Chapter 12 Computer-Assisted Orthopedic Surgery

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Abstract

Orthopedic surgeons treat musculoskeletal disorders such as arthritis, scoliosis, and trauma, which collectively affect hundreds of millions of people and are the leading to computer-assisted surgery (CAS) in several key areas of orthopedic surgery are assess the evaluations of these systems performed to date, with a particular focus on time, and reduced costs. accepted. This means it must demonstrate better performance, less operating room cause of pain and disability. In this chapter, the main technical developments related the value proposition that CAS needs to deliver in order for it to become widely reviewed: hip and knee replacements, spine surgery, and fracture repair. We also

We describe several systems for both hip and knee replacement that are based on computed tomographic (CT) images, intraoperative fluoroscopy, or image-free kinematic techniques, and in each domain consider both manual and robotic systems. Future work in computer-assisted orthopedic surgery will include efforts to develop newer technologies such as 3D ultrasound and ever less invasive procedures, but improved accuracy to nonspecialist orthopedic surgeons working in community hospitals, where the case volumes are lower than in specialized centers. Linkages between improved accuracy during surgery and improved functional outcomes for the patients must be demonstrated for these technologies to be widely accepted. it must also concentrate on improving operative workflow, to transfer the benefits of

12.1 Introduction

Orthopedics is the surgical discipline that treats musculoskeletal injuries and diseases, most notably fractures and various forms of arthritis. Although orthopedic problems do not have the same degree of public awareness as cancer and heart disease, because they are seldom life-threatening, their impact on public health is immense. Hundreds of millions of patients around the world suffer from musculoskeletal disorders, which are a leading cause of pain and disability and account for almost half of all chronic conditions

amongst people who are aged 50 and above in developed countries [CDC 2003]. Because of the *baby boomer* phenomenon, the number of patients with such conditions is expected to increase dramatically in the coming years.

musculoskeletal disorders account for 20% of all visits to outpatient facilities (130 million per year) than any other category of illness, at a cost of \$215B. There is, therefore, significant pressure on public health systems to prevent the disease processes, and on health care systems to provide effective, durable treatments when disease occurs. The focus of this chapter will be on this latter issue, in the use of computer-assisted technologies to improve treatment. to the Arthritis Foundation (http://www.arthritis.org/bone-joint-decade.php), The resulting costs to health care systems will be enormous. According around the world and, in the USA in 1995, generated more visits to physicians

In general, orthopedics is a mature surgical discipline. Practitioners have developed effective techniques for treating both acute injuries and long-term degenerative diseases, and many orthopedic interventions offer immediate and long-lasting relief to their patients. Hip and knee joint replacement surgeries are prime examples of effective interventions, with success rates over 90% (as measured by percentage of implants surviving 10 or more years after implantation). However, because of the sheer number of these procedures performed (over 700,000 hip and knee replacement proannual revision rate represents a substantial number of patients. Given that revision surgery for a failed joint implant costs upwards of \$11,000 [Slover et al. 2006], annual direct surgical costs associated with these failures will soon approach \$1 billion, providing considerable incentive to improve the effectiveness of these procedures. cedures performed annually in the USA alone) [Kozak et al. 2006], a 5–10%

In addition to the potential for improving the longevity of surgical interventions, other challenges faced by orthopedic surgeons relate to improving postoperative function, optimizing fracture repairs to avoid later development of osteoarthritis, minimizing hospital stays following surgery, minimizing the period of recovery and return to work, avoiding infection, and minimizing blood loss during surgery. As all these challenges are affected either by how accurately bone fragments or artificial components are aligned with respect to one another or by the degree of disruption to soft tissues, there is significant potential for computer-assisted surgical techniques to contribute to the refinement of orthopedic interventions by quantifying key aspects of these surgical procedures and enabling surgeons to more precisely control their surgical actions.

In many ways, orthopedic surgery is the most obvious and natural application domain for CAS techniques because so many procedures are performed on bones, which are essentially rigid. It is considerably easier to track bones or fragments across time than to monitor changes in deformable tissues, as occurs in neurosurgery (for more information, please see Chap. 11) and abdominal surgery (Chap. 13). Because of this, many of the

early applications of CAS techniques were in fact in orthopedic surgery. However, despite well over a decade of development, CAS systems still have not been widely adopted by orthopedic surgeons, and there is continuing controversy over their value.

For example, a recent review of the factors influencing acceptance of computer-assisted orthopedic surgical (CAOS) technologies, conducted in 2005 by the University of Nottingham's Multidisciplinary Assessment of concluded that there was "poor validation of accuracy, lack of standardization, inappropriate 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 authors went on to state that more dialogue is needed "between surgeons and manufacturers….to develop standardized measurements and outcomes scoring systems," and that increased attention should be paid to user requirements. Technology Centre for Healthcare (MATCH) group [Craven et al. 2005],

The opinion that the current state of CAOS technology is too premature for widespread market deployment has been echoed by numerous other bodies over the past few years. The US NIH Consensus Development Report on Total Knee Replacement [2003] concluded that although there was evidence that accuracy was enhanced, costs were higher, operating room time was generally increased, and the benefits were unclear. The Ontario Health Technology Advisory Committee [2004] noted that navigation and robotic technologies were still in an investigational phase. In September 2006, the California Blue Cross assessed whether or not navigated orthopedic surgical procedures should be eligible for reimbursement, and concluded that such procedures were considered investigational and not medically necessary. This Blue Cross study noted the relative lack of randomized control trials for femoral nail or pelvic fracture repairs, and with regard to total hip arthroplasty (THA), recognized the link between malignment of the components and a tendency toward subsequent dislocation, but again, there were no controlled trials for THA available. For total knee arthroplasty (TKA), only two randomized trials were identified [Saragaglia et al. 2001; Decking et al. 2005]. Saragaglia showed a tendency toward improvement in alignment (84% of 25 patients within 3° of target for CAS vs. 75% in the conventional group), but this result did not achieve statistical significance. Decking confirmed this result, showing a statistically significantly greater proportion of well-aligned limbs in the CAS group, although there was no significant difference between the groups in the clinical scores (Knee Society Score or Western Ontario and McMaster Universities Osteoarthritis Index), and no follow up beyond three months.

This chapter briefly presents the major areas of orthopedic surgery and the challenges faced by surgeons to identify the clinical opportunities for which computer-assisted techniques can provide a potential solution. The

main technical developments in these various application areas over the past 20 years are reviewed, with a particular focus on the evaluations carried out to date. Finally, some promising directions for future development are highlighted.

12.2 Orthopedic Practice

12.2.1 Clinical Practice of Orthopedics

The term *orthopedics* was introduced in 1741 by a French physician, Nicolas Andre, and literally means *straight child*, reflecting the early orthopedists' concern with bracing of children suffering from limb and spine deformities. In the twentieth century, orthopedic practice became a surgical specialty as its practioners began treating war injuries, poliomyelitis, and other musculoskeletal diseases affecting the structural tissues of bone, ligament, tendon, muscle, and cartilage, as well as the associated nerves, arteries, and veins.

Broadly speaking, orthopedic practice can be divided according to the joints and bones of the body: upper limb (shoulder, elbow, and wrist), spine (neck and back), pelvis and hip, knee, and foot and ankle. The hand can be the domain of orthopedic surgeons as well, although many procedures are now normally handled by plastic surgeons. Clinical conditions addressed by orthopedic surgeons include congenital disorders (e.g., scoliosis), the various forms of arthritis, bone and soft tissue cancers, and trauma.

Another way of classifying orthopedic practice is according to the types of procedures commonly performed. A recent report from the Med-TechInsight consulting group (February 2007) summarizes the 33 million surgical procedures performed in all surgical specialties in the US in 2006. Their categorization of the subset of orthopedic procedures identifies the following five main groups:

- 1. Fracture repair (generally due to trauma)
- 2. Total joint arthroplasty (knee and hip)
- 3. Spine surgery
- 4. Disc replacement (discectomy, laminectomy and laminotomy, spinal fusion, and vertebroplasty)
- 5. Arthroscopy (knee, shoulder, and wrist)

Some key landmarks in the development of orthopedic practice have included the introduction of hip and knee joint replacements in the 1960s, arthroscopic repair of cartilage and ligament injuries in the 1970s and 1980s, rigid bone fixation techniques in the 1980s, and biologic agents in the 1990s.

12.2.2 CAOS Procedures

Within the five surgical areas identified earlier, the developers of CAS technologies have identified several situations where precise positioning or implant orientation could play a strong role in the clinical outcome. Other reasons for developing computer-assisted techniques include the promotion of minimally invasive surgical techniques, reducing radiation exposure, bringing younger surgeons more rapidly up the learning curve, reducing time and cost in the operating room, and documenting operating room actions for medicolegal reasons.

as relating to the following five domains: total knee arthroplasty, anterior cruciate ligament reconstruction, total hip arthroplasty, reconstruction and trauma surgery, and spinal surgery. In an earlier volume, Nolte and Ganz [1999] identified the key applications for CAS as the spine (pedicle screw placement), the hip (acetabular osteotomies, total hip replacement, pelvic osteotomies, iliosacral screw placement), and the knee (arthroplasty, anterior cruciate ligament reconstruction). In addition to procedure-specific techniques, certain technologies such as virtual fluoroscopy (obtaining an initial set of X-rays and subsequently continuously monitoring the position of surgical tools on these images during the procedure as if fluoroscopic imaging were continuing) can be applied to multiple surgical tasks. In a recent review volume, Stiehl et al. [2006a] classify CAOS systems

This chapter focuses on a set of orthopedic surgical applications that have received considerable attention from the developers of computerassisted technologies, which are as follows:

- 1. Hip arthroplasty total joint and resurfacing
- 2. Knee arthroplasty total and unicompartmental
- 3. Pedicle screw insertions
- 4. Fracture fragment alignment and distal intramedullary nail locking.

Two other areas for which CAS systems have been developed, but which are not discussed in detail here, are:

- 1. Anterior cruciate ligament reconstruction
- 2. Pelvic and tibial osteotomies.

For each application, we discuss the clinical challenges associated with the traditional techniques, review the history of CAOS technology as applied to the application, assess the evaluations of the various CAOS systems that have been performed, and identify key directions for future research. Before discussing each application in detail, however, the existing technologies available to orthopedic surgeons are briefly reviewed.

12.2.3 Review of Quantitative Technologies Used in Orthopedics

In conventional orthopedic surgery practice, surgeons have access to a variety of imaging technologies, all of which are also used in CAS systems.

12.2.3.1 X-Rays, CT, and MRI

Orthopedic surgeons rely heavily on X-rays in their practice. Plain, twodimensional X-rays are routinely acquired for virtually all orthopedic problems: trauma, varus (bowlegged) or valgus (knock-kneed) knees, arthritic hips, and spinal deformities, among others. Three-dimensional computed tomographic (CT) scans are more expensive than plain X-rays and involve higher radiation doses, so they are less commonly acquired, although they are used for more complex fracture cases, spinal deformation (e.g., scoliosis) and selected arthritic cases. Magnetic resonance imaging (MRI), another 3D imaging technology is occasionally used, but as it tends to be better suited for soft tissue imaging, it is most commonly employed when the problem is primarily related to soft tissues such as muscle or cartilage.

12.2.3.2 C-Arm Fluoroscopy

None of the technologies described earlier are commonly available in the operating room. However, a portable X-ray device known as a C-arm is widely used for intraoperative imaging. C-arms have an X-ray source at one end of a C-shaped arm and a detector at the other, which enables surgeons to obtain intraoperative images of any portion of the anatomy that can be placed within the cone-shaped radiation beam of the machine. These images are relatively small (up to about 15 cm in diameter), but can typically be acquired in under a minute. In addition, images can be acquired continuously at up to 30 frames per second, so continuous monitoring of a surgical intervention such as a fracture reduction is possible.

In the past 10 years, techniques have been developed for combining multiple images from different angular orientations over a period of several dozen seconds into a low-resolution 3D image similar to that produced by a CT scanner. New surgical techniques based on these capabilities are still in the early stages of development, and some of them are discussed later in conjunction with some recent computer-assisted techniques.

12.2.3.3 Ultrasound

Ultrasound is another imaging technology that is widely used in other areas of medicine, but is relatively uncommon in orthopedics. Its images have generally been considered too noisy for diagnostic purposes, but it has many desirable features as an intraoperative imaging modality; it is radiation-free, comparatively inexpensive, and can produce 3D images in real time. Several research groups, including our own, are currently experimenting with using ultrasound in conjunction with CAS systems to locate anatomical structures intraoperatively.

12.2.3.4 Statistical Shape Modeling

A significantly different way to obtain a 3D model of a bone for use in the operating room is to use a technique known as statistical shape modeling (or anatomical atlases). With this technique, the 3D shapes of a variety of sample bones are measured, and the resulting representations are stored in a database. The stored shapes are analyzed and decomposed into a relatively small number of *modes* describing the main ways in which different bones vary relative to one another. For example, the first mode might represent the average bone scaled for size, the second mode might represent thickness changes for a given size, and the third mode may represent some asymmetry. This is similar in concept to the various signal decomposition techniques used in various engineering domains (e.g., Fourier or wavelet decomposition). Intraoperatively, the patient's anatomy is measured by any of a variety of methods (fluoroscopy, direct digitization with a tracked pointer, ultrasound, or laser scanner) and the parameters of the most significant modes are adjusted to optimize the match between the adjusted model and the intraoperative measurements. In many situations, this technique can produce a well-described 3D model that is accurate to within 2–3 mm over its entire surface.

12.3 Evaluation

We noted earlier that health care funders generally regard computer-assisted orthopedic surgery as still being in a relatively early stage of development with insufficient evidence of value yet being available to justify reimbursement as procedures distinct from their conventional counterparts. The onus is therefore on developers of CAOS systems to demonstrate some combination of improved outcomes, reduced operative and recovery times, shorter learning curves for surgeons, and reduced costs (this set of considerations is sometimes summarized as *Better, Faster, Cheaper*), which can make acquisition of a CAOS system attractive to a hospital, an insurer, or a health maintenance organization, depending on how health care services are funded in a particular jurisdiction. In this section, we consider in more detail how system developers can establish these benefits for their systems.

12.3.1 Improved Technical and Functional Outcomes

To date, most evaluations of computer-assisted technologies or techniques have focused on short-term technical outcomes of the procedures. For example, in total knee replacement surgery, the most commonly reported outcome is the mechanical axis alignment (hip–knee–ankle (HKA) angle) in the frontal plane as evaluated on postoperative X-ray images. This outcome measure is based largely on a study of 115 total knee replacement surgery patients by Jeffery et al. [1991] in which they showed that the risk of early failure of knee implants was significantly increased when the HKA angle was more than 3° off neutral (24% failure rate at 8 years postsurgery in the one-third of patients in this group compared with a 3% failure rate in the two-thirds of patients with a mechanical alignment within this 3° window).

In total hip replacement surgery, the most commonly reported technical outcome is the alignment of the acetabular cup. For example, Haaker et al. [2007] reported that the standard deviation in cup placement was significantly lower using CAOS techniques $(1.0^{\circ}$ in inclination and 1.7° in version vs. 2.6° and 3.8° for the manual technique), although in both cases the range was large $(28^{\circ}$ in inclination and 33° in version for CAOS vs. 38° and 44° for the manual technique).

On the femoral side of total hip arthroplasty, an important issue has been the regularity of the hole that is formed to accept the femoral component. Conventionally, this hole is broached by hand, which produces an irregular hole with significant gaps (up to several millimeter) between the implant and the bone. With cemented implants, this is not a particularly significant problem, but there has been a long-standing debate in the surgical community as to the relative effectiveness of cemented vs. cementless implants. Bone can only effectively integrate into cementless implants if the gap between the implant and bone is in the order of 1 mm or less [Dalton et al. 1995], which cannot be achieved over more than a small portion of the implant surface with hand-broaching techniques. This limitation led to one of the earliest uses of robotics in surgery; Paul, Mittelstadt, and their colleagues adapted an industrial robot to mill the femoral cavity during total hip arthroplasty surgery [Paul et al. 1992]; this system eventually became a commercial product known as RoboDoc. In several papers, the RoboDoc developers and clinical users demonstrated improved accuracy of the femoral cavity [Schneider and Kalender 2003] and showed that the mean error produced by robotic milling was within 0.5 mm.

One final example of a short-term technical outcome is in the field of spinal fusion surgery. In such surgeries, the goal is to prevent relative motion of adjacent spinal segments by attaching mechanical hardware to two or more vertebrae, using screws inserted into the lateral channels of the vertebrae that link the posterior spinal processes to the vertebral body. These lateral channels are known as the pedicles, and the surgeon's task is to insert screws down these channels. If the screws are misdirected so that they pierce the medial side of the channel, they can impinge on the spinal cord and cause nerve injuries. This task is increasingly difficult as one moves up the spinal column because the vertebrae become smaller. Studies comparing computer-assisted to conventional techniques typically report the number of pedicular breaches, for example Lee et al. [2007].

Although these technical measures can serve as evidence that the computer-assisted techniques are generally capable of matching or exceeding the mechanical alignment accuracies achieved by well-trained surgeons using conventional manual techniques, by themselves, they have not been sufficient to allow funders to conclude that there are corresponding functional improvements for the patients that would justify either purchase or reimbursement. The challenge for researchers is to link improvements in these technical measures to demonstrable improvements in outcome measures. To date, there have been few such studies. One main reason for this in the case of arthroplasty procedures is that the success rates are already very good; often exceeding 90% survival at 10 years or longer, which makes it difficult to enroll a sufficient number of patients in a study and track them over a long enough period to show a significant difference in outcome. Furthermore, once an institution begins using CAS techniques, it becomes difficult to enroll patients in the control group; the patients naturally believe that the computer-assisted technique represents the state-of-the-art and are reluctant to be randomized to the control group. This implies that future comparative studies will increasingly become limited either to institutions that are introducing computer-assisted procedures, in which case the results are likely to be confounded with learning curve issues, or to interinstitutional studies in which differences between sites will likely confound the results.

The outcomes used in such studies are themselves an important matter for discussion. In arthroplasty studies, for example, the most common outcome measure used is the revision rate, but this measure does not adequately capture the broad range of ways in which a patient's life might be affected or improved by surgery. Other important considerations are how quickly the patient can return to their normal activities, how much their activities are affected by any deficits in function, and how much pain they continue to suffer. This latter issue has been surprisingly understudied. In a retrospective study performed at our institution [Anglin et al. 2004], we found that a significant fraction of patients reported an increase in the amount of pain they experienced following surgery, despite correction of their varus/valgus malalignment. Fortunately, increasing attention has been paid over the past decade to the need to acquire good measures of surgical outcomes, following some of the earlier studies that demonstrated that scores such as the Short Form 36 could be acquired in a cost-effective manner, which could show demonstrable improvements in several different aspects of a patient's subjective postoperative experience [Patt and Mauerhan 2005; Arslanian and Bond 1999].

A number of studies of computer-assisted orthopedic procedures have now reported a variety of functional outcome measurements ranging from more technical measures such as joint range of motion, to more task-related measures such as ability to walk specified distances or climb stairs. A number of procedure or joint-specific evaluation scores exist that have been shown to be reliable and repeatable measures both of functional results and impact on patients' lives, but many of these measures are relatively coarse and may not accurately reflect the specific aspects that are of most concern to patients. For example, in a study of the functional outcomes of acetabular fracture surgery, Moed et al. [2003] reported that despite achieving good to excellent results according to the modified Merle d'Aubigné clinical hip score, which "is the most generally accepted clinical grading system for evaluating the results of acetabular fracture treatment," the results of a functional assessment using the Musculoskeletal Function Assessment score showed that the patients still had not returned to their preinjury functional levels. The authors concluded that the clinical hip score has limited usefulness in assessing the results of acetabular fracture surgery.

12.3.2 Reduced Operative Times

Although proponents of CAOS systems often have envisioned that such techniques will be able to reduce the time needed to perform surgical procedures, to date most computer-assisted procedures in fact require additional time, both pre and interoperatively, due to the need to set up the equipment before the procedure and to perform various marker attachment and Registration steps during the surgery. The overall impact on operative time has occasionally been reported (for arthroplasty procedures, the increase in operative time is often reported as being in the range of 10–20 min), but few detailed studies yet exist to help researchers understand exactly where these increases in operative time arise, and the potential for decreasing the time impact.

In some selected procedures, time savings have been reported. For example, in spinal fusion procedures, considerable time is spent using fluoroscopy to target the pedicles, and CAS systems have succeeded in reducing both surgical time and fluoroscopy time [Sasso and Garrido 2007]. Time savings are important because of impacts on overall patient throughput, because operating room costs are high – on the order of \$20 per minute [Weinbroum et al. 2003], and because extended anesthesia time can increase the risk to the patient.

12.3.3 Reduced Costs

Even if CAS procedures can be shown to improve patients' functional outcomes or to reduce time in the operating room, they are not cost-free. Early CAOS systems were very expensive, costing upwards of \$300,000, which is comparable to a high-end fluoroscopy machine, and often involved per-procedure supply costs of several hundred dollars. Such costs have made it even more difficult for such procedures to be accepted. There have

been some significant reductions in price of these systems in recent years, with simpler systems now selling in the \$50–100,000 range (or available on a per-procedure basis for several hundred dollars, including supplies), but these expenses must nevertheless be more than compensated for by cost reductions elsewhere in the patient care process. Such reductions could potentially be realized in the form of decreased operating room time, decreased length of stay in hospital, decreased recovery times, decreased revision rates, or increased postoperative function. Accounting for some of these costs is often difficult, and there is often little connection between the entity incurring greater costs at the time of the operation (generally the hospital) and the entity receiving the long-term benefits (potentially the patient). It is, therefore, difficult to make the argument that the hospital incurs the additional costs if they are not going to benefit financially from the resulting benefits. Nonetheless, a full evaluation of CAOS technologies should include a careful assessment of any potential cost savings for any element of the health care system or for the patient [Beringer et al. 2007; Bozic and Beringer 2007].

12.3.4 Other Issues Affecting Adoption

In the end, issues other than direct cost-benefit considerations may drive adoption of computer-assisted technologies. Issues related to how the technologies affect surgical practice may be important, as may be legal considerations and marketing pressures. Although the comments below focus specifically on CAOS systems, they apply in general to the other computerassisted interventional procedures discussed elsewhere in this book.

12.3.4.1 Surgical Practice Implications

Surgeons have a direct interest in CAOS systems because they affect how surgeons practice. Hüfner et al. [2004] point out that a navigation system must fit in with the set of equipment and case mix that a surgeon normally uses. An additional important reason for surgeons to consider adopting CAOS systems is the potential for reducing radiation exposure to themselves and the surgical team. As an increasing number of procedures are done under fluoroscopic or CT guidance, especially with the emergence of newer 3D fluoroscopy systems, surgeons and their teams are exposed to an increasing cumulative radiation dose over their working lifetimes, particularly if they perform particular surgeries or use particular techniques [Rampersaud et al. 2000].

12.3.4.2 Legal Considerations

On the legal side, there is considerable evidence now that computer-assisted procedures, particularly in knee arthroplasty and pedicle screw insertions,

can reduce the number of outliers. Patients who have undergone a conventional procedure that produces an outlying result and who subsequently experience a poorer than expected outcome may increasingly decide to pursue a legal remedy on the basis of the argument that technology exists that could have prevented their poor outcome, and that the hospital is liable for not offering state-of-the-art care. This argument is unlikely to prevail in the short term, given the numerous assessments that deem CAOS technology to be premature, but it will likely become increasingly powerful over time given the number of cases brought against surgeons employing current practices [AAOS 1999]. At the same time, legal issues can potentially limit the introduction of new surgical technologies. In Germany, for example, there have been legal cases brought against the manufacturer of the RoboDoc system related to a purported increased rate of complications when using the device [Schräder 2005].

12.3.4.3 Marketing Pressures

In some jurisdictions, most notably the United States, many hospitals must compete for patients, and a key element in their marketing arsenal is the offer of state-of-the-art health technology. Such hospitals not only face enquiries from educated patients seeking particular types of procedures, but they actively advertise their technological capabilities to patients as an enticement to be treated at their facility. For example, a 2005 article in the Boston Globe described the aggressive marketing program conducted by a Massachusetts hospital, which had acquired a surgical robot. This hospital used billboard ads and sent information kits to potential patients who had enquired about prostate surgery, despite an absence of demonstrated longterm benefits of the robotic procedure, promising as it may be [Kowalczyk 2005]. A similar concern about such marketing efforts for surgical robots was expressed more recently in an editorial in the Medical Journal of Australia [Maddern 2007]: "[the purchase of robots by private hospitals] has caused some concern within segments of the surgical community, as the motives for installing these robotic machines appear to be more commercial and marketing-oriented than based on well-established science and surgical benefit. However, as more than half of the surgical procedures in our health system are performed in the private sector, it is hardly surprising that aggressive marketing and commercial interests should be factors in the availability of robotic surgery."

12.3.5 Prospective Randomized Clinical Trials

The standard for evaluating clinical evidence is often said to be the prospective randomized clinical trial (PRCT). In a PRCT trial, researchers compare a proposed technique against its conventional counterpart by controlling for as many variables as possible. In general, a well-defined patient population is randomly divided into a control and an intervention group: the control group receives the conventional treatment, while the intervention group receives the treatment that is hypothesized to be superior. The criteria for evaluation are specified in advance and are monitored prospectively, that is, after a suitable period of follow up, ideally by assessors who are blinded to the intervention a particular patient received. PRCTs avoid problems with selection or treatment bias and so are regarded as the most reliable type of evaluation study.

In the field of CAOS, however, relatively few such studies have been performed. A Medline search for "randomized computer-assisted orthopedic surgery" produced only three articles that described actual PRCTs, while searching for "prospective computer-assisted orthopedic surgery" added only one more. These studies are briefly outlined below; more detailed discussions of the issues raised can be found in the following sections describing particular procedures.

Three of these four studies relate to pedicle screw placement. Richards et al. [2007] reported that a CAOS system enabled junior surgeons to achieve a significantly higher successful placement rate for pedicle screws in a cadaveric porcine model. Seller et al. [2005] performed a prospective intraindividual comparison of pedicle screw placement in 16 patients undergoing spine surgery and also found a significantly increased successful placement rate. Laine et al. [1997] performed a prospective study of pedicle screw insertion, but did not randomize patients; only patients who could not be treated by the CAOS technique were treated conventionally, so the decreased malplacement rate in the CAOS-treated group may have been due to this group being easier to treat than the conventionally treated group.

In the fourth study, Parratte and Argenson [2007] recently reported a reduction in the variance of acetabular cup placement using an image-free CAOS system with no significant difference in the average position relative to the preplanned target orientation. The CAOS procedure took an average of 12 min longer than the conventional freehand procedure.

In summary, there is currently a paucity of evidence for the benefits of CAOS that meets the standard of the prospective, randomized clinical trial, and even the studies of decreased malplacement rates of pedicle screws do not show any significant difference in functional outcomes for patients. Although somewhat discouraging for those advocating adoption of CAOS systems, some researchers believe that PRCTs may themselves not be justified from a cost-effectiveness point of view. For example, Meikle [2005] argues that in the field of dentofacial interventions, PRCTs have not contributed significant new knowledge, but have served mainly to confirm what was already widely believed based on years of clinical experience.

12.4 Practice Areas

This section discusses in more detail four key practice areas in the field of orthopedic surgery where computer-assisted techniques have been developed. These four are:

- 1. Hip arthroplasty total joint and resurfacing
- 2. Knee arthroplasty total and unicompartmental
- 3. Screw insertions pedicle, iliosacral, and femoral neck
- 4. Fracture fragment alignment and distal intramedullary nail locking

In each of these four areas, we discuss the clinical motivation for using computer guidance, describe examples of the major approaches used to address the clinical problem, and provide an overview of the evaluations of the computer-assisted approaches that have been carried out.

12.4.1 Hip Replacement

12.4.1.1 Clinical Motivation

A large number of people suffer from deterioration of the hip joint because of diseases such as osteoarthritis, rheumatoid arthritis, avascular necrosis, ankylosing spondilytis, tumors and trauma. These diseases cause significant pain and loss of mobility, so the impact on patients' quality of life is large. When these conditions have progressed to the point where more conservative treatments such as nonsteroidal antiinflammatory agents are no longer providing sufficient relief, joint replacement is often considered. The original low friction hip replacement was invented almost 50 years ago by Wrightington, England, and has proven enormously successful with implant survival rates sometimes exceeding 90% at 15–20 years [Skutek et al. 2007]. It is also one of the most commonly performed orthopedic procedures with over 230,000 surgeries performed annually in the United States in 2004 [Kozak et al. 2006]. Nonetheless, for reasons such as increasing obesity at younger ages coupled with a general extension in lifespan, an increasing number of patients become candidates for joint replacement at a point where they can still expect to live another 30–50 years. As revision surgery to replace an implant is more difficult than the original procedure, and surgery places older patients at greater risk than younger ones, there is a strong incentive to take every step possible to maximize the lifespan of the implants. Sir John Charnley, an orthopedic surgeon at the Centre for Hip Surgery in

Hip implants have been shown to fail prematurely for three main reasons: infection, instability, and wear. Infection is the most devastating complication of joint replacement, but infection rates are comparatively low.

Brander, for example, cites a rate of under 1% at her institution [Brander and Stulberg 2006] and points out that aseptic techniques, prophylactic antibiotics, including antibiotic-loaded bone cement, [Block and Stubbs 2005] and laminar airflow operating rooms are the most effective ways to prevent infection. Computer-assisted techniques likely will not play a significant role in further reducing these complications, though if they extend the operative time, they may actually increase infection risk.

Instability refers to the tendency of a hip to dislocate following joint replacement and early series resulted in dislocation rates as high as 10% or more [Etienne et al. 1978]. However, a review performed by Masonis and Bourne [2002] of 14 clinical studies conducted over the previous 30 years and involving over 13,000 primary total hip replacement procedures showed lower dislocation rates ranging from 0.55% to 3.95%, depending on the surgical approach (with the highest rates for the posterior approach) showed that rates of postoperative limp were comparable (up to 20%) for the different surgical approaches. A more recent review [Kwon et al. 2006] noted that performing soft tissue repair when a posterior approach was used had a significant impact on dislocation rates, decreasing them from 4.46% to 0.49% (lower than the 2.0% rate reported in Masonis and Bourne), which is comparable to the rates found for two other surgical approaches (0.43–0.7%) when soft tissue repair was performed. It is, therefore, fair to say that dislocation rates are now in the order of 1–2% when performed using optimal modern surgical techniques.

One important factor affecting dislocation rate is the orientation of the acetabular cup [Morrey 1997]. A number of authors have argued for the existence of a so-called *safe zone*; that is, they suggest that there is a range of angular orientations of the acetabular cup associated with a lower risk of dislocations [Lewinnek et al. 1978]. The conventional manual surgical technique produces such highly variable results that surgeons cannot guarantee that the cup orientation is within the desired bounds; for example, Parratte et al. [2007] found that these manual techniques produced a range of 27° in abduction and 37° in anteversion. Jaramaz et al. [1998] have argued that this large range of achieved orientations increases the occurrence of femoroacetabular impingement, reduces the safe range of motion, and increases the risk of dislocation and wear, and conclude that computer-assisted techniques may reduce the rate of occurrence of such problems. However, the low dislocation rate suggests that CAOS techniques may in fact be more beneficial in addressing suboptimal functional outcomes, which have not been so extensively investigated.

Harris [2001] identifies wear as the key long-term problem in total hip arthroplasty. Wear produces small particles, which can induce osteolysis around the implant, with subsequent loosening and failure. Although patient size and activity level can clearly affect wear, obesity by itself does not necessarily increase the risk of early implant failure, possibly because obese

patients also tend to have lower activity levels than less heavy patients [Stukenborg-Colsman et al. 2005]. Impingement and extreme acetabular cup orientations have also been correlated with increased wear rates [Kennedy et al. 1998; Yamaguchi et al. 2000]. It is, therefore, clear that acetabular cup orientation plays an important role in preventing both dislocation and excessive wear. As cup orientation is not well-controlled using conventional manual techniques, there is a motivation for developing computer-assisted techniques.

In recent years, femoral head resurfacing has emerged as an alternative to total hip arthroplasty for younger, more active patients. The larger head enables greater loads to be carried, and by resecting less bone stock, the ability to perform a primary hip arthroplasty at a later date is preserved. Early failures of resurfaced hips have been correlated with varus placement of the implant, and this advice is supported by the results of recent laboratory experiments by our group [Anglin et al. 2007], where we found increased static failure loads when the implant was placed 10° in valgus relative to a neutral position, and by finite element analyses by others [Radcliffe and Taylor 2007]. However, surgeons find it difficult to reliably place the implant in the desired orientation and even harder to place it in an intentionally valgus orientation (personal communication with Dr. Bas Masri, Vancouver Hospital); a recent study found that experienced arthroplasty surgeons take upward of 60 cases to become proficient enough to place the implant within 5° of the targeted orientation [Back et al. 2007], so computer-assisted techniques may find a role in largely eliminating this learning curve.

Minimally invasive procedures for total hip arthroplasty have been developed in recent years to try to decrease soft tissue trauma, reduce postoperative pain, shorten in-patient stays and return to function, and to improve cosmesis. Although these benefits are still arguable, with some studies showing benefits in short-term outcomes such as reduced blood loss and shorter hospital stays [Vavken et al. 2007; Orozco et al. 2007], while other studies suggest that reliable evidence is still wanting [Woolson 2006], there is little debate that these procedures are technically more demanding and offer the surgeon less visibility and access than traditional techniques. The improved visualization offered by computer-assisted techniques may therefore find an important role in minimally invasive procedures if they prove superior to conventional approaches. At least one major trial is currently being planned to address the hypothesis that computer-navigated [Reininga et al. 2007]. (3 months), and to an outcome at least as good 6 months postoperatively MIS will lead to a quicker recovery during the early postoperative period

A final motivation for developing CAS techniques for hip arthroplasty is related to medicolegal concerns. For example, the most common cause of lawsuits following hip surgery is leg-length discrepancy [Attarian and Vail

2005]. Edeen et al. [1995] found that almost a third of patients in a series of 68 patients were aware of the discrepancy, and half of these were disturbed by it. Visuri et al. [1993] showed that leg length discrepancy was linked to an increased risk of a need for revision because of aseptic loosening. As CAOS techniques are able to assess changes in the position of the limb intraoperatively, they can be used to prevent leg-length discrepancy, so potential reductions in legal costs should be weighed in any calculation of the costs and benefits of these technologies.

12.4.1.2 Computer-Assisted Hip Replacement Techniques

Computer-assisted hip procedures can be categorized in two main ways:

- 1. Operative site: does the system address the placement of the acetabular cup (pelvic side) or the preparation of the femoral canal and the positioning of the femoral component (femoral side)?
- 2. Anatomical reference: is the intervention based on preoperative CT images, intraoperative fluoroscopy, or image-free kinematic measures?

In this section, we will consider examples of each type of system.

RoboDoc

The first application of CAS techniques to hip replacements was on the femoral side. In the 1980s, cemented implants were commonly used, but these posed problems such as adverse cardiovascular responses, difficulties positioning the implant prior to the cement setting, and difficulty extracting cement during revision. Cementless implants were developed to address these problems, but bony ingrowth could only occur if the match between the bone cavity and the implant was accurate to submillimetric precision; this was not possible with manual broaching techniques, and fractures commonly occurred if the implant was forced into too small an opening. Paul and colleagues [1992] therefore proposed and developed a robot-based system in which the cavity was milled under computer control by a robot carrying a milling tool. The original system consisted of a CT-based planner (Orthodoc) and a modified industrial robot (Fig. 12.1).

Prior to the surgery, the surgeon could work with the planning station to select an implant and determine the optimal position relative to the femur. Views of the implant could be obtained from any orientation. During surgery, the femur was placed in a bone clamp and a registration procedure performed to be able to map the preoperative plan to the live operating situation. The original registration process used small titanium fiducial markers that were implanted under local or regional anesthetic in a brief procedure prior to the CT scan. During the procedure, the robot is equipped with a special end-effector that mates to the head of these pins so it can be brought into contact with them to identify their spatial position. From these data, the position of the femur in the robot's frame of reference can be calculated, as can the desired position of the femoral cavity. In later years, a pinless registration process was developed (Digimatch) in which points on the surface of the femur were acquired intraoperatively (a process that took approximately 5 min), but even recently this process has been described as "rather cumbersome" and in need of automation [Bauer 2004]. Following registration, the surgeon attaches a milling cutter to the robot, attaches air and irrigation lines, and moves the cutter into position. During autonomous cutting, the surgeon monitors the progress of the cutting and can shut down the process at any time.

For more information on this system and others, the reader is referred to Kazanzides [2007], who presents an excellent overview of a wide variety of robotic devices, which have been used in joint reconstruction.

Kanzanzides, Johns Hopkins University, Baltimore, USA **Fig. 12.1.** RoboDoc in use in Oldenburg, Germany in 1996. Photo courtesy of Peter

HipNav

The potential for using CT images to control acetabular cup orientation was recognized at roughly the same time as the beginnings of RoboDoc [Mian et al. 1992], and navigation systems based on CT imaging emerged in the mid to late 1990s. The HipNav system from DiGioia and his colleagues in Pittsburgh was one of the first examples of this kind of system [Jaramaz et al. 1998]. In the HipNav system (Fig. 12.2), both the acetabular and femoral component positions were planned using a 3D planning workstation loaded with a patient's preoperatively acquired CT scan. Effects on leg length and hip offset were computed and presented to the surgeon so that the preoperative plan could be optimized. A new feature was a simulation of the range of motion of the hip. This allowed the surgeon to check for predicted impingement of the joint during a range of physiologically realistic situations such as sitting, stair-climbing, and walking.

prosthesis on the pelvis. Image courtesy of Branislav Jaramaz, Robotics Institute, Carnegie Mellon University, Pittsburgh, PA **Fig. 12.2.** Screenshot from HipNav planner showing predicted impingement of the

Intraoperatively, an optical tracker is attached to the pelvis near the iliac crest to monitor movement of the bone during surgery. The pelvis is registered to the preoperative plan using a 3–5 min long surface point acquisition procedure in which points around the acetabulum, the sciatic notch, and the iliac crest are acquired with an optically tracked pointer probe (the latter percutaneously). The insertion tool for the acetabular cup is also tracked, which permits its position to be displayed on the screen as the surgeon aligns it prior to pressfitting the cup into place. In early versions of the system, the femoral reamer was not tracked, although the capability to do so was built into the system from the beginning.

Fluoroscopy-Based Procedures

The research group at the Müller Institute in Bern developed a CT-free navigation system for acetabular cup placement [Zheng et al. 2002] that was based on a hybrid combination of direct landmark digitization and use of virtual fluoroscopy. Virtual fluoroscopy is a technique in which two or more calibrated fluoroscopic images are taken at an angle to one another, which allows optically tracked tools to be located relative to the original images and projected into these images in real time, producing the effect of taking a continuous X-ray image. Using this technique, the pelvic landmarks are identified to define the anatomical reference planes, and the acetabular cup insertion tool is monitored in real-time on the virtual fluoroscopic images.

Image-Free Procedures

Although not much discussed in the research literature, various CAOS companies have introduced image-free hip arthroplasty techniques, as have a small number of independent developers (see Dorr et al. [2005] for one example). A commercial example is the Stryker Hip Navigation System (Stryker Leibinger, Freiburg, Germany) that offers a landmark digitization technique in which the key landmarks (anterosuperior iliac spines (ASIS) and both pubic tubercles) are digitized percutaneously [Nogler et al. 2004].

Hip Resurfacing

Two main CAOS techniques have been described for hip resurfacing.

- 1. OrthoSOFT and Brainlab have both introduced an image-free pointbased surface digitization approach, in which points are acquired on all aspects of the femoral neck, with a particular emphasis on the superior aspect of the neck where notching may potentially occur.
- 2. Our group has developed an approach on the basis of the surgeon using preoperative plain film X-rays to determine the desired valgus/varus angle, and then rapidly transferring this plan to the patient intraoperatively using an optically tracked registration plate [Hodgson et al. 2005, 2007].

Ante/retroversion is determined intraoperatively in both systems; with the commercial systems, the proposed axis position is shown relative to the acquired points, and the surgeon adjusts the targeted axis until satisfied. With our system, the version is determined by acquiring estimated vertical center lines along the femoral neck using a tracked caliper and fitting a line to where these center lines pierce an anteroposterior plane lying at the desired valgus/varus orientation (Fig. 12.3).

 Once the desired orientation has been found, the surgeon places an optically tracked drill guide against the head of the femur, orients it using a computer-based targeting display, and drills a guide pin along the indicated axis. The rest of the procedure proceeds conventionally.

along the neck in the author's femoral head resurfacing system **Fig. 12.3.** Tracked caliper applied to femoral neck during acquisition of center lines

Evaluation

For the most part, the various hip arthroplasty systems have been relatively well evaluated from a technical point of view. Quantities such as accuracy and repeatability have been reported for a variety of systems. Perhaps one of the most detailed and comprehensive technical evaluations performed to date is that of the fluoroscopy-based Medtronic StealthStation Treon Plus system, which was assessed by an independent research group [Stiehl et al. 2005]. In their assessment, they used a National Institute of Standards and Technology (NIST) traceable coordinate measuring machine (CMM) to determine the location of an acetabular cup implanted in a nominal position of 45° inclination and 17.5° anteversion. They found that the CMM method had a repeatability of 1.1° in inclination and 0.4° in anteversion. The intrasurgeon repeatability was 1.5° in inclination and 3.0° in anteversion, which was similar to the intersurgeon reproducibility of 0.9° in inclination and 2.5° in anteversion, which indicates that the technique is relatively insensitive to who is using the system. The increased variability in the anteversion direction was suggested to be due to difficulties in predictably identifying the relevant anatomical points from the fluoroscopic image. This same investigator was involved in a later study [Stiehl et al. 2007] that used a similar evaluation protocol to compare both fluoroscopic and image-free navigation methods against CT and CMM-based reference methods. The CT technique produced excellent repeatability (better than the CMM-based method). The results for the fluoroscopic-based system were comparable to the earlier study, but the reproducibility of 0.8° in inclination and 1.1° in anteversion. Based on the Six Sigma Cp and Cpk capability indices, they concluded that the image-free technique was significantly better with an intra-surgeon repeatability of 0.5° in inclination and 0.8° in anteversion and an inter-surgeon

image-free system was "process capable," but that fluoroscopic referencing posed problems for controlling anteversion.

In comparison with conventional manual acetabular cup placement techniques, navigated techniques do appear to reduce the variability in cup orientation. Nogler et al. [2004], for example, shows a significant reducetion in variability of cup placement when using the commercial image-free navigation system described earlier (Fig. 12.4); the 90th percentile limits spanned a much larger range for the conventional procedure (16*°* inclination; 19° anteversion) than the navigated procedure (4° inclination; 7° anteversion).

Stryker Hip Navigation System. *Cross-bars* indicate the 90th percentile limits. Data derived from Nogler [2004] **Fig. 12.4.** Comparison of variability of cup placement when using the image-free

Similarly, [Kalteis et al. 2006] showed reductions in the ranges of acetabular cup orientation when using two navigated techniques: one CTbased and one image-free (both available as part of the Brainlab VectorVision hip 3.0 system (BrainLAB, Heimstetten, Germany). With the manual technique, the standard deviation was 7° in inclination and 14° in anteversion, whereas the comparable figures were 4.0° in inclination and $5.3-5.5^{\circ}$ in anteversion for the two navigated techniques. Figure 12.5 shows that 53% of the cups positioned manually lie outside the *safe zone* defined by Lewinnek, whereas only 7% and 17% of those positioned by the image-free and CTbased techniques, respectively, lay outside this zone. Kalteis also reported

that the image-free and CT-based systems took slightly longer than the manual technique at 7 and 17 min, respectively.

These orientation results are consistent with several other studies quoted by Kalteis: both Saxler et al. [2004] and DiGioia et al. [2002] found that three quarters of manually implanted cups were malpositioned, and numerous other authors have found reductions in variability with CT-based techniques [DiGioia et al. 1998; Leenders et al. 2002; Jaramaz et al. 1998; Widmer and Grutzner 2004].

Von Recum et al. [2003] (see also Wentzensen et al. [2003] for an earlier report of the first portion of this patient series) evaluated a hybrid fluoroscopy/digitization technique (part of the SurgiGATE application by Medivision) and showed in a series of 256 patients that the variability in cup placement as evaluated by a postoperative CT analysis was relatively low: 3.0° in inclination and 3.9° in anteversion. The authors concluded that this technique was equivalent in performance to the established CT-based systems.

On the basis of the studies summarized earlier, we can conclude that there is evidence that both fluoroscopy-based and image-free navigation techniques can produce acetabular cup alignment results that are comparable

Lewinnek when using the conventional freehand (*open circle*) and two navigated techniques: CT-based (*filled circle*) and an image-free technique (*filled triangle*). Derived from Kalteis et al. [2006] Fig. 12.5. Positions of acetabular cup relative to the "safe zone" defined by

to those produced by CT-based systems. Hube et al. [2003] also compared a fluoroscopy-based system with a CT-based system and concluded that there was no difference in final alignment variability (although there was a slight increase in operating time relative to manual techniques; 9 and 13 min for the CT and fluoroscopy-based systems, respectively). Given the lack of difference in performance and the need for a separate preoperative scan and planning process with the CT-based system, these authors recommended reserving CT-based interventions for cases with significant congenital or posttraumatic abnormalities.

To date, there have been no studies attempting to show improved functional outcomes from using navigated acetabular cup placement techniques, so it is unclear whether the improvements in repeatability achieved to date will be sufficient to justify widespread acceptance of computer-assisted approaches. A small number of studies have identified factors contributing to the final implant orientation error, and such models will be useful in future if further refinements to the techniques become necessary [Wolf et al. 2005a; Tannast et al. 2005].

While the potential for computer assistance with femoral side of a total hip arthroplasty has been recognized for some years [Noble et al. 2003], there has to date been comparatively little evaluation of the outcomes following computer-assisted interventions on the femoral side. Lazovic and Zigan [2006] report that the commercially available Orthopilot system proved useful in inserting short stem prostheses with modular necks by helping to control leg length and femoral head offset.

The RoboDoc system has undergone more scrutiny. Several authors (e.g., Nishihara et al. 2004; Schneider and Kalender 2003] have demonstrated that the robot has indeed been able to improve the shaping of the femoral cavity, with accuracies of better than 1 mm. Bauer [2004] reports that the operating room time requirement has stabilized at about 90 min (20– 30 min longer than the manual technique), that there is some evidence of earlier weight bearing and faster rehabilitation, and that intraoperative fractures could largely be avoided. Honl et al. [2003] reported on a prospective randomized study involving 154 patients that found that the RoboDoc system did improve the accuracy of the implantation, but that its use was associated with higher early revision rates, higher dislocation rates, longer surgery, an increased amount of muscle damage, and an increase in operating room cost of approximately \$700. They concluded that the system required further development before it could be widely recommended. The results of 10-year follow ups will be available shortly as 3,800 cases were performed in Germany between 1994 and 1998.

With regard to computer-assisted femoral head resurfacing, very few results are yet available as the technique has been in use for only about 2 years. In our first cadaver study [Hodgson et al. 2005], we found that our CAOS technique had a standard deviation of only 2.2° in the varus/valgus

direction in the hands of residents, compared with 5.5° for the conventional manual procedure performed by expert surgeons; the time needed to align the drill guide was comparable in the two cases, despite the difference in experience level, which suggests that a CAOS approach could enable surgeons to avoid the 60-case learning curve described by Back (2007). As a change in orientation of 10° can cause a 28% change in static failure load [Anglin et al. 2007], surgeons would like to be able to control placement to difference in the mean implant alignment relative to the femoral shaft between a group of successful and problematic resurfacing patients was on the order of 6°, which suggests that it may be beneficial to control the implant's accuracy of placement to even less than this value. an accuracy substantially better than this. Beaulé et al. [2004] found that the

Davis et al. [2007] showed that a CAOS technique reduced the range of implant placement from 12° with the manual technique to 8° with the CAOS technique. However, to date there have been no reports of functional outcome data. Kruger et al. [2007] compared 9 patients treated with a CAOS technique to 9 with a manual approach and found no statistically significant difference in femoral component orientation.

12.4.2 Knee Replacement

12.4.2.1 Clinical Motivation

The knee is subject to the same kinds of degenerative processes as described earlier for the hip, and in fact has become the most commonly replaced major joint. According to a projection presented at the 2006 American Academy of Orthopedic Surgeons Annual Meeting that was based on combining National Inpatient Sample data from 1990 to 2002 with census data to estimate demographic trends, primary total hip replacements in the United States are likely to increase from a little over 200,000 in 2005 to 450,000 by 2030 [Kurtz et al. 2006]. More dramatically, primary total knee replacements are expected to grow from 430,000 in 2005 to what the authors describe as a *staggering* 2.2 million procedures by 2030. Revision hip procedures will rise from 41,000 in 2005 to almost 100,000 in 2030 (roughly 20%), while revision knee procedures will increase even more dramatically from 37,000 in 2005 to almost 200,000 in 2030 (under 10%). Hernandez et al. [2006] estimates the average cost of these total knee revision surgeries at \$56,000 each, so hospital costs for revisions could exceed \$10 billion per year by 2030. To accommodate this massive increase in demand, significant improvements in both operative efficiency and implant longevity will be required.

Total knee replacement, like total hip arthroplasty, is considered to be an excellent surgical procedure. Sorrells and Capps [2006] reviewed the outcome date for primary, cementless, low-contact stress, total knee

arthroplasty and found that fewer than 1% had patellar difficulties or significant radiological evidence of joint failure, and that over 99% of patients had good to excellent knee scores at follow up. Buechel et al. [2002] evaluated 233 cemented and cementless rotating platform knee replacement implants with a minimum 10-year follow up period and found a survivorship of 98% at 10 and 20 years, with 47% having excellent results in the cemented group and 68% in the cementless group. Different implants have been developed to better approximate the natural kinematics of the knee, but the clinical results are similar (Hospital for Special Surgery knee scores of 89.4 vs. 88.6) [Kim et al. 2004]. Other studies report similarly excellent results (e.g. Papachristou et al. [2006]), although these studies are likely drawn from centers with extensive experience in performing TKAs; the overall revision rate of roughly 10% reported by Kurtz et al. [2006] suggests that not all surgeons are capable of obtaining such results; this figure is in line with the results at 10 years of follow-up from the Swedish Knee Arthroplasty Registry [Robertsson 2001]. Indeed, there is evidence that revision rates are strongly linked to the volume of surgeries a surgeon performs (NIH Consensus Statement 2003). Callahan et al. [1994] presented complication rate was 18%, and the overall rate of revision at an average of 4.1 years was 3.8%. In a different international multicenter study of 4,743 primary total knee arthroplasty with mobile bearing design, the overall survivorship at 16 years' follow up was 79%, and revisions were performed in 5.4% of the knees [Stiehl et al. 2006b]. Approximately half the revisions (2.3%) were due to bearing-related issues such as instability, wear or dislocation. Similar problems occurred in significant proportions of revision cases treated in Canada in 2004 [CJRR 2004]: aseptic loosening (39%), poly wear (36%) , instability (26%) , and osteolysis (20%) . a meta-analysis of 130 studies with a total of 9,879 patients. The mean

Despite these successful survival results in well-established surgical centers, we cannot conclude that there is no potential for improvement. When patients are asked about their postoperative experience, not all are satisfied. Hawker [2006] reported that up to 30% experience a suboptimal outcome or are otherwise dissatisfied with the results. Callaghan et al. [2000] reported 100% implant survival at 9–12 years, but found that 10% of the patients in that study experienced anterior knee pain. In another study, Brander and Stulberg [2003] found that 44% of their patients report moderate to severe pain one month after surgery, declining to 13% at one year. Resurfacing the patella plays an important role in avoiding anterior knee pain – several recent metaanalyses have shown that anterior knee pain occurs in over 20% of patients whose patellas are not resurfaced (range: 21–24%), but in less than 10% of patients whose patellas are resurfaced (range: 6–12%) [Nizard et al. 2005; Parvizi et al. 2005; Pakos et al. 2005] – but has not entirely eliminated the problem.

Postoperative range of motion (ROM) of the knee is important for function, particularly for being able to rise from sitting, but according to Jones et al. [2007], the link between ROM and measures of well-being or patient satisfaction are not well-established, even though various other quality of life measures related to social function, mental health, and vitality do increase postoperatively.

Even though knee replacement does reduce pain and increase mobility, patients rarely recover to the level of health exhibited by age and sexadjusted control groups who have not required surgery [Jones et al. 2007], and TKR patients do not experience as much of an improvement as THR patients. There is also considerable evidence that surgeons express more satisfaction with patients' result than the patients themselves. Overall, as many as 15–30% of patients report "little or no improvement after surgery or are unsatisfied with the results after a few months" [Jones et al. 2007].

In summary, then, modern total knee replacement procedures produce extremely high success rates, which poses a challenge to developers of computer-assisted techniques to demonstrate impact. However, it is widely accepted by surgeons that implant loosening is more common when the alignment of the implant is off neutral. This finding was first reported by Rand and Coventry [1988], who found that the 10-year survival rate of a geometric total knee implant was 73% if the knee was in varus, 90% if in up to 4° of valgus, and 73% if between 5° and 9° of valgus. Jeffery et al. [1991] found that the incidence of loosening at up to 12 years' follow up was 3% if the line connecting the hip and ankle centers passed through the middle third of the prosthesis (approximately $\pm 3^{\circ}$ from neutral), but 24% if outside this zone. Other research found that 5/35 patients with varus alignment required revision, $3/234$ patients with $0-4^{\circ}$ of valgus, and $0/82$ patients with more than 4° of valgus [Ritter et al. 1994].

In addition to the issue of varus/valgus alignment, surgeons must ensure stability of the reconstructed knee joint complex to provide satisfactory function for the patient. Otherwise, patients experience their knees giving way during loading. Stability is primarily governed by the collateral ligaments and the posterior cruciate ligament (or equivalent with PCLsacrificing implant designs). The primary task for the surgeon is to ensure that the gaps between the prepared femoral and tibial bone surfaces are rectangular and equal in both flexion and extension. Griffin et al. [2000] showed that careful attention on the part of the surgeon can generally ensure that the gaps are rectangular in both flexion and extension (84–89%), but that it is considerably more difficult to ensure that they are equal (roughly half were within 1 mm); any resulting differences can lead to either laxity or tightness at different points in the flexion cycle.

A third important consideration that has not received much attention among CAOS system developers until recently has been patellofemoral instability, which can occur when the line of action of the quadriceps tendon pulls the patella too far laterally, particularly close to extension; this can result in subluxation of the patella and knee pain [Kelly 2001]. Parker et al. [2003] and Eisenhuth et al. [2006] both state that patellofemoral complications are the most common cause of postoperative pain and of revision. Avoiding these problems requires careful attention to implant alignment and soft tissue balance.

12.4.2.2 Computer-Assisted Knee Replacement Technique

In knee replacement surgery procedures, the surgeon typically makes a transverse planar cut across the superior aspect of the tibia, followed by a set of five cuts at the distal end of the femur: a distal cut, which determines the varus/valgus orientation of the implant, an anterior and a posterior cut, which determine the rotational orientation of the implant, and two chamfer cuts to accommodate the implant. In addition, a box cut is typically made to accommodate stabilizing lobes designed to augment or replace the function of the cruciate ligaments. In the conventional manual procedure, these cuts are made by using mechanical instruments to position a cutting block (or cutting guide) against the bone, pinning it in place with so-called Kirchner (K) wires, and then inserting an oscillating saw through a slot in the cutting guide to actually make the cut.

Historically, the first goal of CAOS systems for the knee was to control the varus/valgus (or coronal plane) alignment. In subsequent years, it has been increasingly important to control the rotation as well, as that determines the soft tissue balance. As with the hip, several different types of CAOS systems have been developed for total knee replacement surgery. There are two major types of TKA systems: CT-based systems in which a preoperative scan is acquired for planning, and image-free systems in which the key anatomical landmarks are identified intraoperatively (although, as with hip surgery, fluoroscopy-based systems have also been developed). We briefly present examples of each type of system.

Image-Free

One of the most popular types of CAOS system for TKA is an image-free system. This type of system was originally developed over 12 years ago at the Université Joseph Fourier in Grenoble and has since evolved into a variety of different commercial systems. Stulberg et al. [2004] describes a surgical technique on the basis of the Aesculap Orthopilot system. With image-free systems, no preoperative planning is necessary as all anatomical landmarks are determined during the surgery. After conventional draping and exposure, optically tracked marker arrays are attached to the femur and tibia, and optionally to the pelvis. To position the prosthetic implant, the surgeon must identify key anatomical landmarks, particularly the hip center, the ankle center, and landmarks around the knee such as the medial and lateral epicondyles; these allow the system to determine the appropriate rotational orientation for the implant.

The first step in the procedure is to identify the center of rotation of the femoral head. This is accomplished by rotating the femur relative to the acetabulum such that each marker will trace out a path on a surface of a sphere centered on the femoral head. By applying an optimization algorithm to the collected data, the computer is able to calculate an offset vector relative to the femoral marker array that moves least in the pelvic reference frame. This approach is known as a kinematic registration technique.

A similar approach is used to identify the ankle center. A marker array is strapped to the foot and the foot taken through a series of flexion and abduction motions. Alternatively, the ankle center may be found by directly digitizing the medial and lateral malleoli and using the geometric center as an estimate for the ankle center. The knee joint is also flexed, which allows the system to estimate the preoperative axis of rotation of the joint; this is later used as a rotational reference for the femoral component. Several points on the surface of the joint are also acquired for use in setting the joint line and the anteroposterior placement of the implants. On the tibial side, the deepest point on the least damaged side of the plateau is digitized as a reference for the tibial resection depth. The intercondylar eminence is also digitized as a reference for mediolateral placement of the tibial component.

On the femoral side, the posterior aspects of the two condyles are digitized, along with the anterior surface of the femur. This latter point is used to prevent anterior notching. Finally, the origins of the medial and lateral epicondyles are digitized to aid in determining the rotation of the femoral component.

Once these measurements are made, the computer has enough information to construct reference frames and define the desired locations of the bone cuts. The tibial cut is made after placing a slotted cutting block against and pinning it in place. The femoral cuts are made in two stages: first, a made; then a second cutting block is mounted to the resected bone, positioned to ensure that the implant's rotational alignment will be correct, and the balance of the procedure proceeds as with the conventional manual procedure. the anterior surface of the tibia, positioning it under computer guidance, distal cutting block is positioned under computer guidance and the distal cut the anterior, posterior, and chamfer cuts made. Following a trial reduction,

Numerous variants on this basic approach are used in other systems. The methods of identifying the hip and ankle centers may vary, and there is considerable debate as to the most appropriate reference for controlling the femoral component's rotation; the transepicondylar axis, the perpendicular to the so-called Whiteside's line (an anteroposterior line drawn through the femoral notch), and an offset from the posterior condylar line have all been proposed [Siston et al. 2006]. Many surgeons advocate using a direct evaluation of the flexion and extension gaps instead of an explicit geometric reference, because this will relate more directly to function (some systems incorporate some measure of soft tissue balance into their workflows, either manually or with a special tensing device) [Marmignon et al. 2005]. Other systems use the bone-morphing technology described earlier to create a full 3D model of the distal femur, and the surgical plan is defined in relation to this morphed model instead of on the basis of digitized points (Fig. 12.6).

An interesting variant on this image-free system is a technique known as Navigated Freehand Cutting in which the cutting blocks are dispensed with altogether and the surgeon simply places the saw against the bone and relies only on the computer screen to position it correctly [Haider et al. 2007]. The developers of this technique have demonstrated in a cast-foam model that the cutting time is decreased by 15% and the overall alignment of the implant is significantly improved, albeit at the cost of increased surface roughness of the sawn bone models.

free navigation application, based on bone-morphing algorithm. Used with per-**Fig. 12.6.** Screenshot from Praxim-Medivision Total Knee Surgetics (TKS) imagemission.

CT-Based

A number of authors, including our group, have identified significant errors related to the bone sawing process [Plaskos et al. 2002] and have recommended using milling techniques instead. A group of researchers at Imperial College in London has designed a robot that carries a milling tool to perform both unicompartmental and total knee arthroplasty procedures and has

coupled their robot with a CT-based surgical planning system [Davies et al. 2007]. Their philosophy is that a preoperative CT scan is justified because of the opportunity it presents to create a full 3D preoperative plan. The primary justification for such a system is to enhance unicompartmental knee replacements, where it is more difficult to gain access to the bone and to properly visualize its orientation underneath the overlying tissue.

The distinguishing feature of their robot, which is known as ACROBOT (Active Constraint ROBOT), is that it does not operate under autonomous control, but in a servo-enhanced cooperative mode in which the surgeon operates a handle located close to the milling tool and the robot interprets forces applied to the handle as instructions to move in the indicated direction. Because the motors are backdrivable, the surgeon can sense when the tool encounters changes in the environment, such as a sudden change in bone density. In addition, there is a supervisory level built in, predefined as safe. This feature can be used, for example, to avoid cutting the collateral ligaments. In use, the robot is wheeled into the operating theatre and the base put into position using a four degree of freedom gross positioning unit. The tibia and femur are immobilized using clamps that penetrate through 5 mm incisions and engage with the bone. Registration is performed by attaching a small ball-ended probe to the robot's end effector and touching several dozen points on the bone surface; these are matched to the preoperative CT model. which prevents the robot from moving outside of zones that have been

The ACROBOT is not the only robot that has been developed for use in TKA surgery. Siebert et al. [2002] describes the modification of a commercially available robot (CASPAR) for use in TKA procedures. Both

during a cutting trial in 2006. Photo courtesy of Dr. Jacques Rit of Center Hos-**Fig. 12.7.** Praxiteles miniature bone-mounted robot mounted to a cadaveric knee pitalier Princesse Grace, Monaco.

our group [Plaskos et al. 2005] and a group in Pittsburgh [Wolf et al. 2005b] have recently developed miniature bone-mounted robots to facilitate both the standard TKA surgical exposure and less invasive approaches (Fig. 12.7).

Evaluation

As with total hip arthroplasty, the impact of computer assistance in total knee arthroplasty has largely been demonstrated on the basis of technical measures such as the accuracy of varus/valgus (coronal) alignment. Lüring et al. [2006], for example, identified six prospective and randomized clinical studies with more than 30 patients per group that met the requirements for being a level 1 or level 2 study. They consolidated all these data from these six studies and found that 95% of the 375 implants placed using navigation had a mechanical axis alignment that was within the 3° window commonly used to define optimal placement, compared with 82% of the same number of implants placed conventionally. In the sagittal plane, only two of the six studies demonstrated improved alignment of the femoral component. On average, the CAS technique took 20 min longer than the conventional procedure (range: 15–40 min). The authors point out that the alignment results should be judged somewhat critically because the standard method used to evaluate alignment is the weight-bearing, long-leg X-ray, which can introduce errors of up to 4° in the estimated varus/valgus angle.

A slightly more recent study by this same group [Bäthis et al. 2006] involving 1,784 implants reached similar conclusions. Of the 919 CAS implants from 13 studies, 94% were within the optimal 3° window, compared with only 76% of the 865 conventional implants. No remarkable differences in any other clinical indicators were found.

from 33 studies, including 11 randomized trials [Bauwens et al. 2007]. The principle finding of this study was that the relative risk of the mechanical alignment being outside a 3° window from the desired neutral value when a computer-assisted technique was used was less than 80% of the risk for the manual technique. Assuming that the risk of being outside this window using the manual technique is similar to the studies reported above (i.e., 18– 24%), we would expect that CAOS procedures would reduce this by approximately 5%, which appears to be a lower benefit than was found by Lüring or Bäthis. Bauwens also reports that the mean duration of surgery was increased from 73 to 90 min when using CAOS techniques. Only four of the studies investigated functional assessment and no consequential differences were found, with the possible exception of some evidence of improved stiffness scores with CAOS. The most comprehensive meta-analysis to date involved 3,423 patients

From these assessments, we can conclude that CAOS systems have generally proven to produce better coronal alignment outcomes, although little evidence of impact on other functional measures, such as pain or

ability to perform various activities of daily living has been produced. This general picture was recently echoed by Ulrich et al. [2007] in an overview of the scientific evidence supporting computer-assisted surgery for TKA. Ulrich concluded that there was sufficient evidence to justify some expectation of increased success in future, and that this has proven to be enough to motivate manufacturers to develop appropriate surgical tools and updated designs to take advantage of CAOS capabilities. Holt et al. [2006] concurred, and argued that from an ethical point of view, there is sufficient merit to CAOS systems to justify their use on the grounds that they produce at least technically equivalent results. In contrast, Holt regarded the evidence for minimally invasive techniques as insufficient to support widespread use, because of a higher likelihood that long term outcomes would not be as good as those of the current technique.

Davies et al. [2007] notes that concerns about the cost-effectiveness have only recently been recognized. Dong and Buxton [2006] recently applied one of the first economic benefit analyses of computer-assisted surgery to total knee arthroplasty, albeit with a number of assumed values for key estimates of probabilities of different outcomes. Using reasonable point estimates, they showed the potential for CAOS techniques to save over \$1,000 per operation when potential reductions in revision procedures were verified in longer term studies. To strengthen the case for adopting CAOS systems for TKA, more attention must be paid to measuring the impact of more consistent and accurate implant placement and soft tissue balancing on the patient's quality of life. To whatever extent is possible, these impacts should also be assessed in economic terms so that their value may be evaluated against any increased costs because of the use of the CAOS system. Time savings should also be sought whenever possible. Darmanis et al. [2007] showed that paying attention to simple details such as providing feedback via a laser pointer as to where the optical tracker is pointed can save significant amounts of time; in this case, they saved 11 min using this simple innovation alone. taken into account, although they admitted that this reduction needed to be

Finally, given the discrepancy between revision rates in the most successful case sets reported (in the order of 0–2% at 10–20 years) and the actual number of revisions performed in the United States each year resulting in revision are performed by surgeons with lower case volumes ficant economic obstacle, because in order for them to be adopted in the surgical settings where they will likely do the most good, that is, in community hospitals where surgeons do a relatively low number of TKAs annually, the system costs must be proportionately lower to induce the surgeons and hospitals to purchase the equipment. [Kreder et al. 2003]. If this is the case, then CAOS systems face a signi-(~8%; Kurtz et al. [2005]), we hypothesize that many of the cases ultimately

12.4.3 Pedicle Screw Insertion

12.4.3.1 Clinical Motivation

A variety of spinal injuries, as well as disorders resulting from congenital vertebral collapse, arthritis, spondylolisthesis, and tumors, can potentially benefit from a treatment known as spinal fusion. In spinal fusion, two or more adjacent vertebrae are fixed relative to one another and bony connections are allowed to form between them so as to prevent further relative motion, thereby reducing or eliminating pain and reducing the risk of future compromise of neural function or paralysis. deformities such as scoliosis, or progressive conditions such as osteoporotic

Historically, a variety of different kinds of hardware (known as instrumentation) was used to secure one vertebra to another. These included hooks, sublaminar wires, and anterior screws. In recent years, however, pedicle screws have come into widespread use, particularly for the lumbar and thoracic spine, and are commonly regarded as offering mechanical fixation superior to these other instruments [Van Brussel et al. 1996]. The screws, however, must be inserted into the vertebra's pedicles, the channels of bone connecting the anterior vertebral body to the posterior spinal processes and which pass around and enclose the spinal cord. When inserting the screws with conventional freehand or fluoroscopically guided techniques, there is a significant risk of perforating the pedicle and damaging either the nerves passing out of the spinal cord above and below the pedicle or the spinal cord itself if the screw perforates the medial wall of the pedicle. The misplacement rate can vary significantly from institution to institution, and rates as high as 40% have been reported [Castro et al 1996]. However, the significance of this is uncertain. Kim et al. [2004] reported on the safety of over 3,200 freehand pedicle screw placements in the thoracic spine using a palpation technique, and found that, although the cortical perforation rate was 6.2%, they experienced no neurological, vascular, or visceral complications at up to 10 years follow up, and so concluded that this technique was safe and reliable. Similar safety records have been obtained by others [Faraj and Webb 1997]. Overall, outcomes are generally good; Rivet et al. [2004], for example, reported that 73% of a group of 42 consecutive patients experienced a good or excellent outcome as measured by the modified Prolo scale and that 90% of patients would choose to undergo the procedure again.

Perhaps the most detailed look at the outcomes associated with spine surgery on a broader scale was that carried out by the Japan Spine Research Society in 2004 [Nohara et al. 2004]. They surveyed the outcomes of over 16,000 spine patients from nearly 200 institutes during the year 2001. Spinal instrumentation was used on just over one third of this patient group, and pedicle screws were used in 55% of these cases. The most common clinical indications for instrumentation surgery were spinal deformity, trauma,

rheumatoid arthritis, osteoporotic vertebral collapse, spondylolisthesis, and spinal tumors. Instrumentation was employed roughly twice as frequently in the lower thoracic region $\left(\frac{25}{6}\right)$ of the time) as in the upper thoracic and cervical regions (35–38% of the time).

Overall, the complication rate for instrumentation surgery was 12.1%, with lower rates of about 6% for decompression procedures and higher rates of 12% for fusion, or fusion with decompression, and 17% if fusion was combined with correction or reduction. Complication rates were not specifically coupled to the choice of instrumentation in this report, but the four most common complications across the entire cohort of 16,000 patients (representing approximately 55% of all complications) were neurological complications (1.7% of the cases), dural tear and fluid leakage (1.4%), infection (0.9%), and instrumentation failure (0.5%). Neurological complications produced a residual disorder in 40% of patients, whereas 90–93% of those suffering dural tears or infection experienced significant or complete recovery. On the basis of this study, we can conclude that it is highly likely that there were a significant number of patients who suffered persistent neurological complication from misplaced pedicle screws.

An additional consideration in pedicle screw surgery is the radiation exposure experienced by the patient and the surgical team, but particularly the latter as they are subject to radiation on an ongoing basis whereas the patient is exposed on a single occasion. As imaging techniques have been more commonly used in orthopedic surgery, there has been increased concern about the radiation exposure surgeons face [Dewey and Incoll 1998; Hynes et al. 1992], with the hands of the orthopedic surgeon being particularly at risk [Gwynne Jones and Stoddart 1998; Smith et al. 1992].

12.4.3.2 Computer-Assisted Screw Insertion Techniques

As with the arthroplasty procedures, computer-assisted screw insertion techniques can be based on intraoperative fluoroscopy or preoperative CT scans, or can be performed image-free. In this section, we present examples of two image-based techniques.

One of the earliest CAOS pedicle screw insertion techniques was a CT-based approach described by Amiot et al. [1995], who reported promising results on a set of three sheep vertebrae and successfully drilled five of the six targeted holes. The estimated accuracy of the system was reported to be 4.5 mm and 1.6° RMS. A more recent description of a CT-based system is found in Gebhard et al. [2004]. In the system described there, the patient undergoes a preoperative CT scan, which is used initially in a preoperative planning process, and is then transferred to the operating room for the surgery. Intraoperatively, the surgeon attaches a dynamic reference frame to each vertebra that is to have a pedicle screw inserted, uses a tracked pointing tool to digitize a set of 4–5 index points that have been previously identified on the CT image, along with another dozen or so points

distributed across the visible surface of the vertebra, and a combination paired-point/surface matching registration algorithm is executed. The Thandle used to orient and drive the pedicle is then either positioned according to the preoperative plan or tracked in real-time to allow the surgeon to choose the final trajectory on the fly.

Gebhard also describes a C-arm-based technique on the basis of the concept of *virtual fluoroscopy*, originally introduced by Foley et al. [2001]. Virtual fluoroscopy is a clever way to provide the surgeon with the effect of having continuously updated fluoroscopic images from multiple simultaneous perspectives, even though the fluoroscopy machine is not active. This effect is achieved by taking two or more calibrated fluoroscopic images from multiple viewing directions, computing their spatial locations, tracking one or more surgical tools using an optical tracking system, computing the location of the tracked tool(s) relative to the known positions of the fluoroscopic images, and overlaying a representation of the surgical tool onto these images in real-time. In the context of pedicle screw insertion, the surgeon can manipulate a tracked insertion tool and view an instantly updated representation from multiple perspectives of where the screw is relative to the vertebra. In most systems, the axis of the screw can be projected forward from its current location, which assists in targeting the screw.

Related CAOS systems have also been applied to similar screw insertion procedures at the pelvis (iliosacral screw insertions) [Kahler and Zura 1997; Kahler and Mallick 1999; Schep et al. 2004] and the hip [Hamelinck et al. 2007].

As with total knee arthroplasty, some researchers believe that there is an advantage to be gained by using small bone-mounted robots to assist with the surgical intervention. Barzilay et al. [2006] described the design and use of a miniature robot that can be attached to the posterior processes of the spine to position a drill guide. This system was used in nine surgical cases and several relatively minor implementation issues were identified, which the authors expect to address in future cases.

12.4.3.3 Evaluation

The major technical outcome described for pedicle screw insertion techniques presented to date, Kosmopoulos and Schizas [2007] reported on 130 studies over the past 40 years involving over 37,000 pedicle screw insertions in both live patients, and cadavers implanted using both conventional and navigated techniques. Overall, 90% of the screws were considered accurately placed amongst 12,299 screws placed in patients using a conventional technique (32 studies), while over 95% of 3,059 screws placed under navigation were accurately placed (21 studies) (Fig. 12.8), so the general claim that navigation systems improve pedicle screw placement appears to be substantiated. is the rate of cortical perforation. In the most comprehensive meta-analysis

Similar advantages for CAOS systems have been found in detailed laboratory studies. For example, Arand et al. [2006] showed that CT and fluoroscopy-based systems were generally superior to the conventional procedure, although they caution that neither type of CAOS system can offer submillimetric accuracy and conclude that it is unrealistic to expect these systems to completely prevent perforation of the pedicle's cortex.

(21 studies) or a conventional (32 studies) technique. *Cross bars* indicate maximum, median, and minimum results (excluding the single worst study in each group) and the *boxes* indicate the interquartile ranges (25th to 75th percentile results). Data derived from Kosmopoulos and Schizas [2007] **Fig. 12.8.** Percentage of pedicle screws accurately placed using either a navigated

Although no studies to date have demonstrated a decrease in neurological complication rates, there are studies that have shown reduction both in the amount of radiation used during surgery, and in the time taken. Sasso and Garrido [2007] found that in a retrospective review of 105 patients undergoing posterior L5-S1 spine fusion, either with or without virtual fluoroscopic guidance, the virtual fluoroscopic technique reduced the operative time by an average of 40 min ($p < 0.001$; Fig. 12.9).

When only the last 20 cases in each group were considered (in case there were learning effects), the average times in both groups had decreased and the average difference had narrowed to only 22 min in favor of virtual fluoroscopy, although because of the smaller group size, this difference was only on the margins of being statistically significant (*p* just over 0.05).

Rajasekaran et al. [2007] also recently demonstrated in a study of 478 screw placements that a CAOS technique based on the Iso-C technology was able to reduce operative time (from 4.6 min per screw in the conventional group to 2.4 min in the navigated group), and radiation exposure (1.5 movements of the C-arm into the field were required per screw in the conventional group vs. 0.09 movements per screw in the navigated group, indicating that multiple screws could be placed with a single exposure when using navigation).

or virtual fluoroscopic procedures. Data derived from Sasso and Garrido [2007] **Fig. 12.9.** Time needed to complete spinal fusion surgery using either conventional

Given these demonstrated advantages, some surgeons have raised the question of whether or not spinal navigation should now be considered the standard of care. Schröder and Wassmann [2006] reported the results of a survey of German neurosurgery departments. With 107 responses (84% response rate), they found that almost two-thirds of the responding departments (64%) were using spinal navigation systems, and that 58% of the departments not currently having access would like access. Currently, just under half (49%) of the responders believe that spinal navigation enhances safety, and 94% reject the suggestion that it should now be considered mandatory. For now, conventional pedicle screw insertion is still considered acceptable practice.

12.4.4 Fracture Repair

12.4.4.1 Clinical Motivation

When bones are fractured, the surgeon is faced with the problem of placing the fragments back in nominal alignment with one another (reduction) and securing the fragments in place (fixation), so that the bone can heal.

fractures of the humerus, radius, ulna, femur, and tibia are among the most frequently occurring fractures. Van Staa et al. [2001] report that in England in the United States, closed reduction of fractures is the most frequently performed orthopedic trauma procedure, with over 400,000 performed annually [Joskowicz et al. 1998]. most common reasons for presenting at emergency rooms, and long bone and Wales, these long bone fractures occur at a rate of 0.55% per year, and Fractures are extremely common. As a group, they represent one of the

The standard treatment for femoral shaft fractures is now the intramedullary nail [Bong et al. 2007], a hollow metal tube inserted down the intramedullary canal of the bone and secured in place at both ends with pairs of transverse bicortical screws. Union rates are normally close to 100% [Winquist et al. 1984] and there is a low incidence of infection. Despite this, femur fractures represent the single most prevalent and the third most expensive type of malpractice suit brought against orthopedic surgeons [AAOS 1999]. The main reason for patient dissatisfaction is most likely related to difficulties achieving proper alignment of the two fragments; according to Westphal et al. [2006], malalignment in the sagittal and frontal planes occurs in up to 18% of cases and rotations of the bone beyond 10° occur in upwards of 40% of cases. Braten et al. [1995] similarly found rotations of more than 15° in 19% of cases.

From a surgical point of view, it is difficult to be confident that the rotation is correct. In addition, the distal locking process is particularly time consuming and radiation intensive. The reason distal locking is so difficult is that the process of inserting the nail through the femur produces significant deformations in the nail [Krettek et al. 1998a] both laterally and in torsion, which prevent the surgeon from being able to locate the holes relative to the proximal portion of the nail that is accessible. The standard operative technique therefore uses fluoroscopy. The patient's leg is immobilized and a C-arm fluoroscope is repositioned repeatedly until a view is obtained in which the distal locking holes appear circular, which means that the fluoroscope is aimed directly down the holes. A radiolucent drill guide is then pressed against the bone, and when an X-ray image confirms that it is aligned, the surgeon taps it against the bone and drills a screw through the guide.

This fluoroscopic method has two major disadvantages: it is not time efficient, and it exposes the surgical team to a significant amount of radiation. In an in vitro study, Krettek et al. [1998b] found that distal locking of the implant took 22 min out of a total of 31 min for the simulated surgical time. In live surgeries, Suhm et al. [2004] reported that distal locking of two screws was accomplished in a mean time of 27.4 min. Okcu and Aktuglu [2003] reported a total surgical time of 141.6 ± 20.2 min for intramedullary nailing of the femur. Distal locking therefore accounts for approximately 20% of total surgical time. As operating room time costs roughly \$20 per

minute, a significantly more rapid distal locking procedure could save hundreds of dollars per case.

In the *in vitro* study mentioned earlier [Krettek et al. 1999], the distal locking process required 88 s of fluoroscopic screening time out of a total of 93 s for the whole procedure. Total fluoroscopic screening times as low as 0.52 min have been reported for senior orthopedic surgeons performing live surgeries [Madan and Blakeway 2002] but are more commonly reported to be in the range of 4–7 min [Blattert et al. 2004; Muller et al. 1998]. The wide range of reported screening times is likely due to the complexity of reducing comminuted fractures and the variations in experience of orthopedic surgeons [Blattert et al. 2004; Madan and Blakeway 2002; Hafez et al. 2005]. Radiation exposure during distal locking is particularly important because the surgeon's hands are typically either in the beam or very close to it during this process, whereas during guide wire insertion, their hands are further away. Numerous studies in recent years have called attention to the possibility that orthopedic surgeons' cumulative exposure is underestimated [Mehlman and DiPasquale 1997; Herscovici and Sanders argues that previous studies have significantly underestimated the actual radiation exposure received at a surgeon's fingertips, and found that doses there were as much as 75 times higher than at the base of the fingers. This suggests that techniques that can reduce radiation exposure would be welcomed by surgeons. 2000; Madan and Blakeway 2002; Hafez et al. 2005; Singer 2005]. Hafez

The primary motivations for using navigation techniques in fracture repair are therefore to more accurately control the rotational alignment of the bone fragments, to shorten the operative time, and to decrease the radiation exposure of the surgeon.

12.4.4.2 Computer-Assisted Fracture Reduction and Distal Locking

There are currently two major navigated approaches to dealing with long bone fractures: virtual fluoroscopy-based systems for targeting the distal locking screws and CT-based systems for controlling rotational alignment of the bone fragments.

Two early virtual-fluoroscopy-based systems were developed by Phillips et al. [1995] (see also Viant et al. [1997]; and Hofstetter et al. [1999]). The Phillips/Viant system used a mechanical arm with optical encoders to make the intraoperative measurements, while Hofstetter used optical trackers. In use, a pair of calibrated fluoroscopic images were obtained and the 3D locations of the distal locking holes found. A calibrated screw insertion guide was then positioned under computer guidance using guidance displays similar to those described earlier in the section on pedicle screw insertions.

To control the rotational alignment of the bone fragments, a 3D representation of the fragments must be created. Joskowicz et al. [1998] proposed using a preoperative CT scan to identify the fragments, and intraoperative fluoroscopy to register the preoperative 3D model to the patient. In this technique, known as FRACAS (fracture computer-assisted surgery), a preoperative CT is acquired of both the injured and the normal leg, the mirror image of which serves as a reference for setting the relative rotation of the bone fragments. Intraoperatively, a rigid body with optical markers attached is screwed onto each major bone fragment. Two fluoroscopic images are then acquired, and a 2D/3D registration procedure is performed. In effect, the computer generates simulated X-ray images on the basis of an assumed position and orientation of the 3D CT model and compares the simulated outlines with those of the actual images (Fig. 12.10). The estimated spatial position of the CT model is then manipulated to optimize the match between the real and simulated X-ray bone contours. Once registered, the relative position of the fragments can be displayed on a computer monitor in real time, and the fragments are manipulated by the surgeon until an optimal relative alignment is achieved. At this point, a guide wire is inserted, followed by the intramedullary nail itself.

images with projected X-ray contours shown in *white* at initial (*center*) and final pose (*right*). Reproduced with permission from Joskowicz et al. [2004] **Fig. 12.10.** FRACAS system: Anatomic model derived from CT on *left*, fluoroscopic

In addition to these two major approaches to fracture reduction and nail locking, in recent years, several researchers have developed robotic systems to address various aspects of this type of surgery. For example, Fuchtmeier et al. [2004] adapted a Staubli industrial robot to apply the relatively large distraction forces necessary for reduction, while Westphal and his colleagues [2006] also used a Staubli robot to assist in reduction, although to date no reduction in radiation or time has been achieved. Wang locking process; all screws were correctly positioned and the fluoroscopy time was reduced to under 2 s per screw. Grützner et al. [2005] describe a novel application of virtual reality techniques to assist the surgeon in visualizing the 3D relationships between bone fragments during reduction. et al. [2006a] presented the design of a robot, which assisted in the distal

Most recently, our group introduced a radiation-free technique for intramedullary nail locking on the basis of electromagnetic tracking of a small 6 DOF position sensor less than 3 mm in diameter, which is inserted down the central channel of the intramedullary nail [Beadon et al. 2007]. In this technique, the sensor is contained in a plastic carrier designed to engage in the distal locking holes, thereby placing the sensor in a precalibrated position relative to the holes. The surgeon then uses computer guidance to position a tracked drill guide in the correct location to make the holes for the bicortical screws. The accuracy of this technique has been validated in the laboratory and plans are underway for a clinical evaluation. Because the Carm is not needed for the locking process, the operative time required is expected to be less than for the conventional procedure.

12.4.4.3 Evaluation

Joskowicz's group reported results of the FRACAS system in Ron et al. [2002]. In a study performed using five dry femurs, they found that their system was able to recreate the torsion of the healthy side with a mean absolute difference of 1.8° (range: -4.4° to 1.7°). The repeatability on the given specimens was characterized by standard deviations ranging from 0.4° to 0.9°. They concluded that their technique was sufficiently accurate in the laboratory setting to move to clinical trials. To date, we are not aware of any clinical studies reported in the peer-reviewed literature.

Virtual fluoroscopy-based (VF) systems have proven effective in the distal locking process in several studies. The system described by Hofstetter has been evaluated in two studies [Hofstetter et al. 2000; Slomczykowski et al. 2001]. In the first of these studies, the torsion angle produced by the VF system on average was found to be 1.5° off the torsion produced by a full 3D CT-based system. The second study explored the ability of the system to lock the distal holes in a variety of bone models, cadaveric specimens, and one clinical case. All 76 holes attempted were successfully locked, with contact between the drill bit and the nail in 11% of the cases. The fluoroscopy time per pair of screws was 1.67 s (compared with 0.5–7 min with the conventional procedure). This is consistent with the 2.23 s per screw pair fically on the accuracy of the virtual fluoroscopy approach described by Phillips and Viant. In this lab-based study, they found excellent accuracy results; the positional accuracy was within 0.3 mm and the angular accuracy within 0.2° . This is consistent with the accuracy reported by Zheng et al. [2007]. reported by Wang et al. [2006b]. Malek et al. [2005] reported more speci-

Suhm et al. [2004] found similar results to Hofstetter, also for a VFbased system used with a set of 42 patients divided into conventional fluoroscopic and navigated groups. The fluoroscopic time for the conventional procedure was 108 s vs. 7.3 s for the navigated group. The navigated procedure took slightly longer, at 17.9 min per screw compared with 13.7 min per screw in the conventional group. In a different study performed a little earlier with 50 patients, in which a mechanical guide was compared with navigation, Suhm et al. [2003] found that the manual technique failed on one screw, while navigation failed on two screws. The time per screw was 6.9 min for the manual technique and 37.6 min for the navigated process, considerably longer than in the 2004 study. The navigation system required an additional 44 min of setup time in the operating theater before and after the patient was present.

In summary, CT-based systems exist that can align femoral fracture fragments in rotation with good accuracy, and virtual fluoroscopy-based systems have been shown to produce successful targeting rates comparable to the conventional fluoroscopic procedure, but with markedly reduced radiation exposure and comparable, although generally slightly increased, operative times.

12.5 Summary and Future Trends

In this chapter, we have explored a variety of clinical situations in orthopedic surgery in which there is a need for increased accuracy when performing the surgery. Very significant progress has been made in the past decade on the technical side, and in every area there have been demonstrations of improved performance as measured by such outcomes as implant alignment or percentage of implantations within specified bounds. However, demonstrations of long-term benefits relative to the conventional approaches are few in number and significant progress is still required to make computerassisted approaches less disruptive to the surgical process, require less time, and cost less. A recent opinion was expressed by a group of surgeons in an editorial in the Journal of Arthroplasty that computer-assisted surgery was "a wine before its time" [Callaghan et al. 2006], and a number of organizations responsible for approving widespread use of computer-assisted procedures in broader health care systems have reached similar conclusions in the past year or two.

The challenge is therefore before us. Although more advances in technology are clearly possible, ranging from new imaging techniques such as 3D ultrasound to implants combining mechanical and biological functions, widespread adoption of computer-assisted orthopedic surgical techniques will be greatly encouraged by concerted research efforts directed toward workflow improvements, cost reductions, and time savings. Finally, given that the majority of orthopedic procedures are currently performed by general orthopedic surgeons who practice in the community and perform a wide variety of procedures, special attention must be paid to their needs.

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