

Fibrinogen-Thrombin Coated Collagen Sponge (TachoSil®) Usage in Rhinoplasty: Our Experience

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Abstract

Objective: There are multiple techniques to obtain a reasonable augmentation and filling of the nasal dorsum and ensure a smooth and harmonic nasal dorsum in rhinoplasty.

This article will discuss our results of applying fibrinogen and thrombin coated collagen patch named TachoSil® in various rhinoplasties, with or without using an additional bone or cartilage graft.

Material and Methods: We retrospectively analyzed the preoperative and six months postoperative clinical data as well as the overall satisfaction of a total of 78 patients who were applied TachoSil® during their rhinoplasties between Jan 2016 and July 2019.

Results: Rhinoplasties were all performed with a closed approach. No postoperative bleeding and no allergic reactions to TachoSil® were reported. Two patients presented on the 10th postoperative day with nasal dorsum abscess. 83% of the patients were satisfied, whereas nasal retouching was performed in 17% of patients because of dissatisfaction.

Conclusion: In addition to its significant hemostatic role, TachoSil® is considered a safe, effective, and easy method to be applied for graft fixation in Augmentation rhinoplasties, to conceal the nasal dorsum irregularities, to fill and support soft tissue in patients with thin nasal skin.

Keywords: Augmentation, Rhinoplasty, Autografts, Cartilage, Cosmetic techniques, Hemostatic Technics.

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Introduction:

Rhinoplasty is a complicated cosmetic procedure that needs three-dimensional handling of different tissues, often done within limited space. A standard Rhinoplasty does not exist because of the unique anatomy of every patient. Every case needs its specific incision, access, removing, and handling of a specific amount of tissues.

With long years of experience and meticulous documentation, surgeons improved the results of rhinoplasty and made them more convenient for the patients with less need for revision surgeries.^[1] The need and indications for rhinoplasty have undoubtedly increased with the development of various surgical techniques and Modalities.^[2] One of the essential steps in this surgical procedure is nasal dorsum augmentation, i.e., reconstruction and filling of the nasal dorsum to establish a smooth, regular, and harmonic nasal dorsum. Insufficient reconstruction will result in saddle deformity or nasal dorsum irregularity with sharp palpable edges and increase the revision rates. There are multiple modalities to achieve an adequate augmentation and filling of the nasal dorsum in rhinoplasty. Autologous cartilage grafts such as septal, Auricular (conchal), or costal have served this purpose in concrete, crushed, or diced forms.

A wide range of dorsal grafts can be created using fascia and cartilage together in many ways: the only fascia, only diced cartilage (DC), diced cartilage and fascia (DCF) [diced cartilage under the fascia (DC + F), or diced cartilage wrapped in the fascia (DC – F)].^[3] Daniel and others described the use of a DCF graft for moderate dorsal augmentation and final remodeling of the dorsum. Diced cartilage is wrapped with temporal fascia in a precisely measured length and width depending on the needed dorsal augmentation.^[3-5]

TachoSil® is a two-sided collagen sponge with one white uncoated side and a Riboflavin.

Pre-impregnated yellow side coated with coagulation factors (fibrinogen and thrombin). Fig.1 The function of TachoSil® is to stimulate the coagulation cascade by imitating the final step of the natural blood clotting process (Soluble Fibrinogen → insoluble fibrin by the action of the serine protease thrombin) to seal the tissue it is applied to.^[6]

In this case series, we will discuss our result using a fibrinogen and thrombin coated collagen patch named **TachoSil® (Takeda Pharmaceutical, Osaka, Japan, recently acquired by Johnson & Johnson, Ethicon)** with or without using an additional bone or cartilage graft.

Materials and Methods:

In this retrospective case series study, all data were retrieved from the hospital information system and patient files. Retrieved data were organized and analyzed using the MS Excel® 365 program.

Between Jan 2016 and July 2019, TachoSil® was applied in 87 patients for closed rhinoplasties. We excluded nine patients from our study because of insufficient clinical data. All patients underwent surgery with general anesthesia by Professor Lorenz at Ulm Military Hospital. The clinical evaluation was performed by Physical examination and taking photographs of the patients with a standardized position, facial expression, and camera settings. The study was performed according to the principles of the Helsinki Declaration. Informed consent was obtained from each patient preoperatively, declaring approval to public data sharing of detailed information (related to disease history including pre and postoperative photos) under one condition of retaining full privacy of patient's identity.

Preoperatively all of our patients received an intravenous antibiotic (Cefuroxime 1.5g, single dose). We applied the smallest size of TachoSil® (3.0 cm X 2.5cm) to all of our patients. Intraoperatively TachoSil® was shaped by cutting it with scissors. After removing a nasal hump, performing osteotomies or rasping irregularities on the nasal dorsum, TachoSil® was placed as a fleece or after soaking it with fluid extracorporeally using raising retractor and forceps (**Fig. 1**). It was then gently compressed for 3 – 5 minutes to trigger the coagulation cascade and clot the wound with the collagen patch.

The clinical data, prior rhinoplasties, indications, use of TachoSil®, source, and type of the additional grafting material (if used), the postoperative follow-up examinations up to 6 months after the operation, complications, revisions as well as the general satisfaction after the operation has been retrieved and analyzed retrospectively.

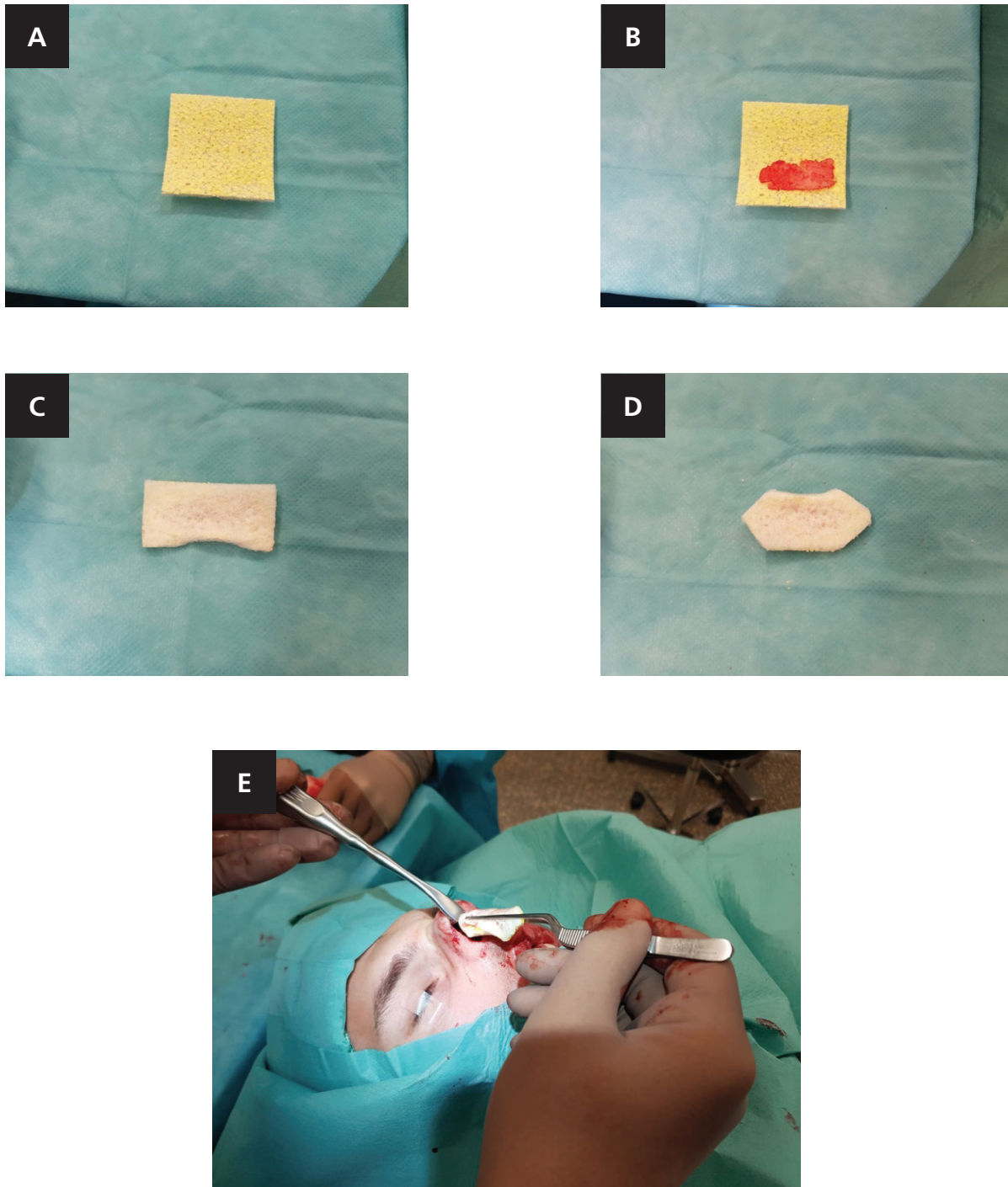


Fig. 1: TachoSil® alone (A). TachoSil® with crushed cartilage (B). In Sandwich form (C). After shaping the TachoSil®-crushed cartilage graft (D). Placing TachoSil® and crushed cartilage in the nasal dorsum in a closed approach (E).

Postoperatively all of our patients were admitted for two days in the ENT ward for the initial postoperative care and explained the postoperative measures like, for example, nasal care. Patients were discharged on the 2nd postoperative day and were asked to come for the follow up on the 10th postoperative day for removal of endonasal splints and the nasal cast, postoperative photos were then taken in frontal, right and left lateral and oblique views in addition to superior and inferior close up views to compare it with the preoperative photos using (Canon EOS 7D). All patients were informed that the initial result is usually seen when the swelling and post-surgical effects are completely subsided, somewhere between four to six weeks after surgery, while the final result is usually seen between 6 months up to one year after the surgery. Some patients, who were satisfied with the operation's initial results, did not attend the final follow-up. In the final follow up, when the patients were unsatisfied with the operation results, they were offered a revision surgery after completion of the healing period.

Results:

Rhinoplasty with a closed approach was performed in all

of our 78 cases in this series. Forty-eight patients (61.5%) were females, and thirty patients (38.5%) were males, all ranging from 17 to 67 years of age with a mean age of 31 years. There were 53 (68%) primary cases and 25 (32%) secondary cases, of which 7 (28% of 2ry cases) were multiple revisions.

There were multiple reasons for performing these surgeries. In six patients (7.7%), the reason for surgery was sequelae of old nasal trauma. In 72 patients (92.3%) were for one or more esthetic reasons. Of these 72 patients, 46 patients (64%) had a nasal hump, 26 patients (36%) had deviated nose (crooked), 17 patients (24%) had nasal dorsum irregularity. Fifteen patients (21%) presented with a broad nose, nine patients (12.5%) had tension nose, nine patients (12.5%) had saddle nose, 7 (9.7%) patients had Polly beak deformity, two patients (2.7%) had scar formation due to foreign body reaction after Injection of silicon in the nasal dorsum, and two revision surgeries are done abroad.

At nasal dorsum and two patients (2.7%) had a hanging tip of the nose. (**Fig., 2**). TachoSil® was used alone without adding extra grafting materials in 45 patients (57.7%) (**Fig. 5**).

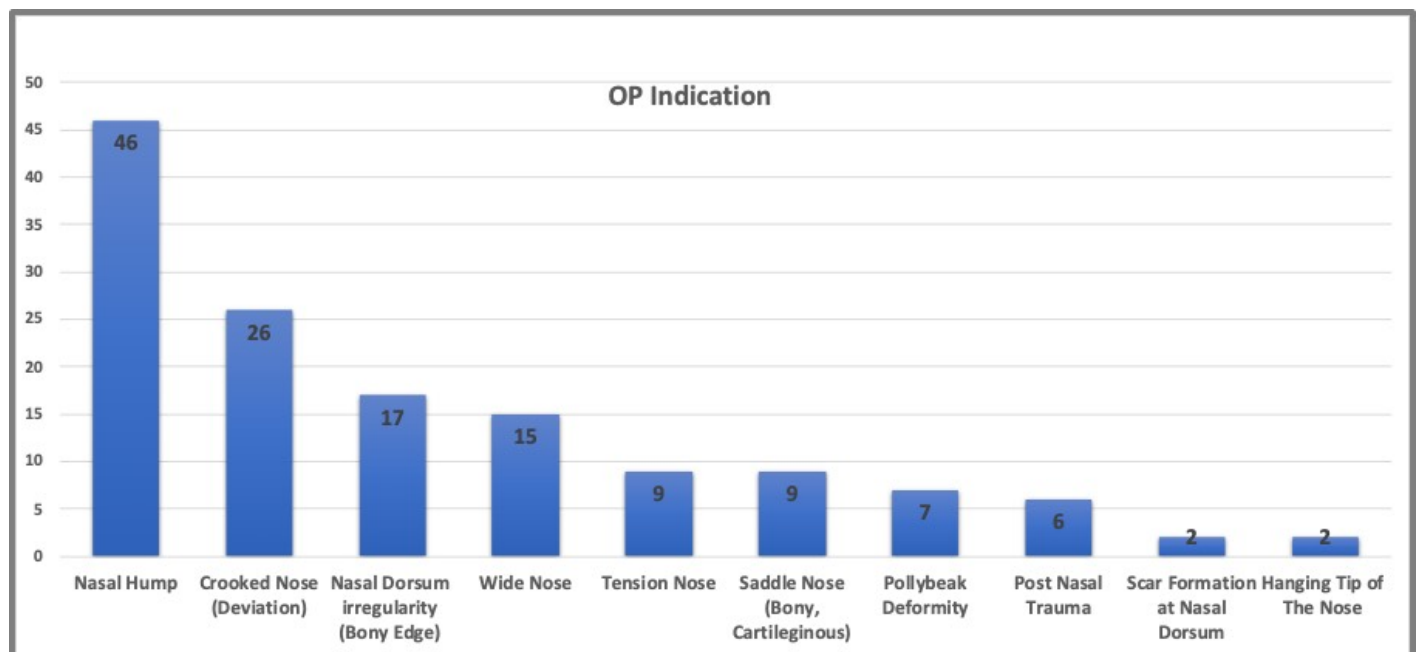


Fig. 2: The esthetic indications for rhinoplasty in our cases, the numbers indicate the cases.

In 33 patients (42.3%), an extra grafting material was applied with TachoSil[®], of which septal cartilage was harvested and used in 28 cases (85%), concha cartilage in 2 cases (6%), Septum bone in one case (3%), cephalic part of alar cartilage in one case (3%) (**Fig. 3**) and costal cartilage in one case (3%) (**Fig.4**). The grafting material added to

TachoSil[®] in these 33 cases were crushed in 28 cases (85%), in chips form in 4 cases (12%), in solid pieces in one case (3%) (**Fig. 6**). TachoSil[®] were placed as a monolayer in 74 cases (95%), a Turkish delight in three cases (3.8%), and strips form in one case (1.2%)



Fig. 3: Preoperative oblique (a) and lateral (b) images and Postoperative oblique (c) and lateral (d) images of a 23-year-old man presenting with cartilaginous saddle nose deformity. The nasal dorsum was augmented with cartilage chips harvested from the cephalic part of Alar cartilage with a monolayer of TachoSil.

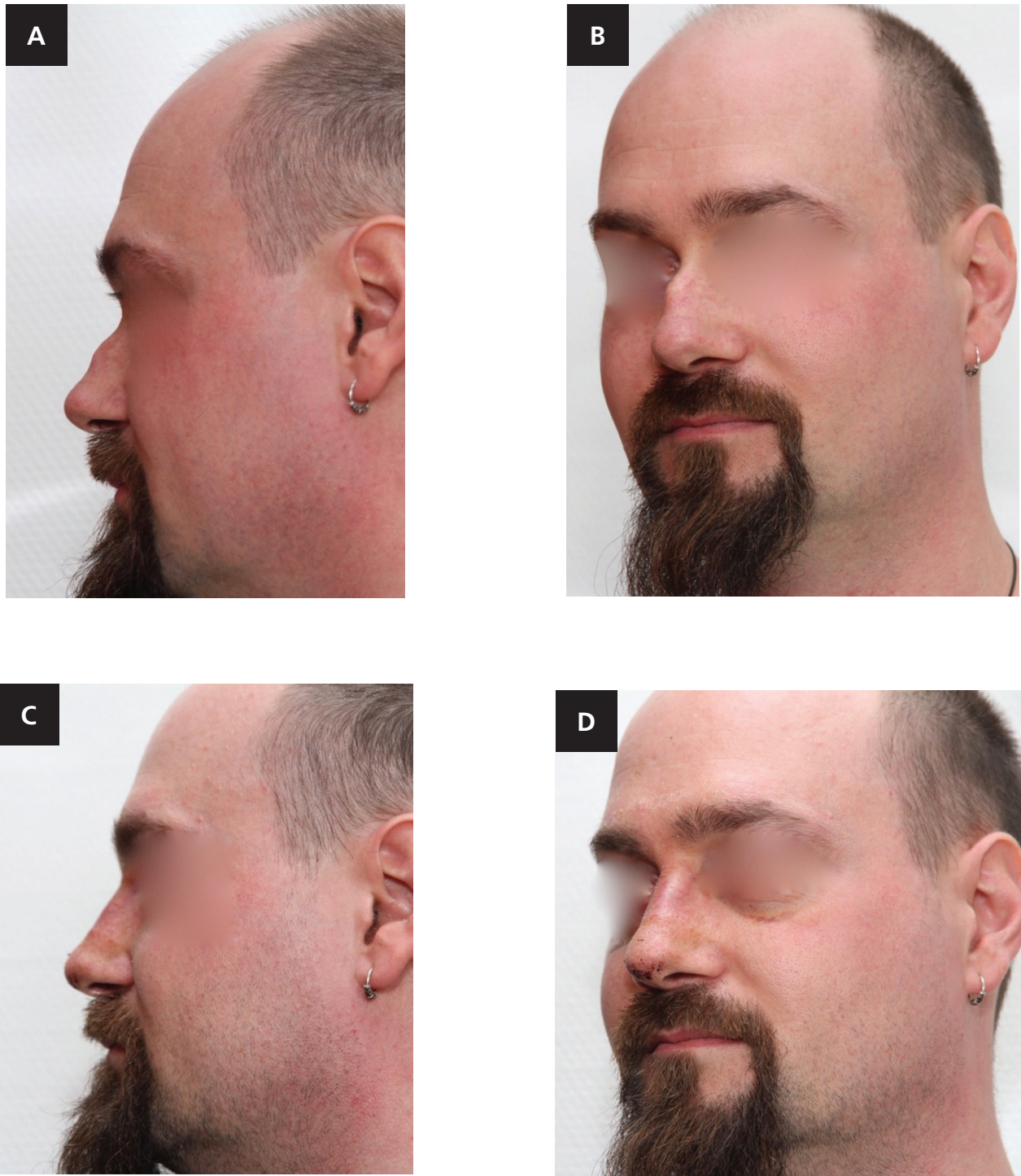


Fig. 4: Preoperative Lateral (a) and oblique (b) images and Postoperative lateral (c) and Oblique (d) images of a 35-year-old man presenting with massive bony Nasal hump after prior surgery in another hospital in 2007 for saddle nose deformity with costal cartilage augmentation. The costal cartilage was extracted, crushed, and placed at the nasal dorsum with a monolayer of TachoSil.

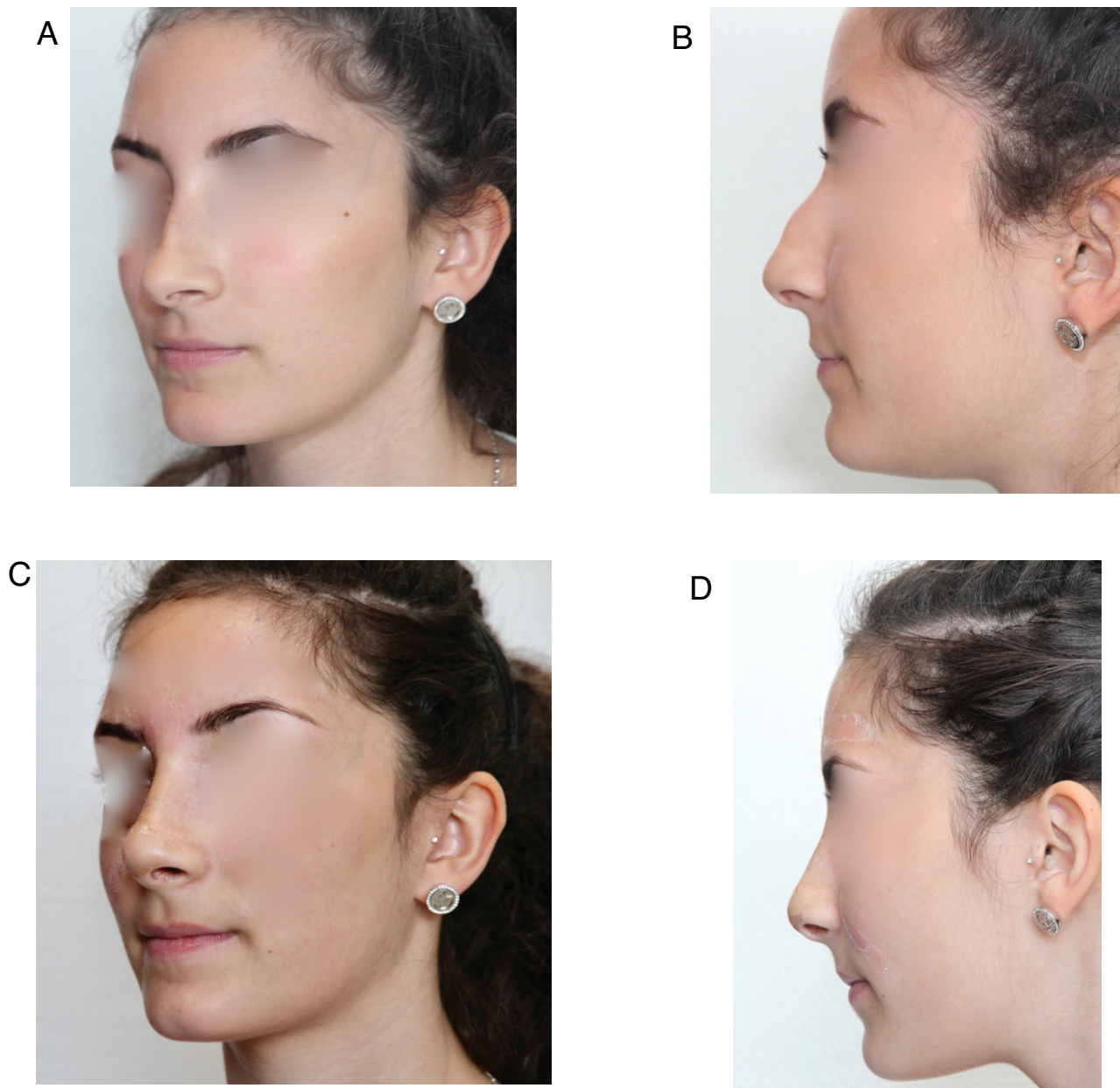


Fig. 5: Preoperative oblique (a) and lateral (b) images and Postoperative oblique (c) and lateral (d) images of a 19-year-old woman presenting with the nasal hump. TachoSil was used alone without adding extra grafting material to ensure smooth contouring of the nasal dorsum and to conceal the sharp edge in this thin-skinned patient.

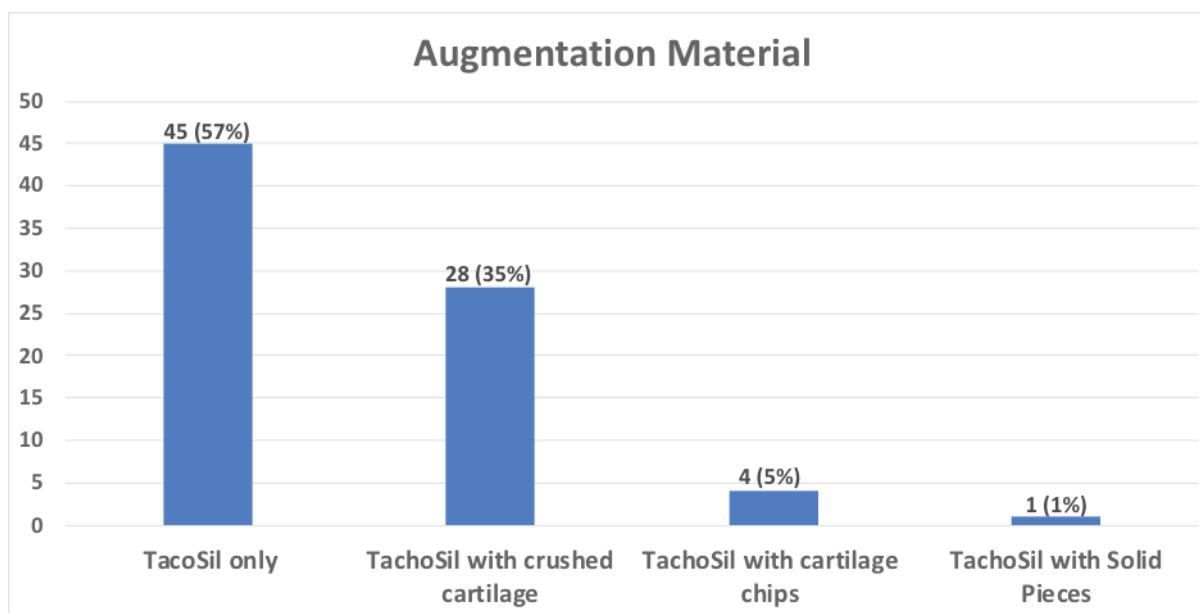


Fig. 6: Augmentation material used in all of our 78 surgeries in number and percentage.

We followed up with all of our 78 patients for six months postoperatively. Forty-four patients (56.4%) had a normal postoperative finding on the first postoperative day. They were all satisfied on the tenth postoperative day directly after removing the nasal cast and nasal splints and were also satisfied at the final follow-up (if they showed up) on the sixth week and the sixth month without having any complications. Twenty-one patients (27%) had an early postoperative complication, and 13 Patients (16.6%) had late postoperative complications. (Fig. 7).

On the **1st postoperative day**, one patient had a mild fever and was treated with antipyretic therapy. Two patients complained of moderate to severe pain and were treated successfully with pain killers. Seven patients had moderate lower eyelid hematoma, which gradually subsided within 7-10 days. Three patients had developed extensive infra-orbital hematoma bilaterally; two were only treated with a Hilotherm Mask, a type of cryotherapy using a polyurethane mask suitable for different regional anatomy gives a constant Temperature between 12.8-C and 15.6-C.^[17] The third patient was treated with a Hilotherm mask, system-

ic cortisone, and antihistamine. As mentioned earlier, all three patients showed a significant improvement on the 2nd postoperative day under the therapies.

On the **7th postoperative day**, two patients showed mild endonasal swelling after removing endonasal splints without showing any signs of fluctuation or infection, and both were treated conservatively with intensive nasal care and local cortisone creme for a couple of days.

On the **10th postoperative day**, one patient presented with septum seroma and had an endonasal revision under local anesthesia. Another patient came with a small foreign body granuloma at the suture site at the hemitransfixion incision and was removed under local anesthesia. One patient came with an asymptomatic septum perforation and had been further followed up and did not want to revise because he was completely asymptomatic. Another patient presented with a furuncle at the nasal tip and showed a significant improvement after seven days of treatment with both local & systemic antibiotics.

Two patients presented with excessive nasal dorsum pain, swelling, and fluctuation, CT-Scan confirmed nasal

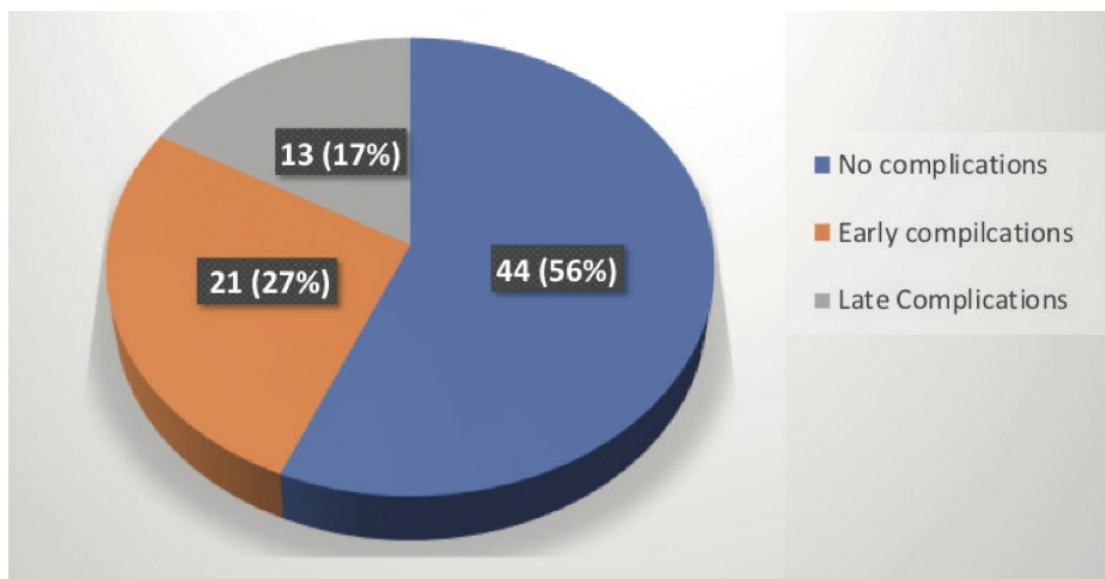


Fig. 7: Patients, according to the complication in numbers and percentage.

dorsum abscess in both patients, and they were admitted for systemic antibiotic therapy in addition to an endonasal revision with incision & drainage and repeated endonasal irrigation with an antiseptic solution and normal saline. A remarkable improvement was noticed directly after the revision. Moreover, both patients were discharged on the second day after the revision.

Gladly, no patients experienced any allergic reaction to TachoSil® or any postoperative bleeding until the 14th postoperative day, thanks to TachoSil's ability to control bleeding.

After six months of follow up in the plastic clinic, we found that 65 patients (83%) were satisfied with the operation. Unfortunately, there were still needed revisions for 6 of them due to other reasons, like early complications in 4 patients (Abscess in 2 patients, seroma in one patient, and small foreign body granuloma at the suture site patient) and postoperative nasal trauma in 2 patients. In comparison, 13 patients (17%) underwent revisions due to dissatisfaction due to the operation or due to late complications (**Fig.8**). (**Fig. 9**). The most common cause of revision was nasal dorsum irregularity. Other causes included deviated

nose, saddle nose, Polly beak, nasal trauma, nasal tip deviation, and nostril asymmetry.

Discussion:

In this case series study, we were able to retrospectively analyze and investigate our full experience of using TachoSil® in a total of 78 patients who underwent augmentation rhinoplasties between Jan 2016 and July 2019. TachoSil® showed promising characteristics when used either as a wrapped graft (Turkish delight) with enclosed additional grafting material or as a monolayer graft with or without additional grafting materials, like septum cartilage, concha cartilage, costal cartilage, and septum bone used in multiple forms: crushed, chips, and solid pieces according to the underlying abnormality in the nasal dorsum, skin thickness, and the required augmentation in every case.

Although septal cartilage is still the gold standard of autografts in rhinoplasty, using it for nasal dorsum augmentation has been reduced because of the lack of septal material sufficient full-length dorsal graft (35 x 8 mm) in most secondary cases and many primary cases among Asian patients.

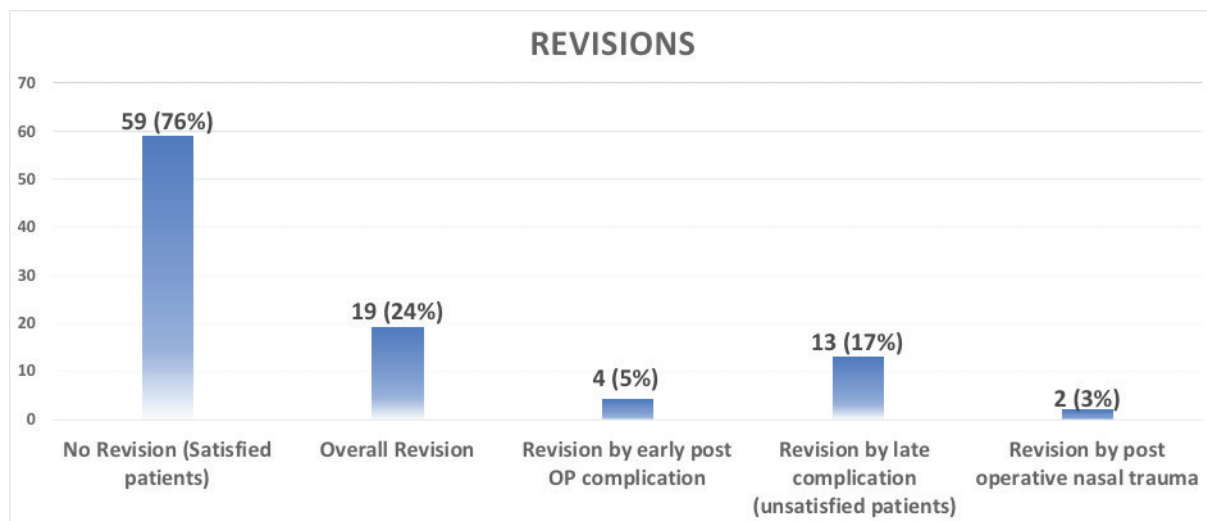


Fig. 8: Patients, according to the revisions in numbers and percentage.

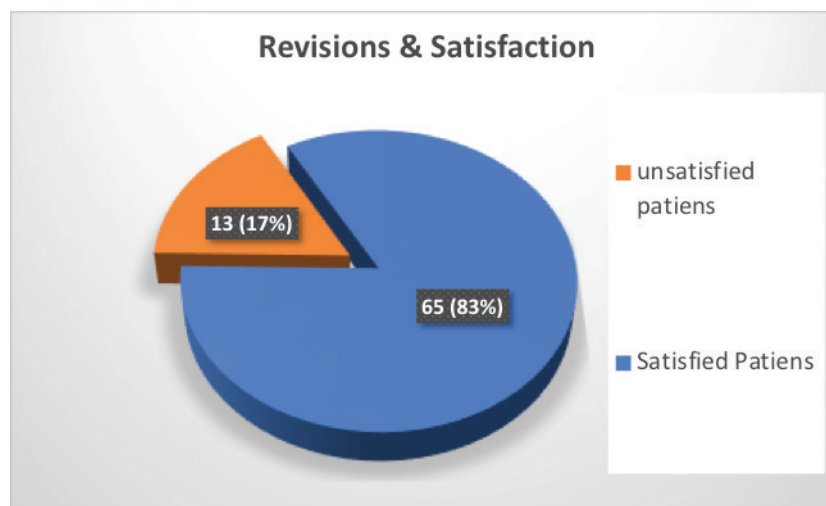


Fig. 9: Revision & satisfaction: the blue color represents the number and percentage of satisfied patients, whereas the orange color represents unsatisfied patients.

Auricular cartilage has been broadly utilized in nasal surgery. Despite outstanding results at an early stage, the limitations of using the conchal cartilage became frustratingly obvious to surgeons and patients with time. The layered conchal graft demand dove-tail techniques to obtain length and stacking to gain height. Conchal grafts should be stitched transversely to enhance their height, but their

lateral juncture with the underlying dorsum is always detectable. Also, as the skin warp tenses, the intrinsic irregularity makes the asymmetry of the concha more visible.^[3]

Utilizing the costal cartilage as an autologous graft for nasal dorsum augmentation is associated with inflexibility, pain at the donor site, the poor shape of the graft and, a high proportion of warping.^[7-9]

Excellent long-term clinical outcomes and predictable esthetic results depend not only on the type of cartilage used but also on the degree of dicing or crushing of the used cartilage. Slight or moderate crushing results in an excellent graft material for concealing irregularities.^[10]

Diced cartilage has also been used with a processed fascia lata (**Tutoplast**[®]; Tutogen Medical, Neunkirchen am Brand, Germany) with predictable outcomes and high satisfaction rates.^[11, 12] In Tasman's technique, the diced cartilage can be used with synthetic fibrin glue consisting of thrombin and fibrinogen (**Tisseel**[®], Baxter International, Deerfield) for nasal dorsum augmentation with a variety of graft shapes and sizes, as well as reduced operating time in comparison to diced cartilage fascia grafts.^[13]

Despite many disadvantages like morbidity at the donor site, graft availability, and graft resorption, autografts remain preferable over alloplastic implants, which showed increased rates of rejection, inflammation, and displacement (e.g., Silicone implants **Gore-Tex**[®], W.L. Gore & Associates, Flagstaff, Ariz).^[14, 15]

TachoSil[®] is commonly used in several surgical specialties as a hemostatic treatment for intraoperative bleeding, protects nerves, provides tissue sealing, supports sutures, prevents adhesions and erosions, and occlude structures such as bronchioles, lymph vessels, or bile duct. The coated side of TachoSil[®] should be applied to the surgical site (directly or after moistening it to make it more flexible). It is available in three different sizes and can be used with additional grafting materials such as septum cartilage, concha cartilage, costal cartilage, and septum bone. These grafts can be used in multiple forms: crushed, chips, and concrete pieces. TachoSil[®] can be applied as a bilayer sandwich graft, wrapped graft (Turkish delight), and a monolayer graft to keep the grafted materials' position and shape before applying a nasal cast. Gentle pressure should be applied to the nasal dorsum for several minutes.^[6, 16]

TachoSil[®] enabled us to achieve small to mid-size augmentation by wrapping diced cartilage in a soaked piece of TachoSil[®] rolled to form the wanted graft. Another way to augment small discrete areas in the supra tip and radix region was achieved by filling these areas with a small

amount of crushed cartilage. After that, we used a monolayer of TachoSil as a cover for these areas. TachoSil also showed promising results as an alternative to sutures in stable boney grafts fixation and smoothed and harmonized the nasal dorsum contour. Due to its fixative effect, we also used it to fix the nasal tip following a cranial rotation or prevent the graft material's floating. Alone as a monolayer, we successfully used TachoSil to fill the soft tissue in patients with thin skin and conceal the dorsal nasal irregularities.

One of the nasal dorsum augmentation methods is to use diced cartilage fascia (DCF) described by Daniel and others. This technique is used for moderate augmentation and the final remodeling of the nasal dorsum. Disadvantages of this technique include longer operation time, the need for a graft fixation with transcutaneous sutures in multiple points, additional swelling especially with graft massaging (so the patient should compress the graft, not massage it), Donor site problems like hematoma, and occasional scar revision.^[3, 10]

Hanci, D, added 1cc of the new cross-linked hyaluronan NCH gel to the diced cartilage (PureRegen[®] Gel Sinus, BioRegen Biomedical Co., Ltd., Changzhou, Jiangsu, China) and formed a paste-like mixture. He also added peripheral venous blood to the pasty graft material. This mixture was introduced to the Nasal dorsum intraoperatively, and after closing the incision, the nasal dorsum was gently compressed and shaped by hand to conceal the irregularities. Hanci, D, found no noticeable irregularities, nor any displacement or resorption of the graft material. Additionally, all patients were happy with the postoperative result.^[18]

Dorsal augmentation using diced septal cartilage wrapped in platelet-rich fibrin matrix (PRFM) was performed by Guler et al. Choukroun has developed the Platelet-rich fibrin (PRF) and published it in 2001. PRFM was prepared by collecting ten ccs of the venous blood in two tubes. After centrifugation for 10 minutes at 3000 rpm, the diced cartilages were then added to PRFM and placed over the dorsal irregularity and tip area. Guler found that the ecchymosis and edema were decreased on the 5th post-

operative day for all patients. Irregularity and nodularity were not detectable in all patients during the follow-up period.^[19]

Despite the good results in the techniques mentioned above, we believe that using NCH gel or PRFM requires more preparations before and during the surgery in addition to the difficulty of handling and manipulation of the gel form grafting material, in contrast to our experience with TachoSil®, which can be easily stored, shaped, cut, and handled in its dry and wet condition. It can be used directly without any particular preparation or fixation.

Berghaus, A et al., used TachoSil® with stable and diced cartilage in rhinoplasty with ten patients in a small pilot study. Clinical examination, photos, and sonographic examination was performed preoperatively and controlled postoperatively up to 8 months. In seven patients, the graft could be detected postoperatively with ultrasound imaging. Berghaus, A, stated that TachoSil showed promising results with comfortable graft shaping and stable in situ placement, and favorable biocompatibility.^[16] These findings are compatible with our results. The main differences between the study of Berghaus and our study were:

1. All our operations were done in a closed approach technique. On the contrary, operations were done in both open and closed techniques in the study of Berghaus
2. The type of cartilage we used was generally crushed cartilage, whereas Berghaus mainly diced cartilage.
3. pre and postoperative sonographic examinations were performed for all patients in the study of Berghaus.^[16]
4. The Postoperative follow-up period extended up to 8 months in the Berghaus study compared to 6 months in our study.
5. The scale of the study, our study included 78 patients versus ten patients in Berghaus study.

The complications of rhinoplasty are generally divided into early and late complications. The early complications occur early on in the postoperative period and include hemorrhage, infection, edema, hematoma, ecchy-

mosis, skin problems, and septal perforations. Whereas the late complications include cartilaginous structures and bony structures abnormalities and nasal tip rotation, and nostril asymmetry.^[11] Twenty-one patients (27%) had an early postoperative complication, and 13 Patients (16.6%) had late postoperative complications. Common complications of rhinoplasty were reported as acne (18,3), numbness (16,7%), hospital revisit (6,5%).^[20] Early complications were as an abscess in 2 patients, seroma in one patient, small foreign body granuloma at the suture site in one patient, and postoperative nasal trauma in 2 Patients. In comparison, 13 patients (17%) underwent revisions due to dissatisfaction due to the outcome of late complications. The most common cause of revision was nasal dorsum irregularity. Other causes included deviated nose, saddle nose, Polly beak, nasal trauma, nasal tip deviation, and nostril asymmetry. The revision rate of surgery varies from 0 to 10,9 percent. The indications for revision surgery in our study were similar to the literature view.^[21]

Conclusion:

This retrospective case series shows our experiences in using TachoSil® in closed rhinoplasty. Our patient satisfaction reached 83% without any allergic reactions or postoperative bleeding events. Despite that, two patients have developed an abscess in the nasal dorsum and were successfully treated with endonasal incision and drainage. In our case series, we found that, in addition to its significant hemostatic role, TachoSil is considered a safe, effective, and easy to handle graft fixation material to manage and conceal the nasal dorsum irregularities and to fill the soft tissue in patients with thin skin. We recommend more prospective studies with more extended follow-up periods and larger sample sizes for generating more data.

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Ethics Committee Approval: The study protocol was approved by the Ethics Committee of the University of Ulm.

Informed Consent: Written informed consent was obtained from all patients.

Author Contributions: Designing the study – N.Y.A., H.R.A., K.J.L.; Collecting the data – N.Y.A., H.R.A., K.J.L.; Analysing the data – N.Y.A., H.R.A., K.J.L.; Writing the manuscript – N.Y.A., H.R.A., K.J.L.; Confirming the accuracy of the data and the analyses – N.Y.A., H.R.A., K.J.L.

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