

microMend® PRO Skin Closure Device

Pre-clinical Studies of Closure of Surgical Wounds in Live Pigs

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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. The two porcine studies reported here demonstrate that microMend is able to achieve excellent closure of surgical wounds. In the first study, microMend was compared to sutures, and was shown to be as effective in closing port site wounds. The second study demonstrated outstanding cosmetic results when microMend was used to close 12cm surgical incisions. Wounds closed with microMend devices showed equivalent tensile strength to sutures during the wound healing process. 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 an attractive alternative to sutures and staples for wound closure.

INTRODUCTION

There continues to be a need for improved wound closure products that can address the current limitations of sutures and staples, which include inflammation and scarring, variable results, risk of infections, and the need for return clinical visits for removal. In the emergency room and clinics, there is also a need to reduce pain associated with use of sutures and staples. Finally, sutures take considerable time to use, which adds costs to surgery and other procedures requiring wound closure.

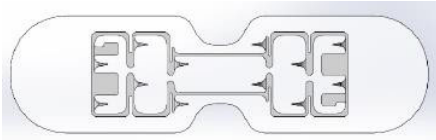
Clinical performance of the microMend PRO skin closure device was tested in pre-clinical studies conducted on juvenile pigs whose skin is similar to that of humans. Two pre-clinical studies were conducted evaluating the use of microMend PRO to close port site wounds produced by trochar insertion (Study 1), and 12cm linear surgical incisions (Study 2).

MATERIALS AND METHODS

microMend PRO Wound Closure Device

microMend PRO is a disposable device with two arrays of tiny Microstaples attached to an adhesive backing in the shape and size of a butterfly closure (Figure 1). The Microstaples enable anchoring of the device into the skin making it possible to close dermal wounds currently closed using sutures and staples. microMend PRO is rapid and easy to use, and is relatively painless upon application.

Figure 1: microMend PRO Device



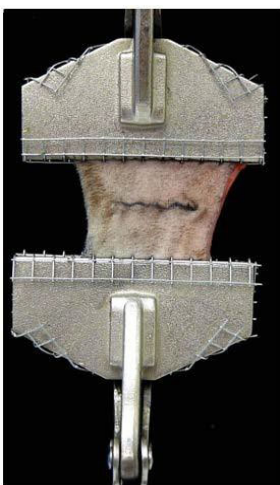
Study Procedures – General

Full-thickness wounds in the skin were made in the abdomen of juvenile pigs. The wounds were closed with either microMend PRO devices or sutures in Study 1, while only microMend PRO devices were used to close wounds in Study 2. No other wound closure products were used to close the wounds in either study. All wounds were covered with Tegaderm[®] (3M).

Evaluations were performed serially via observations by surgical staff over a three-week period, including placement of devices and sutures (Day 0), as well as on subsequent days at intervals of 2-3 days. Wounds were assessed for evidence of inflammation, wound dehiscence, infection, cosmetic results, and any other abnormalities. Photographs were obtained at Day 0, and on Days 10 and 20 to document healing of the wounds. Wound tensile strength was measured on Days 10 and 20.

Tensile strength testing was performed by a standard procedure that utilizes a servo-hydraulic material testing machine. Skin samples were excised using a dog-bone template, and underwent tensile strength testing within an hour of their removal. The skin samples were loaded quasi-statically under tension until construct failure. A custom designed fixture was used to rigidly fix the distal portions of each sample to the testing machine platform (Figure 2). All displacement loads were applied orthogonal to the wound, causing the wound to be loaded across its length. Each sample was loaded until failure at a rate of 40 mm/sec. Force (N) and displacement (mm) data was collected at a rate of 100 Hz.

Figure 2: Skin sample placed within custom designed load fixtures



Specific Procedures – Study 1

Trocar wounds (port site wounds) were made using a standard laparoscopic instrument that was inserted in the lateral dorsal surface of both sides of the abdomen. (Figures 3A and 3B). The trocar had a diameter of 1.2cm and was inserted through all skin layers. The wound was then closed with one microMend PRO device (Figure 3C) or one suture (3-0 Nylon). Excellent wound approximation was achieved using the microMend PRO device.

A total of 36 wounds were closed with microMend PRO, while 12 wounds were closed with sutures in nine pigs.

Figure 3: Trochar wound and microMend PRO closure



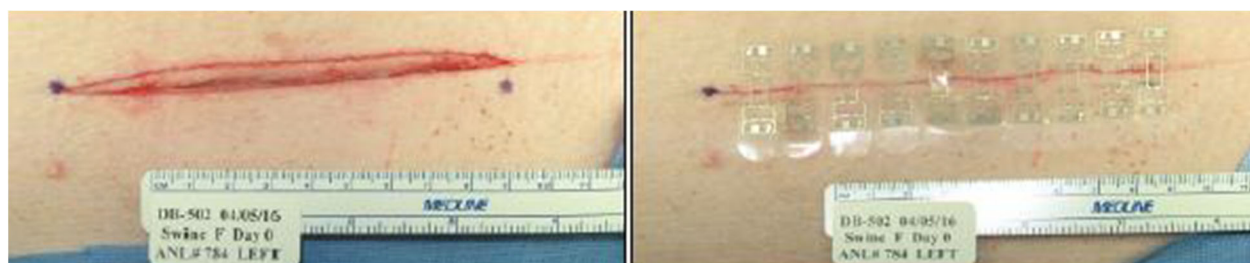
A) Trochar insertion B) Port site wound C) microMend PRO closure

Specific Procedures – Study 2

Incisions, which were 12cm in length, were made using a scalpel to generate linear wounds in the skin (Figure 4A). The wounds were made in a cephalad to caudal direction with one wound made on each side of the abdomen. Ten microMend PRO devices were applied adjacent to one another to close each wound (Figure 4B). Excellent wound approximation was achieved using microMend PRO devices.

A total of 6 wounds were closed with microMend PRO devices in three pigs.

Figure 4: Surgical incision and closure



A) 12cm surgical incision

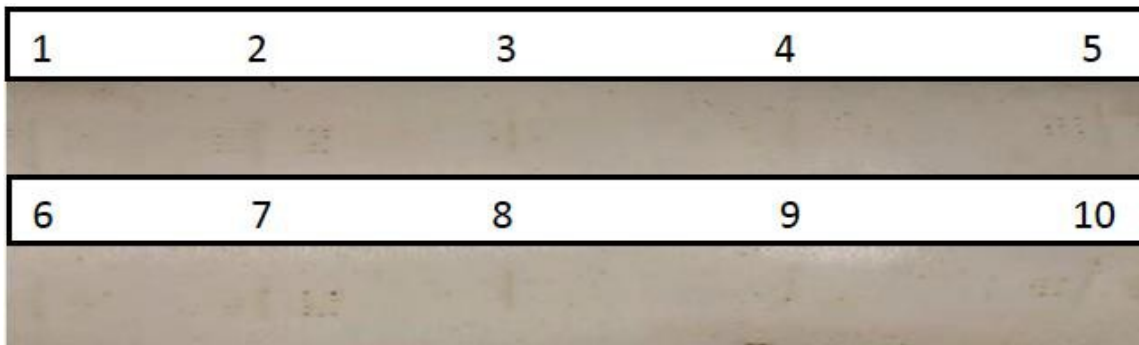
B) microMend PRO wound closure

RESULTS

Study 1

Excellent wound closure results were documented in all wounds closed with microMend PRO devices. No wounds showed significant inflammation, and there was no evidence of wound dehiscence or infections in any of the closed wounds. At Days 10 and 20, excellent wound healing and appearance was observed in wounds closed with microMend PRO. (Figure 5). A Comparison of wounds closed with sutures and microMend PRO showed no significant differences in wound healing or appearance.

Figure 5: Appearance of 10 wounds closed with microMend PRO devices (Day 20)



Wound tensile strength measured in Newtons (N) was equivalent between wounds closed with sutures and staples at Days 10 and 20 (Table 1). At Day 20, microMend PRO closed wounds had approximately 20N of tensile strength per cm of wound length (note: wounds were approximately 1.2cm wide).

Table 1: Wound Tensile Strength

Time Point	microMend PRO	Suture
Day 10	12.7 ± 1.3 N (n=36)	13.8 ± 2.9 N (n=18)
Day 20	23.9 ± 1.4 N (n=12)	21.2 ± 4.8 N (n=6)

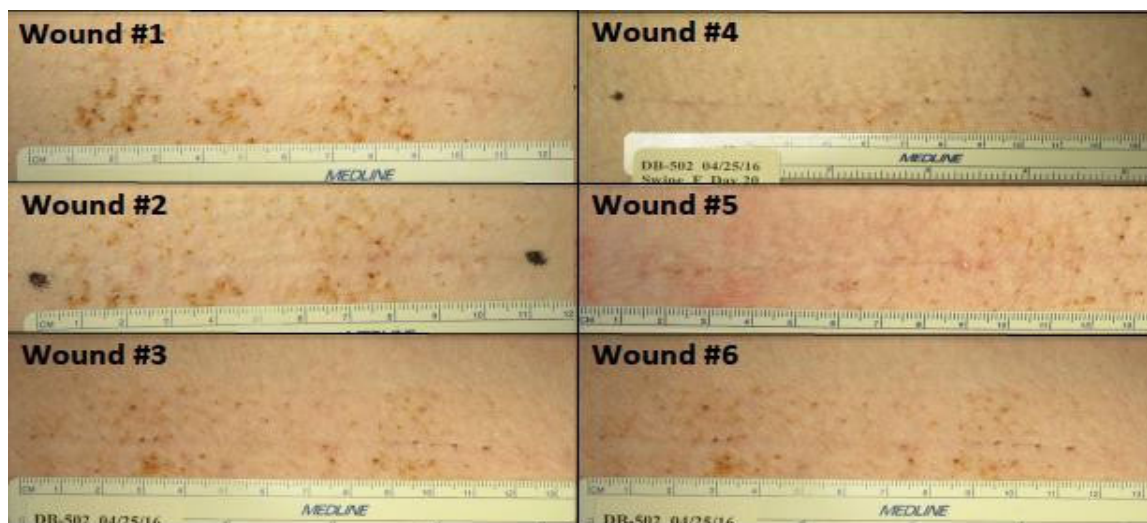
The median time to close each wound (1.2cm width) with one microMend PRO device was 11 seconds (range: 7-19), while the median time to close each wound with one suture was 32 seconds (range: 20-42). Consequently, wound closure with the microMend PRO device was 3 times faster than with the suture.

Study 2

For all 6 wounds, there was no evidence of wound dehiscence, infection, significant inflammation or other abnormalities. Results on Day 20 showed excellent wound healing and

appearance for each wound (Figure 6). (Note: the brown patches are dried blood resulting from the original incisions and are observed with closure using sutures and other devices).

Figure 6: Appearance of wounds (Day 20)



Wound tensile strength averaged 301+/-49N, which translates into approximately 25N per cm of wound length. The total time to close the 12cm wounds was a median of 127 seconds (range: 121-187 seconds) while the median time to close each 1cm of wound length was approximately 11 seconds (range: 12-18).

CONCLUSION

The current studies demonstrate that microMend PRO devices can be used to provide effective wound closure for both short and long wounds associated with surgery. These include both port sites due to insertion of trocar instruments in minimally invasive surgeries (laparoscopic and robotic), as well as surgical incisions associated with open surgeries. Reproducible results were observed with excellent wound healing and appearance. There was no evidence of wound dehiscence, infections, or significant inflammation in any wound. Wound approximation was excellent in both studies.

In Study 1 where closure with sutures and microMend PRO were compared, there were no differences in wound healing or appearance. In Study 2, close wound approximation across the entire length of the wounds was noteworthy, and likely contributed to the excellent cosmetic results achieved in all long wounds. In addition, wounds closed with microMend PRO achieved equivalent tensile strength to sutures at Days 10 and 20.

The surgeon indicated that closure with microMend PRO devices was simple and straightforward (data not shown) for both short and long wounds. Consistent with this observation, closing port site wounds was 3 times faster with microMend PRO than with sutures. For the long surgical wounds, closure was achieved at a similar speed per cm of wound length to that achieved with closing the shorter port site wounds. The long surgical incisions were closed in approximately 2 minutes. Previous studies have

documented that closure of surgical skin incisions takes approximately 30 seconds to a minute for each cm of wound length. If we assume similar closure time in the current study, it would take 6-12 minutes to close the 12cm long wounds with sutures. microMend PRO is projected to be 3-6 times faster in closing these wounds.

To learn more, go to www.micromendskinclosure.com