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Cosmetic

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

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Background: There are different types of grafts for rhinoplasty, each with certain advantages and disadvantages. Fresh frozen cadaveric costal allograft (CCA) provides an alternative to rhinoplasties. The aim of this study was to compare the outcomes of fresh frozen CCA and traditional autologous costal cartilage in cosmetic and reconstructive rhinoplasty procedures.

Methods: This is a prospective, single-center, nonrandomized, open-label clinical trial. Objective assessment to evaluate warping, resorption, and displacement of the cartilage was achieved 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 ($\Delta = |\text{measurement}_6 - \text{measurement}_{12}|$). Subjective assessment was measured by the FACE-Q assessment.

Results: Fifty eligible patients between March 2017 and October 2020 were included. The average 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 and nasolabial angle were greater than in the CCA group ($P < 0.05$). 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 also increased in the CCA group at 6 months postoperatively ($P < 0.05$). Six patients from the CCA group and 10 patients from the control group experienced postoperative complications.

Conclusions: Fresh frozen CCA is a safe and reliable source of rhinoplasty grafts. It is aseptic, readily available, and free of donor site complications. *(Plast Reconstr Surg Glob Open 2023; 11:e5315; doi: 10.1097/GOX.0000000000005315; Published online 4 October 2023.)*

INTRODUCTION

Rhinoplasty is one of the most-performed cosmetic surgical procedures in the United States (352,555 procedures in 2020) and one of the most technically challenging procedures in plastic surgery, because of its limited access and the requirement for a three-dimensional framework.[1] Thus, the use of different types of nasal grafts to provide structural support is essential to a successful rhinoplasty. Although fillers, fascia, and fat can be used for minor corrections, larger and more supportive implants or grafts are critical in procedures that require a large amount of structural support, such as revision, augmentation, and reconstruction rhinoplasties. A variety of grafting materials have been developed, but each carries its own set of challenges.[2] Alloplastic implants are commonly used in Asian countries and have shown a higher incidence of complications.[3] Due to safety concerns, plastic surgeons in the United States often avoid this option.[2,4–6] Autologous cartilages are the preferred option, including septal, conchal, and costal cartilages. Despite different donor sites, cartilaginous autografts similarly exhibit little cellularity and

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abundant intercellular substance, namely homogenously spaced collagen fibers.[7] Septal cartilage is ideal for rhinoplasty due to its location, but it often has an insufficient amount in certain patients. Conchal cartilage is frequently used for nasal alar grafts because of its curved shape, but its volume is also limited.[8] Costal cartilage can provide an abundant volume of cartilage; however, harvesting costal cartilage increases operative time and may cause worrisome donor site complications, such as prolonged pain, pneumothorax, hematoma, and hypertrophic scars.[8–11] Irradiated homologous costal cartilages from deceased donors, on the other hand, can eliminate the problems of a second surgical location and inadequate supplies. However, studies have reported relatively higher resorption, warping, and infection rates using allografts that are terminally sterilized by gamma irradiation.[8,12–15]

A cartilage graft that is abundant in volume, as well as inexpensive, easy to harvest, and free of donor site complications is ideal. A novel nonterminally sterilized, fresh frozen allograft (Profile, MTF Biologics, Edison, N.J.) aseptically processed from deceased donors has been developed and made available as an off-the-shelf option for extra-anatomical cartilage. This study aims to prospectively evaluate the outcomes and patient satisfaction of costal cartilage allograft (CCA) segment and sheet configurations in cosmetic and reconstructive rhinoplasty compared with the traditional autologous costal cartilage.

Takeaways

Question: Does fresh frozen allograft cartilage improve patient outcomes in rhinoplasty?

Findings: This randomized controlled trial demonstrated that when compared with autologous costal cartilage, fresh frozen allograft cartilage provided reliable results in postoperative nasal deviation and nasolabial angles ($P < 0.05$). Mean scores in patient satisfaction of nostrils and facial appearance within the FACE-Q scale among our cohort were greater for those patients who utilized allograft cartilage ($P < 0.05$).

Meaning: Fresh frozen allograft cartilage is a valuable alternative to autologous costal cartilage for patients undergoing cosmetic or reconstructive rhinoplasty. Its safety and feasibility were established in our study.

PATIENTS AND METHODS

Study Design, Participants, and Recruitment Methods

This study was a prospective, nonrandomized, open-label, single-center, controlled clinical trial, conducted at Northwestern Memorial Hospital in Chicago, Illinois. The protocol was approved by the institutional review board (IRB) from Northwestern University (NU IRB#: STU00203524) and was conducted according to the Declaration of Helsinki. The study is registered on www.ClinicalTrials.gov: #NCT05566808. Adults seeking a rhinoplasty were recruited from the investigator's practice and referring physicians between March 2017 and October 2020. IRB-approved advertisements were also used to recruit individuals from social media. The inclusion and exclusion criteria are outlined in Table 1. Written informed consent was obtained from all subjects in this cohort. Eligible and consenting patients chose to receive either the autologous costal cartilage or CCA in addition to the primary surgeon's opinion. The autologous costal cartilage group is the control group. The study flow chart is shown in Figure 1.

Surgical Technique and Postoperative Care

In the CCA group, the aseptically processed, nonterminally sterilized, fresh frozen cartilage (Profile, MTF, N.J.) was provided by MTF and available in 14 sizes and two shapes (cartilage sheets and segments). The allografts were harvested from the seventh to ninth ribs of the donors with debridement of all soft-tissue attachments. A surfactant was applied to remove noncartilaginous materials. The cartilage was then soaked in antibiotic solution for decontamination and packed in sterile conditions after rinsing. Before distribution, negative cultures from the final product were confirmed. The frozen condition (−40°C to −80°C) was maintained during shipment and storage. Before surgery, a pre-cut allograft was thawed in normal saline. During surgery, it was fashioned into rhinoplasty grafts of needed sizes and shapes using no. 10 blades depending on the procedure (Fig. 2). Later, these grafts were secured by 5-0 polydioxanone sutures. The graft types are documented in Table 2.

In the control group, the rhinoplasty was carried out under the investigator's standard practice. Briefly, the autologous rib graft was taken from an incision along the medial part of the inframammary fold. After the surface of the rib was exposed, the primary surgeon used a 15-blade to make a longitudinal incision along the length of the

Table 1. Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
Healthy female and male patients between 18 and 85 years of age.	Presence of significant endocrine, immunologic, dermatologic, or psychiatric abnormalities.
The subject is scheduled to undergo a reconstructive or cosmetic surgical procedure that is anticipated to require a cartilage graft.	History of radiation treatment to the area(s) to be treated in the study.
The subject is a nonsmoker or has stopped smoking at least 6 weeks before study enrollment.	Subjects taking chronic steroids (injected or oral) or other immune modulators
The subject must be willing and able to comply with all scheduled study visits and treatment plans.	Current use or planned use of any medication that could affect wound healing within 14 days, or five half-lives before study day 14.
	Subjects with skin conditions (eg, cutis laxa) that could result in poor healing or widened scars.
	History of anaphylactic reactions resulting from exposure to the anesthetic, suture materials, or dressing materials used in this study.

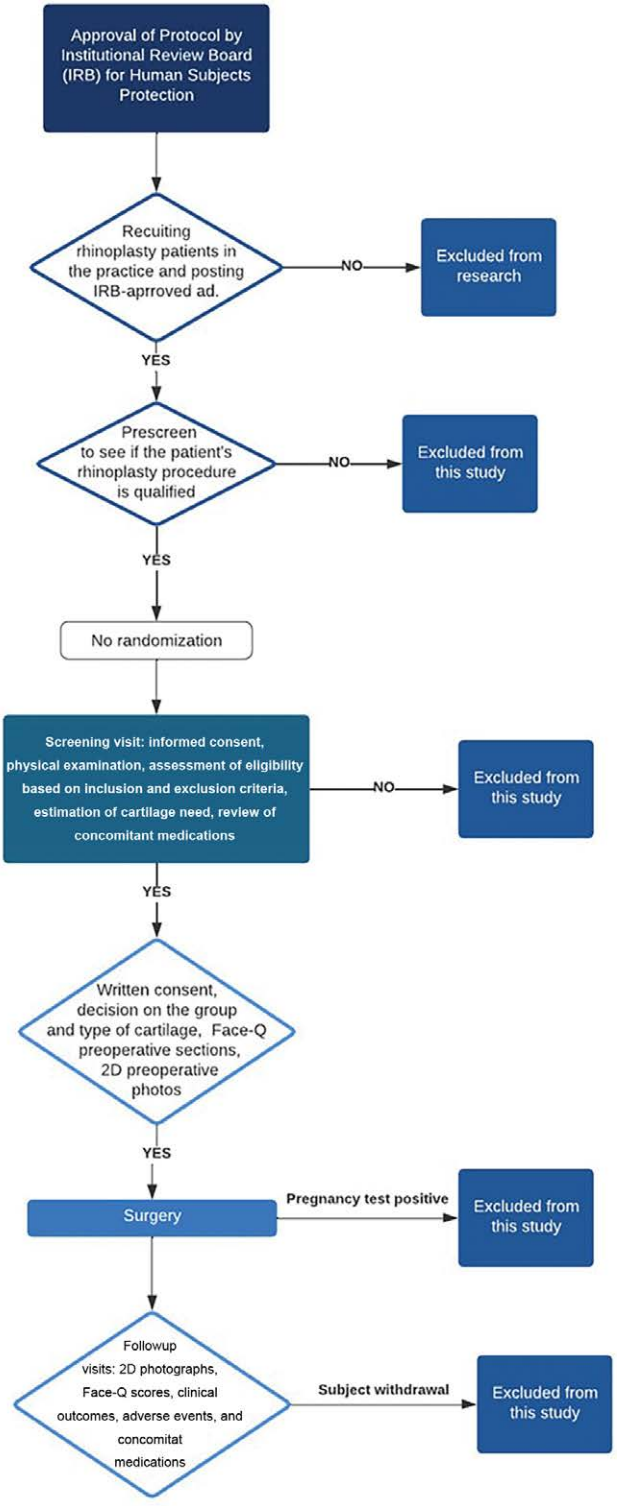

Fig. 1. Study flow chart.

cartilaginous portion of the rib. Deep fascia was incised over the rib, which was carefully palpated throughout the entire procedure. A Bovie cautery was used to incise through the periosteum, and then a series of elevators were used to dissect the perichondrium off the rib. This was done both on the anterior and posterior surfaces, being careful not to violate the pleura beyond the perichondrium. The rib segment was further divided and removed according to the length needed for the procedure. Valsalva maneuver was checked on all patients in the control group to make sure there was no air leak.

All procedures were performed at Northwestern Memorial Hospital by the senior author (R.D.G) with similar settings and staff. All subjects had Steri-Strips over the nasal skin with Mastisol and wore an external Denver splint postoperatively. Patients were instructed not to add pressure on the nose or engage in strenuous activity until one-week postoperative. Pain control (eg, acetaminophen, hydrocodone-acetaminophen) was accomplished if needed. The follow-up period lasted until November 2021, to achieve a minimum postoperative follow-up of 12 months.

Assessment of Clinical Outcomes

Objective assessment was measured by the nasal angles and the maintenance of the nasal shape on two-dimensional (2D) photographs. Standard 2D photographs of the patient's face were taken preoperatively, and at 1 month, 3 months, 6 months, and 12 months postoperatively using a FujiFilm X-T10 digital camera (Fujifilm Corporation, Tokyo, Japan) in the same photograph room. A minimum of four images were captured. Two images were captured from a front view. Two images were captured from a lateral view. We originally used three-dimensional magnetic resonance imaging analysis to evaluate the cartilage volume and shape, but the images were not able to show the cartilage allograft reliably. Therefore, we stopped three-dimensional magnetic resonance imaging evaluation halfway through the study. Observers involved in outcome assessments were blinded to study treatments.

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.

Statistical Analysis

Statistical analysis was accomplished using GraphPad Prism 9.0 (GraphPad Software Inc., Calif.). Continuous variables were summarized by the N, mean, median, SD, and range. Categorical variables were presented by percentage and counts. Comparison between the two grafts was performed by Student *t* test for continuous variables and Fisher exact test for categorical variables. Significance was set at a *P* value less than 0.05.

RESULTS

Sample Characteristics

A total of 50 eligible patients between March 2017 and October 2020 were included, with 25 in the CCA group

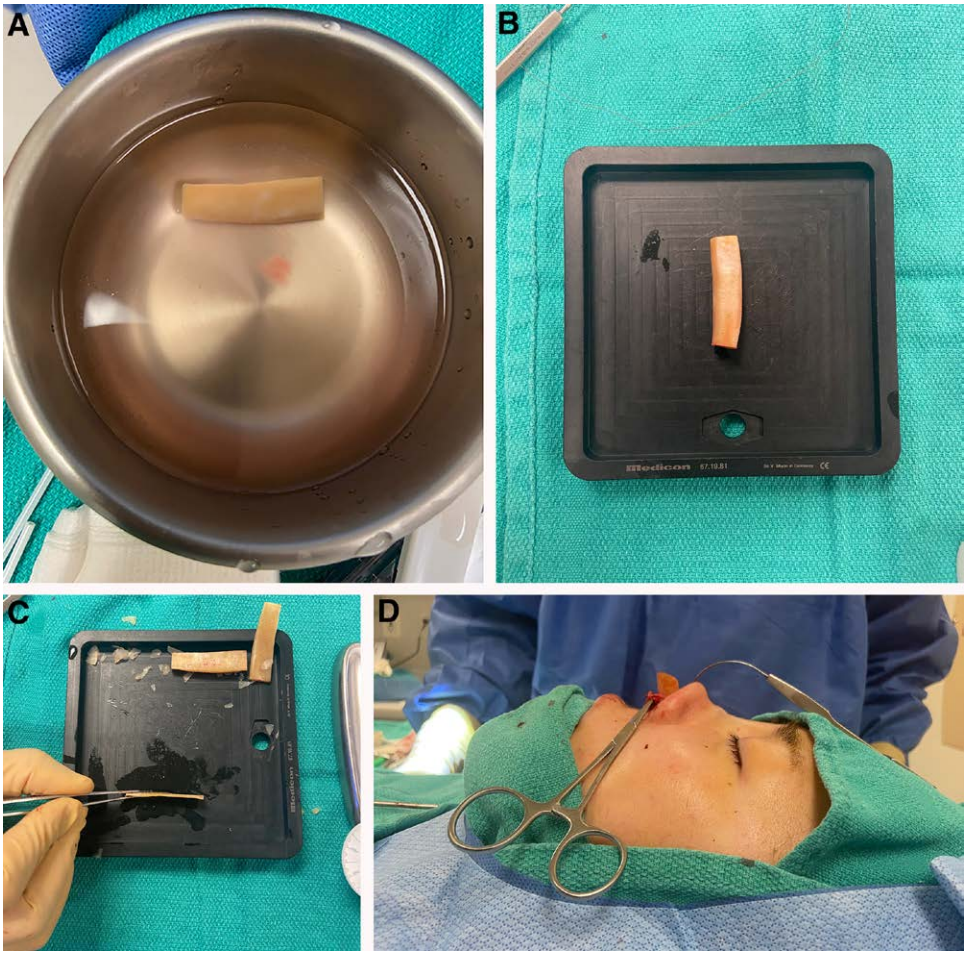

Fig. 2. A block of the study cartilage allograft was thawed in normal saline (A) and fashioned into the shape needed (B-D).

Table 2. Types of Grafts

Graft Type	No. (%)
Nasal tip graft	
CCA	14 (17)
Control	12 (17)
Spreader graft	
CCA	37 (45)
Control	26 (37)
Septal extension graft	
CCA	11 (13)
Control	9 (13)
Dorsal onlay graft	
CCA	8 (10)
Control	11 (15)
Alar graft	
CCA	4 (5)
Control	6 (8)
Columellar strut graft	
CCA	8 (10)
Control	7 (10)

CCA, costal cartilage allograft.

and 25 in the control group. Patient demographics are displayed in Table 3. The study population had an average age of 43.9 ± 16.6 years (range, 20–83), and female patients were the majority (76%). Twelve (25%) patients underwent reconstructive rhinoplasty, and nine (18%) patients had previously undergone rhinoplasty. The rest were primary cosmetic rhinoplasties (57%). The mean follow-up period was 14.8 months and a median of 12 months (range, 1–47 months).

Objective Assessment

Measurements on standard 2D photographs were performed, including the deviation angle, nasofrontal angle, total facial convexity, nasofacial angle, and nasolabial angle. To evaluate warping, resorption, and displacement of the cartilages, differences in measurement values obtained at 6-months and 12-months postoperative follow-up were subtracted ($\Delta = |\text{measurement}_6 - \text{measurement}_{12}|$). In the control group, the changes in the deviation angle, nasofrontal angle, total facial convexity, and nasolabial angle were greater than in the CCA group. The change of nasofacial angle at 12-months postoperative follow-up was greater in the CCA group. The differences in the deviation angle ($P = 0.02$) and nasolabial angle ($P = 0.02$) at 6 and 12 months were statistically significant, respectively (Fig. 3).

In Figure 4, we demonstrated pre- and postoperative photographs of one patient who underwent CCA

Table 3. Patient Characteristics

Variable	All (%)	CCA (%)	Control (%)
No. patients	50	25	25
Gender			
Female	38 (76)	20 (80)	18 (72)
Male	12 (24)	5 (20)	7 (28)
Average age at surgery (y)			
Mean	43.9	38.8	49
SD	16.6	17.7	9.0
Range	20–83	20–83	24–70
Surgical technique			
Asian rhinoplasty	9 (18)	6 (24)	3 (12)
Reconstruction after Mohs surgery	12 (25) 9 (18)	8 (32) 4 (16)	4 (16) 5 (20)
Revision			
Ethnic group			
White	39 (78)	18 (72)	21 (84)
Asian	9 (18)	6 (24)	3 (12)
Black	1 (2)	1 (4)	0 (0)
Indian	1 (2)	0 (0)	1 (4)
Follow-up time (mo)			
Mean	14.8	14.2	15.6
SD	9.0	9.8	8.1
Range	1–47	1–47	3–29.5

CCA, costal cartilage allograft.

rhinoplasty. The patient had satisfying aesthetic and functional outcomes at 10-months follow-up with stable structural support and non-noticeable warping, resorption, or graft displacement. More patient outcome photographs can be seen in Supplemental Digital Content 1. (**See figure, Supplemental Digital Content 1**, which shows a 41-year-old woman who desired a cosmetic Asian rhinoplasty to raise her dorsum and nasal tip significantly. **http://links.lww.com/PRSGO/C799**.)

Subjective Assessment

In the CCA group, the mean score of satisfaction with nose improved from 33.82 preoperatively to 65.73 at 6 months postoperatively ($P = 0.001$) and 48.25 at 12 months postoperatively ($P = 0.007$). The mean score of satisfaction with nostrils increased from 44.32 preoperatively to 70.55 at 6 months postoperatively ($P = 0.037$) and 62.0 at 12 months postoperatively ($P = 0.3$). The mean score of satisfaction with overall facial appearance changed from 39.41 preoperatively to 61.18 at 6 months postoperatively ($P = 0.010$) and 39.52 at 12 months postoperatively ($P = 0.98$).

In the control group, the mean score of satisfaction with nose improved from 49.25 preoperatively to 79.50 at 6 months postoperatively ($P = 0.202$) and 53.34 at 12 months postoperatively ($P = 0.083$). The mean score of satisfaction with nostrils increased from 49.25 preoperatively to 71.75 at 6 months postoperatively ($P = 0.346$) and 61.63 at 12 months postoperatively ($P = 0.639$). The mean score of satisfaction with facial appearance overall was 64.27 preoperatively, 82.0 at 6 months postoperatively ($P = 0.010$), and 58.67 at 12 months postoperatively ($P = 0.908$). None of the score differences between the CCA and control groups were statistically significant ($P > 0.05$).

Adverse Events

In the CCA group, one patient (4%) lost the support of her nasal tip and ala, resulting in the collapse of her external nasal valve. She underwent a revision rhinoplasty using autologous costal cartilage. Of note, this patient was of African American descent and experienced extremely significant and extensive scarring and fibrosis postoperatively; she was eventually referred to see a dermatologist for treatment of her severe scars. One patient (4%) complained that "her implant has fallen a little bit" at 6-months follow-up, and she had a computed tomography scan reporting the implant had dropped approximately 4 mm compared with after surgery. The patient had a slight revision to elevate her nasal tip and obtained a satisfying result. One patient (4%) reported that her nose was lower at 15-months follow-up, but she was still satisfied with the results and did not

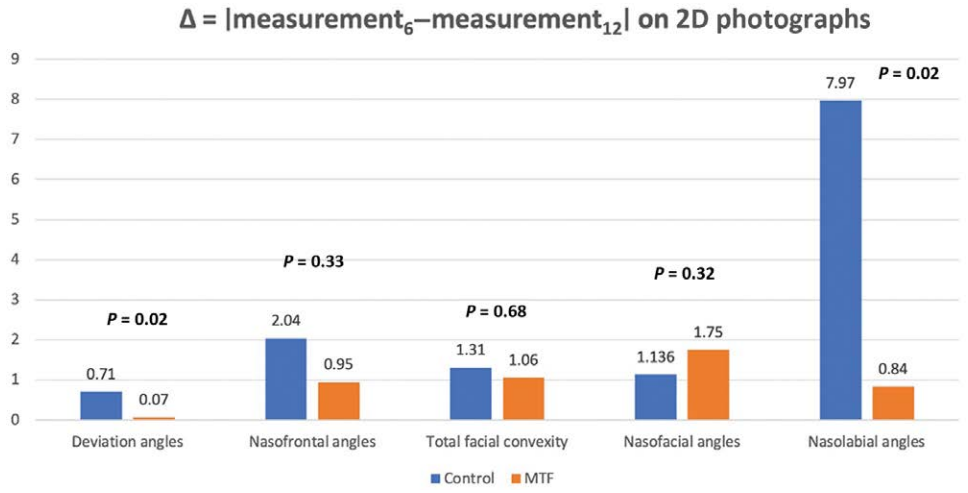

Fig. 3. The change of the measurements (Δ= |measurement$_6$–measurement$_{12}$|) of deviation angle, nasofrontal angle, total facial convexity, and nasolabial angle on standard 2D photographs at 6- and 12-months postoperative visits.

Fig. 4. A 66-year-old woman who had multiple prior rhinoplasties and desired an improvement in her nasal contour. The patient had difficulty breathing and placing her glasses on the very narrow nasal bridge. Preoperative examination revealed that she had a very narrow internal nasal valve, over-resected lower lateral cartilages, and a very mobile nasal tip with essentially zero support. She underwent an open revision rhinoplasty using crushed cadaveric cartilage cased into temporoparietal fascia as an onlay graft. The cadaveric cartilage allografts were also used for her nasal tip graft, spreader graft, septal extension graft, and columellar strut graft. The preoperative (A-C), 3-month postoperative (D-F), and 10-month postoperative (G-I) photos showed reasonable results.

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.

seek more treatment. Two patients (8%) had steroid injections for their scar tissues. One of them underwent a revision rhinoplasty to surgically remove scar tissues and had a new CCA implant to straighten out her dorsum. Of note, this patient was in the chronic phase of myeloid leukemia. One patient (4%) experienced persistent difficulty breathing for 6 months, and a computed tomography scan showed deviated septum and vestibular stenosis of the internal nasal valve. She later underwent a revision septorhinoplasty using autologous costal cartilage. No other complications were reported. In total, six patients (24%) were documented with postoperative complications.

In the control group, three patients (12%) experienced deformity of the nose at postoperative visits. Two patients (8%) had a leftward deviation of their dorsum at 3-months follow-up and underwent revision. One patient had trouble breathing for 3 months, revealing a postoperative deviated septum. Of note, this patient had severe septum deviation obstructing his airway before his primary septorhinoplasty. Two patients (8%) lost the projection of their nasal tip at 12 months of follow-up. Four patients (16%) had steroid injections for scarring, and among them, two were Asian, one was Indian, and one was White. One patient (4%) had a persistent infection, tenderness, and swelling for 6 months postoperatively and underwent intranasal drainage, graft removal, and clindamycin treatment. In total, 10 patients (40%) were documented with postoperative complications. These results are displayed in Table 4.

DISCUSSION

Rhinoplasty with cartilage grafts is a common and well-described practice in both cosmetic and reconstructive procedures. Currently, the gold standard for grafting is autologous cartilage,[15,16] because of its inherent biocompatibility and relatively low complication rates. Costal cartilage also provides the most duration strength and adequate amount with well-established suturing and carving techniques to minimize warping in the application of costal cartilage.[9,17–19] Yet, harvesting ribs requires general anesthesia, operating room settings, prolonged surgical time, and expensive surgical costs, and causes high risks of donor site morbidities, including pneumothorax, chest wall deformity, persistent pain, and hypertrophic scars.[8,17,20–22] In addition, the use of autologous cartilage is restricted by the age and health condition of the patients.[8] Irradiated homologous costal cartilages from healthy donors were introduced decades ago as an alternative option in rhinoplasty. Despite the advantages, these allografts were reported to have higher rates of resorption, infection, and non–donor site graft-related complications compared with autologous cartilages.[13,17] Studies showed that the graft integrity was compromised by gamma irradiation, which was used for sterilizing the allograft cartilage tissue and caused the loss of viable cells in the tissue.[5,13,23,24] Even though some scientists reduced the gamma irradiation from the traditional 30,000 to 50,000 Gy to 25,000 Gy, the complication rate was still high (31%).[8] For these reasons, autologous cartilage is currently more preferentially recommended and utilized than allograft cartilage tissue.

The "off-the-shelf" CCA in this clinical trial is a novel Food & Drug Administration–regulated costal allograft that is provided sterile; the unprocessed donor tissues are pretreated with a low dose of gamma radiation if recovery cultures warrant it. The unique advanced tissue processing used during processing is a disinfecting method that yields essentially sterile allografts while preserving the natural integrity and function of the tissue.[5,25,26] In addition, the fresh frozen allografts are procured and screened under strict acceptance criteria, with less than 2% of offered donors being accepted for further tissue processing. Hence, it is a safe option for use in patients who have questionable cartilage quality, while concurrently eliminating the need for the surgical harvest of autologous tissue. A review of existing literature showed that there are three publications on the experience of using fresh frozen cartilage in revision rhinoplasty, and the three articles are from the same team.[5,8,25] Their preliminary data highlighted the ease of obtainability, avoidance of donor-site morbidity, flexibility of the graft characteristics, and low complication rates, indicating that fresh frozen, nonterminally sterilized cartilage is an ideal source for revision rhinoplasty. Mohan et al. reported only one complication (infection, 2%) among a cohort of 50 CCA revision rhinoplasties over an average period of 3.35 months (range, 1–18 months).[5] Another article examined 186 segments of the fresh frozen costal cartilage in vitro and showed that the degree of warping was generally lower in a freezer setting than at room temperature.[26] The team further suggested that the Profile costal cartilage grafts that are older and appear more yellow in color should be used for more sturdy support and younger, more white grafts should be used for providing soft contour augmentation.[8] This feature, along with numerous available precut shapes and sizes, allows specifically customized planning and treatment for rhinoplasty patients. The most recent study by Dr. Rohrich and his team reported on long-term outcomes of 226 cases, up to 9 years (range, 6 months to 8 years), with no concern related to the longevity of the CCA implant[8] (2.7% warping, 2.7% infection, and 2.2% revision). Thus, significant resorption, warping, or graft displacement at 6-months and 12-months follow-up was not anticipated in our cohort. Of note, we have not found prospective studies on the use of CCA.

In our prospective clinical trial, we compared autologous costal cartilage versus CCA in reconstructive and cosmetic rhinoplasties and demonstrated satisfying and reliable

clinical outcomes up to 1-year evaluation. Most of our 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, even though the cost of shipment and storage of the fresh frozen cartilage was high (between −40° and −80°C), we noticed that the full price of the surgery was still lower than using the autologous costal cartilage. In addition to the reduction in surgical fees, the observed reduction in narcotic medications also represents a significant benefit. The objective assessment in our 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. Due to the heterogenicity of our patient population and procedure types, we did not compare the anthropometric nose measurements to those of an "ideal" nose, or between pre- and postresults. Instead, the change of angles and ratios of the nose on a profile view at different postoperative time points allow the focus on the "change" during the first 12 months after recovery, despite patients' diagnoses, ethnic groups, or surgical types. Patient satisfaction with nose and nostrils were significantly improved in the CCA group postoperatively. The rate of cartilage-related complications was also lower in the CCA group.

The limitations of the study include the loss to photograph follow-ups in 2020 because of the outbreak of COVID-19. We were able to contact the patients and conduct virtual follow-ups, but 2D photographs were not taken until our hospital re-opened for in-person visits. However, none of the patients reported noticing resorption, warping, or graft displacement during their virtual visits. In addition, the types of rhinoplasties included in our study were heterogeneous, which is a confounding factor. Even though the diversity of the surgical types may point to the universal applicability of fresh frozen CCA, controlling the surgical technique will strengthen the analytic evaluations.

CONCLUSIONS

Nonterminally sterilized fresh frozen CCA is a useful, safe, reliable, and economical source of cartilage graft in reconstructive and cosmetic rhinoplasty in comparison to autologous costal cartilage. It is aseptic, readily available, previously tailored, and free of donor site complications. Future prospective studies with larger sample sizes, longer follow-up time, or focusing on a certain type of rhinoplasty (eg, ethnic rhinoplasty, reconstructive rhinoplasty) can be helpful to further verify the utility of the CCA. Investigation directly into the economic benefits of using different sources of cartilage, reduction in narcotic pain medication use, overall postsurgical pain, and rigorous patient-reported outcomes would be worth exploring.

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DISCLOSURE

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