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

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Background: Pelvic ring injuries are associated with a high incidence of mortality and are a common cause of death in motor vehicle accidents. Hemorrhage is the leading cause of death in patients with pelvic ring injuries. Blood loss occurs mainly from injury to the posterior venous plexus, from fracture surfaces, from the surrounding soft tissue, and from arterial sources in the pelvis. Early reduction and stabilization of pelvic ring injuries are believed to be an integral part of effective strategies to reduce hemorrhage. Early stabilization should be provided as soon after injury as possible and should ideally be applied before patient transport. 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 diminishes 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.

Methods: Sixteen patients with pelvic fractures 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 reduction 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

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.25

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

DISCUSSION

Although not specifically designed for this purpose, PASGs have been routinely used for emergent pelvic stabilization. However, their use has decreased, based on reports of complications and adverse outcomes. Over the past several years, pelvic sheets have rapidly become adopted in place of inflatable garments. In 1995, Routt et al. suggested the use of a large sheet wrapped snugly around the pelvis. In a subsequent publication, they recommended circumferential sheeting of the fractured pelvis as the least expensive and most readily available treatment option. Most recently, Ramzy et al. and Routt et al. 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. 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. 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. 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.

In 2002, Bottlang et al. determined in a cadaveric study for the first time the force required to reduce unstable open-book fractures (180° PCCD tension) with a PCCD applied around the trochanters. 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. 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 relief was noted. This safe and effective use of the PCCD is advocated. For this purpose, the PCCD buckle facilitates temporary release and re-tensioning in a timely manner. 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, 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.

REFERENCES