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# The Keller Funnel, Capsular Contracture, and Conflict of Interest

## *A Review*

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**Background:** The Keller funnel (Allergan; AbbVie Inc, North Chicago, IL) is commonly used to insert breast implants as part of a "no touch" protocol. Many plastic surgeons believe that this device reduces the risk of capsular contracture. This review was undertaken to evaluate the evidence regarding any reduction in capsular contracture rate, other possible benefits, safety and to investigate financial conflict of interest.

**Methods:** A PubMed electronic literature search was conducted to identify studies comparing capsular contracture rates with and without the Keller funnel. The Open Payments database was accessed for information regarding corporate payments to plastic surgeons.

**Results:** Two retrospective historical case-control studies, published in 2016 and 2018, were identified. Both studies had important confounders, including implant type and placement, which are known to affect capsular contracture rates. Major financial conflicts of interest were present. Most authors did not disclose these conflicts, which totaled more than $1 million and were usually categorized as gifts from Allergan, which purchased the Keller funnel in 2017.

**Discussion:** Financial conflict of interest, along with publication bias, creates a bias toward publication of positive findings. No reliable evidence supports a "no touch" technique, which is a misnomer because manual handling of implants is unavoidable, even when using a funnel. Recent microbiological studies do not support a specific bacterial etiology for capsular contracture. No evidence supports contamination by the surgeon touching the implant. Among other proposed benefits, such as reduced operating time, less contamination, a shorter incision, and less implant trauma, only a slightly shorter incision (1 cm) is supported by the evidence. The cost is $150 per funnel.

**Conclusions:** No reliable evidence supports the use of a Keller funnel to reduce the risk of capsular contracture. Both supportive studies contain confounding variables, limited follow-up time, and no plausible scientific basis for efficacy. Institutional review board approval of studies on human subjects is not optional. Financial conflicts of interest are extraordinary in their magnitude and potential for creating undue influence. Greater transparency and honest disclosures are needed.

**Key Words:** breast implant, capsular contracture, conflict of interest, contamination, Keller funnel, no-touch

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In their recent publication, Morkuzu et al[1] conclude that the Keller funnel (Allergan; AbbVie Inc, North Chicago, IL) reduces the capsular contracture rate and is a useful method for "no touch" breast augmentation and reconstruction. The Keller funnel is a nylon sleeve with a hydrophilic inner coating.[1] Capsular contracture is the most frequent indication for reoperation after breast augmentation.[2] An effective method to reduce risk is welcome and merits our consideration. This review was undertaken to evaluate the evidence for efficacy of this method. Financial conflict of interest was also evaluated. The "Sunshine Act"[3] allows the public to access manufacturer payments to plastic surgeons.

## METHODS

The PubMed electronic database was searched for articles in English evaluating capsular contracture rates in patients treated with a Keller funnel compared with a control group of patients who were not treated with a Keller funnel. The Open Payments database provided by the Centers for Medicare & Medicaid Services and the Propublica Dollars for Docs Web site were accessed to investigate physician payments.[4,5]

## RESULTS

Only 2 studies were identified that compared capsular contracture rates in patients treated with and without a Keller funnel.[6,7] The first study, a preliminary report by Flugstad et al,[6] did not actually compare capsular contracture rates. Instead, the authors reported the number of revisions for capsular contracture within 1 year of the original surgery, finding a difference of less than 1% (0.68% vs 1.49%). There was no institutional review board (IRB) approval for this retrospective study. Ten plastic surgeons participated at 9 different sites (later reduced to 7 sites). The study period was 2006 to 2012. The Keller funnel was introduced in 2009. Women who were treated without funnels represented a historical control group. Difference in follow-up time represented a confounding variable, although the authors reported that the time to evaluate the need for reoperation for capsular contracture was identical for both groups.

Other confounding variables included the implant type, placement (ie, subpectoral vs subglandular), and incision location. The authors' regression analysis did not account for implant characteristics and the insertion plane, which are known to affect capsular contracture rates.[8,9] The authors did not know how many of the patients were lost to follow-up, making the inclusion rate unknown. Infection rates were not reported.

Keller Medical, Inc (Stuart, FL), manufacturer of the device, provided funding for this study.[6] This funding included reimbursement to support staff and/or the clinical practice. Keller Medical also provided editorial services and compensated the biostatistician. The authors do not report whether the funnels were provided at no charge or at a discount. The funding disclosure paragraph indicates that each author states that there is no corporate or financial conflict of interest related to Keller Medical or with the collection of data.

The second article supporting the Keller funnel for capsular contracture rate reduction was published by Newman and Davison in 2018.[7] This retrospective study compared a small historical control group of 15 women with a much larger group of 151 women treated with periareolar breast augmentations using a Keller funnel, all treated by the same surgeon (Davison). The authors reported a lower risk of capsular contracture in women treated with the Keller funnel ($P = 0.0019$). The method of diagnosing a capsular contracture consisted of contacting patients by telephone or email and asking them questions. Patients who had

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returned for a follow-up appointment 3 years or more after surgery were not contacted. Patients who were unsure whether they had a capsular contracture were asked to return to be examined; those that did not return (n = 21) were excluded.

Newman and Davison[7] included patients treated with saline and silicone implants, although the numbers of each type were not provided. The authors reported that the periareolar incision type was isolated and studied. It is not clear whether other approaches were used during the study period and whether the capsular contracture rate differed according to the incision. Similar to the study by Flugstad et al,[6] women treated without funnels were treated earlier in the study, before the funnels were adopted in practice. In the control group, 15 of the 20 patients were included (75%); 5 were excluded. In the treatment group, 151 patients among the 217 total patients were included (70%); 66 were excluded.[7] An important confounder in the study by Newman and Davison was implant placement. Among women treated without a funnel, 65% underwent subpectoral implant placement, versus 93% of women treated with a funnel. This difference is highly significant ($P = 0.00003$), calculated using a $\chi^2$ test.[10]

Financial disclosures are summarized in Table 1. Only 2 of the 10 authors of the study by Flugstad et al[6] reported a financial relationship with either Keller Medical or Allergan. Three authors reported financial relationships with other companies. Five authors reported no financial conflicts. The second article, published by Newman, who is not a plastic surgeon, and Davison, who is a plastic surgeon, reported no conflicts of interest.[7]

Table 2 reveals payments made from Allergan to the 10 authors of the article by Flugstad et al.[6] The total amount of payments during the years 2013 to 2019 was US $1,257,685, as reported by the Centers for Medicare & Medicaid Services for the years 2015 to 2019 (2015 is the earliest year for this database)[4] and the Propublica Dollars for Docs Web site for the years 2013 and 2014.[5] All 10 authors received payments, ranging from $4835 to $287,701. More than half of this amount ($642,180) was disbursed among 6 authors during the years 2013 to 2015. By 2016, the year of publication, a total of $749,836 was paid out to 8 of the 10 authors. According to the Open Payments Web site,[4] Davison, the senior author of the second study, received $54,465 in payments from Allergan during the years 2015 to 2019 (Table 2).

Payment categories are provided in Table 3, as reported on the Open Payments Web site.[4] More than half (52.4%) of the payments to the 10 authors of the study by Flugstad et al[6] were categorized as gifts. Approximately 40% of payments to the study authors were categorized as services other than consulting, including serving as faculty or a speaker at a venue other than a continuing education program. Payments to Davison, the senior author of the second study,[7] were primarily listed as gifts (89.2%).

**TABLE 1.** Reported Conflicts by Plastic Surgeons

| Plastic Surgeon | Reported Conflict |
|---|---|
| Flugstad et al (2016)[6] | |
| Flugstad | None |
| Pozner | On advisory board for Allergan and stockholder in Keller Medical |
| Baxter | Consultant and speaker for Allergan |
| Creasman | No disclosure for Allergan or Keller Medical |
| Egrari | None |
| Martin | None |
| Messa | No disclosure for Allergan or Keller Medical |
| Oliva | None |
| Schlesinger | None |
| Kortesis | No disclosure for Allergan or Keller Medical |
| Newman and Davison (2018)[7] | |
| Davison | None |

## DISCUSSION

### Study Limitations

Flugstad et al[6] compared the number of revisions performed within 1 year of implant insertion. One year is a short time frame for studying this complication, which can occur at longer follow-up intervals.[2] Confounding variables, particularly implant type and placement, and an unknown inclusion rate make isolating funnel use as a factor affecting the capsular contracture rate (or rather reoperation) challenging, especially when the risk is so low overall, approximately 1%. Deva,[11] the discussant of this study and a proponent of the biofilm theory and barrier strategies (including an introduction sleeve),[11] comments that the supporting evidence was "very weak." Deva recognizes that the study design and funding were derived directly from the manufacturer, and conflict of interest needs to be considered before, as a profession, plastic surgery endorses the use of a Keller funnel to prevent capsular contracture.

Publication bias must be considered.[12] Keller Medical was responsible for the study design and protocol. It would be very unusual for a corporation to fund a study that showed that its product was ineffective and allow it to be submitted for publication. Publications with positive findings are also more likely to be published.[12]

In 2017, 1 year after publication of this study, Keller funnel was acquired by Allergan (now Abbvie) for an undisclosed sum.[13] The announcement emphasized that the Keller funnel allows surgeons to use a "no-touch" technique, which "may help minimize the introduction of bacteria and foreign material into the surgical pocket."

Newman and Davison[7] recognize that subpectoral implant placement is associated with a reduced risk of capsular contracture. Surprisingly, the authors do not acknowledge this confounder, which could account for the difference in capsular contracture rates. The authors (incorrectly) state that the sole surgical difference between patients in the groups was whether the implants were inserted with a Keller funnel.

### Institutional Review Board Approval

Review and approval by an IRB is required for all projects that involve research with human subjects.[14,15] Medical journal guidelines insist on it.[15] In addition, the approval must precede the start of the research.[15] Flugstad et al[6] report that "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." On the contrary, IRB review is available in the private practice setting[15] (this service is not restricted to academic medical centers), and by not applying for this review and gaining approval, the authors violate the federal guidelines they cite.[14,15] These regulations were developed to protect patients from unnecessary and possibly harmful medical treatments and devices.[15] The regulations also call for disclosure of financial conflicts.[15] Although Newman and Davison reported IRB approval,[7] this disclosure requirement was evidently overlooked.

### Conflict of Interest

For most authors, Allergan payments dwarfed any payments received during the period of study from other manufacturers. Contemporaneous payments from other companies were usually small, often less than $100, and listed as food and beverages. Payments from Allergan were typically much larger and categorized as "gifts" or "other services." The amounts do not seem commensurate with reasonable reimbursement for serving as faculty or a speaker at a function that is not considered continuing medical education.

**TABLE 2.** Allergan Payments (in US Dollars) to Plastic Surgeons*

| Plastic Surgeon | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Total |
|---|---|---|---|---|---|---|---|---|
| Flugstad et al (2016)[6] | | | | | | | | |
| Flugstad | | | | | 5051 | 1379 | 2754 | 9184 |
| Pozner | | | 228,137 | 13,476 | 12,406 | 17,647 | 16,035 | 287,701 |
| Baxter | 64,754 | 91,192 | 55,081 | | 14,879 | 2112 | 6788 | 234,806 |
| Creasman | | | 54,585 | 2543 | 11,842 | 16,134 | 4569 | 89,673 |
| Egrari | | | 4004 | 13,735 | 17,786 | 21,485 | 17,519 | 74,529 |
| Martin | | | 47,800 | 13,872 | | 2907 | | 64,579 |
| Messa | | | | 12,705 | 4147 | 7339 | 6624 | 30,815 |
| Oliva | | | | | | | 4835 | 4835 |
| Schlesinger | | | 89,790 | 47,895 | | 26,804 | 27,138 | 191,627 |
| Kortesis | | | 6837 | 3430 | 47,503 | 90,681 | 121,485 | 269,936 |
| All authors | 64,754 | 91,192 | 486,234 | 107,656 | 113,614 | 186,488 | 207,747 | 1,257,685 |
| Newman and Davison (2018)[7] | | | | | | | | |
| Davison | | | 10,727 | 18,413 | 14,007 | 8227 | 3091 | 54,465 |

Amounts less than $1000 were not included. Food and beverages were not included.

*Data obtained from CMS Open Payments Web site for the years 2015 to 2019 and Propublica Dollars for Docs for the years 2013 and 2014.

Allergan is the largest corporate funder of plastic surgeons,[16–18] disbursing almost $10 million to plastic surgeons in 2018.[17,18] The company also spends heavily on plastic surgery societies, which fund scientific journals.[19] The amount spent on professional meetings and activities is not generally known, but presumed to be millions of dollars.[19,20] Society officers, journal editors, and reviewers are among those who are compensated.[20] This funding is meant to build loyalty. The evidence shows that even small gifts induce unconscious feelings of gratitude and reciprocity.[19,21] A *quid pro quo* is established.[21] The link between positive study findings and industry payments to investigators is well-established.[12] Plastic surgery studies that disclose a financial conflict of interest are approximately 7 times more likely to report a positive outcome than those that do not.[12]

Indeed, it is very unlikely for a plastic surgeon who is funded by Allergan to publish a study that is critical of an Allergan product—a problem highlighted by the textured implant crisis and plastic surgeons' willingness to defend a defective Allergan product and failure to act promptly to abandon the use of macrotextured breast implants.[22]

Although there has been discussion of reporting dollar amounts or ranges to show the magnitude of any conflict,[19,23] this change has not been introduced in plastic surgery publications. Readers must look up these payments on their own. Studies comparing information on the Open Payments Web site with author disclosures in plastic surgery publications reveal a troubling reluctance to disclose financial conflicts.[24,25] Luce and Jackman[24] reported that 63% of authors in *Plastic and Reconstructive Surgery* did not disclose a financial conflict when one was present according to the Open Payments records. Boyll et al[25] reported that 87% of authors in 2 plastic surgery publications (*Plastic and Reconstructive Surgery* and *Aesthetic Surgery Journal*) had at least 1 discrepancy between payment data in the database versus their publication. In most cases of a discrepancy (85%), the company reported a payment to the Open Payments database, but the author did not disclose the relationship.[25]

An unsolved problem is the issue of relevance. Plastic surgeons may deem a conflict irrelevant to the subject of their publication and therefore not report it.[24,25] An editorial policy of uniform and complete disclosure is needed, regardless of perceived relevance.[24] Another issue is whether an expiry date is appropriate. Does a financial influence "wear off" after a certain period? Although some journals restrict mandatory reporting of conflicts to a 3-year period before submission of a manuscript,[26] full disclosure is preferred, allowing the reader to decide on the merits.[19,27] An interval of 3 years seems short, especially for the amounts reported in Table 2, and is not supported by evidence that a financial influence soon disappears. A 2018 survey revealed that most plastic surgeons believe they are immune to bias caused by industry payments and that such bias is more likely to affect their colleagues than themselves (51% vs 35.4%).[28] Three-quarters of respondents had never used the Open Payments database to check financial ties between companies and plastic surgeons.[28]

Plastic surgeons may disagree on the influence or importance of commercial funding. However, all plastic surgeons are likely to agree that dishonest disclosures are indefensible. Goldwyn,[29] former longtime editor of *Plastic and Reconstructive Surgery*, once commented, "It is amazing how easy it is to be truthful if one wants to be." It is possible for plastic surgeons to function as a highly paid "consultant" or an independent researcher, but not both.[30] The professional recognition gained by publication is sufficient reward for the investigator; additional cash inducements should not be required. An absence of corporate funding makes any conclusions much more reliable.[12]

**TABLE 3.** Categorization of Payments (in US Dollars) From Allergan to Authors, 2015–2019

| Study | Category (%) |
|---|---|
| Flugstad et al[6] | |
| Gifts | 561,281 (52.4) |
| Other services* | 433,204 (40.4) |
| Consulting | 49,070 (4.6) |
| Travel expenses | 28,126 (2.6) |
| Total | 1,071,681 (100) |
| Newman and Davison[7] | |
| Gifts | 46,457 (89.2) |
| Other services | 2800 (5.4) |
| Consulting | 2800 (5.4) |
| Total | 52,057 (100) |

*Compensation for services other than consulting, including serving as faculty or as a speaker at a venue other than a continuing education program. Food and beverages were not included. Expenses less than $1000 not included.

Once a researcher in plastic surgery accepts corporate control, funding, and any other form of direct or indirect compensation (such as providing devices for free or heavily discounted), all objectivity is lost, and many experienced plastic surgeons will view any findings with skepticism.[30] Our journals need to take their gatekeeper role seriously and not simply act as a marketing tool for manufacturers. Luce[20] has called for a prohibition of editors and reviewers with financial conflicts. In 2010, the Council of Medical Specialty Societies published a code for interactions with companies, with a provision that prohibits society officers and journal editors from accepting any compensation from industry.[31]

The manufacturer should never be given responsibility for study design, preparation of the manuscript, writing, statistics, photographs, other imaging, or the decision of whether to submit an article for publication.[30] Remarkably, some studies supporting new medical devices (eg, Keller funnel, cryolipolysis, radiofrequency) have been published that feature all of these forms of corporate "support," creating undue influence at all levels.[6,30,32,33] In such cases, one wonders what exactly the named authors are responsible for, apart from accepting payment and providing study patients. The authors cannot absolve themselves of responsibility for the conclusions because the manuscript indicates corporate control. If their names are attached to the study, they are responsible for the contents.

Total payments exceeding $1.25 million to the authors of a study on Keller implants, in addition to study funding already provided by the original manufacturer, is a staggering amount, representing $450 for every patient (n = 2797) in the study, paid to the plastic surgeon. Improper financial arrangements designed to promote pharmaceutical products have caused serious (criminal) legal problems for doctors in other specialties.[19] Disclosure of conflicts of interest to the public and patients is mandated by our professional societies.[34,35] The American Society of Plastic Surgeons Code of Ethics includes the provision: "A member's clinical judgment and practice must not be affected by economic interest in, commitment to, or benefit professionally related commercial enterprises."[35] Charging exorbitant fees is also prohibited, defined as fees that are wholly disproportionate to the services rendered and care provided.[35]

The Medicare Fraud Statute makes it illegal for anyone to pay or receive "any remuneration (including any kickback, bribe, or rebate)" to induce the recipient to purchase, order, or recommend purchasing or ordering any service reimbursable under Medicare or Medicaid.[36] Some health care fraud experts recommend a general antikickback statute that would prevent kickback arrangements in all areas of the health care industry, not only Medicare and Medicaid.[36]

## "No Touch" Technique

The scientific foundation for a "no touch" technique is that the surgeon contaminates the implant by touching it, and this contamination results in a capsular contracture, a concept introduced by Mladick[37] in 1993. There is little supportive evidence. The implant comes out of the box sterile. The surgeon is wearing sterile gloves. Under ordinary sterile surgical technique, there is no opportunity for contamination other than by resident microorganisms on the skin and in the breast. A 2016 microbiological study found that the skin bacteria and breast parenchymal microorganisms are similar.[38] A sophisticated microbiological study published in 2019 failed to identify a specific bacterium that is linked to capsular contracture.[39] The microbiome of a breast capsule resembles the microbiome of the patient.[39] Microbiomes are not specific to the diagnosis of capsular contracture but rather specific to the patient.[39]

The biofilm theory for capsular contracture has been challenged.[40,41] The capsular contracture rate has remained steady over the last 2 decades despite efforts to reduce bacterial contamination.[41] One of these measures, Betadine irrigation, involves pouring a nonsterile cytotoxic solution into a breast wound.[41,42] (Many surgeons irrigate the Keller funnel with a dilute Betadine solution.)[43] Such an unauthorized method is likely to do more harm than good, both from the standpoint of possible contamination of the solution and from its cytotoxicity.[42] An open capsulotomy to treat a capsular contracture would be doomed to failure in all cases if the biofilm theory were correct. However, this procedure has a success rate of 77%.[40] In cases of an unruptured implant (ie, no free silicone gel), the success rate is even higher (86%).[40]

Bresnick,[44] who promotes funnel use, clarifies that "no touch" is a misnomer and really a marketing term because it is impossible to insert implants properly without at least some manual contact. This contact is frequently needed to open the funnel, trim the funnel length, adjust the implant within the funnel, and manually verify the implant's position and orientation within the pocket.[44]

## Incision Length and Insertion Time

The Allergan Web site states that the product may allow a smaller incision and faster implant insertion.[45] Of course, during breast reconstruction, there is typically a large open wound already, and there is no benefit in shortening the incision. The breast tissue must be handled by the surgeon in performing the dissection. Any value in using an introduction sleeve is unclear.

Montemurro et al[46] compared insertion times and incision lengths in breast augmentation patients using the Keller funnel on one side and no funnel on the other. The time to push the implant through the incision was 6 seconds using the funnel versus 16 seconds, on average, without the funnel, a savings of 10 seconds. However, when the time to open the package, hydrate the product, and trim it was included, the total times were 35 seconds and 25 seconds, respectively, 10 seconds extra when using the funnel. Regardless, a speed difference of 10 seconds is inconsequential. The incision was 1 cm shorter (3.5 vs 4.6 cm), on average, on the side treated with a funnel.

Deva[11] recommends research to determine the effect of transit through the funnel on the silicone shell. It is important not to trim the funnel too narrowly. Any increased trauma to the implant caused by forcing it through a funnel, particularly if it increases the likelihood of future rupture, is not a fair trade. A slight difference (1 cm) in incision length is likely to be of minimal or no consequence to the patient.

Once the implant is in place, it is helpful for the surgeon to palpate it to be sure that it is correctly oriented by feeling the patch on the posterior surface. It is also helpful to adjust the implant manually to be sure there are no folds and the implant is correctly situated. There is no need to avoid touching the implant.

## Extra Cost to Patients

At a cost of almost $150 per funnel,[45] this product represents a substantial profit source for the manufacturer. Multiplying this figure by 300,000 augmentation patients annually in the United States[1,22] makes this simple device financially attractive, which is no doubt why the product was acquired the year after publication of a preliminary study[6] that established a veneer of scientific authenticity. This cost, although not large, adds unnecessarily to the cost of surgery for patients. Plastic surgeons need to be good stewards to protect our patients from unnecessary spending. If there is no real benefit, then the product should not be used.

Bresnick[44] makes a case for 2 funnels per patient, suggesting that the funnel no longer is truly a "no touch" device after insertion of the first implant. This author reported a higher capsular contracture rate for the second breast treated with the same funnel, which he believes becomes contaminated by the first breast it touches. This plastic surgeon proposes that the manufacturer provide a funnel with each implant so all surgeons and patients benefit and there is no onerous extra cost, especially for 2 devices.[44]

## Safety and Regulatory Status

Morkuzu et al[1] state that the Keller funnel is a US Food and Drug Administration (FDA)–approved class I prosthesis. This is a contradiction

in terms; class I devices are not FDA approved.[47] The FDA database does not include 510(k) clearance for the Keller funnel.[47] A class I device is not exempt from 510(k) clearance if it is intended for a use of substantial importance in preventing impairment of health. Such use includes a condition the device will diagnose, treat, prevent, cure, or mitigate. Reduction of infection risk and capsular contracture risk would constitute such a use. Notably, the manufacturer does not include a statement regarding a reduction in capsular contracture rate on its Web site.[45] The directions for use do not include such an indication.

The device would seem innocuous. However, there are a number of adverse events reported to the Manufacturer and Use Facility Device Experience database.[48] These reports include problems with lubrication and possible damage to the implant envelope as it is pushed through the sleeve. Alarmingly, some surgeons resterilize funnels and use the same funnel for multiple patients.[44] Such an unauthorized practice would be highly counterproductive, exposing patients to a needless increased risk of infection from other patients.

The recommendation for a randomized controlled trial is often made by authors,[1,44] but is rarely feasible. The incidence is low enough that a very expensive and large study would be needed, and the scientific basis is simply not obvious, especially in view of the most recent microbiological evidence.[38,39]

## Realistic Expectations

The "takeaway message" from a recent review[1] is that the Keller funnel shortens operating time, decreases implant contamination and incision length, minimizes shell trauma, leads to quick healing, reduces postoperative pain, and allows an enhanced "no touch" method. Plastic surgery ethical guidelines prohibit misleading public statements, statements that are likely to create false or unjustified expectations of favorable results, and exaggerated claims.[35] Standards for scientific publications should at least meet acceptable standards for advertising. If the term "no touch" is inaccurate, it should not be permitted.

## CONCLUSIONS

Financial conflict of interest, along with publication bias, can create a bias toward publication of positive findings. No reliable evidence supports a "no touch" technique, which is a misnomer because manual handling of implants is unavoidable, even when using a funnel. No evidence supports contamination by the surgeon touching the implant. Among other proposed benefits, such as reduced operating time, less contamination, a shorter incision, and less implant trauma, only a slightly shorter incision (1 cm) is supported by the evidence.

No reliable evidence supports the use of a Keller funnel to reduce the risk of capsular contracture. Both supportive studies contain confounding variables, limited follow-up time, and no plausible scientific basis for efficacy. Institutional review board approval of studies on human subjects is not optional. Financial conflicts of interest are extraordinary in their magnitude and potential for creating undue influence. Greater transparency and honest disclosures are needed.

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