



# The OSSEOTITE® 2 Certain® Implant: A one-year interim report on a prospective clinical and radiographic study

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Although high success rates have been reported for implants placed with immediate-loading procedures, this approach places high demands on clinicians. To meet those demands, surgical methods can no longer be standardized. To test the hypothesis that experienced surgeons can obtain the best primary stability and clinical results by choosing a combination of implants and drilling procedures that suits the bone conditions at the implant sites, this prospective clinical study of OSSEOTITE 2 Certain Implants was designed. In 39 patients, 78 implants were placed; 69 of them (88%) were immediately loaded. After one year, the overall cumulative implant-survival rate was 100%.

**Key Words:** OSSEOTITE 2 Certain Implant, parallel-walled, immediate loading, dental implants

## Introduction

Firm initial stability is regarded as one determinant of success for dental implants placed with two-stage protocols<sup>1</sup> and may be even more important when using an immediate-loading protocol. Meta-analyses of clinical follow-up studies of partially edentulous and edentulous patients treated with implants have shown that an implant-survival rate of 95% can be expected over a five-year period.<sup>2,3</sup> Studies show higher failure rates in soft bone and for short implants, which indicates that a certain degree of implant stability is required for successful integration and function during loading.<sup>4</sup> The degree of primary stability at implant placement depends on factors related to the properties of the bone, the implant design, and the surgical technique used.<sup>5</sup> Secondary implant stability depends on the tissue response to the surgery and the implant material. Implant surface topography may also be an important factor for proper integration.

## Materials and Methods

### *Study patients and preliminary inclusion criteria*

The clinical work was conducted by one investigator at a single study center. Patients needing implant-supported prostheses were selected for study inclusion based on the following preliminary criteria: presence of residual bone sufficient to support at least an 8.5mm length implant, absence of infection at the implant site, and patient willingness to sign a consent form. Exclusion criteria consisted of general contraindications for oral surgery and individuals less than 18 years of age. All patients invited to participate were thoroughly informed about all study procedures and understood that the final decision for enrollment would be based on additional inclusion criteria assessed at the implant-placement surgery.

### *Study implants*

OSSEOTITE 2 Certain Implants (BIOMET 3i) are available in lengths of 8.5mm to 15.0mm and diameters of 3.25mm,

4.0mm, 5.0mm, and 6.0mm (Fig. 1). Compared to the earlier OSSEOTITE® Certain® Implants, the 3.25mm and 4.0mm diameter OSSEOTITE 2 Certain Implants have a longer straight-wall section, a reduced apical taper, and modified cutting flutes. The 5.0mm and 6.0mm OSSEOTITE 2 Certain Implants incorporate these design changes and also have the same thread design as BIOMET 3i Tapered Implants, with a narrower thread pattern, a 35-degree thread angle, and a 0.8mm thread pitch (Fig. 2).

For the present study, only 4.0mm and 5.0mm diameter OSSEOTITE 2 Certain Implants were used.

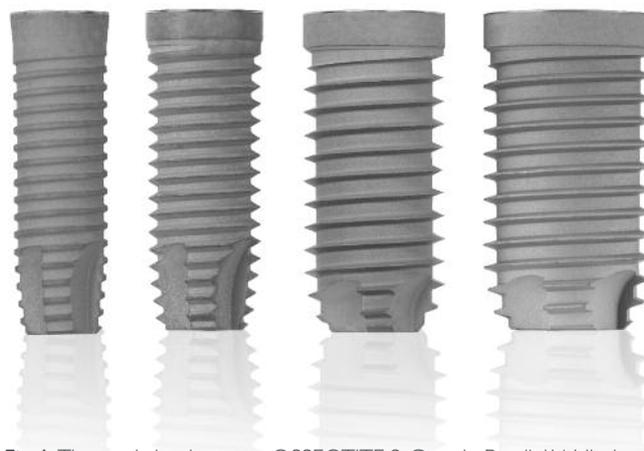
OSSEOTITE 2 Certain Implants are manufactured from commercially pure titanium and are dual-acid-etched (DAE®) to impart the OSSEOTITE Surface from the apex to the implant seating surface. The OSSEOTITE Surface is characterized by one- to three-micron peak-to-peak irregularities. This complex micron-scale topography has been theorized to aid in blood-clot retention, platelet activation, and *de novo* bone interdigitation. In order to adequately view these micron-scale irregularities, the implants had to be analyzed using high magnification ( $\geq 2000\times$ ) scanning electron microscopy (SEM).

In addition to characterization through SEM, interferometry techniques were utilized to explore the surface roughness on which the OSSEOTITE Surface features are present. This analysis was conducted at approximately 312x magnification using a 3D surface profiler and optical interferometer (MicroXAM EX-100, KLA-Tencor Development Series, KLA-Tencor Corporation, Milpitas, California, USA). Two measurements,  $S_a$  (average height deviation, a height-descriptive parameter) and  $S_{dr}$  (developed surface area, a hybrid parameter that includes information from spatial as well as height distributions) were analyzed. The measurements were made at BIOMET 3i Headquarters in Palm Beach Gardens, Florida, USA (Fig. 3).

#### *Implant-placement surgery and final inclusion criteria*

Patients were administered oral antibiotics and sedatives one hour prior to surgery. At 68 of the implant-placement sites (87%), a mid-crestal incision was made, and a mucosal flap was reflected. Both the aesthetic and biomechanical aspects of the site and alveolar ridge were carefully evaluated to determine the optimal implant position. At

10 sites (13%), implant placement followed immediately after extraction (13%), and no flap was reflected.

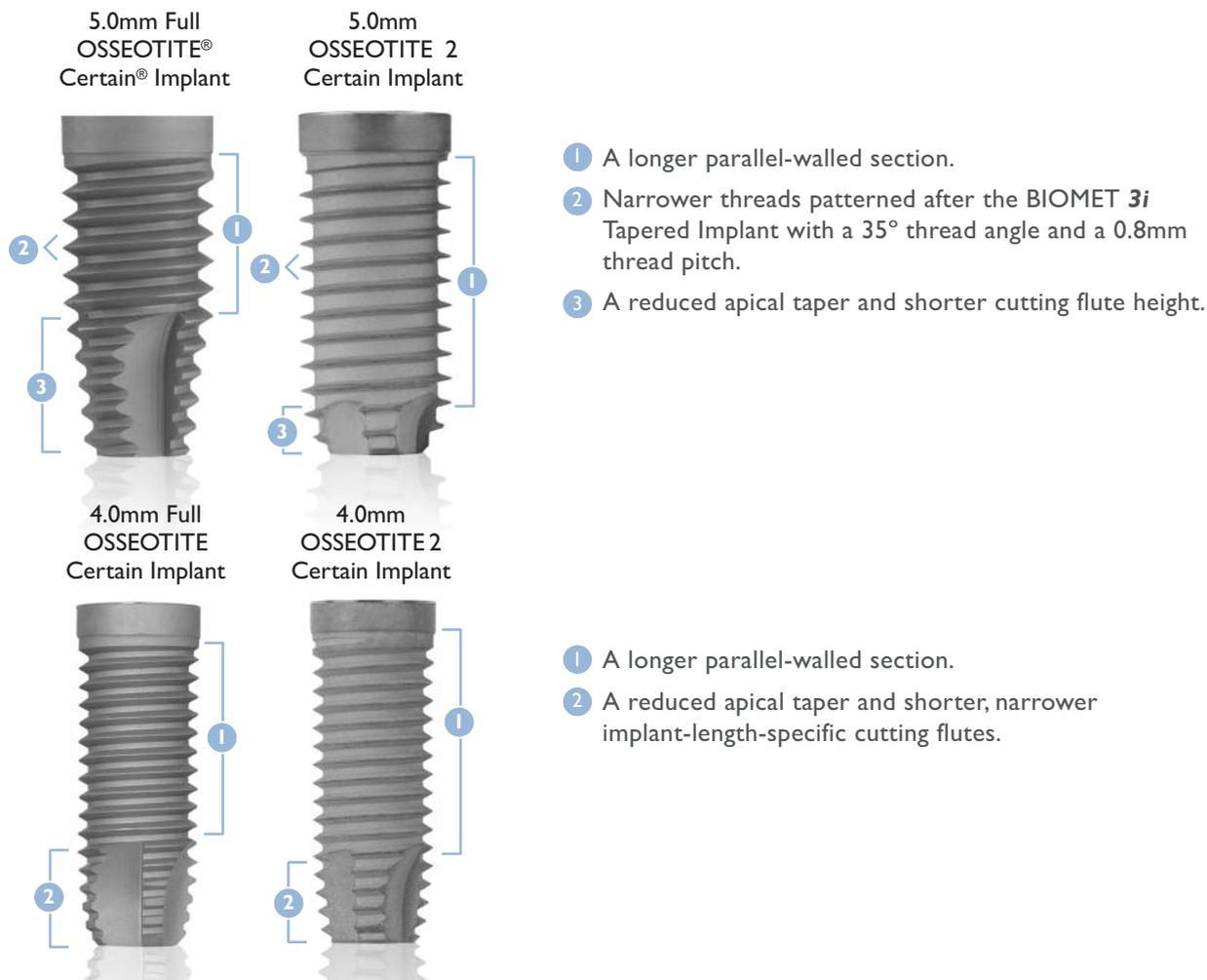


**Fig. 1.** The study implants are OSSEOTITE 2 Certain Parallel Walled Implants with the OSSEOTITE Surface extending from the apex to the implant seating surface. Implants are available in 8.5mm to 15.0mm lengths and 3.25mm, 4.0mm, 5.0mm, and 6.0mm diameters.

At all sites, bone quality and quantity were assessed using Lekholm and Zarb's criteria<sup>5</sup> (Table 1). Implants were placed according to a diagnostic drilling protocol,<sup>6</sup> meaning that selection of the final drill size was based on bone quality to increase initial primary stability. In Type I bone, the final drill size was 3.25mm (4.0mm implant diameter) and 4.25mm (5.0mm implant diameter). In Types II, III, and IV bone, the final diameter drill used to prepare the osteotomy was reduced in order to gain as much immediate bone-to-implant contact (IBIC) as possible (Fig. 4). A countersink drill was not used. Insertion torques were measured with an Elcomed drill unit (W&H Dentalwerk GmbH, Bürmoos, Austria). After seating of the implant, implant stability was assessed using Resonance Frequency Analysis (RFA) performed with an Osstell ISQ (Osstell AB, Göteborg, Sweden).

Had any implants been rotationally unstable, they would have been treated with a two-stage protocol, and those patients would have been dropped from the study. Otherwise, if a minimum insertion torque of 30Ncm was recorded before the final seating of the implant, and the implant stability quotient (ISQ) was 55 or higher, then the implant was immediately loaded. The only exceptions were single units placed in the molar region; all of these implants were placed using a one-stage protocol.

Of the 39 patients initially invited to participate in the study, all met the final inclusion criteria. A total of 78 implants supporting 39 fixed prostheses were placed

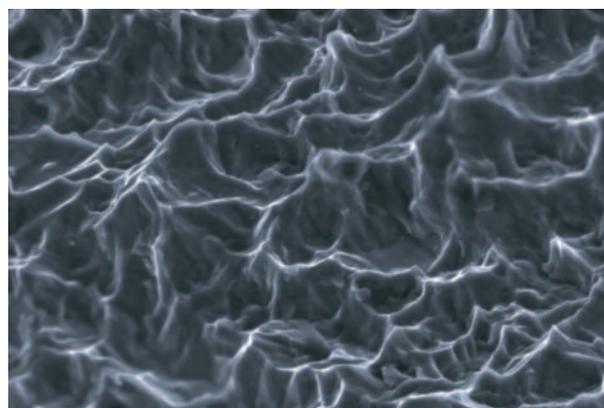


**Fig. 2.** The design of the 3.25mm and 4.0mm diameter OSSEOTITE 2 Certain Implants changed slightly from the existing OSSEOTITE Certain Parallel Walled Implants in that there is a longer straight walled section, a reduced apical taper, and modified cutting flutes. Additionally, the design change for the 5.0mm and 6.0mm diameter implants includes a narrower thread pattern, 35° thread angle, and a 0.8mm thread pitch. The thread design is the same as on the present tapered implants from BIOMET 3i.

(Tables 2 and 3). Sixty-nine of the implants were immediately loaded, while nine implants were loaded following a healing period. For the first ten days after implant placement, patients were prescribed antibiotics, twice-daily mouth rinsing with chlorhexidine (0.1%), and a soft diet.

**Prosthetic Procedures**

Immediately loaded implants were treated as follows: Before adaptation and suturing of the mucosal flaps, either PreFormance® Posts (BIOMET 3i), PreFormance Temporary Cylinders (BIOMET 3i) or Low Profile Abutments with QuickBridge® Provisional Components (BIOMET 3i) were placed to support the provisional restorations. Cantilevers were allowed in the study but were restricted to 5.0mm or less.



**Fig. 3.** SEM of the OSSEOTITE 2 Certain Implant, which is made of commercially pure (CP) Grade IV Titanium and is dual-acid-etched (DAE).

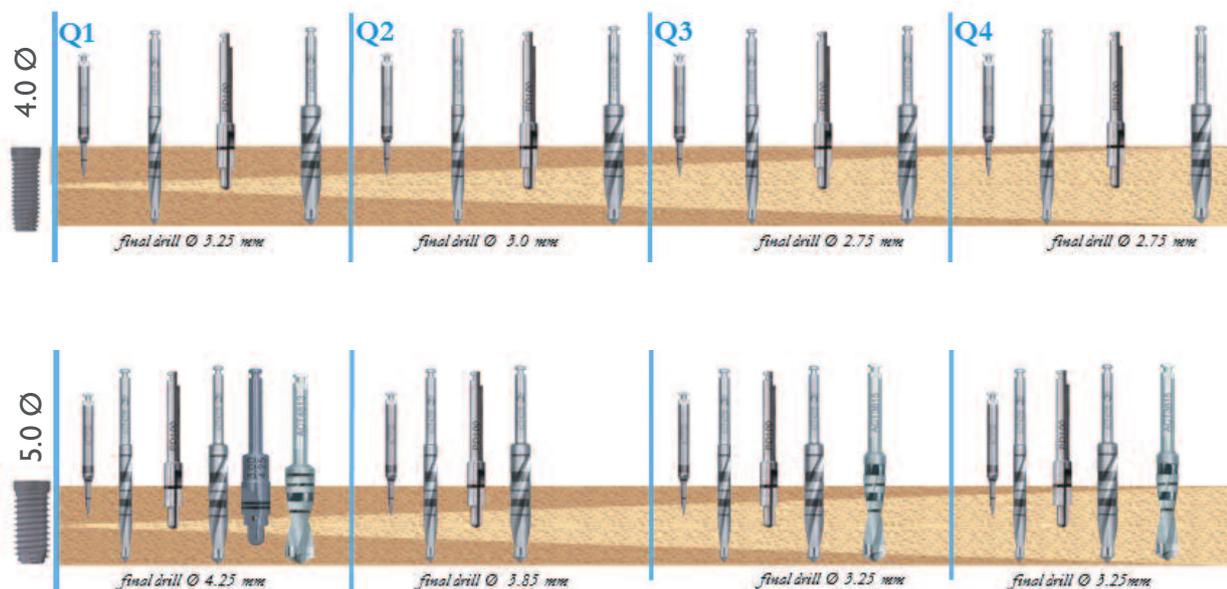


Fig. 4. Implants were placed according to a diagnostic drilling protocol, whereby selection of the final drill size was based on bone quality to increase initial stability. In Type I bone, the final drill size was 3.25mm (4.0mm implant diameter)/4.25mm (5.0mm implant diameter). In types II, III, and IV bone, the final diameter drill used to create the osteotomy was reduced in order to gain as much immediate bone-to-implant contact (IBIC) as possible.

The 30 partially edentulous and two edentulous cases included in the study (Table 2) were provisionally rehabilitated with the QuickBridge<sup>7</sup> method. In Figure 5 a typical multi-unit treatment is illustrated.

Ten single-tooth implants were placed, and for these, a PreFormance<sup>®</sup> Post was adjusted for fabrication of a provisional restoration following a non-occlusal load protocol. All provisional restorations were made chairside. A prefabricated translucent crown shell (Frasaco, Germany) was filled with composite resin and pressed over the modified PreFormance Post/Temporary Cylinder. After light-curing the composite resin, the occlusal surface and interproximal contours of the crown were adjusted extraorally. The single-unit crowns were left out of occlusion and free from proximal contacts. Subsequently, the crowns were cemented with temporary cement. In Figure 6, a typical single-unit treatment is illustrated.

For the six cases (nine implants) that were performed with a one-stage approach, BellaTek<sup>™</sup> Encode<sup>®</sup> Healing Abutments (BIOMET 3i) were placed.

Three months after implant placement, a visit was scheduled to make a new impression for fabrication of a master cast onto

which the definitive fixed restoration would be fabricated. Some impressions were made using conventional implant impression copings and some used the BellaTek Encode Impression System, which enables a traditional or digital impression to be taken of the healing abutment. From the healing abutment impressions, CAD/CAM abutments were fabricated. For the partially edentulous/edentulous cases, BellaTek Copy Mill Frameworks with porcelain application were fabricated. For the single units, BellaTek Abutments and BellaTek Copings were made.

#### Follow-up Evaluation

All patients participating in the study agreed to follow a strict and individually designed maintenance program focusing on: (1) oral hygiene, (2) stability of the fixed restorations, (3) soft-tissue health, and (4) function of the dentition. Post-treatment follow-up examinations were scheduled for three, six, and 12 months.

#### Results

None of the 78 implants failed. The overall cumulative survival rate (CSR) for implants in the study was 100% after one year (Table 4).

Resonance Frequency Analyses, performed for all 78 study implants, yielded ISQ scores at implant placement ranging

OSSEOTITE® 2 Certain® Implants					
Bone Quality	Bone Quality				No. of Implants
	1	2	3	4	
A	0	2	0	2	4
B	0	13	18	4	35
C	1	13	12	5	31
D	5	0	1	2	8
<b>Total</b>	<b>6</b>	<b>28</b>	<b>31</b>	<b>13</b>	<b>78</b>

Table 1. Bone quality and quantity according to the criteria of Lekholm and Zarb.

from 59 to 85. The mean value was 76.0 (S.D 5.4). Final seating torque ranged from 30Ncm to 70Ncm. The mean value was 53.6. No significant difference could be seen between dense and soft bone regarding the ISQ value.

Scanning electron microscopy at 2000x magnification, conducted on representative implants, qualitatively demonstrated the presence of the characteristic 1- to 3-micron peak-to-peak irregularities of the OSSEOTITE® Surface.

### Discussion

Treatment with dental implant-supported restorations has changed over the last few decades from a classic two-stage approach requiring long healing times to faster treatment models that include one-stage surgery, extraction and immediate placement, and immediate loading. Such new treatment concepts increase the demands upon clinicians, both from a surgical and prosthetic perspective.

To meet these demands, the author believes that surgical protocols should be customized. By measuring insertion torque and using RFA, the experienced surgeon can choose a combination of final drills and implants suited to the bone quality at each implant site. This can lead to better primary stability and improved clinical results. Other factors that can influence the clinical outcome are implant design and microgeometry, e.g. surface enhancements.

The macrogeometric design of the implants used in the present study (including a reduced apical taper; modified cutting flutes; and a narrower thread pattern) may contribute to primary stability. In a previous study conducted by the author and co-workers,<sup>6</sup> RFA was used to assess implants placed according to a surgical protocol that

Site	No. Prosthetic Constructions
Total Mandible	1
Total Maxilla	1
Partial Maxilla	20
Partial Mandible	10
Single Maxilla	4
Single Mandible	3
<b>Total</b>	<b>39</b>

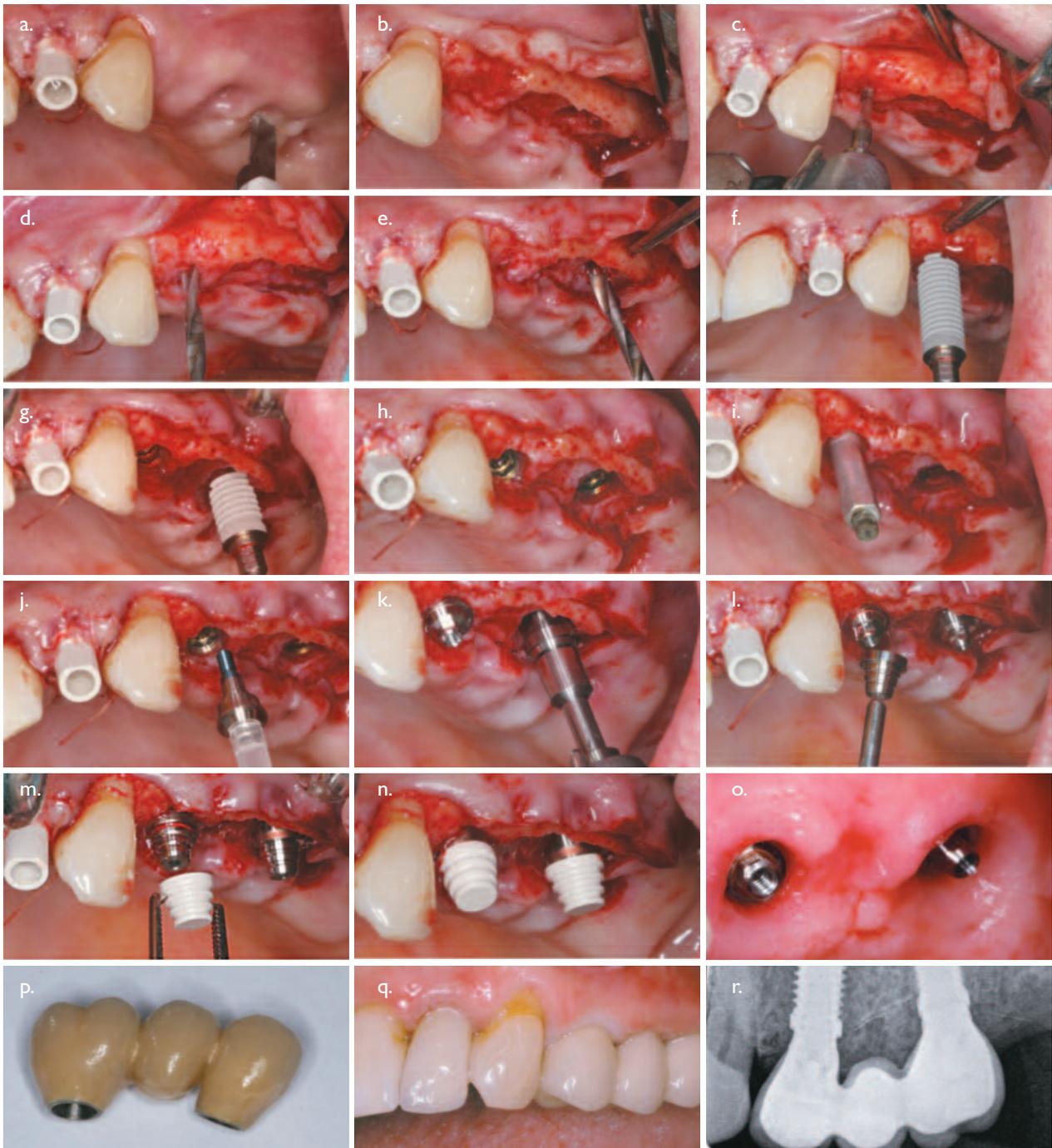
Table 2. Number of prosthetic constructions.

aimed for high primary stability. The aim was also to correlate the RFA measurements with factors related to the surgical technique, the patient, and the implant design. The results of measuring 905 Brånemark dental implants used in 267 consecutive patients showed a mean ISQ value of 67.4 (SD 8.6). A correlation between bone quality and primary stability was found, with lower ISQ values obtained for implants placed in softer bone. Lower stability values also correlated with decreased implant length. In the present study, the ISQ values after surgery were as high as 76.0 (S.D 5.4). The mean final insertion torque of 53.6Ncm also indicates high primary stability. One explanation for the high ISQ values may be the macrogeometry of the implant. The adaptive surgical protocol may also have contributed to the high ISQ values.

The OSSEOTITE 2 Certain Implant is manufactured from commercially pure titanium with the 1- to 3-micron peak-to-peak, dual-acid-etched (DAE) OSSEOTITE Surface. The large scale topography on which the features of the



**Figs. 4a-c.** A 59-year-old female patient presented with a root fracture of the maxillary lateral incisor; which required extraction. **Figs. 4d-f.** The fractured tooth root was removed, and the extraction site was prepared for implant placement. **Figs. 4g-i.** A 3.85mm diameter twist drill was used for final preparation of the osteotomy, and a 5.0mm x 13.0mm OSSEOTITE® 2 Certain® Implant was placed. **Figs. 4j-l.** A PreFormance® Temporary Cylinder was placed into the internal interface of the implant and trimmed for fabrication of a provisional Low Profile Abutment restoration. **Figs. 4m-o.** A crown shell fabricated from a clear template was filled with acrylic resin and seated over the PreFormance Post, then removed for modifications. **Figs. 4p-r.** The provisional restoration was completed extraorally, seated, and a periapical radiograph was taken. The patient left with a provisional restoration in place.



**Figs. 5a-c.** A 57-year-old female patient presented with several recently extracted and missing teeth in the maxilla. She desired fixed restorations. A midcrestal incision was made to reflect a flap. **Figs. 5d-f.** Preparation of the osteotomies was accomplished with a series of twist drills following the manufacturer's protocol. **Figs. 5g-i.** 4.0mm diameter OSSEOTITE® 2 Certain® Implants were placed into the prepared sites. An OSSTELL ISQ was placed to measure the ISQ value of the implants to determine primary stability. **Figs. 5j-l.** Either PreFormance® Temporary Cylinders or Low Profile Abutments were placed into the implants. The Low Profile Abutments were tightened to 20Ncm using a Standard Abutment Driver Tip and a torque device. **Figs. 5m-o.** QuickBridge® Titanium Temporary Cylinders were placed onto the abutments, followed by PEEK QuickBridge Caps for fabrication of a provisional restoration. **Figs. 5p-r.** Eight weeks later, the definitive restoration was placed, and a periapical radiograph was taken.

Implant Length	Diameter 4.0	Diameter 5.0	Total No.
15.0mm	24	20	44
13.0mm	12	4	16
11.5mm	1	2	3
10.0mm	7	6	13
8.5mm	2	0	2
<b>Total</b>	<b>46</b>	<b>32</b>	<b>78</b>

Table 3. Lengths of included implants.

Interval	Implants in Interval	Failures	CSR
0 – 6 months	0	0	100%
6 – 9 months	14	0	100%
9 – 12 months	47	0	100%
12 +	17	0	-

Table 4. Life-table of OSSEOTITE® 2 Certain® Parallel Walled Implants.

OSSEOTITE Surface are superimposed has an average surface roughness of Sa~.5 microns. It should be noted that in terms of surface roughness measured in this manner, the surface is still defined as minimally rough.<sup>8</sup>

The OSSEOTITE Surface is well documented. Histologic analysis<sup>9</sup> indicated that at six months of unloaded healing, the mean BIC value for OSSEOTITE-Surfaced Implants (72.96% ± 25.13%) was statistically significantly higher ( $P < 0.05$ ) than the mean BIC value for machined-surfaced implants (33.98% ± 31.04%). Trisi, et al<sup>10</sup> studied the actual bone-to-implant contact for OSSEOTITE Implants. They found that the OSSEOTITE Surface showed a greater bone-to-implant contact than expected, whereas the actual bone-to-implant contact for machined-surfaced implants was mostly lower than the expected values. They concluded that the OSSEOTITE Surface appears to exert a positive effect on the amount of bone approaching the implant surface and can be described as conductive, while the machined surface is nonconductive.

Drago and Lazzara<sup>11</sup> reported on 93 OSSEOTITE Implants that were restored with fixed provisional crowns out of occlusion immediately after implant placement. Thirty-eight partially edentulous patients were included in the study. All implants were immediately restored with prefabricated

abutments and cement-retained provisional crowns without centric or eccentric occlusal contacts. The implants were restored with definitive restorations approximately 8 to 12 weeks after placement. All patients included in the study were followed for at least 18 months after implant placement. Seventy-seven of the 93 implants satisfied the inclusion criteria. Seventy-five implants became osseointegrated. The overall survival rate was 97.4%.

OSSEOTITE 2 Implants have an etched surface all the way to the top of the implant. An altered microtexture in the coronal part of an implant might have a bone-preserving effect. On the other hand, a rough surface exposed to the oral cavity might lead to peri-implantitis. Zetterqvist, et al<sup>12</sup> followed 112 patients who were enrolled at seven centers. They followed 139 control and 165 test implants (total: 304 implants). With more than five years of post-loading evaluations, there was one declaration of peri-implantitis associated with a control implant that was successfully treated later. Clinical probing and radiographic assessments did not reveal differences between groups in mucosal health outcomes or other signs of peri-implantitis. The researchers concluded that the studied material did not show any increased risk of peri-implantitis for fully etched implants compared to hybrid implants.

## Conclusion

With this one-year follow-up study, OSSEOTITE® 2 Certain® Implants appear to be a viable option for implant rehabilitation. The indications that point to primary stability were present in this study and can provide the clinician with the option to pursue one-stage or immediate-loading protocols. Analysis of radiographic data gathered for this ongoing study, along with longer follow-up time, are required to confirm these initial findings.

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*The contributing clinician has a financial relationship with BIOMET 3i LLC resulting from speaking engagements, consulting engagements, and other retained services.*