



HAL
open science

Perfection and evaluation of patient specific guides for total knee arthroplasty : a cadaveric study : review of literature since 2006 = Mise au point et évaluation des guides de coupe patient spécifique pour la mise en place des prothèses de genou : étude cadavérique : revue de la littérature depuis 2006

Séverine Dao Lena

► **To cite this version:**

Séverine Dao Lena. Perfection and evaluation of patient specific guides for total knee arthroplasty : a cadaveric study : review of literature since 2006 = Mise au point et évaluation des guides de coupe patient spécifique pour la mise en place des prothèses de genou : étude cadavérique : revue de la littérature depuis 2006. Médecine humaine et pathologie. 2013. dumas-00865644

HAL Id: dumas-00865644

<https://dumas.ccsd.cnrs.fr/dumas-00865644v1>

Submitted on 25 Sep 2013

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

AVERTISSEMENT

Ce document est le fruit d'un long travail approuvé par le jury de soutenance et mis à disposition de l'ensemble de la communauté universitaire élargie.

Il n'a pas été réévalué depuis la date de soutenance.

Il est soumis à la propriété intellectuelle de l'auteur. Ceci implique une obligation de citation et de référencement lors de l'utilisation de ce document.

D'autre part, toute contrefaçon, plagiat, reproduction illicite encourt une poursuite pénale.

Contact au SICD1 de Grenoble : **thesebum@ujf-grenoble.fr**

LIENS

Code de la Propriété Intellectuelle. articles L 122. 4

Code de la Propriété Intellectuelle. articles L 335.2- L 335.10

http://www.cfcopies.com/V2/leg/leg_droi.php

<http://www.culture.gouv.fr/culture/infos-pratiques/droits/protection.htm>

Université Joseph Fourier
Faculté de Médecine de Grenoble

Année : 2013

N°

**PERFECTION AND EVALUATION OF PATIENT
SPECIFIC GUIDES FOR TOTAL KNEE
ARTHROPLASTY.
A CADAVERIC STUDY.**

Review of the literature since 2006.

(Mise au point et évaluation des guides de coupe patient-spécifique pour la mise en place des prothèses de genou. Etude cadavérique. Revue de la littérature depuis 2006.)

Thèse présentée pour l'obtention du doctorat en Médecine
Diplôme d'Etat

Thèse soutenue publiquement à la Faculté de Médecine de Grenoble
le 17 septembre 2013

par DAO-LENA Séverine,

née le 30 novembre 1981, à Briançon.

devant le jury composé de :

Président du jury : M. le Professeur MERLOZ Philippe,

Membres : M. le Professeur SARAGAGLIA Dominique
M. le Professeur TONETTI Jérôme
M. le Docteur CHAMBAT Pierre

Université Joseph Fourier
Faculté de Médecine de Grenoble
Domaine de la Merci
38700 LA TRONCHE

Doyen de la Faculté de Médecine : Professeur Jean-Paul ROMANET

Professeurs des Universités – Praticiens Hospitaliers

ALBALADEJO Pierre	Anesthésiologie-réanimation
ARVIEUX-BARTHELEMY Catherine	Chirurgie générale
BACONNIER Pierre	Biostatistiques et informatique médicale
BAGUET Jean-Philippe	Cardiologie
BALOSSO Jacques	Radiothérapie
BARRET Luc	Médecine légale et droit de la sante
BAUDAIN Philippe	Radiologie et imagerie médicale
BEANI Jean-Claude	Dermato-vénérologie
BENHAMOU Pierre-Yves	Endocrinologie, diabète et maladies métaboliques
BERGER François	Biologie cellulaire
BLIN Dominique	Chirurgie thoracique et cardio-vasculaire
BONAZ Bruno	Hépto-entérologie, hépatologie, addictologie
BOSSON Jean-Luc	Biostatistiques et informatique médicale
BOUGEROL Thierry	Psychiatrie d'adultes
BOUILLET Laurence	Médecine interne
BRAMBILLA Christian	Pneumologie
BRAMBILLA Elisabeth	Anatomie et Cytologie Pathologiques
BRICAULT Ivan	Radiologie et imagerie médicale
BRICHON Pierre-Yves	Chirurgie thoracique et cardio-vasculaire
CAHN Jean-Yves	Hématologie
CARPENTIER Patrick	Chirurgie vasculaire ; médecine vasculaire
CARPENTIER Françoise	Thérapeutique ; médecine d'urgence
CESBRON Jean-Yves	Immunologie
CHABARDES Stéphane	Neurochirurgie
CHABRE Olivier	Endocrinologie, diabète et maladies métaboliques
CHAFFANJON Philippe	Anatomie
CHAVANON Olivier	Chirurgie thoracique et cardio-vasculaire
CHIQUET Christophe	Ophthalmologie
CHIROSEL Jean-Paul	Anatomie
CINQUIN Philippe	Biostatistiques et informatique médicale
COHEN Olivier	Biostatistiques et informatique médicale
COUTURIER Pascal	Gériatrie et biologie du vieillissement
CRACOWSKI Jean-Luc	Pharmacologie fondamentale, pharmacologie clinique
DE GAUDEMARIS Régis	Médecine et sante au travail
DEBILLON Thierry	Pédiatrie
DEMATTEIS Maurice	Addictologie
DEMONGEOT Jacques	Biostatistiques et informatique médicale
DESCOTES Jean-Luc	Urologie
ESTEVE François	Biophysique et médecine nucléaire
FAGRET Daniel	Biophysique et médecine nucléaire

FAUCHERON Jean-Luc	Chirurgie générale
FERRETTI Gilbert	Radiologie et imagerie médicale
FEUERSTEIN Claude	Physiologie
FONTAINE Eric	Nutrition
FRANCOIS Patrice	Epidémiologie, économie de la santé
GARBAN Frédéric	Hématologie ; transfusion
GAUDIN Philippe	Rhumatologie
GAVAZZI Gaétan	Gériatrie et biologie du vieillissement
GAY Emmanuel	Neurochirurgie
GRIFFET Jacques	Chirurgie Infantile
HALIMI Serge	Nutrition
HENNEBICQ Sylviane	Génétique et procréation
HOFFMAN Pascale	Gynécologie obstétrique
HOMMEL Marc	Neurologie
JOUK Pierre-Simon	Génétique
JUVIN Robert	Rhumatologie
KAHANE Philippe	Physiologie
KRACK Paul	Neurologie
KRAINIK Alexandre	Radiologie et imagerie médicale
LABARERE José	Département de veille sanitaire
LANTUEJOUL Sylvie	Anatomie et cytologie pathologiques
LE BAS Jean-François	Biophysique et médecine nucléaire
LEBEAU Jacques	Chirurgie maxillo-faciale et stomatologie
LECCIA Marie-Thérèse	Dermato-vénérologie
LEROUX Dominique	Génétique
LEROY Vincent	Gastro-entérologie ; hépatologie ; addictologie
LETOUBLON Christian	Chirurgie générale
LEVY Patrick	Physiologie
LUNARDI Joël	Biochimie et biologie moléculaire
MACHECOURT Jacques	Cardiologie
MAGNE Jean-Luc	Chirurgie Vasculaire
MAITRE Anne	Médecine et santé au travail
MAURIN Max	Bactériologie-virologie
MERLOZ Philippe	Chirurgie orthopédique et traumatologique
MORAND Patrice	Bactériologie-virologie
MORO Elena	Neurologie
MORO-SIBILOT Denis	Pneumologie
MOUSSEAU Mireille	Cancérologie
MOUTET François	Chirurgie plastique, reconstructrice et esthétique, brûlogie
PALOMBI Olivier	Anatomie
PASSAGIA Jean-Guy	Anatomie
PAYEN DE LA GARANDERIE Jean-François	Anesthésiologie-réanimation
PELLOUX Herve	Parasitologie et mycologie
PEPIN Jean-Louis	Physiologie
PERENNOU Dominique	Médecine physique et de réadaptation
PERNOD Gilles	Médecine vasculaire
PIOLAT Christian	Chirurgie infantile
PISON Christophe	Pneumologie
PLANTAZ Dominique	Pédiatrie

POLACK Benoit	Hématologie
PONS Jean-Claude	Gynécologie-obstétrique
RAMBEAUD Jean-Jacques	Urologie
REYT Emile	Oto-rhino-laryngologie
RIGHINI Christian	Oto-rhino-laryngologie
ROMANET Jean-Paul	Ophtalmologie
SARAGAGLIA Dominique	Chirurgie orthopédique et traumatologique
SCHMERBER Sébastien	Oto-rhino-laryngologie
SCHWEBEL Carole	Réanimation médicale
SELE Bernard	Biologie du développement et de la reproduction
SERGENT Fabrice	Gynécologie-obstétrique
SESSA Carmine	Chirurgie vasculaire
STAHL Jean-Paul	Maladies infectieuses ; maladies tropicales
STANKE Françoise	Pharmacologie fondamentale
TIMSIT Jean-François	Réanimation
TONETTI Jérôme	Chirurgie orthopédique et traumatologique
TOUSSAINT Bertrand	Biochimie et biologie moléculaire
VANZETTO Gerald	Cardiologie
VUILLEZ Jean-Philippe	Biophysique et médecine nucléaire
WEIL Georges	Epidémiologie, économie de la santé et prévention
ZAOUI Philippe	Néphrologie
ZARSKI Jean-Pierre	Gastro-entérologie ; hépatologie ; addictologie

Maîtres de Conférence Universitaires – Praticiens Hospitaliers

APEL Florent	Ophtalmologie
BOISSET Sandrine	Agents infectieux
BONNETERRE Vincent	Médecine et santé au travail
BOTTARI Serge	Biologie Cellulaire
BOUTONNAT Jean	Cytologie et histologie
BOUZAT Pierre	Réanimation
BRENIER-PINCHART Marie-Pierre	Parasitologie et mycologie
BRIOT Raphaël	Thérapeutique ; médecine d'urgence
CALLANAN-WILSON Mary	Hématologie ; transfusion
DERANSART Colin	Physiologie
DETANTE Olivier	Neurologie
DIETERICH Klaus	Génétique et procréation
DUMESTRE-PERARD Chantal	Immunologie
EYSSERIC Hélène	Médecine légale et droit de la santé
FAURE Julien	Biochimie et biologie moléculaire
GILLOIS Pierre	Information et informatique médicale
GRAND Sylvie	Radiologie et imagerie médicale
GUZUN Rita	Endocrinologie, diabétologie, nutrition, éducation thérapeutique
LAPORTE François	Biochimie et biologie moléculaire
LARDY Bernard	Biochimie et biologie moléculaire
LARRAT Sylvie	Bactériologie-virologie
LAUNOIS-ROLLINAT Sandrine	Physiologie
MALLARET Marie-Reine	Epidémiologie, économie de la santé et prévention

MAUBON Danièle
Mc LEER (FLORIN) Anne
MOREAU-GAUDRY Alexandre
MOUCHET Patrick
PACLET Marie-Hélène
PAYSANT François
PELLETIER Laurent
RAY Pierre
RIALLE Vincent
ROUX-BUISSON Nathalie
SATRE Véronique
STASIA Marie-Josée
TAMISIER Renaud

Parasitologie et mycologie
Cytologie et histologie
Biostatistiques et informatique médicale
Physiologie
Biochimie et biologie moléculaire
Médecine légale et droit de la sante
Biologie cellulaire
Génétique
Biostatistiques et informatique médicale
Biochimie, toxicologie et pharmacologie
Génétique
Biochimie et biologie moléculaire
Physiologie

Remerciements

Cette thèse doit beaucoup aux nombreuses personnes qui m'ont encouragée, soutenue et confortée tout au long de cette année.

Je souhaite remercier Mr le Professeur Merloz pour avoir proposé et encadré cette thèse.
Je remercie les membres du jury pour avoir accepté de juger mon travail.

Mr le Professeur Saragaglia, vous m'avez donnée de bonnes bases en chirurgie prothétique, j'ai essayé de reproduire ce que vous m'avez enseignée lors de ce travail, en espérant avoir été à la hauteur.

Mr le Professeur Tonetti, vous nous tirez toujours vers le haut, vous nous poussez à donner le meilleur de nous même, j'espère que je serai à la hauteur.

Mr le Dr Chambat, merci d'avoir accepté de juger mon travail, c'est un réel honneur pour moi.

Mes parents, merci de m'avoir toujours soutenue et d'avoir cru en mes capacités, dans tout ce que j'ai entrepris, le ski, la médecine....

Mes grands parents, les mots seront toujours trop faibles pour vous exprimer ma gratitude, vous m'avez été d'une aide précieuse pour mes premières années de médecine, mais surtout vous m'avez beaucoup apportée sur le plan humain.

Ma Mamie, ma soeur et mon frère.

Jonathan, depuis plus d'un an tu es mon meilleur soutien, ton calme et ta sérénité ont été une aide précieuse. Merci d'avoir été là dans les moments difficiles.

Philippe et Nathalie du labo d'anat, merci pour votre aide, désolé pour les retards répétitifs. A Nicolas Demanget sans ton aide je ne serai jamais arrivée au « bout » de ce travail !!! et merci a toute l'équipe d'orthotaxy de m'avoir fait confiance.

Pour tous les bons moments pendant mes études de médecine: Delphine, Klo, Dorlane, Camille, Elo, Christelle, Emma, et toutes celles et ceux que j'oublie.

Aux personnes qui m'ont tant appris pendant mon internat : dans l'ordre chronologique :

- les Drs Chirpaz et Jager, ceux qui essuient nos erreurs de jeunes internes (les sections de long plamaire ne sont pas à suturer !!);
- le Dr Skowron de la rigueur et du sérieux, oui mais il faut savoir aussi détendre l'atmosphère (qu'est ce que vous m'avez fait souffrir sur ma première appendoc' !!!! mais qu'est ce que je me suis marrée sur vos imitations (« I am burning in the sky... »));
- aux chirurgiens de l'hôpital Sud : Numa : l'arthro d'épaule c'est le kiffe (enfin plus à voir qu'à faire !!); Mathieu : merci pour ta pédagogie, ta gentillesse... j'aurai aimé faire plus de bloc avec toi; Marc : oui je voulais opérer mais je ne savais pas la technique, mais tu m'as quand même un peu laisser faire !!!; Gilles, Christophe et Brice,

- aux chirurgiens de Chambéry : Dr Monbarbon, merci de m'avoir laissé faire des PTG, ce fut une grande aide pour ce travail, Dr Beaudouin : merci d'avoir amélioré mes connaissances en chirurgie du membre supérieur.
- à l'équipe de la main : j'ai passé un excellent semestre avec vous, Pr Moutet : votre langage chirurgical était pour moi au début du chinois, maintenant je sais ce qu'est un Ishiguro (enfin lui il est japonais !), Dr Corcella : je veux bien perpétuer les échanges généri- sanglier !, Dr Forli : Madame oui oui versus Madame Pourquoi, merci d'avoir pris le temps de répondre à mes innombrables questions. Marie que de bons moments au bloc et en dehors!!!
- aux chirurgiens de Nord : Dr Milaire, Nicolas M., Steve, Nicolas M-S.
- Pr Mansat, merci pour votre gentillesse, merci de m'avoir accueillie dans votre service, de combler mes (grosses) lacunes en chirurgie du coude et l'épaule, et désolé mais je ne sais pas si un jour les SNAC et les SLAC feront partie de mon domaine de compétence.

Et enfin et mais pas des moindre tous mes co internes qui ont fait que mes 5 ans d'internat restent un très bon souvenir, chacun de vous m'a apporté un petit quelque chose sur le plan professionnel et quelques fois personnel.

- Honneur aux filles, Lydie et Charline, nous n'avons pas été souvent co internes que ce soit avec l'une ou avec l'autre, jamais toutes les 3 (peut être que ce n'est pas plus mal !!!!!), merci pour votre soutien, votre bonne humeur, ne changez rien !!!!

- les Sudistes : Bouchette, Grasset, et futur Sudiste Roch

- les Nordistes: Gaël et Seb, je pense que mes remerciements seront surtout en 2015 si je survis à mon assistanat à Nord!!!

- les plus jeunes: Boud', Marques Da silva de la caravane, Jean Nad, Rouchy, Roudet, Belvisi, petit Billy (je compte sur toi pour l'arthro d'épaule), Cognault, Rabattu (la chir ped un enfer!!), Sage (tu ne seras pas orthopédiste mais tu sais faire les ongles incarnés!!!)

- les toulousaines: Steph, Dr the good, Florie, merci pour votre accueil (quand vous voulez pour un resto entre filles!!)

et les autres croisés pendant de stage en périph : David (ami fidèle, merci pour le coup de main sur la mise en page !), Chateau (je t'attends pour quelques descentes en télémark !)

Les équipes des services d'orthopédie 13^{ème}, du bloc ortho Nord et bloc PU, j'espère que je serai à la hauteur à partir de novembre !!! enfin préparer bas de contention, boules quies et patience !!

En espérant n'avoir oublié personne !!!!

TABLE of CONTENTS

❖ TABLE of ABBREVIATIONS.....	p.1
❖ ABSTRACT	p.2
❖ INTRODUCTION	p.3
❖ MATERIALS and METHODS.....	p.5
○ Anatomical pieces	
○ Preoperative computerized planning	
○ Operative procedure	
○ Post operative procedure	
○ Evaluation criteria	
- Pre operatively	
- Post operatively	
○ Statistical analysis	
❖ RESULTS	p.11
○ Wording	
○ Comparison pre and post operatively in the groups	
○ Comparison between the groups	
○ Plumb line	
○ Operating time	
○ Learning curve	
❖ DISCUSSION	p.18
❖ CONCLUSION	p.25
❖ ANNEX 1	p.28
❖ ANNEX 2	p.33
❖ REFERENCES	p.36

TABLE of ABBREVIATIONS

TKA	Total Knee Arthroplasty
PSG	Patient Specific Guide
SI	Standard Instrumentation
CAS	Computer Assisted Surgery
HKA	Hip-Knee-Ankle
MFA	Mechanical Femoral Angle
MTA	Mechanical Tibial Angle
CT Scan	Computed Tomography Scan
MRI	Magnetic Resonance Imaging
HKS	Hip-Knee-Summit angle

ABSTRACT

Introduction: Coronal alignment in total knee arthroplasty (TKA), regarding the literature, seems to be a major factor in the survivorship of the components and in the functional outcome. The Patient Specific Guides (PSG), based on 3 D imaging, had been introduced in surgical process in order to improve accuracy in TKA, and to reach post operative neutral mechanical alignment.

Hypothesis: Compared with standard instrumentation (SI), PSG can improve the coronal alignment of the TKA and decrease the operative time.

Materials and methods: Thirty-three lower limbs (from femoral head to foot) have been taken from seventeen cadavers. A pre operative CT scan of each lower limb has been realized in order to measure: HKA angle, MFA and MTA, and to plan the TKA for shaping the PSG. 17 TKAs have been implanted with PSG, 16 with SI. 54% (18/33) knees presented osteoarthritis at least on one of the three compartments. Post operatively, a further CT scan has been used to make the measures to compare the two groups. Per operatively, operative time and positioning of PSG have been reported.

Results: Pre operatively, 66,7% (22/33) of the lower limbs were in varus, 27,3% (9/33) were in valgus and 6% (2/33) were in neutral alignment, there was no significant difference between the groups. Post operatively, the overall mechanical alignment was between 177° and 183° for 81,25% (13/16) in SI group, and 76,47% (13/17) in PSG group. The mean HKA in SI was 179,1° ($\pm 2,45$), and 178° ($\pm 2,18$) in PSG group, there was no significant difference between the group (p-Value: 0,17). Only the operative time was significantly lower in PSG group with a median of 43 minutes [35-47] relative to the SI group with a median of 50 minutes [43-62,5] (p-Value: 0,041).

Conclusion: in our study, PSG did not demonstrate a superiority regarding the coronal mechanical alignment comparing with SI in TKA. But the use of PSG process can reduce the operative time.

INTRODUCTION

Over the last decade, the incidence of total knee arthroplasty (TKA) increases of 60%, and for the next ten years the forecast increase exceed 100%(1). The success of TKA depends on multiple factors whose limb alignment, component positioning and soft-tissue balancing(2). Accurate coronal alignment is correlated with good clinical outcomes(3)(4) and contribute to implant longevity(5)(6)(7).

To improve component alignment, computer assisted surgery (CAS) have been introduced, and have demonstrated to be of great value in improving the longitudinal alignment of the limb compared to results with traditional alignment techniques(8).

Recently, a meta-analysis showed that malalignment of the mechanical axis of more than 3° occurs in 30% with standard instrumentation, for only 10% with computer-assisted TKAs(9).

But these systems have some per operatively drawbacks such as accurate landmark registration, increased surgical time and cost, bone fractures, complexity, long set-up time and substantial learning curve(10)(11).Moreover, it has not completely eliminated component outliers (8)(12)(13)(14).

Nowadays, in alternative of computer navigation and conventional instrumentation, emerge patient-specific guide (PSG) based on three-dimensional imaging, to improve postoperative alignment and implant positioning.

These patient-specific guides are designed from 3-D imaging of precise anatomic knee of one patient. They are precisely drawn to match specific landmarks of each patient's knees.

Proprietary software is used to virtually map bone resections and to accurately size and position the knee implant.(10)

The use of PSG should improve the accuracy of bone cuts, but papers published until now are contradictory, some authors found an improvement in coronal alignment using PSG(15)(16), others did not(17).

The aim of this study is to compare TKA implanted with standard instrumentation (SI) versus PSG from computerized tomography scan model, regarding limb alignment, per operative accuracy PSG fitting and operative time, on 33 cadaveric lower limbs; and to compare our results with a review of the literature.

MATERIELS AND METHODS

ANATOMICAL PIECES:

Thirty-three cadaveric lower limbs were obtained from the Anatomy Laboratory at Joseph Fourier University. On 16 cadavers the 2 lower limbs have been chosen. For one cadaver only one lower limb was available. The anatomical pieces were divided in two groups: PSG group (17) and SI group (16).

PREOPERATIVE COMPUTERIZED PLANNING

First, a spiral 3D CT scan (Radiology Departement of Grenoble university hospital) was performed on every lower limb with a **0,5mm** slice thickness from the femoral head to the ankle.

The images were stored in DICOM format and transferred to workstation running the planning software to determine hip, knee and ankle centres.

The femoral head was considered as a sphere, and its centre could then be identified. The middle of the tibial spine was chosen as the knee centre. The ankle centre was the midpoint of the bimalleolar axis. Figure 1.

For each knee: HKA (Hip knee ankle angle), MFA (mechanical femoral angle) and MTA (mechanical tibial angle) were measured.

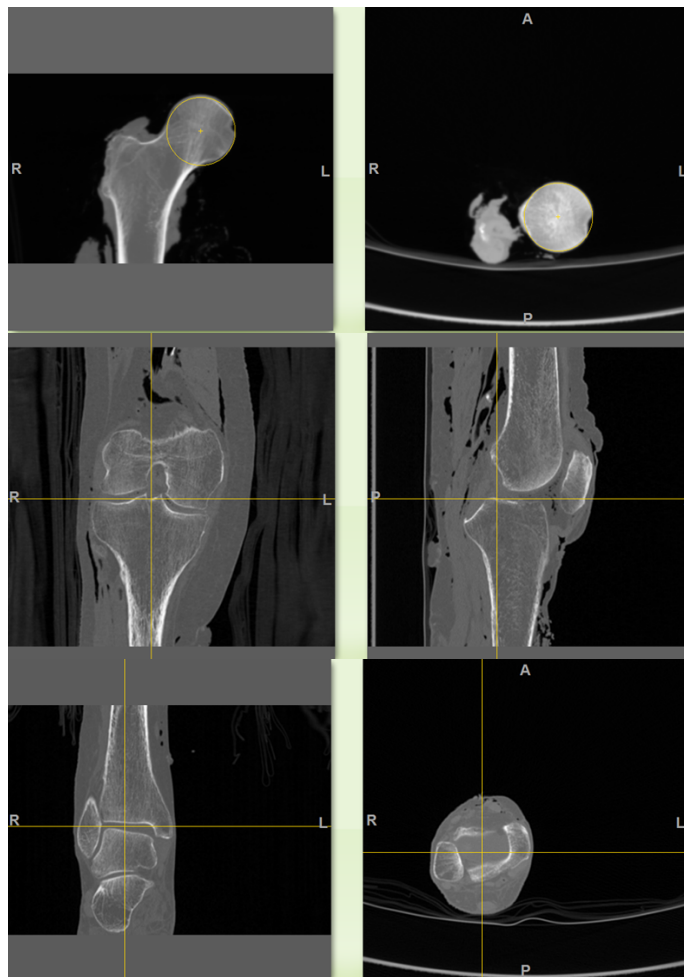


Figure 1: planning of hip, knee and ankle centres

HKA angle is the line from femoral head centre, passing through the knee center, to the ankle centre.

MFA is the angle comprised medially between mechanical femoral axis (line from centre of femoral head to knee centre) and the bicondylien line (or the distal tangent of the femoral component)

MTA is the medial angle between mechanical tibial axis (line from knee centre to ankle centre) and the tangent of the tibial plateau (or tibial component).

Pre operatively: 66,7% (22/33) knees had genu varum, 27,3% (9/33) knees had genu valgum and 6% (2/33) were in neutral position.

With the planning software, for the knees in PSG group, the total knee arthroplasty (TKA) was planned preoperatively. Optimal alignment (HKA equal to 180°) and osteotomy positions (the thickness was depending of type of HKA) were identified. Each tibial PSG was constructed with a 10-mm resection height. Each femoral PSG was also constructed with a 10-mm resection height and two drill guides to define the rotational alignment of the femur. The posterior slope of the tibial PSG was 2°, and the flexion of femoral PSG was 5°, as recommended by Evolutis™. Figure 2.

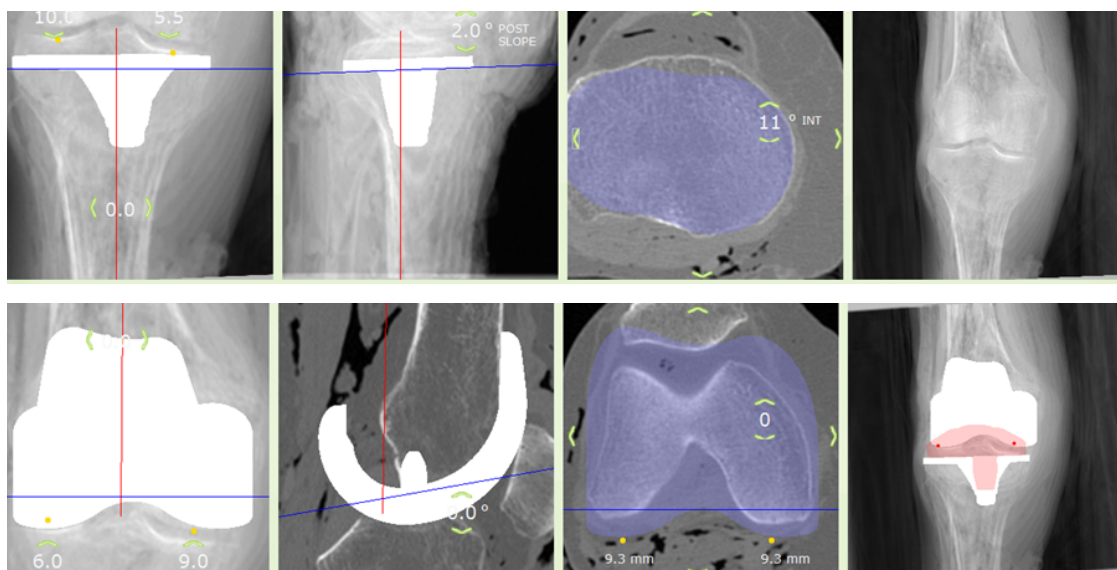


Figure 2 : Pre operative planned TKA with PSGs

The contact areas of each PSG were created to precisely match bone surfaces related to the patient's anatomy. Figure 3.

- For the tibial PSG: the pre spinal surface, the anterior medial epiphyseal and the anterior edge of the lateral tibial plateau. (et médial)
- For the femoral PSG: the anterior cortex of the metaphyseal, the medial edge of the medial distal condyle and the lateral edge of the lateral distal condyle.

The stability of each PSG was inspected before surgery. Moreover, PSGs were positioned on their corresponding bone models to confirm their perfect fit.

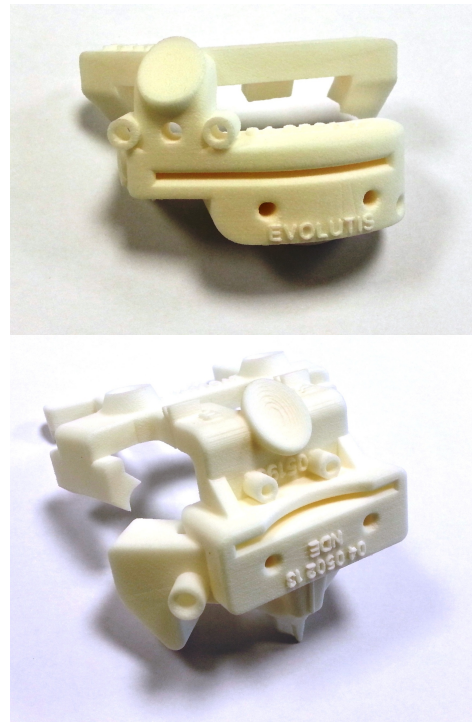


Figure 3: femoral and tibial PSGs

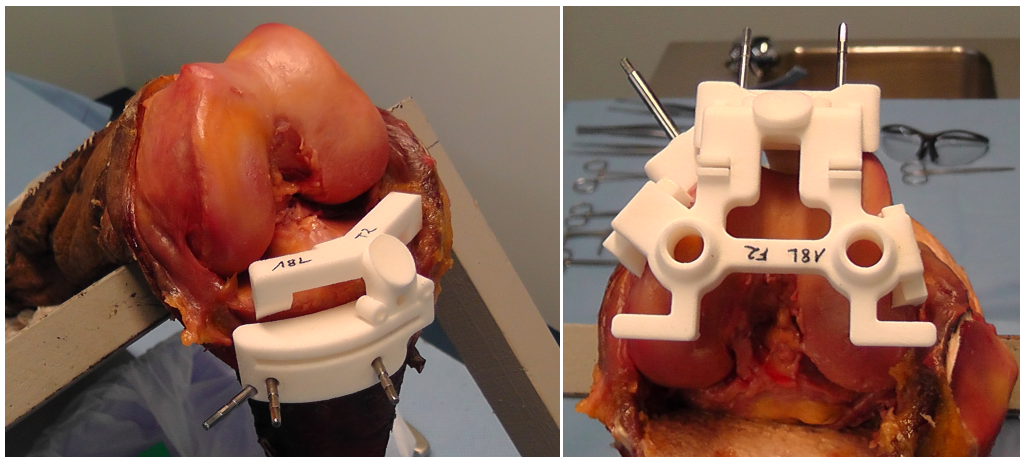


Figure 4: PSGs placed on corresponding landmarks

The femoral and tibial bone models, and their corresponding PSGs were made of nylon (polyamide). Figure 4.

OPERATIVE PROCEDURE

All operations were performed by the same surgeon (S.D.L.).

After medial arthrotomy, and lateral eversion of the patella, the tibial PSG was placed and the proximal tibia cut was made through PSG cutting slot with a blade mounted on an oscillating saw.

Then the femoral PSG was placed from the anterior part of the distal femoral bone to the distal medial and lateral part of the condyles.

Two K-wires were used to mark the position of the rotational alignment depending on ligament balancing in flexion.

For the standard process, an intramedullary system was used for the placement of the femoral (aided with the HKS (hip knee summit angle)) and tibial osteotomies.

The surgical technique is detailed in annex 1.

Trial components present in the Evolutis™ Rolflex plateau were used to replace the knee joint.

POST OPERATIVE PROCEDURE

Each lower limb received post operatively a CT scan with the same procedure as pre operatively, to measure HKA, MTA and MFA. The same independent observer made the measures.

EVALUATION CRITERIA

For each knee, some criteria have been measured and reported.

Pre-operatively:

- On CT scan images: HKA, MFA, MTA, and the size planned for PSG group.

Per operatively:

For every lower limb:

- Osteoarthritis of each compartment: patella, trochlea, femoro-tibial compartment, medially and laterally.
- Plumb line alignment (cord pulled from femoral head centre to the ankle centre) referred to the internal edge of the anterior tibial tubercle, and to the knee centre (middle of tibial spines or middle of tibial component) after the lateral everting of the patella and before closing the skin.
- Operating time: The operator must measure the duration of the surgery (skin-to-skin time).
- Ligament balancing: at the end of the surgery, the operator checked the ligament balancing in flexion and extension.

For PSG group:

- Good positioning of the PSG: The operator had to evaluate if the PSG was well positioned before performing drills and cuts. The PSG was considered well positioned if all degrees of freedom of the PSG were blocked when the operator presses strongly on the finger mark present on the PSG.

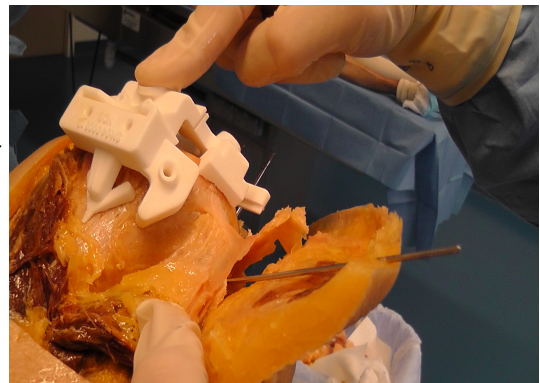


Figure 5: test of PSG stability

- Recut: It had to be indicated if the operator had to perform a recut after the first cut performed with the PSG. The height of the recut was also reported.
- Revert to conventional surgery: The operator had to report if he had to use conventional instrumentation instead of PSG to perform TKA if he came across a problem during the procedure.

Post operatively:

- On CT scan images: HKA angle, MFA, MTA.

ANALYSIS of the LITERATURE

The research of articles was made on pub med, selecting the study employing PSG in TKA. Case reports, and articles studying PSG and patient specific arthroplasty in the same procedure were excluded. In each article, number of TKA, type of PSG, type of 3 D images, coronal alignment, percentage of outliers and operating time were reported when they were studied.

STATISTICAL ANALYSIS

The normality of quantitative parameters was tested by Shapiro Wilk test and variances' homogeneity with Levene test.

Groups' comparisons have been realized by the Student t-test when the sample was normally distributed or by the Mann-Whitney-Wilcoxon test otherwise.

For the comparison pre and post operatively in the same group, the same test has been involved but on paired data.

Concerning the operative time comparison, the ANOVA has been used tacking into account two factors (group and help). A data log transformation was carrying out to confirm the data homoscedasticity for multivariate analysis. The correlation between two parameters was assessed using the Spearman correlation coefficient.

Learning curves were plotted to see if there has been an improvement over time for the post-operative HKA angle and time of surgery.

All P-values were two sided, with a P-value less than 0.05 was considered to indicate a statistically significant difference.

Analysis was performed in July 2013 by using GNU R software (2.15.0) (Vienna, Austria).

RESULTS

Wording:

When the normality of the parameter distribution was obtained, the results were described by their means and standards deviation. Otherwise it was described by its median, 25% and 75% percentiles.

Comparison pre and post operatively in the groups:

SI group:

	Pre op.	Post op.	p-Value
HKA	178 [177,8;181]	180 [177;180,2]	0,47
MFA	93 (2.13)	92 (1.21)	0,13
MTA	88 [86;89]	88 [87;89]	0,36

Table 1: Pre and post operative alignment in SI group

There were no statistical differences in this group between the measures made pre operatively and those made post operatively. Table 1.

PSG group:

	Pre op.	Post op.	p-Value [CI]
HKA	178 [178;180]	178 [177;179]	0,90
MFA	92 [92;93]	92 [90;93]	0,24
MTA	88 [86;88]	89 [88;89]	0,02

Table 2: Pre and post operative alignment in PSG group

For the HKA and MFA there were no statistical differences between the measures made pre operatively and those made post operatively. Concerning the MTA there was a statistical difference between the pre operative and the post-operative measures. The estimation of this difference is 1.5 [0.5;2.5]. Table 2.

Comparison between the groups:

Pre operatively:

Regarding the HKA angle: 66,7% (22/33) of the lower limbs were in varus ($<180^\circ$), 27,3% (9/33) were in valgus ($>180^\circ$), and 6% (2/33) were in neutral position.

There was no statistical difference between the two groups concerning the HKA, MFA and MTA angles. Table 3.

	SI	PSG	p-Value [CI]
HKA	178 [177,8 ;181]	178 [178 ;180]	0,64
MFA	93 (2.13)	92,35 (1.32)	0,3
MTA	88 [86 ;89]	88 [86 ;88]	0,65

Table 3: Comparison of pre operative alignment between the groups

Per operatively:

54% (18/33) of the knees had osteoarthritis on one or more of the three compartments.

For the PSG group, the reverse to standard instrumentation hadn't been necessary.

For the positioning of PSG, four times the PSG had been difficult to place, once on the tibial plateau, and three times on the femoral landmarks.

Regarding the necessity of recut in PSG group, 11,8% had been necessary, corresponding of 2 knees, with a recut of the tibial plateau of 2 mm.

Concerning the PSG group, the sizes of the components between the planned TKA and the effective TKA, 5 femoral components were planned one size smaller than the effective size used for the TKA.

For the PSG group, the polyethylene (PE) size was 8 mm for 12/17 TKA, for the five other ones the size was 10 mm. For the SI group, 10/16 PE were 8 mm, 3/16 were 10 mm and 3/16 were 12 mm.

Post operatively:

78,8% (26/33) of the lower limbs were axed between 177° and 183°, representing 76,47% (13/17) in PSG group and 81,25% (13/16) in SI group. 23,5% in PSG and 18,75% in SI group were considered as outliers (out of the window 180°+/-3°), all of this outliers were in varus (< 177°).

There was no statistical difference between the two groups regarding the HKA, MFA and MTA angles.

	SI	PSG	p-Value [CI]
HKA	179.1 (2.45)	178 (2.18)	0,17
FMA	92 [91 ;93]	92 [90 ;93]	0,72
TMA	88 [87 ;89]	89 [88 ;89]	0,11

Table 4: Comparison of post operative alignment between the groups

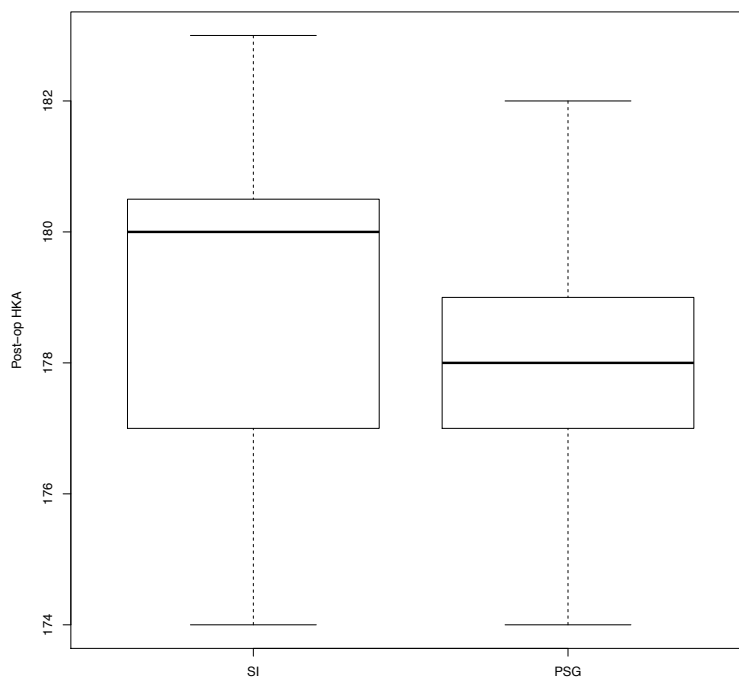


Figure 6: Boxplot post operative HKA

In order to have a statistical difference between the two groups, with a power of 80%, the sample must have 75 lower limbs in each group.

Plumb line:

Pre operatively and post operatively, the measures made with the plumb line compared with the knee centre and the internal edge of the anterior tibial tubercle are correlated together but there is no correlation between these measures and the HKA angles.

Operative time:

The median time for SI group was 50 minutes [43; 62,5], this time was 43 minutes [35 ;47] for the PSG group. There was a statistical difference with a p-value at 0,04.

When the surgery was achieved with help, the median time was significantly lower for the PSG group than the SI group (p-value= 0,02), but there was no difference of operative time between the two groups when the surgery was realized without help (p-value= 0,69). Table 5.

Help	Method	Min	Q1	Median	Mean	Q3	Max	SD	N	P.value
With help	SI	50	50	53	54	57	60	4.9	4	0.017
	PSG	30	34	42	39.89	44	55	8.07	9	
Without help	SI	38	42.25	44.5	60.17	71.25	140	30.25	12	0.699
	PSG	32	42.75	45.5	47.88	52.5	65	10.49	8	

Table 5: Operative time by group and help

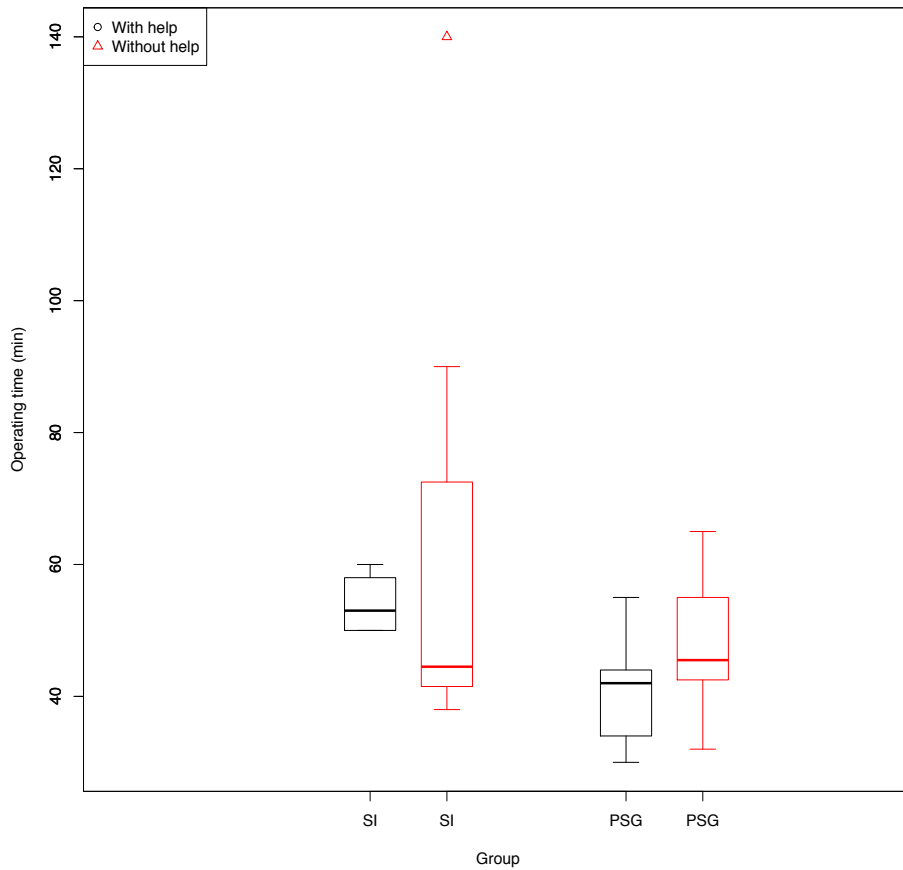


Figure 7: Boxplot operative time by group

The median operative time for the group with help is 44 minutes [35; 50], for the group without help is 44,5 minutes [42,75; 61,25].

There is no statistical difference between the operative time with help and the operative time without help (p-Value =0,25). Figure 7.

So, according to the ANOVA's results, only the group has an influence on the time (p-Value of the group factor = 0.02 and p-Value of the help factor = 0.3). Table 6.

	Df	Sum Sq	Mean Sq	F value	Pr (>F)
Data PSG	1	0.5184	0.5184	6.018	0.0202
Data Help	1	0.0950	0.0950	1.102	0.3022

Table 6: ANOVA study results

Residuals 30 2.5845 0.0861

Learning curve:

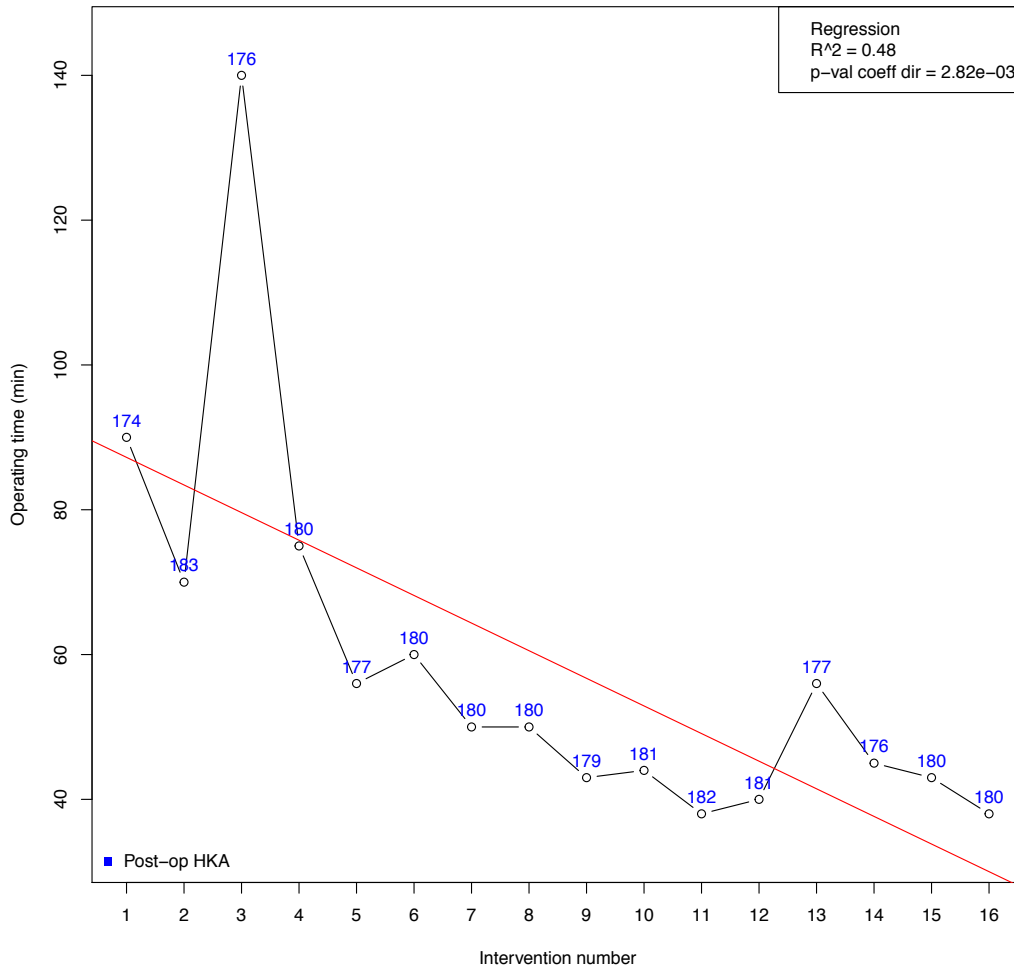


Figure 8: learning curve operative time SI group, with HKA of each knee

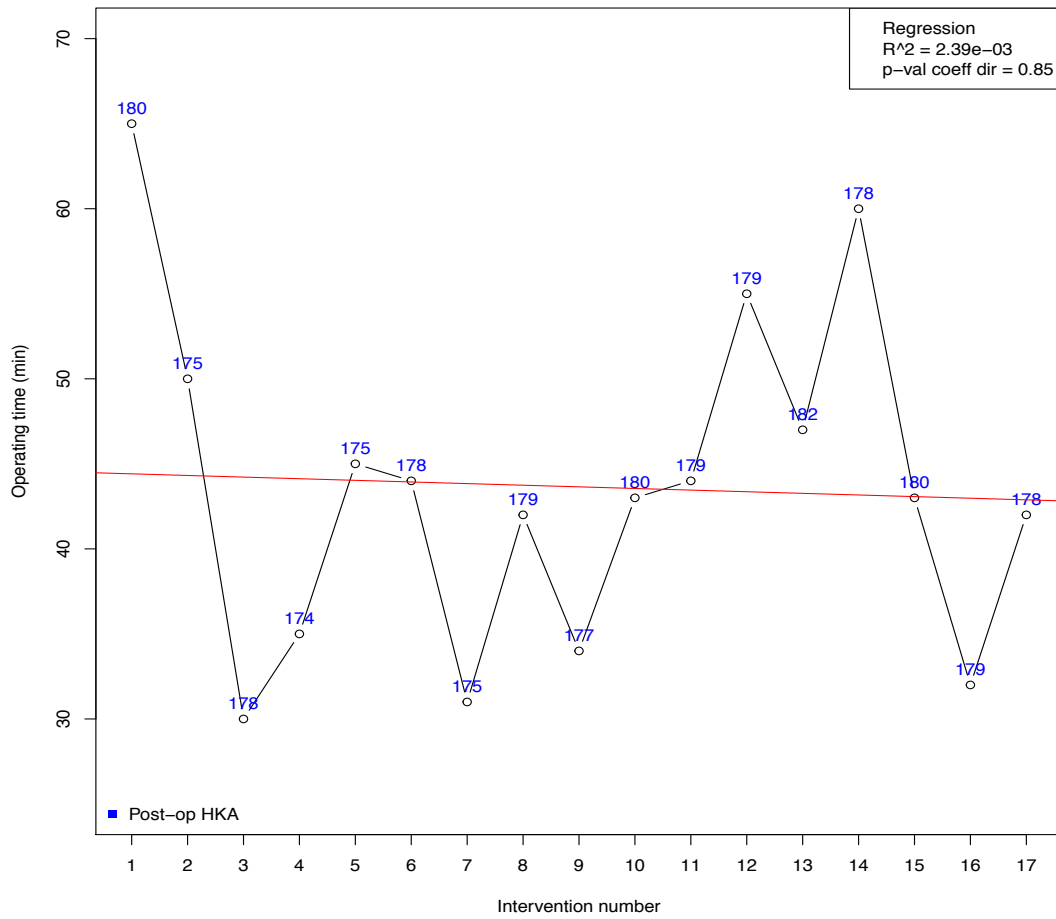


Figure 9: learning curve operative time PSG group, with HKA of each knee

Review of literature:

The tables summering the articles are presented in annex 2.

DISCUSSION

Review

Regarding the literature, the percentage of outliers is comprised from 0% to 75%.

Concerning overall mechanical alignment, in the comparative studies, if we take into account each PSG group in multiple comparative group as one independent group, 6 comparative studies over 12 found more outliers in PSG group than the SI or CAS groups.

The papers which studied PSG produced in order to reach neutral overall mechanical alignment (such as Signature, visionnaire, Tru Match): the percentage of outliers run from 9,40% to 45%. When the PSG was a Otis Med (which kinematically align the lower limb), the percentage is comprised between 9,52% and 75%.

Concerning the operative time, all the papers comparing this criteria with SI group found a lower operative time in PSG group than SI group.

Alignment

We investigated this alleged improvement in 3D, using postoperative imaging as measurement tool and standard instrumentation as a control cohort.

In our controlled cadaveric study, the use of PSGs did not improve the mechanical alignment of TKA.

Since few years, in the literature many articles studied the accuracy of PSG in TKA, but most of them are not comparative studies.

For validating the usefulness of PSG, the goal is to establish its equivalence or superiority to existing modalities: standard instrumentation and Computer Assisted Surgery (CAS).

In our study, pre operatively, there was no statistical difference between the two groups regarding the three angles (HKA, MFA and MTA).

Post operatively, the mean HKA in PSG group was $178^{\circ} \pm 2,18^{\circ}$ versus $179,1^{\circ} \pm 2,45^{\circ}$ in SI group and there was no statistical difference between the groups. Concerning the HKA outliers (outside of $180^{\circ} \pm 3^{\circ}$), there were more outliers in PSG group (23,5%) than in SI group (18,75%).

Regarding the MFA, the median angle in PSG group was 92° [90; 93] versus 92° [91; 93] in SI group, the percentage of outliers over $90^{\circ} \pm 2^{\circ}$ was: 35,3% in PSG group and 31,25% in SI group.

Concerning the MTA, the mean angle was 89° [88; 89] in PSG group and 88° [87; 89] in SI group, the percentage of outliers over $90^{\circ} \pm 2^{\circ}$ was lower in PSG group with 17,65% than SI group with 31,25%.

Regarding the comparative studies in the literature, Ng and al.(16), described a similar mean HKA angle between the groups (PSG: $180,6^{\circ}$, SI: $181,1^{\circ}$), but found statistically less HKA outliers in PSG group (9%) than in SI group (22%).

Noble et al.(15) also found a statistically mechanical alignment closer to neutral zero with the PSG.

In an other hand, Nunley et al.(18) compared 3 groups: 1 group SI, 1 group PSG aligned on mechanical axis and 1 group PSG aligned on kinematic axis, they found 16% outliers in HKA angle in the SI group versus 18% in the PSG subgroup that targeted neutral mechanical alignment and 44% in the PSG subgroup that targeted kinematic alignment. They concluded that PSGs did not improve coronal alignment.

This studies used as PSG, three kinds of different trademark, we can ask if the difference in improvement or not, is due to one kind of PSG.

In a prospective randomized controlled trial, Victor et al.(19), compared four kinds of PSG systems analyzed by both CAS and 3-D radiographic and concluded that these systems did not improve the accuracy of TKA, the PSG procedure was modified in 28% of PSG group (inappropriate size component and level of cut).

And this system did not reduce the number of outliers in any plane in space. The CAS permitted to eliminate the per operative outliers more than 3° in any plane (coronal and

sagittal), but the statistical analyses included the original incorrect value, the PSG procedure had to be abandoned in more than one of five patients.

Some authors compared PSG versus standard instrumentation, regarding the mechanical axis in coronal alignment of the lower limb; three of them(20)(21)(22) did not find any statistical difference between the groups, but two of them(20)(22) found a statistical difference concerning the back slope of the tibial component in sagittal plane.

In our study, as regard the accuracy, the need of recut or changing size of the component during surgery, occurred two times for the recut and 5 times (over 17) for the changing size component, exclusively on femoral component. There were non-overhang tibial component. In comparative study, Stronach et al. (23) indicated that Patient-specific instrumentation predicted the implanted component size in only 23% of femurs and 47% of tibias over 66 TKA. They also pointed the lack of accuracy of these PSGs concerning the alignment of TKA. They analyze the number of directed changes made by the surgeon in order to improve the positioning of TKA implanted with PSG. 2,4 changes per knee occurred, regarding the radiographically measureable changes, 21/95 involved alignment, and 17/21 of the changes were an improvement. The principal drawback of this study is the fact that all changes are subjective.

In most of the comparative studies (15)(16)(18)(20)(21)(22)(23)(24)(25) unlike to our study, the PSG guides were planned from MRI images.

Or one study compared the accuracy of MRI versus CT imaging in patient specific templates for total knee replacement surgery(26), and concluded that the model generated from the CT data were superior to those generated from the MRI, with less numerous discontinuities and unwanted artifacts on the external surfaces.

Only one article(19) studied four subgroups of PSGs images based on either CT scan or MRI, and compared the 4 subgroups together and also to a SI group, they found no statistical difference in the limb alignment in the three planes (coronal, sagittal and rotational).

Ng et al.(16) who demonstrated a lower percentage of outliers in PSG group, also compared their results of TKA with PSG, with a review of literature concerning CAS, they found a number of outliers comparable to CAS.

Operative time

Concerning the operative time, our study showed a statistical reduced time surgery in PSG group, with a median time in SI group of 50 minutes, versus 43 minutes for PSG group. This finding was also supported by previous study.(15)(22)(24)(21). Stronach et al.(23) did not find a reduction of time surgery mainly cause of the surgeon directed changes per operatively. This operative time did not take into account, the time needed for preoperative planning and confirming the final plan.

Others findings

Concerning the plumb line measures, those were not correlated with the HKA angle, but were correlated together. This lack of correlation with the HKA angle is may be due to the medial to lateral size of each knee. This explanation can also highlight the fact that there is a correlation between the plumb line measures themselves.

Learning curve: the graph representing the learning shows a decrease of the operating time greater in the SI group than in PSG group, without so much differences in HKA angle.

Cost effectiveness:

In our study, the price for the production of a pair of PSG (tibial and femoral cutting blocks) was assessed to 500€ without taking account of the realization of CT scan.

Tibesku et al.(27) compared the economic impact of PSG with SI in TKA, based on activity-based costing (ABC). The parameters of the ABC model were: implants and cutting, personnel costs, diagnostics, hospital costs. The operating time saving observed in our study and others(15)(24)(21), the use of less trails during surgery led to save money. The analysis

was established on 350 TKAs per year. Tibesku et al. concluded if the saved time was utilized to perform procedure other than TKA (total hip arthroplasty, arthroscopy...), this will result in additional revenue of 78 240€ per year to the hospital.

Hafez et al.(28) demonstrated that PSG is cheaper than SI TKA. The explanation is the following: the cost of a set for SI process is 30 000\$ every 5 years, based on 150 TKAs every 5 years, the set of implant costs 200\$ per TKA without the sterilization of the set (180\$). The cost of the PSG in their study is 200\$ per pair, and the CT scan: 100\$ per specimen.

Limitations

This study had some limitations.

Firstly, this study was too underpowered (small patient population) to detect a statistical significance, concerning alignment. To have a statistical significance, with a power of 80%, the sample must have 75 lower limbs in each group.

Secondly, the cadaveric lower limb in this study did not have any severe pre-operative deformities (HKA range from 182° valgus to 171° varus).

Thirdly, the results are limited to the coronal plane and do not take into account component positioning on the lateral view. In addition, we could not assess for rotational alignment, the internal, external or neutral position was decided depending on ligament balance in flexion. Moreover the cadaveric knees were most of time rigid, so the testing of ligament balance in flexion and in extension should have been prevaricated.

Fourthly, the influence of the learning curve, the surgeon had no prior experience with PSGs, and the use of a new implant system is a potential bias. In the other hand, this surgeon had not so much experience in standard instrumentation.

Lately, the CT images had been controlled pre and post operatively by only one person, member of the society working out the PSGs.

Futures directions

Patient-specific instrumentation can be engineered to restore the knee alignment to either the mechanical axis or the kinematic alignment.

The kinematic motion of the knee can be referenced to the flexion-extension axis of the distal femur. This axis passes through the centre of the posterior femoral condyles consider as cylindrical.(29)(30)

To create the PSG, the arthritic knee model needs to be transformed in normal knee model by filling articular defects and removing osteophytes.

A recent study(31) on modern TKA showed that the 25% of patients who were outliers (3° varus or valgus) had better survivorship at 15 years than the 75% aligned within the 3° window. Moreover an another recent multicenter study(32) demonstrated that the malalignment of TKA out of HKA $180^\circ \pm 3^\circ$ was not a risk factor of failure.

Some authors performed TKA with PSG in order to reach this kinematic alignment corresponding to pre arthritic joint line.

Klatt et al.(17) in his study, report a high potential of malalignment of TKA component, but this article is based on only 4 TKA performed with PSG in order to reach kinematic alignment of the knee. The 4 TKA were performed under control of CAS, per operatively the overall alignment measured by CAS (referred to mechanical alignment) was between 5° valgus to $7,5^\circ$ varus. The post operative X ray show a tibial component malalignment from 3° of valgus to 7° of varus, but no long leg X Ray were realized and the overall alignment was not evaluated.

Few months later, Howell et al.(33) reported, an initial experience with kinematic based PSG in 48 TKA. All TKA alignment were within $\pm 3^\circ$ of the neutral mechanical alignment. They also reported a high level of patient satisfaction and an acceptable clinical outcome at 3 months.

Spencer et al.(34), compared 21 TKA performed with PSG aligned on the kinematic trans cylindrical axis with previous studies 30 TKA performed with standard instrumentation. There were no statistical difference concerning coronal alignment based on mechanical axis compared with two previous studies based on standard instrumentation and CAS, with only two patients outlying $180^{\circ} \pm 3^{\circ}$. Regarding to clinical outcome at 3 months and 6 months, PSG group flexion was greater than SI group, without statistical difference.

Dossett et al.(35), compared in randomized trial, 41 TKA based on kinematic axis using PSG with 41 TKA based on mechanical axis based on standard instrumentation. Knee and limb alignment were similar between the groups. And the functional outcome at 6 months was higher in the kinematically aligned group.

Recently Howell et al.(36), studied the outcome at minimum of 31 months with Oxford Knee Score and WOMAC scores among 214 TKA performed with kinematic based PSG, and allocated in three alignment categories for tibial component, knee and limb. The categories were classified in in range or outlier. There was no statistical difference between the groups regarding the functional outcome.

Other directions can be taken by PSG, in high deformity of femoral bone in which intra medullary rod cannot be used, or in case of osteopetrosis such as described by Mayer et al.(37), or for unicompartmental to TKA revision surgery described by Kerens et al.(38).

CONCLUSION

In our cadaveric study, patient specific guides (PSG) for total knee arthroplasty did not improve the coronal mechanical alignment of the lower limb compared with standard instrumentation procedure. Indeed, we obtained post operatively a mean HKA angle of $179,1^{\circ} \pm 2,45^{\circ}$ and $178^{\circ} \pm 2,18^{\circ}$, and a percentage of outliers from $180^{\circ} \pm 3^{\circ}$ at 18,75% and 23,5%, in standard instrumentation and PSG groups respectively.

On the contrary, the operative time was significantly reduce in PSG group compared to standard instrumentation group. This result is corroborated by many authors. Some of them add that this diminution can lead to a reduction of cost effectiveness, despite of the price of this new technology.

The emergence of this technique, raise to a new concept of alignment of total knee arthroplasty, focused on kinematic alignment of the lower limb.

But further study is necessary to compare custom cutting guides with traditional instruments and computer navigation with regards to long term implant survival and functional outcome, regardless the type of lower limb alignment.

Introduction: Coronal alignment in total knee arthroplasty (TKA), regarding the literature, seems to be a major factor in the survivorship of the component and in the functional outcome. The Patient Specific Guides (PSG), based on 3 D imaging, had been introduced in surgical process in order to improve accuracy in TKA, and to reach post operative neutral mechanical alignment.

Hypothesis: Compared with standard instrumentation (SI), PSG can improve the coronal alignment of the TKA and decrease the operative time.

Materials and methods: Thirty-three lower limbs (from femoral head to foot) have been taken from seventeen cadavers. A pre operative CT scan of each lower limb has been realized in order to measure: Hip-Knee-Ankle angle (HKA), mechanical femoral angle (MFA) and mechanical tibial angle (MTA), and to plan the TKA for shaping the PSG. 17 TKAs have been implanted with PSG, 16 with SI. 54% (18/33) knees presented osteoarthritis at least on one of the three compartments. Post operatively, a further CT scan has been used to make the measure to compare the two groups. Per operatively, operative time and positioning of PSG have been reported.

Results: Pre operatively, 66,7% (22/33) of the lower limbs were in varus, 27,3% (9/33) were in valgus and 6% (2/33) were in neutral alignment, there was no significant difference between the groups. Post operatively: the overall mechanical alignment was between 177° and 183° for 81,25% (13/16) in SI group, and 76,47% (13/17) in PSG group. The mean HKA in SI was 179,1° +/- 2,45°, and 178° +/- 2,18° in PSG group, there was no significant difference between the group (p-Value: 0,17). Only the operative time was significantly lower in PSG group with a median of 43 minutes [35-47] relative to the SI group with a median of 50 minutes [43-62,5] (p-Value: 0,041).

Discussion: In our cadaveric study, PSG for TKA did not improve the coronal mechanical alignment of the lower limb compared with SI procedure. Indeed, we obtained post operatively a mean HKA angle closer to 180° in SI group than in PSG group, and the percentage of outliers from 180° +/- 3° was lower in SI group with 18,75% versus 23,5% in PSG group.

On the contrary, the operative time was significantly reduced in PSG group compared to standard instrumentation group. This result is corroborated by many authors. Some of them add that this diminution can lead to a reduction of cost effectiveness, despite of the price of this new technology.

The emergence of this technique, raise to a new concept of alignment of TKA, focused on kinematic alignment of the lower limb.

But further study is necessary to compare custom cutting guides with traditional instruments

and computer navigation with regards to long term implant survival and functional outcome, regardless the type of lower limb alignment.

Conclusion: in our study, PSG did not demonstrate a superiority regarding the coronal mechanical alignment comparing with SI in TKA. But the use of PSG process can reduce the operative time.

VU ET PERMIS D'IMPRIMER
Grenoble, le 22 août 2013

LE DOYEN

J.P. ROMANET



LE PRESIDENT DE LA THESE
Professeur P. MERLOZ

CHU De GRENOBLE
HOPITAL A. MICHALLON
ORTHOPEDIE-TRAUMATOLOGIE
Pr. Ph. MERLOZ
Chef de Pôle

A handwritten signature in black ink, appearing to be "P. Merloz", written over the printed name and title.

Annex 1: Surgical technique

Set up:

The lower limb was placed on hand made support, designed especially in order to flex and bend the knee in all degrees of freedom.



Figure 1: set up

Surgical approach:

- When possible a midline knee incision was performed, from the distal part of the anterior tubercle of the tibia to 5 cm proximally from the patella. Some of the cadaveric knees had already been used during practical work performed by medical students and some of them had already a surgical approach. When it was the case, the same incision was chosen.

- Medial parapatellar arthrotomy: the incision followed the medial part of the tibial tubercule, up medially to the femoro-patellar ligament, and turned to the mid vastus at the proximal part of the patella. The medial collateral ligament was elevated from the tibia sufficient to gain sufficient access to the knee joint.

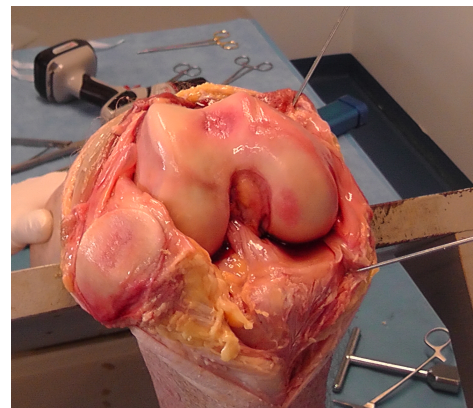


Figure 2: surgical approach

- Lateral everting of the patella.
- The cruciate ligaments, lateral and medial menisci were then removed.

Plumb Line measures:

- In order to check pre operatively the axis of the lower limb, a plumb line test have been made at the beginning of the surgery process to check the correlation between the angles measured from the CT scan (especially HKA angle measure) and the distance between the plumb line and the landmarks.

These measures were made before and after the knee replacement.



Figure 3: Plumb line measures

- Plumb line: from the hip center (obtained by placing a vernier caliper in two orthogonal plans and introducing a K-wire in the middle of both axes) to the ankle center (obtained by choosing the middle of the hook between the medial and lateral malleoli).
- In order to have a referent alignment, the distance (in millimeters) between the plumb line and corresponding anatomical landmarks was measured pre and post-operatively. The corresponding landmarks chosen were the internal edge of the anterior tibial tubercule, and the knee centre (middle of tibial spines or middle of tibial component). When the plumb line went medially from these anatomical landmarks the measure values was considered positive (negative if lateral).

Standard Instrumentation:

- firstly the proximal tibial cut was performed, using a intra medullary system, consisting mainly of a conventional cutting block with a posterior slope of 2° , and a probe placed on the less worm tibial plateau giving the cut height at 12 mm. The block was fixed with three pins. The proximal tibial cut was performed in caring for the insertions of the anterior and posterior cruciate ligaments.

- Secondary, the distal femoral cut was performed using also an intra-medullary system adjusted with the HKS (Hip-Knee-Summit) angle.

PSGs process:

- First the tibial PSG was placed after removing soft tissues in contact with fitting areas of the PSG. The tibial cut was done. The same process was done for the femoral cut.

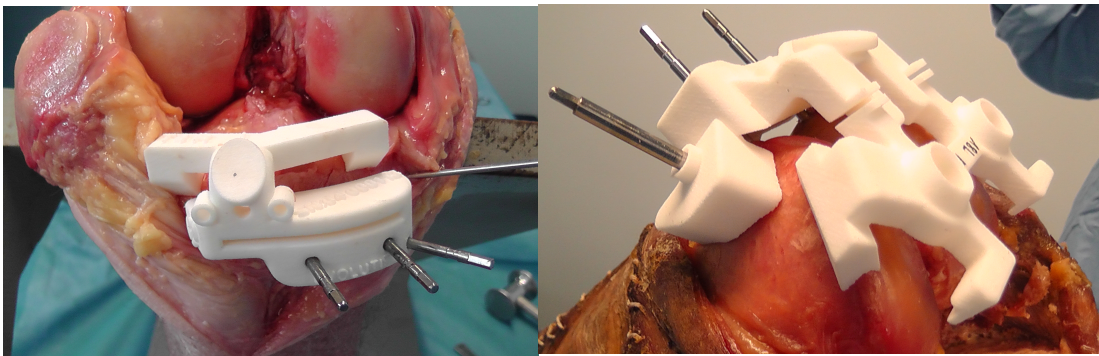


Figure 4: positioning of PSGs

- After tibial proximal cut and femoral distal cut, an long extra medullary spindle, fixed on template for PSG or on control guide, were involved to control the normal mechanical alignment of the components by matching the ankle's center and hip's center.

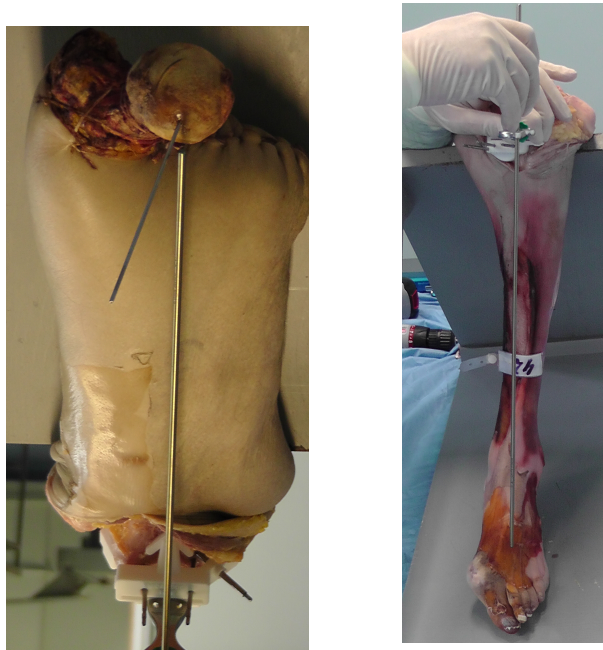


Figure 5: control of mechanical alignment

- Full extension was checked with a spacer equal to the height of definitive TKA.

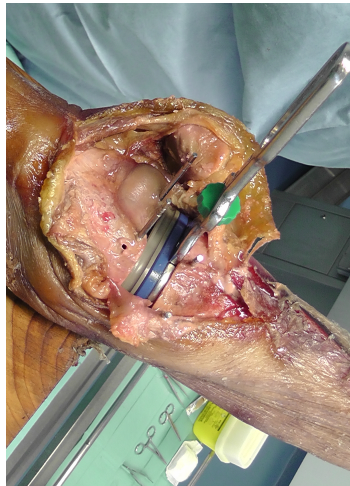


Figure 6: extension spacer

Components and ligaments balancing:

- Before tacking of the block cut, the ligament balance in flexion was checked and adjusted if necessary, the rotational alignment of the femoral was adjusted in order to have a flexion gap equal to the extension gap.

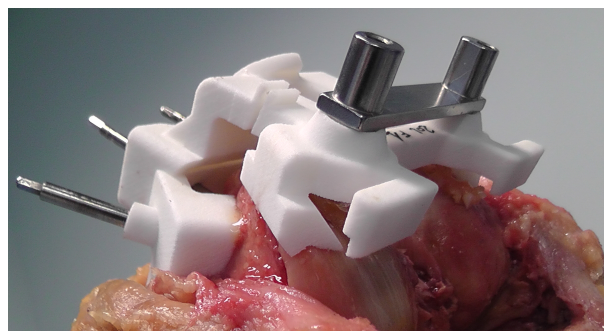


Figure 7: rotational alignment

- After the selection of internal, external or neutral rotation, the 4 in 1 cutting block was fastened on distal cut. Anterior and posterior cuts and chamfers were then performed.

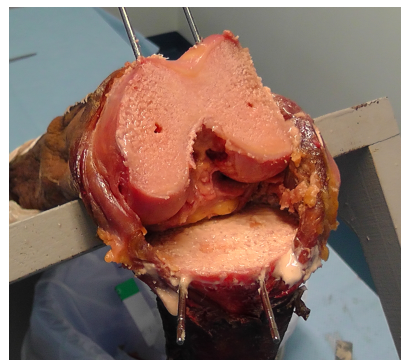


Figure 8: femoral distal and tibial proximal cuts

- The trial components were implemented according to components size planned preoperatively when using PSGs, or chosen regarding the tibial and femoral osteotomies sizes with standard instrumentation.

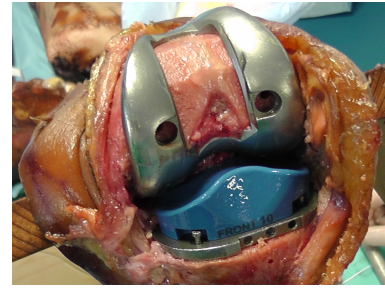


Figure 9: trial components

- The ligament imbalance was controlled in flexion and extension, and reported as tight, lax or normal. If one compartment was too tight a ligament release was performed as a pie-crusting. If both compartments were lax in flexion and in extension a higher polyethylene insert was used.
- Plumb line measurements were done again as a final control.

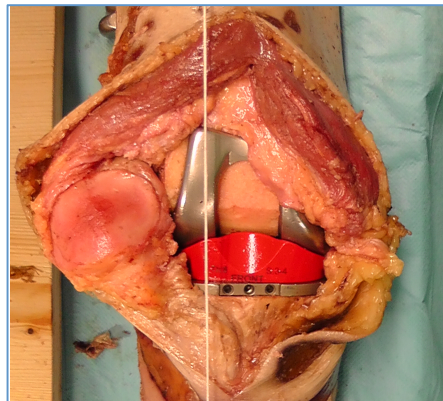


Figure 10: post operative plumb line measures

ANNEX 2: Tables of review

Authors	3D images	Type of PSG	Control cohort	Nb of cases	CAS per op.	Type of alignment	Mean Coronal Mechanical alignment	Outliers	Mean Operative time (min)
Howell et al.(33)	MRI	OtisMed System	No	48	No	Mechanical	1.4° varus +/- 2.8°	NE	52 +/- 8 Tourniquet
Klatt et al.(17)	MRI	OtisMed system	No	4	Yes	Mechanical	5° valgus to 7,5° varus	75%	NE
Lombardi et al.(10)	MRI	NC	No	54	No	Mechanical	4° to 8° valgus	NE	77
Gan et al.(39)	CT scan	NC	No	30	No	Mechanical	NC	0%	50
Bali et al.(40)	MRI	Visionnaire	No	32	No	Mechanical	179,9° +/- 2°	9,40%	67,8
Conteduca et al.(41)	MRI	Visionnaire	No	12	Yes	Mechanical	Tibial: 1,2 +/- 1,5, femoral: 1,2 +/- 0,6	Tibial : 16,7%, femoral : 8,3% (90°+/-2°)	NE
Delpoit et al.(42)	MRI	Signature	No	5	No	Mechanical	MFA 89,2°, MTA 89,4°	NE	65,6
Daniilidis et al.(43)	MRI	Visionnaire	No	100	No	Mechanical	178,5° +/- 1,7°	11%	52,5
Howell et al.(36)	MRI	OtisMed system	No	214	No	Mechanical	- 0.9° +/- 2.7°	27%	NE
Kerens et al.(38)*	CT Scan	Signature	No	10	No	Mechanical	2° (varus)+/- 1,7°	20%	83
Lusting et al.(44)	MRI	Visionnaire	No	60	Yes	Mechanical	179,8°	20,7%	NE

Table 1 : Review of non comparative studies. NE : Non Evaluated, NC : Non Communicated. * revision of Unicompartmental Knee arthroplasty to TKA

Authors	3D images	Type of PSG	Control cohort	Nb of cases	CAS per op.	Type of alignment	Mean coronal Mechanical alignment	Outliers	Mean Operative time (min)
Hafez et al.(28)	CT scan	NC	Yes,SI	39 PSG/ 6 SI	No	Mechanical	Mean errors : Femoral: 1,02° Tibial: 1.06°	NE	9 PSG/ 15 SI (bone cutting)
Spencer et al.(34)	MRI	OrisMed system	Yes,SI	21 PSG/ 30 SI	No	Kinematic	1,2° varus +/-2,4° , NSD	9,52%	Tourniquet time: PSG 80+/-17, SI : 93 +/-12
Barrack et al.(45)	MRI	NC	Yes,SI	100 PSG/ 100 SI	No	Mechanical	PSG: 1,7° valgus+/- 2,5° SI:0,5° valgus+/- 2,3° SD	PSG: 31% SI: 23%	11 min lower in PSG
Boonen et al.(22)	MRI	Signature	Yes,SI	40 PSG/ 40 SI	No	Mechanical	PSG: 181° +/-4° , SI:179° +/-3° , SD	PSG:28,95% , SI :45,71% , NSD	PSG: 51, SI 61,SD
Conteduc a et al.(46)	MRI	Visionnaire	Yes, EM tibial SI	12 (1st :EM, 2 nd :PSG)	Yes	Mechanical	EM : 0,7° +/- 0,39° ; PSG : 1,29° +/-1,55°	PSG: 16,7% EM SI: 0% (90°+/-2°) NSD	NE
Dossett et al.(35)	MRI	NC	Yes, SI	41 PSG (k)/ 41 SI (m)	No	Mechanical	PSG 0,3° (varus)+/- 2,8° SI : 0°+/- 2,2° ,NSD	NE	PSG : 106+/-20, SI : 127+/-24 SD
Ng et al.(16)	MRI	Signature	Yes,SI	569 PSG/ 155 SI	No	Mechanical	PSG: 180,6° , SI: 181.1°	14,4% PSG, 27,7% SI	NE
Noble et al.(15)	MRI	Visionnaire	Yes, SI	15 PSG/ 14 SI	No	Mechanical	PSG: 1.7° , SI: 2.8° SD	NE	PSG: 121.4 SI: 128.1 SD

Table 2 : Review of comparative studies, NE : Non Evaluated, NC : Non Communicated, SD : Statistical Difference, NSD : Non Statistical Difference, EM : extramedullary.

Authors	3D images	Type of PSG	Control cohort	Nb of cases	CAS per op.	Type of alignment	Mean coronal Mechanical alignment	Outliers	Mean Operative time (min)
Nunley et al.(18)	MRI	OtisMed system 1, Signature 2	Yes, 2 PSG gps and 1 SI gp	50 PSG1/ 50 PSG2 /50 SI	No	Mechanical	PSG1 : -2,76° PSG2 : -0, 65° SI : 0,08°	44% PSG1 18% PSG2 16% SI	NE
Yaffe et al.(47)	MRI	PSI system	Yes,CA S	111 PSG/30 CAS	Yes for CAS gp	Mechanical	PSG : 0,77° var. (5,5° val-5,8° var.)	17%	NE
Charcanc holvanich et al (21)	MRI	PSI system	Yes,SI	40PSG/ 40SI	No	Mechanical	PSG : 179,7°, SI :179,7°,NSD	PSG : 2,5%, SI :7,5% NSD	PSG : 62,9, SI : 68, SD
Nam et al.(48)	MRI	Signature	Yes,CA S	41 PSG/ 41 SI	Yes for CAS gp	Mechanical	PSG : 0,8 +/-2,9 CAS : 0,8 +/- 1,9	PSG : 29,30% CAS : 7,3%, SD	NE
Victor et al.(19)	MRI CT Scan	Signature 1, TruMatch 2, Visionnaire 3, PSI system 4	Yes, SI	61 PSG/ 64 SI	Yes	Mechanical	1 : 0,3° varus +/-1,4 2 : 0,9° varus+/- 2,3 3 : 0,5 varus+/- 3,4 4 : 0° +/- 1,8 SI : 0,9° varus+/-1,8	1 : 6% 2 : 25% 3 : 45% 4 : 19% SI : 28,1%	NE
Vundelin ckx et al.(20)	MRI	Visionnaire	Yes, SI	31 PSG / 31 SI	No	Mechanical	PSG : 3°+/- 2,56 SI : 2,7°+/- 2,39,NSD	NE	NE
Our study	CT Scan	NC	Yes,SI	17PSG/ 16SI	No	Mechanical	PSG : 178°+/-2,18° SI : 179,1°+/-2,45°	PSG : 23,5% SI : 18,75%	PSG 43 SI 50, SD

Table 3 : Review of comparative studies., gp : NE : Non Evaluated, NC : Non Communicated, SD : Statistical Difference, NSD : Non Statistical Difference, EM : extramedullary

REFERENCES

1. Iorio R, Robb WJ, Healy WL, Berry DJ, Hozack WJ, Kyle RF, et al. Orthopaedic surgeon workforce and volume assessment for total hip and knee replacement in the United States: preparing for an epidemic. *J Bone Joint Surg Am.* 2008 Jul;90(7):1598–605.
2. Insall JN, Binazzi R, Soudry M, Mestriner LA. Total knee arthroplasty. *Clin. Orthop. Relat. Res.* 1985 Feb;(192):13–22.
3. Lotke PA, Ecker ML. Influence of positioning of prosthesis in total knee replacement. *J Bone Joint Surg Am.* 1977 Jan;59(1):77–9.
4. Ritter MA, Faris PM, Keating EM, Meding JB. Postoperative alignment of total knee replacement. Its effect on survival. *Clin. Orthop. Relat. Res.* 1994 Feb;(299):153–6.
5. Jeffery RS, Morris RW, Denham RA. Coronal alignment after total knee replacement. *J Bone Joint Surg Br.* 1991 Sep;73(5):709–14.
6. Fang DM, Ritter MA, Davis KE. Coronal alignment in total knee arthroplasty: just how important is it? *J Arthroplasty.* 2009 Sep;24(6 Suppl):39–43.
7. Kumar PJ, Dorr LD. Severe malalignment and soft-tissue imbalance in total knee arthroplasty. *Am J Knee Surg.* 1997;10(1):36–41.
8. Chauhan SK, Scott RG, Breidahl W, Beaver RJ. Computer-assisted knee arthroplasty versus a conventional jig-based technique. A randomised, prospective trial. *J Bone Joint Surg Br.* 2004 Apr;86(3):372–7.
9. Mason JB, Fehring TK, Estok R, Banel D, Fahrbach K. Meta-analysis of alignment outcomes in computer-assisted total knee arthroplasty surgery. *J Arthroplasty.* 2007 Dec;22(8):1097–106.
10. Lombardi AV Jr, Berend KR, Adams JB. Patient-specific approach in total knee arthroplasty. *Orthopedics.* 2008 Sep;31(9):927–30.
11. Radermacher K, Portheine F, Anton M, Zimolong A, Kaspers G, Rau G, et al. Computer assisted orthopaedic surgery with image based individual templates. *Clin. Orthop. Relat. Res.* 1998 Sep;(354):28–38.
12. Kim Y-H, Kim J-S, Choi Y, Kwon O-R. Computer-assisted surgical navigation does not improve the alignment and orientation of the components in total knee arthroplasty. *J Bone Joint Surg Am.* 2009 Jan;91(1):14–9.
13. Sparmann M, Wolke B, Czupalla H, Banzer D, Zink A. Positioning of total knee arthroplasty with and without navigation support. A prospective, randomised study. *J Bone Joint Surg Br.* 2003 Aug;85(6):830–5.

14. Victor J, Hoste D. Image-based computer-assisted total knee arthroplasty leads to lower variability in coronal alignment. *Clin. Orthop. Relat. Res.* 2004 Nov;(428):131–9.
15. Noble JW Jr, Moore CA, Liu N. The value of patient-matched instrumentation in total knee arthroplasty. *J Arthroplasty.* 2012 Jan;27(1):153–5.
16. Ng VY, DeClaire JH, Berend KR, Gulick BC, Lombardi AV Jr. Improved accuracy of alignment with patient-specific positioning guides compared with manual instrumentation in TKA. *Clin. Orthop. Relat. Res.* 2012 Jan;470(1):99–107.
17. Klatt BA, Goyal N, Austin MS, Hozack WJ. Custom-fit total knee arthroplasty (OtisKnee) results in malalignment. *J Arthroplasty.* 2008 Jan;23(1):26–9.
18. Nunley RM, Ellison BS, Zhu J, Ruh EL, Howell SM, Barrack RL. Do patient-specific guides improve coronal alignment in total knee arthroplasty? *Clin. Orthop. Relat. Res.* 2012 Mar;470(3):895–902.
19. Victor J, Dujardin J, Vandenneucker H, Arnout N, Bellemans J. Patient-specific Guides Do Not Improve Accuracy in Total Knee Arthroplasty: A Prospective Randomized Controlled Trial. *Clin. Orthop. Relat. Res.* 2013 Apr 25;
20. Vundelinckx BJ, Bruckers L, De Mulder K, De Schepper J, Van Esbroeck G. Functional and radiographic short-term outcome evaluation of the visionaire system, a patient-matched instrumentation system for total knee arthroplasty. *J Arthroplasty.* 2013 Jun;28(6):964–70.
21. Chareancholvanich K, Narkbunnam R, Pornrattanamaneewong C. A prospective randomised controlled study of patient-specific cutting guides compared with conventional instrumentation in total knee replacement. *Bone Joint J.* 2013 Mar;95-B(3):354–9.
22. Boonen B, Schotanus MGM, Kort NP. Preliminary experience with the patient-specific templating total knee arthroplasty. *Acta Orthop.* 2012 Aug;83(4):387–93.
23. Stronach BM, Pelt CE, Erickson J, Peters CL. Patient-specific total knee arthroplasty required frequent surgeon-directed changes. *Clin. Orthop. Relat. Res.* 2013 Jan;471(1):169–74.
24. Pietsch M, Djahani O, Zweiger C, Plattner F, Radl R, Tschauer C, et al. Custom-fit minimally invasive total knee arthroplasty: effect on blood loss and early clinical outcomes. *Knee Surg Sports Traumatol Arthrosc.* 2012 Nov 2;
25. Heyse TJ, Tibesku CO. Improved femoral component rotation in TKA using patient-specific instrumentation. *Knee.* 2012 Nov 7;
26. White D, Chelule KL, Seedhom BB. Accuracy of MRI vs CT imaging with particular reference to patient specific templates for total knee replacement surgery. *Int J Med Robot.* 2008 Sep;4(3):224–31.
27. Tibesku CO, Hofer P, Portegies W, Ruys CJM, Fennema P. Benefits of using customized instrumentation in total knee arthroplasty: results from an activity-based costing

model. *Arch Orthop Trauma Surg.* 2013 Mar;133(3):405–11.

28. Hafez MA, Chelule KL, Seedhom BB, Sherman KP. Computer-assisted total knee arthroplasty using patient-specific templating. *Clin. Orthop. Relat. Res.* 2006 Mar;444:184–92.

29. Eckhoff DG, Bach JM, Spitzer VM, Reinig KD, Bagur MM, Baldini TH, et al. Three-dimensional mechanics, kinematics, and morphology of the knee viewed in virtual reality. *J Bone Joint Surg Am.* 2005;87 Suppl 2:71–80.

30. Eckhoff D, Hogan C, DiMatteo L, Robinson M, Bach J. Difference between the epicondylar and cylindrical axis of the knee. *Clin. Orthop. Relat. Res.* 2007 Aug;461:238–44.

31. Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am.* 2010 Sep 15;92(12):2143–9.

32. Argenson J-N, Boisgard S, Parratte S, Descamps S, Bercovy M, Bonneville P, et al. Survival analysis of total knee arthroplasty at a minimum 10 years' follow-up: A multicenter French nationwide study including 846 cases. *Orthop Traumatol Surg Res.* 2013 Jun;99(4):385–90.

33. Howell SM, Kuznik K, Hull ML, Siston RA. Results of an initial experience with custom-fit positioning total knee arthroplasty in a series of 48 patients. *Orthopedics.* 2008 Sep;31(9):857–63.

34. Spencer BA, Mont MA, McGrath MS, Boyd B, Mitrick MF. Initial experience with custom-fit total knee replacement: intra-operative events and long-leg coronal alignment. *Int Orthop.* 2009 Dec;33(6):1571–5.

35. Dossett HG, Swartz GJ, Estrada NA, LeFevre GW, Kwasman BG. Kinematically versus mechanically aligned total knee arthroplasty. *Orthopedics.* 2012 Feb;35(2):e160–169.

36. Howell SM, Howell SJ, Kuznik KT, Cohen J, Hull ML. Does a kinematically aligned total knee arthroplasty restore function without failure regardless of alignment category? *Clin. Orthop. Relat. Res.* 2013 Mar;471(3):1000–7.

37. Mayer SW, Hug KT, Hansen BJ, Bolognesi MP. Total knee arthroplasty in osteopetrosis using patient-specific instrumentation. *J Arthroplasty.* 2012 Sep;27(8):1580.e1–4.

38. Kerens B, Boonen B, Schotanus M, Kort N. Patient-specific guide for revision of medial unicompartmental knee arthroplasty to total knee arthroplasty. *Acta Orthop.* 2013 Apr;84(2):165–9.

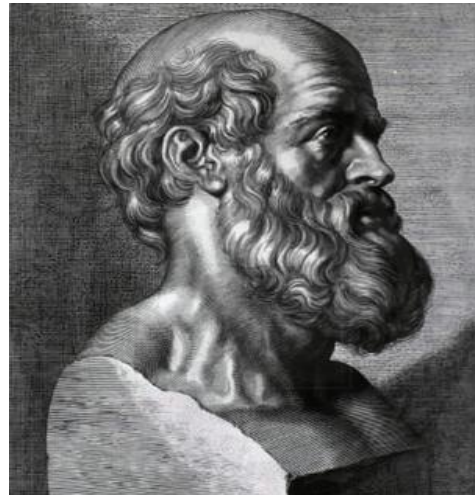
39. Gan Y, Xu D, Lu S, Ding J. Novel patient-specific navigational template for total knee arthroplasty. *Comput. Aided Surg.* 2011;16(6):288–97.

40. Bali K, Walker P, Bruce W. Custom-fit total knee arthroplasty: our initial experience in 32 knees. *J Arthroplasty.* 2012 Jun;27(6):1149–54.

41. Conteduca F, Iorio R, Mazza D, Caperna L, Bolle G, Argento G, et al. Evaluation of the accuracy of a patient-specific instrumentation by navigation. *Knee Surg Sports Traumatol Arthrosc.* 2012 Jun 27;
42. Delpont H, Chandrashekar P. The Use of Patient-Specific Intra-Operative Guides for TKA. *Archives of Clinical and Experimental Surgery (ACES).* 2012;1.
43. Daniilidis K, Tibesku CO. Frontal plane alignment after total knee arthroplasty using patient-specific instruments. *Int Orthop.* 2013 Jan;37(1):45–50.
44. Lustig S, Scholes CJ, Oussedik SI, Kinzel V, Coolican MRJ, Parker DA. Unsatisfactory accuracy as determined by computer navigation of VISIONAIRE patient-specific instrumentation for total knee arthroplasty. *J Arthroplasty.* 2013 Mar;28(3):469–73.
45. Barrack RL, Ruh EL, Williams BM, Ford AD, Foreman K, Nunley RM. Patient specific cutting blocks are currently of no proven value. *J Bone Joint Surg Br.* 2012 Nov;94(11 Suppl A):95–9.
46. Conteduca F, Iorio R, Mazza D, Caperna L, Bolle G, Argento G, et al. Are MRI-based, patient matched cutting jigs as accurate as the tibial guides? *Int Orthop.* 2012 Aug;36(8):1589–93.
47. Yaffe MA, Patel A, Mc Coy BW, Luo M, Cayo M, Ghate R, et al. Component sizing in total knee arthroplasty: patient-specific guides vs. computer-assisted navigation. *Biomed Tech (Berl).* 2012 Aug;57(4):277–82.
48. Nam D, Maher PA, Rebolledo BJ, Nawabi DH, McLawhorn AS, Pearle AD. Patient specific cutting guides versus an imageless, computer-assisted surgery system in total knee arthroplasty. *Knee.* 2013 Aug;20(4):263–7.

Serment d'Hippocrate

En présence des Maîtres de cette Faculté,
de mes chers condisciples
et devant l'effigie d'Hippocrate,
Je promets et je jure d'être fidèle aux lois de
l'honneur et de la probité dans
l'exercice de la médecine.
Je donnerai mes soins gratuitement a
l'indigent et n'exigerai jamais un salaire
au dessus de mon travail.
Je ne participerai a aucun partage clandestin
d'honoraires.



Admis dans l'intimité des maisons, mes yeux n'y verront pas ce qui s'y
passe; ma langue taira les secrets qui me seront confiés et mon état ne
servira
pas a corrompre les mœurs, ni a favoriser le crime.
Je ne permettrai pas que des considérations de religion, de nation, de race,
de
parti ou de classe sociale viennent s'interposer entre mon devoir et mon
patient.
Je garderai le respect absolu de la vie humaine.
Même sous la menace, je n'admettrai pas de faire usage de mes
connaissances médicales contre les lois de l'humanité.
Respectueux et reconnaissant envers mes Maîtres, je rendrai a leurs enfants
l'instruction que j'ai reçue de leurs pères.
Que les hommes m'accordent leur estime si je suis fidèle a mes promesses.
Que je sois couvert d'opprobre et méprisé de mes confrères si j'y manque.