

✚ Evidence in focus

Summary of Clinical Evidence

CORI◊ Surgical System clinical evidence

July 2026

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Smith+Nephew

CORI◊ Surgical System: Personalised knee and hip arthroplasty

The NAVIO◊ Surgical System is the predecessor to the CORI Surgical System. Because both surgical systems share the same core functionality, clinical evidence generated with NAVIO Surgical System is relevant to the clinical profile of CORI System. Throughout this document, evidence relating to NAVIO Surgical System - or studies evaluating both systems - is referred to as evidence for Smith+Nephew handheld robotics.

Versatility with CORI System

- Enables personalisation across **unicondylar, total and revision knee arthroplasty, and total hip arthroplasty procedures**
- Accommodates a broad range of cases through **image-free or image-based pre-operative planning**
- More **compact footprint** than Mako™ (Stryker) and ROSA® Robotics (Zimmer Biomet),[1] making it easy to transport between operating rooms

Redefining revision knee arthroplasty with CORI System[2-4]

- The **first robotics platform indicated for use in revision** knee arthroplasty in the US and Europe
- **Enabling surgeons to prioritise joint-line reconstruction** in revision TKA rather than being constrained by diaphyseal anatomy when using conventional methods[2,4]
- Surgeons and OR nurses reported that revision TKA with CORI System **reduced procedural demands** compared with conventional procedures[3]

Enabling consistent gap balancing with CORI Digital Tensioner

- An objective tool to support **consistent and repeatable** gap balancing and alignment in TKA[5,6]



57
publications*

>49,000
total patients studied†



10 randomised controlled trials (RCTs)‡

1 systematic literature review (SLR) and meta-analysis

3 prospective comparative

2 registry analyses

24 retrospective comparative

10 case series/ single-arm cohort

4 cost/ efficiency analyses

1 modelling study

Publication counts may be higher than study counts, as individual study cohorts may have resulted in more than one publication.



*As of June 2026; †Overall cases analysed in publications (Smith+Nephew RA TKA plus comparators), numbers adjusted to account for publications that report the same cohort of patients and case numbers have not been included for cost analyses or meta-analyses. ‡One used a quasi-RCT design (Migliorini F, et al. *Orthopädie.* 2026;55:48–54.)

Personalised TKA with CORI◊ Surgical System

CORI Surgical System enables surgeons to execute personalised alignment TKA, including functional and kinematic alignment. Both the anatomically designed JOURNEY◊ II TKA and the LEGION◊ Total Knee System, which offers both cementless and cemented options, can be accurately positioned using CORI System.[7,8] Soft tissue tension can then be assessed in real time.



Access TKA studies by clicking or scanning the QR code:

29 publications

In RCTs, Smith+Nephew handheld robotic-assisted (RA) functional alignment TKA has outperformed conventional TKA (cTKA) for accuracy of implant and limb alignment, soft-tissue preservation, natural joint feeling and patient satisfaction, with no clinically relevant differences in procedure time.*[7,9] Real-world analyses have demonstrated OR efficiencies related to reduced instrument requirements[10] and reduced 90-day episode of care costs versus cTKA.[11]

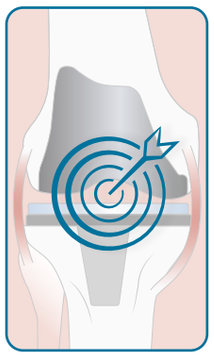
Compared with cTKA, Smith+Nephew RA TKA has been shown to result in:

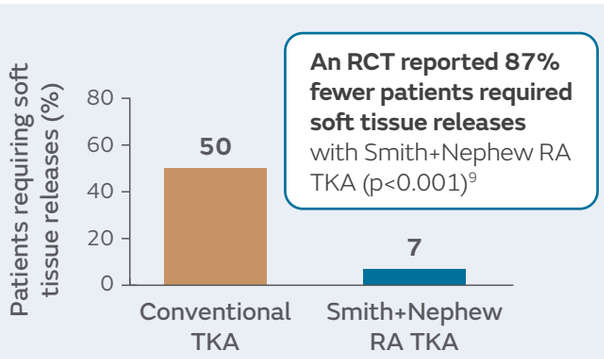
Intra-operative and immediately post-op

More accurate bone resection and improved soft tissue preservation[7–9,12–15]

Improved accuracy of limb and implant alignment has been demonstrated in five RCTs[†7,8,12–14]

RCTs have also shown significantly **improved gap balancing[‡9] and reduced local trauma[§15]**





An RCT reported 87% fewer patients required soft tissue releases with Smith+Nephew RA TKA (p<0.001)[9]

Post-operative

Improved natural joint feeling and patient-reported satisfaction at 1 year[9]

At 1 year, an RCT has shown significantly[9]

- **More natural joint feeling** (better 12-item Forgotten Joint Score)[9]
- **Improved patient-reported function, pain, satisfaction and health-related quality of life[¶9]**

(p≤0.029 for all)

Health economic

OR efficiencies and reduced costs, without a meaningful increase in procedure time[8–11,15]

RCTs have reported **no clinically relevant difference in procedure time** after an initial learning curve[‖8,9,15]

OR efficiencies

In a real-world study of 9 centres:

On average, **45 fewer instruments** used per TKA, resulting in an estimated **cost saving of $286 per procedure** (p<0.001)[10]



Cost analysis

An analysis of >1000 propensity-matched patients from the Premier PINC AI™ Healthcare Database reported:

Lower 90-day episode of care costs ($14,725 vs $15,670; p<0.0001)[**11]

*Surgery duration in Bollars (2025)[9] was 76 minutes in the Smith+Nephew RA TKA group and 73 minutes in the conventional TKA group (p=0.001), authors did not consider the 3 minutes difference to be clinically relevant. [†]p≤0.038 for all. [‡]Improved gap balancing defined as fewer patients required soft tissue releases and inserts >10mm thick (p≤0.004). [§]Lower inflammatory marker c-reactive protein at post-op days 1 and 5; p≤0.0003 in a quasi-RCT. [¶]OKS, KSS [function and satisfaction], EQ-5D index score, VAS pain and satisfaction. [‖]Two RCTs have found no clinically relevant difference in procedure time (1.6–3mins between groups; p≤0.04). **Most patients (80%) in the analysis had a TKA and 20% had a UKA.

Abbreviations: cTKA = conventional TKA, OR = operating room, RA TKA = robotic-assisted TKA, RCT = randomised controlled trial, TKA = total knee arthroplasty.

Accurate UKA with CORI◊ Surgical System

Despite the benefits of UKA over TKA and that considerable numbers (25–47%)[16] of TKA patients are eligible for the procedure, only 8–15% of all knee arthroplasties are UKA.[17] Low utilisation is partly due to surgical complexity and reduced threshold for revision,[18] which it may be possible to overcome using robotic-assistance to help correctly position the implant.[18–21] CORI Surgical System assists with implantation of JOURNEY◊ II UK with OXINIUM◊ Technology, which has shown excellent early survivorship*[22,23] and has a 5A ODEP rating.[24]



Access UKA studies by clicking or scanning the QR code:

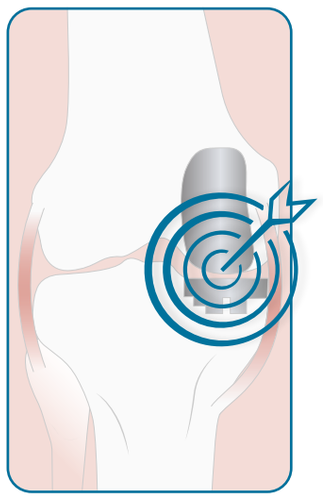
18 publications

Clinical studies have shown implant placement and knee alignment are more accurate with Smith+Nephew robotic-assisted (RA) UKA than conventional UKA (cUKA),[18–21] irrespective of surgeon experience.†[25] The accuracy afforded by robotic-assistance is thought to contribute to the significantly lower revision risk with RA UKA versus cUKA.[26,27] Increasing UKA utilisation results in several patient benefits which have been linked to improved cost efficiency versus TKA, including quicker discharge.[28]

Versus cUKA, Smith+Nephew RA UKA has resulted in:

Intra-operative

Improved accuracy,[18-21] irrespective of surgeon experience†[25]



Improved accuracy of implant placement and knee alignment,[18–21] irrespective of individual surgeon experience with cUKA†[25]

Post-operative

Improved survivorship and patient-reported outcomes (PROMs) with fewer bed days[26,27,29–33]

Versus cUKA, RA UKA has resulted in:

Up to **58%** **lower revision risk** (two independent meta-analyses)[26,27]

Versus cUKA, Smith+Nephew RA UKA:

100% survivorship with JOURNEY II UK in the NJR at 1 year‡[29] n=122

Significantly **earlier discharge** from hospital and physical therapy[30] and higher PROMs§ (p≤0.02)[31–33]

Health economic

Increasing UKA utilisation may lower episode of care costs

Increasing UKA utilisation results in several benefits which have been linked to improved cost efficiency versus TKA:

Lower early complication rates

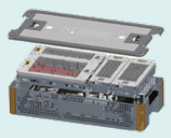
Lower risk of early complications including cardiac events, venous thromboembolism and deep infections[16]

Shorter length of stay and lower costs

Typically, UKA procedures are lower cost[28] and patients are discharged >1 day earlier[16]

Quicker recovery

Patients may regain knee function, and return to sports and work sooner[16]



Using CORI System to implant JOURNEY II UK may only require a **single tray** (versus 2–3 with cUKA)[34]

*Up to 99.6% survivorship at 2 years; †Study conducted on dry bone models; ‡The data used for this analysis was obtained from the National Joint Registry ("NJR"), part of the HQIP, the NJR and/or its contractor, NEC Software Solutions (UK) Limited ("NEC") take no responsibility (except as prohibited by law) for the accuracy, currency, reliability and correctness of any data used or referred to in this report, nor for the accuracy, currency, reliability and correctness of links or references to other information sources and disclaims all warranties in relation to such data, links and references to the maximum extent permitted by legislation including any duty of care to third party readers of the data analysis. §KOOS-JR at 6 months post-UKA (p=0.037)[32] and IKSS-O (p<0.05)[31] and KSS-F (p=0.01)[33] at ≥1-year post-UKA.

Abbreviations: cUKA = conventional UKA, RA UKA = robotic-assisted unicompartmental knee arthroplasty, ODEP = Orthopaedic Data Evaluation Panel, QALY = Quality-Adjusted Life Year, TKA = total knee arthroplasty, UKA = unicompartmental knee arthroplasty.

Redefined revision TKA with CORI◊ Surgical System

The technical challenges of revision TKA (rTKA) can mean more than twice the workload of a primary TKA[35] and conventional methods can result in component overhang, compromised joint line restoration and suboptimal ligament balancing.[4] CORI Surgical System may help to mitigate challenges in revision knee arthroplasty. For example, by allowing for intra-operative, real-time visualisation of the extent of bone loss or anatomical distortion, personalised planning for consideration of augments and joint line preservation plus full range of motion gap assessment.[36] LEGION◊ Primary and Revision Knee Systems share the same bone conserving* femoral resections, and include a full continuum of revision dedicated instrumentation, to ease transitions from primary to revision.[36]



Access revision knee arthroplasty studies by clicking or scanning the QR code:

3 publications

As the first robotics platform indicated for use in revision knee arthroplasty, CORI system has enabled a shift toward anatomical, joint-line based reconstruction[2,4] while potentially reducing procedural demands on surgeons and OR nurses.†[3] A clinical study of CORI system with LEGION Revision Knee System reported joint line restoration in 93% of rTKA patients†‡ while most cases were successfully managed using low constraint inserts.[2] Surgeons and OR nurses reported that revision knee arthroplasty with CORI system reduced procedural demands compared with conventional techniques.[3]

Intra-operative

Ability to restore the joint line[2] with potentially lower demand than conventional procedures[3]

In a retrospective case series of CORI system with LEGION RK System for 115 rTKA patients:[2]

93% **achieved joint line restoration‡** (across a **wide range of cases**)[2]

Most cases were successfully managed using low constraint inserts (77% used PS inserts and 19% used constrained inserts)[2]

In a real-world evaluation of 100 revision knee arthroplasty procedures, versus conventional methods, use of CORI system was associated with:¶

Significantly **lower overall procedural demands** reported by surgeons and OR staff, including **lower** perceived **physical and mental demands, and effort** (p≤0.0065)[3]

No impact on perceived surgical performance or operating pace[3]

Post-operative

Early evidence suggests improved PROMs§ and high home discharge rates

In a retrospective case series of CORI system with LEGION RK System for 115 rTKA patients:[2]

Significantly improved pain and PROMIS depression scores (versus pre-op scores at 90 days post-op; p≤0.013)[2]

Low readmissions at 30 (1%) and 90 days (3%) post-op[2]

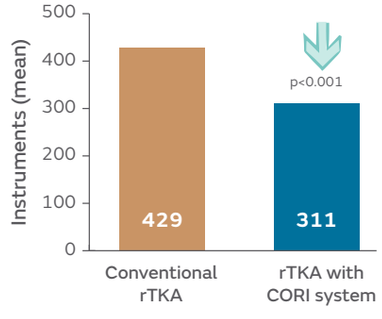
Most (87%) patients **discharged home[2]**

Health economic

OR efficiencies and reduced costs versus conventional rTKA

In a real-world study of CORI system in 9 centres:

On average, **188 fewer instruments** used per rTKA, resulting in an estimated **cost saving of $753 per procedure** (p<0.001)[10]



*Bone conserving versus Insall-Burstein™ II, PFC™ Sigma™, Optitrak™, and Nex-Gen™ Legacy™; †Versus conventional procedures; ‡Within 5mm of the native contralateral knee; §at 30 and 90 days post-op, versus pre-op scores. ¶ Data from 212 total surveys following 100 revision TKA procedures (39 conventional, 61 robotic-assisted cases).
Abbreviations: PS = Posterior Stabilised; rTKA = revision total knee arthroplasty.

Personalised THA with RI.HIP◊ on CORI◊ Surgical System

Although THA is a highly successful surgery, dislocation remains a leading cause of revision and is often caused by impingement.[38] Implant malpositioning and reduced spinopelvic mobility have been shown to increase impingement risk and dislocation,[39-40] highlighting the importance of accounting for spinopelvic mobility and optimal implant positioning for THA success. CORI System uses RI.HIP◊ NAVIGATION for hip arthroplasty, which allows surgeons to assess pelvic tilt to provide a predicted view of the post-op anteroposterior X-ray in surgery and digital measurement of leg length or offset changes.



Access THA studies by clicking or scanning the QR code:

7 publications

CORIOGRAPH◊ Pre-Op Planning and Modeling services enables personalised pre-operative planning based on patient spinopelvic mobility in the context of activities of daily living (ADLs) to help minimise impingement risk.[41] Clinical studies have shown, versus conventional THA, navigated THA with RI.HIP supports optimal implant placement[42] and significantly improves impingement-free range of motion[43-45] and revision risk at 10 years.[46]

Pre-operative

CORIOGRAPH Pre-Op Planning and Modelling services for hips

Personalised THA pre-op planning that operates with 2D (X-ray) and/or 3D (CT) images

Advanced modeling capabilities that go beyond the mechanics of range of motion to **offer 12 ADLs**



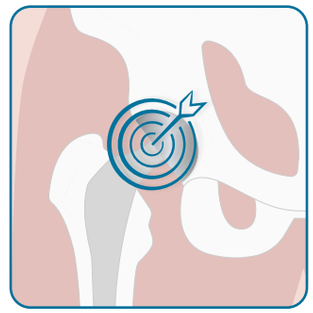
Allows pre-operative **assessment of spinopelvic condition with ADLs** to help mitigate impingement risk[41]

Versus conventional THA, RI.HIP THA has resulted in:

Intra-operative

Optimised implant placement and accuracy

Significantly **reduced deviation from target** component positioning ($p<0.001$)[42]



Post-operative

Improved impingement-free ROM, revision risk and patient satisfaction

When used with Smith+Nephew acetabular components:



Significantly **improved impingement-free ROM** ($p\leq0.05$)[43-45]



Significantly **lower revision risk at 10 years** (1.06 vs 3.88%; $p=0.005$)[46]



Significantly **higher patient satisfaction** ($p=0.003$)[46]

Abbreviations: ADLs = activities of daily living, ROM = range of motion, THA = total hip arthroplasty.

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