THE INTERNATIONAL JOURNAL OF MEDICAL ROBOTICS AND COMPUTER ASSISTED SURGERY
Int J Med Robotics Comput Assist Surg 2009; **5**: 77–84.
Published online 26 January 2009 in Wiley InterScience (www.interscience.wiley.com). **DOI:** 10.1002/rcs.237

ORIGINAL ARTICLE

Accuracy in planar cutting of bones: an ISO-based evaluation

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Accepted: 12 December 2008

Abstract

Background Computer- and robot-assisted technologies are capable of improving the accuracy of planar cutting in orthopaedic surgery. This study is a first step toward formulating and validating a new evaluation methodology for planar bone cutting, based on the standards from the International Organization for Standardization.

Methods Our experimental test bed consisted of a purely geometrical model of the cutting process around a simulated bone. Cuts were performed at three levels of surgical assistance: unassisted, computer-assisted and robot-assisted. We measured three parameters of the standard ISO1101 : 2004: flatness, parallelism and location of the cut plane.

Results The location was the most relevant parameter for assessing cutting errors. The three levels of assistance were easily distinguished using the location parameter.

Conclusions Our ISO methodology employs the location to obtain all information about translational and rotational cutting errors. Location may be used on any osseous structure to compare the performance of existing assistance technologies. Copyright © 2009 John Wiley & Sons, Ltd.

Keywords bone cutting; accuracy evaluation; engineering methodology; surgical navigation; robotics

Introduction

The complexity and frequency of surgical interventions involving the planar cutting of bones has spawned two research areas. First, since the 1990s, there has been extensive development of computer- and robot-assisted systems to improve clinical and functional outcomes through increased accuracy and reproducibility (1,2). Several surgical navigation systems and active or passive robots are undergoing clinical trials or are already in use for procedures such as knee arthroplasty (2–5), high tibial open wedge osteotomy (6–8), periacetabular osteotomy (9,10), tumour resection and reconstruction (11,12), craniotomy (13) and maxillofacial osteotomy (14). The second major research goal is the development of new cutting tools, such as saws and mills (15,16), laser-cutting (17), water-jet (18) and ultrasonic (19) devices.

The parameters for evaluating bone-cutting performance have typically been defined according to the surgical procedure: varus–valgus and flexion–extension angles alignment on the mechanical axis of the lower limb for high tibial osteotomy; safe margin for tumour resection, etc. These clinical and functional parameters are still largely in use (2,7,8,20–23).

In coping with complex combinations of emerging assistance technologies and cutting processes, the evaluation of planar cutting procedures was subject to two substantial evolutionary steps. The first step was the design of a purely geometrical methodology, independent of the surgical procedure or the cutting process. In the early 1990s, Toksvig-Larsen and Ryd (24) defined two geometrical parameters: flatness and roughness after cutting. More recently, Barrera *et al.* (25) proposed an evaluation of planar cuts in total knee replacement, based on two global indices that include translational and rotational errors of the cut plane with respect to a target plane. The second step originated with the Computer Assisted Orthopaedic Surgery Society (CAOS) in conjunction with the American Society for Testing of Materials (ASTM). The multidisciplinary aspect of computer- and robot-assisted systems led these groups to the logical conclusion that a more objective evaluation was necessary (26), and in 2004 they undertook the creation of an ASTM standard for assessing the accuracy of CAOS systems (27).

However, these attempts at formulating a more objective methodology for evaluating the accuracy of bone cutting do not take into account Standard 1101 : 2004 of the International Organization for Standardization (ISO1101 : 2004), commonly used in mechanical engineering. This standard, published in 1983 and revised in 2004, rigorously defines parameters such as form, location, and parallelism for specifying the geometrical tolerances of final products, regardless of the fabrication process (28).

Considering bone as a material with specific mechanical properties, we undertook this study as a first step toward formulating and validating an ISO-based evaluation of planar bone-cutting processes. We addressed the following questions: (a) which parameters of ISO1101 : 2004 would be relevant to the evaluation of bone cutting processes; and specifically (b) are the selected parameters able to distinguish between conventional, computer-assisted and robot-assisted procedures?

Materials and Methods

Experimental model of bone

To cover all surgical applications involving planar cutting, we employed an experimental bone model with a simple rectangular geometry (Figure 1). The simulated bones consisted of polyurethane foam blocks (size $40 \times 40 \times 85$ mm) with a dimensional tolerance of 0.1 mm and a density of 0.24 g/cm^3, simulating bone density according to the manufacturer (Sawbones, Vashon, WA, USA).

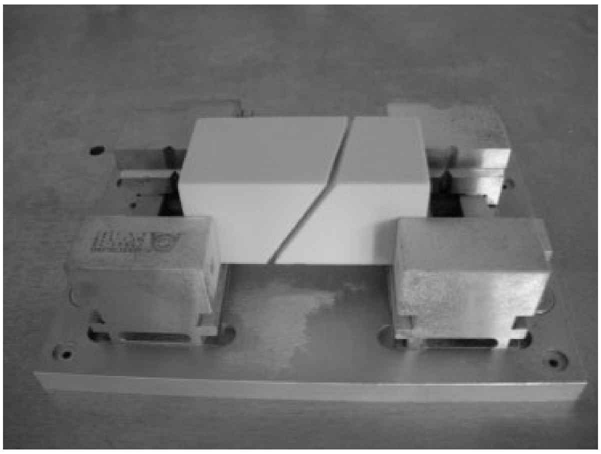

Figure 1. Example of a planar cutting performed with an oscillating saw. The simulated bone is a polyeruthane foam block simulating bone density

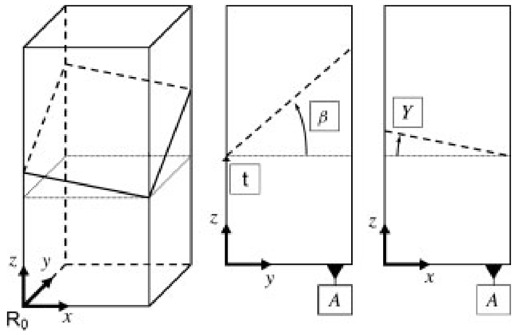

Figure 2. Definition of a plane by a minimal set of independent variables : a height t (mm), a depth angle β (°) and a front angle γ (°). The plane is defined in a reference frame, R_0. The x–y plane is considered reference plane A

Independent variables of target planes

The target planes are the expected planes after cutting. To define them, we geometrically constructed a reference frame (R_0) attached to the bone model (Figure 2). The bottom face, corresponding to the x–y plane of R_0, was denoted reference plane A. We then constructed target planes in R_0, starting from A, using a minimal set of independent variables (t, β, γ). The variable t represents the height of the target plane, as measured in mm along the z axis of R_0. The range of t, as defined on the bone model, is [0 mm; 85 mm]. The parameters β and γ represent the depth and front angles in degrees and were measured in the y–z and x–z planes of R_0. The range of β and γ, as defined on the bone model, is [−90°; 90°]. Finally, we constructed a reference target frame (R_N) fixed at the target plane.

Selected parameters for ISO-based evaluation

The ISO1101 : 2004 standard proposes three parameters for evaluating errors between the cut plane and the target

DOI: 10.1002/rcs

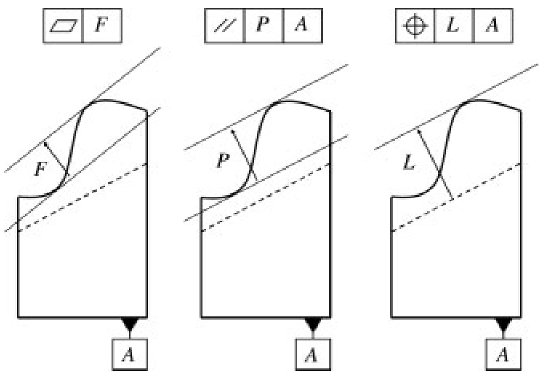

Figure 3. ISO-based parameters for the evaluation of a cut plane: flatness *F* (mm), parallelism *P* (mm) and location *L* (mm). The cut plane is the solid curve; the target plane is the dashed line. See text for details

plane (Figure 3). The flatness (F) evaluates the form of the cut plane and is defined as the minimum distance in mm between two parallel planes that include the cut plane. The parallelism (P) evaluates the orientation of the cut plane with respect to the target plane. P is defined as the minimum distance in mm between two planes parallel to the target plane that include the cut plane. Therefore, P and F are not independent. The location (L) evaluates the position of the cut plane with respect to the target plane. L is defined as the maximum distance in mm between the cut plane and the target plane. In opposition to P, L is independent of F.

Dataset for validating the ISO-based evaluation

Cuts were made in 156 bone models in order to acquire a sufficient dataset for statistical analysis of the parameters F, P and L. All cuts were performed using the same cutting tool, a conventional oscillating saw (Compact Air Drive II, Synthes, Solothurn, Switzerland) equipped with a 100×1.4 mm saw blade. We defined three target planes with the following set of independent variables (t, β, γ): plane 1 (25, 30, 10), plane 2 (30, 10, -20) and plane 3 (45, -20, 20).

We designed three experimental procedures with increasing levels of assistance in order to take into account all potential sources of error in (t, β, γ). We considered the visual and the mechanical assistances because they are largely used in orthopaedic surgery. In consequence, the first procedure (procedure 1) was unassisted. Six operators each cut 12 bone models (four times each of the three target planes) manually, without using conventional jigs. Only the entry point of the target planes was marked on the surface of the simulated bones. The second procedure (procedure 2) was computer-assisted. The same cuttings were performed by the six operators with a real-time visual feedback of the cutting tool, using an optical navigation system (Surgetics®, Praxim, Grenoble, France). The third procedure (procedure 3) was robot-assisted. Twelve cuts (four times each of the three target planes) were performed by an industrial robot (Viper® s650, Adept, Livermore, CA, USA) programmed to move along the target planes. As our goal is to validate a new ISO-based evaluation of planar bone cutting techniques, we focus on the methods of determining F, P and L according to t, β and γ, rather than providing details of the technical aspects of our experimental procedures.

Methodology of evaluation

To evaluate the accuracy of each cut, we designed a six-step process (Figure 4) in accordance with common guidelines for checking ISO-based specifications of final products. This process was implemented using numerical computation software (Matlab®, The MathWorks, Natick, MA, USA).

The first step consisted of digitizing the cut plane at a level of precision higher than the expected magnitude of the cutting errors. The cut planes were digitized with a precision of 1 µm using a coordinate measuring machine (Signum® SL, Mycrona, Elgin, IL, USA). The initial cut-plane dataset consisted of a matrix of 10×10 measurement points in the z direction of R_0 (Figure 4b).

The oscillating saw sometimes wrenched loose fragments of the bone model, especially near corners. Because this damage was due to the oscillatory motion of the saw, measurement points corresponding to the fragmented areas were considered outliers. Therefore, we examined the initial cut plane measurements and removed points located in the damaged areas.

The measurement coordinate set was fitted to a plane for computation of cutting errors. Several fitting planes were considered, such as the least square plane, tangential least square plane, least square plane shifted by half the form error, and the minimum–maximum plane (29). We selected the least square plane (LSP) method because of its common use in checking ISO-based specifications.

To compute errors in the independent variables (e_t, e_β, e_γ), we constructed a least square reference frame (R_{LSP}) attached to the LSP (Figure 4c). The error e_β was computed as the angular difference in the y–z plane of R_0 between the normals of the LSP and the target plane (Figure 4d). The error e_γ was computed as the angular difference measured in the x–z plane of R_0 between the normals of the LSP normal and the target plane. The error e_t was computed as the difference along the z axis of R_0 between the heights of the LSP and the target plane.

To determine F, we calculated the maximum differences (f_{max} and f_{min}) between the measured points and the LSP (Figure 4e). F was computed as the sum of the absolute values of f_{max} and f_{min}.

P and L were obtained by calculating the maximum and minimum differences in mm (d_{max} and d_{min}) between the measured points and the target plane (Figure 4f, g). P was defined as the difference between the absolute values of d_{max} and d_{min}, and L was equal to the absolute value of d_{max}.

DOI: 10.1002/rcs

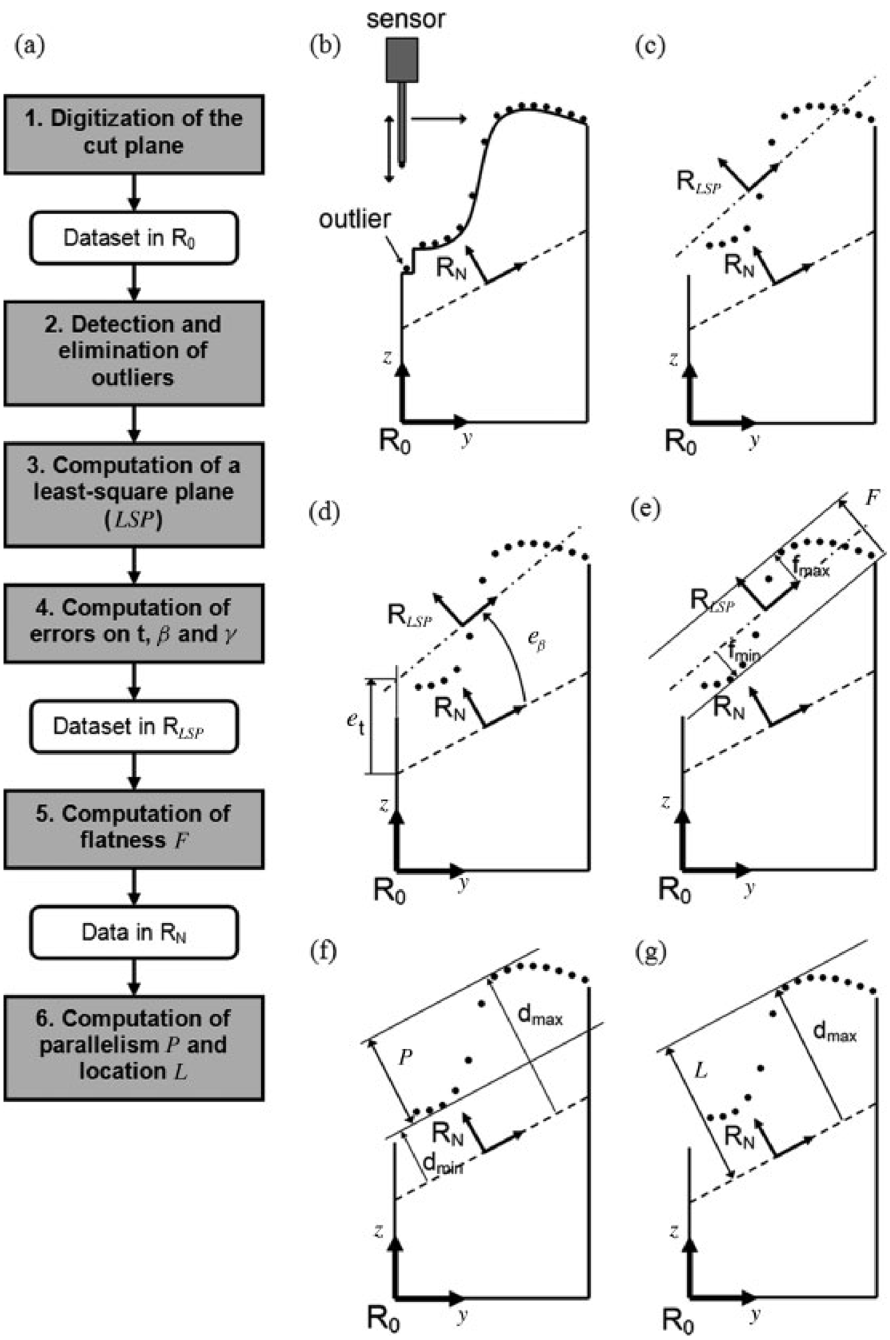

Figure 4. Methodology for an ISO-based evaluation of a planar cutting process. (a) Six-step process to compute errors in the independent variables (t, β, γ) and to compute flatness, parallelism and location. (b) Digitization in the reference frame (R_0) of the cut plane by using a sensor, and detection of outliers. (c) Computation of a least square plane (*LSP*) and a least square reference frame (R_{LSP}), without taking into account the outliers. (d) Computation of errors (e_t, e_β, e_γ) stated in the reference frame (R_0). (e) The flatness is equal to the difference between f_{max} and f_{min} stated in R_{LSP}. (f) The parallelism parameter is equal to the difference between d_{max} and d_{min} stated in the target frame (R_N). (g) The location parameter is equal to d_{max}. See text for details

Statistical analysis

Analyses were performed using the John's MacIntosh Product (JMP) version 7.0, Minitab version 15.1.1.0 and Statistical Package for the Social Sciences (SPSS) version 15.0 software packages.

To address the first research question, we calculated the Spearman correlations (ρ) between the errors e_t, e_β and e_γ and the three parameters F, P and L (30). We also computed partial correlations ($r_{ab,cde}$) in order to reveal potential hidden interactions (31). The Spearman and partial correlations were used to assess the utility of F, P and L in expressing errors in t, β and γ.

To address the second research question, we performed an analysis of variance (ANOVA) on repeated measurements, as described in Armstrong *et al*. (32). The three levels of assistance employed in cutting the 156 bone models (unassisted, visually assisted and mechanically assisted) were considered to be fixed effects. The p values obtained from Fischer statistical analysis were used to

DOI: 10.1002/rcs

assess the ability of F, P and L to distinguish between technically different cutting procedures.

Results

Of the three selected parameters, the location of the cut plane was the most relevant parameter for evaluating planar cutting of bones. Inaccuracies in the height, depth, and front angles of the target plane affected the location of the cut plane, while inaccuracy in the height of the target plane did not affect the parallelism (Table 1). Moreover, inaccuracy in the independent variables of the target plane did not affect the flatness of the cut plane.

When computing the partial correlations $r_{ab,cde}$, a dependence appeared between parallelism and flatness of the cut plane, while the location of the cut plane remained independent of the flatness (Table 1). The Spearman correlations ρ between the parallelism and errors in depth and front angle were so strong that they dominated the Spearman correlation between parallelism and flatness.

The location and parallelism parameters were both capable of distinguishing the cutting technology and the level of assistance. With partial assistance, the location and parallelism errors were significantly decreased (Figure 5). Further improvements in accuracy were obtained with fully-assisted cutting. The various cutting procedures were indistinguishable based on the flatness parameter. The three levels of assistance did not affect the magnitude of the flatness error, reflecting the fact that all cutting was performed using the same cutting tool.

The location of the cut plane contained all information necessary to determine the level of accuracy in both depth and front angles, despite the fact that the accuracy of the target plane height was not increased with the assisted procedures.

Discussion

Our goal was to define a new parameter for evaluating planar cutting of bones. We first determined which of the parameters defined by the ISO1101 : 2004 standard could be applied – flatness, parallelism or the location of the cut plane (Figure 3). The location was the most relevant parameter for assessing the inaccuracy of a planar cutting operation relative to a target plane. We then determined whether the investigated parameters (particularly location) were capable of distinguishing between cuts performed using different levels of technical assistance. We compared the results of an unassisted procedure with both visually-assisted and mechanically-assisted procedures, and found that the location of the cut plane was useful in distinguishing between the various levels of assistance.

Table 1. Spearman (ρ) and partial ($r_{ab,cde}$) correlations between ISO-based parameters (flatness, parallelism and location) and errors in each independent variable (t, β, γ)

	Flatness F (mm)		Parallelism P (mm)		Location L (mm)	
	ρ	$r_{ab,cde}$	ρ	$r_{ab,cde}$	ρ	$r_{ab,cde}$
Error in the height, e_t (mm)	0.00	−0.01	0.03	−0.01	0.30*	0.60*
Error in the depth angle, e_β (°)	0.06	0.02	0.90*	0.99*	0.88*	0.90*
Error in the front angle, e_γ (°)	−0.03	−0.06	0.72*	0.98*	0.49*	0.49*
Flatness F (mm)	–	–	0.08	0.54*	0.04	0.01

*Significance level at ($p < 0.0001$).

To determine the relative effectiveness of flatness, parallelism and location as standard parameters for evaluating planar cutting, we performed a statistical study using Spearman and partial correlations. We defined a target plane using a set of three independent variables. The Spearman and partial correlations were used to assess how the flatness, parallelism and location were affected by errors in the independent variables (30,31). The parallelism was affected by only two of the three independent variables, and none of the variables had an effect on flatness. On the other hand, the location was affected by all of the independent variables. Therefore, the location was chosen as the parameter most capable of expressing all of the information concerning errors in the independent variables.

To check whether location was capable of distinguishing between different levels of assistance, we performed a second statistical study. We were able to perform an analysis of variance (32) with repeated measures, since all cuts were performed under the same experimental conditions with respect to bone geometry, accessibility, cutting tool, target planes and the operators. The three levels of technical assistance were considered as fixed effects. We did not investigate potential learning curves for the operators because it was not part of this study. The location was significantly reduced when we provided the operators with visual or mechanical assistance, even if the accuracy of the target plane height was not significantly improved. Thus, location is roughly able to distinguish different assistance technologies for planar cutting with the same tool.

Our study is the first to consider the ISO1101 : 2004 standard, designed in 1983 for mechanical engineering, as a relevant tool for evaluating orthopaedic planar cutting procedures. The standard defines flatness as the minimum distance between two parallel planes that include the cut plane. Toksvig-Larsen and Ryd (24) defined flatness as the standard deviation (SD) of the measured points, a definition that does not comply with the standard. The same authors defined roughness as the distance between the uppermost and lowermost points of the cut surface, transforming a specification originally defined in ISO1101 : 2004 as a microscopic property into a macroscopic property. We did not investigate roughness simply because it was not part of this study: we were

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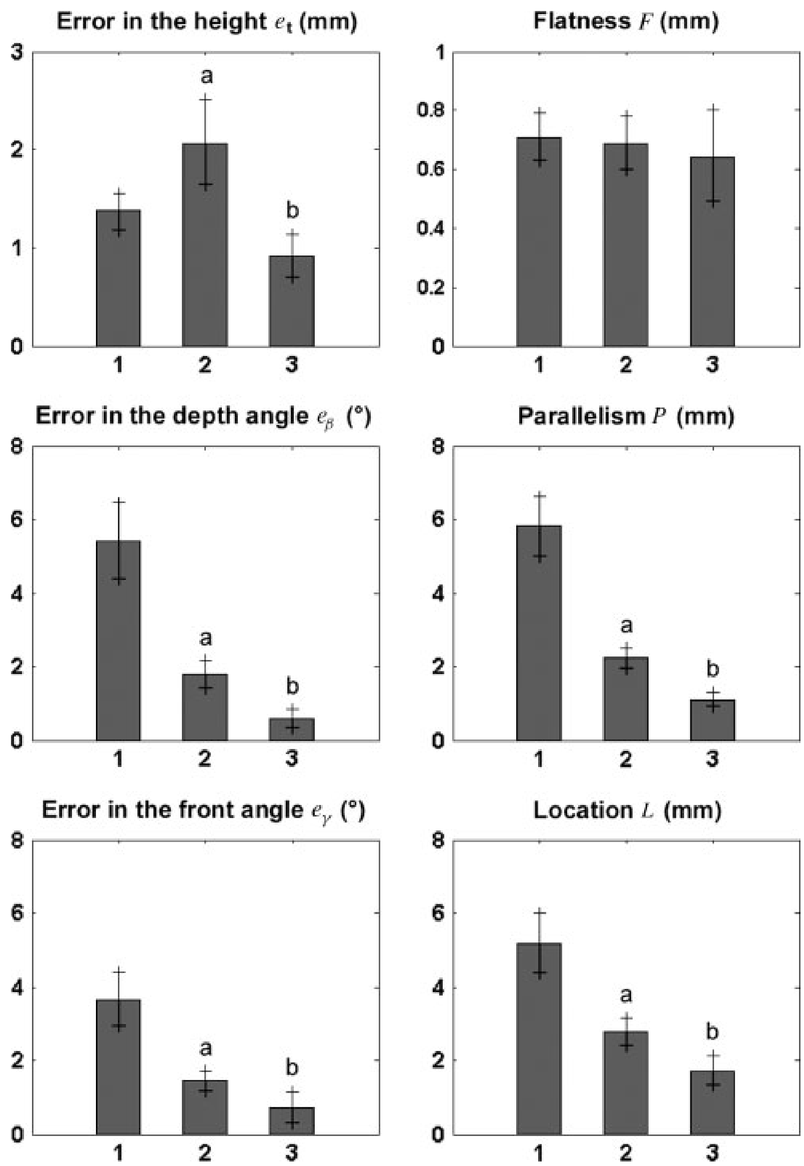

Figure 5. Comparison of flatness, parallelism, location and errors in the independent variables (t, β, γ) between the three cutting procedures : unassisted (procedure 1), computer-assisted (procedure 2) and robot-assisted (procedure 3). Bars represent mean values. Vertical line segments represent the lower and upper limits of the 95% confidence interval. a, Significance level at $p < 0.001$ between procedures 2 and 1; b, significance level at $p < 0.001$ between procedure 3 and procedures 1 and 2

concerned only with the macroscopic properties of the cut plane.

All cuts were accomplished with the same tool, an oscillating saw. Complementary tests could be performed with emerging cutting technologies (16–19), such as milling, laser cutting, water jet cutting or ultrasonic cutting. In this way, microscopic specifications such as roughness could be studied according to the ISO1101 : 2004 standard (28). If several cutting technologies were investigated, we could reasonably expect that the flatness of the cut plane would be subject to potentially significant variations.

Barrera *et al*. (25) also proposed a new methodology for evaluating the planar cutting of bones. They defined two global indices containing all information concerning translational and rotational errors between the cut and target planes. Their methodology is based on the specification of a three-dimensional (3D) distance and three angles for each cut plane, thus requiring the computation of six independent variables. Our methodology, following the general guidelines for an ISO-based evaluation, is based on the computation for each cut plane of only three independent variables (t, β, γ) and condensing all information about translational and rotational errors into a single parameter (location).

ASTM and CAOS are developing a new standard for evaluating the intrinsic performance of computer-assisted systems (27). They define two parameters, accuracy and precision, to enable comparison between two systems of surgical assistance. Our methodology is quite different in that we designed a purely geometrical model of the planar cutting process that complies with ISO1101 : 2004. Therefore, our evaluation of planar cutting has the advantage of being independent of the system used to perform the cutting. The geometrical model (t, β, γ) can be used during planar cutting, independently of the bone structure being machined, the surgical application, the cutting tool and the level of assistance integrated into the surgical procedure.

To compute errors in the independent variables defining a target plane, it is first necessary to acquire an initial dataset of points representing the cut plane (Figure 4). Several measuring systems could be used, including a coordinate measuring machine, an intraoperative navigation system or simply a caliper. We decided to use a coordinate measuring machine with micrometric precision to avoid measurement errors. Belvedere *et al.* (33) showed the feasibility to intraoperatively control the cut plane by a navigation system. However, we should keep in mind that the existing navigation technologies rarely have an accuracy of <0.3 mm, especially because of the localizer resolution.

To acquire the initial dataset, it is necessary to define a reference frame R_0 in which the coordinates will be stated, much the same as the reference coordinate system required when a patient undergoes a computerized tomography scan.

Several methods exist for defining a plane in the 3D frame R_0. A plane can be defined using a set of three points as the geometric element that contains these points. The plane is then defined by nine independent variables comprising the three coordinates of each point stated in R_0. A plane can also be defined in terms of a point and a line. In this case, the plane is the geometric element containing the point and perpendicular to the line. Six independent variables are required: the three coordinates of the point stated in R_0 and the three coordinates of the line stated in R_0. A plane can also be defined in terms of a point and two angles. Because we defined the point on one axis of R_0, the z axis, we were able to define a plane by only three independent variables: the coordinate of the point along the z axis (i.e. the height) and the angles formed by the plane between the x and y axes of R_0. This definition represents the minimum set of independent variables that define a plane, is easy to understand, and is currently used in total knee arthroplasty (34). For example, when cutting the tibial plateau, the anatomical axis of the tibia is considered the z axis of R_0. The first independent variable of our definition, the height t, represents the desired cutting height of the plateau. The other two independent variables, depth and front angles, β and γ, represent the angle in the sagittal plane (flexion–extension) and the angle in the coronal plane (varus–valgus). Our definition (t, β, γ) of a plane is then a generalization of this particular case, applicable to any osseous structure of the skeleton.

Conclusion

Our ISO-based methodology for evaluating the planar cutting of bones presents three main advantages. First, it permits the expression of all of the information concerning translational and rotational errors of the cut plane in one parameter (location). When surgeons require detailed analysis of the cutting procedure, our methodology also enables assessment of the error in each independent variable (t, β, γ) defining the target plane. Second, the location parameter may be used to evaluate planar cutting of any osseous structure of the skeleton. The only requirement is the definition of a reference frame in which the cut plane will be controlled. Third, location may also be used to compare the performance of existing assistance technologies, including surgical navigation and passive or active robots.

Acknowledgements

Funds were received from Fonds National de la Recherche Scientifique (FNRS Télévie, Belgium; Grant No. 7.4570.06) and from Fondation Belge Contre le Cancer (Grant No. SCIE 2006/20).

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