OMNIBotics®

Featuring the Predictive Balance™ technique with BalanceBot®

Alignment, balance, minimal releases

Contents
1. More precise ligament balance correlates with better outcomes, less pain 3
2. Precise predictions, precise balance 4
3. Fewer releases with predictive balancing 5
4. Excellent clinical and patient reported outcomes 6
5. Increased ROI for hospitals, with reduced manipulation rates 7
6. Improved ligament balance compared to standard robotic surgery 8
7. Cost savings with robotics in a bundled episode of care setting 9
8. Superior Improvements in patient reported outcomes 10
9. Improved bone resection accuracy with robotics over conventional cutting blocks 11
10. Short learning curve and high patient satisfaction during learning phase 12
1. More precise ligament balance correlates with better outcomes, less pain

Title
The Impact Of Intra-Operative Coronal Mid-Flexion And Flexion Balance On Early Post-Operative Pain In TKA

Authors

Publication
AAHKS Annual Meeting 2019; ORS 2020

Methods
In a prospective multi-center study, associations between post-operative gap balance and 1 Year KOOS pain scores were investigated in 135 patients.

Results
- Coronal gap balance in extension and flexion, as well as medial laxity in midflexion correlated with KOOS pain scores (p<0.05).
- Joint gap windows throughout flexion were defined for improved outcomes (p<0.002).
- When knees satisfied all windows, further improved outcomes were found (∆ = 11.2, p = 0.0018).

Conclusion
Improved outcomes correlated with coronal balance and laxity and when combined resulted in further improved outcomes, highlighting the importance of soft tissue balance throughout the whole range of motion.
2. Precise predictions, precise balance

Title
Imageless, Robotic-Assisted TKA Combined With A Robotic Tensioning System Can Help Predict And Achieve Accurate Post-Operative Ligament Balance

Authors
Shalhoub S, Lawrence JM, Keggi JM, Randall AL, DeClaire JH, Plaskos C.

Publication

Methods
A robotic-assisted ligament tensioning technique was utilized in 121 sequential knees. Predictive gap profiles were used to plan femoral implant position to achieve a balanced knee. Final gap profiles were then compared to the predictive gap plans.

Results
Over 90% of knees were balanced to within 2mm mediolaterally throughout the range of motion. Over 90% of knees were balanced within 1mm from flexion to extension.

Conclusion
OMNIBotics® Predictive Balance Technique could accurately predict and consistently achieve post-operative gap balance. This allows surgeons to virtually plan femoral implant alignment to optimize balance throughout motion. The rate of balance achieved in this study was significantly higher than previous reports using conventional instrumentation ¹,².

3. Fewer releases with predictive balancing

**Title**
Soft-Tissue Release Rates In Robotic-Assisted Gap-Balancing And Measured-Resection TKA.

**Authors**
Lawrence JM, Keggi JM, Koenig JA, Ponder CE, Randall AL, Declaire JH, Shalhoub S, Plaskos C.

**Publication**
ISTA Conference 2019

**Methods**
Soft tissue releases were recorded in robotic assisted TKA with predictive gap balancing (n=615) and compared to conventional TKA using literature data[1].

**Results**
The percentage of knees requiring no releases was significantly higher in the predictive balancing group (69% vs 33%, p < 0.001). This trend persisted for both varus and valgus deformities (Table 1).

**Conclusion**
OMNIBotics® Predictive Balance technique resulted in significantly lower rates of soft tissue releases compared to conventional TKA.

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**Table 1. Percentage of knees with no releases**

<table>
<thead>
<tr>
<th></th>
<th>Varus</th>
<th>Neutral</th>
<th>Valgus</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Conventional</strong> (n=1,216)[1] (Measured resection, femur first)</td>
<td>37%</td>
<td>59%</td>
<td>17%</td>
<td>33%</td>
</tr>
<tr>
<td><strong>Predictive Balance™</strong> (n=615) (BalanceBot, tibia first)</td>
<td>67%*</td>
<td>89%*</td>
<td>73%*</td>
<td>69%*</td>
</tr>
</tbody>
</table>

*p<0.05, compared to Conventional group
4. Excellent clinical and patient reported outcomes

**Title**
Early Clinical Outcomes Of A Novel Predictive Ligament Balancing Technique For Total Knee Arthroplasty

**Authors**
John M. Keggi, Jeffrey M. Lawrence, Amber L. Randall, Jeffrey H. DeClaire, Corey E. Ponder, Jan Koenig, Sami Shalhoub, Edgar Wakelin, Christopher Plaskos

**Publication**
CAOS 2020; ISTA Congress 2019

**Methods**
533 patients were prospectively enrolled and underwent robotic-balancing (RB) TKA. Pre- and post-op WOMAC, UCLA, HSS-Patient Satisfaction scores were collected and compared to registry data from the Shared Ortech Aggregated Repository (SOAR), a TJA PROM repository of thousands of TKAs from hospitals, teaching institutions and clinics in the US. Overall satisfaction rates were compared using a weighted average of a range of contemporary literature.

**Results**
Post-operatively, all outcome scores remained significantly better in the RB cohort compared to registry data at 3M and 6M (p < 0.012). At 1Y, WOMAC remains significantly better than registry data (p < 0.001). Overall patient satisfaction in the robotic cohort was significantly better than recognized rates reported in literature at > 91% at 3M and > 96% at 1 Y.

**Conclusion**
Predictive Balance™ technique with BalanceBot has demonstrated significant improvements to post-operative patient satisfaction rates compared to traditional TKA.

**Literature:**
5. Increased ROI for hospitals, with reduced manipulation rates

**Title**
OMNIBotics BalanceBot™ case study*

**Authors**
Plaskos C, Gill PS, Lawrence JM.

**Publication**
DOCSF - Digital Orthopaedics Conference
San Francisco, 2019

* 1st Place winner of the 2019 DOCSF Innovation Award

### Methods
A case study for a rural hospital that recently adopted OMNIBotics is presented. Clinical outcomes studied included TKA readmit rates for post-op Manipulations Under Anesthesia (MUA). Economic outcomes included increase in procedure volume and associated revenue, and potential cost savings over a competitive, capital-cost robotic system.

### Results
Post-op MUA rates reduced from 6.1% to 2.4% after introduction of the BalanceBot. TKA procedure volumes increased by 24% over two years, representing a potential $1.5M increase in revenues¹. Cost analysis indicated a $780 cost savings per surgery over a competitive robotic system.

### Conclusion
Introduction of a robotic ligament balancing TKA system resulted in a reduction in MUA readmissions and an increase in TKA procedure volumes and associated potential revenue at one rural hospital.

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¹. Based on average total reimbursement of $14,8k (Institution specific CMS/medicare reimbursement data for In-patient DRG-470) OMNIBotics platform introduced in hospital in Dec 2016
6. Improved ligament balance compared to standard robotic surgery

Title Accuracy Of Soft Tissue Balancing In Robotic-Assisted Measured-Resection TKA Using A Robotic Distraction Tool
Authors Koenig JA, Chen E, Shalhoub S, Plaskos C.
Publication CAOS Int’l Congress 2019

Methods The study compared two prospective sequential cohorts of 52 patients undergoing robotic-assisted TKA using a measured resection technique: 1) a non-sensor-assisted group (n=25), and 2) a sensor-assisted group (n=27). Final gap balance was measured at the end of the case using a robotic distraction tool.

Results Mean mediolateral gap balance throughout flexion was significantly better in the sensor vs non-sensor cohort: 1.5±0.6mm (max 3.8) vs 1.9±0.7mm (max. 7.8), p=0.03. 38-41% of knees were balanced to within 1mm mediolaterally in the non-sensor group compared to 48-70% for the sensor group. 65-76% of knees were balanced to within 2mm for the non-sensor group compared to 78-86% for the sensor-assisted group.

Conclusion Soft tissue balancing with the aid of a robotic tensioning tool resulted in significantly more accurate soft tissue balance than when using navigation measurements and standard trials alone in this single user study.

Figure 1. (A, B) Difference in mediolateral balance throughout flexion. * = max. difference. (C, D) percentage of knees balanced within 0-1mm (blue), 1-2mm (green), >2mm (orange).
7. Cost savings with robotics in a bundled episode of care setting

Title
Total Knee Arthroplasty Technique: OMNIBotics®

Authors
Koenig JA, Plaskos C.

Publication

Methods
Overall procedural costs and clinical outcomes over the 90-day episode of care period were compared for patients undergoing TKA with either robotic-assisted (RAS, 3 surgeons, 147 patients) or conventional (Conv., 3 surgeons, 85 patients) instrumentation at single institution participating in the CMS Bundled Payment for Care Improvement (BPCI) model.

Results
RAS and Conv-TKA procedures exhibited an average gain per episode of $7,600 and $5,579, respectively. The average total cost per episode was $2,085 lower for patients receiving RAS-TKA ($28,943 versus $31,028), with the majority of cost savings in reduced skilled nursing facility (SNF) usage ($1,481) and readmissions ($944). Discharge to home versus Sub-acute Rehabilitation Facilities (SAR’s) was 14% higher in the RAS group (62% vs 48%, p<0.05).

Conclusion
Implementation of a standardized care pathway resulted in a reduction in overall episode of care costs, with further reductions in cost and discharge to SARs observed with the use of RAS.

90 day cost breakdown

<table>
<thead>
<tr>
<th>Cost Category</th>
<th>Robotic</th>
<th>Conventional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anchor inpatient stay</td>
<td>$28,943</td>
<td>$31,028</td>
</tr>
<tr>
<td>SNF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IRF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Home health</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Readmissions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient physical therapy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Outpatient/professional</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 2nd Place winner of the Best Clinical Poster Prize at CAOS 2019
8. Superior improvements in patient reported outcomes

Title: One And Two Year Postoperative Patient Reported Outcomes Of Robotic-Assisted Total Knee Arthroplasty

Authors: Blum CL, Plaskos C, Hussein A, Koenig JA.

Publication: CAOS Int’l 2019

Methods: 106 patients undergoing robotic-assisted (RAS) TKA by a single surgeon were prospectively enrolled. KOOS and KSS patient satisfaction assessments were completed pre-op and at 6M, 1Y and 2Y. Changes in KOOS sub-scales were compared to available literature data from the FORCE–TJR, a large national TKA study cohort (Conv-TKA)\(^1\)\(^2\).

Results: The RAS cohort had significantly higher improvements at 6M for pain (40.5 vs. 31.1, \(p<.001\)) and at 2Y for all five KOOS sub-scores (table 1). Rates of dissatisfaction with knee pain level and function after RAS were 3.0%, 1.0%, and 2.7% at 6M, 12M, and 2Y postoperatively, respectively.

Conclusion: Despite having poorer joint function and higher pain preoperatively, robotic-assisted TKA patients achieved excellent self-reported outcomes, with significantly higher levels of improvement through two years post-surgery when compared with large national cohort studies. Patient dissatisfaction was also lower than rates reported in literature.

### Table 1: Average KOOS scores

<table>
<thead>
<tr>
<th>KOOS Subscale</th>
<th>RAS TKA</th>
<th>Conv. TKA [1]</th>
<th>Conv. TKA [2]</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(\Delta \text{ 6M})</td>
<td>(\Delta \text{ 2Y})</td>
<td>(\Delta \text{ 6M})</td>
</tr>
<tr>
<td>KOOS</td>
<td>40.5</td>
<td>45.9</td>
<td>31.1</td>
</tr>
<tr>
<td>Symptoms</td>
<td>32.8</td>
<td>39.6</td>
<td>32.1</td>
</tr>
<tr>
<td>ADL</td>
<td>38.5</td>
<td>41.7</td>
<td>31.1</td>
</tr>
<tr>
<td>SportRec</td>
<td>29.0</td>
<td>44.4</td>
<td>33.9</td>
</tr>
<tr>
<td>QOL</td>
<td>46.6</td>
<td>56.5</td>
<td>42.8</td>
</tr>
</tbody>
</table>


9. Improved bone resection accuracy with robotics over conventional cutting blocks

**Title**
Sequential Versus Automated Cutting Guides In Computer-Assisted Total Knee Arthroplasty

**Authors**
Koulalis D, O’Loughlin PF, Plaskos C, Kendoff D, Cross MB, Pearle AD.

**Publication**
The Knee 18 (2011) 436–442

**Methods**
Bilateral cadaver study comparing the OMNIBot to conventional block navigation in 12 knees.

**Results**
Increased accuracy and precision in robotic group:
- Guide positioning (0.55° vs 1.1° SD varus, p<0.03)
- Bone cuts (mean error: 0.6mm vs 1.4mm, p=0.01)

- Final implant placement (1.0° vs 2.2° SD varus, p=0.11),
- Faster than freehand navigation of multiple blocks.

**Conclusion**
Robotic guide positioning resulted in more efficient and more accurate femoral cuts in comparison to conventional cut blocks in a cadaveric model.
10. Short learning curve and high patient satisfaction during learning phase

**Title**
Learning Curve And Early Patient Satisfaction Of Robotic-Assisted TKA

**Authors**
Keggi J, Plaskos C.

**Publication**
ICJR Transatlantic Orthopaedic Conference, 2016

**Methods**
The first 29 robotic-assisted TKA cases performed by a single surgeon having no prior experience with computer or robotic-assisted TKA were reviewed for procedure times and satisfaction.

**Results**
All time metrics decreased significantly after the first 7 cases, except the residual time. Mean skin-to-skin time significantly decreased from 83.7min to 57.1min (p=0.0008) beyond 7 cases. 85.7% (24/29) of patients were “Fully satisfied” and 14.3% (5/29) were “Partly satisfied”. No patients were “Not Satisfied”.

**Conclusion**
Improvements in surgical efficiency and quality are becoming increasingly important in today’s healthcare environment. The results of this study indicated equal cost, a short learning curve and comparable procedure times to conventional TKA. The PROMs with this group of patients was very high compared to rates reported in the literature.

*Fig 1. Skin to skin time decreased from 84min to 57min (p=0.0008) after 7 cases.*
OMNIBotics Reference Papers
