ISO-CAOS: toward a new ISO-based quality concept for modeling and evaluating accuracy in computer assisted orthopaedic surgery

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Context: Since 1990s, the complexity and frequency of orthopaedic interventions involving bone cutting and assembly have led to extensive development of computer assistance technologies to improve clinical outcomes through increased accuracy and reproducibility. Navigation systems, robots and patient-specific instruments are undergoing clinical trials or are already in use for knee and hip arthroplasty, high tibial open-wedge osteotomy, periacetabular osteotomy, tumor resection, craniotomy, and maxillofacial osteotomy.

In 2004, the methodology for evaluating the quality in orthopaedic surgery was subject to a substantial evolutionary step with the International Society for Computer Assisted Orthopaedic Surgery (CAOS-International) in conjunction with the American Society for Testing and Materials (ASTM). These societies undertook the creation of the new ASTM F2554-10 standard for assessing and comparing the performances of CAOS systems. This standard was recently used for assessing the positioning accuracy of surgical assistance systems [1]. However, this attempt at formulating an objective methodology for evaluating the quality in orthopaedic surgery did not account for the standards from the International Organization for Standardization (ISO) that are commonly used in mechanical engineering since years, especially the ISO1101 standard that is applied since the 1980s for evaluating mechanical cutting and assembly processes. Considering bone as a specific mechanical material, the ISO1101 standard could be used to define the dimensional and geometrical specifications of the desired bone cutting and assemblies and evaluate the quality of the performed cutting and assemblies. This ISO-based methodological idea is already known among the scientific community. In 2009, Pearle et al. [2] and Rivkin et al. [3] have proposed the concept of orthopaedic quantitative and objective surgery, by emphasizing the needs for quantitative and objective data for evaluating the added value of assistance technologies. However, no research work undertook to implement this quantitative and objective surgery concept by specifically using the ISO1101 standard and guidelines.

In this context, we propose a new quality concept, called ISO-CAOS, which aims at formulating and validating the first ISO-based evaluation of the quality of bone cutting and assembly in CAOS surgery. The specific objectives we aim to achieve are (1) to develop new quantitative models of bone cutting and assembly that comply with the standard ISO1101, and (2) to implement new objective methods and techniques for measuring the quality in CAOS surgery that comply with the common ISO guidelines.

Methodological Approach: The ISO1101 methodological approach relies on three working hypotheses. First, it considers that manufacturing processes (in this case, bone cutting and osseous assembly) always involve manufacturing errors. The ISO1101-based quality models define referential frames, independent modeling variables, types of expected cutting errors and quantitative evaluation parameters, independent of the assistance technologies being used in the surgical procedure. Specifically, using ISO1101 guidelines help to define the desired dimensional and geometrical bone-cutting specifications (distances, angles,
shape, orientation, position…) as well as accepted fitting tolerances (clearance, tightening…) that are clinically relevant.

Secondly, the ISO methodological approach considers that measuring machines always involve measuring errors that are commonly called the “measuring uncertainty”. Special efforts are required to minimize this measuring uncertainty by designing and developing associated instrumentations with a measuring accuracy of an order of magnitude greater than the errors expected during the bone cutting and assembly processes.

Thirdly, ISO guidelines emphasize the need for an accurate and precise intraoperative measurement of the quantitative evaluation parameters (the pre-defined dimensional and geometrical specification parameters). The minimization of the uncertainty of the measurement procedure is complex because it accounts for instrumentation calibration process, construction of measuring referential frames, geometrical transformation between the measurement frames, registration process, error analysis…

**First Results:** We applied the ISO1101 approach for the resection of pelvic bone tumors combined with reconstruction by massive allografts. This surgery is challenging due to the complex 3D geometry, the limited visibility and the restricted working space of the pelvic bone. First experimentations investigated the surgical inaccuracy of pelvic bone tumor resection and reconstruction, and assessed the need to develop assistance technologies and formulate an objective methodology for evaluating the quality.

In accordance with the ISO1101 standard, we proposed a systematic approach to define and evaluate the quality of the bone-cutting process. We implemented a bone-cutting simulator using a simple osseous geometry and validated the ISO1101 parameter “location” as a new quality standard for bone-cutting in orthopaedic surgery.

Then we proposed a quantitative study to compare assistance technologies based on their bone-cutting performances. We investigated navigated and robot-assisted technologies by implementing them first on our simple bone-cutting simulator [4] and then on a more elaborated pelvic simulator [5]. In both cases, bone-cutting accuracy, as measured by the ISO1101 location parameter, is significantly improved when a navigation system or a robot is integrated with the freehand cutting procedure. The new navigation-based procedure was successfully applied for treating several patients with bone tumors. These were world firsts, where both the tumor resection and reconstruction have been navigated.

**Expected Contributions:** The previous results are dedicated to the pelvic bony structure and have to be generalized for any orthopaedic surgical application. When fully developed and validated, the scientific and technological contributions of the new ISO-CAOS quality concept can be listed as following; (1) The new ISO-based models and intraoperative measurement methods may contribute to improve the objective and quantitative assessment of the added value of CAOS technologies for bone cutting and assembly; (2) The new ISO-based tools for specifying and tolerancing bone cutting and assembly processes may contribute to the design and development of the next-generation CAOS technologies.

**References**