

ABSTRACT

2 Year Clinical Experience Using a Novel Device for Gel Implantation

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Background

With the re-introduction of cohesive gel implants in 2006, we were challenged to find a means to continue to offer axillary or periareolar incisions for our primary augmentation patients without enlarging the incision for the gel devices. With this goal in mind, an insertion device called the Keller Funnel™ was developed. The current design prototype is constructed of a high strength nylon fabric with a proprietary hydrophilic coating applied to the interior surface. The coating becomes extremely slick when activated by submersion in any aqueous solution, thus allowing a relatively low stress, simple, and quick insertion method. We hypothesize that use of this device not only allows insertion of silicone gel implants through shorter incisions, but also may protect the implant from shear stress as well as contamination.

Methods & Results

Beginning in 2007, we have treated 148 patients using variations of this device to perform primary augmentation or augmentation with mastopexy. We have performed 32 axillary augmentations, 76 periareolar augmentations, 9 inframamary augmentations, and 31 augmentations with mastopexy. All patients, with the exception of 4, were followed up with an office visit at three months or later. The Keller Funnel™ enabled us to introduce cohesive gel implants easily through the same, smaller incisions used for our saline implants. Additionally, we were also able to exchange expanders for gel implants. The incisions ranged in size from 3 to 5 cm depending on the site, with the majority having an incision size of between 3 and 4 cm. We have exchanged implants of up to 800 cc using this device.

Of the 125 patients in whom this device was used between 2007 and 2008, 57 have been contacted for follow up. Only 1 patient developed a capsular contracture, a patient who was an implant exchange case from a previous capsular contracture. This patient chose to be explanted with mastopexy. One other patient reported firmness, but upon physical examination was found not to have any capsular problems. We had 4 patients with malposition, of whom 2 required surgical intervention to lower the fold, 1 had a suture abscess, and 1 complained of slight asymmetry. In 2009, we have treated 23 patients whom we are actively following. Of the 23 patients there have been no capsular issues reported.

Conclusions

The Keller Funnel™ has been shown in our practice to provide a dependable and effective route for placing a silicone implant into a surgically created pocket through short incisions. We have experienced no implant ruptures using this device. In our experience, the Keller Funnel™ significantly reduced the trauma to the implant with considerably less difficulty of insertion for the surgeon. We hypothesize that use of this device allows for a "No Touch Technique" and mitigates localized shearing stresses to the tissue shell which could lead to lower

complication rates.

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