Rehabilitation of Patients with Congenital Unrepaired Cleft Palate Defects Using Free Iliac Crest Bone Grafts and Dental Implants

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Purpose: *To rehabilitate the mastication and speech of edentulous congenital cleft lip and palate patients with the use of endosseous implants in conjunction with bone augmentation.* ***Materials and Methods:*** *Between 1992 and 1999, 6 partially and 4 completely edentulous adult patients with complex cleft palate defects were treated. Six patients had large, unrepaired defects of the hard and soft palate, whereas the other 4 had residual oronasal fistulas after failed palatoplasty and bone grafting. In 8 patients, free inlay-antral and simultaneous lateral-onlay bone grafts (3 patients) were obtained from the iliac crest, and dental implants were placed secondarily. In the other 2 patients, the implants were placed without grafting in recent extraction sites. Rigid bars with extensions over the defects were used to support obturator prostheses (n = 7), or patients were provided with fixed implant-supported prostheses (n = 3). In all, 50 cylindric, screw-type dental implants were placed and followed up for 1 to 8 years (mean, 5 years).* ***Results:*** *Six implants were regarded as early failures and 1 was lost during the first year of loading; 1 patient lost all 5 implants. The cumulative success rate at 5 years was 85.7%.* ***Discussion and Conclusion:*** *All 9 successfully rehabilitated patients reported a remarkable functional and psychologic improvement after the treatment. The described treatment protocol also seemed to be effective for correcting velopharyngeal insufficiency in patients using an obturator prosthesis.* (Int J Oral Maxillofac Implants 2002;17:573–580)

Key words: *bone grafting, cleft lip and palate, dental implants, osseointegration*

The incidence of isolated congenital cleft palate (CP) defects in Finland is one of the highest in the world (1.21 per 1,000 live births). In addition, the incidence of cleft lip with or without CP is 0.95 per 1,000 births. Complex defects of the lip, alveolar crest, and hard and soft palate constitute 25% of all cleft lip and palate defects.[1] Advances in surgical techniques during the last decades have remarkably reduced the functional and cosmetic handicap in CP patients. Typically, bony defects can be primarily closed in infancy, resulting in small residual oronasal fistulae, if any, thus improving the quality of speech and avoiding rhinolalia. Early surgical corrections of the upper lip create a more harmonic facial appearance, while malposition of the alveolar segments and maxillary retrognathia can be corrected later by orthognathic surgery.

Among elderly patients in Finland, however, large surgically unrepaired defects are not uncommon. Functional disturbances are remarkable, especially if the patient is nearly or completely edentulous. The clinical problems are similar to those of patients who have undergone ablative tumor surgery in the maxilla. Dysphagia, in controlling the leakage of oral fluids, hypernasal speech, compromised chewing ability, and esthetic disturbances are the typical findings in adult edentulous CP patients.

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Most CP patients suffer from poor retention and function of obturator prostheses.

Osseointegrated implants have been proven reliable in the rehabilitation of different stages of edentulism for 30 years.[2–4] In the 1990s, applications of this method were used as an aid to restore acquired jaw and craniofacial defects, even in irradiated tissues.[5,6] In contrast, reports on the use of osseointegrated implants in congenital CP patients have been rare. Most of these studies have dealt with the reconstruction of alveolar clefts with local bone grafts and implants,[7–10] whereas treatment of complex open CP defects has received less attention. Arcuri and coworkers,[11] Jansma and associates,[12] Lilja and colleagues,[13] and Tolman and coworkers[14] have described several patients and, recently, Brånemark and associates[15] reported on 18 complex CP patients treated in Bauru, Brazil. The aim of this retrospective study was to evaluate the outcome of implant rehabilitation in a sample of edentulous adult CP patients collected from a population of 350,000 inhabitants of southwestern Finland.

MATERIALS AND METHODS

Patients

Four completely and 6 partially edentulous congenital cleft lip and palate patients were enrolled for the retrospective clinical evaluation. The 10 patients (6 men and 4 women; mean age 54.3 years) were referred to the Department of Oral Diseases, Turku University Central Hospital, for the treatment of complex unrepaired CP defects and the attendant lack of retention of obturator prostheses (n = 8) or loss of abutment teeth for tooth-supported, fixed prostheses (n = 2). All patients had undergone multiple attempts at closure of oral fistulae and bone grafting in youth or infancy. The oronasal or oroantral communication of 4 patients had been partly closed with palatoplasty, and only small residual fistulae were observed (group A). The other 6 patients had open, complex hard and soft palate defects (group B). Patients with open defects did not accept proposed secondary palatoplasty. Therefore, the implant-supported prosthesis was needed not only for masticatory purposes, but also for speech, hygiene, cosmetic, and psychosocial reasons as well. The clinical data of the patients are presented in Table 1.

Treatment Protocol

The treatment plan was based on a team approach. The team consisted of an oral and maxillofacial surgeon, a prosthodontist, an anesthesiologist, a maxillofacial radiologist, and a speech therapist. Panoramic images and cross-sectional cuts were obtained for all patients preoperatively using the Scanora multimodal radiography system (Soredex/Orion, Helsinki, Finland) for the assessment of bone volume and overall status of the dentition and jaws. In only 2 patients was the amount of maxillary bone found to be sufficient for the placement of oral implants without grafting procedures. These partially edentulous patients were treated according to routine methods. Recent extraction sites were allowed to heal 4 to 5 months before the placement of endosseous Brånemark System implants (2-stage surgery; Nobel Biocare, Göteborg, Sweden; patient TL) or ITI implants (1-stage surgery; Institute Straumann AG, Waldenburg, Switzerland; patient HE). The implants were allowed to integrate for 6 months before loading. These patients were provided with fixed implant-supported prostheses.

In the other 8 patients, the treatment protocol included inlay-antral augmentation with a free, bone-milled, corticocancellous iliac crest graft and simultaneous lateral onlay blocks (3 patients). The graft was harvested from the ilium according to an approach described by Keller and Triplett.[16] The endosseous Brånemark System implants were placed secondarily 6 months later, after remodeling of the previously placed bone grafts. The obturator prosthesis was necessary for deglutination, speech, and social competence of the patients included in group B. The patients were treated with a temporary obturator prosthesis 1 to 2 weeks after both the augmentation and implant placement. The prosthesis was relined with temporary tissue conditioning material (FITT, Kerr Italia, Salerno, Italy) at 2-week intervals for up to 3 months to avoid pressure on the recent augmentation/implantation sites, after which it was relined in the usual way.

The implants were allowed to integrate for 6 to 8 months before loading. Milled or prefabricated rigid bars were constructed over the defects to connect the implants and provide support and retention for the prosthesis (Figs 1a to 1g). The obturator was attached to the implant-bar with clips (CM-rider, Sjöding, Stockholm, Sweden) or Ceka attachments (Type C 723, Antwerp, Belgium). Patients with large, open defects were evaluated and instructed by a speech therapist after prosthodontic treatment (group B).

Follow-up

The following data were registered: surgical complications; implant data (number, type, length, failures, or other complications); marginal bone resorption rate; and prosthetic complications. The clinical evaluation was carried out twice a year for up to 3 years

Table 1 Patient Characteristics

Patient (age/sex)	Type of cleft defect	Status after implant placement	Implant data and type of prosthesis after treatment
Group A			
TL (52/M)			3.75 × 13, 3.75 × 13, 3.75 × 15 (Nobel Biocare) Implant-tooth–supported obturator
MB (36/M)			3.75 × 18, 3.75 ×13, 3.75 × 13, 3.75 × 18, 3.75 × 18 (Nobel Biocare) Fixed implant-supported prosthesis
HE (36/M)			4.1 × 10, 4.1 × 12 (ITI) Fixed implant-supported prosthesis
MA (45/F)			3.75 × 15, 3.75 × 15, 3.75 × 13, 3.75 × 15, 3.75 × 15, 3.75 × 15 (Nobel Biocare) Implant-supported obturator
Group B			
HL (74/M)			3.75 × 15, 4.0 × 15, 4.0 × 15, 4.0 × 13, 4.0 × 13 (Nobel Biocare) Implant-supported obturator
KH (63/M)			3.75 × 15, 3.75 × 15, 3.75 × 15, 3.75 × 15 (Nobel Biocare) Implant-supported obturator
JS (52/M)			3.75 × 15, 3.75 × 15, 3.75 × 13 (Nobel Biocare) Implant-tooth–supported obturator
ST (58/F)			3.75 × 15, 3.75 × 15, 3.75 × 13, 3.75 × 13, 3.75 × 15, 3.75 × 15, 3.75 × 15 (Nobel Biocare) Implant-supported obturator
RA (59/F)			3.75 × 15, 3.75 × 15, 3.75 × 13, 3.75 × 15, 3.75 × 15, 3.75 × 15 (Nobel Biocare) Fixed implant-supported prosthesis
UR (68/F)			Removable mucosa-supported obturator

Group A = small, cleft-related residual fistuale; group B = unrepaired, large, oronasal communications.

Figs 1a to 1g Patient KH, a 63-year-old male with bilateral cleft of the hard and soft palate.

Fig 1a *(above)* Clinical photo of patient before restoration.

Fig 1b *(middle)* Schematic presentation demonstrates the complete lack of premaxilla.

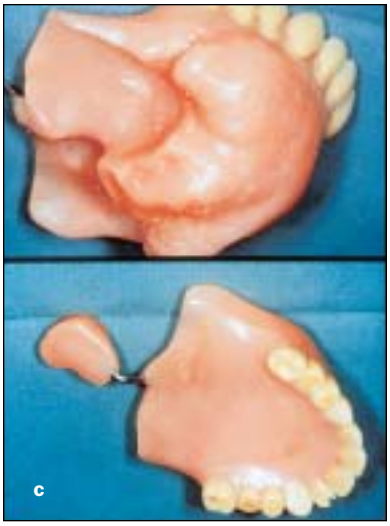
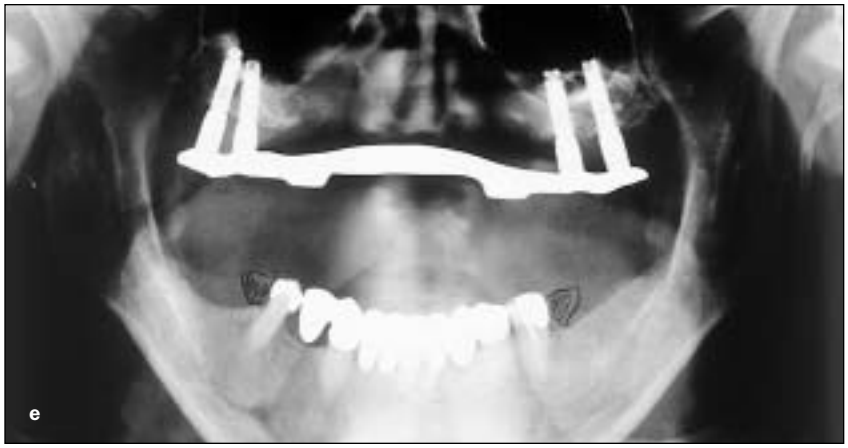


Fig 1c *(right)* The large complete denture-obturator had insufficient retention and stability, thus compromising chewing, speech, and swallowing.



Figs 1d and 1e Four implants were placed in residual maxillary bone 6 months after bilateral inlay-antral augmentation. The graft was harvested from the hip. Note the extremely small amount of basal bone prior to implantation.

Figs 1f and 1g The implants were connected with a milled bar, which extended over the defect and supported the obturator-prosthesis.

and annually thereafter. The bars were unscrewed at each appointment. Narrow-beam radiography with the Scanora system was used for assessment of the marginal bone level and bone quality around the implants, as described before.[17,18] Functional (mastication, phonetic) and cosmetic changes were evaluated by patient questionnaires pre- and postoperatively using a visual analog scale (VAS).

RESULTS

Implant Data and Surgical Complications

Healing after bone grafting was uneventful, except in 1 patient, who had prolonged pain in the iliac crest and walking difficulties for up to 2 months. This patient also had the most challenging defect from the surgical and prosthetic perspectives (patient UR, group B). Wound dehiscence followed soon after implant placement, and although the mucosal dehiscence was treated successfully, 4 of 5 implants were lost at the time of abutment connection. The fifth implant failed later during the first year of loading. Two other patients lost 1 implant each at the time of abutment connection (patients MB and ST). Detailed implant data and the life table analysis are presented in Tables 1 to 3. The cumulative success rate for the implants at 5 years was 85.7% (follow-up of 1 to 8 years; mean follow-up, 5 years). One patient died 3 years after completion of the implant treatment (patient JS).

Prosthetic Rehabilitation

Nine of 10 patients had successful implant-supported prosthetic rehabilitation using the described technique. The patient who lost all of her maxillary implants (patient UR, group B) experienced improved oral function after the edentulous mandible was rehabilitated with an implant-supported overdenture. Another patient (patient RA, group B) did not adapt to the obturator prosthesis, so the prosthesis design was changed to a conventional fixed, implant-supported prosthesis during the follow-up period. Finally, 3 patients were rehabilitated with fixed, implant-supported prostheses and 7 with removable obturator prostheses (Table 1). The functional changes estimated on VAS scales are presented in Fig 2.

Marginal Bone Resorption

The radiologic follow-up period ranged from 2 to 7 years (mean 3.5 years). The mean annual bone resorption per implant by patient was 0.415 mm (SD 0.494; range 0.095 to 1.542 mm). In 1 patient the marginal bone resorption was associated with peri-implantitis (3.1 mm per implant after 2 years). This patient suffered from chronic anemia related to congenital myelofibrosis.

DISCUSSION

Rehabilitation of extremely atrophied edentulous maxillae is a therapeutic challenge. The most advanced surgical reconstruction techniques are required for patients with minimal basal bone volume (classes IV to VI, as defined by Cawood and Howell[19]) and for patients with congenital or post-traumatic clefts. The use of free onlay or inlay-antral-nasal bone grafts, in combination with

Table 2 Implant Life Table According to Patient Subgroups

Group/ patient	No. of implants placed (type of bone graft)*	No. of failed implants	Time of implant loss	Data of failed implants	Total no. of implants functioning (follow-up time in y)
Group A					
TL	3 (no grafts)	0	N/A	N/A	3 (4 y)
MB	6 (I + O)	1	Abutment connection	3.75 × 13 mm	6 (6 y)
HE	2 (no grafts)	0	N/A	N/A	2 (1 y)
MA	6 (I + O)	0	N/A	N/A	6 (5 y)
Group B					
HL	5 (I)	0	N/A	N/A	5 (5 y)
KH	4 (I)	0	N/A	N/A	4 (8 y)
JS	3 (I)	0	N/A	N/A	3 (5 y)
ST	9 (I)	1	Abutment connection	3.75 × 7 mm	8 (7 y)
RA	6 (I)	0	N/A	N/A	6 (4 y)
UR	5 (I + O)	5	Abutment connection (4) during first year (1)	3.75 × 13 mm (3) 3.75 × 18 mm (2)	0
Total	50	7			43

*I = inlay-antral graft; O = lateral onlay graft.

Table 3 Implant Life Table Analysis

Interval (y)	Implants at risk	Lost to follow-up	Failures during interval (%)	Cumulative failure rate (%)	Cumulative success rate (%)
Placement to loading	50	0	6 (12)	12	88
Loading to 1 y	44	0	1 (2.3)	14.3	85.7
1–2 y	41	0	0 (0)	14.3	85.7
2–3 y	41	2	0 (0)	14.3	85.7
3–5 y	39	0	0 (0)	14.3	85.7

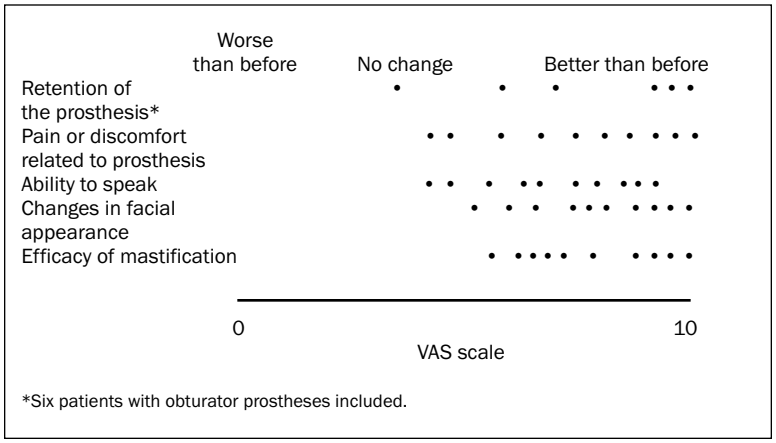


Fig 2 Influence of treatment on mastication, speech, and facial appearance, estimated on a VAS (graded 0 to 10).

implant surgery, is considered the appropriate approach for reconstruction of vertical bone deficiencies and to provide anchorage for an implant-supported dental prosthesis. In selected patients, Le Fort I osteotomy and interpositional grafts are indicated to correct retropositioning of the maxilla.[20,21]

In the earliest reports, only 60% to 70% of implants placed into onlay grafts survived.[22,23] Later, as a result of more refined techniques, the 5-year survival rate with onlay and interpositional grafts rose to 83% to 87%.[24,25] Implants may be placed in a 1-stage procedure or secondarily. Experimental and recent clinical data show that a 2-stage approach may be advantageous, with fewer complications and an acceptable survival rate.[25,26,27] However, Keller and coworkers[28] and Brånemark and associates[15] have described the successful use of onlay grafts with 1-stage implant surgery in patients with complex CP.

The sinus graft technique was presented in the 1970s, and several modifications of this technique have been developed.[29,30] Like onlay grafting, inlay-antral grafting is an acceptable approach only if the sagittal jaw discrepancies can be corrected by prosthetic means without inducing unfavorable loading on the implants. The reported long-term success rates of antral grafts are the same or even higher than with the use of onlay grafts.[29,31] In the current patient material, inlay-antral grafts were preferred for several reasons. First, the technique has lower morbidity, and it enables the early delivery of an obturator prosthesis after grafting. Second, lack of adequate soft tissue volume and elasticity, plus inadequate lip length or available vertical dimension, limit the use of onlay grafts for patients with cleft deformities. And, finally, the treatment team has long experience with this technique. The amount of residual bone in the present patients was extremely minimal, thus favoring a 2-stage approach to achieve primary stability for the implants.

Optimal timing for the placement of implants after bone grafting is currently unknown. The authors have routinely used a healing period of 5 to 6 months, although some clinicians seem to prefer a shorter healing period (3 to 4 months) to minimize resorption.[25] Obviously, the more important questions for long-term success are the quality of bone grafting material and adequate prosthetic loading. Regarding the advantages of autogenous iliac corticocancellous bone, the reader is referred to the discussion by Keller.[32] Particulate (milled) corticocancellous iliac bone has excellent osteogenic potential and is easily packed on the antral floor. The authors have experience of more than 200 inlay-antral grafts using particulate (bone-milled) iliac corticocancellous bone (unpublished data). Although not proved, the assumption is that resorption of autogenous bone is usually related to the quality of the bone graft, eg, the use of both cortical and spongious bone versus spongious bone only. Pure spongious bone seems to demonstrate more resorption (even complete resorption) during a 4- to 6-month healing period.

The surgical management of the grafted subjects was identical. In contrast, prosthetic loading conditions were variable, and in some of the patients was far from optimal (Figs 1e to 1g). Long bar extensions, relatively few implants to carry the prosthetic load, and complex sagittal jaw relationships undoubtedly caused unfavorable biomechanical stress. The patients with the largest defects were provided with temporary obturator prostheses earlier than the patients with small fistulae. One of these patients lost all maxillary implants (patient UR). Although the primary reason for the failure remained unknown, a removable obturator may have induced unfavorable early loading on the implants. However, the social and functional disturbances related to delayed delivery of the obturator prostheses are marked and cannot be underestimated.

Wound dehiscence exposing the implant cover screws (which occurred after implant placement) was observed in the same patient (patient UR). The risk of poor soft tissue coverage caused by a limited amount of scarred, fibrotic soft tissues is a common surgical complication in CP patients and in patients with severe maxillary bone resorption in general.[28] Brånemark and associates[15] used iliac onlay grafts and reported several wound dehiscences after bone grafting in 18 CP patients. In this respect, the use of inlay-antral grafts may have some advantage. In the future, long implants placed in the zygomatic arch, as presented by Brånemark and associates,[15] could prevent these complications by minimizing the need for extensive grafting and could give additional skeletal support for the framework of the obturator prosthesis. Unfortunately, this technique was not available at the time when the most challenging patients of this study were treated (in the early 1990s).

CONCLUSION

The rehabilitation of edentulous CP patients with large unrepaired cleft palate or with smaller residual fistulae was carried out using free iliac bone grafts and dental implants. The results in this extremely compromised patient material are encouraging. However, placement of implants in the zygomatic arch, especially in patients with large CP defects, may have advantages over standard bone grafting and implantation techniques and should be further evaluated.

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