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Influence of flexible fixation for open book injury after pelvic trauma — A biomechanical study

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ABSTRACT

Background: Implant loosening is frequently detected after fixation of open book injuries. Though many authors do not see this as a complication, it is often the reason for hardware removal or reinstrumentation in the case of remaining instability. We hypothesized that the flexibility of the implant has an influence on loosening and thus on failure of the construct.

Methods: We used 6 fresh-frozen pelvic specimens and tested them with our recently introduced test setup for two-leg alternate loading. We subjected them to a non-destructive quasi-static test in the intact condition followed by a non-destructive cyclic test under axial sinusoidal loading with progressive amplitude. Afterwards we simulated an open book injury and performed fixation with three different configurations of a modular fixation system (1-, 2- or 4-rod configuration) in randomized order. Subsequently, the specimens were subjected to 3 cyclic tests with the same loading protocol as previously defined. Finally, each construct was cyclically tested to failure keeping the final rod configuration.

Findings: We detected significantly greater mobility after 1-rod-fixation and no significant differences after 2-rod or 4-rod-fixation compared to the intact symphysis condition.

In the destructive test series the 4-rod-fixation failed first followed by the 1-rod-fixation. The 2-rod-fixation sustained almost 3 times as many load cycles prior to failure as the 4-rod-fixation, whereas the 1-rod-fixation sustained twice as many cycles as the 4-rod-fixation.

Interpretation: In conclusion, flexible fixation of the ruptured pubic symphysis in human specimens shows superior behavior with respect to load bearing capacity and ability to withstand cyclic loading compared to stiff constructs.

1. Introduction

Bridging the ruptured symphysis with plates of various designs has been the treatment of choice for open book injuries Type B1.1 and Type B1.2 according to Tile/AO-CCF Classification since the introduction of this method in the 1970s (Kamhin et al., 1980; Letournel, 1981; Sharp, 1973). Although the results seem to be satisfactory and have certainly enhanced the outcome of such injuries in comparison to conservative treatment, complications related to hardware loosening or breakage are described in the literature (Collinge et al., 2012; Giannoudis et al., 2008; Hamad et al., 2013; Morris et al., 2012; Pizanis et al., 2013; Putnis et al., 2011; Stuby et al., 2012). Although these do not necessarily require further intervention, hardware removal, or in case of instability, reinstrumentation is frequently performed (Putnis et al., 2011; Raman et al., 2005).

We hypothesized that implant loosening after bridging the symphysis will always occur after a certain time, as one bridges a joint and not a fracture. Accordingly, the joint itself will stay flexible and the implants will have to withstand movements even after healing of the joint stabilizing structures. This situation is in contrast to plating of fractured bones, in which bone healing results in a stiff construct with almost no implant loading. Therefore, no further loosening after consolidation of a plated fracture will occur.

Since healing of the stabilized symphysis structures is occasionally compromised by the premature implant failure/loosening, this study seeks to increase the time until loosening, and thereby give the structures more/longer time to heal sufficiently.

In order to approximate the ideal implant characteristics we constructed a stabilizing device that could hold various numbers of

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connection rods. The design allowed for comparisons between different modes of flexibility in bridging the ruptured symphysis of six human cadaveric pelvises according to the ranges of movement of the pelvic ring under constant load application and subsequently their ability to withstand load cycles with increasing loading until loosening.

For instrumented specimens, different flexibility modes (i.e. 1, 2, 4 rods) were tested for bridging the symphysis under cyclic loading until loosening.

2. Methods

2.1. Specimens

Six human pelvises including proximal femora and vertebra L5 with no evidence of bone and soft tissue pathology were harvested from fresh-frozen (−20 °C) cadavers of 3 male and 3 female donors, mean age 75 years, mean body height 167 cm and mean body weight 71.5 kg. Radiological imaging was performed to exclude defects affecting the integrity of the pelvic structure. Specimens were thawed to room temperature for two days prior to preparation and biomechanical testing. The soft tissue was removed preserving the pubic symphysis, sacroiliac ligaments, iliolumbar ligaments, proximal femoral ligaments and hip joints with their capsulae. The L5 vertebra was separated and used for assessment of bone mineral density (BMD) applying high-resolution peripheral quantitative computed tomography (HR-pQCT, XtremeCT™ Scanco Medical, Brüttisellen, Switzerland) with a resolution of 123 μm and a volume of interest defined as a cylinder with a length of 6 mm and a diameter of 15 mm in the vertebral body. The proximal femora were sectioned at a distance of 200 mm from the lesser trochanter. The sacrum was equipped with a 10 mm petroleum jelly-coated stainless steel rod, passing through a hole drilled from the base of the sacrum to the S3–S4 region. Subsequently, the sacrum was embedded in polymethylmethacrylate (PMMA; Beracryl®, W. Troller Kunststoffe AG, Switzerland) which reinforced the bone to hold sufficient load during biomechanical testing. Finally, five clusters of four infrared light-reflecting markers were attached to either side of the pubic symphysis, the sacrum and the left and right iliac crests of each specimen for three-dimensional (3D) motion tracking.

2.2. Injury

The open book injury was produced by scalpel dissection of the pubic symphysis, the left anterior sacroiliac joint, and the sacrospinal and sacrotuberal ligaments on the left side. Subsequently, the pelvic ring was opened until a gap of at least 3 cm was measured at the symphysis. This produced an instability similar to an open book injury (Tile B1.1 or B1.2).

2.3. Implant

To achieve a stabilization of the ruptured symphysis with different modes of flexibility, a special modular implant device was constructed. The aim was to equip the specimen with a single base plate that could accommodate 1-, 2- or 4-rod configurations. The baseplate and the connective rods were virtually constructed using 3D CAD Software (Pro/Engineer, Wildfire 4.0 PTC/PTC Creo Parametric, Inneo Solutions GmbH, Ellwangen, Germany) and were produced in a prototype workshop (DePuy Synthes, Solothurn, Switzerland) from stainless steel 316L and Ti–6Al–7Nb alloy (TAN), respectively (Fig. 1a + b).

The modular implant device was designed such that its bending stiffness in the 3-rod configuration resembled the bending stiffness of a standard symphyseal locking plate (3.5 mm 4-hole LCP DePuy Synthes, Solothurn, Switzerland) made from stainless steel 316L.

This enabled us to equip and test one implant construct with a 4-rod construct to simulate high bending stiffness with regard to the symphyseal plate, and 1-rod and 2-rod constructs to simulate low bending stiffness in comparison to this plate.

Prior to the biomechanical tests of the different flexible fixation methods each specimen underwent biomechanical testing in the intact condition to gain baseline values for further comparison as described below (Agarwal et al., 2014).

2.4. Instrumentation

The baseplate of the stabilization device was fixed to either side of the symphysis using two 3.5 mm locking screws with 50 mm length before simulating the injury (Fig. 1b). As the instrumentation was performed in intact condition and therefore with physiological distances of the symphysis structures we did not use compression for the reassembling after injury. After the dissection of the 6 pelvises, stabilization conditions were tested according to the randomized test-sequence shown in Table 1 with either one, two or four rods (Fig. 2a–f). Stabilization of the dorsal part of the pelvic ring was not performed.

2.5. Biomechanical testing, test set-up and loading protocol

The setup for biomechanical testing was adopted from a previous study where two-leg alternate loading was introduced to investigate fixation methods of the pelvic ring with focus on the pubic symphysis (Agarwal et al., 2014).

Each pelvis was mounted horizontally in the test frame as shown in Fig. 3. Applied torque was proportional to the physiological load on each femur during walking. The jig for sacral fixation was mounted on a Kristler® load-cell, which was free to move in the sagittal plane. The load-cell allowed monitoring and measurement of the vertical and horizontal loads at its attachment point in order to ensure symmetric loading on both legs.

The specimens were first subjected to a non-destructive quasi-static test in the intact condition with an axial ramp load of 170 N, applied at a rate of 17 N/s. Next, a non-destructive cyclic test at 1 Hz with an axial sinusoidal loading and progressive load amplitude was run, starting from 170 N and increasing to 340 N over 1000 cycles at a rate of 0.17 N/cycle. This loading was found to be within the safe limits, such that no instability or disruption would be expected (MacAvoy et al., 1997; van den Bosch et al., 2003).

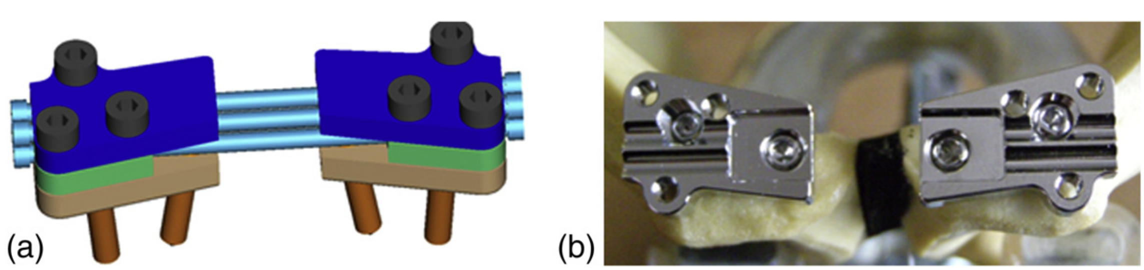

Fig. 1. a: Implant virtually planned with 3D CAD Software Pro/Engineer (Pro/Engineer, Wildfire 4.0 PTC/PTC Creo Parametric, Inneo Solutions GmbH, Ellwangen, Germany). b: Base plates fixed two either side of pubic symphysis of a pelvic bone model with 2 locking screws of 50 mm length. A view to the cranial surface with the two furrows on both sides to hold the rods.