Robotic Surgery: What is it and how does it make a difference in Knee Replacement?

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Supporting healthcare professionals for over 150 years smith&nephew

Goals!

- Eliminate pain
- Replicate normal knee function
  - Preservation of natural ligaments
- Correct deformity

https://www.theindianwire.com/sports/sunil-chhetris-goal-helps-india-win-kyrgyzstan-13144/

Knee Replacement

- Progressive disease -> Progressive Treatment

Partial → Total

Partial Knee Arthroplasty

Current Challenges

- High patient satisfaction[1]
- Low survivorship[2]
  - Pathology/disease progression[3]
  - Patient selection[3]
  - Implant selection[3]
  - Accuracy of implantation[3,4]
- Low Adoption
  - Difficulty of instrumentation

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1. Von Keudell A, et al, Patient satisfaction after primary total and unicompartmental knee arthroplasty: An age-dependent analysis, Knee (2013)
2. Niinimaki T, et al, Unicompartmental knee arthroplasty survivorship is lower than TKA survivorship: a 27-year Finnish registry study. Clin Orthop Relat Res. 2014 May;472(5):1496-501. doi: 10.1007/s11999-013-3347-2. Epub 2013 Nov 19.
3. Collier, Matthew, et al., "Patient, Implant, and Alignment Factors Associated With Revision of Medial Compartment Unicondylar Arthroplasty.", Jour of Arthro, Vol 21 No 6, Suppl. 2, 2006.
4. Hernigou, Ph, Deschamps, G., "Alignment Influences Wear in the Knee After Medial Unicompartmental Arthroplasty.", Clin Orthop Relat Res., Volume 423, June 2004, pp 161-165.
5. G. Deschamps, C. Chol, "Fixed-bearing unicompartmental knee arthroplasty. Patientsâ€™ selection and operative technique", Orthopaedics & Traumatology: Surgery & Research, Volume 97, Issue 6, 2011, Pages 648-661

Total Knee Arthroplasty

Current Challenges

- ***Almost 25% of TKA patients dissatisfied***

Patient satisfaction after TKA: who is satisfied and who is not? Bourne RB, et al. Clin Orthop 2010;468:57

- ***94.5% of surgeons versus 90.3% of patients satisfied 1 year after TJA***

Discordance between patient and surgeon satisfaction after TJA. Harris IA, et al. J Arthroplasty 2013;28(5):722

- ***Only 82% to 89% of primary TKA patients are satisfied***

J Bone Joint Surg Br. 2010 Sep;92(9): Scott CE, Howie CR, MacDonald D, Biant LC

Clin Orthop Relat Res. 2010 Jan;468(1):57-63: Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron

Factors of Success:

- Component design
- Optimal pain protocol and rehab
- Accuracy of implantation
- Soft Tissue Balancing

Why Robotics in Knee Replacement?

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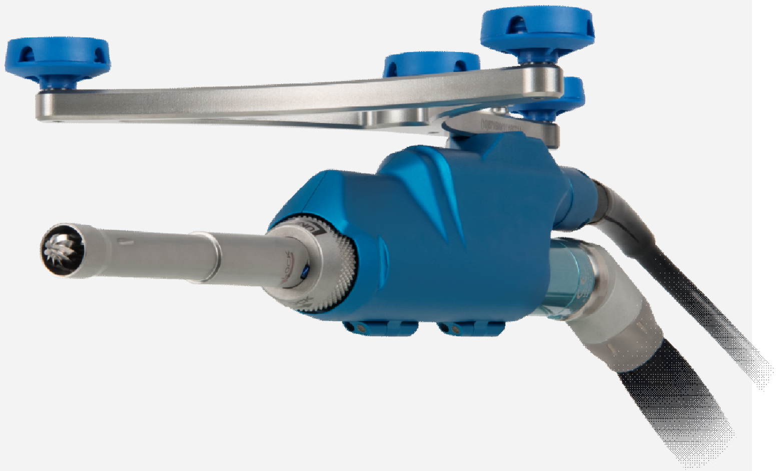
- Survey....



Why Robotics in Knee Replacement?

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- Make Bad Surgeons Good
  - Accuracy in implantation
  - Eliminate outliers
  - Mitigate inexperience with instruments, implants

- Make Good Surgeons Better
  - Patient-specific planning, including soft tissue (ligament) assessment
  - Eliminate outliers even more
  - Perform more difficult procedures (Partials and Complex Primaries)
  - Expand indications

Surgical Robotics
(as proposed by Cinquin in 1993)

- Active
- Robot operates autonomously
  - ROBODOC
- Passive
- Robot remains as a static tool holder
  - MAZOR
- Semi-Active
- Robot assists, restricts, or enhances
  - DAVINCI, ACROBOT, MAKO
  - NAVIO

NAVIO Surgical System

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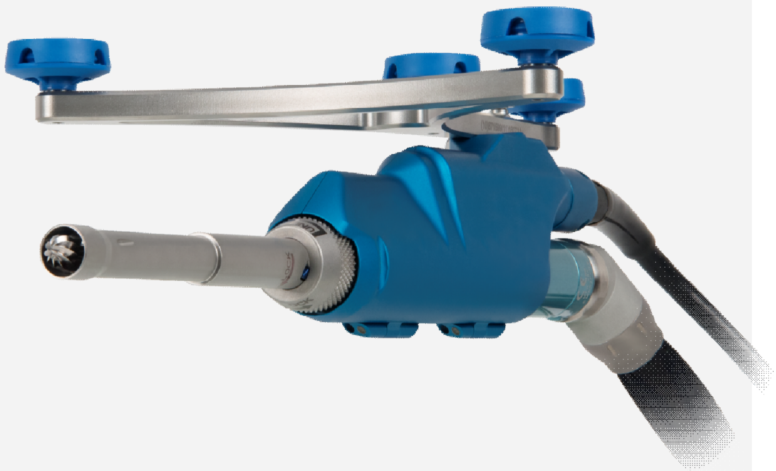
Surgeon-controlled, Handheld Robotics



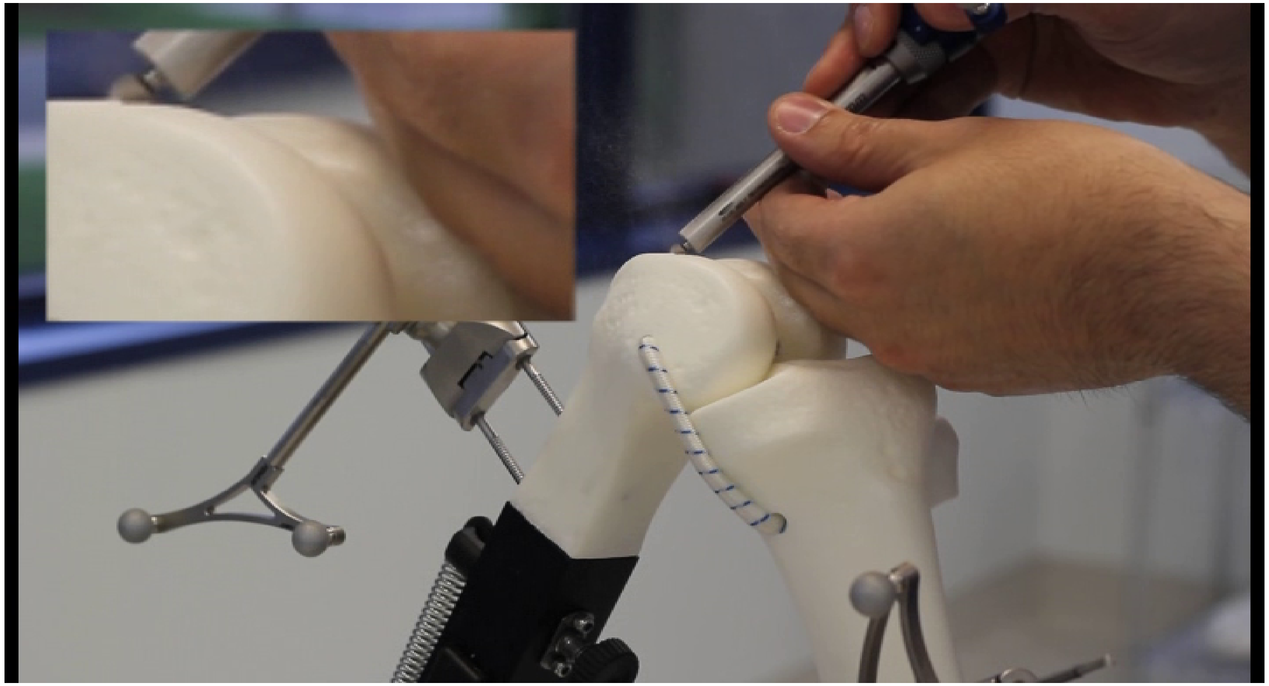
- Invention - Carnegie Mellon University, 2004
- Development - Blue Belt Technologies until 2016

Where is the Robotics in NAVIO?

NAVIO technology tracks the position of the robotic handpiece relative to the surgical plan and adjusts its exposure or speed to control cutting.

+ **Exposure Control** – Continually adjusts exposure of the bur to control depth of cut per the surgical plan.

+ **Speed Control** – Continually varies bur speed to control cutting in deep structures.



NAVIO Indications

Current FDA Cleared Applications:

- Partial Knee Replacement (UKA, PFJ)
- Total Knee Replacement (Journey II CR/BCS/XR, Legion, Genesis)

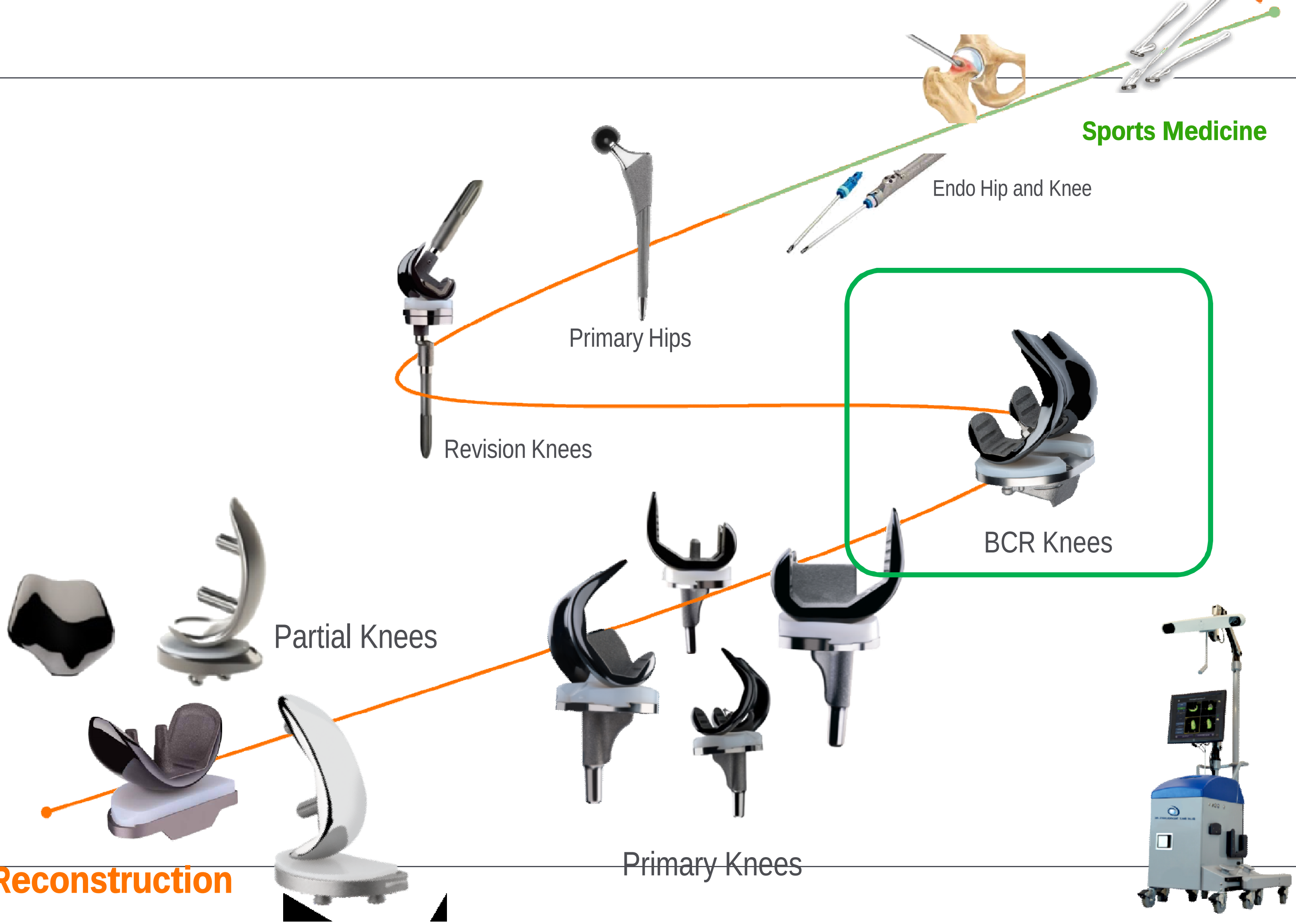
Unicondylar knee replacement

Patello-femoral joint replacement

Total Knee Replacement

Robotic Future Indication Expansion

Roadmap



NAVIO Advantages

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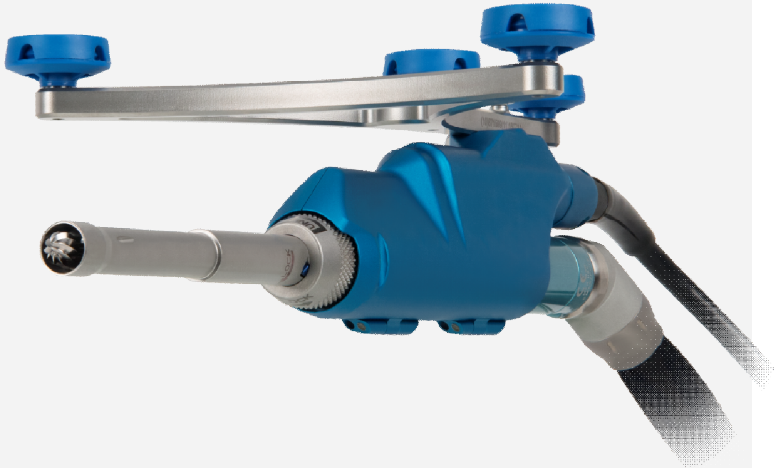
- Surgeon-Controlled
- Image-free patient-specific planning
- Fine tune cut adjustments
- Multiple and expandable indications
  - partial, total and bi-cruciate retaining knees (more to follow!)
- Support multiple workflows
- Small footprint
- Same tray for all procedures



NAVIO Contrasts

Other Knee Recon Robots

- Require preop CT (but still with intraoperative cartilage mapping)
- Control cutting via contrary force through a robotic arm
- Have significant setup times

NAVIO

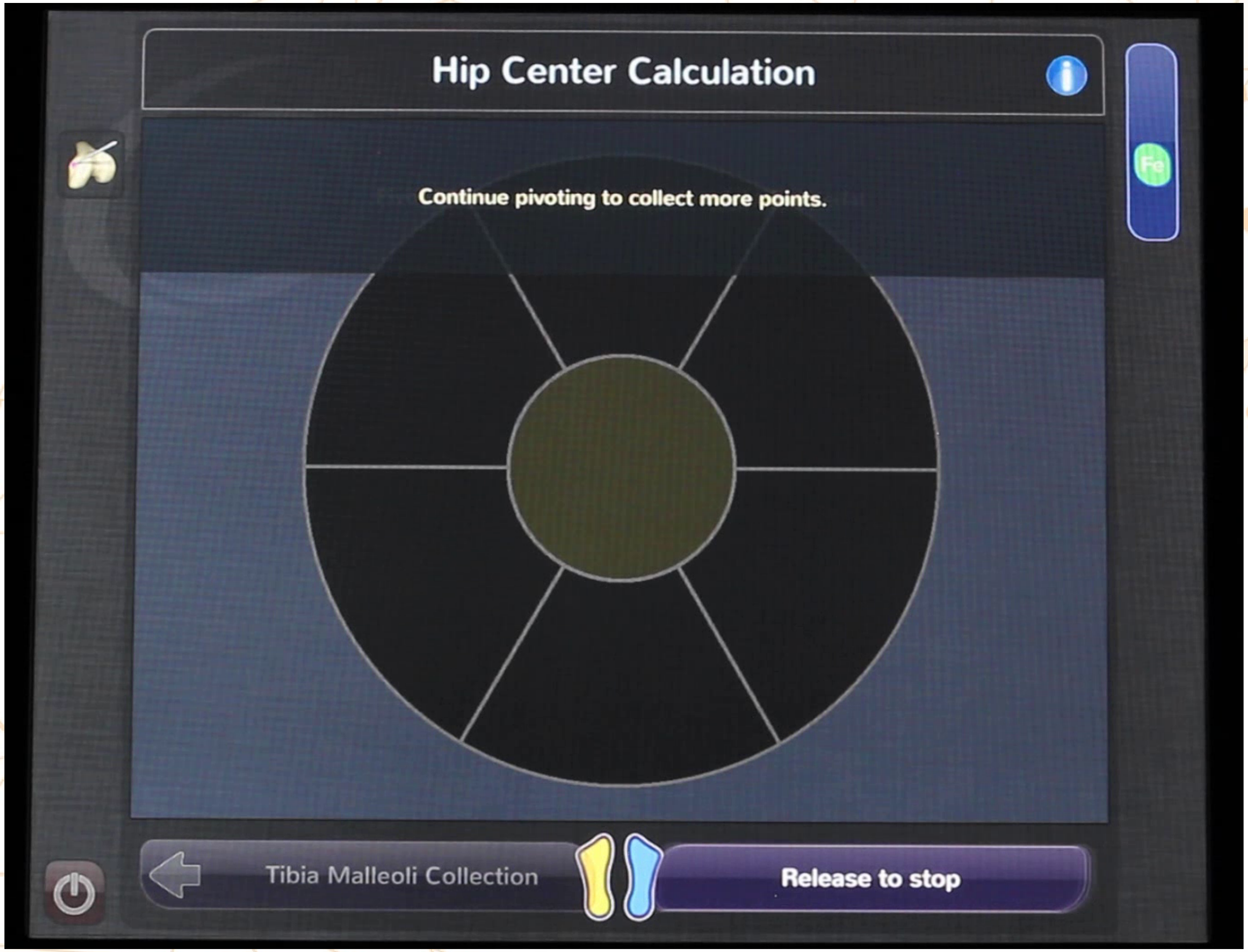
- Requires **no preop scan**
- **Surgeon holds tool** with cutting control at tip
- **Small footprint**, transport between rooms is easy

NAVIO Workflow

Registration, Planning, Execution

NAVIO Workflow

1. **Registration**
2. Planning
3. Execution

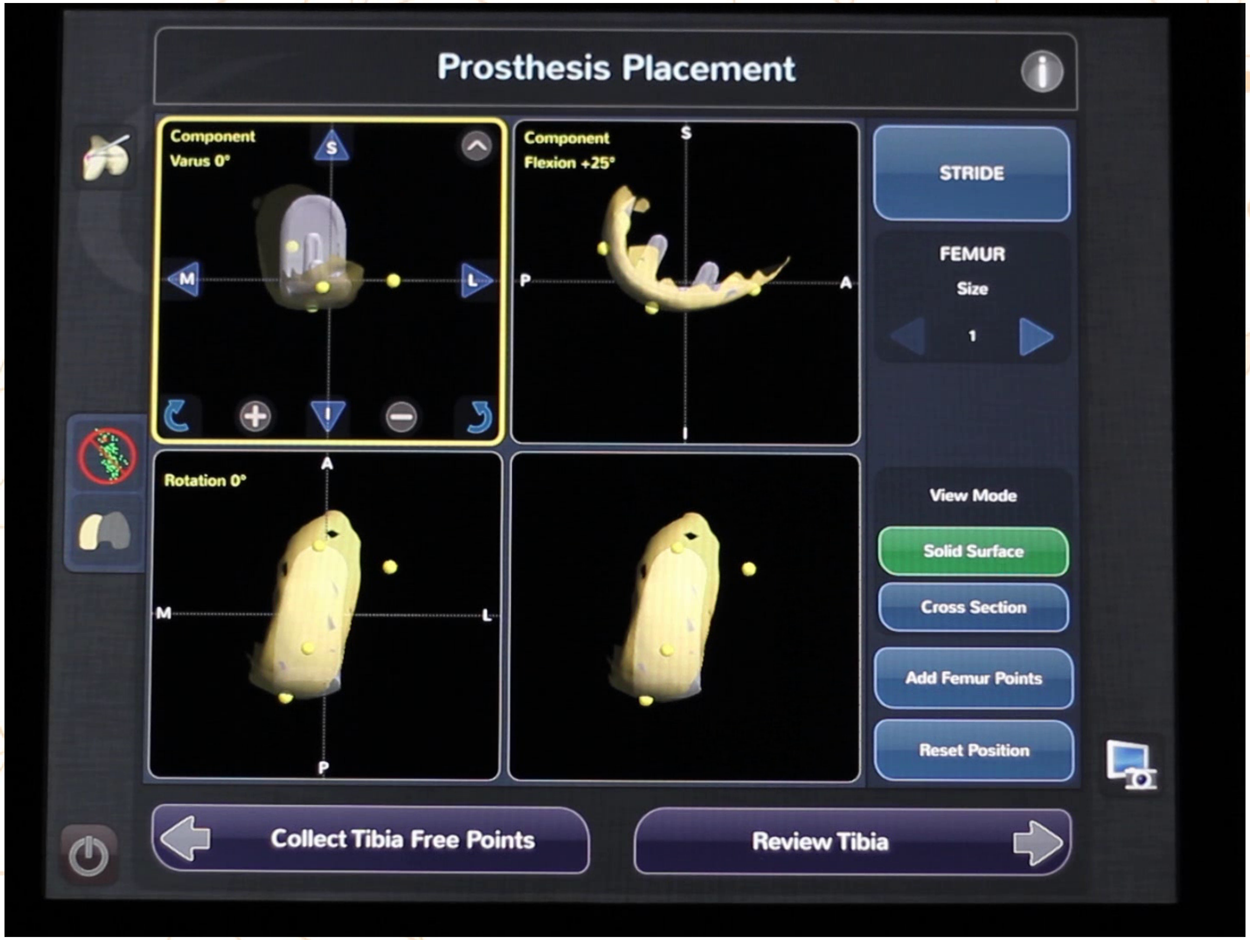


Same steps of registration for Partials or Totals.

Defines anatomic axes, patient's condyles and specific joint laxity

NAVIO Workflow

1. Registration
2. **Planning**
3. Execution



Same steps of planning for Partials or Totals.

Determine optimal implant position, to align joints and achieve best patient balance

NAVIO Workflow

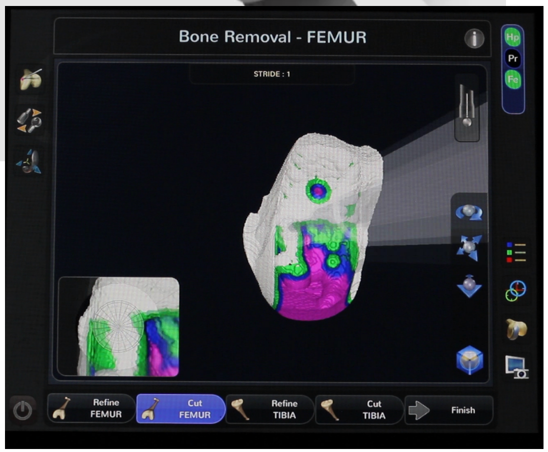
1. Registration
2. **Planning**
3. Execution

NAVIO Workflow

1. Registration
2. **Planning**
3. Execution

NAVIO Workflow

1. Registration
2. Planning
3. **Execution**



The same tool for consistent execution

Precise bone preparation with handheld bur for Partials and totals

NAVIO Studies - UKA

Improved implant position and lower revision rate with robotic-assisted unicompartmental knee arthroplasty[7]

Batailler C, et al. *Knee Surg Sports Traumatol Arthrosc*. 2018.

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)

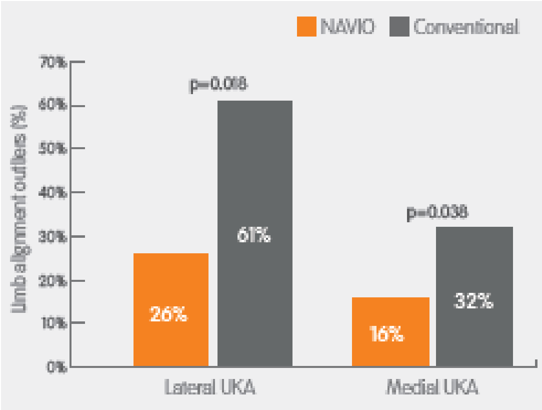


Figure. Rate of post-UKA limb alignment outliers (±2°) in the NAVIO and conventional groups

Early survivorship of robotic-assisted unicompartmental knee arthroplasty[8]

Battenberg A, et al. *35th Annual Meeting of SOA*. July 11-14, 2018; Palm Beach, FL, USA.

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

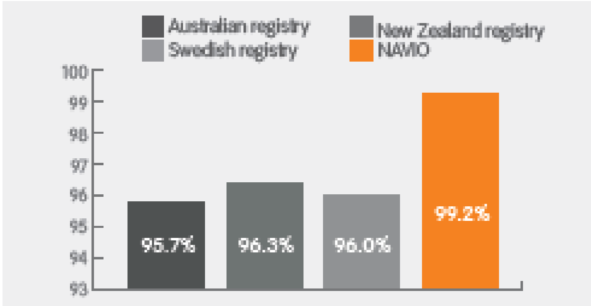


Figure. Survivorship data from this study compared to annual registry data for conventional UKA reporting 2-year UKA survivorship

Conclusion

High early implant survivorship rate for the NAVIO system that is higher than that presented in the literature for annual registries.

NAVIO Joint Line Restoration

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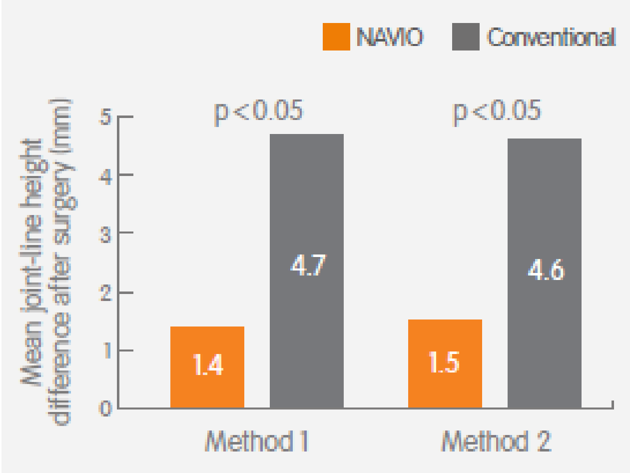
Improved joint-line restitution in unicompartmental knee arthroplasty using a robotic-assisted surgical technique[8]

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

Study design

- Retrospective study comparing joint-line height following unicompartmental knee arthroplasty (UKA) using:
  - NAVIO® robotic assisted (40)
  - Or conventional technique (40)
- Weight bearing radiographs taken pre-UKA and 2 months post-UKA
- Two validated radiologic measurement methods used to assess joint-line height



Key results

- The joint-line was distalised significantly more in the conventional group than in the NAVIO Surgical System ($p < 0.05$)

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.

NAVIO Studies - TKA

- RA TKA reduces postoperative alignment outliers and improves gap balancing compared to conventional TKA
  - Song et al, *Clin Orthop Relat Res* 2013, 471:118.
- Increased Precision of Coronal Plane Outcomes in RA-TKA
  - Mannan et al, *Surgeon* 2018; epub ahead of print
- RA-TKA was associated with reduced bone and soft tissue damage when compared with jig-based TKA
  - Iatrogenic Bone and Soft Tissue Trauma in Robotic Arm Assisted TKA Compared with Conventional Jig-Based TKA, Kayani B, Konan S, Pietrzak J, Haddad F, *J Arthroplasty* 2018, 33:2496
- Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty
  - Kayani B, Konan S, Pietrzak J, Tahmassebi J, Haddad F, *Bone Joint Journal,* July 2018, 100:940

Summary

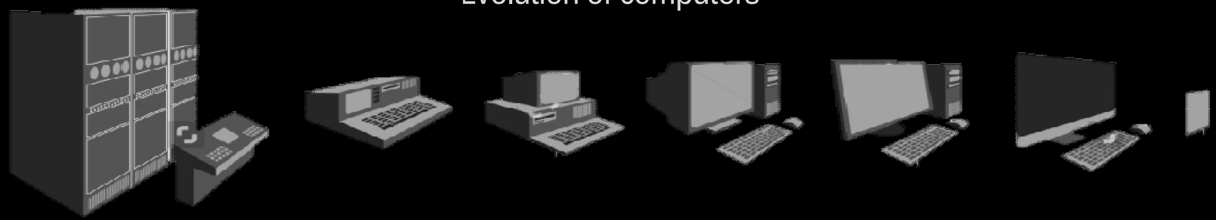
Why Robotics?

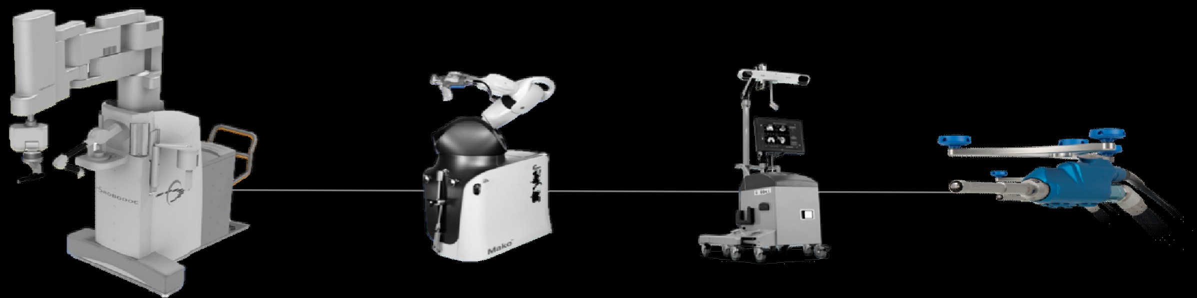
- Place an implant more accurately than conventional surgery
- Reduce failures due to malposition/malalignment
- Enhance your practice after a short learning curve
- Maintain lower radiation doses
- Embrace technology
- Become a better surgeon

NAVIO Surgical System – What Lies Ahead?

The future of Robotics

Evolution of computers

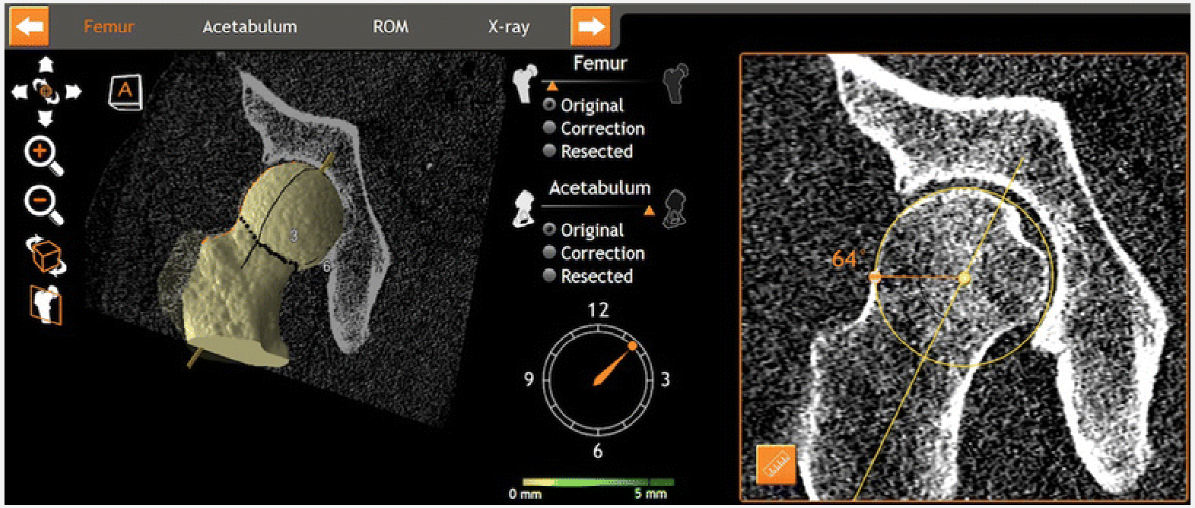


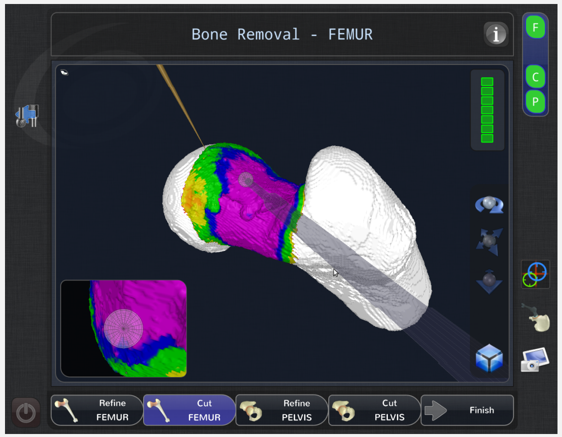


Evolution of Robotics is the **power of smart technology in your hands**

NAVIO Possibilities

- Sports Medicine
- ACL repair
  - Preop planning
  - Patient specific planning
  - Robotic tunnel /anchor placement



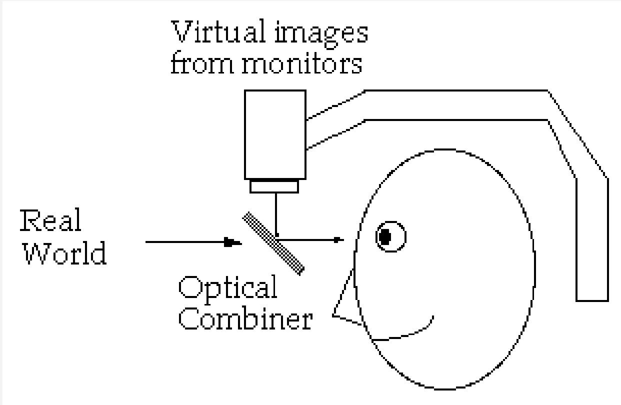


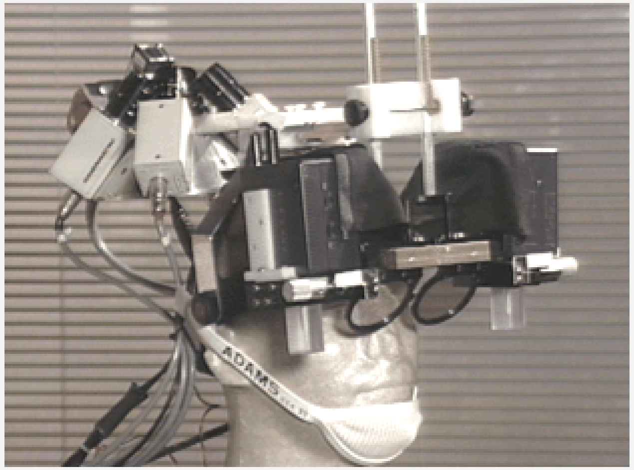
- Femoroacetabular Impingement
  - Preop planning from MRI/CT
  - Robotic execution


AUGMENTED
REALITY

Early Medical Augmented Reality

UNC Pioneers



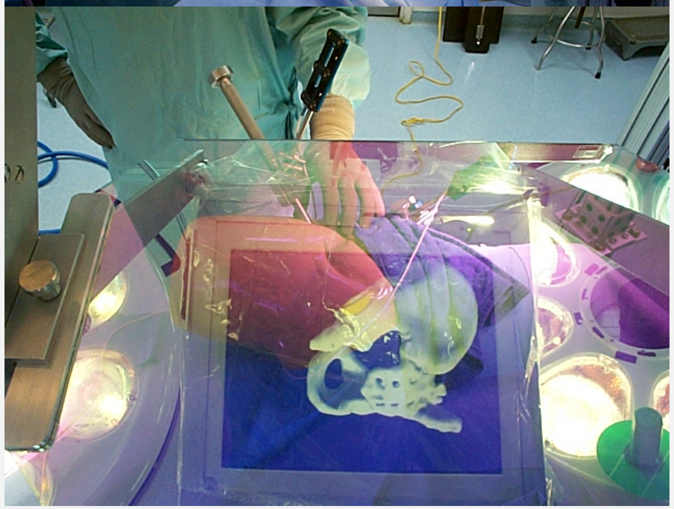


Images from

https://www.cs.unc.edu/~azuma/azuma_AR.html, http://www.cs.unc.edu/Research/us/

Augmented Reality

Circa 2000



Augmented Reality
Modern Capability

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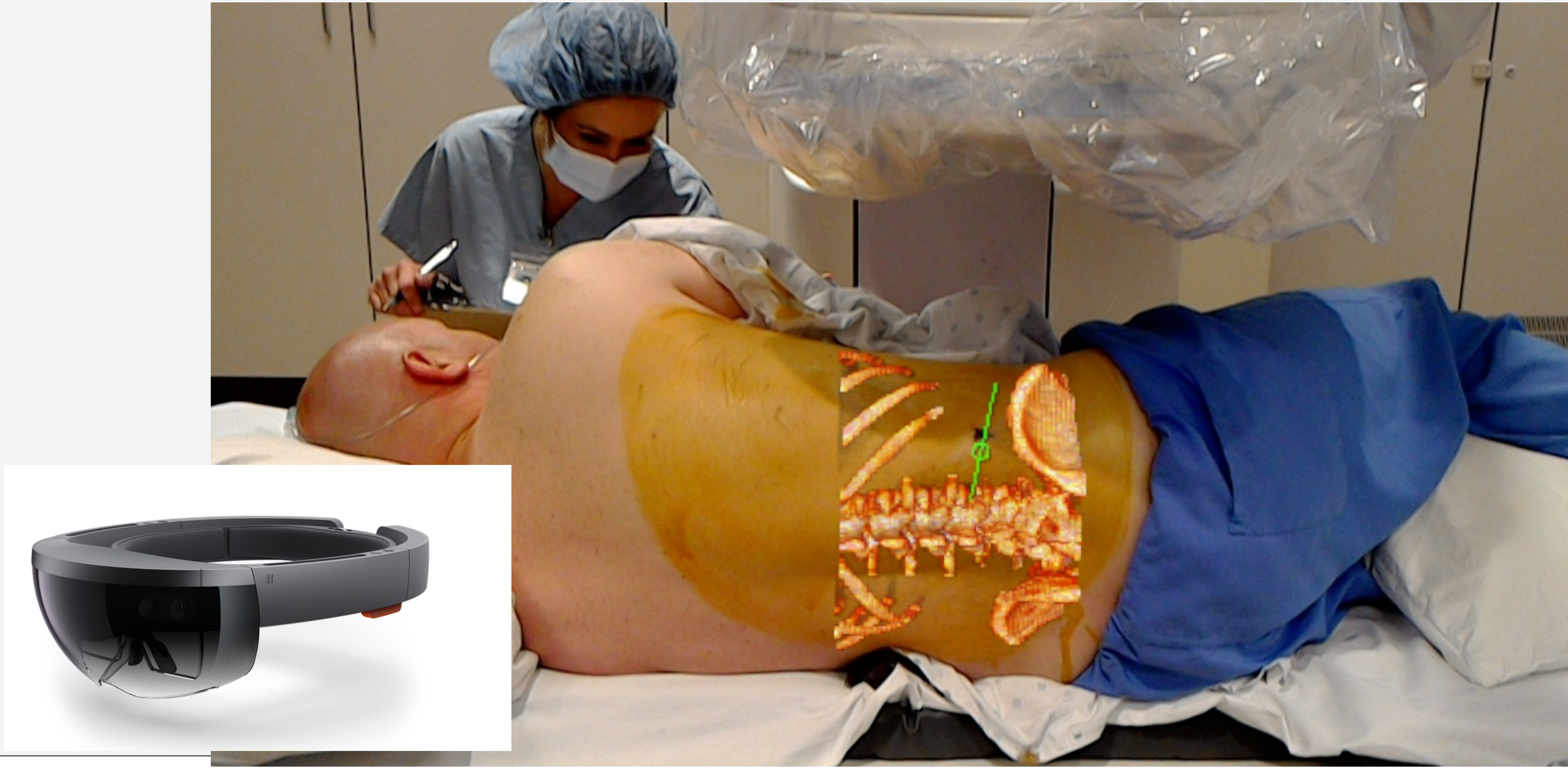
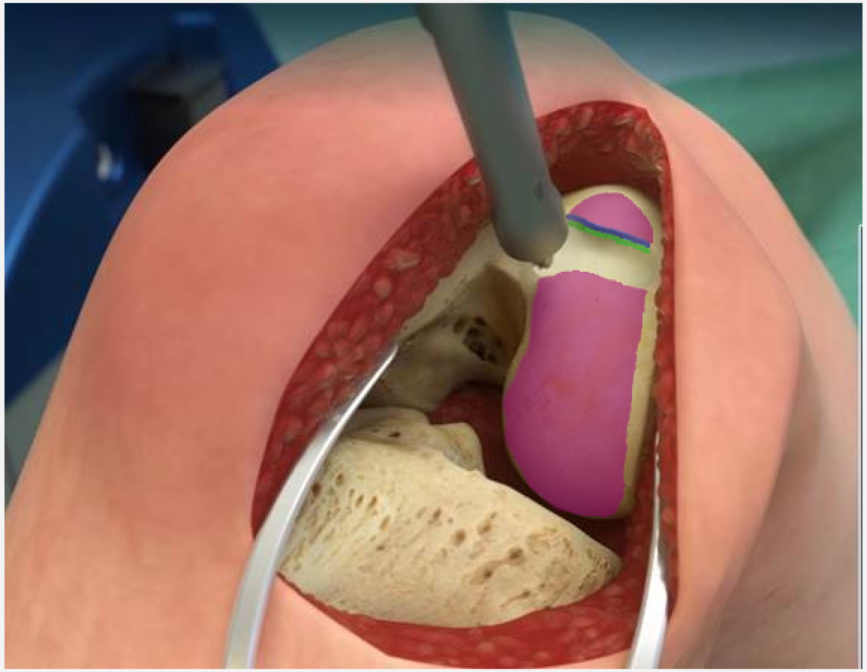
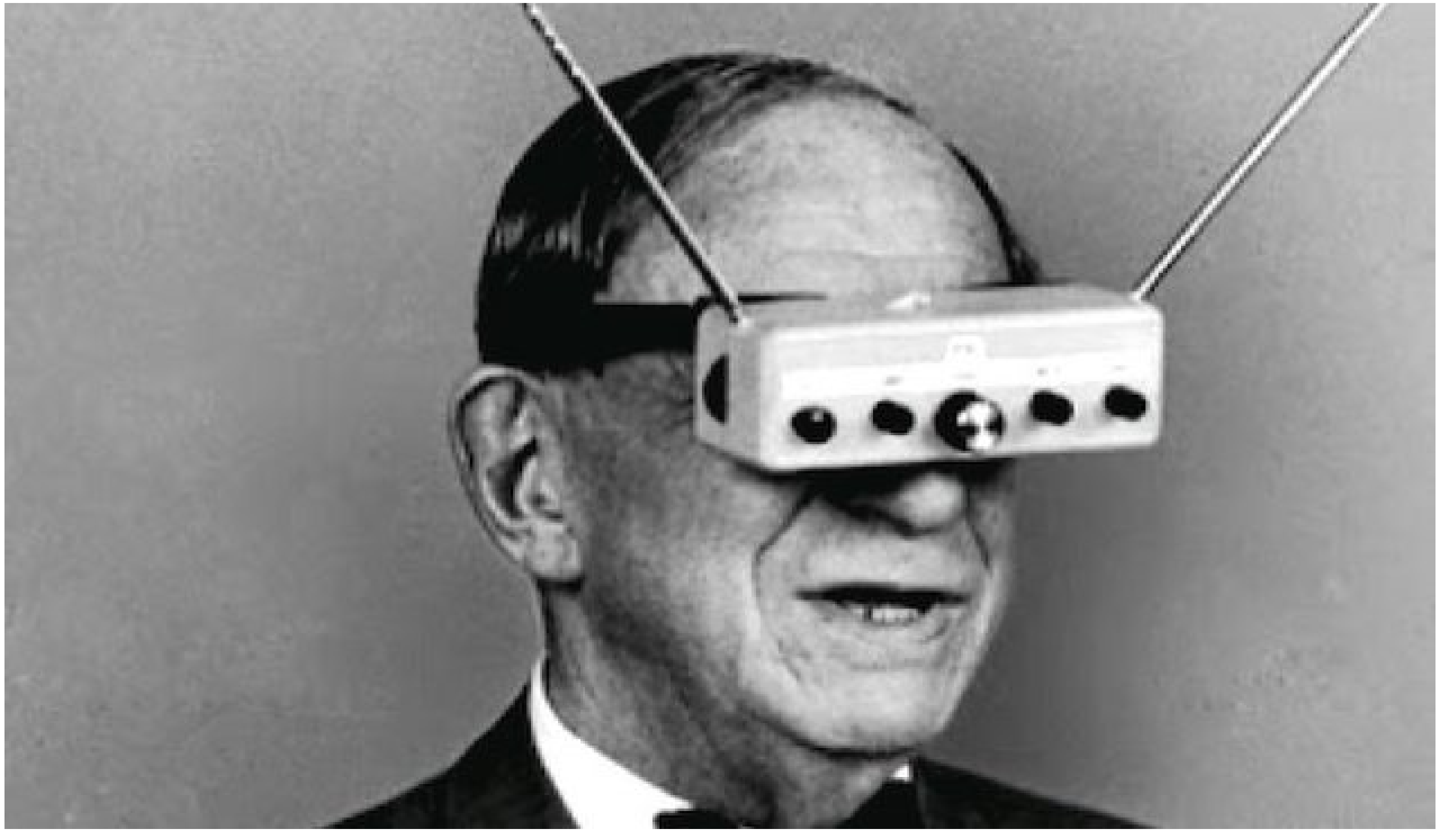


Augment the NAVIO Reality



Augmented Reality

Circa 2021?



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Thank You!

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Cadaveric Accuracy Study – Materials and Methods

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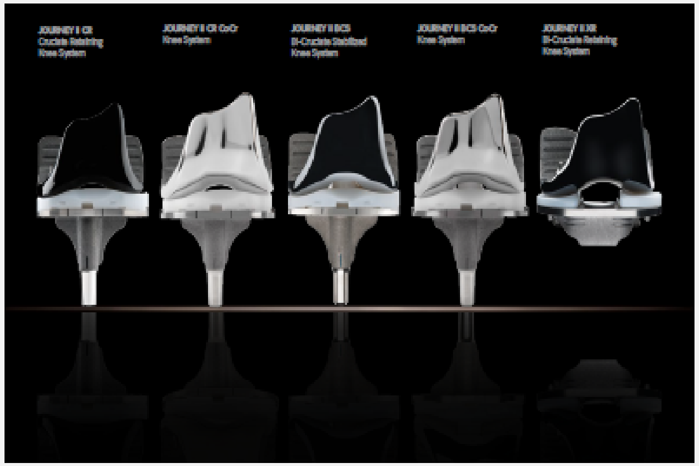
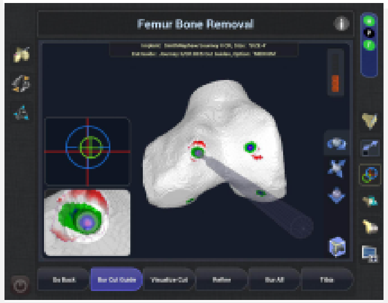
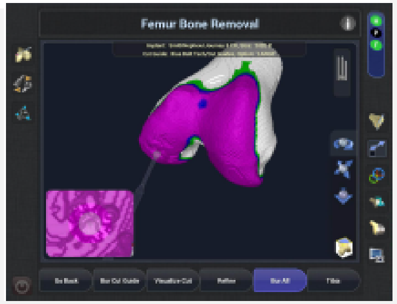
• Materials

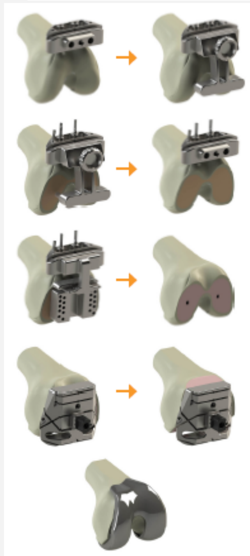
- Eighteen cadaveric specimens
- Eight surgeons
- Bi-Cruciate retaining, cruciate retaining and posterior stabilized designs studied.

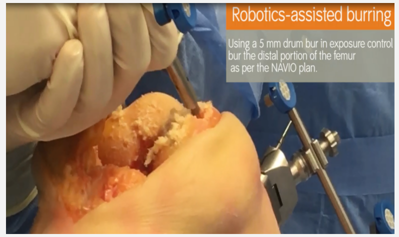


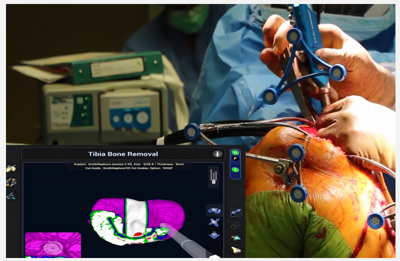
Cut Guide Method	Bur All Method











Cadaveric Accuracy Study – Materials and Methods

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- **Methods**
  - Conical divoted fiducials for anatomic and implant localization
  - Independent tracking camera and software for operation and accuracy measurement
  - 4/18 cuts were made completely using the bur
  - 14/18 cuts were executed with cut guides that were locked on the bone based on bur preparation, as per implant plan.

Figure 1: Initial setup of bone trackers during a Navio TKA procedure. The bone arrays are fixed using bone screws on the femur and the tibia.

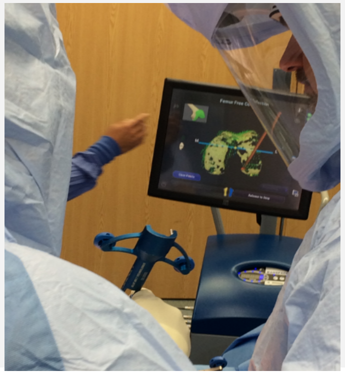

Figure 2: Use of the system point probe to map out the articular surface of the femur

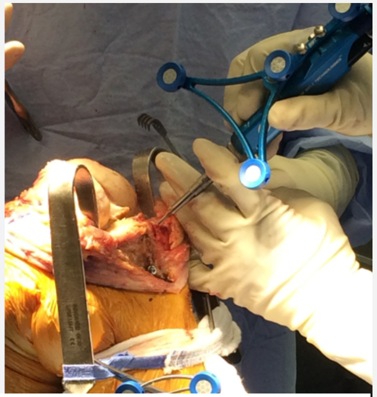

Figure 3: Use of optically-tracked bur to prepare the bone for placement of the cut-guide

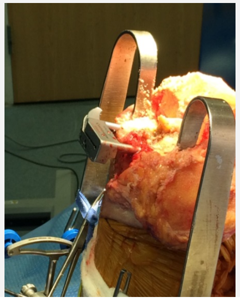

Figure 4: Cut-guide placement based on intra-op plan after the bone cuts

Cadaveric Accuracy Study – Results

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Error type	Total error		Cut-guide error		Bur All error	
	Femoral implant	Tibial implant	Femoral implant	Tibial implant	Femoral implant	Tibial implant
AP error (mm)	0.5±1.1	*	0.8±1.1	*	-0.4±0.9	*
SI error (mm)	0.4±1.0	-0.3±0.6	0.7±1.0	-0.4±0.6	-0.5±0.6	0.4±0.6
Flexion/tibia slope error (°)	-2.0±2.2	-0.2±1.3	-2.2±2.4	-0.2±1.4	-1.0±0.5	-0.3±0.8
Varus/Valgus error (°)	-0.1±0.9	-0.2±0.9	-0.1±0.9	-0.2±0.9	-0.2±0.7	-0.3±1.4
Rotation error (°)	-0.5±1.2	*	-0.6±1.3	*	-0.2±0.5	*

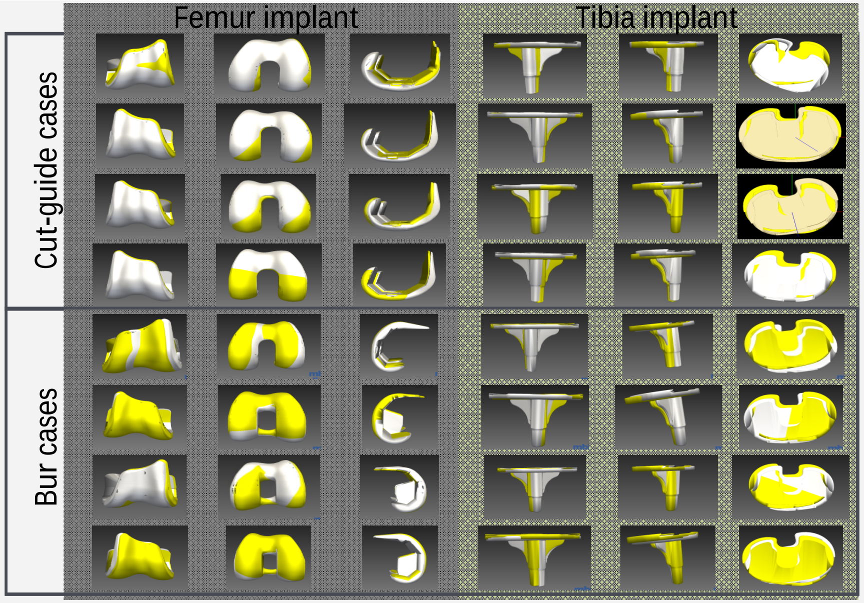

Figure 5: Overlay of planned (yellow) and actual (white) implant positions for 8 cases.

NAVIO Surgical System – Robotics Assisted Execution

Objection

MAKO is true robotics. It's Haptic.
NAVIO is just navigation.

NAVIO and the RIO II are both classified as RAS Systems (FDA Classification: OLO)

Precision freehand sculpting technology tracks the position of the handpiece and bur relative to the surgical plan and adjusts the bur to control cutting

NAVIO TKA is designed to leverage bur and saw for flexibility of workflow and cutting efficiency

NAVIO TKA allows for surgeons to accurately plan and place captured cutting guides with robotic assistance

Linked cuts executed with captured cut guides drive consistency and accuracy.

MODES OF ROBOTIC CONTROL

Exposure Control The bur extends or retracts from guard based on proximity to target cut surface

Speed Control The exposed bur speed is adjusted based on proximity to target cut surface