

Evaluation of Osseointegration of Dental Implants Prepared by Piezosurgery (Clinical Study)

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ABSTRACT

Background: Piezosurgery device is a system developed recently to overcome the limitation of the traditional surgical technique in implant site preparation, which use the principle of ultrasonic microvibrations to create precise & selective cut in bone in harmony with the surrounding tissues. The aim of this study was to evaluate the outcomes of implants inserted by ultrasonic implant site preparation protocol (UISP) using piezosurgery device, regarding the survival rate, stability and other related factors, at 16 weeks postoperative follow up period.

Materials and Methods: A total of (24) patients, (6) males and (18) females, aged between (19-51) years old, contributed in this study receiving a total of (42) implants, all of these implants bed were prepared by means of special tips mounted in piezosurgery device. For each patient thorough clinical and radiographical preoperative assessment was applied. Implant stability quotient (ISQ) values were measured at baseline, 8 weeks and at 16 weeks. Postoperative clinical and radiographic evaluation was applied for each patient for 16 weeks postoperatively.

Results: (24) patients received (42) implants accomplished the follow-up period, After 16 weeks all implants (42) were osseointegrated and the overall implants survival rate was 100% with no failure and no complication was observed. The mean ISQ value at baseline was (74.32±6.42), the mean ISQ value at 8 weeks was (72.62±9.05) and at 16 weeks the mean ISQ (±SD) value was (76.68±7.35) the changes in the mean stability during the healing period showed significant increase in the implant stability ($P \leq 0.05$). At the 16th week the number of implants that achieved $ISQ \geq 70$ was 35 (83.3%), and 7 implants attained $ISQ < 70$ (16.7%).

Conclusions: high and significant survival rate, significant secondary stability, early positive shifting of the mean ISQ value, no remarkable complications in implants inserted by ultrasonic implant site preparation indicated that piezosurgery is a reliable alternative and safe method used in dental implant osteotomy.

Key words: piezosurgery dental implant, survival rate, RFA. (J Bagh Coll Dentistry 2017; 29(1):96-103).

INTRODUCTION

To overcome the limitations of traditional techniques (a lot of heat production during bone cutting and the high amount of external copious irrigation required, application of significant pressure in osseous surgeries so endangered management of fractured and delicate bones) ⁽¹⁾ ⁽²⁾ ⁽³⁾ scientists introduce an advanced therapeutic devices which use the principle of ultrasonic microvibrations to create precise and selective cut on the bone in harmony with the surrounding tissues, ⁽²⁾ ⁽³⁾ so the innovation of piezosurgery creates new possibilities in accomplishment of osteotomies using piezoelectric device.

The effect of piezosurgery device has been widely investigated in many fields of orthopedics, periodontology, oral & maxillofacial surgery and implantology.

Clinical studies have suggested that piezosurgery used in implant site preparation resulted in high initial (primary) stability and earlier shifting from primary to secondary stability.

Also histological and biomolecular studies on bone healing in areas where the osteotomy is performed using Piezosurgery® demonstrated many more advantages to healing than using bone burs. ⁽⁴⁾ Dental implants success rate and survival depend primarily on Osseointegration which was defined by Branemark as the “direct structural and functional connection between the ordered living bone and the surface of load carrying implant”. ⁽⁵⁾

Osseointegration is affected by many factors such as implant material and its biocompatibility, loading protocols (delayed or immediate), patient factors, implant design, primary stability and the surgical technique.

Implant stability is one of the important factors for achieving successful osseointegration, and the overall Implant stability can be evaluated and monitored by many clinical methods (invasive) and (noninvasive) and Osstell Mentor represents a clinical noninvasive device used to delineate stability of implant via magnetic frequencies between a magnetic peg (smart peg) adapted to the top of the implant and a resonance frequency analyzer. ⁽⁶⁾ ⁽⁷⁾ The aim of the study was to evaluate the outcomes of implants inserted by ultrasonic implant site preparation protocol (UISP) using piezosurgery device, regarding the survival rate, stability and other

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related factors, at 16 weeks postoperative follow up period.

MATERIALS AND METHODS

This clinical study was conducted At the department of oral and maxillofacial surgery, College of Dentistry, University of Baghdad during the period from November 2014 to October 2015. The sample included patients indicated for implant treatment to replace single or multiple maxillary and mandibular lost teeth, implant sites were prepared using (UISP) protocol using piezosurgery device, fixtures installed into the prepared site, by means of two-stage implant surgery protocol.

The inclusion criteria were healed edentulous area for at least 6 months after extraction, age above 18 years, good oral hygiene, bone volume must be at least 6 mm in width, enough available bone height and at least 6mm mesiodistally and D2 and/or D3 bone density. (Misch, 1988)⁽⁸⁾

The patients excluded from this study were those with any known systemic diseases that affect dental implants, radiotherapy of the head and the neck within the past 24 months, bisphosphonate history, heavy smokers (>20 cigarettes/day), uncontrolled diabetics, and patient with parafunctional habits, pregnant or lactating women, immunocompromised patients, patients unable to return back for follow up and study recall, medical condition that preclude any surgical intervention such as patient with bleeding disorders or recent myocardial infarction, psychiatric problem, and patients with pacemaker, close proximity of vital structure such as maxillary sinus and mental foramen and inferior alveolar nerve that make impossible to reach the required implants length, insufficient bone volume, width, length and mesio-distal dimension to insert implants, sites that need augmentation or regenerative treatment (dehiscence or fenestration of the residual bony wall), active advanced uncontrolled periodontal disease and bad oral hygiene.

Preoperative assessment

For each patient a preoperative assessment starting with detailed personal information, previous medical and dental history, and reviewing all inclusion and exclusion criteria mentioned before.

Clinical examination included the oral hygiene condition, the absence or presence of active periodontal disease, the edentulous area condition, estimation of the dimensions of the edentulous space, the intra-arch distance. Radiographic assessment preoperative (OPG) to assist in the selection of the correct length of the

fixture, determination of available bone height, estimation of the root inclination of the adjacent teeth, presence of any pathological condition and the proximity to the vital structures (*fig.1*).

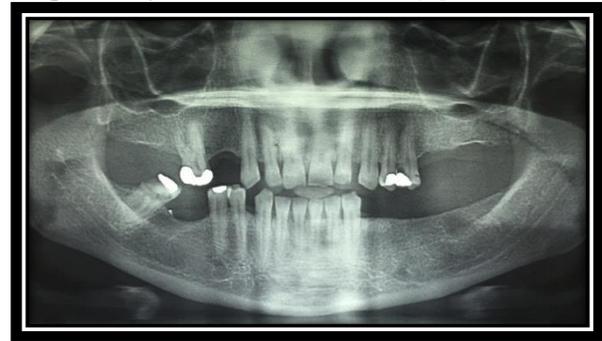


Figure1:Diagnostic preoperative panoramic radiograph (OPG).

Surgical procedure

Prior to surgery perioral skin was scrubbed with povidone-iodine solution and every patient was instructed to rinse his/her mouth with chlorhexidine mouth- wash (lactalut CO. Ltd) for one minute before surgery.

Infiltration technique were used for all surgical procedures, (*lidocaine 2%, adrenalin 1:100000, 2.2 ml cartridge, Septodont, France*), as a local anesthesia.

Full thickness three sided mucoperiosteal flaps were raised and the underlying bone was exposed with palatal bias of the crestal incision in the maxilla and slightly linguallly in the mandible, in order to provide a good coverage of the fixture with keratinized soft tissues and prevent the presence of the fixture beneath the suture line.

Calibrated periodontal probe was used for direct bone measurement to make sure that the width of the bone (bucco-lingual & mesio-distal) is not less than 6mm. (*fig. 2A*) & (*fig. 2 B*).

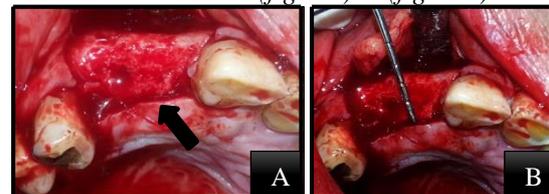


Figure 2: A- Three sided mucoperiosteal flap with palatal bias (black arrow). B- Ridge width measurement by periodontal probe.

piezosurgery device (Mectron Co, Italy) (*fig.3*) & special tips mounted on the device (Implant site preparation Kit) especially designed & used for the preparation of the implant sites) (*fig.4*). Using (UISP) protocol by Vercellotti.



Figure 3: Piezosurgery device (Mectron Co., Italy).



Figure 4: Implant site preparation tips (Mectron CO., Italy).

The preparation started with IM1S insert which is used for the initial osteotomy (fig. 5) then the 2nd insert (IM2A, IM2P- 2mm in diameter) used as the pilot osteotomy reached to the planned working length (fig. 5). Then the implant site preparation continued with (P2-3) insert which is used for enlargement of the of the osteotomy site to accommodate the next implant site preparation tip (fig. 5). The next insert used in the preparation is the (IM3A and IM3P) inserts to enlarge or to finalize the implant site preparation to accommodate the dental implant with 3 mm diameter. In the posterior area the implant site preparations continued by using the P3-4 insert which used to optimize concentricity of implant site preparation between Ø 3 and Ø4 mm. After that insert IM4P was used in implant site preparation to accommodate the implant fixture size 4.3 and 4.8 mm (Fig.5). Directional pins supplied with the operator kit were used step by step to check the preparation axis and corrections were made when needed.

Using these inserts need special techniques, all inserts should rotate in clock and anti-clock wise except IM1 insert movement in upward and down ward direction. For all inserts minimum pressure should be applied on the inserts (not exceeding 300 gram) according to the manufacturer instructions.

The implant fixture (Dentium Co.,S.L.A Korea) inserted at or just below the crestal bone level.

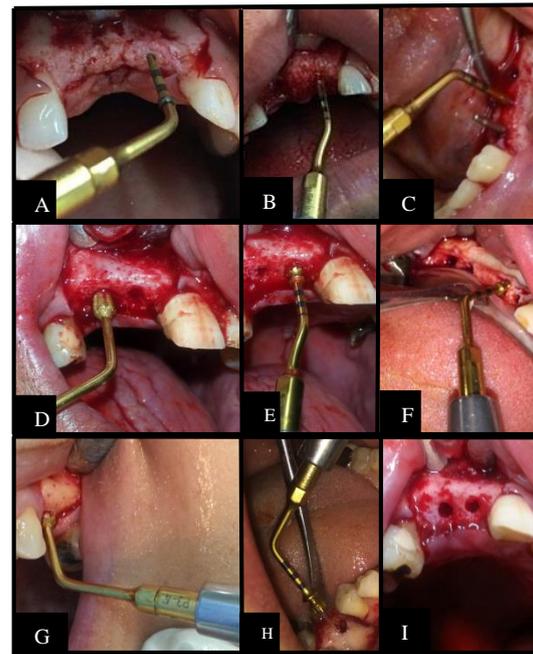


Figure 5: Complete surgical procedure of implant site preparation using piezosurgery (in sequence from A-I).

The implant stability evaluation was accomplished by osstell™ ISQ (Goteborg, Sweden, 4th generation). Smart peg (type six), screwed at the top of implant fixture by using smart peg mount. The transducer probe was directed perpendicular to the top of the Smart peg with a distance of approximately 2mm and held stable until the device beeped and displayed the ISQ value. The measurements were taken twice in bucco-lingual and mesio-distal directions (fig.6 A), the mean of the two measurements represents the primary stability value (ISQ) baseline. Then a cover screw was inserted over the implant fixture (fig.6 B).

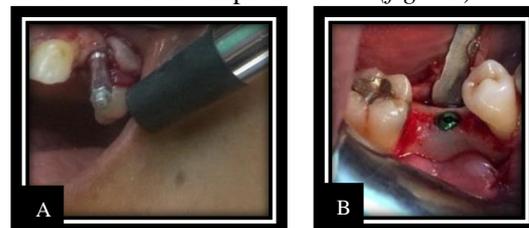


Figure 6: A-ISQ measurement, B-cover screw placement.

The surgical wound closed by simple interrupted suture using 3/0 non-resorbable black silk suture (Dytek, Australia).

Patients were instructed to apply cold packs on the side of the surgery adjacent to the involved area for the rest of the surgery day and the patients also instructed to avoid chewing or applying any pressure on the site of the surgery,

avoid wearing a denture, eating warm diet and rinsing the mouth at the day of surgery.

The patients medicated by Amoxicillin capsules 500mg three times daily for five days post-operatively, and for patients who were allergic to penicillin, azithromycin tablets (500 mg one time per day for three days), and metronidazole tab. (500mg three times daily). The antibiotic treatment continued for 5 days. Mefenamic acid tablets 500mg taken as analgesic on need.

The patients were instructed to use a chlorhexidine mouth wash 0.12% (for one minute, twice daily for two weeks). Sutures were removed at 10-14 days after the surgical procedure.

Follow up and data collection

The patients were recalled in 2, 8, 16 weeks for follow up and stability recording. After 2 weeks the sutures were removed and all the patients were evaluated for pain, discomfort, suppuration, cover screw exposure and any sign of infection. After 8 weeks all implants were exposed using soft tissue punch (Dentium Co., Korea) the smart peg fixed to the implant top and ISQ value calculated by Osstell (Goteborg, Sweden, 4th generation) with buccoligual and mesiodistal direction, the record documented as secondary implant stability at 8 weeks' time interval. At this appointment a suitable healing abutment (gingival former) was placed at the implant top (*fig. 8A*).

At 16 weeks all the patients had an OPG radiograph to assess the relation of implanted fixture with the other dentition and vital structures and for the final documentation (*fig.7*).



Figure 7: postoperative OPG of the same patient in figure 1 taken at 16 weeks.

At 16 weeks second reading of stability was measured by Osstell with buccoligual and mesiodistal direction, the record documented as secondary implant stability at 16 weeks.

At this time an impression was taken for prosthesis construction (*fig.8B*).

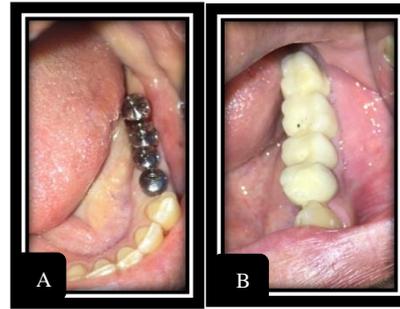


Figure 8: A- gingival formers in its place inside fixture body during the 2nd stage surgery. B- Final prosthesis.

Statistical analysis

Data description, analysis and presentation were performed using statistical Package for social Sciences (SPSS version 18) and Microsoft Office Excel 2007).

Frequency, percentage for qualitative variables, minimum, maximum, range, mean, SD and SE for numeric variables (Quantitative). Two independent sample t-test, and Pearson correlation (r), non-parametric chi-squared (X^2), friedman test were the statistical methods used to analyze the data.

The level of significance tested according to the P-value, were: $P > 0.05$ (Not Significant), $P < 0.05$ (Significant), $P < 0.01$ (Highly significant).

RESULTS

A total of (24) patients with (42) dental implants were inserted by ultrasonic implant site preparation (UISP) protocol (piezosurgery) and were recalled at 8 and 16 weeks for follow up and data recording.

Thirty one (73.8%) of implants for female and 11 (26.2%) of implants for male patients.

Twenty four (57.1%) of implants were inserted in the maxilla and 18 (42.9%) implants were inserted in the mandible.

The implants lengths were used in this study: 8mm length (8 fixtures), 10mm (10 fixtures and 12mm (24 fixtures).

The diameter of the implants used in this study was: 3.4(14 fixtures), 3.8 (13 fixtures), 4.3 (15 fixtures).

All the implants (42) were osseointegrated and overall of implants survival rate 100% of implants with no failure and no complication during the follow-up period. The mean ISQ value and standard deviation at base line was ($74.32ISQ \pm 6.42$) with a range (55.50-85.00 ISQ), the mean ISQ value and standard deviation at 8 weeks was ($72.62ISQ \pm 9.05$) with a range (54.00-86.50 ISQ) (*fig.9*). the mean ISQ value

and standard deviation at 16 weeks was (76.68 ± 7.35) , t-test showed high significant increase in the ISQ value from the primary stability at baseline to the secondary stability at 16 weeks ($P < 0.01$).

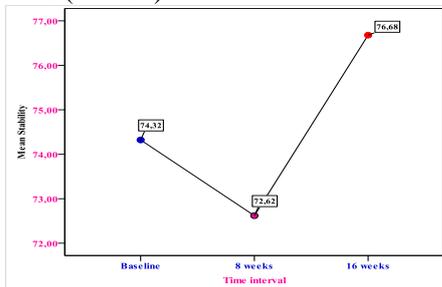


Figure 9: Line diagram showing the changes of mean ISQ (implant stability) at the time of surgery and after 2 successive intervals.

The mean ISQ at baseline was distributed as follow: high stability ≥ 70 (32 implants, 76.19%) low < 60 ISQ were 2 (4.76%), medium > 60 and < 70 ISQ were 8 (19.05%). The mean ISQ at 8 weeks distributed as follow: high stability ≥ 70 ISQ 26 (61.90%) implants, low < 60 ISQ 5 (11.90%) medium > 60 and < 70 ISQ 11 (26.19%). at 16 weeks the mean ISQ distributed as follow: high stability ≥ 70 ISQ were 35 (83.33%) implants, medium > 60 and < 70 ISQ were 6 (14.29%) implants, low < 60 ISQ were 1 (2.38%) implant (fig.10).

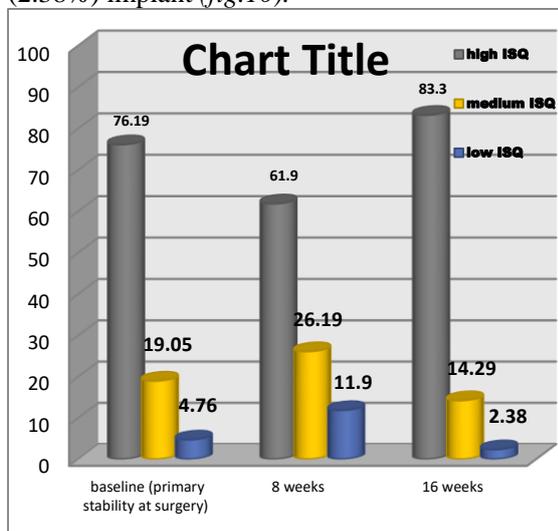


Figure 10: the rate of implants attained high stability (ISQ ≥ 70) & (ISQ > 70) at surgery and after 2 successive intervals (8, 16 weeks respectively) (ISQ threshold level ISQ > 60 low stability, ISQ 60-70 medium stability, ISQ < 70 high stability).

DISCUSSION

The results of this clinical study show an excellent short term survival rate. All implants were successfully osseointegrated and the survival rate achieved in this study was (100%) without

any evidence of failure and no remarkable complications for 16 weeks (about 4 months) follow up period, which meet the criteria of success of dental implant presented by Misch et al⁽⁹⁾ and this is in the line with many recently published clinical studies.⁽¹⁰⁾⁽¹¹⁾⁽¹²⁾⁽¹³⁾

The high excellent survival percentage (100%) in this study could be explained by, the application of this new surgical technique (ultrasonic implant site preparation) protocol using Mectron-piezosurgery device which is characterized by precise selective cutting, less traumatic, internal cooling, micro-vibration, selective cutting, cavitation's action, proper case selection, local oral health measure, oral and general health, proper selection of the implants site regarding the bone volume (3D) without any bony defect (dehiscence or fenestration), strict rules of aseptic technique, preoperative preparation, postoperative instructions and follow up, all these factors may explain this high percentage of survival (success) rate in this study.

Da silvaneto, et al⁽¹²⁾ in their clinical study comparing the stability of dental implants by conventional or piezosurgery showed that all implants survived and were well osseointegrated.

Vercellotti, et al⁽¹³⁾ in their extensive multicenter clinical study using ultrasonic device analyzing 3,579 implants with a 1-3 years follow up showed 97.74% overall survival rate without remarkable surgical complications.

The lowest mean value (ISQ) of stability recorded at the 8th week after implant placement is (72.62) ISQ, compared to the mean value (ISQ) of primary stability recorded at the time of surgery (74.32) ISQ, then at the 16th week post implant placement in which the mean value increased to (76.68) ISQ, these findings represent a normal change that occurred during the healing period and the ongoing osseointegration process at the bone-implant interface, and this process could reflect the transition from the primary mechanical stability to the secondary biological stability as a result of osteoclastic activity during the early postoperative healing period cause decrease in the initial mechanical stability.⁽¹⁴⁾⁽¹⁵⁾⁽¹⁶⁾ The decrease and following increase in the mean ISQ values in this study are in accordance with many clinical and experimental studies using piezoelectric devices in implant site preparation osteotomy⁽¹¹⁾⁽¹²⁾⁽¹⁶⁾⁽¹⁷⁾⁽¹⁸⁾⁽¹⁹⁾, which confirm the dipping curve of early healing period after implant placement noticed in most of the clinical studies by using this device or the conventional drilling ways. The results of this study showed

that all the inserted implants at the time of surgery achieved a good primary (initial) stability with a mean value (74.32) ISQ, and if we set the high threshold value at (70) ISQ, 32 (76.19%) of the inserted implants achieved high primary stability ISQ values with a range of (70-85) ISQ, and 8 (19.05%) achieved a medium (60- 69) ISQ values with a range of (67-69) ISQ with a mean (68.25) ISQ, and these results are comparable with other clinical studies using piezoelectric device for implant site preparation.⁽¹¹⁾⁽¹⁸⁾⁽¹²⁾⁽¹⁹⁾ This high primary stability values can be explained by the fact that piezoelectric device is more delicate instrument and less traumatic to the bone, with less pressure and less vibration during the osteotomy of the implant beds, and the achievement of this high value may explain the excellent survival rate (100%) in this study. Many studies support this explanation and suggest that primary stability may be useful predictor for osseointegration and the surgical technique is one of the important factors that have influence on the primary stability.⁽²⁰⁾⁽²¹⁾⁽²²⁾ Comparing the ISQ values related to the primary stability in this study and the stability after the two following successive intervals with two recent studies on a sample of Iraqi patients using conventional drilling osteotomy⁽²³⁾ with a slight difference follow-up time, showed that all the ISQ values were superior (higher) than that recorded by those aforementioned recent Iraqi study which can denote that the use of piezoelectric device (ultrasonic implant site preparation) as an alternative and useful method for the instillation of dental implants. After 8 weeks although the number of implants still achieving high (70 ISQ) decreased and although the differences were non-significant but the number of implants with medium ISQ values increased to eleven ($P \leq 0.005$) but the ISQ values for those implants with medium values remained with a relatively high ISQ with a mean value of (65.27) ISQs, and this value according to many clinical studies is regarded as an indicator for immediate or early immediate loading protocols.⁽²⁴⁾⁽²⁵⁾⁽²⁶⁾⁽²⁷⁾

At 16 weeks (at the end of the observation period) comparing the results of this study with other clinical studies using the piezoelectric device and RFA for the recording of ISQ, the final implants stability showed different patterns and results (values). parts of these studies⁽¹¹⁾⁽¹²⁾⁽¹⁸⁾⁽¹⁹⁾ show progressive increase in the ISQ values *Canullo et al*⁽¹⁹⁾ which in contrast with our study and with other studies⁽¹¹⁾⁽¹²⁾⁽¹⁷⁾ follows the ordinary regular increase of the ISQ values during the healing process period in dental

implants and this pattern was consistent with the first part (during the 8 weeks) of this study and in disagreement with the final part when there was a sharp elevation ($P = 0.000$) in the mean ISQ values reading from 72.62 to 76.68 ISQ. On the other hand the final ISQ values of the stability in accordance with many clinical studies⁽¹¹⁾⁽¹²⁾⁽¹⁹⁾ in which the recorded final ISQ values, (almost with the same post-operative follow-up period) surpassed (higher) the initial primary stability, and this result may be related to the increase of neo-osteogenesis, increase in bone stiffness, density and to better osseous response in the bone around implants using piezoelectric bone surgery according to many radiological, histomorphological and experimental studies⁽⁸⁾⁽¹⁰⁾⁽²⁹⁾ and in disagreement with *Blaszczyszyn et al*⁽¹⁸⁾ wherein they recorded inferior value in the mean ISQ value of the initial stability to the overall final mean ISQ value readings in other studies, and this could be explained by the fact there was obvious differences between these studies regarding, the patients samples, the follow up period, the piezoelectric device tips used, the statistical analysis methods and the variables included, so further clinical studies with large sample, better standardization, close monitoring of the ISQ values postoperatively seem to be crucial.

Within the limitation of this study, regarding the small sample size and the short post-surgical follow up period, Piezosurgery is a safe and predictable tool in implant sites preparation and could be used as alternative method to traditional techniques.

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الخلاصة

خلفية: تعتبر طريقة العملية الجراحية احد العوامل المؤثرة على عملية الاندماج العظمي. ان استخدام جهاز piezosurgery و هو نظام حديث الصنع يستخدم للتغلب على المعوقات التي تواجه الطريقة التقليدية في عملية الزراعة وهذا الجهاز يستخدم الاهتزازات الصغيرة بالموجات فوق الصوتية لخلق عملية قطع للعظم تتسم بالدقة والانتقائية في القطع بدون قطع الأنسجة المحيطة بها

المواد وطريقة البحث : ساهم في هذه الدراسة ما مجموعه (24) مريضاً، (6) من الذكور و (18) إناث، تتراوح أعمارهم بين (19-51) سنة، وقد تلقى المشتركون ما مجموعه (42) غرسية، أعدت كل من هذه الغرسات عن طريق استخدام الادوات الخاصة بجهاز piezosurgery. تم تطبيق التقييم قبل الجراحة لكل مريض بما في ذلك الفحص السريري الشعاعي الشامل. تم قياس ISQ للغرسات في يوم الجراحة، 8 أسابيع، وفي 16 أسبوعاً. تم تطبيق التقييم السريري والشعاعي بعد العملية الجراحية لكل مريض. الغرض من هذه الدراسة هو تقييم نسب النجاح و التغير الحاصل لثبات الزرع والتي استخدم جهاز piezosurgery لتحضيرها.

النتائج: (24) من المرضى تلقى (42) غرسية اكملت جميعها فترة المتابعة، وبعد 16 أسبوعاً لوحظ ان جميع الغرسات (42) قد اندمجت عظمياً ومعدل البقاء والنجاح للغرسات 100%. بدون أي فشل، ولا مضاعفات (0%). وكانت القيمة المتوسطة ISQ في الأساس (6.42 ± 74.32)، كان متوسط قيمة ISQ في 8 أسابيع (9.05 ± 72.62) وبنسبة 16 أسبوعاً كان متوسط قيمة ثبات الزرعات ISQ (76.68 ± 7.35). ان التغييرات في معدل ثبات الزرعات خلال فترة الشفاء أظهرت زيادة كبيرة في ثبات الغرسية. ($P \leq 0.05$) في الأسبوع الـ 16 عدد الغرسات التي حققت $ISQ \geq 70$ كان 35 (83.3%)، الغرسات التي حققت $ISQ > 70$ كان 7 (16.7%)

الاستنتاجات: ان نتائج الزراعة باستخدام جهاز piezosurgery اظهرت نتائج ثبات عالية وتقلل من وقت الشفاء ويؤدي إلى تحول مبكر في ثبات الغرسات عند تحضير موقع الغرسات بواسطة piezosurgery مستعدة..

الكلمات الرئيسية: piezosurgery ، معدل النجاح، الغرسات السنية، تحليل الترددات الرنينية.