

microMend® Skin Closure Device

Clinical Study Using microMend to Close Skin Excisions and Mohs Surgeries

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EXECUTIVE SUMMARY

KitoTech Medical has developed a revolutionary wound closure product, microMend®, which combines the ease of application of a bandage with the anchoring strength of sutures and staples. In the study reported here, microMend was used to close the skin after dermatologic surgeries, including excisions of tumors or cysts and Mohs surgeries. The dermatologist, who performed the procedure, rated microMend excellent in all 16 patients in the study in all measurements, including ease of use, speed of use, wound appearance, and overall assessment. Closure with microMend was extremely rapid with rates that were 7x faster than what has been reported with sutures in other published studies. Cosmetic results were rated as good or excellent in nearly all evaluable patients. These results confirm and extend previous studies demonstrating that microMend represents an attractive product for the closure of skin wounds.

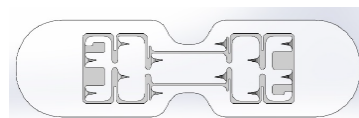
INTRODUCTION

There is a strong need for new wound closure products that can address the limitations of current devices, such as sutures and staples. Inconsistent results, potential for scarring, painful application, risks of needle sticks and infections, and the need for return clinic visits to remove devices are challenges with use of these products. In addition, closing with sutures is a time consuming process adding to procedure costs.

microMend is a novel wound closure device that incorporates two arrays of tiny Microstaples with an adhesive backing that enables secure attachment to the skin (Figure 1). In previous porcine studies, microMend demonstrated excellent wound closure results of surgical incisions as well as port site wounds resulting from insertion of laparoscopic trocar instruments. A clinical study demonstrated the superiority of microMend over sutures when they were directly compared to one another in closing port site wounds associated with laparoscopic and robotic surgeries.

In the current study, we evaluated the use of microMend to close skin wounds associated with excisions of skin cancers and cysts as well as Mohs surgeries. In addition to clinical outcomes, the efficiency of closure was assessed by measuring the time of the procedure.

Figure 1. microMend Device (actual size)



CLINICAL STUDY

This was a single arm study in which all patients undergoing skin excisions for tumors or benign lesions or Mohs surgeries underwent closure of their surgical wounds with microMend devices. The wound closure procedures were conducted by one dermatologist.

Sixteen patients enrolled in the study. A total of 6, 3, and 7 patients underwent Mohs surgeries, excisions of basal cell carcinoma, and excisions of cysts, respectively. The length of each wound

and the time of closure was measured. Evaluations of microMend were made via questionnaires completed by the dermatologist performing the procedures on the day of surgery (Day 0), and cosmetic results by an independent dermatologist at 3 months (Month 3). Four patients were unevaluable at Month 3 and thus cosmetic results represent the data from the 12 evaluable patients.

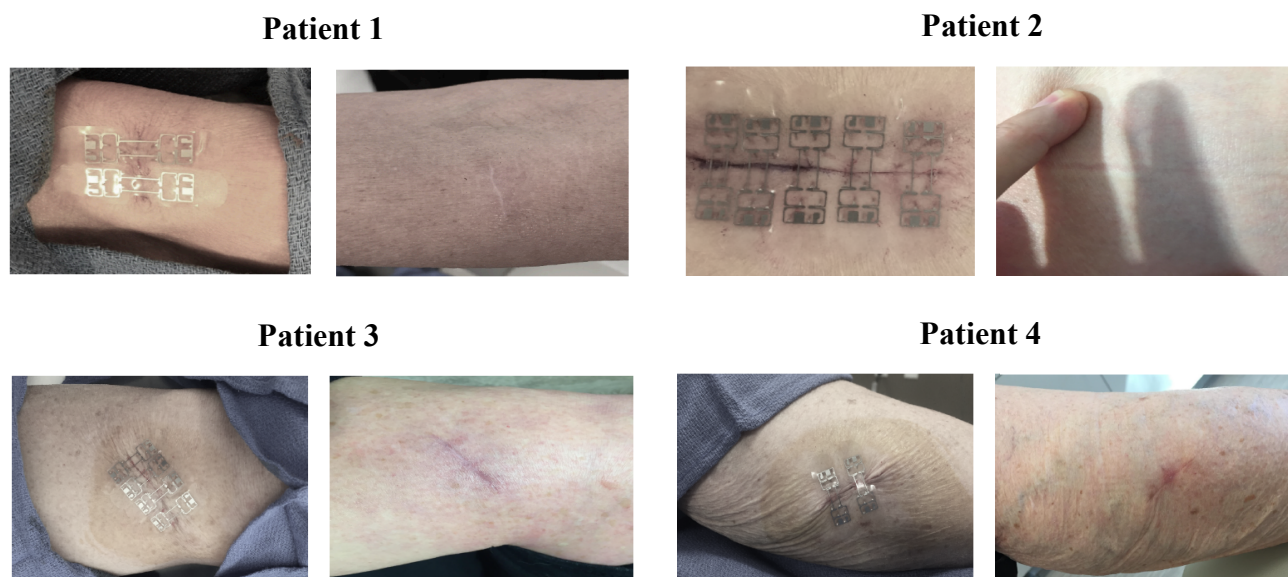
The median length of wounds was 4.0 cm (range = 1.2-7.0 cm) and the median number of microMend devices used was 4 (range: 1-7). The median time to close the wounds was 20 seconds (range: 8-65). The rate of closure was 7 seconds per cm of wound length (range: 5-12). There was no correlation between the length of the wound and the rate of closure – i.e., longer wounds were closed with equal speed to shorter wounds. Historical data from several clinical studies have reported that skin wounds closed with sutures at a rate of approximately 50 seconds per cm (range: 45-63).¹⁻⁴ Thus, microMend closes wounds approximately 7x faster than sutures based on previous studies.

At Day 0, the dermatologist rated wound appearance, speed of use, and ease of use as excellent in all 16 patients (Table 1). In the 12 evaluate patients at Month 3, the cosmetic results were rated by an independent dermatologist as excellent, good, fair, and poor in 6 (50%), 3 (25%), 2 (17%), 1 (8%), respectively. Representative results from several patients are shown in Figure 2.

Table 1: Evaluations at Day 0 and Month 3

	Excellent	Good	Fair	Poor
Ease of use	16 (100%)	0 (0%)	0 (0%)	0 (0%)
Speed of use	16 (100%)	0 (0%)	0 (0%)	0 (0%)
Wound appearance	16 (100%)	0 (0%)	0 (0%)	0 (0%)
OVERALL ASSESSMENT	16 (100%)	0 (0%)	0 (0%)	0 (0%)

Figure 2. Closure of Wounds with microMend (Day 0 and Month 3)



CONCLUSION

In this clinical study using microMend to close skin wounds associated with skin excisions or Mohs surgeries, there were consistently excellent outcomes documented by the dermatologist in all patients for all of the measured parameters, including ease of use, speed of use, and wound appearance at Day 0. In addition, the overall assessment of microMend was rated as excellent by the dermatologist in all patients. The appearance of the wounds was rated as excellent or good at three months by an independent dermatologist in 75% of the patients. A striking finding was the extremely rapid closure that was achieved with microMend – median closure rate of 7 seconds per cm of wound length. This is 7x faster than what has been reported with sutures in several clinical studies.

This study confirms and extends the results of a previous clinical study in which port sites associated with minimally invasive surgeries were closed with microMend or sutures. In both studies, microMend received high ratings in terms of ease of use, speed of use, wound appearance, and the overall assessment of the product. In addition, both studies documented superior cosmetic outcomes with the use of microMend. A previous porcine study documented the rapid rate of wound closure with microMend. The current clinical study confirmed previous porcine studies demonstrating the marked time savings in closing wounds with microMend that should translate into reduced costs of these procedures.

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