profile®

COSTAL CARTILAGE ALLOGRAFT

CLINICAL COMPENDIUM

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profile® COSTAL CARTILAGE ALLOGRAFT

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INTRODUCTION

Rhinoplasty Procedures On the Rise

Since the launch of costal cartilage sheets in 2016, the Profile® portfolio of costal cartilage grafts has grown to include surgeon users at more than 800 hospitals and practices throughout the US as well as Canada, Equador, Puerto Rico, Republic of Korea, Switzerland, Turkey and UAE.

This growth is in keeping with the surge in demand for rhinoplasty. In 2020, Rhinoplasty was the most requested cosmetic surgery in the US, with more than 352,000 procedures performed [1]. This is believed to be a result of more people working from home during the pandemic, which has caused a "zoom boom;" people seeing themselves on camera during virtual meetings and finding things they want to change about their appearance. Working from home also allows for the downtime needed to recover from this and other major surgical procedures.

Growing Use of Allograft Costal Cartilage

As rhinoplasty procedures grow, so does the use of allograft in not only revision but primary rhinos as well. Autologous costal cartilage is still the gold standard, but allograft usage is much more widely accepted and often preferred. Profile® has been a major catalyst in this shift, as Profile performs better than other allografts have historically. This is attributed to the fact that Profile is the **only non-terminally irradiated costal cartilage allograft** available on the market today.

The Profile Difference

According to Dr. Rod Rohrich, "the terminal radiation process for sterilization likely contributes to decreased viability and contextual structural integrity of the graft, which is avoided in fresh frozen rib cartilage grafts (**Fresh Frozen Rib Cartilage Grafts in Revision Rhinoplasty: A 9-Year Experience**. Page 60. 2022)" In all of his Profile publications, Dr. Rohrich highlights the processing differences between "fresh frozen" costal cartilage (Profile) and terminally irradiated allografts offered by other tissue banks.

In addition to being the only allograft for rhinoplasty that is not terminally irradiated, Profile also has the **widest selection of sizes (14)** and is the **only allograft that is available in sheets with a precut thickness of 2mm**. This provides further convenience to the surgeon and reduces OR time and risk of comorbidities associated with autograft harvest, not the least of which is pain, "often the main memory patients have from autologous rib harvest" (Rohrich's 9-year Study. Page 61).

Profile also provides a readily available grafting material of known quality, important when performing rhinoplasty on older patients whose own costal cartilage may be compromised due to ossification or calcification.

Compendium Overview

In this compendium you will find summaries for each of the studies currently published on the use of Profile costal cartilage in both primary and revision rhinoplasty. Each summary includes links to the actual clinical paper as well as buttons that allow the reader to easily toggle between sections, including the **"Key Figures and Tables"** section.

Demonstrating low rates of infection, resorption and warping, the 11 studies showcase the clinical safety and efficacy of Profile in nearly 1,000 patients over more than 9 years and provide assurance that Profile is a safe, reliable, cost-effective rhinoplasty grafting material for your practice.

Please contact your MTF Biologics Surgical Consultant or click **here** for more information on Profile.

[1] Plastic Surgery Statistics Report. American Society of Plastic Surgeons. @ASPS 2021.

PROFILE CLINICAL STUDY COMPLICATIONS SUMMARY TABLES

Profile® is the only costal cartilage allograft with 11 published studies and up to 9-year data on nearly 1,000 patients showing low rates of infection, resorption and warping similar to autograft, without the hassle, pain and scarring of autologous cartilage harvest.

Table I Summary of Average Complication Rates with Profile vs. Autologous Costal Cartilage and Terminally Irradiated Allograft

Complication	Profile	Autograft*	Terminally Irradiated Allograft*
Avg Infection Rate	1.14%	0.6-2%	3%
Avg Resorption Rate	1.9%	0.2-1%	4%
Avg Warping Rate	0.95%	3.1-6%	5%

*Vila PM, Jeanpierre LM, Rizzi CJ, Yaeger LH, Chi JJ. Comparison of autologous vs homologous costal cartilage grafts in dorsal augmentation rhinoplasty: A systematic review and meta-analysis. JAMA Otolaryngology Head Neck Surg. 2020; 146:347–354

Table II Summary of Profile Complication Rates by Study

Profile Clinical Paper *Click on Title for Link*	No. of Patients	Mean Follow-up in Mo	Infection Rate	Resorption Rate	Warping Rate
Wan, R. et. al. *Nasal Alar and Tip Reconstruction Following Mohs Surgery Using Fresh Frozen Human Costal Cartilage Allograft: A Novel Approach* PRS Global Open, May 2025	25	12	N/A	0%	0%
Datta, S. et. al. *Does Soaking Fresh Frozen Costal Cartilage in an Antibiotic Solution Reduce Postoperative Infection in Rhinoplasty?* PRS Global Open. July 2024	310	20.4	1.3%	N/A	N/A
Hanna, S. et. al. *Outcomes of the Use of Fresh Frozen Costal Cartilage in Rhinoplasty.* PRS Journal. Sept 2023	280	20.3	2.1%	N/A	N/A
Wan, R. et. al *Prospective Clinical Trial Evaluating the Outcomes Associated with the Use of Fresh Frozen Allograft Cartilage in Rhinoplasty.* PRS Global Open. Oct 2023	50	14.8	0%	4% Profile 4% autograft	4% Profile 6% autograft
Wan, R. et. al *The Utilization of Fresh Frozen Cartilage in Asian Rhinoplasty: A New Approach.* PRS Global Open. Apr 2023	5	14.2	0%	0%	0%
Milkovich, J. et.al *A Canadian Experience with Off-the-Shelf, Aseptically Processed, Costal Cartilage Segment Allografts in Complex Rhinoplasty.* Aesthetic Surgery Journal Open Forum 2022	21	15.0	0%	4.8% (crushed cartilage graft)	0%
Chen,K. et. al *Optimizing the Use of Autografts, Allografts, and Alloplastic Materials in Rhinoplasty.* PRS Journal. 2022	N/A	N/A	N/A	N/A	N/A
Rohrich, R. et.al *Fresh Frozen Rib Cartilage Grafts in Revision Rhinoplasty: A 9-Year Experience.* PRS Journal. 2022	226	12.18	2.7%	0%	2.7%
Rogal, J. et.al *Safety and Efficacy of Non- and Minimally Irradiated Homologous Costal Cartilage in Primary and Revision Rhinoplasty.* Facial Plastic Surgery & Aesthetic Medicine. 2021	26	15.9	1%	2.6%	0%
Rohrich, R. et.al *Rhinoplasty Refinements: Revision Rhinoplasty Using Fresh Frozen Costal Cartilage Allograft.* PRS Journal. 2020	1	N/A	N/A	N/A	N/A
Mohan. R.et.al *Role of Fresh Frozen Cartilage in Revision Rhinoplasty.* PRS Journal 2019	50	3.35	2%	0%	0%

Title: Nasal Alar and Tip Reconstruction Following Mohs Surgery Using Fresh Frozen Human Costal Cartilage Allograft: A Novel Approach

Author: Wan,R, Li,R, O'Connor, M, Bartler, A, Bricker, J, Williams, T, Alam, M, Galiano, R.

Source: *PRS Global Open. May 2025.*
DOI: 10.1097/GOX.0000000000006790

Full Publication

STUDY OBJECTIVE

To evaluate the safety and efficacy of using nonterminally irradiated fresh frozen human costal cartilage allografts for nasal reconstruction after basal cell carcinoma removal via Mohs surgery.

METHODS

- Retrospective chart review of 25 patients at Northwestern Memorial Hospital (2016–2024)
- Patients received nasal reconstruction using CCA after Mohs surgery
- Anthropometric analysis using 2D pre- and postoperative photographs (nasolabial angle, Goode ratio)
- Complication monitoring

RESULTS

Participants: 25 patients (16 men, 9 women), average age 71 (range 42–90)

Follow-up: Mean duration 12 months (range 3–66 months)

Grafts Used:

- Alar batten graft: 17 (68%)
- Nasal tip graft: 7 (28%)
- Both: 1 (4%)

Complications:

- 2 with mild airflow restriction, 1 with congestion (none required revision)
- No resorption, warping, or structural failure noted

Anthropometric Stability:

Nasofrontal Angle: 2.74°, Nasofacial Angle: 1.66°, Nasolabial Angle: 3.94°, Goode Ratio: 0.059

CONCLUSION

CCA offers structurally sound, biocompatible, and cosmetically satisfying results with a low complication profile. It is particularly beneficial for older patients or those unable or unwilling to use autologous cartilage.

HOW TO USE THIS DATA

- A significant point made by the author in the Discussion section is his statement pointing out that despite the cost of the Profile allograft, its shipment and storage, the full price of the procedure is still lower than the use of autologous rib cartilage. This he attributes to the following factors:
  - No use of general anesthesia which can be costly in itself
  - Shorter operative time
- The author points out that there are ten previously published Profile studies. This study is now the eleventh. No other costal cartilage allograft has as many published studies. Refer your surgeon to the Profile Clinical Compendium or Clinical Study Summary piece for access to all published data.
- Outline the risks associated with harvesting autologous costal cartilage, including the need for general anesthesia, prolonged surgical time, expensive surgical costs, as well as donor-site complications ,all of which can be avoided with the use of allograft, such as Profile.
- Underscore the fact that Profile provides cartilage material of known quality. This is especially important when considering autologous cc harvest in older patents in which the quality of the cartilage used, primarily due to age, may be "stiffer" as a result of calcification from aging. The average patient age in this study was 71 years old, which is older compared with the average Profile donor age which is younger than 55 years old.

Title: **Does Soaking Fresh Frozen Costal Cartilage in an Antibiotic Solution Reduce Postoperative Infection in Rhinoplasty?**

Author: Datta, S, Mattos, D, Hanna S, Reish, R.

Source: *PRS Global Open. July 2024.*

Full Publication

STUDY OBJECTIVE

Evaluate the efficacy of intraoperative antibiotic soaks in reducing surgical site infection rate when using MTF FFCC grafts.

METHODS

Retrospective chart review of 310 patients who underwent rhinoplasty (26 primary, 284 revision rhinoplasties) with the use of MTF FFCC in the senior author's practice was conducted between May 2017 and June 2022. The inclusion criteria were rhinoplasty cases using MTF FFCC with minimum of 12 months of follow-up. Two hundred patients received FFCC grafts soaked in 1gm vancomycin in 20ml normal saline. 110 patients received FFCC prepared without the antibiotic soak. Mean follow up was 20.4 months.

RESULTS

Four cases of infection were noted (1.3%); all from the cohort who received grafts intraoperatively soaked in antibiotics.

All cases of postoperative infection occurred within the first month, with no occurrences of late infection within our minimum 12-month follow-up. All cases of infection occurred in revision rhinoplasty cases in which the patient had undergone at least two prior open rhinoplasty procedures.

See Table 2 (below) for more details on demographics and outcomes.

Table 2. Demographics and Outcomes of Infection Cases

Characteristic	No. (%)
Total infection cases	4 (1.3%)
Age range	
30–39 years	2 (0.6%)
40–49 years	0
50–59 years	1 (0.3%)
60–69 years	0
70+ years	1 (0.3%)
Sex	
Female	3 (1.0%)
Male	1 (0.3%)
Body mass index	
<20	1 (0.3%)
20–24.9	2 (0.6%)
>25	1 (0.3%)
Smoker	0
No. patients with infection *	
Abx	4 (1.3%)
No-Abx	0

*Fisher exact test, $P = 0.301$.

CONCLUSION

Retrospective cohort study demonstrates that soaking MTF FFCC in an antibiotic solution intraoperatively does not reduce postoperative infection rates in rhinoplasty.

HOW TO USE THIS DATA

- Use the low infection rates of this study (1.3%) to underscore the safety of Profile and address concerns surgeons may have that using allograft may increase risk of infection vs using autologous cartilage.

  Compared to the avg rates of infection provided in Table 3 of Dr. Rod Rohrich's 9-Year data study, **https://www.mtfbiologics.org/docs/defaultsource/product/fresh_frozen_rib_cartilage_grafts_in_revision_9_year_experience_rohrich_2022_published.pdf?sfvrsn=1cc24a93_2**, Profile's 1.3% rate of post operative infection is similar to that reported for autologous cartilage (0.6-2%) and lower than the infection rate reported for irradiated allograft provided by other tissue banks (3%).

- In this study, the average rate of infection for primary rhinoplasty is cited as 2-2.5% and "more common in revision rhinoplasty or rhinoplasty with use of implants." So, the fact that the infection rate in this study is comparatively low despite the majority (284 of 310 or 91.6%) of cases being revisions rhinoplasties further highlights the fact that the use of Profile does not by an means increase the risk of post-operative infection.
- **Profile is the only non-terminally irradiated costal cartilage allograft available.** This low rate of infection underscores the fact that Profile's process is gentle yet effective in yielding grafts that are safe for implant and will not increase post-operative infection rates.
- Although seemingly innocuous, introducing an intraoperative antibiotic soak introduces a potential allergen and increases the overall cost of surgery, without the benefit of a decreased incidence of postoperative infection, per the results of this study. The time and cost of performing this step can be avoided with the use of Profile.

Title: Outcomes of the Use of Fresh Frozen Costal Cartilage in Rhinoplasty

Author: Hanna, S, Mattos, D, Datta, S, Reish, R.

Source: *Plast Reconstr Surg 2023* Oct 9. doi: 10.1097/PRS.0000000000011125. Online ahead of print.

Full Publication

STUDY OBJECTIVE

Determine the long-term stability of Fresh Frozen Costal Cartilage (FFCC) by assessing infection rate, warping, resorption, and associated surgical revision rates.

METHODS

Retrospective study analyzing rates of infection, warping and resorption of Fresh Frozen Costal Cartilage (FFCC) grafts in 282 patients undergoing rhinoplasty in the senior author's practice between March 2018 and December 2021. The inclusion criteria were cases with a minimum of 12 months of follow-up. The study included both revision rhinoplasty patients as well as primary rhinoplasty patients, secondary to trauma, intranasal medication use, cocaine use, previous septoplasty, or generally insufficient cartilage.

RESULTS

The study includes 282 patients who underwent either primary rhinoplasty, secondary to trauma, intranasal medication use, cocaine use, previous septoplasty, or generally insufficient cartilage, (14.2%) or revision rhinoplasty (85.8%) with the use of FFCC. Most participants were female (90.4%), with mean age of 35.8 years old (range: 15 to 68 years old). The mean follow-up period was 20.3 months, with a minimum of 12 months follow-up.

Six patients (2.1%) demonstrated signs of infection which required treatment with empiric antibiotics, with all cases resolving without need for further antibiotic or operative management. None of the patients in our review had clinical signs of warping, resorption, or displacement of the FFCC grafts. There were six patients (2.1%) who required a return to the operating room for further revision rhinoplasty.

CONCLUSION

FFCC is a safe, convenient, and patient-centered option for graft tissue in rhinoplasty. Acute infection, warping, and resorption rates were found to be no greater than rhinoplasty complication rates when autologous or homologous tissue are used.

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HOW TO USE THIS DATA

- Use this paper to share Dr. Reish's best practices for preparing and using Profile.
  - Thaw the graft at least one hour. Complete thawing before carving or suturing mitigates the risk of warping and yields a more accurate assessment of the shape of the piece of cartilage .
  - Keep several units of different size Profile grafts on hand at all time.
  - Profile is Dr. Reish's grafting material of choice primarily to create spreader grafts and columellar struts.
- Use the low complication rate of 2.1% to underscore the fact that Profile is a viable alternative to autologous costal cartilage.
  - Resorption was not seen in any patients at the time of post operative assessment or in the 6 patients patients who went back to the OR for revisionary surgery.
  - In these six revisionary cases requiring a trip back to the OR, Profile grafts were found to be well-incorporated, similar to what is seen with septal or autologous rib cartilage.

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Title: **Prospective Clinical Trial Evaluating the Outcomes Associated with the Use of Fresh Frozen Allograft Cartilage in Rhinoplasty**

Author: Wan, R, Weissman, J, Williams, T, Joshi, C, Huffman, K, Galiano, R.

Source: *PRS Global Open*. October 2023. DOI: 10.1097/GOX.0000000000005315KTakeaways

Full Publication

STUDY OBJECTIVE

Compare the outcomes of fresh frozen costal cartilage allograft (Profile®) and traditional autologous costal cartilage in cosmetic and reconstructive rhinoplasty procedures.

METHODS

Prospective, single-center, nonrandomized, open-label clinical trial to evaluate warping, resorption, and cartilage displacement in 50 patients by measuring the differences of standardized values (deviation angle, nasofrontal angle, total facial convexity, nasofacial angle, and nasolabial angle) obtained at 6-months and 12-months postoperative follow-up on standard two-dimensional photographs (Δ = measurement 6 measurement 12).

Subjective assessment was measured by the FACE-Q assessment completed by the patients preoperatively, and at 1 week, 6 weeks, 12 weeks, 6 months, and 12 months postoperatively. Each assessment is a set of four to 17 statements,including satisfaction with overall facial appearance, satisfaction with nose, satisfaction with nostrils,social function, psychological well-being, and so on, for which the patients rated their agreement on a scale of 1–4.

Postoperative adverse effects, including clinically evident resorption, warping, graft displacement, scarring, and infection, were also recorded at every assessment visit.

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RESULTS

Fifty patients underwent rhinoplasty using fresh frozen costal cartilage allograft (25 patients) or autologous costal cartilage (25 patients) between March 2017 and October 2020. Nine patients underwent Asian rhinoplasty, 12 patients had reconstruction after Mohs and 9 patients had revision rhinoplasty. The average patient age was 43.9 ± 16.6 years and the mean follow-up period was 14.8 months.

In the control group, the changes (Δ) in the deviation angle, nasofrontal angle, total facial convexity and nasolabial angle were greater than in the CCA group ($P < 0.05$). See Figure 3 for additional details.

Patient Satisfaction

In the CCA group, the mean score of satisfaction with nose improved at 6 months and 1 year postoperatively ($P < 0.05$). The mean score of satisfaction with nostrils and overall facial appearance was greater for those patients who utilized allograft cartilage ($P<0.05$) vs autologous cartilage.

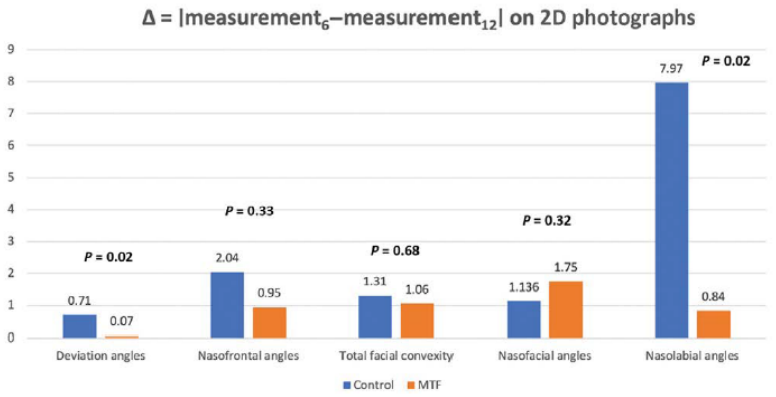

Fig. 3. The change of the measurements (Δ= |measurement$_6$–measurement$_{12}$|) of deviation angle, nasofrontal angle, total facial convexity, and nasolabial angle on standard 2D photographs at 6- and 12-months postoperative visits.

Postoperative Complications

Total postoperative complications in the control group were 10 vs 6 with costal cartilage allograft (CCA), with a higher rate of infection (1 vs 0), warping (3 vs 2) and scarring (4 vs 2) in the control group. Rates of resporption were the same between the two groups. See Table 4. Posteroperatie Complications.

Table 4: Postoperative Complications

Complications	Control	CCA
Infection	1	0
Resorption	2	2
Warping	3	2
Pneumothorax	0	NA
Scarring	4	2
Total	**10**	**6**

CONCLUSION

Non-terminally sterilized fresh frozen CCA is a useful, safe, reliable, and economical source of cartilage in reconstructive and cosmetic rhinoplasty in comparison to autologous costal cartilage. It is aseptic, readily available, previously tailored, and free of donor site complications. The objective assessment in the study demonstrated long-standing structural support in the CCA group with no significant changes in the values of deviation angle, nasofrontal angle, total facial convexity, nasofacial angle, and the nasolabial angle at 6-months and 12-months follow-up. Most patients in the CCA group benefited from having only one surgical site, reduced time of harvesting the cartilage grafts, and decreased operating room cost.

Of note, despite the cost of shipment and storage of the fresh frozen cartilage the full price of the surgery was still lower than using the autologous costal cartilage. In addition to the reduction in overall surgical fees, using CCA vs autologous cartilage, the observed reduction in narcotic medications also represents a significant benefit.

HOW TO USE THIS DATA

- Highlight the fact that this is the second prospective clinical study published on Profile and the first study directly comparing Profile to autologous costal cartilage. This study is now one of 9 published clinical studies, making **Profile the costal cartilage allograft with the most published evidence demonstrating safety and efficacy.**
- The evaluation of changes in various angles documented in Figure 3, including deviation angle, nasofrontal angle, total facial convexity, nasofacial angle, and nasolabial angl,e was conducted to assess resorption, one of the main concerns some surgeons have with using allograft costal cartilage in general. Profile showed less change in angle (i.e. less signs of resorption) in 4 of the 5 angles studied and statistically significantly less resorption in the deviation angle($P = 0.02$) and nasolabial angle ($P = 0.02$) at 6 and 12 months. Profile resorbs less than other costal cartilage allografts published on years ago because it is not terminally sterilized. In fact, it is the only costal cartilage allograft that is not.
- Fewer patients had postoperative complications with Profile (6 patients) vs autologous cartilage (10 patients).
- Despite the added cost of the Profile graft and shipping charges, overall surgery cost was still lower with the use of Profile than autologous costal cartilage.
- Patients who received Profile grafts benefited from not having a secondary surgery site and needed less narcotic pain meds.

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Title: The Utilization of Fresh Frozen Cartilage in Asian Rhinoplasty: A New Approach

Author: Wan, R, Weissman, J, Ullrich, P, Joshi, C, Williams, T, Galiano, R.

Source: *PRS Global Open*. April 2023. https://doi.org/10.1097/GOX.0000000000004903

Full Publication

STUDY OBJECTIVE

Prospective study to evaluate and report the use of fresh frozen allograft cartilage from the Musculoskeletal Transplant Foundation (Edison, N.J.) for rhinoplasty in five Asian patients.

METHODS

Five Asian rhinoplasties using fresh frozen allograft costal cartilage were performed by the senior author between May 2018 and January 2020. Patients were followed up for an average of 14.2±3.35 months.

Before and after photographs were taken in a standard photograph room. Anthropometric measurements on standard two-dimensional photographs were collected. Four measurements were taken, and the changes in the values between two follow-up visits were documented ($\Delta = |measurementvisit1 - measurementvisit2|$) to assess resorption and warping.

FACE-Q scales6 were used to assess patient-reported outcomes. The FACE-Q Satisfaction with Nose and the FACE-Q Satisfaction with Nostrils include 10 and five items, respectively. A higher score indicated a higher degree of satisfaction.

Postoperative complications were also recorded.

RESULTS

There were no major adverse events or complications among any patients. No resorption or warping was recorded at 1-year follow-up. The objective measurements had a mean of 0.93 degrees, ranging from 0.01 degrees to 3.63 degrees. At the time of the 1-year follow-up, mean FACE-Q Satisfaction with Nose, and Satisfaction with Nostrils scores improved from a preoperative score of 35.2±10.06 to 60±15.48 ($P = 0.0002$), and from a preoperative score of 42.6±20.31 to 59.8±38.21 ($P = 0.12$), respectively.

CONCLUSION

Fresh frozen costal cartilage is an excellent option for Asian rhinoplasty. Compared with current standards, it has the advantages of a more abundant supply, no donor site morbidity, shorter operative time, and lower surgical costs. Our case series also proves that it is safe and yields satisfactory surgical outcomes. Further investigation involving a greater number of patients and longer follow-up time is needed.

HOW TO USE THIS DATA

- Many surgeons only use allograft costal cartilage for revision rhinoplasty, preferring to use autologous septal cartilage in primary rhinoplasty procedures. However, this study shows Profile costal cartilage is an ideal grafting material for primary augmentation rhinoplasty in Asian patients who on average have less septal cartilage than other ethnicities (861 mm compared with 750 mm in Asian women).

  Profile is also a better option than alloplast materials that are more prone to extrusion, thinning of the skin, displacement, and translucency of the implant.

- Many plastic surgeons still believe allograft costal cartilage is prone to higher rates of resorption. Use the lack of change (<1 degree change) in objective measurements taken 2-4 mos post- surgery to those taken 8-20 mos to support the resistance of Profile to resorption.

- Profile's better than historical allograft complication rates, including lower resorption rates, are attributed to the fact that we do not terminally sterilize Profile grafts. According to the study, terminal irradiation may reduce the chondrocyte viability and the integrity of the cartilage.

  Use this study to talk about MTF's approach to tissue processing and explain the difference between pre-treatment and terminal irradiation.

  - MTF Profile grafts are aseptically processed without the use of harsh chemicals and terminal irradiation, so they behave most like autologous cartilage grafts.
  - Processing of Profile sheets and segments consists of a triple antibiotic soak. Profile sheets also go through a soak in triton, a mild detergent that removes blood and lipids. Both sheets and segment grafts are then packaged in triple layer tyvek and stored frozen at -40C
  - Representative samples are tested for bacterial growth before units are released for distribution, in accordance with USP sterility guidelines.

Title: A Canadian Experience with Off-the-Shelf, Aseptically Processed, Costal Cartilage Segment Allografts in Complex Rhinoplasty

Author: Milkovich, J, Ahmad, J.

Source: *Aesthetic Surgery Journal Open Forum* 2022, 1-7. www.asjopenforum.com

Paper Presentation. The Aesthetic Meeting. Apr 2023

Full Publication

STUDY OBJECTIVE

Evaluate the safety and efficacy of aseptically processed, non-terminally sterilized costal cartilage segment allografts (CCSAs) in complex primary and secondary rhinoplasty procedures performed in Canada.

METHODS

Retrospective review of twenty-one patients who received non -terminally sterilized costal cartilage segment allografts between June 2019 and April 2022 during primary or secondary rhinoplasty. Eleven of the procedures were primary rhinoplasties and ten were secondary. The mean operative time was 185 minutes. Follow up time ranged from 2.0-37.8 months with a mean of 15 months.

Grafts carved included columellar strut (9, 42.8%), septal extension (13, 61.9%), Alar contour (16, 66.1%) Dorsal onlay (2, 9.5%), Extended spreader (10, 47.6%), Splinting (7, 33.3%), Infratip shield (2, 9.5%), Lateral crural strut (5, 23.8%) and Diced cartilage (1, 4.8%).

CCSAs were carved with cuts made in the anterior -posterior orientation as opposed to cranial-caudal orientation. Figure 1 shows CCSA carved in the correct (on the right) vs incorrect (on the left) orientation.

Grafts were also carved from the central segment of the CCSA (Figure 2) vs peripheral carving which has a higher tendency toward warping.

Figure 1. It is important to carve the segments in the correct orientation using more central sheets which have less potential to warp. Peripheral sheets have much more tendency toward warping. With reference to the native anatomic position, the costal cartilage segment should be carved into sheets with cuts made in the anterior-posterior orientation as opposed to the cranial-caudal orientation. The piece of cartilage on the left was carved from the periphery of the rib in the cranial-caudal orientation, while the piece of cartilage on the right was carved from the center of the rib in the anterior-posterior orientation.

RESULTS

Nineteen patients (90.5%) reported being very satisfied with their aesthetic results with the remaining two patients being satisfied. There was no evidence of aesthetic deformity secondary to graft warping. One patient (4.8%) experienced some resorption when the CCSA was modified to be used as diced cartilage wrapped in autologous temporal fascia for dorsal augmentation. Two patients (9.5%) underwent revision surgery for further aesthetic refinement not attributed to failure of the CCSA.

At revision the previously placed CCSAs were observed to be intact in both patients.

Figure 2. Grafts carved from the central segment of a fresh frozen, nonterminally sterilized, costal cartilage. ACG, alar contour graft; SEG, septal extension graft.

CONCLUSION

Overall, fresh frozen, aseptically processed and non-terminally sterilized CCSAs meet the criteria for an ideal grafting material in primary and secondary rhinoplasty when inadequate autologous cartilage is available from the nose, avoiding donor -site morbidity.

HOW TO USE THIS DATA

- Make the distinction between terminally sterilized costal cartilage allograft, which historically demonstrated up to a 31% resorption rate when used in the past, and aseptically processed Profile.

Title: Optimizing the Use of Autografts, Allografts, and Alloplastic Materials in Rhinoplasty

Author: Chen, K, Schultz, B, Mattos, D, Reish, R.

Source: *Plast. Reconstr. Surg.* 150:675e, 2022

Full Publication

STUDY OBJECTIVE

Review of current and most common options available for graft source and implant material and the techniques in graft/implant choice and placement in both primary and revision rhinoplasties.

METHODS

The pros, cons and optimal areas for placement for the following rhinoplasty grafting materials are reviewed:

Autograft: Septal cartilage, Auricular/Conchal cartilage, Costal Cartilage, Bone Grafts
Allografts: Irradiated Costal Cartilage, Nonirradiated costal cartilage (Profile)
Alloplasts: Silicone, High-density Polyethylene, Polytetrafluoroethylene, Gore-Tex, Polydioxanone Foil

RESULTS

AUTOGRAFT

Septal cartilage is the work horse for rhinoplasty. Easy to access and harvest with minimal donor site morbidity, it provides a straight, large source of cartilage. While it can be made into spreader grafts, septal extension grafts, columellar strut, batten grafts and alar rim contour grafts, it tends to be too stiff for tip grafts (palpable in thin-skinned patients).

Auricular/Conchal cartilage is a convenient cartilage source when septal cartilage is not available. It is softer and more pliable than septal cartilage, making it ideal for tip grafts such as onlay grafts and lateral crural strut grafts but less desirable for structural grafts.

Costal Cartilage offers an abundant source of structurally sound cartilage, especially when septal cartilage is not available. It is often a first choice of cartilage in Asian patients who may have short or insufficient septal cartilage. It carries low rates of warping (3%) and resorption (.22%) but high morbidity associated with harvest, including the risk of pneumothorax, as well as chest scarring (hypertrophic in patients of Asian and African descent).

Bone Grafts are a reliable source of rigid autograft that can produce reliable results. Calvarial bone is often the site of choice given its proximity to the head and neck and well-hidden donor site scar. Given its rigidity, the edges of this graft may be palpable and it may be more predisposed to resorption compared to autograft cartilage grafts. Fascia may be used as an adjunct graft to camouflage the edges of bone and other grafts when needed.

ALLOGRAFT

Costal Cartilage: Irradiated vs Nonirradiated

Irradiated costal cartilage was introduced as an option to provide costal cartilage without the donor-site morbidities (pain, scarring, pneumothorax) associated with autologous cartilage harvest. These grafts have proven to be safe but, compared to autologous costal cartilage, have demonstrated a much higher rate of (31% resorption rate vs 3% with autologous costal cartilage) and histological differences in chondrocyte viability and collagen fiber content, causing them to fall out of favor for use in rhinoplasty.

However, in recent years, fresh frozen costal cartilage allograft (Profile) was introduced by MTF Biologics. It is processed without terminal irradiation and is cleaned using an antibiotic soak. It's available as a sheet which decreases the need to carve the graft.

Nuances to working with the graft:
Allow graft to fully thaw before using. If warping occurs after thawing the graft, select the straightest part of the graft for use or use oppositional suture techniques (*Figure 2*) to control and counteract the warping. Cartilage from older donors appears yellow and heterogeneous and is stiffer and less prone to warping. Cartilage from younger donors appears white and homogenous. A sheet graft can be divided and used for the following grafts: Bilateral alar rim grafts, spreader grafts and a columellar strut (*Figure 3*).

Although there is a paucity of long-term data on the use of fresh frozen costal cartilage, Dr. Rohrich's study (**Role of Fresh Frozen Cartilage in Revision Rhinoplasty**.2019) shows good results in 50 patients with little resorption.

Fresh frozen costal cartilage allograft use decreases operative time associated with harvesting a second source of autologous cartilage and should be considered any time septal cartilage may be not available and the need for grafts is anticipated.

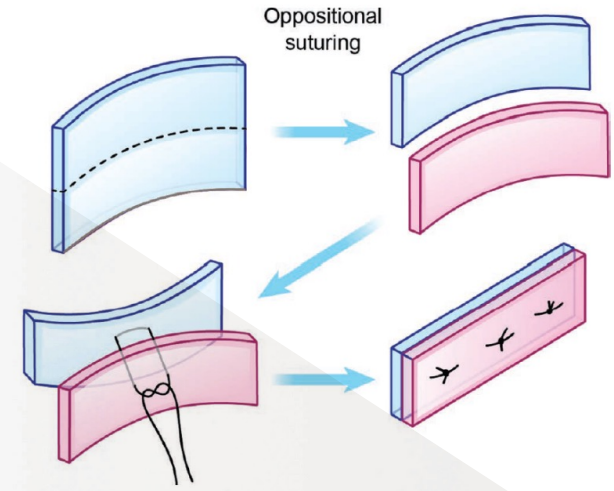

Fig. 2. This figure demonstrates the technique of oppositional suturing.

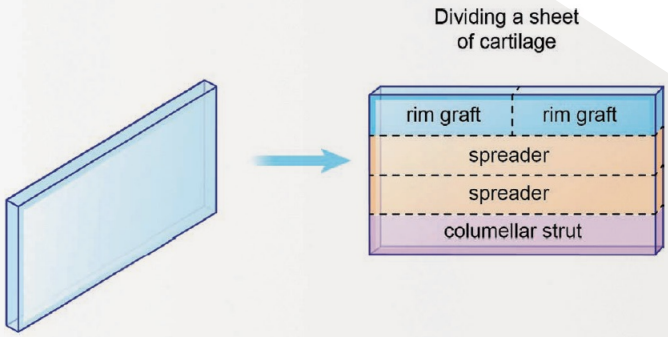

Fig. 3. This figure demonstrates the typical method of dividing a sheet of cartilage for use in the nose.

ALLOPLASTIC MATERIALS

Silicone is frequently used for nasal augmentation, especially in Asian populations. It provides an easy-to-use material with low foreign body reaction that is easily carved and customized to the patient. However, revision procedures to remove silicone implants are increasingly common because the solid construct without pores does not allow for vascular or soft-tissue ingrowth, causing chronic inflammation and formation of a thick fibrous capsule which can lead to bacterial colonization and capsular contracture and deformity. Capsular contracture occurs at a rate of 34.8% and results in tip deviation, short nose deformity, implant demarcation, color change and functional problems up to twenty years post implantation. Revision rhinoplasty is often necessary to remove the capsule and implant and correct the shortened nose. Extrusion of silicone implants is another issue and occurs as high as 10% for dorsal nasal implants and 50% for columellar struts. Silicone nasal implants may also become displaced due to insufficient implant fixation, implant placement in the supraperiosteal plane and over-augmentation with inappropriately large implants. These overly large implants may cause increased pressure on the columella and nasal tips, leading to higher rates of soft tissue ischemia, necrosis and eventual perforation and extrusion requiring removal. Of all alloplasts, silicone has the highest rate of complication requiring removal. Prolonged implantation of silicone implants induces calcification with up to 50% of implants showing evidence of calcification after 9 years and visible deformities secondary to calcification were found in implants up to 15 years after implantation.

High-Density Polyethylene (Medpor®)

Medpor is a porous product made of high-density polyethylene developed in the 1970s for facial augmentation. It is highly flexible and relatively noncompressiable, allowing it to be easily carved. And because of its excellent biocompatibility profile, Medpor may be applied directly onto the facial bones as an onlay implant using sutures or screws. It is often used for correction of a severe saddle nose deformity, overresected nose and other nasal deformities. However, it is often stiff and palpable and may be visible with an abnormal appearance and feel if not used in conjunction with a camouflage graft. The large pore size (200 um) of Medpor allows for vascular ingrowth and enhanced implant fixation but shedding of particles in mobile or stress-bearing areas may lead to chronic inflammation and subsequent tissue fibrosis. Thinning over the overlying skin envelope, contour irregularities and full -thickness button holing upon explantation may occur. Cases of Medpor extrusion in the nasal dorsum and tip have been reported. Turned up or short nose and tip stiffness are the most common reasons for revision in patients receiving Medpor implants.

Polytetrafluoroethylene is a hydrophobic carbon/fluorine polymer with pores up to 30 um allowing for tissue ingrowth. Introduced in 1971, Gore-Tex, an expanded polytetrafluoroethylene, was approved for soft tissue augmentation. The three Gore-Tex patch sizes are pliable and easily cut, carved, and beveled with a scalpel or scissors. This material is best suited for treating an overresected dorsum but owing to its minimal rigidity and tensile strength, should be avoided when structural support is needed, such as in reconstruction of the nasal valve or septum or when tip-columellar subunits is performed.

Polydioxanone Foil is a biodegradable, crystalline colorless polymer commonly used as a suture material but also available as a thin foil sheet. It's absorbable, and stiff but thin, making it suitable for correction of septal deviation and reinforcement of other grafts, such as columellar struts and alar batten grafts. It is well tolerated with minimal infection and extrusion.

CONCLUSION

A movement away from reductive rhinoplasty has many plastic surgeons looking to use grafts for structural support. While septal cartilage remains the ideal source for most needed grafts, alternative graft materials such as nonirradiated cadaveric costal cartilage (Profile) are attractive options to avoid donor site harvest and morbidity. Clinical experience and understanding of this and other available materials is needed. Refer to Table 1 from the paper for a direct comparison between all materials reviewed.

Table 1 provides a comparison of complication rates, including resorption, infection and extrusion, as well as cost, among the materials discussed in the paper.

Table 1. Complication Rates of Homologous Grafts and Allogenic Implants*

Graft	Resorption	Infection	Extrusion	Relative Cost
Fresh frozen cadaveric cartilage	Very low	Very low	Very low	+++
Irradiated cartilage	Moderate to high	Low	Low	++++
Freeze-dried acellular dermis	Moderate to high	Very low	Very low	++++
Silicone	Very low	Low to moderate	Moderate to high	+
High-density polyethylene	Very low	Low	Moderate	+++
Polytetrafluoroethylene	Very low	Low to moderate	Low	++
Hydroxyapatite	Variable	Variable	Variable	++
Polydioxanone foil	High	Very low	Very low	+

*Table 1 is a simplification of the complication rates, which may vary depending on implant location, implantation technique, and application.
Very low, <1%; low, 1–5%; moderate, 5-15%; high, >15%.

HOW TO USE THIS DATA

- Make the distinction between terminally sterilized costal cartilage allograft, which historically demonstrated "moderate to high" rates of resorption compared to fresh frozen cadaveric cartilage (Profile) which is aseptically processed without terminal irradiation.
- Profile is biocompatible with very low rates of resorption, infection, and extrusion. It provides a durable grafting material and while many of the materials discussed in the paper have limited uses, Profile is suitable for most graft types and graft placement.
- Profile is available at a relatively low cost. Cost savings are enhanced when factoring in OR time saved with avoidance of autologous graft harvest and associated donor site morbidities such as excessive pain which may require pain medication, and chest wall deformity and pneumothorax which would necessitate additional surgical intervention.

Title: **Fresh Frozen Rib Cartilage Grafts in Revision Rhinoplasty: A 9-Year Experience**

Author: Rohrich, R, Abraham, J, Alleyne, B, Bellamy, J, Mohan, R.

Source: *Plast. Reconstr. Surg.* 150:58, 2022.

Full Publication

STUDY OBJECTIVE

Retrospective review to assess rates of warping, resorption, displacement, and infection in 226 patients who underwent primary or revision rhinoplasty by Dr. Rod Rohrich between 2011 and 2020 using fresh frozen costal cartilage (Profile®).

METHODS

A retrospective review of medical charts for complications, including warping, resorption, displacement, infection and reoperation was performed for 226 patients who underwent open rhinoplasty with fresh frozen allograft cartilage produced by MTF Biologics. All procedures were performed by the senior author (Rohrich) at the Dallas Plastic Surgery Institute between 2011 and 2020. Location of grafts, number of prior rhinoplasties, patient age and length of follow up were also reviewed. Follow up ranged from 6 mos to 8 years with a mean follow-up period of 12.18 months.

Patient & Procedural Information:

- Female: 82%/Male: 18%
- Patient Age Range: 19-74 Mean Patient age: 40.59
- Avg # of previous rhinoplasty procedures: 54% had one prior rhinoplasty;4% had undergone four or more nose procedures
- Types of Grafts Used: (%)
  - Alar contour (49%)
  - Columellar strut 23%)
  - Dorsal Onlay (12%)
  - Lateral Nasal Wall (4%)
  - Septal extension (40%)

RESULTS:

Overall infection rate was 2.7% (n=6). Mild nasal tip erythema was noted in nine patients (4.0%), all cases of which were self-limiting and resolved within two -three weeks. Six patients experienced warping (three with dorsal onlay grafts ,two with alar contour grafts, one with septal extension graft). Four of the six patients underwent reoperation for replacement or repositioning of the grafts. None of the patients experienced displacement or extrusion. These results were compared with historical data on autologous and irradiated grafts (Table 3).

Table 3. Comparison of Autologous, Irradiated Homologous, Tutoplast Homologous, and Fresh Frozen Nonirradiated Allografts in Revision Rhinoplasty

Complication	Autologous (%)*†	Irradiated Homologous (%)†	Tutoplast Homologous (%)†	Fresh Frozen (%) (n = 226)
Warping	3.1-6	5	4	2.7
Infection	0.6-2	3	0	2.7
Resorption	0.2-1	4	11	N/A
Pneumothorax	0 (0-0.3)	N/A	N/A	N/A
Revision surgery	5-14.1	7	3	2.2

N/A, not applicable.

*Wee JH, Park M-H, Oh S, Jin H-R. Complications associated with autologous rib cartilage use in rhinoplasty: A meta-analysis. JAMA Facial Plast

Surg. 2015;17:49–55.

†Vila PM, Jeanpierre LM, Rizzi CJ, Yaeger LH, Chi JJ. Comparison of autologous vs homologous costal cartilage grafts in dorsal augmentation

rhinoplasty: A systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2020;146:347–354.

Autologous cartilage and fresh frozen cartilage (Profile) appear to have similarly low rates of resorption, in stark contrast to irradiated homologous cartilage. The terminal radiation process likely contributes to decreased viability and contextual structural integrity of the grafts.

The risk for postoperative infection with fresh frozen rib cartilage is similar to both autologous and irradiated grafts and adequately managed with antibiotic therapy. Only one patient required reoperation which occurred six months after the explanation with no additional complications.

CONCLUSION

Revision rhinoplasty results are significantly enhanced with the creation of a stable framework using off the shelf, easily accessible, specifically tailored fresh frozen allograft rib grafts. This 9- year retrospective study demonstrates the safety and longevity of fresh frozen rib graft in comparison to autologous and irradiated homologous cartilage.

HOW TO USE THIS DATA

- Many plastic surgeons still believe allograft costal cartilage is prone to higher rates of resorption and warping than autograft.

  Use this study as proof that MTF allograft costal cartilage has similar or better complication rates, including resorption (0% in Profile, vs 0.2-1% for autologous costal cartilage, 3% for irradiated allograft and 11% for RTI's Tutoplast grafts) than autologous cartilage and other allografts (Tutoplast from RTI and another terminally sterilized cartilage allograft) while eliminating the comorbidities associated with harvest of autologous tissue.

- Use the complications data in **Table 3** to support this statement. In the table, the rates of warping, infection, resorption, pneumothorax, and revision surgery using Profile (Fresh Frozen allograft) were compared with autologous costal cartilage, irradiated allograft, and allograft processed using Tutoplast. Tutoplast is RTI's tissue processing method that uses an alkaline solution and terminal irradiation, among other steps.

  Except for a slightly higher rate of infection (2.7% for Profile vs. 0.6-2% in Autologous tissue and 0% in Tutoplast costal cartilage), Profile showed lower rates of warping, resorption, pneumothorax and revision surgery than autologous cartilage, irradiated allograft and Tutoplast allograft.

  By eliminating the need to harvest autograft, Profile spares surgeons the time and patients the pain of autologous cartilage harvest. As the article relates, the post-op pain associated with autologous costal cartilage harvest is "…often the main memory patients have from their rhinoplasty, even years later."

- Use this study to talk about MTF's approach to tissue processing and explain the difference between pre -treatment and terminal irradiation.
  - MTF Profile grafts are aseptically processed without the use of harsh chemicals and terminal irradiation, so they behave most like autologous cartilage grafts.
  - Processing of Profile sheets and segments consists of a triple antibiotic soak. Profile sheets also go through a soak in triton, a mild detergent that removes blood and lipids. Both sheets and segment grafts are then packaged in triple layer tyvek and stored frozen at -40C.
  - Representative samples are tested for bacterial growth before units are released for distribution, in accordance with USP <71> sterility guidelines.
  - In RTI's Tutoplast process, costal cartilage grafts are dehydrated with peroxide and acetone before irradiation with up to 25 kGy of gamma irradiation.
  - Except for an additional step for soft tissues that includes treatment with sodium hydroxide (NaOH), at room temperature, for one hour, all RTI grafts; i.e.. musculoskeletal grafts, dermal grafts, costal cartilage, etc. go through this same process.
  - In contrast, MTF tailors our processes to each tissue form. The Allograft Tissue Purification process for MTF MS tissues differs greatly from our soft tissue/cartilage process and from our dermal process, which again differs from the process we have for adipose. This ensures the inherent properties of each unique tissue type are maintained. Our gentle but adequate to ensure safety process for Profile is why our complication data is so low compared to both autologous costal cartilage and other allografts, including RTI's offering.

Title: Safety and Efficacy of Non- and Minimally Irradiated Homologous Costal Cartilage in Primary and Revision Rhinoplasty

Author: Rogal, J, Glasgold, A, Glasgold, RA.

Source: *Facial Plastic Surgery & Aesthetic Medicine.* Volume 23, Number 1. 2021.

Full Publication

STUDY OBJECTIVE

Retrospectively evaluate the safety and efficacy of Non- or Minimally Irradiated Homologous Costal Cartilage (NIHCC) in primary and revision rhinoplasty

METHODS

- Retrospective review of 26 patients undergoing primary or revision rhinoplasty using NIHCC (Profile) between 2010 and 2014
  - Follow up range: 2-43.2 Mo Mean Follow up: 15.9 Mo
- All patients underwent open rhinoplasty
  - 7 patients underwent primary rhinoplasty
  - 19 patients underwent revision rhinoplasty
- A total of 100 NIHCC grafts were used
- Columellar strut grafts and extended shield grafts were used in all cases
- Surgery included some or none of the following additional grafts:
  - Septal extension grafts (4)
  - Alar rim grafts (23)
  - Lateral crural strut grafts (6)
  - Spreader grafts (19)
  - Batten grafts (9)
  - Dorsal Augmentation grafts (8)
- Patients were assessed for warping, infection, infective and non-infective resorption, graft mobility and extrusion.

RESULTS

- Non-infective resorption was noted in 2/77 grafts (2.6%)
- Infection occurred in 1/100 grafts (1%)
- Total complication rate was 3.6%
- No instances of warping, mobility or extrusion occurred

CONCLUSIONS

NIHCC is safe and effective for grafting in functional and cosmetic primary and secondary rhinoplasty.

HOW TO USE THIS DATA

- Point of Differentiation: Profile is the only non-terminally sterilized costal cartilage allograft available
- Explain the difference to surgeons between pretreatment and terminal irradiation with gamma
  - Pretreatment: Prior to processing, on all recovered, non-processed tissues. Uses a low dose of gamma (12-18 kGy)
  - Terminal irradiation: After processing, on single finished good graft. Uses a high dose of gamma (>25 kGy)
- Discuss the negative effects of terminal irradiation using gamma irradiation
- Per the paper, extensive studies of the effect of high dose gamma irradiation in orthopedic cartilage grafts demonstrate the following:
  - Decreased allograft strength
  - Increased rates of warping
  - Smaller and less uniform chondrocytes
  - Severe cell degeneration of chondrocytes
- Study demonstrated very low rates of warping (0%) and resorption (2.6%), making a case that Profile costal cartilage is as safe and efficacious to use in rhinoplasty as autograft cartilage

Title: Rhinoplasty Refinements: Revision Rhinoplasty Using Fresh Frozen Costal Cartilage Allograft

Author: Rohrich, R, Shanmugakrishnan, R, Mohan, R.

Source: *PRS Journal.* Volume 145. Number 6. 2020.

Full Publication

STUDY OBJECTIVE

Retrospective case study of a single secondary rhinoplasty using fresh frozen allograft (Profile) to address a crooked nose and retracted columella.

Introduction: Dr. Rohrich defines a retracted columella and how to correct. He explains his preference for Profile vs. autologous rib cartilage (avoid donor-site morbidity) and irradiated costal cartilage allografts (higher incidence of resorption and infection resulting in poor patient satisfaction). He explains that he has used Profile in more than 50 patients with no cases of resorption and just one infection.

Table 1 compares key characteristics of septal, costal and conchal autograft cartilage as well as irradiated and fresh frozen allograft cartilage, including warping, donor site morbidity, ease of harvest, structural support and operative time with fresh frozen scoring as well as or better than autologous cartilages in all categories.

Table 1. Comparison of Grafts

Characteristic	Septal	Costal	Conchal	Irradiated	Fresh Frozen
Amount	++	+++	+	+++	+++
Donor-site morbidity	––	++	–	N/A	N/A
Warping	–	+	+	++	+
Ease of harvest	++	–	+	N/A	N/A
Structural support	+	++	–	+	+
Scarring	–––	++	+	N/A	N/A
Operative time	–	++	+	–	–
Ease of carving	++	+	–	++	++

+, increased; –, decreased; N/A, not applicable.

PROCEDURE

Through a series of three videos, Dr. Rohrich explains his procedure for correcting a crooked nose with a retracted columella in a 28 year old woman. Profile was used to create extended spreader grafts and a columellar strut.

Video 1 Summary:

- Analysis of the nasal deformities
- Incision and approach in an open rhinoplasty
- Dorsal reduction procedure
- Exposure of the anterior septal angle

Video 2 Summary:

- Dr. Rohrich's percutaneous osteotomy technique
- Profile carving and fashioning into grafts to straighten the nose and correct the retracted columella
- Use of sutures to reduce flaring of the media crura

Video 3 Summary

- Tip refinement details, including suturing techniques and butterfly graft placement
- Use of alar contour grafts to support external nasal valve
- Columellar closure

CONCLUSION

Fresh frozen costal cartilage allograft is a promising cartilage graft material in secondary rhinoplasty which often requires costal cartilage grafts to rebuild cartilaginous framework

HOW TO USE THIS DATA

- Point of Differentiation: Profile is the only non-terminally sterilized costal cartilage allograft available
- Explain the difference to surgeons between pretreatment and terminal irradiation with gamma
  - Pretreatment: Prior to processing, on all recovered, non-processed Tissues. Uses a low dose of gamma (12-18 kGy)
  - Terminal irradiation: After processing, on single finished good graft. Uses a high dose of gamma (>25 kGy)
- Discuss the negative effects of terminal irradiation using gamma irradiation
- Discuss the benefits of using Profile vs. autologous cartilage harvest; risk of comorbidities, such as scarring, chest wall deformity and pneumothorax, OR time savings, known cartilage quality when using Profile (vs unknown or poor quality autologous cartilage in patients over age 30)

Title: Role of Fresh Frozen Cartilage in Revision Rhinoplasty

Author: Mohan, R, Krishnan, R, Rohrich, R.

Source: *Plast. Reconstr. Surg.* 144: 614, 2019

Full Publication

STUDY OBJECTIVE

Retrospective analysis of charts and photographs of 50 patients who underwent revision rhinoplasty between 2014 and 2017 using fresh frozen cartilage from the Musculoskeletal Transplant Foundation.

METHODS

A retrospective review of medical charts for complications, including infection, resorption and warping, was performed for 50 patients who underwent revision rhinoplasty with fresh frozen allograft cartilage produced by MTF Biologics. All procedures were performed by the senior author (Rohrich) at the Dallas Plastic Surgery Institute between 2014 and 2017.

Patient & Procedural Information:

- Female: 38 patients/Male: 12 patients
- Avg # of previous rhinoplasty procedures: 2.62
- Patient Age Range: 21-70. Mean Patient age: 40
- Operative time: 70-370 min. Avg: 159 min

• Types of Grafts Used: No (%)

- Dorsal augmentation 15 (30)
- Columellar strut 14 (28)
- Alar contour 44 (88)
- Infratip 8 (16)
- Dorsal spreader 8 (16)
- Septal extension 3 (6)

In addition, to assess the aesthetic outcomes of each procedure, an objective evaluation of aesthetic results was performed by four blinded plastic surgeons. These surgeons reviewed preoperative and postoperative photographs of the patients in the study cohort. The outcomes were assessed using the Independent Rhinoplasty Outcome Score.

The following components were assessed: Symmetry, dorsal height, dorsal length, dorsal width, tip projection, tip rotation, tip width, and overall result; using a scoring system of 1-4.

1=no improvement. 2=moderate outcome. 3=good outcome. 4=excellent outcome.

Post- operative follow- up ranged between 1 and 18 months, with a mean follow up of 3.35 months.

RESULTS

One case of infection was reported in the 50 patients studied (2%). It was treated with minimal debridement and a short course of antibiotics. No cases of warping or resorption were reported.

Table 5 shows complication rates of Autograft costal cartilage and Irradiated and Fresh Frozen (Profile) allograft costal cartilage.

Table 5. Comparison of Autografts, Irradiated Allografts, and Fresh Frozen Nonirradiated Allografts for Use in Revision Rhinoplasty

Characteristic	Autologous (%)*	Irradiated (%)*	Fresh Frozen (%)
Warping	13	10	0
Infection	6	10	2
Resorption	3	30	0
Pneumothorax	2	N / A	N / A
Donor-site pain	0	N / A	N / A
Total no. of complications	27	45	2

N/A, not applicable.

*Wee JH, Park MH, Oh S, Jin HR. Complications associated with autologous rib cartilage use in rhinoplasty: A meta-analysis. *JAMA Facial Plast Surg.* 2015;17:49–55.

The average score for each component of the aesthetic outcomes by blinded surgeon was greater than 3 (good outcome).

CONCLUSION

Autologous costal cartilage is the predominant donor cartilage source in revision rhinoplasty. However, it is associated with postoperative pain and prolonged operating times, and carries the risk of pneumothorax, atelectasis, and the need for prolonged narcotic pain control. Allograft costal cartilage biologic mesh for reinforcement of complex repairs is a viable, safe option in complex cases delivering clinically acceptable short and mid-term results in challenging clinical situations.

HOW TO USE THIS DATA

- Many plastic surgeons still believe allograft costal cartilage is prone to higher rates of resorption and warping than autograft.

  Use this study as proof that MTF allograft costal cartilage is an effective and safe alternative to autograft costal cartilage in revision rhinoplasty, resulting in lower complication rates than autograft and irradiated (terminally sterilized) allograft costal cartilage, and eliminating the comorbidities associated with harvest of autologous tissue.

HOW TO USE THIS DATA (continued)

Use the complications data in Table 5 to support this statement. In the table, the rates of warping, infection, resorption, and pneumothorax, as found in a meta-analysis "Complications associated with autologous rib cartilage use in Rhinoplasty," and donor-site pain were compared among patients receiving autograft, irradiated (terminally sterilized) and *Fresh Frozen (MTF Profile grafts) tissue.

Rates of complication in all categories were lowest for Fresh Frozen (Profile).

- By eliminating the need to harvest autograft, an off the shelf allograft alternative, like Profile, also saves surgeons time and cost.

  As the study points out, more than half (64%) of plastic surgeons perform 20 or fewer rhinoplasties per year. This infrequency in harvesting autologous costal cartilage results in longer time to harvest, adding to the time and cost of the rhinoplasty procedure.

- Use this study to talk about MTF's approach to tissue processing and explain the difference between pre -treatment and terminal irradiation.

  MTF Profile grafts are aseptically processed without the use of harsh chemicals and terminal irradiation so they behave most like autologous cartilage grafts, and are not terminally sterilized.

  Processing of Profile sheets and segments consists of a triple antibiotic soak. Profile sheets also go through a triton soak, a mild detergent that removes blood and lipids. Both sheets and segment grafts are then packaged in triple layer tyvek and stored frozen at -40C.

  Representative samples are tested for bacterial growth before units are released for distribution, in accordance with USP <71> sterility guidelines.

- Some donors used to make Profile units are **pretreated** with a low dose of gamma radiation prior to production. This is **NOT** the same as terminal irradiation in which individual processed units are subjected to gamma radiation or other harsh processes in their final packaging.

  Pre treatment has less ill effects than terminal irradiation, while still providing sterile (per USP <71>), safe grafts.

  Currently, all other allograft costal cartilage grafts available on the market are terminally sterilized.

  *Dr. Rohrich used both aseptic and pretreated Profile units in this study, and he continues to do so today. His use of the term "fresh frozen" is referring to the fact that our grafts are not freeze dried or terminally sterilized.

- Use this study to emphasize that not all allograft costal cartilage is the same… processing matters and affects clinical outcomes!

  The allografts used in the Wee and Welling studies (references # 24, 25, respectively) cited in this article as showing higher complication rates than autograft, were terminally sterilized.

  In the 2017 Wee study, resorption rates of 30% in the allograft arm vs. 3% in the autograft arm were observed. The costal cartilage grafts in that study are from South Korean company CG Bio Co, LTD, and are terminally sterilized using 30-40 kGy of gamma radiation.

HOW TO USE THIS DATA (continued)

Also in the Wee study, histology showed a decrease in chondrocyte viability and collagen fiber content in the irradiated allograft vs. the autograft.

In the 1987 Welling study (reference # 25), the use of terminally sterilized costal cartilage resulted in high rates of resorption and low rates of patient satisfaction.

In that study, sixty-two of an original 145 irradiated allograft costal cartilage grafts were followed for an average of nine years. An average resorption rate of 75% was observed. Eighteen of 24 grafts followed for 11-16 years completely resorbed.

Both of these studies demonstrate the adverse effects caused by terminal irradiation, and support MTF's choice not to use it in any of our tissue forms, including Profile sheets and segments.

Key Figures and Tables
Profile Clinical Compendium

Datta, S. Mattos, D. Hanna, S. Reish, R. *Does Soaking Fresh Frozen Costal Cartilage in an Antibiotic Solution Reduce Postoperative Infection in Rhinoplasty?*

Table 2

Wan, R. Weissman, J, Williams, T, Ullrich, P.,Joshi, C, Huffman, K, Galiano, R. *Prospective Clinical Trial Evaluating the Outcomes Associated with the Use of Fresh Frozen Allograft Cartilage in Rhinoplasty*

Figure 3 ***Table 4***

Milkovich, J. Ahmad. J. *A Canadian Experience with Off-the-Shelf, Aseptically Processed, Costal Cartilage Segment Allografts in Complex Rhinoplasty*

Figure 1 ***Figure 2***

Reish, R. *Optimizing the Use of Autografts, Allografts and Alloplastic Materials in Rhinoplasty.*

Figure 2 ***Figure 3*** ***Table 1***

Rohrich, R,Abraham, J, Alleyne, B, Bellamy, J. Mohan, R. *Fresh Frozen Rib Cartilage Grafts in Revision Rhinoplasty: A 9-Year Experience.*

Table 3

Rohrich, R. Shanmugakrishnan, R. Mohan, R. *Rhinoplasty Refinements: Revision Rhinoplasty Using Fresh Frozen Costal Cartilage Allograft.*

Table 1

Mohan, R, Krishnan, R, Rohrich, R. *Role of Fresh Frozen Cartilage in Revision Rhinoplasty.*

Table 5

Datta, S. Mattos, D. Hanna, S. Reish, R. *Does Soaking Fresh Frozen Costal Cartilage in an Antibiotic Solution Reduce Postoperative Infection in Rhinoplasty?*

Table 2. Demographics and Outcomes of Infection Cases

Characteristic	No. (%)
Total infection cases	4 (1.3%)
Age range	
30–39 years	2 (0.6%)
40–49 years	0
50–59 years	1 (0.3%)
60–69 years	0
70+ years	1 (0.3%)
Sex	
Female	3 (1.0%)
Male	1 (0.3%)
Body mass index	
<20	1 (0.3%)
20–24.9	2 (0.6%)
>25	1 (0.3%)
Smoker	0
No. patients with infection *	
Abx	4 (1.3%)
No-Abx	0

*Fisher exact test, $P = 0.301$.

Wan, R. Weissman, J, Williams, T, Ullrich, P., Joshi, C, Huffman, K, Galiano, R.
Prospective Clinical Trial Evaluating the Outcomes Associated with the Use of Fresh Frozen Allograft Cartilage in Rhinoplasty

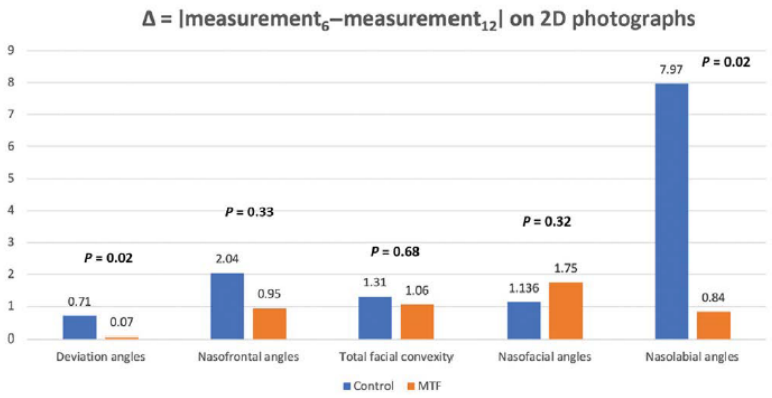

Fig. 3. The change of the measurements (Δ= |measurement$_6$–measurement$_{12}$|) of deviation angle, nasofrontal angle, total facial convexity, and nasolabial angle on standard 2D photographs at 6- and 12-months postoperative visits.

Table 4: Postoperative Complications

Complications	Control	CCA
Infection	1	0
Resorption	2	2
Warping	3	2
Pneumothorax	0	NA
Scarring	4	2
Total	**10**	**6**

CCA, costal cartilage allograft; NA, not applicable

PREVIOUS
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Figure 1. It is important to carve the segments in the correct orientation using more central sheets which have less potential to warp. Peripheral sheets have much more tendency toward warping. With reference to the native anatomic position, the costal cartilage segment should be carved into sheets with cuts made in the anterior-posterior orientation as opposed to the cranial-caudal orientation. The piece of cartilage on the left was carved from the periphery of the rib in the cranial-caudal orientation, while the piece of cartilage on the right was carved from the center of the rib in the anterior-posterior orientation.

Figure 2. Grafts carved from the central segment of a fresh frozen, nonterminally sterilized, costal cartilage. ACG, alar contour graft; SEG, septal extension graft.

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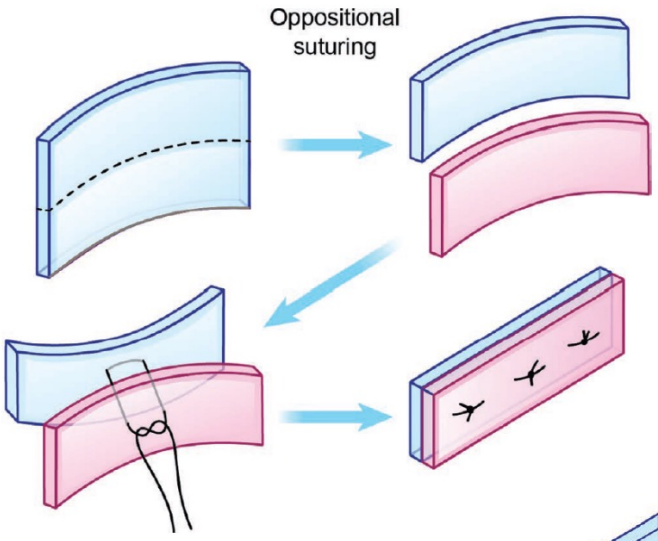

Fig. 2. This figure demonstrates the technique of oppositional suturing.

Reish, R. *Optimizing the Use of Autografts, Allografts and Alloplastic Materials in Rhinoplasty.*

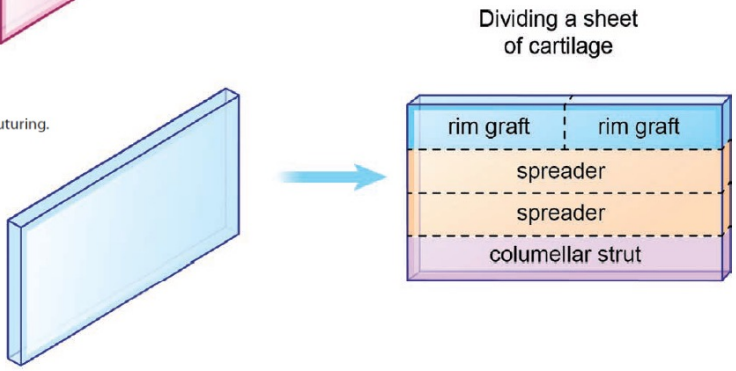

Fig. 3. This figure demonstrates the typical method of dividing a sheet of cartilage for use in the nose.

Table 1. Complication Rates of Homologous Grafts and Allogenic Implants*

Graft	Resorption	Infection	Extrusion	Relative Cost
Fresh frozen cadaveric cartilage	Very low	Very low	Very low	+++
Irradiated cartilage	Moderate to high	Low	Low	++++
Freeze-dried acellular dermis	Moderate to high	Very low	Very low	++++
Silicone	Very low	Low to moderate	Moderate to high	+
High-density polyethylene	Very low	Low	Moderate	+++
Polytetrafluoroethylene	Very low	Low to moderate	Low	++
Hydroxyapatite	Variable	Variable	Variable	++
Polydioxanone foil	High	Very low	Very low	+

*Table 1 is a simplification of the complication rates, which may vary depending on implant location, implantation technique, and application.
Very low, <1%; low, 1–5%; moderate, 5-15%; high, >15%.

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Rohrich, R,Abraham, J, Alleyne, B, Bellamy, J. Mohan, R.
Fresh Frozen Rib Cartilage Grafts in Revision Rhinoplasty: A 9-Year Experience.

Table 3. Comparison of Autologous, Irradiated Homologous, Tutoplast Homologous, and Fresh Frozen Nonirradiated Allografts in Revision Rhinoplasty

Complication	Autologous (%)*†	Irradiated Homologous (%)†	Tutoplast Homologous (%)†	Fresh Frozen (%) (n = 226)
Warping	3.1-6	5	4	2.7
Infection	0.6-2	3	0	2.7
Resorption	0.2-1	4	11	N/A
Pneumothorax	0 (0-0.3)	N/A	N/A	N/A
Revision surgery	5-14.1	7	3	2.2

N/A, not applicable.

*Wee JH, Park M-H, Oh S, Jin H-R. Complications associated with autologous rib cartilage use in rhinoplasty: A meta-analysis. JAMA Facial Plast

Surg. 2015;17:49–55.

†Vila PM, Jeanpierre LM, Rizzi CJ, Yaeger LH, Chi JJ. Comparison of autologous vs homologous costal cartilage grafts in dorsal augmentation

rhinoplasty: A systematic review and meta-analysis. JAMA Otolaryngol Head Neck Surg. 2020;146:347–354.

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Rohrich, R. Shanmugakrishnan, R. Mohan, R.
Rhinoplasty Refinements: Revision Rhinoplasty Using Fresh Frozen Costal Cartilage Allograft.

Table 1. Comparison of Grafts

Characteristic	Septal	Costal	Conchal	Irradiated	Fresh Frozen
Amount	++	+++	+	+++	+++
Donor-site morbidity	−−	++	−	N/A	N/A
Warping	−	+	+	++	+
Ease of harvest	++	−	+	N/A	N/A
Structural support	+	++	−	+	+
Scarring	−−−	++	+	N/A	N/A
Operative time	−	++	+	−	−
Ease of carving	++	+	−	++	++

+, increased; −, decreased; N/A, not applicable.

Mohan, R, Krishnan, R, Rohrich, R. *Role of Fresh Frozen Cartilage in Revision Rhinoplasty.*

Table 5. Comparison of Autografts, Irradiated Allografts, and Fresh Frozen Nonirradiated Allografts for Use in Revision Rhinoplasty

Characteristic	Autologous (%)*	Irradiated (%)*	Fresh Frozen (%)
Warping	13	10	0
Infection	6	10	2
Resorption	3	30	0
Pneumothorax	2	N / A	N / A
Donor-site pain	0	N / A	N / A
Total no. of complications	27	45	2

N/A, not applicable.

*Wee JH, Park MH, Oh S, Jin HR. Complications associated with autologous rib cartilage use in rhinoplasty: A meta-analysis. *JAMA Facial Plast Surg.* 2015;17:49–55.

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