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PELVIC MANIPULATOR FOR FRACTURES REDUCTION

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ABSTRACT

The surgical treatment of pelvic fractures has been proved to be technically challenging; 3D imaging and navigation can give a substantial benefit; a further step is here introduced with robotized fracture reduction.

A specific device to be interfaced with existing surgical tables has been designed; its main specifications are allowing 3D fluoroscopy of wide areas, and housing a hexapod robot for fracture reduction. This robot can be remotely controlled by a joystick; therefore it can accurately reproduce reduction trajectories established in the pre-operative planning and it can maintain the reduced position while synthesis devices are applied.

A prototype has been built and tested in order to assess its range of movement, its accuracy, and its learnability.

Further efforts will address the implementation of navigated surgery and to the development of a haptic interface in order to let the surgeon sense soft tissue resistance.

Keywords: Medical robotics; Pelvic Fractures; Computer assisted surgery; Hexapod; Surgical Table; 3D imaging

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1. INTRODUCTION

The pelvic ring (composed by the two hemipelvis (formed by the union of ilium, ischium and pubis) and the sacrum) is made of an anterior and a posterior arch [1]; its shape and stability are provided by the pubic symphysis and by sacroiliac ligaments mainly (Figure 1).

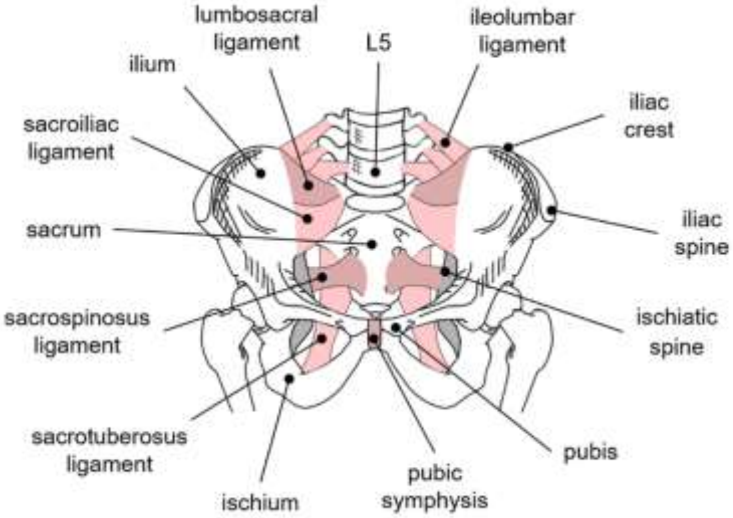

Figure 1 The pelvis and its ligaments

Tile [2] compared the back of the pelvic ring to a bridge with two pylons that are the postero-superior iliac spines; sacroiliac ligament complex works as the tensile structure, while the bridge itself is constituted by the sacrum. This tensile structure, which is the strongest ligamentous structure of the human body, is further reinforced by the iliolumbar ligaments that are inserted into the transverse processes of L5 (5th Lumbar Vertebra) and the iliac crest. The sacrospinous ligament joins together the lateral margin of the sacrum with the ischiatic spine and offers resistance to the external rotation of the hemipelvis. The sacrotuberous ligament resists both rotating moments applied on the horizontal plane and shear forces applied along the vertical plane. The anterior sacroiliac complex is, on the contrary, less strong and essentially it is useful to limit the outer rotation of the hemipelvis.

Traumatic injuries of the pelvic girdle have an incidence equal to about 20-37/100000 per individual [3], reaching 43/100000 for adults aged 40 years or over [4], and have a relevant impact leading to mortality [3] or significant disability [5]. With reference to all orthopaedic fractures, they have an incidence of approximately 3% [3], raising to 20% in poli-traumatic patients [6]. The main cause of pelvic girdle fracture are high-energy impacts as in case of traffic accidents (about 60%), or in case of falls from high heights (about 26-28%) [7][8]. Experimental tests can be performed on synthetic pelves in order to visualise loads levels producing dangerous stress distributions, where peak stresses exceed bone resistance [9].

Usually fractures are located at the upper pubic ramus (about 42%) or involve the sacroiliac joint (about 23%) or the sacrum (23%) [8]. Treating these patients may be complex since pelvic girdle fractures are often associated to other fractures (61%,) or to soft tissue injuries (12%) at the liver, bladder or the urethra [8].

Pelvic fractures historically have been treated non-surgically. However the superior outcome of surgically treated patients has been clearly demonstrated in literature for unstable fractures (instability is defined as the inability to withstand physiological loading). In facts, non-operated patients are more likely to be affected by non-union or mal-union issues, functional impairment and pain, while surgical management of unstable pelvic ring injuries allows earlier patient mobilization, correction and prevention of significant pelvic deformities, improved clinical outcomes [10].

Surgical management of unstable pelvic injuries is complex due to difficulties in reaching a good fracture reduction and performing an internal synthesis. It has now increased thanks to advances in intraoperative fluoroscopic imaging techniques, the availability of new fixation devices, and a better biomechanical understanding of injury and deformity patterns. Being true that the first objective of patient treatment is controlling life-threatening injuries, such as severe haemorrhage, a concurrent objective is reaching a good pelvic stabilization since several studies have demonstrated how this leads to less complications, shorter hospital stays, and improved final outcome [11][12].

External fixators and other external pelvic clamps [13][14] can allow achieving early stabilization [2][15].

Definitive stabilization can be performed once a good fracture reduction has been achieved, by means of external fixators as well [16] or through internal fixation by plates and screws [17][18][19].

In fracture reduction, bone fragments need to be positioned and aligned to reconstruct the fractured bone as precisely as possible in order to achieve the best functional outcome, and to avoid chronic pain, arthritis, pseudo-artrosis or other complications [20].

Fixators materials, layout and insertion torque value of the screws must be also taken into account [21].

Fracture reduction can require employing combination of clamps [22], external fixators, and, occasionally, a femoral distractor [23].

Preoperative traction is required for patients with displaced pelvic fractures, with election towards the ipsilateral distal femur if not contraindicated.

Considering that each bone fragment has six degrees of freedom that are three translations and three rotations, the complex manoeuvre required for fracture reductions might involve all six degrees of freedom, as established through an accurate preoperative planning.

Fracture reduction usually requires two clamps; each clamp is hold by an operator, while one more operator inserts fixation devices. It can be a complex operation, and 3D fluoroscopic systems can give a substantial support allowing real-time navigation [24].

Reduction can be assessed manually by palpation, and radiographically with intraoperative fluoroscopic imaging.

With reference to external fixation, two locations for pin placement have been described: antero-superior (into the iliac crest) and antero-inferior (into the supra-acetabular dense bone). The second solution has been demonstrated to provide superior stability [25], however, this technique requires fluoroscopic guidance, due to its greater risk of nerve injury [26]. Seemingly, percutaneously placed ilium-sacral screws are gaining popularity; but their safe use requires an accurate evaluation of sacral morphology through plain radiographs and CT scans and intraoperative fluoroscopic techniques. These two applications give one more reason of the emphasis given to multi-dimensional fluoroscopy in recent years [27], and in the current project.

The patient can be positioned either prone or supine, depending upon injuries; fractures treated from the prone position are exposed with a vertical paramedian dorsal surgical approach; in supine patient’s position, the lateral window of the ilium-inguinal surgical exposure is used to access the sacroiliac joint.

The object of this project is to design a pelvic manipulator for pelvic fracture reduction: it should allow reducing the number of operators involved, and providing adequate forces thanks to his proper energy source. In facts, fracture reduction can require a demanding physical effort, according to experimental measurements performed during femoral fracture reduction [28], [29]; and an insufficient force applied by the surgeon occasionally results in suboptimal fracture reduction [30]. Other benefits which can be expected from a robotic pelvic manipulator are a greater accuracy and repeatability in fracture reduction, and shortened surgery times.

Since adopting new technologies requires dedicated training section, and relevant economic investments, it is important to establish if this effort would be worthy. In literature, it is hard to find examples of robotic assistance with specific reference to pelvic fracture reduction, while more references can be found regarding femoral fracture reduction: various authors [31][32][33] illustrate the support given by a hexapod robot; Wang et al. [34] make use of a parallel manipulator robot (PMR) on a traction table.

Generally speaking, robot-assisted reduction of the femur has been demonstrated to produce a better alignment while surgery times may increase [35]. However, the above cited systems are restricted to long bone fracture, while pelvic fractures reduction is a more demanding task, requiring higher accuracy and more complex 3D trajectories [36][24].

2. MATERIALS AND METHODS

2.1. Clinical requirements and surgical system

Clinical requirements were established through discussions with orthopaedic surgeons and analysis of various fracture types, according to existing classifications [19], and their respective treatment options [37]; the final aims are reaching a more accurate fracture reduction, being able to follow trajectories defined in the preoperative planning, shortening surgery times, minimising patient and surgeon exposure to X-rays.

As explained in the introduction section, the surgical table must be X-ray transparent in order to allow intraoperative fluoroscopic imaging.

Surgical treatments may require anterior, posterior or both anterior and posterior fixation, therefore, both supine and prone positioning must be possible along with eventual lumbosacral support, padded arm boards, abdominal chest rolls to relieve abdominal pressure and allow ventilation, pads and pillows for legs positioning.

The robot for fracture reduction produces a relative movement between two pelvic parts; it is therefore necessary to fully constrain the unaffected side of the pelvis to the surgical table through a proper frame [38]. At the same time, the affected part of the pelvis must be fully constrained to the robot. The possibility of constraining both parts not only allows performing an accurate reduction, but also maintaining bone fragment positions when synthesis devices are being applied.

The surgical table must be interfaced to a traction apparatus for lower limbs in order to support their weight and to not incur in robot overloading.

The robotic device is intended to produce accurate and repeatable movements, unbiased by operator ability; it should be mounted indifferently on the left or on the right side of the surgical table, depending on fracture location.

Finally, the whole system volume must be restricted in order to avoid overcrowding the surgical room or interfering with operator movements.

Hexapod Robot

This device (M-820 hexapod by PI, USA) is shown in Figure 2: it is made of two plates and six motorised linear actuators constrained to the plates at their ends. The hexapod allows displacements of ±50 mm in the horizontal plane and ±25 mm vertically; it can reach ±15° tilt angle and up to ±30° of torsion. Displacement repeatability is equal to ±20 µm, while its actuators can reach a speed up to 20 mm/s with a load capacity of 200 N.

Figure 2 The hexapod

The maximum displacement range of pelvis fractures is rarely higher than 35 mm [39], [40], while the mass of the human pelvic zone is equal to a maximum of about 16 kg [41].

It was decided to use only one hexapod considering that bilateral fractures are not so common (5-7%) and in any case two sides are not treated simultaneously. Therefore it was not worthy incrementing costs significantly, as required to use two hexapods.

Operator interface

The operator can control the six degrees of freedom (dof) of the robot through a dedicated joystick: this controller has three dof and a selector, used to define the ‘translation’ or the ‘rotation’ mode; in the rotation mode; the movable platform of the robot keeps its centre of mass fixed and it rotates around three main axes.

The joystick allows setting the sampling frequency; it can be calibrated demanding to the operator to explore the full range of movement; finally it is initialised based on the current joystick position.

The joystick analogue outputs are read by a computer board, located in a computer running Linux operative system, through its serial port. The computer transmits the signal to a controller through Ethernet; the controller has a low-voltage input tension and moves the hexapod. The computer has a graphic interface where the operator can visualise hexapod movements generated by the joystick.

Hexapod position

Different spatial configurations have been considered. In the first one, the table plane is actually made of four surfaces; two independent surfaces are placed just underneath the pelvis and the surface placed under the affected side of the pelvis is moved by the hexapod robot (Figure 3a). This configuration would be affected by two major shortcomings: the hexapod in not X-ray transparent and this would hamper navigated surgery. Secondly, the volume occupied by the robot would not allow positioning the C-arm brilliance amplifier.

In the second solution, the hexapod is placed horizontally, as illustrated in Figure 3b; the surgical table is cantilever supported by a column in correspondence of the upper patient body. The main advantage of this solution is leaving more space for the brilliance amplifier and for the operators; however the hexapod has to support its own weight and the cantilever portion of the table under the pelvis, resulting in reduced and insufficient load capacity, added to lower movement accuracy.

In the third solution (Figure 3c) the hexapod is positioned vertically, but the pelvis is cantilever supported by the surgical table. The advantage of this solution is leaving space free under the pelvis for the brilliance amplifier and for operators; at the same time, in this solution the hexapod is properly loaded; finally, this configuration is also stiffer than the previous one, resulting in greater movement accuracy. These observations have led to choose the last solution.

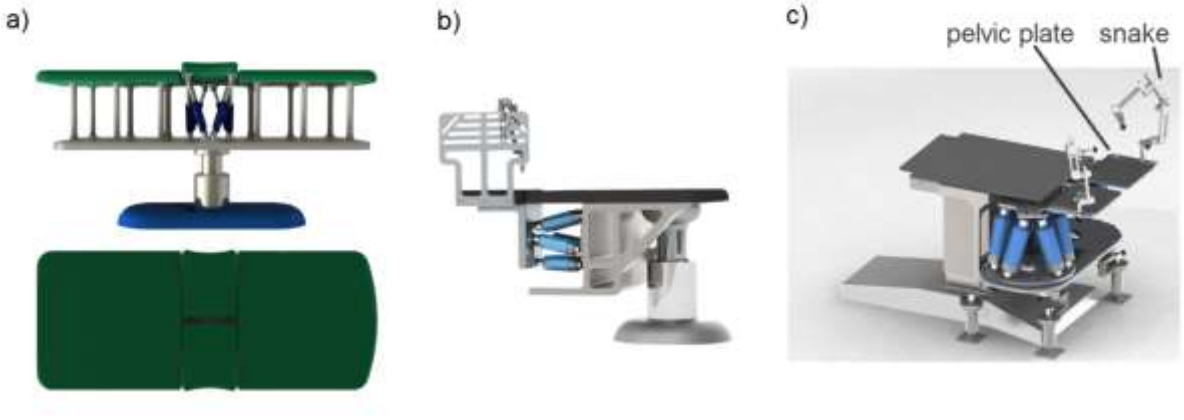

Figure 3 Different possibilities for hexapod position; c) solution has been chosen

Pelvic plates

The pelvis is supported by two independent plates: a movable plate, bounded to the hexapod robot, and a fixed plate, bounded to the surgical table.

The movable plate has to be carefully designed: it has to be sufficiently resistant in order to allow cantilever load, transparent to X-rays, and lightweight. Material choice has fallen on a composite material with carbon fibres: it has been realised by layer deposition of carbon fibre sheets under vacuum, followed by autoclave polymerization; fibre orientation changes from one layer to the next one. This material is water resistant and it can be sterilised; Figure 4 shows the plate shape. This plate holds a lateral oval hole to allocate ‘snake’ arms (described in the following section) used to fully constrain the part of the pelvis which needs to be moved by the robot.

Figure 4 The pelvic plate

The fixed plate has to be transparent to X-rays, as well; however its weight is not a concern. Therefore it has been made of resin impregnated celluloid fibres, obtained at high temperature and pressure: this material is water resistant and it can be sterilized. Also this plate holds a lateral oval hole to allocate articulated arms used to fully constrain the part of the pelvis which needs to stay fixed.

Snake arms

Both bone parts must be securely fastened to the respective plates. This connection has been realised through articulated arms, called ‘snakes’ in the following (Figure 3c). In facts, considering both patient and bone pin position variability, it is not possible to foresee the relative position between the pelvic plates and the bone pins, therefore a modular, flexible system has been designed.

These arms have been made in aluminium in order to avoid artefacts in X-rays.

Each snake is made of at least three rods; apposite joints allow modulating angles between two consecutive rods, and each rod length. Snake ends have been designed to be interfaced to 5 or 10 mm diameter pins on one end and to be inserted into the plate holes at the other end.

The surgical table must be coupled to traction devices used to support both limbs, whose weight must not load the hexapod.

3. EXPERIMENTAL TESTS

Preliminary experimental tests have been performed using a synthetic pelvis and securing the two parts to the movable and to the fixed plate respectively. Fractures belonging to all Tile classification classes have been simulated [2], with dislocations similar to those clinically encountered (<20 mm). The operator has been required to use the joystick to control the hexapod and to reduce the fracture. These tests must be considered as a feasibility study; a more extensive experimentation is required and is going on to quantitatively assess system performance.

4. RESULTS AND DISCUSSION

The first prototype has been built, assembling all components described in the previous section and simulating the patient by means of a man lower half dummy, as visible in Figure 5.

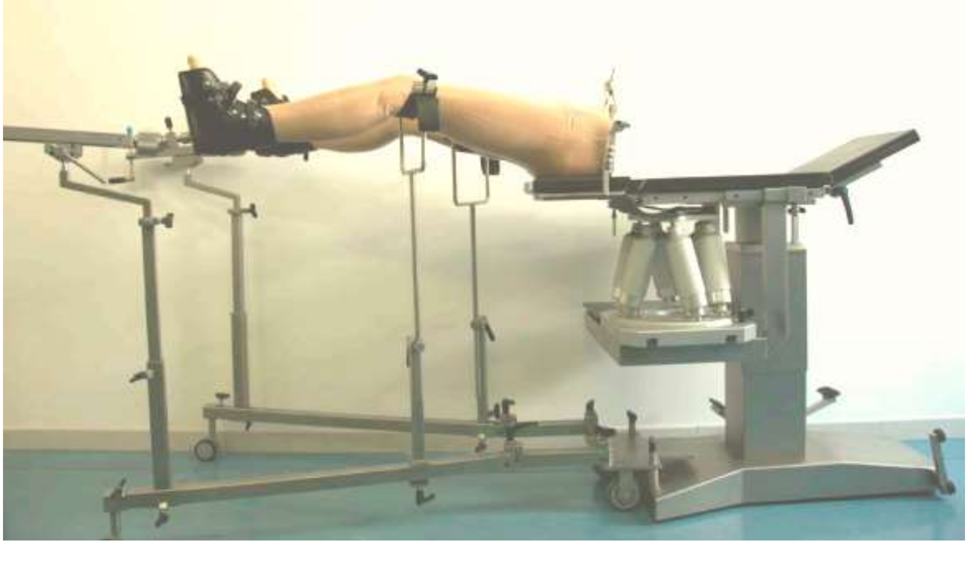

Figure 5 Pelvic manipulator prototype

The joystick has proved to allow controlling translations and rotations with 3 µm and 0.3° resolution, respectively. Its output is elaborated by a computer software base on Linux and C language, which can be installed on whatever PC. Its graphical interface is user friendly, and operator learning times are very limited.

One of the benefits of the set up system is that pelvic parts are securely bounded to their support by means of orthopaedic pins and snake arms, so the number of operators directly involved for this surgery is drastically reduced [38]. This approach can also allow accurate fracture reduction (robot-assisted) through small incisions, and is therefore particularly indicated for minimally invasive surgery [19].

The range of movement allowed by the hexapod robot may or may not be adequate, depending on pins positions, and on fracture dislocation. In some cases two different systems of bone pins are required to bind the pelvis to the movable plate, and fracture reduction has to be performed in two steps. In these cases the traditional manual displacement could be more straightforward, though remaining less accurate.

Intraoperative imaging through fluoroscopy [24][36] is guaranteed in the pelvic area thanks to X-ray transparency of the composite material used for the pelvic support, to the limited volume occupied of the device (352x317x317 mm), and to its location under the surgical table. Tests performed with the dummy have demonstrated that the whole pelvic volume is visible.

Dealing with the above cited pelvic support, it has been here realised through layer by layer deposition of sheets with different fibre orientation, followed by autoclave polymerization, since a single prototype was being realised. Mass production would allow using different technologies such as composite moulding, opening new chances such as structural optimization, and reaching significant weight reduction.

The designed system is modular and it can actually be configured as an addition which can be interfaced with existing surgical tables, and its indications can be extended to proximal femoral fractures in a near future. The same system could be extended to the treatment of over-weight patients employing a more powerful robot.

The key limitations of this system include the lack of force feedback and closed loop position control [35][42][43]. This limitation is not too heavy when a careful preoperative planning is performed (based on CT scans [44][45] or on X-rays [46]), coupled to navigated surgery. The second one has been made possible by the partial transparency of the surgical table.

Further tests are being planned on dummies to precisely assess the system performance in terms of repeatability and accuracy.

5. CONCLUSIONS

A robotised pelvic manipulator has been designed and realised. This device can be applied to surgical tables commonly used for orthopaedics. It allows to reduce pelvic fractures, applying forces up to 200 N and reaching 35 mm displacements; the robot is controlled by a joystick. The fractured pelvic parts are securely fastened to the respective plates, therefore there is no need of operators to keep these parts in place. The whole device in X-ray transparent in order to allow performing intraoperative fluoroscopy. Further efforts will address the implementation of navigated surgery and to the development of a haptic interface in order to let the surgeon sense soft tissue resistance.

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