In vitro Study Using Cadavers

For Evaluation of a Bone-Mountable Surgical Robot System

Seong-Young Ko, Jong-Ha Chung, Jonathan Kim, Dong-Soo Kwon, Jung-Ju Lee, Yong-San Yoon
Department of Mechanical Engineering
KAIST
Yuseong-gu, Daejeon
Korea

Abstract—This paper describes a bone-mountable surgical robot system for hip surgery and its in vitro experiments with cadavers. The system eliminates the need for obtaining CT scan data by adopting gauge-based, bone-mounting registration method and is designed to replace only the broaching procedure, which is known to be the most error-prone procedure in the manual surgery. The performance of this system is evaluated with specimens of six human cadavers. X-ray images and photographed image of femurs are utilized for measuring the difference between the implant and the anatomical axes. As this deviation implies how the gait pattern of the operated patient may be influenced by the surgery, the amount of deviation is used as the indicative of system performance. The nominal differences of anteversion angle, valgus-varus angle, and flexion-extension angle are $0.02 \pm 0.73^\circ$, $0.98 \pm 0.39^\circ$, and $0.51 \pm 0.87^\circ$, respectively. In case of the change in leg length after the surgery, the nominal error is $-0.88 \pm 1.26$mm. Experimental results show that the performance of the developed system is comparable to other surgical robots that use preoperative planning with CT scan data.

I. Introduction

Hip surgery is a surgical procedure that replaces a damaged or fractured hip joint with an artificial femoral implant and an acetabulum. The damage can be induced by trauma, disease or congenital deformity and it reduces the range of motion or completely prohibits the motion at the hip joint. Two types of procedures are available for this process: cemented and cementless. For the cementless procedure, a porous implant is used for bone ingrowth and its use is shown to have a lower rate of revision and improved clinical outcomes compared to the procedure with cement [3]. However, the cementless procedure requires that the carved hole precisely matches the shape of the artificial hip implant, as the bone growth to the porous surface of the implant cannot be achieved if the gap is more than $0.25$mm[4].

In a conventional cementless hip surgery, the surface conformity between the bone and the implant is less than $20\%$ [5]. This causes slow recovery and shortens the life of the implant. To improve the conformity, robotic surgical systems such as ROBODOC and CASPAR are developed and tested for performance and clinical applicability [6], [7], [8]. The use of these surgical robots can generate machined surface of high precision, but such robotic systems require preoperative planning such as insertion of fiducial markers on the femur and CT scanning to construct the 3D image of the femur. This preoperative procedure may require as much as a day of preparation [6]. Besides the time, complexity and high operational cost also hinder its usage in the real operation.

To overcome these problems, we had developed a new surgical robot system for hip surgery, which consists of a compact, bone-mountable robot and a new, simple registration method without complex preoperative procedures such as placement of fiducial markers, CT scanning, or the use of vision-based surface tracking modules [1][2].

Some experiments using model femurs and pig femurs show that this surgical robot system has sufficient machining accuracy and precision [2]. Model femurs may provide the human-like geometric features while the pig femurs may provide the hardness that is similar to or harder than human femurs. For more accurate performance evaluation, in vitro study using human cadavers is conducted. In this paper, the developed system and its surgical procedures are presented. Its experimental result with six human cadavers is also presented.

II. Developed Surgical Robot System

We have developed the system with the following two premises: the reamer can provide physically accurate machining guideline and most of the errors in the manual surgery occur in the broaching process where a hammer is used to carve out the desired shape of the implant. If we can replace these shortcomings of the manual operation with robot-guided processes, we may be able to drastically improve the surgical outcome with a simple registration.

A reamer is one of the conventional surgical tools in the manual operation and is inserted through the medullary cavity in the femur. Since the reamer may produce the optimal hole along the medullary cavity, we can use the
position information of the hole made by the reamer for simple registration. In the broaching process, if the inconsistent hammering of the operation surgeon can be replaced by robot-guided machining process, the misalignment and overshaping problems in the manual surgery can be minimized if not all eliminated. Based on these assumptions, the design concept is adopted to develop a bone-mountable robotic system that employs a gauge-based registration method.

To satisfy the requirements, the system should have following functions: it should accurately machine the femur along the pre-programmed tool path and must be able to determine, using the information obtained during the registration method, the accurate location to be machined. We developed a small robot system for machining and a block gauge with a rod, whose radius is identical to the reamer’s, for obtaining position information of a medullary cavity. In addition, we developed a femoral frame for mounting the small robot on the femur and a compact distance-measuring device for measuring relative position from the robot to the block gauge [1][2].

First overall, to develop a surgical robot, several types of 3 DOF, bone-mountable robots are considered. After consultation with medical doctors and graphical simulation for the determination of necessary DOF, it is determined that a 4-DOF robot, including one redundant DOF, is sufficient to machine the shapes of various implants. Most of the femoral implants have monotonically decreasing cross-sectional towards the bottom and thus, do not require undercut. Fig 1 shows the developed bone-mountable surgical robot. Its size and weight are about 190 × 150 × 200 mm³ and 1.4kg without pneumatic actuator. The robot is designed to have sufficient workspace to machine the largest commercially available implant. So, its workspace is greater than a cylinder with radius of 50 mm and height of 110mm. To avoid extra incision for the implementation of bone-mounting scheme, the system components are designed so the robot can be attached about 5cm above the proximal tip of the femur.

Prior to machining, we must know the position of the medullary cavity relative to the robot. As mentioned above, the block gauge is for determining the reference position for machining. In current manual surgery, the reamer is aligned along center of the medullary cavity through the conventional hand reaming process. So, if the position of the hole made by the reamer is measured, the position of the medullary cavity can be easily calculated. For this purpose, the block gauge is attached at the end of the rod with the same radius as the reamer as shown in Fig. 2.

In order to connect the robot to the femur and to support the robot during machining process, a femoral frame is developed. It consists of bone clamps, a base plate and joints. In initial design, the femoral frame provided 4DOF: rotation about 3 axes and translation along the longitudinal axis of the femur. However, such configuration is not suitable if the degree of bending in femur is severe. To make it work with bent femur, we added a prismatic joint as shown in Fig.4. Bone clamps are used to attach the frame to the femur. They are widely used in orthopedic surgeries and can provide sufficient rigidity for fixation. Such clamps are used in other surgical robots to fix the bones [11]. Some of the knee surgery systems fasten the femur and the tibia with screws to obtain the solid fixation [12][13]. However, we used conventional bone clamps to avoid additional damage and incision. In addition to the robot-supporting function, the

![Fig. 1. Surgical robot](image1.png)

![Fig. 2. Block gauge](image2.png)

![Fig. 3. Block gauge inserted into femur and the femoral frame attached on femur](image3.png)

![Fig. 4. Femoral frame](image4.png)

![Fig. 5. Distance-measuring device](image5.png)
femoral frame informs us about the robot's position. Since the robot is attached at the base plate of femoral frame on the predetermined specific position, we use the femoral frame to determine the location where the robot is set. Fig. 3 shows how the femoral frame is attached to the femur, while the gauge is inserted.

The distance-measuring device (Fig. 5) is designed to measure the robot's position and orientation with respect to the femur and has the resolution of 0.04mm.

In order to compensate the pre-programmed tool-path according to the robot's present position/orientation, the six conical holes on the block gauge and the three conical holes on the base plate of the femoral frame are used. As shown in Fig. 6, the relationship between the base plate and the block gauge can be considered as a 3-6 Stewart platform. We can obtain the homogeneous transformation matrix from the block gauge to the base plate simply using inverse kinematics of parallel manipulator.

III. Surgical Procedure using ARTHROBOT

In using the proposed registration method, a surgeon prepares the femoral cavity using a conventional manual reaming process, which aligns the reamer along the center of the medullary cavity. After reaming, the block gauge is inserted into the hole made by a reamer, which constrains 4 DOF of the block gauge as this procedure is similar to peg-and-hole assembly. The surgeon can constrain the additional 1 DOF by contacting the bottom of the block gauge to the proximal end of the femur. The remaining 1 DOF is constrained by rotating the reamer to the desired direction on the femoral neck (Fig. 7). The last confinement is critical as it is directly related to the anteversion of the leg and must be determined by the operating surgeon.

While the block gauge is still in the femur, the surgeon clamps the femoral frame to the femur. The feasibility of this frame-mounting procedure is tested in a real surgery without extra incision (Fig. 8). The surgeon then measures the distances between three conical holes on the femoral frame and six conical holes on the block gauge (Fig. 9c). The tool path is then compensated based on the relative orientation and the translation. The block gauge is removed (Fig. 9d) and the surgical robot is mounted using clamps (Fig. 9e). The surgical robot machines the femoral cavity along the pre-programmed path. After the femur is machined, the robot and the frame are removed, and the cementless implant is inserted into the machined cavity (Fig. 9f).
IV. Evaluation Method

Our previous experiments [2] with model femurs (Sawbone®) and pig femurs show that this surgical robot system has sufficient machining accuracy and precision. In this paper, we present comprehensive analysis of orientation/translation accuracy using X-ray and photo images. The objective of the previous work was to determine how accurately the machining is conducted with respect to the doctor's intended position. This paper, on the other hand, deals with the error analysis when the implant is finally inserted into the machined femur. Therefore, the error or deviation described in this section represents the cumulative error from reaming, machining and implant insertion. The errors are defined as the variation in the inserted implant's orientation i.e. valgus/varus, flexion/extension, and anteversion angles with respect to the anatomical axes as well as the change in the leg's length after the surgery. For deviation measurement, orthopedic surgeons were consulted.

In order to compare the valgus-varus angle of the femur after implant insertion, X-ray images of the anterior view acquired before and after the surgery are compared. To establish a reference, the femur is fixed to the leveled ground and a horizontal line is drawn from the outer most point in the lesser trochanter. Another line parallel to the first line is drawn with 10cm offset. The midpoints of these two lines are connected and defined as a reference line for valgus-varus angle measurement.

The way to determine the reference line for flexion-extension angle is similar, but different in that it uses the X-ray image from the lateral view instead of the anterior view. For flexion-extension angle measurement, a line through the center of the lower region of the implant, which looks similar to a tapered cylinder, is drawn and defined as the center line of the implant or the implant line as shown in fig 11(b). The angle between the implant line and the reference is defined as the difference in flexion-extension angle. Similar to varus-valgus angle, the flexion-extension angle is determined by the direction of the deviation with respect to the reference line as shown in fig. 11(a).

Finally, photo images taken from transverse plane (top view) of femur are utilized to determine the difference in anteversion angle. Initially, CT images were taken to compare the variation in anteversion angle, but it was not possible due to difficulty in aligning the images before and after the machining. The photo images from top view are taken after placing the femur on a flat surface as shown in figure 12. The angle between lines A1 and B, and A2 and B are measured and defined as the difference in anteversion angle.

The non-tapered region of the implant is compared to the reference line and the state of being whether valgus or varus is determined by the shifted direction as indicated in fig. 10(a).
V. Experimental Results

Figure 13 is the experimental setup of the system. The PID controller is a Pentium 166 PC with real-time OS QNX. The sampling time of the controller is 1 msec. Six human femurs are prepared and the femoral heads were removed as in a real operation. The femoral cavity is reamed by an orthopedic surgeon and the robot is mounted onto a base plate that is fixed to the bone through the mounting frame. The general procedure is identical to the manual surgery except that the broaching procedure is replaced by a robot-guided machining. Used stem types in this study are Versys® tapered stems (Zimmer, Inc.) and their sizes are 10mm and 12mm.

Table 1 shows the change in anteversion, valgus/varus and flexion/extension angles after the surgery.

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Orientation/Translation Difference Using Cadaver</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation / Translation</td>
<td>Cadaver mean ± sd</td>
</tr>
<tr>
<td>Anteversion</td>
<td>0.02 ± 2.73°</td>
</tr>
<tr>
<td>Varus/Valgus</td>
<td>0.98 ± 0.39°</td>
</tr>
<tr>
<td>Flexion/Extension</td>
<td>0.51 ± 0.87°</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Table 2</th>
<th>Orientation/Translation Difference Using Synthetic and Pig Femurs[2]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Orientation / Translation</td>
<td>Model Femurs mean ± sd</td>
</tr>
<tr>
<td>Anteversion</td>
<td>0.07 ± 0.74 °</td>
</tr>
<tr>
<td>Varus/Valgus</td>
<td>0.69 ± 0.26 °</td>
</tr>
<tr>
<td>Flexion/Extension</td>
<td>-0.09 ± 0.35 °</td>
</tr>
<tr>
<td>Change in Leg Length</td>
<td>-0.09 ± 0.55 mm</td>
</tr>
</tbody>
</table>

The difference of anteversion angle, valgus-varus angle and flexion-extension angle are 0.02±2.73°, 0.98±0.39° and 0.51±0.87°, respectively. As shown in table 2, greater difference was observed compared to the experiments conducted with model femurs (Sawbone®) and pig femurs. This is due to the fact the errors listed in table 1 include all errors from reaming, machining and implant-inserting processes. The reason that there's a greater deviation in anteversion, compare to others, is because the surgeon chooses the anteversion angle based on his eye estimate and experience. Therefore, the anteversion angle error contains the inherent human error. A simple experiment with the developed block gauge was conducted to find out the range of this eye estimation error and the error range is shown to be less than 2.0°.

In order to measure the change in leg length, an x-ray image is taken with implant inserted. From the image, depth of insertion is measured and compared to the depth defined in the preoperative planning procedure. The change in depth is -0.88±1.26mm. In most cases, the implants are inserted deeper than as planned, due to excessive amount of force applied during the insertion process. According to previous study [10], the amount of errors in our experiment has nearly no effect on the patient's gait after operation; therefore, the developed system may be suitable for clinical application. J. Jerosch and et al. compared the outcome of manual surgery with that of robot-guided surgery with CT data [9]. In his analysis, the differences in anteversion angle in the manual and the robot-guided procedures are 10.8±6.4° and 0.4±0.9°, respectively. The changes in leg length in the manual and the robot-guided procedures are 7.9mm and 5.4mm, respectively. Despite our surgical robot system has a bit larger error in anteversion angle, our system is advantageous in that it neither requires CT imaging nor additional preoperative procedures.

VI. Summary

This paper describes a bone-mountable surgical robot system for hip surgery and its in vitro experiments with cadavers. Six human femurs were prepared to evaluate the developed surgical system. Experiments are performed by an orthopedic surgeon. X-ray images and photo images are utilized for measuring the orientation and translation differences. The differences of anteversion angle, valgus-varus angle and flexion-extension angle are 0.02±2.73°, 0.98±0.39° and 0.51±0.87°, respectively. In case of the change of leg length, the error is -0.88±1.26mm. Experimental results show that the developed surgical robot seems to have comparable accuracy with other surgical robots that require CT scanning for pre-operation planning.
VII. Further Work

As a next step, we will evaluate the surface conformity with cadavers and carry out in vivo study. To analyze the surface conformity, we will use plastic implants with similar geometric features. The same procedure as described in [2] will be used to evaluate the surface conformity. Since the surface conformities of both model femurs (Sawbones®) and pig femurs are greater than 93%, we expect the surface conformity for human femurs to be in the vicinity. The following in vivo study will provide more realistic performance evaluation and will be used to determine the system's applicability in real operation.

VIII. Acknowledgments

This work has been supported by the Human-friendly Welfare Robot System Engineering Research Center (HWRS-ERC) at KAIST in Korea.

IX. References


