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Robotic Joint Replacement Surgery: Does Technology Improve Outcomes

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ROBOTIC JOINT REPLACEMENT SURGERY: DOES TECHNOLOGY IMPROVE OUTCOMES?

ABSTRACT

Introduction: Osteoarthritis is a common disease that leads patients to seek Total Joint Replacement (TJR). Component misalignments leads to failure of TJR. Computer navigation enhances the precision of component alignment, but the addition of robotic guidance, can boost TJR to a higher level of accuracy. **Methodology:** This literature reviewed 29 English language peer reviewed articles from 2002 – 2013 and one website. A conceptual framework was adapted to explain benefits and barriers of adoption of robotic TJR.**Results:** A total of ten studies were reviewed with focus on more precise alignment, outcomes, length of stay, and costs. Cost to obtain robotic surgical equipment was found to be about $1 million with maintenance costs approaching $350,000. **Discussion:** Robotic techniques compared to convential orthopedic surgery showed slight variances, in favor of robotic procedures. While hospitals have the potential to reduce costs and improve outcomes with robotic TJR, but the expenditure and maintenance have not been proven a clear ROI. **Conclusion:** As surgical robotic technology evolves in accuracy and accessiblity, joint replacement surgery may benefit from improved precision and decreased healthcare costs. But, costs of equipment purchase, upkeep and surgeon training may impact it’s full potential in orthopedic surgery in the United States.

Key Words: Complications, Costs, Robotics, Joint Replacement, Robotics, Surgery, Outcomes,

INTRODUCTION

Osteoarthritis is a common disease that leads patients to seek Total Hip Arthoplasty (THA) and/or Total Knee Arthoplasty (TKA). Total Joint Replacement (TJR) is the surgical fixation of osteoarthritis by resurfacing of bones with prosthetic components.[1] Conventional surgical methods have been standard practice for TJR, but in recent years computer assisted and robotic assisted orthopedic surgeries are coming into the spotlight. While Robotic surgery for orthopedics continues to evolve, it has potential to transform the future of orthopedics, but it must demonstrate clinical value, ease of use, and cost benefit.[2]

Acurracy of component placement in TJR is crucial for success . In fact, it is the most important maneuver the surgeon performs to prevent malalignment of the components.[3] Pain, instability and loosening are results of TKA malalignment.[4] In Unicompartmental Knee Arthroplasty (UKA), tibial and/or femoral malalignment are poorly endured, and it has been identified that corolonal malalignment of beyond three degrees in the tibial component leads to failure.[5] Outcome measures, such as pain, Range of Motion (ROM) and Western Ontario and McMaster Universities OsteoArthritis Index (WOMAC) have been proven valid, but are variable related to individual patient characteristics, while excess varus or excess valgus alignment are early predictors of failure.[6] Computer navigation enhances the precision of component alignment, but the addition of robotic guidance, can boost TJR to a higher level of accuracy.[3]

A surgical robot is a computer controlled manipulator that uses synthetic recognition to relocate and reposition surgical instruments to perform a variety of surgical tasks.[7] In Computer Assisted Surgery (CAS), robots do not do the work in place of the surgeon, they assist the surgeon.

Augmentation is the category of robotics research which concentrates on humans and robots working together to accomplish a goal that could not be accomplished otherwise.[8]

Robotics and CAS allow orthopedic surgery to take care of five fundamental characteristics: geometric precision, reproducability, perfect memory, insensitivity to radiation and lack of fatigue.[9]

The early practice of cementless femoral components in THA have brought concern that the manual practice of reaming and broaching left gaps could inhibit growth between the bone and the implant.[10] In 1986, a robotic surgical system, with a milling robotic component Robodoc, was created, and first used on humans in 1992 for THA.[11] Later the procedure was developed beginning with a Computed Tomography (CT) of the femur with titanium pins to mark the medial and lateral condyles, followed by surgical approach that incorporates the Robodoc into an external fixator that prepares the femoral cavity for the surgeon to implant the femoral component.[10] CAS using robotic or image guideded technology has been organized into passive, semi-active or active systems, in which passive systems are primarily used for surgical planning, semi-active systems are used for some actions needed for surgery such as a cutting jig, and active systems such as Robodoc because some surgical actions are preoperatively programed.[12]

Research before year 2000 comparing robotic assisted and manual implantation in THA surggested negative outcomes for the robotic group such as high dislocation rates, the need for more frequent revisions, and high gluteal medius tendon ruptures, as well as, longer sugery duration were found in the robotic group.[13] Research has highlighted better stem alignment, with less leg length discrepency, fewer incidence of pulmonary emboli and less stress shielding on bone scans with Robodoc for THA than with convential methods.[14] However, the actual cost of robotic surgical equipment as well as, the indirect cost of training surgeons properly for use, have been significant barriers to use, especially with little evidence-based support.[15]

The purpose of this research was to examine the barriers and benefits of robotic use in orthopedic surgery for Total Knee Arthroplasty and Total Hip Arthroplasty to determine the overall outcome of robotic technology with TJR.

METHODOLOGY

The methodology for this study was a literature review. The West Virginia University library on the Charleston Area Medical Center Memorial Campus in Charleston, West Virginia was used for full text articles, utilizing the Cochrane Database of Systematic Reviews, PubMed, EbscoHost, ProQuest, and CINHAL databases. Google and Google Scholar were used when articles could not be located through the above data bases. Key terms used in the search included 'robotics' AND 'joint replacement' AND 'complications' OR 'outcomes', as well as, 'outcomes' AND 'robodoc' OR 'acrobot'. The search was limited to articles published 2002 through April 2014 as this body of evidence has evolved in recent years. Articles were limited to the English language. Primary and secondary data were included from original articles, research studies and reviews. Relevant articles were selected after review of abstracts was performed. Twenty-nine articles and one website were chosen for this research. Articles were categorized based on outcomes and costs. This search was completed by CH, RE, and LJ and validated by AC.

Figure 1 uses a modified research framework from Yao, Chao-Hsien and Li to describe the conceptual framework of adopting robotics into TJR surgeries.[16] To determine if robotics can improve surgical outcomes in TJR, it is important first to recognize existing complications. Upon identifying the need for improved precision, the adaptation of robotics for TJR will be guided by the benefits and barriers of implementation. Using modern technology with robotics for orthopedic TJR, patients can suffer fewer complications, have better outcomes and ultimately reduced healthcare dollars will be spent. The precision offered by robotic intervention can enhance TJR surgery and superior outcomes will be noted. Barriers and benefits will positively or negatively impact the ultimate use of robotics, and will influence the final outcome.

Insert Figure 1

RESULTS

Total Hip Aprthoplasty

Clinical accuracy of femoral canal preparation was evaluated using the Robodoc system in 69 patients (75 THA) from September 2000 through October 2001.[17] Clinical results indicated no statistically significant differences in preoperative and postoperative Merle D'Aubigne scores of pain, motion and gait. The mean Length Of Stay (LOS) was 41 days, and no intraoperative femoral fractures were reported . CT images comparing preoperative and postoperative measurements demonstrated mean differences of less than 5% with canal fill, less than 1mm in gap, and a less than 1% difference in alignment both mediolaterally (ML) and anteriorposteriorly (AP) (Table 1).

A prospective randomized case control study comparing hand rasping and robotic milling for stem implantation in cementless THAs was performed on 156 patients from September 2000 through September 2002[18] (Table 1). At a three month follow up, there were no significant differences in outcomes of pain and range of motion, but did find statisically significant differences in favor of Robodoc at two year follow up. From the robotic group, 41 patients were able to walk more than 6 blocks without a cane within 13 days compared to only 28 in the hand rasping group. Significant differences were noted in operating time, as well as, in femoral canal preparation time, in favor of manual rasping, while the estimated blood loss was of significance in favor of the Robodoc milling group[18] (Table 1). No intraoperative femoral fractures were noted in the Robodoc group, which was statistically significant when compared to the hand rasping group. It was noted all interaoperative femoral fractures were in female participants.[18]

Total Knee Arthoplasty

Cobb, et al, performed a prospective randomized, double blinded, case control trial for UKA using the Acrobot System in a sample size of 28 from December 2003 through July 2004.[19] The tibiofemoral alignment in the coronal plane was within 2 degrees of the planned position in all of the Acrobot patients, which was statistically significant compared to the conventional group. No statistical signficance was noted in operating time or in WOMAC scores, but statistical significance was noted in favor the the Acrobot group with American Knee Society (AKS) scores[19] (Table 1).

A comparison of robotic assisted and conventional manual implantation for TKA was completed in a prospective randomized case control trial with a sample size of 62, 30 in the conventional group and 32 in the robotic group[20] (Table 1). There were no statistically significant differences in clinical outcomes of ROM or Knee Society score. There was a statistically significant difference in the femoral flexion angle of the robotic group, but not in the tibial ankle of the AP imaging. Also, the authors found statistically significant differences in the lateral imaging of the femoral flexion angle and the tibial angle in the robotic group (Table 1). Additionally, Park & Lee, found that the mean age of the robotic group was five years younger than the conventional group, and that the robotic group had six complications consisting of superficial infection, patella tendon rupture, patella dislocation, postoperative supracondylar fracture, patella fracture and peroneal nerve injury[20] (Table 1).

In 2010, Pearle, et al, reported the results in a preoperative and postoperative study on the first ten cases using a semiactive robotic system for UKA. A haptic guided system was used and results indicated the planned and intraoperative tibiofemoral angle was 1 degree, and the postoperative radiographs were within 1.6 degrees.[21] The average operating time was 132 minutes and the average hospital LOS was 2.2 days, and no complications were reported at 6 weeks follow up (Table 1).

A case control study was performed to compare tibial component alignment in UKA using robotic arm technology in 31 patients and using the conventional manual technique in 27 patients[22] (Table 1). Using the robotic arm for assistance with bone preparation demonstrated a root mean square error of 1.9 degrees of posterior tibial slope compared with 3.1 degrees in the manual group. In using manual techniques, the variance was 2.6 times greater than use robotic guided technique. The average coronal alignment error was 2.7 degrees +/- 2.1 degrees in a varus direction of the tibial component compared to the mechanical axis for the manual group, but only 0.2 degrees +/- 1.8 degrees in the robotic group. Also, the varus/valgus root mean square was less in the robotic group, 1.8 degrees compared to 3.4 degrees (Table 1).

A prospective, randomized case control study, in a single institution, performed simultaneously on bilateral TKA in 30 patients with both robotic and convential technique to each limb examined outcomes, including patient satisfaction and radiologic and clinical outcomes[23] (Table 1). Clinical outcomes were improved with robotic surgery, although no statistically significant differences were noted. Radiologically, mechanical axis, coronal inclination of femoral component, and sagital inclination of tibial component, were improved with statistical significance on the convential knee compared to the robotic knee. While the robotic assisted knees had significantly less post operative bleeding, skin incisions were longer and average operating time was increased by 25 minutes[23] (Table 1).

Using robot assisted implantation in minimally invasive TKA was examined using 10 pairs of fresh cadaver femur in a case control study[24] (Table 1). Conventional minimally invasive surgery was performed on one side and robot assisted on the other side. Results yielded improved alignment accuracy in the robotic assisted prostheses as demonstrated by 0.7 degrees +/- 3 degrees compared to 3.6 degrees +/- 2.2 degrees of the femoral component in the conventional group and 7.8 degrees +/- 1.1 degrees compared to 5.5 degrees +/- 3.6 degrees in the sagital angle of the tibial component in the conventional group. There was one outlier in the robotic group and six outliers in the conventional group (Table 1).

One hundred patients for unilateral TKA were prostectively randomized into evenly divided groups for either robotic assisted surgery utilizing the Robodoc system or conventional manual surgery in a controlled trial.[25] Functionally there were no statistically significant differences in ROM, or outcome measures.[25] No mechanical outliers were noted in the Robodoc group, but 24% of the knees were not in the range of optimal alignment precision in the conventional group. The Robodoc group had statistically significant better balance with flexion-extension gap balance, and better PCL tension balance compared with the conventional group. Less post operative blood drainage was noted in the Robodoc group, but an increased average operating time was noted with Robodoc. Both groups had a combination of 11 local and systemic complications[25] (Table 1).

Clark & Schmidt performed a retrospective study to compare the effiency and accuracy between Robotic Assisted Navigation (RAN) and Computer Assisted Navigation (CAN).[26] After adjusting for age, BMI and presurgical alignment, RAN was found to have shorter navigation times, better alignment and shorter LOS (Table 1).

Costs

Using a standardized cost model to reflect healthcare payer and patient costs, Marshall, et al, concluded the average cost of inpatient and subacute care for TJR was $24,422 in patients seen between March 2005 and April 2006.[27] The cost of the RIO MAKO system platform was $793,000 in August 2010, with additional cost of $148,000 for the partial knee application software.[28] Grey literature authored by Dr. Rosen in 2013 indicated a Robotic system costs 1 million dollars and adds $1500 to each surgical procedure.[28] Bolenz, et al, reported that in 2007, robotic systems for prostate surgery cost $1-2 million initially, with $340,000 required for yearly maintenance, and $220 for disposable instruments for each surgery.[30] Bolenz, et al, examined the costs of radical prostatectomies versus robotic and laproscopic prostatectomies and found that the robotic procedure cost $800 more than laproscopic and $2300 more than the open procedure. It was reported that the robotic surgeries had 1 day shorter LOS.[30]

DISCUSSION

Comparison of results of curent literature utilizing Robotic techniques compared to convential orthopedic surgery showed slight variances, if any at all, in each study regarding statistical differences in preoperative and postoperative results in several areas. Robotic surgery had faintly better clinical outcomes and improved alignment accuracy, but had longer surgery times and longer incisions. Overall,based solely on outcomes and not cost, robotic assisted procedures appeared to have an advantage compared to conventional techniques.

Limitations related to the use of robotic assisted surgery included the direct and indirect financial costs, soft tissue pliability contributing to easy tissue and nerve damage, and the many disadvantages found with autonous systems which included increased operation time, increased blood loss, potentially higher numbers of nerve damage and infections, as well as, increased litigation rates due to the perception that surgeons were less involved. The focus of robotic devices needed to be on bone due to their ability to retain their structure. Surgeons in general preferred the haptic design of tactile systems.

Nishihara, et al., noted no intraoperative femur fractures in the robotic group, but five intraoperative fractures in the hand rasping group.[18] These fractures only occurred in female patients. Perhaps due to female propensity to bone density loss, robotic milling for THA is safer in this population to prevent femoral fractures during surgery.

Study limitations:

Several limitations were noted with this research. Clinical outcome data is lacking in long term follow up to support the use of robotics in orthopedic surgery. The study by Cobb, et al, revealed benefits using Acrobot, but was also funded by Acrobot.[19] Because THA was studied in detail prior to 2000, this research focused on TKA. True costs of orthopedic robotic systems were difficult to obtain and assumptions using robotics for prostatectomies had to be made. LOS data was also limited in several studies and assumptions were made based on prostatectomy research.

Clinical implications:

Reduced hospital costs is a potential benefit of implentating robotic systems for orthopedic surgery due to fewer complications, reduced LOS, less blood loss and faster rehabilitation. But true numbers are lacking in current research as it is difficult to place a cost on inpatient care, outpatient care, follow up with all providers, lost work time and cost to quality of life. Results from this study suggest that improved pre operative planning leads to improved precision. With this improved precision, it is expected that patients will experience less pain, have fewer complications, need less frequent revisions, and that ultimately healthcare expenses for TJR will be reduced. Even with a reduced LOS of 1 day for robotic prostatectomies, the cost savings did not make up for the extra cost of actual surgery

Cost is of importance in considering clinical implications regarding robotic procedures for orthopedics. Fixed and variable costs are higher for robotic surgery than for open or laproscopic procedures. The costs of robotic surgery are also higher because the robotic procedures take longer. Small hospital systems will not be able to utilize such high technology because the start up costs and maintenance costs are too much to bear. If Robotic surgical technology benefits the majority of the patients, then the cost is likely justifiable, but if the technology only helps a small percentage of patients, it will not be worth the cost.

CONCLUSION

As surgical robotic technology evolves in accuracy and accessiblity, joint replacement surgery may benefit from improved precision and decreased healthcare costs. But, costs of equipment purchase, upkeep and surgeon training may impact it's full potential in orthopedic surgery in the US. With the emergence of new robotic technology in orthopedics, effectiveness studies will be required to ensure that the benefits outweigh the costs.

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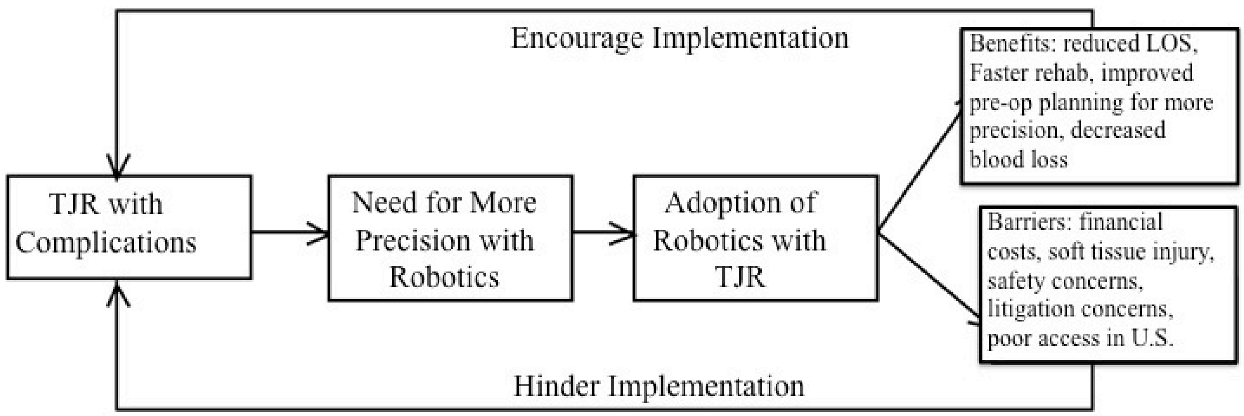

Figure 1: Conceptual Framework Implementing Robotics in TJR adapted from Yao, et al., (2010)

Table 1: Robotic Aignment and Outcome Results of Robotic Surgery in Hip and Knee Replacement

Author	Sample size (n)	Procedure (Joint)	Alignment	Outcomes	Comlications	Other Data
Nishihara, et al, 2004[17]	69 pts with 75 total	THA- Robodoc (hip)	Less than 1% difference in alignment M-L and A-P, and less than 5% canal fill	Merle D'Aubigne scores of pain, motion and gait NS (pre and post op comparison)	No intra-operative fractures noted	LOS= 41 days
Nishihara, et al, 2006[18]	156 pts 78 hand Rasping and 78 Robotic Milling	THA Robodoc (hip) Hand Rasping vs. Robotic Milling	NA	No differences in pain or ROM at 3 month follow up, but SS differences at 2 year follow up in favor of Robodoc. Robotic group had a SS greater number of participants who could walk more than 6 blocks with cane within 13 days of surgery	No intra-operative fractures in robotic group	Op time SSs in favor of hand rasping group (122 min vs 102 min), femoral canal prep time in favor of hand rasping (23 min vs 42 min), blood loss ss in favor of robotic group (527mL vs 694mL)
Cobb, et al, 2006[19]	28 pts Acrobat = 13 Conv = 15	UKA- Acrobot (knee)	Planned tibiofemoral angles within 2 degrees in all Acrobot, only 8/15 Conv	AKS: p=.004 SS Acrobot 62.5 Conv 32.5 WOMAC= NS	Not studied.	Surgery time= NS Acrobat 104 min vs 88 min Conv
Park & Lee, 2007[20]	62 pts 30 = conv 32 = Robotic	TKA (knee)	Robotic group with SS differences in A-P femoral flexion angle, and lateral imaging of femoral angle and tibial angle	No differences in AKS or ROM	Robotic group with 6 complications (superficial infection, PTR, 2 fractures, and one nerve injury)	Mean age of robotic group was 5 years younger
Pearle, et al, 2010[21]	10 pts	UKA semiactive robotic system (knee)	Planned and intra operative tibiofemoral angle was 1 degree, and post operative Xrays within 1.6 degrees	NA	No complications at 6 weeks follow up	LOS: 2.2 days Ave op time: 132 minutes
Lonner, et al, 2010[22]	68 pts Robotic = 31 conv = 27	UKA (knee)	Variance 2.6 times greater in conv tech vs robotic guided.	NA	NA	NA

Song, et al, 2011[23]	30 pts 30 conv and 30 robotic	Bilateral TKA (knees)	Mechanical axis, coronal inclination of femoral component, and sagital inclination of tibial component were SS on conv knee than robotic group	Improved outcomes in robotic knees, but not SS		Robotic had an ave of 25 min longer op time, and longer skin incisions but less bleeding
Kim, et al, 2012[24]	10 pairs of fresh cadavers-one side robotic, the other conventional	TKA (knee)	SS difference in favor of mechanical axis alignment in both femoral and tibial components in robotic compared to conven.	NA	NA	NA
Song, et al, 2013[25]	100 pts 50 conv 50 Robotic	TKA Robodoc (knee)	Robodoc had SSbetter balance in flex/ext gap balance, and better PCL tension balance compaired to conv group, Robodoc had no outliers, conv group had 24% of mechanical outliers	No SS in ROM or other outcome measures	11 complications in each group	Less post op blood drainage noted in Robotic group, but ave increase in op time was 25 min in robotic group
Clark, et al, 2013[26]	52 RAN 29 CAN	TKA (knee)	RAN alignments were on ave 0.5 degrees closer to mechanical axis compared to CAN.	None studied.	Not reported	RAN time 9 min shorter than CAN SS LOS.6 days shorter RAN group SS

Key: UKA: Unicompartmental Knee Arthroplasty, THA: Total Hip Arthroplasty, AKS: American Knee Society, NS: not statistically significant, Conv: conventional, M-L: Mediolaterally, A-P: Anterioposteriorly, WOMAC: , PTR: Patella Tendon Rupture, vs: versus, SS: statistically significant, PCL: Posterior Crutiate Ligament, RAN: Robotic Assisted Navigation, CAN: Computer Assisted Navigation, OP: operation, pts; patients, min: minutes, NA; not available