

## Breast Surgery

## Preliminary Report

## Does Implant Insertion with a Funnel Decrease Capsular Contracture? A Preliminary Report

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**Abstract**

**Background:** Capsular contracture remains a common and dreaded complication of breast augmentation. The etiology of capsular contracture is believed to be multi-factorial, and its causes may include biofilm formation due to implant/pocket contamination with skin flora. It has been shown that insertion funnel use reduces skin contact and potential contamination by 27-fold in a cadaver model. After incorporating the funnel into our surgical protocols, we anecdotally believed we were experiencing fewer capsular contractures in our augmentation practices.

**Objectives:** The purpose of this study was to test the hypothesis that capsular contracture related reoperation rates decreased after insertion funnel adoption using data from multiple practices.

**Methods:** At seven participating centers, we retrospectively reviewed the surgical records from March 2006 to December 2012 for female patients who had undergone primary breast augmentation with silicone gel implants. Group 1 consisted of consecutive augmentations done without the insertion funnel, and Group 2 consisted of consecutive augmentations done with the insertion funnel. The primary outcome variable was development of grade III or IV capsular contracture that led to reoperation within 12 months.

**Results:** A total of 1177 breast augmentations met inclusion criteria for Group 1 and 1620 breast augmentations for Group 2. The rate of reoperation due to capsular contracture was higher without use of the insertion funnel (1.49%), compared to Group 2 with funnel use (0.68%), a 54% reduction ( $P = 0.004$ ).

**Conclusions:** The insertion funnel group experienced a statistically significant reduction in the incidence of reoperations performed due to capsular contracture within 12 months of primary breast augmentation.

**Level of Evidence: 3**

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Silicone gel implants have become the most popular implant type for breast augmentation procedures worldwide. Implant

construction (both in terms of manufacturing processes and raw materials) and surgical techniques have evolved since

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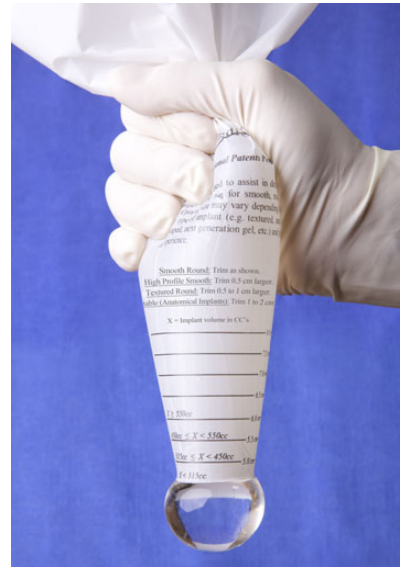
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**Figure 1.** The silicone implant may be directly poured from its packaging into the mouth of the funnel, without handling of the implant.



**Figure 2.** With controlled hand squeezes, the surgeon advances the implant through the funnel and into the pocket with minimal force and no finger manipulation.

their first clinical use in the 1960s. Silicone implant safety has been studied extensively, and problems such as spontaneous rupture and silicone gel bleed have been greatly diminished by improved device standards.<sup>1,2</sup> Capsular contracture, however, remains a relatively common and dreaded complication of breast augmentation. Due to its impact on both patient and surgeon, including its resultant reoperation requirements, prevention of capsular contracture is of great interest to the plastic surgery community. In addition, the psychological and financial implications for both the patient and surgeon are significant.

It is well established that the etiology of capsular contracture is multi-factorial, and its root cause may be linked to biofilm formation secondary to implant/pocket contamination with bacteria, blood, synthetic fibers, etc. The reported long-term rates of capsular contracture vary from 5% to 50% or more depending on the source.<sup>3-9</sup> It has been shown to be one of the most common reasons for revision breast surgery.<sup>4,9-11</sup>

As our understanding of capsular contracture improves, major efforts have focused on decreasing bacterial contamination. Pocket irrigation, with antimicrobials and/or betadine, in particular has yielded solid evidence. Several authors report dramatic reductions in capsular contracture rates and this practice is widely accepted.<sup>4,12-14</sup>

Decreasing implant contact with both surgeon gloves and the skin surface is the other logical route to decreasing contamination, but practical solutions for this are less apparent. Until the introduction of the Keller Funnel (Keller Medical, Inc., Stuart, FL) in 2009, there was no alternative to direct surgeon handling and manipulation of implants. Manual

insertion of the implant into the pocket and contact of the implant with the skin edges were unavoidable as potential sources of implant trauma and bacterial colonization. The insertion funnel, constructed of polymeric vinyl, was developed to make silicone gel implant insertion easier for the surgeon, minimize implant trauma during insertion, and to allow for minimal contact with surgeon hands or the skin. It has been shown that use of the funnel reduces skin contact and thus potential contamination by 27-fold ( $P = 0.00059$ ) in a cadaver model.<sup>15</sup> The rapid commercial adoption of the funnel, currently estimated by the manufacturer to be used in approximately 30% of silicone gel procedures in the United States, is likely related to the added ease of implant placement and potentially decreased contamination.

Intraoperatively, the insertion funnel is cut to size and hydrated, inducing a low friction internal surface. The silicone implant may then be directly poured from its packaging into the mouth of the funnel (Figure 1). The narrow opening of the funnel is placed 1 centimeter into the center of the surgically prepared and irrigated implant pocket. With controlled hand squeezes, the surgeon advances the implant through the funnel and into the pocket with minimal force and no finger manipulation (Figure 2). The hydrophilic coating on the inner surface of the funnel lowers the coefficient of friction, allowing the implant to slide into the pocket smoothly while the funnel acts as a barrier against skin contamination. Minimizing skin surface contact with the implant through the use of the insertion funnel provides a “no-touch” insertion method, similar to that first described by Mladick.<sup>16</sup>

After incorporating the funnel into our surgical protocols, we anecdotally believed we were experiencing fewer

capsular contractures in our augmentation practices. The aim of this study was to test the hypothesis using data from multiple practices, comparing capsular contracture reoperation rates before and after insertion funnel adoption.

## METHODS

At nine participating private practice centers, we retrospectively reviewed the surgical records from March 2006 to December 2012 for consecutive female patients undergoing primary breast augmentation with silicone gel implants. To minimize the number of technique-related factors introduced by various surgeons, revisionary breast augmentation, breast reconstruction, or breast augmentation, surgeries performed in combination with secondary surgical procedures of the breast (eg, mastopexy, fat injection) were excluded. The study sites selected were well established practices that performed a large volume of breast augmentation surgery, and had recently adopted the use of the Keller Medical KF-1 insertion funnel in virtually all of their primary augmentation cases. (The KF-1 is the first generation Keller Funnel. In 2014, the next generation funnel, the KF-2 replaced the KF-1 and has slightly different construction). Nine centers were originally used (two were subsequently excluded), reporting reoperation rates in a historical control without the insertion funnel and a retrospectively reviewed experimental group with use of the funnel. Institutional Review Board review was not available in this setting, but all study practices followed the guidelines of the Department of Health and Human Services Regulations for the Protection of Human Subjects.<sup>17</sup>

Group 1 was a historical control, consisting of consecutive augmentations done without the insertion funnel, and Group 2, the experimental group, consisted of consecutive augmentations done with the insertion funnel. The primary outcome variable was development of Baker Grade III or IV capsular contracture that led to reoperation. A one year study period after implant placement was chosen. Capsule-related reoperations occurring within 12 months of implant placement were included as events in each group. Bilateral reoperations were recorded as 2 events. The time period to evaluate if a reoperation due to capsular contracture occurred after primary surgery was identical for both groups.

Demographic data such as age and BMI were not available from all sites. Since all sites were high volume centers in different regions of the United States, the study population was thought to closely represent the population of breast augmentation patients as a whole. For each breast augmentation, the following data were collected: initial surgery date, secondary surgery date(s) if occurring within 12 months or less. Only Baker Grade III or IV contracture resulting in a reoperation was compiled as an event for data analysis. Statistical analysis was performed using Fisher's exact test and a logistic regression was used to control for differences between surgical sites.

This study design depended on introducing the funnel in surgical practices that were otherwise unchanged throughout data collection. The specific goal was to use study sites whose only practice change throughout the study period was insertion funnel adoption. To detect significant modifications in surgical protocol between Groups 1 and 2 that may confound the impact of funnel use, a survey was conducted at each center, specifically addressing surgical technique changes during the study period. The variables included antibiotic use, pocket type, incision placement, implant type, and other technique-related data (a blank copy of the survey is available as Supplementary Material at [www.aestheticsurgeryjournal.com](http://www.aestheticsurgeryjournal.com)). The survey results, including pocket irrigation type employed at each study site, are shown in Table 1.

## RESULTS

Of the 11 variables covered by the survey questions (Table 1), all nine surgeons responded. Five of the 9 surgeons reported changes in implant handling technique, which is related to incorporation of the insertion funnel. However, one surgeon reported increased use of textured implants, and one surgeon reported increased use of nipple shields. Both of these changes occurred at an unknown date during the study period. Since these surgeons (Sites #7 and 9) reported changes in protocol during the study period that may confound the impact of the funnel, those two sites were excluded.

The remaining 7 sites, with a total of 1177 breast augmentations (2354 implants), met inclusion criteria for Group 1 (no funnel) and 1620 surgeries (3240 implants) for Group 2 (funnel). Table 2 shows the incidence rates of reoperation for both groups due to capsular contracture within 12 months or less of the original surgery date. The rate of reoperation due to capsular contracture was higher without use of the insertion funnel (1.49%), compared to Group 2, using the funnel (0.68%). The reduction in Grade III and IV capsule detection was 54.4%. The difference between Groups 1 and 2 was statistically significant at  $P = 0.004$  using Fisher's exact test. Logistic regression analysis was used to examine the effects of treatment (funnel vs no funnel) and study site (surgeon) on the incidence of reoperation. A logistic regression was conducted using Statistical Analysis Software (SAS Institute, Inc.; Cary, NC) and controlling for differences between practices, use of the funnel remained statistically significant in reducing the need for reoperation due to capsular contracture. By logistic regression, the odds ratio for reoperation due to capsular contracture for Group 1 (no funnel) was 2.31 (95% CI: 1.18-4.53)  $P = 0.023$ . Statistical analysis was performed by Exponent, Inc., (Menlo Park, CA).

## DISCUSSION

Capsular contracture after primary breast augmentation is a potentially painful, costly, and frustrating complication for

**Table 1.** Answers to Survey Questions for Each Clinical Site

|        | Q1 | Q2 | Q3 | Q4  | Q5  | Q6 | Q7 | Q8  | Q9 | Q10 | Q11 | Pocket Irrigation Throughout Study* |
|--------|----|----|----|-----|-----|----|----|-----|----|-----|-----|-------------------------------------|
| Site 1 | No | No | No | No  | Yes | No | No | No  | No | No  | No  | Triple Antibiotic plus Betadine     |
| Site 2 | No | No | No | No  | Yes | No | No | No  | No | No  | No  | Triple Antibiotic                   |
| Site 3 | No | No | No | No  | No  | No | No | No  | No | No  | No  | Saline                              |
| Site 4 | No | No | No | No  | Yes | No | No | No  | No | No  | No  | Dilute Betadine                     |
| Site 5 | No | No | No | No  | Yes | No | No | No  | No | No  | No  | Triple Antibiotic                   |
| Site 6 | No | No | No | No  | Yes | No | No | No  | No | No  | No  | Dilute Betadine                     |
| Site 7 | No | No | No | No  | No  | No | No | Yes | No | No  | No  | Triple Antibiotic plus Betadine     |
| Site 8 | No | No | No | No  | No  | No | No | No  | No | No  | No  | Triple Antibiotic plus Betadine     |
| Site 9 | No | No | No | Yes | No  | No | No | No  | No | No  | No  | Triple Antibiotic                   |

Q, question. (a) Sites that answered "yes" to question 5 were referring to changes due to insertion funnel adoption. Site 7 reported increased use of textured implants, and site 9 reported adoption of nipple shields during the study. \*All surgeons also reported type of pocket irrigation they used, and that is was unchanged throughout the study. Triple antibiotic: bacitracin, cefazolin, gentamicin.

**Table 2.** Incidence of Revision Due to Capsular Contracture in Groups 1 and 2

| Site* | Group 1: Breast Augmentation Without Funnel |                |             |                    |           | Group 2: Breast Augmentation With Funnel |                |             |                    |           |
|-------|---|----------------|-------------|--------------------|-----------|--|----------------|-------------|--------------------|-----------|
|       | Total Cases                                 | Total Implants | No Revision | Revision due to CC | Incidence | Total Cases                              | Total Implants | No Revision | Revision due to CC | Incidence |
| 1     | 128   | 256            | 243         | 13                 | 5.08%     | 224                                      | 448            | 440         | 8                  | 1.79%     |
| 2     | 84  | 168            | 165         | 3                  | 1.79%     | 105                                      | 210            | 209         | 1                  | 0.48%     |
| 3     | 282   | 564            | 560         | 4                  | 0.71%     | 287                                      | 574            | 570         | 4                  | 0.70%     |
| 4     | 307   | 614            | 611         | 3                  | 0.49%     | 510                                      | 1020           | 1017        | 3                  | 0.29%     |
| 5     | 93  | 186            | 184         | 2                  | 1.08%     | 93                                       | 186            | 184         | 2                  | 1.08%     |
| 6     | 64  | 128            | 125         | 3                  | 2.34%     | 78                                       | 156            | 156         | 0                  | 0.00%     |
| 8     | 219   | 438            | 431         | 7                  | 1.60%     | 323                                      | 646            | 642         | 4                  | 0.62%     |
| Total | 1177  | 2354           | 2319        | 35                 | 1.49%     | 1620                                     | 3240           | 3218        | 22                 | 0.68%     |

CC, capsular contracture. \*Sites 7 and 9 are excluded in the final analysis to eliminate any site where surgical technique changes were made during the study period.

surgeon and patient alike. Additionally, it is believed that patients undergoing secondary surgery to treat capsular contracture have a higher risk of recurrent development of contracture. Decreasing the recurrence of capsular contracture after secondary surgery is an area of active study.<sup>10,18-24</sup> Due to cost and difficulty of revision implant surgery, prevention is clearly the strategy of choice for capsular contracture. This study provides evidence that funnel use may prevent capsular contracture-related reoperations.

We acknowledge that there are many important variables not directly analyzed in this protocol that may influence development of capsular contracture including implant type,

texturing, incision placement, pocket placement, average volume, aftercare such as bra use, variations between centers, etc. These are all technique-related factors that have suggested effects on capsule rates.<sup>3,8,25-29</sup> Comprehensive data collection and analysis were beyond the scope of this study, and these factors were assumed to remain unchanged at each site after funnel adoption. Therefore Group 1 (no funnel), is reported as a historical control group of consecutive breast augmentations performed before funnel adoption. While not ideal, this model made participation in the study simple for surgeons and staff. A randomized controlled trial or matched cohort study would likely have provided the best control

group. This investigation sets the stage for further studies with more precise control of all variables and follow-up to determine the impact of funnel use on absolute rates of capsular contracture, as opposed to the indirect measurement of the occurrence of reoperations due to capsular contracture. In addition, capture of more demographic data would help confirm that the 1177 patients in Group 1 and 1620 patients in Group 2 were similar in age, BMI, and comorbidity.

The strengths of this study include large numbers (with over 5000 implants studied), and the robust reduction in capsular contracture reoperation rate of over 50% seen with insertion funnel adoption. The study design was simple, including mechanism of follow-up and length of time to follow-up that were typical of breast augmentation patients. Unfortunately, the true number of patients lost to follow-up is not known. Furthermore, the question remains as to how long the study period should be to generate a representative rate of capsule occurrence, and there are varying opinions in the literature. Baker originally reported 92% of capsules occur within 12 months of surgery.<sup>30</sup> In a more recent meta-analysis comparing complications between smooth and textured surface implants, the average time to capsule occurrence in seven studies was 3 to 10.5 months.<sup>29</sup> However, in a recent single surgeon breast augmentation series with long-term follow-up, the capsule rate was 1.3% at 12 months, but 7.4% at 72 months.<sup>31</sup> It is clear that capsular contracture continues to occur over the life of an implant, and more capsules could be captured in a longer study period. For the purposes of this study, we believe the large difference in capsule-related reoperations between Groups 1 and 2 will continue to be reflected in subsequent years. Several other often-cited studies including Blount et al<sup>4</sup> and Adams et al<sup>12</sup> (both with average follow-up of 14 months) note that the majority of capsules occur in the first 12 months, with a steady few occurring in the following years. Regardless, longer-term follow-up is planned.

Site #1 had a much higher capsule rate compared to the remaining 8 study sites before funnel adoption, and a more dramatic reduction in capsules than other groups (Table 2). According to survey results and surgeon report, there were no changes in the surgical protocol of Site #1 other than the incorporation of the funnel. This study did not attempt to compare surgical protocols or establish best practices at each center, but rather determine if the introduction of the funnel changed the incidence of reoperations occurring within the individual practice. There is no identified explanation for this dramatic change, but it is possible that surgeons with higher capsule rates for various technical reasons may experience more robust reductions in capsule-related complications after adoption of the insertion funnel. This is presumably due to the benefit of decreased contamination and improved implant handling that the funnel affords.

This study provides preliminary evidence that utilizing an insertion funnel reduces the incidence of reoperations

due to capsular contracture as experienced within community based surgical practices. The study does not purport to identify the exact occurrence rate of capsular contracture-related complications or the absolute rate of reoperations due to capsular contracture as no special efforts were made to provide comprehensive post-surgical follow-up beyond routine postoperative visits. Only patients that organically returned to the practice and were again operated on by the surgeon who originally performed the primary augmentation were included in the incidence of reoperations. As such, another critique of the study is that reoperations on patients lost to follow-up who were operated on by another surgeon are not included (although this is assumed to have the same effect on both Group 1 and 2). Rather, the goal was to identify the potential for reduction of reoperations at each center due to capsular contracture, utilizing a group of surgeons that did not vary in their technique and protocols during the course of the investigation period. Although use of the funnel achieved strong statistical significance in reducing the rate of reoperations due to capsular contracture, had 100% of patients been captured and none lost to follow-up, it is plausible that the absolute rate of capsular contracture may have been higher in both Groups 1 and 2.

A follow-up study is planned using longer follow-up time and collection of more surgical data such as pocket placement, incision placement, implant size, and implant type. Each study site should also provide demographic data to detect any biases between the two groups. Recording these additional variables is necessary to validate assumptions made in this study design: that funnel and no funnel groups are demographically similar and that these surgical variables are similar in the two groups. The present study is potentially biased by not analyzing this data. Additionally, some inter-site variability undoubtedly occurs in capsular contracture grading. Applanation tonometry is a technology that can help standardize capsule grading and ideally would be used in this type of multi-site trial.

Lastly, further study would ideally include the funnel's impact on other breast augmentation-related complications, such as infection, hematoma, seroma, implant failure, and occurrence of mild, non-operative capsules. In addition, since this study concluded, the next generation Keller Funnel, the KF-2, has been introduced and has replaced the KF-1. Further study will include the KF-2. Finally, it should be mentioned that Keller Medical funded this study without the input of a third party organization in place to control the protocol and actively prevent any biases. The protocol itself was designed by Keller Medical and carried out by individual private practitioners.

## CONCLUSIONS

With insertion funnel use in primary breast augmentation, a significant reduction in the incidence of reoperations

performed due to capsular contracture within 12 months of primary breast augmentation was observed. Further study is needed using the funnel while more precisely controlling for the many variables that contribute to capsular contracture. A more traditional controlled, prospective study is needed; however, this study does provide encouraging preliminary evidence to support the hypothesis that use of the insertion funnel may significantly benefit breast augmentation patients.

### Supplementary Material

This article contains supplementary material located online at [www.aestheticsurgeryjournal.com](http://www.aestheticsurgeryjournal.com).

### Disclosures

Dr Pozner is on the Advisory Board for Allergan (Irvine, CA), Canfield (Fairfield, NJ), Merge (Chicago, IL), Midmark (Dayton, OH), New Beauty (Boca Raton, FL), and Valeant (Bridgewater, NJ); a Speaker for Alma (Buffalo Grove, IL), Lifecell (Bridgewater, NJ), Solta/Sound Surgical (Hayward, CA), and Zeltiq (Pleasanton, CA); a Stockholder in Keller Medical (Stuart, FL), Revance (Newark, CA), and TDM (Miami, FL); on the Advisory Board and Stockholder for Cytrellis (Boston, MA) and RealSelf (Seattle, WA); an Investigator for Cynosure/HOYA (Westford, MA); a Board Member and Stockholder for the Plastic Surgery Channel (Dallas, TX); an Investigator for and Stockholder in Invasix (Irvine, CA); on the Clinical Advisory Panel for Mentor (Santa Barbara, CA); on the Medical Advisory Board and Consultant for Merz (Raleigh, NC); a Consultant for and Stockholder in Sciton, Inc. (Palo Alto, CA); a Consultant and Speaker for Ulthera (Mesa, AZ); on the Advisory Board and an Investigator for Syneron (Irvine, CA); and a Speaker for and Stockholder in Thermi (Irving, TX). Dr Baxter is a Consultant and Speaker for Allergan (Irvine, CA). Dr Creasman is an Investor in Strathspay Crown (Newport Beach, CA) and Alphaeon (Irvine, CA). Dr Messa is a Shareholder in Strathspay Crown (Newport Beach, CA). Dr Kortesis is a Consultant for Mentor (Santa Barbara, CA); an Investigator for RXI (Marlborough, MA); and a Research Study Coordinator and Participant for Cohera (Pittsburgh, PA), Mentor, Sientra (Santa Barbara, CA), and RXI. Drs Flugstad, Egrari, Oliva, Martin, and Schlesinger have nothing to disclose.

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