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Clinical Application of Three-Dimensionally Printed Biomaterial Polycaprolactone (PCL) in Augmentation Rhinoplasty

Young Jin Park[1] · Jong Hyun Cha[1] · Sa Ik Bang[2] · So Young Kim[3]

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Abstract

Background This clinical study aimed to investigate the safety and surgical outcome of three-dimensionally (3D) fabricated polycaprolactone (PCL) mesh in rhinoplasty. In particular, this study explored how a 3D-printed PCL mesh performs as a bioabsorbable scaffold after a long period following implantation.

Methods A retrospective review of 101 patients who received primary or secondary rhinoplasty with a PCL mesh was performed. Patient demographics and surgery-related outcomes were examined. Clinical efficacy and safety were evaluated using the Global Aesthetic Improvement Scale at postoperative 18 months. From two revisional cases, a biopsy specimen of implanted PCL was acquired and histopathological analysis was performed.

Results Of all the patients, 98.0% showed no postoperative infection-related foreign body reaction or distinct abnormal reaction, and the implants were observed to maintain long-term efficacy until 18-month follow-up. In patients who received spreader grafts, significant differences between preoperative and postoperative Cottle sign scores were found. Histopathological analysis showed features of adjacent tissue infiltration into pores of the PCL mesh and regeneration of neo-cartilaginous tissue and collagen around the mesh 20 months after implantation.

Conclusion This study demonstrates that a novel biodegradable PCL mesh with a 3D structure is a safe and effective material for corrective rhinoplasty because it is easy to use and capable of maintaining its volume in the long term without foreign body response. This biocompatible material will have a wide range of applications as the most suitable alternative to nonabsorbable materials in rhinoplasty and reconstruction surgeries, such as fashioning spreader grafts and septal extension grafts.

Level of Evidence IV This journal requires that authors assign a level of evidence to each article. For a full description of these Evidence-Based Medicine ratings, please refer to the Table of Contents or the online Instructions to Authors www.springer.com/00266.

Keywords Rhinoplasty · Alloplastic implant · 3D PCL mesh

Dr. So Young Kim and Young Jin Park were equally contributed as co-corresponding authors to this article.

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✉ Young Jin Park
dryjp@daum.net

✉ So Young Kim
pajamakim@naver.com

[1] Kangnam-Samsung Aesthetic Plastic Surgery, 1306-1, HyoBong 601, Seocho-Dong, Seoul 06614, South Korea

[2] Department of Plastic Surgery, Samsung Medical Center, Sungkyunkwan University School of Medicine, Irwon-dong 50, Gangnam-gu, Seoul 135-710, South Korea

[3] Department of Plastic and Reconstructive Surgery, Inje University Sanggye Paik Hospital, Inje University School of Medicine, 1342 Dongil-ro, Nowon-gu, Seoul 01757, South Korea

Introduction

Choosing a proper material remains a critical issue in augmentation rhinoplasty. This procedure is usually performed in patients with deviated nasal septal structure and wide lobule with frequent columellar retraction, and

deficient tip projection [1]. In particular, obtaining the ideal nasal tip, which is characterized by both proper tip projection and nasal prolongation of length and height, poses a challenge to surgeons regarding selection of the most appropriate graft and technique. Although autologous material is certainly ideal for all implant types in rhinoplasty, there are several problems associated with autologous material, such as limited and unpredictable amounts available for use, morbidity or mortality at the donor site, and unpredictable resorption rates after insertion [2]. Furthermore, as the numbers of secondary or revision cases are increasing, autologous cartilage availability is frequently limited. As an alternative to autologous material, new alloplastic materials are required. Silicone, expanded polytetrafluoroethylene (Goretex®; Surgiform Technology, Lugoff, SC, USA), and porous high-density polyethylene (Medpor®; Stryker Corporate, Portage, MI, USA) are the most frequently used synthetic materials [3]. However, the currently used nonabsorbable materials possess serious limitations and morbidities, including varying degrees of hardness, extrusion, deviation, infection, and delayed inflammation. These factors must be seriously considered by rhinoplasty surgeons [2, 3].

Recently, the basic paradigm of alloplastic material in rhinoplasty has shifted toward biodegradable and biocompatible synthetic material, which can replace or complement nonabsorbable alloplastic material. Developed in the early 1930s, polycaprolactone (PCL) is a polymer due to which biomedical interest has resurged [4]. PCL is a hydrophobic, semicrystalline polymer with good flexibility originated from the characteristics of a low melting point (59–64 °C). PCL also has many advantages over other resorbable polymer counterparts, such as polydioxanone (PDO), poly-D-lactide (PDLA), and poly-L-lactide (PLLA), including a slower degradation rate, lesser foreign body reactions, and ease of manipulation. These advantages have motivated extensive research into the potential biomedical applications of PCL, such as drug delivery devices, sutures, and fixation devices [4]. 3D-printed PCL mesh also has the advantage of biocompatibility, originating from its three-dimensional and microporous structures and excellent durability to load mechanical strength. These advantages have prompted PCL to be investigated as a mechanically and structurally implantable scaffold in rhinoplasty [4]. Park et al. [5] suggested that PCL is a safe material for implants in nasal reconstruction, showing good stability via incorporation into the host tissue and maintenance of the immune response. Moreover, Kim et al. reported that PCL scaffold designed by a 3D-printing method seeded with fibrin/chondrocytes can be a biocompatible augmentation material in rhinoplasty [6]. To the best of our knowledge, recent studies on PCL implants in rhinoplasty have been limited to animal models [5, 6]; no clinical studies in humans have examined PCL mesh implantation in rhinoplasty.

Our aim was to report the clinical application of 3D-printed bioresorbable PCL mesh in rhinoplasty and investigate the safety and surgical outcome of its use. In particular, this study also explored how a 3D-printed PCL mesh performs as a bioabsorbable scaffold after a long period following implantation.

Patients and Methods

Study Subjects

One hundred and one patients who received primary or secondary rhinoplasty between February 2015 and July 2017 were included. The mean patient age at surgery was 30.4 years, 62.3% (n = 63) of the patients were female, and the mean postoperative follow-up period was 20.6 months (range 12–30 months). The related patient data are shown in Table 1.

3D-Fabricated PCL Mesh Scaffold

Three-dimensionally fabricated PCL mesh (TnR mesh; T&R Biofab Co., Ltd, Siheung, Korea) was used. The full-size PCL mesh was 40 mm by 10 mm, with thicknesses of 0.8 mm or 1.0 mm. Its porosity was 50% with a pore size of 500 μm [7, 8]. Morphology of the mesh was observed using a field emission scanning electron microscope (FE-SEM) (S-4700; HITACHI Co., Tokyo, Japan) with an acceleration voltage of 10 kV.

Table 1 Demographics and surgery-related data

Variable	
Sex	
Male, *n* (%)	38 (37.6%)
Female, *n* (%)	63 (62.3%)
Mean age, years	30.4
Type of surgery	
Primary	42 (41.5%)
Secondary	59 (58.4%)
Type of graft used	
Spreader only	18 (17.8%)
Septal extension only	28 (27.7%)
Columellar strut only	5 (4.9%)
Spreader + septal extension	24 (23.7%)
Septal extension + columellar strut	14 (13.8%)
Spreader + septal extension + columellar strut	12 (11.8%)

Surgical Implantation Technique

The PCL mesh was implanted in spreader grafts, septal extensions for tip elongation or the septal pillar for tip projection, and columellar struts. A spreader graft was considered for cases with narrow bony vaults (inverted V deformity) or a short dorsal aesthetic line and deviation of the nasal septum [9]. In spreader grafts, the PCL mesh was trimmed to fit each case using scissors. The PCL mesh was fixed directly to the cartilaginous nasal septum by passing through a 5–0 polydioxanone or nylon suture, thus forming a horizontal mattress suture. Sometimes, harvested septal or rib cartilage was additionally placed between the 3D PCL mesh and medial cut of the upper lateral cartilage to increase the amount of spreader graft. For aesthetically short noses combined with inadequate tip projection, a septal extension graft or a columellar strut was used to control tip projection and rotation (Fig. 1). When autologous septal cartilage was available, usually in a primary case, a small segment of the autologous cartilage was inserted unilaterally, in addition to the PCL graft and strut, to decrease thick fibrous capsule formation around the PCL graft, which is regarded as a natural phenomenon in the presence of a foreign body. The specific surgical technique is presented in supplemental Video 1.

Outcome Measurement for Postoperative Appearances

For objective evaluation of aesthetic outcomes following rhinoplasty with a PCL graft, two plastic surgeons who were blinded to the purpose of the present study and to each other reviewed the preoperative and 18-month post-operative photographs using a standardized protocol. Four views, including front, full, semi-lateral, and worm's eye,

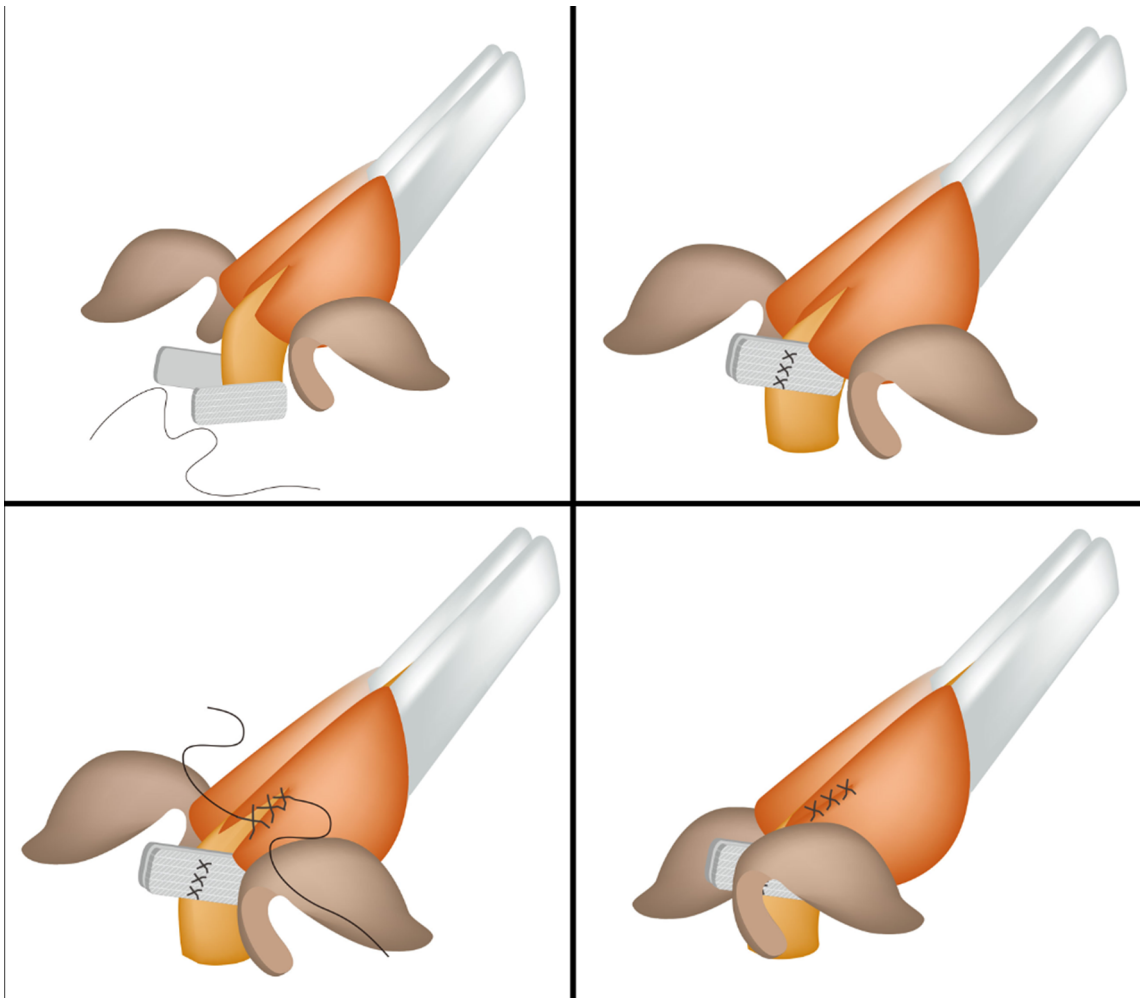

Fig. 1 Illustration demonstrating the septal extension graft (upper left). A small split of upper lateral cartilage for space of the septal extension graft (upper right). This graft is usually fixed to the septal angle margin forming an oblique 70-degree angle to the septal cartilage (lower left). Continuous sutures of incised upper lateral cartilage and (lower right) interdomal suture for coverage of the septal extension graft

were scored on a 4-point Global Aesthetic Improvement Scale (GAIS; 0 = worse, 1 = no change, 2 = improved, 3 = much improved, and 4 = very much improved) [9]. In patients who received spreader graft, the Cottle maneuver (Cottle sign) was performed at the preoperative and 18-month postoperative period to assess improvement in the nasal airflow, grading 1 to 4 points (1, no improvement; 2, mild improvement; 3, moderate improvement; and 4, significant improvement) on the Wilcoxon signed-rank test. For the analysis of improvement of NOSE score at postoperative status when compared to that at preoperative status, a paired *t* test was performed using SPSS, version 19.0, for Windows (SPSS, Inc., Chicago, IL, USA).

Histopathological Analysis of Implanted PCL Mesh

From two patients who wished to reduce the height of the nose and the projection of the nasal tip despite acceptable nasal appearance, we were able to obtain specimens at 18 and 20 months post-insertion of the PCL mesh graft for septal extension and columellar strut and its surrounding tissue. To investigate the biocompatibility and regenerative potential of 3D-printed PCL mesh, the biopsied specimen was analyzed histopathologically. The acquired specimen was inspected intraoperatively and prepared for histopathological examination under a light microscope, fixed in 4% formalin, and embedded in paraffin according to conventional histological methods. The sections were stained with hematoxylin and eosin (H&E), Masson's trichrome (MT) and Safranin O staining for identification of the newly regenerated chondrocytes. Immunohistochemistry staining for collagen types I and II was used as a soft tissue and cartilaginous tissue ingrowth marker.

Result

Of the 101 total cases, 59 (58.4%) were secondary cases and the remaining 42 (41.5%) were primary cases. PCL was preferentially selected when autologous cartilage tissue was not available due to its previous use in the primary rhinoplasty. The PCL graft was mostly used for septal extension grafts or pillar (78 patients), followed by spreader grafts (54 patients) and columellar struts (31 patients). Twelve patients (11.8%) underwent all three kinds of grafts. The other PCL graft combinations are described in Table 1.

Morphology of 3D-Printed PCL Mesh

Figure 2a shows the gross appearance of a 3D-printed PCL mesh, a sheet-type scaffold with uniform line width that comes in many sizes and thicknesses, so a suitable size for each patient can be selected. In microscopic morphological findings, fully interconnected triangular pores, which play a role in transporting material and inducing surrounding tissues and cells to grow in the mesh, could be observed (Fig. 2).

Surgery-Related Complications and Outcome of PCL Mesh

A long-term observation of 101 patients showed no definite graft warping, absorption, or contracture. The main PCL graft-related complication was infection, which occurred in two (2.0%) cases. Infection developed approximately 2 months (47 and 56 days) postoperatively in both cases and was accompanied by swelling and redness in the nasal dorsum and tip, without synthetic implant exposure on the skin envelope. Upon noticing these infection-related symptoms, injection of intravenous antibiotics was started, and the PCL graft was removed and the area was irrigated with povidone-iodine solution. Infection was well controlled postoperatively in both cases. Both patients with infection were heavy smokers (more than 20 units/day) and secondary cases (Table 2).

Regarding esthetic evaluation using GAIS scores at 18-month postoperative photographs with 98.0 of interrater reliability, most patients (97.0%) showed improvement; no change or worse change was observed in only three patients (Table 3) (Fig. 3). In the group with spreader grafts, the mean NOSE score of preoperative status was 3.62 and that of postoperative status was 1.66. A statistically significant decrease between preoperative and postoperative Cottle sign scores was observed ($p = 0.02$).

A Clinical Case of Histological Analysis of Implanted PCL Mesh: Neo-cartilaginous Tissue Formation

During removal of the grafted implant, we observed that the PCL mesh that had been previously inserted as a septal extension graft 20 months ago was well integrated into the surrounding host tissue. Moreover, significant fibrovascular tissue had grown into the PCL mesh graft pores grossly and these tissues maintained well as a scaffold structure for tip projection. In H&E staining under the lower-power field, preservation of the scaffold structure without any definite inflammation was observed (Fig. 4). Under a high-magnification field, material-related inflammatory cell infiltration was not detected except mild fibrosis surrounding the implant. Therefore, the implanted PCL mesh had no inflammation or immune response. Analysis of collagen type showed high positive staining for collagen types I and II within the pore structure around the PCL mesh (Figs. 5, 6). Type II collagen is specifically found in cartilaginous

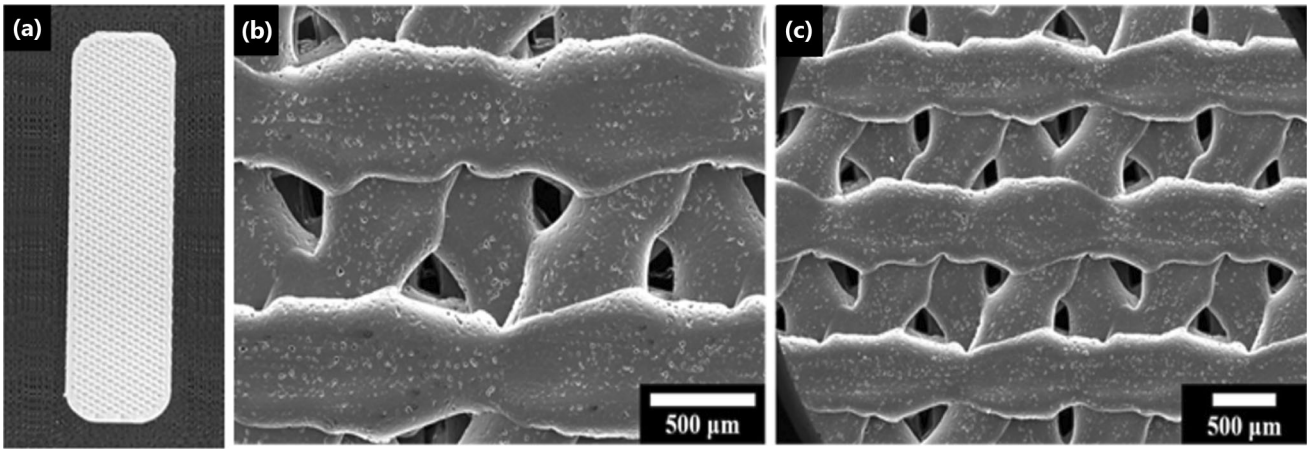

Fig. 2 Gross appearance and microscopic morphology of the polycaprolactone (PCL) mesh confirmed by field emission scanning electron microscope (S-4700; HITACHI Co., Tokyo, Japan). **a** Sheet-type PCL scaffold mesh with a uniform line. **b** and **c** Fully interconnected triangular pores in PCL mesh

Table 2 Summary of patients who had complications related to PCL graft

Case	Kinds of case	Kinds of PCL graft	Onset (days)	Smoking	Presentation	Treatment
2	Secondary	Septal extension	47	> 20 ea/days	Infection	IV antibiotics, removal of PCL graft
7	Secondary	Septal extension + columellar strut	56	> 20 ea/days	Infection	IV antibiotics, removal of PCL graft

Table 3 Long-term surgical outcome of 3D-printed polycaprolactone (PCL) mesh

Patient	Score	Number of patients (%)
Very much improved	4	91 (90.1%)
Much improved	3	0 (0%)
Improved	2	7 (6.9%)
No change	1	1 (1.0%)
Worse	0	2 (2.0%)

tissues (Fig. 6). In Safranin O staining, proteoglycans were confirmed as uniformly colored red along the pores inside the PCL mesh, and chondrocytes with a lacuna structure, which are a distinct feature of cartilaginous tissue, were observed at high magnification, indicating that the newly formed tissue consists of neo-cartilaginous tissue (Fig. 7). Specific patient history and serial progress of this patient are demonstrated in Fig. 8.

Discussion

Most surgeons prefer autologous cartilage in donor sites from the nasal septum or rib cartilage because this cartilage is associated with a lower risk of graft-related complications than alloplastic materials. However, an increasing rate of primary rhinoplasty in young patients coupled with a higher expectation from surgery has increased the demand for revision rhinoplasty in recent years [10]. As a result, autologous cartilage is frequently absent. Furthermore, regarding septal extension grafts for the nasal tip in Asian patients, autologous septal cartilage seems to be weaker and smaller in Asian patients. Therefore, the amount of autologous septal cartilage is sometimes insufficient to perform effective tip modification. Additionally, donor-related complications have been reported. Specifically, harvesting of septal cartilage may weaken the supporting structure of the nose, resulting in collapse due to mechanical loading from the skin and soft tissue over time. Autologous costal cartilage can also be used for grafting. Typically, there is abundant rigid cartilage available for use. However, two main concerns of using this type of cartilage are warping, which can reach rates as high as 10%, and donor morbidities such as postoperative pain, chest scarring, and risk of pneumothorax [11].

Considering these disadvantages, the use of alloplastic materials for grafts is extremely attractive. Several absorbable copolymers, namely PDO and PLLA, have been used in rhinoplasty. PDO-absorbable sheets, which are frequently used as supporting material (i.e., in columellar struts and dorsal onlay grafts in simple rhinoplasty), are rapidly resorbed and are generally eliminated from the body in approximately 6 months. Therefore, it is difficult

Fig. 3 A 40-year-old patient who had low height of nose and underwent an operation on the columellar strut. Preoperative frontal and lateral images showing low height of nose (white arrow, left upper and lower). Three-month postoperative frontal and lateral images showing change of nose height (middle upper and lower). Twenty-month postoperative frontal and lateral images showing good maintenance of nasal height and tip projection (right upper and lower)

to maintain the elasticity and durability of the plates in a supporting structure such as a spreader graft or septal extension graft, which are usually used in combination with an autologous cartilage graft [12, 13]. PLLA degrades very slowly into lactic acid and replaces fibrovascular tissue; this process can take up to 2 years [14]. Despite this advantage, the acidic metabolites of PLLA produced during the degradation process are still problematic. Thus, a potential risk of infection or inflammation remains under the nasal cavity, where nasal discharge is always present [13]. Furthermore, PLLA is usually hard and brittle; this property is beneficial in supporting structures such as columellar struts or spreader grafts, but hinders its use in tip extension, where the prominent and sharp rigid graft angles should be hidden to enable the graft to remain soft and movable [15].

Polycaprolactone (PCL) was one of the earliest polymers prepared by ring opening polymerization of ε-caprolactone using a variety of anionic, cationic, and coordination catalysts. PCL safely degrades into CO_2 and H_2O and was used in early drug delivery devices and absorbable suture materials due to its slow degradation and biocompatibility [4]. For use as the supporting structure in rhinoplasty, three superior rheological and viscoelastic properties of PCL mesh over many of its resorbable polymer counterparts are relevant. First, the PCL mesh used in the present study was made by 3D-printing, enabling it to have a three-dimensional cross-stripe design with a micropore structure. This structure allows adequate mass transport of nutrients for vascularization and washout of acidic metabolic waste, which stimulates inflammatory reactions to facilitate cellular infiltration and guides tissue regeneration [4]. The 50% porosity and 500 μm pore size of PCL mesh used in the present study are thought to be adequate for enhancing cell growth and maintaining durability for sufficient mechanical resistance; this has been proven in a previous animal study reporting that prominent soft tissue ingrowth and neo-vascularization without postoperative infection or inflammation were observed in implanted PCL mesh with this porosity and pore size [7, 8]. Actually, according to the histological results of in vivo biopsies, neither inflammation nor any immune response was observed around grafted PCL mesh, demonstrating that the degradation metabolite of PCL mesh is safe. Second, PCL mesh has relatively high elasticity, making it a good match for nasal cartilage of living tissue at implantation. Thus, outcomes similar to cases using only autologous cartilage can be expected. In particular, the relatively high elasticity of PCL allows the surgeon to manipulate the mesh easily into elaborate segment shapes, even thin and

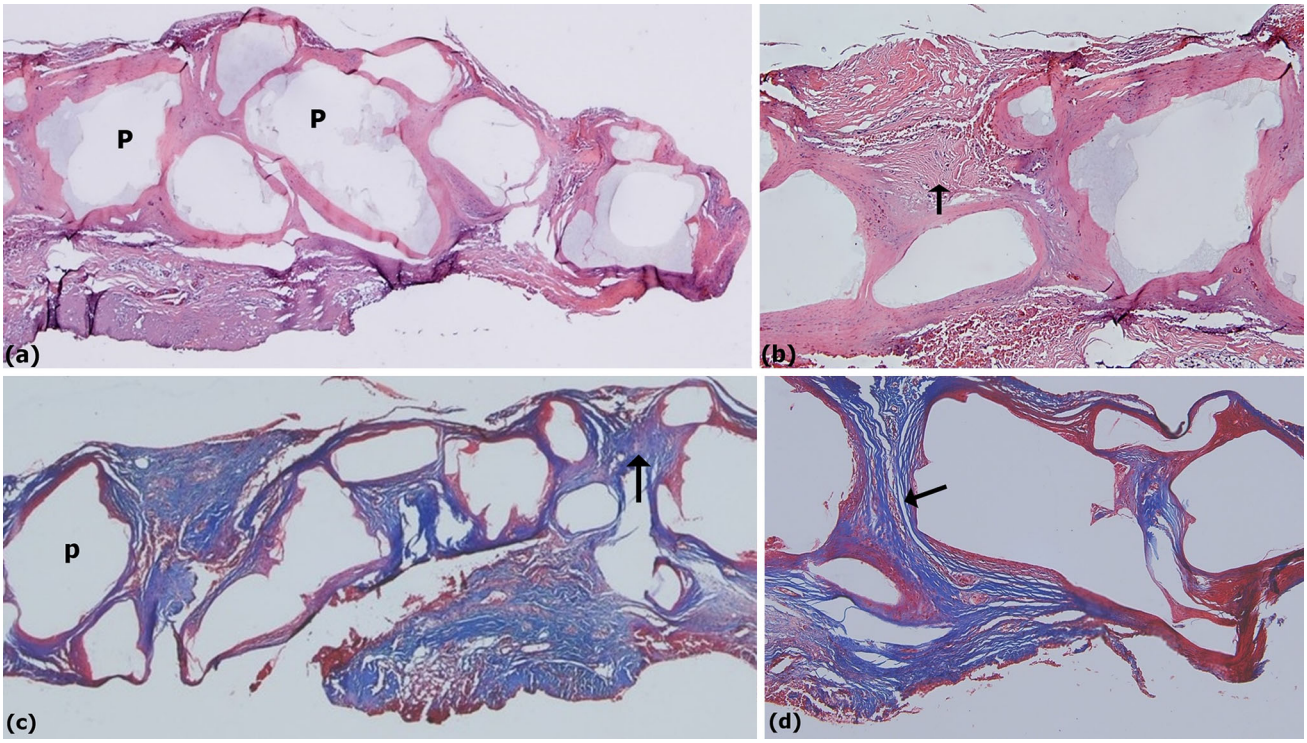

Fig. 4 H&E and MT staining images are shown. No inflammation or any immune response was observed. **a**, **b** Histological image of H&E staining; **c**, **d** histological image of MT staining. P: cavity of grafted PCL mesh, black arrow: fibrovascular tissue (original magnification: 40 × (surrounding host tissue in a critical-sized rabbit, **c**), 100 × (**b**, **d**))

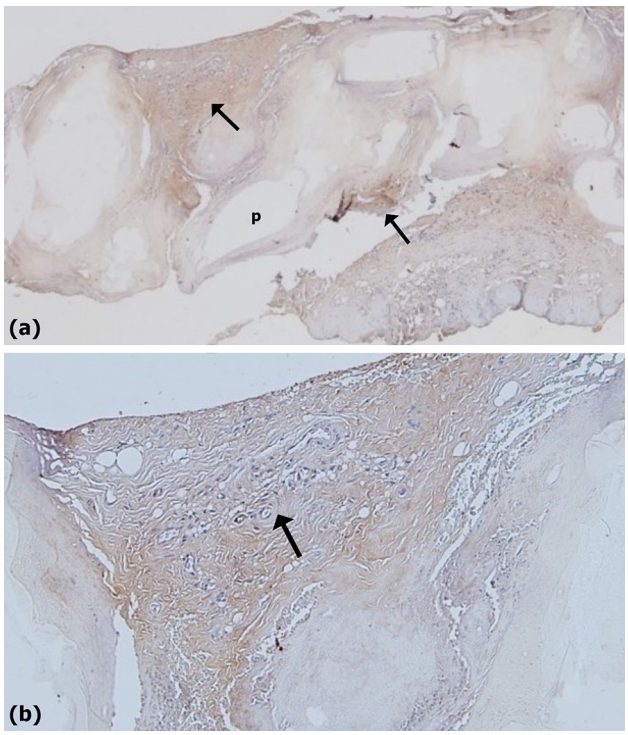

Fig. 5 Immunohistochemistry staining of collagen type I is shown in brown. Each collagen is indicated with black arrow lines. P: cavity of grafted PCL mesh (original magnification: 40 × (**a**), 100 × (**b**))

slender spreader grafts and columellar struts, with scissors alone. Furthermore, the advantage of easy manipulation can lead to a decrease in overall operative time. Third, bioabsorbable PCL mesh has controllable degradation and resorption rates to match the surrounding living tissue ingrowth. Although there are still fundamental concerns related to the ultimate outcome when this biodegradable material is completely resorbed, which could lead to a drooping tip, we believe that retention of this biocompatible material for a 24-month period is sufficient to allow for fibrosis to stabilize the augmented nose in its corrected position; this is because PCL degrades more slowly (up to 3–4 years) than other absorbable alloplastic materials [11–14]. This degradation period is sufficient for the PCL graft to integrate with and be replaced by viable host tissue. Based on these properties, we attempted to apply 3D-printed PCL mesh to augmentation rhinoplasty for spreader, septal extension or pillars, and columellar struts. We showed that the use of this novel biodegradable PCL implant for rhinoplasty is safe and effective in terms of maintaining its volume without postoperative foreign body reaction or special abnormal reaction. Good aesthetic outcomes, evaluated by two blinded plastic surgeons, were acquired with demonstrable improvement in tip projection and nasal extension.

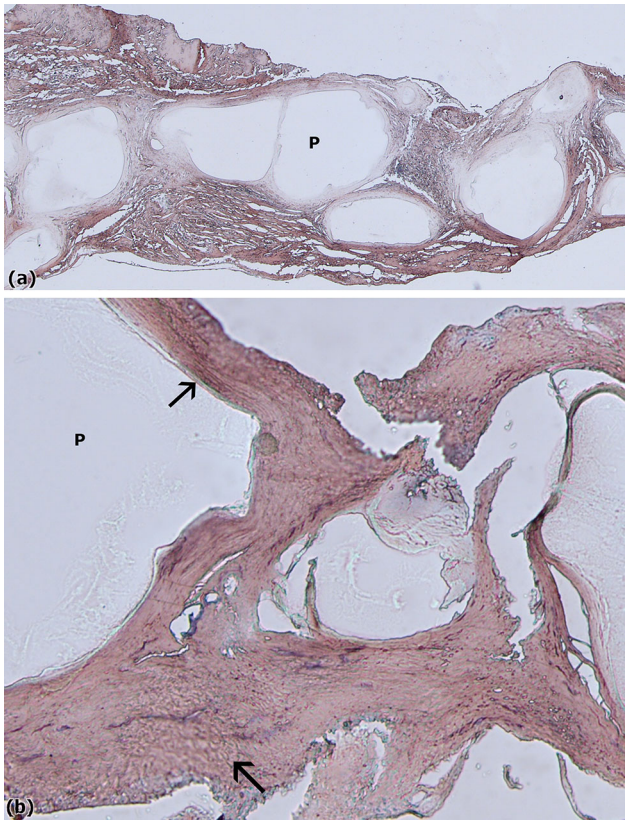

Fig. 6 Immunohistochemistry staining of collagen type II is shown in brown. Each collagen is indicated with black arrow lines. P: cavity of grafted PCL mesh (original magnification: 40 × (**a**), 100 × (**b**))

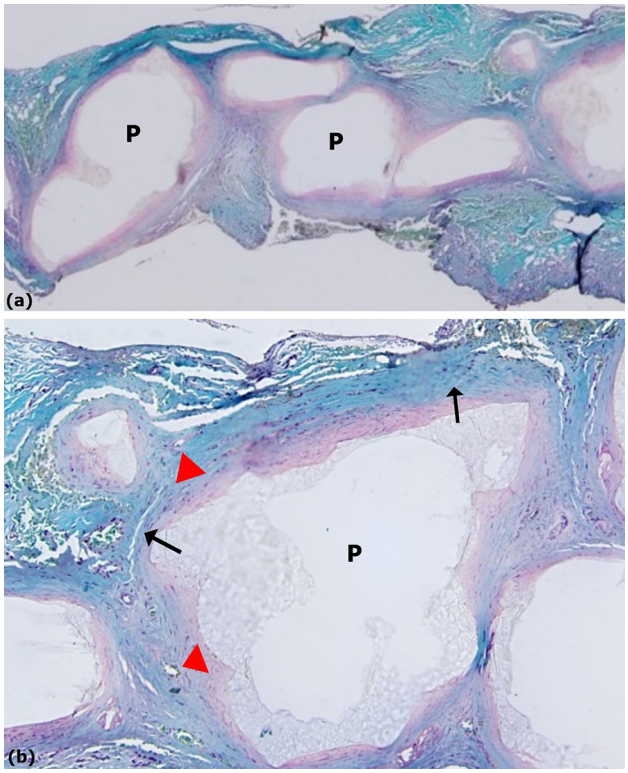

Fig. 7 In Safranin O staining of chondrogenesis, positive staining of proteoglycan (red) is markedly noted around outer margins of the grafted PCL mesh; space of grafted PCL implant (P) was well maintained. In a high-magnification field, the chondrocyte and lacunae (black arrow) characterized by specific structure for the chondrocyte were noted. P: cavity of grafted PCL mesh (original magnification: 40 × (**a**), 400 × (**b**))

Both cases of infection were revision cases; revision is known to be strongly associated with hypovascularity. This hypovascularity originates from disruption of the soft tissue envelope and multiple operation times, which make the nose more vulnerable to infection [11]. Furthermore, these patients were active, heavy smokers. Smoking is predicted to interrupt PCL graft integration into host tissue and reduce graft vascularization, thereby increasing potential risk of infection. Although PCL has a 3D and microporous structure, the use of this alloplastic material should be carefully considered in decreased perfusion regions, including severe scarring, and in patients with a previous history of allograft implantation and infection.

An advantage of the PCL mesh graft is that it is not just an implant, but also a biocompatible scaffold that enhances vascular and soft tissue ingrowth through its pores and regeneration into host tissue. Recent work in tissue engineering has aimed to develop a structurally and mechanically sound scaffold that promotes tissue repair or acts as a replacement. Using PCL mesh seeded with autologous mesenchymal progenitor cells and osteoblasts, Schantz et al. [16] reported histological evidence of neo-bone formation with partial integration into the surrounding host tissue in a critical-sized rabbit calvarial defect. Although a previous animal study that reported the short-term histological results of the PCL scaffold in rabbit augmentation rhinoplasty did not observe neo-chondrogenesis in a biopsy of the construct [6], our histological examination, which was of long term (more than one and half years), revealed the presence of type II collagen and chondrocytes in high density on the newly formed tissue within the pore structure around the PCL mesh. In other words, regeneration of chondrocytes and neo-cartilaginous tissue requires a long period of time with PCL mesh in and around the PCL mesh. This result may be due to the biocompatibility of PCL, which allows the grafts to infiltrate well into the host tissue and to regenerate the soft tissue, including chondrocytes.

Furthermore, other extracellular matrices (ECM) such as proteoglycan were also established uniformly along the pores inside the PCL mesh. This suggests that the PCL mesh has potential as a biocompatible scaffold that optimizes the formation of adjacent neo-tissues such as ECM. It may provide a vascularized layer that acts as an additional barrier for thin nasal skin flaps, even in the event of exposure, and provide tissue support, especially in the

Fig. 8 A 29-year-old patient who had a complaint of low tip projection and underwent revisional rhinoplasty using septal extension and a columellar strut. Preoperative frontal and lateral images showing tip drooping and crater (white arrow, left upper and lower). Twenty months after the first revisional rhinoplasty, frontal and lateral images showing maintenance of acceptable tip projection (middle upper and lower). Twenty-six months after the second implant removal surgery, frontal and lateral images after the removal of all implants except the septal extension PCL graft showing good maintenance of nasal tip projection (right upper and lower)

columellar and nasal tip area. Actually, although most patients included in the present study were secondary cases, we did not experience the occurrence of PCL mesh graft extrusion or mobilization. Furthermore, according to follow-up progress for the case patient who removed all implants except the PCL septal extension graft, nasal tip projection has been well maintained for a long-term period; we suggest that this result is attributable to the role of PCL mesh graft as a biocompatible scaffold providing mechanical tissue support.

This study has several limitations. Because of the retrospective study design, outcomes reported in the present study were based on the relatively subjective measurement of the preoperative and postoperative photographs by plastic surgeons. Further study with a prospective design based on the actual measurement of the nasal tip or nasolabial angle should be conducted. Regarding specific surgical techniques using PCL grafts, this study could not analyze the effect of autologous cartilage in addition to PCL and has not yet concluded whether this combination is necessary because of the small number of subgroups. An outcome study based on the comparison between PCL only and composite PCL groups is warranted in the future. Nevertheless, to the best of our knowledge, our study is the first long-term outcome study reporting safety and usefulness of 3D-printed PCL mesh in rhinoplasty. In conclusion, given its availability, ease of use, well-documented clinical safety, and exceptional biocompatibility inducing regeneration of soft tissue, PCL is an optimal alternative for fashioning spreader grafts and septal extension grafts when autologous material is not available.

Conclusion

The present study demonstrates that the use of a novel biodegradable PCL implant for rhinoplasty is safe and effective in terms of maintaining its volume without any postoperative foreign body reaction or special abnormal reaction. This mesh could serve as a scaffold to form neocartilaginous tissue through movement of adjacent cartilaginous tissues. Furthermore, PCL mesh as a spreader graft is beneficial for postoperative functional improvement in airway obstruction. These results show that a PCL mesh with 3D structure is the most suitable alternative to nonabsorbable materials in rhinoplasty and reconstruction surgeries and may have a wide range of applications, such as in the fashioning of spreader grafts and septal extension grafts.

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