Cutting Edge Technology in Computer Assisted Surgery for Total Knee Replacement

State-of-the-art of techniques and relevant results

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***Abstract* — After the initial exploitation of robotic assistance, computer assisted surgery in total knee replacement has proposed recently a number of surgical navigation systems and patient-specific instrumentations. These have contributed to achieve more accurate alignments than those obtained with conventional procedures. The present work wants to report on current intra- and post-operative measurements and analyses with these two technologies, aimed also at investigating the tracking of additional structures, as well as accuracy and efficacy of the surgical results. In a first study, a novel procedure to trace patello-femoral joint kinematics during navigated knee replacement is described, together with the initial very encouraging results in initial surgical case. From these measurements, an original procedure is proposed also to describe slackening and tightening of patellar tendon fibers. In a second, two patient-specific instrumentation procedures are evaluated by comparing the alignments planned preoperatively and achieved perioperatively, by using traditional and original techniques based on medical imaging. Both techniques demonstrated to be feasible, reliable, safe, and accurate enough for the purposes.**

Keywords — Human knee joint; patello-femoral joint; osteoarthritis - rheumatoid arthritis; joint replacement; knee prostheses; patient-specific instrumentation; surgical navigation; gait analysis; three-dimensional video-fluoroscopy

I. Introduction

Computer assisted surgery has investigated a number of different technologies after the initial exploitation of robotic assistance [1]. This is particularly true in total knee replacement (TKR), likely because of the huge number of operations, suitable traditional operative techniques, and the interest of vendors and surgeons. Surgical navigation systems (SNS) has been largely utilized since the late nineties to track the tibio-femoral joint (TFJ) together with corresponding bone cutting guides, for the three-dimensional (3D) alignment of the knee prosthesis components to the bones and of the whole lower limb to be targeted and assessed carefully according to anatomical reference frames defined at the beginning of the operation [2,3]. More recently, a so-called patient-specific instrumentation (PSI) has been proposed, with the aim of positioning prosthetic components according to the patient lower-limb and single bone alignments [1]. Computer models of the distal femur and proximal tibia are defined from scan acquisitions using computer tomography (CT) or magnetic resonance imaging (MRI) [1]. Based on these models, pre-surgical planning is then arranged by the TKR vendor and offered to the examination and adjustment of the surgeon via web-based interfaces. Corresponding patient- matched cutting guides are then manufactured and delivered to the hospital for guiding unequivocally bone resections during the operation. The final objective is to eliminate the standard huge instrumentation sets [1], which have to be taken sterilized in the operating theatre, for the surgeons to use simply the patient-matched guides and the corresponding TKR implant.

Both these computer-assisted technologies apparently have resulted in more accurate alignments than those after conventional implantation. However, surgical navigation still needs to exploit the tracking of the patella [4,5], known to be fundamental for the final patient outcome, much affected by a good restoration of the extensor apparatus (extensor muscles, patello-femoral joint – PFJ, patellar tendon). PSI has not demonstrated yet its final accuracy and efficacy in terms of restoration of physiological joint function [6]. The present work wants to contribute to these issues by reporting on current intra- and post-operative measurements and analyses in TKR patients operated with these technologies.

II. Knee Extensor Mechanism: In-vivo measures

A. PFJ tracking

1) *Rationale* - TKR also alters normal PFJ kinematics within the extensor mechanism resulting frequently in PFJ disorders and TKR failure [4]. Patellar tracking in case of resurfacing is further affected by patellar bone preparation and relevant component positioning. The traditional technique used to perform patellar resurfacing, even using SNS, is based only on visual inspection of its articular aspect for clamping the cutting jig and on a simple caliper to check for the thickness before and after bone cut, and, thus, without any computer assistance [4]. Although the inclusion in in-vivo navigated TKR of a procedure for supporting also patellar resurfacing via patient-specific bone morphology seems fundamental, this have been completely disregarded so far [7]. A novel procedure for measuring the effects of every surgical action on PFJ kinematics during navigated TKR using an extension of current SNS will be reported together with

relevant software and surgical instrumentation, and relevant results of the first applications in-vivo in patients.

2) *Materials and Methods* – Sixteen patients affected by primary gonarthrosis were implanted with a TKR prosthesis (10 and 6 patients, respectively, with NRG® and Triathlon®, Stryker®-Orthopaedics, Mahwah, NJ-USA) with patellar resurfacing. All TKR were performed by means of two SNS (Stryker®-Leibinger, Freiburg, Germany; 0.5°/0.5mm accuracy) with the standard femoral/tibial trackers, the pointer, and an original specially-designed patellar tracker [7]. The novel procedure for patellar tracking was approved by the local ethical committee; the patients gave informed consent prior the surgery. This procedure implies the use of a second system, i.e. the patellar SNS (PSNS), with dedicated software for supporting patellar resurfacing and relative data processing/storing (Fig. 1), in addition to the traditional knee SNS (KSNS) [7]. TFJ anatomical survey and kinematics were assessed according reccomandations [4,7] and data are shared between the two. The procedures for standard navigation were performed to calculate preoperative joint deformities and TFJ kinematics. The anatomical survey was performed also with PSNS, with relevant patellar anatomical reference frame definition and PFJ kinematics assessment (Fig. 2). After standard procedures for femoral and tibial component implantation, the procedure for patellar resection was performed with the support of the PSNS to plan a most proper level and orientation of the patellar cut and location of the patellar component. For all this, TFJ and PFJ kinematics were assessed, and possible adjustments in component positioning performed, until both kinematics were satisfactory.

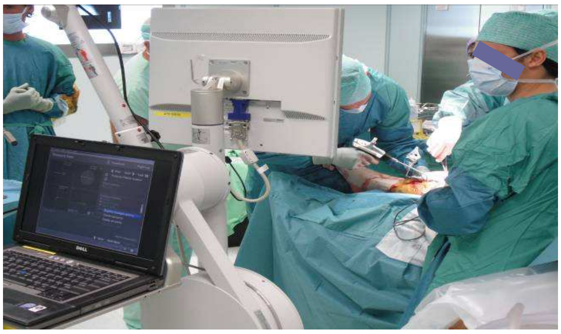

Fig. 1. Operating theatre during navigated TKR with PFJ tracking.

3) *Findings* - The novel procedure was performed successfully in all cases without complications, resulting in about 30 min longer than standard TKA. The final lower limb misalignment was within 0.5°, resurfaced patella was 0.4±1.2 mm thinner than the native, and patellar cut was 0.4°±4.1° laterally tilted. Final PFJ kinematics after patellar resurfacing was taken the reference normality. This showed a mean range of flexion, tilt and medio-lateral shift of 66.9°±8.5° (mean of minimum ÷ maximum values, 15.6°÷82.5°), 8.0°±3.1° (-5.3°÷2.8°), and 5.3±2.0 mm (-5.5÷0.2 mm), respectively. Significant correlations were found between the internal/external rotation of the implanted femoral component and the range of PFJ tilt (p=0.05; R^2=0.41). The goodness of patellar implantation parameters were confirmed also by successive X-ray inspections. Discrepancies in thickness up to 5 mm were observed between SNS- and calliper-based, i.e. not computer assisted, measurements.

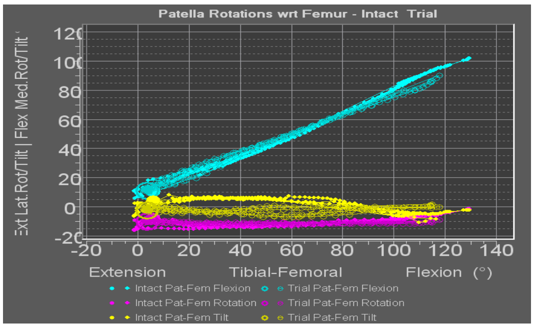

Fig. 2. Real-time PFJ rotations on the SNS monitor during surgery.

B. Patellar Tendon tracking

1) *Rationale* – The mobility and the stability of the human knee are controlled not only by a synergic interaction between TFJ and PFJ surfaces, but also between these and a number of important knee soft tissues [5]. Among these, the patellar tendon (PT) plays an important role in transmitting tensile forces within the extensor apparatus [5]. A thorough anatomy-based mapping of PT attachments is essential for a reliable assessment of fibres location and deformation during knee motion, to understand its contribution to knee function, and to restore physiological knee kinematics after TKR. Past methodologies did not allow the acquisition of accurate, natural and continuous movements over a large flexion range in the assessment of PT biomechanics. The inaccessibility of important anatomical landmarks prevented 3D PT mapping, robust anatomical reference definitions, and, ultimately, the identification of reliable patterns for PT fibre deformations and orientations [5]. Among possible measuring devices, current SNS enable direct digitization of bony landmarks and surfaces [4] together with the relevant attachment areas for PT [5]. A novel procedure for thorough description of lengthening and orientation patterns via careful anatomy-based PT fibre mapping will be reported below together with relevant results of the first applications in-vivo in patients.

2) *Materials and Methods* - Six patients affected by primary gonarthrosis were implanted with TKR prosthesis with patellar resurfacing using a Stryker®-Leibinger SNS. Similarly to what reported in the previous section, before TKR the standard trackers were pinned onto the femur and the tibia [4], and an additional novel tracker cluster was rigidly fixed onto patellar anterior aspect [7]. A pointer was used for system control and landmark digitization. Anatomical and articular definitions were according to recommendations [4]. Series of 3 trials of manually driven knee flexion-extension cycles in a 0°-140° arc were recorded with the intact and replaced knee. For PT fibre recruitment analysis, points on the proximal attachment on the patella were digitized together with distal attachment on the tibia. Point strips were also collected along the medial, central and lateral PT fibres. The centroids of the proximal/distal attachments and the strips extremities were assumed as fibre origins and insertions. Corresponding distances were calculated over flexion and reported as % of the

corresponding maximum length at the intact knee (L_{max}). Location of the most isometric fibres (ISO) was also investigated. Fibre orientation was calculated in tibial frontal and sagittal planes with respect to the proximo-distal axis, anterior and lateral inclination being positive.

		Pre TKR		**Post TKR**	
		At full ext.	***At full flex.***	***At full ext.***	***At full flex.***
Elongation ($\%_{Lmax}$)	*Lat*	78.1 ± 10.8	99.4 ± 0.4	89.0 ± 5.5	99.7 ± 2.7
	Med	78.7 ± 7.4	99.4 ± 0.2	91.5 ± 4.2	100.9 ± 3.8
	Cent	78 ± 9.5	99.5 ± 0.2	90.3 ± 3.6	100.5 ± 2.8
Frontal Inclination (°)	*Lat*	-14.1 ± 17.8	-6.1 ± 6.8	-8.6 ± 6.3	-1.8 ± 4.3
	Med	-7.5 ± 7.9	-2.0 ± 4.3	-3.0 ± 6.4	1.9 ± 6.2
	Cent	-10.7 ± 11.8	-4.0 ± 3.5	-5.6 ± 2.5	0.1 ± 3.2
Sagittal Inclination (°)	*Lat*	20.0 ± 9.3	-4.9 ± 6.3	20.5 ± 8.8	-2.2 ± 5.6
	Med	21.5 ± 5.7	-8.6 ± 7	17.7 ± 5.1	-7.1 ± 10.5
	Cent	20.9 ± 7	-6.8 ± 6.2	19.2 ± 6.6	-4.7 ± 7.9

3) *Findings* - Repeatable patterns of TFJ, PFJ and PT kinematics were observed versus flexion within each knee, standard deviation over trials being smaller than 1.0 mm and 1.0°, both at the intact and replaced knees. The corresponding values over specimens were larger due to the different status of the diseased knees, these being about 7 mm and 9°. At the natural knees, PT lengthening occurred with different extents mainly in the initial 30°-40° of flexion for all fibres. This was observed also after TKR, although at near full extension all fibres were about 15% tighter than by in the intact knee (see Table). Fibres in the intact knee inclined laterally and posteriorly of about 11° and 30°, respectively; after TKA, an extra lateral inclination of 4° was observed. ISO had no anatomical consistency. PT kinematics was always correlated to TFJ flexion. After TKR, frontal orientation was correlated to medio-lateral PFJ shift, but this was not observed at the intact knees, likely due to the eroded status of the native patella.

III. Patient-Specific Instrumentation (PSI) tests

Recent improvements in the biomechanical understanding of mobility and stability of the knee joint, prosthetic design and surgical technique have contributed to the success of TKR [1]. There is still debate about the maximum admitted misalignment for the lower limb mechanical axis, although alignment errors larger than 3° would result in a more rapid implant wear and mobilization [6]. In the last decade, SNS has been exploited to improve prosthesis component positioning. Recent studies have revealed that these systems are able to reduce outliers in prosthetic component alignments and result in a better mechanical axis when compared to conventional instrumentations [6]. Nevertheless, the majority of surgeons continue to prefer the conventional technique because of the lack of long-term functional results. The most recent advance in TKR is Patient-Specific Instrumentation (PSI, Fig. 3), which claims to achieve better positioning of prosthetic components while avoiding complex instrumentation in the operating theatre [1]. These technologies offer original patient-matched cutting blocks that are expected to generate more accurate bone cuts and better alignments of the prosthesis components. Particularly, these cutting blocks are derived from lower-limb computer tomography (CT) or magnetic resonance imaging (MRI). Computer-aided design (CAD) models of the distal femur and proximal tibia are reconstructed from the image scanning techniques [1] (Fig. 4). Relevant cutting blocks are, then, designed and manufactured based on surgeon's recommendations with only one fitting position on the patient native anatomy. To date, only a few studies have reported early relevant results, whereas the actual effectiveness has yet to be demonstrated [6].

Here below two different PSI systems for TKR are assessed and compared, particularly the accuracy with which of two procedures result in positions and alignments of the components consistent with the corresponding in the preoperative plan. For this purpose two evaluating techniques were used, and two studies were conducted accordingly: A. intra- and post-operative measures by using respectively SNS and measurements on radiographs, and B. post-operative bi-planar video-fluoroscopy for final 3D poses.

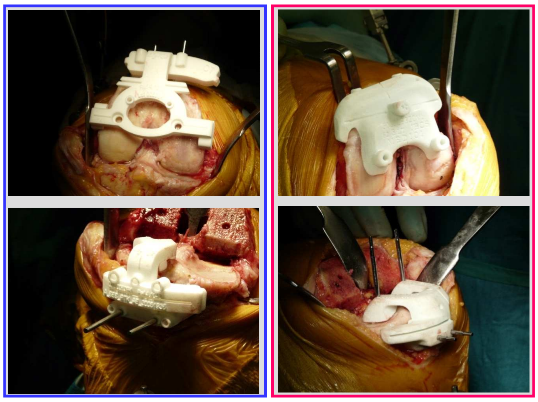

Fig. 3. MyKnee® (left) and VISIONAIRE® (right) PSI: fixation on bones.

A. *Intra- and post-operative accuracy assessment using SNS and radiographs*

1) *Purpose* - The aim of the first study is to assess and compare the accuracy of two different PSI systems for TKR both intra-operatively for bone preparation and post-operatively for final component alignment, with the main hypothesis being that a good accuracy can be achieved by these two PSI systems in all three anatomical planes.

2) *Materials and Methods* - Fifty patients affected by primary gonarthrosis were recruited for unilateral TKR using PSI systems and signed relevant informed consent. Two different patient groups consisting of twenty-five subjects each were created. Each group was associated to a different PSI system and TKA prosthesis design. Particularly, in Group A, these were MyKnee® and GMK®, both by Medacta®-International, Castel S. Pietro, CH; in Group B, these were VISIONAIRE® and Journey®, both by Smith&Nephew®, London, UK (Fig. 3). PSI systems in Group A and Group B were derived from a CT-based and an MRI/X-Ray-based system technique, respectively (Fig. 4). At both the femur and the tibia, alignments on the three anatomical planes and resection thickness at the cutting blocks and at the resulting bone cuts were recorded intra-operatively by a SNS [3]. Corresponding alignments of the prosthetic components and

mechanical axis were also measured post-operatively on radiographs [3]. All measurements were compared with those of the corresponding pre-operative planning. Discrepancies larger than 3° were considered as outliers.

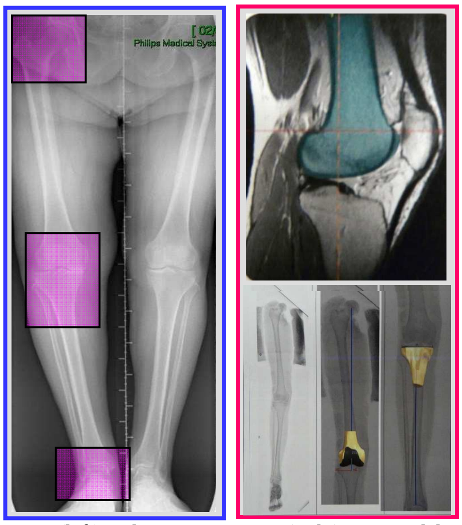

Fig. 4. MyKnee® (left) and VISIONAIRE® (right) PSI: model creation.

3) *Findings* - In both groups, the mean absolute differences between pre-operatively planned alignments and corresponding intra- and post-operatively measurements, ranged between 1.2° and 2.9° in all three anatomical planes. In both groups, both at the femur and the tibia, the plane with the smallest percentage of outliers was the coronal. The comparison between two groups was statistically significant ($p<0.05$) in the femoral sagittal plane, where group B showed smaller alignment discrepancies at the cutting blocks. Generally, both PSI systems showed good alignments in the coronal plane. Slight better performances were observed in the MRI-based system.

B. Post-operative accuracy assessment using 3D video-fluoroscopy

1) *Purpose* - The aim of the second evaluating technique is to assess and compare the accuracy of the two different PSI systems described in the previous for TKR also post-operatively for final component alignment using accurate 3D video-fluoroscopy.

2) *Materials and Methods* – Patients groups are the same of the previous point. For each patient, starting from two quasi-orthogonal fluoroscopic images, i.e. the coronal and the sagittal view of the replaced knee, and by a standard shape-matching technique in each of these images, the position and orientation of the femur and tibial two metal components and of the two prepared bones were estimated [8]. Component-to-bone relative positions and orientations were then obtained in 3D. Assuming the corresponding values at the preoperative plan equal to zero, small discrepancies were indication of highly accurate overall instrumentation. A repeatability test was performed to assess the reliability of this evaluation technique.

3) *Findings* - The repeatability test revealed that the present technique was reliable enough. The range over all patients for the position and orientation discrepancies was from zero to respectively 5.9 mm, i.e. femoral component in proximal-distal direction, and 4.2°, i.e. the femoral component in flexion. The comparison revealed also larger ($p<0.05$) antero-posterior and medio-lateral positions at the tibia in group A than in B. Generally, good match in three-dimensional position and orientation was found between the final implantation and the corresponding preoperative plans, with mean discrepancies smaller than 3.1 mm and 1.9°, respectively.

IV. CONCLUDING REMARKS

Surgical navigation systems and patient-specific instrumentations are augmenting the available technologies for advanced computer-assisted TRK [7]. In addition to fully controlled operations via surgical robots, hospitals and surgeons have now the options of navigated surgery via optical cameras and trackers, or of patient-specific cutting-blocks obtained from careful 3D computer based planning starting from medical imaging. All these three procedures can provide a valuable support to surgeons for achieving a successful TKR, with good fixation of the components, and mobility and stability at the replaced knee joint. These results however should be assessed at follow-ups, by means of the available gait analysis and 3D video-fluoroscopy [8]. The relevant evident advantages shall be opposed with costs of the instrumentation, time and arrangement of the procedures, and the learning curve. Definitely, the integration in these technologies of current biomechanical models for the knee joint, particularly those able to assess mobility and stability in terms of the mutual contribution of articulating surfaces and ligaments, can provide in the future further support for a best possible knee joint replacement.

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