Clinical Paper

Cleft Lip and Palate and Palate

Early secondary closure of alveolar clefts with mandibular symphyseal bone grafts and β-tri calcium phosphate (β-TCP)


Abstract. Alveolar reconstruction of bony defects in cleft lip and palate patients is a widely accepted treatment regimen for which multiple donor sites can be used. For 25 years, autogenous bicortical mandibular symphyseal bone grafts have been used at the authors’ centre. In cases in which the alveolar defect was too large to match the volume of the mandibular symphyseal bone transplant, β-TCP granules were packed against the bone transplant to fill the defect completely. In a retrospective study, 18 patients, who were treated with mandibular symphyseal bone wrapped in β-TCP granules, were compared with 29 patients, who were treated with mandibular symphyseal bone only. To assess alveolar height, occlusal radiographs were taken directly postoperatively and 1 year later. Mean alveolar bone loss was calculated and compared between groups using Student’s t-test and linear regression analysis. No statistically significant difference in alveolar height was found between the two groups. It was concluded that mandibular symphyseal bone grafts enriched with β-TCP granules can be used successfully in cases in which the alveolar cleft is too large to be grafted with mandibular symphyseal bone alone.

Secondary bone grafting of the residual alveolar cleft in patients with cleft lip and palate has become a well-established procedure. Successful grafting allows eruption of teeth into the former cleft area and the achievement of orthodontic movement of teeth adjacent to the cleft site, to obtain non-prosthetic rehabilitation. Secondary alveolar bone grafting (SABG) is ideally carried out between 9 and 11 years of age, before eruption of the maxillary canine. To allow the canine to erupt through the grafted site, a slight reduction in anterior vertical maxillary growth has been found after SABG. This effect is partially compensated by the capacity of the erupting canine to generate alveolar bone.

After bridging the alveolar cleft with bone, functional loading either by resumption of eruption of the canine or by orthodontic guidance into the new bone will help to maintain the bone graft. At present, autologous bone is the preferred material for closure of the osseous defect in the alveolar process. Iliac crest particulate cancellous bone is most commonly used for this purpose. Reports advocating the use of mandibular symphyseal bone, rib bone, calvarial bone and bone harvested from the tibia have been published. Harvesting an autologous bone graft has several disadvantages. Donor site surgery requires prolonged operating time and may cause morbidity.
effects of taking iliac crest bone transplants, such as hypersensitivity, pelvic instability, infection, and paraesthesia affect 10–30% of patients. The mandibular symphysis has been advocated as an alternative donor site, although it is associated with minor complications such as paraesthesia and apical root damage.

In the authors’ hospital, the SABG-procedure has been performed using a mandibular symphyseal bone transplant for 25 years. In most cases, the volume of the harvested bone was sufficient to fill the cleft region, but sometimes there was a shortage of bone. In those cases, the use of an alternative donor site was considered. To avoid the disadvantages mentioned above alloplastic materials are also an option.

In cases where a discrepancy was found between the volumes of the chin bone transplant and the alveolar defect, β-TCP granules were positioned at the buccal side of the graft and the remaining minor spaces, in such a way that the central part of the cleft region was always filled by autogenous bone, forming a bony bridge between the adjacent parts of the maxilla.

The aim of this study was to compare alveolar height and canine eruption between clefts grafted either with chin bone or with chin bone and β-TCP.

Material and methods

Patients

From April 1998 to December 2005, 182 patients with a cleft lip and palate underwent surgery for early secondary reconstruction of the alveolar process using a symphyseal bone graft. All patients were operated on by one surgeon. SABG was performed when one-quarter to one-half of the final root length of the adjacent canine was formed, as indicated by the radiographic appearance of a root length equal to that of the crown. In all cases the canine crown was still completely covered by bone.

β-TCP as an adjunct to autologous symphyseal bone was used in 31 patients (17%) of whom 18 patients, who had complete records, were included in this study. A control group of 29 patients, grafted with symphyseal bone only was taken at random from the remaining 151 patients. In case of a bilateral cleft, the clefts were scored as two solitary clefts. The inclusion criteria for the study were based on the presence of sufficient and accurate radiographs preoperatively, directly postoperatively and 1 year postoperatively. Exclusion criteria were radiographs of insufficient quality and inability to conform to the 1 year postoperative follow up.

Cleft surgery

All operations were performed under general anaesthesia. At induction, a prophylactic antibiotic regimen with cefazolin and metronidazol was given. Surgery began by infiltration of local anaesthetic with adrenaline 1:200,000 (Ultracain DS★) into the anterior vestibulum of both the lower and upper jaw and into the palatal foramen region of the maxilla. The cleft area was exposed subperiosteally by making vertical incisions along the edges of the cleft. On the buccal side the vestibular gingival sulcus incision was extended distally along the attached mucosa of the adjacent teeth to the second molar area. In this region, a buccal relieving incision with an additional periosteal relieving incision was performed. A mucoperiosteal transposition flap was created that covered the alveolar cleft and bone transplant in a tension free manner. At the cleft site, first the nasal mucoperiosteum was separated from the oral mucoperiosteal lining, then elevated and freed from the cleft site extending posterior along the nasal floor. The soft tissue nasal floor was reconstructed using 5–0 vicryl sutures. No tissue glue was used.

Grafting procedure

To harvest the mandibular symphyseal bone transplant, a marginal incision into the gingival sulcus along the lower incisors with two vertical relieving incisions in the canine region was made (Fig. 1). After deflecting the mucoperiosteum, the chin region was exposed. Keeping a minimal distance of 5 mm from the apices of the lower incisors to prevent damage, a rectangle was outlined in the symphyseal region between the developing canine teeth. By drilling a ‘through and through’ hole using a 2 mm round bur, a starting point was created. Then, using an oscillating saw with a small blade, a rectangular bone transplant was created leaving the

Fig. 1. Donor site procedure. (a) A complete thickness hole was created with a drill. (b) Using an oscillating saw a rectangular bone transplant was harvested. (c) The bicortical mandibular symphyseal bone graft was elevated, leaving (d) the lower border intact.
lower border of the symphysis intact. The bicortical mandibular symphyseal bone graft was elevated and then delivered by freeing it from the lingualy attaching muscles. Bone wax or a gelatin sponge were applied for haemostasis routinely. The mucoperiosteum was replaced and sutured with interdental interrupted stitches (3–0 Vicryl). No drains were used.

**Grafting of the cleft**

The mandibular symphyseal bone graft was reshaped and wedged into the alveolar cleft in such a way that the buccal cortex of the chin graft functioned as the buccal cortex of the reconstructed alveolus. In the control group the cleft was totally filled up. In the bucco-palatal direction the reconstructed area was the same or broader than the original alveolar width. In case this bucco-palatal dimension could not be achieved, additional bone substitute granules were applied to cover the positioned mandibular symphyseal bone graft to prevent resorption. A prerequisite was that at least a bony bridge was created between the two original alveolar bone segments (Figs. 2 and 3).

As bone substitute, β-TCP 1000–2000 μm particles (Cerasorb® Curasan AG, Germany) were used mixed with fresh locally derived autogenous blood to create a paste-like substance. If primary closure was impossible, palatal incisions were made from the anterior teeth posteriorly, parallel to the course of the greater palatine artery. Palatal flaps were created, mobilized and sutured together to close the palatal cleft. An extra oral submental elastic dressing was applied to create pressure over the chin region and removed after 5 days.

**Follow up**

Occlusal radiographs were taken preoperatively, and 1 week and 1 year postsurgically. Alveolar bone height was assessed on the two postsurgical radiographs (Fig. 4). The height of the alveolar bone in the cleft region was expressed as a percentage of the length of the root of the incisor adjacent to the former cleft. Taking the length of the root of the incisor as a reference, differences in magnification ratio and inclination of the ‘immediate’ postoperative and ‘late’ postoperative radiographs were corrected. By comparing the two radiographs the percentage of alveolar bone height loss could be determined.

To describe the postoperative status of the canine at the cleft side, its eruption was categorized as completely erupted, surgically assisted forced eruption or in eruption. All measurements were performed by two independent observers who were blinded for the treatment. In both groups medical charts were searched for postoperative complications.

**Statistical analysis**

From the measurements, the average alveolar bone height was calculated at the two ages for each group. Comparisons between the two groups were made using Student’s t-test to detect any statistically significant differences. The postoperative complication rate and the status of canine eruption were analysed. Fisher’s Exact test...
Table 1. Distribution of patients and patient characteristics.

<table>
<thead>
<tr>
<th>Patient data</th>
<th>Autogenous symphyseal bone</th>
<th>Autogenous symphyseal bone and β-TCP granules</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (clefts)</td>
<td>29 (31)</td>
<td>18 (22)</td>
</tr>
<tr>
<td>Mean age (year and month)</td>
<td>10.4 (range 8.9–13.5)</td>
<td>10.2 (range 9.3–11.7)</td>
</tr>
<tr>
<td>Male to female ratio</td>
<td>12–17</td>
<td>12–6</td>
</tr>
<tr>
<td>Uni-bilateral ratio</td>
<td>18–11</td>
<td>14–4</td>
</tr>
<tr>
<td>Left-right ratio (clefts)</td>
<td>16–15</td>
<td>10–12</td>
</tr>
</tbody>
</table>

In 9 patients only one site could be included due to overlap, which made tracing of the radiographs impossible.

Table 2. Association between canine eruption and bone grafting material (Fisher’s exact test P = 0.574).

<table>
<thead>
<tr>
<th>Canine eruption</th>
<th>Autogenous symphyseal bone</th>
<th>Autogenous symphyseal bone and β-TCP granules</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N</td>
<td>Percentage</td>
</tr>
<tr>
<td>Spontaneous eruption</td>
<td>12</td>
<td>38.7</td>
</tr>
<tr>
<td>Forced eruption</td>
<td>10</td>
<td>32.3</td>
</tr>
<tr>
<td>In eruption phase</td>
<td>9</td>
<td>29</td>
</tr>
<tr>
<td>Total</td>
<td>31</td>
<td>100</td>
</tr>
</tbody>
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Test was used to test if the type of grafting material had a significant influence on the eruption of the canine. P-values <0.05 were considered to be statistically significant. All statistical analyses were performed using SPSS version 16.0.1 software (SPSS Inc., Chicago, IL, USA, 2007).

Results

Patient characteristics of the two groups are given in Table 1. In all patients the maxillary dental arch was expanded orthodontically prior to bone grafting.

All operations were uneventful. In the control group, 3 cases with minor complications were found: one minor dehiscence and two small bony sequestrations. In the experimental group, 3 patients experienced leakage of not more than five β-TCP granules out of the nose during the first postoperative days.

The duplicate measurement error appeared to be 5%. In order to minimize the inter-observer variability, the mean scores of the two observers were used for the statistical analyses. The mean percentage of the immediate postoperative bone levels of the control group was 64% (SD 0.23; range 26–95%) and 66% (SD 0.18; range 33–95%) for the group of patients treated with β-TCP. No significant difference between groups was found for preoperative bone height (P = 0.650) using Student’s t-test. It was not necessary to correct for confounding by indication.

In order to explore the effect of β-TCP on alveolar height after 1 year, Student’s t-test was carried out. As result of the remodelling process, bone resorption and bone apposition were seen, resulting in an average of 1% bone resorption (SD 0.20; range −43% to +51%) for the control group compared with an average of 3% bone apposition (SD 0.25; range −32% to +36%) in the group of patients treated with a symphyseal bone transplant and β-TCP. No significant difference was found between the two groups (P = 0.306).

A Student’s t-test was performed to explore the effect of other variables on the percentage of bone resorption after 1 year. The derived P values for each of the variables were as follows: gender (P = 0.695), unilateral or bilateral cleft (P = 0.792) and side of cleft (P = 0.518).

Table 2 shows the fate of the canine at the cleft side. In order to investigate a trend in probabilities of an eruption disturbance across the two groups, Fischer’s exact test was applied. No significant association between eruption disturbance and grafting material was found (P = 0.574).

Discussion

Among the advantages of chin bone grafts are the accessibility of the donor site and the fact that no visible scars are made.9 One of the disadvantages is the relatively small volume of the graft, especially when a bilateral cleft is present.20 Owing to the relatively small chin prominence and the presence of unerupted canines, insufficient volume of bone may be found when broad clefts or bilateral clefts have to be grafted. The present series of 181 mandibular symphyseal bone grafts shows that the surgeon needed to augment the bone graft with other material in only 17% of the cases. Only 18 of 31 patients could be included in the present study due to incomplete follow up. Missing radiographs were the major reason for exclusion from the study so the authors think that, although the sample size is relative small, the results are not biased, but the results should be interpreted with caution.

Whether the size of the cleft influenced the results of this study cannot be answered by this retrospective study, since no absolute dimensions of the cleft were measured. One could assume that in the β-TCP-group the clefts were wider or the bone grafts had less volume than in the control group. This could have a negative effect on the remaining alveolar bone height disadvantaging the β-TCP-group. The results of this study, revealed no statistically significant differences between the clefts grafted solely with symphyseal bone and those grafted with symphyseal bone supplemented by β-TCP. Leakage of some β-TCP granules out of the nose during the first postoperative days was of no clinical consequence. Patients experienced no complaints and no infections were observed. The explanation for leakage is incomplete closure of the nasal layer.

To avoid the complications associated with bone grafting, the use of a bone substitute seems to be a logical step.24 Using a bone substitute when grafting the alveolar cleft before eruption of cleft-adjacent teeth means that the graft scaffold has to be resorbable as the teeth should be able to move into the graft either by resumption of eruption or by orthodontic interference.22,23 In a study by Horch et al.,24 SABG was performed using a mixture of autologous bone and β-TCP (ratio 1:1) in 27 unilateral and 2 bilateral cleft patients. They reported that maxillary growth, orthodontic tooth movement and eruption of canines were uncomplicated. In beagle dogs, it was possible, to move a
tooth orthodontically into an area of an alveolar ridge that had previously been augmented solely with anorganic bovine bone mineral (ABBM) particles (Bio-Oss\textsuperscript{®}).\textsuperscript{3} That study showed that comparable amounts (about 30%) of root resorption could be detected at the pressure side of the Bio-Oss\textsuperscript{®} -TCP and in the autogenous bone group. The finding that the augmented bone did not impede tooth movement in agreement with results by HOSSAIN et al.\textsuperscript{25} They moved maxillary incisors into bone compartments that had been augmented with autogenous bone or synthetic, sintered, -TCP ceramics. They noted that root resorption consistently occurred at the pressure side of the orthodontically moved teeth.

While it is unclear if bone substitutes cause root resorption during orthodontic tooth movement, the authors advocate an alternative approach. By packing -TCP granules against the transplanted mandibular symphysal bone, less interference with orthodontic movement and therefore less root resorption might be expected, compared with using a mixture of autologous bone and -TCP. This requires further investigation. A second possible advantage of packing -TCP granules against the transplanted mandibular symphysal bone may be that it protects the transplant from being resorbed. MAJORANA et al.\textsuperscript{27} showed the beneficial effect of block graft coverage using ABBM particles. In 26 patients who needed bone augmentation prior to implant placement, bone blocks from the chin or ascending ramus were placed onto the atrophied alveolar ridge. 12 blocks were covered with ABBM (Bio-Oss\textsuperscript{®}). Resorption of only 9% for sites treated with ABBM particles was reported, whereas sites without such a coverage demonstrated bone resorption of 18%. VON ARX & BUSER\textsuperscript{3} used ABBM filler material for block graft protection and not for osteopromotion. As the filler particles were placed onto the outer cortical portion of the block graft, osseous integration of the particles was not anticipated because of the lack of vascular supply from the block graft.\textsuperscript{30}

Radiographs, used in this study, were made with an interval of 1 year. During this period some of the patients received orthodontic treatment, so inclination of the adjacent incisor could be altered due to growth and orthodontic treatment. Together with different magnification factors this questions the reliability of the applied method. Assuming that the length of the adjacent incisor is constant, differences in the magnification ratio and inclination of the ‘immediate’ postoperative and ‘late’ postoperative radiographs were corrected. Root shortening due to root resorption during orthodontic treatment might influence the measurements and this is one of the shortcomings of a two-dimensional (2D) radiographic evaluation.

To overcome the limiting factors of conventional radiographs such as distortion, the lack of reliable landmarks and superimposed structures computed tomography (CT) can be used to determine bone volume achieved with bone grafting.\textsuperscript{12,19,36,38} The advantage is that the cleft can be visualized in three dimensions and a high level of standardization can be achieved.\textsuperscript{38} ROSENSTEIN et al.\textsuperscript{32} compared periapical and occlusal radiographs with three dimensional (3D) calculations from CT scans regarding bony support for cleft-adjacent teeth following early alveolar bone grafting. They concluded that conventional radiographs were in excellent agreement if the CT scan indicated extremely good bone support (>90%) or extremely poor bone support (<50%). In the middle range of bony support (70–90%), there was more variability in the agreement between both methods.\textsuperscript{32} The present study gives a first impression of the use of -TCP in the early secondary closure of alveolar clefts, but the use of volumetric measurements in a prospective setting would enrich the results.

This study suggests that mandibular symphysal bone grafts enriched with -TCP granules can be used successfully in cases in which the alveolar cleft is too large to be grafted with mandibular symphysal bone alone. Using this technique, the indication for autogenous mandibular symphysal bone grafts can be expanded to cleft sizes for which iliac or rib bone grafts were used previously. Orthodontic therapy is not hampered by using -TCP, as the cleft-sided canine still can be moved into its proper position. Owing to the shortcomings of 2D X-ray evaluation, a 3D volumetric evaluation of the use of -TCP in early secondary closure of alveolar clefts, is necessary to confirm these preliminary results.

**Competing interests**

None declared.

**Funding**

None.

**Ethical approval**

Not required.

**References**


14. **DAMIEN CJ, PARSONS JR.** Bone graft and bone graft substitutes: a review of current
Early secondary closure of alveolar clefts with mandibular symphyseal bone grafts and β-tri calcium phosphate (β-TCP)