

Clinical Evaluation of Stability of Short Implants versus Standard Implants Placed with Internal Sinus Floor Elevation in Edentulous Posterior Maxilla: A Randomized Controlled Clinical Trial (Part 1)

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ABSTRACT:

Objective: To clinically evaluate the primary stability of short (5.5mm) implants versus standard length (10mm) implants placed with osteotome sinus floor elevation.

Methods: 16 implants in 12 different patients with a mean age of 37.5. 8 implants in each group. All patients received full mouth mechanical debridement. Primary stability and crestal bone loss were both assessed initially, at 4, 6 and 12 months. Pain and swelling scores were recorded. Recession, probing depth, bleeding and plaque indices were also recorded at 4 months and 12 months.

Results: No statistical significant difference was found between both groups in regards to all parameters. No recession was observed in either group.

Regarding complications, BPVV was observed in one case in the control group and one implant failed in the test group. Two drop-outs occurred in the control group.

Conclusion: Both techniques achieved excellent comparable clinical and radiographic outcomes at 1 year after implant placement. No differences were observed between 5.5mm implants versus 10 mm implants placed with OSFE in the posterior atrophic maxillae in terms of ISQ, CBL, PD, mPI, mBI and recession.

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INTRODUCTION

Dental implants portray a highly successful treatment approach. However, implants in the maxillary posterior region were associated with compromised bone quantity and quality ¹. In order to overcome these shortcomings, an array of augmentation techniques have been traditionally employed to increase the residual ridge dimension including open and closed sinus lift ^{2,3}. However, such procedures have been reported to have several drawbacks including increased patient morbidity, costs and complications ^{4, 5, 6}. A valid alternative for such cases, is the use of short implants ⁷.

This study was conducted to test the hypothesis that there is no difference in implant stability when comparing short dental implants with standard length dental implants placed with osteotome sinus floor elevation.

Due to a large sample size, this study was divided into 3 parts with the exact same methodology and executed as a team project between 3 different post-graduate students in partial fulfillment of the requirements for their Master's Degree in Periodontology-Cairo University.

SUBJECTS, MATERIALS AND METHODS

The study consisted of a total of 12 patients (All 12 were females, aged 25-50 years) with a maxillary posterior edentulous area whom were recruited from the outpatient clinic of the Periodontology department, Faculty of Oral and Dental Medicine, Cairo University

between 2016 and 2017.

Criteria for patient selection

Inclusion criteria:

Partially edentulous patients in the maxillary posterior region whom are: medically free, have adequate inter-arch space, adequate soft tissue biotype ($\geq 2\text{mm}$), 7-8mm of available bone height below the maxillary sinus, bucco-palatal bone width of $\geq 6.5\text{mm}$, ≥ 20 years old, good oral hygiene, accepted a one year follow-up period, provided an informed consent

Exclusion criteria:

Patients with local pathological defects related to the area of interest, habits that may jeopardize the implant longevity and affect the results of the study such as alcoholism or para-functional habits, smokers, pregnant females, aggressive periodontitis.

Patients were randomly allocated to test (short 5.5mm implants) and control groups (Standard 10mm implants placed with OSFE (osteotome sinus floor elevation)). Blinding of the participants and operator was not applicable. All patients enrolled in the study provided an informed consent prior to surgery and had a pre-operative CBCT taken to determine bone height, width and density. They were also equally prepared for surgical implant placement by the principal investigator 2 weeks prior to the surgery. Diagnostic impressions were taken and a cast was poured out to create a radiographic stent at the area of interest.

Surgical steps

After administration of local anesthesia, a crestal incision was performed at the site and a full thickness mucoperiosteal flap was elevated. A retraction suture was placed in the palatal flap to aid with proper visibility and accessibility. The correct point of drilling was marked using a round bur and the drilling was then performed sequentially according to the manufacturer's instructions. The implant system used was "Super Line" by DENTIUM*.

A 2 mm safety margin was kept between the maxillary sinus and the short implants in the test group. In the control group, the sequential drilling stopped 2mm away from the maxillary sinus floor. The appropriate osteotome tip was then inserted into the osteotomy (Fig. 1) and the sinus lift technique was performed by gently tapping the osteotome with its corresponding hammer to fracture the 2mm of remaining bone height. Sinus lift was ensured when a sense of drop was felt or the correct marking on the osteotome was flushed with the bone crest.

Once the osteotomy was ready, the appropriate implant was inserted and a smart peg was attached to it to measure its stability using the Osstell device** (Fig. 2) and two readings were recorded in the patient's file; a mesio-distal and a bucco-palatal reading. The smart peg was then removed and replaced with a cover screw. The flap was then sutured back to its original position. A standardized digital periapical radiograph was then taken using a radiographic holder and a custom-made stent to determine the initial crestal bone level.

*Superline, DENTIUM, Seoul, Korea

**Osstell™ AB, Gothenburg, Sweden.

Post-operative instructions

Administration of Amoxicillin 1g twice daily for 5 days⁸. Ibuprofen 600mg three times daily for 5 days⁹. 0.12% Chlorhexidine oral rinse for 60 seconds twice a day for 14 days¹⁰.

Patient self-care; application of an ice bag to the treated area for the first 24 hours and avoiding any brushing and trauma to the surgical site for one week⁹.

Prosthetic part construction:

After four months from the date of the intervention, implants were exposed and a healing abutment was placed for two weeks. Impressions were taken and the prosthetic part was constructed consisting of a single porcelain fused to metal (PFM) crown with an occlusal access hole to ease removal during follow ups.

Clinical Parameters (One year follow-up)

Primary outcome:

Implant stability: measured at baseline, 4, 6 and 12 months using the Osstell device as ISQ readings

Secondary outcomes:

Pain: Readings were recorded by the patient for the first 12 days after the surgery using the descriptive NRS (numerical rating scale) of 0 to 10.

Swelling: Readings were recorded by the primary investigator for the first 8 days after the surgery using the tissue edema index which is a descriptive categorical rating scale of 0 to 4

Crestal bone loss: recorded at baseline, 4, 6 and 12 months using standardized digital periapical radiographs taken using the Minray Xray machine*** (Fig. 3, Fig. 4) and interpreted using the Digora Software and scanner****. All exposure parameters were fixed.

Probing depth, recession, modified gingival and plaque indices were recorded at 4 and 12 months using a periodontal probe.

***Minray, Soredex, Tuusula, Finland

****Digora optime, Soredex, Tuusula, Finland



Figure (1): Osteotome tip placed inside the osteotomy to perform internal sinus floor elevation



Figure (2): Measuring implant stability using a smart peg and the Osstell device



Figure (3): A periapical radiograph showing a 10mm implant placed with osteotomes to replace a missing upper right first molar (control group)



Figure (4): A periapical radiograph showing a 5.5mm short implant placed to replace a missing upper left first molar (test group)

RESULTS

The results of the study revealed that there was no statistical significant difference between

both groups in regards to pain and swelling in each of the observation days.

In regards to implant stability, the bucco-palatal readings were similar initially for both groups, higher in the sinus lift group (control) at 4 and 12 months, but higher for the short implant group (test) at 6 months, whilst the mesio-distal readings were higher initially, at 4, 6 and 12 months for the control group. However, tests revealed no statistically significant difference between both groups.

Concerning, crestal bone loss, tests revealed no statistically significant difference between both groups initially, at 4 and 6 months. However, at 12 months, crestal bone loss was greater in the sinus lift group but was also found to be statistically insignificant.

In reference to probing depth, bleeding and plaque scores, no significant difference was observed at 4 months. However, at 12 months all three parameters were greater for the sinus lift group but tests revealed these findings as statistically insignificant. No recession was observed in either group.

Regarding complications, BPPV (benign paroxysmal positional vertigo) was observed in one case in the control (sinus lift) group and one implant failed in the test (short implant) group. Two drop-outs occurred in the control group.

DISCUSSION

The present RCT was designed to evaluate whether 5.5mm implants could be an effective alternative treatment approach for the rehabilitation of posterior atrophic maxillae with 7 to 8 mm of residual bone height below the maxillary sinus. The control procedure involved using standard-length implants (10 mm) placed simultaneously with osteotome sinus augmentation which is considered to be a predictable augmentation procedure and is a commonly used technique for such situations¹¹. 8 implants were placed in each group with diameters 4.0mm, 4.5mm & 5.0mm according to the case.

The primary outcome of the present study was implant stability. The implant stability quotient (ISQ) is the world standard for measuring implant stability due to its reproducibility as well as its ability to non-invasively assess axial implant stability in different directions. The ISQ scale ranges from 1 to 100, but the acceptable stability range is 55–85¹².

In the present study, when comparing the initial ISQ values, both groups recorded the same mean stability with no statistically significant difference ($p=1$). These results indicate good primary stability in both groups which is the key factor for implant survival. No statistically significant difference was found in regards to implant stability among the two groups at any follow-up times (initially, at 4, 6 and 12 months). In agreement with these findings, previous RCTs indicated that the implant length did not seem to negatively affect stability and that shorter implants could achieve a very comparable stability to standard length implants placed in the posterior maxilla^{9, 13, 14}. In terms of mean change over time, ISQ values gradually increased by time to reach its highest level at 12 months for both groups. This ISQ increase during the first year of loading was observed in other studies on implants placed in the posterior maxilla^{9, 15, 16, 17}. This change pattern also agreed with the histological process of osseointegration¹⁸.

The long-term preservation of crestal bone height around osseointegrated implants is considered as one of the most critical criteria when assessing implant success. Originally, a mean CBL (crestal bone loss) ≥ 1.5 mm during the first year after loading and ≥ 0.2 mm every year after that had been accepted^{19, 20}.

In the present study, the mean CBL was 0.7mm in the short implant group and 1.09mm in the standard length group. A shorter surgical time and less soft and hard tissue manipulation around the osteotomy may account for a lower crestal bone resorption rate in the short implant group. **Felice et al in 2015**²¹ proved similar results. Our results also agreed with a recent RCT²².

In reference to pain and swelling, the

difference between the two groups was not statistically significant.

In respect to soft tissue peri-implant parameters, no recession was detected throughout the 12 month follow up in both groups. PPD (Probing pocket depth) and mPI (modified plaque index) revealed no statistically significant difference after 4 and 12 months. This was in agreement with a similar recent RCT by **Pohl et al in 2017**²³. In terms of mBI (modified bleeding index), results revealed no significant difference between both groups after 4 months. However, after 12 months, a significantly higher modified bleeding score was recorded in the control group (mean of 1.33) in comparison to a mean of 1 in the test group.

In terms of post-operative complications, only one case showed a post-operative complication referred to as BPPV (benign paroxysmal positional vertigo) in the control group. However, tests revealed that the difference was not statistically significant ($p=0.23$). These results were in agreement with a recent Meta-analysis of RCTs which reported that compared with long implant group, the short implant group had less complications. However, complications reported were all pre-loading²⁴. BPPV is an unfamiliar and rare complication occurring following osteotome sinus floor elevation (OSFE) and simultaneous implant placement. It is characterized by brief attacks of vertigo and nausea that are stimulated by angular positional changes of the head²⁵. The most classical treatment for BPPV is the Epley Maneuver which is expressed as highly effective^{26, 27}.

Respecting, implant survival, only one case showed early (pre-loading) implant failure in the test group. Tests revealed that the difference was not statistically significant ($p=0.4$). These results were in contrast to the 100% survival rate found in both groups in a similar RCT and a very recent meta-analysis reporting no significant difference between the survival rate of short and long implants^{22, 24}. In terms of drop-outs, 2 occurred in the control group.

CONCLUSION

Data from this RCT indicates that both treatment approaches for the rehabilitation of atrophic posterior maxillae achieved successful and similar outcomes after 8 months of loading (12 months of placement). Both short and standard length implants placed with osteotome sinus lifting showed excellent implant stability values suggesting that short implants could be used as an alternative to augmentation.

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