LASER Sintered One-Piece Early-Loaded Dental Implants for Mandibular Premolars Replacement

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This study was designed to evaluate laser-sintered early-loaded 1-piece implants (OPI) based on clinical and radiographic findings. Thirty OPI were placed in the mandibular premolar area and subjected to early loading after 3 weeks of initial placement; patients were followed up for 6 months. Clinical evaluation included pocket depth, gingival health, implant stability, and esthetics. Periapical radiographs were used to measure the marginal bone loss (MBL). All implants were considered successful resulting in a survival rate of 100%. A remarkable difference (P < 0.01) existed when comparing MBL levels at 1 month with those at 3 and 6 months. Significant differences (P < 0.01) existed when comparing implant stability at 1 month to 3 months and at 3 months to 6 months. Moreover, significant differences (P < 0.01) were observed when comparing peri-implant probing depth at 1 month to that at 3 and 6 months on both the mesial and distal sides. The mean value of pink esthetic score was 11 at time of final restoration. The laser-treated early-loaded OPI design is associated with satisfactory clinical and radiographic follow-up results and it is a good alternative to the 2-piece design.

Key Words: dental implant(s), implant dentistry/implantology, laser, oral implants/implantology, osseointegration, peri-implant infection(s)

INTRODUCTION

The 2-stage surgical procedure was supported by the original Branemark concept of osseointegration, in which, following initial placement, the implant is covered by the mucosa and the surgical site is allowed to heal. A few months later, a second surgical intervention is planned for the placement of an abutment, which penetrates the soft tissue. Recently, a 1-stage technique was developed, where a prosthetic restoration is placed immediately/early after implant placement. With the use of immediate/early loading implants, the patients will have immediate restoration of function and esthetics. One-piece implant (OPI) was designed to minimize marginal bone loss based on the theory that the causes of initial bone loss are the contamination of the implant–abutment junction, the presence of microgaps, and violation of the biological width. Although, some experimental studies supported such theory, other clinical studies reported a similar degree of initial bone loss for nonsubmerged OPIs and submerged 2-piece implants (TPIs), during the first year of follow up. One-piece implant is designed to use a moderately rough and oxidized surface, even at the part of the implant facing the soft tissues, which is believed to produce “soft tissue integration” and better long-term esthetics. This belief is supported by the general perception that fibroblasts and endothelial cells are “rugophobic” and thus prefer to attach to the smooth surfaces of soft tissue.

Laser sintering is an additive method of treating implant surfaces to produce a high degree of purity with surface roughness, necessary for good osseointegration. The development and use of these surface modifications were based on the fact that improved bone-to-implant contact can be achieved by increasing the topography of the implant surface. In addition, a positive correlation between the degree of bone-implant contact and torque removal was reported. Therefore, we aimed to evaluate the function, stability, and esthetics of laser-sintered 1-piece early loaded dental implants in the mandibular premolar area based on clinical and radiographic measures.

MATERIALS AND METHODS

This study was conducted at the Department of Oral and Maxillofacial Surgery, Faculty of Dentistry, Mansoura University, from December 2010 to October 2011. This study followed the Declaration of Helsinki on medical protocol and ethics and was approved by the regional Ethical Review Board of Mansoura University. Thirty patients who had 1 missed mandibular premolar were recruited in this study after a signed informed consent. The inclusion criteria were as follows: the presence of...
adequate vertical and horizontal amount of bone in the edentulous area and adequate opposing occlusion. For a complete presurgical evaluation, standard panoramic (Figure 1a) and periapical (Figure 2a) radiographic examination, diagnostic casts (Figure 1b), and a surgical template (Figure 3b) were prepared for each implant site. Exclusion criteria were as follows: the presence of natural teeth adjacent to surgical area that are affected by untreated periodontal and endodontic infections, peri-implant bone defects requiring bone augmentation, presence of any alveolar bone undercuts or concavities, and absence of opposing occlusion. Additional exclusion criteria were as follows: poor oral hygiene, smoking, parafun-ctional habits, severe maxilla-mandibular space discrepancies, any drug use (including bisphosphonates), or alcohol abuse. The study involved the replacement of premolars lost due to extraction (n = 26 patients, Figure 3a) or congenitally missed (n = 4 patients, Figure 2b).Thirty screw-shaped, single-piece, commercially available titanium implants (Implant Leader System, Milano, Italy) were used in this study. All of them had laser-treated surfaces. The implants were 11.5 mm in length and 3.2 mm in diameter.

**Surgery**

All patients received the same surgical protocol conducted by the same surgeon. The patients were instructed in oral hygiene procedures and scaling was performed whenever needed. Local anesthesia was induced by infiltration with mepivacaine HCL 2% with levonordefrin 1:20 000 (Alexandria Co for Pharmaceuticals and Chemical Ind, Alexandria, Egypt). Crestal incisions were done with maximum effort to maintain intact periodontal tissues of the adjacent teeth, and vertical incisions were made only if necessary to obtain better visibility. A full-thickness mucoperiosteal flap was reflected to expose the alveolar ridge.
at the implant site. The preparation of the recipient site was performed following the implant manufacturer’s recommendations under abundant saline solution irrigation. Initial preparation was performed through the surgical guide (Figure 3c) while the subsequent drilling was performed after removal of the surgical guide. After a presurgical evaluation and radiographic examination, all the implants were placed to the last apical half with a hand driver to engage the alveolar bone (Figures 1c, 1d and Figures 2c, 2d). The flap was replaced and sutured without tension using 3.0 silk sutures (Figure 3e). Patients were instructed to have liquid or semiliquid diet for the first 3 days postsurgery and to gradually return to their normal diet. Oflam 50 (diclofenac potassium, Mepha Pharma, Cairo, Egypt) was prescribed to the patients when needed. Provisional restorations were placed within 48 hours postsurgery and immediate postoperative periapical radiographs were taken (Figures 1e and 2e) and the patients were recalled 7 days postsurgery for sutures removal. After a healing period of 3 weeks, all implants were functionally loaded with permanent crowns (Figure 2f). All patients were recalled for regular follow-up and evaluation.

**Clinical evaluation**

1) Implant stability was assessed during all follow-up visits using Periotest.

2) Gingival health was registered according to the Angulated Bleeding Index (AngBI). A periodontal probe was passed along the buccal margin at 60 degrees angulation in the gingival sulcus. The subsequent bleeding was recorded as present (+) or absent (−).

3) Peri-implant pocket depth: The distance between the base of the pocket and the gingival margin was measured mesially and distally using a graduated periodontal probe.
4) Esthetics: Each implant was photographed with a digital camera (Cybershot 12.1 mega pixels, Sony, Tokyo, Japan) and esthetics was evaluated according to the pink esthetic score (PES). Four dentists participated in recording the PES where each dentist was given a chart containing the 7 variables. The PES is based on those 7 variables: mesial papilla, distal papilla, soft-tissue level, soft-tissue contour, alveolar process deficiency, soft-tissue color, and texture. Each variable was assessed with a 2-1-0 score, where 2 is the best and 0 is the poorest score. The mesial and distal papillae were evaluated for completeness, incompleteness, or absence. All other variables were assessed by comparison to adjacent teeth. Each dentist recorded the PES, then the means of the 4 dentists’ records were calculated for each case.

**Radiographic evaluation**

Standard periapical radiographs were used to evaluate the changes in the marginal bone level at one month following implant loading (7 weeks from the day of implant placement, Figures 1f and 2g), 3 (Figures 1g and 2h), and 6 months (Figures 1h and 2i). The images were analyzed using ImageJ software (1.42q, Wayne Rasband, National Institutes of Health, Bethesda, Md). Computer-assisted measurements were made on the mesial and distal sides of each implant. The initial marginal bone loss level was measured from the lower corner of the collar pixels then converted to millimeters using the implant length as a reference. These calibrations allowed a correct measurement even if there was a slight deviation of the central beam and a consequent magnification of the image. The amount of bone change over the baseline to 6 months after implant placement was calculated for all implants.

**Statistical analysis**

The description of data was presented as mean ± SD for quantitative data, and frequency and proportion for qualitative data. To compare the different measurements (paired sample Student t test) was employed. To compare qualitative data, the Chi square test was used. The difference among groups was considered significant when \( P < 0.05 \) and at a confidence interval of 95%.

**Results**

Soft tissue healing was satisfactory in all patients except for 1 patient who showed some inflammatory changes in his soft tissue, around the implant, without severe bone loss; this case was improved after 2 weeks of good oral hygiene and adequate antibiotic treatment. All implants were considered successful at the end of the 6-month follow-up period. Three cases showed positive Angulated bleeding index at the first follow-up visit only; however, the mean of peri-implant pocket depth was almost normal and not deeper than 1.8 mm. The periotest values at one month ranged from \(-3.0\) to \(-1.5\) with a mean of \(-2.4\), while at 3 months it ranged from \(-0.7\) to 0.7 with a mean of 0 and at 6 months it ranged from \(-2.7\) to \(-1.3\) with a mean of \(-2.0\). Two significant differences \((P < 0.01)\) were observed...
Laser-Sintered One Piece Implants for Replacement of Premolars

Table

This table shows comparisons of clinical and radiographic measures for laser-treated 1-piece implants at follow-up visits scheduled at 1 month, 3 months, and 6 months following prosthetic restoration placement.

<table>
<thead>
<tr>
<th>Compared Variable</th>
<th>T-test (P value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Periotest (1 month &amp; 3 months)</td>
<td>0.004*</td>
</tr>
<tr>
<td>Periotest (1 month &amp; 6 months)</td>
<td>0.541</td>
</tr>
<tr>
<td>Periotest (3 months &amp; 6 months)</td>
<td>0.003*</td>
</tr>
<tr>
<td>Mesial Pocket Depth (1 month &amp; 3 months)</td>
<td>0.004*</td>
</tr>
<tr>
<td>Mesial Pocket Depth (1 month &amp; 6 months)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Mesial Pocket Depth (3 months &amp; 6 months)</td>
<td>0.080</td>
</tr>
<tr>
<td>Distal Pocket Depth (1 month &amp; 3 months)</td>
<td>0.004*</td>
</tr>
<tr>
<td>Distal Pocket Depth (1 month &amp; 6 months)</td>
<td>0.005*</td>
</tr>
<tr>
<td>Distal Pocket Depth (3 months &amp; 6 months)</td>
<td>0.374</td>
</tr>
<tr>
<td>Marginal Bone Loss (1 month &amp; 3 months)</td>
<td>0.000001*</td>
</tr>
<tr>
<td>Marginal Bone Loss (1 month &amp; 6 months)</td>
<td>0.0000001*</td>
</tr>
<tr>
<td>Marginal Bone Loss (3 months &amp; 6 months)</td>
<td>0.049*</td>
</tr>
</tbody>
</table>

*Indicates a significant difference where P < 0.05.

when comparing implant stability at 1 month versus 3 months and at 3 months versus 6 months (Table 1).

The peri-implant probing depth at 1 month mesially ranged from 0.426 to 0.973 with a mean of 0.7, while distally it ranged from 0.542 to 1.097 with a mean of 0.28. At 3 months, the peri-implant pocket depth mesially ranged from 0.809 to 1.311 with a mean of 1.06, and distally, it ranged from 1.176 to 1.623 with a mean of 1.4. At 6 months, the peri-implant pocket depth mesially ranged from 0.926 to 1.473 with a mean of 1.2 and distally it ranged from 1.146 to 1.853 with mean of 1.5. A high significant difference (P < 0.01) was observed when comparing peri-implant probing depth at 1 month to those at 3 and 6 months, both mesially and distally (Table 1).

At time of final restoration, the pink esthetic score value ranged from 9.78 to 12.22 with a mean of 11. The marginal bone loss (MBL) at one month was 0.38, and at 3 and 6 months was 0.614, and 0.662, respectively. There was a remarkable significant difference (P < 0.01) when comparing MBL at 1 month to those at 3 and 6 months (Table 1).

Discussion

In this study, our patients were followed up for 6 months; all implants were considered successful resulting in a survival rate of 100%. The mean marginal bone loss level was 0.38 mm at 1 month, 0.614 and 0.662 at 3 and 6 months, respectively. A remarkable difference (P < 0.01) existed when comparing the marginal bone loss levels at 1 month to those at 3 and 6 months. Two significant differences (P < 0.01) were observed when comparing implant stability at 1 month to 3 months and at 3 months to 6 months. Significant differences (P < 0.01) were also observed when comparing peri-implant probing depth at 1 month to those at 3 and 6 months on both the mesial and distal sides (P < 0.01). The mean of pink esthetic score was 11 at time of final restoration.

Laser treatment technique is clean and offers easy methods of implant surface modification. Itala et al. reported that a pore of 100 μm was large enough for the consistent growth of new bone within the porous space and it will not reduce the mechanical strength of the implant. In laser treatment, Energy Dispersive Spectroscopy analysis revealed high purity of the implant surface compared to other treatments. Gaggl et al. reported that laser-treated titanium implants surfaces showed high purity and satisfactory roughness required for good osseointegration. In the present study, we had an initial drop in the Periotest measurements (PTM) followed by elevation to levels close to initial implant placement levels. In their study, Glauser et al. showed similar observations to ours. Cochran et al. explained that immediately after placement, the implant is stabilized by a press-fit of the implant that has slight larger diameter against the cut bone surface; this was referred to as primary bone contact. When reversible bony damage occurs during osteotomy preparation, bone healing gradually occurs adjacent to the titanium implant surface, resulting in secondary bone contact. During the healing process, woven bone turns into lamellar bone, thus secondary bony contact increases, and primary contact decreases. Glauser et al. explained the initial drop in PTM and implant stability, in their study, due to several factors as bone relaxation following compression, biologic changes associated with early bone healing, initiation of marginal bone resorption, and immediate loading conditions. Furthermore, they explained the consequent elevation in PTM to occur due to bone remodeling and maturation, hence leading to a consequent increase in the implant stability to levels comparable to the stability obtained at initial placement.

The slight increase in PTM in the laser-treated implants may be related to the percentage of bone-implant contact and bone density in the threaded area. In an animal model, Rong et al. showed that the mean percentage of the bone-implant contact in sandblasted and acid-etched (SLA) implants was 42.71% while in laser-treated implants was 83%. Furthermore, they reported the bone density mean in the threaded area for SLA implants to be 30.38% and for laser treated implants to be 33.36%.

Published criteria stipulated that a range of 1 mm to 1.5 mm of marginal bone loss (MBL) is acceptable when measured from the lower corner of the implant head. One-piece implants were designed to minimize the marginal bone loss based on the theory that contamination of the implant–abutment junction, the presence of microgaps and violation of the biological width are the main causes of initial marginal bone loss. Therefore, to achieve a minimal MBL in the current study we decided to use of 1-piece implants. The flap procedures may be associated with minimal MBL as Ostman et al. stated in their study on Nobel Direct and Nobel Perfect 1-piece implants. They used both flap and flapless techniques, in our study we used only the flap technique however in future studies we would compare the outcomes of the 2 different techniques. We reported here very low marginal bone loss levels observed in the last follow-up visits at 6 months compared to MBL levels at 3 months’ post-implant insertion. Berglundh et al. reported similar results in an experimental study. However, Cooper et al. declared the largest amount of MBL during the initial 3 months following fixture installation and only minor changes occurred subsequently.

In the present study, the gingival health adjacent to the implants was initially unsatisfactory in 3 patients only, however, subsequent improvement took place following the replace-
ment of temporary with definitive crowns. This was probably due to the lack of good marginal adaptation of the temporary restoration, which should have been more accurate especially in the critical first period of healing. Only 1 of these 3 patients who experienced gingival inflammatory changes suffered marginal bone loss and we are uncertain, whether the unfavorable soft tissue status influenced the marginal bone loss level. When considering the peri-implant pocket depth, the OPI design is more favorable as it enables undisturbed healing of the peri-implant soft tissue and avoids traumatizing the soft tissue seal that might occur during the placement of definitive prosthetic restoration. It was reported that the second stage surgical procedure in a 2-stage implant could reduce or eliminate the amount of keratinized mucosa in the peri-implant tissues.\textsuperscript{16} Garcia et al\textsuperscript{19} found that although there were no significant differences in terms of pocket depth, plaque retention and gingival health between single-stage and 2-stage implants, there was a great tendency of single-stage implants to retain a band of keratinized mucosa, indicating possible benefits of OPIs surgical protocol over the TPIs. The evaluation of the pink esthetic score around the abutments at time of final restoration showed acceptable score. This might be related to the 1-stage surgical protocol we followed, where no second disturbance of soft tissue took places compared to the second-stage surgeries. However, some patients gave lower PES and this might be a result of slight inflammatory response or inadequate oral hygiene, the mean of the PES was 11 after 6 months.

In this study, we used a simple and effective method to replace missing premolars via the combination of early loading option with 1-piece implants that were laser sintered. These early loaded implants were associated with patient satisfaction in a short treatment plan. Laser-sintered dental implant is a promising technique to create 3-dimensional surface roughness that enhances bone-to-implant contact ratio and our study shows a proof-of-concept clinical application of this new technology. However, this study had some limitations; the unavailability of reasonable number of patients selected for this study made it difficult for our group to compare the treatment outcomes in patients with congenitally missing premolars to those who had their premolars extracted. A second limitation point was the short-term follow-up period, 6 months. Longer follow-up periods and the use of more implant evaluation criteria will be considered in our future studies.

**CONCLUSION**

Laser sintered 1-piece dental implants combined with early loading are associated with satisfactory clinical outcomes, good stability for osseointegration, improved esthetics, and minimal marginal bone loss.

**CLINICAL RELEVANCE**

Laser-sintered 1-piece implant (OPI) was designed to minimize marginal bone loss based on the theory that contamination of implant–abutment junction, microgaps, and violation of the biological width are the main causes of initial bone loss. Laser sintering is a recent method of treating implant surfaces to produce a high degree of purity with 3-dimensional roughness and improve bone-implant contact for rapid osseointegration. Laser-treated OPIs when combined with early loading are associated with satisfactory stability, esthetics, and minimal marginal bone loss. Laser-treated OPIs are simple and successful treatment option with satisfactory clinical outcomes.

**ABBREVIATIONS**

MBL: marginal bone loss

OPI: one-piece implants

PES: pink esthetic score

PTM: Periotest measurements

SLA: sand-blasted and acid-etched

TPI: one-piece implants

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