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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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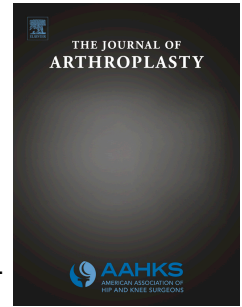
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# Accepted Manuscript

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

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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  $20\pm 21$  points;  $p=0.0005$ ) mainly  
63 due to a difference in the IKS pain subscore (mean difference  $11\pm 15$  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  $0^\circ$  to  $100^\circ$  (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 ( $\pm 5$  years), gender, Body Mass Index ( $\pm 3$   
119  $\text{kg}\cdot\text{m}^{-2}$ ), preoperative International Knee society objective and subjective score as well as  
120 KOOS pain subscores ( $\pm 5$  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  $-1^\circ$  and  $1^\circ$  was defined as "neutral". An angle of rotation between  $-5^\circ$   
152 and  $5^\circ$  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).

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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  $4.9^\circ$  (MTT) vs.  $4.2^\circ$  (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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<b>Variable</b>	<b>Intraobserver</b>	<b>Interobserver</b>
<b>Rotation</b>	0,95 (0,93– 0,97)	0,91 (0,85 – 1)
<b>Coverage</b>	0,98 (0,97-0,99)	0,96 (0,90 – 0,99)
<b>Overhang</b>	0,96 ( 0,94-0,98)	0,92 (0,89-0,97)

Table 2: Intra and Interobserver reliability by variable

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

Table 4: Multivariate analysis

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

Table 1: Preoperative data

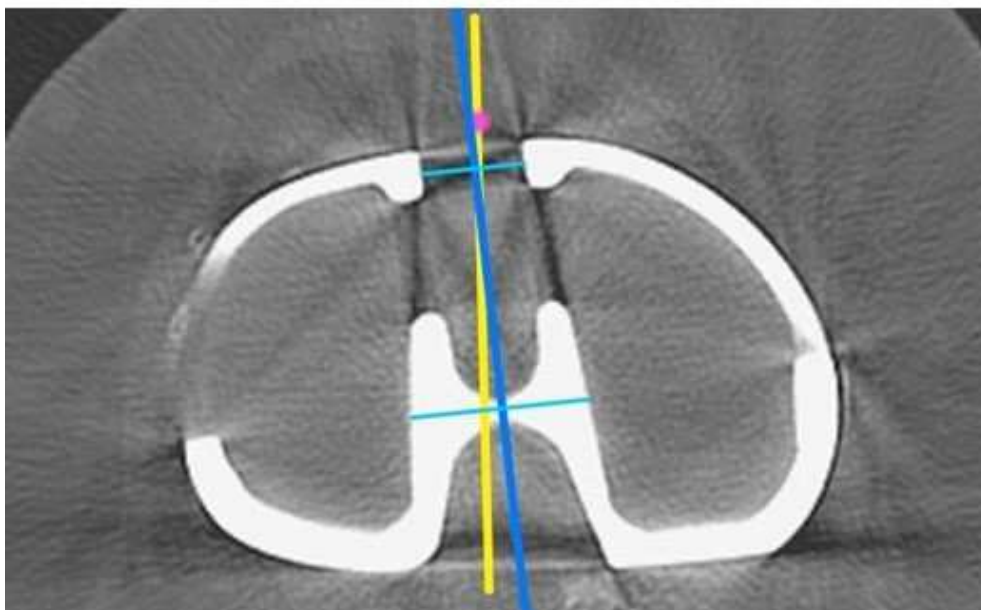
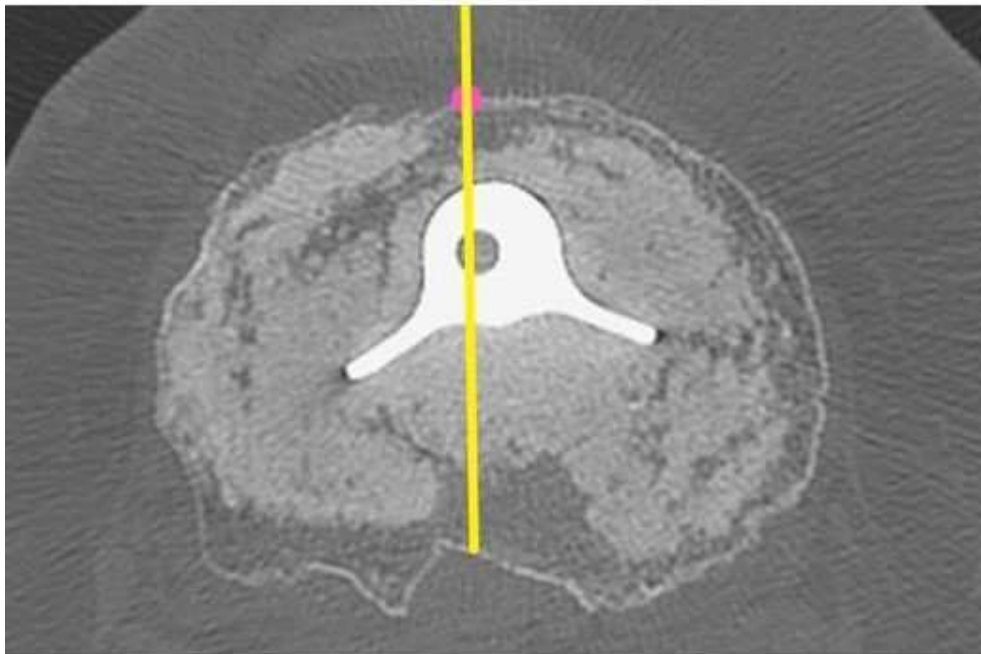
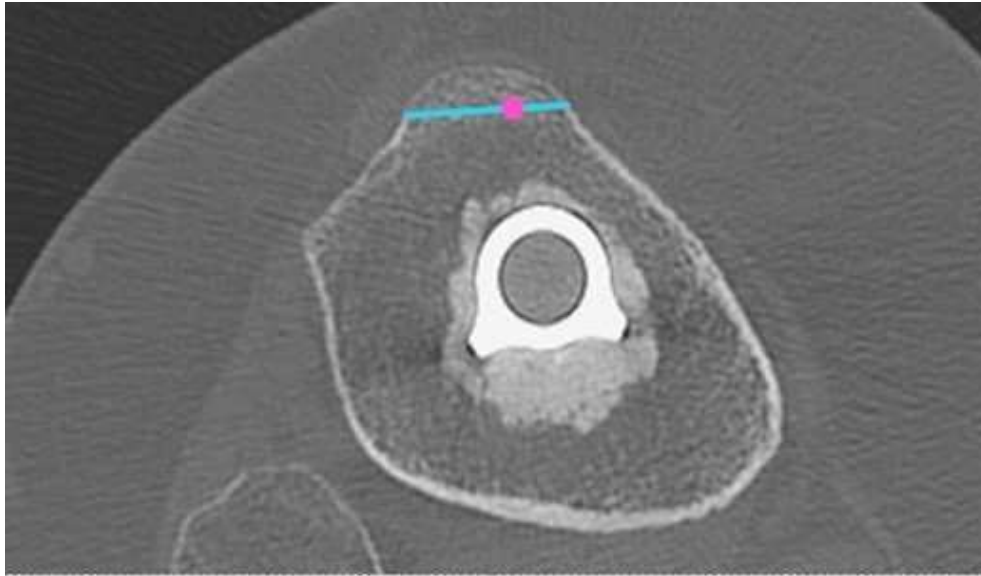
	<b>MTT group</b>	<b>STT group</b>	<b>P</b>
<b>International Knee Society Score</b>			
<b>Pain (/50)</b>	47 ± 4,2	36 ± 15,7	0,0002
<b>Objective (/100)</b>	94 ± 6,2	80 ± 18,2	0,0002
<b>Subjective (/100)</b>	93 ± 10,6	87 ± 12,6	0,047
<b>Global (/200)</b>	187 ± 14,3	167 ± 26,1	0,0005
<b>KOOS</b>	16 ± 10,9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

Table 3: Functional results

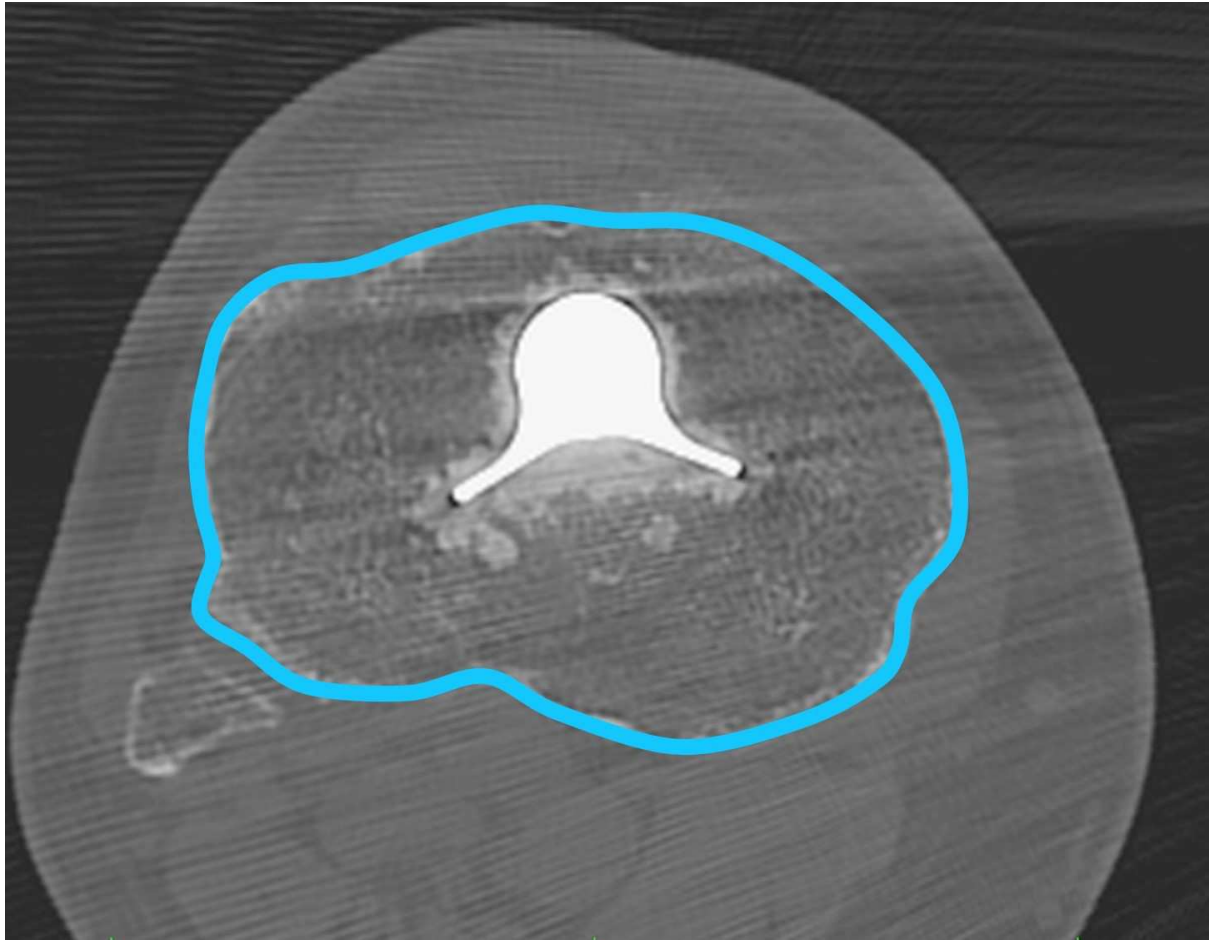


	<b>MTT group</b>	<b>STT group</b>	<b>P</b>	<b>Odds Ratio</b>
<b>HKA</b>	178 ± 2,9	177 ± 3,9	0,64	
<b>Tibial tray rotation</b>				
<b>Average (°)</b>	4,9 ± 5,2	4,2 ± 7	0,69	
<b>internal</b>	5	5	0,91	
<b>neutral</b>	7	5	0,53	
<b>external</b>	21	25	0,49	
<b>outlier</b>	15	18	0,95	
<b>Bone coverage (%)</b>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

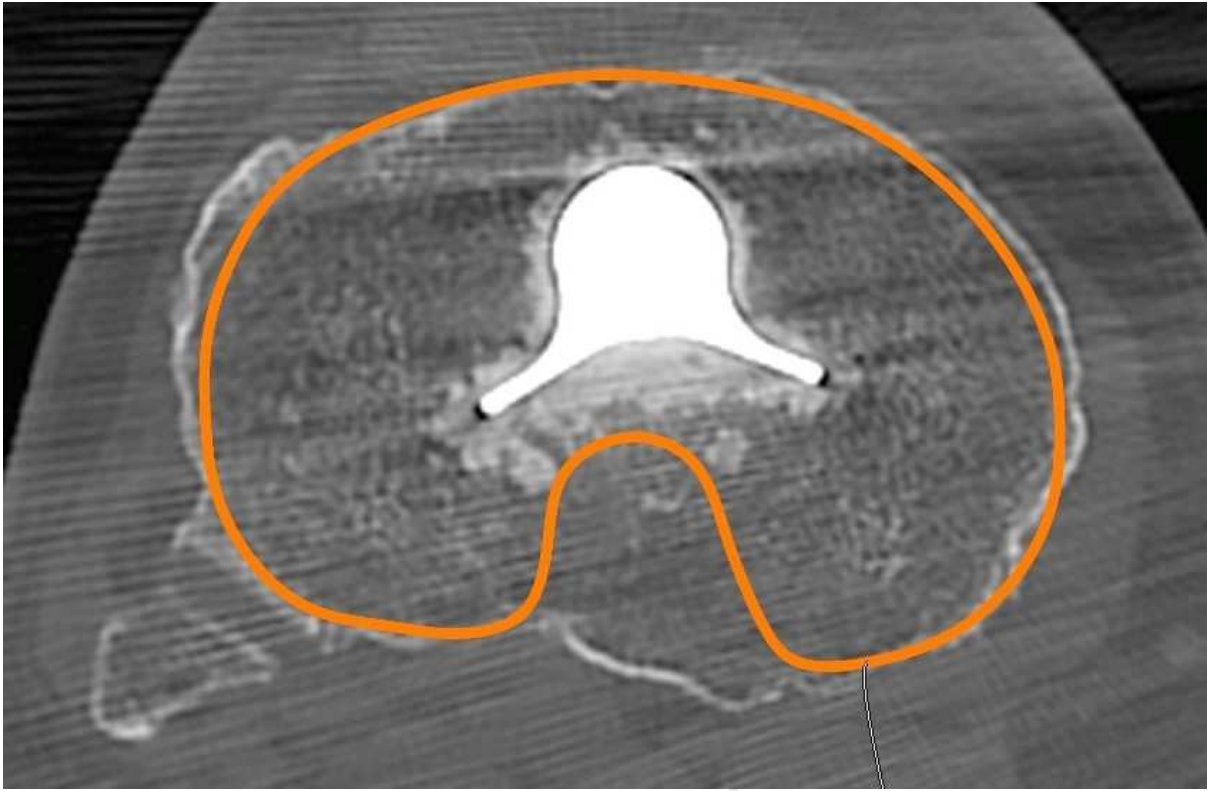
Table 5: Radiological results



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