Retrospective Clinical Study of Osseotite Implants: Zero- to 5-year Results

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Purpose: *Over the last few years, particular attention has been paid to the implant surface and its influence on the formation and maintenance of surrounding bone. The surface of Osseotite implants (Implant Innovations) is produced by a process of thermal etching, which produces a surface with an average roughness that is twice that of machined implants produced by the same manufacturer. In addition to reducing osseointegration time, this factor appears to favor its maintenance over time. This study presents the results of a clinical trial of Osseotite implants.* ***Materials and Methods:*** *Five hundred fifty-five Osseotite implants were placed in 244 patients over 5 years, between September 1996 and September 2001. The average follow-up period from implant placement was 26 months (SD 13.1).* ***Results:*** *After the first surgical stage, 8 failures were noted in 6 patients. Life table analysis showed a cumulative survival rate of 98.5%, but no implant was lost after prosthetic loading, with a 100% survival rate both for the mandible and for the maxilla. For the prosthetic loading time, only the implants with more than 12 months of loading were considered, obtaining an average prosthetic loading time of 34 months (SD 9.2).* ***Discussion:*** *The implant survival rate after loading was 100% both in the anterior and posterior regions, and no difference was noted in relation to the different types of prostheses, or length and width of implants.* ***Conclusion:*** *The results obtained in this retrospective study population revealed an acceptable survival rate for these implant-supported restorations.* (INT J ORAL MAXILLOFAC IMPLANTS 2003;18:589–593)

Key words: *endosseous dental implants, implant-supported dental prosthesis, surface properties*

The success of dental implants placed to support fixed or removable prostheses has been well documented in the literature for 20 years.[1–3] Consequently, a number of patients have sought implant-supported oral rehabilitation. The use of osseointegrated implants can provide predictable results in the presence of certain clinical conditions: residual alveolar bone width of at least 6 mm, alveolar bone height of at least 10 mm, appropriate maxillomandibular relationships, and peri-implant tissue of good quality with an adequate amount of keratinized mucosa.[4,5]

Following implant placement, tissue reactions are related to several factors such as implant material, implant shape, surgical procedure, and prosthetic design.[6] In recent years, notable importance has been devoted to investigation of implant surface properties, because they may significantly influence the formation and maintenance of bone around the implant. Osseointegration is obtained by a cellular process that contributes to bone formation at the alloplastic surface.[7,8] Bone maintenance depends on continuous adaptation to functional loading and repair of damage subsequent to overload at the implant-bone interface.[9,10] Surface topography may directly mediate changes in cell behavior. A rough implant surface may contribute to an increase in bone-implant contact, promote superficial adhesion of osteoblasts, and improve biomechanical interactions between bone and implant.[11]

Osborn and Newesely[12] demonstrated, with animal studies, that new bone growth around titanium implants is determined by 2 different mechanisms: distance osteogenesis and contact osteogenesis. Distance osteogenesis is a gradual process of bone healing inward toward the implant; bone does not grow directly on implant surfaces. Contact osteogenesis is the direct migration of bone-building cells through the clot matrix to the implant surface. Bone is quickly formed directly on the implant surface. The migration of osteogenic cells through the clot matrix causes contraction of the fibrin strands in the

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clot matrix, which can detach the strands from the implant, disrupting or stopping contact osteogenesis and osteoconduction altogether. The contact between fibrin strands and the implant is relatively simple to achieve but difficult to maintain and is promoted by a rough implant surface.[13,14]

On the basis of these considerations and after investigation, 3i/Implant Innovations (Palm Beach Gardens, FL) developed the Osseotite surface. This surface is produced by thermal etching a smooth titanium surface with hydrochloric and sulfuric acid. The Osseotite surface obtained with this process has 1 to 3 μm peak-to-peak and 5 to 10 μm peak-to-valley characteristics, which have proven to be optimal for strengthening the clot-implant attachment and increasing platelet activation and red blood cell agglomeration.[15] Average Osseotite surface roughness is 2 μm, approximately double that of the 3i titanium machined-surface implant.

The Osseotite implant has a "hybrid design": The apical is rough-surfaced, and the cervical 3 mm are machine-surfaced. As a result, if bone loss occurred, the soft tissue would be in contact with the smoother machined surface.

Lazzara and coworkers,[16] in a human histologic study, confirmed the increase in osteoconduction and contact osteogenesis with the Osseotite surface. Two-mm-diameter screws, each having one Osseotite side and one machined-surface side, were placed in the posterior maxilla and removed after 6 months of healing. The sections prepared showed a mean percent bone-implant contact for Osseotite of 72.96%, compared to 33.98% for the machined surface.

Different controlled clinical studies have been done to evaluate the removal torque for the Osseotite surface.[16,17] The mean torque values registered were 40.85 ± 4.14 Ncm and 25.28 ± 3.35 Ncm for the Osseotite and machined 3i implants, respectively.

Approximately 2,000 Osseotite implants placed and reported in different retrospective studies worldwide confirmed that the cumulative survival rate was 98.2% after 12.6 months of prosthetic loading.[18,19] Other studies have evaluated the possibility of early loading of the Osseotite implant and have achieved the same success rate as the classic Brånemark protocol.[20–22]

The aim of this retrospective study was to investigate the long-term predictability of prosthetic restorations supported by Osseotite implants in the treatment of different stages of edentulism.

MATERIALS AND METHODS

Between September 1996 and September 2001, 244 consecutive patients aged between 24 and 75 years (106 men [43%] and 138 women [57%]) were treated with Osseotite implants for different stages of edentulism ranging from single tooth absence to complete edentulism. Exclusion criteria consisted of: poor oral hygiene, active periodontal infections, uncontrolled diabetes, bruxism, or heavy smoking habit (more than 10 cigarettes/day).

Five hundred fifty-five Osseotite implants were placed over a period of 5 years. These were screw-type implants with an external hexagonal prosthetic connection.

Surgical Procedures

Potential implant sites were identified from panoramic and lateral cephalometric radiographic views utilizing a radiographic template. In some cases a computerized tomographic scan was necessary. Following this, a surgical template was fabricated to aid the ideal positioning of implants. The surgical placement of all the implants was undertaken by 4 different oral surgeons.[23] A 2-stage technique was used to place the 555 implants following the classic Brånemark protocol.[24] One hundred fifty-nine implants (28%) were placed in the maxillary posterior region, 55 implants (10%) were placed in the maxillary anterior region, 234 implants (42%) were placed in the mandibular posterior region, and 107 implants (20%) were placed in the mandibular symphyseal area.

The implant diameters were as follows: 11 (2%) were 3.25 mm in diameter, 470 (84%) were 3.75 mm in diameter, and 74 (14%) were 5 mm in diameter. Distribution of implant lengths was as follows: 245 implants (approximately 50% of the total) were 13 mm long, 138 implants (24%) were 11.5 mm long, 85 implants (15%) were 10 mm long, 65 implants (11%) were 15 mm long, 18 implants (3.5%) were 8.5 mm long, and 4 implants (0.8%) were 18 mm long.

All patients were requested not to wear their partial or complete dentures for 2 weeks postsurgery, after which the dentures were modified and lined with a tissue conditioner over the implant site. The patients were advised to wear removable prostheses only when absolutely necessary during the implant osseointegration period time. Second-stage surgery was performed after 4 and 6 months for the mandible and the maxilla, respectively, and a healing cuff was positioned.

Prosthetic Procedures

Prosthetic treatment was performed 15 days after implant exposure. One hundred five implants (19%) were restored with a single-tooth prosthesis, 312 implants (56%) were utilized for fixed partial prostheses of 2 to 4 units, 78 implants (14%) were used for overdentures, and 60 implants (11%) were used to achieve

full-arch fixed-detachable restorations ad modum Brånemark (Fig 1). According to individual experience and prosthodontist recommendation, in some patients, acrylic resin provisional restorations were used to monitor implant stability under a progressive load and to obtain good soft tissue healing around the implant before fabrication of the definitive restoration.

Single-tooth prostheses and the fixed partial prostheses were metal-ceramic, the overdentures were fabricated of acrylic resin, and the full-arch prostheses were fabricated of acrylic resin with a metal framework. The overdentures were fabricated with bar or ball retention systems; in the mandibular arch, overdentures were supported by 2 or 4 implants, while in the maxilla 4 implants were always used. The gold screw for the abutment-implant prosthetic connection was tightened at 32 Ncm with the use of a dynamometric torque driver control device. The implant-supported prostheses were fabricated by different prosthodontists and technicians.

Clinical and Radiographic Re-evaluations

The first examination after placement of the definitive prostheses was conducted at 2 months; thereafter, patients were examined every 6 months. Patients were evaluated for symptoms of pain and evidence of infection. Implants were evaluated for signs of failure, including mobility, gingival inflammation, and suppuration. Follow-up panoramic and periapical radiographs were obtained annually. Evaluation of crestal bone loss was not performed.

For survival criteria, the permanence of implants under function was assessed according to the following implant success criteria described by Albrektsson and coworkers in 1986.[25]

1. Absolute implant immobility when clinically tested
2. Absence of peri-implant radiolucency
3. Absence of pain, swelling, and paresthesia

This retrospective study reported survival rates, because the absence of mobility of the individual implant can only be tested for non-connected implants or after removal of the prostheses. However, this procedure can lead to prosthetic complications, and some patients were reluctant to have the prosthesis removed in the absence of any adverse clinical or radiographic signs.

RESULTS

All of the 244 patients are still undergoing follow-up examination. Of the 555 Osseotite implants placed over a 5 year-period, 8 were lost. The average follow-up period from implant placement was 26 months (SD 13.1). After the first surgical stage, 8 failures (early failures) in 6 patients were noted; 4 were 3.75×13-mm implants, 3 were 3.75×11.5-mm implants, and 1 was a 3.75×10-mm implant. Within 3 weeks after surgery, 2 implants exhibited pain and swelling, whereas the other 6 showed lack of primary stability at the second surgical stage (Table 1). Therefore, 547 implants remained for prosthetic rehabilitation. The percentage of survival of the placed implants after the first surgical stage was 98.5% (Fig 2).

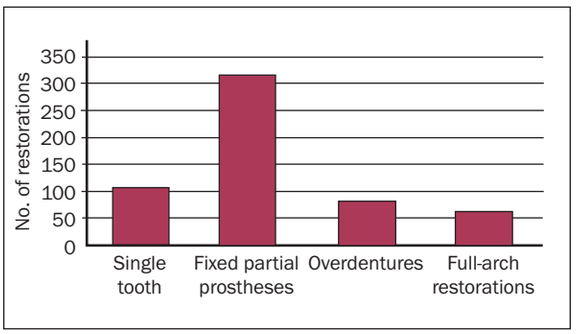

Fig 1 Distribution of implants according to type of prosthetic restoration.

With respect to prosthetic loading, the decision was made to consider only the implants with more than 12 months of loading. Thus, the sample to be analyzed was reduced to 392 implants with an average prosthetic loading period of 34 months (SD 9.2). During the 5 years of follow-up, no implant failed after loading. The life table analysis shown in Table 2 indicates that the overall cumulative implant survival rate at 5 years of functional loading was 98.5%. The post-loading cumulative implant survival rate was 100% at 5 years. In this same period, some abutments for single-tooth restorations demonstrated screw loosening, although they had been tightened with a torque driver to 32 Ncm. No screw loosening was noted with fixed partial restorations, overdentures, or fixed-detachable full-arch prostheses. No gold screws and no implants fractured during the considered time, whereas the acrylic resin component of a fixed detachable prosthesis fractured twice in 4 years.

Soft tissues around the implants were healthy over the entire observation period. Temporary swelling of the peri-implant mucosa was routinely the result of loosening of the abutment screw and completely disappeared after mechanical stabilization of the crown.

DISCUSSION

It has been demonstrated that bone-implant interfacial shear strength may be increased with a rough

Table 1 Characteristics of Failed Implants

Location	Length (mm)	Diameter (mm)	Reason for failure
Mandibular right lateral incisor	13	3.75	Mobility
Maxillary right first premolar	13	3.75	Mobility
Maxillary left second premolar	11.5	3.75	Mobility
Mandibular right first premolar	11.5	3.75	Persistent infection
Mandibular right second premolar	11.5	3.75	Mobility
Mandibular right first molar	10	3.75	Mobility
Mandibular left first molar	13	3.75	Persistent infection
Mandibular left first molar	13	3.75	Mobility

Table 2 Life Table Analysis of Implants with More Than 12 Months of Loading

Interval (mo)	Implants at risk	Failed implants	Survival rate (%)	Cumulative survival rate (%)
12 to 18	392	0	100	98.5
18 to 24	338	0	100	98.5
24 to 30	257	0	100	98.5
30 to 36	182	0	100	98.5
36 to 42	120	0	100	98.5
42 to 48	83	0	100	98.5
48 to 54	34	0	100	98.5
54 to 60	18	0	100	98.5

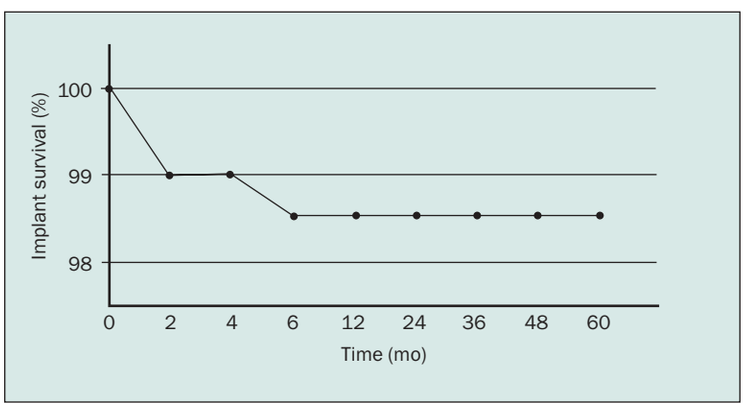

Fig 2 Implant survival curve.

surface.[26] For this reason, various rough implant surfaces have been developed by the implant manufacturers. Different types of rough implant surfaces available include coated surfaces, abrasive blasted surfaces, acid-etched surfaces, blasted and etched surfaces, and sintered surfaces.[11]

In this study the authors analyzed 555 Osseotite implants placed in 244 patients over a period of up to 5 years. The implants were utilized for both fixed and removable prostheses. Eight implants in 6 patients failed before prosthetic treatment; 2 failed immediately after the first surgical stage and 6 were detected at the uncovering, meaning that osseointegration had not been achieved. Two of these 8 early failures occurred in the same patient, who had a history of other implant failures in the past. No correlation could be made between implant length and failures, as the implants themselves had different lengths.

In addition, the failures could not be related to a particular region of the oral cavity, since they were distributed along the arches: 5 occurred in posterior mandibular segments, 2 in posterior maxillary segments, and 1 in the mandibular symphysis. Failures were more likely related to one of the classic causes of lack of osseointegration reported in the literature: overheating during drilling, poor bone quality, or compromise of local blood supply. However, none of these could be confirmed in this patient series.

Regarding analysis of the results of prosthetic loading in the 392 implants with more than 12 months of function, no failures were noted, with an average loading time of 34 months. These results are comparable with the survival rates reported in other studies.[20,27] There was no relationship between the percentage of implant survival and the type of prosthetic rehabilitation, since none of the prosthetic treatments failed. For the same reason, survival percentages after prosthetic loading of implants placed in different regions of the jaws were identical.

In contrast to what has been reported in the literature about the lower success rate for 5-mm-diameter implants submitted to loading,[28] no differences

in success rates were noted among the implants of different diameters in the present study. Length of the implants did not appear to influence the survival rate of restorations. No so-called "short implant" (8.5 mm) failed, although these made up 3.5% of the sample. The 10-mm implants, together with the 8.5-mm implants, comprised 20% of the sample, and no failures were seen during the follow-up period.

CONCLUSIONS

The authors analyzed 555 Osseotite implants placed over a period of up to 5 years in 244 patients and obtained a 98.5% survival rate after the first surgical stage. This percentage compares with the values obtained using other implant surfaces[27] and by other authors using Osseotite implants.[18,19] The results obtained in this retrospective study population revealed an acceptable survival rate for these implant-supported restorations.

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