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The application of a computer-assisted thermoplastic membrane navigation system in screw fixation of the sacroiliac joint – A clinical study

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ABSTRACT

Background: We inserted iliosacral screws with the aid of a computer-assisted thermoplastic membrane navigation (CATMN) system which is widely used for the accurate and repeatable location tumour in radiation therapy. We hypothesised that application of the CATMN system on IS screws' insertion will provide a superior result to conventional fluoroscopic imaging with less operative time, more accuracy and lower complication rates.
Methods: We prospectively evaluated 26 consecutive patients who suffered from sacroiliac joint fractures and dislocations (type C, Tile classification) from April 2007 to June 2010 in our hospital. Patients were randomised into two groups: 13 patients in control group and 13 patients in CATMN groups. After operation, inlet and outlet X-ray views and computed tomography (CT) scanning were performed to confirm and compare the screw positions. The operative time, blood loss and accuracy (measured with postoperative CT) were analysed between groups.
Results: In the control group, 18 screws were placed in 13 patients with conventional fluoroscopic technique; two of 18 (11.1%) screws were misplaced. The average intra-operative blood loss was 145.4 ± 112.0 ml, and operation time was 619.2 ± 199.5 s. In the CATMN group, 21 screws were placed in 13 patients with the application of the CATMN system. All 21 screws were in safe zones. The average intra-operative blood loss was 46.2 ± 24.3 ml and the operation time was 353.8 ± 111.2 s. Operative time and blood loss were reduced significantly with the CATMN system ($p < 0.05$).
Conclusion: Application of CATMN system has high accuracy in treating sacroiliac joint dislocations and provides a new alternative method for guidance of the IS screw placement.

Percutaneous iliosacral (IS) screw positioning is the most popular method of stabilising the posterior pelvic ring and provides excellent biomechanical stability through a minimally invasive approach.[1] The most critical step during the posterior ring fixation is correct placement of the screws, avoiding nearby vessels and nerves whilst traversing the joint or fracture fragments. Several authors have reported a significant misplacement rate for IS screws placed fluoroscopically.[2–4] In response, many strategies have been proposed to improve accuracy, although few of these have been universally adopted due to a variety of logistical obstacles.[5–7]

IS screw insertion for posterior pelvic stabilisation using computed tomography (CT) scan guidance and computer-assisted orthopaedic surgery has been advocated by some authors.[8,9] Although more accuracy of percutaneous IS screw placement has been shown, these computer-assisted devices are expensive and difficult to set up and perform in the operating room.

The thermoplastic membrane is constructed from a synthetic material that shares characteristics of plastic and rubber material. It has been widely used for the accurate and repeatable location of tumours during radiation therapy.[10] The thermoplastic membrane is malleable in a 65 °C water bath, and can be moulded into a matched configuration with the patient desired field's anatomy after cooling. A three-dimensional (3D) laser location instrument (USA) is applied to select the standard plane for CT scanning, which was marked by three plumbum points on the mould. Then the CT scan is performed parallel to the standard plane and the location of the tumour is calculated by treatment planning system (XIO, USA). The data were transferred to the 3D location instrument, through which the tumour is located. Since the mould is rigid and portrays accurate anatomical detail of the patient, it can be placed repeatedly for multiple radiation sessions, and the desired tumour can be targeted using the three plumbum point markers alone.

We applied this innovative tumour location technique to posterior pelvic ring injuries and successfully inserted the IS screws on a cadaveric model prior to our current investigation. Our *in vitro* assessments provided the rationale to extend the technique

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to the clinical setting. The objective of this study was to prospectively assess the efficacy and safety of the computer-assisted thermoplastic membrane navigation (CATMN) system for the insertion of IS screws as compared with the conventional fluoroscopic imaging. We hypothesised that the use of the CATMN system based on preoperative CT scan images for the placement of IS screws will provide a superior result with less operative time, more accuracy and lower rates of complication.

Patients and methods

Patients

Between April 2007 and June 2010, all patients admitted to our trauma department with the Tile C posterior pelvic ring fracture who were stabilised using cannulated IS screw fixation were enrolled in our study. Inclusion criteria included patients older than 18 years and those whose fracture dislocation could be reduced by traction before operation. Exclusion criteria were skeletal immaturity, pathologic fractures and patients who suffered from serious chest injuries and could not tolerate the prone position. Twenty-six of 45 consecutive patients who met the inclusion criteria were randomly enrolled into two groups: 13 patients each in the control group and CATMN group. This study was approved by the local Ethics Committee and all participants gave signed informed consent.

Procedure

All patients were treated in a standardised fashion with initial resuscitation, followed by stabilisation with skeletal traction for rotationally and vertically unstable injuries. Patients with vertically unstable fracture dislocations were placed in femoral traction with 12–18 kg for 2–4 days. Anterior–posterior, inlet and outlet X-rays were performed to confirm the type of pelvic injury and reduction.

CATMN group

The operation was performed in a sterile CT operating room. The patient was placed in a prone position on the base plate of the location system. The operative area and thermoplastic mould are prepared in a sterile fashion. A size-specific thermoplastic membrane based on the size of the patient was selected and submerged into a 65 °C sterile water tank. After the thermoplastic membrane softened, it was extracted from the water tank and immediately placed around on the patient's pelvis. (Note: for the lower heat ratio of the membrane, there is no risk of skin burn.) After the membrane was moulded with the pelvic contours, the two edges of the thermoplastic mould were locked on the base plate bilaterally. The patient was placed in between the mould and the base plate, which was defined as one 'unit' (Fig. 1A). The thermoplastic mould became hardened soon after the temperature dropped. The 3D laser location instrument (USA) was applied to select the standard plane for CT scanning, which was marked by three points on the mould (Fig. 1B and C). Three-millimetre fine-cut CT scanning (Siemens, Germany) was performed in the S1 and S2 vertebra regions. The CT data were collected and transferred to the treatment planning system (XIO, USA), which automatically establishes a 3D model of the pelvis. The optimal screw trajectory of IS screw was designated as a line through the centre of the sacral 1 or sacral 2 pedicles and perpendicular to the IS joint. The screw trajectory was determined by two points, entry point and exit point, the screw trajectory across the skin of the both sides (Fig. 1D). Depending on the marked plane, the spatial orientation data of entry point and exit point were calculated. The data were transferred to the 3D laser location instrument, through which entry point and exit point were located and marked on the thermoplastic mould (Fig. 1E and F). The length of the screw was also measured based on the CT images. The C-shaped aiming device (Fig. 2A) was applied and adjusted until the tips of both the sleeves touched the entry and exit point marker of the mould, respectively (Fig. 2B). A 2.5-mm guide wire was placed into the IS joint under the guide of the C-shaped aiming device followed by insertion of a screw (6.5 mm) with the appropriate length. Postoperative inlet and outlet X-ray views (Fig. 2C) and postoperative CT scan were performed to confirm the IS screw position (Fig. 2D).

Control group

The patient was prone on the operation table. The same surgeon performed the conventional method for screw placement using C-arm image intensifier to obtain inlet, outlet and lateral view of the pelvis. When the direction of screw was determined, a 2.5-mm guide wire was placed into the sacral vertebra followed by insertion of a screw.

Postoperative evaluation

Patients' demographic details and injury mechanism at presentation were recorded. Treatment-related variables such as the fracture classification, the time of the first screw insertion and the volume of intra-operative blood loss were also collected. The time of the screw insertion was defined as the duration from the beginning of guide wire placement to the successful insertion of the first screw. The accuracy of the IS screw position was assessed on the postoperative transverse plane CT scan for each patient of both groups by two independent observers blinded to the grouping and treatment. The shortest distance of the screw in the transverse plane CT scan was measured. If the screw penetrated out of bone cortex of the anterior sacral ala or the posterior vertebral canal of the pedicle structures, the procedure would be recorded as failed.

After data collection, basic descriptive statistical analyses were used to describe the patient population and treatment outcomes. Statistical analyses were performed using the Student's *t*-test, rank sum test or Chi-square test. Categorical variables were presented as rates. All calculations were made using SPSS11.0 software (SPSS Company, USA). Statistical significance was defined as $p \leq 0.05$. Values were reported as mean $\pm$ standard errors of the mean (SEM).

Results

The demographic and preoperative variables were comparable between the two groups (Table 1). There were eight women and 18 men, with an average age of 35.5 ± 11.2 years. Based on the Tile classification, there were 17 C1 type pelvic fractures, 5 C2 type fractures and 4 C3 type fractures. There were 15 patients with right SI joint dislocation and 11 with left. All of the above fractures were closed fractures. The majority of fractures resulted from high-energy injury. No patient sustained bilateral fractures and no fractures were associated with neurovascular injury.

The results for both groups are displayed in Table 2. There were 21 screws placed into 13 patients in the CATMN group. All IS screws were positioned in the sacrum without perforation to the anterior or posterior cortex of the pedicle. Eighteen screws were placed in 13 patients in the control group using the conventional fluoroscopic technique. Two of 18 (11.1%) screws were misplaced; one penetrated the ventral cortex of the sacrum and another penetrated the vertebral canal. No neurologic compressions were observed in either case.

The average intra-operative time was 353.8 ± 111.2 s in the CATMN group. In comparison, the time of placement of the first screw under the guidance the fluoroscopic was 619.2 ± 199.5 s. The CATMN