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Modified lateral sinus lift using disc-form silica calcium-phosphate NanoComposite and consequent implant placement

Arwa Hosnia
arwa.loay@fue.edu.eg

Waleed Ragab El-Beialyb
wbeialy@den.hokudai.ac.jp

Mostafa Ezzc
mostez@hotmail.com

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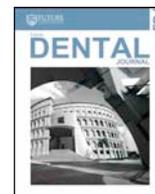
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Peer review under responsibility of Faculty of Oral & Dental Medicine, Future University. * Corresponding author. E-mail addresses: arwa.loay@fue.edu.eg (A. Hosni), wbeialy@yahoo.com, wbeialy@den.hokudai.ac.jp (W.R. El-Beialy), mostez@hotmail.com (M. Ezz).



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Modified lateral sinus lift using disc-form silica calcium-phosphate NanoComposite and consequent implant placement

Arwa Hosni^{a,*}, Waleed Ragab El-Beialy^b, Mostafa Ezz^c^a Department of Oral and Maxillofacial Surgery, Future University in Egypt, 90th st., New Cairo, Egypt^b Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University, 11 Al-Saraya st., Manial, Cairo, Egypt^c Oral and Maxillofacial Surgery, Faculty of Dentistry, Cairo University, 11 Al-Saraya st., Manial, Cairo, Egypt

1. Introduction

Maxillary Sinus Floor Elevation (SFE) was first described in 1974 by Hilt Tatum [1] and modified by Boyne and James in 1980 [2] as a modified Caldwell Luc procedure for placing grafts in the maxillary sinus floor. The procedure has also been referred to in the literature as maxillary sinus augmentation, maxillary sinus lift, subantral augmentation [3] and open sinus lift [4].

The two main techniques of SFE for dental implant placement are: A two-stage technique with a lateral window approach, followed by implant placement after a healing period; and a one stage technique using either a lateral or a transalveolar approach. The decision to use one- or two-stage techniques is based on the amount of residual bone available and the possibility of achieving primary stability for the inserted implants [5]. Lateral sinus lift technique allows obtaining a bone height of 8–15 mm.

SFE is accompanied by a very low complication rate with most frequent intraoperative complication as sinus membrane perforation (4.8–58%) [3]. Hemorrhage from blood vessels in the mucoperiosteal flap, the sinus membrane, or bone and postoperative complications (3%) as infection, soft tissue perforation, swelling, pain, development of oro-antral fistula [3] and/or postoperative maxillary sinusitis may also occur. Sinus mucosa perforations are usually well tolerated and regenerate over the bone graft postoperatively. These perforations can be corrected either by closing them with resorbable barriers or by simply folding the sinus mucosa after a more extended elevation. Post-operative complications such as sinusitis occur in previously unhealthy sinuses; therefore a thorough preoperative screening of maxillary sinus status is mandatory [6].

A variety of technical modifications have been proposed since the development of open sinus lifting. In 1998 by Wood and Moore [7], in 1997 by Smiler [8] and a breakthrough by Vercellotti et al. [9] in 2001, who successfully used the piezoelectric technique to enable window access with a greatly decreased chance of membrane perforation. In 2017 Goodacre et al. reported a technique that will allow the precise

planning of the lateral approach using radiographic information and 3-dimensional (3D) software to 3D-print a surgical guide [10].

Bone grafting materials, particulate or block grafts, are generally classified as autografts, allografts, xenografts and alloplasts. Out of these, autografts harvested from the patient's own body are regarded as the “gold standard” to which other graft materials compete [11,12] but still carries its disadvantages. Alloplasts (usually derivatives of calcium &/or phosphate) are synthetic chemically derived bone substitute. Research and development in alloplasts is a continuously growing field especially due to its advantage over allografts and xenografts.

El Ghannam theorized that a silica-based calcium phosphate composite would optimally enhance bone cell function. He reported on the synthesis and characterization of a new, resorbable, porous, bioactive silica-based calcium phosphate composite (SCPC) that has the ability to stimulate rapid bone generation and resorb when grafted in large bone defects. He showed in a cross section of silica-calcium phosphate composite (SCPC) that the entire structure is based on interconnected phases of modified silica and calcium phosphate minerals. Enforcing ion substitution and formation of solid solutions induces the bioactivity and resorbability of these phases. The porosity of the new SCPC provides high surface area for protein adsorption, cell adhesion, and new bone formation. The unique chemical composition modified crystalline structure, and the porosity of SCPC work out synergistically to enhance material resorbability and bone bioactivity [13]. The aim of this study was to evaluate silica calcium-phosphate nano-composite (SCPC) both histologically and radiographically as an alloplast in open sinus lift surgeries.

2. Materials and methods

2.1. Patient selection

Six patients (3 females 50%, 3 males 50%, age range 41–56 years with a mean age of 48.2 years) with partially/fully edentulous maxillae and a total of 9 sinuses in need for restoration of 20 sinus

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* Corresponding author.

E-mail addresses: arwa.loay@fue.edu.eg (A. Hosni), wbeialy@yahoo.com, wbeialy@den.hokudai.ac.jp (W.R. El-Beialy), mostez@hotmail.com (M. Ezz).

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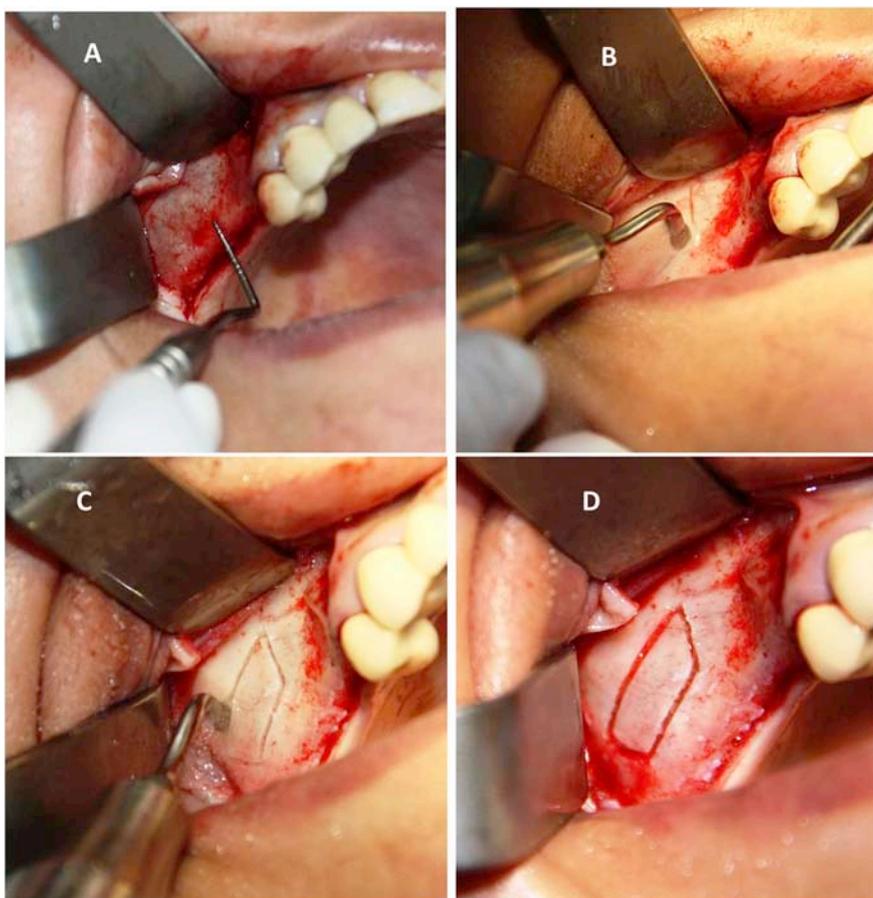


Fig. 1. Steps of lateral trap-door osteotomy and graft material placement: a) Measurement of the height of the inferior osteotomy cut from the crest of the edentulous alveolar ridge, b) inferior osteotomy of lateral trap-door osteotomy using piezosurgery tip, c) superior osteotomy d) final shape of lateral trap-door osteotomy before Schneiderian membrane elevation.

approximating missing premolars/molars, with residual bone height category C and/or D ($RBH \geq 4\text{--}6\text{mm}/\geq 1\text{--}3\text{mm}$) according to the Consensus Conference on Maxillary Sinus Elevation were included in this study. This research has been conducted in full accordance with the World Medical Association Declaration of Helsinki, and the study has been independently reviewed and approved by an ethics committee review board at Cairo University. All patients were consented in writing following explanation of the designated procedure.

2.1.1. Inclusion criteria

Patients had partially/fully edentulous maxillae in need for restoration of sinus approximating missing premolars/molars and residual bone height category C and/or D ($RBH \geq 4\text{--}6\text{mm}/\geq 1\text{--}3\text{mm}$) according to the Consensus Conference on Maxillary Sinus Elevation and adequate bone width to accommodate an average dental implant. Patients were free from uncontrolled systemic diseases directly affecting bone metabolism and healing. Designated edentulous ridge free from local pathosis that may interfere with bone healing or threaten the future stability of the implant (lesions of reported recurrence rates) and/or any history of any grafting procedure.

2.1.2. Exclusion criteria

Patients with uncontrolled osteoporosis and/or diabetes. Hepatic patients with extremely elevated liver enzymes. History chemotherapy or radiotherapy.

2.2. Preoperative phase

Collection and documentation of baseline data, medical history, preliminary clinical examination and panoramic radiographs were performed for early scouting and laboratory investigations were requested. Cone Beam Computerized Tomography (CBCT) was done to

evaluate density and quantity of available bone in the edentulous areas.

2.3. Operative phase I

Surgery was performed under local anesthesia. Mucoperiosteal flaps were reflected via a horizontal mid-crestal incision and either one vertical releasing incision anteriorly or two vertical releasing incisions (one anteriorly and a shorter one posteriorly) to visualize the lateral wall of the maxillary sinus.

Sinus membrane elevation was achieved utilizing a lateral trap-door window technique in which osteotomies were performed using ultrasonic piezoelectric device (Piezotome Solo, Acteon Group, France) with SL1 and SL3 piezosurgery tips (Essential kit - Satelec® tips, Acteon Group, France). Osteotomies were performed with the inferior cuts modified than the classical technique and placed at the sinus floor level as calculated from CBCT, all sides of the window were osteotomized to full depth using SL1 piezosurgery tip except for the superior cut which was incompletely cut and sharp corners were rounded off (Fig. 1).

The Schneiderian membrane was initially elevated using SL3 piezosurgery elevator tip followed by a small-sized mucoperiosteal elevator ensuring full elevation at the lateral, inferior and medial sinus walls (Figs. 2 and 3). No specialized sinus lift elevators were needed using this modified sinus lift technique.

The bony wall was then gently pushed from the center and fractured rotating the trap-door window inwards and upwards becoming the new maxillary sinus floor and creating a space below the lifted membrane in which the graft material is placed (Fig. 4), membrane integrity was then checked using Valsalva maneuver, bone augmentation was done using silica–calcium phosphate nano-composite (SCPC) discs. The discs were tightly packed inside the sinus below the Schneiderian membrane (Fig. 5).

The mucoperiosteal flap was then repositioned and sutured back to



Fig. 2. Initial elevation of the Schneiderian membrane using SL3 peizosurgery tip.

place. Immediate postoperative panoramic radiographs were acquired. CBCT was commenced both immediate and 4 months postoperatively.

Postsurgically, patients were instructed to rest, apply extraoral ice packs and to avoid excessive negative or positive pressure through both their nose and oral cavity as drinking through a straw, blowing their nose, coughing and sneezing; that should be done with an open mouth.

A combined antibiotic coverage: Amoxicillin with beta-lactamase inhibitors¹ (b.i.d) and Clindamycin² (b.i.d) was initiated post-operatively; and continued for one week postoperatively. An anti-histaminic³ (q.h.s), a non-steroidal anti-inflammatory (NSAID)⁴ (b.i.d) and a chlorhexidine mouthrinse⁵ (t.i.d) were also prescribed. Systemic⁶ and topical⁷ nasal decongestants (q.h.s and t.i.d respectively) were used to improve ostial drainage.

2.4. Radiographic assessment

CBCT images were acquired using a classic Planmeca Promax scanner.⁸ Invivo Dental software⁹ was utilized for linear and density measurement; while Mimics software¹⁰ was used for graft volumetric measurement. A certified radiologist performed the CBCT analysis.

2.5. Operative phase II

Second stage surgery was conducted under local anesthesia 4 months following sinus-grafting procedure. Bone core biopsies (Fig. 6) were obtained by a crestal approach using a trephine drill¹¹ with a 4 mm diameter at the designated sites of implant placement to be processed for histological analysis (histochemistry and immunohistochemical staining). Immediate implant placement and necessary drilling for larger sized implants was performed at biopsy sites.

2.6. Histological assessments

Stained specimens were examined using an inverted light microscope¹² with 100×-magnification power and images were captured



Fig. 3. Elevation of Schneiderian membrane using a small-sized mucoperiosteal elevator.

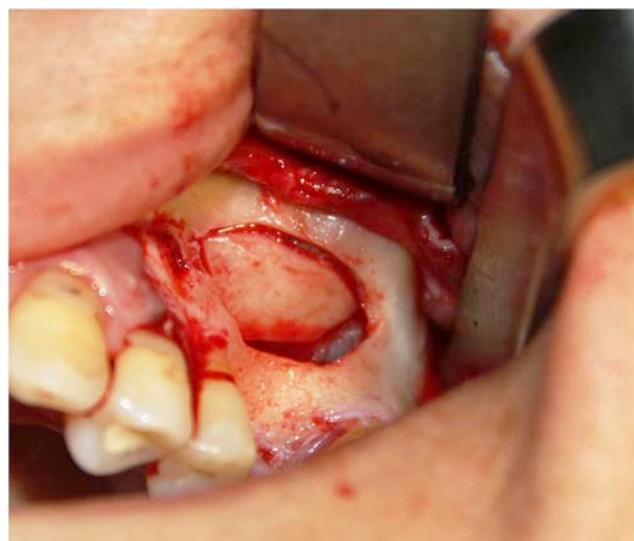


Fig. 4. In-fracture of the lateral trap-door osteotomy.

simultaneously using a mounted camera.¹³

2.7. Statistical analysis

All collected numeric data was tabulated and statistically analyzed. Numerical data were presented as mean and standard deviation (SD) values. Using ANOVA statistical analysis, the significance level was set at $P \leq 0.05$. Statistical analysis was performed with GraphPad Instat.¹⁴

3. Results

All cases had uneventful healing following both surgical phases. There were no exaggerated surgical sequelae in terms of edema and pain. Clinically the tactile sensation on implant placement was reflective of the nature of the newly formed bone; however, all implants were placed at a minimum torque of 20Ncm.

¹ Julmentin 1000 mg, Julphar, Ras Al-Kheima, United Arab Emirates.

² Dalacin-C 300 mg, Pfizer, New York City, NY, USA.

³ Claritine 10 mg, Schering, Kenilworth, NJ, USA.

⁴ Brufen 600 mg, Abbott, Chicago, IL, USA.

⁵ Hexitol mouthwash, ADCO Pharma, Cairo, Egypt.

⁶ Congestal, Sigma-Aldrich, St Louis, MO, USA.

⁷ Otrivin nasal drops, Novartis Pharma, Switzerland.

⁸ Planmeca, Finland.

⁹ Version 5.4, Anatomage, San Jose, CA, USA.

¹⁰ Version 15.4, Materialise, Belgium.

¹¹ Trephine basic kit, Meisinger, Germany.

¹² CXK41, Olympus Corp., Japan.

¹³ XC30, Olympus Corp., Japan.

¹⁴ GraphPad, Software Inc., USA.

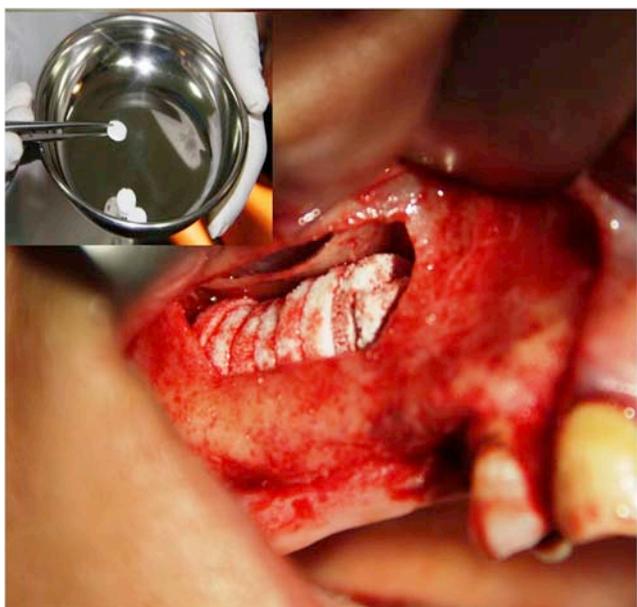


Fig. 5. Graft material placed inside the created chamber (in-photo: graft material in disc form).

3.1. Radiographic results

3.1.1. Panoramic radiography (Fig. 7)

The graft discs were clearly visible in radiographs postoperatively with some loss of structural integrity at 4 months postoperatively.

3.1.2. Cone-beam computed tomography

CBCT were utilized to comparatively assess (immediate versus 4 months postoperatively):

- Linear bone height (Fig. 8)
- Gray scale (HU) denoting bone density (Fig. 10)
- Bone volume (Fig. 12)

All measurements were precisely performed at the same points guided by the radiographic stent (radiopaque markers) and superimposition.

- Linear measurements (Fig. 9):

The mean linear bone height increased from 5.2 mm preoperatively, to 14.5 and 14.4 mm in the immediate and 4 months postoperatively which is a statistically significant increase in bone height between preoperative and both postoperative measurements ($P < 0.05$); while the slight decrease in height between the immediate and 4 months

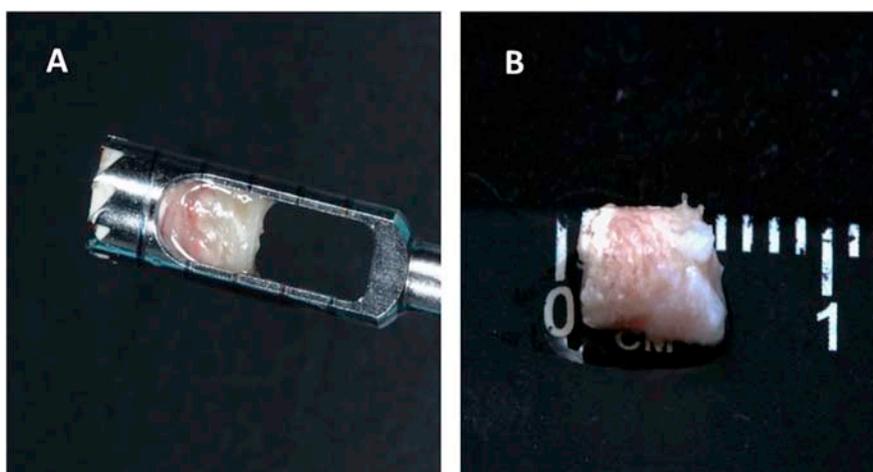


Fig. 6. Operative phase II: a) bone core biopsy collection using a 4 mm diameter trephine bur, b) calibration of bone core biopsy.

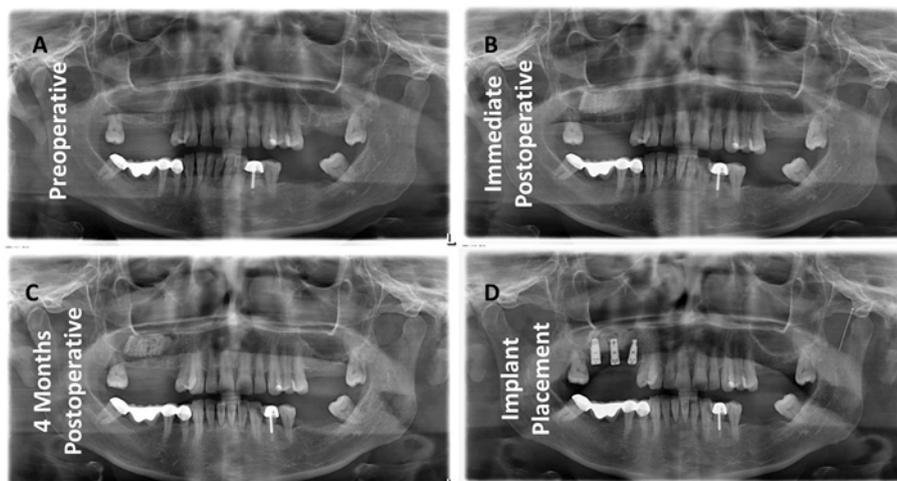


Fig. 7. Panoramic radiographs: a) preoperatively, b) immediate post-operative, c) 4 months postoperative and d) following implant placement.

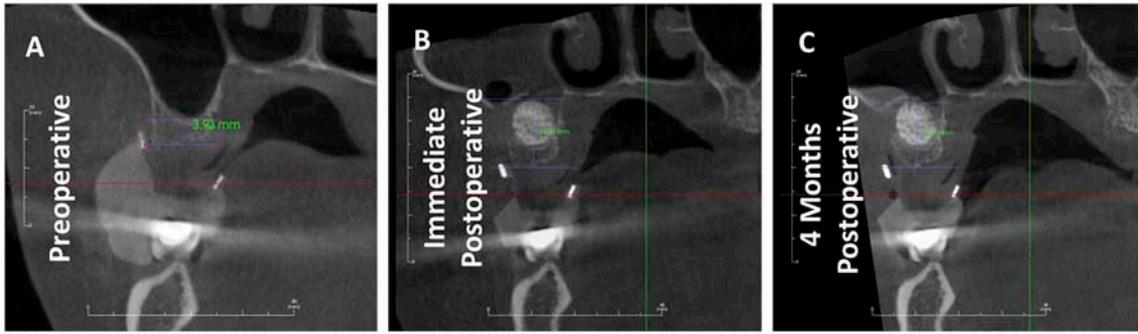


Fig. 8. Coronal cuts showing linear height measured at the same point guided by radiopaque markers: a) preoperative, b) immediate postoperative and c) 4 months postoperative.

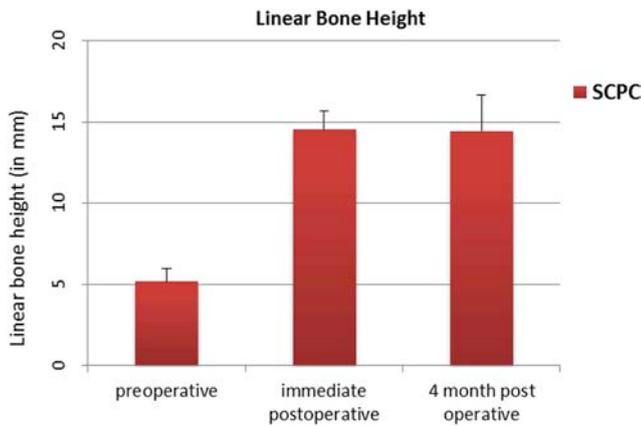


Fig. 9. Bar chart of mean values of linear bone height measurements SCPC. Error bars demonstrating standard deviation.

postoperative was statistically insignificant.

- Measurement of density (Fig. 11):

The mean density increased from 973.5 HU to 1116.9 HU immediately postoperative and 4 months postoperatively which is a statistically insignificant difference ($P < 0.05$).

- Volume measurements (Fig. 13):

The mean volume measurement increased from 1163 mm³ to 1173.5 mm³ in the immediate and 4 months postoperative. Despite the very limited sample size, which should be taken into consideration,

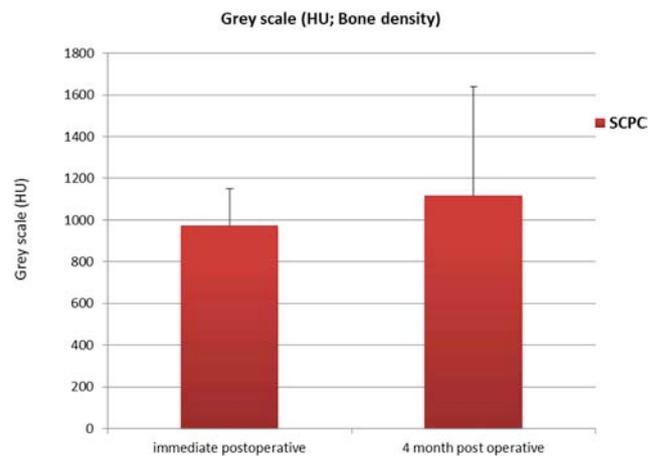


Fig. 11. Bar chart of the mean values of density using SCPC. Error bars demonstrating standard deviation.

there were no statistical significant differences ($P < 0.05$).

4. Histological results

Specimens examined under light microscope showed the following findings:

4.1. Hematoxyline & Eosin

Specimens revealed islands of forming bone with apparently different degrees of maturation and incremental bone deposition, as

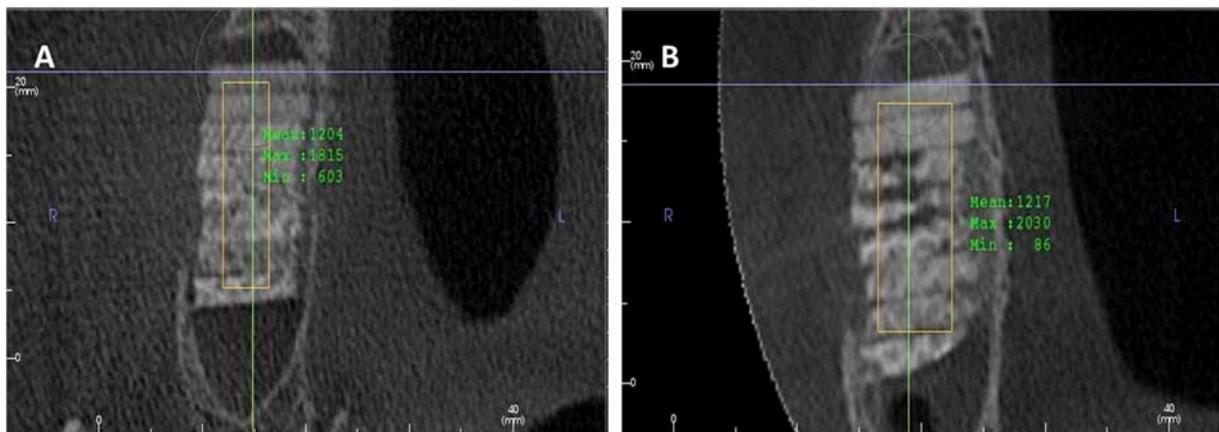


Fig. 10. Axial cuts showing measurement of density: a) immediate postoperative b) 4 months postoperative.

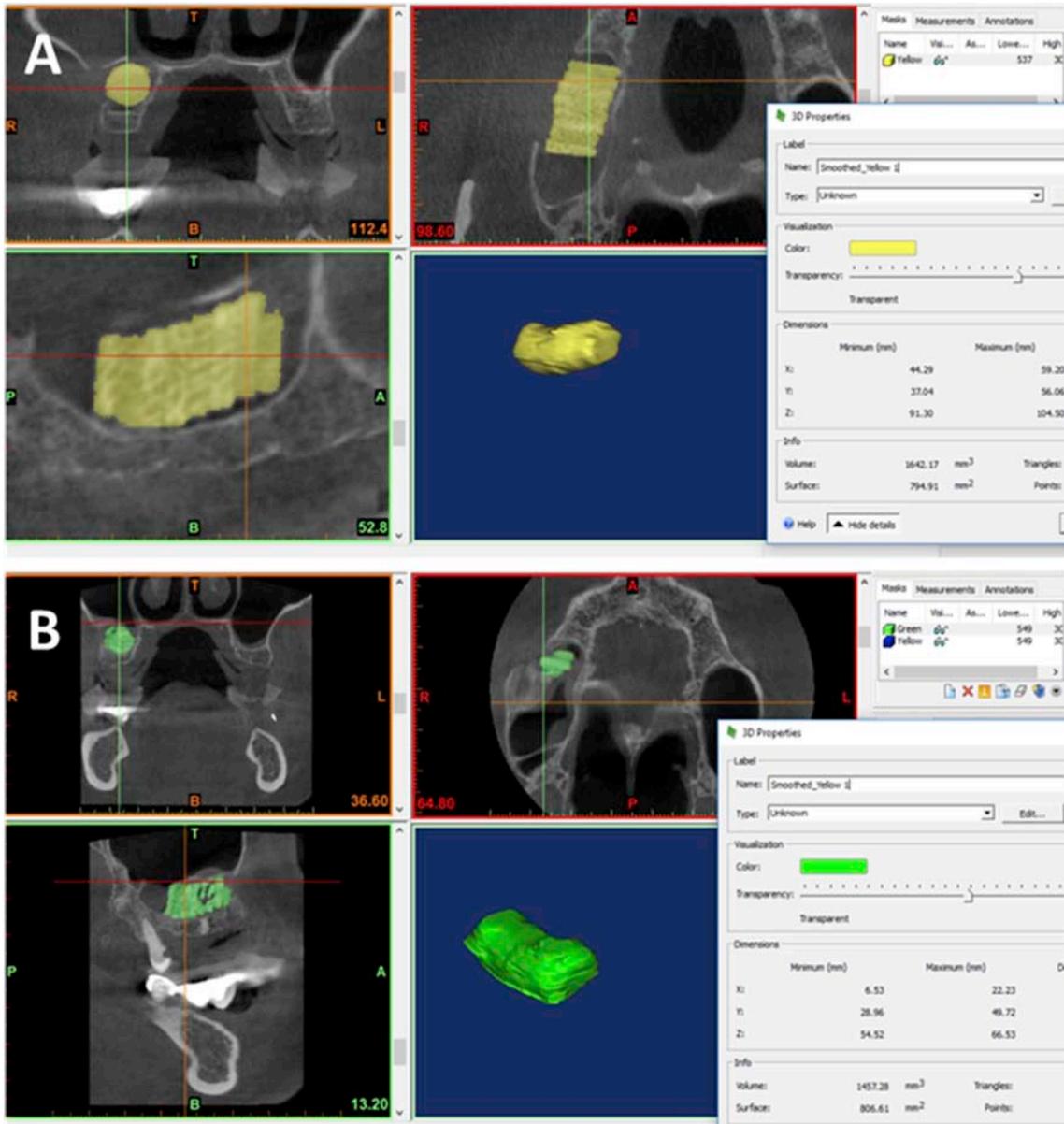


Fig. 12. Measurement of volume in: a) immediate postoperative b) 4 months postoperative.

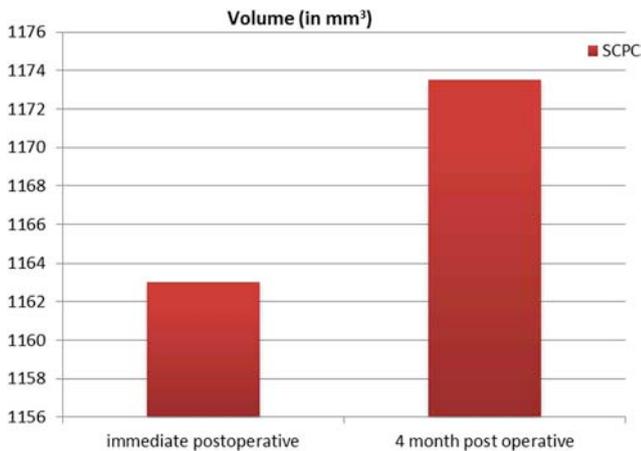


Fig. 13. Bar chart comparing immediate and 4 months mean values of density using SCPC.

demonstrated by varying staining intensities, number of osteocytes and stacking of resting lines. Relatively, earlier formed bone exhibiting deeper staining; less osteocytes and closely arranged resting lines denoting rapid bone formation was clearly seen in specimens. Contrary to the findings in recently formed bone showing: the lighter stained abundant osteocytes and existence of marrow spaces with active osteoblasts. Residual graft material was observed with dense collagenous matrix infiltration and neovascularization encapsulating the residues (Fig. 14).

4.2. Masson - goldner trichrome special stain

It was used to detect areas of new bone formation as blue color while older bone areas without new collagen formation appear red in color when examined by light microscope [14]. Specimens revealed neo-bone formation (Fig. 15).

4.3. Immunohistochemical staining

Specimens revealed positive immunoreaction (Fig. 16). Positive

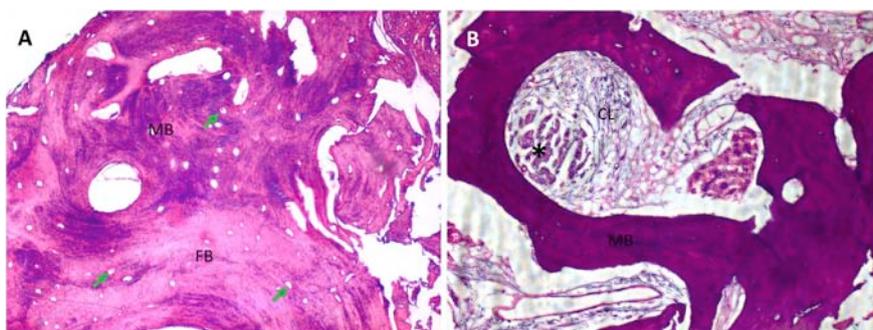


Fig. 14. Photomicrographs of core bone biopsy: a) showing a bone island with numerous osteocytes (green arrows) entrapped in the matrix in mature (MB) and forming bone (FB), b) showing residual SCPC material (*) surrounded by heavy collagenous matrix (CL) and mature bone (MB) (H&E, 100×).

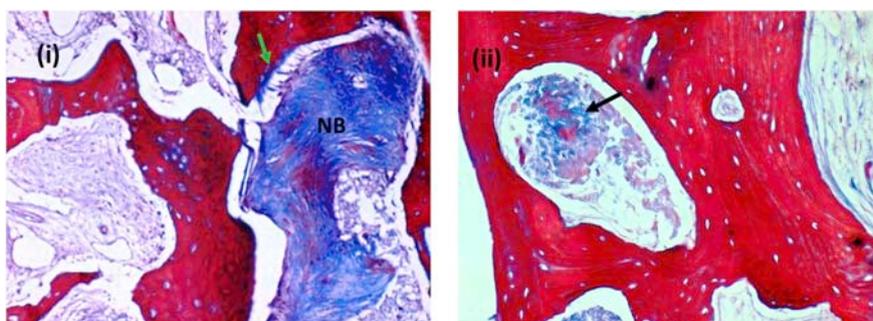


Fig. 15. Photomicrographs showing neo-bone formation (NB) note the neo-bone formation at the margins of the earlier formed mature bone island (green arrow) (i) mature bone formation. (ii) Neo-bone formation (black arrow). (Masson tri-chrome, 100×).

results are interpreted as osteocalcin secretion from osteoblasts within the substance of the bone biopsies.

5. Discussion

Open sinus lift for augmentation of over pneumatized maxillary sinus from a lateral approach has been a well-established treatment protocol since its debut in 1974 [1]. This can be attributed to the numerous reports on its use and proposed modifications throughout the literature [1,2,7–9,15]. While in core modifications have been limited to provide more consistent results and simplify the procedure, as well as, reducing the risks or complications encountered; herewith in this study a proposed modification for the classical approach is presented. The modification includes situating the inferior cut of the trap door at

the level of the maxillary sinus floor in maxillary sinus with residual bone height category C and/or D ($RBH \geq 4-6\text{mm} / \geq 1-3\text{mm}$) according to the Consensus Conference on Maxillary Sinus Elevation [16]. Of course, this modification was supported by the shape of the used graft disc form, rather than the commonly used particulate/powder form which necessitates the cut to be at a height of 4–6 mm from the actual sinus floor [17]. This minor modification in trap door, allowed us to use a regular periosteal elevator rather than the commercial sinus lift kits for such procedure. While such kits were introduced for safer and simpler elevation of Schneiderian membranes, the proposed modification provided the same safety and even better simplicity to the procedure at a lower financial burden.

Intact elevation of Schneiderian membranes has been an influential factor in the success of open sinus lift procedures for implant placement. Piezoelectric surgical units and sinus lift tips were introduced to augment such safe elevation [18]. The use of piezoelectric units in this study allowed for smooth and gradual cuts in bone at the lateral maxillary wall. We definitely agree with the superiority of piezoelectric usage over rotary shavers and surgical burs; however, this should not be regarded as a safe tool that will not violate the membrane; but rather a safer tool that should be handled with care and caution to avoid insult to the membrane especially over thinned membranes. This remark is based on the results of this study where 2 perforations were encountered despite using piezoelectric unit. While one was attributed to over thinning of the membrane, the other however, took place despite seemingly having an acceptable membrane thickness. This might be due to the abnormality of the inner wall of the maxillary sinus in the form of stepping, yet being from the first cases for the operator, it might as well be due to overconfidence in labeling piezo-surgery as safe.

Autogenous grafts are sought to be the ideal bone graft as they exhibit: osteointegrative, osteoconductive, osteoinductive and osteogenic properties, as well as, being volume stable. To achieve its role the graft should be placed in an appropriate aseptic environment with sufficient blood supply. Allograft on the other hand, are osteointegrative and osteoconductive and may exhibit osteoinductive potential,

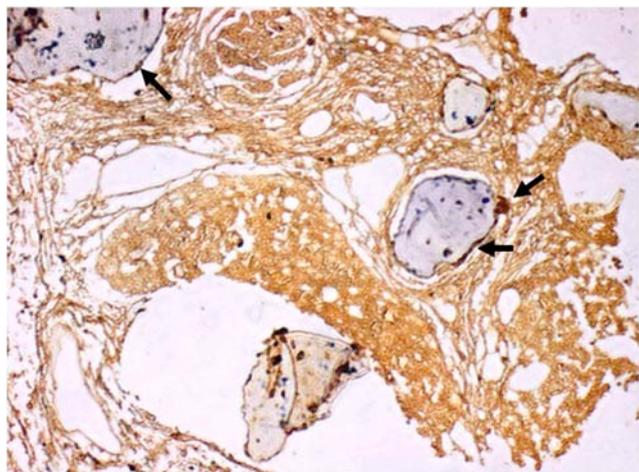


Fig. 16. Photomicrographs showing positive Osteocalcin immunoreaction exhibited by osteoblasts rimming (black arrows) (Osteocalcin, 100×).

but are not osteogenic because they contain no live cellular component. Synthetic bone graft substitutes currently possess only osteointegrative and osteoconductive properties [19,20]. Regarding the severely atrophied maxillae included in this study, autogenous grafts with of such volume around 1200 mm³ would necessitate a remote donor site as hip, tibia or cranium. Such donor sites dictate a second surgical site, accompanying transient or permanent donor site morbidity and unpredictable integration and resorption at recipient site [2,21–24]. While bone substitutes were historically of limited use due to their -thought to be-limited regenerative capacity in comparison to autogenous grafts; yet, evidence-based research have documented the efficacy of all forms of grafts in indicated clinical situations. Moreover, reports of more favorable outcomes using non-autogenous graft materials rather than autogenous have been reported [2,21–23,25–27]. In the current study, all patients were offered the option of an autogenous graft from the anterior iliac crest [28], yet they all preferred participating in this study using alloplastic grafts. Needless, to point out that the presented alloplastic bone substitute included in this study allows for performing the open sinus lift procedure under local anesthetic setting, which is not the case for autogenous iliac crest grafts that necessitate general anesthesia. Xenografts and allografts exhibit undesirable qualities that include but are not limited to: slow particle resorption, potential of disease transmission, host immune reaction, and refusal of some patients to introduce grafts of other species origin into their bodies. Such disadvantages were overridden with alloplastic grafts as HA and SCPC used in the current study, as well as, exhibiting advantages of availability, ease of manipulation, fewer complications and higher security of usage [29]. The rate of resorption of HA and SCPC can be easily manipulated through customizing varying levels of porosity and pore size [30–32].

In the current study, we took the advantage of being able to shape the alloplastic graft to produce disc-form grafts rather than the commercial particulate or powder form. This aided the earlier noted modification in the trap door design, since such discs do not necessitate a bounded defect where the particulate/powder graft material is placed from the top. The disc-form reduced the amount of time needed to augment the sinus, and provided a simpler technique. Discs also provided space in between the grafted material that can be claimed to provide better ingrowth of tissues and neo-vascularization when compared to block form alloplastic grafts. However, further comparative clinical and histologic studies would be necessary to evidence-base such claim.

SCPC used in this study were found to be in agreement with the rules proposed by Iezzi et al. [33] for biomaterials used in bone regeneration. Those included: ability to work as a scaffold for successful integration; adequacy of pore size and volume, as well as, pore interconnectivity for vascular invasion; mechanical characteristics similar to the regenerated tissues [34,35]; biologic stability to ensure volume maintenance and induce the formation of a high rate of vital bone and bone remodeling [36]. Histological assessment in this study, documents the reported biocompatibility, osteoconductivity and resorbability of SCPC [13,37,38]. SCPC was confirmed to have unique bioactive resorbable nanocrystalline phases may be due to the reported hierarchical porous structure with two levels of porosity: nano- and micropores [13,37,38].

On analyzing the presented results qualitatively a few conclusions can be drawn as follows. There was a slight decrease in the linear bone height gain, overall volume of the graft and density (in terms of Hounsfield units) at 4 months postoperatively compared to immediately after their grafting. This can be interpreted as resorbability of SCPC, which can be considered as a disadvantage in terms of biological stability; yet, it can be also considered an advantage in terms of being replaced by host new bone formation as evident in histologic findings. However, the debate can continue in terms of better outcome of SCPC supported by the increase in graft volume and density after 4 months, which was evident by the Masson-Goldner Trichrome special stain,

which revealed pronounced neo-bone formation in SCPC, and was further confirmed by the positive reaction using osteocalcin immunohistochemical staining.

As for the SCPC histological specimens the bone trabeculae appeared with well defined, uniformly spaced and evenly stained resting lines. No inflammatory cells and multi-nucleated giant cells were present around the particles or at the interface with bone denoting the biocompatibility of SCPC, which is in agreement to earlier results by Frenken et al., 2010 [39] and Iezzi et al., 2012 [33]. There were regularly arranged osteocytes with lacunae and canaliculi. Moreover, areas with Haversian systems and concentrically arranged lamellae were observed and areas of bone marrow with few blood vessels were also detected. This might be attributed to the superiorly designed structure of SCPC in terms of nano- and microporosity [13,37,38]. It can also be indicative of earlier bone deposition and remodeling using SCPC.

At such short interval, 4 months post grafting we tend to agree with reported approximately 25–40% new bone formation [40–45], rather than the claimed significant amounts of bone [46]. Following recent augmentation and as expected varying degrees of residual materials were observed in histologic specimens with different stains in this study of both groups, in agreement with earlier reports [13,33,37,38]. Total lack of such residues might have caused early resorption of the grafts with consequent loss of volume and density, which was not the case in this study. Osteoblastic bone formation was clearly observed in all histological specimens. Gradual material resorption, and incremental substitution by newly formed bone was also observed. This might be attributed to the reported superiority of SCPC hierarchical porosity in structure that allowed better ingrowths within the graft [13,37,38].

Despite the clearly visualized bone formation in all histologic specimens, we find it difficult to withdraw quantitative assumptions from such samples regarding the percentage of newly formed bone. This might be explained in the terms of technical errors in making the slides due to the rather small size of the bone core biopsies and difficulty in orientation within the blocks, angulations of the cuts and the unfeasibility as well as, difficulty of staining each slice of the biopsy. However, we were able to place dental implants in all grafted sinuses, at an acceptable minimal torque. While tactile handling during drilling and implant insertion is rather a factor that is purely subjective, yet we have to note that the site of implantation in SCPC, felt quite soft than expected. Further research is necessary to evidence base this comment, and whether the hierarchy and orientation of pores in SCPC or the degree of calcification/mineralization of bone and its maturation is the cause.

Within the limitations of this research in terms of limited sample size and short term of follow-up, we can conclude that the modified trapdoor technique, the disc form alloplastic grafts SCPC presented here within, are suitable for severely atrophied posterior maxillae to receive implants within a minimum of 4 months postoperatively. However, further research with larger sample sizes, prolonged follow-up intervals, functional implant survival rates and comparative to block form alloplastic grafts are necessary to support our conclusions.

In conclusion: The proposed technique provided simplicity and ease of access to the sinus without the need for special sinus lift kits, using only a straight periosteal elevator. Piezoelectric surgery unit is a handy tool that provides better safety to the Schneiderian membrane, yet, should be handled with care. The disc form of alloplastic grafts (SCPC) is a simpler form for augmenting such severely pneumatized maxillae and sinuses and allowed for such modification in the trapdoor. Moreover, the discs allow for ingrowth of tissues and neovascularization in between as well as, within due to their porous nature. Such grafts can substitute remote autogenous grafts as anterior iliac crest that necessitate a second surgical site, and associated donor site morbidity along with unpredictability of integration and resorption which is not acceptable in cases of autogenous grafting. The proposed SCPC discs allowed for dental implant placement at the recipient sites 4 months postoperatively. However, further research with larger sample sizes,

prolonged follow-up intervals, functional implant survival rates and comparative to block form alloplastic grafts are necessary to support our conclusions.

Conflicts of interest

No conflict of interest.

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