Reconstruction of the Nasal Septum Using Perforated and Unperforated Polydioxanone Foil

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Objective: To present our experience of reconstruction of the nasal septum using perforated and unperforated foils, particularly with respect to functional and aesthetic sequelae.

Methods: A retrospective medical record review of a prospectively conducted case series was undertaken of all consecutive patients who underwent septal reconstruction using polydioxanone foil in a 4-year period. Procedures included septrhinoplasty and isolated septoplasty via external and endonasal approaches using corporeal and extracorporeal techniques. The polydioxanone foils were in battens or sheets.

Results: Fifty patients underwent septal reconstruction using unperforated (first 26 patients) or perforated (next 24 patients) polydioxanone foil. Median total postoperative follow-up was 51.5 months (range, 34-60 months) for unperforated foil and 20.5 months (range, 12-31 months) for perforated foil. All the patients were reviewed for assessment of appearance and function. Forty-three patients had satisfactory results, needing no further treatment. Three patients required minor septal or tip revision surgery. Four patients experienced moderate saddling of the dorsum (all involved unperforated polydioxanone foil) and underwent successful revision surgery using auricular cartilage grafts.

Conclusions: Synthetic materials are a useful alternative to autologous tissues during reconstruction of the nasal septum. To our knowledge, we present the largest single-center series of septal reconstructions using unperforated and perforated polydioxanone foils—shown to be useful in the correction of complex septal deformity. However, the unperforated form seems to be associated with a significant risk of postoperative saddling, and we warn against its use in this context. No such complications were observed with the use of thin, 0.15-mm perforated polydioxanone foil, which we exclusively recommend for this application. The use of this implant warrants further evaluation.

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The principal functions of the nasal septum are to provide midline support for the external nose while separating the nasal passages, supporting nasal mucosa, and (in conjunction with other structures) promoting regulated cyclical nasal air flow. Septal deformities may have dramatic cosmetic and functional effects. Hence, the goal of corrective surgery is to produce a straight and intact nasal septum that is structurally solid. This may be challenging, particularly in cases of extreme deformity and after previous surgery or trauma.

A variety of surgical strategies and approaches may be used, but a successful outcome depends on several mandatory operative steps. Deformities are first skeletonized and demonstrated via a closed (endonasal) or open (external) approach. Next, the septum is mobilized appropriately. It may be left largely in situ or, alternatively, removed from the nose (extracorporeal septoplasty). Angulations are then corrected, and the curved or deformed segments are isolated for reconstruction. Finally, the septal components are replaced and stabilized in the nose. This final repositioning and stabilization of the septum is potentially difficult. Fragments of cartilage must be connected meticulously and anchored to key structures in the nose, thereby minimizing the risks of sequelae, such as persistent deformity and saddling. Cartilage fragments may be simply sutured together, but this is often time-consuming, and the resulting combination may not provide sufficient support for the nasal dorsum. Surgery to the tip cartilages or the bony vault is performed where appropriate.

In such situations, a variety of implanted materials (grafts) have been used either to facilitate the connection of septal fragments or to reconstruct deficient...
components of the septum and external nose. Materials are chosen on the basis of certain properties, such as strength, stability, and durability, with the aim of reproducing the typical functional and aesthetic characteristics of the healthy nose. At the same time, ideal implants are cheap and readily available, inert, nontoxic, and easy to modify and insert (and to remove, if necessary), and they interact favorably with host tissues, thereby resisting extrusion.

Autologous grafts, derived from the patient, are used wherever possible. These grafts include cartilage (septal, auricular, and costal),3,6 bone (septal, calvarial, costal, and iliac) 4,6,7 fascia, and dermis.4 Such tissues remain the gold standard of nasal graft materials given their availability in most patients, unrivaled biocompatibility, low risks of infection and extrusion, minimal cost, and acceptability. Indeed, some researchers recommend and use only autologous implants for nasal reconstruction.4 However, it must be considered that many patients undergo nasal reconstruction after extensive previous surgery such that the most suitable autologous tissues (particularly septal and auricular cartilage) have been harvested already. The use of other available tissues, including costal cartilage and bone, may not yield such satisfactory results, particularly in aesthetic terms, and are prone to warping, resorption, displacement, and fracture. Donor site morbidity, prolonged immobility, and an extended hospital stay are other important considerations, particularly in patients already troubled by their nasal appearance and function.

For these reasons, other graft options have been sought. Homografts (typically cadaveric) and xenografts (from another species) address these difficulties in principle. However, apart from a few notable exceptions, such as AlloDerm (LifeCell Corp, Branchburg, New Jersey), these grafts are rarely used in practice on the grounds of uncertainty that the materials will stimulate cartilage regrowth and promote healing.12 How- ever, note that although these studies were carefully conducted and provide useful information, such findings might not necessarily apply to human subjects. Apart from anatomical and tissue differences between the species, the rabbit subjects were young and healthy, having experienced no previous trauma (or surgery), and were, therefore, inherently different in these respects from most patients undergoing nasal sepal reconstruction.

Despite these potential limitations, polydioxanone foils have been used successfully in human subjects for several years, prompting their use at Royal Surrey County Hospital. We present our experience of reconstruction of the nasal septum using perforated and unperforated foils, particularly with respect to functional and aesthetic sequelae.

Fifty patients were included in this study who presented to one of us (J.M.R.-J.) consecutively between April 16, 2004, and February 28, 2008, with septal deformities that were corrected using polydioxanone foils. Forty-nine of these patients had an associated external deformity. A proportion of these cases were direct referrals from primary care physicians, and the remainder were referrals for a specialist second opinion from other otorhinolaryngologic centers. All of the patients were evaluated and counseled preoperatively, paying particular attention to the objectives of surgery (cosmetic or functional improvement) and possible limitations. Clinical photographs were obtained at this point and during follow-up visits at regular intervals postoperatively. Patients were identified from the prospectively collected operative database of one of us (J.M.R.-J.), and data were retrieved by retrospective medical record review. Patients gave informed written consent for publication of clinical and operative information and, in selected cases, for publication of photographs. Ethical approval was not deemed necessary by the ethics committee of Royal Surrey County Hospital.

**METHODS**

**SURGICAL TECHNIQUE**

An open approach is used for most such cases, using transcolumnellar and marginal incisions. Tip split, separation of up-
per lateral cartilages, and bilateral mucoperichondrial flaps are used for maximal exposure. The septum is then mobilized. In some cases, isolated segments of deformed cartilage may be freed and removed from the nose, leaving the remaining septum in situ. For more complex deformities, particularly those that affect the dorsal and caudal extremities, an extracorporeal technique is used. A posterior chondrotomy is used to separate the quadrilateral cartilage from the perpendicular plate of the ethmoid bone, and the upper lateral cartilages are then detached. Finally, the cartilage is disconnected from the vomer and maxillary crest, allowing its removal from the nose in toto. These maneuvers allow detailed examination of the cartilaginous deformities. Correction typically entails the excision of fracture lines and grossly deformed sections to yield smaller pieces of flat cartilage.

If the septal cartilage is reconstructed in situ (corporeal approach), the polydioxanone foil is always inserted on the concave side of the deformity, unless a mucosal tear has been sustained inadvertently on that side during the dissection, which will expose the implant. If the cartilaginous septum is reconstructed extracorporeally, the fragments are laid out on a layer of polydioxanone foil (Figure 1). The sections are positioned in a manner that results in a stable and straight septum, regardless of their original position. Particular attention is paid to the dorsal and caudal borders of the graft. If at all possible, cartilage fragments of very small sizes are avoided to minimize the risk of displacement. Finally, the cartilage pieces are sutured onto the implant using 5/0 polydioxanone sutures, and the polydioxanone foil edges are trimmed to size, resulting in a foil sheet that measures approximately $3 \times 4$ cm.

In situations in which the resulting septum remains unstable, a second piece of polydioxanone foil may be attached opposite, sandwiching the cartilage between 2 layers of polydioxanone (Figure 2). Some cases require removal of 2 or 3 smaller segments of deformed cartilage rather than the whole cartilaginous septum. Reattachment of these segments (to one
another and to the intranasal remnants of the septum) may be facilitated by small struts (battens) of polydioxanone foil, measuring approximately 0.75 × 2.5 cm. This is particularly appropriate for endonasal corporeal septal surgery.

Any other intranasal deformities may be corrected before insertion of the reconstructed neoseptum, which is placed between the mucoperichondrial flaps. It is vital that this is anchored, via further polydioxanone sutures, to the K-area, the upper lateral cartilages, and the periosteum of the anterior nasal spine. At this point, deformities of the bony vault may be addressed by osteotomies, and modification of the tip cartilages may also be considered. The medial crura of the lower lateral cartilages are reconnected using 5/0 polydioxanone sutures, and further anchoring of the graft is provided by quilting sutures (4/0 Monocryl; Ethicon Inc.), which also reduces dead space and the risks of postoperative hematoma and abscess. The skin is closed using quilting sutures along the marginal incisions and, finally, using 6/0 nylon sutures for the columella.

POSTOPERATIVE MANAGEMENT

If the bony vault has been manipulated, an external plaster of Paris splint is applied. Otherwise, self-adhesive surgical tape (Steri-Strip; 3M, St Paul, Minnesota) dressings alone are laid over the dorsum. Intranasal packs are almost never used in this context. Silastic splints are rarely required, only when the septal mucosa has been significantly damaged and postoperative synchiae are likely. Hospital discharge is usually possible on the same day. Along with a prophylactic dose of intravenous cefuroxime (750 mg) at the time of induction, all patients underwent reconstructive septal surgery using polydioxanone foil. If the bony vault has been manipulated, an external plaster of Paris splint is applied. Along with a prophylactic dose of intravenous cefuroxime (750 mg) at the time of induction, all patients undergoing reconstructive septal surgery (be it with autologous tissue or synthetic implants) are given a 1-week course of oral amoxicillin-clavulanate (625 mg 3 times a day) and chloramphenicol, 1%, ointment to apply to the columellar and intranasal incisions. Patients are reviewed 1 week postoperatively. Columellar sutures, plaster casts, and intranasal splints may all be removed at this time.

Assuming that no complications are encountered, most patients are subsequently seen at 6 weeks and then at 3 months, with further visits at 6, 9, and 12 months if required. Patients are finally discharged from further clinical follow-up with specific instructions and are offered open access to care in the event of any further nasal symptoms, cosmetic changes, or other problems. Their primary care physicians are also invited to refer them again to the clinic in these circumstances. Any subsequent visits are recorded prospectively in the surgical database of one of us (J.M.R.-J.).

POLYDIOXANONE FOIL SELECTION

Several varieties of polydioxanone foil (PDS plate) are produced by Ethicon Inc, ranging in size and thickness, with or without perforations (Table 1). The thinner foils (particularly ZX3, ZX7, and ZX8) are most suited for septal reconstruction, and the thicker foils are primarily used for orbital floor surgery.

ZX5 foil was initially used for septal reconstruction at Royal Surrey County Hospital, having been used successfully by colleagues in the departments of maxillofacial surgery and ophthalmology to repair orbital defects and in septal surgery at other medical centers. However, after a few complications associated with ZX5 foil, ZX7 has been used exclusively as an alternative since September 2005.

RESULTS

We identified 50 patients (40 males and 10 females aged 15-56 years; median age, 33 years) who consecutively underwent reconstructive septal surgery using polydioxanone foil between April 16, 2004, and February 28, 2008, under the care of one of us (J.M.R.-J.). Their presentations and operative details are summarized in Table 2, which gives separate consideration to patients receiving unperforated and perforated foil implants, facilitating comparison between the materials in terms of outcome.

All the patients were typically reviewed 1 week after surgery and subsequently at 6 weeks and then at 3 months, when postoperative clinical photographs were first obtained. Of the 50 patients, 43 were entirely satisfied with function and appearance (confirmed by interview, clinical examination, and photographic evaluation) and required no further treatment (Figure 3 and Figure 4). Thirty-three of these patients were discharged from clin-
cal care by 3 to 6 months, satisfied with the shape and function of the nose. The other 10 patients required more prolonged clinical follow-up, although no additional operative intervention was needed before discharge. Specific instructions and open access were offered in all cases, but none of the patients reported problems or presented again after final discharge from the clinic. In this context, the overall range of follow-up was 34 to 60 months (median, 51.5 months) for the group treated with unperforated polydioxanone foil and 12 to 31 months (median, 20.5 months) in the group receiving perforated foil.

Further surgery was indicated in 7 patients. Two of these patients required minor revision of the nasal tip and columella. One further patient had persistent anterior septal edema after insertion of a unilateral unperforated ZX5 polydioxanone foil batten during septoplasty. The swelling did not settle with topical corticosteroid therapy, and revision surgery was undertaken after 7 months. This surgery revealed granular tissue in the nasal septum. Histologic analysis demonstrated a multinucleated giant cell granuloma typical of a foreign body–type reaction. Translucent material was also seen, although it was not possible to determine whether this represented residual polydioxanone foil or polydioxanone suture material. No further treatment was required. Four other patients experienced saddling of the nasal dorsum. These were all of moderate severity, with loss of dorsal height, tip support, and columellar retraction, according to the 3 “M” classification (mild-moderate-major) proposed by Tardy et al. All of these patients had undergone septal reconstruction using unperforated polydioxanone foil (ZX5) and are described in the following paragraph.

A 33-year-old man was referred for revision septorhinoplasty after an original trauma in adolescence, pri-
mary septorhinoplasty overseas, and then a subsequent trauma. He was otherwise healthy. Extracorporeal reconstruction of the septum was performed via an external approach using bilateral ZX5 foil battens. Within 6 weeks, the dorsum had saddled to a moderate degree, with associated columellar retraction. Revision was undertaken at 6 months using auricular cartilage. One further minor operative correction was required. A 39-year-old man underwent primary external septorhinoplasty after a childhood nasal trauma. Corporeal reconstruction of the septum included insertion of a unilateral ZX5 foil sheet. Moderate saddling developed by 6 weeks that required revision using auricular cartilage 18 months later. This achieved satisfactory results. A 52-year-old man was referred for secondary external septorhinoplasty (after previous septrhinoplasty at another center). Corporeal septal reconstruction included insertion of bilateral ZX5 battens. The dorsum was moderately saddled within 6 weeks and was revised satisfactorily using auricular cartilage after 18 months. A 59-year-old male heavy smoker with no known history of trauma underwent primary extracorporeal septoplasty via an external approach using a unilateral ZX5 sheet. Moderate saddling was evident by 6 weeks, and revision was undertaken at 1 year using auricular cartilage. A subsequent minor final refinement was required.

Figure 4. Preoperative (A-C) and 3-month postoperative (D-F) photographs of a 33-year-old man. He had experienced a childhood nasal injury and had bilateral nasal obstruction. He had an underprojected broad tip, poorly supported and twisted to the left. Corporeal septorhinoplasty was performed via the external approach. The posterior segment of quadrilateral cartilage mobilized onto the anterior nasal spine and was stabilized with respect to adjacent cartilage using bilateral ZX5 battens. Final clinical review occurred at 3 months, with no problems reported since.
A variety of published series have described reconstruction of the nasal septum using polydioxanone foils. Most such cases have involved extracorporeal septoplasty techniques using either 0.25-mm unperfòrated (ZX5) battens or thinner 0.15-mm perforated foils (ZX7 and ZX8) as single sheets to which cartilage fragments are attached before reinsertion and fixation. Results have been positive, albeit in relatively few patients. Such studies have not discussed the presence in individual patients of major risk factors for adverse outcomes, such as previous surgery or trauma, or other local or generalized comorbidities. Serious sequelae of septal surgery, such as perforation, columellar retraction, and saddling, would be more likely in this context.

From our experience, we suggest several possible predictors of poor outcome when polydioxanone foils are used, which may be divided into surgery- and patient-related risk factors. Note that these have been inferred from the relatively small number of patients in this study population and may be impossible to extrapolate on an individual basis.

The type of polydioxanone foil used seems to have an important effect on outcome. ZX5 (0.25 mm, unperfòrated) was used in all 4 cases in this series complicated by saddling. This prompted the use of ZX7 foil (0.15 mm, perforated) as an alternative, after which no cases of saddling have occurred. There is an obvious reason for this apparent difference. The viability of the reimplanted septum depends on the reestablishment of an adequate blood supply from the mucoperichondrial flaps. In rabbit models, microscopic evidence of resorption of 0.15-mm perforated polydioxanone foil occurred only after at least 10 weeks. Throughout this period, contact between cartilage and mucoperichondrium would be compromised by the layer of polydioxanone, although a blood supply could still be drawn through the foil’s perforations and via the contralateral side (in the case of unilateral application of foil). However, the ZX5 foil is thicker and unperfòrated and could obstruct the blood supply from the ipsilateral mucoperichondrial flap for many weeks. We, therefore, strongly recommend against the use of unperfòrated polydioxanone foils in nasal septal surgery.

The mode of application of the polydioxanone foil may also contribute to postoperative saddle deformity. Of the 4 cases complicated by saddling, unilateral ZX5 sheets were used in 2, with bilateral struts (battens) in the remainder. Given the dimensions of the polydioxanone sheets (3 × 4 cm) or battens (0.75 × 2.5 cm), significant areas of cartilage were covered by unperfòrated material, affecting overall blood supply to the implanted cartilage from 1 or both sides. However, note that unilateral ZX5 foil sheets or bilateral battens were used for reconstruction in another 22 cases in this series and in previous studies without complication, suggesting that cartilage viability and integrity is not consistently compromised by these methods. This inconsistency, together with the proven granulomatous foreign body-type reaction seen in 1 patient in this series, suggests that cartilage breakdown might be mediated by inflammatory processes in addition to possible disruption of vascular supply.

Cartilage crushing methods are not used in our practice to minimize trauma and possible disruption to the reestablishment of vascular contact with the mucoperichondrium. In addition, polydioxanone foil is applied only where the overlying mucoperichondrium is intact to limit the risk of extrusion or perforation, as practiced at other medical centers.

The approach used, be it external or endonasal, does not affect postoperative outcome as far as complications are concerned. Most of the present cases (including all 4 complicated by saddling) were performed via an external approach, achieving unrivaled exposure of the nasal septum to allow demonstration and correction of deformities of the septum and nasal cartilages. Although this method is generally associated with more nasal soft-tissue swelling and prolonged recovery, there is no evidence to suggest an increased risk of septal collapse and saddling compared with the endonasal approach, supported by other published series involving septal reconstruction with polydioxanone.

Corporal and extracorporeal methods were used in this series, according to individual requirements. Saddling was seen after both techniques. Extracorporeal septoplasty has not been associated with adverse outcomes in other studies provided that the reconstructed septum is appropriately positioned and secured before closure.

The relatively high rate of saddling after implantation with unperfòrated ZX5 foil has led us to abandon it entirely in favor of thin, perforated ZX7 foil. This foil has been used successfully at Royal Surrey County Hospital for 4 years in selected reconstructive cases as an alternative to autologous tissues without any serious complications. This compares well with results from other published polydioxanone foil series and with results of septal reconstruction using autologous tissues at this and other medical centers.

Patient-related factors that might affect cosmetic and functional outcomes after reconstructive septal surgery are given in Table 2, but these may be difficult to infer on an individual basis from such a small sample. Three patients who experienced saddling gave a history of trauma or surgery, and 1 was a heavy smoker. However, these factors were relatively common in the cohort as a whole, most of whom had good results.

In conclusion, synthetic implantable materials represent an important alternative to autologous tissues during reconstruction of the nasal septum. Such implants are particularly useful when the availability of appropriate host tissues is limited. Donor site morbidity is also avoided. Polydioxanone foil is a versatile biodegradable material, facilitating the stabilization of septal fragments while minimizing the cosmetic and functional sequelae associated with nonabsorbable implants. However, although most cases have resulted in successful outcomes, saddling occurred in a few patients after insertion of unperfòrated foil, and we warn against its use in this context. As in other studies, no such complications were associated with thin, perfòrated polydioxanone foil. We recommend this as an excellent implant for selected cases of septal reconstruction, although it warrants further clinical evaluation.
Techniques in Facial Plastic Surgery

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David M. Lieberman, MD; Sam P. Most, MD

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