Aesth Plast Surg (2019) 43:881–889
https://doi.org/10.1007/s00266-019-01401-w

ISAPS

ORIGINAL ARTICLE BREAST SURGERY

Implant Insertion Time and Incision Length in Breast Augmentation Surgery with the Keller Funnel: Results from a Comparative Study

Paolo Montemurro[1] · Sebastian Fischer[1] · Sybille Schyllander[1] · Patrick Mallucci[2] · Per Hedén[1]

Received: 12 March 2019 / Accepted: 7 May 2019 / Published online: 17 May 2019

Abstract

Background The Keller funnel is an easy-to-use mechanical device that aids breast implant insertion. This study analyzed implant insertion time and incision length using the Keller funnel versus conventional manual insertion.

Methods This was an analysis of two cohorts of adult patients undergoing primary breast augmentation with anatomical implants at a single center. In the 'insertion time cohort' ($N = 20$), implants were inserted with a Keller funnel on one side and manually on the other; follow-up lasted 4 years. In the 'incision length cohort,' both implants were inserted with a Keller funnel ($N = 50$) or manually ($N = 50$), with follow-up lasting 12 months.

Results In the insertion time cohort, mean total insertion time (from implant sterile-package opening to final positioning in the pocket) was 35 s (range 13–76 s) with the Keller funnel and 25 s (range 13–43 s) using manual insertion ($p = 0.07$); the mean time needed to push the implant through the incision was 6 s (range 3–10 s) with the Keller funnel and 16 s (range 13–40 s) with manual insertion ($p = 0.04$). In the incision length cohort, mean incision length was shorter with the Keller funnel versus manual insertion (35.5 ± 2.1 mm vs. 46.2 ± 3.2 mm; $p < 0.001$). There were no differences in complications based on insertion method.

Conclusion The Keller funnel was associated with decreased incision length and reduced time to push the implant through the incision. This brings potential clinical advantages in minimizing scarring and reducing contamination of the device.

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

Keywords Breast augmentation · Breast implantation · Incision length · Insertion sleeve · Keller Funnel

Introduction

The Keller funnel is a mechanical device that was developed to aid the insertion of a breast implant into its surgical pocket [1]. It is made using flexible, transparent, polymeric vinyl film, and is easy to prepare and load. A hydrophilic coating on the inside surface facilitates straightforward, low-friction delivery of the implant.

Use of this system may have several advantages compared with conventional manual insertion. First, it was developed to decrease the risk of implant shell trauma during insertion. Second, it allows for a 'no-touch technique' in which the implant has no contact either with the skin of the patient or with the surgeon's gloves. Indeed, in a cadaver study, the use of a Keller funnel was associated with a 27-fold decrease in skin contact compared with manual insertion ($p < 0.001$) [1]. As a result, bacterial contamination was reduced by twofold [1]. Several studies have suggested that this leads to significant reductions in the rates of capsular contracture and consequent

Electronic supplementary material The online version of this article (https://doi.org/10.1007/s00266-019-01401-w) contains supplementary material, which is available to authorized users.

✉ Per Hedén
per.heden@ak.se

[1] Akademikliniken, Storängsvägen 10, 11452 Stockholm, Sweden

[2] Mallucci London, London, UK

reoperations [2–4]. The use of an introduction sleeve, like the Keller funnel, is among 14 key recommendations for the prevention of device-associated infection when using breast implants [5, 6].

On a similar theme, a third potential advantage of the Keller funnel is in reducing the time required to insert the implant through the skin incision—the critical moment at which the device may be most likely to be contaminated with bacteria (particularly during manual insertion). However, this time reduction has never been formally assessed.

A fourth possible advantage of the Keller funnel is in reducing the required incision length, by facilitating the insertion process. This should therefore result in a shorter scar, helping to address a key concern that many women express during their consultation regarding postoperative scarring. However, to the best of our knowledge, no formal evidence of this reduction in incision length with the Keller funnel has ever been published.

The purpose of the present study was therefore to assess changes in insertion time and incision length during breast augmentation surgery using the Keller funnel compared with conventional manual implant insertion.

Materials and Methods

Study Design

This was an analysis of data from two different cohorts of patients undergoing primary breast augmentation with anatomical implants at a single center. Eligible subjects were females aged $\geq$ 18 years with symmetrical breasts, receiving bilateral, primary breast augmentation using the same implants on each side. All included patients received anatomically shaped, form-stable devices via an inframammary fold (IMF) incision with dual-plane placement. The study was conducted in accordance with the Declaration of Helsinki. All patients provided written informed consent before surgery.

The first data set is from the 'insertion time cohort', made up of consecutive patients operated on by a single surgeon (PH). Implants were inserted using a Keller funnel^{TM} (Allergan, Dublin, Ireland) on one side and conventional manual insertion on the contralateral side. Half of patients were randomized to Keller funnel use on the left side and manual insertion on the right side, and the other half were randomized to the opposite. All patients were followed up for 4 years.

The second cohort (the 'incision length cohort') contained consecutive patients operated on by a different surgeon (PM) at the same center between January 2016 and October 2017. In half of these individuals, both implants were inserted manually; in the other half, both implants were inserted using a Keller funnel. Only those with 12 months of follow-up were included in the final analysis.

Surgical Techniques and Assessments

For all patients included in this study, preoperative planning, surgery, and postoperative patient management were carried out in accordance with the Akademikliniken (AK) method [7, 8]. All patients were given one dose of antibiotic (a first-generation cephalosporin) 15 min prior to surgery, with no additional antibiotic given postoperatively. Implant pockets were dual plane and were irrigated with a solution of saline and clindamycin. The surgeon changed gloves before inserting each implant. No drains were used.

The only variation in technique between groups was in the method used for inserting the implants: either manually (as per the AK Method [7]) or using a Keller funnel (in accordance with the manufacturer's guidance). For manual insertion, the implant was held at a 90-degree angle below the retractor and the upper pole was rotated into the pocket, followed by alternating pushing of the right and left sides of the device. For Keller funnel insertion, the funnel was first cut to implant size and hydrated, and the implant was then poured directly in from its packaging. To place the implant, the funnel was inserted around 1 cm inside the dissected pocket, and the implant was then advanced completely into the pocket without touching the patient's skin.

In the incision length cohort, whichever insertion method was used, the appropriate size of the incision was determined as the shortest length that would (in the opinion of the surgeon) allow the implant to be inserted without excessive effort and without substantial risk of injuring the tissue or implant. In the incision time cohort, similar criteria were applied, but the incision length used was always the same on both sides.

In the insertion time cohort, the time required to insert the implants was measured from opening of the implant's sterile packaging to final positioning in the pocket; the specific time needed to push the implant through the skin incision was also assessed. Time measurements were made by a fellow plastic surgeon (the same person for all measurements). In the incision length group, the IMF incision length was measured during surgery.

Complications—including surgical wound-healing problems, hematoma, seroma, implant malposition, and capsular contracture—were assessed up to 4 years postsurgery in the insertion time group and up to 12 months postsurgery in the incision length group.

To assess possible damage, visual inspections were also made of two different implants passed through a Keller

funnel cut to an appropriate diameter in laboratory conditions.

Statistical Analyses

Descriptive statistics are provided throughout. Differences in insertion time parameters were analyzed using the student's *t* test for paired samples. The difference between the manual insertion and Keller funnel groups in incision length was assessed using the *t* test. The correlation between incision length and implant size characteristics was analyzed using Kendall Tau and the Spearman test.

Statistical significance was determined based on two-sided $p < 0.05$.

Results

Insertion Time Cohort

In total, 20 patients were included in this cohort. Of these, 10 had their implants inserted using the Keller funnel on the left side and by manual insertion on the right side, and 10 vice versa. All patients received the same implants on both sides, with a mean volume of 310 cc (range 220–410 cc).

The mean total insertion time (measured from opening the implant's sterile packaging to final positioning in the pocket) when using the Keller funnel was 35 s (range 13–76 s), compared with 25 s (range 13–43 s) using manual insertion ($p = 0.07$) (Table 1). However, the time required to push the implant through the incision was significantly shorter with the Keller funnel (mean 6 s; range 3–10 s) compared with manual insertion (mean 16 s; range 13–40 s; $p = 0.04$).

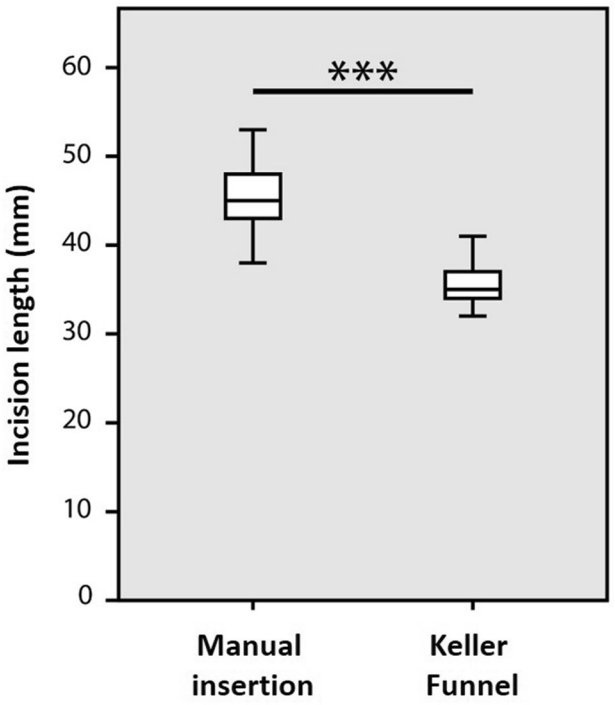

Fig. 1 Incision length. The figure shows median incision length (horizontal band), inter-quartile range (box), and range (whiskers). Data are from the incision length cohort ($N = 100$). ***$p < 0.001$

Table 1 Implant insertion time

Variable	Manual insertion ($N = 20$ breasts)	Keller funnel ($N = 20$ breasts)	p value
Total insertion time, seconds, mean (range)	25 (13–43)	35 (13–76)	0.07
Time required to push the implant through the incision, seconds, mean (range)	16 (13–40)	6 (3–10)	0.04

Data are from the insertion time cohort

Table 2 Baseline characteristics and implant specifications in the incision length cohort

Characteristic	Manual insertion ($N = 50$)	Keller funnel ($N = 50$)
Age (years), mean (SD; range)	34.4 (9.9; 18–60)	35.0 (9.3; 20–56)
Implant volume (cc), mean (SD; range)		
Right breast	325.0 (66.3; 165–495)	322.4 (55.5; 215–450)
Left breast	325.0 (66.3; 165–495)	322.4 (55.5; 215–450)
Implant width (cm), mean (SD; range)		
Right breast	12.2 (0.7; 10.0–14.0)	12.2 (0.5; 11.0–13.5)
Left breast	12.2 (0.7; 10.0–14.0)	12.2 (0.5; 11.0–13.5)

SD standard deviation

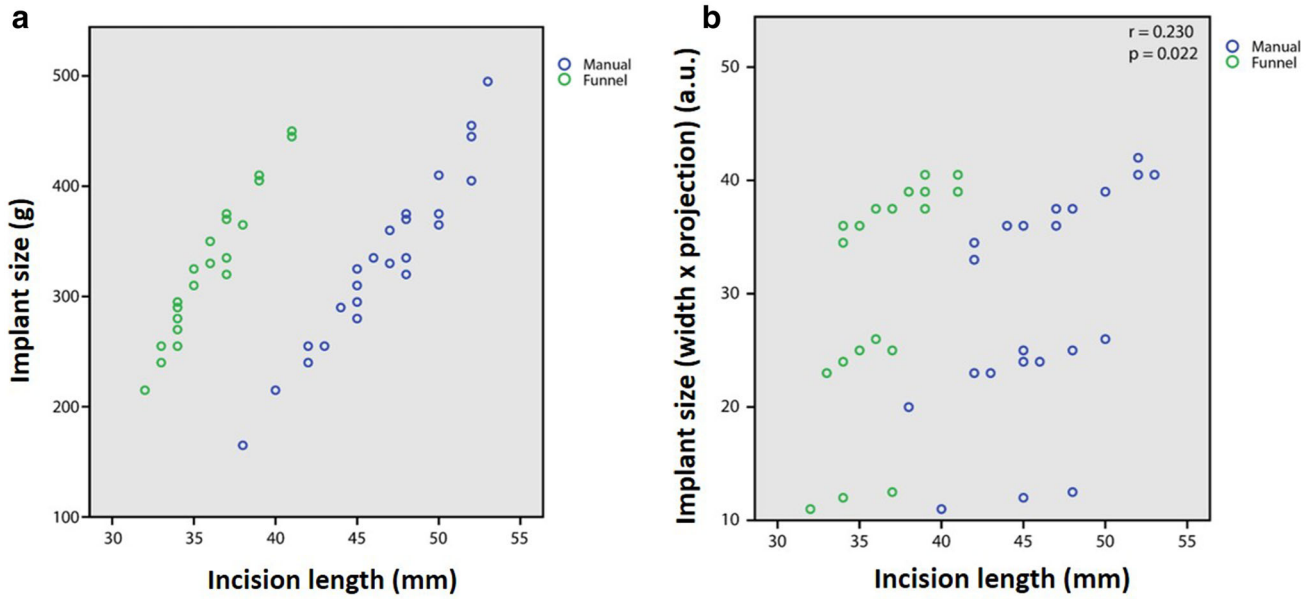

Fig. 2 Relationship between implant size and incision length. Implant size was assessed according to manufacturer-supplied implant volume (**a**) or width × projection (**b**). *a.u.* arbitrary unit. Data are from the incision length cohort ($N = 100$)

Incision Length Cohort

In total, 168 consecutive patients who underwent primary breast augmentation with anatomical implants were assessed to obtain 100 subjects for whom 12 months of follow-up data were available: 50 with implants inserted manually and 50 with implants inserted using a Keller funnel. The mean age of the 100 patients included in the analysis was 34.7 ± 9.6 years (range 18–60 years) and was well matched between groups (Table 2).

All patients in both groups received the same implants on both the left and right side. The implant characteristics of the two groups were very similar (Table 2). The mean implant volume was 325.0 ± 66.3 cc (range 165–495 cc) in the manual insertion group and 322.4 ± 55.5 cc (range 215–450 cc) in the Keller funnel group. Mean implant width was 12.2 cm in both groups.

The mean incision length was significantly shorter in the Keller funnel group compared with the manual insertion group: 35.5 ± 2.1 mm versus 46.2 ± 3.2 mm, respectively ($p < 0.001$) (Fig. 1). This equates to a 23.2% reduction.

Irrespective of whether implants were inserted manually or using a Keller funnel, the incision length was significantly correlated with implant volume ($p < 0.001$) and with a combined measure of implant width multiplied by projection ($p = 0.022$) (Fig. 2). Incision length also correlated with implant width alone ($p < 0.001$) but not with implant projection alone ($p = 0.143$).

Sample images from the two groups are provided in Figs. 3 and 4, showing patients before surgery and at 12 months postsurgery.

Complications

In the insertion time cohort ($N = 20$), there were two complications over 4 years of follow-up (Table 3): One patient had an early postoperative hematoma, which was immediately evacuated and the subsequent clinical course was uneventful, and one patient had mild inferior implant malpositioning (on the side treated with the Keller funnel), which was corrected with creation of a neo-submuscular pocket and IMF reset. A third patient had no complication but regretted her decision to have an augmentation, and the implants were therefore removed and the breast fat grafted. No other patients experienced any complications, and there were no cases of capsular contracture.

In the incision length cohort ($N = 100$), there were seven cases of early minor wound-healing problems (manual insertion, $n = 3/50$ [6.0%]; Keller funnel, $n = 4/50$ [8.0%]) (Table 3). All were unilateral and superficial, with no implant exposure, and all resolved within 2 weeks without surgical intervention. After 12 months of follow-up, the only other complications recorded were one case of seroma and one case of implant malposition (bottoming out), both unilateral and both in the manual insertion group. The seroma was evacuated under ultrasound guidance; the malposition required surgical correction. There was no recurrence during the follow-up. No other patients required reoperation, and none experienced capsular contracture within the follow-up period.

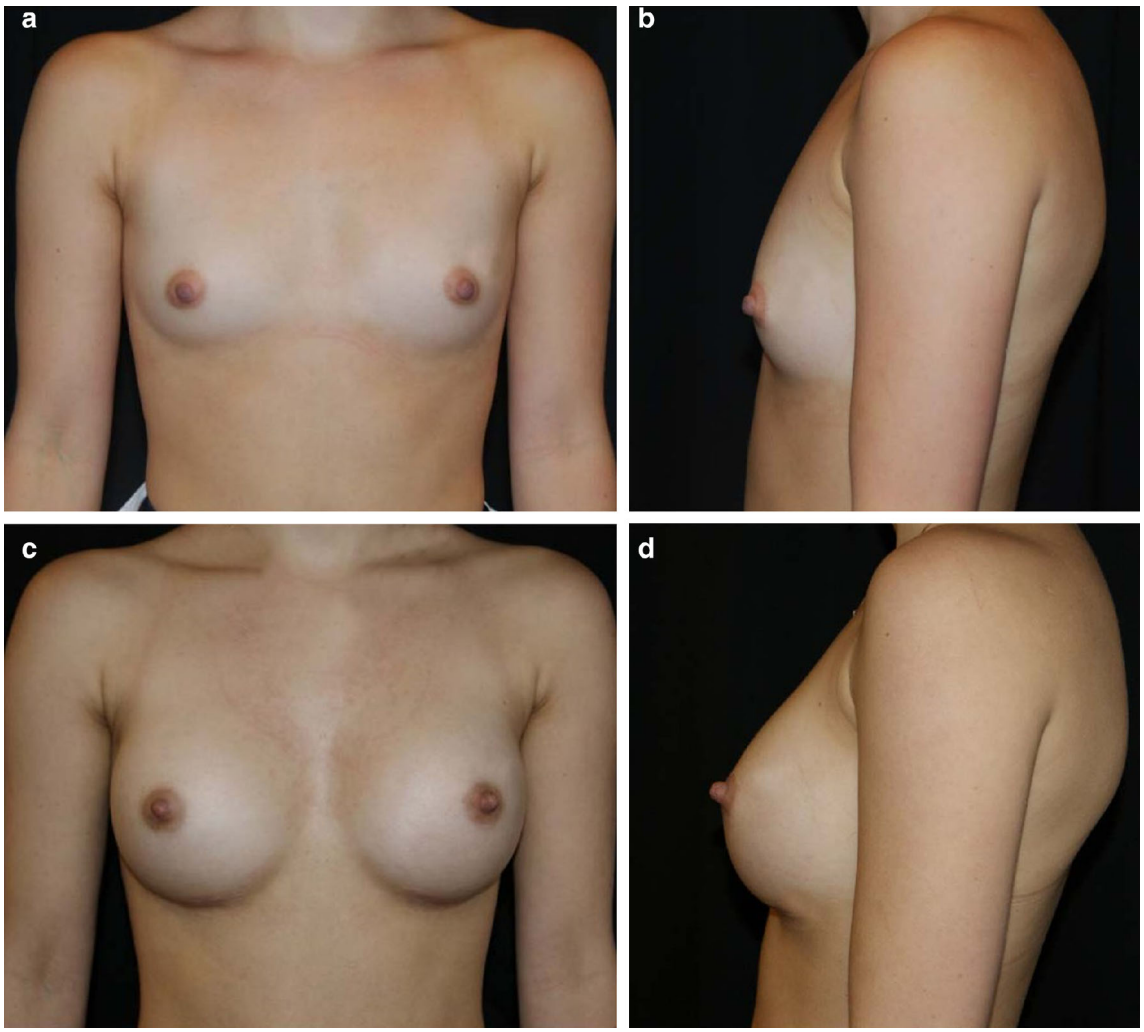

Fig. 3 Breast augmentation with conventional manual insertion of implants. A 27-year-old woman undergoing breast augmentation with anatomical implants (280 cc) using conventional manual insertion, before surgery (**a, b**) and at 12 months postsurgery (**c, d**)

Visual Inspection of Implants

To assess potential damage to implants passed through a Keller funnel, two visual inspections were undertaken in a laboratory setting. When a 295-cc device was pushed through a Keller funnel cut of 34 mm diameter (similar to the mean incision length in the Keller funnel group of the incision length cohort), there was no evidence of damage (Fig. 5). Similarly, there was no obvious trauma when a larger, 445-cc device was passed through an appropriately sized Keller funnel (diameter 41 mm; see accompanying video).

Discussion

This study is the first to demonstrate that incision length in IMF-based breast augmentation can be safely reduced through the use of a Keller funnel. The mean decrease was around 10 mm—a relative reduction of almost 25% compared with manual insertion. This effect was evident across all sizes of implants. Form-stable implants were used throughout, and these devices typically require a slightly larger incision than less form-stable implants because they do not deform as readily. However, the relative reduction in incision length with the Keller funnel is likely to be applicable across all implant types.

Although use of the IMF incision, as in the present study, makes the scar locate within the fold where it is not likely to be highly visible, scarring is nonetheless a postoperative concern for many patients, irrespective of the

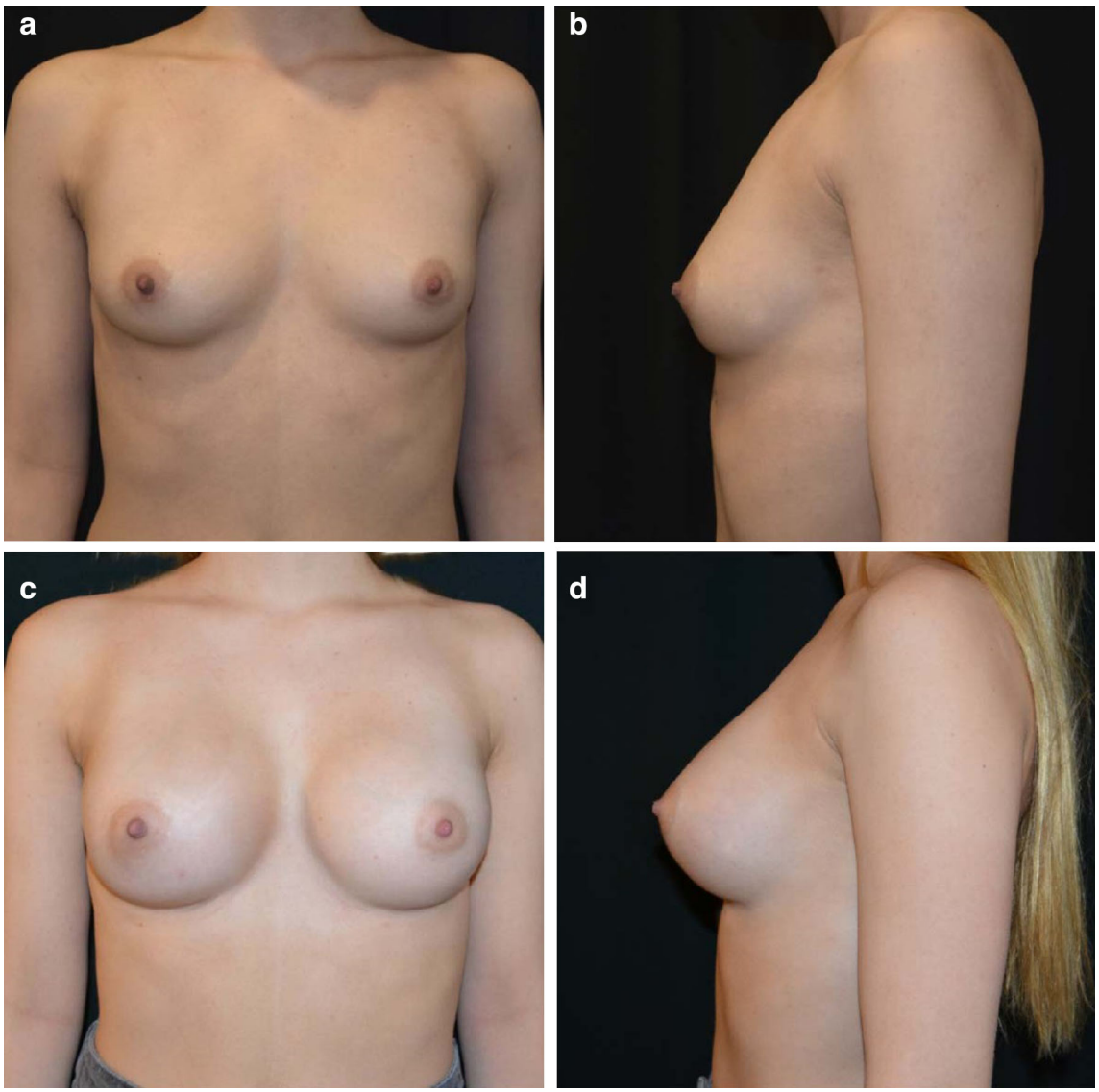

Fig. 4 Breast augmentation with Keller funnel-based insertion of implants. A 27-year-old woman undergoing breast augmentation with anatomical implants (295 cc) using Keller funnel insertion, before surgery (**a, b**) and at 12 months postsurgery (**c, d**)

incision type used [7, 9, 10]. Any technique that reduces overall scarring is therefore valuable.

The current study also demonstrated that the time needed to insert the implant through the skin incision can be statistically significantly reduced with the Keller funnel compared to conventional manual insertion. This is clinically significant because the insertion phase is the critical period in which the device may be most likely to be contaminated (particularly when using manual insertion). Although the total insertion time was somewhat longer with the Keller funnel, this is less likely to be *clinically significant* because it does not define the most sensitive period of the process.

It therefore appears reasonable to suggest that use of the Keller funnel may reduce contamination of the device at the time of implantation. This aligns with previous data demonstrating that insertion sleeves can reduce bacterial contamination and hence decrease the risk of capsular contracture [1–4]. In a multicenter study of almost 3000 breast augmentations, use of the Keller funnel was associated with a relative reduction in reoperations due to capsular contracture of 54.4% (p = 0.004; absolute rates: 1.49% without the funnel, 0.68% with the funnel) [2].

Furthermore, a faster and smoother implant insertion with the Keller funnel may contribute to reduced mechanical stress for both the implant and the skin around the incision site. This could be very important because mechanical stress can cause gel fracture and rupture of the implant shell; consequent gel bleeding may be associated with siliconoma and tissue inflammation [11–13].

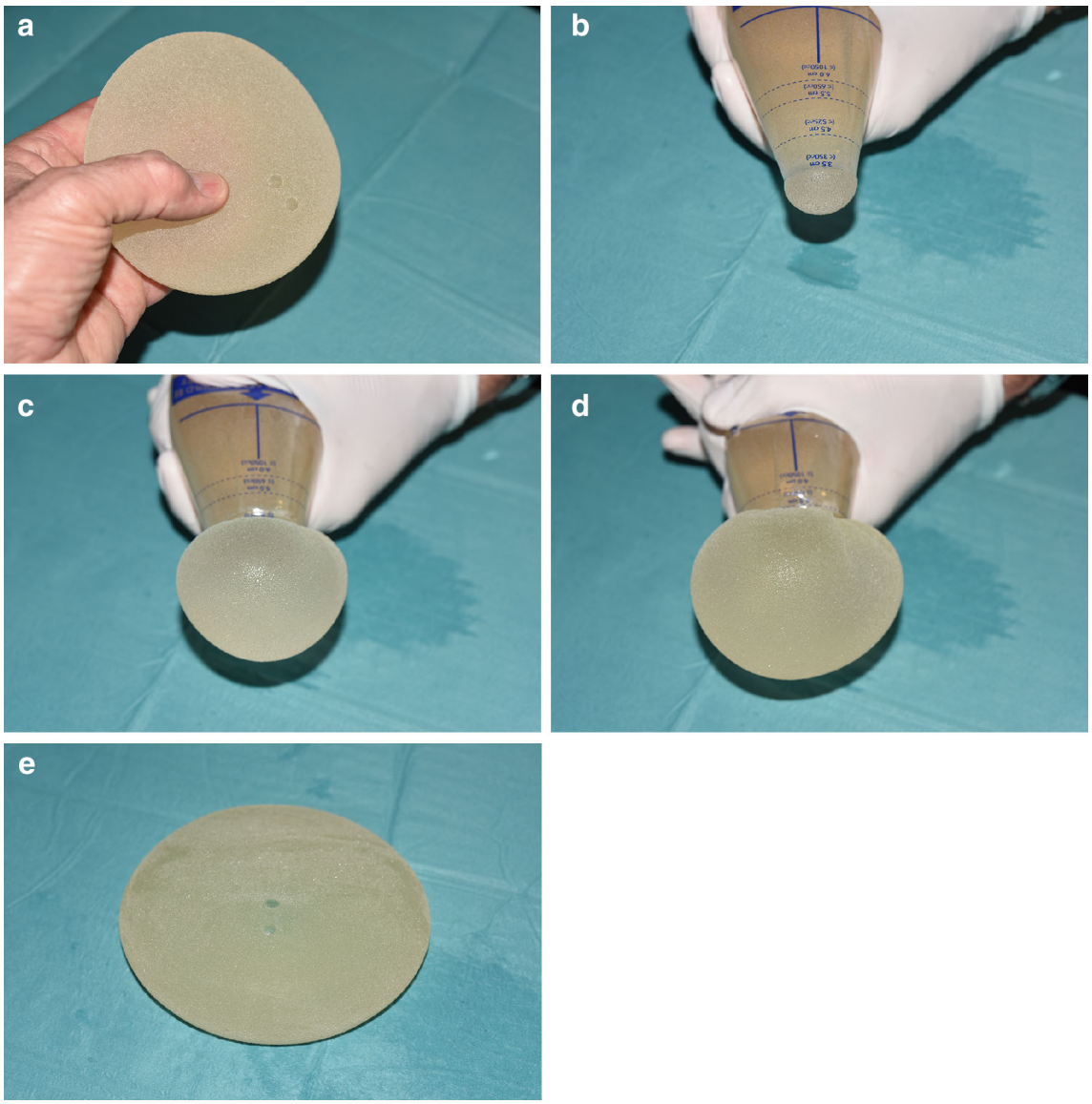

Fig. 5 A breast implant pushed through an appropriately sized Keller funnel in laboratory conditions. A 295-cc device (**a**) was passed through a Keller funnel cut of 34 mm diameter (**b**–**d**) and came through with no obvious damage (**e**)

Meanwhile, stretching of the skin can compromise perfusion and hence wound healing [14].

A preference for insertion sleeves has been incorporated into recent technical guidance, as a means of reducing implant-associated infection and hence complications [5, 6]. Uptake has been substantial: In a recent survey of 253 members of the American Society of Plastic Surgery, 69% said that they have adopted a no-touch technique using the Keller funnel [15].

With regard to the present study, it could of course be argued that the length of incision chosen by the surgeon in the comparative 'incision length cohort' was arbitrary. Indeed, for any given patient and implant, the surgeon was free to use a longer or shorter incision as he saw fit, and a different surgeon might have made a different choice. However, irrespective of whether the Keller funnel was used or not, the incision length was the minimum possible to allow implant insertion without excessive effort or substantial risk of damaging the tissue or implant.

The manual insertion group was initially part of a study aimed at developing an algorithm for determining the minimum appropriate incision length based on implant size. This study was abandoned when the Keller funnel was introduced, and our standard practice was changed. However, the conditions under which the manual insertion data were collected should eliminate any potential fear that the surgeon may have biased the present study when determining the incision length in that group of patients.

Table 3 Complications

Complication	All patients ($N = 20$)
Insertion time cohort	
Hematoma	1 (5.0)
Malposition	1 (5.0)

Complication	Manual insertion ($N = 50$)	Keller funnel ($N = 50$)
Incision length cohort		
Early minor wound-healing problem	3 (6.0)	4 (8.0)
Healing problems with implant exposure	0 (0)	0 (0)
Hematoma	0 (0)	0 (0)
Seroma	1 (2.0)	0 (0)
Malposition	1 (2.0)	0 (0)
Capsular contracture	0 (0)	0 (0)

All data are *n* (%)

Of note, the specific length used for any given implant was not important. Instead, the crucial point is that the same surgeon used the same criteria to choose the shortest possible incision, in two near-identical groups of patients. Hence, the relative reduction in incision length is trustworthy and valid. In this study, the key principal was not the length of a given incision per se, but that it could be reduced in length with the Keller funnel.

The length of the incision was significantly correlated with implant dimensions, as would be expected with a surgeon attempting to minimize incision length as much as safely possible. Importantly, the complications profile suggests that the shorter incisions used in the Keller funnel group did not increase the rate of early wound-healing problems. Had the incision been too small, we might have expected an increase in healing-related events, owing to excessive pulling and stretching and hence trauma to the tissue during insertion. We would also have expected an increase in the rate of device rupture. Although some such events could have remained silent, it is unlikely that all would have done so, and none were observed in this study. Rates of other complications were low or zero in both groups.

In addition, visual inspection of two differently sized implants passed through a Keller funnel cut to an appropriate diameter in laboratory conditions did not demonstrate any obvious trauma. This experiment included an implant of similar size to the mean size in the incision length cohort passed through a Keller funnel cut to approximately the mean incision length (Fig. 5). As similar criteria were used to determine the incision length in patients, this demonstration is likely to be valid across the surgical cohort.

We should acknowledge some limitations of the present analysis. First, it was a single-center study. Although precise operative specifications will always differ between surgeons, we see no reason why the demonstrated advantages of the Keller funnel in *relative* incision length and insertion time (compared with conventional manual insertion) should not be applicable to other surgeons. However, we recognize that formal demonstration of this, by means of a multicenter study, would be valuable. On the flipside, the advantage of the single-center methodology—which was also single surgeon within each cohort—was that it guaranteed a homogenous method for performing the surgeries and for deciding on the minimum incision length. Second, the cohort in the insertion time study was relatively small ($N = 20$), although this was a relatively straightforward analysis and hence these numbers would appear to be sufficient. Third, the follow-up period for the incision length cohort was only 12 months. However, healing and implant stabilization after surgery typically require around 6 months, and hence the follow-up time was probably sufficient to assess the effects of incision length on complications related to tissue trauma. The purpose of the analysis was not to assess the impact of the Keller funnel on longer-term complications such as capsular contracture, for which a longer follow-up would have been required, although it is reassuring to see that there were no such events over the study period. Fourth, it would be worthwhile to perform an ultrasound study to assess the impact of the smaller incision (and of the Keller funnel technique in general, relative to manual insertion) on implant trauma. This was not done in the present work, owing to cost and patient compliance concerns. However, visual inspection of two different implants passed through a Keller funnel in laboratory conditions showed no obvious signs of damage. Finally, all of the patients in present study received anatomical, form-stable devices. We see no reason why the observed advantages of the Keller funnel should not apply to other implants, including smooth devices, but this remains to be formally proven. Furthermore, a comparative study of Keller funnel insertion with smooth and textured devices would be valuable.

Conclusion

This study demonstrates that although use of the Keller funnel does not accelerate the overall process of implantation, it does reduce the time in which the device is in contact with the skin and subcutaneous breast tissue. Furthermore, deployment of the Keller funnel significantly reduces the length of incision required to safely insert a

breast implant into the pocket. Although anatomical, form-stable implants and the IMF incision were used for all patients, there is no technical reason to believe that these advantages do not also apply to other implant types and access techniques.

Acknowledgements We would like to thank Dr. Timothy Ryder from Biological Communications Limited for editorial assistance, funded by Allergan. Allergan had no input into the content of the paper.

Author contributions All authors participated in study conduct, data collection, and writing of the manuscript, and all approved the final draft.

Compliance with Ethical Standards

Conflict of interest Dr. Montemurro is a consultant and speaker for Allergan. Dr. Fischer and Dr. Schyllander report nothing to disclose. Dr. Mallucci is a shareholder in B-Lite (Polytech). Dr. Hedén has had consultancy agreements with Allergan, Mentor, Establishment Labs, G&G Medical and GC Aesthetics, is a shareholder in Polytech and Establishment Labs, and has a Development Contract with Allergan.

Ethical Approval The study was conducted in accordance with the Declaration of Helsinki.

Informed Consent All patients provided written informed consent before surgery.

References

1. Moyer HR et al (2012) Contamination in smooth gel breast implant placement: testing a funnel versus digital insertion technique in a cadaver model. Aesthet Surg J 32:194–199
2. Flugstad NA et al (2016) Does implant insertion with a funnel decrease capsular contracture? A preliminary report. Aesthet Surg J 36:550–556
3. Horsnell JD, Searle AE, Harris PA (2017) Intra-operative techniques to reduce the risk of capsular contracture in patients undergoing aesthetic breast augmentation—a review. Surgeon 15:282–289
4. Newman AN, Davison SP (2018) Effect of Keller funnel on the rate of capsular contracture in periareolar breast augmentation. Plast Reconstr Surg Glob Open 6:e1834
5. Deva AK, Adams WP Jr, Vickery K (2013) The role of bacterial biofilms in device-associated infection. Plast Reconstr Surg 132:1319–1328
6. Adams WP Jr et al (2017) Macrotextured breast implants with defined steps to minimize bacterial contamination around the device: experience in 42,000 implants. Plast Reconstr Surg 140:427–431
7. Hedén P (2011) Breast augmentation with anatomic, high-cohesiveness silicone gel implants (European experience). In: Spear SL (ed) Surgery of the breast: principles and art, 3rd edn. Wolters Kluwer/Lippincott Williams & Wilkins, Philadelphia, pp 1322–1345
8. Montemurro P et al (2017) Implementation of an integrated biodimensional method of breast augmentation with anatomic, highly cohesive silicone gel implants: short-term results with the first 620 consecutive cases. Aesthet Surg J 37:782–792
9. Park AJ, Chetty U, Watson AC (1996) Patient satisfaction following insertion of silicone breast implants. Br J Plast Surg 49:515–518
10. Kalaaji A et al (2013) Survey of breast implant patients: characteristics, depression rate, and quality of life. Aesthet Surg J 33:252–257
11. Bizjak M et al (2015) Silicone implants and lymphoma: the role of inflammation. J Autoimmun 65:64–73
12. De Boer M et al (2017) Breast implant-associated anaplastic large-cell lymphoma in a transgender woman. Aesthet Surg J 37:83–87
13. Carson B, Cox S, Ismael H (2018) Giant siliconoma mimicking locally advanced breast cancer: a case report and review of the literature. Int J Surg Case Rep 48:54–60
14. Hsu CK, Lin HH, Harn HI (2018) Mechanical forces in skin disorders. J Dermatol Sci 90:232–240
15. Gowda AU et al (2017) Preventing breast implant contamination in breast reconstruction: a national survey of current practice. Ann Plast Surg 78:153–156