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1 *Original Article*

2

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° $p<0.001$, prosthetic 7.2° $p<0.001$).
31 For osteoarthritic knees, both varus and valgus stress manoeuvres had greater angular
32 displacements intraoperatively by a mean value of 1.5° for varus ($p=0.002$) and 1.6° for
33 valgus ($p<0.001$). For prosthetic knees, only valgus angular displacement was greater
34 intraoperatively (0.9° , $p=0.002$).

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.

38

39

40 **Keywords**

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

43

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 survival¹⁻⁴ and poorer knee
56 function.^{5,6} However more recent controversy about the effect of knee alignment on long
57 term TKA survivorship⁷⁻⁹ 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.^{10,11} Nonetheless, a generally accepted supine intraoperative target is
62 the restoration of full passive extension.^{10,12}

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.^{13,14} 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,¹⁵ 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 poor¹⁶ and this has led to
71 quantitative adjuncts such as stress radiographs¹⁷ which, as with standard AP knee "short
72 view" and hip-knee-ankle "long leg" radiographs, are susceptible to limb positioning
73 errors.^{18,19}

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 laxity²⁰⁻²² to within 1° or 1mm.^{23,24} 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.²⁵⁻²⁹ 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.³⁰⁻³⁵

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 measures³⁰.

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° , or 2° 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°
132 in both the coronal and sagittal planes. All implants were cemented PCL-retaining condylar
133 knee replacements (CR Columbus[®], 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.

150

151

152

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°) compared to the extension seen in
168 clinic. Prosthetic knees had an even greater tendency to more extension intraoperatively ($-$
169 7.2°) 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° 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° 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.^{36,37}
197 The correction of preoperative fixed flexion deformities may therefore require release
198 beyond a sagittal MFT angle of 0° 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^{38,39} 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° 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,²⁵⁻²⁹ 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 process⁴⁰ 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.³¹ 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
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287

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290

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292

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

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