Computer-navigated joint-replacement surgery

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Computer-navigated total joint arthroplasty (TJA) surgery is a recently introduced technique used to improve alignment of total knee and total hip replacement surgeries. Alignment of components has been found to be associated with implant longevity in TJA. Recent clinical studies of computer navigation surgery have shown a decrease in variability of component positioning and limb alignment. However, no long-term clinical data is available regarding the impact of computer-navigated TJA. The widespread adoption of computer navigation in TJA will be dependent on clinical outcomes and cost–effectiveness. Rising implant costs and large healthcare spending on TJA procedures will force further scrutiny of the incremental cost of computer navigation.

Keywords: computer-assisted surgery, computer navigation, cost–effectiveness, CT-guided surgery, image-guided surgery, minimally invasive total joint replacement, total hip replacement, total knee replacement

Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are considered to be among the most successful and cost-effective surgeries performed by orthopedic surgeons. The volume of total joint arthroplasty procedures (TJA) is expected to rise considerably. In 2005, 285,000 total hip replacements and 523,000 total knee replacements were performed in the USA. By 2030, these two procedures are expected to jump to 572,000 and 3.4 million, respectively [1]. This will pose a considerable challenge to the healthcare system. The rising population of TJA patients will create a significant cost burden to Medicare, especially because many of these patients are having TJA procedures at a younger age, are living longer and will eventually need more costly and complex revision surgeries. The situation is further complicated by the fact that TJA implant prices are increasing, while the number of surgeons training in revision TJA procedures is decreasing as a response to declining reimbursements. In light of these challenges, efforts are being made to maximize the cost–effectiveness of TJA procedures by improving surgeon technique and implant materials.

The recent development of computer-navigated TJA surgery has been aimed at improving the accuracy of component positioning and limb alignment and, by doing so, improving the longevity of implants and decreasing the need for revision surgery. Several studies have demonstrated the importance of limb alignment in determining clinical outcome. For TKA procedures, errors as small as 3 degrees have been shown to significantly change the rate of component loosening that requires revision surgery [2]. Similarly, small deviations in the positioning of the acetabulum and femoral components in THA can lead to increased dislocation and bearing surface wear rates. In the operating room, the surgeon's ability to accurately determine component positioning may be affected by patient positioning, visualization, variable anatomy, deformity, bone loss, ligamentous anatomy and surgeon error. Minimally invasive surgery has been criticized by many surgeons who believe that smaller incisions impair visualization, which, in turn, compromises component positioning. Patients with rheumatologic conditions can be particularly challenging because they often have bony deformities and soft-tissue contractures that affect the standard surgical landmarks. Computer navigation attempts to address many of these concerns by giving the surgeon intraoperative feedback regarding the orientation of bone cuts, soft tissue balancing and component positioning. When considering computer-navigated TJA, it is important to understand how computer-navigated surgery works, to be familiar with the published clinical data, and to have a basic understanding of the cost–effectiveness of the technology. Rheumatologists may find this information useful when discussing TJA with their patients and when referring patients to an orthopedic surgeon for consideration for TJA surgery.

How computer navigation works

There are three types of computer-navigation systems: CT-guided, image-guided and image-free. These differ in terms of how the bone geometry is uploaded to the computer. In a CT-guided navigation system, a preoperative CT is obtained. This provides the most accurate bony model for the computer system. However, these systems have fallen out of favor because of the extra radiation and cost that is required. Image-guided systems use intraoperative fluoroscopy to confirm the location of various bony landmarks, but also require added radiation to the patient. Image-free systems are based on intraoperative digitization of key bony landmarks and kinematic algorithms to determine axes of joint motion. These systems are the most popular systems because they do not require additional radiation, preoperative imaging or equipment in the operating room.

Computer navigation systems require some added equipment and steps to aid the surgeon in choosing alignment. The equipment in the operating room includes a computer tower, a camera that detects the position of the bones and the instruments used, and specialized instruments that can be detected by the camera. The computer tower has a monitor that gives the surgeon visual feedback regarding the orientation of cuts being made and the preoperative plan. At the beginning of the case, the surgeon places pins in the pelvis (THA), femur (THA and TKA) and the tibia (TKA). Each of these pins, as well as a number of the instruments, is mounted with reflective optical trackers or radiofrequency (RF) emitting signal trackers. The camera or RF detector captures the positions of all the instruments and the trackers in the bone, processes the relative location of all the signals, and generates images for the surgeon in real time on the computer monitor.

In image-free navigation systems, the bone geometry is uploaded to the computer during the surgery. This process, called registration, is carried out by touching a digitizing stylus to a number of key landmarks on the bone and saving them to the computer. Biomechanical studies have found that there are particular landmarks and axes that define the mechanical function of a limb – such as the axis of rotation of the knee, the center of the hip and the center of the ankle. As an example, surgeons use the surgical epicondylar axis (the line connecting the medial and lateral epicondyles) to determine the rotational alignment of the femoral component in TKA. In a conventional TKA, the surgeon would have to palpate these landmarks and then estimate the relative position of the cutting instruments with the line connecting these points. Developers of navigation systems argue that there is inherent error in this estimation process, especially when the surgeon has to make these approximations in multiple planes and multiple axes of rotation.

Finally, computer navigation systems can objectively measure and evaluate soft tissue balancing, which many surgeons believe is just as important as the orientation of the prosthesis. Even if a TKA prosthesis is implanted perfectly, ‘tight’ soft tissues can cause the prosthesis to wear out earlier. One can imagine that assessing how ‘loose’ or ‘tight’ a joint is can be very subjective. With a surgical navigation system, the surgeon can objectively measure the soft tissue laxity and make appropriate adjustments.

Clinical studies

Clinical outcome studies have just started to be published over the past 5 years as surgeons have gained experience with computer navigation surgery. Overall, there are more clinical studies on computer-guided TKA procedures than THA. For TKA procedures, most studies show no difference to slight improvement in the mean alignment in the coronal plane [3–10]. Recent prospective, randomized trials have demonstrated that the navigation does reduce variability of alignment, thus decreasing the number of outliers [7–10]. There are fewer studies demonstrating any difference in rotational alignment, partly because a postoperative CT would be required to measure the rotation. However, in one recent randomized, prospective trial, navigation did not improve rotational alignment [8]. Studies on computer-navigated THA have shared a similar theme to TKA papers. There is a decrease in the variability of positioning of the acetabular prosthesis [11,12]. It has been suggested that significant limb length discrepancies can be avoided with navigated THA [11]. There are no studies with significant long-term clinical follow-up to confirm an improvement in limb length discrepancies.

The value of navigation assistance for minimally invasive surgery is a heavily debated topic. Some surgeons believe that navigation can help the surgeon align the components better because the surgeon has decreased visualization of the bony anatomy. Others believe that with decreased visualization, the surgeon cannot accurately register key bony landmarks to the computer during the initial registration steps. This leads to a ‘garbage in, garbage out’ phenomenon. Studies examining navigation-assisted minimally invasive surgery are rare, in part because there is no standard minimally invasive technique. One recent randomized, prospective study showed that navigation used with minimally invasive techniques does improve variability of alignment [10].

The complications for computer-navigated surgery appear to be minimal compared with conventional surgeries. The surgery time is increased by 10–20 min and there is no significant change in blood loss [4]. Case reports of fractures, infection and delayed wound healing at the pin sites are also rare.

Economics of computer navigation

Although computer navigation has demonstrated some early potential clinical benefit, its widespread adoption will likely depend on its cost–effectiveness. In orthopedic surgery, as in many fields, a recent surge in technology development has forced decision makers to scrutinize new costs closely [13–17]. Computer navigation comes at a significant additional cost of US$650–4000 per surgery [16]. The benefit of navigation is that it potentially decreases the number of complications and revision surgeries that patients undergoing TJA procedures may need. Health policy researchers often define a technology as cost-effective if its incremental cost is less than US$50,000 per quality-adjusted life year gained by using the technology. A technology is considered to be cost saving if the cost of the technology is directly offset by the decreased future costs of revision surgery and management of complications. In a recent study performed by our group, a Markov model was used to demonstrate that navigation would be considered a cost-effective technology if it costs an additional US$1500 per surgery, and a cost saving technology at US$629 or less per operation [16].

The adoption of computer navigation will depend on the incentives and perspectives of each of the stakeholders involved: patients, physicians, hospitals and payers [18]. The current patient population is more educated about their healthcare options and demand better outcomes as they are more active and undergoing TJA procedures at a young age compared with earlier generations. In addition, because of how insurance coverage is structured in the USA, patients do not bear the cost of additional technology and often demand high-cost procedures. For surgeons, use of navigation can improve outcomes, but also serve as a marketing tool to attract patients. However, surgeons are facing increasing implant and technology costs as reimbursements are also declining. Initiating a computer navigation surgery program involves a large initial investment, extensive staff training and a ‘learning curve’ for the initial cases performed. Hospitals similarly may be motivated by the potential marketing advantage of having a navigation program, but be dissuaded by the additional costs associated with surgical navigation. Also, as margins on TJA procedures are declining, the pressures to increase surgical volume are rising. The increased time per operation will decrease a hospital’s ability to increase their surgical volume. Medicare and other payers will be influenced by improved clinical outcomes that result in cost savings on a shorter time horizon. Given the available outcomes data and current pricing of navigation systems, payers may be reluctant to cover the costs associated with computer-assisted surgical navigation.

Future perspective

Computer navigation is an impressive technological advancement that has shown some promise in early clinical data, but long-term clinical data are needed to clearly justify its use. As the number of TJA procedures continues to increase, there will be a significant need to reduce the number of complications and revision TJA procedures. Navigation may be helpful in accomplishing this goal. However, costs of navigation systems must also decrease for the technology to be cost-effective. The case of computer navigation raises two important questions:

- As resources become limited, how will we decide which technologies are worth adopting?
- How will we respond to the significant rise in medical device costs?

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Executive summary

- By 2030, the number of total knee arthroplasty (TKA) and total hip arthroplasty (THA) procedures is expected to reach 3.4 million and 572,000, respectively.
- Slight malalignment of total joint arthroplasty (TJA) prostheses can lead to implant failure requiring revision surgeries.
- Computer navigation systems have been designed to improve alignment of TJA prostheses by giving the surgeon accurate intraoperative measurements and visual feedback.

How computer navigation works

- A computer navigation system consists of a computer, a camera and multiple trackers placed in the bone, and various instruments.
- The surgeon registers various key bony landmarks that are significant to the bone geometry at the beginning of the case.
- The computer gives visual feedback regarding the alignment of the surgeon's cuts in multiple planes and multiple axes of rotation.
- The computer aids in the measurement of various subjective parameters such as soft tissue laxity.

Clinical data

- Prospective, randomized trials have shown little improvement in the mean alignment of components, but significant decrease in the variability of alignment.
- Operative time is increased, but few complications have been reported.
- No long-term clinical data is available.

Economics of computer navigation

- Computer navigation in TKA may be considered cost-effective at an incremental cost of US$1500 per operation and cost saving if it costs less than US$629 per operation.
- Patients are likely to demand computer navigation because of increasing direct-to-consumer marketing and rising expectations from TJA procedures.
- Surgeons and hospitals may adopt navigation to increase market share and improve outcomes, but are challenged by rising implant costs and declining reimbursements.
- Payers will adopt navigation if there are cost savings in the short term and if coverage will improve loyalty.

Future directions

- All stakeholders (patients, physicians, hospitals and payers) are awaiting long-term clinical data to demonstrate a benefit in using computer navigation for TJA also in the long term.
- Rising implant costs and a surge in medical device innovation will force the healthcare system to scrutinize new technologies from clinical and economic perspectives.

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