✚ Evidence in focus

Robotics Compendium of Clinical Evidence

December 2021

Smith+Nephew

Smith+Nephew Robotics Compendium of Evidence

What are the pain points with conventional UKA & TKA?

How can robotic-assisted surgery help?

Why S+N robotics?

Key clinical evidence:

UKA evidence

Canetti R, et al. 2018

Mergenthaler G, et al. 2020

Sephton BM, et al. 2020

TKA evidence

Vaidya NV, et al. 2020

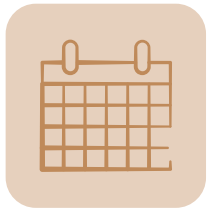
Khan H, et al. 2021

Savov P, et al. 2021

Key outcomes:

Accuracy

Early recovery & clinical outcomes



Survivorship

Surgical time

Cost effectiveness

All clinical evidence:

View all **34 studies**

Abbreviations

FJS:	Forgotten joint score
IKSS-O:	International knee society score-objective
KOOS:	Knee injury and osteoarthritis outcome score
KSS:	Knee society score
LOS:	Length of stay
NJR:	National Joint Registry
OKS:	Oxford knee score
QALY:	Quality adjusted life year
RMS:	Root mean square
ROM:	Range of motion
RTS:	Return to sport
TKA:	Total knee arthroplasty
UKA:	Unicondylar knee arthroplasty
UKR:	Unicompartmental knee replacement

What are the issues with conventional UKA & TKA?

UKA

Conventional UKA is a complex procedure leading to a high rate of limb alignment outliers,[1,2] with a higher revision rate than TKA.[3]

With low surgeon caseloads, the revision risk is high.[4] This drives surgeons to perform UKA in narrower indications, leading to further reduced use.[5]

TKA

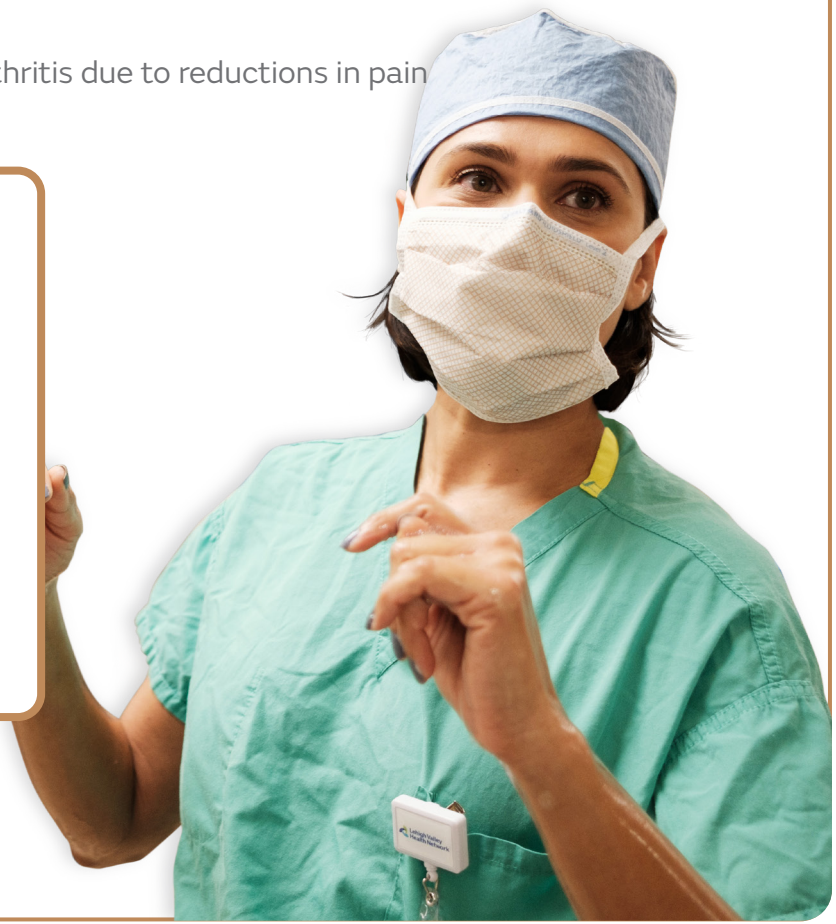
Conventional TKA is a successful intervention for the treatment of end-stage arthritis due to reductions in pain and its longterm survivorship.[6] However:

Over 50%

of patients report some degree of limitation to their functional ability,including activities of daily living and sports activities following TKA[7]

Up to 20%

of patients are not satisfied with their total knee replacement[6]



How can robotic-assisted surgery help? →

How can robotic-assisted surgery help?

Robotic-assisted surgery uses computer-aided technology to complement conventional surgical procedures	✓
Robotic-assisted surgery has been shown to help improve surgical outcomes,[8] and enhance the surgeon's ability to reproduce alignment of the knee,[9] compared to conventional techniques	✓
Pre-operative and intra-operative planning permits an individualised surgical approach,[10] which is designed to allow for optimal implant sizing, positioning and soft tissue balancing	✓

"Robotic surgery is here to stay and will occupy a key place in the future of trauma and orthopaedics"[11]

Why Smith+Nephew Robotics?

2012

NAVIO◊ Surgical System partial knee arthroplasty launched by Blue Belt Technologies

2015

Smith+Nephew acquired Blue Belt Technologies and NAVIO partial knee arthroplasty

2017

Launch of NAVIO TKA

2020

Launch of CORI◊ Surgical System UKA and TKA

Enhanced robotic software solution that delivers:

Fast learning curve

From junior orthopaedic trainees to experienced surgeons, the total surgical time decreases as the number of procedures increases[12-14,22,23]

Portability

Featuring simple calibration and a footprint designed for use in the surgery centre or hospital, Smith+Nephew Assisted Robotic technology can easily be moved between operating rooms to support the demand for efficiency needed by orthopaedic programmes

No requirement for a CT scan

Unlike other robotic systems, Smith+Nephew Assisted Robotic technology uses real-time imaging, eliminating the need for a CT scan which would otherwise be required to plan the operation

Choice of implants

Smith+Nephew Assisted Robotic technology is compatible with multiple implant options for both partial and total knee replacement procedures, including JOURNEY◊ II, LEGION◊ and GENESIS◊ II systems

Faster return to sport after robotic-assisted lateral unicompartmental knee arthroplasty: a comparative study[15]

Canetti R, Batailler C, Bankhead C, Neyret P, Servien E, Lustig S. *Arch Orthop Trauma Surg*. 2018;138:1765-1771

Retrospective, single-surgeon case-control study of:

11 NAVIO◊ lateral UKAs	17 Conventional lateral UKAs
Mean follow up: **34.4 months & 39.3 months**	

Assessed at pre-UKA, at 2 months, 1 year, and every year after surgery:

Knee scores – IKSS objective and functional / FJS / Lysholm knee scale	✓
Sports Participation – UCLA Activity score	✓

Results

NAVIO UKA resulted in significantly faster return to sport* compared to conventional UKA (4.2 vs 10.5 months; p<0.01)

*mainly low- and mid-impact sports (hiking, cycling, swimming, and skiing)

100% patients returned to sport and 91% returned to their presymptomatic intensity level following NAVIO UKA

Significantly better post-operative IKSS-O score with NAVIO UKA compared to conventional UKA (97.2 vs 91.2; p<0.05)

Conclusion

Compared to conventional surgery, NAVIO robotics-assisted lateral UKA reduced time to return to sport at pre-symptomatic levels

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Full summary

Full paper

Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study[16]

Mergenthaler G, Batailler C, Lording T, Servien E, Lustig S. *Knee Surg Sports Traumatol Arthrosc.* 2020; doi: 2021;29:931-938

Retrospective, single-centre, study of:

200 NAVIO◊ UKAs	191 Conventional UKAs
Mean follow-up: **22.5 months & 30.2 months (p<0.001)**	

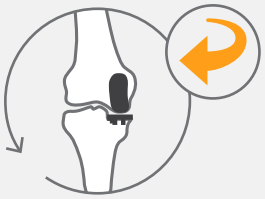
Assessed at 1 year-post-UKA:

Implant position using radiographs ✓

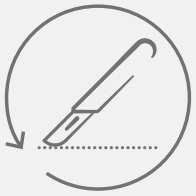
Assessed at last follow-up:

Revision rate ✓

Results



Significantly lower revision rate than conventional UKA (4 vs 11%; p=0.014)



Numerically lower reoperation rate compared to conventional UKA (6.5 vs 9.4%)

No complications related to the NAVIO Surgical System

Conclusion

NAVIO UKA demonstrated a significantly lower revision rate for UKA than conventional methods, and was not associated with any robotic specific complications at the short-term follow up

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Achieving discharge within 24h of robotic unicompartmental knee arthroplasty may be possible with appropriate patient selection and a multi-disciplinary team approach[17]

Sephton BM, De la Cruz N, Shearman A, Nathwani D. *J Ortho.* 2020;19:223-228

Single-surgeon case-control study of:

71 NAVIO◊ UKAs (19 discharged within 24 hours)

Follow up: **6 weeks**

Assessed during hospital stay:

Length of stay	✓
Complications / readmissions	✓
Functional assessment	✓

Results

Average length of stay was 19.5 hours (range: 6-23 hours)

Sixteen (84.2%) patients were mobilised without walking aids; three (15.8%) with the use of a single walking stick

No complications or readmissions within 6 weeks post-UKA

Conclusion

With appropriate patient selection and education, NAVIO UKA patients were able to be safely discharged within 24 hours of their operation

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TKA

Robotic-assisted TKA leads to a better prosthesis alignment and a better joint line restoration as compared to conventional TKA: a prospective randomized controlled trial[18]

Vaidya NV, Deshpande AN, Panjwani T, Patil R, Jaysingani T, Patil P. *Knee Surg Sports Traumatol Arthrosc.* 2020 Nov 9; https://doi.org/10.1007/s00167-020-06353-2

Independent, prospective, randomised controlled trial of:

32 NAVIO◊ TKA	28 conventional TKA

Assessed:

Radiographs were assessed pre- and post-TKA to determine alignment and joint line deviation

Results

NAVIO TKA achieved significantly lower mechanical axis deviation than conventional TKA (p=0.019)

NAVIO TKA resulted in a significantly lower elevation of the joint line than conventional TKA (p<0.001)

Conclusion

NAVIO TKA resulted in improved implant positioning and mechanical axis alignment, compared to conventional TKA. The joint line was significantly elevated following conventional TKA, whereas it was restored with NAVIO TKA

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TKA

Blood loss and transfusion risk in robotic-assisted knee arthroplasty: A retrospective analysis[19]

Khan H, Dhillon K, Mahapatra P, Popat R, Zakieh O, Kim WJ, Nathwani D. *Int J Med Robot.* 2021;e2308

Retrospective, multi-surgeon, cohort analysis of:

50 NAVIO◊ TKA	vs	50 conventional TKA
50 NAVIO UKA	vs	50 conventional UKA

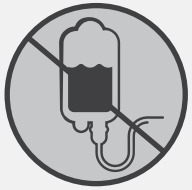
Assessed:

Blood parameters ✓

Results

NAVIO TKA patients experienced a 23.7% less blood loss than conventional TKA patients (911.0 vs 1193.7ml; p<0.01)

NAVIO TKA patients were associated with a 83% relative risk reduction of receiving a blood transfusion compared to conventional TKA (2 vs 12% of patients; p=0.02)



No blood transfusions were required for any NAVIO or conventional UKA patients. There was no significant difference in blood loss between NAVIO UKA and conventional UKA patients (821.7 vs 854.7ml; p=ns)

Conclusion

NAVIO TKA significantly reduced blood loss and reduced the risk of requiring a blood transfusion compared to conventional TKA

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TKA

Imageless robotic handpiece-assisted total knee arthroplasty: a learning curve analysis of surgical time and alignment accuracy[20]

Savov P, Tuecking LR, Windhagen H, Ehmig J, Ettinger M. *Arch Orthop Trauma Surg.* 2021: doi: 10.1007/s00402-021-04036-2

Single-surgeon, case-controlled study of:

Surgeon's first 70 NAVIO◊ TKAs	70 conventional TKAs

Assessed:

Surgical time	✓
Implant alignment	✓
Joint line height	✓

Results

NAVIO TKA learning curve was completed after 11 cases

No significant difference in surgical time between NAVIO TKA and conventional TKA after the learning curve (69 vs 67min; p=ns)

No learning curve for accuracy of implant positioning with NAVIO TKA

Conclusion

Surgical time required with NAVIO TKA was similar to that of conventional TKA following the short learning curve

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All published clinical evidence 1/3

Select the study icon to see the report overview. Highlighted reports are key studies.

UKA studies

Gonzalez D, et al 2014	Preliminary results of UKR implanted using an image free handheld robotic device
Gregori A, et al. 2014	Handheld precision sculpting tool for unicondylar knee arthroplasty. A clinical review
Wallace D, et al. 2014	The learning curve of a novel handheld robotic system for unicondylar knee arthroplasty
Gregori A, et al. 2015	Accuracy of imageless robotically assisted unicondylar knee arthroplasty
Herry Y, et al. 2017	Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique
Vega Parra P, et al. 2017	Robotic-assisted unicompartmental knee arthroplasty with NAVIO◊ surgical system: Outcome evaluation using knee injury ostearthritis outcome score
Batailler C, et al. 2018	Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty
Canetti R, et al. 2018	**Faster return to sport after robotic-assisted lateral unicompartmental knee arthroplasty a comparative study**

TKA studies

Shah S, et al 2018	Robotic assisted revision total knee replacement - early experience
Bollars P. 2019	The learning curve and alignment assessment of an image-free handheld robot in TKA: The first patient series in Europe
Geller JA, et al. 2019	Rate of learning curve and alignment accuracy of an image-free handheld robot for total knee arthroplasty
Kaper BP, et al. 2019	Measurement of full arc range of motion soft tissue balance in robotic-assisted total knee arthroplasty
Kaper BP, et al. 2019	Initial safety profile assessment of the NAVIO robotic-assisted total knee arthroplasty
Kaper BP, et al. 2019	Accuracy and precision of a handheld robotic-guided distal femoral osteotomy in robotic-assisted total knee arthroplasty
Kaper BP, et al. 2019	Learning curve and time commitment assessment in the adoption of NAVIO robotic-assisted total knee arthroplasty
Bollars P, et al. 2020	Preliminary experience with an image-free handheld robot for total knee arthroplasty: 77 cases compared with a matched control group

All published clinical evidence 2/3

Select the study icon to see the report overview. Highlighted reports are key studies.

UKA studies

Di Benedetto P, et al. 2019	Comparison between standard technique and image-free robotic technique in medial unicompartmental knee arthroplasty. Preliminary data
Lonner JH, et al. 2019	Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems
Battenberg A, et al. 2019	A novel handheld robotic-assisted system for unicompartmental knee arthroplasty surgical technique and early survivorship
Leelasetaporn C, et al. 2020	Comparison of 1-year outcomes between MAKO® versus NAVIO◊ robot-assisted medial UKA: nonrandomized, prospective, comparative study
Mergenthaler G, et al. 2020	**Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study**

TKA studies

Vaidya NV, et al. 2020	**Robotic-assisted TKA leads to a better prosthesis alignment and a better joint line restoration as compared to conventional TKA: a prospective randomized controlled trial**
Collins K, et al. 2021	Initial experience with the NAVIO robotic-assisted total knee replacement-coronal alignment accuracy and the learning curve
Held MB, et al. 2021	Improved compartment balancing using a robot-assisted total knee arthroplasty
Khan H, et al. 2021	**Blood loss and transfusion risk in robotic-assisted knee arthroplasty: A retrospective analysis**
Savov P, et al. 2021	**Imageless robotic handpiece-assisted total knee arthroplasty: a learning curve analysis of surgical time and alignment accuracy**
Sicat CS, et al. 2021	Component placement accuracy in two generations of handheld robotics-assisted knee arthroplasty

All published clinical evidence 3/3

Select the study icon to see the report overview. Highlighted reports are key studies.

UKA studies

Nherera LM, et al. 2020	Early economic evaluation demonstrates that noncomputerized tomography robotic-assisted surgery is cost-effective in patients undergoing unicompartmental knee arthroplasty at high-volume orthopaedic centres
Sephton BM, et al. 2020	**24 hour discharge in unicompartmental knee arthroplasty using the NAVIO◊ robotic system: a retrospective analysis**
Yeroushalmi D, et al. 2020	Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis
Negrin R, et al. 2020	Robotic-assisted unicompartmental knee arthroplasty optimizes joint line restitution better than conventional surgery
Bataillier C, et al. 2021	No difference of gait parameters in patients with image-free robotic-assisted medial unicompartmental knee arthroplasty compared to a conventional technique: early results of a randomized controlled trial
Bataillier C, et al. 2021	Improved sizing with image-based roboticassisted system compared to image-free and conventional techniques in medial unicompartmental knee arthroplasty: a case control study
Khan H, et al. 2021	Blood loss and transfusion risk in robotic-assisted knee arthroplasty: A retrospective analysis
Shearman AD, et al. 2021	Robotic-assisted unicondylar knee arthroplasty is associated with earlier discharge from physiotherapy and reduced length of stay compared to conventional UKA

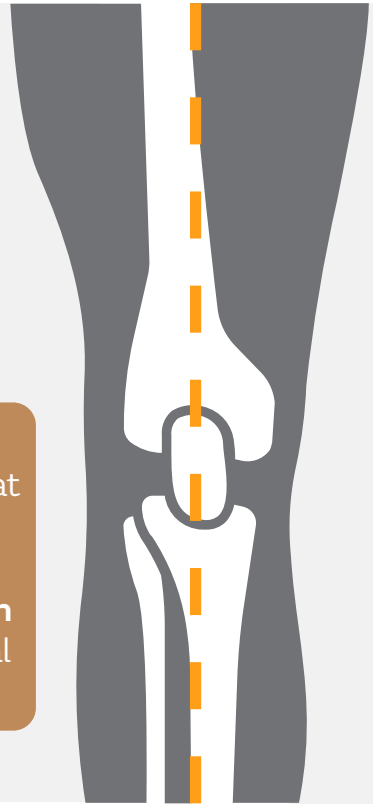
Key outcome: **Accuracy**

15 studies
reporting on accuracy
SEE HERE >

Compared to conventional methods, both NAVIO◊ UKA and TKA result in improved accuracy and reliability in implant placement[2,25,42]

NAVIO Surgical System allows surgeons to precisely plan and execute highly accurate implant placement and mechanical axis alignment[13,18,22]

A randomised controlled trial has demonstrated that **NAVIO TKA results in significantly reduced mechanical axis deviation** compared to conventional TKA (p=0.019)[18]



Significantly less distalised joint line with NAVIO UKA (p<0.05)[25,33] and TKA (p<0.001)[18]	✓
Lower revision rate due to malalignment with NAVIO UKA[2]	✓
Significantly lower rate of outliers in the frontal tibial component with NAVIO TKA (p=0.038)[42]	✓

91% NAVIO UKAs achieved **mechanical axis alignment within 1° of the intra-operative plan**[22] (n=57)

Mean difference in planned vs achieved coronal alignment NAVIO TKA = 0.2° (n=172)[13]

Key outcome: **Accuracy**

15 studies

reporting on accuracy

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Key outcome:
Early recovery & clinical outcomes

13 studies
reporting on recovery
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NAVIO◊ UKA patients reported substantial improvements in quality of life, pain and function over the first year post-UKA compared to pre-UKA[26] (Figure) . Compared to conventional UKA, NAVIO UKA patients have demonstrated significant improvement in both IKSS-objective (p<0.05)[15] and function scores (p=0.01).[16]

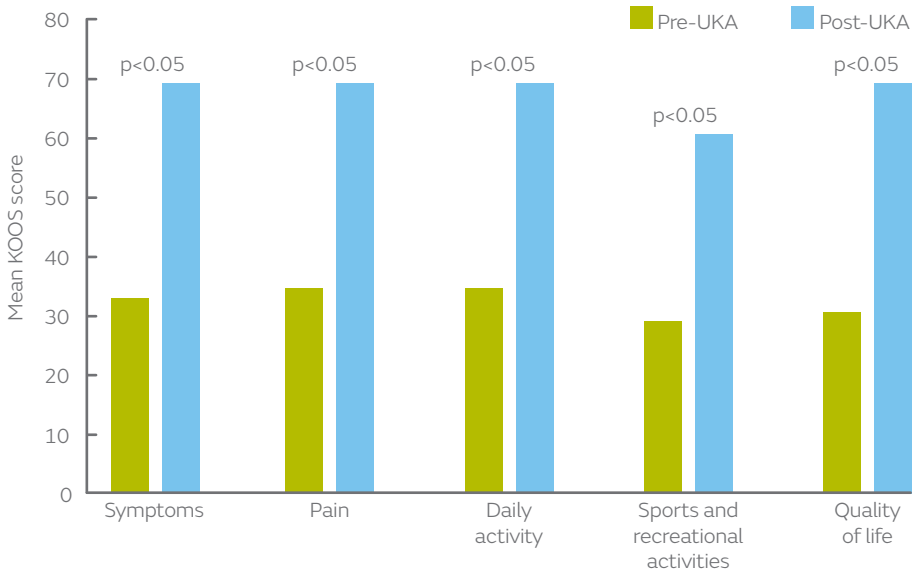

Figure. KOOS scores pre- and post-NAVIO robotic-assisted UKA[26]

A study (n=31) has shown, that compared with patients receiving computer navigated UKA, NAVIO UKA patients were:

Discharged from hospital **38% sooner (p=0.005)**[29]	✓
Discharged from physiotherapy **13% sooner (p=0.02)**[29]	✓

A study has shown
>50% faster
mean time to return to sports[15] with NAVIO UKA compared to conventional UKA

NAVIO TKA patients experienced
23.7% less
blood loss
than conventional TKA patients (p<0.01)[19]

Patients may be safely discharged within **24 hours** post NAVIO UKA (n=19)[17]

Key outcome:
Early recovery & clinical outcomes

13 studies
reporting on recovery

UKA studies

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Key outcome: **Survivorship**

6 studies
reporting on survivorship
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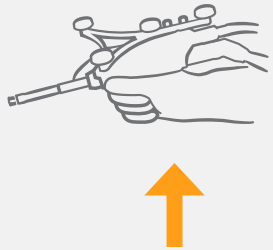
NAVIO◊ UKA is associated with high early survivorship, compared to registry data for conventional UKA[30]

2yrs

95.7%
Australian registry

96%
Swedish registry

96.3%
New Zealand registry



99.2%
NAVIO

Revisions due to malposition or malalignment are lower for NAVIO UKA, compared to conventional UKA[2,16]

0% (0/4 revisions)	Vs	86% (6/7 revisions)[2]
12.5% (1/8 revisions)	Vs	76.2% (16/21 revision)[16]

Key outcome: **Survivorship**

6 studies

reporting on survivorship

UKA studies

Batailler C, et al. 2018	Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty
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Key outcome: **Surgical time**

9 studies
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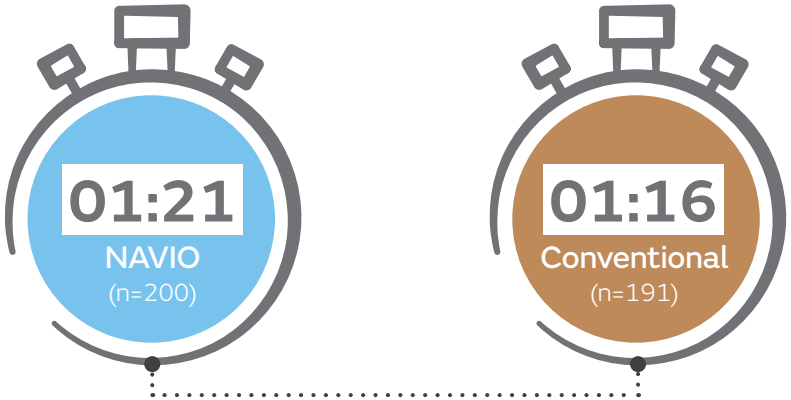
NAVIO◊ UKA and TKA surgeons have experienced no significant differences in surgical time compared to conventional procedures after the initial learning curve[16,20]

NAVIO UKA surgeons have experienced clinically significant reductions in surgical time after only a small number of cases ($p<0.001$)[13]	✓
15.5% reduction in NAVIO UKA surgical time (after 12 cases)[13]	✓

UKA:



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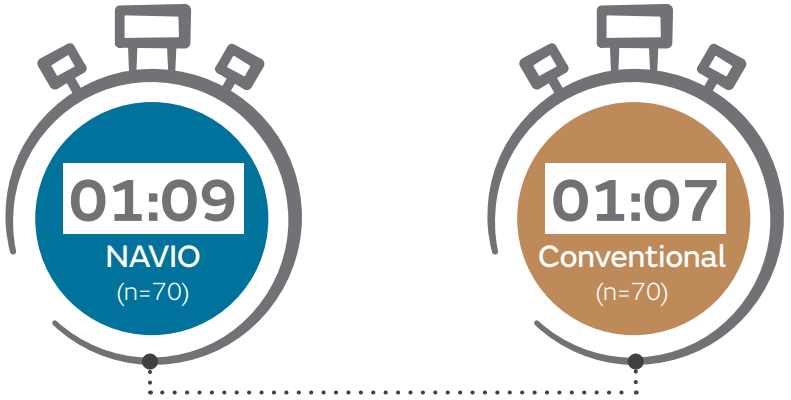
TKA:



p=ns

Key outcome: **Surgical time**

9 studies
reporting on surgical time

UKA studies

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Key outcome:
Cost effectiveness

2 studies
reporting on cost
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NAVIO◊ UKA is estimated to be cost-effective compared to conventional methods over a 5 year period in high volume centres (≥100 UKAs per year)[32,34]

$14,737 estimated cost per revision avoided with NAVIO UKA for high volume centres (≥100 UKAs per year)[34]	✓
£2,831 cost per QALY with NAVIO UKA[32]	✓

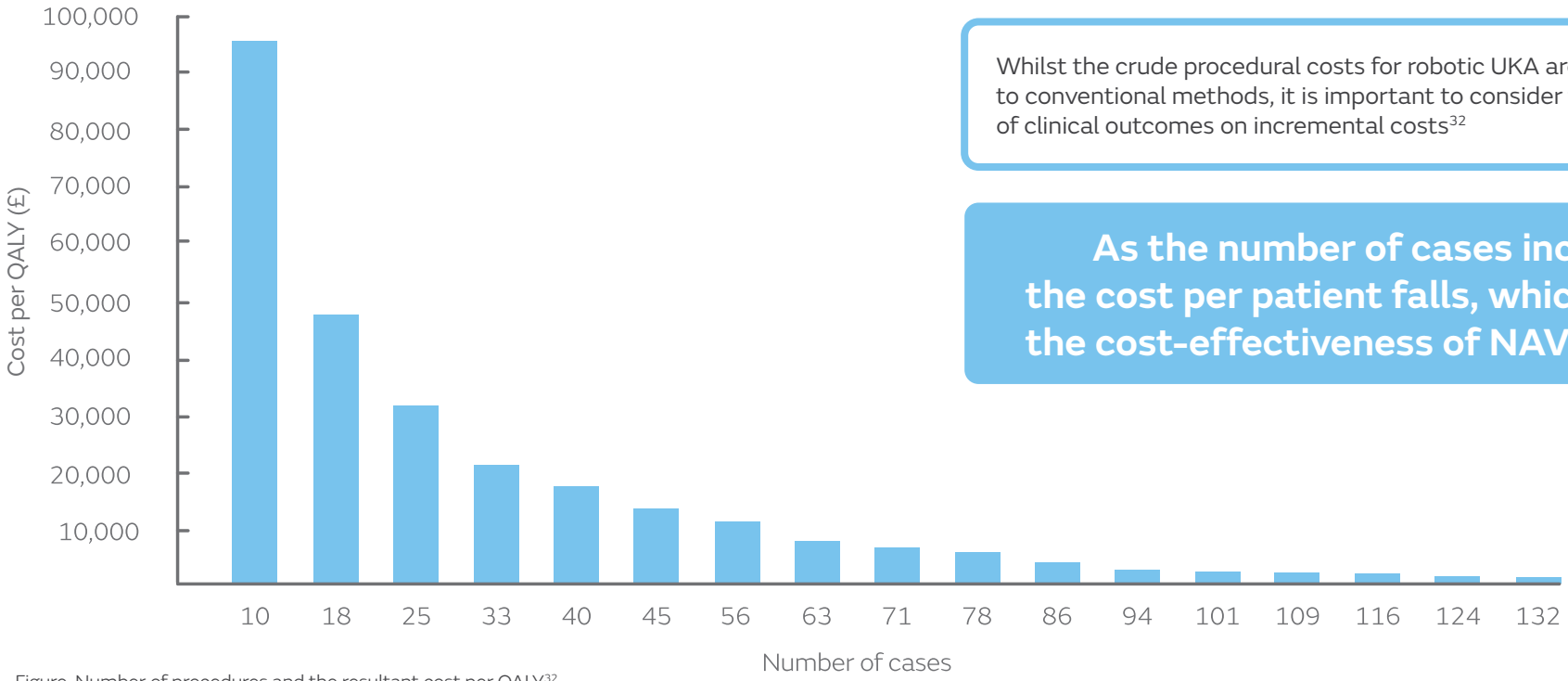

Figure. Number of procedures and the resultant cost per QALY[32]

Whilst the crude procedural costs for robotic UKA are higher compared to conventional methods, it is important to consider the potential impact of clinical outcomes on incremental costs[32]

As the number of cases increases, the cost per patient falls, which improves the cost-effectiveness of NAVIO UKA[32,34]

Key outcome:
Cost effectiveness

2 studies
reporting on cost

UKA studies

Yeroushalmi D, et al. 2020	Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis
Nherera LM, et al. 2020	Early economic evaluation demonstrates that noncomputerized tomography robotic-assisted surgery is cost-effective in patients undergoing unicompartmental knee arthroplasty at high-volume orthopaedic centres

Preliminary results of UKR implanted using an image free handheld robotic device[21]

Gonzalez D, Deakin AH, Picard F. BASK Annual Meeting. April 8-9, 2014; Norwich, UK

Overview

A single surgeon performed UKA on 18 patients with NAVIO◊ Surgical System (2012 to 2013)

Key results

OKS improved from 22 pre-UKA to 37 six weeks post-UKA ✓

Conclusion

Preliminary analysis showed satisfactory post-UKA outcome for UKR with NAVIO UKA

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Handheld precision sculpting tool for unicondylar knee arthroplasty. A clinical review[22]

Gregori A, Picard F, Bellemans J, Smith J, Simone A. 15th EFORT Congress. June 4-6, 2014; London, UK

Overview

Evaluation of the clinical and functional outcomes of the first 57 patients undergoing UKA with NAVIO◊ Surgical System

Key results

Post-UKA mechanical axis alignment within 1° of intra-operative NAVIO plan in 91% of cases	✓
UKA reduced mean mechanical axis deformity from -6.2° pre-UKA to -3.4° six weeks post-UKA	✓
Mean NAVIO time (from tracker placement to implant trial acceptance) decreased from 69 to 54 minutes	✓
Cutting phase time decreased by 32.5 minutes from first to quickest procedure	✓
Mean OKS showed clinical improvement from 22 pre-UKA to 36 six weeks post-UKA	✓
All patients achieved full extension post-UKA	✓

Conclusion

NAVIO UKA allowed the surgeons to precisely plan and execute highly accurate mechanical axis alignment. The learning curve with NAVIO UKA was short, with mean NAVIO Surgical System time reduced by 15 minutes after ten cases

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

The learning curve of a novel handheld robotic system for unicondylar knee arthroplasty[23]

Wallace D, Gregori A, Picard F, Bellemans J, Lonner J, Marquez R, Smith J, Simone A, Jaramaz B.
***Bone Joint J.* 2014;96B(:SUPP16)**

Overview

- Five surgeons performed UKA on at least 15 patients with NAVIO◊ Surgical System
  - Two surgeons had experience with robotic devices for UKA
  - All surgeons had experience with conventional UKA and navigation for other knee procedures
- The number of surgeries to reach 'steady state' surgical time was calculated as the point at which two consecutive cases were completed within the 95% confidence interval of the surgeon's 'steady state' time

Key results

Average surgical time for the first 15 cases:	56.8 minutes
Average improvement from slowest to quickest surgical time:	46 minutes
Average number of procedures to steady state:	8
Average steady state surgical time:	50 minutes

Conclusion

NAVIO UKA demonstrated a comparable learning curve to other robotics-assisted devices on the market

Full paper

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Accuracy of imageless robotically assisted unicondylar knee arthroplasty[24]

Gregori A, Picard F, Lonner J, Smith J, Jaramaz B. 15th Annual Meeting of CAOS. June 17-20, 2015; Vancouver, Canada

Overview

Authors prospectively collected radiographic data on 92 patients who underwent medial UKA with NAVIO◊ Surgical System at four centres (four surgeons)

Key results

89% of patients had post-UKA alignment within 3° of the planned coronal mechanical axis alignment

RMS error	1.98°

RMS error between plan and post-UKA radiographic implant position:

▪ Femoral coronal alignment:	2.6°
▪ Tibial coronal alignment:	2.9°
▪ Tibial slope:	2.9°

Conclusion

Use of NAVIO UKA can accurately prepare the bone surface of the tibia and femur; this allowed for few errors resulting in high levels of accuracy in the planned coronal mechanical axis alignment when comparing planned versus achieved component placement

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique[25]

Herry Y, Batailler C, Lording T, Servien E, Neyret P,Lustig S. *Int Orthop.* 2017;41:2265-2271

Overview

- Retrospective, single-surgeon, case-control study of
  - 40 NAVIO◊ UKAs
  - 40 conventional UKAs

Radiographs were taken pre-UKA and 2 months post-UKA to assess joint-line height using the methods of Weber

Key results

The joint line was distalised significantly less following NAVIO UKA compared to conventional UKA when assessed using two measurement methods (method 1, 1.4 vs 4.7mm; method 2, 1.5 vs 4.6mm; p<0.05)

Conclusion

NAVIO UKA allowed for highly accurate bone resection, resulting in improved joint-line restitution when compared with a conventional technique

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Robotic-assisted unicompartmental knee replacement with NAVIO surgical system: outcome evaluation using knee injury osteoarthritis outcome score[26]

Vega Parra P, Dionisio Palacios Barajas J, Márquez Ambrosi RA, Duarte JR. *Rev Chil Ortop Traumatol.* 2017;58:7-12

Overview

- Single-surgeon case series of 47 patients (mean age, 67 years; females, 49%; males, 51%) who underwent UKA with NAVIO◊ Surgical System using the STRIDE◊ UNI prosthesis (November 2013 to February 2014)
- KOOS was recorded pre-UKA and 12 months post-UKA

Key results

All categories of KOOS were improved significantly at 12 months post-UKA following NAVIO UKA compared to pre-UKA (p<0.001)		
Symptoms:	33.11 to 70.79 (p<0.05)	✓
Pain:	35.30 to 71.62 (p<0.05)	✓
Daily activities:	35.23 to 71.47 (p<0.05)	✓
Sports and recreational activities:	28.51 to 63.62 (p<0.05)	✓
Quality of life:	31.15 to 72.98 (p<0.05)	✓

Conclusion

NAVIO robotics-assisted UKA with STRIDE UNI demonstrated a substantial improvement in patients' quality of life, reducing pain and improving function during sports and recreational activities

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty[2]

Batailler C, White N, Ranaldi FM, Neyret P, Servien E, Lustig S. *Knee Surg Sports Traumatol Arthrosc.* 2019;27:1232-1240

Overview

- Retrospective case-control study comparing implant position and revision rate for UKA performed with NAVIO◊ Surgical System or conventional technique
  - NAVIO group: 80 UKAs (lateral, 23; medial, 57; mean age, 69 years; mean length of follow-up, 19.7 months)
  - Conventional group: 80 UKAs (lateral, 23; medial, 57; mean age, 68 years; mean length of follow-up, 24.2 months)
- Implant position was assessed via radiographs at 1 year post-UKA
- Revision rate was calculated at the last follow up

Key results

NAVIO group revision rate: 5% (lateral UKA, 0%; medial UKA; 7%)	✓	Conventional group revision rate: 9% (lateral UKA, 9%; medial UKA, 9%)	✓
The total reoperation rate was significantly lower in the NAVIO group compared to the conventional group for lateral UKAs (0 vs 22%; p=0.025) but there was no significant difference for medial UKAs (18 vs 14%)			✓
Rate of post-UKA limb alignment outliers (±2°) was significantly greater in the conventional group compared to the NAVIO group for both lateral (26 vs 61%; p=0.018) and medial (16 vs 32%; p=0.038) UKAs			✓
Coronal and sagittal tibial baseplate position had significantly fewer outliers (±3°) in the NAVIO group compared to the conventional group (11 vs 35%; p=0.0003)			✓

Conclusion

Revisions due to implant malposition or limb malalignment were more common after conventional UKA than NAVIO robotic-assisted UKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Comparison between standard technique and image-free robotic technique in medial unicompartmental knee arthroplasty. Preliminary data[27]

Di Benedetto P, Buttironi MM, Magnanelli S, Cainero V, Causero A. *Acta Biomed.* 2019;90:104-108

Overview

- Retrospective analysis comparing accuracy and clinical outcomes of NAVIO◊ UKA compared to conventional UKA
  - 29 NAVIO UKA
  - 30 conventional UKA
- Patients were assessed pre-UKA and at 4 months post-UKA

Key results

Mean flexion for NAVIO UKA was 127°, compared to 118° for conventional UKA	✓
Mean IKDC at 4 months post-UKA was 89.9 for NAVIO UKA, compared to 87 for conventional UKA	✓
Mean KSS at 4 months post-UKA was 83.2 for NAVIO UKA, compared to 81.1 for conventional UKA	✓
Mean variance from the anatomical axis was ±1.3° for NAVIO UKA, compared to ±2.1° for conventional UKA	✓

Conclusion

NAVIO UKA allowed for the accurate implantation of the prothesis

Full paper

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems[28]

Lonner JH, Kerr GJ. *Knee.* 2019;26:745-749

Overview

- Retrospective review of a prospectively maintained database of consecutive unicompartmental knee arthroplasties (UKA) carried out by a single surgeon (from March 2008 to March 2017) with either NAVIO◊ Surgical System or MAKO® Robotic-Arm Assisted Surgery (Stryker Corporation, Fort Lauderdale, FL, USA)
  - 572 NAVIO UKAs
  - 492 MAKO UKAs
- Post-operative follow up at 6 weeks and 3 months (91% patients)

Key results

No inadvertent/iatrogenic soft tissue injuries, bone injuries or other complications related to either robotic bone preparation tool	✓
No cases where either robotic tool was abandoned due to a complication or perception that structures were at risk	✓
Six complications related to computer navigation pins (0.6% cases):	✓
▪ 1 pseudoaneurysm of a branch of the tibialis anterior artery	✓
▪ 1 tibial metaphyseal stress fracture patient underwent manipulation under anaesthesia. This complication was 'healed with bracing and protective weight-bearing'	✓
▪ Four areas of pin site irritation/superficial infection	✓

Conclusion

Semiautonomous robotic systems, such as NAVIO Surgical System, are safe with a low rate of intra-operative complications

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

A novel handheld robotic-assisted system for unicompartmental knee arthroplasty: surgical technique and early survivorship[30]

Battenberg A, Netravali NA, Lonner JH. *J Robot Surg.* 2020;14:55-60

Overview

- Retrospective study to assess revision rates of patients who received UKA with NAVIO◊ Surgical System
- 128 UKA patients (mean age, 64.7 years) included who had undergone UKA with NAVIO at five US sites
- Surgeon adopter's initial cases

Key results

Mean follow up of 2.3 years	✓
Survivorship at 2 years with NAVIO: 99.2%, greater than that reported in the Australian, New Zealand and Swedish registry for conventional UKA	✓
One revision with NAVIO due to hamstring irritation and ischial tuberosity bursitis in 60 year old male	✓

Conclusion

Early implant survivorship rate for the NAVIO UKA system is higher than that presented in annual registries

Full paper

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Comparison of 1-year outcomes between MAKO versus NAVIO robot-assisted medial UKA: nonrandomized, prospective, comparative study[31]

Leelasetaporn C, Tarnpichprasert T, Arirachakaran A, Kongtharvonskul J. *Knee Surg Relat Res.* 2020;32:13

Overview

- Single surgeon, prospective cohort study comparing clinical outcomes and operative time of NAVIO◊ UKA and MAKO® Robotic-Arm Assisted Surgery (Stryker Corporation, Fort Lauderdale, FL, USA)
- UKA
  - 16 NAVIO UKAs
  - 17 MAKO UKAs
- Post-operative follow-up to 1-year post-UKA

Key results

No significant difference in KSFS (99.9 vs 99.5; p=ns) or KSS (96.9 vs 94.7; p=ns) between NAVIO and MAKO at 1-year post-UKA	✓
Mean intra-operative time of seven steps (registration of hip and ankle, femur and tibia, ligament tension, implant planning, preparation femur, tibia, and trial implant) for NAVIO UKA was 98min, compared to 82.5min for MAKO UKA (p=0.0002)	✓

Conclusion

NAVIO UKA demonstrated similar clinical outcomes as MAKO UKA at 1-year post-UKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Early economic evaluation demonstrates that noncomputerized tomography robotic-assisted surgery is cost-effective in patients undergoing unicompartmental knee arthroplasty at high-volume orthopaedic centres[32]

Nherera LM, Verma S, Trueman P, Jennings S. *Adv Orthop.* 2020;3460675

Overview

- Assessment of costs and outcomes of NAVIO◊ UKA and conventional UKA in patients with osteoarthritis
  - 5-year model
  - Case volume assumed as 100 patients per year
- Revision rates for conventional UKA were taken from the NJR (1.19%)
- Revision rates for NAVIO UKA (0.8%) were obtained from a retrospective cohort study (n=128) with a follow up of 2.3 years

Key results

NAVIO UKA was more costly than conventional UKA but offered better clinical outcomes (there were fewer revisions and more QALYs) and the estimated cost per QALY was £2,831	✓
Although NAVIO UKA was cost effective across all age groups, sensitivity analysis showed it was greater in younger patients (<55 years) compared to older age groups (>75 years)	✓
For follow up beyond 7 years, NAVIO becomes cost-saving compared to conventional UKA ie, results in lower overall costs and better clinical outcomes (based on assumptions)	✓
The model results are sensitive to assumptions around the case load	✓

Conclusion

NAVIO UKA was shown to be a cost effective procedure over a 5-year model, and with estimated cost saving after 7 years, compared to traditional UKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Robotic-assisted unicompartmental knee arthroplasty optimizes joint line restitution better than conventional surgery[33]

Negrín R, Duboy J, Reyes NO, Barahona M, Iñiguez N, Infante C, Cordero JA, Sepulveda V, Ferrer G.

***J Exp Orthop*. 2020;7:94**

Overview

- Retrospective, cohort study of 62 consecutive UKAs using JOURNEY◊ UNI implant
  - 40 NAVIO◊ UKA
  - 22 Conventional UKA
- Pre and post-UKA radiographs were taken to assess joint line height using three methods

Key results

Distalisation of the femoral component was higher in the conventional group than the NAVIO group using all methods and was significantly higher when assessed using the methods of Weber (method 1: 2.3 vs 1.5mm, p=0.0025; method 2: 2.9 vs 1.1mm, p<0.0000)

A higher proportion of patients achieved a femoral component position ≤2mm from the joint line using NAVIO UKA compared to the conventional UKA, which was significantly higher using the methods of Weber (method 1, 75.00 vs 31.82%, p=0.001; method 2: 75.00 vs 22.73%, p<0.000)

Conclusion

NAVIO UKA resulted in better restoration of the knee joint line when compared to conventional UKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis[34]

Yeroushalmi D, Feng J, Nherera L, Trueman P, Schwarzkopf R. *J Knee Surg.* 2020; doi: 10.1055/s-0040-1712088

Overview

- Health economic model of 100 NAVIO◊ UKAs
- Model assumed:
  - 5 year time period
  - High volume centre (100 UKAs/year)
  - Mean age of 65 years

Key results

$14,737 estimated cost per revision avoided with NAVIO UKA	✓
Although NAVIO UKA was cost effective across all age groups, sensitivity analysis estimated that it was greater in younger patients (<55 years old) compared to older age groups (>75 years)	✓
For follow up beyond 7 years, the model estimates that NAVIO UKA becomes cost-saving	✓

Conclusion

NAVIO UKA was estimated to be a cost effective procedure over a 5-year time period, and can potentially be cost saving beyond a 7-year time period, compared to conventional UKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

No difference of gait parameters in patients with image-free robotic-assisted medial unicompartmental knee arthroplasty compared to a conventional technique: early results of a randomized controlled trial[35]

Batailler C, Lording T, Naaim A, Servien E, Cheze L, Lustig S. *Knee Surg Sports Traumatol Arthrosc.* 2021; doi: 10.1007/s00167-021-06560-5

Overview

- Prospective, single-centre randomised controlled study
  - 33 NAVIO◊ UKAs
  - 33 Conventional UKAs
- Gait analysis and clinical outcomes (IKS and FJS) were collected at 6 months
- Radiographs were assessed pre-UKA and 6 months post-UKA

Key results

Walking speed was significantly improved at 6 months following NAVIO UKA compared to conventional UKA (p=0.015) - No other significant differences in gait parameters between NAVIO UKA and conventional UKA	✓
No significant differences in clinical outcomes, implant position, revision and complication rates	✓

Conclusion

No significant differences in gait cycle between NAVIO UKA and conventional UKA

Full paper

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Improved sizing with image-based robotic assisted system compared to image-free and conventional techniques in medial unicompartmental knee arthroplasty: a case control study[36]

Batailler C, Bordes M, Lording T, Nigues A, Servien E, Calliess T, Lustig S. *Bone Joint J.* 2021;103-B:610-618

Overview

- Multicentre, retrospective analysis
  - 93 NAVIO◊ UKA
  - 93 MAKO® Robotic-Arm Assisted Surgery (Stryker Corporation, Fort Lauderdale, FL, USA)
  - 93 conventional UKA
- Radiographs were taken pre-UKA and at 2 months post-UKA to assess UKA sizing, using 6 parameters
  - Incorrect sizing was defined by an over- or under-sizing greater than 3mm

Key results

Conventional UKA resulted in:

- The highest risk of tibial under-sizing posteriorly, followed by NAVIO UKA and MAKO UKA (47.3 vs 29.0 vs 6.5%; p<0.001)
- The highest risk of tibial under-sizing anteriorly followed by MAKO UKA and NAVIO UKA (11.8 vs 5.4 vs 1.1%; p=0.009)
- The highest risk of femoral under-sizing posteriorly, followed by MAKO UKA and NAVIO UKA (30.1 vs 12.9 vs 7.5%; p<0.001)

Conventional UKA and NAVIO UKA had a significantly higher risk of increasing posterior femoral offset compared to MAKO UKA (43.0 vs 30.1 vs 8.6%; p<0.001)

Conclusion

Robotic UKA reduced the risk of tibial and femoral under-sizing compared to conventional UKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Robotic-assisted unicondylar knee arthroplasty is associated with earlier discharge from physiotherapy and reduced length of stay compared to conventional navigation techniques[29]

Shearman AD, Sephton BM, Wilson J, Nathwani DK. *Arch Orthop Trauma Surg. 2021;* 2021;141:2147–2153

Overview

- Single-centre, retrospective case series analysis of patients receiving NAVIO◊ UKA (n=31) compared to those who received conventional navigation UKA (n=31)
- Length of operation, transfusion requirements, time to discharge, ROM and analgesia requirements were assessed

Key results

Compared to navigation UKA, NAVIO UKA resulted in:	
▪ Significantly shorter time to straight leg raise (23.0 vs 37.5hrs; p=0.004)	✓
▪ Significantly increased ROM on discharge (81.4 vs 64.5°; p<0.001)	✓
▪ Significantly earlier discharge from physiotherapy (42.5 vs 49.0hrs; p=0.02)	✓
▪ Significantly earlier hospital discharge (46 vs 74hrs; p=0.005)	✓
Operating time was longer with NAVIO UKA, compared to navigation UKA (102.8 vs 85.6mins; p<0.001)	✓

Conclusion

Patients receiving NAVIO UKA regained knee function earlier, and were able to be discharged from hospital sooner than patients with UKA carried out by conventional navigation

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Robotic assisted revision total knee replacement - early experience[37]

Shah S, Fick D, Khan R, De Cruz P. 19th Annual Scientific Meeting for APAS. September 6-8, 2018; Bangkok, Thailand

Overview

- Single-centre prospective study recruiting patients for revision TKA with NAVIO◊ Surgical System (August 2017 to January 2018)
- Ten patients were included (females, 6; males, 4; mean age, 67.5 years)
- Pre-operative and post-operative ROM, OKS, KSS and leg alignment were recorded

Key results

Mean length of stay: 4.5 days	✓
Mean operating time: 92 minutes	✓
Improvements in ROM, OKS and KSS and leg alignment compared to pre-operative values	✓
No mechanical axis outliers	✓

Conclusion

NAVIO TKA is capable of producing consistent coronal mechanical alignment (within 3°) in revision TKA

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The learning curve and alignment assessment of an image-free handheld robot in TKA: the first patient series in Europe[38]

Bollars P. 19th Annual Meeting of CAOS. June 19-22, 2019; New York, USA

Overview

- Retrospective analysis of the first 69 TKAs with NAVIO◊ Surgical System by two experienced surgeons
- Pre- and post-operative mechanical limb alignment and balancing were measured
- Registration, planning and cutting times were monitored pre-operatively

Key results

Mean intra-operative planned angle was 0.59° varus	✓
NAVIO achieved a mean post-operative alignment angle of 1.17° varus	✓
Mean extra surgical time with NAVIO for registration and planning decreased from 23.4 to 13.2 minutes throughout the learning curve	✓

Conclusion

NAVIO TKA minimised outliers in alignment, accurately performing TKA within 1° of the planned mechanical alignment, and only required an additional 13 minutes for registration and planning after the learning curve

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Rate of learning curve and alignment accuracy of an image-free handheld robot for total knee arthroplasty[13]

Geller JA, Rossington A, Mitra R, Jaramaz B, Khare R, Netravali NA. EKS Arthroplasty Conference. May 2-3, 2019. Valencia, Spain

Overview

- Intra-operative data from 172 NAVIO◊ TKA procedures conducted by seven surgeons were assessed
- Data included intra-operative case time (steps of registration of bony surfaces, intra-operative planning and bone resection), planned long-leg coronal alignment and achieved coronal alignment

Key results

Average intra-operative time with no experience was 58 minutes	✓
After 12 procedures, average time reduced to 49 minutes, average time continued to reduce to 39 minutes	✓
Average difference in planned versus achieved coronal alignment was 0.2°	✓
Percent of outliers in alignment beyond ±3° was 8.5%	✓

Conclusion

NAVIO TKA was highly accurate and resulted in a clinically significant decrease in operative time after just 12 procedures

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Learning curve and time commitment assessment in the adoption of NAVIO robotic-assisted total knee arthroplasty[14]

Kaper BP, Villa A. EKS Arthroplasty Conference. May 2-3, 2019; Valencia, Spain

Overview

- Single-surgeon case-control study of:
  - A surgeon's first 100 NAVIO◊ TKA cases
  - 50 conventional TKAs
- Surgical time was recorded and the surgeon's learning curve was assessed

Average surgical time for first 100 NAVIO TKA cases was 68.2 minutes and 50 conventional TKAs was 51.7 minutes	✓
After 40 cases (learning curve) NAVIO TKA only took 10 minutes longer than conventional TKA (18% more time)	✓
After 80 cases, NAVIO TKA was time neutral (required less than 5% more time than conventional TKA)	✓

Conclusion

NAVIO TKA demonstrated an acceptable learning curve and was able to achieve similar surgical time to conventional instrumentation within 80 cases

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Measurement of full arc range of motion soft tissue balance in robotic-assisted total knee arthroplasty[39]

Kaper BP, Villa A. EKS Arthroplasty Conference. May 2-3, 2019; Valencia, Spain

Overview

- The study assessed the ability of NAVIO◊ Surgical System TKA to plan, execute and deliver an individualised approach to soft tissue balancing of the knee in 'mid flexion'
- NAVIO TKA performed on 50 patients (between May and September 2018)

Key results

Average deviation from predicted plan between 0° and 90° was 0.9mm (medial and lateral compartments)	✓
Final soft tissue stability in mid-flexion arc (15-75°) was within 1mm of the predicted plan	✓

Conclusion

NAVIO TKA demonstrated accurate and reproducible implementation of the TKA surgical plan and soft tissue balancing

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Initial safety profile assessment of the NAVIO robotic-assisted total knee arthroplasty[40]

Kaper BP, Villa A. EKS Arthroplasty Conference. May 2-3, 2019; Valencia, Spain

Overview

- The safety profiles of the first 200 patients undergoing NAVIO◊ TKA were assessed
- All intra-operative and post-operative complications during the first 90 days following TKA were recorded

Key results

No increased risk of intra-operative complications relative to known risks associated with TKA, readmissions or reoperations due to surgical-related complications	✓
Complications during 90 days post-TKA:	
▪ 1 deep infection	✓
▪ 1 periprosthetic fracture (remote to pin tracts) due to a fall	✓
▪ 3 patients underwent manipulation under anaesthesia	✓

Conclusion

NAVIO TKA was shown to be a safe procedure resulting in no increased risk of intra-operative complications, reoperation or readmission for surgical related complications

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Accuracy and precision of a handheld robotic-guided distal femoral osteotomy in robotic-assisted total knee arthroplasty[41]

Kaper BP, Villa A. EKS Arthroplasty Conference. May 2-3, 2019; Valencia, Spain

Overview

- Accuracy and reliability of the distal bur technique was assessed in 50 patients undergoing NAVIO◊ TKA
- The mean error of planned versus actual distal femoral resection, varus/valgus and femoral flexion angle were calculated

Key results

Deviation	Mean error
Varus/valgus angle	0.43°
Femoral flexion angle	0.46°
Distal femoral resection depth	0.48mm

Conclusion

NAVIO TKA was accurate within 0.5° and 0.5mm of planned femoral resection, varus/valgus and femoral flexion angle

Back to All studies | Accuracy | Early recovery | Survivorship | Surgical time | Cost effectiveness

Preliminary experience with an image-free handheld robot for total knee arthroplasty: 77 cases compared with a matched control group[42]

Bollars P, Boeckxstaens A, Mievis J, Kalaai S, Schotanus MGM, Janssen D. *Eur J Orthop Surg Traumatol.* 2020;30:723-729

Overview

- Retrospective, case-control study of
  - 77 NAVIO◊ TKAs
  - 77 conventional TKAs
- Weightbearing and standard lateral radiographs were taken pre-UKA and 6 weeks post-UKA to assess pre-TKA alignment and post-TKA component position

Key results

Mean mechanical axis was 180.1° for NAVIO TKA and 179.1° for conventional UKA (p=0.028)	✓
Lower rate of mechanical axis outliers with NAVIO TKA, compared to conventional TKA (6 vs 18%; p=0.051)	✓
Significantly lower rate of outliers of the frontal tibial component for NAVIO TKA compared to conventional TKA (0 vs 8%; p=0.038)	✓

Conclusion

NAVIO TKA allowed the surgeon to accurately achieve the planned mechanical axis, with significantly fewer outliers than conventional TKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Initial experience with the NAVIO robotic-assisted total knee replacement-coronal alignment accuracy and the learning curve[43]

Collins K, Agius PA, Fraval A, Petterwood J. *J Knee Surg.* 2021; [ePub online ahead of print]

Overview

- Single-surgeon, retrospective analysis of the first 72 consecutive NAVIO◊ TKA cases
- Weight-bearing, long leg radiographs were taken pre-TKA and 6 weeks post-TKA to assess coronal alignment
- Intraoperative robotic registration data and duration of use were recorded

Key results

93.1% (n = 67) of NAVIO TKAs were corrected to the desired alignment of within 3 degrees of neutral	✓
Average NAVIO time was 41 mins ▪ A learning curve was not observed	✓
Four complications recorded ▪ Two manipulations under anaesthesia for stiffness at 6 weeks post-TKA ▪ One intraoperative tibial fracture during impaction of the final tibial component ▪ One non-fatal pulmonary embolism	✓
No revisions at 24 months and no pin-site fractures or infections	✓

Conclusion

NAVIO TKA resulted in accurate alignment in more than 93% of cases

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Improved compartment balancing using a robot-assisted total knee arthroplasty[44]

Held MB, Grosso MJ, Gazgalis A, Sarpong NO, Boddapati V, Neuwirth A, Geller JA. *Arthroplast Today.* 2021;7:130-134

Overview

- Retrospective cohort study
  - 37 NAVIO◊ TKAs
  - 49 Conventional TKAs
- Intraoperative data was collected and PROMs (Short Form 12, WOMAC and KSS functional score) and ROM were assessed pre-TKA and post-TKA at 3 and 12 months, and then annually

Key results

No significant difference in medial and lateral compartment loads in extension, mid-flexion and 90° flexion between conventional TKA and NAVIO TKA (15.1, 15.9 and 13.4lbs vs 14.2, 15.1 10.3lbs, respectively; p=ns)	✓
Percentage of unbalanced knees in flexion (>20lbs differential between medial and lateral compartments) was significantly higher with conventional TKA compared to NAVIO TKA (24 vs 5%; p=0.018)	✓
Percentage of patients with high load compartment pressure in flexion (>40lbs) was significantly higher with conventional TKA compared to NAVIO TKA (18 vs 3%; p=0.025)	✓
No significant differences in PROMS scores between NAVIO and conventional TKA, except NAVIO TKA patients reported significantly lower Short Form 12 Mental Scores compared to conventional TKA (49.28 vs 44.13; p=0.004) at 12 months post-TKA.	✓

Conclusion

NAVIO TKA resulted in significantly improved intraoperative compartment balancing during flexion compared to conventional TKA

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

Component placement accuracy in two generations of handheld robotics-assisted knee arthroplasty[45]

Sicat CS, Chow JC, Kaper B, Mitra R, Xie J, Schwarzkopf R. *Arch Orthop Trauma Surg.* 2021; 2021;141:2059–2067

Overview

- Retrospective analysis of NAVIO◊ and CORI◊ TKA
  - 435 TKAs (365 NAVIO TKAs and 70 CORI TKAs)
- Intraoperative data including pre-operative limb deformity, limb axes, range of motion, kinematic balance, and the resulting plan for component placement in three-dimensional space were assessed
- Patients were stratified based on their preoperative coronal lower limb mechanical alignment

Key results

Of 435 TKAs, 229 with ≥3° varus, 78 with varus <3°, 58 with valgus <3° and 70 with valgus >3°	✓
Mean difference between planned vs achieved in the valgus patients was <1° across all groups	✓
Overall mean total time was significantly shorter with CORI TKA compared to NAVIO TKA (55.0 vs 67.3min; p<0.001)	✓
Significantly higher proportion of cases were rated “easy” in the context of achieved alignment difficulty with CORI TKA compared to NAVIO TKA (87.1 vs 71.2%; p=0.001)	✓

Conclusion

Both NAVIO and CORI TKA demonstrated high levels of accuracy and ease of use

Full paper

Back to All studies Accuracy Early recovery Survivorship Surgical time Cost effectiveness

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T +61 2 9857 3999
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Smith & Nephew Ltd
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T +64 9 820 2840
F +64 9 820 2841

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Publication summary

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Comparison of return to sport (RTS) following NAVIO◊ unicompartmental knee arthroplasty (UKA) and conventional UKA

Canetti R, Batailler C, Bankhead C, Neyret P, Servien E, Lustig S. Faster return to sport after robotic-assisted lateral unicompartmental knee arthroplasty: a comparative study. *Arch Orthop Trauma Surg.* 2018;138:1765-1771.

Available at: Archives of Orthopaedic and Trauma Surgery

Key points

NAVIO UKA resulted in **significantly faster RTS** compared to conventional UKA (4.2 vs 10.5 months; p<0.01)

100% **of patients returned to sport** and 91% returned to their pre-symptomatic intensity level following NAVIO UKA*

Significantly better **post-operative International Knee Society Score- objective (IKSS-O)** with NAVIO UKA compared to conventional UKA (97.2 vs 91.2; p<0.05)

Overview

- A retrospective analysis of lateral NAVIO and conventional UKAs performed by a single surgeon between April 2012 and December 2016
  - NAVIO group: 11 UKAs (mean age, 66.5 years; mean follow-up, 34.4 months)
  - Conventional group: 17 UKAs (mean age, 59.5 years; mean follow-up, 39.3 months)
- Follow-up was performed at 2 months, 1 year and then yearly to assess:
  - IKSS-O, International Knee Society Score- function (IKSS-F), Lysholm knee scale and Forgotten Joint Score (FJS)
  - Sports participation and UCLA activity score
  - Patient-reported satisfaction

Results

- NAVIO UKA reduced mean time to RTS by 6.3 months compared to conventional surgery (4.2 vs 10.5 months; p<0.01; Figure)
- By end of follow-up, all NAVIO UKA patients returned to sport (100%) and the majority returned to their pre-symptomatic intensity level (91%)*; respective outcomes were 94% and 82% for conventional UKA
- NAVIO UKA resulted in significantly better post-operative IKSS-O compared to conventional UKA (97.2 vs 91.2; p<0.05)
- Compared to conventional UKA, NAVIO UKA resulted in significantly better postoperative IKSS-O (97.2 vs 91.2; p<0.05) and significantly greater IKSS-O improvement after surgery compared to preoperative scores (+30.9 vs +22.8; p<0.05)
- Results of the IKSS-F, Lysholm Knee Scale and FJS were similar with both procedures

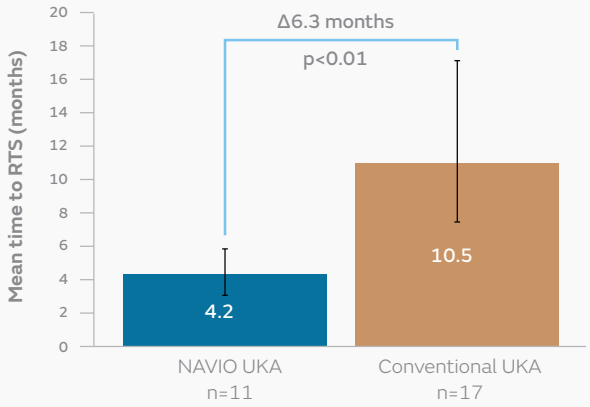

Figure. Mean time to RTS after UKA with NAVIO versus conventional surgery. Error bars represent standard deviation.

Conclusions

Compared to conventional surgery, NAVIO UKA significantly reduced time to RTS at pre-symptomatic intensity levels.

*Mainly low and mid-impact sports (hiking, cycling, swimming, and skiing)

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Publication summary

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Short-term comparative assessment of revision rates and complications following NAVIO◊ UKA and conventional UKA

Mergenthaler G, Batailler C, Lording T, Servien E, Lustig S. Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study. *Knee Surg Sports Traumatol Arthrosc.* 2021;29:931–938.

Available at: Knee Surgery, Sports Traumatology, Arthroscopy

Key points

Significantly lower revision rate with NAVIO UKA compared to conventional UKA (p=0.014)

No specific complications related to the use of NAVIO UKA (no soft tissue or bone lesions and no complication related to the use of navigation pins)

Significantly increased Functional Knee Society Score (KSS) with NAVIO UKA compared to conventional UKA at last follow-up (≥1 year; p=0.01)

Overview

- Single centre, retrospective study performed between January 2013 and December 2018 comparing the use of NAVIO UKA and conventional UKA
  - 200 NAVIO UKAs (mean age, 66.7 years)
  - 191 conventional UKAs (mean age, 67.1 years)
  - Mean follow-up was 22.5 months for NAVIO UKA and 30.2 months for conventional UKA (p<0.001)
- Data were collected preoperatively and at 2, 6, 12 months and at last follow-up
  - Revisions, intra-operative and post-operative complications, functional and radiological results were collected

Results

- NAVIO UKA had a significantly reduced total revision rate compared to conventional UKA at last follow-up (4 vs 11%, p=0.014; Figure)
  - Revision due to malalignment was significantly lower with NAVIO UKA compared to conventional UKA (0 vs 5.2%, p=0.002)
- No specific complications associated with use of NAVIO UKA, in particular, no issues due to the use of navigation pins
- Total reoperation rate (without implant removal) was reduced with NAVIO UKA compared to conventional UKA at last follow-up (6.5 vs 9.4%) n.s.
- At the last follow-up, functional KSS was significantly higher with NAVIO UKA compared to conventional UKA (92.8 vs 88.4, p=0.01)
- No significant difference in duration of surgery (NAVIO UKA, 81 min; conventional UKA, 76 min)

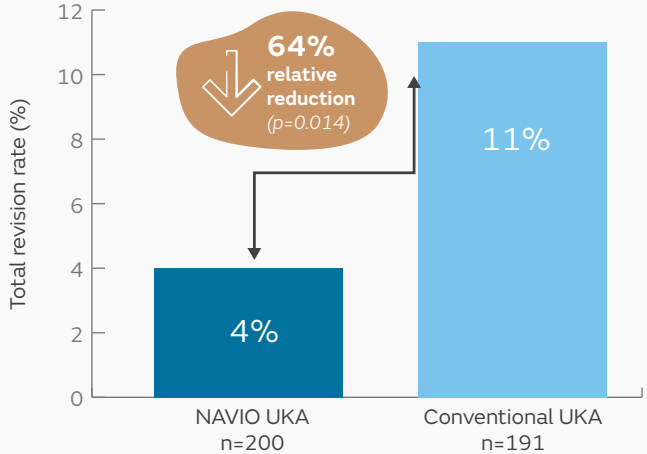

Figure. Total revision rate (%) of NAVIO UKA and conventional UKA at last follow-up

Conclusions

NAVIO Surgical System demonstrates a significantly lower revision rate for UKA than conventional methods, and is not associated with robotic specific complications at the short-term follow up.

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Publication summary

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Assessment of the ability to safely discharge patients within 24 hours following NAVIO◊ Surgical System unicompartmental knee arthroplasty (UKA)

Sephton BM, De la Cruz N, Shearman AD, Nathwani D. Achieving discharge within 24h of robotic unicompartmental knee arthroplasty may be possible with appropriate patient selection and a multi-disciplinary team approach. *J Orthop.* 2020;19:223–228.

Available at: Journal of Orthopaedics

Key points

Mean length of stay of **19.5 hours**

Mobilisation of 84.2% of patients without the use of walking aids

0 Post-operative complications or readmissions at 6 weeks post-UKA

Overview

- Single surgeon, retrospective analysis of 71 NAVIO UKA patients, from which 19 patients were discharged within 24 hours between June 2017 and October 2019 (mean age, 66.8 years; percentage of females, 47.7%)
- All 71 patients were assessed clinically pre-UKA and were offered pre-UKA education sessions from a multidisciplinary team

Results

Of the 19 NAVIO UKA patients discharged within 24 hours:

- Mean operative time was 92.6mins (range: 64–132 mins)
- Average length of stay was 19.5 hours (range: 6–23 hours; Figure)
- No complications or readmissions within 6 weeks post-UKA
- Sixteen (84.2%) patients were mobilised without walking aids; three (15.8%) with the use of a single walking stick (Figure)
- Safe mobilisation on the ward was necessary prior to discharge:
  - Fifteen patients were mobilised at a mean of 12.6 hours post-UKA
  - Four patients were mobilised without post-UKA physiotherapy
- Mean range of motion at 6 weeks was 105.8°
- Mean Oxford Knee Score increased from 24.5 pre-surgery (n=19) to 44 at 6 months post-UKA (n=16)

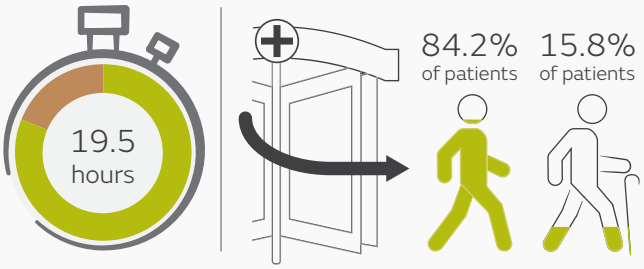

Figure. Average length of stay following NAVIO UKA (n=19) and percentage of patients who were mobilised with or without walking aids

Conclusions

With appropriate patient selection and education, NAVIO UKA patients may be safely discharged within 24 hours of their operation.

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+ Evidence in focus

Study summary: Vaidya NV, et al. *Knee Surg Sports Traumatol Arthrosc* (2020)*

Smith+Nephew

Implant alignment and joint line restoration of NAVIO◊ total knee arthroplasty (TKA) compared to conventional TKA

+ Plus points

NAVIO TKA **achieved significantly lower mechanical axis deviation than conventional TKA** (p=0.019)

NAVIO TKA resulted in a **significantly lower elevation of the joint line** than conventional TKA (p<0.001)

Overview

- An independent, prospective, randomised controlled trial assessing alignment and joint line restoration of NAVIO TKA and conventional TKA in patients with varus deformity
  - 32 NAVIO TKA (mean age, 62.2 years)
  - 28 conventional TKA (mean age, 59.9 years)
- Radiographs were assessed pre- and post-TKA to determine alignment and joint line deviation

Results

Compared with conventional TKA, NAVIO TKA resulted in:

- Significantly lower joint line deviation (0.9 vs 3.5mm; p<0.001; Figure)
- Significantly lower mechanical axis deviation (1.8 vs 3.0 °; p=0.019)
  - One NAVIO TKA outside 3° range (3.1%), compared to 8 conventional TKAs (28.5%)
- Significantly lower mechanical axis deviation of the femoral component position (1.1 vs 2.0 °; p=0.03) and tibial component position (1.0 vs 1.5°; p=0.04) in the coronal plane

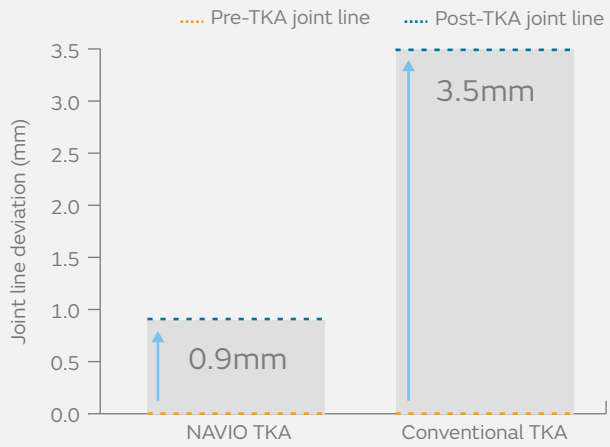

Figure. Joint line deviation (mm) from pre-TKA to post-TKA with NAVIO Surgical System or conventional methods

Conclusions

NAVIO TKA resulted in improved implant positioning and mechanical axis alignment, compared to conventional TKA. The joint-line was significantly elevated following conventional TKA, whereas it was restored with NAVIO TKA.

Citation

*Vaidya NV, Deshpande AN, Panjwani T, Patil R, Jaysingani T, Patil P. Robotic-assisted TKA leads to a better prosthesis alignment and a better joint line restoration as compared to conventional TKA: a prospective randomized controlled trial. *Knee Surg Sports Traumatol Arthrosc.* 2020 Nov 9;[Epub ahead of print].
Available at: Knee Surgery, Sports Traumatology, Arthroscopy

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Publication summary

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Comparison of blood loss and transfusion risk following knee arthroplasty using NAVIO◊ Surgical System and conventional methods

Khan H, Dhillon K, Mahapatra P, Popat R, Zakieh O, Kim WJ, Nathwani D. Blood loss and transfusion risk in robotic-assisted knee arthroplasty: a retrospective analysis. *Int J Med Robot.* 2021;e2308.

Available at: The International Journal of Medical Robotics and Computer Assisted Surgery

Key points

NAVIO TKA patients experienced **23.7% less blood loss** than conventional TKA patients (p<0.01)

NAVIO TKA patients were associated with a **83% relative risk reduction of receiving a blood transfusion** (p=0.02)

No blood transfusions required for any NAVIO UKA or conventional UKA procedures

Overview

- Retrospective, multi-surgeon, cohort study to assess the blood loss in NAVIO UKA and TKA patients compared to conventional UKA and TKA
  - 50 consecutive NAVIO UKA patients (median age, 67.0 years)
  - 50 consecutive NAVIO TKA patients (median age, 74.0 years)
  - 50 consecutive conventional UKA patients (median age, 67.0 years)
  - 50 consecutive conventional TKA patients (median age, 71.5 years)
- Pre-operative and post-operative haemoglobin (Hb) and haematocrit (Hct), estimated blood volume, total blood loss and the proportion of patients that required a transfusion were assessed

Results

- Conventional TKA patients experienced a significantly greater fall in Hb levels compared to NAVIO TKA patients (16.0 vs 13.1%; p=0.01)
- Conventional TKA patients experienced a significantly greater fall in Hct levels compared to NAVIO TKA patients (18.0 vs 14.4%; p<0.01)
- NAVIO TKA resulted in significantly less blood loss compared to conventional TKA (911.1 vs 1193.6ml; p<0.01; Figure)
  - NAVIO TKA patients experienced 23.7% less blood loss than conventional TKA
  - NAVIO TKA blood loss was comparable to conventional UKA blood loss (911.1 vs 854.7ml)
- No significant difference between conventional UKA and NAVIO UKA patients' Hb or Hct levels
- No significant difference in blood loss between conventional UKA and NAVIO UKA (854.7 vs 821.8ml; p=ns)
- NAVIO TKA patient demonstrated a 83% relative risk reduction of receiving a blood transfusion compared to conventional TKA (2 vs 12% of patients, p=0.02; Figure)
- There were no blood transfusions required for NAVIO UKA or conventional UKA patients

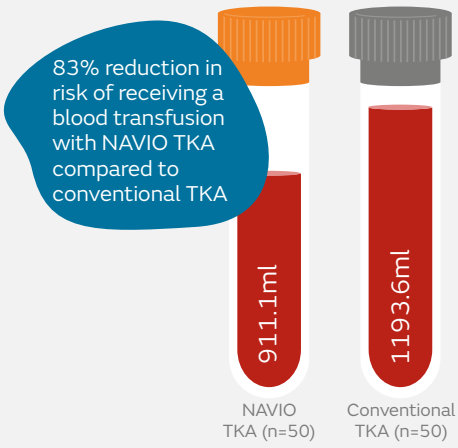

Figure. Mean blood loss for NAVIO TKA and conventional TKA

Conclusions

NAVIO TKA reduced blood loss to conventional UKA levels, and significantly reduced the risk of a blood transfusion compared to conventional TKA.

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Publication summary

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Single surgeon assessment of surgical time and accuracy of NAVIO◊ Surgical System total knee arthroplasty (TKA) and conventional TKA

Savov P, Tuecking LR, Windhagen H, Ehmig J, Ettinger M. Imageless robotic handpiece assisted total knee arthroplasty: a learning curve analysis of surgical time and alignment accuracy. *Arch Orthop Trauma Surg.* 2021: doi: 10.1007/s00402-021-04036-2.

Available at: Archives of Orthopaedic and Trauma Surgery

Key points

- NAVIO TKA learning curve was completed after **11 cases**
- **No significant difference in surgical time** between NAVIO TKA and conventional TKA after the learning curve
- **No learning curve for accuracy** of implant positioning with NAVIO TKA

Overview

- Case-controlled study of an experienced surgeon's first NAVIO TKA cases to assess the learning curve and accuracy of implant positioning compared to conventional TKA
  - First 70 consecutive NAVIO TKAs (mean age, 64.4 years)
  - 70 consecutive conventional TKAs (mean age, 65.9 years)
  - JOURNEY◊ II BCS implant was used for all TKAs
- Surgical time, implant alignment and joint-line height were assessed

Results

- The learning curve for NAVIO TKA was completed after 11 cases
- No significant differences in surgical time were observed between NAVIO TKA and conventional TKA after the learning curve (69 vs 67min; Figure)
- The post-TKA medial proximal tibial angle, lateral distal femur angle and hip-knee-ankle angle were accurate to 1.0°, 1.6° and 2°, respectively, compared to the intraoperative plan for NAVIO TKA
- No learning curve was observed for implant positioning with NAVIO TKA
- Mean joint line shift for NAVIO TKA and conventional TKA was:
  - 0.9mm and -0.7mm on the medial side for the varus groups, respectively
  - 1.9mm and -1.2mm on the lateral side for the varus groups, respectively
  - 2.6mm and -0.1mm on the medial side for the valgus groups, respectively
  - 3.7 mm and 1.7mm on the lateral side for the valgus groups, respectively
- A significant positive correlation was observed between the preoperative morphotype and the postoperative joint line shift for NAVIO TKA ($p<0.001$)

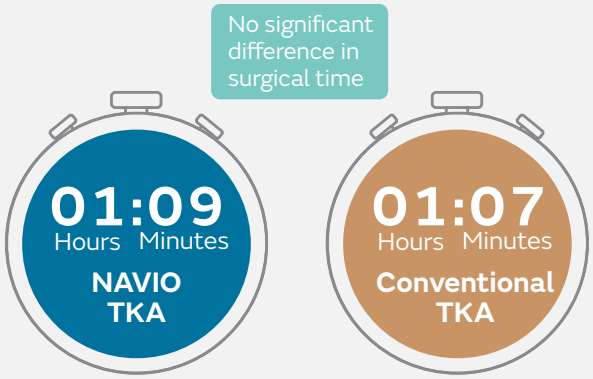

Figure. Mean surgical time reported for NAVIO TKA, following completion of the learning curve, and conventional TKA

Conclusions

After an initial learning curve of 11 cases, NAVIO TKA surgical time was similar to that taken for conventional TKA.

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