Robotics, Navigation, and Custom Implants

Is it Time for Widespread Adoption?

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9/19/2019
Disclosures

- Depuy – Consulting

- I will be intentionally controversial
Technology Adoption

- Does it improve patient outcomes and/or lower risk?
- What problem does it solve?
- What problems may it introduce?
- Is it easily adoptable, generalizable, and scalable?
- Is it cost effective?
- Is the Timing Right?
Where we are now

- Robotic assisted surgery
- Navigation
- Patient Specific Instrumentation
- Custom Implants

- Increased Adoption
- Clear Evidence for Increased Precision
- Unclear effect on surgical time
- Unclear effect on cost
- No difference in outcomes
So, let’s talk about robots

- What do we have?
- What do they do?
- Where are we today?
The Robot

- Passive, Semi-Autonomous, Autonomous
- Image based or Imageless
- Closed versus Open platform
- Soft tissue versus Hard Tissue

FDA approved
2000
Early Orthopaedic Robotic Systems

- CASPAR - Image guided active
  - Improved tibial alignment in TKA but longer surgery (45 minutes) and needed an initial surgery to place markers in the tibia and femur
  - Improved bone contact for THA but longer surgery (50 minutes), increased risk of abductor dysfunction, and increased Hgb loss
  - No longer in business

- Acrobot - Image guided semi-active system
  - Stopped working on robotics as part of a patent infringement lawsuit with MAKO
What do we have now?

Some Current Orthopaedic Robotic Systems

<table>
<thead>
<tr>
<th>Name</th>
<th>Applications</th>
<th>Control</th>
<th>Resection</th>
<th>Platform</th>
<th>Preop Image</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tsolution-One (Robodoc)</td>
<td>TKA, THA (F)</td>
<td>Autonomous</td>
<td>Mill</td>
<td>Open</td>
<td>CT</td>
</tr>
<tr>
<td>MAKO</td>
<td>TKA, THA, UKA</td>
<td>Semi</td>
<td>Burr/reamer/saw</td>
<td>Closed</td>
<td>CT</td>
</tr>
<tr>
<td>Navio</td>
<td>TKA, UKA</td>
<td>Semi</td>
<td>Burr</td>
<td>Closed</td>
<td>None</td>
</tr>
<tr>
<td>Rosa</td>
<td>TKA</td>
<td>Semi</td>
<td>Saw</td>
<td>Closed</td>
<td>X-ray</td>
</tr>
<tr>
<td>Omnibotics (iblock)</td>
<td>TKA</td>
<td>Semi</td>
<td>Saw</td>
<td>Closed</td>
<td>None</td>
</tr>
</tbody>
</table>
Robots make us more precise

What do they do?
An Experienced Surgeon Can Meet or Exceed Robotic Accuracy in Manual Unicompartmental Knee Arthroplasty

Ashleigh N. Bush, BS, BS, Mary Ziembas-Davis, BA, Evan R. Deckard, BSE, and R. Michael Meneghini, MD

Investigation performed at IU Health Saxony Hospital, Fishers, Indiana


Fig. 4
Root mean square (RMS) errors for tibial slope (left) and tibial component alignment (right) in published studies on robotic and surgeon-guided UKAs and in the current study of surgeon-guided UKAs.
How About Cost

- Significant barrier for adoption in the current healthcare landscape
- Large up-front expense ($1 million or more)
- Unclear/non-transparent ongoing cost (subscription fee, use fee, upkeep fee, software updates).

But… Is it cost effective?
- Depends on how you ask the question and what models you use
- Depends on how the technology is incorporated into the finances of the hospital versus the implant company

| Table 7.2 Percentage increase in cost by annual case volume and robotic life span relative to traditional TJA based upon capital investment, maintenance fees, disposable cost, and imaging requirements |
|---------------------------------|-----------------|-----------------|-----------------|-----------------|
| Estimated robotic lifetime      | Annual case     | Mako            | Navio           | TSolution       |
|                                 | volume          |                 |                 | One             |
| 5                               | 100             | 12.19%          | 6.10%           | 13.90%          |
|                                 | 300             | 6.05%           | 3.53%           | 6.61%           |
| 10                              | 100             | 9.19%           | 4.82%           | 10.04%          |
|                                 | 300             | 5.05%           | 3.11%           | 5.33%           |

***Implant pricing was not factored into this model***
Can Robot-Assisted Unicompartmental Knee Arthroplasty Be Cost-Effective? A Markov Decision Analysis

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ABSTRACT

Background: Unicompartmental knee arthroplasty (UKA) is a treatment option for single-compartment knee osteoarthritis. Robotic assistance may improve survival rates of UKA, but the cost-effectiveness of robot-assisted UKA is unknown. The purpose of this study was to delineate the revision rate, hospital volume, and robotic system costs for which this technology would be cost-effective.

Methods: We created a Markov decision analysis to evaluate the costs, outcomes, and incremental cost-effectiveness of robot-assisted UKA in 64-year-old patients with end-stage unicompartmental knee osteoarthritis.

Results: Robot-assisted UKA was more costly than traditional UKA, but offered a slightly better outcome with 0.06 additional quality-adjusted life-years at an incremental cost of $47,180 per quality-adjusted life-years, given a case volume of 100 cases annually. The system was cost-effective when case volume exceeded 94 cases per year, 2-year failure rates were below 1.2%, and total system costs were <$1.426 million.

Conclusion: Robot-assisted UKA is cost-effective compared with traditional UKA when annual case volume exceeds 94 cases per year. It is not cost-effective at low-volume or medium-volume arthroplasty centers.

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3.4 Meta-analysis of revision rate

The revision rate was reported in a total of 3 studies with 4 data sets [13, 18-19]. Using a fixed-effects model (P = .024, I² = 0%), no significant difference was found in the revision rate between robotic-assisted UKA and conventional UKA (RR: 0.49, 95% CI: 0.17–1.41; P = .188).
MAKO Orthopedic Computer, Stryker Robot

Condition: Used
“Cosmetic paint chips etc. but otherwise in great shape.”

Price: US $450,000.00
Buy It Now
Add to cart

Best Offer:
Make Offer

Ships from United States
No returns
23 watchers

Shipping:
Free Local Pickup | See details
Item location: Redlands, California, United States
Ships to: Local pick-up only

Delivery:
Varies

Payments:
PayPal, VISA, MasterCard, Discover, Pay on pickup

Returns:
Seller does not accept returns | See details

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Contact seller
See other items

Earn a $30 Statement Credit
Open a new eBay Mastercard® account and spend $50+ on eBay within 30 days.
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Limited-time offer.
How about Outcomes

- Maybe, maybe not….we have to be very careful in our interpretation
- 2016 Review paper
  - “Clinical outcomes may be positively affected by the use of robotics as well. Mako robotic arm-assisted UKA resulted in significantly lower postoperative pain (P < .05) and greater functionality 3 months after surgery as measured by American Knee Society Scores >160 (excellent), compared with manual UKA (P < .01) [29].”

Primary Arthroplasty

Robotic-Arm-Assisted vs Conventional Unicompartmental Knee Arthroplasty. The 2-Year Clinical Outcomes of a Randomized Controlled Trial

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Matthew S. Banger, MEng, PhD b, Iona Donnelly, BSc (HONS) a,
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b Biomedical Engineering Department, University of Strathclyde, Glasgow, Scotland, UK

Results: At 2 years, there were no significant differences for any of the outcome measures. Sub-group analysis (n = 35) of participants with a preoperative University of California Los Angeles Activity Scale >5 (more active) was performed. In this sub-group, the median Oxford Knee Score at 2 years was 46 (IQR 42.0-48.0) for robotic-arm-assisted and 41 (IQR 38.5-44.0) for the manual group (P = .036). The median American Knee Society Score was 193.5 (IQR 184.0-198.0) for the robotic-arm-assisted group and 174.0 (IQR 166.0-188.5) for the manual group (P = .017). Survivorship was 100% in robotic-arm-assisted group and 96.3% in the manual group.
Outcomes

- To date, no high level, convincing, unconflicted studies of improved outcomes or survivorship for any platform.

- For all systems we are making assumptions that improved precision without a clear target will result in better outcomes.

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**In Younger Patients with End-Stage Knee Osteoarthritis, Computer-Assisted Versus Conventional Total Knee Arthroplasty Did Not Improve Function at 15 Years**


**Table I: Computer-assisted versus conventional total knee arthroplasty in patients with end-stage osteoarthritis in both knees**

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Computer-assisted</th>
<th>Conventional</th>
<th><em>p</em></th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean total KSS</td>
<td>92</td>
<td>92</td>
<td>0.46</td>
</tr>
<tr>
<td>Mean Function KSS</td>
<td>80</td>
<td>80</td>
<td>1.00</td>
</tr>
<tr>
<td>Mean WOMAC Index score</td>
<td>15</td>
<td>14</td>
<td>0.50</td>
</tr>
<tr>
<td>Knee with mild or severe</td>
<td>98%</td>
<td>98%</td>
<td>0.98</td>
</tr>
<tr>
<td>Knee mean score of motion</td>
<td>137</td>
<td>138</td>
<td>0.78</td>
</tr>
</tbody>
</table>

**Design:** Randomized (unclear allocation concealment), blinded (patients and outcome assessors), controlled trial with a mean 15 years of follow-up (range, 14 to 16 years).

**Setting:** The Joint Replacement Centre in Seoul, Republic of Korea.

**Patients:** 296 patients <65 years of age (mean age, 59 years; 79% women) who had end-stage osteoarthritis in both knees that was appropriate for total knee arthroplasty. Exclusion criteria included inflammatory arthritis, dementia, foot and ankle disorders, or previous stroke or hip disease. 95% of patients completed follow-up.

**Intervention:** 1 surgeon performed same-day bilateral total knee arthroplasties, with 1 knee in each patient allocated to computer navigation with an optical tracking unit (Vector Vision CT-free knee system; BrainLab) that included an infrared camera to detect reflecting markers spheres (n = 296) and the other knee allocated to conventional navigation (n = 296).

**Main results:** At a mean of 15 years, computer-assisted and conventional total knee arthroplasty did not differ for any clinical outcomes (Table I), radiographic outcomes (femoral offset angle, +6° vs. +7°, p = 0.73; joint line, 16 vs. 15 mm, P = 0.23; posterior condylar offset, 26 vs. 26 mm, p = 0.12; rotational alignment for femoral [±6° vs. ±7°, p = 0.078] and tibia [±6° vs. ±7°, p = 0.033] components, or implant survival (99% in both groups, p = 0.58). Computer-assisted total knee arthroplasty increased anterior femoral notching compared with conventional total knee arthroplasty (4% vs. 9% of knees, p = 0.046; groups did not differ for deep infection (0.7% in each group).

**Conclusion:** In younger patients with end-stage osteoarthritis in both knees, computer-assisted and conventional total knee arthroplasty did not differ for function or implant survival at 15 years.

Source of funding: No external funding.

For correspondence: Dr. Y.H. Kim, The Joint Replacement Centre, Banda Women's University, Seoul National University, Seoul, Republic of Korea.

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Mako robotic total knees up 80% in Q2; technology headed to Japan, China

Written by Laura Dyrda / July 29, 2019 / Print  |  Email

During the second quarter conference call, as transcribed by Seeking Alpha, Stryker's Katherine Owen gave an update on the company's Mako Surgical robotic technology line.

The company sold 44 Mako robots worldwide, including 35 in the U.S., up from 39 total robots in the second quarter of 2018. The company also reported it has more than 700 procedures installed globally, with around 600 being in the U.S.
If you’re facing surgery, you might be wondering if robotic-assisted surgery is appropriate for only certain patients. But anyone is a good candidate, says orthopedic surgeon Robert Molloy, MD. If you’re a good candidate for joint replacement surgery in general, robotic joint replacement is for you. “It’s a technology that’s not limited to any particular type of patient,” he says. Surgeons currently are using robotic technology for partial knee replacements, full knee replacements and hip replacements, he says.
Robotic arm-assisted knee surgery offers hope for arthritis patients

“We know that the more accurate we can be in positioning implants, the longer the implant will last, and the better the patient’s knee will feel and function,” Dr. Ortiguera says.

By Cynthia (Cindy) Weiss

More than 800,000 knee replacement surgeries are performed in the U.S. each year. The typical patient is over 60 and has osteoarthritis, the most common joint disorder.
Concern

- Are we buying into marketing for patient share or because we truly believe we are offering a better treatment?

- Is this true to our oath? Evidence based?
  - We need to be very careful interpreting the literature = lots of conflict

- This technology has HUGE promise
  - Will the development and innovation slow down as market adoption increases?
  - Minimal incentive for companies to progress if they are already making money
Conflict

- One author published > 10 reviews, commentaries or studies in the last 2 years. All favoring robotic surgery

Top Companies Making General Payments

Total General Payments

$1,328,434.33

Source: Openpaymentsdata.cms.gov
Not Without Complications or Challenges

Causes and Patterns of aborting a Robot-Assisted Arthroplasty

Young Soo Chun, MD,* Kang Il Kim, MD,* Yoon Je Cho, MD,†
Yoon Hyuk Kim, PhD,‡ Myung Chul Yoo, MD,* and Kee Hyung Rhyu, MD*

Abstract: For a successful robot-assisted arthroplasty, every step should be executed harmoniously. However, when we encounter serious obstacles during surgery, it is sometimes better to abort the procedure in a timely manner. This study investigated the possible causes and patterns of aborted robot-assisted arthroplasties. Of 100 consecutively planned robot-assisted arthroplasties, 22 cases were aborted. Most involved total knee arthroplasty (21/22 cases). We classified the causes according to the stage at which they occurred and the type of error. Abortions after starting the milling procedure and abortions due to an interactive factor were the most common. We believe that this study can guide surgeons to effective decision making during robot-assisted arthroplasty. Keywords: robot-assisted arthroplasty, abortions.

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Table 2. Simplified Causes of Aborting a Robotic Arthroplasty

<table>
<thead>
<tr>
<th>Causes of Abortion</th>
<th>Time of Action</th>
<th>Placement of Action</th>
<th>No. of Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interruption of patella tendon</td>
<td>After milling</td>
<td>Patient</td>
<td>5</td>
</tr>
<tr>
<td>Repetitive failure</td>
<td>After skin incision</td>
<td>Interactive</td>
<td>5</td>
</tr>
<tr>
<td>Error in tibial workspace</td>
<td>After milling</td>
<td>Interactive</td>
<td>3</td>
</tr>
<tr>
<td>Damaged CD-ROM</td>
<td>After anesthesia</td>
<td>Mechanic</td>
<td>2</td>
</tr>
<tr>
<td>Failed sterile calibration</td>
<td>After anesthesia</td>
<td>Interactive</td>
<td>2</td>
</tr>
<tr>
<td>Error in defining SMG</td>
<td>During planning</td>
<td>Surgeon</td>
<td>2</td>
</tr>
<tr>
<td>Corrupted file in RCC</td>
<td>After anesthesia</td>
<td>Mechanic</td>
<td>1</td>
</tr>
<tr>
<td>Errors in pendent handling</td>
<td>After milling</td>
<td>Surgeon</td>
<td>1</td>
</tr>
<tr>
<td>Limited motion in hip joint</td>
<td>After milling</td>
<td>Patient</td>
<td>1</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td></td>
<td>22</td>
</tr>
</tbody>
</table>

SMG indicates surface model generator; RCC, robot control cabinet.
I’m not a luddite….
Particular Areas for Use

- Partial Knee Replacement particularly for low-volume surgeons
- Pre-existing hardware
- Specific extra-articular deformity or where traditional alignment tools won’t work
- This technology has a lot of promise
Fundamental needs for widespread adoption

- We need to know the target
  - Caveat: technology will likely help us figure out the target

- We need clear and open access to the data

- The cost needs to be absorbed by the system/payers and the onus for upkeep placed on the company
  - This will keep it cost effective by market forces not by theoretical longevity

- The technology needs to reach the point of spontaneous adoption
What’s our target?
So, where are we with the robot?
CHARTING A NEW PATH

The stimulus bill accomplished one of its goals in dramatic fashion: driving the rapid adoption of EHRs at physician practices and hospitals.

EHR ADOPTION FOR OFFICE-BASED PHYSICIANS

<table>
<thead>
<tr>
<th>Year</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>100%</td>
</tr>
<tr>
<td>2017</td>
<td>86%</td>
</tr>
</tbody>
</table>

EHR ADOPTION FOR NONFEDERAL ACUTE CARE HOSPITALS

<table>
<thead>
<tr>
<th>Year</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2008</td>
<td>100%</td>
</tr>
<tr>
<td>2017</td>
<td>96%</td>
</tr>
</tbody>
</table>

American Recovery and Reinvestment Act in February 2009
“The promise of robotics remains seductive and should be pursued. Objective scientific evidence must necessarily precede its general implementation. And one cannot ignore the subjective aspects of unsophisticated patient demand, marketing allure, possible psychological patient satisfaction, and the “Dumbo’s feather” effect for the inexperienced surgeon. Yet one should not forget the impact of computerized electronic medical record on the timeliness, volume, convenience, quality of care, and patient/physician satisfaction. **Bringing a robot to your operating room may be much like bringing the electronic medical record to your clinic.**”
Spontaneous adoption – Inflection Point?
Conclusions

- Technology holds immense promise!!!

- Clear evidence for precision

- It is not time for widespread adoption
  - Marketing over evidence for outcomes
  - Cost and time
  - Unclear targets

- We need to continue to study and improve
Technology is a word that describes something that doesn’t work yet. - *Douglas Adams*

Computers are useless. They can only give you answers. - *Pablo Picasso*

If we continue to develop our technology without wisdom or prudence, our servant may prove to be our executioner. - *Omar Bradley*