Background: The multitude of factors involved with a unilateral cleft lip nasal defect has spurred various surgical techniques in the past. Recently, synthetic materials have been introduced for use in nasal reconstruction.

Objective: To report on and illustrate the use of porous high-density polyethylene implants in cleft lip nasal reconstruction.


Setting: Facial plastic surgery private practice.

Patients: Eighteen patients with a unilateral cleft lip without a history of formal rhinoplasty.

Interventions: All 18 patients required multiple implants, including a columellar strut, premaxillary and prealveolar plumper grafts, a dorsal tip implant, and a unilateral nasal valve batten, using the open rhinoplasty approach.

Results: Favorable aesthetic results, as judged by one of us (T.R.), were achieved in all patients. All implants were well tolerated. Postoperative follow-up ranged from 6 months to 7 years. A complication occurred in 1 patient (6%), which resolved with removal of a single implant and intravenous antibiotic therapy. No other complications, including skin erosion or implant extrusion, have been noted.

Conclusions: Porous high-density polyethylene implants for cleft lip nasal reconstruction are well tolerated and achieve good aesthetic results. Porous high-density polyethylene implants lend stability through fibrovascular ingrowth, with integration of the implants to the surrounding tissue.

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SECONDARY NASAL deformity associated with the unilateral cleft lip humbles even the finest facial aesthetic and reconstructive surgeons. The challenges posed by secondary unilateral cleft lip nasal defects have spurred the creation of various surgical techniques and the use of autogenous and alloplastic materials to reinforce the structure of the nose and augment the nasal tissue. In this article, we report our 7-year experience using porous high-density polyethylene (PHDPE) implants in correcting the common challenges of secondary unilateral cleft lip nasal defects.

Secondary unilateral cleft lip nasal defects are an undesirable and, as yet, unavoidable consequence of primary cleft lip nasal reconstruction. After the primary operation, scar formation, growth in the facial-skeletal and soft tissue structures, and other natural anatomical developments result in deformities that the secondary operation seeks to correct. Some of these include the following: (1) the columella is shortened, (2) the dome on the cleft side is retrodisplaced, (3) the medial crura slumps laterally, (4) the lower lateral cartilage and the alar rim shift superiorly and caudally, (5) an alar-columellar web forms, and (6) the vestibular skin near the vestibular dome is insufficient.

To correct these common defects, several surgical techniques have been developed over time, all sharing the focus of correcting the soft tissue envelope and the structural support mechanism. During the earlier part of the 20th century, the surgical methods relied primarily on surgical incisions and manipulation of the soft tissue and surrounding structure. In 1964, Converse² applied a different method. By replacing the midcolumellar incision with a marginal incision, he created a composite flap of the medial crura, which in turn...
created a defect at the base of the columella. This defect was then repaired with auricular cartilage.2

Reconstructive surgeons, in applying different methods, have used other autogenous materials, such as bone grafts and various cartilages, to augment the tissue around the defects of a secondary unilateral cleft lip. For example, in creating columellar strut or shield grafts, surgeons have frequently used auricular, sepal, or rib cartilage. Unfortunately, conchal cartilage is curved, has an irregular surface, and is prone to resorption. Rib cartilage harvesting has unfavorable donor site morbidity, risks pneumothorax, and leaves a conspicuous scar. Septal cartilage might have already been used in a prior rhinoplasty or is often defective. The obtainable volume may be insufficient, and preparing the graft may be cumbersome and time-consuming.3

Dissatisfaction with autogenous tissues catalyzed the development and use of synthetic alloplastic materials, which seemed to overcome these common failures. In this article, we report our experiences with PHDPE implants in secondary unilateral cleft lip nasal reconstruction. This material has been used safely and reliably in head and neck and cranial facial reconstruction for more than 2 decades, and is extremely stable and well tolerated by patients4-6; we witnessed similar results with our cleft lip nasal repair.

METHODS

Between January 1, 1993, and June 30, 2000, 18 patients (7 women and 11 men) underwent secondary cleft lip nasal reconstruction using multiple PHDPE implants (Medpor surgical implants; Porex Surgical Inc, College Park, Ga) while under our care. The patients, aged 19 to 52 years, had undergone at least 1 cheiloplasty for their unilateral cleft lip defect, but none had undergone rhinoplasty. They were informed of and accepted the risks and potential complications of using an alloplast.

Three types of PHDPE implants (a columellar strut, a dorsal tip implant, and a unilateral nasal valve batten) and 2 kinds of plumper grafts (premaxillary and prealveolar) using the open rhinoplasty technique were used in all patients (Figure 1 and Figure 2).

An inverted “V” incision was made to start the open rhinoplasty approach. The tip and dorsum were carefully degloved, leaving as much soft tissue as possible on the flap. The marginal incisions were made along the columella, superior to the facet, and then rim incisions were made along the alae. On the depressed side, the rim incision was extended over and close to the pyriform aperture, providing 2 to 3 mm of soft tissue coverage to prevent exposure to the inferior edge of the nasal batten implant to be placed there. The residual lower lateral cartilage on the depressed side was dissected from the vestibular mucosa and resected 5 mm lateral to the nasal dome. Any fenestration or perforations in the vestibular mucosa, on removal of the lower lateral cartilage, were closed with interrupted 5.0 chromic sutures.

Figure 1. Preformed porous high-density polyethylene nasal implants. A, An 0.85-mm external nasal valve batten. B, A nasal dorsal implant with a tip. C, A 1.1-mm columellar strut.

Once the soft tissue envelope was successfully dissected and a sufficient pocket had been created for the unilateral nasal valve batten to be placed, secondary cleft lip nasal reconstruction commenced with the insertion of small plumper implants onto the premaxilla. These implants were 2 × 2-mm portions carved from the ultrathin (1.1-mm) sheet and inserted through the midcolumellar incision (Figure 2). Next, a 1.3-mm ultrathin columellar strut was inset between the medial crura and secured with 3.0 synthetic monofilament absorbable poliglecaprone 25 sutures (Monocryl).

Binding of the nasal tip cartilage at the dome was secured if necessary with 5.0 nonabsorbable surgical sutures (Prolene). A curved unilateral nasal valve batten was inset into the appropriate pocket and secured to the lateral edge of the residual tip cartilage with a 6.0 nonabsorbable surgical suture. The average batten measured 23 × 11 mm and was 0.85 mm thick. This size implant allowed for placement of the batten just anterior to the pyriform aperture, 2 to 3 mm superior to the rim of the alar and 2 to 3 mm lateral to the nasal angle and tip.

The standard nasal dorsal tip implant (No. 7516) was carved and shaped with a No. 10 scalpel blade. The implant was then inset into the nasal dorsal pocket. If the implant sat unevenly, either the nasal bones were rasped or the undersurface of the implant was shaved.

A separate incision was made at the anterior nasal floor mucosa deep to the peristomeum. A carved 6-mm block implant was inset into the prealveolar defect. The nasal tip and columellar skin were redraped, and the columellar and marginal incisions were closed with 6.0 nylon and 5.0 chromic sutures, respectively (Figure 3 and Figure 4).

A splint (Aquaplast) was placed on the dorsum. All noses were packed with tampons (Merocel), covered with a gauze dressing (Telfa). The nasal packing, sutures, and splints were removed by the fifth to the seventh postoperative day.

All patients have been followed up for 6 months to 7 years after the operation, with an average 20-month follow-up. The results comparing the preoperative and postop-

Figure 2. A 1.1-mm porous high-density polyethylene (Medpor) sheet is cut into 2 × 2-mm pieces to make premaxillary plumper grafts.
ervative photographs showed functional aesthetic improvements in all patients (as determined by one of us [T.R.]) (Figure 5). Of the 18 patients, complications have been limited to 1 (6%) with an infection 6 months after the operation. This patient wore an upper dental plate or prosthesis, which eroded the premaxillary mucosa over the prealveolar block implant, causing a fistula between the gingival labial sulcus and the floor of the nose. The patient eventually required removal of the block implant and intravenous antibiotic therapy, but his other implants and his nasal contour remained unaffected. No other patient has required revision surgery, and no delayed infections have been noted. Other complications, including implant warping, exposure, extrusion, and nasal skin erosion, have not been noted.

COMMENT

Although facial implants for reconstruction were popularized in the early part of the past century, various autogenous implants had been used even earlier. In 1896, J. Israel, MD, used tibial bone for nasal reconstruction, and in 1900, H. Von Mangold, MD, reported the use of costal cartilage. Later reports showed, however, that, although autogenous bone and cartilage offered the advantage of tissue compatibility, they had their drawbacks: donor site morbidity, restricted availability, difficulty of shaping the graft, unpredictability of remodeling, and resorption. Irradiated homologous tissue overcame some of the problems of autogenous implants, such as donor site morbidity and restricted availability. However, the fear of transmitted diseases, such as the human immunodeficiency virus, and studies showing unpredictable resorption and graft warping reduced the use of irradiated homologous tissue as the donor tissue of choice.

To circumvent the shortcomings of autogenous tissue materials, synthetic materials for facial aesthetic and reconstructive use were developed. While alloplastic materials gained much of their popularity in the past few decades, it was Roussett, in as early as 1828, who realized the versatility of gold implants in the nose for facial contouring. In 1900, Jacques Joseph, MD, used ivory as donor site morbidity and restricted availability. However, the use of gold implants in the nose for facial contouring was limited by the difficulty of shaping the graft, unpredictability of remodeling, and resorption. In the 1950s, silicone and other synthetic implantable alloplastic materials became widely available. Since then, many researchers have reported their experiences with other biomaterials, such as silicone rubber, polyamide, and expanded polytetrafluoroethylene (Gore-Tex; W. L. Gore & Assoc, Inc, Flagstaff, Ariz), with varying degrees of success; each has specific drawbacks.

Solid silicone implants, while more extensively used for breast and chin augmentation, have also been used for nasal reconstruction. In addition to forming a fibrous capsule, silicone implants, although relatively inert, do not become integrated into recipient tissues, making them prone to extrusion. Silicone has also caused resorption of the underlying bone in animal and human studies. Unlike the silicone implants, polyamide mesh (Supramid; S Jackson Inc, Alexandria, Va) allows for a substantial amount of ingrowth of fibrous tissue over several months. This tissue infiltration anchors and fixes the implant in place and, thus, prevents extrusion. However, polyamide mesh undergoes hydrolytic degradation with a gradual loss of bulk, and has been associated with a severe inflammatory response. Expanded polytetrafluoroethylene has not been linked to extrusion or degradation, but its inability to maintain an exact shape or provide a support structure limits its use in nasal reconstruction to only certain cases.

Porous high-density polyethylene may offer many advantages to these synthetic materials. It closely resembles the ideal alloplastic material for facial augmentation and reconstruction by offering excellent host tissue tolerance, easy manipulability to produce the required shape, minimal recipient capsule formation, and demonstration of host tissue ingrowth for stabilization.

Developed in the early 1970s, PHDPE comprises polyethylene resins as straight chain aliphatic hydrocarbons. Porous high-density polyethylene is an inert material with low tissue reactivity, and causes minimal inflammatory foreign body reactions. It is partially flexible at room temperature and, when soaked in hot water (82°C [>180°F]), becomes malleable to the desired contour and shape.

Porous high-density polyethylene is a sintered form of high-density polyethylene with an interconnected network of pores, offering high-tensile strength. These pores range from 160 to 368 µm (average pore sizes, >100 µm). Spector et al showed that a pore size of greater than 100 µm promotes tissue ingrowth. Histological analyses
of PHDPE implants by Romo et al\textsuperscript{13} showed a rapid ingrowth of fibrous tissue with mature blood vessels and collagen. The soft tissue ingrowth results in firm attachment and integration of the implant to the surrounding tissue, which leads to decreased movement of the implant. Previous work\textsuperscript{14,15} has also shown that the rapidity of vascularized tissue ingrowth and its vessel network reduce the likelihood of infection. Histological analysis of PHDPE reveals a lack of capsule formation and minimal foreign body reactions.\textsuperscript{16}

Our 7-year experience using PHDPE implants to augment soft tissue bulk and restore structural support in cases of secondary cleft lip nasal deformity achieved excellent aesthetic results. The postoperative follow-up has ranged from 6 months to 7 years, with only 1 patient of 18 requiring removal of a single implant because of local infection. The complication resulted from a dental plate or prosthesis, which eroded the premaxillary mucosa, exposing the prealveolar block implant. Although Sclafani et al\textsuperscript{17} have shown that PHDPE implants tolerate exposure well, our attempts to salvage the exposed implant failed.

Results of work performed by Merritt et al\textsuperscript{13} suggest that porous implants are more resistant to infection than nonporous implants if bacterial contamination occurs on fibrous tissue ingrowth. Despite these results, our complication occurred 6 months after the surgery, where fibrous ingrowth had likely occurred. The complication may have been prevented had the patient been warned against the use of the prosthesis.

Compared with our results, Romo et al\textsuperscript{13} have described their experience with PHDPE in 121 cases of revision rhinoplasty, and have noted 5 cases of infections requiring removal of implants. Similar to our results, they reported no other complications, including implant extrusion, exposure, or skin erosion. Our overall complication rate of 6\% also compares favorably with that of Wellisz et al,\textsuperscript{18} who used 116 PHDPE implants in various areas of the face, including use for nasal reconstruction. Of the 116 implants, 7 were exposed and 2 were removed. Frodel and Lee\textsuperscript{19} recently studied the use of PHDPE implants in facial deformities and subcutaneous defects, such as those in the orbital tissue, temporal fossa, maxillary tissue, microtia, and chin. Of 40 implants, the researchers noticed only 1 that had to be removed because of infection, and 2 had limited exposure. We believe that, with more subjects and increased experience with PHDPE implants in secondary cleft lip nasal reconstruction, the overall complication rate will decline.

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In conclusion, the multitude of approaches to secondary unilateral cleft lip nasal repair is a testament to the challenge of secondary cleft lip nasal reconstruction. An individualized approach, with the appropriate surgical technique and an understanding of the fundamental anatomical changes, is imperative to a successful outcome. We believe PHDPE implants can provide aesthetically and functionally pleasing results by providing structural support and augmentation to the nasal soft tissue bulk. The natural, but slightly firmer, feel of PHDPE implants is well tolerated by patients. The conduciveness of soft tissue ingrowth and the relatively low infection rate associated with PHDPE implants mean they will provide many years of comfort and facial beauty.

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