

DEVELOPING EVIDENCE-BASED PROTOCOL FOR EFFICACY OF OSTEOTOME, CAS KIT AND OSSEODENSIFICATION TECHNIQUES OF CRESTAL SINUS LIFTING WITH IMMEDIATE IMPLANT PLACEMENT IN ATROPHIC POSTERIOR MAXILLA (RBH 3 TO 5 MM)- Randomized Controlled Trial

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Abstract

Background: Implant placement in the posterior maxilla is often complicated by reduced residual bone height, poor bone quality, and sinus pneumatization following tooth loss. To address these challenges, maxillary sinus floor elevation (SFE) is widely used to augment bone volume and facilitate successful implant placement. More than half of implants in the posterior maxilla require this procedure, with the choice of technique largely dependent on the available bone height.

The lateral sinus lift is recommended for cases with less than 4–5 mm of residual bone height, while the transalveolar approach is preferred for heights exceeding 5 mm due to its minimally invasive nature. Advancements such as osseodensification and the Crestal Approach to the Sinus (CAS) kit have further enhanced outcomes by preserving bone, improving implant stability, and reducing complications like sinus membrane perforation.

This study explores evidence-based protocols for SFE and immediate implant placement in the atrophic posterior maxilla.

Objective: To develop evidence based protocol for efficacy of Osteotome,CAS kit and osseodensification techniques of crestal sinus lifting with immediate implant placement in atrophic posterior maxilla (RBH 3 to 5 mm)”

Methods: A Prospective randomized study will be conducted in the Department of Oral and Maxillofacial Surgery at Sharad Pawar Dental College, Wardha (M). The detailed synopsis of the study would be subjected to approval from institutional ethical committee Sharad Pawar Dental College and initiated after its approval.The Fisher exact test will be used for statistical analysis, and the level of significance will be set at $P < 0.05$.

Results: Efficacy of Osteotome,CAS kit and osseodensification techniques of crestal sinus lifting with immediate implant placement in atrophic posterior maxilla (RBH 3 to 5 mm)”

Conclusions: This study explores evidence-based protocols for SFE and immediate implant placement in the atrophic posterior maxilla. Clinical Trial: in processs

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“DEVELOPING EVIDENCE BASED PROTOCOL FOR EFFICACY OF OSTEOTOME, CAS KIT AND OSSEODENSIFICATION TECHNIQUES OF CRESTAL SINUS LIFTING WITH IMMEDIATE IMPLANT PLACEMENT IN ATROPHIC POSTERIOR MAXILLA (RBH 3 TO 5 MM)”

Abstract:

Introduction: Implant placement in the posterior maxilla is often complicated by reduced residual bone height, poor bone quality, and sinus pneumatization following tooth loss. To address these challenges, maxillary sinus floor elevation (SFE) is widely used to augment bone volume and facilitate successful implant placement. More than half of implants in the posterior maxilla require this procedure, with the choice of technique largely dependent on the available bone height.

The lateral sinus lift is recommended for cases with less than 4–5 mm of residual bone height, while the transalveolar approach is preferred for heights exceeding 5 mm due to its minimally invasive nature. Advancements such as osseodensification and the Crestal Approach to the Sinus (CAS) kit have further enhanced outcomes by preserving bone, improving implant stability, and reducing complications like sinus membrane perforation.

This study explores evidence-based protocols for SFE and immediate implant placement in the atrophic posterior maxilla.

Need for the Study: This study is necessary because of Implant placement in the posterior maxilla is often challenging due to reduced residual bone height, sinus pneumatization, and poor bone quality. Maxillary sinus floor elevation (SFE) is a common solution, but complications like sinus membrane perforation and the choice of appropriate techniques—lateral or transalveolar—remain critical considerations. Recent advancements, such as osseodensification and the CAS kit, have shown promise in improving outcomes by preserving bone and enhancing implant stability. However, evidence-based protocols combining these innovations with immediate implant placement are limited

Aim: To develop evidence based protocol for efficacy of Osteotome,CAS kit and osseodensification techniques of crestal sinus lifting with immediate implant placement in atrophic posterior maxilla (RBH 3 to 5 mm)”

Materials and Methods

A Prospective randomized study will be conducted in the Department of Oral and Maxillofacial Surgery at Sharad Pawar Dental College, Wardha (M). The detailed synopsis of the study would be subjected to approval from institutional ethical committee Sharad Pawar Dental College and

initiated after its approval. The Fisher exact test will be used for statistical analysis, and the level of significance will be set at $P < 0.05$.

Keywords*

Maxillary sinus floor elevation (SFE), Posterior maxilla, Immediate implant placement, Osseodensification, Residual bone height

Introduction

Implant placement in the posterior maxilla is a challenging procedure when residual bone height is reduced. Maxillary sinus elevation technique is a common surgical procedure which allows to augment the available bone volume in posterior maxilla in order to place implants.

More than half of the implants placed in the posterior maxilla require sinus floor elevation (SFE). The need for this procedure is explained by continuous ridge resorption in an apical direction after tooth extraction combined with progressive sinus pneumatization in addition to poor bone quality that is frequently seen in the maxilla. Residual bone height is considered fundamental in deciding which augmentation technique can be used to obtain an adequate bone volume.

Sinus membrane perforation is considered the most common complication during sinus floor elevation procedures, and its percentage varies according to the method used. Perforations happen either while fracturing the floor of the sinus or during the elevation of the mucosa.

In general, sinus lifting with a lateral approach works best when there is less than 4–5 mm of remaining bone height. To lower the morbidity and invasivity of the treatment regimen, a transalveolar approach may be recommended when there is more than 5 mm of residual bone height available.

Tatum first suggested the osteotome-mediated transcrestal sinus lift technique in 1986. The original method involved placing implants following a controlled sinus floor fracture and immersing them during the healing process. Summers described a variation of this method in 1994. The author suggested using conical osteotomes to prepare the implant site, which enables the posterior maxilla's bone to be compressed by applying lateral stress. According to the author, by avoiding drilling, these techniques preserve bone while increasing lateral bone density.

Crestal approach to the sinus kit (CAS kit) was introduced by OSSTEM implants (Osstem Implant Co., Busan, Korea) as a safe and effective method for sinus elevation with the advantage of using a reamer (the CAS

drill) to perform the osteotomy in a conical shape and break the bony floor.

As the sinus floor is raised, a new procedure called osseodensification uses high-speed, densifying burs of progressively larger diameters to consolidate and preserve the bone [3]. This new invention has the added advantages of maintaining bone during osteotomy preparation and boosting the implant's primary stability, both of which improve osseointegration and implant success.

Cone beam computed tomography (CBCT) can precisely visualize the sinus complexity in 3D, with low irradiation to the patient. In implant dentistry, recent guidelines recommend the use of CBCT for three-dimensional treatment planning, especially prior to SFE for evaluating both residual alveolar and sinus conditions.

The current study is conducted to develop evidence based protocol for use of sinus lift technique and immediate implant placement in atrophic posterior maxillary region.

Primary objectives:

1. To evaluate and compare the membrane perforation in Osteotome, CAS kit and osseodensification assisted sinus lift technique.
2. To evaluate and compare the time required to perform procedure in Osteotome, CAS kit and osseodensification assisted sinus lift technique..
3. To evaluate and compare the primary and secondary stability of implant in Osteotome, CAS kit and osseodensification assisted sinus lift technique..
4. To evaluate and compare the amount of bone generation in Osteotome, CAS kit and osseodensification assisted sinus lift technique.
5. To evaluate and compare the marginal bone loss in Osteotome, CAS kit and osseodensification assisted sinus lift technique.

Review of literature

Rocío Antonaya-Mira, Cristina Barona-Dorado, Natalia Martínez-Rodríguez, et al (2012):- conducted meta analytic study to compare the different variation of sinus elevation techniques with

osteotomy's., analysing a total of 11 articles published between the years 2003 and 2008. They found average Osseo integration period is 4.9 months with a high success rate and concluded that it is predictable technique in achieving an increase in bone height.(10)

Young-Kyun Kim, et al(2013):-conducted study to analyse the dentist's subjective satisfaction with the crystal approach sinus kit. The study carried with 30 dentist with considerable amount of experience in the same field. The evaluation of the dentists was done by giving them questionnaire. 28 dentists answered the questionnaire. In particular, 24 dentists gave their satisfaction with CAS kit. The study concluded that respondents were satisfied with the system(CAS kit) (11).

“Aghiad Yassin Alsabbagh, et al(2017):- evaluated three different method of indirect sinus lifting, bone added osteotome sinus floor elevation, inflatable balloon and crystal approach system . The study was conducted on 18 freshly slaughtered sheep head. Total thirty six sinus lift were done twelve in each group the study concluded that balloon and CAS kit showed superior to bone added osteotome sinus floor elevation (BAOSFE) in the reference of safety in membrane elevation. The study also concluded that CAS kit requires longer time for doing the procedure while BAOSFE causes biggest perforation.”(12)

Panapohn Suk-Arj, et al(2019):- conducted a study in which the osteotome technique was used to increase volume of bone at maxillary sinus through transalveolar approach on 27 patient and CBCT was taken prior to surgery and again 6 month after the implantation. The study concluded that significant amount of new bone formation was detected around implant. (13)

Bijan Movahedian Attar, et al(2020):radiologically evaluated 24 implant patients placed in posterior maxillary height ranging from 5-8 mm with sinus lift technique after 19 months follow up. They concluded that OSL technique is a non invasive surgical method and also successful technique in the case where there is insufficient bone height.(14)

Yassin Alsabbagh et al. International Journal of Implant Dentistry (2017) : The ability of three distinct indirect sinus lifting techniques—the crestal approach system (CAS kit) from OSSTEM, sinus floor elevation using an inflatable balloon, and bone added osteotome sinus floor elevation (BAOSFE)—to raise the sinus without rupturing the Schneiderian membrane was evaluated. 18 recently killed sheep heads were used in the study (36 sinus lifts total, 12 for each procedure). To determine the ideal site for the sinus lift, CBCT pictures of the heads were obtained. The membrane was then revealed from the medial aspect after the heads were cut in half. Each procedure was then carried out. Seven millimeters was the desired elevation height. The highest elevation was measured if the 7 mm was not met. BAOSFE was linked to the greatest number of perforations (58.4%, n = 7), compared to 8.3% and 8.3% for the balloon and

CAS kit procedures, respectively. The method employed was substantially connected with the occurrence of perforation (p value = 0.014). When comparing the BAOSFE kit to the CAS kit, the odds ratio for perforation occurrence was significant ($OR = 0.091$, $p = .022$). When comparing the balloon approach to the CAS kit, no significant odds ratio was discovered. Furthermore, the technique employed was substantially correlated with both the duration of operation and the length of perforation (p value < 0.001), with the CAS kit requiring the most time and BAOSFE producing the largest perforations. (15)

Materials and methods:

A prospective randomized split-mouth study will be conducted in the Department of Oral and Maxillofacial Surgery, Sharad Pawar Dental College, Sawangi Wardha for a period of ...??? A written Informed consent will be taken from the subjects. Ethical approval received from Datta Meghe Institute of Higher Education and Research, Sawangi, Wardha with IEC reference number-DMIHER(DU)/IEC/2023/

ELIGIBILITY CRITERIA:

Inclusion criteria

All the patient requiring implant prosthesis in atrophic (RBH 3 to 5mm) posterior maxillary edentulous patient with age 18 > years, minimum width 6mm and he/she must willing to sign a risk consent.

Exclusion criteria

1. All patients who are contraindicated for implant therapy Patient with healing socket (History of extraction < 3 months)
2. Patient who underwent radiation treatment in head neck area (< 1year)
3. Heavy smoker (> 10 cigarettes/day), Uncontrolled diabetic patient
4. Pregnant or nursing woman
5. Patient who are substance abuse
6. Patient with unrealistic expectation or on psychiatric treatment
7. Immunosuppressed or immunocompromised patient
8. Patient on oral or intravenous bisphosphonates treatment.
9. Patient with opposing missing teeth, having habit of clenching/bruxism.
10. Patient with Inflammation or acute sinusitis
11. Patient with periodontitis or with poor oral hygiene.

Derivation of sample size:

$$n = \frac{(Z_{\alpha} + Z_{\beta})^2 [P_1(1-P_1) + P_2(1-P_2)]}{(P_1 - P_2)^2}$$

Where,

Z_{α} is the level of significance at 5% i.e. 95% confidence interval -1.96

Z_{β} is power of the test = 80% = 0.84

P_1 = proportion of occurrence of perforation in OSFE = 58.4% = 0.584

P_2 = proportion of occurrence of perforation in CAS kit = 8.3% = 0.083

$$n = \frac{(1.96 + 0.84)^2 [0.584(1-0.584) + 0.083(1-0.083)]}{(0.584 - 0.083)^2}$$

$$= 9.96$$

→ n = 10 patient needed in each group

Study Reference: - "Alsabbagh A, Alsabbagh M M, Nahas B D, Rajih S comparison of three different method of internal sinus lifting for elevation height of 7mm: an ex vivo study International journal of implant dentistry (2017) 3:40 DOI 10.1186/s40729-017-0103-5"

The study will comprise 30 consecutive systemically healthy individuals who visited the oral and maxillofacial surgery department between September 2022 and September 2024 and needed an implant prosthesis in the atrophic posterior maxillary region.

Patients with RBH (measured from the bone crest to the most inferior part of the sinus floor parallel to the implant) of 3 to 5 mm and width of 6 mm or more, as well as all patients with a comprehensive case history and initial clinical investigation for implant prosthesis subjected to CBCT of region using (PLANMECA CBCT), will be included in the study.

Thirty patients will be informed about the procedure's nature, and written informed consent will be

obtained for the prothetic and surgical phases as well as for the utilization of radiological and clinical data. The patient will be brought up for the procedure and made ready in accordance with the guidelines. The first dosage of antibiotic (625 mg augmentin or 600 mg clindamycin if allergic to penicillin) will be given prophylactically one hour before operation. Mouthwash containing 0.2% chlorhexidine will be used to prepare the oral cavity. Following a sensitivity test for local anesthesia, 2% xylocaine and 1:100,000 adrenaline will be given.

for regional block and local infiltration a Para-crestal incision will be made and full thickness mucoperiosteal flap will be elevated and implant recipient site again inspected clinically. Implant site will be prepared and divided randomly according to one of the following protocols.

- Group A: Sinus lift with Osteotome(n=10)
- Group B: Sinus lift with CAS kit(n=10)
- Group C : Sinus lift with Osseodensification (n=10)

SINUS LIFT WITH OSTEOTOME

Initiation of the osteotomy with pilot drill up to the depth of 1 to 2mm coronal to sinus floor followed by 2mm twist drill up to the same depth then sequential and suitable osteotome will be selected to expand the alveolar bone to reach the proper diameter for implant placement. One size smaller diameter osteotome is used to fracture the sinus floor and then same diameter osteotome is used to elevate the sinus membrane to desire length.

SINUS LIFT WITH CAS Kit

Initiation of the procedure with 2mm twist drill with a stopper set 1 -2mm inferior to sinus floor. Increase diameter of drill to 2.8mm with stopper in place at 400 to 800rpm to avoid possible tearing of membrane. Preparation of sinus floor and flexibility of maxillary sinus membrane will be examined through depth gauge with last used stopper. If sinus floor found intact 2.8mm twist drill will be used with stopper 1mm longer until complete erosion of floor achieved. The hydraulic lifter will be inserted into drill holed and 1 to 3ml of saline solution will be gently injected and retracted back into the sinus to elevate the membrane of maxillary sinus. After confirmation sinus lift the diameter of the drill will be increased with the last stopper still connected, according diameter of the planned implant with a drill speed not more than 800rpm.

SINUS LIFT WITH OSSEODENSIFICATION :

The osteotomy is started with the pilot drill in clockwise mode 1 mm short of the sinus floor. Then the osteotomy orientation in relation to the adjacent teeth was checked by inserting paralleling pin on radiovisiograph (RVG). Following this, a 2.5 mm Densah™ bur (Jackson, MI: Versah, LLC) at 800 rpm speed in an anticlockwise direction is inserted 1 mm short of the sinus floor. Sequential widening using 3 mm, 3.5 mm, and 4 mm performed, changing the drill motor to reverse-densifying mode with a gentle pumping motion following the manufacturer's instructions. Additional vertical depth and membrane lift (in 1.0 mm increments) can be achieved in the process. Intermittent pressure of one second off and on the bone, under copious saline irrigation was followed throughout the procedure. The final 4.5 mm drill is inserted only half the depth of the osteotomy to attain primary stability.

After completion of osteotome and sinus lift procedure, check the integrity of sinus membrane by Valsalva manoeuvre. Finally, a self-taping implant (osstem) of selected diameter will be placed in prepared site by motor connection at the speed of 15rpm and 30 Ncm torque to submerge the implant, if any threads remain open that will be submerged by hand ratchet and note down the final torque which will denote the primary stability of implant. "The cover screw will be connected the wound will be sutured with 3-0 vicryl (polyglactin910). Antibiotic (amoxicillin and clavulanic acid or clindamycin) will be continued twice daily for 5 days. Analgesic will be administered in case of pain, continue chlorhexidine mouth wash for 10 days. At three months after implant placement a second step surgery will be performed, using a mid-crestal incision exposing the implant, replace the cover screw by suitable gingival former, close the wound and recall patient 10 days after for prosthetic impression. The stability of each implant will be measured manually by tightening the abutment screw at torque 20Ncm by blind assessor. Take an impression, fabricate and deliver an individual crown for each implant, adjusting occlusion to avoid premature contact. Clinical photograph and CBCT will be taken and follow up visit will be scheduled every 3 months".

OUTCOME MEASURES

Sinus membrane perforation: - clinically assess at the time of osteotomy by Valsalva manoeuvre.

Time required to perform procedure: - time measured from starting of osteotomy procedure to the final implant insertion.

Primary stability: - It is a mechanical stability measured on implant insertion by hand ratchet.

Secondary stability: It is a biomechanical phenomenon measured after 3 months of implant insertion measured by RFA device

Amount of bone generation: - evaluate by blinded clinician on CBCT at three months after implant placement i.e. during prosthetic phase and six months after prosthesis i.e nine months after implant placement.

Marginal bone loss: -mesial and distal bone level will be calculated as a distance from most coronal point where the bone appeared to be in contact with the implant to the distance between mesial and distal margin of implant neck. Measurements will be evaluated on CBCT at three months after implant placement and six months after prosthesis.

STATISTICAL ANALYSIS:

“Data will be collected in excel sheet as a master chart. all data will be analysed according to the plan and will be carried out as pre-established analysis by a statistician with expertise in faculty of dentistry. Descriptive analysis will be performed using Mean $\pm$ SD, median and 95% confidence interval. Differences in means will be compared by non-parametric Mann-Whitney U test. The patient is the statistical unit of the analysis. Dichotomous and continuous outcomes will be compared using chi-square test and one-way analysis of variance, respectively. All statistical comparison will be conducted at the 0.05 level of the significance”.

Dissemination*

Generating evidence for a best treatment method in elevating sinus floor with minimum complication and better outcomes in posterior edentulous patients with RBH 3mm to 5mm.

Study status*

Not started yet.

Data availability*

Not applicable as this is a protocol.

Competing interests*

No competing interests.

Grant information*

Self-funded.

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References*

1. Tan WC, Lang NP, Zwahlen M, Pjetursson BE. A systematic review of the success of sinus floor elevation and survival of implants inserted in combination with sinus floor elevation. Part II: transalveolar technique. *J Clin Periodontol*. 2008;35(8Suppl):241–54.
2. Cho SC, Wallace SS, Froum SJ, Tarnow DP. Influence of anatomy on Schneiderian membrane perforations during sinus elevation surgery: three-dimensional analysis. *Pract Proced Aesthet Dent*. 2001;13(2):160–3.
3. Valentini P, Abensur DJ. Maxillary sinus grafting with an organic bovine bone: A clinical report of long-term results. *Int J Oral Maxillofac Implants* 2003; 18:556-60.
4. Tong DC, Drangsholt M, Beirne OR. A review of survival rates for implants placed in grafted maxillary sinuses using meta-analysis. *Int J Oral Maxillofac Implants* 1998; 13:175-82.
5. Emmerich D, Att W, Stappert C. Sinus floor elevation using osteotomes: A systematic review and meta-analysis. *J periodontol* 2005; 76:1237-51
6. Tatum H Jr. Maxillary and sinus implant reconstructions. *Dent Clin North Am* 1986; 30:207–229
7. Summers RB. The osteotome technique: Part 3—Less invasive methods of elevating the sinus floor. *Compendium* 1994;15: 698–700.
8. Summer RB. A new concept in maxillary implant surgery: the osteotome technique. *Compendium* 1994;15(2):152 4-6, 8 passim; quiz 62.
9. Kim YK, Cho YS, Yun PY. Assessment of dentists' subjective satisfaction with a newly developed device for maxillary sinus membrane elevation by the crestal approach. *Journal of periodontal & implant science*. 2013;43(6):308–14.
10. Suk-Arj, Panapohn et al. "Evaluation of bone formation following the osteotome sinus floor elevation technique without grafting using cone beam computed tomography: a preliminary study." *International journal of implant dentistry* vol. 5,1 27. 1 Aug. 2019, doi:10.1186/s40729-019-0181-7.
11. Attar, Bijan Movahedian et al. "Clinical and radiological evaluation of implants placed with osteotome sinus lift technique: 19-month follow-up." *Annals of maxillofacial surgery* vol. 6,2 (2016): 190-194. doi:10.4103/ams.ams_7_16.
12. Comparison of three different methods of internal sinus lifting for elevation heights of 7

mm: an ex vivo study YassinAlsabbagh et al. International Journal of Implant Dentistry
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