



Clinical Effectiveness of the Asteame Nipple Guard in Maintaining Projection Following Inverted Nipple Repair:

Results of a Prospective Clinical Outcome Study

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Summary An inverted nipple is a nipple that is retracted into the breast mound. Complications regarding inverted nipples are varied but may include difficulty in breast feeding and psychological distress. Multiple surgical and non-surgical techniques for nipple eversion exist. All of these are vulnerable to loss of projection and recurrence.

A prospective clinical study was undertaken in a group of patients undergoing inverted nipple repair in order to assess how the combination of a surgical correction and the postoperative use of the Asteame™ Nipple Guard™ work together to preserve the long-term surgical outcome. A total of 17 nipples in 10 female patients comprised the study. The observed mean decrease in long-term nipple projection at six months was 3.65% -- corresponding to a mean preservation of 96.35% with no recurrences. In conclusion, the Nipple Guard helps to maintain nipple projection and helps to prevent recurrence for patients using the device after the surgical repair of an inverted nipple.

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KEYWORDS

Clinical study;
Inverted nipple surgery;
Nipple Guard;
Plastic surgery;
Projection;
Recurrence

An inverted nipple is a nipple that instead of projecting outward is retracted into the breast mound as shown in Figure 1.

Estimates for the percentage of women that have inverted nipples widely vary. Han and Hong observed that a little more than 3% of women in their study have one or more congenital inverted nipples – with the condition bilaterally presenting in 87% of affected women (Park H.S., 1999). Other sources estimate that as many as 10-20% of all women are born with at least one

inverted nipple (Bracaglia R., 2011) (Goodman, 2010).



Figure 1 Inverted Nipple

In some cases, it may be possible through manual manipulation to cause an inverted nipple to temporarily protrude. However, in other cases, the nipple remains inverted regardless of the stimulus. The cause is usually shortened connections to underlying tissue, e.g., ligaments.

Han and Hong have defined a classification system for inverted nipples – see Table 1 (Han S., 1999). Clinical study has determined that the majority of inverted nipples belong to “Grade II” of the Han and Hong system. Grade II nipple inversions are thought to be caused by moderate fibrosis beneath the nipple (Han S., 1999). Grade II and grade III inverted nipples are thought to respond most optimally to surgical correction.

Possible complications regarding inverted nipples include difficulty in breast feeding (Kaufman, 2010), psychological distress, and aesthetic considerations.

Grade I	The inverted nipple is easily pulled out and temporarily maintains its projection fairly well without further traction. Gentle finger pressure around the areola or gently pinching the skin causes the nipple to pop back out.
Grade II	The inverted nipple can be pulled out, but not as easily as in Grade 1. After releasing traction, the nipple tends to fall back and invert again.
Grade III	The nipple is severely retracted and inverted. It is difficult to physically force this nipple out and hold it there.

Table 1 Han and Hong Inverted Nipple Classification System

Surgical correction may be indicated for the eversion of grade II and grade III inverted nipples and a multitude of surgical techniques have been developed and/or are

in practice (Han S., 1999) (Kim D.Y., 2003) (Sakai S., 1999) (Ritz M., 2005) (Min K.H., 2010). Most surgical methods have enjoyed satisfactory outcomes. Though, a loss of sensitivity, marked scarring of the nipple areola and other donor regions, destruction of breast function, and incomplete correction have been reported (Yamada N., 2004). Additionally, recurrence (or re-inversion) is a widely known possible complication.

Non-surgical methods for protracting inverted nipples have also been proposed and include regular stimulation and the use of suction cups or clamps. Two methods which have been proven to be ineffective are the use of breast shells and the Hoffman technique (Alexander, 1992).

The purpose of the present study is to prospectively assess the effectiveness of using the Asteame Nipple Guard (Asteame Medical Devices, Inc., Saratoga, CA) as a postoperative external sheltering device that protects a surgically repaired inverted nipple in order to preserve long-term nipple projection.

Methods and Material

Device

The Asteame Nipple Guard is a protective, reinforced bandage. The device is recommended for use following nipple reconstruction and inverted nipple surgery, to help protect the nipple from both compression and shearing forces, and from scar-tissue contraction within and surrounding the nipple (Clark, 2011).

The Nipple Guard comprises a thermoplastic elastomer core which is encased in a hypoallergenic spun-laced fabric tape (see Figures 2 and 3). The protective inner core cradles an inserted nipple and provides comfortable protection against compression, shearing and tensile forces. The device is easy to apply (see Figures 4-6). Patients who are using the Nipple Guard following inverted nipple eversion surgery are instructed to wear the device for minimum of 6 weeks postoperatively.



Figure 2 Physical dimensions of Asteame Nipple Guard: 102 mm (diameter) x 13 mm (height)

The Nipple Guard is intended to be worn at all times, except when a patient is engaged in activities in which the device might get wet (e.g., bathing). The device may be worn for up to 24 consecutive hours, after which a Nipple Guard should be applied.

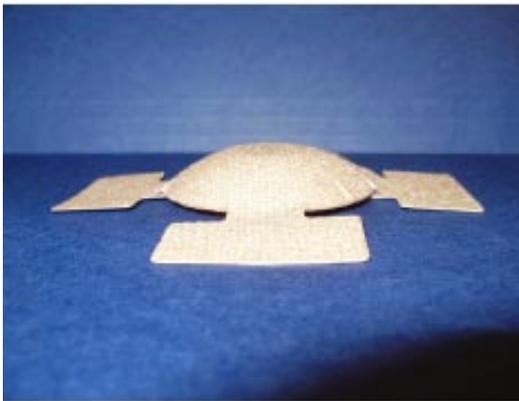


Figure 3 Physical dimensions of Asteame Nipple Guard: 102 mm (diameter) x 13 mm (height)

Trial

Motivated by the successful results achieved in a study undertaken by the Division of Plastic and Reconstructive Surgery at Stanford University Medical Center, wherein the researchers reported that “a statistically significant difference with regards to improved nipple projection was observed in the group treated with the nipple guard [following nipple reconstruction surgery]”

(Rosing J.H., 2009), a single-center prospective clinical study was undertaken in a group of 10 female patients undergoing inverted nipple repair in order to evaluate the effectiveness of the Asteame Nipple Guard in preserving long-term nipple projection and in helping to prevent recurrence.



Figure 4 Remove Liners from Asteame Nipple Guard Tabs



Figure 5 Center Asteame Nipple Guard Opening at Bottom of Device over Nipple

The clinical study was conducted at the Cosmetic, Cleft and Craniofacial Center in Munich, Germany. All surgeries, pre-operation examinations and post-operation examinations were performed by coauthor Michael A. Kremer. According to European Union guidelines, the Nipple Guard is not considered to be a medical product and is not considered to be a drug. Because of this, the study did not require, nor did the authors request approval by an ethics committee or similar medico-legal body.

All patients in the study presented with congenital nipple deformity. No cases were due to infection, trauma or malignant disease.

The clinical results of the Stanford study (Rosing J.H., 2009) were explained to each patient, and each patient was presented with the option of using or not using the Nipple Guard after their surgery. All 10 patients, 100% (n=10), opted to use the device by giving written informed consent for both the surgery and the clinical trial.



Figure 6 Adhere Asteame Nipple Guard Tabs to Skin

The surgical technique performed on each patient in the study consists of a semi-circular incision (120–180°) at the lower pole of the to be everted, mechanically pulled-out nipple (see Figure 7); followed by partial or complete transection of the milk ducts depending on clinical stage (I–III); and completed with a purse-string suture procedure (see Figure 8) using a 4-0 PDS suture with skin closure achieved using self-absorbing stitches (5-0 Monocryl, Ethicon™).

Though inverted nipple repair is a fairly simple surgical procedure that is performed under local anesthesia, on an outpatient basis, and typically in a plastic surgery office, there can be complications. As such, each patient was informed that the surgery would probably harm the integrity of milk ducts and would probably result in the permanent loss in the ability to breast feed. Other possible complications discussed with each patient included infection and recurrence. All patients consented, 5 of

them already having finished their family planning.

The initial clinical assessment, of the nipple areola complex and the grading of the severity of the deformity, consisted of the following: taking a history of the breast and deformity development; performing a clinical examination; and digital imaging. Four patients denied imaging for personal reasons.



Figure 7 Inverted Nipples Surgical Procedure: Incision

Three patients presented with unilateral deformity and 7 patients with bilateral deformity, for a total of 17 examined nipple repairs. The clinical stage of each inverted nipple was assessed according to Han and Hong as presented in Table 2.



Figure 8 Inverted Nipples Surgical Procedure: Purse-string Suture

Eight patients were treated under local anesthesia, eventually with only light

sedation. Two patients received general anesthesia for the reason that a simultaneous submuscular breast augmentation through the submammary route was performed as well.

Stage (n=17)	I	II	III
Bilateral	-	6	8
Unilateral	-	2	1

Table 2 Classification of Inverted Nipples included study according to Han and Hong system

Based on the surgeon's personal clinical experience, shortened milk ducts were consequently transected by electrocautery needle. All shortened ducts were treated, as they can be a main reason for recurrence – irrespective of the postoperative care. Additionally, non-shortened ducts surrounded by fibrous tissue were dissected and freed using microsurgical techniques under loop magnification. The goal of the procedure was to achieve the best anatomically possible length and symmetry.

Results

Upon the completion of the surgery, the length of the now everted nipple was measured from the level of the surrounding areola to the tip with a caliper and confirmed by a sterile flexible plastic ruler up to 0.5 mm accuracy. Nipple length on average was measured at 9.59 mm, ranging from 8.0 to 11.0 mm, immediately following the surgery.

The initial postoperative dressing consisted of a sterile gauze sponge wrapped like a "doughnut" around the nipple, able to take up wound secretions but completely protecting the everted nipple from external pressure. Using a bra was prohibited. Patients were administered oral antibiotics (Cephalexin 500 mg bid) as well as NSAID on a routine basis for at least 5 days starting preoperatively.

Patients were seen back for an examination and dressing change at day 2 to 4 postoperatively. No patient displayed any evidence of wound dehiscence, impaired arterial blood perfusion or infection. After a thorough cleansing, the Asteame Nipple

Guard was initially applied¹. Patients were instructed to change the device on a daily basis for 6 weeks and were told to avoid getting the Nipple Guard wet². No measurements were taken at this time due to the unreliable degree of swelling.

The percentage change in nipple projection was calculated based on measurements performed at 3 points in time.

At 6 weeks postoperatively, the measured average nipple length was found to be 9.47 mm, representing a significantly unchanged length from the immediately postoperative result. This corresponds to a mean decrease in nipple projection at 6 weeks of 1.25%, or alternatively stated a mean preservation of 98.75%. There were no recurrences. At this point in time all patients discontinued the use of the Nipple Guard, but were instructed to avoid compression forces like those applied by tight and heavy bras for example. No wound healing problems were discovered in any patient.

At the 3 months follow-up time, the mean measured nipple length was 9.35 mm (range 8.0 – 11.0) and again not found to be significantly changed from the immediately achieved surgical result. This corresponds to a mean decrease in nipple projection at three months of 3.65% -- corresponding to a mean preservation of 96.35% with no recurrences.

The long-term measurements were taken at 6 months postoperatively and the average measured nipple length was found to be 9.24 mm, ranging from 8.0 mm to 10.5 mm. The observed mean decrease in long-term nipple projection at six months was calculated to be 3.65% -- corresponding to a mean preservation of 96.35%. There were no recurrences. All wounds had healed primarily. There were no unusual nipple

¹ There were no technical difficulties during the application of the Nipple Guard, though the diameter was deemed a little tight at the initial application due to the presence of swelling.

² Patients were additionally instructed to avoid bathing (e.g., full emersion in a tub) for 3 weeks – at which time the wound was expected to be closed. Showers were permitted subject to the constraint of not getting the Nipple Guard wet.

shapes or any other undesirable findings. See Table 3 for more detailed results.

Patient	Pre-op	@ 6 wks.	@ 3 mo.	@ 6 mo.	Change
1	10.0	10.0	10.0	9.5	0.5
1	10.0	10.0	10.0	9.5	0.5
2	11.0	11.0	10.5	10.0	1.0
2	11.0	11.0	11.0	10.5	0.5
3	9.0	9.0	9.0	9.0	0.0
3	9.0	9.0	9.0	9.0	0.0
4	8.5	8.5	8.5	8.0	0.5
4	8.5	8.5	8.0	8.5	0.0
5	9.5	9.5	9.0	9.0	0.5
5	9.5	9.0	9.5	9.0	0.5
6	10.0	10.0	9.5	9.5	0.5
6	10.0	9.5	9.5	10.0	0.0
7	10.5	10.0	10.0	10.0	0.5
7	10.5	10.0	10.0	10.0	0.5
8	8.0	8.0	8.0	8.0	0.0
9	9.0	9.0	8.5	9.0	0.0
10	9.0	9.0	9.0	8.5	0.5
Len. (mm)	9.59	9.47	9.35	9.24	0.35

Table 3 Nipple Projection Results for Patients in the Study who used the Nipple Guard Postoperatively

Discussion and Conclusion

The surgical repair of inverted nipples is a minor surgical procedure, with most techniques reported to provide satisfactory results. Still, all techniques are vulnerable to the loss of projection and full recurrence; both of which can be a function of multiple factors, including surgical technique, skill of the surgeon, postoperative care and patient compliance. With this in mind, a prospective clinical study was undertaken in a group of patients receiving inverted nipple repair in order to assess how the combination of surgical correction and the postoperative use of the Asteame™ Nipple Guard™ work together to preserve the long-term surgical outcome.

In the study, the authors observed that patients using the Asteame Nipple Guard postoperatively, following inverted nipple repair surgery, experienced a minimal loss

of projection (3.65% on average) and none of the patients (comprising 17 nipples) experienced recurrence. However, given the design parameters of the study, which allowed the patients to opt in or out of testing the Nipple Guard³, it is difficult to definitively isolate the respective contributions of the surgeon, the surgical technique, the Nipple Guard, and patient compliance in the achievement of the study's results.

Still, the authors' own experience and numerous reported incidents of recurrence, including the below representative examples, strongly suggest that the use of the Nipple Guard played an important role in the overall results:

- Up to 3.9-10.6% of corrected nipples experience re-inversion according to (Han S., 1999);
- "Approximately 1 in 4 cases [25%] have recurrence" as reported in (Raurell); and
- "Recurrences occurred in 13 of 58 nipples corrected (22%)" (Kolker, 2009);

So much so, that in light of the achieved steady mean nipple projection and a 0% recurrence rate, coupled with very favorable patient impressions (see Table 4), the Cosmetic, Cleft and Craniofacial Center, Munich, Germany has adopted the use of the Asteame Nipple Guard following inverted nipple surgery into its standard practice.

	Very good	Good	Moderate	Not good
Wearing comfort	6	3	1	-
Ease of application	8	2	-	-
Will recommend	10	-	-	-

Table 4 Patient Experiences using the Asteame Nipple Guard

³ All patients in the study opted to use the Nipple Guard, resulting in the lack of a comparative control group of patients who did not use the Nipple Guard.

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