Factors influencing wider acceptance of

Computer Assisted Orthopaedic Surgery (CAOS) technologies for Total Joint

Arthroplasty

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Abstract

Computer-assisted orthopaedic surgery (CAOS) promises to improve outcomes of joint arthroplasty through better alignment and orientation of implants, but take up has so far been modest. Following an overview of CAOS technologies covering image-guided surgery, image-free and robotic systems, several factors for lack of penetration are identified. These include poor validation of accuracy, lack of standardisation, inappropriate clinical outcomes measures for assessing and comparing technologies, unresolved debate about the effectiveness of minimally invasive surgery, and issues of medical device regulations, cost, autonomy of surgeons to choose equipment, ergonomics and training. The paper concludes that dialogue between surgeons and manufacturers is needed to develop standardised measurements and outcomes scoring systems that are more appropriate for technology comparisons, and encourages an increased awareness of user requirements.

Introduction

A central issue concerning wider acceptance of computer-assisted orthopaedic surgery (CAOS) systems [1,2] is the difficulty of proving a new technology for orthopaedics in an evidence-based environment where: conventional methods already have a very high degree of success; proof of improved quality and longevity from an innovation may only be obtained several years later; capital and procedure costs are generally higher; and variation in outcome of the procedure depends on several other factors that are not directly related to choice of technology.

The 2003 US NIH Consensus Development report on Total Knee Replacement [3] states that "Computer navigation may eventually reduce the risk of substantial malalignment and improve soft tissue balance and patellar tracking. However, the technology is expensive, increasing operating room time, and the benefits remain unclear". The Ontario Health Technology Advisory Committee [4] following a review of navigation and robotic technologies for orthopaedics, whilst noting that short-term outcomes were encouraging, decided that it was still in an investigational phase, stating, "There is insufficient evidence at the present time assessing the long-term precision, length of surgery/hospitalisation, adverse effects, revision rates and functional ability of patients who underwent computer-assisted hip and knee arthroplasty using navigation and/or robotic systems for OHTAC to make a recommendation at this time." Furthermore CAOS was not even mentioned in the US Agency for Healthcare Research and Quality Evidence Report/Technology Assessment review of TKA in December 2003, which states only that many of the "basic questions posed remain unanswered", including "effect of surgical technique on outcomes" [5].

This scepticism is mirrored by statistics from the U.K. National Joint Register (NJR) [6] that show there has been a relatively slow uptake of these kinds of new technology by surgeons such that in the latest (September 2005) report only 1.3% (267 operations) of primary total knee replacements and 0.9% (213 operations) of primary total hip replacements were registered in the category for image guided surgery in 2004, which is only a small increase from 1.1% for knees and 0.7% for hips in 2003.

We first present an overview of the technologies involved to provide a context for subsequent identification and discussion of the factors affecting acceptance of CAOS systems. Targeted searching was carried out for material dated from 1990 using OVID Medline, contents search of specialised orthopaedics journals, and a general internet search. Reference explosion was performed on key papers and books to identify additional relevant studies.

Overview of CAOS configurations: image-guided, image-free and robotic systems

Picard et al. classify CAOS systems according to use of imaging and the degree of autonomy of the machine assistance with respect to the surgeon [7]. We follow this classification in the following brief technology overview.

A number of computer aided orthopaedic surgery (CAOS) systems use imaging methods to acquire information about bone geometries of the joint and limbs, especially from preoperative CT and/or intraoperative Fluoroscopy [1, 2]. These

are generally termed image-guided surgery (IGS). A CT (multi-planar or helical/spiral) scan is usually carried out preoperatively in a separate facility than the operating room (OR). Interoperative CT is also possible, but is considered prohibitively expensive for widespread adoption. Interoperative imaging using fluoroscopy involves acquisition of x-ray images, typically by means of a stereotaxic or C-arm device. 2D fluoroscopy provides real-time images in one plane at a time although this can be time-consuming and result in high radiation doses for both patient and surgeon, and images can suffer from image distortion. 3D fluoroscopy makes use of a sequence of such images to produce multiple views in a single pass, known as virtual fluoroscopy. The virtual model can be updated if required by taking more images. The advantage of virtual fluoroscopy is a reduction in radiation dose (especially for the surgeon who can stand away from the x-ray source during image acquisition) and the ability of the digital system to produce optically correct views. Two non-radiographical image-based alternatives are Magnetic Resonance Imaging (MRI) and ultrasonography that are potentially attractive as they do not expose the patient to harmful radiation, but neither are widely used at present. All IGS systems require registration of the images obtained with the patient's anatomy.

An increasingly prevalent alternative to IGS is image-free (or imageless) CAOS where the joint geometry is acquired during surgery, starting with a computer model of a default joint that is modified (morphed) in a step-by-step process whereby the surgeon selects points and/or surfaces on the patient's joint. The acquired points also allow the default model to be deformed into a graphical representation of the joint to be operated on and used as a guide, although only the acquired points and surface can be properly relied on.

Geometry information in both IGS and image-free CAOS is used before and during surgery to assist in some or all of the following: planning resections and selection of implant components, navigating of instruments, placing of implant components, and verification. Navigational guidance is facilitated by 3D spatial tracking of surgeon-held instruments, cutting jigs and placement guides with respect to a dynamic reference base (DRB) that is fixed to the bone. In image-free systems, the DRB for each bone is linked to the respective computer model. In IGS systems, a registration process links the location (position and orientation) of the DRB to radiographic data. The DRB and other points on the anatomy are identified by fixed spatial locations that are marked by physical or artificial fiducials. One kind of physical fiducial arrangement, used in image-based systems, is comprised of metallic pins that are placed directly in the bone prior to x-ray or CT scan and used for registration. The other kind of physical fiducial arrangement, typically found in image-free systems, is comprised of locators constructed from arrays of infra-red (IR) markers ('active' LEDs or 'passive' reflective spheres) that are viewed by a stereo-camera, or alternatives based on electromagnetic tracking or ultrasound. IR locators are attached to self-tapping screws that are implanted in the bone during surgery. As well as physical fiducials, a combination of radiographic and/or kinematics data obtained from moving the limb can be used to allow the computer to determine artificial fiducial points e.g. by calculation of the rotation centre of the femoral head for THA [8].

The other dimension of Picard's CAOS system classification is the degree of autonomy of the computer assistance. In contrast to navigation technologies that leave control fully in the hands of surgeon, an array of robotic systems have been devised, classified as active or semi-active according to the degree of autonomy of the robot. In their review of robotic surgery systems [9], Howe and Matsuoka describe automated forming of the femoral cavity for THA cementless implants by ROBODOC, which is an active robotic system based on an industrial robot and first trialed in 1992. Preoperative CT scans are loaded into pre-surgical software to allow selection of implant and to plan placement. Then, in the operating room, the femoral head is removed by the surgeon as in a manual operation, the femur is clamped to a reference point (fixator) on the robot base, and previously implanted metallic fiducial pins are located by the robot to complete registration. After a safety check by the surgeon, the robot forms the femoral cavity using a high-speed milling machine whilst a separate system alerts any excessive bone shifting that would require re-registration. Once the cavity is formed, the surgery proceeds as in a manual operation. Siebert et al. describe the CASPAR bone preparation system for TKA [10]. A third example of an active robotic system CRIGOS (Compact Robot for Image Guided Orthopaedic Surgery) was developed as part of a European Fourth Framework project BIOMED2 by Brandt et al. [11] although this does not appear to have been commercialised.

Semi-active robotic systems are the other class of CAOS system where the robot typically assists the surgeon in placing jigs and supporting instruments but the surgeon is still responsible for reaming and cutting. Such robots can help the surgeon avoid nerve and ligament areas by excluding them from the workspace [9]. A more recent promising commercial example of the semi-active approach is Acrobot [12]. Troccaz and Merlot cite two additional prototype "synergistic" robotic assistants: PADyC and Cobot, and point to future possibilities for miniature and disposable robots [13].

A selection of commercially available CAOS systems is given in Table 1. Some of these are implant specific systems arising from partnerships between implant manufacturers and navigation system developers. Others are available as generic components for either radiological imaging or surgical navigation and tracking.

Table 1: A selection of commercially available CAOS systems and components

Assessment of CAOS for TJA

One approach towards proving the benefit of CAOS in an evidence-based framework is to draw the relationship between the accuracy of implant placement and quality of outcome which is usually measured either by implant survival rate or loosening rate. Incorrect positioning, axis alignment or orientation of implant components can lead to abnormal wear, osteolysis and the need for early revision. The following subsections look at the issues surrounding this relationship.

Placement, alignment and orientation accuracy

Limits of accuracy and repeatability of the mechanical and navigation sub-systems will fundamentally constrain the best possible results of implant placement, and these are first considered. Mechanical sub-systems are limited in accuracy by a number of factors including machining precision of the component dimensions, flexibility of the component and stability of the mounting. Widths of saw blades and their guide slots will further affect accuracy of placement of the implant. In addition to this, navigation systems are limited by resolution in determination of location and orientation of the markers, which may in turn be affected by the configuration of the markers with respect to the camera e.g. distance and inclination. Langlotz discusses many of these problems in his paper on the pitfalls of CAOS [14], including stability of markers with respect to fixation to the bone, deformation of slim tools and obscuration of markers by blood, although this may be mitigated by careful choice of locator geometry and by over-specifying the location using more than the minimum of three markers per locator [15]. An additional problem for optical tracking systems is operating room lights or light from an operating microscope shining into the camera [14, 16]. For image-free systems, acquiring accurate axes or centres for artificial fiducials may not be possible for certain pathologies which do not conform to geometrically perfect models e.g. of ball and socket joint, or where the range of motion (ROM) of the joint is limited. In another paper, Langlotz outlines pros and cons of non-optical tracking systems [17]. Electromagnetic tracking systems are susceptible to distortion due to interference from ambient electrical devices (such as wires, lights, MRI) or other electrical OR equipment, and from ferromagnetic materials in instruments or implants. Advantages of electromagnetic tracking are its non-line-of-sight (NLOS) capability and if markers with radio-frequency telemetry are placed in the bone or are present within the implant and instruments, obtrusive and potentially unstable external arrays are not needed. Furthermore, if left implanted, markers have the potential for use in post-operative monitoring of the joint and implant. For ultrasound there is difficulty with calibration and the air temperature dependence of speed of sound.

Accuracy of placement can be validated by radiographic, CT and goniometric methods at some time after surgery as outlined by McDaniel et al. [18], however there is considerable debate about the process. Mor et al. [19] report on various studies of navigation accuracy but state that there is little standardisation in validation of system performance for IGS. Furthermore, the literature repeatedly recognises the differences between potential accuracy (as quoted in the manual) and actual accuracy when the system is in use and under OR conditions. Stifter et al. reported that accuracy of an optical tracking device appeared to degrade with age of deployment of devices such that over 30% were not within the acceptable range after 1-2 years, and that errors could drift by as much as 2 mm over a 'warm-up time' of 1-2 hours from switching on power to the device [20]. Wagner et al. concluded that all tracking systems included in their 'phantom-skull' model study proved to be considerably less precise under realistic OR conditions when compared to the technical specifications in the manuals of those systems [16]. Changes in the angle of inclination of the stylus axis resulted in deviations of up to 3.40 mm indicating a strong need for improvements of stylus design. The electromagnetic

tracking system included in this particular study was deemed not significantly affected by small ferromagnetic surgical instruments. However, Poulin et al. did report interference during the use of an electromagnetic tracking system under OR conditions and stated that inaccuracies between 1-15 mm and 1-4° could be caused just by using common surgical tools within the digitizer range of the tracking system [21]. Towards mitigation of this problem, Perie et al. are investigating algorithms to calibrate electromagnetic systems to improve accuracy, the latter citing errors on position and orientation of up to 150 mm and 10 degrees before calibration, and less than 20 mm and 2 degrees after calibration [22]. Frantz et al. of Northern Digital Inc. stress that assessments of spatial tracking systems are "inherently statistical" and typically complicate understanding of accuracy [23]. For robotic systems accuracy is a major issue, especially when conventional industrial robots are redeployed in surgery as in the ROBODOC system since these do not tend to have good inherent positional precision due to flexibility in the arm, although repeatability is generally good [9].

Clinical outcomes

Several studies have been carried out to determine whether accuracy of alignment or orientation in TJA has a significant affect on clinical outcome. DiGioia III et al. outline studies for THA that have shown correct orientation of the acetabular cup to be a significant factor in affecting the risk of dislocation, impingement, pelvic osteolysis, acetabular migration, and wear between components [24]. There are a number of suggestions for optimal orientation although 45° of abduction and 20° of forward flexion are often quoted. McCollum and Gray [25] give the safest range for cup position to avoid dislocation as 30-50° abduction and 20-40° flexion from the horizontal. It is worth noting that measurements for this work were stated as reproducible from x-ray only to within 10° reflecting the considerable challenge to radiographers in obtaining good orientation measurements from x-rays for validation purposes.

The connection between accuracy of axes on outcome for TKA has previously been studied by Rand and Coventry [26] showing 10-year survival of implants of 90% when deviation from the ideal mechanical axis was between 0-4° of valgus, but reduced to 71% for deviations above 4° of valgus. Jeffrey et al. [27] discuss the contribution of incorrect alignment in increased prosthetic loosening rates, showing a 24% rate of revision for deviations above 3°, compared to 3% for optimal alignment. Results from these papers are employed as the baseline for studies of CAOS systems such that in a study using the Aesculap OrthoPilot system, Clemens et al. describe recommended ranges for deviations from the ideal mechanical axis, denoting excellent for 0-4°, good for 4-5° and poor for >5° (and ranges for other axes are denoted as excellent for 0-2°, good for 3-4°and poor for >4°) [28]. In another OrthoPilot study, Lampe and Hille use a Radiological alignment index that involves adding the 5 individual angle deviations, denoting very good to good for 0-10°, satisfactory for 11-20°, poor for 21-30° and unacceptable for >30° [29]. This literature indicates that whilst great attention is being paid to alignment measurements based on a few landmark papers, use of these is not standardised even amongst the CAOS community using the same navigation system.

Furthermore, there are some limitations in dependence on alignment and other technology-related measurements for assessing outcomes. For example, Troccaz and Merlot state that improvements in accuracy of orthopaedic interventions should improve the fit of hip prostheses, improve alignment of knee prostheses and help better define the tunnel for ACL reconstruction, but they also note that mathematical accuracy will not equate to better outcome in every case and that there may be cases when an exact fit is a hindrance to good clinical outcome as it inhibits the natural processes of acceptance of the prosthesis as part of the body [13]. This is just one example where an objective variable might be overridden by the surgeon. All global scoring methods in common use for both hip and knees include subjective variables, some exclusively so, and even amongst those that do include objective measurements, very few intentionally separate objective and subjective components, the Knee Society Score (KSS) from the American Knee Society being a notable exception [30]. The KSS separates functional results reported by the patient such as pain and walking ability from those of technical clinical assessments based on alignment and ROM.

Even when global scores have the potential to compare procedures across technology-related parameters there are some points for caution. The first point is that the wide choice and application of scores in use can make it difficult to understand results of different studies. For example, preferred choice of score may vary between countries and results may be reported as comparisons between whole scores or between components of scores, and given as either absolute scores or as improvements in scores. Particular care must be taken with ROM since knee patients with good flexion prior to surgery might find ROM reduced after their procedure whereas those with poorer prior flexion may find ROM increased.

The second point is that subjective variables can override objective ones in terms of overall judgment of a surgical technique. For example, in comparative studies where there are measurable differences in alignment accuracy there may still be no significant differences in subjective scores in the long-term, or even in the short-term.

The third point is that although a number of studies have been carried out in order to look at the reliability of scoring methods by comparing interobserver variations [31-33], lower agreement between observers was achieved for the objective score component compared to the subjective component. Davies states that for knee scores in use, not all had been studied for reliability and validity and the only validated scores with objective component were considered to be the AKS/KSS and its forerunner the Hospital for Special Surgery (HSS) Knee Rating System, and concludes by recommending WOMAC, SF-36 and Oxford Knee Score (all subjective scoring systems) as most appropriate for assessment of outcome after total knee replacement, since these were the most studied [34]. Rice et al. aimed to find a radiological proxy for the Merle d'Aubigne clinical outcome score for assessment of reconstruction of acetabular fractures by studying correlations between the score and radiological outcome. They found good overall correlation but poor prediction of specific outcomes, and so concluded that their aim was not realised, although they proposed that the patient's walking ability could be used as an objective local outcome measurement [35].

A fourth point made by Callahan et al. concerns patient selection affecting perception of outcomes. In their meta-analysis of outcomes for bicompartmental and unicompartmental TKA, they found that because patients enrolled in biocompartmental studies had more poorly functioning knees before surgery, they actually had greater absolute improvements in global knee rating scores, even though patient outcomes appeared to be worse for bicompartmental arthroplasties than for other prosthetic designs [36]. Therefore it is important to distinguish between studies that attempt to compare absolute score values and those that compare changes in score, and preferably to know both pre- and post-surgery scores.

Comparative studies

A few comparative studies have been carried out to assess CAOS systems versus manual methods for TJA. The largest comparative studies found in the literature for a number of CAOS systems are shown in Table 2.

Table 2: Clinical comparisons of CAOS vs. Manual TJA

Stulberg tables five smaller studies of comparisons of OrthoPilot with manual TKA [40] and the Danish Centre for Evaluation and Health Technology Assessment (DACEHTA) report additional robotic system studies [41]. The overall story is one of improved accuracy and longer mean operating time, with varying impact on blood loss and complications, but with no clear difference in outcome based on global hip/knee scores reported after longer follow-up periods. These results tend to reflect the NIH report quoted earlier [3]. Bäthis et al. [42] studied 130 patients who received TKA using the BrainLAB VectorVision navigation system, 65 with the CT-based module (Knee 1.1) and 65 with the CT-free module (CT-free knee 1.0). 63/65 CT-based patients had post-operative leg-axis within 3º varus/valgus compared to 60/65 for CT-free. No significant differences were found between the methods for orientation of femoral and tibial components.

For the ROBODOC active robotic system, the DACEHTA alert [41] points to the additional problem of heating of bone and bone cement resulting from the high-speed milling. Furthermore this and other image-based systems require additional surgery prior to the THA to implant compared fiducial pins for registration, although Bauer describe a 'pin-less' alternative using DiGiMatch Technology, which uses surface points for registration, plus two pins inserted during the THA surgery [43].

Other factors influencing acceptance of CAOS

Regulatory differences have an effect on the availability of CAOS in different countries. For example, CAOS equipment manufacturers have generally acquired US FDA approval for navigation software products via a lower-evidence 510(k) pre-market notification route since these are deemed similar enough to devices already in use for neurology [44]. On the other hand, robotic systems have generally had more difficult obtaining approval in the US, for

which the more stringent pre-market approval (PMA) routes to compliance have been applied. Since the US is a major market for CAOS technology, as well as one of its developers, delayed approval in the US might tend to affect general acceptance of any such technology.

Cost is another dominant factor influencing uptake of CAOS, since technology is expensive and a judgement must be made on whether the increased benefit is financially justifiable for a procedure that already has a high success rate. Dong and Buxton have used economic modelling techniques to show the cost effectiveness of CAOS for TKA [45]. However, a decision to adopt CAOS is unlikely to be made solely by the surgeon but with peers and other stakeholders who will may have differing opinions on what contributes most to successful outcomes, based on their past experience and interpretation of evidence from the literature. Hospital or surgeon throughput or choice of prosthesis could be deemed to be at least as important as the choice between CAOS and manual techniques [46–48], and spending in these and other areas could therefore be prioritised. Furthermore, the autonomy that surgeons have in relation to choice of surgical equipment and prostheses is likely to vary between public and private health care sectors and between countries. This factor is identified by Hardidge et al. [49] who state that the structure of the UK National Health Service means that surgeons in this sector are more likely to use cheaper prostheses with good long-term results due to financial constraints. The authors contrast this with Australia where surgeons have more autonomy and may be more likely to adopt new technology more quickly.

Ergonomics and other user-related factors are also identified in the literature. The practical issues related to the "man-machine interface" are discussed by Visarius et al. who state that the presence and operation of a computer terminal and other associated equipment in the OR are potentially problematic in terms of both practicality and maintaining a sterile environment, and suggest voice-recognition or virtual keyboard technology as possible solutions [50]. Layout of the operating theatre to afford computer interaction will require further consideration by developers. Troccaz and Merlot mention current neglect of human/computer interface (HCI) design in the domain of computer-aided surgery, and also discuss the problem of learning in CAOS systems with respect to variations in educational experience [13]. Langlotz highlights the degree of concentration required of the surgeon during acquisition of digitising spots or surfaces [14], concluding that a surgeon's understanding of concepts and limitations and, therefore, training in CAOS is needed to avoid "prolonged operating time and mediocre clinical outcome".

Finally, it is important to note that CAOS systems are currently being promoted as a facilitator of minimally invasive surgery (MIS) for joint arthroplasty [51] since they have the potential to assist surgeons in operating in the smaller spaces afforded by shorter incisions and especially for resurfacing where the implant is smaller, and for multi-component or unicompartmental implant designs [52]. Not only is the surgical field of view reduced, but because minimising soft tissue disruption is a primary goal of MIS arthroplasty, navigation requirements are different [53]. However, the academic literature is divided about MIS. Proponents of MIS using CAOS for THA have shown

significant improvements in some Harris Hip Score parameters (limp, distance walked and stair climbing) after 3 and 6 months suggesting an improved recovery time, but no differences in the other parameters and no differences at all after 1 year [54]. Other studies have failed to show even short-term improvement in outcomes from mini-incisions [55, 56]. A recent study on 219 patients admitted for THA concludes that MIS techniques performed through a single incision posterior approach by an appropriately trained and experienced surgeon is a safe and reproducible procedure but offers no significant benefit in the early post-operative period compared to a 'standard' incision of 16 cm [57]. Further to this, recent UK National Institute of Clinical Excellence guidance on Interventional Procedures states that on current evidence mini-incision surgery for TKA does not appear adequate without special arrangements and more evidence on the long-term safety and efficacy of this procedure [58], although their guidance on single mini-incision surgery for THA states that current evidence appears adequate to support its use [59]. Even from this small selection of literature it is not hard to suggest that surgeons who are currently unconvinced by MIS will require strong evidence that CAOS increases its viability. On the other hand it could be argued that is only by combining it with CAOS that improvements in outcomes will be made using MIS.

Conclusions

In 2003 Sikorski and Chauhan optimistically compared computer-assisted surgery with other technical aids within orthopaedics such as fluoroscopy and arthroscopy and argued that CAOS would have a similar impact, but that it was currently going through the formal process of introduction, assessment and acceptance that is necessary for any technical aid [60]. Mohsen and Philips state that CAOS is being increasingly adopted but at quite a slow rate [61]. A modest increase in the use of CAOS is borne out by small increases reported in the UK National Joint Register, but consensus and health technology reports show that CAOS for joint arthroplasty still appears to be a quite a way off its wider adoption tipping point. Whilst several manufacturers are producing CAOS equipment for TJA (and unicompartmental knee arthroplasty) and there are enthusiastic proponents amongst some surgeons, the call from assessors is still for an increased amount of evidence of improved clinical outcomes.

For computer-assisted navigation systems in TKA, there is evidence of improved alignment accuracy and some improvements in clinical outcomes in the first few months, but acceptance appears to rest on evidence that will show long-term benefits. Justification of CAOS currently depends on a small number of landmark papers linking alignment accuracy to loosening or revision rate and the larger number of papers showing improved accuracy with CAOS, especially for TKA. Longer-term studies will be needed to show definitive improvements in outcomes from the use of CAOS. In the medium term, the few papers comparing clinical outcomes for CAOS versus conventional surgery do not show improvements in common outcomes measurements conducted after one year although some short-term improvements are apparent. This may be in part due to the subjective nature of scoring/rating systems in use for

research, which is especially an issue for THA as there appears to be no good equivalent of the Knee Society Score for more objective measurements of hip outcomes. Furthermore, for hips, it is more difficult to extract accurate angle measurements from x-rays than for knees and there is less consensus on the target angles to achieve. Great care must be taken in interpretation of hip and knee scores for the purpose of assessing technologies. Furthermore, the potential of CAOS for improving the results of minimally invasive surgery is not yet realised.

In order to provide a stronger basis for assessing the advantages promised by CAOS technologies, we propose increased dialogue amongst surgeons and manufacturers towards further research and development in the following areas: development of measurement techniques for hip alignment and orientation; agreement on standards for technology-related measurements that are used to study the relationship of accuracy measurements to clinical outcomes; development of more appropriate outcome scoring systems for technology comparisons; a closer examination of user needs issues from both patient and surgeon perspectives; and further demonstration of the cost benefits of CAOS.

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Acknowlegements

Table 1: A selection of commercially available CAOS systems and components

Company	System name	Classification and description
Acrobot (The Acrobot Company Ltd.)	Acrobot, MI-Navigation	Semi-active robotic assistant, planning software. Resurfacing.
Aesculap	Orthopilot	Image-less TKA and ACL, planning and navigation
BrainLAB	VectorVision	Image-free and CT-based planning and navigation.
CASurgica Inc.	HipNav KneeNav	CT-based. Preop. Planning, RoM simulation, acetabular placement for hips. Navigation for TKA.
DePuy/BrainLAB	iOrthopaedics Ci System	Image-less, TKA and THA planning and navigation
GE Healthcare	FluoroTrak/Flexiview	Fluoroscopy navigation system/Mobile C-arm
Integrated Surgical Systems (ISS)	ROBODOC/ORTHODOC	Active robotic system/associated planning system
Medivision Synthes	SurgiGATE	CT-based navigation system
Medtronic SNT (Surgical Navigation Technologies)	StealthStation	Image-based navigation system, TKA and MIS knee working with various third party C-arms, CT or MRI
Northern Digital Inc.	Optotrak/Aurora	Generic IR tracking system/Electromagnetic tracker
PI Systems	PiGalileo	Image-free navigation system, TKA and THA, plus electromechanical positioning 'mini-robot' for TKA.
Siemens Medical Solutions	SIREMOBIL Iso-C/Iso-C3D	2D/3D C-arm Fluoroscopy working with various third party navigation systems
Smith & Nephew/ORTHOsoft	AchieveCAS, Navitrack	Image-less navigation for TKA and THA (models derived from CT)
Stryker Orthopaedics/Leibinger	Navigation System/Knee Navigation System	Image-free THA/TKA,with wireless tracking technology (can be image-based for other procedures)
Universal Robot Systems (URS) Ortho	CASPAR	Active robotic system for bone preparation in TKA

Table 2: Clinical comparisons of CAOS vs. Manual TJA

System	Hip/Knee, trial type, n	Measurement method	Reported alignment differences for CAOS	Other differences noted for CAOS	Reference
Stryker Knee Navigation	Primary TKA, single surgeon prospective randomised trial, n=70	Post-operative CT, at discharge & after 6 weeks.	Improved accuracy in some measures, no difference in others.	Lower blood loss Longer mean operation time +13 mins	Chauhan et al. 2004 [37]
ORTHOpilot	Primary TKA, multi- centre RCT, n=821	KSS (AKS score) + radiographs, 3 months	Improved accuracy in all measures.	Longer mean operation time +8 to 10 mins	Jenny et al. 2003 [38]
ROBODOC	Primary THA, 2 surgeons single site prospective level I-1a RCT, n=141	Harris/Merle d'Aubigne/Mayo preop. & after 3/6/12/24 months + radiographs	Improved accuracy. Some improved scores at 6/12 months. No difference in all 3 scores after 24 months	Longer mean operation time +25 mins 18% manual revisions required due to system failure, all involving muscle damage, over half with frequent dislocation and limping. Increased heterotopic ossification from radiographs	Honl et al. 2003 [39]
CASPAR	Primary TKA, Prospective clinical study, n=114	KSS preop. &after 3/6 months + radiographs, preop & 2 after weeks.	Improved accuracy in tibiofemoral alignment. No difference in scores at 3 and 6 months follow-up.	Reports 'increased' operating times.	Siebert et al. 2004 [10]