A systematic review of complications associated with nasal augmentation implants: expanded polytetrafluoroethylene (Gore-Tex) versus silicone

Han Le Thuc Hoang, MD¹, Michael Januszyk, MD², J. Brian Boyd, MD²

¹Institute of Cosmetic and Reconstructive Surgery, Fountain Valley, CA, USA, ²Department of Surgery, University of California, Los Angeles, CA, USA

Background: Augmentation rhinoplasty has been one of the most common cosmetic procedures in Asian population. Silicone is the most widely used nasal augmentation material in Asia. However, in the past few decades, expanded polytetrafluoroethylene (ePTFE, Gore-tex®) has become more popular as an alternative.

Objective: In this study, complications associated with each implant are systematically reviewed.

Methods: Heuristic searches of MEDLINE, PubMed, and the Cochrane Library were performed using the keywords “ePTFE”, “Goretex”, “silicone”, and “rhinoplasty” to identify manuscripts for inclusion. The reference lists of these articles were systematically reviewed to further identify relevant articles. Only studies with detailed complication reports (i.e., infection, malposition) were considered. Random effects meta-analysis was performed to calculate the significance of differences in complication rates between silicone and ePTFE.

Results: Eighteen studies encompassing a total of 7,759 patients were analyzed, 12 with ePTFE and 6 with silicone. Among studies in which sex was reported, 88.8% of the patients were female. 88.4% of cases in the silicone group were primary, as compared to 78% in the ePTFE group. Overall complications were 5.3% for the ePTFE group and 9.2% for silicone ($p < 0.05$). Infection rate was similar between the two groups, 1.4% for ePTFE versus 1.9% for silicone group ($p > 0.05$). Exposure rate was also similar, 0.7% for silicone and 1.2% for ePTFE ($p > 0.05$). Malposition rates were significantly lower in ePTFE group compared to those receiving silicone implants (2.4% versus 6.8%, $p < 0.05$).

Conclusion: Although the gold standard graft material for rhinoplasty remains autologous tissue, implant based rhinoplasty is far more common in Asian populations. Both silicone and ePTFE have acceptable risk profiles when used in selective patients for dorsal augmentation. However, given the additional risks of capsular contracture and implant malposition associated with silicone implants, ePTFE should be considered as a first-line option for implant-based nasal augmentation.

Keywords: ePTFE; Gore-tex; nasal augmentation; rhinoplasty; silicone

Introduction

The common nasal aesthetic complaints from Asian patients are: lack of dorsal height, short nose, round and ill-defined tip, and wide and thick ala. To address these complaints, an aug-

mentation rhinoplasty including increased tip projection and ala reduction is often required. The augmentation rhinoplasty procedure has long been one of the most common cosmetic procedures in Asian populations [1-3], and silicone is the most widely used nasal augmentation material in Asia [2-5]. How-

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Corresponding author: Han Le Thuc Hoang

E-mail: hanhoang@gmail.com, ORCID: <https://orcid.org/0000-0001-9011-1254>

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ever, in the past few decades, expanded polytetrafluoroethylene expanded polytetrafluoroethylene (ePTFE, Gore-Tex®) has become more popular as an alternative implant [2-5]. Both implant materials have been used for decades in plastic and cardio-vascular surgery, and they both have excellent biocompatibility profiles. The solid silicone implants used for nasal augmentation are known to induce a tissue reaction, resulting in capsular contracture [6,7], as seen in other types of silicone implants. This is in addition to the standard implant-related complications. The ePTFE, which has been used in surgery for as long as silicone has been employed, has been thought to have a higher infection rate due to the porous nature of the implant. This concern, along with the technical difficulty in removing the implant, has swayed many surgeons to avoid using ePTFE implants [1-3]. In this study, complications associated with each implant are systematically reviewed.

Materials and methods

Search strategy

Two independent reviewers performed heuristic searches of MEDLINE, PubMed, and the Cochrane Library using the keywords: “ePTFE”, “Gore-Tex”, “silicone”, and “rhinoplasty”, to identify manuscripts for inclusion. The reference lists of these articles were systematically reviewed to further identify relevant

articles.

A total of 267 articles were found on PubMed using “silicone” and “rhinoplasty”, 108 using “Gore-Tex” and “rhinoplasty”, and 16 using “ePTFE” and “rhinoplasty”. MEDLINE yielded the same articles. Only studies with detailed complication reports (i.e., infection and malposition) were considered.

Data extraction

Two reviewers reviewed the articles and extracted data independently. Any discrepancies were resolved through an independent review by the senior author. Collected data included: the number of subjects; gender; age and age range; number of revision rhinoplasty patients within the studied population; history of nasal trauma; follow-up; overall complications; as well as implant-related complications such as: infection, malposition, exposure, the need for reoperation, and the need for implant removal.

The paired sample t-test was performed to calculate the significance of differences in complication rates between the silicone and ePTFE groups.

Results

Eighteen studies, encompassing a total of 7,759 patients were analyzed; 12 with ePTFE and 6 with silicone implants (Table

Table 1. Demographics of patients in included studies demographic

Reference	Implant used	Patient (n)	Female (n)	Age (yr)	Revision
Deva et al., 1998 [8]	Silicone	422	413	26 (17-36)	41
Zeng et al., 2002 [9]	Silicone	98	77	NR (17-49)	NR
Lam and Kim, 2003 [10]	Silicone	1,079	NR	NR	NR
Ahn et al., 2004 [11]	Silicone	100	93	NR	28
Tham et al., 2005 [12]	Silicone	355	316	26 (13-67)	52
Chuangsuwanich and Lohsiriwat, 2013 [13]	Silicone	548	519	NR	45
Godin et al., 1999 [14]	ePTFE	309	NR	NR	147
Lohuis et al., 2001 [15]	ePTFE	66	44	NR	47
Jin et al., 2006 [16]	ePTFE	853	NR	NR	197
Inanli et al., 2007 [17]	ePTFE	74	45	30 (22-48)	28
Conrad et al., 2008 [18]	ePTFE	521	399	13-70	NR
Dong et al., 2010 [19]	ePTFE	1,700	1,570	18-57	0
Hong et al., 2010 [20]	ePTFE	257	NR	24 (18-57)	476
Yap et al., 2011 [21]	ePTFE	1,054	955	34 (15-72)	46
Serin et al., 2012 [22]	ePTFE	32	20	28.4	23
Winkler et al., 2012 [23]	ePTFE	75	NR	46 (7-86)	NR
Shadfar et al., 2015 [24]	ePTFE	40	24	36.8	NR
Joo and Jang, 2016 [25]	ePTFE	176	80	30.3 (11-69)	41

Values are presented as number or mean (range).

NR, not reported; ePTFE, expanded polytetrafluoroethylene.

1 [8-25]). Of the studies in the silicone group, 3/6 reported age ranges and/or average age, and 9/12 studies in the ePTFE group reported these variables. Of the 6 studies in the silicone group, 5 reported gender, with 93.2% female patients. Of the 12 ePTFE studies, 8 reported gender, with 87.4% female patients. The differences in gender were not significant between the 2 groups ($p>0.05$). Of the studies in the ePTFE group, 9/12 reported revision sub-groups, as compared to 4/6 studies in the silicone group. Out of the studies that reported revision cases, 88.4% of cases in the silicone group were primary, as compared to 78% in the ePTFE group (Table 1).

Of the 12 studies in the ePTFE group, 9 reported the mean follow-up (range, 11.4 to 71 months), of which 8 also reported the follow-up range (range, 0 to 17 years). The reported follow-ups were much lower in the silicone group. Only 2 studies out of 6 reported any follow-up. Ahn et al. [11] reported a 2 to 5-year follow-up. Tham et al. [12] reported a mean follow-up of 160 days, with a range of 3 months to 3 years (Table 2).

Overall complications were 5.3% for the ePTFE group and 9.2% for the silicone group. This difference was statistically significant ($p<0.05$). The infection rate was similar between the 2 groups; 1.4% for ePTFE versus 1.9% for the silicone group ($p>0.05$). The exposure rate difference was not statistically significant between the 2 groups; 0.7% for silicone and 1.2% for the ePTFE group ($p>0.05$). However, malposition rates were

significantly lower in the ePTFE group when compared to those receiving silicone implants (2.4% versus 6.8%, $p<0.05$; Table 3).

Discussion

Rhinoplasty is one of the most common cosmetic surgeries requested and performed worldwide [26]. Yet, the revision rate is notoriously high when compared to other cosmetic procedures, and it is reported to be 5% to 15% [27]. One may argue that a rhinoplasty specialist may have a lower rate; however, it is difficult to truly assess, as patients often change surgeons or even go to different cities and different countries to have cosmetic surgeries performed. In Asian rhinoplasty, augmentation is a key part of the surgery, and implants are used almost exclusively in Asia, particularly for primaries [1-5]. Both silicone and

Table 3. Systemic analysis of silicone versus ePTFE groups

Variable	Silicone	ePTFE	p-value
Total no. of patient	2,602	5,157	
All complication	239 (9.2)	271 (5.3)	0.017
Infection	50 (1.9)	71 (1.4)	0.426
Malposition	177 (6.8)	126 (2.4)	0.016
Exposure	18 (0.7)	56 (1.1)	0.039

Values are presented as number only or n (%).
ePTFE, expanded polytetrafluoroethylene.

Table 2. Reported follow up, complications, infections, malpositions, and exposure, in included studies

Reference	Implant used	N	Follow up	Complications	Infection	Malposition	Exposure
Deva et al., 1998 [8]	Silicone	422	NR	41	0	39	2
Zeng et al., 2002 [9]	Silicone	98	NR	39	1	38	2
Lam and Kim, 2003 [10]	Silicone	1,079	NR	60	28	40	0
Ahn et al., 2004 [11]	Silicone	100	2-5 yr	6	0	5	0
Tham et al., 2005 [12]	Silicone	355	3 mo-3 yr	57	19	28	10
Chuangsuwanich and Lohsiriwat, 2013 [13]	Silicone	548	NR	36	2	27	4
Godin et al., 1999 [14]	ePTFE	309	5 mo-10 yr	10	10	2	0
Lohuis et al., 2001 [15]	ePTFE	66	3-72 mo	1	0	1	0
Jin et al., 2006 [16]	ePTFE	853	NR	34	18	16	0
Inanli et al., 2007 [17]	ePTFE	74	5-62 mo	1	0	1	0
Conrad et al., 2008 [18]	ePTFE	521	1-17 yr	33	7	20	2
Dong et al., 2010 [19]	ePTFE	1,700	6 d-4 yr	119	17	51	51
Hong et al., 2010 [20]	ePTFE	257	12-98 mo	34	9	16	0
Yap et al., 2011 [21]	ePTFE	1,054	NR	24	4	15	0
Serin et al., 2012 [22]	ePTFE	32	6-34 mo	0	0	0	0
Winkler et al., 2012 [23]	ePTFE	75	0-74 mo	6	4	0	2
Shadfar et al., 2015 [24]	ePTFE	40	NR	2	1	1	1
Joo and Jang, 2016 [25]	ePTFE	176	4-115 mo	7	1	3	0

Values are presented as number.

ePTFE, expanded polytetrafluoroethylene; NR, not reported.

ePTFE implants have a long track-record with regards to biocompatibility and implant-related risks. This systematic review demonstrates that although the infection rate is comparable between the 2 types of implants, silicone has a statistically significant higher malposition rate and overall complication rate when compared to ePTFE. Other known complications associated with both types of nasal implants are capsular contracture and calcinosis. Kim et al. [6] recently published an extensive report on silicone capsular contracture in the nose. In their study, 29.3% of patients developed noticeable contracture, and 13.8% required capsulectomy plus or minus significant revisions. Chang and Jung [28] also reported a high rate of capsular contracture with silicone nasal implants in a new study published by the *Journal of Cosmetic Medicine*. In this study, 77% of all capsular contracture cases were related to the usage of silicone implants. Calcinosis of both type of implants has also been reported, however the data are very limited [29,30]. This study did not compare these complications due to their rarity and low reporting rate.

The most feared complication for any type of nasal implant is exposure. Looking in depth into the reviewed studies, this complication, in either the silicone or ePTFE groups, appeared to be almost exclusively related to implant placement within the tip. In the ePTFE group, Dong et al. [19] reported the highest exposure rate of 3%. In their study, ePTFE was also used for tip augmentation. In the silicone group, Tham et al. [12] also reported a similar used and exposure rate. Given the above findings, the authors' recommendation is to use ePTFE implants for dorsal augmentation only.

There are several weaknesses to this systematic review. The included studies are heterogeneous. There was no control or randomization, and most of the studies are retrospective. Not all complications associated with nasal implants are included. However, this study captured many patients in both arms, and it had sufficient power to demonstrate statistical differences in the overall complication and malposition rates of each type of implant.

Although the gold standard graft material for rhinoplasty remains autologous tissue, implant-based rhinoplasty is far more common in Asian populations. Both silicone and ePTFE have been shown to exhibit acceptable risk profiles when used in selective patients for dorsal augmentation. However, given the additional risk of capsular contracture and implant malposition associated with silicone implants, as suggested by the findings of this systemic analysis, ePTFE should be strongly considered as a first-line option for implant-based nasal augmentation.

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Conflicts of interest

The authors have nothing to disclose.

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