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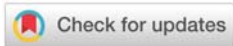
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Research Article

Titanium Septum Plate: A novel technique to straighten and to stabilize the Nasal Septum using a Modified Titanium Breathe-Implant

Abstract

Importance: The cartilaginous nasal septum remains a difficult structure to straighten and to stabilize as it tends to bend. Recurrence of an asymmetric and bent septum is a frequent complain in patients as it may lead to asymmetric nasal breathing and/or aesthetic asymmetries of the shape of the nose.

Objective: To investigate a novel technique: the implantation of a titanium septum plate (TSP) in its use as a septum stabilizer and straightener. To present a clinical study on the experience of a modified titanium Breathe-Implant used as a septum plate.

Design Settings and Participants: In this retrospective study, medical records as well as preoperative and postoperative functional studies in which a titanium septum plate had been used between February 2014 and May 2016 in a total of 31 consecutive patients subjected to septoplasty with the use of one or two Titanium Septum Plates (TSP) in closed and open surgeries by the same surgeon were reviewed. All (100 %) were eligible and included in the study.

Interventions: Before surgery, a complete rhinological examination was conducted including nasal endoscopy, digital endonasal photography, rhinomanometry, PNIF mask testing, and a SNOT 20 questionnaire.

Results: This is the first report in the literature to use a titanium plate in septoplasty. There were no intra- or postoperative complications in the use of TSP. In all 31 patients all TSP remain in the nose. In the accumulated observational period of 544 months there were no exposures internally or externally, no extrusions, no infections and no explantations. In the usual placement of TSP the implant runs parallel to the axis of the nose. Metal is much stronger than cartilage to straighten the nasal axis. No postoperative infection was observed and no antibiotic prophylaxis or therapy were necessary.

Conclusions and Relevance: The implantation of TSP has proven over time to be safe and reliable. Titanium is an inert metal suited for septal surgery. Future implants specifically designed for septoplasty will facilitate septal surgery and will help to achieve more stable long-term results with hopefully better patient satisfaction than septoplasty alone.

Introduction

A novel surgical technique is presented using a modified Titanium Breathe-Implant as a Titanium Septum Plate (TSP) to duplicate the anterior nasal septum. In 31 patients over a period of 2.3 years no complications arised. The TSP has improved surgical and aesthetical results of septoplasty in all patients. The use of TSP might provide a reliable addition in septoplasty.

The cartilaginous nasal septum is the main supporting

structure of the nasal dorsum. The shape of the nose greatly depends on the septum [1]. Symmetric nasal breathing relies on symmetric airways due to a straight septum. In septoplasty the cartilaginous septum is approached and all efforts are made to straighten the septum [2]. The septal cartilage often presents with anterior deflections that have proven over time to be difficult to correct. Various surgical techniques have been applied to straighten the cartilage among them scoring, scratching, incisions, sutures, cartilaginous duplications, sheething by autologous bony ethmoidal plate

or Polydioxanone (PDS) [3-5]. Permanent reliable results are difficult to achieve. Surgeons need all possible help to achieve a strong septum in the midline of the nose.

Methods

Breathe-implant modified as a flat titanium plate

The Titanium nasal implant « Breathe-Implant » has been surgically implanted since its CE mark in 2003 in thousands of patients worldwide [6,7]. Over a period of more than 15 years Breathe-Implant has stood the test of time. Breathe-Implant is designed to be sutured to the Upper Lateral Cartilage (ULC) to open and to stabilize the internal nasal valve in a reliable and efficient way. Breathe-Implant has all edges rounded off and it has proven to be safe and reliable. Metal is stronger than any other material. Bone might break and autologous cartilage is too weak and too thick: it might narrow the endonasal airspace. Breathe-Implant is only 0.5 mm in thickness: it will not obstruct the airway. Breathe-Implant is available in 6 sizes. For TSP only the largest size XXL was used. This is an off-label use of Breathe-Implant and the patients were informed about it. However there was no IRB approval obtained in Switzerland. Breathe-Implant is bent straight by hand and then by hammer. It must be protected from direct metal contact by the hammer by putting it between layers of surgical gauze before it can be hit by the hammer and used as a straight plate (Figure 1). This results in a boomerang shaped Titanium plate that can be used as a paraseptal plate (Figure 2). The open angle of the implant of 100 degrees between the two branches conforms well with the angle between the anterior septal edge and the nasal dorsum. Several implants can be used at the same time. They can be positioned side by side or overlapping due to the need of surgery. The caudal part of TSP toward the anterior nasal spine provides a more stable structure than cartilage alone for septal sutures of the lower nasal septum to the anterior nasal spine. The criteria applied to choose this Titanium implant included absence of usable bony splints from the perpendicular plate of the septum and the necessity for a straight and strong septal structure. This could be due to a septal fracture or massive septal deflections of the anterior half of the cartilaginous septum.

Clinical experience in 31 patients

Between 2013 and 2016 a total of 31 patients have received one or more Titanium Septum Plates (TSP). The TSP were always used on the same side of the septum. Twentyone were male and 10 were female (Figure 3). Mean age of patients was 45 y. Postsurgical observation was from 3 to 30 months with a total of 544 observational months and a mean of 18 months. In 10 patients TSP was implanted in primary surgery and in 21 patients in revision surgery. In 27 patients a single TSP was implanted and in 4 patients two TSP were used. In combination with TSP 28 (90%) of patients also had a Titanium Breathe-Implant placed on their ULC. The TSP is sutured to the septal cartilage with permanent sutures of Prolen 5-0 and care is taken that the Titanium plate does not exceed cartilage size. Free metal edges must be avoided as they might increase the risk of soft tissue perforation. Two or more TSP may be

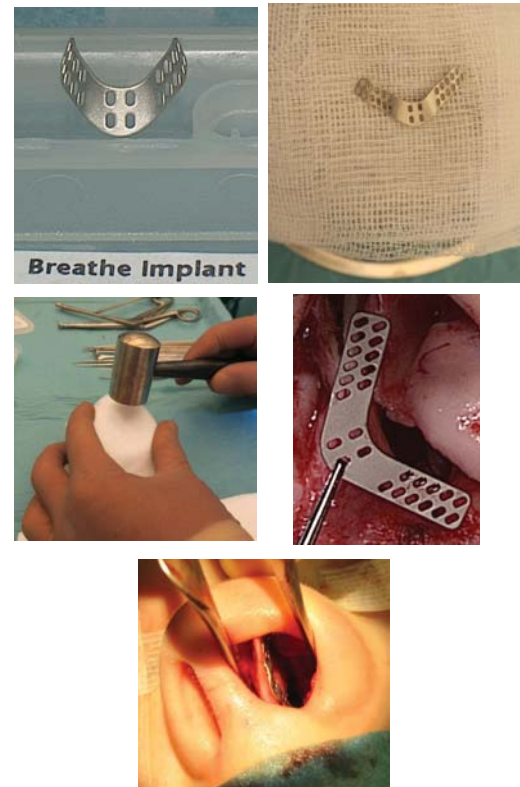


Figure 1: Titanium Breathe-Implant XXL flattened as a Titanium Septum Plate for use in septoplasty.

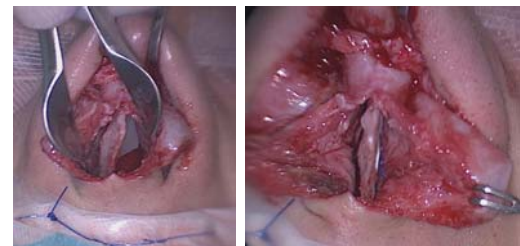


Figure 2: Anterior septal deflection corrected by the paraseptal Titanium Septum Plate.

| Figure 3: Titanium Septum Plates. | |
|-----------------------------------|---------------------|
| n | 31 |
| Gender | 21 males 10 females |
| Mean age at sx | 45 y |
| Primary surgery | 10 of 31 |
| Revision surgery | 21 of 31 |
| w Turbinoplasty | 27 of 31 |
| w Breathe-Implant | 28 of 31 |
| Months of observation | 544 months |
| Mean observation per patient | 18 months |
| Closed Sx / hemitransfixion | 20 of 31 |
| Open Sx / external rhinoplasty | 11 of 31 |
| 1 Titanium Septum Plate | 27 |
| 2 Titanium Septum Plates | 4 |

Figure 3: Titanium Septum Plates.

combined in various frame works such as an open U-shape or an overlap as needed as in extracorporeal septoplasty (Figures 4-5) [8,9]. Surgical procedures were uneventful. All surgeries were performed by a single surgeon. The decision to use a

TSP was taken at the time of surgery. Patients were informed by informed consent that a titanium plate might be used to improve results on their septum. In addition to septal surgery submucous turbinoplasty was also performed in 27 patients and 28 patients also had a Titanium Breathe-Implant sutured on their Upper Lateral Cartilage at the time of surgery to open and to stabilize their internal nasal valve.

Results

Functional results

Pre- and postoperative rhinomanometry [10], measurements in 21 patients of the sum of right and left values at 150kPa changed from a mean 452 to 641 cm³/sec for an average improvement of 189 cm³/sec (Figure 6). The PNIF test (Peak Nasal Inspiratory Flow) was obtained in 19 patients with a mean improvement of 32 liter per minute air flow. In 17 patients the SNOT 20 (Sino-Nasal Outcome Test) questionnaire was completed where 16 (94%) improved their score and 1 patient (6%) became worse. The mean preoperative score of 36 changed to 17 points postoperative for a mean improvement of 19 points per patient. Postoperative measurements were taken 3 to 9 months after surgery. All tests are routinely collected for all of our patients operated on.

An absolute symmetry of nasal breathing is physically impossible to achieve. However, with the use of TSP values of flow in rhinomanometry measurements were more symmetric in 23 (74%) of patients.

Long-term stability of titanium septum plate

In all 31 patients all implanted TSP remain in the nose. In the accumulated observational period of 544 months there were no exposures internally or externally, no extrusions, no infections and no explantations. The TSP has proven over time to be a safe and reliable tool.

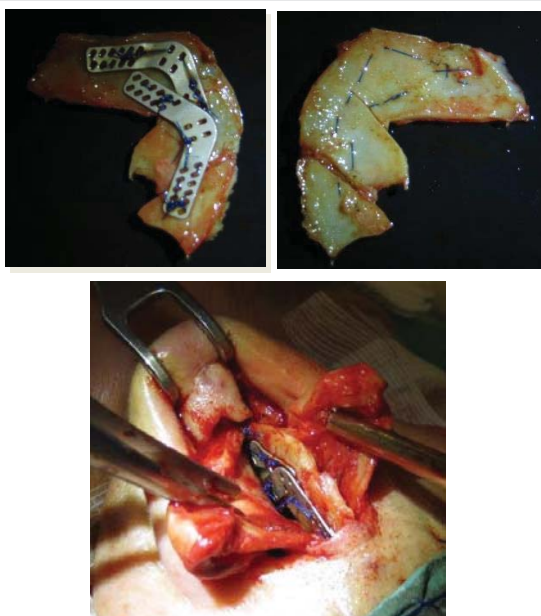


Figure 4: Titanium Septum Plates in extracorporeal septoplasty.

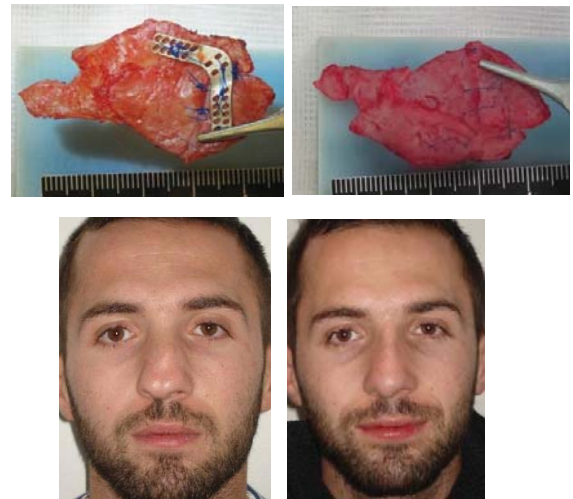


Figure 5: Titanium Septum Plate in extracorporeal septoplasty.

| Figure 6: Functional results | |
|--|--------------------------|
| Rhinomanometry | |
| n = 21 | |
| Mean preop right and left at 150 kPa | 452 cm ³ /min |
| Mean postop right and left at 150 kPa | 641 cm ³ /min |
| Mean improvement right and left at 150 kPa | 189 cm ³ /min |
| Pre/ post PNIF | |
| n = 19 | |
| Mean preop PNIF | 110 l/min flow |
| Mean postop PNIF | 142 l/min flow |
| Mean improvement | 32 l/min flow |
| Pre/ post SNOT 20 questionnaire | |
| n=17 | |
| Mean preop SNOT 20 | 36 |
| Mean postop SNOT 20 | 17 |

Figure 6: Functional results.

The usual position of TSP along the cartilaginous septum in a sagittal CT scan (Figure 7) where one part of TSP runs more parallel to the nasal dorsum and the other part more parallel to the anterior edge of the septal cartilage. The open angle of 100 degrees conforms well to septal anatomy.

The TSP also helped to achieve a straighter external nasal axis. In the usual placement of TSP the implant runs parallel to the axis of the nose. Metal is much stronger than cartilage to straighten the nasal axis. In the future cartilaginous spreader grafts might be needed less often to straighten and to structure the nose [11]. Due to their volume cartilaginous grafts may also cause nasal obstruction. TSP is significantly thinner and will cause less airway obstruction.

Discussion

Previously surgeons depended on various techniques in order to achieve a straight and stable cartilaginous septum. Postoperative results were often unreliable with uncontrollable deviations of the septal cartilage leading to persistent asymmetric nasal breathing : A major cause for dissatisfaction by the patient. The TSP may help to achieve better straightening of the nasal septum. Potential indications for the use of TSP include among others : weak or deviated anterior septum,

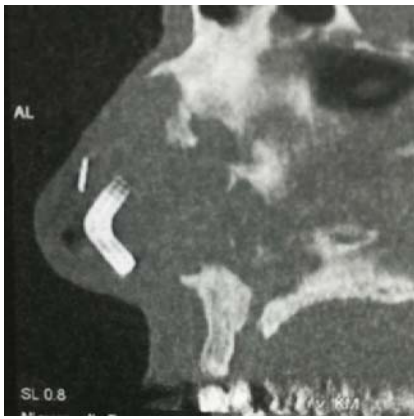


Figure 7: Sagittal CT scan of a Titanium Septum Plate along the septum and a Breathe-Implant on the Upper Lateral Cartilage.

deviation of nasal axis, loss of projection of the nasal tip, for septal extension grafts in end-to-end technique, for revision surgery, for tongue-in-groove, for extracorporeal septoplasty or other.

The outcome measures used in this study are the standard program for all our functional and aesthetic nasal surgeries. The PNIF test provides information about the soft tissue stability of the nasal septum as well as the nasal side walls. For the placement of Breathe-Implant on the original position on top of the Upper Lateral Cartilage the PNIF test provides valuable information.

Rhinomanometry is measured in all our patients as health insurances increasingly demand preoperative values to provide financial support.

The SNOT 20 questionnaire is also standard procedure in our work-up. Alternatively the NOSE test could also be used to monitor subjective nasal obstruction.

The resorbable PDS (Polydioxanone) plate has been used for the same purpose for years. However, PDS will only remain in the nose for a limited number of months. Infection rate of PDS septal plates is high: if any part of the PDS plate is not fully covered by mucosa infection fast resorption might follow. The TSP however has not caused a single infection even in difficult surgeries requiring closure of septal perforations or in extracorporeal septoplasties. No antibiotic prophylaxis nor treatment were used in all of these patients in spite of the foreign body implant.

TSP may not be used as a structure alone. It must always be sutured to cartilage and no edge may extend the limits of cartilage in order to avoid potential complications such as exposure, extrusion or infection. With the positive results of this patient group we have designed a new implant for the nose for the future that will not need shaping of flattening: the Septum-Clip.

Summary

The modified Titanium Breathe-Implant used as a flat metal plate has proven to be safe and reliable in 31 patients over a mean observational period of 18 months with a total of 544 observational months. No complications like exposure, extrusion, infection or removal occurred in this time. Titanium is an inert metal widely used in the human body. The use of Titanium in the nasal septum is a new and promising field of application. Titanium will help surgeons to achieve straighter and stronger septal structures.

Conflict of interest disclosures

The author receives a royalty for Breathe-Implant by Heinz Kurz GmbH Dusslingen Germany. No financial interest in the distributor of Breathe-Implant: Karl Storz, Tuttlingen Germany.

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