Title :

Is cannulated-screw fixation an alternative to plate ostheosynthesis in open book fractures? A biomechanical analysis.

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There are no conflicts of interest.

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Abstract:

Objectives: the current biomechanical work compares the symphyseal and sacroiliac stability obtained with two systems of bone osteosynthesis. These compared methods are the 6-hole suprapubic non-locked plate, and pubic fixation with two cannulated screws, a novel technique which can be applied percutaneously in the clinical practice. The purpose is to support the use of two-cannulated-screws osteosynthesis to minimize the secondary effects of open fixation, specially in patients in whom an open reduction is contraindicated.

Methods: A biomechanical study was designed in 9 fresh, human pelvis specimens, simulating an AO B1.1 type injury, using both fixation systems sequentially in each specimen. In both parts of the test, the specimens were subjected to an axial load of 300N and displacements and rotations between the different pelvic elements were studied by means of a discrete set of points. The absence of differences between the two systems has been set as the null hyposthesis.

Results: There are significant differences in favor of the cross-cannulated screws in all the displacements measured at the pubic symphysis and sacroiliac joint.

Conclusions: Fixation of the AO B1.1 type fractures treated with cross cannulated screws restores the biomechanical behavior of the pubic symphysis, obtaining better stability results than fixation with the 6-hole non-locked plate. To date, no comparative, biomechanical studies have been conducted with these two systems of osteosynthesis. This study demonstrates the cross-cannulated screws system of symphyseal osteosynthesis in B1.1 fractures to be an alternative to the conventional plate system.

Introduction:

Since its description in 1973, open reduction and osteosynthesis with symphyseal plates has widespread to become the standard surgical treatment of AO B1.1 pelvic lesions because it is simple, fast, and effective. Nevertheless, it is not without its complications: exposure of deep pelvic structures, delayed wound healing, damage to important vascular-nervous elements, and an infection rate of up to 25% [1,2,3,4,5,6,7,8,9]. Complications related to implant retention have been reported in 7.5% of the cases[6]: spontaneous migrations to the ischiorrectal fossa[10] and even urinary expulsion of screws[11,12]. In order to avoid complications related to the surgical approach and implant, as well as patient-related issues (clinical context of poly-traumatized, critical patients and patients with multiple surgeries), alternative fixation systems have arisen for the anterior pelvis. In 2009 and 2011, the first two clinical works using percutaneous techniques in the symphyseal region were published[10,13]. Mu and Wang (2009)[14] reported the clinical results of 8 patients with heterogenous pelvic injury patterns treated with percutaneous synthesis using navigation-guided cannulated screws. Chen et al.[13] published a study comparing the results of open plate fixation and percutaneous screw fixation techniques in the treatment of traumatic pubic symphysis (PS) diastasis in 90 patients. There are very few clinical studies about this issue, and those that do exist are retrospective studies of heterogenous injury patterns, with a relatively short follow-up[15,16]. There are no standardized biomechanical studies that support their approaches, analyze their influence on pelvic behavior and compare the gold standard (symphyseal plate) with this alternative therapy.

This work seeks to verify if fixation of the pubic symphysis with 6.5-mm cannulated screws achieves stability comparable to unlocked, 3.5-mm, 6-hole plates, analyzing both methods in terms of articular displacements and rotation between bony elements. Likewise, it seeks to provide a rationale for the clinical use of percutaneous osteosynthesis of the pubic symphysis.

Materials and Methods:

A biomechanical study in nine fresh, frozen, non-embalmed human pelvis specimens (mean age 83.1 years, range 55-92) from female cadavers has been performed. A history of prior pelvic fracture, surgeries, bone tumors or metabolic diseases were set as exclusion criteria. This work had the approval of the institutional ethical committee. The pieces were dissected until a set consisting of the L4-L5 vertebrae, pelvis, and lower third of both femurs was extracted. All capsular and ligamentous elements of the pubic symphysis and sacroiliac joints were kept intact, together with the sacrospinous and sacrotuberous ligaments and the soft tissues of the lumbar spine, as well as both coxofemoral joints (figure 1). All muscles were removed. Following preparation, the specimens were frozen to -20ºC ; prior to the trial, the specimens were thawed, minimizing the bone changes associated with bone or ligament dehydration by submerging the specimens in water for 16-20 hours at room temperature and keeping them moist before and during experimentation[17].

Interventions:

A B1.1 type injury was simulated, by sectioning the pubic symphysis, right sacrotuberous and sacrospinous ligaments, right anterior sacroiliac (SI) ligaments and right interosseous ligaments, thus achieving an anterior sacroiliac diastasis, while maintaining the posterior sacroiliac ligaments intact. (figure 2,3)

Subsequently a senior orthopedic surgeon from a center with a vast experience in pelvic surgery, reduced the injury and performed the osteosynthesis of the PS. In 4 specimens randomly chosen, two 6.5-mm titanium, partially threaded, cannulated screws (CS) were used first (Asnis III, Stryker-Howmedica, Michigan, USA) while in the other 5, the 6-hole superior symphyseal plate (3.5-mm Symphysis Plate, Low Profile Pelvis System, Synthes, Solothurn, Switzerland) with 6 unlocked 3.5-mm cortical screws was the first treatment. After the first test on each specimen, the implants were removed and osteosynthesis was then performed with the alternative system to the one used in the first test (CS or plate). A standard placement position was defined for the cannulated screws, with an anterior 45º inclination relative to the coronal plane: one with the entry point at the inferior base of the pubic tubercle directed to the opposite obturator framework, and the other one inserted from the contralateral pubic bone (1 cm caudal to the first screw) to the obturator foramen in opposite direction (figure 4). The screws were parallel one to another in the outlet X-Ray view, and crossed in the inlet view. The 6-hole plate was anchored in the superior symphyseal cortical bone with descending unlocked screws (figure 5).

Each pelvis was fixed to a Zwick/Roell Z100 (BT1-FB100TN, Zwick GmbH & Co. KG, Ulm, Germany) electromechanical materials testing machine with TestXpert II load controlling software, using a registered experimental device for the biomechanical analysis of pelvic fractures[18,19]. This device was used in a previous work[20] and made it possible to simulate a standing position, aligning the anterior-superior iliac spines and the pubic tubercle in the same sagittal plane (figure 6)[17].

Each specimen was subjected to 300N axial load cycles, applied on the fourth lumbar vertebra and sacrum, in 3 phases: (A) healthy pelvis, (B) injured pelvis with synthesis-1 (CS or symphyseal plate), and (C) injured pelvis with synthesis-2 (plate symphyseal or CS, respectively). A set of points was defined and fixed with adhesive markers, around the pubic symphysis and sacroiliac joints, to analyze the movement of the pelvis under the axial loads applied in each phase of the study (figures 4 and 5). The PONTOS 5M system (GOM System, Optical Measuring Techniques, Braunschweig, Germany) was used to localize the markers and register their position, with a resolution of 2448 x 2050 pixels and 0.005 mm precision error. This system has been validated for micromotion biomechanical studies[21]. The location of the adhesive markers was as follows:

- 3 markers 1 cm medial to the sacroiliac joint (right and left), in craneo-caudal line, 2 cm one from another.
- 4 markers 1 cm lateral to the sacroiliac joint (right and left), set in a rhombus manner.
- 2 markers on the superior iliopubic cortex, 1 cm lateral to the pubic symphysis (right and left)
- 2 markers in the junction point between iliopubic and ischiopubic rami (right and left).

Additional lower loads (80N) were applied between the different 300N loads. The data obtained during the 80N loads were used to construct force-deformation regression lines, from which the apparent stiffness of each specimen was evaluated at each stage of the overall test. The aim of these intermediate loads was verifying that the 300N loads do not damage (and thus reduce the stiffness) the specimens, which would have invalidated the study.

A multivariate version[22] of the Friedman test (non-parametric ANOVA for repeated measures) was performed to compare the overall effect of the independent variable injury status of the pelvis (with 3 levels: physiological, injured and fixed with screws, injured and fixed with a plate) on the 7 dependent variables (4 displacements and 3 rotations). Basically, this test consists of performing a MANOVA on the ranks. There was special interest in comparing the dependent variables separately. Thus, the multivariate test was performed three times: a) for displacements (mm) at the superior and inferior symphysis; b) for displacements (mm) at the right superior and inferior sacroiliac joint, and c) for the rotation (degrees) of the right iliac bone relative to the sacrum around X, Y and Z axes.

Results:

Displacements and rotations are shown in tables 1, 2 and 3. With regard to displacements at the pubic symphysis, CS fixation provided more stability than non-locked plates ($p=0.001$ in superior pubic symphysis and $p<0.001$ in the inferior pubic symphysis). Box's M test for homogeneity of covariance matrices was not significant ($p=0.122$). The multivariate version of the Friedman test revealed a significant multivariate main effect for injury status: Wilks' $\lambda=0.248$, $F(4,34) = 11.600$, $p <.001$, partial eta squared=0.502. Power to detect effect was 1.0. Thus, the H_0 hypothesis (no effect of injury status on displacements at the symphysis) was rejected. Given the significance of the overall test, the univariate main effects were examined. Significant univariate main effects for injury status were obtained for both displacement at the superior symphysis ($F(2,24) = 11.941$, $p <.001$, partial eta squared=.499, power=.989) and displacement at the inferior symphysis ($F(2,24)=18.250$, $p <.001$, partial eta squared=.603, power=1.0). Additionally, post-hoc pairwise comparisons for each displacement at the symphysis were made. The p-values of those comparisons are shown in table 4.

Regarding displacements at the sacroiliac joint, Box's M test for homogeneity of covariance matrices was not significant ($p=.623$). The multivariate version of the Friedman test revealed a non-significant multivariate main effect for injury status: Wilks' $\lambda=0.734$, $F(4,46)=1.924$, $p=0.122$, partial eta squared=0.143. Power to detect the effect was .537. Thus, the H_0 hypothesis (no effect of injury status on displacements at the right sacroiliac joint) could not be rejected (figure 7).

Finally, when comparing right iliac bone rotations (figure 8), Box's M test for homogeneity of covariance matrices was not significant ($p=.960$). The multivariate version of the Friedman test revealed a non-significant multivariate main effect for injury status: Wilks' $\lambda=0.582$, $F(6,44)=2.278$, $p=0.053$, partial eta squared=0.237. Power to detect effect was 0.733. Thus, the H_0 hypothesis (no effect of injury status on right iliac bone rotations relative to the sacrum) could not be rejected at the

0.05 significance level. However, it could be rejected if the significance level were slightly increased. The power to detect the effect is high, despite the small sample size, which is probably what hindered a more precise conclusion about rotations. This led us to examine the univariate main effects and post-hoc pairwise comparisons as if a significant difference had been found.

Significant univariate main effects for injury status were obtained for rotation around the craneo-caudal (Y) axis, (F (2,24)=5.419, p=0.011, partial eta squared=0.311, power=0.796) and for rotation around the antero-posterior (Z) axis (F (2,24)=6.993, p=0.004, partial eta squared=0.368, power=0.891). However, the univariate main effect for rotation around the medio-lateral (X) axis was not significant (F (2,24)=0.694, p=0.509, partial eta squared=0.055, power=0.153). The p-values of the post-hoc pairwise comparisons for each rotation are shown in table 5.

The comparative analysis of the stiffness (based upon force-deformation regression lines) of each piece in the 80N load phases, did not show statistically significant differences in anyone of them, thus making sure that A, B and C experimental phases were undertaken in each specimen under equivalent mechanical conditions.

Discussion:

Open osteosynthesis of the pubic symphysis by means of conventional plates is not a complication-free technique, infection being the most common[1,2,3,4,5,6,7,8,9,23,24]. In the last decade, progress made in percutaneous surgical techniques in pelvic fractures has led to consider its application as an alternative to conventional plates, also in the pubic symphysis. To date, few clinical works have been published concerning these systems, albeit good initial results are being reported[15,16]. Recently only one biomechanical study has been published analyzing percutaneous osteosynthesis in Tile B1 injuries[20].

This work is the first biomechanical study to compare a potentially percutaneous technique with standardized open treatment in pelvic open book injuries. Results of greater stability following symphyseal osteosynthesis have been attained with CS, compared with non-locked symphyseal 6-hole plating.

The main limitation of biomechanical tests is the inability to reproduce true patient conditions. To minimize this limitation, specimens were used preserving all the osteo-capsular-ligamentous structures and the testing device was built to apply a bipedal load reproducing human standing mechanics[20]. Another potential limitation is the influence of repeated treatments. To minimize this risk, fixation systems (screws-plates) were randomized, starting with each alternately. Since osteoligamentous structures could be affected by the previous test[25], the apparent stiffness of the specimens was compared between the various stages of the overall test, showing no significant difference between measures and thus statistically confirming that the mechanical integrity of the specimens had not been affected by the load cycles (Friedman test, $p=0.45$). Finally, the small sample size ($n=9$) might affect comparison outcomes, although we must consider the scant availability of specimens. Previous biomechanical studies by other authors used a similar number of cadavers to the one used in this work.

At the symphysis, CS has proven greater stability than conventional symphyseal plates, being capable of achieving pelvic biomechanics without significant differences versus physiological conditions. Conventional 6-hole plating was unable to restore the symphyseal stability of the healthy pelvis. Other published biomechanical studies aimed at assessing different osteosynthesis techniques of the PS in horizontally unstable B1 type pelvic injuries, obtained results regarding plate fixation of the PS that are similar to those obtained in the present study. In the last years, the use of symphyseal plates with locked screws has been contemplated, but recent experimental tests have revealed no significant differences with respect to conventional plating[26].

Some published works state that anterior plate fixation of the PS in open book injuries of the pelvis only reduces symphyseal movements and does not affect the SI joint[27,28,29,30]. In this study, there were no significant differences in SI displacements with respect to the situations analyzed. In other biomechanical studies, Hearn and Willet[31] and Varga[17] have postulated that greater stabilization of the inferior symphysis (with systems other than conventional plating) would translate into greater stability in the superior part of the SI joint and decreased mobility of the sacrum relative to the iliac. The present study has not obtained conclusive results in this regard.

The analysis of rotation around the three axes is a novel issue of this study, given that previous authors[27,32,33] only measured rotation around the X axis. Considering the three rotations has provided additional and interesting information. In the X axis, both systems have proved to be capable of restoring the physiological behavior of the pelvis. However, in the Y and Z axes, only CS fixation of the symphysis provided rotational stability with no differences with the healthy pelvis, whereas the conventional plates demonstrated significantly greater rotation than physiological conditions.

The current work is the first biomechanical study to compare conventional plating and CS symphyseal fixation (potentially percutaneous) in AO B1.1 injuries. The results obtained reveal that CS fixation generates greater anterior stability than conventional unlocked, 6-hole plates, without significant differences with respect to displacements recorded in physiological conditions of the pelvic ring. Moreover, CS has been seen to provide rotational stability around the 3 axes. The objective data presented here underpins the initial clinical outcomes of similar techniques and highlight the usefulness and effectiveness of percutaneous CS as a symphyseal fixation technique, alternative to standard plate osteosynthesis. Nonetheless, prospective, randomized clinical trials with a longer follow-up period are needed to determine if the residual micromotion in the SI region is of clinical relevance.

Level of evidence: level V, basic science research.

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Figure Legends:

Figure 1.- Specimen with the anchored proximal plate and screws distributed to attach markers.

Figure 2.- (A) Section of symphysis joint and (B) disruption of sacrotuberous and sacrospinous ligaments.

Figure 3.- (A) Right sacroiliac injury with anterior sacroiliac and interosseous ligaments section. (B) Right hemipelvis opening with a 2.5 cm symphysis diastasis.

Figure 4.- Percutaneous screws placement position. (A) Inlet view. Kirschner wires guiding screws in a 45º insertion angle. (B) Outlet view. First screw entry at the inferior base of the pubic tubercle. The other one is inserted 1 cm caudal to the first screw in opposite direction.

Figure 5.- Anteroposterior View. Pelvis specimen synthesized with a standard 6-hole superior symphyseal plate.

Figure 6.- Setup model in a synthetic bone model on pretest trials.

Figure 7.- Predefined rotation axes. In Rx axis the extension-flexion movement is referred. Ry axis registered the iliac internal or external rotation. Rz rotational datas determined recorded movements in z-axis. Positive directions are indicated for each rotation.

Figure 8.- Field of view of the displacement of the right camera, specimen 5: (A) injured; (B) injured reconstructed with symphyseal screws; (C) Injured synthesized with plate.