

Minimally invasive 3D data registration in computer and robot assisted total knee arthroplasty

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Abstract—Computer and robot assisted surgery is concerned with the improvements achievable by using computer methods and robotic devices to plan and execute surgical interventions. The registration of different coordinate frames, often achieved through the matching of 3D data sets, represents a crucial step connecting planning and execution. Orthopaedic surgery already features a number of functioning applications which include registration routines relying on presurgically implanted fiducial markers. Replacing such invasive routines with non-fiducial registration procedures is regarded as a necessary step towards a minimisation of surgical invasiveness. A minimally invasive registration technique based on the iterative closest point algorithm is presented and conceived for a specific computer and robot assisted orthopaedic reconstructive intervention, namely total knee arthroplasty. The whole surgical protocol is examined in detail and the experimental results, relative to tests performed on synthetic and animal specimens, are thoroughly reported and discussed. The authors indicate that the proposed registration approach is well-suited for the relevant application and appropriate for *in vivo* testing.

Keywords—Registration, Iterative closest point, Computer assisted surgery, Total knee arthroplasty, Joint replacement

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1 Introduction

COMPUTER ASSISTED surgery (CAS) is becoming a widely popular technology and is now leaving laboratories and universities and entering surgical rooms. The application of computer techniques in the simulation, planning and execution of surgical interventions, aimed at increasing the rate of surgical success, is CAS's primary target.

The advantages of CAS systems are widely recognised and orthopaedic surgery, in particular, can already feature a number of operative implementations. This is mostly due to a compelling need for high geometric accuracies and to some coexisting inherent characteristics of the skeletal system such as relative rigidity and fairly differentiated visualisation in standard diagnostic imaging technologies. Computer and robot assisted joint replacements (HO *et al.*, 1995; KAZANZIDES *et al.*, 1995), osteotomies (CAPONETTI and FANELLI, 1993), screw and nail placements (LAVALLÉE *et al.*, 1994; NOLTE *et al.*, 1994; 1995; VIANT *et al.*, 1995) and ligament reconstructions (ORTI *et al.*, 1993) have been investigated in recent years. Our group has already contributed to the ongoing debate by submitting a computer integrated approach to total knee arthroplasty (TKA) (MARCACCI *et al.*, 1995).

The implant of knee prostheses, specifically TKA, is among the surgical procedures which would principally benefit from a computer integrated approach. A computer based planning system reduces the number of decisions the surgeon has to

take intraoperatively by enabling them to be taken preoperatively. As a consequence, it ensures a larger degree of safety in the surgical procedure and a reduction of the intraoperative time (RAND, 1993). Conversely, robotic assistance during the execution phase is a means for improving the absolute accuracy in positioning and guiding surgical tools. The latter is a point of utter importance for implant fixation and long-term stability in TKA (PETERS and ROSENBERG, 1994).

Successful implementation of CAS protocols requires a coherent integration of spatial data relative to a broad variety of imaging, sensing and actuating devices, each with its own coordinate system. This is why an accurate estimation of the geometric relationships between different coordinate frames and 3D data sets, normally referred to as 'registration,' plays a crucial role in virtually all CAS applications. In computer and robot assisted TKA (CRA-TKA) the registration step is a critical link between the planning and execution phases, because attainment of the same high geometric accuracy achieved during preoperative planning in the actual surgical execution is extremely important.

Most of the current high accuracy protocols employ artificial markers—fiducials—which need to be implanted before surgery. The fiducials are both identifiable in the preoperative images and accessible intrasurgically by means of a position transducer. Registration is then generally performed through fast and robust point-to-point matching algorithms (TAYLOR *et al.*, 1994; MITTELSTADT *et al.*, 1995; KIENZLE *et al.*, 1995a; 1995b; LEA *et al.*, 1995). Following a widespread trend towards a reduction in surgical invasiveness, intensive investigation of non-fiducial registration techniques is currently in progress. Such effort concerns computer assisted orthopaedic surgery as well as other related fields (SIMON *et al.*, 1995a;

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CUCHET *et al.*, 1995; RYAN *et al.*, 1995; LAVALLÉE *et al.*, 1995; GRIMSON *et al.*, 1994; SUBSOL *et al.*, 1995) and is expressly directed at avoiding the need for an external marker implant, a factor which also increases the risk of postoperative infection and trauma.

The aim of this study is to present a non-fiducial, minimally invasive registration method based on the Iterative Closest Point (ICP) algorithm (BESL and MCKAY, 1992; ZHANG, 1994) within the framework of a CRA-TKA procedure. The distinctive role played by the registration phase and its synergism with the other steps of the relevant protocol are taken into account. This is to provide a comprehensive outlook on the specific CAS application analysed and to stress its influence over the material and methodological constraints that the registration routine must comply with. Though widely adopted, non-fiducial registration techniques are, in fact, highly application-dependent. No implementation concerning TKA has yet been divulged and very few results on 'close-to-reality' testing have been disclosed regarding the whole field of computer assisted orthopaedic surgery. In this paper, particular emphasis is given to the dependence of the routine's accuracy standard on input data features. This issue has already been addressed by SIMON *et al.* (1995a) in their work on registration techniques for computer assisted total hip replacement. We have tried, however, to include the physical constraints which existed during an actual intervention in the laboratory trials that we performed on synthetic and animal specimens. This element is, in our opinion, very important to increase the reliability of the reported experimental results and assess the actual applicability of the described protocol.

2 System overview

TKA is the principal reconstructive procedure for patients suffering from severe knee arthritis. Progress in implant design and surgical technique lead to success rates close to 85% (CALLAHAN *et al.*, 1994). During the intervention, the articular surfaces of the femur and tibia are replaced with two prosthetic components. Alignment errors of such components, particularly those exceeding 1° in orientation or 1 mm in position, can severely affect the kinematic and kinetic functionality of the operated limb and might eventually lead to implant failure. Hence the usefulness of careful presurgical planning (RAND, 1993; BARNES *et al.*, 1993). A robotic execution of the planned bone resections can ensure further improvement to the procedure because of the higher intrinsic geometric accuracy of a robot as compared to that of a human operator. Moreover, recent studies on bone remodelling following cementless joint replacement show that the adhesion of the prosthetic components due to bone ingrowth, which is a key condition for surgical success, is strongly related to the structural features of the bone/prosthesis interface (PETERS and ROSENBERG, 1994; CARLSSON *et al.*, 1988). Also from this viewpoint a robotic execution could be advantageous.

Our system for CRA-TKA is composed of a surgical planning toolbox, a robotic assistant and a registration protocol, which will be described in detail in the following paragraphs.

The planning toolbox runs on an Indigo2 workstation*. It incorporates OpenGL-based graphic tools, uses a 3D model of the patient's joint, as reconstructed from computed tomography (CT) scans, and allows the surgeon to:

- analyse the patient's anatomy and the pathological alterations;
- determine the geometric and mechanical characteristics of the subject's limb interactively with the help of computational and graphic facilities;
- choose the most appropriate model and size of prosthesis;
- assess the best placement for the femoral and tibial prosthetic components based on the above mentioned anatomical, geometric and mechanical features;
- simulate bone resections and prosthetic implantation so as to check the compliance with biomechanical constraints;
- include circumstantial refinements in the surgical approach or decide to change some of the components.

The planning system yields as output a spatial dataset describing the resection planes—five relative to the femur and one to the tibia—in the CT reference frame.

Laboratory tests on robotic bone cutting have been performed using a Puma 560 industrial robot† equipped with a force sensor for manual guidance, safety system‡ and an air powered motor with milling tools**. Resections were executed through incremental steps along the axial direction of the bone. Bone slices 2–3 mm thick were removed at each crossing of the milling tool until the whole of the planned surface was covered. As far as the geometric characteristics of the resected bony surfaces were concerned, robotic machining gave better results than manual cutting (FADDA *et al.*, 1996). Design and manufacture of a new dedicated custom-built robot is in progress.

Once the intervention has been carefully planned, since the robotic system ensures a high standard of intrinsic preciseness and reliability, the outcome of the entire procedure depends on how accurately the robot will execute the planned tasks. This strongly depends on how accurately the reference frames of the robot, preoperative model and intraoperative patient anatomy can be registered with one another. In the past, this task was accomplished by locating preoperatively implanted artificial markers with the robot's end-effector. The detection of such markers in the preoperative environment also permitted the computation of the transformation between the two reference systems with a satisfying degree of accuracy. The new, less invasive technique described below, tries to eliminate the need for artificial marker implantation while retaining the good accuracy level of the previous approach.

3 Registration protocol: theory and implementation

Broadly speaking, registration is the assessment of the affine transformations linking different coordinate frames. In fact, the problem is often stated in terms of the matching of spatial data sets embedded in the relevant frames. Non-fiducial registration techniques generally exploit the geometric characteristics of such data sets in order to find a correlation between them, as pointed out in the extensive review published by LAVALLÉE (1995).

The basis of our registration protocol is the ICP algorithm (BESL and MCKAY, 1992; ZHANG, 1994), which provides a simple approach to the solution of the two point sets matching problem. Neither point-to-point correspondence nor extraction of any specific geometric feature—axes, curves, ridges, etc.—is required. Although the algorithm was not expressly proposed for biomedical applications, several research groups

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‡LORD 30/100, Assurance Technologies Inc., Garner, NC, USA

**MIDAS Rex Pneumatic Tools Inc., Forth Worth, TX, USA

*Silicon Graphics Inc, Mountain View, CA, USA

have been investigating its use in CAS or other related problems (CUCHET *et al.*, 1995; SUBSOL *et al.*, 1995; SIMON *et al.*, 1994; 1995a; 1995b).

The algorithm acts on two input point sets, which we will call 'model' and 'data.' The two sets are subject to only one restriction: the model set cannot include a smaller number of points than the data set. It is also assumed that the object portion enclosed by the model is not smaller than the one covered by the data point set. In its original version the routine iteratively brings the data closer to the model according to the following steps:

1. Predict an initial affine transformation between the two reference frames and apply it to the data.
2. Determine the model subset which lies closest to the data in a Euclidean distance sense.
3. Compute the point-to-point optimal transformation between data and model subset, using a least-squares method (FAUGERAS and HEBERT, 1986; HORN, 1987), and apply it to the data.
4. Calculate the cost function value (root mean square distance, RMSD, between the two sets).
5. Repeat steps 2–4 until the cost function variation relative to the previous iteration drops below a predefined threshold.

Since the anatomical structures involved in surgery are firmly secured to the operating table and therefore rigid with respect to the outer environment, the registration protocol can be performed only once.

In our application the model set is composed of points extracted from the preoperative CT images whereas the data set includes the points acquired intrasurgically with a precision mechanical digitiser††. The order of magnitude of our model set is 10^4 points, whereas that of the intrasurgical data set is 10^2 .

It has been proved that the algorithm converges to a local minimum (BESL and MCKAY, 1992) and that this convergence is reasonably fast. The problem of reaching the global minimum, however, remains and there is a substantial dependence of the final outcome on a good initialisation. BESL and MCKAY'S advice is to consider a set of different initial transformations, paying special attention to the rotation component. The sensitivity to the initial translation is, in fact, fairly weak.

From a computational point of view, the most demanding step is the closest point search—step 2 of the previous list. Unless it is optimised, this step requires a number of operations proportional to the product of the input data set dimensions for each iteration. Both BESL and MCKAY (1992) and, more recently, SIMON *et al.* (1995a) and CUCHET *et al.* (1995) have proposed a number of techniques for speeding up the process. Since our application time requirements, which are within the limit set in the protocol requirements section, do not stand as a major restriction, we focused particularly on accuracy issues.

To solve the problem of the initial transformation estimate, we developed a preparatory phase, which has been called 'preregistration'. Four points are preoperatively selected by the surgeon on the model of each bone involved, taking into account accessibility during surgery, identifiability of anatomical structures and maximisation of the three-dimensionality of point arrangement. Three-dimensionality of a four-point set is highest when the points are located at the vertices of a regular tetrahedron and lowest when they are coplanar. At the beginning of the intrasurgical data collection phase the selected points are displayed in sequence on a 3D view of

the joint model. The surgeon touches the corresponding points on the patient's limb with the digitiser tip as accurately as possible. Although three points for each bone would be sufficient to assess the initial affine transformations, a larger number allows us to exploit information redundancy and increase estimation accuracy. Four or five points seem to be a sensible compromise between redundancy and procedural complexity. Once collected, the intraoperative points are matched with the preoperative ones using a one-step least-squares procedure (FAUGERAS and HERBERT, 1986; HORN, 1987), which is also the main element of the ICP algorithm—step 3 in the above scheme. Procedures based on other approaches, such as those employing single value decomposition (SVD) (HANSON and NORRIS, 1981; ARUN *et al.*, 1987; SÖDERKVIST and WEDIN, 1993), would be applicable as well. By implementing a preregistration step, we expect to obtain preliminary estimates of the desired transformations between the model and anatomy reference frames, including errors smaller than $10\text{--}15^\circ$ and $10\text{--}15$ mm. Such estimates are used as starting points for the subsequent position enhancement step, which we ordinarily refer to as registration.

The position enhancement or registration procedure uses as inputs the preoperative model, the intraoperative data, collected by the surgeon from the joint areas accessible during the intervention, and an initial transformation, which is the output of the previous preregistration phase. Our approach to solving the problem of convergence to local minima is closer to that described in CUCHET *et al.* (1995) than to the one proposed by BESL and MCKAY (1992). When the relative variation of the cost function falls below the predefined threshold and the ICP algorithm stops, we keep a note of the solution obtained and, after applying a random rotational perturbation of constant magnitude, precisely 0.5° , to the currently assessed optimal transformation, we restart the registration procedure until a new local minimum is reached. If its value is lower than the previous one, the current optimal solution is updated. Perturbations are applied in this way until the output is adequately stable, i.e. contained in a tolerance interval about the current optimal solution.

Owing to instrumental inaccuracies and intrasurgical data collection problems—presence of cartilage and other tissues on the relevant bony structures, acquisition errors, etc.—intraoperative data will unavoidably include outliers. After performing the above outlined steps, our routine removes from the data set all points located beyond a certain distance from the model. This boundary value is calculated as a function of the average (root mean square) distance between data and model. The registration is finally repeated on the modified data set. A compact data flow chart outlining the different phases of the routine is given in Fig. 1. The steps are numbered in progressive order.

4 Experimental work and results

4.1 Accuracy assessment and repeatability trials on plastic phantoms

The experiments were performed using two phantoms, a plastic femur* and a plastic tibia†.

A preliminary trial was conducted out on the plastic femur. The 'preoperative' model was built through contour detection and segmentation of 78 CT slices (512×512 pixel slices, field of view, 120 mm, slice thickness and interslice spacing, 1 mm) of the entire distal part of the bone. The final outcome was a regular lattice of 11427 points (Fig. 2).

††FARO Arm model 806, FARO Technologies Inc., Lake Mary, FL, USA

*Model 1103, Sawbones Europe AB, Malmö, Sweden

†Model 1101, Sawbones Europe AB

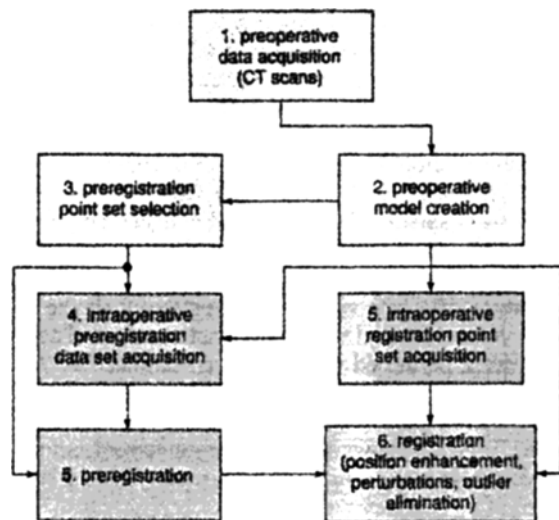


Fig. 1 Registration protocol. Arrows reproduce data flow while step sequence is indicated by progressive numbers (notice synchronicity of the two phases marked 5). Light grey boxes denote preoperative phases, whereas dark grey boxes denote intraoperative phases

Four points were selected on the model and stored for use in preregistration. 'Intraoperative' data collection involved acquisition of the second preregistration point set and of a further 144 points with the FARO Arm, which has an intrinsic accuracy of 0.30 mm (95.5% confidence interval). The data collection avoided the posterior compartment of the bone, which is not accessible during surgery, and attempted to track all the distinctive geometric features of the femur—condylar margins, the intercondylar notch, areas of peculiar curvature, etc.—while limiting the number of points in the set.

To obtain a good estimate of the 'true' registration to use as reference, five tantalum spherical markers (\varnothing 0.8 mm) of the kind used for Roentgen stereogrammetric analysis (RSA) were implanted just under the bone surface before CT scanning. Such markers are accurately identifiable on the CT images and can also be located and pointed with the digitiser during the intraoperative data acquisition phase. Their application in evaluating standard registration procedures was described in a recent paper (ELLIS *et al.*, 1996).

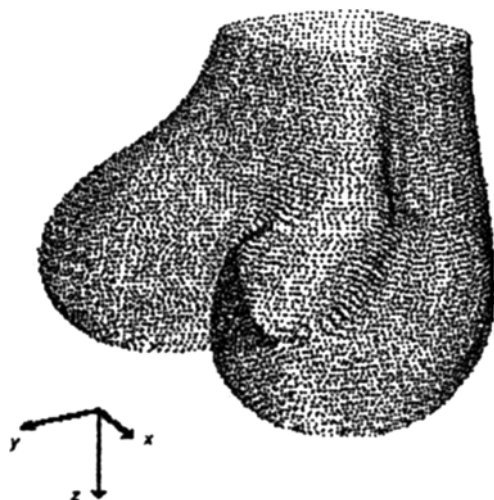


Fig. 2 Preoperative model of the distal compartment of the plastic femur used in the experiment. The model embedded coordinate frame is also shown

Preregistration placed the data within approximately 4° and 2 mm of the model. Following preregistration, the optimal affine transformation between data and model was assessed by the position refinement routine with an error of $1^\circ 21'$ and 1.72 mm, which dropped to $1^\circ 14'$ and 1.66 mm after outlier elimination. The whole registration procedure was performed on an Indigo2 workstation in about 4 min.

A more exhaustive analysis of the error components was also performed. The affine transformation obtained using the registration process was compared with the 'true' one as assessed using the artificial markers, by calculating the 'error transformation' subsisting between the two transformations and expressing it through the associated helical, v_{err} , and translation T_{err} , vectors. The error transformation is, in fact, the rigid transformation which matches the registered data set, as estimated by the registration routine, with its counterpart after the 'true' registration. Representing the rotational component of such transformation through the associated helical vector (WOLTRING, 1994) gives an immediate feel for the distribution of the orientation error in the model embedded reference frame. In our application, this frame is directly inherited from the CT frame and in the present experiment its three axes were approximately aligned with the mediolateral (x -axis), anteroposterior (y -axis) and proximodistal (z -axis) anatomical directions (Fig. 2).

Table 1 displays the components of the error vectors (v_{err} , and T_{err}) in the model embedded frame before and after outlier elimination. A quick look at Table 1 reveals that the largest component of the orientation error is distributed along the x -axis, whereas the largest position error occurs along the y -axis. This might not be an accident, since the lack of data in the posterior compartment and the concurrent presence of such a compartment in the model could account for a certain 'freedom of movement' in the matching procedure.

To confirm the above-outlined results, a multiple validation test was performed using the same model and data. The data, previously registered according to the 'true' transformation, were now perturbed by applying rototranslations of random directions and increasing magnitudes ($5^\circ/5$ mm, $10^\circ/10$ mm, $15^\circ/15$ mm). 20 perturbations were applied for each magnitude and, following all of them, the data set was re-registered and the registration errors were determined. The results of this validation test agreed well with those of the previous trial, as shown in Table 2.

A deeper inspection of the error components did not reveal any significant differences from the values displayed in Table 1. The latter results were regarded as a positive indication of protocol stability.

The plastic tibia was used to investigate the algorithm sensitivity to the size of the intraoperative data set, the geometric conformity between model and data and the relative position of those two data sets after preregistration.

A 'preoperative' model of 11809 points was determined from 78 CT slices (512×512 pixel slices, field of view, 100 mm, thickness and spacing, 1 mm) of the proximal compartment of the bone. The coordinates of the centroids of five

Table 1 Error vector components before and after outlier elimination

		before outlier elimination	after outlier elimination
v_{err}	θ_x	$1^\circ 17'$	$1^\circ 07'$
	θ_y	$0^\circ 07'$	$0^\circ 12'$
	θ_z	$0^\circ 22'$	$0^\circ 27'$
T_{err}	T_x	0.18 mm	0.26 mm
	T_y	1.43 mm	1.42 mm
	T_z	0.94 mm	0.79 mm

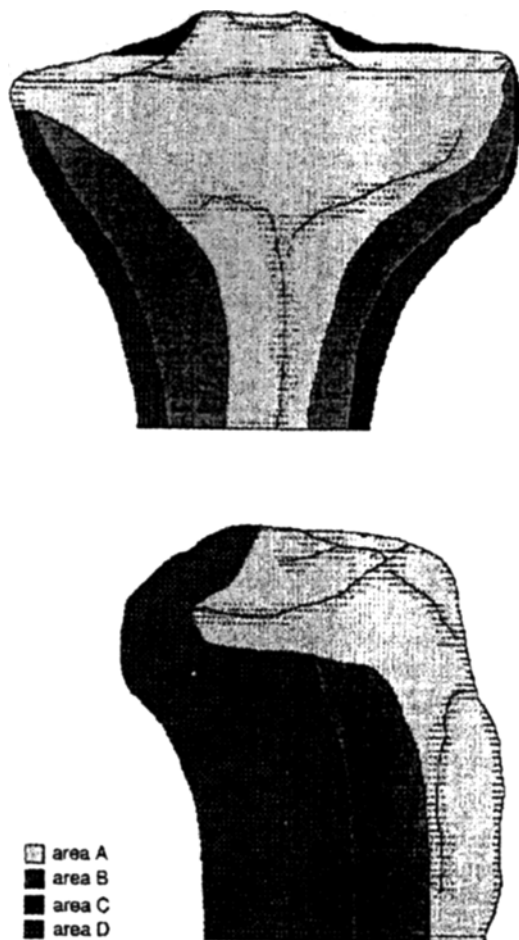


Fig. 3 Front and lateral views of the plastic tibia, showing the four regions considered in the experiment

tantalum pellets (\varnothing 0.8 mm) used as references were also calculated in the CT frame.

The 'intraoperative' data points were collected during two separate experimental sessions. The data collection distinguished four regions of the bone characterised by a different degree of accessibility during surgery (Fig. 3). Area A includes \sim 39% of the whole model surface and is the most easily accessible, areas B and C each include about 12% of the surface and area D includes the remaining 37%, which is normally inaccessible during intervention.

In the first experimental session 386 points were collected from area A (set A1), 115 points from area B (set B1) and 127 points from area C (set C1). No data were acquired from area D, to comply with the actual intraoperative constraints. The main goal of this session was to assess the sensitivity of the procedure outcome to the size of the data set and its geometric conformity with the model. 'Intraoperative' data sets of 50, 100 and 200 points were created, spanning different regions of

the bone. Regions A (39% of the surface), A + B (51% of the surface) and A + B + C (63% of the surface) were considered. Whereas in the first case (region A) all points were selected from set A1, in the second case (region A + B) 75% of the points were picked from set A1 and 25% from set B1 and in the third case (region A + B + C) 60% of the points came from set A1, 25% from set B1 and 15% from set C1. All the selections from sets A1, B1 and C1 were executed randomly.

10 different sets were created for each combination of set size and geometrical distribution. This yielded 90 simulated intraoperative data sets which were registered to the model according to the fiducial assessed transformation. The registered sets were perturbed with a rototranslation of $10^\circ/10$ mm in order to imitate a possible configuration after an average preregistration and re-registered with our surface based approach. Table 3 shows the registration errors before and after outlier elimination expressed as mean value \pm standard deviation.

It is evident that the registration performance improves as either the size of the data set or its geometric conformity with the model are increased. A further improvement is added by the outlier elimination phase.

In the second experimental session we focused principally on algorithm sensitivity to the geometrical distribution of the data set and its position relative to the model after preregistration. Taking into account the results of the previous session, we acquired 361 points from area A (set A2), 111 from area B (set B2) and 202 from area C (set C2), assembled three data sets of 200 points—one for each of the regions A, A + B and A + B + C—following the same method as in the preceding experiment and registered them to the model according to the marker assessed transformation. The registered sets were then perturbed with rototranslations of $5^\circ/5$ mm, $10^\circ/10$ mm and $15^\circ/15$ mm and re-registered with our routine. The results of this test, involving ten random perturbations for each magnitude, are shown in Table 4.

The results in Tables 3 and 4 suggest that the registration outcome is sensitive to all the investigated parameters, although to different extents. The geometric distribution of the data, for example, seems to be a more crucial element than the relative misalignment of data and model after preregistration provided that the latter is maintained within reasonable limits. Data sets of 100–200 points (1–2% of the model set size) extending over 50–60% of the model surface should ensure a satisfactory outcome if preregistration errors are kept below $15^\circ/15$ mm.

4.2 Validation on animal specimens in close-to-reality conditions

The experiments were carried out on porcine knees. The first specimen was a complete knee. The preoperative model was derived from 143 CT scans (512×512 pixel slices, field of view, 140 mm, slice thickness and interslice spacing, 1 mm) of the distal femur and proximal tibia. The entire model

Table 2 Femur multiple test: registration errors before and after outlier elimination. Errors are reported as mean value \pm standard deviation

Perturbation magnitude	Error	before outlier elimination	after outlier elimination
5°/5 mm	orientation	$1^\circ 21' \pm 0^\circ 00'$	$1^\circ 14' \pm 0^\circ 00'$
	position	1.72 ± 0.00 mm	1.66 ± 0.00 mm
10°/10 mm	orientation	$1^\circ 19' \pm 0^\circ 04'$	$1^\circ 13' \pm 0^\circ 02'$
	position	1.71 ± 0.03 mm	1.66 ± 0.02 mm
15°/15 mm	orientation	$1^\circ 20' \pm 0^\circ 04'$	$1^\circ 14' \pm 0^\circ 02'$
	position	1.71 ± 0.03 mm	1.66 ± 0.02 mm

Table 3 Tibia test 1: registration errors before and after outlier elimination (b.o.e. and a.o.e., respectively). Errors are reported as mean value \pm standard deviation

Region	Error	50 points		100 points		200 points	
		b.o.e.	a.o.e.	b.o.e.	a.o.e.	b.o.e.	a.o.e.
A	orientation position	$7^{\circ}49' \pm 9^{\circ}37'$	$6^{\circ}23' \pm 10^{\circ}31'$	$3^{\circ}50' \pm 3^{\circ}38'$	$3^{\circ}39' \pm 3^{\circ}38'$	$1^{\circ}25' \pm 0^{\circ}36'$	$1^{\circ}13' \pm 0.35'$
		8.98 ± 8.88 mm	7.31 ± 11.0 mm	3.50 ± 2.85 mm	3.12 ± 2.66 mm	1.38 ± 0.53 mm	1.12 ± 0.40 mm
A + B	orientation position	$3^{\circ}59' \pm 1^{\circ}37'$	$3^{\circ}14' \pm 1^{\circ}41'$	$2^{\circ}34' \pm 1^{\circ}29'$	$2^{\circ}08' \pm 1^{\circ}19'$	$1^{\circ}26' \pm 0^{\circ}41'$	$1^{\circ}10' \pm 0^{\circ}34'$
		3.38 ± 1.64 mm	2.55 ± 1.58 mm	2.20 ± 0.85 mm	1.70 ± 0.89 mm	1.27 ± 0.47 mm	0.94 ± 0.42 mm
A + B + /C	orientation position	$2^{\circ}31' \pm 1^{\circ}38'$	$2^{\circ}14' \pm 1^{\circ}02'$	$2^{\circ}03' \pm 0^{\circ}53'$	$1^{\circ}46' \pm 0^{\circ}50'$	$1^{\circ}16' \pm 0^{\circ}40'$	$1^{\circ}01' \pm 0^{\circ}33'$
		2.27 ± 1.40 mm	1.63 ± 0.98 mm	1.60 ± 1.00 mm	1.20 ± 0.56 mm	1.23 ± 0.51 mm	0.97 ± 0.38 mm

Table 4 Tibia test 2: registration errors. Errors are reported as mean value \pm standard deviation

Region	Error	5°/5 mm perturbation	10°/10 mm perturbation	15°/15 mm perturbation
A	orientation	0°56' \pm 0°00'	0°59' \pm 0°05'	1°08' \pm 0°15'
	position	0.85 \pm 0.00 mm	0.84 \pm 0.01 mm	0.94 \pm 0.16 mm
A + B	orientation	0°56' \pm 0°00'	0°57' \pm 0°03'	0°59' \pm 0°05'
	position	0.85 \pm 0.00 mm	0.85 \pm 0.01 mm	0.84 \pm 0.01 mm
A + B + C	orientation	0°56' \pm 0°00'	0°58' \pm 0°04'	0°59' \pm 0°05'
	position	0.85 \pm 0.00 mm	0.85 \pm 0.01 mm	0.84 \pm 0.01 mm

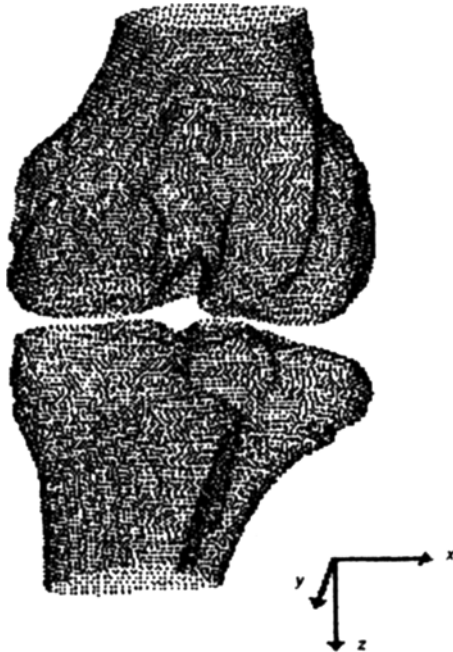


Fig. 4 Preoperative model of the porcine knee used in the experiment (posterior view). The model embedded coordinate frame is also shown

consisted of 21484 points (Fig. 4), 12572 of which belonged to the femur and 8912 to the tibia.

Prior to CT scanning eight titanium pins (size and structural details are displayed in Fig. 5) were implanted, four into each bone, to provide the necessary reference for determining the 'true' registration. The coordinates of the pin head centroids were both calculated from CT data and measured with the precision mechanical digitiser equipped with a special spherical tipped probe. The data collected were then used in conformance with the marker coordinates in the previous experiment.

As in the first experiment four points for each bone were selected for preregistration and their intraoperative equivalents were collected using the mechanical digitiser. A further 334 points, 223 on the femur and 111 on the tibia, were acquired over areas which are entirely accessible during surgery (Fig. 6).

Two different preregistrations were performed, which resulted in a misalignment of the data with respect to the models of around 15° and 4 mm for the femur and 10° and 4 mm for the tibia. The errors were well above those of the previous test, but still within the limits stated in the protocol requirements paragraph. Starting from these positions the iterative part of the algorithm assessed the optimal matching transformations between the data sets. The execution of the whole routine, including the outlier elimination task, took about 4 min for the femur and 2 min for the tibia.

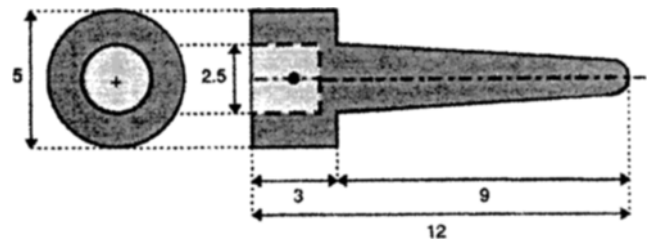


Fig. 5 Design characteristics of the implantable titanium pins used as fiducials during the experiment. All lengths in mm. Pin head centroid position is also displayed

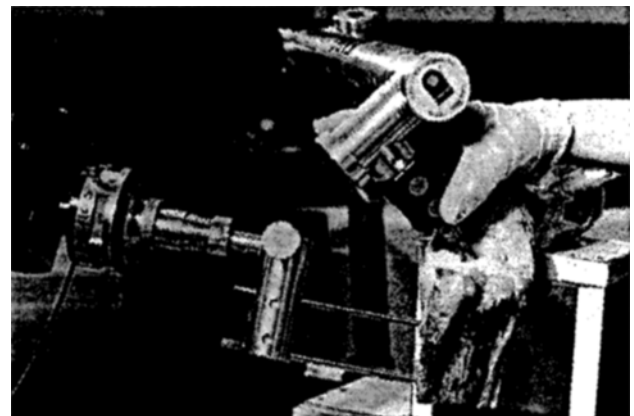


Fig. 6 'Intraoperative' data collection with the precision mechanical digitiser during the experiment on a porcine knee

The final registration errors were 2°51' and 1.43 mm for the femur and 6°12' and 5.62 mm for the tibia. An error distribution analysis is possible, starting from the data reported in Table 5, which displays θ_{err} and T_{err} components in the model frame. Axis orientation is comparable to that of the previous experiment and is shown in Fig. 4.

For the tibia, the results and a visual inspection of the registered data and model revealed that the data set was both quantitatively and qualitatively inadequate. Conversely, femur data appeared skilfully collected. Nevertheless the orientation error, which exceeded the expected magnitude, was once again mostly distributed about the mediolateral (x) axis. This reinforced the feeling that the lack of data in the posterior compartment along with the presence of such a compartment in the model could account for considerable rotational inaccuracy about the mediolateral axis.

We therefore modified the femur model by removing the inaccessible region. The new reduced model consisted of 9028 points (Fig. 7). Preregistration and position enhancement were performed again using exactly the same data set as in the previous trial (223 points). Owing to the smaller number of points included in the model, time consumption decreased to about 3 min. The final registration accuracy in this case was impressive, the alignment error being only 0°23' and 0.64 mm.

Table 5 Error vector components for porcine femur and tibia

		femur	tibia
v_{err}	θ_x	2°40'	2°42'
	θ_y	0°15'	5°34'
	θ_z	1°01'	0°21'
T_{err}	T_x	0.54 mm	3.19 mm
	T_y	0.89 mm	4.58 mm
	T_z	0.99 mm	0.65 mm

The second trial was carried out on a porcine femur. The preoperative model derived from 38 CT scans (512 × 512 pixel slices, field of view, 120 mm, thickness and spacing, 1 mm) of the distal part of the bone and included 8489 points. The model point set was intentionally set to be smaller than in the previous trial so as to exclude the proximal areas which are not intraoperatively accessible. The experimental arrangement was identical to the one described above. Four points were selected on the model for preregistration and collected during the trial with the digitiser. A further 224 points were acquired on the femur surface.

The preregistration brought the data set within a distance of ~10° and 12 mm from the model and the registration was completed in <3 min with a final error of 1°20' and 1.33 mm.

5 Discussion

General requirements for a non-fiducial registration routine adoptable in CAS concern global accuracy, time consumption and data acquisition issues. A suitable routine must provide a satisfactory accuracy standard so as to guarantee that the CAS application will be more reliable than its more traditional counterpart. Furthermore, as the routine is executed during surgery, it has to be adequately fast. This necessity becomes stricter when registration needs to be performed more than once. Finally, data acquisition during surgery must comply with safety, ergonomics and efficiency constraints and must not add further invasiveness to the intervention.

The above listed requirements apply to virtually all CAS systems but are not detailed enough to provide an operative guideline for design and validation strategies. Quantitative assessments of protocol requirements are only possible in association with a specific CAS application. Focusing our attention on TKA, we observed that the involved bones, femur and tibia, are not free to move during the intervention. Thus registration can take place only once and this loosens the constraint on time consumption. In this perspective, we estimate 4 min a reasonable time limit for task completion. Accuracy constraints are more demanding. Following the above-listed considerations on post-surgical functionality and long-term implant stability, our goal is to ensure a misalignment between the planned and actual implant below 1° and 1 mm. In addition, all targets must be accomplished taking into account the environmental factors existing in a busy surgical room.

The experiments on plastic phantoms were expected to prove the suitability of our registration routine to the CRA-TKA protocol, its dependence upon the geometric attributes and relative initial pose of the input data sets.

Preregistration yielded an outcome which turned out to exceed our expectations. This considerable performance must be mainly attributed to the virtually ideal conditions in which the experiment took place and so cannot be assumed as a standard. The plastic bone surface was clean and smooth, all the anatomical landmarks were clearly visible and accessing

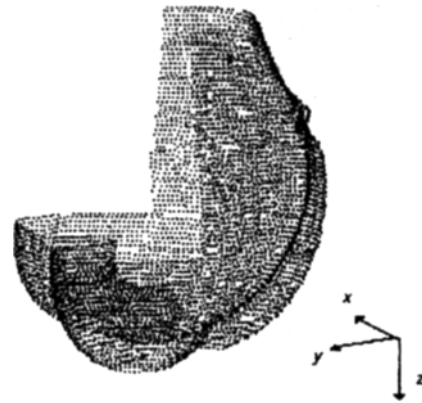


Fig. 7 'Reduced' preoperative model of the porcine femur employed in the experiment. As compared with the model shown in Fig. 4, the posterior compartment is almost entirely missing. The model embedded coordinate frame is also shown

the bony structures with the pointer tip was particularly easy. A further remark concerns the outlier elimination step which only added a slight improvement to the overall estimation accuracy in this first experiment. Our opinion is that this could also be due to the excellent experimental conditions already mentioned. Testing the protocol in more realistic conditions appeared advisable to obtain further indications about the usefulness of this phase. The final registration errors, which were judged fair but not outstanding, called for a deeper analysis. The error component analysis (Table 1) actually provided an additional reason for performing a new test that better approximated the actual operative setting. The uneven error distribution along the axes of the model reference frame seemed to ascribe part of the final inaccuracy to insufficient geometric data conditioning and inadequate mutual conformity between data and model. If the data set does not include an adequate number of points, or if they are not geometrically representative of the object under analysis, the cost function minimised by the registration algorithm is likely to feature a large number of local minima (CUCHET *et al.*, 1995). Moreover, the cost function might exhibit negligible gradients in the vicinity of the global minimum if perturbed along particular directions. This would also affect the estimation accuracy (SIMON *et al.*, 1994).

The sources of error in the whole registration protocol can be schematically classified as follows:

1. Inaccuracy in the assessment of the reference transformation (fiducial-based registration).
2. Inaccuracy in the determination of the preoperative model.
3. Inaccuracy and errors in intraoperative data collection.
4. Data driven algorithmic inaccuracy.

As far as the reference transformation is concerned, an error analysis is advisable, to assess a lower boundary for result significance. The symmetric structure of the markers used as fiducials and their physical properties allow for the determination of their positions in the CT frame with sub-pixel accuracy (0.1–0.2 mm). In our case the predominant inaccuracy is to be attributed to the digitiser (0.3 mm). The uncertainty with which the transformation can be known is nevertheless reduced by exploiting the information redundancy derived from the use of four or five markers. As a result, the reference transformation, assumed as the ground truth, can be calculated with an error within 0.5° and 0.25 mm. These figures set a definite limit in the evaluation of the experimental results.

Model construction and intraoperative data acquisition are affected by the same sources of error, but the effects are more visible here than in the above described case. Because of their physical and geometric characteristics, bone contours cannot

be detected with sub-pixel accuracy and the intrinsic inaccuracy of the digitiser is increased by the presence of cartilage and soft tissues on the cortical surfaces of the bones. In addition, errors during intraoperative data acquisition can occur and not all the data points collected from the bony surface can be automatically identified as outliers.

Finally, even in the ideal case of precisely extracted bone contours, very accurately collected intraoperative data and optimal preregistration ensuring a factual minimisation of the algorithm's cost function, the algorithm might introduce an extra error due to the inexact coincidence between the global minimum of the cost function and the true registration (CUCHET *et al.*, 1995). This is a factor on which error reduction techniques based on data conditioning can work successfully. The concurrence of all the enlisted error components, however, makes the attainment of a global inaccuracy below 1° and 1 mm an ambitious goal.

The way in which position errors are reported might also deserve a brief digression. Unlike orientation (rotation) errors, position (translation) errors are 'reference dependent.' While the relative orientation between two rigid bodies can be calculated from the coordinates of at least three couples of corresponding non-collinear points and expressed numerically without ambiguity if the reference frames are non-ambiguously defined, the expression of their relative positions needs specification of a further reference point (SIMON *et al.*, 1995b). If no specifications are provided, it is generally assumed that the relative position refers to the origin of the two embedded reference frames. In our case such an assumption might be misleading since frame origins are normally located apart from the items under analysis and the distance between them might give no immediate idea of the 'common sense' distance between the objects. Our position errors are therefore always expressed with respect to the centroid of the fiducial markers used for 'true' registration assessment. These markers, and thus their centroids, are always positioned inside the area involved in the operation and reasonably close—within a few cm—to the intrarticular region.

All the tests performed on the plastic femur except the repeatability trial, which had given fully satisfactory results (Table 2), were repeated on the porcine specimens. These tests also helped to better simulate the actual intraoperative conditions. The results shown in Table 5 emphasised the need for an accurate selection of the data sets and a good correspondence between data and model. Tibia data sets were flawed from both points of view. The 'intraoperative' data set only included condylar margins, tuberosity and part of the plateau. As the specimen was no longer available for further acquisitions once data had been processed, both tibia sets were discarded. Conversely, the femur data set spanned a congruous region of the distal bone compartment, so that an adaptation of the model (Fig. 7) was sufficient to visibly improve the final accuracy. The accuracy was in this case remarkable and any deeper investigation over error distribution appeared scarcely meaningful, since the precision with which the 'true' registration was known and the errors were of the same order of magnitude.

A quantitative comparison with the accuracy standard of other analogous registration procedures is not an easy task, since data provided in the literature mostly refer either to fiducial based techniques (KIENZLE *et al.*, 1995b; LEA *et al.*, 1995; WATANABE, 1995) or to quite different applications (Cuchet *et al.*, 1995; Ryan *et al.*, 1995). CUCHET *et al.*, in particular, designed an ICP based protocol for neurosurgery achieving a final registration error of 0°37' and 0.22 mm. These results were obtained using a model of the head of a patient, originating from NMR scans, and an intraoperative data set including 10³ points. A more similar application is the

one presented by SIMON *et al.* (1995b), which is aimed at a computer assisted total hip replacement protocol. Their fast ICP based routine was tested on a cadaveric bone resulting in a final registration inaccuracy of 0°58' and 0.31 mm.

Computing times proved adequate to the operative specifications, which currently permit real-time tracking of the patient's anatomy. Although registration took no more than 4 min, a faster version of the procedure capable of running in 1 min is currently being tested.

6 Conclusions

The registration of multimodal 3D data proved to be a point of crucial concern for several CAS implementations. Although fiducial based registration techniques are readily available and still provide higher accuracy and reliability levels than non-fiducial methods, the latter are widely regarded as a necessary step towards a minimisation of surgical invasiveness.

Ample variability in the accuracy standards required for distinct applications, significant sensitivity of the non-fiducial registration algorithms to input data and diversity in material and environmental constraints hinder a definite and universal judgement on the suitability of non-invasive registration protocols in CAS. That is why we presented our ICP based registration procedure in the frame of a specific CAS application (TKA).

The experimental results seem to show that our approach is well-suited for the relevant application both from a technical (accuracy around 1°/1 mm, computing times below 4 min) and from an operational (intraoperative environmental constraints) point of view. A comparison with other experiences reported in the literature indicates that its suitability can even extend to other computer assisted surgical procedures. Indeed, any application permitting the gathering of geometrically well-conditioned input data might be an appropriate groundwork for an ICP based registration approach.

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