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Radiographic Assessment of Bone Changes Around Implants Placed using Computer-Guided Approach with Single Drilling Protocol: A Randomised Clinical Trial

Research Article

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Abstract

Objectives: The aim of this randomized prospective study was to evaluate and compare peri-implant radiographic bony changes following computer-guided osteotomy preparationusing novel single drill design versus conventional drilling technique.

Materials And Methods: A total of 51 patients with maxillary single missing teeth prepared for implant placement using computer-guided template (CGT) in conjunction with either traditional sequential drilling approach (Group I, 26 patients) or single drilling approach (Group II, 25 patients). Seven days post-operatively, the patients expressed the degree of pain; and 6 months after surgery, marginal bone (MB) loss was evaluated radiographically for both groups.

Results: Single drill approach showed significantly reduced MB loss and minimal post-operative pain when compared to sequential drilling approach

Conclusion: Within the present study limitations, results concluded that preparation of osteotomy site using CGT with single drill approach demonstrated better conditions regarding peri-implant bony tissue, postoperative pain and reduce the surgical time.

Keywords: Dental Implants; Conventional Drilling; Single Drill; Computer-Guided Template; Marginal Bone Loss.

Introduction

Recently, The insertion of dental implants using computer-guided template (CGT) is more precise than the freehand technique [1]. Digital 3-D radiographic assessment of the implant bed is incorporated into planning software that can then be used for manufacturing of a CGT [2]. This CGT provides information about implant position, depth, and angulation. Trans-gingival implant placement using CGT minimises postoperative pain, surgical time, intraoperative bleeding, postoperative swelling and perimplant bone loss [3]. Horizontal and vertical Implant procedure regardless the surgeon's experience [4].

Implant bed preparation is important for appropriate fixture placement, assuring initial implant stability, reduction of heat generation, and then achievement of osseointegration. Massive traumatic surgery and heat generation during typical drilling technique are critical parameters that could be controlled by surgeon and whose significance is often overlooked. [5].

To conserve bone without affecting its healing ability, atraumatic bone drilling is strongly suggested using numerous surgical approaches to avoid traumatic bone cutting and improve primary implant stability including 10% narrower implant bed than the implant diameter, using osseodensification technique, using miniimplants and using minimal number of drills [6].

The drill design (including tip geometry, the number of flutes, drill walls, and drill material) plays an important role in heat generation [7].

The concept of using single drill for implant bed preparation have been raised recently against conventional multiple drilling because

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AMR Zahran, Ahmed Mortada, Maha Bahammam, Walid Elamrousy. Radiographic Assessment of Bone Changes Around Implants Placed using Computer-Guided Approach with Single Drilling Protocol: A Randomised Clinical Trial. Int J Dentistry Oral Sci. 2021;8(9):4254-.4258. of time-saving, less invasive, reduction of patient discomfort, minimal heat generation and reduced postoperative pain, discomfort and edema [8].

The aim of this study is to compare radiographically between implant osteotomy preparations using conventional drilling approachversus single drill approach in terms of peri-implant bone changes.

Materials and Methods

Patient Recruitment and Randomisation

From August 2019 to April 2021, 51 subjects with good health of both sexes (23 men and 28 women) between the ages of 18 and 50 years were recruited in our prospective research to replace edentulous regions in maxilla. Prior to commencement of the research, the advisory panel of the school of medicine at Assiut University granted academic research ethics approval (number 173005867), and the study was recorded in clinical trials registration with registration number NCT04877145. Every participant signed an informed consent form.

Compliant patients with a healthy medical state and no pathological abnormalities at the implantation sites were included in the present study. Whereas, This study excluded drug abusers, individuals with systemic illnesses that may preclude implant therapy, psychiatric disorders, habitual conditions such as frequent smoking and drinking, and para-functional habits such as bruxism and clenching.

Participants were randomly categorized using computerized software into 2 groups: GI (26 patients) used traditional sequential drilling approach and GII (25 patients) used single drilling approach for preparation of the implant osteotomy.

Preoperative Preparation

Preoperative periapical and CBCT radiographs were taken for all patients. Initial periodontal therapy was performed including scaling, root planning and oral hygiene instructions.

Study casts were created for every patient to assess the presence of adequate inter-arch space and to check occlusal discrepancies. 3D radiographic imaging was performed utilizing CBCT (Vatech Green C.T., VATECH, USA) for all subjects involved in the study, after which the desired implant position was transferred to the surgical site using 3D planning software (On Demand 3D softweare, Cybermed Inc., USA). Digitally controlled drilling machine (EnvisionTec., Germany) was utilised to obtain the CGT by drilling holes on the template and on the plaster cast in accordance with the anticipated planned implant position.

Surgical Procedures

Patients were locally anaesthetised, and then the prepared CGT was fitted in position intra-orally. The drill sleeve was placed into the CGT hole, for GI the pilot drill was then run through that hole to form an entryway at the alveolar ridge followed by sequential drills (Osteocare conventional drills, Osteocare, USA) (Fig. 1) to prepare the implant bed, whereas specially designed single drill (Osteocare Ultra 3.25mm, Osteocare, USA) (Fig. 2) was utilized for GII without the need for pilot drill. Finally, the implant fixture platform (Osteocare Maxi Z two-piece, Osteocare, USA) was inserted 2mm apical to the buccal bone plate.

Postoperative Care

Postoperative antibiotic (Augmentin[®] 1g tablets twice daily for 5 days), mouthwash (chlorhexidine gluconate 0.12% twice daily for 10 days), and analgesic (Paracetamol 500mg t.d.s for 5 days) were prescribed.



Figure 1. Showing conventional Osteocare multiple drills.

Figure 2. Showing Osteocare Ultra 3.25mm single drill.



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Follow-Up Evaluation and Success Criteria

tistical significant level.

Results

Clinical evaluation: Patients were asked to express the degree of pain experienced after surgery using a 0 to 10 visual analogue scale (VAS) (0 = not painful at all, 10 = the greatest subjective conceivable pain).

According to Buser and co-authors (1997) and Cochran and colleagues (2002), implant success was checked 6 months after surgery. If there was no clinically observable mobility, no periimplant radiolucency, no recurring or persistent peri-implant infection, and no complaints of discomfort, neuropathies, or paraesthesia, the implant was judged successful.

Radiographic Evaluation: Periapical and CBCT radiographs were taken preoperatively, immediately postoperatively, and six months following implant insertion to determine peri-implant marginal bone level (MBL). Each measurement was taken from the implant platform as a reference point to the highest bone-toimplant contact in linear axial axis.

Sample size calculation

The sample size was estimated using the PASS program. A priori, the noninferiority margin record was modified to 1, the significance threshold was set to 0.05, and the power (β) was set at 95 percent. Depending on these early findings, each group would require 22 participants. A total of 54 people were recruited, assuming a 25% dropout rate.

Statistical analysis

Mean values and standard deviations were determined for all parameters. IBM[®] SPSS[®] Statistics Version 25 for Windows was used to conduct the statistical analysis. The Chi-square test was used to compare categorical parameters, whereas the Mann Whitney test was used to analyse continuous variables. To compare intra-group means with repeated measures with continuous variables paired sample t-tests were utilised. P≤0.001 was set as a sta-

The population characteristics of this study are summarized in table 1 and the candidate's flow diagram is presented in Fig. 3. A total of 51 patients (26 participants in G1 and 25 participants in G2) completed the 6 months follow-up. The clinical and radiographic parameters at baseline immediately after implant placement, and

6 months are summarized in Table 2.

The postoperative healing was uneventful in all patients in both groups with no signs of local persistent pain, tenderness, neuropathies, or paraesthesia were observed throughout the evaluation period.

The implants survival rates were 100% with no detected mobility 6 months after surgery.

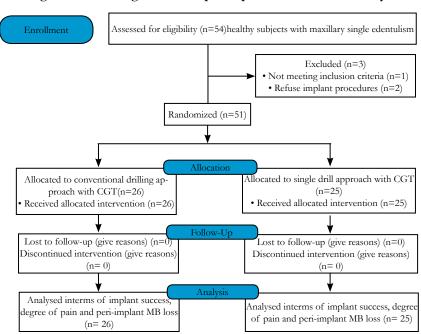
Degree of pain expressed by patients involved in GI was found to be 4.15+0.67, whereas in GII was 1.72+0.79. The mean degree of painwasstatistically significantly decreased with single drill approach as p<0.001 (table 2).

Six months postoperatively, the mean MB loss accompanied with conventional drilling approach was found to be 0.055+0.005mm, whereas single drill approach demonstrated 0.043+0.002mm mean MB loss. Upon comparing both groups in terms of MB loss at 6 months after implant insertion, a statistical significant radiographic MB loss was noticed in GIwhen compared to GII as p<0.001 (table 2).

Disscussion

The currentrandomised clinical trial was conducted to evaluate the peri-implant bone loss around dental implants placed using CGT and to compare the osteotomy preparation using either conventional drilling procedure versus single drill technique in terms of peri-implant bone changes and post-operative degree of pain.

Figure 3. Flow diagram for the participants in the current study.



To avoid outcome bias, the same operator placed all implants in both groups. Also, one operator performed postoperative radiographic assessment for all patients.

Computer-assisted surgery has been appliedin this study because it provides a minimal invasive procedure. It is apopular, clinically accepted evidence-based technique with high success rates, large accessibility, extreme reliability and good outcomes. CGT is used for accurate reproduction of the planned implant sites [9, 10]. Moreover, in the case of anatomical limitations (i.e., nerves, roots, vessels), CGT approach is considered safe, when compared to free hand technique [11].

Nowadays, CGT provides predicting outcomesregarding the safety, accuracy of implant positioning and fitting with the planned prosthesis. The study of Franchina and colleagues(2020) have reported a significant deviation from the planned strategy upon using free hand technique leading to compromised prosthethesis with a high risk of influencing the procedure safety [12].

Regarding the implant design, Osteocare Maxi Z plus (tapered, two-pieces with platform switched collar) dental implants were inserted in this study. The impact of platform-switching is a well-established strategy that preserves the crestal bone surrounding the implant collar, preserves ridge proportions, and improves peri-implant soft tissue stability [13, 14].

Drilling of the implant osteotomy traditionally involves utilising successive drills of increasing diameters. To reduce the osteotomy timing and heatproduction, sharp drills with a high rotation speed and copious irrigation should be used [5].

The Ultra drill used in the present study was designed for single drill approach with external irrigation; this specially designed tapered tri-flute drill has two cutting planes: the first plane has an acute angle at the drill tipfor drill stabilization and precise initial positioning, whereas the second plane is extending along the wholelateralwalls of the drill, for lateral osteotomy drilling producing tapered osteotomy site. This unique design is responsible for reduction of the cutting pressure, less power consumption and minimal heat generation [8].

Single drilling approachshowed better performance throughheat control, reducing the friction between the drills and the osteotomy walls, shortening of the procedure timeand obtaining satisfactory outcomes with minimal intra-operative trauma and postoperative complications if compared to traditional drilling using multiple drills [15].

The results of the current study demonstrated 100% success rate for both groups. This is in accordance with the study of Bettach and co-workers (2015) who reported high success rates (98% of implant survival) of using of either single drillor conventional sequential drills during the osteotomy preparation in 350 implants [16]. Moreover, other studies reported comparable outcomes between single and sequential drilling manoeuvres regarding periimplant bony healing and osseointegration [17-19]. In addition, Marheineke and colleagues in 2018 demostrated that using singledrill technique is less invasive and could enhance osseointegration [20]. On the other hand, Li et al. (2014), reported a high risk of heat generation and accumulation of bone residues between the drill flutes particularly in dense boneupon using single drill and they recommended vigorous cooling and irrigation to washbonychipsfrom the drill flutes and to control temperature [21].

With regard to MB loss 6 months after implantation, the 2 groups in the present study demonstrated minimal MB loss than that observed by Guazzi and colleagues who observed 0.54 mm mean peri-implant bone loss related to single-drilling group compared with 0.41mm mean loss in the conventional-drilling group [24]. This could be referred to several factors including being atraumatic as possible by using CGT, flapless technique, and platformswitched implants as discussed above by Franchina and colleagues (2020) [12], Garber et al. (2001) [15], and Farronato and co-work-

Variable	GI	GII		
Age (years)				
Mean + SD	39.54+6.98	39.80+7.35		
Minimum	26	27		
Maximum	50	50		
Gender (n[%])				
Male	12 (46.15%)	11 (44%)		
Female	14 (53.85%)	14 (56%)		

Table 1. Showing the demographic data of participants in this study.

SD: Standard Deviation

Table 2. Mean MBLoss and degree of paininboth groups.

	GI	GII	
Parameter	Mean + SD	Mean + SD	Р
MBL loss 0-6	0.055 ± 0.005	0.043+0.002	< 0.001*
Post-operative Degree of pain	4.15+0.67	1.72+0.79	< 0.001*

MBL: Marginal Bone Level*: Statistical significant difference; SD: Standard Deviation

ers (2021) [14].

Single drill group (GII) demonstrated significant reduction in MB loss when compared to sequential drilling group (GI). This could be due to minimal surgical trauma during preparation of the osteotomy and minimal bone heating during single drillapproach [22]. Moreover, minimalbone trauma with singledrilling was found to maintainbony tissues without reducing its healing power [23]. Conversely, as described by Guazzi and colleagues (2015)who compared the clinical outcomes of implants placed in sites drilled with single drill against conventional drills, reported shorter operation time with minimal post-surgical morbidity with single drill group, but non-significant differences were observed regarding MBL changes in between the 2 approaches [24].

Another aspect assessed was the degree of post-operativepain, results of our study revealed minimal postoperative pain associated with single drill approach, this significant reduction of pain degree could be explained by minimally exerted pressure on the osteotomy wall and minimally generated heat by single drill that reduces post-operative inflammatory reaction. Parallel to the recorded results here, Guazzi et al. (2015) reported that the single drilling approach required shorter operation timing by 3.6 min less than the classical drilling approach, that results in minimal patient post-operative pain, discomfort and good acceptance of the procedures by the patients [24].

The tiny sample size was one of the study's significant limitations. Also, only 6 months observational period was considered sufficient to resalise the effects of the drilling method in osseointegration. Because both methods were performed in randomised clinical settings and the patient inclusion criteria were quite broad, the findings of this study can be applied to patients with similar features.

Conclusion

Within the current study limitations, preparation of the osteotomy sites of dental implants with CGT and single drill approach demonstratedminimal postoperative pain and minimal MB loss. Further studies with more participants, longer evaluation period, histological assessment and evaluation of heat generation would be necessary to validate the present study.

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