

Clinical Paper Cleft Lip and Palate

Osteogenesis effect of guided bone regeneration combined with alveolar cleft grafting: assessment by cone beam computed tomography

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Abstract. Cone beam computed tomography (CBCT) allows for a significantly lower radiation dose than conventional computed tomography (CT) scans and provides accurate images of the alveolar cleft area. The osteogenic effect of guided bone regeneration (GBR) vs. conventional alveolar bone grafting alone for alveolar cleft defects was evaluated in this study. Sixty alveolar cleft patients were divided randomly into two groups. One group underwent GBR using acellular dermal matrix film combined with alveolar bone grafting using iliac crest bone grafts (GBR group), while the other group underwent alveolar bone grafting only (non-GBR group). CBCT images were obtained at 1 week and at 3 months following the procedure. Using Simplant 11.04 software, the bone resorption rate was calculated and compared between the two groups. The bone resorption rate from 1 week to 3 months following bone grafting without the GBR technique was $36.50 \pm 5.04\%$, whereas the bone resorption rate using the GBR technique was $31.69 \pm 5.50\%$ (P = 0.017). The application of autogenous iliac bone combined with the GBR technique for alveolar bone grafting of alveolar cleft patients can reduce bone resorption and result in better osteogenesis.

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Alveolar bone grafting is an integral part of the surgical management of oral clefts. The key to the success of this operation is to effectively secure the bone grafts and prevent soft tissue and bacteria invasion into the bone regeneration zone, thus reducing complications such as bone resorption, infection, and dehiscence.¹ Guided bone regeneration (GBR)² uses acellular dermal matrix (ADM) membranes to block the invasion of the surrounding soft tissue, allowing sufficient time for osteoblast proliferation in this reserved bone growth space for new bone generation.³ Clavijo-Alvarez et al. found that using ADM in alveolar bone grafting could prevent postoperative cancellous bone graft exposure without increasing the risk of mucosal disruption or the time to complete healing.³ It has been shown that ADM, as a cell membrane bracket, can promote cell adhesion and growth, providing a matrix that is conducive to wound healing.⁴

Various methods have been proposed to evaluate the process of alveolar bone grafting. Although the bone graft can be evaluated to a certain extent on conventional plain films, disadvantages inherent in this method include the inability to assess changes in volume, morphology, and bony architecture.^{5,6} Using a navigation system based on computed tomography (CT), Feichtinger et al. created threedimensional (3D) models showing the amount and site of bone resorption.⁷ CT scanning has some disadvantages, such as cost, the large size of the equipment, and increased radiation exposure.⁸

3D cone beam CT (CBCT) imaging has recently been introduced for diagnosis and treatment planning in the oral and maxillofacial region. This technique appears to be superior to plain radiography.9 Hamada et al. compared CBCT with dental occlusal and panoramic radiographs for the evaluation of bone grafting of the alveolar cleft.¹⁰ They found that CBCT provided more precise information and better assessment of the alveolar bone graft for the placement of dental implants. They also found that CBCT could clearly display the boundary of the transplanted bone and the surrounding bone tissue. Thus CBCT has become the preferred imaging modality to observe the osteogenesis effect after alveolar bone grafting. CBCT allows the quantitative assessment of the residual alveolar bone graft based on the changes in the bone graft, which is important when determining the quality of the grafted bone.^{9,11} Volume rendering using CBCT and 3D reconstruction software is a reproducible and practical method to assess the outcome of alveolar bone grafting.

The purpose of this study was to systematically evaluate the osteogenesis effect of the GBR technique in alveolar bone graft surgery, as well as the resorption rate of bone grafts.

Patients and methods

Patients

A 3-month prospective study was performed. Sixty consecutive patients with complete unilateral alveolar clefts, who presented to the study institution for alveolar bone grafting surgery from February 2012 to December 2014, were included in the study. The patients were allocated randomly to one of two groups, based on a computer-generated random number assigned to the patient. In the GBR group, ADM film was used during alveolar bone grafting, whereas no ADM film was used in the non-GBR group.

All participants were assessed against defined inclusion and exclusion criteria. The inclusion criteria were (1) a confirmed diagnosis of non-syndromic congenital unilateral complete alveolar cleft without systemic or genetic disorders, (2) cleft lip and palate (CLP) repair surgery and alveolar bone grafting surgery with iliac crest bone grafting, (3) absence of a palatal fistula, infection, or bone graft exposure following alveolar bone grafting surgery. (4) clear 3D images of the reconstructed alveolar bone grafting areas were available. All surgeries were performed by a senior cleft surgeon using the same surgical technique. CBCT scanning was performed for all patients at 1 week and at 3 months (± 3 days) after the alveolar bone grafting operation. The exclusion criteria were (1) a confirmed diagnosis of syndromic congenital unilateral complete alveolar cleft with systemic and genetic disorders, (2) the presence of a palatal fistula, infection, or bone graft exposure following alveolar bone grafting surgery, (3) guardian refusal to sign the written informed consent on behalf of the patient.

Ethics statement

This investigation was conducted according to the principles expressed in the Declaration of Helsinki. Written informed consent was obtained from all of the participants and also from all of the guardians on behalf of the children enrolled in the study. The institutional ethics committee approved all protocols.

Surgical techniques

The procedure consisted of two basic components: ADM placement and bone grafting. The ADM heterograft (Heal-All; Zhenghai Biotechnology Co., Ltd, Yantai, China) was rehydrated in normal saline for 5 min before being placed firmly on the periosteal bed. The ADM film was then secured to the periosteum and surrounding connective tissue with absorbable sutures. Bone grafts were harvested from the iliac crest. Cancellous bone grafts of approximately $2-6 \text{ cm}^2$ were harvested using an osteotome.

After complete sub-periosteal dissection of the alveolar cleft, the nasal lining near the anterior nares was repaired with 4-0 Vicrvl sutures, followed by nasal lining repair in the hard palate. Watertightness of the nasal lining repair was confirmed by flushing diluted methylene blue through the nostril. Next, a piece of ADM was placed on the oral side of the nasal lining near the anterior nares and in the hard palate as an onlay graft, reinforcing the soft tissue repair. The cancellous bone graft, harvested from the iliac crest, was then packed tightly within the bony cleft. A second piece of ADM was placed over the cancellous bone graft. Finally, the oral mucosal repair was completed over the ADM with 4-0 or 5-0 Vicryl sutures.

For patients in the non-GBR group, bone grafting was performed without the use of ADM. Secondary bone grafting was performed by the same surgeon in accordance with the standardized method published by Perry et al.¹²

Image acquisition and analysis

Images of the bone graft area were obtained using a ProMax 3D device with tube voltage range of 60-84 kV, tube current range of 9-16 mA, exposure time of 6 s (high-frequency pulse exposure, cumulative exposure time), and image resolution no less than 2.0 line pairs per millimetre (lp/mm) (Planmeca Oy, Helsinki, Finland). Data were stored in DICOM format. 3D images were obtained by CBCT at 1 week and at 3 months (\pm 3 days) after surgery. For consistency, CBCT scans of all participants were performed by the same radiologist. Images were then uploaded into Simplant 11.04 software (Materialise Inc., Leuven, Belgium) to reconstruct the bone graft area of the alveolar cleft. Measurements were repeated three times on different days with no reference to the original data. The average of the three measurements was used for the final data analysis.

Measurement of the bone graft volume

The boundary between the bone graft and the native bone could be seen clearly on the images. The bone graft area was outlined in the coronal, sagittal, and horizontal views (Fig. 1). Every plane was labelled layer by layer. The labelled planes were accumulated and imported into Simplant 11.04 software. 3D images were reconstructed automatically. Finally, the volumes of the bone grafts were calculated (Fig. 2).

Statistical analysis

A paired *t*-test was used to compare the absorption rates of the bone graft between

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