Efficacy of Robot-Assisted Hip Stem Implantation. A Radiographic Comparison of Matched-Pair Femurs Prepared Manually and with the Robodoc[®] System Using an Anatomic Prosthesis

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Abstract. The number of robots in operation in the German-speaking orthopaedic community more than doubled last year, reflecting considerable excitement among patients and doctors over the prospects of improving the accuracy of endoprosthesis surgery in both the planning and implantation stages. The purported improvement, however, adds considerable expense to the procedures although little data exist still in many applications to prove its efficacy.

The following study compares pre- and post-operative radiographs of conventionally- and robotically-prepared groups of donor femurs implanted with an anatomic hip stem to quantify their respective preservation of three anatomic parameters— leg length, anterior bow angle, and mediolateral offset. All femurs were planned blindly both with virtual fitting using 3D reconstruction from CT scans and with conventional templates.

Maintenance of leg length as well as anterior bow angle were significantly higher ($p < 0.05$) for the robotically-prepared group than for the manually-prepared group. Maintenance of mediolateral offset, however, was significantly higher for the manually-prepared group, likely due to the common varus implantation experienced with this prosthesis type. Further studies will examine microradiographic slices in the transverse plane to quantify the gap size resulting from the two methods.

Introduction

The recent surge in the adaptation of robotic technology for surgical purposes in a sweeping range of medical fields speaks for a new era in the precision with which tumors, stenoses, and diseased joints are treated. What began over a decade ago in the neurosurgical field (1) now has found application in areas as disparate and complex as laparoscopic surgery (2), cardiovascular and ocular surgery (3), as well as orthopaedic surgery (4).

The primary goals of robotically-assisted hip replacement surgery are to improve the reliability of placement of the prosthesis stem and to optimize the amount of bony contact in the trabecular bone region proximally. The Robodoc[®] system from Integrated Surgical Systems (Davis, California, USA) provides an Orthodoc[®] computer station for planning

the implantation procedure in three dimensions, based on CT scan data. The milling path and the prosthesis silhouette are displayed together in A-P, lateral, and transverse plane views, over more than a decade of available zoom range, to allow detailed planning of the placement of the prosthesis and to help determine the amount of cortical bone, if any, that will be removed in the procedure.

Currently in Germany there are over two dozen Robodoc[®] units in operation, with at least six different hip stems presently programmed for application. The reported functional accuracy of the robot, in deviation from plan, is ± 0.4 mm; working in an artificially rigid environment, the deviation is much lower. Given this order of mechanical precision, clearly the critical factor for the success of the implantation lies in the planning itself and how well it is supported by the technology associated with the implantation method. Jerosch et al. (5) recently compared CCD and antetorsion angles pre- and post-operatively in two cadaveric femur groups, one prepared with manual techniques and the other with a robot. They found that the CCD angle changed by a similar amount in the two approaches, but that the antetorsion angle changed almost 10° with hand preparation, whereas with robotic preparation there was virtually no change.

In this study, our goals were to compare the preservation of three anatomical parameters complementing those of the Jerosch et al. study in manually-prepared and robotically-prepared femoral cavities implanted with an anatomical hip stem. The parameters were: 1) leg length; 2) anterior bow angle in the sagittal plane; and 3) mediolateral offset. The prosthesis used in the study is now available for manual and robotic implantation in Europe.

Methods

Ten pairs of donor femurs were obtained fresh then maintained frozen at -20°C until scanning and testing. Femurs larger or smaller than the common-sizes range currently programmed for this prosthesis were excluded before forming the final test groups with $n=10$ for each. A two-pin registration system was employed, with one 10-mm proximal pin set into the anteromedial aspect of the femur slightly above the level of the trochanter minor, and one 30-mm distal pin set into the medial condyle. The femurs were scanned in a Siemens Somatom +4 model using a spiral CT method. Slice thickness in the pin region was 1.0 mm, otherwise 3.0 mm.

Radiographs were obtained in the A-P and lateral views using a perpendicular block and podiatric orthosis foam to assure the stability of the femur during exposure in the upright position as well as the trueness and orthogonality of the perspectives. A long Steinmann pin, attached in length to the block, defined an anatomically-vertical axis between the block contact points on the femoral condyles and lesser trochanter. The distance between the femur and the film plane, as well as that between the film plane and source, was maintained constant. Antetorsion bow was measured in the lateral radiograph, and mediolateral offset and leg length in the A-P radiograph by two authors, then averaged.

After pair-wise random assignment to the manual and robot groups, the femurs of both groups were blindly planned for operation with an Antega[®] anatomical hip stem prosthesis from Aesculap AG & Co. KG (Tuttlingen, Germany) by the same two authors.

Table 1 lists the distribution of sizes for the study groups, with size 13 being predominantly represented. After the one surgeon agreed with the planning of the other in all cases, the femoral cavities were appropriately prepared either manually, using the existing instrument set, or robotically. In one case a different size was planned for the left and right femurs of a pair. Additional planning was performed on all specimens using the manufacturer's template system and the radiographs.

Following cavity preparation and implantation, with all manual aspects of the various procedures performed by the senior surgeon, the femurs were again radiographed for postoperative measurements. Anticipated cutting time of the robot was about 30 minutes, with two tool changes required to accommodate a fillet length on the anterior aspect of this particular prosthesis. Distal reaming was performed by hand, pending certification of that aspect of the software.

Statistical analysis consisted of a Kruskal-Wallis analysis of variance using a level of significance of 0.05.

Results

Leg length change in the manual group (Table 1) was 7.5 mm (SD 4.9 mm), and in the robot group, 1.3 mm (SD 3.8 mm). This difference was statistically significant ($p < 0.05$). Anterior bow angle change in the manual group was -7.4° (SD 4.6°), and in the robot group -5.0° (SD 2.7°). Mediolateral offset change in the manual group was -3.1 mm (SD 3.6 mm), and in the robot group -7.3 mm (SD 3.6 mm). Neither of these differences was significant. Actual milling time, with two tool changes, averaged about 35 minutes. The diagnostics and preparation procedures attendant on the robot increasingly became more efficient as the team gained experience with setup procedures. Still, there is an irreducible time when the surgery waits on the robot before it begins milling.

Fig. 1. Examples of robotically- (left) and manually-prepared femurs (right). Images are not intended to be viewed as results, but rather as indications of fit in some cases.

Fig. 1 shows an example of the resulting fit of the prosthesis in the two groups on radiographs. These images are intended to provide a general perspective on the outcome of the implantations and should not be taken as truly representative, since such images do not lend themselves easily to statistical treatment. Based on a clinically subjective assessment, however, it was consistently appraised among the authors through blind radiographic analysis that the robot group overall demonstrated better-fitting hip stems.

Table 1. Differences of Pre- and Post-Op in Robot and Hand Preparation Groups

Robot					Hand				
Sp		Leg	Med-Lat	AT	Sp		Leg	Med-Lat	AT
No	Size	Length	Offset	Angle	No	Size	Length	Offset	Angle
R1	13	-1	-9	-5	H1	13	12	-9	-3
R2	13	1	-13	-3	H2	14	8	-8	-7
R3	14	0	-5	-1	H3	14	3	-6	-4
R4	13	-6	-2	-8	H4	13	0	-1	-10
R5	14	5	-5	-4	H5	13	11	-2	-6
R6	16	0	-12	-4	H6	16	0	3	-17
R7	10	1	-7	-5	H7	11	9	-3	-7
R8	13	6	-9	-5	H8	12	10	-2	-11
R9	13	0	-3	-11	H9	14	8	-2	-1
R10	13	7	-8	-4	H10	13	14	-1	-8
AV	13.2	1.3	-7.3	-5.0	AV	13.3	7.5	-3.1	-7.4
SD	1.5	3.8	3.6	2.7	SD	1.3	4.9	3.6	4.6

Discussion

The use of a robot to improve accuracy of placement of a hip stem and to preserve leg anatomy is experimentally supportable, based on the results of this study, especially regarding retention of anterior bow angle and leg length. Mediolateral offset was actually larger in the robot group, but this may reflect a larger error in the manual group from the commonly-observed varus placement of the prosthesis by hand.

In the Jerosch et al. study (5), the measured CCD angle of the femur represented a combined anatomical parameter, which we attempted in the current study to separate into the more individual and indicative mediolateral offset and leg length. Using the combined parameter of CCD angle, Jerosch et al. found no differences between the two groups. In the present study, the decoupled parameter of leg length revealed differences in the performance of the two approaches, with the robot group indicating less change from the preoperative value than that of the manual group, although the ranges were similar for the two. The greater change in mediolateral offset in the robot group may reflect a relatively consistent varus malpositioning of the prosthesis using the manual technique. Further analysis is needed to determine whether this difference can be categorized as one of accuracy or misplaced precision.

A limit of this study is that the use of one surgeon discourages extrapolation to the general case. For our purposes, however, it served to control the inter-surgeon variability that otherwise could mask or distort group differences. Also, measurement of the parameters from the radiographs relied on common clinical techniques, using hand measurements with an accurate mechanical rule rather than a more exact, but less practiced digitizing technique. Further study of these groups is planned using microradiographic techniques from which a more detailed analysis of the bony contact will complement the anatomical parameters studied here.

Although it represents a costly sophistication to hip replacement procedure options, this particular surgical robotic system does provide an enhanced measure of reliability in the implantation of the anatomical hip stem used in this study.

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