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Inside this issue:

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report

Clinical performance of the *3i* T3® Implant: Observations and an interim report

Pär-Olov Östman, DDS, PhD[†] and Johanna Östman, DDS



Contemporary implant dentistry has increasingly focused on ways of accelerating treatment and sustaining aesthetic results over the long term. To accomplish this, achievement of both primary and secondary stability are essential. The implant surface significantly influences the extent to which both kinds of stability occur; with submicron, micron, and course roughness properties all playing a role. In the prospective clinical study described here, 164 *3i* T3 Implants were placed in 97 patients. After 6-18 months of follow-up, the cumulative survival rate was 100%.

Key Words: implants, accelerated loading, immediate provisional restoration, implant surface, immediate loading

Introduction

Implant design and surgical protocol modifications aim at shortening treatment time and expanding the indications for implant treatment in conjunction with improving functional and aesthetic outcomes. All this is done with the ultimate goal of increasing patient satisfaction. Due to improved implant macro designs, surface modifications, insights into surgical techniques, and better biologic understanding, implant therapy has become more predictable, yielding high survival rates.^{1,2} Whereas in the past, implant osseointegration was the main concern, the focus has shifted to accelerated loading protocols and preservation of crestal bone levels. The latter is a prerequisite for soft-tissue stability and predictable aesthetic outcomes.

Primary and secondary stability of the implant are preconditions for a successful outcome.³ The degree of primary stability at the time of implant placement

depends on factors related to the properties of the bone, the design of the implant, and the surgical technique.⁴ Secondary implant stability depends on the tissue response to the surgery and the implant material.⁵ In a prospective immediate loading study by Östman et al,⁶ the investigators placed 139 NanoTite™ Tapered Implants (BIOMET *3i*, Palm Beach Gardens, Florida, USA) and reported a mean insertion torque of 53.1Ncm, a mean ISQ of 73.3, and a survival rate of 99.2%. Placing tapered implants into fresh molar extraction sockets, Block⁷ reported mean ISQ values of 77 in the mandible, 73 in the maxilla, and a survival rate of 97.2%. Even when accelerated treatment is not applicable, good primary stability minimizes micromotion and reduces the risk of non-integration.⁸ When clinical conditions are good, primary stability can provide additional benefits, permitting early or immediate provisional restoration for Guided Tissue Preservation™ to better meet aesthetic demands.



The surface of dental implants is critical to establishing and sustaining aesthetic outcomes. One of the earliest strategies for enhancing osseointegration was to roughen the implant surface. When compared to the relatively smooth, anisotropic turned titanium surface, a roughened surface was found to increase bone-to-implant contact and improve the strength of the bone-to-implant interface.⁹ Histological research showed *de novo* bone formation on surface-modified implants. In contrast, osseointegration of turned surface implants mainly was achieved by distance osteogenesis.

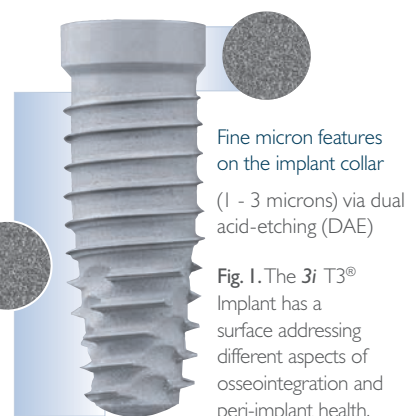
While these early surface alterations were effective at improving aspects of osseointegration in terms of bone-to-implant contact and healing response, they often caused unforeseen problems. Mucosal and other peri-implant complications such as delamination of HA coatings were reported for this first generation of roughened dental implants. This led to efforts to better understand the effect of surface roughness on bone biology and assess the risk of biological complications. Research demonstrated that it was possible to influence implant anchorage by altering the surface structure morphology.¹⁰ In this context, Wennerberg and coworkers described and classified surface roughness in a series of animal studies using tools including histomorphometry and mechanical testing. These experiments provided clear evidence that the bone response to moderately roughened (Sa 1-2 μm) surfaces was significantly stronger than to smoother (Sa <1.0 μm) or rougher (Sa >2.0 μm) ones.¹¹⁻¹³

Implant survival rates in compromised bone improved with the Dual Acid-Etched (DAE) OSSEOTITE® Surface as compared to the turned BIOMET 3i Surface.^{14,15} This prompted interest in extending the DAE OSSEOTITE Surface coronally up to the implant seating platform.

Coarse and fine micron features

Coarse:
(10+ microns)
via resorbable
calcium phosphate
media blast

Fine:
(1 - 3 microns)
via dual acid-etching
(DAE) on top of the
blasted surface



Fine micron features
on the implant collar
(1 - 3 microns) via dual
acid-etching (DAE)

Fig. 1. The 3i T3®
Implant has a
surface addressing
different aspects of
osseointegration and
peri-implant health.

The potential benefits of having the DAE complexity on the entire implant surface in contact with bone were weighed against the possibility of increasing the incidence of peri-implantitis. A series of animal investigations were initiated in beagle dogs to determine the safety of the roughened surface in contact with the peri-implant soft-tissue lining. Abrahamsson and coworkers¹⁶ performed an experiment to study the composition of the soft-tissue barrier that formed in response to turned or DAE-surfaced healing abutments. At the end of a six-month period during which

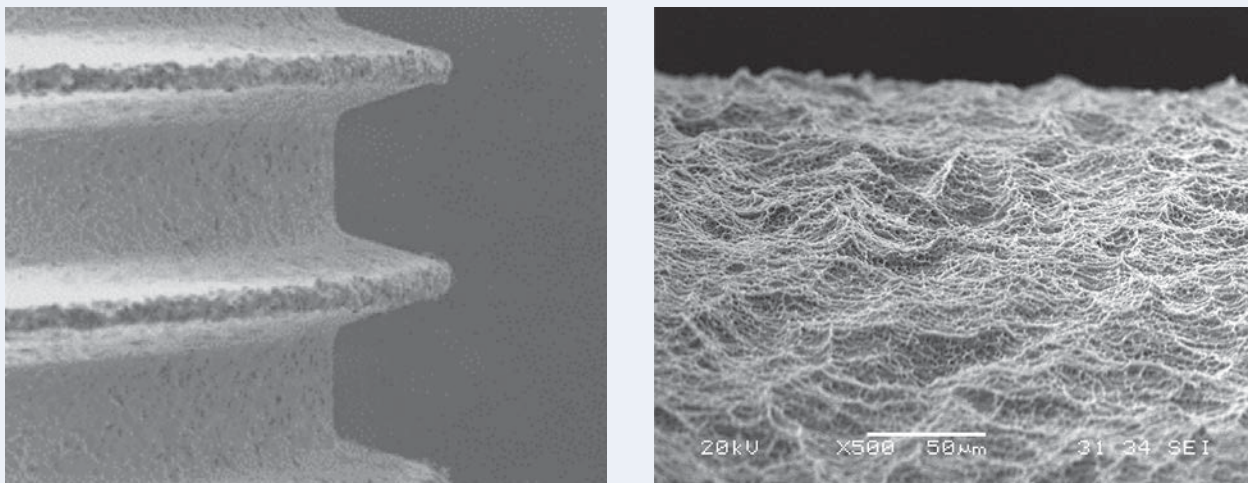


Fig. 2. The 3iT3® Implant surface at different magnifications: 50x, 500x, 2,000x, and 30,000x.

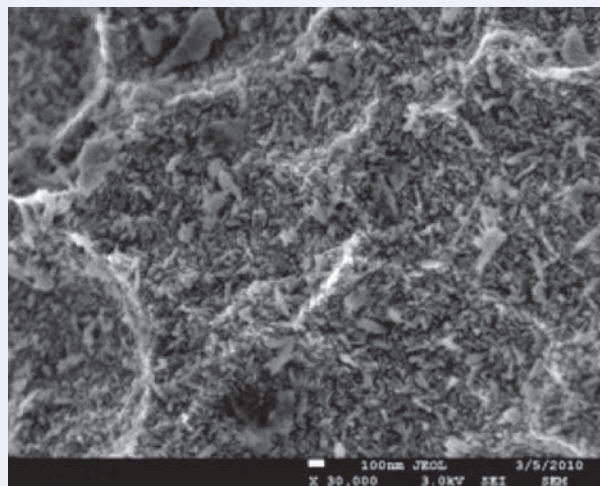
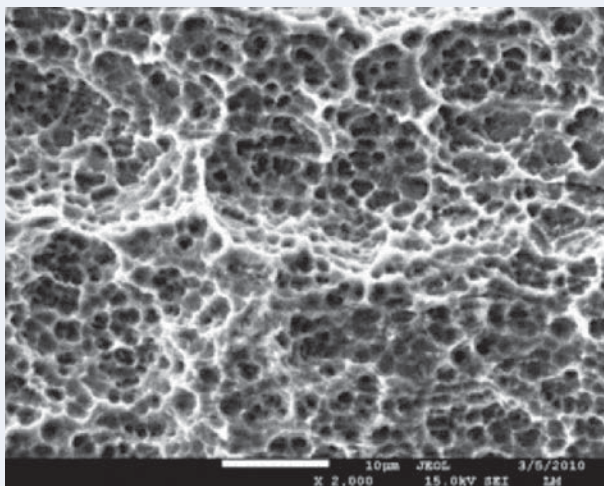
proper plaque control was maintained, biopsies including the implant and the surrounding soft and hard tissues were obtained. The attachment between the peri-implant mucosa and abutment was similar both quantitatively and qualitatively. The attachment was comprised of a barrier epithelium and a zone of connective tissue attachment of similar dimensions. It was concluded that the roughness of the titanium surface did not influence soft-tissue attachment formation. A similar experiment involving six months of plaque accumulation resulted in the establishment of an inflammatory lesion in the connective tissue of the peri-implant mucosa, but the location, size, and cell composition of this lesion did not differ between DAE OSSEOTITE® and turned abutments. Hence it was concluded that the different surface characteristics failed to influence plaque formation and inflammatory response in the peri-implant mucosa.¹⁷

To assess the risk for peri-implantitis, a long-term randomized-controlled multicenter study of hybrid versus full OSSEOTITE Implants was designed. In that study, the control implants had the hybrid design, while the entire surface of the test implants received the DAE treatment. All implants were placed in a one-stage surgical approach, and provisional prostheses were delivered and functioning six weeks after surgery. Definitive prostheses were delivered within six months and were followed for up to five years. In this study, determination of the presence of peri-implantitis was declared if the following were observed:

severe mucositis with positive findings of bleeding and/or suppuration upon probing; a probing depth of more than 5mm; and radiographically detectable crestal bone loss that was progressive, i.e. greater than 5mm. The outcome of the study after five years, with 139 control and 165 test implants, showed one hybrid implant having peri-implantitis (0.7%) and none of the fully etched implants showing an increased risk. Other than the one infected control implant, in both groups there were no increases in probing depths greater than or equal to 3mm. Zetterqvist and coworkers demonstrated that the fully etched surface reduced crestal bone loss as compared to the hybrid design (0.6mm versus 1mm, $p < .0001$).¹⁸ This result was consistent with the 2009 one-year results of Baldi et al,¹⁹ who found a statistically significant reduction in bone loss for fully etched versus hybrid implants (0.6mm versus 1.5mm, $p < .02$).

The NanoTite™ Surface, featuring nanotopography with calcium phosphate nanoparticles added to the dual acid-etched titanium surface, was introduced in 2007. The application of nanotechnology to implant surfaces may enhance the osteoconductivity of the implant.²⁰ Theoretically, the bioactive topographical feature, which enhances the initial osseointegration cascade, may enhance implant success.²⁰⁻²²

In recent years, studies of submicron, micron, and coarse roughness properties have been conducted. All three layers appear to play an important role in overall



osseointegration, with each layer addressing bone formation at different time points. *In vitro* studies have evaluated the surface-topography effects on bone formation through osteoconduction, including the steps of protein absorption, fibrin clot retention, and platelet interaction.²³⁻²⁶ For example, Davies reported that surfaces enhanced via blasting or acid etching displayed significantly greater fibrin-retention forces than machined surfaces.²⁵ Kikuchi et al have documented that microtopographic surfaces, defined as those exhibiting features in the scale range of platelets (≤ 3 microns), displayed greater platelet activation than smoother surfaces.²⁶ The **3i T3**® Implant surface targets different needs in two distinct regions of the implant. The coronal aspect of the implant has a microtopography similar to the fully etched OSSEOTITE® Implant.

Materials and Methods

Study patients and preliminary inclusion criteria

This prospective single-center study reports on consecutive included patients in need of implant-supported prostheses. Inclusion was based on the following 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, a patient age of less than 18, and failure to achieve a final insertion torque of at least 20Ncm. 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, one-stage surgery, or immediate loading assessed at the implant-placement surgery.

Study implants

The **3i T3** Implants are available in lengths of 8.5mm to 15mm and diameters of 4mm, 5mm, and 6mm (Fig. 1). The present study used only 4mm diameter implants with 3.4mm restorative platforms and 5mm diameter implants with 4.1mm restorative platforms.

The **3i T3**® Implant surface (Fig. 2) addresses different aspects of osseointegration and peri-implant health. The coronal aspect has a microtopography similar to the fully etched OSSEOTITE Implant, consisting of a minimally rough ($S_a < 1.0\mu\text{m}$) surface topography due to the 1 – 3 micron pitting. From the base of the collar to the apical tip, the **3i T3** Implant has greater roughness ($S_a \sim 1.4$ microns) attributable to the 10+ micron pitting from the resorbable CaP grit blast treatment, which is applied prior to the etching in this area. The entire implant has CaP nano particles superimposed on the surface as a final step, thereby creating a tri-level surface below the coronal aspect.²⁷ These features moreover are intended to influence *de novo* bone formation and the strength of the resulting bone-to-implant interface at different time points: nano roughness to initiate osseointegration, DAE for the next osseointegrative time point, and coarse micron features for long-term bone locking.

Quality I, Dense Bone



Quality 2 & 3, Medium Bone



Quality 4, Soft Bone



Fig. 3. Implants were placed according to the manufacturer's recommended drilling protocol. In Type I bone, the final QSD drill size was 4mm or 5mm, depending on the implant diameter; with an appropriate tap used as the final step. In medium (Type II and III) bone, the final diameter QSD drill used to prepare the osteotomy corresponded to the implant diameter and length. In soft bone (Type IV), the final QSD drill used was one length shorter than the implant length, enabling apical compression. For complete and detailed surgical protocol, refer to the *3iT3®* Implant surgical manual.

Implant-placement surgery and final inclusion criteria

Patients were administered oral antibiotics and sedatives one hour before surgery. At all sites, bone quality and quantity were assessed using Lekholm and Zarb's criteria.²⁸ Implants were placed according to the manufacturer's recommended drilling protocol. In Type I bone, the final drill used was the 4mm or 5mm Quad Shaping Drill (QSD) (depending on the implant diameter), with an appropriate tap used as the final step. In medium (Type II and III) bone, the final diameter QSD drill that was used to prepare the osteotomy corresponded to the implant diameter and length. In soft bone (Type IV), the final QSD drill used was one length shorter than the implant length, enabling apical compression intended to lead to higher primary stability (Fig. 3). Insertion torques were measured with an Elcomed drill unit (W&H Dentalwerk GmbH, Bürmoos, Austria). After seating of the implant, stability was assessed using Resonance Frequency Analysis (RFA) performed with an Osstell ISQ (Osstell AB, Göteborg, Sweden). If a minimum insertion torque of 30Ncm was recorded, and the Implant Stability Quotient (ISQ) was 65 or higher, 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.

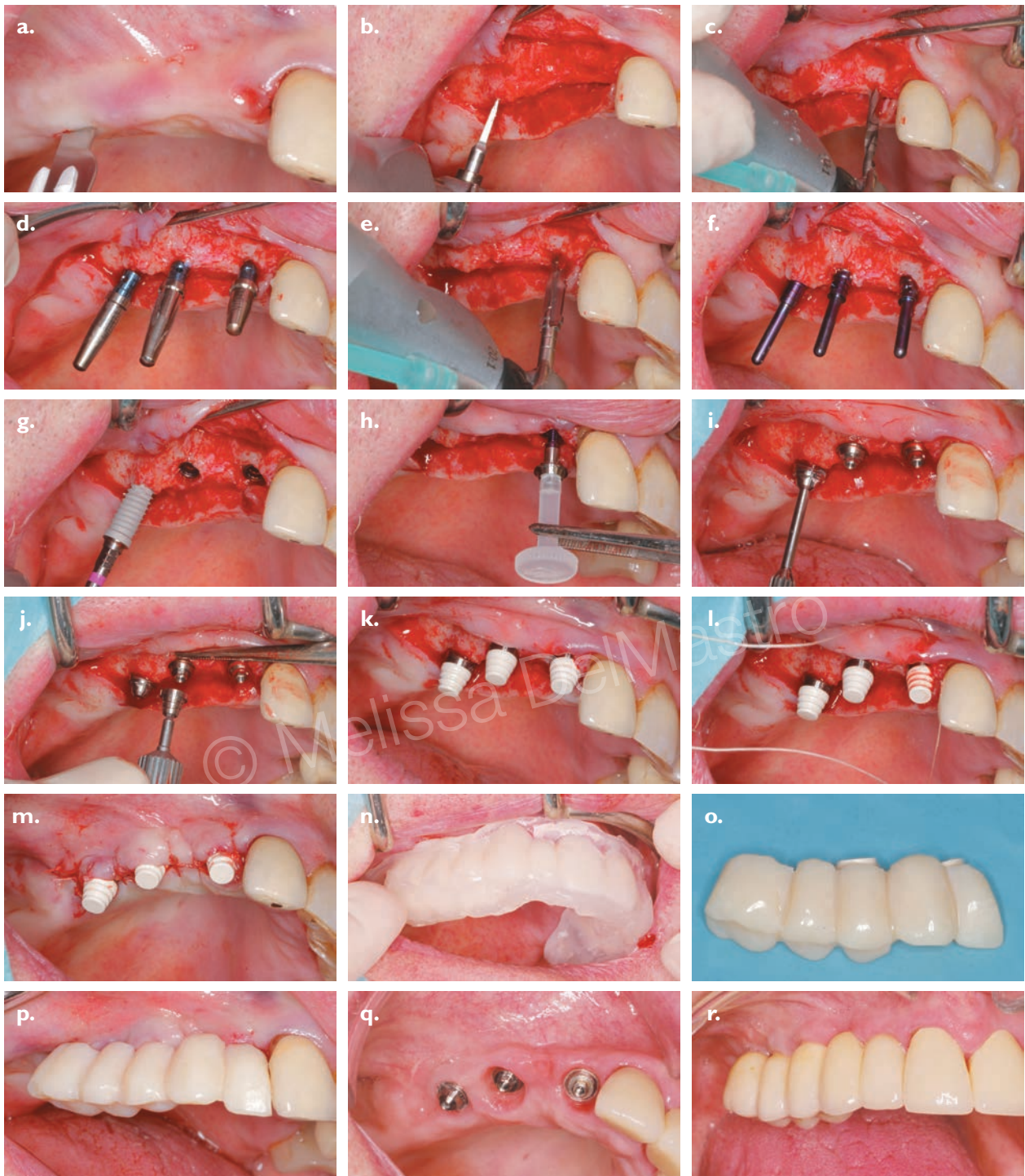
Prosthetic procedure

Immediately loaded implants were treated as follows: Before adaptation and suturing of the mucosal flaps, either PreFormance® Temporary Cylinders (BIOMET 3i) or Low Profile Abutments with QuickBridge® Provisional Components (BIOMET 3i)²⁹ were placed to support the provisional restorations. In partial and full-arch restorations, cantilevers were allowed but restricted to 5mm or less. The provisional restorations were designed to give soft-tissue support and shape the peri-implant mucosa for optimal aesthetic results. Figures 4 and 5 are examples of multiple-unit and single-unit rehabilitations.

BellaTek® Encode® Healing Abutments were placed into the implants for a single-stage protocol. Healing abutments of various sizes were selected to optimize the soft-tissue architecture. The implants were loaded after eight weeks of healing.

Results

A total of 164 implants were placed in 97 patients. No patients were excluded, as all implants had a final insertion torque of 20Ncm or more. At 89 (54%) of the implant sites, a mid-crestal incision was made, and a mucosal flap



Figs. 4a-b. A 75-year-old male presented seeking treatment for his edentulous right maxilla. A midcrestal incision was made extending from the lateral incisor through the first molar tooth position, and a mucoperiosteal flap was elevated. **Figs. 4b-e.** The standard drilling protocol was followed to create three osteotomies, and a 4mm x 15mm QSD drill was used for final preparation in each site. **Fig. 4f.** Proper implant depth and position were evaluated using the QSD depth indicators. **Fig. 4g.** The most posterior osteotomy was tilted to avoid interference with the sinus cavity. Three 4mm x 15mm 3i T3® Implants were placed with a final seating of 50Ncm and ISQs ranging from 72 to 78. **Figs. 4h-i.** Immediately after implant placement, Low Profile Abutments were placed. The most posterior abutment was a 17-degree angled abutment, while the two anterior abutments were straight with a 1mm collar. The seating surface diameter of the abutments was 3.25mm, thus enabling platform switching with the 4mm diameter implant seating surface. **Figs. 4j-p.** Following abutment placement, QuickBridge® Provisional Components were placed on the abutments, and a provisional restoration was fabricated chairside using a translucent mold and self-curing acrylic resin. **Figs. 4q-r.** Eight weeks later, a pick-up impression was made, and a BellaTek® Copymilled Framework with porcelain applied was fabricated as the definitive restoration.

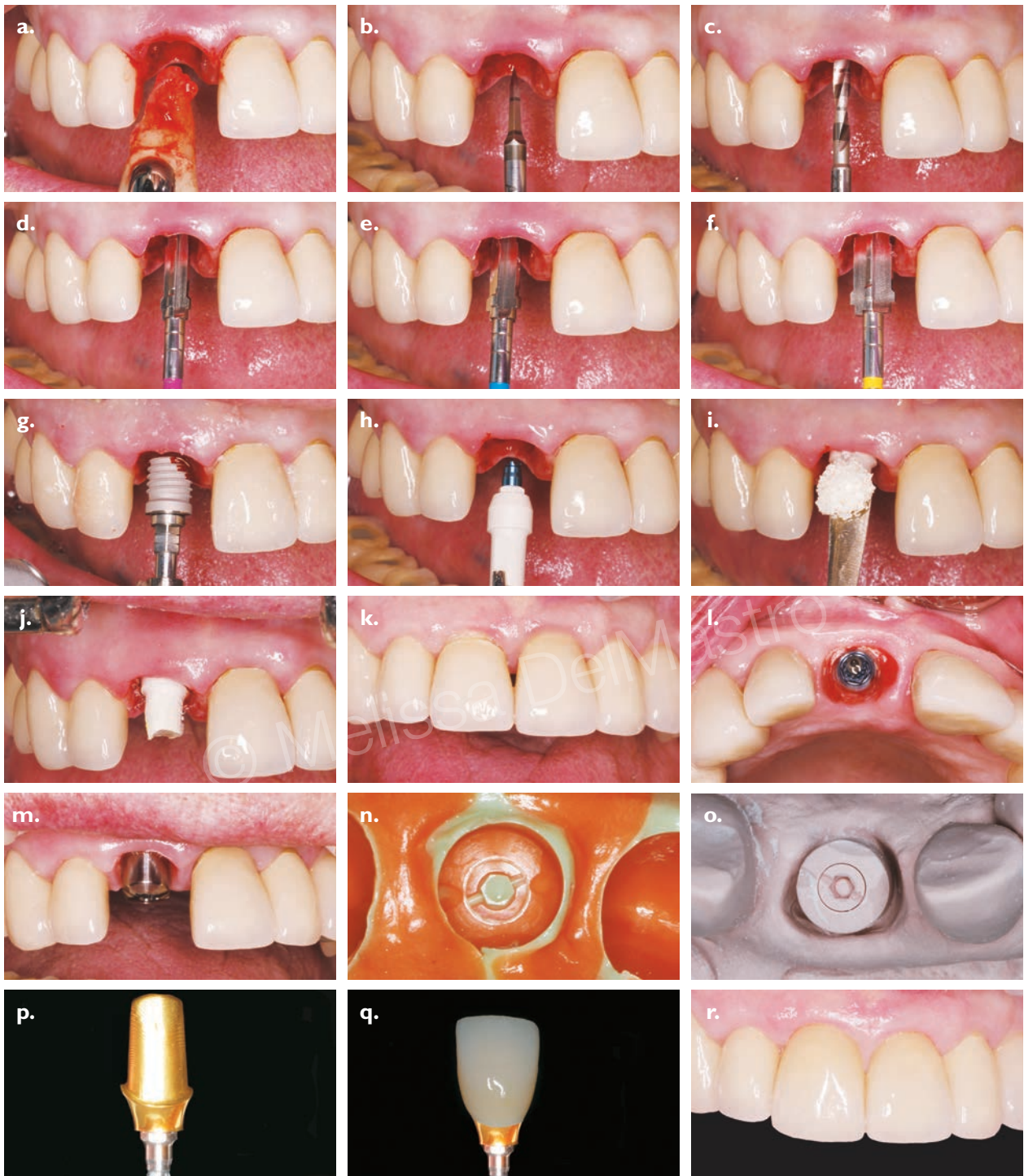


Fig. 5a. An 84-year-old female patient presented with a maxillary central incisor requiring extraction due to periodontal complications. **Figs. 5b-e.** The tooth was extracted, and the site was prepared for implant placement. **Figs. 5f-g.** A 5mm x 15mm QSD Drill was used for final preparation of the osteotomy, and a 5mm x 15mm 3iT3® Implant was placed. Final seating torque for the implant was 70Ncm, and the ISQ reading was 82. **Figs. 5h-i.** A PrePerformance® Post was placed into the internal interface of the implant, and the void between the implant and the buccal bone was filled with Endobon® Xenograft Granules. **Figs. 5j-k.** The post was trimmed to fit into the reused crown, which was then filled with self-curing acrylic resin to secure it to the post. **Figs. 5l-o.** Eight weeks after implant placement, the provisional restoration was removed, a BellaTek® Encode® Healing Abutment was placed, and an impression was made. **Figs. 5p-r.** A definitive BellaTek Abutment with a titanium nitride coating was fabricated and delivered to the patient, along with a zirconia crown.

Bone Quality				
Bone Quantity	I	II	III	IV
A	0	0	0	4
B	3	21	70	29
C	4	13	4	12
D	0	0	4	0
Total	7(4%)	34(21%)	78(48%)	45(27%)

Table 1. Distribution of study implants according to bone quality and quantity. One hundred twenty-three (75%) of the implants were placed in soft bone (Type III or IV).

	Patients	Implants
Total Maxilla	9	40
Total Mandible	2	8
Partial Maxilla	16	37
Partial Mandible	8	17
Single Maxilla	47	47
Single Mandible	15	15
Total	97	164

Table 2. Number of patients and implants, according to treatment.

was reflected. At 75 sites (46%), implants were placed immediately after extraction, and no flap was reflected. One hundred twenty-three (75%) of the implants were placed in soft bone (Type III or IV) (Table 1).

A total of 11 full-arch, 24 partial, and 62 single restorations were included (Table 2). The overall cumulative survival rate for implants in the study was 100% after 6-18 months (mean follow-up 12 months).

One hundred thirty-four (82%) implants were non-occlusally immediately loaded, and 30 (18%) implants were placed in a one-stage delayed loading procedure.

Final seating torque ranged from 20 to 70 with a mean value of 48.3Ncm (SD 14.3) (Table 3). The final seating torque of 148 implants (90.2%) was 35Ncm or more. Resonance Frequency Analyses (RFA) ranged from 53 to 83 ISQ, and the mean value was 73.8 (S.D 7.6) (Table 4). One hundred forty-four (88%) of the implants had an ISQ of 65 or higher.

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 extraction, one-stage surgery with immediate placement, and immediate loading. Such new

treatment concepts increase the demands upon clinicians, both from a surgical and prosthetic perspective. Firm initial stability of the implant is a prerequisite for more challenging treatments. In the present study, the mean final torque of 48.3Ncm and ISQ of 73.8 indicate that when using the 3iT3® Implant, sufficient stability can be reached in most of the cases with demanding treatment modalities. Studies have shown that implants with a torque of 30-35Ncm and an ISQ of 65 or more are candidates for immediate loading.³⁰

Almost 90% of the implants in this study reached these levels. In an *in vitro* study by Pagliani et al,³¹ RFA and displacement measurements correlated with bone density were analyzed. It was concluded that RFA measurements reflect the micromobility of dental implants, which in turn is determined by the bone density at the implant site. The study also showed that the correlation between ISQ and micromotion is non-linear: Whereas micromotion is reduced by approximately 50% as the ISQ increases from 60 to 70, the increase in stability as ISQ increases from 70 to 80 is dramatically less.

The majority of dental implants in use today are moderately rough at the micro level, with an Sa value in the range of 1-2 microns.²⁰ One way of increasing the roughness but retaining the documented effect of DAE is to grit-blast the surface and then etch it to obtain

Torque	No. Implants	%
20	15	9%
30	1	1%
35	5	3%
40	47	29%
50	57	35%
60	5	3%
70	34	21%
Total	164	100%

Table 3. Final seating torque ranged from 20 to 70 with a mean value of 48.3Ncm (SD 14.3). Ninety-one percent of the implants had a torque equal to or higher than 35Ncm.

ISQ	No. Implants	%
50-60	9	5.4%
60-65	9	5.4%
65-70	17	10 %
70-85	129	79.2%
Total	164	100%

Table 4. Resonance Frequency Analyses (RFA) ranged from 53 to 83 ISQ, and the mean value was 73.8 (SD 7.6). Eighty-nine percent had an ISQ equal to 65 or higher.

a dual surface roughness and remove any embedded blasting particles. The etching also reduces the highest peaks while creating smaller pits, leading to a more complex surface texture. Clinical comparative studies have shown a tendency towards better clinical results with moderately roughened surfaces than minimally rough (e.g. less than 1 micron Sa) ones. However, this difference is seldom significant, except in compromised bone sites.²⁰

Östman and co-workers showed excellent short-term results for immediately loaded NanoTite™ PREVAIL® and Tapered Implants with an Sa value of approximately 0.4 microns and a nanometer Sa value of 23.^{6,21} Klokkevold et al²² measured reverse torque (RTQ) for dual acid-etched and moderately rough surfaced implants at one, two, and three months after placement in rabbit tibias. They showed that the rougher-surfaced implants had significantly higher RTQ results at two and three months after placement as compared to the dual acid-etched surface. However, there was no difference between the two surfaces at one month. The authors attributed the higher RTQ to the moderately rough surface's effect later in the osseointegration process, when the increased depth of the topography and subsequent void volume permitted additional bone in-growth for mechanical interlocking. Davies et al³³ showed similar results in an animal study. They concluded that nano, micro, and coarse-

micro features all play an important role at different time points in the initial stage of osseointegration.

Conclusion

Short-term data show a high survival rate for the 3i T3® Implant. High primary stability can be achieved using the recommended drilling protocol in all bone qualities. Almost 90% of the implants may be candidates for immediate loading. Radiographic analysis and longer follow-up is needed to verify the clinical success.

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Education Through Innovation.

The Institute for Implant and Reconstructive Dentistry (IIRD®) located in Palm Beach Gardens, Florida is the global training and education department of BIOMET 3i. Based on the principles developed by Dr. Richard Lazzara,[†] the IIRD seeks to apply evidence-based research, advanced techniques, and practical methods into educational content that allows clinicians to develop meaningful clinical expertise.

The IIRD delivers a world of innovation to help clinicians progressively grow their knowledge and capabilities in all areas of their practice. In addition to learning about the latest technologies and techniques from the world-class faculty, the IIRD provides educational programs on topics from identifying candidates for implant and reconstructive therapy, to treatment planning and team development.

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[†]Dr. Lazzara has a financial relationship with BIOMET 3i LLC, resulting from speaking engagements, consulting engagements and other retained services.



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