A new technology combined robotics and 3D printing facilitates closed reduction of tibia shaft fractures using a minimally invasive plate as a reduction template: A technical note.

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Abstract

Less invasive fixation techniques are the mainstay in the treatment of tibial shaft fractures (TSFs), Intramedullary nailing (IMN) and minimally invasive plate osteosynthesis (MIPPO) are the least invasive and the preferred choices used nowadays. However, malreduction and radiation exposure are the main deficiencies associated with less invasive fixation techniques, especially rotation around the shaft axis is difficult to assess intra-operatively. Our focus is on describing a novel technology that integrates robotics and 3D printing to facilitate closed reduction of Tibial shaft fractures using minimally invasive plates as reduction templates. Using this technique, we have achieved anatomic reduction on phantom bone.

Introduction

Tibial shaft fractures (TSFs) are one of the most frequent long bone fractures. The yearly incidence of TSFs varies between 17 and 22 per 100,000 people, accounting for 1–5% of all fractures. (1–3) Historically, closed Intramedullary nailing (IMN) was the gold standard treatment for TSFs in adults. (4) Nowadays, many studies have demonstrated that MIPO is superior to IMN in terms of fewer angular deformities in proximal and distal tibial shaft fractures. (5–8)

Malalignment is a common complication of IMN for TSFs, which has been reported to account for 19–41% of cases, (9, 10) due to the lack of endosteal fit at the fracture site and the means of assessing rotation around the shaft axis intra-operatively. (11) Malalignment of MIPO for TSFs has a similar incidence because the technical complexity of achieving anatomical alignment made closed reduction a demanding surgical technique. (7)

The radiation exposure of the operating staff and the patient are another serious deficiency associated with MIPO and IMN which is caused by closed reduction. The conventional approach for closed reduction is a trial-and-error and time-consuming process because the surgeon needs to reduce a 3D deformity based on 2D fluoroscopic images to control 6 degrees of freedom of fragments simultaneously. A good reduction needs many times adjustments. The surgeon often has to make a compromise between the quality of the reduction and the time taken. Furthermore, soft-tissue damage caused by repetitive manipulations needs consideration. The risk of delayed fracture healing is increased by further soft-tissue damage. (12)

Since Bouazza-Marouf et al. (1995) first described robotic assistance for the reduction and fixation of femoral fractures, (13) various types of robots have been created to improve the reduction process. However, there is no robot-assisted fracture reduction (RAFR) system which is currently available on the market, robotics in fracture reduction remains at laboratory stage and cannot solve the clinical problem of TSFs. (14–17) The purpose of this paper is to present a new technology combined robotics and 3D printing to achieve anatomic reduction of TSFs with MIPO.

Material and methods
To illustrate the methodology outlined in this paper, we utilize a phantom model featuring a transverse fracture of the tibial shaft. The overall experimental flow is depicted in Figure 1.

**Experimental models**

A desiccated tibia was used to create the experimental model(Figure 2 ). The desiccated bone was scanned using a 3D optical scanner (3DSS-MIRG4MB-III, Shanghai Digital Machinery Technology Co. Ltd, China, resolution of 0.02 mm) to create a digital tibia model. The 3D reconstructed bone image was converted to the STL format and then imported into Unigraphics® NX version 12.0 software (Siemens PLM Software, Co, Ltd, Plano, Texas). Virtual osteotomy was performed in the middle of the model to simulate the transverse fractures using Unigraphics® NX software. After that, the prototype and the virtual fracture were printed using an FDM 3D printer (Do 50, Shanghai Digital Machinery Technology Co. Ltd, China).

But with regard to real clinical cases, the fractured tibia underwent computed tomography scanning. Subsequently, 3D models were generated from CT data and virtually reduced through the use of 3D planning software.

**Prepare minimally invasive plate**

Before operation, the 4.5-mm locking compression plates (Fulekeji®, Beijing, China) with 12 holes, size 2.8×184×14.5mm, was pre-contoured to fit the medial surfaces of the model, then the pre-contoured plate was scanned using the 3D optical scanner. The datasets of the plates was imported into the 3D planning software in a graphic workstation for virtual fixation and screw path planning.

**Virtual bone fracture reduction and fixation planning**

The digital fracture model was virtually fixed with the imported plate, using two screws at each fragment. The screw paths were planed and the software autonomously programmed the screw hole drilling trajectories for robot navigation. Pre-operative planning data are stored in the system for intra-operative robot motion planning.

**Surgical system configuration**

The surgical system used in this research consists of the following components: the 3D planning software (in charge of 3D model construction, virtual bone fracture reduction and planning and assembling plate and screws), Tibia holding equipment, robotic system (SantanRobo, Hangzhou Santan Medical Technology Co. Ltd., Hangzhou, China).

Our robotic system consists of three main parts (Figure. 3): a 6 degree-of-freedom robot arm (UR5e, Universal Robots A/S, Odense, Denmark), the system workstation (in charge of screw path plan, registration, robot arm control), the end-effector.

**Intra-operative operations**
The experiment were conducted at operating theater on the phantom bone (3D printed Tibia fracture model).

Following fixation of the phantom bone onto a specialized holding frame, the robot arm equipped with a reference frame was positioned over the fragment to obtain anteroposterior and lateral radiographs for automatic image registration(Figure 4). This step serves to accurately define the position of each fragment in three-dimensional space relative to the mounting platform. The images are then matched by the system software (Santanrobo) to the preoperative digital models containing the preoperative plan (Figure. 5). Once the images are made and the registration is verified, remove the reference frame from the robot arm, and move the fluoroscope out of the surgical field. Subsequently, the robot arm was dispatched to the previously planned, precise position for screw placement at each of the fragments. Once the robot arm reaches the preset positions, pass the drill guide through the end effector of the arm. Place the drill into the guide and perform the drilling process (Figure.6). Repeat this procedure for all screw holes.

Before reduction, the proximal fragment was fixed with the proximal half of the plate accurately. Hence, the pre-contoured plate can now serve as a template to guide the operator in manipulating the distal fracture. Then, releasing the distal fragment from the holding frame, the operator holds the distal fragment with two hands and manually aligns the screw holes in the distal fragment and the holes of the plate. Finally, drive the locking screws into the holes in the distal fragment through the plate. Thus the anatomic reduction is achieved with the pre-contoured plate as a reduction template. (figure 7)

**Discussion**

Achieving anatomical reduction is crucial in the surgical treatment of fractures for full functional recovery while avoiding complications caused by malalignment. Only with accurate reduction can stable and safe fixation be achieved.

The main challenges for utilization of robot-assisted fracture reduction (RAFR) include: (1) invisibility and complexity of fractured bones; (2) higher precision of fracture reduction for better function achieved postoperatively; (3) adequate workspace to be provided by suitable degree-of-freedom (DOF) of the robot; (4) sufficient robot output force required during fracture reduction of lower extremities. (16)

The prevailing robot-assisted fracture reduction devices are mostly external fixation-like, which increases additional damage, and their reduction and fixation devices cannot be united as one(14). Although various types of robots, such as serial, parallel, and hybrid mechanisms have been developed, resolving the contradiction between output force and workspace requirements remains a challenge for these devices. The serial robot has the advantages of better maneuverability, dexterity, and a larger workspace, but has the disadvantages of low stiffness, low accuracy, and decreased payload-to-weight ratio because its kinematic chains bring on every joint the burden of the following joints, hardware, and target object. The limited workspace, especially the rotational one, is a drawback of parallel robots because of their closed structure. The hybrid robots developed by incorporating a serial mechanism into a parallel
mechanism, or vice versa, still have the weakness of serial robots, because reduction force conducted through serial robots as before(16). However, the devices’ size expansion inevitably encroaches upon the surgical workspace. Although these robots have demonstrated exceptional precision in vitro testing, no clinical studies have been conducted on them to date.

To the best of our knowledge, there is no literature that reports on a technique combining robotics and 3D printing for fracture reduction prior to ours. Therefore, our technique can be considered as pioneering in this field.

The technique we developed conforms more closely to clinical norms and is therefore more likely to be utilized in a clinical setting. In comparison with other techniques, our system's registration process does not require the implantation of markers prior to surgery, thereby reducing patient discomfort and the risk of infection. Additionally, our technology boasts a simple system structure and ease of use without necessitating a complex end-effector equipped with optical markers.

The critical innovation of our solution lies in the utilization of a minimally invasive plate as a reduction template. During the actual MIPO operation, it is more convenient to secure the proximal shaft of the fractured tibia with the proximal half of the plate prior to closed reduction. Subsequently, both the proximal tibial shaft and plate form a single unit, with the plate serving as an extension of the proximal fragment. At this point, our solution ingeniously transforms closed reduction into open reduction and integrates the reduction tool with the fixation device. By manually aligning the screw holes in the distal fragment and those of the plate under direct vision, surgeons can complete the reduction process. The accuracy of screw hole positions is crucial, as is ensuring that the curve of the plate is anatomical. These requirements are met through robotics and 3D printing technology. The current experiment's results demonstrate that our technology has achieved anatomic reduction on a phantom bone.

This technology presents certain limitations, such as the additional costs associated with 3D printing and robotics, the need for further training of operation staff due to a steep learning curve, among others. Although a cost-effectiveness analysis is currently unfeasible, the value of this new technology is evident and varies from patient to patient. It should be noted that our study was limited by its demonstration on phantom bone without soft tissue coverage or muscle interference. In addition, our study is limited by the fact that the demonstration was conducted on a phantom bone without accounting for soft tissue coverage and muscle forces in a real-life scenario.

Currently, refinement of the proposed technology, its corresponding analysis and execution procedure is still ongoing, and it has not yet been tested on in clinical settings. In light of the potential for improved reduction outcomes and reduced operating and intraoperative fluoroscopy time, further investigations will be conducted to evaluate the efficacy of the proposed solution on cadaveric specimens and ultimately in clinical settings.

There are various avenues for future research to expand upon the concepts presented in this paper. In subsequent studies, efforts will be made to streamline the registration and virtual reduction processes
into an automated procedure. Additionally, sensors will be integrated at the robot's end effector to enable real-time monitoring of force-torque feedback.

**Conclusion**

The proposed technology achieved precise anatomical reduction of FSFs on a simulated bone model. We have demonstrated the feasibility and effectiveness of our approach in this study, however, further investigations are warranted to validate its performance in more realistic scenarios.

**Declarations**

**Conflict of Interest**

The authors have stated explicitly that there are no conflicts of interest in connection with this article.

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**References**


Figures
Figure 1

The flowchart of overall experiment.

Figure 2

The desiccated Tibia used to create the experimental model.
Figure 3

robotic system.

1) Robot arm

2) System workstation

3) End-effector
Figure 4

Image registration

1) Reference frame

2) Tibia model
Figure 5

Images match

a. Before image match (A) 3D image reconstructed from preoperative CT data (B) Radiograph obtained during operation

b. After image match (A) Lateral view of matched images (B) Anteroposterior view of matched view
Figure 6

Drilling process
Figure 7

Overall effect of reduction

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Drillingprocess.mp4