Clinical and Histological Results of Septoplasty With a Resorbable Implant

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**Background:** The use of a resorbable implant connected with septal cartilage would facilitate external septoplasty, offering mechanical stability until the cartilage fragments heal.

**Objective:** To study the histological and clinical results of septoplasty with a resorbable implant (polydioxanone [PDS; Ethicon, Norderstedt, Germany]) in conjunction with cartilage.

**Design:** To provide histological information in 5 rabbits, PDS foil was implanted into the outer ear in conjunction with an artificial cartilage defect. Observations were made at 2, 5, 10, 15, and 25 weeks. Resorption of the implant was investigated, including the time to complete elimination. In addition, septoplasty with PDS foil was performed on 71 patients with severe septal deformities. Surgery consisted of excision of the quadrilateral cartilage and division into straight fragments, which were sutured to the PDS foil and replaced as a free graft.

**Setting:** Ear, nose, and throat department of the General District Hospital Steyr, Steyr, Austria.

**Results:** Histological examination showed that the foil remained unchanged for at least 10 weeks and was completely resorbed after 25 weeks with minimal remaining scar tissue. Newly formed cartilage developed bordering the cartilage defect. In the clinical study, all patients experienced varying degrees of improvement in nasal blockage. No immediate or long-term complications occurred.

**Conclusions:** The use of PDS foil in connection with cartilage facilitates surgical correction of severe septal deformities, additionally providing support for the nasal dorsum. The histological examination showed that no inflammatory or foreign body reaction occurred. Cartilage regeneration was even found. The foil was completely resorbed within 25 weeks, avoiding the long-term complications that occur with other artificial implants.

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**EXTERNAL septoplasty is useful in correcting severe, especially posttraumatic, septal deformities without compromise.**

This well-known surgical technique involves dissecting the septal cartilage free from the mucoperichondrium via endonasal or external approach. The entire quadrilateral cartilage or, if the deformity remains in the basilar portion, only the deviated part is removed intact and divided into straight pieces. These fragments are trimmed and reconnected to each other. Any osseous septal deformities are corrected. The free graft thus constructed is reimplanted into the nose.

To avoid postoperative sequelae such as saddling, the pieces of cartilage must be reconnected meticulously to form a straight and solid plate. This difficult and time-consuming technique can be facilitated by the use of a connecting material. A resorbable material that provides good support of the nasal dorsum would be particularly useful, and since it would be completely eliminated, it would prevent long-term complications as well. Since 1996, we have used polydioxanone (PDS) foil as a resorbable supporting material. Polydioxanone foils have been successfully used for years to reconstruct bony defects, eg, in orbital floor reconstruction. Polydioxanone is a resorbable material that is degradable by hydrolysis and completely metabolized in the body. The foils are available in various sizes and gauges. The thicker foils are resorbed within 8 months. The general biological properties of the implant and its degradation products in combination with bone have been examined in numerous studies. Additionally, the foils have histoconductive properties, stimulating the regeneration of bone.
MATERIAL AND METHODS

HISTOLOGICAL STUDY

Five rabbits aged 4 weeks were operated on under general anesthesia with ketamine hydrochloride (100 mg/kg intramuscularly). A PDS foil was implanted in combination with cartilage into the outer ear. After a 2-cm-long vertical skin incision on the dorsal side of the outer ear and blunt division of the muscle were performed, the perichondrium was incised to free the cartilage. Next, a 0.5×0.5-cm cartilage defect was created and a 1.5×1.5-cm piece of PDS foil (No. ZX8; Ethicon, Norderstedt, Germany; 0.15 mm thick) was implanted, covering both the defect and the cartilage. The incision was closed with catgut sutures in one layer. Finally, the rabbits received a single dose of antibiotics orally. The animals were observed periodically. All wounds healed primarily, and the further development of the animals was undisturbed.

After 2, 5, 10, 15, and 25 weeks, the animals were killed and the prepared region of the outer ear was removed in toto. Specimens were fixed in formalin, stained with hematoxylin-eosin, and examined by light microscopy. Guidelines for the appropriate use of laboratory animals were followed throughout the study.

In examining the specimens, we obtained information on the following points:
• How long does the continuity of the implant remain unchanged?
• How long does the resorption process take?
• What kind of side effects (inflammatory or foreign-body reaction) occur during the resorption process?
• Is the cartilage modified (1) underneath the foil or (2) at the border of the cartilage defect?
• What happens with the scar tissue after resorption of the PDS foil?

CLINICAL STUDY

Seventy-one patients underwent external septoplasty with the use of the PDS combined with cartilage. The patients' ages ranged from 21 to 57 years. In constructing the combined graft, we used a perforated rectangular piece of PDS foil (No. ZX8; Ethicon, Norderstedt, Germany; available in the United States from Ethicon Inc, Somerville, NJ) measuring 40×50 mm, 0.15 mm thick. In 42 patients with marked, especially posttraumatic, deformities of the septum and the nasal pyramid, we carried out external septal reconstruction during rhinoplasty with the use of an external approach with an inverted-V midcolumella incision.

In 29 patients with severe septal deformities but without deformation of the nasal pyramid, we performed partial external septal reconstruction during septoplasty by means of an endonasal incision. After excision of the quadrilateral cartilage, the outlines of the removed cartilage were copied onto the foil to determine the exact size of the graft needed (Figure 1). Next, the cartilage fragments were trimmed as usual and arranged on the foil (Figure 2). To achieve good fixation, they were sutured to the foil with PDS suture material, thereby creating a straight and solid graft (Figure 3). After the foil was cut with scissors, the graft was reimplanted into the nose. Finally, sutures were used to secure the graft to the nasal dorsum or the cartilage remnant and the nasal spine.

RESULTS

HISTOLOGICAL STUDY

Two weeks after implantation, the implant was completely unchanged and surrounded by minimal reactive tissue, forming a thin capsule. There was no inflammatory infiltration and no foreign body reaction. The cartilage remained unchanged as well (Figure 4).

Five weeks after implantation, appearance was similar. The continuity of the implant was unchanged. There was no inflammatory or foreign body reaction. The cartilage was unchanged (Figure 5).
Ten weeks after implantation, resorption of the implant had already begun, and continuity of the implant was interrupted. The implant was still surrounded by the thin layer of reactive tissue, which additionally filled the perforation of the foil, ensuring good fixation. For the first time, chondroblasts were seen on the border of the cartilage defect (Figure 6).

Fifteen weeks after implantation, the resorption process had progressed, and the PDS particles were encapsulated by fibrous tissue. Noticeable tissue reaction remained solely in the area of the implant (Figure 7A). Bordering the cartilage defect, newly formed cartilage had developed. The cartilage underneath the foil was unchanged (Figure 7B).

Twenty-five weeks after implantation, the implant was completely resorbed. Even after examination of the entire specimen, no residue was found. Only minimal fibrous scar tissue remained (Figure 8).
CLINICAL STUDY

To evaluate results of the clinical study, we used patient report, preoperative and postoperative photographs, and anterior rhinoscopy during follow-up examinations at 2, 4, and 8 weeks; 6 months; and then yearly postoperatively. The average follow-up period was 24 months (range, 18-30 months).

No immediate complications, such as hematoma, inflammatory response, or necrosis, occurred. The reconstructed septum healed well in every case. Postoperative crusts disappeared in nearly every case after 2 weeks. In only 2 cases they lasted 2 weeks longer. Patients had a slight thickening of the septum for 3 weeks postoperatively, which disappeared completely during the following 2 weeks.

A postoperative straight septum was achieved in 70 cases. In 1 case a minimal subluxation of the caudal edge remained, without functional problems. All patients reported an improvement of the nasal airway.

Late complications, such as atrophy of the septal mucosa, or cosmetic defects, such as saddle deformity, retraction of the columella, or loss of tip projection, have not occurred. There was no septal perforation even after intraoperative tearing of the mucosa. No patient experienced rejection of the foil.

In 2 cases in the rhinoplasty group, slight residual cosmetic deformities (namely, pollybeak caused by overcorrection) remained. One patient underwent correction by revision surgery after 5 months; the second patient refused a reoperation. Even in patients with severe preoperative nasal deformities, the cosmetic results were satisfactory (Figure 9).

COMMENT

External septoplasty has been recommended by several authors1-3 to correct severe, especially posttraumatic, deformities of the nasal septum. The use of resorbable PDS foil facilitates this difficult and time-consuming procedure. The trimmed septal cartilage fragments are sutured to the resorbable PDS foil, thus creating a stable and straight free graft, which can easily be reimplanted into the nose. The foil fixes the cartilage fragments, thereby supporting the nasal dorsum until the healing process.
stabilizes the cartilage. Afterward, the foil is completely resorbed, thus avoiding the long-term complications of other artificial implants.

In this type of application of a resorbable implant, we have to consider 3 questions concerning the implant:

1. Are stability of the form and continuity of the implant maintained until the supporting tissue completes the healing process?
2. Do the degradation products interfere with the healing tissue?
3. How much scar tissue remains after resorption in the implantation area?

The general biological properties of PDS have been examined in numerous studies in which the implant was combined with bone. They proved that the degradation products of the synthetic aliphatic polymer did not interfere with the normal healing process at all, but stimulated the regeneration of bone by their osteoconductive properties.

In our animal study, we were able to examine the histological characteristics of the healing process of an artificial cartilage defect in combination with the PDS foil. Up to the 10th week after the implantation, the foil remained undegraded and the continued stability of the form provided the desired supporting function. If the foil was implanted subperichondrially directly covering the cartilage, thin reactive tissue quickly formed a pseudocapsule, preventing necrosis of the underlying cartilage as reported after implantation of some nonresorbable implants. In addition, this thin tissue layer ensured nutrition of the chondrocytes. Therefore, from a histological view, the cartilage underneath the implants remained completely unchanged. Formation of chondroblasts and, after that, new cartilage occurred along the border of the cartilage defect. Obviously new cartilage developed in the area of the artificial cartilage defects. The degradation products resulting from the resorption and metabolism of the PDS had no deleterious effect on regeneration of the cartilage, as has been seen with other artificial implants. The process even supports cartilage regeneration, similar to the osteoconductive properties. During the resorption process, tissue reaction remained confined to the area of the implant, which can account for the lack of reaction of the septal mucosa after septal surgery with the PDS foil. In addition, tissue reaction disappeared completely after the end of the resorption process, thus eliminating unilateral scarring, which can lead to postoperative deformation and bending of the septal cartilage, as well as persistent postoperative thickening of the septum.

Alloplastic implants are generally used for their mechanical stability as supporting material, which is also useful for the combination of cartilage and resorbable PDS foil. In addition, implants are necessary only as long as the supporting tissue is healing; afterward they have to be removed to avoid long-term complications. This can easily be avoided with the use of resorbable implants, which are completely eliminated after a limited period.

The combination of septal cartilage with a resorbable PDS foil therefore provides both technical advantages during the operation and the postoperative advantages of a resorbable implant. The histological examination confirmed the good clinical findings. No inflammatory or foreign-body reactions were found, and new cartilage developed in the area of the artificial cartilage defect.

The use of PDS foil during septal surgery not only facilitates external septal surgery, but also helps to avoid postoperative saddle deformities, with no risk to the patient.

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