# VELYS™ Robotic-Assisted Solution – Evidence Summary

**Version 2 - Updated January 2025**

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Johnson&Johnson MedTech

Orthopaedics

# Accuracy

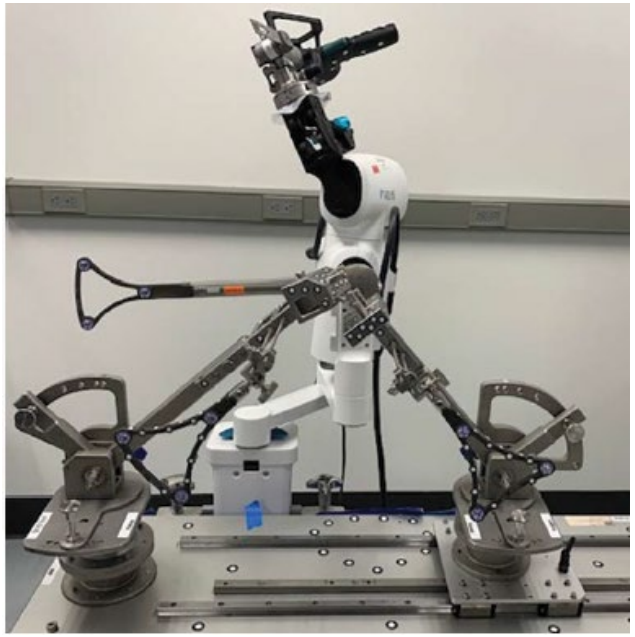
# Benchtop Positional Accuracy Assessment of a Robotic-Assisted Surgical System Using Digital Image Correlation

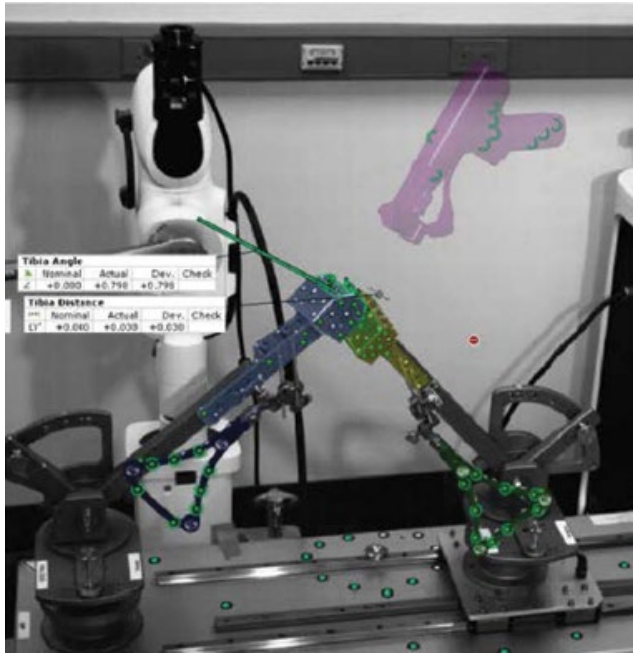
[1]Mote et al., ORS 2021. Paper No. 1078

An Accuracy Test Bench represented single leg anatomy, defining anatomical landmark locations (pre-operative) and respective cut planes (postoperative). Optical measurement was used to track position of the saw handpiece and saw blade during pseudo bone cuts on the test bench.

Overall pooled linear positional accuracy of 0.33±0.25 mm and angular position accuracy of 0.36±0.61°.

In this test the VELYS™ Robotic-Assisted Solution shows high level of linear and angular accuracy





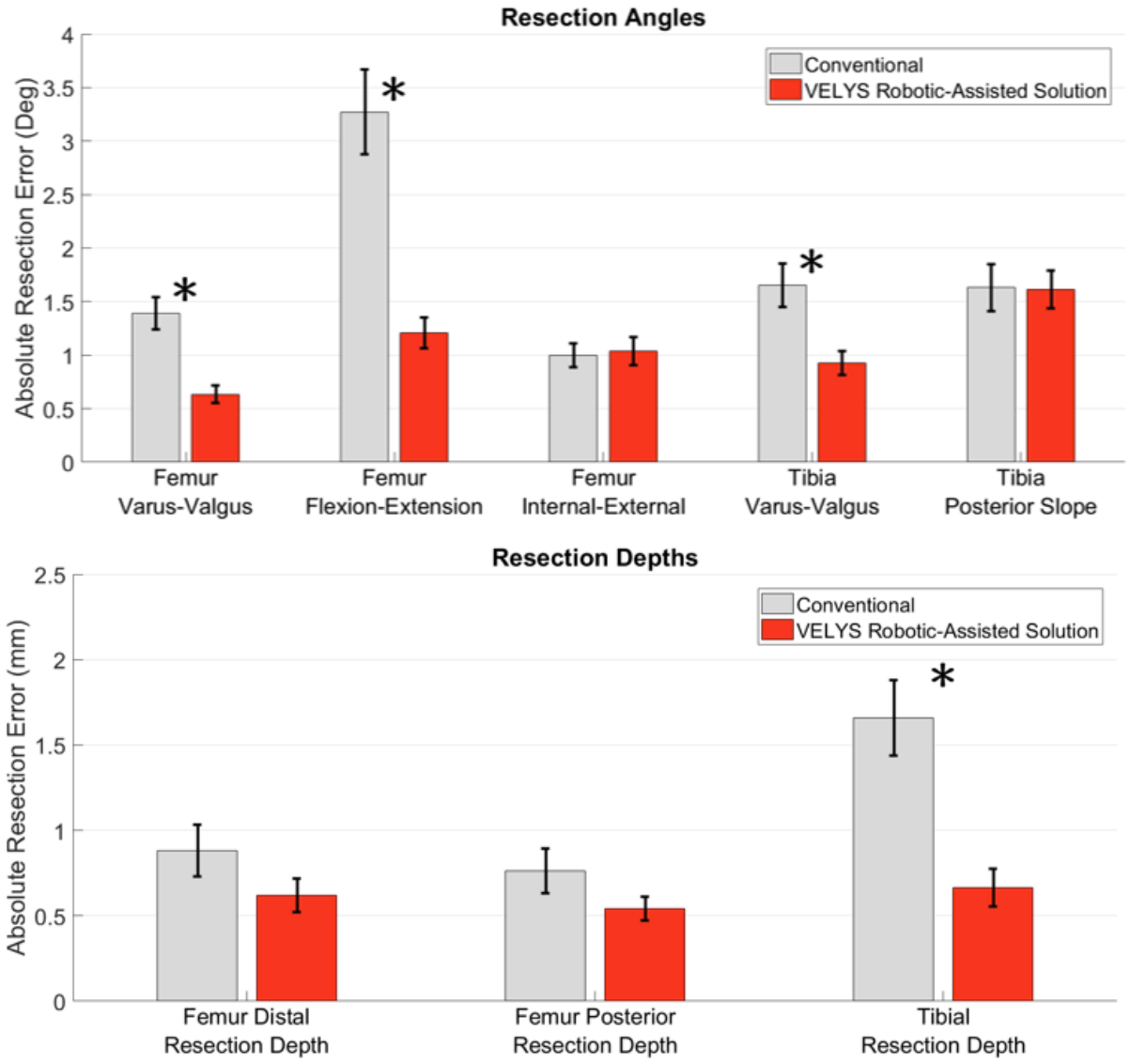
# Image-Free Robotic-Assisted Total Knee Arthroplasty Improves Implant Alignment Accuracy: A Cadaveric Study

[2]Doan et al., 2022.

N=40 Cadavers (80 Knees), N=5 Orthopedic Surgeons.

CT and White-Light Scan (measures of accuracy) were independent of the coordinate system of the VELYS™ Robotic-Assisted Solution, unlike some previous assessments of Robotic System accuracy.

The results of this study demonstrated the ability of a robotic-assisted surgical system to improve the coronal implant alignment during TKA, which may help surgeons more consistently achieve their surgical plan and reduce surgical outliers.






Total Knee Arthroplasty (TKA) | Proximal (Prox) | Distal (Dist) | Anterior (Ant) | Posterior (Post) | *Indicates statistically significant difference, two sample t-test, p-value <0.05.

# Improvement in Primary Resection Accuracy with Image Free Robotic Assisted Total Knee Arthroplasty.

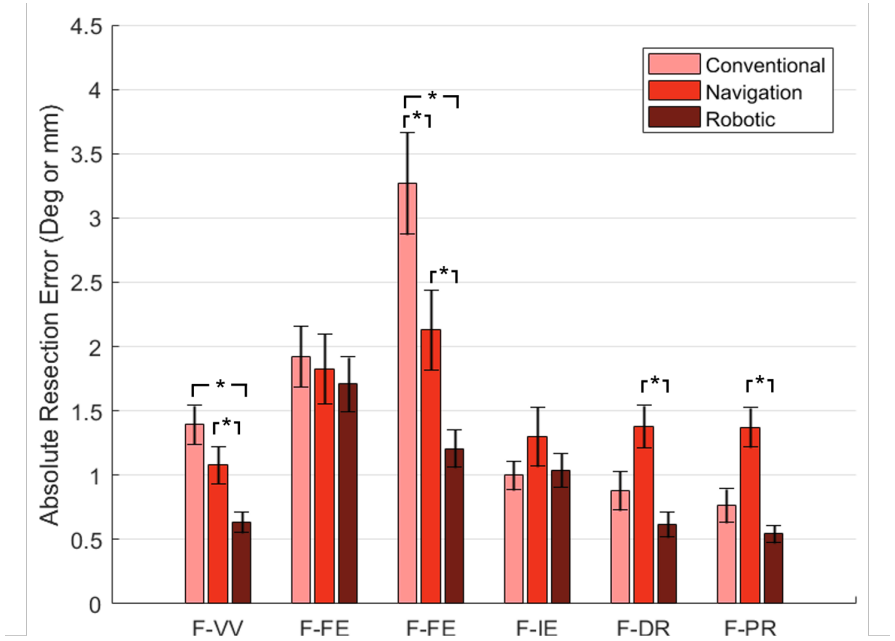
**[3]Doan et al., CAOS 2022.**

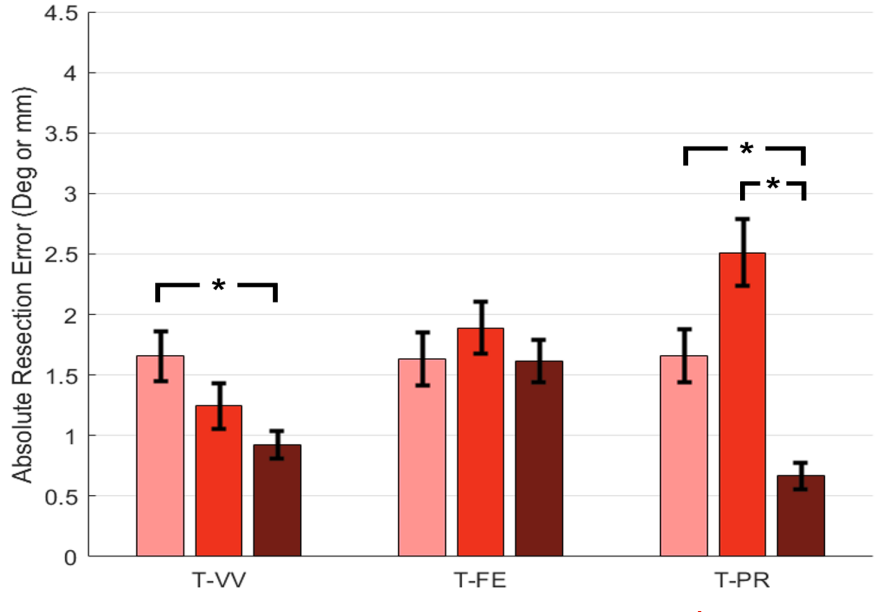
N=18 Cadavers (36 knees), N=4 Orthopaedic Surgeons. Navigation performed on all 36 knees. Similar measurement and analysis techniques as cadaveric accuracy study (Doan et al., JoA 2022). Resection accuracy of VELYS™ Robotic-Assisted Solution (rTKA) and mTKA with Navigation compared.

rTKA was superior or non-inferior to all resection metrics. Statistically significant improvements with rTKA compared to navigation for:

- Femur Varus-Valgus Alignment ($p = 0.005$)
- Femur Flexion-Extension Alignment ($p = 0.005$)
- Femur Distal and Posterior Resection Thickness ( $p < 0.001$)
- Tibia Proximal Resection Thickness ($p < 0.001$)

This study demonstrates the resection accuracy of VELYS™ Robotic-Assisted Solution with notable improvements in resection thickness allowing surgeons to consistently execute the plan and avoid unnecessary bone loss.

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# Image-Free Robotic-Assisted Total Knee Arthroplasty Improves Implant Alignment Accuracy: A Cadaveric Study

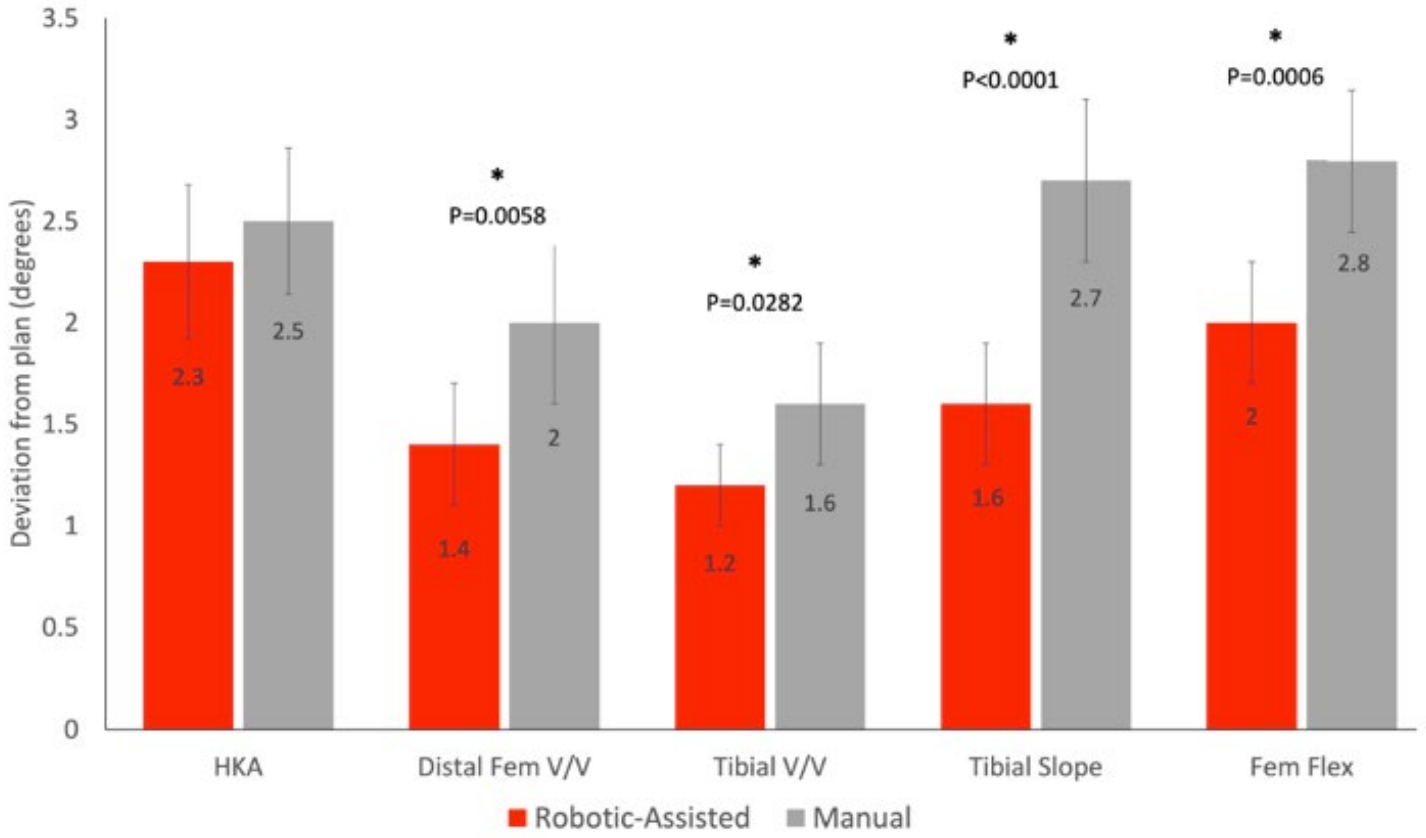
**[4]Alton et al., BOA, 2024. Poster No.376**

U.S. Multi-Center, prospective non-randomized 1:1 cohort study of 200 patients (100 Robotic-Assisted, 100 Manual) studying early outcomes during the adoption phase.

Accuracy to plan assessed on long leg radiographs.

First VELYS™ Robotic-Assisted Solution cases at each site - representative of adoption phase.

The accuracy of the individual bone resections was improved compared to manual surgery.



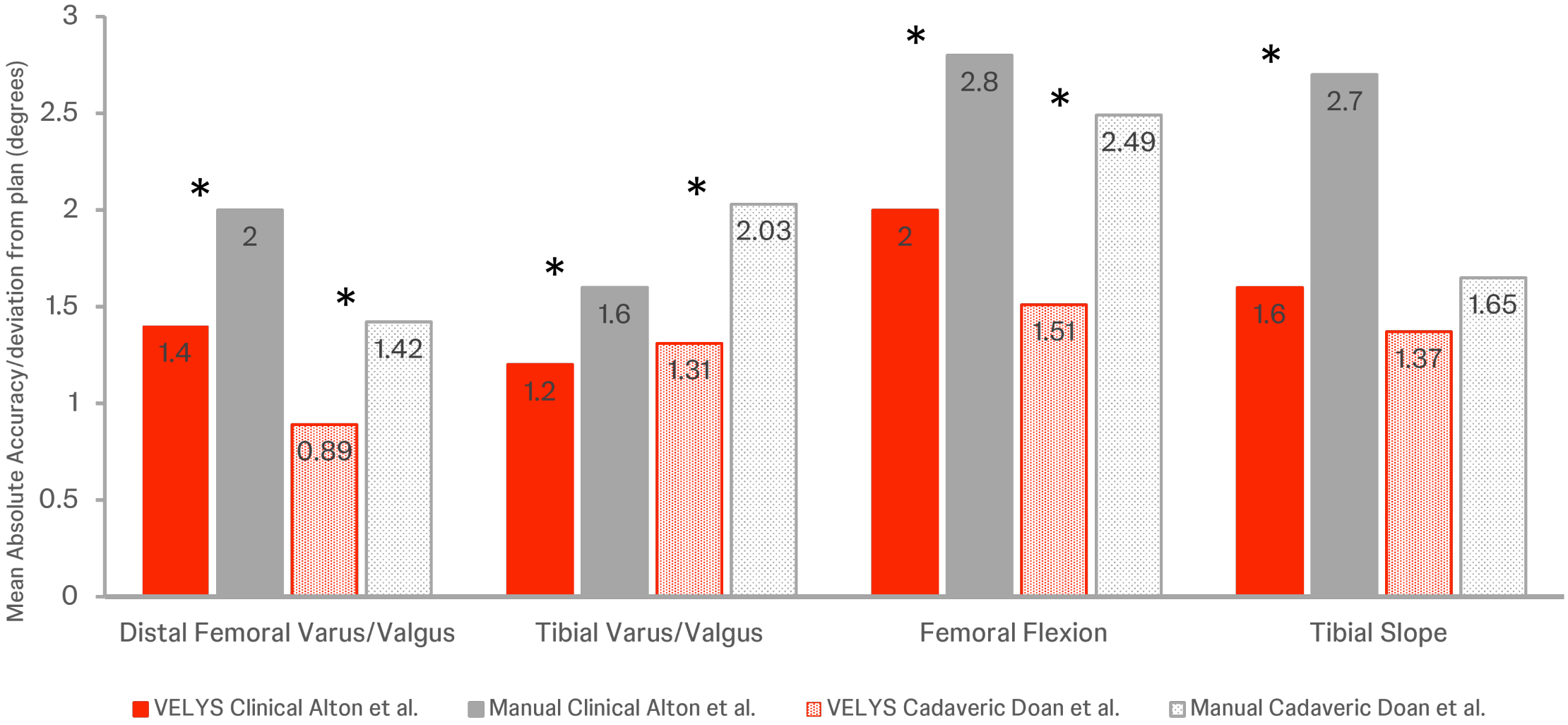

Mean Accuracy to plan of Robotic-Assisted and Manual. Error bars +/-95% CI



Hip Knee Ankle Angle (HKA) | Femoral (Fem) | *Indicates statistically significant difference, p-value <0.05.

# Good agreement between cadaveric and clinical assessments of accuracy

**[2]Doan et al., 2022 | [4]Alton et al., 2024. Poster No.376**




*Indicates statistically significant difference, p-value <0.05.

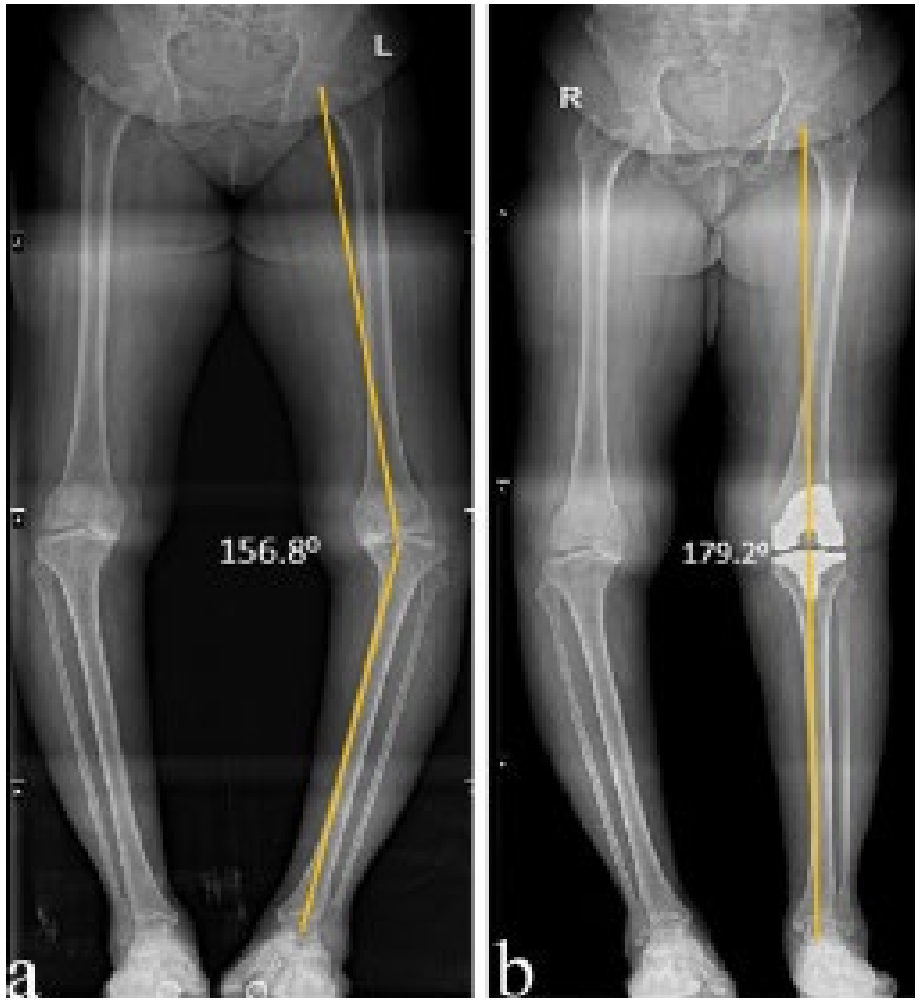
# Comparison of imageless robotic-assisted total knee arthroplasty and conventional total knee arthroplasty: early clinical and radiological outcomes of 200 knees

**[5]Rajasekaran et al., 2024**

Retrospective cohort study on 200 consecutive knees undergoing TKA (100 robotic, 100 conventional TKA) between January 2022 and February 2023.

“The number of HKA, LDFA and tibial slope outliers were 31, 29 and 37, respectively, in the conventional group compared to 13, 23 and 17 in the robotic group ($p < 0.01$).”

“Radiologically robotic TKA showed better accuracy and consistency with fewer outliers compared with conventional TKA”.




Long leg film from hip to ankle showing bilateral osteoarthritis of knees with severe varus deformity of the both knees (HKA of 153° in the right side and 149° in the left side) **b** Postoperative long leg film showing correction of deformity by imageless robotic TKA



Total Knee Arthroplasty (TKA) | Hip Knee Ankle Angle (HKA) | Lateral Distal femoral Angle (LDFA)

# Accuracy Of A Novel Imageless Guided Robotic System Using Patient Specific Alignments

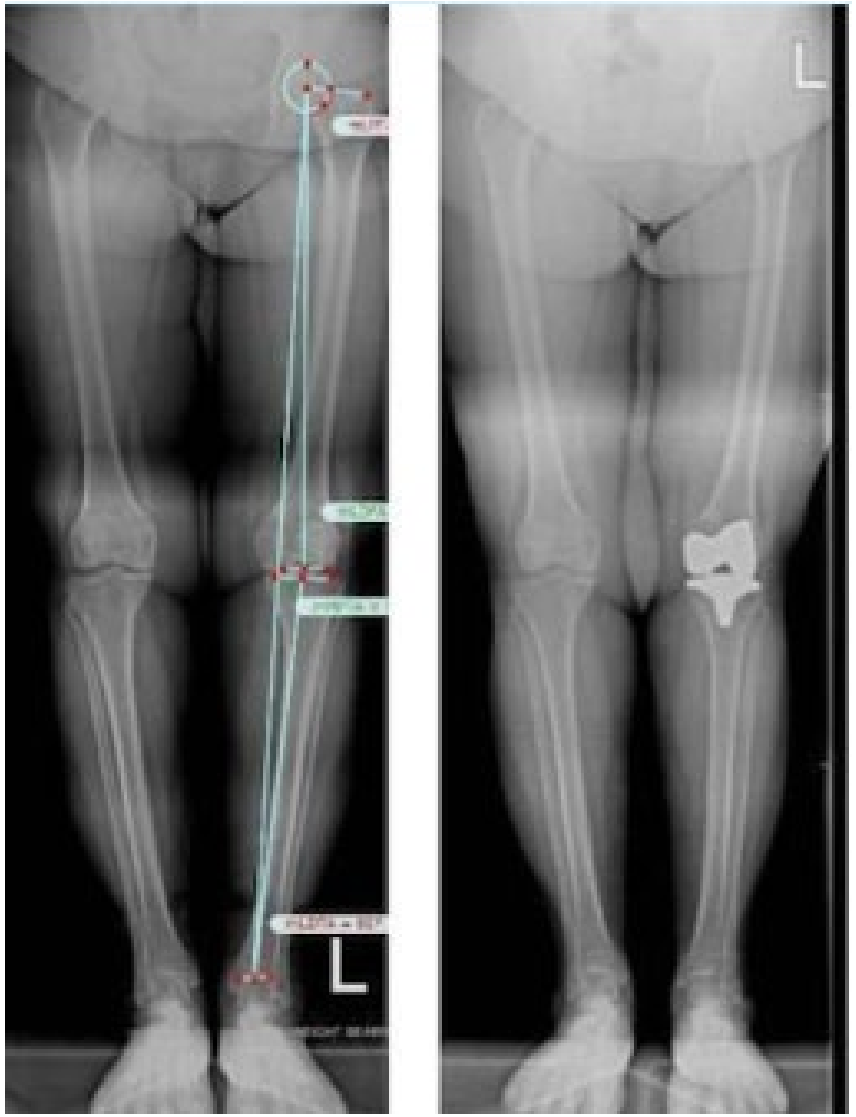
[6]Hallak et al. EFORT, 2024. Poster No. 337

| Measurement | Mean difference Vs. Plan |
|---|---|
| Lateral Distal Femoral Angle | 0.14° ± 1.80° |
| Medial Proximal Tibial Angle | 0.79° ± 1.29° |
| aHKA | 0.66° ± 2.16° |

Prospective study of 105 patients who underwent TKA between January 2022 and July 2023.

To examine “the accuracy of bony resections using a novel imageless robotic arm system to achieve patient specific alignment (PSA)”.

The use of an “imageless navigation robotic-assisted TKA system to achieve PSA conferred with high accuracy of bony cuts for both MPTA and LDFA with adequate coronal alignment postoperatively.”




Preoperative (A) and postoperative (B) full-length standing AP radiographs



Total Knee Arthroplasty (TKA) | Hip Knee Ankle Angle (HKA) | Lateral Distal femoral Angle (LDFA) | | Medial proximal Tibial Angle (MPTA) | Anterior-to-Posterior (AP)

# Robotic-Assisted Total Knee Arthroplasty Improves Accuracy and Reproducibility of the Polyethylene Insert Thickness Compared to Manual Instrumentation or Navigation: A Retrospective Cohort Study

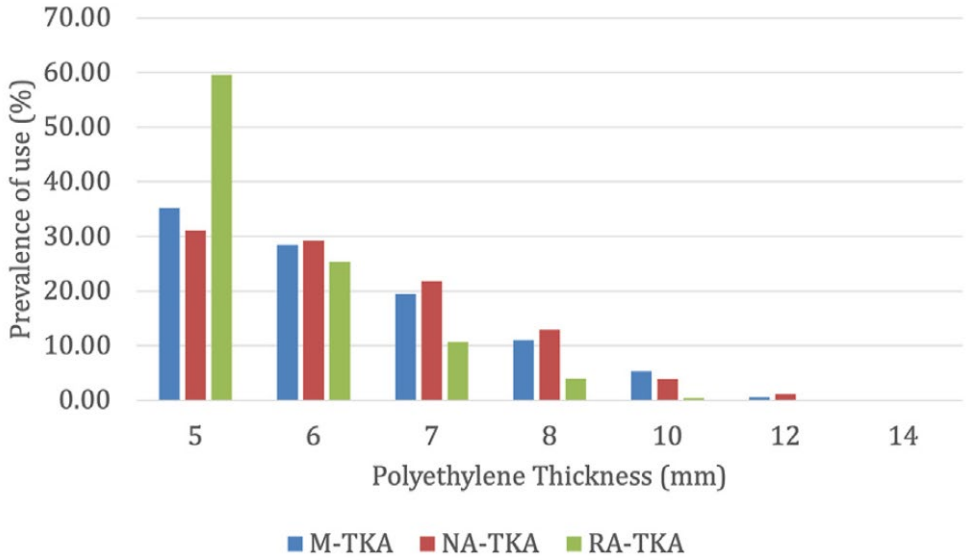
**[7]Bourgeault-Gagnon et al., 2024**

Single Surgeon retrospective cohort study of 956 patients (474 manual, 257 Navigated (KNEE3) and 225 VELYS™ Robotic-Assisted Solution).

Accuracy to planned PE thickness is more reproducible in robotic-assisted than in navigated-assisted or manual instrumentation TKA , and prevalence of outliers were lower for VELYS™ Robotic-Assisted Solution compared to Navigation and Manual. First 30 VELYS™ Robotic-Assisted Solution cases show a greater mean PE thickness per case.

Accuracy assessment of the different techniques used.

| Polyethylene thickness | M-TKA | NA-TKA | RA-TKA | P-value |
|---|---|---|---|---|
| Number of outliers ≥ 9 mm (%) | 28 (5.9) | 13 (5.1) | 1 (0.4) | 0.004* |
| Mean deviation from planned thickness (SD), mm | 1.3 (1.4) | 1.4 (1.4) | 0.6 (0.9) | ≤ 0.001* |




Polyethylene thicknesses prevalence. M_TKA, manual instrumentation total knee arthroplasty; NA_TKA, navigation-assisted total knee arthroplasty; RA_TKA, robotic-assisted total knee arthroplasty.



Polyethylene (PE) | Manual Total Knee Arthroplasty (M-TKA) | Navigation Total Knee Arthroplasty (NA-TKA) | Robotic-Assisted Total Knee Arthroplasty (RA-TKA) | |*Indicates statistically significant difference, p-value <0.05.

# Learning Curve

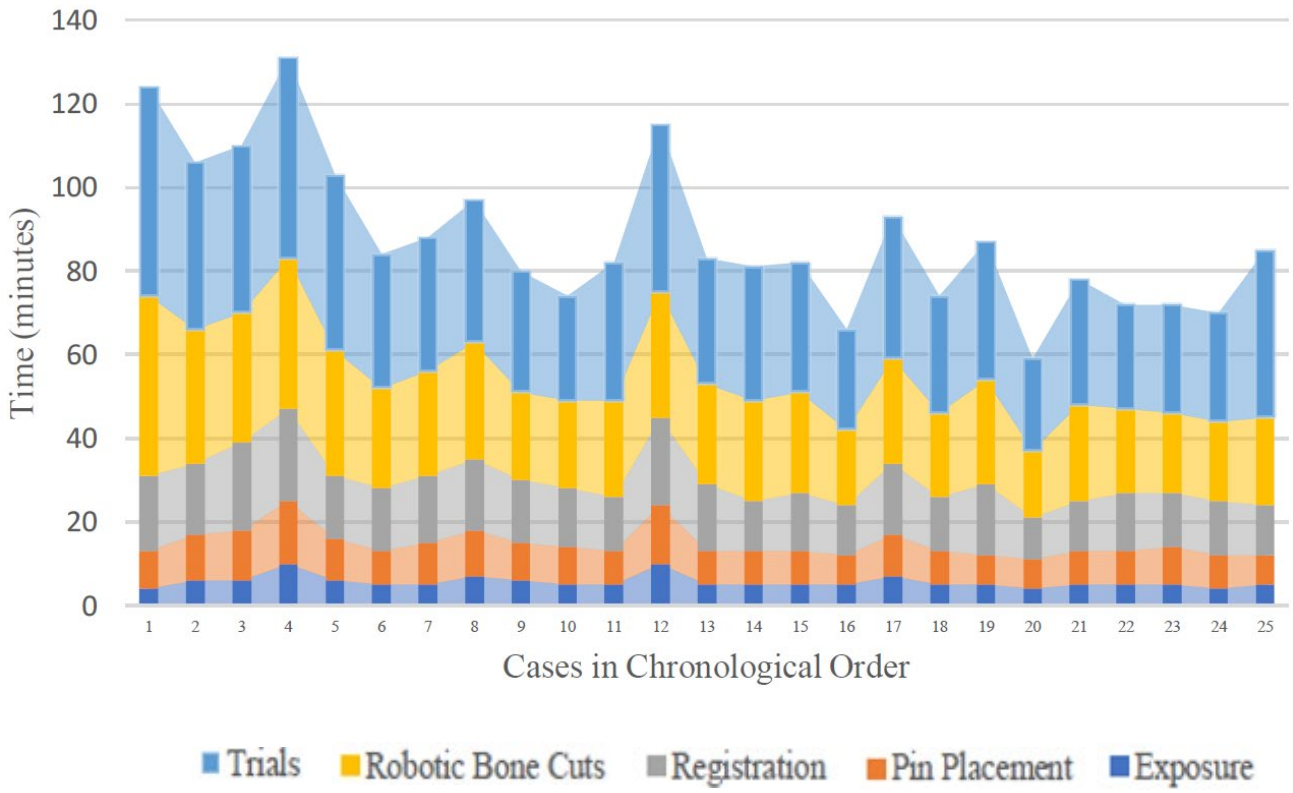
# Learning Curve for VELYS™ Robotic-Assisted TKA System

[8]Lall et al., ORAS 2023. Paper No. 1677

Prospective Observational Study of 25 patients. Based on a single U.S surgeon's learning curve.

"Our study found that the learning curve for adopting the VELYS™ Robotic-Assisted TKA system was approximately 15 cases, a number that is 25% less than those reported in similar studies with other RATKA platforms."

Operative Stage Times in 25 Individual Chronologically Sorted Cases



# The Learning Curve in Robotic-Assisted Total Knee Arthroplasty: A Single Surgeon Cohort

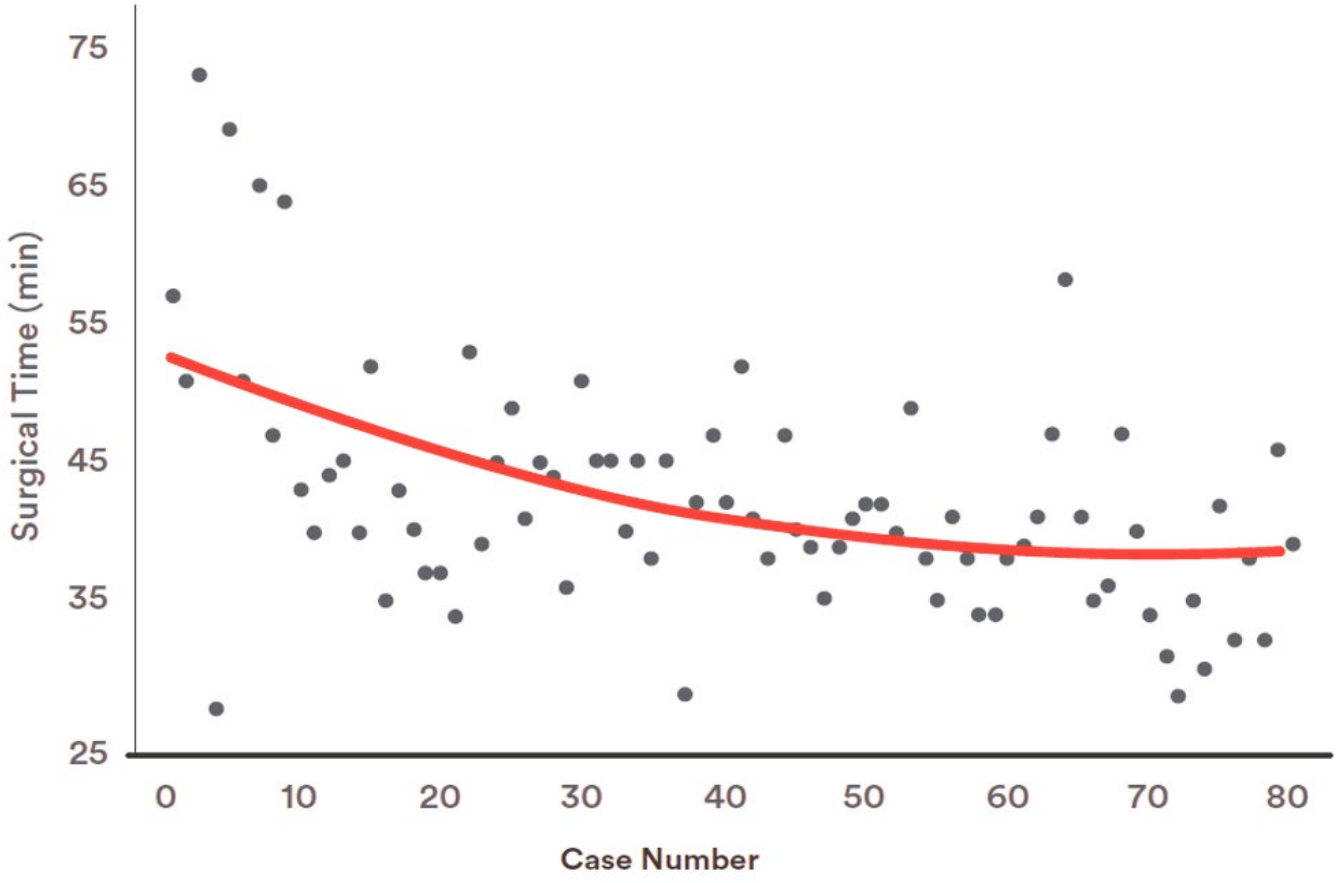
**[9]Pagan et al., CCJR, 2022.**

The first 80 robotic-assisted TKA and 80 manual TKA cases of a single US surgeon were assessed.

The main proficiency gain was within the first 10 cases but improvements in efficiency were continued to be made as the process was optimized out to 60 cases and beyond.

Last 20 RA-TKA cases had a mean surgical time of 38.5 mins.

VELYS™ robotic-assisted TKA is a “surgical tool which can be integrated efficiently with a rapid learning curve of 10 cases”




Surgical Time plotted chronologically by case number [21]

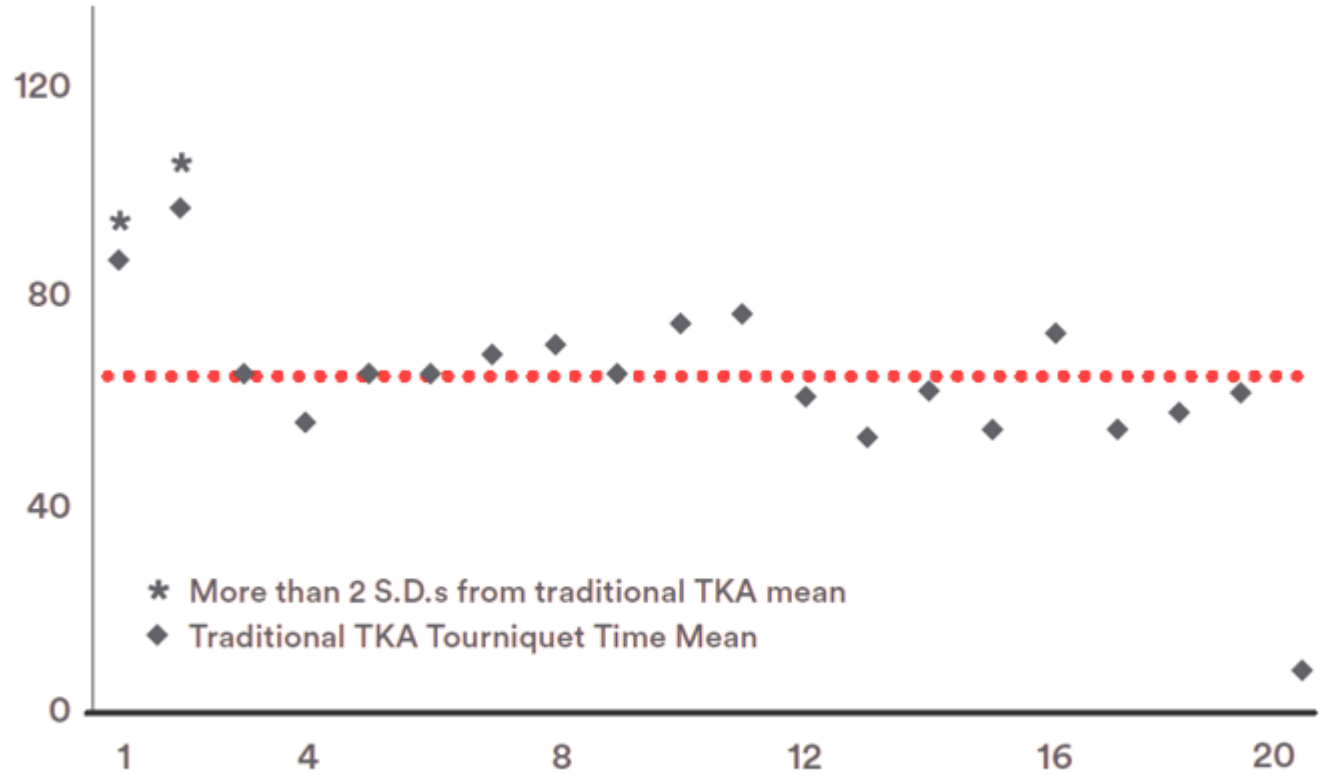
# Transition to Robotic Total Knee Arthroplasty With Kinematic Alignment Is Associated With a Short Learning Curve and Similar Acute-Period Functional Recoveries

**[10]Morrisey et al., 2023**

Single U.S surgeon retrospective review of 99 traditionally instrumented TKA and 66 robotic TKA (VELYS™ Robotic-Assisted Solution) between January 2021-October 2021 and October 2021-April 2022.

"Surgery times with the robotic system were similar to traditional instrumentation after the first two surgeries performed. Tourniquet times from robotic surgeries three through 10 were no different from surgeries 11 through 66".

The learning curve of VELYS™ robotic-assisted solution was "shorter than previous research on the transition to robotic TKA".



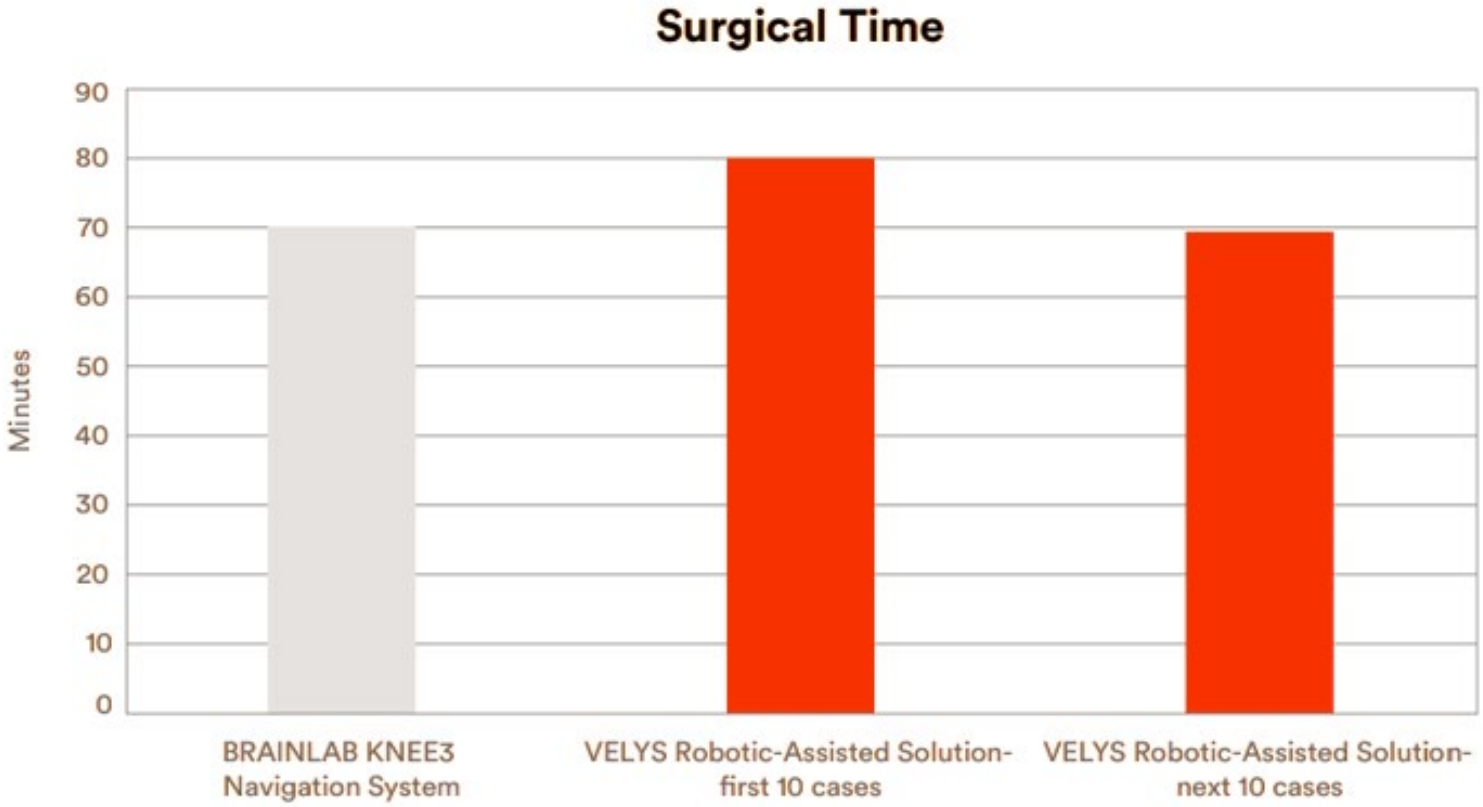

**First 20 VELYS™ Robotic-Assisted Solution TKA tourniquet time mean**

# Patient-Specific TKA with the VELYS™ Robotic-Assisted Solution

[11]**Clatworthy et al., 2022**

Prospective study comparing the last 45 cases using Navigation (Brainlab KNEE3 Navigation system) to the first 45 cases using VELYS™ Robotic-Assisted Solution for TKA.

"There was no difference in the surgical skin-to-skin time. The mean VRAS time for the second 10 cases was 10.7 minutes faster than the first 10 cases and was equivalent to navigation TKA time, indicating time neutral surgery with VRAS was quickly achieved."



# Early Clinical Outcomes

# Robotic-assisted total knee arthroplasty reduces soft tissue releases which improves functional outcomes: A retrospective study.

[12]**Spitzer et al., 2024**

## SUMMARY

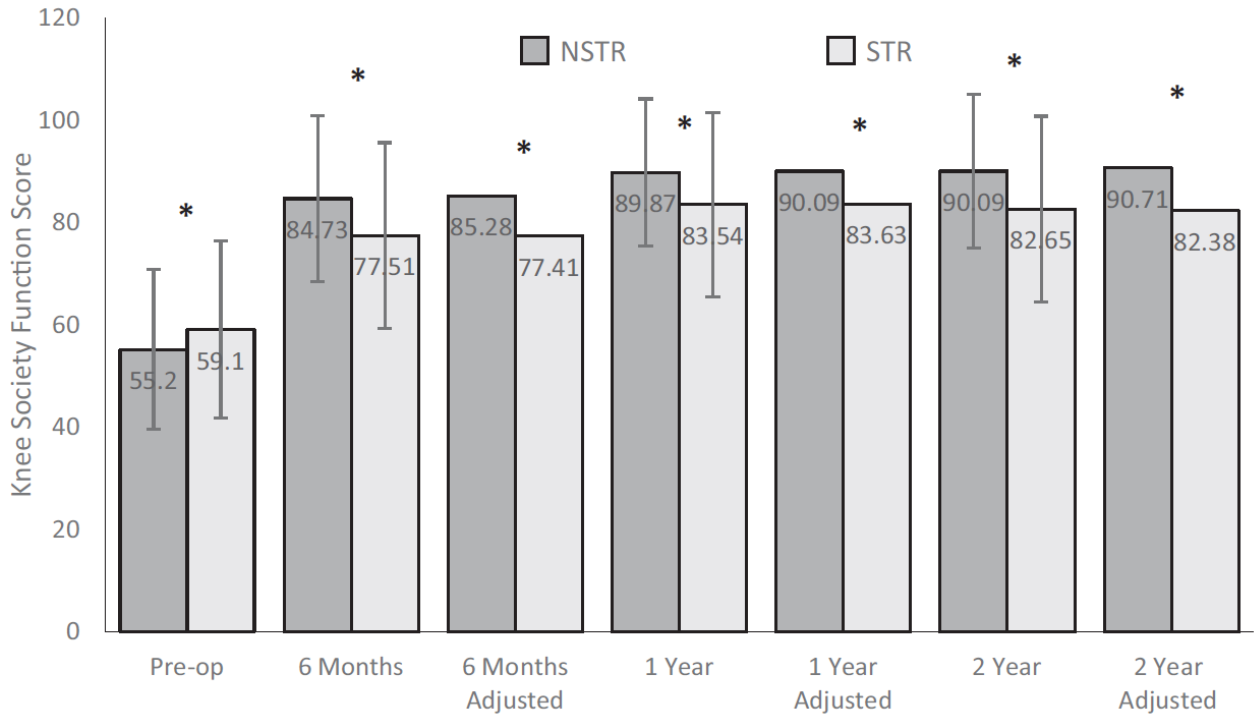
Retrospective analysis of standard of care Registry assessing 5982 procedures (331 RA, 5651 manual) for rate of soft tissue release; 948 of which had 2-year PROM data to assess impact of releases on outcomes.

The use of VELYS™ Robotic-Assisted Solution was associated with reduction in rate of soft tissue release.

Subjects with no soft tissue releases were associated with improved Knee Society Function Score at 2 years.

Incidence of soft-tissue release in robotic assisted (RA) and manual procedures.

| | RA (*N* = 331) | Manual (*N* = 5651) |
|---|---|---|
| **NSTR** | 186 (56.2%) | 756 (13.4%) |
| **STR** | 145 (43.8%) | 4895 (86.6%) |
| **P-Value, RA Vs. Man** | _ | <0.0001 |




Comparison of the effect of soft-tissue release on the Knee Society Function score at 6 months, 1 year and 2 years, Error bars +/- one standard deviation.



Total Knee Arthroplasty (TKA) | Robotic-Assisted (RA) | Manual (Man) | Patient Recorded Outcome Measures (PROMs) | Soft Tissue release (STR) | No Soft Tissue Release (NSTR) | |*Indicates statistically significant difference, p-value <0.05.

# Image Free Robotic-Assisted Total Knee Arthroplasty is Associated with Improved Knee Society Function Score Compared to Manual Instrumentation

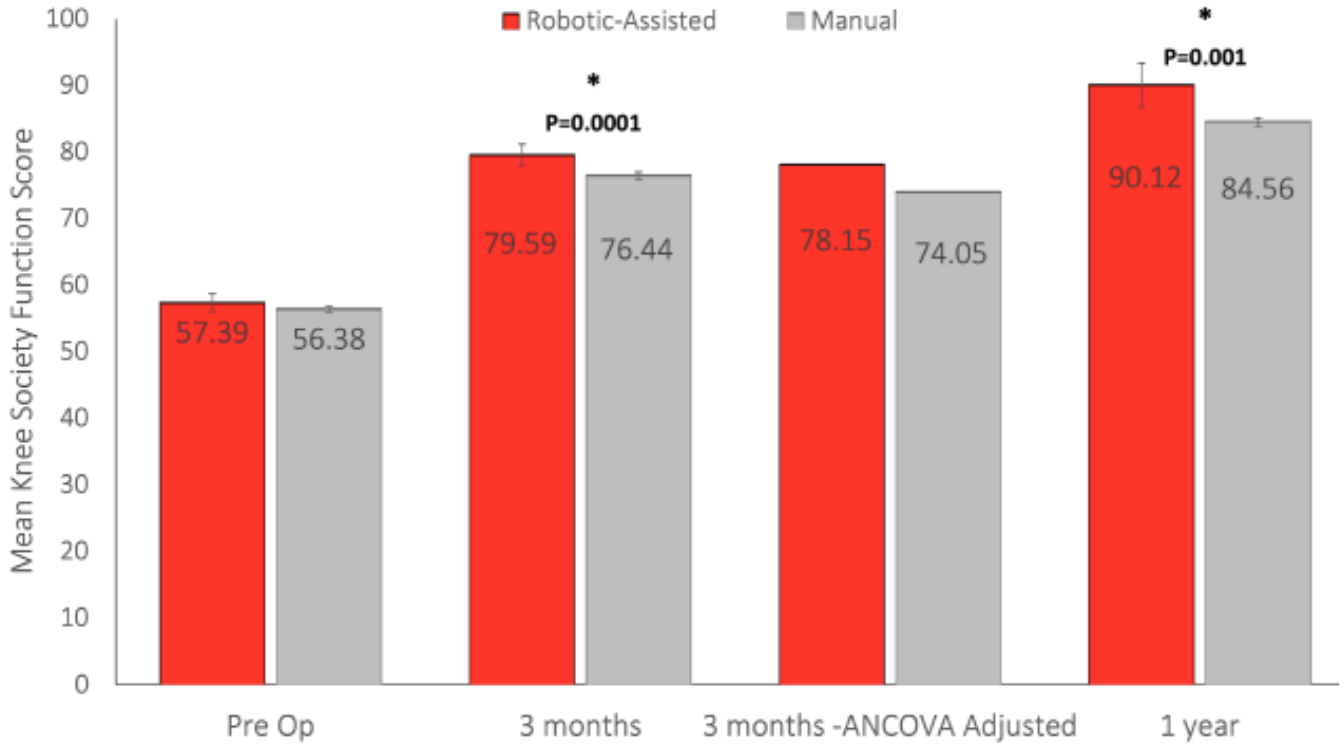
**[13]Spitzer et al., WAC 2024. Poster No. 336**

A retrospective review of a prospective company sponsored standard of care registry (DOTS) was conducted to assess post-operative KSFS for all ATTUNE Knee primary TKAs.

N=1,056 Robotic, N=11,927 manual procedures both with 3-month PROMs.

RA combined with patient specific techniques can improve patient outcomes in TKA and Knee Society Function Score at 3 month follow up compared to manual instrumentation.

However, this analysis is exploratory and therefore subject to limitations. Further prospective studies with longer-term follow-up are required to confirm the findings.




KSFS for RA and Manual. Error bars +/-95% CI.



Total Knee Arthroplasty (TKA) | Knee Society Function Score (KSFS) | |*Indicates statistically significant difference, p-value <0.05

# Assessment of Accuracy and Early Outcomes During the Adoption Phase of a Novel Image-Free Robotic-Assisted System for Total Knee Arthroplasty

**[4]Alton et al., BOA, 2024. Poster No.376**

A multicenter, prospective non-randomized 1:1 cohort study was conducted at five sites.

N=100 RA, N=100 manual.

Positive trends in FJS and pain at 12 weeks post op for VELYS™ Robotic-Assisted Solution compared to manual instrumentation.

“All 100 RA procedures were performed without any intra operative Adverse Events”.

| | RA Mean (SD) | Manual Mean (SD) | P-Value |
|---|---|---|---|
| FJS | 35.4 (25.73) | 26.4 (23.39) | **0.0165** |
| KOOS ADL | 72.0 (19.21) | 69.5 (18.77) | 0.3879 |
| KOOS Pain | 67.1 (19.86) | 63.8 (19.33) | 0.2737 |
| KOOS Symptoms | 67.8 (17.35) | 64.7 (17.27) | 0.2438 |
| KOOS Sports & Rec | 45.0 (30.68) | 39.9 (29.64) | 0.2850 |
| KOOS QoL | 55.9 (24.29) | 51.1 (22.47) | 0.1755 |
| EQ-5D 5L | 0.78 (0.129) | 0.77 (0.143) | 0.5340 |
| EQVAS | 78.8 (13.47) | 77.8 (14.35) | 0.6129 |
| Pain (scale 0 -10 high) | 2.3 (2.38) | 3.4 (2.75) | **0.0074** |
| Pain during activity (scale 0 -10 high) | 2.9 (2.43) | 3.6 (2.81) | 0.0709 |
| Satisfaction (scale 0 -10 low) | 1.3 (2.03) | 1.6 (2.29) | 0.4851 |
| Range of Motion (°) | 115.8 (11.22) | 112.3 (16.14) | 0.0851 |

PROMs at 12 weeks for RA and Manual



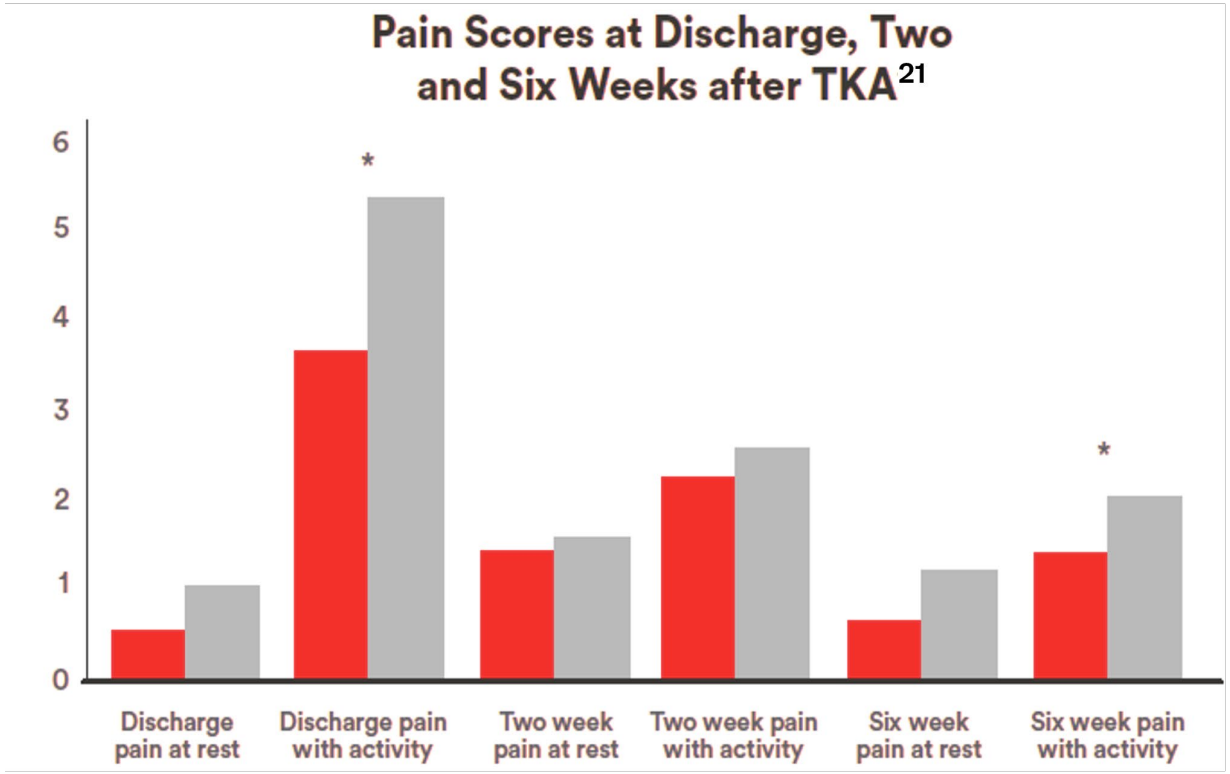
Patient recorded outcome measures (PROMs) | Robotic-Assisted (RA) | Forgotten Joint Score (FJS) | Knee Injury and Osteoarthritis Outcome Score (KOOS) | activities of daily living (ADL) | Recreation (Rec) | Quality of Life (QoL) |*Indicates statistically significant difference, p-value <0.05.

# Patient-Specific TKA with the VELYS Robotic-Assisted Solution

**[11]Clatworthy et al., 2022**

N=45 Navigation, N=45 VELYS™ Robotic-Assisted Solution TKA from two prospective studies.

Positive trends in pain and function at 2- and 6-weeks post op for VELYS™ Robotic-Assisted Solution compared to Navigation.





VELYS™ Robotic-Assisted Solution

BRAINLAB KNEE3 Navigation System

# Transition to Robotic Total Knee Arthroplasty With Kinematic Alignment Is Associated With a Short Learning Curve and Similar Acute-Period Functional Recoveries

**[10]Morrisey et al., 2023**

Six-week and six-month postoperative data from 99 traditionally instrumented, mechanically aligned and 66 kinematically aligned robotic TKA patients was examined between January 2021-October 2021 and October 2021-April 2022, respectively.

Adoption phase has no negative impact on early outcomes.

“Transition to a kinematic, semi-active, robotic TKA demonstrated encouraging results by demonstrating acute-period recovery of function consistent with the current standard of care, as well as a better range of motion at six months postoperatively.”

Early functional recovery of robotic total knee arthroplasty versus traditional instrumentation.

| Variable | VELYS – early transition (N=20) | VELYS – Late Transition (N=46) | P-Value |
|---|---|---|---|
| Range of Motion flexion | 110.25 ± 24.45 | 110.10 ± 11.98 | 0.53 |
| ROM Extension | 1.43 ± 1.77 | 2.07 ± 3.28 | 0.88 |
| Pain Level | 1.75 ± 1.77 | 1.82 ± 2.27 | 0.83 |
| Use of Assistive devices | 11 (55) | 15 (32.6) | 0.09 |
| Tourniquet time | 66.00 ± 17.21 | 64.01 ± 8.16 | 0.42 |
| Emergency department or hospital admission within 6 weeks. | 3 (15) | 10 (21) | 0.53 |



Total Knee Arthroplasty (TKA) | Range of motion (ROM) | Use of assistive devices reported as N using assistive devices at six wks (% using assistive devices) | Emergency department or hospital visits reported as N who had emergency department visits or admissions (% of emergency department visits or admissions) | All others are reported as mean ± SD.

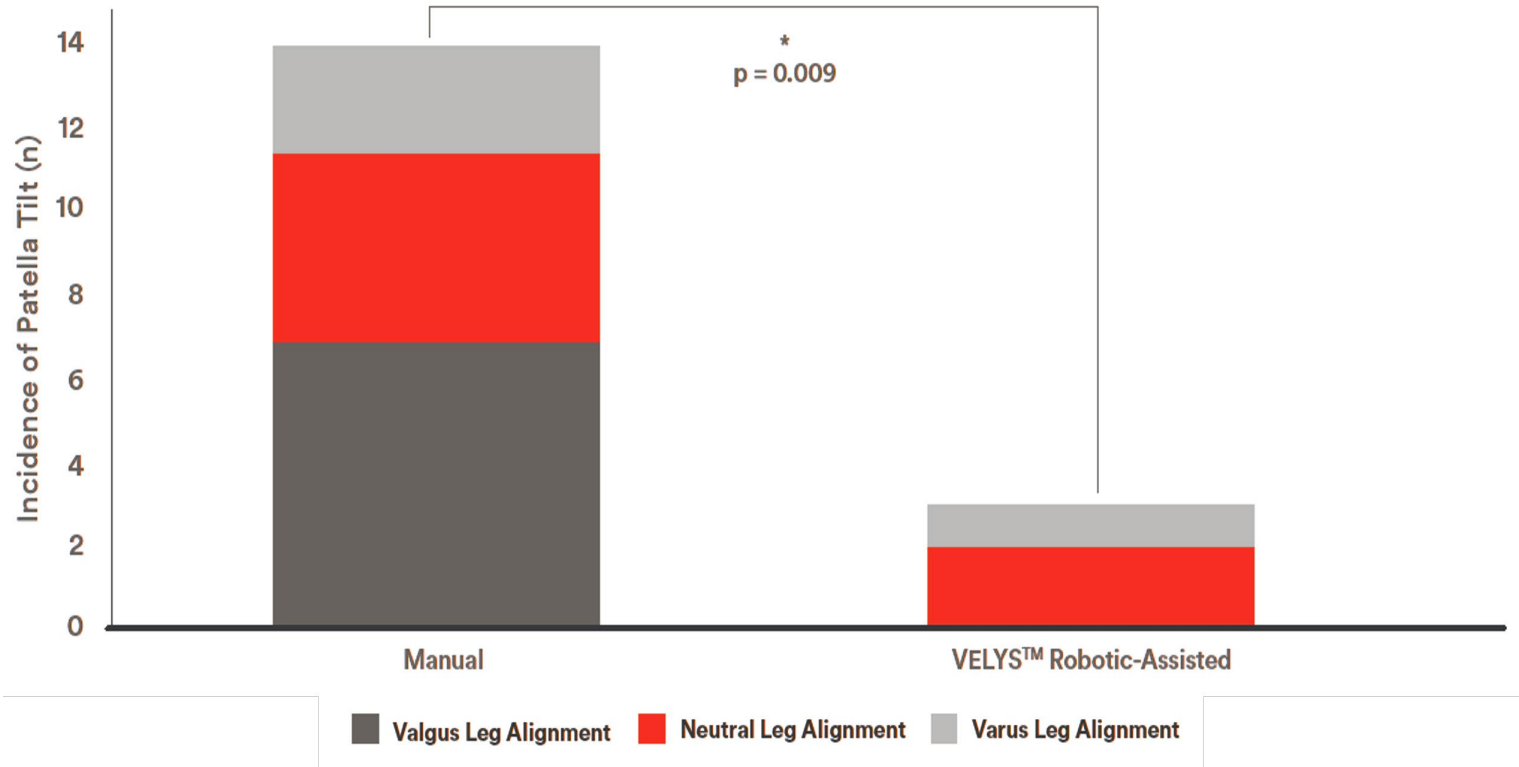
# Improved Patellar Tracking in Image-Free-Robotic-Assisted Total Knee Arthroplasty

[14]Severson et al., AOA 2023

N=100 manual, N=100 robotic-assisted TKA.

Use of VELYS™ with a patient specific technique, varying the femoral rotation resulted in a reduction in the incidence of patella tilt compared to the use of mechanical instruments with systematic external rotation of the femoral component.

**Study results demonstrate a higher incidence of patellar tilt in the manual TKA compared to the VELYS™ Robotic-Assisted Solution cohort [14]**



# Robotic-Assisted Total Knee Arthroplasty Results in Shorter Navigation Working Time With Similar Clinical Outcomes Compared to Computer-Navigated Total Knee Arthroplasty

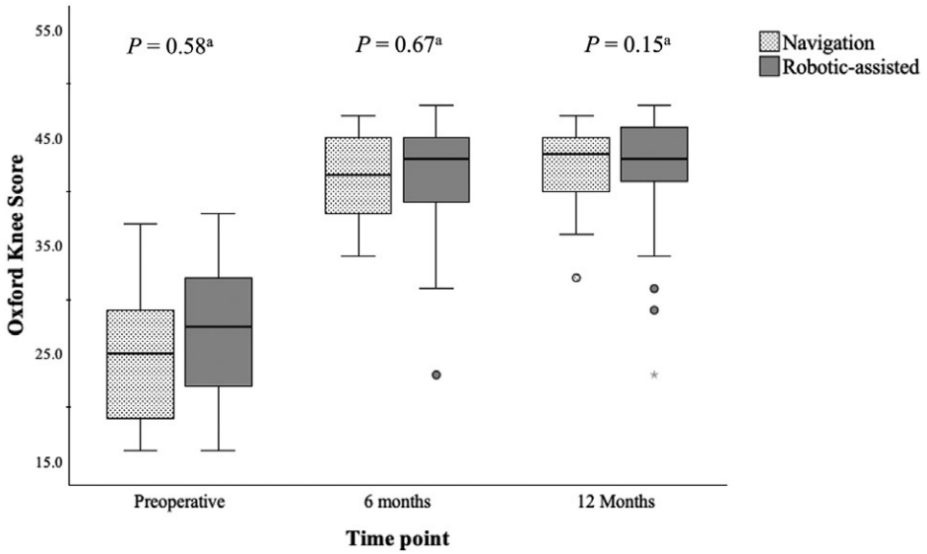
**[15]Ho et al., 2024**

Single Surgeon retrospective cohort study, 79 VELYS™ patients' propensity matched to 79 Navigation patients.

No complications or technical failures in the VELYS™ cohort.

VELYS Robotic-Assisted Solution had significantly shorter navigation time (defined as the duration of time taken from the start of femoral head center acquisition to the end of assessment of final limb alignment with trial implants in place) compared to Navigation ($p < 0.0001$)
Compared to pre-operatively, both groups showed high levels of satisfaction and significant improvement in PROMs but there were no differences in PROMs between the groups.

| Variables | Overall | Navigation | Robotic-Assisted | P value | Mean Difference (95% CI) |
|---|---|---|---|---|---|
| Navigation time (minutes) | 23.9 ± 7.9 | 37.3 ± 4.1 | 21.9 ± 6.1 | <0.0001* | 15.4 (11.7 – 19.2) |
| Length of stay (days) | 4.62 ± 1.67 | 4.73 ± 1.57 | 4.52 ± 1.77 | 0.43 | 0.2 (-0.3 – 0.8) |
| Complications | | | | 0.50 | |
| Yes | 2 (1.3) | 2 (2.5) | 0 (0.0) | | |
| No | 156 (98.7) | 77 (97.5) | 79 (100.0) | | |




Boxplot showing Oxford Knee Scores preoperatively and at 6 and 12 months after surgery in navigated versus robotic-assisted TKA. TKA, total knee arthroplasty. A P value determined by independent samples t-test.



Patient Recorded Outcome Measures (PROMs) | Total Knee Arthroplasty (TKA) |*Indicates statistically significant difference, p-value <0.05 | Confidence Interval (CI) | Values are expressed as mean ± SD and frequency (percentage).

# Economic Evidence

# Resource Utilization with VELYS™ Robot and Manual

[16]Severson et al., AOA 2023. Paper No. 58

Retrospective review of electronic healthcare records at a single U.S. site following adoption of the VELYS™ Robotic-Assisted Solution. Single-arm, non comparative analysis from January 2021 to May 2022.

Length of stay (LOS), emergency department (ED) visits, Morphine Milligram Equivalents (MME) , post-op pain intensity, and operative time of VELYS Robotic-Assisted Solution TKA cases relative to manual TKA cases are summarized in the table:

| | Manual TKA (N=121) | VELYS™ Robotic-Assisted Solution rTKA (N=104) |
|---|---|---|
| Mean LOS Days (ED) | 1.3 (0.4) | 1.1 (± 0.7) |
| Number of 30-day ED Visits | 8.3% | 5.8% |
| Mean MME (SD) | 112.9 (96.3) | 86.6 (± 94.6) |
| Mean Post-operative Pain Intensity (SD) | 4.6 (2.0) | 4.7 (± 2) |



Total Knee Arthroplasty (TKA) | Robotic Total Knee Arthroplasty (rTKA) | Morphine milligram equivalents (MME)

# Early Clinical and Economic Outcomes for the VELYS™ Robotic-Assisted Solution Compared with Manual Instrumentation for Total Knee Arthroplasty

**[17]Huang et al., 2024**

Analysis of U.S. Premier Healthcare database comparing the VELYS™ Robotic-Assisted Solution (n=866**) to manual (n=128,643**) total knee arthroplasty cases from September 1, 2021, to February 28, 2023.

Results show statistically significant reductions in 90-day all-cause and knee-related revisits across all sites of care, and knee-related readmissions for VELYS™ Robotic-Assisted Solution compared to manual TKA ($p < 0.01$*).

| Rate of | VELYS Robotic-Assisted Solution (95% CI) | Manual (95% CI) | Mean Diff (95% CI) | P-value | % Difference |
|---|---|---|---|---|---|
| All-cause Revisits | 13.9% (11.56 to 16.16) | 17.2% (16.99 to 17.4) | -3.34 (-5.65 to -1.03) | P < 0.01* | -19% |
| Knee-related Revisits | 2.7% (1.58 to 3.73) | 4.8% (4.69 to 4.93) | -2.15 (-3.23 to -1.08) | P < 0.01* | -45% |
| Knee-related Readmissions | 0.7% (0.14 to 1.25) | 1.5% (1.39 to 1.53) | -0.77 (-1.32 to -0.21) | P < 0.01* | -53% |

Similar hospital cost for both the VELYS™ Robotic-Assisted Solution and manual TKA (without accounting for acquisition cost)

- 90-day all-cause cost of care: ($15,357 vs. $14,944; MD: $413 [-$112 to $938])
- 90-day knee-related cost of care: ($14,956 vs. $14,547; MD: $409 [-$69 to $887])

Operative time for VELYS™ Robotic-Assisted Solution TKA cases was 137.96 minutes while the operative time for manual cases was 133.67 minutes, a difference of only 4 minutes.



Total Knee Arthroplasty (TKA) | |*Indicates statistically significant difference, p-value <0.05 | **Indicates the number of patients with 90-day follow up

# Are all robotic technologies created equal? Comparing one of the latest image-free robotic technologies to all other robotic systems for total knee arthroplasty

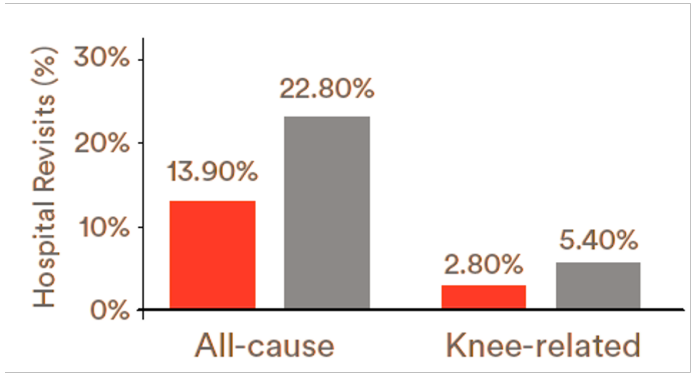
**[18]Huang et al., 2024**

Analysis of U.S. Premier Healthcare database comparing the VELYS™ Robotic-Assisted Solution (n=827) to the class of other robotic-assisted solutions (n=16,428) for TKA from September 1, 2021, to February 28, 2023.

Results show a statistically significant reductions in 90-day all-cause and knee-related revisits and lower 90-day all cause and knee-related cost of care for the VELYS™ Robotic-Assisted Solution TKA cohort.

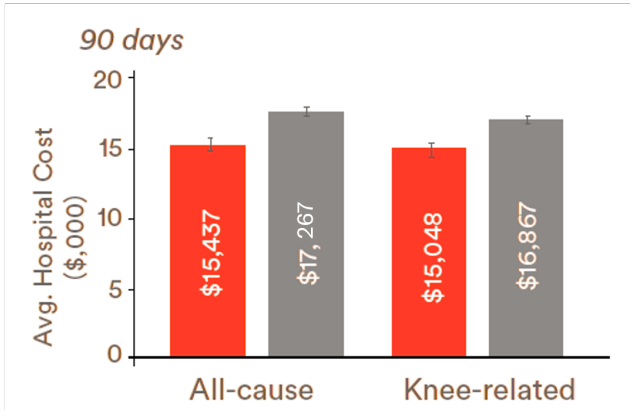
Average operating room time was similar for VELYS™ Robotic-Assisted Solution and ORAS (138 vs. 137 minutes).

VRAS - VELYS Robotic-Assisted Solution | ORAS – Other robotic assisted solution



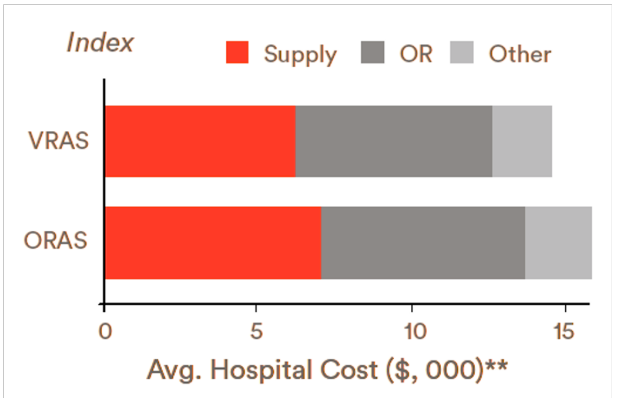

Significantly lower 90-day all-cause (13.9% vs. 22.8%, p-value < 0.01) and knee-related (2.8% vs. 5.4%, p-value < 0.01) revisit rates.

Lower all-cause and knee-related 90-day readmission rates, though this was not found to be statistically significant.




Overall, 90-day all-cause and knee-related cost of care was significantly lower for the VELYS ™ Robotic-Assisted Solution compared to the ORAS TKA cohort.

The cost for the VELYS ™ Robotic-Assisted Solution cohort was lower by $1,830 [$1,423 to $2,236] for all-cause and $1,819 [$1,445 to $2,194] for knee-related revisits. The initial acquisition of the robot is not accounted for in this study.




Average hospital cost during the index admission for the VELYS ™ Robotic-Assisted Solution cohort was $15,012 compared to $16,255 for ORAS.

Supply and operating room cost contributed to more than 85% of the total cost for both cohorts.

On average, VELYS ™ Robotic-Assisted Solution supply cost was lower by $682 [517 to 846] and operating room cost was lower by $453 [307 to 599] compared to ORAS for TKA.



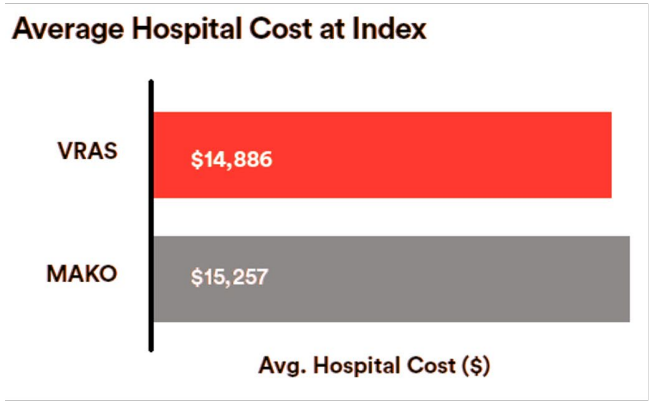
Total Knee Arthroplasty (TKA) | VELYS Robotic-Assisted Solution (VRAS) | Other Robotic-Assisted Solution (ORAS) | Operating Room (OR)

# Economic Outcomes for VELYS™ Robotic-Assisted Solution and MAKO for Total Knee Arthroplasty

[19]**Thakkar et al. CAOS 2024**

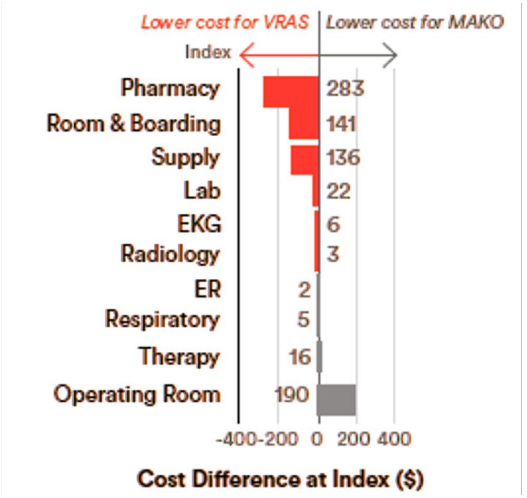
Analysis of the Premier Healthcare database comparing the economic impact of the use of the VELYS™ Robotic-Assisted Solution (n=826) to the MAKO Robotic-Arm Assisted Surgery (n=9,719) for total knee arthroplasty from 2022 to April 2023.

Results show a statistically significant reduction in the cost associated with the index hospital admission, 90-day all-cause and knee-related revisits cost of care for VELYS™ Robotic-Assisted Solution compared to MAKO.




Hospital cost during the index admission was significantly lower for the VELYS ™ Robotic-Assisted Solution cohort compared to MAKO cohort (p-value < 0.01).

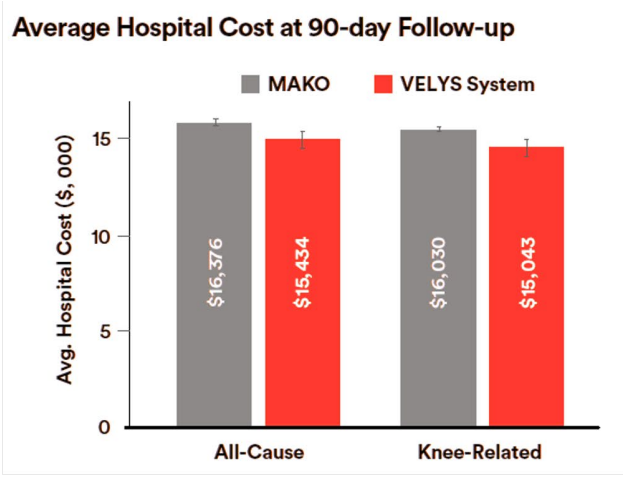
The average mean difference in total cost (with 95% CI) was $371 ($22 to $720).




On average, the cost was lower for the VELYS ™ Robotic-Assisted Solution compared to MAKO patients for:

- Pharmacy [$283 (245 to 319)],
- Room & boarding [$141 (88 to 192)]
- Supply costs [$136 (-157 to 453)]

On average, operating room cost was higher for VELYS™ Robotic Assisted Solution cases compared to MAKO cases by $190 (6 to 373).




The total cost of care (index admission + follow-up cost) at 90-day follow-up was 5.8% and 6.1% lower for the VELYS™ Robotic Assisted Solution cohort (p-value < 0.001) compared to the MAKO cohort for all-cause and knee-related, respectively.

The average mean difference (with 95% CI) for all-cause cost of care was -$942(-1420 to -465) and for knee-related cost of care was -$986 (-1438 to -533).

# Image Free Robotic-Assisted System for Total Knee Arthroplasty Associated with Reduced Surgical Times Compared to Manual Instrumentation; A retrospective Controlled Single Surgeon Study.

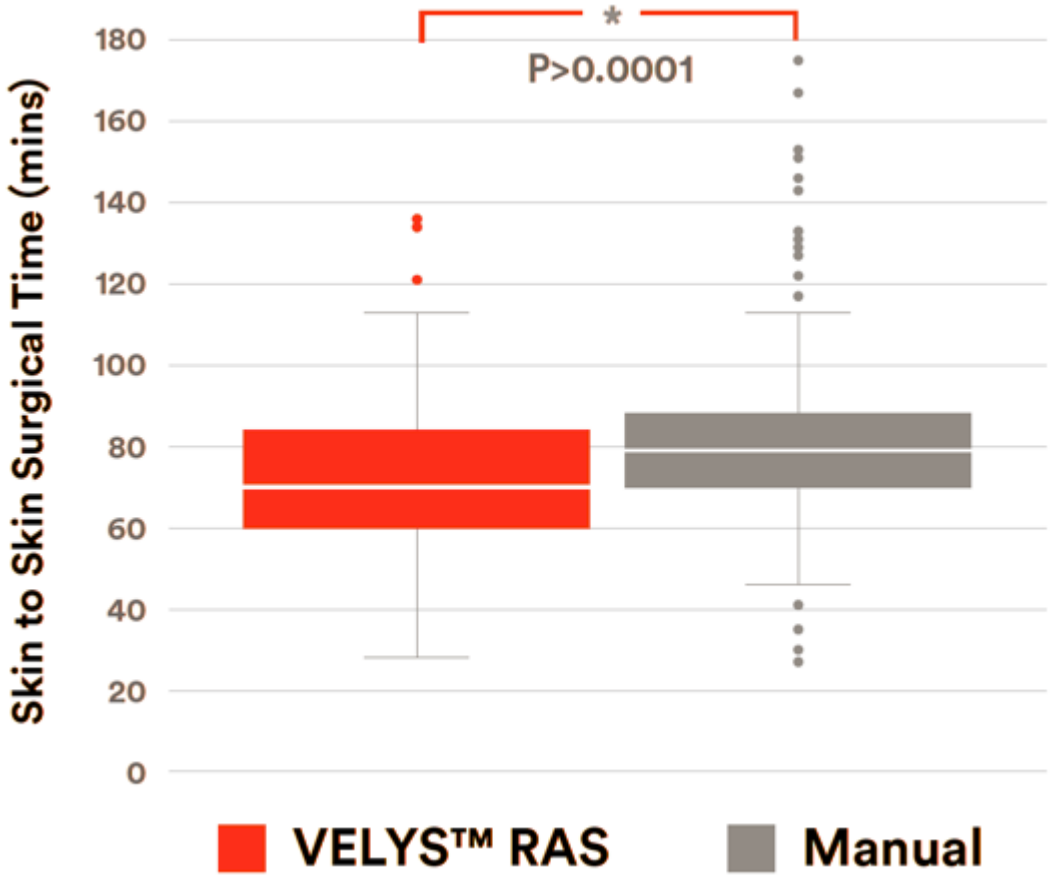
**[20]Alton et al. EFFORT 2024. Poster No. 1495**

N=310 Manual, N=299 VELYS™ Robotic-Assisted Solution.

Retrospective Analysis of Single Surgeon surgical time.

“This study demonstrated that a single surgeon with RA TKA with VELYS ™ RAS had reduced surgical time compared to manual instrumentation”.

May not be representative of all surgeons, but challenges perception that robotics is slower than manual surgery.




Box plot of surgical time comparing VELYS™ RAS and Manual TKA procedure time



Total Knee Arthroplasty (TKA) | Robotic Assisted (RA) | Robotic-Assisted Solution (RAS) | |*Indicates statistically significant difference, p-value <0.05

# Summary & Disclaimers

# Summary

- Robust pre-clinical and clinical data to support accuracy of the system, which is improved compared to manual instrumentation.
- Users can become time neutral with the system after completion of an adoption phase – the specific length will vary based on multiple factors.
- System facilitates adoption of patient specific techniques which may result in a reduction in the rate of intra-operative soft tissue releases.
- Early studies show either equivalent or improved clinical outcomes compared to manual instrumentation even including the adoption phase.
- Economic database studies show positive trends with robotic-assisted TKA compared to manual instrumentation.

# Limitations with Current Evidence

- Current Clinical and economic evidence has short term follow up, mid and long-term influence unknown.
- Majority of studies are observational and therefore susceptible to bias and influence of unaccounted for confounding factors.
- There is significant variation in how surgeons are using the system which can mean results from one center may not be replicated in another.
- Majority of studies are US based.

# Disclaimers

Prior to use, please refer to the instructions for use supplied with the device(s) for indications, contraindications, side effects, warnings and precautions

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# Thank you

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