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EVALUATION OF IMMEDIATELY PLACED ULTRA WIDE DIAMETER IMPLANT PLACED IN MANDIBULAR MOLARS (A SINGLE ARM CLINICAL TRIAL)

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ABSTRACT

INTRODUCTION: In immediate implant placement, Grafting materials should be used if there is a gap of more than 2mm between socket walls and the implant body. Ultra-wide diameter implants (UWD) "7 - 9 mm diameter " were introduced to allow more engagement to molar socket walls and to reduce the necessity for using bone grafts in immediate molar placement.
OBJECTIVES: Evaluation of both radiographical and clinical outcomes of osteointegration and peri-implant bone density outcomes when using UWD implant placed immediately in molar extraction socket.
MATERIALS AND METHODS: 12 ultrawide dental implants were placed immediately in freshly atraumatically extracted molar sockets of 12 patients without raising flaps or using bone grafts. Cement retained crown was loaded 6 months postoperatively. All patients underwent clinical and radiographical evaluations for 9 months.
RESULTS: Implant stability and peri-implant bone density showed a statistically significant increase through follow-up time periods.
CONCLUSION: This study demonstrated that using ultrawide dental implants immediately in freshly extracted mandibular molar sockets is a predictable modality to improve implant stability and bone density with less marginal bone resorption.
KEYWORDS: Implants, Immediate implant placement, Ultra-wide diameter, Implant stability, Bone density
RUNNING TITLE: UWD implants immediately placed in mandibular molar sockets.

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INTRODUCTION

Alveolar bone undergoes dimensional alterations vertically and horizontally after tooth extraction as a result of periodontal loss and bundle bone resorption in the bony socket, leading to a reduction of bone volume that affects negatively the dental implant placement and the restorative treatment functionally and esthetically (1). It was suggested that immediate implant placement after a tooth extraction is more favourable than delayed implant placement since it results in less buccolingual bone reduction (2).

The immediate implant as a single surgical procedure has many advantages. These advantages include precise implant positioning, socket bone preservation, and shortened treatment time (3). Furthermore, studies reported a decrease in the amount of bone loss with the immediate implant placement after tooth extraction (4).

The final outcome of immediate placement depends on many important factors including alveolar bone preservation especially the buccal plate of bone, the oral hygiene state, the surgical and prosthetic protocol followed, the surgical technique used, the implant position in the socket, the use of bone grafts and the elevation approach either flapless or with a flap (5).

Successful immediate implant placement is determined by primary stability which is an essential factor (6) this is also very challenging in molar sockets due to many reasons such as the presence of multiple roots with large socket voids, and the anatomical limitations due to the presence of maxillary sinus and inferior alveolar nerve (7).

When the jumping gap "which is the residual space remains between the implant body and the socket wall due to a discrepancy in size between the implant and the socket wall" exceeded 2 mm, a grafting material should be used to decrease this gap as the larger the jumping gaps, the higher the risk of bone resorption and the decrease in implant stability (8).

Wider diameter implants in immediate molar implant placement have many advantages over the narrow conventional implant. These advantages are increasing the contact area engaging the implant with the socket walls and inter radicular area for better osteointegration and more favorable occlusal forces distribution (9) it also enhances the emergence profile and permits using wider and stronger prosthetic components (10).

Ultra-wide dental implants increase primary stability and diminish the residual gap in the molar socket reducing the need for bone graft with a predictable outcome and very little bone loss (11). This technique requires high clinical experience in teeth removal atraumatically for bone preservation and site preparation and also requires a careful case selection for a successful treatment (9).

Hattingh et al., (11) concluded that the immediate placement of UWD dental implant in a freshly extracted molar socket following atraumatic extraction without any flaps has a predictable outcome esthetically with minimal contour changes and accepted stability over time.

The null hypothesis stated that using the ultra-wide implant placed immediately after molar extraction doesn't have any significant effect on implant stability or peri-implant bone density.

MATERIALS AND METHODS

This study was conducted as a single-arm clinical trial following the CONSORT guidelines (12).

Study sample: For this clinical trial, 12 Patients with unrestorable mandibular molar teeth were recruited from the outpatient clinic of the Oral and Maxillofacial Surgery Department, Faculty of Dentistry, Alexandria University. It included 12 ultrawide dental implants placed immediately in freshly atraumatically extracted mandibular molar sockets.

Method of sample randomization: The sample was stratified by gender into two groups.

Sample size calculation: The sample size was based on Rosner's method (13) and calculated via Gpower 3.0.10 (14). All collected data was statistically analyzed by the IBM Statistical Package for Social Science (SPSS) software version 23.

All procedures were carried out following the guidelines of Ethics research committee, Faculty of Dentistry, Alexandria University. Ethics committee No: 0210-01/2021.

Clinical trial registration: This clinical trial was listed on clinicaltrials.gov as Ultra-wide Diameter Implants in Mandibular Molars (UWD) with the registration number NCT05972447.

Consent: Before the surgical procedure, all patients got informed about the study's purpose, and every patient signed an informed written consent after receiving a clear uncomplicated explanation of all the benefits and side effects of the procedure.

Eligibility criteria (15)

Inclusion criteria: The patients included in this study aged between 20 and 40 years with non-restorable mandibular molars to be extracted atraumatically, adequate bone beyond teeth apices 2 mm at least should be present without jeopardizing any anatomical structure (2), The available buccal bone plate thickness should be >1mm (15), Peri-implant bone defect should be 2mm or lesser.

- **Exclusion criteria:** This study excluded patients who smoke, medically compromised patients with uncontrolled diabetes or coagulation disorders, and teeth with periapical pathosis or bony defects.

Materials used:

- Superline II ultrawide implant 7mm diameter, length 8-10mm (Dentium, South Korea).
- Osstell. (Osstell, Göteborg, Sweden).
- Physiodispenser (COXO | C-SAILOR IMPLANT MOTOR, China).

Methods

1) Presurgical phase

Detailed personal information, past medical history, and dental history were recorded for each patient who participated in this clinical trial.

All patients underwent Cone-Beam Computed Tomography (CBCT) to evaluate the periapical tissues and bone condition and exclude the presence of any pathosis or bony defect before the surgical procedure.

2) Surgical phase (16) (Figure 1)

According to the INFECTIOUS DISEASE SOCIETY of AMERICA standards, all patients were given a prophylactic dose of Amoxicillin clavulanate antibiotic (Augmentin: Clavulanic acid 125 mg + Amoxicillin 875 mg GlaxoSmithKline, UK) to control infection before the operation (17).

Surgical procedure: The patient was given local anaesthesia then the molar teeth were extracted atraumatically. The implant was then placed according to the manufacturer's instructions, without the need for raising flaps or removing bone. After the implant was in place, a healing abutment was attached to it. To help the soft tissue adapt and fill any gaps, sutures and a hemostatic collagen sponge were used around the healing abutment.

3) Post-operative phase

a) **Early postoperative stage:** After surgery, each patient was advised to avoid rinsing for 24 hours and apply cold fomentation for the same duration. They were then advised to take a soft diet, high in protein, calories, and fluids for 2 weeks postoperatively.

b) **Postoperative medication**

- 1 gram of Amoxicillin-clavulanate (Augmentin: Clavulanic acid 125 mg + Amoxicillin 875 mg GlaxoSmithKline, UK) every 12 hours for 7 days.
- 50 gram of Diclofenac potassium (Cataflam by Novartis Switzerland) every 8 hours for a duration of 5 days.

- Chymotrypsin 300 E.A.U (14 micro katals) + Trypsin 300 E.A.U (5 micro katals) (Alphintern by Amoun Pharmaceutical Co. S.A.E) every 8 hours for a duration of 5 days. Every patient was instructed to rinse using an antiseptic mouthwash containing chlorhexidine (Hexitol: Chlorhexidine 125mg/100ml, conc 0.125%, ADCO).

4) Follow-up phase

Clinical follow-up phase

a) Postoperative pain (17)

The postoperative pain was recorded for each patient 48 hours and one week postoperatively through a 10-point Visual Analogue Scale (VAS) from 0 to 10.

b) Postoperative Edema (18)

Edema was assessed for all patients 48 hours postoperatively, then after one week through a scale with 4 parameters: None (no swelling), light (localized intraoral), moderate (localized extraoral), and severe (extraoral swelling extending beyond the treated area).

Implant stability (Figure 2)

Implant stability meter (Osstell™) was used to assess peri-implant stability immediately postoperatively and at 6 months (20). The implant stability was assessed on all implant sides including the palatal, buccal, distal, and mesial sides, and then the mean values of implant stability quotient (ISQ) were obtained.

c) Peri-implant probing depth

Evaluation of probing depth was done following the guidelines of Gallagher and Silver (17) immediately, at 6 months and at 9 months postoperatively. Probing pocket depth refers to the distance between the gingival margin and the deepest part of the gingival sulcus. The measurement of both buccal and lingual pockets was done at the implant's midline, whereas the measurement of mesial and distal pockets was done to the closest contact point from the buccal aspect.

Radiographic evaluation

A CBCT was taken immediately postoperatively, at 6 months and 9 months postoperatively to evaluate marginal bone loss (MBL) and peri-implant bone density using OnDemand3D™* system (OnDemand3D™ software, Cybermed Inc, Korea).

a) Marginal bone loss (20) (Figure 3)

From the reconstructed corrected sagittal images, both mesial and distal crestal bone levels were estimated by drawing a line tangent to the implant serration extending from the most apical point of the implant to the point representing the crest of the bone margins. The mean of the two sides was determined at each time period and statistically analyzed.

b) Peri-implant bone density (21) (Figure 4)

The peri-implant bone density was evaluated radiographically using OnDemand3D™* (OnDemand3D™ software, Cybermed Inc, Korea) at immediate postoperatively, 6 months and 9 months postoperatively. The bone density was measured within 3 predetermined fixed points around the implant (buccal, lingual and apical) and the immediate postoperative bone density measurements were taken as a reference point for each time interval. The system displayed standard deviation, the mean, minimum and maximum readings automatically using Hounsfield Unit (H.U).

5) Prosthetic phase (Figure 5)

After 6 months of integration, a cemented retained crown was attached to the implant.

Statistical Analysis of the Data

The collected data was analyzed using IBM SPSS version 23, Armonk, NY, USA. Normal distribution was approved for all variables thus data were presented using mean, standard deviation (SD), 95% Confidence Intervals (CI), minimum and maximum values. While ordinal variables "pain and swelling scores" were presented using median, Inter Quartile Range (IQR) in addition to minimum and maximum values.

The used tests were:

1. Shapiro Wilk test and Q-Q plots
2. Paired t .test
3. Wilcoxon sign Rank test
4. ANOVA with repeated measures

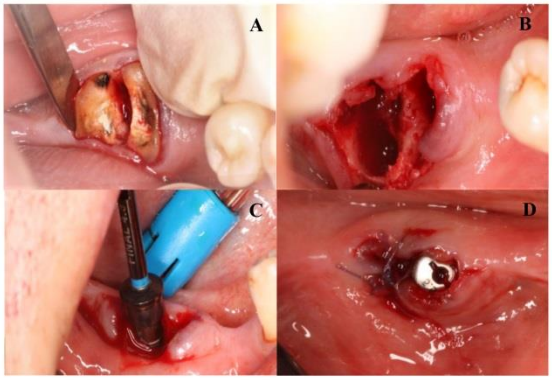

Figure (1): Showing the surgical phase A) atraumatic extraction of unrestorable molar B) post-extraction socket C) immediate implant placement with flapless approach D) healing abutment and suturing.

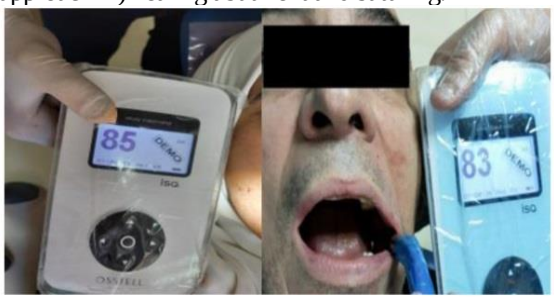

Figure (2): Showing peri-implant primary stability assessment using Osstell device**.**

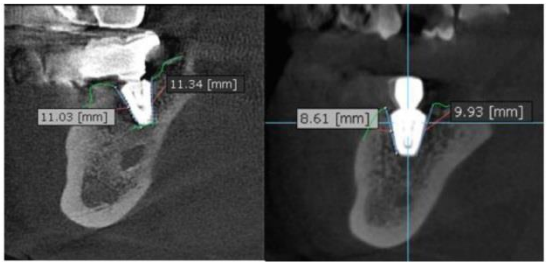

Figure (3): Showing marginal bone loss assessment via CBCT sagittal images.

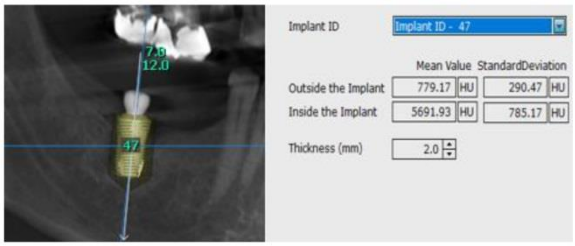

Figure (4): Showing calculating peri-implant bone density using OnDemand3D™.

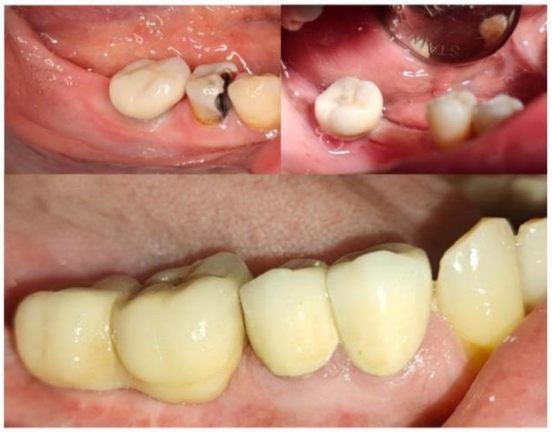

Figure (5): Showing the prosthetic phase (cemented retained crown) after 6 months of integration.

RESULTS

Clinical evaluation

1) Pain

By the second day after surgery, five patients had no pain at the surgical site, four patients experienced slight mild pain, and three patients experienced moderate pain. The pain had subsided totally by the 7th day postoperatively except for two patients who experienced slightly mild pain after one week postoperatively showing a statistically significant difference between the different time periods. (p-value 0.011)

2) Edema

By the second day Postoperatively, six patients had experienced no swelling, five patients had experienced slight mild swelling and only one patient had experienced moderate swelling. The swelling had subsided totally by the 7th day postoperatively except for one patient who reported slight mild swelling after one week postoperatively showing a statistically significant difference between the different time periods. (p-value 0.014)

3) Peri-implant probing depth

The mean value of peri-implant probing depth postoperatively was 2.63 (0.46) ranging from 1.74 to 3.24 mm, while the mean value of peri-implant probing depth was 2.56 (0.46) at 6 months ranging from 1.68 to 3.12mm, and the mean value of peri-implant probing depth was 2.54 (0.46) at 9 months ranging from 1.68 to 3.12mm showing a statistically significant difference between the time periods.

4) Implant stability (Table 1)

The mean value of implant stability immediately postoperatively was 78.42(7.34) ranging from 66 to 85. While in the sixth month, the mean value of implant stability was 79.7(7.4) ranging from 65 to 87. It showed a statistically significant increase along the two-time intervals.

Radiographic evaluation

According to the data collected from the different radiographic views along the postoperative periods, it was specifically assessed and statistically analyzed as follows:

1) Peri-implant Marginal Bone Loss evaluation (Table 2)

In the sixth month phase, the mean value of MBL recorded 0.33 (0.23) mm ranging from 0.05 mm to 0.90 mm.

In the ninth month phase, the mean value of MBL recorded 0.24(0.11) mm ranging from 0.10 to 0.41 mm.

2) Peri-implant bone density evaluation (Table 3)

The mean value of peri-implant bone density immediately postoperatively was 734.61(139.52) HU ranging from 510.45 HU to 930.40 HU. In the sixth month, the mean value of peri-implant bone density was 801.79 (127.57) HU ranging from 644.09 HU to 1011.67 HU. In the ninth month, the mean value of peri-implant bone density was 857.72(100.88) HU ranging from 698.99 HU to 1023.22 HU.

These findings revealed a significant statistical difference between the two-time intervals (P_1=0.009*, P_2=0.003*, P_3=0.010*).

Table (1): Comparison of implant stability immediately post-operative and after 6 months

	Postoperative	6 months
Mean (SD)	78.42 (7.34)	79.7 (7.4)
95% CI	74.267 , 82.573	75.513 , 83.887
Min - Max	66.00 – 85.00	65.00 – 87.00
Paired t test (p value)	2.32 (0.040)	

*Statistically significant difference at p value<0.05, CI: confidence interval

Table (2): Comparison of peri-implant marginal bone loss at 6 and 9 months follow up

	6 months	9 months
Mean (SD)	0.33 (0.23)	0.24 (0.11)
95% CI	0.18, 0.47	0.17, 0.31
Min - Max	0.05 – 0.90	0.10 – 0.41
Paired t test (p value)	1.412 (0.186)	

*Statistically significant difference at p value<0.05, CI: confidence interval

Table (3): Comparison of peri-implant bone density postoperatively, at 6 and 9 months follow up

	Postoperative	6 months	9 months
Mean (SD)	734.61 (139.52)	801.79 (127.57)	857.72 (100.88)
95% CI	645.96, 823.25	720.74, 882.84	793.62, 921.81
Min - Max	510.45 – 930.40	644.09 – 1011.67	698.99 – 1023.22
Repeated F test (p value)	17.580 (<0.0001*)		
Pairwise comparisons	P_1=0.009*, P_2=0.003*, P_3=0.010*		

*Statistically significant difference at p value<0.05, CI: confidence interval, P_1: Comparison between postoperative and 6 months, P_2: Comparison between postoperative and 9 months, P_3: Comparison between 6 months and 9 months

DISCUSSION

This study reported a 100% survival rate through a 9-month follow-up period which was agreed with Krennmair et al 2004 results that revealed survival rates of more than 95% of using wide-diameter implants along one year follow-up period (22). Also, Wadhwa et al 2021 reported an excellent survival rate of wide-diameter implants (97.29%) compared to standard diameter implants (94.87%) with lower MBL over a 6-year follow-up period (23).

Regarding our study, all the 12 implants placed in this study have shown a 100% success rate with no failure and this was correlated with Vandeweghe et al results that reported a 97.9% implant success rate of using 98 implants with 8-9 mm diameter placed in 89 patients after 20 months (24). Unlike Shin et al in a 5-year retrospective study that stated that using wide-diameter implants in posterior areas may exhibit a higher probability of implant failure in comparison to the standard implants (25).

Pain and edema had subsided completely after the first week postoperatively and these findings were agreed with Al-Khabbaz et al who reported that the post-operative pain after dental implantation was bearable and mild and gradually diminished over time (26).

In agreement with our study, Fortin et al 2006 in his study demonstrated that using a flapless approach and minimally invasive surgical procedures decreased the post-surgical swelling and patients felt less intensive pain and for a shorter duration when compared with the conventional procedures (27). While Aizenberg et al in his study found that pain intensity showed no differences between the open flap and flapless surgery (28).

In this study, the peri-implant probing depth was assessed immediately, 6 months and 9 months postoperatively using minimal force to avoid any injury in peri-implant tissue (29) the mean value of peri-implant probing depth recorded in this study at 9 months was 2.54 (0.46) in agreement with Hattingh et al 2018 results that reported mean peri-implant probing depth of a value of 2.59 mm (SD 0.70) after one year follow-up period (11), and these values were correlated with Araugo et al. who demonstrated that the healthy peri-implant probing depth should be less than 5mm (30).

Implant stability was considered an important clinical parameter. ISQ was evaluated for all patients after implant placement immediately and 6 months postoperatively using Osstell device, the results showed a significant statistical increase among time intervals to reach 79.7(7.4) on the 6th month postoperatively. These findings agreed with Tallarico et al 2016 in which UWD implants of 7 mm diameter recorded a high ISQ level of a value of 78.8(2.8) 6 months after immediate implant placement and achieved a high success rate with favourable clinical outcomes (31).

In agreement with our study and according to Ramakrishna et al, ISQ with values higher than 65 was reported to be most favourable regarding implant stability, while ISQ values less than 45 were reported as poor primary stability (32). This was also agreed with Rodrigo et al. study in which the implant stability was measured following implant placement and prior to prosthetic loading, and categorized into two groups showing a 99.1% success rate of implants with ISQ values higher than 60 and 97.2% for implants with ISQ values less than 60 (33).

The mean value of post-operative marginal-bone loss assessed in the present study at 6 months period was 0.33 ± 0.23 mm and its mean value at a 9-month period was 0.24±0.11. These findings were matched with Elsaid et al study that recorded 0.32 ± 0.23mm for the mean value of marginal-bone loss 6 months post-operatively (34). Also, Kim et al 2023 in their study about the effect of using UWD implants in posterior areas reported a one-year MBL of 0.2mm after prosthesis loading and 0.54 mm along the follow-up phase (35). While Tiwari et al in 2020 recorded MBL of a value of 1.02mm 6 months after immediate mandibular molar placement (36). However, in this study the MBL along the different time periods was acceptable and these findings were agreed with Tallarico et al in 2016 in which the overall MBL was better than other studies that revealed more MBL when using UWD dental implants (31, 37).

Regarding the peri-implant bone density, the mean peri-implant bone density value outside the implant immediately post-operatively was 734.61 (139.52) HU ranging from 510.45 HU to 930.40 HU and at 6 months was 801.79 (127.57) HU ranging from 644.09 HU to 1011.67 HU which was agreed with Hiasa et al (38) in 2011 in his study about the measurement of peri-implant bone densities outside the implant using Hounsfield units (HU) in 73 implants in the mandibular region immediately post-operatively showing the mean peri-implant bone density outside the implant in posterior

mandibular areas 712.4 (222.3) and also correlated with Misch classification of bone densities in which the posterior mandibular area represents D2 and D3 that range 850 to 1250 HU for D2 and 350 to 850 HU for D3 bone densities next to the implant-bone interface (39).

Our study reported a significant statistical increase in the mean value of peri-implant bone density since the operation to 9 months postoperatively and this increase indicates the enhancement of osseointegration along the evaluation period which agreed with Manoj et al in his study about the immediate implants in mandibular molars that showed improved peri-implant bone density level at the 6 months follow up period (40).

This study has some limitations, the first limitation is the small sample size and the second limitation is the lack of prior research studies about using UWD implants so further studies are recommended using a larger sample size.

CONCLUSIONS

Our findings suggest that placing UWD dental implants immediately in posterior molar sockets improves peri-implant osseointegration and reduces the need for graft materials.

CONFLICT OF INTEREST

The authors declare no conflicts of interest.

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