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ORIGINAL INVESTIGATION

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

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Abstract

Importance: Despite favorable results with conventionally irradiated homologous costal cartilage, there have been no clinical studies to date evaluating the utility of non- or minimally irradiated homologous costal cartilage (NIHCC) in rhinoplasty.

Objective: To evaluate the safety and efficacy of NIHCC in primary and revision rhinoplasty.

Design, Setting, and Participants: We conducted a retrospective medical record review of patients undergoing primary and revision rhinoplasty between January 2010 and December 2014. Twenty-six patients who underwent primary or revision rhinoplasty with NIHCC were identified. Patient follow-up ranged from 2 to 43.2 months (mean 15.9 months) at the study took place in a single-center private practice, and surgery was performed by the two senior authors. Twenty-seven consecutive patients who underwent primary or revision rhinoplasty for functional and/or cosmetic concerns with NIHCC were identified. One patient was excluded due to concomitant use of GORE-TEX, leaving 26 patients for retrospective review. Seven patients underwent primary rhinoplasty and 19 patients underwent revision rhinoplasty.

Main Outcomes and Measures: The purpose of this study is to demonstrate whether non- or minimally irradiated homologous rib cartilage used for primary and revision rhinoplasty has acceptable rates of warping, resorption, and infection.

Results: A total of 26 patients underwent surgery with NIHCC; 20 (77%) were women, and the average patient age was 42 years (median 45 years). A total of 100 NIHCC grafts were used. Seven patients underwent primary rhinoplasty and 19 (73%) patients underwent revision rhinoplasty. The total complication rate related to grafts was 3.6%, which included 2 cases of partial noninfective resorption of 77 palpable or superficial grafts (2.6%), 1 infection of 100 grafts (1.0%), and zero cases of graft mobility and warping.

Conclusion and Relevance: Non- or minimally irradiated homologous costal cartilage is safe and effective for grafting in primary and revision rhinoplasty, with low rates of resorption, infection, mobility, and warping. Further larger studies will need to be conducted to determine whether or not the reduced radiation improves outcomes compared with traditionally radiated homologous cartilage.

Introduction

Much debate surrounds the use of grafting materials in cosmetic and reconstructive rhinoplasty. Ideally, grafting material should be readily available, biocompatible, inexpensive, harvested with minimal donor site morbidity, and have a low complication rate.[1,2] Autologous grafts such as septum and conchal cartilage are generally accepted as the gold standard for grafting material in rhinoplasty due to the ease of harvest, and low risk of extrusion and infection. Their use, however, is sometimes limited by their availability and strength.[3] Autologous rib cartilage is the preferred choice when substantial grafting material is needed, particularly for dorsal augmentation in rhinoplasty. However, the use of autologous rib cartilage is

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KEY POINTS

Question: Is non- or minimally irradiated homologous costal cartilage (NIHCC) safe and effective in primary and revision rhinoplasty?

Findings: In this retrospective case study that included 26 patients, the total complication rate related to grafts used for primary and revision rhinoplasty was 3.6%.

Meaning: NIHCC is safe and effective for grafting in functional and cosmetic primary and secondary rhinoplasty. Further studies will need to be conducted to determine whether or not the reduced radiation further reduces warping and resorption compared with conventionally radiated homologous costal cartilage.

accompanied by donor site morbidity, and the increased operative time can be considerable.[4]

Irradiated homologous costal cartilage has been used as an alternative source of cartilage in rhinoplasty with conflicting results regarding resorption and warping. The rib is initially procured from prescreened donors, and exposed to 30,000–40,000 Gy of gamma irradiation to minimize infection risk.[5,6] It is then readily available, can be contoured easily, significantly reduces operative time by eliminating graft harvest, avoids donor-site morbidity, and has excellent tissue tolerability.

Clinical differences between nonirradiated and irradiated allografts have been studied extensively in the orthopedic literature, and suggest that gamma irradiation decreases allograft strength in a dose-dependent manner.[7–9] Conrad et al. demonstrated that irradiation degraded the mechanical properties of the allograft tendons.[9] By contrast, a study by Adams et al. comparing the in vitro characteristics of irradiated and nonirradiated homologous costal cartilage demonstrated that there was no significant difference in warping between the two groups.[5] There was a trend toward more warping in the irradiated cartilage, although this was not statistically significant. Studies evaluating chondrocytes from irradiated costal cartilage and autologous costal cartilage demonstrate chondrocytes that are smaller, less uniform, more unevenly distributed, and have fewer nucleated lacunae than those of autologous costal cartilage. Moreover, electron microscopy of irradiated costal cartilage demonstrates severe cell degeneration of the chondrocytes.[10] The evidence suggests that perhaps lower irradiation of allografts may be more favorable in a clinical setting.

Despite favorable results with conventionally irradiated homologous costal cartilage, there have been no clinical studies to date evaluating the utility of non- or minimally irradiated homologous costal cartilage (NIHCC). We hypothesize that NIHCC used in primary and secondary rhinoplasty will have more favorable results with regard to warping, resorption, and infection. The purpose of this study is to demonstrate whether NIHCC used for primary and revision rhinoplasty has acceptable rates of warping, resorption, and infection.

Methods

Patients

Twenty-seven consecutive patients who underwent primary or revision rhinoplasty for functional and/or cosmetic concerns with NIHCC were identified. One patient was excluded due to concomitant use of GORE-TEX (W. L. Gore, Flagstaff, AZ), leaving 26 patients for retrospective review. The patients in this study were seen in the senior authors' private practice from January 2010 through December 2014. Seven patients underwent primary rhinoplasty and 19 patients underwent revision rhinoplasty.

Grafts

All NIHCC grafts were obtained from Muscoloskeletal Transplant Foundation (MTF; Edison, NJ), where prior microbial testing was performed at the time of donor recovery to determine if the donor could be processed aseptically (without any gamma irradiation) or pretreated with a low dose (8–12 kGy) of gamma irradiation. None of the costal cartilage grafts were terminally sterilized with gamma irradiation (usually >25 kGy).

MTF has indicated the following process regarding the safety of the product. Microbial and serology testing is reviewed, and suitability is determined. Suitable costal cartilage is harvested and completes a proprietary purification process, consisting of 4–8.5 h soak in a mixture of phosphate buffer, gentamicin, amphotericin B, and Primaxin. The grafts then undergo two rinses of 5–20 min each. Representative samples are taken from the segments and sent out for sterility testing. If any samples come back positive for growth of any organisms, all of the segments are discarded. The processing record and sterility test results are reviewed by the quality assurance team, who then releases grafts for distribution.

At the time of surgery, the NIHCC is aseptically removed from its packaging and placed in three sequential sterile saline baths, each for 10 min with the last containing clindamycin for a total of at least 30 min of soaking before graft manipulation. The cartilage is left in the clindamycin saline solution during the remainder of the surgery unless it is being cut or until implantation. Grafting material is supplied as either a block of costal cartilage or two sheets of previously cut costal cartilage (Profile Costal Cartilage; MTF). The precut costal cartilage sheets are evaluated for calcification by MTF before being distributed. In general, this avoids grafts that are unusable. When requesting homologous rib cartilage, it was the practice of the two senior authors to request donors <30 years old to avoid calcification as much as possible. Despite this, it is inevitable that some grafts are softer or more

calcified than others. However, the authors were never limited enough that there was no usable cartilage.

The precut cartilage grafts are shaped with a fresh 15 blade scalpel. Alternatively, the block of costal cartilage is cut down into smaller usable sheets with a 10 blade, and then further refined with a 15 blade. The rib grafts are examined in all dimensions to determine the ideal orientation for carving to obtain straight grafts. For this study no other grafting material was used in conjunction with NIHCC, except the patient's native cartilage.

Surgical procedure

All primary and revision cases were completed through an open rhinoplasty approach by the two senior authors. For each patient, a transcolumellar inverted V-shaped incision was connected to bilateral marginal incisions. The osseocartilaginous skeleton was exposed, and septal mucoperichondrial flaps were elevated, beginning at the anterior septal angle. After vertical angle division, the medial crura were sutured together, and a columellar strut graft was placed between the medial crura.[11] An extended shield graft was placed.[12] Surgery included some or none of the following: medial and/or lateral osteotomies, septal extension grafts, spreader grafts, alar rim grafts, batten grafts, lateral crural strut grafts, or dorsal onlay grafts. A nasal splint was taped over the dorsum in all cases. All patients were instructed to use mupirocin 2% topical ointment intranasally for 1 week preoperatively and 1 week postoperatively. All patients received a combination of intravenous and oral antibiotics in the immediate perioperative period.

Clinical factors used to evaluate the degree of graft resorption included reviewing medical charts, surgical notes, and intraoperative diagrams. In addition, standard preoperative and postoperative photographs were taken of each patient using the same lighting, background, patient positioning, and photographic equipment. The grafts were evaluated for warping, infection, infective resorption, noninfective resorption, mobility, and extrusion. Postoperative photographs were taken as early as 6 weeks postoperatively. Photographs were then taken at each subsequent visit.

Owing to the difficulty in inspecting deeper nonpalpable grafts such as spreader and septal extension grafts, these nonpalpable grafts were excluded from the total number (100) of NIHCC grafts ($100 - 23 = 77$) for evaluation of warping, noninfective resorption, and mobility as described by Kridel.[2]

Results

A total of 26 patients underwent surgery with NIHCC; 20 (77%) were women, and the average patient age was 42 years (median 45 years). A total of 100 NIHCC grafts were used (Table 1). Seven patients underwent primary rhinoplasty and 19 (73%) patients underwent revision rhinoplasty. The decision to use homologous cartilage was required in all patients due to limited donor availability (Table 2). Every attempt was made to harvest any remaining septal cartilage; however, nine patients had no usable septal cartilage. In 16 patients a combination of remaining septal cartilage and NIHCC was used. One patient required use of septum, conchal cartilage, and NIHCC. Of the six patients who underwent primary rhinoplasty with NIHCC, four had undergone previous septoplasties, one had septal cartilage deficiency due to previous trauma, and one required significant dorsal augmentation that could not be achieved with septal cartilage alone (Table 1). Of the 19 revision rhinoplasties, 12 patients had undergone more than one previous rhinoplasty. The need for NIHCC in the revision group was often due to multiple factors in addition to lack of septal cartilage. All revision rhinoplasty patients had septal deficiency due to previous rhinoplasty, except for one patient who had a silicone implant extruding through the skin of the nasal tip that required significant grafting material for dorsal augmentation (Fig. 1). In addition to lacking enough septal cartilage, two patients had septal perforations due to previous surgery. Seven of the revision rhinoplasty patients required dorsal augmentation.

Patient follow-up ranged from 2 to 43.2 months (mean 15.9 months). The total complication rate related to NIHCC grafts was 3.6%, which included 2 cases of partial noninfective resorption of 77 palpable or superficial NIHCC grafts (2.6%), 1 infection of 100 NIHCC grafts (1.0%), and zero cases of graft mobility. The two patients who had partial resorption of the NIHCC used as a tip graft, required minor revision surgery. The one infection occurred in a patient who had a previously

Table 1. Types of NIHCC grafts used

Breakdown of type of graft using NIHCC	n
Columellar strut	19
Extended shield	12
Spreader	19
Batten	9
Alar rim	23
Septal extension	4
Dorsal augmentation	8
Lateral crural strut	6
Total	**100**

NIHCC, non- or minimally irradiated homologous costal cartilage.

Table 2. Patient characteristics (26 patients)

Indications for NIHCC	n
Primary rhinoplasty	
Previous septoplasty	4
Dorsal augmentation	1
Trauma	1
Revision rhinoplasty	
Previous septoplasty	17
Dorsal augmentation	7
Septal perforation	2

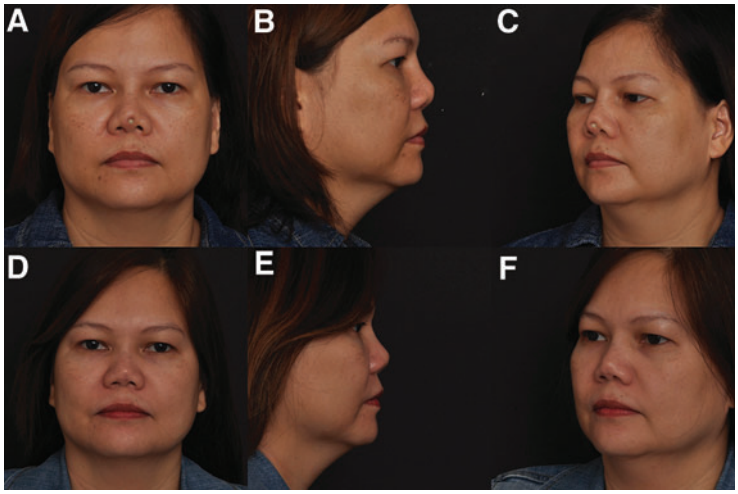

Fig. 1. Use of NIHCC for dorsal augmentation, a septal extension graft, a columellar strut, and a crushed cartilage graft to the tip. **(A)** Preoperative frontal view, demonstrating a previously placed silicone implant extruding through the skin of the nasal tip. **(B)** Preoperative profile view. **(C)** Preoperative oblique view. **(D)** Six-month postoperative frontal view. **(E)** Six-month postoperative profile view. **(F)** Six-month postoperative oblique view. NIHCC, non- or minimally irradiated homologous costal cartilage.

infected silicone implant (Fig. 1). At the time of surgery, the silicone implant was removed, and immediate reconstruction with NIHCC was completed. After this surgery, the patient had a minor infection of the right vestibule, which resolved uneventfully with oral antibiotics. There were no other complications attributed to the homologous rib cartilage. Sixteen patients were healing well without complications or complaints at last follow-up (Fig. 2). Seven patients were healing well without complications, but had minor complaints. One patient complained of minor tip asymmetry, and was offered surgery, but declined. One patient complained of left cheek pain after surgery; however, workup for an infection or other abnormality was negative. Of note, the patient had several comorbidities, including fibromyalgia, ulcerative colitis, and anxiety, which may have contributed to these symptoms. One patient complained of fullness and ptosis of the tip, but noted improved breathing. This patient was subsequently lost to follow-up. One patient complained of asymmetry, but was lost to follow-up. One patient had a satisfactory cosmetic outcome but wanted more narrowing of the tip. One patient's chart was incomplete, but had no documented complications at last follow-up.

Discussion

Historically, preservation of cartilage homografts involved refrigeration in merthiosaline or 70% alcohol.[13] Both techniques were effective, however, not practical due to the time burden required to obtain negative cultures for spore forming organisms. In 1956, Grabb reported the use of irradiation to sterilize canine costal

Fig. 2. Use of NIHCC for functional and cosmetic concerns in a patient who had undergone prior septoplasty. NIHCC was used to construct a left spreader graft, bilateral alar rim grafts, a columellar strut graft, and a portion of an extended shield graft. The remainder of the extended shield graft was constructed using septum. **(A)** Preoperative frontal view. **(B)** Preoperative profile view. **(C)** Preoperative oblique view. **(D)** Eight-month postoperative frontal view. **(E)** Eight-month postoperative profile view. **(F)** Eight-month postoperative oblique view.

cartilage. Later in 1961, Dingman and Grabb studied the clinical effects of irradiated cartilage homografts in humans.[13]

Today, the US Food and Drug Administration (FDA) regulates biologic materials such as homologous costal cartilage. As clinical devices, they must be properly processed and sterilized before clinical use. Sterilization of biologic materials involves unique considerations to avoid loss of structure and functionality during the sterility process. Gamma sterilization is conducted by placing the target device in front of a radiation source (^{60}Co). Although gamma irradiation is compatible with many materials and produces minimal amount of toxic residues, it may adversely affect proteins in a dose-dependent manner by the introduction of free radicals. It has been associated with a reduction in strength of grafts and collagenous biomaterials. Lower doses of gamma irradiation effectively sterilize biologic materials with minimal adverse effects to the physical properties of the materials.[14]

Dingman and Grabb reported favorable results with irradiated homologous costal cartilage in a large patient series.[13] However, its use fell out of favor in the 1980s due to reportedly high rates of resorption.[5,15,16] Kridel and Konior reported a successful long-term experience using irradiated homologous costal cartilage for nasal reconstruction.[2,17] They emphasized that previously reported high resorption rates seemed to be limited to generalized facial reconstruction, whereas results from nasal reconstruction were more promising.

Our retrospective study was designed to review the safety and efficacy of NIHCC in primary and revision rhinoplasty. Within our cohort, NIHCC proved to be a safe and effective graft in primary and revision rhinoplasty. The total complication rate related to NIHCC grafts was 3.6%, and consistent with previously reported studies using higher dose irradiated homologous cartilage.[1,2] By comparison, the published rates of resorption and infection for *autologous* septal and auricular cartilage grafts used in the nose are <2%.[4]

Our experience for a 5-year period in 26 cases demonstrates that NIHCC is safe and effective (Fig. 3). Similar to irradiated homologous costal cartilage, NIHCC eliminates the need for donor-site morbidity of costal cartilage harvest, and reduces operative time. Although we hypothesized that NIHCC would lead to lower rates of resorption and infection, our complication rates were similar to previously reported studies with irradiated cartilage. There is potentially an advantage of using NIHCC over irradiated cartilage; however, this study could not support that hypothesis. It does, however, demonstrate the safety and efficacy of NIHCC, and will hopefully lead to more robust data in the future.

There are several limitations to this study. First, this study has a relatively small sample size and short follow-up. Despite the small sample size, many grafts were used in each patient, allowing for a larger number of grafts to be evaluated. Further studies in a larger number of patients with longer follow-up periods could highlight more clinically significant results. Second, due to the retrospective nature of the study, the methods of monitoring warping were not objective. Further studies utilizing intraoperative and serial postoperative measurements of graft volume would improve the scientific validity of the study. Third, patient satisfaction and nasal function were not reported in a standardized manner in this study. Additional studies utilizing patient-reported outcome measures would further validate these studies.

Fig. 3. Use of NIHCC in revision rhinoplasty addressing functional and cosmetic concerns. NIHCC was used to construct a left spreader graft, bilateral batten grafts, and a columellar strut graft. Septum was used to construct an extended shield graft and right alar rim graft. **(A)** Preoperative frontal view, demonstrating a crooked nose. **(B)** Preoperative oblique view. **(C)** Preoperative profile view, demonstrating poor tip support. **(D)** Six-month postoperative frontal view with improvement in symmetry. **(E)** Six-month postoperative oblique view. **(F)** Six-month postoperative profile view with improved tip support.

Conclusion

NIHCC is safe and effective for grafting in functional and cosmetic primary and secondary rhinoplasty. Further studies will need to be conducted to determine whether or not the reduced radiation reduces complications typically seen with these grafts.

Author Disclosure Statement

No competing financial interests exist.

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