Intraoperative Assessment of Mechanical Alignment Accuracy Determined by Computer Navigation in a Patient Specific Implant and Instrumentation Total Knee Arthroplasty System

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INTRODUCTION

Obtaining neutral mechanical alignment is a vital factor in the long term success of total knee arthroplasty (TKA)[1,2] Patient specific instrumentation has been introduced with the goals of improving the accuracy of bone cuts and achieving neutral mechanical alignment.

The purpose of this study was to utilize computer navigation intra-operatively as a confirmatory assessment of the accuracy of the bone cuts, made utilizing the patient-specific jigs, in setting alignment to the neutral mechanical axis.

Table A. Study Demographics

Number of patients (male/female)	37 (23/14)
Mean age (range)	63 (44-85)
L:R	27:10
Mean pre-operative alignment (range)	5.5° (12° valgus–15° varus)
Pre-operative flexion contraction (mean, range)	22/37 (7.3°, 1-30°)

METHODS

A consecutive series of 37 patients undergoing TKA, utilizing patient specific instruments and implants, were prospectively measured with intraoperative computer navigation (Table A). The instruments and implants are first created utilizing a pre-operative CT scan. All patients were then navigated during surgery prior to implantation, to determine mechanical alignment.

The patient-specific instruments were then utilized per the manufacturer's recommendations and bone cuts were made (Image A,B). All bone cuts were recorded utilizing the navigation system as a confirmatory measurement). The patient-specific implants were then fixated and surgery completed (Image C). Final mechanical alignment was then recorded, again utilizing the navigation system for the assessment.

Figure 1. Patient-specific tibial cut guide

Figure 2. Patient-specific femoral cut guide

Figure 3. Patient-specific femoral and tibial components

RESULTS

The patient-specific instruments and implants provided neutral mechanical alignment of zero degrees, in 87% of patients (32/37). In the remaining 5 patients each had a post-operative alignment within ±2° of neutral, with no outliers.

The average pre-operative amount of deformity for this cohort was 5.5° (range 0-15°) v. 0.19° (range 0-2°) postoperatively (p<0.0001). The mean correction angle for this cohort was 5.6°. Additionally, 60% (22/37) of patients presented with a pre-operative extension deficit averaging 7.3° (range 1-30°). Post-operatively no patients had extension deficits as measured with navigation (See Table B).

Table B. Study Results

Post-operative neutral mechanical alignment	87% (32/37)
Post-operative within ± 2° of neutral mechanical alignment	100% (37/37)
Mean post-operative alignment (range)	0.19° (0-2°)
Mean alignment correction	5.6°
Post-operative full extension obtained	100% (37/37)

DISCUSSION

Patient-specific instruments and implants accurately restore neutral mechanical alignment as measured by intra-operative computer navigation. The patient-specific instruments aligned all patients in this cohort to within ±2° of neutral (See Table C).

It is well documented that the restoration of neutral mechanic axis is a factor in achieving long-term survivorship. Specifically legs that are aligned to within ±3° of neutral have been shown to have significantly better survivorship.

Table C. Conclusion

CT based custom instrumentation and implants accurately restored neutral mechanical alignment as measured by intra-operative computer navigation.

The patient specific instruments aligned all patients to within ± 2° of neutral with no outliers. A key factor in implant survivorship.

Author Disclosures:

Surgical Advisory Committee, Surgeon Visitation Program – Master Surgeon Trainer Proctor, ConforMIS, Inc.

References:
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2 Green GV, Berend, KR, Berend ME, et al. The effects of varus tibial alignment on proximal tibial surface strain in total knee arthroplasty; the posteromedial hot spot. J Arthroplasty 2002; 17;1033