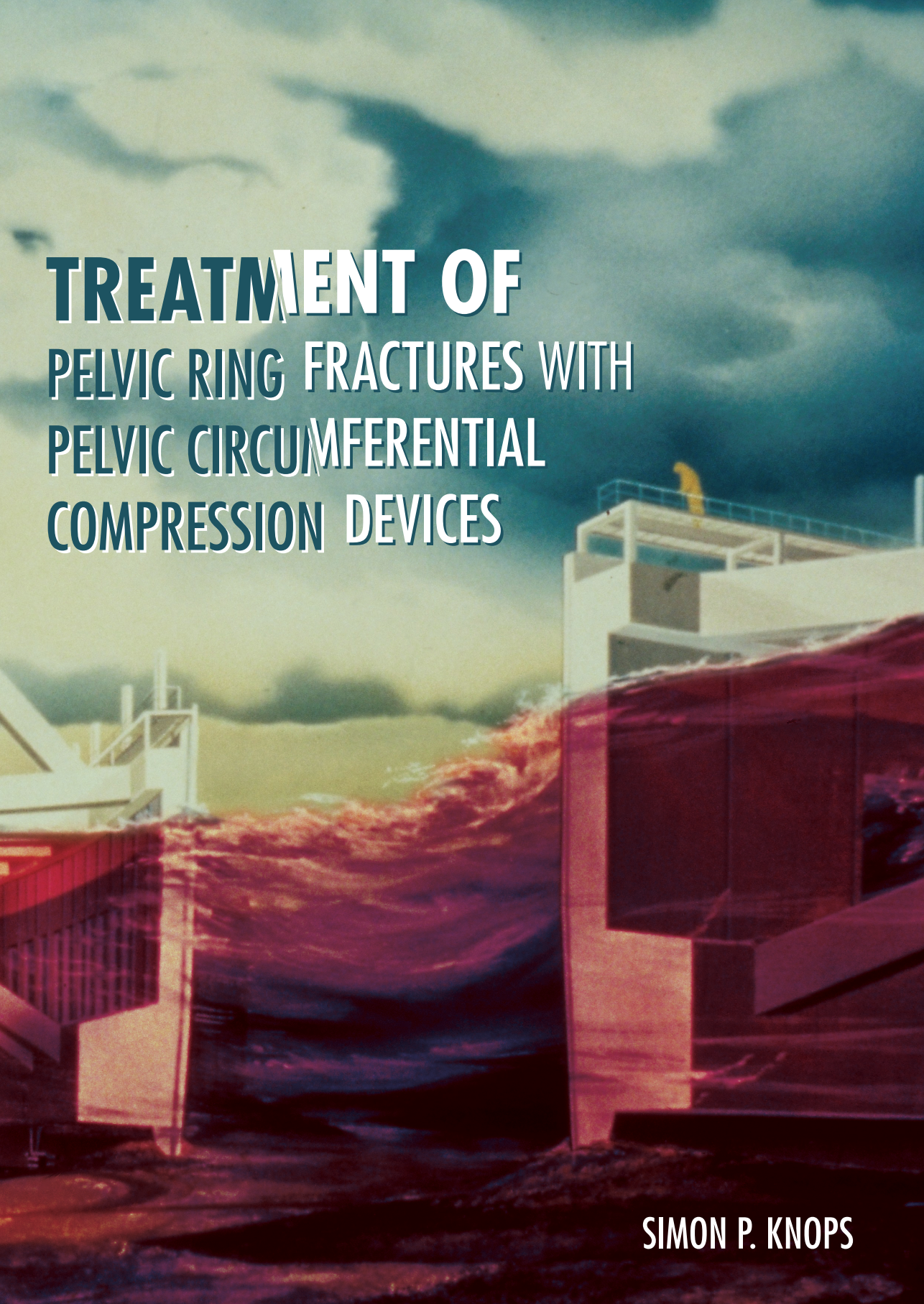
TREATMENT OF
PELVIC RING FRACTURES WITH
PELVIC CIRCUMFERENTIAL
COMPRESSION DEVICES
SIMON P. KNOPS

TREATMENT OF PELVIC RING FRACTURES WITH PELVIC CIRCUMFERENTIAL COMPRESSION DEVICES

Simon P. Knops

COLOFON

ISBN: 978-94-6169-547-5

Cover: Adapted from Beeldbank.rws.nl, Rijkswaterstaat / CSW
Layout & Printing: Optima Grafische Communicatie BV, Rotterdam, The Netherlands

Grants: Part of the research described in this thesis was funded by grants from De Stichting Prof. Michaël-van Vloten Fonds and Fonds NutsOhra

Printing and distribution of this thesis has been financially supported by
Centrum Orthopedie Rotterdam
ChipSoft
Congress Company
DePuy Synthes
Erasmus MC Afdeling Heelkunde
Erasmus Universiteit Rotterdam
ERBE Nederland
Ikazia Ziekenhuis Rotterdam
KCI Medical
Knops TuinDesign
Livit Orthopedie
Nederlandse Vereniging voor Traumachirurgie
Pfizer
Traumacentrum West
Traumacentrum Zuid West Nederland

TREATMENT OF PELVIC RING FRACTURES WITH PELVIC CIRCUMFERENTIAL COMPRESSION DEVICES

Behandeling van bekkenringfracturen met bekkenbinders

Proefschrift

ter verkrijging van de graad van doctor aan de
Erasmus Universiteit Rotterdam
op gezag van de
rector magnificus

prof.dr. H.A.P. Pols

en volgens besluit van het College voor Promoties.

De openbare verdediging zal plaatsvinden op
vrijdag 26 september 2014 om 13.30 uur

door

Simon Peter Knops

geboren te Tilburg, Nederland

"Kijk naar de letters, naar de woorden, naar de zinnen, ik kan het niet aan... Ik sluit m'n ogen, ik sluit m'n ogen, en zie je staan..."

Rens Savenije en Max Linsen

Voor Steven
27 november 1984 - 17 juli 2014

PROMOTIECOMMISSIE

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CONTENTS

Chapter 1

General Introduction to the Topic and Outline of this Thesis

GENERAL INTRODUCTION ON PELVIC RING FRACTURES

THE KILLING FRACTURE

High energy pelvic fractures are life-threatening injuries and are among the most challenging injuries to treat.[1-6] Complete evaluation of the patient with a high energy pelvic fracture is essential because this is rarely an isolated injury. Most deaths in patients with pelvic fractures are not caused by the pelvic fracture itself but are linked to associated injuries.[7] The same forces that lead to disruption of the pelvic ring are frequently associated with abdominal, head, and thoracic injury.[8, 9] Bleeding remains the leading cause of death in patients with pelvic fractures but is rarely the only cause of blood loss in the patient with multiple injuries. In addition to bleeding from the fracture surfaces (*i.e.*, cancellous bone) bleeding from the venous plexus and arterial lesions in a patient with a pelvic ring fracture potentially causes serious complications. These anatomical structures that are at risk are discussed into more detail in the pelvic anatomy section below.

Overall mortality rates from pelvic fractures range between 5 and 35%.[9, 10] Open pelvic fractures constitute of even more devastating injuries. Mortality rates were reported to be as high as 50% in the 1970s and 1980s and have decreased significantly in recent decades (some authors have described mortality rates as low as 5%).[2] Patients with combined pelvic and acetabular fractures represent two serious injuries with resulting difficulties of precise reduction.[11] Data from the Pelvic Injury Trauma Registry in Germany show that the survival rate of patients sustaining pelvic fractures has improved significantly in the last decades with a reported mortality in multiply injured patients of 5%.[7] Data of trauma patients collected in the Trauma Audit and Research Network (TARN) database provide a cumulative mortality rate of 14.2% in patients with pelvic injuries.[12] Mortality after a high energy trauma (HET) is mainly due to hypovolemic shock, following failed resuscitation in 'the golden hour'.[13]

Hypotension is associated with an increased risk of mortality, adult respiratory distress syndrome (ARDS), and multisystem organ failure (MOF).[14] Pre-hospital resuscitation and treatment of unstable pelvic ring fractures is according to the known principles of Advanced Trauma Life Support (ATLS)[15] and Damage Control Surgery (DCS)[16]. The aim is to treat hypovolemic shock and to prevent hypothermia, metabolic acidosis, and progressive coagulopathy, otherwise known as the 'lethal triad' (Figure 1).[17]

The prevention of hypovolemic shock is accomplished by stabilizing the fractured pelvic ring. This stabilization is aimed at limiting the internal blood loss by reducing the increased pelvic volume and thereby facilitating tamponade of the vessels, reducing the diastasis of the pubic

Figure 1 'Lethal triad'.

symphysis and stabilization of the fracture parts. Death within 24 hours is most often a result of acute blood loss while death after 24 hours is most often caused by MOF.[10] Level I trauma centers are reported to have better outcomes than lower level centers in patients with specific injuries, like pelvic fractures, that are associated with high mortality and poor functional outcomes.[18-20]

CLINICAL ASSESSMENT AND DIAGNOSTICS

In cases of suspected pelvic fracture bleeding, based on the trauma mechanism, provisional pelvic stabilization should occur immediately during initial evaluation and resuscitation. Predictors of major hemorrhage in patients with a pelvic fracture are a hematocrit value of ≤ 30%, a pulse rate of ≥ 130 beats/min, a displaced fracture of the obturator ring and a pubic symphyseal diastasis.[21] Provisional, non-invasive, stabilization may consist of circular compression by a pelvic binder or a simple sheet wrapped securely around the pelvis.

The severity of blood loss can be determined on initial evaluation by assessing pulse, blood pressure, and capillary refill. The four different shock classes (I-IV) of the Advanced Trauma Life Support classification of hemorrhage are useful for understanding the manifestations associated with hemorrhagic shock in adults.[22] The trauma screening should always include an adequate physical examination. The evaluation of a leg length discrepancy or a rotation of the lower extremity should be checked. Furthermore, pain on axial compression, anterior-posterior compression and pain with inward and outward pressure on the superior iliac spines can be tested ('rocking the pelvis') but an apparently normal examination does not exclude severe pelvic injury. It is advocated that this examination should be performed only once, because fracture motion may disturb the pelvic hematoma and may lead to further bleeding.

When there is evidence of instability, a sheet should be tight wrapped around the pelvis or a Pelvic Circumferential Compression Device (PCCD) should be applied. The skin, including the perineum, should be examined for lacerations. Soft tissue trauma of the pelvis must be noted. These lesions range from simple bruises and abrasions to closed degloving injuries (Morel-La-

vallée lesions) in which the soft tissue envelope is dissociated from the underlying musculature. Soft tissue trauma may seriously influence fracture care, and therefore any skin lesion should be documented. The examiner should search the flank as well, because blood spreading into the retroperitoneal space can layer out along the flank and lower back. Furthermore, the urethral meatus should be inspected for gross blood. If blood is noticed, the urinary tract must be explored radiographically for injury, with a retrograde urethrogram. If no urethral trauma is found a cystogram should be performed before a transurethral catheter is inserted. Also, the anus and vagina should be checked for blood, and sensation to light touch. If there is any indication of anal or rectal injury, a sigmoidoscopy should be performed to identify the injury. If a vaginal injury is suspected, a vaginal speculum examination must be performed. The bulbocavernosus and cremaster reflexes should be inspected and documented. During the rectal examination, the position of the prostate in males should be noted, because a "high riding prostate" can be indicative of urethral disruption.

An anteroposterior radiograph of the pelvis is mandatory in polytraumatized patients although it may not give a definitive diagnosis of pelvic fractures. A systematic assessment of this radiograph is important.[23, 24] If there is doubt about the classification and diagnosis, additional recordings can be obtained but only after hemodynamic stability has been achieved. Oblique projections will be able to reduce the percentage of diagnostic errors. A caudal projection (inlet view) evaluates for posterior displacement of the pelvic ring or diastasis of pubic symphysis. A cephalad projection (outlet-view) evaluates vertical shift of the pelvic ring. It is important to realize that approximately 30% of the fractures which are diagnosed on CT are missed on conventional radiographs.[25] CT imaging is particularly valuable for defining posterior ring instability. However, prolonged CT scanning in the acutely hypotensive patient should be avoided. Contrast-enhanced CT imaging of the pelvis, which is often done in the hemodynamically stable trauma patient, is a noninvasive technique that has proved to be reasonably accurate in determining the presence or absence of ongoing pelvic hemorrhage.[26] Another accurate diagnostic modality for identification of ongoing bleeding from an arterial injury is angiography which also has the advantage of direct intervention. This option is discussed in more detail in the management of pelvic ring injuries section below.

PELVIC ANATOMY

For a better understanding of the injury mechanism and subsequent instability of a pelvic ring fracture, general knowledge of pelvic anatomy is fundamental. This vital information will help the surgeon to recognize which fracture patterns are more likely to cause direct damage to the vulnerable arterial, venous and (autonomous) stuctures and subsequently

result in significant retroperitoneal bleeding and significant post-operative problems in the autonomous functions of the pelvic organs.

Bones and ligamentous structures

The bony pelvic girdle is anatomically composed of the two hipbones (consisting of the ossa ilium, ischii and pubis) and the sacrum. The iliac bones both articulate posteriorly with the sacrum in the sacro-iliac joint (an amphiarthrosis), whereas both the pubic bones articulate with each other ventrally in the pubic symphysis (a symphysis, i.e. a junctura cartilaginea). These joints are stabilized by a number of ligamentous structures (Figure 2). The posterior sacroiliac ligaments are the strongest and most important. They merge with the sacro-tuberous ligaments and provide vertical stability to the pelvis. The anterior sacroiliac ligaments are

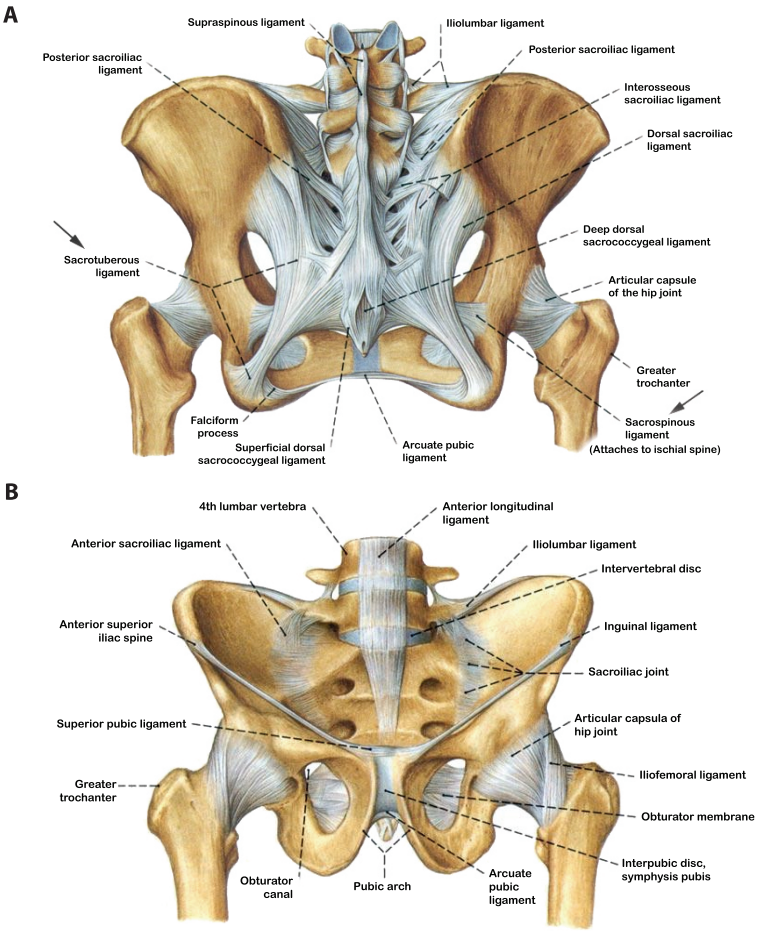

Figure 2 Posterior view (A) and anterior view (B) of the supporting ligamentous structures of the pelvis. (Ref: Anatomy: A Regional Atlas of the Human Body, 4th Edition, by Carmine Clemente, 1997).

less robust than the posterior sacroiliac ligaments. The sacro-tuberous ligaments are strong bands and provide vertical stability to the pelvis. The sacro-spinous ligaments run from the lateral edge of the sacrum to the sacro-tuberous ligaments and inserts onto the ischial spine. The ilio-lumbar ligaments stabilize the connection between the fourth and fifth lumbar transverse processes and the pelvis, and limit side-flexion of the trunk. The lumbo-sacral ligaments run from the fifth lumbar transverse process to the sacral ala and further strengthens the lumbo-sacral joint. The pelvic inlet is the plane drawn between the sacral promontory and the superior aspect of the symphysis pubis. The pelvic outlet is a similar plane drawn from the tip of the fifth sacral vertebra to the inferior aspect of the symphysis pubis.

Arterial and venous pelvic structures

A complex system of arteries circulates blood throughout the pelvic region (Figure 3). The abdominal aorta branches into the right and left common iliac arteries at the level of the 4th lumbar vertebra. The common iliac arteries descend to the pelvic brim, where they divide into the external and internal iliac arteries. The external iliac arteries leave the abdominal cavity to supply the lower extremities. They have two branches, the inferior epigastric and deep circumflex iliac arteries. The internal iliac artery (formerly known as the hypogastric artery) enters the pelvis over the pelvic brim and lies in close proximity to the sacroiliac joint. The internal iliac artery supplies blood to pelvic organs, gluteal muscles, and the perineum. Although infrequent, injury to the common or external iliac artery in association with pelvic fractures can be devastating.

The anterior division comprises of the superior and inferior vesical artery, obturator artery, middle rectal artery, internal pudendal artery, inferior gluteal artery, uterine artery, vaginal artery. The pudendal and obturator arteries are anatomically related to the pubic rami and can be injured with fractures or injuries to these structures. The most frequent cause of active bleeding in pelvic fractures is the internal pudendal artery. This artery can be traumatized in anterior-posterior compression, the so-called "open-book" fracture. It supplies the blood supply to the perineum. Fracture lines involving the superior part of the obturator foramen, the superior pubic ramus, or the pubic acetabulum are prone to cause injury to the obturator artery.

The posterior division of the internal iliac artery supplies blood to the pelvic wall and the gluteal region and comprises of the ilio-lumbar artery, lateral sacral arteries and superior gluteal artery. The presence of the ilio-lumbar artery is in immediate proximity to the anterior sacroiliac joint and at risk with sacroiliac joint disruption. The injury of the lateral sacral arteries is commonly associated with lateral compression pelvic fractures or vertical shear injury. Noteworthy is that the superior gluteal artery sweeps around to exit the greater sciatic notch, where it lies directly on bone. Fracture lines involving the greater sciatic foramen, the superior part of the ischial tuberosity, and the ischial spine are prone to cause injury of the

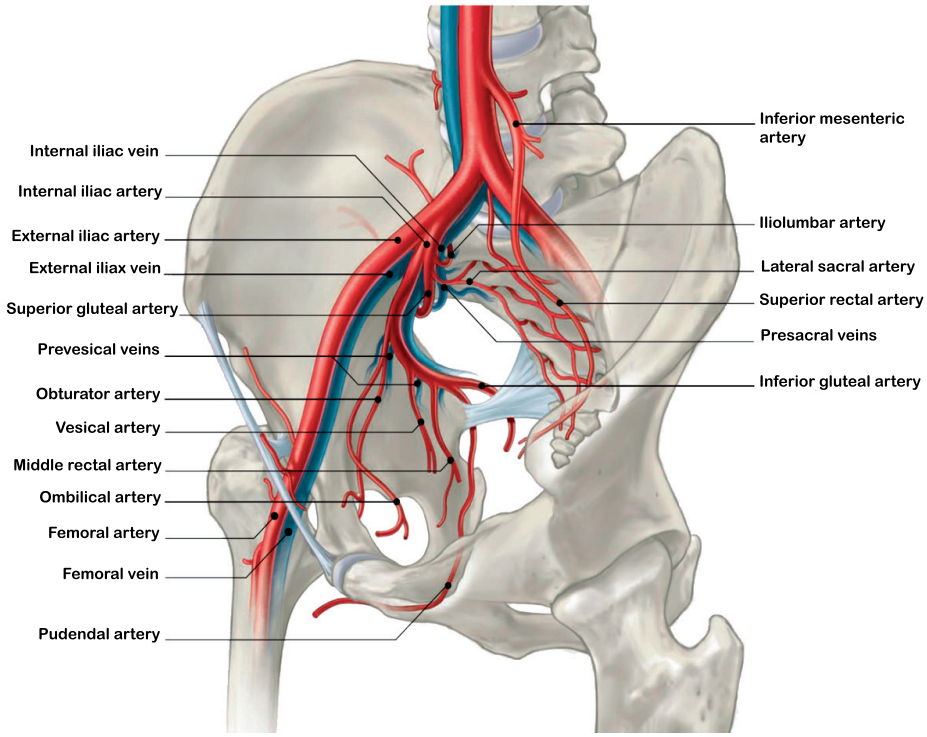

Figure 3 Overview of the complex system of arteries throughout the pelvic region.

superior gluteal artery. The remaining arteries also supply blood to various organs of the pelvis: the superior rectal artery, median sacral artery and ovarian / testicular arteries.

The plexuses of the pelvic organs consist of large thin-walled veins and have extensive mutual anastomoses. The pre-sacral venous plexus (Figure 4) is formed by the two lateral sacral veins, the middle sacral vein and the communicating veins. The pre-sacral venous plexus veins course into the pelvic fascia, covering the anterior aspect of the body of the sacrum. Further, the presacral venous plexus is connected to the internal vertebral venous system through the basi-vertebral veins that pass through the sacral foramina.

The internal iliac vein is the main site of drainage of the smaller pelvic veins. It begins superior to the sciatic foramen as the continuation of the superior gluteal vein. It receives the superior/inferior vesical veins, the middle rectal vein, pudendal vein and obturator vein. The internal iliac veins unite with the external iliac veins anterior to the sacroiliac joints to form the common iliac veins. The external iliac veins are the continuation of the common femoral veins, beginning beneath the inguinal ligament and medial to the artery. They pass, medial and posterior to the artery, along the superficial surface of the psoas muscle along the pelvic

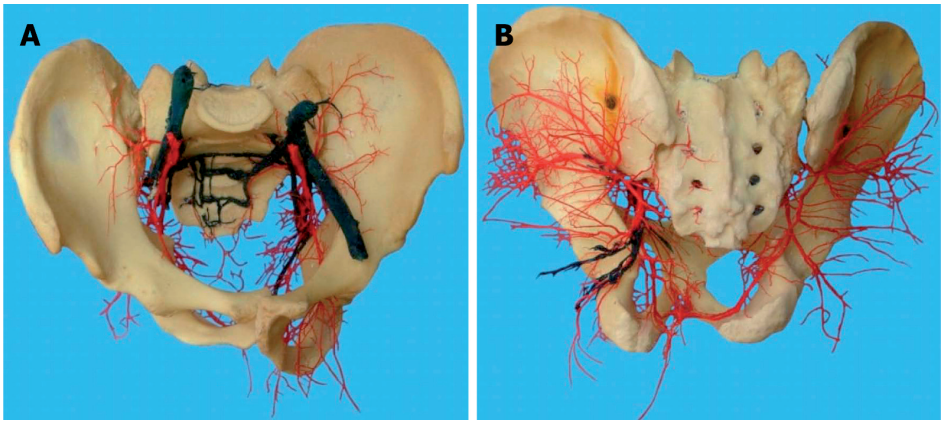

Figure 4 Presacral vascular cast in a pelvic fracture. Front view (A) and dorsal view (B). (Ref: World J. Gastroenterol 2013; 19(25): 4039-44).

inlet. It receives the same tributaries as the external iliac artery (inferior epigastric vein and deep circumflex iliac vein).

Besides ongoing venous hemorrhage, patients with pelvic (and acetabular) fractures are also at high risk for deep vein thrombosis (DVT). Pelvic thrombi are of particular concern because the risk of embolization is as high as 50%. There are no universally accepted guidelines for the use of prophylaxis for DVT in patients with pelvic injuries or for the duration of the prophylactic treatment.[27]

Pelvic plexus

Although neurologic injury does not lead to mortality after pelvic fracture, it can lead to significant post-injury morbidity. The anatomy of pelvic nerves must also be considered during surgical management of fractures. Percutaneous screws, for example, may damage nerve roots. The pelvic girdle is innervated by nerves that come from the sacral plexus, coccygeal plexus, and pelvic autonomic nerves. The fourth and fifth lumbar spinal nerves form the lumbosacral trunk. The lumbosacral trunk goes on to join the first - fourth sacral nerves as they exit the sacrum to form the sacral plexus. The sacral plexus runs down on the posterior pelvic wall anterior to the piriformis muscle.

The nerves that stem from the sacral plexus include the sciatic nerve, pudendal nerve, superior and inferior gluteal nerve. The sciatic nerve passes through the greater sciatic foramen and the pudendal nerve enters the pelvis through the lesser sciatic foramen.

The coccygeal plexus of nerve fibers is formed by the fourth and fifth sacral spinal nerves and the coccygeal nerves. It supplies the coccygeus and levator ani muscles and the sacro-

coccygeal joint. Anococcygeal nerves innervate the skin between the coccyx and anus. The obturator nerve arises from the lumbar plexus and doesn't innervate anything in the pelvis, but it runs through the pelvis to the medial thigh.

Pelvic autonomic nerves innervate the pelvic cavity. Pelvic autonomic nerves include the sacral sympathetic trunks, superior and inferior hypogastric plexuses and pelvic splanchnic nerves (S2–S4). The autonomous nerves are situated in the pelvis, dorsal to the rectum between the visceral rectal (pelvic) fascia and the parietal endopelvic fascia (Figure 5). These fibers originate from the superior hypogastric plexus (L4-S1) from which the two (left and right) hypogastric nerves run a straight caudal course. These hypogastric nerves run dorsal to the mesorectum and run parallel to the ureters. The hypogastric nerves end in the two inferior hypogastric plexus. At the level of the inferior hypogastric plexus, the space between visceral and parietal endopelvic fasciae only contains sympathetic ganglions. However the space is also crossed by the parasympathetic fibers of the nervi erigentes ending in the

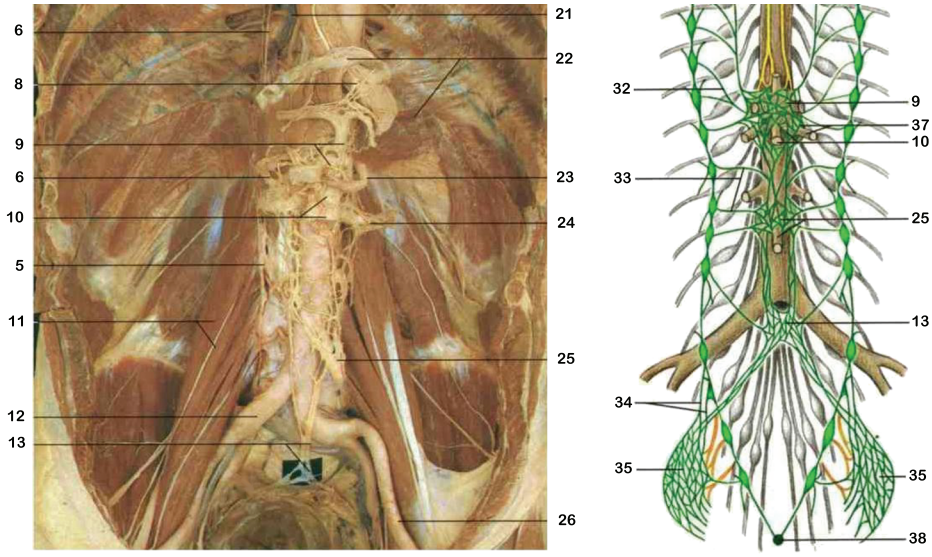

Figure 5 Anterior aspect of the posterior wall with the autonomic nervous system within the retroperitoneal space and a schematic drawing of the parasympathetic nerves (yellow) and the sympathetic nerves (green). (Ref: Rohen Yokochi & Lutjen-Drecoll. Color Atlas of Anatomy, 6th edition, 2006; p334).

5 Sympathetic trunk
6 Greater splanchnic nerve
8 Abdominal part of esophagus and vagal trunk
9 Celiac trunk with celiac ganglion
10 Superior mesenteric artery and ganglion
11 Psoas major muscle and genitofemoral nerve
12 Common iliac artery
13 Superior hypogastric plexus and ganglion
21 Azygos vein
22 Diaphragm
23 Splenic artery
24 Left renal artery and plexus
25 Inferior mesenteric ganglion and artery
26 Left external iliac artery
32 Lesser splanchnic nerve
33 Lumbar splanchnic nerves
34 Sacral splanchnic nerves
35 Inferior hypogastric ganglion and plexus
37 Aorticorenal plexus and renal artery
38 Ganglion impar

inferior hypogastric plexus. The hypogastric nerves and the nn. erigentes are especially at risk in fractures of the sacrum and during opening of the SI joints as seen in Tile B1 ('open book') fractures. Post traumatic complications of lesions to the nervi erigentes can be: urinal incontinence (internal urethral sphincter), erection problems, probles with vaginal transudation, fecal incontinence (rectal ampulla; internal anal sphincter) etc.

CLASSIFICATION SYSTEMS

For a better understanding of the principle of stabilization of pelvic ring fractures, knowledge of the classification of the various types of fractures and the underlying mechanisms is important. Each classification has been developed to provide guidance to surgeons about the type and likelihood of difficult management problems that might be encountered with each fracture type.[28] The ability to recognize the pelvic fracture pattern and the direction of the corresponding injury force can help the resuscitation team anticipate requirements for fluids and blood transfusion as well as help to direct early assessment and treatment. As outlined previous, in a patient with complete posterior instability severe hemorrhage can be foreseen.

The French surgeon Malgaigne (1806–1865) was the first to describe a classification system for pelvic fractures as early as the 19th century. Pennal and Sutherland were the first to incorporate the trauma mechanism in their classification by describing the force and direction of the injury in 1961.[29] They described pelvic ring fractures as lateral compression (LC), antero-posterior compression (APC) and vertical shear (VS) injuries. A "stability" component was added later (1980) by Tile.[30, 31] Young and Burgess incorporated more subsets of the LC and APC groups and added a fourth category; combined mechanical (CM) injury.[9, 32, 33] Acetabular fractures are addressed separately by these systems. This classification of pelvic fractures and presumed force vectors has been shown to correlate well with the pattern of organ injury, resuscitation requirements, and mortality.[33] The Müller-AO/OTA classification of pelvic ring and acetabular fractures is based on the work of Pennal and Tile and Judet and Letournel. This OTA classification was developed to accommodate the alpha-numeric system of The Comprehensive Long Bone System.[34] The basics of the classification system that will be used throughout this thesis is the Tile-classification. Tile introduced the treatment of pelvic ring fractures in relation to the degree and direction of the instability.[35] Fractures are classified according to the main fracture location. The pathomechanical Tile classification is based on the direction of the force that caused the injury and the progressive instability (stable, rotationally stable and both rotationally and vertically unstable) of the pelvic ring. The Tile classification was modified by the Arbeitsgemeinschaft für Osteosynthesefragen (AO) and divides pelvic fractures into three groups:

Figure 6 Tile A fractures include avulsion fractures of the iliac wing that do not cause pelvic ring instability (type A1) and minimally displaced (impacted) fractures of the ring through the pubic rami (type A2).

Tile Type-A fractures (Figure 6) are stable pelvic ring fractures. These can be avulsion fractures of the pelvis not involving the ring (A1), minimally displaced (impacted) fractures of the ring (A2) and transverse sacral/coccygeal fractures (A3).

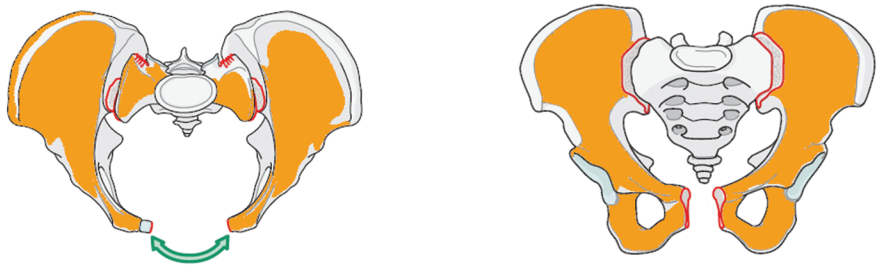

Figure 7 Tile B fractures include fractures caused by compression resulting in symphysis pubis disruption and disruption of the anterior SI joints (type B1).

Tile Type-B fractures (Figure 7) are open book pelvic ring fractures (B1), caused by anterior-posterior compression (APC) and external rotation, lateral compression fractures: ipsilateral (B2) which are caused by lateral compression forces, and lateral compression (LC) fractures: contralateral (bucket-handle) (B3). These pelvic ring fractures are rotationally unstable, but vertically stable.

The subdivision of anterior posterior compression fractures (APC) by Young and Burgess resulted into 3 subtypes:

- APC Type I: anterior ring widening with intact posterior elements
- APC Type II: SI anterior widening, with external rotation of the ilium and disruption of the sacro-tuberous and sacro-spinous ligaments
- APC Type III: Complete posterior/SI disruption

A Tile Type-B1 fracture is caused by an external rotational force which disrupts the symphysis pubis and causes the pelvis to open like a book. This fracture type is a common motorcycle accident injury. In this particular injury, posterior ligamentous structures remain intact so no vertical instability is possible. The lesion may be unilateral or bilateral. As a general rule, if the symphysis is open more than 2.5 cm there is disruption of the sacro-spinous and anterior sacro-iliac ligaments.

The subdivision of the lateral compression (LC) fractures by Young and Burgess also yielded 3 subtypes:

- LC Type I: pubic rami fractures with impaction of the SI joint
- LC Type II: pubic rami fractures with internal rotation, posterior disruption
- LC Type III : LC fracture on one side with APC fracture on the other side

The lateral compression (LC) injury pattern is the most common type of pelvic fracture (Type B). This injury is sustained by a lateral force to the iliac wing ("T-bone" motor vehicle collision), causing an internal rotation deformity to the affected hemi-pelvis. This injury pattern is less likely to produce uncontrolled hemorrhage than the APC or vertical shear injuries. The internal rotation deformity of the injured hemi-pelvis may impinge on the bladder and anterior pelvic contents.

Tile Type-C fractures (Figure 8) are completely unstable pelvic ring fractures. They are mainly caused by vertical shear forces (usually results from fall from height onto lower limbs) and are both rotationally and vertically unstable. Type-C fractures can be unilateral (C1), bilateral (C2)

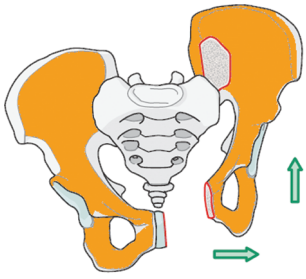

Figure 8 Tile C fractures include fractures caused by rotational and vertical shear forces (type C1).

and can be associated with acetabular fractures (C3). Vertical shear fractures, or Malgaigne fractures, are characterized by rupture of the entire pelvic floor, including posterior SI complex as well as sacro-spinous and sacro-tuberous ligaments.

Although retroperitoneal hemorrhage is associated with APC injuries much more than LC injuries, retroperitoneal bleeding can occur in both types. Especially open book pelvic ring fractures (B1) and vertical shear (C3) injuries increase pelvic volume.

ACUTE MANAGEMENT OF PELVIC RING INJURIES

According to ATLS guidelines, all patients with a suspected pelvic ring injury should receive immediate pelvic ring stabilization regardless of the fracture type.[36] Also institutional guidelines recommend urgent non-invasive pelvic ring stabilization in shocked patients regardless of the fracture pattern. The adherence to these guidelines is sometimes suboptimal.[37] The initial management of pelvic ring injuries is aimed at achieving tamponade by reducing the increased pelvic volume, compressing and stabilizing fractures and reducing bleeding from fracture surfaces. This is achieved by early external circumferential compression to the pelvic ring. Remarkably, three-dimensional analysis data suggest that emergent reduction of pelvic volume may be less important than reduction and stabilization of the injury to a more anatomic position.[38] Most of the following discussed treatment modalities serve as a temporary treatment until definitive stabilization and fixation is achieved.

Military Anti Shock Trousers

In the 1970s and 1980s, the use of Military Anti Shock Trousers (MAST) and Pneumatic Anti Shock Garments (PASG) were advocated to induce pelvic tamponade and increase venous return to aid resuscitation. MAST en PASG can provide temporary compression and immobilization of the pelvic ring and lower extremity via pneumatic pressure.[39] MAST and PASG have fallen out of favor[40, 41] because there use limits abdominal examination and may cause or aggravate an existing lower extremity compartment syndrome.[42, 43]

Pelvic sheet and pelvic binders

External rotation of the lower extremities is commonly seen in persons with displaced pelvic fractures, and forces acting through the hip joint may contribute to pelvic deformity. Correction of lower extremity external rotation can be achieved by taping the knees or feet together[44], and this may improve the pelvic reduction that can be achieved with circumferential compression. Circumferential compression can be readily achieved in the pre-hospital setting and provides early, beneficial stabilization during transport and resuscitation. A folded sheet wrapped circumferentially around the pelvis is cost effective, non-invasive, and easy to apply.[45-47] However, tightening of a sheet could lead to an uncontrolled force that is inadequate for reduction.

Various commercial Pelvic Circumferential Compression Devices (PCCDs) have been developed and they are now widely used in the management of hemodynamically unstable patients with pelvic ring injuries.[46-54] PCCDs provide a simple method for controlled compression of unstable pelvic fractures. Because of their simplicity and controlled compression they are a preferred early stabilization method. A tension of about 180 Newton and application at the level of the greater trochanters has been shown to provide maximum effectiveness.[55-57] Immobilization may limit pelvic displacement during patient movements and transfers, decreasing the possibility of clot disruption. PCCDs reduce transfusion requirements, length of hospital stay, and mortality in patients with APC injuries.[49] Besides their effect on reducing retroperitoneal volume, PCCDs act as splints to the pelvic fractures. Like splinting in other fractures, PCCDs are also expected to reduce motion at the fracture site and as a result reduce bleeding and pain. PCCDs serve as a temporary treatment until definitive stabilization and fixation.

C-Clamp

The C-clamp has been developed to apply a compressive force posterior across the sacroiliac joints. Care must be exercised to avoid iatrogenic injury during its application; the procedure is generally performed under fluoroscopic guidance.[58] As an alternative to standard anterior external fixation for provisional fixation of APC injuries the C-clamp can be applied to the trochanteric region.[59]

Standard anterior external fixation

Resuscitation of the hemodynamically unstable patient with an unstable pelvic fracture with emergent pelvic external fixation has been reported in multiple studies.[33, 60-63] Reduction of pelvic volume may be achieved by application of the external fixator in certain fracture patterns. Reduction of open book pelvic injury is thought to increase retroperitoneal pressures, which may aid in tamponade of venous bleeding.[64] Furthermore, realignment of the displaced fracture can facilitate the hemostatic pathway to control bleeding from bony surfaces. An anterior external fixator is not effective in fracture patterns that involve significant posterior disruption and in cases in which the iliac wing is fractured.[35]

Pelvic packing

Venous bleeding represents the most frequent hemorrhage source in high energy pelvic fractures. Pelvic packing is a method to achieve direct hemostasis and to control venous bleeding.[65] Exploratory laparotomy followed by pelvic packing is believed to be especially useful in patients in extremis.[66, 67] Another treatment option is retroperitoneal packing, leaving the peritoneum intact to help develop a tamponade effect.[68, 69]

Angiography

Hemodynamically unstable polytraumatized patients with continued unexplained blood loss despite pelvic fracture stabilization and aggressive fluid infusion are increasingly being treated with angiography and Pelvic Arterial Embolization (PAE) for diagnostic and therapeutic purposes respectively.[70-72] Embolization occludes the arterial lumen and may effectively control retroperitoneal bleeding. Early angiography and subsequent embolization have been demonstrated to improve patient outcomes.[73-76] Some authors promote "preemptive embolization" to avoid the risk of delayed hemorrhage that can occur with clot lysis.[77] Other authors advocate "nonselective embolization" to control multiple bleeding sites and concealed arterial injuries caused by vasospasm.[72]

Although pelvic arterial embolization is considered by many as a safe procedure[72, 78] with minimal short-term complications, indiscriminant loss of blood supply to end organs may have undesirable consequences. Complications such as gluteal necrosis,[79-82] bladder necrosis,[83, 84] femoral head necrosis,[85] skin necrosis,[86] impotence[87, 88], paresis,[89] and surgical wound complications[90, 91] have been reported after embolization in the pelvic region but can also be produced by the injury itself. Other possible consequences of this procedure may result from the time spent in performing the procedure as opposed to continued resuscitation of the patient. Angiography and embolization are not effective in controlling bleeding from venous injuries and bony sites and time spent in the angiography suite for hypotensive patients without arterial injury may not contribute to survival.[92]

ASSOCIATED INJURIES

Apart from the previous discussed hemorrhage and thrombo-embolic disease, pelvic fractures have other important associated injuries which can lead to soft-tissue, gastro-intestinal, infectious, genitourinary and neurologic complications.

Soft-tissue injury

Soft-tissue injury, like abrasions, echymosis, hematomas, degloving and Morel-Lavallee injuries, caused by the initial trauma, frequently go along with severe pelvic trauma.

Deglovement is defined as detachment of skin and subcutaneous tissues from underlying fascia thereby avulsing segmental perforating vessels. A particular soft-tissue injury is the so-called Morel-Lavallee injury.[93, 94] This injury is a closed internal degloving injury that results from violent, direct, and tangentially applied forces impacting on the superficial soft tissues over the underlying aponeurotic fascia.

Another import category of soft-tissue injury consists of open pelvic fractures. The extent of these injuries is classified according to the Gustilo-Anderson classification.[95] Most fractures are grade III open fractures. The location of soft-tissue injury of open pelvic fractures can be classified in three zones. Zone I include the perineum, anterior pubis, medial buttock and posterior sacrum. This zone is the most common area of open soft tissue injury. Zone II consists of the medial thigh and groin crease and zone III incorporates the postero-lateral buttock and iliac crest.

Treatment of soft tissue injuries must be aggressive, including early administration of broad-spectrum antibiotics and repeated, meticulous wound debridements and irrigation. Open wound care is imperative in these injuries and is initiated in the trauma room.

These soft tissue injuries can be aggravated when essential pelvic circumferential compression is applied. This exerted pressure and (prolonged) immobilization can lead to more tissue damage and the development of pressure sores.[96, 97] The primary cause of a pressure sores is based on the exerted pressure and shear forces on the patient's dermal tissues whereby the supply of oxygen is reduced or cut-off causing necrosis of these tissues.[98] Pressure sores and skin necrosis may occur when pressures above 9.3 kPa are sustained continuously for more than 2–3 h.[99] Immobilization on a spine board is a well-known potential risk factor for development of pressure sores.[100, 101]

Gastrointestinal injury

Direct injury to the gastro-intestinal tract can occur from laceration caused by fracture fragments at the moment of injury. These injuries usually involve the anus or rectum, and often have extension into the perineum. Especially APC type fractures are noteworthy to stretch and then rupture the soft tissues of the perineum and anus. Also severe crushing of the pelvis and perineum could lead to shearing and disruption of the anus and lower gut. These injuries are considered open fractures. Injuries to the more proximal portions of the gut are far more difficult to diagnose and may manifest themselves only as infection sets in. CT scanning is sometimes useful in the diagnosis of hollow viscous injuries. Any suspicion of trauma to the sigmoid colon or rectum should be further investigated, either with a study using oral contrast or, preferably, directly by colonoscopy. The occurrence of deep pelvic infection associated with an open pelvic fracture is life threatening[102] and should be aggressively managed with irrigation and debridement, diversion of the fecal stream, and broad-spectrum antibiotic coverage.[2]

Genitourinary injury

Injuries to the urinary tract must be suspected in all patients with pelvic fractures.[103] If gross hematuria is noted, a retrograde urethrogram is performed to rule out any urethral injury. If

the urethra is normal, a Foley catheter is placed, and a retrograde cystogram is performed. Urethral injury is usually confined to men because of the longer length of the male urethra and most injuries are ruptures caused by blunt trauma or avulsion injury. Bladder rupture usually presents with gross hematuria. Most bladder ruptures are extraperitoneal, with the injury often localized to the anterolateral wall of the bladder. Intra-abdominal ruptures are more rare and usually involve the dome of the bladder. The diagnosis of bladder rupture begins with physical examination.

Neurologic injury

Nerve injury is a common cause of disability after pelvic fracture. Lower-extremity motor function, sensory function, bladder and bowel control, and sexual function can all be affected by neurologic trauma. Injury can result from compression, traction, or disruption of nerve tissue. The rate of nerve deficit is higher among patients with more severe trauma to the posterior pelvic ring especially with fractures that extend medial to the foramina. Compression injury of the anterior sacral nerve roots is often seen after sacral fracture, whereas avulsion injury can affect the nerve roots exiting the cauda equina. Traction injury may affect nerves as they exit the greater sciatic notch or as they cross the anterior aspect of the SI joint. Detailed neurologic examination is a necessity to rule out injury. The mainstay of treatment for these injuries remains reduction of pelvic fracture displacement. Early reduction and stabilization of bony displacement alleviate traction injury to nerves and should protect nerves from later trauma.

LONG-TERM OUTCOMES AND PERMANENT SEQUELAE

The burden of pelvic fractures is high and consists of permanent sequelae like pelvic pain, limb-length discrepancy, gait abnormalities, nerve injuries and urogenital symptoms. The impact of these long-term outcomes is often underestimated. As expected there are poorer clinical outcomes in the patients with more serious types of pelvic injury, especially if there is residual dislocation of the dorsal pelvic segment.[104, 105] Urological and sexual problems are more often associated with the presence of neurological deficit than with the type of pelvic fracture and injury to the lower urinary tract.[106] Common complications of urethral disruption are urethral stricture, incontinence, and impotence.[103] Even in the absence of diagnosed urogenital injury at the time of trauma, late sequelae, such as voiding and sexual dysfunction can occur. Sexual dysfunctions are often neglected and underreported and may consist of erectile dysfunction, pain, impotence in male patients[107-109] and dyspareunia and obstetric complications in female patients.[110, 111] In general motor function deficits are more persistent than the sensory, with the ischiadic nerve most frequently injured.[112] Despite their relative

rarity, malunions and nonunions cause disabling symptoms and have major socioeconomic implications.[113]

There is a variety of generic outcome instruments to inform surgeons or patients in a meaningful way about the functional outcomes of these fractures. The existing literature in this area is scarcely available.[114]

Each unstable pelvic disruption must be treated to minimize complications and maximize long-term functional outcome. Furthermore, the impact of timing of operative pelvic fixation on functional outcome has been researched and showed that definitive fixation should be performed after the fourth post-injury day, when the physiological state of the patient is conducive to surgery.[115]

In summary, high energy pelvic fractures are demanding injuries to treat and patients sustaining these injuries are at high risk of associated injuries. Both strongly influence outcome and survival rates. Thorough knowledge of the pelvic anatomy and fracture classification systems is fundamental for the diagnosis and treatment of unstable pelvic ring fractures. Structured clinical assessment and hemodynamical evaluation are necessary to guide proper use of diagnostic modalities. Awareness of possible associated injuries and potential complications is imperative for decision-making and long-term treatment outcomes. Resuscitation and treatment of unstable pelvic ring fractures has a variety of acute management options, some of them more invasive than others.

The focus of this thesis is on the use, efficacy and potential complications of Pelvic Circumferential Compression Devices that facilitate provisional stabilization of pelvic fractures until definitive fixation is possible. There is limited clinical scientific evidence regarding the efficacy of PCCDs and many questions remain unanswered: Is the use of these devices potentially complicated by the risk of development of tissue damage like pressure sores? Do these devices adequately stabilize unstable pelvic fractures with different injury mechanisms and fracture types? Do the shape and construction of current PCCDs suffice the specific biomechanical demands in order to prevent complications? And more in general, what is the impact of trauma center care on outcomes after pelvic injuries? This thesis intends to provide answers to many of these questions, and more, as described below.

OUTLINE OF THIS THESIS

This thesis explores the efficacy of Pelvic Circumferential Compression Devices (PCCDs) for the treatment of pelvic ring fractures. The current evidence for the effectiveness and complications of non-invasive PCCDs is considered. The pressure characteristics of PCCDs are studied to assess the risk of developing pressure sores. Furthermore, biomechanical testing of PCCDs on the realignment and the quality of reduction of different types of pelvic fractures is performed. The mortality and function following pelvic ring (and acetabular injuries) is reviewed and subsequently the importance of trauma center care is investigated. Finally, new strategies for the development of a new Pelvic Circumferential Compression Device are explored.

A general introduction to the topic and an overview of valuable literature on pelvic ring fractures are presented in **Chapter 1**. The impact of these killing injuries is described. Clinical assessment of patients with pelvic ring injuries and the necessary diagnostics are discussed. Followed by an elaboration on the fundamental pelvic anatomy and fracture classification systems. Furthermore the acute management of pelvic ring injuries with different treatment modalities is presented. Finally, associated injuries which potentially complicate treatment of pelvic ring injury and influence long-term outcomes and permanent sequelae are described. This chapter also provides an outline of this thesis on the treatment of pelvic ring fractures with Pelvic Circumferential Compression Devices.

Pelvic fractures can cause massive hemorrhage. Early stabilization and compression of unstable fractures are thought to limit blood loss. Reposition of fracture parts and reduction of pelvic volume by circumferential compression devices may provide hemorrhage control. **Chapter 2** presents an overview of the history, development, indications, and application of PCCDs and attempts to answer the following questions:

- What is the evidence for the effectiveness of PCCDs?
- Is there a risk of complications with the use of PCCDs?

The results of a systematic review of the current evidence for the use of commercially available PCCDs (*i.e.*, Pelvic Binder®, SAM Sling®, and T-POD®) in patients with unstable pelvic ring fractures are described in **Chapter 3**. This chapter aims to answer the following questions:

- What are the biomechanical effects of PCCDs on fracture reduction?
- What is the clinical efficacy of PCCDs in the initial treatment in terms of hemostasis, clinical applicability, and patient outcomes?

High pressure on the skin and prolonged use of PCCDs might put patients at risk for tissue damage and accompanying co-morbidity. To gain insight into the pressure build-up at the

binder-skin interface the PCCD-induced pressure when applying pulling forces to different PCCDs was measured in a simplified artificial model. The results of this study are outlined in **Chapter 4**, aiming to answer the following questions:

- What is the pressure build-up at the binder-skin interface at different locations and what is the variation between the different types of PCCDs?
- Is there a potential risk to exceed the tissue damaging level?
- Are there apparent factors in binder designs and closing mechanisms that account for the difference in PCCD-induced pressure?

Skin damage associated with the use of pelvic binding with various methods and devices, including PCCDs, has been described. This implies the need to avoid over-tightening and prolonged use of pelvic compression over the skin. Most of the research on and development of PCCDs focuses on long-term lying comfort on various surfaces and not so much at distribution of pressure at specific sites. **Chapter 5** presents the results of a randomized clinical trial quantifying the exerted pressures of PCCDs on the skin in a 'best case' scenario with healthy volunteers.

- To what extent might the skin be at risk for developing necrosis and associated tissue problems?
- Does the exerted maximum pressure on the skin in the pelvic region exceed the tissue damaging pressure level?
- What is the variation in the absolute pressure, the pressure gradient and number of cells exceeding the tissue damaging level on the skin in the pelvic region?
- Is the pressure influenced by the type of PCCD, BMI, waist size, age, or gender?

The efficacy of PCCDs for different types of pelvic fractures is uncertain because the effects of these devices on the reduction of fracture fragments have not been quantified so far. In **Chapter 6** the results of a biomechanical cadaver study with the use of a three-dimensional infrared video system are presented. The aim of this study was to compare the effects of three commercially available PCCDs on the dynamic realignment and final reduction of pelvic fracture fragments in order to find answers to the following questions:

- Is the reduction provided by these PCCDs significant?
- Can PCCDs provide compression in partially stable and unstable pelvic fractures?
- Is there a risk for adverse over-reduction with PCCDs in specific fracture types?
- Which PCCDs requires the lowest pulling force to attain complete reduction?

Patients with pelvic injuries benefit from the specialized care, with concentration of resources, offered at trauma centers. However, the majority of studies supporting this notion have been retrospective studies. **Chapter 7** focuses on the effect of trauma center care versus non-trauma center care on outcomes among patients with major trauma including pelvic

and/or acetabular injuries from the National Study on Cost and Outcomes of Trauma. This observational study aimed to answer the following questions:

- What is the mortality rate of patients with pelvic (and/or acetabular) injuries?
- Are these rates different in patients admitted to trauma centers compared with patients in non-trauma centers?
- Do patients that have been treated in trauma centers value their physical functioning differently than patients treated in non-trauma centers?

The use of external pelvic compression with PCCDs in severely injured trauma patients poses specific biomechanical demands upon the devices in order to prevent complications. The shape and construction of currently available PCCDs seem not to suffice these demands. The design process and development of a new PCCD are described in **Chapter 8**. The focus during the different development phases was directed on a number of items:

- What are the biomechanical properties, applicability, and pressure reducing characteristics of the currently available PCCDs?
- What are the requirements for the development of a new PCCD with optimized functional characteristics and minimized peak pressure on the tissue?
- Which material properties are required, how can they be integrated into concepts and in which combination of techniques and materials would they result in the best solutions for a new PCCD?
- What is the improved pressure distribution that can be reached with a functional prototype of a new PCCD?

The final result of this development process is a functional prototype of a new PCCD: the Guardian**.**

Chapter 9 presents a general discussion, critical reflection, possible controversies and a vision for future possibilities.

Chapter 10 summarizes the main findings and general conclusions presented in this thesis.

Chapter 11 presents a Dutch summary of the contents.

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Chapter 2

Pelvic Circumferential Compression Devices for Acute Stabilization of Unstable Pelvic Fractures

Translated from Nederlands Tijdschrift voor Traumatologie 2011;19(5):126-131

S.P. Knops[1], P. Patka[2], T. Schepers[1], E.M.M. van Lieshout[1]

[1] Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

[2] Department of Emergency Medicine, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

ABSTRACT

Pelvic circumferential compression devices have been developed for the initial treatment of unstable pelvic ring fractures in the pre-hospital situation. The treatment is aimed at achieving tamponade by reducing the increased pelvic volume and reducing the bleeding from fracture surfaces. The effect of commercially available pelvic circumferential compression devices on the reduction of symphysis pubis diastasis and the resuscitation has been proven. Since prolonged use of these devices is complicated by the risk of development of pressure sores, prolonged immobilization on a spine board should be avoided. A number of different pelvic binders will be discussed in this article.

INTRODUCTION

Pelvic binders are used in trauma surgery for the initial treatment of unstable pelvic ring fractures. Mortality after a high energy trauma (HET) is mainly due to hypovolemic shock, following failed resuscitation in 'the golden hour'. In addition to bleeding from the fracture surfaces (*i.e.*, cancellous bone) bleeding from the venous plexus and arterial lesions in a patient with a pelvic ring fracture potentially causes serious complications. Pre-hospital resuscitation and treatment of unstable pelvic ring fractures is according to the known principles of Advanced Trauma Life Support (ATLS)[1] and Damage Control Surgery (DCS). The aim is to treat hypovolemic shock, and to prevent hypothermia, metabolic acidosis, and clotting disorders, otherwise known as the 'lethal triad'. The prevention of hypovolemic shock is accomplished by stabilizing the fractured pelvic ring. This stabilization is aimed at limiting the internal blood loss by reducing the increased pelvic volume, reducing the diastasis of the pubic symphysis and stabilization of the fracture parts. This is achieved by early external circumferential compression to the pelvic ring. In addition, PCCDs reduce pain and movement during transport and transfers by the principle of immobilization. PCCDs serve as a temporary treatment until definitive stabilization and fixation.

This article discusses the history and development of PCCDs and provides an overview of the current commercially available binders. In addition, the indication and the application are described. The effectiveness and the risk of complications are mentioned briefly. Finally, the use of a PCCD will be illustrated with reference to a case.

CLASSIFICATION OF PELVIC RING FRACTURES

For a better understanding of the principle of stabilization of pelvic ring fractures, knowledge of the classification of the various types of fractures and the underlying mechanisms is important. Tile introduced the treatment of pelvic ring fractures in relation to the degree and direction of the instability.[2] Fractures are classified according to the main fracture location. The pathomechanical Tile classification is based on the direction of the force that caused the injury and the progressive instability of the pelvic ring. The Tile classification was modified by the Arbeitsgemeinschaft für Osteosynthesefragen (AO) and divides pelvic fractures into three groups:

- Type-A fractures are stable pelvic ring fractures, such as a superior ramus fracture.
- Type-B fractures are open book pelvic ring fractures (B1), caused by anterior-posterior compression and external rotation, lateral compression fractures (B2) which are caused by lateral compression forces, and bilateral lesions (B3). These pelvic ring fractures are rotationally unstable, but vertically stable.
- Type-C fractures are completely unstable pelvic ring fractures. They are mainly caused by vertical shear forces and are both rotationally and vertically unstable.

A (relative) contra-indication for the application of a PCCD is a lateral compression type fracture. Such fractures carry a risk of over compression, which may cause secondary bladder injury.

HISTORY AND DEVELOPMENTS

The development of the PCCD has some interesting preceding stabilization methods. Lieutenant-Colonel Burton Kaplan, a surgeon in the U.S. Army in Vietnam in 1972, developed the military anti-shock trousers for hemodynamic stabilization and transportation of patients with hemorrhagic shock. In subsequent years, the medical anti-shock trouser (MAST) and pneumatic anti-shock garment (PASG) have been used. However, randomized trials showed no survival benefit, yet an increase in complications such as abdominal compartment syndrome and pressure ulcers was noted.[3] Furthermore, when using the MAST, surgical access to the abdomen, the inguinal region and lower extremities is impeded. Therefore the use of MAST has become obsolete.

Circumferential compression of the pelvic region can also be obtained by applying a bed sheet around the pelvis at the level of the greater trochanters, that is then bound together.[4-6] Complementary internal rotation and taping of the lower extremities may further increase the stabilization.[7] This could be a useful alternative for patients with morbid obesity.

PCDDs, intended for pre-hospital treatment of unstable pelvic ring fractures, were first described in 1999.[8] Since then, these PCCDs have become available in several commercial binders, belts, slings and wraps.[9-12] The PCCDs discussed in this article should not be confused with stabilizing treatment methods for non-traumatic (including pregnancy-related) pelvic instability. In the Netherlands PCCDs are available for physician-staffed Helicopter Emergency Medical Services (HEMS) and in ambulances, but also in the emergency department of the hospitals.

AN OVERVIEW OF THE PCCDS

Current PCCDs, such as the Pelvic Binder®, SAM Sling ® and the T-POD ® (Figure 1) are easy to use and can be applied quickly (*i.e*, within 30 seconds) on patients in a supine position. These PCCDs are X-ray permeable and are safe for use in Magnetic Resonance

Imaging (MRI) machines. Additional diagnostics are not compromised by pre-hospital application of a PCCD.

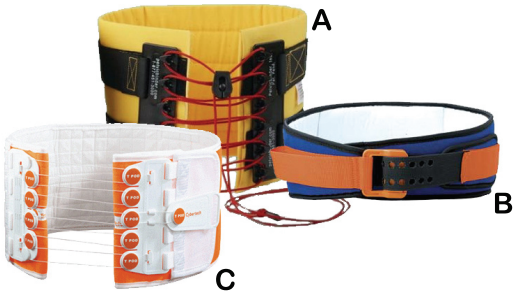

Figure 1 PCCDs A) Pelvic Binder®, B) SAM Sling®, C) T-POD®.

The Pelvic Binder® (Pelvic Binder Inc., Dallas, TX, USA) is "one size fits all" and needs to be "cut-to-fit" with a 6-8 inch gap. The Pelvic Binder® has a Velcro-backed fastener with a shoelace mechanism. Health care providers should be able to insert at least two fingers between the patient and the binder after maximal tensioning.

The SAM Sling® (SAM Medical Products, Newport, OR, USA) is available in sizes "extra small", "standard" and "extra large". The narrow design of the belt leaves more space for clinical diagnostics and access to the abdomen. The SAM Sling® needs to be pulled tight with two hands in opposite direction. It is equipped with a fastener with an auto-stop buckle that limits the circumferential compression at a strap tension of 150 Newton for adequate volume reduction. This is an attempt to prevent over compression and over reduction.

The T-POD® (Trauma Pelvic Orthotic Device: Bio Cybernetics International, La Verne, CA, USA) is also "one size fits all" and needs to be "cutt-to-fit" with a 6-8 inch gap. Simultaneous circumferential compression is accomplished through a Velcro-backed mechanical advantage pulley system with a pull-tab. Adequate compression with the T-POD® is easily obtained by tightening the binder with at least two fingers between the binder and the patient.

INDICATION AND APPLICATION

When a pelvic fracture is suspected, based on the trauma mechanism, there is an indication for pre-hospital application of a PCCD, especially in hemodynamically unstable patients and patients in hypovolemic shock. The trauma screening should always include an adequate physical examination. The evaluation of a leg length discrepancy or a rotation of the lower extremity should be checked. Furthermore, pain on axial compression, anterior-posterior compression and pain with inward and outward pressure on the superior iliac spines should be tested ('rocking the pelvis'). When there is evidence of instability, a PCCD should be applied. The stability should be tested only once, because there is a risk of secondary displace-

ment and associated risk of bleeding. The most effective compression is achieved when the PCCD is applied at the level of the greater trochanters, and not at the level of the os ilium.[13, 14]

EFFECTIVENESS

A systematic review of the effectiveness of PCCDs for the treatment of unstable pelvic ring fractures has recently been published.[15] In this review, the use of commercially available PCCDs for acute stabilization of pelvic ring fractures, such as the Pelvic Binder®, SAM Sling® and T-POD® is discussed. Systematic reviews (level I) and randomized controlled clinical trials (level II) that study the clinical effectiveness of these PCCDs are lacking; only a few cohort studies and case-control studies (level III-IV) are currently available. The latter show that PCCDs are effective in reducing the pelvic volume and the symphysis diastasis, and in stabilizing the fracture parts. Some illustrative studies from this review and more recent publications are briefly mentioned.

Reduction of the pelvic volume and transfusion requirements

As indicated earlier, reducing the increased pelvic volume, reducing the internal blood loss and thereby decreasing of transfusion requirements are important measures for the effectiveness of PCCDs. It has been shown that in unstable pelvic ring fractures (*i.e.*, Tile type B, and C) the T-POD® has a compressive effect on the pelvic volume and hemodynamic stability in the acute phase, based on measurements of the circulatory response before and after application of the T-POD®.[16] Patients have lower transfusion requirement and carry a lower risk of developing infectious complications like pneumonia after circumferential compression with a PCCD.[9] The evidence that PCCDs significantly reduce bleeding and mortality, such as associated with pelvic ring fractures is not unambiguous.[17] The use of PCCDs in a hospital where acute arterial embolization is a possible treatment option would therefore not always be the treatment of first choice.

Reduction of the diastasis

Another important measure for the effectiveness of PCCDs is the quality of the diastasis reduction at the symphysis pubis and the sacroiliac joints. The different PCCDs achieve adequate reduction of the pelvic ring in partially stable (Tile type B) and unstable (Tile type C) pelvic ring fractures without increasing the risk of unwanted over-reduction. The necessary pulling force to obtain adequate reduction is lowest for the T-POD® (40 N).[18] In another cadaver study it was demonstrated that the T-POD® gives a better reduction of the diastasis (Tile type B1) than a simple bed sheet.[19] In a cohort study, the reduction of the symphysis pubis diastasis using PCCDs was similar to the reductions with final operative fixation.[11]

Stability

Finally, the effectiveness of the pelvic belts depends on the stability. The effect of pelvic bands should be compared with other (temporary) fixation options. The stability which is obtained with a prototype PCCD is comparable to the stability of a 'C-clamp' (*i.e.*, closed reduction by means of percutaneously inserted pins and an external frame).[13] The stability which is obtained with a PCCD is, however, only one third of the flexion-extension stability and a tenth of the internal-external rotation stability that can be obtained with an external fixator. Applying a 'C-clamp' and an external fixator, however, requires specific technical knowledge and experience, and is not available in the pre-hospital setting. The use of a PCCD, on the other hand, is non-invasive and can easily take place pre-hospitally.

COMPLICATIONS

The use of PCCDs is constrained by traumatic lesions of the skin and soft tissue, such as severe abrasions, burns, deglovement, and Morel-Lavallée lesions. A Morel-Lavallée lesion is an internal deglovement of the subcutaneous tissue filled with blood and serous fluid, which in pelvic ring fractures occurs particularly at the level of the sacrum and the posterior pelvis. There is limited data on complications of PCCD use and severity of these complications. Available cases suggest a risk of developing ulcers and skin necrosis.[20, 21] An extraordinary complication is bilateral peroneal nerve palsy after application of a PCCD.[22] In the literature, no other serious complications have been attributed to the use of a PCCD.

Tissue damage is expected to occur when a continuous pressure higher than 9.3 kPa (9300 N/m^2, corresponding to 70 mmHg) is exerted to the skin for 2-3 hours. Pressure characteristics with application of a PCCD (Pelvic Binder®) have been previously studied.[10, 23, 24] Differences in binder design and functional characteristics such as the various closure mechanisms result in PCCD-specific pressure distribution patterns. If the manufacturer's instructions of the PCCDs are followed, there is a clear risk of exceeding the level at which tissue damage is to be expected.[23] Prolonged use of these PCCDs is expected to constitute a risk of developing pressure ulcers. Therefore frequent monitoring of the skin is indicated in case of prolonged use of a PCCD. Pelvic circumferential compression with a PCCD in combination with immobilization on a spine board causes a considerable exceeding of the tissue pressure.[24] This increases the risk of development of pressure ulcers. Clinicians should be aware of these potential adverse effects associated with the use of PCCDs. Facilitating an early transfer of the spine board to a hospital mattress is essential as the risk of pressure ulcers after a transfer drops significantly.

CASE

A 51-year-old man was examined and treated according to the ATLS principles upon arrival at the Emergency Department after a high energy trauma caused by the crash of a helicopter. The patient was fully immobilized, intubated and hemodynamically unstable due to a hypovolemic shock. The additional trauma screening showed multiple fractures, including an open-book pelvic ring fracture with diastasis of the sacroiliac joints and symphysis pubis (Figure 2A), proximal femoral fractures bilaterally and multiple unstable vertebral fractures. A PCCD (T-POD®) was applied immediately in the trauma unit, resulting in a clear reduction of the symphysis pubis diastasis (Figure 2B). According to the principles of damage control surgery (DCS), an external fixator was placed on the pelvis. Bilaterally, two schanze pins were inserted in the os ilium, after which the pelvis was repositioned. Subsequently, two schanze pins were inserted in both the right and left femur and a body was placed from the external fixator to both femora. The patient responded well to fluid resuscitation and became hemodynamically stable. A suprapubic catheter was placed because the retrograde urethrogram showed a laceration of the urethra.

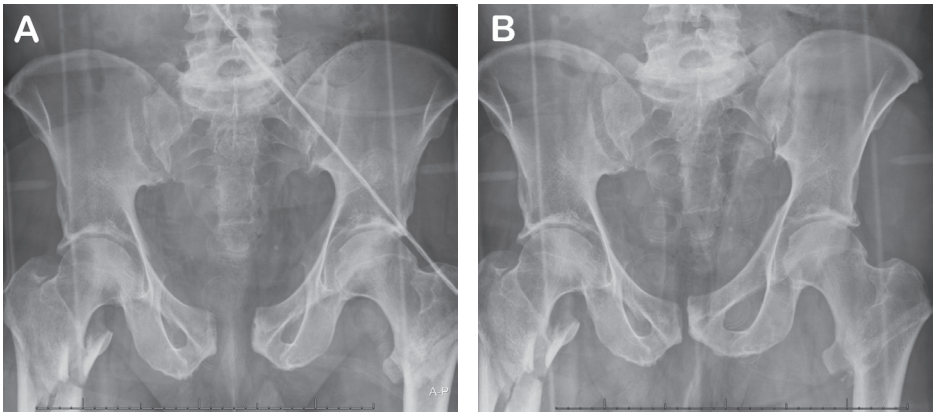

Figure 2 Open-book pelvic ring fracture
A) with obvious diastasis of the symphysis pubis (30 mm), B) with a PCCD (T-POD®) in place and obvious reduction of the diastasis of the symphysis pubis (6 mm) after tensioning of the PCCD.

IN PERSPECTIVE

PCCDs are an important treatment modality in the pre-hospital and acute treatment of trauma patients with an unstable pelvic fracture. When developing a new generation of PCCDs the stabilizing capacity and comfort are important and the design should be aimed at limiting the risk of developing pressure sores. Prospective randomized controlled trials are needed in order to further assess the clinical relevance and safety of PCCDs. Ultimately this knowledge will contribute to the development of evidence-based guidelines for effective and safe use of PCCDs.

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Chapter 3

Effectiveness and Complications of Pelvic Circumferential Compression Devices in Patients with Unstable Pelvic Fractures: a Systematic Review of Literature

Injury, Int. J. Care Injured 2009;40(10):1031-1035

W.R. Spanjersberg, S.P. Knops, N.W.L. Schep,
E.M.M. van Lieshout, P. Patka, I.B. Schipper

Erasmus MC, University Medical Center Rotterdam,
Department of Surgery-Traumatology, Rotterdam,
The Netherlands

ABSTRACT

Background: Pelvic fractures can cause massive haemorrhage. Early stabilisation and compression of unstable fractures is thought to limit blood loss. Reposition of fracture parts and reduction of pelvic volume may provide haemorrhage control. Several non-invasive techniques for early stabilisation have been proposed, like the specifically designed Pelvic Circumferential Compression Devices (PCCD). The purpose of this systematic review was to investigate current evidence for the effectiveness and safety of non-invasive PCCDs.

Methods: To investigate current literature the search string: '*pelvi* AND fract* AND (bind* OR t-pod OR tpod OR wrap OR circumferential compression OR sling OR sheet)*' was entered into EMBASE, PubMed (Medline), PiCarta, WebofScience, Cochrane Online, UptoDate, CINAHL, and Scopus. All scientific publications published in indexed journals were included.

Results: The search resulted in 17 included articles, none of which were level I or II studies. One clinical cohort study (level III) and 1 case–control study (level IV) were found. These showed a significant reduction of pelvic volume after applying a PCCD, without an effect on outcome. Other included literature consisted of 4 case series (level V). Two biomechanical analysis studies of fractures in human cadavers showed pelvic stabilisation and effective volume reduction by PCCD, especially when applied around the greater trochanters. Finally, 7 case reports (level VI) and 3 expert opinions (level VII) were identified. These case reports suggested complications such as pressure sores and nerve palsy.

Conclusion: PCCDs seem to be effective in early stabilisation of unstable pelvic fractures. However, prospective data concerning mortality and complications is lacking. Some complications, like pressure sores have been described.

INTRODUCTION

The pelvis is comprised of a bony ring, made up by the sacrum and 2 fused bone planes on each side, consisting of the ischiac, iliac and the pubic bones. Distortion of this ring due to fractures may lead to extensive haemorrhage, pelvic instability and organ damage (e.g., urinary bladder). Blood loss can occur from several sources, like venous plexus lesions, bleeding fracture sites and, less common, arterial injuries. Life threatening bleeding from arterial origin may occur in 5–20% of patients.[3,8,11] Theoretically, the reduction of pelvic fracture fragments diminishes the pelvic volume, thereby reducing the potential space for bleeding. Moreover, a reduction of fracture surfaces may reduce bony bleeding.[8,9] Unstable pelvic fractures should be considered as life threatening at all time, and constitute a high incidence of mortality causes in polytraumatised patients.[29]

During resuscitation of polytraumatised patients, priority is given to preventing and treating the lethal triad; hypothermia, acidosis, and progressive coagulopathy.[12,27-29] In this context, the most efficient resuscitative measure to reduce blood loss in pelvic fractures is early cessation of bleeding. Application of a non-invasive Pelvic Circumferential Compression Device at the scene of the accident is frequently applied as early fracture fixation. With a PCCD in place, patients can be transported to a trauma centre, where definitive stabilisation of the pelvis can be performed by the application of a pelvic C-clamp, operative placement of an external fixation device, or coiling of an arterial haemorrhage.

Several non-invasive stabilisation methods have been developed over time. Ways to reduce hemorrhaging from pelvic fractures date from as early as 1974 with the introduction of the Medical Anti-Shock Trouser (MAST) or Pneumatic Anti-Shock Garment (PASG).[2,18] Randomised trials revealed no survival benefit from these devices.[20,21] Several complications, like abdominal compartment syndrome and pressure sores have been reported.[1,6] Moreover, these devices severely limited the surgical access to the abdomen, groin and upper legs. Overall, these limitations have rendered their use obsolete.

Circumferential compression can be achieved by using a simple bed sheet, tightened around the pelvis, or by using a specially designed commercial device. These Pelvic Circumferential Compression Devices (PCCDs) were first described in 1999.[30] The use of PCCDs in the initial care for pelvic fracture patients is currently incorporated in the Advanced Trauma Life Support guidelines, as put forward by the American college of Surgeons.[27] PCCDs are easy to use, can be applied quickly, thereby significantly contributing to survival of severely injured patients. However, evidence for the effectiveness for this treatment modality is scarce.

The purpose of this systematic review was to make an inventory of the current evidence for the use of PCCDs in patients with unstable pelvic ring fractures, both in terms of biomechan-

ics (fracture reduction) and clinical efficacy (haemostasis, clinical applicability, and patient outcome in the initial treatment).

MATERIALS AND METHODS

In order to investigate the effectiveness of PCCDs in the initial treatment of unstable pelvic fractures, a systematic review of literature was performed. For this, a systematic search of relevant databases in medical literature was used.

Search strategy

Using the search string *'pelvi* AND fractur* AND (bind* OR t-pod OR tpod OR wrap OR circumferential compression OR sling OR sheet)'* all relevant literature investigating the effectiveness of PCCDs were retrieved. Relevancy on achieving reduction of fracture parts or symphysic diastases, or on obtaining clinical improvement in patients that sustained an unstable fracture of the pelvic ring was assessed.

The search string was used for retrieving manuscripts from EMBASE, PubMed (Medline), PiCarta, WebofScience, Cochrane Online, UptoDate, CINAHL, and Scopus. Subsequently, the abstracts of all hits were reviewed in order to assess whether the article was eligible. Inclusion criteria were scientific articles concerning the use of PCCDs or sheets in either clinical patients or in an experimental setting. Scientific articles in any language, published in indexed journals, pertaining all levels of evidence concerning effectiveness, safety and biomechanics of PCCDs were considered eligible. Exclusion criteria were articles classified as product advertisements or articles describing only invasive compression devices. Duplicate hits were filtered and references were hand screened to find relevant articles not identified by the initial search string. Included articles were analysed and divided by design, research question and evidence level (Table 1). Results classified as product advertisements were excluded after hand searching references, because no scientific merit can be derived from these papers.

Table 1 Level of evidence[19].

Type of study	Level of evidence	Studies included
Systematic review with or without meta-analysis	I	0
Randomised controlled trials	II	0
Cohort studies	III	1
Case-control studies	IV	1
Case series	V	5
Case reports	VI	7
Opinion	VII	3

RESULTS

The search strings used resulted in 176 hits. After comparison and removal of duplicate manuscripts, 100 manuscripts remained. After reading all abstracts, 16 relevant articles concerning the use of PCCDs were identified (Table 2). Screening the references of these articles yielded 1 additional publication. In total, 17 articles concerning the use of PCCDs were included in the review. These consisted of 3 biomechanical laboratory studies, 2 clinical studies, 1 experimental in vivo study, 1 case series, 7 case reports describing complications and adverse outcome of PCCDs, and 3 expert opinions. Four of the included articles discuss some form of experimental PCCD, while 5 articles investigate specially designed and commercially used PCCDs. Seven articles discuss the use of a bed sheet wrapped around the pelvis, and one biomechanical study compares the bed sheet to the commercially available T-POD®. The main results and corresponding level of evidence are depicted in Table 2. Below, all studies will be discussed by order of level of evidence[19].

The search resulted in only one level III study. In a prospective study, Krieg et al., investigated the effectiveness of an experimental PCCD (prototype SAM-Sling®) in reducing partially stable and unstable pelvic fractures.[16] Thirteen adult patients were included into this 16 months trial, which was performed in two level I trauma centers. PCCDs were applied in the emergency department and time between fracture and PCCD was on average 4.3 h (range 1–10 h). Pelvic fractures were confirmed on AP X-rays. A second AP X-ray was made upon application of a PCCD and finally a third radiograph was made after definitive stabilisation. Reduction of the pelvic ring was assessed by measuring the change in horizontal and vertical position of the femoral heads. Horizontal translation was defined by coronal plane reduction and vertical displacement was used to assess the quality of anatomical reduction. PCCD placement significantly reduced the horizontal displacement by 9.9 ± 6.0% in the 8 externally rotated fractures, which was comparable to definitive stabilisation. Vertical displacement was reduced from 12.5 ± 10.0 mm to 7.4 ± 7.6 mm. Definitive stabilisation further reduced vertical displacement to 3.8 ± 4.0 mm. For the 5 internally rotated fractures, PCCD application decreased the horizontal displacement by 5.3 ± 4.9%. Upon definitive treatment, this was further decreased by 1.9 ± 7.2%. Vertical displacement was on average over 50% less than in the group of patients with externally rotated fractures, and was not significantly affected by PCCD application or by definitive stabilisation. Six patients were initially treated by wrapping a bed sheet around the pelvis and 2 patients had received PASG in the field. No effect on outcome is mentioned. Overall, this study showed a good effect for reducing horizontal displacement, comparable with definitive treatment, without investigating the effect on outcome.

Table 2

Reference	Design	Level of evidence[a]	N of cases	PCCD	Fracture type(s)	Outcome measure(s)	Clinical outcome
Bottlang et al.[4]	Case series biomechanical cadaver study	V	7	Experimental sling (50 mm wide)	Y&B type II/III AP compression, 50 and 100 mm diastases	• Most effective application site • Pelvic stabilisation • Safety	Stability provided by PCCD comparable with C-clamp
Bottlang et al.[5]	Case series biomechanical study	V	7	Experimental sling (50 mm wide)	Partially stable/rotator unstable fractures (OTA 61-B1 and 61-C1) with 50 and 100 mm diastases	• Most effective application site • Pelvic reduction • Effect on interperitoneal pressure • Strap-skin interface pressure	No risk for overcorrection or unstable correction
Croce et al.[7]		IV	186	T-POD	Anterioposterior II and III fractures	• Transfusion requirement • Outcome	• No significant difference in outcome (i.e. mortality, hospital stay, morbidity) after T-POD vs external fixation • Transfusion requirement lower (resuscitative, 24hr, 48hr) after T-POD vs external fixation
DeAngelis et al.[9]		V	12	Sheet vs T-POD	Rotationally unstable (Y&B APC II/Tile B1)	• Pelvic reduction • Difference between T-POD and sheet	T-POD more effective in reduction than sheet (21.9 mm vs 32.2 mm reduction)
Eastridge[10]		VII	NA	Unknown	None	None	
Higgins[14]		VII	NA	Sheet	None	None	
Jowett and Bowyer[15]		V	10	Pelvic Binder	None	• Skin pressure • Risk of pressure sores	Risk of pressure sores with use longer than 3 hr
Krieg et al.[17]		VI	1	SAM Sling	Tile C	Pressure sores	Pressure sores after using PCCD
Krieg et al.[16]		III	13	Experimental binder (15 cm wide)	Internal and external rotation fracture patterns (OTA class 61-B1 and 61-C1)	Reduction pelvic displacement	• Significant reduction of pelvic volume, comparable to definitive stabilisation • No significant effect on outcome (i.e. mortality, hospital stay, morbidity)

Reference	Design	Level of evidence[a]	N of cases	PCCD	Fracture type(s)	Outcome measure(s)	Clinical outcome
Nunn et al.[22]		V	7	Sheet	Various, hemodynamically and anatomically unstable	Hemodynamic stability / fluid resuscitation requirements	Transient positive effect on fluid resuscitation requirement
Routt et al.[23]		VI	1	Sheet	Tile A	None	
Schaller et al.[24]		VI	1	Sheet	AP compression type II	Complication rates	Pressure sores after using bed sheet
Shank et al.[25]		VI	1	Sheet with lower extremity wrap	Tile B	Bilateral peroneal nerve palsy	Bilateral nerve palsy after using bed sheet
Simpson[26]		VI	2	Sheet	OTA 61B/C	Reduction symphysic diastases and pelvic inlet	
Vermeulen[30]		VII	NA	Experimental sling	Not identified	• Stability • Time to application	
Ward[31]		VI	1	Pelvic stabilizer	Open book with symphysic diastases 7.5cm and bilateral SI disruption (Tile C)	Hemodynamic stability	Improved hemodynamic stability
Warme[32]		VI	1	Sheet	Tile C, caudal displacement of right hemipelvis	Hemodynamic instability	Improved hemodynamic stability

Overview of the included publications showing the study design, level of evidence, type of PCCD used, fracture type(s) discussed and outcome measures used. Y&B, Young and Burgess; OTA, Orthopaedic Trauma Association; AP, anterior–posterior; PCCD, Pelvic Circumferential Compression Device. [a] Level of evidence, according to Table 1.

A retrospective clinical study by Croce et al. was the only level IV study retrieved.[7] In a period of 10 years, 186 patients with structural and hemodynamically unstable pelvic fractures were enrolled. These had received emergent pelvic fixation by means of a PCCD (T-POD; N = 93) or had underwent emergent external pelvic fixation (N = 93). PCCD application significantly reduced the transfusion requirements in the first 48 h after injury compared with the controls. Moreover, the number of pneumonias, as a marker for infectious complications was significantly lower in the PCCD group. The length of hospital stay and mortality was similar in both groups.

Five level V studies were found. In three studies the biomechanical properties of PCCDs were investigated using a biomechanical model in human cadavers. Bottlang et al.[4] investigated the most effective application site of an experimental PCCD for reducing open book type fractures in 7 non-embalmed human cadavers. Using 180 N of tension, their PCCD was applied to the greater trochanters, the midpelvis or around the iliac crests. A complete reduction was best achieved when the PCCD was applied at the greater trochanter level. For this, a tension of 177 ± 44 Nand 180 ± 50 N was needed for Young and Burgess type II and III anterior– posterior compression fractures, respectively. This result was compared with the use of the pelvic C-clamp and the anterior external fixator. The stability provided by the PCCD was comparable with stability provided by the posterior pelvic C-clamp. However, the PCCD provided only one-third of the flexion-extension (horizontal displacement) stability and one-tenth of the internal/external rotation stability compared with a regular external fixator applied on the anterior iliac wing. Safety of using a PCCD was investigated by assessing the risk in terms of internal rotation of one hemipelvis and increase in pelvic inlet area. This was not significant and the authors therefore stated that no risk of over-reduction in lateral compression fractures existed.

In a second study, Bottlang et al. evaluated pelvic reduction with respect to strap tension and the strap application site.[5] The effect of circumferential compression on intra-peritoneal pressure and skin–strap interface pressure was also measured. Reduction of the unstable pelvic fracture by PCCD application at the level of the greater trochanters was characterised by an intra-peritoneal pressure increase of 6.2 ± 5.8 mmHg (0.825 ± 0.771 kPa) and a strap–skin interface pressure of 24 mmHg (3.192 kPa). This is consistent with the PASG, which could be left in place safely for 48 h without resulting in soft tissue damage.[2]

The third biomechanical study was performed by DeAngelis et al.[9] They created rotationally unstable pelvic fractures (Tile B1) in 12 non-embalmed human cadavers by sectioning the pubic symphysis and all anterior SI ligaments on the left side of the pelvis. Effects on symphysic diastases throughout the study were measured using standardised X-rays. First, a circumferential bed sheet (8 in. diameter) was placed around the pelvis and greater trochanters

and held in place with a clamp. After removal of the sheet, the original diastasis was recreated and a trauma pelvic orthotic device (T-POD®) was applied following the manufacturer's instructions. This process was repeated in 12 specimens. Using a bed sheet the diastases was reduced by an average of 21.9 mm, and diastases was reduced to normal (<10mm) in 2 of 12 cadavers. The T-POD® reduced the diastases by an average 32.2 mm and reduced diastases to normal in 9 out of 12 cadavers. The authors therefore conclude that the T-POD® is more effective in reducing pelvic diastases, and thus in reducing volume, than a simple bed sheet.

The fourth level V study is a case series performed by Nunn et al.[22] Herein, 7 patients with hemodynamically unstable pelvic fractures were initially treated using an improvised PCCD made of a cotton draw sheet. In a variety of fractures and associated injuries, all patients were described as seeming to have an excellent response to initial fluid therapy. However, all patients continued to need fluid resuscitation upon application of the PCCD. Three patients became hemodynamically unstable while undergoing further diagnostic examinations. So, although a transient effect of PCCDs was reported, patients did need continued fluid resuscitation. However, definitive treatment could be delayed and further diagnostics or interventions like laparotomy could be performed.

The fifth level V study was performed by Jowett and Bowyer,[15] who investigated the pressure characteristics of the Pelvic Binder[1] as a measure for the risk of developing pressure sores. The pressure exerted on the skin by a Pelvic Binder at the anterior superior iliac spine, the greater trochanters and the sacrum was measured in 10 healthy volunteers. The mean pressure was found to be 17.0, 13.4, and 11.1 kPa, respectively. Since tissue damage is believed to occur when pressures of more then 9.3 kPa are sustained continuously for more than 2–3 h[13] their results suggest that PCCDs may not be suited for prolonged use.

Further reports on clinical efficacy of PCCDs are based upon case reports. In total, 7 level VI studies were found.[17,23-26,31,32] Two reports claim adequate anatomic reduction of dislocated pelvic fractures with application of circumferential sheets,[23,26] and two reports claim stabilisation of hemodynamic instability in patients sustaining unstable pelvic ring fractures.[31,32]

Reports on adverse outcome and complications have also been published. Krieg et al. reported on a 15-year-old girl who sustained bilateral sacroiliac joint injuries, symphysic disruption, and bilateral rami fractures.[17] She was hypotensive (55/ 30 mmHg) and tachycardic (120 beats/min). A PCCD was applied (SAM-Sling®, The Seaberg Co., Newport, OR). Within 48 h, she received 14 l of fluid, and developed oedema. The patient developed skin necrosis over the area of PCCD application, specifically at the greater trochanteric region, which required several debridements and split skin grafts. The case presented by Schaller et al. also developed skin necrosis within 10 h after application of a bed sheet.[24] Another patient sustained

bilateral nerve palsy within 16 h of application of a bed sheet. Motor function of the tibialis anterior, extensor hallucis longus and extensor digitorum longus was absent, but eventually returned to normal.[25]

Three reports contain only expert opinions, while no patients are presented.[10,14,30] Some authors describe techniques of application of PCCDs, especially improvised devices, i.e. sheets.

DISCUSSION

Pelvic fractures are life-threatening injuries.[29] Reduction and stabilisation lead to haemostasis. Early intervention may decrease blood loss, resulting in reduced morbidity and mortality. A method of early fracture stabilisation that has been increasingly used in recent years is the use of non-invasive Pelvic Circumferential Compression Devices. These devices are well suited for use in the acute (out of hospital) phase of resuscitation, as they can easily be applied at the accident scene. Effects of these devices may be more effective in pelvic fracture patients than minimally invasive techniques like the C-clamp that can only be used in the in-hospital setting.

The aim of the current literature review was to gather the current evidence concerning the use of PCCDs. In total, 17 articles were found, none of which were level I or II (Table 2). The majority of reports were case reports, in which mainly instructions on how to use improvised PCCDs were described. Level III and IV evidence does exist, reporting effective fracture and pelvic volume reduction by PCCDs. Experimental studies, performed on human cadaveric specimens, also provide evidence of effective pelvic reduction and stability in several types of unstable pelvic fractures.[4,5,9] The fractures studied in these experimental studies were artificially inflicted. Fracture patterns occurring in vivo may show greater variation, and/or may involve more ligament disruptions. Therefore, results cannot be directly related to clinical effectiveness. A retrospective case–control study by Croce et al. suggests less blood loss upon application of a PCCD compared with invasive pelvic stabilisation, resulting in lower transfusion requirements. However, this did not result in a statistically significant reduction in mortality rates. The number of pneumonias was, however, lower in the PCCD group.

Other factors, like advancements in pre-hospital life support protocols and quality of clinical resuscitation and intensive care treatment can obviously bias results. The main findings concerning efficacy of the use of PCCDs are summarised in Table 2. Results on studies of differences between the use of specially designed PCCDs or improvised devices like bed sheets have not been published.

Another aspect concerning the use of PCCDs that remains unresolved is whether the use of PCCDs in general, or a type of PCCD device in particular, is contra-indicated in certain fracture subtypes. Overall, it is insufficiently established whether PCCDs can be safely used on all types of pelvic fractures.

Certain risk factors have been described, mostly in case reports. Skin pressure exerted upon application of a PCCD following instructions of the manufacturer may exceed the safe threshold for developing skin necrosis. It is unclear from current data if a protocol can be developed for safe use of PCCDs in terms of pressure sore risk.

CONCLUSIONS

The currently available literature on PCCDs in patients with suspected pelvic fractures indicates a reduction of blood loss, and does not show life threatening complications associated with the PCCD use. Despite the absence of level I and II evidence for the clinical effectiveness of PCCDs, publications so far (level III–V) report that PCCDs are effective in reducing fractures and associated hemorrhaging. The nature, severity, and rates of PCCD related complications are not fully known. The effectiveness and safety of PCCD use in individual fracture types, also remain to be determined. Cases published do suggest a certain risk of skin damage and possible damage to internal organs after the use of a PCCD. The authors therefore state that prospective randomised clinical trials should be performed in order to further assess clinical relevance and safety of these devices. Information resulting from such level II studies may facilitate the development of an evidence based guideline for safe and effective use of PCCDs.

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Chapter 4

Measurement of the Exerted Pressure by Pelvic Circumferential Compression Devices

The Open Orthopaedics Journal 2010;4:101-106

S.P. Knops[1], M.P.J.M. van Riel[2], R.H.M. Goossens[3], E.M.M. van Lieshout[1], P. Patka[1], I.B. Schipper[§,1]

[1]Department of Surgery-Traumatology and [2]Neuroscience, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

[3]Department of Industrial Design Engineering, section Applied Ergonomics and Design, Technical University Delft, Delft, The Netherlands

[§]Current Address: Department of Surgery, Leiden University Medical Center, Leiden, The Netherlands

ABSTRACT

Background: Data on the efficacy and safety of non-invasive Pelvic Circumferential Compression Devices (PCCDs) is limited. Tissue damage may occur if a continuous pressure on the skin exceeding 9.3 kPa is sustained for more than two or three hours. The aim of this study was to gain insight into the pressure build-up at the interface, by measuring the PCCD-induced pressure when applying pulling forces to three different PCCDs (Pelvic Binder®, SAM-Sling® and T-POD®) in a simplified model.

Methods: The resulting exerted pressures were measured at four 'anatomical' locations (right, left, posterior and anterior) in a model using a pressure measurement system consisting of pressure cuffs.

Results: The exerted pressure varied substantially between the locations as well as between the PCCDs. Maximum pressures ranged from 18.9-23.3 kPa and from 19.2-27.5 kPa at the right location and left location, respectively. Pressures at the posterior location stayed below 18 kPa. At the anterior location pressures varied markedly between the different PCCDs.

Conclusion: The circumferential compression by the different PCCDs showed high pressures measured at the four locations using a simplified model. Difference in design and functional characteristics of the PCCDs resulted in different pressure build-up at the four locations. When following the manufacturer's instructions, the exerted pressure of all three PCCDs tested exceeded the tissue damaging level (9.3 kPa). In case of prolonged use in a clinical situation this might put patients at risk for developing tissue damage.

INTRODUCTION

Pelvic fractures are common injuries as a result of high- energy trauma. The incidence of these fractures is increasing.[1] Pelvic fracture often results in massive hemorrhage. The origin of the blood loss can be found in venous plexus lesions, arterial injury, and bleeding from fracture sites. Anatomic reduction and stabilization of pelvic fractures prevents blood loss by limiting bleeding from the fracture site and by reducing the pelvic volume. By reducing pelvic volume, bleeding can be stopped by mechanisms of tamponade, clotting or hemostasis.[2] External stabilization of the pelvis should reduce transfusion requirements and length of hospital stay, and has shown to improve survival in patients with unstable pelvic fractures.[3] In order to provide fast and easy reduction and stabilization, external pelvic compression is necessary. The biomechanical approach of pelvic compression has resulted in an introduction of a non-invasive compression method: the Pelvic Circumferential Compression Device (PCCD). A PCCD is a belt that is wrapped around the fractured pelvis and tightened with the closing mechanism. Currently, the three most commonly used PCCDs (Pelvic Binder®, T-POD® and SAM-Sling®) (Figure 1A-C) are applied in pre-clinical and clinical situations for patients with pelvic fractures.

Pelvic circumferential compression is used in the pre-hospital phase and contributes to early non-invasive hemodynamical stabilization within the 'Golden hour'.[4, 5] Advanced Trauma Life Support (ATLS) guidelines advise the use of a PCCD when an unstable pelvic fracture is suspected or diagnosed as a technique to stabilize the patient hemodynamically by reducing blood loss. The PCCDs provide circumferential compression to the bones within the pelvis. Compression forces will be most pronounced at the area of the pelvic bones that lie closely underneath the PCCD. In a clinical setting this denotes bony landmarks like the sacrum and the greater trochanters.[6] Also, the exact application location of the PCCD strongly affects the local pressure level and overall effects. Research into the transverse application level of a specific sling showed that the sling should be applied at the area of the greater trochanters and the symphysis pubis.[7]

Data on the efficacy and safety of PCCDs is limited. The PCCDs currently available differ in design (material, shape and size) and closing mechanism, and may therefore have different functional characteristics, resulting in different mechanical and clinical effects. The applied pulling forces according to manufacturer's application instructions differ substantially. A study on human cadaveric specimens showed the minimum strap tension required to achieve complete reduction of symphysis diastasis was 177 ± 44 N and 180 ± 50 N in the partially stable and unstable pelvis, respectively.[7] As opposed to the tension required to achieve complete reduction, there is no data available for the required tension to achieve hemostasis for initial resuscitation.

The forces that can be applied to the pelvic ring by the PCCDs are uncontrolled and unrestricted, except for the SAM-Sling®, which has a fastener with an auto-stop buckle that limits circumferential compression when exceeding 150 N tensional force. The exerted pressure after applying a pulling force to the PCCD and the resulting effect on the underlying skin is unclear.

Figure 1A-C The three most frequently used PCCDs tested in this study.

1A Pelvic Binder®

Manufacturer:	Pelvic Binder Inc., Dallas, TX, USA
Size:	One size fits all. "Cut-to-fit" 6-8" gap
Closing mechanism:	Velcro-backed fastener with shoelace mechanism
Application instructions:	Health care providers should be able to get at least two fingers between the patient and the binder after applying pressure

1B SAM-Sling®

Manufacturer:	SAM Medical Products, Newport, OR, USA
Size:	Sized to fit. Extra Small, Standard, and Extra Large. Small belt leaving more space for clinical diagnostics or entrance to the abdomen
Closing mechanism:	Fastener with an auto-stop buckle (33lbs) that limits circumferential compression at the time of PCCD application to the minimal required pulling force for pelvic reduction
Application instructions:	Buckle placed close to midline. Pulled tight with or without assistance with two hands in opposite directions

1C Trauma Pelvic Orthotic Device® (T-POD)

Manufacturer:	Bio Cybernetics Inter-national, La Verne, CA, USA
Size:	One size fits all. "Cut-to-fit" 6-8" gap.
Closing mechanism:	Simultaneous circumferential compression through Velcro-backed mechanical advantage pulley system with a pull-tab
Application instructions:	Health care providers should be able to insert two fingers between the patient and the T-POD

Adverse effects are related to high pressures on the skin and long-term use of the PCCD. The compression devices may cause pressure induced skin breakdown and accompanying co-morbidity in case of prolonged use in the period before invasive pelvic fixation. Tissue damage may occur if a continuous pressure exceeding 9.3 kPa (9300 N/m2, corresponding with 69.8 mmHg) is sustained for more than two or three hours.[8] It is recommended that the pressure at the interface is kept below 4.66 kPa, i.e. below capillary blood pressure, allowing circulation to the skin to be maintained.[6, 8]

The aim of this study was to gain insight into the pressure build-up at the interface, by measuring the PCCD-induced pressure when applying pulling forces to three different PCCDs (Pelvic Binder®, SAM-Sling® and T-POD®) in a simplified artificial model.

MATERIALS AND METHODS

Study design

The model used in this study was chosen to measure the pressure build-up without taking into account the anatomy of the human pelvis and should be considered as a simplified artificial model of a human pelvis. The model (Figure 2) consisted of a cylindrical paper roll, with a height of 36 cm and a diameter of 38 cm, wrapped in plastic foil. The model was placed upright in order to measure the exerted pressure produced by the PCCD, exclusively, without the weight of the model pressurizing as well.

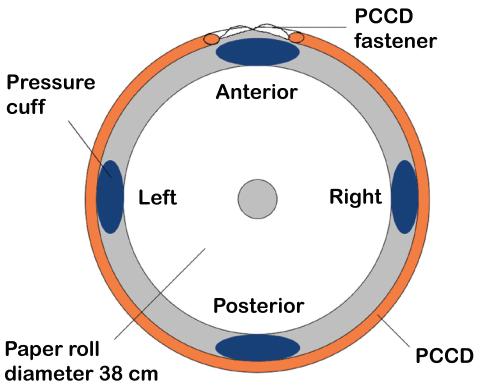

Figure 2

A top view of the simplified artificial model of a pelvis consisting of a cylindrical paper roll, with a height of 36 cm and a diameter of 38 cm, wrapped in plastic foil. The four air-filled oscillometric pressure cuffs were positioned in vertical position to the outside of the roll at the right, left, posterior and anterior locations. A PCCD covers the cuffs in the middle of the width of the PCCD with the fastener over the anterior location.

The commercially available PCCDs that were used are the Pelvic Binder®, SAM-Sling® and the T-POD® (Figure 1A-C). All three PCCDs are disposable, radiolucent and MRI safe. In these pressure measurements the smallest size non-invasive oscillometric pressure cuffs (Hewlett-Packard™, #1, limb circumference 3.1–5.7 cm) were used. These cuffs are the same as cuffs used for measuring blood pressure in newborn infants.

An identification mark was pointed out at 0 degrees on the outside of the roll to mark the posterior location, representing the 'anatomical' location of the sacrum. Subsequently three marks were determined at 90, 180 and 270 degrees to mark the left, the anterior and the right location, representing estimated 'anatomical' locations of the left GT, the symphysis pubis, and right GT, respectively. Four pressure cuffs were attached in vertical position to the outside of the roll with tape. They were placed in line with the marks, with the tubes directed upward. The pressure cuffs were attached to the model of the pelvis and not directly to the binders to measure the pressure at the locations given. A schematic representation of the measurement setup is shown in Figure 2.

Disposable transducers (DTXPlus™ Pressure Transducer, PRESS VENEUS, REF 686495, Becton Dickinson, Franklin Lakes, NJ, USA) were attached to the pressure cuffs. The pressure cuffs were pressurized manually up to 6.7 kPa (50 mmHg) before use and the pressure system was calibrated with a manometer. This pressure level was chosen to prevent collapse of the pressure cuffs. Measurements were recorded and displayed with use of the Multiple Channel Registration (MKR) digital data acquisitioning system (version 3.3.1, Directie Informatie, Erasmus MC, Rotterdam, The Netherlands). The resolution of this pressure system is 0.13 kPa (1 mmHg). Each of the four pressure cuffs was connected separately to amplifier units that were connected to an ADC-board (Analogue-Digital Converter) in a personal computer.

Description of application of the PCCDs

The PCCDs were tensioned with a stepwise (20N per step) increased pulling force until the maximum pulling force as mentioned in the manufacturer instructions was reached (Figure 3). Except the SAM-Sling®, which has a fastener with an auto-stop buckle that limits the pulling force to 150 N. Pulling forces were consecutively increased every five seconds. The force applied to the binders was measured using a digital force gauge (9000 series CPU, AIKOH Engineering corp.) This gauge was connected to a separate amplifier unit. Measurements were performed in 'track' modus, implying continuous measurement.

The PCCDs were applied in a way that the cuffs were covered in the middle of the width of the PCCDs. The application instructions of the manufacturers were followed (Figure 1). The application instructions did not consider the direction in which the PCCDs should be pulled tight. In order to measure in a standardised way the PCCDs were pulled tight with

a horizontal pulling force at the tangens of the closing mechanism. The Pelvic Binder® was pulled tight downwards in the model with one hand, the SAM-Sling® was pulled tight with two hands in opposite directions and the T-POD® was pulled tight towards the right-hand side with one hand.

Measurement series

The PCCDs were applied around the model and pulled tight and loosened three times before the measurements started. For each PCCD triplicate measurements were performed on day one. The four pressure cuffs were removed, switched and replaced at the same four locations on the model on day two. A second series of identical measurements was performed on day two. Each series consisted of four pressure signals measured at the four locations under the PCCD and the simultaneous recorded pulling force signal. The MKR digital data acquisitioning system was designed to process, plot and store the pulling force (one channel) and the resulting pressures (four channels), separately in two panels (Figure 3).

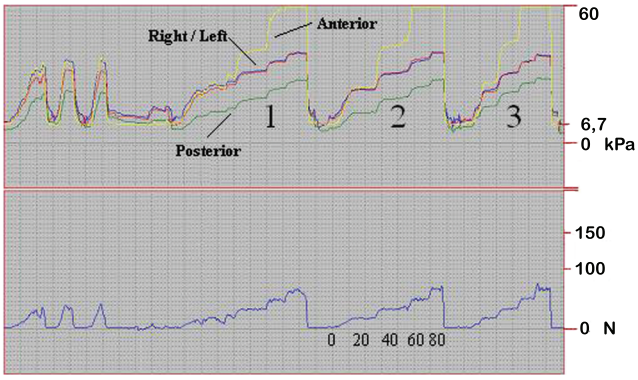

Figure 3

A print from the MKR digital data acquisitioning system. Graphic representation of the exerted pressure (kPa) on the cuffs (upper panel) at four locations upon application of stepwise (20N per step) increasing pulling forces (N) to the PCCD (lower panel). 1, 2, and 3 represent effects of triplicate measurements of tightening and subsequent release of a PCCD. In each case, the pressure dropped to baseline upon release of the PCCDs.

Statistical analysis

The means of all signals were calculated with MKR viewer (version 3.3.1., Direction Information, Erasmus MC) over manually selected intervals of approximately three seconds at sequenced levels of gradually increased pulling force of 20N per step. For each interval the applied gauge force and the difference in pressure were corrected for baseline values. The data was further processed using GraphPad Prism, version 4.00.

RESULTS

The non-invasive pressure cuffs behaved elastically. Upon fastening and releasing the PCCDs, the cuffs always returned to their original state and calibrated pressure. A stepwise increase in tension resulted in a stepwise increase in exerted pressure (Figure 3). The mean exerted pressure series on day one and day two are illustrated (Figure 4). All twelve bar graphs show a linear trend for the exerted mean pressure on day one and two. The exerted pressure varies substantially, both between the different locations as well as between the different PCCDs. In order to calculate the average maximum pressure when strictly following the application instructions of the manufacturers, data of the six replicates were combined. The average maximum exerted pressure on the right location is 23.3 kPa for the Pelvic Binder®, 18.9 kPa for the SAM-Sling® and 19.9 kPa for the T-POD®. Likewise, the average maximum pressure is 21.3 kPa, 27.5 kPa and 19.2 kPa at the left location, 18 kPa, 11.5 kPa and 15.3 kPa at the posterior location and 2.7 kPa, 18.4 kPa, and 51.2 kPa at the anterior location, respectively.

An exerted pressure of 10 kPa is achieved with the Pelvic Binder® and the T-POD® when a pulling force of 20 N is applied. For the SAM-Sling®, on the other hand, a pulling force up to 40 N must be applied before the exerted pressure reaches 10 kPa.

An apparent observation is that measurements using the SAM-Sling® structurally produced higher mean pressures on the left location as compared to the right location. The measured exerted pressure on day one was markedly higher than the exerted pressure on day two.

With all three different PCCDs the exerted pressure on the posterior location was generally lower than the pressure measured at the right and left location. At the anterior location, the pressure exerted by the different PCCDs varied. Pressures with the Pelvic Binder® did not exceed 4 kPa, whereas with the T-POD® the pressure reached values that exceeded 52 kPa (Figure 4).

DISCUSSION

The measurements in this study provided insight into the pressure build-up by the three different PCCDs at the interface at four locations when using a novel simplified, artificial model of the human pelvis. Since the shape of the model does not reflect the anatomy of the human pelvis, extrapolation of the data to the human situation should be done with great caution. Knowing the pulling force at which the pressure exerted by PCCDs exceeds the tissue damaging level (9.3 kPa) is relevant from a clinical point of view, as that will indicate the risk of developing soft tissue damage upon prolonged use.

The finding that pressures returned to baseline upon release of the PCCDs implies that hysteresis (a property of systems that do not return completely to their original state, depending on its immediate history) has not affected these measurements. This is perceptible in Figure 3. The linear trend between mean exerted pressure and mean force was expected. The finding that mean pressures of both days were most alike for the T-POD® might imply that reproducibility of the measurements was best when using the T-POD®. Measurements

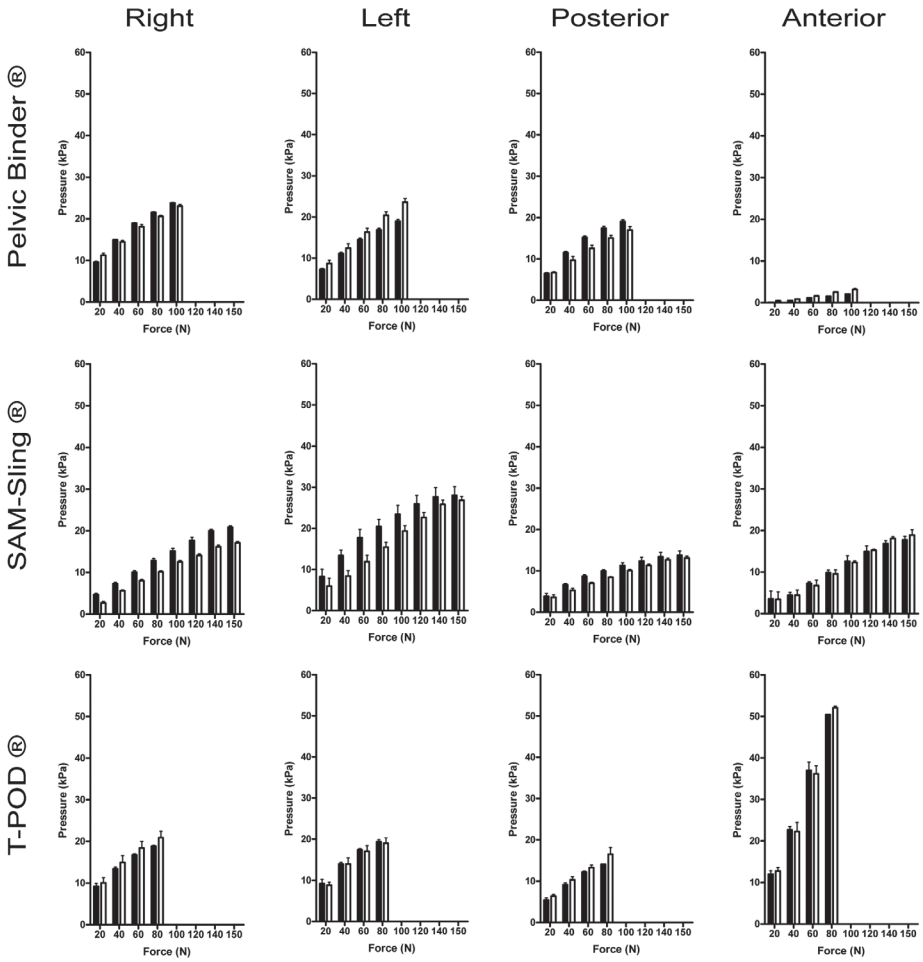

Figure 4 Exerted pressure by three different PCCDs

For each PCCD triplicate measurements were performed on two consecutive days at the right, left, posterior and anterior locations.. The mean exerted pressure series on day one (black bars) and day two (white bars) are illustrated. For each PCCD the error values: mean pressure and the Standard Error of the Mean (SEM) are represented. The y-axis scale shows the mean exerted pressure (kPa) from 0 to 60 kPa. The x-axis shows the mean pulling force (N) with a categorical 20 N interval and ends with 150 N. This categorical deviance at 150 N is due to the SAM-Slings auto-stop buckle. Measurements were performed according to manufacturer application instructions.

with the SAM-Sling® were subjected to the highest "between-day" variations. Measurements with the SAM-Sling® showed the lowest pressure build-up at the right and posterior locations and measurements with the T-POD® showed the lowest pressure build-up at the left location.

The most important differences between the binders are the closing mechanisms or fasteners and the size of the slings (Figure 1A-C). The Pelvic Binder® has a shoelace mechanism which is liable to friction, causes a wedge shaped tightened binder, and results in increased pulling force. The SAM-Sling® has an auto-stop buckle (limited at 150 N) and needs to be pulled together with two hands in opposite direction.

The sling is relatively small as opposed to the other two PCCDs. It has the advantage of leaving more space for clinical diagnostics or entrance to the abdomen and the disadvantage of early misplacement at the level of the trochanters. The T-POD® has a mechanical advantage pulley system and only a small amount of pulling force is needed to accomplish simultaneous circumferential compression.

A quantification of the exerted pressure in the model showed that, when a standardized pulling force was put upon the PCCDs using the gauge, the pressure varied at the different locations underneath the PCCDs. There was a markedly difference between the different types of PCCD. Some of this variation is caused by the differences in the designs and the closing mechanisms of the PCCDs. Right location and left location mean pressure differences can be explained for the SAM-Sling® and the T-POD® as follows. The Velcro-belt of the SAM-Sling® is pulled tight through the auto-stop buckle with two hands in opposite directions, but most of the force is provided towards the right-hand side (left location), while facing the model. The pulling force first encounters the left location, thereby exerting a higher pressure on the left location than on the opposite right location. In contrast, the design of the T-POD® accounts for slightly higher mean pressures on the right location because this device is pulled tight in the opposite direction; towards the right-hand side in a straight line, while facing the model. The T-POD® is pulled tight against the substratum, the right location.

Because the measurements have been performed with the model in an upright position, the exerted pressure at the posterior location is due to the pressure delivered by the binder, and not by the gravitation. The exerted pressure on the posterior location in the current model is generally lower than the pressure measured at the right and left locations. A reason for this is that the posterior reference point is the farthest point from the fastener. The pulling force is not completely proportional passed on both right and left locations because of opposing friction forces. In clinical practice, the pressure at the posterior location will probably be higher, as patients will be in a supine position. In such situations, the resulting pressure at the posterior location (i.e. posterior pelvic region and the sacrum) will be a combination

of the bodyweight of the patient and the pressure exerted by the binder. As a consequence, it is to be expected that in clinical situations the posterior pressure will be the highest of all four pelvic locations.

The mean pressure at the anterior location was difficult to assess and not reproducible for day one and two, although repeatability of multiple measurements on the same day showed only marginal differences in reproducibility. Major differences in closing mechanisms (i.e., shoelace *versus* auto-stop buckle *versus* pulley system) may be an explanation for these differences in exerted pressure. The exerted pressure with the T-POD® at the anterior location is very high as the fastener strings were cutting in the pressure cuff. In general, the data for the T-POD® show that the anterior location could form a risk-bearing area for the development of vascular insufficiency to skin tissue, especially in adipose persons (enlarged circumference with protrusive tissue). Placing a cover beneath the closing mechanism to protect the substratum might be a recommendable improvement.

CONCLUSION

The circumferential compression by the different PCCDs showed high pressures measured at the four locations using a simplified artificial model. Difference in design and functional characteristics of the PCCDs resulted in different pressure build-up at the four locations. When following the manufacturer's instructions, the exerted pressure of all three PCCDs tested exceeded the tissue damaging level (9.3 kPa) in case of prolonged use. If these results were to be carefully extrapolated to a clinical setting, all three binders would cause a risk for skin problems, with regard to the exerted pressure.

Clinical research is necessary in order to measure the exerted pressure and resulting reduction characteristics of the different PCCDs *in vivo*. This may contribute to optimizing the application protocol of the current PCCDs for patients with pelvic fractures, and could also aid in the development of effective and safe PCCDs.

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Chapter 5

Randomized Clinical Trial Comparing Pressure Characteristics of Pelvic Circumferential Compression Devices in Healthy Volunteers

Injury, Int. J. Care Injured 2011;42(10):1020-1026

S.P. Knops, E.M.M. Van Lieshout, W.R. Spanjersberg, P. Patka, I.B. Schipper

Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

ABSTRACT

Introduction: The role of Pelvic Circumferential Compression Devices (PCCDs) is to temporarily stabilise a pelvic fracture, reduce the volume and tamponade the bleeding. Tissue damage may occur when PCCDs are left in place longer than a few hours. The aim of this randomised clinical trial was to quantify the pressure at the region of the greater trochanters (GTs) and the sacrum, induced by PCCDs in healthy volunteers.

Materials and methods: In a crossover study, the Pelvic Binder®, SAM-Sling® and T-POD® were applied successively onto 80 healthy participants in random order. The pressure was measured using a pressure mapping system, with the volunteers in supine position on a spine board and on a hospital bed. Data were analysed using Mixed Linear Modelling.

Results: On a spine board, the pressure exceeded the tissue damaging threshold at the GTs and the sacrum. Pressure at the GTs was highest with the Pelvic Binder®, and lowest with the SAM-Sling®. Pressure at the sacrum was highest with the Pelvic Binder®. The pressure at the GTs and sacrum was reduced significantly for all three PCCDs upon transfer to a hospital bed.

Conclusion: The results of this randomised clinical trial in healthy volunteers showed that patients with pelvic fractures, temporarily stabilised with a PCCD, are at risk for developing pressure sores. The pressure on the skin exceeded the tissue damaging threshold and is, besides PCCD type, influenced by BMI, waist size and age. Regardless with which PCCD trauma patients are stabilised, early transfer from the spine board is of key importance to reduce the pressure to a level below the tissue damaging threshold. Clinicians should be aware of the potential deleterious effects associated with the application of a PCCD, and every effort must be made to remove the PCCD once hemodynamic resuscitation has been established.

INTRODUCTION

Pelvic ring fractures often result in massive haemorrhage. Related mortality rates range from 5 to 55%, depending on the fracture type and overall injury severity. [8,20] Fracture reduction and stabilisation reduce the inner pelvic volume and concomitant blood loss, and may tamponade massive venous haemorrhage. [13,26] Massive hemorrhage in poly-traumatised patients causes hypotension and impaired perfusion of the skin, which enhances local tissue hypoxia, ultimately followed by necrosis. [1] According to the Advanced Trauma Life Support® (ATLS®) guidelines, all patients with suspected pelvic ring injury should receive immediate application of pelvic ring compression. [12] For this purpose, non-invasive pelvic circumferential compression devices (PCCDs) can be applied pre-hospital, i.e., at the accident scene, or ultimately at the emergency department. PCCDs act as a temporary fixation of the pelvis until surgical fixation interventions can be initiated, or until unstable pelvic fractures are excluded on radiographic examination. PCCDs act by imposing pressure to the pelvis. This pressure also involves the overlying skin, which induces associated risks for developing skin breakdown. In severely injured patients, such as patients with pelvic fractures, these preventable complications should receive early attention.

PCCDs seem to be effective in early stabilisation of unstable pelvic fractures. [2,3,7,13,25] The results of cadaveric biomechanical studies by Bottlang et al. [2,3] suggested that, for optimal reduction of open-book pelvic fractures, a pelvic sling should be applied around the greater trochanters and the symphysis pubis and should be tensioned to 180 N. The reduction with a prototype strap at the level of the greater trochanters was characterised by a strap–skin interface pressure of 24 mm Hg (=3.2 kPa). [3] Clinical data to support that the exerted pressure on the skin with PCCDs would cause adverse effects on skin viability are limited.

Skin damage associated with the use of pelvic binding with various methods and devices, including PCCDs, has been described in a systematic review. [25] Skin breakdown at the level of the symphysis and bilaterally around the greater trochanters (GTs) following circumferential pelvic anti-shock sheeting (folded sheet) was reported by Schaller et al. [23]. This implies the need to avoid over-tightening and prolonged use of pelvic compression over the skin. Krieg et al. [14] reported skin necrosis over the area of PCCD application for a patient with an unstable pelvic ring injury and associated Morel–Lavallee lesion (i.e., closed internal degloving injury). Soft-tissue injury, caused by the initial trauma, frequently accompanies severe pelvic trauma. [15,22] Jowett and Bowyer [10] studied effects of PCCDs in 10 healthy individuals and reported that the use of PCCDs might carry a risk of pressure sores and additional skin necrosis. However, prospective data concerning influence of PCCDs on morbidity and complications are lacking.

Tissue damage (e.g., pressure sores and skin necrosis) may occur when pressures above 9.3 kPa are sustained continuously for more than 2–3 h. [27] Pressure sores are best seen as potentially preventable complications of acute immobility. Patients suffering from high-energy trauma are often immobilised on spine boards with cervical collars, to prevent aggravation of injuries during transfer to the hospital. Immobilisation is most often continued until diagnostic imaging rules out spinal injury and frequently lasts up to 3 h. [16] Immobilisation on a spine board is a well-known potential risk factor for development of pressure sores. [6,18] Most of the research on and development of PCCDs focuses on long-term lying comfort on various surfaces [11] and not so much at distribution of pressure at specific sites. [9,24]

The aim of this randomised controlled trial was to quantify the exerted pressures of PCCDs on the skin in a 'best case' scenario with healthy volunteers at the region of the GTs and sacrum.

MATERIALS AND METHODS

Study design

Eighty healthy volunteers aged 18–70 years, without a history of pelvic or low back problems were enrolled in this randomised clinical trial (Registration number: NTR1214 (http://www.trialregister.nl)). Proportional distribution of volunteers in different BMI strata (<18.5,

Table 1 Product description.

PCCD	Product details
	**Pelvic Binder®** • One size fits all, "cutt-to-fit" 6–8 in. Gap • Velcro-backed fastener with shoelace mechanism • Health care providers should be able to insert at least two fingers between the patient and the binder after maximal tensioning
	**SAM-Sling®** • Sized to fit, three different standard sizes • Fastener with an Autostop buckle (33 lb) that limits circumferential compression • Pulled tight with two hands in opposite directions • Small belt, leaving more space for clinical diagnostics or entrance to the abdomen in case of laparotomy
	**T-POD®** • One size fits all, "cut-to-fit" 6–8 in. gap • Simultaneous circumferential compression through Velcro-backed mechanical advantage pulley system with a pull-tab • Health care providers should be able to insert two fingers between the patient and the T-POD after maximal tensioning

Product description of the currently available pelvic circumferential compression devices. Pelvic Binder® (Pelvic Binder Inc., Dallas, TX, USA), SAM-Sling® (SAM Medical Products, Newport, OR, USA), T-POD® (Bio Cybernetics Inter-national, La Verne, CA, USA).

18.5–24.9 and ≥25.0 kg/m^2) was pursued. Signed informed consent was obtained from each volunteer. The study was performed with approval of the local Medical Ethics Committee.

Three commercially available PCCDs were tested: Pelvic Binder®, SAM-Sling® and T-POD® (Table 1). The PCCDs were applied in random order by the principal investigator (SPK), who could not be blinded. A cross-over design was chosen to minimise the influence of biological variation. The measurements were performed using a force sensing array (FSA) pressure mapping system (Vista Medical Ltd., Winnipeg, Canada), which was operated by the principal researcher. This system consists of a pressure-sensing mat comprised of thin, flexible fabric piezo resistive sensors (16 x 32), forming an array. The sensing area of the mat is 81.3 cm x 40.6 cm.

Data were transferred to a computer using a Parani SD200 BlueTooth adapter (Vista Medical Ltd., Winnipeg, Canada). The computer software (FSA Version 4.0) allowed for viewing, annotating and storing of information for all sensors. The FSA software generates a pressure distribution (pressure map), which is a visual representation of the normal forces between the surfaces of the skin and the PCCD.

The FSA-system was calibrated prior to the first measurement, using a Calibration Jig and an aneroid sphygmomanometer (calibration range: 0–300 mm Hg). A second calibration was performed upon completion of the study.

Study protocol

The body mass index (BMI) was calculated and waist size (circumference at the level of the GTs) was measured of all volunteers. Whilst lying on a spine board, the FSA-mat was placed loosely around the pelvis of the volunteer. Only underwear was worn under the FSA-mat. Volunteers were instructed to lie still in supine position with their legs extended next to each other (Figure 1). The three different PCCDs were applied over the FSA-mat respectively, strictly following the recommendations of the manufacturers. To exclude carry-over effects and to prevent any risks for the volunteers an interval of 30 min between measurements with the different PCCDs was taken. Pilot recordings showed that the FSA-mat itself (i.e., without PCCD around it) does not give a pressure profile, therefore no baseline correction was needed. From pilot measurements it was furthermore noted that pressures returned to baseline levels immediately upon loosening of the PCCD (data not shown).

Measurements were performed whilst volunteers were lying on a spine board and secondly after transfer onto a hospital bed, representing the pre-hospital and hospital situation, respectively. The transfer was made through a log roll manoeuvre. The PCCDs remained tensioned during the entire measurement period. At the end of the measurement on the spine board

Figure 1 The measurement setup
A first measurement was performed with the volunteer situated on a spine board with application of the FSA-mat around the pelvis and a SAM-Sling® in situ. The PCCDs were applied following the instructions of the manufacturer. A second measurement was performed after transfer of the volunteer from the spine board to a hospital bed through a log-roll manoeuvre. The PCCDs remained tensioned between these two consecutive measurements.

as well as on the hospital bed, the location of the GTs was determined by palpation. The corresponding FSA-mat sensor codes were registered. After completion of measurements, all files were blinded for data extraction and data analysis.

Outcome measures

The primary outcome measure was the exerted maximum pressure on the skin in the pelvic region, expressed in kilo Pascals (1 kPa = 7.5 mmHg). The absolute pressure and the pressure gradient and number of cells exceeding 9.3 kPa served as secondary outcome measures. All are relevant, since it is not only the pressure level per se, but also the pressure at a given location relative to the surrounding area that indicates the risk of developing pressure-related complications. The exerted pressure was recorded continuously, with a scan frequency of 5 Hz. Pilot measurements had revealed stabilisation of pressure within 5 min, therefore the following two time points were chosen for analyses: 5 min after application of the PCCD whilst lying on a spine board, and 5 min after the transfer to a hospital bed.

In the pressure distributions of all volunteers the sensors corresponding with the palpated right and left GT were manually selected including the sensors surrounding the palpated sensor. In this way a pressure window (area of 9 sensors) was selected wherein the value of the sensor with the maximum pressure (kPa) was identified. The absolute pressure recorded with that sensor was taken as outcome measure at the location of the GT. An additional way to review the data is to look at the pressure gradient. Mueller et al. [21] described this pressure variable as an indicator of skin injury (plantar neuropathic ulcers). They defined the pres-

sure gradient as a spatial change in pressure around the maximum pressure and a potential useful indicator of skin trauma. The pressure gradient has been used before as a mechanical parameter in combination with a force sensing array. [19] In order to determine the maximum pressure gradient, the pressure gradient between the palpated sensor and its eight surrounding sensors was calculated, and expressed as kPa/cm. The maximum pressure gradient is a measure for the highest absolute pressure gradient. The maximum pressure gradient was calculated for the same pressure window at the GT areas.

Three parameters were analysed for the sacrum location because the FSA-system was limited to 40 kPa (300 mm Hg) due to the calibration. First, the highest average pressure was selected manually within a pressure window spanning the area of the sacrum. Secondly, the true recorded pressure, of the sensor that was selected as the sensor with the highest average pressure, was selected as the maximum pressure. Third, the number of cells with a pressure exceeding 9.3 kPa within this pressure window was counted.

Data analysis

Statistical analyses were performed using the Statistical Package for the Social Sciences, Version 16 (SPSS, Chicago, IL, USA). The sample size in this study was based upon a measured mean pressure (13.4 ± 6.0 kPa) for the Pelvic Binder® at the sacrum. [10] The current study was powered (alpha 0.05 and beta 0.20) to detect a difference of 3 kPa between the different devices.

Normal distribution of continuous variables (e.g., maximum pressure, pressure gradient, age, BMI, and waist size) was confirmed using the Kolmogorov–Smirnov test. Homogeneity of variance between groups was confirmed using the Levene's test. Mixed linear models [4,17,28] were developed in order to test for any confounding effect of BMI, waist size, period (sequence of application based upon randomisation), PCCD type, age, or gender on the pressure (dependent variable). All potential confounding variables were entered into the model in a stepwise order. The type of PCCD, period, BMI, waist size, age, and gender were included as fixed effects, and subject number was included as random effect. Residual maximum likelihood (REML) covariance modelling was applied, using sum of square (SS) type 3 and covariance type covtype (vc). Next, the findings resulting from the stepwise model building approach were cross-validated and confirmed by entering all variables into the model at the same time in order to see the impact of each when considered alongside the others. Post-hoc pair-wise comparisons (i.e., paired t-test) were performed in order to assess statistical significance of differences between the PCCD types. Bonferroni correction was applied, and adjusted *p*-values following correction for multiple testing are provided. A p-value < 0.05 was taken as level of statistical significance.

RESULTS

Demographic description of study population

A demographic description of the study population is shown in Table 2. The majority of the 80 individuals enrolled, was female (N = 49). Overall, the participants had a mean age of 29 ± 12 years and a BMI of 23 ± 3 kg/m^2. There were no statistically significant differences between males and females with respect to age, BMI, and waist size.

Table 2

	All	Males	Females	p-Value
Individuals	80 (100.0)[a]	31 (38.8)	49 (61.3)	
Age (years)	29.1 ± 11.8[b]	27.4 ± 8.7	30.1 ± 13.4	NS[c]
BMI (kg/m^2)	23.0 ± 3.3[b]	24.0 ± 2.8	22.4 ± 3.5	0.002[c]
< 18.5	3 (3.8)[a]	0 (0.0)	3 (6.1)	NS[d]
18.5 – 24.9	59 (73.7)[a]	21 (67.7)	38 (77.6)	
≥ 25.0	15 (22.5)[a]	10 (32.3)	8 (16.3)	
Waist size (cm)	98.1 ± 7.1[b]	98.5 ± 5.9	97.8 ± 7.8	NS[c]

Demographic description of the study population.

BMI, body mass index; NS, not significant.

[a] Numbers of participants are displayed, with the percentages given within brackets.

[b] Data are displayed as mean_SD.

[c] Student's t-test.

[d] Chi square test.

Each type of PCCD displayed unique pressure characteristics, as shown in Figure 2. The SAM-Sling® comes in three sizes. In this sample, 70% of the volunteers were fitted with the medium size SAM-Sling®. The two Velcro straps of the Pelvic Binder® caused increased pressures as shown by the imprint (area of increased pressure). The SAM-Sling® and T-POD® showed a pressure peak (exceeding 40 kPa) at the area of the sacrum whilst volunteers were lying on the spine board. Overall, three areas of high pressure were identified: the right and left greater trochanter (GTR and GTL), and the sacrum.

Pressure at the greater trochanters

The maximum pressure (Pmax) at the area of the GTs is shown in Figure 3. Whilst lying on a spine board, the maximum pressure on the skin at the area of the GTR exceeded 9.3 kPa with all three PCCDs. The Pelvic Binder® exerted the highest Pmax (12.2 ± 3.5 kPa), which was higher than that of the T-POD® (10.7 ± 2.6 kPa, p = 0.005). The Pmax at the area of the GTL exceeded the tissue damaging threshold of 9.3 kPa only with the Pelvic Binder® (9.6 ± 4.6 kPa) and was higher than the Pmax caused by both the SAM-Sling® (7.1 ± 3.2 kPa, p < 0.001) and

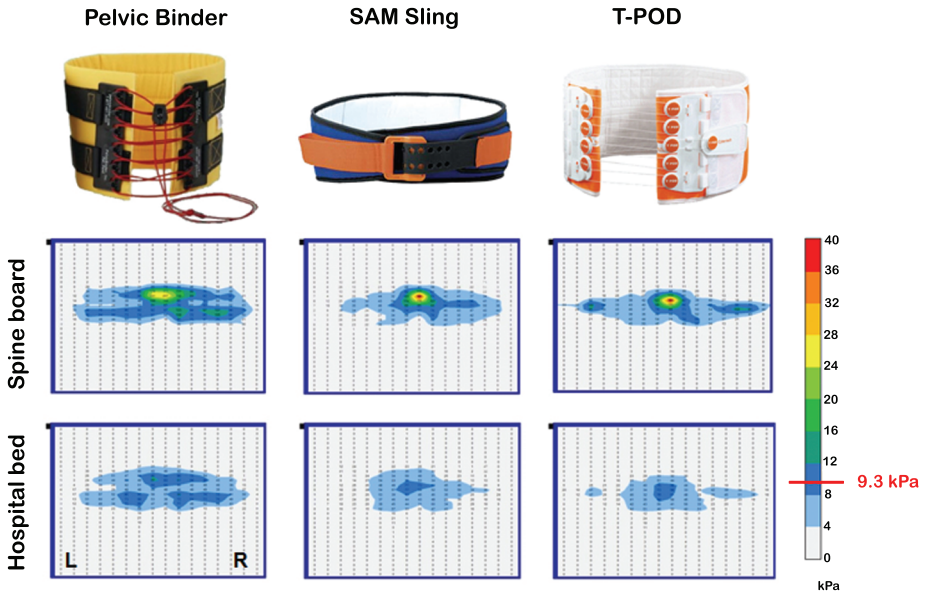

Figure 2 Visual representation of the exerted pressure.
A visual representation (imprint) of the exerted pressure (kPa) generated by the FSA software, between the surfaces of the skin and the PCCD after application of a PCCD on a spine board and after the transfer to a hospital bed. L and R mark left and right sides, respectively. The green/yellow/red (>18 kPa) area in the spine board measurements in the middle is the area of the sacrum. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

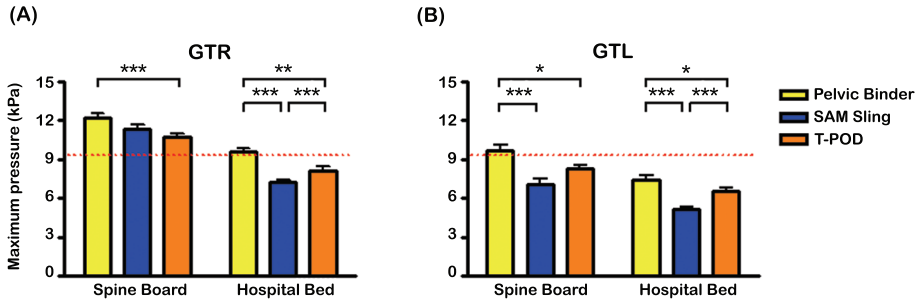

Figure 3 Exerted maximum pressure on the right and left greater trochanters.
The maximum pressure (kPa) measured with the FSA-system at the area of the right (GTR) and left greater trochanters (GTL) for all three PCCDs on the spine board and after the transfer to a hospital bed. The trochanters were palpated and the maximum pressures of the corresponding sensors were analysed in a mixed-linear model and corrected for BMI, waist size, age and gender. The dashed red line indicates the tissue damage level (9.3 kPa). The bars marked with an asterisk indicate statistical significance between two types of PCCDs (*$p < 0.05$; **$p < 0.01$; ***$p < 0.005$). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

the T-POD® (8.3 ± 2.4 kPa, p = 0.014). Using the SAM-Sling®, the Pmax increased with age (p = 0.031). No correlations with the Pmax were found with BMI, waist size or age on a spine board at the area of the GTs.

Upon transfer to a hospital bed, a considerable reduction in pressure was observed with all PCCDs, in most cases to a level below 9.3 kPa (Figure 3). The Pmax at the GTR was lowest with the SAM-Sling® (7.2 ± 1.9 kPa). Only the Pmax at the GTR with the Pelvic Binder® remained above 9.3 kPa; 9.6 ± 2.4 kPa. Pairwise comparisons between the PCCD types revealed statistical significant differences between all PCCD types as long as the volunteers were lying on a hospital bed (p < 0.050). A negative correlation was found between age and the Pmax levels at the GTR with the Pelvic Binder® (p = 0.022) and the T-POD® (p = 0.014).

The Pmax at the GTL was highest with the Pelvic Binder® (7.4 ± 3.1 kPa) and lowest with the SAM-Sling® (5.1 ± 1.9 kPa). Similarly as described above, pairwise comparisons between the PCCD types indicated statistically significant differences between all PCCDs (p < 0.010). With all three PCCDs, a negative correlation between Pmax and BMI (p = 0.019) and between Pmax and waist size (p = 0.004) was found. Whilst lying on a hospital bed, the pressure at the GTs was inversely correlated with BMI (p < 0.020), waist size (p < 0.005) and age (Pelvic Binder® and T-POD® p < 0.020).

Subsequently, the maximum pressure gradient (kPa/cm) was analysed at the area of the GTs (Figure 4). At the GTR, the pressure gradient was highest with the use of the Pelvic Binder® (2.0 ± 0.9 kPa/cm) and lowest with the T-POD® (1.3 ± 0.6 kPa/cm). The pressure gradient diminished upon transfer to a hospital bed; at that point the pressure gradient remained

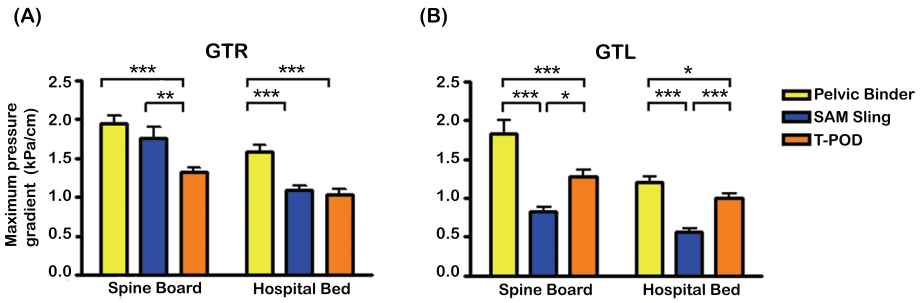

Figure 4 Maximum pressure gradient over the right and left greater trochanters.
The maximum pressure gradient (kPa/cm) measured with the FSA-system at the area of the right (GTR) and left greater trochanter (GTL) with all three PCCDs on the spine board and after the transfer to a hospital bed. The trochanters were palpated and the maximum pressure gradient of the corresponding sensors were analysed in a mixed-linear model and corrected for BMI, waist size, age and gender. The bars marked with an asterisk indicate statistical significance between two types of PCCDs (*p < 0.05; **p < 0.01; ***p < 0.005).

highest with the Pelvic Binder® (1.6 ± 0.7), which was statistically significantly higher than with the use of the other two PCCDs ($p < 0.001$). With all three PCCDs, the pressure gradient was lower in females than in males ($p = 0.017$).

For the GTL, the pressure gradient was highest with the Pelvic Binder® and lowest with the SAM-Sling®, both whilst lying on the spine board and in a hospital bed. In both situations, all pairwise comparisons reached statistical significance ($p < 0.015$ for the spine board, $p < 0.045$ for the hospital bed).

Pressure at the sacrum

In addition to the trochanters, a large area at risk was seen at the sacrum, for which three parameters were analysed. Measurements of the first parameter, the average pressure at the sacrum, are presented in Figure 5A. Whilst lying on a spine board, this pressure was higher than the tissue damage threshold of 9.3 kPa with all PCCD types. The average pressure reduced significantly upon transfer to a hospital bed, in most cases only marginally below

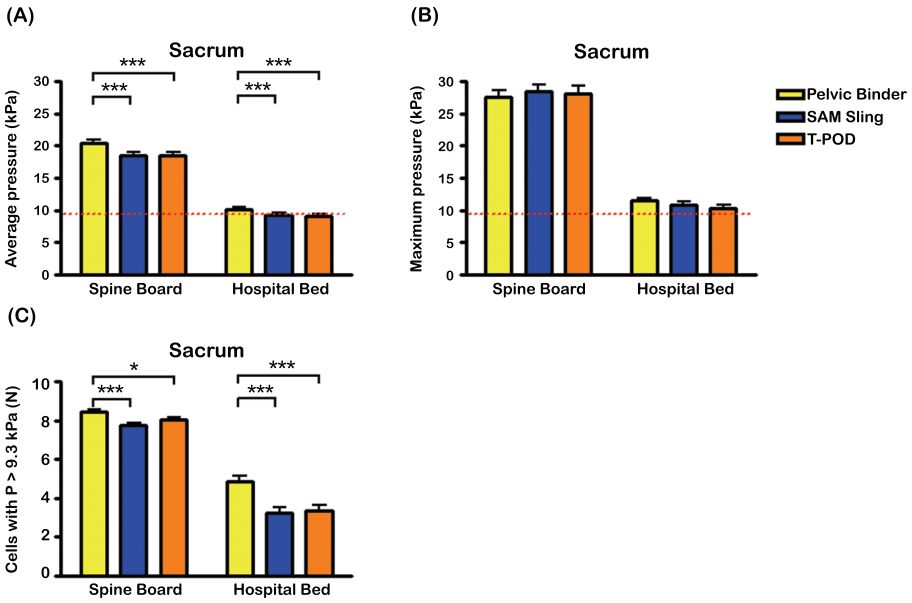

Figure 5 Exerted pressure at the area of the sacrum

A) the average pressure (kPa), (B) the maximum pressure (kPa) and (C) the number of cells with a pressure exceeding 9.3 kPa (N) measured with the FSA-system at the area of the sacrum with all three PCCDs on the spine board and after the transfer to a hospital bed. A pressure window at the sacrum was manually selected and the pressures of the corresponding sensors were analysed in a mixed-linear model and corrected for BMI, waist size, age and gender. The dashed red line indicates the tissue damage level (9.3 kPa). The bars marked with an asterisk indicate statistical significance between two types of PCCDs (*$p < 0.05$; **$p < 0.01$; ***$p < 0.005$). (For interpretation of the references to color in this figure legend, the reader is referred to the web version of the article.)

9.3 kPa. Pressure exerted by the Pelvic Binder® was higher than the exerted pressure by the SAM-Sling® ($p < 0.004$) and the T-POD® ($p < 0.001$) in both situations. Whilst lying in a hospital bed, pressure was statistically lower for females than for males ($p = 0.012$).

Results on the second parameter, the maximum pressure at the sacrum, are presented in Figure 5B. Whilst lying on a spine board, the pressure exceeded the upper threshold of the FSA-system (40 kPa; 300 mm Hg) in 37 volunteers (46%) with either one of the three PCCDs. In 16 volunteers (20%) the pressure exceeded the threshold with all three PCCDs. The pressure exceeded the threshold of the FSA-system in 21 volunteers with Pelvic Binders®, 24 volunteers with SAM-Slings® and 22 volunteers with T-PODs®. There was a distinct decrease in the exerted pressure after the transfer to a hospital bed; however, levels remained higher than 9.3 kPa. No statistically significant differences between types of PCCDs were noted. Pressures recorded in females were lower than those recorded for males ($p < 0.005$), both whilst lying on the spine board and the hospital bed.

In order to get more insight into the size of the pressure area at the sacrum, a third parameter, the number of measuring cells displaying a pressure higher than 9.3 kPa, was calculated (Figure 5C). The area at risk was higher with the Pelvic Binder® compared to the SAM-Sling® ($p < 0.001$ in both measurement settings) and the T-POD® ($p = 0.018$ on the spine board and $p < 0.001$ on the hospital bed). Whilst lying on a spine board, the size of the pressure area at the sacrum was positively correlated with BMI ($p = 0.013$), waist size ($p < 0.001$) and inversely correlated with age ($p < 0.030$). Whilst lying in a hospital bed no correlations were found with BMI, waist size or age. The pressure area at risk was smaller in females than in males ($p < 0.010$), both whilst lying on the spine board and the hospital bed.

DISCUSSION

The PCCDs that were tested in this randomised clinical trial are primarily designed for reduction of the pelvic volume and stabilisation of the bony elements after fracture, thereby reducing haemorrhage. The role of PCCDs is temporary, for transfer and transient situations in the hospital. The pressure needed to accomplish pelvic ring reduction may put the underlying skin at risk of tissue damage. Upon achievement of hemodynamic stability, the PCCD should therefore be removed as soon as possible in order to prevent associated risks of skin necrosis. The aim of the current study was to quantify the PCCD induced skin pressure, in order to determine to what extent the skin might be at risk for developing necrosis and associated tissue problems due to PCCD related high pressures. The three most commonly used PCCDs for which literature data was available were selected based upon our previous systematic literature review. [25]

The pressure measurements with the FSA-system showed that each type of PCCD produced a unique pressure distribution pattern. These patterns are direct results of the PCCD design. The TPOD® is equipped with a mechanical advantage pulley system and tensioning could theoretically severely increase circumferential compression. The Pelvic Binder® has a shoelace mechanism which causes friction and a wedge shaped tightened binder. Although the application protocol for the T-POD® and Pelvic Binder® are identical, the exerted pressure by the Pelvic Binder® was significantly higher and its straps caused an uneven pressure distribution. In general, the pressure at the right greater trochanter (GT) was markedly higher than at the left GT. For the T-POD® and SAM-Sling® that might be attributed to the application mechanism; pulling to the left side of the study participant was expected to cause a higher pressure at the opposite side. No explanation can be given why a similar phenomenon also occurred when using the Pelvic Binder®, in which pulling forces are applied in the direction of the legs of the participant.

The Pelvic Binder® induced pressures exceeding the tissue damage pressure of 9.3 kPa, elicited the highest pressure on the skin, and showed the highest absolute pressure gradient of the three PCCDs. Consequently, the Pelvic Binder® could be considered as the PCCD with the highest potential risk for development of skin problems in case of prolonged use. The SAM-Sling® has a small belt, leaving more space for clinical diagnostics or entrance to the abdomen in case of a percutaneous interventional radiology procedure or laparotomy. We hypothesised that a small belt would be less successful in distribution of the pressure. Unexpectedly, the pressure exerted by the SAM-Sling® was lower than the pressure exerted by the Pelvic Binder® and the T-POD® at the area of the trochanters. This could be due to the fact that the auto-stop buckle of the SAM-Sling® limits the circumferential compression at a strap tension of 150 N. Moreover, the availability of different devices for different waist sizes may be beneficial.

At the sacrum area the pressures exerted by the SAM-Sling® and T-POD® were not statistically significantly different. Overall, the SAM-Sling® exerted the lowest pressure on the trochanteric skin. Limitation of the maximally exerted pressure by the auto-stop buckle of the SAM-Sling® might explain this finding. Whether the auto-stop buckle still allowed for proper compression of the pelvis is unclear from these results, as reduction of diastasis was not measured. The SAM-Sling® could be advocated in terms of the least risk for tissue damage.

Literature data indicate a relation between BMI and decubitus risk. Extra body fat reduces the risk of pressure sores. [5,10] The pressures that Jowett and Bowyer obtained in their study, demonstrated an inverse correlation with the BMI. In the current study the pressure at the GTL, whilst lying on a hospital bed, showed a similar inverse correlation with BMI ($p < 0.020$). There are no literature data supporting the finding that the exerted pressure with the use

of PCCDs is correlated with age, waist size or gender. In this study, whilst lying on a spine board, pressure at the GTs was correlated positively with age (SAM-Sling® only; $p = 0.031$). As opposed to this, on a hospital bed, the pressure was inversely correlated with age (Pelvic Binder® and TPOD® $p < 0.020$). On a hospital bed the pressure at the GTL was inversely correlated with waist size ($p < 0.005$). Whilst lying on a spine board the size of the pressure area at the sacrum correlated positively with waist size ($p < 0.001$). The origins of these differences in correlation with age and waist size remain unclear. The lower pressure levels ($p = 0.017$) and smaller high-pressure area ($p < 0.005$) seen in females might be due to the shape of the female pelvis (gynecoid-type) or to differences in fat distribution.

At the GTs and at the region of the sacrum there was a distinct reduction of exerted pressure on the skin after the transfer from the spine-board to the hospital bed, irrespective of the PCCD used. The observed reduction in pressure at the sacrum was to be expected. The observed reduction in pressure at the GTs upon transfer of the test subjects to a hospital bed is presumably due to a shift in the distribution of the exerted pressure throughout the entire PCCD. This pressure is not only reflected by a change of perpendicular forces, but also by a change of shearing forces between the surfaces of the skin and the PCCD. Therefore unnecessary prolonged immobilisation of patients with a PCCD on a spine board should be avoided. Furthermore, if prolonged application of a PCCD is necessary, the skin should be carefully examined at a daily base for any signs of tissue damage.

During the immobilisation phase the risk of inducing tissue problems like pressure sores and skin necrosis depends upon both local and systemic etiological factors. [27] Polytraumatised patients are often subordinated to these factors. Pressure on the skin is a local factor that may affect the risk of developing pressure sores; the lower the pressure, the lower the risk. Of the tested PCCDs, the SAM-Sling® and the T-POD® seemed to cause the least risk for skin problems in the setting of this trial, regarding the exerted pressure. Redesigning of PCCDs should be focused on material use and shape for optimal pressure distribution; however, clinical efficacy for achieving fracture reduction and haemostasis control should always prevail over risk reduction. Incorporation of controlled limitation of pressure (like the auto-stop buckle of the SAM-Sling®) or an objective measure of pressure could be recommended. In addition to redesigning PCCDs, there is also room for improvement of spine boards. Using spine boards with a softer topping will beneficial to all patients that need immobilisation due to (suspected) injuries.

As with most studies, a few limitations were associated with this study. First, the principal investigator was not blinded to the study hypothesis during application of the PCCDs. All PCCDs were applied by the principal investigator following proper training by an experienced trauma surgeon. The PCCDs were applied strictly according to manufacturer's recommenda-

tions. This trauma surgeon randomly checked and confirmed proper placement of the PCCDs in a subset or participants. In order to prevent further bias, all files were blinded after recording. This way, data extraction and further statistical analyses were done in a blinded fashion.

The FSA-system enabled several ways of quantification of the pressure at the areas of the GTs and the sacrum. It should be mentioned that the calibration of the FSA-mat was not performed 'in situ'. In the current study the FSA-mat was placed around the pelvis, for which no specific calibration was possible. Pre- and post-calibration were matching and confirmed stability of the FSA-system during the course of the study, thereby confirming reliability of the measurements. Furthermore it is not clear in what way shearing forces that might have occurred during fastening of the PCCD, may have influenced the measurements.

The results of this study should be confirmed in a trauma patient population through a randomised controlled trial, to also account for systemic influences, and the actual effectiveness in fracture reduction haemorrhage control. At this stage, it is not warranted to draw reliable conclusions on the clinical significance of the numeric differences between the different PCCDs in patients. The patient's systemic influence may dictate whether or not the pressures exerted to the skin by a PCCD will result in actual skin damage. It also remains unclear if a PCCD that yields the least skin pressure is also the most effective for reducing the pelvic volume. Data from clinical studies should be used to further optimise the application protocol of the current PCCDs for patients with pelvic fractures, and will help to design more effective and safer PCCDs.

CONCLUSIONS

The results of this randomised clinical trial using healthy volunteers showed that patients with pelvic fractures, temporarily stabilised with a PCCD, will be at risk for developing pressure sores. The PCCDs exerted pressures on the skin that generally exceeds the tissue damaging threshold of 9.3 kPa. The amount of pressure is influenced by the type of PCCD, BMI, waist size, age and gender. PCCDs have been proven to be clinically effective. [25] There is room for improvement of the PCCD design (e.g., include an objective pressure recording mechanism). Regardless with which pelvic circumferential compression device trauma patients are stabilised, early transfer from the spine board is of key importance to reduce the pressure to a level below the tissue damaging threshold. Clinicians should be aware of the potential deleterious effects associated with the application of a PCCD, and every effort must be made to remove the PCCD once hemodynamic resuscitation has been established.

Acknowledgements

The Fonds NutsOhra is greatly acknowledged for their financial support of this study (grant nr. SNO-T-0701-117). The data of the current study has been presented in the Best abstract session at the meeting 'Chirurgendagen 2009' (May 15, 2009, Veldhoven, The Netherlands).

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Huisman

Chapter 6

Comparison of the Three Different Pelvic Circumferential Compression Devices: a Biomechanical Cadaver Study

The Journal of Bone & Joint Surgery Am
2011;93(3):230-40

S.P. Knops[1], N.W.L. Schep[1], C.W. Spoor[2], M.P.J.M. van Riel[2], W.R. Spanjersberg[1], G.J. Kleinrensink[2], E.M.M. van Lieshout[1], P. Patka[1], I.B. Schipper[1]

[1] Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
[2] Department of Neurosciences and Anatomy, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands

Awarded the NVT Biomet Award 2011

ABSTRACT

Background: Pelvic circumferential compression devices are designed to stabilize the pelvic ring and reduce the volume of the pelvis following trauma. It is uncertain whether pelvic circumferential compression devices can be safely applied for all types of pelvic fractures because the effects of the devices on the reduction of fracture fragments are unknown. The aim of this study was to compare the effects of circumferential compression devices on the dynamic realignment and final reduction of the pelvic fractures as a measure of the quality of reduction.

Methods: Three circumferential compression devices were evaluated: the Pelvic Binder, the SAM-Sling, and the T-POD. In sixteen cadavers, four fracture types were generated according to the Tile classification system. Infrared retro-reflective markers were fixed in the different fracture fragments of each pelvis. The circumferential compression device was applied sequentially in a randomized order with gradually increasing forces applied. Fracture fragment movement was studied with use of a three-dimensional infrared video system. Dynamic realignment and final reduction of the fracture fragments during closure of the circumferential compression devices were determined. A factorial repeated-measures analysis of variance with pairwise post hoc comparisons was performed to analyze the differences in pulling force between the circumferential compression devices.

Results: In the partially stable and unstable (Tile type-B and C) pelvic fractures, all circumferential compression devices accomplished closure of the pelvic ring and consequently reduced the pelvic volume. No adverse fracture displacement (>5 mm) was observed in these fracture types. The required pulling force to attain complete reduction at the symphysis pubis varied substantially among the three different circumferential compression devices, with a mean (and standard error of the mean) of 43 ± 7 N for the T-POD, 60 ± 9 N for the Pelvic Binder, and 112 ± 10 N for the SAM- Sling.

Conclusions: The Pelvic Binder, SAM-Sling, and T-POD provided sufficient reduction in partially stable and unstable (Tile type-B1 and C) pelvic fractures. No undesirable over-reduction was noted. The pulling force that was needed to attain complete reduction of the fracture parts varied significantly among the three devices, with the T-POD requiring the lowest pulling force for fracture reduction.

Clinical Relevance: The results of this biomechanical cadaver study suggest that circumferential compression devices can provide early, non-invasive circumferential compression in partially stable and unstable pelvic fractures for advantageous realignment and reduction of these fractures without over-reduction. Clinical effectiveness of circumferential compression devices in patients with pelvic ring fractures remains to be determined.

INTRODUCTION

Pelvic fractures following high-energy trauma are frequently accompanied by massive hemorrhage and are considered potentially lethal injuries. Reported mortality rates for trauma patients with pelvic fractures have ranged from 5% to 55%, depending on the fracture type and overall injury severity.[1,2] It is commonly accepted that anatomic reduction and stabilization of pelvic fractures prevents further blood loss by limiting the bleeding from the fracture fragments and reducing the pelvic volume. In the majority of patients, the bleeding source is the injured sacral venous plexus or bone surfaces. Reducing the pelvic volume may therefore have a tamponading effect[3,4] and may consequently decrease blood loss and transfusion requirements.[5]

Early reduction and stabilization of pelvic fractures may lead to less blood loss and improved patient survival. This early reduction and stabilization should preferably be achieved at the scene of the accident and, at the latest, on arrival at the emergency department. Both invasive and non-invasive treatment modalities have been described. [3,5,6] However, invasive methods like the C clamp[7-10] and external fixators[11,12] are not feasible at the injury scene because application requires emergency department or operating-room facilities. Even in the hospital setting, these invasive measures often take considerable time to apply. Hence, various methods of early, fast, and non-invasive pelvic fracture stabilization have been applied. The most commonly known methods are bed-sheet wrapping[13,14], internal rotation and taping of the lower extremities[15], and, more recently, the application of a pelvic circumferential compression device.[3,16-26] Pelvic circumferential compression devices are commercially available pelvic wraps designed to stabilize the pelvic ring and to reduce the volume of the pelvis by controlled external circumferential compression.

Limited data are available on the efficacy of the pelvic circumferential compression devices. To our knowledge, only Level-III evidence[27] concerning their efficacy has been reported.[16] In a prospective cohort study, Krieg et al. described sixteen patients with partially stable and unstable pelvic ring fractures.[3] In the patient group with externally rotated fractures, the pelvic circumferential compression device significantly reduced the pelvic width. In the internal rotation group, the device did not cause over-compression. As it is unclear whether patients were consecutively included, a selection bias cannot be ruled out. Until now, the quality of reduction provided by the pelvic circumferential compression device for all types of pelvic fractures is uncertain, since the effect of the device on the position of the fracture fragments is unknown.

Before undertaking clinical trials, it is essential to establish the biomechanical effects of these devices through laboratory experiments. Therefore, the aim of this cadaver study was to com-

pare the effects of three commercially available pelvic circumferential compression devices on the dynamic realignment and final reduction of pelvic fracture fragments. These effects were considered a measure of the quality of reduction provided by the devices.

MATERIALS AND METHODS

A biomechanical cadaver study aimed to determine the quality of reduction induced by the pelvic circumferential compression devices in relation to the pulling force required for proper application. Three commercially available pelvic circumferential compression devices were evaluated: the Pelvic Binder (Pelvic Binder, Dallas, Texas), the SAM-Sling (SAM Medical Products, Wilsonville, Oregon), and the Trauma Pelvic Orthotic Device (T-POD; Bio Cybernetics International, La Verne, California) (Table 1). The three available sizes of the SAM-Sling(extra small, standard, and extra large) were used when indicated.

Table 1 Product description.

PCCD	Product details
	**Pelvic Binder**® (Pelvic Binder Inc., Dallas, TX, USA) • One size fits all, "cutt-to-fit" 6–8 in. Gap • Velcro-backed fastener with shoelace mechanism • Health care providers should be able to insert at least two fingers between the patient and the binder after maximal tensioning
	**SAM-Sling**® (SAM Medical Products, Newport, OR, USA) • Sized to fit, three different standard sizes • Fastener with an Autostop buckle (33 lb) that limits circumferential compression • Pulled tight with two hands in opposite directions • Small belt, leaving more space for clinical diagnostics or entrance to the abdomen in case of laparotomy
	**T-POD**® (Bio Cybernetics Inter-national, La Verne, CA, USA) • One size fits all, "cut-to-fit" 6–8 in. gap • Simultaneous circumferential compression through Velcro-backed mechanical advantage pulley system with a pull-tab • Health care providers should be able to insert two fingers between the patient and the T-POD after maximal tensioning

Product description of the three commercially available pelvic circumferential compression devices evaluated in this study (Pelvic Binder, SAM-Sling, and T-POD) with the product details and manufacturers' guidelines for their application.

Ten male and six female cadavers without a known history of pelvic fractures were randomly selected. The cadavers were embalmed forty-eight to seventy-two hours post mortem at room temperature, with use of a 6% paraformaldehyde solution. The specimens consisted of the complete pelvic region including all soft tissues, from the level of the third or fourth lumbar vertebral body and including the proximal two-thirds of both femora.

In order to identify anatomic regions and fracture fragments of the osseous pelvis, stainless steel pins, each with five retro-reflective markers, were firmly fixed adjacent to planned fracture lines (Figure 1A).

The pins were placed under fluoroscopic guidance close to the sacroiliac joint, close to the symphysis pubis, and on either side of the created fractures in the iliac and pubic bones. Pin position was confirmed with anteroposterior, inlet, and outlet fluoroscopic views. The pins re-

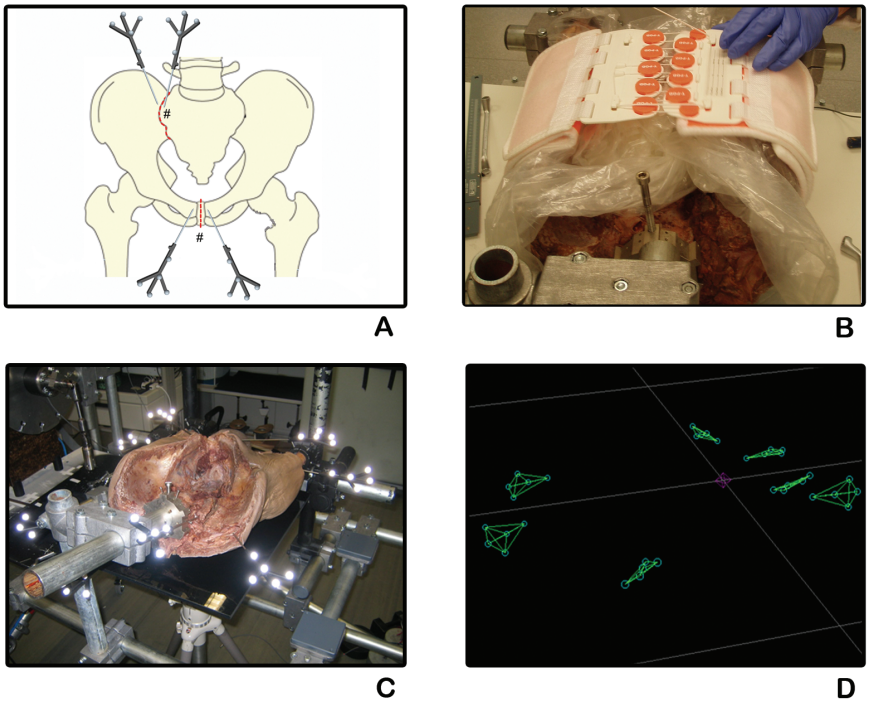
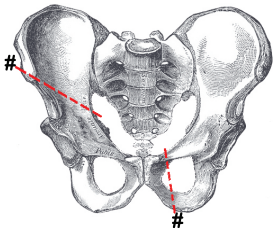
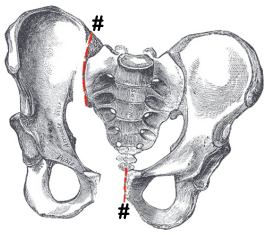
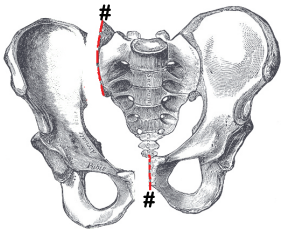


Figure 1 Overview of the measurement setting.
(A) Placement of stainless steel pins with five retroreflective markers close to the planned fracture sites for a Tile type-B1 fracture (fracture lines are indicated in red). Pins were placed close to planned fracture sites for all different fracture types and remained in place until the end of measurements. (B) A pelvic specimen screw-fixed with a lumbar clamp at the proximal lumbar vertebral body, with placement and tensioning of a pelvic circumferential compression device (T-POD). (C) Pelvic specimen with retroreflective markers fixed in a custom-made frame. (D) Visualization of a measurement with the Vicon software.

mained in place during application of the pelvic circumferential compression devices, which were rigidly fixed into the bone. Coordinates of the retro-reflective markers were recorded with use of a Vicon system (Vicon Motion Systems, Oxford, United Kingdom). The specimens were mounted in a custom-made frame on a platform, and the proximal lumbar vertebral body was screwfixed with a lumbar clamp to ensure standardized measuring (Figure 1B and C). Light emitted by infrared light-emitting diodes was captured by the cameras on reflection from the retro-reflective markers placed at the fracture sites (Figure 1C and D). Prior to each measuring session, static and dynamic calibrations were carried out according to the Vicon instruction manual. Static calibration was used to set the origin and the direction of the axes, and dynamic calibration was used to calculate the relative positions and orientation of the cameras.

Table 2 The study definitions of the pelvic fractures.

Classification	Stability	Study definition	
Tile A	Stable	A fracture in the os pubis was created 2 cm lateral from the symphysis pubis combined with a large fracture of the os ilium, ranging from the spina iliaca up to the tuber	
Tile B1 (50 mm) (100 mm)	Partially stable	A fracture in the os pubis was created through the symphysis pubis and displaced (50 or 100mm) with a Finochiettto rib spreader, causing unilateral rupture of the anterior ligaments of the SI-joint	
Tile C	Unstable	Complete pelvic ring instability was created through a fracture of the os pubis and a unilateral rupture of the SI-joint, including disruption of the soft tissue and rupture of the sacroiliac and sacrotuberous ligaments	

The study definitions of the pelvic fractures according to the classification system of Tile et al. The fractures were classified by the principal fracture, and the classification was based on the direction (pathomechanics) of the impact force that caused the trauma and the progressive instability of the pelvic ring. A schematic representation of the study definition of the fractured pelves in this cadaveric study is shown in the right column. The red dashed lines indicate the fracture lines. SI = sacroiliac.

First, pins with retro-reflective markers were placed in unfractured pelves. Subsequently, reference measurements were performed to establish the exact positions of the ilium, sacrum, and pubis in the unfractured state. Subsequently, all sixteen pelves were osteotomized to simulate fractures in randomized order with the pins and retro-reflective markers in place. All fractures were created according to the study definition on the basis of the Tile classification[28] (i.e., four type-A fractures, four type-B1 fractures with a 50-mm pubic diastasis, four type-B1 fractures with a 100-mm pubic diastasis, and four type-C fractures) (Table 2). All fractures were produced with an osteotome, and diastasis was achieved with a Finochietto rib spreader placed between the symphysis pubis. In the type-B1 fractures, two widths of diastasis were created to differentiate between a mild and a severe disruption of the pelvic ring at trauma. Prior to each new measurement with a different pelvic circumferential compression device, a rib spreader was used to create sufficient diastasis. The soft-tissue envelope was preserved whenever possible. Fracture subtypes were confirmed with use of anteroposterior, inlet, and outlet fluoroscopic images.

Subsequently, the specimens were placed on the platform and the three pelvic circumferential compression devices were successively applied in randomized order. The pelvic circumferential compression devices were applied at the level of the greater trochanters[29] and were tensioned according to the manufacturer's guidelines (Table 1). A stepwise (20 N per step) increased pulling force was applied, measured with a digital force gauge (9000 series CPU; AIKOH Engineering, Osaka, Japan). This pulling force was increased until the pelvic circumferential compression device was fitted according to the manufacturer's recommendations (Table 1). With the Pelvic Binder and the T-POD, two fingers were inserted between the specimen and the device. From the digital force gauge, it could be read that the Pelvic Binder and the T-POD were tensioned to a maximum of 120 and 100 N, respectively. The SAM-Sling was pulled tight with two hands in opposite directions and the fastener with the Autostop buckle limited the circumferential compression at a strap tension of 150 N.

During tensioning, the three-dimensional positions of the fracture fragment markers were recorded in real time with the Vicon system (Figure 1D). All marker positions were transformed to a single orthogonal coordinate system (Figure 2), with the blue X-axis indicating movement in the caudocranial direction; the red Y-axis, the mediolateral direction; and the green Z-axis, the posteroanterior direction.

The marker coordinates were processed with MATLAB software (version 7.1; The MathWorks, Natick, Massachusetts). Comparison of the unfractured pelvis set with the fractured pelvis set showed the displacement of pin points was caused by fracturing and application of pelvic circumferential compression devices, with this displacement representing displacement at fracture sites. The pin-point displacements (in millimeters) of the fragments after application

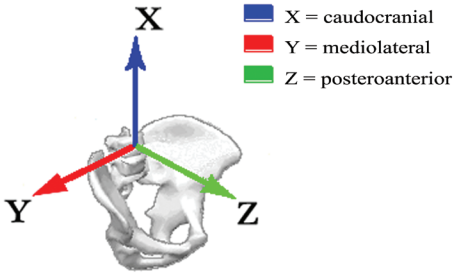


Figure 2
The orthogonal system used to describe the movements of the fracture fragments in three directions. The blue X-axis represents the caudocranial direction, the red Y-axis represents the mediolateral direction, and the green Z-axis represents the posteroanterior direction.

and tensioning of the pelvic circumferential compression devices, relative to their reference positions, were used as a measure of quality of reduction. Differences in pulling force between the pelvic circumferential compression devices that was needed to reach reduction at the symphysis in Tile type-B1 and C fractures were analyzed. Reduction was defined as the lowest amount of diastasis at the symphysis. However, diastasis of <10 mm is considered normal[20] and unlikely to be clinically relevant; in this study, diastasis of <5 mm was considered acceptable. The results were visualized with GraphPad Prism (version 4.00; GraphPad Software, La Jolla, California).

Statistical Methods

No preliminary or published data that could be used to calculate the required sample size existed. Therefore, initial measurements were restricted to four cadaveric specimens with a Tile type-A fracture, eight with a Tile type-B fracture, and four with a Tile type-C fracture, for all three pelvic circumferential compression devices. Statistical analysis was performed with use of the Statistical Package for the Social Sciences software (version 16.0; SPSS, Chicago, Illinois). A factorial repeated measures analysis of variance was performed to analyze the differences among the pelvic circumferential compression devices with regard to the pulling force required to reach reduction at the symphysis. The Mauchly test was used to test the assumption of sphericity. Post hoc pairwise comparison tests with Bonferroni correction were used to test the differences between group means.

Source of Funding

There was no external financial funding source for this study. The pelvic circumferential compression devices used for this study were provided by Pelvic Binder (Pelvic Binder), Innoventa BV (SAM-Sling), and Rescue 3000 BV (T-POD). Neither the companies providing the pelvic circumferential compression devices nor the device manufacturers played a role in this study.

RESULTS

Figure 3 shows the displacements relative to the reference position in a Tile type-B1 (50-mm diastasis) fracture before and during tensioning of a T-POD. On application of an increasing pulling force, the displacements of the fracture fragments reduced to <1 mm in caudocranial (X), mediolateral (Y), and posteroanterior (Z) directions. All pelvic circumferential compression devices were evaluated in this manner in all pelvic fractures.

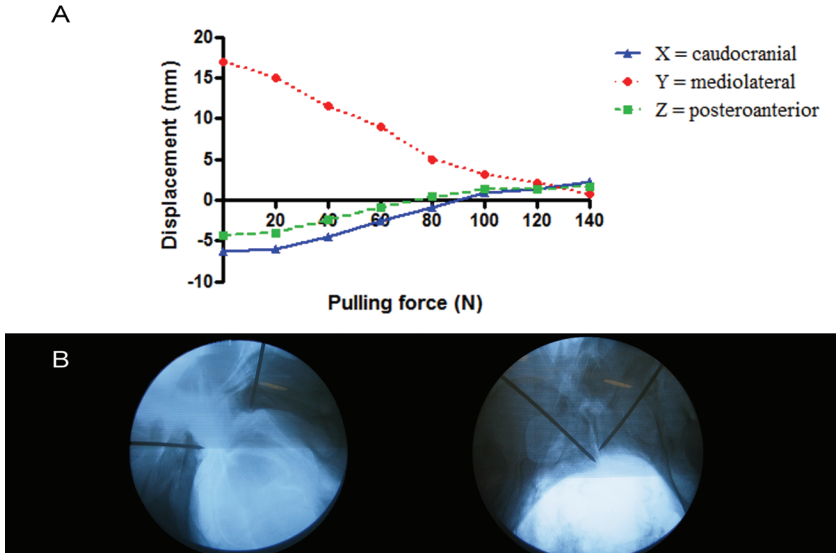


Figure 3

An example of the reduction of the displacement of a Tile type-B1 (50-mm) fracture at the symphysis pubis before and during tensioning of a T-POD device. A: Displacements of fracture fragments in the X, Y, and Z directions. The reduction of the fracture fragments is shown in all three directions during tensioning of the pelvic circumferential compression device. B: Anteroposterior radiographs showing displacement of the fracture fragments and pin position before tensioning (left panel) and reduction of the fracture fragments after tensioning of the device (right panel).

The combined results (four per fracture type) of the measurements are presented in Figures 4A-D. The average displacements in all three directions and the corresponding standard error of the mean (SEM) of the fractured pelves are presented adjacent to all three pelvic circumferential compression devices.

Tile Type A

In Tile type-A fractures (Figure 4A), the average displacement of the pubic and iliac bones was <5 mm in all three directions before tensioning of the pelvic circumferential compression devices. Tensioning the devices according to the manufacturers' guidelines resulted in an over-reduction of <5 mm in the medial direction at the pubis. Following tensioning of the

Pelvic Binder, an average posterior displacement of 5.96 ± 2.59 mm was found at the ilium. The average displacement at the ilium for the SAM-Sling and T-POD was <5 mm.

Tile Type B1 (50 mm)

Tile type-B1 fractures with a 50-mm pubic diastasis (Figure 4B) resulted in an average diastasis of 18.87 ± 5.59 mm at the symphysis pubis before tensioning of the pelvic circumferential compression devices. The displacement in the mediolateral direction at the symphysis pubis during tensioning showed a gradual decline of the diastasis with each step of 20-N applied force. Average pulling forces of 60 N (Pelvic Binder), 120 N (SAM-Sling), and 40 N (T-POD) were needed to reduce the lateral displacement to the reference position. A pulling force according to the manufacturers' guidelines resulted in a medial over-reduction of <5 mm at the symphysis pubis for all devices. At the location of the sacroiliac joint, the displacement in all three directions was <5 mm before and after tensioning the devices.

Tile Type B1 (100 mm)

The Tile type-B1 fractures with 100-mm pubic diastasis (Figure 4C) were characterized by an average diastasis of 20.44 ± 2.42 mm at the symphysis pubis. Similar to the type-B1 (50-mm) fractures, a gradual diastasis reduction per step of 20 N was observed in the mediolateral direction. Applying a pulling force according to the manufacturers' guidelines resulted in an average diastasis at the symphysis pubis of <5 mm for the Pelvic Binder and T-POD and 6.70 ± 1.55 mm for the SAM-Sling. The average displacement at the sacroiliac joint in either direction remained <5 mm for all devices.

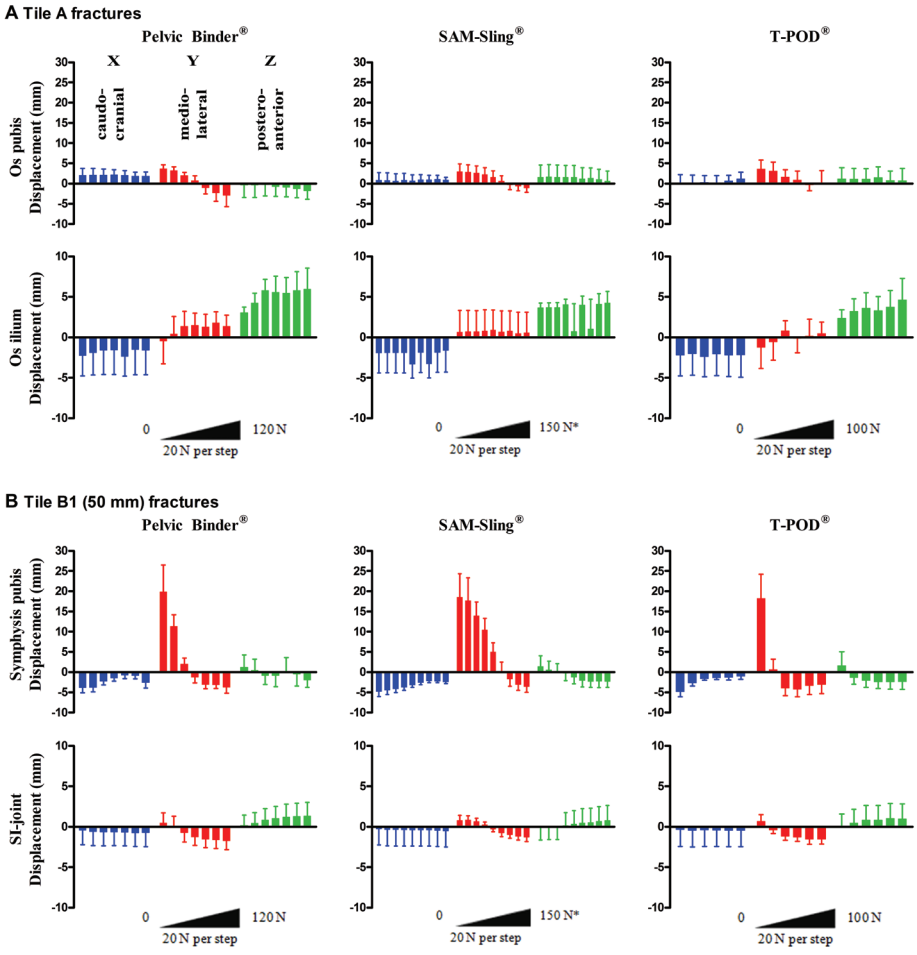
Tile Type C

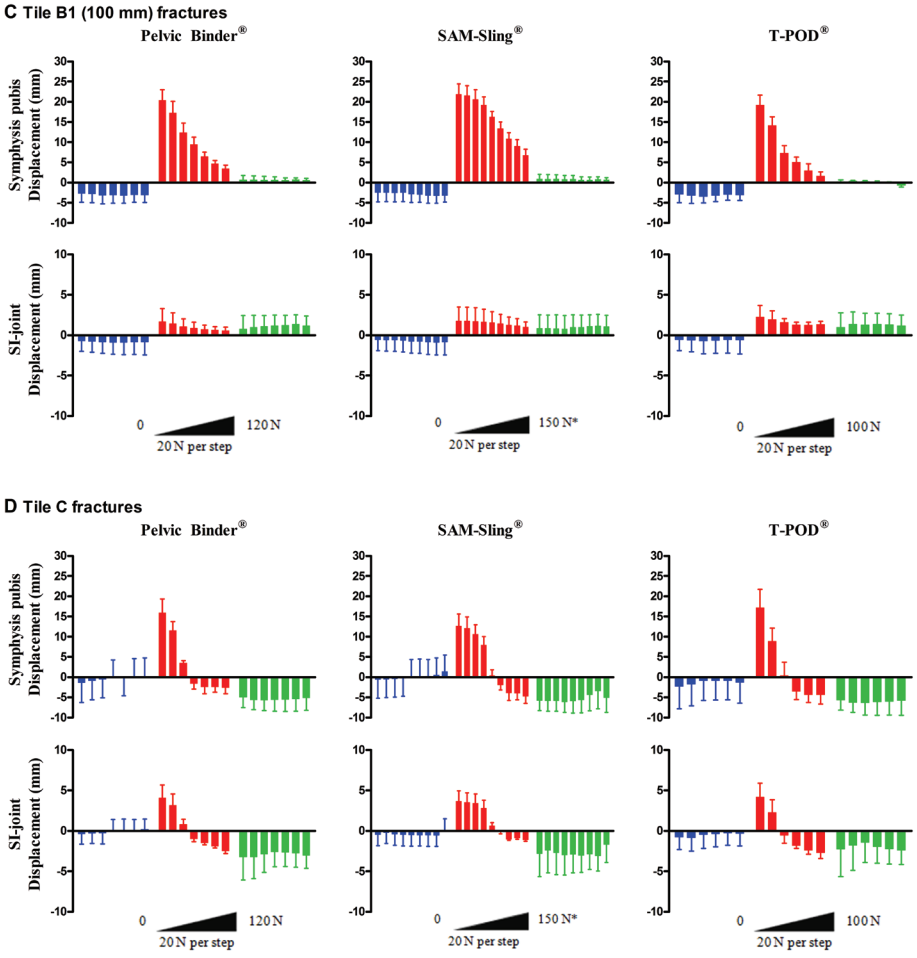
Before tensioning of the pelvic circumferential compression devices, the average displacement at the symphysis pubis in the Tile type-C fractures (Figure 4D) was 1.38 ± 4.58 mm cranially, 15.26 ± 3.51 mm laterally, and 5.45 ± 2.30 mm anteriorly. The negative posteroanterior displacement at the symphysis pubis and the sacroiliac joint indicated a displacement of the fractured hemipelvis in an anterior direction.

Tile type-C fractures resulted in an average displacement of <5 mm at the sacroiliac joint in all three directions before tensioning. An average pulling force of 60 N (Pelvic Binder and T-POD) and 100 N (SAM-Sling) was necessary to reduce the lateral displacement at the symphysis pubis to the reference position. At the location of the symphysis pubis, tensioning of the pelvic circumferential compression devices according to the manufacturers' guidelines resulted in an over-reduction. For the Pelvic Binder, the average over-reduction was 0.08 ± 4.67 mm caudally, 2.57 ± 1.53 mm medially, and 5.07 ± 3.11 mm anteriorly. For the SAM-Sling, the average over-reduction was 1.38 ± 4.10, 4.69 ± 1.78, and 5.06 ± 3.66 mm, respectively. For the T-POD, the average over-reduction was 1.26 ± 5.15, 4.28 ± 2.33, and 5.74 ± 3.66 mm,

respectively. The anterior displacement at the symphysis pubis (5 to 6 mm) was unaffected by any of the pelvic circumferential compression devices. At the sacroiliac joint, tensioning according to manufacturers' guidelines resulted in an average cranial displacement of 0.02 ± 1.30 mm, an average over-reduction of 2.09 ± 0.57 mm medially, and displacement of 2.34 ± 1.75 mm anteriorly.

The average pulling force required to reach the same position of the symphysis pubis as that in the unfractured, reference measurement in Tile type-B1 and C fractures was 60 ± 9 N for the Pelvic Binder, 112 ± 10 N for the SAM-Sling, and 43 ± 7 N for the T-POD. The Mauchly test had a p value of 0.04, indicating violation of sphericity. Therefore, a Greenhouse-Geisser corrected F statistic was used. The F value was 43.7 ($p < 0.01$), which indicates a significant difference in pulling force among the different pelvic circumferential compression devices.





Figures 4A-D

Movements of pelvic fracture fragments after application of pelvic circumferential compression devices at the symphysis pubis (upper panel) and the ilium (lower panel) in Tile type-A fractures (Figure 4A), at the symphysis pubis (upper panel) and the sacroiliac (SI) joint (lower panel) in Tiletype-B1 (50-mm) fractures (Figure 4B), at the symphysis pubis (upper panel) and the sacroiliac joint (lower panel) in Tile type-B1 (100-mm) fractures (Figure 4C), and at the symphysis pubis (upper panel) and the sacroiliac joint (lower panel) in Tile type-C fractures (Figure 4D). The combined results (four per fracture type) of the application of the Pelvic Binder (left panels), SAM-Sling (middle panels), and T-POD (right panels) are presented. Data are given as the mean and the standard error of the mean. The Y-axis shows the displacement (in millimeters) relative to the reference position in the unfractured pelvis. A Y-axis value of zero represents the 'anatomic' position. Positive caudocranial displacement (blue bars) means that the lateral pelvic part moved cranially relative to the medial part, positive mediolateral displacement (red bars) means that the lateral part moved laterally, and positive posteroanterior displacement (green bars) means that lateral part moved anteriorly. The X-axis shows the mean pulling force (N) with a categorical 20-N interval and the last bar of each direction ends with 120 N, 150 N, and 100 N for the Pelvic Binder, the SAM-Sling, and the T-POD, respectively. The maximum force value of 150 N (*) is due to the SAM-Sling auto-stop buckle.

Between-group post hoc tests showed that the average required pulling force to attain complete reduction was 52 ± 6 N lower for the Pelvic Binder than the SAM-Sling ($p < 0.01$), 17 ± 6 N higher for the Pelvic Binder than the T-POD ($p = 0.05$), and 68 ± 10 N higher for the SAM-Sling than the T-POD ($p < 0.01$). The average symphysis diastasis reduction for the Tile type-B1 and C fractures was 19.64 ± 2.86mmfor the Pelvic Binder, 18.18 ± 2.25 mm for the SAM-Sling, and 20.11 ± 2.87 mm for the T-POD. The average diastasis reduction was similar for all three binders (Greenhouse-Geisser F value, 1.7; $p = 0.213$).

DISCUSSION

In the acute management of pelvic ring fractures, a pelvic circumferential compression device is recommended as one of the first steps for prompt and easy stabilization of hemodynamically unstable patients.[6,30] However, only limited scientific evidence is available to support this recommendation. For most patients in whom a pelvic fracture is suspected, current guidelines recommend the application of a pelvic circumferential compression device. The exact behaviour of the fracture fragments after application and tensioning of a pelvic circumferential compression device remains unknown, so this cadaver study was performed to assess the quality of reduction by pelvic circumferential compression devices in different types of pelvic ring fractures.

No clinically important displacement of the fracture fragments was observed when any of the pelvic circumferential compression devices were applied for Tile type-A fractures. Complete reduction was observed after application and tensioning of all three pelvic circumferential compression devices in Tile type-B1 (50-mm) fractures. In these fractures, the T-POD required the lowest mean pulling force (i.e., 40 N) to achieve complete reduction of the laterally displaced os pubis. In Tile type-B1 (100-mm) fractures, the remaining diastasis at the symphysis pubis was <5 mm compared with the initial reference coordinates after application of the Pelvic Binder and T-POD. A diastasis of 7 mm in the symphysis pubis remained after application of the SAM-Sling. However, diastasis of <10 mm is considered normal[20] and unlikely to be clinically relevant. Following application and tensioning of the pelvic circumferential compression devices in Tile type-C fractures, a mean anterior displacement of 5 mm of the fractured hemipelvis was observed. Anteriorly, the symphysis pubis closed with a slight over-reduction in all three devices, although this is unlikely to be clinically relevant. More importantly, no significant displacement was observed at the sacroiliac joint. Even in Tile type-C fractures, the sacroiliac joint displacement was <5 mm.

The average lateral displacement in type-B1 (50-mm) and B1 (100-mm) fractures after removal of the rib spreader was approximately 20 mm. This was due to passive recoil in a

cadaveric pelvic fracture model as previously reported by Gardner et al.[31]. They showed that, in anteroposterior compression fractures (corresponding to Tile type B), the amount of recoil was consistent regardless of the severity of maximal injury.

Biomechanical research on the quality of reduction with pelvic circumferential compression devices is limited. DeAngelis et al.[20] created rotationally unstable pelvic fractures (Tile type B1) in twelve cadavers and showed that the T-POD was more effective in reducing symphysis diastasis than was a circumferential sheet. They defined a symphysis diastasis of <10 mm as normal. In nine of twelve pelvic specimens, the T-POD was able to reduce the mean symphysis diastasis to 7.1 mm (95% confidence interval, –2.2 to 16.4 mm). In the current study, a reduction in diastasis to a clinically acceptable <10 mm was achieved in all fracture types and with each type of pelvic circumferential compression device.

The results of the Vicon measurements showed that most of the displacement during compression with a circumferential compression device on the pelvic ring is in the mediolateral direction at the symphysis pubis.

There is ongoing controversy regarding the required pulling force for optimal pelvic reduction with use of pelvic circumferential compression devices. In the prospective cohort study by Krieg et al.[3], radiographs were analyzed in order to quantify pelvic reduction following application of a pelvic circumferential compression device compared with pelvic reduction after definitive stabilization. A 140-N tension-limited device was used to ensure safe application of the pelvic circumferential compression device around the trochanters. This pulling force was chosen to be 20% lower than the 180-N tension level reported in the cadaveric study by Bottlang et al.[25]. In the current study, the auto-stop buckle of the SAM-Sling (150-N tension limitation) accounted for an incomplete fracture reduction in Tile type-B1 (100-mm) fractures at the location of the symphysis pubis in a mediolateral direction and caused over-reduction in the Tile type-B1 (50-mm) and C fractures.

Bottlang et al.[25] measured the minimum strap tension with a prototype pelvic strap in order to achieve complete reduction of the displacement in a cadaveric study. Symphyseal contact was confirmed with a symphysis pubis sensor. This minimum strap tension was a mean of 177 ± 44 N and 180 ± 50 N in the partially stable and unstable pelves, respectively. This pulling force was markedly higher than the pulling forces necessary for complete reduction of Tile type-B1 or Tile type-C fractures in the current study. The required pulling force to attain complete reduction varied substantially among the three different pelvic circumferential compression devices. The T-POD reached the same reduction as the other pelvic circumferential compression devices with use of the lowest pulling force. A significant difference in the required pulling force was noted between the Pelvic Binder and the T-POD. The differ-

ences in the required pulling forces for reduction are influenced by the design of the closure mechanisms of the three pelvic circumferential compression devices, the influence of the pulley-blocks (i.e., T-POD), and the friction caused (i.e., Pelvic Binder and SAM-Sling). The Pelvic Binder and the T-POD are available as 'one size fits all' and need to be cut to fit before application, so their application can be more time-consuming than the sized-to-fit SAM-Sling that is available in three fixed sizes. Furthermore, the Pelvic Binder and the T-POD do not provide feedback on the applied force. Both manufacturers prescribe that the straps should be pulled until two fingers just fit between the binder and the patient. The SAM-Sling, on the other hand, has an auto-stop buckle that limits tension to 150 N. The results of the current study indicate that these guidelines result in clinically sufficient pulling force to reduce the displacement in pelvic fractures with the three pelvic circumferential compression devices.

The straightforward and quick method for application of circumferential compression with a pelvic circumferential compression device makes the use of these devices at the accident scene uncomplicated. However, the ideal pelvic circumferential compression device should provide enough circumferential compression to maximally reduce the displacement, without gross over-compression. Tissue damage is thought to occur when the exerted pressure on the skin exceeds 9.3 kPa for more than two to three hours continuously.[32] A drawback of the pressure needed to accomplish pelvic ring reduction is the increased risk of skin problems.[33] Although pelvic circumferential compression devices are clinically effective in early fracture reduction, the development of pressure sores and complications of associated soft-tissue injury have been reported.[34-37]

Each of the pelvic circumferential compression devices uses different pulley mechanisms, so the applied pulling force does not necessarily relate to the circumferential exerted pressure under the device. As noted above, the pressure on the skin is clinically the limiting factor. No conclusions about the risk for pressure-induced skin necrosis can be drawn from this study. An inherent limitation in this study was the use of embalmed cadavers, causing the tissues to be much stiffer than normal. These cadaveric specimens may not be truly representative of all or even most pelvic fractures and could affect tissue recoil and diastasis reduction.

In conclusion, the Pelvic Binder, SAM-Sling, and T-POD provided sufficient reduction in partially stable and unstable pelvic fractures. There was no adverse over-reduction with any of these pelvic circumferential compression devices in Tile type-A, B1, and C fractures. The required pulling force to attain complete reduction was lowest for the T-POD. The efficacy of pelvic circumferential compression devices in patients with pelvic ring fractures remains to be determined.

Acknowledgements

The authors thank Yvonne Steinvoort (Department of Anatomy and Neurosciences, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands) for her valuable assistance in the tissue fixation and preparation of the pelvic specimens; Wibeke van Leeuwen (Department of Radiology, Erasmus MC, University Medical Center Rotterdam, The Netherlands) for her support with the radiography; and Alex Brouwer (Department of Experimental Medical Instrumentation, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands) for the design and manufacturing of the stainless steel pins with retro-reflective markers. The pelvic circumferential compression devices used for this study were provided by Pelvic Binder (Pelvic Binder), Innoventa BV (SAM-Sling), and Rescue 3000 BV (T-POD).

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Chapter 7

The Importance of Trauma-center Care on Mortality and Function Following Pelvic Ring and Acetabular Injuries

Submitted

S. Morshed[1], S.P. Knops[2], G.J. Jurkovich[3], J. Wang[4], E. MacKenzie[5], F. P. Rivara[6]

[1] Univeristy of California San Francisco / San Francisco General Hospital Orthopaedic Trauma Institute (OTI), San Francisco, California, USA
[2] Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
[3] Department of Surgery, Denver Health Medical Center, Denver, Colorado, USA
[4] Harborview Injury Prevention & Research Center, University of Washington School of Medicine, Seattle, Washington, USA
[5] Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, USA
[6] Department of Pediatrics, Harborview Injury Prevention and Research Center, University of Washington School of Medicine, Seattle, Washingthon, USA

ABSTRACT

Background: Lower mortality and improved physical function following major polytrauma have been associated with treatment at level-1 trauma centers compared with that at non-trauma centers. This study investigates the impact of trauma center care on outcomes after pelvic and acetabular injuries, recognizing that these results could have important implications for appropriate triage of these severely injured patients.

Methods: Mortality and quality of life related measures were compared among patients treated in 18 hospitals with level-1 trauma centers and 51 hospitals without trauma centers in 14 U.S. states. Complete data were obtained on 829 adult trauma patients (18-84 years old) with at least one pelvic ring or acetabular injury (OTA 61 or 62). We used inverse probability of treatment weighting to adjust for observable confounding.

Results: After adjustment for case mix, in-hospital mortality was significantly lower at trauma centers versus non-trauma centers (RR 0.10, 95% CI 0.02-0.47), as was death by 90 days (RR 0.10, 95% CI 0.02-0.47), and one year (RR 0.21, 95% CI 0.06-0.76) for patients with more severe acetabular injuries (OTA 62-B and 62-C). Patients with combined pelvic ring and acetabular injuries treated at trauma centers had lower mortality by 90 days (RR 0.34, 95% CI 0.14-0.82) and one year (RR 0.30 95% CI 0.14-0.68). Average absolute differences in SF-36 physical functioning and Musculoskeletal Functional Assessment at one year were 11.4 (95% CI 5.3 – 17.4) and 13.2 (1.7 – 24.7) respectively, indicating statistically and clinically significant improved outcomes with treatment at trauma centers for more severe acetabular injuries.

Conclusions: Our findings show that risk of mortality is significantly lower for patients with severe acetabular injuries and that survivors also enjoy improved physical functioning at one year when care is provided in a trauma center compared to a non-trauma center. Patients with severe acetabular injuries and any combined acetabular and other pelvic ring injury represent a well-defined subset of trauma patients that should be preferentially triaged or transferred to a Level-1 trauma center.

INTRODUCTION

Critically injured trauma patients benefit from an organized trauma service and integrated multidisciplinary care.[1] Efforts at regionalization of trauma care have been based on the premise that concentration of resources for delivery of this complex specialty care will result in improved outcomes.[2,3] However, the majority of studies supporting this notion have been retrospective studies of panel and registry data.[4] The National Study on Costs and Outcomes of Trauma (NSCOT) is a prospective study initiated to examine variations in care provided across level-1 trauma centers (TC) and non-trauma centers (NTC), identify predictors of outcomes, and estimate cost-effectiveness of trauma care[5]. This study showed that the risk of death is significantly lower when care to critically injured patients is provided in a level-1 TC than in a NTC hospital[6]. While data from this study also demonstrated modest functional benefits associated with treatment at a level-I trauma center among patients with a major lower-limb injury, similar mortality benefits were not found in patients across the broad spectrum of orthopaedic injuries.[7]

Patients with pelvic and acetabular injuries comprise a subset of trauma patients with particularly high morbidity and mortality.[8-10] These injuries typically result from high-energy trauma and are often accompanied with severe hemorrhage and other potential life threatening injuries. Given the complexity and multimodal needs of trauma patients with pelvic and acetabular injuries as compared to other extremity trauma, we hypothesize that such patients will show significant mortality and functional benefits from trauma center care. We conducted a secondary analysis of the NSCOT data to assess both the effect on mortality and functional outcomes of trauma center care, specifically for those patients with pelvic and acetabular injuries.

MATERIALS AND METHODS

The NSCOT was conducted in 15 regions defined according to contiguous Metropolitan Statistical Areas in 14 states according to sampling procedures that have been previously described.[5] The Metropolitan Statistical Areas were selected from among the 25 largest such areas in 19 states, and excluded those in which large non-trauma centers collectively treated fewer than 75 patients with major trauma (Injury Severity Score of more than 15, on the basis of diagnostic codes)[4]. Within each Metropolitan Statistical Area, all level-1 trauma centers and large non-trauma centers were identified, as were large non-trauma centers that treated at least 25 patients with major trauma annually. Verifications were based on state, regional authority or the American College of Surgeons Committee on Trauma. Level-2 and Level-3 centers were not included. Virtually all non-trauma centers that met criterion were asked

to participate whereas only a sample of trauma centers was asked to participate in order to achieve approximately even numbers of small, medium, and large center on the basis of the annual volume of patients with major trauma. Ultimately, 18 of the trauma centers and 51 of the non-trauma centers agreed to participate and received institutional review board approval.

Non-trauma centers were smaller than trauma center, less likely to be members of the Council of Teaching Hospitals, and treated fewer patient**s** overall. Still, 17 of the non-trauma centers had designated trauma teams and 8 had trauma directors. Over the course of the study, one non-trauma center received level-1 designation and one level-1 trauma center lost its verification. For the analysis, hospitals were categorized based on their status at the time of enrollment.

Patients

Patients were included if they were 18 to 84 years of age, arrived alive at a participating hospital, and were treated for a moderate-to-severe injury (defined by at least one injury with a score of at least 3 on the Abbreviated Injury Scale)[11] between July 2001 and November 2002. Patients who presented with no vital signs and were pronounced dead within 30 minutes of arrival were excluded, as were patients who delayed seeking treatment for more than 24 hours, patients 65 years of age or older with a first listed diagnosis of hip fracture, patients with major burns, those who spoke neither English nor Spanish, non-U.S. residents, and patients who were incarcerated or homeless at the time of injury.

Patients were selected and eligibility was determined in two stages, followed by a third stage query to identify and include only those subjects with pelvic and/or acetabular injuries. In the first phase, administrative discharge records and emergency department logs were prospectively reviewed to identify patients with a principal International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9_CM) diagnosis code of 800 to 959 (excluding those due to late effects, foreign bodies, complications, burns, and [among patients 65 years of age or older] hip fractures). A computer program was then used to map ICD-9-CM diagnoses to Abbreviated Injury Scale scores to select patients with at least one diagnosis involving a score of at least 3 on the Abbreviated Injury Scale.[12] A total of 18,198 patients satisfied these initial eligibility criteria.

In the second stage, all 1438 patients who died in the hospital and a sample of 8021 patients who were discharged alive were selected. A quota sampling strategy was used with the goal of enrolling approximately 3000 patients who were 18 to 64 years of age and 1200 patients who were 65 to 84 years of age, evenly distributed across trauma centers and non-trauma centers and across categories of injury severity and principal region injured. Completed medical records were obtained for 1391 of the patients who died in the hospital. After exclu-

sion of 287 who did not meet eligibility criteria, 1104 eligible subjects were identified and for whom medical records were abstracted. Patients discharged alive and selected for the study were contacted at 3 months by mail and then telephone, and informed consent was obtained to access their medical records and interview them at 3 and 12 months after injury. Of the 8021 such patients who were selected for the study, 4866 were enrolled and 4087 were ultimately found eligible and for whom complete medical-record data were abstracted.

For the purposes of this study, a third stage involved inclusion of only patients with a traumatic pelvic injury (pelvic and/or acetabulum fracture and/or sacrum and coccyx fracture) from the Emergency Department (ED) and Hospital deaths and live discharges found eligible in stage 2. Patients with at least one diagnosis ICD-9 code in the range 808.0 – 808.9 (fracture of pelvis, open/closed) and/or 805.6 – 806.79 (fracture of sacrum and coccyx, open/closed)) and an Orthopaedic Trauma Association (OTA) fracture classification[13] of 61- or 62- were selected for inclusion in the final cohort for this study. This resulted in 278 patients included from non-trauma centers and 551 patients from level-1 trauma centers.

There are two reasons why it is necessary to weight data on the 829 eligible included participants with pelvic injuries and complete medical record data to the population of eligible patients. First, the sampling protocol selected all patients who died in the hospital but only a proportion of patients discharged alive. Second, not all patients selected for inclusion in the study were enrolled. The resulting "sampling" weights consisted of the reciprocal product of two probabilities: the conditional probability of being selected and the probability of being enrolled and having data abstracted from the medical record, given that the patient was selected. The target population to which inferences are made for this secondary analysis of the NSCOT consists of 2644 patients with pelvic and acetabular injuries projected to meet the inclusion criteria.

Outcomes and Data Collection

Outcomes of primary interest included death in the hospital and death within 90 days after injury. Deaths that occurred after discharge were identified either by interviewing a proxy or through a match with the National Death Index. Secondary outcomes were twelve-month follow-up functional assessments including the Short Form-36 (SF-36)[14] and the Short Musculoskeletal Functional Assessment (SMFA).[15]

Characteristics of patients and their injuries that were associated with their risk of death and treatment place (thereby potentially confounding the relationship between level of care and mortality) were obtained from the medical record and used for adjustment. Nurses with training specifically for NSCOT and certified in scoring of the Abbreviated Injury Scale by the Association for the Advancement of Automotive Medicine abstracted data from the patients'

medical records. The Charlson Comorbidity Index[16] was used to characterize pre-existing medical conditions for the purposes of analysis. Obesity and coagulopathy were included in the analysis as individual covariates. Obesity is a strong independent risk factor for post-injury organ dysfunction and multiple organ dysfunction[17] and persistent hemorrhagic shock is the leading cause of death in obese patients[18]. Coagulopathy may impact the need for blood transfusions and associated complications[19].

Injuries were characterized on the basis of their mechanism, anatomic severity, and physiologic effect. The anatomical severity of individual injuries was assessed with the Abbreviated Injury Scale. Scores derived manually from a review of the medical record were used in all analyses. Several summary measures of the overall severity of injury were derived from the injury specific Abbreviated Injury Scales (AIS), including the Injury Severity Score (ISS)[20], the New Injury Severity Score (NISS)[21], the Anatomic Profile Score (APS)[22], and the worst survival risk ratio. We used the first assessment of blood pressure and pupillary response in the ED and the first assessments of the motor score of the Glasgow Coma Scale (GCS) in the field and the emergency department to measure the degree of physiological derangement.

Statistical Analysis

Multiple imputation techniques were used to account for missing covariates. All analyses were performed with the use of data weighted to the population of eligible patients (n=2644). To adjust for potential confounding bias by observable factors explaining differences in patients treated at trauma centers and those treated at non-trauma centers, the inverse probability of treatment weighting approach described by Robins[23] was used. In this approach, data on each patient are further weighted by the reciprocal of the conditional probability of receiving care at a trauma center, given all demographic and injury characteristics listed in Table 1, plus ED first shock, First ED assessment of pulpils, midline shift, flail chest, open skull fracture, obesity and paralysis, together with relevant two-way interaction terms. The result is a reweighted population in which measured variables that may confound the estimated association between trauma center and outcome are balanced between treatment groups. Then**,** generalized linear models were used to model outcomes (mortality and functional outcomes) in order to generate estimates of causal effects. Robust standard error**s** were computed to account for clustering within hospitals. Mortality risk was compared both in-hospital and within 90 days; effects attributable to level of care were hypothesized to exist within this period of time from injury. Quality of life outcomes (SF-36 physical and mental component summary scores, SMFA) were compared at one year after injury. We used SAS 9.2 (Cary, NC, USA) and R2.1.1 (Vienna, Austria) for all of the analyses.

Table 1 Patient characteristics.

		Before Adjustment			After Adjustment		
	Number of Patients (Unweighted)	Non-trauma Center[§] N=278 (n=638) %	Trauma Center[§] N=551 (n=2006) %	P - value	Non-trauma Center[§] N=278 (n=2331) %	Trauma Center[§] N=551 (n=2520) %	P - value
Age							
Mean years (SD)		58.3(33.4)	40.0(31.1)	<0.0001	42.3(63.3)	42.2(37.8)	0.96
<55	494	35.6	81.9	<0.0001	68.2	77.1	0.17
55-64	81	12.6	8.9		9.6	9.2	
65-74	114	17.3	5.7		9.0	7.5	
75-84	140	34.5	3.5		13.2	6.2	
Gender				<0.0001			0.003
Male	451	33.5	63.7		41.8	62.4	
Female	378	66.5	36.3		58.2	37.6	
Race				0.09			0.87
Hispanic	107	9.1	17.9		14.0	6.2	
Non-Hispanic,White	594	81.9	61.8		70.5	64.9	
Non-Hispanic, Non-White	128	9.0	20.3		15.5	18.9	
Insurance				<0.0001			0.21
None	162	10.7	30.6		18.4	27.5	
Medicare only	183	38.2	6.9		16.3	10.5	
Medicare+Private	104	15.2	6.3		7.0	7.2	
Private	295	26.4	46.3		41.5	45.4	
Medicaid	52	4.7	5.3		10.0	4.8	
Other	33	4.9	4.6		6.8	4.6	
Injury Mechanism				0.24			0.44
Penetrating	35	3.1	5.5		7.4	4.8	
Blunt	794	96.9	94.5		92.6	95.2	
First ED motor GCS				0.0002			0.24
6	636	93.3	75.5		73.3	78.5	
4,5	50	3.0	7.3		4.3	6.7	
2,3	13	0.4	1.8		1.6	1.6	
1,not paralyzed	49	0.8	4.2		1.5	3.9	
1,paralyzed	81	2.5	11.2		19.3	9.3	
Injury Severity Score							
Mean(SD)		11.3(14.7)	22.5(22.3)	<0.0001	22.3(44.8)	21.0(25.0)	0.80
<16	348	77.4	34.6	<0.0001	42.0	40.8	0.06
16-24	206	12.7	27.5		22.7	25.8	
25-34	165	5.3	22.9		10.3	20.5	
>34	110	4.6	14.9		25.0	12.9	
Maximum Abbreviated Injury Score (AIS)				<0.0001			0.44
≤3	551	89.2	63.6		65.0	67.4	
4	187	7.7	24.6		17.1	22.1	
5,6	91	3.1	11.8		17.9	10.5	

		Before Adjustment			After Adjustment		
	Number of Patients (Unweighted)	Non-trauma Center[§] N=278 (n=638) %	Trauma Center[§] N=551 (n=2006) %	P - value	Non-trauma Center[§] N=278 (n=2331) %	Trauma Center[§] N=551 (n=2520) %	P - value
Head Region*	164	8.2	24.0	<0.0001	28.0	21.7	0.54
Face Region *	23	1.0	3.3	0.05	3.0	3.0	0.98
Thorax Region *	319	14.7	42.0	<0.0001	40.9	37.9	0.75
Abdomen Region *	170	4.4	24.4	<0.0001	11.8	21.3	0.02
Upper Extremity Region *	111	7.7	15.4	0.002	12.8	14.8	0.53
Lower Extremity Region *	487	39.5	70.5	<0.0001	50.7	68.9	0.01
Neck Region *	2	0	0.7	NA	0.0	0.3	NA
Spine Region *	55	1.7	8.9	0.001	2.9	8.0	0.02
External Region *	3	0.4	0.4	0.90	0.7	0.3	0.58
Charlson Comorbidity Index				<0.0001			0.07
0	535	50.5	76.0		69.9	72.5	
1	137	17.5	16.0		12.0	16.7	
2	75	13.6	4.5		9.3	6.3	
≥3	83	18.4	3.5		8.8	4.5	

[§]N = number of study subjects, n = weighted number of subjects, * = Maximum AIS ≥ 3

RESULTS

On the basis of data weighted back to the target population of 2644 eligible patients (1727 pelvis, 297 acetabulum, and 620 combined injuries), 92% survived at least 12 months after injury. Compared with trauma-center patients, non-trauma center patients were older, carried more comorbidities, more likely to be female and insured (Table 1). Patients treated at trauma centers had higher Injury Severity Scores and lower admission motor score of the GCS (Table 1). Higher scores in trauma center-treated patients were present in nearly every AIS region, suggesting that these patients were more severely injured. After inverse probability of treatment-weighted adjustment of the population for reduction of confounding bias due to imbalances in covariates, the two groups were similar (Table 1). Only gender and AIS maximum scores in the abdominal, extremity and spine regions remained different in the reweighted population and these variables were subsequently adjusted for in the statistical analysis.

In-hospital crude (unadjusted) mortality rates were higher at trauma centers (6.1% versus 2.5%, p-value <0.0001) though rates were similar (6.9% versus 5.9%, p=0.44) at 90 days after injury (Table 2) and at both time points after adjustment for case-mix (Table 3). Stratifica-

Table 2 Unadjusted mortality

	Number of Patients (weighted number)	Non-trauma Center[§] N=278 (n=638) (%)	Trauma Center[§] N=551 (n=2006) (%)	P - value
Hospital death	136(139)	2.5	6.1	<0.0001
Death within 90 days	154(177)	5.9	6.9	0.44

N = number of subjects in study sample, n = weighted number of subjects

Table 3 Adjusted mortality

Outcomes	Relative Risk (95% Confidence Interval)
Hospital death	
All Subjects	1.39 (0.59, 3.28)
Pelvis only	1.89(0.75,4.76)
Acetabulum only	2.20(0.26,18.63)
Combined injury	0.51(0.15,1.72)
Death within 90 days	
All Subjects	0.96 (0.64, 1.46)
Pelvis only	1.18(0.60,2.31)
Acetabulum only	4.04(0.53,30.86)
Combined injury	0.34(0.14,0.82)

Adjusted* Mortality (Trauma Center versus Non-trauma Center) among the total cohort of patients with Pelvis (weighted number = 1727), Acetabulum (weighted number = 297) or Combined (weighted number = 620) injuries and by Orthopaedic Trauma Association Classification Fracture Type *Propensity Score-based adjustment model including the following covariates: all demographic and injury characteristics listed in Table 1, plus ED first shock, First ED assessment of pulpils, midline shift, flail chest, open skull fracture, obesity and paralysis, together with relevant two-way interaction terms.

tion by severity of pelvic and acetabular injuries revealed two subgroups to be particularly high risk for adverse outcomes. Tables 4 and 5 demonstrated covariate balance that was maintained within subgroups of combined pelvic and acetabular injuries and more severe acetabular injuries (OTA 62-B and 62-C).

Patient with combined pelvic ring and acetabular injuries treated at trauma centers had lower mortality at 90 days (RR 0.34, 95% CI 0.14-0.82) after adjustment for differences in the case mix (Table 3). In-hospital mortality was significantly lower at trauma centers versus non-trauma centers (RR 0.10, 95% CI 0.02-0.47), as was death by 90 days (RR 0.10, 95% CI 0.02-0.47), for patient with more severe acetabular injuries (OTA 62-B and 62-C) (Table 6). Conversely, patients with stable pelvic ring injuries (61-A) had a higher mortality risk at trauma centers versus non-trauma centers. Patients with more severe pelvic ring injuries (OTA 61-B and 61-C) had relative risk reductions in in-hostpital and death by 90 days associated with trauma center care that did not achieve statistical significance.

Table 4 Patient characteristics after inverse probability of treatment weighted adjustment among patients with combined pelvic and acetabulum injuries.

	Non-trauma Center§ N=38 (n=327) %	Trauma Center§ N=139 (n=648) %	P - value
Age			
Mean years (SD)	45.9(51.0)	40.9(32.0)	0.43
<55	70.8	83.8	0.10
55-64	9.7	9.9	
65-74	10.2	2.8	
75-84	9.3	3.5	
Gender			0.29
Male	52.8	69.3	
Female	47.2	30.7	
Race			0.92
Hispanic	18.0	15.5	
Non-Hispanic,White	55.8	62.4	
Non-Hispanic, Non-White	26.1	22.1	
Insurance			0.01
None	13.8	33.9	
Medicare only	17.0	4.5	
Medicare+Private	4.5	4.3	
Private	28.8	64.7	
Medicaid	31.6	8.2	
Other	4.1	4.3	
Injury Mechanism			0.58
Penetrating	4.1	7.5	
Blunt	95.9	92.5	
First ED motor GCS			NA
6	81.6	84.3	
4,5	0.0	5.3	
2,3	9.9	0.3	
1,not paralyzed	2.0	1.5	
1,paralyzed	6.4	8.6	
Injury Severity Score			
Mean(SD)	19.4(36.2)	20.4(23.0)	0.76
<16	37.0	39.9	0.99
16-24	35.4	32.7	
25-34	15.9	26.7	
>34	11.7	10.8	

Maximum Abbreviated Injury Score (AIS)			0.80
≤ 3	70.1	71.8	
4	18.2	20.9	
5,6	11.7	7.3	
Head Region *	17.9	16.7	0.90
Face Region *	0.0	1.7	NA
Thorax Region *	30.5	38.3	0.48
Abdomen Region *	9.2	20.1	0.13
Upper Extremity Region *	8.7	10.2	0.79
Lower Extremity Region *	53.4	74.5	0.08
Neck Region *	0.0	1.2	NA
Spine Region *	7.4	10.2	0.69
External Region *	0.0	0.8	NA
Charlson Comorbidity Index			0.74
0	61.3	75.7	
1	26.9	14.7	
2	7.7	5.0	
≥3	4.1	4.5	

§N = number of study subjects, n = weighted number of subjects, * = Maximum AIS >= 3

Table 5 Patient characteristics after inverse probability of treatment weighted adjustment among patients with more severe pelvic injuries (OTA 62-B and 62-C).

	Non-trauma Center§ N=10 (n=70) %	Trauma Center§ N=43 (n=182) %	P - value
Age			
Mean years (SD)	43.7(52.1)	44.6(42.2)	0.93
<55	67.0	74.7	0.74
55-64	9.5	5.4	
65-74	14.2	5.2	
75-84	9.3	14.7	
Gender			0.12
Male	95.2	75.8	
Female	4.8	24.2	
Race			0.41
Hispanic	29.6	3.1	
Non-Hispanic,White	39.4	74.4	
Non-Hispanic, Non-White	31.1	22.5	
Insurance			NA
None	27.9	14.2	
Medicare only	23.5	19.9	

	Non-trauma Center§ N=10 (n=70) %	Trauma Center§ N=43 (n=182) %	P - value
Medicare+Private	9.6	11.3	
Private	9.6	47.1	
Medicaid	29.6	0.0	
Other	0.0	7.4	
Injury Mechanism			NA
Penetrating	13.2	0.0	
Blunt	86.8	100.0	
First ED motor GCS			NA
6	60.9	77.1	
4,5	0.0	1.2	
2,3	0.0	1.2	
1,not paralyzed	9.5	0.0	
1,paralyzed	29.6	20.6	
Injury Severity Score			
Mean(SD)	23.7(30.6)	18.6(22.0)	0.42
<16	28.5	41.9	0.69
16-24	14.4	28.1	
25-34	48.7	22.6	
>34	8.3	7.3	

Table 6 Adjusted mortality effect by OTA sub-classification

Outcomes	Relative Risk (95% Confidence Interval)
Hospital death	
Pelvis A -Type	3.40(1.23,9.39)
Pelvis B or C - Type	0.90(0.22,3.67)
Acetabulum A-Type	2.66(0.32,22.15)
Acetabulum B or C- Type	0.10(0.02,0.47)
Death within 90 days	
Pelvis A -Type	1.08(0.51,2.30)
Pelvis B or C - Type	0.69(0.23,2.06)
Acetabulum A-Type	5.17(0.72,37.02)
Acetabulum B or C- Type	0.10(0.02,0.47)

Adjusted Mortality Effect (Trauma Center versus Non-trauma Center) by Orthopaedic Trauma Association Sub-classification[§] Pelvis A-type (weighted number = 1240), Pelvis B or C - Type (weighted number = 941), Acetabulum A-Type (weighted number = 209), Acetabulum B or C-Type (weighted number = 152). Thirty Pelvis and 8 Acetabulum injuries were non sub-classified and excluded from the stratified analysis.
[§]A-Type is stable with regards to pelvic ring disruptions and involving single column with regards to acetabular injuries; B – Type is partially unstable with regards to pelvic ring disruption and including a transverse component with regards to acetabular injuries; C – Type is unstable (complete disruption of posterior arch) with regards to pelvic ring disruption and complete articular injuries involving both columns with regards to acetabular injuries.

Eighty two percent of patients discharged alive, eligible for NSCOT and enrolled in the study were successfully located and interviewed at twelve months. Average differences in SF-36 physical functioning and Musculoskeletal Functional Assessment at one year were 11.4 (95%CI 5.3 – 17.4) and -13.2 (-24.7 to -1.7) respectively, indicating statistically and clinically significant improved outcomes with treatment at trauma centers for more severe acetabular injuries (Table 7).

Table 7 Twelve month adjusted Functional Assessment differences by OTA sub-classification

	SF-36 Physical Component*	SF-36 Mental Component*	Musculoskeletal Functional Assessment**
	Mean Difference (95% Confidence Interval)	Mean Difference (95% Confidence Interval)	Mean Difference (95% Confidence Interval)
Unstratified Sample	0.8(-2.1,3.7)	1.3(-1.4,4.1)	13.8(-2.1,29.7)
Pelvis only	2.3(-0.8,5.3)	2.1(-1.9,6.0)	7.9(-11.3,27.2)
Acetabulum only	-2.8(-9.7,4.0)	-0.5(-7.5,6.5)	12.5(-10.5,35.5)
Combined	1.7(-3.2,6.6)	0.5(-6.7,7.6)	14.7(-10.2,39.6)
Pelvis A-Type	1.5(-1.8,4.7)	2.3(-1.0,5.7)	10.4(-6.6,27.3)
Pelvis B or C-Type	2.9(-7.1,12.9)	-0.7(-8.5,7.1)	16.3(-10.3,42.8)
Acetabulum A-Type	-2.8(-10.5,4.8)	-4.1(-11.2,3.1)	9.4(-13.3,32.1)
Acetabulum B or C-Type	11.4(5.3,17.4)	3.8(-1.7,9.3)	-13.2(-24.7,-1.7)

Twelve Month Adjusted[§] Functional Assessment Differences (Trauma Center vs. Non-trauma Center) by Orthopaedic Trauma Association Sub-classification[§§]

[§] Propensity Score-based adjustment model including the following covariates: all demographic and injury characteristics listed in Table 1, plus ED first shock, First ED assessment of pulpils, midline shift, flail chest, open skull fracture, obesity and paralysis, together with relevant two-way interaction terms.

[§§] A-Type is stable with regards to pelvic ring disruptions and involving single column with regards to acetabular injuries; B – Type is partially unstable with regards to pelvic ring disruption and including a transverse component with regards to acetabular injuries; C – Type is unstable (complete disruption of posterior arch) with regards to pelvic ring disruption and complete articular injuries involving both columns with regards to acetabular injuries.

* SF-36 Physical and Mental Health Components - positive score implies improved quality of life.

** Standardized MFA mobility subscale – negative score implies less functional impairment

DISCUSSION

We studied the effects of trauma center versus non-trauma center on mortality and functional outcomes among patient with major trauma including pelvic and/or acetabular injuries from the National Study on Cost and Outcomes of Trauma. It is important to note that the inferences drawn from the findings of the present study pertain only to the comparison of level I versus non-trauma centers. Conclusions about relative performance of level II and level III centers cannot be made from these data. Despite treating more severely injured patients, trauma center care was associated with reduced risk of mortality for patients with combined

pelvic and acetabular injuries and those with severe acetabular injuries. Moreover, these most critically injured patients experience improved physical functioning at one year when care is provided in a trauma center as compared to non-trauma center.

These findings are consistent with a growing body of trauma literature examining the trauma center effect on mortality and functional outcome. One reason for the benefits of dedicated trauma center care is the concentration of expertise cultivated by high volumes of severely injured patients. The hypothesis that greater experience leads to better outcomes is supported by the results of a retrospective cohort study by Nathens who studied patients with penetrating abdominal and blunt multisystem trauma patient at 31 level I and level II trauma centers participating in the University Healthsystems Consortium Trauma Benchmarking Study[24]. Treatment at high volume centers (>650 trauma admission per year) was associated with significant reduction in mortality risk and length of stay among patients at high risk for adverse outcomes.

Much work has focused on elucidating which subsets of severely injured trauma patient benefit most from trauma center care given the ramifications that this knowledge would have on improving triage. An analysis of National Trauma Data Bank (NTDB) data including only those patients with severe cardiovascular, neurological, liver or complex pelvic injuries had mortality and disablement benefits associated with level-1 trauma center care.[25] Patients with complex pelvic injuries had significantly better functional outcomes when treated at level I centers. Similarly, a retrospective cohort analysis from the State of Ohio Trauma Registry analyzing data from 18,103 primary trauma admission demonstrated improved survival associated with level I trauma center care.[26] This survival advantage was present among those with ISS>15 as well as those with head and pelvic injuries. These studies suggest that pelvic injuries define a subset of trauma patients more likely to benefit from treatment at trauma centers.

Given that injuries to the pelvis and acetablum represent among the most life threatening of orthopaedic injuries, these injuries have been implicated as indicators of patients most likely to benefit from the expertise, experience and multidisciplinary resources available at trauma center. Injuries to the pelvis are associated with high rates of blood loss, morbidity and mortality,[27-31] though relatively little has been written about these severe complications in management of high-energy acetabular fractures. Magnussen found that among 289 high-energy isolated pelvic or acetabular injuries, similar rates of subjects required blood transfusion.[32] However, patient with combined pelvic and acetabular injuries among this cohort required transfusions at significantly higher rates (57%) as compared to either isolated pelvic (24%) or acetabular (35%) injuries. These findings were supported by another study of 82 patients with combined pelvic and acetabular trauma compared to matched controls with

isolated injuries.[9] In the present study, we benefit from the increased granularity of NSCOT data that classified pelvic and acetabular injuries using the OTA classification scheme in order to make more precise comparisons than were possible from NTDB and registry data. The large mortality risk reductions associated with trauma center we report among those with combined pelvic and acetabular injuries and those with more severe acetabular fractures are consistent with the notion that patients with the most devastating pelvic injuries benefit from the resources and expertise available at trauma centers.

Fewer studies have been conducted on the benefit of trauma center care with respect to functional outcomes or health related quality of life. Demetriades used data from the National Trauma Data Bank (NTDB) to show that patients with complex pelvic fractures (defined by ICD-9 codes: 808.43, 808.53) had significantly better functional outcomes (functional independence measure at discharge) when taken to a level-1 trauma center versus lower level trauma center.[25] Unfortunately, measurement of function at the time of discharge, is a problematic and inconsistent time point for analysis.[33] Gabbe and colleagues[34] used 12-month functional outcomes (Glasgow Outcome Scale - Extended) to show longer term benefits of level-1 trauma center care among survivors of blunt major trauma (Injury Severity Score > 15). While reporting inferior function associated with orthopaedic injuries, no subgroup analysis was conducted to assess whether specific skeletal injuries benefited more or less from trauma center care. Mackenzie et al. analyzed functional outcomes among those with major lower extremity trauma and found that the physical component of the SF-36 and MFA showed greater improvements for those treated at trauma centers.[7] NSCOT patients with at least one injury to a lower limb (including pelvis and acetabulum) with an AIS score of ≥3 points were included for the analysis. In this sub-study, as well as the parent NSCOT study,[6] there were trends towards relative trauma center benefit for those with more severe trauma. However, the functional outcome of patients with specific pelvic and acetabular fractures was not explored separately. We reported improvement in prospectively obtained physical function measurements at one year associated with trauma center care, specifically among those with the most severe acetabular injuries, a finding that is consistent with these prior studies.

Among subjects with less severe injuries such as stable pelvic ring (61-A) or more limited acetabular injuries (62-A), there was a less coherent explanation of the findings. In most of these subgroups, there was no significant trauma center effect, and in some cases, results favored non-trauma centers. Adjustment for case mix has been studied by Nathens and at least when considering mortality outcomes, the consideration of ISS, age, systolic blood pressure at ED arrival, presence of severe head injury (AIS), mechanism, gender and the presence of severe abdominal injury (AIS) have been considered sufficient.[35] Still, one possible reason for this finding is incomplete confounding adjustment for the disproportionately more severe

injuries and sicker patients treated at TC (Table 1). The lack of therapeutic benefit of TC for these older patients may be related to their lack of need for surgical management of their pelvic injury and the many related specialized services provided at trauma centers, and their greater need for continuity in care of their complex medical co-morbidities. The findings presented here do not support recommendations to preferentially triage older patients with stable A-Type pelvic or acetabular injuries to trauma centers.

This study has several potential limitations. First, this study is observational and despite sophisticated sampling and confounding adjustment to enhance causal inferences, it is still prone to bias from unknown or unmeasured confounding. Second, multiple subgroup analyses were run which could inflate the possible false positive rate for the hypothesis tests we conducted. Still, this study used high quality prospectively gathered data for the largest ever study of its kind to assess the relationships between level of trauma center care and outcomes. Rather than emphasize the magnitude of effects of trauma center care, we focus on the consistency of finding across subgroups of the most critically injured to convey a coherent finding of improved survival and functional outcomes at trauma centers.

In conclusion, these findings show that risk of mortality is significantly lower for patients with severe acetabular injuries and that these patients also have improved physical functioning at one year when care is provided in a trauma center than in a non-trauma center. Trauma patients with combined pelvic and acetabular injuries also show reduced mortality risk when treated at trauma centers. Patients with evidence of severe acetabular or pelvic ring injuries should be triaged to a trauma center directly.

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EDF

Chapter 8

Development of a New Pelvic Circumferential Compression Device: The Guardian

Submitted

S.P. Knops[1], R.H.M. Goossens[2,5], M. Hofwegen[2], P. Patka[1,3], E.M.M. van Lieshout[1], I.B. Schipper[4]

[1]Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
[2]Department of Industrial Design Engineering, section Applied Ergonomics and Design, Technical University Delft, Delft, The Netherlands
[3]Department of Emergency Medicine, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands
[4]Department of Surgery- Traumatology, Leiden University Medical Center, Leiden, The Netherlands
[5]Department of Neuroscience, Erasmus MC, Rotterdam, The Netherlands

ABSTRACT

Background: Pelvic Circumferential Compression Devices (PCCDs) are designed for the acute treatment of trauma patients with an unstable pelvic fracture during the primary stabilization phase. The currently available devices, the Pelvic Binder®, the SAM-Sling® and the T-POD®, potentially give rise to skin pressure related adverse effects such as pressure sores. The shape and construction of these binders and slings are probably the main causes for the development of these adverse effects. The aim of this study was to design a new PCCD with optimised functional characteristics and minimized peak pressure on the tissue.

Methods: The process for the development of a new PCCD is described in detail. The focus during the development was on use of materials and pressure distribution as well as applicability and ergonomics. Multiple concepts with different pressure adapting techniques, materials, and shapes were tested. The pressure characteristics of the resulting functional prototype were tested.

Results: Primary and secondary requirements showed that solutions for the development of a new PCCD can be found in the use of new materials, pressure distribution and reduction, and functional use. The Basic concept showed to perform best and resulted in the development of a functional prototype of a PCCD, called the Guardian. This new PCCD with a circumferential closing system provides steady pressure over bony prominences with the help of new, high-tech peak pressure-reducing and vapor permeable materials, ergonomic shape and padding, easily controllable pulling tab (limited to 150N) with a cord lock and instruction manual to facilitate usability.

Conclusions: The newly developed PCCD has biomechanically improved characteristics that are indicative of reduction of the peak pressure of the PCCD on the underlying skin. It thereby potentially reduces the risk of skin necrosis at the area of the greater trochanters and the sacrum, as compared to the currently available PCCDs.

INTRODUCTION

Pelvic circumferential compression devices (PCCDs) serve as an initial- and temporary treatment for unstable pelvic ring fractures. Pelvic ring fractures occur after high impact forces, for example after a motor cycle accident, a fall from height, or a car collision. The majority of patients that die after sustaining a high energy trauma pelvic ring fracture, die as a result of severe internal hemorrhage caused by the pelvic ring fracture. The incidence of high energy pelvic ring fractures is around 10 per 100.000 persons of which 3 per 100.000 die before reaching the hospital.[1] The fractures of the pelvic ring allow for increased volume of accumulated blood in the pelvic cavity, before tamponade occurs, The most important initial aim of resuscitation in these patients is to reduce internal bleeding by decreasing the expanded pelvic volume in pelvic ring fractures. External compression reduces the diastasis between the pubic bones and stabilizes the fracture fragments.[2, 3] PCCDs impose external circumferential compression to the pelvis at the level of the greater trochanters, by means of a sling around the pelvis that is manually tightened. By tightening the PCCD at the front, the binder is pulled together, resulting in external circumferential compression. Due to immobilization of the fracture, the PCCDs are likely to also reduce pain. They act as temporary fixation devices for the pelvis until surgical fixation can be initiated or until unstable pelvic fractures are excluded on radiographic examination. According to the Advanced Trauma Life Support® (ATLS®) guidelines[4], all patients with suspected pelvic ring injury should have immediate application of a pelvic ring compression device. These devices can be applied at the accident scene or ultimately upon arrival at the Emergency Department. Several PCCDs, also called "binders", "slings", or "wraps" are already commercially available[5-8]. Examples are the Pelvic Binder®, SAM-Sling®, and the T-POD® (Figure 1). Application of these PCCDs to patients in supine position is relatively simple and rapid (30 seconds).

Figure 1 PCCDs
(A) Pelvic Binder®; (B) SAM-Sling®; (C) T-POD®.

Their beneficial features are mainly based upon adequate compression and stabilization of the pelvic ring.[8,9] Only little attention has been paid to possible deleterious side effects, like the formation of pressure sores and skin necrosis. Data on both the positive and adverse effects of the PCCDs are increasing.[8, 10-13] The use of PCCDs is associated with a chance of pressure sore development (*i.e.*, skin breakdown). Data to support that the exerted pressure on the skin with PCCDs would cause adverse effects on skin viability or aggravate peri-pelvic soft tissue injury like open en closed degloving injuries are limited to case reports.[14-16] What percentage of patients actually experience pressure sores and suffer from irreversible skin breakdown is unknown. External circumferential pressure on the pelvic ring poses the risk of peak pressure over local skin areas at bony prominences like the greater trochanters, the sacrum, symphysis pubis, and sometimes the ventral iliac spinae. Although the etiology of pressure sore development has not been fully elucidated, the main cause is attributed to the long-term unrelieved compression of soft-tissue. Tissue damage is expected to occur with a continuous pressure on the skin, higher than 9.3 kPa (9300 N/m^2, corresponding with 70 mmHg), during a period of two to three hours.[17] The pressure interface often exceeds this limit if the recommendations of the manufacturers are followed.[15, 16]

The development of pressure sores due to the use of PCCDs depends upon several local and systemic factors.[17] Locally, PCCDs impose high pressures to the skin. Immobilization (on a spine board), traumatic tissue injury and the moist micro-climate between the binder and the skin increase the risk on pressure sores. Recent data show that healthy volunteers immobilized with a PCCD on a spine board are potentially at risk of developing pressure sores after having put on a PCCD.[15] Also shear forces that occur during fastening of the PCCD might influence the development of pressure sores. Systemic factors like hypotension add to this risk, since they further reduce the microcirculation under the PCCD. Furthermore, measurements indicate an inverse relationship between the exerted pressure and the body mass index (BMI).[14, 15]

The use of external pelvic compression with PCCDs in severely injured trauma patients poses specific biomechanical demands upon the devices in order to prevent skin pressure related complications. The shape and construction of most PCCDs seem not to suffice these demands yet. The aim of this study was to design a new PCCD with optimised functional characteristics and minimized peak pressure on the tissue.

METHODS

The aim of this project was to design a PCCD for stabilization of unstable pelvic ring fractures with an optimized functional shape and pressure reducing characteristics. First the biome-

chanical properties, applicability, and pressure reducing characteristics of the currently available PCCDs were evaluated. Pressure relieving solutions were investigated and a user test with existing pelvic binders regarding their functionality and applicability was conducted in order to evaluate their advantages and disadvantages. The user test panel consisted of four physicians and one trainee from the Helicopter Emergency Medical Services (HEMS). The results were evaluated in a Harris profile (*i.e.*, a graphic representation of the strengths and weaknesses of design concepts)[18].

Subsequently the collected information was summarized in a set of primary and secondary requirements. The primary requirements were regarded as necessities for the PCCD to be designed. The secondary requirements were regarded as preferences; they would be very useful features and ideally incorporated in the design.

Next, the primary and secondary requirements were used as a guide to decide which material properties were required, how they could be integrated into concepts and in what way combinations of techniques and materials would result in the best solutions. The forces that act on the pelvis were studied, as were existing pressure reducing systems like alternating pressure mattresses. Also, ideas to improve the force distribution of the pelvic binders were explored.

The degree to which these ideas fulfilled the fundamental requirements (*i.e.*, materials, fitting, price, size, and risks) was tested, and concepts were ranked according to their performance in another Harris profile. Determination of PCCD belt dimensions was performed with help of human dimensions in the DINED table (http://dined.io.tudelft.nl/dined/). This provides an overview on how anthropometric data can be used when facing design challenges with P1, P5, P50, P95 and P99 male and female hip circumferences.

Finally the materials, shapes, and functional mock-ups were tested. The concept that complied best with the requirements was used as a frame for a fully functional prototype.

A user test and a pressure mapping test were performed with the prototype, and suggestions for improvements were made accordingly.

The user test panel again consisted of four physicians and one HEMS trainee. The binder and pulley plates were handed to the panel without any information, to see if they would intuitively use it correctly. When they had finished testing the prototype, they were questioned what kind of problems they encountered with the current binders and if this prototype was advantageous.

In order to get a first impression of differences in pressure distribution between the prototype and the existing PCCDs, a pilot test was performed with 10 healthy volunteers in supine position using a Force Sensing Array (FSA) pressure mapping system (Vista Medical Ltd., Winnipeg, Canada). This system consists of a pressure-sensing mat comprised of thin, flexible fabric piezo resistive sensors, forming an array. The FSA software generates a pressure distribution (pressure map), which is a visual representation of the normal forces between the surfaces of the skin and the PCCD. As a comparison, the T-POD® and the SAM-Sling® were tested.[15]

RESULTS

The properties of the three currently available PCCDs, the Pelvic Binder® [14], the SAM-Sling® [2, 7, 19] and the T-POD® [6, 20-22], were assessed. All these PCCDs are disposable, radiolucent and MRI-safe. Differences in PCCD design and functional characteristics, like the different fasteners and closure mechanisms result in a specific pressure distribution[15, 16]. Distinct right/left pressure differences have been described before, especially with the SAM-Sling®.[16] The exerted pressures on the skin by PCCDs generally exceed the tissue damaging threshold. [15] Furthermore, the amount of pressure is influenced by the body mass index, waist size, age and gender[15]. The currently available PCCDs have some important disadvantages. Some of the used materials are non-vapor permeable and have poor pressure distributing characteristics. The belt shape and design are markedly different and sometimes cause mal-positioning, displacement during transport and increased pressure, like the SAM-Sling® that has a narrow belt. The T-POD® and the Pelvic Binder® need to be cut to the appropriate size, which takes time. Therefore, in practice the ends are often folded inwards. The Pelvic Binder's® closure mechanism causes closure in a tapered form through friction of the shoelace system. For application of the SAM-sling® two persons are necessary to fasten the belt.

The primary and secondary requirements that were addressed are summarized in Table 1. Complaints from physicians about the uncertainty of the applied pressure indicated that pressure feedback was an important part in the application process. Some of the variation in the exerted pressure is caused by the differences in the designs and the closing mechanisms of the PCCDs. Solutions for the pressure complications can probably be found in the use of new materials, pressure distribution, pressure reduction, and functional use of the PCCD from an applier's perspective.

The 'hypothetical forces' of the PCCD on the pelvis in a supine position were calculated based on assumptions. The pressure on the inner surface of the pelvis depends on the volume of the pelvic hematoma, represented by the gravitational force which is distributed along the

inner cavity of the pelvis. Therefore the hydrostatic pressure equation ($p = \rho \cdot g \cdot h$) was used in order to measure the pressure of a blood column, where p is the pressure, ρ is the density of the liquid (blood plasma and cells), g is the acceleration due to gravity, and h is height of the column of liquid.

Furthermore vector calculations ($M = F \cdot d$) were used to calculate the reactive forces on the outside of the pelvis, where M is the moment, F is the force, and d is the perpendicular distance between them. The ratio between the forces acting on the trochanters showed that it would be beneficial to use a wider binder and showed the relevance of the additional effect of rotating the hips and knees inwards.
New materials like spacer and Coolmax® fabric were explored. Spacer fabric is a relatively

Table 1 Primary and secondary requirement for a new PCCD.

Primary requirements		**Secondary requirements**	
Skin pressure reduction	Needs validation	Provide stable fixation	Needs validation
Compression force delivery between 150N – 180N	Yes	Pressure below 35 mmHg, or capillary pressure, with an exception of the sacrum	Yes
No X-ray interference	Yes	Consist of a maximum of 2 parts	Yes
Vapor permeable	Yes	No loose or re-usable parts	Yes
Fit P5 to P95 of the European population	Yes	Prevent / camouflage blood staining	Yes
One-size-fits-all	Yes	No corners, ridges and holes, to prevent accumulation of dirt or bacteria	Yes
Delivery of equal distribution of force	Needs validation	Unaffected by extremes of temperature, moisture and exposure to hard or sharp objects	Needs validation
Remain equal pressure throughout immobilization period	Needs validation		
No folding or creasing when tightened	User tests		
No seams in the area that applies pressure to the trochanters, sacrum, or iliac spine	User tests		

Primary and secondary requirements for a new Pelvic Circumferential Compression Device for non-invasive treatment of pelvic ring fractures and a checklist if these design inputs were met.

new material, used in the mattress industry for its ventilating properties, and in protective garment for its pressure dividing properties. Coolmax® fabric transports moist to the outer layer and can be heat molded into a concave shape.

Several materials, with different gauges and foams with different densities were tested using the Force Sensing Array (FSA) pressure mapping system. Only the pressure at the sacrum was tested. The best results were achieved with a combination of spacer fabric and a high density (memory) foam. The spacer reduces the high pressure points to bigger surfaces with

less pressure, reducing the pressure points due to a point-concentrated load, whereas foam is soft and shapes well to the body.

Multiple concepts with pressure adapting techniques, functional mock-ups, materials, and shapes were tested. A Basic concept was designed that forms the basis for all other concepts. This concept doesn't use special pressure adapting techniques. This Basic concept has a spring system in the pulling mechanism to limit the applied tension.

The final result was a functional prototype of the Basic concept; later called the Guardian (Figure 2). The binder of this prototype is twenty cm wide and is curved towards to sacrum and the trochanters. The binder consists of an outer layer, an inner layer, and the sacrum and trochanter paddings that are placed in between these layers. The outer layer was made of blue Velcro. Fluorescent yellow stitching indicates the level where the binder should be placed over the trochanters (Figure 2A). The inner layer, which is in contact with the skin, was made of soft blue spacer fabric with a Coolmax® coating.

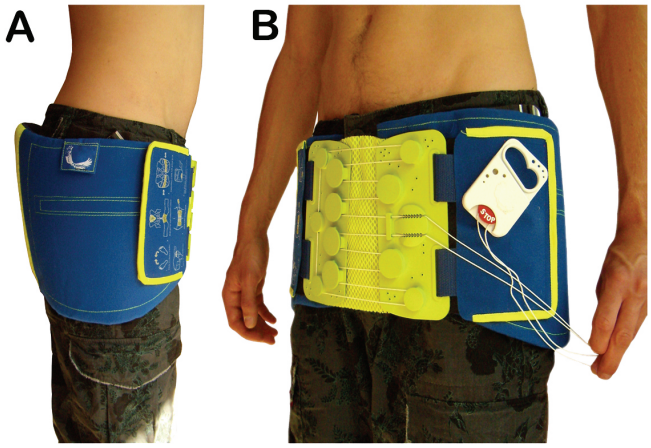

Figure 2
(A) Side view of the application of the final prototype, with the yellow stitched identification line for correct placement and the manufacturer's instructions manual on one of the Velcro flaps and (B) Front view of application of the final prototype, with the closing system (pulley wheels), Velcro flaps, cord lock, and pulling tab.

At the location of the sacrum, a spacer was added between the outer and the inner layer in order to provide extra cushioning. Two slight bumps to the sides of the sacrum padding provide extra dorsal support for the iliac wings. The edges of the foam decline gradually and soft memory foam is extended from the sacrum padding to the trochanters.

An instructions manual (Figure 3) was placed on one of the Velcro flaps. The main guidelines for application of the PCCD are given in clear text and are supported with explanatory pictures.

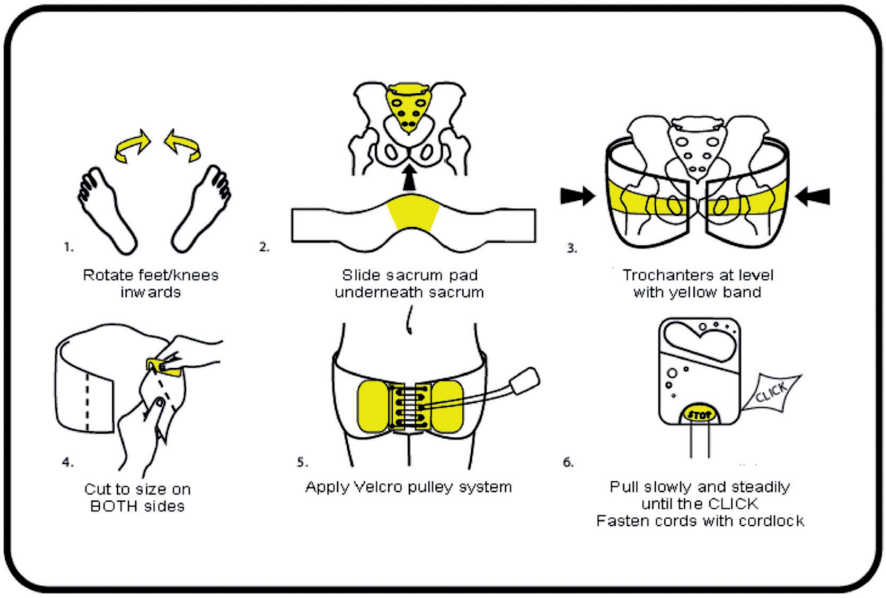

Figure 3
Manufacturer's instructions manual on one of the Velcro flaps of the final prototype.

The final prototype is "one size fits all" and needs to be "cut-to-fit" to the preferred size with the removable binder cutter (Figure 3), that is attached with Velcro (hook-and-loops fastener) to one of the pulley system's Velcro flaps. At the front, near the symphysis pubis, a twenty cm gap is left open that is overlapped with the closing system which is applied to the binder with the Velcro flaps. Underneath the closing system, a layer of spacer fabric and Lycra is connected to the Velcro flaps in order to prevent the abdomen from bulging through the gap between the binder edges.

The closing system of the final prototype is a Velcro backed pulley system (Figure 4) with a pulling tab (Figure 5). One can feel the pulling tab click into position, and there is a visual signal when the stop sign shows up on the handle with a force equal to 150N.

The final prototype is equipped with a cord lock (Figures 2B and 4), that can be operated with one finger and released with a sharp tug to the cord again. The back of the pulling tab is

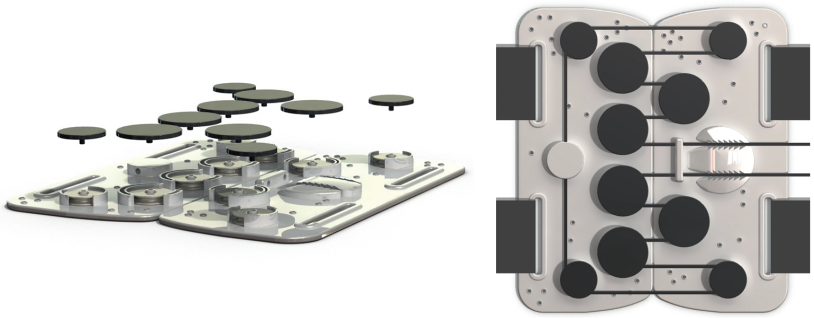

Figure 4
Closing system of the final prototype with a detailed version of the pulley wheels and cord lock.

Figure 5
Pulling tab with stop spring system to give feedback when the desired force of 150N has been reached.

covered with Velcro to attach it to the binder. Some more detailed information and potential advantages of the prototype are presented in the discussion.

The results of the pilot pressure mapping tests with the T-POD® and the SAM-Sling® represent a qualitative assessment of the resulting peak pressure at key locations. They show that the sacrum/buttocks marked red in both pictures, while the trochanters are depicted as green dots, encircled with purple (Figures 6A and 6B). For the same person with the final prototype of the Guardian the trochanters are not visible, only the sacrum displays elevated pressure (Figure 6C). Similar results were seen for all ten persons that were tested.

Prototype user tests that were performed showed that except for the cutting of the binder no other adjustments to belt or pulley system were necessary to attach the PCCD. The sliding of the belt underneath the patient was effortless and the closing mechanism was easily

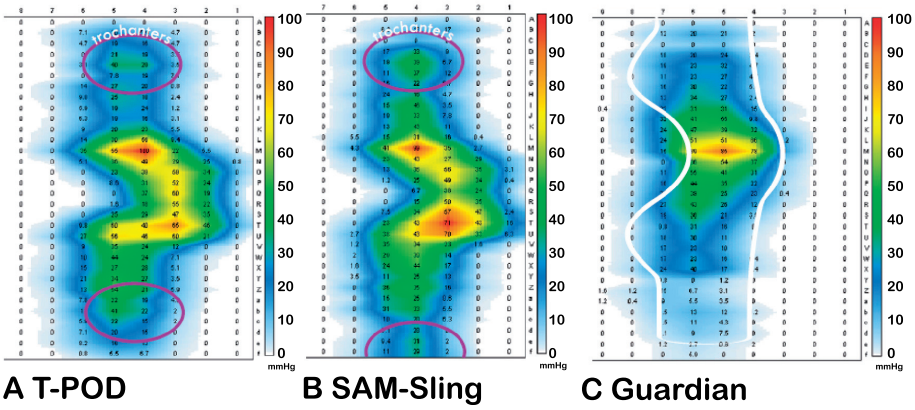

Figure 6

Force Sensing Array pressure mapping. The sacrum/buttocks show up red in both pictures, while the trochanters are depicted as green dots, encircled with purple. Upon application of the final prototype only the sacrum displays elevated pressure. No pressure peaks are visible at the area of the trochanters.

manageable by just one person. The application instructions and the pressure feedback of the pulling tab were appreciated.

DISCUSSION

While designing a new PCCD, the focus was on use of materials and pressure distribution as well as applicability, and ergonomics. The prototype of the Guardian seems to suffice the important primary and secondary general requirements and user requirements.

The shape of the binder plays a significant role in its efficacy and comfort. The Guardian has a slightly concave shape at the area of the buttocks and the area of the sacrum and the joining with the lumbar spine. This shape was chosen to ensure complete coverage of the sacrum and the trochanters and better fit the anatomy. The Guardian is designed with a wide belt in order to avoid misplacement and to facilitate pressure distribution. The blue color partly camouflages blood staining.

The reason for the combination of Velcro, spacer fabric and Coolmax® coating is to facilitate vapor permeability and pressure distribution. The extra padding at the sacrum and towards the iliac wings primarily distributes the pressure but also provides comfort. The two slight bumps to the sides of the sacrum padding provide extra dorsal support for the iliac wings. This should prevent the sacroiliac ligaments from being pulled apart when tightening the PCCD. The extension of the soft memory foam, from the sacrum padding to the trochanters, distributes the

pressures at these compromised bony prominences during tensioning of the PCCD. On the inside of the binder no seams are present in the areas that apply pressure to the trochanters, sacrum and iliac spine. When a flexible mesh Velcro would be used, the risk of folding or creasing when the binder is tightened could even be improved. The layer of spacer fabric underneath the closing system is a safety feature to protect the abdominal and pubic skin from getting caught between the pulley plates and divides the pressure on the symphysis pubis.

The removable binder cutter, to "cut-to-fit" the binder to the preferred size, is always within reach. Knowledge on the maximum and minimum circumferences (DINED) was used for determining the length of the PCCD and where to place the trochanter flaps. The Guardian is 1400 mm long, which is consistent with P99 in women and comparable with the length of the T-POD® and Pelvic Binder®. The dimensions of the binder including the location of the paddings have been chosen to best fit the P50 group, but the binder will still be effective between P5 and P99 of men and women. Because the Guardian is "one size fits all" only one binder size is needed. This reduces purchase costs, improves availability and simplifies storage management.

The closing system of the Guardian is a pulley system (Figure 4) that is based upon the system used in the T-POD®. This system distributes the pressure equally at the trochanters. Application of this pulley system is almost frictionless. The pulley wheels are made of poly-oxy-methylene (POM), an engineering thermoplastic used in precision parts that require high stiffness, low friction, and excellent dimensional stability. The pulley wheels have a conical gap on the lower side (the side connecting to the base plate) in order to reduce friction by creating a smaller contact surface.

Another safety feature is the designed pulling tab of the Guardian (Figure 5). This pulling tab prevents unnecessary pressure on the skin and associated risk of pressure sore development. The pulley ratio is 1:5, so in theory the person applying the binder should have to deliver a force of only 30N. To prevent the cords form loosening during normal wear and to secure quick handling the Guardian is equipped with the cord lock.

Furthermore, the Guardian is equipped with a cord lock (Figure 2B and 4), that can be operated with one finger and released with a sharp tug to the cord again.

Usability is facilitated by placing the instructions manual on top of the binder. This manual serves as a useful reminder to position the binder at the level of the greater trochanters and to inward rotate the hips and knees.

The qualitative assessment of the pressure mapping test with the prototype showed that the Guardian distributes pressure over the key locations (greater trochanters and sacrum). It does

however not completely provide the desired pressure relieve on the tissue over the sacrum, which is most probably a body weight effect. In order to improve the distribution of the pressure over the sacrum, the Guardian could be used in combination with a foam padded spine board and dynamic mattresses[15]. The pilot pressure mapping tests lacked standardized and randomized conditions and performing statistics on such a small group of volunteers would not result in proving definitive significance. Actual pressure data of the Guardian is not described in this article and will be subject of future research, preferably in a clinical setting. The quality of reduction and stabilization of pelvic ring fractures with the Guardian is not described in this article and will be subject of future research. Overall the performed user test indicated that the Guardian was user- and patient-friendly.

CONCLUSION

The aim of this study was to design a new PCCD with optimised functional characteristics and minimized peak pressure on the tissue. The final result of this development process is a functional prototype of a novel PCCD; the Guardian. The binder in combination with the circumferential closing system divides pressure over bony prominences with the help of new, high-tech pressure reducing materials, ergonomic shape, and easily controllable pulling tab and cord lock. The functional prototype meets most of the primary and secondary requirements that were addressed in the design specifications. Pressure mapping tests indicate that the Guardian distributes and thereby reduces peak pressure on the tissue over the greater trochanters and the sacrum. Pressure testing to quantify the pressure reducing characteristics and pressure sore prevention of the Guardian and a comparison with current binders remains to be tested in a clinical setting.

CONFLICT OF INTEREST

None of the authors have to disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Competing interests: None declared. Funding: None. Ethical approval: Not required.

ACKNOWLEDGEMENTS

The authors would like to thank Ir. J.F. Prins for his supervision and overview during the design and prototyping of the Guardian.

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Chapter 9

General Discussion and Future Perspectives

GENERAL DISCUSSION

In this chapter the results of the studies described in this thesis will be put into perspective and will be discussed in relation to the current opinions of the treatment of pelvic ring fractures with Pelvic Circumferential Compression Devices (PCCDs). The questions raised in the outline of this thesis and the answers found in this thesis are discussed. This chapter also elaborates on how the study results support these answers and how they fit in with already existing knowledge on the topic. Finally, implications of the current study findings are outlined and suggestions for future research are made.

Several devices and techniques have been described for the acute management of pelvic ring injuries. In addition to the three most commonly used commercial PCCDs described in this thesis (Pelvic Binder®, Sam-Sling®, and T-POD®) there are also other circumferential compression devices like the 'Stuart Pelvic Harness'[1] (Medistox Ltd., Blackburn, UK) and the 'Pelvigrip' (Ysterplaat Medical Supplies, South Africa) that are not discussed in this thesis. More versatile is the use of a pelvic sheet or improvised binder as described by Nunn *et al*.[2] They also describe the advantage of lower extremity internal rotation on the pelvic disruption, as previous described by Gardner *et al*. [3].

Pelvic sheets, PCCDs and C-clamps

Data of a recent Level III study suggest that emergency stabilization of the pelvic ring by PCCDs and pelvic C-clamps is associated with a lower incidence of lethal pelvic bleeding than tightened sheet wrapping. [4] The authors suggest some interesting explanations for their findings. The circumferential sheet mechanically provided a less appropriate tool to compress the pelvic ring than the binder and C-clamp, and circumferential sheets might have been removed earlier because they hindered diagnostic examinations by covering a larger body surface than PCCDs.

The stability obtained with a PCCD is only one-third of the flexion-extension stability and one-tenth of het internal-external rotation stability that can be obtained with an external fixator. [5] In a clinical trial, stabilization of the T-POD® was compared with emergent pelvic external fixation and showed significant reduced transfusion requirements in the T-POD® group. [6] With the T-POD® the pelvic injury is stabilized immediately, while even in the best hands, emergent pelvic external fixation may easily take 30 minutes or more if performed in the operating room.

A more invasive device that can be applied in the emergency department is a pelvic C-clamp with pin placement in the posterior ilium. This device requires appropriate equipment and training and has several additional adverse effects like perforation of the ilium, fracture

fragment displacement, and pin dislodgement. The pelvic C-clamp could also be applied to the trochanteric region. [7] Nevertheless, despite this alternative anatomical location for the C-clamp application, some contraindications like acetabulum fractures and/or extensive Morel-Lavallee lesions remain. Other potential limitations include access difficulty for femoral puncture in case of angiography and inability to fit the patient into some CT scanners because of the C-clamp hardware.

Prasarn *et al.* showed that in a cadaveric study during bed transfer, log-rolling and head of bed elevation there were no significant differences in displacements observed when the pelvis was fixated with either a sheet or T-POD®. [8] In another recent study Prasarn *et al.* advocated acute stabilization with a PCCD, because in a cadaveric study they found no significant differences in pelvic stability after fixation by an external fixator or a T-POD®. [9] This recommendation is in accordance with the results of a clinical study by Croce *et al.*, where the authors reported on outcome parameters (blood transfusions, hospital length of stay, ventilator associated pneumonia and mortality) and not on stability. [6]

Application of PCCDs

From the overview of history and development of PCCDs (Chapter 1) it may be concluded that the current PCCDs provide an important non-invasive treatment modality in the acute treatment of trauma patients with an unstable pelvic ring fracture. They are designed for acute pelvic reduction in the pre-hospital setting and facilitate early pelvic stabilization during transport and resuscitation. It is important to understand that all circumferential and external compression devices are thought to stabilize pelvic volume and decrease venous hemorrhage. They probably provide limited assistance in controlling arterial hemorrhage. When arterial hemorrhage is suspected the treatment algorithms propose pelvic arterial embolization or pelvic packing.

In 2013, Fu *et al.* showed in a retrospective study that patients with unstable and stable pelvic fractures who were treated with PCCDs applied pre-transfer, required significantly fewer blood transfusions, shorter intensive care unit, and hospital length of stay than patients who did not receive the PCCD prior to transfer. [10] The effectiveness of PCCDs depends on the provided stabilization of the bony elements after fracture and volume reduction to reduce hemorrhage and subsequent transfusion requirements. Our data of the biomechanical study were in accordance with those of Tan *et al.*, concerning the fact that the T-POD® proved to reduce the symphysis diastasis. Tan *et al.* also showed that in the acute setting this resulted in an improved circulatory response (increase in mean arterial response and heart rate decline), presumably by a reduction of the pelvic volume. [11]

A national survey in the UK on the use of pelvic binders by Jain *et al.* revealed interesting findings. Although there is clear evidence that compression around the greater trochanters is most effective in reducing unstable open book fractures, less than half of the registrars stated they would place the PCCD at the level of the greater trochanters. This indicates there is room for improvement in het pelvic binder application skills-teaching .

Bottlang *et al.* demonstrated in a cadaveric study that it is important that PCCDs should be applied at the level of the greater trochanters. [5, 12] A case report by Fleiter *et al.* shows an illustrating example of misplacement of a SAM-Sling® at the level of the iliac wings with insufficient compression and continued pelvic diastasis. [13] Although the greater trochanter is an easily identified and reliable anatomic landmark, misplacement of a PCCD is a common problem and an inadequate method of reducing pelvic fractures. [14] Prasarn *et al.* also advocate the placement of the PCCD at the level of the greater trochanters for improved control of hemorrhage, better access to the abdomen, and greater patient comfort. [15]

Another interesting issue is that there seems to be no clear consensus in the use of PCCDs in lateral compression type fractures. Theoretically over-reduction in lateral compression fractures could cause worsening of the diastasis posteriorly by widening of the sacroiliac joint. Over-compression on the symphysis might cause the (fracture fragments of the) pubic bones to slide over each other and potentially damage the internal organs such as the bladder, uterus or bowel. Although there have been concerns that a PCCD may produce secondary displacement of such a lateral compression fracture, there are no case reports of PCCD application causing damage to neurovascular structures and viscera with further internal rotation from binding. Anterior over-reduction in lateral compression fractures could in theory cause injury to the protruding bladder. It is important to realize that in the pre-hospital trauma setting the type of pelvic ring fracture is often unknown. Application of a PCCD is probably the safest approach if an unstable pelvic ring fracture is expected.

Efficacy of PCCDs

The aim of the systematic literature review (Chapter 3) was to gather evidence concerning efficacy of commercially available PCCDs in patients with unstable pelvic ring fractures. No systematic reviews, meta-analyses, or randomized trials (level I or II evidence) were found. Cohort studies (level III evidence) and case-control studies (level IV evidence) support effective fracture and pelvic volume reduction by PCCDs. The majority of reports were case reports on how to use improvised PCCDs. This systematic review provided an introduction to a number of specific issues like the pressure build-up at the binder-skin interface and the potential complication of soft-tissue necrosis and the effectiveness of pelvic ring compression and the risk for adverse over-reduction. It should be noted that studies describing only invasive compression devices (like the pelvic C-clamp) were excluded from review.

There is a theoretical risk of an applied PCCD masking an anatomically reduced anterior-posterior compression (APC) fracture or 'open-book' type pelvic injury. Leaving an applied PCCD in place during the primary survey radiography is probably the safest approach in order to avoid disturbing initial clot formation. According to the national survey by Jain *et al.* the majority of registrars leave the binder in place during radiographic. [16] Also it remains uncertain how long a PCCD can be safely maintained, and if and how often it should be released periodically to relieve pressure and to inspect soft-tissues. One should follow the manufacturer's instructions, if available (expert opinion).

Skin pressure and pelvic compression

The ideal PCCD should provide enough circumferential compression to maximally reduce the displacement, without gross over-compression. A drawback of the pressure needed to accomplish pelvic ring reduction is the increased risk of tissue damage. Tissue damage is thought to occur when the exerted pressure on the skin exceeds 9.3 kPa for more than two to three hours continuously. [17, 18] Jowett *et al.* already showed that the pressures developed between the PCCD and the skin over bony prominences were all higher than the pressure recommended at interfaces to avoid the development of tissue damage. [19]

In order to gain insight into the pressure build-up at the binder-skin interface the PCCD-induced pressure when applying pulling forces to different PCCDs was measured in a simplified artificial model of the human pelvis. When following the manufacturer's instructions, the exerted pressure of all three PCCDs tested exceeded the tissue damaging level (9.3 kPa). If these results were to be carefully extrapolated to a clinical setting, all three binders would cause a risk for skin problems with regard to the exerted pressure. Since the shape of the experimental model did not reflect the anatomy of the human pelvis, extrapolation to the human situation should be with great caution. In this model, especially the pressure at the anterior location (os pubis) formed a risk-bearing area for the development tissue necrosis. Placing a cover beneath the closing mechanism to protect the substratum was also a recommendable improvement.

Following this experimental study a randomized clinical study quantifying the exerted pressures of PCCDs on the skin in a 'best case' scenario was performed in healthy volunteers**.** The results showed that individuals with pelvic fractures, temporarily stabilized with a PCCD, are potentially at risk for developing pressure sores. The PCCDs exerted pressures on the skin generally exceeded the tissue damaging threshold of 9.3 kPa. Adequate reduction of diastasis and limitation of ongoing hemorrhage is more important than potential tissue damage. The ideal PCCD should provide enough circumferential compression to maximally reduce the displacement, without gross over-compression. Whether improvements to these PCCDs could involve pressure reduction to below this tissue damaging threshold remains

to be studied. Improvements like closure mechanisms with a pulley system (T-POD®) and the Autostop buckle (SAM-Sling®), the use of pressure dividing materials with low shearing forces, and the use of paddings over bony prominences will probably be most effective in pressure reduction if used in synergy.

The pressure measurements with the Force Sensing Array-system showed that each type of PCCD produced a unique pressure distribution pattern. These patterns were direct results of the PCCD differences in belt designs and closing mechanisms.

The risk of skin problems was highest with the Pelvic Binder®, as this PCCD elicited the highest pressure on the skin and showed the highest absolute pressure gradient of the three PCCDs.

The SAM-Sling® could be advocated in terms of the least risk for tissue damage. This could be due to the fact that the Autostop buckle of the SAM-Sling® limits the circumferential compression at a strap tension of 150 N. [20] The small belt of the SAM-Sling® also leaves more space for clinical diagnostics or entrance to the abdomen in case of an interventional radiology procedure or laparotomy. Whether the Autostop buckle still allowed for proper compression of the pelvis is unclear from these results.

Literature data indicated an association between BMI and the risk of pressure sores. [19, 21] The results of our randomized clinical study in healthy volunteers showed a similar inverse correlation with BMI. The protective influence of extra body fat seems to result from improved pressure distribution with subsequent pressure sore risk reduction. The lower pressure levels seen in females might be due to the shape of the female pelvis (gynaecoid-type) or to differences in fat distribution (soft-tissue padding).

The exerted pressure on the skin markedly reduced upon transfer from a spine board to a hospital bed, irrespective of the PCCD used; this shows that unnecessary prolonged immobilization of patients with a PCCD on a spine board should be avoided.

Quality of fracture reduction

The behavior of fracture fragments after application and tensioning of a PCCD was studied in a biomechanical cadaveric study with the use of a three-dimensional infrared video system. In this study the effects of three commercially available PCCDs on the dynamic realignment and final reduction of pelvic fracture fragments were compared. Sufficient reduction in diastasis (to a clinically acceptable <10 mm) was achieved in partially stable (Tile type A) and unstable pelvic fractures (Tile type B1 50mm, B1 100mm and type C) with each of the PCCDs tested (Pelvic Binder®, SAM Sling®, and T-POD®). More importantly, no significant adverse displacement or over-reduction was observed at the symphysis pubis or sacro-iliac joints.

The results of this biomechanical study are interesting because biomechanical research on the quality of reduction with PCCDs is limited. Where others [22] showed that the T-POD® was more effective in reducing symphysis diastasis than a circumferential sheet, the results of our study showed that a reduction in diastasis to a clinically acceptable <10 mm was achieved in all fracture types and with each type of PCCD.

There has been ongoing controversy regarding the required pulling force for optimal pelvic reduction with the use of PCCDs. The required strap tension to achieve complete reduction of the displacement reported by Bottlang *et al.* [12] (180 N) was markedly higher than the pulling forces necessary for complete reduction of Tile type-B1 (50mm) and Tile type-C fractures in this biomechanical study. Krieg *et al.* showed that a PCCD with a 140 N tension limit (chosen 20% lower than the 180 N) posed a minimal risk for over-compression and complications as compared to reduction alternatives that do not provide feedback on the applied reduction force. [20]

The results of our cadaveric study indicated that the application guidelines result in clinically sufficient pulling force to reduce the displacement in pelvic fractures although the required pulling force to attain complete reduction varied substantially among the three different PCCDs. The T-POD® reached the same reduction as the other PCCDs with use of the lowest pulling force (60 N). One should realize that each of the PCCDs uses different pulley mechanisms, therefore the applied pulling force does not necessarily relate to the circumferential exerted pressure under the device. In our study, the Autostop buckle of the SAM-Sling® (150 N tension limitation) accounted for an incomplete fracture reduction in Tile type-B1 (100 mm) fractures at the location of the symphysis pubis in a medio-lateral direction and caused over-reduction in the Tile type-B1 (50 mm) and C fractures. However, both the amount of incomplete reduction and over-reduction are probably not clinically relevant.

Design of a new PCCD

The amount of pulling force needed to accomplish pelvic ring reduction is inextricably linked to the risk of tissue damage. The T-POD® reached the same reduction as the other PCCDs with use of the lowest pulling force (60 N). The SAM-Sling® could be advocated in terms of the least risk for tissue damage (with a limiting circumferential compression of 150 N). These two PCCDs use different closing mechanisms (pulley system *versus* Autostop buckle) and the applied pulling forces do not necessarily relate to the resulting circumferential exerted pressure under the devices. As mentioned above, the ideal PCCD should provide enough circumferential compression to maximally reduce the displacement, without gross over-compression. The shape and construction of the current PCCDs seemed not to suffice these demands yet. This supported the need for a new PCCD that addressed these shortcomings.

In the final chapter of this thesis the development process of a new PCCD is described. This resulted in a functional prototype, named The Guardian.

The Guardian has a concave shape that was designed to better fit the anatomy and a wide belt in order to avoid misplacement and to facilitate pressure distribution. A combination of materials was chosen in order to facilitate vapor permeability and pressure distribution. Extra paddings and soft memory foam were integrated to distribute the pressure and provide comfort at compromised bony prominences. The layer of spacer fabric underneath the closing system was a safety feature to protect the abdominal and pubic skin from getting caught between the pulley plates and divides the pressure on the symphysis pubis. The closing system of the prototype is a pulley system that is based upon the system used in the T-POD®. Another safety feature was the newly designed pulling tab of the Guardian. This pulling tab prevented unnecessary pressure on the skin and associated risk of pressure sore development.

The pilot pressure mapping tests lacked standardized and randomized conditions and the statistical power was too low to perform statistics on such a small group of volunteers. Overall, the user tests indicated the Guardian was both user-friendly and patient-friendly. Some of the requirements of the prototype of this new PCCD need further validation, like whether it actually provides clinically significant stabilization and contributed to better pressure distribution. In order to further improve the distribution of the pressure over the sacrum, the Guardian could be used in combination with a foam padded spine board and dynamic mattresses.

The current PCCDs are effective and deliver the stabilization and reduction they were designed for. However, the shortcomings that were now addressed with the design of the Guardian are worthwhile exploring because the suggested improvements could aid in reduction of PCCD associated complications in the future.

Mortality and functional outcomes

The National Study on Cost and Outcomes of Trauma (NSCOT) study in the United States of America used high quality prospectively gathered data, for the largest study of its kind, to assess the association between level of trauma center care and mortality and functional outcomes. The results showed that despite treating more severely injured patients, trauma center care was associated with a reduced risk of mortality at 90 days (RR 0.34) for patients with combined pelvic and acetabular injuries and those with severe acetabular injuries (RR 0.10). Moreover, these most critically injured patients experienced improved physical functioning at one year when care was provided in a trauma center compared with a non-trauma center. These findings were consistent with a growing body of trauma literature [23] examining the effect of trauma center care on mortality and functional outcome.

In the Netherlands pelvic and/or combined acetabular injuries are considered 'low-volume highly-complex operations'. These fractures are rare injuries with a small caseload at primary and secondary hospitals. Treatment is often a major challenge even without vascular or neurological compromise. Therefore the Nederlandse Vereniging voor Traumachirurgie (NVT) presented the first volume standards. They decided on an initial volume of at least 20 operatively treated pelvic and acetabulum fracture patients per year in order to retain the certification for treatment of pelvic fracture patients. The same number is required for operative treatment of patients with vertebral fractures. Regionalization of trauma care in the Netherlands and the implementation of 10 dedicated trauma centers, in the nineties, has helped to improve survival even while the severity of accidents increased. Centralization of the treatment of pelvic and acetabular injuries should aid in further improvement of the level of care and optimization of the cost-benefit ratio by increasing the caseload and re-allocating resources.

Few studies have been conducted on the benefit of trauma center care with respect to functional outcomes. [24-26] Often a long duration of follow-up is required to obtain these outcomes. The reported improvement in prospectively obtained physical function measurements at one year associated with trauma center care in our study is consistent with prior studies. One can only speculate, based on these findings, what causes these benefits. It could be due to improved operative repair, improved care coordination involving social and psychological services, or better access to extensive rehabilitation.

Among patients with less severe injuries such as stable pelvic ring (OTA class 61-A) or more limited acetabular injuries (OTA class 62-A), there was a less coherent explanation of the findings. In most of these subgroups, there was no significant trauma center effect, and in some cases, results even favored non-trauma centers. One likely reason for this finding is incomplete confounding adjustment for the disproportionately more severe injuries and sicker patients (higher Injury Severity Scores and lower admission motor score of the GCS) treated at trauma centers. Non-trauma center patients were older and carried more comorbidities than trauma-center patients. The lack of therapeutic benefit of trauma centers for these older patients may be related to their lack of need for surgical management of their pelvic injury and their greater need for continuity in care of their complex medical co-morbidities. Our findings do not support recommendations to preferentially triage older patients with stable 61-A-Type pelvic or acetabular injuries to trauma centers.

FUTURE PERSPECTIVES

The benefits of Pelvic Circumferential Compression Devices have proven to outweigh the risks, particularly when used in a pre-hospital setting or on sites that lack the surgical capability to rapidly stabilize the pelvis otherwise. Focus of treatment of severely injured trauma patient is and will be on life saving measures. Risks of local damage will usually be accepted for this reason. With improved care, survivors of severe injuries such as pelvic fractures, will after time predominantly complain about residual minor injuries. Therefore, although the PCCDs obviously fulfill the lifesaving requirements, there is room for improvement in acute care of pelvic fracture patients to minimize resulting functional impairment. Some interesting direct and indirect aspects of potential future developments are worthwhile to pursue.

The ideal PCCD

The ideal PCCD should provide enough circumferential compression to maximally reduce the displacement, without clinically relevant over-compression. Improving the PCCD design should focus on material use and shape for optimal pressure distribution. However, clinical efficacy like complete fracture reduction and hemostasis control should always prevail over risk reduction of local complications. Development should also be aimed at other features to control limitation of compression. Like the compression control with the Autostop buckle of the SAM-Sling® a device could be developed that indicates the actual pressure under the binder at the area of bony prominences by incorporating a pressure cell in the belt of the device. A new PCCD like the Guardian should be validated with statistical analysis of functional characteristics like stabilization, dynamic realignment, and volume and pressure reducing capabilities. Further research should focus on a comparison with current devices like the Pelvic Binder®, SAM-Sling® and T-POD®. This research should also include safety evaluations, preferably in a clinical setting. In order to brand a new PCCD, the current patents need to be checked and a sound business plan should be developed to attract investors and secure funding.

In addition to redesigning PCCDs, it is important to realize that there is also substantial room for improvement of spine boards. Using spine boards with a softer topping would be beneficial to all patients that need transportation and temporarily immobilization for their (suspected) injuries, but especially those that have sustained a pelvic fracture.

Centralization of trauma care

The treatment of pelvic ring and acetabular injuries should be further centralized, because of their low incidence and highly complex multidisciplinary management. Patients with a suspected pelvic ring injury should immediately receive a PCCD at the accident scene to facilitate transfer to the nearest trauma center. Trauma centers are equipped with a fully

trained trauma team with all the expertise and resources necessary for further resuscitation and definitive management to treat these severe injuries. Pelvic ring injuries are often associated with substantial abdominal, head and thoracic injuries. Patients with high Injury Severity Scores, low Glasgow Coma Scores, and head injury with potential traumatic brain injury are more likely to survive when triaged to trauma centers. The current standard volume of 20 patients per year will probably be further increased in the next decades.

Education on PCCD use

There is clearly room for improvement of pelvic binder application skills. Training should primary be directed at pre-hospital emergency medical personnel and emergency department staff. PCCDs are too often wrongly placed at the level of the iliac wings, making them an inadequate method for reducing pelvic fractures. Also the additional inward rotation of lower extremities is a worthwhile manoeuvre that is often forgotten. Emergency medical personnel are likely to unnecessary over-tighten PCCDs during application when they are in high stress environments. It is important to stop pulling once sufficient compression force has been obtained. Awareness should be created with PCCDs users that prolonged immobilization, especially in combination with an unpadded spine immobilization board increases the risk for tissue damage like decubitus. When a PCCD is in place for a prolonged period of time it should be released periodically to relieve the pressure and inspect soft-tissues.

Future PCCD research

The efficacy of PCCDs has never been really put to the test. Comparing treatment of patients with pelvic ring fractures with *versus* without a PCCD in a randomized trial would probably be judged unethical. Future studies should be aimed at mortality and determinants of long-term functional outcomes of patients with pelvic ring fractures treated with PCCDs.

Both the research on the risk of pressure induces complications (Chapter 5) and the research on the quality of reduction (Chapter 6) should be confirmed in a trauma patient population in order to also account for systemic influences. This would provide evidence for the actual effectiveness in fracture reduction and hemorrhage control. Additional clinical research is also necessary in order to measure the exerted pressure and resulting reduction characteristics of the different PCCDs. This may contribute to optimization of the application protocol for the current PCCDs and could also aid in the development of more effective PCCDs. To specifically address the safety of these devices, observational cohort studies or large series of randomized controlled trials would be necessary.

Different theories exist on the efficacy of pelvic binders on reducing pelvic volume: Pelvic volume reduction has a tamponing effect to control hemorrhage. Stabilization of the injured pelvis is important to control motion at fracture edges. Stabilization encourages thrombus

formation in lacerated vessels and decreases bone and soft tissue bleeding. Stover *et al.* demonstrated that changes in volume are less dramatic with closure of the pelvic ring than hypothesized by others. [27] This raises the question of what the relation is between fracture type and dislocation and increase of pelvic volume? It would be interesting to study if this could be measured from a plain radiograph. This would also facilitate early identification of the location (like diagnosing a hemothorax on a chest X-ray) and estimation of the amount of potential blood loss without having to take a patient to a CT-scanner during resuscitation.

Besides their effect on reducing retroperitoneal volume, PCCDs act as splints to the pelvic fractures. Like splinting in other types of fractures, PCCDs are expected to reduce motion at the fracture site and as a result reduce bleeding and pain and decrease additional soft tissue injury and pain in the trauma patients who is moved, turned, and inspected numerous times. There are no clinical data in the present literature on PCCDs concerning their possible effect on pain reduction. Literature on the hemodynamic effects of binder removal and subsequent release of pressure, if clinical suspicion continues with regards to pelvic injury, is also lacking. There are no reports that removal of the binder can lead to haemodynamic instability. Furthermore, it is unclear whether use of PCCDs is beneficial in all pelvic injury types, specifically in lateral compression injuries.

A clinical study could be designed that addresses these clinical issues at the same time. The objective would be to assess the change in hemodynamic measurements after release of a PCCD in patients with a pelvic ring fracture. With the hypothesis that PCCDs quickly improve vital parameters during resuscitation. This research could also be aimed at an assessment of the ability of PCCDs to reduce pain in patients with pelvic fractures. With the hypothesis that PCCDs increase stability of pelvic fractures and will reduce self-reported pain. This study could also be aimed at the association between the type of pelvic fracture and pain reduction, using an additional hypothesis that PCCDs provide pain reduction regardless of the fracture type. This study would have to be a prospective observational study. Assessments will be made in two separate groups. Group I consists of subjects with a pelvic ring fracture stabilized with a PCCD, scheduled for removal (ordered by an attending surgeon). Group II concerns application of a PCCD in subjects sustaining a pelvic ring injury deemed for non-emergent surgical fixation and not treated with a PCCD. In both groups vital signs will be measured and self-reported pain will be assessed (using a Visual Analog Scale), and location and type of pain will be assessed (short questionnaire) before and after removal and application of the PCCD.

GENERAL CONCLUSION

The use of PCCDs in acute stabilization of pelvic ring fractures has considerably improved the primary emergency management and control of hemorrhage. PCCDs fulfill lifesaving requirements and achieve sufficient reduction in diastasis independent of the fracture type and without significant adverse displacement or over-reduction. There are opportunities for improvement in acute care of pelvic fracture patients, to optimize overall outcome and minimize the risk of local complications and residual functional impairment.

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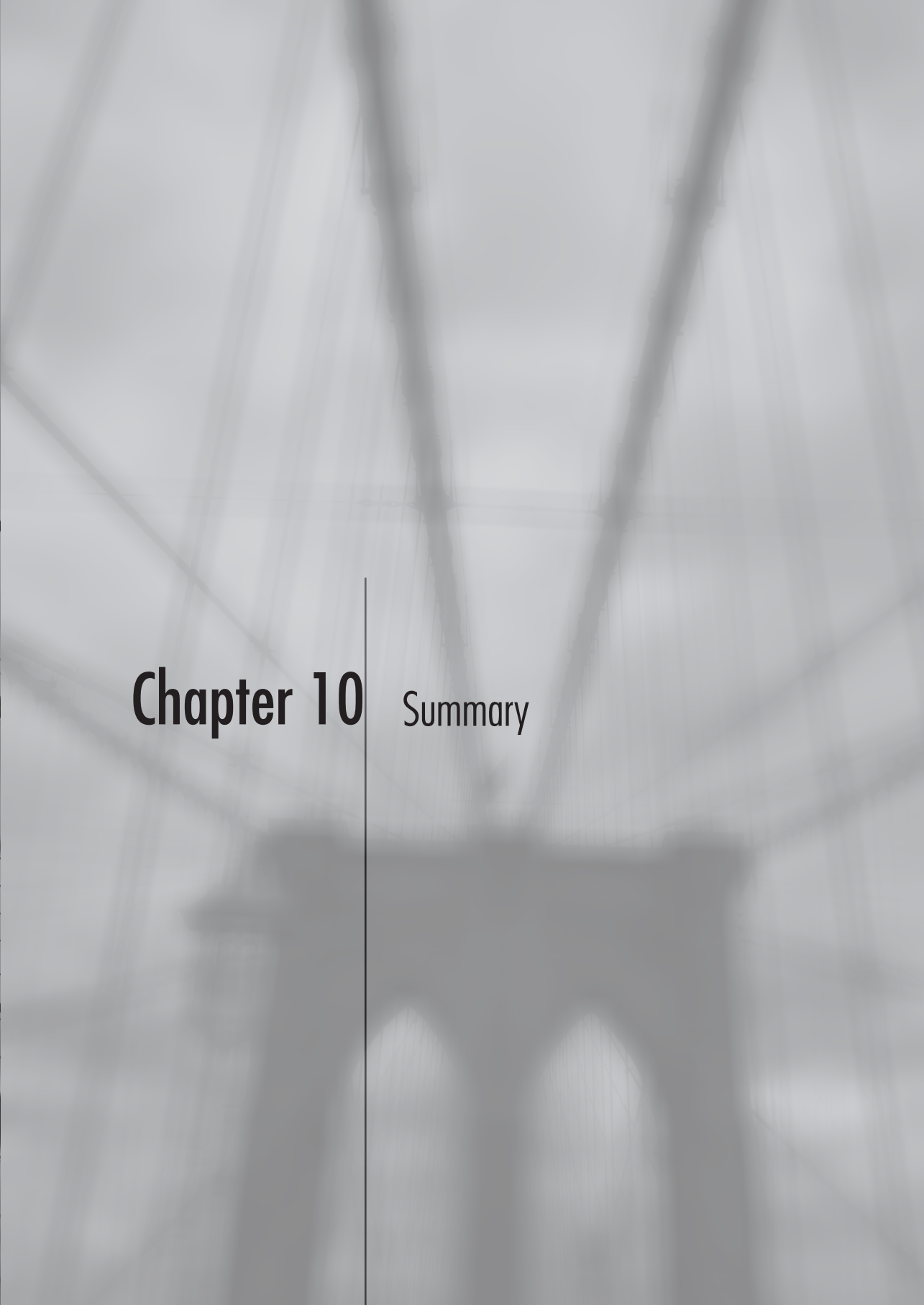

Chapter 10 Summary

INTRODUCTION

Various commercial Pelvic Circumferential Compression Devices (PCCDs) have been developed and are nowadays often used in the initial management of patients with pelvic ring injuries. It is unambiguous that these PCCDs have taken an important place in the pre-hospital and acute treatment of trauma patients with an unstable pelvic fracture. These devices provide a simple method for controlled compression of unstable pelvic fractures and serve as temporary treatment until definitive fracture stabilization and fixation. Immobilization may limit pelvic fracture displacement during patient movements and transfers, decreasing the possibility of clot disruption. PCCDs reduce transfusion requirements, length of hospital stay, and mortality. Besides their effect on reducing retroperitoneal volume, PCCDs act as splints to the pelvic fractures. Like splinting in other fractures, PCCDs are also expected to reduce motion at the fracture site and as a result reduce bleeding and pain.

AIM OF THIS THESIS

The aim of this thesis was to study the use, efficacy and risk of complications of PCCDs for the treatment of pelvic ring fractures.

MAIN FINDINGS

Chapter 1 is a general introduction to the topic and an overview of specific literature on pelvic ring fractures. It shows that these fractures are often associated with substantial abdominal, head and thoracic injuries, and subsequent high mortality rates. Bleeding remains the leading cause of death in patients with disruption of the pelvic ring. In case of suspected pelvic fracture bleeding, provisional pelvic stabilization should occur immediately during the initial evaluation and resuscitation. The trauma screening should always include an adequate clinical assessment with a high index of suspicion for associated soft-tissue and other organ injuries. Often additional recordings, CT imaging and/or angiography are necessary. Knowledge of the fundamental pelvic anatomy and fracture classification systems is vital in the acute management of pelvic ring injuries. Different non-invasive (pelvic sheets, PCCDs) and invasive treatment modalities (C-clamp, external fixator, packing and pelvic arterial embolization) are presented. Important associated injuries like deglovement and Morel-Lavallee injuries and other anorectal and genitourinary injuries which potentially complicate treatment of these injuries are discussed. Finally, long-term outcomes and permanent sequelae like pain, gait abnormalities, incontinence and sexual dysfunction are described. This chapter

also provides an outline of this thesis on the treatment of pelvic ring fractures with Pelvic Circumferential Compression Devices.

The subject of this thesis: Pelvic Circumferential Compression Devices (PCCDs) is introduced in **Chapter 2**. Their use in pre-hospital stabilization of pelvic ring fractures has improved acute management and control of hemorrhage considerably. Additional to the reduction of retroperitoneal volume, PCCDs act as splints to pelvic fractures and also diminish pain and disrupted pelvic ring movement during transport and transfers by direct immobilization. PCCDs serve as a temporary management until definitive surgical stabilization and fixation can be accomplished. All patients with a suspected pelvic ring injury based on the trauma mechanism and/or physical examination findings (as described in Chapter 1) should immediately receive pelvic ring stabilization regardless of the fracture type according to ATLS guidelines. Correction of lower extremity external rotation and application of the PCCDs at the level of the greater trochanters has been shown to provide maximum effectiveness. The overall effectiveness and the risk of complications are discussed briefly. Chapter 2 concludes that in the development of a new generation PCCDs the ability to stabilize the pelvic ring, hemorrhage control and an increase of patient comfort are important. Furthermore the risk of iatrogenic tissue damage should be limited.

Chapter 3 is a systematic review that was conducted to gather the current evidence concerning the effectiveness and complications of commercially available PCCDs (*i.e.*, Pelvic Binder®, SAM Sling®, and T-POD®) in patients with unstable pelvic ring fractures. Literature indicates a reduction of blood loss, and shows no life threatening complications associated with the use of PCCDs. Publications so far (evidence level III - V) report that PCCDs are effective in reducing fractures and associated hemorrhaging. The only available prospective study (evidence level III) showed a good effect for reducing horizontal displacement, comparable with definitive treatment with a PCCD (SAM Sling®) in reducing stable and unstable pelvic fractures. In a retrospective clinical study (evidence level IV) PCCD (T-POD®) application significantly reduced the transfusion requirements in the first 48 hours after injury compared with the control group, in which patients were treated with emergent external pelvic fixation. Moreover, the number of pneumonias, as a marker for infectious complications, was significantly lower in the PCCD group. The nature, severity, and rates of PCCD-related complications are not fully known. Case descriptions do suggest a certain risk of skin damage and possible damage to internal organs after the use of a PCCD. The effectiveness and safety of PCCD use in individual fracture types remain to be determined. High pressure on the skin and prolonged use of PCCDs might put patients at risk of tissue damage like skin necrosis and accompanying comorbidity.

Chapter 4 is an experimental study to gain insight into the pressure build-up at 'the binder device-skin interface'. The PCCD-induced pressure when applying pulling forces to different PCCDs was measured in a simplified artificial model. Difference in design, closing mechanisms (*i.e.*, shoelace versus auto-stop buckle versus pulley system) and functional characteristics of the PCCDs resulted in different pressure build-up at four locations (representing estimated 'anatomical' locations of the right and left greater trochanter, the symphysis pubis, and the sacrum). When following the manufacturer's instructions, the exerted pressure of all three PCCDs tested exceeded the tissue damaging level (9.3 kPa) in case of prolonged use. If these results were to be carefully extrapolated to a clinical setting, all three binders would cause a risk of skin problems, with regard to the exerted pressure. The data for the T-POD® showed that the anterior location (under the closing mechanism) could form a risk-bearing area for the development of tissue damage. Placing a cover beneath the closing mechanism to protect the substratum could result in improvement. As indicated in the previous chapter, the pressure needed to accomplish pelvic ring reduction may put the underlying skin at risk of tissue damage. This implies the need to avoid over-tightening and prolonged use of pelvic compression over the skin.

The results of a randomized crossover study quantifying the exerted pressure of PCCDs (Pelvic Binder®, SAM-Sling® and T-POD®), on the skin in a 'best case' scenario with healthy volunteers are presented in **Chapter 5**. The results of this study in healthy volunteers showed that patients with pelvic fractures, temporarily stabilized with a PCCD, are potentially at risk of developing pressure sores. The PCCDs exerted pressures on the skin that exceeds the tissue damaging threshold of 9.3 kPa. The amount of pressure is influenced by the shape of the PCCD, BMI, waist size, age, and gender. Of the tested PCCDs, the SAM-Sling® seemed to cause the least risk of skin problems in the setting of this study, regarding the variation in the absolute pressure, the pressure gradient and number of cells exceeding the tissue damaging level on the skin in the pelvic region. Upon transfer to a hospital bed, a considerable reduction in pressure was observed with all tested PCCDs, in most cases to a level below 9.3 kPa. Regardless with which PCCD trauma patients are stabilized, early transfer from the spine board to a hospital bed is of key importance to reduce the pressure to a level below the tissue damaging threshold. Therefore, clinicians should be aware of the potential deleterious sequelae associated with the application of a PCCD and every effort must be made to remove the PCCD once hemodynamic resuscitation has been established.

Chapter 6 is a biomechanical cadaver study with the use of a three-dimensional infrared video system. The aim of this study was to compare the effects of three commercially available PCCDs on the dynamic realignment and final quality of reduction for different type of pelvic fracture fragments. The ideal pelvic circumferential compression device should provide enough circumferential compression to maximally reduce the displacement, without gross

over-compression. Sufficient reduction in diastasis (to a clinically acceptable <10 mm) was achieved in partially stable (Tile type A) and unstable pelvic fractures (Tile type B1 50mm, B1 100mm and type C) with each of the PCCDs tested (Pelvic Binder®, SAM Sling®, and T-POD®). More importantly, no significant adverse displacement or over-reduction was observed at the symphysis pubis or sacro-iliac joints. Furthermore the results of the three-dimensional video system showed that most of the displacement during compression with a PCCD on the pelvic ring was in the mediolateral direction at the symphysis pubis. There is ongoing controversy regarding the required pulling force for optimal pelvic reduction with use of PCCDs. The required pulling force to attain complete reduction varied substantially among the three tested PCCDs. The required pulling force to attain complete reduction was lowest for the T-POD® (43 ± 7 N) and highest for the SAM Sling® (112 ± 10 N).

Patients with unstable pelvic injuries are thought to benefit from the specialized care, with concentration of resources, offered at trauma centers. However, the majority of studies supporting this notion have been retrospective. **Chapter 7** compares functional outcome and mortality of patients with major trauma including pelvic and/or acetabular injuries, treated in a trauma center versus a non-trauma center. Data were extracted from the US National Study on Cost and Outcomes of Trauma (NSCOT). The NSCOT study is an observational study with high quality prospectively collected data and is probably the largest study of its kind. Data showed that mortality is significantly lower for patients with severe acetabular injuries, and that these patients also have improved physical functioning at one year, when care is provided in a trauma center as compared to a non-trauma center. Patients with either evidence of acetabular or pelvic ring injuries, or a mechanism of injury consistent with such a potential serious injury might best be triaged to a level 1 trauma center directly.

The use of external pelvic compression with PCCDs in severely injured trauma patients poses specific biomechanical demands upon the devices in order to prevent complications like adverse displacement or over-reduction and over-compression with subsequent tissue damage. The shape and construction of the currently available PCCDs seem not to suffice these demands. In **Chapter 8** the development of a new design of an improved PCCD is described. The aim of this study was to design a PCCD with optimized functional characteristics and minimized peak pressure on the tissue. The final result of this development process is a functional prototype of a novel PCCD, named the Guardian. The binder in combination with the circumferential closing system divides pressure over bony prominences with the help of new high-tech pressure reducing materials, ergonomic designs and an easily controllable pulling tab and cord lock. The functional prototype meets most of the primary and secondary requirements that were addressed in the design specifications. Pressure mapping tests indicated that the Guardian distributed and thereby reduced peak pressure on the tissue over the greater trochanters and the sacrum. More rigorous pressure testing to quantify and

validate the pressure reducing characteristics of the Guardian remains to be tested in a clinical setting.

Finally, the general discussion in **Chapter 9** concludes that the use of PCCDs in acute stabilization of pelvic ring fractures has considerably improved the primary emergency management and control of hemorrhage. PCCDs fulfill lifesaving requirements and achieve sufficient reduction in diastasis independent of the fracture type and without significant adverse displacement or over-reduction. There are opportunities for improvement in acute care of pelvic fracture patients, to optimize overall outcome and minimize the risk of local complications and residual functional impairment.

Future perspectives that are addressed in Chapter 9 include the development of an ideal PCCD, centralization of trauma care, education on PCCD use and future PCCD research.

GENERAL CONCLUSIONS

Chapter 1
Bleeding remains the leading cause of death in patients with disruption of the pelvic ring. In case of suspected pelvic fracture bleeding, preliminary pelvic stabilization should occur immediately during the initial evaluation and resuscitation, if not already performed in the pre-hospital phase.

Chapter 2
The use of PCCDs in acute stabilization of pelvic ring fractures has improved the primary emergency management and control of hemorrhage considerably.

Chapter 3
Despite the absence of level I and II evidence for the clinical effectiveness of PCCDs, publications so far (evidence level III–V) report that PCCDs are effective in reducing fractures and associated hemorrhaging.

Chapter 4
The exerted pressure of PCCDs exceeds the tissue damaging level (9.3 kPa) in case of prolonged use and potentially puts patients at risk of tissue damage like skin necrosis and accompanying comorbidity.

Chapter 5

Patients with pelvic fractures, temporarily stabilized with a PCCD are potentially at risk of developing pressure sores. The amount of pressure is influenced by the type of PCCD, BMI, waist size, age and gender. The SAM-Sling® causes the lowest risk of skin pressure in the setting of this study.

Chapter 6

PCCDs achieve sufficient reduction in diastasis in stable and unstable pelvic fractures and no significant adverse displacement or over-reduction was observed at the symphysis pubis or sacro-iliac joints. The required pulling force to attain complete reduction was lowest for the T-POD® and highest for the SAM Sling®.

Chapter 7

Patients with either evidence of acetabular or combined pelvic and acetabular injuries, or a mechanism of injury consistent with such a potential serious injury might best be referred to a level 1 trauma center directly. Mortality is significantly lower for patients with severe acetabular injuries and these patients also have improved physical functioning at one year when care is provided in a level 1 trauma center.

Chapter 8

The functional prototype of a novel PCCD (the Guardian) divides pressure over bony prominences with the help of new high-tech pressure reducing materials, an ergonomic design and an advantageous closing mechanism with an easily controllable pulling tab and cord lock.

C**hapter 9**

Future improvements in acute care of pelvic fracture patients should lead to optimization of overall outcome and minimize the risk of local complications and residual functional impairment. These improvements should aim towards the development of new PCCDs, research and education focused on the application of PCCDs and centralization of complex trauma care.

Chapter 11 Nederlandse Samenvatting

INTRODUCTIE

Bekkenbinders of Pelvic Circumferential Compressie Devices (PCCDs) zijn ontwikkeld voor gebruik bij de acute opvang en de eerste behandeling van traumapatiënten met bekkenringfracturen. Deze PCCDs hebben inmiddels een belangrijke plaats ingenomen in de prehospitale en acute behandeling van traumapatiënten met een instabiele bekkenringfractuur. Bekkenbinders zijn een eenvoudige methode voor gecontroleerde compressie van instabiele bekkenringletsels (fracturen, luxaties en rupturen) en dienen als tijdelijke behandeling tot een definitieve fractuurstabilisatie en fixatie verricht kan worden. Immobilisatie draagt bij aan stabilisatie van het gefractureerde bekken. Dit zou de kans op mogelijke loslating van reeds gevormde stolsels verlagen. Daarnaast verkleint een bekkenbinder het volume van het bekken, waardoor het bloedverlies beperkt zou kunnen worden. PCCDs verminderen de noodzaak tot bloedtransfusies, de duur van ziekenhuisopname en bekkenfractuur gerelateerde mortaliteit. Naast het effect op het verkleinen van het retroperitoneale volume, fungeren PCCDs ook als een spalk. Zoals immobilisatie bij fracturen van extremiteiten, dragen PCCDs bij aan het verminderen van bewegingen van de fractuurdelen wat leidt tot reductie van bloedverlies en vermindering van pijn.

DOEL VAN DIT PROMOTIEONDERZOEK

Het doel van dit promotieonderzoek was het onderzoeken van het gebruik, de doeltreffendheid en het risico op complicaties van Pelvic Circumferential Compression Devices voor de behandeling van bekkenringfracturen.

BELANGRIJKSTE BEVINDINGEN

Hoofdstuk 1 is een inleiding van het onderwerp en presenteert een overzicht van de belangrijkste literatuurgegevens over bekkenringfracturen. Deze fracturen gaan vaak gepaard met andere substantiële abdominale-, hoofd- en thoraxletsels, en worden mede daardoor gekenmerkt door een hoge mortaliteit. Exsanguinatie blijft de belangrijkste doodsoorzaak bij patiënten met een disruptie van de bekkenring. Bij het vermoeden op verbloeding ten gevolge van een bekkenringfractuur moet tijdens de initiële evaluatie en resuscitatie acuut een tijdelijke fixatie van de bekkenring worden verricht. Tijdens de traumascreening mag een adequaat lichamelijk onderzoek niet ontbreken en moet men bedacht zijn op geassocieerde letsels van weke delen en organen. Vaak zijn aanvullende röntgenopnamen, CT-scans en/of angiografie noodzakelijk. Fundamentele kennis van de anatomie van de bekkenregio en classificatie systemen van de verschillende fractuur typen zijn onontbeerlijk bij de acute be-

handeling van bekkenringletsels. Verschillende non-invasieve (sluitlaken, bekkenbinders) en invasieve behandelingsmodaliteiten (C-clamp, externe fixateur, packing en arteriële embolisatie) worden in detail besproken. Belangrijke geassocieerde letsels worden besproken, zoals deglovement en Morel-Lavallee letsels en andere anorectale en urogenitale letsels die de behandeling potentieel verder kunnen compliceren Tenslotte worden lange-termijnresultaten en blijvende letsels zoals pijn, looppatroonafwijkingen, incontinentie en seksuele dysfunctie als gevolg van bekkenringletsels, beschreven.

In **Hoofdstuk 2** wordt het onderwerp van dit proefschrift, Pelvic Circumferential Compression Devices, geïntroduceerd. Het gebruik van PCCDs voor directe stabilisatie van bekkenringfracturen heeft de acute behandeling van deze letsels en de resultaten van resuscitatie in het geval van verbloeding, aanzienlijk verbeterd. Behoudens de verkleining van het retroperitoneale volume, fungeert de PCCD ook als een spalk en draagt hiermee bij aan vermindering van pijn en aan directe stabilisatie tijdens bewegingen en patiënt transport. PCCDs bieden een tijdelijke oplossing voor stabilisatie van de bekkenringfracturen tot een definitieve chirurgische interventie en fixatie kan worden verricht. Volgens de ATLS richtlijnen dient bij alle patiënten met het vermoeden op een bekkenringfractuur, gebaseerd op het traumamechanisme en/of bevindingen bij lichamelijk onderzoek, onmiddellijk een bekkenbinder aangebracht te worden, ongeacht het type fractuur. Endorotatie van de onderste extremiteit en applicatie van een PCCD op het niveau van de trochanter major is aangetoond doeltreffend. In hoofdstuk 2 wordt geconcludeerd dat bij de ontwikkeling van een nieuwe generatie PCCDs de mogelijkheid om de bekkenring te stabiliseren, het tegengaan van verbloeding en het bieden van patiëntcomfort belangrijke eisen zijn. Eveneens moet het risico op additionele en iatrogene weefselbeschadiging door PCCDs worden beperkt.

Hoofdstuk 3 is een systematische review van de huidige literatuur betreffende de effectiviteit en complicaties bij het gebruik van commercieel beschikbare PCCDs (Pelvic Binder®, SAM-Sling® en T-POD®) bij patiënten met instabiele bekkenringfracturen. In de literatuurreview wordt bij het gebruik van PCCDs een vermindering van bloedverlies beschreven zonder dat het PCCD gebruik aanleiding geeft tot levensbedreigende complicaties. Publicaties tot dusver (evidence level III - V) melden dat PCCDs effectief zijn in het reduceren van fractuurdiastase en geassocieerd bloedverlies. De enige beschikbare prospectieve studie (evidence level III) toont een duidelijk effect van de PCCD (SAM-Sling®) op diastasereductie, vergelijkbaar met het effect van definitieve chirurgische fixatie bij de stabiele en instabiele bekkenfracturen. Uit retrospectief klinisch onderzoek (evidence level IV) blijkt dat het aanleggen van een PCCD (T-POD®) significant de noodzaak tot transfusie in de eerste 48 uur na trauma vermindert in vergelijking met de controlegroep van patiënten die behandeld werden met vroegtijdige externe fixatie van de bekkenring. Bovendien was het aantal pneumoniae, als marker voor infectieuze complicaties, significant lager in de groep die behandeld werd met een PCCD. De

aard, de ernst en het aantal PCCD-gerelateerde complicaties zijn niet volledig bekend. Het risico op weefselschade en mogelijke schade aan organen ten gevolge van het gebruik van een PCCD wordt voornamelijk in casuïstische mededelingen besproken. De doeltreffendheid en veiligheid van PCCD gebruik in verschillende fractuurtypen, zoals laterale compressiefracturen, moet nog worden vastgesteld. Hoge druk op de huid en langdurig gebruik van PCCDs zijn mogelijke risicofactoren voor het ontwikkelen van weefselbeschadiging als necrose van de huid en daarmee samenhangende co–morbiditeit.

In **Hoofdstuk 4** is een experimentele studie beschreven waarin meer inzicht wordt verkregen in de drukopbouw in de zogenaamde "bekkenbinder-huid-interface'. De PCCD-geïnduceerde druk bij de toepassing van verschillende trekkrachten met verschillende PCCDs werd gemeten in een vereenvoudigd model. Verschillen in het design van de binder, het sluitmechanisme (schoenveter versus auto-stop gesp versus katrolsysteem) en functionele kenmerken van de PCCDs resulteerden in een specifieke drukopbouw op vier locaties die de 'anatomische' locaties van de rechter en de linker trochanter major, de symphysis pubis en het os sacrum representeren. Wanneer de instructies van de fabrikant werden opgevolgd, was de uitgeoefende druk van de drie afzonderlijk geteste PCCDs hoger dan het niveau waarbij weefselbeschadiging optreedt (9,3 kPa) bij langdurig gebruik. Als deze resultaten zorgvuldig worden geëxtrapoleerd naar een klinische situatie zouden alle drie de PCCDs potentieel weefselschade kunnen veroorzaken ten gevolge van de uitgeoefende druk. De metingen met de T-POD® lieten zien dat de anterieure locatie (onder het sluitmechanisme) risicodragend is voor de ontwikkeling van weefselschade. Het plaatsen van een bescherming onder het sluitmechanisme zou de onderliggende huid kunnen beschermen. De druk die nodig is om reductie van de diastase te bereiken kan een risico vormen op weefselbeschadiging van de onderliggende huid. Dit impliceert de noodzaak om overcompressie en het te lang in situ blijven van PCCDs te voorkomen.

In **Hoofdstuk 5** worden de resultaten van een gerandomiseerde cross-over studie waarin de uitgeoefende druk van PCCDs (Pelvic Binder®, SAM-Sling® en T-POD®) op de huid is gekwantificeerde in een 'best case' scenario met gezonde vrijwilligers gepresenteerd. De resultaten van deze studie toonden aan dat patiënten met een bekkenfractuur, tijdelijk gestabiliseerd met een PCCD, potentieel een verhoogd risico hebben op het ontwikkelen van decubitus. De PCCDs oefenden druk uit op de huid die het niveau waarbij weefselschade optreedt (9,3 kPa) overschrijdt. De hoeveelheid druk wordt beïnvloed door de vorm van de PCCD, de BMI, de heupomtrek, de leeftijd en het geslacht. Van de geteste PCCDs lijkt de SAM-Sling® het minste risico op huidproblemen te veroorzaken, zowel wanneer de variatie van de absolute druk, de drukgradiënt en/of het aantal cellen met een drukniveau hoger dan het niveau waarop weefselschade optreedt, wordt gemeten. Bij een transfer van een spine-board naar een ziekenhuisbed werd met alle geteste PCCDs een aanzienlijke drukverlaging waargenomen,

meestal tot onder 9,3 kPa. Ongeacht met welke PCCD traumapatiënten zijn gestabiliseerd is een vroege transfer van het spine-board naar een ziekenhuisbed van essentieel belang om de druk tot onder 9,3 kPa te verlagen. Daarom moet men zich bewust zijn van de mogelijke nadelige gevolgen van de toepassing van een PCCD. Alles moet in het werk worden gesteld om de PCCD tijdig te verwijderen en zo nodig definitieve fixatie te verrichten zodra de omstandigheden dit toelaten.

Hoofdstuk 6 beschrijft een biomechanische kadaverstudie. De effecten van drie verschillende PCCDs op de dynamische verplaatsing en de uiteindelijke kwaliteit van de reductie op verschillende typen bekkenringfracturen werd vergeleken door middel van een driedimensionaal infrarood videosysteem. De ideale bekkenbinder moet voldoende circumferentiële compressie geven om de diastase maximaal te reduceren, zonder overcompressie. Voldoende reductie van de diastase (een klinisch aanvaardbare < 10 mm) kon worden bereikt in gedeeltelijk stabiele (Tile type A) en instabiele bekkenfracturen (Tile type B1 50mm, type B1 100mm en type C) met elk van de geteste PCCDs (Pelvic Binder®, SAM-Sling® en T-POD®). Nog belangrijker is dat er geen significante ongewenste verplaatsing of overreductie werd waargenomen ter plaatse van de symphysis pubis of sacro-iliacale gewrichten. Bovendien bleek uit de resultaten van het driedimensionale videosysteem dat de meeste verplaatsing nabij de symphysis pubis tijdens compressie met een PCCD op de bekkenring in mediolaterale richting was. Er blijft controverse over de benodigde trekkracht voor een optimale reductie van de diastase bij bekkenringfracturen met het gebruik van PCCDs. De benodigde trekkracht voor volledige reductie varieerde aanzienlijk tussen de drie geteste PCCDs. Deze benodigde trekkracht was het laagst voor de T-POD® (43 ± 7 N) en het hoogst voor de SAM-Sling® (112 ± 10 N).

Patiënten met instabiele bekkenringfracturen worden verondersteld te profiteren van de specialistische zorg en concentratie van middelen, die wordt aangeboden in traumacentra. Echter, een meerderheid van de studies ter ondersteuning van dit begrip is retrospectief.

In **Hoofdstuk 7** worden de functionele uitkomsten en mortaliteit van patiënten met ernstig trauma inclusief bekken en/of acetabulum letsels met een opvang en behandeling in een trauma centrum versus een niet-trauma centrum vergeleken. Gegevens werden geëxtraheerd uit de Amerikaanse National Study on Cost and Outcomes of Trauma (NSCOT). De NSCOT studie is een observationele studie met hoge kwaliteit prospectief verzamelde gegevens en is waarschijnlijk de grootste studie in zijn soort. De analyse toonde aan dat de mortaliteit significant lager was bij patiënten met ernstige acetabulumfracturen en dat deze patiënten na een jaar ook fysiek beter functioneren, wanneer zorg wordt verleend in een traumacentrum vergeleken met een niet-traumacentrum. Patiënten met verdenkingen op een acetabulum- of bekkenringfractuur, of bij een traumamechanisme dat in overeenstemming is met een

dergelijk ernstig letsel kunnen het best direct naar een traumacentrum getransporteerd worden; zowel voor opvang als ook voor verdere behandeling.

Het gebruik van externe bekkenringcompressie met PCCDs bij ernstig gewonde traumapatiënten stelt specifieke biomechanische eisen aan deze binders om complicaties zoals nadelige fractuurverplaatsing of overreductie en overcompressie met daaropvolgend mogelijke weefselbeschadiging te voorkomen. De vorm en de constructie van de momenteel beschikbare PCCDs lijken onvoldoende aan deze eisen te voldoen.

In **Hoofdstuk 8** wordt de ontwikkeling van een nieuw ontwerp van een verbeterde PCCD beschreven. Het doel van deze studie was om een PCCD met geoptimaliseerde functionele eigenschappen en minimale piekdrukken op de onderliggende weefsels te ontwerpen. Het uiteindelijke resultaat van dit designproces was een functioneel prototype van een nieuwe PCCD, genaamd The Guardian. Deze bekkenbinder heeft een circumferentieel sluitmechanisme en verdeelt de druk over de trochanter major en sacrum regio met behulp van nieuwe high-tech drukverlagende materialen. Bovendien is er sprake van een ergonomisch design met een praktisch sluitmechanisme en een gemakkelijk controleerbaar handvat en koordslot. Het functionele prototype voldoet aan de meeste van de primaire en secundaire eisen die bij de ontwerpspecificatie waren gesteld. Drukmetingen toonden dat de Guardian de druk verspreidt en daarmee een lagere piekdruk op de weefsel over de trochanters en het sacrum uitoefent. Meer uitgebreide druktesten zijn noodzakelijk voor het kwantificeren en valideren van de drukverlagende eigenschappen van de Guardian in een klinische setting.

In **Hoofdstuk 9** wordt geconcludeerd dat het gebruik van PCCDs voor acute stabilisatie van bekkenringfracturen de trauma opvang en de behandeling van ernstige bloedingen aanzienlijk heeft verbeterd. PCCDs kunnen levensreddend zijn en leveren noodzakelijke circumferentiële compressie om de diastase maximaal te reduceren, zonder overcompressie. Mogelijkheden voor verbetering van de acute behandeling van patiënten met bekkenringfracturen worden besproken. Dit moet leiden tot optimalisatie van de uitkomsten en minimalisatie van het risico op lokale complicaties en resterende functionele beperkingen. Tot slot wordt een aantal toekomstperspectieven besproken waaronder de ontwikkeling van een ideale PCCD, de centralisatie van complexe trauma zorg, onderwijs gericht op de toepassing van PCCDs en mogelijkheden voor toekomstig onderzoek.

ALGEMENE CONCLUSIES

Hoofdstuk 1
Bloeding blijft de belangrijkste doodsoorzaak bij patiënten met een disruptie van de bekkenring. Bij verdenking hierop moet direct voorlopige bekkenring stabilisatie plaatsvinden tijdens de initiële evaluatie en resuscitatie indien dit niet al pre-hospitaal heeft plaatsgevonden.

Hoofdstuk 2
Het gebruik van PCCDs voor acute stabilisatie van bekkenringfracturen heeft het management van deze acute letsels en de resuscitatie in het geval van verbloeding aanzienlijk verbeterd.

Hoofdstuk 3
PCCDs zijn effectief in het reduceren van fractuurdiastase en beperken van het hiermee gepaard gaande bloedverlies (evidence level III-IV).

Hoofdstuk 4
De door PCCDs geïnduceerde druk overschrijdt het niveau waarbij weefselschade optreedt (9,3 kPa) in geval van langdurig gebruik. Hierdoor vormt het gebruik van PCCDs bij patiënten een risico op het ontwikkelen van decubitus.

Hoofdstuk 5
Patiënten met een bekkenringfractuur, tijdelijk gestabiliseerd met een PCCD, hebben potentieel een verhoogd risico op decubitus. De hoeveelheid druk wordt beïnvloed door de vorm van de PCCD, BMI, heupomtrek, leeftijd en geslacht. Van de geteste PCCDs lijkt de SAM-Sling® het minste risico op huidproblemen te veroorzaken.

Hoofdstuk 6
PCCDs bereiken voldoende reductie van stabiele en instabiele bekkenringfracturen en leiden niet tot ongewenste verplaatsing of overreductie bij de symhysis pubis of de sacro-iliacale gewrichten. De voor complete reductie benodigde trekkracht was het laagst voor de T-POD® en het hoogst voor de SAM-Sling®.

Hoofdstuk 7
De mortaliteit is significant lager bij patiënten met ernstige acetabulumfracturen wanneer zorg wordt verleend in een trauma centrum vergeleken met een niet-traumacentrum. Deze patiënten functioneren fysiek ook beter na een jaar. Patiënten met verdenking op een acetabulum- of bekkenringfractuur, of een traumamechanisme dat in overeenstemming is

met een dergelijk ernstig letsel, kunnen bij triage het best direct naar een traumacentrum getransporteerd worden voor opvang en verdere behandeling.

Hoofdstuk 8

Het functionele prototype van een nieuwe PCCD (The Guardian) verdeelt druk over de trochanter en sacrum regio met behulp van nieuwe high-tech drukverlagende materialen. Bovendien heeft de Guardian een ergonomisch design en een praktisch sluitingsmechanisme met een gemakkelijk controleerbaar handvat en koordslot.

Hoofdstuk 9

Toekomstige verbeteringen in de acute behandeling van patienten met bekkenringfracturen moeten leiden tot optimalisatie van uitkomsten en minimalisatie van het risico op lokale complicaties en blijvende functionele beperkingen. Deze verbeteringen moeten worden gezocht in de ontwikkeling van nieuwe PCCDs, onderzoek en onderwijs gericht op de toepassing van PCCDs en centralisatie van complexe trauma zorg.

Appendices

I. Scientific Output
II. Contributing Authors
III. Acknowledgements
IV. PhD Portfolio
V. Curriculum Vitae

I. SCIENTIFIC OUTPUT

THIS THESIS

Spanjersberg WR, Knops SP, Schep NWL, van Lieshout EMM, Patka P, Schipper IB. Effectiveness and complications of pelvic circumferential compression devices in patients with unstable pelvic fractures: a systematic review of literature. Injury 2009;40(10):1031-1035.

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II. CONTRIBUTING AUTHORS

Richard H.M. Goossens, MD, MSc, PhD
Department of Industrial Design Engineering, section Applied Ergonomics and Design, Technical University Delft, Delft, The Netherlands and Department of Neuroscience, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Mariena Hofwegen, MSc
Department of Industrial Design Engineering, Technical University Delft, Delft, The Netherlands.

Gregory J. Jurkovich, MD
Department of Surgery, Denver Health Medical Center, Denver, Colorado, USA.

Gert-Jan Kleinrensink, MD, PhD
Department of Neuroscience-Anatomy, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Esther M.M. van Lieshout, MSc, PhD
Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Ellen J. MacKenzie, PhD
Department of Health Policy and Management, Bloomberg School of Public Health, Johns Hopkins University, Baltimore, Maryland, USA.

Saam Morshed, MD, PhD, MPH
Univeristy of California San Francisco / San Francisco General Hospital Orthopaedic Trauma Institute (OTI), San Francisco, California, USA.

Peter Patka, MD, PhD
Department of Emergency Medicine, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Marcel P.J.M. van Riel, MSc
Department of Neuroscience, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Frederick P. Rivara, MD, MPH
Department of Pediatrics, Harborview Injury Prevention and Research Center, University of Washington School of Medicine, Seattle, Washingthon, USA.

Niels W.L. Schep, MD, MSc, PhD
Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Tim Schepers, MD, PhD
Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Inger B. Schipper, MD, PhD
Department of Surgery-Traumatology, Leiden University Medical Center, Leiden, The Netherlands.

W. Richard Spanjersberg, MD
Department of Surgery-Traumatology, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Cees W. Spoor, PhD
Department of Neuroscience, Erasmus MC, University Medical Center Rotterdam, Rotterdam, The Netherlands.

Jin Wang, PhD
Harborview Injury Prevention & Research Center, University of Washington School of Medicine, Seattle, Washington, USA.

III. ACKNOWLEDGEMENTS

Promoveren kun je niet alleen. Dit proefschrift ontleent zijn bestaansrecht aan de inzet en toewijding van vele collega's en vrienden en een aantal in het bijzonder.

Prof. Patka, beste Prof. Altijd heb ik op uw begeleiding kunnen rekenen. Ook heeft u in belangrijke mate bijgedragen aan een aantal onvergetelijke ervaringen, waaronder het co-schap Trauma Chirurgie in het Groote Schuur Hospitaal in Kaapstad en het research fellowship in San Francisco U bent altijd bijzonder betrokken geweest en daar ben ik u veel dank voor verschuldigd.

Prof. Schipper, beste Inger. Door jou ben ik hier in verzeild geraakt. Via Gert-Jan Kleinrensink kwam ik in 2008 bij je aankloppen om onderzoek te verrichten als onderdeel van de opleiding Geneeskunde. Ik wilde graag praktisch en tastbaar bezig zijn. Nou dat heb ik geweten… vele uren met kadavers in de snijzaal en het biomechanische lab waren het directe gevolg. Regelmatig hebben we de grote lijnen voor het onderzoek uitgezet en heb jij bij mij de wind in de zeilen weten te houden (Simon against material!). Schitterend dat je nu als hoogleraar én hoofd van de afdeling Traumachirurgie aan het Leidse roer staat. Je bent doortastend, kritisch en reëel. Hopelijk is er aan de horizon nog meer samenwerking voor ons.

Dr. van Lieshout, beste Esther. Ik denk dat ik je met recht de dragende kracht achter de onderzoeksmachine van de Trauma Research Unit mag noemen. Met name je ondersteuning bij de statistiek is onmisbaar geweest. Je bent punctueel, hebt een allesziend oog voor detail en bent altijd goed geïnformeerd. Zelfs in moeilijke tijden met persoonlijke tegenslagen voor jou en je familie, is de snelheid waarmee ik correcties van je heb mogen ontvangen ongekend geweest. Veel dank hiervoor.

De hooggeleerde leden van de promotiecommissie, Prof. Verhofstad, Prof. Kleinrensink, Prof. Goossens, Prof. Leenen, Dr. Ponsen en Prof. Goslings. Hartelijk dank dat jullie plaats willen nemen in de promotiecommissie.

Beste Gert-Jan Kleinrensink, mijn eerste kennismaking met jou was als student in de collegebanken van de medische faculteit. Wat een fantastische passie heb jij voor de anatomie. We hebben dankbaar gebruik gemaakt van je ondersteuning, het beschikbaar stellen van preparaten en het gebruik van de snijzalen. Je bent altijd bijzonder toegankelijk en betrokken bij 1001 projecten van studenten, onderzoekers en specialisten. Ook het Wondcongres draag je nog steeds een warm hart toe.

Beste Richard Goossens, zoals je weet heb ik ook ooit gestudeerd in Delft. Jij bekleed twee mooie posities binnen de Medische Delta. We hebben samen Mariena Hofwegen begeleid bij het ontwerpen van een nieuwe bekkenbinder. Jij draagt op bijzondere wijze bij aan het ontwerpen van veilige, comfortabele en efficiënte medische ontwikkelingen in de gezondheidszorg. Ik werk in de toekomst graag met je samen aan de verbetering of ontwikkeling van nieuwe instrumenten en apparaten voor de chirurgische praktijk.

Beste Niels Schep, als coassistent werd ik tijdens een nachtdienst door jou, 'de traumachirurg in spe' op sleeptouw genomen. Dit was voldoende om mij te overtuigen, wat een heerlijk uitdagend beroep! De appendectomie via wisselsnede die nacht is overigens de eerste operatie die ik me kan herinneren. Ik heb veel van je geleerd en hoe kan het ook anders, want je bent niet alleen chirurg maar ook nog klinisch epidemioloog. Je betrokkenheid bij de kadaverstudie was groot. In de snijzaal en het biomechanische lab hebben we samen bijzondere bekkenchirurgie bedreven. Jij hebt net als ik het studentenleven altijd een warm hard toegedragen, steekt graag je handen uit de mouwen en gaat ongetwijfeld nog een interessante carrière tegemoet in de chirurgie van de bovenste extremiteit. De tips & tricks van de behandeling van deze complexe letsels moet je mij over een paar jaar maar leren.

Mijn dank gaat ook uit naar de overige coauteurs die hebben bijgedragen aan de verschillende hoofdstukken van dit proefschrift. Richard Spanjersberg, Tim Scheepers, Mariena Hofwegen, Kees Spoor en Marcel van Riel.

My supervisors and colleagues at the Orthopaedic Trauma Institute (OTI) and the San Francisco General Hospital in San Francisco, USA; Prof. Miclau, Saam Morshed, Amir Matityahu, Meir Marmor, Tigist Belaye and all the others that made my start at the OTI so easy. Thank you all and especially Saam and Meir for your efforts and support during my stay in San Francisco. Saam, even years after my stay at your department we are working on one of our publications. It would be great if we could arrage your presence at the thesis presentation and I hope we can continue to work together. A life time experience in one of the most extraordinary cities of the world. My time in San Francisco was a perfect work-sports-mixture in preparation for the Tour de France.

A special thanks goes out to the close and warm family of the institute for Global Orthopaedics and Traumatology (IGOT). Amber Caldwell, Jonathan Philips, Tom Penoyar, Harry Jergesen and Richard Coughlin. Healing bones mending lives! I especially remember the work-lunches in the Mission District, the drinks at the Homestead, the house sitting's and bar hang-out's and our trip to the AAOS in New Orleans.

Beste Yvonne Steinvoort, zonder jou geen 'smooth-operating' op de snijzaal. Wat is het prettig samenwerken met jou. Altijd ongelooflijk lief en geïnteresseerd. Helaas is Jan van Ophemert, je collega, in die periode overleden. Ook Jan ben ik veel dank verschuldigd voor alle voorbereidende prepareerwerkzaamheden.

Ed Heule, bij een onderzoek naar decubitus is ook de kennis en kunde van een dermatoloog onmisbaar. Hartelijk dank voor het overleg dat we met elkaar hebben gehad en ik zie u weer bij de volgende lustrumeditie van het Wondcongres.

Beste Alex Brouwer, het ontwerpen en fabriceren van de retroreflectieve markers en de meetopstelling voor de biomechanische kadaver studie vond ik een uitdagend onderdeel. Als instrumentmaker draaide jij hier je hand niet voor om! Jij hebt een voor velen onbekend, maar waardevol beroep.

Mijn collega onderzoekers van de afdeling Traumachirurgie, onderzoekers van het Z-gebouw, skillslab en kelder onderzoekers. Met zijn allen zaten we in hetzelfde schuitje. Ongelooflijk wat we allemaal voor mooie activiteiten en evenementen hebben georganiseerd, voor elkaar en voor de assistenten en chirurgen uit de regio Rotterdam.

Lieve Stephanie, mijn onderzoeksmaatje. Ik herinner me onze eerste kennismaking in een aftands onderzoekskamertje na wederom een verhuizing van werkplek nog goed. We hadden al snel een carnavalsfeestje gebouwd. Jij bent ook mijn Traumadagen partner in crime en een garantie voor een avond swingen in de Bubbels. Succes met de laatste loodjes van je promotie. Het is bijna onmogelijk dat wij in de toekomst niet weer samen zullen werken gezien onze passie voor de Traumachirurgie.

Beste Ted, belofte maakt schuld: het is klaar voordat ik aan mijn differentiatie ga beginnen. Ook van jou heb ik de ruimte gekregen om tijdens mijn opleiding dit proefschrift te schrijven. Schitterend zoals jij iedereen scherp weet te houden. Als iets goed geregeld moeten worden dan moet je het zelf doen. Met jou zal de Algemeen Chirurg helaas in het harnas sterven.

Beste collega's en bazen van de afdeling Heelkunde in het Ikazia Ziekenhuis. Wibo, Dr. Boel, Ted, Kees, Wouter, Boudewijn, Anne-Marie, Nike en Akkie. Al sinds mijn coschap chirurgie, bijna 7 jaar geleden, werk ik dagelijks met veel plezier in het Ikazia. Een heerlijke werkplek met veel persoonlijke contacten en vriendschappen. Akkie jij bent me nu in meerdere stappen voorgegaan en ik lijk dankbaar gebruik te maken van jouw voetsporen.

Fietsvrienden. De ongelooflijk noodzakelijke afleiding na een lange dag werken deel ik ook nog vaak met jullie. Jullie zijn met teveel om op te noemen. In het bijzonder Gijs: met jou

fietsen is vrijwel ongecompliceerd. “Alles goed, ja prima …..” niet lullen maar in de beugels over de kasseien. En Freek, misschien lopen we toch nog eens samen een marathon.

Woundcongres vrienden! Dat wij de traditie nu al weer een aantal jaren samen voortzetten is schitterend. Het organiseren van dit congres is iets heel bijzonders, op meerdere manieren de moeite waard en bovenal uiterst gezellig.

Beste clubgenoten van JC Raak, Heren Huischgenoten, Oud-Huischgenoten en sierpaarden van de Voorstraat 42, dispuutgenoten van CGS en elite lichting Tokkies en vrienden van de legendarische Gercie in het bijzonder. Dr. Knops is eindelijk klaar…

Lieve familie, ook jullie zie ik te weinig. Tante Marianne. Ome Don, tante Marian en neef Ger. Tante Ine en ome Nico en neven Bart en Paul. Het zou mooi zijn als jullie er bij zijn op de grote dag. Jullie zijn een fijne familie.

Beste Paranimfen, Dustin en DJ, dat jullie mij bijstaan op deze gedenkwaardige dag is als vanzelfsprekend. We hebben de voorbereidingen in ieder geval goed aangepakt met een decadent weekend in Barca.

Brother, lieve Erik, wij zijn twee verschillende personen met duidelijk andere interesses en dat is prima. Ik ben ongelooflijk trots op wat je allemaal hebt bereikt in de afgelopen jaren. Oprecht, je blijft me verbazen. Knops TuinDesign blijf ik natuurlijk aan iedereen aanbevelen. Samen met Anne in Breda is een hele mooie stap.

Ons pap en ons mam, lieve Wiel en Wilma, veel hebben Erik en ik aan jullie te danken. Jullie staan altijd als vanzelfsprekend voor ons klaar. Soms besef ik me dat het rustig moet zijn zonder ons thuis in Tilburg. Jullie zijn samen echt fantastische ouders.

Lieve Jet, lieverd, een cliché, maar nu echt meer tijd voor jou… Jij verdient het. Met jou kan ik alles delen. Thuiskomen is ontspannen. Ik vertrouw op je, geniet van je en hou van je!

IV. PHD PORTFOLIO

Summary of PhD training and teaching activities

Name PhD-candidate:	Simon Peter Knops, MD
Erasmus MC Department:	Surgery-Traumatology
PhD period:	August 2008- September 2014
Research group:	Erasmus MC, Department of Surgery-Traumatology
Supervisor:	Dr. E.M.M. van Lieshout, MSc, PhD
Promotor:	Prof.dr. P. Patka, MD, PhD
	Prof.dr. I.B. Schipper, MD, PhD

1. PhD Training	**Year**	**Workload (ECTS)**
General courses		
MUSC Onderzoeksmethoden voor het bewegingsapparaat	2007	1.0
EWP 01: Introduction to Clinical Research	2008	1.0
EWP 22: Biostatistics for Clinicians	2008	1.0
Seminars and Workshops		
Journal Club	2011-2014	4.0
WMO GCP	2013	0.3
Presentations		
Chirurgendagen	2009	1.0
Traumadagen	2009	1.0
OTA (international conference)	2010	2.0
AAOS (international conference)	2012	2.0

2. Teaching	**Year**	**Workload (ECTS)**
Lecturing		
Teaching (medical students, nurses in training)	2011-2014	4.0
Supervising practical's and excursions		
Dissection course	2012-2013	2.0


Deloitte
Unelf
Nalini
EASTON

V. CURRICULUM VITAE

Simon Knops was born on May 23th, 1984 in Tilburg, the Netherlands, as the son of Wiel Knops and Wilma van Alphen. In 2002 he graduated from the Cobbenhagen College in Tilburg. Simon started studying Technical Informatics at Delft University and eventually enrolled into medical school at the Erasmus MC, Rotterdam in 2003. From 2002 to 2007 he lived 'In den Vergulden Klooi' at the Voorstraat 42 in Delft. During his medical school he became a managing partner of IT-company Kojac CV. In 2008 the groundwork for this thesis was laid with a study on 'Measurements of exerted pressure by Pelvic Circumferential Compression Devices' at the Department of Surgery-Traumatology (Prof. Peter Patka, Prof. Inger Schipper and Dr. Esther van Lieshout). During a medical elective in 2009 he explored the Trauma Unit at the Groote Schuur Hospital in Cape Town (Prof. Andrew Nicol). Successively he visited the Orthopaedic Trauma Institute in San Francisco for a Research Fellowship (Prof. Ted Miclau, Dr. Saam Morshed). He cycled the 3.642 km of the 97th edition of the Tour de France in 2010 for Tour for Kika. September 2010 he obtained his MD and in July 2011 he started his training in General Surgery (Prof. Jan IJzermans, Dr. Bas Wijnhoven) at the Ikazia Hospital in Rotterdam (Dr. Ted den Hoed). Simon has one younger brother who graduated as a Landscape and Garden Architect at the Erasmus University College in Brussels and founded Knops TuinDesign. Simon is living together with Jet Derksen in their 'Garden with a House' in Rotterdam.