

Robotic alignment of femoral cutting mask during total knee arthroplasty

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Abstract

Objective To investigate a new navigation system integrated with a robotic arm for total knee replacement (TKR) procedures.

Materials and Methods The study here reported attempts providing the surgeon with a robotic assistant handling the surgical tools with superior stability removing tremors. The system is equipped with an optical localization system, which allows the real-time monitoring of the position and orientation of the surgical tools carried by the robot end-effector and provides a feedback control to optimize the reaching of the goal position.

Results Pilot experiments, performed aligning the femoral cutting mask to the surgical position, together with the feasibility of the system, proved its accuracy and reliability.

Conclusion This paper shows the feasibility of a robotic system for TKR, integrated with a navigation system, in order to overcome limitations of both approaches.

Keywords Total knee replacement · Computer assisted orthopedic surgery · Robotic surgery · Robot calibration · Closed-loop control

Introduction

Computer assistance of surgical intervention improves the quality of total knee replacement (TKR) outcome in terms

of pain relief, joints range of motion, prostheses stability, durability and lower limb mechanical alignment [7]. Navigation offers also improvements in the assessment of ligamentous stability [10], indicates proper components size and pose and provides better placement, thus reducing implant wear and loosening and consequently increasing prosthetic lifespan [16]. The goal of computer assisted surgery (CAS) is to reduce deviations from best practice and to eliminate outliers in components alignment.

Before the surgical operation starts, reference frames built with light-reflecting, light-emitting, or electromagnetic markers (trackers) are fixed on the distal femur and on the proximal tibia by self-cutting screws. Pivoting the femur around the hip allows computing the hip joint centre, and detecting bony landmarks with a tracked pointer allows computing the knee and the ankle centres. Such mechanical centres define the limb mechanical axis and determine the orientation of the distal cut of the femur (perpendicular to the femoral mechanical axis). Traditional cutting guides are equipped with trackers: the surgeon can thus drive cutting guides, jigs, saw-blades and drills in real time while the interactive user interface represents ideal and actual tools position and orientation at the same time. When the desired pose is reached, in case of TKR, cutting tools pose is maintained inserting cortical pins and self-cutting screws inside the exposed bone surface. Data displayed on the visualization monitor (bone angle cuts and distance measurements) informs the surgeon about alignment, implant size, orientation and relationship between bone and implant. In order to accurately balance the ligaments, the surgeon can measure residual laxities: anterior-posterior and medio-lateral at each level of knee flexion. Finally, the surgeon can also control the range of motion of the knee.

Jenny and Boeri [9] reported a significant improvement in the femoral sagittal angle and in the tibial anterior posterior

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angles for navigated surgery. Mielke et al. [11] reported a tendency toward an optimal overall leg axis in computer assisted interventions. Sparman et al. [17] reported a significant difference in favour of navigation concerning the mechanical axes, the frontal and the sagittal femoral and the frontal tibial axes between 2 randomized patient groups. Although the comparative studies on computer-navigation systems do not show a definite trend in the outcome, all authors stated that the use of the navigation results in a reduction of cases with a high deviation from the desired alignment [5]. Notwithstanding the above cited advantages, CAS systems present some drawbacks. The surgical cutting tools have to be manually aligned by the surgeon, while he/she follows indications provided by the visualization interface. After alignment between the desired cutting plane (or axis) and the current plane (or axis), the surgical instrument has to be maintained in the desired in pose during the cutting (or reaming) phase. Therefore the robot could act as a surgeon assistant holding firmly the surgical tools.

Examples of active medical robotic devices are the CASPAR system (OrtoMaquet, Rastatt/Germany) [12], whose clinical application include hip arthroplasty and knee surgeries (TKR—and anterior cruciate ligament—ACL) and Robodoc system (Integrated Surgical Systems, USA), which is used for total hip replacement. Semi-active robotic assistive system were developed for orthopaedic surgery [4, 14] starting from 1990s. In the ACROBOT system the surgeon guides the robot using a handle with a force sensor serving fixed to the robot tip. The robot provides a 3D motion constraint that prevents milling outside a predefined safe region.

Robotic systems (both active and semi-active systems) make use of CT scans and information input during a preoperative planning session to create a sequence of instructions to the robot defining where the bone is to be prepared or removed. Also, the bone has to be rigidly fixed on the operating table and registered with respect to the robot, with an invasive approach.

Recently, minimally invasive approach has lead to the development of a mini bone-attached robotic system based on parallel kinematics (MBARS) for joint arthroplasty and for patellofemoral replacement in particular [20]. Despite the reduced dimensions of the 6 degrees of freedom (DoF) robot footprint, the attachment of the robot to the bone exposed surface requires invasive fixation and the robot working volume is rather limited. A current drawback to most bone-mounted robotic TKA systems, however, is that they require substantial incision of the quadriceps muscle and reflection of the patella in order to fix the robot. With a similar approach, Praxiteles [13] is a miniature robot with 2 motorized DoF, precisely aligned to the cutting planes with a 2 DoF adjustment device. In mini-invasive approach, Praxiteles is laterally fixed on the femur, if the bone is resistant enough. Since the

robot proximity to the knee, the actuation unit has to be sterilized and replaced after a while. While the robot is moving towards the desired pose, there is no control on the current robot pose and no further correction, in case of misalignment, is possible.

In order to overcome previously listed limitation, the approach presented herein integrates a navigation system with a robotic arm, as proposed by [1]. The study here reported attempts providing the surgeon with a robotic assistant handling the surgical tools, removing tremor or unintentional slipping of the tool. Pilot experiments, performed aligning the femoral cutting mask to the goal position on sawbones lower limb models, together with the feasibility of the system, proved its accuracy and reliability.

Materials and methods

The proposed system integrates a prototypical navigation system (KNEELAB) [2], which uses an Hybrid Polaris (NDI, Canada) optical localization system (sampling rate 20 Hz), with a 6 DoFs serial robot FS-03N with D70 controller (Kawasaki Heavy Industries) (see Table 1 for characteristics). In order to rigidly connect the surgical instrument (femoral distal cutting mask, Lima-Lto, Udine, Italy) to the robot end-effector, a modular surgical tool device was designed and developed.

Table 1 FS-03N Kawasaki robot characteristics

Type	Articulated robot		
	JT	Motion range	Maximum speed
Degrees of freedom	6		
Working envelope and maximum speed			
	1	320°	250°/s
	2	210°	180°/s
	3	480°	180°/s
	4	720°	600°/s
	5	270°	300°/s
	6	720°	600°/s
	JT	Torque	Moment of inertia
Wrist load capacity			
	4	4.0Nm	0.078 Kg m ²
	5	4.0Nm	0.078 Kg m ²
	6	2.0Nm	0.020 Kg m ²
Repeatability		0.03 mm	
Maximum payload		2Kg	
Driving motors		Brushless AC servomotors	
Mass		~20Kg	

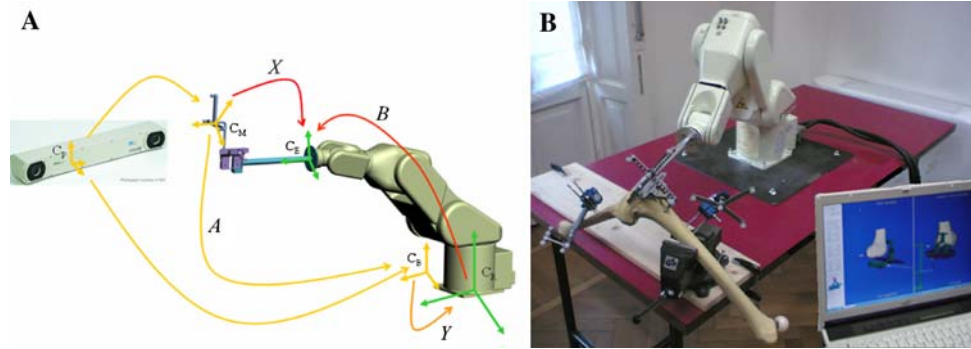


Fig. 1 a Robot calibration scheme: A is the known transformation matrix between C_M (coordinate system of the femur mask) and C_B (coordinate system of the robot base measured by the localization system); B is the known transformation matrix between C_E (coordinate system of the robot end-effector) and C_R (internal coordinate system

of the robot base); X is the unknown transformation matrix between C_M and C_E ; Y is the unknown transformation matrix between C_B and C_R . **b** Picture of the system developed. On the left the graphical user interface is shown

Robot calibration

Two Dynamic Reference Bases (DRBs), rigid bodies composed by three or more light-reflecting markers, are attached to the robot base and to the robot end-effector. During robot calibration transformation matrices X (transformation between the surgical tool and the end-effector) and Y (transformation between the DRB fixed on the robot base and the robot base internal reference frame), as shown in Fig. 1, are computed. Transformation matrices A and B , represented in Fig. 1 as well, are provided given by the localization system and by the direct kinematic chain from the joint-angle readings of the robot, respectively. For N different poses of the robot, the so called “sensor-actuator” calibration procedure (or “hand-eye calibration”, [19]) is then performed in order to solve the system of equations, expressed by means of homogeneous transformation matrices:

$$A_i^{-1} \cdot X = Y \cdot B_i \quad i = 1, \dots, N \tag{1}$$

where 6 independent parameters for transformation matrix X and 6 independent parameters for transformation matrix Y are needed.

Two methods were applied to compute X and Y and their performances were compared: the closed form solution of the system of equation, as proposed by [3], and an iterative approach we developed. The latter proved to be more robust to noise, confirming the hypothesis of [6], who stated that iterative approaches behave better than closed form solution in presence of noise. In our approach, transformation matrices are expressed as exponential maps and the following cost function F is minimized with respect to the 12 unknown parameters (6 DoFs for X and 6 DoFs for Y), with Levenberg Marquardt optimization algorithm:

$$F = \left\| A_i^{-1} \cdot X - Y B_i \right\| \quad i = 1, \dots, N \tag{2}$$

Rotational and translational parameters are both determined in each minimization step, combining the metric for translation and rotation errors and bringing them to the same order of magnitude [18].

Patient calibration

The patient femur positions and orientations are firstly computed in order to perform anatomy calibration. A DRB is rigidly attached to the bone (femoral reference frame). Joint centres of rotation are automatically computed via kinematic passive movements (hip centre) or via manual point digitisation (knee centre) in order to compute the femoral mechanical axis and the epicondylar line (in the femoral coordinate systems). The navigation software automatically computes the optimal distal cutting plane, perpendicular to the femoral mechanical axis, in terms of varus/valgus, internal/external rotation and posterior/anterior slope and cutting resection level. Automatic tracking of possible movements of the anatomical structure to be operated upon eliminates the need for rigid patient fixation.

Robotic alignment and feedback correction

Given the calibration matrices X and Y , the end effector pose in the robot internal reference frame (robot input) for achieving the desired mask alignment is therefore computed, with reference to the femoral DRB (Fig. 2):

$$B_{\text{robot}} = Y \cdot C \cdot M \cdot X \tag{3}$$

where X and Y were determined during the calibration procedure already described, M is the current position of the limb, expressed in the robot base DRB fixed to the robot base, and C is the transformation matrix of the desired cutting plane expressed in the femoral DRB.

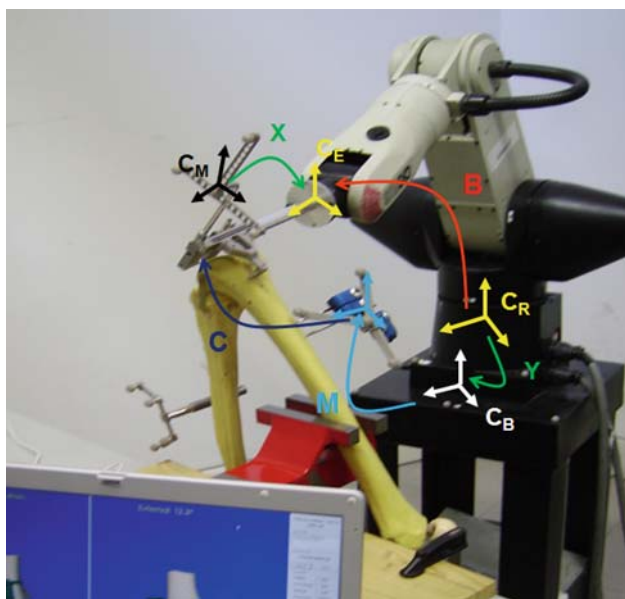


Fig. 2 Robot command determination (B) in order to reach the desired position and orientation with the surgical tool, given current M transformation (position and orientation of the femur)

In order to further correct the alignment of the femoral cutting mask (reducing the difference between the current and the desired position and orientation), the transformation matrix C is consequently updated, as shown in Fig. 3. Whenever the localization system detects a difference between the desired position of the mask (in the femoral DRB), \hat{C} , and the current one, C , matrix \hat{C} is updated in $\hat{C}_{\text{corrected}}$ and the robot input (B) consequently computed.

Experimental protocol: robot calibration

The robot calibration was performed 7 times moving the end-effector in 20 approximately equispaced positions in a 3D grid within the defined working volume ($0.75 \text{ m} \times 0.75 \text{ m} \times 0.5 \text{ m}$). Both the end-effector position in the robot reference frame (B), read by the robot encoders, and the surgical tool DRB expressed in the robot base DRB (A), detected by the localization system, were collected. Both the algorithm (closed form solution and iterative approach) were then applied to the collected data (leaving one acquisition out from each calibration session for validation purposes) and residual errors were computed, using the metrics introduced by [19], for each one of the acquisitions left out from the calibration. The Root Mean Square Error (RMSE) error in the rotation unit quaternion were computed as $\|q - \hat{q}\|$ and the RMS of the relative errors in the translation as $\|\mathbf{t} - \hat{\mathbf{t}}\| / \|\hat{\mathbf{t}}\|$, where q and t are the quaternion and the translation parameters representing the estimated calibration matrices and \hat{q} and \hat{t} the parameters computed with the acquisition left out.

Calibration repeatability was also tested, repeating the unknown transformation matrices computation in different experimental conditions, without either perturbing the pose of the surgical tool with respect the end-effector or displacing the DRB on the robot base.

Experimental protocol: robot accuracy and performances

In order to check the overall system performances, we carried out several tests in our laboratories using sawbones lower limb models. After DRB fixation on the sawbone femoral and tibial models, desired cutting plane were computed using the navigator software developed (KNEELAB).

The overall system accuracy was tested transforming the desired femoral cutting mask position, expressed in the anatomical reference frame, to the robot reference frame, giving such a command to the robot end effector, and recording the automatically reached pose. The test was performed 40 times, changing the position of the bone in the optical localization device working volume for three experimental sessions (re-calibrating the system before each session). Bone motions were detected and actuation signals for the robot were generated in order to align the femoral mask in the desired pose with respect to the femoral reference frame. The reached pose was acquired for 10 s at 20 Hz. For each trial, the difference between the desired surgical tool position and the actual one was computed in terms of varus/valgus, internal/external angles and anterior/posterior slope and resection level RMSEs:

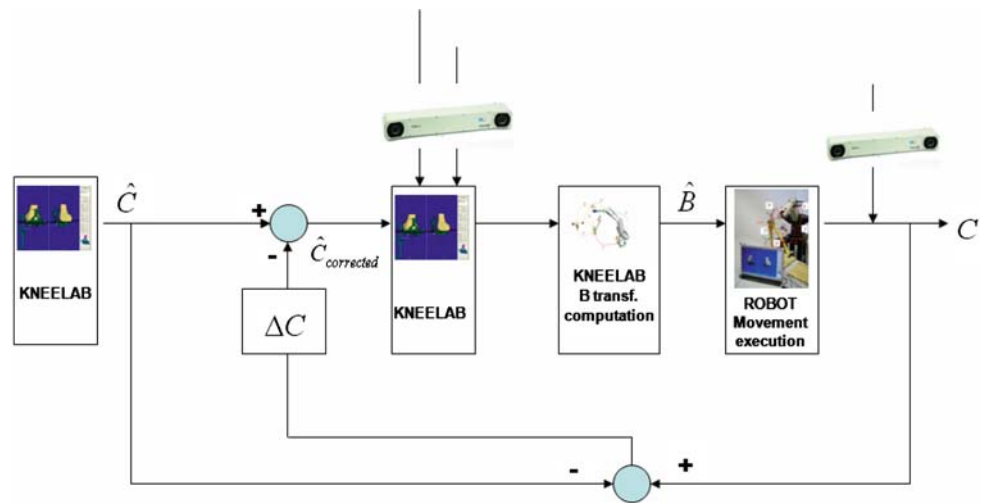
$$RMSE = \sqrt{\frac{\sum_{i=1}^M (\hat{v}_i - v_i)^2}{M}} \quad (4)$$

where $M = 10 \text{ s} \cdot 20 \text{ Hz} = 200$ samples, \hat{v} is the obtained value (for positions and orientations) and v the desired one.

In order to assess robot performances in terms of alignment stability with respect to manual positioning, 4 orthopedic surgeons (not expert in navigation; subjects 1–4) were asked to manually align the femoral cutting mask as indicated by the navigation software and to maintain the goal position for 10 s. Each trial was repeated 10 times, allowing the subject to rest between trials. The same alignment was performed by the robot 10 times and the reached position was registered for 10 s. Errors were computed as RMSEs between the target position and orientation and the actual ones during the registration phase. A non parametric tests (Kruskal–Wallis $p < 0.05$) was then performed in order to validate the robot alignment performances against the manual positioning.

The robot is provided with a basic control scheme which allows it to further correct the reached position, once the localization system detects a difference between the desired position and the actual one. The robot transformation matrix describing the robot end effector pose respect to the robot

Fig. 3 Update of matrix C if an error between the desired mask position and orientation and the actual ones, with reference to the anatomical DRB, is detected by the localization system



internal reference base is therefore updated in order to minimize the error between the desired position and the actual one.

The stability provided by the robotic alignment, with respect to the manual positioning, was also computed in terms of data dispersion (evaluated as the difference between the 95° and the 5° percentile of the acquired data distribution), grouping together the ten trials for each subject, resembling a single trial lasting 100 s.

Results

Experimental protocol: robot calibration

As shown in Fig. 4, residual errors of the iterative method are lower than those of the closed form solution (Danilidis) in all the calibration sessions (relative translation errors less than 0.005 and norm of the differences of the quaternions less than 0.015). Danilidis performances appeared to be unacceptable in 2 calibration sessions (#3 and #7).

Experimental protocol: robot accuracy and performances

The errors of the robot are below 0.7° in varus/valgus alignment (with currently accepted clinical threshold of 3°), below 1.3° in internal/external alignment and below 2° in case of anterior/posterior slope. The errors are almost uniformly distributed in the working volume considered and in the different experimental sessions performed.

Figure 5 shows the comparison between the performances of the manual positioning performed by the four subjects and the robotic automatic alignment. Even if there is a residual error always present in the actual position and orientation of the cutting mask with respect to the desired position,

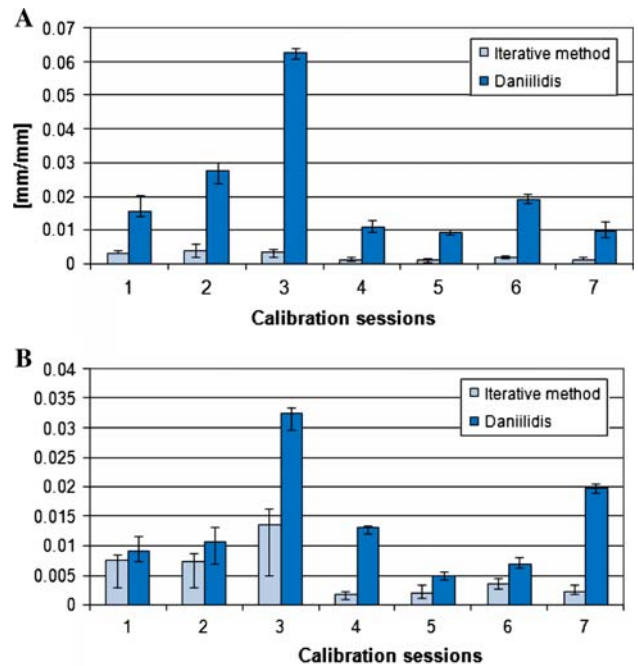


Fig. 4 Residual errors (median values ±25° percentile 75° percentile) in the robot calibration for both translation (a) and rotation (b)

the robot behaves better with a statistically significant difference both in the translation (resection level) and in the rotation (varus/valgus, internal/external, anterior/posterior). The better behaviour is particularly evident as far as the internal/external and the varus/valgus values are concerned.

The feedback control allows further correction of the surgical cutting tool towards the desired position, as reflected by Fig. 6. One can see how the adjustment of the robot end-effector transformation allows for error reduction in each alignment parameter, except from the internal/external value which was already low.

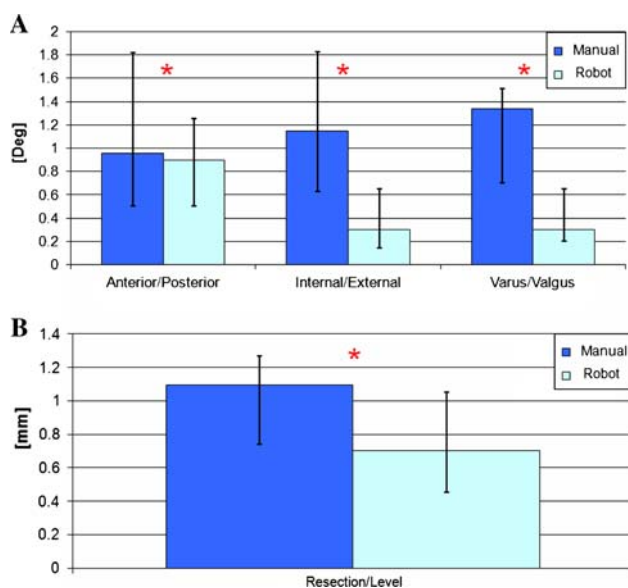


Fig. 5 Accuracy (median values \pm 25° percentile 75° percentile) in the cutting mask alignment in terms of orientation (a) and position (b). The stars indicate the statistical difference

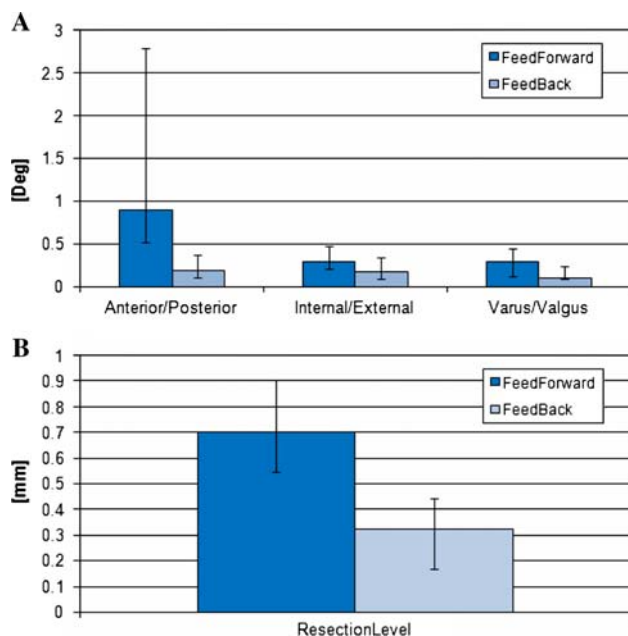


Fig. 6 Residual errors median values \pm 25° percentile 75° percentile) before and after the feedback correction in terms of orientation (a) position (b) of the cutting mask

Robot stability, along the whole trial duration, was greater with respect to each subject stability in terms of lower data dispersion for both the position and the orientation of the cutting mask and was less than 30% with respect to the best performing subject. Figure 7b shows the great difficulty of all the subjects to hold the mask in the desired anterior/posterior alignment with respect to the varus/valgus orientation.

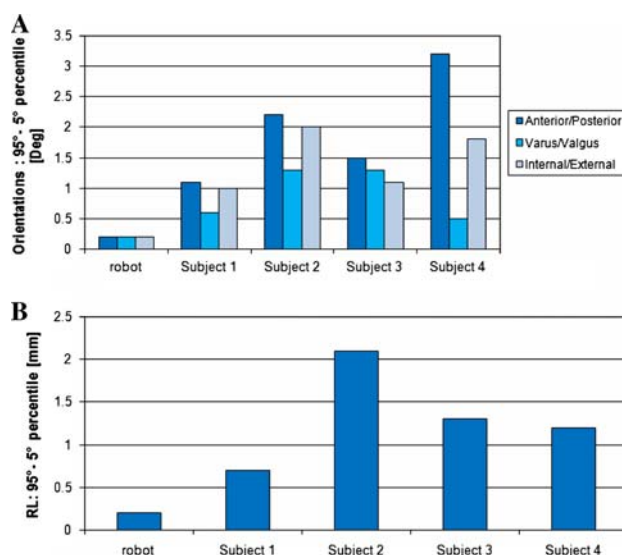


Fig. 7 Stability in the orienting (a) and in the positioning (b) of the cutting mask

Discussion and conclusion

This paper shows the feasibility of a robotic system for TKR, integrated with a navigation system, in order to overcome limitations of both these approaches. In current navigation system, the surgeon faces some difficulties when fixing the cutting masks to the bones with cortical pins and screws. On the contrary, all robotic systems currently on the market or reported in literature require the rigid fixation of the patient limbs [8] or the rigid fixation of the robot directly on the patient exposed bone surfaces [13, 15]. Our approach, allowing the real time tracking of the bone pose with respect to the robot, avoids any rigid fixation of the bone, thus allowing a mini-invasive intervention. At the same time, it overcomes the limitations of the navigation systems and offers the surgeon help in holding firmly the surgical instrument.

Our robotic system does not require any pre-operative image since the operative plan is based on biomechanical information acquired during the navigated surgical procedure (image-less procedure). Also, since the robot is not directly in contact with the patient, sterilization of robotic parts is not required since the robotic arm could be easily draped and the sterile surgical tool easily attached to the robot end effector. The robot end effector was modified in order to host a wide range of surgical instrument since the carrier depth can be easily adapted to host different shapes.

Since the medical procedures require maximum precision and accuracy, the robot calibration method has to be robust to noise sources, which can occur in the operating room, and repeatable if performed in different operation conditions. For this reason, we chose an iterative approach to compute the two unknown transformation matrices X (transformation

from the robot end effector to DRB of the surgical tool) and Y (from the robot internal reference frame to DRB fixed on the robot base). Residual errors have the same order of magnitude of the tracking RMSE reported in the optical localization system datasheet (0.35 mm). Further investigation will concern the metric for the rotation and translation errors, since residuals are not frame invariant [18] and preconditioning is crucial for minimization convergence.

Robots performances, tested with several alignment repetitions within the operating working volume, assessed the robotic system reliability for different limb positions and orientations, even if the robot operates with an open-loop control modality. Biggest residual errors regards the anterior/posterior orientation with respect to the femoral mechanical coordinate system and are due to the non-perfectly fixed femur sawbone blockage system. It was therefore necessary to keep into account the update of the matrix describing the transformation (M) of the limb in real time.

When compared with the accuracy reached by the manual alignment, robots performances are significantly better with regards to all the performances indices evaluated. Robotic alignment is further improved by the feedback correction which consider both the displacements due to the limb motion and possible errors in the kinematic chain and updates the robot command accordingly. Stability of the feedback control loop must be improved by properly design a controller. At now, the real time control has not yet been implemented, but the Kawasaki robot control provides the possibility to be programmed in real time, compensating any unwanted patient movements. The patient limb could therefore be maintained fixed by a non invasive cast. Localizing both the robot and the patient positions in real time allows increasing the safety of the surgical procedure, since unwanted collisions with the system could be avoided.

Another crucial issue the robotic alignment tries to solve is to assure mask stability during pins insertion in the bone while fixating the mask for cutting. It is clearly visible that, in order to align the femoral cutting mask to the desired position and orientation, the subjects took advantage of the physiological anatomy of the used sawbones, in fact varus/valgus values are more stable than the other measured parameters. This trick would not be possible in the real operating room, since the patients present arthritic knees where the condylar symmetry has been compromised.

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