Removal Torque Values of Titanium Implants in the Maxilla of Miniature Pigs

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The purpose of this study was to compare side-by-side two different titanium screw-type implants in the maxillae of miniature pigs. The test implants had a machined and acid-etched surface (Osseotite) whereas the control implants were sandblasted and acid-etched (SLA). After 4, 8, and 12 weeks of healing, removal torque testing was performed to evaluate the shear strength of the bone-implant interface for both implant types. The results demonstrated significant differences between both implant types ($P < .01$). Osseotite implants revealed mean removal torque values (RTV) of 62.5 Ncm at 4 weeks, 87.6 Ncm at 8 weeks, and 95.7 Ncm at 12 weeks of healing. In contrast, the SLA implants demonstrated mean RTV of 109.6 Ncm, 196.7 Ncm, and 186.8 Ncm at corresponding healing periods. The mean RTV for SLA implants was 75% to 125% higher than for Osseotite implants up to 3 months of healing.

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Key words: interface shear strength, removal torque values, Osseotite surface, sandblasted and acid-etched surface, SLA surface, titanium implants

Over the past 30 years, the use of osseointegrated implants has become a scientifically accepted and well-documented treatment modality for the rehabilitation of completely and partially edentulous patients. This development is based on fundamental studies by the research teams of Brånemark et al[1,2] and Schroeder et al[3–5] of commercially pure (CP) titanium implants. Successful long-term stability of osseointegrated implants was reported in clinical studies using CP titanium implants.[6–14] Other clinical studies, however, reported increased failure rates in areas with low bone density or reduced bone height, such as in the posterior maxilla, especially for screw-type implants with a machined surface.[15–18] Therefore, attempts have been made over the past 12 years to improve bone anchorage of dental implants. Thomas and Cook[19] examined the variables that could potentially influence implant anchorage in bone. Of 12 parameters examined, only the implant surface had a significant effect on bone integration. This observation has been confirmed over the past 10 years in a series of in vivo studies evaluating different surface configurations of titanium implants both in the long bones and in the jaws.[20–23] Among the tested surfaces, a new sandblasted and acid-etched surface (SLA) consistently showed the best results both in histometric and biomechanical testing. A recent removal torque study by Buser et al[24] in the maxillae of miniature pigs compared this SLA surface with the two best-documented titanium surfaces in implant dentistry, the machined and the titanium plasma-sprayed (TPS) surface. The study confirmed that the

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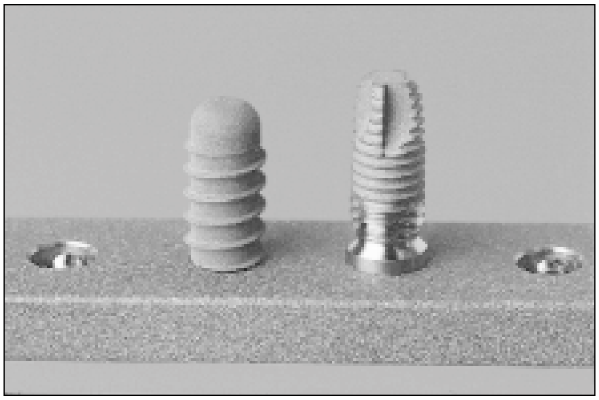

Fig 1 The two tested titanium implants: the 8-mm-long SLA implant without apical grooves, and the 10-mm-long Osseotite implant with four apical grooves.

machined surface had 8 to 10 times lower removal torque values (RTV) when compared with the two rough surfaces, and that the SLA surface showed higher RTV than the TPS surface (without reaching statistical significance) during initial healing of 4 weeks. At 8 and 12 weeks, both surfaces showed similar values.

In 1996, another acid-etched titanium surface was introduced to the implant market under the brand name Osseotite. When introduced, the dearth of scientific documentation on this surface provoked critical remarks by Taylor[25] in an editorial in *The International Journal of Oral & Maxillofacial Implants*. Recently, an animal study published by Klokkevold et al[26] compared an acid-etched surface with a machined titanium surface in a removal torque test. The study demonstrated significantly better results for the acid-etched surface. As of today, however, no data are available on how this acid-etched surface compares with other rough titanium surfaces that have been used in implant patients for many years.

The purpose of this study was to compare the surface of this new implant (Osseotite) with the sandblasted and acid-etched surface of the scientifically well-documented SLA implant in a side-by-side analysis in the maxillae of miniature pigs by measuring removal torque values after 4, 8, and 12 weeks of healing.

Materials and Methods

Approval for Animal Research. The protocol for the animal study was approved by the standing committee on Animal Research at the University Hospital, Medical Faculty, University of Berne, Switzerland, and by the Committee for Animal Research, State of Berne (approval no. 97/04). The State of Berne guidelines for the care and use of laboratory animals were followed.

Implant Shapes and Surfaces. Two different CP titanium screw-type implants with different shapes and surfaces were placed in edentulous areas of the anterior maxillae of miniature pigs. Both implant types are used clinically in patients (Fig 1). For the test implant, a standard, 3.75-mm, self-cutting, screw-type implant with a length of 10 mm and four grooves in the apical portion was used. This implant has a standard hex on top and is characterized by a hybrid design, a short, approximately 2- to 3-mm-long machined surface in the crestal area, and an acid-etched (sulfuric acid–hydrochloric acid) surface overall (Osseotite, Implant Innovations, Palm Beach Gardens, FL). For the control group, an 8-mm-long solid-screw implant (4.05 mm diameter), characterized by a sandblasted (large grit of 250 to 500 µm) and acid-etched (sulfuric acid–hydrochloric acid) (SLA) surface (Institut Straumann, Waldenburg, Switzerland). This implant shape, which has been commercially available for more than 10 years with a TPS surface, has no macroscopic retentive elements such as vents or grooves in the apical portion, but has a square top to allow for proper removal torque testing.

The surface characteristics of both implants were examined qualitatively by scanning electron microscopy. To determine the profile quantitatively, an additional profilometric analysis was performed using a Form Talysurf Series-2 laser interferometric system (Rank Taylor Hobson, Leicester, UK) equipped with a custom-made 0.6-µm-diameter diamond stylus. For both implant types, two samples were scanned along the circumference in three or four different areas over a length of 2 mm. Thirty-one different amplitude, spacing, and hybrid parameters were calculated from the profile data. Average roughness R_a and the mean spacing of adjacent local peaks S were selected as the variables to best describe the surface characteristics.

R_a is a universally recognized and widely used parameter to describe roughness. It is the arithmetic mean of the departures of the roughness profile from the mean line, and is calculated as:

$$R_a = \frac{1}{L}\int_0^L \left|y(x)\right| dx$$

where L is the assessment length and y(x) is the profile amplitude. S is the mean spacing of adjacent local peaks, and is calculated as:

$$S = \frac{1}{N}\sum_{i=1}^{n} s_i = \frac{S_1 + S_2 + \ldots + S_n}{n}$$

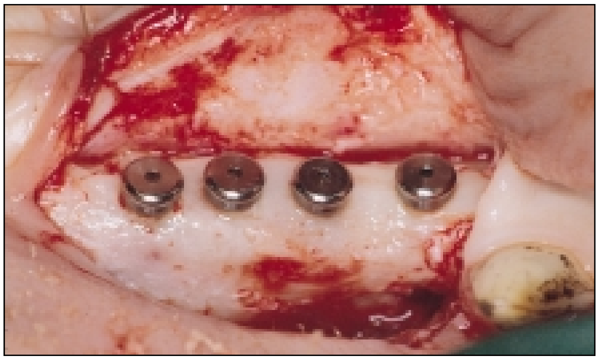

Fig 2a Self-cutting Osseotite implants served as the test implants in this split-mouth study design.

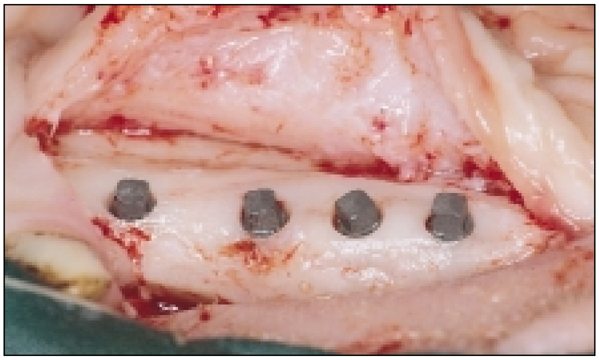

Fig 2b SLA implants were pretapped into place in the contralateral side and served as controls.

where n is the number of spacings over the assessment length and S_i is the spacing between the local peaks. A local peak is the highest part of the profile measured between two adjacent minima.

Surgical Procedures. A total of nine adult miniature pigs with a minimum age of 2 years were used in the study. In each animal, two surgical interventions were performed. First, the anterior teeth in the maxilla were removed under general anesthesia using extended mucoperiosteal flaps to provide sufficient access to the alveolar crest containing the teeth to be removed (Surgical Research Unit ESI and Clinic for Large Animals, University of Berne). Prior to surgery, the animals were given 1 g of prophylactic amoxicillin intramuscularly. Following tooth removal, the elevated flaps were repositioned and closed with interrupted sutures. Second, after a healing period of at least 6 months, 6 to 8 implants were placed in each animal. Six implants were scheduled for biomechanical evaluation with removal torque testing, and one implant per side was scheduled for histologic analysis. If the anatomic situation allowed, this implant was always located closest distally to the canine. In all, 70 implants were placed, 54 of which were intended for biomechanical testing. The recipient sites in the created edentulous areas of the maxilla were exposed by elevation of buccal mucoperiosteal flaps. When necessary, the alveolar crest was flattened to allow precise preparation of the implant recipient sites. The sites were prepared under copious irrigation with sterile physiologic saline using standard commercially available drills for both implant types. For the SLA implants, the thread was pretapped into the bone cavity, while the Osseotite implants were self-cutting, as recommended by the manufacturer. A split-mouth design, using one side for the test and the contralateral side for the control implants (Figs 2a and 2b), was employed. Following application of healing caps for Osseotite implants, primary wound closure was achieved with resorbable sutures.

Removal Torque Testing of the Bone-Implant Interface. The miniature pigs were sacrificed after healing periods of 4, 8, or 12 weeks. Each subgroup consisted of three miniature pigs, each with six implants for biomechanical testing. Immediately after sacrifice, the soft tissues in the edentulous areas of the maxilla were removed to expose the integrated implants. Subsequently, the maxilla was excised and the left and right halves were isolated with a diamond-plated saw (Makro Trennsystem, Exakt Apparatebau AG, Norderstedt, Germany). To improve further handling and for temperature isolation, each of the samples was molded into dental cement (Kerr Suprastone Green, Kerr Europe AG, Basel, Switzerland).

The removal torque testing was performed on a biaxial servohydraulic materials-testing machine (MTS Minibionix 358.02, MTS Systems, Minneapolis, MN). To apply pure axial moments in the test, the axis of the implant to be tested had to correspond exactly with the axis of the testing machine. For this reason, the implant was first attached to the actuator, thereby guaranteeing the implant-actuator alignment. The implant-bone–dental cement complex was lowered into a tub on the rigid part of the machine, which was then filled with low melting temperature metal alloy (Legierung 47 Grad, Billiton Witmetaal BV, Naarden, Netherlands). The cooling of the alloy effectively fixed the implant-bone–dental cement complex to the machine (Figs 3a and 3b). To allow for proper removal torque testing, a commercially available insertion device for screw-type implants with a standard hex (Nobel Biocare, Lucerne, Switzerland) was used for Osseotite implants, which fit precisely onto the hex. For SLA implants, a specially manufactured adapter with a square shape that fit precisely onto the head of SLA implants was used.

Fig 3a One specimen with three implants is embedded in dental cement and attached to the actuator, guaranteeing a perfect implant-actuator alignment. The implant-bone–dental cement complex is now affixed to the tub by filling in low temperature melting metal alloy.

Fig 3b The entire setup for removal torque testing, using the MTS servohydraulic materials testing machine, the affixed implant-bone–dental cement complex attached to the actuator, and the PC.

The removal torque test was performed by applying a counterclockwise rotation to the implant axis at a rate of 0.1 degree/second. The resulting torques were measured by an axial-torsional load transducer (MTS 662.20D-04, MTS Systems).

After testing of one implant was completed, the alloy was melted to remove the implant-bone–dental cement complex from the fitting tub. The next implant was secured to the actuator, and the entire process was repeated until all implants were tested. To avoid drying of the bone, the specimens were sprayed with saline solution every 15 minutes. For each implant, the torque-rotation curve was recorded. To characterize the bone-implant interface, the removal torque was defined as the maximum torque on the curve.

Failure Torque Testing of Hex Connection of Osseotite Implants. Since the hex of Osseotite implants is rather short, and thus possibly not able to withstand the occurring shear stresses during removal torque testing of the bone-implant interface, the failure torque of the hex connection of four Osseotite implants inserted in dental cement was also tested in vitro. The same insertion device as was used for reverse torque testing was mounted onto the hex of the four individually embedded implants. Each single implant was precisely aligned to the long axis of the actuator as outlined above.

Statistical Analysis. Because of the small number of implants being tested, the assumption of normally distributed groups could not be made. A multifactor analysis of variance (ANOVA) could not be applied because of missing values in the test protocol. Therefore, simple nonparametric methods were used separately for each implant position. To investigate the influence of implant type, a sign test was used to calculate the differences between the paired variables at each implant position (position 1 being mesial, position 3 distal).

Results

Characterization of Both Surfaces. The scanning electron microscope (SEM) analysis (Figs 4a and 4b) revealed similar features for the two implant surfaces: both showed small micropits with a diameter of 1 to 2 µm produced by the acid-etching procedure. The Osseotite surface, however, seemed to have a flatter profile when compared with the SLA surface. This impression was confirmed by profilometric analysis (Figs 5a and 5b) since the SLA surface yielded higher values for average roughness (R_a = 2.0 µm) than the Osseotite surface (R_a = 1.3 µm). Concerning mean spacing of peaks, both implants demonstrated similar values (S = 12.0 µm for SLA versus 15.0 µm for Osseotite).

At sacrifice and following soft tissue removal, four implants, two of each implant type, demonstrated a penetration of their apical portion into the nasal cavity as a result of a reduced vertical bone height at this specific site and/or a misangled implant, thus reducing the extent of bone-anchoring surface for these four implants. Consequently, it was decided to exclude these implants from further analysis. The remaining 50 implants, which demonstrated firm anchorage in the maxilla, were used for removal torque measurements.

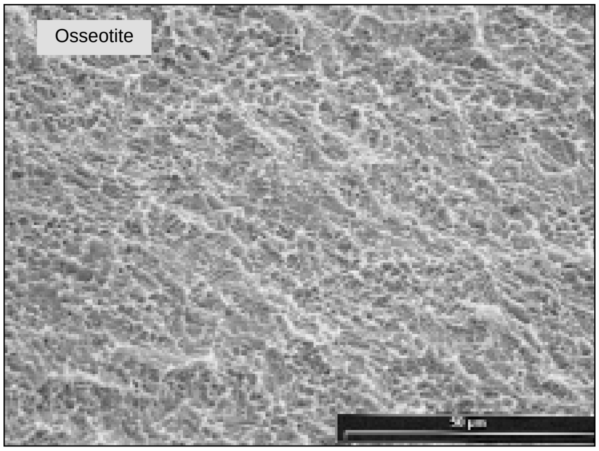

Fig 4a SEM analysis showing the Osseotite surface with micropits of 1 to 2 µm in diameter produced by the acid-etching procedure. Note that the Osseotite surface has a rather flat profile when compared to the SLA surface (original magnification × 620).

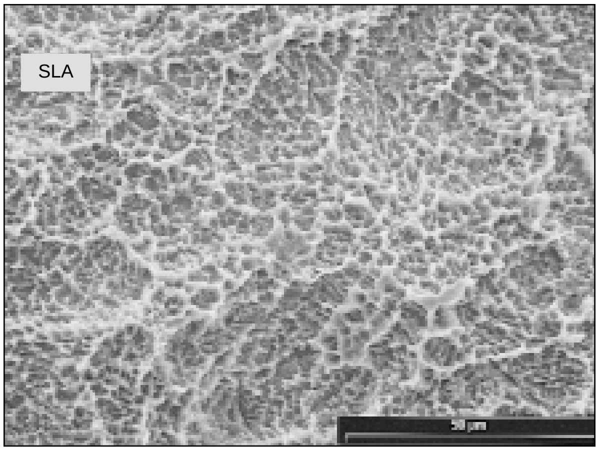

Fig 4b SEM analysis showing the SLA surface with a rough-blasted surface recognized as "valleys" and micropits of 1 to 2 µm in diameter produced by the acid-etching procedure (original magnification × 620).

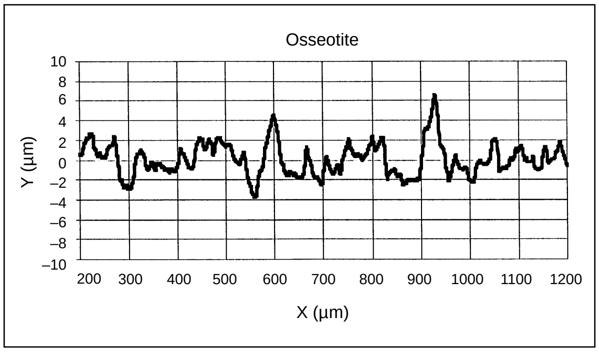

Fig 5a Profilometric analysis of the Osseotite surface. Values for average roughness were 1.3 µm, lower than those for the SLA surface.

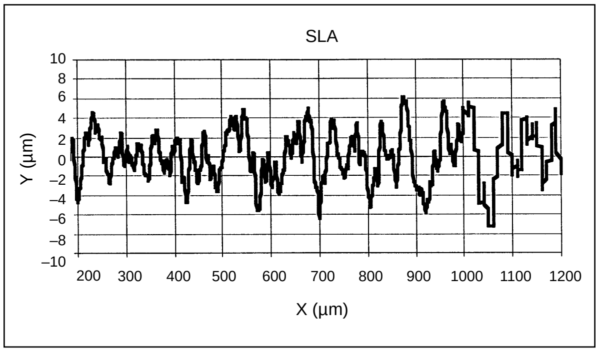

Fig 5b Profilometric analysis of the SLA surface. Values for average roughness were 2.0 µm.

The removal torque testing resulted in a typical curve for both implants, where its peak was assumed to be the failure (removal) torque of the bone-implant interface. The Osseotite implants showed a flatter curve without a clear reduction following failure torque after 12 to 18 degrees of counterclockwise rotation (Fig 6). In contrast, the curve for SLA implants demonstrated a higher slope to the maximum level at approximately 10 to 12 degrees of counterclockwise rotation, and a subsequent clear reduction following fracture at the bone-implant interface (Fig 6). A summary of all removal torque values (RTVs) for both implant types at the three different healing periods is shown in Table 1. At all time periods, SLA implants demonstrated 75 to 125% higher mean RTV than Osseotite implants. The mean RTV ranged between 109.6 and 196.7 Ncm for SLA implants, whereas the corresponding values ranged between 62.6 and 95.7 Ncm for Osseotite implants (Fig 7). The differences between the two implant types were highly significant (implant position 1: $P < .008$; implant positions 2 and 3: $P < .004$). The measurements of the failure torque for the hex connection of four Osseotite implants demonstrated values between 148 and 163 Ncm, with a mean failure torque of 156.0 ± 6.8 Ncm (Table 2). The curve demonstrated a constant increase and reached the failure torque at approximately 30 degrees of counterclockwise rotation (Fig 6).

Discussion

In the present study, two titanium screw-type implants of different shapes and surface characteristics were tested in the maxillae of miniature pigs. This animal model was chosen to measure removal

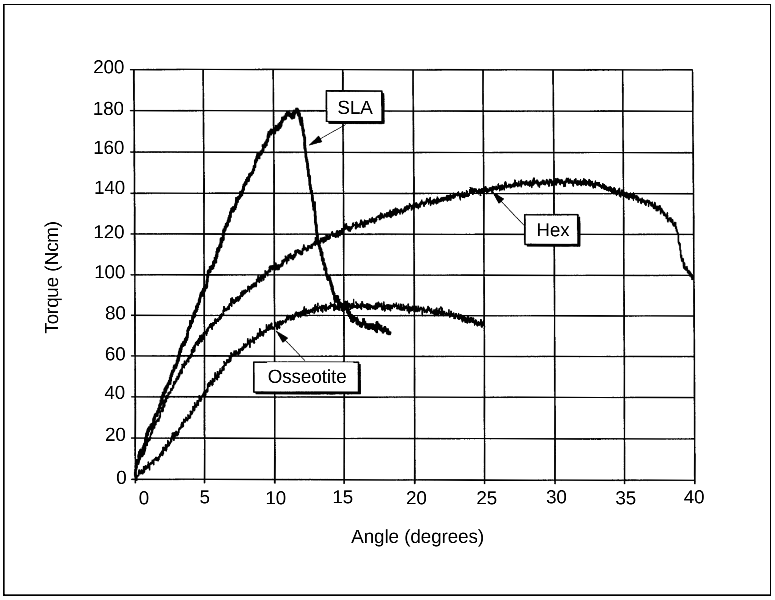

Fig 6 Removal torque testing of SLA and Osseotite implants after 3 months of healing. Osseotite implants showed a rather flat curve and the interface failure occurred around 95 Ncm at about 15 degrees of counterclockwise rotation. In contrast, SLA implants yielded a constant increase to the maximum level, around 180 Ncm at approximately a 12-degree rotation, followed by a steep reduction after failure. The failure torque testing of the hex connection demonstrated an increase to the maximum level of around 150 Ncm at approximately 30 degrees of counterclockwise rotation.

Table 1 Removal Torque Values (Ncm) for Both Implant Types at Three Different Healing Periods*

	Healing periods					
	1 (4 weeks)		2 (8 weeks)		3 (12 weeks)	
Animal	Osseotite	SLA	Osseotite	SLA	Osseotite	SLA
	74	124	96	218	70	228
1	78	119	94	214	82	200
	70	98	88	181	80	180
	57	108	94	194	121	—
2	46	110	83	215	93	203
	46	92	79	139	92	129
	73	116	—	227	123	161
3	57	121	85	—	113	209
	—	98	81	185	88	186
Mean RTV[†]	62.5	109.6	87.6	196.7	95.7	186.8
	12.9	11.6	6.4	30.6	18.9	30.8

*Three animals were tested at each healing period.

[†] RTV = removal torque value.

torques of implants in maxillary bone because its bone structure is comparable to that of humans, in whom dental implants are placed in daily practice.

The two tested implants were chosen for their rough titanium surface in the bone-anchoring portion, which can be attributed in part to a sulfuric acid–hydrochloric acid etching procedure. The two implants differ, however, in that the SLA surface is sandblasted (large grits of 250 to 500 µm) and acid-etched, whereas the Osseotite surface is acid-etched superimposed on a machined surface. The characterization of the surface topography was performed with stylus profilometry. This method has been used frequently to characterize titanium surfaces with different roughness values.[27] This analysis demonstrated that SLA implants have a rougher surface (R_a = 2.0 µm) when compared with Osseotite implants (R_a = 1.3 µm). This difference was also apparent in SEM analysis. The SLA surface is characterized by a primary roughness produced by the sandblasting procedure that creates "valleys" whereas the acid-etching procedure removes remnants of grits and attacks the titanium surface, producing 1- to 2-µm-diameter micropits superimposed on the rough-blasted surface. The Osseotite surface has similar micropits produced by the etching procedure, but its profile is flatter, since no sandblasting procedure is used prior to etching. It is important to note, however, that stylus

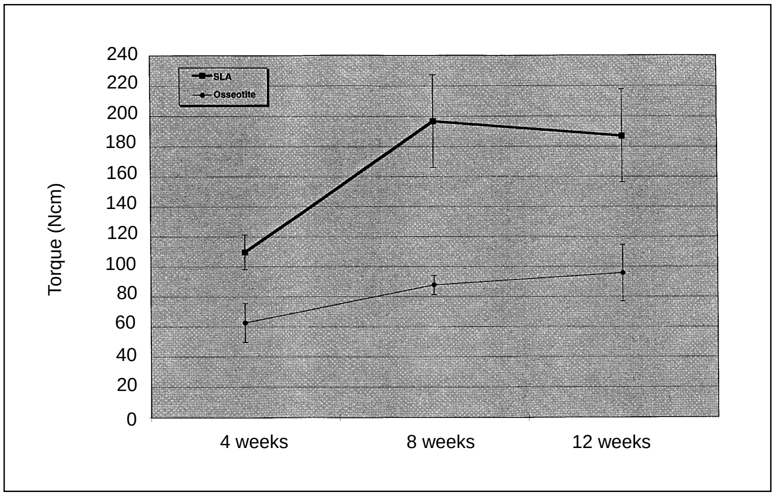

Fig 7 Comparison of mean removal torque values for Osseotite and SLA implants at 4, 8, and 12 weeks (± SD). The observed differences between the two implant types are significant (*P* < .01).

profilometry cannot resolve the finer features of both surfaces with their micropits. Development of a more precise method to capture the small-range (1 to 10 µm) as well as the long-range features (10 to 30 µm) is required. However, the measured values represent the major topographic features of each surface.

The significant difference observed in removal torque testing can most likely be attributed to the different surface characteristics, although the tested implants also differed concerning their macroscopic implant shape. On the one hand, the SLA implants profited from a slightly larger diameter (4.05 mm versus 3.75 mm). On the other hand, Osseotite implants were favored as a result of four grooves in the apical portion for the self-cutting procedure during implant placement, and this feature provided additional bone anchorage against removal torque testing. The SLA implants were solid screws and lacked any macroscopic retention elements. This difference in implant shape most likely explains the observed difference in the characteristics of the removal torque curves. The SLA curve showed an immediate decrease following the peak in the curve, whereas Osseotite implants were characterized by a slow, creeping failure of the interface, since the four grooves in the apical portion continued to provide resistance to shear by their macroscopic anchorage in the bone. Summarizing all these aspects of microscopic and macroscopic properties of the two tested implants, it can be assumed that the surface characteristics had the most significant impact on the interface shear strength, since SLA implants without apical grooves had 75 to 125% higher mean RTV than Osseotite implants with four apical grooves.

Table 2 Failure Torque Testing of the Hex of Four Osseotite Implants (Ncm)

Implant	Failure torque of hex
1	148
2	163
3	160
4	153
Mean	156.0
SD	6.8

The in vitro testing of the hex connection of Osseotite implants was necessary since it could be argued that the relatively short hex connection would not resist the shear stresses during removal torque testing. The examination of four Osseotite implants embedded in dental cement demonstrated failure torques of between 148 and 163 Ncm (mean RTV of 156 Ncm). These values are clearly higher than all measured RTVs of the 25 osseointegrated Osseotite implants. In addition, the hex failure torque was always observed at approximately 30 degrees of counterclockwise rotation, whereas Osseotite implants demonstrated failure torques at 12 to 18 degrees of counterclockwise rotation (Fig 6). Therefore, it can be concluded that the mean RTVs, ranging between 62 and 96 Ncm, do in fact represent the failure torques at the bone-implant interface at various time points.

The results of this study confirm the findings of previous biomechanical studies in various animal models. These studies all demonstrated higher RTV for roughened titanium surfaces when compared with fine-structured or machined titanium surfaces.[20,22,24,26,28–35] The two most recent studies evaluated the two implant surfaces that were tested in the present study. The study by Klokkevold et al[26] examined screw-type implants with an Osseotite surface and a length of 4 mm, but no macroscopic grooves in the tibiae of rabbits. Titanium implants of the same shape but with a machined surface served as controls. The removal torque testing after 8 weeks of healing revealed a mean RTV four times higher than that for machined implants, although the values were rather low (mean RTV of 20.50 Ncm for Osseotite and 4.95 Ncm for machined implants). The recent study by Buser et al[24] compared titanium screw implants of identical shape but with three different surfaces. The SLA and TPS surfaces demonstrated 8 to 10 times higher mean RTV than the machined surface. These two studies, though carried out in different animal models, compare well with the results of the present study.

The SLA surface, produced by a sandblasting and acid-etching procedure, has the potential to become important in implant dentistry in the future. Based on more than 10 years of scientific evaluation, this surface is scientifically well-documented in both in vitro[36–41] and in vivo[20–24] studies. All of these studies demonstrated that the SLA surface offers equal or even better results when compared with the TPS surface, in particular during the initial healing period. The trend for faster bone integration of SLA implants might create the opportunity to reduce the current healing period of 3 months without functional loading, a standard routinely used for implants with a TPS surface in clinical practice.[9,10,13] A multicenter study is currently testing this hypothesis using 6 weeks of healing for implants in sites with normal bone density (Classes I to III).

Conclusions

The present biomechanical study in the maxillae of miniature pigs compared two different titanium screw implants with a rough surface in the bone-anchoring portion. The study demonstrated significant differences ($P < .01$) in mean removal torque values between two different titanium screw implants with a sandblasted and acid-etched surface (SLA) and a machined and acid-etched surface (Osseotite) at 4, 8, and 12 weeks of healing. Mean RTVs ranged between 62 and 96 Ncm for Osseotite implants, while SLA implants revealed mean RTVs between 109 and 196 Ncm. Differences exist between roughened titanium implants with different surface characteristics; therefore, proper scientific evaluation of new titanium surfaces, including both in vitro and in vivo studies, is mandatory prior to clinical application in patients.

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