Collection of evidence

RI.HIP NAVIGATION
Total Hip Athroplasty

Evidence in focus
Developed by Evidence Communications, Global Clinical & Medical Affairs

Smith+Nephew

July 2021

RI.HIP NAVIGATION collection of evidence

The need for navigation-assisted THA

Why RI.HIP NAVIGATION?

POLAR3◊ Total Hip Solution

Key studies

- Ulivi et al. 2014
- Davis et al. 2015
- Renkawitz et al. 2015
- Woerner et al. 2016
- Chaudhry et al. 2018
- Davis et al. 2021

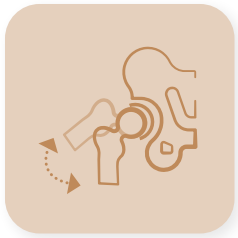
Studies in brief

View 5 studies

Key outcomes

Acetabular component positioning

Leg length and offset



Range of motion

Surgical time

Survivorship

References

Abbreviations

ADL:	Activities of daily living
CAOS:	Computer-assisted orthopaedic surgery
CT:	Computed tomography
DAA:	Direct anterior approach
HHS:	Harris Hip Score
KOOS:	Knee injury and osteoarthritis outcome score
LL:	Leg length
LOS:	Length of stay
NJR:	National Joint Registry
NS:	Not significant
OHS:	Oxford Hip Score
OS:	Offset
PROM:	Patient-reported outcome measure
PT:	Pelvic tilt
ROM:	Range of motion
THA:	Total hip arthroplasty

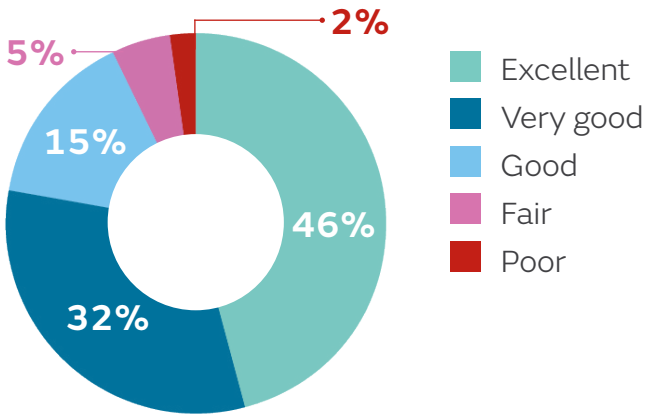
The need for navigation-assisted THA

THA is recognised as a highly successful operation, with a high survivorship at 15 years. The world's largest registry - the National Joint Registry (NJR) of England, Wales and Northern Ireland - reports:[1]

92.47%
15-year survivorship

However, with between 7 and 23% of THA patients reporting long-term pain[2] and fewer than 50% patients describing the results of their operations as excellent,[3] there is still room for improvement.

How would you describe the results of your operation?[3]



The most common technical complications associated with THA are:

1. Component malpositioning[4]
2. Postoperative limb length discrepancy[4]

Up to 50% of acetabular cups may be incorrectly placed[5-7]

Complications of component malpositioning:[8]

- Dislocation
- Hip instability
- Excessive early liner wear
- Impingement
- Shell-liner dissociation
- Leg-length discrepancy
- Limited range of motion (ROM)
- Osteolysis
- Hardware squeaking in ceramic bearing hips

Change in leg length and offset leads to functional deficiencies[9-11]

- Leg length discrepancy after THA may lead to patient dissatisfaction resulting from back pain and gait disorders[9,10]
- Change in offset affects the biomechanical forces affecting the joint; leg length and offset differences >5mm after THA are associated with altered gait kinematics[11]

Pelvic tilt (PT): an important consideration for successful component positioning

Lewinnek et al. defined a safe zone to minimise dislocation risk; operative cup inclination of 40±10° and operative cup anteversion of 15±10°.[12] Yet, most dislocations occur with an implant initially placed within the Lewinnek safe zone,[13] therefore the ideal cup position for some patients may lie outside this safe zone.[14] With pelvic tilt influencing cup positioning, the position of the pelvis is of high importance during THA surgery[14]

95% of patients undergoing THA have some degree of anterior or posterior PT, with 16% having >10° tilt[15]

Why RI.HIP NAVIGATION?

Acetabular component positioning

Using RI.HIP NAVIGATION in THA has been shown to **reduce outliers and improve acetabular component positioning** compared to conventional THA:[16-18]

Significantly improved precision for both inclination and anteversion compared to non-navigated hips[16]

Good correlation between intraoperative RI.HIP NAVIGATION and postoperative CT measurements[17]

Low number of outliers from safe zone target[18]

Leg length and offset

RI.HIP NAVIGATION allows a **more accurate measurement of leg length and offset change** compared to the conventional THA[5,19,20]

Range of motion

RI.HIP NAVIGATION delivers **significantly improved impingement-related ROM outcomes** compared to conventional THA:

Lower implant-to-implant impingement (p=0.01)[21]

Lower bone-to-bone impingement (p=0.05)[21]

More patients reached ROM boundaries for ADL[22,23]

Surgical time

Surgical times with RI.HIP NAVIGATION are **very similar to conventional THA** performed through the posterior approach[24]

Survivorship

Accurate component positioning using navigation-assisted surgery has been shown to correlate with improved long-term survivorship compared to conventional THA surgery.[25]

Use of navigation-assisted surgery with Smith+Nephew THA implants has been shown to result in:[26]

- Significantly lower 10-year revision rate with computer-guided THA than with conventional THA (1.06 vs 3.88%, p=0.005)
  - Revision risk was 55% lower with computer-guided vs conventional THA (p=0.038)

POLAR3◊ Total Hip Solution delivers excellent performance[27]

POLARSTEM◊
cementless stem system

19 years
of clinical heritage
10A* ODEP rating[28]

OXINIUM◊
with XLPE

19 years
of clinical heritage

In 2005, OXINIUM Technology was the first and only medical device material to receive the prestigious Engineering Achievement Materials Award from ASTM International

R3◊
Acetabular System

13 years
of clinical heritage
10A* ODEP rating[28]

98% survivorship at 8 years[27†]

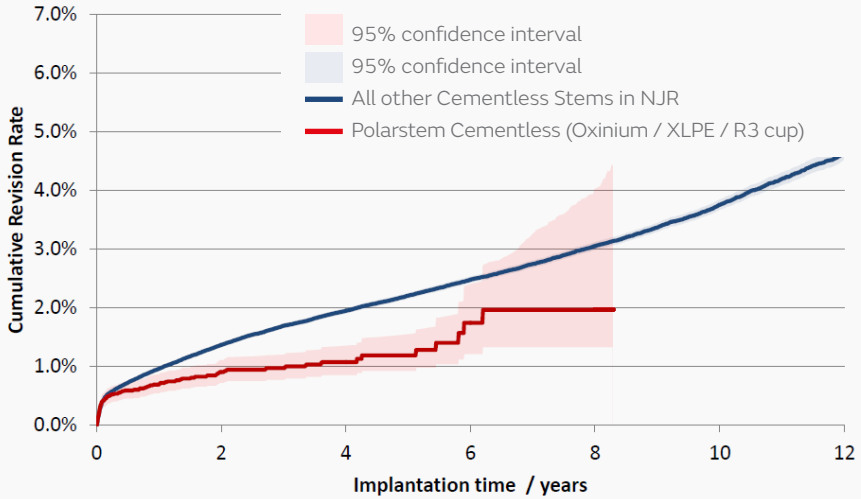


Figure. Incidence of cumulative revision rate of POLAR3 (POLARSTEM, OXINIUM/XLPE, R3) compared to all other cementless stems in NJR, with endpoint as any revision. All reasons for revision, excluding metal-on-metal

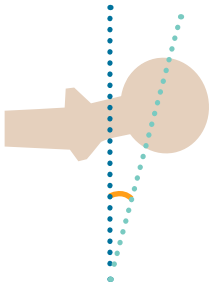
†The data used for this analysis was obtained from the NJR Supplier Feedback System. The Healthcare Quality Improvement Partnership ("HQIP") and/or the National Joint Registry ("NJR") take no responsibility for the accuracy, currency, reliability and correctness of any data used or referred to in this 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.

35% ↓
significantly lower revision risk compared to all other cementless stems ($p<0.001$)[27]

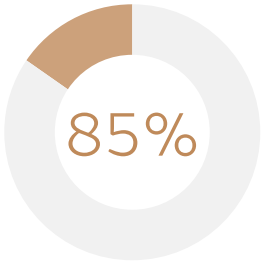
Significantly higher patient satisfaction and **better PROMs** compared to class average for cementless stems ($p<0.001$)[27]

Key outcome
Acetabular component positioning

Navigation versus conventional THA	RI.HIP NAVIGATION



Deviation from desired angle
Navigation has been shown to **significantly reduce the deviation from the planned acetabular anteversion** (p=0.0005) and **inclination angle** (p<0.0001) compared to conventional THA surgery[27]



Safe/target zone placement
85% reduction in the odds of outliers with navigation-assisted THA when compared to conventional THA (p<0.0001)[27]

Key outcome
Acetabular component positioning

Navigation versus conventional THA | RI.HIP NAVIGATION

Using RI.HIP NAVIGATION in THA has been shown to reduce outliers and improve acetabular cup positioning compared to conventional THA

Davis et al. 2015, reported successful safe zone placement for 99.75% of inclination and 97.68% of anteversion angles.[18]

This study also demonstrated that RI.HIP NAVIGATION achieved lower mean error for inclination and anteversion when patients were placed in the lateral decubitus position compared to the more traditional anterior pelvic plane positioning.[18]

Go to Davis et al. 2015[18] summary

High acetabular component position accuracy with RI.HIP NAVIGATION seen in several studies: **Improved precision for both inclination[16,30] and anteversion compared to non-navigated hips**[16]

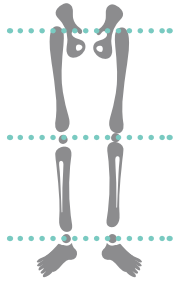
Go to Sendtner et al. 2011[16] summary

Accuracy of RI.HIP NAVIGATION has been confirmed with postoperative CT measurements for both cup inclination and anteversion[17]

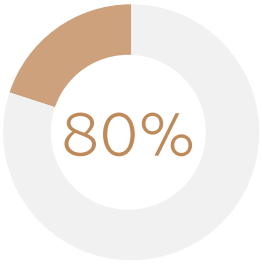
Go to Rizzi et al. 2012[17] summary

Key outcome
Leg length and offset

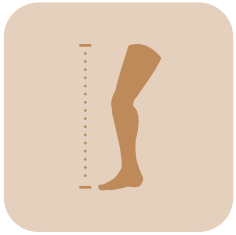
Navigation versus conventional THA	RI.HIP NAVIGATION



Leg length discrepancy was **significantly reduced** with navigation-assisted THA (-1.24mm; p=0.0001)[29]



80% (8 out of 10 studies) of identified studies reported that **leg length discrepancies were reduced** with the use of a navigation system[29]



Key outcome
Leg length and offset

Navigation versus conventional THA

RI.HIP NAVIGATION

Using RI.HIP NAVIGATION in THA has been shown to achieve consistent leg length restoration

The validity and accuracy of RI.HIP NAVIGATION was confirmed in a comparison with X-ray based measurements:

- Mean difference between the navigation measurements and the expected values was 0.00±1.16mm (leg length) and -0.20±1.21mm (femoral offset)[4]

Go to Ulivi et al. 2012[4] summary

A further study compared accuracy of intraoperative leg length and offset measurements with RI.HIP NAVIGATION and pelvic radiographs:

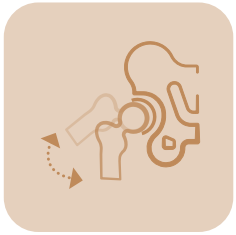
- No significant differences were seen between mean measurements or both leg length (p=0.51) and offset (p=0.072)[20]

Go to Renkawitz et al. 2014[20] summary

In a comparison with other navigation systems, RI.HIP NAVIGATION was shown to be as accurate as THS* (p=0.986) and more accurate than Amplivision* (p=0.044)[19]

Go to Clavé et al. 2015[19] summary

*THS™ (Praxim, Tronche, France); Amplivision® navigation system (Amplitude Surgical, Valence, France)



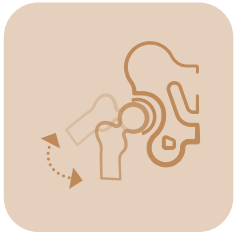
Key outcome
Range of motion

Navigation versus conventional THA

RI.HIP NAVIGATION

Impingement-related ROM outcomes are significantly improved with navigation-assisted THA, compared to conventional THA:[29]

- ↓ Less implant-to-implant impingement (p=0.01)
- ↓ Less bone-to-bone impingement (p=0.05)
- ↓ Fewer impingement related complications
- ↑ More patients reached ROM boundaries for ADL



Key outcome
Range of motion

Navigation versus conventional THA

RI.HIP NAVIGATION

Impingement is associated with reduced ROM, higher risk of dislocation, component wear and patient dissatisfaction[31]

Higher proportions of patients in the RI.HIP NAVIGATION treatment groups achieved impingement-free ROM within the boundaries for essential ADL than non-navigated patients[22,23]

Go to Renkawitz et al. 2015[23] summary

Impingement severity for implant-to-implant (p=0.01) and bone-to-bone impingement (p=0.05) was reduced in patients who received surgery with RI.HIP NAVIGATION versus non-navigated surgeries[21]

Go to Palit et al. 2017[21] summary

Intraoperative estimation of ROM by eye may differ by up to 30° compared to measurements with RI.HIP NAVIGATION[31]

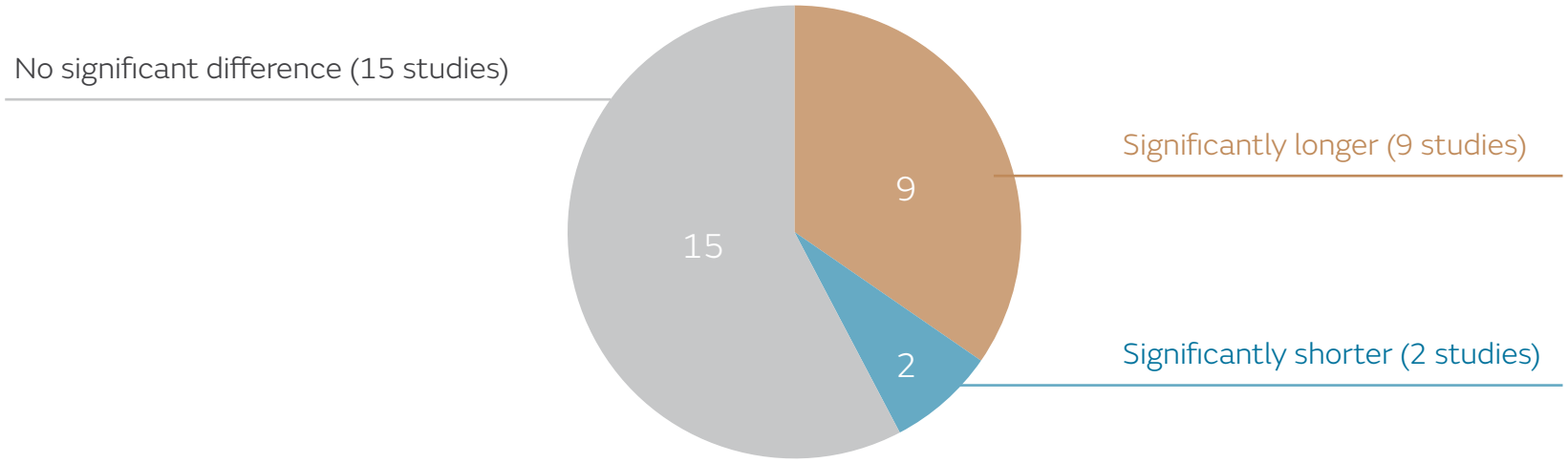
Go to Woerner et al. 2016[31] summary

Key outcome
Surgical time

Navigation versus conventional THA

RI.HIP NAVIGATION

Surgical time for navigation-assisted THA compared to conventional THA[29]



Key outcome
Surgical time

Navigation versus conventional THA

RI.HIP NAVIGATION

Simplified registration combined with no patient repositioning leads to reduced surgical time compared to previous models[18,24]

Surgical times with RI.HIP NAVIGATION are very similar to cases performed through the posterior approach without navigation[24]

Go to Chaudhry et al. 2018[24] summary

Key outcome
Survivorship

Navigation versus conventional THA

Navigation-assisted THA results in high long-term survivorship[25,26,32]

Sugano et al. (2012) investigated whether the short-term achievement of more precise implant placement leads to long-term improvement in survivorship.[25] In their retrospective review of 180 THAs (navigation-assisted THA, n=60; conventional THA, n=120), they showed that navigation-assisted THA resulted in higher cup orientation placement precision (within a target zone) than conventional methods.

In a small study of 60 THAs, Parratte et al. (2016) also demonstrated high long-term survivorship with navigation-assisted THA.[32]

Davis et al. (2021) investigated the effect of computer guidance on the survival of THA implants and on patient satisfaction using the NJR dataset and linked PROMs.[26] All THA surgery was performed using Smith+Nephew implants.

Go to Davis et al. 2021[26] summary

13 years Survivorship — **100%** navigation-assisted THA vs 95.6% conventional THA (p=ns)[25]

10 years Survivorship — **100%** navigation-assisted THA vs 100% conventional THA (p=ns)[32]

10 years Survivorship — **98.94%** computer-guided THA vs 96.12% conventional THA (p=ns)[26]

55% Revision risk with computer-guided vs conventional THA (p=0.038)[26]

Key study

Intraoperative validation of navigated limb measurements in THA using a pinless femoral array[4]

Ulivi M, Orlandini L, Pascale W, Consonni O, Sansone V. *J Arthroplasty.* 2014;29:1026–1029

Prospective case series:

RI.HIP NAVIGATION (n=60)

Surgical approach:

Lateral decubitus position; postero-lateral approach

Aim:

Determine accuracy of an imageless navigation system with a minimally-invasive femoral reference array in recording differences in LL and offset compared to X-ray measurements

Results

Mean difference between the intra-operative navigation measurements and the varus valgus corrected values:

- LL; 0.00±1.16mm (95% CI: -2.27 to 2.28mm)
- Offset; -0.20±1.21mm (95% CI: -2.58 to 2.18mm)

Conclusion

RI.HIP NAVIGATION is a valid and accurate intraoperative tool for measuring LL and femoral offset

Full publication

Key study

A new method of registration in navigated hip arthroplasty without the need to register the anterior pelvic plane[18]

Davis ET, Schubert M, Wegner M, Haimerl M. *J Arthroplasty.* 2015;30:55–60

Prospective case series:

RI.HIP NAVIGATION (n=48)

Surgical approach:

Lateral decubitus position; femur first approach

Aim:

Analyse the accuracy of the epicutaneous anterior pelvic plane (APP) registration technique to the supine and lateral registration technique

Results

	Inclination		Anteversion	
	Deviation to CT scan [°]	**Percentage of outliers***	**Deviation to CT scan [°]**	**Percentage of outliers***
Epicutaneous APP registration	-1.8±1.8 (CI: -5.3 to 1.8)	0.00%	-4.8±2.7 (CI: -10.2 to 0.5)	2.98%
New lateral registration	-1.1±3.1 (CI: -7.3 to 5.0)	0.25%	0.9±4.3 (CI: -7.5 to 9.3)	2.32%
Pubic-free supine registration	0.5±2.2 (CI: -3.8 to 4.7)	0.00%	0.9±3.9 (CI: -6.3 to 8.0)	1.20%

*Outliers are defined in terms of cup orientation compared to conventional technique

Conclusion

The new lateral registration technique does not require access to the APP and can be performed in a fully prepared patient in the lateral decubitus position, providing accurate and precise acetabular component orientation

Full publication

Back to ROM

Key study

Impingement-free range of movement, acetabular component cover and early clinical results comparing 'femur-first' navigation and 'conventional' minimally invasive total hip arthroplasty: a randomised controlled trial[23]

Renkawitz T, Weber M, Springorum H, et al. *Bone Joint J.* 2015;97:890–898

Randomised clinical trial:

RI.HIP NAVIGATION (n=66)	Conventional THA (n=69)

Surgical approach:

Lateral decubitus position; femur first approach

Aim:

Assess whether RI.HIP NAVIGATION results in a potential increased ROM compared with conventional THA

Results

Compared to conventional THA, patients in the RI.HIP NAVIGATION group:

- Achieved impingement-free ROM boundaries for essential ADL*; 84 vs 65% (p=0.016)
- Achieved significantly higher HHS at 6 weeks postoperatively (p=0.01)
- Mean operating time; 71.8 vs 64.1 mins (p<0.001)

*>110° of flexion, >30° of extension >45° of external rotation at 0° of hip flexion, >30° of internal rotation at 90° of hip flexion, >50° of abduction, >30° of adduction

Conclusion

RI.HIP NAVIGATION improves the theoretical or potential ROM before potential prosthetic impingement

Full publication

Back to ROM

Key study

Visual intraoperative estimation of range of motion is misleading in minimally invasive total hip arthroplasty[31]

Woerner M, Weber M, Sendtner E, et al. *Arch Orthop Trauma Surg.* 2016;136:1015–1020

Retrospective case series:

RI.HIP NAVIGATION (n=60)

Surgical approach:

Lateral decubitus position; minimally invasive anterolateral approach

Aim:

Investigate intraoperative accuracy of visual estimation of ROM by eye compared to RI.HIP NAVIGATION

Results

	Mean difference between RI.HIP NAVIGATION measurements and visual intraoperative estimations (SD)	Occurrence of a difference >10° between RI.HIP NAVIGATION and visual intraoperative estimations (%)
Flexion	5.6° (±10.9)	37%
Extension	-0.4° (±10.7)	35%
Abduction	8.7° (±9.0)	52%
External rotation	5.9° (±18.3)	43%
Internal rotation	-5.8° (±12.1)	43%

Conclusion

Simple visual estimation of ROM during minimally invasive THA is susceptible to error and differs up to 30° compared to measurements with RI.HIP NAVIGATION

Full publication

Back to Surgical time

Key study

A new system of computer-assisted navigation leading to reduction in operating time in uncemented total hip replacement in a matched population[24]

Chaudhry FA, Ismail SZ, Davis ET. *Eur J Orthop Surg Traumatol.* 2018;28:645–648

Retrospective, observational study:

RI.HIP NAVIGATION (n=256*)

Surgical approach:

Lateral decubitus position; posterior approach

Aim:

Determine whether there is a significant difference in operative time between the traditional anterior pelvic plane registration and the new lateral position registration

Results

Mean operating time:

- Traditional APP registration (n=128): 65.79 minutes (range, 40–98)
- New lateral position registration (n=128): 50.87 minutes (range, 33–74)
- Operative time declines with lateral position registration (0.19min per month; p=0.019)

Cup positioning accuracy was comparable between groups

Conclusion

The new lateral registration technique significantly reduces operative time compared to the traditional APP registration technique. A continued improvement in the operative time is seen with the lateral position registration as the surgeon becomes more proficient in the technique

Full publication

*Compared BrainLab versions 2.1–5.1 (APP registration; n=128) with BrainLab version 6.0 (lateral position registration; n=128)

Key study

Computer guided total hip arthroplasty is associated with a reduced risk of revision and increased patient satisfaction. An analysis of a single manufacturer acetabular components from the National Joint Registry of England, Wales, Northern Ireland and the Isle of Man[26]

Davis ET, McKinney KD, Kamali A, Kuljaca S, Pagkalos J. Poster presented at: World Arthroplasty Congress (WAC) Virtual Meeting; April 22–24, 2021

Registry data analysis:

Computer-guided THA (n=871) | Conventional THA (n=41,683)

Surgical implants:

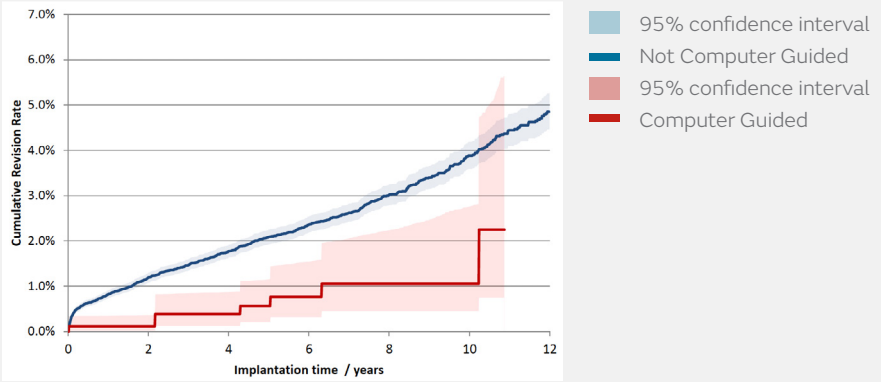
Smith+Nephew cementless acetabular components

Aim:

Analyse the effect of computer guidance on the survival of THA implants and on patient satisfaction using the NJR† dataset and linked PROMs

Results

- Significantly lower 10-year revision rate with computer-guided THA than with conventional THA (1.06 vs 3.88%, p=0.005)
  - Revision risk was 55% lower with computer-guided versus conventional THA (p=0.038)
- Satisfaction rate was significantly higher in the computer-guided group compared to conventional THA (p=0.003)



Conclusion

Use of computer-guided surgery with Smith+Nephew implants was associated with a significant reduction in the risk of long-term revision and significantly improved patient satisfaction compared to conventional THA surgery.

†The data used for this analysis was obtained from the NJR Supplier Feedback System. The Healthcare Quality Improvement Partnership ("HQIP") and/or the National Joint Registry ("NJR") take no responsibility 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.

Full publication

Back to Acetabular

Studies in brief

Sendtner et al. 2011[20]

Rizzi et al. 2012[17]

Renkawitz et al. 2014[20]

Clavé et al. 2015[19]

Palit et al. 2017[21]

Accuracy of acetabular cup placement in computer-assisted, minimally-invasive THR in a lateral decubitus position[20]

Sendtner E, Schuster T, Wörner M, Kalteis T, Grifka J, Renkawitz T. *Int Orthop.* 2011;35:809–815

Prospective, randomised clinical trial:

RI.HIP NAVIGATION (n=32) Freehand (n=30)

Surgical approach:

Lateral decubitus position; approach not specified

Aim:

Assess accuracy of acetabular component placement using RI.HIP NAVIGATION compared to freehand technique with a minimally invasive surgical approach

Results

Parameter measured		Navigation	Freehand	p-value
Inclination	Mean Range	42.3° 32.7–50.6°	37.9° 25.6–50.2°	0.002
	SD	3.8°	6.3°	0.007
Anteversion	Mean Range	24.5° 12.0–33.3°	23.8° 5.6–46.9°	0.739
	SD	6.0°	10.1°	0.024

Target acetabular component position for all patients was 40–45° inclination and 15–20° anteversion (operative definition)

Full publication

Back to Acetabular

Studies in brief

Sendtner et al. 2011[20]

Rizzi et al. 2012[17]

Renkawitz et al. 2014[20]

Clavé et al. 2015[19]

Palit et al. 2017[21]

Acetabular cup positioning using computer navigation through direct anterior approach[16]

Rizzi L, Gotti V, Castelli CC. *Hip Int.* 2012;22:431–432

Retrospective, observational study:

Prospective case series (RI.HIP NAVIGATION, n=20); no comparator

Surgical approach:

Supine position; DAA

Aim:

Compare intraoperative RI.HIP NAVIGATION measurements with postoperative CT scan

Results

Good correlation of the intraoperative RI.HIP NAVIGATION and postoperative CT measurements:

	Mean cup inclination (range)	Mean version (range)
RI.HIP NAVIGATION	44.4° (39–48°)	15.8° (10–21°)
CT scan	44.9° (39–53°)	15.6° (10–22°)

Full publication

Back to Leg length

Studies in brief

Sendtner et al. 2011[20]

Rizzi et al. 2012[17]

Renkawitz et al. 2014[20]

Clavé et al. 2015[19]

Palit et al. 2017[21]

Femoral pinless length and offset measurements during computer-assisted, minimally invasive total hip arthroplasty[20]

Renkawitz T, Sendtner E, Schuster T, Weber M, Grifka J, Woerner M. *J Arthroplasty.* 2014;29:1021–1025

Prospective case series:

RI.HIP NAVIGATION (n=50)

Surgical approach:

Lateral decubitus position; minimally invasive modified Smith Petersen approach

Aim:

Determine accuracy of measuring LL and OS change intraoperatively with a novel femoral pinless navigation system (RI.HIP NAVIGATION) by comparison with postoperative radiographs

Results

There was substantial agreement between the postoperative radiographic results and the intraoperative results from the femoral pinless navigation system with mean differences ≥1.0mm:

- Differences of the mean leg length changes: 0.35mm (p=0.51)
- Differences of the mean offset changes: -1.0mm (p=0.072)

Full publication

Back to Leg length

Studies in brief

Sendtner et al. 2011[20]

Rizzi et al. 2012[17]

Renkawitz et al. 2014[20]

Clavé et al. 2015[19]

Palit et al. 2017[21]

Comparison of the reliability of leg length and offset data generated by three hip replacement CAOS systems using EOS™ imaging[19]

Clavé A, Fazilleau F, Cheval D, Williams T, Lefèvre C, Stindel E. *Orthop Traumatol Surg Res.* 2015;101:647–653

Retrospective observational study:

RI.HIP NAVIGATION (n=42)	Amplivision* (n=23)	THS* (n=41)

Surgical approach:

Lateral decubitus position; posterolateral approach

Aim:

Compare reliability of leg length (LL) and offset (OS) data generated by three navigation assisted THA systems

Results

- RI.HIP NAVIGATION demonstrated comparable accuracy to THS (p=0.986) and higher accuracy than Amplivision (p=0.044) for leg length
- Ability to achieve a maximum error of ±2mm was not significantly different between groups (p=0.61)
- All systems had error values <1mm

Full publication

*THS™ (Praxim, Tronche, France); Amplivision® navigation system (Amplitude Surgical, Valence, France)

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Studies in brief

Sendtner et al. 2011[20]

Rizzi et al. 2012[17]

Renkawitz et al. 2014[20]

Clavé et al. 2015[19]

Palit et al. 2017[21]

Femur first navigation can reduce impingement severity compared to traditional free hand total hip arthroplasty[21]

Palit A, Williams MA, Turley GA, Renkawitz T, Weber M. *Sci Rep.* 2017;7:7238

Retrospective, observational study:

RI.HIP NAVIGATION (n=65) Conventional (n=56)

Surgical approach:

Lateral decubitus position; femur first approach

Aim:

Investigate if RI.HIP NAVIGATION is more effective than conventional THA at providing impingement-free ROM

Results

- Implant-to-implant impingement severity significantly decreased with RI.HIP NAVIGATION compared to conventional THA: 1.6 vs 2.6% (p=0.01)
- Bone-to-bone impingement severity significantly decreased with RI.HIP NAVIGATION compared to conventional THA: 3.7 vs 5.0% (p=0.05)

Full publication

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Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

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Smith+Nephew