A Four-Year Survival Rate Multicenter Prospective Clinical Study on 377 Implants: Correlations Between Implant Insertion Torque, Diameter, and Bone Quality

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The purpose of this study was to evaluate the survival rate and incidence of prosthetic complications in 377 implants with a double octagon connection. Furthermore, the correlations among implant dimensions (diameter and length), bone quality, and insertion torque were investigated. A 4-year multicenter prospective clinical study was designed to evaluate the survival rate of 377 dental implants inserted in 189 patients between January 2004 and April 2010. After an average follow-up of 46 months, the implant survival rate was 99.7%, and the incidence of complication was 0.53%. Moreover, insertion torque was statistically related in a significant way to implant diameter. The connection system seemed to reduce the risk that the prosthetic component screw would loosen. Within the limits of this study, it was observed that a wider diameter corresponded to a higher implant primary stability. Implant length did not seem to be critical in obtaining higher primary stability.

Key Words: dental implants, bone quality, torque

INTRODUCTION

D ental implant/prosthetic rehabilitations are supported by more than 30 years of scientific evidence, which proves that these kinds of procedures are safe and predictable. 1 The concept of survival and success rates is of great importance for clinicians in implant dentistry. Survival rate is a liberal assessment related to dental implant mobility as a primary criterion for evaluation. Clinical success rates, however, are more stringent and take into account additional factors, including bone loss, pain, signs of bleeding and inflammation around the peri-implant tissues, and prosthetic complications. Recent long-term studies have reported a success rate of 95% in 668 dental implants supporting fixed partial denture prostheses. The observation period was 6.5 years with a range from 1.5 to 15 years. 5 In another study, 1583 implants were observed for a period ranging from 1 to 5 years with a success of 96.5%. 6 A survival rate of 98% was described in a sample of 2549 implants followed for 1 to 6 years. 2–4 The efficiency of implant abutment connection is an important factor for clinical success. 5

The biomechanical aspect of a connection is fundamental because it is subjected to micromovements and, consequently, a pumping effect. 6 These factors may adversely affect the long-term stability of the peri-implant hard and soft tissues. Connection micromovement is also a risk factor that can lead to the loss of screw preload, thus increasing biological (eg, bacterial infiltration, stress on marginal bone) and biomechanical (eg, screw fracture) risks. 7 Internal connections have generally proven to be more reliable from a biomechanical point of view. The purpose of the new connection shape of dental implants is to improve fixture-abutment stability and reduce a prosthetic step. 6–8

To overcome the antirotation deficiency of the external hexagon, a variety of new connections have evolved. A study 8 comparing 3 kinds of connections demonstrated that the internal hexagon and internal octagon offer greater stability of the abutment and a higher resistance to cyclic fatigue than the external hexagon. Studies on external connections suggest they are less efficient than internal connections. 9,10 The advantages offered by internal connections include greater stability and a better response to lateral forces. The highest percentage of prosthetic complications occurs in single-tooth rehabilitations in posterior areas with a high masticatory load. 11,12 A meta-analysis 13 showed an incidence of connec-
tion-related complications of 7.3% after 5 years of prosthetic loading. These data are confirmed in a more recent systematic review, where the authors report a 12.7% incidence of screw preload loss and a 0.35% incidence of screw fracture.

It is generally accepted that the diameter and length of an endosseous dental implant and its stability at placement are critical in establishing and maintaining osseointegration. The biomechanical success of a dental implant is related to stress transfer to the surrounding bone. Stress distribution from an implant to the surrounding bone depends on the type of loading, the bone-to-implant contact, the length and diameter of the implants, the shape and characteristics of the implant surface, the prosthesis type, and the quantity and quality of the surrounding bone. A fundamental aspect that determines the effectiveness of a dental implant is related to the osseointegration process. All of these factors are also influenced by operator experience. Increasing the diameter and length of an implant decreases the stress and strain on the alveolar crest, and the stress and strain values notably increase under masticatory loading compared with vertical loading. However, the diameter of an implant has a more significant effect than length on relieving the bone-level stress and strain concentration.

The main purpose of this 4-year multicenter prospective clinical study was to evaluate the survival of 377 dental implants (Global Sweden & Martina, Padova, Italy) inserted in 189 patients between January 2004 and April 2010 with a mean follow-up of 46 months. Furthermore, the correlations among implant dimensions (diameter and length), bone quality, and insertion torque were investigated.

**Materials and Methods**

**Patient selection**

From January 2004 to April 2010, 377 implants were placed in 189 consecutively treated patients. Of these, 187 implants were placed in male patients and 190 in female patients. At the time of implant placement the patients’ average age was 51 years, and they were followed for approximately 46 months. The experimental protocol was described to all patients, and they signed an informed consent before undergoing treatment. Patients were told this study was an observational protocol with the aim of evaluating the performance of an implant system already used. Moreover, the surgical and prosthetic procedures the patients would undergo had been previously published in the scientific literature, thus, no experimental technique would be performed. For this reason the protocol did not require approval by an ethics committee.

This multicenter study included the participation of 10 oral surgeons with varied surgical experience, including faculty members, practitioners, and postgraduate students. All practitioners followed a strict manufacturer’s protocol.

**Exclusion criteria**

The exclusion criteria were insufficient oral hygiene, smoking more than 20 cigarettes per day, alcohol or drug abuse, acute oral infections, untreated metabolic disorders, radiotherapy of the oral maxillofacial region, recent chemotherapy, and pregnancy. To increase the heterogeneity of the sample, consecutive enrollment was followed. The surgical protocols were not subject to any limitations. In the protocol, immediate loading or delayed procedures as well as implants inserted in native bone or associated with guided bone regeneration techniques (29% of patients) were included. All patients received treatment as presented in Tables 1 and 2.

**Dental implant selection**

The implant used in the study has a partially cylindrical body at the coronal section with a progressively conical shape at the apex. The variable taper is narrower at the neck and at the first middle section and wider at the apical section. The thread has a
conical profile with a pitch of 0.6 mm and depth of 0.4 mm. The outer spire has a progressive profile with an angle of 60°, and it continues to the apex of the implant. Moreover, the implant is characterized by 2 long, apical, spiral, and deep grooves with a rounded apex. In terms of length and diameter, all implant sizes were used as provided by the manufacturer. The most common implant diameter was 5.5 mm, and the most common narrow implant was 3.8 mm. The surfaces of all the implants were sandblasted, acid-etched, and modified with hydrogen peroxide rinse (ZirTi).

The implant connection consists of 2 internal octagons and a terminal collar (Figure 1). The coronal octagon is used during implant placement to apply the necessary torque for implant insertion. The deeper octagon is precision-designed to reduce mechanical stress between the implant and the prosthetic connection, and to provide the smallest degree of tolerance for the prosthetic restoration. The collar functions as a prosthetic guide and allows for a longer connection (3.5 mm in total), thereby improving biomechanical stability. The connection is designed this way in order to house the head of the screw inside the implant neck. In addition, the surfaces between the components are not flat, but formed by 2 spheres that interface according to their concavity, coming into contact along an ideal line that coincides with the diameter of the smaller sphere (Figure 2).

Preoperative and postoperative instructions

One week before surgery, patients underwent a single session of oral hygiene. All patients were premedicated with an oral antibiotic of amoxicillin and clavulanic acid (Zimox, 1 g cpr, Pfizer Italia Srl, Rome, Italy) 2 hours before surgery, and received an additional 1 g every 8 hours for 6 days. Acetaminophen and codeine (Coefferalgan 500 mg + 30 mg cpr, Bristol-Myers Squibb Srl, New York, NY) was prescribed for postoperative pain control. Patients were also prescribed a chlorhexidine rinse to administer 3 times daily starting 1 week before surgery and continuing until suture removal.

Implant surgery

Surgery involved a full-thickness flap to expose the bone. Osteotomies were created following the manufacturer’s protocol, using a sequence of varied diameter drills under saline irrigation. A 2-stage procedure was indicated for the dental implant brand used in the study, and healing screws were placed about 3 or 4 months after the dental implant positioning. The 3/0 silk sutures were removed approximately 1 week after surgery, except in situations that involved bone reconstruction, in which case they were removed at approximately 2 weeks after surgery.

Clinical and radiographic evaluations

Intraoral radiographs were standardized through a parallel beam technique using Rinn centering devices individualized with polyvinyl siloxane occlusal registrations. During surgery, implant length and diameter, insertion torque, and bone quality were recorded. Insertion torque was measured using a dynamometric screw at the moment of insertion and recorded in the patient record. Bone quality ranged between 2 and 3 per the Lekholm and Zarb23 classification. Implant healing, including mobility, was assessed clinically and radiographically at each follow-up visit. The soft tissues were evaluated for the presence of inflammation, bleeding, suppurative, or exudate using a periodontal probe. In addition, bone support was evaluated and proper prosthetic fit confirmed.
One investigator performed a periodontal evaluation using the Periodontal Screening Index (PSI) at 4 proximal sites per implant. All dental implants were probed at 4 sites (mesiovestibular, distovestibular, mesio-oral, and disto-oral) and the PSI score (0 to 4) was recorded. A peri-implant sulcus deeper than 4 mm was considered a pathologic condition based on the Community Periodontal Index of Treatment Needs.24 The following classifications were assigned for each participant in this study: a PSI score of 0, 1, and 2 indicates no periodontitis, and a PSI score of 3 or 4 indicates peri-implantitis.24

The prostheses were evaluated for stability, fit, screw or abutment fracture lines, and ceramic chips or fractures (Figure 2).

**RESULTS**

In total, 377 implants were placed: 179 in the maxilla and 198 in the mandible. Of these, 276 implants were placed in the posterior region (distal to the first premolar) and 101 in the anterior (up to the first premolar) (Figure 3).

The average implant insertion torque was approximately 45 Ncm with a minimum of 10 Ncm and a maximum of 70 Ncm. Sufficient primary stability was achieved in all cases, even in patients with poor bone quality. Of the implants, 3% were mobile to rotation; however, none were mobile when subjected to horizontal or axial forces. All implants achieved osseointegration.

Of the implants, 192 were used to support a fixed bridge and 156 were used to replace single teeth. Furthermore, 18 implants were immediately placed in extraction sockets, 11 implants were used for a full arch rehabilitation, and 15 implants received an immediate load provisional prosthesis (Table 3 and Figure 4).

Guided bone regeneration techniques were used in 29% of the patients (117 of 377). Of these 117 patients, 5 were treated by means of autogenous bone grafts, 21 using a mixture of autogenous and heterologous bone graft, and the other 91 using deprotenized bovine bone mineral only. All of these included a resorbable collagen membrane (Table 4 and Figure 5).

After an average of 453 days (some patients could not undergo the prosthetic procedure on time because of economic reasons) following implant placement, the permanent restorations were cemented onto the abutments. Provisionals were placed after an average of 135 days following implant placement. The complication rate was 0.53% after approximately 4 years following implant place-
ment. This included 1 case of peri-implantitis at about 2 years, and 1 case of screw loosening 1 year after final prosthesis delivery. The implant with peri-implantitis was removed and replaced. Therefore, the implant survival rate at 46 months was 99.7%.

**Statistical analysis**

The data were statistically evaluated using a Student t test, Pearson correlation test, and scatterplot graphics. The statistical analysis was performed using Excel, Numbers, and SPSS 19 programs.

Insertion torque was statistically significant for implant diameter \((P = .017\) Pearson 2-tailed test\) (Figure 6), that is, insertion torque increased as implant diameter increased. No significant relation was found between implant length and insertion torque \((P = .933\) Pearson 2-tailed test\).

Similarly, there was a strong correlation \((P = .000\) Pearson 2-tailed test\) between insertion torque and bone quality. In particular, the increase in bone density coincided with a steady increase in implant insertion torque (Figure 7). Except for a small number of patients, the implant design showed adequate levels of primary stability, even in areas of poor bone quality.

**DISCUSSION**

In accordance with the literature, the present study confirms the reliability of implant therapy with regards to medium- and long-term survival. This study also confirms the reliability of the internal octagon connection. Only 1 case of abutment screw loosening was found out of 377 implants. The incidence of screw loosening in this study is much better than that found in some studies reporting the performance of the classic external and internal hexagon connections.

Two assumptions may be made about the favorable performance of the evaluated connection. First, the use of the octagon may provide a smaller tolerance to rotation and, therefore, less micromovement compared with the hexagonal connection. The octagon connection in this study is unique as the coronal octagon is used for placing the implant and the apical octagon for prosthetic connection. Second, implant stability is crucial to establish osseointegration. Based on the findings of the present study, sufficient primary stability and limited micromovement are essential in achieving osseointegration, especially in immediate loading cases.

Some studies report an acceptable range of implant micromovement between 50 \(\mu\)m and 100 \(\mu\)m, beyond which bone cells and newly formed vessels undergo rupture, which results in bone resorption and formation of interposed fibrous tissue. It has also been shown that in poor-quality bone, lateral forces can cause micromovement up to 250 \(\mu\)m, which is harmful for osseointegration.

Bone density of the implant site influences the amount of bone-to-implant contact and, therefore, is a variable factor for implant stability. The findings of this study show primary stability is easier to achieve in dense bone and more difficult to achieve in poor-quality bone. It is well understood that bone-to-implant contact is critical for long-term clinical success. Studies suggest that implant diameter is an important variable for obtaining good primary stability.

Initial stability can be quantified by insertion torque value; therefore, it can be assumed that higher insertion torque corresponds to a smaller amount of initial micromovement. According to the statistical findings of this study, values of low bone quality seem to correspond to less primary stability (recorded as insertion torque) with a statistically significant relationship. It can be assumed that, regardless of the insertion-site bone quality, increasing implant diameter may be a way to increase primary stability. The same assumption cannot be made for implant length. No correlations were found between implant length and primary stability. In one study, it was shown that cortical bone is 10 times more rigid than cancellous bone. Therefore, it seems that diameter, as opposed to length, plays a more important role in achieving primary stability because a greater amount of cortical bone can be engaged using a wider implant. Lastly, bone augmentation may also aid in increasing primary stability, thereby decreasing the incidence of failures, especially in areas with poor bone density.

**CONCLUSION**

This 4-year multicenter prospective clinical study reports excellent survival rates of the evaluated implant system in various clinical situations. In addition, the evaluated implant system seems to reduce the incidence of prosthetic screw loosening. Within the limitations of this study a wider dental implant diameter corresponded to greater implant primary stability. Therefore, for certain anatomic conditions, the use of a wider implant is recommended to increase primary stability. Implant length does not appear critical in obtaining primary stability.

**ABBREVIATION**

PSI: Periodontal Screening Index
REFERENCES