Mechanical Alignment of a Customized TKA Implant System as Determined by Intraoperative Computer Navigation

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INTRODUCTION

A neutral mechanical limb alignment has been linked to increased Total Knee Arthroplasty (TKA) survivorship[1,2]. Patient-specific cutting blocks have demonstrated close to neutral alignment on average, but have also found a varying number of outliers (>3°) within specific brands (Otismed, Visionaire, Signature etc.) as well as between brands[3-6]. However, no study has investigated patient-specific cutting guides in conjunction with customized TKA implants (ConforMIS iTotal CR). Hence, the purpose of this study was to utilize computer navigation intra-operatively to measure the mechanical alignment of a patient-specific implant and instrument TKA system.

METHODS

A consecutive series of 63 patients undergoing TKA, utilizing patient-specific instruments and implants, were prospectively measured with intraoperative computer navigation. The instruments and implants were first created utilizing a pre-operative CT scan. The mechanical alignment of all patients was measured using computer navigation. The patient-specific instruments were then utilized per the manufacturer's recommendations and bone cuts were made (Figure 1). All bone cuts were recorded utilizing the navigation system as a confirmatory measurement. The patient-specific implants were then fixated and surgery completed. Final mechanical alignment was recorded with computer navigation.

Figure 1. Computer assisted navigation was used to measure the pre-op and post-op mechanical alignment intra-operatively.

RESULTS

The patient-specific instruments and implants provided neutral mechanical alignment, zero degrees, in 84.1% of patients (53/63). The remaining 10 patients each had a post-operative alignment within ±2° of neutral, with no outliers. The average pre-operative degree of deformity for this cohort was 5.57° v. 0.19° postoperatively (p<0.0001) (Table 1). The mean correction angle for this cohort was 5.70°. Additionally, no patients had extension deficits as measured with navigation post-operatively (7.5° pre-op for 40/63 patients).

Table 1: Average pre-op and post-op mechanical axis measurements

	Pre-op	Post-op
Average Deformity	5.57° ±6.5°	0.19° ±0.47°
Deformity Range	12° varus - 15° valgus	1° varus - 2° valgus
Extension Deficit	7.5° (5.58-30)	Full extension in all patients

DISCUSSION

Customized, 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. It is well documented that the restoration of a neutral mechanic axis within ±3° is important to achieve long-term survivorship.[1]

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