National Journal of Clinical Orthopaedics

ISSN (P): 2521-3466
ISSN (E): 2521-3474

www.orthoresearchjournal.com
2023; 7(2): 31-35
Received: 10-02-2023
Accepted: 15-03-2023

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Clinical viability of novel safety-engineered sharps device in wound closure for foot and ankle surgery

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DOI: https://doi.org/10.33545/orthor.2023.v7.i2a.404

Abstract
Unsafe injections are a major burden of death and disability among healthcare workers. This study aimed to determine if Operative Armour, a device that reduces the passage of exposed needles, is an effective tool to reduce wound closure time. Orthopaedic foot and ankle fellows performed surgical wound closure of cadaveric specimens. Group A had a traditional suture passing technique involving a technologist, while Group B had Operative Armour without the presence of a technologist. Average number of suture passes for anterior incisions was greater in Group A (52+8.9) than Group B (5.3+0.7), $p<0.05$. Closure time anteriorly was also greater in Group A than Group B, at 16:51+0.2 minutes and 16:13+0.1 minutes, respectively. Among posterior approaches, Group A (48+0.0) had more suture passes than Group B (5+0.0), $p<0.05$. Closure was faster in Group A (16:18+0.2 minutes) than Group B (16:53+0.1 minutes). Overall, there was no significant difference in time to wound closure between the technologist and Operative Armour. However, Operative Armour fills a need by reducing reliance for suture passing, thus creating a safe neutral zone and also increasing the efficiency of the operation.

Keywords: Foot surgery techniques, wound care, surgical complications, soft tissue repair/trauma, other

Introduction
Healthcare providers are at a much greater risk of contracting infections via bloodborne pathogens than is the general population. The vast majority of these workers are exposed to bloodborne infections as a result of injuries caused by objects called "sharps"-classified by the WHO as needles, scalpels, lancets and broken glass [1]. Hauri *et al*. recognized injuries from sharps as falling under the overarching risk factor of "unsafe injections" contributing to the global burden of death and disability among healthcare workers. Unsafe injections are those that cause harm to either the recipient, the provider, or the community at large [2]. In fact, unsafe injections are predicted by some models to become a major driver for substandard healthcare delivery as a direct result of the impact these injections have on healthcare providers. In turn, injuries from sharps will have their greatest detrimental effects in those regions where the infrastructure for the provision of medical care is already weak or nonexistent [1, 2]. Aside from the global health burden incurred by sharps injuries, other major costs include costs to the healthcare facility. With each unsafe injection comes a loss of employee work time, a cost to replace injured staff, a cost to investigate the injury, a cost of conducting appropriate laboratory testing, and a cost to providing post-injury treatment [3]. Therefore, it becomes imperative to investigate methods to reduce the risk of sharps injuries in healthcare settings.

According to a report by the International Safety Center examining injuries, the vast majority of injuries caused by sharp objects or needlesticks occurred during the direct use of the instrument. Of the sharps injuries, over half the incidences were directly attributable to either disposable syringes (27%) or suture needles (25%) [3, 4]. Although there are over 20 known bloodborne pathogens that have been transmitted via sharps injuries, the ones that have the greatest risk of morbidity and mortality are HIV, Hepatitis B, and Hepatitis C [5]. In fact, it wasn't until needlestick-associated HIV infections were first reported in 1984 that this matter began to come to the surface of public attention, finally reaching a state of urgency in 1987 when the Centers for Disease Control and Prevention (CDC) reported six documented cases of occupationally acquired HIV [6].

That same year, CDC partnered with the Occupational Safety and Health Administration (OSHA) to issue "Universal Precautions" for healthcare workers which promoted increased use of personal protective equipment, safer handling of sharp medical devices, easily accessible puncture-proof containers for disposal of sharps, and annual training for all at-risk workers [6, 7].

While regular training and means of disposal are important to reduce sharps-related injury risk, the design of these instruments is paramount to determining incidence. In 1987, OSHA declared that hazard reduction to healthcare workers was best achieved through controls such as safety engineering of needles and sharp devices. This effect was seen following the Food and Drug Administration's Safety Alert in 1992, which led to a 100% drop in injuries from IV line connectors (previously a very common cause of injury) across 8 years as institutions stopped using hypodermic needles for these purposes [6, 8, 9]. The U.S. Congress passed official legislation in 2000 with the Needlestick Safety and Prevention Act, holding employers of healthcare workers accountable for regular evaluation and implementation of safety-engineered needles and sharps, as well as establishing a system to document sharps injuries [6, 10, 11].

Despite these precautions, the rate of sharps injuries has not changed in the setting where it is most deleterious - the operating room. Globally, the prevalence of sharps injuries did not show a significant decline until safety devices became the predominant technology on a large scale [12, 13]. This phenomenon may explain why the surgical setting, both inside the hospital and outside, has been resistant to a similar drop in injury risk. There have been many reports of a lack of adoption of safety-engineered devices (blunt suture needles, shielded scalpels) in hospital operating rooms, private clinics, dentists' offices, and laboratories at rates 25-35% lower than those in traditional hospital settings [14]. When considering that 60% of healthcare workers are employed outside of the hospital setting, this figure becomes even more alarming [15].

Among surgical subspecialties, the field of Orthopaedic surgery has the highest prevalence of exposure to blood and bodily fluids intraoperatively [16]. Therefore, it is important to assess the utility of novel safety-engineered sharps devices in an attempt to reduce the overall injury burden. The aim of this study is to determine if Operative Armour (Sharp Fluidics®, LLC), a device that reduces the passage of exposed needles by allowing surgeons to secure and dispose of the needle themselves, is an effective tool in the surgical setting to aid in reducing wound closure time and in the handling of sequentially passed needles.

Methods

For this controlled, non-randomized study with a crossover design, three participants were recruited. All three participants were Foot and Ankle fellows in our institution's Department of Orthopaedic Surgery. Three lower extremity specimens were obtained from cadavers for the purposes of testing the efficacy of Operative Armour to the control. For each specimen, a standard 12 cm surgical incision was utilized in both anterior and posterior approaches to the ankle joint. A surgical marking pen was used to cross-hatch the incisions at intervals of 1 cm to indicate points of surgical closure. Each incision was made along the marked site with a 15 blade scalpel, going through the adipose tissue layer, superficial to the fascial plane.

Two groups were created for the purposes of this study. In Group A, all participants performed a traditional suture passing technique with the aid of a surgical technologist. In Group B, participants utilized the Operative Armour device without the presence of a surgical technologist. Each participant was initially assigned to either Group A or Group B, and then was assigned to the alternate group in the second round. Operative Armour is an arm guard device allowing surgeons to independently access needles, and contains a foam insert for disposal of the needle (Figure 1).

In both groups, surgical wound closure was performed utilizing an interrupted suture technique with a 2-0 vicryl pop-off suture (*Ethicon, Inc.*). Two layers of the wound were closed, the subcuticular layer as well as the skin layer, by each participant enrolled in the study. Participants underwent three trials each for Groups A and B, first through an anterior approach and then through the posterior. Data collected included number of needle passes, number of dropped needles, and total time for wound closure. Paired student t-tests were performed for statistical analyses of collected outcome measures, using a p-value <0.05 to illustrate statistical significance.

Results

A summary of collected data including number of needle passes, number of dropped needles, total wound closure time, is listed in Table 1. Participants in Group A performed a standard suture technique for wound closure without the assistance of a surgical technologist, while participants in Group B used the Operative Armour assistive device without a surgical technologist present.

In Group A, the average number of suture passes was 52+8.9, significantly higher than in 5.3+0 passes in Group B ($p<0.05$). There was no statistically significant difference observed (p=0.8) in overall wound closure time between Group A (16:35+0.2 minutes) and Group B (16:33+0.1 minutes). No needles were dropped in either group by any of the participants.

A comparison of the anterior and posterior approaches for surgical incision showed that the average number of suture passes for anterior incisions was greater in Group A (52+8.9) than in Group B (5.3+0.7), $p<0.05$ (Figure 2). Wound closure time with the anterior approach was also greater among participants in Group A compared to Group B, at 16:51+0.2 minutes and 16:13+0.1 minutes, respectively.

Posterior approaches showed a similar pattern as the ones seen by the anterior incisions. In Group A, the average number of suture passes was 48+0.0 while Group B had an average of 5+0.0 passes (Figure 2), $p<0.05$. However, the average time for wound closure using a posterior incision was significantly higher in Group B (16:53+0.1 minutes) than in Group A (16:18+0.2 minutes), $p<0.05$.

Table 1: Wound closure time, number of dropped suture needles, and suture passes using the standard technique and the Operative Armour™ device

Outcome	Group A Standard Technique	Group B Operative Armour™	*p*-Value
Closure Time (minutes)	16:35±0.2	16:33±0.1	P=0.8
Number of Dropped Needles	0	0	
Number of Suture Passes	52±8.9	5.3±0.7	$p<0.05$

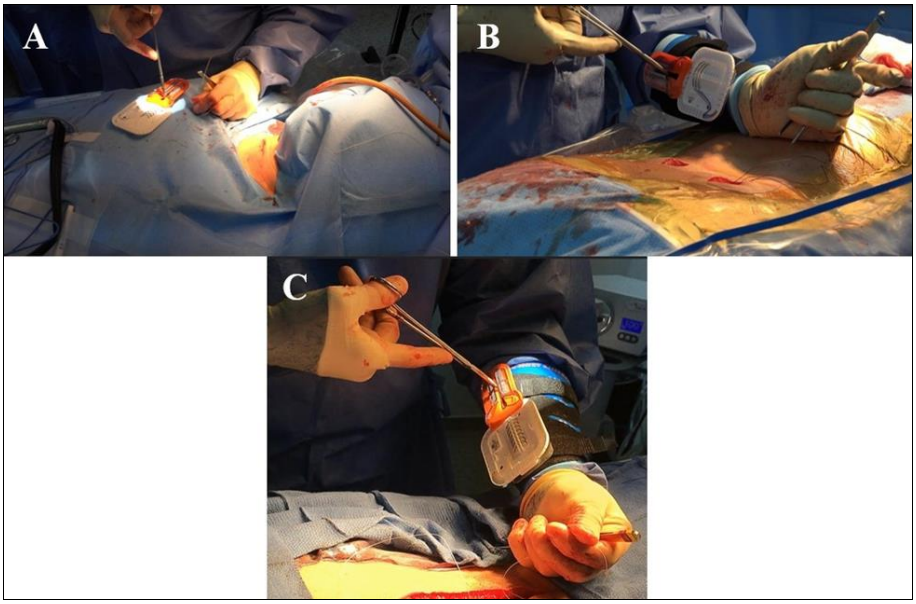

Fig 1: A: Demonstration of Operative Armour self-secured suture on surgical field, B: Demonstration of the Operative Armour on a surgical barrier, C: Demonstration of the Operative Armour during surgery

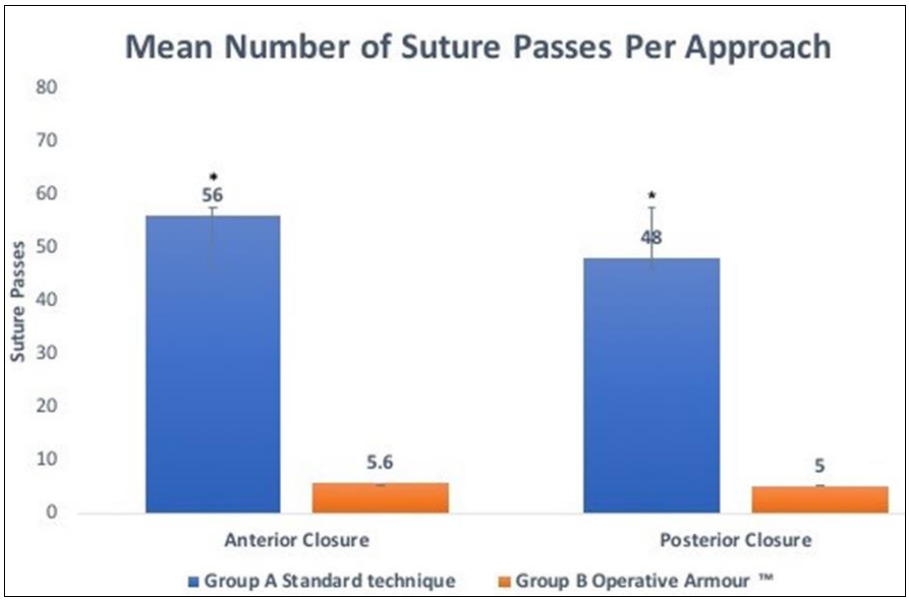

Fig 2: Mean number of suture passes using the standard technique or the Operative Armour device for the anterior and posterior approach to the ankle

Discussion

Needlestick injuries and injuries attributed to sharps accrue a host of clinical, economic, and humanistic burdens, especially among healthcare workers [17]. Previous literature has reported a high prevalence, with up to 69.4% of healthcare workers around the world having experienced a needlestick injury; furthermore, the CDC estimates that over half the sharps injuries in the US go unreported [18-21]. The monetary weight of each injury is also significant, as follow up and treatment for each episode can be as high as $5,000 [18-21]. Finally, though less tangible, the emotional effects of sharps injuries are numerous and equally taxing, as these incidents are linked to depressive symptoms, adjustment disorder, anxiety, panic attacks and even post-traumatic stress disorder (PTSD) [22-24]. Unfortunately, even with the advent of new legislation such as the Needlestick Safety and Prevention Act, the number of intraoperative sharps-related injuries has not decreased. This study addressed this issue by assessing the safety and efficacy of Operative Armour, a device that reduces the passage of exposed needles by allowing surgeons to secure and dispose of the needle themselves.

Underlying strategies for the prevention of sharps injuries have been reported in the current literature. Widespread incorporation of engineered safety devices such as protective covers or retraction devices are projected to reduce rates by 56%, while cutting down on the number of sharps devices in the operating room would have an even greater, compounded effect [25]. However, recognizing that it is not feasible to eliminate needles and sharps from many orthopaedic surgeries, many safety researchers believe that a decline in hand-to-hand passing of these devices would make a large dent as well. For example, the concept of a “neutral zone,” which is a dedicated space to pass sharp instruments, has been shown to reduce sharps injuries by up to 60% [26, 27].

In a large multicenter retrospective study conducted across 87 hospitals by Jagger and colleagues, it was determined that 75% out of the 31,324 total sharps injuries documented occurred during the direct use or passing of suture devices [28]. Therefore, it is reasonable to conclude that devices such as Operative

Armour, by eliminating the need to pass suture devices between surgical personnel and therefore effectively creating an aforementioned "neutral zone," would go a great length in driving down the incidence of sharps injuries within the operating room. This outcome becomes more apparent when juxtaposing the average number of suture passes required in Group A (conventional handoff with a surgical technologist) of our study with that in Group B (Operative Armour only). Group A had an average of 52+8.9 passes, significantly higher than 5.3+0 passes in Group B ($p<0.05$).

It is difficult at present to extrapolate the preliminary findings of our study to make a meaningful conclusion regarding the role of Operative Armour in time to wound closure. Overall, this study did not yield a significant difference in the total time to wound closure between the conventional surgical technologist group and the Operative Armour group. However, when segmenting the cohort into anterior and posterior approaches, we observed that time to wound closure with the anterior approach was greater among participants in Group A compared to Group B, 16:51+0.2 minutes and 16:13+0.1 minutes, respectively, though this finding was not statistically significant. This relationship did not hold true for wound closure time with the posterior approach to the ankle joint, as it was found to be significantly higher in Group B (16:53+0.1 minutes) than in Group A (16:18+0.2 minutes), $p<0.05$.

Another factor which invariably affects patient safety and outcomes following surgery is the amount of intraoperative time, as longer surgeries are associated with increased postoperative complications [29, 30]. To this effect, it seems that Operative Armour fills a need by reducing the reliance on a surgical technologist for suture passing, thereby not only creating a safe neutral zone but also increasing the efficiency of the operation. In turn, this would contribute to less time spent in the operating room and subsequently lower complication rates.

As this is a preliminary study, there are some limitations. Firstly, our study comprises a small sample size of three surgeons. This directly affects the power of the study, and we believe this could also explain a lack of statistical significance seen between some of our direct comparisons between the two groups. Though the number of participants plays a role in limiting the generalizability of the work, it is important to note that we have found some statistically significant results that address principles of surgical management and safety. Another limitation to our study is that our conventional arm only focused on one surgical technologist paired with one surgeon; we did not incorporate multiple surgeons being assisted by the same technologist. Additionally, as this was simply a pilot study to assess efficacy and safety of the device, we were not able to look at how this device might be employed during an actual surgery in which different surgical personnel have different responsibilities. Future research with Operative Armour should therefore include controlled trials with larger sample sizes in which the device is used during real-time operations. Finally, there are economic and humanistic costs associated with needlestick and sharps injuries that we have not identified in this study. Further information on fees to the surgical center as well as patient emotional well-being in the postoperative period would contribute to a more holistic understanding of the utility of Operative Armour.

Conflict of Interest
Not available

Financial Support
Not available

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How to Cite This Article
S Akhil, P Selene G. Clinical viability of novel safety-engineered sharps device in wound closure for foot and ankle surgery. National Journal of Clinical Orthopaedics**.** Yy;vol(issue):pp.