

microMend™ Skin Closure Device

Clinical Study Comparing microMend to Sutures for Closing Port Site Wounds

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EXECUTIVE SUMMARY

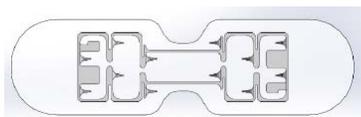
KitoTech Medical has developed a revolutionary wound closure product, microMend, which combines the ease of application of a bandage with the anchoring strength of sutures and staples. In the study reported here, wound closure of port sites with microMend was compared to sutures in 18 patients undergoing minimally invasive surgeries (laparoscopic or robotic). Both healthcare providers (surgeons and nurses) and patients preferred wound closure with microMend to sutures in over 90% of the cases. In addition, 90% of providers and patients rated wound appearance better with microMend compared to sutures. Patients reported that microMend was more comfortable to wear and remove than sutures. Over 80% of the surgeons judged microMend to be easier and more rapid to use than sutures for wound closure. These results, combined with its many other advantages, including: ease of use, time savings, reduced pain, elimination of the need for return clinic visits for device removal, reduced risk of needle sticks, and consistent and reproducible results, make microMend devices an attractive alternative to sutures and staples for wound closure.

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 for healthcare providers and patients. In addition, closing wounds with sutures is a time consuming process adding to the costs of procedures.

microMend (Figure 1) is a novel wound closure device that incorporates two arrays of tiny microstaples with an adhesive backing that enables secure attachment to the skin. 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.

Figure 1. microMend Device (actual size)



CLINICAL STUDY

Patients undergoing minimally invasive surgeries (laparoscopic and robotic) underwent closure of their port site wounds with microMend devices and a suture control in the same patient. Three surgeons in general, gynecologic, and urologic surgery participated in the study.

A total of 18 evaluable patients enrolled in the study. Evaluations were made via questionnaires completed by surgeons on the day of surgery (Day 0), and by healthcare providers (surgeons and nurses) and patients at 10 days (Day 10) and 30 days (Day 30) after surgery. All collected data on the key parameters were analyzed and included in Table 1 (note: in a small cohort of patients, data were unavailable at some time points).

At Day 30, both healthcare providers and patients rated both wound appearance and overall assessment of microMend closure better than sutures in over 90% of the patients. Examples of wound appearance with microMend compared to suture closure at Day 30 are shown in Figure 1. Patients reported that comfort was better while wearing and upon removal of microMend compared to sutures. Of note, there was case in which microMend was rated worse than sutures by healthcare providers or patients. On Day 0, surgeons rated microMend easier and more rapid to use than sutures for closing wounds in 83% of the patients.

Figure 2: microMend vs. suture closed wounds (Day 30)

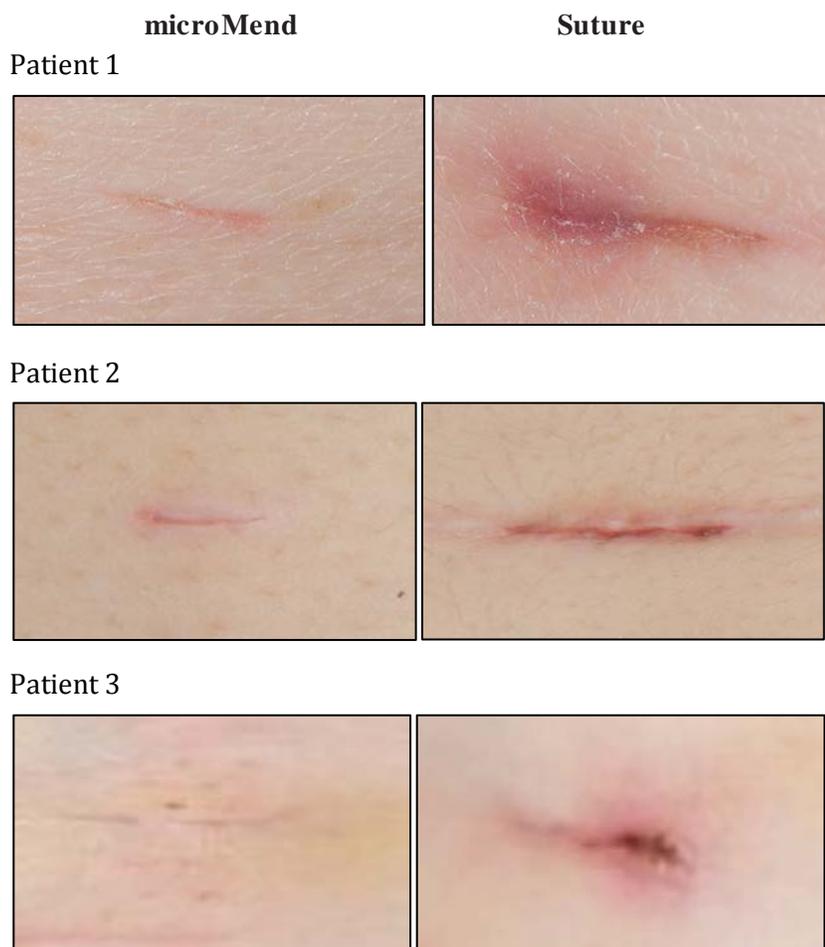


Table 1: Evaluation of healthcare providers and patients

	Much Better	Somewhat Better	TOTAL BETTER	SAME	WORSE
SURGEONS (Day 0)					
Ease of use	28%	56%	83%	0%	17%
Speed	44%	34%	78%	5%	17%
PROVIDERS (Day 30)					
Appearance	36%	57%	93%	7%	0%
OVERALL ASSESSMENT	33%	58%	91%	8%	0%
PATIENTS					
microMend comfort	19%	38%	57%	43%	0%
Removal comfort	18%	29%	47%	53%	0%
Appearance	58%	33%	91%	9%	0%
OVERALL ASSESSMENT	55%	36%	91%	9%	0%

CONCLUSION

In this clinical study, healthcare providers and patients strongly preferred microMend to sutures for closing port site wounds associated with minimally invasive surgeries. Importantly, wound appearance was rated better with microMend, which is a benefit for healthcare providers and patients, who can experience scarring with wounds closed with sutures. The increased comfort with microMend is an advantage for patients in reducing the pain and itching associated with sutures and eliminating the painful process of removing them. Finally, surgeons found microMend easier and more rapid to use than sutures. This study along with the many other benefits of microMend, which include ease of use, time savings, reduced pain, elimination of the need for return clinic visits for device removal and reduced risk of needle sticks, make it an attractive alternative for closing wounds that currently need sutures.

To learn more, go to www.micromendskinclosure.com