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Use of a novel adhesive suture retention device in non-traumatic diabetic lower extremity amputations: A multicenter review

Introduction

Non-traumatic lower extremity amputations in diabetic patients are complicated by wound dehiscence in up to 80% of cases.[1]

A novel adhesive suture retention device (ASRD) (HEMIGARD ARS device; SUTUREGARD Medical, Inc; Portland, OR) has been shown to reduce fragile skin tearing, improve wound edge perfusion and reduce lower extremity excisional wound dehiscence when compared with standard layered closures.[2,3]

Methods

A multicenter review of cases was performed in five centers that had adopted the ASRD. Retrospective reviews were performed for the six months prior to and six months following adoption of the ASRD. All data was de-identified prior to release from the facility and prior to further analysis.

Figure 1: A single ASRD strip

Each ASRD pouch contains two adhesive, sterile, single-use disposable strips. Each ASRD strip measures 6cm long x 1.6cm wide and one strips is placed perpendicular to the wound edges on each side of a wound so that their leading holes are 10mm from the wound edges. The ASRD must be applied to clean, dry skin with minimal hair prior to proceeded to the next step.

After adhering the ASRD strips, nylon suture (usually 2-0 or 3-0) is sutured through the holes of the ASRD strips (Figure 2) to close the wound. The ASRD strips prevent skin tearing, improve perfusion compared to sutures alone and have been shown to reduce lower extremity wound dehiscence. [2,3]

Figure 2: Outline of ASRD use (Source: suturegard.com)

In cases without ASRD, standard closure methods (i.e.: dermal absorbable and percutaneous nonabsorbable sutures) were used. With ASRD, **minimal, or in some cases no, dermal absorbable sutures** were used. The ASRD and percutaneous nylon suture is used for both tension management and wound edge apposition.

Results

In the period prior to adoption of the ASRD, a total of 25 cases were reviewed; 55 cases were reviewed in the period after ASRD adoption. The range of number of ASRD pairs used per case is outlined in Table 1.

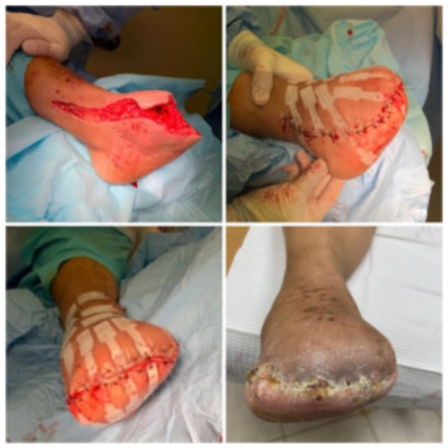

Figure 3: Use of ASRD in a transmetatarsal amputation. 10 pairs of ASRD strips were used in this case.

Amputation level	ASRD pairs per case (range)
Toe	1 to 2
Ray	2 to 3
TMA	5 to 10
Other (2 Lisfranc, 1 Chopart, 1 Pirogoff, 1 ERTL)	4 to 5

Table 1: Range of number of pairs of ASRD strips per amputation case

We found an overall decrease in wound dehiscence of 81% ($p<0.01$) with use of the ASRD for lower extremity amputations in patients with DM (Table 2).

	Standard	ASRD	p-value
Toe	8/10 (80%)	1/17 (6%)	<0.01
Ray	-	1/13 (8%)	-
TMA	9/15 (60%)	3/20 (15%)	<0.01
Other	-	2/5 (40%)	-
Total	**17/25 (68%)**	**7/55 (13%)**	**<0.01**

Table 2: Wound dehiscence in lower extremity diabetic amputations before (standard closure) and after adoption of ASRD

Of the 25 patients who had their amputations performed without ASRD, 4 (16%) went on to have complications requiring a higher-level amputation (2 AKA and 2 BKA). Of the 55 patients who had their amputations performed with ASRD and minimal or no dermal absorbable sutures, only 1 (1.8%) went on to require a higher-level amputation (1 BKA). This represents an 89% reduction in progression to higher level amputation ($p=0.015$).

Discussion

In this multicenter retrospective review, the use of the ASRD in lower extremity amputations in patients with DM was associated with significantly fewer postoperative complications, including a reduction in need for return to the OR for a higher-level amputation.

Adhesive zip-type and microneedle-based skin-closing devices instruct the surgeon to use dermal absorbable sutures to manage tension and reduce the incision edge gap to a maximum of 4-5mm prior to applying the device.[4] Many amputations are performed in the setting of necrosis and infection, where it is undesirable or even contraindicated to place absorbable sutures that will become a nidus of infection. The ASRD allows surgeons to manage tension and minimize or avoid dermal absorbable sutures.

Zip-type devices have shown some promise for reduced scarring or operative time, but have not shown significant differences in wound complications when compared with standard closure methods.[4] To our knowledge, the ASRD is the first adhesive wound closure to have multiple studies demonstrating reduced lower extremity wound complications when compared to standard layered closure.

The ASRD is oriented perpendicular to the wound edges and has its widest and most adhesive portion at least 3cm from the wound edges. Amputations and other lower extremity closures often produce copious amounts of drainage that could affect the adhesion of some zip-type technologies, which are oriented parallel to and usually less than 3cm from the wound edges (See Figure 4).

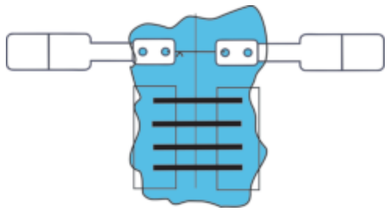

*Figure 4: Effect of typical zone of wound exudate (**blue**) on adhesion of ASRD (upper) versus a zip-type closure device (lower)*

Future research should be directed to other surgical procedures in which the ASRD can reduce complications including orthopedic and vascular surgery. Future research should also consider the scarring and time saving potential of the ASRD versus other zip-type and microneedle-based closure systems.

References

[1] Vassalo IM, et al. Healing and mortality rates following toe amputation in type II diabetes mellitus. Exp Clin Endocrinol Diabetes (2021) 129(6): 438-42.

[2] Stoecker A, et al. Enhanced perfusion of elliptical wound closures using a novel adhesive suture retention device. Health Sci Rep (2021) 4(3): e364.

[3] Cole W, et al. Use of a novel adhesive suture retention device in lower leg excisional closure: A retrospective review. Wounds (2021) 33(9): 222-5.

[4] Ko, JH et al. Do zip-type skin-closing devices show better wound status compared to conventional staples devices in total knee arthroplasty? Int Wound J (2017) 14: 250-4.