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Assessment of bone augmentation using silica calcium phosphate nanocomposite (SCPC)versus hydroxyapatite in open sinus lift Surgeries(A Scanning Electron Microscope, Cone Beam Computerized Tomography and histological study)

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ABSTRACT

Objectives: Maxillary sinus pneumatization and extraction of posterior maxillary teeth are among the most common factors attributing to the diminished alveolar process. Implants placed in posterior region of maxilla showed the highest failure rates due to poor bone density in addition to insufficient remaining bone volume needed for implant primary stability.

Materials and methods: Ten patients were selected from out patient clinic with partially or fully edentulous maxilla missing premolars or molars with residual alveolar bone height less than 6 mm, both groups received open sinus lift surgery with different grafting material group1 (control group) received hydroxyapatite (HA)in a disc form, group 2(Study group) received silica calcium phosphate nanocomposite (SCPC) in a disc form. Clinical evaluation, Cone Beam Computerized Tomography (CBCT) (Pre-operative, 0 & 4 months postoperatively), Scanning Electron Microscopy (SEM) (4 months postoperatively) and histological study (4 months post-operatively)were performed for both groups as follow-up following either stages of surgery.

Results: all patients had uneventful wound healing, and none experienced excessive postsurgical edema. Following surgical stage II (implant placement) all patients exhibited proper dental implant osseointegration, and all were properly restored by fixed prosthodontics. For radio graphical results the bone height and bone width showed statistically significant increase in both groups; The histopathological results of both groups revealed new bone formation in the histological sections attained from the core bone biopsies over 4 months postoperatively. While the analysis of the SEM images revealed that in the control group (HA), the new bone exhibited an irregular and porous appearance In the study group (SCPC), the bone appeared as a continuous plate with nearly homogenous surface.

Conclusion: within the limitations of the present study, the present data support the fact that both HA and SCPC can be used, successfully, in sinus augmentation procedures. Moreover, the suggested technique in combination with grafts in the form of discs, and using piezoelectric surgical units are simpler and safer approaches to lateral sinus lift augmentation procedures.

1. Introduction

The edentulous posterior maxilla presents a clinical challenge for rehabilitation with endosseous oral implants [1]. The most obvious difficulty lies on the anatomical state, which is characterized by less favorable bone quality and insufficient bone volume resulting from pneumatization of the maxillary sinus and crestal bone resorption [2,3]. Without augmentation of these areas, successful placement of osseointegrated implants is unpredictable. Misch CE in 1988 [4] further demonstrated that bone density of the implant bed is an important factor in determining the treatment plan along with; implant design, surgical approach, healing time and initial progressive bone loading during prosthetic reconstruction [4,5].He classified bone according to its density: D1: Dense cortical bone,D2: Thick dense to porous cortical

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bone on the crest and coarse trabecular bone,D3: Thin porous cortical bone on the crest and fine trabecular bone,D4: Fine trabecular bone,D5: Immature, non-mineralized bone; sinus floor elevation is among methods used for augmentation of posterior maxilla in order to accommodate for implant placement via various lifting procedures [6,7]. The ultimate goal of a sinus augmentation technique is to increase the sinus height to the level necessary for dental implant placement. Maxillary sinus augmentation is a surgical procedure that compensates for this pathologic condition by increasing the alveolar bone height before or simultaneous with endosseous implant placement [2,8]. Increasing bone volume in posterior maxilla and bone quality has been achieved by combing various procedures and materials [9] Elevation and augmentation of the maxillary sinus can increase the bone height in the posterior area of the maxilla [10].At the Consensus Conference on Maxillary Sinus Elevation in 1996 [1,7,11], the members made the following recommendations which depend on the residual bone height (RBH): Category A (RBH ≥ 10 mm): classic implant procedure; Category B (RBH ≥ 7–9 mm): osteotome technique with simultaneous placement of implants; Category C (RBH ≥ 4–6 mm): maxillary sinus elevation with lateral access and bone graft and immediate or deferred placement of implants; Category D (RBH ≥ 1–3 mm): maxillary sinus elevation with lateral access and bone graft and deferred placement of implants. In the present study we select patients with remaining alveolar bone height of from 0 to 3 mm so we need to elevate the floor for at least 9 mm so the lateral window approach (open sinus lift) is the technique of choice in the present study. Autogenous bone has long been considered as the best option among all grafting materials. Scientific-based evidence supports the idea that bone formation occurs through the multiple pathways of osteoinduction, osteoconduction, and osteogenesis when a viable autogenous graft is placed in an appropriate aseptic environment with sufficient blood supply. Therefore, autogenous bone was initially considered as the first choice of filling material for maxillary sinus augmentation. Considering of the relatively large volume of grafting material required, extraoral donor sites from the hip, tibia or cranium were additional sourcing choices to provide an adequate amount of autogenous bone for sinus augmentation. However, use of such supplemental autogenous bone, may be accompanied by various transient or permanent donor site morbidity, Donor site morbidity is often considered a drawback when contemplating the use of autogenous bone for implant surgery, In the past, using bone substitutes for this procedure was limited due to their poor regenerative capacity as compared to natural autogenous bone. [12,13], Currently, additional evidence-based updated reviews have reported on the efficacy of all forms of graft material, noting that allografts, alloplasts, and xenografts can be effective in indicated clinical situations. By contrast, regarding the use of bone grafts or bone substitutes, one literature series reported on a case of sinus lift without graft [5,8,9]. Recently, a novel porous silica calcium-phosphate nanocomposite (SCPC) [14]. has been proposed as a candidate for bone tissue engineering scaffold. The new resorbable porous bioactive silica-calcium phosphate composite has the ability to adsorb high quantities of serum protein and stimulate rapid bone generation. The high porosity of the SCPC enhanced cell colonization and bone formation on and within the graft material. The high rate of silica dissolution from SCPC promoted rapid bone regeneration and graft material resorption. Thermal treatment of the SCPC induced ion substitution and formation (14) of solid solutions at significantly low temperature. These ultra structural modifications facilitated protein adsorption and controlled SCPC solubility. [15,16], It has been demonstrated that silica-calcium phosphate nanocomposite (SCPC) has a superior bone regenerative capacity and resorbability when compared to HA and bioactive glass [16]. The nanoporous structure, superior bioactivity, controlled dissolution kinetics, and strong stimulatory effect on osteoblast differentiation suggest wide applications of SCPC in the field of bone tissue reconstruction in maxillofacial surgeries [9]. The aim of the current study is to compare maxillary sinus lift using SCPC versus HA grafts using CBCT, EM, histological studies.

2. Patients & methods

Patients with partially/fully edentulous posterior maxillae experiencing deficient vertical alveolar bone height and in need for open sinus lift procedure were included (with remaining alveolar bone height from 0 to 6 mm).

2.1. Patient selection

10 patients were selected from the outpatient clinic of oral and maxillofacial surgery department, Faculty of oral and dental medicine, Cairo University. All patients were informed about the procedure and signed written informed consents. 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. Patients exhibiting vertically deficient alveolar bone height, that were in need for placement of 20 sinus approximating/perforating premolar/molar implants were selected according to the following criteria:

2.2. Inclusion criteria

Patients with partially/fully edentulous maxillae, in need for restoration of sinus approximating missing premolars/molars; with residual vertical bone height ≤6 mm. Patients free of any systemic disease that directly affects bone metabolism and healing. (ASA Class I and II), No local pathosis that may interfere with bone healing or threaten the future stability of the implant (lesions of high recurrence rates) and with no history of any grafting procedure at the designated edentulous ridge.

2.3. Exclusion criteria

Osteoporotic patients, uncontrolled diabetic patients, hepatic patients with extremely elevated liver enzymes, women in menopause and patients with uncontrolled hormonal imbalance were excluded, Patient Grouping:

Patients were blindly divided into 2 groups, both receiving open sinus lift procedure and consequent bone augmentation using: Group I (Control): Hydroxyapatite (HA) and Group II (Study): Silica–Calcium Phosphate nanoComposite (SCPC).

Biopsies were harvested at the time of implant placement and 4 months after the sinus lift procedure. The implants were exposed and restored with fixed crowns or bridges. The implants were considered successful if they fulfilled the criteria defined by Albrektsson et al. [17], namely immobility, lack of periimplant radiolucency, bone loss not exceeding 0.2 mm after the first year of function, and an absence of persistent and/or irreversible signs and symptoms, such as pain, infections, and neuropathies. A trained oral hygienist at 2 to 4 periodic appointments per year maintained the patients' oral health.

2.4. Methods & evaluation

The study entailed different study parameters to evaluate the patients, as follows: Cone Beam Computerized Tomography (CBCT) (Preoperative, 0 & 4 months postoperatively), Scanning Electron Microscopy (SEM) (4 months postoperatively) and finally Histological study (4 months postoperatively).

A. Preoperative Evaluation: All patients had their full personal, past medical and dental, as well as, clinical observations data is filled out.

1. Study Cast Analysis: Study casts and occlusal bite registration were fabricated for all patients. Casts were mounted on articulators and assessed for edentulous span, inter-arch space and teeth orientation. Further wax up of the proposed prosthetic teeth was completed, for ease of demonstration to the patients, and for fabrication of a

radiographic guiding stent.

2. Radiographic Examination:
   - Panoramic examination for early scouting, to evaluate the edentulous ridge in relation to the maxillary sinus floor. Panoramic radiograph for early scouting & evaluation of sinus pneumatization & approximation.
   - Cone Beam Computerized Tomography (CBCT) was performed for patients who fitted the inclusion criteria. CBCT was further utilized to assess the bone quality and quantity in the edentulous area of interest, using OnDemand3D (CyberMed, Seoul, Korea)
3. Laboratory Investigations: All patients underwent routine laboratory investigations to rule out diseases that might interfere with normal healing and bone metabolism, according to our selection criteria.

2.5. Surgical technique

All patients included in this study underwent surgery under local anesthesia except those receiving bilateral sinus lift procedures, underwent surgery under general anesthesia. The whole procedure was done under full aseptic atraumatic technique, in which the patients rinsed with chlorohexidine 0.125%, skin was disinfected with betadine (povidonebovidone iodine) and sterile draped to guarantee maximum asepsis. Local anesthesia (Scandonest 2% L; mepivacaine hydrochloride 2% with levenordefrin 1:20,000; Septodont, USA) was administered using an aspirating syringe to achieve maxillary nerve block as well as, greater palatine nerve block, further field block infiltration injections were delivered for homeostasis. Crestal incision was carried out along the edentulous ridge, slightly toward the palatal aspect throughout the entire length of the edentulous segment. Buccal releasing incisions mesial and/or distal were carried out when needed to allow for tension free reflection of the flap, Crestal incision followed by releasing vertical incision to allow for tension free flap, Full thickness flaps were elevated to expose the alveolar crest and the lateral wall of the maxillary sinus using mucoperiosteal elevator.

Elevation of the flap using periostal elevator to expose the lateral side of the sinus. A trap door was made using piezo surgery unit (Piezosurgery Mectron, via Loreto, Italy) under sterile saline irrigation, in the lateral sinus wall based on the preplanning performed on CBCT analysis.

The plan entailed an inferior horizontal cut almost at the level of the pneumatized sinus floor. The trap door was carefully rotated medially and superiorly while maintaining a superior hinge (green stick fracture), while carefully and gently reflecting the Schneiderian membrane from the lateral, inferior and medial sinus walls.

This was carried out till the trap door reached the designated new sinus floor level. (Fig. 1).

2.5.1. Surgical stage I, grafting stage

Wound debridement with copious saline irrigations was performed and the intactness of the sinus membrane was assessed through repeated nasal inhalation and exhalation cycles, where the trap door (attached medially to the intact sinus membrane) moves in coordination with those cycles. The grafts used had been custom fabricated in the form of discs and were carefully placed and packed in the maxillary sinus up to the level of the trapdoor (Fig. 2) according to the preplanning to later on accommodate interosseous implants. The patients received different types of disc grafts as follows:

Group I (Control): Hydroxyapatite (HA).

Group II (Study): Silica–Calcium Phosphate nanoComposite (SCPC).

After which, the muccoperiosteal flap was repositioned and suturing (interrupted or continuous sutures) using coated vicryl 3-0 (polygalactine 910) (Ethicon, Johnson-Johnson Inc., USA) Systemic antibiotics were amoxicillin-clavulanate 1000 mg (Augmentin-Glaxo-SmithKline) b.d.s. was prescribed for 1 week; Metronidazole 500 mg (Flagyl 500 mg, Sanofi, Egypt) b.d.s. for 5 days; and a NSAID t. i.d. for 3–5 days. Antiseptic mouthwash of 0.125% chlorhexidine HCL (Hexitol mouthwash, ADCO, Egypt) was used 2 times/day (30 s each time) for 2 weeks. Local nasal decongestants Otrivin nasal drops (Xylometazoline Menthol, Novartis, Egypt) were prescribed b.d.s. for 5–7 days postperatively. The patient was clinically followed up on the 3rd postoperatively day, and on a weekly basis afterwards for the first month, then on monthly basis. CBCT was taken immediate postoperatively (Fig. 3).

2.5.2. Surgical stage II, core bone biopsy and implant placement

At least four months postoperatively following surgical stage I, CBCT was taken for the patients (Fig. 4).

The same surgical routine as in surgical stage I was carried out, except that all patients underwent the procedure under local anesthesia. The surgical flap was performed to evaluate the previous surgical site and graft material from the lateral aspect. A trephine bur (diameter 2.5 mm) (Meisinger, Neuss, Germany) was inserted from a crestal aspect along the designated endosseous implant sites under copious saline irrigations, and a core bone biopsy was harvested and kept in saline. Endosseous dental implants (SwissPlus, Zimmer Dental Inc., U.S.A), were placed using torque wrench and the torque (Nm) was documented). All patients had their implants covered by cover screws and the flap was approximated and sutured as mentioned in surgical stage I; followed by the routine aforementioned postoperative medications. Immediate post-implantation panoramic x-ray was taken.

2.6. PostSurgical assessments

A. Clinical Follow up The patients were followed up clinically at the 3rd postoperative day, weekly for the first month then monthly for the rest the study period; following each surgical stage. The follow up included clinical evaluation of the surgical wound, postsurgical oedema, oral hygiene, signs of nasal congestion or discharge; and peri-implant gingival condition following implant placement.

B. Radiographic Follow up CBCT was taken immediate and 4 months postoperatively following surgical stage I (Grafting stage), prior to implant placement.

2.7. Histologic study

Histological Assessments The samples were carefully removed from the trephine drill using a blunt-ended instrument. Biopsy preparation depth never exceeded the appropriate depth required for the planned implant length at each specific site. The biopsy samples were first stored inside the trephine burs in a 10% buffered formaldehyde solution. After some time for fixation, the bone cores were pushed carefully out of the trephine burs, while registering the apico-coronal orientation of the cores for future reference during evaluation. Then core biopsy specimen was fixed in 10% neutral buffered formalin for 24 h, decalcified in 5% formic acid for 14 days, and embedded in paraffin [18]. The specimens were processed for the production of undecalcified ground sections. Briefly, the specimens were rinsed in running tap water, dehydrated in ascending concentrations of ethanol, and embedded in methylmethacrylate. The embedded tissue blocks were cut along the central axis of the biopsy into two approximately 400-µm-thick ground sections using a slow-speed diamond saw (Varicuts VC-50, Leco, Munich, Germany). After mounting the sections onto acrylic glass slabs, they were ground and polished to a final thickness of about 100 µm [19,20].

A. Scanning Electron Microscopic Study Samples from the core bone biopsy blocks were mounted on stubs using double-sided conductive tap The samples were then air dried from volatile solvents, then sputter gold coaters were applied to all mounted samples [15].

The sputter coater device for coating of the core bone biopsy before scaning by electron microscope. Following gold coating of the core bone biopsies. The samples where then examined under Scanning Electron microscope (SEM) and recording was performed using a Nikon

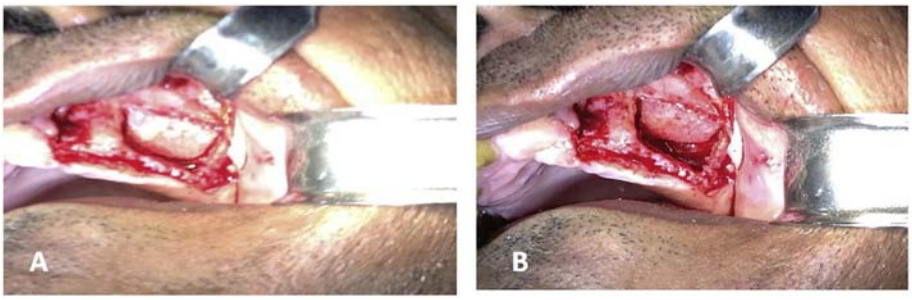

Fig. 1. (A) The trapdoor is performed and a green stick fracture (hinged superiorly) is performed to allow for rotation of the trapdoor superior and medial on its axis. (B) The trapdoor attached to the intact schneiderian membrane moves upward during exhalation under local anesthesia.

DN100 Digital Net Camera connected to a Zeiss microscope (Carl Zeiss, Göttingen, Germany) (Fig. 5).

C. Statistical Analysis All collected numeric data was tabulated and statistically analyzed. Numerical data were presented as mean and standard deviation (SD) values. The significance level was set at $P \leq 0.05$. Statistical analysis was performed with GraphPad Instat (GraphPad, Software Inc., USA.).

3. Results

Based on a parallel group design, five patients were treated with HA (two females, three male; mean age of 51.6 ± 4.3 years), five patients with SCPC (five males; mean age of 52.4 ± 1.2 years). None of the patients was a smoker, with osteoporosis, or with diabetes or irradiation. All treated patients were in good health condition and with presence of 1.5–6 mm of crestal bone between the sinus floor and the alveolar ridge.

3.1. Clinical results

On their initial postoperative follow-up following either stages of surgery, all patients had uneventful wound healing, and none experienced excessive postsurgical edema. Following surgical stage II (implant placement) all patients exhibited proper dental implant osseointegration, and all were properly restored by fixed prosthodontics (Fig. 6). All implants were inserted at a torque of 20N.

3.2. Radiographic results

Numeric data were collected from the CBCT scans taken for each patient preoperatively, immediate and 4 months postoperatively. The quantitative data were those of bone height, width and density (in term of Hounsfield Units "HU"). The gain in bone height as shown in (Fig. 7).

Bone Height; The mean bone height was 4.57 mm (with a standard deviation of 2) in HA group and 5.3 mm in the SCPC group preoperatively; which increased to a mean of 17.4 mm (STDEV 3.9) and 15.25 mm (STDEV 1.88) immediate postoperatively and reached 14 mm and 15.79 mm (STDEV for both 2.9) 4 months postoperatively (with a standard deviation of 3) for the HA and SCPC groups respectively, as shown in figure [7].

Between both HA and SCPC groups preoperatively, immediate and 4 months postoperatively (Error Bars denoting the Standard Deviation).

Two-way ANOVA statistical analysis was performed for the tabulated data of the bone height ($P < 0.0001$) all showed statistically significant increase in bone height in both groups; while both groups also demonstrated a statistically non-significant change between immediate and 4 months postoperative values for bone height. However, there was also a statistically non-significant increase in bone height between the two groups.

3.3. Bone width

The mean alveolar bone width available for dental implant placement was 4.49 mm and 4 mm preoperatively (with a standard deviation of 0.41 & 0.59) was increased to a mean of 5.22 mm and 6 mm, immediate postoperatively (with a standard deviation of 1.12 & 1.33) and reached 5.49 mm and 6 mm, 4 months postoperatively (with a standard deviation of 1.55 & 1.39) for HA and SCPC respectively, as shown in (Fig. 8).

Two-way ANOVA statistical analysis was performed for the tabulated data of the bone width ($P < 0.0001$) all showed statistically significant increase in bone width in both groups; while both groups also demonstrated a statistically non-significant change between immediate and 4 months postoperative values for bone width. However, there was also a statistically non-significant increase in bone height between the two groups.

3.4. Bone density (in terms of HU)

Bone density was estimated in terms of Hounsfield units along the

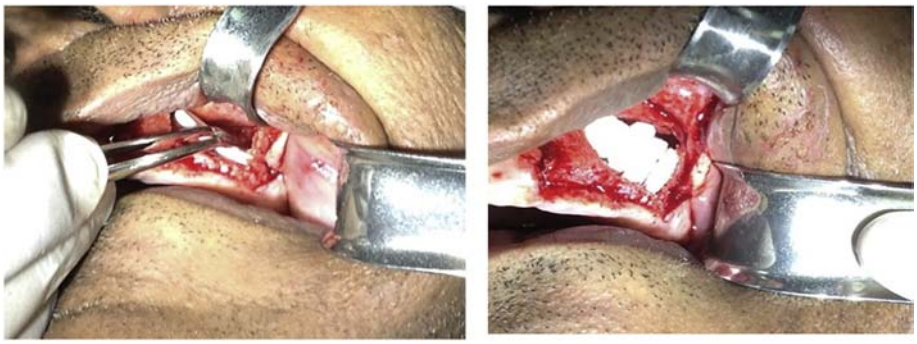

Fig. 2. Sequential application of the disc form bone graft (HA and SCPC); The discs are packed mediolaterally to fill the whole sinus floor width; (More discs are added vertically up to the trapdoor level filling the whole sinus cavity in the most achievable condensation).

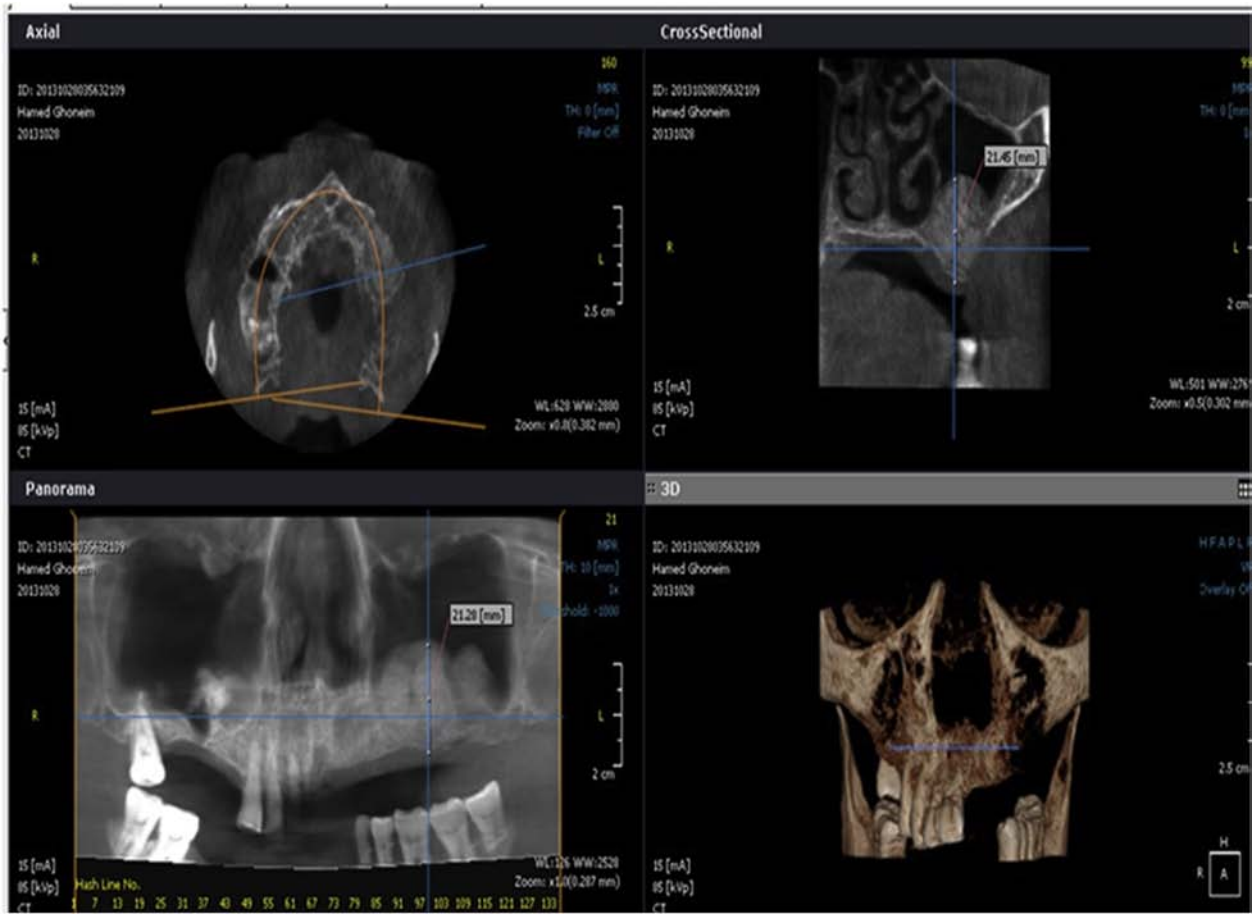

Fig. 3. Immediate post grafting CBCT to assess the achieved sinus lift.

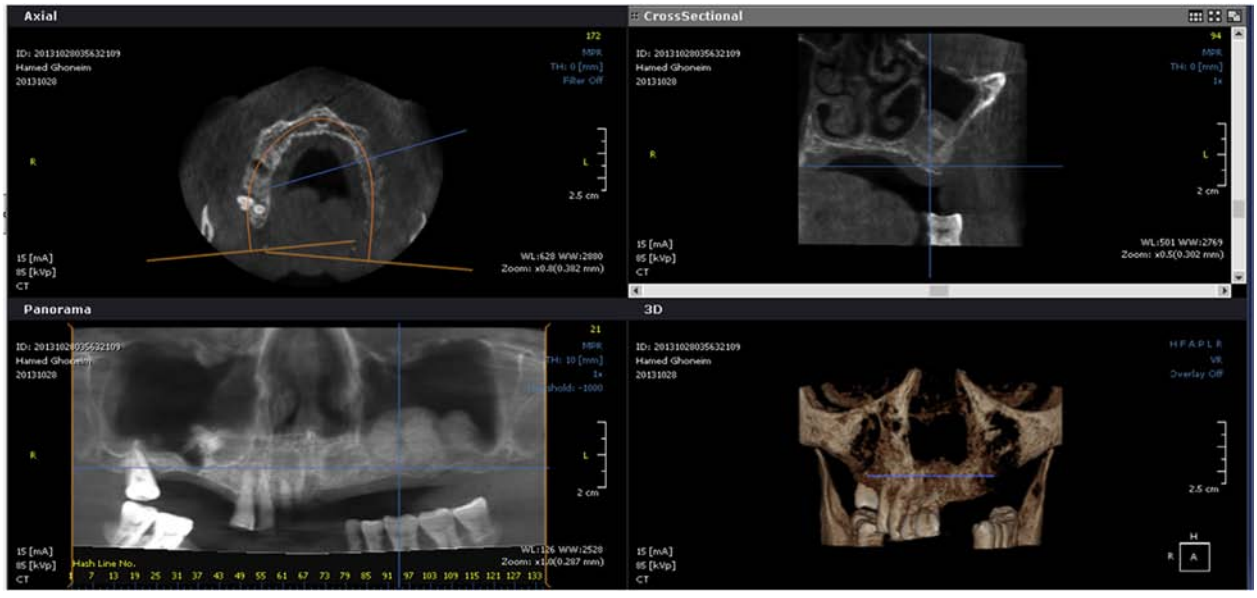

Fig. 4. CBCT after 4 months is performed before implant placement for planning of the required implant length and diameter and to assess the amount of bone and its density.

sites of endosseous dental implant placement in the crossectional cuts of the CBCT preoperatively, immediate and 4 months postoperatively; using OnDemand3D software. The mean density along the available bone height was tabulated and presented in figure (9).

The mean bone density was 165HU and 270HU preoperatively, 465HU and 666HU immediate, and 642HU and 682HU 4months post-operatively for the HA and SCPC groups respectively. Two-way ANOVA statistical analysis was performed for the tabulated data of the bone density ($P < 0.0001$) all showed statistically significant increase in bone density in both groups; while both groups also demonstrated a

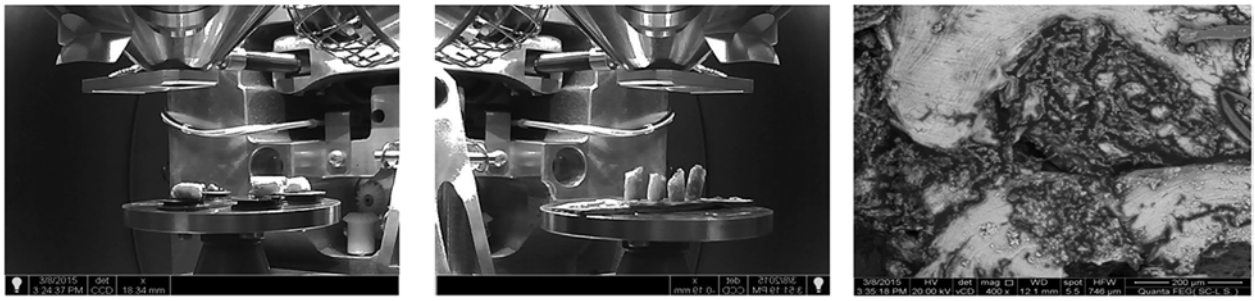

Fig. 5. Inside the SEM core bone biopsies laid out for (A) Longitudinal section imaging; (B) Cross sectional imaging; (C) Capturing of the surfaces at different magnifications to assess new bone formation.

statistically non-significant change between immediate and 4 months postoperative values for bone density. However, there was also a statistically non-significant increase in bone density between the two groups. The sequential CBCT taken at the designated intervals are presented for one case from each group.

3.5. Histopathological results

The histopathological results of both groups revealed new bone formation in the histological sections attained from the core bone biopsies over 4 months postoperatively. In the control group (HA) interconnected bone trabeculae were seen with widely spaced resting lines; often darkly stained, wide and undulating. The osteocytic lacunae were relatively wide with shrunken osteocytes (Fig. 10).

On the other hand, in the study group (SCPC) the bone trabeculae appeared with well defined, uniformly spaced and evenly stained resting lines. There were regularly arranged osteocytes with lacunae and canaliculi. Moreover, areas with haversian systems and concentrically arranged lamellae were observed. Areas of bone marrow with few blood vessels could be detected (Fig. 11).

3.6. Scanning electron microscopic (SEM) results

Analysis of the SEM images revealed that in the control group (HA), the new bone exhibited an irregular and porous appearance. The bone became irregular in appearance with massive cavitations giving the impression of a torn bony surface. Hollowing and cavitations could be observed along with diffuse bright nodular areas, however, this can be a result of the nature of the biopsy, being taken by a trephine bur (Fig. 12). In the study group (SCPC), the bone appeared as a continuous plate with nearly homogenous surface. Few irregularities were seen along with elevated and depressed areas. Localized areas revealed minor cavitations. Furthermore, the bone surface exhibited scattered nodular areas (Fig. 13).

4. Discussion

Ever since the introduction of sinus augmentation from a lateral access back in 1960 [21], it had been subject to numerous modifications [1,3–5] that it seems difficult to introduce updates to the technique itself; however, in the current study the modification in the technique was in terms of the positioning of the inferior cut of the trap door. Routinely, this cut is made at a height of 4–6 mm from the actual sinus floor, and special sinus lift elevators –kits- have been developed for such a purpose [22]. In the current study this cut was made exactly at the most inferior level of the pneumatized sinus floor, that lead to simple elevation of all sinuses using only the routine periosteal elevators; the aim was to achieve a safer and easier technique for open sinus lift procedures. Moreover, this technique is claimed to be safer as none of our cases experienced tears in Schneiderian membranes despite not using any specialized sinus lift kits. However, this safety can also be attributed to using piezoelectric surgical unit to develop the bone cuts in agreement to previously reported safety results [10,15,23]. Of note, the use of piezoelectric surgical handpieces, does not provide a risk free usage, and should be handled with care to avoid insults to the Schneiderian membrane.

Autogenous bone is generally the preferred graft material [12], but the use of autogenous bone is associated with risk of donor site morbidity and unpredictable graft resorption [13] so, increasingly, various bone substitutes have been used. Also, for pneumatized sinuses selected in this study: categories C and D according to the Consensus Conference on Maxillary Sinus Elevation in 1996 with respect to residual bone height [7], the amount of bone volume necessary for sinus augmentation is enormous and can only be acquired from iliac crest graft [24], which is not the most favorable site for patients, owing to the fact that it is a distant site and obligating the need for performing the procedure under general anesthesia. Biomaterials have stepped in to provide a viable alternative to autogenous bone grafts. The main rules set for biomaterials used in bone regeneration procedures as mentioned by Lezzi et al. include that it should work as a scaffold to obtain successful integration; have an adequate pore volume, pore interconnectivity and

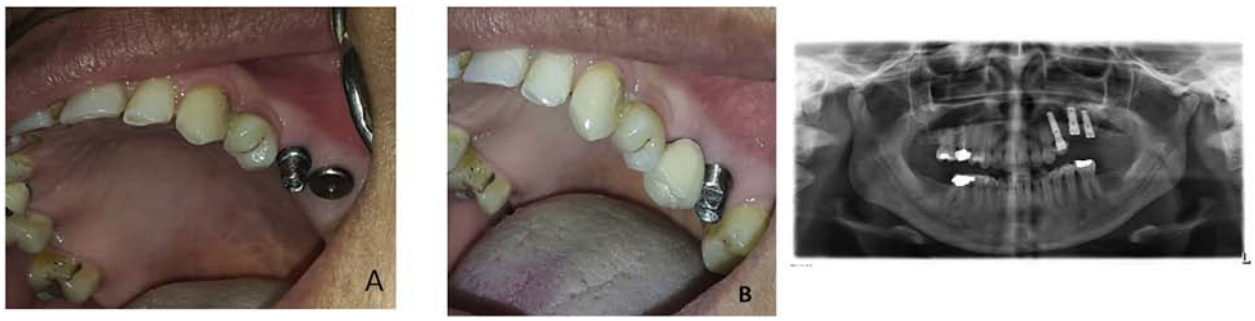

Fig. 6. (A) Normal gingival lining around the healing colar and temporary abutment; (B) Following cementation of the crown; (C) Panoramic X-ray prior to prosthetic stage and implant loading.

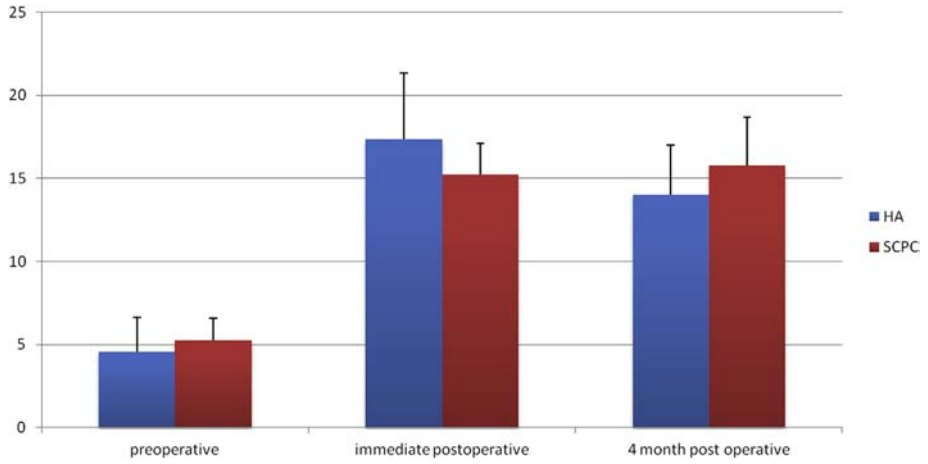

Fig. 7. Comparison of the mean residual maxillary alveolar bone height.

a size of the pores large enough for vascular invasion; and have mechanical characteristics similar to the tissue to be regenerated [25,26].

To fully assess the healing process, bone substitute materials should be evaluated histologically. An ideal grafting material should provide biologic stability, ensure volume maintenance and induce the formation of a high rate of vital bone and bone remodeling [27]. While both HA and SCPC [14,28,29] have been shown to be biocompatible, osteoconductive and resorbable biomaterials; HA has been reported to provide good mechanical properties along with open porosity. Due to their interconnected porous architecture, high compressive breaking stress, good biocompatibility and resorbability, corals have been used as scaffolds for bone tissue engineering. SCPC on the other hand, characterized by unique bioactive resorbable nanocrystalline phases and a hierarchical porous structure. The grain boundaries of the nanophases were rich in Ca and P, whereas the grain bulk was rich in Si. In addition, the SCPC is engineered with two levels of porosity; nano- and micropores [14,29]. Generating custom-made HA and SCPC discs in the current study allowed for modification of the technique, and hence the negligence of specific sinus lift kit usage, as mentioned earlier. The need for placement of the inferior trap door cut at a higher level was dictated by the structure of commercially available bone substitutes (grain or powder), which necessitate a bounded defect in which the graft material is placed from the top. The discs reduced the amount of time needed to augment the sinus, and provided a simpler technique. Discs also provided space in between for neo-vascularization and in growth of tissues, when compared to the recently available bone block substitutes.

SCPC demonstrated comparable quantitative results in this study, in terms of gain in bone height, width and density to the more intensely researched HA. SCPC was capable of maintaining the achieved bone height and width for up to 4 months postoperatively; similar to HA, as there were no statistically significant differences between the two groups in terms of gain in bone height and width immediate and 4 months postoperatively. While there was also no statistically significant difference between the two groups in Hounsfield units (representative of density), it should be noted that SCPC exhibited higher immediate postoperative density (666HU) compared to HA (465HU). At 4 months postoperatively, SCPC had a density of 682HU compared to 642HU in the HA group. While this might indicate new bone formation in the HA group, due to increase in density throughout the follow-up period, and not so much increase for the SCPC. It might also be suggestive of increased turnover of SCPC to new bone. To avoid unsupported assumptions, histological and SEM studies were conducted. Histopathological HA specimens revealed interconnected bone trabeculae with widely spaced resting lines; often darkly stained, wide and undulating. The osteocytic lacunae were relatively wide with shrunken osteocytes. No inflammatory cells and multi-nucleated giant cells were present around the particles or at the interface with bone denoting the biocompatibility of HA, which is in agreement to earlier results by Frenken et al. (2010) [30] and Ieezi et al., 2012. As for the SCPC histopathological specimens the bone trabeculae appeared with well defined, uniformly spaced and evenly stained resting lines. 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 when compared

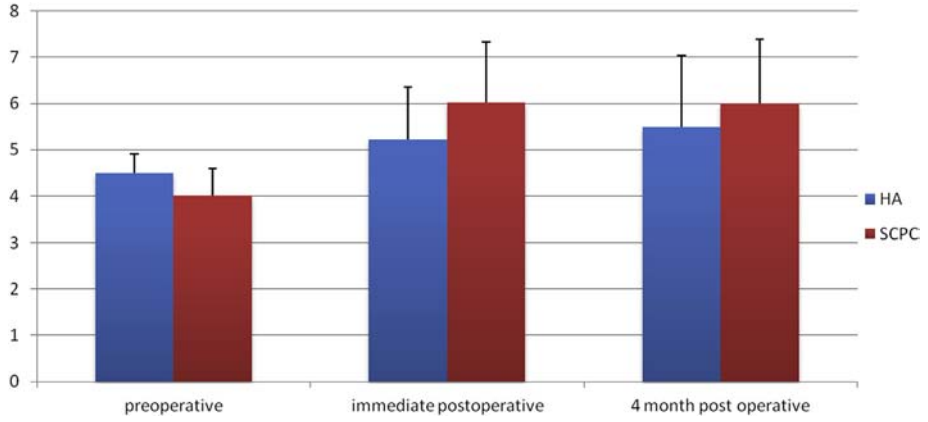

Fig. 8. The Mean residual maxillary alveolar bone width preoperatively, immediate and 4 months postoperatively in both HA and SCPC groups (Error Bars denoting the Standard Deviation).

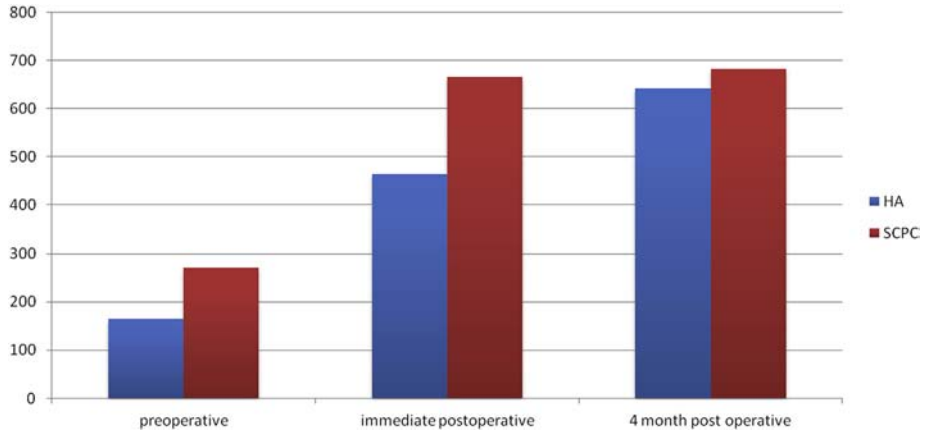

Fig. 9. The comparative mean bone density (HU) preoperatively, immediate and 4 months post-operatively; for both HA and SCPC groups.

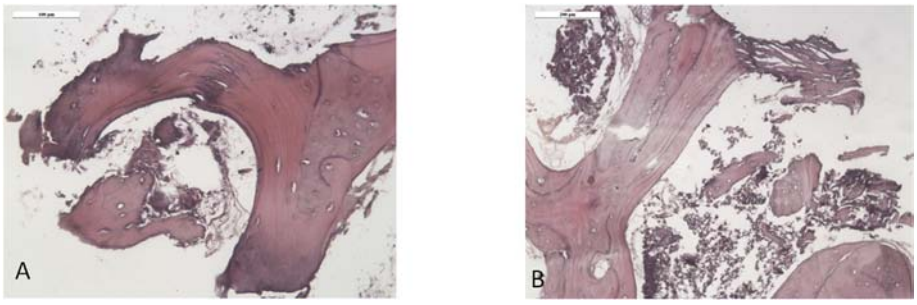

Fig. 10. Photomicrograph of Control group (HA): interconnected bone trabeculae were seen with widely spaced resting lines; often darkly stained, wide and undulating. The osteocytic lacunae were relatively wide with shrunken osteocytes. (A) at the magnification of 200x and (B) at the magnification of 400x.

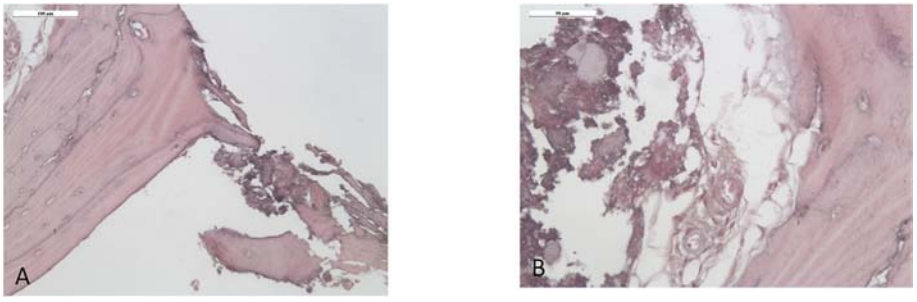

Fig. 11. Photomicrograph of Study group (SCPC): bone trabeculae with well defined, uniformly spaced and evenly stained resting lines. Regularly arranged osteocytes with lacunae and canaliculi. Areas with haversian systems and concentrically arranged lamellae are observed. Areas of bone marrow with few blood vessels could be detected. (A) at the magnification of 200x and (B) at the magnification of 400x.

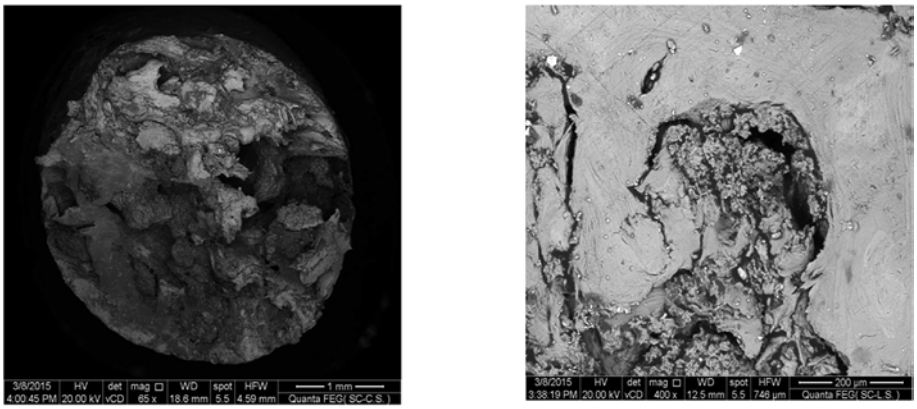

Fig. 12. SEM micrographs at 65x cross-sectional view (left); and 400x longitudinal section (right) of the HA group core bone biopsy showing bone with cavitations.

to HA [14,28,29].

SEM provided further useful insight to our comparison between HA and SCPC. In the control group (HA), the new bone exhibited an irregular and porous appearance. The bone became irregular in appearance with massive cavitations giving the impression of a torn bony surface. Hollowing and cavitations could be observed along with diffuse

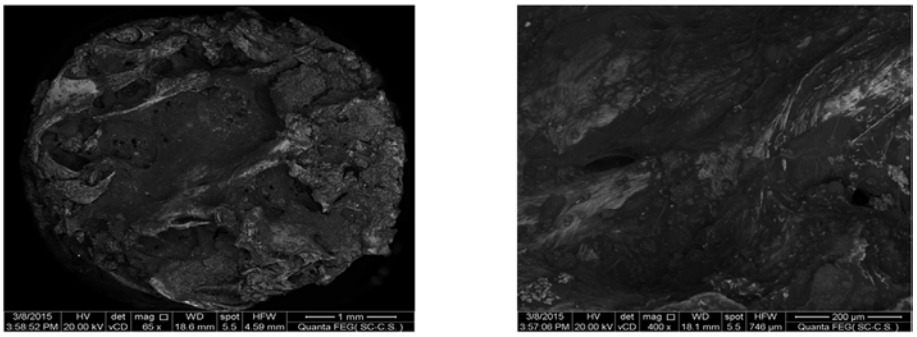

Fig. 13. SEM micrographs at 65x cross-sectional view (left); and 400x longitudinal section (right) of the SCPC group core bone biopsy showing continuous bone plate with nearly homogenous surface. Few irregularities could be seen accompanied by elevated and depressed areas. Localized areas revealed minor cavitations. Furthermore, the bone surface exhibited scattered nodular areas.

bright nodular areas. This might be due to the endowed *per se* with the striking prerogative of initiating *de novo* bone formation by induction as mentioned by Ripamonti et al., in 2008 [19]. It might also be attributed to the interconnected porosity that integrates better in terms of new bone formation. A decrease in porosity will lead to a subsequent reduction in the flow of nutrients and flow of oxygen in a less vascular environment as suggested by Ramirez Fernandez et al., in 2011 [20]. In the SCPC study group, the bone appeared as a continuous plate with nearly homogenous surface. Few irregularities were seen along with elevated and depressed areas. Localized areas revealed minor cavitations. Furthermore, the bone surface exhibited scattered nodular areas. This can also be attributed to the more sophisticated nanocrystalline structure of SCPC, its biocompatibility and resorbability [14,28,29].

Contrary to previous results, however, we cannot claim that significant amounts of bone have been observed, maybe biased by the CBCT results, despite being significant in histopathological sections. But, the current study is rather in agreement with reports that after 4–6 months healing period an approximate 25–40% new bone formation was observed [20]. Similar to others, in both groups residual particles could be observed. [28,29,14)]

The results achieved by the current study sample were in accordance with previous reports concerning the biocompatibility of both materials HAand SCPC [14,29] as none of our histological specimens revealed otherwise. Both materials were partially substituted by new bone formation. However, the results of the present study have shown that both biomaterials HA and SCPC can be used successfully for augmentation of maxillary sinus. Both HA and SCPC demonstrated good biocompatibility and osteoconductive properties, with no histological signs of adverse reactions. Osteoblastic bone formation was demonstrated clearly in histological and SEM specimens. They seem to be gradually resorbed materials, partially substituted by newly formed bone. However, in the current study a high quantity of HA and SCPC was still evident 4 months postoperatively, which is similar to the results presented by Ieezi et al. who reported high residues after 6 months. Longer term histological and SEM studies will be necessary to understand better the resorption times of these biomaterials. The high interconnecting microporosity –nanoporosity in case of SCPC- allowed, the ingrowths of newly formed bone and vessels in the pores of the partially resorbed particles.

In conclusion, within the limitations of the present study, the present data support the fact that both HA and SCPC can be used, successfully, in sinus augmentation procedures. Moreover, the suggested technique in combination with grafts in the form of discs, and using piezoelectric surgical units are simpler and safer approaches to lateral sinus lift augmentation procedures.

Conflicts of interest

No conflict of interest.

Disclosure statements

The authors declare that there are no financial or other conflicts of interest related to this publication.

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