Evidence in focus
Compendium of evidence

Summary of the current preclinical and clinical evidence on NAVIO

February 2019
# NAVIO Surgical System

## Purpose
To summarise the current preclinical and clinical evidence on NAVIO (Smith & Nephew Memphis, TN, USA).

### 22 studies reporting on NAVIO

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## Compendium of evidence in focus

**NAVIO Surgical System**

### Purpose

To summarise the current preclinical and clinical evidence on NAVIO (Smith & Nephew Memphis, TN, USA).

### Studies

<table>
<thead>
<tr>
<th>Author/year</th>
<th>Study title</th>
<th>Study outcomes</th>
<th>Study type</th>
<th>Page number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Why robotics? Conventional techniques versus robotics</td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>NAVIO Surgical System design</td>
<td></td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>Batailler C, et al. 2018</td>
<td>Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty</td>
<td></td>
<td></td>
<td>5</td>
</tr>
<tr>
<td>Battenberg A, et al. 2018</td>
<td>Early survivorship of robotic-assisted unicompartmental knee arthroplasty</td>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>Canetti R, et al. 2018</td>
<td>Faster return to sport after robotic-assisted lateral unicompartmental knee arthroplasty: a comparative study</td>
<td></td>
<td></td>
<td>7</td>
</tr>
<tr>
<td>Casper M, et al. 2018</td>
<td>Accuracy assessment of a novel image-free handheld robot for total knee arthroplasty in a cadaveric study</td>
<td></td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>Gregori A, et al. 2013</td>
<td>Case study: totals aren’t always an inevitability</td>
<td></td>
<td></td>
<td>8</td>
</tr>
<tr>
<td>Gregori A, et al. 2015</td>
<td>Accuracy of imageless robotically assisted unicompartmental knee arthroplasty</td>
<td></td>
<td></td>
<td>10</td>
</tr>
<tr>
<td>Gonzalez D, et al. 2014</td>
<td>Preliminary results of UKR implanted using an image free handheld robotic device</td>
<td></td>
<td></td>
<td>10</td>
</tr>
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<tr>
<td>Herry Y, et al. 2017</td>
<td>Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique</td>
<td></td>
<td></td>
<td>11</td>
</tr>
<tr>
<td>Jamaraz B &amp; Nikou C. 2012</td>
<td>Precision freehand sculpting for unicondylar knee replacement: design and experimental validation</td>
<td></td>
<td></td>
<td>12</td>
</tr>
<tr>
<td>Jamaraz B, et al. 2015</td>
<td>Accuracy validation of semi-active robotic application for patellofemoral arthroplasty</td>
<td></td>
<td></td>
<td>13</td>
</tr>
<tr>
<td>Khare R, et al. 2018</td>
<td>Implant orientation accuracy of a hand-held robotic partial knee replacement system over conventional technique in a cadaveric test</td>
<td></td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Lonner JH, et al. 2015</td>
<td>High degree of accuracy of a novel image-free handheld robot for unicondylar knee arthroplasty in a cadaveric study</td>
<td></td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Shah S, et al. 2018</td>
<td>Robotic assisted revision total knee replacement - early experience</td>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Simons M &amp; Riches P. 2014</td>
<td>The learning curve of robotically-assisted unicondylar knee arthroplasty</td>
<td></td>
<td></td>
<td>15</td>
</tr>
<tr>
<td>Smith JR, et al. 2013</td>
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<td></td>
<td></td>
<td>16</td>
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<td></td>
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<td></td>
<td></td>
<td>17</td>
</tr>
</tbody>
</table>

References 18

Abbreviations
UKA: unicondylar knee arthroplasty
KOOS: knee injury and osteoarthritis score
OKS: Oxford knee score
TKA: total knee arthroplasty
RMS: Root mean square
UKR: unicompartmental knee replacement
### Why robotics?

#### Conventional techniques versus robotics

<table>
<thead>
<tr>
<th>Conventional</th>
<th>Robotics</th>
</tr>
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<tbody>
<tr>
<td>Manual instruments include alignment rods that are intra- or extra-medullary that centralise and align the components according to the surgical plan.</td>
<td>Robotic systems include passive, semi-active, and active systems with a robotic arm, robotic guided cutting jigs, and robotic milling systems.</td>
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<tr>
<td>Conventional alignment guides:</td>
<td>For total and partial knee replacement, robotic systems may:</td>
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<tr>
<td>• Lack precision</td>
<td>• Help surgeons avoid surgical errors</td>
</tr>
<tr>
<td>• Are not tailored to each patient’s individual morphology</td>
<td>• Decrease variability</td>
</tr>
<tr>
<td>• Can result in inadvertent deviations from the surgical plan</td>
<td>• Increase accuracy in mechanical alignment for more natural kinematics</td>
</tr>
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</table>

“*The current literature demonstrates that using computer navigation for UKA [compared to conventional techniques] results in better limb alignment and component positioning*”

### NAVIO° Surgical System design

**NAVIO is an image-free, freehand sculpting semi-active robotic tool, that allows for intraoperative patient-specific planning**

The NAVIO system has two types of robotic control modes, Exposure Control and Speed Control. The surgeon can alternate between these two cutting control modes.

<table>
<thead>
<tr>
<th>Exposure Control</th>
<th>Speed Control</th>
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</thead>
<tbody>
<tr>
<td>Exposure Control adjusts the bur’s exposure with respect to a guard. If the surgeon encroaches on a portion of bone that is not to be cut, the NAVIO Surgical System retracts the spinning bur behind the guard, disabling cutting. The NAVIO Surgical System software adjusts the depth of the cut by adjusting the exposure of the bur outside of the guard.</td>
<td>Speed Control regulates the speed of the bur, from 0 to 80,000 rpm, depending on its position. The control mode limits the speed of the spinning bur or disables bur motion entirely if the target surface has been reached. Bur motion is also disabled if the bur is moved outside of planned cutting boundaries.</td>
</tr>
<tr>
<td>During Exposure Control, the bur spins at full power (80,000 rpm), regardless of exposure level.</td>
<td></td>
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</table>

*The NAVIO handpiece accurately removes bone identified by the surgeon approved, patient-specific plan*
Study 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%)
  – 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)

• 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 robotics-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 were adapted to a decreased tibial cut following these revisions
Study overview

- Retrospective study to assess revision rates of patients who received UKA with NAVIO Surgical System
- 128 UKA patients 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% (Figure)
  - Greater than that reported in the Australian, New Zealand and Swedish registry
- One revision with NAVIO
  - Due to hamstring irritation and ischial tuberosity bursitis in 60 year old male

Conclusion

High early implant survivorship rate for the NAVIO system that is higher than that presented in the literature for annual registries.
Faster return to sport after robotic-assisted lateral unicompartmental knee arthroplasty: a comparative study


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
- Return to sport (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

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.
Accuracy assessment of a novel image-free handheld robot for total knee arthroplasty in a cadaveric study


**Study 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

<table>
<thead>
<tr>
<th>Error type</th>
<th>Total error</th>
<th>Tibial</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion/posterior slope</td>
<td>-2±2.2°</td>
<td>-0.2±1.3°</td>
</tr>
<tr>
<td>Varus/valgus</td>
<td>-0.1±0.9°</td>
<td>-0.2±0.9°</td>
</tr>
<tr>
<td>Rotation</td>
<td>-0.5±1.2°</td>
<td>NR</td>
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</tbody>
</table>

**Conclusion**
NAVIO provides accurate implementation of the surgical plan with small errors in implant placement.

Case study: totals aren’t always an inevitability


**Study 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 intraoperatively 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 allows surgeons to confidently approach a challenging surgery with the knowledge that they can execute a predetermined plan accurately to get the best outcome for the patient.
Case study: first in man: using the NAVIO° surgical system to implant a JOURNEY° UNI knee¹²

Study 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

Handheld precision sculpting tool for unicondylar knee arthroplasty. A clinical review¹³

Study overview

• Clinical review
• 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 (Figure)
• 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 allows surgeons to repeatedly precisely plan and execute highly accurate mechanical axis alignment. The learning curve of NAVIO is short, with mean NAVIO time reduced by 15 minutes after ten cases.
Accuracy of imageless robotically assisted unicompartmental knee arthroplasty


**Study 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 (Figure)
- RMS error 1.98°
- RMS error between plan and post-UKA radiographic implant position:
  - Femoral tibial alignment: 2.6°
  - Tibial coronal alignment: 2.9°
  - Tibial slope: 2.9°

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

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


**Study overview**
- A single surgeon performed UKR on 18 patients with NAVIO Surgical System (2012 to 2013)

**Key results**
- OKS (old) improved from 38 pre-UKA to 23 six weeks post-UKA (22 to 37 new OKS*, respectively; Figure)

*To convert from the old OKS to the new OKS, the old OKS score is subtracted from 60

**Conclusion**
Preliminary analysis shows satisfactory post-UKR outcome for UKR with NAVIO.
Study overview

- Single-surgeon retrospective, case-controlled study comparing joint-line height following UKA using NAVIO™ robotics-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](image_url)

Conclusion

NAVIO robotics-assisted UKA allows for intraoperative planning of implant position and highly 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 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

Key results

- Total cutting time: 6.5 to 9.5 minutes
- Mean cut time: 8.01 minutes
- Average distance from the planned implant position was 0.54mm
- Average total error: 0.54mm/1.08° (Figure 1)

Conclusion

NAVIO achieves high levels of accuracy, adequate for joint replacement surgery, with low levels of error.

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**NAVIO PFS for unicondylar knee replacement: early cadaver validation**


Study overview

- Three operators performed medial UKR 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

<table>
<thead>
<tr>
<th>Error type</th>
<th>Mean total error</th>
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<tbody>
<tr>
<td>Maximum translation error</td>
<td>1.31mm</td>
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<tr>
<td>Maximum rotational error (femoral)</td>
<td>1.90°</td>
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<tr>
<td>Maximum rotational error (tibial)</td>
<td>3.26°</td>
</tr>
<tr>
<td>RMS error over all components</td>
<td>0.69mm/1.23°</td>
</tr>
</tbody>
</table>

Conclusion

Use of NAVIO shows high levels of accuracy comparable to other robotics-assisted devices.
Accuracy validation of semi-active robotic application for patellofemoral arthroplasty

Study 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 establish a reference frame to determine the accuracy of prosthesis placement
- Final implant position and planned position were compared

Key results

<table>
<thead>
<tr>
<th>Error type</th>
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<tbody>
<tr>
<td>Maximum RMS error</td>
<td>0.87mm</td>
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<tr>
<td>Maximum rotational error</td>
<td>1.2°</td>
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</tbody>
</table>

Conclusion
The high levels of accuracy demonstrated by NAVIO 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.

Accuracy assessment of a novel image-free handheld robot for knee arthroplasty in bi-cruciate retaining total knee replacement

Study overview
- The study compared the planned and final implant placement using the JOURNEY™ II XR bi-cruciate retaining knee implant with NAVIO Surgical System
- TKA was performed on 24 cadaveric femurs, eight synthetic femurs, two cadaveric tibias, 10 synthetic tibias
- Final implant position was measured and compared to the surgical plan using a separate position tracking camera and analysis software
- A quantitative analysis was performed to determine the translational, angular, and rotational differences between the planned and achieved positions of the implant

Key results

<table>
<thead>
<tr>
<th>Error type</th>
<th>Mean RMS error</th>
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<tbody>
<tr>
<td>Varus/valgus</td>
<td>0.7°</td>
</tr>
<tr>
<td>Rotation (femoral/posterior slope tibial)</td>
<td>0.7°</td>
</tr>
<tr>
<td>Distal resection</td>
<td>0.86mm</td>
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<td>Tibial implant</td>
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<td>0.7°</td>
</tr>
<tr>
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<td>Distal resection</td>
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</table>

Conclusion
NAVIO allows for high levels of accuracy in the implementation of the planned procedure for JOURNEY™ II XR placement.
Study 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

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

Conclusion

NAVIO provides improved implant alignment accuracy over conventional approaches to UKA.

High degree of accuracy of a novel image-free handheld robot for unicompartmental knee arthroplasty in a cadaveric study


Study overview

- Four individuals 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 (Figure 1 and 2)

Conclusion

NAVIO provides accurate implementation of the surgical plan, with low levels of error, and is comparable to other semi-autonomous robotic orthopaedic devices.
Study overview

- Single-centre prospective study recruiting patients for revision TKA with NAVIO Surgical System (Aug 2017 to Jan 2018)
  - Ten patients were included (females, 6; males, 4; mean age, 67.5 years)
- Preoperative and postoperative 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 (Figure) and KSS and leg alignment compared to preoperative values
- No mechanical axis outliers

Conclusion

NAVIO is safe and capable of producing consistent coronal mechanical alignment in revision TKA.

The learning curve of robotically-assisted unicompartmental knee arthroplasty


Study 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
- 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 (Figure)
- Translational and rotational accuracy of the implants did not significantly vary with surgery number
- Adequate accuracy was achieved from the first surgery

Conclusion

NAVIO achieves high levels of accuracy from the first procedure, with up to 44% reduction in time after five procedures.
**Accuracy of a freehand sculpting tool for unicondylar knee replacement**


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**Study overview**

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

**Key results**

- Fiducial marker analysis:
  - Minimal movement of the arrays
- Mean cut surface data:
  - Slight undercut of 0.14mm for femur and 0.21mm for tibia
- All implant positions compared favourably to the plan and were within the expected target zone with low errors in rotational and translational placement (Figure 1 and 2)

**Conclusion**

NAVIO implant positions are accurate to plan, with low levels of error in rotational and translational placement.

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


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**Study 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**

<table>
<thead>
<tr>
<th>Error type</th>
<th>Mean total error</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximum implant rotational error</td>
<td>3.7°</td>
</tr>
<tr>
<td>Maximum implant translational error</td>
<td>2.6mm</td>
</tr>
<tr>
<td>Maximum RMS angular error</td>
<td>2.0°</td>
</tr>
<tr>
<td>RMS translational error across all directions</td>
<td>1.1mm</td>
</tr>
</tbody>
</table>

**Conclusion**

NAVIO offers optimal positioning and sizing of implants, and the freehand sculpting tool produces high levels of accuracy in implant placement with low levels of error.
Robotic-assisted unicompartmental knee replacement with NAVIO® surgical system: Outcome evaluation using knee injury osteoarthritis outcome score


Study 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 5, 2013 to February 30, 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; Figure)
  - Symptoms: 33.11 to 70.79 (p<0.001)
  - Pain: 35.30 to 71.62 (p<0.001)
  - Daily activities: 28.51 to 63.62 (p<0.001)
  - Quality of life: 31.15 to 72.98 (p<0.001)

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.

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


Study 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 was 56.8 minutes
- Average improvement from slowest to quickest surgical time was 46 minutes
- Average of eight procedures to steady state
- Average steady state surgical time was 50 minutes (Figure)

Conclusion

NAVIO has a comparable learning curve to other robotics-assisted devices on the market.
References


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