

Silicone-Polytetrafluoroethylene Composite Implants for Asian Rhinoplasty

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Background: Silicone and Gore-Tex implants are mainstays of Asian rhinoplasty. Silicone implants are inexpensive and wieldy, but may elicit a foreign-body reaction and are prone to migration. Gore-Tex implants are more biocompatible and capable of ingrowth but expensive. Silicone-polytetrafluoroethylene (PTFE) composites have a silicone core and PTFE liner. Composite implants have been marketed for several years, but are not yet established alternatives for rhinoplasty because of a lack of relevant reports.

Methods: From February 2012 to June 2015, 177 Asian patients underwent primary (n = 63) or secondary (n = 114) rhinoplasty using an I-shaped composite implant. One hundred fifty-nine women and 18 men were 19 to 72 years old (mean, 34 years) at the time of surgery. Composite implants were 1.5 to 5 mm thick and 3.8 to 4.5 cm long. Autologous cartilage from the septum, concha, or both was used for tip refinement in every case. Glabellar augmentation was performed in 19 (10.7%) cases.

Results: Follow-up was 6.0 months (range, 1–36 months). There were 19 (10.7%) complications including malposition/deviation (4.5%), erythema (2.3%), and infection (1.1%). Four patients were unsatisfied, citing inadequate dorsal height correction. There was an 8.8% revision rate; 7 of 12 revisions were for malposition/deviation. We did not observe implant step-offs or extrusion. There were no differences in outcomes after primary or secondary rhinoplasty, although there was a trend toward higher infection rate after primary rhinoplasty ($P = 0.06$).

Conclusions: I-shaped silicone-PTFE composite implants are feasible for both primary and secondary augmentation rhinoplasty in Asians. Early outcomes data suggest an overall complication rate that is comparable to PTFE alone.

Key Words: Asian rhinoplasty, composite, Gore-Tex, dorsal augmentation, aesthetic, outcomes, feasibility

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Asian rhinoplasty is distinguished from white rhinoplasty by its typical augmentative nature. Accordingly, the focus of consultations and clinical research in East Asia is dorsal augmentation. An expansive literature investigates ways to minimize complications and maximize results in this population. Although many would argue that the ideal implant material is autologous costal cartilage or a dermal graft,^{1–4} donor resources may not be reliable or available. Furthermore, donor site risks and visible scars cannot be ignored, and warping or absorption may occur.⁵ For their limitless availability, time savings, predictability, and technical ease, it is understandable why alloplastic implants have become the mainstay for dorsal augmentation rhinoplasty.^{6,7} Still, current trends in Asian rhinoplasty favor prosthetic-autologous constructs, reserving alloplast for the dorsum and autologous graft for tip refinement.⁸

Considerations for implant choice include shape, size, and material. Shape and size are patient-dependent and evaluated on a case-by-case basis. Silicone and expanded polytetrafluoroethylene (PTFE, Gore-Tex; W.L. Gore & Associates, Phoenix, AZ), the 2 most popular materials in Asian rhinoplasty⁹; each featuring unique strengths and weaknesses.^{10–12} Silicone is more stable and easy to use than PTFE, but may be challenging to camouflage. Implant failure is reported more frequently for silicone than PTFE with capsule formation and occasional contracture.¹⁰ Polytetrafluoroethylene is microporous and amenable to tissue ingrowth with little inflammatory reaction, but is flimsy, may lose height over time,¹³ is expensive, difficult to carve, and may be difficult to remove in secondary operations.

No alloplast is immune to extrusion and infection. In a systematic review, Lee et al⁴ identified a 2% to 4% extrusion rate, 4% infection rate, and 3% displacement rate when silicone was used. In comparison, there was a 1% extrusion rate and 1% to 3% infection rate when Gore-Tex was used. A superior alternative would exploit biomechanical features of silicone and the biocompatibility of PTFE. Rib-PTFE composites have been described,¹⁴ but these carry risks of alloplast and donor site morbidity. The Implantech Composite nasal implant (Implantech, Ventura, CA) is the only available prosthetic consisting of flexible silicone bonded to a 0.3-mm PTFE shell (Fig. 1). It is available as a straight (dorsal nasal) or L-shaped (dorsal columella) implant in various sizes.¹⁵ It was designed for improved integration and stability. In Taiwan, the product is marketed as Chimera, and in Korea, the implant is marketed as Silitex.

In theory, a silicone-PTFE composite might perform as well as Gore-Tex implants with the workability of traditional silicone implants. Unfortunately, there are no series or reports of composite implant outcomes, to the authors' knowledge—other than brief mentions in textbooks^{16,17} and one review.¹⁸ Further data are needed to support ongoing use, and to validate the comparatively high cost of composite implants. The present study examines outcomes and complications of a rhinoplasty technique that includes I-shaped silicone-PTFE composite implants. The purpose of this series was to describe early outcomes of this technique and compare composite implant findings with those of similar studies in Asian patients using Gore-Tex or silicone alone.

MATERIALS AND METHODS

Chart data and photographs of 177 patients who underwent augmentation rhinoplasty by the senior surgeon using Chimera composite implants from February 2012 to June 2015 were reviewed. All patients were Asian, most of Taiwanese extraction, and 34 years old at the time of surgery (range, 19–72 years). Eighteen men and 159 women were treated. All cases were categorized as primary or secondary (regardless of the number of revisions); there were 63 (35.6%) primary cases and 114 (64.4%) secondary cases. Table 1 summarizes demographic data of patients studied. In 42 patients with preexisting implants, 36 (85.7%) were L-shaped, 6 (14.3%) were I-shaped, 32 (76.2%) were silicone, 9 (21.4%) were composite, and 1 (2.4%) was autologous rib. Six patients were previously treated with fillers. Complications were evaluated for positional displacement, contour irregularities, exposure, and infection.

Exposure and Management of the Nasal Tip

All procedures were performed at this institution under general anesthesia. An external (open) approach was used in every case. In

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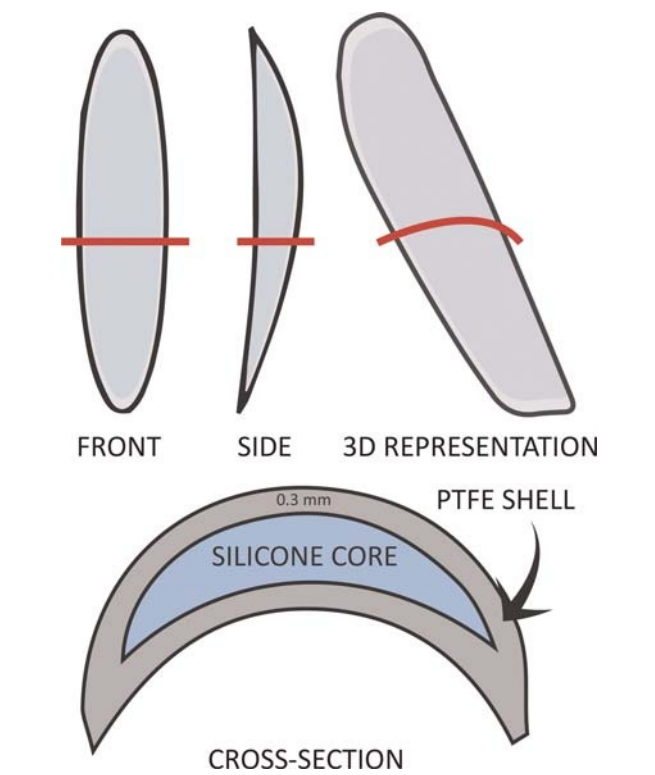


FIGURE 1. Schematic of a composite implant (adapted from Implantech Product Catalogue, Superior Products for Facial Contouring. Implantech Catalog. Ventura, CA: Implantech, 2011). Adaptations are themselves works protected by copyright. So in order to publish this adaptation, authorization must be obtained both from the owner of the copyright in the original work and from the owner of copyright in the translation or adaptation.

primary cases, the desired site of augmentation was marked before instillation of local anesthetic. A midcolumellar inverted-V incision was made and the alar cartilages were exposed through a marginal approach. Supraperichondrial dissection proceeded along the lower lateral

TABLE 1. Patients' Information

	All Patients	Chimeric	Traditional	P*
n	49	19	30	
M/F, n	5:44	2:17	3:27	0.954
Age, y	31.8 ± 12.3	28.3 ± 11.7	34.0 ± 12.4	0.111
Type, n (%)				
Primary	34 (69.4)	15 (78.9)	19 (63.3)	0.257
Secondary	15 (30.6)	4 (21.1)	11 (26.7)	
Previous implant	8	3 (15.8)	5 (16.7)	0.717
Indication				
Cosmetic, n (%)	41 (83.7)	13 (68.4)	28 (93.3)	0.021
Trauma, n	3	2	1	
OGS, n	4	3	1	
Cleft lip, n	1	1	0	

*Comparing chimeric and traditional groups, $P < 0.05$ is considered significant.

OGS indicates combined with orthognathic surgery.

cartilage (LLC) and upper lateral cartilage and transitioned to subperiosteal dissection at the nasal bone. Minor dorsal humps were addressed by rasping in most cases; the base of the implant was carved for optimal apposition only when necessary. The LLCs were released from the upper lateral cartilages at the scroll area and the medial crura were teased apart to expose the septum via submucoperichondrial dissection when septal cartilage was harvested.

The nasal tip was addressed first using autologous conchal or septal cartilage (Fig. 2). Tip projection was achieved with a small septal extension graft flanked by 2 extended spreader grafts, a tip graft and a shield graft, and tailored to cartilage supply, deficiencies, and aesthetic goals (Fig. 3). A columellar strut was used to reinforce the tip, when necessary.

Nasal Dorsum

Attention was turned to dorsal augmentation. A subcutaneous pocket was conservatively dissected for a “hand-in-glove” fit with an appropriately sized I-shaped (straight) composite implant. One of 4 implant sizes was chosen, guided by silicone sizers. Implant thickness was determined by skin characteristics and desires. After removal from sterile packaging, implants were handled with clean instruments, fresh gloves, and minimal handling. Before insertion, a 50-mL syringe was

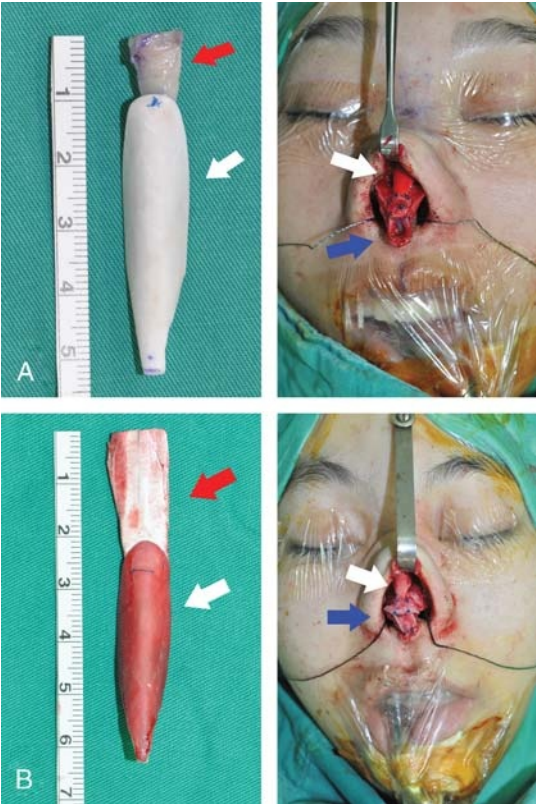


FIGURE 2. A, A 30-year-old woman underwent primary rhinoplasty with glabellar augmentation using conchal cartilage (red arrow); a 4.5-mm-thick, 4.5-cm-long I-shaped composite implant (white arrow); and tip grafting with septal and conchal cartilage (blue arrow). There were no complications. B, A 23-year-old woman underwent primary rhinoplasty for posttraumatic nasal deformity with alar reduction; glabellar augmentation using Gore-Tex (red arrow); a 5-mm-thick, 5-cm-long I-shaped composite implant (white arrow); and tip grafting with septal and conchal cartilage (blue arrow). There were no complications.

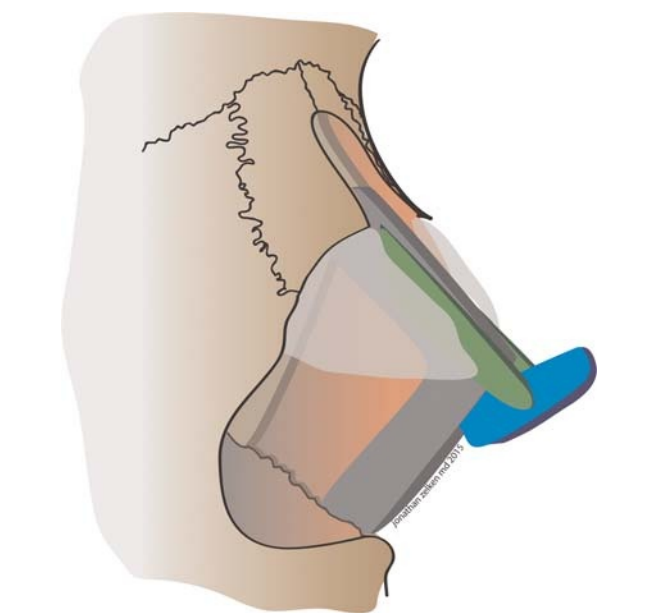


FIGURE 3. The senior author's approach to tip refinement in Asians includes extended spreader grafts (green) and a septal extension graft (blue). Durability depends on cantilever-type load transmission across the spreader grafts and the dorsal septum. Additional support is derived from direct abutment and load transmission through the caudal septum. A partial-length septal extension graft is easy to manipulate, does not influence columella position or nasolabial angle, and requires less cartilage.

filled with a first-generation cephalosporin solution and the implant was placed in that syringe. The stopper and a cap were replaced after letting the air escape and the plunger was withdrawn to create a vacuum and facilitate antibiotic solution to bathe every pore of the PTFE lining. The implant was inserted into the pocket after the recipient site and implant were rinsed with antibiotics.

The implant was positioned so that the lower pole of the implant abutted the cephalic margin of the lateral crura just lateral to the tip-defining points. The upper border of the implant was positioned at the level of the intercanthal line. If the patient requested a higher radix, then the upper border was positioned at the level of the supratarsal crease. Two 5-0 monofilament nonabsorbable sutures were used to loosely fix the PTFE layer of the implant to the lateral crura of the LLCs to

maintain position. After appropriate contour was achieved, hemostasis was obtained, and the mucosa and skin were closed in 1 layer. When applicable, quilting transfixion sutures were used to obliterate dead space between mucoperichondrial flaps and prevent hematoma. Closure with 4-0 chromic suture, tape, and splints were used in every case. Patients were typically discharged on the day of surgery; tape and splints were removed after 1 week. All patients completed a 1-week course of oral antibiotics postoperatively.

Glabella

In suitable and willing candidates, the composite graft was augmented with a trapezoidal appendage fixed with 1 or 2 interrupted 5-0 nonabsorbable mattress sutures for glabellar augmentation. The material used was either autologous conchal cartilage (Fig. 2A) or PTFE (Fig. 2B). That decision was made on an individual basis and depended on the patients' budget and donor resources. Patients with small ears or previous rhinoplasty may not have adequate donor cartilage. The pocket shape and size was determined by the anatomy, and the graft or implant was shaped for a hand-in-glove fit. The glabellar implant was carefully delivered into position using a fine hemostat and assessed in the lateral view for contour.

Paranasal Augmentation

When indicated, paranasal augmentation was achieved using ready-made 4.5-mm porous polyethylene implants (Medpor; Porex Surgical, Inc, Newnan, GA). A subperiosteal pocket was created through vestibular incision above the root of the central incisor at the level of the canine eminence and implants were tailored as needed to the depressed recipient site. Two 10-mm miniscrews were used to fix each implant into position. The mucosa was closed bilaterally with interrupted sutures.

Outcomes and Comparisons

Demographic data and outcomes were summarized by descriptive statistics using Microsoft Excel 2011 (Microsoft Corp, Redmond, CA). Outcomes after primary and secondary cases were compared using the 2-tailed Student *t* test using SPSS software (SPSS, Inc, Chicago, IL; version 17.0). Significance was established with values of *P* < 0.05.

RESULTS

Operative details for this series are summarized in Table 2 and representative cases are shown in Figures 4 and 5. All patients underwent hybrid autologous-prosthetic augmentation rhinoplasty featuring an I-shaped silicone-PTFE composite implant. Implants used were, on average, 4.1 cm long (range, 3.8–4.5 cm) and 3.7 mm thick (range,

TABLE 2. Photogrammetric Parameters

Parameter	Abbreviation	Formula	What It Tells Us
Profile			
Nasofrontal angle	NFA	Angle between G', <i>se</i> , <i>prn</i>	Depth of radix (180 degrees = no radix)
Nasal height index	NHI	(<i>se</i> – <i>sn</i>) ÷ (G' – Pg')	Length of nasal dorsum
Bridge length index	BLI	(<i>se</i> – <i>prn</i>) ÷ (G' – Pg')	Height of nose
Radix			
Horizontal position index (postoperative)	xI (xI')	xI ÷ (Co – Ca)	How far anterior radix is
Vertical position index (postoperative)	yI (yI')	yI ÷ (Co – Ca)	How superior the radix is
Vertical/horizontal ratio	VHR	yI' ÷ xI'	Reflects radix <i>position</i>
Hsiao ratio	HR	abs[(yI' – yI) ÷ (xI' – xI)]	How the position of the radix has <i>changed</i> (Fig. 5A)

abs indicates absolute value; Ca, canthus; co, most anterior point of cornea; G, glabella; Pg', pogonion; *prn*, pronasale; *se*, sellion; *sn*, subnasale.



FIGURE 4. Preoperative (above) and 3-month postoperative (below) appearance of patient presented in Figure 2A.

1.5–5.0 mm). Glabellar augmentation was performed in 19 (10.7%) patients, wherein PTFE was used more often (63.2%) than conchal cartilage (36.8%). Glabellar implants measured an average of 1.8 cm on the upper border, 1.5 cm along the lower border, were 1 cm tall, and 1.3 mm thick. Paranasal augmentation was performed in 4 (2.3%) patients.

Seventeen (9.6%) patients had alar reduction, 1 patient had alar augmentation, 20 (11.3%) patients required nasal osteotomies, and 4 (2.3%) patients required inferior turbinectomy.

Average follow-up was 6.0 months (range, 1 months–3 years). Nineteen (10.7%) patients had complications, and one or more revisions



FIGURE 5. Preoperative (above) and 8-month postoperative (below) appearance of patient presented in Figure 2B.

were necessary in 12 (6.8%) patients. Eight (4.5%) patients had persistent or new deviation or malposition of the implant. This was the most common complication and required revision in 7 cases (66.6% of revisions). Four (2.3%) patients were unhappy with the cosmetic result, citing inadequate height correction. Revisions were performed in all 4 cases (33.3% of revisions). Four (2.3%) patients had idiopathic persistent postoperative erythema that was not infectious in nature and did not respond to antibiotics (Fig. 5). Two (1.1%) patients had postoperative infection. In one case, the infection was successfully managed with antibiotics. In the other, the infection did not respond to oral antibiotics, and the implant was removed and replaced. Complications and indications for revision are summarized in Table 3. There were zero implant exposures and zero capsular contractures reported or observed during the follow-up period.

DISCUSSION

The Departments of Health in Korea and Taiwan approved composite rhinoplasty implants in the past 5 years. Chimera is the trade name for the composite implant used in Taiwan, chosen perhaps to reflect the hybrid nature of the product. The senior author takes the hybrid concept one step further by supplementing the prosthesis with autologous cartilage in the tip and columella, and in some cases, the glabella. The decision to incorporate multiple materials in augmentation rhinoplasty address current controversies that exist, each material being handpicked to reflect current trends and evidence in Asian rhinoplasty.^{4,8,9,14} The senior author prefers the composite implant because it is just as stable and controllable, but maintains its position better than silicone implants, has an acceptable infection rate, and there is low capsule formation or prominent step-off.

Advantages of Composite Prostheses

The porosity of PTFE is amenable to ingrowth and positional maintenance. We observed an implant malposition rate of 4.5% overall; there was no difference after primary or secondary surgery. This warranted revision surgery in 7 of 8 cases, and was the most common

indication for revision surgery. In 406 Asian patients undergoing silicone rhinoplasty, Zeng et al¹⁹ reported implant “maldirection” in 9.4%, accounting for nearly 40% of complications encountered. The authors also reported a mobile prosthesis in 76.5%. In contrast, Hong et al¹¹ reported implant displacement in 1.2% of 257 Asian patients who underwent “hard-type” Gore-Tex rhinoplasty with long-term follow-up.

Theoretical risks of bacterial colonization and infection of a porous surface may be attributed to increased surface area and a complex topography. Two (1.1%) patients in this series had an infection; one required surgical treatment. Hong et al reported an infection rate of 3.5% of 257 patients with Gore-Tex prostheses after 34 months' follow-up, which was consistent with data obtained from large Western series (3.2%–3.7%).^{4,11,20,21} Other series reported infection rates of 0%–5.3% when silicone prostheses were used in Asian patients.^{22–26} The assuring infection rate in this series may be explained in part by pre-treatment with antibiotics, exclusive use of I-shaped implants, or short follow-up. As such, there are too many variables to generate meaningful comparisons across studies, but the infection risk of PTFE implants does not seem to be significant at 6 months.

Polytetrafluoroethylene has demonstrated biocompatibility and a minimal foreign-body reaction for nearly half a century. The concept of lining silicone with PTFE to curb that reaction is not new,^{27,28} although rhinoplasty applications are more recent. The PTFE lining provides additional width that improves camouflage and improved contour, for example, at the nasal bridge. We did not observe visible transitions at the implant boundaries in this series even when patients achieved the “surgical look” or white profile they desired. This may be attributed to glabellar augmentation with a contiguous implant in 11% of patients, implant design, and meticulous technique including beveling implant and cartilage edges. However, material properties of PTFE probably play an important role. Zeng et al reported steplike deformities in 6.4% of 406 Asian patients with silicone implants, and Hong et al reported the same in 3.2% of 257 patients with Gore-Tex implants.^{11,19}

Disadvantages of Composite Prostheses

Four (2.3%) patients in this series demonstrated persistent erythema over the implant (Fig. 6). We do not know whether if implant material is implicated; Zeng et al¹⁹ reported persistent or permanent color changes in 0.6% of Asians with silicone implants. Conrad et al²⁰ reported a soft tissue reaction in 4 (0.6%) of 685 Gore-Tex implants but did not elaborate further. The same authors described occasional hyperemia that did not respond to antibiotics in a similar review 10 years earlier²⁹; presumably, it was the same phenomenon. In Hong's series, and many others that evaluate Gore-Tex, persistent hyperemic change was not mentioned.¹¹ We did not manage erythema with surgery and therefore it was not an important cost-generator. However, persistent erythema can be a source of patient dissatisfaction and the authors are currently investigating ways to prevent and mitigate or cure erythematous change. Possible causes of the condition include a delayed hypersensitivity reaction, localized dysvascularity, and rosacea. It has yet to be determined if corticosteroids serve a definitive therapeutic role.

Although the porosity of PTFE serves to anchor the implant in position, it may pose a challenge when implant removal is necessary. Unlike silicone implants that can be removed with ease, and through a closed approach, the authors recommend an open approach for composite implant removal. The implant should be exposed as widely as necessary to ensure that the PTFE lining does not delaminate from the inner silicone core and no prosthetic material is retained.

The significance of maintaining the integrity of the 0.3-mm PTFE lining is not well understood, and its thinness makes the prostheses difficult to refine and shape. The more the preformed implant is recontoured and PTFE stripped, the more it biologically resembles a silicone implant. The authors do not recommend breaching the PTFE lining when possible, although it is often necessary. To maximize contact

TABLE 3. Outcomes

Parameter	Chimeric	Traditional	P*
n	19	30	
Follow-up, mo	9.7 ± 6.8	11.6 ± 7.7	0.372
VHR, postoperative	0.95 ± 0.71	1.51 ± 1.25	0.09
Change, all cases†			
NHI, increase, %	107.3 ± 8.4	112.7 ± 9.1	0.005
BLI, increase, %	104.8 ± 7.6	117.6 ± 13.3	<0.001
NFA change, degrees	5.6 ± 4.7	5.8 ± 3.9	0.88
Hsiao ratio	0.59 ± 0.56	3.35 ± 2.81	<0.001
Vector of translation, degrees‡	26.1 ± 19.1	63.4 ± 18.5	<0.001
Change, primary cases only			
n	15	19	
NHI, increase, %	108.5 ± 9.1	113.2 ± 8.6	0.13
BLI, increase, %	106.3 ± 7.9	116.9 ± 9.8	0.002
NFA change, degrees	5.4 ± 4.9	5.4 ± 4.4	0.98
Hsiao ratio	0.68 ± 0.60	3.69 ± 3.26	0.001
Vector of translation, degrees	29.2 ± 20.2	64.4 ± 17.0	<0.001

*P < 0.05 is considered significant.

†Compared to preoperative measurements.

‡Angle of radix position translation = $\arctan(\text{Hsiao ratio})$ in degrees.

BLI indicates bridge length index; NFA, nasofrontal angle; NHI, nasal height index; VHR, vertical/horizontal ratio.



FIGURE 6. Idiopathic persistent postoperative erythema (red arrow) in a 25-year-old woman 3 years after secondary rhinoplasty. This image is representative of an uncommon complication that occurred in 2.3% of patients. We do not have enough data to implicate the PTFE lining or silicone core as an etiologic factor. Current studies are underway to prevent and mitigate this vexing complication.

with the nasal dorsum, the authors encourage dorsal rasping, not implant shaping, to improve fit. We recognize that dorsal shaping alone may not be sufficient. To optimize skin ingrowth, the authors recommend conservative carving of the base—not the upper surface—of the implant. Unfortunately, the implant manufacturer does not offer a broad range of sizes, making tailoring an often-necessary evil. The authors do not know whether raising and replacing a “flap” of PTFE before silicone sculpting is worthwhile.

Economic Considerations

Silicone implants are inexpensive, at a cost of around \$100 (USD) to patients at the senior author's center. In contrast, pure PTFE

implants cost patients \$500 (USD) at the same center. Preformed PTFE implants have not been available since 2006, and the softness of PTFE necessitates an open rhinoplasty approach to ensure proper placement. The Chimera is less expensive than Gore-Tex, around \$300 (USD), and as form-stable as pure silicone prostheses, allowing for insertion through a closed rhinoplasty approach if so desired.

Gore-Tex and PTFE composite implants are more expensive than silicone, but they may be associated with fewer complications that warrant reoperation.^{30,31} Although there is no fixed price, reoperation cost may approach \$8000 (USD) at the second author's center in Seoul, where national insurance does not cover cosmetic surgery. The potential for PTFE ingrowth to reduce malposition—the most common cause for revision rhinoplasty—and therefore cost, is an important consideration.

The greatest limitation of this study is follow-up, attributable to the recent approval and introduction of composite implants to the Taiwanese market. Because of short follow-up, it is conceivable that long-term complications including contracture, malposition, contour deformities, exposure, and infection were underestimated. Two cases with greater than 30 months' follow-up demonstrated versatile results (Fig. 7). Still, care should be taken when comparing the outcomes we present, to other literature that presents longer follow-up.

Alloplast implants are a mainstay of Asian rhinoplasty, possibly in part of a more tolerant, thicker skin envelope than in the non-Asian. We cannot say whether the acceptably low complication rate we report would apply to the non-Asian population; this warrants ongoing study. The increased cost of the composite silicone-PTFE implants (Composite, Chimera, and Silitex) appears warranted in appropriate Asian candidates, although limitations must be recognized. I-shaped composite implants used alone, or in conjunction with tip and glabellar augmentation, are rigid like silicone and have the potential to generate significant physical changes. The authors are pleased with the material properties and workability of composite implants and most patients are satisfied. As we continue to collect data, outcomes data in this series demonstrate the feasibility of composite implants and a complication profile that resembles that of Gore-Tex implants.



FIGURE 7. Long-term follow-up demonstrates durable results. A, A 30-month follow-up of a 29-year-old woman who had secondary cosmetic rhinoplasty for improvement of nasal contour and tip projection using autologous cartilage, an I-shaped composite implant, and osteotomy. B, A 36-month follow-up of a 34-year-old woman who had secondary cosmetic rhinoplasty for dimple creation, improvement of nasal contour and tip projection using autologous cartilage, an I-shaped composite implant, and osteotomy.

CONCLUSIONS

I-shaped silicone-PTFE implant composite implants are a feasible alternative for use in Asian rhinoplasty. Early outcomes data suggest an overall complication rate that is comparable to PTFE, with the ease of handling and visible improvement provided by traditional silicone implants. Composite implants are effective in both primary and secondary rhinoplasty. Appropriate candidates should be informed about the data presented and allowed to decide whether proposed benefits, such as a decreased revision rate, warrant the disparity in cost.

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