Original article

The immediate functional loading of seven and mistral implants with new multi unit titanium abutments. 24 Months follow up report.

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Aim The ultimate goal of an immediate loading protocol is to reduce the number of surgical interventions and shorten the time frame between surgery and prosthetic delivery, all without sacrificing implant success rates. The aim of this study was to evaluate the use of a new titanium abutments for screw retained prosthesis in edentulous patients in a immediate loading procedure in order to reduct the number of surgical steps.

Materials and Methods 20 patients completely edentulous, 10 maxillae and 10 mandibles were treated with 6 implants and 5 implants respectively for a total of 110 implants. All patients received SLA screw-shaped Seven and-or Mistral implants (MIS, Shalomi, Israel). The treatment objective involved delivery of the provisional prosthesis within 4 h of implant placement, final rehabilitation was completed 6 months later. The patients were on a strict recall program during the first 6 months and Periapical radiographs were also performed subsequently, after 3, 6, 12 and 24 months of occlusal loading.

Results and conclusions One implant was lost out of the 110 inserted. The observed marginal bone change around immediate loaded implants was similar to that reported for delayed loading implants in the literature. The immediate loading of SLA surface Seven and Mistral implants for support of full-arch prostheses represents a viable therapy for the totally edentulous maxilla and mandible.

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Key Words: immediate loading, dental implant, multi unit titanium abutments, full-argh prostheses

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INTRODUCTION

Immediate loading of dental implants has been defined as a situation where the superstructure is attached to the implants at time of the surgery and no later than 72 h after surgery[1,2]. The definition of immediate functional loading also includes occlusion with the teeth of the opposite jaw. Under these conditions, successful immediate loading of screw-type dental implants has been reported as early as 1979 [3]. Micromovements have been deeply studied in dental implants loading but the question of reduction of micromovements has not been addressed in controlled studies dealing with immediate loading of oral implants. Passive fit of provisional prostheses has been mentioned as an important factor in the osseointegration of immediately loaded implants. A prosthesis that is ill-fitting may become loose, resulting in increased stress on the implants, which can lead to excessive micromotion and loss of an implant [4]. In this context, it has been hypothesized that screw-retained passively fitting restorations may be superior to cement-retained ones with respect to this problem, because they are less likely to loosen. If a cemented restoration is desired, the abutments should be long enough to provide adequate retention[4].

The exclusion criteria for dental implants, immediate loading and immediate functional loading are of extreme importance and they include insufficient bone volume, severe maxillomandibular skeletal discrepancy, drug and alcohol abuse, heavy smoking, local radiotherapy to the head and neck region for malignancies, antiblastic chemotherapy, severe chronic renal or liver disease, uncontrolled diabetes, stroke, recent infarction, pregnancy at the time of evaluation, haemophilia, bleeding disorders or coumadin therapy, metabolic disorders, acute infection of the implant site, signs of chronic bone disease, and general contraindications for surgical procedures[4-10]. The ultimate goal of an immediate loading protocol is to reduce the number of surgical interventions and shorten the time frame between surgery and prosthetic delivery, all without sacrificing implant success rates. The aim of this study is to evaluate the use of new titanium abutments for screw-retained prosthesis in edentulous maxillary bones in a immediate loading procedure in order to reduce the number of surgical steps.

Figure 1. Follow up control at 3 months after surgery and loading. It is possible to note the quality of the soft tissues and the integration with all titanium components.

MATERIALS AND METHODS

The study was performed in two clinical centers by two investigators who followed the same clinical protocol for immediate occlusal loading of implants placed in the edentulous mandible or maxilla. 20 patients were enrolled in the study. Of these patients 10 maxillae and 10 mandibles were treated with 6 implants and 5 implants respectively for a total of 110 implants. All patients were edentolous on the maxilla and/or the mandible at the time of surgery. All patients were treated with Seven and/or Mistral implants (MIS, Israel) and a screwed resin prosthetic appliance as a provisional was fixed at the time of surgery.

Inclusion and exclusion criteria

Patients were included in the study according to the following criteria: (1) completely edentulous in the jaws; (2) rehabilitation with oral implants considered an elective treatment; (3) physically able to tolerate conventional surgical and restorative procedures; (4) informed consent signed; (5) implants seated with a torque >45Ncm showing good primary stability; and (6) dense/normal bone quality. Bone quality was scored according to the classification proposed by Trisi &Rao (14) as dense (type I according to the classification proposed by Lekholm & Zarb, normal (type II–III) and soft (type IV) bone. (Table 1).

The exclusion criteria were: (1) active infection in the sites intended for implant placement; (2) systemic diseases such as diabetes (all types, regardless of control); (3) treatment with therapeutic radiation to the head within the past 12 months; (4) need for bone augmentation at the intended implant site; (5) radiographic evidence of unresorbed allograft at the implant site; (6) severe bruxism; (7) pregnancy; and (8) patients smoking more than 10 cigarettes a day. (Table 2).

Success criteria

The following success criteria were applied in evaluating each implant: (1) no clinically detectable mobility when tested with Ostell; (2) no evidence of peri-implant radiolucency on periapical radiographs; (3) no recurrent or persistent peri-implant infection; (4) no complaint of pain at the site of treatment; (5) no complaint of neuropathies or paraesthesia; (6) crestal bone loss not exceeding 1.5mm by the end of the first year of functional loading [11].

Table 1. Inclusion criteria of the clinical study.

INCLUSION CRITERIA	
1	Controlled diabetic patients
2	Rehabilitation with oral implants considered an elective treatment
3	Physically able to tolerate conventional surgical and restorative procedures;
4	Informed consent signed
5	Implants seated with a torque >40 Ncm showing good primary stability
6	Dense/normal bone quality

Table 2. Exclusion criteria of the clinical study

EXCLUSION CRITERIA	
1	Active infection in the sites intended for implant placement
2	Systemic diseases other than diabetes
3	Radiation therapy to the head within the past 12 months
4	Need for bone augmentation at the intended implant sites
5	Radiographic evidence of unresorbed allograft at the implant sites
6	Severe bruxism
7	Pregnancy
8	Patients smoking more than 10 cigarettes a day

Surgical procedures

All patients received SLA screw-shaped Seven and-or Mistral implants (MIS, Israel). All clinicians followed the implant manufacturers instructions for implant site preparation and implant insertion procedures. The initial primary stability was assessed by setting the insertion torque of the surgical unit and recorded according to the following modified classification: 'tight' when torque was >45Ncm, 'firm' between 30 and 44Ncm or 'loose' when less than 30 Ncm (modified of Testori et al.[15]). The type, length and the diameter of the individual implants could vary from subject to subject, depending upon bone quality and quantity at each surgical site. (Table 3).

Prosthetic procedures

The treatment objective involved delivery of the provisional prosthesis within 4 h of implant placement, by utilizing standard abutments (MIS, Shlomi, Israel) and the prosthetic procedure that best suited the clinical case.

The design of the prosthesis was determined by a collaborative effort between the surgeon, the restorative doctor and the patient, as long as the outcome was consistent with the study's objectives.

A reinforced acrylic provisional bridge was relined over titanium provisional multi unit cylinders and immediately screwed onto the abutments. The occlusion was carefully checked.

Follow-up procedures

No specific diet was recommended to the patients. The patients were on a strict recall program during the first 6 months: every week during the first month, and every two weeks between the second and third month and every month until the sixth month. Orthopantograms and periapical radiographs were obtained for image analysis at implant insertion. Periapical radiographs were also performed subsequently, after 3, 6 , 12 and 24 months of occlusal loading.

Radiographic evaluation

Peri-implant marginal bone change was evaluated utilizing a computerized measuring technique applied to intraoral periapical radiographs (RVG, Kodak, USA). The evaluation of the marginal bone level around the implants was carried out using Kodak RVG's image analysis software (Kodak, USA). Bone loss at each follow-up visit was calculated for each implant by determining the difference between baseline values.

Figure 2. Components for immediate loading for Seven implants.

Figure 3. Components for Mistral implants.

RESULTS

One implant was lost out of the 110 inserted. The implant showed extensive marginal bone resorption and signs of peri-implantitis. The patient had a history of bruxism/ smoking and periodontitis. The implant lost was located distally (ie. the last implant placed) in one of the mandibles. (Table 4).

No patients enrolled in the study dropped out during the study period and all patient showed great satisfaction for the effectiveness of the treatment.

The RFA registrations showed higher values for mesial-distal measurements than for buccal-palatal ones; 65.3 ISQ (SD 6) vs. 55.8 ISQ (SD 6.9) for all implants.

Radiographic findings

The marginal bone level was situated more coronally for the study implants at all points in time in comparison to the literature . After 6 months the marginal bone level was on average 0.7mm (SD 1.1) below the implant shoulder for the mandibular implants and 1.7mm (SD 1.2) for the maxillary implants. On average 0.8mm (SD 1.2) of bone loss was observed for the mandibular implants in comparison to a loss of 1.8mm (SD 1) for the control implants during the 12 month period ($P<0.05$) More implants in the maxillary group showed bone loss during these 12 months. A combination of marginal bone loss and soft tissue health problems were found for two implants in one maxillary patient.

Table 3. Characteristics of 110 immediately loaded implants.

	IMPLANT LENGHT			
IMPLANT DIAMETER	**10**	**11.5**	**13**	**TOTAL**
	2	22	13	37
	6	24	10	40
	4	3	0	7
	4	10	0	14
	4	8	0	12
	20	67	23	110

Technical complications

Resin-related technical complications occurred more often in mandibular than in maxillary patients. One study provisional bridge showed loosening of assembly screws at the three month check-up. The occurrence of adverse events after prosthodontic treatment are shown in Table. It was clear in this study that the titanium abutments were effective in preventing technical complications, in both the maxilla and mandible.

DISCUSSION

There is a tendency in medicine to reduce the treatment time and simplify the treatment in order to increase patient acceptance and reduce the risk of complications. Treatment simplification for implant dentistry may be obtained either by early or by immediate loading procedures .

Early loading has been made possible by using textured surfaces that promote osseointegration[12-15]. By contrast, immediate occlusal loading procedures can be successful only when the amount of micro-motion at the bone–implant interface is kept beneath

Table 4. Analysis of 148 immediately loaded implants

Interval Time (Months)	N° of Patients	N° of Implants	Failed Implants	Interval Survival rate (%)	Cumulative Survival Rate (%)
0	20	148	0	100	100
2	20	147	1	99,32	99,32
4	20	147	0	100	99,32
6	20	147	0	100	99,32
8	20	147	0	100	99,32
10	20	147	0	100	99,32
12	20	147	0	100	99,32
18	20	147	0	100	99,32
24	20	147	0	100	99,32

a certain threshold during the healing phase[16,17].

Extended bone implants integration periods and multiple surgeries present challenges towards gaining patient acceptance for implant therapy as a treatment option in partially dentate and edentulous jaws. Immediate loading of oral implants could potentially overcome these problems.

It is widely accepted that immediate loading is a desirable procedure, if the outcome in terms of implant survival and success is comparable with that of conventional loading. Therefore, it has been the aim of the present study to show the clinical outcome and indications for screwed immediate loaded prosthetic appliances, to assess the level of evidence and to discuss implant survival and success rates of this protocol.

The experience in immediate occlusal loading of oral implants has led to different consensus papers [1,2,18]. In most of the studies on immediate loading, good bone quality has been mentioned as an important prognostic factor for the success of the procedure [5,19]. Although this conclusion seems reasonable, the level of evidence that supports this assumption is low. The same is true for the implant lengths and diameters that should be used for immediate loading. In a controlled study, rough implant surfaces improved the survival rate of immediately loaded implants [20]; however, the influence of the rough as opposed to machined surfaces was not significant.

Review papers on immediate loading have addressed additional biomechanical aspects of this procedure [5,17,21]. Based on different experimental studies, they have stated that a micromotion threshold should not be exceeded;

Figure 4. Particular of the titanium abutment components for immediate loading of Seven and Mistral implants.

Figure 5. Full arch resin embedded prosthesis with titanium components inserted and ready to be fitted over multi-unit and trans-octa attachments.

otherwise, osseointegration would be hindered. The critical threshold seems to be 50–15 μm)[16,22]. Therefore, it has been claimed that a high initial stability is necessary for immediate loading of dental implants[24,25].

Besides high initial stability, it has been stressed that immediately loaded implants in multi-unit situations should be rigidly splinted by their superstructures[26,27]. In order to optimize splinting, metal reinforced superstructures have been used; however, it could be shown that high success rates may be achieved with superstructures that were not metal reinforced[26]. Again, there are no evidence-based data that support the hypothesis that superstructures supported by immediately loaded implants should be metal reinforced.

RFA was used to assess implant stability after 2 years. Measurements were made in both the mesial–distal and the buccal–palatal directions. Interestingly, the buccal–palatal measurements were some 10 ISQ units lower than the mesial–distal readings. This supports the findings of Veltri et al.[28]. The RFA technique measures stability as a function of interface stiffness and the results indicate a higher stiffness in the mesial–distal direction. This finding can be explained by the fact that the bone is thinner at the buccal and palatal aspects of the implants. However, the manufacturers' recommendation is to make measurements perpendicular to the jaw bone which may give a false impression of low stability.

Other authors have also used RFA on the present implant design in the maxilla and reported similar ISQ values for measurements in the buccal–palatal directions[29]. No implant, abutment, abutment screw or assembly screw fractured during the 2 years of function. This is in accordance with the results obtained by Jemt[30] after two-stage implant installation.

In the present study, 20 patients received their provisional prosthesis as planned, within 4 h after surgery, whereas their final rehabilitation was completed 6 months later. All the patients were pleased that they could avoid wearing a removable prosthesis and be fitted with a fixed appliance within 4 h. In this study, the observed marginal bone change around immediate loaded implants was similar to that reported for delayed loading implants in the literature[11].

We conclude that immediate loading of SLA surface Seven and Mistral implants for support of full-arch prostheses represents a viable therapy for the totally edentulous maxilla and mandible.

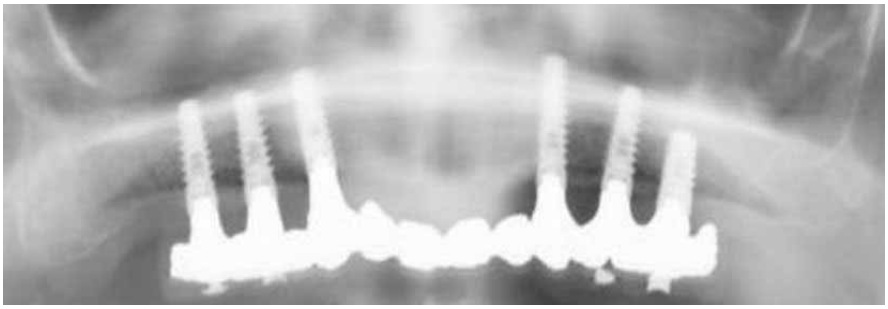

Figure 6. 24 months X-ray follow-up of full arch immediate loading with screwed titanium components firstly and finally with screwed Toronto bridge over Seven and Mistral implants

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