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Clinical Paper
Cleft lip and palate

The use of Medpor implants for midface contouring in cleft patients

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Abstract. Three-dimensional midfacial deficiency in cleft patients is common and is frequently connected to impairment of the aesthetic facial appearance. Different approaches to augment relevant facial regions are available. Alloplastic facial implants have been established as a viable alternative to autologous tissue augmentation in various circumstances. However, in cleft patients, the application of facial implants has rarely been reported. This retrospective study aimed to evaluate the use of Medpor implants for midfacial contouring in cleft patients. Fifty-one patients with orofacial clefts were assessed with regard to defined parameters. A range of Paranasal, Malar and Nasal Dorsum Medpor implants had been used. Unilateral cleft lip and palate (UCLP) represented the most common indication, followed by bilateral cleft lip and palate (BCLP). Bilateral implant insertion was performed as a general rule with few exceptions. Insertion of implants was frequently combined with other cleft-related surgical procedures. Even after orthognathic surgery, midfacial augmentation was implemented to specifically address residual volume deficiency, particularly in the malar region. The complication rate amounted to 4.9% (6/122 implants). Based on our findings, Medpor implants are reliable and long-term stable materials to successfully augment paranasal, subnasal and malar areas as well as a solid nasal dorsum material with few complications in cleft patients.

Key words: Medpor; facial implant; cleft; midfacial hypoplasia; paranasal; malar; nasal dorsum.

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Midfacial asymmetry and hypoplasia are among the typical characteristics associated with adolescent and adult cleft patients. These cleft-related facial features are multifactorial and are related to severity of the cleft expression, the genetically programmed maxillary growth deficiency and the correcting surgical techniques used[1,2].

While midfacial hypoplasia is expressed bilaterally in unilateral cleft lip and palate (UCLP), it is frequently more pronounced on the cleft-side[3]. The midfacial area is affected more symmetrically in patients with bilateral cleft lip and palate (BCLP) and cleft palate (CP)[1]. Restriction of midfacial growth typically presents with maxillary retrusion and skeletal class III malocclusion. Additionally, restricted prominence of the malar and paranasal region leads to a concave facial profile.

The impairment of skeletal midfacial support further contributes to the characteristic nasal deformities in cleft patients, such as displacement of the alar base, narrowing and asymmetry of the nostrils and impaired nasal tip projection[4].

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In traditional two-dimensional facial analysis, in particular with lateral cephalograms, the paramedian and lateral congenital volume deficiency is often overlooked, and hence not diagnosed or corrected.

Eliminating the collective cleft-identity involves therefore not only correction of nasolabial asymmetry in UCLP, or a shortened columella–philtrum complex combined with a widened nose in BCLP, but also the correction of the paranasal, infraorbital and malar hypoplasia.

Various surgical concepts address aesthetic and functional issues, associated with cleft-related midfacial deficiency and nasal appearance. Orthognathic surgery, secondary cleft-rhinoplasty and corrective procedures of the upper lip are well-established treatment options. However, despite the wide range of available reconstructive techniques, asymmetric and hypoplastic alterations of the midfacial area often remain a challenge.

For instance, achieving adequate nasal tip projection without excessive lengthening of the columella is not feasible as long as the paranasal and subnasal bones are severely retruded.

Maxillary advancement has been shown to have beneficial effects on the facial profile, particularly in the nasolabial region. Detailed three-dimensional soft tissue analyses in cleft and non-cleft patients identified significant volumetric midfacial changes related to LeFort-I osteotomies[5–7]. Although, LeFort-I advancement demonstrates soft tissue changes in the central midface, the extent of volumetric changes in the malar region remains controversial[6,8]. Adjunct zygomatic osteotomy and other more invasive orthognathic procedures have been used to specifically address malar deficiency[9–11].

Soft tissue volume augmentation[12] and skeletal onlay grafts allow for improvement of the midfacial profile in patients without skeletal malocclusion. Even in cases where orthognathic surgery is performed, residual paranasal and malar hypoplasia and asymmetry are common, thus, additional midfacial augmentation can be necessary to improve facial appearance and facial harmony[8,13–15].

Autologous tissue grafting is used to augment deficient midfacial sites, yet it only partly qualifies to sustainably reduce complex hypoplasia of the midface[16,17]. High aesthetic demands, a relatively high risk of resorption, unpredictable results in terms of volumetric changes, increased rates of displacement, donor site morbidity and elaborate surgery add to the complexity of these procedures[17,18].

Solid alloplastic facial implants were established as an alternative to autologous grafts in a wide range of aesthetic and reconstructive facial procedures[16,19,20]. Various materials of solid implants are currently available with specific designs for the respective anatomical areas. Common areas for facial implant placement include the chin, the mandible, the frontal and temporal region, the malar and paranasal region and the nose[16,19,21,22].

Besides silicone and Gore-Tex implants, solid porous, high-density polyethylene implants (Medpor) are used for facial augmentation[17]. Temporary and permanent augmentation of deficient facial contours and the nose are feasible regarding this specific implant material[19,23,24]. Orofacial cleft deformities are frequently listed as a potential field of application, however, only a small number of cleft patients were included in previous studies[16,19,23,25].

The aim of this retrospective study was to review our data regarding the use of Medpor implants in secondary cleft surgery, incorporating surgical technique, range of indications, area of placement, surgical pathways and rate of complications.

Material and methods

A retrospective analysis of the data regarding Medpor implant insertion in the context of secondary cleft surgery was performed.

Male and female cleft patients treated for secondary cleft-related nasal deformity and midfacial hypoplasia were included. The insertion of at least one solid Medpor implant to correct the midfacial and nasal deficiency was defined as inclusion criteria. Regular follow-up appointments were fundamental. Exclusion criteria consisted of placement of midfacial silicone and Goretex implants, insufficient follow-up attendance and inconsistency in medical records.

The intra-departmental cleft database was searched to identify the relevant patient cohort.

The obtained pool of patient-specific data including age, gender and underlying diagnosis was closely screened in terms of the aforementioned inclusion and exclusion criteria.

The following data was collated: incidence, distribution and localization of implants, surgical pathways in conjunction with alloplastic facial contouring, age distribution at implant insertion, combined surgical interventions with implant placement and the surgical technique. Complications such as inadequate augmentation, implant migration, fistulae, purulent drainage and removal of implants, due to infection were documented.

Results

Study population

In 24 male and 27 female patients, total 51, with a mean age of 25.6 years, augmentative procedures with solid Medpor implants were performed. Thirty-four of the patients included presented with a complete UCLP, 23 were left-sided. Eleven patients had a history of BCLP. Three patients with a unilateral cleft lip and alveolus (UCLA) received augmentation with alloplastic implants. Additionally, two patients with an isolated cleft palate and one patient with a cleft type Tessier II were among the study population (Fig. 1).

Localization and implant distribution

A total number of 122 Medpor implants were inserted. In detail, 63 paranasal implants, 38 Malar implants, 20 Nasal dorsal implants and one infraorbital rim implant were applied. The mean follow-up period amounted to 34.2 months with a range from 1 month to 106 months (Fig. 2).

The 63 paranasal implants were placed in 36 patients. UCLPs were found to be the

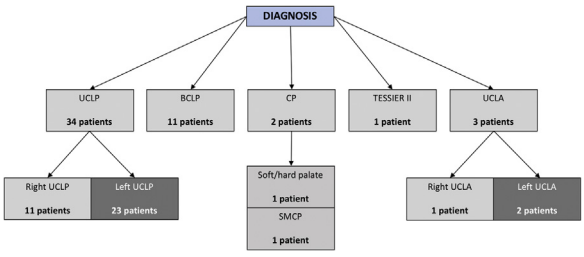

Fig. 1. Underlying orofacial cleft deformity associated with facial Medpor implant placement. BCLP, bilateral cleft lip and palate; CP, cleft palate; UCLA, unilateral cleft lip and alveolus; UCLP, unilateral cleft lip and palate.

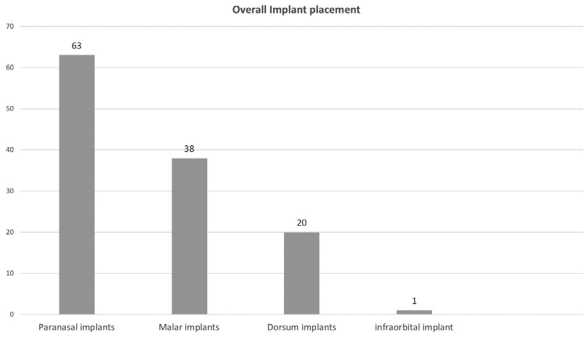

Fig. 2. Detailed breakdown of Medpor implants used.

most common indication for paranasal augmentation (39 implants/22 patients), followed by BCLPs (16 implants/nine patients). Bilateral implant insertion was performed in 75% (27/36 patients) of the patients, whereas unilateral placement of paranasal implants was carried out in 25% (9/36 patients). Regarding unilateral placement left-sided UCLP (55.6%; 5/9), BLCP (22.2%; 2/9), UCLA (11.1%, 1/9) and Tessier II (11.1%; 1/9) were the underlying diagnoses. In all of the patients, the 'petite' implant design was exclusively used (Table 1).

Malar implants were applied in 20 patients. Two patients (10%) underwent unilateral and in one patient this was combined with a unilateral paranasal implant. Twenty-four of 38 malar implants (66.7%) were inserted in UCLPs. The RZ-implant design was applied in the available sizes 'petite' and 'super-petite'.

Twenty patients were treated with nasal dorsum implants. This was carried out in the context of secondary cleft rhinoplasties. In 85% (16/20) the nasal dorsum implant was used in patients with a UCLP. The nasal dorsum implant 'design A' (small and large) was used.

Combinations of different surgical implants were common. In 51% more than one type of surgical implant was used.

A combination of bilateral paranasal and malar implants was most frequently applied (17.6%). Bilateral paranasal implants combined with a Medpor Dorsum implant were used in 16% of cases. Only one case had all of paranasal, malar and nasal dorsum implants (Fig. 3).

Surgical pathways

Three patient groups with regard to facial implant insertion were identified (Fig. 4).

The first group represented a supplementation of previous skeletal maxillary advancement. (Fig. 5). The implants were inserted at least 9 months after orthognathic surgery. Twenty patients (39.2%) underwent LeFort-I advancement in combination with a releasing mandibular osteotomy and consecutive implant placement. Malar augmentation was the most common adjunct (20 implants), 12 dorsum implants and 11 paranasal implants were also inserted. A detailed breakdown of underlying diagnosis and combination of different implants after orthognathic surgery is highlighted in Figs 6 and 7.

The second subgroup of patients were those who underwent midfacial contouring with Medpor implants without having had previous maxillary advancement surgery. Patients with no or minor skeletal class III malocclusion but hypoplastic

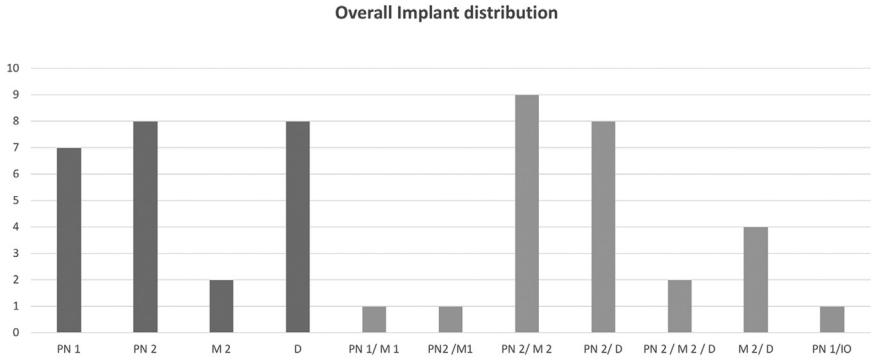

Fig. 3. Distribution and combination of Medpor implants in this study population. PN 1 = unilateral placement of paranasal implant; PN 2 = bilateral paranasal implants; D = Nasal dorsum implant; M 1 = unilateral malar implant; M 2 = bilateral malar implant; IO = infraorbital implant.

Table 1. Implant placement, relative to the underlying diagnosis.

Diagnosis	No. of patients	No. of implants	Paranasal implants 63			Malar implants 38			Dorsum implants 20	Other 1
			Bilateral	Unilateral	Total	Bilateral	Unilateral	Total		
UCLP			Pt (**Imp**)	Pt (**Imp**)	Pt (**Imp**)	Pt (**Imp**)	Pt (**Imp**)	Pt (**Imp**)		
Right UCLP	11	**28**	6 (**12**)	0	6 (**12**)	4 (**8**)	0	4 **(8)**	**8**	
Left UCLP	23	**53**	11 (**22**)	5 (**5**)	16.**(27)**	8 (**16**)	2 (**2**)	10.**(18)**	**8**	
UCLP total	34	**81**	17 **(34)**	5 (**5**)	22.**(39)**	12 (**24**)	2 (**2**)	**26**	**16**	
UCLA										
Right UCLA	1	**5**	1(**2**)	0	1(**2**)	1 (**2**)	0	1 **(2)**	**1**	
Left UCLA	2	**3**	1 (**2**)	1(**1**)	2 **(3)**	0	0		0	
UCLA total	3	**8**	2 **(4)**	1 (1)	3 (5)	1 (2)	0	1 **(2)**	**1**	
BCLP	11	**26**	7 **(14)**	2 (**2**)	9 **(16)**	4 **(8)**	0	8	**2**	
CP	2	**5**	1 **(2)**	0	2	1 **(2)**	0	2	**1**	
TESSIER II	1	**2**	0	1 **(1)**	**1**	0	0	0	0	1
TOTAL	51		27 pt (75%)	9 pt (25%)	36 pt	18 pt (90%)	2 pt (10%)	20 pt	20 pt	1 pt
		122	**54**	**9**	**63**	**36**	**2**	**38**	**20**	**1**
			85.7%	14.3%		94.7%	5.3%			

Detailed breakdown of uni- and bilateral implant placement. BCLP, bilateral cleft lip and palate; CP, cleft palate; Imp, implant; Pt, patient; UCLA, unilateral cleft lip and alveolus; UCLP, unilateral cleft lip and palate.

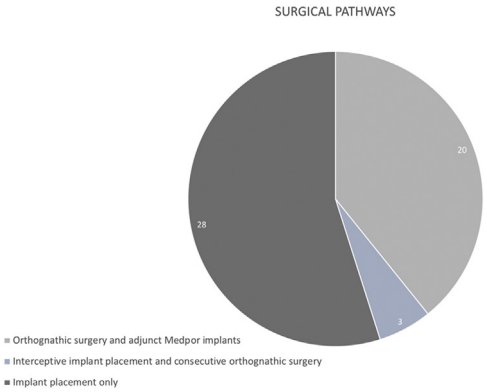

Fig. 4. Three surgical pathways were deployed. The chart shows the number of patients treated within each surgical pathway.

midfacial features qualified for this treatment pathway. This group (55%, 28/51) also included patients who had declined orthognathic surgery for personal reasons (Figs 8 and 9). In this patient cohort 73% of the paranasal implants, 42.1% of the malar implants and 35% of the nasal dorsum implants were inserted.

The third patient group included three cases (5.9%), in which midfacial implants were placed prior to orthognathic treatment as a temporary measure until the end of growth, when orthognathic surgery was performed[23]. Six paranasal implants, two malar implants and one nasal dorsum implant were inserted. The implants were removed in the context of the orthognathic procedure.

Accompanying surgical procedures and age at implant insertion

In only 7.8% of the patients, implant placement was performed as a stand-alone procedure. In 92.2% implant insertion was combined with at least one additional surgical intervention, performed in the same session. Most commonly this was a combination of Medpor implant placement with secondary cleft rhinoplasties (88.2%), scar revisions of the upper lip in 56.9%, and a plethora of other procedures (Figs 10 and 11).

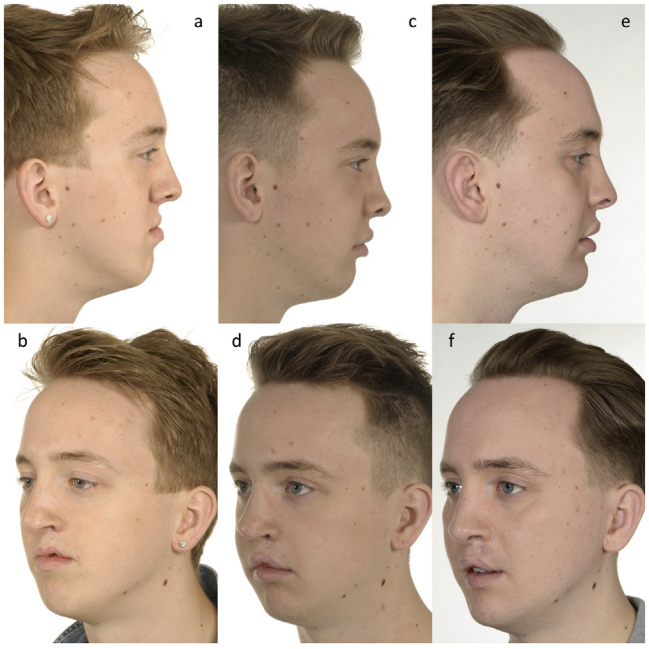

Fig. 5. Pre- and postoperative side-views of a patient with a left-sided unilateral cleft lip and palate, who underwent malar and nasal dorsum augmentation as an adjunct to bimaxillary surgery. (A, B) Pre-orthognathic view, showing skeletal class III malocclusion and lacking paranasal and malar prominence. (C,D) Post-orthognathic side-view. (E, F) Postoperative images showing the patient after malar and nasal dorsum augmentation with Medpor implants. Midfacial augmentation was combined with a genioplasty and a rhinoplasty in the same session.

The age distribution regarding implant placement was analysed in detail. Two patients (3.9%) were aged between 11 and 15 years. The age distribution shows a majority of cases between 21 and 25 years of age (Fig. 12).

Surgical technique

Implant placement was performed under general anaesthesia. Tranexamic acid, dexamethasone and antibiotics were administered intravenously at induction. Postoperatively two further doses of intravenous antibiotics were given. Oral antibiotics were continued over a course of 5 days.

Paranasal and Malar Implants

Access to the midface to insert the paranasal and malar implants, was accomplished via a labial mucosal approach. Wide subperiosteal tunnelling of the overlying soft tissue was performed, to establish adequate space to safely position the implants.

Prior to insertion, the Medpor implants were put into 50-ml syringes, filled with 80 mg gentamycin in 20 ml saline solution. A vacuum was repeatedly applied, until no air bubbles were observed escaping from the implants, which allowed the fluid to properly infiltrate the porous texture of the implant. The implants were accurately adapted to the underlying bone, to prevent gaps between their surface and the skeletal base. Titanium screws were used to fix the implants in position. The labial mucosa was sutured with Vicryl 4.0. In the subnasal region, a collagen membrane was regularly used to cover the subnasal portion of paranasal implants.

Nasal Dorsum Implants

Nasal Dorsum Implants Type A were inserted via an open rhinoplasty. The implants were placed subperiosteally. Most of the implants were secured with a titanium screw. Similar antibiotic pretreatment was performed.

Complications

Complications were seen in 9.8% (5/51) of the patients and 4.9% of all inserted implants (6/122). Infection occurred in 3.3% of all inserted implants (4/122), leading to removal of the implant in 2.5% (3/122). In 0.8% (1/122) systemic antibiotic treatment was sufficient.

One Dorsum implant, one Malar implant and two Paranasal implants were

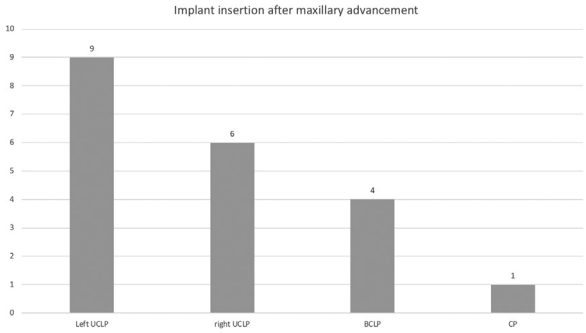

Fig. 6. Implant placement after orthognathic surgery.

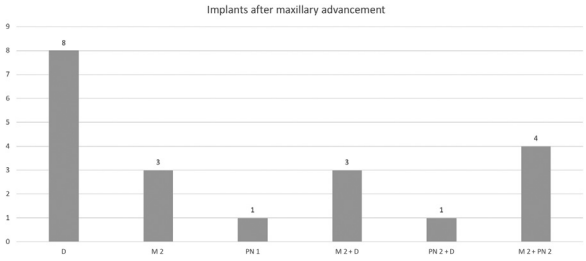

Fig. 7. Distribution and combination of implants after orthognathic surgery.

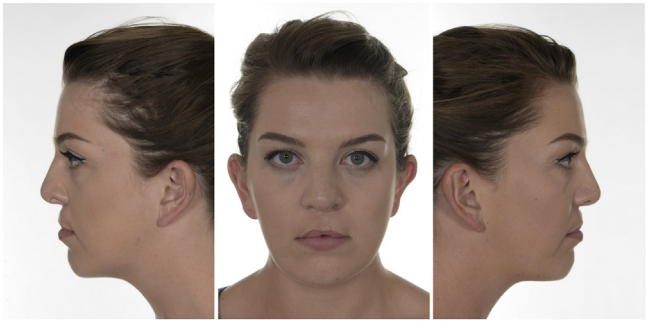

Fig. 8. Twenty-eight-year-old female patient with a left-sided unilateral cleft lip and palate, midfacial hypoplasia and a skeletal class III relationship. Orthognathic surgery was declined.

Fig. 9. Midfacial augmentation with bilateral paranasal and malar implants was performed. Additionally, a revision rhinoplasty and a minor lip revision was done in the same session.

infected, associated with swelling and purulent drainage. Implant removal due to infection averaged 19.7 months; displacement occurred in 1.6% (2/122) of all inserted implants. These were exclusively nasal dorsum implants, one of which was dislocated by trauma (Table 2).

Discussion

Facial augmentation with Medpor implants (Porex Surgical, Inc. College Park, GA, USA) is regularly used to correct midfacial volume deficiency. A relatively low risk of complications has been demonstrated[16,17,19,26]. The large pore size of 100–50 μm enables rapid vascular ingrowth, which contributes to the implants' integration and stability[19]. The implants can easily be trimmed and shaped during surgery allowing precise augmentation and the ability to compensate for facial asymmetry. The manufacturers recommend that the implant is screwed into place providing stability and a low rate of displacement.

Studies have described their use in patients with congenital deformities, including patients with orofacial clefts[16,19,23,25]. However, the numbers were small and the results include patients with midfacial hypoplasia of different aetiologies. Cenzi et al.[16] included 44 patients with congenital deformities in his analysis of 285 Medpor implants, of which only some were cleft patients. Menderes et al.[25] described nasal sill augmentation in two cleft patients. Yaremchuk et al.[19] included eight adult cleft patients in his study of 162 implants. To the best of the authors' knowledge, there are no papers that look specifically at the use of facial Medpor implants in cleft patients.

Fifty-one cleft-patients treated with facial Medpor implants were included in this study. Midfacial volume deficiency and less frequently asymmetry were indications of implant insertion. Malar, paranasal and nasal dorsum implants were used to augment deficient midfacial sites; one infraorbital rim implant was used for the treatment of a Tessier II cleft.

Midfacial augmentation was most commonly associated with complete UCLPs, followed by patients with BCLPs (Table 1). Insertion of implants was frequently combined with simultaneously performed cleft-related procedures, especially with corrective procedures of the lip and the nose. The combination of these procedures with implant insertion did not interfere with the feasibility of one another. On the contrary, facial implant placement

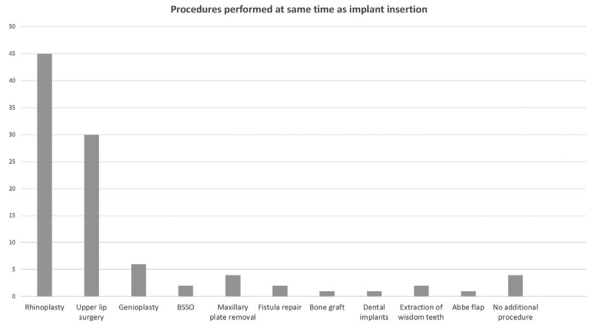

Fig. 10. Combination of implant placement with other cleft-related procedures, performed in the same operative session.

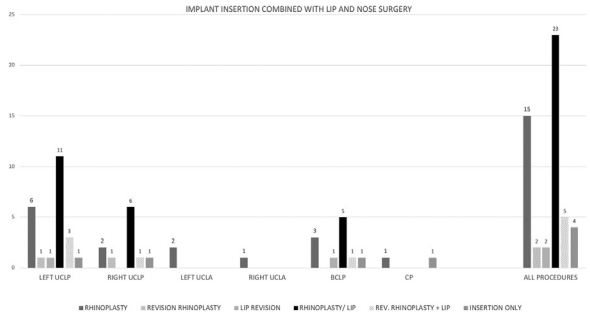

Fig. 11. Detailed breakdown of rhinoplasty and lip surgery combined with implant placement in relation to the underlying diagnosis.

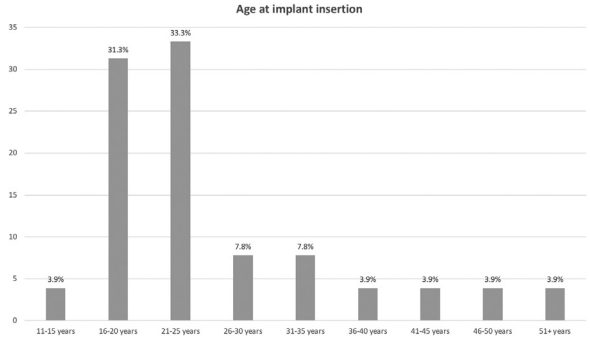

Fig. 12. Graph showing the age distribution at implant insertion.

seemed to facilitate nasal correction, improve upper lip posture and enhance facial profile.

Different approaches to reduce midfacial hypoplasia with the aid of Medpor implants were identified. In over 50% of the study population, implants were inserted without orthognathic treatment being required or planned (Fig. 13). It is not uncommon for cleft patients to decline the relatively lengthy course of orthodontics and surgery required for orthognathic surgery. In addition, in particular malar implants were regularly used to contour hypoplastic midfacial areas in patients who had previously undergone orthognathic surgery.

Despite the evidence of significant midfacial soft tissue changes following maxillary advancement, residual hypoplastic and asymmetric midfacial areas after maxillary advancement surgery are common[8,13,27].

Alloplastic facial implants have been used as a minimally invasive technique to specifically augment residual hypoplastic areas after orthognathic surgery[8,13,14]. In this study, 39.2% of the cases underwent midfacial augmentation following LeFort-I advancement.

Malar augmentation was frequently performed, with 52.6% of all malar implants inserted after maxillary advancement to specifically improve the lateral midfacial prominence. Yaremchuk et al.[8] even suggested further infraorbital augmentation in this context, as the infraorbital region commonly remains deficient after LeFort-I advancement, due to the design of the osteotomy. Following skeletal maxillary correction, 17.4% of the paranasal implants (11/63) were inserted into four UCLPs and two BCLPs. This was mainly performed during post-orthognathic cleft rhinoplasty procedures to give specific hard tissue support to the paranasal area and/or to correct an asymmetric skeletal base.

In 5.9% (3/51 patients) implant placement prior to orthognathic surgery was performed as an interceptive procedure. In particular, growing adolescents, who do not yet qualify for orthognathic surgery and choose not to undergo early maxillary advancement but are psychologically affected by their hypoplastic facial appearance, have been shown to benefit from temporary insertion to bridge the time to definitive correcting procedures[23].

Overall, paranasal implants were most frequently used. Paranasal augmentation showed similar effects on the soft tissues in the midfacial area as LeFort-I advancement. Volumetric changes were found to affect the malar and infraorbital region but were particularly accentuated in the nasolabial area[28].

On the basis of modern imaging techniques, the fabrication of patient-specific PEEK and Medpor implants to correct midfacial deficiency has been reported. Patient-specific implants qualify to specifically augment affected midfacial areas, without further need for elaborate adaptive processes[27,29,30]. However, high production costs and additional radiation exposure for three-dimensional imaging have to be considered. Whereas this can be justified in complex, e.g., post-traumatic conditions and skeletal defects, the standard implants still have a place in simple augmentation[30].

Diverging complication rates, ranging from 6% to 32%, were reported in the literature[16,17,19,21,25]. Certain implant locations have shown higher complication rates than others. Varying parameters have been considered as a complication, which makes it more difficult to draw comparisons. Infection rates range between 0.9% and 12.5%[17].

There are often less favourable surgical preconditions for midfacial implant insertion in cleft cases. Previously performed operations in the cleft region result in scarring and impaired blood supply. Discontinuities and fistulae of the nasal mucoperiosteum additionally increase the

Table 2. Rate of complications associated with insertion of Medpor implants.

Complications	Infection		Dislocation	Overall
Number of patients (51)	3 patients (5.9%)		2 patients (3.9%)	5 patients (9.8%)
Number of implants (122)	4 implants (3.3%)		2 implants (1.6%)	6 implants **4.9%**
	Removal	**Local/systemic Therapy**		
	3 implants (2.5%)	1 implant (0.8%)		
	2 patients	**1 patient**		
	Patient 1: right PN	**Patient 1:** Dorsum implant		
	Patient 2: right PN, right M			
Dorsum implants (20)		1 (5%)	2 (10%)	3 (15%)
Paranasal implants (63)	2 (3.2%)			2 (3.2%)
Malar implants (38)	1 (7.9%)			3 (7.9%)

The overall complication rate amounted to 4.9%. M, Malar implant; PN, paranasal implant.

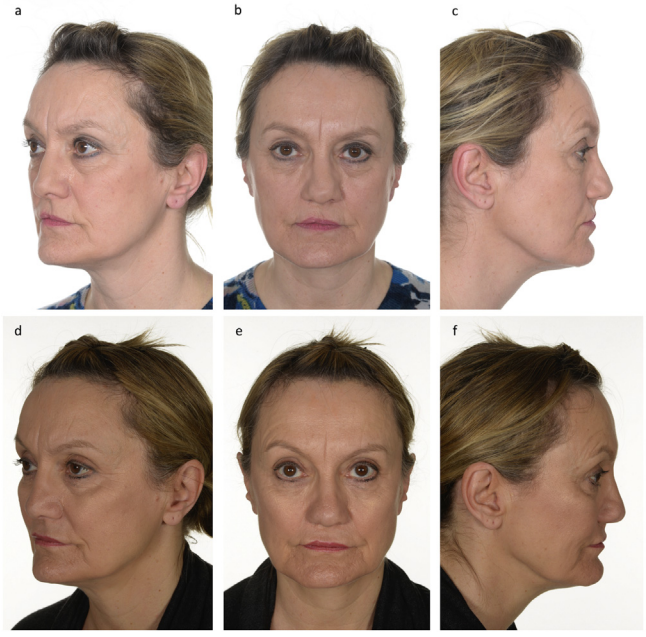

Fig. 13. Preoperative (A–C) and postoperative (D–F) side-views of a patient (unilateral cleft lip and palate) with malar Medpor implant insertion.

likelihood of implant contamination. These factors can lead to a higher risk of infection; hence, additional topical precautions were taken. Besides adequate surgical closure, elaborate antibiotic implant impregnation was performed. In 2014, a change in the surgical protocol was implemented, as the antibiotic treatment of implants was expanded from soaking only, to antibiotic vacuum impregnation. Occasionally a collagen membrane was used to cover paranasal implants adjacent to poor nasal and oral mucoperiosteal tissue.

In the study, a complication rate of 4.9% (6/122) was found. The study of Cenzi et al.[16] including several cleft patients, showed a complication rate of 6.31%.

In our series 3.3% (4/122) of all inserted implants showed signs of infection, leading to implant removal in 2.5% (3/122).

In 1.6% (2/122) re-operation due to dislocation of the implant had to be performed. Only nasal dorsum implants were affected (Table 2). A correlation between the nose as the most exposed facial area and the displacement of dorsum implants is conceivable and is commonly observed in other forms of alloplastic materials[17]. Implant removal due to infection was found on average after 19.7 months and may have been related to oral bacterial colonization in conjunction with the intraoral surgical approach. Controversially, early-onset infection has typically been reported in Medpor implants[17]. All the implants which had to be removed due to infection, were inserted before amending the surgical protocol in 2014. Since this amendment, none of the inserted implants have been found to be infected.

Based on our results, Medpor implants represent a reliable technique to sufficiently address cleft-related midfacial hypoplasia in various indications and provide specific hard tissue support to hypoplastic malar and paranasal areas and the nasal dorsum.

Funding

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Competing interests

There were no competing interests related to this paper.

Ethical approval

Written approval provided by Guy's and St. Thomas Hospital NHS Trust (no. 8537).

Patient consent

Written patient consent was obtained.

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