Editorial

Computer Aided Orthopaedic Surgery: Incremental shift or paradigm change?

Leo Joskowicz a,*, Eric J. Hazan b

a CASMIP Lab – Computer Aided Surgery and Medical Image Processing Laboratory, The Rachel and Selim Benin School of Computer Science and Engineering, The Hebrew University of Jerusalem, Givat Ram Campus, Jerusalem 91904, Israel
b Traumatology and Emergency Departments, Instituto Nacional de Rehabilitacion, Mexico City, Mexico

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A B S T R A C T

Computer Aided Orthopaedic Surgery (CAOS) is now about 25 years old. Unlike Neurosurgery, Computer Aided Surgery has not become the standard of care in Orthopaedic Surgery. In this paper, we provide the technical and clinical context raised by this observation in an attempt to elucidate the reasons for this state of affairs. We start with a brief outline of the history of CAOS, review the main CAOS technologies, and describe how they are evaluated. We then identify some of the current publications in the field and present the opposing views on their clinical impact and their acceptance by the orthopaedic community worldwide. We focus on total knee replacement surgery as a case study and present current clinical results and contrasting opinions on CAOS technologies. We then discuss the challenges and opportunities for research in medical image analysis in CAOS and in musculoskeletal radiology. We conclude with a suggestion that while CAOS acceptance may be more moderate than that of other fields in surgery, it still has a place in the arsenal of useful tools available to orthopaedic surgeons.

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1. Introduction

Computer-based technologies, including both software and hardware, are playing an increasingly larger and more important role in defining how surgery is performed today. Orthopaedic surgery was, together with neurosurgery, the first clinical specialty for which image guided navigation and robotic systems were developed. Computer Aided Orthopaedic Surgery (CAOS) is now about 25 years old. During this time, a wide variety of novel and ingenious systems have been proposed, prototyped and commercialized for most of the main orthopaedic surgery procedures, including knee and hip joint replacement, cruciate ligament surgery, spine surgery, corrective osteotomy, bone tumor surgery, and trauma surgery, among others.

While CAOS technologies are nowadays visible and known to many orthopaedic surgeons worldwide, their adoption has been relatively slow, especially when compared to other technologies such as robotic minimally invasive surgery (daVinci Surgical System, Intuitive Surgical). This raises a number of questions, e.g., what are the known clinical benefit of CAOS technologies? Why has CAOS been a progressive technology and not a disruptive one? Has CAOS lead to a paradigm change in some of the orthopaedic surgery procedures? What is the future of CAOS? What role has medical image analysis played in CAOS and what is its future?

In this paper we present a personal perspective on the key aspects of CAOS in an attempt to answer these questions. We start with a brief history of CAOS from its beginnings, emergence, expansion, and steady progress phases. We then outline the main CAOS technologies and describe how they are evaluated. Next, we summarize the current views on their clinical impact and their acceptance by the orthopaedic community worldwide. We focus on total knee replacement surgery as a case study and present the clinical results and contrasting opinions on CAOS technologies. We then discuss the challenges and opportunities for research in medical image analysis in CAOS and in musculoskeletal radiology and conclude with an observation: while CAOS acceptance may be more moderate than that of other fields in surgery, it still has a place in the arsenal of useful tools available to orthopaedic surgeons.

2. A brief history of CAOS

CAOS started over 25 years ago, with the introduction of four key technologies: 3D bone surface modeling from CT scans, surgical robotics, real-time surgical navigation, and later, patient-specific templates. The main CAOS concepts and technical elements emerged in the mid to late 1990s; the first clinical results started

* Corresponding author. Fax: +972-2-549-4544.
E-mail address: josko@cs.huji.ac.il (L. Joskowicz).

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to appear in the clinical literature in the late 1990s. The International Society for Computer Assisted Orthopaedic Surgery was established in 2000 and has held yearly meetings since. The early and mid 2000s witnessed a rise in the introduction of commercial systems and the publication of small and medium size clinical studies. The late 2000s to date featured a slow consolidation period, with larger and more specific comparative clinical studies, multi-centre studies, and meta-studies. It also featured mature image processing and surgical planning software, image-based navigation systems, robotics systems, and routine patient-specific guides design and related production services.

Bone modeling from CT scans stemmed from 3D segmentation and surface mesh construction methods such as the Marching Cubes algorithm introduced by Lorensen and Cline (1987) in the late 1980s. A variety of segmentation methods and mesh smoothing and simplification methods were developed in the early 1990s. These patient-specific anatomical models are essential for preoperative planning, intraoperative registration, visualization, navigation, and postoperative evaluation.

The first robotic system in orthopaedics was ROBODOC, a customized industrial active robot designed for total hip replacement (THR) to optimize the bone/implant interface by machining the implant cavity (Taylor et al., 1994). ROBODOC development started in the late 1980s at the IBM T.J. Watson Research Centre and at the University of California at Davis; it was first used for human surgery in 1992, and became a commercial product in 1995 (developed by Integrated Surgical Systems and owned since 2008 by Curexo Technology Corp.). The system includes a preoperative planning module that allows surgeons to select the size and position of the acetabular cup and femoral stem based on automatically built 3D surface models of the pelvis and hip joint bone from a preoperative CT scan. Based on this plan, it automatically generates a specific machining plan for the femoral stem cavity, which is then executed during surgery after pin-based contact registration between the patient and the plan. The system was later extended to total knee replacement (TKR) surgery to perform the femoral and tibial cuts; the first human surgery was performed in the year 2000. To date, over 28,000 ROBODOC surgeries have been performed worldwide. Other robotic systems, such as Acrobat for TKR and Ortho Marquet for THR were also developed in the late 1990s.

Computer aided navigation concepts for various orthopaedic procedures were developed in the early 1990s. The first CAOS navigation systems for pedicle screw insertion in spine surgery were presented in Lavallee et al. (1995) and Nolte et al. (1995). They were based, as many others that followed, on accurate off-the-shelf real-time optical tracking technology (Northern Digital Inc., NDI). Preoperative planning and intraoperative visualization is based on 3D surface models of the vertebrae obtained from a CT scan. These systems were shown to greatly improve the accuracy and safety of pedicle screw insertion, particularly in deformed vertebrae and spine scoliosis. Fluoroscopy-based and imageless navigation systems were later developed for total hip and total knee replacement, for bone fracture surgery (FRACAS, Joskowicz et al., 1999), and for anterior cruciate ligament (ACL) reconstruction. Commercial systems for these procedures were launched in the early 2000s by companies such as Medtronic, BrainLab, Stryker, Aesculap, and Praxim.

Individual templates, also called patient-specific jigs, were introduced in the late 1990s by Radermacher et al. (1998). The idea is to create a disposable custom-made cutting and/or drilling jig that is then stably and uniquely mounted on the patient bone anatomy to guide the surgeon’s surgical actions. The advantages of individual templates are that they uniquely fit the patient, that they do not require adjustment, and that they are closest to the conventional surgical approach. Initially, the custom jigs were manufactured by Computer Numerical Control (CNC) machining. The first human intervention was performed in 1993 for periacetabular repositioning osteotomy and in 1997 for TKR. Their clinical adoption was relatively slow until the late 2000s. With the popularization of 3D additive printing and related cloud-based design and manufacturing systems, their use has considerably expanded.

From 2000 to 2008, CAOS witnessed rapid technology transfer and the introduction of new commercial systems by both established and new companies. This trend included about a dozen navigation systems for hip, knee, and spine surgery, and the advent of several robotics systems such as patient-mounted miniature systems for pedicle screw insertion in spine surgery (Mazor Robotics) Shoham et al. (2007), and unicompartamental knee arthroplasty (UKA) (Mako Surgical Corporation, Fig. 1). Also, larger and midterm clinical studies appeared for navigated TKR, THR, and spine surgery.

The 2008–2014 period was a relatively slow consolidation period. CAOS technologies did not achieve the expected across-the-board clinical acceptance and associated market penetration. Specific adoption rates varied by procedure and by country: CAOS navigation technologies were found to have better acceptance in France, Europe and certain Asian countries, while robotic UKA fared much better in the USA. An interesting development was the introduction of smart tools such as the Hip Sextant (HipXpert, Surgical Associates Ltd.) and the Navio handheld drill for knee surgery (Bluebelt Technologies. In parallel, a series of critical meta-studies showed that while the radiological outcomes of CAOS surgeries were superior to those of conventional surgery, there was no proven clinical/functional benefit to the use of CAOS, in particular for TKR.

Since 2014, CAOS technologies appear to be progressing steadily, with a ramp-up in their clinical use and acceptance for specific procedures and locations worldwide. A major event was the acquisition of Mako Surgical Corporation by Stryker, a large and established medical devices and medical equipment manufacturer. While CAOS did not cause the disruption and revolution some expected it to be, it is carving its own space in the orthopaedic surgeon portfolio.

3. CAOS technologies

CAOS relies on a number of mature technologies. These include a variety of imaging modalities (X-Ray, MRI, CT, US, video), real-time tracking (optical, electromagnetic, mechanical), 3D additive printing, and various robotics technologies, including smart instruments. From the medical image analysis perspective, the key technologies include bones segmentation in X-ray and CT images, and rigid 2D/3D and 3D/3D registration.

CAOS is about integration, so most commercial systems combine mature technologies with new ones. Existing CAOS systems can be broadly categorized into either image-guided (CT-based, X-ray fluoroscopy-based, and imageless) navigation systems, positioning systems (patient-specific jigs, bone- and table-mounted self-positioning robots), assistive (semi-active) robotic systems, and active robotics systems. Nearly all include a preoperative planning system, which constitutes an orthopaedic CAD station. Careful attention is paid to two key aspects: the surgical workflow and the surgeon ergonomy. For a detailed description of the principles of CAOS technologies and clinical applications, see Liebergall et al. (2015) and Zheng and Li (2016).

4. Evaluation of CAOS technologies

The clinical and technical evaluation of CAOS technologies is essential to establish indications and counter-indications of the
Fig. 1. Illustration of the intraoperative setting for a unicompartmental knee replacement robotic surgery: (a) view from behind the surgeon (centre) showing him machining the condyle with support from the semi-active robot arm based on the screen plan; (b) computer screen showing the bone upper tibial bone model (white), the contour of the condylar implant cavity to be machined (red), and the machining progress (green); (c) surgeons evaluating the intraoperative situation (part of the optical tracker can be seen on the upper left corner); (d) view of the surgeon hand holding the optically tracked drill. (Photos courtesy of Dr. Andrew Pearle, Hospital for Special Surgery, New York, USA, while performing a surgery with the MAKO robotic-arm assisted surgery, Stryker). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)
Fig. 1. Continued
technologies, to establish risk and cost/benefit assessments, to objectively compare between commercial systems, and to evaluate emerging technologies.

Clinical evaluation consists of radiological and functional studies based on preoperative and short, mid, and long-term postoperative data. Radiological studies are mostly X-ray based – they report common quantitative measures such as leg length, abduction angles, implant alignment, and implant wear. Functional studies report standardized orthopaedics measures, such as Hip and Knee Society Scores. The studies evaluate the outcome of an approach and/or technology on a cohort of patients, or can be comparative, usually conventional surgery versus CAOS. Some studies target specific populations and/or conditions, e.g., young patients, obese patients, patients with severe deformities and/or revision surgery. Comprehensive meta-studies for THR (Gandhi et al., 2009), TKR (van der List et al., 2016), and spine surgery (Aoude et al., 2015) have been recently published.

Technical evaluations analyse the characteristics of the CAOS system, such as precision, accuracy, repeatability and related issues. The technical evaluation measures are provided with respect to one or more clinical targets, e.g., angle, leg-length discrepancy and include in-vitro and cadaver studies. In 2010, a standard for assessing the accuracy performance of surgical assistance technologies, jointly developed by the International Society for Computer Assisted Orthopaedic Surgery and the American Society for Testing of Materials was introduced (ASTM Standard, 2010). However, it is not relevant for directly measuring the accuracy of an actual surgical gesture, so its actual impact on surgical procedures is difficult to evaluate.

CAOS technologies have obviated the need to revise and extend existing clinical and technical evaluation procedures. Currently, there is no consensus on how to evaluate the accuracy of surgical procedures (Cartiaux et al., 2016). Three basic questions are: (1) How is accuracy defined? (2) How can accuracy be measured experimentally? and (3) How should accuracy be analysed from a clinical perspective? Clearly, surgical accuracy is multifactoral – the lack of a standardized evaluation protocol affects the ability to compare clinical results from different hospitals using different surgical protocols, tools and technologies. Moreover, the definition of a patient-specific surgical accuracy target – e.g., axis alignment, varus-valgus angles – has an intrinsic uncertainty that also needs to be quantified. Improving the accuracy of a surgical procedure whose main technical target measure has a large uncertainty is unlikely to yield a clinical benefit and/or be cost-effective.

The lack of agreed-upon standards also affects how clinical studies are conducted. For example, many studies compare the performance of conventional versus CAOS technology. Some studies report that CAOS technologies help, while others report no benefit. However, without a clear understanding of what the target value and its uncertainty are, the interpretation may be partial and inconclusive. For example, common misconceptions fail to distinguish between measurement error and measurement uncertainty, and between accuracy and precision. Another misconception is that improved accuracy yields improved outcomes. Moreover, the accuracy and precision of the execution of a surgical procedure (or part of it) can easily be overshadowed by other factors such as patient demographics and co-morbidities, pre-and post-operative care protocols, individual adherence to these protocols, and variations in the surgical technique. Indeed, this is most likely the reason that many computer-aided techniques have not been able to show clinical benefit as measured by validated patient-assessed outcome measures.

An important task for the CAOS community is to improve and extend clinical and technical standards to allow objective quantitative comparison.

5. Clinical impact and acceptance

The clinical impact and acceptance of CAOS systems has been slow when compared to other surgical technologies. Considering that orthopaedic surgery is one of the specialties with the largest patient volumes worldwide, it is, on average, infrequently used. While a few centres report a use of CAOS technologies for nearly all their joint and spine procedures, CAOS technologies are not used broadly, even in developed countries. A conservative estimate places CAOS surgeries to less than 5% of all orthopaedic surgeries in the USA, Europe, and Asia. There are several reasons for this state of affairs, which we will examine next.

CAOS technology is currently mostly used for primary TKR and THR surgery. Next come anterior cruciate ligament (ACL) reconstruction, spine surgery (pedicle screw insertion), UKA, osteotomies (high tibial and hip), and trauma surgery (long bones and pelvic fractures). Emerging procedures include hip resurfacing, bone tumor resection, reverse shoulder arthroplasty, and elbow, hand, and ankle surgery.

It is recognised that the main technical advantages of CAOS technologies over conventional surgery include improved implant positioning accuracy and the homogenisation of positioning results (smaller variation and fewer outliers) as compared to conventional techniques. The benefits are greater for difficult cases and for revisions. It is commonly inferred that greater accuracy translates in lower rates of implant failure, and therefore into better long-term outcomes.

To illustrate the clinical effects and acceptance of CAOS technologies, consider next the case of knee surgery. Computer-assisted TKR is today the most successful and widespread application of CAOS technology, with nearly 500,000 surgeries documented in various registries around the world. CAOS assistance consists mostly of support for the accurate positioning of the bone cutting tools to shape the ends of the femur and tibia to match the implant interface. It is mainly performed with imageless navigation and patient-specific templates. Soft tissue balancing tools and software are also available and are important for optimal joint stability and outcome.

While navigated TKR has become the standard of care in some centres in Germany, its penetration in North America has been nearly inexistent. For example, over 30% of surgeons in Germany use TKR CAOS technology, while in France 6% and in the UK less than 3% (Picard et al., 2014). Some of the reasons are stated in a variety of studies; they include: good results and high satisfaction of existing conventional procedures, additional operative time, extra cost, lack of insurance coverage, poor ergonomics, surgeon age, lack of quantitative results, and lack of evaluation standards.

Indeed, there is an ongoing debate about the benefits of CAOS in TKR. A recent study of the Australian Orthopaedic Association National Joint Replacement Registry (2003–2012, 44,573 patients) that examines the effect of computer navigation on the rate of revision of primary TKR shows that computer navigation reduced both the overall revision rate of TKR and specifically the revision rate due to loosening/lysis, which is the most common reason for revision. In patients less than 65 years of age at 9 years from surgery, the rate was reduced from 7.8% for conventional TKR to 6.3% for navigated TKR.

The study by Picard et al. (2014) reports that in 29 studies of CAOS versus conventional TKR, three main measures – mechanical axis misalignment >3, frontal plane femoral component misalignment, and tibial component misalignment – occurred in 9.0% of CAOS versus 31.8% of conventional TKR patients. They note that while navigation has indisputably demonstrated an improvement in alignment of TKR components, the question concerning the tolerable limits of acceptable alignment that guarantees functionality
without compromising the function and longevity of the prosthesis remains debatable.

Very recently, van der List et al. (2016) conducted a meta-analysis of 40 comparative studies and three registries on computer navigation with a total of 474,197 patients, and 21 basic science and clinical studies on robotic-assisted TKR. Twenty-eight of these comparative computer navigation studies reported Knee Society Total scores in 3504 patients. Stratifying by type of surgical variables, no significant differences were noted in outcomes between surgery with computer navigated TKR controlling for alignment and component positioning versus conventional TKR. However, significantly better outcomes were noted following computer navigated TKR that also controlled for soft tissue balancing versus conventional TKR. The literature review on robotic systems showed that these systems can, similarly to computer navigation, reliably improve lower leg alignment, component positioning and soft tissues balancing. Furthermore, two studies comparing robotic-assisted with computer navigated surgery reported the superiority of robotic-assisted surgery in controlling these factors. They observe that even though most clinical studies, meta-analysis and systematic reviews of TKR favor a higher accuracy and consistency of optimal implant alignment and soft-tissue balancing with navigation or robotic assistance over conventional surgery, no clear improvement in functional outcome could be demonstrated as of today. They recognize that larger randomized control trials as well as a longer follow-up are needed to elicit significant differences in the future to justly evaluate these technologies.

Overall, we observe that CAOS technologies have neither become the standard of care of any orthopaedic procedure, nor has it lead to a paradigm shift. This is in contrast with stereotactic neurosurgery, in which navigation is the standard of care, or various laparoscopic surgeries with a robotic system. Unlike neurosurgery, most orthopaedic procedures are not life threatening, have a larger margin of tolerance for inaccuracies, and require longer evaluation times to determine their mid to long term benefits.

In terms of surgeon acceptance, CAOS is facing challenges similar to those of faced by laparoscopic surgery when it was introduced. Picard et al. (2014) point out that the main factors limiting TKR navigation spreading amongst orthopaedic surgeons are most likely ergonomics and economics. They conclude that the main reasons for which there is opposition to CAOS technologies are based on inaccurate and/or misleading observations, and the lack of data to support the cost-effectiveness of using navigation (Walker et al. 2010). On the other hand, certain procedures, such as UKA, are recently experiencing an upward trend in the USA for younger patients with severe wear of one knee compartment thanks to the introduction of the Mako RIO system (Stryker) – over 50,000 UKA surgeries have been reported to date since its inception in 2010 (Fig. 1). We believe that while CAOS TKR is not yet mainstream, it will still prove to be a useful tool for surgeons, especially for surgeons that do only a few surgeries per year (“low volume surgeons”) and for difficult and unusual cases.

6. Medical image analysis in orthopaedics and CAOS

Medical image analysis (MEDIA) research is at the core of CAOS technologies and has made significant contributions to orthopaedics in general. We expect this to be increasingly so in the future.

We identify next what are, in our opinion, the challenges and opportunities of medical image analysis research in CAOS and orthopaedics at large. These include musculoskeletal radiology (Zheng and Li, 2016), surgical planning and execution and outcomes evaluation (Kovler et al., 2015; Ritaco et al., 2016), and surgical training and surgeon skills evaluation.

Musculoskeletal radiology presents a vast field of untapped opportunities. It covers a wide spectrum of imaging modalities used in orthopaedics, mostly X-ray, CT, and MRI. The opportunities include computerized support for image interpretation and diagnosis of various orthopaedic conditions – dislocation, occult fractures, spine instability, and various injuries – the automatic detection of missed conditions, and the identification of diagnostic misclassifications. It also includes automatic and systematic incidental findings discovery and early warning for clinical conditions, e.g., osteoporosis and scoliosis.

In parallel, the continuous development of new and improved imaging protocols and devices, such as the EOS® full-body standing low-dose X-ray orthopaedic imaging system, intraoperative X-ray fluoroscopy and cone-beam CT scans (O-arm, Medtronic), robotized patient positioning and imaging system (Ariths zeego, Siemens) all include image processing and modeling capabilities. Additional image processing opportunities including image stitching for panoramas, statistical model creation, image fusion, and multimodal registration, to name a few.

An emerging field with great potential is big data radiology. The increasing amount medical imaging scan acquired in clinical practice constitutes a vast database of untapped diagnostically relevant information. Radiologists and clinicians are increasingly struggling under the burden of diagnosis and follow-up of such an immense amount of data. The vast amount of information in this valuable, unstructured clinical data represents an untapped gold mine to support a wide variety of clinical tasks, such as the retrieval of patient cases with similar radiological images, image-based retrospective incidental findings, large-scale radiological population and epidemiologic studies, and preventive medicine by early radiological detection. In the context of CAOS and musculoskeletal radiology, these tasks include optimization of patient-specific surgery planning, population-based post-operative radiological assessment, and treatment and condition assessment, e.g., osteoporosis assessment and saccroiliac joint pain.

Finally, surgeons teaching, training, accreditation, and evaluation is another developing area in which the generation of patient-specific 3D anatomical models play a key role in the development of simulators, case studies, and examination platforms.

7. Closing remarks

In conclusion, we believe that there has never been a better time for the development of CAOS technologies and for related medical image analysis research. According to BCC Research (2015), the global market for medical robotics and computer-assisted surgical (MRCAS) technologies is expected to grow to $4.6 billion by 2019, with a five-year compound annual growth rate of 7%. Factors such as steadily aging global population and increasing demand for minimally invasive surgical procedures such as heart and orthopaedic surgery are spurring significant opportunities in this market worldwide. In particular, CAOS applications are expected to more than triple their market share between 2013 and 2019. We expect CAOS systems to become that standard of care in many orthopaedic applications and to continue to provide challenging applied research topics. We suggest that while CAOS acceptance may be more moderate than that of laparoscopic surgery, whose adoption was met with initial resistance and took many years to lead to a paradigm change and may not be disruptive, it still has a place in the arsenal of useful tools available to orthopaedic surgeons, in the benefit of the patient.

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