5 (−0.4, 19.4)	0.06
Post op visit Week 2	−3.4 (−8.9, 2.1)	0.23	4.1 (−6.6, 14.8)	0.45
3 months	−3.0 (−8.0, 1.9)	0.23	4.0 (−5.9, 13.9)	0.43
6 months	8.3 (0.1, 16.6)	0.048	**21.8 (6.1, 37.4)**	0.006
9 months	−8.5 (−16.7, −0.3)	0.042	−3.3 (−18.9, 12.4)	0.68
12 months	−3.9 (−10.0, 2.2)	0.21	10.8 (−1.4, 22.9)	0.08
All abutments				
Post op visit Week 1	−0.21 (−2.55, 2.14)	0.86	1.05 (−1.42, 3.52)	0.40
Post op visit Week 2	0.04 (−2.75, 2.83)	0.98	0.66 (−2.72, 3.60)	0.66
3 months	**6.51 (4.03, 8.99)**	<0.0001	**8.42 (5.80, 11.04)**	<0.0001
6 months	**6.85 (3.20, 10.49)**	<0.0001	**8.66 (4.82, 12.50)**	<0.0001
9 months	**8.82 (5.83, 11.82)**	<0.0001	**8.20 (5.08, 11.32)**	<0.0001
12 months	**9.03 (6.12, 11.95)**	<0.0001	**8.43 (5.36, 11.50)**	<0.0001

Statistically significant results are in bold. ISQ indicates implant stability quotient.

centre's experience with the Cochlear BIA300 implant demonstrated a significant 77% skin reaction rate and 35% revision rate. However, it is important to consider that dermatome was applied in 57% of patients in the BAI300 study, a practice that was phased out when the Oticon wide system was introduced (29). Taken together, the present study therefore demonstrates significant improvement in the implant loss and revision surgery rates, as well as comparable soft tissue complications, compared with previous implant systems utilized at our center.

Another important factor to consider is the continued use of BAHIs as this is an excellent indication of real-world application of hearing aids. If patients or carers found skin complications intrusive, they would discontinue their use. Our previous reports have shown that 97% were wearing the system daily with audiological benefit (27). Although the present study concerns a 12-month follow-up, at the time of submission, we have had a 99.1% retention rate as of January 2021 (2–5 years follow up). The one nonuser was influenced by peer pressure and esthetics.

The implant ISQ showed a nonsignificant increase between the first and second stages and an upward trend in the mean abutment level ISQ H and ISQ L, with statistical significance achieved from the 3-month review point onwards. Application of the ISQ is controversial, and previous publications support early loading in the pediatric population with ISQs above 60 and, similarly, in the adult population (10–12). Nelissen et al. (25) suggest that conclusions cannot be drawn regarding individual ISQ values alone but rather that trends can be followed but only in individuals or groups in which variables remain the same, as implant systems vary widely in their designs. Hence, the application of absolute ISQ figures from one model of implant to another should be done with caution. Nevertheless, preclinical comparison of laser-modified BHX implants with machined implants failed to capture any difference in stability between the two implant types in terms of ISQ, despite a significantly higher removal torque required for the BHX implant, underscoring the limitations of the ISQ measurement to distinguish the degree of osseointegration (22).

TABLE 4. *ISQ and Holgers scores for each failed implant*

	P1	P2	P3	P4	P5
Age	4	7	5	15	9
Sex	F	F	M	F	F
BMI Centile	18.6	26.2	35	18.5	15.4
Implant size	3	3	3	3	4
Abutment size	9	9	9	6	9
Surgery 1					
Fixture					
ISQH	70	77	81	80	77
ISQL	70	67	80	71	56
Surgery 2					
Fixture					
ISQH	80	66	IL	80	77
ISQL	56	66	–	71	56
Abutment					
ISQ H	39	46	–	48	35
ISQ L	39	44	–	38	34
1 week post					
ISQ H	44	36	–	x	37
ISQ L	40	36	–	x	37
Holgers	0	2	–	x	0
2 weeks post					
ISQ H	67	x	–	x	x
ISQ L	60	x	–	x	x
Holgers	2	x	–	x	x
3 months					
ISQ H	40	IL	–	61	IL
ISQ L	40	–	–	59	–
Holgers	3	–	–	0	–
6 months	IL	–	–	IL	–

IL indicates implant loss; ISQ, implant stability quotient; x, missing data.

A limitation in the present study is the small sample size in both the 12-mm abutment and fixture failure groups. Each group lacks significant statistical power to identify trends with regards to ISQ levels. Due to the wide range of indications for surgery and physical and psychological comorbidities of the recipients in our study cohort, comparisons with other published literature should be done with caution. The variation in surgical technique is also considered a limitation although the patient demographics, postoperative protocol, and routine follow-ups were identical for the three groups. In addition, the impact of missing reviews should be considered when interpreting the results of this study. Explanations reside in the exceptionally large geographic area from which many patients are referred. Time away from school, organization of care for siblings, and the additional challenges to attend contributed to the missing data. The added burden of additional reviews was considered a further inconvenience, especially when parents and carers had no concerns regarding the implant site or hearing following abutment placement. This was confirmed with telephone consultations when investigating missing appointments.

It is concluded that the use of laser-ablated titanium implant for BAHIs in a large pediatric cohort resulted in superior survival rates and excellent clinical outcomes compared with previous implant systems utilized at BCH. Although absolute figures for the abutment-level ISQ increased over time, statistical significance was only demonstrated at 3 months. The absolute ISQ data did not provide an indication of probable fixture failure.

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