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The evidence base

Corin
Connected Orthopaedic Insight

Dynamic Balance
Plan. Implement. Learn.



Contents

Balance and Alignment

1. Balance is difficult to reproduce manually, and standardization is needed
2. Robotic ligament balance correlates with better outcomes, less pain
3. Balance has a greater impact on outcomes than alignment does
4. Fewer releases with predictive balancing
5. Alignment strategies that rely on bone anatomy alone lead to unacceptable variability in laxity
6. Alignment contributes more towards laxity variability than implant design does
7. Multiple alignment strategies are possible with Corin Robotics - a) MR vs GB, b) rKA vs GB, c) iKA vs GB

Accuracy

8. The BalanceBot can accurately predict and achieve post-op ligament balance
9. The BalanceBot Improves ligament balance compared to standard robotic surgery
10. The OMNIBot improves boney resection accuracy compared to manual surgery
11. OMNIBot and BalanceBot deliver accurate component positioning

Satisfaction and Survivorship

12. Excellent clinical and patient reported outcomes with Corin Robotics
13. 99.5% Survivorship at 6 years

ROI

14. Increased ROI for healthcare system with improved QALY and reduced revision rate
15. Cost saving of \$2085 with Corin Robotics in a bundled episode of care setting
16. Increased ROI for hospitals, with reduced manipulation rates and higher procedural volume

Ease of Use

17. Short learning curve and high patient satisfaction during learning phase
18. Minimal operative and storage footprint

Balance and Alignment

1. Balance is difficult to reproduce manually, and standardization is needed

Title	Arthroplasty Surgeons Differ in Their Intraoperative Soft Tissue Assessments: A Study in Human Cadavers to Quantify Surgical Decision-making in TKA
Authors	Shady SS, Sculco PK, Kahlenberg CA, Mayman DJ, Cross MB, Pearle AD, Wright TM, Westrich GH, Imhauser CW
Publication	Clin Orthop Relat Res. 2022 Aug 1;480(8):1604-1615

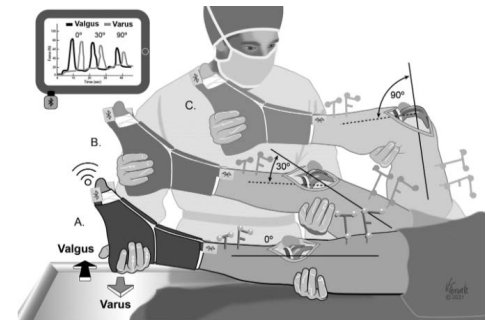
Methods In seven cadavers, five knee surgeons with varying levels of experience and one chief orthopaedic resident independently evaluated soft tissue balance at different flexion angles and selected polyethylene inserts based on their assessments. Pliable force sensors measured the applied loads, a 3D motion capture system recorded knee kinematics, and dynamic analysis software estimated medial and lateral gaps. The study aimed to determine whether surgeons applied different moments, assessed different gaps, and whether applied moments were associated with insert thickness choice.

Results The applied moments differed among surgeons, with the largest mean differences occurring in varus in midflexion (16.5 Nm; $p = 0.02$) and flexion (7.9 Nm; $p < 0.001$).

The measured gaps differed among surgeons at all flexion angles, with the largest mean difference occurring in flexion (1.1 ± 0.4 mm; $p < 0.001$).

In all knees except one, the choice of insert thickness varied by 1 mm among surgeons.

Conclusion Subjective soft tissue assessment yielded 1 to 2 mm of variation in their choice of insert thickness. Therefore, developers of tools to standardize soft tissue assessment in TKA should consider controlling the force applied by the surgeon to better control for variations in insert selection.



Balance and Alignment

2.a Robotic ligament balance correlates with better outcomes, less pain

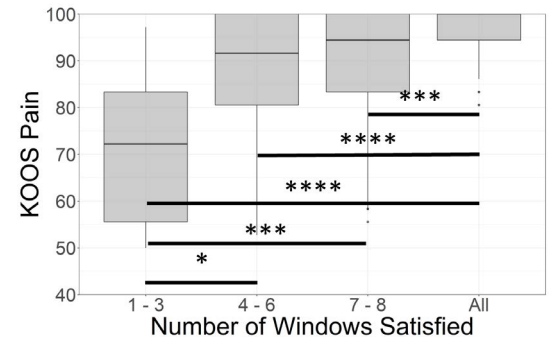
Title	Intra-Operative Laxity and Balance Impact 2-Year Pain Outcomes in TKA: A Prospective Cohort Study
Authors	Wakelin EA, Ponder CE, Randall AL, Koenig JA, Plaskos C, DeClaire JH, Lawrence JM, Keggi JM
Publication	Knee Surg Sports Traumatol Arthrosc. 2023 Oct 14

Methods

A prospective study investigating 310 robotically assisted TKAs was performed. Final intra-operative joint gap data were recorded using a digital tensioner and component alignment data were recorded by the robotics system. Patient demographics and KOOS/HSS satisfaction were recorded at 2 years post-op. A random search Simulated Annealing (SANN) optimization algorithm was used to determine global optimum laxity and balance windows at different flexion angles which maximized the 2-year KOOS pain scores. The windows were combined to determine the impact of achieving optimal laxity and balance throughout flexion.

Results

Nine laxity and balance windows were defined: Extension (Med lax: -2.0 to 2.5 mm, Lat lax: -0.5 to 2.5 mm, Balance: -3.0 to 0.0 mm), mid-flexion (Med lax: -1.0 to 2.5 mm, Lat lax: -0.5 to 3.0 mm, Balance: -2.0 to 2.0 mm), and flexion (Med lax: -2.0 to 3.5 mm, Lat lax: -2.0 to 1.5 mm, Balance: -3.0 to 3.0 mm). When all windows were satisfied, the greatest difference in KOOS pain score was observed (100.0 vs 94.4, $p < 0.0001$). The highest percentage of knees satisfying the Patient Acceptable Symptom State (PASS) for KOOS pain was also observed in knees which satisfied all windows compared to knees which did not (93% vs 71%, $p = 0.0009$).



Conclusion

Intra-operatively measured joint gaps are associated with all KOOS sub-score outcomes at 2 years after TKA.

Balance and Alignment

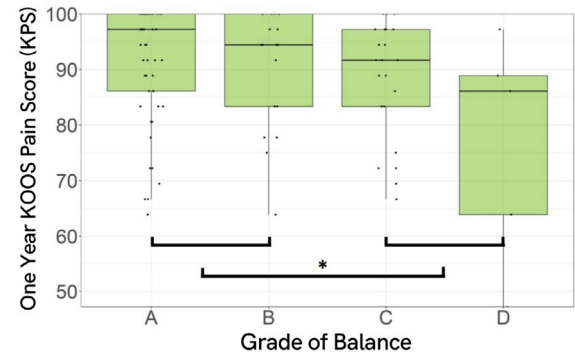
2.b Robotic ligament balance correlates with better outcomes, less pain

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 The data of 134 consecutive patients enrolled in a prospective trial was reviewed. Each TKA was graded according to the final recorded mediolateral ligament 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 a higher grade of balance (A and 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.

Balance and Alignment

2.c Robotic 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](#)

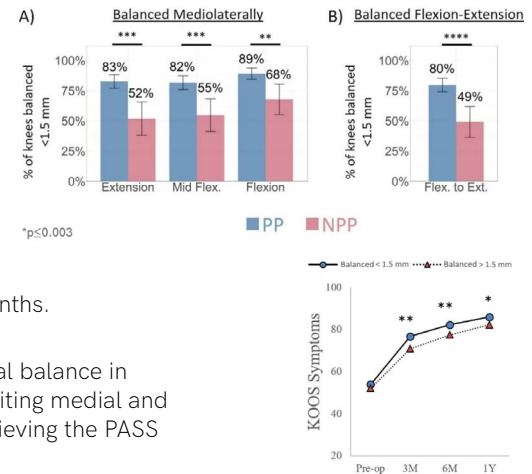
Methods 280 patients were prospectively enrolled and followed up at 3, 6, and 12 months post-operatively. Patients were divided into those in which a Predictive Plan with the BalanceBot was used (PP) and those in which it was not (NPP). Optimal balance difference between PP and NPP was defined and compared 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 scores were observed in knees balanced within 1.5mm across all sub-scores at various 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.

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.



Balance and Alignment

3. Balance has a greater impact on outcomes than alignment does

Title	Impact of Component Alignment and Soft Tissue Release on 2-Year Outcomes in Total Knee Arthroplasty.
Authors	J.M. Vigdorchik, E.A. Wakelin, J.A. Koenig, C.E. Ponder, C. Plaskos, J.H. DeClaire, J.M. Lawrence, J.M. Keggi
Publication	J Arthroplasty. 2022 Oct;37(10):2035-2040

Methods

In a multicenter study, soft tissue releases during TKA were prospectively documented in 330 robotic-assisted TKAs. Knee Injury and Osteoarthritis Outcome Scores (KOOS) were captured postoperatively. Delphi analysis was used to determine inlier and outlier component alignment boundaries:

Table 2
Outlier Boundaries: Results of Delphi Analysis of 6 Fellowship Trained Orthopedic Surgeons.

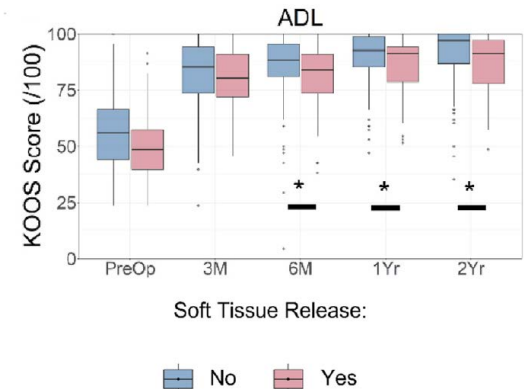
Angle	'Inlier' Range
Tibial Coronal	$\pm 3^\circ$
Femoral Coronal	$\pm 3^\circ$
Femoral Axial	3° Int to 6° Ext
Tibiofemoral Coronal	3° Valgus to 4° Varus
Tibiofemoral Axial	3° Int to 6° Ext

Results

No significant differences were found between any individual or grouped inlier and outlier alignment criterion and KOOS at any timepoint. A higher proportion of patients achieved Minimal Clinically Important Difference for pain at 6 months for those having no releases versus released (92.3% versus 81.0%, $p = 0.021$). No significant associations were found between preoperative deformity and preoperative or postoperative KOOS.

Conclusion

The addition of soft tissue releases after bony cuts is associated with worse KOOS scores out to 2 years and was more prevalent in knees with worse deformity, while no such association was found for alignment.



Balance and Alignment

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.

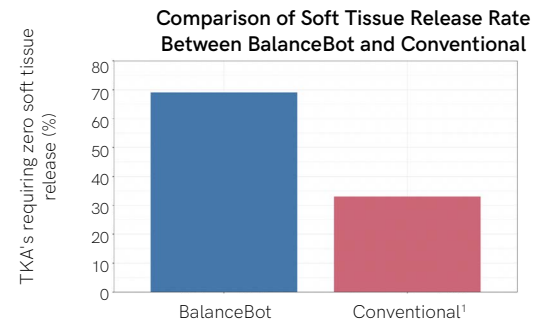


Table 1. Percentage of knees with no releases

	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

Balance and Alignment

5. Alignment strategies that rely on bone anatomy alone lead to unacceptable variability in laxity

Title Laxity, Balance, and Alignment of a Simulated Kinematic Alignment Total Knee Arthroplasty

Authors Edelstein AI, Wakelin EA, Plaskos C, Suleiman LI

Publication [Arthroplast Today. 2023 Sep 18:23:101204](#)

Methods

We used data from 382 robot-assisted TKA performed with a digital joint tensioner to simulate TKA with a pure resurfacing KA technique for both femur and tibia. All knees had the posterior cruciate ligament retained. Knees were subdivided into 4 groups based on preoperative coronal alignment: valgus, neutral, varus, and high varus. Medial and lateral laxity in extension and flexion, balance in extension and flexion, and coronal plane alignment were compared between groups using analysis of variance testing.

Results

In simulated pure resurfacing KA TKA across a range of preoperative coronal plane deformities, only 11%-31% of knees would have mediolateral extension ligament balance within ± 1 mm, and 20%-41% would have a medial flexion gap that is looser than the lateral flexion gap. Over 45% of knees would have coronal hip-knee ankle angle >3 degrees from mechanical neutral.

Breakdown of coronal balance distribution in extension according to preoperative coronal deformity.

Balance (M-L)	Valgus ($<-3^\circ$)	Neutral ($\pm 3^\circ$)	Varus ($>3^\circ$)	High varus ($>10^\circ$)
± 1 mm	31%	13%	19%	11%
± 2 mm	63%	30%	43%	31%
± 3 mm	81%	43%	57%	51%
M > L	56%	21%	13%	17%

Conclusion

In simulations of pure resurfacing KA TKA, there was wide variability in the resulting laxity and alignment outcomes. Most knees had alignment and balance outcomes outside of normally accepted ranges. Techniques that deviate from pure resurfacing in order to achieve balance appear favorable.

Balance and Alignment

6. Alignment contributes more towards laxity variability than implant design does

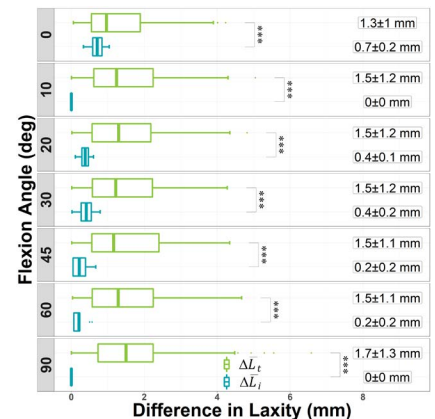
Title Midflexion Laxity in TKA: Alignment Matters, Implant Choice Does Not.
Authors Forlenza E, Orsi AD, Plaskos C, Slotkin E, Kreuzer S, Karas V
Publication ISTA Conference 2023

Methods Ligament balance data was collected using a robotic ligament tensioner at a static tensioning force of 70-90N in 154 consecutive TKAs. A tibia-first resection technique and a single-radius cruciate-retaining implant was used for all cases. Simulation software was used to virtually replace the single-radius with a multi-radius design of equivalent size, by aligning the implants to have equivalent gaps at 10° and 90° flexion. Two alignment techniques were assessed by aligning the implants in gap balanced (GB) and measured resection (MR) positions.

Results Technique had a greater contribution to mean laxity variability compared to the implant design at 0° (1.3 ± 1 vs. 0.7 ± 0.2 mm, $p < 0.001$), 20° (1.5 ± 1.2 vs. 0.4 ± 0.2 mm, $p < 0.001$), 30° (1.5 ± 1.2 vs. 0.4 ± 0.2 mm, $p < 0.001$), 45° (1.5 ± 1.1 vs. 0.2 ± 0.2 mm, $p < 0.001$), and 60° (1.5 ± 1.1 vs. 0.2 ± 0.2 mm, $p < 0.001$). Single-radius implant laxity was 0.7 mm looser at full extension and 0.4 mm tighter in midflexion compared to the multi-radius design.

MR had greater lateral ML imbalance compared to GB in extension (-0.7 ± 3.1 vs 0.1 ± 1 mm, $p < 0.01$), midflexion (-1.4 ± 2.7 vs -0.4 ± 1 mm, $p < 0.001$), and flexion (-2 ± 2.9 vs -0.4 ± 0.9 mm, $p < 0.001$).

Laxity Difference for Technique (MR vs GB) and Implant (Single vs Multi-Radius)



Conclusion Alignment technique contributes more towards laxity and balance variability than implant design. Implant geometry has no effect on ML balance variability. The laxity variability from alignment technique was similar to the variability measured from the arthritic knee population. Greater consideration should be given to alignment technique than implant geometry when achieving balance in TKA.

Balance and Alignment

7.a Multiple alignment strategies are possible with Corin Robotics - MR vs GB

Title Predictive Gap-balancing Reduces the Extent of Soft-tissue Adjustment Required After Bony Resection in Robot-assisted Total Knee Arthroplasty - A Comparison With Simulated Measured Resection.

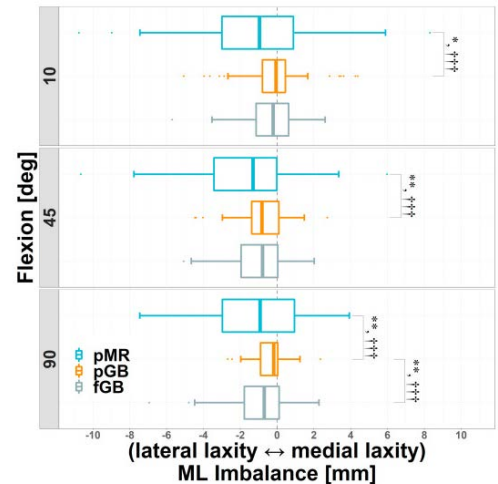
Authors Orsi AD, Wakelin EA, Plaskos C, Gupta S, Sullivan JA

Publication [Arthroplast Today. 2022 May 20:16:1-8](#)

Methods Two surgeons performed 95 robot-assisted GB total knee arthroplasties with predictive balancing, limiting tibial varus to 3° and adjusting femoral positioning to optimize balance. A robotic ligament tensioner measured joint laxity. Planned MR (pMR) was simulated by applying neutral tibial and femoral coronal resections and 3° of external femoral rotation. ML balance, laxity, component alignment, and resection depths were compared between planned GB (pGB) and pMR. ML balance and laxity were compared between pGB and final GB (fGB).

Results The proportion of knees with >2 mm of ML imbalance in flexion or extension ranged from 3% to 18% for pGB vs 50% to 53% for pMR ($p < 0.001$). Rates of ML imbalance >3 mm ranged from 0% to 9% for pGB and 30% to 38% for MR ($p < 0.001$). The mean pMR laxity was 1.9 mm tighter medially and 1.1 mm tighter laterally than pGB throughout flexion. The mean fGB laxity was greater than the mean pGB laxity by 0.5 mm medially and 1.2 mm laterally ($p < 0.001$).

Conclusion MR led to tighter joints than GB, with ML gap imbalances >3 mm in 30% of knees. GB planning improved ML balance throughout flexion but increased femoral posterior rotation variability and bone resection compared to MR. fGB laxity was likely not clinically significantly different than pGB.



Balance and Alignment

7.b Multiple alignment strategies are possible with Corin Robotics - rKA vs GB

Title Restricted kinematic alignment achieves similar relative lateral laxity and greater joint line obliquity compared to gap balancing TKA.

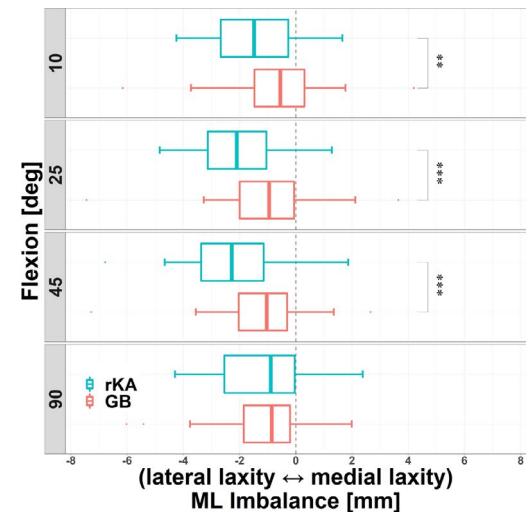
Authors Orsi AD, Wakelin EA, Plaskos C, Petterwood J, Coffey S

Publication [Knee Surg Sports Traumatol Arthrosc. 2022 Sep;30\(9\):2922-2930](#)

Methods One surgeon performed 68 rKA, another performed 73 GB TKAs using the same CR implant and robotic system. rKA limited femoral valgus and tibial varus to 6°, with tibial recuts performed to achieve balance. GB limited tibial varus and femoral valgus to 2°, with femoral resections adjusted to achieve mediolateral balance throughout flexion using predictive-gap planning software. Final joint laxity was measured using a robotic ligament tensioner. Statistical analyses were performed to compare differences in mediolateral balance and joint laxity throughout flexion. Further analyses compared alignment, joint line elevation and orientation (JLO), and frequency of ligament releases and bone recuts.

Results Both techniques reported greater lateral laxity throughout flexion, with GB reporting improved mediolateral balance from 10° to 45° flexion. GB resected 1.7 mm more distal femur ($p \leq 0.001$) and had greater overall laxity than rKA throughout flexion ($p \leq 0.01$). rKA increased JLO by 2.5° and 3° on the femur and tibia ($p \leq 0.001$). Pre-operative and post-operative coronal alignment were similar across both techniques. rKA had a higher tibial recut rate: 26.5% vs 1.4%, $p < 0.001$.

Conclusion rKA and GB both report lateral laxity but with different JLO and elevation. Use of a predictive-gap GB workflow resulted in greater mediolateral gap symmetry with fewer recuts.



Balance and Alignment

7.c Multiple alignment strategies are possible with Corin Robotics - iKA vs GB

Title Restricted Inverse Kinematic Alignment Better Restores the Native Joint Line Orientation While Achieving Similar Balance, Laxity, and Arithmetic Hip-Knee-Ankle Angle to Gap Balancing Total Knee Arthroplasty.

Authors Orsi AD, Wakelin EA, Plaskos C, McMahon S, Coffey S

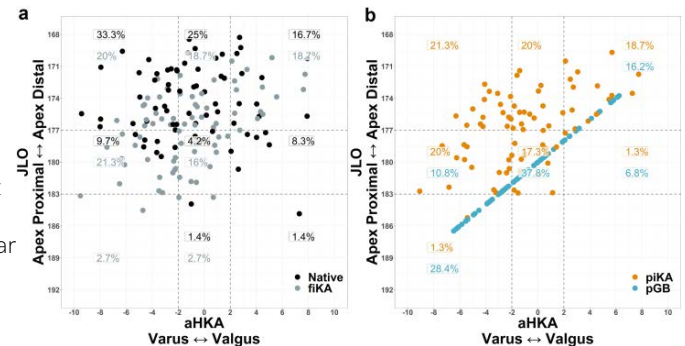
Publication [Arthroplast Today. 2023 Jan 16;19:101090](#)

Methods

Two surgeons performed 75 robot-assisted iKA total knee arthroplasties. A digital joint tensioner collected laxity data throughout flexion before femoral resection. The femoral component position was determined using predictive gap-planning to optimize the balance throughout flexion. Planned gap balancing (pGB) simulations were performed for each case using neutral tibial resections. Mediolateral balance, laxity, and CPAK were compared among pGB, planned iKA (piKA), and final iKA (fiKA).

Results

Both piKA and pGB had similar mediolateral balance and laxity, with mean differences <0.4 mm. piKA had a lower mean absolute difference from native JLO than pGB ($3 \pm 2^\circ$ vs $7 \pm 4^\circ$, $p < 0.001$). aHKA was similar ($p < 0.05$) between pGB and piKA. piKA recreated a more native CPAK distribution, with types I-V being the most common ones, while most pGB knees were of type V, VII, and III. Final iKA and piKA had similar mediolateral balance and laxity, with a root-mean-square error <1.4 mm.



Conclusion

Although balance, laxity, and aHKA were similar between piKA and pGB, piKA better restored native JLO and CPAK phenotypes. The neutral tibial resection moved most pGB knees into types V, VII, and III. Surgeons should appreciate how the alignment strategy affects knee phenotypes.

Accuracy

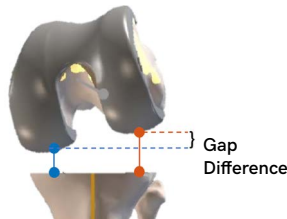
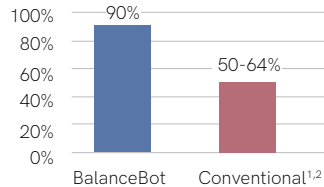
8. The BalanceBot™ can accurately predict and achieve post-op ligament balance

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	Arthroplast Today. 2019 Sep; 5(3): 334-340

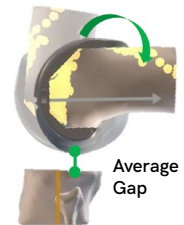
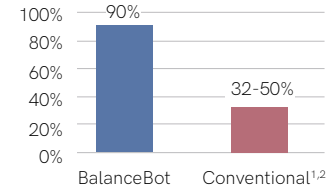
Methods A robotic-assisted ligament tensioning technique was utilised in 121 sequential knees. Predictive gap profiles were used to plan femoral implant position to achieve a balanced knee. Final gap profiles were then compared to the predictive gap plans.

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.

Accuracy

9. The BalanceBot™ Improves ligament balance compared to standard robotic surgery

Title	Impact of a Digital Balancing Tool on Femur and Tibial First Total Knee Arthroplasty: A Prospective Nonrandomized Controlled Trial.
Authors	Koenig JA, Wakelin EA, Passano B, Shalhoub S, Plaskos C
Publication	Arthroplast Today. 2022 Sep 22;17:172-178

Methods

One-hundred six patients had posterior cruciate ligament sacrificing total knee arthroplasty using a digital joint tensioner. The participants were divided into 4 groups with different visibility to balance data

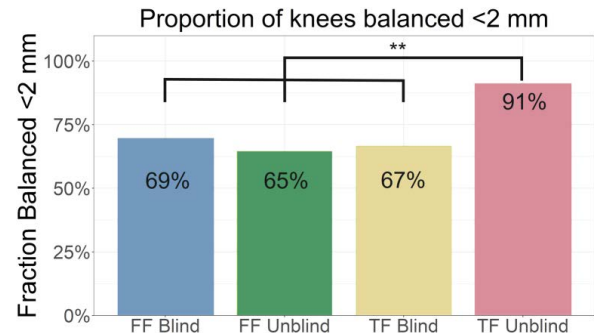
- 1) Femur-first blinded data,
- 2) Femur-first not blinded data,
- 3) Tibia-first blinded data,
- 4) Tibia-first not blinded data with predictive balancing.

Results

Group 4 reported less midflexion imbalance (40°) compared to all other groups (1: 1.5 mm, 2: 1.7 mm, 3: 1.6 mm, 4: 1.0 mm, $p < 0.031$) and reduced variance compared to all other groups at 40° and 90° ($p < 0.012$), resulting in an increased frequency of joints balanced within 2 mm throughout flexion in group 4.

Conclusion

Improvements in balance were observed in midflexion instability and balance variability throughout flexion when a tibia-first approach in combination with a digital balancing tool was used. The combination of a digital balancing tool and a tibia-first approach allowed a target joint balance to be achieved more accurately compared to a non-sensor augmented or femur-first approach.



Accuracy

10. The OMNIBot™ improves boney resection accuracy compared to manual surgery

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 [Knee. 2011 Dec;18\(6\):436-42](#)

Methods

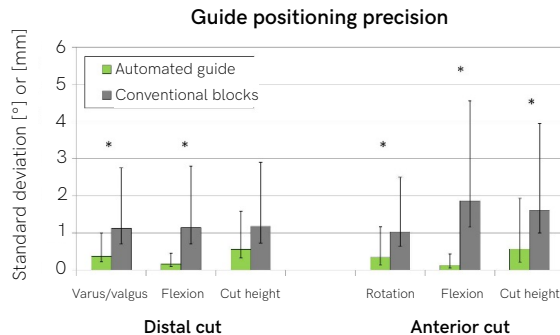
Bilateral cadaver study comparing the OMNIBot to conventional block navigation in 12 knees.

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, $p = 0.01$)

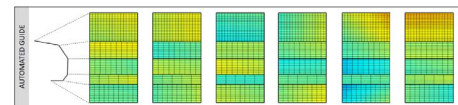
- Final implant placement (1.0° vs 2.2° SD varus, $p = 0.11$),
- Faster than freehand navigation of multiple blocks.



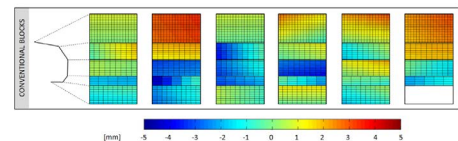
Accuracy of bone cut surfaces

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.

Accuracy

11. OMNIBot™ and BalanceBot™ deliver accurate component positioning

Title	Comparison of CT with intra-operative navigation reported implant position utilizing a robotic assisted technique in total knee arthroplasty
Authors	Sharma N, Berera V, Petterwood J
Publication	Med Eng Phys. 2022 Oct;108:103881

Methods

We evaluated 87 patients (92 knees) undergoing robotic assisted TKA. Position estimated by the navigation software and postoperative CT scan were compared. Post-operative CT scans were interpreted by a senior radiologist blinded to intra-operative component position. Recorded were femoral varus/valgus, tibial varus/valgus and overall limb alignment in the coronal plane. In the sagittal plane tibial slope and femoral flexion/extension. Femoral component rotation was assessed in relation to the transepicondylar axis (TEA).

Results

Mean difference between software estimation and postoperative CT scan of the femoral component position in the coronal plane was 1.02° (0.86–1.18, 95%CI). Tibial coronal position was 1.19° (0.97–1.41). Sagittal plane component position for the femur was 1.64° (1.41–1.87). Tibial slope was 1.44° (1.21–1.68). Mean femoral component rotation was 1.27° (1.01–1.53). Overall 94.57% of intraoperative measures were within 3° of the component position measured on CT.

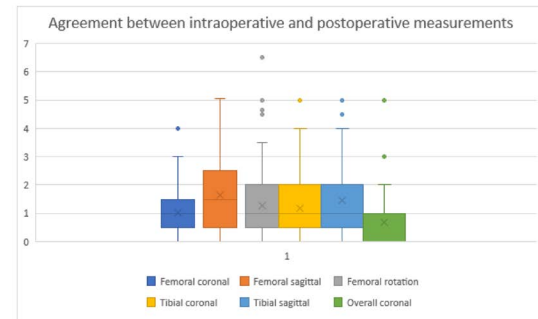


Fig. 1. Box and whisker plot of agreement between intraoperative estimation of component position and postoperative CT measurement.

Conclusion

Robotic assisted navigation used in combination with a novel balancing system can result in very accurate component positioning during total knee arthroplasty.

Satisfaction and Survivorship

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

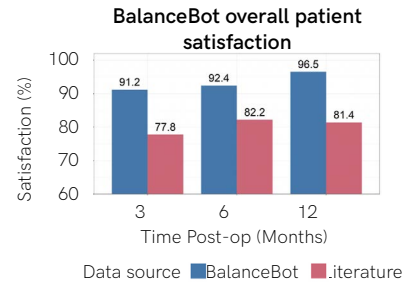
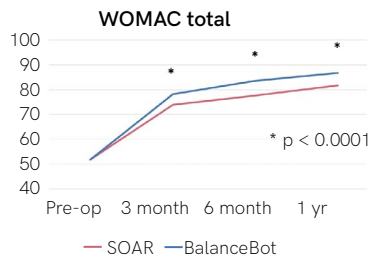


12.a Excellent clinical and patient reported outcomes with Corin Robotics

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.

Satisfaction and Survivorship

12.b Excellent clinical and patient reported outcomes with Corin Robotics

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 Dec;141\(12\):2155-2164](#)

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 than average KSS expectation fulfillment at 3M reported significantly higher KSS satisfaction scores at 1Y, and patients with greater than average 6M expectation fulfillment reported improved satisfaction at 1Y and 2Y. When compared to the FORCE-TJR database, significant differences in post-operative KOOS outcomes were observed for Sports and Recreation, for which the RAS group demonstrated higher scores. 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 dissatisfaction rates were 2.9%, 1.0%, 0.0% and 1.3% at 3, 6, 12, and 24 months postoperatively, respectively.

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.

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)

Satisfaction and Survivorship

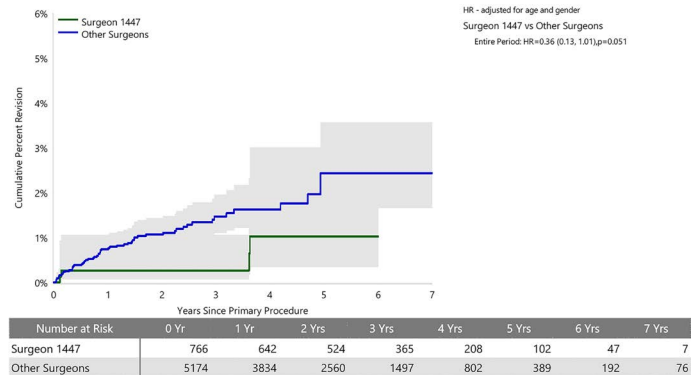
13. 99.5% Survivorship at 6 years

Title Robotic-assisted total knee arthroplasty with the OMNIBot™ platform: a review of the principles of use and outcomes.
Authors Shartrov J, Murphy GT, Duong J, Fritsch B
Publication [Arch Orthop Trauma Surg. 2021 Dec;141\(12\):2087-2096](#)

Methods Materials and methods A literature review was conducted using the PRISMA guidelines. Thirteen papers were included for the final review.

Results The OMNIBot is an accurate and consistent delivery tool in TKA surgery and compares favourably to instrumented, navigation-assisted and patient-specific cutting guides. The OMNIBot has been shown to be a reliable tool for delivering different alignment philosophies as well as planning and achieving tibio-femoral coronal balancing. The utility of the system is increased when the robot is used in conjunction with a soft-tissue tensioning device—the BalanceBot. Survival analysis of RATKA using the OMNIBot is limited to one study which reported 99.26% survivorship at 3 years. We report our own outcomes using the OMNIBot, having performed 766 TKA's using the OMNIBot, since 2014 with 99.48% survivorship at 6 year follow-up.

Conclusion The OMNIBot platform is an imageless, passive robotic system available since 2007, with over 30,000 TKA's being performed with its assistance. It has a small physical footprint, is relatively inexpensive and time efficient. Our review demonstrates a high level of precision of the surgical planning, with a modestly improved accuracy compared to conventional and navigation technology.



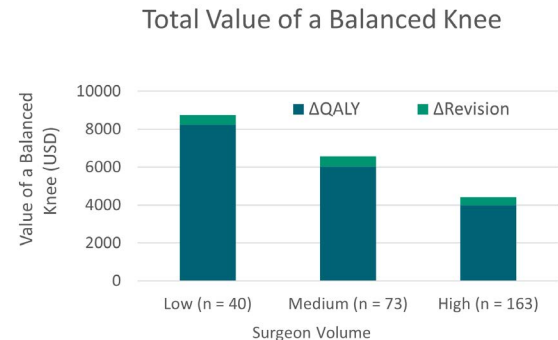
ROI

14. Increased ROI for healthcare system with improved QALY and reduced revision rate

Title What is the Value of a Balanced Total Knee Arthroplasty? Getting It Right the First Time.
Authors Lee GC, Smith GH, Wakelin EA, Garino JP, Plaskos C
Publication [J Arthroplasty. 2023 Jun;38\(6S\):S177-S182](#)

Methods A Markov model was developed to determine the value from reduced revisions and improved outcomes associated with TKA joint balance. Patients were modeled for the first 5 years following TKA. The threshold to determine cost-effectiveness was set at an incremental cost effectiveness ratio of \$50,000/quality-adjusted life year (QALY). A sensitivity analysis was performed to evaluate the influence of QALY improvement (Δ QALY) and Revision Rate Reduction on additional value generated compared to a conventional TKA cohort.

Results The total value of a balanced knee for the first 5 years was \$8,750, \$6,575, and \$4,417 per case, for low, medium, and high-volume surgeons, respectively. Change in QALY accounted for greater than 90% of the value gain with a reduction in revisions making up the rest in all scenarios. The economic contribution of revision reduction was relatively constant regardless of surgeon volume (\$500/case).



Conclusion Achieving a balanced knee had the greatest impact on Δ QALY over early revision rate. These results can help assign value to enabling technologies with joint balancing capabilities.

ROI

15. Cost saving of \$2085 with Corin Robotics in a bundled episode of care setting

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

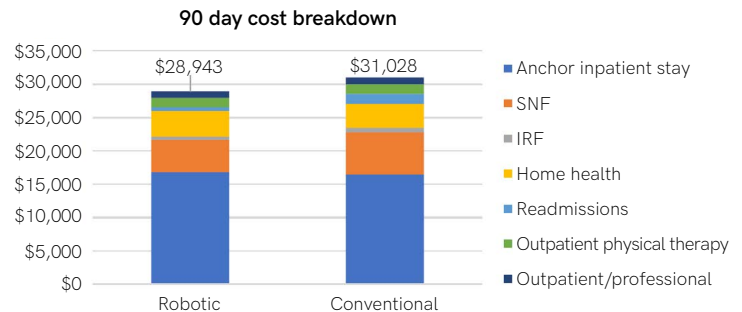


Title Total Knee Arthroplasty Technique: OMNIBotics®.
Authors Koenig JA, Plaskos C
Publication [In Robotics in Knee and Hip Arthroplasty: Current Concepts, Techniques and Emerging Uses. Ed. Lonner JH. Springer 2019](#)

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.



ROI

16. Increased ROI for hospitals, with reduced manipulation rates and higher procedural volume

*1st Place winner of the 2019 DOCSF Innovation Award

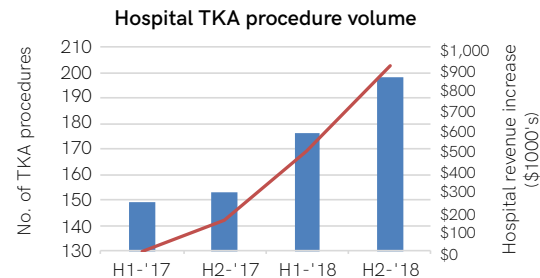
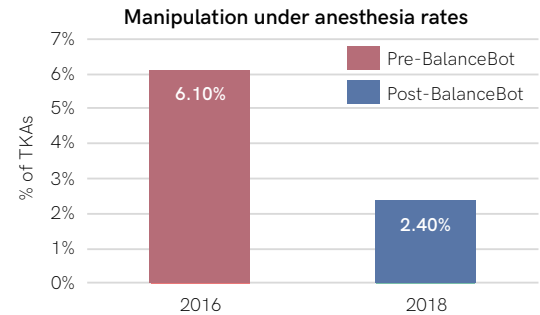


Title	OMNIBotics® BalanceBot™ case study.*
Authors	Plaskos C, Gill PS, Lawrence JM
Publication	DOCSF - Digital Orthopaedics Conference, San Francisco, 2019

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.

Ease of Use

17. 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 JM, 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.

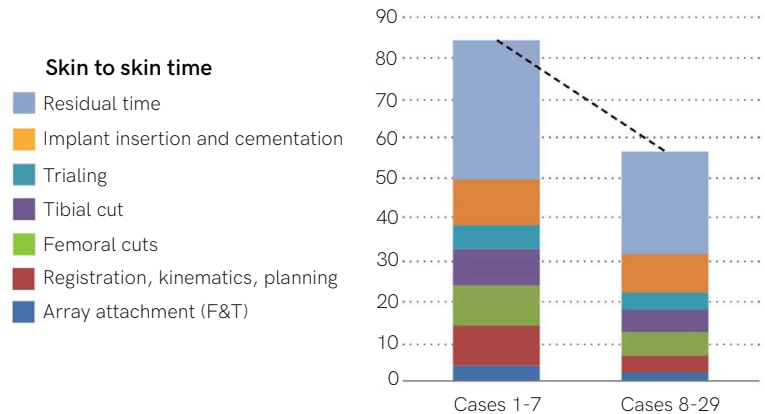


Fig 1. Skin to skin time decreased from 84min to 57min ($p=0.0008$) after 7 cases.

Ease of Use

18. Minimal operative and storage footprint

Title	A Comparison of Robotic-Assisted Systems' Footprint in the OR
Authors	Corin Internal Study
Publication	Data on file at Corin Group LTD (NL-011)

Methods

This analysis compares the OMNIBotics overall operating room 2D footprint, sterile field 2D footprint and surgical access 2D footprint to the Stryker MAKO and Depuy Synthes VELYS Robotic-assisted TKA systems. The 2D footprint is defined as the sum of the projection of each component in the worst-case scenario clinically relevant position.

- The Overall Operating Room footprint includes all robotic components and stations used in the procedure
- The Sterile Field footprint includes all robotic components and stations used within the sterile field
- The Surgical Access footprint includes all robotic components in direct contact with the patient.

For the OMNIBotics station, only one robotic component would be in contact with the patient at a time. As a worst-case, the OMNIBot (being the larger of the two) is used for this measurement

Results

Company (Robotic System)	Surgical Access Footprint (in ²)	Sterile Field Footprint (in ²)	Overall OR Footprint (in ²)
Stryker (MAKO) ³	1715	1715	4064
Depuy (VELYS) ⁴	336	1165 (w/ satellite station) 436 (w/o satellite station)	1816
Corin (OMNIBotics)	54.3	71.5	395.5

Robotic System	Surgical Access Footprint (in ²)	Sterile Field Footprint (in ²)	Overall OR Footprint (in ²)
MAKO	97%	96%	90%
VELYS	84%	94% (w/ satellite station) 84% (w/o satellite station)	78%

Conclusion

The OMNIBotics systems consists of compact, handheld robotic components and is substantially smaller than major competitive systems, Stryker MAKO and Depuy Synthes VELYS. The compactness of the system is expected to reduce OR inefficiencies and its portability will allow the OR station to transfer it from OR to OR and potentially maximize utilization.

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OPT-REC-MK-94 Rev 1