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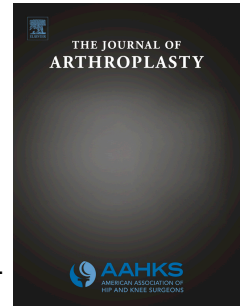
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**Morphometric Tibial implant decreases posterior overhang rate and improves Clinical outcomes.
Results of a prospective matched controlled study.**

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ACCEPTED MANUSCRIPT

44 Background:

45 Tibial implant's positioning in total knee arthroplasty (TKA) requires a compromise between
46 implant's rotation and bone coverage. We hypothesized that morphometric tibial trays (MTT)
47 would improve implants positioning and clinical outcomes as compared to symmetrical tibial
48 tray (STT).

49 Methods:

50 Thirty-three patients were included prospectively according to the following criteria: age from
51 18 to 85 years, BMI <35kg.m⁻², postero-stabilized cemented TKA performed for primary
52 arthritis. Patients were matched on age, gender, BMI and Preoperative IKS scores and KOOS
53 pain score, in a 1:1 fashion with patients from a prospectively collected database receiving a
54 STT TKA. Tibial implant's rotation, bone coverage and the percentage of patients with a
55 posterior overhang (PO) > 3mm were assessed using computerized-tomography. The
56 international knee score (IKS) and the knee injury and osteoarthritis outcome score (KOOS))
57 were compared at 3 years follow-up.

58 Results:

59 Bone coverage (90% vs 88%, $p=0.07$) and rotation (mean difference $0.7\pm 3^\circ$; $p=0.69$) were
60 not different between the two groups. The percentage of patient with a PO was lower in the
61 morphologic group (2/33 vs 14/33, $p=0.01$, OR = 10.3 [2.12-50.24]). Functional scores were
62 superior in the morphometric group: IKS (mean difference 20 ± 21 points; $p=0.0005$) mainly
63 due to a difference in the IKS pain subscore (mean difference 11 ± 15 points; $p=0.0002$).
64 According to the multivariate analysis, MTT had a positive, independent effect on IKS pain
65 ($p=0.006$) and KOOS pain Subscores ($p=0.03$) at last follow-up.

66 Conclusion:

67 The use of a MTT in TKA did not modify tibial implant position in the axial plane, however,
68 it decreases implant's posterior overhang and improves functional scores. The clinical
69 improvement was mainly found on pain scores.

70

71 **Keywords :** total knee arthroplasty; morphometric; symmetric; tibial tray; comparative study

72 INTRODUCTION.

73 Many factors are involved in the clinical results of total knee arthroplasty (TKA) : 3
74 dimensional placement of components, ligament balance, adequate perioperative management
75 [1-3]. The frontal and sagittal positioning of the implants follows rather clear rules even if
76 questions persist [4]. In the axial plane, positioning objectives are often more difficult to
77 obtain intraoperatively for both the femur and the tibia, while axial positioning errors will
78 have a significant impact on the knee flexion and function and on the survival of the implants
79 [5-7]. An error in the rotational positioning of the tibial tray can lead to stiffness,
80 patellofemoral pain or posterolateral conflict with the soft tissues in case of an oversized tibial
81 component or posterior overhang [8]. The latter can happen with symmetrical trays when
82 setting the adequate rotation of the tibial implant [9-13]. Conversely, a too small tibial
83 component is at risk of early loosening due to insufficient cortical support [14]. With a
84 symmetrical tibial tray, due to the anatomical asymmetry of the tibial plateau between the
85 medial and lateral compartments, compromises in size and rotational positioning might have
86 to be done intra-operatively [15-16]. To optimize rotational-coverage ratios and limit the
87 potential conflicts with the soft-tissues, new designs of tibial implants have been developed
88 using large anatomical data-bases and specific software simulating bone cuts. Thus,
89 morphometric trays have been designed to perfectly adapts not only to the morphology of the
90 proximal tibial plateau, but also to its dimensions. Recent in vitro studies, using positioning
91 simulations of the tray on the basis of CT-scans, demonstrated that a morphometric tray
92 allows an optimum rotational positioning, while optimizing the tibial coverage without
93 causing any posterolateral conflict with the soft tissues [15,17,18]. To confirm these in-vitro
94 observations, we sought to evaluate in vivo the potential radiological and clinical benefits of
95 these new design of tibial trays. It was our hypothesis that the use of a morphometric tibial
96 component can improve the prosthetic positioning and consequently the clinical results at a
97 minimum follow-up of three years.

98 Therefore, we aimed to compare: 1) the clinical and radiological results of two different
99 designs of tibial components of the same company, one symmetrical and the other called
100 morphometric. Our secondary objective was to compare the clinical outcomes between
101 subgroups regarding tibial tray positioning and prosthetic overhang.

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106 **MATERIALS AND METHODS.**

107 After institutional review board approval, from a prospectively collected database (including
108 1231 patients undergoing knee arthroplasty in our department), a cross sectional study
109 identified 403 patients who underwent primary cemented morphometric tibial tray (MTT)
110 knee arthroplasty between January 2012 and December 2013. Then 33 patients were selected
111 during a matching process creating a control group of patients who received primary
112 cemented symmetrical tibial tray (STT) TKA.

113 Inclusion criteria were: 1) $18 < \text{age} < 85$ years-old the day of surgery, 2) TKA performed for
114 primary arthritis or osteonecrosis of the knee. Patients with post-traumatic knee osteoarthritis
115 or with a history of prior surgery on the homolateral knee were excluded. Range of motion
116 below 0° to 100° (extension to flexion), or personal history of trauma, sepsis, tumor,
117 inflammatory or skeletal disease (that could influence functional outcomes) were also
118 exclusion criteria. Matching criteria were: age (± 5 years), gender, Body Mass Index (± 3
119 kg.m^{-2}), preoperative International Knee society objective and subjective score as well as
120 KOOS pain subscores (± 5 points) (Table1).

121 Every patient from the MTT group received a cemented metal-backed fixed-bearing
122 Morphometric prosthesis (Persona®, Zimmer; Warsaw, IN, USA) and every patient from
123 STT group received a Symmetric prosthesis (LPS ® Flex, Zimmer; Warsaw, IN, USA). All
124 surgeries were performed by the two senior authors using the same previously described
125 technique [19]. The same perioperative protocol for pain, blood management and
126 rehabilitation was used in both groups [20].

127 Clinical and standard radiographic follow-up was completed at 3 months, 6 months, one year
128 and every year thereafter. Clinical outcomes were measured using the knee injury
129 osteoarthritis outcome score (KOOS) [21] and international knee society scoring system (IKS)
130 [22]. Standardized weight-bearing short anteroposterior (AP) and true lateral radiographs
131 were taken pre-operatively, post-operatively and at last follow-up. Radiological evaluation
132 was done according to the Knee Society radiographic evaluation and scoring system.
133 Changes in alignment and wear of the components were analyzed comparing the angles of the
134 first and last available radiographs. All radiographs were examined for progressive
135 radiolucencies as defined by Ewald [23] by two of the authors not involved in the surgical
136 interventions.

137 A sub-millimetric CT scan with protocol for attenuation of metal artifacts was performed at a
138 minimum follow-up of three months after TKA. Images were analyzed using the HOROS™
139 medical imaging reader (Horos Project, LPGL 3.0) and Mimics® software (Materialize®,
140 Leuven, BELGIUM) to calculate:

141 ***Tibial Tray axial plane positioning (TTP)***

142 TTP was defined by the angle between the anteroposterior axis of the tibial implant
143 and the antero-posterior axis of the tibial plateau. The latter was defined by the line
144 connecting the medial third of the anterior tibial tuberosity to the insertion of the posterior
145 cruciate ligament, as described by Insall [24]. The anteroposterior axis of the prosthesis was
146 marked differently according to the shape of the implant. In the symmetrical group, the axis
147 was represented by the line perpendicular to the posterior border of the component, passing
148 through its middle [25]. In the morphometric group, the anteroposterior prosthetic axis, was
149 estimated by the line passing through the middle of the anterior plane and the posterior "H"
150 (dividing the posterior notch of the prosthesis in two) [15] (Figure 1). An angle of rotation of
151 the implant between -1° and 1° was defined as "neutral". An angle of rotation between -5°
152 and 5° was defined as "optimal" [6,10]. Outside from this range implants were considered as
153 "outliers".

154 **Tibial Bone Coverage (TBC)**

155 TBC of each knee was measured by subtraction of the surface of the tray from the surface of
156 the tibial cut. The surface of the tibial cut was defined as the first distal section after the
157 absence of cement under the tibial base (Figure 2). The surface of the implant was secondarily
158 marked on a section passing through the thickness of the tibial prostheses. (Figure 3).

159 **Prosthetic overhang (PO)**

160 PO was defined as the distance between the postero-lateral cortex of the tibial section and the
161 postero-lateral edge of the prosthetic implant. A positive value was attributed to an
162 overlapping implant, a negative value to an implant within the tibial plateau. A value greater
163 than +3mm was considered unsatisfactory [16]. Intra and interobserver reproducibility
164 calculation assessed on the first 20 patients included (10 MTT and 10 STT) are presented
165 table 2.

166

167 ***Statistical Methods***

168 Data are presented as mean values with ranges. Chi square tests were used to compare binary

169 variables (demographic datas, complication rates) and two-sample (paired) t tests to compare
170 independent variables (functional scores) in the two groups. Wilcoxon test was used for
171 subgroup analysis. Regarding our primary outcome with our available sample size and
172 postoperative score standard deviation, this study had 80% power to detect a difference >8
173 points out of 100 on the KOOS subscore or IKS objective/subjective Score with a $p < 0.05$
174 level. As the Minimal Clinical Important Difference (MCID) of the KOOS score have been
175 described to be 8 to 10 points [26], our sample size was sufficient to detect potential relevant
176 differences between MTT and STT patients regarding this clinical parameter. A post hoc
177 analysis confirmed that our study was able to detect coronal position difference $> 3^\circ$ between
178 the two groups, with a power of 80% and $p < 0.05$. Statistical analyses were performed with
179 use of SPSS software (IBM; Armonk, New York).

180

181

182 **RESULTS.**

183

184 At a mean follow-up of 45 months (minimum 37 months, maximum 62 months), all
185 postoperative clinical scores improved in both groups. However, the results were significantly
186 superior for all components of the IKS score in the morphometric group compared to the
187 symmetric group (Table 3). No difference was found between groups for the short version of
188 the KOOS score and the maximum flexion of the operated knee. The overall IKS score and its
189 pain component were statistically higher in the morphometric group after multivariate
190 analysis (Table 4)

191 Tibial implants were positioned with a mean external rotation of 4.9° (MTT) vs. 4.2° (STT: p
192 = 0.69) relative to the Insall line (Table 5). TT was positioned in internal rotation (mean
193 value: $-4.4 \pm 3.2^\circ$) in 5 cases in the morphometric group, and in 5 cases in the control group
194 ($-5.3 \pm 2.6^\circ$ $p = 0.91$). According to the definition of the implant's optimal rotation angle, 15
195 patients were outliers in the morphometric group versus 18 in the symmetric group ($p = 0.95$).
196 Regarding TBC 90 \pm 4% of tibial bone was covered in the MTT group versus 88 \pm 3% STT
197 group ($p = 0.07$). The rate of overhang was significantly higher in the STT group with 6% of
198 MTT (2/33) positioned with a posterolateral overhang > 3 mm versus 39% (13/33) in STT
199 group ($p = 0.001$). Significant difference regarding IKS pain score and mini KOOS was found
200 in favor of the overhang < 3 mm subgroup vs the overhang > 3 mm subgroup with respectively

201 45.1 +/- 9.1 vs 35.7 +/- 14.4, p=0.44 and 23.7 +/- 8.3 vs 17.3 +/- 11.2, p=0,02. No clinical
202 difference was found between subgroups regarding TTP.

203

204

205 **DISCUSSION.**

206

207 Tibial component malrotation can be a cause of pain and limited flexion after TKA
208 in the absence of infection or aseptic loosening [11,27]. Poor rotation of the tibial component
209 can result in aberrant patellar tracking [27,29] limited range of knee flexion and early revision
210 surgery [29]. Optimal rotational positioning of the tibial component remains challenging [30].
211 Numerous tools including computer assistance have been developed to try to achieve the ideal
212 positioning of the implants, with however limited results in the axial plane [31-33]. In the
213 other hand using symmetrical tibial tray, implants' axial positioning often requires a
214 compromise between optimal rotation and bone coverage [15,16] and thus design
215 modification might represent a new approach to improve TKA positioning. It was our
216 hypothesis that the use of a morphometric tibial component can improve the prosthetic
217 positioning and consequently the clinical results at a minimum follow-up of three years.
218 Therefore, we aimed to to compare: 1) the clinical results as measured by the new
219 International Knee Society Score (IKS) and Knee injury and Osteoarthritis Outcome Score
220 (KOOS)), and 2) the radiological results as measured by the rotation, bone coverage and
221 posterolateral overhang on the CT scan of two different designs of tibial components of the
222 same company, one symmetrical and the other called morphometric. Our results partially
223 confirm our hypothesis as the results of our study have shown that the use of a new generation
224 of morphometric tibial tray in TKA enabled to reduce postero-lateral overhangs without any
225 compromise on axial rotation with better functional results at a minimum follow-up of three
226 years.

227

228 There are limitations to the present study. First, although the two groups were
229 comparable for pre-operative demographic and radiological data, no randomization was
230 performed. However, our matching process associated with a multivariate analysis avoided
231 potential bias related to demographical or preoperative confounding factors. Our sample size
232 was low but sufficient to detect a significant clinical difference with adequate statistical
233 power. To assess the clinical results, we used patient reported outcome measures that allowed

234 us to capture patient perspectives to measure quality of life and functional outcomes, yet they
235 have limited evidence for their psychometric properties despite a serious process of validation
236 and cross-cultural validation [21,22,34]. Furthermore, the analysis of the correlation between
237 the clinical scores and the radiological results was performed with small samples.

238

239 Regarding our radiological criteria, complexity of tibial component analysis on the
240 axial plane has already been documented [35-39]. To define the anteroposterior axis of the
241 symmetrical tibial component (LPS), we used the technique described by Roper [25]. After
242 defining the tangent of the posterior part of the tray, the center of the implant was located. The
243 line perpendicular to the tangent through the center of the implant materialized the
244 anteroposterior prosthetic axis. However, this method was not adapted to morphometric
245 implants. We then, used the method described by Stulberg [15] and thus, introduced a
246 potential methodological bias, but the results of our reproducibility analysis, confirmed that
247 those two methods allowed similar evaluation of implant positioning. Despite all these
248 limitations, to our knowledges, our study is the first to evaluate in vivo the potential
249 radiological and clinical benefits of a morphometric tibial plateau.

250

251

252 *Clinical scores*

253

254 The pain component of the IKS score was 11 points higher in the morphometric
255 group than in the symmetric group which explains the difference in the IKS score at last
256 follow-up between the two groups. A direct relationship between the rotation of the tibial
257 component and clinical outcomes of TKA had been reported [6,9-11]. However, tibial trays
258 positions were comparable in both groups and no significant difference regarding TTP was
259 find in our subgroup analysis. These results might be explained by the small number of
260 prostheses with posterolateral overhang in the morphometric group. Conflicts between
261 prosthetic components and soft tissues have been advocated to be responsible for pain after
262 primary TKA [40]. They may involve the popliteal tendon [41,42], the patellar tendon [43],
263 the iliotibial band [44] or the medial collateral ligament [12]. These conflicts might be due to
264 over-sizing or misalignment of prosthetic components. Allardyce reported two cases of well-
265 aligned TKA, with a joint range of motion of 0 ° to 120 ° and popliteal tendon pain distant

266 from surgery, requiring arthroscopic release of the popliteal tendon [45]. The knowledge of
267 this potential conflict allowed Kazakin to pay particular attention to it intraoperatively [42].
268 For Bonnin, a non-overhung tibial component was associated with lower pain score compared
269 to an overhung component [8], which corroborates our subgroup analysis results.

270

271

272 *Radiological scores*

273 *TTP*

274 No statistically significant difference in the rotational positioning of the implants
275 was found. In each group, 5 tibial trays were internally rotated and Twenty-eight were
276 positioned in neutral or external rotation. Actually, we paid particular attention to positioning
277 the implant along the Insall line. With the anterior tibial tuberosity as a landmark, we chose to
278 set the adequate rotation rather than optimizing bone coverage with an inherent risk of
279 prosthetic overhang. Rotation of the tibial component seemed essential to us in order to
280 optimize the prosthetic kinematics and the patella tracking, regardless of the type of prosthesis
281 used. The mean rotation positioning of the tibial implant in the two groups (4.9 ° and 4.2 °)
282 was comparable to the series of Berhouet [35] who found an average rotation of 6.11° in a
283 group of TKA with a preoperative genu varum. However, few series in the literature report
284 the results of tibial tray rotations with a consistent and validated measurement method [46].

285 *TBC*

286 The average bone coverage of the tibia by the prostheses was 90% in the morphometric
287 group and 88% in the symmetrical group, with no statistical significance which confirmed the
288 absence of prosthetic undersizing in each group while being superior to the imaging software
289 simulations performed by Stulberg (81% vs 76%) [15] and Wernecke (LPS: 80%) [16]. The
290 benefit of an anatomical design of the tray on the prosthesis coverage was also confirmed by
291 Jin in a population of Asian patients [18]. For Stulberg, the use of an anatomical tray enabled
292 a greater bone coverage, for the same given rotation, than with an asymmetric or symmetrical
293 tibial component [15]. We thus confirmed that, despite a “smaller” implant design,
294 morphometric component allowed a better adaptation to tibial bone surface and increased
295 bone coverage.

296 *BO*

297 The symmetrical tibial implant was more frequently positioned with an overhang of more than
298 3mm (40% of cases versus 6% of cases). Bonnin found a lateral overhang in 87% of patients
299 operated in his series with a symmetrical tibial tray [18]. However, the definition of size

300 mismatch was deduced by comparing a preoperative computed tomography with the size of
301 the implanted prosthesis [8]. It was therefore not possible for him to evaluate the positioning
302 of the implant, to locate the overhang and to measure its size. Asymmetry of the proximal
303 tibia has been described by many authors [47-50]. It is thus difficult to insure bone coverage
304 with a symmetrical implant in patients with asymmetrical tibial plateau. Despite a deliberate
305 undersizing of 1.7 mm at the medial tibial plateau, Bonnin found a mean overhang of 3.2 mm
306 at the lateral tibial plateau [8]. The literature data are nonetheless controversial. Indeed, for
307 Wernecke, the use of an asymmetric component did not allow to reduce the posterolateral
308 overhang compared to symmetrical implants [16]. However, the results of our series are in
309 favor of the use of a morphometric implant allowing to significantly reduce the number of
310 overhung tibial implants.

311

312 **CONCLUSION.**

313 The modification of the design of the tibial tray in TKA is a new approach to better
314 adapt implants and improve patients' outcomes. In this matched controlled study the use of a
315 morphometric tibial tray improved implant positioning, reducing prosthetic overhang.
316 Compared to the use of a symmetrical tray, at midterm follow-up, it allows better clinical
317 results. Longer follow-up will be needed to further assess benefits of this type of implant.

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453

454 **FIGURES LEGENDS.**

455

456 **Figure 1:** Morphometric tibial tray rotation: point represents the medial third of anterior tibial
457 tubercule, the first line the Insall line, the second line the anteroposterior axis of the tibial tray

458 **Figure 2:** Definition of the tibial bone cut

459 **Figure 3:** Outline of tibial tray marked on the proximal tibial bone cut

460

461

Figure 1: Morphometric tibial tray rotation: point represents the medial third of anterior tibial tubercle, the first line the Insall line, the second line the anteroposterior axis of the tibial tray

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Figure 2: Definition of the tibial bone cut

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Figure 3: Outline of tibial tray marked on the proximal tibial bone cut

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Variable	Intraobserver	Interobserver
Rotation	0,95 (0,93– 0,97)	0,91 (0,85 – 1)
Coverage	0,98 (0,97-0,99)	0,96 (0,90 – 0,99)
Overhang	0,96 (0,94-0,98)	0,92 (0,89-0,97)

Table 2: Intra and Interobserver reliability by variable

	IKS (global)		IKS (pain)	
	<i>R</i> ²	<i>p</i>	<i>R</i> ²	<i>p</i>
Age	-0,4	0,07	-0,3	0,1
Sex (Male)	0,5	0,05	0,4	0,08
BMI	0,3	0,1	0,4	0,1
HKA	0,1	0,5	-0,1	0,6
Preoperative global IKS	0,7	0,01	0,5	0,04
Preoperative pain IKS	0,4	0,1	0,7	0,02
Type of tibial tray	0,6	0,03	0,7	0,01
Rotation	0,3	0,3	0,2	0,5
Coverage	0,4	0,2	0,5	0,05

Table 4: Multivariate analysis

Variable	MTT group	STT group	P
Number	33	33	-
Age (years)	77 (57-92)	75 (66-89)	0,420
Sex ratio (female/male)	17/15	17/15	-
Body Mass Index (kg/m²)	28 (23-37)	29 (19-40)	0,210
Side (left/right)	12/21	14/19	-
Follow-up (month)	44 ± 5,4	46 ± 5,7	0,17
Flexion (°)	111 (100-130)	117 (100-130)	0,095
HKA (°)	174 (163-190)	174 (163-194)	0,765
Valgus	6	8	-
Varus	27	25	-
IKS objective	39 ± 14,5	44 ± 9,9	0,097
subjective	61 ± 16,2	62 ± 11	0,574
KOOS	38 ± 11,4	40 ± 9,1	0,562

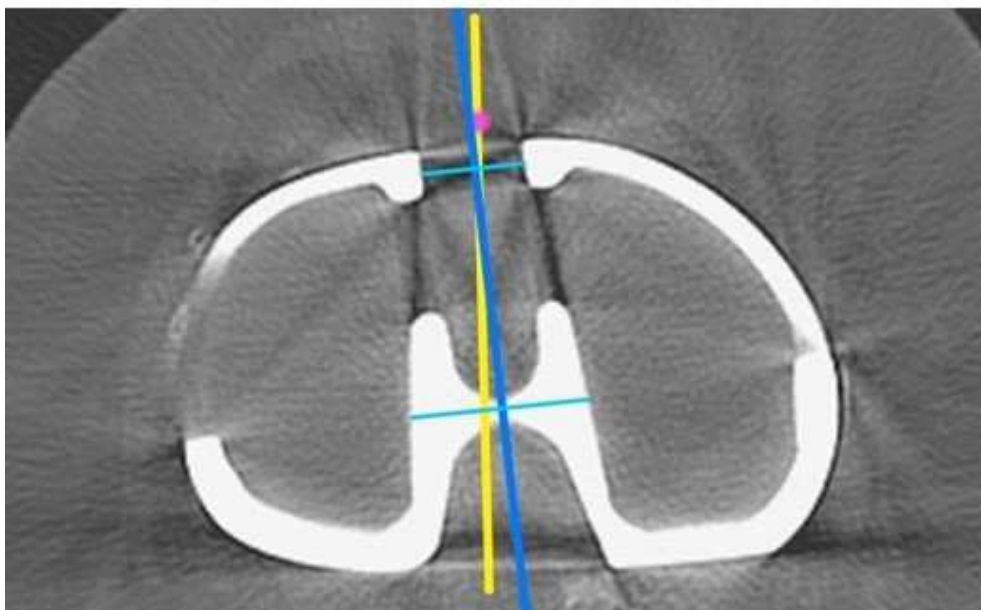
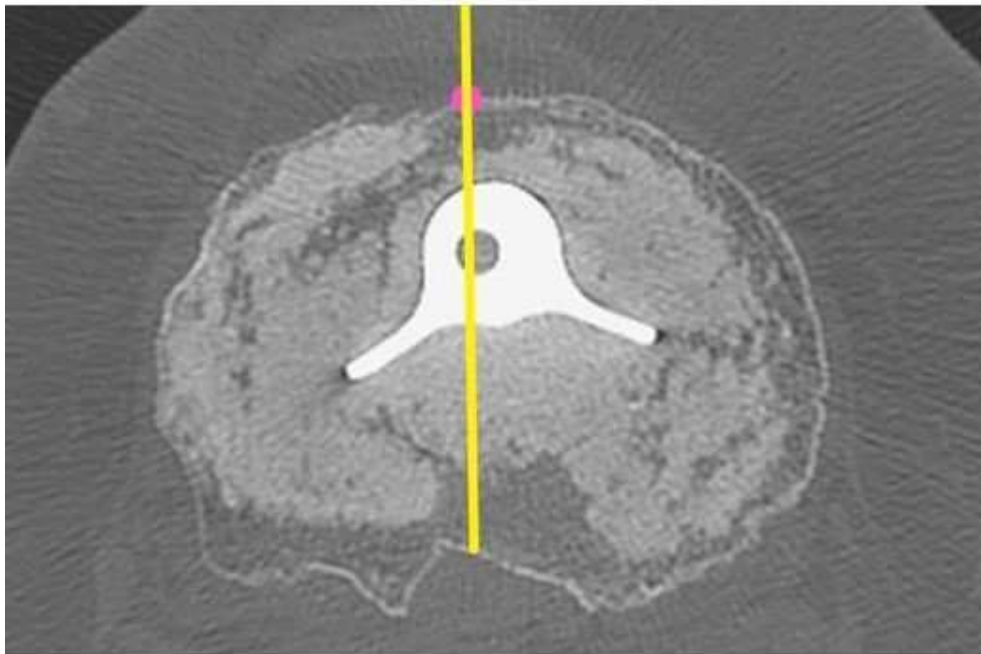
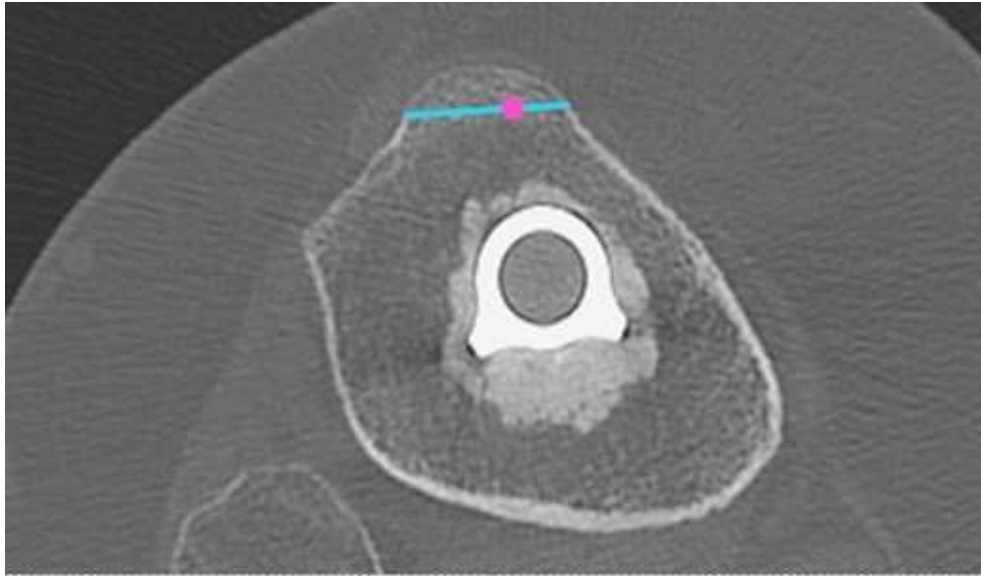
Table 1: Preoperative data

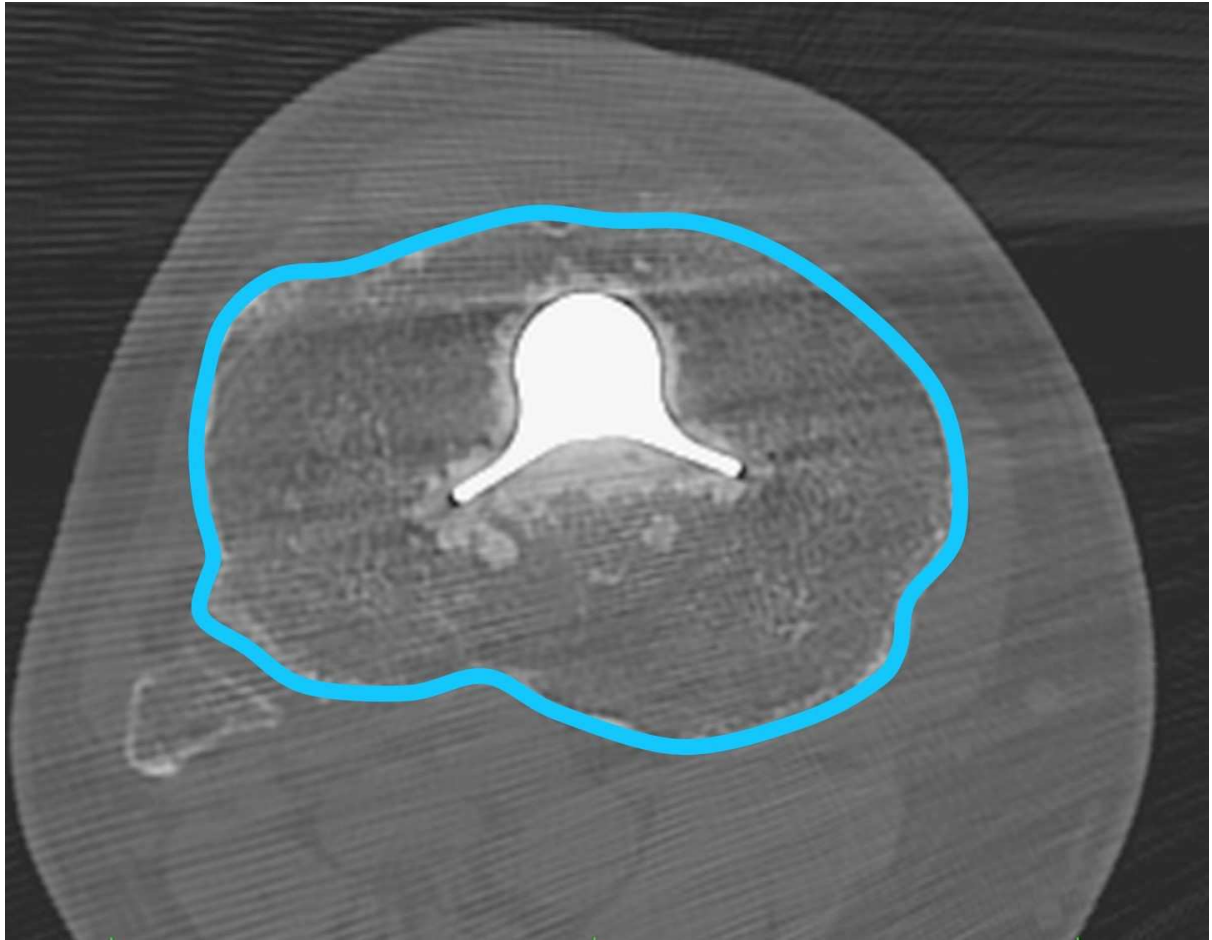
	MTT group	STT group	P
International Knee Society Score			
Pain (/50)	47 ± 4,2	36 ± 15,7	0,0002
Objective (/100)	94 ± 6,2	80 ± 18,2	0,0002
Subjective (/100)	93 ± 10,6	87 ± 12,6	0,047
Global (/200)	187 ± 14,3	167 ± 26,1	0,0005
KOOS	16 ± 10,9	21 ± 10,5	0,12
Flexion (°)	123 ± 10,8	124 ± 7,8	0,45

Table 3: Functional results

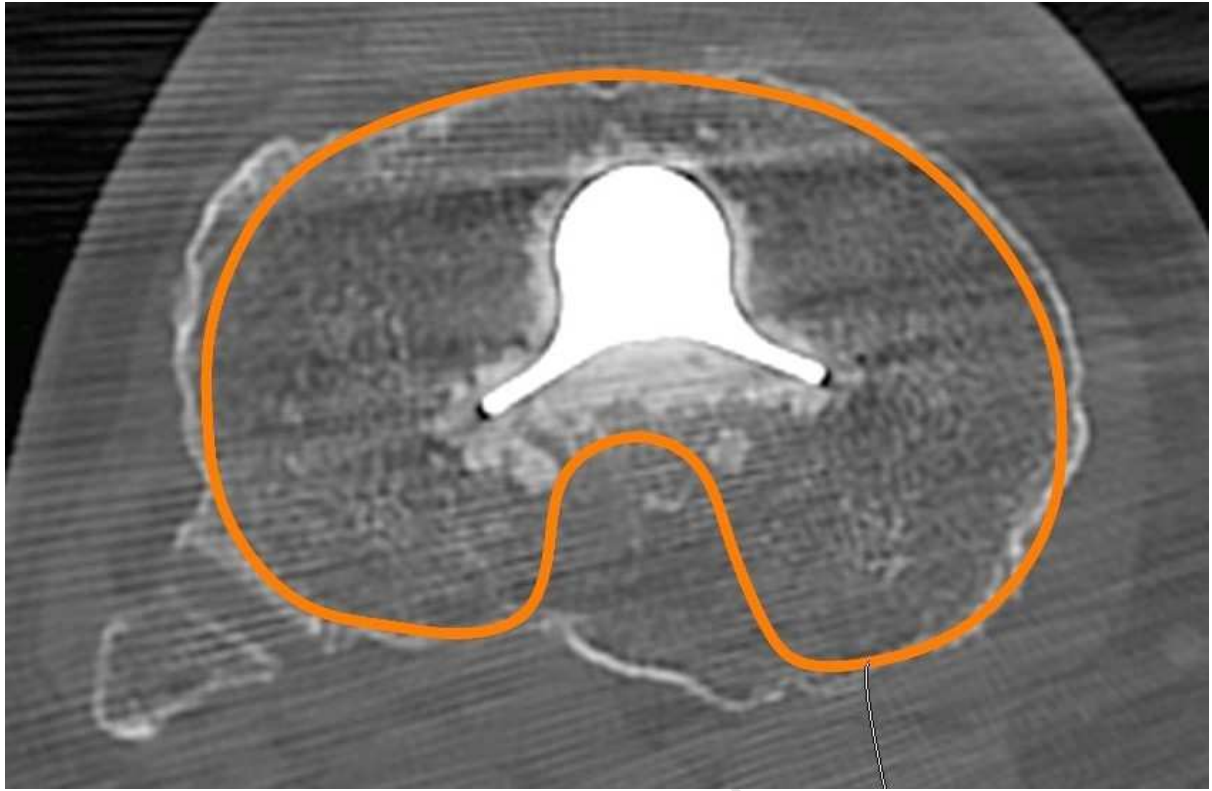
	MTT group	STT group	P	Odds Ratio
HKA	178 ± 2,9	177 ± 3,9	0,64	
Tibial tray rotation				
Average (°)	4,9 ± 5,2	4,2 ± 7	0,69	
internal	5	5	0,91	
neutral	7	5	0,53	
external	21	25	0,49	
outlier	15	18	0,95	
Bone coverage (%)	90 ± 4	88 ± 3	0,07	
Overhang				<i>10,33</i>
<3mm	31	20	<i>0,001</i>	<i>IC95%[2,12-</i>
>3mm	2	13		<i>50,24]</i>

Table 5: Radiological results





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