

1 *Original Article*

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3 **Lower limb alignment and laxity measures before, during and after total knee**  
4 **arthroplasty: a prospective cohort study**

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17

18 **Abstract**

19 *Background.* This study compared knee alignment and laxity in patients before, during and  
20 after total knee arthroplasty, using methodologically similar procedures, with an aim to help  
21 inform pre-operative planning.

22 *Methods.* Eighteen male and 13 female patients were recruited, mean age 66 years (51-82)  
23 and mean body mass index of 33 (23-43). All were assessed pre- and postoperatively using  
24 a non-invasive infrared position capture system and all underwent total knee arthroplasty  
25 using a navigation system. Knee kinematic data were collected and comparisons made  
26 between preoperative clinical and intraoperative measurements for osteoarthritic knees, and  
27 between postoperative clinical and intraoperative measurements for prosthetic knees.

28 *Findings.* There was no difference in unstressed coronal mechanical femoral-tibial angles  
29 for either osteoarthritic or prosthetic knees. However, for sagittal alignment the knees were  
30 in greater extension intraoperatively (osteoarthritic  $5.2^\circ$   $p<0.001$ , prosthetic  $7.2^\circ$   $p<0.001$ ).  
31 For osteoarthritic knees, both varus and valgus stress manoeuvres had greater angular  
32 displacements intraoperatively by a mean value of  $1.5^\circ$  for varus ( $p=0.002$ ) and  $1.6^\circ$  for  
33 valgus ( $p<0.001$ ). For prosthetic knees, only valgus angular displacement was greater  
34 intraoperatively ( $0.9^\circ$ ,  $p=0.002$ ).

35 *Interpretation.* Surgeons performing total knee arthroplasties should be aware of potential  
36 differences in alignment and laxity measured under different conditions to facilitate more  
37 accurate operative planning and follow-up.

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40 **Keywords**

41 Total knee arthroplasty, lower limb alignment, soft tissue laxity, non-invasive infrared  
42 tracking, computer assisted surgery

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44

45 **Introduction**

46 Lower limb alignment in stressed and unstressed conditions are fundamental measurements  
47 in the assessment, monitoring and surgical management of patients with knee osteoarthritis.  
48 However, accurate, consistent and comparative assessment throughout the pre-, intra- and  
49 postoperative stages of total knee arthroplasty (TKA) is not currently possible due to the  
50 variety of techniques adopted. Variation between alignment and laxity measurements  
51 assessed in the clinic and the operating theatre may have implications for the surgical  
52 planning of TKA patients.

53 In the absence of alternative evidence, restoring the coronal mechanical femoral-tibial  
54 (MFT) angle of the lower limb to 0° (or 180°) is a common intraoperative target with a  
55 deviation beyond 3° widely associated with reduced implant survival<sup>1-4</sup> and poorer knee  
56 function.<sup>5,6</sup> However more recent controversy about the effect of knee alignment on long  
57 term TKA survivorship<sup>7-9</sup> has revived the debate and highlighted the importance of accurate  
58 and reproducible measurement of coronal knee alignment. In contrast to the coronal plane,  
59 sagittal alignment has been studied relatively little in the context of TKA, in spite of  
60 recognition that fixed flexion deformities or excessive recurvatum can lead to poorer  
61 functional outcomes.<sup>10,11</sup> Nonetheless, a generally accepted supine intraoperative target is  
62 the restoration of full passive extension.<sup>10,12</sup>

63 Soft tissues should be balanced so as to work synergistically with the knee implant and  
64 provide stability, optimal range of motion and ultimately reduce implant wear.<sup>13,14</sup> Varus  
65 and valgus laxity, assessed by the application of a manual stress, is a fundamental yet  
66 subjective component of many soft tissue management techniques providing qualitative  
67 evidence for intraoperative soft tissue release. Attempts have been made to categorise soft  
68 tissue laxity, such as Krackow's classification of medial ligament tightness,<sup>15</sup> but this  
69 assumes that all clinicians have similar examination methods and are able to reliably judge  
70 knee alignment. However, human assessment of angles is poor<sup>16</sup> and this has led to  
71 quantitative adjuncts such as stress radiographs<sup>17</sup> which, as with standard AP knee "short  
72 view" and hip-knee-ankle "long leg" radiographs, are susceptible to limb positioning  
73 errors.<sup>18,19</sup>

74 Optical tracking systems have provided surgeons with quantitative measurement tools that  
75 permit real time intraoperative assessment of knee alignment, passive range of motion and  
76 ligament laxity<sup>20-22</sup> to within 1° or 1mm.<sup>23,24</sup> As well as improving the positional accuracy  
77 of TKA implants, this technology can help to guide the extent of any surgical releases  
78 performed on restraining soft tissues in order to give a balanced knee.<sup>25-29</sup> Due to the  
79 requirement for bone pins to provide temporary rigid tracker fixation, it is not possible to  
80 replicate this procedure in a clinical setting. However a similar non-invasive measurement

81 technique has been recently developed and validated by the authors, facilitating quantitative  
82 objective monitoring of static and dynamic knee alignment throughout the complete TKA  
83 process.<sup>30-35</sup>

84 The purpose of this study was to quantify lower limb alignment and coronal knee laxity  
85 pre-, intra- and postoperatively using methodologically-similar procedures. The hypothesis  
86 was that there would be no difference between alignment and laxity assessed in the clinic  
87 and intraoperatively.

88

## 89 **Methods**

90 This was a prospective cohort study for which ethical approval was obtained from the West  
91 of Scotland Research Ethics Committee. For an estimated effect size of 0.5, at  $\alpha = 0.05$  and  
92 a power of 0.8, a sample size of approximately 30 was required for a paired t-test. Patients  
93 were approached at their pre-assessment clinics. Between May and August 2010 35 patients  
94 scheduled for TKA surgery attended the clinics. Three patients were excluded as they were  
95 not due to attend routine follow-up for geographic reasons. One patient did not speak  
96 English and so was unable to provide informed consent in the absence of an interpreter.  
97 Therefore 31 patients were approached and recruited to the study (no patients declined to be

98 in the study). Eighteen were male and 13 female with a mean age of 66 years (range 51-82)  
99 and a mean body mass index (BMI) of 33 (range 23-43). Eighteen right knees and 13 left  
100 knees were assessed. The mean pre-operative Oxford knee score was 16, with a standard  
101 deviation of 6, and the pre-operative radiographic coronal MFT angle (as measured on  
102 long-leg film) was 2° varus with a standard deviation of 8°), ranging from 14° varus to 20°  
103 valgus. All patients had primary OA. Within the cohort five patients were morbidly obese  
104 (BMI > 40), three had lower limb lymphoedema and one with Parkinsonian tremor. All  
105 were due to undergo primary TKA by one of two consultant surgeons who routinely used  
106 the OrthoPilot® (Braun Aesculap, Tuttlingen, Germany) navigation system.

107 For clinical measurements, a previously validated non-invasive infrared (IR) position  
108 capture system was used. Intra-registration repeatability of this system was to 1° and inter-  
109 registration repeatability was 1.6° for coronal measures and 2.3° for sagittal measures<sup>30</sup>.

110 Patients were assessed during routine preoperative and six-week postoperative clinics to  
111 quantify their lower limb alignment and knee laxity. They were positioned supine with  
112 active IR trackers non-invasively secured to the distal thigh, proximal calf and dorsum of  
113 the foot using straps and instructed to relax their leg muscles. Anatomical landmarks  
114 (femoral epicondyles and ankle malleoli) were palpated and hip, knee and ankle joint  
115 centres were located in three dimensions through a tracked sequence of clinical manoeuvres

116 in order to determine coronal and sagittal mechanical femoro-tibial (MFT) angles. This was  
117 initially recorded with the lower limb in maximum passive extension, achieved by  
118 supporting the leg only under the heel.

119 Varus and valgus stress manoeuvres were then performed by applying manual force  
120 directly over the medial (valgus) or lateral (varus) ankle malleolus with the supporting hand  
121 placed over the medial (varus) or lateral (valgus) femoral epicondyle. The application was  
122 directed in the coronal plane and perpendicular to the mechanical axis of the tibia. The  
123 target sagittal MFT angle during stress testing was  $2^\circ$ , or  $2^\circ$  of flexion relative to maximum  
124 passive extension if there was a fixed flexion deformity. The magnitude of the applied  
125 stress was based on the perception of having reached a point where no further angular  
126 displacement was possible with manual load or until the patient indicated discomfort. The  
127 on-screen display of coronal angular displacement was not visible during testing to avoid  
128 operator bias and the sequence of varus-valgus stress was repeated twice. Finally, the lower  
129 limb was supported under the heel to measure coronal and sagittal MFT angles in  
130 maximum passive extension.

131 During TKA, the target mechanical lower limb alignment with the knee in extension was  $0^\circ$   
132 in both the coronal and sagittal planes. All implants were cemented PCL-retaining condylar  
133 knee replacements (CR Columbus<sup>®</sup>, BBraun Aesculap, Tuttlingen, Germany). All but one

134 of the knee joints were exposed using a medial parapatellar approach, the other approached  
135 laterally due to a large, fixed valgus deformity. IR trackers were secured to the distal femur  
136 and proximal tibia using bone fixation screws. Intraoperative knee alignment assessments  
137 were performed twice, on the native knee following initial surgical exposure (defined as  
138 pre-implant) and on the definitive implants after cementation (defined as post-implant), in a  
139 manner methodologically identical to the preoperative and postoperative clinical measures.  
140 The same clinician performed all clinic-based and intraoperative knee alignment measures  
141 but did not perform the TKA procedures. Statistical analysis was carried out using SPSS  
142 17.0 (IBM Corporation, Armonk, New York). Preoperative and pre-implantation intra-  
143 operative measures were assigned as osteoarthritic (OA) data, whilst post-implant  
144 intraoperative and postoperative clinic measures were defined as the prosthetic group. Data  
145 were defined as negative for varus alignment and negative for hyperextension. For  
146 variables where more than one measurement was taken the mean value was used. Data  
147 were assessed for normality using Kolmogorov-Smirnov test and paired t-tests were used to  
148 assess changes in alignment between different measurement conditions for OA and TKA  
149 knees. Analysis was done on a complete-case basis for each measurement condition.

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153 **Results**

154 Preoperatively there were no exclusions as non-invasive assessment was completed on all  
155 patients following recruitment. For intra-operative data collection, one patient had no data  
156 due to an error in the recording process and a second patient had no varus-valgus stress  
157 measurements due to the unavailability of the clinician to perform the manoeuvres. Post-  
158 operatively there was one case of deep infection requiring washout and exchange of the  
159 polyethylene tibial insert leading to exclusion of this patient from the trial. Therefore there  
160 were complete datasets for 31 patients pre-operatively, 29 intra-operatively and 30 post-  
161 operatively. For comparison of intra-operative and post-operative varus-valgus stress, the  
162 exclusion and missing data resulted in 28 paired measurements.

163 There was no statistical difference between clinical and operative measurements of  
164 unstressed coronal lower limb alignment for both OA and prosthetic knees (Table 1).  
165 However, for sagittal alignment there was a significant difference between the  
166 measurement conditions for both OA and prosthetic knees (Table 1). OA knees were in  
167 greater relative extension intraoperatively (mean  $-5.2^\circ$ ) compared to the extension seen in  
168 clinic. Prosthetic knees had an even greater tendency to more extension intraoperatively ( $-$   
169  $7.2^\circ$ ) compared to the relatively more flexed positions in the postoperative clinic.

170

171 For OA knees, both varus and valgus stress manoeuvres resulted in statistically greater  
172 angular displacements when performed intraoperatively (mean differences 1.5° more varus  
173 and 1.6° more valgus) compared to the clinic (Table 2). For prosthetic knees, valgus  
174 angular displacement was statistically greater intraoperatively, whereas for varus angular  
175 displacement the two conditions were not statistically different (Table 2).

176

## 177 **Discussion**

178 The purpose of this study was to compare clinical and operative knee alignment and laxity  
179 in patients undergoing total knee arthroplasty (TKA) to determine any differences due to  
180 measurement condition. The study showed that there was no difference in unstressed  
181 coronal mechanical femoral-tibial (MFT) angles for either OA or prosthetic knees.  
182 However, for sagittal alignment the knees were in greater extension intraoperatively. For  
183 OA knees, both varus and valgus stress manoeuvres had greater angular displacements  
184 intraoperatively whereas for prosthetic knees only valgus angular displacement was greater  
185 intraoperatively.

186 The fact that sagittal MFT angles were more extended intraoperatively for OA and  
187 prosthetic knees may have been due to the absence of muscle tone: in the clinical setting,  
188 muscular contraction could have potentially restricted the amount of knee extension. The  
189 removal of this muscular inhibition along with exposure of the knee possibly resulted in a  
190 more extended intraoperative position. Therefore, in spite of surgically correcting the pre-  
191 operative fixed flexion contractures to close to  $0^\circ$  intraoperatively, at the six week  
192 postoperative stage most patients were unable to achieve this degree of extension in the  
193 clinical setting, with the mean postoperative maximum extension only  $1^\circ$  more extended  
194 than the preoperative osteoarthritic measurement. This supports the widely-held belief that  
195 preoperative range of motion prior to TKA surgery is a major determinant of postoperative  
196 movement regardless of the degree of passive knee motion achieved intraoperatively.<sup>36,37</sup>  
197 The correction of preoperative fixed flexion deformities may therefore require release  
198 beyond a sagittal MFT angle of  $0^\circ$  to account for the tendency for the knee to adopt a more  
199 flexed position postoperatively. However, it is possible that flexion deformities at six  
200 weeks following TKA would improve over time as reported in previous studies<sup>38,39</sup> and so  
201 this requires longer follow up using this IR measurement technique. Until then, and in the  
202 absence of alternative evidence, the intraoperative target for flexion deformities should be  
203 correction to  $0^\circ$  with an emphasis on extension exercises in the early postoperative period.

204 For OA knees, varus and valgus angular displacements were statistically greater  
205 intraoperatively in comparison to the clinic setting. During preoperative clinical  
206 assessment, the limiting factor during stress testing was often the discomfort of the  
207 manoeuvre rather than the perception of a definitive end-point. Furthermore, muscular  
208 inhibition during stress testing was absent intraoperatively. Together with the effect of an  
209 open incision, we hypothesise that these differences resulted in 1.5° less angular  
210 displacement than would be expected intraoperatively for both varus and valgus stress  
211 manoeuvres. Since coronal angular displacement can form the basis of decision-making  
212 algorithms regarding soft tissue release during TKA surgery,<sup>25-29</sup> our results indicate that  
213 preoperative assessment is likely to underestimate the degree of intraoperative varus and  
214 valgus angular displacements by an average of approximately 1.5°. Following TKA, the  
215 valgus stress angulation was greater intraoperatively than in the clinic, whereas for varus  
216 angular displacement there was no significant difference between clinical and operative  
217 conditions. This may be due to differences in pain between varus and valgus stress  
218 manoeuvres, the latter placing strain on the more surgically traumatised medial tissues for  
219 the majority of knees. In addition, we hypothesise that contracture of the medial  
220 parapatellar wound as part of the normal healing process<sup>40</sup> may have added an additional  
221 restraint to valgus angulation of the knee.

222 The above arguments are also borne out with regards to the correlation coefficients between  
223 clinical and operative measures, pre and post TKA (Tables 1 and 2). Reassuringly, the  
224 correlations between clinical and operative measures was high prior to TKA, demonstrating  
225 reliability between the measures. Post TKA, the MFTA correlations decrease, reflecting the  
226 fact that, for coronal measures, the standard deviations are approaching the level of the  
227 repeatability of the measures, and for sagittal measures, the reappearance of flexion  
228 contracture postoperatively, irrespective of correcting to neutral alignment intraoperatively.  
229 With regards to the correlations under varus and valgus stress, the observed correlations  
230 may low due to the arguments above regarding pain, muscular inhibition and open-  
231 incisions.

232 We believe this is the first time that lower limb alignment has been quantified and followed  
233 through the TKA assessment and procedure using the same infrared tracking technology;  
234 the one difference in methodology being the attachment of the active trackers. In spite of  
235 the potential challenges to the registration process presented by the patient cohort, all  
236 subjects were successfully evaluated in the clinical setting with repeatable kinematic  
237 measurements providing further evidence for the effectiveness and stability of the tracker  
238 straps. Continued use of this IR system on a larger patient cohort over a longer period of

239 time may further enhance our understanding of the relationship between intraoperative and  
240 clinical knee kinematics.

241 Surgeons performing TKA surgery should be aware of the potential differences in  
242 alignment and laxity measured under different conditions and to adjust their aims  
243 accordingly. A coronal deformity that is fixed or only partially corrects with manual load in  
244 the preoperative clinic may fully correct on the operating table and therefore may influence  
245 choice of surgical approach or extent of soft tissue release performed. Intraoperatively, a  
246 knee that feels “tight” in the coronal plane is unlikely to become more lax over the first six  
247 weeks, whereas a knee that feels “loose” may well “tighten” over this same period.  
248 Nevertheless, appropriate ligament balancing should be performed intra-operatively and  
249 surgeons should not rely on postoperative tightening to achieve their surgical stability aim.  
250 In the sagittal plane, intraoperative correction of fixed flexion deformities to 0° may not be  
251 enough to overcome the tendency of the knee to adopt the preoperative flexed position.  
252 Failure to achieve full passive extension intraoperatively seems unlikely to result in a knee  
253 that will “stretch out” to 0° over the first six weeks post-surgery. These are fundamental  
254 considerations for the planning and follow-up of TKA patients and may influence the long  
255 term function and survival of implants.

256 In spite of this study having the potential to change clinical practice, there were several  
257 methodological limitations which may restrict the wider adoption of its findings. Whilst the  
258 surgical and clinical systems were the same make and model, marker fixation differences  
259 existed. The intra-operative accuracy and repeatability of the operative measures would  
260 potentially be better than the clinical measures, due to bone fixation of the markers: soft  
261 tissue movement has the potential to introduce unquantifiable error into the clinical  
262 measures. This may not be an issue, however, since the standard deviations of the  
263 measures, which would include inter-subject variation together with other experimental  
264 errors, are essentially equivalent for clinical and operative measures, suggesting that marker  
265 fixation difference did not manifest in heterogeneous error between the groups.  
266 Additionally, the varus and valgus stress measurements were performed by a single  
267 observer with no standardisation of the applied load. Therefore, it is possible that different  
268 angular displacements would have been achieved by other clinicians, although previous  
269 work has shown a high level of inter-observer agreement for this type of manoeuvre.<sup>31</sup> The  
270 majority of OA knees evaluated were varus aligned, which limits the application of our  
271 findings to valgus knees, particularly with larger deformities. The follow-up period of six  
272 weeks is likely to be too early to make an assessment of long-term laxity, but nonetheless

273 provides important and previously unreported information on knee behaviour at this post-  
274 operative stage.

## 275 **Conclusions**

276 This study has highlighted the dynamic nature of lower limb alignment and the potential  
277 variation in soft tissue envelope laxity based on the condition in which it is evaluated.  
278 Surgeons performing TKA surgery should be aware of the potential differences in  
279 alignment and laxity measured under different conditions and to adjust their aims  
280 accordingly. Continued use of the novel IR tracking technology used in this study may  
281 enhance our understanding of knee kinematics and could provide a new avenue for progress  
282 in the field of arthroplasty.

283

## 284 **Conflicting interests**

285 JVC was employed to carry out this work by the Golden Jubilee National Hospital using a  
286 grant from BBraun Aesculap. FP has licences and patents with BBraun Aesculap.

287

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		<b>OA (n=31)</b>	<b>Prosthetic (n=29)</b>
<b>Supine coronal MFT angle (°)</b>	<b>Clinical</b>	-2.5 (5.7)	-0.7 (1.4)
	<b>Operative</b>	-2.0 (5.7)	-0.2 (1.1)
	<b>Difference</b>	0.5 (2.8)	0.5 (1.4)
	<b>p value</b>	0.3	0.08
	<b>r</b>	0.88	0.36
<b>Supine sagittal MFT angle (°)</b>	<b>Clinical</b>	7.7 (7.1)	6.7 (5.1)
	<b>Operative</b>	2.5 (7.7)	-0.5 (3.3)
	<b>Difference</b>	-5.2 (4.3)	-7.2 (4.7)
	<b>p value</b>	<0.001	<0.001
	<b>r</b>	0.83	0.44

406

407

408 Table 1: Comparison of clinical and operative unstressed alignment for OA and prosthetic  
 409 patient groups. Values are groups means with the SD in brackets. Negative values indicate  
 410 varus in coronal plane and hyperextension in sagittal plane. r values are Pearson correlation  
 411 coefficients between the clinical and operative measures.  
 412

413

		<b>OA (n=30)</b>	<b>Prosthetic (n=28)</b>
<b>Varus angular displacement (°)</b>	<b>Clinical</b>	-3.8 (1.5)	-4.3 (1.1)
	<b>Operative</b>	-5.3 (2.2)	-4.1 (1.4)
	<b>Difference</b>	-1.5 (2.4)	0.3 (1.4)
	<b>p value</b>	0.002	0.3
	<b>r</b>	0.20	0.36
<b>Valgus angular displacement (°)</b>	<b>Clinical</b>	3.3 (1.6)	2.8 (0.8)
	<b>Operative</b>	5.0 (1.6)	3.7 (1.3)
	<b>Difference</b>	1.6 (1.6)	0.9 (1.3)
	<b>p value</b>	<0.001	0.002
	<b>r</b>	0.51	0.24

414

415 Table 2: Comparison of clinical and operative coronal laxity for OA and TKA patient  
 416 groups. Angular displacement is from unstressed resting position. Values are groups means  
 417 with the SD in brackets. r values are Pearson correlation coefficients between the clinical  
 418 and operative measures.  
 419