ABSTRACT

**Aim** The aim of this study is to compare immediate versus delayed loading protocol of a new conical connection implant in the esthetic zone.

**Materials and methods** Patients requiring single-tooth extraction for root fractures or periodontal disease in the maxillary or mandibular anterior or premolar areas were selected for the present study. After extraction, implants were placed immediately in fresh sockets. After randomization process, in group A immediate loading was performed while in group B a delayed loading protocol was followed. In both groups mean marginal bone loss was measured through intraoral digital radiographs at 3, 6, 12 and 24-month follow-up.

**Results** At 24-month, a survival rate of 100% was reported. For group A a mean marginal bone loss of 0.10 ± 0.09 mm was found, while for group B a value of 0.11 ± 0.08 mm was measured. No statistically significant differences between groups were found at each time point (P>0.05).

**Conclusion** When used in postextraction immediate and delayed loading implant rehabilitation, the new conical connection implant showed a good clinical outcome at 24-month follow-up.

**INTRODUCTION**

Primary stability is the first prerequisite for osseointegration of dental implants (1) and it is one of the factors to enhance treatment success (2, 3). This is possible through different surgical procedures (such as drilling technique) (4–5) and friction between implant and bone (6), therefore the macro-structure of the implant is very important. In 2014 Jimbo et. al (7) demonstrated that implants with self-tapping design showed a greater insertion torque than implants with modified cutting flute shape. Indeed, this type of cutting edge normally guides the implants into the osteotomy site, which is prepared to be slightly smaller than the diameter of the implant, thus decreasing oscillations(8). In 2011 Shu-Wei Wu (9) demonstrated that conical implants with bowl flutes is the optimal design with a lower resistance to initial insertion and higher stability for final instrumentation with respect to conical ones.

On the other hand, a decrease in treatment success is linked to the incidence of peri-implant inflammatory reaction and the design of implant abutment connection could play a crucial role, indeed an increase in inflammatory cells can be found in the peri-implant soft tissue at the level or slightly coronal to the implant-abutment junction (10–12). Internal designs have a larger and deeper contact area inside the implants and in vitro studies reported an increased stability and better force distribution in the surrounding bone (13). In addition, several studies demonstrated that internal tapered connection experienced a lower level of bacterial leakage, an important risk factor for peri-implantitis and marginal bone loss (14, 15). If the initial gingival tissue thickness at the crest is 2.0 mm or less, crestal bone loss up to 1.45 mm may occur, despite supracrestal positioning of the implant-abutment interface (16).
Immediate post-extractive implants have the main advantage of reducing duration of the treatment required for soft tissue (2 to 6 weeks) and bone healing (4 to 6 months), but, as shown in the literature, there might be a higher risk of complications and failures (17). A moderately rough implant surface plays a role in primary stability, but its significance lies in promoting the establishment of secondary stability (18).

Schropp et al in 2003 (19) studied that vertical bone loss is between 1 and 4 mm at single extracted sites depending on site location, but it can be reduced with immediate post-extractive implants. Crespi in 2014 (20) showed that a vertical bone gain of 1.20 ± 0.49 mm at almost 3 years after implant placement may be supported by both clinical parameters as presence of keratinized gingiva thickness, implants with a 2-mm collar, and the axis of implant insertion perpendicular to the opposing occlusal surface.

In some studies (21, 22), comparing immediate postextractive implants with delayed implant placement, no statistically significant differences were found because occlusion might not be the only determinant of implant survival. Crespi et al. reported in 2008 (23) that the success rate of immediate restorations with dental implants placed in fresh extraction sockets is comparable to those obtained with delayed loading protocols.

So the aim of this study is to compare immediate versus delayed loading protocol of a new conical connection implant in the esthetic zone.

MATERIALS AND METHODS

Patient selection

Patients requiring single-tooth extraction for root fractures or periodontal disease in the maxillary or mandibular anterior or premolar areas were selected according to the following inclusion criteria:

- good systemic health;
- non-smoking or smoking ≤10 cigarettes/day;
- good oral hygiene;
- full-mouth plaque score (FMPS) ≤25% at baseline;
- full-mouth bleeding of probing (FMBS) ≤25% at baseline;
- probing pocket depth (PPD) at six aspects of the teeth adjacent to the implant site ≤3 mm
- periodontal attachment level (PAL) at six aspects of the teeth adjacent to the implant site ≤2 mm;
- absence of active infection around the surgical site;
- presence of natural teeth adjacent to the implant site;
- presence of adequate bone tissue (at least 4 mm beyond the root apex) to ensure the implant primary stability;
- presence of keratinized tissue (KT) ≥2 mm;
- stable posterior occlusion;
- absence of parafunctional habits (bruxism, clenching).

Exclusion criteria were as follows:

- pregnant or lactating females;
- systemic diseases;
- presence of fenestrations or dehiscences on buccal plate of extraction socket;
- non-treated periodontal disease;
- inadequate bone volume;
- inability to comply with implant treatment and maintenance;
- inability or reluctance to provide informed consent.

This study was performed at the Department of Dentistry, San Raffaele Hospital, Milan, Italy, from June 2015 to March 2016. All patients signed and informed consent form for immediate and delayed loading group and were treated by one surgeon and one prosthodontist. The study was approved by the local ethical committee.

Pretreatment

Following clinical and radiographic examination, the impression of both jaws was taken for model analysis. To guide implant placement according to the prosthetic planning, a diagnostic waxup was obtained. A preoperative antibiotic therapy with amoxicillin 875 mg + clavulanic acid 125 mg (Augmentin, GlaxoSmithKline, Belgium) was administered. Oral disinfection was performed using a 0.2% chlorhexidine mouthwash (Corsodyl, GlaxoSmithKline, Belgium) for 3 minutes.

Surgical protocol

After local anesthesia with mepivacaine 2% with adrenaline (optocaine 20 mg/ml with adrenaline 1:80000, Molteni Dental, Firenze, Italy), teeth were extracted avoiding flap elevation and taking care in maintaining the integrity of the socket. A periodontal probe was used to verify the integrity of the socket walls. Implant site was prepared according to manufacturer instructions (CSR implant system, Sweden & Martina, Due Carrare, Padova, Italy), with standard drills following the palatal wall as guide, and the apical portion of implant site was prepared at least 4 mm beyond the apex. To obtain a primary stability, underpreparation was applied. The coronal margin of the implant was located 0.5 mm apically to the buccal level of the bone crest. In order to achieve adequate primary stability, all implants were inserted with a torque value of at least 35 N/cm.

The implant (CSR, Sweden & Martina, Due Carrare, Padova, Italy) had a machined neck of 0.8 mm and a bevel of 0.3 mm for the platform switching technique, the coronal segment presents a tapered morphology, the central portion is cylindrical and the apex is tapered, with a round shape and 4 incisions (Fig. 1). Implants of 3.8 or 4.2 mm diameter and 11.5, 13 or 15 mm length were placed (Table 1). The implant has a rough surface (ZirTi surface, Sweden & Martina, Due Carrare, Padova, Italy) and an internal connection with double taper. The first taper is an internal cone that supports and closes the prosthesis combined with an internal hexagon. This
Immediate versus delayed loading in a conical connection implant

**Post-surgical instruction**

Post-surgical instructions were given to each patient in order to avoid any complication. The antibiotic therapy was prescribed for 5 days (Amoxicillin 875 mg + Clavulanic acid 125 mg twice a day) and, if necessary, the analgesic therapy with ibuprofen 600 mg was continued. The use of 0.20% chlorhexidine was mouthwash (Corsodyl, GlaxoSmithKline, Belgium) rinse three times a day was recommended for five days after surgery, patients were instructed on oral hygiene procedures. All patients were informed to follow a soft diet and avoid chewing on the threatened area for 2 months. The light smokers were remembered to limit and possibly to refrain from smoking. Post-surgical appointments were planned at 1, 3, 6, 12 and 24 months following implant placement. At these time-points, patients came back to assess both implant and prosthesis function and evaluate oral health.

**Provisional restoration**

In group A, within 24 h from implant insertion, the healing screw was removed and the temporary abutment screwed at 32 N/cm. The temporary acrylic resin crown was adapted with acrylic resin along margins of the abutment and placed with temporary cement (Temp Bond, Kerr, Scafati, Italy). In order to minimize lateral forces and to prevent dangerous micro-movements during implant healing all provisional crowns were in centric occlusal contact without excursive contacts. In group B, after 3 months, a re-entry procedure was performed, and temporary crowns were placed.

**Definitive restoration**

After 3 months, the provisional restoration was removed, the metal framework was placed on the definitive abutment, and final impression (Impression II Garant, 3M ESPE, Germany) was taken. The definitive prosthesis was performed with a cemented porcelain fused to metal single-unit crown.
Success and failure criteria

A “successful implant” is an implant which:
- Does not cause allergic, toxic, or gross infectious reactions either locally or systemically.
- Offers anchorage to a functional prosthesis.
- Does not show any signs of fracture or bending.
- Does not show any mobility when individually tested by tapping or rocking with a hand instrument.
- Does not show any signs of radiolucency on an intraoral radiograph using a paralleling technique strictly perpendicular to the implant–bone interface.

A “surviving implant” is when the implant remains in the jaw and is stable and when the subject’s treatment is functionally successful even though all the individual success criteria are not fulfilled. A “successful prosthesis” is a prosthetic reconstruction that is stable and in good function.

A “failed implant” is an implant that has been removed or fractured beyond repair or cannot be classified as a successful or surviving implant. Therefore, implant survival, implant success, implant failure, marginal bone loss were considered.

Radiographic evaluation

Intraoral digital radiographs were taken periapical radiographs were taken before extraction, at the time of implant placement, and after 3, 6, 12 and 24 months (Figure 3) with the parallel long-cone technique, using a standardized film holder (Rinn XCP Evolution 2003, Dentsply, Italy) and occlusal template. A blinded radiologist measured the changes in marginal bone height over time.

The marginal bone level was measured from the most coronal portion of the implant in contact with the bone, to the point where the bone met the implant surface at the mesial and distal sites. The mean value between mesial and distal sites was considered for statistical evaluation. The difference of bone level was measured by means of the DIGORA 2.5 (Soredex, Tuusula, Finland) software. The intraexaminer error was calculated by comparing the first and second measurements with a paired t test at a significant level of 5%. No statistically significant difference was calculated between values (P > 0.05).

Statistics

A dedicated software was used for all statistical analyses (SPSS 11.5, SPSS). All values are presented as means ± standard deviations.

To compare mean marginal bone loss values between groups, a Student t test was performed, and P values < .05 were considered significant.

RESULTS

Ninety-eight patients were evaluated for the present study. 32 patients were excluded for systemic diseases, 16 patients were intrasurgically excluded: 15 for dehiscence of at least one wall of the socket, 1 was excluded because did not show an adequate torque value. In total 50 patients (50 implants) were included in the study. They had a mean age of 48.12 ± 14.2 years (range from 36 to 62 years), 32 were females and 18 were males.

Suitable wound healing was observed around the temporary abutment, with good adaptation to the temporary crown. After a 24-month follow-up period, a success and survival rate of 100% was found in both groups. No prosthetic and implant failures were registered.

Radiographic evaluation

Radiographic results at 3, 6, 12 and 24 months from implant placement are reported in table 2. At the 24-month follow-up, a mean marginal bone loss of 0.10 ± 0.09 mm was found in group A, while a value of 0.11 ± 0.08 mm was recorded in group B. No statistically significant differences between Group A and Group B were found at each time point (P > 0.05).

DISCUSSION

The aim of the present investigation was to evaluate the effect of immediate and delayed loading of single tooth rehabilitation using a new conical connection implant.

A recent in vitro study evaluated the resistance against bacterial microleakage of this new conical connection (24), but the present study is the first clinical report on this implant.

Primary stability is a basic requirement for surgical success, indeed the failure of an implant is linked to the presence of movements that induce the risk of soft tissue encapsulation and lack of osteointegration. Both immediate and delayed loading implants showed no statistically significant differences in radiographic results at 24 months.

In fresh extraction socket, the width of the gap between the implant surface and the bone walls at the time of implant placement could represent an issue for bone healing (Botticelli, 2006) (25).

Crespi et al. in 2008 (23) reported a mean bone loss of 1.02 ± 0.53 mm around 20 single implants placed in fresh extraction sockets in the esthetic zone and immediately loaded, but no significant differences were found compared to delayed loading control group.
Esposito's systematic review in 2010 (26) suggests that immediate and immediate-delayed implants might be better when placing implants just after tooth extraction, therefore there is a higher risk of implant failure and complications in immediate loading. Primary stability is due to drilling techniques and the implant macro-design. In 2011 Toyoshima (27) reported that self-tapping implants could achieve a high primary stability which supports their use in low-density bone. However, the influence of under-dimensional drilling on primary stability is still debated. Markovic in 2013 (28) reported that bone drilling is not an effective technique for improving implant stability and the use of self-tapping implants is highly recommended because implant stability optimization in soft bone can be achieved by lateral bone-condensing technique.

In the present study, no statistically significant differences were found at 24-month follow-up, even if encouraging results in marginal crestal bone maintenance were found in comparison to previous studies. Moreover, as shown in others studies (29), the temporary crowns had a positive impact on soft tissues with preservation of the papillae, and further studies will investigate the correlation between the new conical connection implant and these features.

CONCLUSIONS

When used in postextraction immediate and delayed loading implant rehabilitations, the new conical connection implant showed a good clinical outcome at 24-month follow-up. However, further clinical studies are needed to evaluate soft tissues outcomes, patient satisfaction, and long-term follow-up.

REFERENCES