The ROBODOC® Surgical System

Surgery beyond the imagination

“GOLD Standard” for all Orthopedic surgery
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1. Concept_ The ROBODOC® Surgical System

- **Manual Surgery**
  - 2D X-ray base
  - Perceptual planning
  - Cutting by surgeon

- **Robot Surgery**
  - CT data base
  - Pre-planning
  - Robot cutting

**Manual Surgery**
- 2D X-ray base
- Perceptual planning: generate magnificence & rotational error
- Cutting by surgeon: inaccurate cut & inaccurate alignment

**Robot Surgery**
- CT data base: generate 3D bone image
- Pre-planning: optimal implant selection for patients (size, shape), able to adjust MA, Slop, Rotation, Extension/Flexion gap, Notching for accurate position of implant
- Robot cutting: sub-millimeter dimensional accuracy, precision milling for optimal alignment and fit, 95% bone to implant contact
2. Configurations _ ROBODOC® Surgical Assistant System

The ORTHODOC®
Pre-surgical Planning

ROBODOC®
Surgical Assistant
2. Configurations _ The ORTHODOC® Pre-Surgical Planning

ORTHODOC® Pre-surgical Planning Workstation

- Pre-surgical planning based on CT data
- Pre-surgical MA evaluation
- Able to choose optimal implants
- Construct 3D modeling based on CT data (SMG)

Wireless Keyboard & Mouse

All-in-one PC

*Ongoing relationship with implant manufacturers provide ORTHODOC with most current library of available implants

Knee Implant Library
- Stryker Duracon
- Stryker Scarpin
- Zimmer NexGen LPS
- Zimmer NexGen LPS-Flex
- Zimmer MBK
- Zimmer NexGen CR
- Zimmer NexGen Micro

Hip Implant Library
- Aesculap Antega
- DePuy Replica
- DePuy SROM
- DePuy V2K
- DePuy AMK
- Stryker ABG
- Stryker Meridian
- Stryker Meridian Short
- Stryker CentPillar

- Zimmer Versys
- Zimmer Versys PHT
- Zimmer Anatomic
2. Configurations

The ROBODOC® Surgical Assistant

- **Robot Arm**: Provide accurate movement for bone cutting.
- **Force Sensor / Cutting Assembly**: Sensing the press during cutting and performing accurate cutting.
- **OR Monitor**: Monitor to show the surgery process in OR.
- **Bone Motion Monitor (BMM)**: Sensing the patient's movement during surgery.
- **Digitizer**: Sensing actual bone through 3D image.
- **Control Cabinet**: Robot control device.
3. Process _ Pre-surgical Procedure

**Patient Selection**
- Consultation

**Scanning Patient**
- CT Scan

**Pre-Surgical Planning**
- ORTHODOC®

**Surgical Implementation**
- ROBODOC® Surgical Assistant
3. Process_Surgical Procedure

- Surgical Exposure
- Wound Closure
- Patient Setup & Fixation
- Soft Tissue Assessment (gab balance)
- Registration
- Implant Placement
- Exact Milling by Robot
4. Comparisons _ Between ROBODOC® & Manual

GOOD RESULT using special Cutter

Milling (Robot)

The result of Surgery compare to cutting bone

UNCERTAIN RESULT using manual tools
4. Comparisons _ Between ROBODOC® & Manual

The post-op X-ray results for KNEE!!!

Manual

ROBODOC®

H.K.A – Alignment ≠ 0 degree

H.K.A – Alignment ≒ 0 degree
5. Clinical Outcomes _ Expected(THA)

**Lower intra-operative complications**

**Less immediate post-operative problems**

**Improved mechanical alignment with resulting outcomes**

**Historical medical literature**

- 3% to 28%.
  - < Martell JH, [Clinical experience with primary cementless total hip arthroplasty_ 1992 year >

**More recent studies**

- 6% - 10%
  - < Berend ME, Comparison between Hand Rasing and Robotic Milling for Stem Implantation in Cementless THA _ 2006 >

**ROBODOC system**

- **NO SUCH AN INTRA-OPERATIVE FRACTURE**
  - (Not yet)
  - < Nishihara S Sugano N et al., Comparison between Hand Rashing and Robotic Milling for Stem Implantation in Cementless THA _ 2006 >
5. Clinical Outcomes _ Expected(THA)

The effectiveness of the ROBODOC system
Conducted by Hagio et al, <Acta Orthop. Scand, 2003, 74(3); 264-9>

<table>
<thead>
<tr>
<th></th>
<th>ROBODOC N=50</th>
<th>Conventional N=25</th>
<th>P-values</th>
</tr>
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<tbody>
<tr>
<td>Grade of PE</td>
<td>1 2 3</td>
<td>1 2 3</td>
<td></td>
</tr>
<tr>
<td>Femur preparation</td>
<td>4(8%) 0 0</td>
<td>16(64%) 8(32%) 1(4%)</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Stem insertion</td>
<td>18(36%) 0 0</td>
<td>17(68%) 4(16%) 1(4%)</td>
<td>P&lt;0.001</td>
</tr>
<tr>
<td>Relocation</td>
<td>29(58%) 4(8%) 0</td>
<td>13(52%) 11(44%) 1(4%)</td>
<td>P&lt;0.001</td>
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</tbody>
</table>

The authors conclude that “the ROBODOC system reduces the risk of clinically significant pulmonary embolism in cementless THA”. 

Lower intra-operative complications

Less immediate post-operative problems

Improved mechanical alignment with resulting outcomes
5. Clinical Outcomes _ Expected(THA)

Lower intra-operative complications

Less immediate post-operative problems

Improved mechanical alignment

With good clinical outcomes

The most important factor of cementless THA

**FIT** < 2mm (femoral prosthesis and cortical bone)

**FILL** > 90% (canal filled with prosthesis)

**ALIGNMENT** < 2°

Douglas Robertson, M.D. Ph.D., “The review compared using 129 radiographs, with 65 control and 64 ROBODOC cases.”
## 5. Clinical Outcomes _ Expected (TKA)

### Radiographic Evaluation

<table>
<thead>
<tr>
<th>Radiographic Results</th>
<th>ROBODOC</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>Excellent</td>
</tr>
<tr>
<td>Mechanical axis</td>
<td>-0.8</td>
<td>92%</td>
</tr>
<tr>
<td>Coronal, femur</td>
<td>88.5</td>
<td>88%</td>
</tr>
<tr>
<td>Coronal, tibia</td>
<td>90.1</td>
<td>90%</td>
</tr>
<tr>
<td>Sagital, tibia</td>
<td>85.6</td>
<td>76%</td>
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</table>

- **Outlier in ROBODOC**

<table>
<thead>
<tr>
<th>CT (Postoperative)</th>
<th>Mean</th>
<th>Excellent</th>
<th>Acceptable</th>
<th>Outlier</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical axis, leg</td>
<td>0.49</td>
<td>96%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Coronal inclination, femur</td>
<td>89.52</td>
<td>98%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Tibia</td>
<td>90.12</td>
<td>98%</td>
<td>2%</td>
<td>0%</td>
</tr>
<tr>
<td>Sagital inclination, femur</td>
<td>0.64</td>
<td>96%</td>
<td>4%</td>
<td>0%</td>
</tr>
<tr>
<td>Tibia</td>
<td>84.1</td>
<td>96%</td>
<td>4%</td>
<td>0%</td>
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</table>

- **Outlier of Coronal Alignment in Navigation**

<table>
<thead>
<tr>
<th>Author</th>
<th>Error Margin</th>
<th>Outlier</th>
<th>Major Outlier (&gt;5°)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Saragalia</td>
<td>0~3°</td>
<td>16%</td>
<td>8%</td>
</tr>
<tr>
<td>Mielke</td>
<td>0~3°</td>
<td>38%</td>
<td>6.7%</td>
</tr>
<tr>
<td>Jenny&amp;Boeri</td>
<td>0~3°</td>
<td>5%</td>
<td>Not listed</td>
</tr>
<tr>
<td>Sparmann</td>
<td>0~2°</td>
<td>2.5%</td>
<td>0%</td>
</tr>
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(Source: Chennam Univ. by Dr. Song)
6. Objective of ROBODOC®

Expected Additional Application

- MIS THA
- MIS TKA
- Hip Resurfacing
- UKA
- ACL Recon.
- FOOT & ANKLE
TKA surgery case: approx. 4.1 times increase in 2009 compared to in 2001
2001 yr: 15,473 cases / 2009 yr: 63,661 cases
(lateral: 61.4%, bilateral: 38.6%)
Silver population over 65 years old of Korea in 2009 increases 1.5 times more than in 2001

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<tr>
<td>TKA</td>
<td>34,966</td>
<td>41,598</td>
<td>52,413</td>
<td>56,853</td>
<td>63,661</td>
</tr>
<tr>
<td>Growth ratio</td>
<td>(124.3)</td>
<td>(119.0)</td>
<td>(126.0)</td>
<td>(108.5)</td>
<td>(112.0)</td>
</tr>
<tr>
<td>THA</td>
<td></td>
<td></td>
<td></td>
<td>18,949</td>
<td>19,968</td>
</tr>
<tr>
<td>Growth ratio</td>
<td></td>
<td></td>
<td></td>
<td>(100.0)</td>
<td>(105.4)</td>
</tr>
<tr>
<td># of patients</td>
<td>25,217</td>
<td>29,439</td>
<td>36,464</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growth ratio</td>
<td>(222.3)</td>
<td>(259.5)</td>
<td>(321.4)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

※ Data in 2008, 2009 are filed out the estimated figures by the industry

(자료출처: 건강보험심사평가원)
8. Understandings - Clinical Benefits

✓ Clinical Benefits Very low incidence of any intra-operative fracture reported in OR

✓ Ultimate accuracy in terms of implant sizing, fit, fill, alignment, leg length, etc.

✓ Better Hip and Knee score (Harris, KSS)

✓ Better bone remodeling around the implant

✓ ROBODOC® surgeons have noted: longer implant life is expected, as the close contact between the bone and implant (fit, fill) prevent the introduction of wear particle, which can cause implant loosening, osteolysis, etc.
Due to superior implant fit and fill, the bone to implant interface allows the ROBODOC® patient next day weight bearing (in most cases), where conventional THA, TKA allows weight bearing at 2-3 days post-op (on average).

Optimal result is ‘volume independent’; surgeon that performs lower volume of THA, TKA will still obtain excellent clinical result with ROBODOC®

ROBODOC® -vs- Navigation: surgical navigation can tell you where to cut (manually with cutting blocks), but does not guarantee the cut will match the plan; ROBODOC® implements the surgeon’s plan with sub-millimeter precision—every time.
8. Understandings - Economic Benefits

✓ ROBODOC® is a “Patient Magnet” for your healthcare facility. Patients are seeking hospitals with leading-edge technologies that have the potential to deliver a superior clinical result.

✓ ROBODOC® is a great sales and marketing tool. Robotic technology (da Vinci) gives the hospital a “Technology Halo”. All types of media coverage effectively draw patients from surrounding communities and beyond. This incremental patient volume will not only enhance the orthopaedic service (incremental THA, arthroscopy, TKA, Sports Med), but it will also have a positive growth impact on other hospital services as new patients and their families select your facility.
8. Understandings – Clinical/Economic Benefits

✓ Curexо Technology Corporation’s ‘Open Architecture’ platform: allows surgeons to utilize current implant of choice, which allows the hospital purchasing department to continue to leverage existing implant pricing contracts.

✓ ROBODOC® is the ultimate universal instrument, reducing the number of instrument trays that need processing; reducing room turnover time and possibly increasing cases per day per O.R.
8. Understandings – Strategic Benefits / Initiatives

✓ Establishing true ‘Robotic Center of Excellence’ at hospital provides a very competitive advantage in regional market, and allows exclusivity in all marketing materials and media efforts for an extended period of time

✓ Enhance ability to attract incremental patients seeking robotic solutions due to exclusivity in surrounding communities and beyond

✓ Local media is very attracted to leading edge medical technology and will showcase new medical systems to further educate patients on new offerings

✓ Co-marketing package will assist in developing and implementing a very robust and effective campaign
8. Understandings – Strategic Benefits / Initiatives

- ROBODOC® has been used in over 28,000 total joint replacements worldwide. It is a proven technology that delivers accurate, reproducible, precise results that are unmatched by conventional instruments and techniques.
Thank you for your attention

Good Oh / E. Director
WITHUS TECHNOLOGY PTE LTD
Blk 1008 Toa Payoh North #03-01
Singapore 318996
Tel : + 65 6253 6585
HP: + 65 9852 0250
goodoh@wt.sg