

# SAM Pelvic Sling™ II

## SAM Pelvic Sling II Press Kit

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### **Product Overview**

SAM Pelvic Sling II Fact Sheet  
Product Overview Brochure

### **Studies**

Emergent Stabilization of Pelvic Ring Injuries by Controlled Circumferential Compression

### **About SAM Medical**

### **Recent Press Releases**

Press Release – August 18, 2009 (SAM Medical Products Named to Inc. 5000)

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# SAM Pelvic Sling™ II

For stabilization of pelvic fractures with the correct force

Trauma surgeons around the world agree on the importance of stabilizing pelvic fractures during the critical first “golden hour” following severe trauma. The SAM Pelvic Sling™ II is the first and only force-controlled circumferential pelvic belt scientifically proven in peer-reviewed studies to safely and effectively reduce and stabilize open-book pelvic ring fractures. Because of the potentially devastating hemorrhage associated with such fractures, standard first aid protocol has included applying some type of circumferential binder around the victim’s hips.



## FEATURES AND BENEFITS

- Scientifically and clinically proven to provide safe and effective force to stabilize pelvic fractures
- Buckle maintains correct force—cannot be over-tightened
- Standard size fits 98% of population
- “Click” provides clear feedback to confirm correct application
- Pulling gradually and symmetrically increases sling tension and reduces the pelvis
- Low friction posterior slider facilitates transfers
- Front of Sling is narrow and tapered to facilitate urinary catheterization, interventional radiology, external fixation and abdominal surgery
- Fabric does not stretch and cleans for reuse with standard detergents or antimicrobial solutions
- Radiolucent (allowing for X-rays without removal)
- Ease of application: just insert belt through buckle, pull strap, and secure
- Velcro on strap and sling for quick and easy fastening
- Reusable, not a onetime use device
- Every sling is tested for quality

## TECHNICAL DATA

- Extra Small: Hip Circumference: 27”-47”; 9oz
- Standard: Hip Circumference: 32”-50”; 9oz
- Extra Large: Hip Circumference: 36”-60”; 9oz
- Military: Hip Circumference: 32”-50”; 9oz

## ORDERING INFO

Part Number	Description	Case Size
SL556652-SM	SAM Pelvic Sling™ II Extra Small	18/case
SL556652	SAM Pelvic Sling™ II Standard	18/case
SL556652-LG	SAM Pelvic Sling™ II Extra Large	18/case
SL556652M	SAM Pelvic Sling™ II Military - Olive	18/case

## PUBLICATIONS

**Emergent Stabilization of Pelvic Ring Injuries by Controlled Circumferential Compression: A Clinical Trial;** James C. Krieg, MD, Marcus Mohr, MS, Thomas J. Ellis, MD, Tamara S. Simpson, MD, Steven M. Madey, MD, and Michael Bottlang, PhD; Journal of Trauma; 59:659-664, 2005.

**A New Technology - What’s New in Orthopedic Trauma;** Cole, P.A. Specialty Update; Journal of Bone and Joint Surgery; 85-A, 11: 2260-2269, 2003.

**Non-Invasive Reduction of Open-Book Pelvic Fractures by Circumferential Compression;** Bottlang, M., Simpson, T., Sigg, J., Krieg, J.C., Madey, S.M., Long, W.B.; Journal of Orthopedic Trauma; 16:6, 367-73, 2002.

**Stabilization of Pelvic Ring Disruptions with a Circumferential Sheet;** Simpson, T., Krieg, J. C., Heuer, F., Bottlang, M.; Journal of Trauma; 52:158-61, 2002.

**Emergent Management of Pelvic Ring Fractures with Use of Circumferential Compression;** Bottlang, M., Krieg, J. C., Mohr, M., Simpson, T. S., Madey, S.M.; Journal of Bone and Joint Surgery; 84-A (Supplement 2): 43-47, 2002.

## VIDEO RESOURCES

- View instructions for using the SAM Pelvic Sling II at: [www.sammedical.com](http://www.sammedical.com)
- Video also available on youtube.com

NSN # 6516-01-509-6866

ISO 13485:2003



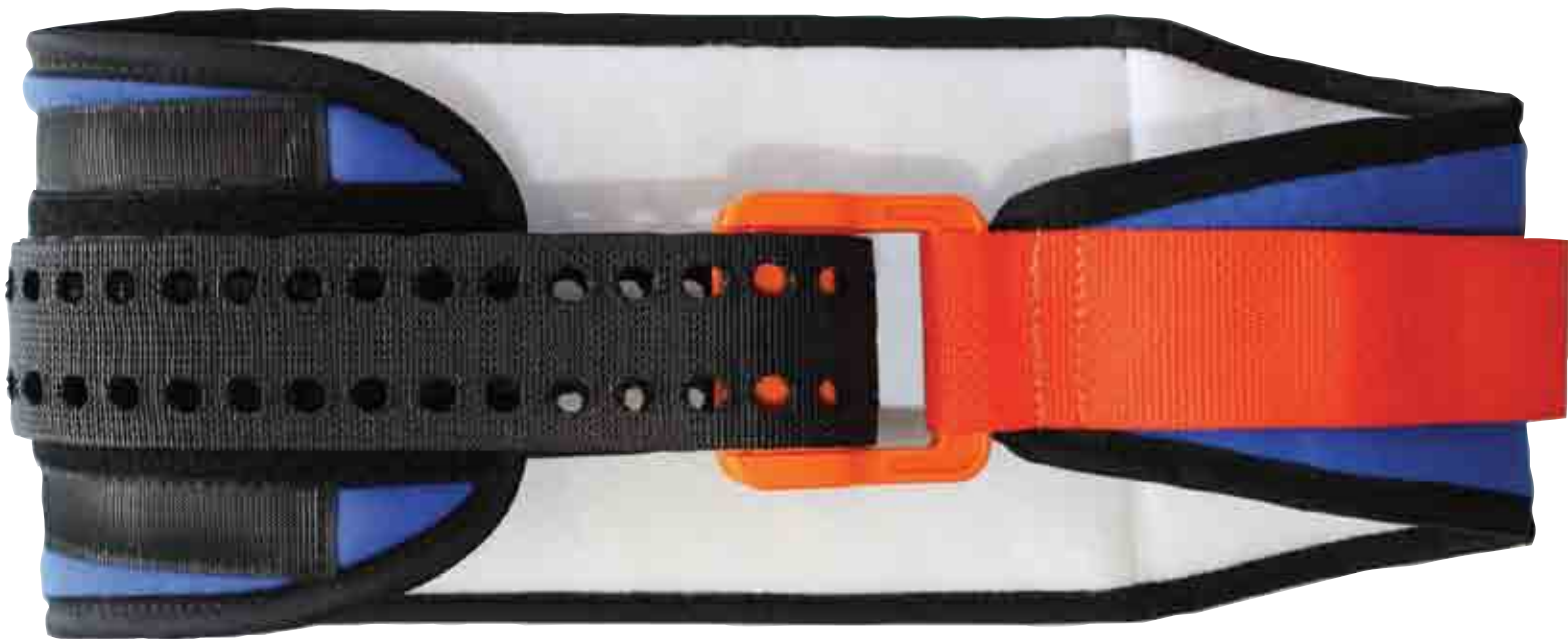
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# SAM Pelvic Sling™ II

FOR STABILIZATION OF PELVIC FRACTURES  
WITH THE  
CORRECT FORCE

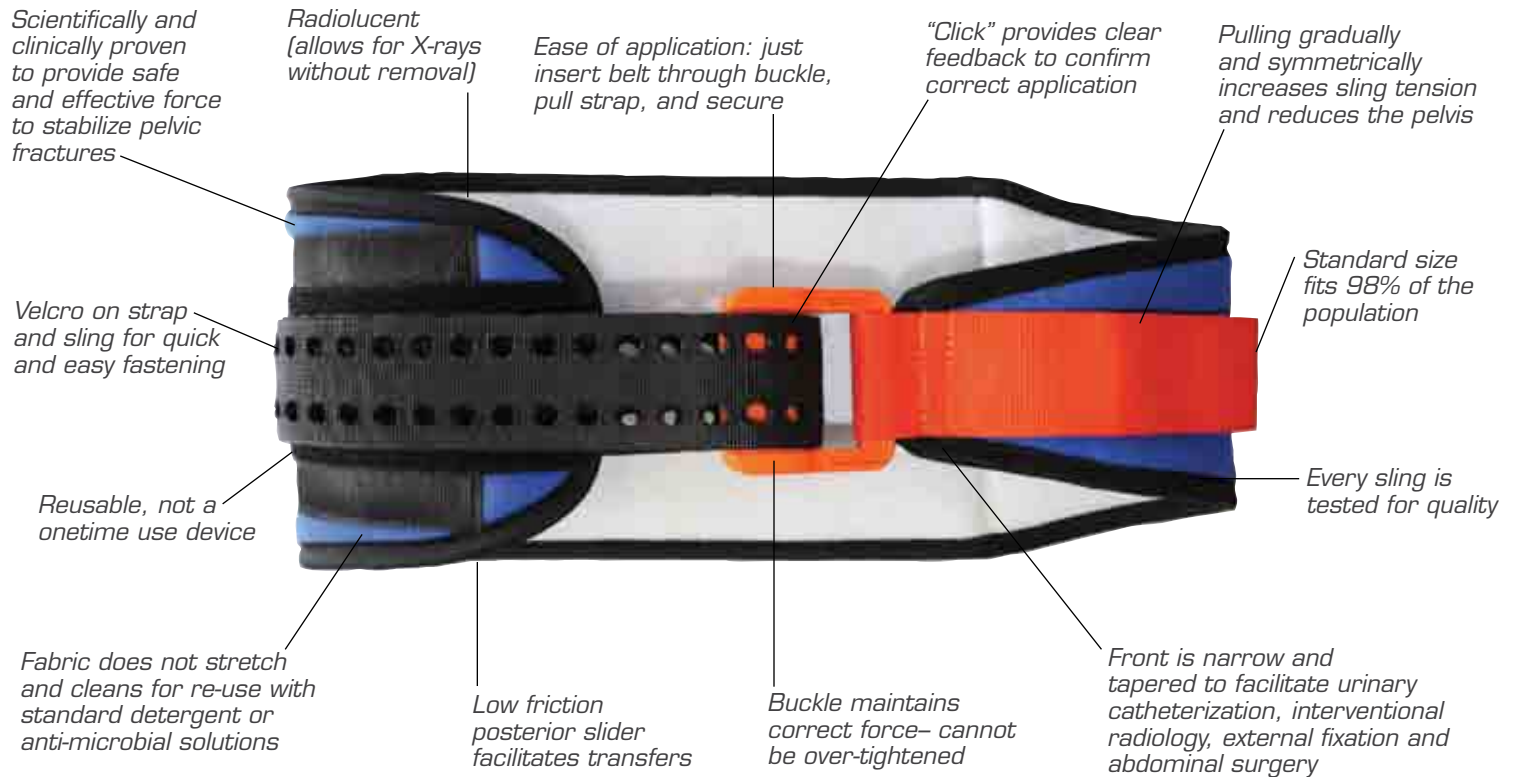
IMPROVED  
ONE PIECE DESIGN  
APPLIES IN  
3 EASY STEPS



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# What Makes The SAM Pelvic Sling II Unique



## Newly Improved Design

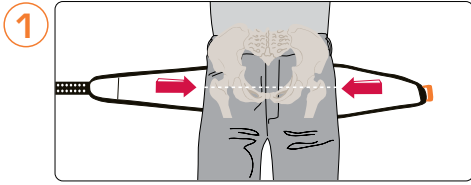
The SAM Pelvic Sling II improves upon our groundbreaking original pelvic sling. It is still the only force-controlled circumferential pelvic belt scientifically proven in peer-reviewed studies to safely and effectively reduce and stabilize open-book pelvic ring fractures.

The SAM Pelvic Sling II is an improved, simpler design with no detachable hardware. It is more compact, easy to use (only three steps), quick to apply (usually in less than one minute), and is sized to fit (without cutting or trimming) 98% of the adult population. It does not require a fine touch to operate and gives clear feedback by sound and feel to confirm correct application.

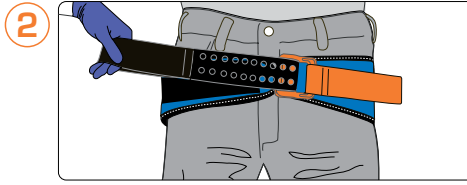
The sling is durable i.e. not affected by extremes of moisture, temperature, or by exposure to hard or sharp objects. It is also radiolucent, MRI safe, and cleans for re-use with common detergents or anti-microbial solutions.



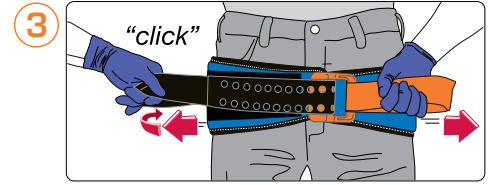
# Easy As 1, 2, 3



1 Remove objects from patient's pocket or pelvic area. Place SAM Pelvic Sling II gray side up beneath patient at level of trochanters (hips).



2 Place BLACK STRAP through buckle and pull completely through.



3 Hold ORANGE STRAP and pull BLACK STRAP in opposite direction until you hear and feel the buckle click. Maintain tension and immediately press BLACK STRAP onto surface of SAM Pelvic Sling II to secure.

## Limits Compression To An Effective Force

The SAM Pelvic Sling II was designed not to over-tighten or under-tighten, unlike other commercial binders which allow unlimited force to be applied to the patient. Researchers at Legacy Health System utilized cadaver studies and clinical trials to determine the optimum range of force required to safely and effectively close an unstable pelvic fracture.

The SAM Pelvic Sling II's patented Autostop buckle will not allow a compression force greater than 33lbs. This is vital in high stress environments where over-tightening by emergency medical personnel under duress could potentially be extreme and harmful.

Trauma surgeons around the world recognize the importance of stabilizing pelvic fractures during the critical first "golden hour" following severe trauma. Because of the potentially devastating hemorrhage associated with such fractures, standard first aid protocol includes applying some type of circumferential binder around the victim's hips.

## Research Studies

**Pelvic Circumferential Compression in the Presence of Soft-Tissue Injuries: A Case Report.** Krieg JC, Mohr M, Mirza AJ, Bottlang M. *The Journal of TRAUMA Injury, Infection, and Critical Care.* 59, pp 470-472, 2005.

**Emergent Stabilization of Pelvic Ring Injuries by Controlled Circumferential Compression: A Clinical Trial.** Krieg JC, Mohr M, Ellis TJ, Simpson TS, Madey SM, Bottlang M. *Journal of Trauma,* 59, pp 659-664, 2005.

**The Pelvic Fracture; Stabilization in the field.** Bottlang M, Kreig JC. *EMS Magazine.* September, pp 126-129, 2003.

**Non-Invasive Reduction of Open-Book Pelvic Fractures by Circumferential Compression.** Bottlang M, Simpson T, Sigg J, Krieg JC, Madey SM, Long WB. *Journal of Orthopedic Trauma.* 16:6, pp 367-73, 2002.

**Stabilization of Pelvic Ring Disruptions with a Circumferential Sheet.** Simpson T, Krieg JC, Heuer F, Bottlang M. *Journal of Trauma.* 52, pp 158-61, 2002.

**Emergent Management of Pelvic Ring Fractures with Use of Circumferential Compression;** Bottlang M, Krieg JC, Mohr M, Simpson TS, Madey SM. *Journal of Bone and Joint Surgery.* 84-A (Supplement 2), pp 43-47, 2002.

### We Removed The Guesswork



Our patented Autostop buckle provides the correct compression every time, taking the guesswork out of tightening. The buckle is programmed to stop your pull once the correct compression force has been obtained. Two prongs are released from the buckle which stops the belt from further tightening.

# FAQ

## Why does controlling circumferential force matter in the treatment of pelvic fractures?

At the time of initial evaluation, the exact type of fracture is usually unknown. In some cases, too little force will not close or stabilize the fracture; in others, too much force can collapse the pelvic ring. The SAM Pelvic Sling II stands alone as the only pelvic binder pre-programmed to apply the safe and correct force for all pelvic fractures.

## What is the difference between the SAM Pelvic Sling II and other devices used in emergent care?

The SAM Pelvic Sling II is designed so it cannot be over-tightened. It is the only pelvic binder that will not allow a compression force greater than required to safely and effectively stabilize pelvic ring fractures. It provides the correct force each time, every time. This is documented in five peer review journals and has been the subject of fifteen national and international plenary session presentations.

## Can the SAM Pelvic Sling II be used on a suspected pelvic fracture, even if it is not an open-book fracture?

There are no reported contraindications to using the SAM Pelvic Sling II on any suspected pelvic fracture or injury. The compression forces are distributed broadly across the Sling belt and are unlikely to exacerbate fractures or injury. Peer-review studies have shown no contraindication to applying the SAM Pelvic Sling II on lateral compression fractures.

## Can the SAM Pelvic Sling II be placed on a patient in the car before extraction?

It is not recommended to apply the SAM Pelvic Sling II before extraction from a vehicle.

## How do I clean the SAM Pelvic Sling II?

Do not clean the Sling using steam autoclave. You can use a broad spectrum disinfectant such as Virkon. You may contact an EMS or hospital provider for more details about Virkon.

## Can the SAM Pelvic Sling II be used on children?

We do not recommend using the SAM Pelvic Sling II on children. To date no studies have been conducted on children.

## How does the SAM Pelvic Sling II affect skin's surface?

Interface pressures have been measured under the SAM Pelvic Sling II and these pressures are usually very low (less than 25 mmHg). If the SAM Pelvic Sling II is to be applied for extended periods, the skin should be inspected at regular intervals. Be especially observant when massive fluid resuscitation is required. Under these conditions, the SAM Pelvic Sling II may have to be periodically released to accommodate increased pelvic volume. Be aware the SAM Pelvic Sling II should be released very slowly.

## PRODUCT INFORMATION

Part Number	Description
SL556652-SM	SAM Pelvic Sling™ II Extra Small - Hip Circumference: 27-47" (69-119cm)
SL556652	SAM Pelvic Sling™ II Standard - Hip Circumference: 32-50" (81-127cm)
SL556652-LG	SAM Pelvic Sling™ II Extra Large - Hip Circumference: 36-60" (91-152cm)
SL556652M	SAM Pelvic Sling™ II Military - Olive - Hip Circumference: 32-50" (81-127cm)

## ABOUT SAM MEDICAL PRODUCTS



SAM Medical Products® is a developer and manufacturer of innovative medical products used for emergency, military, and hospital care. Our products include the widely used SAM Splint, SAM Pelvic Sling II, Soft Shell Splint, CELOX line of hemostatic agents, BursaMed line of shear and friction relieving dressings, and Blist-O-Ban blister prevention bandages. For more than 25 years, SAM Medical Products® has represented innovation and quality to the medical professional. More information about SAM Medical Products® can be found on the company's website at: [www.sammedical.com](http://www.sammedical.com).

# Emergent Stabilization of Pelvic Ring Injuries by Controlled Circumferential Compression: A Clinical Trial

James C. Krieg, MD, Marcus Mohr, MS, Thomas J. Ellis, MD, Tamara S. Simpson, MD, Steven M. Madey, MD, and Michael Bottlang, PhD

**Background:** Pelvic ring injuries are associated with a high incidence of mortality mainly due to retroperitoneal hemorrhage. Early stabilization is an integral part of hemorrhage control. Temporary stabilization can be provided by a pelvic sheet, sling, or an inflatable garment. However, these devices lack control of the applied circumferential compression. We evaluated a pelvic circumferential compression device (PCCD), which allows for force-controlled circumferential compression. In a prospective clinical trial, we documented how this device can provide effective reduction of open-book type pelvic injuries without causing overcompression of lateral compression type injuries.

**Methods:** Sixteen patients with pelvic ring injuries were enrolled. Pelvic fractures were temporarily stabilized with a PCCD until definitive stabilization was provided. Anteroposterior pelvic radiographs were obtained before and after PCCD application, and after definitive stabilization. These radiographs were analyzed to quantify pelvic reduction due to the PCCD in comparison to the quality of reduction after definitive stabilization. Results were stratified into external rotation and internal rotation fracture patterns.

**Results:** In the external rotation group, the PCCD significantly reduced the pelvic width by  $9.9 \pm 6.0\%$ . This re-

duction closely approximated the  $10.0 \pm 4.1\%$  reduction in pelvic width achieved by definitive stabilization. In the internal rotation group, the PCCD did not cause significant overcompression. No complications were observed.

**Conclusions:** A PCCD can effectively reduce pelvic ring injuries. It poses a minimal risk for overcompression and complications as compared with reduction alternatives that do not provide a feedback on the applied reduction force.

**Key Words:** Pelvic injury, Open-book fracture, Stabilization, Circumferential compression

*J Trauma.* 2005;59:659–664.

Pelvic ring injuries are associated with a high incidence of mortality<sup>1</sup> and remain a common cause of death in motor vehicle accidents.<sup>2</sup> Hemorrhage is the leading cause of death in patients with pelvic ring injuries.<sup>3–5</sup> Blood loss occurs mainly from injury to the sacral venous plexus, from fracture surfaces, from the surrounding soft tissue, and from arterial sources in the pelvis.<sup>1,3,5–7</sup> Early reduction and stabilization of pelvic ring injuries are believed to be an integral part of effective strategies to reduce hemorrhage.<sup>8–13</sup> Stabilization should be provided as soon after injury as possible and should ideally be applied before patient transport.<sup>14,15</sup> Early stabilization seeks to control potentially exsanguinating hemorrhage on multiple levels. It minimizes motion at the fracture sites to promote formation of a stable hematoma. It dimin-

ishes the potential pelvic volume, which may in turn tamponade venous bleeding, and it can contribute to patient comfort and pain relief to facilitate patient transport.<sup>11,16,17</sup>

Various noninvasive techniques and devices are available to provide emergent stabilization of pelvic ring injuries. These include vacuum beanbags,<sup>18</sup> inflatable pneumatic antishock garments (PASGs),<sup>19–21</sup> and circumferential pelvic wrapping with a sheet<sup>22,23</sup> or belt.<sup>24</sup> Most recently, a pelvic circumferential compression device (PCCD) has been developed, which provides circumferential pelvic stabilization similar to a sheet.<sup>14</sup> However, unlike a sheet, this PCCD controls the applied reduction force to an effective level that has previously been determined in a series of biomechanical studies.<sup>14,25</sup> Therefore, the PCCD allows for the first time to apply and maintain controlled and consistent stabilization, while accounting for the risk of over-reduction in case of internal rotation injuries of the pelvic ring.

This study documented employment of the PCCD to reduce and stabilize pelvic ring injuries in a prospective clinical trial at two Level I trauma centers. This well-controlled environment allowed assessment of the ability of the PCCD to safely and effectively stabilize a spectrum of pelvic ring injuries.

## MATERIALS AND METHODS

### Enrollment

Over a 16-month period, adult patients (>16 years) with partially stable and unstable pelvic ring injuries (OTA 61-B

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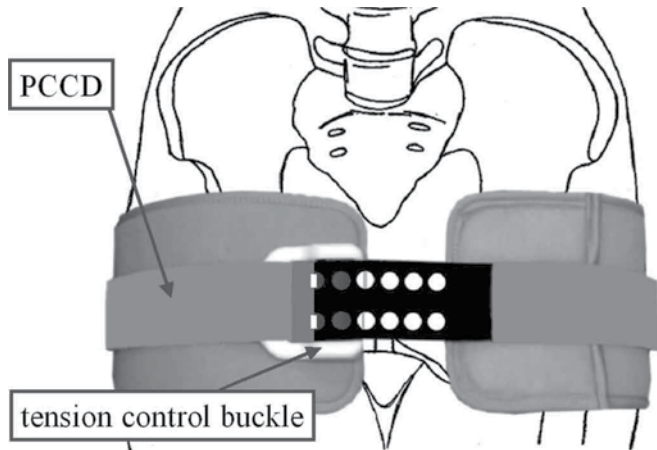


Fig. 1. PCCD with tension control buckle, applied at the level of the greater trochanters.

and 61-C) admitted to two Level I trauma centers were entered into a prospective clinical trial. Pelvic inlet and outlet views were routinely obtained on all patients with pelvic ring injuries as identified on the screening AP pelvis film and, in combination with computed tomographic (CT) images, were used for definitive fracture classification. The trial protocol was approved by the internal review boards of both institutions, and enrollment was contingent on written consent of the patient or a legal representative. Exclusion criteria were pregnancy, burns, evisceration, and the presence of impaled objects in the abdominal region.

### Intervention

Upon arrival at the emergency room, a plain anteroposterior pelvic radiograph was obtained to assess the fracture pattern. The PCCD was applied around the patient's pelvis at the level of the greater trochanters to temporarily reduce and stabilize the fractured pelvic ring (Fig. 1). The PCCD consisted of a 15-cm wide belt that is soft but does not stretch. Anteriorly, both ends of the device were guided through a buckle. Pulling on both ends in opposite directions gradually and symmetrically increased the PCCD tension and provided equally distributed compression to the soft tissue envelope surrounding the pelvis, which in turn stabilized the pelvic ring. The buckle provided a mechanism that limited the PCCD tension force to 140 N. This force approaches a tension level that has previously been determined in a series of laboratory studies on human cadaveric specimens to effectively reduce open-book type pelvic fractures without causing significant internal rotation of lateral compression type fractures.<sup>25</sup>

Unless treatment or diagnostic procedures required temporary release of the PCCD, it remained applied until definitive stabilization could be achieved by means of an anterior external fixator and/or by open reduction and internal fixation. In case of delayed definitive fixation, skin conditions

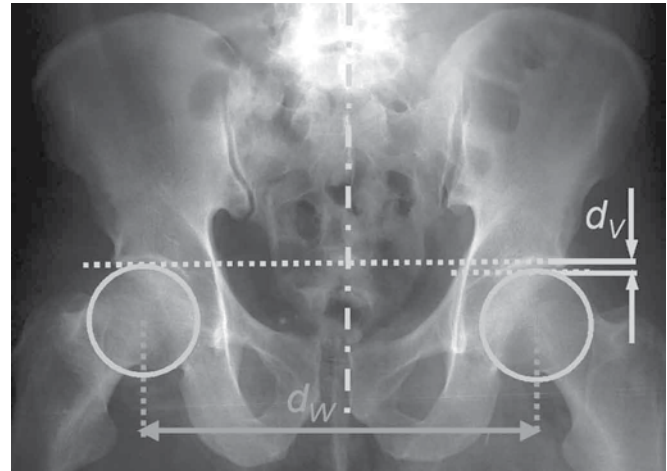


Fig. 2. Measurement of pelvic displacement:  $d_w$  = pelvic width in terms of distance between femoral heads;  $d_v$  = vertical displacement.

were carefully monitored to prevent pressure-induced skin breakdown.

### Outcome Parameters

In addition to the initial anteroposterior pelvic radiograph, a second anteroposterior pelvic radiograph was taken immediately after the PCCD was applied. A third anteroposterior radiograph was obtained after definitive stabilization. On each radiograph, the pelvic width was measured as the distance  $d_w$  between the femoral head centers (Fig. 2). Changes in  $d_w$  allowed for assessment of coronal plane reduction provided by the PCCD in comparison to the initial displacement of the pelvic ring. In addition, vertical displacement  $d_v$  of the pelvic ring was assessed by the difference in distance of the femoral heads to a line perpendicular to the mid-sagittal plane of the sacrum. All measurements were obtained on digitized radiographs and aided by quantitative image analysis software and a custom circle-fitting algorithm to objectively identify femoral head centers. Both variables,  $d_w$  and  $d_v$ , were statistically analyzed to determine whether the PCCD significantly reduced the unstable pelvic ring, and whether this reduction was significantly different from the reduction after definitive treatment. Significant differences were detected at an  $\alpha = 0.05$  level of significance using a paired one-sample Student's *t* test.

In addition to  $d_w$  and  $d_v$ , the time between injury and PCCD application, the time required to apply the PCCD, and the duration the PCCD remained on the patient were recorded. The patient population was characterized by age, sex, weight, height, injury mechanism, OTA fracture classification, length of hospital stay (LOS), length of intensive care unit stay (ICULOS), Injury Severity Score (ISS), Glasgow Coma Score (GCS), blood pressure, blood requirements, and pre-hospital treatment. Due to the complexity of blood requirements in polytraumatized patients, no attempt was made



to quantify the effect of PCCD application on hemodynamic parameters.

**RESULTS**

In a 16-month period beginning in September 2001, 16 patients were enrolled. Three patients were excluded from the outcome analysis due to incomplete radiographic data sets. Age, gender, weight, and mechanism of injury of the remaining 13 patients are listed in Table 1. Their average ISS was 24.7, range 10 to 57. Average blood requirements over the first 2 days were 3208 mL (red blood cells) and 4420 mL (total blood products). On average, the lowest systolic blood pressure of each patient during the initial 5 hours postinjury was 86 mm Hg, representing a hypotensive patient population.

Seven patients had partially stable pelvic ring fractures (OTA 61-B), and six patients had unstable fractures (61-C). Eight fractures were displaced in open-book type external rotation (61-B1, C1, C2.3b1), and five fractures were internally rotated (61-B2, B3.2, B3.3). Six patients arrived at the hospital with a sheet wrapped around the pelvis, two patients were stabilized in military anti shock trousers (MAST), and the remaining patients were transferred from the accident scene without any pelvic stabilization.

The PCCD was applied at the hospital on average 4.3 hours after injury, range 1 to 10 hours. Applying the PCCD required on average 4.5 minutes, range 2 to 10 minutes. The PCCD remained applied for an average of 59 hours, range 2 to 192 hours, after which definitive stabilization was provided.

Results describing the reduction of the pelvic ring in terms of  $d_w$  and  $d_v$  were stratified into open-book type external rotation fractures (ER group: patients 1, 3, 5, 6, 7, 9, 11, and 12) and internally rotated fractures (IR group: patients 2, 4, 8, 10, 13).

PCCD application in the ER group significantly reduced the pelvic width  $d_w$  by  $9.9 \pm 6.0\%$ , range 1.2 – 20.7% ( $p = 0.003$ ) (Fig. 3). Definitive stabilization delivered a comparable reduction ( $10.0 \pm 4.1\%$  decrease in  $d_w$ ,  $p = 0.001$ ) to that temporarily achieved with the PCCD. PCCD application to ER fractures significantly reduced vertical displacement from  $d_v = 12.5 \pm 10.0$  mm to  $d_v = 7.4 \pm 7.6$  mm ( $p = 0.007$ ) (Fig. 4). Definitive stabilization further decreased  $d_v$  to  $3.8 \pm 4.0$  mm.

PCCD application in the IR group decreased  $d_w$  by  $5.3 \pm 4.9\%$ , range 0.6 – 12.8% ( $p = 0.07$ ) (Fig. 5). Definitive treatment resulted in a decrease of  $d_w$  by  $1.9 \pm 7.2\%$ . Vertical displacement  $d_v$  in the IR group ( $6.1 \pm 6.1$  mm) was on average over 50% less than in the ER group, and was not significantly affected by PCCD application ( $d_v = 3.5 \pm 4.2$  mm,  $p = 0.45$ ) or by definitive stabilization ( $d_v = 6.6 \pm 2.6$  mm,  $p = 0.79$ ).

The efficacy with which the PCCD reduced open-book type fractures is illustrated by exemplary radiographs of patient 12, demonstrating a 15.2% decrease in  $d_w$  (Fig. 6).

**Table 1 Characterization of enrolled patient population**

Pat.	Age (yrs)	Sex	Weight (kg)	Height (cm)	Mechanism of Injury	OTA Class	LOS (days)	ICULOS (days)	ISS	GCS	Red Cells (mL)	Blood Prod. (mL)	Earliest Blood Pressure (mmHg)	Min. Blood Pressure (mmHg)	Initial Care	Time to PCCD (h)	PCCD Time (min)	Total PCCD Time (h)
1	42	M	80	178	Crushed by object	C2.3	16	4	19	15	300	1100	122	108	Sheet	6.5	5	72
2	39	M	77	175	Pedestrian vs. car	B3.3	16	4	19	15	1200	1330	85	85	MAST	4.5	2	2
3	67	M	104	180	Fall from height	C1.3	22	3	41	15	3000	3400	61	61	Sheet	10	7	33
4	66	F	93	173	Car accident	B2.2	14	5	34	15	1100	1650	116	84	MAST	9	4	40
5	51	M	85	178	Industrial	C1.2	29	9	14	15	2100	2100	86	86	None	4	5	53
6	47	M	102	180	Fall from height	B1.1	8	2	17	15	700	700	124	90	Sheet	3	3	68
7	34	M	90	175	Pedestrian vs. train	C1.2	23	12	17	15	5400	6825	82	72	Sheet	4	7	192
8	17	M	79	178	Car accident	B3.2	89	35	57	8	15300	25465	102	70	None	1.5	3	32
9	54	M	94	178	Motorcycle vs. car	C1.2	39	12	24	11	2400	3843	92	74	None	1	5	78
10	46	F	71	165	Pedestrian vs. car	B2.1	13	4	34	15	1200	1253	102	83	None	2	3	60
11	38	F	90	175	Fall from height	C2.3	61	20	22	15	9000	9800	100	100	None	1	2	57
12	41	F	80	173	Crushed by object	B1.2	8	1	13	15	0	0	120	92	Sheet	4.5	10	11
13	17	M	73	183	Crushed by object	B2.1	12	0	10	15	0	0	140	112	Sheet	4.5	3	64
AVG	43	n/a	86	176	n/a	n/a	27	9	25	14	3208	4420	102	86	n/a	4.3	5	59
SD	15	n/a	10	4	n/a	n/a	24	10	13	2	4419	6926	22	15	n/a	2.8	2	46

LOS, length of hospital stay; ICULOS, length of intensive care unit stay; ISS, Injury Severity Score; GCS, Glasgow Coma Score; MAST, Military anti-shock trousers, n/a, not applicable.

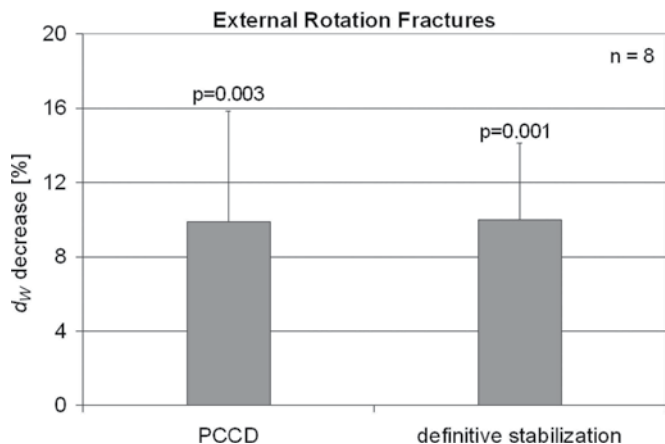


Fig. 3. ER group: average decrease in pelvic width  $d_W$  due to PCCD application and after definitive stabilization, with respect to initial pelvic width.

Over-reduction by PCCD application to internal rotation fractures is illustrated on radiographs of patient 4, demonstrating a 6.9% decrease in  $d_W$ .

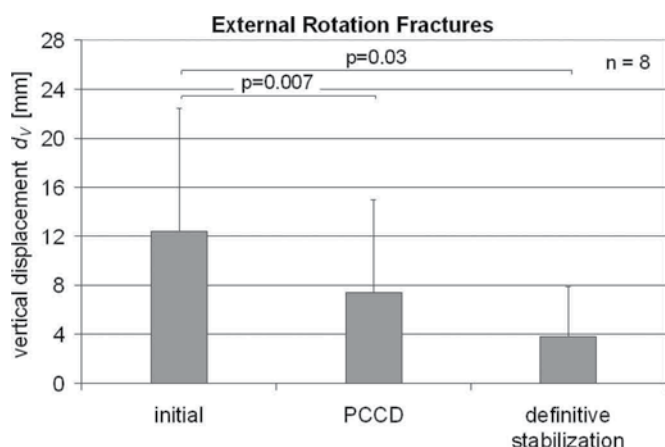


Fig. 4. ER group: average vertical displacement  $d_V$  before and after PCCD application, and after definitive stabilization.

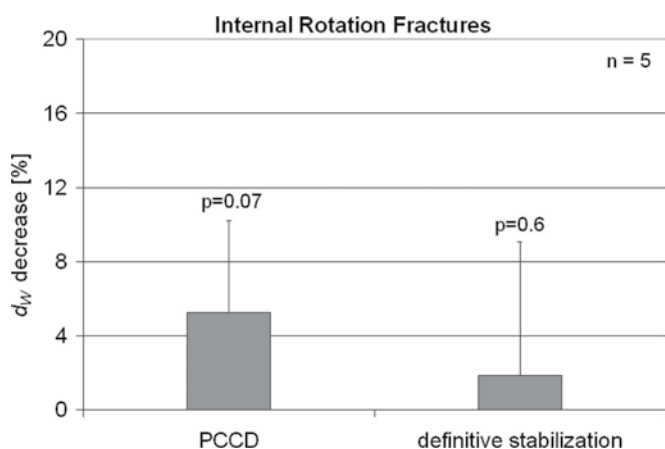


Fig. 5. IR group: average decrease in pelvic width  $d_W$  due to PCCD application and after definitive stabilization, with respect to initial pelvic width.

### External Rotation Fracture



### Internal Rotation Fracture



Fig. 6. ER group example (patient 12): (a) partially stable open-book type fracture, (b) reduced with PCCD, and (c) after definitive stabilization. IR group example (patient 4): (d) partially stable lateral compression fracture, (e) after PCCD application, and (f) after definitive stabilization.

## DISCUSSION

Although not specifically designed for this purpose, PASGs have been routinely used for emergent pelvic stabilization.<sup>19</sup> However, their use has decreased, based on reports of complications and adverse outcomes.<sup>21,26,27</sup> Over the past several years, pelvic sheets have rapidly become adopted in place of inflatable garments.<sup>14,15,18,22–24,28–30</sup> In 1995, Rountt et al. suggested the use of a large sheet wrapped snugly around the pelvis.<sup>18</sup> In a subsequent publication, they recommended circumferential sheeting of the fractured pelvis as the least expensive and most readily available treatment option.<sup>28</sup> Most recently, Ramzy et al.<sup>23</sup> and Rountt et al.<sup>22</sup> published technique guides on their preferred technique for sheet application. Both techniques provide practical advice to apply a “taut” sheet, but rely on radiographic visualization to ensure sufficient reduction and absence of over-compression.

Vermeulen et al. advanced the pelvic sheet concept into the prehospital arena by equipping ambulances with anti-shock strap pelvic belts.<sup>24</sup> They reported on pelvic belts applied by paramedics to 19 patients. Pelvic belts were applied around the trochanters with unspecified tension, and application required a maximum of 30 seconds.

To date, a sheet wrapped around the pelvis as a sling is part of the management algorithm in the Advanced Trauma Life Support guidelines of the American College of Surgeons.<sup>31</sup> Despite its widespread recommendation, application methods for a pelvic sheet remain obscure, and documentation of its efficacy is confined to a small number of case studies.<sup>22,29</sup> Application of a pelvic sheet remains further complicated by the challenge to apply and maintain a sufficient reduction force with a knot or clamps, while avoiding overcompression if the pelvic sheet is applied at the accident scene in absence of fluoroscopic guidance.<sup>28</sup>

In 2002, Bottlang et al. determined in a cadaveric study for the first time the force required to reduce unstable open-book fractures ( $180 \pm 50$  N PCCD tension) with a PCCD applied around the trochanters.<sup>25</sup> When the device was ap-

plied superior to the trochanters, significantly more tension was required to achieve reduction. In a subsequent cadaveric study, they demonstrated that a PCCD tensioned to 180 N did not significantly overcompress unstable lateral compression fractures.<sup>14</sup> Their PCCD caused on average less than one quarter of the displacement observed during creation of the lateral compression fractures. Based on these research findings, the PCCD for the presented clinical trial was developed to ensure consistent and controlled reduction with a defined tension, while avoiding complications due to overcompression.

This study quantified for the first time the efficacy of a PCCD to reduce open-book type pelvic fractures in a clinical trial. Accounting for the pelvic ring geometry, the 9.9% decrease in pelvic width in the ER group correlates to an average symphysis diastasis reduction of 31 mm, and corresponds to 97% of the diastasis reduction achieved by definitive stabilization.

This study furthermore demonstrated absence of complications, when the PCCD was applied to pelvic fractures that were prone to internal rotation and over-reduction. The 5.3% decrease in pelvic width in the IR group correlates to an over-reduction of the anterior pelvic structures of 14 mm. Interestingly, definitive stabilization in the IR group yielded on average a residual over-reduction of 5 mm. The PCCD did not cause complications in any enrolled patient. No cases of skin necrosis or compartment syndrome were observed. In one case, a skin abrasion in the right gluteal region resulting from the injury worsened during the 48 hours while the PCCD was in place. However, this healed uneventfully after PCCD removal for definitive fixation. Nevertheless, in presence of compromised skin, periodic monitoring of skin condition is advocated. For this purpose, the PCCD buckle facilitates temporary release and re-tensioning in a timely manner. In several alert patients anecdotal evidence of pain relieve was noted. This safe and effective use of the PCCD is limited to device application around the trochanters with a 140 N tension limit. This tension level was chosen 20% lower than the 180 N tension level reported in the cadaveric study<sup>25</sup> to ensure safe PCCD application for a wide range of patient morphometric parameters and fracture scenarios. Application around the soft tissue envelope of the pelvis effectively prevented direct compression of prominent bony structures of the pelvis, which otherwise could affect the quality of reduction and give rise to pressure-induced skin breakdown. PCCD application required on average less than 5 minutes. However, since the PCCD was applied in the hospital and not by paramedics at the accident scene, pelvic stabilization was delayed on average by 4.3 hours.

The stratification of enrolled patients into external and internal rotation patterns according to injury mechanism was chosen to investigate the PCCD's ability to reduce open-book fractures while documenting its safety when applied to fracture patterns prone to internal collapse. While this stratification leads to the constitution of heterogeneous subgroups

containing both partially stable and unstable fractures, a further stratification was not undertaken in consideration of the small sample size.

The belt and buckle of the PCCD are made of plastic and textile, whereas only the two compression springs inside the buckle are made of stainless steel. Artifacts on CT images caused by these springs proved negligible and did not affect posterior fracture visualization.

The PCCD was designed to accommodate patients with a hip circumference ranging from 77 cm to 127 cm. While prior biomechanical studies provided optimized PCCD application parameters for this morphometric range,<sup>25</sup> no reduction force data have been obtained on morbidly obese specimens. It was therefore decided to prospectively exclude morbidly obese patients from study enrollment.

The study protocol was approved by the Institutional Review Board (IRB) of each participating hospital. Both institutions' IRBs required that informed consent be obtained from all enrolled patients before inclusion. This was obtained from either the patient or his/her legal representative. This enrollment criterion significantly impacted the number of patients enrolled during the clinical trial period.

The relatively small sample size in this study has implications for the power of the statistical analysis. In the ER group, differences in pelvic width of 10 mm could be detected with a power exceeding 90%, using a two-tailed one-sample *t* test. In the IR group, a one-tailed one-sample *t* test was used, since we were particularly concerned with over-compression. This allowed for a power of 75% to detect a difference in pelvic width of 20 mm. However, no statistically significant differences were found in this group.

At the institutions of this clinical trial, open-book fractures account for less than 30% of all pelvic ring injuries, yet the open-book type ER group in the trial population was larger than the IR group. This may reflect a selection bias, in which surgeons more readily enrolled patients with open-book fractures due to their dramatic radiographic manifestation. On the other hand, detection and definitive fracture classification in the IR group was difficult and remained controversial at times.

General practice at the two institutions of this trial, based on the biomechanical studies that have previously been published, and the teaching principles of ATLS, is to apply the PCCD to all patients with suspected or identified pelvic ring injury. PCCD application is indicated until definitive fixation can be provided, or until the presence of an unstable fracture can be ruled out with certainty.

Outcome parameters of the clinical trial were strictly limited to describe the mechanical effects of the PCCD on pelvic ring displacement. Blood requirements and cardiovascular parameters were reported solely to describe the patient population enrolled in the study. A large-scale study elucidating the effect of a PCCD on hemodynamic stability is clearly desirable and should be a logical extension in future clinical trials. In addition to providing emergent stabilization,

the PCCD was used in one case to maintain reduction during application of an anterior external fixator for definitive stabilization.

In conclusion, results of this clinical trial suggest that the PCCD can rapidly reduce and stabilize open-book type pelvic ring injuries, without causing complications if applied to a range of pelvic ring injuries, including internal rotation type injuries that are prone to internal collapse. Albeit confined to a relatively small patient group, these findings suggest that the PCCD can be applied by paramedics at the accident scene to provide early stabilization within the "golden hour" and before patient transport, as well as by physicians at the time of hospital admission.

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