



An Investigation of Innovative 3D Modelling Procedures for Patient-specific Total Knee Arthroplasty

Anna Ghidotti¹ , Andrea Vitali¹  Daniele Regazzoni¹  and Caterina Rizzi¹ 

¹University of Bergamo, anna.ghidotti@unibg.it

¹University of Bergamo, andrea.vitali1@unibg.it

¹University of Bergamo, daniele.regazzoni@unibg.it

¹University of Bergamo, caterina.rizzi@unibg.it

Corresponding author: Andrea Vitali, andrea.vitali1@unibg.it

Abstract. Total Knee Arthroplasty (TKA) is a widely performed surgical procedure, which is advised to treat knee osteoarthritis. However, the literature reported that 25% of the patients are unsatisfied by the functional outcomes after the intervention. The main causes seem to be the prosthesis malalignment and the anatomical mismatch between the prosthetic components and the different people anatomy. Even if there exist several commercial solutions, whose aim has always been to provide a reliable prosthesis with high survivorship, the most recent scientific literature is focusing its aim to improving the patients' clinical outcome, kinematics and satisfaction. For this reason, three approaches have been experimented and then discussed with an orthopedic surgeon. Open-source software applications for 3D modelling have been exploited, such as 3D Slicer and Meshmixer. Starting from medical images, through the segmentation process, the 3D model of the knee has been reconstructed. For the first approach, standard off-the-shelf prosthesis have been used for the virtual planning of the intervention. To overcome the limits of this method, two more customized approaches have been experimented. The first one is based on the patient-specific resurfacing prosthesis that fits the patient's anatomy, preserving the femur and maintaining the natural joint line. The third approach allows to create a customized prosthesis, that is a compromise between the two previous methods. Among the three previous procedures, the most suitable one can be chosen according to the patient's anatomy, knee size and articular cartilage damage.

Keywords: 3D modelling, Total Knee Arthroplasty planning, Customized knee prosthesis

DOI: <https://doi.org/10.14733/cadaps.2022.306-319>

1 INTRODUCTION

Total knee arthroplasty (TKA) is a widely performed surgical intervention, which is commonly advised to treat knee osteoarthritis. Up to 25% of the patients reported to be unsatisfied by their functional outcomes after the surgery [9]. Implant malalignment seems to be one of the most important causes of surgical failures in TKA.

Another reason for the patient dissatisfaction has been identified in the anatomical mismatch between the prosthetic components and the different people anatomies. Prostheses are usually available in standardized off-the-shelf sizes. It means that they would be about the patient's size and a close fit, but not customized to the specific knee. Indeed, it is well known that there is an anatomical difference between genders and among ethnicities, with the consequent possible improper fit of the implants [4]. In particular, two events can happen, both resulting in pain for the patient: overhang and underhang. The former occurs when the implant is bigger than the bone surface, which can impact on the soft tissues surrounding the knee joint; likewise, the latter occurs when the implant does not cover all the exposed cut bone.

In order to improve patient satisfaction after TKA and to mitigate such complaints, two ways can be followed: surgical planning and customized implants. The surgical planning is crucial for TKA, since it provides the surgeon with a reliable starting point in determining implant size and position without making aberrant cuts during the initial sizing. It may decrease surgical time and, therefore, decrease complications [17]. Customized implants, which are created for the patient-specific anatomy, try to overcome the limits of the off-the-shelf prosthesis. Making and using medical devices that are designed for specific patients are becoming increasingly feasible due to developments in 3D imaging software and 3D printing [2].

In this context, the present investigation starts from a collaboration with the clinicians, in particular the orthopedic surgeons, and their needs. In addition, a literature research highlights the surgical issues, presented above, that the authors wants to overcome, exploring new techniques. Therefore, the project aims at providing a preliminary exploration of methods and tools to reduce the rate of patients' dissatisfaction and to design an implant with a shape like the native knee with a high level of detail. Starting from the analysis of different patients' knees, the first task is to define a procedure to perform an accurate and precise virtual planning of the intervention, to reach a personalized alignment for each patient by means of 3D modelling tools. The second purpose is to investigate possible procedures to create customized implants and overcome the limits of the standard prostheses. This trend towards customization can be reached choosing the most suitable technique depending on the patient's characteristics. This means that the final goal is to provide a set of 3D modelling procedures among which the surgeons can choose the optimal one according to the patient's anatomy.

The paper first introduces the scientific background about the current, innovative technology in TKA and the 3D modeling approach. Then, the studied procedures are presented and described in detail. In particular, benefits and disadvantages of each method are analyzed. The results, obtained with the three different approaches, are discussed. Finally, conclusions and future research activities are drawn.

2 SCIENTIFIC BACKGROUND

Conventional surgery of TKA relies on an intra-medullary guiding system for cutting bones. Some factors may influence the application of such a system, including varus or valgus deformity, obesity, or a narrow canal. Furthermore, there is the risk of increased bleeding due to intra-marrow penetration. Hence, in recent years, different technologies have been implemented to achieve a more satisfactory outcome, such as Patient-Specific Instrumentation (PSI), Computed Assisted Surgery (CAS) or even robotic TKA.

PSI is a modern technique in TKA, which aims at facilitating the implant of the prosthesis. The customized cutting blocks of the PSI are generated from pre-operative three-dimensional model, using computed tomography (CT) or magnetic resonance imaging (MRI). The PSI guide takes into account any slight deformities or osteophytes and applies preoperative planning for bone resection, using the pre-determined implant size, position, and rotation. The apparent benefits of this technology are that neutral postoperative alignment is more reproducible, surgical time is decreased, and the entire procedure results more efficient and cost-effective. In addition to that, PSI finds its indication when intra-medullary guides cannot be used. However, there is no

consensus in literature regarding the accuracy and reliability of PSI. Some studies do not underline any improvement in components alignment, surgical time, blood loss or functional outcomes [15].

CAS involves the use of computer assistance during the surgery. A computer is connected to an infrared camera, which is positioned above the patient and connected to 'trackers' fixed to the femur, tibia and the cutting blocks. In this way, real-time 3D images of the knee and the surgical instruments guide the surgeon during the procedure while preparing the femur and tibia and positioning the joint. Literature studies found that CAS decreased the risk of malalignment to achieve superior short-term functional outcome. However, CAS has numerous limitations, such as complex landmark registration, pin complications, a steep learning curve, increased duration of surgery, and questionable cost effectiveness [13].

Robotic TKA involves using an advanced surgical robot. The surgeon uses the virtual model, reconstructed from the 2D images, to plan optimal bone resection, implant positioning, bone coverage, and limb alignment based on the patient's unique anatomy. An intraoperative robotic device helps to execute this preoperative patient-specific plan with a high level of accuracy. Robotic TKA is associated with improved accuracy of achieving the planned femoral and tibial implant positioning, joint line restoration, limb alignment, and posterior tibial slope compared with conventional jig-based TKA. However, it requires huge investment and there is limited literature on functional outcomes [5], [11].

The market up to few years ago has been focused on matching the bone to the implant shape and size [22]. Nowadays, the attention has shifted: it is necessary to match the implant to the shape and size of the bone, in order to improve patient satisfaction after TKA. Customized implants have the potential to improve mechanical alignment, implant fit, bone coverage and restoration, bone preservation, knee strength, range of motion and axial rotation [19]. The information from CT or MR scans are carefully used to examine 3D images of the joints. Then, computerized technology is used to measure the size, shape, and position of the patient's knee joint and lower extremity. A total knee joint prosthesis is then fabricated to fit the exact shape and contour of the specific knee. Since customized total knee replacement surgery is a relatively new concept, there is limited research to determine if the use of custom prosthesis provides superior results when compared to the standard off-the-shelf knee replacement.

The investigation and the design of new methods and tools to replicate the native alignment and anatomy of the knee by preserving soft tissues and ligaments are the areas of current and future developments in the field. Indeed, the aim of the available commercial solutions has always been to provide a reliable prosthesis with high survivorship. Instead, the most recent scientific literature is focusing its aim to improving the patients' clinical outcome and kinematics, leading to greater satisfaction. Knee kinematics studies parameters, such as the range of motion, the maximum flexion, the adduction angle or the external tibial rotation [5].

All the new presented techniques have a common factor: they are all based on a 3D modelling approach. It is a process in which software applications are employed to obtain a three-dimensional model of the knee starting from CT or MRI scans.

There are a lot of commercial software applications, which are certified for medical purpose, available in clinics. For example, Materialize Mimics allows to import medical image data (DICOM) and segment the anatomy to create accurate 3D models. The 3D models are used as the starting points for advanced 3D analysis, planning, personalized device design, finite element meshing, or 3D printing [14].

Symbios, which is a Swiss medical technology company leader in custom-made orthopedic implants, has developed a proprietary pre-operative planning software system, KNEE-PLAN®. This technology uses CT scan images of the patient's knee to create a 3D computer reconstruction. This allows a 3D simulation of the knee to be modelled to determine patient's native anatomy and its bony contours. From this information, a custom prosthesis is designed. It is the same shape as the native knee and is optimally sized and contoured to create a prosthesis that feels as 'natural' as it possibly can, carefully reproducing the balance within the soft tissues that surround the knee joint.

Following the design, 3D-printed customized surgical guides are manufactured. These assist the surgeon to accurately position the implants intra-operatively [7], [21]. Depuy Synthes Company, which is a global leader in joint replacement, uses a CAS system for the implantation of the ATTUNE® Knee System Family of Implants. It allows to prepare the operation and identify the landmarks on the bones, through the registration process [8]. Zimmer Biomet, another global leader in joint replacement, with the Rosa Knee System offers a computer software program to convert 2D knee radiographs into a 3D patient-specific bone model, and a robotic device to help position the cutting blocks and execute the planned bone resections with greater accuracy [22]. Conformis, which is a medical technology company, uses its proprietary iFit Image-to-Implant technology platform to develop, manufacture and sell joint replacement implants that are individually sized and shaped to fit each patient's unique anatomy [6]. The current software available in clinics allows the reconstruction of the model for the planning of the intervention, but in a predetermined way, requiring investments from the hospitals.

In this context, there are even open-source software applications, that are not intended to be used in clinics, because they do not have any medical certification. Otherwise, they can be exploited in the research filed to investigate new ways of planning and performing procedure in a free three-dimensional environment. Among these open-source software applications for 3D modelling, there is 3D Slicer and Meshmixer [1], [16]. The former is a platform for medical image informatics, image processing, and three-dimensional visualization; the latter is a 3D sculpting-based CAD software, that works with triangle meshes. Kumar Y.S. et al. in a single patient study have exploited 3D Slicer to create a three-dimensional model, used for the planning of the intervention [12]. Balwan A.R. et al. employ open-source software, including 3D Slicer and Meshmixer, to generate 3D models of the knee [3].

Therefore, the aim of this paper is to employ these open-source software applications to provide a set of 3D modelling procedures to improve the patient's function, kinematics and satisfaction. These tasks can be reached through the combination of patient-specific/customized prosthesis, implanted with precision to match patient anatomy, and a preoperative planning of the intervention. Hence, the present preliminary investigation moves towards the future of TKA, that is the personalized joint reconstruction [5].

3 METHODS AND TOOLS

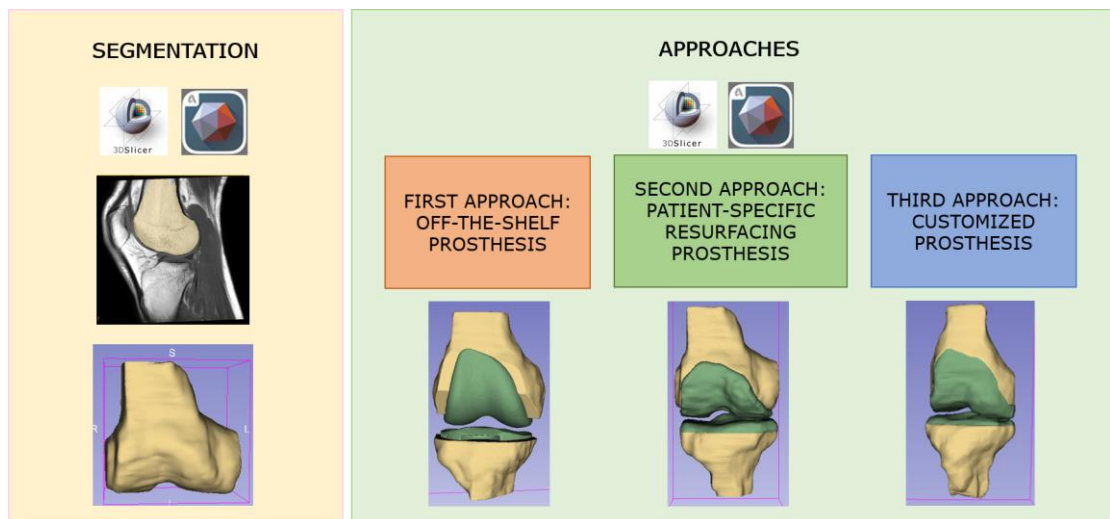


Figure 1: Phases of the project.

Figure 1 identifies the two main phases of the project. The first phase consists in the reconstruction of a 3D model of the knee, through a segmentation process, starting from MR images. 'Segment editor' in 3D Slicer is exploited for this purpose. Meshmixer is chosen for the polygonal mesh modelling. Once the model is ready, three procedures have been studied.

3.1 Segmentation

Starting from MR images, the three-dimensional model of the knee is reconstructed through a segmentation process. Segmentation can be achieved in three different ways: manual, automatic and semiautomatic. With the first procedure, an image portion is assigned to a specific label drawn by hand. With the second method, the algorithm automatically divides the image into regions that show similar characteristics within the considered areas, and differ from one region to the other for the same characteristics. In the end, the semiautomatic process is a compromise between the two previous techniques [2]. In the study, the employed software allows to use both manual and semiautomatic tools. In particular, 'Level tracing' is used for the bone segmentation (Figure 2). This algorithm consists in adding uniform intensity region to selected segment. It allows to locate all the voxels in the DICOM image that present a brightness parameter equal to or less than the single voxel selected by the user.

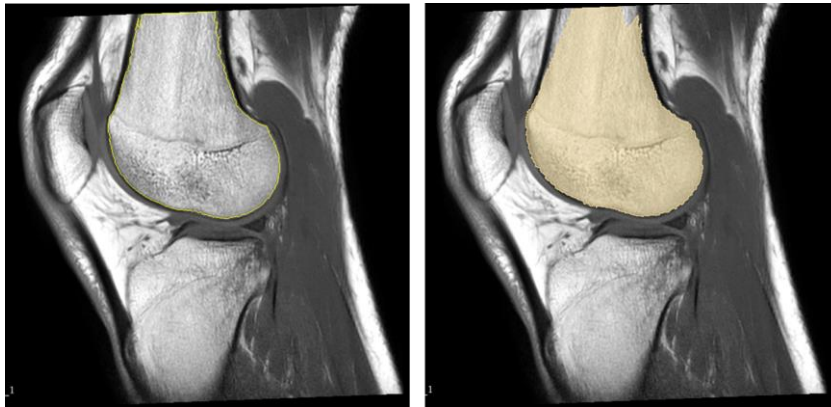


Figure 2: 'Level tracing' module for the segmentation of the femur.

However, this tool is able to act only and uniquely on the single slice of analysis and cannot expand the obtained result on adjacent slices. Hence, it is necessary to complete manually the segmentation for each individual slice. Furthermore, even manual tools are used for some refinement on the boundary. In particular, it is possible to surround the region of interest or paint it, exploiting 'Draw' or 'Paint' tools, respectively. In order to obtain the final 3D model, 3D Slicer smoothing tools are exploited to make segment boundaries smoother by removing extrusions and filling small holes. Then, more powerful tools are used: Meshmixer brushes allow to draw or flatten some parts to obtain the final bone models.

3.2 Approaches

Starting from the 3D models of the knee, three procedures are studied. The first approach consists in the planning of the intervention through the alignment of the standard off-the-shelf prosthesis. The anatomy of the patient is analyzed and the bones are virtually cut as in the traditional TKA to fit the standard prosthesis. Then, two more customizable methods are proposed, in order to overcome the limits of the first approach. In particular, the former consists of patient-specific resurfacing implants, which preserves the femoral bone, without any cut, and allows also to

choose the thickness of the tibial component. The latter enables the creation of prosthesis, that resemble the commercial standard ones, but that are highly customizable.

In the following the three procedures are presented and discussed.

3.2.1 First approach: off-the-shelf prosthesis

Figure 3 summarizes the main phases of the first approach. Standard models of the prosthesis are available in six different sizes, obtained by a previous work through a 3D scanning procedure, using a mid-low cost and performant 3D laser scanner, i.e. NextEngine [20]. The femoral components and tibial inserts are studied to understand the exact shape of the prosthesis, their thickness and the angles between the segments (Figure 3(a)). Furthermore, the anterior/posterior (A/P) and medial/lateral (M/L) lengths of both the components are measured in the 3D scene. The size of the femoral component is chosen for each patient, measuring A/P and M/L lengths of the femur in the three-dimensional space.

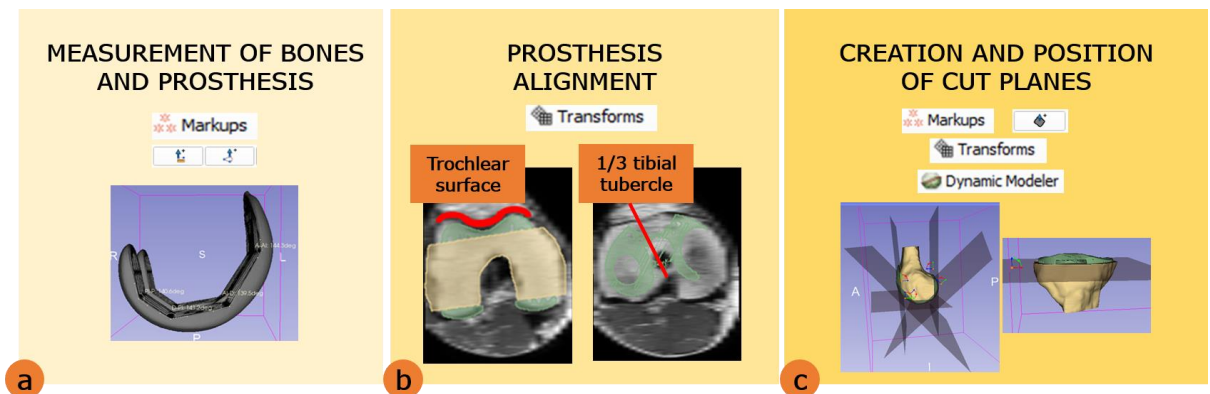


Figure 3: Steps for the alignment of the off-the-shelf prosthesis to obtain the final result.

Some attempts are done to understand which is the best size that fits a knee. Hence, the correct prosthesis is aligned to the segmented femur, using a linear transformation. It consists in the manual alignment of segments, translating and rotating them along the three axes (Figure 3(b)).

An anterior reference, as is pointed out in the literature, is used to not create notching or patellar overstuff, as shown in Figure 4. It is opposite to the posterior reference, which requires the cut of a fixed portion of femur posteriorly.

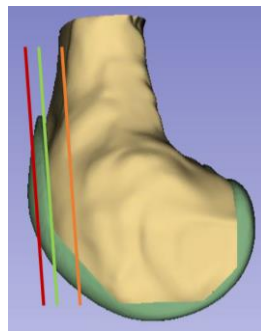


Figure 4: Anterior reference followed for the cut (green line) in order to avoid notching (orange line) or overstuffing patella (red line).

The intercondylar notch and the natural distance between the femoral condyles are used as reference. The prosthesis respects the trochlear shape: its surface is followed through the images in the axial plane, during the alignment. Some measurements can be made on the trochlea to exclude diseases, such as trochlear dysplasia that can determine the instability of any implant used. In particular, it is interesting to analyze the sulcus angle, trochlear depth (TD) and lateral trochlear inclination (LTI) angle, as in Figure 5. Table 1 reports the measurements of the involved patients. Their sulcus angles are lower than 145° , LTI angles are greater than 11° and TD lengths measure more than 3 mm. These are the limits to exclude trochlear dysplasia.

The position of the tibial insert is assessed to maximize tibial coverage while avoiding overhang. The correct rotation is crucial. It is typically centered on the junction between the medial and central third of the tibial tubercle [10].

Once alignment is performed, the bones are cut to fit the prosthesis (Figure 3(c)). Five planes are generated for the cut of the femur, respectively for the anterior, posterior, distal, and the two slope surfaces. They are created in correspondence of the inner prosthesis surfaces. Only one plane cut is enough for the tibia: 9 mm have been easily cut from the bone in the less worn-out compartment, as suggested by the experienced surgeon and supported by the literature [18].

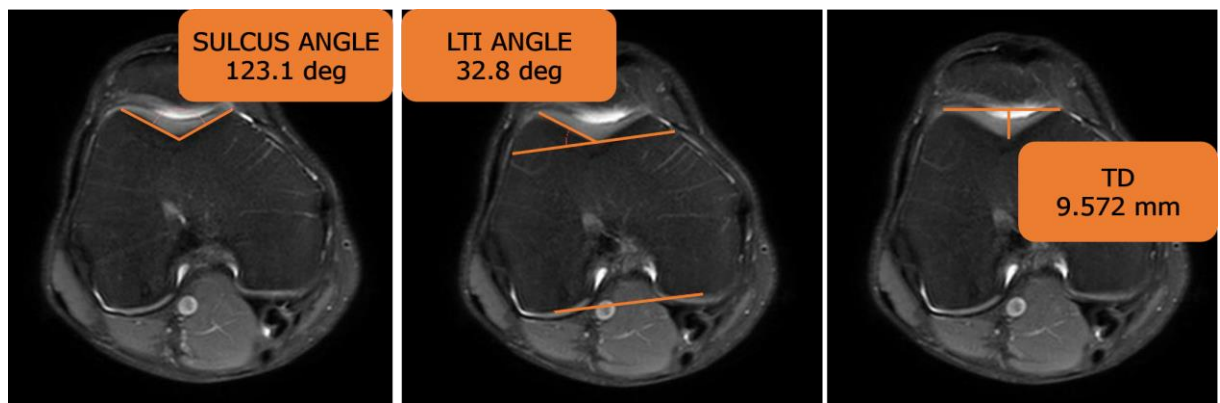


Figure 5: The analyzed patient presents a normal trochlear surface.

Patient	Sulcus angle (deg)	LTI angle (deg)	TD (mm)
09	123.1	32.8	9.572
14	130.8	21.8	7.517
13	141.2	18.2	6.116
07	131.1	27.8	8.032
12	128.2	26.9	8.246

Table 1: Sulcus angle, LTI angle and TD measurements in the considered patients.

The final virtual models are represented in Figure 6.

3.2.2 Second approach: patient-specific resurfacing prosthesis

The second approach proposes a more personalized method. Starting from the bone segmentation, the personalized resurfacing prosthesis is created. Two different methods are used for the femoral and the tibial component, as described in Figure 7.

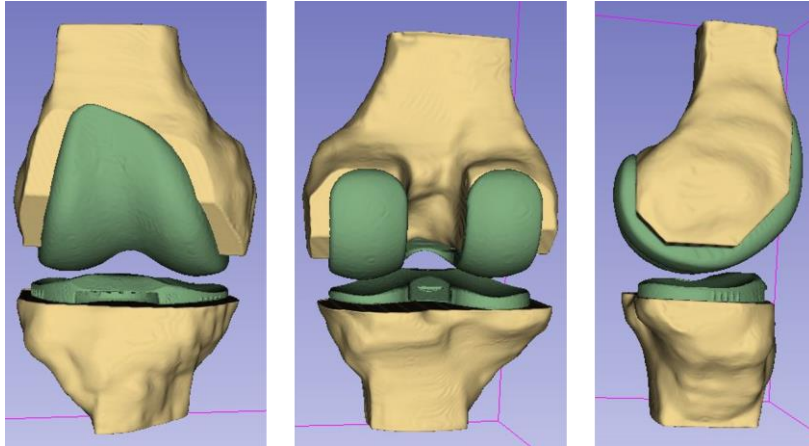


Figure 6: 3D models of the knee with the off-the-shelf prosthesis.

The inferior contour of the femur is followed with a constant thickness in the sagittal. The points in which the cartilage starts and ends on the condyles are taken as reference for the prosthesis extremities. The resurfacing prosthesis is smoothed and remodeled with Meshmixer brushes to reach a homogeneous result. The generated femoral component follows the natural anatomy of the femur. The intercondylar notch and the natural distance between the femoral condyles are maintained. Moreover, the prosthesis respects the trochlear shape. No cuts are performed to preserve the bone (Figure 8).

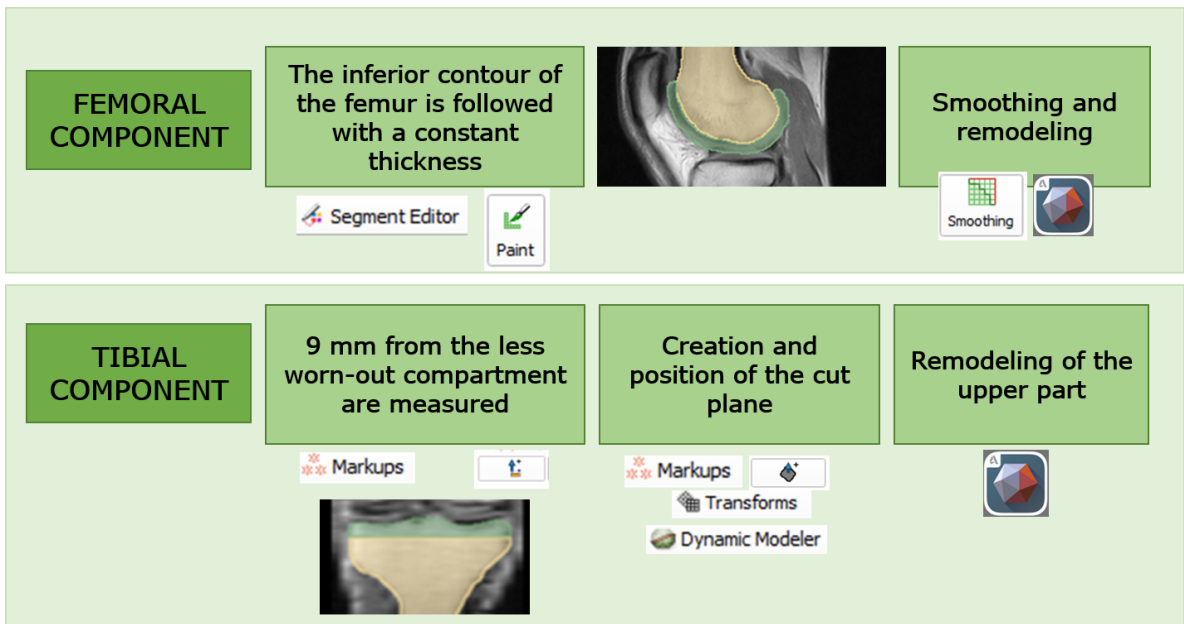


Figure 7: Steps for the creation of patient-specific resurfacing prosthesis.

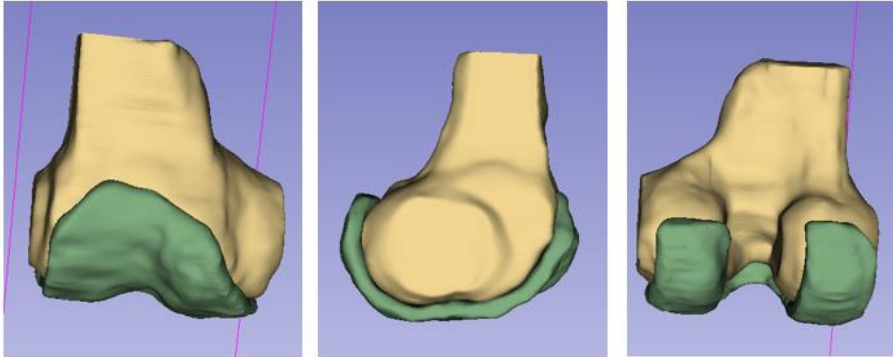


Figure 8: 3D models of the femur and the patient-specific prosthesis.

It is not possible to reproduce the same approach even for the tibial component because the space between femur and tibia is too narrow. So, for the tibial part, a cut plane is necessary: as for the first approach, 9 mm are measured from the top of the tibia, in the less worn-out compartment and a cut plane is placed there.

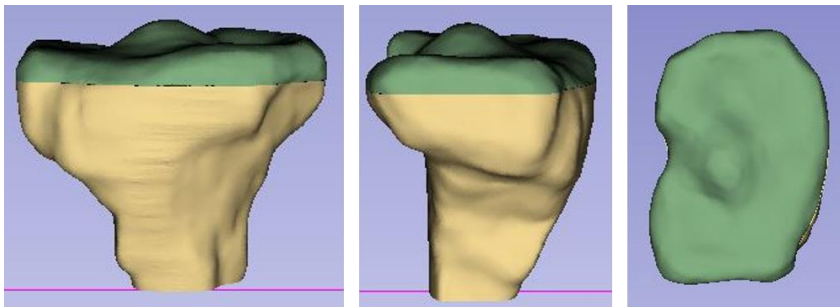


Figure 9: 3D models of the tibia and the tibial component.

The upper part of the tibia is remodeled in order to become the tibial component of the implant. In this way, the natural anatomy with the tibial plateaus is maintained, but it is more smoothed and homogeneous, as it can be seen in Figure 9.

3.2.3 Third approach: customized prosthesis

A third approach, that is a compromise between the two previous presented methods, is applied and the phases are portrayed in Figure 10. The method consists in the segmentation of both the femur and the femoral cartilage together. If the cartilage is too worn, a fixed thickness is considered, between 4 mm and 7 mm, depending on the patient's space (Figure 10(a)). Then, five planes are added. The anterior reference is used even in this case, to avoid notching and overstuff. 9 mm are measured distally and posteriorly for the femoral component. The slope planes are positioned according to the angles, measured in the off-the-shelf prosthesis (Figure 10(b)). In this way, it is possible to divide the model into two models: the cut femur and the customized prosthesis (Figure 10(c)). Finally, the personalized femoral component is redefined in Meshmixer to thin or thicker some parts (Figure 10(d)). The result perfectly fits the patient's anatomy, as it is shown in Figure 11.

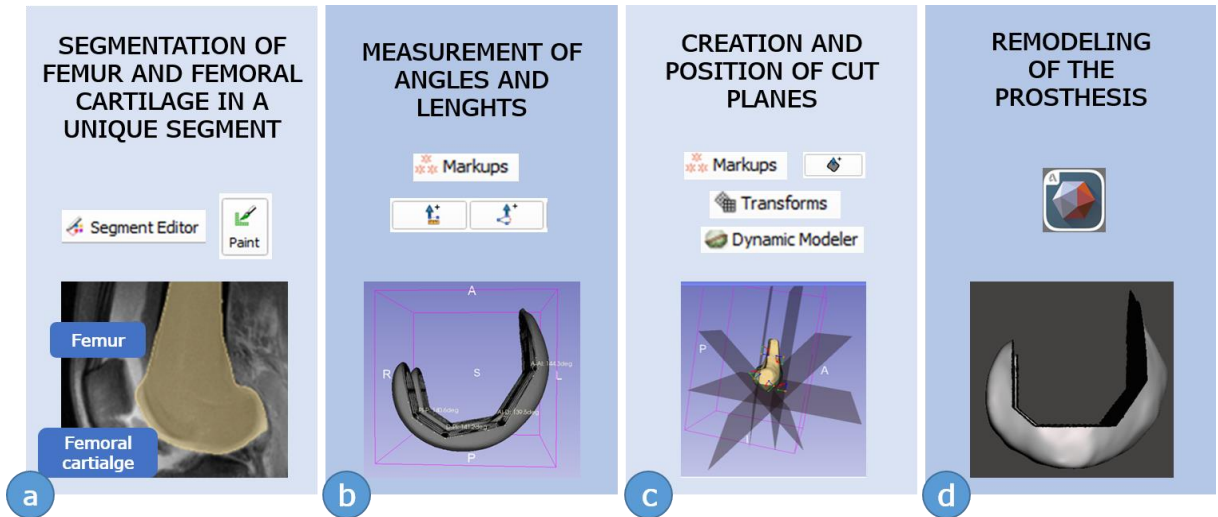


Figure 10: Steps for the creation of a customized prosthesis.

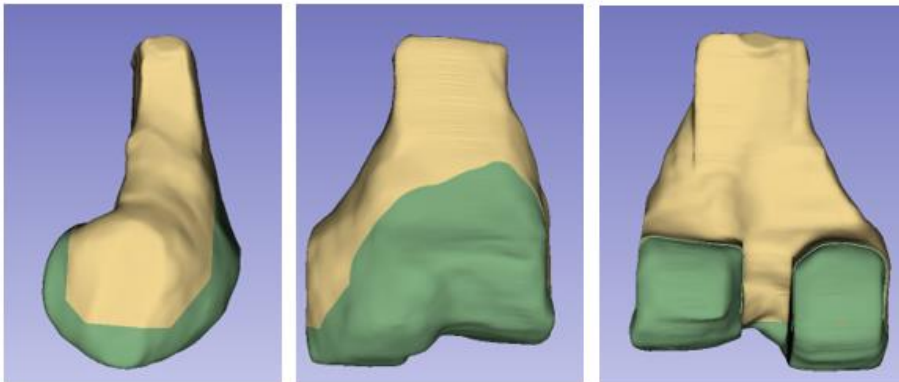


Figure 11: 3D models of the femur with the customized prosthesis.

The tibial component is realized in the same manner of the second approach to assure the complete coverage of the cut tibia. Different thickness of the tibial component can be chosen, changing the position of the cut plane, according to the need.

4 DISCUSSION

For the testing of the proposed solutions, fourteen patients and an orthopedic surgeon have been involved. Every patient is different from the others. However, the most appropriate procedure can be chosen, adapting the main steps of the process to the patient, every time. Hence, the reproducibility of the procedures has been verified, applying it to the available set of the different knees. Furthermore, the surgeon has been consulted to assess the feasibility of the solutions from the medical point of view. In this study the role of the physician is to provide the medical knowledge about the intervention and supervise the procedure. However, in the future, the surgeon will be the final user of the procedure, since it will be simplified and automated.

The accuracy of the 3D models, obtained through the segmentation process, depends on the quality of the MR exam and the thickness between the slices. The MR images, employed in the study, comes from the clinical practice, with a minimum thickness value of 1.65 mm and a mode value of 3.85 mm. Even if it is not the optimal condition, it is possible to obtain acceptable results.

Starting from the 3D model, the anatomy of each knee has been studied and the most suitable method has been applied. If the patient has a quite standard anatomy, a planning with an off-the-shelf prosthesis could be performed. In more complex cases, it would be possible to choose between the last two approaches. If osteoarthritis has not affected the bone yet, it would be possible to preserve the bone and apply a patient-specific resurfacing implant. Otherwise, the customized prosthesis of the third approach is the one recommended. Hence, five patients are treated virtually with the off-the-shelf prosthesis, five with a patient-specific resurfacing approach and the other ones with a personalized method.

The planning of the intervention, obtained with the first approach, allowed the surgeon to predict the size of the off-the-shelf prosthesis before the intervention. An idea about the predicted sizes helps in decreasing the costs associated with transportation and storage of unnecessary sizes. Moreover, the insertion of the ideal size is crucial for the restoration of the correct biomechanics in the knee, avoiding a reduction of the range of motion. Indeed, an oversized component may lead to soft tissue impingement, whereas a smaller component may sit on purely cancellous bone and also lead to higher stress over a small bone cement interface. In the present study, the problem of underhangs (Figure 12) or overhangs (Figure 13) has been faced in all the treated patients, some more than others. These mismatches can create pain in them. Moreover, problems can be related to big or small femur. If the femur is big relative to the size, it is possible that too much bone is removed posteriorly. It can cause the decrement of the posterior condyle offset and may reduce the range of motion.

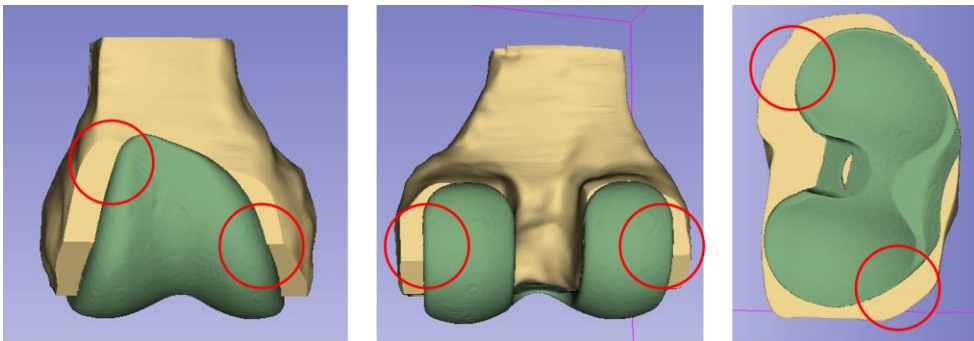


Figure 12: Mismatch between the prosthesis and the bone are underlined: underhangs.

Hence, something more customizable is tried. Actually, the patient-specific resurfacing implants are very used in monocompartmental knee arthroplasty. Recently, this femoral bone-preserving approach has shown satisfactory results even in the bicompartmental knee replacement. Now, the idea is to extend it even to the TKA. With the second approach, it is possible to create an implant that follows the inferior contour of the femur with a predefined constant thickness. Hence, the femoral component perfectly fits the patient's anatomy, preserving the bone, without the need of any cut. The thickness of the implant can be chosen according to the available space between the femur and tibia, which is different from patient to patient. Furthermore, it is possible to select different thickness of the tibial component according to the need. In this way, a complete coverage of the cut tibia is guaranteed. However, it is known that osteoarthritis leads to the articular cartilage breakdown and can even affect the underlying bone. In the cases in which the bone is too much ruined, the prosthesis is not able to perfectly match it.

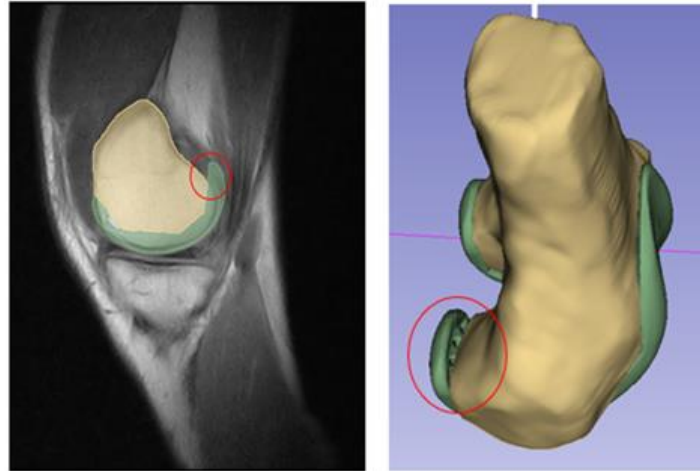


Figure 13: Mismatch between the prosthesis and the bone are highlighted: overhangs in the sagittal and in the 3D scene.

For this reason, the third approach is studied, connecting the two previous techniques. The second approach can be considered the starting point of the third method. A layer with a constant thickness is created following the inferior contour of the femur. Then, cut planes are added to cut the ruined bone. In this way, it is possible to create something that resembles the commercial off-the-shelf femoral component, but highly patient-specific. It perfectly fits the patient's anatomy; there are no overhangs or underhangs and it matches the condylar offset and the intercondylar notch. The natural joint line is preserved by restoring the distal femoral offset. Moreover, there are no problems if the femur is too big or too small because the prosthesis follows the patient's femur. According to the surgeon, this solution is a good compromise between the previous two approaches. The strong point is its adaptability in presence or without the cartilage. Moreover, there are five cut planes as in the standard off-the-shelf prosthesis, that could be useful when even the bone is ruined.

In cases in which the prosthesis is custom made for the specific knee, less work has to be done at the time of surgery to determine alignment and the correct position of the implant is guaranteed, with less tissue disruption. The hope for the long-term is the duration of the implant and the improved satisfaction and mobility for the patients, due to the accurate position of the implants. This is the ideal condition that both the second and the third approach would like to reach. However, the second approach has limits in the way it has been conceived. If osteoarthritis is advanced and the femur is too much damaged, the inferior contour of the bone can not be taken as reference for the creation of the implant. Instead, the third method can be adapted even in this condition, cutting away the ruined bone. According to each clinical case, the surgeon can choose between the two customized approaches.

The remodelling phase involves both the second and the third approach. It affects only the external surface of the implant, preserving the contact with the bone. In particular, in the second approach, the remodeling is used to obtain a resurfacing implant that is more homogeneous than the result achieved by the segmentation. In the third approach, the remodeling is used to thin or thicken some external part of the prosthesis surface, to obtain the optimal final result.

5 CONCLUSIONS

The paper investigates methods and tools to replicate the native alignment and anatomy of the knee, which can be applied in the research field both for the surgical planning and the creation of

patient-specific implants. After the reconstruction of the 3D model of the knee in the virtual space, it is possible to study the patient's anatomy. Hence, among the three previous procedures, the most suitable one can be chosen according to the patient's anatomy, knee size and articular cartilage damage. The combination of the patient-specific prosthesis and the preoperative planning of the intervention can lead to a better clinical outcome, kinematics and satisfaction.

Even if 3D Slicer does not have FDA approval, the investigated procedure could potentially be replicated using other software. Indeed, the same steps of segmentation, measurement, alignment, creation of the plane and cutting could be standardized even in the commercial available software.

The future work will be the automatization of the steps, presented in this research. A specific package for the treatment of the knee will be created as a plug-in of the software. It will have all the useful functions for the knee. The operator will study the anatomy of the specific knee and perform the segmentation. Then, according to the need, he/she will choose among the three proposed approaches. In the meanwhile, a FEM analysis will be performed in order to understand the feasibility of the proposed solution. It will be possible to study how loads and stress are distributed on the components. In particular, it will be interesting to compare the last two innovative procedure with the traditional one.

ACKNOWLEDGEMENTS

The authors would like to thank Doctor Francesca De Caro for her precious clinical contribution.

ORCID

Anna Ghidotti, <https://orcid.org/0000-0002-6415-3167>

Andrea Vitali, <https://orcid.org/0000-0001-9261-4357>

Daniele Regazzoni, <https://orcid.org/0000-0001-5533-7047>

Caterina Rizzi, <https://orcid.org/0000-0002-1779-5183>

REFERENCES

- [1] 3D Slicer, <https://www.slicer.org/>
- [2] Auricchio, F., & Marconi, S.: 3D printing: clinical applications in orthopaedics and traumatology. *EFORT open reviews*, 1(5), 2016, 121-127. <https://doi.org/10.1302/2058-5241.1.000012>
- [3] Balwan, A.; Shinde, V.: Development of patient specific knee joint implant. *Materials Today: Proceedings*, 27, 2020, 288–293. <https://doi.org/10.1016/j.matpr.2019.11.032>
- [4] Benazzo, F.; Ghiara, M.; Rossi, S.M.P.; Pruneri, E.; Tiwari, V.; Perelli, S.: Clinical and radiological analysis of a personalized total knee arthroplasty system design. *International orthopaedics*, 43(5), 2019, 1113–1121. <https://doi.org/10.1007/s00264-018-4095-4>
- [5] Blakeney, W.G.; Vendittoli, P.A.: The future of tka. *Personalized Hip and Knee Joint Replacement*, 2020, 169–174. https://doi.org/10.1007/978-3-030-24243-5_15
- [6] Conformis, <https://www.conformis.com/>
- [7] Franceschi, J.P.; Sbihi, A.; Surgery-France, C.A.O.: 3d templating and patient-specific cutting guides(knee-plan®) in total knee arthroplasty: postoperative ct-based assessment of implant positioning. *Orthopaedics & Traumatology: Surgery & Research*, 100(6), 2014, S281–S286. <https://doi.org/10.1016/j.otsr.2014.04.003>
- [8] Depuy Synthes Company, http://synthes.vo.llnwd.net/o16/LLNWMB8/US%20Mobile/Synthes%20North%20America/Product%20Support%20Materials/Technique%20Guides/DSUS-JRC-0514-0141%20ATTUNE_CAS_ST.pdf

- [9] Giannotti, S.; Sacchetti, F.; Citarelli, C.; Bottai, V.; Bianchi, N.; Agostini, G.; Capanna, R.: Single-use, patient-specific instrumentation technology in knee arthroplasty: a comparative study between standard instrumentation and psi efficiency system. *Musculoskeletal surgery*, 2019, 1–6. <https://doi.org/10.1007/s12306-019-00612-3>
- [10] Indelli, P.F.; Graceffa, A.; Marcucci, M.; Baldini, A.: Rotational alignment of the tibial component in total knee arthroplasty. *Annals of translational medicine*, 4(1), 2016. <https://doi.org/10.3978/j.issn.2305-5839.2015.12.03>
- [11] Kayani, B., & Haddad, F. S.: Robotic total knee arthroplasty: clinical outcomes and directions for future research, 2019. <https://doi.org/10.1302/2046-3758.810.BJR-2019-0175>
- [12] Kumar, Y.S.; KVS, R.R.; Yalamalle, S.R.; Venugopal, S.; Krishna, S.: Applications of 3d printing in pre surgical planning for design optimization—a case study. *Materials Today: Proceedings*, 5(9), 2018, 18833–18838. <https://doi.org/10.1016/j.matpr.2018.06.230>
- [13] Li, J.t.; Gao, X.; Li, X.: Comparison of iassist navigation system with conventional techniques in total knee arthroplasty: A systematic review and meta-analysis of radiographic and clinical outcomes. *Orthopaedic surgery*, 11(6), 2019, 985–993. <https://doi.org/10.1111/os.12550>
- [14] Materialize Mimics, <https://www.materialise.com/en/medical/mimics-innovation-suite/mimics>
- [15] Mattei, L.; Pellegrino, P.; Calò, M.; Bistolfi, A.; Castoldi, F.: Patient specific instrumentation in total knee arthroplasty: a state of the art. *Annals of translational medicine*, 4(7), 2016. <https://doi.org/10.21037/atm.2016.03.33>
- [16] Meshmixer, <https://meshmixer.com/>
- [17] Miller, A.G.; Purtill, J.J.: Total knee arthroplasty component templating: a predictive model. *The Journal of arthroplasty*, 27(9), 2012, 1707–1709. <https://doi.org/10.1016/j.arth.2012.03.055>
- [18] Murgier, J.; Clatworthy, M.: Variable rotation of the femur does not affect outcome with patient specific alignment navigated balanced tka. *Knee Surgery, Sports Traumatology, Arthroscopy*, 2020, 1–10. <https://doi.org/10.1007/s00167-020-06226-8>
- [19] Namin, A.T.; Jalali, M.S.; Vahdat, V.; Bedair, H.S.; O’Connor, M.I.; Kamarthi, S.; Isaacs, J.A.: Adoption of new medical technologies: the case of customized individually made knee implants. *Value in Health*, 22(4), 2019, 423–430. <https://doi.org/10.1016/j.jval.2019.01.008>
- [20] Rossoni, M.; Regazzoni, D.; Vitali, A.; Colombo, G.; Spandre, L.; De Caro, F.: Knee prostheses reverse engineering: A preliminary investigation. In *International Design Engineering Technical Conferences and Computers and Information in Engineering Conference*, vol. 83983, V009T09A031. American Society of Mechanical Engineers, 2020. <https://doi.org/10.1115/DETC2020-22485>
- [21] Symbios Orthopédie SA, <https://symbios.ch/>
- [22] Zimmer Biomet, <https://www.zimmerbiomet.com/>