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Cover Page Footnote
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Evaluation of piezotomed alveolar ridge splitting with stereolithographic surgical guide for implant placement (clinical study)

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ABSTRACT

Introduction: Narrow dentoalveolar ridges remain a serious challenge for the successful placement of endosseous implants. Several techniques for this procedure may be considered, such as guided bone regeneration, bone block grafting, and ridge splitting for bone expansion. The ridge split procedure provides a quicker and a more reliable method. Advances in technology, Stereolithography allow fabrication of surgical guide from 3D generated models for precise implant placement.

Objectives: Evaluation of minimally invasive ridge splitting procedure aided with surgical guide.

Materials and methods: A clinical study was performed on a total of 7 patients with mandibular free end saddle. The sample was selected conveniently to fulfill a list of inclusion and exclusion criteria. Then the selected participants performed ridge splitting with the aid of surgical guide. After ridge splitting, all patients had simultaneous implant placement followed by clinical and radiographical evaluation over a period of 6 months.

Results: Merging the preoperative, immediate and 6 months postoperative CBCT images showed statistically significant values of accuracy and increase in bone width and bone density.

Conclusion: Alveolar ridge splitting with the aid of stereolithographic surgical stent is a well acceptable technique for implant placement.

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1. Introduction

Dental implants have become an integral part of comprehensive management of dental patients. Scipioni et al. [1] suggests that wherever dental implants are placed, a minimum thickness of 1–1.5 mm of bone should remain on both buccal and lingual/palatal aspects of the implant(s) to ensure a successful outcome. Thus, a major limitation for successful implant placement remains the problem of inadequate ridge. Several methods have been described to augment the alveolar crest such as onlay lateral ridge bone grafting [2], horizontal osteodistraction [3], and guided bone regeneration techniques [4]. These methods have drawbacks, such as greater financial cost, an increase in the overall treatment period, and possible donor site morbidity. Ridge split technique is a way to solve the problem of the width in narrow ridges with adequate height [5].

Two devices for cutting hard alveolar bone under adequate control have been described: microsaw devices [6] and piezoelectric devices [7]. Both may be used, regardless of bone quality [6,7]. Additionally, with these devices, it is possible to prepare thinner cuts than with conventional burs [8].

Stereolithography, a rapid prototyping technology (CAD/CAM), a newer outcome in dentistry allows fabrication of surgical guides from 3D computer generated models for precise implant placement. The advantages of this surgical protocol are its minimally invasive nature, accuracy of implant placement, predictability, less post-surgical discomfort and reduced time required for definitive rehabilitation [9].

In the light of the above information, this study was designed to introduce alveolar ridge splitting with the aid of surgical guide. A new idea that will reflect several advantages including preservation...
of the periosteum thus reducing the liability of complete bone fracture, increased accuracy of the surgical procedure, and the decreased operating time and postoperative complications as the segmental ridge splitting is done through a flapless approach with preservation of soft and hard tissues.

2. Materials and methods

2.1. Informed consent

Appropriate institutional ethical clearance from the Faculty Ethical Committee and written informed consent from the patients were obtained. All patients were informed about the aim of the study.

2.2. Patient selection

In this study fifteen implants were placed in 7 patients at the posterior mandible with deficient alveolar bone width using the stereolithographic surgical stent. Patients were selected from the Outpatient Clinic of Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University.

The inclusion criteria of this study were; patients having mandibular free end saddle with deficient ridge width (less than 5 mm), adequate ridge height between alveolar crest and inferior alveolar canal to accommodate implants, adequate oral hygiene, free of soft tissue or dental pathology, and patients accepting to participate in the study. The exclusion criteria were; patients suffering from relevant systemic and/or metabolic diseases, immunosuppressive and/or autoimmune diseases, and heavy smokers.

3. Materials

The materials used in the surgical procedure were; stereolithographic surgical guide using In2Guide™ system (manufactured by Kavo Dental Gmbh on behalf of Cybermed Inc., Korea), implant system (Kisses Biogenesis dental implant system, Korea), piezotome using specialized crest splitting tips (Satelec, a company of Acetion Group, France) and expanders (Dentium RS kit, Korea).

3.1. Patient evaluation

Presurgical clinical examination was performed for all patients: Patients data were collected; name, gender and age, medical and dental history were taken and the oral mucosa of the edentulous area was examined for color, texture, firmness and buccolingual measurement. Also, preoperative evaluation for all patients included cone beam computerized tomography (veraviewepocs 3D R100, J. morita, Japan, at 8 mA, 90 KV) (Fig. 1) to verify bone width, implant position, angulation, depth, and the planned position of ridge splitting by using reformatted cross-sectional images in the vertical plane.

Fabrication of the CAD/CAM surgical stent by stereolithography using In2Guide™ system. CBCT scan (veraviewepocs 3D R100, J. morita, Japan, at 8 mA, 90 KV) for all patients and scanning of the stone models were performed after taking impression of maxillary and mandibular arches. The treatment plan was performed using In2Guide™ software powered by OnDemand3DTM (version 1.0.9, Cybermed, Korea).

The surgical stent is mouth guard shaped rapid prototyping sculpture with custom sleeves which controls the drilling location, direction and depth. It is made with certified bio-compatible resin, the custom sleeves are made from titanium and are completely harmless to the body. Manufactured by a dental technician under...
the ISO 13485 quality management system and certified by FDA (US), CE (Europe) and KFDA (Korea).

3.2. Surgical procedure

All patients were treated under local anesthesia using Artcaine hydrochloride 4% and adrenaline 1:100,000 (Septanest; Septodont, France). Mouthwash for 30 s using Chlorhexidine gluconate (Hexitol, The Arab Drug Company, Cairo, A.R.). The stereolithographic surgical template was placed on ridge and adapted well (Fig. 2). Blade No. 15 was used to incise mucosa midcrestally and vertically at the mesial end of the midcrestal incision (guided by slot area of stent) without any flap reflection (Fig. 3). An osteotomy was done using piezotome splitting tips midcrestally and vertically at the mesial end of the midcrestal osteotomy (guided by slot area of surgical stent) (Fig. 4). Drilling points of implant guided by the stent were initiated. Stent was removed and expansion completed with expanders (Fig. 5) sequentially according to manufacturer’s instructions. Implant-insertion was done immediately after the horizontal distraction (Fig. 6), following precisely the drill-protocol provided by the implant-manufacturer and followed by implant insertion using a torque-wrench, engaging the basal bone for primary stability. A periosteal releasing incision was performed on the inner aspect of the mucosa (periosteal side) in order to obtain tension free wound-closure and to compensate for increased ridge width. Closure was performed using 3-0 Vicryl sutures.

All patients were instructed to Cold fomentation over cheek at 5 min interval for 1 h in the first day, warm Chlorhexidine mouthwash (Hexitol: the Arab Drug Company, Cairo, A.R.) every 8 h from the second day after surgery till 1 week, and proper Oral hygiene instruction.

Postoperative medications include; broad spectrum antibiotic Amoxicillin 875 mg + Clavulanic acid 125 mg tablets (Augmentin...
1 gm Glaxosmith Kline Beecham Pharmaceutical Co., Bentford, England) every 12 h for 5 days to avoid post-operative infection. Non-steroidal anti-inflammatory analgesic diclofenac potassium 50 mg tablets (Cataflam 50 mg tablets, Novartis Pharma AG, Basle, Switzerland) every 8 h for 3 days to avoid the possibility of pain.

3.3. Postoperative evaluation

All patients were followed for 1 week postoperatively in the first month, then on intervals of 1, 4 and 6 months postoperatively. The clinical parameter of importance for determination of implant success were postoperative parathesia, implant mobility, signs of infection, pain using visual analogue scale (VAS) [10] and edema.

Immediate and 6 months Postoperative CBCT scans (Fig. 7 and Fig. 8) were conducted with the same apparatus and settings as the preoperative scans to evaluate the accuracy and significance in bone width and bone density using the stent. The preoperative and immediate postoperative scans were over-lapped using a dedicated algorithm, which allowed the comparison of the virtually planned and the actual implant positions and thus accuracy achieved. Three deviation parameters between each planned and placed implant were measured. Angular deviation (measured in degrees), coronal differences (error at the entry point, measured at the center of the implant head in mm) and apical differences (error at the apex, measured at the center of the implant apex in mm). Preoperative, immediate and 6 months postoperative CBCT scans were compared to evaluate significance in bone width and bone density.

3.4. Prosthetic protocol

Second stage (loading) was done at 4 months postoperatively with Re-opening of the implant site with a tissue punch and placement of gingival formers for 1–2 weeks to provide good gingival contour around implant collar. Impressions were taken using implant analogues and abutments were inserted. Cement retained final restorations were delivered in place after thorough check of occlusal interferences (Fig. 9).

3.5. Statistical analysis of the data [11]

Data were fed to the computer and analyzed using IBM SPSS software (Package version 20.0. IBM Corporation, 1 New Orchard Road, Armonk, New York, United States). Quantitative data were described using range (minimum and maximum), mean, standard deviation and median. The distributions of quantitative variables were tested for normality using Kolmogorov-Smirnov test, Shapiro-Wilk test and D’Agstino test. If it reveals normal data distribution, parametric tests were applied. If the data were abnormally distributed, non-parametric tests were used. For abnormally distributed data, comparison between two independent population was done using Mann Whitney. Significance of the obtained results was judged at the 5% level.

4. Results

A total of 15 implants were placed with flapless surgery using CAD CAM surgical stent. Seven patients (5 females and 2 males) who were suffering from missing mandibular posterior teeth were included in the study. Their ages ranged between 28 and 50 years with mean age of 42 years.

Patients suffered from missing either 3 teeth (mandibular second premolar, first molar and second molar) or two teeth (mandibular first and second molars). The average preoperative bone width was 4.0 ± 0.8 mm and the average bone height was 12.0 ± 2.0 mm. Implants placed ranged from 4.5 mm to 5.0 mm in diameter and 8.5 mm–10.0 mm in length.

Fig. 7. Immediate postoperative CBCT atright mandibular second premolar. (Bone width = 7.56 mm, Bone density = 1615.54HU) and right mandibular second molar. (Bone width = 7.75 mm, Bone density = 1374.43HU).
4.1. Clinical evaluation

4.1.1. Operating time

Three surgeries were performed with a total of two implants in each patient. An average operating time of 45 min was noted in each surgery. Two patients had done two surgeries each (one in each side) with a total of 4–5 implants in each patient, an average operating time of 60 min was noted in each patient.

4.1.2. Parathesia, tenderness, infection and/or swelling

Two patients showed mild edema which subsided totally by the 2nd post-operative day. All patients continued the follow up period without signs of parathesia, infection, gingivitis, or peri-implantitis.

4.1.3. Postoperative pain

Pain was evaluated daily for the first week and after 2 weeks using visual analogue scale (VAS) from 0 to 10 (0 is pain free and 10 is extremely painful). After surgery, five patients experienced no pain (VAS = 0) and two patients experienced mild pain (VAS = 4) at surgical site for 1–2 days duration.

4.2. Radiographic evaluation

Evaluation of the accuracy was based on a comparison of pre-operative and postoperative CBCT images for all 15 implants. Angular deviation, coronal deviation and apical deviation, were determined. Data collected were tabulated (Table 1).

The mean angular differences in implants were $10.9 \pm 9.4^\circ$ with a minimum recorded value of $2.2^\circ$ and a maximum recorded value of $29.1^\circ$. The mean of coronal differences were $(0.96 \pm 0.7 \text{ mm})$ with a minimum recorded value of $0.30 \text{ mm}$ and a maximum recorded value of $2.8 \text{ mm}$. The mean of apical differences were $(1.8 \pm 1.3 \text{ mm})$ with a minimum recorded value of $0.5 \text{ mm}$ and a maximum recorded value of $4.1 \text{ mm}$. The deviations were statistically significant ($p < 0.004$).

4.3. Evaluation of bone

Bone width was measured preoperatively, immediate post-operatively and 6 months postoperative and tabulated (Table 2). Bone width measured preoperatively was $4.1 \pm 0.4 \text{ mm}$ with a minimum value of $3.6 \text{ mm}$ and a maximum value of $4.8 \text{ mm}$. Immediate postoperative bone width was $7.8 \pm 1.1 \text{ mm}$ with a minimum value of $6.4 \text{ mm}$ and a maximum value of $9.9 \text{ mm}$. 6 months postoperative bone width was $7.9 \pm 1.1 \text{ mm}$ with a minimum value of $6.1 \text{ mm}$ and maximum value of $10.9 \text{ mm}$. Value between pre-operative and immediate postoperative was statistically significant. Value between preoperative and 6 months postoperative was statistically significant. Value between immediate postoperative and 6 months postoperative was statistically insignificant.

Bone density was measured preoperative, immediate postoperative and 6 months postoperative and tabulated below.
problem of inadequate ridge width. Ridge split technique is a way to solve the problem of the width in narrow ridges with adequate height [5].

In this study, three patients needed two implants in one side, which was simply done with a very short operating time. Meanwhile, two patients needed four to five implants bilaterally; this was done in a reasonable amount of time but caused slight discomfort for the patients after the operation.

Evaluation of the accuracy of placement was done by measuring the overall deviations between virtually planned and surgically placed dental implants. The mean of total angular difference in implant with stereolithographic stent were 10.9 ± 9.4°. These differences were close to angular differences reported by Di Giacomo et al. [12] in 2005 and Valente et al. [13] in 2009.

The Mean of total coronal differences in stereolithographic guided implant were 0.96 mm ± 0.7 mm. These differences were close to coronal differences reported by Di Giacomo et al. [12] and Farley et al. [14] in 2013. The Mean of total apical differences in stereolithographic guided implant were 1.8 ± 1.3 mm. These differences were close to apical differences reported by Valente et al. [13], Farley et al. [14], Schneider et al. [15] in 2009 and D’haese [16] in 2012.

In summary, the accuracy of the stereolithographic guides used for the current study was well accepted within the range of results reported by previous authors.

The final result of accuracy shown in this study is the sum of deviations that occurred during each step of the whole treatment procedure. These were similar to deviations of studies reported by, Block and Chandler [17], Dreiseildor et al. [18], Viegas et al. [19], Meloni et al. [20], Yu et al. [21], Cassetta et al. [22] and Bruno et al. [23] in 2013.

The deviations in this technique may be attributed to the acquisition of tomographic image, inaccurate planning, inaccurate positioning of the guide resulting in displacement during implant placement, improper guide fixation. Mechanical errors caused by angulation of the expanders during expansion, reduced mouth opening, the length of the implants and human errors, such as not following the implant installation protocol, all influence accuracy [17–22].

An error might also occur during the manufacturing of the surgical template for example in the simulation software, the precision of the stereolithographic machine, production and quality control, rigidity and physical properties of the material used, the precision of the guide cylinders and metal tubes, and verification of the guide [24].

Many sources of error may affect the results when using stereolithographic surgical templates, but the most important source of error is the intrinsic or inherent error that originates from the mechanical component tolerance in the surgical guides [22].

Limited studies in the literature consider potential errors that could arise from the inherent limitations of stereolithographic surgical guides (the intrinsic error). Despite the lack of data in the literature, it remains important to examine the mechanical factors that may influence the accurate placement of an implant when a stereolithographic surgical guide is used, in order to fabricate a surgical guide that limits the deviation of the drills being used [25].

Theoretically, all errors could have a cumulative effect even if, in most instances, they compensate each other. Therefore, it is important when using a system, to be aware of the largest deviation reported. It is possible to minimize some of the errors if the surgeon considers these sources of variation and carefully follow the instructions of the protocol. For example, patient movements during CBCT scan, and fitting and placement of the surgical template are considered to be clinical factors that influence the final implant positions. The surgeon should remember that even the patient

## Table 1

<table>
<thead>
<tr>
<th>Bone Density in HU</th>
<th>Pre-operative</th>
<th>Post-operative</th>
<th>Immediately</th>
<th>6 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Min. – Max.</td>
<td>328.6–1095.3</td>
<td>1221.8–1930.4</td>
<td>1213.2–1995.7</td>
<td></td>
</tr>
<tr>
<td>Mean ± SD.</td>
<td>786.8</td>
<td>1622.6</td>
<td>1750.3</td>
<td></td>
</tr>
<tr>
<td>% of change</td>
<td>9.4 ± 7.1</td>
<td>18.5 ± 10.9</td>
<td>28.1 ± 12.1</td>
<td></td>
</tr>
</tbody>
</table>

Sig. bet. periods p1 < 0.001*, p2 < 0.001*, p3 < 0.006

Sig. bet. Periods was done using Post Hoc Test (LSD) for ANOVA with repeated measures.

*p1: p value for comparing between pre-operative and immediatelypost-operative.

*p2: p value for comparing between pre-operative and 6 months post-operative.

*p3: p value for comparing between immediately post-operative and 6 months post-operative.

*p: Statistically significant at p ≤ 0.05.

## 5. Discussion

A major limitation for successful implant placement remains the...
selection, the first step in the treatment, will affect the accuracy of implant placement [26].

Although the guided surgery in implantology exhibits some limitations, Evers et al. [27,28] with clinical experience during 7 and 12 years with virtual planning, described that this technology is essential for evolution of clinical safety and treatment success with implants. The mean bone width of the newly formed bone values were recorded immediately and 6 months postoperatively in mm. The mean bone width value immediately postoperative was found to be 7.8 ± 1.1 mm and this was statistically significant (p-value < 0.001). This shows that this technique shows noticeable and significant increase in bone width immediately postoperative. At 6 months postoperative, the bone width value was found to be statistically significant when compared to preoperative values but shows no statistical significance when compared to immediately postoperative value. This clarifies that such technique preserves the achievement gained immediately postoperative and prevents upcoming bone loss and resorption.

The mean bone density of the newly formed bone values were recorded immediately postoperative and 6 months postoperatively in Hounsfield unit (HU). The immediate postoperative bone density value was found to be 1606.4 ± 277.2 HU and this was statistically significant (p-value < 0.001). This shows that such a technique provides great increase in bone density immediately postoperative. At 6 months postoperative the increase in the bone density was found to be statistically significant when compared preoperatively but shows no statistical significance in contrast to immediate postoperative value. This reflects such a technique preserves the gain achieved immediately postoperative.

In this study, screw expanders were used as they are non-traumatic alternatives to osteotomes for the expansion and condensing of bone for dental implant insertions. Because of the compactor thread design, they improve the clinical success by improving stability, maintaining bone density and increasing fixation. As they compact bone around the implant for better osseointegration, allow perfect control of the insertion axis, universal application for all system implants and the gradual thread introduction causes bleeding, also favouring osseointegration [29].

The manual screwing of the expanders ensures precision during the cortical approach. This technique does not depend on the operator's skills and decreases the onset of adverse effects due to the hammering with classical osteotomes [29]. The screwing effect itself is responsible for the significant increase in bone width immediately postoperative. This technique represents a minimally invasive procedure that avoids a large flap elevation. The main advantage of this technique include less bone resorption as there is no flap elevation, thus maintaining blood supply to the alveolar ridge, minimal bleeding, minimal postoperative discomfort, and better patient acceptance for this surgical procedure [30]. Besides, the computer-guided surgery is less affected by human precision in comparison to the conventional technique [31]. Also, Becker et al. [32] stated that the conventional technique presents surgical complications due to raising the soft tissue as infections, dehiscence, and necrosis.

Furthermore, the currently used procedure was assisted by the CAD/CAM surgical sent that allowed precise incision and osteotomy, as the scalpel and the piezotome were guided by the slot designed by CAD/CAM. The stent also allowed accurate drilling for implant placement as it was guided by the holes made in the surgical stent.

6. Conclusions

The technique represents a minimally invasive procedure preserving the periosteum for better blood supply thus decreasing postoperative complications. Ridge splitting with the aid of stereolithographic surgical guide showed a great deal of accuracy. Furthermore, this technique results in an immediate and significant increase in bone width and bone density, and maintains such increase with no upcoming bone resorption.

Conflict of interest

The authors declare that they have no conflicts of interest.

References


