Randomized clinical trial comparing pressure characteristics of Pelvic Circumferential Compression Devices in healthy volunteers

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ABSTRACT

Introduction: The role of Pelvic Circumferential Compression Devices (PCCDs) is to temporary stabilize 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 randomized 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 analyzed using Mixed Linear Modeling.

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 randomized clinical trial in healthy volunteers showed that patients with pelvic fractures, temporarily stabilized 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 stabilized, 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 hemorrhage. Related mortality rates range from 5 to 55%, depending on the fracture type and overall injury severity.[8,20] Fracture reduction and stabilization reduce the inner pelvic volume and concomitant blood loss, and may tamponade massive venous hemorrhage.[13,26] Massive hemorrhage in poly-traumatized 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-hospitally, *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 injures patients, such as patients with pelvic fractures, these preventable complications should receive early attention.

PCCDs seem to be effective in early stabilization 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 characterized by a strap–skin interface pressure of 24 mmHg (= 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 et al.[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 hours.[27] Pressure sores are best seen as potentially preventable complications of acute immobility. Patients suffering from high-energy trauma are often immobilized on spine boards with cervical collars, to prevent aggravation of injuries during transfer to the hospital. Immobilization is most often continued until diagnostic imaging rules out spinal injury and frequently lasts up to three hours.[16] Immobilization 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 randomized 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 randomized clinical trial (Registration number: NTR1214 (http://www.trialregister.nl)). Proportional distribution of volunteers in different BMI strata (<18.5, 18.5-24.9 and ≥25.0 kg/m2) 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 minimize 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 (SPK). 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: $0 - 300$ mmHg). 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. While lying on a spine board, the FSA-mat was placed 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 minutes 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 while 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 maneuver. The PCCDs remained tensioned during the entire measurement period. At the end of the measurement on the spine board 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 stabilization of pressure within 5 minutes, therefore the following two time points were chosen for analyses: 5 minutes after application of the PCCD while lying on a spine board, and 5 minutes 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 pressure 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 analyzed for the sacrum location because the FSA-system was limited to 40 kPa (300 mmHg) 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, Ill., 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 randomization), 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 modeling 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).

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 while 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 (P_{max}) at the area of the GTs is shown in Figure 3. While 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 P_{max} (12.2 ± 3.5 kPa), which was higher than that of the T-POD$^®$ (10.7 ± 2.6 kPa, p=0.005). The P_{max} 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 P_{max} caused by both the SAM-Sling$^®$ (7.1 ± 3.2 kPa, p<0.001) and the T-POD$^®$ (8.3 ± 2.4 kPa, p=0.014). Using the SAM-Sling$^®$, the P_{max} increased with age (p=0.031). No correlations with the P_{max} 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 P_{max} at the GTR was lowest with the SAM-Sling[®] (7.2 ± 1.9 kPa). Only the P_{max} 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 P_{max} levels at the GTR with the Pelvic Binder[®] (p=0.022) and the T-POD[®] (p=0.014).

The P_{max} 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). Similar 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 P_{max} and BMI (p=0.019) and between P_{max} and waist size (p=0.004) was found. While 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 analyzed 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 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 while lying on the spine board and in a hospital bed. In both situations, all

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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 analyzed.

Measurements of the first parameter, the *average pressure* at the sacrum, are presented in Figure 5A. While 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 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. While 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. While lying on a spine board, the pressure exceeded the upper threshold of the FSA-system (40 kPa; 300 mmHg) 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 while 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). While 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 ($p<0.030$). While 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 while lying on the spine board and the hospital bed.

DISCUSSION

The PCCDs that were tested in this randomized clinical trial are primarily designed for reduction of the pelvic volume and stabilization of the bony elements after fracture, thereby reducing hemorrhage. 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 T-POD® 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.

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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 hypothesized 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 et al. obtained in their study, demonstrated an inverse correlation with the BMI. In the current study the pressure at the GTL, while 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, while lying on a spine board, pressure at the GTs was correlated positively with age (SAM-Sling® only; $p = 0.031$). As opposed

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to this, on a hospital bed, the pressure was inversely correlated with age (Pelvic Binder[®] and T-POD[®] p<0.020). On a hospital bed the pressure at the GTL was inversely correlated with waist size (p<0.005). While 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 immobilization 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 immobilization phase the risk of inducing tissue problems like pressure sores and skin necrosis depends upon both local and systemic etiological factors.[27] Polytraumatized 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 hemostasis control should always prevail over risk reduction. Incorporation of controlled limitation of pressure (like the SAM-Sling®'s auto-stop buckle) 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 immobilization 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 recommendations. 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 randomized controlled trial, to also account for systemic influences, and the actual effectiveness in fracture reduction hemorrhage 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 optimize 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 randomized clinical trial using healthy volunteers showed that patients with pelvic fractures, temporarily stabilized 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 stabilized, 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.

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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Table 1 Product description

PCCD	Product details
	Pelvic Binder ® • One size fits all, "cutt-to-fit" 6-8" 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 (33lbs) 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'' 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).

Table 2 Demographic description of the study population

	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[+]
BMI (kg/m^2)	23.0 ± 3.3[b]	24.0 ± 2.8	22.4 ± 3.5	0.002[+]
<18.5	3 (3.8)[a]	0 (0.0)	3 (6.1)	NS[++]
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[+]

[a] Numbers of participants are displayed, with the percentages given within brackets; [b] Data are displayed as mean ± SD; [+] Student's t-test; [++] Chi square test; BMI, Body Mass Index; NS, not significant.

FIGURE LEGENDS

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 maneuver. The PCCDs remained tensioned between these two consecutive measurements.

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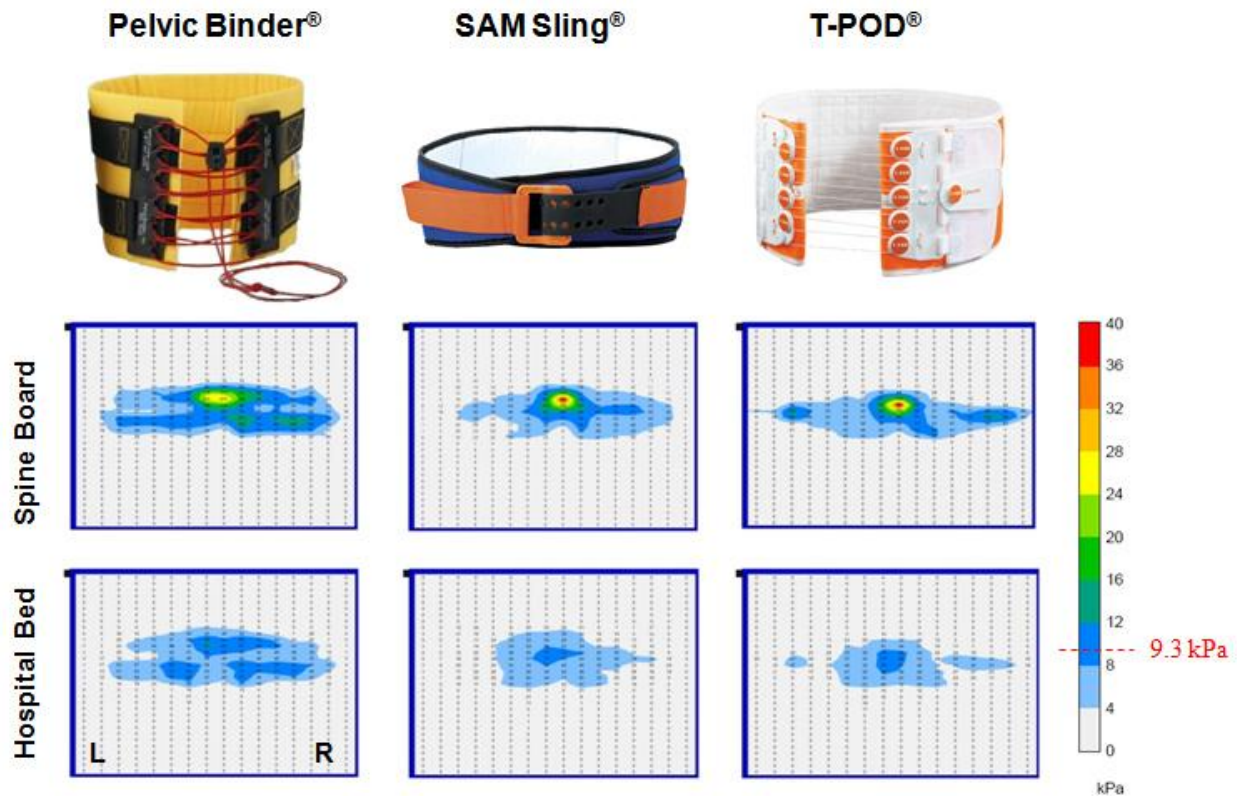
A visual representation (imprint) of the exerted pressure (kPa) generated by the FSA software, between the surfaces of the skin and the PCCD after application of a PCCD on a spine board and after the transfer to a hospital bed. L and R mark left and right sides, respectively. The green/yellow/red (>18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

Figure 3
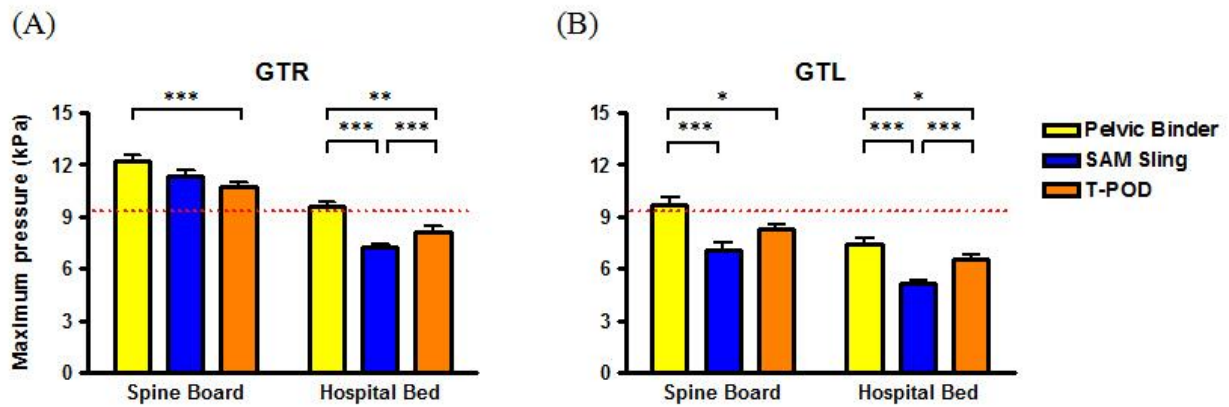
Exerted pressure on the trochanters: the maximum pressure (kPa) measured with the FSA-system at the area of the right (GTR) and left greater trochanters (GTL) for all three PCCDs on the spine board and after the transfer to a hospital bed. The trochanters were palpated and the maximum pressures of the corresponding sensors were analyzed 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 (* $p < 0.05$; ** $p < 0.01$; *** $p < 0.005$).

Figure 4
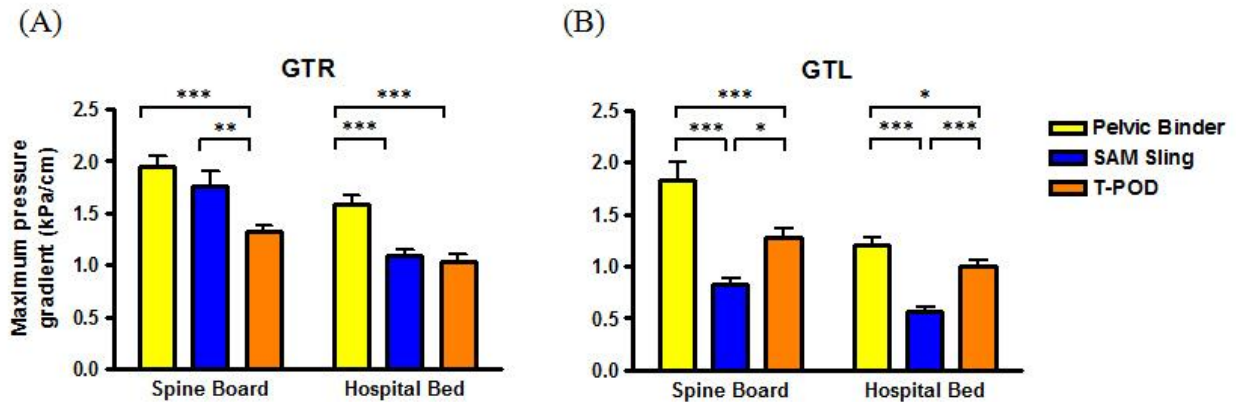
Pressure gradients over the trochanters: the maximum pressure gradient (kPa/cm) measured with the FSA-system at the area of the right (GTR) and left greater trochanter (GTL) with all three PCCDs on the spine board and after the transfer to a hospital bed. The trochanters were palpated and the maximum pressure gradient of the corresponding sensors were analyzed 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 (* $p < 0.05$; ** $p < 0.01$; *** $p < 0.005$).

Figure 5
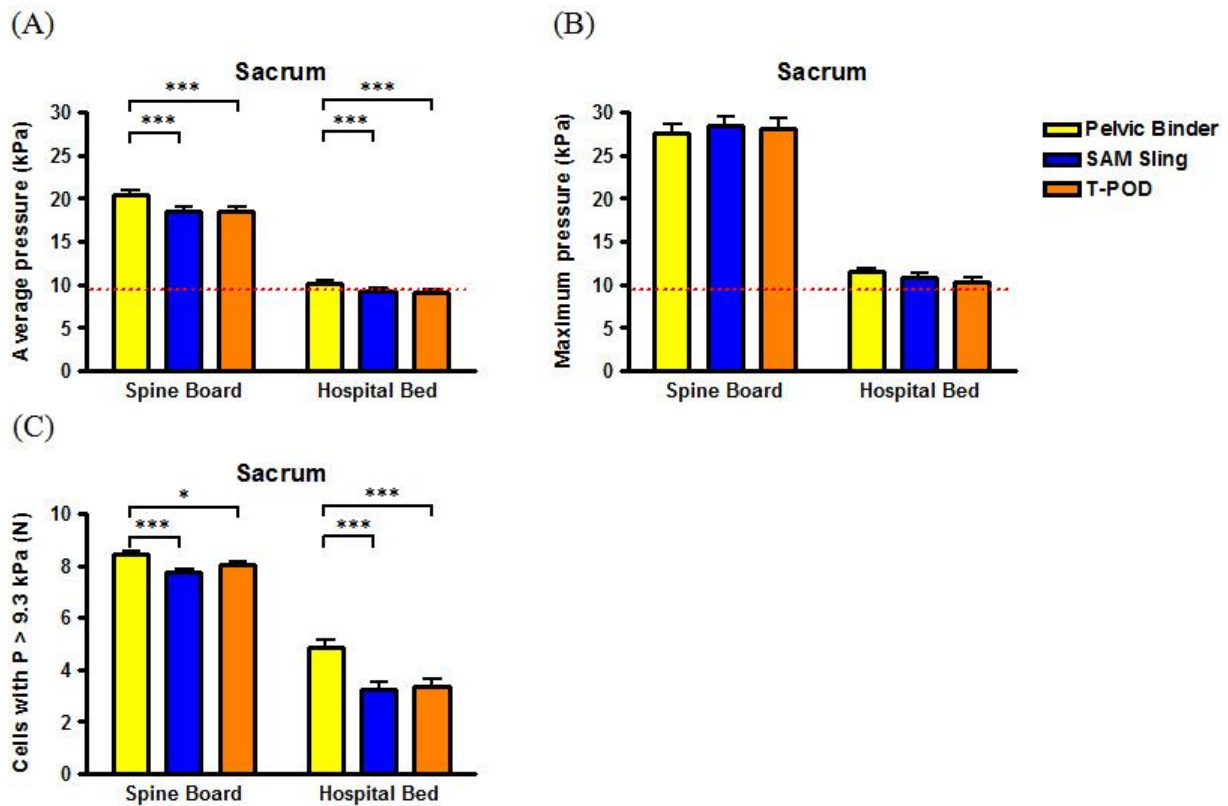
Exerted pressure on the sacrum: (a) the average pressure (kPa), (b) the maximum pressure (kPa) and (c) the number of cells with a pressure exceeding 9.3 kPa (N) measured with the FSA-system at the area of the sacrum with all three PCCDs on the spine board and after the transfer to a hospital bed. A pressure window at the sacrum was manually selected and the pressures of the corresponding sensors were analyzed 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 (* $p < 0.05$; ** $p < 0.01$; *** $p < 0.005$).