RevitaliZe Patient Solutions: preliminary results from a single cohort prospective study using Screw-Vent TSVT implants

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Purpose: The aim of this paper was to report preliminary results from a cohort of subjects treated with the RevitaliZe Patient Solutions approach. Clinical and radiographic results of axial and tilted implants up to fourteen months of loading are presented. Material and Methods: From September 2011 to May 2012, 7 patients were recruited and treated with a metal reinforced fixed full-arch prosthesis screw-retained over two axial and two tilted implants within 24 hours from the surgery. Final restorations were placed 6 months later. Follow-up visits were scheduled every 6 months and radiographic evaluation of peri-implant bone level changes was conducted. Results: Seven patients (5 females and 2 males) were followed up for an average of 11.88 months (range 8-16 months). Five subjects received implant treatment in both arches, resulting in 12 restorations. A total of 48 fixtures (Zimmer Screw-Vent TSVT) were placed and no failure was reported during the follow-up period, leading to 100% implant and prosthetic survival rates. Radiographic analysis after 6 months of loading was conducted for all prostheses. No significant difference in marginal bone loss was found between tilted and axial implants in both jaws. Conclusions: The present preliminary data suggests that immediate loading with RevitaliZe Patient Solutions could be considered a predictable and cost- and time-effective approach for the treatment of total edentulism.

Keywords: Dental implants, Fixed implant restoration, Immediate loading, Tilted implants.

INTRODUCTION

According to the most recent review of the dental literature, immediate loading procedures for total edentulism have reported high percentages of clinical success1-2, therefore an increasing number of clinicians have adopted these protocols in their daily practice.

The reduction of total treatment time and the possibility to deliver a functional implant prosthesis a few hours after the surgery represents notable advantages for patients, specially for individuals with a failing dentition because they can avoid the psychological trauma and discomfort of a transitional removable prosthesis3. An essential condition for immediate loading protocols is a minimum amount of fixtures primary stability, quantifiable in 35 Ncm4. Implant design, bone quality and quantity and a proper surgical technique strongly contribute to a fixed implant at the time of placement4-6 and the rigid splinting effect of provisional restoration directs the healing process towards osseointegration7,8.

In the last years, different clinical studies assessed tilted implants as a feasible treatment option, bringing surgical and prosthetic advantages9. The rehabilitation of complete arches with only four implants (two anterior axial and two posterior tilted), supporting a fixed prosthesis with limited distal cantilever was analyzed in recent studies10,11. Encouraging clinical outcomes have been reported in the medium term12 and no difference in implant survival rate and marginal bone loss have been registered between axial and tilted fixtures13.
The aim of this paper was to report preliminary results of RevitaliZe Patient Solutions, a new treatment modality that allows clinicians to immediately restore complete arches with a full-arch bridge screw-retained over two straight anterior and two posterior angled fixtures.

MATERIALS AND METHODS

Study protocol
The study was designed as a prospective single-cohort clinical trial conducted according to the principles of the Helsinki Declaration of 1975, as revised in 2000. Consecutively treated patients were included and scheduled to be followed for up to 10 years after loading. Subjects were explained all potential adverse effects and complications of treatment and they signed an informed consent to be included in the study. Surgical interventions and prosthetic phases were done in two clinical centers by one operator (AA) with experience in immediate loading rehabilitations.

Selection Criteria
Patients were enrolled if they were older than 18 years as well as physically and psychologically able to undergo conventional implant surgery and restorative procedures (American Society of Anesthesiologist (ASA) class I or II). Further inclusion criteria were: edentulous arch or presence of teeth with unfavorable long-term prognosis; adequate bone volume in the anterior maxilla and anterior mandible for implant placement (10 mm height and 3.7 mm wide), based on the pre-operative CT scan measurements; patients who preferred fixed implant-supported rehabilitation without recurring to any bone grafting procedure. All implants had to reach a minimum insertion torque of 30 Ncm. If one or two implants failed to reach that level but the other fixtures have adequate primary stability, immediate loading was still performed.

Main exclusion criteria were: presence of active infection or inflammation in the planned implant area; untreated periodontitis; serious problems of coagulation, disease of the immune system, uncontrolled diabetes and metabolic disease affecting bone; severe bruxism or clenching, heavy smoking (more than 25 cigarettes/day), radiation therapy to the head or neck region in the previous 5 years, alcoholism or use of drugs, pregnancy or lactation at the time of surgery, poor oral hygiene and motivation, and unavailability to attend regular follow-up visits.

Pre-surgical assessment and treatment planning
Arch size, bone volume, inter-arch relation and distance were evaluated pre-operatively by means of a clinical examination (Figure 1 and 2) and analysis of panoramic radiographs, periapical radiographs (Figure 3),

Fig. 1 57 year old patient presenting metal crowns from upper canine to contralateral and a partial removable denture to replace posterior teeth. Opposing dentition is composed by metallic crowns. Smile line can be considered average, exposing 10 teeth during maximum smile, while the incisal superior plane is distant from the inferior lip.

Fig. 2 Plaque and calculus were observed, as well as gingival recessions on some teeth in both arches. Mismatch in dental midlines is observed as well as disharmony in dental proportion.
computerized tomography scans, radiograph of the skull in lateral view and study models mounted in articulator.

Before the surgery, a resin transfer plate was made duplicating the patient’s denture or based on a wax-up for partially edentulous patients, with a secure stop on the palate vault or on the retromolar triangle. Subsequently, an opening approximately at the level of the occlusal surface was made to use the plate as a surgical guide, as described by Biscaro.15

**Surgical technique**

All surgical procedures were performed under intravenous sedation and local anesthesia (Figure 4). If some remaining teeth were present, they were extracted and their sockets were debrided with sterile saline solution. A mid-crestal incision was made, always excluding the retromolar triangle or the maxillary tuberosity, and a full thickness flap was reflected. Direct visualization of the mental nerve was made and the anterior loop was estimated with an atraumatic periodontal probe gently placed into the canal. Where necessary, regularization of the crest was performed with bony forceps and rotary instruments before stabilizing the resin transfer plate using the palatal vault or the retromolar area.

Bone quality was evaluated based on Lekholm and Zarb classification16 and Tapered Screw-Vent implants (Zimmer Dental Inc., Carlsbad, California) were placed according to RevitaliZe Patient Solutions protocol.

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**Fig. 3** Peri-apical x-rays show severe bone loss and a scenario of failing dentition, with horizontal resorption and vertical defects around natural teeth and maxillary implants. Pneumatization of maxillary sinuses prevents implants placement without recurring to sinus lift augmentations.

**Fig. 4** After two sessions of scaling and root planning necessary to reduce the marginal inflammation, some failing roots on the lower jaw were extracted, while the remaining pillars with a minimal stability were maintained to support a provisional acrylic bridge. A soft diet was suggested until the day of the surgery.

**Fig. 5** A 3.7 mm wide Tapered Screw-Vent implant (TSVT) is inserted with a 30 degree inclination according to the protocol. Anterior straight fixture is already placed.

**Fig. 6** Tooth extraction and immediate implant placement in the mandible. Post extraction gaps were filled with a mixture of autogenous bone and xenograft.
(Figure 5 and 6). Tapered Screw-Vent abutments (Figure 7) and Spectra-Angle abutments (Zimmer Dental Inc., Carlsbad, California, USA) were screw retained to straight and tilted implants, respectively.

**Immediate provisional restoration**

Copings for open tray impression were positioned over the abutments and isolated with a sterile piece of rubber dam. Copings were connected to each other by orthodontic wire and acrylic resin (Pattern Resin, GC America) or composite Protemp 4 (3M ESPE, Pioltello, Milan, Italy) and then fixed to the surgical guide with the same material 17. After 5 minutes, the complex of impression copings and guide was removed, healing abutments were placed and flaps were sutured with Gore-Tex 5/0 (WL Gore & Associates, Flagstaff, Arizona, USA).

Implant analogs were screwed on the impression copings and the stone was removed from the study model in the area corresponding to implant placement. The entire complex made by surgical guide, impression copings and analogs were positioned again over the study model. New stone was placed to secure implant analogs, converting the study model in the final master cast 17 (Figure 8). A screw retained metal reinforced provisional was made (Figure 9 and 10) and positioned in the patient’s mouth the same day or within 24 hours after surgery (Figure 11). The immediate restoration contained no more than 12 teeth and distal cantilevers were usually avoided. Full occlusal contacts in centric occlusion were maintained for all teeth, while lateral interferences were removed.

**Fig. 7** Spectra-Angle abutments were positioned over posterior implants to correct their inclination and get a favorable access for the prosthetic screw.

**Fig. 8** The complex made by surgical guide, impression copings and analogs rigidly connected with composite resin were positioned again over the study model to create the master model for the fabrication of the provisional bridge.

**Fig. 9** A metal framework is glued over 4 titanium cylinders to provide rigidity at the provisional prosthesis.

**Fig. 10** Provisional restoration contains 12 teeth, with pink gingiva if necessary.
Final restoration protocol

In absence of pain and inflammatory signs (Figure 12), the final restoration based on a CAD/CAM framework was delivered 6 months after loading. Five patients for a total of 10 arches were treated with a monolithic zirconium-oxide bridge, where just an external layer of 0.6 mm thickness from first premolar to the contralateral was modeled by dental technician to get a natural esthetic appearance (Figure 13-16). The morphology of the occlusal surfaces was entirely created from the monolithic block of zirconia. Two subjects were rehabilitated with titanium frameworks and veneering composite according to their desires.8

Fig. 11 Immediate restorations are delivered within 24 hours from the surgery. Contacts in centric occlusion are maintain for all the 12 teeth while distal cantilevers, if present, are under the occlusal plane. Interferences in lateral excursion are removed.

Fig. 12 After six months necessary for osseointegration, hard and soft tissues are stable for the final restorations.

Fig. 13 Final bridge consists of a monolithic zirconium-oxidized framework with a layer of 0.6 mm of veneering porcelain at the vestibular side of frontal teeth and first premolars.

Fig. 14 Frontal intra-oral view of final bridges.

Fig. 15 A natural smile was obtained thanks to the materials used for the restorations and to the work of the dental technician.

Fig. 16 Final panoramic x-ray showing implant distribution and bone level around implants after 1 year of loading.
Outcome Measures

The main outcome measures for the present study were:

1. Prosthesis success: when the prosthesis was in function, without mobility or pain, even in face of the loss of one or more implants. Prosthesis stability was tested at each follow-up visit by means of two opposing instruments’ pressure.

Secondary outcomes were:

1. Implant survival: when the implant was in function and stable with no evidence of peri-implant radiolucency, no suppuration or pain at the implant site or ongoing pathologic processes18.

2. Biological and prosthetic complications, such as peri-implantitis, fistula or abscess, mechanical or prosthetic complications like fracture of the implant or any prosthetic component19,20.

3. Plaque and Bleeding Indexes at implant level. Each implant was examined on four aspects (mesial, distal, vestibular, palatal/lingual). The percentage of sites in which plaque could be found, regardless of its amount, was recorded. A total of 16 sites per patient were examined, as previously described11. Briefly, any site in which plaque could be detected by naked eye or with a probe accounted for 6.25% (1/16) of the total score (100%). The same was made for bleeding index, considering positive any site that showed bleeding on probing11.

4. Patient satisfaction in term of aesthetics, phonetics and masticatory function was recorded by means of a questionnaire at baseline (before the treatment), at 7 months (after delivering the final prosthesis) and then at the 1-year and 2-year follow-ups21. The answers were based on a 5-point Likert-type scale, with scores ranging from “poor” to “excellent” (1 = poor, 2 = sufficient, 3 = good, 4 = very good, 5 = excellent). Data were statistically analyzed by means of the Fisher’s exact test.

5. Marginal bone level change: Periapical radiographs were performed using a long-cone paralleling technique and an individual x-ray holder at baseline, at 6 and 12 months, and yearly thereafter. Marginal bone level was assessed with an image analysis software (UTHSCSA Image Tool version 3.00 for Windows, University of Texas Health Science Center in San Antonio, TX, USA) by two experienced blinded evaluators. Mesial and distal values were averaged so as to have a single value for each implant. Bone loss around tilted and axial implants was compared by using paired Student’s t-test. Analysis of variance (ANOVA) was used to analyze bone level changes over time and P = 0.05 was considered as the level of significance.

RESULTS

From September 2011 to the same month of 2012, 7 healthy patients (5 women and 2 men; mean age 58 years; range 46-74 years) have been rehabilitated according to the RevitaliZe Patient Solutions. Five subjects were treated in both arches (4 of them during the same day) for a total of 12 immediately loaded fixed prostheses (7 maxillae and 5 mandibles) supported by four implants. Four patients were smokers with a daily consumption of 4.7 cigarettes.

Forty-eight Tapered Screw-Vent TSVT (Zimmer Dental Inc., Carlsbad, California, USA) implants with MTX® surface were placed and all of them were immediately loaded. Forty-four fixtures had a diameter of 3.7 mm, while length ranged from 10 to 16 mm. Posterior implants had a mesio-distal inclination ranging between 20 and 40 degrees according to anatomical limitation and local condition.

No complication occurred during surgical or prosthetic phases and no fracture of the final prostheses or any screw loosening have been reported.

The mean follow-up duration was 11.88 ± 2.38 months (range 9-16 months) and no implant or prosthetic failure occurred, resulting in 100% survival rates.

Peri-implant bone loss after 1-year follow-up could be evaluated for 7 arches (n = 14 implants per group) and this parameter averaged 1.02 ± 0.10 mm and 1.02 ± 0.08 mm for axial and tilted implants, respectively. Such difference was not statistically significant (p > .05).

Plaque and bleeding scores were recorded after 6 months of loading for all prosthesis and they were 12.08 ± 5.33 and 9.58 ± 5.03, respectively.

All patients completed the questionnaire for satisfaction. Aesthetic, phonetics and masticatory function were judged as excellent or very good by all of them.

DISCUSSION

The purpose of this paper was to report preliminary outcomes of immediate implant-supported fixed bridges for edentulous patients or for subjects who will become edentulous due to a failing dentition. Seven
patients for a total of 15 arches were treated according to the RevitaliZe Patient Solutions, consisting on a functional screw-retained metal reinforced provisional restoration delivered within 24 hours from the placement of two axial and two tilted fixtures.

The results of 100% implant and prosthetic survival rates after a mean follow-up of 12 months are in line with similar studies with immediate loading protocols$^9$-$^{12,22}$. Agnini and coworkers$^{17}$ reported 98.02% implant survival rate for 202 fixtures followed for an average of 44 months.

In this study, 1-year marginal bone loss of $1.02 \pm 0.10$ mm and $1.02 \pm 0.08$ mm was registered for 14 axial and 14 tilted implants, respectively. These results are similar to the data of a recent study from the same authors$^{14}$ tilted implants, respectively. These results are similar to the data of a recent study from the same authors where the same implant morphology was used but a variation of the implant collar exists. Tapered Screw-Vent TSV fixtures placed in that study differ from the tapered Screw-Vent TSVT version used in this investigation for the presence of a 0.5 mm MTX® Microtextured Surface followed by 1.8 mm of Textured Microgrooves. The full textured neck placed in sub-crestal position should increased the amount and stability of the fibrin clot, leading to a major bone formation, while the role of the six microgrooves is to augment fixture primary stability in the most coronal area, specially in soft bone, and to provide more surface for new bone formation. However, a larger number of patients with a longer follow-up is necessary to draw conclusions about a possible role of TSVT implants in marginal bone level maintenance.

In this protocol posterior implants are tilted with an inclination ranging between 20 to 40 degrees. A 15 and 30 degrees tapered angulated abutments can correct up to 30 and 45 degrees implants inclination, respectively, thanks to the 15 degrees conical shape of their platform. The use of these abutments results in a most favorable orientation of the prosthetic screw.

Great results in terms of esthetics and function were registered from all patients, especially in case of zirconia frameworks. The vestibular part of frontal teeth were left open to dental technician veneering ability for the characterization of every single element. The fact that the occlusal surface was part of the monolithic block decrease the working time for the technician, with a reduction of economic cost.

CONCLUSION

The preliminary results of the present prospective study are positive and in agreement with similar studies. No incidence of surgical or prosthetic complications, high implant and prosthesis survival rates and improved hygienic level throughout the study reveal that RevitaliZe Patient Solutions is a predictable technique for the rehabilitation of complete arches. However, long-term clinical data are necessary to confirm this statement.

REFERENCES


