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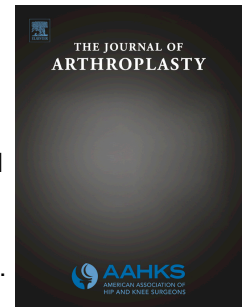


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Results of a prospective matched controlled study.

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Results of a prospective matched controlled study.

Background:

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

Methods:

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

Results:

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

Conclusion:

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

Keywords : total knee arthroplaty; morphometric; symetric; tibial tray; comparative study

INTRODUCTION.

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

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

MATERIALS AND METHODS.

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

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

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

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

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

Tibial Tray axial plane positioning (TTP)

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

Tibial Bone Coverage (TBC)

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

Prosthetic overhang (PO)

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

Statistical Methods

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

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

RESULTS.

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

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

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 difference was found between subgroups regarding TTP.

DISCUSSION.

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

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

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

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

Clinical scores

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

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

Radiological scores

TTP

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

TBC

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

BO

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

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

CONCLUSION.

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

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454 FIGURES LEGENDS.

456 **Figure 1:** Morphometric tibial tray rotation: point represents the medial third of anterior tibial
457 tubercle, 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

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

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)	
	R^2	p	R^2	p
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/m ²)	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

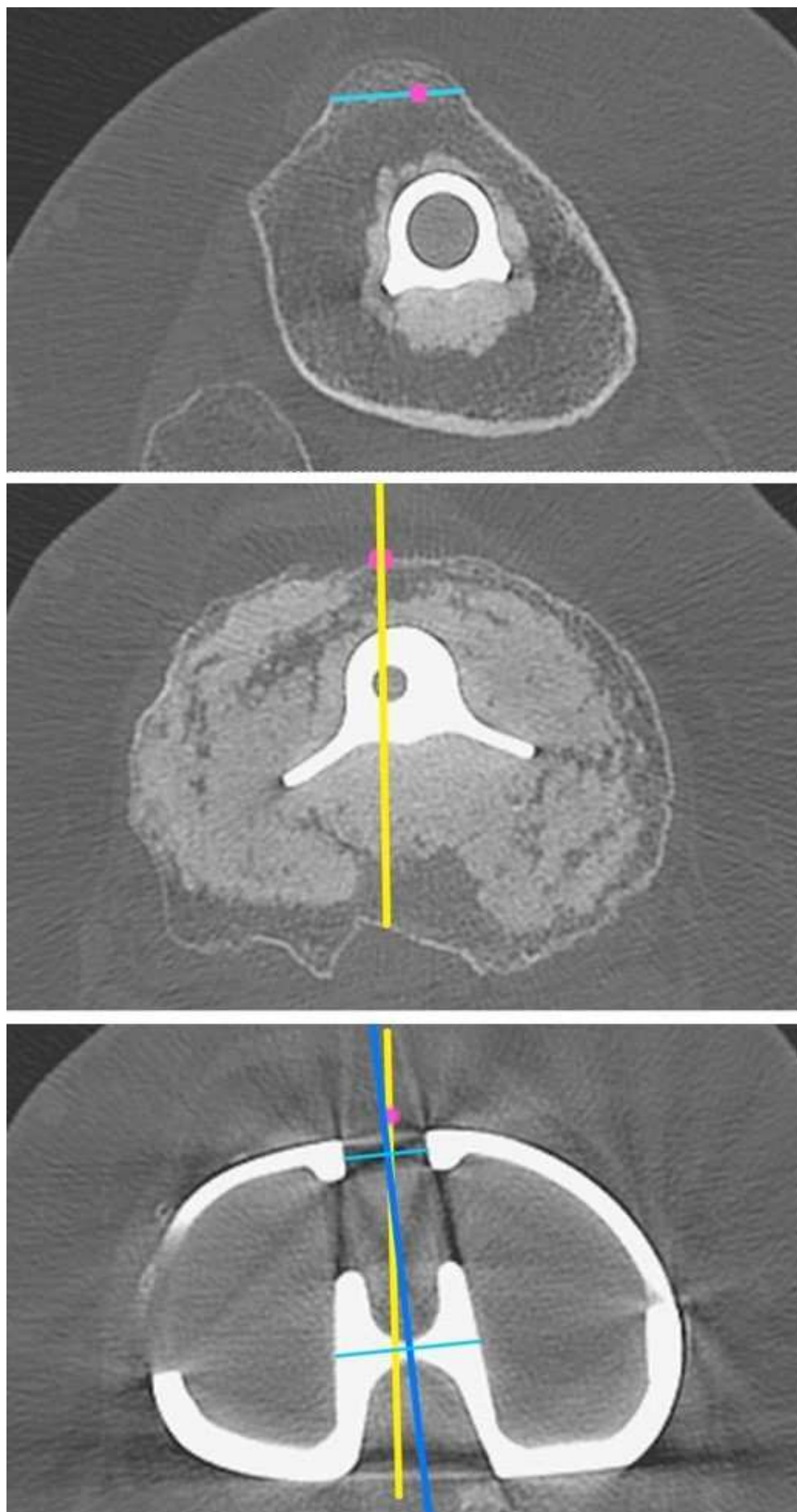
Table 1: Preoperative data

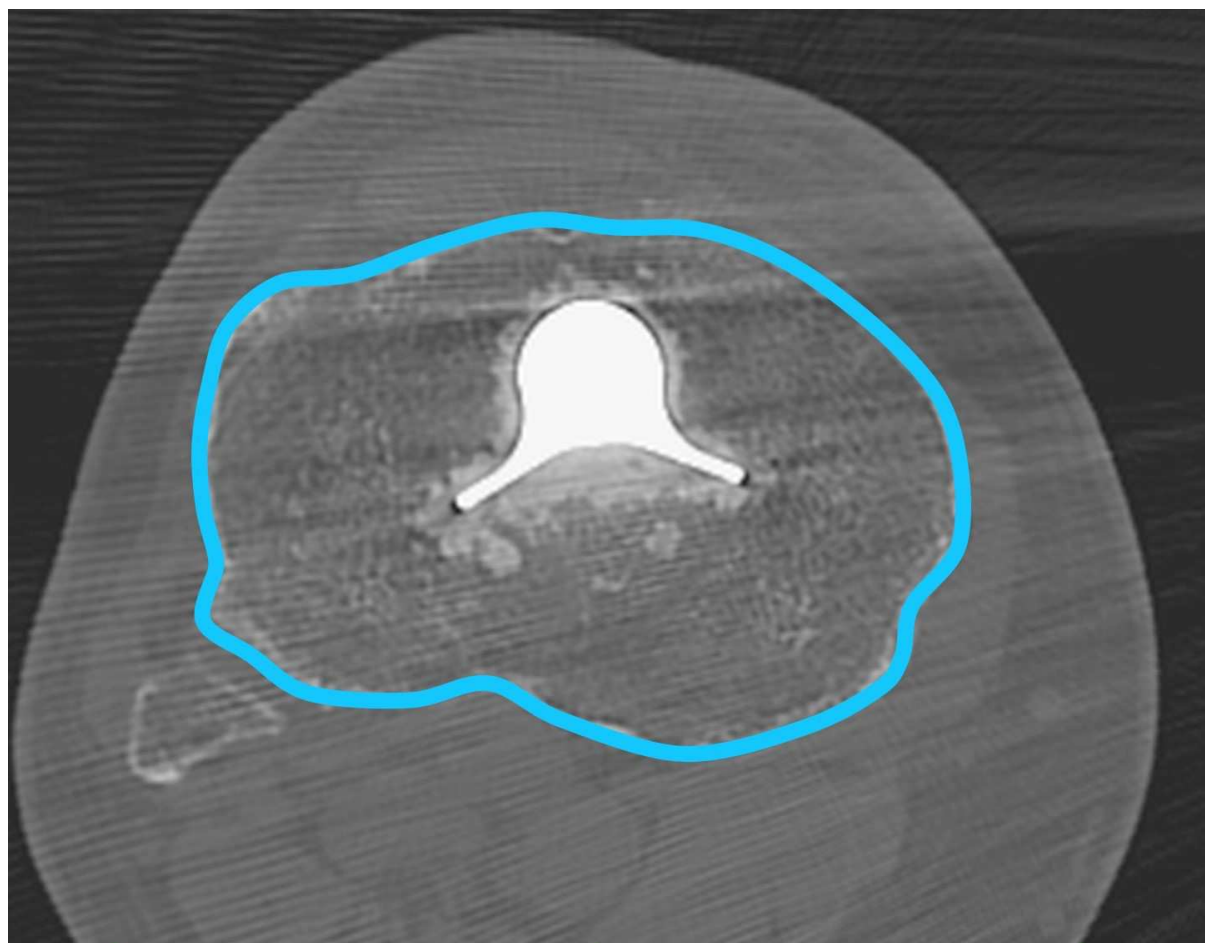
	MTT group	STT group	P
International Knee Scociety Score			
Pain (/50)	47 ± 4,2	36 ± 15,7	0,0002
Objective (/100)	94 ± 6,2	80 ± 18,2	0,0002
Subjective (/100)	93 ± 10,6	87 ± 12,6	0,047
Global (/200)	187 ± 14,3	167 ± 26,1	0,0005
KOOS	16 ± 10,9	21 ± 10,5	0,12
Flexion (°)	123 ± 10,8	124 ± 7,8	0,45

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				10,33
<3mm	31	20	0,001	IC95%[2,12-
>3mm	2	13		50,24]

Table 5: Radiological results





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