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Intra-operative deviation in limb alignment occurring at implantation in total knee arthroplasty

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ABSTRACT

Background: Long-term survival of knee replacement depends on accurate alignment. Despite improvements in cut accuracy mal-alignment of 3° or more is still seen. All methods share common implantation techniques. This study examines the effect of implantation on overall limb alignment relating it to cut alignment and trial alignment.

Methods: A retrospective review of navigated primary knee replacements was undertaken ($n = 113$). Overall coronal limb alignments for the aggregated cuts, trial and final implanted components were examined.

Results: All 113 knees had coronal aggregated cut alignment within 2° of neutral (range: 2° varus to 2° valgus). With trial components 99 knees (88%) had an overall coronal limb alignment within 2° of neutral (range: 3° varus to 4° valgus). After final implantation 106 knees (94%) were within 2° of neutral (range: 4° varus to 4° valgus). Forty eight knees (42%) showed no alignment deviation occurring between trial and the final implanted prostheses and 16 knees (14%) shoed a deviation of 2° or more. There was a correlation of both aggregated cut ($r = 0.284$, $p = 0.002$) and trial ($r = 0.794$, $p < 0.001$) with final alignment. There was no significant difference between the final alignment and the aggregated cut alignment(mean difference $= -0.15°$, $p = 0.254$) or trial alignment (mean difference $-0.13°$, $p = 0.155$).

Conclusions: Even when the aggregated alignment produced by the bone cuts is accurate, inaccuracy in final alignment can result from the implantation process. It may be productive for surgeons to concentrate on the implantation process to improve alignment and reduce outliers.

1. Introduction

The long term survival of a knee replacement is known to depend on accurate alignment at the time of primary implantation [1–3]. Much attention has been focussed on technique to improve the accuracy of bony cut alignment with reference to the mechanical axis [4–6]. These include recent innovations such as refined manual instrumentation, computer navigation, robotics and shape matching. Despite these efforts malalignment of 3° or more is still seen to occur [4]. Although the methods guiding the bone cuts vary, all the techniques share a common implantation process.

Deviation of component position at implantation was originally described by Sambatakakis et al. [7] in 1991. They noted on postoperative radiographs that the tibial component did not always sit parallel to the tibial cut, which they called the 'cement wedge sign'. They found that this 'cement wedge sign' was strongly associated with the subsequent development of radio-lucent lines beneath the tibial component and was thought to be due to residual ligament imbalance when reducing the knee with soft cement. More recently Catani et al. [8] used a computer navigation system to demonstrate individual component deviation of over a degree occurring at implantation. Catani et al. also observed an apparent tendency to correct alignment to neutral during implantation. This occurs when the final components are placed, the limb is in extension, and the cement is curing, the real time limb alignment figure can be observed and an appropriate varus/valgus force is applied to obtain zero degrees. This could compensate for possible cut inaccuracies, but may alter the cement mantle and could be detrimental to the final fixation of the implant.

Overall limb alignment has been compared to cut alignment using long leg films which have their own limitations [9,10]. Overall limb alignment has also been compared to aggregated tibial and femoral cuts which have been used to calculate overall alignment [8]. There is no published literature where the specific effect of implantation on overall limb alignment and its relationship to both cut alignment and trial alignment have been observed using the same system.

The aim of this study was to examine the effects of implantation on overall limb alignment using alignment recorded by a computer navigation system and to relate final alignment to both the aggregated cut alignment and the trial alignment. The null hypothesis was that there

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would be no significant difference between overall coronal limb alignment with the trial components and the overall coronal limb alignment following final cemented implantation.

2. Methods

Formal ethical consent was deemed unnecessary by the local research ethics service and institutional clinical governance approval was obtained. A retrospective review of a single surgeon (AWGK) consecutive series of navigated primary knee replacements was undertaken using data collected prospectively during patient care from July 2006 to July 2011 (n = 235). Data was not saved centrally for analysis in 39 patients. Patients with incomplete intra-operative data were excluded, n = 83 (34 had incomplete cut data recorded, 32 had no trial alignment recorded, seven patients had no final alignment recorded and 10 patients had missing demographic data). Therefore 113 computer-assisted primary total knee replacements with dissimilar base plate designs, but similar femoral geometries were included, Scorpio (n = 18), Scorpio NRG (n = 75) and Triathlon (n = 19) all manufactured by Stryker. The patient demographics are displayed in Table 1.

All surgeries were carried out using the image free eNlite navigation system (Stryker, Kalamazoo, Michigan, USA) through a medial parapatellar approach following the same surgical sequence; bicortical femoral and tibial trackers were placed, the navigation system was calibrated, and anatomical landmarks and joint centres were acquired in the usual manner. Using the navigation system the distal femoral and tibial cutting blocks were aligned at 90° to the overall mechanical axis in the coronal plane and cuts made. The remaining femoral cuts were then made using standard cutting blocks. The final distal femoral cut, posterior condylar cuts and tibial cut were recorded by the system using an instrumented probe.

The final trial alignment, as balanced with the chosen insert thickness, was recorded throughout the knee range of motion. The senior author ensured that during both trial and final implant data recording there was no soft tissue interposed between trials/bone/implant. Care was also taken to ensure that the limb was in neutral rotation and visual confirmation was made that each of the femoral condyles were seated against the tibial articular surface.

Manual impaction of the definitive components was undertaken separately using a single mix of cement, with care taken to seat both femoral and tibial components flush with the bone cuts, using the final polyethylene bearing, and putting the knee into extension whilst the cement cured. Final alignment of the knee throughout its range of motion was then recorded before closure.

The overall coronal limb alignment data for both the trial components and the final implanted components at 0° flexion were examined. The orientations of the distal femoral and proximal tibial cuts, recorded by the navigation system, were used to determine an overall aggregated cut alignment, a method used by Catani [8].

2.1. Data analysis

Data were analysed using IBM Statistics (IBM New York, USA), and graphs were produced in Excel 2007 (Microsoft, Washington, USA).

Table 1
Demographic data of study cohort, mean (SD), is presented.

Age (years)	67.7 (8.5)
	43 to 86
Gender (M/F)	49/64
Body mass index (kg/m^2)	31.7 (5.3)
	18.3 to 45.7
Pre-implant deformity [a]	2.4° varus (±5.7°, range 14° varus to 16° valgus)

[a] Patient's pre-implant deformity was recorded by the navigation system after initial approach to the knee was made, trackers were placed and landmarks were acquired with the limb in maximum extension.

For the purposes of mathematical analysis varus was defined as a negative angle and valgus as a positive angle. Analysis of relationships between parameters was performed using Pearson's correlation coefficient. Student's T test (paired two sample means) was used to look for significant differences between the data sets.

3. Results

Following bone resection all 113 knees had coronal aggregated cut alignment in the range of 2° varus to 2° valgus (Fig. 1). When the trial components were placed overall coronal limb alignment ranged from 3° varus to 4° valgus (Fig. 2). After final implantation overall coronal limb alignment ranged from 4° varus to 4° valgus (Fig. 3). Statistically there was no significant difference found between the final alignment and the aggregated cut alignment (mean difference = −0.15°, $p = 0.254$) or trial alignment (mean difference = −0.13°, $p = 0.155$).

The deviation in coronal plane limb alignment (towards and away from neutral) occurring at implantation is represented in Fig. 4. This shows the change in alignment occurring between trial prosthesis and the final implanted prosthesis. Forty eight knees (42%) showed no change at implantation whilst 16 (14%) showed overall limb alignment change of 2° or more occurring at implantation, 14 of these were improvements in alignment, and two were worsening alignment. The deviation in coronal plane limb alignment occurring between aggregated cut alignment and trial alignment is seen in Fig. 5. 32 (28%) and showed no change at implantation whilst 32 knees (28%) showed overall limb alignment change of 2° or more occurring at implantation.

A weak correlation was seen between final alignment and aggregated cut alignment (Pearson's correlation $r = 0.284$, $p = 0.002$). A strong correlation was seen between final alignment and trial alignment (Pearson's correlation $r = 0.794$, $p < 0.001$). Analysing tibial and femoral cuts individually; the tibial cut had a stronger correlation than distal femoral cut to final limb alignment ($r = 0.222$, $p = 0.18$ vs $r = 0.138$, $p = 0.16$).

A weak negative correlation (Pearson's correlation $r = -0.270$, $p = 0.004$) between the aggregated cut alignment and the alignment deviation occurring between the trial and final implantation was found — i.e. an improvement in alignment following implantation.

4. Discussion

A number of studies have supported the use of navigation as a means to reduce outliers and improve the accuracy of bone resection [1,4–6]. The intra-operative data from this study showing final limb alignment obtained following implantation is in keeping with previously published work on the alignment achievable using navigation.

The given accuracy of computer navigation systems is usually quoted at 1° and 1 mm, although some authors have reported higher accuracies than this [11]. We therefore took a difference of 2° or more between measurements as a real change in lower limb alignment as 1° could be measurement error. For the assessment as to whether or not overall limb alignment was acceptable we took the widely accepted limits of ±3° from neutral (0°).

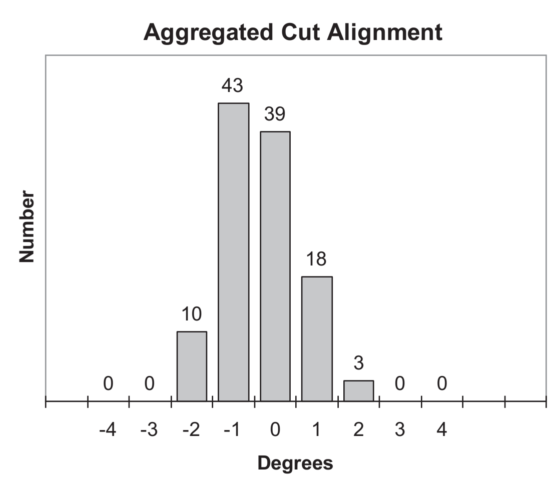

Fig. 1. Histogram of aggregated (tibial and femoral) cut alignment, rounded to the nearest degree. (Positive values: valgus, negative values: varus).