

## NAVIO<sup>®</sup> 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<sup>1,2</sup>
- Both NAVIO TKA<sup>2-4</sup> and unicompartmental knee arthroplasty (UKA)<sup>5</sup> are associated with high levels of accuracy
- NAVIO UKA fulfils patient expectations of return to sports,<sup>5</sup> improved function<sup>6,7</sup> and pain relief<sup>7</sup>
- NAVIO UKA and TKA are safe procedures, which are not associated with an increased risk of complications<sup>5,7,8</sup>
- NAVIO UKA patients can be safely discharged within 24 hours of their operation<sup>7</sup>

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.<sup>1</sup> 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).<sup>1</sup>

**“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.<sup>1</sup>

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.<sup>2</sup> 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.**<sup>1,2</sup>

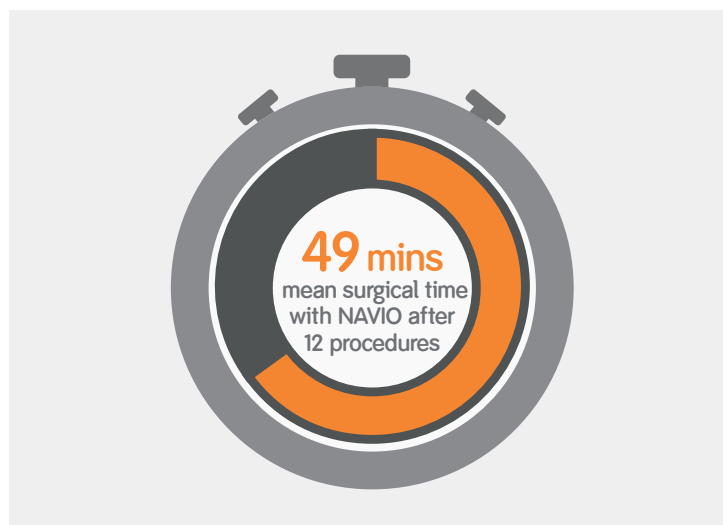


Figure 1. Mean surgical time after 12 procedures for NAVIO TKA<sup>2</sup>

## Evidence in focus (continued)

### Improving accuracy with NAVIO<sup>◇</sup>

A high degree of implant accuracy and soft-tissue balancing is essential for a durable implant with long-term survivorship.<sup>9</sup> Conventionally, the mechanical axis during knee arthroplasty is restored using intra- and extramedullary rods to align components along a universally agreed mechanical axis.<sup>10</sup> This method frequently results in inaccurate placement, patient dissatisfaction and early failure.<sup>10</sup> 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.<sup>3</sup> 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°.<sup>2</sup>

**“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.<sup>3</sup>

In another presentation by Kaper BP, et al. the accuracy and reproducibility of NAVIO TKA to execute soft-tissue balancing was reported.<sup>4</sup> 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.<sup>5</sup> 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.<sup>5</sup>

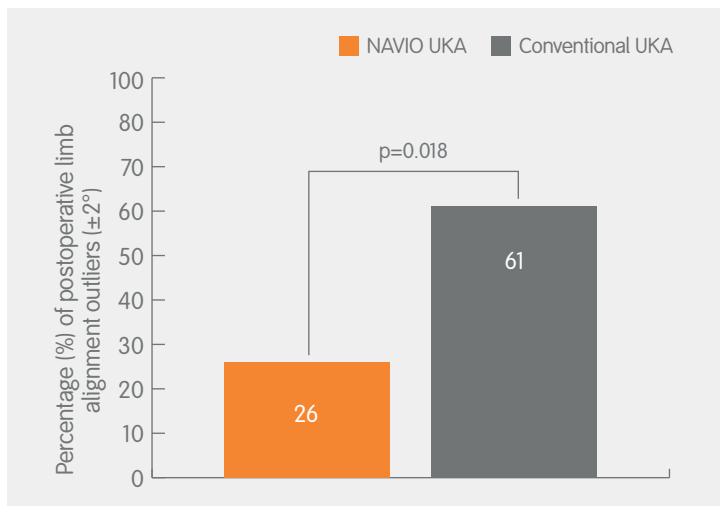


Figure 2. Percentage of postoperative limb alignment outliers (±2°) with NAVIO UKA and conventional UKA<sup>5</sup>

### 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.<sup>11,12</sup> The primary determinant of patient satisfaction is the fulfilment of patient expectations,<sup>13</sup> of which pain relief, improved knee function and return to sports are the most common.<sup>14</sup> Three studies presented at EKS described the fulfilment of patient expectation following NAVIO UKA by showing faster return to sport,<sup>5</sup> improved functional ability<sup>6,7</sup> and reduced pain levels.<sup>7</sup>

**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.<sup>5</sup>



Figure 3. Mean time to return to sports (months) following NAVIO UKA<sup>5</sup>

## Evidence in focus (continued)

“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.<sup>5</sup>

Loss of range of motion (ROM) is detrimental to the ability of a patient to perform activities of daily living.<sup>15</sup> 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°).<sup>6</sup> **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).**<sup>6</sup>

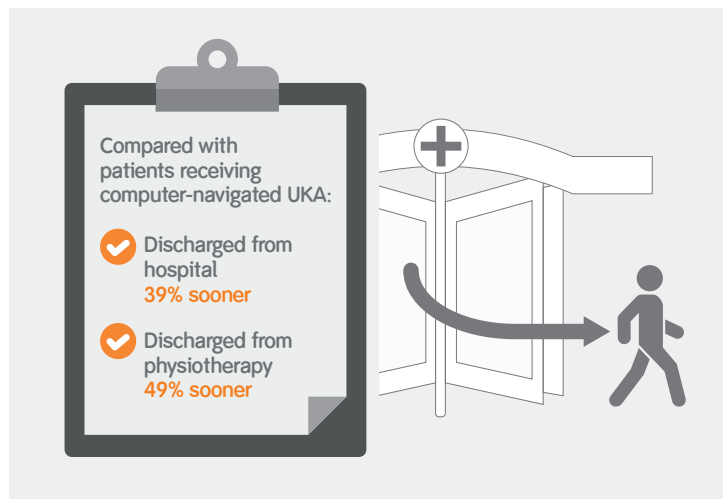


Figure 4. Difference in time of hospital and physiotherapy discharge of NAVIO UKA patients compared to computer navigated UKA<sup>6</sup>

The Oxford Knee Score (OKS) is a patient-reported outcome tool designed to specifically assess function and pain following knee arthroplasty.<sup>16</sup> 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.<sup>17</sup> 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.**<sup>7</sup>

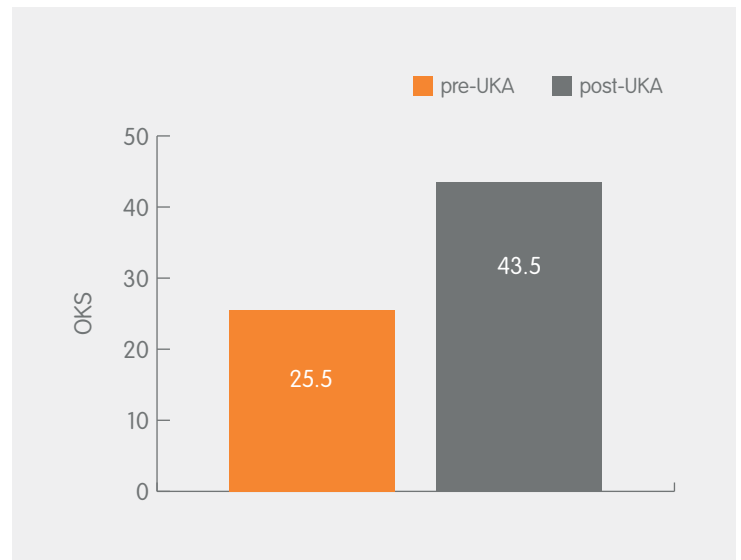


Figure 5. Mean OKS pre- and post-NAVIO UKA<sup>7</sup>

### 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.<sup>18,19</sup>

The safety profile of NAVIO TKA was assessed by Kaper BP, et al. in a study of 200 patients presented at EKS.<sup>8</sup> 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.**<sup>8</sup>

“Relative to known risks associated with total knee arthroplasty, no increased risk of perioperative 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.<sup>8</sup>

## Evidence in focus (continued)

Safety was considered in a UKA case control study of 23 NAVIO<sup>®</sup> UKAs and 23 conventional UKAs by Batallier C, et al.<sup>5</sup> 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.<sup>5</sup> 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.**<sup>7</sup>

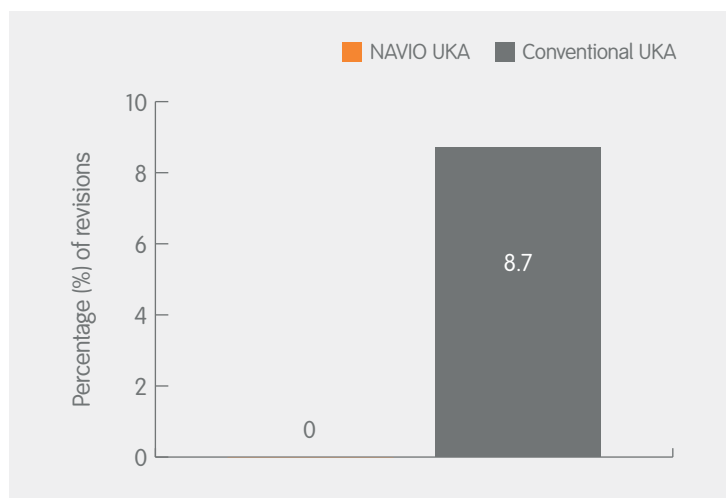


Figure 6. Percentage of revisions post NAVIO UKA and conventional UKA at a mean follow up of 22.7 and 25.4 months, respectively<sup>5</sup>

## 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.<sup>1,2</sup> NAVIO UKA may increase patient satisfaction by fulfilling patient expectations of returning to sport,<sup>5</sup> reduced pain<sup>7</sup> and increased functional ability<sup>6,7</sup> compared to pre-UKA. In addition, NAVIO TKA and UKA are safe procedures, demonstrating no increase in risk of revision compared to conventional techniques<sup>5,7,8</sup> and NAVIO UKA patients can be safely discharged within 24 hours of the procedure.<sup>7</sup>

## 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. Batallier 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 unicompartmental 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, Condit 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.