

Revascularized Fibula Free Flap Reconstruction and Curvilinear Transport Distraction Osteogenesis in Closure of Large Postmaxillectomy Defects: A New Gold Standard?

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Abstract

Introduction: The revascularized fibula free flap (RFFF) is the most popular method of postmaxillectomy reconstruction. This article proves that the use of curvilinear transport distraction osteogenesis (CTDO) is an efficacious way in closing large defects in the maxilla and a superior alternative to the RFFF. **Methods and Materials:** In a prospective cohort study of six postmaxillectomy patients, CTDO was applied and the new bone (regenerate) was compared with the parent bone from which it had been regenerated. These results were compared with a retrospective group of six participants of similar age and sex who had undergone RFFF reconstruction as an external control. Clinical measurements taken at the depth of the alveolar vestibule were recorded at three different exact points juxtaposed, namely (A) lateral incisor, (B) first premolar, and (C) first molar. These areas of interest were similar to those chosen on the CT scans. Impressions were taken from all the patients and stone casts were made. The width of the alveolar bone was computed based on the measurements made from the stone casts. The stone casts were then used to calculate the width and depth of the soft tissue and bone in the maxilla in the (A), (B), and (C) regions. **Results:** The regenerate possessed anatomical and physiological characteristics equal to the parent bone. For the CTDO patients, prosthetic rehabilitation of the dentition was supported by dental implants after osseointegration of the latter into the newly created bone and soft tissue. **Discussion:** The production of the curvilinear bone and soft tissue along a horizontal plane has been demonstrated. The new alveolar bone achieved the correct width and depth to create a physiological vestibule and a functional/esthetic zone for the placement of dental implants. In addition, the shape of the palatal vault was also maintained. The CTDO method is a reliable method of maxillary reconstruction and has a better anatomical and functional outcome than the RFFF.

Keywords: Distraction osteogenesis, maxillary reconstruction, maxillectomy defect, revascularized fibula free flap, transport distraction

INTRODUCTION

Postmaxillectomy defects can be most disfiguring for the patient with significant psychosocial impact and hence present a formidable challenge in reconstruction and rehabilitation to both surgeon and prosthodontist.^[1,2] The functional aspects predating this reconstruction concern mainly occlusal forces related to mastication, articulation, and phonation as well as deglutition or swallowing.^[3] When defects of the oral cavity are small and inconspicuous, the placement of an obturator usually fulfills the need of such patients. However, when defects are large and cumbersome (Brown classification classes II, III, and IV [b–d]), these obturators do not function with hermetic

closure due to the lack of a physiological seal between the prosthesis and the soft tissues being a huge inconvenience to the patient.^[4] Patients who are obliged to use obturator prostheses often become frustrated in having to deal with

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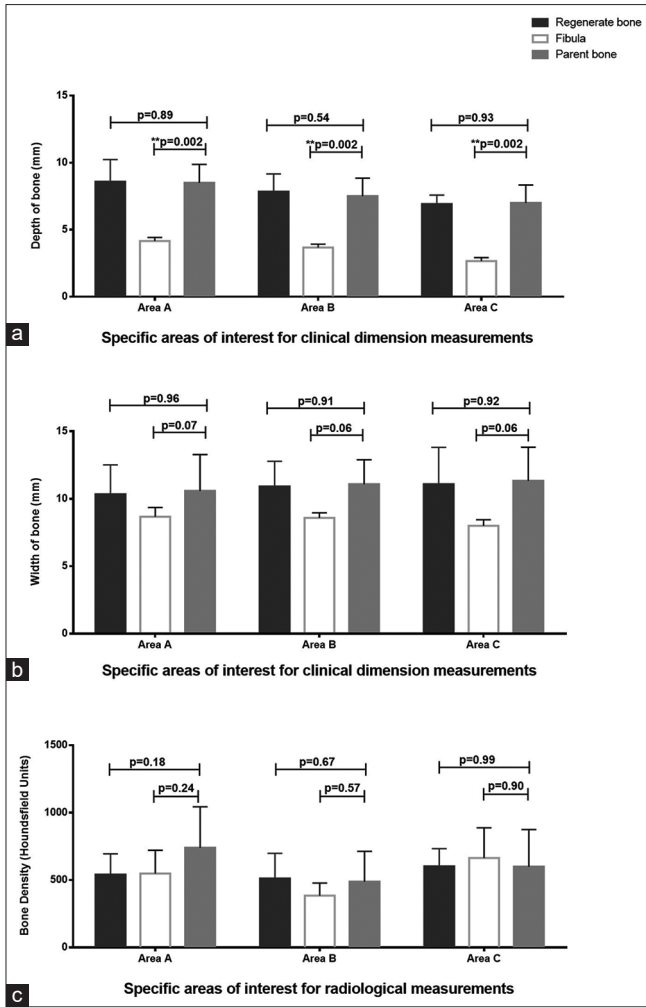


Figure 1: (a) Depth of the bone, (b) shows width of the bone and (c) shows bone density when comparing revascularized fibula free flap (fibula) to regenerate and parent bone

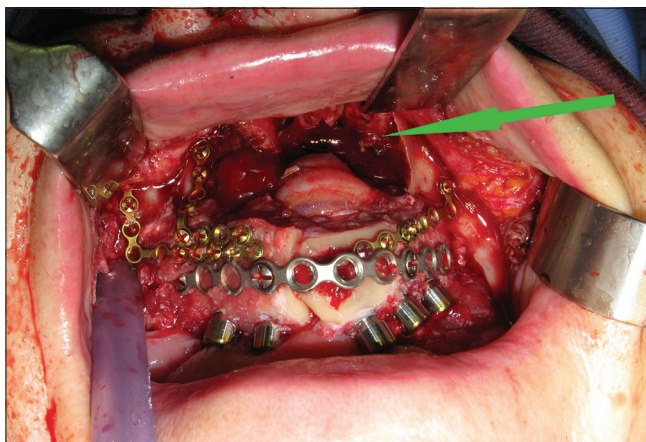


Figure 3: Immediate reconstruction of the maxilla with revascularized fibula free flap showing five dental implants *in situ*. The green arrow shows the palatal vault consisting of a skin paddle with muscle and fat

these removable devices, and most of them wish to have permanent closure of the maxillectomy defect.

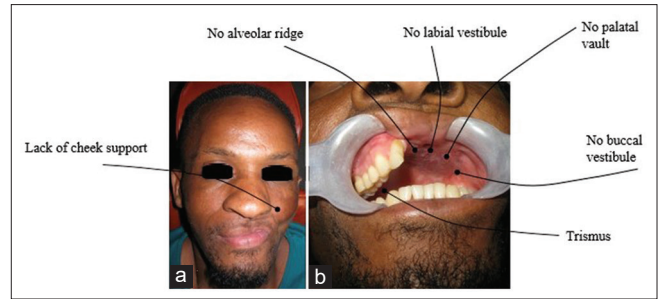


Figure 2: (a) An unsatisfactory result of revascularized fibula free flap reconstruction post maxillectomy for the treatment of a malignant salivary neoplasm. (b) The lack of alveolar bone and vestibular obliteration is evident. In this case, the placement of dental implants was unsuccessful

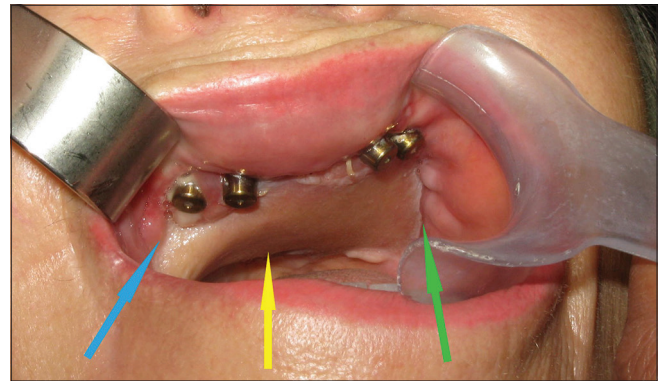


Figure 4: A postmaxillectomy patient with revascularized fibula free flap rehabilitation. Note the hyperplasia of skin paddle around the dental implants (blue arrow), lack of a vestibule (green arrow), and lack of palatal vault (yellow arrow)

Several options are available for reconstructing defects of the mid-face. These involve the use of local flaps, in combination with nonvascularized bone grafting, and are usually sufficient to deal with the reconstruction of small defects.^[5] However, in the case of large resections of the mid-face, the extensive size of the defects and the possible compromise of blood supply as well as the use of adjuvant chemoradiation therapy call for the use of microvascular free flaps. The latter usually includes an adequate soft-tissue paddle to achieve proper soft-tissue function and esthetic closure. While there are many modalities of free-flap transfer, the most popular one for maxillary closure to date has been the revascularized fibula free flap (RFFF).^[6]

It is common cause that the RFFF has been popularized to the extent where it is known as the current “gold standard.”^[7] Prior to this method, the creation of bone in a curvilinear trajectory on a horizontal plane did not exist. The authors have successfully created in the maxilla (by means of curvilinear transport distraction osteogenesis [CTDO]), an alveolar ridge, a palatal vault, and a vestibule.^[8] The regenerated bone was validated both radiologically and histologically for its integrity.^[9] This method has proven to be successful in creating a curvature within the regenerate. In the present study, a clinical and radiological comparison between RFFF and CTDO was made.

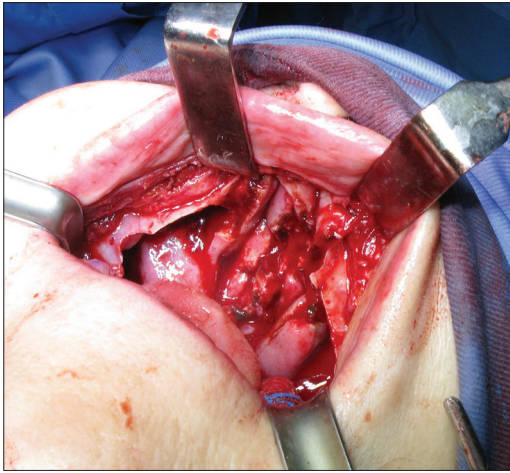


Figure 5: Postmaxillectomy surgical defect at the Le-Fort one level. Note the lack of residual alveolar bone

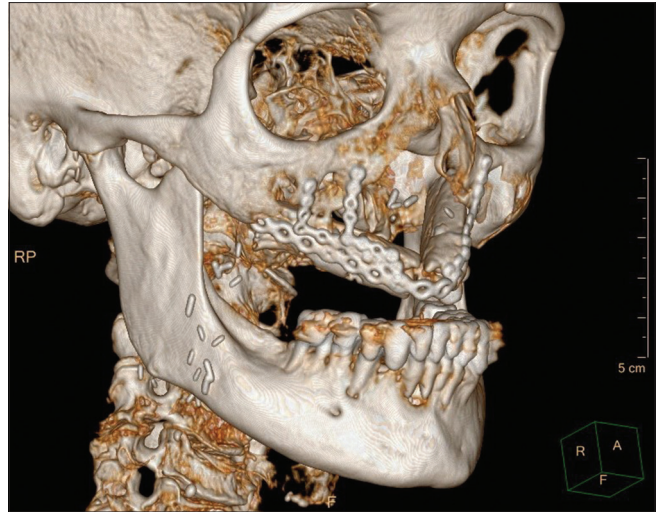


Figure 6: Postoperative three-dimensional CT scan showing the immediate reconstruction of the post-maxillectomy defect using revascularized fibula free flap. Note the lack of anterior curvature of the premaxilla, lack of a bony palatal vault, and the unfavorable occlusal relationship between the maxilla and the mandible

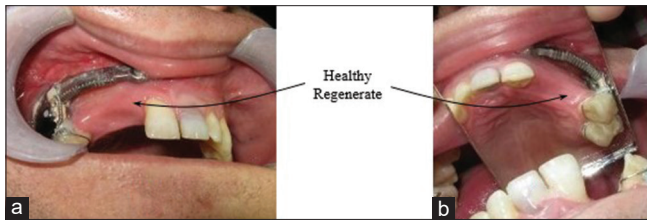


Figure 7: Healthy regenerate with a curvilinear trajectory is shown in (a) and recreation of palatal vault anatomy is shown in (b)

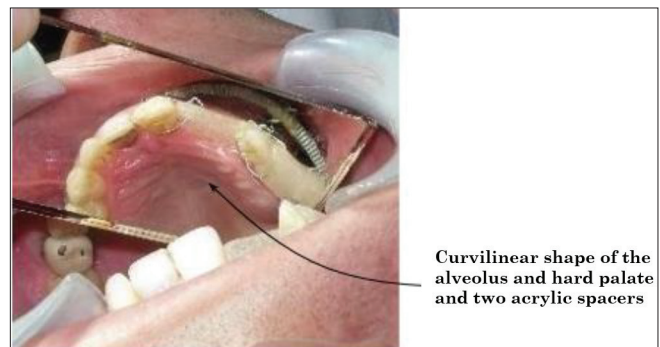


Figure 8: The superlatively recreated palatal vault with rugae in the palate. Note also the depth of the palatal vault and the creation of a vestibule. The two acrylic interdigital spacers are wired to the abutment teeth

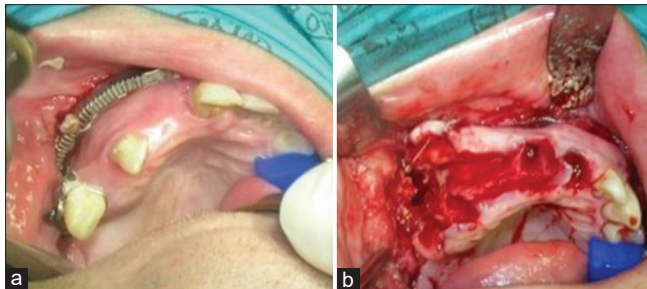


Figure 9: (a) The favorable curvilinear shape of the new maxilla. (b) The thick and deep new regenerated maxillary bone and healthy dental sockets

Disclosure

The patent held by University of Cape Town (UCT), of the distraction device, does not bestow any financial benefit or conflict of interest concerning the research team. The intent of the patent is to prevent any potential misuse of the concept and to allow the study to proceed unhindered.

MATERIALS AND METHODS

Study design and ethical considerations

The study was approved by the Ethics Committee of the UCT (Human Research Ethics Committee [HREC]). Informed consent was obtained from all the study participants as per the UCT HREC guidelines (HREC REF: 147/2012). Ethical issues considered at all times were patient confidentiality,

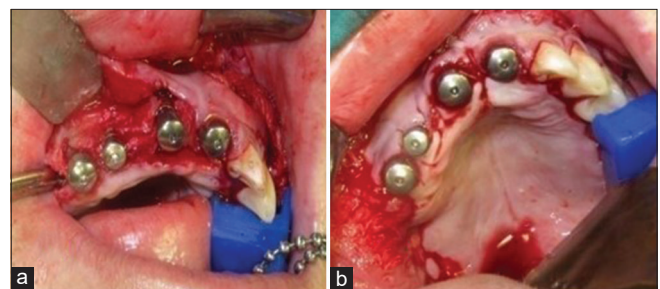


Figure 10: (a) The placement of four dental implants with healing abutments. (b) Primary closure of soft tissue around the dental implants

privacy, and patient dignity. Given the sensitive nature of this kind of work involving patient esthetics (gross deformity) and function, informed consent to publish the results of the study was obtained from all participants. A prospective cohort study of six postmaxillectomy patients who had

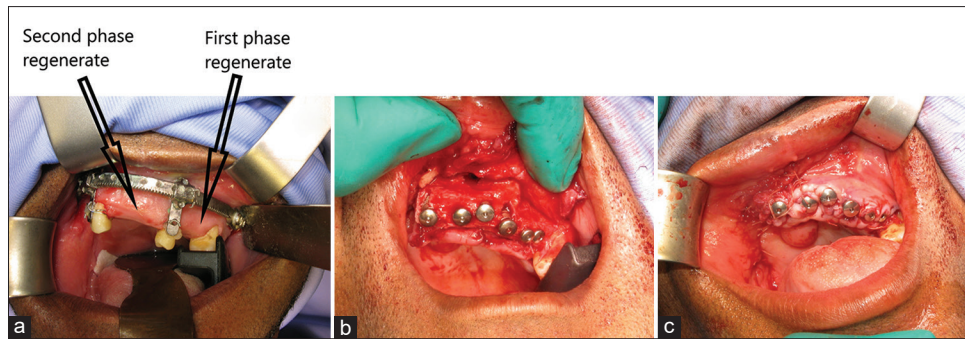


Figure 11: (a) The regenerated trifocal curvilinear bone supported by the trajectory rail and (b) and (c) Show the placement of dental implants into healthy regenerated bone sufficient to support a full-arch Prettau bridge

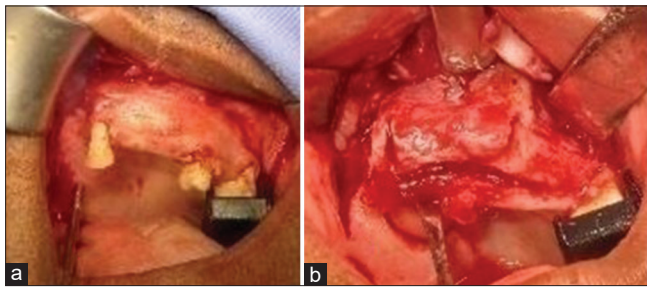


Figure 12: (a) The trifocal favourable curvilinear shape of the new maxilla. (b) The thick and deep new regenerated maxillary bone and healthy dental sockets before dental implant placement

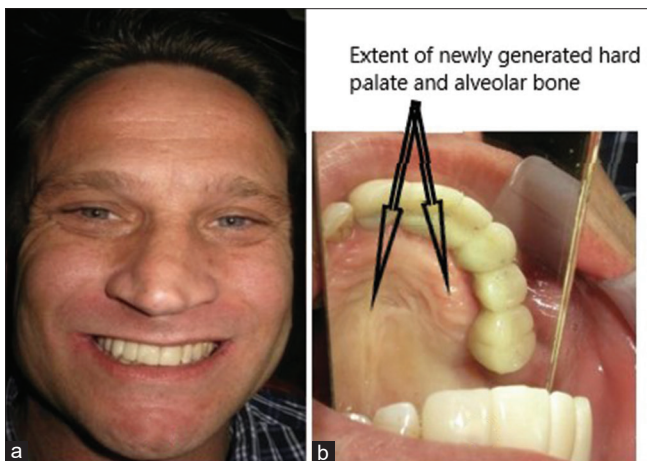


Figure 13: (a) The highly pleased patient with a most esthetic and functional temporary Prettau bridge *in situ*. (b) The very pleasing anatomical recreation of the hard palate, alveolus, and vestibule (mirror view); (consent obtained)

undergone CTDO reconstruction was compared regarding clinical outcome of function and esthetics with a group of six patients who had undergone RFFF reconstruction. The study was designed to appraise the clinical outcome between the two methods of reconstruction. The RFFF patients were not subjected to any invasive procedures except to undergo a clinical evaluation and have a CT scan performed of their maxillae by independent radiologists (Morton and Partners in Claremont, Cape Town).

Participant selection and recruitment

Study population

Patients of both sexes, irrespective of age, who between February, 2010 to February 2014 had undergone partial maxillectomy procedures for tumor ablation or trauma or congenital defects, were eligible for the study. The surgical defects were anatomically classified according to Brown *et al.* (2010) and limited to classes II, III, and IV with subclasses (b) to (d) in any combination.

Inclusion criteria

All patients conforming to Brown classification classes II, III, and IV (b) to (d) were eligible for the study. For accurate statistical comparison, it was critical that both the groups of participants (CTDO and RFFF) fell within the same Brown classification groupings.

Exclusion criteria

Patients who were immunologically compromised owing to either systemic disease (e.g., uncontrolled diabetes mellitus and HIV/AIDS) or being administered immunosuppressive agents were not eligible for the study (i.e., any preexisting possible impediment to healing or predisposition to infection).

Study procedures

Participant evaluation

Participants were seen and followed up by the primary investigator (RH) at his private maxillofacial clinic and at the Department of Plastic Reconstructive and Maxillofacial Surgery in Groote Schuur Hospital in Cape Town.

Participant education

The aim and purpose of the study was explained in simple terms and in detail, including the use of visual aids to inform the participants of their problem and the treatment method/s. Prospective participants were duly informed about the experimental nature of the study, as well as possible alternative treatment modalities.

Informed consent

Signed informed consent for participation in the proposed study was obtained in the patients' first language before the commencement of any treatment.

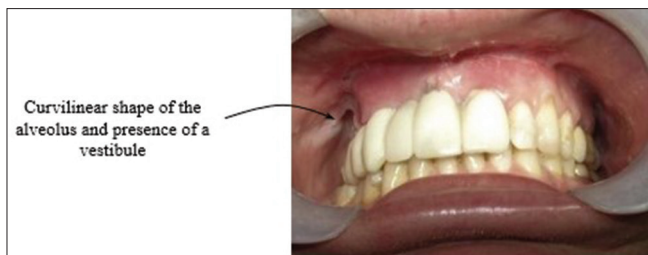


Figure 14: The esthetically constructed Prettau bridge *in situ*

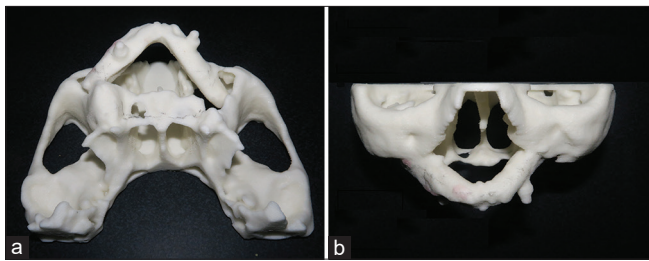


Figure 15: (a) Ventral view of a three-dimensional stereolithographic model, fabricated from the computerized tomogram scan of the patient, showing the revascularized fibula free flap *in situ*. Note the lack of an anterior curvature of premaxilla as well as palatal vault. (b) Dorsal view of revascularized fibula free flap confirms the sub-optimal (triangular) shape of the newly created maxilla

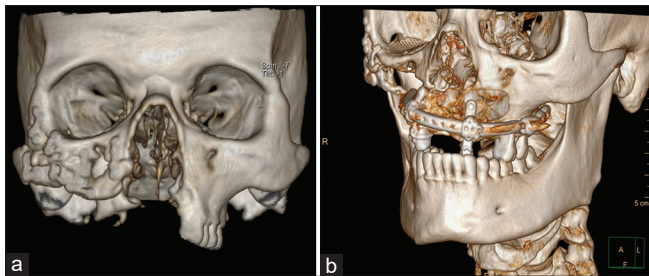


Figure 16: Preoperative (a) and postoperative (b) three-dimensional CT scans showing the reconstruction of the post-maxillectomy defect by means of trifocal curvilinear transport distraction osteogenesis as shown in Figures 11 and 12 above

Preoperative radiological evaluation

Preoperative radiographs, computerized tomography (CT), and stereolithography were used throughout the study.

Installation of distraction apparatus

The installation and surgical technique of placement have been described.^[10]

Postoperative radiological evaluation

Evaluation of the regenerate was done by CT scanning (independent radiologists Morton and Partners). Evaluation of the new bone formation regarding quality and quantity (densitometry) was computed in Hounsfield units (HU) according to Hashemi and Javidi in 2010. An independent radiologist monitored the capturing of the radiological data after a period of 9 month postdistraction. Three particular regions of interest (ROIs), lateral incisor (A), first premolar (B), and first molar (C), namely areas measuring an

area of approximately 10 mm², were preselected in the native or existing bone (control group), on a juxtaposed mirror image selected in the regenerated bone (test group) as well as in the bone of the six RFFF cases. In the latter, the age and ROIs were matched like-for-like with the parent bone and the CTDO.

Depth of the bone

Impressions were taken from all the patients and stone casts were made. The stone models were then used to calculate the depth of the soft tissue and bone in the maxilla in the (A), (B), and (C) regions. The depth of the vestibule from the crest of the alveolar bone to the labial or buccal sulcus was exact points measured by Zilinsky® calipers.

Width of the bone

Clinical measurements of the width of the alveolar bone were computed based on the measurements made from stone casts similar to the depth of bone. The designation of an area is based on a ROI not dissimilar to that seen on the CT scans, except for the fact that these clinical measurements are finite points or entities.

Radiological investigation

The bone produced by CTDO was analyzed in the ROIs within an area of 10 mm². Three areas of interest, namely (A), (B) and (C), were chosen equidistant to the mirror image of the regenerate versus the RFFF. A like-for-like comparison was made for each area of interest. The bone density was expressed in HU.

Statistical analysis

The Mann–Whitney U-test was used to compare the median bone density in the bone produced by the CTDO of the test participants with the matched controls using the RFFF method.

RESULTS

Statistical analysis

The results showed no statistically significant difference in the bone density of the bone produced by CTDO versus RFFF.

Compared to the parent bone, the regenerate bone showed no statistically significant differences in the measure of depth, whereas the RFFF was much less in depth when compared to the parent bone, i.e., $P = 0.002$ [Figure 1a]. Similarly, the measurement of width was less with the RFFF when compared to the regenerate bone, but this did not reach statistical significance [Figure 1b]. There were no differences in bone density when the two methods were compared to the parent bone [Figure 1c].

Depth of bone

While the depth of the alveolar bone formed by means of CTDO regenerate compared favorably with the parent bone, i.e., $P = 0.84, 0.53, \text{ and } 0.93$ for areas (A), (B), and (C) respectively, the readings for the RFFF for the same three ROIs were different [Figure 1a]. In area (A), the depth of the sulcus for RFFF is approximately half that of the parent bone, i.e., $P = 0.002$. In area (B), the depth

of the sulcus for the RFFF is less than half of the parent bone, i.e., $P = 0.002$. In area (C), the depth of the sulcus for RFFF is almost one-third that of the parent bone, i.e., $P = 0.002$. The comparison between RFFF sulcus depth and the bone produced by CTDO shows clearly that the vestibule produced by the new alveolar bone is superior to that generated by RFFF. When the average of the three areas, namely (A), (B), and (C), was calculated, it was found that the bone produced by CTDO had a vestibular depth almost double of that created by RFFF, i.e., $P = 0.002$.

Width of the bone

The width of the bone produced by CTDO was superior to that of RFFF, i.e., $P = 0.96$, 0.91 , and 0.92 for areas (A), (B), and (C), respectively [Figure 1b]. In the areas (A), (B), and (C), there was no statistically significant difference between the CTDO bone and the RFFF, i.e., $P = 0.07$, 0.06 , and 0.06 .

Radiological comparison (bone density)

The three ROIs in the bone produced by CTDO, namely (A), (B), and (C), were compared with similar areas in RFFF [Figure 1c]. It was noted that there was no statistically significant difference between the bone produced by CTDO and RFFF, indicating that the bone densities were similar.

DISCUSSION

Aesthetics

As shown in Figure 2b, the lack of a bony palatal vault is unsightly. It is also noted that the lack of a palatal vault does not provide good peri-implant support to the bone on the palatal aspect.^[11] When using RFFF, a myocutaneous flap [green arrow in Figure 3] substitutes for the palatal vault [yellow arrow in Figure 4]. Some key aspects of the surgical process of RFFF placement are shown in Figures 4–6. Hence, the lack of a bony palate not provided by the myocutaneous flap complicates the creation of a contoured three-dimensional vault.^[12] This is a major drawback of RFFF. As shown in Figure 1a, the alveolar height which produced the depth of the sulcus was poor in RFFF and compared unfavorably with CTDO cases.^[13]

This lack of sulcular or vestibular depth is related to the anatomical composition of the skin paddle being muscle, fat, and skin [Figure 3]. This paddle tends to fibrose and contract and therefore a shallow, if not nonexistent, vestibule often results [Figure 4]. As a consequence, the upper lip line (high-smile line), as well as cheek function, is affected negatively because the lack of a vestibule does not allow the muscles of facial expression to animate during the function [Figure 2a]. In the experience of the authors, subsequent vestibuloplasties have proved to be unsuccessful in mitigating this problem [Figures 2b and 4].^[14]

Another significant complication of the RFFF is that the skin paddle does not do well around the dental implants, owing to the inflammation and hyperplasia that lead to pain and potential to bleed [blue arrow, Figure 4]. In addition, the maximum height of the RFFF is 14 mm, thereby presenting an

undesirable problem in the esthetic zone of the mouth.^[2,15] In particular, patients treated by partial resection of the maxilla have a residual dentition on the healthy side. In these cases, despite successful reconstruction, an inappropriate step at the graft-to-residual stump level may be present.

In the case of CTDO, the recreation of the hard palate is naturally formed by the process of osseodistraction. Dental implants are placed into the regenerate after a minimum consolidation period of 3–6 months based on the mean bone density of 400 HU.^[16-19]

As shown in Figure 7a, the healthy new regenerate in the premaxillary region measured approximately 20 mm with a curvilinear appearance. In the hard palate, the presence of a palatal vault was visible and rugae replication was also noted in the palatal mucosa [Figure 7b]. Figure 8 shows the secured acrylic spacer in position and the newly created regenerate which is on a curvilinear trajectory. In Figure 9a, the new maxilla can be seen before the removal of the distraction apparatus. The trajectory rail and the rest of the distraction device were removed. The incisor and canine teeth were carefully removed so that the sockets of the teeth could be preserved for the placement of dental implants [Figure 9b].

As shown in Figure 10a, the dental implants were well placed with healing abutments. Bone scrapings were taken from the areas of excess tissue and placed into the sockets around the dental implants to accelerate osseointegration. There was a good bony union between the regenerate and the malar corpus, and hence, no interpositional bone grafting was required in this case. Figure 10b shows primary soft-tissue closure around all the dental implants.

With the “tandem distractor” eliciting tetrafocal distraction, as shown in Figure 11a, the bone was grown following the curvature of the premaxilla, using the method of creating a second (possibly a third) transport disk from the first one. The quality of the newly created bone was found to be more than satisfactory, and the transported teeth were eventually extracted. Dental implants were placed into their respective sockets [Figure 11b and c]. The results of the newly regenerated bone produced are shown in Figure 12a and b.

The recreation of the hard palate [Figure 13b] is an advantage over the RFFF [Figure 4], and moreover, the recreation of a vestibule [Figure 14] allows for optimization of function and esthetics. Figure 13a shows a highly pleased patient sporting his new smile with temporary Prettau bridge rehabilitation.

Soft-tissue biotype around the implants

A solution to the problem of hyperplasia around the dental implants of skin paddles is free palatal grafting from the vault of the hard palate. When this procedure was done by Chiapasco *et al.* in 2006, it was shown that implant survival in RFFF cases was as high as 98.6% after 7 years.^[20] However, in the absence of sufficient hard palate mucosa as a donor site, which often occurs in RFFF cases, the donor site would either be small or impractical for use [Figure 15].

This shortcoming makes a strong case for using CTDO where there is an abundant regeneration of keratinized palatal mucosa, as well as the underlying supporting palatal shelf. However, it must be noted that the use of CTDO is dependent on a residual fragment of maxilla comprising at least four teeth in the alveolar bone [Figure 16a]; otherwise, the use of RFFF is the only solution. Figure 16b shows the use of trifocal CTDO. Note the natural horse-shoe shaped pre-maxilla created by CTDO as compared to the pointed triangular shaped maxillary arch created by RFFF, as shown in Figure 6.

In all the categories of bone and soft-tissue regeneration, namely in respect of width, depth, density, and radiological presentation, there was no statistically significant difference between the bone created by the CTDO procedure and the parent bone which was used as a control.

CONCLUSIONS

Based on the clinical and radiological findings, the following can be concluded:

The clinical appearance is appraised as follows: the lack of a bony palatal vault is unsightly and a major drawback of RFFF, such as, the flatness of the palate reduces the space required for phonation and deglutition and the lack of a vestibule interferes with animation of facial musculature and a neutral zone for dental implant placement. All of the above issues make the RFFF unattractive as a gold standard, whereas in contradistinction, the CTDO method complies with all of the above requirements.

Where the alveolar height is concerned, it has been shown that the alveolar height responsible for the formation of the depth of the sulcus/vestibule was indeed poor in RFFF as compared to the CTDO cases.

Histologically, the CTDO-generated bone appeared superior to the parent bone.^[17] These results reinforce the notion that the new bone created can function and appear as good as the bone that it replaces, mainly in the area of implantology.

The statistical and clinical comparisons made to the RFFF technique show that CTDO is superior in mainly the anatomical and esthetic areas and as good as the RFFF in the dental implant domain. It is to be understood that the bone density of RFFF, owing to its physiological function before harvest, will be superior to the maxillary bone. However, the RFFF remodels with time to the new function and stresses of the maxillary bone. This is the only area of superiority where the bone density is naturally better, but it does not represent any advantage over the CTDO, as the HU figures of the regenerate have shown with respect to dental implant placement.

From a clinical perspective, the anatomical and functional rehabilitation of postmaxillectomy patients is much better served by the CTDO method as compared to RFFF. Radiologically, both the methods are equitable.

Based on the findings of this comparative study, it can be concluded that the CTDO technique should be considered as the new surgical “gold standard” for postmaxillectomy reconstruction.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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