

OmniBotics®

The evidence base



Corin

Connected Orthopaedic Insight

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



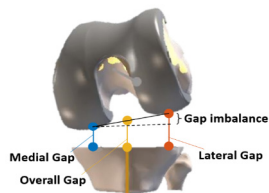
1. More precise ligament balance correlates with better outcomes, less pain

Title	The Impact Of Intra-Operative Coronal Mid-Flexion And Flexion Balance On Early Post-Operative Pain In TKA
Authors	Wakelin E, Shalhoub S, Lawrence J, Koenig JA, Ponder CE, DeClaire JH, Randall A, Keggi J, Plaskos C
Publication	AAHKS Annual Meeting 2019; ORS 2020

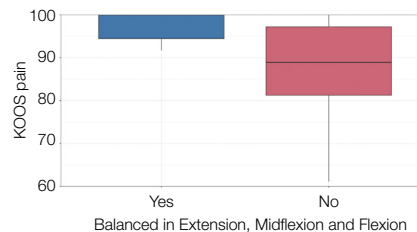
Methods In a prospective multi-center study, associations between post-operative gap balance and 1 Year KOOS pain scores were investigated in 135 patients.

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



Impact of Balance Throughout Flexion on Outcome



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

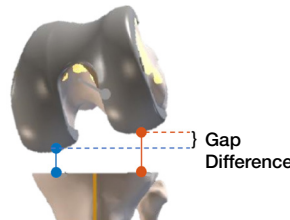
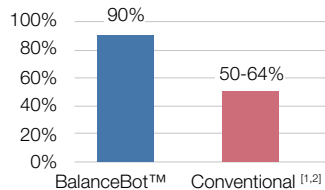
Authors Shalhoub S, Lawrence JM, Keggi JM, Randall AL, DeClaire JH, Plaskos C.

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

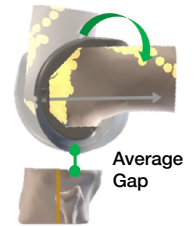
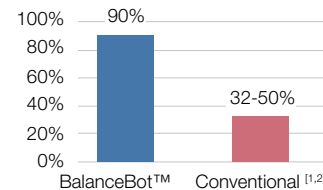
Methods A robotic-assisted ligament tensioning technique was utilized in 121 sequential knees. Predictive gap profiles were used to plan femoral implant position to achieve a balanced knee. Final gap profiles were then compared to the predictive gap plans.

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.

Knees balanced within 2mm mediolaterally



Knees 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].

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

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.

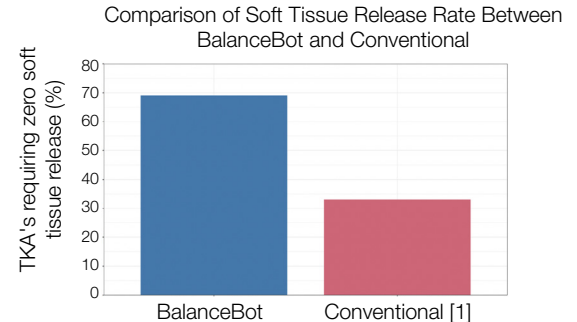


Table 1. Percentage of knees with no releases

	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

4. 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	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

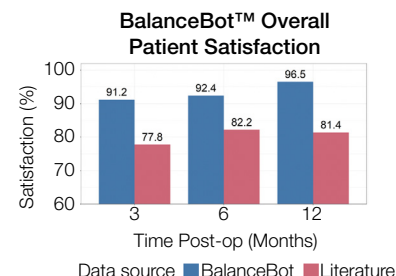
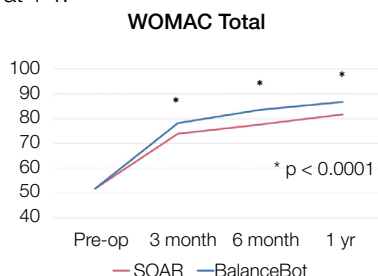


Methods

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: 1. Turcot, JOA 2013. 2. Van Onsem JOA 2016. 3. Vissers BMCMD 2010. 4. Kiran, JOA 2015. 5. Bourne, CORR 2010. 6. Heck, CORR 1998. 7. Baker, JBJS, 2007. 8. Noble, CORR 2006. 9. Robertsson, Acta 2000. 10. Lange, JOA 2018

5. Increased ROI for hospitals, with reduced manipulation rates

* 1st Place winner of the
2019 DOCSF Innovation Award

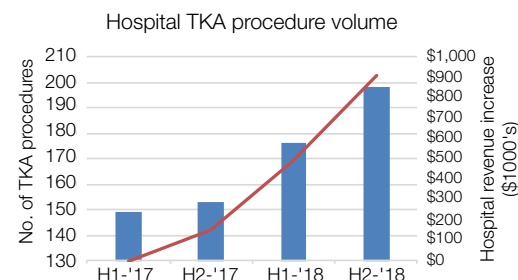
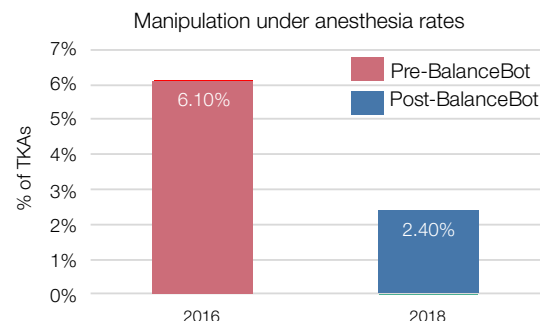
Title OMNIBotics BalanceBot™ case study*
Authors Plaskos C, Gill PS, Lawrence JM.
Publication DOCSF - Digital Orthopaedics Conference
San Francisco, 2019



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



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: $1.5 \pm 0.6\text{mm}$ (max 3.8) vs $1.9 \pm 0.7\text{mm}$ (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.

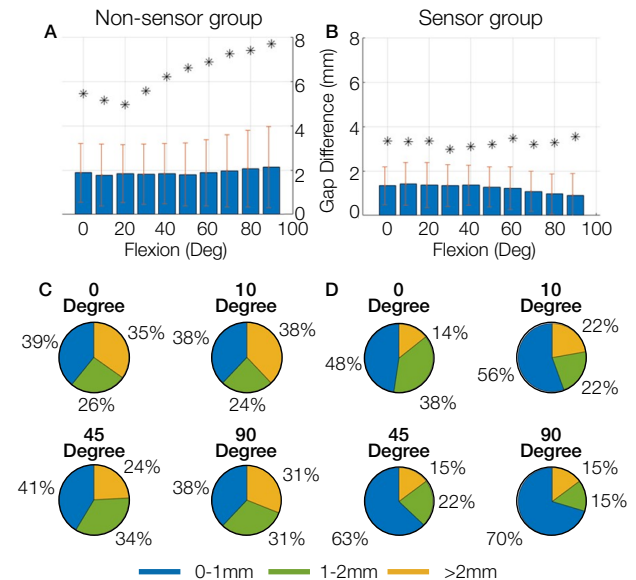


Figure 1. (A, B) Difference in mediolateral balance throughout flexion. * = max. difference. (C, D) percentage of knees balanced within 0-1mm (blue), 1-2mm (green), >2mm (orange).

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

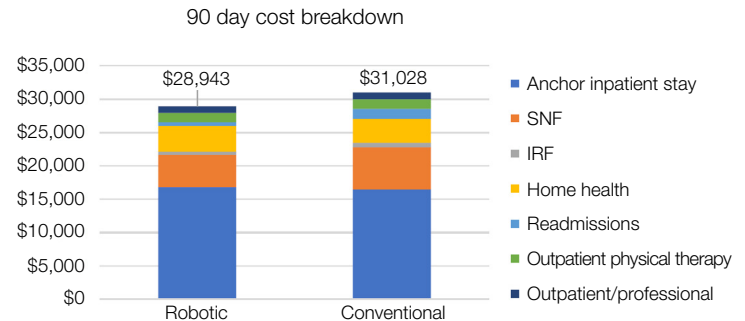
Title Total Knee Arthroplasty Technique: OMNIBotics®
Authors Koenig JA, Plaskos C.
Publication [In Robotics in Knee and Hip Arthroplasty: Current Concepts, Techniques and Emerging Uses. Ed. Lonner JH. Springer 2019](#)



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.



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.

	RAS TKA		Conv. TKA [1]		Conv. TKA [2]	
	Δ 6M	Δ 2Y	Δ 6M	p value	Δ 2Y	p value
KOOS Subscale	N = 101	N = 74	N = 2792		N = 1114	
KOOS	40.5	45.9	31.1	< 0.001	38.2	0.001
Symptoms	32.8	39.6			32.1	0.002
ADL	38.5	41.7			31.1	< 0.001
SportRec	29.0	44.4			33.9	0.005
QOL	46.6	56.5			42.8	0.001

Table 1: Average KOOS scores

1. Li W. et al Functional Gain and Pain Relief After Total Joint Replacement According to Obesity Status. J Bone Joint Surg Am. 2017 Jul 19;99(14):1183-1189.
2. Lyman S. et al. Validation of the KOOS, JR: A Short-form Knee Arthroplasty Outcomes Survey. Clin Orthop Relat Res. 2016 Jun;474(6):1461-71.

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](#)

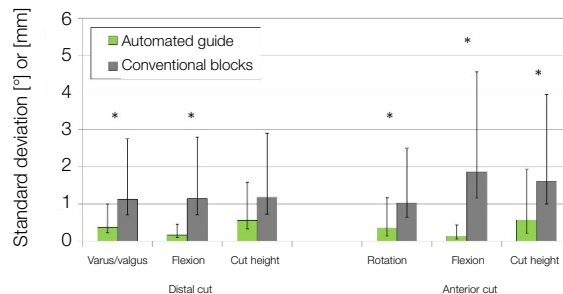
Methods Bilateral cadaver study comparing the OMNIBot to conventional block navigation in 12 knees.

Results

Increased accuracy and precision in robotic group:

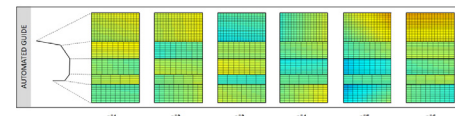
- Guide positioning (0.55° vs 1.1° SD varus, $p < 0.03$)
- Bone cuts (mean error: 0.6mm vs 1.4mm, $p = 0.01$)
- Final implant placement (1.0° vs 2.2° SD varus, $p = 0.11$),
- Faster than freehand navigation of multiple blocks.

Guide positioning precision

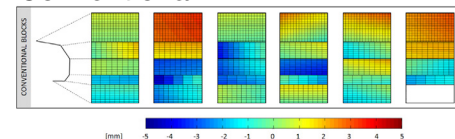


Accuracy of bone cut surfaces
Distance between measured and planned cutting planes (mm)

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. 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 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.

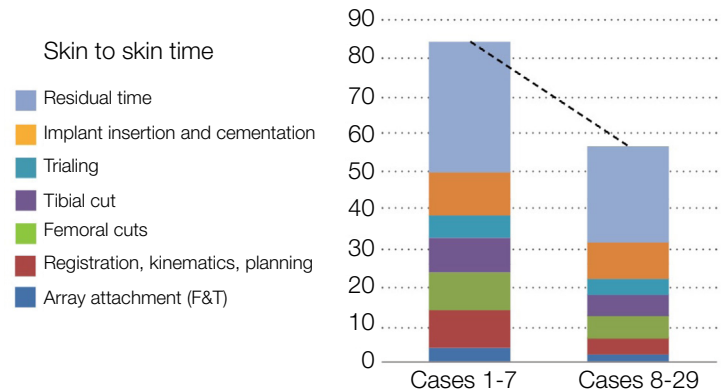


Fig 1. Skin to skin time decreased from 84min to 57min ($p=0.0008$) after 7 cases.

OmniBotics®



OMNIBotics Reference Papers

1. [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](#)
2. [Koenig JA, Plaskos C. Total Knee Arthroplasty Technique: OMNIBotics. In Robotics in Knee and Hip Arthroplasty: Current Concepts, Techniques and Emerging Uses. Ed. Lonner JH. Springer 2019](#)
3. [Shalhoub S, Moschetti WE, Dabuzhsky L, Jevsevar DS, Keggi JM, Plaskos C. Laxity Profiles in the Native and Replaced Knee-Application to Robotic-Assisted Gap-Balancing Total Knee Arthroplasty. J Arthroplasty. 2018 Sep;33\(9\):3043-3048.](#)
4. [Figueroa F, Wakelin E, Twiggs J, Fritsch B. Comparison between navigated reported position and postoperative computed tomography to evaluate accuracy in a robotic navigation system in total knee arthroplasty. Knee. 2019 Aug;26\(4\):869-875](#)
5. [Hernández-Vaquero D. et al. The Use of PS or CR Models is not Suf-ficient to Explain the Differences in the Results of Total Knee Arthroplas-ty. Study of Interactions. British Journal of Medicine and Medical Research, 2016, 12\(8\):1-9.](#)
6. [Martín-Hernández C. et al. Navigated versus conventional total knee arthroplasty: A prospective study at three years follow-up. Rev Esp Cir Ortop Traumatol. 2018 Mar 28.](#)
7. [Martín-Hernández C. et al. Does the medial-lateral stability of total knee replacements have an effect on short-term clinical outcomes? One-year results of a multicentre study with computer assisted surgery. Rev Esp Cir Ortop Traumatol. 2014 Mar-Apr;58\(2\):101-7.](#)
8. [Clark TC, Schmidt FH. Robot-assisted navigation versus computer-as-sisted navigation in primary total knee arthroplasty: efficiency and accuracy. ISRN Orthop. 2013;794827.](#)
9. [Nam D, Maher PA, Rebolloledo BJ, Nawabi DH, McLawhorn AS, Pearle AD. Patient specific cutting guides versus an imageless, computer-assisted surgery system in total knee arthroplasty. Knee. 2013 Aug;20\(4\):263-7.](#)
10. [Suero EM, Plaskos C, Dixon PL, Pearle AD. Adjustable cutting blocks improve alignment and surgical time in computer-assisted total knee re-placement. Knee Surg Sports Traumatol Arthrosc. 2012 Sep;20\(9\):1736-41.](#)
11. [Koulalis D, O'Loughlin PF, Plaskos C, Kendoff D, Cross MB, Pearle AD. Sequential versus automated cutting guides in computer-assisted total knee arthroplasty. Knee. 2011;18\(6\):436-442.](#)
12. [Koulalis D, O'Loughlin PF, Plaskos C, Kendoff D, Pearle AD. Ad-justable cutting blocks for computer-navigated total knee arthroplasty - A cadaver study. J Arthroplasty. 2010 Aug;25\(5\):807-11.](#)
13. [Suero EM, Citak M, Claps C, Pearle AD, Plaskos C. Variations in ankle registration using two different anatomic landmarks: a radiographic study. Knee Surg Sports Traumatol Arthrosc. 2013 Dec;21\(12\):2759-63.](#)
14. [Hodgson AJ, Plaskos C. Robotics in orthopedic surgery: proven versus predicted benefits of commercially available systems. In Robotic Surgery: Applications and Advances, Eds. D Kendoff, AD Pearle. Future Medicine Ltd. March 2013, Pages 134-149](#)
15. [Plaskos C, Koenig JA, Ponder CE. Robotic-assisted knee replacement surgery. In Medical Robotics: Minimally Invasive Surgery. Edited by P. Gomes. Woodhead Publishing Ltd, Cambridge, UK, 2012 pp 113-158](#)

Notes

Corin

Connected Orthopaedic Insight

Distributed by Corin

The Corinium Centre
Cirencester, GL7 1YJ, UK
t: +44 (0)1285 659 866
f: +44 (0)1285 658 960
e: info@coringroup.com
w: www.coringroup.com

Manufacturer

OMNLife science Inc.
480 Paramount Drive
Raynham, MA 02767

™ Trademarks and ® Registered marks of OMNlife Science, Inc.
©2020 OMNlife Science, Inc. All Rights Reserved. NL-005 Rev 08/20