

Practical Guide to Plan and Evaluate Bone Cutting & Drilling in CAOS

Olivier Cartiaux¹, Bernard G Francq²

1: Computer Assisted and Robotic Surgery (CARS), Institut de recherche expérimentale et clinique, Université catholique de Louvain, Brussels, Belgium

2: Robertson Centre for Biostatistics, University of Glasgow, Glasgow, Scotland

olivier.cartiaux@uclouvain.be

Introduction

In orthopaedic surgery, there exist several assistance technologies such as imaging and navigation systems, positioning robots and additive-manufacturing patient-specific instrumentation (PSI). These generic technologies can be used for different applications, i.e. knee arthroplasty, spine instrumentation and bone tumor resection. Practically, these technologies enable surgeons to identify patient anatomy, define preoperative surgical planning and intraoperatively replicate this planning on the patient.

Since 2010, there exists a standard protocol from ASTM society to assess technical specifications of navigation systems and positioning robots in CAOS [1]. The standard presents both parameters to be used and tracking tests to be performed to define accuracy and precision (bias and variability) of navigation and robotic systems. The logical continuation of this first ASTM standard is to develop new standard protocols to evaluate quality of bone-preparation tasks, i.e. bone cutting, milling, drilling and assembly of bone fragments, performed with the aid of such CAOS systems.

This paper introduces a practical guide for orthopaedic surgeons to plan and evaluate bone-preparation tasks in CAOS. The practical guide consists in a systematic six-steps approach to plan and evaluate a bone-preparation task, independent from the CAOS systems being used to execute the task. The practical guide also provides guidelines to implement the systematic approach for specific task and surgical application, i.e. femoral and tibial cutting in knee arthroplasty, vertebral drilling in spine instrumentation, and bone cutting and assembly in tumor surgery.

Materials and methods

Systematic approach to plan and evaluate bone-preparation tasks in CAOS

The systematic approach is composed of six steps (Figure): (1) Planning frame is defined as a coordinate system presenting three orthogonal axes (x, y, z) according to patient anatomy; (2) Target specification of the task (cutting, milling, drilling or assembly) is defined in the planning frame as nominal (desired) geometry of the bone being prepared; (3) Accepted tolerances on nominal geometry are defined with relevant quality indicators accounting for desired functional outcomes and the level of accuracy provided by available CAOS systems; (4) Evaluation frame is defined as a new coordinate system with three orthogonal axes being registered to planning frame; (5) Errors on nominal geometry are computed and expressed in the registered planning frame; (6) Computed errors are investigated to determine whether the geometrical tolerances are respected.

Validation process

The implementation of the systematic approach for a specific task during a CAOS surgery may be validated in two phases.

SYSTEMATIC APPROACH

PLANNING OF THE DESIRED TASK	
1. PLANNING FRAME	<i>Define a coordinate system $R_0(x;y;z)$</i>
2. TARGET SPECIFICATION	<i>Define the nominal geometry d (mm) α (degrees)</i>
3. ACCEPTED TOLERANCES	<i>Define the geometric tolerances L, F, A, P (mm) Account for desired functional outcomes and level of accuracy of available CAOS technologies</i>
EVALUATION OF THE ACHIEVED TASK	
4. EVALUATION FRAME	<i>Define an evaluation coordinate system Register with the planning coordinate system</i>
5. MEASUREMENT OF ERRORS	<i>Compute the errors on nominal geometry e_d (mm) e_α (degrees) ...</i>
6. VERIFICATION OF TOLERANCES	<i>Determine whether the geometric tolerances L, F, A, P (mm) are respected</i>

Figure - Systematic six-steps approach to plan and evaluate bone-preparation tasks in CAOS

First, in-vitro experimentation on synthetic bone models with realistic simulations of the CAOS surgery will enable to validate the relevancy of the quality indicators used to define the geometric tolerances on bone cutting and drilling. This step will also enable to statistically investigate input factors with potential significant effect on outputs of the planning and evaluation process (i.e. geometric distortion during 3D reconstruction of medical images, manual identification of anatomical landmarks to define planning frame, semi-automatic registration between planning and evaluation frames, automatic identification of cut planes in postoperative images, ...).

Second, in-vivo studies with data provided by actual CAOS surgeries will enable to validate the reliability of the planning and evaluation process. This step will also enable to detect potential irrelevancies and inconsistencies in the planning and evaluation of the task (i.e. the postoperative CT images are unsuitable for the evaluation process because of the presence of a metallic implant).

Results

The systematic approach is currently undergoing the validation process for three specific tasks and surgical applications: bone cutting in knee arthroplasty, bone drilling in spine instrumentation (pedicle screw insertion), and bone cutting and assembly in pelvic tumor surgery.

Simulations currently performed on experimental models of the knee, spine and pelvis, are validating the relevancy of the planning and evaluation process of computer-assisted planar cutting and axial drilling of bones. We demonstrated that target specifications and geometrical tolerances can be defined by relevant quality indicators in accordance with ISO1101 standard [2], such as location (L) and flatness (F) parameters for planar cutting of bones, and angularity (A) and position (P) for axial drilling. As an example, detailed information on the use of location L to evaluate bone-cutting can be found in [3].

Clinical studies are currently validating the reliability of the planning and evaluation process of planar cutting and axial drilling of bones with data taken from actual CAOS surgeries. For bone tumor surgery, we showed that a millimetric accuracy can be evaluated by registering pre- and postoperative CT images and computing location L between planned and achieved cuts. For spine

surgery, we also showed that a millimetric accuracy of inserted pedicle screws (in terms of angularity A) can be measured using intra-operative fluoroscopic images and compared with the preoperative CT-based insertion planning.

Discussion

The work presented here in the form of a practical guide is a first step toward developing new standard protocols to evaluate quality of bone-preparation tasks that could be assisted with CAOS technologies. The philosophy of these new standard protocols is not only to perform a quantitative evaluation of the quality in CAOS, but also to improve the objectivity of the planning and evaluation process in CAOS.

Practically, for surgeons, such a practical guide can serve as a standard application-specific protocol to evaluate how accurately a preoperative planning can be intraoperatively replicated on the patient. For researchers, this can be a standard protocol to investigate performances of new CAOS technologies that are still in prototyping in laboratories. For industrials, this can be useful for the certification of new CAOS technologies that are ready for marketplace.

In 2014, joint application to ISO and CAOS societies will aim the setting-up of a new international technical committee composed of voluntary academicians and industrials, surgeons and engineers, to develop new application-specific ISO standards dedicated to the planning and quality evaluation in CAOS.

References

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3. Cartiaux O, Paul L, Francq BG, *et al.*, "Improved Accuracy with 3D Planning and Patient-Specific Instruments During Simulated Pelvic Bone Tumor Surgery," *Ann Biomed Eng* 2014 Jan;42(1):205-13.