



EVALUATION USE OF OXIDIZED REGENERATED CELLULOSE AS A GRAFT MATERIAL IN TRANSALVEOLAR MAXILLARY SINUS FLOOR ELEVATION AND IMPLANT INSERTION

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ABSTRACT

Objectives: The objective of this study was to evaluate clinically and radiographically use of oxidized regenerated cellulose as a graft material in transalveolar sinus lifting and implant insertion. **Subjects and methods:** Eighteen implants were inserted in sixteen patients with missed upper molar teeth. They were divided into two groups: group **A** (study group) included patients who received dental implants after sinus lift with oxidized regenerated cellulose graft; group **B** (control group) included patients who received implants after sinus lift without graft. The patients were clinically and radiographically evaluated preoperatively and postoperatively immediate and 6 months post-surgery. Clinical evaluation included pain and discomfort, swelling and implant stability using osstell. Radiographical evaluation was done by CBCT to measure the bone height and density. **Results:** Both sinus lifted groups with or without graft have significant success rates with superior radiographic results of oxidized cellulose grafted group over non grafted one after a follow up period up to 6 months. **Conclusion:** Transalveolar sinus lifting with oxidized regenerated cellulose graft is a promising graft for sinus augmentation.

KEY WORDS: Oxidized regenerated cellulose, Transalveolar sinus floor elevation, CBCT, Dental implants.

INTRODUCTION

The edentulous ridge in the posterior maxilla characterized by progressive and irreversible vertical bone resorption after teeth extraction, this leads to an atrophic bone situation and limits the application of implant therapy. In such cases, the sinus lift procedure is indicated; it is expected to provide sufficient bone for optimal implant osseointegration, and provide long-term success⁽¹⁾.

Different technique were used for sinus lifting procedures, lateral window technique was the most frequently procedure which used for vertical bone augmentation of the atrophic posterior maxilla. Osteotome sinus floor elevation procedure was an alternative to the lateral approach. It is less invasive and the treatment can be achieved with a single surgery⁽²⁾. Another surgeon used short implants with a textured surface in sites with limited residual bone height, the surgical procedure is simpler, and

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the treatment duration can be reduced⁽³⁻⁷⁾. The latter was even found to be inversely correlated with the residual bone height⁽⁸⁾. To enable placement of implants other than short one because the minimum length for predictable dental implant success is 10 mm or what is called standard implant length⁽⁹⁾.

Recently, the need for autogenous bone grafts and grafting material to achieve successful sinus augmentation procedures has been questioned^(10,11). Researchers have not reached an agreement about most suitable material for sinus augmentation⁽¹²⁻¹⁵⁾.

The use of oxidized regenerated cellulose (ORC) graft in enlarged sinuses showed a feasible substitute to other grafting materials. This technique was safe, cheap, and fast, its application does not require sophisticated procedure through transalveolar sinus membrane elevation and simultaneous implant insertion. Gray et al⁽¹⁶⁾ in 2001 evaluated the efficacy of oxidized regenerated cellulose in sinus lift, their result showed similarity between graft and normal bone. Another study was indicated to evaluate the use ORC as a graft in transalveolar sinus lift and implant insertion.

SUBJECTS AND METHODS

This is an interventional clinical study, which included eighteen implants were inserted in patients of both sexes with an average age ranged between 20 to 55 years with missed upper molar teeth indicated for sinus lift. They were selected from the Outpatient Clinic of Oral and Maxillofacial Surgery Department at Faculty of Dental Medicine, Al-Azhar-University, Boys, Cairo. These patients were randomly assigned to one of two groups (group A or group B); eight patients were allocated in each group, patients in group A (study group) received implants after transealveolar sinus lifting with oxidized regenerated cellulose (Surgicel^(R)) graft, while those in group B (control group) received implants after sinus lifting without graft. The inclusion criteria of this study were; patients with edentulous posterior maxilla, with adequate subantral bone height ≥ 5 mm

to ensure primary stability for the placement of implants (single-stage surgery), and with good oral hygiene. While the exclusion criteria were patient with uncontrolled medically compromised state that affect bone healing or suffering from uncontrolled bleeding or coagulating disorder or heavy smoker, mentally challenged patients and patients with previous history of radio and/or chemo-therapy treatment in the head and neck region.

Patients were fully informed about the treatment procedures and follow up examination. Appropriate institutional ethical clearance and written informed consent were obtained.

Pre-operative evaluation:

- Clinical assessment of patient's past medical history, oral condition, evaluation of the implant site by digital examination of the covering mucosa and applying finger pressure, to detect sharp ridges, tender areas or extremely thin mucosa.
- Radiographic evaluation included preoperative digital panoramic and CBCT (On Demand 3D™ viewer software CybermedInc, Korea) were taken to verify the bone height and the implantation site. (Fig. 1a)

Surgical procedure:

All patients were instructed to use chlorhexidine mouth rinse regularly. The day before surgery, patients received a suitable prophylactic antibiotic amoxicillin clavulnic (Curam^(R)) 1 gm capsules twice per day and Metronidazole (Flagyl^(R))*** 500 mg tablets (t.d.s) for 7 days, ibuprofen (Brufen^(R)) 400 mg tablets (t.d.s) as analgesic was taken. After disinfection and draped the surgical site anesthesia using 4% articaine with adrenaline 1:200,000 (Septodont Articaine HCL with vasoconstrictors) was secured, a paracrestal incision with palatal inclination was made in the ridge, at the site of predetermined implant. A full thickness mucoperiosteal flap was reflected buccally. Drilling was done with a low

speed high torque externally irrigated contra-angle hand piece with surgical motor unit. The implant position was marked with a round bur; Sequential drilling was accomplished first with pilot drill to the pre-determined height (1mm less than vertical height between sinus floor and alveolar ridge crest). The standard drilling sequence for the implant started from the pilot drill, an intermediate drill, and then ended with the final drill. (Fig. 1b) Parallel pin was used to check the orientation of osteotomy site. It was used to gauge parallelism. The intact sinus floor was broken by osteotome type A (perform green sticky fracture) by gentle firm tapping was done, osteotome diameter used initially was 2.2 mm followed by 3.3 mm diameter and finally 3.7 mm diameter. (Fig. 1c) For group A only graft was prepared by aspiration fresh blood sample in test tube and saturates oxidized cellulose membrane with it. The ORC graft (SurgicelSNoW® Absorbable Hemostat, Ethicon Inc., USA) pressed at osteotomy site by osteotome lifting the sinus membrane before implant insertion, while in group B implant inserted without any graft. (Fig. 1d) For both group sealed

sterile implant package was opened and the implant with its attached insertion tool were removed from the inner vial and carried to the prepared osteotomy site. Implant insertion was done at torque 35 Ncm, Osstell was used to evaluate primary stability, then cover screw was used. Patients were instructed to avoid any trauma at implant area. The surgical site was irrigated with sterile saline solution and the mucoperiosteal flap was repositioned to its original site and sutured using 3-0 black silk, Suture was removed after 8-10 days. (Fig.1e,f)

Post-surgical care: Postoperative antibiotic and analgesic were prescribed. Patients were instructed for maintaining good oral hygiene with Chlorhexidine-gluconate (antiseptol solution) (0.12%). All patients were instructed to have soft diet for the first week.

Post-operative assessment:

Clinical and radiographic evaluations were done 7 to all cases immediate and 6 months postoperatively, as the following:

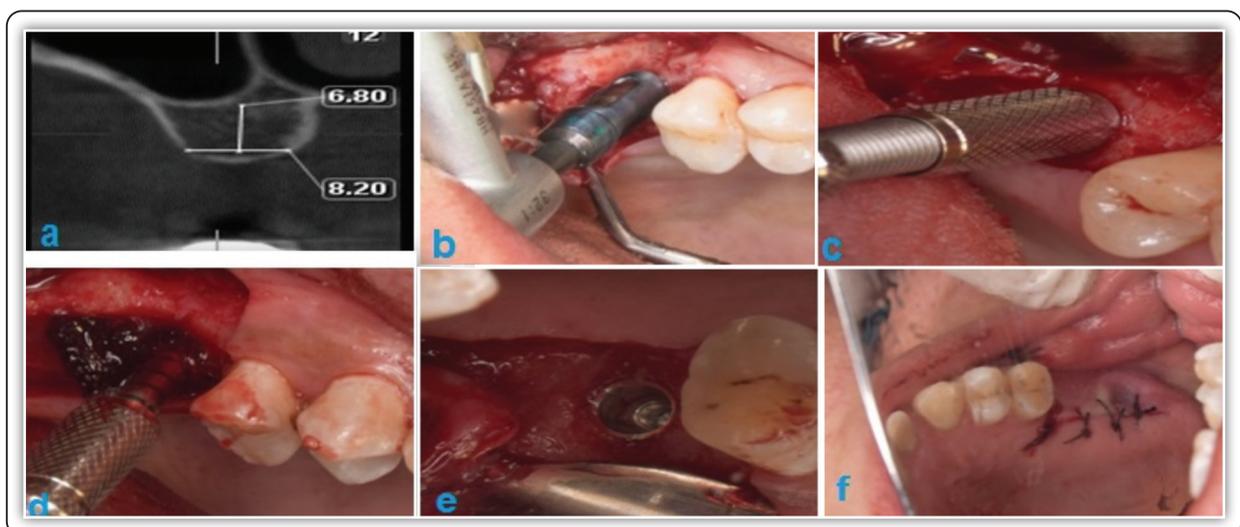


FIG (1) (a) Preoperative CBCT showing alveolar ridge height. (b) A photograph showing drilling for implant insertion. (c) A photograph showing sinus lifting by osteotome. (d) A photograph showing ORC graft insertion. (e) A photograph showing implant after insertion. (f) A photograph showing the flap closure.

A) Clinical evaluation:

All patients were examined post operative and after six months to check for the presence of pain, discomfort, swelling, or infection. Also, implant stability was assessed at the same follow up visits by using Resonance Frequency Analysis (RFA) by Osstell^(R) which was expressed by implant stability quotient (ISQ) scale.

B) Radiographic evaluation:

Cone beam computed tomography was taken preoperatively, immediate and 6 months postoperatively to evaluate changes of alveolar bone height and density at apical region around the dental implant. (Fig. 2 a,b, c,d)

Prosthetic phase:

At 6 months, crowns were fabricated and cemented to the abutments.

Statistical analysis:

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 22. Independent samples t-test was used to compare between two independent groups of normally distributed variables (parametric data) while Mann Whitney U test was used for non-

normally distributed Data (non-parametric data). For comparison of data at two different time points, paired samples t-test was used to compare between two related groups of normally distributed variables (parametric data) while Wilcoxon Signed Rank test was used for non-normally distributed Data (non-parametric data), these data not significant at $P > 0.05$, significant at $P < 0.05$, highly significant at $P < 0.01$.

RESULTS

In this study eighteen implants were placed in patients with missing tooth in upper molar regions. All patients were subjected to clinical and radiographic evaluation immediate and after 6 months.

I. Clinical evaluation:

- **Pain and Discomfort:** The pain was evaluated at first, third, fifth and seven day after implant insertion and recorded in Visual Analogic Scale (VAS of 10). In group A, the mean value of the pain was 6.25 ± 0.89 at first day, 6.50 ± 1.20 at the third day, 7.25 ± 0.89 at the fifth day and 7.63 ± 0.74 at the seventh day. The pain was increased at third, fifth and seventh day respectively with significant statistical difference, where ($P < 0.004^*$). In group B, the

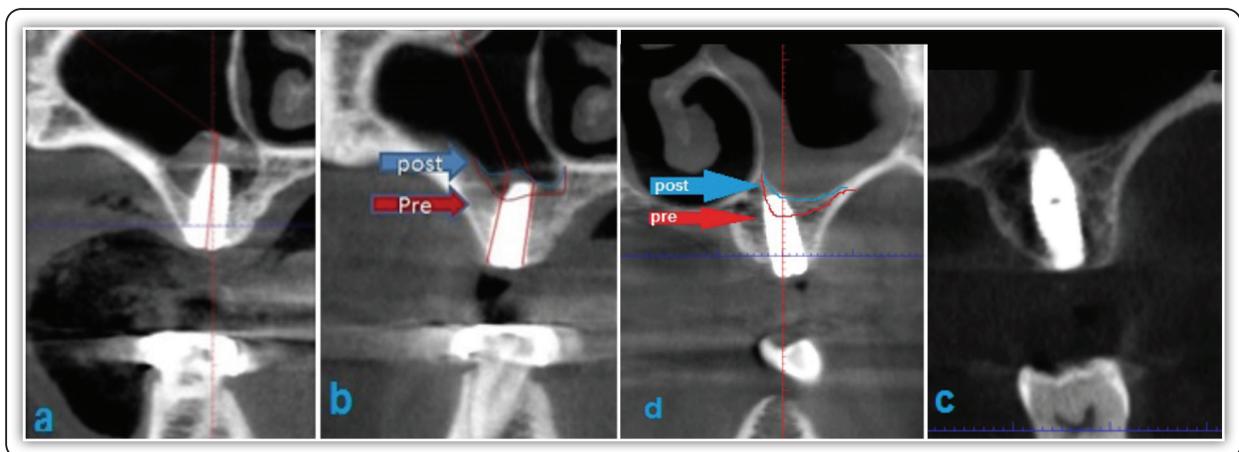


FIG (1) Fig. 2: Postoperative CBCT showing changes in alveolar ridge height, immediate (a) and after 6months (b) in group A and immediate (c) and after 6months (d) in group B.

mean value of the pain was 5.0 ± 0.76 at first day, 5.25 ± 0.46 at the third day, 5.63 ± 1.41 at the fifth day and 5.88 ± 1.13 at the seventh day. The pain was increased at third, fifth and seventh days respectively with non-significant statistical difference, where ($P < 0.716$).

- Swelling:** It was recorded by measuring distance between two reference points at first, third, fifth and seven days. In group A, the mean value of the swelling was 11.76 ± 0.88 at first day, 11.68 ± 1.02 at the third day, 12.64 ± 0.96 at the fifth day and 12.08 ± 0.96 at the seventh day. The swelling was increased at third, fifth and seventh day with significant statistical difference, where ($P < 0.001^*$). In group B, the mean value of the swelling was 12.51 ± 1.14 at first day, 13.10 ± 1.64 at the third day, 12.80 ± 1.34 at the fifth day and 12.52 ± 1.13 at the seventh day. The swelling was increased at third, and decreased at fifth and seventh day with non-significant statistical difference, where ($P < 0.084$). At Day 1-7: there was a statistically non-significant difference in mean swelling in the two groups.

II. Implant stability:

The **stability** was evaluated in all groups with ostell immediate and after six months. In group A, the mean value of the **stability** was 50.0 ± 4.07 immediate and 70.25 ± 2.87 after six months. The **stability** was increased with significant statistical difference, where ($P < 0.001^*$). In group B, the mean value of the **stability** was 58.25 ± 1.67 immediate and 71.63 ± 2.13 after six months. The **stability** was increased with significant statistical difference, where ($P < 0.001^*$). Immediate and 6month Post: there were no a statistically significant difference in mean stability in the two groups.(Table 1) .

TABLE (1) Comparison between the two groups according to stability.

	Group A (n = 8)	Group B (n = 8)	T	P
Stability				
Immediate	50 ± 4.07	58.25 ± 1.67	5.304*	<0.003*
6 month	70.25 ± 2.87	71.63 ± 4.21	0.766	No. sig.

t: Student t-test p: p value for comparing between the studied groups

**: Statistically significant at $p \leq 0.05$*

Radiographic evaluation:

- Bone Height:** The Bone Height was evaluated in all groups with (CBCT) pre-surgery and six months postsurgery. In group A, the mean value of the Bone Height was 5.93 ± 0.79 pre-treatment and, 11.13 ± 1.36 post-treatment. The Bone Height was increased with significant statistical difference, where ($P < 0.001^*$). In group B, the mean value of the Bone Height was 8.60 ± 0.21 pre-treatment and, 11.0 ± 0.0 post-treatment. The Bone Height was increased with significant statistical difference, where ($P < 0.001^*$), (table 2).

TABLE (2): Comparison between the two time periods in each group according to Bone Height.

	Bone Height		T	p
	Pre	Post		
Group A	5.93 ± 0.79	11.13 ± 1.36	22.101*	<0.001*
Group B	8.60 ± 0.21	11.0 ± 0.0	31.749*	<0.001*

t: Paired t-test , p: p value for comparing between Pre and Post in each group

**: Statistically significant at $p \leq 0.05$*

Pre-treatment and post-treatment: there was a statistically significant difference in mean bone height in the two groups. Group A showed a statistically significant increase in bone height than group B. Post-treatment: there was a statistically non-significant difference in mean bone height in both groups.(tab.3)

TABLE (3): Comparison between the two groups according to bone height.

	Group A (n = 8)	Group B (n = 8)	Test of sig.	P
Bone Height				
Pre	5.93 ± 0.79	8.60 ± 0.21	t=9.238*	<0.001*
Post	11.13 ± 1.36	11.0 ± 0.0	t=0.261	0.802
% Change	88.22 ± 8.77	27.98 ± 3.18	U=0.0*	<0.001*

t: Student t-test *U*: Mann Whitney test

p: *p* value for comparing between the studied groups

*: Statistically significant at $p \leq 0.05$

Bone Density: The density was evaluated in all groups with CBCT. In Group A, the mean value of the density was 408.1±154.1 HU pre-treatment, 408.4±149.0 HU immediate and, 456.4±144.7 HU six months post-treatment. The density was increased with significant statistical difference, where ($P < 0.002^*$). In Group B, the mean value of the density was 479.0 ± 9.62HU pre-treatment,

490.0±37.42 HU immediate and, 524.5 ± 27.26 HU six months post-treatment. The density was increased with significant statistical difference, where ($P < 0.002^*$).

Pre-treatment and six months post-treatment: there was a statistically non-significant difference in mean density in the two groups. (tab. 4)

TABLE (4): Comparison between the two groups according to density.

	Group A (n = 8)	Group B (n = 8)	U	P
Density				
Pre	408.1 ± 154.1	479.0 ± 9.62	16.0	0.105
Immediate	408.4 ± 149.0	490.0 ± 37.42	16.0	0.105
Six months Post	456.4 ± 144.7	524.5 ± 27.26	24.0	0.442
% Change from pre to				
Immediate	↑0.81 ± 5.53	↑2.20 ± 5.76	32.0	1.000
Six months Post	↑14.06 ± 7.62	↑9.44 ± 3.49	24.0	0.442

U: Mann Whitney test

p: *p* value for comparing between the studied groups

DISCUSSION

Rehabilitation of the atrophic maxilla with dental implant constitutes a therapeutic problem, since bone augmentation is often required to enable placement, ensure stability of a sufficient number and length of implants. Various grafting procedures and materials have been described. Maxillary sinus floor elevation has been shown to be a highly predictable and reliable solution in many situations. However, the quest for the optimal protocol and the ideal grafting material to achieve high implant success rates, shorten treatment periods, and minimize morbidity is permanent and continuous⁽¹⁷⁾.

The residual bone height (RBH), measured from the crest of the ridge up to the sinus floor, for all patients enrolled in this study was within the range of (5 to 9 mm). In the literature of Summers⁽¹⁸⁾ and Reiser⁽¹⁹⁾, they stated that Transcrestal approach of osteotome to elevate sinus membrane can be performed with residual bone height beyond 4 to 5mm, also Davarpanah et al⁽²⁰⁾, proposed a modified osteotome technique, in which the bone thickness below the sinus was ≥ 5 mm.

The measurements of implant stability using Osstell were obtained immediately after implant insertion, to assess the primary stability and set a baseline for comparison, and after 6 months to assess the secondary stability before implant loading. The mean values of ISQ were increased with a significant statistical difference from immediate to after six months in both groups which indicated successful osteointegration. The ISQ values showed no a significant statistical difference between two groups. The implant stability reported in this study was in correspond to that reported by Cricchio⁽²¹⁾, where the mean of change in the ISQ values readings from immediate to 6 months postoperatively in Group A and Group B were 19.9 ± 5.16 and 13 ± 4 respectively. Nedir⁽⁶⁾, reported that implant stability could be reliably determined for implants with an $ISQ \geq 47$. According to this, all implants included in this study showed acceptable primary and secondary stability.

The radiographic parameters of this study include measuring the bone height and density in both groups. The bone height in the group A was 5.93 ± 0.79 pre-treatment and, 11.13 ± 1.36 six months post-treatment. While in group B, was 8.60 ± 0.21 pre-treatment and, 11.0 ± 0.0 six months post-treatment, the bone height was increased significantly in group A than B. The results of this study agree with result of Hussein and Hassan⁽²²⁾ which was 11,36 for study group, and agree with result of Yan⁽²³⁾ which were no significant difference in the survival rate between two groups (RR: 1.02; $p = 0.18$), no statistically significant difference in marginal bone loss was detected between the groups at 12 months (0.57, $p = 0.07$) or 36months (0.05, $p = 0.61$) and the endo-sinus bone gain in the non-graft group was significantly lower than in the grafted group at 12 months (-1.10 , $p = 0.0001$) and 36 months (-0.74 , $p = 0.02$). Also bone height achieved with less invasive transcrestal approach was nearly comparable to the results reported by other clinical studies using autogenous bone, osteon II.^(24,25) However, higher bone gain achieved by other clinical studies is due to immediate postoperative measurement of bone height without accounting for bone graft resorption during healing period^(26,27).

The bone density of neoformed bone for both groups was increased from pre to after six months that lies within D3 category which presented with 70% of sinusal dental implants. Regarding results of both groups, there was a statistically non-significant difference in mean density in the two groups which was in agree with study reported by Shawky et al⁽²⁸⁾, where a significant increase in density of neoformed bone after augmented sinus lifting with Nanobone more than non grafted one.

Lee et al.⁽²⁹⁾ evaluated bone graft density of augmented sinus by CBCT after 20 week, and reporting 312 HU as a mean, which became 512.75 HU after 1 year, the authors concluded that there was a direct proportion between progressive maturation

of bone mineral density assessed by Hounsfield units (HU) and amount of new bone assessed histological. The result of ORC showed that, it is a feasible substitute to other grafting materials as it was technically safe, cheap, fast and its application does not require sophisticated procedure. When it becomes saturated with blood it swells into a black gelatinous mass to provide tenting effect along with installed dental implant maintaining elevated Schneider membrane against collapse, this space is then populated by bone forming cells to create new bone which is acceptable clinically as evidenced by implant immobility (acceptable secondary stability) and radiographically crosses 11mm of minimum augmentation height. These results agree with clinical studies of Fugazzotto and Vlassis⁽³⁰⁾ and Kim et al⁽³¹⁾.

CONCLUSION

The present study showed that osteotome mediated maxillary sinus lifting with simultaneous implant placement using oxidized regenerated cellulose graft is a promising technique compared to the graft free technique, and ORC is a reasonable grafting with a comparable outcomes when compared to other graft materials in closed sinus lifting.

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