Osteotomy Timing of the Implant Surgical Site: A Comparative Study in Immediately Loaded Implant Denture Cases Using Split-Mouth Design

Abstract
This study is designed to compare tissue response to immediately loaded endosseous implants supporting mandibular dentures. One insertion timing stage combined with early and immediate osteotomy preparation was used in each case; thanks to split-mouth design.

The comparison included soft tissue healing and bone response to the osteotomy procedure from the time of surgery to the stage of punch approach and implants’ insertion and loading with the overdenture.

The criteria of comparison included soft tissue healing around the implants, implants mobility, and bone level changes around the implants.

Key words: osteotomy timing, punch technique, immediate loading, split-mouth design, atraumatic implant placement.

Introduction
Many edentulous patients suffer from reduced stability, retention, and load-bearing areas especially in mandibular dentures.1-4

With the introduction of osseointegration concept by Branemark, osseointegrated implant supported overdentures have been used in the rehabilitation of the edentulous lower jaw with excellent results.1 An overdenture supported by two implants is the simplest and least expensive alternative that also presents fewer complications and maintenance requirements than fixed prosthesis in the mandible.1, 2

The survival rate of dental implants has been correlated with the formation of a bone-implant interface.5 A two-stage approach with a 3-to-6 month healing period is recommended for the conventional osseointegration technique with oral implants. However, this may induce inconvenience and discomfort for patients, and immediate loading protocols are preferable.6

The success rate for immediately loaded mandibular implants is similar to that obtained in cases of delayed loading and there is no significant difference between results.7 Accordingly, immediate loading of the edentulous mandible with an implant-borne restoration is an acceptable and predictable method to deliver efficient return of function for the edentulous patient.8

With appropriate patient selection, single-stage surgery, and immediate loading, significant benefits to implant patients can be achieved.9 However, two main problems seemed to face protocols of immediate loading, namely bone and soft tissue healing.

Several types of research designs are available including, split-mouth design, whole-mouth design, and cross-over clinical trials….etc. Split-mouth designs are trials in which each subject receives greater than or equal to 2 treatments, each to a separate section of the mouth.10 Split-mouth design seems to be an effective type of clinical trial giving the advantages of reducing bias, obtaining definitive results, and decreasing cost.11,12

Review Of Literature
1. Concerning soft tissue healing and response to surgery:
Second stage surgery in single or multiple implant cases is currently a simple procedure. Nevertheless, complications arising from inappropriate handling of the soft tissues, particularly during exposure of several implants, can lead to poor cosmetic and/or functional results.13
Rationale for New Approach

Perrone reported that bone healing after osteotomy passes through three stages:27

1. Inflammation (granulation tissue).
2. Fibrous tissue phase.
3. Maturation phase.

The fibrous tissue phase was chosen to be definitely an acceptable implant bed configuration since it shows irregular collagen formation and revascularization. Moreover, at the second week, maximum resorption is complete at the margins of the bony defect and by the third week, rapid formation of new trabecular bone to repair the defect begins.27

Atraumatic heat-free insertion of implants at the fibrous tissue stage and before maturation stage provides primary stability that enables the immediate loading of implants.26

Accordingly, it seems logical to try avoiding most of the factors resisting ideal osseointegration combined with immediate loading, namely, heat generation, edema and soft tissue problems.

Materials and Methods

Six healthy edentulous male patients were selected for the present study from the out-patient clinic, Faculty of Dentistry; Alexandria University, Egypt, with their ages ranging from 53 to 62 years. (Fig.1)

For all patients, screening test for hemostasis, fasting blood sugar, measuring the blood pressure, and preoperative panoramic radiographs were done.

According to split-mouth design, each patient was a member of the control group and the study group, simultaneously as follows:

For all patients, the left mandibular canine area was considered as group I and the right side was considered as group II.

Pre-Surgical Procedures

Upper and lower complete dentures were constructed. All lower dentures were then duplicated and clear surgical stents were fabricated using a plastic vacuum forming machine.

Two small metallic balls were attached bilaterally to the cuspid area of each stent. Patients were asked to wear their stents and panoramic x-rays were taken to check the bone height and the relation of the balls to the mental foramina. The stents were perforated in the pre-determined implant areas.

Surgical Procedures

Step 1: Group I (Study Group)

A lingualized full thickness mucoperiosteal flap was reflected for the osteotomy procedure of the implant. The flap was sutured after osteotomy without inserting the implant. (Figs.2, 3, 4) Patients were instructed to follow a soft diet and a drug therapy (antibiotics, anti-inflammatories, and mouth wash) was prescribed. One week later, the sutures were removed.
A very simple technique of cutting the gingiva and soft tissues covering the implants’ coronal aspect with a circular blade is called “punch technique.”

Punch technique provides a mean for implant placement that greatly reduces associated surgical morbidity and increases patient acceptance. The benefits of avoiding a mucoperiosteal flap increases final esthetic outcome and may result in reduction of crestal bone loss. The accuracy of the punching site can be determined by using the surgical stent again. The previously performed holes for placing the implant will be a very accurate guide to perform the punch. A probe was used, after anaesthetizing the patient, to produce a bleeding point, exactly above the implant site, which will be the center of the punch.

2. Concerning bone healing:
Lamellar and woven bones are the primary bone tissues types found around a dental implant. The Lamellar bone is organized and highly mineralized. It is the strongest bone type and has the highest modulus of elasticity. Thus it is described as load-bearing bone.

On the other hand, woven bone is unorganized, less mineralized, of less strength, and more flexible (lower modulus of elasticity). Woven bone may form at a rate of up to 10 microns per day.

The two-stage surgical approach of dental implants permits the bone repair around the implant avoiding the early loading response by 3 to 6 months. The surgical process of the implant osteotomy preparation and implant insertion cause a regional accelerated phenomenon of bone repair around the implant interface.

As a consequence of the surgical placement, organized, mineralized lamellar bone in the preparation site becomes unorganized, less mineralized woven bone of repair next to the implant. At 4 months, the bone is still 60% mineralized, organized lamellar bone.

However, this has proven to be sufficient in most bone types and clinical situations for implant loading. Therefore, a rationale for immediate loading is not only to reduce the risk of fibrous tissue formation (which results in clinical failure) but also to promote lamellar bone maturation to sustain a continued occlusal load.

The risks of the immediate implant loading procedure are often perceived during the first week after the implant insertion surgery.

As a matter of fact, the bone in the macroscopic thread design of implant is stronger on the day of the implant placement compared with 3 months later, since there is more mature bone in the threads of the implant. However, the cellular connection of the implant surface condition does not yet exist.

On the day of surgery, there is residual cortical and trabecular bone around the implant. When the implant is inserted, it has some contact with this prepared bone. Early cellular repair is triggered by the surgical trauma and begins to form an increased vascularization and repair process to the injured bone.

Woven bone formation by appositional bone growth may begin to form as early as the second week after insertion at a rate of 30 to 50 microns per day. The implant-bone interface is weakest and at highest risk of overload at approximately 3 to 5 weeks after surgical insertion, since the implant-bone interface is least mineralized and unorganized during this time frame.

Causes of surgical trauma include thermal injury and mechanical trauma that may cause microfracture of bone during implant placement, which may lead to osteonecrosis and possible fibrous and granulation tissue encapsulation around the implant.

Roberts reported a devitalized zone of bone of 1 mm or more around the implants as a result of the surgery.

Eriksson and Albrektsson reported bone cell death at temperatures as low as 40°C. Sharawy et al reported that the amount of heat generated in the bone next to the implant drills was dependent on their design and revolutions of the drill. The temperature next to the drill ranged from 38°C to more than 41°C from a 37°C baseline and requires 34 to 58 seconds to return to base line. The two implant drill systems tested with internal cooled drills cut at a higher temperature than the two implant drill systems with external irrigation.

Other factors related to heat generation within bone during drilling include the amount of bone prepared, drill sharpness, depth of the osteotomy, variation in cortical thickness, and the temperature and solution chemistry of the irrigant.

One method for decreasing the risk of immediate occlusal load is to have more vital bone in contact with the implant interface by decreasing the surgical trauma at implant placement.

Misch et al suggested a method to decrease microstrain and the associated remodeling rate in bone by providing conditions to increase functional surface area to the implant-bone interface. The surface area of load may be increased in a number of ways, i.e., implant number, size, design and body surface conditions.

A new clinical approach offers a solution to this dilemma. The approach is based on an atraumatic surgical technique through which gradual drilling (by following the regular protocol for cutting using the pilot drill, 2mm drill, and 3.5 mm drill in my case) and increasing the cutting speed will decrease the cutting force and specific energy which is defined as the energy per unit mass.

Accordingly, the heat generation will decrease avoiding thermal bone necrosis that may influence bone healing and implant fixation, as increasing the cutting speed will decrease the time needed for cutting so less friction with bone will occur, and as a result, less heat will be produced.

Also, increasing the cutting speed will need less energy to perform the drilling and thus less heat will be produced, and as a result, less osteonecrosis.
The data collected from the measurements of the bone level at the mesial and distal aspects of all implants of both groups were tabulated.

Wilcoxin signed rank test revealed statistically significant difference of bone level changes around the implants from LT-3 months, from LT-6 months, and from LT-9 months at P<0.05. Results showed more bone loss around the implants of group II at the mentioned periods of evaluation.

**Discussion**

Although predictable long-term osseointegration had been reported after the two-stage surgical protocol established by Branemark for placement of implants in both completely and partially edentulous patients, studies of immediate loading have shown encouraging results.18, 29, 30, 31

Recent researches reported that root form implants may osseointegrate during early bone remodeling, even when loaded immediately. Immediate loading has the merit of significantly decreasing patient discomfort and eliminating the need for a second stage surgery.18, 32, 33

Two implants were used to support the mandibular overdenture in all patients of this study. The screw implant design helps to increase the surface contact area between the bone and the implant, and thus minimizing the shear forces.34 Implants’ length and diameter were the same for all patients of this study (11 mm and 3.5 mm respectively), since any difference may influence pressure per unit area in the supporting bone.35

All surgical procedures for implant placement are considered to be traumatic to the host tissues.9 Furthermore, atraumatic surgical technique is one of the most important factors that may influence the success of immediate loading, an approach aiming to reduce the trauma to the host tissues was used in this study (group I).18

The presence of paired or multiple organs (arches, quadrants, teeth) and the chronic nature of many dental diseases suggest the use of split-mouth design. In the present study each patient was a member of both groups; considering the left mandibular canine area as group I, and the right mandibular canine area as group II. The left side was prepared first, two weeks later, the right side was prepared and both implants were placed and immediately loaded with the prostheses.

By applying appropriate methods of sequencing and assignment, this design offers potential savings in resources, reduction of variables, and accurate results.40-42

Consequently, implants were placed in an excellent implant bed formed of vital bone obtained by this atraumatic surgical technique. This was in agreement with Misch who reported that decreasing the surgical trauma at the time of implant placement will decrease the risk of immediate occlusal overload. He added that this can be achieved by obtaining more vital bone in contact with the implant interface.18

Since soft tissue health is one of the factors involved in the osseointegration process, another benefit from this approach was gained by applying a linguinalized full thickness mucoperiosteal flap during preparation of the implant site.36 Reflecting the flap and repositioning it in the same place allowed uncomplicated healing of the soft tissue by primary intention, leaving the area of gingiva covering the implant bed intact.26, 27 Thereby decreasing the possibility of any peri-implant soft tissue problems affecting osseointegration.38

Consequently, application of punch technique at the time of implant placement over the prepared site giving excellent soft tissue healing besides the advantages of punch technique including simplicity, excellent esthetics, minimal bleeding, pain, discomfort, and tenderness. Also, no sutures were needed and attachment gingiva was rapidly and completely achieved.13

The new brand of cold-cured acrylic resin prevented the harmful effects of heat produced by conventional self-cured types of acrylic resin on underlying tissues.39 In this study, clinical evaluation of soft tissue healing around the implants showed that the study group had less inflammation than the control group especially 7 days after surgery.

This may be attributed to the difference in the soft tissue condition around the implants at the time they were loaded with the prosthesis. As for the study group, the soft tissue had enough time to heal properly (2 weeks) before the prepared osteotomy site was re-entered with the soft tissue punch to place the implant which was then loaded by the prosthesis.

The approach included preparation of the implant site two weeks before implant placement. This timing allowed tissues to be relieved from the trauma induced by the preparation and ensured the placement of the implants at the fibrous tissue phase of bone healing which showed revascularization, and irregular collagen formation. Moreover, maximum alveolar bone resorption was completed at the margins and new trabecular bone was rapidly formed which is essential for repair.26, 27

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By applying appropriate methods of sequencing and assignment, this design offers potential savings in resources, reduction of variables, and accurate results.40-42

**Table 3 shows the mean and standard deviation of bone level changes around the implants of both groups.**

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>LT 1 month</th>
<th>3 month</th>
<th>6 month</th>
<th>9 month</th>
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<tbody>
<tr>
<td>Mean</td>
<td>10.96</td>
<td>10.92</td>
<td>10.88</td>
<td>10.83</td>
<td>10.80</td>
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<tr>
<td>SD</td>
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<td>0.0121</td>
<td>0.0121</td>
<td>0.0163</td>
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<td>Mean difference</td>
<td>0.04</td>
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<tr>
<td>SD</td>
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<td>0.0155</td>
<td>0.0179</td>
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<tr>
<td>Mean</td>
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<td>10.84</td>
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<td>0.0141</td>
<td>0.0151</td>
<td>0.0110</td>
<td></td>
</tr>
</tbody>
</table>

Wilcoxin Signed Rank Test

| PV | 0.18652 | 0.00008² | 0.00032² | 0.00003² |

* Significant at P<0.05, LT: Loading time, n: number of cases.
Implantology

Step 2: (2 Weeks Later)
Group I (Study Group)

Punch technique was applied to expose the previously prepared osteotomy site; fibrous tissue curettage and copious irrigation of the site were performed, and then, an endosseous screw type implant (ENDURE, IMTEC Co., 11 mm length, and 3.5 mm diameter) was placed. (Figs. 5, 6)

Group II (Control Group)

At the same time, similar implant was placed in the mandibular right canine area immediately after osteotomy preparation using conventional technique and the flap was sutured around the implant.

Two mm collar O-ball abutments were placed and secured in position and the implants were immediately loaded with the overdenture. O-rings and keepers were secured over the O-ball abutments. Pick-up technique was applied to attach the O-ring system in place using cold-cured, self-cured acrylic resin SECURE (Hard Pick-Up Kit, IMTEC Co.) The patient was recalled during the week following the denture insertion to relief the denture at certain areas that may cause pain and ulceration in the mucosa. (Figs. 7, 8)

Results

1. Results of Clinical Evaluation:

A. Results of soft tissue healing:

Soft tissue healing around the implants was assessed for group I, immediately after implant placement, after 7 days, and after 14 days from implant placement and loading with the prosthesis.

For group II, evaluation was made immediately after surgery for implant placement, after 7 days, and after 14 days from implant placement and loading with the prosthesis.

The evaluation was carried out visually by inter-examiner observation according to the following criteria: 28

1. Incision line dehiscence.
2. Sloughing of the flap area.
3. Inflammation.
4. Infection.

The criteria for assessment were graded as follows:

0 = Excellent healing.
1 = Slight redness at maximum 1 suture area.
2 = Moderate redness, swelling and oedema at 2-4 suture areas.
3 = Severe redness, swelling and oedema at more than 4 suture areas.

B. Results of implant mobility:

Mobility of the implants was assessed at 1, 3, 6 and 9 months intervals. For all patients of both groups, none of the implants showed signs of mobility. The success rate was 100%.

2. Results of Radiographic Evaluation:

Both groups were examined radiographically using indirect standardized digital periapical radiographs immediately after osteotomy, implant insertion, 1 month, 3 months, 6 months and 9 months postoperatively, to measure the amount of marginal bone remodeling around each implant.

Rinn technique was employed using the XCP instrument for extension cone paralleling technique.

3. Assessment of Alveolar Bone Change:

Mesial and distal bone heights of the implants were evaluated using the linear assessment system supplied by the specially designed Image J software.

| Table 1 shows results of soft tissue healing regarding patients of group I (study group). |
|---------------------------------|---|---|---|
| Patient | Time | Immediate | 7 days | 14 days |
| Patient 1 | 0 | 0 | 0 |
| Patient 2 | 0 | 0 | 0 |
| Patient 3 | 0 | 0 | 0 |
| Patient 4 | 1 | 1 | 0 |
| Patient 5 | 0 | 0 | 0 |
| Patient 6 | 0 | 0 | 0 |

| Table 2 shows results of soft tissue healing regarding patients of group II (control group). |
|---------------------------------|---|---|---|
| Patient | Time | Immediate | 7 days | 14 days |
| Patient 1 | 0 | 1 | 0 |
| Patient 2 | 1 | 1 | 0 |
| Patient 3 | 0 | 1 | 0 |
| Patient 4 | 0 | 2 | 1 |
| Patient 5 | 1 | 1 | 0 |
| Patient 6 | 0 | 0 | 1 |
Conclusion
From the results of this study, it could be concluded that:
1. Soft tissue healing around the implants showed marked progression by the use of punch technique in patients of group I.
2. None of the implants showed any degree of mobility in all patients of both groups.
3. Significant difference in bone level was reported around the implants starting from the 3rd month till the 9th month after implants placement and loading with the prostheses. Group II showed more bone resorption.

Disclosure
The authors claim to have no financial interest in any company or any of the products mentioned in this article.

References