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Effect of maxillary alveolar reconstruction on nasal symmetry of cleft lip and palate patients: A study comparing iliac crest bone graft and recombinant human bone morphogenetic protein-2

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Summary *Background:* Recombinant human bone morphogenetic protein (rhBMP)-2 has been used in some craniofacial centers worldwide. However, its influence on nasal morphology is unknown. Thus, the objective of this investigation was to assess the effect of maxillary alveolar reconstruction on nasal position and symmetry in unilateral complete cleft lip patients who underwent traditional iliac crest bone grafting transferring versus reconstruction using rhBMP-2.
Methods: Nineteen unilateral complete cleft lip patients were randomly divided into two groups. In group 1, patients underwent traditional iliac crest bone grafting transferring ($n = 11$) and in group 2, patients underwent alveolar reconstruction using collagen matrix with lyophilized rhBMP-2 ($n = 8$). Computerized tomography (CT) imaging was performed preoperatively and at 6 months postoperatively using a previously standardized protocol. Linear distances using anatomic landmarks were performed using tridimensional CT data reformatted by the OsiriX® software. Quantitative and qualitative measurements to assess intra- and inter-group nasal position modifications were performed.
Results: Intra-group pre- and postoperative comparisons showed significant differences ($p < 0.05$) in two linear measurements of group 1, while group 2 did not present a difference ($p > 0.05$). Group 2 presented significant postoperative enhancement ($p < 0.05$) in the

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quantitative nasal symmetry in one measurement. Qualitative analysis showed postoperative nasal symmetry enhancement in 75% of the measurements of group 2 and 36% of group 1. There was no statistically significant difference in the inter-group comparisons.
Conclusions: Our study demonstrated that both groups showed similar effect on nasal symmetry.

Introduction

Unilateral cleft lip nasal repair is challenging because of the complexity of the deformity.[1,2] This three-dimensional deformity involves several structures such as: the alar base, the alar cartilage (the medial and lateral crus), the nasal dome, the columella, the nasal septum, and the skeletal base, which includes the alveolus, maxillary segments, and palate.[1] Thus, to obtain the realistic treatment goal (normal appearance and function, with better symmetry, balance, and less scarring), both skeletal and soft-tissue structures must be adequately managed.[1,2] In fact, the open alveolar gap and the hypoplastic maxilla have been described as two major problems in achieving consistent, favorable results following cleft lip nasal repair.[1]

Alveolar bone grafting is an essential procedure in the overall osseous framework rehabilitation of patients with unilateral cleft lip alveolus, with or without cleft of the secondary palate.[3] Among numerous donor sites, cancellous iliac crest bone grafting at the time of cuspid or lateral incisor root formation has proven to provide consistently excellent, stable long-term results and has become the standard approach for filling maxillary alveolar clefts.[4,5] However, as donor-site morbidities such as acute and chronic pain, infection, hemorrhage, and nerve injury are quite significant,[3] many investigations have been conducted to evaluate bone substitutes.[6]

In this context, our group[7,8] and others[9,10] have reported the successful use of the recombinant human bone morphogenetic protein (rhBMP)-2 for alveolar cleft repair in skeletally mature and immature patients. Alveolar cleft repair using rhBMP-2 had the same overall success as traditional iliac crest bone grafting.[710] Additionally, this bone tissue engineering approach spares the need of a donor site, while excellent results can be obtained, with reduction of the surgical time and overall financial costs.[7–10]

Within the specific management of the cleft lip nasal deformity, the alveolar osseous graft has been used for restoring the maxilla at the piriform rim, providing improved stability and aesthetics by supporting the alar base.[3] Even though previous studies[11–19] have demonstrated nasal changes (nasal morphology, symmetry, and nostril shape) following alveolar bone grafting, it is unclear, however, how the rhBMP-2 influences the nasal symmetry.

Such previous information led us to hypothesize that the positive effect on nasal symmetry generated by the inclusion of rhBMP-2 in the maxillary region does not differ from the effect yielded by autologous bone transferring from the iliac region. Thus, the purpose of this investigation was to assess the effect of maxillary alveolar reconstruction on nasal position and symmetry in unilateral complete cleft lip patients during secondary dental eruption, comparing resorbable collagen matrix with rhBMP-2 versus traditional iliac crest bone grafting approaches.

Methods

A retrospective study of 24 consecutive non-syndromic unilateral complete cleft lip patients, who underwent alveolar cleft repair between 9 and 12 years of age, was conducted at a single Brazilian Craniofacial Surgery Unit between 2010 and 2012. The data were started to be collected in 2010 resulting in a previous publication.[7]

All patients previously underwent primary rhinocheiloplasty between 3 and 6 months of age, according to the modified technique described by our group,[20] and underwent palate repair at 1 year of age. Before secondary alveolar cleft repair, all subjects underwent preoperative orthodontic expansion of maxillary segments and were randomly assigned to group 1 (traditional iliac crest bone grafting transferring) or group 2 (reconstruction using collagen matrix with lyophilized rhBMP-2). No revision of lip surgical repair was performed during secondary alveolar cleft repair. All patients ($n = 5$) who did not have adequate computed tomographic documentation, previous eruption of the canine, previous alveolar or nasal surgeries, and/or incomplete follow-up were excluded from the study. Additionally, complications such as infections, wound dehiscence leading to bone graft loss or rhBMP-2 exposure were recorded.

All subjects were enrolled upon a consent form signed by their parents, in accordance with the Helsinki Declaration of 1975, as amended in 1983. A local institutional research ethics board approval was obtained for this study.

Surgical procedures

All surgical interventions were performed by the same senior surgeon (N.A.) in a standard fashion. Key information included below and additional details were previously described by our group.[7,8]

Iliac crest bone graft (group 1) and collagen matrix with lyophilized rhBMP-2 (group 2) were placed in the maxillary alveolar defect after wide exposure of the cleft area. In group 1, through a 3-cm incision, a cortical bone trap door was raised and hinged on the inner edge of the iliac crest and enough chips of cancellous bone (20—40 mL) were then removed. In group 2, rhBMP-2 was reconstituted with distilled water and impregnated the supplied absorbable