

Clinical Data Indicates Pelvic Stabilization Devices Improve Patient Outcomes

Pelvic fractures present a clinical treatment challenge in both the prehospital environment as well as in early stage treatment at most emergency departments. Pelvic fracture mortality is currently between 5% and 50%.

For more than 100 years bed sheets have been a commonly used technique in treating pelvic fractures (stabilization) because of their low cost and easy availability.

However, research has shown that bed sheets do not provide adequate stabilization or compression and are difficult to apply.

Recent studies have demonstrated the effectiveness of pelvic stabilization devices in stabilizing the pelvis, increasing critical mean arterial pressure, reducing the need for pain medications, reducing the need for blood products, reducing hospital stay, and improving mortality.

Given such data, it is critical for improved outcomes on pelvic fracture patients that pelvic stabilization devices be used as part of treatment protocols, and that bed sheets not be used.



For improved patient outcomes, clinical data suggests it is critical to use pelvic stablization devices - and stop using bed sheets.

Background:

Traditional and successful treatment of pelvic fractures has been based upon immobilization and stabilization. Immobilization and stabilization are effective in reducing pain, preventing additional damage to veins and arteries in the area of the fracture, preventing additional damage to nerves in the area of the fracture, and in preventing additional movement of the bones near the fracture site. Compared to stabilizing "long bone" fractures, stabilizing pelvic fractures at the site of injury remains a challenge.

Pelvic fractures result from significant forces to multiple bones in the pelvic region that may also lacerate large arteries and veins and cause significant damage to a number of very vascular organs. Hemorrhage, the leading cause of death in pelvic fractures, must be managed and controlled beginning in the pre-hospital environment.

Supporting Data and Research:

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Pelvic Binders and Arteriography: Effect of a Pelvic Fracture Management Protocol on Mortality: Malekzadeh, Steve, et al (1)

In this pelvic fracture clinical study, a protocol aimed at decreasing mortality was implemented that emphasized rapid pelvic stabilization using a pelvic binder and pelvic arteriography in selected cases.

The study demonstrated that:

- Before protocol implementation, 32 of 65 patients (49%) in shock on arrival or within the first 24 hours of hospital stay died, whereas 18 of 80 (23%) in shock died after protocol implementation, a 53% and statistically significant drop in mortality (p<0.001).
- Triggers for protocol activation were:
 - 1) Age greater than 54
 - 2) Hemodynamic shock (systolic blood pressure <100mm Hg) on arrival or within the first 24 hours of hospital stay
 - 3) Unstable fracture pattern (APC2, APC3, LC3, VS)

Emergent Fixation in Patients with Exsanguinating Pelvic Fractures: Croce, Martin A, et al (2)

This study evaluated 3,359 patients with blunt pelvic fractures over a 10-year period. 186 (6%) met entry criteria; 93 received EPF (external pelvic fixation) and 93 received POD (pelvic orthotic device). Inclusion required multiple pelvic fractures with vascular disruption and severe retroperitoneal hematoma, open book fracture with symphysis diastasis, or sacroiliac disruption with vertical shear. Study outcomes included transfusions, hospital stay, and mortality.

The study demonstrated that:

- Both 24-hour (4.9 versus 17.1 U, p<0.0001) and 48-hour transfusions (6.0 versus 18.6 U, p<0.0001) were reduced via the POD with statistical significance.
- Hospital length of stay (16.5 versus 24.4 days, p<0.03) was less with POD with statistical significance.
- There was decreased mortality with POD (26%) versus EPF (37%), but not statistically significant (p=0.11).

This study found that separation of the pubic bones (symphyseal diastasis) was reduced by 60% when using pelvic stabilization. More importantly for the pre-hospital provider, mean arterial pressure increased from 65.3 to 81.2 (about 25%), and heart rate beneficially declined from 107 bpm to 94 bpm. (1)



Studies indicate a statistically significant drop in mortality when pelvic stabilization devices are used.

Use of the Trauma Pelvic Orthotic Device (TPOD) for Provisional Stabilization of Anterior-Posterior Compression Type pelvic Injuries: A Cadaveric Study; DeAngelis, Nicola A, et al (3)

This study evaluated and compared a standard bed sheet (folded to a width of approximately 8 inches and wrapped circumferentially around the pelvis and greater trochanters) to pelvic stabilization by applying a T-POD (Pyng Medical – and also applied circumferentially around the pelvis and greater trochanters).

Results of the study indicated a stepwise decrease in survival in-hospital with each additional minute until the first administration of epinephrine:

- Results illustrated that, while both a circumferential sheet and the T-POD were
 consistently able to decrease the symphyseal diastasis, only the T-POD showed a
 statistically significant improvement in the diastasis when compared with injury
 measurements.
- In 75% of the cadaveric specimens (9 of 12), the T-POD was able to return the symphysis to normal (<10 mm of diastasis). On average, bed sheets were able to reduce the separation by about 44% while T-POD reduced separation by over 70%.

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Effect of a new pelvic stabilizer (T-POD) on reduction of pelvic volume and haemodynamic stability in unstable pelvic fractures; Tan, Edward, et al (4)

In this study, 15 patients with unstable pelvic fractures presented to the emergency department with signs of hypovolemic shock. Vital signs were measured just before the application of a pelvic stabilization device (T-POD), and two minutes after application. X-Rays were also taken after POD application.



Fig. 1. X-ray of the pelvis before applying the T-POD.



Fig. 2. X-ray of the pelvis after applying the T-POD (same patient) combined with retrograde urethrography/cystography (no leakage).

Reference for Graph: Tan ECTH, et al. Effect of a new pelvic stabilizer (T-POD1) on reduction of pelvic volume? and haemodynamic stability in unstable pelvic fractures. Injury (2010), doi:10.1016/j.injury.2010.03.013

"Although both a circumferential sheet and the T-POD were consistently able to decrease the symphyseal diastasis, only the T-POD showed a statistically significant improvement in the diastasis when compared with injury measurements. In 75% of the cadaveric specimens (9 of 12), the T-POD was able to return the symphysis to normal (<10 mm of diastasis)." (3)

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Conclusions:

- Statistically significant improvement in diastasis was seen when using a POD device (T-POD) compared to the utilization of bed sheets, for pelvic fractures, when compared with injury measurements.
- Critical improvement in mean arterial pressure and heart rate was seen when using a POD device on pelvic fracture patients.
- A statistically significant improvement in patient mortality was seen utilizing a protocol that emphasized rapid pelvic stabilization for pelvic fractures.
- A statistically significant improvement in transfusion requirement and hospital length-of-stay was seen when using a POD device over external pelvic fixation for blunt pelvic fractures.

The data is overwhelming that the utilization of POD devices improves pelvic fracture patient outcomes and that POD devices are superior to Sheets and/or EPF in critical areas such as closure of diastasis, transfusion rates, and length of hospital stay.



Studies indicate that using a pelvic stabilation device reduces hospital stay times.

References:

- 1. Pelvic Binders and Arteriography: Effect of a Pelvic Fracture Management Protocol on Mortality; Malekzadeh, Steve, et al, Departments of Orthopaedic and General Surgery and Radiology, UT Southern Medical Center, Dallas, Texas. Paper presented at the 73rd Annual Meeting of the American Academy of Orthopedic Surgeons, Chicago, IL 22 MAR 2006.
- 2. Emergent Fixation in Patients with Exsanguinating Pelvic Fractures; Croce, Martin A, et al, Journal of the American College of Surgeons, 2007, 204:5; pp. 935-939. Access or purchase the full article at: http://www.sciencedirect.com/science/article/pii/S1072751507001408
- 3. Use of the Trauma Pelvic Orthotic Device (TPOD) for Provisional Stabilization of Anterior-Posterior Compression Type pelvic Injuries: A Cadaveric Study; DeAngelis, Nicola A, et al, University of Massachusetts Medical School, Worcester, Massachusetts. Injury. 2008 Aug; 39(8):903-6. Access or purchase the full article at: http://www.sciencedirect.com/science/article/pii/S0020138307005025
- 4. Effect of a new pelvic stabilizer (T-POD) on reduction of pelvic volume and hae-modynamic stability in unstable pelvic fractures; Tan, Edward, et al, Department of Surgery Division of Trauma Surgery, Radboud University Nijmegen Medical Centre, Nijmegen, The Netherlands, Injury. 2010 Dec; 41(12): 1239-43. Access or purchase the full article at: http://www.ncbi.nlm.nih.gov/pubmed/21374905



A study comparing the use of a bed sheet and a T-POD pelvic stabilization device indicated that T-POD improved patient outcomes. (3)

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The clinical studies and data referenced in this paper were summarized by Dr. Alan Moloff. With more than 30 years of operational military medical experience, Dr. Moloff is Board Certified in aerospace, undersea and disaster medicine. Col. Moloff's final assignment encompassed four years as Commander of the Defense Medical Readiness Training Institute (DMRTI) where he focused on joint medical readiness, combat casualty care and the medical aspects of Homeland Security planning and training focused on CBRNE and complex disasters.

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