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Immediate versus delayed loading of a new conical connection implant in the esthetic zone: a randomized study with 2-year follow-up

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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.

KEYWORDS Bone loss; Conical connection; Dental implant; Prospective study.

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 compy 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

	Diameter and length of implants (mm)					
Teeth	3.8 x 11.5	3.8 x 13	3.8 x 15	4.2 x 11.5	4.2 x 13	Total
Incisor	11	4	2	0	0	17
Canine	3	2	5	1	0	11
Premolar	2	7	3	4	6	22
Total	16	13	10	5	6	50

TAB. 1 Implant site and dimensions.

FIG. 1 Macromorphology of the new conical connection implants.

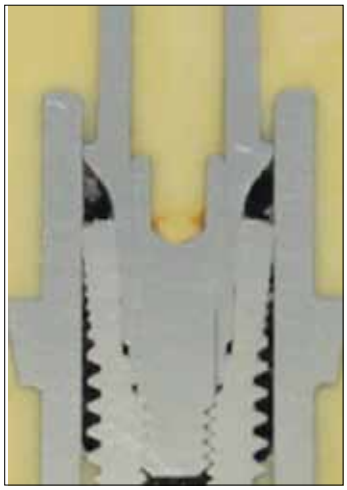
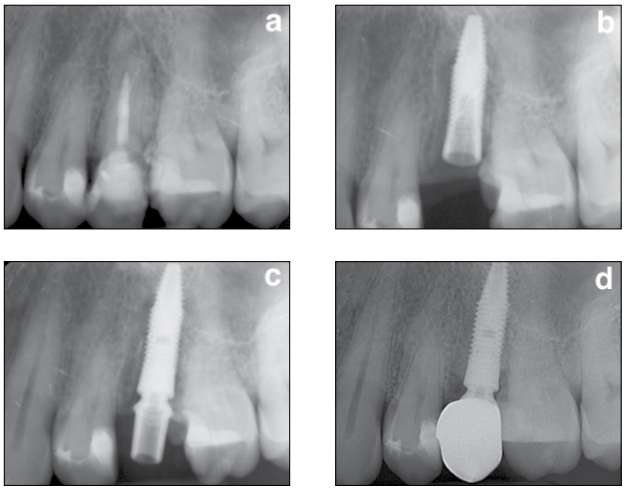


FIG. 2 Section of the new double conical connection. Light microscopy, 10 x magnification view.



FIGG. 3 Root fracture of a second premolar (a). Immediate implant placement in the fresh extraction socket (b). Radiographical results at 3-month (c) and 24-month (d) follow-up.

is used for implant screwing and prosthesis repositioning. The second taper is an interaction surface between the prosthetic abutment and the head of the tightening screw, which is conical (Fig. 2).

After implant insertion, a randomization process was performed using lots in closed envelopes. Patient allocation was performed: they were scheduled in group A and group B.

In group A immediate loading protocol was applied while in group B prosthetic loading was applied after 3 months.

In group A, sutures were used to close the gap between the temporary abutment and gingival margin, while in the control group, after implant placement, the flap was coronally repositioned to obtain primary wound closure and then sutured.

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 washmouth (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 threated 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 (Imprint II Garant, 3M ESPE, Germany) was taken. The definitive prosthetic restoration was performed with a cemented porcelain fused to metal single-unit crown.

	3 months	6 months	12 months	24 months
Group A	0.08 ± 0.03	0.10 ± 0.05	0.11 ± 0.06	0.10 ± 0.09
Group B	0.06 ± 0.04	0.09 ± 0.07	0.12 ± 0.10	0.11 ± 0.08

TAB. 2 Mean marginal bone levels measured for group A and group B.

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 intra-oral 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 meand 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 dehisence 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-dimensioned 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 satisfation, and long-term follow-up.

REFERENCES

1. Brånemark PI, Hansson BO, Adell R, Breine U, Lindström J, Hallén O, Ohman A Osseointegrated implants in the treatment of the edentulous jaw. Experience from a 10-year period. Scans J Plast Reconstr Surg Suppl. 1977;16:1-132.
2. Morton D, Jaffin R, Weber HP Immediate restoration and loading of dental implants: clinical considerations and protocols.Int J Oral Maxillofac Implants. 2004;19 Suppl:103-8.
3. Attard NJ, David LA, Zarb GA. Immediate loading of implants with mandibular overdentures: one-year clinical results of a prospective study.Int J Prosthodont. 2005 Nov-Dec;18(6):463-70.
4. Jimbo R, Giro G, Marin C, Granato R, Suzuki M, Tovar N, et al. Simplified drilling technique does not decrease dental implant osseointegration: a primary report. J Periodontol 2013; 84: 1599-605.
5. Campos FE,Gomes JB,Marin C,Teixeira HS, Suzuki M, Witek L, et al. Effect of drilling technique on the early integration of plateau root form endows teal implants: an experimental study in dogs. J Oral Maxillofac Surg 2011; 69:2158
6. Hudieb MI, Wakabayshi N, Kasugai s. Magnitude and direction of mechanical stress at the osseointrated interface of the microthread implant. J Periodontol 2011;82:1061
7. Jimbo R, Tovar N, Marin C, Teixeira H S, Anchieta R B et al. The impatto of a modifiche D cutting flute implant design on osseointegration J Oral Maxillofac Surg 2014;43:883-888.
8. Wu SW, Lee Cc, Fu PY, Lin Sc. The effects of flute shape and thread profile on the insertion torque and primary stability of dental implants. Med Eng Phys 2012;34:797.
9. Shu-Wei Wu, Chia-Ching Lee, Ping-Yuen Fu,Shang-Chih Lin The effects of flute shape and thread profile on the insertion torque and primary stability of dental implants. J Med Eng Phy 2012;34:797-805.
10. Broggini N., McManus L.M., Hermann J.S., Medina R.U., Oates T.W., Schenk R.K., Buser D., Mellonig J.T., Cochran D.L. (2003). Persistent acute inflammation at the implant-abutment interface. J Dent Res 82, 232-7.
11. Peñarrocha-Diago MA1, Flichy-Fernández AJ, Alonso-González R, Peñarrocha-Oltra D, Balaguer-Martínez J, Peñarrocha-Diago M. Influence of implant neck design and implant-abutment connection type on peri-implant health. Radiological study. Clin Oral Implants Res. 2013 Nov;24(11):1192-200. doi: 10.1111/j.1600-0501.2012.02562.x. Epub 2012 Aug 28.
12. Stanford CM. Surface modification of biomedical and dental implants and the processes of inflammation, wound healing and bone formation. Int J Mol Sci 2010;11:354-369.
13. Maeda Y1, Satoh T, Sogo M In vitro differences of stress concentrations for internal and external hex implant-abutment connections: a short communication. J Oral Rehabil. 2006 Jan;33(1):75-8.
14. Tesmer M, Wallet S, KoutouzisT, LundgrenT. Bacterial colonization of the dental implant fixture-abutment interface: An in vitro study. J Periodontol 2009;80:1991-1997.
15. Flarder S, Dimaczek B, Agil Y, et al. Molecular leakage at implantabutment connection—in vitro investigation of tightness of internal conical implant-abutment connections against endotoxin penetration. Clin Oral Investig 2010;14:427-432.
16. Hartman GA, Cochran DL. Initial implant position determines the magnitude of crestal bone remodeling. J Periodontol 2004;75:572–577
17. Linkevicius T, Apse P, Grybauskas S, Algirdas, Puisys A. The influence of soft tissue thickness on crestal bone changes around implants: A 1-year prospective controlled clinical trial. Int J Oral Maxillofac Implants 2009;24:712–719.
18. Esposito M, Grusovin MG, Polyzos IP, Felice P, Worthington HV. Interventions for replacing missing teeth: dental implants in fresh extraction sockets (immediate, immediatedelayed and delayed implants). Cochrane Database Syst Rev 2010;(9):CD005968.
19. Schropp L, Kostopoulos L, Wenzel A. Bone healing following immediate versus delayed placement of titanium implants into extraction sockets: a prospective clinical study.Int J Oral Maxillofac Implants. 2003 Mar-Apr;18(2):189-99.
20. Bruschi BG, Crespi R, Capparè P, Grande N, Bruschi E, Gherlone E Radiographic Evaluation of Crestal Bone Levels of Delayed Implants at Medium-Term Follow-up. Int J Oral Maxillofac Implants 2014;29:441-447
21. Lindeboom JA, Frenken JW, Dubois L, Frank M, Abbink I, Kroon FH. Immediate loading versus immediate provisionalization of maxillary single-tooth replacements: a prospective randomized study with BioComp implants.J Oral Maxillofac Surg. 2006 Jun;64(6):936-42.
22. Block MS, Mercante DE, Lirette D, Mohamed W, Ryser M, Castellon P. Prospective evaluation of immediate and delayed provisional single tooth restorations. J Oral Maxillofac Surg. 2009 Nov;67(11 Suppl):89-107.
23. Crespi R, Capparé P, Gherlone E, Romanos GE. Immediate versus delayed loading of dental implants placed in fresh extraction sockets in the maxillary esthetic zone: a clinical comparative study.Int J Oral Maxillofac Implants. 2008 Jul-Aug;23(4):753-8.
24. Gherlone EF, Capparé P, Pasciuta R, Grusovin MG, Mancini N, Burioni R. Evaluation of resistance against bacterial microleakage of a new conical implant-abutment connection versus conventional connections: an in vitro study. New Microbiol. 2016 Jan;39(1):49-56.
25. Botticelli D, Persson LG, Lindhe J, Berglundh T. Bone tissue formation adjacent to implants placed in fresh extraction sockets: an experimental study in dogs.Clin Oral Implants Res. 2006 Aug;17(4):351-8.
26. Esposito M, Grusovin MG, Polyzos IP, Felice P, Worthington HV. Interventions for replacing missing teeth: dental implants in fresh extraction sockets (immediate, immediate-delayed and delayed implants).Cochrane Database Syst Rev. 2010 Sep 8;(9)
27. Toyoshima T, Wagner W, Klein MO, Stender E, Wieland M, Al-Nawas B. Primary stability of a hybrid self-tapping implant compared to a cylindrical non-self-tapping implant with respect to drilling protocols in an ex vivo model. Clin Implant Dent Relat Res. 2011 Mar;13(1):71-8.
28. Marković A, Calvo-Guirado JL, Lazić Z, Gómez-Moreno G, Ćalasan D, Guardia J, Čolic S, Aguilar-Salvatierra A, Gačić B, Delgado-Ruiz R, Janjić B, Mišić T. Evaluation of primary stability of self-tapping and non-self-tapping dental implants. A 12-week clinical study. Clin Implant Dent Relat Res. 2013 Jun;15(3):341-9.
29. Cosyn J1, De Bruyn H, Cleymaet R. Soft tissue preservation and pink aesthetics around single immediate implant restorations: a 1-year prospective study. Clin Implant Dent Relat Res. 2013 Dec;15(6):847-57. doi: 10.1111/j.1708-8208.2012.00448.x. Epub 2012 Feb 29.