BandGrip® Micro-Anchor Skin Closure

BandGrip Closure of Surgical Incisions Following Arthroscopic Surgery

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EXECUTIVE SUMMARY

Secure wound closure is an integral step of nearly every surgical procedure. If the closure device does not provide the strength and support required by the skin tissue, the wound edges may separate, providing a potential pathway for bacterial contamination, which can lead to infection, suboptimal cosmesis, and low patient satisfaction. Traditional closures include sutures, metal staples, paper tape and skin glues.

BandGrip Micro-Anchor Skin Closure is a novel skin closure device, designed for speed, simplicity and strength. It does not require injection of a local anesthetic, is less time consuming than use of sutures, staples, glues and can be removed without additional trauma to the skin or medical involvement.

BandGrip is intended for use as a wound closure device for skin approximation, including use in trauma wounds, lacerations, or minimally invasive surgical incisions and other surgical incisions.

BandGrip does not puncture the skin dermis and can easily be removed. with little or no discomfort to the patient. As would be the case with standard wound closure, patient satisfaction on application, removal and cosmetic outcome was expected and achieved.

This study evaluated the performance of BandGrip when used for closure of simple, cleansed, surgical incisions created for port sites following arthroscopic shoulder procedures as an alternative closure to standard sutures and/or paper tape.

STUDY DESIGN AND OBJECTIVE

This prospective, single-center, unblinded post marketing study evaluated the performance of BandGrip when used for closure of simple, cleansed, surgical incisions following arthroscopic shoulder surgery.

The purpose of this study is to assess the use of BandGrip Micro-Anchors Skin Closures when closing the port sites following arthroscopic shoulder surgery. The assessments will consist of ease of wound closure, cosmetic appearance of the healed wound, and time needed to apply and remove BandGrip.

The hypothesis was that BandGrip would be safe and effective at providing approximation of surgical incisions that match the selection criteria following an arthroscopic procedure. There would be little or no discomfort to the patient, equal cosmetic outcome and patient satisfaction as would be expected with standard wound closure.

The time to BandGrip removal will be based on the investigator's clinical judgement as to when adequate intrinsic bonding strength is sufficient, depending mostly on the specific body region (up to 7-14 days).

STUDY OUTCOMES

Of the 25 patients were enrolled, twenty-four (24) were treated and followed with BandGrip Micro-Anchors, with one placed on the anterior and one on the posterior surgical incision sites for each of the 25 patients. The study occurred between June 26, 2018 and August 30, 2018.

The mean patient age was 53 years old (range 28-73) and fifty-six percent (14/25) were female. All subjects were Caucasian. All arthroscopic surgical incisions were estimated to be 0.25 cm in length.

The Visual Analog Scale (0-100 mm) with 100 mm, the best, was used for measurements for ease of wound closure, quality of wound closure and satisfaction with wound closure as well as cosmetic appearance. Both physician and patient's measurements were noted at the time of application and/or removal. Time to apply and remove was measured in seconds.

Upon application, the mean physician visual analog scale (VAS) for easy of wound closure was 11.7 mm (range 8mm-18mm) for the anterior surgical incision and 11.3mm (range 7mm-16mm) for the posterior surgical incision.

The patients' mean VAS for assessment of quality of the closure were 81 mm and 85 mm for the anterior and posterior surgical incisions respectively (0 is worst and 100 mm is the best). The mean VAS for satisfaction with the wound closure were 83.6 mm and 83.6 mm for the anterior and posterior surgical incisions, respectively.

The mean duration of time to apply BandGrip to the anterior surgical incisions was 8.8 (range 4 sec.-19 sec.) seconds, while the time to apply BandGrip on the posterior surgical incisions was 6.5 (range 3-11) seconds. There were no reported adverse events or device deficiencies reported during BandGrip application.

Upon removal, the mean physician cosmetic appearance VAS at the time of BandGrip removal were 89.9mm (range 67mm-98mm) and 91.8mm (range 76mm-98mm) for the anterior and posterior surgical incisions respectively.

The patients' mean VAS for assessment of quality of the closure were 88.8 mm and 91.8 mm for the anterior and posterior surgical incisions, respectively. The mean VAS for satisfaction with the wound closure were 89.5 mm and 92.0 mm for the anterior and posterior surgical incisions respectively.

The wound evaluation score of 6 (the highest rating) was reported for 20 of the anterior surgical incisions. 1 was not reported and 6 reported a (5) rating due to mild redness and/or redness and discharge. Twenty-one (21) posterior surgical sites had a wound evaluation score of 6, with four sites reported as 5 due to mild redness (4) or redness and discharge (1).

Other than those BandGrip Micro-Anchors that were removed by the patients or by loosening (total 13), the remaining were removed by medical personnel with a mean of 4 seconds to remove the anterior BandGrip Micro-Anchors (range 3 sec.-15 sec.) and 3.6 seconds for the posterior BandGrip Micro-Anchors (range 3 sec.-8 sec.).

At the time of BandGrip removal 2 adverse events were reported on the surgical incision sites (1 pins and needles and 1 mild itching and redness) and 3 on the posterior site (1 uncomfortable, 1 mild redness and 1 mild itching and redness). All resolved with no treatment.

All anterior and posterior surgical incisions had 100% closure with continuous approximation of the skin edges including those there were removed early by the patients. No puncture sites required re-closure or experienced dehiscence post application.

At the 30-day evaluation, All anterior and posterior wounds had a wound evaluation score of 6. The mean physician cosmetic appearance VAS at the 30-day follow up were 89.2 mm and 87.5 mm for the anterior and posterior surgical incision sites, respectively.

All surgical incision sites at 30 days had 100% apposition with complete approximation of the edges, and no reported itching, redness or reported adverse events.

BACKGROUND AND RATIONALE

Standard laceration or surgical incision closure has involved sutures. The skin edges are approximated by passing a needle with attached suture through the skin edges and pulling the edges together by tightening the suture with a knot. Several passes through the skin with suture may be needed, depending on the length of the laceration or incision. At a later time, when healing has produced sufficient tensile strength across the wound, the sutures are removed.

Metal staples have also been used to approximate skin edges in surgical incisions and traumatic lacerations. Again, the skin edges may be injected with a local anesthetic, the skin edges are pulled together, and then metal staples are placed across the wound into the skin edges. At a later time, the metal sutures are removed.

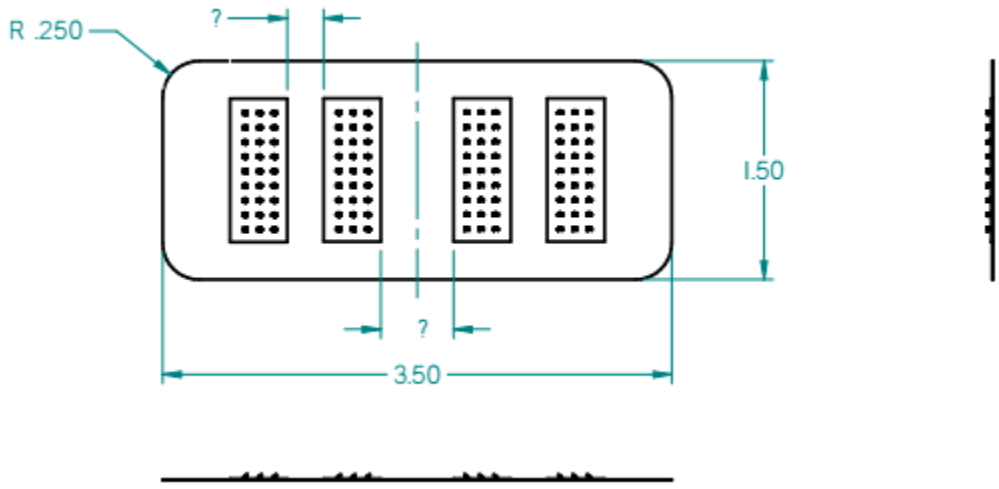
Adhesive bandages, such as Steri-Strips, can also be used to approximate skin edges for small low-tension wounds or incisions. They work by using an adhesive on a bandage that sticks to the skin and holds the wound skin edges together while healing takes place.

Skin glues, such as Dermabond, have also been developed for wound closure. The glues are generally not used across wound exposed to high tension, such as across joints. The holding potential of glues is sufficient for approximation of skin edges in simple, low tension, dry wounds. The glues hold the skin edges in apposition while allowing skin healing. The glue is gradually released from the skin over a 14 (or more) day interval, so there is no need for medical removal of the glue.

An alternative method that addresses these on-going issues is needed.

DEVICE DESCRIPTION

BandGrip is considered a Class I, non-significant risk device.
BandGrip is made of Polycarbonate. It is provided sterile and ready for application. BandGrip's dimensions: 1.50 inches x 3.50 inches. The series of dots represent the location of the micro-anchors.



BandGrip can be applied to a wound without the use of a local anesthetic. There is no need for medical removal as the patient can easily remove the bandage if directed to do so by a medical professional.

BandGrip is a wound closure device that can be used to approximate skin edges of wounds from small surgical incisions and traumatic lacerations. It is a bandage-type patch with several small skin anchors that are used to hold the skin edges together. The clear micro-anchors are 0.029 inches in height and do not puncture through the dermis.

CONCLUSIION

BandGrip Micro-Anchor Skin Closures have been shown to be a satisfactory alternative to standard port closure of surgical incisions in arthroscopic shoulder surgery saving time and providing a high level of acceptance from both a patients and physician for application, removal and quality of closure.

Previous bench top studies demonstrated BandGrip Micro-Anchor time to failure and maximal tension were greatly increased verses PDS Sutures during tensile strength tests and animal studies have shown it to be non-pyrogenic, non-cytotoxic and non-sensitizing to the skin.

Raw data on file

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