A New Standard of Care for Diabetic Partial Foot Amputation Closures?

Novel Adhesive Suture Retention Device (ASRD) for High Tension Closures, A Case Series

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Introduction

Complications of diabetic foot disease are the main contributors to lower extremity amputations, including partial foot amputation. Partial foot amputation in patients with type 2 diabetes (T2DM) are complicated by wound dehiscence in up to 80% of cases[1]. Additionally, in a systematic review of 22 publications with a total of 2334 patients, Rathnayake and colleagues (2020) reported that partial foot amputations in patients with T2DM have a re-amputation rate approximately 20% to 45% .[2]

Conventional sutures enclose and compress tissue. Poorly perfused diabetic tissue is vulnerable to compression and standard, unsupported sutures may cause ischemic necrosis and or mechanically tear through the skin before the closure can successfully heal. The use of a novel adhesive suture retention device (ASRD) supports standard suture by offloading wound tension and, thus, improving blood flow to the healing wound edge[3]. In a multi-center case review, the ASRD reduced wound complications in diabetic amputations [4]. Specifically, the use of the ASRD reduced the rate of dehiscence by 81% and need for re-operation by 89%. This resulted in a net savings of $6245.88 to $9997.52 per amputation.

This study explored the use of the novel ASRD in one clinical setting with the aim to reduce wound healing complications and corroborate results from prior studies.

Methods

This study was designed as a single-center retrospective analysis of patient outcomes using the ASRD. A retrospective chart review was performed to identify patients with diabetes who had undergone nontraumatic foot amputation within a period of three months after adoption of the ASRD. Demographic and site-specific details were recorded without any identifying patient data. The method of closure and rates of complications including progression to higher amputations were recorded.

Skin closure was achieved using nylon (2-0 or 3-0 caliber) sutures and ASRD (HEMIGARD adhesive suture retention device; SUTUREGARD Medical; Corvallis, OR). Each ASRD pouch contains two sterile, adhesive, single-use disposable strips; each measuring 6.0 cm x 1.6 cm. ASRD were placed on clean, dry skin according to Instructions for Use. ASRD are placed such that holes are 1cm from wound edge, and one ASRD is placed on each side of the wound to offload the stress of a single percutaneous suture; one pair of ASRD is placed per inch of wound closure. All patients had edema control through total contact casting perioperatively.

Statistical analysis: The statistical significance between the cohorts in categorical variables was tested using the Fisher Exact test and, in continuous variables, using t-tests. All tests were 2-tailed with a significance level of $p<0.05$.

Results

There were 8 patients identified with an average age of 68 years. There was over-representation of males in the group, but it was not statistically significant. The group had poor diabetic control with average HbA1c of 7.6% and 25% of patients requiring dialysis. Of the amputations five were transmetatarsal (TMA); one was ray; one was partial foot; and one was toe.

	Patients undergoing lower extremity amputation using ASRD
Age (y) – Mean (range)	68 (54-76)
Gender	1F/7M
HbA1c (%) - Mean (range)	7.6 (5.8-8.5)
BMI (kg/m²)– Mean (range)	30.8 (25-40)
Osteomyelitis at time of amputation	8/8 (100%)
Dialysis-dependent	2/8 (25%)
Peripheral neuropathy	7/8 (87.5%)
Peripheral vasculopathy	8/8 (100%)
Requiring intervention for arterial inflow	3/8 (38%)
Vasculopathy not requiring intervention	5/8 (63%)

Table 1: Baseline demographics of patients undergoing lower extremity amputations using ASRD

	Re-amputation	Dehiscence
ASRD	0	1
Expected events	2.1-2.8	6.4
Significance (p value)	0.47-0.20	0.04

Table 2: Complications of ASRD versus expected outcomes based on literature complication rates

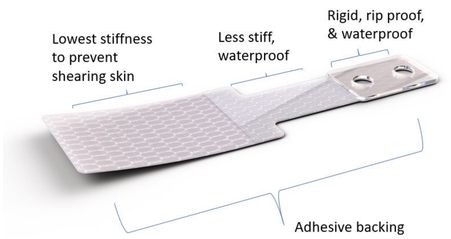

Figure 1: One-half of the Novel Adhesive Suture Retention Device (ASRD)

Discussion & Conclusion

This case series corroborates prior findings on the efficacy of ASRD in preventing lower extremity wound complications. While the results on re-amputation were not statistically significant, there was a strong trend observed towards reduced re-operation as no case required re-amputation. Aligning with prior studies, there was also a strong reduction in wound dehiscence compared with literature rates. In this study, 1 patient had a dehiscence (12.5%), which is an 84% reduction from literature controls.

There are other adhesive wound closure devices on the market, most of which are “punctureless” (ie: no percutaneous suture). Noninvasive devices and negative pressure wound therapy have both proven ineffective in reducing wound dehiscence and in reducing need for re-amputation.[5, 6] We hypothesize that the combination of ASRD and suture explains the superior performance to adhesive-only devices. With percutaneous suture alone, there are areas of very high stress and reduced perfusion. With only an adhesive or minimally invasive (non-percutaneous puncture) device, there is risk of the adhesive product losing adhesion due to moisture and high epidermal turnover and thereby resulting in failure. The combination of an ASRD and suture results in offloading of suture stress, improved perfusion and reduced complications.

Further studies should be conducted to understand the unique mechanisms behind the ASRD and other procedures in which it might have benefit.

References

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