Misfit and Functional Loading of Craniofacial Implants

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Purpose: This study sought to develop an understanding of the magnitude and types of loads generated on craniofacial implants supporting an auricular prosthesis. ***Materials and Methods:*** Strain gauges were used to measure the in vitro and in vivo misfit loads generated when connecting auricular-style superstructures to implants and the in vivo functional load generated during the removal and insertion of the auricular prostheses. In addition, the vertical misfit of the 11 custom-built two-implant superstructures used in the in vitro study was measured. ***Results:*** Superstructures used in the in vitro study that were considered clinically passive still had considerable preloads. In addition, the calibrated loads, which would result from the vertical misfit alone, did not account for the magnitude of the generated preloads. ***Conclusion:*** The clinical definition of misfit based on vertical distortion of the superstructure did not quantify the resulting misfit load. Measured in vivo functional loads were smaller than the misfit loads. *Int J Prosthodont 2004;17:267–273.*

While the failure rates in extraoral implants are low, the cause of these losses remains unexplained.[1,2] The health of the bone-implant interface is thought to be dependent on several factors; however, high on the list of these suspected factors is the effect of loading.

The theories relating to mechanical loading and bone adaptation are based on the strain in the bone, not the load in the implant.[3] There is a general understanding that a certain level of strain is required for normal bone remodeling; this has led to the study of mechanical loading on implants. For prostheses supported by multiple implants, the two main types of loads transferred to the bone are preloads generated by any misalignment present when the prosthetic superstructure is connected to the implants, and any functional loads generated during use.

While there have been both in vitro and in vivo studies to determine loading on oral implants,[4,5] little work has been done on the loading of craniofacial implants. Del Valle[6] measured the removal forces of various mechanical retention devices in vitro and developed a finite element model to investigate the strains developed in the bone surrounding extraoral implants. Some preliminary work on measuring in vivo functional loading on craniofacial implants used to support auricular prostheses has identified attachment and removal of the prostheses as the only significant functional loads.[7]

The preloads on implants are a result of connecting a misfitting superstructure to the abutment-implant system. As there is essentially no completely passive (perfect) fit, this effectively results in all superstructures having some degree of preload. Several clinical methods have been developed to determine so-called passive fit. Two of these methods are the one-screw test and the screw resistance test.[8] In the one-screw test, the superstructure is placed on the abutments, and one of the screws is tightened at one of the abutments while the vertical gaps between the superstructure and the other abutments is observed. The

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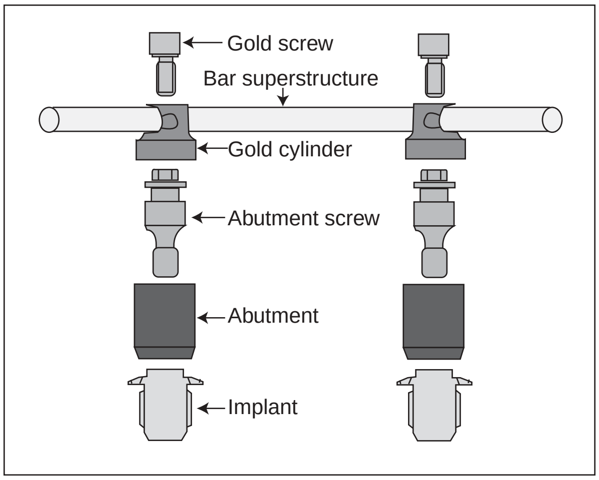


Fig 1 Two-implant bar-and-clip system used in both in vitro and in vivo studies.

Table 1 Superstructure Construction Techniques

Sample No.	Flame type	Preheating	Gold screw tightening
C1 C2	Natural gas	None	Hand tightened
C3 C4 E1	Propane	500°C for 1 h	Torqued to 10 Ncm
C5 C6	Laser welded	None	Hand tightened
C7 C8	Natural gas	None in oven; flame used for 15 min	Hand tightened
C9 C10	Oxyacetylene	350°C for 1 h	Torqued to 10 Ncm

C = centric; E = eccentric.

screw resistance test is performed by tightening each of the gold screws until the first resistance is encountered. The screw is then tightened a further half turn (180 degrees). If more than half a turn is required to fully seat the superstructure on the abutments, it is considered to have a poor fit. Half a turn corresponds to 150 μm of vertical misfit, which is half the pitch of a currently used gold screw. To understand what these misfits represent in terms of preloads, Smedberg et al[5] introduced predefined misfits of 100 μm, which resulted in preloads of 200 N on the implants. Jemt[9] measured the three-dimensional misfit of gold-alloy castings and two different welded titanium frameworks. In that study, all of the castings and frameworks were deemed to have a clinically acceptable fit, and the maximum vertical misfit was about 100 μm. In addition, the misfits were comparable for both the castings and titanium frameworks, although there were greater variations in misfit for the castings and older titanium framework design.

The purpose of the present work was to develop a better understanding of the magnitude and distribution of loads applied to craniofacial osseointegrated implants measured both in vivo and in vitro. For comparison, in the in vivo situation, the functional loads applied to the bar superstructure were also measured. The in vitro study evaluated different superstructure constructions made from the same template at five laboratories. The hypothesis was that current clinical techniques to measure misalignment of superstructures are not well correlated to the actual loads these superstructures apply to implants.

Materials and Methods

Superstructure Construction

Both the in vitro and in vivo studies used a two-implant bar-and-clip system (Fig 1). This system consisted of two 4-mm flanged implants (SEC 002, Entific Medical Systems), two 5.5-mm standard abutments and abutment screws (SEC 007, Entific Medical Systems), and a three-segment bar (CM-52028, Vident) attached to the 4-mm gold cylinders (DCA 072, Entific Medical Systems), which, in turn, were attached using two hexagon-head gold screws (DCA 074, Entific Medical Systems).

The in vitro testing used a 10-mm-thick 100 mm × 100 mm square acrylic resin test base that contained two extraoral implants cemented into place, with 5.5-mm abutments connected and cemented to the implants. To ensure that the same bar-superstructure geometry was produced, the same test base and superstructure materials were sent to five separate centers: COMPRU (Craniofacial Osseointegration Maxillofacial Prosthetic Rehabilitation Unit) in Edmonton, Canada; Morriston Hospital in Swansea, Wales, United Kingdom; Queen Elizabeth Hospital in Birmingham, England, United Kingdom; Institut für Epithesen in Siegen, Germany; and Sahlgrens Hospital in Göteborg, Sweden. Each center used its typical solder or laser construction method (Table 1) to create two bar superstructures to fit the implant configuration provided (Fig 2). One center also constructed an eccentric superstructure in which the bar was continuous and attached to the edge of the cylinders. This resulted in the construction of 11 superstructures that were subsequently tested.

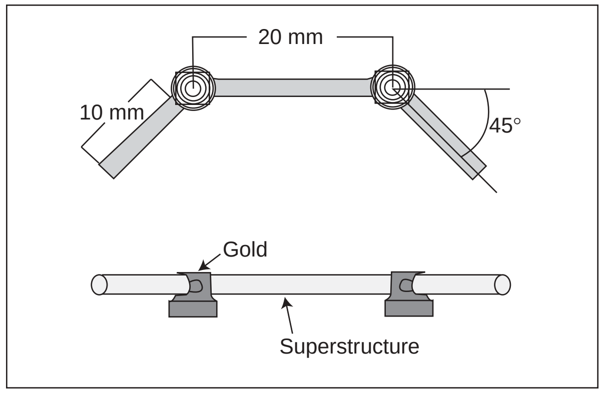
The in vivo study was done at COMPRU and included four patients who had auricular prostheses. The patients were all adults (two men and two women) and had had their prostheses for a mean of 7 years (range 3 years 10 months to 9 years 2 months) at the time of testing. The details of their superstructures are shown in Fig 3.

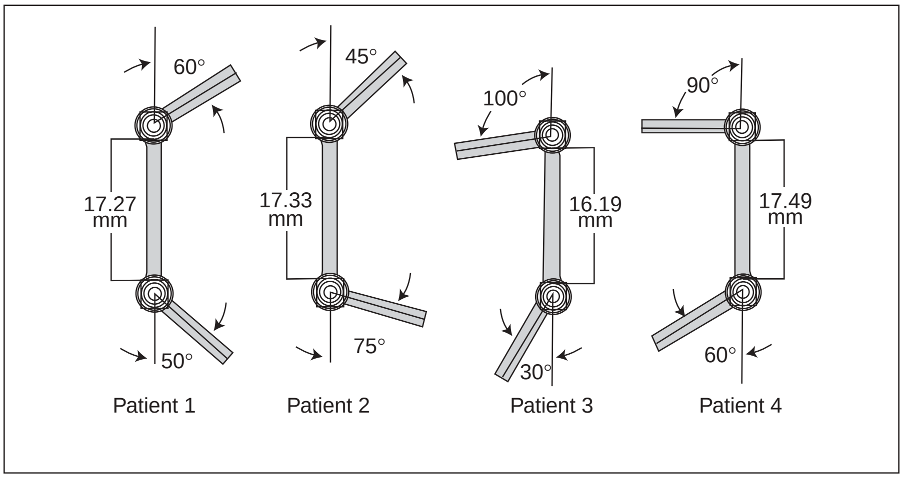
Misalignment Measurements (In Vitro)

The in vitro misalignment measurements of the superstructure were done using a cathetometer (Griffin and

Fig 2 *(right)* Each center used its typical solder or laser construction method to create two bar superstructures to fit the implant configuration provided.

Fig 3 *(below)* Details of patient superstructures used for in vivo study.





George) with a specified accuracy of ± 10 µm. The procedure used to test for misalignment mimicked the one-screw test.[8] The two abutments were attached to the test base by the abutment screws, tightened to 20 Ncm. All screw tightening was done using a Brånemark system torque controller (DEA 020, Entific Medical Systems). The test base was then positioned such that the front of the superstructure faced the cathetometer. The superstructure was positioned on the abutments, and the first gold screw was tightened to 10 Ncm. The resultant vertical gap between the second abutment and its corresponding gold cylinder was measured (Fig 4). This was repeated three times; the procedure was then reversed, with the second gold screw first tightened and the misalignment measured on the other one. The test base was then turned so the cathetometer faced the rear of the superstructure, and the procedure was repeated.

Misalignment Force Measurement Technique

While the displacement misfits could be readily measured in vitro, this was not possible in vivo. To measure the forces, the abutments that were attached to the test base had strain gauges mounted on the lateral surface. (These abutments will be referred to as the study abutments.) The study abutments were used for both the in vitro and in vivo tests. Before each in vivo test, they were disinfected using glutaraldehyde according to accepted sterilization procedures.

Three Micro-Measurements precision strain gauges (EA-06-015EH-120, Measurements Group) were mounted with their sensitive axes along the axis of each of the cylinders, at 120 degrees to one another around the periphery. The gauges were placed in the region of the abutment where the cross-sectional area was constant. Each strain gauge was connected and monitored by a Hewlett-Packard E1413A Data Acquisition System (Instrument Systems). This system allowed both static and dynamic measurements to be taken from each of the six gauges simultaneously.

The gauges on the study abutments were calibrated using a method similar to that used by Glantz et al.[4] A single abutment was mounted in a base plate to which known forces and moments were applied using a calibration disk. A multiple regression was completed for each strain gauge to determine the moment and axial calibration.

Misalignment Preload Testing

To calculate the misalignment (misfit) loads, two loading situations were measured: the reference load and the resultant load. The reference load was the load generated in

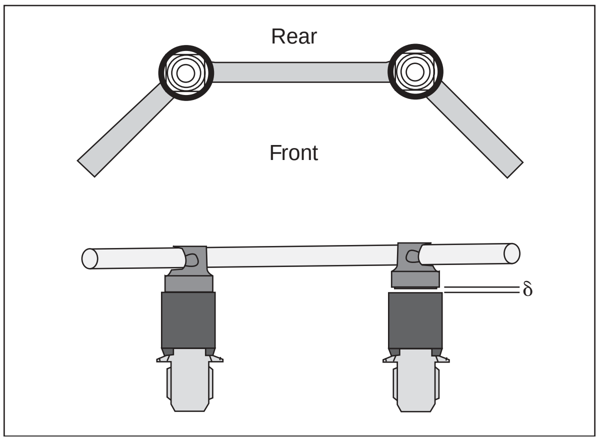


Fig 4 Setup for in vitro misalignment measurements. Vertical gap between second abutment and corresponding gold cylinder is measured.

the abutment caused solely by the fastening (using a 10-Ncm torque) of the gold cylinder via the gold screw. This was done by turning the superstructure so that only one of the gold cylinders was in place and the superstructure was supported by one of the abutments. The resultant load was the load generated in the abutment when the superstructure was completely fastened into place using a 10-Ncm torque on both screws. The misfit load was the difference between the resultant and reference loads.

Four sets of measurements were taken for each superstructure, including a reference set for each of the two abutments and a set of resultant measurements for each of the two possible tightening sequences (tightening first one and then the other gold cylinder, then reversing the order, denoted, respectively, as T1T2 and T2T1). The latter sequence was carried out to determine if the tightening sequence influenced the misfit loads.

For the in vitro testing, the reference load was measured immediately after tightening the gold screw on the first abutment to 10 Ncm and again 1 minute later. The screw was loosened and the process was repeated 10 times, which gave 20 measurements for the one abutment. A similar procedure was used for the second abutment, as well as for the two tightening sequences that used both screws.

For the in vivo tests, the patient's prosthesis and superstructure were removed. The patient's abutments were removed and replaced with the study abutments. The patient's superstructure was first evaluated visually for misfit using the one-screw test. Reference and resultant loads were measured as indicated; however, because of time constraints with each patient only four trials instead of ten were done for the reference load, and three trials instead of ten were done for the resultant load measurements. The resultant load was measured with both abutments attached to the implants.

Functional Load Testing (In Vivo)

After completion of each of the in vivo preload tests, dynamic measurements of the additional loads applied when attaching or removing a prosthesis were done. For attachment, the three prosthesis clips were aligned with the bars, and the strain gauges were continuously monitored as the prosthesis was attached.

For removal of the prosthesis, three techniques were used to measure the largest loads. In the first, the prosthesis was simply pulled, with essentially all three clips being removed simultaneously. For the second technique, the prosthesis was removed by lifting from the extreme end. The third technique used a combination of pulling and twisting. This was repeated four times. After completing the functional load testing, the patient's abutments, superstructure, and prosthesis were reinserted.

Results

In Vitro Measurements

The mean vertical misfit for the 10 concentric superstructures was 90 µm (standard deviation [SD] 50) and ranged from 10 to 210 µm. The lone eccentric superstructure had a vertical misfit of 120 to 290 µm (Table 2). The laser-welded superstructures (C5 and C6) had comparable misfits to the soldered superstructures, whereas the eccentric superstructure had the largest vertical misfit. The mean reference load was –290 N (SD 41), with a range of –218 to –383 N. Excluding C2, reference bending moments had a mean of 12 Ncm (SD 7) and ranged from 8 to 31 Ncm. Superstructure C2 had soldering material on the lip of the gold cylinder that resulted in an improper fit with the abutment.

The resultant loads had a large variation (–143 to –413 N), and there was a significant difference between the tightening sequences for nine of the eleven superstructures. Misfit loads (resultant – reference) ranged from –78 to 117 N. The misfit loads and measured vertical misalignment distances showed little correlation (Fig 5). However, treating the bar between the two abutments as a cantilever beam, the theoretic load required to close the mean gap measured (between front and rear) between the abutment and gold screw was on the same order of magnitude as the experimental results. Note that because of the variations in construction three effective lengths of the cantilever were used for comparison.

In Vivo Measurements

For each of the four patients' superstructures (Fig 3), a qualitative assessment of misfit was undertaken using the one-screw test, and all four superstructures were judged

Table 2 Vertical Misfit Measurements (µm)*

Superstructure	Vertical opening between gold cylinder 1 and abutment 1 Front	Rear	Vertical opening between gold cylinder 2 and abutment 2 Front	Rear	Passive/ nonpassive
C1	210	40	120	30	Nonpassive
C2	70	40	110	40	Passive
C3	30	20	70	50	Passive
C4	30	190	80	70	Nonpassive
C5	120	100	130	130	Passive
C6	50	20	170	150	Nonpassive
C7	50	40	160	120	Nonpassive
C8	10	40	100	30	Passive
C9	190	120	120	100	Nonpassive
C10	40	40	140	90	Passive
E1	140	120	290	250	Nonpassive

*Mean of three measurements; the standard deviation was less than 10 µm for each measurement.
C = centric; E = eccentric.

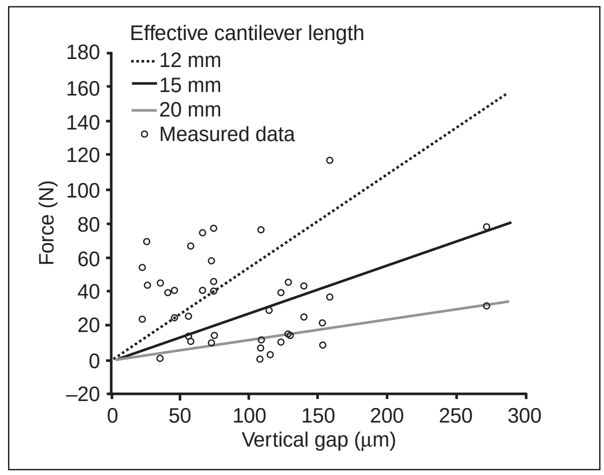
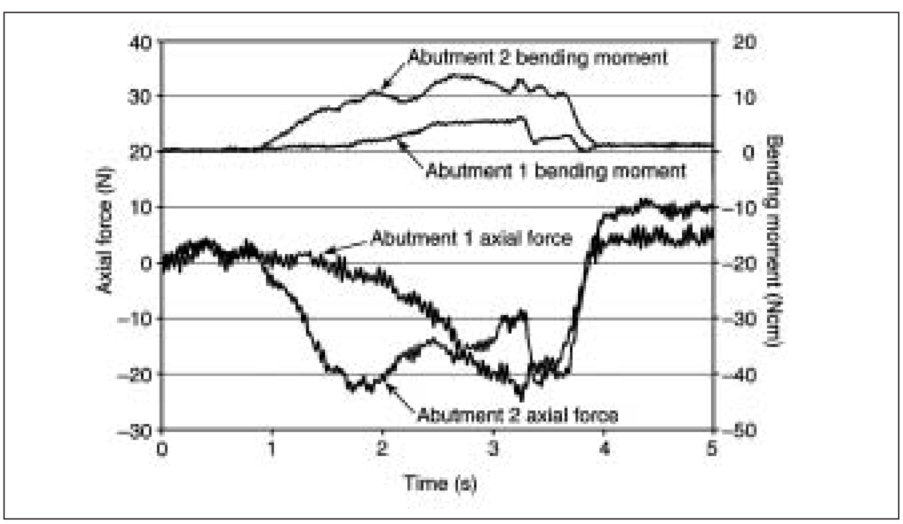


Fig 5 *(right)* Theoretic results for the three effective cantilever lengths: Misfit loads and measured vertical misalignment show little correlation.

Fig 6 *(below)* Typical record of additional load and moment measured during attachment of the prostheses.



to have a clinically acceptable fit. The reference axial forces had a mean of –373 N (SD 81). Again, the bending moments were relatively low. The misfit loads ranged from 129 to –72 N, and the tightening sequences were significantly different for three of the four patients.

A typical record of the additional load and moment measured during attachment of the prostheses is shown in Fig 6. The results from each test were variable, but the attachment functional loads and moments on the two abutments ranged from –26 to 51 N and 3 to 37 Ncm,

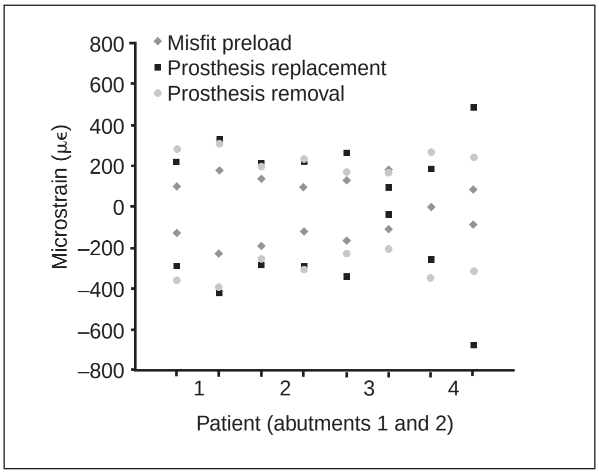


Fig 7 In vivo misfit and functional loading are compared by estimating the maximum strain that would be developed in the supporting tissues for each of the four patients under the loading they experienced.

respectively. The removal functional loads had a range of –14 to 30 N and 3 to 21 Ncm, respectively.

Figure 7 is included as a means of comparing in vivo misfit and functional loading. This was done by estimating the maximum strain that would be developed in the supporting tissues for each of the four patients under the loading they experienced. The misfit loads generated strains of between 200 and –200 με; however, when the functional loads were superimposed on the preloads, the resulting strains ranged between 200 and 600 με and –200 and –600 με.

Discussion

The measured in vitro reference loads were comparable to the expected value of –250 to –300 N generated when the gold cylinder is attached to an abutment by tightening a gold screw with 10 Ncm.[10] It should be noted that the reference loads are not transferred to the supporting tissue, but simply represent preloading of the abutment (compression) and abutment screw (tension). While the resultant loads were also in the –250 to –300 N range, suggesting that on average the fits were relatively passive, individually the misfit loads (resultant – reference load) were considerable.

For the in vitro vertical misfit measurements, it is noteworthy that if 150 μm is used as the criterion for clinically acceptable vertical misfit, one of each of the two superstructures constructed at each of the five locations was below and the other was above the limit. However, it must be mentioned that this simple criterion does not account for any other type of misfit that could actually create more loading of the implants. In one study,[9] the measured horizontal gaps were larger than the vertical gaps for the five-implant prostheses. In the present study, the differences between the front vertical misfit and the back vertical misfit were often large, suggesting that the misfit would be one with a considerable amount of rotation about the longitudinal axis of the bar. No measurement of the vertical misfit was made at either of the sides next to the attachment points of the bars. These side measurements may also have been different and contributed to a rotational misfit.

Some of the superstructures that were judged to be passive had higher misfit loads and moments than those judged to be nonpassive. This was again probably due to the fact that the misalignment was not simply a vertical gap, but was vertical and horizontal with rotational misfit as well. While all these misfits were not measured, when compared to the theoretic force required to close the gap, the experimental axial loads were larger but of the same order of magnitude. Furthermore, while the distance between the centers of the two abutments was 20 mm, the actual length of the bar was approximately 15.5 mm. In addition, the solder joints could actually reduce the effective length to approximately 12 mm. Consequently, the effective length of the "cantilever beam" could be different between different superstructures. The theoretic results for each of these three effective lengths (20, 15, and 12 mm) are shown in Fig 5.

Similar to the in vitro study, the in vivo reference and resultant measurements were comparable to the expected range of –250 to –300 N, suggesting a passive fit. There were, however, significant moments generated by the connection of the two abutments for some of the patients. These moments, although significantly different, were still not large. The measured functional loads were comparable to the removal loads measured by del Valle[6] but lower than the misfit or functional occlusal loads (45 to 255 N).[11]

As mentioned, it is generally believed that the level of strain in the bone initiates bone modeling/remodeling. One of the most often cited theories, Frost's mechanostat theory,[3] attempts to relate the response of load-bearing bone to various levels of strain. In that theory, strains from 100 to 300 με represent the minimum effective strain for bone remodeling—the normal turnover of healthy bone. Strain below this level would result in bone loss or resorption. For bone modeling or the formation of new bone, strains in the 1,500 to 2,500 με range are necessary, whereas bone fracture occurs above 25,000 με. However, it should be noted that these values are for normally loaded long bones, not for craniofacial bones containing implants. In the case of late failure of craniofacial osseointegrated implants in nonirradiated bone, the remodeling rate may be impeded and cannot sustain this strain history generated through the loads and strains identified. In addition, craniofacial bones into which implants are to be placed may have been compromised by the administration of radiation therapy. Comparison of the strains for misfit and functional loads (Fig 7) indicated that the resulting strains were in the equilibrium region based on Frost's mechanostat theory.[3]

Conclusions

The results of the in vitro study indicate:

- The vertical misfit alone did not account for the magnitude of misfit loads.
- The estimated strains generated by the misfit loads were well within the normal bone remodeling range.

The results of the in vivo testing indicate:

- The preloads that existed were relatively small.
- The functional loads generated on the implants were smaller than the preloads and resulted in approximate strain values within the normal bone remodeling range.

Acknowledgments

The authors would like to thank the five centers involved in the study: COMPRU (Craniofacial Osseointegration Maxillofacial Prosthetic Rehabilitation Unit) in Edmonton, Alberta, Canada; Morriston Hospital in Swansea, Wales, United Kingdom; Queen Elizabeth Hospital in Birmingham, England, United Kingdom; Institut für Epithesen in Siegen, Germany; and Sahlgrens Hospital in Göteborg, Sweden. We also thank the clinical staff at COMPRU for their help with the in vivo portion of the study, and Entific Medical Systems, Göteborg, for their contributions to the in vitro portion of the study.

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