Preliminary Results of an Early Clinical Experience with the Acrobot™ System for Total Knee Replacement Surgery

Matjaž Jakopec[1], Simon J. Harris[1], Ferdinando Rodriguez y Baena[1], Paula Gomes[1], Justin Cobb[2], and Brian L. Davies[1]

[1]Imperial College of Science, Technology and Medicine, Exhibition Road, London, SW7 2AX, UK; [2]The Middlesex Hospital, Mortimer Street, London, W1N 8AA, UK

Abstract Early clinical experience with a "hands-on" robotic system for total knee replacement surgery is presented. The system consists of a pre-operative CT based planning software, a small special purpose robot called Acrobot (active constraint robot) mounted on a gross positioning device and special leg fixtures. The surgeon guides the Acrobot under active constraint control, which constrains the motion into a predefined region, and thus allows surfaces of the bones to be machined safely and with high accuracy. A non-invasive anatomical registration method is used. The system was clinically tested on 7 patients with encouraging results.

1 Introduction

Total knee replacement (TKR) surgery is a common orthopaedic procedure with the purpose of restoring functionality and reducing the pain caused by injury or by degenerative bone disease in the elderly. Damaged surfaces of the knee bones are replaced with a knee prosthesis, which typically consists of three components: tibial, femoral and patellar. To implant the prosthesis successfully, the bone surfaces must be precisely machined to a specific shape to match the prosthesis components. Typically, a single flat plane is cut across the tibia and the patella, while five planes are required on the femur.

Conventionally, the surgeon uses a complex set of jigs and fixtures in an attempt to accurately position the cutting guides, which are then used to guide the blade of an oscillating saw to cut the flat planes. It is very difficult to achieve a good fit and proper placement of the prosthesis, even by a skilled surgeon using state-of-the-art tools. Poor quality of fit and improper alignment of the prosthesis can lead to pain and reduced functionality of the joint, as well as accelerated wear and loosening of the components, and subsequent need for a revision surgery. A clinical study into conventional TKR surgery [1] reported that the deviation from the ideal prosthesis alignment is over 9^{O} in 7% of cases, and over 5^{O} in 34% of cases.

To overcome the problems and improve the results of the procedure, a robotic surgery system has been developed at Imperial College , and is currently undergoing clinical trials [2]. In contrast to other orthopaedic robotic systems, such

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as Robodoc [3] or Caspar [4], which use modified industrial robots, a small, low-powered, special-purpose robot called Acrobot (active constraint robot) has been built to ensure safe use in a crowded sterile operating theatre environment. In addition, a novel type of control — active constraint control — has been developed [5,6], where there is a synergy between the surgeon and the robot. The surgeon guides the robot by pushing on the force controlled handle at the tip of the Acrobot, and is thus kept in the control loop, while the robot constrains the motion into a predefined region. This "hands-on" approach allows the surgeon to use his/her sensory capability and understanding of the overall situation to dictate the pace and direction of the procedure, while the robot ensures that the pre-operative plan is executed safely, and with high accuracy.

2 Acrobot TKR System

The Acrobot surgical procedure is divided into two phases: pre-operative planning and intra-operative robotic procedure. An early Acrobot prototype has been successfully tested on plastic phantom bones and cadaveric legs, using fiducial markers for registration [7]. A very good fit of the prosthesis onto the bones was observed, with correct alignment of the leg achieved. The system was subsequently adapted to make it more suitable for the demanding operating theatre environment, and an anatomical registration procedure was introduced to avoid the invasive fiducial marker placement.

2.1 Pre-operative Planning

The pre-operative planning software runs on a standard PC computer, and allows the surgeon to interactive plan the procedure. First, the CT images are processed and the knee bones are segmented in a semi-automatic process. The 3-D models of the bones are built and the bone axes are determined. The surgeon then interactively decides the prosthesis size and placement of the tibial and femoral components onto the bones. The surface of the patella is prepared as in conventional surgery, as the manual preparation is thought to be accurate enough. A number of different 3-D views of the leg and the implant are provided to aid the surgeon to place the components to ensure the correct alignment of the leg (see Figure 2). Once the surgeon is satisfied with the plan, the software generates a constraint boundary for each of the cutting planes (five on the femur and one on the tibia), and a number of locating hole boundaries (for stems and locating features of the prosthesis components). The software also generates bone surface models, which are used intra-operatively for anatomical registration. The planning data is then transferred to the intra-operative system.

2.2 Intra-operative Robotic System

The intra-operative robotic system consists of the Acrobot, a gross positioning manipulator and leg fixtures. The Acrobot is a special-purpose robot with 3

orthogonal axes (Yaw, Pitch and Extension), with a relatively small range of motion. This ensures accurate and safe operation with low-powered motors over a small region. A force sensor handle is mounted near the tip of the Acrobot. The surgeon holds onto this handle and is able to move the robot with low guiding force, due to Acrobot's low mechanical impedance. The guiding force signal is used as part of the active constraint control algorithm to apply a compensating force to stop the motion at the boundary of the pre-defined region. A high-speed orthopaedic cutter system (Stryker Instruments) is used to mill the bone tissue away.

Due to the small workspace of the Acrobot, it is placed on a gross positioning device (see Figure 1), which allows the knee to be accessed from different directions (depending on the plane being cut). The device (manufactured by Armstrong Healthcare Ltd.) is built around a 6-axes robot, with secondary encoders and limited velocity to ensure safe operation. Furthermore, the device is locked-off when the bone is machined, and is only powered-on for a short period between cutting two consecutive planes to move the Acrobot to the next optimal cutting location. The gross positioning manipulator is mounted on a trolley, which allows quick placement and removal of the system. During the procedure, the trolley is clamped to the operating table and its wheels are locked. To ensure sterility, the Acrobot and the gross positioning device are covered with sterile drapes. Only the cutter is autoclaved and mounted through sterile drapes at the start of the procedure.

During the surgery, the tibia and the femur are immobilised with respect to the operating table. This is achieved with two special bone clamps (manufactured by Finsbury Instruments Ltd.), which are rigidly clamped to the exposed parts of the tibia and the femur. Each of the two clamps is fixed to the operating table by means of three telescopic links, connected to the base frame mounted onto the side rails of the operating table. The ankle is placed into a special foot support mounted on the operating table. The weight of the patient has proven enough to immobilise the femur at the hip joint. The bone fixtures are sterilised before the surgery.

3 Clinical Application

The Acrobot TKR system was first tested on plastic phantom bones, to analyse the performance of the overall system, the suitability of the devised surgical protocol, and the accuracy of the anatomical registration. Having obtained very good results with plastic phantoms, the system was brought into the operating theatre and is currently undergoing clinical trials. 7 clinical trials have been performed to date. The first two cases were performed to test the surgical protocol and anatomical registration, but without cutting the bone. The third case involved using the robot to cut the femur only. Full robotic assisted surgery was performed in the rest of the cases.

The procedure was similar in all cases: A CT scan of the patient's leg was taken a few days before the surgery. The CT slices were taken at 1mm intervals

Figure 1. The Acrobot mounted on a gross positioning device

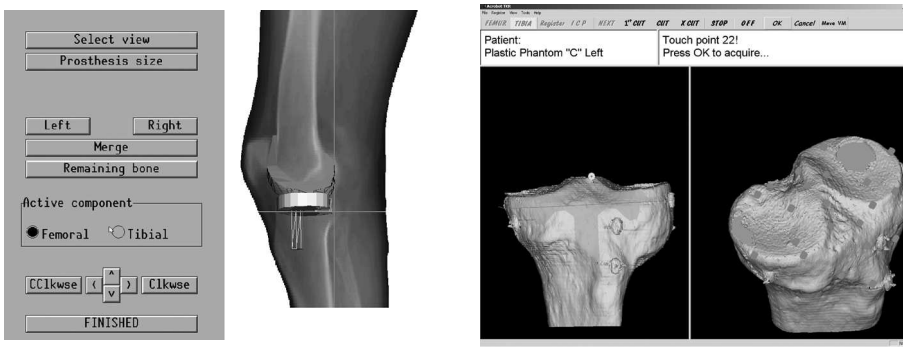

Figure 2. User interface of the planning software (left) and intra-operative user interface during anatomical registration (right)

in the region of the knee and 5 mm intervals for the rest of the leg. The procedure was planned using the planning software, and the intra-operative data was generated.

Intra-operatively, the knee was exposed and the bones were immobilised using the leg fixtures (see Figure 3). During the first trial it was noted that the tibial knee clamp could be improved upon, and it was subsequently modified, which substantially reduced the time required to fit the clamp onto the bone. The robot was covered with sterile drapes and wheeled next to the operating table and clamped to it.

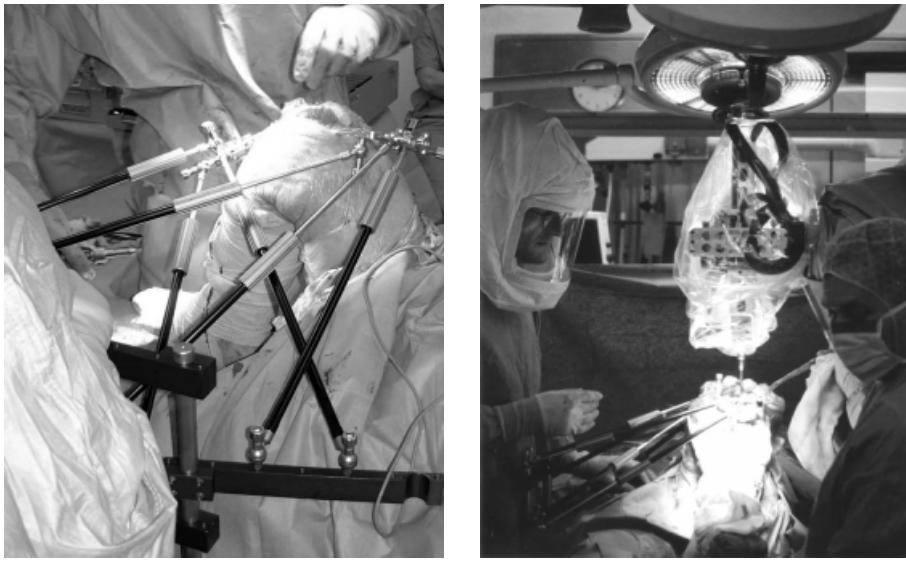

Figure 3. Clinical trial: leg fixtures in place (left) and preparation for registration (right)

Each of the bones was then registered and cut. Registration was performed by first acquiring 4 pre-operatively defined landmarks to obtain an initial registration estimate. The points were acquired by the surgeon moving the Acrobot with a special registration probe (1 mm diameter ball) mounted in the cutter motor. The surgeon then acquired a set of points (typically 20-30) spread over the surface of the exposed bone. An iterative closest point (ICP) algorithm [8,9] was then used to compute the registration transformation. The accuracy of the registration was then verified by using the on-screen colour coded display of the point-set matched onto the surface model, and by touching various landmarks and checking their position on the real-time display (see Figure 2). In case of unsatisfactory registration, the ICP procedure was repeated with a new set of points. The registration results are shown in Tables 1 and 2.

Patient	Sequence	*Num. of points*	*RMS err* (*mm*)	*Std Dev* (*mm*)	*Max err* (*mm*)	*Min err* (*mm*)
A	Initial	4	9.99	—	—	—
	ICP 1	29	0.61	0.361	1.71	0.04
	ICP 2	40	0.59	0.366	1.59	0.01
	ICP 3	36	0.38	0.240	0.85	0.01
B	Initial	4	1.13	—	—	—
	ICP 1	26	0.57	0.352	1.31	0.02
	ICP 2	13	0.27	0.178	0.72	0.01
D	Initial	4	18.58	—	—	—
	ICP 1	17	0.40	0.269	1.01	0.00
E	Initial	4	10.04	—	—	—
	ICP 1	18	1.69	1.255	5.37	0.07
	ICP 2	18	0.71	0.356	1.33	0.01
F	Initial	4	6.20	—	—	—
	ICP 1	17	0.67	0.369	1.20	0.00
	ICP 2	20	0.41	0.226	0.77	0.01
G	Initial	4	15.87	—	—	—
	ICP 1	14	0.36	0.218	0.96	0.02

Table 1. Registration sequences for the tibia

Patient	Sequence	*Num. of points*	*RMS err* (*mm*)	*Std Dev* (*mm*)	*Max err* (*mm*)	*Min err* (*mm*)
A	Initial	4	0.60	—	—	—
	ICP 1	34	0.80	0.537	2.33	0.01
	ICP 2	29	0.21	0130	0.50	0.01
B	Initial	4	2.56	—	—	—
	ICP 1	22	0.96	0.615	2.95	0.09
	ICP 2	19	0.52	0.264	1.13	0.12
	ICP 3	12	0.17	0.116	0.35	0.00
C	Initial	4	5.71	—	—	—
	ICP 1	26	0.85	0.620	3.19	0.11
	ICP 2	24	0.44	0.280	1.16	0.04
D	Initial	4	5.46	—	—	—
	ICP 1	16	0.67	0.498	2.20	0.05
E	Initial	4	23.70	—	—	—
	ICP 1	20	0.86	0.534	2.09	0.06
	ICP 2	17	0.61	0.461	1.43	0.00
F	Initial	4	145.27	—	—	—
	ICP 1	18	0.74	0.462	1.76	0.01
	ICP 2	23	0.39	0.210	0.74	0.00
G	Initial	4	4.56	—	—	—
	ICP 1	18	0.99	0.640	1.97	0.03
	ICP 2	18	0.38	0.228	0.75	0.01

Table 2. Registration sequences for the femur

Once successfully registered, the registration probe was replaced with a drum cutter (7.8 mm diameter) and the surfaces of the bone were machined (see Figure 4). After the surfaces on both the tibia and the femur were prepared, the robot and the leg fixtures were removed from the operating table (see Figure 4). The surgery then proceeded in a conventional way: The knee function was checked with prosthesis trial components in place, the surface of the patella was manually prepared, and all three prosthesis components were cemented onto the bone.

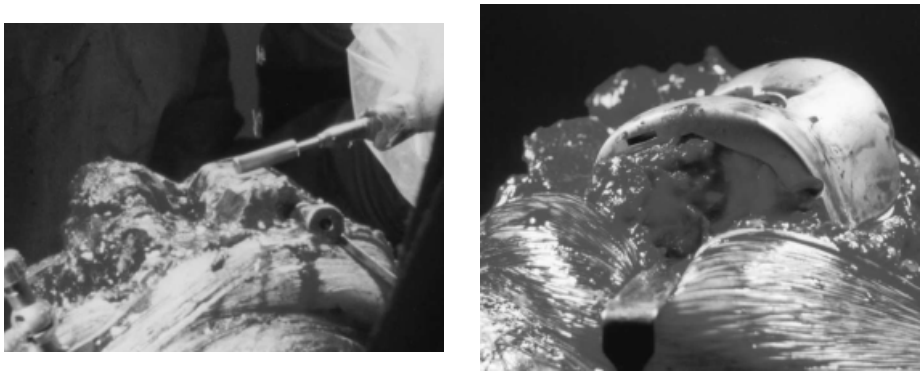

Figure 4. Cutting a plane on the femur (left) and femoral trial in place (right)

In all cases involving cutting the bone with the aid of the robot, the fit of the femoral and tibial components onto the bone was very good, with no femoral notching. The two components were found to mate correctly, giving proper bone alignment and a good range of motion.

4 Conclusions

A "hands-on" robotic system for TKR surgery was successfully applied clinically. The pre-operative planning system was found easy to use, providing an accurate plan for the surgery. The planning alone improved the surgery by giving the surgeon accurate quantitative information about the knee that is unavailable in conventional surgery.

Two preliminary clinical trials were successfully performed to test the suitability of the surgical protocol and the performance of the anatomical registration. All parts of the robotic system performed very well, and the registration results were encouraging. However, the bones were not cut and the procedure was completed in a conventional way.

A further five clinical trials were then performed, which included cutting the bones with the robot. A very good prosthesis fit and proper functioning of the knee was achieved in all cases. However, the time required for the robotic

procedure was longer than in conventional surgery, due to added time for leg fixtures setup and registration, and the time spent verifying the progress at each step of the procedure. The robotic system was found easy to use, and its high accuracy and active constraint control, which prevented damage and inaccurate cuts, were welcome improvements over the conventional procedure. No deviation of the prostheses placement from their planned location could be measured on the post-operative CT scans.

More extensive trials are planned, to assess the accuracy of the overall procedure with post-operative CT scans. As a result of these clinical trials, the surgical protocol will be further refined, which will substantially reduce the duration of the surgery. It is felt that these early experiences demonstrate the considerable promise of a "hands-on" approach to robotic assisted surgery.

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