+ Evidence in focus

Robotics Compendium of Evidence
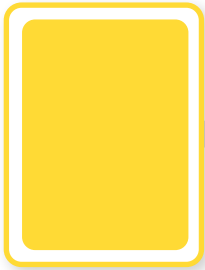
October 2020

Smith+Nephew

✚ Smith+Nephew Robotics Compendium of Evidence

Key Study Timeline

Key Outcomes

Accuracy   Early recovery & clinical outcomes   Survivorship   Surgical time   Cost effectiveness

Abbreviations

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

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

TKA

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

Over 50%

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

Up to 20%

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

✚ 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[12,13,16]

Portability

Featuring simple calibration and a footprint designed for use in the surgery centre or hospital, Smith+Nephew 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 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 Robotic technology is compatible with multiple implant options for both partial and total knee replacement procedures, including JOURNEY◇ II, LEGION◇ and GENESIS◇ II

Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique[14]

Herry Y, et al. *Int Orthop.* **2017;41:2265-2271**

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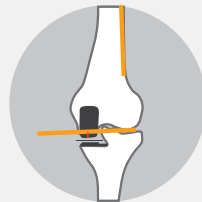
40 NAVIO◊ UKAs   40 Conventional UKAs

Follow up: **Two months**

Assessed at pre-UKA and 2-months post-UKA:

Restitution of joint-line height was assessed using the methods of Weber on radiographs   ✓

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
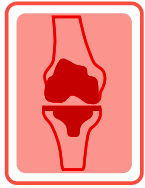
Technique and accuracy assessment of a novel image-free handheld robot for knee arthroplasty in bi-cruciate retaining total knee replacement[33]

Jaramaz B, et al. *Health Sciences*. 2018;2:98-101

Preclinical study of:

24 cadaveric femurs
8 synthetic femurs

2 cadaveric tibias
10 synthetic tibiae

JOURNEY◊ II XR◊ implanted with NAVIO◊

Assessed:

Planned and final implant placement ✓

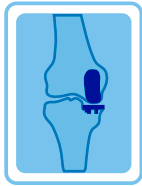**Results : NAVIO TKA resulted in:**

<1mm error for femoral varus/valgus, rotation and distal resection

<1mm error for tibial posterior slope, varus/valgus and resection depth

Conclusion

NAVIO TKA achieved accurate implementation of the TKA surgical plan with small errors in implant placement with cadaveric and synthetic specimens

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

Canetti R, et al. *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**	

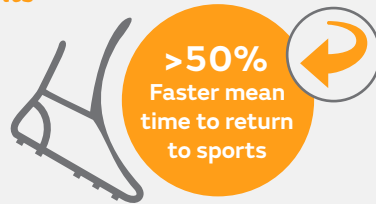### Assessed at pre-UKA, at 2 months, 1 year, and every year after surgery:

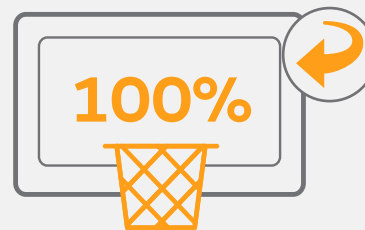|	
Knee scores – IKSS objective and functional / FJS / Lysholm knee scale	✓
Sports Participation – UCLA Activity score	✓

Results

>50% Faster mean time to return to sports

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

100%

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
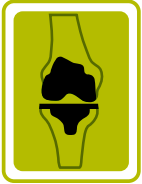
Learning curve and time commitment assessment in the adoption of NAVIO robotic-assisted total knee arthroplasty[16]

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

Single-surgeon case-control study of:

Surgeon's first 100 NAVIO◇ TKAs	50 Conventional TKAs

Assessed during TKA surgery:

Surgical time	✓

Results

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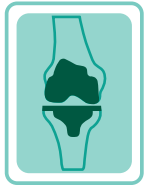
After 40 cases (learning curve) NAVIO only took 10 minutes longer than conventional TKA (18% more time)

After 80 cases, NAVIO 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

Preliminary experience with an image-free handheld robot for total knee arthroplasty: 77 cases compared with a matched control group[20]

Bollars P, et al. *Eur J Orthop Surg Traumatol.* 2020;30:723-729

Retrospective, case-control study of:

77 NAVIO◊ TKAs	77 Conventional TKAs
	Follow up: **6 weeks**

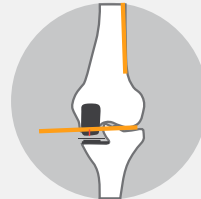**Assessed at pre-TKA and 6 weeks post-TKA:**

Pre-TKA alignment and post-TKA component position on weight bearing and standard lateral radiographs ✓

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
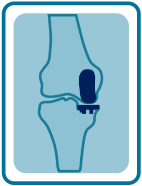
Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study[19]

Mergenthaler G, et al. *Knee Surg Sports Traumatol Arthrosc.* 2020; doi: 10.1007/s00167-020-06051-z

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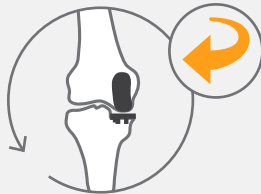
Significantly lower revision rate than conventional UKA (4 vs 11%; p=0.014)
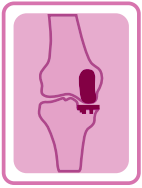

Numerically lower reoperation rate compared to conventional UKA (6.5 vs 9.4%)

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

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, et al. *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
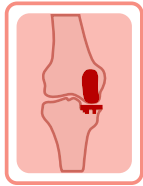
Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis[18]

Yeroushalmi D, et al. *J Knee Surg.* 2020; DOI: 10.1055/s-0040-1712088

Health economic model assessment of:

100 NAVIO◊ UKAs

Model assumptions:

5 year time period	✓
High volume centre (100 UKAs/year)	✓
Mean age of 65 years	✓

Results

<55yrs

7+wks

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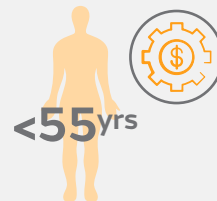
Although NAVIO UKA was cost effective across all age groups, sensitivity analysis estimated that it was greater in younger patients (<55 years) compared to older age groups
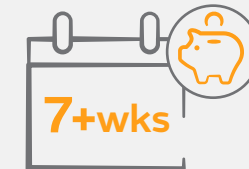
For follow up beyond 7 years, the model estimates that NAVIO UKA becomes cost-saving

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

1 All studies 2012-2018

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

Jamaraz B & Nikou C. 2012	Precision Freehand Sculpting for unicondylar knee replacement: design and experimental validation
Jamaraz B et al. 2013	NAVIO◇ PFS for unicondylar knee replacement: early cadaver validation
Smith JR, et al. 2013	Accuracy of a freehand sculpting tool for unicondylar knee replacement
Smith JR, et al. 2013	The accuracy of a robotically-controlled freehand sculpting tool for unicondylar knee arthroplasty
Gonzalez D, et al 2014	Preliminary results of UKR implanted using an image free handheld robotic device
Gregori A, et al. 2014	Case study, first in man: Using the NAVIO surgical system to implant a JOURNEY◇ UNI Knee
Gregori A, et al. 2014	Handheld precision sculpting tool for unicondylar knee arthroplasty. A clinical review
Simons M, at al 2014	The learning curve of robotically-assisted unicondylar knee arthroplasty
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
Jamaraz B et al. 2015	Accuracy validation of semi-active robotic application for patellofemoral arthroplasty

Lonner JH, et al. 2015	High degree of accuracy of a novel image-free handheld robot for unicondylar knee arthroplasty in a cadaveric study
Herry Y, et al. 2017	**Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique**
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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**
Casper M et al. 2018	Accuracy assessment of a novel image-free handheld robot for total knee arthroplasty in a cadaveric study
Khare R, et al. 2018	Implant orientation accuracy of a hand-held robotic partial knee replacement system over conventional technique in a cadaveric test
Jamaraz B et al. 2018	**Technique and Accuracy assessment of a novel image-free handheld robot for knee arthroplasty in bi-cruciate retaining total knee replacement**
Shah S, et al 2018	Robotic assisted revision total knee replacement - early experience

2 All studies 2019-2020

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

Bollars P. 2019	The learning curve and alignment assessment of an image-free handheld robot in TKA: The first patient series in Europe		Battenberg A, et al. 2019	A novel handheld robotic-assisted system for unicompartmental knee arthroplasty surgical technique and early survivorship
Di Benedetto P, et al. 2019	Comparison between standard technique and image-free robotic technique in medial unicompartmental knee arthroplasty. Preliminary data		**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**
Geller JA, et al. 2019	Rate of learning curve and alignment accuracy of an image-free handheld robot for total knee arthroplasty		Leelasetaporn C, et al. 2020	Comparison of 1-year outcomes between MAKO versus NAVIO robot-assisted medial UKA: nonrandomized, prospective, comparative study
Iniguez et al. 2019	Robot-Assisted Unicompartmental Knee Arthroplasty: Increasing Surgical Accuracy? A Cadaveric Study		**Mergenthaler G, et al. 2020**	**Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study**
Kaper BP, et al. 2019	Measurement of full arc range of motion soft tissue balance in robotic-assisted total knee arthroplasty		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
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		**Sephton BM, et al. 2020**	**24 hour discharge in unicompartmental knee arthroplasty using the NAVIO robotic system: a retrospective analysis**
Kaper BP, et al. 2019	**Learning curve and time commitment assessment in the adoption of NAVIO robotic-assisted total knee arthroplasty**			
Lonner JH, et al. 2019	Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems		**Yeroushalmi D, et al. 2020**	**Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis**
Shearman AD, et al. 2019	Robotic-assisted unicondylar knee arthroplasty is associated with earlier discharge from physiotherapy and reduced length of stay compared to conventional UKA			

Key Outcome: **Accuracy**

Compared to conventional methods, both NAVIO UKA and TKA result in significantly improved accuracy and reliability in implant placement[2,14,20]

NAVIO allows surgeons to precisely plan and execute highly accurate implant placement and mechanical axis alignment[13,27]

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

Significantly less distalised joint line with NAVIO UKA[14] ✓

Significantly lower revision rate due to malalignment with NAVIO UKA[2] ✓

Significantly lower rate of outliers in the frontal tibial component with TKA[20] ✓

91% NAVIO UKAs achieved mechanical axis alignment within 1°[27] (n=57)

23 Studies

reporting on accuracy

Jamaraz B & Nikou C. 2012	Precision Freehand Sculpting for unicondylar knee replacement: design and experimental validation
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Leelasetaporn, et al. 2020	Comparison of 1-year outcomes between MAKO versus NAVIO robot-assisted medial UKA: nonrandomized, prospective, comparative study

Key Outcome:
Early recovery & clinical outcomes

A study has shown that NAVIO◇ UKA patients (n=31) may regain knee function earlier, and are able to be discharged from hospital sooner[43], than patients with UKA carried out by computer aided navigation

NAVIO UKA patients report substantial improvements in quality of life, pain and function over the first year post-UKA compared to pre-UKA[46] (Figure) . Compared to conventional UKA, NAVIO UKA patients have demonstrated significant improvement in both IKSS-objective[14] and function scores.[19]

A study showed, that compared with patients receiving computer navigated UKA, NAVIO UKA patients were:

Discharged from hospital **39% sooner[43]** ✓

Discharged from physiotherapy **49% sooner[43]** ✓

Figure. KOOS scores pre- and post-NAVIO robotic-assisted UKA[47]

A study has shown **>50% faster mean time to return to sports[15]**

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

12 Studies
reporting on recovery

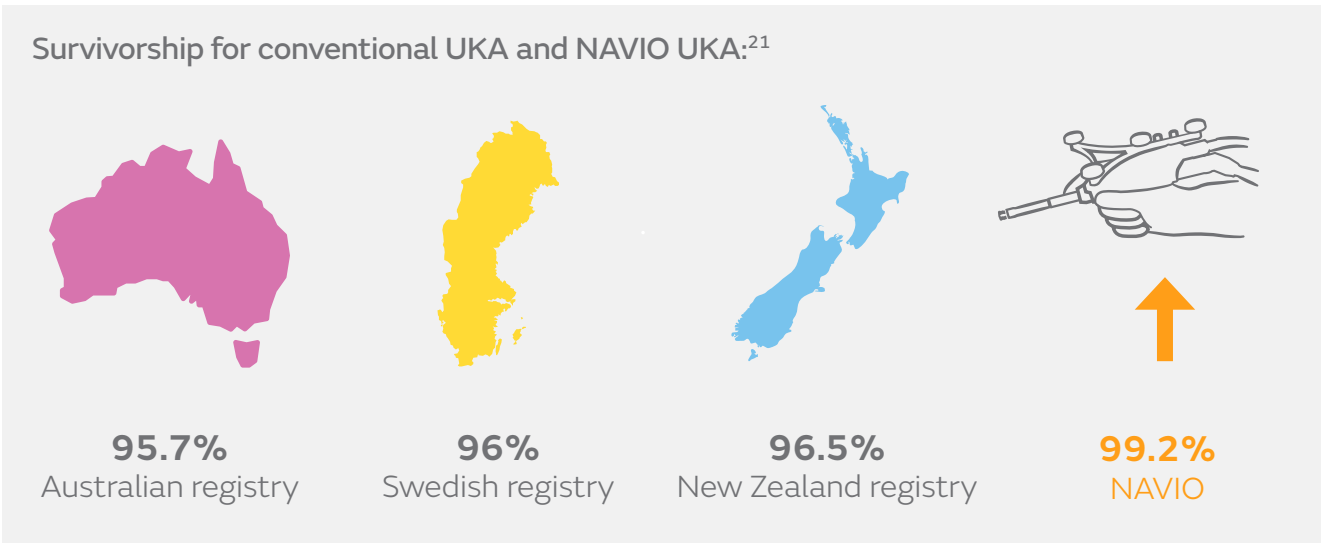|	
Gregori A, et al. 2013	Case study: totals aren't always inevitable
Gregori A, et al. 2014	Case study: first in man: using the NAVIO surgical system to implant a JOURNEY UNI Knee
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Sephton BM, et al. 2020	**24 hour discharge in unicompartmental knee replacement using the NAVIO robotic system: a retrospective analysis**

Key Outcome:
Survivorship

2yrs

NAVIO◊ UKA is associated with high early survivorship, compared to registry data for conventional UKA (99.2% at 2 years)[21]

NAVIO TKA and UKA are safe procedures with no increased risk of surgical complications or reoperations[19,35]

Survivorship for conventional UKA and NAVIO UKA:[21]

95.7%	96%	96.5%	99.2%
Australian registry	Swedish registry	New Zealand registry	NAVIO

Revisions due to malposition or malalignment are lower for NAVIO UKA, compared to conventional UKA[2,19]

0% (0/4 revisions)	**Vs**	86% (6/7 revisions)[2]
12.5% (1/8 revisions)	**Vs**	76.2% (16/21 revision) p=0.0002[19]

Key Outcome:
Survivorship

5 Studies
reporting on survivorship
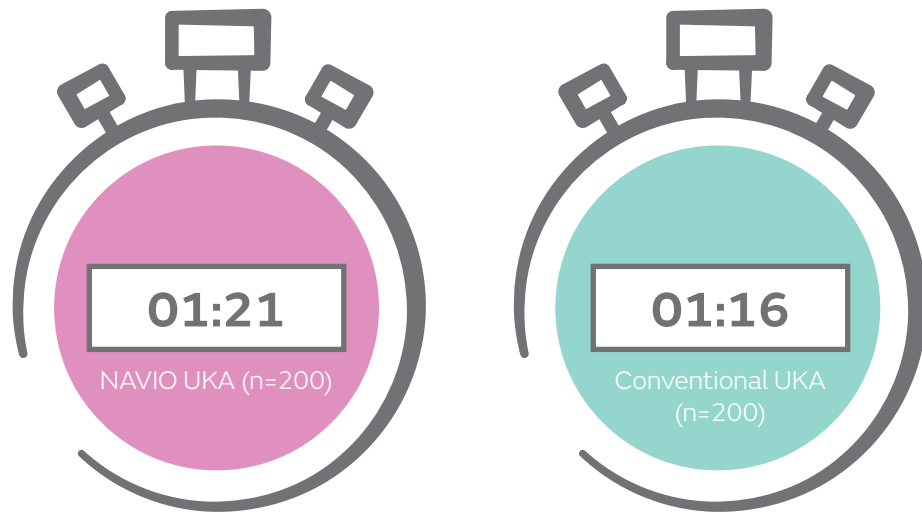
Batailler C, et al. 2018	Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty
Battenberg A, et al. 2019	A novel handheld robotic-assisted system for unicompartmental knee arthroplasty surgical technique and early survivorship
Kaper BP, et al. 2019	Initial safety profile assessment of the NAVIO robotic-assisted total knee arthroplasty
Lonner JH, et al. 2019	Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems
Mergenthaler, et al. 2020	**Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study**

Key Outcome:
Surgical time

NAVIO◊ UKA and TKA surgeons have experienced clinically significant reductions in surgical time after only a small number of cases (p<0.001)[12,13]

15.5% reduction in NAVIO UKA surgical time (after 12 cases)[13] ✓

44% reduction in NAVIO TKA surgical time (after 5 cases)[12] ✓

01:21
NAVIO UKA (n=200)

01:16
Conventional UKA (n=200)

No difference in operational time[19]

<5%
More time than conventional TKA (after 80 cases)[16]

After the learning curve, studies have shown that both NAVIO TKA and UKA result in comparable surgical time to conventional methods[16,19]

8 Studies

reporting on surgical time

Jamaraz B & Nikou C. 2012	Precision Freehand Sculpting for unicondylar knee replacement: design and experimental validation	
Wallace D, et al. 2014	The learning curve of a novel handheld robotic system for unicondylar knee arthroplasty	
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Key Outcome:
Cost effectiveness

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)[18,41]

$14,737 estimated cost per revision avoided with NAVIO UKA[18] ✓

£2,831 cost per QALY with NAVIO UKA[41] ✓

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[41]

As the number of cases increases, the cost per patient falls, which improves the cost-effectiveness of NAVIO UKA[17,41]
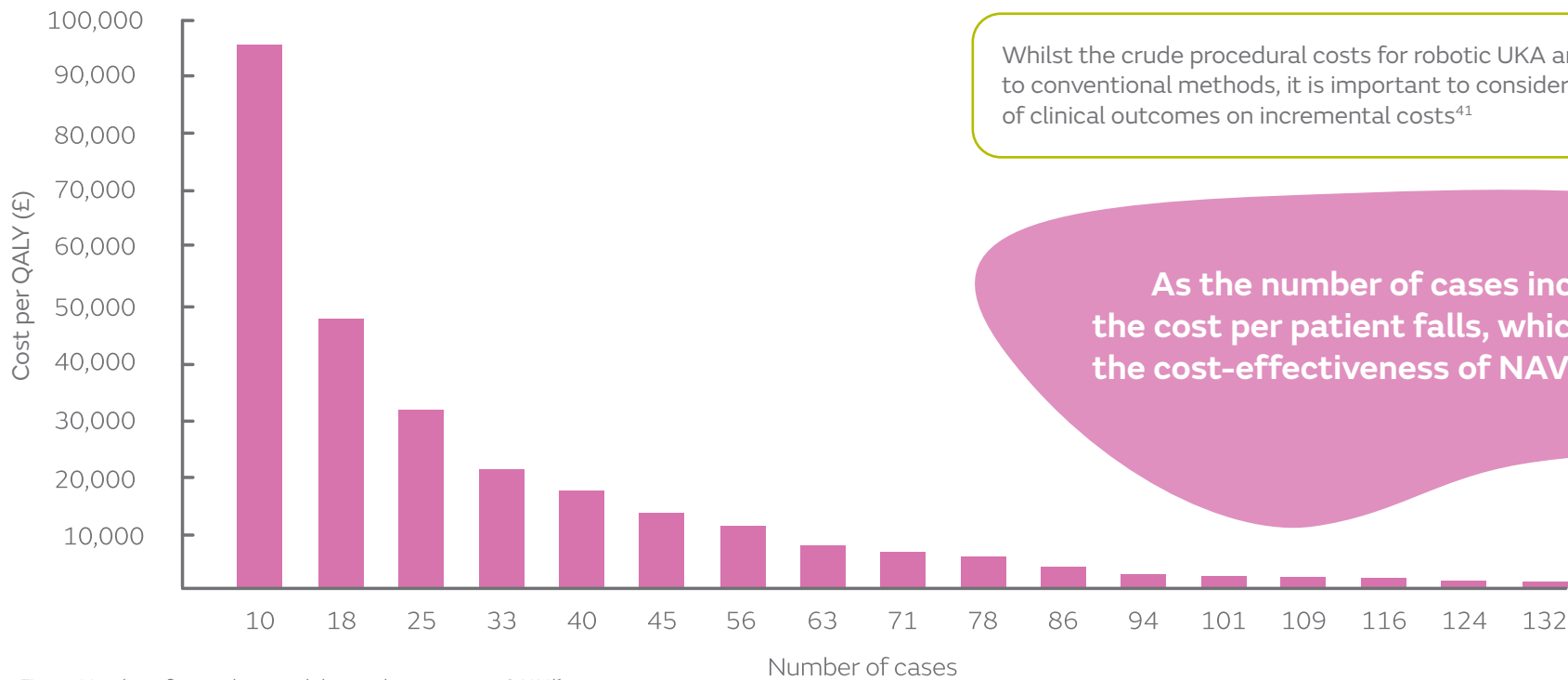

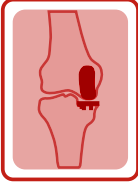Figure. Number of procedures and the resultant cost per QALY[41]

2 Studies

reporting on cost

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

Precision freehand sculpting for unicondylar knee replacement: design and experimental validation[30]

Jaramaz B, Nikou C. *Biomed Tech.* 2012;57:293-299

Overview

- Evaluation of NAVIO◊ Surgical System performance for UKR in terms of implant fit and cutting time
    - Three users with different levels of experience
    - Five sawbone specimens per surgeon

Key results

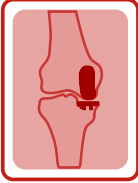|	
Total cutting time:	6.5 to 9.5 minutes
Mean cut time:	8.01 minutes
Average distance from the planned implant position:	0.54mm
Average total error:	0.54mm/1.08°

Conclusion

NAVIO UKA achieved high levels of accuracy, adequate for joint replacement surgery, with low levels of error, on sawbone specimens

Back to

Early recovery   Survivorship   Cost effectiveness

NAVIO◇ PFS for unicondylar knee replacement: early cadaver validation[31]

Jaramaz B, et al. 13ᵗʰ annual meeting CAOS. June 13-15, 2013; Orlando, FL, USA

Overview

- Three operators performed medial UKA surgery with NAVIO◇ Surgical System on two cadaver specimens (four knees)
- Each component included a set of eight conical divots in predetermined locations to allow for measurement of the position

Key results

All NAVIO-assisted implants were within 1.5mm of the target in all directions	✓

Conclusion

Use of NAVIO, on cadaveric knees, PFS showed high levels of accuracy comparable to other robotics-assisted devices, when used on cadaver specimens
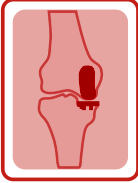
Back to

Early recovery   Survivorship   Surgical time   Cost effectiveness

Case study: totals aren't always an inevitability[26]

Gregori A, et al. BLUE BELT Technologies Inc. 2013

Overview

- Active, 53 year old male
- Satisfied with prior partial knee procedure in right knee, now severe pain in medial compartment with no lateral/anterior compartment pain in left knee
- Surgeon exploring partial knee replacement as first option but considering total due to extreme varus deformity of 12°

Key results

At the planning stage, NAVIO◊ allowed the surgeon to make an informed decision intra-operatively on best way to proceed	✓
NAVIO allowed the surgeon to plan an implant fit and position with minimal bone resection to balance knee and correct long leg alignment without over-correction	✓
Post-operative long leg alignment 2° varus (improvement of 10°)	✓

Conclusion

NAVIO UKA allowed surgeons to confidently approach a challenging surgery with the knowledge that they could execute a predetermined plan accurately to get the best outcome for the patient
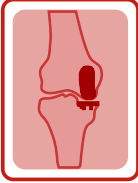
Back to

Accuracy   Survivorship   Surgical time   Cost effectiveness

Accuracy of a freehand sculpting tool for unicondylar knee replacement[44]

Smith JR, et al. *Int J Med Robotics Comput Assist Surg.* 2013;10:162-169

Overview

- A single-surgeon tested accuracy of NAVIO◊ Surgical System
- Carried out UKA with 20 identical femur and tibia synthetic bone pairs
- Four fidicular markers drilled in each femur and tibia sawbones were used to measure pre- and post-UKA position

Key results

Fidicular marker analysis: minimal movement of the arrays	✓
Mean cut surface data: slight undercut of 0.14mm for femur and 0.21mm for tibia leg alignment without over-correction	✓
All implant positions compared favourably to the plan and were within the expected target zone with low errors in rotational and translational placement	✓

Conclusion

NAVIO UKA implant positions were accurate to plan on synthetic bones, with low levels of error in rotational and translational placement, when used on synthetic bone pairs
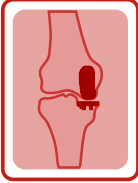
Back to

Early recovery   Survivorship   Surgical time   Cost effectiveness

The accuracy of a robotically-controlled freehand sculpting tool for unicondylar knee arthroplasty[45]

Smith JR, et al. Congress of ISB. August 4-9, 2013; Natal, Brazil

Overview

- Two users trained with the NAVIO◊ Surgical System, performed UKA on nine cadavers
    - Consultant orthopaedic surgeon performed four implants
    - Research associate performed five implants
- 3D image of the actual implant position was overlaid on the planned implant image to quantify differences in planned and achieved cuts in three planes and three rotations

Key results

Error Type	Mean total error	
	Femoral implant	Tibial implant
Maximum implant rotational error	3.7°	4.1°
Maximum implant translational error	2.6mm	2.7mm
Maximum RMS angular error	2.0°	2.6°
RMS translational error across all directions	1.1mm	2.0mm

Conclusion

NAVIO UKA offers optimal positioning of implants, and the freehand sculpting tool produced high levels of accuracy in implant placement with low levels of error when used on cadaver specimens
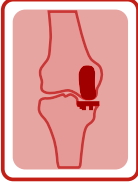
Back to

Early recovery | Survivorship | Surgical time | Cost effectiveness

Preliminary results of UKR implanted using an image free handheld robotic device[29]

Gonzalez D, et al. BASK Annual Meeting. April 8-9, 2014; Norwich, UK

Overview

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

Key results

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

* To convert from the old OKS to the new OKS, the old OKS score is subtracted from 60 (old OKS, 38 and 23, respectively)

Conclusion

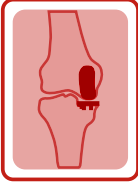Preliminary analysis showed satisfactory post-UKR outcome for UKR with NAVIO UKR

Handheld precision sculpting tool for unicondylar knee arthroplasty. A clinical review[27]

Gregori A, et al. 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 Oxford Knee Score 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 time reduced by 15 minutes after ten cases

Back to

Survivorship

Cost effectiveness
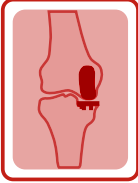
Case study First in man: using the NAVIO◊ surgical system to implant a JOURNEY◊ UNI knee[25]

Gregori A, et al. BLUE BELT Technologies Inc. 2014

Overview

- 67 year old male with left knee osteoarthiritis
- Pain predominantly on medial side of knee
- Pre-operative deformity of 8° varus, medial compartmental cartilage thinning and joint space narrowing
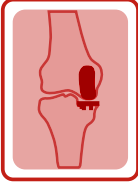- Previous right knee UKR

Key results

Planned post-UKR alignment = 2° of varus	✓
Achieved post-UKR alignment = 3°- The surgeon increased planned insert thickness during surgery, as NAVIO◊ is a flexible platform	✓
Surgical time from tracker placement to trial acceptance: 50 minutes	✓
Total cutting time: 20 minutes	✓
Both patient and surgeon satisfied	✓
Patient discharged two days post-UKR with >90° knee flexion	✓

Back to

Survivorship   Surgical time   Cost effectiveness

The learning curve of robotically-assisted unicondylar knee arthroplasty[12]
Simons M, Riches P. *Bone Joint J.* 2014;96B(:SUPP11)

Overview

- Five junior orthopaedic trainees all underwent initial NAVIO◊ Surgical System UKA training and performed five UKAs with NAVIO on left-sided synthetic femurs and tibiae
- Each procedure was video recorded and timed
- A ballpoint probe with four reflective spherical markers attached was used to record the position of prepared divots on the implant to allow the 3D position of the implant to be compared to the planned position

Key results

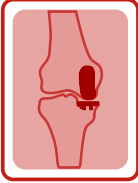|	
Total surgical time decreased significantly from 85 to 48 minutes after five surgeries (p<0.001)	✓
All stages, except cutting tool set up, demonstrated a significant difference in operative time with increasing number of surgeries performed (p<0.05) - Cutting phase decreased from 41 to 23 minutes	✓
Translational and rotational accuracy of the implants did not significantly vary with surgery number	✓
Adequate accuracy was achieved from the first surgery	✓

Conclusion

NAVIO UKA achieved high levels of accuracy from the first procedure, with up to 44% reduction in surgical time after five procedures on synthetic femurs and tibiae

Back to

Early recovery   Survivorship   Cost effectiveness

The learning curve of a novel handheld robotic system for unicondylar knee arthroplasty[47]

Wallace D, et al. *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
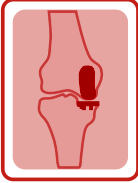
Back to   Accuracy   Early recovery   Survivorship   Cost effectiveness

Accuracy of imageless robotically assisted unicondylar knee arthroplasty[28]

Gregori A, et al. 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
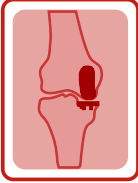
Back to   Early recovery   Survivorship   Surgical time   Cost effectiveness

Accuracy validation of semi-active robotic application for patellofemoral arthroplasty[32]

Jaramaz B, et al. 15th Annual Meeting of CAOS. June 17-20, 2015; Vancouver, Canada

Overview

- Tests were performed (n=24) for four different implant designs, with a minimum of five cases per implant design
- NAVIO◊ surgery was simulated with four implant designs (two 'inlay' and two 'onlay')
- Minimum of three synthetic bones and two cadavers were used for each design
- Fiducial markers established a reference frame to determine the accuracy of prosthesis placement
- Final implant position and planned position were compared

Key results

Maximum RMS error	0.87mm	✓
Maximum rotational error	1.2°	✓

Conclusion

The high levels of accuracy demonstrated by NAVIO PFS are in accordance with those reported for UKR surgery. The results of this study are based on using the NAVIO Surgical System with the bur and saw function on synthetic bones and cadaveric specimens
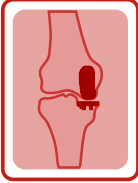
Back to   Early recovery   Survivorship   Surgical time   Cost effectiveness

High degree of accuracy of a novel image-free handheld robot for unicondylar knee arthroplasty in a cadaveric study[39]

Lonner JH, et al. *Clin Orthop Relat Res.* 2015;473:206-212

Overview

- Four surgeons carried out medial UKA on 25 cadavers with NAVIO◇ Surgical System
- Planned implant orientation and actual implant orientation were compared

Key results

Bone preparation and implant position were within the range of 0.8 to 1.3mm and 1 to 2° of the planned implant position ✓

Conclusion

NAVIO UKA provided accurate implementation of the surgical plan, with low levels of error, comparable to other semi-autonomous robotic orthopaedic devices, when used on cadavers
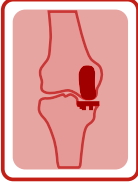
Robotic-assisted unicompartmental knee replacement with NAVIO◇ surgical system: outcome evaluation using knee injury osteoarthritis outcome score[46]

Vega Parra P, et al. *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
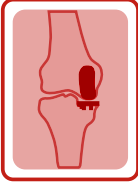
Back to   Accuracy   Survivorship   Surgical time   Cost effectiveness

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

Batailler C, et al. *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◇ robotics-assisted 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 robotics-assisted UKA

Back to   (Early recovery)   (Surgical time) (Cost effectiveness)
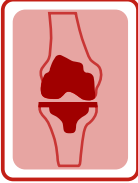
Accuracy assessment of a novel image-free handheld robot for total knee arthroplasty in a cadaveric study[23]

Casper M, et al. *Comput Assist Surg.* 2018;23:14-20

Overview

- Eight experienced TKA surgeons carried out TKA using NAVIO◇ Surgical System on 18 cadavers (2 or 3 per surgeon)
- JOURNEY◇ II, GENESIS◇ II and LEGION◇ implants were used
- Conical divots were prepared at known positions on the implants to allow for accuracy assessment

Key results

All (bur and cut-guide) absolute mean tibial and femoral errors were within 1mm/° of neutral - except for femoral flexion (with cut-guide) which was within 2° of neutral	✓

Conclusion

NAVIO TKA provided accurate implementation of the surgical plan with small errors in implant placement, when used on cadavers
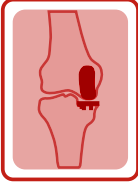
Back to   Early recovery   Survivorship   Surgical time   Cost effectiveness

Implant orientation accuracy of a hand-held robotic partial knee replacement system over conventional technique in a cadaveric test[37]

Khare R, et al. *Computer Assisted Surgery.* 2018;23:8-13

Overview

- Two surgeons each carried out medial bilateral UKA on six cadavers
    - Equal number of UKAs were carried out with NAVIO◊ Surgical System used on one knee and conventional methods for the other knee
- Conical divots were prepared at known positions on the implants to allow for accuracy assessment
- CT scans were obtained pre and post-UKA to identify final implant position, which was then compared to the planned position

Key results

	NAVIO	Conventional
Maximum RMS femoral implant orientation error:	≤2.81°	≤7.52°
Maximum RMS tibia implant orientation error:	≤2.96°	≤4.06°

Conclusion

NAVIO UKA provided improved implant alignment accuracy over conventional approaches to UKA, when used on cadavers

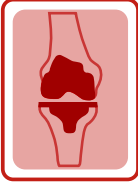# Robotic assisted revision total knee replacement - early experience[42]

Shah S, et al. 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

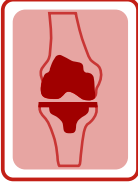|	
Mean length of stay: 4.5 days	✓
Mean operating time: 92 minutes	✓
Improvements in ROM, OKS and KSS and leg alignment compared to pre-operative values	✓
No mechanical axis outliers	✓

Conclusion

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

Back to

Survivorship   Surgical time   Cost effectiveness

The learning curve and alignment assessment of an image-free handheld robot in TKA: the first patient series in Europe[22]

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

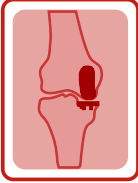|	
Mean intra-operative planned angle was 0.59° varus	✓
NAVIO achieved a mean post-operative alignment angle of 1.17° varus	✓
Mean extra surgical time with NAVIO for registration and planning decreased from 23.4 to 13.2 minutes throughout the learning curve	✓

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

Back to

Early recovery   Survivorship   Cost effectiveness

Comparison between standard technique and image-free robotic technique in medial unicompartmental knee arthroplasty. Preliminary data[24]

Di Benedetto P, et al. *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 at pre-UKA and 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

Back to   Survivorship   Surgical time   Cost effectiveness
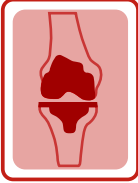
Rate of learning curve and alignment accuracy of an image-free handheld robot for total knee arthroplasty[13]

Geller JA, et al. 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
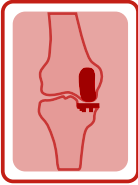
Back to

Accuracy   Early recovery   Survivorship   Cost effectiveness

Robot-Assisted unicompartmental knee arthroplasty: increasing surgical accuracy? A cadaveric study[48]

Iñiguez M, et al. *J Knee Surg.* 2019; doi:10.1055/s-0039-1698771

Overview

- Cadaveric study comparing the accuracy of position and alignment of NAVIO◊ Surgical System compared to conventional UKA
    - 13 UKAs with NAVIO
    - 13 UKAs with conventional method
- Radiographs were assessed pre-and post-UKA

Key results

Measurement	Robotic Median	Conventional Median	P value
Medial distal femoral angle (°)	1.07	2.12	0.00130
Medial proximal femoral angle (°)	1.28	1.28	0.00640
Tibial slope (°)	5.25	4.72	0.00343
Mechanical axis (°)	1.03	0.92	0.12140
Sagittal femoral angle (°)	4.6	7.19	0.01480

Conclusion

NAVIO UKA allowed for improved accuracy of positioning of the components in the coronal and sagittal planes, compared to conventional UKA in a cadaveric model
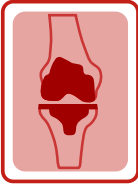
Back to   (Early recovery)   (Survivorship)   (Surgical time)   (Cost effectiveness)

Measurement of full arc range of motion soft tissue balance in robotic-assisted total knee arthroplasty[34]

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

Overview

- The study assessed the ability of NAVIO◊ robotic-assisted 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
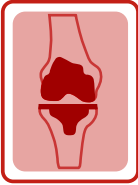
Back to   Early recovery   Survivorship   Surgical time   Cost effectiveness

Initial safety profile assessment of the NAVIO robotic-assisted total knee arthroplasty[35]

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

Overview

- The safety profiles of the first 200 patients undergoing NAVIO◇ robotic-assisted 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
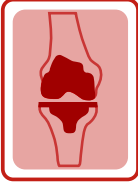
Back to Accuracy   Early recovery   Surgical time   Cost effectiveness

Accuracy and precision of a handheld robotic-guided distal femoral osteotomy in robotic-assisted total knee arthroplasty[36]

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
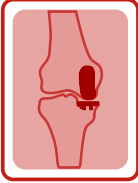
Back to

Accuracy   Early recovery   Survivorship   Surgical time   Cost effectiveness

Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems[40]

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
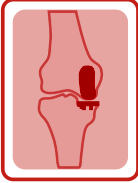
Back to   Accuracy   Early recovery   Surgical time   Cost effectiveness

Robotic-assisted unicondylar knee arthroplasty is associated with earlier discharge from physiotherapy and reduced length of stay compared to conventional navigation techniques[43]

Shearman AD, et al. EKS Arthroplasty Conference. May 2-3, 2019; Valencia, Spain

Overview

- Patients receiving NAVIO◊ UKA (n=31) were compared to those who received navigation UKA (n=31)
- Length of operation, transfusion requirements, time to discharge, ROM and analgesia requirements were assessed

Key results

Operating time was longer with NAVIO UKA, compared to navigation UKA (102.8 vs 85.6 mins; p<0.001 ✓

Compared to navigation UKA, NAVIO 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 (25 vs 49hrs; p=0.016;) ✓
- Significantly earlier hospital discharge (45.5 vs 74 .0hrs; p<0.05) ✓

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
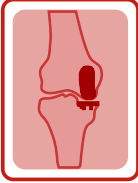
Back to   Accuracy   Survivorship   Surgical time   Cost effectiveness

A novel handheld robotic-assisted system for unicompartmental knee arthroplasty: surgical technique and early survivorship[21]

Battenberg A, et al. *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
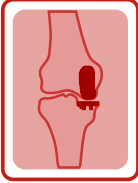
Back to   Accuracy   Early recovery   Surgical time   Cost effectiveness

Comparison of 1-year outcomes between MAKO® versus NAVIO◇ robot-assisted medial UKA: nonrandomized, prospective, comparative study[38]

Leelasetaporn C, et al. *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

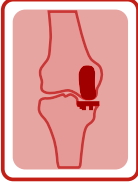|	
No significant difference in KSFS (99.9 vs 99.5) or KSS (96.9 vs 94.7) between NAVIO and MAKO at 1-year post-UKA	✓
Mean intra-operative time of seven steps (registration of hip and ankle, femur and tibia, ligament tension, implant planning, preparation femur, tibia, and trial implant) for NAVIO UKA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

Conclusion

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

Back to   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[41]

Nherera LM, et al. *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	✓
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

Back to   Accuracy   Early recovery   Survivorship   Surgical time

REFERENCES

1. Murray DW, Parkinson RW. Usage of unicompartmental knee arthroplasty. *Bone Joint J.* 2018;100-b(4):432-435.

2. Batailler C, White N, Ranaldi FM, Neyret P, Servien E, Lustig S. Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2019;27:1232-1240.

3. National Joint Registry for England, Wales and Northern Ireland: 17th Annual Report. 2020. Available at: https://reports.njrcentre.org.uk/

4. Liddle AD, Pandit H, Judge A, Murray DW. Effect of surgical caseload on revision rate following total and unicompartmental knee replacement. J Bone Joint Surg [Am]. 2016;98-A:1–8.

5. Ebohon S. Learning curve experienced during UKA. Smith& Nephew internal report: EO/RECON/NAVIO/003/v1. 9 August 2019.

6. Scott CEH, Howie CR, MacDonald D, Biant LC. Predicting dissatisfaction following total knee replacement. *J Bone Joint Surg Am.* 2010;92–B:1253–1258.

7. Noble PC, Gordon MJ, Weiss JM, et al. Does total knee replacement restore normal knee function? *Clin Orthop Relat Res.* 2005;431:157–165.

8. Chen K, Kim K, Vigdorchik J, Meere P, Bosco J, Iorio R. Cost-effectiveness analysis of robotic arthroplasty. *Lonner JH, editor. Robotics in Knee and Hip Arthroplasty: Springer; 2019.*

9. Allen MW, Jacofsky DJ. Evolution of Robotics in Arthroplasty. In: Lonner JH, editor. Robotics in Knee and Hip Arthroplasty: *Springer; 2019.*

10. Jacofsky DJ, Allen M. Robotics in arthroplasty: a comprehensive review. *J Arthroplasty.* 2016;31:2353-2363.

11. Karuppiah K, Sinha J. Robotics in trauma and orthopaedics. *Ann R Coll Surg Engl.* 2018;100(6_sup):8-15.

12. Simons M, Riches P. The learning curve of robotically-assisted unicondylar knee arthroplasty. *Bone Joint J.* 2014;96B:SUPP11.

13. Geller JA, Rossington A, Mitra R, Jaramaz B, Khare R, Netravali NA, editors. Rate of learning curve and alignment accuracy of an imagefree handheld robot for total knee arthroplasty. Abstract presented at: EKS Arthroplasty Conference; 2019 2-3 May; Valencia, Spain.

14. Herry Y, Batailler C, Lording T, Servien E, Neyret P, Lustig S. Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique. *Int Orthop.* 2017;41:2265-2271.

15. 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.

16. Kaper BP, Villa A. Learning curve and time commitment assessment in the adoption of NAVIO robotic-assisted total knee arthroplasty. Abstract number O32 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.

17. Sephton BM, De la Cruz N, Shearman A, 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.

18. Yeroushalmi D, Feng J, Nherera L, Trueman P, Schwarzkopf R. Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis. *J Knee Surg.* 2020; DOI: 10.1055/s-0040-1712088.

19. 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.* 2020; doi: 10.1007/s00167-020-06051-z.

20. Bollars P, Boeckxstaens A, Mievis J, Kalaai S, Schotanus MGM, Janssen D. Preliminary experience with an image-free handheld robot for total knee arthroplasty: 77 cases compared with a matched control group. *Eur J Orthop Surg Traumatol.* 2020;30:723-729.

21. Battenberg A, Netravali NA, Lonner JH. A novel handheld robotic-assisted system for unicompartmental knee arthroplasty: surgical technique and early survivorship. *Robot Surg.* 2019;14:55-60.

22. Bollars P. The learning curve and alignment assessment of an image-free handheld robot in TKA: the first patient series in Europe. Abstract presented at: 19th Annual Meeting of the International Society for Computer Assisted Orthopaedic Surgery. June 19-22, 2019; New York, USA.

23. Casper M, Mitra R, Khare R, et al. Accuracy assessment of a novel image-free handheld robot for total knee arthroplasty in a cadaveric study. *Comput Assist Surg* (Abingdon). 2018;23:14-20.

24. Di Benedetto P, Buttironi MM, Magnanelli S, Cainero V, Causero A. Comparison between standard technique and image-free robotic technique in medial unicompartmental knee arthroplasty. Preliminary data. *Acta Biomed.* 2019;90:104-108.

25. Gregori A, Smith J, Simone A. Case study: First in man: using the NAVIO surgical system to implant a JOURNEY UNI knee. BLUE BELT Technologies Inc. 2014.

26. Gregori A, Lethbridge R, Simone A. Case study: totals aren't always an inevitability. BLUE BELT Technologies Inc. 2013.

27. Gregori A, Picard F, Bellemans J, Smith J, Simone A. Handheld precision sculpting tool for unicondylar knee arthroplasty. A clinical review. Abstract presented at: 15th European Federation of National Associations of Orthopaedics and Traumatology Congress; June 4-6, 2014; London, UK.

28. Gregori A, Picard F, Lonner J, Smith J, Jaramaz B. Accuracy of imageless robotically assisted unicondylar knee arthroplasty. Paper presented at: International Society for Computer Assisted Orthopaedic Surgery; June 17-20, 2015; Vancouver, Canada.

29. Gonzalez D, Deakin AH, Picard F. Preliminary results of UKR implanted using an image free handheld robotic device. Poster presented at: Annual Meeting of the British Association for Surgery of the Knee; April 8-9, 2014; Norwich, UK.

30. Jaramaz B, Nikou C. Precision freehand sculpting for unicondylar knee replacement: design and experimental validation. *Biomed Tech (Berl).* 2012;57:293-299.

31. Jaramaz B, Nikou C, Simone A. NAVIO PFS for unicondylar knee replacement: early cadaver validation. Abstract presented at: International Society for Computer Assisted Orthopaedic Surgery; June 12-15, 2013; Florida, USA.

32. Jaramaz B, Noickou C, Casper M, Grosse S, Mitra R. Accuracy validation of semi-active robotic application for patellofemoral arthroplasty. Paper presented at: International Society for Computer Assisted Orthopaedic Surgery; June 17-20, 2015; Vancover, Canada.

33. Jaramaz B, Mitra R, Nikou C, Kung C. Accuracy assessment of a novel image-free handheld robot for knee arthroplasty in bi-cruciate retaining total knee replacement. *Health Sciences.* 2018;2:98- 101.

34. Kaper BP. Measurement of full arc range of motion soft tissue balance in robotic-assisted total knee arthroplasty. Abstract number SP2 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.

35. Kaper BP, Villa A. Initial safety profile of the NAVIO robotic-assisted total knee arthroplasty. Abstract number P45 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.

36. Kaper BP, Villa A. Accuracy and precision of a handheld robotic-guided distal femoral osteotomy in robotic-assisted total knee arthroplasty. Abstract number P46 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.

37. Khare R, Jaramaz B, Hamlin B, Urish KL. Implant orientation accuracy of a hand-held robotic partial knee replacement system over conventional technique in a cadaveric test. *Computer Assisted Surgery.* 2018;23:8-13.

38. Leelasetaporn C, Tarnpichprasert T. Arirachakaran A, Kongtharvonskul. Comparison of 1-year outcomes between MAKO versus NAVIO robot-assisted medial UKA: nonrandomized, prospective, comparative study. *Knee Surg Relat Res.* 2020;32:13.

39. Lonner JH, Smith JR, Picard F, Hamlin B, Rowe PJ, Riches PE. High degree of accuracy of a novel image-free handheld robot for unicondylar knee arthroplasty in a cadaveric study. *Clin Orthop Relat Res.* 2015;473:206-212.

40. Lonner JH, Kerr GJ. Low rate of iatrogenic complications during unicompartmental knee arthroplasty with two semiautonomous robotic systems. *Knee.* 2019;26:745-749.

41. Nherera LM, Verma S, Trueman P, Jennings S. Early economic evaluation demonstrates that noncomputerized tomography robotic-assisted surgery is cost-effective in patients undergoing unicompartmental knee arthroplasty at high-volume orthopaedic centres. *Adv Orthop.* 2020;3460675.

42. Shah S, Fick D, Khan R, De Cruz P. Robotic assisted revision total knee replacement- early experience. Abstract presented at: 19th Annual Scientific Meeting for APAS. September 6-8, 2018; Bangkok, Thailand.

43. Shearman AD, Sephton B, Nathwani DK. Robotic-assisted unicondylar knee arthroplasty is associated with earlier discharge from physiotherapy and reduced length of stay compared to conventional navigated techniques. Abstract number O71 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.

44. Smith JR, Riches PE, Rowe PJ. Accuracy of a freehand sculpting tool for unicondylar knee replacement. *Int J Med Robot.* 2014;10:162-169.

45. Smith JR, Picard F, Lonner J, Hamlin B, Rowe P, Riches P, Deakin A. The accuracy of a robotically-controlled freehand sculpting tool for unicondylar knee arthroplasty. Abstract presented at: Congress of the International Society of Biomechanics. August 4-9, 2013; Natal, Brazil.

46. Vega Parra PD, Dionisio Palacios Barajas J, Marquez Ambrosi RA, Duarte JR. Robotic-assisted unicompartmental knee replacement with NAVIO surgical system: Outcome evaluation using knee injury osteoarthritis outcome score. *Rev Chil Ortop Traumatol.* 2017;58:7-12.

47. Wallace D, Gregori A, Picard F, et al. the learning curve of a novel handheld robotic system for unicondylar knee arthroplasty. *Bone Joint J.* 2014;96B:SUPP16.

48. Iñiguez M, Negrín R, Duboy J, Reyes NO, Díaz R. Robot-Assisted Unicompartmental Knee Arthroplasty: Increasing Surgical Accuracy? A Cadaveric Study. *J Knee Surg.* 2019;doi: 10.1055/s-0039-1698771.

Evidence in focus

Publication summary
Herry Y, Lustig S, et al. *Int Orthop* (2017)*

Restitution of joint-line height in unicompartmental knee arthroplasty (UKA) was significantly improved with NAVIO◇ Surgical System compared with control group (p<0.05)

Results from the first study comparing joint-line restitution following robotic-assisted UKA or a conventional technique

Study design

- Single-surgeon retrospective, case-controlled study comparing joint-line height following UKA using NAVIO robotic-assisted (40 patients; mean age, 69 years) or conventional technique (40 patients; mean age, 68 years)
- Weight-bearing radiographs were taken pre-UKA and 2 months post-UKA

Key results

- The joint-line was distalised significantly more following UKA in the conventional group than in the NAVIO Surgical System group when assessed using two methods (p<0.05; Figure)
  - Method 1: angle between joint-line and lateral femoral cortex
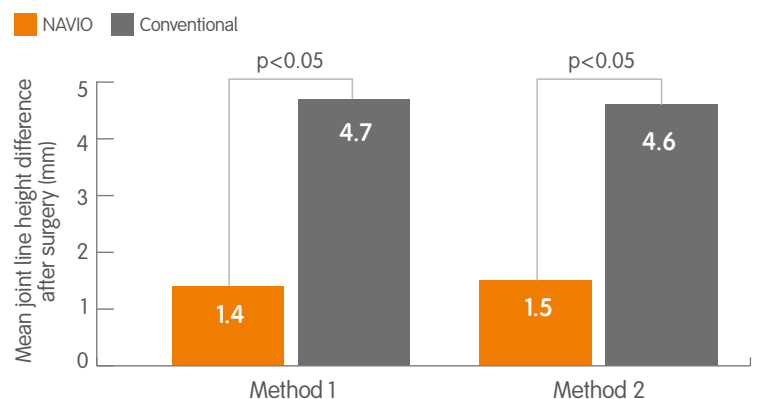 - Method 2: angle between joint-line and femoral intramedullary axis

Figure. Mean joint-line height difference (mm) following UKA using robotics-assisted or conventional techniques, as analysed by two methods

Conclusion

NAVIO robotics-assisted UKA allows for intraoperative planning of implant position and accurate bone resection, resulting in improved joint-line restitution when compared with a conventional technique. Furthermore, NAVIO Surgical System may avoid creating femoral superstructures, thereby reducing tibial resection and helping to prevent pain and other post-UKA complications. Further studies should be undertaken to assess long-term outcomes.

Study citation

*Herry Y, Batailler C, Lording T, Servien E, Neyret P, Lustig S. Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique. *Int Orthop*. 2017;41:2265–2271.

Evidence in focus

Poster summary

Battenberg AK et al, *Southern Orthopaedic Association* **(2018)***

NAVIO◇ robotic-assisted unicompartmental knee arthroplasty (UKA) demonstrates 99.2% survivorship at two years

Survivorship at two years was higher than that reported in several national joint registries for conventional UKA

Study overview

- Retrospective study evaluating revision rate following NAVIO robotic-assisted UKA, at five US sites
- 128 patients, representing surgeon adopters', initial cases (mean age, 64.7 years; females, 54; males, 74)
- Post-operative follow-up (mean, 2.3 years) was carried out to determine survivorship and number of adverse events

Key results

- Survivorship at two years, 99.2%
  - One revision due to hamstring irritation and ischial tuberosity bursitis
  - Survivorship was higher than that reported in several registries for conventional UKAs
    - Australian Orthopaedic Association National Joint Registry, 95.7%[1]
    - New Zealand Joint Registry, 96.3%[2]
    - Swedish Joint Registry, 96%[3]
  - Survivorship was statistically non-inferior to that reported in the Australian registry
- Adverse events
  - Four patients (3.1%) reported adverse events that were possibly or definitely related to NAVIO
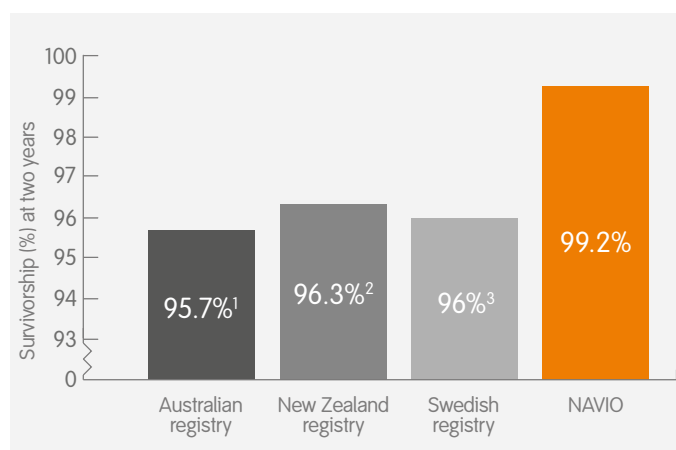

Figure. NAVIO survivorship data compared to annual registry data reporting 2-year conventional UKA survivorship

Conclusion

This is the first study to evaluate the NAVIO UKA revision rate.
NAVIO UKA results in 99.2% implant survivorship, which is higher than that reported for conventional UKA in several annual registries.

Study citation

*Battenberg AK, Netravali NA, Lonner JH. Early survivorship of robotic-assisted unicompartmental knee arthroplasty. Poster presented at: Southern Orthopaedic Association 35th Annual Meeting; July 11-14 2018; Florida, USA.

References
1. Australian Orthopaedic Association National Joint Replacement Registry. Hip and Knee Arthroplasty Annual Report 2015. Available at: https://aoanjrr.sahmri.com/documents/10180/217745/Hip and Knee Arthroplasty.
2. The New Zealand Joint Registry. Fourteen year report January 1999 to December 2012. Available at: nzoa.org.nz/system/files/NJR 14 Year Report.pdf.
3. Swedish Knee Arthroplasty Register. Annual Report 2013. Available at: myknee.se/pdf/SKAR2013_Eng.pdf. 2013.

Evidence in focus

Publication summary
Canetti R, et al. *Arch Orthop Trauma Surg* (2018)*

NAVIO◇ Surgical System enables significantly faster return to sport (RTS) after unicompartmental knee arthroplasty (UKA) than conventional surgery

All patients returned to sport, with the majority (91%) returning to their pre-symptomatic intensity level

Patient outcomes

Study overview

- A retrospective analysis of lateral UKAs in patients with isolated osteoarthritis, performed by a single surgeon between April 2012 and December 2016 with either NAVIO handheld robotics technology or conventional techniques

  – NAVIO: 11 UKAs (mean age, 66.5 years)

  – Conventional surgery: 17 UKAs (mean age, 59.5 years)

  – Mean follow-up of 37.2 months

- RTS and knee function outcomes were compared

Key results

- NAVIO reduced mean time to RTS by 6.3 months compared to conventional surgery (4.2 vs 10.5 months; $p<0.01$; Figure)

- With NAVIO, by end of follow-up all patients returned to sport (100%) and the majority returned to their pre-symptomatic intensity level (91%); respective outcomes were 94% and 82% for conventional surgery

- NAVIO achieved favourable knee function outcomes compared to conventional surgery, as measured by the International Knee Society Score-Objective (IKSS-O):

  – Significantly better postoperative IKSS-O (97.2 vs 91.2; $p<0.05$)

  – Significantly greater IKSS-O improvement after surgery compared to preoperative scores (+30.9 vs +22.8; $p<0.05$)

- Results of the International Knee Society Score-Functional, Lysholm Knee Scale and Forgotten Joint Scale were similar with both procedures
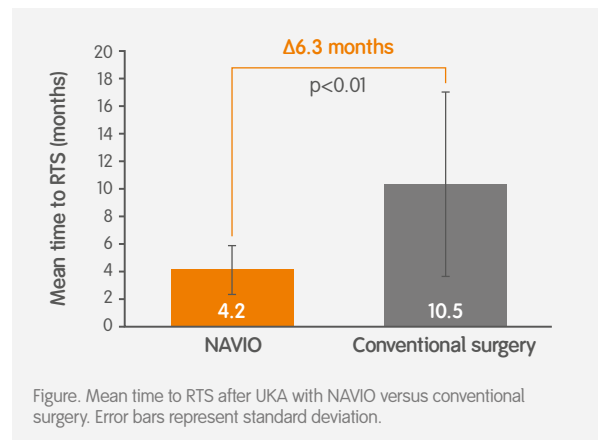
Figure. Mean time to RTS after UKA with NAVIO versus conventional surgery. Error bars represent standard deviation.

Conclusion

Compared to conventional surgery, NAVIO robotics-assisted lateral UKA reduced time to RTS at pre-symptomatic levels. This could be attributed to the less invasive approach with NAVIO, limiting soft tissue damage and enabling faster muscle recovery, or better implant positioning. These results may help surgeons to inform patients in planning their anticipated level of postoperative activity following lateral UKA, especially young, active patients with high expectations.

Study citation

*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(12):1765-1771.

Available at: Archives of Orthopaedic and Trauma Surgery

✚ **Evidence in focus**

Publication summary: Bollars P, et al. *Eur J Orthop Surg Traumatol* (2020)*

Smith+Nephew

Use of NAVIO◊ Surgical System is associated with accurate implementation of the surgical plan and reduced outliers, compared with conventional total knee arthroplasty (TKA)

✚ Plus points

Significant increase in mean MA (p=0.028) with NAVIO TKA (180°) compared to conventional TKA (179.1°)

**Lower rate of MA 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 (p=0.038)

Overview

- A case-controlled, retrospective study comparing the use of NAVIO Surgical System and a matched cohort of conventional TKA, performed between May 2018 and March 2019
  - NAVIO TKA (n=77)
  - Conventional TKA (n=77)

- Planned and achieved mechanical axis (MA) was calculated
  - Outliers were >3° deviations
- Alignment and component positioning were measured using a full-leg, weight-bearing X-ray, taken preoperatively and at week 6 postoperatively

Results

- At 6 weeks post-TKA, compared to conventional TKA, NAVIO TKA resulted in:
  - Lower rate of MA outliers (6 vs 18%; p=0.051; Figure)
  - Significantly reduced rate of outliers in the frontal tibial component (0 vs 8%; p=0.038)
  - Improved postoperative MA (180.1 vs 179.1°; p=0.028)

Lower rate of MA outliers *(p=0.051)*

Figure: Percentage of MA outliers with NAVIO TKA and conventional TKA
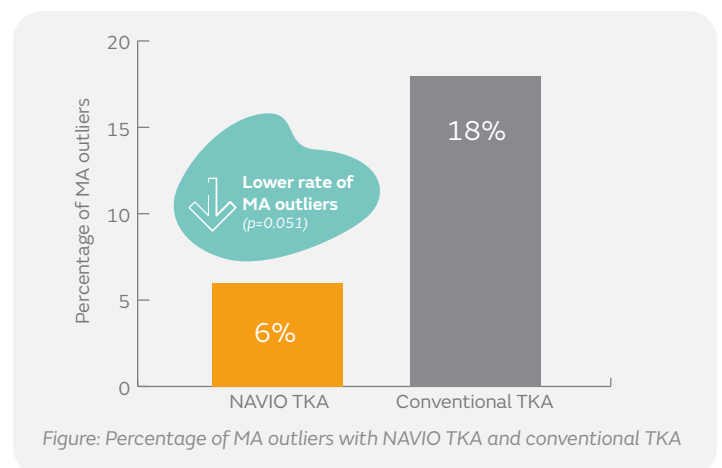
Conclusions

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

Citation

* Bollars P, Boeckxstaens A, Mievis J. et al. Preliminary experience with an image-free handheld robot for total knee arthroplasty: 77 cases compared with a matched control group. *Eur J Orthop Surg Traumatol.* 2020;30:723–729.

Available at: European Journal of Orthopaedic Surgery & Traumatology

Smith+Nephew

Use of NAVIO◊ Surgical System for unicompartmental knee arthroplasty (UKA) resulted in a significantly reduced total revision rate compared with conventional UKA at short-term follow up

+ Plus 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, intraoperative and postoperative 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, 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%)
- At the last follow-up, KSS functional score 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)

64% relative reduction *(p=0.014)*

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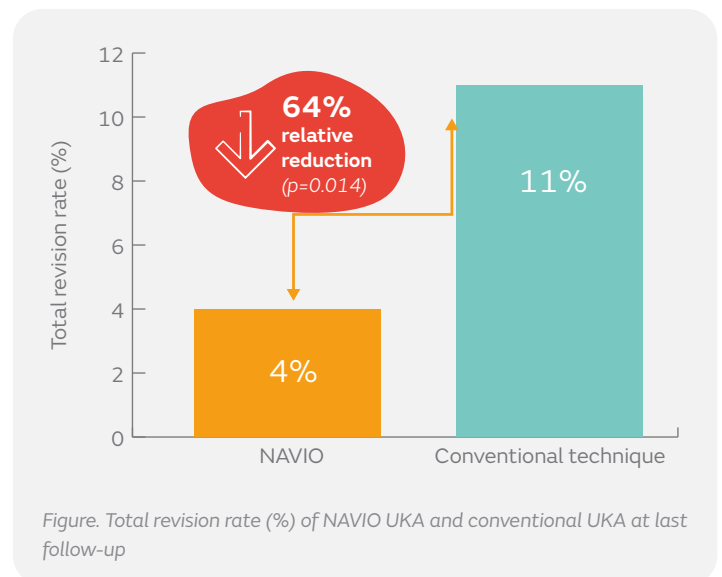
Conclusions

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

Citation

*Mergenthaler G, Batailler C, Lording T, et al. Is robotic-assisted unicompartmental knee arthroplasty a safe procedure? A case control study. *ESSKA*. 2020. [Epub ahead of print]
Available at: European Society of Sports Traumatology, Knee Surgery, Arthroscopy

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Evidence in focus

Publication summary
Batailler C, et al. *Knee Surg Sports Traumatol Arthrosc* (2018)*

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NAVIO◇ robotic-assisted unicompartmental knee arthroplasty (UKA) demonstrated a lower revision rate and improved implant alignment compared to conventional UKA

No revisions occurred due to component malposition or limb malalignment with NAVIO

Accuracy

Study overview

- Retrospective case-control study comparing implant position and revision rate for UKA performed with NAVIO robotic-assisted 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%)
  - Reasons for revision:
    - Change to a thicker polyethylene due to persistent medial pain (1)
    - Tibial plate subsidence (1)
    - Aseptic loosening of the tibial implant (1)
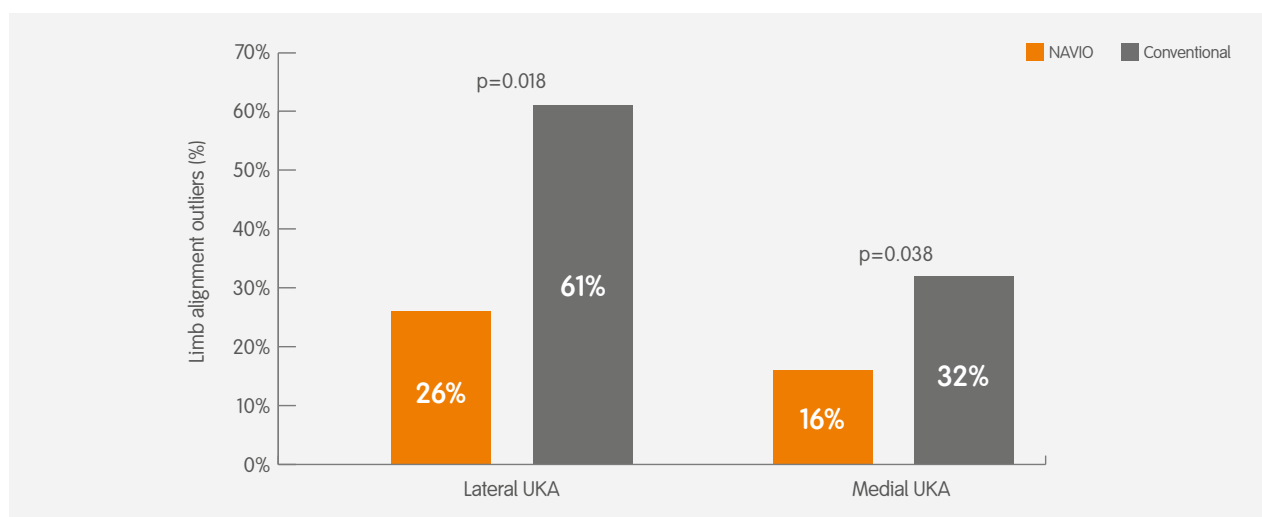   - Unexplained pain, localised to the medial compartment (1)

Figure. Rate of post-UKA limb alignment outliers (±2°) in the NAVIO and conventional groups

Key results (continued)

- Conventional group revision rate: 9% (lateral UKA, 9%; medial UKA, 9%)
  - Reasons for revision:
    - Malposition of the femoral implant (1)
    - Overcorrection (1)
    - Pain and tibial loosening (1)
    - Change to a thicker polyethylene due to persistent pain and hypocorrection (2)
    - Persistent pain without loosening (1)
    - Tibial loosening with varus alignment (1)
- 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 higher 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 (Figure)
- 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 are more common after conventional UKA than NAVIO robotics-assisted UKA.

Considerations

- The HLS Uni evolution, Tornier® implant was used in both groups of this study
- Two revisions with lateral NAVIO robotic-assisted UKA were likely due to the surgeon planning larger than usual tibial resection. The surgical technique and planning for cases with NAVIO at this institution was adapted to a decreased tibial cut following these revisions

Study citation

*Batailler C, White N, Ranaldi FM, Neyret P, Servien E, Lustig S. Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2018 Jul 31. [Epub ahead of print]

Available at: Knee Surgery, Sports Traumatology, Arthroscopy

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NAVIO◇ Surgical System demonstrates high levels of accuracy, fulfilment of patient expectations and safety for both unicompartmental and total knee arthroplasty in data presented at EKS 2019

Key results

- NAVIO total knee arthroplasty (TKA) is associated with a clinically significant reduction in operative time after only a small number of cases[1,2]
- Both NAVIO TKA[2-4] and unicompartmental knee arthroplasty (UKA)[5] are associated with high levels of accuracy
- NAVIO UKA fulfils patient expectations of return to sports,[5] improved function[6,7] and pain relief[7]
- NAVIO UKA and TKA are safe procedures, which are not associated with an increased risk of complications[5,7,8]
- NAVIO UKA patients can be safely discharged within 24 hours of their operation[7]

The EKS Arthroplasty Congress brings together leading experts on knee arthroplasty to discuss the latest advances in knee surgery, taking into consideration the impact of knee technologies on patient outcomes and cost effectiveness. NAVIO Surgical System featured strongly in the programme, with three studies presented on UKA and five on TKA.

Data presented at EKS 2019:

Achieving surgical efficiency with NAVIO

Most new surgical technologies are associated with a learning curve before a surgeon can expect to perform to the same ease as a conventional surgical approach. At EKS, two studies reported on the learning curve associated with NAVIO robotics-assisted TKA. Kaper BP, et al. reported learning curve analysis for a single surgeon who carried out their first 100 NAVIO TKAs, where surgical time was defined as the time from surgical incision to capsular closure.[1] The average surgical time for NAVIO TKA was reported as 68.2 minutes compared to an average surgical time of 51.7 minutes for conventional TKA (n=50). The authors reported that after 40 cases NAVIO only took 10 minutes longer than conventional TKA (18% more time), but after 80 cases NAVIO TKA was time neutral (<5% more time).[1]

"This study demonstrates that implementation of robotic-assisted technology in TKA can achieve a high level of surgical efficiency within an acceptable learning curve" Kaper BP, et al.[1]

Geller JA, et al. reported on the learning curve of 172 NAVIO TKAs conducted by seven surgeons. Intraoperative time included the steps of registration of bony surfaces, the digital reconstruction, intraoperative planning and bone resection.[2] The average intraoperative case time with no previous experience with NAVIO TKA was 58 minutes. The intraoperative case time dropped the most within 12 procedures, with an average time of 49 minutes after 12 procedures, and 39 minutes after that (Figure 1). Both studies show that **surgeons starting out with NAVIO TKA can expect a clinically significant reduction in operative time after only a small number of cases.**[1,2]
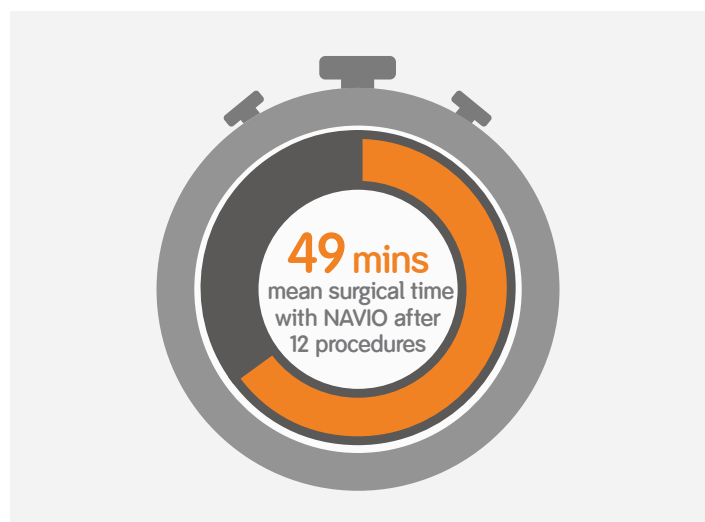

49 mins
mean surgical time with NAVIO after 12 procedures

Figure 1. Mean surgical time after 12 procedures for NAVIO TKA[2]

Improving accuracy with NAVIO◇

A high degree of implant accuracy and soft-tissue balancing is essential for a durable implant with long-term survivorship.[9] Conventionally, the mechanical axis during knee arthroplasty is restored using intra- and extramedullary rods to align components along a universally agreed mechanical axis.[10] This method frequently results in inaccurate placement, patient dissatisfaction and early failure.[10] The accuracy associated with both NAVIO TKA and UKA were presented at EKS.

TKA accuracy

Kaper BP, et al. assessed the accuracy and reliability of the distal burr technique in 50 TKAs performed with NAVIO.[3] Accuracy was reported to be within 0.5°/0.5mm in all three measured planes (coronal-plane varus/valgus angle, sagittal-plane femoral flexion angle and depth of femoral resection), showing NAVIO to facilitate a highly accurate and reproducible procedure for TKA. The results of this study were corroborated by Geller JA, et al. who showed that coronal alignment was within a mean of 0.2° of the planned alignment for the 172 procedures assessed, with only 8.5% of alignment outliers beyond ±3°.[2]

"This study demonstrates a highly accurate, reproducible and efficient surgical technique to prepare the distal femoral surface in RA [robotics-assisted]-TKA" Kaper BP, et al.[3]

In another presentation by Kaper BP, et al. the accuracy and reproducibility of NAVIO TKA to execute soft-tissue balancing was reported.[4] Average deviation from the predicted plan between 0-90° was 0.9mm in both the medial and lateral compartments. In the midflexion arc (15–75°) final soft tissue stability was within 1.0mm of the predicted plan.

UKA accuracy

Significantly higher levels of accuracy with NAVIO UKA compared to conventional UKA were reported at EKS by Batailler C, et al.[5] The authors compared 23 lateral NAVIO UKAs with 23 patients undergoing conventional lateral UKAs. **A significantly lower rate of postoperative limb alignment outliers with NAVIO UKA compared to conventional UKA** (26 vs 61%; p=0.018; Figure 2) was shown.

"The accuracy of implant positioning is improved by this robotic-assisted platform" Batailler C, et al.[5]
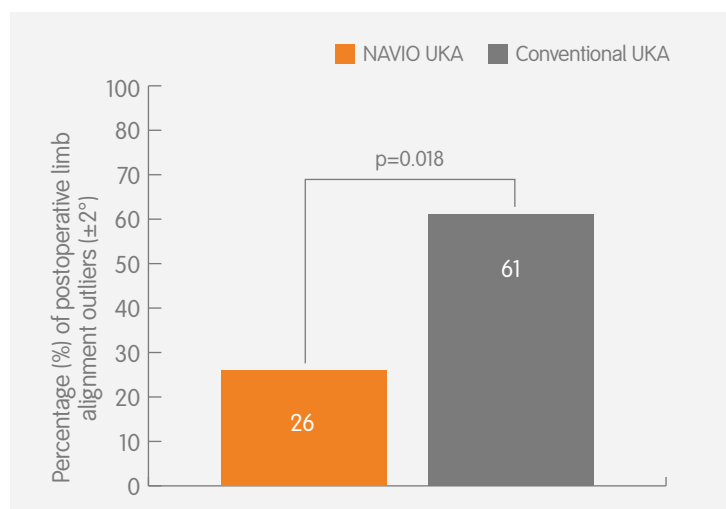

Figure 2. Percentage of postoperative limb alignment outliers (±2°) with NAVIO UKA and conventional UKA[5]

Fulfilling patient expectations with NAVIO

Improving patient satisfaction is not only important for quality of care but is also becoming increasingly important for payers and healthcare providers because of its link to reimbursement and patient loyalty.[11,12] The primary determinant of patient satisfaction is the fulfilment of patient expectations,[13] of which pain relief, improved knee function and return to sports are the most common.[14] Three studies presented at EKS described the fulfilment of patient expectation following NAVIO UKA by showing faster return to sport,[5] improved functional ability[6,7] and reduced pain levels.[7]

NAVIO UKA was reported to result in a significantly faster return to sports, compared to conventional UKA (4.2 vs 10.5 months; p<0.01; Figure 3), with 100% of patients returning to sport.[5]

>50% faster mean time to return to sports

Figure 3. Mean time to return to sports (months) following NAVIO UKA[5]

"Robotic-assisted lateral UKA improve functional and radiological results. They reduce the time to return to sports at pre-symptomatic levels when compared with conventional surgical technique." Batailler C, et al.[5]

Loss of range of motion (ROM) is detrimental to the ability of a patient to perform activities of daily living.[15] Shearman AD, et al. demonstrated a significant increase in ROM at time of discharge in patients who had received NAVIO° UKA compared to patients who received computer-navigated UKA (81.4 vs 64.5°).[6] **Patients also demonstrated improved functional ability with NAVIO UKA compared to computer-navigated UKA, demonstrated by earlier discharge of (at least 1 day) from both physiotherapy** (25 vs 49; p=0.016) **and hospital** (45.5 vs 74hr; p<0.05; Figure 4).[6]

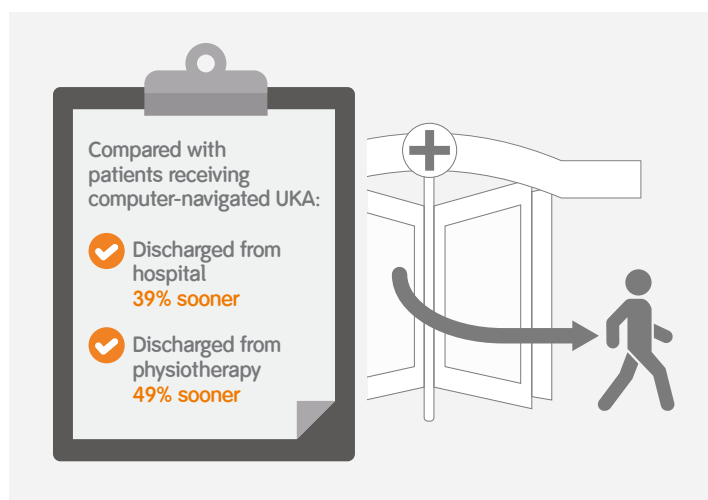Figure 5. Mean OKS pre- and post-NAVIO UKA[7]

Figure 4. Difference in time of hospital and physiotherapy discharge of NAVIO UKA patients compared to computer navigated UKA[6]

The Oxford Knee Score (OKS) is a patient-reported outcome tool designed to specifically assess function and pain following knee arthroplasty.[16] An improvement of just eight points has been shown to be the minimal improvement that the average knee arthroplasty patient finds important at 1 year.[17] The OKS was reported in one study presented at EKS, which showed a mean improvement of more than 18 points at 6 months post-NAVIO UKA compared to pre-UKA (43.5 vs 25.5; n=11; Figure 5), demonstrating a **significant improvement in NAVIO UKA patients' levels of pain and functional ability.**[7]
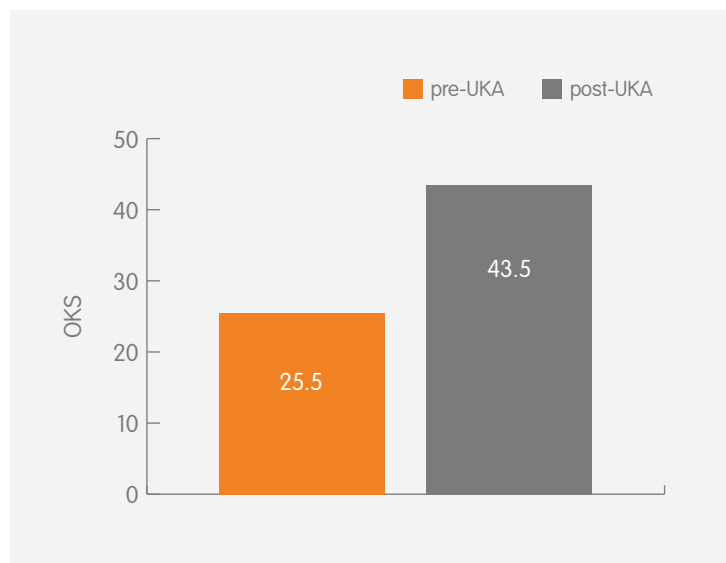
High levels of safety with NAVIO

Despite demonstrating improvements in surgical accuracy and mechanical alignment, concerns have been raised regarding the safety aspect of using robotic-assisted techniques for knee arthroplasty, specifically due to a high reported incidence of soft tissue damage seen with early technology.[18,19]

The safety profile of NAVIO TKA was assessed by Kaper BP, et al. in a study of 200 patients presented at EKS.[8] The authors reported no intraoperative complications, with no complications associated with the introduction of the high-speed burr. Within the 90-day follow-up, one case of deep infection, one periprosthetic femoral fracture due to a fall (remote to the femoral pin tracts), and three manipulations under anaesthesia were recorded. The authors concluded that **NAVIO TKA was not associated with any increased risk in perioperative complications, reoperations or readmission, relative to known TKA risks.**[8]

"Relative to known risks associated with total knee arthroplasty, no increased risk of peri-operative complications, re-operation or re-admission for surgical related complications was identified with the introduction of the NAVIO RA [robotics-assisted]-TKA" Kaper BP, et al.[8]

Safety was considered in a UKA case control study of 23 NAVIO° UKAs and 23 conventional UKAs by Batallier C, et al.[5] The authors reported no revisions for NAVIO UKA, compared to two revisions for malalignment and malposition with conventional TKA (Figure 6) in a case control study of 23 NAVIO UKAs and 23 conventional UKAs.[5] The results were supported by a study presented by Sephton BM, et al. who showed **no postoperative complications and no readmissions to hospital in 11 patients who had been discharged from hospital within 24 hours of their NAVIO UKA.**[7]
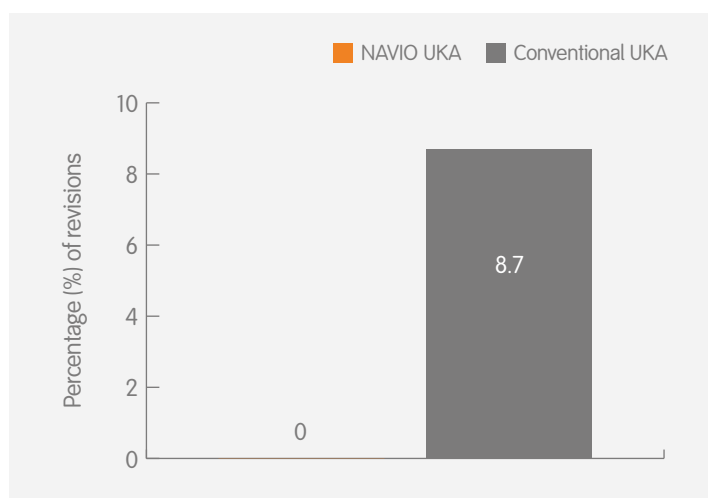

Figure 6. Percentage of revisions post NAVIO UKA and conventional UKA at a mean follow up of 22.7 and 25.4 months, respectively[5]

Conclusion

New evidence presented at EKS 2019 shows NAVIO robotics-assisted knee arthroplasty is highly accurate and can be time neutral compared with conventional techniques after use in a small number of cases.[1,2] NAVIO UKA may increase patient satisfaction by fulfilling patient expectations of returning to sport,[5] reduced pain[7] and increased functional ability[6,7] compared to pre-UKA. In addition, NAVIO TKA and UKA are safe procedures, demonstrating no increase in risk of revision compared to conventional techniques[5,7,8] and NAVIO UKA patients can be safely discharged within 24 hours of the procedure.[7]

References

1. Kaper BP, Villa A. Learning curve and time commitment assessment in the adoption of NAVIO robotic-assisted total knee arthroplasty. Abstract number O32 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
2. Geller JA, Rossington A, Mitra R, Jaramaz B, Khare R, Netravali NA. Rate of learning curve and alignment accuracy of an image-free handheld robot for total knee arthroplasty. Abstract number O44 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
3. Kaper BP, Villa A. Accuracy and precision of a handheld robotic-guided distal femoral osteotomy in robotic-assisted total knee arthroplasty. Abstract number P46 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
4. Kaper BP. Measurement of full arc range of motion soft tissue balance in robotic-assisted total knee arthroplasty. Abstract number SP2 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
5. Batailler C, Derouche E, Canetti R, Neyret P, Servien E, Lustig S. Functional and radiologic improvement after robotic-assisted lateral UKA: a comparative study. Abstract number O70 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
6. Shearman A.D., Sephton B., Nathwani D.K. Robotic-assisted unicondylar knee arthroplasty is associated with earlier discharge from physiotherapy and reduced length of stay compared to conventional navigated techniques. Abstract number O71 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
7. Sephton BM. Shearman A, Nathwani D. 24 hour discharge in unicompartmental knee replacement using the NAVIO robotic system: a retrospective analysis. Abstract number O40 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
8. Kaper BP, Villa A. Initial safety profile of the NAVIO robotic-assisted total knee arthroplasty. Abstract number P45 presented at: European Knee Society; May 2-3, 2019; Valencia, Spain.
9. Lonner JH. Robotically assisted unicompartmental knee arthroplasty with a handheld image-free sculpting tool. *Orthop Clin North Am.* 2016;47:29-40.
10. Pastides P, Nathwani D. The role of newer technologies in knee arthroplasty. *Orthop Trauma.* 2017;31:47-52.
11. Lyu H, Wick E, Housman M, Freischlag J, Makary M. Patient satisfaction as a possible indicator of quality surgical care. *JAMA Surg.* 2013;148:361–367.
12. Otani K, Waterman B, Faulkner K, Boslaugh S, Burroughs T, Dunagan W. Patient satisfaction: focusing on "excellent". *J Healthc Manag.* 2009;54:93–102.
13. Noble PC, Gordon MJ, Weiss JM, Reddix RN, Conditt MA, Mathis KB. Does total knee replacement restore normal knee function? *Clin Orthop Relat Res.* 2005;431:157–165.
14. Husain A, Lee GC. Establishing realistic patient expectations following total knee arthroplasty. *J Am Acad Orthop Surg.* 2015;23:707-713.
15. Matsuda S, Kawahara S, Okazaki K, Tashiro Y, Iwamoto Y. Postoperative alignment and ROM affect patient satisfaction after TKA. *Clin Orthop Relat Res.* 2013;471:127-33.
16. Dawson J, Fitzpatrick R, Murray D, Carr A. Questionnaire on the perceptions of patients about total knee replacement. *J Bone Joint Surg Br.* 1998;80:63–69.
17. Ingelsrud LH, Roos EM, Terluin B, Gromov K, Husted H, Troelsen A. Minimal important change values for the Oxford Knee Score and the Forgotten Joint Score at 1 year after total knee replacement. *Acta Orthop.* 2018;89:541-547.
18. Chun YS, Kim KI, Cho YJ, Kim YH, Yoo MC, Rhyu KH. Causes and patterns of aborting a robot-assisted arthroplasty. *J Arthroplasty.* 2011;26:621-625.
19. Park SE, Lee CT. Comparison of robotic-assisted and conventional manual implantation of a primary total knee arthroplasty. *J Arthroplasty.* 2007;22:1054-1059.
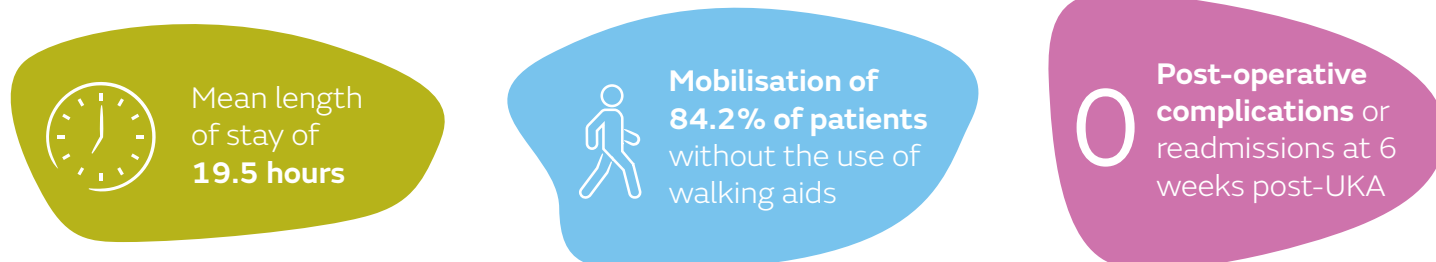
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NAVIO◊ Surgical System unicompartmental knee arthroplasty (UKA) patients may be safely discharged within 24 hours with appropriate patient selection and education

+ Plus points

NAVIO UKA patients safely discharged within 24 hours (n=19 of 71) demonstrated:

Mean length of stay of **19.5 hours**

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

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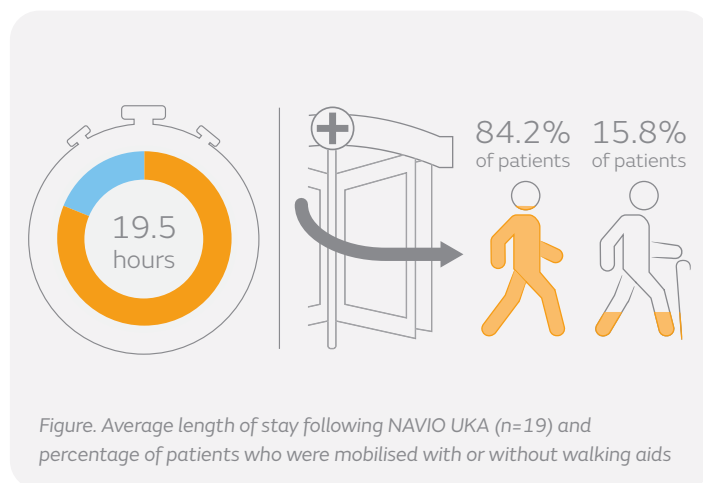
Overview

- 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: 64-132mins)

- 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 with an average of two physiotherapy sessions
  - 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)

19.5 hours

84.2% of patients   15.8% of patients

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. Reduced length of stay is associated with reduced peri-operative complications, improved clinical outcomes and potential cost savings for health care providers.

Citation

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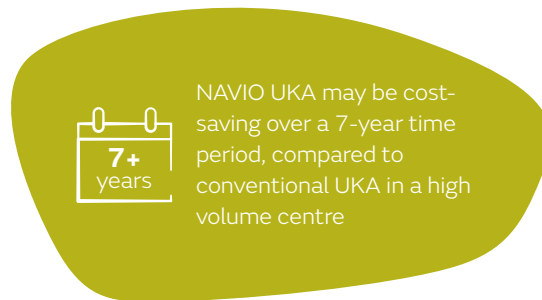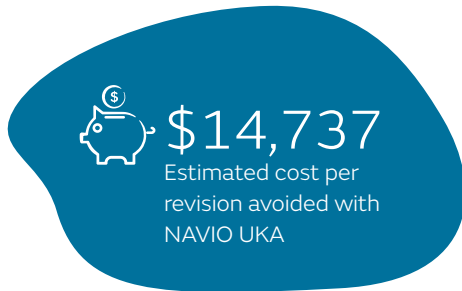Available at: Journal of Orthopaedics

✚ Evidence in focus

Publication summary: Yeroushalmi D, et al. *J Knee Surg* (2020)*

Smith+Nephew

NAVIO◊ Surgical System unicompartmental knee arthroplasty (UKA) may be more cost-effective than conventional UKA over a 5-year time period

✚ Plus points

$14,737
Estimated cost per revision avoided with NAVIO UKA

7+ years
NAVIO UKA may be cost-saving over a 7-year time period, compared to conventional UKA in a high volume centre
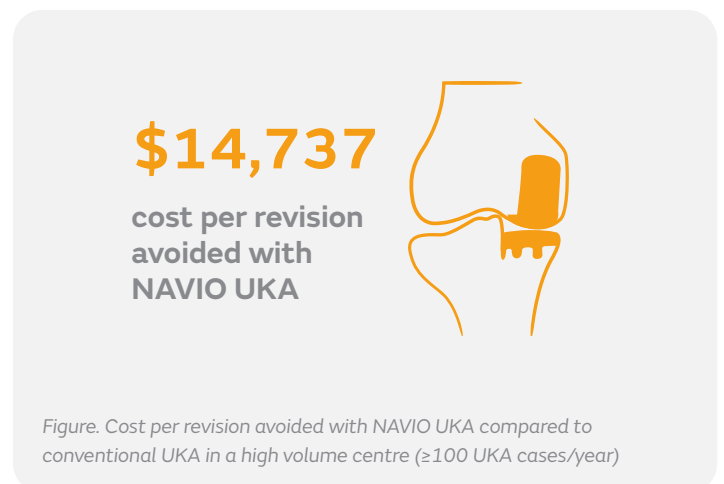
Overview

- A Markov model was used to evaluate the cost-effectiveness of NAVIO UKA compared to conventional UKA in the US over a 5-year time period

- The model assumed a high volume centre conducting 100 UKA cases/year and a cohort mean age of 65 years

- Five year revision rate for conventional UKA was taken from the 2018 National Joint Registry for England, Wales, Northern Ireland and the Isle of Man

- Revision rate for NAVIO UKA was obtained from a retrospective cohort study (n=128) with a follow up of 2.3 years

- Sensitivity analyses were conducted to assess the impact of various model assumptions, such as patient age, case load and time period

Results

- NAVIO UKA resulted in an estimated additional cost of $173,890 (2018 US dollars), but resulted in 12 fewer revisions per every 100 cases

- The estimated cost per revision avoided with NAVIO UKA was $14,737 (Figure)

- 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

- For follow up beyond 7 years, NAVIO UKA becomes cost-saving ie, results in cheaper overall total costs and better clinical outcomes (based on assumptions)

- Model results are sensitive to assumptions around the case load, where low volume centres may not be as cost-effective

$14,737

cost per revision avoided with NAVIO UKA

Figure. Cost per revision avoided with NAVIO UKA compared to conventional UKA in a high volume centre (≥100 UKA cases/year)

Conclusions

NAVIO UKA was shown 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. Younger patients benefit more compared to older age groups and the model is sensitive to case volumes.

Citation

*Yeroushalmi D, Feng J, Nherera L, Trueman P, Schwarzkopf R. Early economic analysis of robotic-assisted unicondylar knee arthroplasty may be cost effective in patients with end-stage osteoarthritis. *J Knee Surg*. 2020; DOI: 10.1055/s-0040-1712088
Available at: Journal of Knee Surgery