Pelvic Ring Emergency Stabilization System (PRESS)

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Conflict of Interest The authors have no conflicts to declare. This technology was protected by a US provisional patent application during prototype development (No. 62/432386). A full patent application has been submitted to the US Patent and Trademark Office (2016-042-04US) filed December 9, 2016.

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ABSTRACT

Pelvic ring fractures can be lethal owing to the potential for hemodynamic instability or arterial hemorrhage when the pelvic volume is increased. Pelvic binders are the standard of care used to provide circumferential compression to the pelvis, reducing the volume and increasing the intra-pelvic pressure. While commercially available options have been shown to provide adequate stability to the unstable pelvis, the circumferential nature of the binders limits access to the abdomen and groin regions, where accessibility is often necessary during the course of emergency treatment. We introduce a new technology known as the Pelvic Ring Emergency Stabilization System (PRESS). The PRESS device satisfies all required characteristics of a pelvic binding system in a configuration that does not obstruct abdominal or groin access to the patient.

Keywords: Pelvis, Medical Device Design, Closed Fractures, Bone Fractures

INTRODUCTION

Pelvic ring fracture is a disruption of the bony structure of the pelvis in at least two locations, (both anteriorly and posteriorly), causing a separation of the bones that form the pelvic ring (Figure 1). This fracture can occur due to high-energy trauma such as motor vehicle accidents or fall from a great height and represents 2% to 8% of all skeletal injuries.[1] While the incidence of pelvic ring fracture is low, hemodynamic instability or arterial hemorrhage from this fracture type results in a 40% to 60% mortality rate.[2] In emergency transport, the pelvis must be stabilized to prevent death before definitive treatment can be performed at a primary surgical facility. This is especially impactful in a state like New Mexico, where the only level 1 trauma center is located in Albuquerque and emergency transport from rural areas may occur frequently.

Historically, a pelvic binder has been the ideal choice for initial stabilization of pelvic ring injuries and the

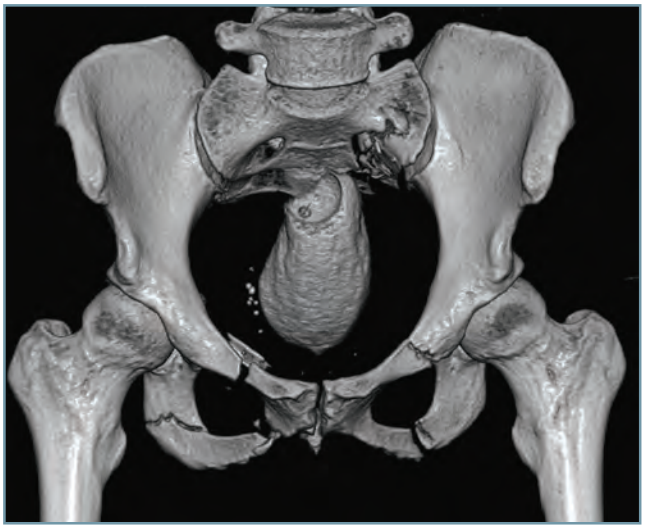
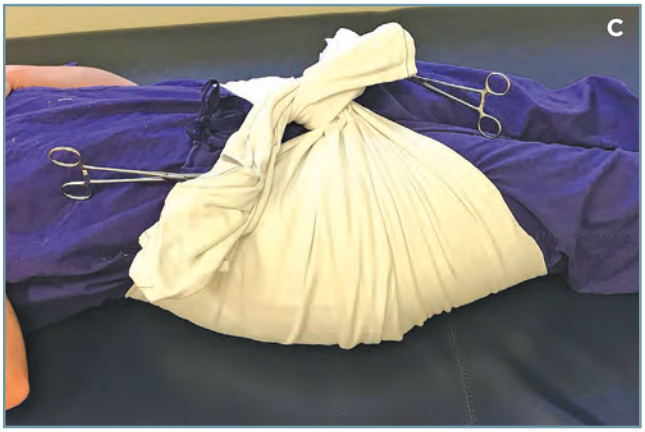


Figure 1. Pelvic ring fracture indicated by a fracture or tissue disruption in two or more areas. This image shows how the opening of the pelvis can increase volume, allowing for hemodynamic instability. Reprinted with permission from CTisus and image courtesy of Elliot K. Fishman MD and www.ctisus.com.

Figure 2. A) The T-POD (Teleflex, Wayne, PA) is a circumferential pelvic binder that uses a pulley system to bring the two ends of the device toward each other, across the abdomen. Depending on placement, there is limited groin access between the pulley cables. Reprinted with permission from Teleflex. B) The SAM Pelvic Sling is a force-controlled circumferential pelvic belt (SAM Medical, Wilsonville, OR). Notably, the buckle lies directly over the groin but allows for lower abdomen access. Reprinted with permission from SAM Medical. C) Bed sheets have long been used for temporary pelvic stabilization. This method of circumferential compression allows for abdominal access but no groin access. Photograph curtesy of Tony Pedri, MD, and Brianna Patti, MD.

management of exsanguinating pelvic trauma. The binder should be placed over the greater trochanters of the femurs, which provides the best mechanical stability for the pelvic ring.[3] This is a very effective, simple procedure to limit the motion of the fracture by applying a large compressive force to the pelvic ring to reduce the volume of the pelvis and reduce pain during transport or pre-surgical care. Though the pelvic binder cannot control arterial hemorrhage directly, it helps in stabilizing and compressing the pelvis, thus reducing hemodynamic instability by increasing intra-pelvic pressure.[4] While patients undergo emergency treatment, the binder should allow easy access to the groin and the abdominal area without removal or reposition of the device. Removal of this device, even temporarily, may risk arterial hemorrhage into the enlarged pelvic region.

In the present market, several types of non-invasive binders are available (Figures 2A through 2C). The most commonly used pelvic binders include the T-POD (Teleflex, Wayne, PA; Figure 2A) and SAM Pelvic Sling (SAM Medical, Wilsonville, OR; Figure 2B). These have been shown to provide sufficient reduction in partially stable and unstable pelvic fractures with little adverse reaction.[5] Often, bed sheets are used as temporary circumferential stabilization devices but have been



associated with a higher incidence of lethal hemorrhage than the commercially available options.[6] Unfortunately, most of the non-invasive, mobile binders on the market do not allow for abdominal or groin access. Because of the increased demand for surgical access in the current binders market, we propose the development of a model for a totally exposed abdominal and groin region, which may potentially provide less complexity in emergency intervention.

An ideal pelvic binder should satisfy the following characteristics: 1) easy to use and require limited training for paramedic, pre-hospital area, and emergency department personnel; 2) allow for full abdominal and groin access during use with procedures such as laparotomy and angioembolization; 3) stabilize the pelvis for a period of time that may extend beyond 24 hours and must maintain stabilization during patient movement; 4) allow for two-person deployment, with an option for single-person deployment; 5) be radiolucent for radiograph and computed tomography (CT) scans; 6) have an evenly distributed load area to minimize pressure sores[7]; 7) be adjustable to various shapes and sizes; and 8) be low cost and disposable or high cost and sterilizable. We introduce the Pelvic Ring Emergency Stabilization System (PRESS), a pelvic binder that improves the efficiency of application and ease for pre-surgical/emergency treatment access.

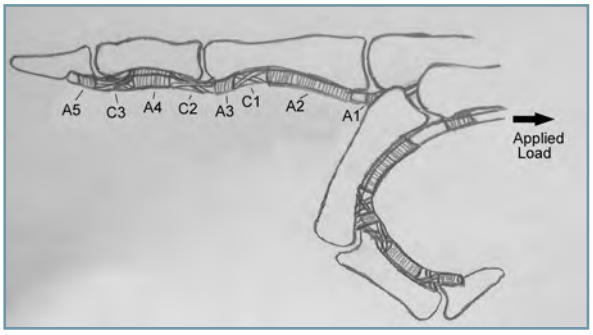


Figure 3. Representative image of the tendon-and-pulley system of the hand. Annular and cruciate pulleys in the finger are noted as A-1 through A-5 and C-1 through C-3, respectively. The tendon is pulled by the muscle along the trajectory of the arrow. A bending motion occurs at each joint. This mechanical system was used as the model for the proposed device.

DESIGN

The device is bioinspired by the movement of the fingers in the hand (Figure 3). As muscles contract, they apply tensile load to tendons that extend along the fingers. These tendons pass under flat pulleys that

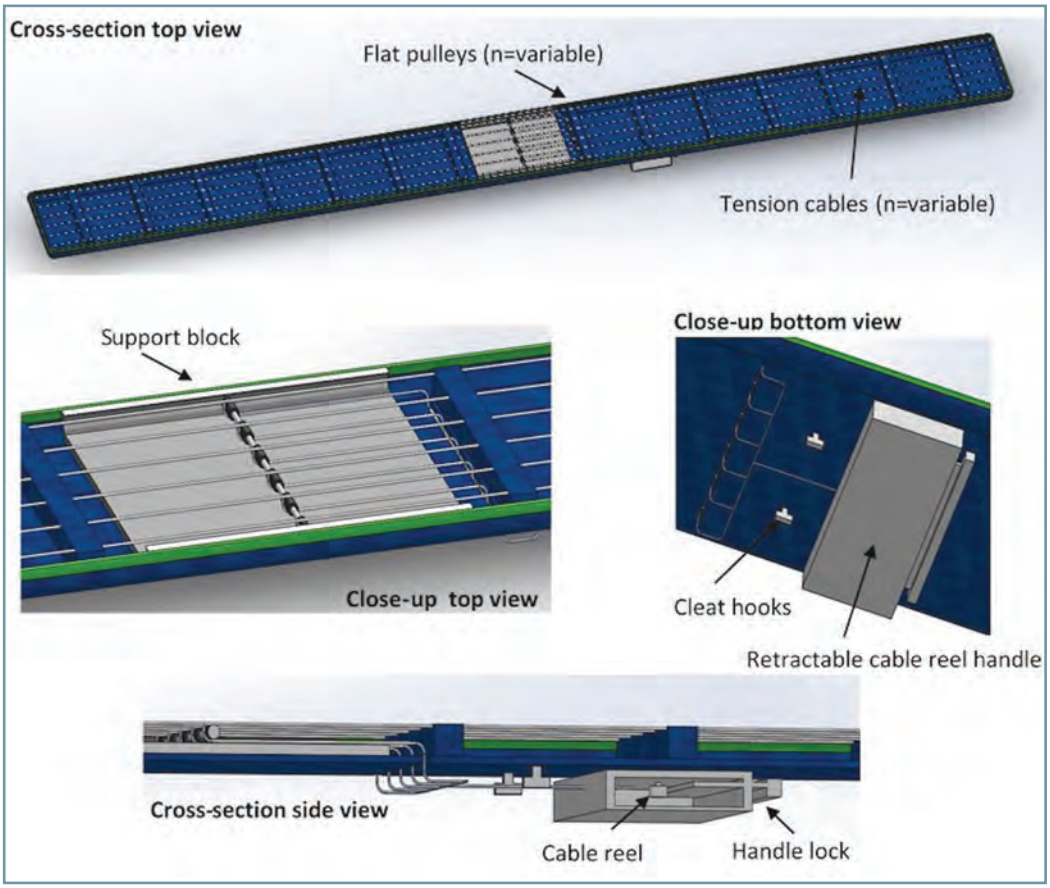


Figure 4. Graphical description of the device design using cross-sectional views to show interior details. The top-views show the flat pulleys, tension cables, and support block. The bottom view shows the cleat hooks and retractable cable reel handle. The side view shows a cross section of the cable handle detailing the handle lock mechanism.

produce a bending motion at each joint. This simple, mechanical system allows for high-strength pinch and grip actions. We used this same mechanical system to meet the user requirements one through eight, outlined above.

The top-view in Figure 4 shows the fully extended device with a cross-sectional display showing the interior of the technology. Tension cables extend along the length of the PRESS system, stabilized by flat pulleys spaced evenly along the length of the system, anchored at each end. The number and spacing of the tension cables and flat pulleys are variable based on the size and expected compression strength of the system. The cables converge at the center and flow through a support block as seen in the close-up top view. All cables exit the lower end of the device and merge into a single cable system as shown in the close-up bottom view. The merged cables proceed into the retractable cable reel of the handle as shown in the cross-section side view (Figure 4). The cleat hooks serve to temporarily support the cable when the device is deployed. The handle lock provides the ability to tension the cable when deploying the device and allows for retracting the excess cable when released.

The fabric surface of the PRESS is a multi-ply device made from flexible, biocompatible materials. The internal surface of the PRESS (adjacent to the body) includes a soft, comfortable, breathable liner with optional extended ribs adapted to reduce the potential for developing pressure ulcers. This surface transitions from a breathable liner to the female side of a hook-and-loop system toward the ends of the device, longitudinally. The internal hook-and-loop surface is used for connection to an optional attachment that serves as a temporary anterior support made from the male side of a hook-and-loop system that can be used when deploying the device. The external surface of the PRESS is made from a hook-and-loop system (female), but transitions to the male side of a hook-and-loop system toward the ends, longitudinally. When the PRESS is deployed, the ends are folded down against the side to adjust for length; as such, the hook-and-loop system maintains the adjusted size.

The device is deployed using the following procedure (Figure 5). First, the PRESS is laid flat under the body; centered at the support block, in line with the greater trochanters. Second, the device is lifted around the body; ends are folded down to adjust for patient size. A temporary anterior support strap connecting the two ends of the anterior portions of the PRESS (using a hook-and-loop attachment) can be used to hold the device around the body during tensioning and would be removed when the device is deployed. Third, the retractable handle is locked and pulled until the device is completely secured around the body. Finally, the cable is wrapped around the cleat hooks to temporarily maintain the compression applied by the tensioned cable; the handle retracts and secures to the device.

CONCLUSION

The technology presented in this manuscript is recommended as an alternative to commercially available pelvic binders. We propose that the PRESS device would perform similarly to the commercially available options regarding maintenance of fracture stability and exsanguinating pelvic trauma. Furthermore, the device has the following additional features: 1) allows for complete access to the abdominal and groin regions; 2) can be designed with one or two handles allowing for single or two-person deployment; 3) requires limited training for use; 4) is made from radiolucent materials for radiograph and CT scans;

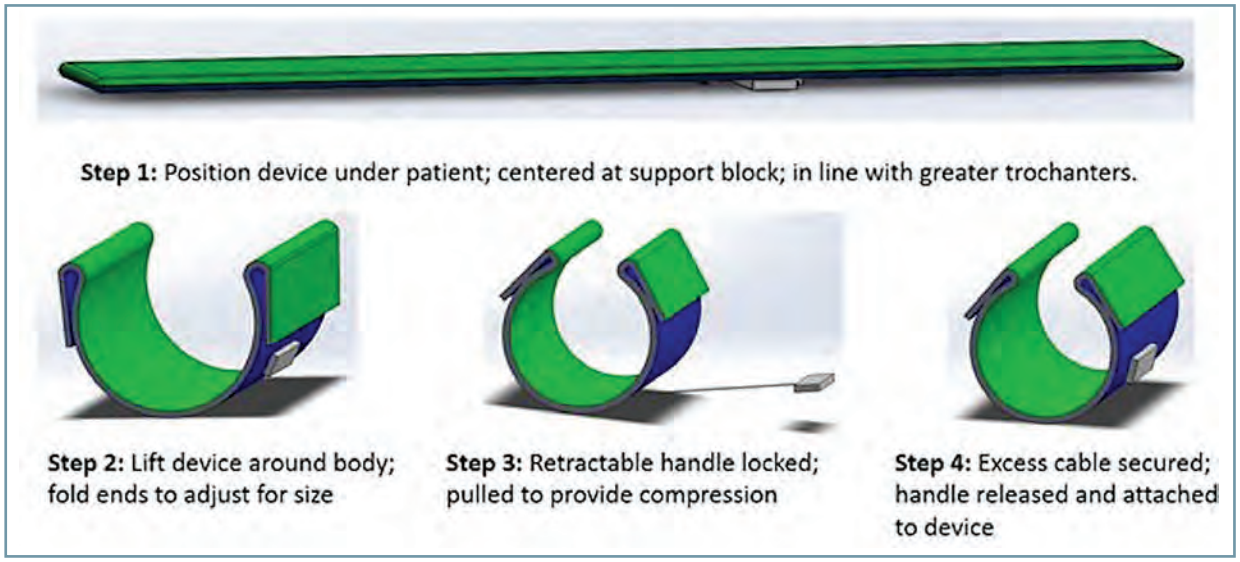


Figure 5. Detailed steps 1 through 4 for device deployment, indicating the ease of use and limited training needed. Notably, step 2 shows where the temporary anterior support strap may be used to hold the ends around the body while the device is being deployed (step 3). Once deployed, the support strap may be removed.

5) has a breathable, soft, load area, optimized to provide distributed coverage to the greater trochanters to limit pressure sores; and 6) is low cost and disposable. Future testing of the prototype will be used to quantitatively evaluate the features described above.

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