

Effect of Y-shaped Nasal Columella Made of Autologous Cartilage in Secondary Nasal Deformity after Cleft Lip Surgery

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Xuwen Li¹, Xiuyu Ge¹, Zhijian Liu¹, Yifan Wang¹, Jing Xu¹, Peijun Song¹

¹Department of Plastic Surgery, The First Affiliated Hospital of Bengbu Medical University, 233004 Bengbu, Anhui, China

AIM: Due to the diversity and complexity of tissues involved in secondary nasal deformities following unilateral cleft lip, secondary nasal deformity correction surgeries are challenging and often yield unsatisfactory results, posing a difficult problem for plastic surgeons. Autologous cartilage, with its low sculpting difficulty, minimal absorption, and stable tissue compatibility, is considered the optimal material for reconstructing the columella, nasal tip, and alar. This study analyzed the clinical outcomes of using autologous cartilage to create a Y-shaped columella to correct secondary nasal deformities after cleft lip surgery.

METHODS: In this retrospective study, 75 patients with secondary nasal deformity after unilateral cleft lip surgery were treated from January 2018 to December 2023. Appropriate costal cartilage, auricular cartilage, and iliac crest cartilage were fashioned into Y-shaped stents and implanted into the nasal columella of the patients to strengthen the tip cartilage. The free alar cartilage was sutured and fixed with a Y-shaped bracket. The wound healing rate, subjective satisfaction evaluation, and complications were analyzed. The nasal appearance, nasal deformity classification, and objective indices of healthy and affected nasal sides, function, and quality of life were compared before and after the operation.

RESULTS: All patients healed well during the first stage without related complications, and the average incision healing time was 5.16 ± 1.37 days. The scores of nasal tip position, nasal tip shape, nostril shape, nasal dorsum shape, and nasal floor shape at 6 months post-operation were significantly lower compared to pre-operation ($p < 0.001$). The grade of nasal deformity at 6 months post-operation was lower than the pre-operation ($p < 0.001$). Pre-operation, the nasal base and nasal width of the affected side were higher than those of the healthy side, while the nasal columellar and nostril height were lower ($p < 0.001$). At 6 months post-operation, the nasal base and nasal width decreased, and the nasal columellar and nostril height increased ($p < 0.001$), with no significant difference between the two sides ($p > 0.05$). The nasal obstruction symptom evaluation (NOSE) and Functional Rhinoplasty Outcome Inventory-17 (FROI-17) scores at 6 months post-operation were significantly lower than pre-operation, while the rhinoplasty outcome evaluation (ROE) score was higher ($p < 0.001$). The total patient satisfaction was 97.33% (73/75).

CONCLUSIONS: Y-shaped nasal columella made of autologous cartilage can effectively correct secondary nasal deformity after cleft lip surgery, improve nasal alar collapse, lengthen nasal columella, elevate nasal end, enhance the quality of life, nasal appearance, and nasal ventilation function of patients, with high satisfaction and few complications.

Keywords: cleft lip surgery; secondary nasal deformity; autologous cartilage; Y-shaped nasal columella

Introduction

Congenital cleft lip is often complicated with varying degrees of nasal deformities, primarily characterized by a transverse nostril on the cleft side, nasal septum deviation, nasal columella shortening, nasal alar collapse, nostril flattening, and nasal tip deviation towards the non-cleft side [1]. Epidemiological studies indicated that the incidence of secondary nasal deformities following unilateral cleft lip surgery accounted for 84% of all lip and nose deformities [2, 3]. Currently, the conventional treatment approach in-

volves a one-stage surgery to correct the lip deformity and repair the cleft lip, followed by a two-stage nasal deformity correction procedure after adulthood [4]. However, secondary nasal deformities after unilateral cleft lip surgery involve diverse and complex tissues, and the correction of secondary nasal deformities is often difficult and unsatisfactory, which has become a tricky problem for plastic surgeons.

According to the anatomical characteristics of secondary nasal deformity after cleft lip surgery, the key point of the treatment is to strengthen the support of nasal tip cartilage and the inferior lateral nasal cartilage in the affected side, and promote the symmetry of the morphology of the nostrils and the nasal alar in both sides [5, 6]. For patients with mild secondary nasal deformities, clinical treatments focus on tissue displacement to reduce the appearance of the nasal deformity. Techniques such as embedding guide needles

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Correspondence to: Peijun Song, Department of Plastic Surgery, The First Affiliated Hospital of Bengbu Medical University, 233004 Bengbu, Anhui, China (e-mail: peijunsong22@163.com).

and suspension methods can elevate the affected nasal alar, aligning both nasal wings horizontally [7]. For moderate to severe nasal deformities, allogeneic tissue materials or autologous cartilage, such as concha cartilage, nasal septum cartilage, and costal cartilage, are used to create scaffolds that strengthen the support of the nasal tip cartilage [8]. Among these, autologous cartilage is preferred due to its low sculpting difficulty, minimal absorption, and stable histocompatibility, making it the best material for reconstructing the nasal columella, tip, and wing.

Despite the variety of nasal deformity correction using autologous cartilage transplantation, therapeutic effects on nasal appearance, function, and quality of life vary among patients, and there is no unified clinical standard. This study retrospectively analyzed the medical records of 75 patients with secondary nasal deformities after unilateral cleft lip surgery from January 2018 to December 2023. The aim was to confirm the clinical effect and technical operation points of creating a Y-shaped nasal columella using autologous cartilage to correct these deformities, providing a reference for clinical surgical method selection.

In this study, 75 patients were treated with costal cartilage, auricular cartilage, and iliac crest cartilage as supporting structures to reconstruct nasal cartilage scaffolds. These patients underwent nasal malformation reconstructive surgery, which improved their nasal appearance, function, and overall quality of life.

Materials and Methods

Clinical Characteristics

A total of 75 patients with secondary nasal deformity following unilateral cleft lip surgery at The First Affiliated Hospital of Bengbu Medical University from January 2018 to December 2023 were selected retrospectively. This study was approved by the medical ethics committee of the First Affiliated Hospital of Bengbu Medical University (approval number: 2020038), and informed consent was obtained from all patients or their guardians. In addition, all patients or their guardians agreed to have their photos or data used for scientific research. This study complied with the ethical guidelines of the Declaration of Helsinki.

Screening Criteria

Inclusion criteria: There were nasal deformities with unilateral cleft lip in all cases, including nasal septum deviation, nasal columella shortening, nasal alar collapse, nostril flattening, lateral foot of nasal alar lateral shift, nasal base depression and nasal alar collapse on the affected side. These conditions were often accompanied by irregular red and white lips, lip scars, and other deformities. All patients voluntarily signed informed consent forms. **Exclusion criteria:** (1) Anticoagulant medication was administered 1 week before surgery. (2) Acne and folliculitis were found in the nose and adjacent parts. (3) Vital organs, such as the heart, liver and kidney may fail. (4) Patients who do not meet

the indications for surgery, have other congenital malformations affecting facial development, or those with respiratory tract infection or systemic diseases, such as lupus erythematosus, diabetes mellitus. (5) Pregnant and lactating women, patients with a history of rhinoplasty or other facial surgeries, and patients with nasal deformities unrelated to unilateral cleft lip surgery were excluded. (6) Congenital heart disease and craniofacial malformation, presence of nasal polyps and sinusitis, and post-operative follow-up were considered exclusion criteria.

Cartilage Extraction

The degree and characteristics of the deformities in each nasal subunit were carefully analyzed, and thorough communication with the patient was conducted to select the appropriate autologous cartilage graft material and surgical method. Autologous costal cartilage was used for patients with severe nasal deformities, while autologous auricular cartilage was chosen for patients with mild nasal deformities and a low, flat nasal dorsum with thicker skin. The classification of cleft lip nasal deformities is shown in Table 1 [9, 10, 11].

(1) **Auricular cartilage:** For patients ($n = 32$), methylene blue was used to mark the target area on the back of the cavum conchae ($2.5 \text{ cm} \times 1.2 \text{ cm}$), with a (3 cm) longitudinal incision line in the middle. Local anesthesia was administered with 1% lidocaine containing 1:200,000 epinephrine. The skin and subcutaneous tissue were incised layer by layer to the marked area. The cartilage was cut at the posterior edge of the auricle, the subcutaneous tissue in front of the cartilage was separated, and the concha cartilage within the marked range was fully dissociated. The labeled cartilage was cut, hemostasis achieved, and the wound sutured and pressure bandaged.

(2) **Costal cartilage:** For patients ($n = 25$), general anesthesia was administered along with local anesthesia using 1% lidocaine containing 1:200,000 epinephrine. An incision was made to access the right 7th costal cartilage, and the periosteum was separated. The costal cartilage was then cut to a length of 5–6 cm. In the absence of pneumothorax or bleeding, the wound was sutured.

(3) **Iliac crest cartilage:** General anesthesia was administered for patients ($n = 18$). An incision of approximately 3 cm was made about 2 cm above the anterior superior iliac spine along the direction of skin creases. The skin, subcutaneous tissue, and muscle were dissected layer by layer to expose the anterior superior iliac spine. A bone chisel was used to open the anterior superior iliac spine, and a piece of iliac crest cartilage was harvested approximately 3 cm wide, 2 cm long, and around 4 mm thick, ensuring that the corners were not too sharp.

Cartilage Shaping

The cartilage was shaped according to its natural curvature. It was cut along the long axis in the middle of the concave

Table 1. Grading of unilateral cleft lip nasal deformities.

Grade	Nasal tip	Nasal alar	Columella	Nasal septum and airway function	Nasal base	Other
Mild	Essentially normal shape	Slight collapse	Slightly short or deviated	Not deviated or slightly deviated, no significant airway obstruction on the affected side	Not significantly collapsed	None
Severe	Low, more noticeable deviation	Noticeable asymmetry or even horizontal positioning of nostrils	Short and small, significantly shifted towards the healthy side	Noticeable deviation, significant airway obstruction on the affected side	Significant collapse	Accompanied by symptoms such as alveolar ridge cleft, oro-nasal fistula, etc.

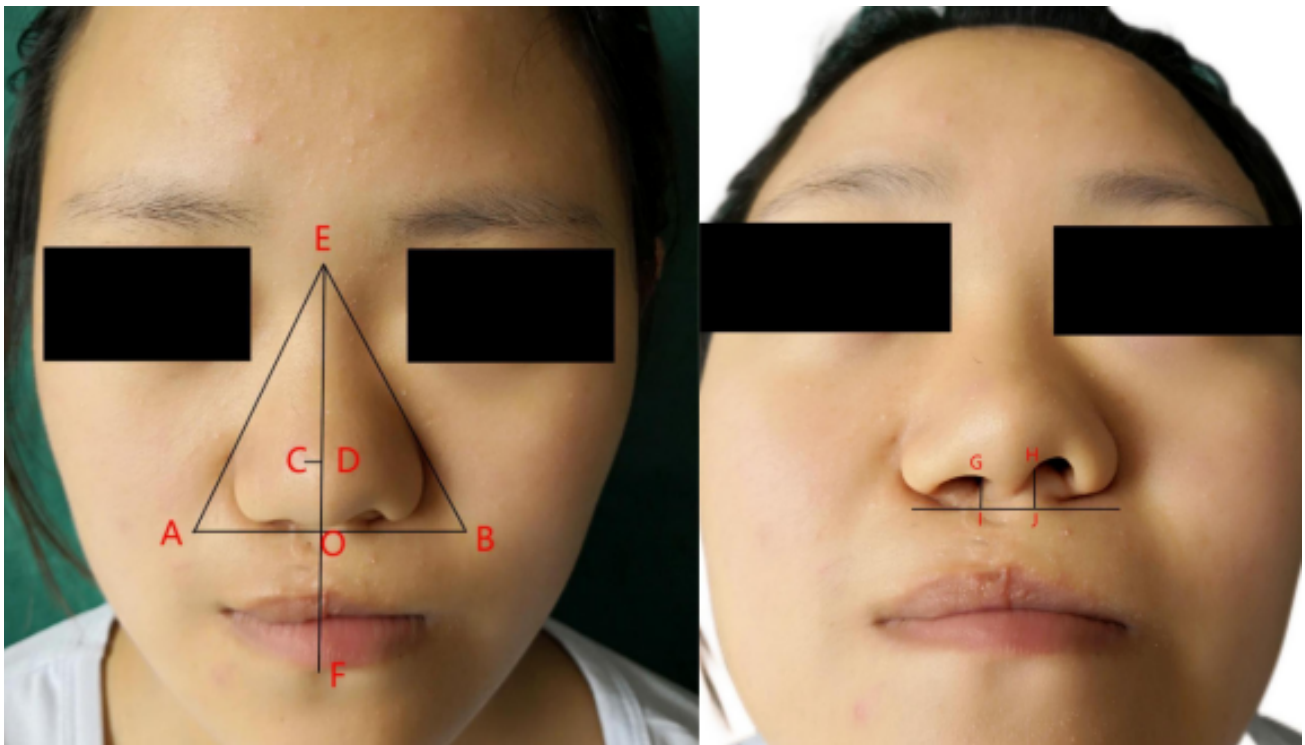


Fig. 1. Evaluation of the degree of nasal deformity secondary to cleft lip.

surface, retaining the periosteum on the contralateral side. This cartilage was then folded and fixed. The upper third or quarter of the cartilage was completely cut to create a Y-shaped scaffold, which was preserved in normal saline with wet gauze.

Surgery for Revision

Methylene blue was used to mark the nasal alar margin and nasal columella falciform incision. The skin and subcutaneous tissue were incised in layers, and the cartilage on both sides of the alar was quickly separated from the skin until fully exposed. The anterior nasal spine, nasal columella, and the lateral and medial feet of the affected side were separated, with the medial feet of the alar being cut off horizontally. The Y-shaped stent was transplanted into the nasal columella to strengthen the support of the nasal tip carti-

lage. The bilateral alar cartilage was widely separated and sutured with the upper part of the Y-shaped stent. Homeostasis was achieved, and the incision was sutured.

Detection Indices

Primary indicators: (1) Wound healing time and complications: The healing time of the wound and any complications were recorded. (2) Nasal appearance assessment: Two plastic surgeons who were not involved in the surgeries evaluated the nasal shape of patients before and 6 months after the operation. The assessment included the position of the nose tip, the shape of the nose tip, the shape of the nostrils, the shape of the nasal dorsum, and the shape of the nasal floor. Each aspect was scored from 0 to 3, with lower scores indicating less deformity. (3) Classification of nasal deformity: In the frontal view, point F was the midpoint of



Fig. 2. Schematic diagram of measurement. Sn: subnasal point; A1 and A1' points are the nasal alar points on the affected and healthy sides, respectively; Ac and Ac' points are the curved points of the nasal alar on the infected side and the healthy side, respectively; Ch and Ch' are the highest points of the nostril on the affected side and healthy side, respectively; Cm is the nasal columella point.

the lower lip, and point E was the glabella point. Triangle $\triangle EAB$ was constructed using E as the vertex, the baseline of the nostril as the bottom edge, and the outermost point of the alar on both sides as the tangent line. Point O was the intersection of the AB and EF lines, point C was the tip of the nose, and point D was the intersection between the horizontal line through the C and EF segments. In the elevation view (Fig. 1), points G and H were the highest points on the medial edge of the nostril. Points I and J were the intersections of the AB line segment with vertical lines drawn downward through G and H. Classifications were as follows: Class I: AO-BO, GI-HJ, and CD all ≤ 1 mm, Class II: AO-BO, GI-HJ > 1 mm but ≤ 2 mm, and CD ≤ 1 mm, Class III: AO-BO, GI-HJ > 2 mm, and CD > 1 mm.

Secondary indicators: (1) Measurements of healthy and affected sides of the nose (Fig. 2): Nasal base (Sn-A1), nasal width (vertical distance between Ac and Sn-Cm), nasal columella (Sn-Cm), and nostril height (Sn-Ch) were measured before surgery and 6 months after surgery. (2) Function and quality of life: Nose Symptom Assessment Scale (NSAS) contains 10 items scored from 0–4, indicat-

ing asymptomatic to severe symptoms. The total score was converted to a 100-point scale, with lower scores indicating less nasal congestion. The Rhinoplasty Effect Assessment scale contains 6 items, with 5 related to the aesthetic appearance of the nose, each scored from 0 to 4. The total score was converted to a 100-point scale, with higher scores indicating better-shaping effects. Functional Rhinoplasty Outcome Inventory-17 (FROI-17) has 17 items assessing recent general mental state, nasal congestion symptoms, nasal function, and nasal aesthetics. Each item was scored from 0 to 5, with the total score converted to a 100-point scale. The lower the score, the better the quality of life. The evaluation time of the three scales was before operation and 6 months after operation. (3) Patient satisfaction: At 6 months after surgery, the nasal collapse was obviously improved, the nasal column was significantly lengthened, and the two sides of the nose were in complete alignment as very satisfied; the nasal collapse and the length of the nasal column were improved, and the two sides of the nose were basically in symmetry as basically satisfied; the nasal column was not significantly lengthened, the nasal collapse was improved, and the symmetry of the two sides of the nose was poor as generally satisfied; the nasal collapse was not relieved, the nasal column was not lengthened, and the two sides of the nose were not in alignment as not satisfied. Total satisfaction was calculated as the sum of very satisfied, basically satisfied, and generally satisfied responses: very satisfaction + basic satisfaction + general satisfaction = total satisfaction.

Statistical Analysis

All statistical analyses were performed using SPSS version 24.0 (Released 2016, IBM Corp., Armonk, NY, USA). Measurement data were represented as mean \pm standard deviation ($\bar{x} \pm s$). The normality of the data was assessed using the Shapiro-Wilk test and Quantile to Quantile plots. If the data were normally distributed, they were represented as mean \pm standard deviation. Intra-group comparisons were conducted using paired sample *t*-tests. Count data were expressed as percentages (%) and analyzed using the χ^2 test. A *p*-value < 0.05 was considered statistically significant.

Results

General Information

The study included 75 patients, with 38 males and 37 females. The average age was 20.12 ± 3.74 years, ranging from 7 to 36 years. The mean time since the last cleft lip repair was 15.75 ± 2.97 years. There were 47 cases of left cleft lip and 28 cases of right cleft lip. The breakdown of cleft lip severity included 39 cases of simple second-degree cleft lip, 28 cases of simple third-degree cleft lip, 5 cases of second-degree cleft lip combined with third-degree cleft palate, and 3 cases of third-degree cleft lip combined with third-degree cleft palate.

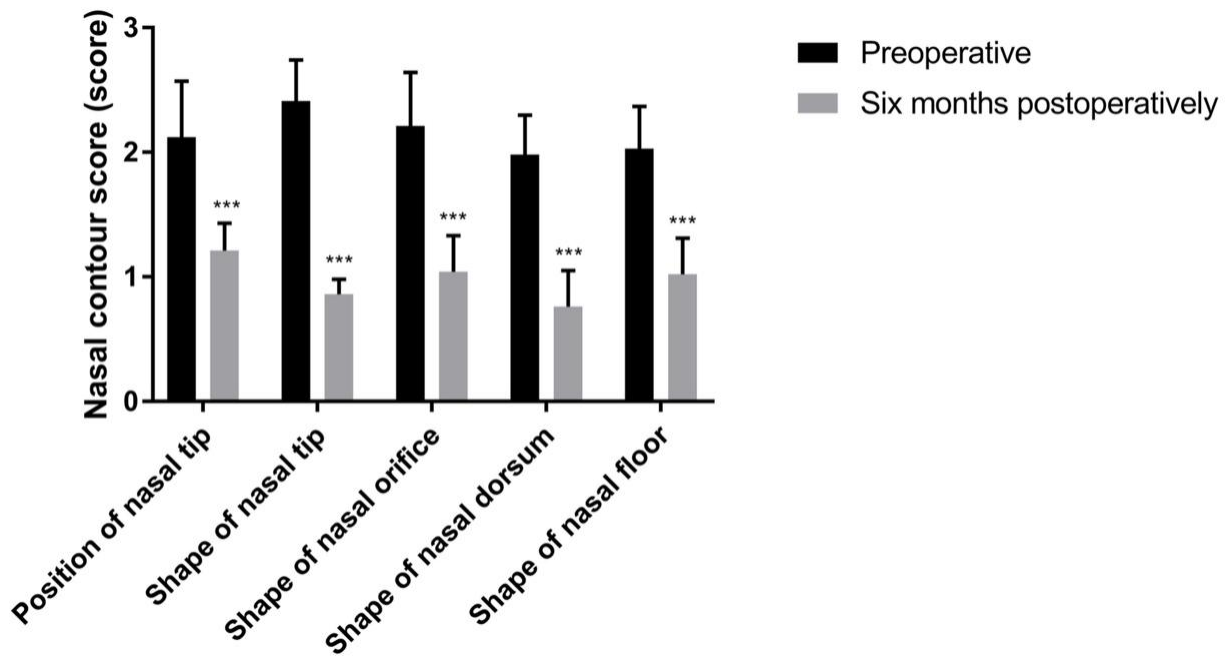


Fig. 3. Comparison of appearance scores of 75 patients before and 6 months post-operation. Compared with preoperative, *** $p < 0.001$.

Table 2. Comparison of nasal deformity grades in 75 patients before and 6 months post-surgery.

Time	N	Class I	Class II	Class III
		n (%)	n (%)	n (%)
Before surgery	75	0 (0.00)	15 (20.00)	60 (80.00)
6 months post-surgery	75	11 (14.67)	58 (77.33)	6 (8.00)
χ^2		80.51		
p		<0.001		

Healing Condition

All 75 patients completed the surgery. The mean incision healing time was 5.16 ± 1.37 days. All incisions healed well at phase I, with no complications such as hematoma or infection in the donor cartilage area.

Nasal Contour Assessment

The scores for nasal tip position, nasal tip shape, nostril shape, nasal dorsum shape, and nasal floor shape were significantly lower at 6 months post-surgery compared to pre-surgery ($p < 0.001$) (Fig. 3).

Classification of Nasal Deformity

As shown in Table 2, the grade of nasal deformity in the 75 patients was predominantly class III before surgery and shifted to class I and II at 6 months post-surgery. The grade of nasal deformity significantly decreased at 6 months post-surgery compared to pre-surgery ($p < 0.001$).

Objective Indices of Healthy and Affected Side Nose

As shown in Fig. 4, the nasal base and nasal width of the affected side were significantly greater than those of the

healthy side before surgery, while the nasal columella and nostril height were significantly lower ($p < 0.001$). At 6 months post-surgery, the nasal base and nasal width decreased, and the columella and nostril height increased ($p < 0.001$). There were no significant differences in nasal base, nasal width, nasal columella, and nostril height between the affected and healthy sides ($p > 0.05$).

Function and Quality of Life

As shown in Fig. 5, the nasal obstruction symptom evaluation (NOSE) and FROI-17 scores were significantly lower at 6 months post-operation compared to pre-operation, and the rhinoplasty outcome evaluation (ROE) score was higher than that before operation ($p < 0.001$).

Patient Satisfaction

At 6 months post-operation, 24 patients were very satisfied, 31 were basically satisfied, 18 were generally satisfied, and 2 were unsatisfied. The total satisfaction rate was 97.33% (73/75).

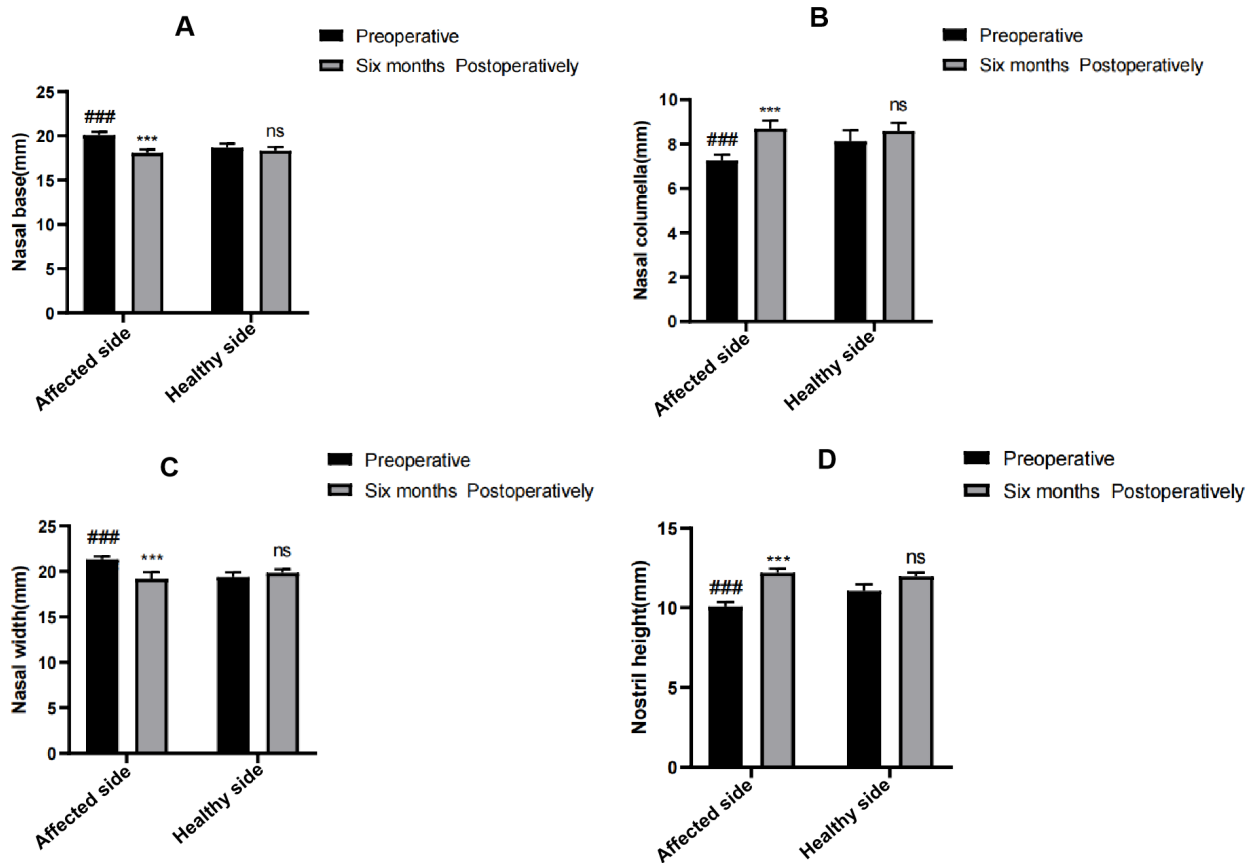


Fig. 4. Comparison of objective nasal indices before and 6 months after operation between the healthy and affected sides of 75 patients. (A) Nasal base, (B) Nasal columella, (C) Nasal width, and (D) Nostril height. Compared with preoperative, $***p < 0.001$; Compared with the healthy side, $###p < 0.001$. Compared with affected side postoperatively, ns, $p > 0.05$.

Discussion

Patients with secondary nasal deformities after cleft lip surgery often present with complex clinical symptoms due to tissue displacement and dysplasia in bone, cartilage, skin, and soft tissue. This complexity increases the difficulty of repair to some extent [8, 12]. The pathogenesis of these deformities is multifactorial, typically involving the combined effects of nasal base fracture, maxillary, and jawbone hypoplasia, lateral foot displacement of alar cartilage, and teratogenicity induced by orbicularis oris muscle dislocation [13]. Despite advancements in clinical research on the mechanisms underlying secondary nasal deformities, the results in terms of nasal function and anatomy remain unsatisfactory.

In our study, we observed that the degree of piriform fossa depression on the affected side increased with the severity of the nasal deformity. Additionally, cartilage development on the affected side was weaker compared to the healthy side. The results demonstrated that the nasal base and nasal width of the affected side were higher, while the nasal columella and nostril height were lower than those of the healthy side, highlighting the anatomical and histological abnormalities associated with secondary unilateral cleft lip nasal deformities.

At present, there are some controversies about the time of second stage correction of secondary cleft lip nasal deformity. Some physicians believe that the development of nasal septum cartilage and alar cartilage in 12-year-old children is not fully formed, and surgery at this time may promote the development of malformed cartilage into normal cartilage [14]. Gawrych and Janiszewska-Olszowska [15] reported that simple repair of secondary cleft lip nasal deformities does not significantly impact nasal ventilation function or morphology and has minimal effects on nasal growth and development. However, due to the uncertainty in the development of nasal septum cartilage and alar cartilage, and the incomplete jaw development in children, early surgical interventions have been largely abandoned by experts worldwide.

Conversely, other scholars argue that facial appearance and deformity are more stable in adults, with nasal septum and alar cartilage fully developed. The peak of jaw development has passed, making it the ideal time for surgical repair using sufficient grafts to strengthen nasal cartilage [16, 17]. In our study, all 75 patients completed surgery with an incision healing time of less than one week and primary healing in phase I. There were no complications, such as hematoma or infection in the cartilage donor zone, supporting the effi-

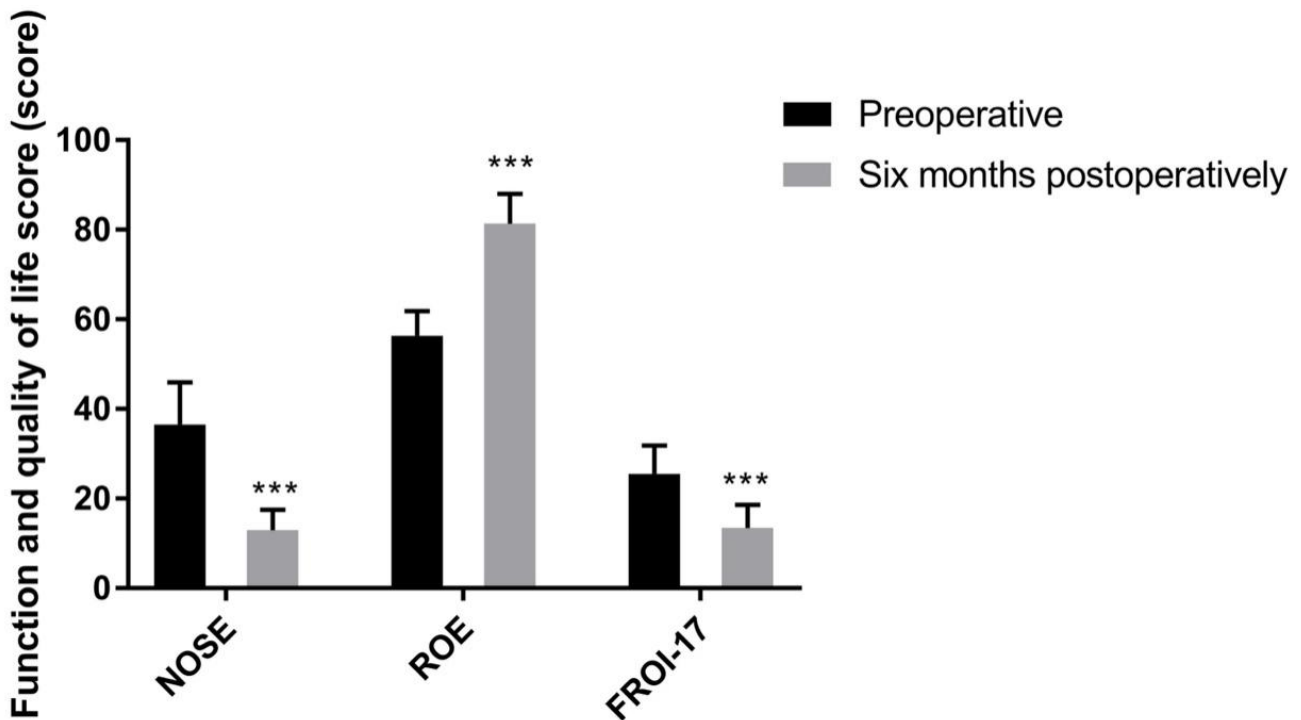


Fig. 5. Comparison of nasal obstruction symptom evaluation (NOSE), rhinoplasty outcome evaluation (ROE), and Functional Rhinoplasty Outcome Inventory-17 (FROI-17) scores before and 6 months post-operation in 75 patients. Compared with preoperative, *** $p < 0.001$.

cacy of secondary nasal deformity surgery in adults. Using a Y-shaped nasal columella made of autologous cartilage resulted in shorter incision healing time and fewer complications.

The columella, a subunit anatomical structure of the outer nose, generally extends 2–4 mm beyond the alar margin. The shape of the nasal tip is determined by the nasal tip reflection point, composed of the medial and lateral feet of the lateral nasal cartilage and alar cartilage on both sides. The support strength, size, and shape of the columella and tip directly influence the external appearance of the nose tip [18, 19]. Common clinical methods for nasal tip lifting and columella lengthening include biomaterial implantation, autogenous cartilage suppression, and the suspension and fixation of alar cartilage on the affected side. One previous study have demonstrated that, after releasing, suturing, and fixing the displaced and distorted alar cartilage, patients can achieve a good appearance of the alar at an early post-operative stage [20]. However, factors such as nasal skin and soft tissue traction, insufficient support, and nasal alar cartilage dysplasia can increase the risk of malformation recurrence post-surgery. Subsequent studies have found a high recurrence rate in patients with moderate or severe nasal deformities who underwent a simple suspension method, indicating the necessity of relying on nasal septum support [21].

In this study, costal cartilage, auricular cartilage, and iliac crest cartilage were used as nasal septum supports due to

their strong anti-infection properties and good histocompatibility. Results indicated that nasal appearance scores, as well as NOSE and FROI-17 scores, decreased while ROE scores increased in the 75 patients at 6 months postoperatively. Additionally, the nasal base, nasal width, nasal columella, and nostril height of the affected side showed significant improvement, with no significant differences compared to the healthy side. Zhang *et al.* [22] reported that self-made costal cartilage could correct nostril asymmetry in patients with secondary nasal deformity due to unilateral cleft lip, enhancing nasal morphology and aesthetics. Han *et al.* [23] found that the transplantation of concha cartilage played a critical role in correcting secondary cleft lip nasal deformities, increasing the height of the nasal columella and nostril, reducing nasal width, and significantly decreasing the difference in soft tissue volume between the affected and the healthy sides post-surgery. These findings are consistent with the conclusions of this study, further confirming that a Y-shaped nasal columella made from autologous cartilage can effectively correct secondary nasal deformities after cleft lip surgery. This method prolongs the nasal columella, corrects nasal alar collapse, elevates the nasal tip, and improves the quality of life of the patients, nasal appearance, and nasal ventilation function.

The success of this technique can be attributed to several factors: costal, auricular, and iliac crest cartilage are cut, sutured, and fixed by folding, which can increase the strength of the cartilage and the support of nasal columella, address-

ing the issues of insufficient columella support and low nasal tip deformity caused by inadequate chondrogenesis. Additionally, the natural mechanical structure of cartilage is used to make a “Y-shaped” scaffold, where the “V-shaped” part at the top provides strong support for nasal tip formation and alar cartilage [24, 25]. The implanted cartilage is sutured and fixed simultaneously at the medial and lateral feet of the alar cartilage of the affected and the healthy sides, increasing the height of the nasal tip, prolonging the nasal columella, ensuring columella alignment, and improving nasal appearance and function [26]. Postoperatively, only 2 out of 75 patients were unsatisfied, resulting in a total satisfaction rate of 97.33%. This high satisfaction indicates the effectiveness and acceptance of the Y-shaped nasal columella made of autologous cartilage for correcting secondary nasal deformities post-cleft lip surgery.

Prospective, double-blinded randomized controlled trials are needed to further explore the long-term effects on the quality of life of patients, nasal appearance, nasal ventilation function, and other indicators.

However, this study still has limitations, including a small sample size, a short follow-up period, a single-source sample, and the absence of a classical clinical method as a control group. Prospective, double-blinded randomized controlled trials are needed to further explore the long-term effects on the quality of life of patients, nasal appearance, nasal ventilation function, and other indicators. Only changes in various indicators before and after the corrective surgery using autologous cartilage for Y-shaped columella reconstruction are compared, possibly introducing some bias into the conclusions. Therefore, in the future, it is necessary to increase the sample size and sample sources, extend the follow-up duration, and establish a control group for further exploration.

Conclusions

The Y-shaped nasal columella made of autologous cartilage can effectively correct secondary nasal deformities after cleft lip surgery, improve nasal alar collapse, lengthen nasal columella, elevate nasal end, enhance the quality of life, nasal appearance and nasal ventilation function of patients, with high satisfaction and few complications.

Availability of Data and Materials

The datasets used and/or analyzed during the current study were available from the corresponding author on reasonable request.

Author Contributions

PJS and XWL designed the study; XWL and XYG collected and analyzed the data. ZJL, JX and YFW performed the research. XWL and PJS wrote the manuscript. All authors contributed to the critical revision of the manuscript for important intellectual content. All authors gave final approval

of the version to be published. All authors participated fully in the work, take public responsibility for appropriate portions of the content, and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or completeness of any part of the work are appropriately investigated and resolved.

Ethics Approval and Consent to Participate

This study was approved by the Ethics Committee of the First Affiliated Hospital of Bengbu Medical University (approval number: 2020038) and was performed in accordance with the principles of the Declaration of Helsinki. All eligible participants or their guardians signed an informed consent form. All patients or their guardians agreed to have their photos or data used for scientific research.

Acknowledgment

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Conflict of Interest

The authors declare no conflict of interest.

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