

Long-term stability of alveolar bone grafts in cleft palate patients

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Introduction: Many authors have examined the surgical bone treatment of cleft palate patients, but no study has emphasized the role of orthodontic therapy. The aims of this study were to evaluate the long-term stability of bone grafts when using an orthodontic-surgical protocol, to determine the success of bone grafts in minor vs severe clefts, and to develop a qualitative method for assessing the success of bone grafting. **Methods:** Forty-nine patients were included in this study. Occlusal x-rays were taken before (T0), immediately after (T1), and at least 1 year after bone grafting (T2). Two radiographic parameters were analyzed adjacent to the cleft side: the vertical bone level (Bergland scale) and the horizontal bone level (Witherow-derived scale). **Results:** The bone graft success at T2 was 91.84% (95% confidence interval, 84.55-96.41). The severity of the cleft before grafting was not statistically correlated with success at T2 ($P < 0.05$). The concordance rate between Bergland and Witherow values was 87.07% (95% confidence interval, 82.69-90.69). The variables analyzed (sex, age, type of cleft, lateral incisor agenesis) were not statistically correlated ($P < 0.05$) with the stability of bone graft. Based on the results, the only factor involved in the stability of the graft seems to be dental age at the time of bone grafting and the orthodontic therapy before and after grafting. **Conclusions:** It seems appropriate to recommend early application of a surgical-orthodontic protocol to treat cleft lip and palate patients, prevent postoperative bone resorption, and guarantee correct positioning of the teeth. (Am J Orthod Dentofacial Orthop 2012;142:289-99)

Many studies have examined the surgical bone treatment of cleft palate patients; however, only a small number of these have addressed the long-term stability of the alveolar grafts.¹⁻²⁰

There is a consensus among academic oral surgeons regarding the necessity of postponing bone grafting until the mixed dentition and then using a technique called "secondary bone grafting."¹⁻¹⁶ Boyne and Sands^{15,16} distinguished an "early" secondary bone grafting, usually performed between the ages of 2 and 5, and a "late" secondary bone grafting, usually after 5 years of age. This surgical technique has many advantages, including unified maxillary reconstruction and continuous alveolar formation, physiologic eruption of the teeth adjacent to the cleft, stabilization of cleft

fragments, opportunity for a rapid expansion of the midline suture, elimination of oronasal fistulas, and overall facial esthetic improvements.¹⁷ However, all surgical and grafting procedures can cause growth alterations with bone dysplasias that are more severe when the procedure is performed early.^{18,19} For this reason, Kuijpers-Jagtman and Long⁵ concluded that a critical and customized case assessment is necessary to determine the risks and benefits of the procedure.

Despite the many studies on the outcomes after secondary bone grafting, they have significant limitations, including reported success rates of less than 100%, small sample sizes, inconsistent inclusion and exclusion criteria, incomplete and heterogeneous clinical records, limited follow-ups, and subjective methods for assessing the success of bone grafts.^{17,20-26}

Many factors are involved in the success of alveolar bone grafting. The first important factor is the canine position and its eruption stage at the time of bone grafting. Several studies have demonstrated that the success of bone grafts decreases if the procedure is performed after canine eruption on the cleft side.^{21,23,25,27} The second fundamental factor is the role of the therapy protocol and the orthodontic role, which have not been explored in the literature.

The aims of this study were to evaluate the long-term stability of bone grafts with an orthodontic-surgical

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The authors report no commercial, proprietary, or financial interest in the products or companies described in this article.

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Submitted, July 2011; revised and accepted, April 2012.

0889-5406/\$36.00

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doi:10.1016/j.ajodo.2012.04.015

protocol, to determine the success rate of bone grafts in minor vs severe clefts, and to develop a qualitative method for assessing the success of bone grafting.

MATERIAL AND METHODS

In this retrospective clinical trial, we analyzed the records of 446 complete cleft lip and palate patients, recruited from the Regional Hospital of Vicenza (Italy), Cleft Palate Patients National Reference Centre, between 1994 and 2011. There was only 1 data manager (D.T.), and all records were digitized. The study population consisted of white patients matched for sex and age.

Patients were included in the study based on the following criteria: (1) congenital complete cleft lip and palate; (2) treatment with the protocol of the Regional Hospital of Vicenza and the University of Ferrara; (3) digital occlusal radiographs before (T0), immediately after (T1), and at least 1 year after bone grafting (T2); (4) performance of the alveolar bone graft by the same surgeon; (5) digital occlusal x-rays exposed with a standardized radiologic technique (long-cone technique and root direction perpendicular to the palatine midline, compared with 2 other projections, to prevent radiologic superimpositions, image artefacts, and interpretation errors) by the same radiologist; (6) standardized radiographic evaluations; and (7) informed consent from each patient. Patients were excluded if they had syndromic cleft lip and palate. A total of 117 patients met all inclusion criteria. The study was double-blinded, and the statistical analysis was performed by an external statistician. Of the 117 patients who met the inclusion criteria, 68 were excluded for various reasons, leaving 49 patients in the study cohort (Table I). A flow chart of the study participants is shown in the Figure. Table II gives the sex distribution. There were 45 unilateral and 4 bilateral clefts. Among the 45 patients with unilateral clefts, 15 were right sided, and 30 were left sided. Thirty-two patients demonstrated lateral incisor agenesis, and 8 patients had agenesis of other teeth, contralateral to their clefts.

All patients had a surgical-orthodontic protocol in accordance with the Regional Hospital of Vicenza and the Postgraduate School of Orthodontics at the University of Ferrara in Italy. The chronologic order of the treatment, according to the protocol, is outlined below.

1. At birth: placement of a passive palate plate, constructed of soft resin.
2. At 3 months of age: soft-palate surgery²⁸⁻³⁰ and lip and nostril surgery³¹ with definitive lip repair.
3. At 6 months of age: unilateral and bilateral rhinoplasty.³²

Table I. Patients excluded from the study

| | <i>Patients (n)</i> |
|---------------------------------------|---------------------|
| Impossible to find radiographs | 5 |
| Preoperative radiographs not exposed | 10 |
| Postoperative radiographs not exposed | 22 |
| Bone graft unnecessary | 8 |
| Bone graft not currently performed | 5 |
| Digital radiographs not exposed | 18 |
| Patients excluded from study | 68 |

4. At 8 to 12 months of age: initiation of speech therapy.
5. At 18 to 20 months of age: hard palate surgery³⁰ and continuation of speech therapy.
6. At 5 years of age: placement of a hyrax-type rapid palatal expander bonded onto the deciduous teeth, with palatal and buccal arms reaching to the canines, activated at a quarter turn per day. The average activation period depended on the degree of maxillary constriction. A 2- to 3-mm overcorrection at the molars was recommended to counteract relapse. Immediately after the expansion, a maxillary traction device (Delaire mask) was applied with 450 g of force per side for 14 hours per day for 7 months. The rapid palatal expander was passively maintained in the mouth for 1 year after the expansion.
7. At 6 to 9 years of age: placement of a passive transpalatal bar (0.036-in wire) bonded onto the first permanent molars (to prevent transverse relapse) and continuation of speech therapy.
8. At 9 to 11 years of age: placement of an alveolar graft in the cleft side, using bone from the iliac crest, once canine root development was between one fourth and two thirds of its final root length as identified on the occlusal x-ray.^{18,19,33}
9. At 9 to 15 years of age: orthodontic fixed therapy with preadjusted 0.022 × 0.028-in brackets to obtain alignment, leveling, malocclusion correction, and canine repositioning in the arch. Orthodontic therapy began when canine root development was between one fourth and two thirds of its final root length. Orthodontic appliances were kept in place through the transitional phase of the dentition until all teeth had erupted and definitive orthodontic treatment was completed, when all occlusal and functional goals of therapy were achieved.
10. At 18 years of age: plastic (lip revision, nose revision, rhinoplasty, nasal septum surgery, adenoid surgery, sinus mucous membrane surgery, scar surgery) or maxillofacial surgery and implantation if necessary. In this study, no patient received jaw surgery, plastic surgery, or implantation.

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