Implants for reconstructive surgery of the nose and ears

Abstract

Implants shorten reconstruction, reduce trauma for the patients, are, in principle, of unlimited availability and can be given definable qualities that outnumber those of biological transplants. Lots of sometimes exotic materials have already been suggested for facial surgery and most of them have turned out to be unsuitable in the short or long term, because they did not satisfactorily fulfil the requirements of a “perfect implant”. However, transplants obviously cannot be regarded as ideal either because they often involve the necessity of a second intervention for removal, they are only available to a limited extent and some are at risk of postoperative deflection, shrinkage and absorption.

This article is concerned with current knowledge about implant materials for rhinoplasty and ear reconstruction. Autogenous transplants will also be briefly discussed. The repetition of known facts should be largely avoided. In relation to this reference will be made to earlier papers [1].

1 Materials for rhinoplasty

1.1 Autogenous transplants

In nasal surgery, alloplastics have to be pitted against autogenous transplants, which have been regarded as the most suitable materials for use until now [1]. Septum cartilage is stable, seldom absorbed, well tolerated and comparatively easy to work with. It is still the first choice as a spreader graft, onlay graft for the bridge of the nose and columellar strut and for revision rhinoplasty [2], [3]. However, there is frequently not enough septum cartilage for revisions. Crushed cartilage already has a distinctly higher absorption rate. Concha cartilage is especially suitable if small quantities of soft and flexible cartilage are required [4].

Autogenous costal cartilage can be extracted in large quantities and poses few problems during healing [5]. However, its extraction involves risks and unwanted consequences at the point of extraction, such as the risk of pneumothorax, deformities of the costal arch and a visible scar. In addition, costal cartilage has an inhomogenous consistency and is not easy to work with. It is absorbed to an unsafe extent and it bends. For these reasons, numerous rhinosurgeons do not use rib cartilage in principle today [2], [6], [7]. The biological behaviour of an autologous costal transplant can also be disadvantageous: Baek et al. [8] reconstructed the nasal skeleton with autologous rib cartilage in a congenital defect. Over the course of seven years a “Pinocchio” nose developed through disfiguring, over proportional growth of the costal strut, which had to be corrected in a new operation. Apparently the authors transplanted a growth zone with the transplant and it continued to be effective. Walton et al. [9] managed to save an infected costal strut that was at risk of going under and being lost by continually flushing the transplant and the implant site with antibiotics using a catheter.

The removal of iliac crest bone can trigger pain and difficulty in walking and absorption was often reported. However, there are proponents of the transplant [2], [7] because larger parts can be extracted than from skull bones, for example. The tabla externa (split calvarial bone) of the cranium offers transplants of up to 3 mm thick, the extraction point is near the operation field of rhinoplasty, morbidity is uncommon and the absorption rate is low [10]. If only the external bone layer is taken, the risk of injury of the dura or even the brain is reasonably low.

Irradiated costal cartilage (ICC) was given a contradictory evaluation [11], [12], [13]. The absorption that is frequently observed – especially in animal experiments – did not essentially accompany a poor end result in patients. In more recent investigations neither absorption nor other complications of irradiated costal cartilage were reported [2], [14]. In German-speaking countries there have scarcely been any reports on the use of preserved, irradiated costal cartilage in recent times.

1.2 Plastics as implants

In comparison with ceramics or even metals, for example, which only play a subordinate role in rhinoplasty – e.g. titanium braces for stabilising the valve region – some plastics have earned a firm place (cf. Table 1). Porous materials, that more or less allow tissue to grow in, can be differentiated from smooth, compact materials [15]. Porous implants are at risk from earlier infections before connective tissue has grown in, while later infections can be prevented by the grown in tissue with its immunocompetent cells. This therefore particularly depends on a sterile implantation technique and an uninterrupted early healing phase. Compact implants with smooth surfaces – namely silicone – tend to create a fibrous capsule, remain flexible and are therefore more at risk from later infections and rejection. Because the tissue has not grown in they are also easy to remove if
Table 1: Properties of implant materials

| Material                                      | Quality | Stable, with supporting function | Soft, suitable for camouflage | Shaping easy | Rejection frequently described | Absorption frequently described | Complete removal unproblematic |
|------------------------------------------------|---------|---------------------------------|--------------------------------|--------------|------------------------------|-------------------------------|-------------------------------|
| Silicone                                       | +       | -                               | -/+                           | +            | -                           | -                             | +                             |
| Porous polyethylene (PE; Medpor ®)             | +       | -                               | +                             | -            | -                           | -                             | +                             |
| Proplast (polytetrafluoroethylene; PTFE)       | +/-     | -                               | +/-                           | -            | -                           | -                             | +/-                           |
| GoreTex (Expanded polytetrafluoroethylene; ePTFE) | -       | (+)                             | +/-                           | -            | -                           | -                             | +                             |
| “Turkish Delight” (Diced cartilage, surrounded with SurgiCel (methylcellulose) or fascia) | -       | +                               | +                             | -            | -                           | -                             | -                             |
| Mersilene mesh (polyethylene terephthalate; PETP) | -       | +                               | (+)                           | -            | -                           | -                             | -                             |
| AlloDerm (acellular bank skin)                  | -       | +                               | +                             | -            | -                           | -                             | -                             |
| Irradiated, preserved costal cartilage         | +       | -                               | -/+                           | -            | +                           | -                             | /+                            |

required. Independently from porosity, plastics can also be differentiated according to whether they can assume a supporting role as block implants or whether they are more suitable as soft, fabric tissue for volume compensation or contouring. Silicone and porous polyethylene (PE) belong to the first group and mersilene mesh (polyethylene terephthalate; PETP) and Gore-Tex (expanded polytetrafluoroethylene; ePTFE) belong to the second group.

1.2.1 Silicone

Although subsequent observations of larger groups over longer periods of time have repeatedly demonstrated that silicone implants have an unacceptably high rejection rate [16], [17], so the material has become increasingly less popular, frequent use is still reported from Asia [18], [19]. It is unclear – as is sometimes suspected – whether the stronger skins of people from Asia increase tolerance of silicone implants [20] or whether it is possible that a higher rate of complications is tolerated when faced with lower costs, easier management and unproblematic removal of the implants. 355 patients subsequently investigated by Tham et al. [18] already still had a complication rate of nearly 8% after just 160 days. Nevertheless the material was described by the authors as being “effective and safe” for nose augmentation. 52 of the patients had already received silicone implants twice and in 5 patients the attempt had failed several times. The largest implants had the highest rates of extrusion and infection. On the basis of experimental investigations, Yang et al. [19] recommended that silicone implants are inserted subperiostally. However, this recommendation cannot always be implemented, because the perioseum of the nose bridge can now hardly be lifted off as a closed layer, especially during revisions. Nevertheless, surgeons have made frequent attempts at subperiostal implants [18], but it was not possible to achieve sustainable results.

1.2.2 Proplast

Proplast (polytetrafluoroethylene, PTFE; Vitek, Houston, Tx) did not demonstrate the same high tissue tolerance and stability in experimental and clinical investigations as e.g. porous polyethylene (PE) and demonstrated a higher susceptibility to infection [21]. In 1990 the FDA withdrew approval for Proplast [22]. However, because it is easy to shape, it continued to be used in rhinosurgery. In the case of implantation via a vertical incision in the columnella where the mucous membrane is intact on all sides, Baran et al. [6] achieved good results even in longer term follow up in 62 patients with saddle nose correction. The authors are nevertheless considering the use of PE implants for future cases.

1.2.3 Gore-Tex

Gore-Tex is expanded polytetrafluoroethylene (ePTFE; W.L. Gore, Flagstaff, Ariz.) of a more textile character that is less suited to a supporting function but more suitable for volume equalisation of small defects [23], [24]. Even though the material has been shown to have good biocompatibility, Bracaglia et al. [7] found that it had only been used to correct smaller defects with 10.6% relatively frequent infections in their patient group. Formation of fistulae precedes infection and rejection.

1.2.4 Mersilene mesh

Mersilene mesh (polyethylene terephthalate, PETP; plaited polyester fibre net; Ethicon, Somerville, NJ) can be used...
for volume correction in the nose area, but it cannot fulfil a supporting role. Connective tissue that is growing in attaches the material. However, removal can be difficult. Unlike the Supramid mesh that was previously common but that has since been abandoned, a nylon progeny, mersilene is not broken down by hydrolysis and is not then reabsorbed. Current investigations [25], according to which rolled or layered mersilene net is used for premaxillary augmentation and that have been subsequently investigated for 32 months, have shown a good success rate with no infection, rejection or absorption. There was only once incident of partial implant loss through contact with an existing septum perforation.

1.2.5 “Turkish Delight”

“Turkish Delight” is called a compound implant whereby autogenous cartilage – usually from the septum – is cut into 0.5 to 1 mm cubes and then mixed with blood and antibiotics and encased in Surgicel (methyl cellulose; Johnson & Johnson, Ethicon, Somerville, NJ) [26]. Surgicel is absorbed after 7 to 14 days. Erol [26] reported on successful use of “Turkish Delight” in augmentation and camoufage in more than 2300 cases. However, others later found unexpected regular absorption of the entire compound implant within a few months with the same methods, but good and lasting results when the diced pieces of cartilage were encased in autogenous temporal fascia [27]. Animal experiment studies [28] confirm the observation of Daniel und Calvert [27], in which cartilage encased in Surgicel was absorbed, while no absorption occurred when encased in fascia. It is accepted that Surgicel has a negative effect on the vitality of the encased cartilage that does not occur when it is encased in fascia [29]. The beneficial quality of such implants is namely that they remain malleable over a certain period after implantation until stability occurs [26], and remain, even in the event of use of a fascia case. In the place of the autogenous cartilage, others have encased solvent-preserved, irradiated, homologous costal cartilage cubes [14]. Admittedly reports of absorption were not announced immediately, but in five cases the saddle on the nose bridge reoccurred and there was one incidence of infection. There were no investigations with irradiated costal cartilage in a fascia case.

1.2.6 AlloDerm

AlloDerm (LifeCell Corporation, Branchburg, NJ, USA) is an acellular dermal matrix of donated human skin tissue that is produced for tissue banks in accordance with the guidelines of the Food and Drug Administration (FDA) and is regarded as a human bank tissue. In rhinoplasty the material is used to even out irregularities, to cover transplant edges or as a tip graft. Current follow-up investigations [30], [31] with a follow-up up to eight years initially did not show any notable changes. After a year had passed partial absorption between 10 and 30% of materials was seen in around half of the patients. This absorption forces overcorrection. However, subsequent correction is possible. Dislocation of the material or complete absorption was not observed. The only extrusion happened through the endonasal access with a rolled implant, which is why the use of stacked AlloDerm implants in up to eight layers is recommended. A height of up to 3 mm can be augmented on the bridge of the nose. The material does not assume a supporting function.

1.2.7 Porous polyethylene

Porous polyethylene (high density polyethylene (HDPE); PE; Medpor®, Porex Surgical, Newnan, Ga.) is a chemically pure, porous plastic implant that can take on a supportive function [32]. The material can be shaped after heating, cut, punctured with needle and thread and for example welded into a point shape using an electrocauter, which makes it form a connection with two individual elements possible. The result is individually adapted, fine but stable implants that are preferably inserted using expanded endonasal access (Figure 1). Good histocompatibility with connective tissue growing in and associated vessel supply has been known for a long time [33]. The material is increasingly being used in rhino surgery, in particular increasingly fine and soft special implants are available for the nose bridge, the middle third, the septum and the sides of the nose [34]. Newer literature also evaluates porous polyethylene in rhinoplasty as being overwhelmingly positive if it is noted that no distinct overcorrection is made, especially with pre-damaged skin and damaged soft tissue coating during augmentation, because the extrusion of the material would be assisted [2]. The value of spreader grafts made from porous polyethylene in secondary or tertiary rhinoplasty is primarily emphasised here [35], independently of the choice of operative access. There are also advantages in the stability of PE in comparison when faced with subsequent trauma or long-lasting effects of scar contracture [36]), which is why the material is considered to be unusually safe and reliable. These positive qualities make porous polyethylene generally interesting as a reconstructive measure beyond rhinoplasty [37].

Initially experimentally, but then also clinically, Ozdemir et al. managed to produce prefabricated, axial vessel tissue flaps with integrated PE alloplasty, which was epithelisated after healing and vascularisation with thin full-thickness skin transplants [38] – a new option for provision of combined skeletal and soft tissue defects that are principally taken into consideration in patients with limited donated tissue and that could presumably be developed further. With these composite flaps it is shown that the vessel supply in PE pore systems is so good after healing that the full-thickness skin flaps grow on them. This has already been experienced in the use of porous polyethylene for ear reconstruction (see below; cf. e.g. [39], [40].
Figure 1: Implant made from PE for correction of saddle nose defect. Nose bridge strut and septum replacement were fused using point heating with an electrocautery.
  a: Side view
  b: Frontal; demonstration of flexibility of septum replacement

Two PE implants may be combined with one another through “point welding” with electrocauteries (Figure 1). In exceptional cases partial extrusion of a PE implant occurs after weeks or months, e.g. through intranasal access, then partial resection can be undertaken up to the areas, in which undisturbed tissue infiltration can be seen in the pores. Partial removal is technically unproblematic and the remaining implant can remain in situ. This is where porous polyethylene is very different from silicone or Proplast, for example.

1.3 Own results with porous polyethylene nose implants

In a retrospective analysis of 32 patients where a total of 36 Medpor® implants were used in rhinosurgery, the average age was 36 years [41]. In over ¼ of cases these were revision operations (cf. Figure 2).

Corresponding to each indication, 28 columellar struts, 15 nose bridge implants (only grafts), 7 batten grafts and 3 shield grafts were implanted, whereby all 15 nose bridge implants were fused with columellar struts and then implanted as a complete, L-shaped unit.

Of the 32 patients, 7 developed a complication, which made a complete explantation of the PE necessary for 4 patients and partial explantation necessary for 3. On average the explantations took place after 126 days, whereby the last implant had to be explanted after 266 days and the first after just 24 days. All of these patients had been operated on several times previously, some 5 to 6 times, with correspondingly high formation of scars and perforation of the septum. In the case of three of these seven patients reconstruction of the nasal skeleton had already been attempted with costal cartilage and each attempt had been unsuccessful.

The most frequently occurring complication (n=4) consisted of a partially open, but irritation-free implant in the region of the anterior septum, where it came out via the intranasal incision through which it was inserted.

In one case there was a skin defect and in one patient there was a strong, distinct reddening of the skin with secretion (with no perforation of the skin) in the region of the nose bridge above the implant, which was placed very close underneath the skin of the nose, which had already been damaged by a scar. Even after several weeks of local care with grease and antibiotic cream the skin in the area of the lesion failed to regenerate, because of which explantation was done after 52 or 132 days. In both cases the nose implant has grown in well in the region of the unexposed areal, which was however completely removed for safety reasons. In both of these patients the plastic implant was replaced with a costal strut during the same operation to maintain the shape of the nose, once the patients had given their consent. These transplants healed without problems, even if they had to be closed with a rotation skin flap in one case of skin defect.

In one patient there was an infection with extrusion in the region of the columella, 40 days after implantation, which could only be controlled through partial removal of the infected part of the columellar strut. However, the stability of the nose did not suffer as a result of the remov-
al and the columella was able to heal up successfully, although part of the implant remained in situ. In five patients there was no new implantation following the explantation either of autologous or alloplastic materials. The shape of the nose remained stable with the scarring that had taken and was satisfactory for the patients.

27 patients were satisfied with the result (Figure 3). 5 patients hoped for an even better cosmetic result. However, they currently did not want to have any further operations. 4 patients complained about impaired nasal breathing following the rhinoplasty. All 6 patients that were given a batten graft for nasal valve stenosis experienced clearly improved breathing. No patients experienced a deterioration of their functional or cosmetic situation.

2 Materials for ear reconstruction

2.1 Costal cartilage

Autogenous costal cartilage is often used for the partial and total reconstruction of the auricle [42], [43]. As early as 1908 Schmieden was shaping auricle skeletons from costal cartilage, which were then implanted in the abdominal skin and then inserted into the defective location in the form of advancing flaps [44]. In the English-speaking world, Gillies was one of the first to carry out an auricle reconstruction using autologous costal cartilage, in 1920 [45]. Since then the material has had a firm place in this issue. Nevertheless costal cartilage has various disadvantages: It requires special surgical experience and it takes a considerable amount of time to shape a natural, three-dimensional framework from costal cartilage. And despite experience with ear reconstruction there is an unsatisfactory aesthetic result not so rarely because of bending or absorption [46], [47]. In the postoperative phase there are often increasing weaknesses in the definition, the structural detail and the projection in comparison to the healthy counterpart in an ear made out of costal cartilage.

In addition, this method usually requires several reconstruction steps and the time needed for the design of an adequate auricle increases again as a result. According to Lindig et al. [48] the removal of costal cartilage for larger transplants is also painful and there is a distinctly increased risk of pneumonia because of shallow breathing caused by pain if there is insufficient postoperative analgesia. Severe pain also leads to an increased catabolic metabolism with the risk of slower wound healing. In addition, operative complications such as pneumothorax and atelectasis and later deformities of the rib cage and formation of unattractive scars at the site of removal are feared [46], [47]. Ohara et al. [49] observed deformities of the thorax in 18 cases in over 64% of patients under 10.

Absorption is a widely feared postoperative complication which involves the associated flattening of the implanted costal cartilage [47], which occurs in up to 40% of cases [46]. Skin necroses and skin perforation are also observed in the use of costal cartilage. Skin coverage is primarily done with local skin, which because of the deep lying hair line can sometimes lead to hair growth on the new auricle. This is very upsetting cosmetically and can be very difficult to correct in the long term. Sufficient costal cartilage for reconstruction also requires a certain minimum age. Good long term results should only be expected from 9th to 10th year [50]. Attempts to get by with less cartilage regularly result in an unsatisfactory result or insufficient projection of the new ear. However, because patients with auricle deformities can be targets for teasing and therefore may be suffering emotionally, it is recommended that the corrective operation is carried out as early as possible, preferably before reaching nursery age [50].
Progressive calcification of the costal cartilage with increasing age is a further disadvantage that should be mentioned. An increase of around 6% in the third decade of life up to 45% in the ninth decade of life is assumed [51]. Therefore treating older patients with cartilage becomes increasingly difficult. In order to bend the helix without the cartilage breaking is then almost impossible [52].

Despite the varied possible complications the opportunity to share the statistical coverage of the long term results in newer publications about the results of ear reconstruction with costal cartilage [53], [54], even during alleged observation of a large stock of patients, remains unused, even though experience has shown the positive results that are shared are suspected to be contrary to an unknown number of complications and failures.

2.2 Plastic implants for ear reconstruction

Because they are easy to work with and readily available and because of short operation times in comparison with costal cartilage, silicone implants have been used for auricle reconstruction [55]. However, this material was not able to meet expectations. The complication rate for reconstruction of the ear skeleton is very high. Lynch et al. [56] observed a complication rate of 27% with silicon in 46 cases. Infections, skin perforations and dislocations, foreign body reactions and capsule fibrosis should be named as the most frequently occurring complications of silicone implants. The cause of such unsatisfactory results is, according to Spitalny et al. [57], the lack of sufficiently stable subcutaneous padding, which is a requirement for long term healing of this implant. In addition, the thin soft tissue cover – as required in the case of ear reconstruction – is often not suitable for the strain caused by the implant beneath it. According to literary information the complication rate in the use of silicone implants is still higher than with autogenous costal cartilage [46].

Dissatisfaction with the results from the use of autogenous costal cartilage led to porous polyethylene being used for total auricle reconstruction for the first time [32], [58]. If covered with parietotemporal flaps and full-thickness skin transplant, growth of connective tissue and vessels can already be seen. Ears reconstructed in this way prove to be extremely tough. Pressure from outside is well tolerated. Positive experiences with polyethylene in ear reconstruction even in problematic cases, such as in burns sufferers [59], have been repeatedly confirmed by other authors in the meantime [60], [61], [62], [63], [64].

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The polyethylene skeleton is intraoperatively composed of two basic elements (helical rim and ear base) (Figure 4). Both parts are bound together by heating the plastic using point welding with a single-use cautery device or by stitching them together. So that the contours match the other side as closely as possible, a mirror image three-dimensional print of the healthy ear is used, if possible, to help with orientation and as an example. However, an image of the reverse side drawn on silicone film is, in principle, suitable for this purpose as well. Corrections to the shape of the implant are carried out using a scalpel until it exactly corresponds to the requirements in the given case and is adapted to the rudimentary ear cartilage, if required.

Soaking the implant in an antibiotic solution prevents early infection. In order to reach all of the pores of the implant, the skeleton is placed under suction with in a large syringe filled with antibiotic solution by pulling the plunger.

2.2.1 Use of implants

The Medpor skeleton will then be placed in the location that has been measured in advance for this purpose, completely encased in a parietotemporal fascia flap (PTF) and fixed in the required position using stitches [65] (Figure 5). One or two relatively strong needles with long term absorbable thread that are passed through the plastic hold the implant in the ideal location, once it has been found. Because of the stitches that are absorbed within a short period, the enveloping PTF flaps will become a shell that lies close to the implant.
Figure 5: Ear reconstruction with PE skeleton and parietotemporal fascia flap
a: Marking of hairline, incision, position of planned ear, position of Temp. superficial artery
b: Parietotemporal fascia flap with artery contained in it
c: The flap over the ear region from below
d: The PTF flap encase the PE skeleton
e: Result after full-thickness skin covering
f: Demonstration of postauricular sulcus

Two drains suck away wound secretions for around 7 postoperative days and ensure close contact between the skin, fascia flaps and skeleton.

2.2.1.2 Skin covering of the new auricle

The skin covering of the newly formed auricle on the ventral side is done partly with local skin and partly with full-thickness skin from the retroauricular surface of the other ear. The postauricular skin defects that still exist afterwards on both sides are covered with full skin-thickness skin transplants from the groin region or the abdominal wall. The collection point is within the "bikini zone" and, if possible, outside of the pubic hair between the centre line and the spina iliaca anterior superior. When the wound has been closed and the drains have been fixed, saline is applied to the reconstructed ear and a D-shaped foam ring is placed around the ear. This is filled with a two-component silicone foam (Cavi-Care®, Smith & Nephew Comp.), which should be carried out without excessive pressure on the new ear.

2.2.2 Own results of ear reconstruction with Medpor implants, parietotemporal fascia flaps and full-thickness skin

Since 2002 we have reconstructed 51 ears with the method described here [65]. This included 47 congenital microtia and 4 traumatic defects. 34 patients were male and 17 female. 16 cases involved children up to 12 years old (male:female = 10:6). 35 patients were adults or aged 12 years or older. A tragus was reconstructed in a second sitting in 5 cases. In 12 cases subsequent operations for correction and secondary improvement of the results were necessary, up to 3 times in individual cases. The period of subsequent observation was between 0.5 and 5 years.

We observed the following complications:

- unfavourable hair loss 3 times (slow spontaneous improvement in one case, plastic correction in two cases);
- implant perforation 3 times (each corrected by renewed fascia or skin covering);
- unsatisfactory cosmetic end result 4 times (skeleton retained, subsequent corrections).

We have not observed defective healing of a skin transplant, suppurating infection or break of an implant. No patients have complained of disturbing hair growth on the reconstructed ear.

The results targeted with the methods illustrated are of the same value or higher with clearly less reconstruction expenditure compared to costal cartilage (Figure 6, Figure 7, Figure 8, Figure 9). In accordance with a comparable overview [66] the operative morbidity and duration of operation with PE skeletons during ear reconstruction compared with autogenous costal cartilage is clearly less and the cost of intervention is almost halved with the plastic skeleton. Thus during the operation time that is required for the correction of one side using costal cartilage, we can carry out bilateral ear reconstructions with PE skeletons, without further taxing the patient with narcosis or transplant removal. In addition we have also experienced that the quality of the result is at least the same as with costal cartilage, with a smaller number of operations per patient. Therefore the writer prefers this procedure.
3 Concluding remarks

No surgical discipline can manage without alloplastic materials. Lots of investigations show that in the event of careful diagnosis and appropriate operative technique, alloplastics also have their place in rhinosurgery and ear reconstruction. If surgeons only accept grafts as transplant materials there is the risk that their disadvantages and risks will not be recognised and that technological progress will be denied. An aim of current research is the further improvement of interaction between implant and site. In addition to the unavoidable need for the best possible quality, it must be accepted that implant materials – like pharmaceutical products and autogenous transplants – can also have certain side effects. The “ideal implant“, free from all unwanted effects, may never exist.

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