

OMNIBotics®

The evidence base



Corin
Connected Orthopaedic Insight

OMNIBotics®

Featuring the Predictive Balance™ technique with BalanceBot®

Alignment, balance, minimal releases

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OMNIBotics Reference Papers

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1. Precise ligament balance correlates with better outcomes, less pain

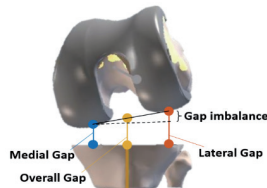
| | |
|--------------------|---|
| Title | Improved total knee arthroplasty pain outcome when joint gap targets are achieved throughout flexion |
| Authors | Wakelin EA, Shalhoub S, Lawrence JM, Keggi JM, DeClaire JH, Randall AL, Ponder CE, Koenig JA, Lyman S, Plaskos C. |
| Publication | Knee Surg Sports Traumatol Arthrosc. 2021 Feb 12. |

Methods

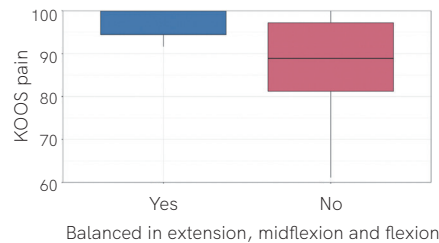
In a prospective multi-center study, associations between postoperative gap balance and 1 Year KOOS pain scores were investigated in 135 patients.

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 ($\Delta = 11.2$, $p = 0.0018$).



Impact of balance throughout flexion on outcome



Conclusion

Improved pain scores not only correlated with joint laxity and balance, but showed a synergistic relationship, highlighting the importance of soft tissue balance throughout the whole range of motion.

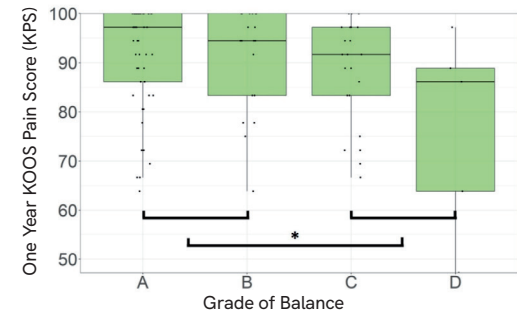
1. Precise ligament balance correlates with better outcomes, less pain

Title Can a Robot Help a Surgeon Predict a Good Total Knee Arthroplasty?
Authors Lee GC, Wakelin EA, Randall AL, Plaskos C.
Publication [Bone Joint J 2021;103-B\(6 Supple A\):67-73.](#)

Methods 134 consecutive patients in a prospective trial were reviewed. Each TKA was graded according to the final recorded ML balance achieved at 10° and 90°: A) <1mm with an implanted insert thickness equal to planned; B) <1mm; C) <2mm; D) >2mm. The 1-year KOOS Pain Score (KPS) for each knee grade were compared.

Results

- Patients with grade A or B had higher 1-year KPS compared to knees rated C and D, see figure.
- Patients with a high grade of balance (A and B) and with KPS < 90 had lower PROMIS mental health scores compared to patients reporting KPS > 90.
- Grade A and B patients who scored KPS > 90 were more likely to respond with “my expectations were too low”, and with “the knee is performing better than expected” compared to Grade A and B patients who scored KPS < 90.
- In this series, the percentage of knees balanced to within 1 and 2 mm was 75% and 95% respectively, and overall patient satisfaction was 99%.



Conclusion A knee balanced with a robot to within 1mm of difference between the medial and lateral sides in both flexion and extension correlated with higher KPS at 1 year.

1. Precise ligament balance correlates with better outcomes, less pain

Title Impact of Intra-Operative Predictive Ligament Balance on Post-operative Balance and Patient Outcome in TKA: A Prospective Multicenter Study.

Authors Keggi JM, Wakelin EA, Koenig JA, Lawrence JM, Randall AL, Ponder CE, DeClaire JH, Shalhoub S, Lyman S, Plaskos C.

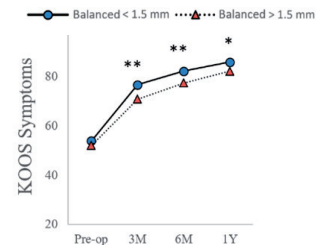
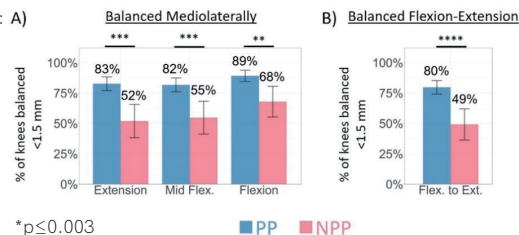
Publication [Arch Orthop Trauma Surg 2021 Jul 13](#)

Methods 280 patients were prospectively enrolled and followed up at 3, 6, and 12 months postoperatively. Patients were divided into those in which a Predictive Plan with the BalanceBot was used (PP) and those in which it was not (NPP). Optimal balance difference between PP and NPP was defined and compared using area-under-the-curve analysis (AUC). Outcomes were then compared according to the results from the AUC.

Results

- AUC analysis yielded a mediolateral balance threshold of 1.5mm, in which the PP group achieved a higher rate of balance throughout flexion compared to the NPP group, fig 1 A B.
- Higher KOOS symptoms scores were observed in knees balanced within 1.5mm across all time points, fig 2.
- Patients with <1.5 mm flexion laxity medially or laterally had an increased likelihood of achieving the Patient Acceptable Symptom State (PASS)¹ for KOOS Pain at 12 months.

Figure 1: A)



Conclusion

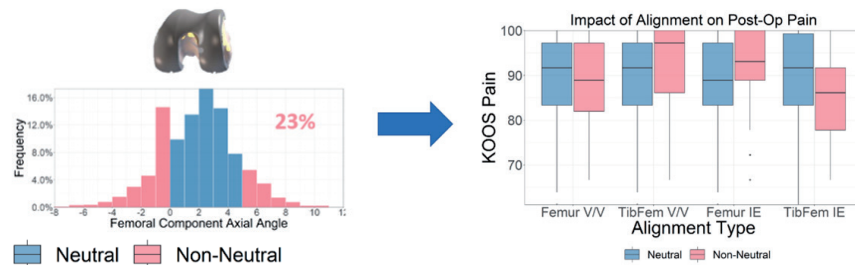
Use of Predictive Balancing with the BalanceBot improved final balance in TKA. Improved outcomes were found in balanced knees. Limiting medial and lateral flexion laxity resulted in an increased likelihood of achieving the PASS for KOOS Pain.

2. Ligament balance has greater impact than implant alignment on outcomes

| | |
|--------------------|--|
| Title | Joint Balance Has Greater Impact on 1-Year Pain Outcome than Component Alignment in TKA. |
| Authors | Wakelin EA, Ponder CE, Lawrence JM, Koenig JA, Keggi JM, DeClaire JH, Randall AL, Shalhoub S, Plaskos C. |
| Publication | AAHKS 2020 |

Methods 135 patients were prospectively enrolled and underwent robot assisted TKA. Component alignment parameters and postoperative joint gaps throughout flexion under a load of 70-90 N were recorded. Patients completed 1-year KOOS pain questionnaires.

Results Significant correlations were found between KOOS Pain and joint balance ($p < 0.05$)¹. No significant correlations were identified between femoral coronal and axial or tibiofemoral extension and flexion coronal alignments and KOOS Pain. Neutral and non-neutral femoral ($\pm 3^\circ$ coronal and 0° - 5° external) and tibiofemoral ($\pm 3^\circ$ extension and -2° - 5° in flexion) subgroups also reported no difference.



Conclusion Joint balance had a greater impact on outcome than alignment, indicating that small intra-operative compromises on component alignment to achieve joint balance may result in improved outcomes.

1. [Wakelin EA, et al \(2021\). Knee Surgery, Sports Traumatology, Arthroscopy:1-9.](#)

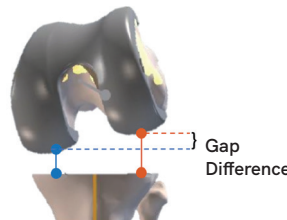
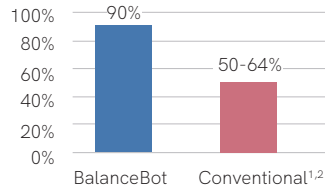
3. Precise predictions, precise balance

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 [Arthroplasty Today 5 \(2019\) 334-330](#)

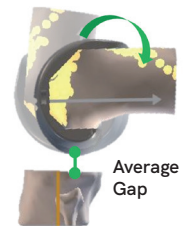
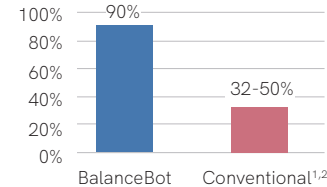
Methods A robotic-assisted ligament tensioning technique was utilised in 121 sequential knees. Predictive gap profiles were used to plan femoral implant position to achieve a balanced knee. Final gap profiles were then compared to the predictive gap plans.

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.

Knees balanced within 2mm mediolaterally



Knees balanced within 1mm from flexion to extension



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

1. Joseph et al, The Knee 20 (2013) 401-406.
2. Lee et al, Knee Surg Sports Traumatol Arthrosc (2010) 18:381-387.

4. 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 | Bone & Joint Surgery Orthopaedic Proceedings, Vol. 102-B, No. SUPP_2. Feb 2020 |

Methods Soft tissue releases were recorded in robotic-assisted TKA with predictive gap balancing (n=615) and compared to conventional TKA using literature data¹.

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.

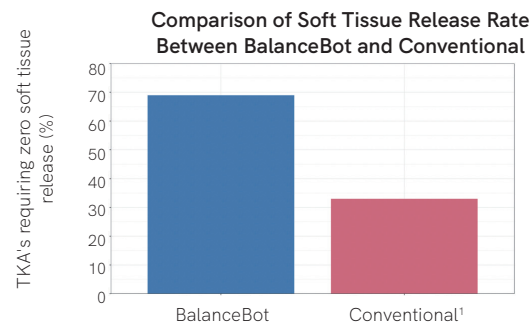


Table 1. Percentage of knees with no releases

| | Varus | Neutral | Valgus | Overall |
|--|-------|---------|--------|---------|
| Conventional (n=1,216)¹ (Measured resection, femur first) | 37% | 59% | 17% | 33% |
| Predictive Balance (n=615) (BalanceBot, tibia first) | 67%* | 89%* | 73%* | 69%* |

1. Peters CL et al. Lessons learned from selective soft-tissue release for gap balancing in primary TKA: an analysis of 1216 consecutive TKAs: AAOS exhibit selection. J Bone Joint Surg Am. 2013 Oct 16;95(20):e152.

* $p < 0.05$, compared to Conventional group

5. Excellent clinical and patient reported outcomes

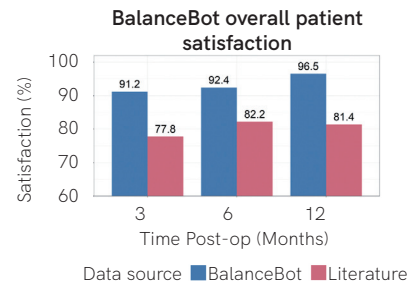
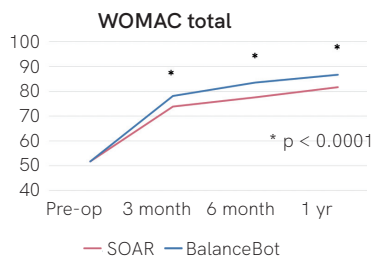
*2nd Place winner of the
Best Clinical Podium Prize at CAOS 2019



| | |
|--------------------|--|
| Title | Early Clinical Outcomes Of A Novel Predictive Ligament Balancing Technique For Total Knee Arthroplasty. |
| Authors | Keggi JM, Lawrence JM, Randall AL, DeClaire JH, Ponder CE, Koenig JA, Shalhoub S, Wakelin EA, Plaskos C. |
| Publication | Epic Series in Health Sciences. Volume 4, 2020, Pages 160-164 |

Methods 533 patients were prospectively enrolled and underwent robotic-balancing (RB) TKA. Pre- and postop. 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 Postoperatively, 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 recognised rates reported in literature at $> 91\%$ at 3M and $> 96\%$ at 1Y.



Conclusion Predictive Balance™ technique with BalanceBot has demonstrated significant improvements to postoperative patient satisfaction rates compared to traditional TKA.

5. Excellent clinical and patient reported outcomes

Title Patient Expectations and Satisfaction in Robotic-assisted Total Knee Arthroplasty - A Prospective Two Year Outcome Study.
Authors Blum CL, Lepkowsky E, Hussein A, Wakelin EA, Plaskos C, Koenig JA.
Publication [Arch Orthop Trauma Surg 2021 Jul 20](#)

Methods 106 patients received robotic-assisted TKA with OMNIBotics by a single surgeon and followed for 2 years. KSS expectation fulfillment and satisfaction were compared at 1Y and 2Y post-TKA. KOOS scores were also compared to nationwide US outcomes database, FORCE - TJR.

Results

- Patients with greater KSS expectation fulfillment at 3M reported significantly higher KSS satisfaction scores at 1Y.
- Patients with greater 6M expectation fulfillment reported improved satisfaction at 1Y and 2Y.
- Compared to the FORCE-TJR database:
 - The robotic cohort also reported significantly greater improvements in KOOS Pain at 6M, 1Y and 2Y, Symptoms at 2Y, ADL at 1Y and 2Y, Sports at 2Y and Quality of Life at 1Y and 2Y.
 - Overall patient satisfaction rates were 97.1% at 3M, 99% at 6M, 100% at 1Y and 98.7% at 2Y.

Table 1 – Change in 2 Year KOOS subscale scores for robotics assisted total knee arthroplasty (RAS-TKA) and FORCE-TJR data from literature.

| KOOS Subscore | Study (n=106) | FORCE-TJR (Lyman 2016) N=2291 | Mann-Whitney-U test p-value |
|---------------|---------------|-------------------------------|-----------------------------|
| Pain | 46.3±15.0 | 38.2 | p < 0.001 |
| Symptoms | 40.3±15.7 | 32.1 | p < 0.001 |
| ADL's | 42.9±15.4 | 31.1 | p < 0.001 |
| Sports & Rec | 45.2±27.2 | 33.9 | p < 0.001 |
| QOL | 57.2±18.9 | 42.8 | p < 0.001 |

Months (M) Years (Y), Knee Injury and Osteoarthritis Outcome Score (KOOS)

Conclusion High early expectation fulfillment was associated with improved satisfaction at 1Y and 2Y, indicating the importance of managing patient specific postoperative care to ensure patients reach their preoperative goals. Greater improvements in all KOOS subscores were observed in this robotics assisted cohort compared to a large contemporary database.

6. Increased ROI for hospitals, with reduced manipulation rates

*1st Place winner of the
2019 DOCSF Innovation Award

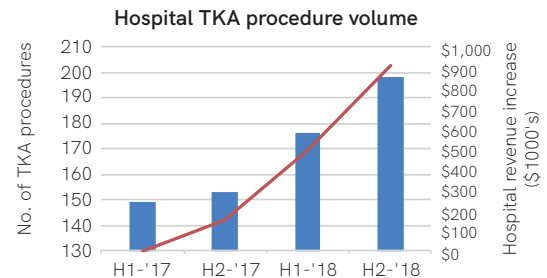
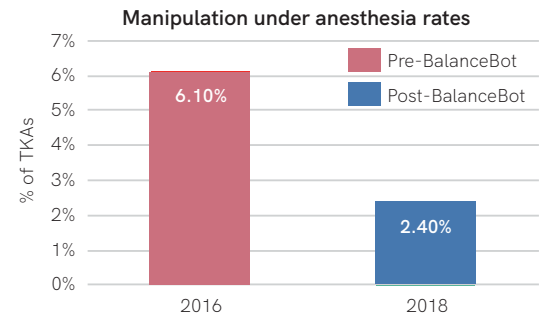
Title OMNIBotics BalanceBot case study*
Authors Plaskos C, Gill PS, Lawrence JM.
Publication DOCSF - Digital Orthopaedics Conference,
 San Francisco, 2019.



Methods A case study for a rural hospital that recently adopted OMNIBotics is presented. Clinical outcomes studied included TKA readmit rates for postop. 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 Postop. 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.



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.

7. Improved ligament balance compared to standard robotic surgery

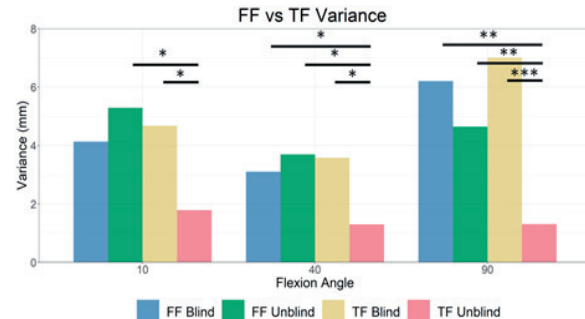
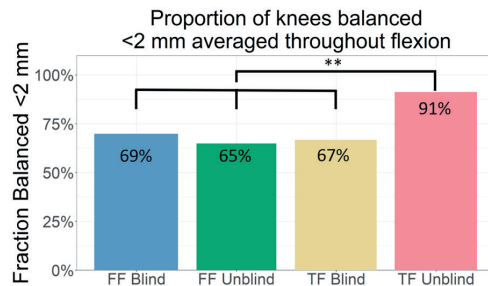
| | |
|--------------------|---|
| Title | Accuracy of Balance in Tibia and Femur First Total Knee Arthroplasty Using Digital Balancing Tools. |
| Authors | Koenig JA, Wakelin EA, Shalhoub S, Plaskos C. |
| Publication | AAHKS 2020 |

Methods

100 patients were prospectively enrolled and underwent robotic TKA using a digital gap balancing tool. The cohort was divided into four groups: 1) Femur first blinded to gap data, 2) Femur first non-blinded to gap data, 3) Tibia first blinded to gap data, 4) Tibia first non-blinded to gap data (Predictive Balancing with the BalanceBot).

Results

Group 4 reported significantly less midflexion imbalance (40°) compared to all groups (1: 1.5 mm, 2: 1.7 mm, 3: 1.7 mm, 4: 0.9 mm, $p < 0.02$). Group 4 also reported reduced variance compared to all other groups at 90° ($p = 0.009$) (Figure Left), resulting in a reduced frequency of outlier balance in group 4 (1: 30%, 2: 35%, 3: 33%, 4: 12%, $p = 0.017$) (Figure Right).



Conclusion

A tibia first approach with digital predictive gap balancing resulted in more accurate gap balancing, particularly in midflexion and flexion where manual balance may be difficult to assess.

*2nd Place winner of the
Best Clinical Poster Prize at
CAOS 2019

8. Cost savings with robotics in a bundled episode of care setting

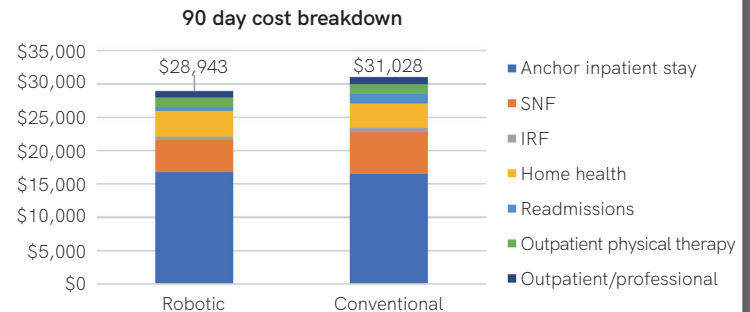
Title Total Knee Arthroplasty Technique: OMNIBotics®.
Authors Koenig JA, Plaskos C.
Publication [In Robotics in Knee and Hip Arthroplasty: Current Concepts, Techniques and Emerging Uses. Ed. Lonner JH. Springer 2019](#)



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.



9. Improved bone resection accuracy

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.

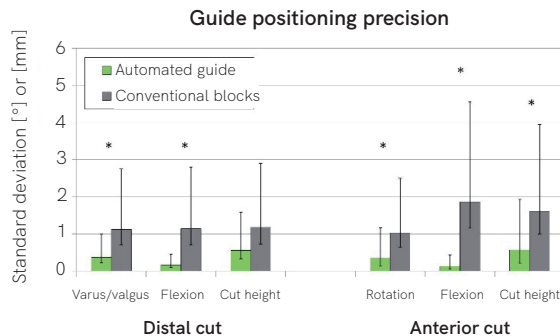
Publication [The Knee 18 \(2011\) 436-442](#)

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

Results

Increased accuracy and precision in robotic group:

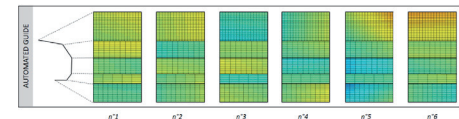
- Guide positioning (0.55° vs 1.1° SD varus, $p < 0.03$)
- Bone cuts (mean error: 0.6mm vs 1.4mm, $p = 0.01$)
- Final implant placement (1.0° vs 2.2° SD varus, $p = 0.11$),
- Faster than freehand navigation of multiple blocks.



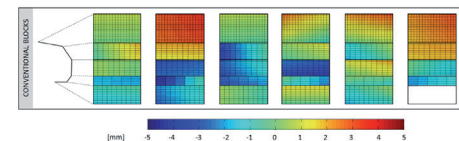
Accuracy of bone cut surfaces

Distance between measured and planned cutting planes (mm)

OMNIBot™



Conventional



Conclusion

Robotic guide positioning resulted in more efficient and more accurate femoral cuts in comparison to conventional cut blocks in a cadaveric model.

10. Accurate component alignment

Title Comparison between navigated reported position and postoperative computed tomography to evaluate accuracy in a robotic navigation system in total knee arthroplasty

Authors Figueroa F, Wakelin E, Twigg J, Fritsch B

Publication [The Knee 26 \(2019\) 869-875](#)

Methods 173 knees received OMNIBotics robot assisted TKA. Navigated femoral and tibial cuts were compared to postoperative CT. Femoral coronal alignment (FCA), femoral sagittal alignment (FSA), femoral rotational alignment (FRA), tibial coronal alignment (TCA) and hip-knee-ankle (HKA) angle were compared for accuracy.

Results Bone resection and component placement accuracy was found to be very high (table 1). Differences in functional leg position between intra-operative measurements and post-operative CT scans highlight the difficulties in defining a true HKA.

| Component Angle | % inside 3° |
|-----------------|-------------|
| FCA | 98 |
| FSA | 100 |
| FRA | 94 |
| TCA | 99 |
| TSA | 93 |
| HKA | 83 |

Conclusion The OMNIBotics robotic navigation system accurately achieves the desired component alignment within industry leading alignment thresholds.

11. Short learning curve and high patient satisfaction during learning phase

*1st Place winner of 2016
Transatlantic Orthopaedic Congress
Award of Excellence for an Oral
Scientific Poster: Knee

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 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 increasing 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.

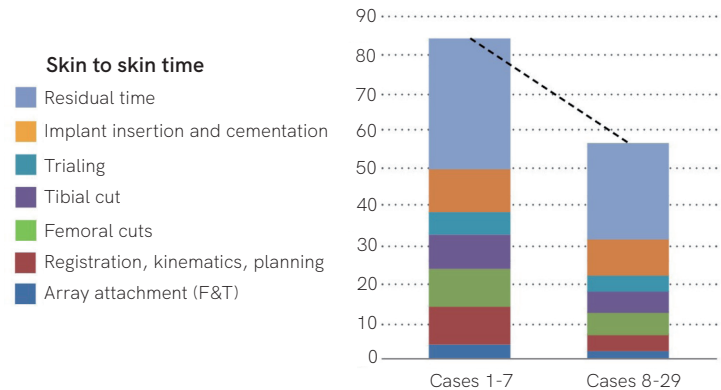


Fig 1. Skin to skin time decreased from 84min to 57min ($p=0.0008$) after 7 cases.

12. 99% Survivorship at 6.5 years

Title Mid-term Patient Reported Outcomes and Survivorship Following Robotic Assisted Total Knee Replacement: A Cohort Study
Authors Chen EA, Husain A, Billow N, Koenig JA, Plaskos C
Publication [EPiC Series in Health Sciences Vol 2 109, CAOS 2019](#)

Methods Recipients of 152 consecutive total knee arthroplasties (Apex Knee, Corin USA) using a computer- navigated TKA system (OMNIBotics, Corin USA) performed by a single surgeon between June 2010 and January 2012 were surveyed between 5-7 years post-operatively. 94 patients were reachable for outcome measures and survivorship data was obtained in 98 patients.

Results Implant survivorship was 99.0% at an average of 6.5 years. Mean patient reported knee outcome scores were 62.7 (KSS-SF) and 79.5 (KOOS-JR). Overall satisfaction rate was reported as “satisfied or very satisfied” in 80.2%, “neutral” in 11.0%, and “dissatisfied or very dissatisfied” in 7.7% of patients.

Conclusion Robotic assisted TKA with OMNIBotics provides a durable outcome with sustainable midterm patient reported outcomes and excellent survivorship.



OMNIBotics Reference Papers

Featured references

1. Wakelin EA, Shalhoub S, Lawrence JM, Keggi JM, DeClaire JH, Randall AL, Ponder CE, Koenig JA, Lyman S, Plaskos C. Improved total knee arthroplasty pain outcome when joint gap targets are achieved throughout flexion. *Knee Surg Sports Traumatol Arthrosc.* 2021 Feb 12. doi: 10.1007/s00167-021-06482-2
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4. Wakelin EA, Ponder CE, Lawrence JM, Koenig JA, Keggi JM, DeClaire JH, Randall AL, Shalhoub S, Plaskos C. Joint Balance Has Greater Impact on 1-Year Pain Outcome than Component Alignment in TKA. AAHKS 2020 Annual Conference
5. Shalhoub S, Lawrence JM, Keggi JM, Randall AL, DeClaire JH, Plaskos C. Imageless, robotic-assisted TKA combined with a robotic tensioning system can help predict and achieve accurate post-operative ligament balance *Arthroplasty Today* 5 (2019) 334-330
6. Plaskos C, Wakelin EA, Shalhoub S, Lawrence JM, Keggi JM, Koenig JA, Ponder CE, Randall AL, DeClaire JH. Soft-Tissue Release Rates in Robotic-Assisted Gap-Balancing and Measured-Resection TKA. *BJJ Orthopaedic Proceedings*, Vol. 102-B, No. SUPP_2. Feb 2020.
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9. Plaskos C, Gill P, Lawrence JM. OMNI Case Study - OMNI BalanceBot Technology. *Digital Orthopaedics Conference San Francisco (DOCSF) 2019*
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