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Efficacy of Calcium Phosphosilicate Putty in Sinus lift Bone Augmentation Procedures.

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Introduction

Physiological or traumatic loss of teeth is a predictable phenomenon and this leads to impaired masticatory function, negatively influencing the nutritional requirements and general health of an individual. The goal of modern dentistry is to restore normal contour, function, comfort, esthetics, speech and health regardless of the atrophy, disease, or injury to the stomatognathic system. Ideal requirement for the placement of dental implant is the availability of sufficient bone in terms of both quality and quantity for acceptable Osseo integration. This however, is compromised in posterior maxillary region due to poor bone quality and pneumatised maxillary sinus.

Characteristically maxillary bone shows medullary and trabecular pattern, which has less quantity and bone density than the premaxilla or mandible. Also, adjacent cortices of compact bone are generally very thin, providing minimal strength. [4]

Unfortunately, due to these anatomic and physiologic limitations associated with the posterior maxilla, [4-7] rehabilitation with implants becomes a challenging procedure.

With the advent of sinus augmentation procedures, these limitations have been overcome making implant therapy a more feasible treatment option.

Sinus augmentation procedures/ techniques can be done via Lateral window approach or Crestal approach techni que and in these procedures placement of graft material is required to achieve primary stability and Osseo integration.

A wide array of bone-grafting materials like autogenous bone, demineralized freeze-dried bone, xenogeneic bone, and alloplastic materials have been used in maxillary sinus augmentation to accelerate the bone healing process and prevent re-pneumatisation of the maxillary sinus after grafting.

Calcium Phosphosilicate (CPS) Putty is a Alloplastic bioactive graft material containing four components; two bioactive phase components, a 55% standard calcium phos pho silicate particulate and a 14% CPS smaller particulate, 12% polyethylene glycol as an additive and 19% glycerine as binder.

The putty form of calcium phos pho silicate is used in several aspects of reconstructive domain of dentistry like sinus augmentation procedure as well as osseous regeneration of Perio dontal bone defects, cystic cavity defects and alveolar socket preservation. In this study, Calcium Phosphosilicate (CPS) Putty is used for Indirect sinus lift bone augmentation procedures and the quantitative evaluation of regenerated bone radio graphically using CBCT scan is done to evaluate the efficacy of the graft material used.

Aim

• This study desires to evaluate the use of calcium phosphosilicate putty for its efficacy in enhancing bone regeneration following indirect sinus lift bone augment ation procedure.

Objective

• To radiographically evaluate the regenerative potential of calcium phosphosilicate putty following indirect sinus lift bone augmentation procedure.

• To evaluate the efficiency of calcium phosphosilicate putty as an alloplastic graft material and to assess the increase in bone height of the alveolar ridge.

Source of data

10 patients requiring implant prosthetic rehabilitation of posterior maxilla but having insufficient bone height due to early loss of teeth and hyper-pneumatization of maxillary sinus were included in the study.

Method of data collection

Inclusion criteria

1. Patients presenting with edentulous, atrophic posterior maxillary arch either due to physiological ageing, trauma, or periodontal conditions.

2. pre-operative bone height of less than 10 mm but more than 5 mm.

3. Patient with a pre-operative residual bone height of <9mm in the posterior maxilla. 4. Patients willing for long term follow-up. 5. Patients between 15 - 60 years of age. 6. Patients voluntarily willing to be included in the study. **Exclusion criteria**

1. The presence of uncontrolled diabetes, immune disease, or other contraindicating systemic conditions affecting post-operative healing.

2. Patient on systemic drugs which would affect the surgical procedure, post-operative healing or the expected osseointegration.

3. Patients with pre-existing sinus pathology.

4. Chronic smokers.

5. A psychological problem that in the opinion of the researcher would have rendered the delivery of com prehensive therapy untenable, including depressed states and extreme nervousness or agitation that could preclude

the patient from undergoing numerous lengthy treatment visits.

6. An unwillingness to commit to a long-term post-therapy maintenance program.

A total of 10 patients satisfying the above criteria requiring placement of implants in atrophic maxilla/ increased pneumatisation of the maxillary sinus were selected for the study. The patients were informed about the study including the use of the synthetic graft material and their approval was sought before their participation in the study. A written consent was obtained from each of the participating patient.

For each patient a detailed history was taken including chief complaint, history of presenting illness, medical history and personal history. A thorough clinical exam ination, including systemic and regional exam ination was done.

Diagnostic record for study

The following procedures were carried out for all patients included in the study

• Routine blood investigations

- Haemoglobin
- Complete blood count
- Bleeding time and clotting time
- HIV/ HbsAg

• Random blood sugar level

• Orthopantomographs- pre-operative, immediate post-operative and 6 month follow up.

• Diagnostic study models

• CBCT scans – pre-operative and 6 month follow up.

Method

A study sample consisting of a total 10 patients requiring sinus lift procedure prior to implant placement were included. The residual bone height was recorded using CBCT scan and a computer-based software where the measurements were made from the crest of the ridge till the sinus floor lining.

Surgical techniques

Under complete aseptic conditions, Local anaesthesia with adrenaline (2% lignocaine with 1:80,000 adrena line) was used to obtain ample anaesthesia. Indirect sinus membrane elevation followed by implant place ment was done in cases with residual bone height of greater than 5mm but less than 9mm.

Alloplastic graft material was then dispensed through the crestal osteotomy site after raising the sinus floor im plants were placed simultaneousy followed by primary closure.

Indirect sinus augmentation

Anaesthesia

Regional local anaesthesia is achieved by the posterior superior alveolar nerve block, infra orbital nerve block and greater palatine nerve block based on the region of interest using xylocaine 2% containing 1:80,000 adrena line. The surgical scrub follows the usual routine for implant surgery.

Draping the patient is performed after the surgical team scrubs. Preparation is carried out using the povidone-iodine solution except for patients who give a positive known hypersensitivity.

Xylocaine 2%, 1:80,000 epinephrine is infiltrated in the labial mucosa and the corresponding palatal region to decrease initial haemorrhage and evaluate the effective ness of the regional local anaesthesia.

Incision and reflection

An incision is made on the crest of the ridge and a full-thickness mucoperiosteal flap is reflected. Once the tissue is reflected, the width of the available bone is evaluated and reconfirmed.

Osteotomy and sinus lift

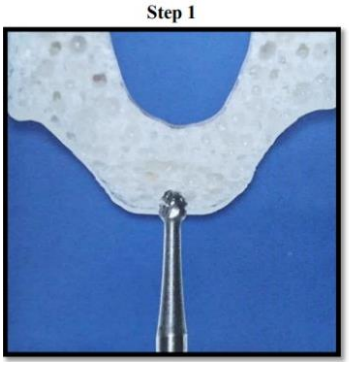
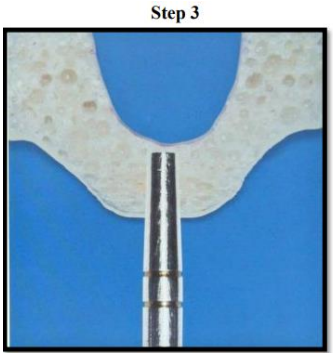


Figure 1: Pilot Drill

Figure 2: Final Drill



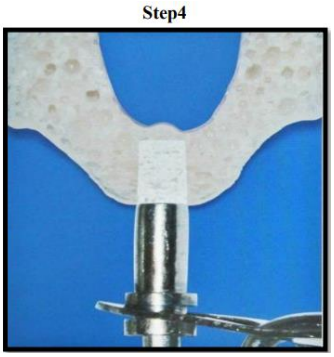
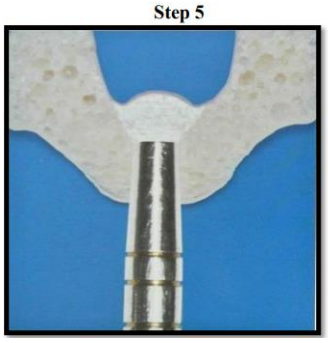


Figure 3: Sinus osteotome with gradations in Place through the crestal osteotomy.

Figure 4: Dispensing of the graft material.



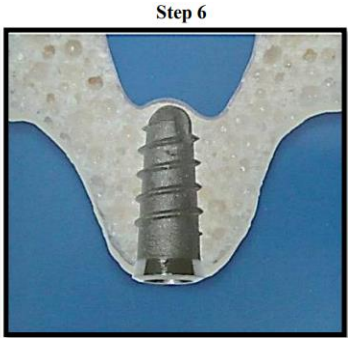


Figure 5: Condensation and compaction of the graft material.

Figure 6: Implant in place.

The endosteal implant osteotomy is prepared till the depth of the osteotomy is 2mm below the floor of the antrum. Reduced speed of the hand piece rotation (less than 120rpm) allows more tactile sense and may permit the surgeon to feel the cortical plate of the inferior antral floor and prevent penetration with a rotary drill.

A sinus osteotome which is a flat-ended instrument is started from a size of 2.2 to 2.7 mm diameter and sequentially increased till the desired width of the implant. It is inserted and tapped firmly into final position 4-6mm beyond the prepared implant osteotomy and 2mm to 4mm beyond the floor of the antrum. A greenstick type fracture occurs in the antral floor during this technique and usually elevates the bone and sinus membrane over the broad-based, flat ended osteotome. Do not luxate the osteotome as this will increase the width of the final osteotomy, the graft material is the dispensed through the osteotomy to maintain the elevated sinus membrane and also to assist and encourage accelerated bone regeneration. The intended height and width of the implant is then placed through this crestal osteotomy with a torque of at least 30 N for acceptable primary implant stability. Cover crew is then placed and primary closure done.

Follow up and study technique

The patients were assessed clinically at immediate post-operatively, 1 week, 1 month, 3 months, and 6 months post-operatively. Radio graphic assessment for bone height was done pre-operatively and at 6 months post operatively using cone beam computer tomography.

In this comparative study the measurements were tabulated and statistically analysed to evaluate the difference in increase in bone height between direct and indirect sinus augmentation procedures radiographically.

Radiographic analysis

• Orthopantomographs (screening tool) were taken to rule out other pathologies and as a part of initial assessment.

• CBCT scans were assessed for pre-operative and post-operative bone height, bone width and bone density.

Illustration of the surgical procedure for indirect sinus lift

Figure 7: edentulous maxillary posterior region

Figure 8: incision of the implant recepient site.

Figure 9: Exposure of the implant recepient site.

Figure 10: Checking bur hole orientation with paralleling pins.

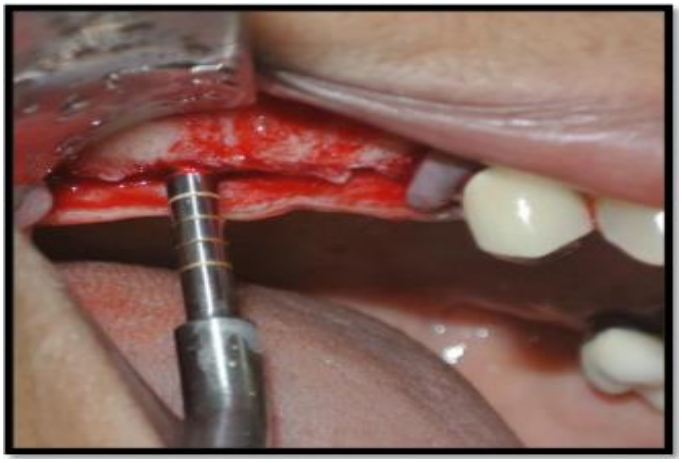


Figure 11: Indirect sinus lift using sinus osteotomes.

Figure 12: Dispensing the graft material through the osteotomy site.

Figure 13: implants after final osteotomy.

Figure 14: implants with cover screw.

Figure 15: closure of surgical wound with 3-0 vicryl.

Figure 16: rehabilitated posterior maxillary edentulous arch.

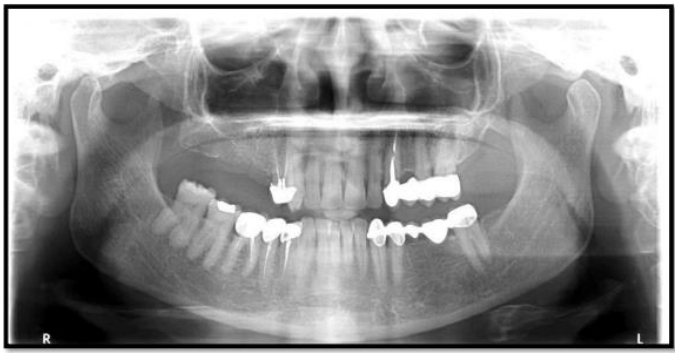


Figure 17: PRE-OP OPG.

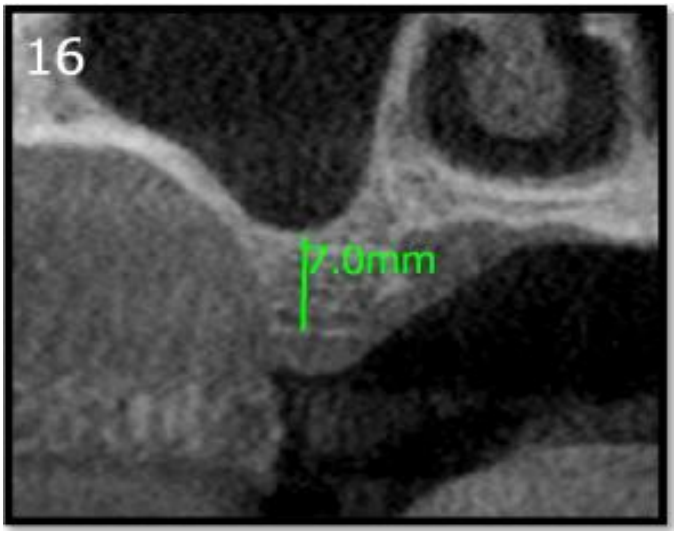


Figure 18: PRE-OP CBCT.

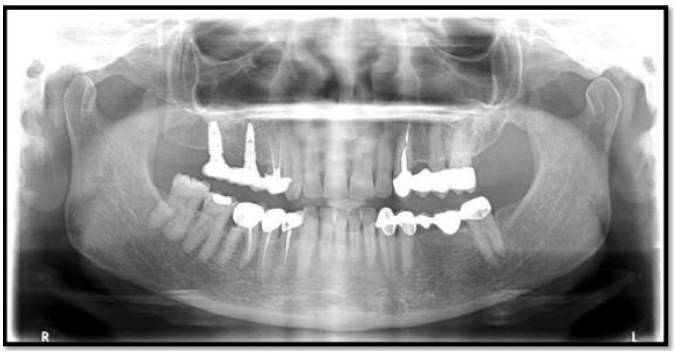


Figure 19: POST-OP OPG

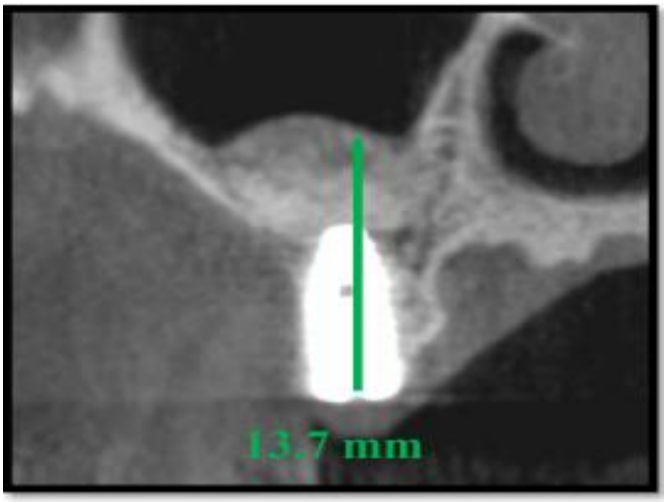


Figure 20: POST-OP CBCT.

Results

This study is aimed at evaluating the use of calcium phosphosilicate putty for its efficacy in enhancing bone regeneration following sinus lift procedure. Calcium phosphosilicate putty being an alloplastic material in putty form had an advantage of easy and convenient dispensing at the intended site after the sinus lift procedure. Regenerative potential was radiographically evaluated by assessing the increase in bone height of the alveolar ridge, which was a direct determinant of the efficiency of calcium phosphosilicate putty as an alloplastic graft material. This prospective study included a sample of 20 segments requiring sinus aug mentation either by an indirect or a direct approach. The study included 9 males (53%) and 8 females (47%) with a mean age of 46.05 years. (As illustrated in the graph)

Table 1: Gender Distribution in This Study Sample

	MALE	FEMALE	TOTAL
NUMBER OF PATIENTS	6	4	10
PERCENTAGE	60%	40%	100%

Table 2: Site Distribution in This Study Sample (Indirect Sinus Augmentation).

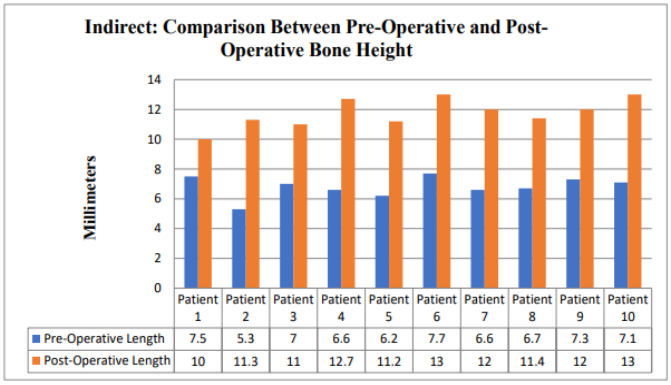
REGION OF AUGMENTATION	NUMBER OF PATIENTS
PREMOLAR	1
1ST MOLAR	7
2ND MOLAR	2

The region of sinus augmentation in the study varied from premolar, 1st molar to 2nd molar. The 10 patients were underwent indirect sinus augmentation were distributed as one the premolar region, 7 in the 1st molar region and 2 in the 2nd molar. This was followed by the placement of implants in their respective regions.

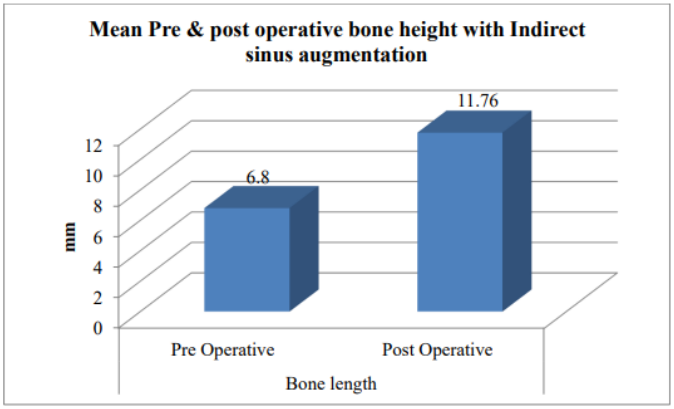
Table 3: Comparison between Preoperative and Post-Operative Bone Height.

	BONE HEIGHT (mm)		DIFFERENCE	PAIRED T TEST	
	MEAN	STD. DEVIATION		t	P VALUE
PRE-OPERATIVE	6.8	0.70	4.96 ± 1.1	14.4	<0.005 (Significant)
POST-OPERATIVE	11.76	0.97			

Graph 1:



Graph 2:



In this study, the preoperative height of bone ranges from 6.2 mm to 7.7 mm, the average being 6.8 mm. The post-operative height of bone ranges from 10 mm to 13 mm, the average bone height being 11.76 mm.

A paired samples t test was carried out to know the difference in pre & post treatment measurements of bone height with indirect sinus augmentation. The post treatment bone height (11.76 + 0.97) was significantly higher than pre-treatment bone height (6.8 +0.70) (t= 14.4, p<0.005).

Discussion

A successful implant therapy requires the presence of an adequate quantity and quality of bone. With advancing age or loss of teeth, there is depletion of bone quantity and quality and the posterior maxillary region presents with increased pneumatisation of the maxillary sinus. Following tooth extraction, edentulous area continues to atrophy causing increased antral pneumatisation (3, 4) due to the increased osteoclastic activity of the Periosteum of the schneiderian membrane. (5) affecting the overall bone height and density.

Maxillary sinus augmentation has become a pivotal replacement procedure in advanced implant dentistry. A sinus-lift procedure was first performed by Dr. Hilt Tatum Jr. in 1974 during his period of preparation to begin sinus grafting. The first sinus graft was done by Tatum in February, 1975 in Lee County Hospital in Opelika, Alabama. This was followed by the placement and successful restoration of two endosteal implants. Between 1975 and 1979, much of the sinus lining elevation was done using inflatable catheters. After this, suitable instruments had been developed to manage the lining elevation from the different anatomical surfaces encountered in sinuses.

In keeping with the past provinces currently two proficient techniques of sinus floor elevation for dental implant placement are in use: A lateral window approach followed by implant placement as a two-stage technique and a one-stage lateral or trans crestal approach. The decision to use one these techniques is primarily based on the amount of residual bone and on the possibility of achieving primary stability of the implants. Depending on the available bone height Carl. E. Misch has developed a protocol to categorize implant placement in posterior maxilla.

In this study a total of 10 patients underwent indirect sinus lift bone augmentations procedure and simultaneous implant placement. As per vigilant treatment proto cols, statistical analysis was done as a sequel. When a paired sample t test was carried out to know the difference in pre and post treatment bone height with Indirect sinus augmentation, it was seen that the post treatment bone height (11.76 + 0.97) was significantly higher than pre-treatment bone height (6.8 + 0.70) (t=14.4, p<0.005)

CPS biomaterial (FDA 510,2006) is a third-generation biomaterial which has been able to achieve results similar to autogenous bone grafts. This material has attracted attention due to its osteoconductive and Osseo stimulative properties i.e. its ability to stimulate osteo progenitor cells, multiple generations of undifferentiated cells to osteoblasts (75). When implanted, this material undergoes both physical and chemical dissolution, as a

result of ion release mechanism and formation of hydroxyl carbonite apatite (HCA). CPS consists mainly of 2 phases; Phase 1 (bio glass particles of 90-710 microns) and Phase 2 (calcium phosphosilicate particles of sizes ranging from 32 to 125 microns. It provides a Young's modulus of 30–35GPa, which is close to that of cortical bone.

A prime prerequisite for a predictable success of these procedures solely depends on gathering information on quantity and quality of bone available for implant placement and to localize the anatomical structures is of utmost importance. Dental implant imaging thus provides information about the implant site with regards to osseous morphology, developmental variations, post extraction irregularities and approximation of the crest of the ridge to the sinus floor, pneumatisation of maxillary sinus, and presence of septae (in case of posterior maxilla) which does influence the success and outcome of the procedure.

CT enables the evaluation of proposed implant sites and provides diagnostic information that varied imaging techniques cannot possibly provide.

CT has given several advantages over conventional radiography. Firstly, CT eliminates the superimposition of images of structures outside the area of interest. Second, because of the inherent contrast resolution of CT, differences between tissues that differ in physical density of less than 1% can be distinguished, in contrast conventional radiography requires a 10% difference in physical density to distinguish between tissues. Third, the data from a single CT imaging procedure, consisting of either multiple contiguous or one helical scan. This can be viewed as images in the axial, coronal or sagittal planes or in any arbitrary plane depending on the diagnostic task. Denta Scan (CT for implant assessment) provides programmed reformation, organization and display of the imaging study. The radiologist simply indicates the curvature of the maxillary and mandibular arch, and the computer is programmed to generate referenced cross-sectional and tangential or panoramic images of the alveolus along with three-dimensional images of the arch. The cross-sectional and panoramic images are spaced 1 mm apart and enable accurate preoperative treatment planning. Resnik et al., 2008.

3D planar imaging dedicated to the maxillofacial region at low cost and low dose of radiation makes CBCT a lucrative modality. Due to the various above-mentioned advantages of CBCT we intended to use CBCT scans for the height evaluation over the conventional two-dimensional radiographs and computed tomography. It was an easy and effective way of measuring the bone height pre-operatively and post-operatively. [78]

In accordance to our study, a study by Nishida et al., in 2013 assessed the radiographic appearance of bone graft domes long itudinally after osteotome sinus floor elevation using cone beam computed Tomography (CB CT). This study presents the radio logical findings of a 6-month follow-up CBCT study in maxillary osteotome sinus floor elevation. Implant survival is dependent on both bone quantity and quality.

Physiological adaptation of sinus mucosa has been proved experimentally leading to development of chronic sinusitis after maxillary sinus floor augmentation. Penetration of the sinus by implants may increase the risk of infection and can be regarded as a contraindication. However Brånemark et al. in 1984 reported that sinus penetration by implants caused no undesirable effects. (74)

CPS putty material proved to be highly efficient with excellent ease of handling and dispensing characteristics. Apart from the superior results obtained with the use of CPS as a graft material of choice, the patients with

severely atrophic maxillae enrolled in study had immensely positive response to treatment as never before, with respect to vertical bone height, increased bone density and superior quality of post-operative trabecular bone formation. We were able to bring in explicitly informative result about the components of studies and the superior outcome of our prospective study on patient management.

CBCT scans proved to be an effective tool for the radiographic assessment of various parameters and surgical anatomy of maxillary sinus pre-operatively and in quantifying the results achieved post-operatively.

Summary and conclusion

Calcium phosphosilicate putty material is a bioactive synthetic material with osteoconductive properties. It is available in a device which requires no mixing or preparation prior to application. The non-hardening putty is supplied ready-to-use, to be applied directly to the intended graft site with a convenient gun dispenser.

In this study involving 10 patients we have attempted and to a large extent in evaluating the efficacy of the role of calcium phosphosilicate as a bone regenerative material and its assessment using CBCT scans. Our study was designed with 10 patients requiring sinus augmentation either in indirect way wherein calcium phosphosilicate putty was used. The patients were subjected to OPG and CBCT scans pre and post treatment. Bone regeneration rate in terms of increase in bone height was assessed radio graphically at 6 months and compared with that of the pre-operative values.

In this study, the indirect sinus augmentation procedure was followed by placement of the implants of various sizes in 10 patients. The implant stability and Osseo integration was clinically assessed throughout the period of follow up and satisfactory results were obtained. In extrapolation, radiological analysis through CBCT should be recommended in all cases for sinus lift per forming to improve the surgeon's confidence in knowing the anatomy of the maxillary sinus and the accuracy of the sinus lift technique. When only panoramic radiographs are used, bone quantity and quality are risked to be overestimated. The present study demonstrates that CBCT increases the accuracy of both sinus morphology and vertical bone height achieved as a result of sinus augmentation.

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