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**ACCURACY OF IMAGE-FREE COMPUTER NAVIGATED TOTAL KNEE
ARTHROPLASTY IS NOT COMPROMISED
IN SEVERELY DEFORMED VARUS KNEES**

20 Abstract

21 In severe varus knee deformity, image-free computer navigated total knee
22 arthroplasty (TKA) may result in a malaligned knee. The aim of this study was to
23 compare the results of 17 severe varus knees ($\geq 20^\circ$) and 81 varus knees ($< 20^\circ$) that
24 underwent image-free computer navigated TKA and analyze postoperative malalignment.
25 Computer navigated TKA was performed according to standard protocol, and component
26 angles and mechanical axes were evaluated postoperatively with weight bearing
27 full-length standing radiographs. All severe varus knees were corrected to within 3° of
28 neutral lower limb alignment despite having a mean preoperative varus deformities of
29 22.4° . Neutral alignment was obtained in 88.9% of the varus group (mean preoperative
30 varus deformity of 11.7°), without significant difference between the two groups. No
31 significant difference was found in either the femoral or tibial component angles, or in the
32 frequency of complications. Severity of varus deformity did not affect the accuracy of
33 image-free computer navigated TKA.

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39 Introduction

40 Large varus deformities may be predisposing factors to suboptimal component
41 alignment by conventional total knee arthroplasty (TKA) and there are suggestions that
42 it is difficult to correctly align severe knee deformities with computer navigated TKA [1-3].
43 The success of total knee arthroplasty is determined by accurate component placement
44 and prosthetic knee component placement within 3° varus/valgus of the mechanical axis
45 (MA) is important since it reduces the risk of early aseptic loosening and component
46 failure [4-8]. While some recent literature has questioned the importance of postoperative
47 alignment in TKA longevity, generally the alignment goals of TKA is to provide a neutral
48 mechanical axis [9-11]. Computer-assisted navigation in joint surgery has been developed
49 to increase accuracy of component placement and lower limb alignment and improve
50 postoperative survival rates of implants. Introduction of computer-assisted navigation in
51 total knee arthroplasty (TKA) has reduced bone-cutting and soft tissue release errors to
52 improve lower limb alignment to achieve good long-term outcomes [12-14]. However,
53 whether component placement accuracy and lower limb alignment is compromised by the
54 degree of knee deformity with image-free computer navigated TKA has not been
55 established. The purpose of this study was to assess the accuracy of image-free computer
56 navigated TKA in varus and severe varus knees by comparing postoperative component
57 alignment and lower limb alignment results in patients undergoing TKA. We

58 hypothesized that there is no difference in component alignment and mechanical axes
59 between varus and severe varus knees in these patients after surgery.

60

61 Materials and Methods

62 Between 2008 and 2009, 112 primary TKAs were performed at two institutions. Of
63 these, 108 knees had preoperative varus alignment and underwent TKA using an
64 image-free computer navigation system (OrthoPilot™ software version 4.2, B.Braun
65 Aesculap, Tuttlingen, Germany). Six knees were excluded for lack of high quality full
66 length standing preoperative and postoperative radiographs. Four knees were excluded
67 for less than 2 years of clinical follow up. This left 98 knees, consisting of 65 women and
68 nine men with a mean age of 74.1 years (range 54-82 years) available for review (Table 1).
69 Exclusion criteria were knee joint deformity due to rheumatoid arthritis, valgus OA of the
70 knee, patients with severe restriction in the range of motion of the hip, and history of
71 TKA revision surgery.

72 For determining the severity of knee deformity, degree of varus deformity was
73 calculated by examining lower limb alignment in the coronal plane on full-length weight
74 bearing standing radiographs preoperatively (Fig 1A,B), then categorized into two groups.
75 The degree of knee deformity was obtained by measuring the acute angle between the
76 femoral mechanical axis and the tibial mechanical axis. The mechanical axis of the femur

77 was defined as the line connecting the center of the femoral head to the highest point of
78 the intracondylar notch. The tibial axis was defined as the line connecting the midpoint of
79 the tibial spines to the center of the tibial plafond [15]. The severe varus group (SV group)
80 was defined as having greater than or equal to 20° of varus deformity while varus knee
81 group (V group) was defined as having less than 20° of varus deformity. The mean varus
82 deformity for the SV group was 22.4°±2.0° (range 20°-27°), and 11.7°±4.5° (range 1°-19°)
83 for the V group.

84 All TKAs were performed with the same computer navigated system under the
85 supervision of one of two senior surgeons (Y.I. and H.O.), both with extensive experience
86 in both conventional TKA and computer navigated TKA. All components in this study
87 were implanted with e.motion or Columbus Total Knee System (B.Braun Aesculap,
88 Tuttlingen, Germany) using OrthoPilot™ ver. 4.2 software (B.Braun Aesculap, Tuttlingen,
89 Germany). A total of 97 TKA implants of cruciate retaining design were used versus one
90 posterior stabilizing design, implanted due to PCL insufficiency in this patient.

91 Image-free computer navigated TKA was performed according to standard protocol. A
92 medial parapatellar approach was performed to expose the knee. After knee joint
93 exposure, tracker diodes were positioned and fixed to the proximal tibia and distal femur.
94 After registration of kinematics data, anatomical landmarks were registered, followed by
95 ACL and menisci removal. The tibia cutting block was positioned on the tibia with a

96 varus/valgus and anterior/posterior slope of 0°. The tibia was cut perpendicularly to the
97 tibial mechanical axis and the navigation computer confirmed that alignment did not
98 change significantly. All bone spurs of the distal medial and lateral femur and the
99 proximal medial tibia were removed.

100 With the knee at full extension, the medial soft tissues of the knee were released first,
101 then the overall soft tissues balance was adjusted and measured for straight alignment.
102 The medial and lateral sides of the distractor (Distraction clamp, B.Braun Aesculap,
103 Tuttlingen, Germany) were separated at equal forces. The gap distance was then
104 analyzed with the navigation computer. When there was a discrepancy between the gaps
105 at extension and flexion, some looseness of the joint at flexion was permitted. However,
106 while the lateral side was allowed some leeway, the medial side was made to be tight.
107 Release of medial soft tissues was performed based on the procedure described by Clayton
108 et al [16]. First, the deep layer of the medial collateral ligament (MCL) was released,
109 removing any osteophytes from the medial tibia and femur as required. Second, the
110 superficial MCL was released, followed by the gradual release of the tibial insertion of the
111 semimembranosus if required. Third, the pes anserine tendons were detached from the
112 tibia if medial tightness further remained. This procedure was performed gradually such
113 that the medial and lateral gap difference was less than 3 mm at both full extension and
114 90° flexion [17,18]. The amount of femoral cut was determined by adjusting the femoral

115 component size, rotation angle, and the insert size such that the joint gap was
116 rectangular at extension and flexion.

117 Rotational alignment of the tibial plateau was corrected using ventral marking.
118 Internal rotation was avoided in all cases. Tibial and femoral trial implants were used to
119 check component angles and lower limb alignments in flexion and extension before final
120 component implantation. None of our patients required bone augmentation during
121 surgery.

122 Postoperatively, femoral component angle (FCA), tibial component angle (TCA), and
123 MA were examined on weight bearing full-length standing radiographs (Fig 1C,D). FCA
124 was defined as the angle between a line drawn from the center of the femoral head to the
125 center of the component and a line drawn across the femoral condyles in standing coronal
126 plane radiographs. TCA was defined as the angle between a line drawn from the center of
127 the ankle mortise to the center of the component and a line drawn across the tibial
128 component surface. The mechanical axis in this study was defined as 180° subtracted
129 from the sum of FCA and TCA ($MA = FCA + TCA - 180^\circ$). A positive value indicated varus
130 angle, while a negative value indicated a valgus angle.

131 Statistical analysis was performed using the SPSS package for Windows version 12.0
132 (IBM SPSS, Tokyo, Japan). The arithmetic mean, standard deviation, and distribution
133 were determined for each measure for the two groups. Shapiro-Wilk test was first

134 performed to ensure a normal distribution of data. The Mann-Whitney U test was then
135 used to compare data of the V and SV groups, with p values less than 0.05 being
136 statistically significant. Significant difference of postoperative complications between V
137 and SV groups was calculated using Pearson's χ^2 test.

138

139 Results

140 The SV group consisted of 17 knees (15 female knees, two male knees, mean age of
141 75.9±4.1 years) and the V group consisted of 81 knees (72 female knees, nine male knees,
142 mean age of 73.4±5.4 years) (Table 2). BMI as a factor for indication of surgical complexity
143 and difficulty was not significantly different between the two groups (p=0.22). Average
144 FCA for the SV group was 90.8°±1.3° while the V group was 90.8°±2.0°, and difference
145 between the groups was not significant (p=0.77, Fig 2). There were two outliers at 4°
146 varus and 4° valgus in the V group. Average TCA for the SV group was 90.2°±1.1° while
147 the V group was 90.3°±1.3°, and difference between the groups was not significant
148 (p=0.84, Fig 3). One outlier was observed at 4° varus in the V group. MA within 3° of
149 neutral lower limb alignment in the SV group was 100% with all 17 knees and the V
150 group was 88.9% with 72 (Fig 4). There were nine outliers, seven at 4° and two at 5° varus
151 angles.

152 For postoperative complications, we looked for surgical site infection, component

153 loosening, component failure, and varus/valgus stress instability. With a minimum of two
154 years of follow-up period, there were three complications for the V group but no
155 complications for the SV group. Complications for the V group included one case of
156 superficial dermal infection around the operated knee at three months, two cases of
157 mediolateral instability at 22 and 30 months (both less than 10°) postoperatively.
158 Pearson's χ^2 test indicated that these complications occurred by chance alone ($p=0.65$)
159 and that there is no significant difference in the occurrence of complications between SV
160 and V groups when undergoing computer navigated TKA.

161

162 Discussion

163 This study focused on the magnitude of preoperative varus alignment on the efficacy
164 of image-free computer navigated TKA, with particular emphasis on severe varus
165 deformity greater than or equal to 20°. In this series of 98 computer navigated TKA cases,
166 all severe varus knees were corrected to within 3° of MA despite having average
167 preoperative varus deformities of 22.4° (standard deviation of 2.0), which may lead to
168 longer implant longevity and better patient outcomes. The degree of preoperative varus
169 deformity did not affect component placement and MA in TKA performed with image-free
170 computer navigation.

171 Improved component placement in varus knees through computer navigated surgery

172 has been verified previously by other authors and better radiographic results were
173 obtained in computer-assisted TKA than with conventional surgery techniques [19-23].
174 Obtaining neutral MA in TKA is more difficult in patients with large knee angle
175 deformities because it requires extensive soft tissue balancing. However, our results
176 suggest that image-free computer navigated TKA can facilitate tissue balancing and
177 component placement to attain neutral alignment in severe varus knees if step-by-step
178 soft tissue release and navigation procedures are carefully followed. Proper identification
179 of landmarks and their registration, and accurate soft tissue balancing is mandatory for
180 appropriate component placement and limb alignment [24]. Image-free computer
181 navigated TKA registers anatomical landmarks and kinematics data to apply an
182 algorithm to decide the center of joint motion and lower limb alignment for more accurate
183 MA identification [7]. With image-free computed navigation, it is relatively easy to correct
184 lower limb alignment without being influenced by local bone morphology as well as being
185 able to perform soft tissue balancing during flexion and extension positions of the knee.
186 Furthermore, expensive imaging and time consuming preoperative planning is not
187 required, cutting both cost and time compared to other computer navigated techniques
188 [24].

189 Some recently published studies question the importance of a neutral mechanical
190 alignment within $0^{\circ}\pm 3^{\circ}$ [9-11]. These studies have found that neutral mechanical axis

191 alignment did not improve component survival rate or that the results remain unproven,
192 and consequently a wider margin of alignment did not compromise component longevity.
193 There is also the concept of “constitutional varus” in which a significant number of
194 mature healthy adults have a natural mechanical alignment greater than 3°. Restoring
195 neutral alignment in these patients may be abnormal and undesirable, although it has no
196 correlation with patients with knee OA or patients who have undergone TKA [25].
197 However, further research is required to support these hypotheses.

198 Studies have been performed to investigate the cause of component malalignment in
199 computer-assisted TKA surgeries. Takasaki and coworkers used a tibial bone model to
200 study the alignment accuracy of an image-free navigation system in severely varus
201 deformed knees [1]. Their results suggest that image-free navigation has a tendency to
202 cut the tibia in the varus. The preoperative tibial mechanical axis may be registered in
203 varus compared to the postoperative tibial mechanical axis due to tibial deformities as
204 suggested by conventional TKA studies [26-28]. The image-free navigation system may
205 not precisely estimate the bone morphology of severely deformed knees, which may cause
206 the tibial component to be implanted in the varus position [1]. However, their study
207 involved deformity only in the tibia with none in femur. Furthermore, they used a
208 different navigation system which utilized the surgeon’s registration point of the knee
209 center instead of using the theoretical knee center determined by the computer not only

210 by registering several anatomical landmarks but also by registering kinematics data, as
211 in our study. The different calculated mechanical angles may account for the different
212 outcomes of the two studies. In our current study, there was no tendency for varus
213 malalignment, even when only comparing TCA of the S and V groups.

214 The present study has some limitations. First, component angles and lower limb
215 alignment were evaluated on full-length standing radiographs in the coronal plane only
216 and did not assess the effect of rotation on component or leg alignment. However, each
217 radiograph was taken with the patellae pointing straight ahead with the feet internally
218 rotated at approximately 20°, minimizing the amount of rotation on plain film. Second,
219 final lower limb alignment was slightly worse than other navigation studies, but this may
220 be attributed to multiple operators with various degrees of experience with the
221 image-free navigation system although all procedures were performed or supervised by
222 one of the two extensively trained senior authors. Improvements in registration error can
223 be attained through further experience with the navigation system and by developing a
224 consistent technique for registration, which may improve our results with data attained
225 at later dates [29]. Despite these limitations, we believe that the present study shows
226 that, with some care during surgery, the severity of preoperative varus deformity does not
227 affect alignment of implant components and lower limb alignment when performing
228 image-free computer navigated TKA.

229 In conclusion, our study shows that good component and lower limb alignment can be
230 achieved with severe varus knees when performing TKA with an image-free computer
231 navigated system. Consistent correction of knee alignment to within $\pm 3^\circ$ of MA achieved
232 with image-free computer navigated TKA suggest that the severity of varus deformity
233 does not affect component placement accuracy. Better component placement and soft
234 tissue balancing of the knee with an image-free navigation system may decrease
235 component wear, maximize component longevity, and improve functional outcome.
236 However, further long term studies are needed to validate these hypotheses.

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Figure Legends

Fig 1. A 67 year old female with advanced osteoarthritis of the left knee.

A: Full-length standing radiograph revealing severe varus knee of 23°.

B: Short-film radiograph reveals asymmetric joint space narrowing, osteophyte formation, and medial subchondral sclerosis, typical of knee OA.

C: Postoperative weight bearing full-length standing radiograph shows FCA of 89° and TCA of 90°, MA=89°+90°-180°=-1° (a slightly valgus alignment).

D: A magnified radiograph of the knee components. Careful component placement and soft tissue balancing results in MA within 3° of neutral limb alignment.

Fig 2. Femoral Component Angle (FCA).

Angles between dashed lines indicate $\pm 3^\circ$ from neutral limb alignment. Grey = varus group, black = severe varus group.

Fig 3. Tibial Component Angle (TCA).

Angles between dashed lines indicate $\pm 3^\circ$ from neutral limb alignment. Grey = varus group, black = severe varus group.

Fig 4. Mechanical Axis (MA).

Angles between dashed lines indicate $\pm 3^\circ$ from neutral limb alignment. Grey = varus group, black = severe varus group.

Table 1. Preoperative Demographic Data.

A summary of patient data of severe varus and varus groups.

MA = mechanical axis; SD = standard deviation

Values are shown as mean \pm SD (range) or n (%) where appropriate.

Table 2. Operative Data.

A Summary of Results for Severe Varus and Varus Knees Undergoing Image-free Navigated TKA.

CR = cruciate retaining; PS = posterior stabilizing; SD = standard deviation; FCA = femoral component angle; TCA = tibial component angle; BMI = body mass index; MA = mechanical axis

Values are shown as mean \pm SD (range) or n (%) where appropriate.

Figure 1A



Figure 1B



Figure 1C

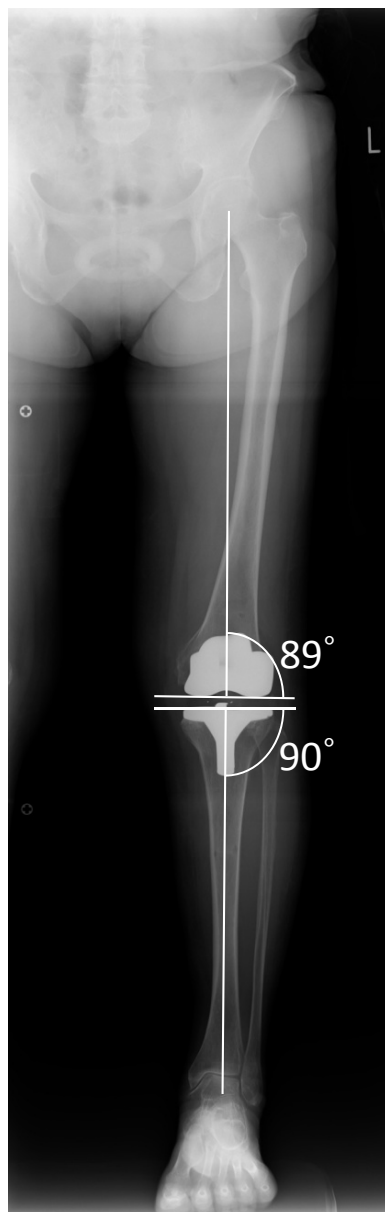


Figure 1D



Fig 2

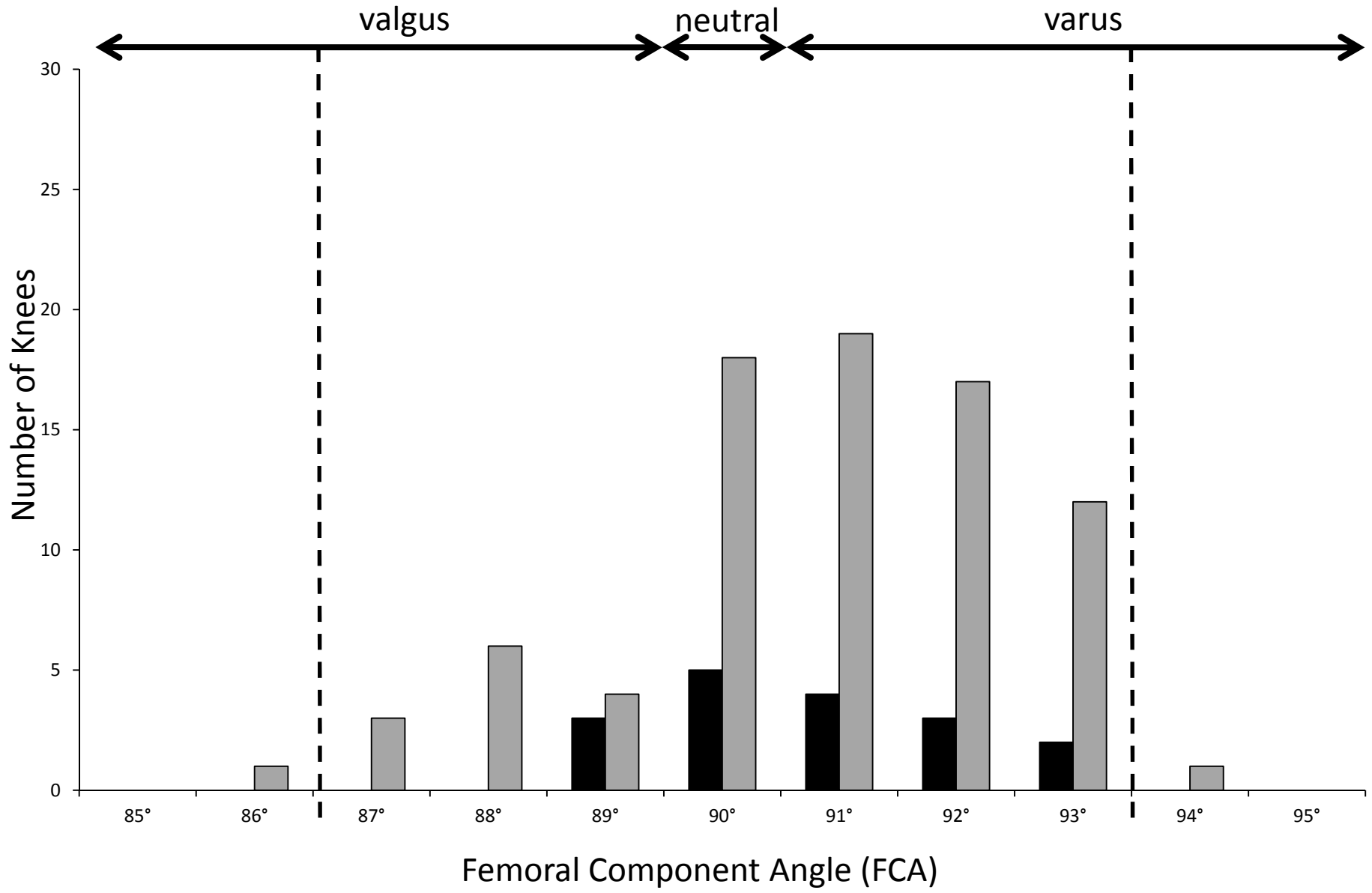


Fig 3

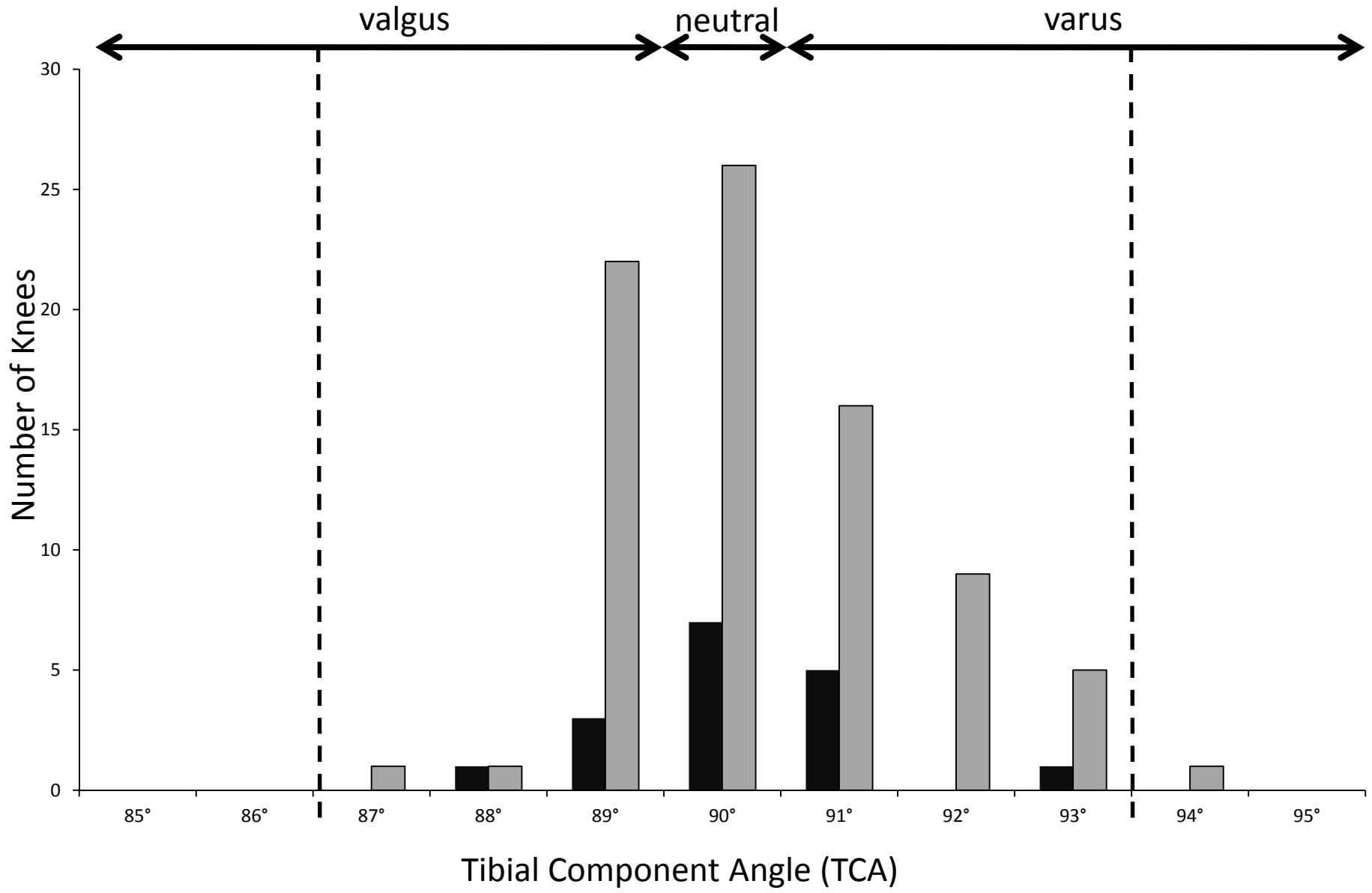


Fig 4

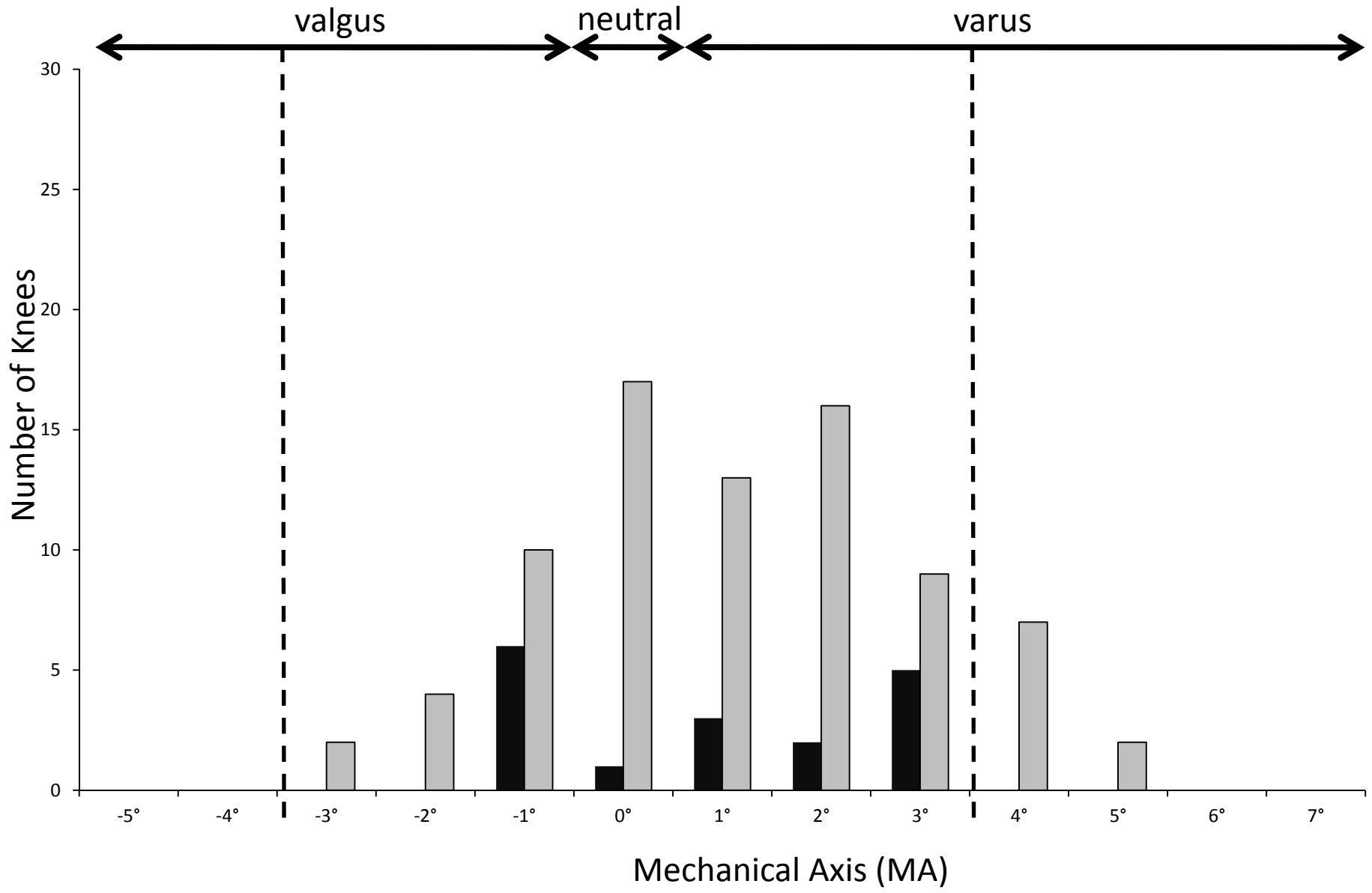


Table 1

	Severe Varus Knees	Varus Knees
Number of knees	17	81
Female knees	15	72
Male knees	2	9
Mean age	75.9\pm4.1 yrs	73.4\pm5.4 yrs
Avg FCA	90.8$^{\circ}$ \pm1.3$^{\circ}$	90.8$^{\circ}$ \pm2.0$^{\circ}$
FCA >3$^{\circ}$ or <-3$^{\circ}$	0	2
Avg TCA	90.2$^{\circ}$ \pm1.1$^{\circ}$	90.3$^{\circ}$ \pm1.3$^{\circ}$
TCA >3$^{\circ}$ or <-3$^{\circ}$	0	1
MA within \pm3$^{\circ}$	17 knees (100%)	72 knees (88.9%)
Complications	0 (0.0%)	3 (3.7%)