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Critical review of the current practice for computer-assisted navigation in total knee replacement surgery: cost-effectiveness and clinical outcome

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Abstract In this article, we present a review of the current practice regarding computer-assisted navigation in total knee replacement together with the bearing on cost-effectiveness and clinical outcome.

Keywords Computer-assisted navigation · Total knee replacement surgery · Cost-effectiveness · Clinical outcome

Introduction

Osteoarthritis of the knee is common, affecting almost a tenth of the population aged over 55 [1]. This number would certainly increase with extended longevity of patients. Severe osteoarthritis of knee joint is a common problem in older people and a major concern for pain and disability. Apart from osteoarthritis, conditions like rheumatoid arthritis, seronegative arthritis, posttraumatic arthritis and malignant tumour conditions of the knee joint do cause significant morbidity to patients.

Most patients with osteoarthritis of the knee are able to manage their symptoms with medical treatment and conservative methods, but a large number of patients referred to the specialist surgeon for further management have debilitating disease.

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Total knee replacement

Total knee replacement (TKR) has evolved as an accepted, cost-effective and efficacious treatment modality for osteoarthritis and other forms of arthritic conditions of the knee joint.

Approximately 30,000 TKRs were carried out in 2000/01 in England and Wales [2]. The total number of TKRs performed in UK has risen by over 20,000 between the years 2002 and 2004. Despite the rise in number, there are also reports of poor uptake of this treatment in the UK.

The demand for TKR is increasing mainly because of longer life expectancies and rising public expectations for quality of life and mobility in later years. Currently, approximately 2% of the population of 55 years age and above are so disabled that they need TKR, and this rate increases with age. The estimated prevalence in women is nearly twice as high as in men [3].

Total knee replacement is indicated for pain relief and functional improvement in severe knee joint degeneration and arthritis. The goals of TKR surgery include adequate alignment of the prosthesis components and the limb, stability of the knee, and attainment of sufficient range of motion, which permits adequate movement to attain improved quality of life [4].

TKR usually presents excellent results, although serious complications occur in around 5% of cases because of loosening, infection, instability, dislocation or fracture [5]. The surgeons' experience in patients' selection, soft tissue balancing, the alignment of the leg, the restoration of the joint line and also the prosthetic design are all possible factors influencing the success of TKR [6].

In the history of orthopaedics, surgeons have been presented with many tools and techniques that both help and hinder progress. In orthopaedic surgery, there is a well-recognised relationship between accuracy and outcome. A well-aligned hip or knee replacement is less likely to dislocate and will last longer. Orthopaedic surgeons respond to the need for accuracy by taking care and continually modifying their techniques to improve their performance. In joint replacement, freehand techniques have been augmented by the introduction of mechanical alignment jigs and cutting blocks. Each of these technical refinements has initially met some resistance, but has become established as the resulting improvement in outcome has become clear.

Despite the continuing improvement in mechanical alignment systems, it has been estimated that the error in tibial and femoral alignment of over 3° occurs in about 10% of total knee replacements even when they are carried out by well-trained surgeons using the most up-to-date mechanical alignment tools [7]. This is due to drawbacks of the conventional alignment systems. Preoperative X-ray templating always carries an error of measurement. It is difficult to determine intraoperative anatomical landmarks such as the centre of the femoral head and talus. The conventional alignment tools assume a standard bone geometry which may not apply to specific patients. Finally, all mechanical alignment tools rely on direct visual inspection to confirm the accuracy of implant positioning at the end of the procedure.

Computer-assisted surgery

The procedure of TKR consists of joint articular surface replacement with a knee prosthesis whose positioning has been conventionally performed with the use of intramedullary or extramedullary alignment. More recently, computer-assisted systems have been developed to improve the positioning of the prosthesis components with the goal of improving the postoperative prosthesis alignment, which in turn improves the overall survivorship of the prosthesis. Computer-assisted surgery (CAS) has shown to improve the positioning of implant placement and more properly align the lower limb mechanical axis according to the desired plan [8]. CAS has shown to reduce outliners of mechanical leg axis >3° valgus/varus deviation compared to the conventional technique [9].

History of CAS

Navigation was first introduced experimentally in the 1980s and clinically in the 1990s, but has only entered mainstream orthopaedics in the last 7 years.

Intraoperative navigation in total joint replacement began in 1992, when William Barger, in Sacramento, California, performed the first computer-assisted surgery in orthopaedics on a total hip replacement. Frederich Picard performed the first intraoperative computer-navigated knee replacement surgery in 1997, updating work that he conducted in a postdoctoral thesis in 1993 [6]. Computer-assisted systems are active (surgical robots) or passive i.e. systems that do not perform any part of the surgery, but assist in the positioning of the surgical instruments.

Basics of CAS—how it works?

A digital image, which serves as a map for each procedure, is created. This image is provided to the operating surgeons for guidance during surgery. Surgical instruments can also be incorporated into the map for knowing their position, attitude and accuracy even in millimetres or fractions of degrees during operation. The technique utilized to achieve accurate imaging modalities intraoperatively can be divided into three types:

1. Preoperatively imaged technique—This type of modality requires information from CT/MRI scan of the knee about the anatomy of the knee.
2. Intraoperative imaging technique—In this type, modified fluoroscopy is used to help in anatomical mapping of the knee during surgery. The data collected are transferred to the computer via wired connection directly in the operating theatre. Recent technologies for trauma applications also include the use of intraoperative 3-D fluoroscopy; however, those are not commonly used in TKR.
3. Image-free technique—An anatomical model that is fixed in the software is upgraded by the process of a so-called surface registration process or bone morphing. This is recently the most used technique for navigated TKR. However, there has been no study yet showing a comparison of precision of this technique vs image-based modality techniques.

All the above techniques or systems require the process of registration. This is a predetermined sequence in which a surgeon identifies the key anatomical landmark for the computer. Registration in orthopaedic procedures tells the computer where the bone is in space. The prerequisite for registration is that there is a tracking marker on the bone that can be recognised by the computer's tracking system. The most fundamental aspect of registration is accuracy in doing this. Once registration is done, it is possible to proceed with operation.

There are various methods of registration available, which include simple fluoroscopy, optical tracking and a newer technology like electromagnetic tracking. Other techniques like the use of ultrasound in the process of registration are being evaluated.

Planning

After the initial process of registration, the computer gathers the information regarding joint anatomy and size and limb alignment and matches the anatomy with the size and type of implant. The computer then gives the information regarding the orientation of bony cuts, implant sizing and soft tissue tension. Recent technique includes so-called kinematic-based workflows, where before bony cuts are made based on the optimized knee kinematics and optimized flexion/extension gaps, adequate cutting is suggested for optimal soft tissue balancing.

Implementation and verification

The essential components after registration are setting up of the cutting blocks and rechecking of the cuts. The alignment is confirmed on the computer screen. The hardware used is similar in most systems. The computer receives the information from an infrared camera. This in turn transfers signals from the beacons fixed to the patient. The computer screen provides the visual images required for the surgery.

The software provides a structural model which provides interactive images and allows storage of data that describe the surgery. The software used is of two types, namely, closed and open system. The closed system produces visual displays of the prosthesis, and the open system needs its own software, which is operation-specific and not prosthesis-specific.

The next step is to determine the component-to-component position and soft tissue balance, which in turn help in analysing the radiological and clinical outcomes.

There are several advantages of the CAS:

1. Dynamic assessment of deformity at any angle of flexion with patella in situ as opposed to conventional TKR where tensioning devices can be used in zero and 90° only.
2. Calculation of soft tissue tension to give a perfectly balanced knee [10].
3. Accurate restoration of mechanical limb axis [10].
4. Reduced blood loss [11].
5. Decrease in incidence of fat embolism due to extra-medullary instrumentation.
6. Accuracy of data on soft tissue tensions even in 1 mm and 1°. Surgeon is given control, feedback, ability to correct errors and documentation needed by CAS.

But there are some disadvantages:

1. Prolonged operative time
2. Certain learning curves
3. Significant cost implication for purchase and maintenance of the system
4. Lack of adequate evidence of the long-term benefits of CAS over conventional surgery in terms of implant survivorship and patient benefits for TKA.

Review of literature

According to Swank [12], there are nearly 20 articles in peer-reviewed literature comparing CAS with conventional surgery. The literature is equally divided between the outcome and benefits of CAS. The superiority of CAS has been reported in terms of decreased variance in radiographic alignment in TKR [13] and decreased blood loss [11]. Several studies have raised concerns about duration of surgery, cost-effectiveness and long-term benefits of the usage of CAS. There are anecdotal reports of fracture and potential neurovascular injury by CAS based on the invasive reference marker fixation.

A current meta-analysis done by Bauwens et al. [14] reviewing 33 studies (11 randomised controlled trials) of varying methodological qualities has thrown much light into the current trends, concepts of CAS and compared the results with conventional TKR surgery. They found no difference in alignment of mechanical axes in either group. There was lower risk of malalignment at critical thresholds of >3° and >2° in the CAS group. They also found that navigation lengthened the duration of surgery by 23% and found no difference in infection rates or thromboembolic events in both groups. There were no conclusive inferences on functional outcomes or complication rates.

They concluded that there are few advantages of CAS over conventional surgery on the basis of radiographic end points. They suggested that clinical benefits are unclear and remain to be defined on large scale as trials aimed at functional outcomes did not show any difference in terms of pain and function in either group.

Brophy [15] gave a final report to the joint technology assessment unit of the Mc Gill University on the usage of image-free computer-assisted systems in total knee replacement surgeries after a systematic review of literature and summarisation of data. The report evaluated the usage of CAS in TKR surgery to reduce postoperative malalignment. He concluded that there was no convincing evidence that demonstrates improved clinical outcomes with the CAS.

Furthermore, in a recent study by Parratte et al. [16] reviewing 398 computer-assisted total knee replacements, they concluded that postoperative mechanical axis of 0±3 did not improve the 15-year implant survival rate.

A prospective randomised study comparing the positioning of total knee arthroplasty with and without navigation support by Sparmann et al. [17] reported a highly significant difference between the two groups in favour of navigation with regard to the mechanical axis, frontal and sagittal femoral axis and frontal tibial axis. There was no difference in axis of alignment of the tibial component in the sagittal plane between the two groups.

Chauhan et al. [18] did a controlled study comparing CAS and conventional jig-assisted total knee replacement in six cadavers to provide a quantitative assessment of the alignment of the component placements. They concluded that CAS showed better alignment in rotation and flexion of the femoral component, the posterior slope of the tibial component and the rotation of the tibial and femoral component.

According to Sikorski [19], CAS is extremely useful in revision TKR surgeries, in which significant bone defects are encountered and bone grafting is needed. Another prospective randomised controlled trial of CAS and conventional total knee arthroplasty done by Matziolis et al. [20] concluded that CAS improved sagittal alignment of the femoral component but not of the tibial component. Rotational alignment of the component was not improved through navigation.

Cost implications/cost-effective analysis of CAS

Currently, the benefit of CAS is conjectural. Cost involving CAS in TKR surgery is significant. The CAS involves additional steps, which take both time and manpower. The machines are very expensive, and the software contracts with each system can be very exorbitant, especially if closed type technique is used [19].

Except for the study done by Dong and Buxton in 2006 [21] applying a Markov model, there is no published literature on the cost-effective analysis of comparing CAS with conventional TKR surgery.

Dong and Buxton [21] conclude that CAS is a cost-saving technology in the long term and may offer additional quality-adjusted life years. They also predict that CAS can reduce the revision rates and complications through more accurate and precise alignment. As per their study, for the conventional technology, the average NHS cost for elective primary TKR was £5,197 and if used, CAS added an additional £235 per surgery.

According to Brophy [15], due to unproven correlation between an improvement in postoperative alignment and clinical benefits, especially in the magnitude observed with the CAS compared to conventional technique, the cost-effectiveness of the device could not be calculated.

Discussion

Initially, most orthopaedic surgeons viewed the development of navigation systems for total joint replacement with great scepticism. Computer-assisted navigation systems are designed to increase the precision of implantation. Restoration of mechanical axis is considered a major goal of knee arthroplasty. Several studies have demonstrated this to be the case for the mechanical axis [22]. Apart from the mechanical axis, the rotational alignment of the femoral and tibial components and the equalised gap are also important for the functional outcome. Even small deviations have a considerable influence on patellar tracking, stability and the overall biomechanics of the joint [17]. However, there is conflicting evidence on the causal role of these minor axis deviations for clinical failures.

The role of CAS in primary total knee replacement is still controversial. One of the main problems for the surgeon is that CAS depends on mathematical algorithms. The exact charting of landmarks is not possible with full certainty [17].

Given the lack of long-term evidence for improved outcomes, it is difficult to determine the clinical importance of the benefits observed with the use of CAS. Unfortunately, this may require at least 10 years of follow-up [23]. Survey information from orthopaedic surgeons across the world using the CAS suggests that the technology is valuable at least in more complicated total knee replacement surgeries [15]. According to Sikorski [19], in spite of the shortcomings, the alignments were comparable in accuracy with those after primary TKR. Computer assistance shows considerable promise in producing accurate alignment in revision TKR surgeries with bone defects and complex cases.

Future of CAS

CAS is developing rapidly and undergoing drastic evolution. It is being used in orthopaedics with a multiple applications, ranging from knee and hip arthroplasties to pedicle screw placement. The current optical systems are likely to be replaced by electromagnetic or other types of registration and tracking systems [12].

Although noninvasive registration has not been precisely enough to track the limb during active motion, future applications might solve this problem.

Rapid development is also taking place especially in terms of preoperative templating, in which the 2-D images shall be converted to 3-D images and loaded as part of the intraoperative plan. Several changes are taking place in the advancement of CAS to make the process of data acquisition, planning, postoperative verification and clinical outcome very effective.

It is clear that navigation technology in its current form is not likely to be universally accepted, as this technology develops over the next 3–5 years, and as the form changes and some of the early problems of registration and user interface are overcome, this technology will be available throughout all aspects of orthopaedic reconstructive surgery [12].

Conclusions

There is no convincing evidence that demonstrates improved clinical outcomes with CAS in total knee arthroplasty. However, majority of studies show that navigated TKR decreases the malalignment of the mechanical limb axis compared with conventional TKR. It is not very clear whether this marginal benefit makes any much difference in long-term outcome of the patient. The technology of navigation appears promising in complex primary and revision knee arthroplasties.

The main challenge in the future for all advocates of CAS is to prove that it works well, aid in improving clinical outcome of the TKR and is cost-effective. As the cost of machinery falls in near future and as the learning curve decreases, the popularity of navigation systems will increase such that they become an essential part of day-to-day surgery.

It is important to realise that conventional techniques in TKR surgery have resulted in high prosthesis survival rate lasting up to 15–20 years. As the CAS has survived its infancy, it is therefore important that functional and clinical outcomes be collected on a regular basis in order to elucidate the role of it.

Hence, further multicentre randomised controlled clinical trials comparing conventional TKR with CAS need to be undertaken with large follow-up to demonstrate better clinical and functional outcomes, lesser complication rate along with cost-effectiveness of the CAS procedure over conventional primary TKR surgery to make it universally acceptable.

Conflict of Interest The authors declare that they have no competing interests. They have full control of all primary data and that they agree to allow the journal to review their data if requested.

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