Ph.D. Dissertation of Seung Hyun Ahn

A Clinical Study on Rhinoplasty Using Polycaprolactone Mesh

폴리카프록락톤 메시를 이용한 코성형술에 대한 임상적 연구

August 2022

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Submitting a Ph.D. Dissertation of Medicine
April 2022

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Seung Hyun Ahn
July 2022

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Examiner	_____	(Seal)
Examiner	_____	(Seal)
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Abstract

A Clinical Study on Rhinoplasty Using Polycaprolactone Mesh

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Background: Despite the great demand of aesthetic rhinoplasty in Asian population, it is difficult to obtain the lasting ideal tip projection along with lengthening of the nose due to the small and weak nasal septum. The shortage of available septal cartilage to work with is another major obstacle.

Methods: A retrospective study was conducted between January 2017 and December 2019 in Seoul, Korea. A total of 774 patients underwent septorhinoplasty using polycaprolactone (PCL) mesh for the cosmetic enhancement of the nasal tip and the projection. Comparisons of aesthetic outcomes, patients' satisfaction surveys, and complications were performed between PCL mesh-only group and composite PCL group.

Results: Of all the patients, 97.5% of the patients in composite PCL group were rated more than 3 scores in aesthetic outcomes,

whereas 90.4% in mesh-only group (p-value=0.0002). About 96.7% of the patients with composite PCL rated their satisfaction level as more than satisfied, whereas 94.3% in mesh-only group (p-value=0.0365). Overall, there were 17 patients in composite PCL group who exhibited complications including decreased tip projection, deviated nasal tip, mesh infection, and mesh exposure. However, there were two patients who had mesh infection in mesh-only group.

Conclusion: Septorhinoplasty with septal extension graft using composite PCL graft provides a robust support to the aesthetically modified projection and the lengthened nose without obvious complications on the nasal tip. Such technique allows surgeons to overcome the nature of Asian nose that is weak and small, and also provides satisfaction to patients who desire ideal tip projections and dramatic changes.

Keyword : Polycaprolactone, PCL mesh, Septal extension graft, Rhinoplasty

Student Number : 2013-30552

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· Ahn SH, Cho SW, Baek RM. Polycaprolactone Mesh for Asian Rhinoplasty: Outcomes and Complications of Composite Septal Extension Graft Compared to Mesh-Only Graft. Facial Plast Surg. 2021 Jun 23.

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Chapter 1. Introduction

1.1. Study Background

Patients for augmentation rhinoplasty usually have deficient tip projection, deviated nasal septal structure, wide lobule, and retracted collumelar.[1] Ideal nasal tip with proper nasal tip projection and appropriate length and height poses a challenge to surgeons regarding selection of the most suitable technique and graft.[2] In particular, a septal extension graft (SEG) has been found to be a very useful tool for East Asian patients, especially with a thicker skin and relatively weak lower lateral cartilage (LLC). SEG helps maintaining tip projection through strong support and has become a popular surgical procedure in Korea.[3] However, there are several problems associated with conventionally used autologous material such as limited and unpredictable amounts of septal cartilage, morbidity of donor site, unpredictable resorption rate, and weak resistance to tension resulting in twisting, bending, or drooping of the nasal tip.[4] Moreover, as secondary or revision cases increase, autologous cartilage is not sufficient frequently. Therefore, choosing an appropriate material has been a critical issue on the result in augmentation rhinoplasty. Several alloplastic materials have been introduced as alternatives to autologous material. Silicone, porous high-density polyethylene (Medpor; Stryker Corporate, Portage, MI), and polytetrafluoroethylene (Goretex; Surgiform Technology, Lugoff, SC) are frequently used synthetic materials.[5] However, these nonabsorbable materials have serious limitations such as extrusion, hardness and infection.[6]

Biodegradable and biocompatible synthetic polymers have gained popularity and gradually replaced nonabsorbable alloplastic materials in rhinoplasty recently. Polycaprolactone (PCL) is a hydrophobic, semicrystalline polymer that is biodegradable and decomposed into CO_2 and H_2O. Its safety is proven from various biodegradable medical devices approved by the United States Food and Drug Administration.[7] PCL has several advantages over other biodegradable materials, such as poly-L-lactic acids (PLLA) and polydioxanone (PDS). PCL is degraded slowly resulting in lesser foreign body reaction and can be manipulated more easily. These advantages led to extensive research into biomedical applications such as threads for sutures and fixation devices. Three-dimensional (3D)-printed PCL mesh has gained popularity over other polymers in rhinoplasty for similar reasons.[8] Kim et al.[9] suggested that PCL scaffold designed by a 3D-printing method with fibrin/chondrocytes can be a biocompatible augmentation material in rhinoplasty. Moreover, Park et al.[2] reported the clinical application of 3D-printed bioresorbable PCL mesh in 101 patients.

1.2. Purpose of Research

In this study, we performed rhinoplasty with 3D-printed bioresorbable PCL mesh as a material for various grafts. To the best of our knowledge, there have been no other clinical studies involving composite graft of PCL mesh and autologous material. Our aim was to apply 3D-printed PCL mesh combined with autologous cartilage and evaluate the safety and surgical outcome compared with graft composed of mesh only. This study will provide guidance for future investigations.

Chapter 2. Patients and Methods

2.1. Study Subjects

Before commencing the study, the institutional review board of Seoul National University Bundang Hospital approved this study (IRB No. B-2008/628-105). Seven-hundred and seventy-four patients who received primary or secondary rhinoplasty with PCL mesh between January 2017 and December 2019 were included. A single surgeon (SH Ahn, MD) performed rhinoplasties for all cases, and all patients underwent nasal SEG. The mean patient age at surgery was 26.9 years and 34.8% (n=269) of the patients were female. The mean postoperative follow-up period was 11.9 months. The related patient data are demonstrated in Table 1.

Table 1. Demographics and data of operation types

Variable	
Sex	
Male, *n* (%)	505 (65.2)
Female, *n* (%)	269 (34.8)
Mean age, years	26.9
Type of surgery	
Primary (%)	715 (92.4)
Secondary (%)	59 (7.6)
Materials	
Mesh + augologous cartilage (%)	722 (93.3)
Mesh only (%)	52 (6.7)
Type of grafts	
Septal extension only (%)	39 (5.0)
Spreader + septal extension (%)	724 (93.6)
Septal extension + columellar strut (%)	2 (0.3)
Spreader + septal extension + columellar strut (%)	9 (1.1)

2.2. 3D-Fabricated PCL Mesh

3D-fabricated PCL mesh (TnR mesh; T&R Biofab Co., Ltd, Siheung, Korea) was used in all cases (**Fig. 1A**). This multipore synthetic mesh was composed of interconnected triangular pores and 40mm by 10mm in full size, with thicknesses of 0.8mm. A pore size was 500um with porosity of 50%.[10]

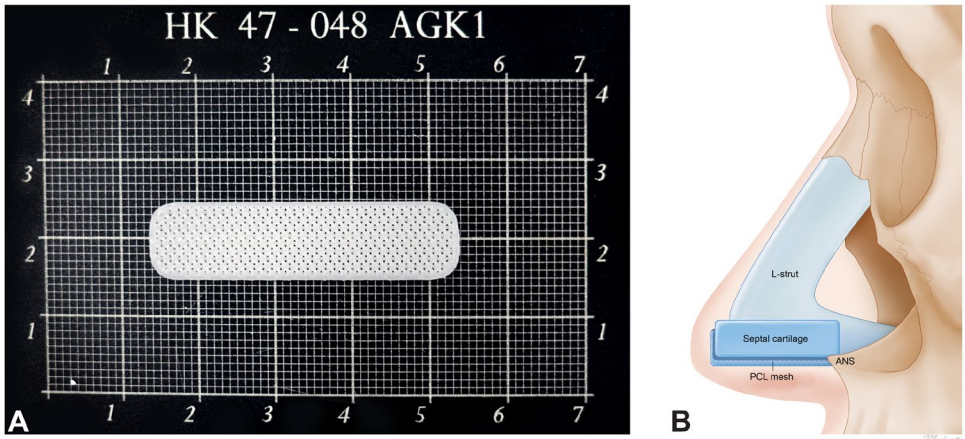

Fig. 1. (A) Polycaprolactone (PCL) mesh. Multipore synthetic mesh is composed of cylindrical fibers of 0.5mm diameter with porosity of 50%. (B) Illustration of composite septal extension graft. The PCL and the septal cartilage were stacked. The base of the complex is securely fixed to the cartilaginous ground directly posterior to the anterior nasal spine (ANS).

2.3. Operative Technique

All operations were performed under sedative anesthesia or local anesthesia upon patients' requests. The anesthetic solution consisted of 1% lidocaine with 1:200,000 epinephrine. The septum and mucoperichondrium were infiltrated and hyperinflated with the solution. A total of 10 to 15mL of the solution was used for infiltration. An open rhinoplasty involving modified seagull technique at the columellar-labial junction was taken for the dissection. The columella and dorsal skin flaps were elevated to the level of the perichondrium of the LLC with iris scissors. The alar cartilage and upper lateral cartilages (ULC) were skeletonized by supraperichondrial dissections with either scissors or scalpel. After the complete separation of the LLC, the right and left LLC were separated from each other, and the nasal septum was exposed. The septal mucoperichondrium was elevated bilaterally making mucoperichondrial pockets for the insertion of the SEG. The septal cartilage was carefully harvested leaving L-strut. The septal cartilage was designed to a size of 30mm long, 10mm wide on the grid plate. The septal cartilage harvested from septoplasty was mainly used for the cartilage material for the complex. However, in case of insufficient septal cartilage due to the previous septoplasty or naturally hypoplastic septal cartilage, mesh-only graft was considered.

To construct a semirigid graft on the base, the PCL mesh-cartilage complex was sutured together using 5-0 PDS. The cartilage was inserted to either side of the anterior nasal spine (ANS) to which the septum was originally deviated (**Fig. 1B**). The PCL mesh was inserted to the other side of the ANS. The size of

the graft was 40mm in length and 10mm in width originally. It is trimmed and cut at the distal tip portion for the targeted projection of nasal tip and the length of the nose.

Once the PCL mesh-cartilage composite graft is constructed, the strong base portion is containing at least one side of the PCL. This base of the graft is inserted directly posterior to the ANS. The base of the composite graft makes direct contact with the ground, providing vertical strength. The PCL and cartilage are also sutured to the cartilaginous ground, and they provide stability in horizontal vector. The base portion of graft is securely fixated deeply, but it is not fixed directly to the caudal portion of the septal cartilage. As the LLC is advanced caudally and anteriorly, the tip portion is fixed together with LLC using intercrural sutures to achieve the optimal projection and lengthening (**Fig. 2**). Any excess of the SEG was trimmed to prevent impingement. The PCL mesh of the complex should not extend beyond the tip of LLC. It is better to have a round margin of the PCL mesh to avoid pressure to the soft tissue. The length of the complex ranges from 26 to 30mm, and the width ranges from 8 to 10mm. Further modifications are selectively performed, and those include spreader graft, columellar strut and on-lay graft. Finally, the nasal skin was closed with 6-0 nylon sutures.

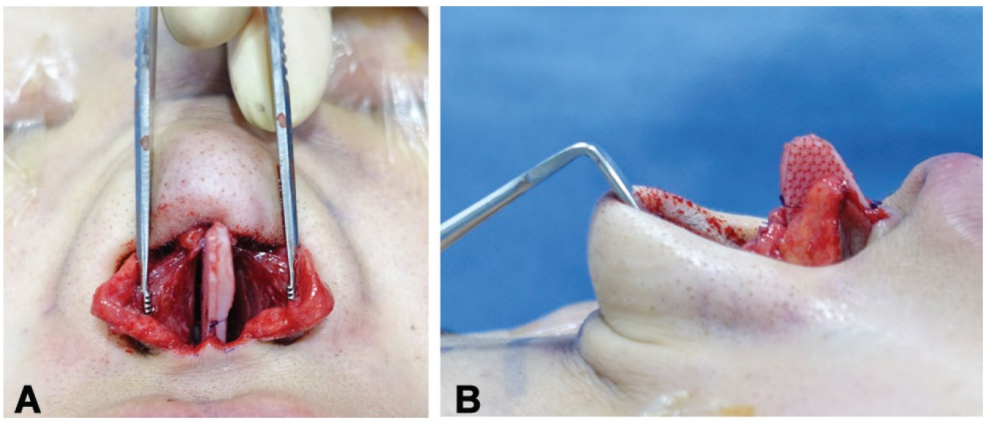

Fig. 2. (A, B) Intraoperative photos present a composite septal extension graft (SEG) (left side of the graft is an SEG using septal cartilage and the opposite side is a 3D-printed polycaprolactone graft.

2.4. Outcome Measurement

For objective evaluation of aesthetic outcomes following rhinoplasty with a graft containing PCL, two plastic surgeons who were blinded to the purpose of the present study and to each other reviewed the preoperative and 6-month postoperative photographs using a standardized protocol. Six views, including front, full, semilateral, and worm's eye, were scored on a 4-point Global Aesthetic Improvement Scale (GAIS; 0=worse, 1=no change, 2=improved, 3=muc improved, and 4=very much improved) (Table 2).

For subjective evaluation of outcomes, we used the survey of patient satisfaction regarding the aesthetic outcome. The survey was performed at least 6 months after the operation. The outcomes were divided to four grades: excellent, good, fair, and poor (Table 3).

Finally, we compared complication rates of composite SEG group and mesh-only group (Tables 4 and 5).

2.5. Statistical Analysis

All quantitative data were presented as mean±standard deviations based on data derived measurements. Aesthetic outcomes, patients' satisfaction, and each complication of two groups were compared with the Fisher's exact test. A $p<0.05$ was considered statistically significant. Statistical analyses were performed through SPSS 21.0 software for Windows (SPSS, Inc, Chicago, IL).

Chapter 3. Results

Of the 774 total cases, 715 (92.4%) were primary cases and the remaining 59 (7.6%) were secondary cases. The source materials for the nasal SEG were only PCL mesh for 52 cases (7.6%) and composite grafts of PCL mesh and septal cartilage for 722 cases (92.4%). All patients underwent SEGs, spreader grafts were performed in 733 cases (94.7%), and columellar struts were used in 11 cases (1.4%). Nine patients (1.1%) underwent all three kinds of grafts (Table 1).

3.1. Outcomes of PCL Mesh

Regarding aesthetic evaluation using GAIS scores at 12-month postoperative photographs with 98.0 of interrater reliability, most patients (97.5% in composite group, 90.4% in mesh-only group) showed improvement; no change or worse change was observed in only three patients in composite group and two patients in mesh-only group (Table 2).

Most patients (96.7% in composite group, 93.5% in mesh-only group) were satisfied with the surgical outcomes throughout the study period. Twenty-seven patients (24 in composite group, three in mesh-only group) were unsatisfied with the results (Table 3).

3.2. Complications

Complications were reported by subjective symptoms followed by examination of the operator (Table 4). Average onset was calculated by the average duration from the operation to the report of the symptoms. There were nine cases of tip drooping, all of which had composite grafts. Tip drooping was corrected by lowering of supratip or reduction in lobule volume. There were two patients with deviation of the nasal tip. All of them had composite grafts and corrected by removal of SEG at convex side. Mesh infection was reported in three patients, two of whom had mesh-only SEGs. There were five patients with exposed composite grafts without obvious infection signs. These patients were treated with intravenous antibiotics followed by removal of PCL grafts.

Overall, there were 17 cases (2.4%) of complication in composite group and two cases in mesh-only group (3.8%) (Table 5).

Table 2. Aesthetic outcomes of rhinoplasty with polycaprolactone (PCL) mesh*

Aesthetic outcomes	Score	Number of patients in composite group (%)	Number of patients in mesh only group (%)
Very much improved	4	321 (44.5)	10 (19.2)
Much improved	3	383 (53.0)	37 (71.2)
Improved	2	15 (2.1)	3 (5.8)
No change	1	1 (0.1)	1 (1.9)
Worse	0	2 (0.3)	1 (1.9)

p-value = 0.0002

* $p < 0.05$ indicates a statistically significant difference

Table 3. Patients' satisfaction after rhinoplasty with polycaprolactone (PCL) mesh*

Satisfaction	Score	Number of patients in composite group (%)	Number of patients in mesh only group (%)
Very satisfied	3	165 (22.9)	7 (13.5)
Satisfied	2	533 (73.8)	42 (80.8)
Unsatisfied	1	24 (3.3)	2 (3.8)
Very unsatisfied	0	0 (0)	1 (1.9)

p-value = 0.0365

* $p < 0.05$ indicates a statistically significant difference

Table 4. Summary of patients with complications related to PCL graft

Presentation	Number of cases in composite group (%)	Number of cases in mesh only group (%)	Methods of PCL graft	Average Onset (months)	p-value
Decrease of the projection	9 (1.2)	0 (0)	SEG + Sp	2.5	> 0.05
Deviation of the nasal tip	2 (0.3)	0 (0)	SEG or SEG + Sp	15.8	> 0.05
Mesh infection	1 (0.1)	2 (3.8)	SEG + Sp	3.7	0.0127*
Mesh exposure	5 (0.7)	0 (0)	SEG + Sp	12.9	> 0.05

SEG : septal extension graft, Sp : spreader graft

* $p < 0.05$ indicates a statistically significant difference

Table 5. Complication rates according to the graft materials

Groups	Number of cases	Complication rate (%)
Composite group	17	2.4
Mesh only group	2	3.8

p-value = 0.3691

$p > 0.05$ indicates a statistically not significant difference

Chapter 4. Discussion

The small and weak nasal septum and alar cartilage are the key concerns in aesthetic rhinoplasty in Asian population. Various surgical methods and numerous biomaterials have been tried, but no unique surgical technique or material was yet to be found that can completely overcome these anatomical obstacles. Historically, a silicone implant with L-shaped distal end was used for supporting the nasal tip.[11] Unfortunately, high incidences of protrusion, excessive tension, and implant-related infections pushed L-type silicone implant out of the market. The current Asian nasal tip rhinoplasty mostly involves autologous cartilages harvested from various sources such as septal cartilages, conchal cartilages, and rib cartilages.

Although several new surgical techniques have developed, the gold standard for nasal tip plasty is a SEG technique introduced by Byrd et al.[3] SEG may improve nasal tip projection with less cephalic rotation and the derotation of short noses. However, complication reports have been compiling, and those include a loss of tip projection, excessive hardness on the tip, and nasal tip deviation.[4] The theory behind such unwanted events involves the weak L-strut cartilage after the harvest of septal cartilage, and the implanted cartilage on top of L-strut becomes vulnerable to twisting, bending, and sinking.

Another main issue in Asian rhinoplasty is a scarcity of the source cartilage. Primarily, septal and conchal cartilages are commonly used. In cases with insufficient septal or conchal cartilages, and in cases requiring a stronger, more pliable, and more

abundant cartilage, a rib cartilage could be a choice with the cost of donor site morbidity and potential cartilage warping.[12] If the surgeon and the patient only wish to use autologous graft, a rib cartilage is a favorable choice. However, young patients planning for cosmetic surgery rarely expect the invasive procedure of rib cartilage harvesting. Furthermore, this type of cartilage tends to warp.

For these considerations, nonautologous grafts have been focused recently. Previously, a porous high-density polyethylene sheet for nasal tip rhinoplasty was introduced. Instead of using septal cartilage, several authors introduced a method of using non-absorbable porous high-density polyethylene sheets (Medpor) for SEG.[13,14] Immediate postoperative results were acceptable with a few minor problems including the tip stiffness and unnatural look. A few literatures have reported the long-term complications of using polyethylene sheets, such as high extrusion and infection rate that requires revision rhinoplasties.[12] Additionally, there have been growing negative opinions from rhinoplasty surgeons regarding the high incidences of complications requiring reoperations recently. Subsequently, Caughlin et al.[15] introduced SEG using absorbable polymer, PDS plate. Due to the absorbable nature of the polymer, extrusion can rarely occur. However, there are some disadvantages; absorption rate is relatively rapid and resorbed in ~6 months, tensile strength is weak, and manipulation of thin rigid plate is not easy. PLLA derivatives are also available and degrade slowly in 2 years. In spite of this advantage, these polymers are known to cause tissue responses due to the acidic metabolites.[16] Furthermore, PLLA has a hard and brittle property followed by limited applications.[17]

Ideal augmentation materials should have the following characteristics: (1) sufficient amount; (2) biocompatibility; (3) easy to manipulate and design; and (4) the maintenance of augmentation level.[18,19] PCL has emerged as a favorable polymer in the tissue-engineering field because it is biocompatible and safely breaks down in the body over 3-4 years. PCL is ideal for the 3D printing process because this technology enables the precise control of material properties, such as shape, bioactivity, and porosity as well as customization and reproducibility for specific applications.[20]

In vivo behavior of PCL, a bioresorbable and biointegratable polymer, is well studied over decades. There are several advantages of PCL mesh over its resorbable counterparts due to its properties. First, it has superior biocompatibility. Ester bonding of this high molecular weight polymer is hydrolyzed slowly, and resultant substrates are resorbed through the normal metabolic pathway without abrupt change in local pH. The final metabolites can be completely secreted, and they produce no toxic substances throughout the series of degradations.[21-23] The 3D-printed multipore structure of PCL mesh allows red blood cells and immune cells to migrate through, and it provides strong resistance to the infection as well as a capacity of biointegration through the host tissue ingrowth.[24]

The average molecular weight of PCL may generally vary from 3,000 to 80,000 g/mol. PCL can be graded according to the molecular weight.[25] In vivo degradation of PCL showed a two stages pattern. The first stage involves a decrease in molecular weight without mass loss and deformation. The second stage begins when the molecular weight dropped to 5,000. At that point the material broke into pieces and mass loss occurs. An increase in the initial

molecular weight results in a longer resorption time. By this means, the degradation time of PCL-based implants can be controlled by the initial molecular weight of the PCL used for implant production.[26,27] The tailorable degradation kinetics and mechanical properties enable PCL as the appropriate augmentation material, expecting it would maintain the desired tip shape. The long-term biodegradability of PCL mesh can resist deformations from contractions of the skin and scars during the healing process related to rhinoplasty. Complete absorption is helpful for avoiding skin thinning and ulcerations from excessive local mechanical pressure from a long-term perspective.[8]

Second, apart from the biocompatibility, PCL mesh has relatively high elasticity making it fabricable to various shapes and sizes.[21] Therefore, similar surgical outcomes can be expected as in cases with only autologous cartilage. Moreover, easy manipulation due to its elasticity can result in a decrease in overall operative time.

Finally, the structural stability can be sustained up to 2 years.[21] Although there are concerns about the final outcome after the complete resorption, we support the idea that this period is sufficient for fibrosis to reinforce the nasal structure.[2] Based on the characteristics of porous PCL implants, we demonstrated the composite SEG with the use of PCL mesh implant along with autologous cartilage.

Several trials have demonstrated PCL-based implants to have adequate structural integrity to withstand biomechanical loads over time.[28] 3D-printed PCL mesh has the advantage of excellent durability to load mechanical strength, originating from its microporous structures. The tensile strength and bending strength of PCL mesh were 7.83 and 24.10 Mpa.[29] In three-point bending

test, the flexural strength of septal cartilage was found to be 5.73 Mpa.[30] PCL mesh of 1-mm thickness has the flexural strength of 15.2 Mpa. Relatively high elasticity of PCL mesh makes it a good match for nasal cartilage of living tissue at implantation. Therefore, outcomes similar to cases using only autologous cartilage can be expected.[16] PCL implants are produced with a compressive stiffness range of 2.74 to 55.95 Mpa, which are inclusive of septal cartilage parameters (12.8-22.5 Mpa).[31,32] These mechanical properties are adjustable according to the microstructure of PCL mesh. Thus, the mechanical properties of PCL mesh can match up with those of septal cartilage without difficulty.

Microscopic morphology of the PCL mesh confirmed by field emission scanning electron microscope showed fully interconnected triangular pores in PCL mesh.[2] The interconnected triangular pores played an important role in the induction of the ingrowth of the surrounding tissues. The 50% porosity and 500μm pore size of PCL mesh used in the present study are appropriate for implants and are associated with enhancing cell growth and maintaining durability for sufficient mechanical resistance. This has been proven in a previous preclinical animal study reporting that soft tissue ingrowth and neo-vascularization without postoperative infection were observed in implanted PCL mesh with this porosity and pore size.[10] The microporosity of PCL controlled by 3D printing promotes rapid fibrovascular ingrowth without granulation-tissue formation.[8]

Clinically, PCL implant has shown to have good functional and aesthetic outcomes for the repair of both small and large orbital floor fractures.[23] Using PCL mesh seeded with autologous mesenchymal progenitor cells and osteoblasts, histological evidence of neo-bone formation with partial integration into the surrounding

host tissue in a critical-sized rabbit calvarial defect was reported.[33]

There has been several animal researches which evaluate histological changes after implantation of PCL into nose. Kim et al.[9] reported that PCL scaffold seeded with fibrin/chondrocytes can be a dorsal augmentation material in rhinoplasty. Histological evaluations at 12 weeks after implantation showed that the scaffold architectures were maintained with minimal inflammatory reactions. However, neo-chondrogenesis was not observed in a biopsy of the construct. Park et al.[8] showed fibrovascular ingrowth at 12 weeks with presence of collagen type I without granulation tissue formation in SEG using a PCL mesh. PCL mesh is not just an implant in rhinoplasty, but also a biocompatible scaffold that enhances vascular and soft tissue ingrowth and provides good stability via incorporation into the host tissue. Wiggenhauser et al.[34] performed dorsal augmentation using a PCL implant. Histological examination showed formation of connective tissue with the presence of cartilaginous-like tissue rich in cartilage-defining proteins with cells of chondrocyte appearance after 6 months. However, the low ratio of collagen type II indicates that there was more fibrous cartilaginous-like tissue than mature hyaline cartilage.

Park et al.[2] reviewed 101 patients who received rhinoplasty with a PCL mesh. This study demonstrated the presence of collagen type II, proteoglycans and chondrocytes on the newly formed tissue within the pore structure around the PCL mesh at 20 months postoperatively. Analysis of collagen type showed high positive staining for collagen types I and II. Chondrocytes with a lacuna structure, which are a distinct feature of cartilaginous tissue, indicate that the newly formed tissue consists of neo-cartilaginous tissue. The results suggest that the PCL mesh has potential as a

biocompatible scaffold that regenerate the adjacent soft tissue.

One of the most critical aspects of SEG for a good final outcome is to prevent the collapse and deviation caused by weak remnant L-strut, and it is a bigger problem for Asians who tend to have smaller and weaker septal cartilages. Previously, various modifications were introduced to overcome the instability, but most techniques applied fixations to the caudal portion of the septal cartilage. The L-shaped columellar strut graft with a secure fixation of the graft onto the caudal septum was one of the modifications.[35] If the graft is fixed to the caudal septal cartilage that is in continuity of dorsal septal cartilage, the nasal tip becomes less mobile. Consequently, the nasal tip has less natural appearance. In our composite SEG, we applied the rigid base of PCL mesh-cartilage complex on top of the concrete supporting floor right behind the ANS. Securely positioned graft was then fixed to the base portion of L-strut preventing the collapse and providing horizontal stability. At the same time, the graft framework is not connected to the caudal or dorsal portion of the septal cartilage. The nasal tip is separated from the immobile nasal dorsum, and it allows flexibility and natural look of the nasal tip (**Figs. 3** and **4**).

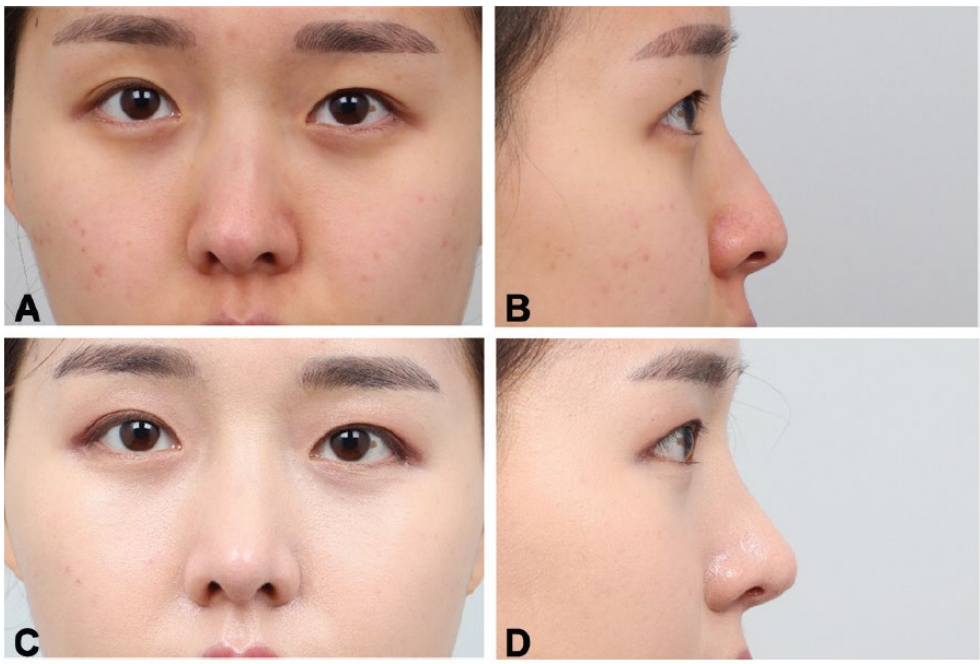

Fig. 3. A 25-year-old female patient who had low height and deviation of nose underwent rhinoplasty with composite septal extension and spreader grafts. (A, B) Preoperative frontal and lateral images present low height and deviation of the nose. (C, D) Nine months postoperative frontal and lateral images show good maintenance of nasal height and tip projection.

Fig. 4. A 27-year-old male patient with a complaint of low tip projection and hump underwent an operation using composite septal extension and spreader grafts. (A, B) Preoperative frontal and lateral images shows tip drooping and hump at the nasal dorsum. (C, D) Twelve months after the rhinoplasty, frontal, and lateral images present good maintenance of the nasal tip and dorsum.

In our composite graft, the PCL mesh is located in the opposite side of the cartilaginous pedestal that was inserted in the originally deviated side. PCL mesh provides elasticity and great tensile strength. The mesh is also easy to manipulate, and desired form and height of nasal tip can be achieved through several intercrural sutures and domal sutures. The location directly posterior to ANS is specifically targeted because it is a stable and fixed structure even after the septoplasty. In many of previous SEG methods, the base of graft was sutured more posteriorly to the ANS where cephalic portion of L-strut is weak. Using such less stable posterior buttress may cause collapse of the architecture, and unfavorable tip projection will result in a long term. In addition, septal mucosa is thicker anteriorly; therefore, there is a less chance of graft exposure (**Fig. 1B**). Though spreader graft is usually used for maintaining the internal valve, we used it for additional tip support. With all these techniques, the composite graft forms a SEG with appropriate strength vertically.

Considering aesthetic evaluation using GAIS scores at 12-month postoperative photographs with 98.0 of interrater reliability, most patients (97.5% in composite group, 90.4% in mesh-only group) presented improvement. However, there was statistically significant difference between two groups. This may contribute to more natural appearance in composite group by matching the deviated side with septal cartilage. Moreover, mesh-only group may include more difficult patients who are lack of autologous cartilage to be used for composite grafts.

When analyzing the patients' satisfaction levels, most patients (96.7% in composite group, 93.5% in mesh-only group) were satisfied with the surgical outcomes throughout the study period.

Thus, a high level of satisfaction was observed in both groups. Although there was a slightly higher proportion of patients with higher scores (3 and 2) in composite group, there was no statistically significant difference (p=0.200). This gap between specialists' opinion and patients' satisfaction means that aesthetic outcomes may not always represent patients' satisfaction. Therefore, rhinoplasty surgeons should listen to patients' needs.

With regard to the complications, decrease in the tip projection with drooping was the most prevalent. Deviation of the tip was observed only in composite group, which means the difference of the material at each side could have affected the symmetry. Mesh infection was significantly higher in mesh-only group though there were five cases of mesh exposure without obvious infection signs in composite group (p<0.05). We inserted the PCL side of SEG to the concave selectively; thus, this led to minimal exposure of PCL mesh that had only subclinical impact. In total, complication rate was lower in composite group (2.4%); however, further study is needed because mesh-only group involves much fewer cases (p>0.05). Complication rates of our study are much lower in both groups than previous studies.[4,36] There are several points that caused fewer complications. First, as mentioned above, we thoroughly determined the concave side and the convex side of septum to avoid the exposure or infection of the mesh. Second, we inserted the base of SEG deep to the ANS to avoid the deviation or change of the tip. Finally, we used spreader grafts not only to maintain the internal valve, but to support the tip projection. Longer spreader grafts were fixed with SEG and LLCs to prevent the change of the tip.

Several companies produce and supply commercially available

PCL meshes for rhinoplasty. TnR mesh (T&R Biofab Co., Ltd, Siheung, Korea) and Osteomesh (Osteopore International Pte., Ltd, Singapore) are widely used products. Although they both are manufactured using 3D printing technology, they have some differences (Table 6). There were two clinical studies using Osteomesh in rhinoplasty. Kim et al.[36] suggested that the PCL mesh provided additional support for weak or insufficient harvested graft. They emphasized the importance of bilateral graft to keep the tension between the bilateral LLCs symmetrical and care to prevent complications, such as tip drooping and stiffness. Ahn et al.[37] showed significant improvement of nasal length, tip projection, nasofrontal angle, and nasolabial angle lasting 2 years after SEG with PCL mesh. These studies did not observe the final outcome when this biodegradable material is completely resorbed. The patient satisfaction rates in rhinoplasty using Osteomesh were 90.7 - 96.7%, which are similar to this study. The complication rates of this study (6.1%) are lower than that of studies using Osteomesh (14 - 20%). The difference in complication rates may be attributable to the design and inset position of SEG protecting the septal mucosa and supporting the tip from the ANS.

Table 6. A comparison of TnR mesh and Osteomesh

	TnR mesh	Osteomesh
Manufacturer	T&R Biofab Co., Ltd, Siheung, Korea	Osteopore International Pte., Ltd, Singapore
Size	40 X 10 X 0.8 mm	40 X 10 X 1.0 mm
Molecular weight	N/A	80 kD
Pore size	500 μm	400 μm
Porosity	50 %	70 %

There are several limitations in this study. First, because this is a retrospective study, outcomes are based on the relatively subjective evaluation by plastic surgeons and patients. A prospective study based on the objective measurement of the nasal tip projection, nasal length, or nasolabial angle should be performed. Second, this study is not including the result after 2 years. As we mentioned above, we expect that the resorption period is sufficient to support the nasal structure after complete absorption. However, there are few patients who underwent the surgery before 2 years ago. Therefore, further measurements need to be performed to show the strength, height, and shape of nasal tip remains. Finally, the numbers of cases involved in subgroups in this study were different. We compared results between composite PCL group and PCL only group. However, PCL was used solely only when autologous cartilage is not sufficient; PCL only group is much smaller than composite PCL group. Even there is statistically significant difference in complication rates and other scores, this could be a confounding factor. Nevertheless, to the best of our knowledge, our study is the first long-term outcome study comparing two large groups reporting safety and utility of 3D-printed PCL mesh in rhinoplasty.

Chapter 5. Conclusion

When there is not enough autologous material, PCL mesh, especially combined with autologous cartilage, provides a robust support to the aesthetically modified projection and the lengthened nose for the postoperative period under study. This technique allows surgeons to overcome the nature of Asian nose that is weak and small, and it provides satisfaction to patients who desire ideal tip projections and dramatic changes. However, care needs to be taken to prevent complications such as tip drooping, deviation, infection, and exposure. Further research is required to evaluate long-term stability after PCL mesh is absorbed.

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국문 초록

폴리카프록락톤 메시를 이용한 코성형술에 대한 임상적 연구

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배경: 아시아인에서 미용적 코성형술의 수요는 지속적으로 증가하고 있다. 작고 약한 비중격 연골을 가진 코의 코끝 길이를 늘리면서 높이를 높인 후, 교정한 코끝의 높이와 길이를 장기적으로 유지하기는 쉽지 않다. 사용할 수 있는 비중격 연골의 양이 제한적이기 때문에 안정적인 수술 결과를 얻기 위한 재료가 부족한 경우가 많다.

방법: 2017년 1월부터 2019년 12월까지 폴리카프로락톤 메시를 이용하여 미용적 목적의 코끝 성형술을 받은 774명의 환자를 대상으로 후향적 연구를 수행하였다. 코끝 성형술은 코끝의 높이와 길이를 증가시키는 방향으로 진행되었다. 환자군을 폴리카프록락톤 메시만 사용한 군과 비중격 연골과 폴리카프로락톤 메시를 복합적으로 이식한 군으로 나누어 미용적 결과, 환자 만족도, 합병증 발생을 비교 분석하였다.

결과: 미용적 결과 분석에서 3점 이상을 받은 환자는 복합 이식한 군에서 97.5%로 메시 단일 이식한 군의 90.4%보다 유의하게 높았다 (p-값=0.0002). 환자 만족도 분석에서 만족함 이상의 만족도를 나타낸 환자는 복합 이식한 군에서 96.7%, 메시 단일 이식한 군에서 94.3%로

유의한 차이를 보였다 (p-값=0.0365). 복합 이식한 군 중 17명에서 코끝 높이의 감소, 코끝의 휨, 메시의 감염, 메시의 돌출과 같은 합병증이 발생하였다. 메시 단일 이식한 군에서는 2명에서 메시 감염이 있었다.

결론: 본 연구를 통하여 비중격 메시 복합 이식을 이용한 비중격 연장 이식술은 유의한 합병증 발생을 피하면서, 교정한 코끝의 높이와 길이를 튼튼하게 지지해줄 수 있음을 알 수 있다. 비중격 메시 복합 이식을 이용한 비중격 연장 이식술은 약하고 작은 아시아인 코의 해부학적 특성을 극복하고 환자들이 원하는 이상적인 코끝 높이와 만족스러운 변화를 얻는데 도움을 줄 수 있을 것이다.

주요어 : 폴리카프로락톤, 폴리카프로락톤 메시, 비중격 연장 이식, 코성형술

학번 : 2013-30552

· 본 학위논문은 이미 출판된 논문을 기반으로 하였다. 논문의 공동저자들은 연구결과를 본 학위논문에 사용하는데 동의하였다.

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