Interface of Unloaded Titanium Implants in the Iliac Crest, Fibula, and Scapula: A Histomorphometric and Biomechanical Study in the Pig

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Purpose: *Prefabrication of free vascularized fibular flaps is a 2-stage procedure for the reconstruction of maxillary and mandibular defects. The delay between prefabrication and flap transfer is 6 weeks and depends on biomechanical stability and osseointegration of the implants. The purpose of this animal study was to evaluate implant stability by measuring the removal torque values (RTVs) at 3, 6, and 12 weeks and to compare the results with interface strength of the bone-implant surface in the fibula, the scapula, and the iliac crest under unloaded conditions.* ***Materials and Methods:*** *ITI implants (n = 108) with a sandblasted and acid-etched surface were placed in the fibula, the scapula, and the iliac crest of 6 Yorkshire pigs. Biomechanical, histologic, and histomorphometric results were collected at 3, 6, and 12 weeks, respectively.* ***Results:*** *Bicortical anchored 8-mm implants in the fibula (63.7 to 101.8 Ncm) showed RTVs similar to those of monocortical anchored 12-mm implants in the scapula (62.3 to 99.7 Ncm). The RTVs of monocortical anchored 8-mm and 10-mm implants in the iliac crest (19.1 to 44.3 Ncm) and the scapula (27.2 to 55.3 Ncm) were significantly lower. The bone-to-implant contact in the fibula at 3, 6, and 12 weeks (35.2%, 44.4%, and 46.8%, respectively) was similar to that in the iliac crest (24.2%, 44.2%, and 52.5%, respectively), but significantly lower than in the scapula (63.7%, 73.8%, and 74.2%, respectively).* ***Discussion and Conclusion:*** *Bicortical anchorage determined implant stability in the fibula, whereas interfacial strength seemed to define stability in the scapula. The quality and type of bone determined the bone's response in terms of biomechanical press fit or biologic interface strength.* INT J ORAL MAXILLOFAC IMPLANTS 2004;19:52–58

Key words: *bone grafting, bone-to-implant contact, histomorphometric analysis, removal torque values, surface properties, surgical flaps, titanium implants*

Complex defects of the facial skeleton can be reconstructed routinely with free vascularized flaps.[1–4] Free vascularized bone grafts are used for the reconstruction of mandibular and maxillary defects. The fibula, the scapula, and the iliac crest are the most preferable donor sites. Not only must the surgeon reconstruct the defect with bone tissue; he or she must, if possible, make it possible for the patient to achieve normal function within the restored jaws. Normal function and a positive esthetic outcome with complete oral rehabilitation depend largely on the placement of stable, implant-supported prostheses. The combination of free vascularized bone flaps with dental implants is the standard procedure for the reconstruction of maxillofacial defects, including those in the dentoalveolar region. The success rates of implants placed in these free vascularized bone grafts are similar to those placed in the alveolar crest of the mandible or maxilla.[4,5] However, achievement of complete oral rehabilitation with prostheses takes about 6 to 12 months.

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Prefabrication of free vascularized grafts, which shortens the time of the entire treatment to about 3 to 6 months, is becoming a promising and important technique. In addition, precise placement of the dental implants and the exact transfer of the planning tools during the surgical reconstruction improve the final outcome.[6–9] Prefabrication of the free vascularized fibula flap, which was described initially by Rohner and associates,[7,8] would allow for immediate function and loading.

However, currently no data are available on what the reasonable time of prefabrication could be. A recently published clinical study demonstrated a high success rate for implants that had been placed only 6 weeks prior to their functional loading.[10] However, histologic evaluations of the tested implants showed little bone-to-implant contact at 6 weeks. Although these findings indicate that mechanical stability of the implant is more important for immediate loading, biologic bone response to the implants might be a determinant for long-term success. This appears to be the only report that has demonstrated the success rate of early loaded implants in free vascularized bone flaps.

The aim of the present study was to measure the biomechanical properties (ie, removal torque values [RTVs]) and biologic properties (using histomorphometric analysis) of titanium implants with sandblasted and acid-etched (SLA) surfaces (ITI; Straumann, Waldenburg, Switzerland) in the fibula, the scapula, and the iliac crest of pigs at 3, 6, and 12 weeks of healing. The titanium implant with an SLA surface, which has been widely tested, was used because of its excellent biomechanical and histologic results.[11–19] The objective was to determine whether the bicortical layered fibular bone would guarantee enough primary stability and whether the histologic bone response would match the biomechanical results.

MATERIALS AND METHODS

Animals and Anesthesia

Six female Yorkshire pigs, weighing 40 to 45 kg each, were used in this study. The animals were housed in the animal holding facility at the Department of Experimental Surgery, Singapore General Hospital, for the entire duration of the experiment. Housing and feeding were according to standard animal care protocols. The study was approved by the Animal Welfare Committee of the Singapore General Hospital and followed the guidelines found in the US National Institutes of Health's Guide for Care and Use of Laboratory Animals.

Table 1 Distribution of the Implants in 3 Different Recipient Sites

Group/ implant length	Fibula	Scapula	Iliac crest	Total
3 weeks				
8 mm	10 (2)	7 (1)	0	17
10 mm	0	0	5	5
12 mm	0	7 (1)	7 (2)	14
6 weeks				
8 mm	12 (2)	6 (1)	0	18
10 mm	0	0	7 (1)	7
12 mm	0	8 (1)	5 (1)	13
12 weeks				
8 mm	10 (2)	0	0	10
10 mm	0	8 (2)	7 (2)	15
12 mm	0	4	5	9
Total				108

Numbers in parentheses indicate samples used for histologic analysis.
Pigs were grouped by time of sacrifice (weeks after surgery).
The mean diameter of the pig fibula was 8 mm or less. Therefore, only 8-mm implants were used for the fibula.

The pigs were premedicated with ketamine. Unconsciousness was induced by means of orally intubated pentobarbitone and maintained with 1% halothane. Approximately 5 mL of 3% lignocaine was also injected into the areas exposed to surgery.

Surgery

A total of 108 screw-type ITI implants, 4.1 mm in diameter with SLA surfaces, were used (Straumann). The iliac crest, the fibula, and the scapula on one side of every pig were chosen as recipient sites for this investigation. Distribution of the implants in the 3 different sites is shown in Table 1.

Using the appropriate drills and taps, the implants were placed with a ratchet and a torque control device. The implants were placed until the margin of the sandblasted surface was completely covered with bone. Closure of the wounds was accomplished with resorbable sutures. Postoperatively, all animals were given antibiotics (Amoxi-Mepha; 500 mg/d; Mepha, Aesch, Switzerland) and analgesics (Temgesic, 2.5 mg/d; Essex Chemie, Luzern, Switzerland) in single intramuscular injections.

Torque Measurements

The animals were divided into 3 groups. At 3 weeks, one group was sacrificed by an intravenous overdose of pentobarbitone; at 6 weeks, the second group was sacrificed; and at 12 weeks, the third group was sacrificed. The RTVs were measured with an Instron test machine (Instron 8872 tension-torsion system; Instron, Canton, MA). Ninety implants were used for torque measurement. To correctly screw an

Fig 1a *(Left)* The RTVs were collected with an Instron tension-torsion system using an axial-torsional load cell.

Fig 1b *(Below)* The specimen mounting plate was fixed on the load cell. The axial screw on top of the implant was used to stabilize the axis of the implant and to allow the test machine to get enough grip and fixation.

implant mount on the implant, any overgrowth of bone was carefully removed. The bone blocks, which each contained 4 to 6 implants, were harvested, and radiographs of each specimen were made. Bone sections, each of which included 1 implant, were prepared and fixed to a mounting plate with a specimen holder. The fixation of the bone sections was done with autopolymerizing acrylic resin (Simplex Rapid; Associated Dental Products, Wiltshire, United Kingdom). To allow for proper removal torque, a stainless steel screw and a nut were attached at the inner hexagon of the implants. The test machine held this screw, the nut, and the implant neck. The removal torque test was carried out by applying a counterclockwise rotation to the implant axis at a rate of 0.1 deg/s (Figs 1a and 1b). An axial-torsional load cell (AMTI biaxial load-cell MC3A-2-500; AMTI, Arlington, VA) measured the results. The removal torque was defined as the peak value on the curve.

Histologic Preparation and Histomorphometric Analysis

Eighteen implants, 6 from each group, were used for histologic evaluation. Block sections including the implants were placed in 4% formalin/1% calcium chloride fixative. A radiograph was made of each specimen. The specimens were dehydrated and embedded in methylmethacrylate resin. Undecalcified sections 500 µm thick were obtained parallel to the axis of the implants using an Exakt sawing machine (Exakt Apparatebau, Norderstedt, Germany) and subsequently polished down to a thickness of about 80 µm. In general, 4 sections from each implant with a final thickness of approximately 80 µm could be evaluated. The sections were stained using toluidine blue and basic fuchsin.

The sections were histologically analyzed in a Zeiss Axioskop microscope (Carl Zeiss, Thornwood, NY) equipped with a charge-coupled distributor camera system (Sony, Tokyo, Japan). The morphometric analysis to measure the bone-to-implant contact was done with Analysis 3.0 (Soft Imaging System, Münster, Germany).

Calculations

Statistical calculations for the RTVs were performed using a paired Student *t* test with the significance set at $P < .05$. A statistical evaluation of the histomorphometric results was not possible because of the low number of specimens for histologic analysis. All values are reported as mean ± standard deviation.

RESULTS

Clinical Findings

The animals recovered well from surgery and healed uneventfully. All of the 108 implants were found clinically stable at re-entry. These clinical findings were confirmed with longitudinal radiographs of the recipient sites, which demonstrated no evidence of peri-implant radiolucency. Ninety

Fig 2 (Left) Micrograph of an implant in the fibula at 6 weeks (original magnification ×2.5). Accurate press fit of the implant in the cortical layers of the fibula.

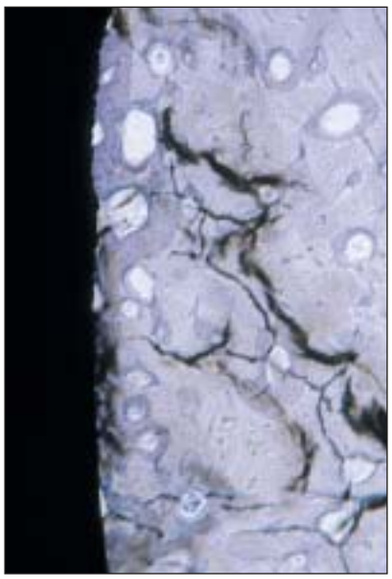


Fig 3 Secondary bone-to-implant contact with new, more intensely stained bone at 6 weeks (original magnification ×100).

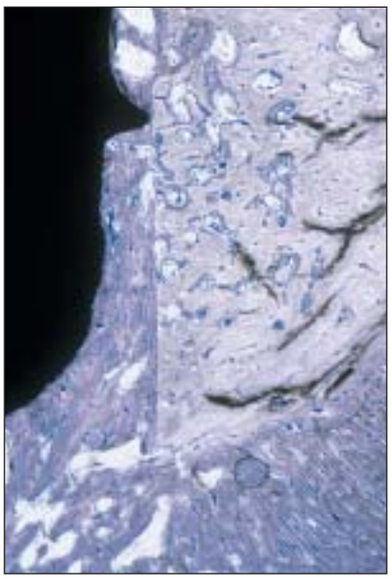


Fig 4 Bone-to-implant contact at 3 weeks in the scapula by secondary bone apposition (original magnification ×100).

implants were used for removal torque measurements. Another 18 implants were used for histomorphometric analysis.

Removal Torque Values

The removal torque test resulted in a typical curve, the peak of which was assumed to be the failure torque of the bone-implant interface.

Fibula. The mean RTVs for the bicortically anchored 8-mm implants were 63.7 ± 9.8 Ncm at 3 weeks, 91.5 ± 34.1 Ncm at 6 weeks, and 101.8 ± 28.7 Ncm at 12 weeks. There was a statistically significant increase in RTVs between 3 and 6 weeks (P = .024) and between 3 and 12 weeks (P = .009), but there was no significant difference between 6 and 12 weeks (P = .507).

Scapula. The RTVs for the monocortically anchored 12-mm implants were 62.3 ± 25.4 Ncm, 97.6 ± 38.6 Ncm, and 99.7 ± 1.4 Ncm at 3, 6, and 12 weeks, respectively. Shorter implants showed significantly lower values. The RTVs for monocortically anchored 8-mm and 10-mm implants were 27.2 ± 25.4 Ncm, 26.5 ± 11.9 Ncm, and 55.3 ± 16.0 Ncm at 3, 6, and 12 weeks, respectively. The 12-mm implants were more stable at 3 and 12 weeks, but only at 6 weeks were they significantly more stable (P = .012).

Iliac Crest. The RTVs for the monocortically anchored 12-mm implants were 71.4 ± 9.8 Ncm, 63.1 ± 6.8 Ncm, and 61.6 ± 8.8 Ncm at 3, 6, and 12 weeks, respectively. The RTVs for the monocortically anchored 10-mm implants were 19.1 ± 2.5 Ncm, 22.8 ± 3.4 Ncm, and 44.3 ± 5.9 Ncm at 3, 6, and 12 weeks, respectively. The 12-mm implants were significantly more stable at 3 weeks (P = .001) and at 6 weeks (P = .006).

Histologic Findings

The histologic analysis of implants placed in the fibula showed an accurate press fit within the cortical layer (Fig 2). New, more intensely stained bone was seen in bone-to-implant contact at 6 weeks (Fig 3). In the scapula, remodeling was well underway at 3 weeks, with new bone in direct contact with the surface of the implant (Fig 4). At 6 weeks, bone ongrowth spread along the surface of the implant in the cancellous area of the scapula (Figs 5 and 6). The iliac crest showed less cancellous bone than the scapula (Fig 7). Secondary bone-to-implant contact could be seen at 12 weeks in the iliac crest (Fig 8).

Histomorphometric Analysis

The histomorphometric analyses at 3 weeks revealed bone-to-implant contact of 35.2% ± 11.5% for the fibula, 63.7% ± 6.8% for the scapula, and 24.2% ± 10.9% for the iliac crest. There was an increase at 6 weeks to 44.4% ± 10.9% for the fibula, 73.8% ± 8.2% for the scapula, and 44.2% ± 10.6% for the iliac crest. The results at 12 weeks were 46.8% ± 12.6% for the fibula, 74.2% ± 6.5% for the scapula, and 52.5% ± 11.2% for the iliac crest. The histomorphometric analyses are summarized in Table 2.

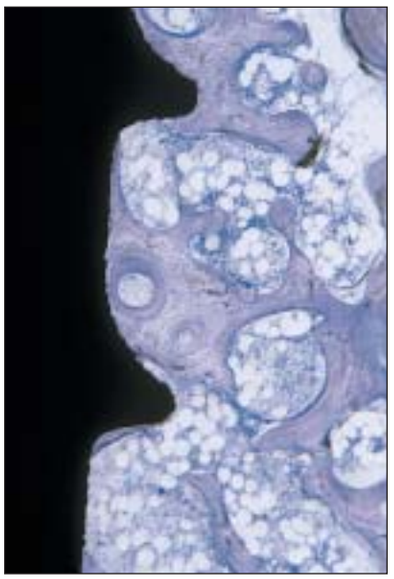
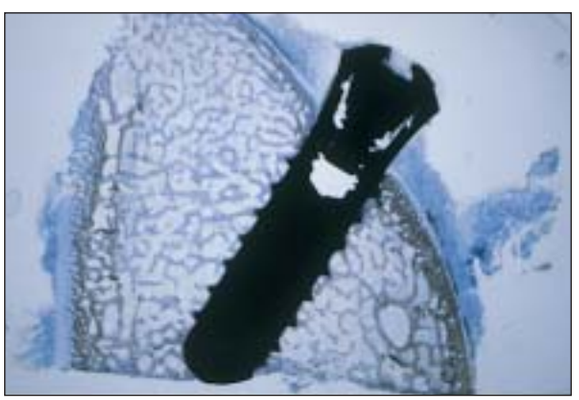


Fig 5 *(Left)* Secondary bone contact was achieved in the cancellous area of the scapula, forming bony anchors (original magnification ×100).

Fig 6 *(Right)* Micrograph of an implant in the scapula at 6 weeks showing the dense cancellous portion (original magnification ×2.5).



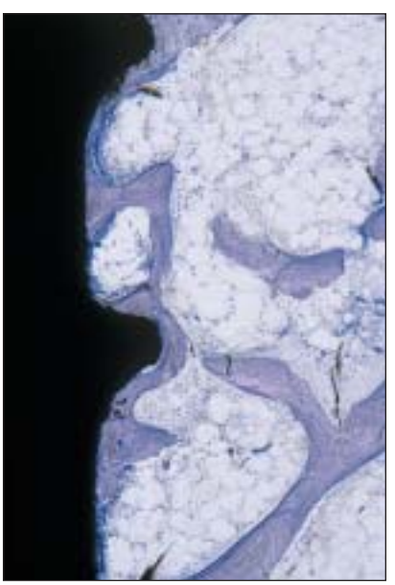


Fig 7 *(Above)* Micrograph of an implant in the iliac crest at 6 weeks (original magnification ×2.5). The density of cancellous bone is obviously lower than in the scapula.

Fig 8 *(Right)* Secondary bone-to-implant contact is achieved by ongrowth of bone in the iliac crest at 12 weeks (original magnification ×100).

Table 2 Bone-to-Implant Contact in Different Recipient Sites

	Bone-to-implant contact (%)					
	3 weeks		6 weeks		12 weeks	
Site	Mean	SD	Mean	SD	Mean	SD
Fibula	35.2	11.5	44.4	10.9	46.8	12.6
Scapula	63.7	6.8	73.8	8.2	74.2	6.5
Iliac crest	24.2	10.9	44.2	10.6	52.5	11.2

Two implants in each group were tested for histomorphometric analysis. Because of the low number of implants, no statistical evaluation was possible. However, the scapula showed a much higher amount of bone-to-implant contact than the fibula or the iliac crest.

The scapula showed the best results, followed by the fibula and the iliac crest.

DISCUSSION

The use of free vascularized bone flaps for the reconstruction of extended maxillofacial defects has become state-of-the-art technology. The fibula, scapula, and iliac crest are the most preferable donor sites for the reconstruction of defects in the maxillofacial area. The applicability of these bones has been tested and compared in several studies.[20–22] To achieve appropriate oral rehabilitation with implant-supported prostheses, implants need to be

placed within the free vascularized bone flap. A newer technique, which is known as prefabrication of fibular flaps, deals with the placement of implants at the donor site several weeks before defect reconstruction. This technique has clinically shown promising results.[7,8,10] However, there is still some uncertainty about the in vivo stability of implants placed in the fibula, scapula, or iliac crest at different healing times.

In the present study, different biomechanical values could be expected for the different qualities of bone. Niimi and coworkers showed significantly better primary stability of dental implants in the fibula (46.3 Ncm) of human cadavers than in the scapula (21.4 Ncm) or the iliac crest (15.2 Ncm).[23] In the present study, the RTVs for monocortically anchored 12-mm implants were 62.3 Ncm in the scapula and 71.4 Ncm in the iliac crest but only 19.1 Ncm for monocortically anchored 10-mm implants in the iliac crest and 27.5 Ncm for monocortically anchored 8-mm implants in the scapula. Similar results with increasing values could be found at 6 and 12 weeks. The interface strength of the bone-implant surface seemed to be dependent on the length of the implant. The RTVs increased significantly with time, which was expected. In accordance with Sennerby and associates,[24] bone in the cortical passage seemed to give the main support to the implants. The RTVs at 3 weeks were 63.7 Ncm in the fibula for bicortically anchored 8-mm implants. The bicortically anchored 8-mm implants in the fibula and the monocortically anchored 12-mm implants in the iliac crest and the scapula showed similar values. The RTVs of monocortically anchored 8-mm and 10-mm implants in the iliac crest and the scapula were significantly lower. These results emphasized the significance of implant length with regard to monocortical or bicortical anchorage. Although this study has been carried out in an animal model, it could be hypothesized that bicortically anchored 8-mm implants would be similar in interface strength to monocortically anchored 12-mm implants at 3, 6, and 12 weeks of healing in the human situation.

As several studies have demonstrated, bone-to-implant contact depends on implant surface texture.[11,13,16–19,25–29] In the present study, implants with a sandblasted and acid-etched surface were used. At 3 weeks, bone-to-implant contact was greater in the scapula (63.7%) than in the fibula (35.2%) or the iliac crest (24.2%). At 12 weeks, the values increased to 74.2%, 46.8%, and 52.5% in the scapula, the fibula, and the iliac crest, respectively.

Bicortical anchorage seemed to be an important factor for short-term stability regardless of the amount of bone-to-implant contact. The quality of the monocortical anchorage was dependent on the length of the implant. Bone-to-implant contact may be an additional factor for long-term stability.

In this animal study, bicortically anchored 8-mm or monocortically anchored 12-mm implants showed enough stability at 3 and 6 weeks healing to allow for immediate function after reconstruction. Though this animal study may not be comparable to the human situation, data from clinical studies show successful outcomes using the technique of prefabrication with subsequent immediate function.[7,8,10]

CONCLUSION

The present biomechanical and histomorphometric study in the fibula, scapula, and iliac crest of pigs showed good interface strength of bone to the ITI SLA implant surface at 3, 6, and 12 weeks. The RTVs were similar in the tested bones at 3 weeks and increased with the amount of healing time. Bicortically anchored 8-mm implants placed in the fibula were biomechanically as stable as monocortically anchored 12-mm implants placed in the cancellous bone of the scapula and the iliac crest. The length of the implant and the amount of bone-to-implant contact were the determinants for interface strength in cancellous bone.

The results of this animal study showed that the healing period of 3 to 6 weeks led to sufficient strength of the bone implant interface to consider early loading.

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