A novel skin closure device accelerates early cosmesis in orthopaedic surgical incisions: a randomised controlled trial

Objective: Cosmesis of surgical incisions can greatly impact postoperative patient satisfaction. This study aimed to compare the rate and overall cosmetic improvement of orthopaedic surgical incisions between conventional suture closure and a novel skin closure device.
Method: In this single-blind, randomised, prospective controlled trial, a consecutive series of patients undergoing orthopaedic sports medicine procedures of the knee, shoulder and elbow were randomised to undergo wound closure via either conventional suture or a micro-anchor skin closure device (BandGrip; BandGrip, US). Wounds were stratified by incision length (small ≤2cm and large >2cm). Wound cosmesis was evaluated by two blinded observers' ratings according to the Hollander Wound Evaluation Scale (HWES) at two weeks, two months and one year postoperatively. For both small and large incisions, mean HWES was compared between groups at each timepoint.
Results: A total of 149 incisions were evaluated from 83 patients, including 111 incisions ≤2cm and 38 incisions >2cm. Among incisions ≤2cm, HWES ratings were significantly improved at two weeks and two months postoperatively for incisions closed with a micro-anchor skin closure device, whereas no significant differences between treatment groups were detected at one year postoperatively. Among incisions measuring >2cm (mean incision length = 7.74cm), mean HWES ratings were improved using the micro-anchor adhesive device at two months postoperatively, while HWES ratings were comparable at one year postoperatively.
Conclusion: A novel micro-anchor skin closure device achieves comparable cosmetic outcomes to conventional suture and may reach satisfactory cosmesis more rapidly following orthopaedic sports medicine surgery.
Declaration of interest: This research study was supported by funding from BandGrip, Inc., Chicago, IL, US. BJC is a former board member of BandGrip (resigned) and a former investor; his involvement with the company is no longer active. None of the authors has any conflicts of interest to declare.

incision closure • infection • skin closure • wound • wound care • wound dressing • wound healing

An estimated 1.77 million surgical arthroscopic procedures are performed annually in the US.[1] As the volume of orthopaedic operations increases, there is a commensurate increase in the importance of efficient and effective surgical wound closure. Wound closure following surgery is a crucial yet often overlooked component of a surgical procedure that can have a substantial impact on patients' overall satisfaction.[2–6] Variations in the final closure of surgical incisions can cause poor healing and lead to increased skin scarring. Although serious consequences of inadequate wound closure include dehiscence or infection, increased postsurgical scar formation can have a heightened psychosocial impact linked to a change in physical appearance.[5,7,8] Traditionally, sutures, staples and, more recently, cyanoacrylate-based adhesives have been used for wound closure.[6] Sutures require manipulation of the skin and adequate tension to approximate the two wound edges, which can lead to further trauma and local ischaemia of the soft tissue. Recently, adhesive bandages as alternatives to traditional wound suturing or stapling methods have increased in popularity, as they are often more efficiently applied at the time of surgery and do not require return office visits for removal, which can otherwise be associated with additional patient discomfort. Advancements in technology have allowed these bandages to demonstrate clinical outcomes equal to, and potentially exceeding, traditional methods in measurements of infection rates, the time required for surgical closure, and wound cosmesis.[9–11]

A novel, US Food and Drug Administration (FDA)-approved micro-anchor adhesive skin closure device (BandGrip; BandGrip, US), which employs a polycarbonate backbone with non-piercing anchors, has become widely available.[12] This device has demonstrated a significant reduction in the duration of surgical closure time compared with traditional suturing methods.[12] However, the short- and long-term cosmetic results associated with its use have not been

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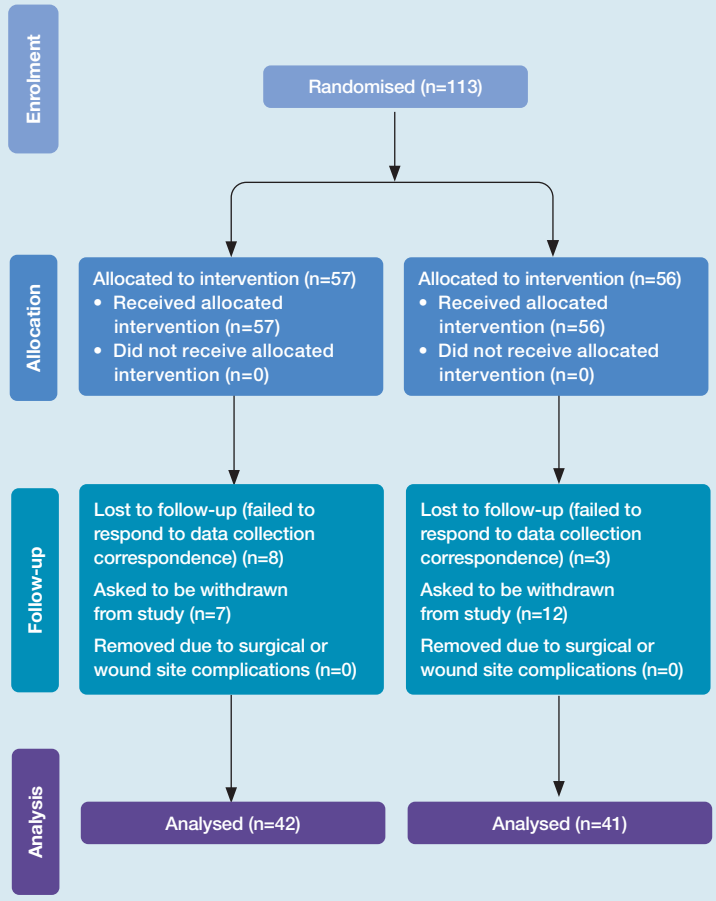
Fig 1. CONSORT flow diagram



systematically investigated. The present study aims to evaluate the cosmetic outcomes of a novel micro-anchor wound closure device within an orthopaedic sports medicine practice. We hypothesised that the cosmetic outcomes of orthopaedic surgical incisions closed with a micro-anchor wound closure device would be comparable to those closed with conventional sutures.

Methods

Ethical approval and patient consent

This research study received approval from the Institutional Review Board (IRB) of Rush University Medical Center (ORA: 19070102-IRB01-CR03). The study adhered to the guidelines set out in the Declaration of Helsinki. Patients provided informed written consent for publication of their data, including for publication of photographs.

Patient selection and group allocation

Institutional review board regulatory approval was obtained prior to beginning the investigation. Patients aged ≥18 years indicated for primary arthroscopic or open surgery at Midwest Orthopaedics at Rush University Medical Center (RUMC) Department of Sports Medicine between November 2020 and September 2021 were eligible to be enrolled in the study. Patients undergoing revision surgery or surgery with compromised skin at or adjacent to the surgical site (i.e., open wounds or visible abrasions) were excluded. Patients with a self-reported history of keloid scar formation were also excluded. A total of 113 patients were enrolled preoperatively by providing their informed, written consent to dedicated research personnel. Block randomisation was performed via a computer-generated random number list. Patients were randomised to undergo surgical wound closure with either a micro-anchor wound closure device (BandGrip) or conventional subcuticular and subcutaneous suture placement, consistent with standard of care (Fig 1). Patients with multiple incisions had each incision closed with the same technique.

Surgical wound evaluation

Intraoperatively, after all surgical procedures were completed, each surgical incision was measured with a sterile ruler by an orthopaedic sports medicine fellow or physician assistant and recorded. Each incision was stratified according to its length as either ≤2cm or >2cm.

Application of micro-anchor wound closure device

To apply the micro-anchor wound closure adhesive, the surrounding skin was first cleaned and dried. The device was applied to the skin on one side of the wound, ensuring the entire surface had been fully seated onto the skin. The skin edges were then approximated and held in place with light opposition forces during the placement of the second pad of anchors onto the opposing skin edge (Fig 2). The micro-anchor wound closure adhesive was left in place until the patient's first postoperative visit at 10–14 days, when a telemedicine visit was used to instruct patients on how to remove their dressing at home. Patients were instructed to avoid submersion of the incision but were permitted to shower 24 hours postoperatively as the dressing is water resistant. Alternatively, patients undergoing traditional suture placement to close their surgical incisions were seen in the office 8–10 days postoperatively for suture removal where necessary. They were then allowed to shower without wound coverage 24 hours after this office visit.

Closure of ≤2cm surgical incisions

For patients randomised to undergo surgical closure with a BandGrip adhesive, incisions measuring ≤2cm were closed with a buried 3-0 absorbable monofilament suture (Monocryl; Ethicon Inc., US) and covered superficially with a single, small-sized BandGrip adhesive. For wounds ≤2cm closed exclusively with suture, 3-0 nonabsorbable polypropylene suture (Prolene; Ethicon Inc., US) was used.

Closure of >2cm surgical incisions

Incisions >2cm randomised to closure with a BandGrip adhesive were closed using a buried 3-0 absorbable monofilament suture (Monocryl) and final closure was completed with the micro-anchor device. Either a small or large-sized BandGrip adhesive was selected, according to optimal wound coverage, depending on incision length. Incisions measuring >2cm in the traditional suture cohort were closed by a buried 3-0 absorbable monofilament suture (Monocryl), followed by a superficial running 3-0 nonabsorbable polypropylene suture (Prolene) in a knotless technique with suture tails at each end.

Study outcomes

The primary outcome of wound cosmesis was evaluated by two blinded observers' ratings according to the Hollander Wound Evaluation Scale (HWES) at two weeks, two months and one year postoperatively (Table 1).[7,13–15] The HWES is a previously validated instrument for evaluating wound cosmesis that has been applied extensively in the evaluation of surgical wounds in a multitude of settings.[16–20] In the HWES, a lower score indicates a more favourable cosmetic outcome. Additionally, a secondary outcome was patients' numeric rating scale (NRS) satisfaction scores at the same three postoperative timepoints (Fig 3).

For each surgical wound, a photograph was taken with a digital camera at a resolution of 12 megapixels at the first postoperative visit (7–14 days postoperatively), at approximately two months postoperatively and at approximately one year postoperatively. Each photograph was scored on the HWES by two independent study personnel blinded to group allocation.[13,14] Photographs were de-identified and evaluated at a time distinct from the patient's clinical visit to ensure that raters were blinded. The mean HWES value for each surgical wound at each postoperative timepoint was employed in data analyses. Patients responded to a single-question numeric survey to determine their overall satisfaction with wound healing. The reporting question was phrased as follows:

> *On a scale from 0–10, where 0 is the worst and 10 is the best, how satisfied are you with the cosmetic appearance of your wound?*

Patients reported their satisfaction on a 10-point scale, with 0 representing complete dissatisfaction and 10 representing complete satisfaction.

Statistical analysis

R Studio Version 2022.07.1 (Posit Software, US) was used for all statistical analyses. Mean, variance and standard deviation were calculated for all data. The treatment effect at each follow-up interval was calculated using the difference in means between treatment groups. Significance testing was completed using an unpaired t-test. The level of significance was established at a two-sided alpha level of $p<0.05$.

Fig 2. The micro-anchor adhesive skin closure device can be placed in an overlapping manner to provide optimal wound coverage: Sterile BandGrip micro-anchor devices prior to application **(a)**; three incisions following final closure with BandGrip **(b)**

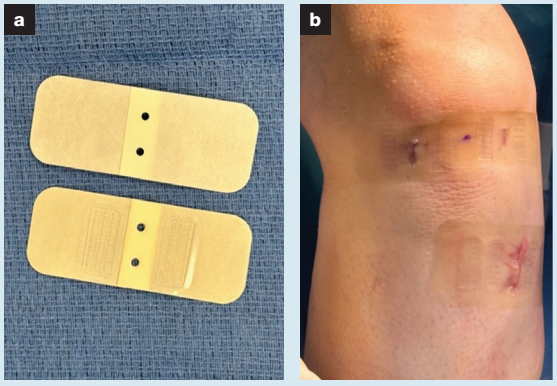


Fig 3. Hollander Wound Evaluation Scale (HWES) mean outcome score for incisions ≤2cm **(a)** and >2cm **(b)** in both suture and BandGrip groups at each postoperative visit. A lower HWES value signifies a better outcome. Visits 1, 2 and 3 correspond to approximately 7–14 days postoperatively, 8 weeks postoperatively and 1 year after surgery, respectively. A paired t-test was performed to evaluate for a significant difference between group means. *Indicates a statistically significant difference between BandGrip and suture group means

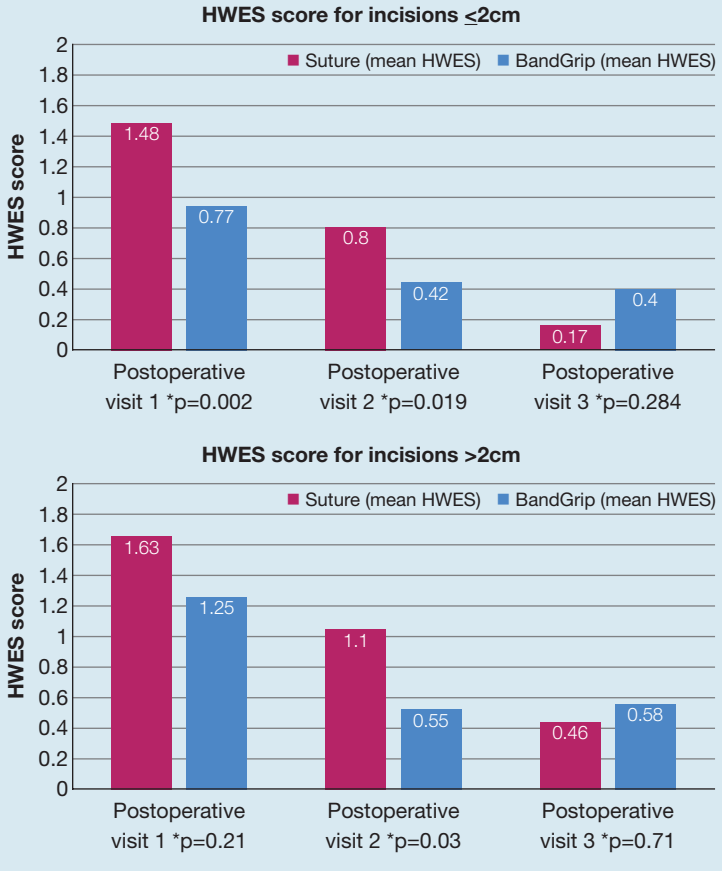


Table 1. Hollander Wound evaluation scale (HWES)[21]

Evaluation criteria	Present	Absent (ideal)
Step-off borders	1	0
Wound margin separation	1	0
Contour irregularities	1	0
Edge inversion	1	0
Change in colour or appearance of excess inflammation	1	0
Overall appearance	1	0

For each characteristic that is present, one point is assigned to the overall score. 0 represents the best possible cosmetic appearance, while 6 represents a poor healing outcome

Table 2. Patient demographics (n=83)

Characteristic	Value
Age, years, mean±SD	48.39±8.28
Sex, n (%)	
Female	37 (44.6)
Male	46 (55.4)
Laterality, n (%)	
Left	40 (48.2)
Right	43 (51.8)
BMI, kg/m^2, mean±SD	30.2±5.16

BMI—body mass index; SD—standard deviation

Results

Eighty-three of 113 (73.4%) enrolled patients were included for final statistical analysis. Of the 30 patients not included for analysis, 19 patients asked to be withdrawn from the study, while 11 patients were lost to follow-up. No patients were removed from the study for surgical or wound site complications. Demographics of the 83 patients included for analysis can be found in Table 2.

Among the 83 patients included for analysis, there were a total of 149 incisions, with 111 incisions measuring ≤2cm and 38 incisions measuring >2cm. For all incisions ≤2cm, 54 closures were performed following shoulder procedures, 53 closures following knee surgery, and four closures following elbow arthroscopy. For incisions measuring >2cm, 15 closures were performed for shoulder procedures and 23 for knee procedures.

Incisions ≤2cm

Of patients with incisions ≤2cm, 23 individuals (60 incisions) had a traditional suture closure method, and 23 patients received the novel adhesive device (51 incisions). HWES ratings were significantly improved at two weeks (p=0.002) and two months (p=0.019) postoperatively for incisions closed with a micro-anchor skin closure device, whereas no significant differences between treatment groups were detected at one year (p=0.284) postoperatively (Fig 3a). There was no difference in mean NRS satisfaction scores at first or second postoperative follow-up, but there was a significant difference at the one-year follow-up (Fig 4a: NRS score: suture: 9.37, BandGrip: 8.63; p=0.043).

Incisions >2cm

In patients with incisions >2cm, the average incision size was 7.74cm (range: 2.5–15cm). Mean HWES ratings were improved with use of the micro-anchor adhesive device at two months postoperatively (p=0.03), while HWES ratings were comparable at one year postoperatively (Fig 3b, HWES score: suture: 0.46, BandGrip: 0.58; p>0.05). Patient-reported satisfaction regarding the appearance of their incisions was significantly higher at two months postoperatively (p=0.03) with the micro-anchor adhesive device, while no significant differences were observed at one year postoperatively (Fig 4b).

Discussion

In this prospective, randomised comparative analysis, the principal finding is that a micro-anchor adhesive wound closure device produces earlier attainment of cosmetic outcomes when compared to standard subcutaneous suture closure. Arthroscopic portals <2cm closed with the adhesive device demonstrated an early cosmetic advantage, although this difference diminished at the 12-month cosmetic evaluation. Larger incisions demonstrated a similar trend in cosmetic outcomes but did not reach the predetermined significance threshold of p=0.05 at the first postoperative visit.

The early cosmetic benefit identified via HWES ratings at two months postoperatively with the adhesive closure device is likely multifactorial. The micro-anchor design and semi-rigid polycarbonate structure of BandGrip likely support a favourable healing environment by inducing uniform compression, preventing excessively dry tissue, and minimising local ischaemic conditions.[22–24] However, the objective early improvements associated with use of a micro-anchor wound closure device are tempered by the findings that patient-reported satisfaction of surgical wounds did not differ at any timepoint within the study period. The current findings build upon previous work that demonstrated that BandGrip was approximately five times faster than a suture-only wound closure.[12] Thus, at minimum, the tested skin closure device provides increased operating room efficiency while providing comparable long-term cosmetic results.

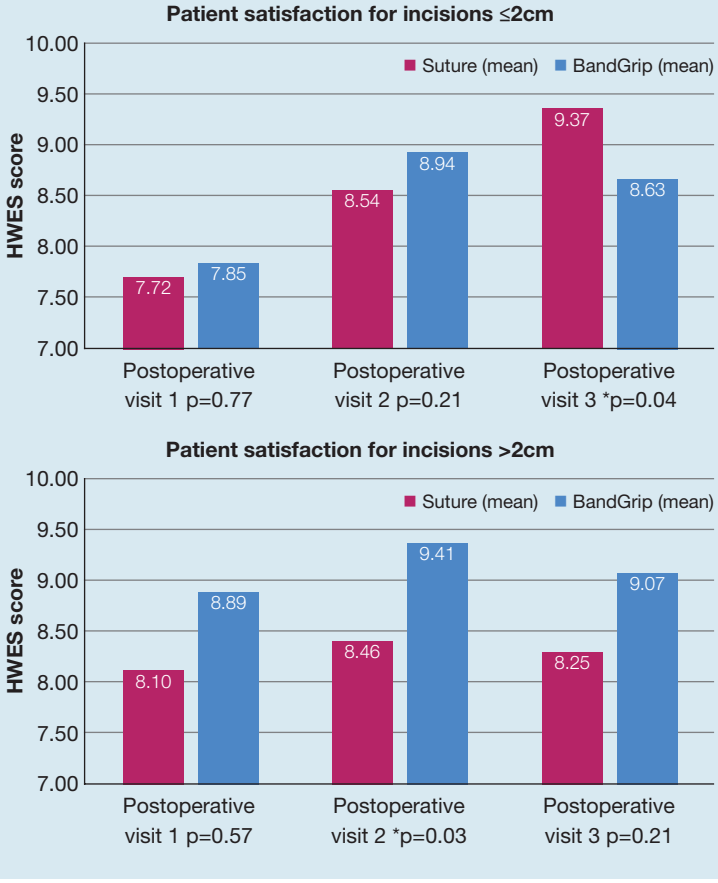
There is growing interest in alternative surgical wound closure devices that improve operative efficiency and minimise wound-related surgical complications.[25–27] Devices, including BandGrip, Clozex (Clozex Medical LLC, US), and Zip (Stryker Medical, US), offer the potential to expedite wound closure and improve

cosmesis, as well as reduce the potential for needle-stick injuries.[28] In a randomised trial comparing cosmetic outcomes following wound closure of 32 arthroscopic knee portal incisions using Zip, Clozex, or a running 3-0 Prolene suture, Burke et al.[29] reported more favourable cosmetic outcomes among wounds closed with Clozex at three months postoperatively. However, a longer-term follow-up comparison was not reported. In the present study, BandGrip similarly demonstrated improved cosmesis compared to conventional suture closure at two months postoperatively; however, evaluation at one year postoperatively revealed comparable cosmetic outcomes. The present study highlights the importance of long-term evaluation of surgical wounds to determine the durability of improved cosmesis over conventional skin closure techniques.

Limitations

The study's findings must be considered within the context of its limitations. First, surgical wound closures were performed by a multitude of orthopaedic sports medicine fellows and physician assistants, introducing the potential for differing technical expertise as a confounding variable. However, all individuals who performed wound closure had extensive experience in orthopaedic surgery and received explicit training in proper application of the BandGrip adhesive. Second, there was minor variability in the timepoints at which surgical wounds were photographed for evaluation. To minimise participants' time burden, patients were evaluated at their normally scheduled clinical evaluations, which varied based on patients' and surgeons' clinical schedule. Finally, a cost analysis was not the focus of the present study and further investigation is required to evaluate the cost-effectiveness of alternative wound closure devices.

Fig 4. Patient satisfaction evaluated in response to a single question for incisions ≤2cm **(a)** and >2cm **(b)**. Responses were collected using a 10-point numerical rating scale, with 0 representing total dissatisfaction and 10 representing complete satisfaction. Significance testing between mean BandGrip and suture satisfaction scores were evaluated using a t-test. *Indicates a statistically significant difference between BandGrip and suture group means



Conclusion

A novel micro-anchor skin closure device achieves comparable cosmetic outcomes compared with conventional suture closure and may reach satisfactory cosmesis more rapidly following orthopaedic sports medicine surgery. JWC

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Reflective questions

- How does a patient's satisfaction with regards to wound healing affect their overall satisfaction with the procedure?
- What is the significance of achieving improved cosmetic outcomes at an earlier postoperative follow-up?
- What are the benefits of using this novel wound closure device?

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