Prevention and Resolution of Silicone Implant–Related Problems in Secondary Rhinoplasty Using a Cross-Linked Human Acellular Dermal Matrix

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Background: Silicone implant augmentation rhinoplasty along with various tip plasties are commonly performed in Asian patients, but a revision rhinoplasty is frequently required because of various problems. Secondary rhinoplasties are often performed using silicone, dermofat, costal cartilage block, or diced rib cartilage, but often result in unsatisfactory outcomes. This study assessed the surgical outcomes and complications of cross-linked acellular dermal matrix (ADM) as an alternative biological substitute for silicone implant in secondary rhinoplasty.
Methods: The authors prospectively studied 56 patients with a minimum follow-up of 1 year among 104 patients who underwent secondary rhinoplasty in their clinic between January of 2015 and December of 2018. Silicone implant, capsule, and scar tissue removal; dorsal augmentation with ADM; and tip plasty using autogenous cartilage were performed for all of them. The results were assessed using the modified Rhinoplasty Outcome Evaluation, consisting of a 10-item questionnaire completed preoperatively, 6 months postoperatively, and over 1 year postoperatively.
Result: One infection and three cases of excessive resorption were noted, with no other major complications. The mean modified Rhinoplasty Outcome Evaluation score was 31.7 on preoperative evaluation, 77.3 at 6 months postoperatively, and 81.4 at 1 year postoperatively (mean difference, 45.6 and 49.7, respectively; $P < 0.001$).
Conclusions: Various problems that occur after primary rhinoplasty using silicone implants can be resolved successfully with secondary rhinoplasty by dorsal augmentation using the cross-linked human ADM along with various nasal tip work using autogenous cartilage. Surgical outcome showed favorable resolution of contracture deformities, a low infection rate, firm fixation of the implant, good skin texture/thickness of the skin/soft-tissue envelope, and gain of desired height and dorsal line. *(Plast. Reconstr. Surg.* 152: 45, 2023.)
CLINICAL QUESTION/LEVEL OF EVIDENCE: Therapeutic, IV.

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Dorsal augmentation and various techniques of tip plasty using silicone implant and autogenous cartilage grafts are performed widely to make a nose slimmer and higher in primary Asian rhinoplasty. Despite many advantages, however, use of a silicone implant can lead to unfavorable results such as immediate and delayed infection, contracture deformity, and

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inappropriate contour of implant requiring revision surgery. To resolve these problems, it is common to replace the preexisting silicone implants with various materials including a new silicone implant, dermofat, costal cartilage block, or diced rib cartilage wrapped in temporal fascia on the dorsum while performing the tip work with autogenous cartilage.

Techniques such as creating a new pocket underneath the previous silicone capsule and inserting into it, relocating the silicone implant after widening the pocket, increasing the skin coverage thickness with a capsular flap over the silicone implant,[1] or wrapping the silicone implant with an ADM sheet[2] are attempts to resolve problems related to the skin/soft-tissue envelope (SSTE). Reinserting the silicone implant with the capsule in place increases the risk of complications, including infection, capsular contracture, implant malpositioning, implant mobility, and unnatural texture of the SSTE.[3–11] Dermofat graft has the shortcomings of donor-site scarring, inconsistent and excessive absorption rate, and dull appearance of dorsum.[12] Rib cartilage block grafts have the disadvantages of donor-site morbidity; long operation time; waring, hard, and transparent dorsal framework; difficulty to carve accurately along the dorsal contour; and the need for a thick SSTE. A diced cartilage graft wrapped in fascia on the dorsum has technical difficulties associated with permanently keeping the graft in a proper position and accurately matching the dorsal contour.[13,14]

Cross-linked human acellular dermal matrix (MegaDerm) acts as a biological scaffold for neovascularization, fibroblast infiltration, deposition of collagen and elastin fibers, and slower extracellular matrix remodeling, leading to long-term structural integrity and increased durability. However, it does not induce an immune reaction[12,15] (Fig. 1).

The authors' techniques of secondary rhinoplasty include capsulectomy, dorsal augmentation with cross-linked human ADM (MegaDerm L&C BIO, Seongnam-Si, Gyeonggi-Do, Republic of Korea), and appropriate tip work with autogenous cartilages. The aim of this study was to evaluate the availability and effectiveness of MegaDerm as a biological substitute for dorsal silicone implant in secondary rhinoplasty by means of a new model of patient-reported outcomes research instrument called the modified Rhinoplasty Outcome Evaluation (ROE), and to validate it on assessing patient satisfaction after secondary augmentation rhinoplasty (Table 1).

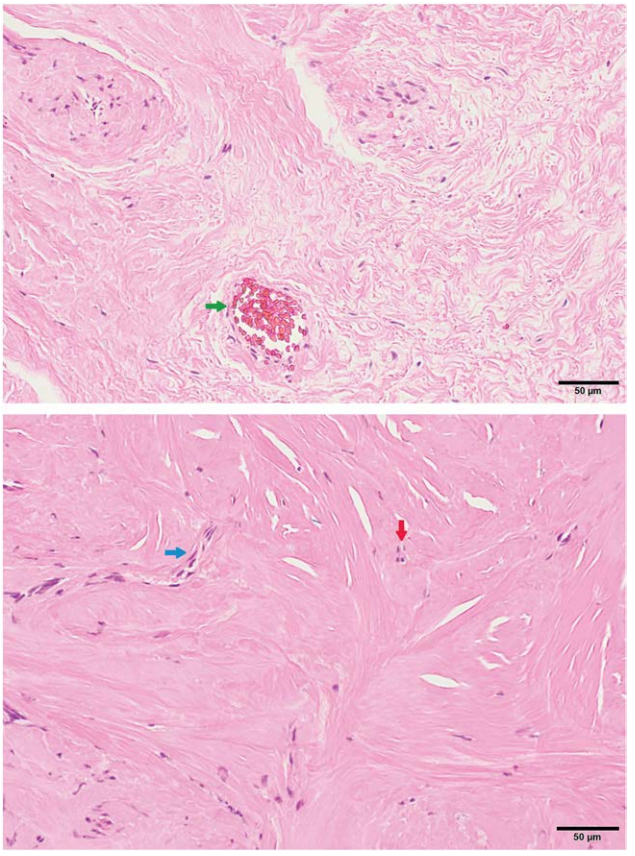

Fig. 1. Histologic examination of the implanted MegaDerm at 16 months postoperatively (hematoxylin and eosin; original magnification, × 400). (*Above*) Newly formed vessels (*green arrow*) were identified in the collagen tissues. (*Below*) The structure was mainly composed of dense collagen tissue, with infiltration of a few fibroblasts (*blue arrow*) and a few lymphocytes (*red arrow*).

PATIENTS AND METHODS

The study was executed in accordance with the Declaration of Helsinki and was approved by the Yonsei University Medical Center Institutional Review Board (number 4-2020-1066). Patients in the figures provided informed consent for use of their photographic images.

This study was conducted using the modified ROE created by Dr. Kook, which is a patient-reported outcome instrument composed of 10 items that measure and quantify the patient's subjective aesthetic and functional satisfaction and social well-being after secondary augmentation rhinoplasty (Table 1). The study period extended from January of 2015 to December of 2018, during which time secondary augmentation rhinoplasty was performed by the first author (W.S.K.) for 104 patients. Among 104 patients who underwent secondary rhinoplasty, 56 patients were included in

Table 1. Quality of Life Instrument for Secondary Augmentation Rhinoplasty

Modified ROE
1. How well do you like the appearance of your nose? (overall attractiveness)
Not at all (0); somewhat (1); moderate (2); very much (3); completely (4)
2. How well are you able to breathe through your nose during normal activity? (nasal airway function)
Not at all (0); somewhat (1); moderately (2); very much (3); completely (4)
3. How do you feel the occurrence of contracture deformity of your nose (upturned tip, implant demarcation, tip deformities, skin tightness)? (occurrence of contracture)
Definitely (0); most likely (1); possibly (2); probably not (3); not at all (4)
4. How do you feel the implant mobility of your nose? (implant mobility)
Definitely (0); most likely (1); possibly (2); probably not (3); not at all (4)
5. How well do you like the texture of skin and soft-tissue envelope (softness and feel on touch)? (texture of SSTE)
Not at all (0); somewhat soft (1); moderately (2); very much (3); completely soft (4)
6. How much do you feel your friends and loved ones like your nose? (familial acceptance)
Not at all (0); somewhat (1); moderately (2); very much (3); completely (4)
7. Do you think your current nasal appearance limits your social or professional activities? (social acceptance)
Absolutely (0); very much (1); moderately (2); rarely (3); never (4)
8. How do you like the height and contour of your dorsal line? (shape of dorsal contour)
Not at all (0); somewhat (1); moderately (2); very much (3); completely (4)
9. How confident are you that your nasal appearance is the best it can be? (mental-confidence)
Definitely (0); most likely (1); possibly (2); probably not (3); no (4)
10. Would you like to surgically alter the appearance or function of your nose? (emotional confidence)
Not at all (0); somewhat (1); moderately (2); very much (3); completely (4)

this prospective study. The inclusion criteria of 56 patients were (1) follow-up period more than 1 year, (2) photographic data from more than three occasions, and (3) three different completions of the modified ROE questionnaire.

All patients had a history of silicone implant augmentation rhinoplasty at least once in other hospitals. Secondary rhinoplasty was performed to correct various complications including capsular contracture, implant demarcation and shifting, inflammation, asymmetric nasal tip and nostril, surgical appearance, tough and blunt dorsal contour because of scarring, and other unsatisfactory results. The patients were asked to complete the modified ROE instrument on three separate occasions: (1) preoperatively on the day of surgery, (2) postoperatively 6 months after surgery, and (3) postoperatively more than 1 year after surgery. Data were collected prospectively by consecutive enrollment of patients and included age, sex, history of prior nasal surgery, postoperative complications, follow-up period, infection rate, and subjective patient-reported outcomes. Preoperative and postoperative facial photographs were taken in five full face basic views and the worm's-eye view for all of the patients.

Operative Technique

Under intravenous sedation with propofol, midazolam, and ketamine, local anesthetics of 1% lidocaine mixed with 1:100,000 epinephrine solution were injected into the nasal tip and dorsal area. The lower lateral cartilage was exposed through both infracartilaginous and transcolumellar incisions by means of an open approach, and the capsule was detached from the subcutaneous plane by closely approaching the anterior surface of the silicone implant. In this procedure, the capsule was dissected as thin as possible to leave the dorsal skin flap thick. The undersurface of the posterior capsular plane was separated to remove the implant and capsule en bloc. Conservative capsulectomy was performed if there was no contracture deformity. After removing the silicone implant, capsule, and surrounding scar tissue, the lower lateral cartilage was released from the scroll area, the membranous septum, scar tissue, and upper lateral cartilage to allow the tip cartilage to move freely. Reconstruction of the nasal tip was carried out to make appropriate length and shape using autogenous cartilage with various techniques, including onlay tip grafts; columellar struts; septal extension grafts; alar batten; lateral crural strut graft; derotation graft; septal extension graft and spreader grafts; shield graft; and intercrural, intracrural, transcrural suture depending on the degree of tip deformity, availability of cartilage, and previous surgical techniques of each patient. Dorsal augmentation was performed by inserting cross-linked human ADM (MegaDerm) in a supraperiosteal or subperiosteal pocket after carving according to dorsal contour of each patient with suturing to nasal framework to fix internally. The volume of

ADM implant was usually 30% oversized to compensate for resorption. [**See Figure, Supplemental Digital Content 1**, which shows the shape of cross-linked ADM, carving, and insertion. (*Above, left*) Rectangular block type. (*Above, right*) After carving of rectangular block. Usually, 30% of volume added to necessary height of implant. (*Center, left*) Carving type. (*Center, right*) Insertion of carved ADM implant soaked in povidone-iodine solution with guide needle. (Courtesy of L&C Bio, Gyeonggi-do, South Korea; with permission.) Capsule surrounding the silicone implant of contracted and infected nose (hematoxylin and eosin stain). (*Below, left*) Microscopic finding of capsule in contact with silicone implant which shows avascular collagen fiber deposition. (*Below, right*) Microscopic finding of surrounding tissue in contract with capsule shows some cellularity and thick dense bands of highly aligned fibers, ***http://links.lww.com/PRS/F860***.]

Measurements

The modified ROE is composed of a 10-item questionnaire, of which six items are from the ROE scale defined by Alsarraf[16] regarding aesthetic and functional aspects, and four items were added to evaluate the subjective satisfaction for the characteristics of the MegaDerm, as follows: (1) occurrence of contracture, (2) implant mobility, (3) texture of SSTE, and (4) cosmetic improvement of dorsal contour. Each patient scaled the 10 questions from 0 to 4, with 0 representing the least satisfaction and 4 the best response (Table 1). The total score was divided by 40 and multiplied by 100.

Statistical Analysis

All statistical analysis was performed using Microsoft Office Excel and R Studio, and RexSoft. Test-retest reliability was assessed using the Pearson correlation coefficient. Internal consistency reliability was estimated by means of the Cronbach α, a statistical tool that determines the correlation of items, and estimates the reliability of psychometric tests. Construct validity was confirmed by analyzing responsiveness to change by comparison of preoperative and postoperative modified ROE scores by means of paired samples *t* test.[17] Reliability for consistency and reproducibility, and validity for responsiveness to change and accuracy were assessed using the Pearson correlation and Cronbach α.[16,17]

RESULTS

The total number of evaluated patients was 56. The mean patient age was 39.9 years (range, 21 to 68 years), and the mean follow-up period was 55.9 weeks (range, 49 to 71 weeks). During the follow-up period, no patient developed severe complications such as hematoma formation, contracture deformity, infection, skin necrosis, or skin thinning, except one case that showed immediate postoperative infection. Three patients had significant resorption, and two patients had a deviation of implant that necessitated a revision rhinoplasty (Table 2). Resorption cases showed a 70% decrease in dorsal height and required reinsertion of a MegaDerm implant in the appropriate shape to make it higher. Biopsy of MegaDerm for three patients who underwent revision because of remarkable resorption revealed that the grafts were softly incorporated into the surrounding tissue without signs of infection and encapsulation. On microscopic examination, the main portion of MegaDerm was composed of dense collagen and elastin fibers; the newly formed vascular structure was detected with infiltration of fibroblasts and lymphocytes in it. There was no evidence of foreign body reaction, giant cells, or thick capsule formation (Fig. 1). Two cases of deviation were treated by immediate relocation procedure by means of a closed approach at 2 weeks postoperatively.

Modified ROE scores of each of the 10 items on three occasions and in groups divided according to presence of contracture were calculated

Table 2. Patient Demographics

Characteristic	Value (%)
Total no. of patients	56
Sex	
Male	7
Female	49
Age, yr	
Average	39.9
Range	21–68
Follow-up, wk	
Average	55.9
Range	49–71
No. of previous operations	
Average	2.7
Range	2–6
Complications and unfavorable results	
Infection	1 (1.8)
Significant resorption (reoperation)	3 (5.4)
Deviation	2 (3.6)
High-lying implant	2 (3.6)
Hematoma	0
Extrusion	0

statistically. Of all 10 items, the item of emotional confidence showed the highest increase of score in the overall group, the contracted group, and the uncontracted group. The second highest increased score was for the item recurrence of contracture, of which the mean scores were 28.1, 87.5, and 93.8 in overall group, with mean differences of 59.4 ($P < 0.001$) and 65.7 ($P < 0.001$). The third most highly increased score was for the item texture of SSTE, of which the mean scores were 25.4, 77.7, and 91.5 in the overall group, with mean differences of 52.2 ($P < 0.001$) and 66.1 ($P < 0.001$) (Table 3). Based on nonparametric analysis, the median score (100.0) of items of recurrence of contracture and texture of SSTE after more than 12 months was significantly higher than the median (75.0) for all 10 items ($P < 0.001$) (Table 3), which means that cross-linked human ADM showed good effect of resolving and preventing capsular contracture deformities as a dorsal implant in secondary rhinoplasty (Figs. 2 and 3). Of all 10 subjective items in the contracted group, the item of occurrence of contracture showed the highest increase of scores after surgery, which were 10.4, 88.5, and 99.0 on three occasions, with differences of 78.1 ($P < 0.001$) and 88.5 ($P < 0.001$), respectively (Table 3). Of these three patients who underwent revision, two patients showed a significantly decreased height of more than 50% again, but one patient showed good dorsal contour with cosmetic satisfaction after follow-up of more than 1 year (Fig. 4).

Mean scores of dorsal contour item were 32.1, 76.3 and 76.8 with differences of 44.2 ($P < 0.001$) for 6 months and 44.6 ($P < 0.001$) for more than 12 months after surgery, which shows similarly increased score compared with overall mean scores despite some cases of dissatisfaction with resorption. The score at 1 year postoperatively was higher than at 6 months postoperatively for most of the items, especially regarding texture of the SSTE category (14 points higher). For the item nasal airway function, the difference in the score before and after surgery was relatively small because there was not much of an airway problem before surgery, as reoperation was performed to solve the side effects associated with silicone implants (Table 3).

When it comes to comparison of each item, this study used nonparametric statistical methodology. The sample size is small; that is why nonparametric methodology is recommended for more advanced statistical analysis.

The overall average scores of 10 items of the modified ROE questionnaire from 56 patients were 31.7 for preoperatively, 77.3 for 6 months

Table 3. Modified ROE Scores of All 10 Items on Three Occasions and Causal Factors for Secondary Rhinoplasty (Contracted Patients/Uncontracted Patients)

Group of Patients	Item[a]										
	1	2	3	4	5	6	7	8	9	10	Mean ± SD[b]
Overall ($n = 56$)											
Preoperatively	18.8 ± 15.3	61.2 ± 19.6	28.1 ± 28.2	47.8 ± 21.5	25.4 ± 14.7	27.7 ± 17.0	39.7 ± 18.3	32.1 ± 17.0	24.1 ± 15.8	12.1 ± 14.3	31.7 ± 14.4
6 mo postoperatively	74.1 ± 17.8	77.2 ± 13.7	87.5 ± 14.3	79.5 ± 13.6	77.7 ± 13.2	71.9 ± 19.1	77.7 ± 18.3	76.3 ± 19.3	75.9 ± 17.2	75.0 ± 23.4	77.3 ± 4.2
>12 mo postoperatively	74.6 ± 19.4	78.6 ± 13.8	93.8 ± 11.9	79.9 ± 13.0	91.5 ± 16.0	75.9 ± 20.2	81.7 ± 18.1	76.8 ± 21.2	81.3 ± 18.6	80.4 ± 21.7	81.4 ± 6.4
Contracted group ($n = 24$)											
Preoperatively	13.5 ± 14.7	53.1 ± 18.5	10.4 ± 14.6	53.1 ± 21.3	24.0 ± 13.8	21.9 ± 17.0	34.4 ± 19.2	28.1 ± 15.3	18.8 ± 13.3	7.3 ± 13.8	26.5 ± 16.2
6 mo postoperatively	80.2 ± 14.7	77.1 ± 14.6	88.5 ± 12.7	81.3 ± 13.3	81.3 ± 11.1	74.0 ± 13.8	78.1 ± 17.0	85.4 ± 12.6	78.1 ± 17.0	77.1 ± 22.0	80.1 ± 4.3
>12 mo postoperatively	83.3 ± 15.9	79.2 ± 14.1	99.0 ± 5.1	81.3 ± 13.3	97.9 ± 7.1	80.2 ± 12.7	82.3 ± 17.3	82.3 ± 15.6	81.3 ± 18.4	85.4 ± 19.4	85.2 ± 7.2
Other group ($n = 32$)											
Preoperatively	22.7 ± 14.7	67.2 ± 18.4	41.4 ± 28.8	43.8 ± 21.1	26.6 ± 15.5	32.0 ± 15.9	43.8 ± 16.8	35.2 ± 17.8	28.1 ± 16.5	15.6 ± 13.8	35.6 ± 14.5
6 mo postoperatively	69.5 ± 18.8	77.3 ± 13.3	86.7 ± 15.5	78.1 ± 13.8	75.0 ± 14.2	70.3 ± 22.4	77.3 ± 19.4	69.5 ± 20.8	74.2 ± 17.4	73.4 ± 24.5	75.2 ± 15.2
>12 mo postoperatively	68.0 ± 19.3	78.1 ± 13.8	89.8 ± 14.0	78.9 ± 12.9	86.7 ± 19.0	72.7 ± 24.1	81.3 ± 19.1	72.7 ± 24.1	81.2 ± 19.1	76.6 ± 22.8	78.6 ± 6.6

[a]Subjects of questionnaire items: 1, overall attractiveness; 2, nasal airway function; 3, occurrence of contracture; 4, implant mobility; 5, texture of SSTE; 6, familial acceptance; 7, social acceptance; 8, shape of dorsal contour; 9, mental confidence; 10, emotional confidence.
[b]For all items.

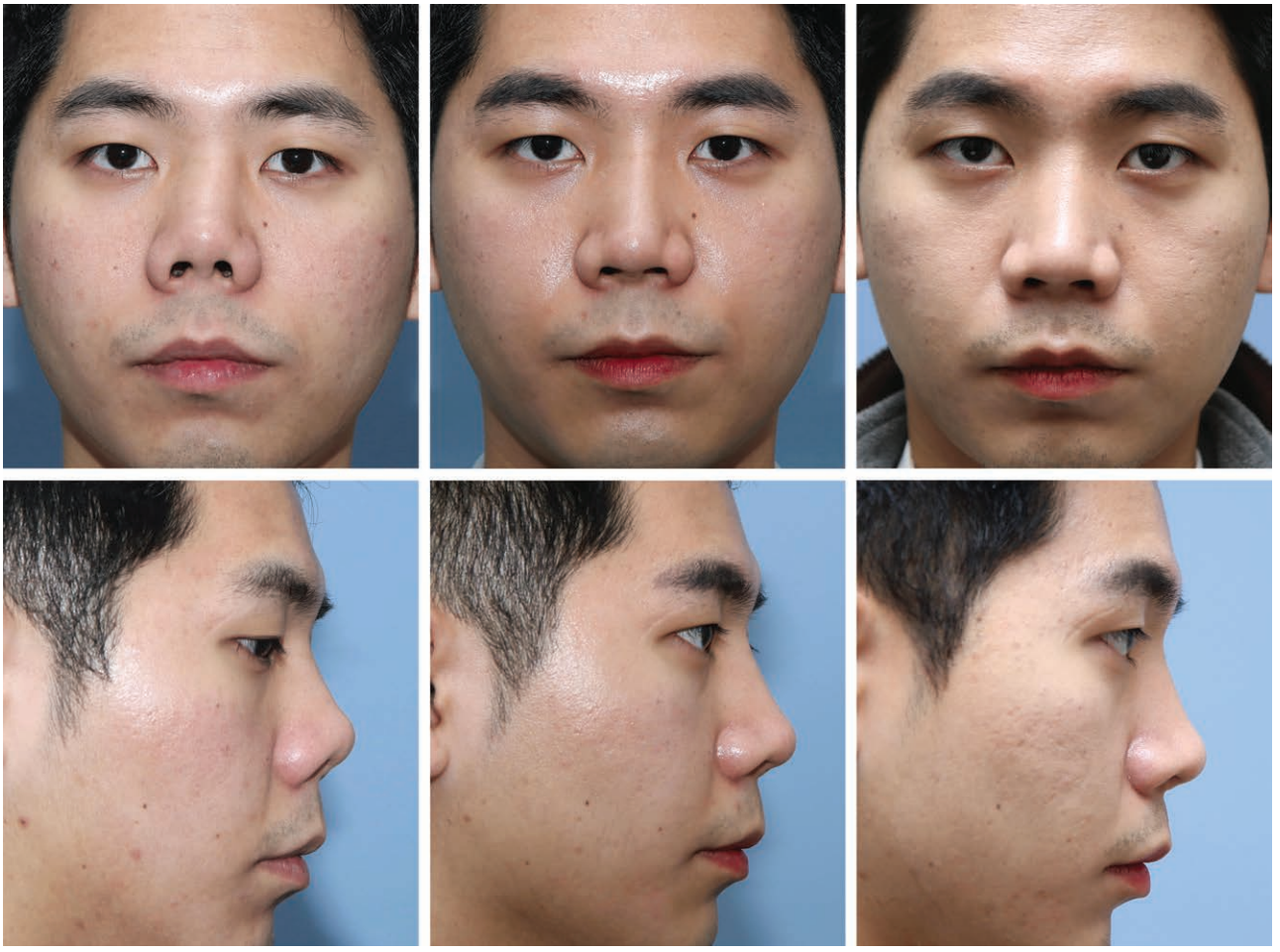

Fig. 2. This 26-year-old male patient has undergone augmentation rhinoplasty two times using a silicone implant 4 and 3 years ago at another clinic. Corrective rhinoplasty, septoplasty, and silicone implant insertion have been performed because of deviated nose and flat dorsum at the first operation, 4 years ago. Shifted and high-lying implant were corrected with additional revision rhinoplasty by relocation of the silicone implant during the second operation, 3 years ago. However, contracture ensued and resulted in an upturned nose, with insufficient tip definition, tough and blunt dorsal contour, and palpation stiffness. He then underwent a third revision rhinoplasty, including silicone implant removal, septal extension graft reusing septal cartilage, columella strut and derotation graft using conchal cartilage, and dorsal augmentation with supraperiosteal MegaDerm (thickness, 5 to 6 mm). (*Left*) Preoperatively; (*center*) 6 months postoperatively; and (*right*) 17 months postoperatively.

postoperatively, and 81.4 for more than 12 months, which show significant increase of scores by 45.6 ($P < 0.001$) and 49.7 ($P < 0.001$) after secondary rhinoplasty. Twenty-four of 56 patients (42.9%) underwent secondary rhinoplasty for contracture deformity. Mean scores of the contracted group on three occasions were 26.5, 80.1, and 85.2, which show mean differences of 53.7 ($P < 0.001$) at 6 months postoperatively and 58.8 ($P < 0.001$) over 1 year postoperative respectively. Mean scores of the noncontracted group were 35.6, 75.2, and 78.6, which show mean differences of 39.5 ($P < 0.001$) for 6 months preoperatively and 43.0 ($P < 0.001$) for more than 12 months after surgery. Mean score of the contracted group was significantly lower than the noncontracted group before surgery ($P = 0.0026$). However, the mean score for satisfaction in the contracted group started to show a significantly higher value than that of the noncontracted group after more than 12 months after surgery ($P = 0.0276$). There was less of a difference between the two groups at 6 months after surgery (Table 4).

Reliability Assessment

Test-retest reliability was evaluated by means of Pearson correlation coefficient ($r = 0.94$; $P < 0.001$), with results indicating statistically significant reliability and reproducibility. Internal

Fig. 3. This 62-year-old female patient underwent augmentation rhinoplasty two times using silicone implants 24 and 3 years ago at another clinic. Simple augmentation rhinoplasty with a silicone implant insertion 24 years ago and revision rhinoplasty 3 years ago to correct the shifted and high-lying implant by relocating the same silicone implants. However, contracture ensued and resulted in an upturned nose with insufficient tip definition, tough and blunt dorsal contour, implant deviation, and palpable stiffness. She also had a deviated nasal framework, including septal deviation. Subsequently, she underwent secondary rhinoplasty, which included silicone implant removal, spreader graft using septal cartilage, columella strut and derotation graft using conchal cartilage, and dorsal augmentation with insertion of MegaDerm (thickness, 5 to 6 mm) in the supraperiosteal plane. (*Left*) Preoperatively; (*center*) 6 months postoperatively; and (*right*) 15 months postoperatively.

consistency reliability was assessed by calculating Cronbach α coefficient, with an $\alpha > 0.70$ generally considered acceptable for instrument reliability. Analysis of internal consistency for the entire 10-item inventory demonstrated adequate internal consistency with $\alpha = 0.74$.

Test-Retest Reliability

With regard to the Pearson coefficient, $r = 0.9169$ and $P < 0.001$.

Internal Consistency Reliability

With regard to the internal consistency reliability, items tested (Cronbach α) included preoperative score, 0.8256; 6-month postoperative score, 0.8491; and greater than 12-month postoperative score, 0.8340. Paired samples *t* tests were performed by comparing the averaged preoperative Rhinoplasty Health Inventory and Nasal Outcomes scale scores with the postoperative score (6 months and >12 months), demonstrating a statistically significant increase in scores postoperatively ($P < 0.001$).

DISCUSSION

The incidence of complications after augmentation rhinoplasty with silicone implants varies between 4% and 36%.[4,5,18–25] The most common complication was contracture, seen in 34.8% of patients; deviation (implant shift), 30.1%;

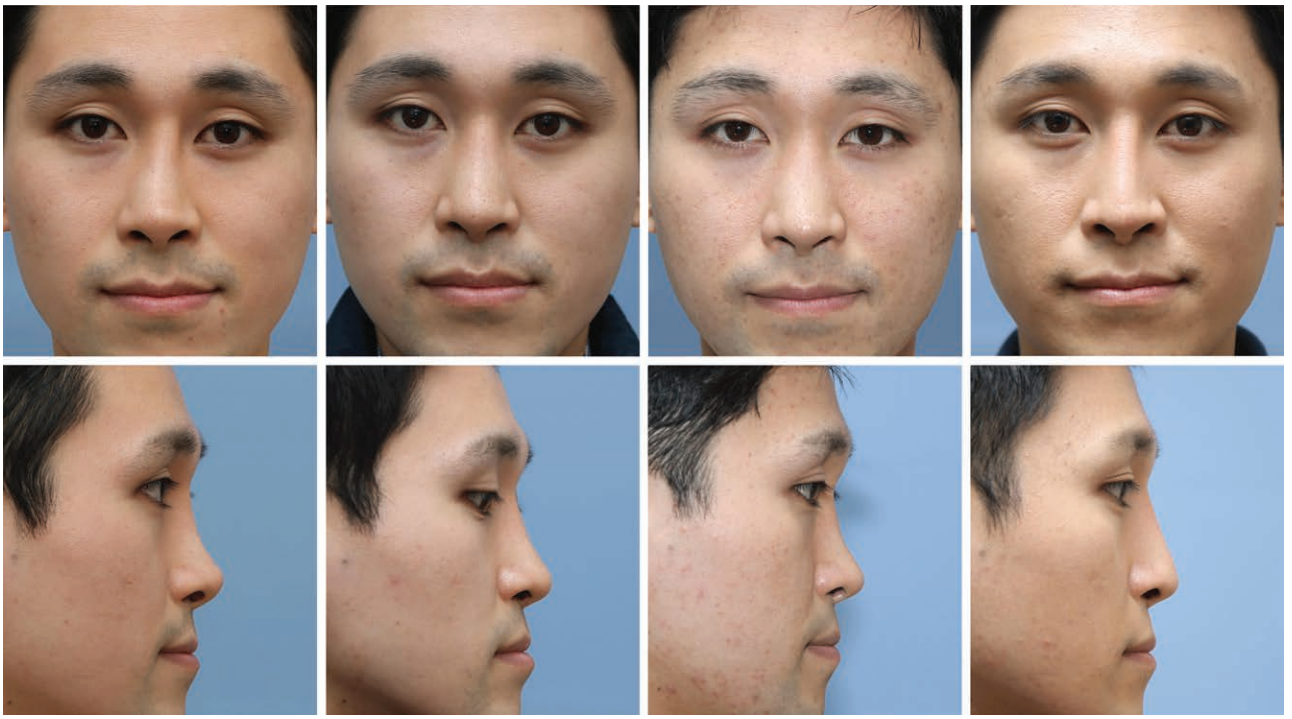

Fig. 4. This 29-year-old male patient had undergone corrective rhinoplasty, septoplasty, and silicone implant insertion to correct the deviated nose and flat dorsum 4 years previously at another clinic. However, the patient ended up with a saddled and deviated dorsum. He underwent a secondary rhinoplasty, which included silicone implant removal, spreader graft, medial and lateral osteotomy, columella strut, derotation graft using ear cartilage, and dorsal augmentation with supraperiosteal MegaDerm (thickness, 5 to 6 mm). The dorsal line became straight, but the dorsal height became lower because of remarkable resorption, resulting in a deep concave line 20 months after the operation. In the third revision operation, MegaDerm (4 to 5 mm thick) was reinserted in the subperiosteal pocket by means of intranasal incision. The dorsal line became high and straight even after 15 months after the revision procedure, and the texture of the SSTE was soft and natural. The dorsal line became higher and straight, and the texture of the SSTE is soft and natural even after 15 months. (*Left*) Preoperatively, before the first operation. (*Center*, *left*) Postoperatively, 3 months after the first operation. (*Center*, *right*) Postoperatively, 20 months after the first operation (preoperatively, before revision surgery). (*Right*) Postoperatively, 15 months after revision surgery.

Table 4. Mean Scores of 10 Items of Modified ROE Questionnaire on Three Occasions for Each Group

Group	12 Mo	6 Mo	Pre	Mean Difference	*t*	*P*[a]
Overall ($n = 56$)	81.4 ± 11.2	77.3 ± 11.2	31.7 ± 11.6	49.7 ± 14.4 (12 mo vs. Pre)	25.8	<0.0001
				45.6 ± 13.5 (6 mo vs. Pre)	25.3	<0.0001
Contracted ($n = 24$)	85.2 ± 9.8	80.1 ± 11.0	26.5 ± 9.7	58.8 ± 12.5 (12 mo vs. Pre)	23.0	<0.0001
				53.6 ± 12.6 (6 mo vs. Pre)	20.9	<0.0001
Noncontracted ($n = 32$)	78.6 ± 11.5	75.2 ± 11.1	35.6 ± 11.5	43.0 ± 12.0 (12 mo vs. Pre)	20.2	<0.0001
				39.5 ± 10.8 (6 mo vs. Pre)	20.7	<0.0001

Pre, preoperatively.
[a]Significance level is set to 0.05 (5%) using two-tailed *t* test.

infection, 10.1%; skin problem, 19.9%; and protrusion, 5% noted in some articles.[21–24] The major reasons for revision rhinoplasty are (1) contracture deformity; (2) inappropriate contour of implant; (3) infection; (4) malposition of implant; (5) SSTE problems such as thin skin, redness, transparency of implant; (6) mechanical effects of implant on tip cartilage; and (7) unattractive tip. Contracture deformity causing nasal shortening, pinched tip, nostril notching, implant demarcation, high-lying and/or deviated implant, color change, skin tightness, and palpation stiffness are very common reasons for revision surgery, but are challenging problems.[18–24]

Capsule formation is a natural inflammatory foreign body immune reaction to the silicone implant that results in the formation of collagenous capsule around implants.[4,24,25] Silicone implants are at a higher risk for infection because of (1) the lack of vascular ingrowth, (2) their propensity for biofilm formation,[5,6] and (3) avascular plane of the capsule. The inner lining of the capsule is the avascular plane that provides microorganisms with a good environment to survive inside the capsular cavity[5–9] (**see Figure, Supplemental Digital Content 1**, ***http://links.lww.com/PRS/F860***). Unabsorbed and persistent capsule can serve as a source of subclinical infection because microorganisms on the capsular surface and biofilms are difficult to be eradicate even with implant removal and aggressive washing because of its propensity to stick on the avascular plane.[4–8] This acute or subclinical infection around the silicone implant makes the capsule thick and tough.[9,10] A thickened and contaminated capsular flap acts as a contractile force generated by myofibroblasts.[5,11,26] These risks were the impetus for finding an alternative biological substitute for silicone implants to reduce the occurrence of contracture deformity, implant mobility, and unnatural texture of the SSTE.

In the data of this study, there was a significant increase in the scores of the modified ROE scale, by more than 40 points, for the items of contracture recurrence, texture of the SSTE, implant immobility, and contour of the dorsal line, which are related to the characteristics of human ADM; and six items of the ROE scale, including overall attractiveness, self-confidence, and familial and social acceptance after surgery demonstrated promising results. That is, secondary rhinoplasty using cross-linked human ADM block showed effectiveness for resolution and prevention of contracture deformities, infection, mobility, tough and blunt dorsal contour, and obtaining a good dorsal line in addition to natural texture of the nasal SSTE from patients with various problems. The score related to the occurrence of capsular contracture was excellent and highest among 10 items, indicating that cross-linked human ADM can be a useful alternative, especially in resolving capsular contracture deformities. The resorption rate, usually ranging between 30% and 40%,[15,27] can be a significant preoperatively voiced concern, but it was not a critical complaint for the cases of secondary rhinoplasty. The restoration of natural dorsal lines and contour, softness, and good texture of the SSTE, and the absence of contracture deformity, seemed to be more important than the dorsal height of the nose to patients undergoing secondary rhinoplasty. Although the resorption rate varies, it generally ceases at approximately 6 months when tissue in-growth achieves structural stability.

The optimal material used as an implant for reconstruction possesses the following properties: facilitation of vascular ingrowth, decreased propensity to incite inflammation, biological inertness, resistance to infection, and ease of handling. Acellular dermal matrix possesses many of these properties and is used in reconstructing nasal soft-tissue and skeletal support, and other soft-tissue deficits.[28–31] MegaDerm is a cross-linked human ADM, derived from cadaveric skin, irradiated with low-density electron beams to affect collagen secondary structure. Reports with non–cross-linked ADM showed rapid degradation and resorption before the collagen deposition and neovascularization, resulting in volume loss.[30,31] Cross-linked collagen maintains its three-dimensional matrix function for cellular infiltration and neovascularization. It also allows a delayed remodeling process through increased interfibrillar and intrafibrillar bonds that lead to long-term structural integrity and durability after implantation.[15,27] It serves as a biological scaffold without forming a biofilm or capsule and provides structural stability by allowing ingrowth of collagen and elastin fiber within 5 to 6 months after insertion. These merits allow a natural appearance of the nose and adequate tissue ingrowth without graft migration. It is also safe and carries a low risk of infection or foreign body reaction because of the specialized manufacturing process that removes cell debris, antigens, and potential viruses.[31]

Decreased dorsal height because of resorption over time and inappropriate positioning/shape of the MegaDerm can account for the lower satisfaction with the dorsal contour in some patients, but the scores of dorsal contour showed a similar increase in the overall average score. The range of volume reduction as much as 30% to 70% depends on the status of the donor skin (site, condition, age) and the surgical technique. The insertion plane can be considered a surgical variation factor,[15] but no significant difference was found between the subperiosteal and supraperiosteal planes in this study. Dorsal contour irregularities suspected to occur because of uneven absorption of MegaDerm along the dorsal line were not observed in this study. However, one needs to carve carefully to make the contour of MegaDerm smooth and of a good shape. The aesthetic dissatisfaction of the "squared and long dorsal line" was caused by the inappropriate shape and/or high-lying positioning of the MegaDerm implant. The initial period's technical errors were reduced gradually by carving the

implant smoother and in good shape and by fixing it in a more appropriate position. Four patients underwent a revision operation with reinsertion of MegaDerm; three patients showed a significantly decreased height of more than 50% again, but one patient showed good dorsal contour with cosmetic satisfaction. This modified ROE instrument was verified as having a high level of reliability and validity by test-retest assessment using the Pearson correlation coefficient and internal consistency reliability by means of Cronbach α.

CONCLUSION

Cross-linked human ADM (MegaDerm) can be an excellent alternative substitute for the nasal silicone implant in patients who have silicone implant–associated complications.

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DISCLOSURE

None of the authors has a financial interest in any of the products, devices, or drugs mentioned in this article.

PATIENT CONSENT

Patients provided written informed consent for the use of their images.

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