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KneeAlign® Clinical Studies Summary

Extramedullary Guides versus Portable, Accelerometer-Based Navigation for Tibial Alignment in Total Knee Arthroplasty: A Randomized, Controlled Study
Denis Nam, MD; Elizabeth Cody, MD; Mark Figgie, MD; David Mayman, MD
The Journal of Arthroplasty
June 5, 2013

Purpose of Study
Compare the tibial alignment obtained using KneeAlign versus extramedullary (EM) alignment guides in TKA.

1. Determine if use of KneeAlign increases the accuracy of obtaining a tibial resection within 2° of perpendicular to the tibial mechanical axis in the coronal plane, and within 2° of a 3° posterior slope in the sagittal plane
2. Determine if KneeAlign improves the surgeon's ability to achieve a desired intraoperative alignment
3. Determine if KneeAlign leads to improved overall, mechanical alignment
4. Determine if KneeAlign increases the amount of time required to perform the tibial resection when compared to conventional, EM alignment guides.

Number of patients in study
N= 100

Key Assumption
Component alignment plays a crucial role in clinical outcomes following TKA, driving a majority of surgeons to continue aiming for a neutral mechanical axis in TKA. A neutral mechanical axis in TKA will provide the most optimal results and reduce implant failure

Initial postoperative visit results
Standing AP hip-to-ankle and lateral knee-to-ankle radiographs obtained for comparative values

- Navigation Cohort (starting n=50, ending n=47)
  - 95.7% of tibial components were within 2° of perpendicular to the tibial mechanical axis
  - 95% of tibial components were within 2° of a 3° posterior slope
  - 70.2% of femoral components were within 2° of perpendicular to the femoral mechanical axis
  - 89.4% of overall mechanical alignment within 3° of a neutral mechanical axis
- EM Cohort (starting n=50, ending n=47)
  - 68.1% of tibial components were within 2° of perpendicular to the tibial mechanical axis
  - 72.1% of tibial components were within 2° of a 3° posterior slope
  - 66% of femoral components were within 2° of perpendicular to the femoral mechanical axis
  - 74.5% of overall mechanical alignment within 3° of a neutral mechanical axis

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Conclusion

KneeAlign decreases the incidence of outliers for tibial component alignment in both the coronal and sagittal planes, and improves the surgeon's ability to achieve a specific, intraoperative goal, compared to conventional, tibial EM alignment guides in TKA.

Increased time associated with use of KneeAlign when compared to conventional, EM alignment guides.

Continued follow-up is required to determine if these improvements in alignment result in improved survivorship and function.

Compared to CAS

- KneeAlign avoids the use of additional pin sites and reference arrays in the femur and tibia
- KneeAlign does not require a large computer with an infrared camera
- KneeAlign eliminates intraoperative line of site issues between the camera and reference arrays.

Reasons why CAS is inferior technology

- Steep learning curve
- Increased Capital Costs
- Longer operative times
- Extra pin sites
- Less than 3% of TKAs are performed using CAS in the United States

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Accelerometer-Based, Portable Navigation vs. Imageless, Large-Console Computer-Assisted Navigation in Total Knee Arthroplasty
Denis Nam, MD; K. Durham Weeks, MD; Keith R. Reinhardt, MD; Danyal H. Nawabi, MD; Michael B. Cross, MD; David J. Mayman, MD
The Journal of Arthroplasty
April 17, 2012

Purpose of Study
Determine the accuracy of overall lower-extremity, femoral, and tibial component alignment obtained when using the KneeAlign 2 and to compare these results to a large-console, imageless CAS system. The purpose of this study was to assess the radiographic results obtained when using KneeAlign to perform both the proximal tibial and distal femoral resections in TKA versus those obtained when using a large, console, imageless CAS system.

Number of patients in study
N= 160 (KneeAlign Cohort= 80, CAS Cohort= 80)

Key Assumption
Component alignment plays a crucial role in clinical outcomes following TKA and implant failure rates, driving a majority of surgeons to continue aiming for a neutral mechanical axis in TKA. The most common reason for tibial component revision was medial bone collapse, which is associated with varus tibial component alignment (tibial varus alignment of greater than 3° increased the odds of implant failure by roughly 17 times).

6-week postoperative visit results
Standing AP hip-to-ankle radiographs obtained, from which the lower extremity mechanical axis, tibiofemoral anatomical axis, and tibial component varus/valgus alignment were digitally measured

- Average lower extremity mechanical alignment was -0.9° ± 3.1° in those with a preoperative varus deformity (n=34) and -0.6° ± 1.1° in those with a preoperative valgus deformity (n=8).
- Average tibial component alignment was -0.7° ± 0.9°, with 97.1% aligned 90° ± 2° to the mechanical axis in those with a preoperative varus deformity and -0.4° ± 0.8°, with 100% aligned 90° ± 2° to the mechanical axis in those with a preoperative valgus deformity.
- 97.6% of the tibial components were placed 90° ± 2° to the mechanical axis and 100% of the components were placed 90° ± 3° to the mechanical axis.

Conclusion

KneeAlign® Clinical Studies Summary

KneeAlign is highly accurate for overall mechanical, femoral, and tibial component alignment in TKA and compares favorably to large-console, CAS systems.
KneeAlign is highly accurate in achieving a neutral mechanical axis for overall lower-extremity, femoral, and tibial component alignment and is as accurate as a predicate, large-console CAS system. The percentage of patients who had an alignment within 3° of a neutral mechanical

axis in the KneeAlign cohort was 92.5% vs 86.3% in the CAS cohort. In addition, significant differences were seen with regard to the accuracy of femoral component alignment, with 94.9% of patients in the KneeAlign cohort having an alignment within 2° of neutral vs 92.5% in the CAS cohort. Both methods were equally accurate with regard to tibial component positioning. In addition, use of the KneeAlign device demonstrated a significant decrease in tourniquet times.

Surprisingly, the CAS cohort was less accurate than expected with regard to overall mechanical alignment and femoral component alignment in patients with a preoperative valgus deformity.

Overall Lower-Extremity Mechanical Alignment

- KneeAlign cohort: Average lower-extremity mechanical alignment was 0.6° ± 1.5° in those patients with a preoperative varus deformity and -0.8° ± 2.3° in those patients with a preoperative valgus deformity. Overall mean post-operative lower-extremity alignment was -0.1° ± 2.1°, with 92.5% of patients having an alignment within 3° of a neutral mechanical axis.
- CAS cohort: Average lower-extremity mechanical alignment was 1.2° ± 1.9° in those patients with a preoperative varus deformity and 1.6° ±3.0° in those patients with a preoperative valgus deformity. Overall mean post-operative lower-extremity alignment was 1.3° ± 2.3°, with 86.3% of patients having an alignment within 3° of a neutral mechanical axis.

Tibial Component Mechanical Alignment

- KneeAlign cohort: Mean tibial component alignment was 0.2° ± 1.0° in those patients with a preoperative varus deformity and -0.1° ± 1.1° in those patients with a preoperative valgus deformity. Overall tibial component alignment was 0.04° ± 1.1°, with 96.2% of patients having an alignment within 2° and 100% within 3° of perpendicular to the coronal mechanical axis of the tibia. The mean absolute difference between the intraoperative goal and the postoperative alignment was 0.8° ± 0.6°.
- CAS cohort: Mean tibial component alignment was 0.1° ± 1.1° in those patients with a preoperative varus deformity and 0.1° ± 0.9° in those patients with a preoperative valgus deformity. Overall tibial component alignment was 0.08° ± 1.0°, with 97.5% of patients having an alignment within 2° and 100% within 3° of perpendicular to the coronal mechanical axis of the tibia. The mean absolute difference between the intraoperative goal and the postoperative alignment was 0.9° ± 0.6°.

Femoral Component Mechanical Alignment

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- KneeAlign cohort: Mean femoral component alignment was -0.02° ± 0.9° in those patients with a preoperative varus deformity and -0.2° ± 1.4° in those patients with a preoperative valgus deformity. Overall, the mean femoral component alignment was -0.1° ± 1.2°, with 94.9% of patients having an alignment within 2° and 98.7% within 3° of perpendicular to the coronal mechanical axis of the femur. The mean absolute
- difference between the intraoperative goal and the postoperative alignment was 0.9° ± 0.7°.
- CAS cohort: Mean femoral component alignment was 0.6° ± 0.9° in those patients with a preoperative varus deformity and 0.9° ± 2.5° in those patients with a preoperative valgus deformity. Overall femoral component alignment was 0.7° ± 1.6°, with 92.5% of patients having an alignment within 2° and 95% within 3° of perpendicular to the coronal mechanical axis of the femur. The mean absolute difference between the intraoperative goal and the postoperative alignment was 1.2° ± 1.2°.

Tourniquet Time

- KneeAlign cohort: mean tourniquet time was 48.1 ± 10.2 minutes
- CAS cohort: mean tourniquet time was 54.1 ± 10.5 minutes

One notable disadvantage of the accelerometer-based system is that after the tibial or femoral resection is performed, the accuracy of the resection cannot be checked using a navigation array (as with most large-console CAS systems).

Several advantages of portable navigation compared with large-console CAS systems:

- KneeAlign avoids the use of additional pin sites and reference arrays in the femur and tibia
- KneeAlign does not require a large computer with an infrared camera
- KneeAlign eliminates intraoperative line of sight issues (between the infrared camera and reference arrays)

Other benefits:

- KneeAlign avoids violation of the IM canals

Compared to conventional, IM femoral alignment guides

- KneeAlign does not rely on assumptions based on the anatomical axis of the femur and is reliably able to register the true, femoral mechanical axis
- KneeAlign provides a degree of familiarity to surgeons accustomed to using conventional alignment guides because the tibial jig is similar to an EM alignment guide and the femoral jig and cutting block are similar to an IM alignment guide, minus the invasive IM rod. KneeAlign successfully combines the benefits and accuracy of large-

console CAS systems while providing a level of familiarity with conventional alignment methods.

Versus Patient Specific Instrumentation (PSI)

- According to Moussa Hamadouche, MD in *RCT Multicenter Comparison of Primary TKA Using Patient Specific versus Conventional Instrumentation*, PSI should be reconsidered, as PSI over conventional instrumentation in primary TKA demonstrated a significant trend towards varus placement of the femoral component.
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- According to Denis Nam, MD in *Patient Specific Instrumentation versus Large-Console Computer-Assisted Navigation in Total Knee Arthroplasty*, that while PSI may potentially decrease operative times and increase the cost-effectiveness of TKA, in its current form, PSI is not able to reproduce the same degree of alignment accuracy as CAS techniques.
    - PSI cohort (n=38, 41 knees)
        - 70.7% of patients had an overall alignment within 3° of a neutral mechanical axis
        - 87.8 of patients had a tibial component alignment within 2° of perpendicular to the tibial mechanical axis
        - 90.2% of patients had a femoral component alignment within 2° of perpendicular to the femoral mechanical axis
    - CAS cohort (n=37, 41 knees)
        - 92.7% of patients had an overall alignment within 3° of a neutral mechanical axis
        - 100% of patients had a tibial component alignment within 2° of perpendicular to the tibial mechanical axis
        - 100% of patients had a femoral component alignment within 2° of perpendicular to the femoral mechanical axis
- According to William G. Hamilton, MD in Patient Specific Instrumentation does not Shorten Surgical Time: A Prospective, Randomized Trial, Patient Specific Instrumentation does not shorten surgical time or improve alignment compared to Traditional Instrumentation.
    - PSI Cohort (n=26)
        - Total Surgical Time was 61.8 minutes
        - Time for Tibial Cut was 130 seconds
        - Time for Femoral Cut was 170 seconds
    - Traditional Instrumentation Cohort (n=26)
        - Total Surgical Time was 57.4 minutes
        - Time for Tibial Cut was 113 seconds
        - Time for Distal Femoral Cut was 94 seconds