Comparative Efficacy of Osteotome vs CAS kit Assisted Indirect Maxillary Sinus Lift and Immediate Implant Placement In Posterior Atrophic Maxilla – A Study Protocol.

Abstract:

Background- In today's era implants are mostly used substitute for replacing missing teeth. The greatest challenge for placing an implant is posterior maxillary teeth where the problems occur due to presence of maxillary sinus due to which there are higher chances of perforating the sinus membrane while placing an implant. In literature there are many techniques to overcome these problems and place the implant without perforating the sinus membrane. The current study is conducted to check either the traditional technique osteotome or modern technique CAS-Kit is better for placing an implant in posterior maxillary region.

Objectives- The aim of these study is to compare and evaluate clinical and radiological outcomes of conventional osteotome technique and CAS kit use for indirect sinus lifting in atrophic posterior maxilla.

Methodology- Two groups (study & control) with 20 individuals requiring implant prosthesis in atrophic posterior maxillary region with RBH ≤ 3mm and minimum crestal width of 6mm are considered for the study model. After completion of osteotome and sinus lift procedure, integrity of sinus membrane will be checked by Valsalva manoeuvre. At three months after implant placement a second step surgery will be performed, stability of each implant will be checked. Marginal bone loss and amount of bone generation will be checked on CBCT at 3, 6 & 9 month interval.

Expected Results- CAS kit is relatively newer and advanced equipment which is safer in placing implant in posterior atrophic maxilla without perforating sinus membrane with good amount of bone generation and stability of implant. with minimal marginal bone loss.

Conclusion- Placement of an implant with CAS-Kit is better option than performing osteotome procedure which is time consumable with high chance of membrane perforation and large amount of marginal bone loss.

Keywords- CAS-Kit, Implant, Osteotome, sinus lift

INTRODUCTION:

In day to day practice of implant dentistry in fact it is most recommended procedure for replacing single or multiple missing teeth's, most difficult part is to place a implant in posterior maxillary region [1]. In this region, after extraction there is constant ridge resorption occurs in apical direction which is combined with progressive pneumatisation and more coarse nature of bone put collectively area more complex for implant rehabilitation. Approximately, 50% patients required sinus procedure for implant placement. Most common complication during sinus elevation is perforation which can occur at the time of floor fracture or during elevation. [2,3]

After first report by Boyne, maxillary sinus augmentation become a routinely performed procedure with various bone graft material since 15 years; there are number of literatures suggesting high success rate of implant survival into augmented sites.[3,4] Various studies reported that for simultaneous sinus and implant placement minimum 5mm of residual bone height (RBH) is required to get an optimum primary stability, however when there is ≤5mm of RBH is present a two-step approach is recommended.[5]

There are number of techniques described in the literature to lift the sinus with different indications, merits and demerits reserved for each technique. Broadly, sinus lift technique is classified into lateral approach /direct sinus lift and crystal approach / indirect technique.

Tatum first described crystal approach sinus lift technique and later on modified by Summer's. [6,7] Summer's technique is popularly known as osteotome technique, which is oldest and being used since 1994 successfully with number of modifications in osteotome design [8] intervening material like PRF (protein rich fibrin), with bone graft or without bone graft. These techniques uses a

series of osteotome tapped by mallet to create an osteotomy and simultaneously fracturing the sinus floor and elevating the membrane. This technique increases the primary implant stability by increasing peri-implant bone volume resulting from compaction of the bone instead of removing it.

Today various new modalities are been used for elevation of sinus floor membrane (Schneiderian membrane). Dealing with sinus floor elevation is became more easier now a day, due to modern technique like CAS kit (crystal approach system) introduced by Korean implant company 'OSSTEM'. In this technique, reamer [safe end cutting drill] with vertical stoppers used to perform the osteotomy in conical shape simultaneously fracturing the bony floor and elevating the sinus membrane with hydraulic pressure. CAS kit provide high predictable outcome, together with extremely low morbidity and higher bone gain and also to shortened the working time, however there is only a single questionnaire that assess the satisfaction of the dentist using the CAS kit is available on this method and single prospective cohort study evaluated clinical and radiological outcomes by this method in the literature till date.[9,10] This study compares the radiological with the clinical outcomes of Summer's osteotome technique and CAS kit utilised in sinus lifting in atrophic posterior maxilla.

AIM: To compare and evaluate clinical and radiological outcomes of conventional osteotome technique and CAS kit use for indirect sinus lifting in atrophic posterior maxilla.

OBJECTIVES:

1. To compare and evaluate the amount of bone generation.
2. To compare and evaluate the time required to perform procedure.
3. To compare and evaluate membrane perforation.
4. To compare and evaluate the primary stability of implant.
5. To compare and evaluate the marginal bone loss.

MATERIAL AND METHODOLOGY

Sources of the Data: The Subjects To Be Studied Will Be Selected From The Outpatient Section, Department Of Oral & Maxillofacial Surgery, Sharad Pawar Dental College And Hospital, Sawangi.

STATISTICAL ANALYISIS:

The sample size was calculated using;

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

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_1= 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.

So, by above formula sample size will be 20. Thus, each group will have a sample of 10.

- **Group A**: Sinus lift with osteotome(n=10)
- **Group B**: Sinus lift with CAS kit(n=10)

Criteria for inclusion:

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

Criteria for exclusion:

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

A total of 20 consecutive systemically healthy patients requiring implant prosthesis in atrophic posterior maxillary region reported to oral and maxillofacial surgery department from October 2020 to May 2022 will be included in the study.

All the patients after detailed case history and preliminary clinical investigation for implant prosthesis subjected to CBCT of region using (PLANMECA CBCT) and patients with RBH (Distance between the bone crest and most inferior part of sinus floor measured along the long axis of planned implant) ≤ 3mm and width 6mm will be included in study. The nature of procedure will be informed to 20 patient and will take written informed consent for surgical and prosthetic phase and for the use of clinical and radiological data.

Patient will be taken up for the surgery and prepared according to the protocols. Prophylactically one hour prior to surgery, First dose of antibiotic (625 mg augmentin or 600 mg clindamycin if allergic to penicillin) will be administered. Oral cavity will be prepared with 0.2% chlorhexidine mouthwash. After local anaesthesia sensitivity test, xylocaine 2% with 1:100000 adrenaline will be administered for regional block and local infiltration a Para crystal incision will be made and fill 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)

After completion of osteotome and sinus lift procedure, check the integrity of sinus membrane by Valsalva maneuvre. Finally, a self-taping implant (osteom) 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 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 a 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.

Evaluation of CAS Kit and Osteotome:

The evaluation of Osteotome and CAS Kit will be done double blinded. Time measurement will be done from starting of osteotomy procedure till the implant placement. Biomechanical stability

of the implant will be checked by hand rachet. Sinus membrane perforation will be assessed at the time of osteotome procedure by Valsalva maneuvre method. After placement of implant CBCT will be taken at duration of three months, six months and nine months for radiographic evaluation of marginal bone loss and amount of bone generation.

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.

EXPECTED RESULTS:

Osteotomy is a traditional technique but CAS kit is relatively newer and advanced equipment which is safer in placing implant in posterior atrophic maxilla without perforating sinus membrane with good amount of bone generation and stability of implant. with minimal marginal bone loss.

DISCUSSION:

In the literature the study given by Rocío Antonaya-Mira et al had compared 11 article related to maxillary sinus elevation techniques and came with an conclusion that success rate in elevation of maxillary sinus membrane by osteotomy technique are higher as compared to other technique in elevating the sinus membrane. Thus osteotome is best method for implant placement in posterior atrophic maxilla.

A second study conducted by Aghiad Yassin Alsabbagh et al compared three different technique of indirect sinus lift by sinus floor elevation by bone added osteotomy, by inflatable balloons and crestal approach system known as CAS Kit from OSSTEM, this study was performed in 18 heads of slaughtered sheep. 36 sinus lift procedure were performed 12 for each technique. The study significantly showed that there are high chances of sinus membrane perforation by bone added osteotomy technique (58.4%) and 8.3% for balloon inflatable and CAS kit technique respectively. The author concluded that CAS kit and balloons inflatable technique are having better advantages and superior than bone added osteotomy technique.

Bijan Movahedian Attar et al evaluated the success of SFE by osteotome in an radiographic method by placing Fifty implants in posterior atrophic maxilla with 19 months follow up period and concluded that SFE with osteotomy technique is most thriving technique in placing an implant in posterior maxilla with less amount of residual bone height. Related studies on maxillary sinus[11,12] and resorbed alveolar ridges [13,14] were reviewed. A number of studies on placement of alveolar implants in different situations were reported by Meher et. al.[15], Datarkar et. al.[16], Dubey et. al. [17], Ghoshal et. al.[18], Shinde et. al. [19] and Arora et. al.[20].

In the current study we had plan to evaluate the effectiveness of CAS kit over osteotomy technique in view of amount of sinus membrane elevation, risk of membrane perforation, time consumption and amount of marginal bone loss. Study will be helpful in achieving the advantages of newer modalities over traditional techniques in elevation of sinus membrane by less time consumption, adequate amount of sinus membrane elevation, good amount of bone generation and minimum risk of sinus membrane perforation.

CONCLUSION:

Placement of an implant with CAS-Kit is better option than performing osteotome procedure which is time consumable with high chance of membrane perforation and large amount of marginal bone loss.

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