ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

CLINICAL AND RADIOGRAPHIC EVALUATION OF POST-EXTRACTION SOCKET PRESERVATION WITH DEPROTEINIZED XENOGRAFT (A CLINICAL TRIAL)

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Abstract

Aim: evaluate clinical and radiographic dimensional changes of the alveolar process following tooth extraction and socket preservation with deproteinized xenograft.

Materials and Methods: 10 Patients were subjected to tooth extraction and assigned to socket preservation with deproteinized bovine bone mineral. After 6 months, digitalized soft tissue assessment through taking intra-oral scanning superimposed over underlying bone was done. Also, radiographic assessment of dimensional hard tissue changes in vertical and horizontal aspects using cone beam computed tomography (CBCT) was performed.

Results: There was statistical significant difference in soft tissue changes at different levels with a p-value of 0.34. with a statistically significant difference in soft tissue changes only between 2 mm and 8 mm levels with a p-value of 0.032. There was no statistical significant difference between baseline and 6 months follow-up for both bone height and width values

Conclusion: digital assessment of soft and hard tissue changes after socket preservation is a valuable method for alveolar ridge preservation.

Keywords: bone regeneration, socket preservation, xenografts.

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ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

Introduction

The alveolar process is a tooth-dependent tissue that develops in conjunction with the eruption of the teeth. The tooth is anchored to the jaws via the bundle bone into which the periodontal ligament fibers invest. The volume as well as the shape of the alveolar process is determined by the size and shape of the teeth, their axis of eruption and eventual inclination and the site of tooth eruption (Schroeder, 2012).

Tooth extraction is a common procedure in dentistry. Tooth extraction doesn't include only tooth loss, but also, local changes of hard and soft tissue. The normal socket healing response to this procedure results in a significant loss of alveolar bone and collapse of the surrounding gingiva. The horizontal bone loss is generally the greatest and occurs more frequently on the facial side than the lingual side of the ridge. In addition to normal healing, a substantial percentage of extraction sites suffer from uneventful healing and postoperative complications (**Araújo** et al., **2015**). Sufficient alveolar bone volume and favorable architecture of the alveolar ridge are essential for implant placement to obtain optimal functional and aesthetic prosthetic reconstructions. Therefore, knowledge about the healing process at extraction sites, including contour changes caused by bone resorption, is essential for treatment planning (**Vignoletti** et al., **2012**).

A wide range of treatment modalities over years were described to decrease amount of dimensional changes following tooth extraction including partial extraction protocols, forced orthodontic extrusion and regenerative approaches including alveolar ridge preservation (ARP). Alveolar ridge preservation is defined as alveolar ridge preservation within the bone envelope remaining after tooth extraction. A wide variety of ARP surgical techniques have been illustrated in the past 20 years (**Tonetti** *et al.*, **2019**).

Alveolar ridge preservation has gained in popularity in recent years due to its conceptual attractiveness and technical simplicity. A large variety of biomaterials have been employed and tested in several studies, including autologous bone, bone substitutes (allografts, xenografts and alloplasts), autologous blood-derived products and bioactive agents (Avila-Ortiz, Chambrone and Vignoletti, 2019). Several techniques and bone substitute materials can be used to preserve the socket after tooth extraction. A wide variety of socket preservation treatment modalities have been described in the literature, including socket grafting with a biomaterial alone, overbuilding of the facial bony wall, occluding the access to the socket by interposing a barrier element, or a combination of some of them, with or without primary intention healing (Avila-Ortiz et al., 2014). Socket grafting could be achieved through filling the socket with bone replacement grafts. Traditionally, bone replacement grafts are classified according to its nature into; autogenous graft, which is harvested from the patient's own body from one site to another; allograft, obtained from other individuals of the same species but different genotype, xenograft, which is transplanted from one species to a member of a different species and alloplast, which is synthetic bone grafting material (Kumar, Vinitha and Fathima, 2013). The most commonly available form of xenografts is bovine bone xenografts and the most commonly studied type of it is Bio-Oss®. Bovine bone xenografts markedly encounteracted the reduction in the hard tissue component (Gholami et al., 2012).

Outcomes of socket preservation assessment could be categorized into 3 categories: Clinical: Dimensional (linear and volumetric) changes of the alveolar ridge (including soft tissue and bone measurements), rate of complications, feasibility of implant placement, need for additional grafting at the time of implant placement, and implant survival and success rate; Radiographic: Dimensional (linear and volumetric) radiographic changes of the alveolar bone and marginal bone loss around implants; Patient-reported outcome measures (PROMs): Reported discomfort, perceived benefit and quality of life (Avila-Ortiz, Chambrone and Vignoletti, 2019).

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

Soft tissue is more difficult to be assessed topographically over time. Horizontal and vertical soft tissues dimensional changes could be assessed digitally with the help of oral scanning taken intra-orally or extra-orally over plaster casts. The final analysis done using appropriate computer-assisted design (CAD) software (Vanhoutte et al., 2014; Zadeh et al., 2016). Linear horizontal and vertical soft tissue changes can be assessed at different levels of the alveolar process and measured as difference between post-operative and baseline situation (Vanhoutte et al., 2014). Volumetric changes could be evaluated through assessing percentage of volume loss, which is defined as percentage of volume changes obtained by subtracting the baseline from the postoperative value; then the result was divided by baseline (Barone et al., 2017).

Radiography is considered the most frequent diagnostic tool in daily dental practice. While the required 3D acquisition for dental applications was initially realized by medical computed tomography (CT), dental CBCT rapidly took over. The main reasons for the success of CBCT are its capabilities of volumetric jaw bone imaging at reasonable costs and doses. Nowadays, rapid advances of digital technology and computer-aided design/computer-aided manufacturing (CAD/CAM) systems are indeed creating challenging opportunities for accurate assessment of dimensional bony changes of extraction socket (Vandenberghe, Jacobs and Yang, 2007a; Jacobs et al., 2018).

Our study was conducted to evaluate both clinical and radiographic outcomes for bovine bone xenograft in alveolar socket preservation.

MATERIALS AND METHODS

Patients were selected from faculty clinic in the Oral Medicine and Periodontology department, Faculty of Dentistry, Cairo University. With the following eligibility criteria (**Hämmerle, Araújo and Simion, 2012**):

Inclusion criteria included:

- Patients with remaining roots in the maxillary inter-bicuspid region.
- Patients with non-restorable teeth indicated for extraction due to reasons such as root fracture, endodontic treatment failure, advanced carious lesions.
- Teeth with or without periapical lesions not affecting buccal wall integrity.
- Patients should be 18 years old or more.
- Patients with clinical periodontal health on an intact periodontium and adequate volume that allow for implant placement after follow-up period.
- Pristine extraction socket (Type I socket).

Exclusion criteria included:

- Patients with any systemic condition that may affect surgical procedure and healing process.
- Patients with active acute infection related to teeth of interest.
- Pregnant females.

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

- History of malignancy or radiotherapy/chemotherapy for malignancy in the past 5 years.
- History of active bone metabolic disease.

All patients participated in this clinical trial were informed about detailed surgical procedure and follow-up period. Informed consent provided by faculty ethics committee was obtained from all patients who agreed to participate in the study.

Pre-operative preparation

A thorough pre-operative assessment for all patients including taking a full medical and dental history. A comprehensive clinical examination including extra-and intra-oral examination was executed. Intra-oral examination was essential to assess restorability of the teeth, relation with adjacent teeth with available mesio-distal space and relation to the opposing teeth with available inter-arch space. Meticulous clinical protocol was followed for diagnosing the damaged teeth including removal of all caries and old restoration to assess residual tooth structure. Periodontal examination was crucial to determine periodontal condition of the surgical site and to survey probing depth and gingival bleeding through periodontal chart. Radiographic examination through parallel periapical radiography for area of interest to assess relation to adjacent teeth. All patients underwent full mouth periodontal treatment including mechanical and chemical plaque control. Mechanical plaque control included: professional supra-gingival scaling and sub-gingival debridement, if needed, combined with brushing twice daily and interdental cleaning to be followed at home in order to provide a more favorable oral environment for wound healing. Chemical plaque control included toothpaste and mouthwash twice daily for two weeks.

Intra-oral scanning protocol

Direct intra-oral scans were taken for all patients before extraction and after 12 weeks, using CS 3600® access with 13×13mm field of view and depth of field that range from -2 to +12mm, accompanied with acquisition software. Scans were then exported in STL formats, standard triangle language or standard tessellation language, with keeping orientation presets. After exporting of STL file, the design of radiographic stent was done using dental CAD-CAM software, ExocadTM. A standard cube of 5×5×5 mm was designed over the tooth to be extracted with a mid-cut of 0.5mm width and 1mm depth from the facial, occlusal and palatal aspects. Figure (1)

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

Figure (1): The radiographic stent design adapted over 3D model

For the fabrication of a radiographic stent, 3D resin desktop printer that use stereolithography (SLA) technology. The stent was fabricated using gray resin supplied by the same company. The radiographic stent was supported over adjacent teeth from both mesial and distal aspects for better stabilization and accuracy. The cut was filled with flowable radio-opaque resin-bonded composite to be detected radiographically. The aim of the radiographic stent was to standardize radiographic assessment before extraction and after healing.

CBCT scanning protocol

Patient CBCT examination protocol CBCT scans for all patients, were obtained preoperatively and after 6 months using Caresream CS 8100 3D CBCT machine. Standardized scanning protocol was followed with all patients. Patients were asked to remove all metal objects and to wear lead apron. Each patient was positioned in the machine and imaged at the same manner according to the recommendations of CBCT manufacturer. On the positioning panel, the patients were asked to bite into the bite block, making sure that the upper incisors placed before the incisive stopper. The Frankfurt plane was positioned parallel to the horizontal plane and the midsagittal plane was perpendicular to the horizontal plane. All patients remained still during launching the X-ray. The patients were asked to wear the custom-made radiographic stent, making sure it was stable in place with the aid of biting over cotton rolls.

The CBCT scans were acquired at a fixed exposure parameters used for all patients: 90 kilovoltage peak, 3.2 milliamperage and 150 μm voxel size 15 seconds exposure time and field of view encompassing the entire arch. The scan should be of optimum quality and free of any motion artifacts. The scans were done before treatment and repeated 6 months post-extraction.

Surgical intervention

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

A local infiltration anesthesia using articaine (4%) with epinephrine 1:10000 was provided. Teeth were extracted, using a flapless approach atraumatically as much as possible. Atraumatic extraction started by dissection of periodontal ligaments in crestal part using 15C blades, mounted over a round-handed blade holder to facilitate rotation without lacerating the soft tissues. Then, teeth were luxated using micro-elevators and the final delivery movement was done using forceps. Sockets were then thoroughly debrided using a curette, especially in cases with periapical lesions, to ensure complete removal of granulation tissue. Assessment of socket walls integrity was done visually and using a UNC-15 periodontal probe. All patients received standard preservation of extraction sockets with commercially available deproteinized bovine bone mineral (DBBM). After packing of extraction socket with the graft till crestal bone level, a collagen sponge was placed to cover the extraction socket and stabilized in place using a criss-cross suture, using non-resorbable 4-0 monofilament polypropylene suture material. Postoperatively, all patients were given antibiotic course 3 times per day for one week (Amoxycillin 500mg, capsules) and analgesics twice daily for 3 days (Ibuprofen 400mg, tablets) after socket preservation. Patients were advised to avoid brushing at surgical area for 2 weeks and to use antiseptic mouth wash (Chlorhexidine, 0.12%, oral rinse) twice per day for the same period. Patients were monitored weekly till complete soft tissue closure. Sutures were removed 12 days after the surgery.

Figure (2.3.4)







Intra-operative occlusal photograph showing a) pristine extraction socket, b) socket filled with Bio-Oss®, c) socket covered with collagen sponge and secured with criss-cross suture.

Outcomes

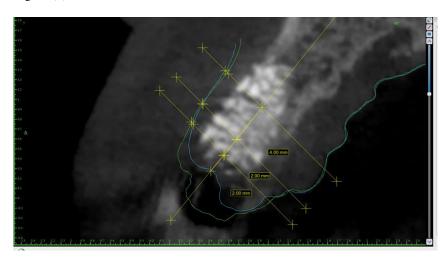
Clinical analysis

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

Following CBCT scanning, digital imaging and communications in medicine (DICOM) files were imported from CareStream software into Blue Sky Plan®. Also, STL files of pre- and post-operative intra-oral scans were exported to same software. Proper alignment of all files was confirmed using point functionality in the model manipulation panel. Extra screening of cross-sectional cuts to ensure accurate superimposition.

To quantify soft tissue changes happened, superimposition of postoperative CBCT, preoperative and postoperative intra-oral scan was done. With the standard box showing, a vertical line bisecting the socket was drawn. With other 3 horizontal lines intersecting the parallel lines at 2,4,8 mm from level of post-operative crestal bone respectively. At each line, the difference between superimposed pre- and post-operative scan was taken as soft tissue differences at the 2 time points represented by the STL surface scan.

Figure (5)



The green surface STL is the pre-operative intra-oral scan. The blue surface STL is the 3 months' post-operative intra-oral scan.

4.1.1. Radiographic assessment

To assess quantitative changes in alveolar bone, CBCT imaging of patients underwent tooth extraction was conducted preoperatively and repeated at 6 months postoperatively. Radiographic assessment relied on registration of the pre-treatment CBCT plan upon the post-treatment CBCT results. The pre-operative data from the CBCT scans were imported into InvivoDental application v.5.3.1. From the "Superimposition" tab, the "Import New Volume" option was selected, and the post-operative DICOM file was selected. At first, point based registration was employed to approximate the two scans. Dental and skeletal points in the maxillary region away from extraction sites were utilized. Following point base registration, high precision automatic volume based registration is utilized for perfect superimposition between the pre-operative and post-operative scans. The second scans, now superimposed, were reoriented along the long axis of the remaining root to be measured. The coronal plane was set to bisect the remaining root in the buccolingual dimension, while the sagittal plane was set to bisect the remaining root mesiodistally. The axial plane was then moved to coincide with the root apex.

• Vertical bone changes:

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

The Bone Height buccally and lingually was then measured on the coronal cut from crestal bone to level of root apex.

• Horizontal bone changes:

On the same coronal cut, the Buccolingual Bone Width was then measured at intervals of 2 mm, 4 mm, and 8 mm from the level of buccal crestal bone.

4.2. Statistical analysis

All data were collected, tabulated and subjected to statistical analysis. Statistical analysis was performed with IBM® SPSS® (SPSS Inc., IBM Corporation, NY, USA) Statistics Version 23 for Windows, while Microsoft office Excel is used for data handling and graphical presentation. Soft and hard tissue dimensional changes are continuous numeric variables described by the Mean, Standard Deviation (SD), Standard Error (SE) and 95% confidence interval of the mean.

RESULTS

Soft tissue changes

On comparing soft tissue shrinkage at different levels (2,4,8mm), the highest value of soft tissue change was detected at the level of 2 mm while the lowest value was at the level of 8 mm with a mean and standard deviation values of $(0.66\pm0.24\text{mm})$ and $(0.33\pm.015\text{mm})$ respectively.

There was statistical significant difference in soft tissue changes at different levels with a p-value of 0.34. Multiple comparison between different levels of soft tissue changes indicated that there was a statistically significant difference in soft tissue changes only between 2 mm and 8 mm levels with a p value of 0.032. On the other hand, there was no statistically significant difference in soft tissue changes between 4 mm level compared to 2 mm or 8mm levels with a p value of 0.44 and 0.51 respectively.

Table (1): Mean, standard deviation (SD), minimum and maximum and P value of different levels of soft tissue changes at 2,4,8mm for DBBM

	Mean	± SD		nfidence for Mean			
Soft tissue change level	Mean	SD	Lower Bound	Upper Bound	Minimum	Maximum	P value
2 mm	0.66	0.24	0.37	0.96	0.40	0.98	
4 mm	0.49	0.10	0.37	0.62	0.34	0.60	0.03421
8 mm	0.33	0.15	0.14	0.52	0.21	0.60	

Significance level < 0.05

Table (2): Multiple comparison showing the mean difference, 95% confidence interval and P value between different soft tissue changes at 2,4,8mm for DBBM

			Mean	95% Confide	ence Interval	
Soft tissue changes			Difference	Lower Bound	Upper Bound	P value
	2 mm	4 mm	0.17	-0.13	0.47	0.44095
	2 mm	8 mm	0.33	0.03	0.63	0.03260

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

4 mm 8 mm 0.16 -0.14 0.46 0.51048

Significance level < 0.05

Radiographic changes

Bone height values

For the buccal bone height, there was a slight reduction in the mean bone height with mean and standard deviation values of 11.53±6.03mm and 11.39±6.46mm at baseline and 6 months follow-up respectively with mean difference and standard deviation values of -0.14±0.62. Also, there was a similar reduction in the lingual bone height with mean and standard deviation values of 10.38±6.47mm and 10.09±6.33 at baseline and 6 months follow-up respectively with mean difference and standard deviation values of -0.30±1.12.

There was no statistical significant difference between baseline and 6 months follow-up bone height values with p value of 0.644 and 0.587 at buccal and lingual measurements respectively.

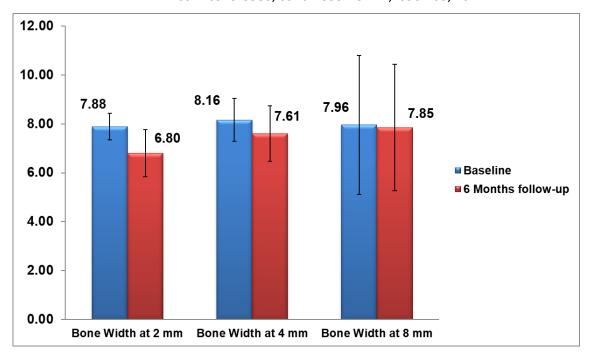
Bone width values

Assessment of horizontal bone width changes was done at different levels 2,4,8 mm from level of crestal bone. There was an overall reduction in the bone width changes with the largest mean difference coronally at 2mm and the smallest mean difference apically at 8 mm. The paired differences of the mean and standard deviation was as following: $(-1.08\pm0.88\text{mm})$, $(-0.55\pm0.79\text{mm})$ and $(-0.11\pm0.42\text{mm})$ for 2,4,8 mm bone width respectively.

There was no statistical significant difference between baseline and 6 months follow-up bone width change with p value of 0.19 and 0.57 at 4mm and 8mm measurements respectively. However, there was almost statistically significant difference between baseline and 6 months follow-up bone width change at 2mm with a p value of 0.051.

Figure (6)

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021



Bar chart showing mean bone width values of DBBM

DISCUSSION

The alveolar process is a tooth-dependent tissue that is developed in conjunction with tooth eruption. Subsequent to tooth extraction, the alveolar ridge undergoes resorption and atrophy resulting in loss of vital soft and hard tissues. The range of this dimensional change varies greatly among individuals. The magnitude of the resorption depends on the morphology and state of health of the tooth to be extracted and of its neighboring soft and hard tissues. Thinner, more highly scalloped hard and soft tissues are more prone to exhibit hard tissue resorption and soft tissue recession than the thicker less scalloped phenotype (Schroeder, 2012).

One of the most reliable, widely used bone replacement grafts in socket preservation is xenografts. Xenografts of bovine origin have been increasingly applied for bone regeneration in different types of defects. Bovine xenografts could be easily obtained with unlimited availability and without great ethical considerations. Generally, bovine bone is subjected to various purification procedures to eliminate organic components producing an inorganic matrix containing hydroxyapatite, and some of the minor and trace elements originally present in bone, such as Mg^{2+} , Na^+ and $(CO_3)^{2-}$. Thus, bovine xenografts have chemical composition and architectural geometry similar to human bone (**Stavropoulos, 2008**).

Regarding effect of atraumatic extraction, atraumatic extraction resulted in significantly less bone resorption than did the classic extraction technique. Atraumatic extraction preserves bone, gingival architecture and allows for option of future or immediate implant placement (**Sharma** *et al.*, 2015). Therefore, in our study, atraumatic extraction started by dissection of periodontal ligaments in crestal part using 15C blades mounted over a round-handed blade holder to facilitate rotation without lacerating the soft tissues. Then, teeth were luxated using microelevators and the final delivery movement was done using forceps

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

The flapless approach was the technique of choice in the current study since it is proven to counteract the alveolar socket modeling. It has to be considered that the tooth extraction procedure removes the periodontal ligament and the detachment of a mucoperiosteal flap compromises the blood supply from both sides. When dealing with a thin buccal bone, generally cortical in the coronal portion and poorly vascularized, significant bone resorption can be expected (de Barros et al., 2017).

Concerning soft tissue assessment, the scan acquisition of soft tissues was mostly taken using extra-oral scan of plaster models (**Sbordone** *et al.*, **2017**; **Vanhoutte** *et al.*, **2014**). However, in our study we used direct intra-oral scans. In vitro studies showed an accuracy of $<60 \mu m$ when matching full arch plaster cast scans based on the impressions of an accurately known reference model (**Ender and Mehl, 2011**). Some in vivo studies reported changes in reference points as the positions of the reference teeth may differ slightly between baseline and follow-up visits. This may lead to an increase of matching inaccuracies along the reference structures (**Imburgia** *et al.*, **2017**). However, (**Zhang, Suh and Lee, 2016**) studied the validity of intraoral scans compared with plaster models and they concluded that the intraoral scans are clinically acceptable for diagnosis and treatment planning in dentistry and can be used in place of plaster models. Another study conducted by (**Imburgia** *et al.*, **2017**) studied the accuracy of different commercially available intra-oral scanners showed that CS 3600® used in our trial, had the best trueness (45.8 \pm 1.6 μ m). However, no statistically significant differences were found between different types of scanners.

Different techniques describing soft tissue variations have been developed in the literature. In the present study, superimposition of preoperative and postoperative intra-oral scans and postoperative CBCT was done, using point functionality in the model manipulation panel. Extra screening of cross-sectional cuts to ensure accurate superimposition. However, in another study, the preoperative CBCT scan were first superimposed on the preoperative digital study cast model using a semi-automatic alignment wizard. Another superimposition of the pre- and post-operative casts was performed. (Zadeh et al., 2016). In our opinion, both approaches are accepted without affecting the final results as long as all other cuts ensure proper superimposition.

Likewise, different methodologies were followed for leveling of soft tissue changes measurements. In our study, soft tissue measurements were taken at 2, 4, 8 mm from a horizontal line passing through crest of bone. Other studies are available with different leveling like 2,4,7 mm (Vanhoutte et al., 2014). However, no single technique is adopted to be standardized. Our study measured 2-D linear dimensional soft tissue changes measured in the facial aspect of extraction-socket at different levels (2,4,8mm) from crestal bone. This is in similar to methodology reported by (Vanhoutte et al., 2014) who assessed soft tissue changes at buccal side of three horizontal sections located at 2,4,7 mm levels in the mesial, central and distal buccal aspects. On different expression way, different studies reported 3-D volumetric dimensional soft tissue changes measured in volume (mm3) or in percentage. Scans of the cast models were acquired from the experimental sites, digitally superimposed and analyzed, allowing a qualitative and quantitative evaluation of changes of the volume and contour at different time points (Barone et al., 2016; Thalmair et al., 2013). Volumetric studies measured the whole volume and contour area changes happened in the ridge and does not differentiate between changes that result from soft tissue and those resulting from hard tissues. Conversely, our study measured soft tissue linear changes occurring at the buccal side only which has a more clinical relevance.

Concerning hard tissue changes, different methodologies were reported for hard tissue assessment. Clinical direct evaluation of buccal plate of bone thickness or the alveolar height after tooth extraction measured at the lingual and buccal aspects using a periodontal probe to the nearest millimeter. Also, the difference between the buccal and lingual heights and the alveolar ridge width can be measured at time of extraction (Jung et al., 2013; Schropp et al., 2003). Radiographic evaluation is considered as the most frequently used assessment methodology for bone changes. Intraoral or extra-oral radiographic assessment are available. However, intraoral

ISSN: 0975-3583, 0976-2833 VOL 12, ISSUE 03, 2021

radiography is 2-dimensional (2D) and the amount of bone loss can be underestimated due to projection errors. CBCT is the most commonly used 3D radiographic assessment tool due to its low radiation exposure and increasing availability and use with adequate accuracy for measurement. Several intra-oral and extra-oral techniques developed with the aim of standardization of pre-and post-operative scan. Limited data are available on the accuracy and reproducibility of these techniques. It is difficult to compare between different protocols due to high level of heterogeneity. However, the outcomes could be compared (Vandenberghe, Jacobs and Yang, 2007b). In our study, the superimposition of the pre- and post-operative CBCT was done using a third party software. Currently, three methods of registration are available to superimpose the postoperative to the preoperative scans: point, surface or voxel based registration. Superimposition has to be done on a non-surgically exposed region. Point based registration which is the least accurate relies mainly on predefined landmarks on unoperated regions. Voxel based registration relies on volumetric data rather than the surfaces of 3D objects, which might be affected by the quality of the segmentation performed. It is considered as the most accurate method (Gaber et al., 2017). Hence, point based registration was employed in our study to approximate the two scans using dental and skeletal points in the maxillary region away from extraction sites were utilized. Following point base registration, high precision automatic volume based registration is utilized for perfect superimposition between the pre-operative and postoperative scans.

CONCLUSION

Based on the results of the present clinical trial, the following conclusions may be reached:

There was statistical significant difference in soft tissue changes at different levels with a p-value of 0.34. with a statistically significant difference in soft tissue changes only between 2 mm and 8 mm levels with a p-value of 0.032.

There was no statistical significant difference between baseline and 6 months follow-up for both bone height and width values

RECOMMENDATIONS

- Consistent standardized assessment protocols (clinical, radiographic) are needed to allow for better comparison between different bone replacement grafts.
- Additional standardized studies are necessary to determine the effect of individual surgical protocols on soft and hard tissues and esthetic outcomes of dental implant restorations.
- Decision tree is needed to establish a reference guideline for alveolar ridge preservation patient selection, techniques and different biomaterials used.

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