



Medical Services Advisory Committee Public Summary Document

Application No. 1123 – Computer-navigated Total Knee Arthroplasty

Sponsors: Professor Jerzy Marian Sikorsi and Johnson & Johnson
Date of MSAC consideration: 45th MSAC meeting, 5 June 2009, Sydney

1. Purpose of Application

The application to MSAC was premised on the claim that computer assistance for total knee arthroplasty (TKA) improves mechanical limb alignment and as a consequence reduces the complication rates associated with conventional total knee arthroplasty.

TKA is a surgical procedure to replace the damaged knee with a prosthesis. The procedure involves removal of the condyles of the femur and tibia and replacing these with either metal or plastic components. The femoral and tibial prostheses are inserted following treatment of any bone deficiencies and after ligamentous balancing has been achieved using a cemented or cementless technique.

Success of total knee arthroplasty depends on the surgeon creating a kinetically stable, solidly fixed and well functioning knee using the prosthesis through accurate bony resection, good fixation techniques, soft tissue balancing and restoration of the mechanical axis. Restoration of the mechanical axis of the knee joint is particularly important as malalignment may affect postoperative complication and revision rates.

The conventional method of achieving correct limb alignment includes the use of special jigs provided with the knee prosthesis. Computer-navigated TKA provides an alternative method of achieving correct limb alignment. Computer navigation for the purposes of TKA requires a system consisting of a computer, a tracking device (eg an infrared camera) and arrays which are attached to the patient's bone (allowing the bone's position to be tracked in virtual space).

There are two types of computer navigation systems: image-free or image-based. Image-free systems, which were the subject of this report, use information for registration obtained intra-operatively by digitising various anatomical landmarks with a navigated pointer.

2. Background

Applications to MSAC undergo an eligibility step that includes an assessment of the application's compliance with any required Therapeutic Goods Administration (TGA) listing, conformity with MSAC's Terms of Reference, and consistency with Government policy.

MSAC receives a report from expert independent evaluators on the strength of the evidence of the safety, effectiveness and cost-effectiveness of the requested procedure and related technology, which is produced under the guidance of an Advisory Panel consisting of MSAC members, clinical experts, and consumer representatives. The applicant is consulted at the initial research protocol stage and at the final draft report stage of the production of this report.

The comparator proposed in the research protocol and subsequently used in the report was conventional, manual, jig-based Total Knee Arthroplasty (standard TKA).

At its 45th MSAC meeting, MSAC considered the strength of the evidence for the safety, effectiveness and cost-effectiveness for computer-navigated Total Knee Arthroplasty (TKA) compared with standard TKA. Members considered the final report of the evaluation of the evidence (as endorsed by the Advisory Panel), the applicant's response and evaluator's rejoinder, as well as presentations/input from the 1st discussant (independent MSAC member), 2nd discussant (MSAC Advisory Panel Chair), and the MSAC Economics Sub Committee.

3. Safety

Comparative studies indicate that computer-navigated TKA is as safe as standard TKA in the short-term, and no long-term adverse events were reported from Level IV evidence.

4. Clinical effectiveness

The studies and reviews provided short-term follow-up data (usually days to weeks) with little long-term data available (longest follow-up to 3 years).

A radiological outcome such as satisfactory alignment (defined as within 3° in either direction) was 3-4-fold more likely with computer-navigated TKA. This finding was statistically significant and appeared robust. Clinical outcomes were rarely reported. In the short- to medium-term, the range of motion and Knee Society score (which rates the knee joint and the functional activity) were similar with computer-navigated and standard TKA.

The comparative studies were of insufficient duration to assess whether improved alignment with computer-navigated TKA would result in better long-term clinical outcomes (for example, by decreasing revision rates). The evidence-base for a correlation between post-operative mechanical alignment and long-term revision rates following standard TKA was inconclusive.

5. Cost effectiveness

A cost-utility analysis using a Markov model with a 15-year cohort simulation was performed (the 15-year period was chosen based on the expected life of a contemporary prosthesis). The principal assumption was that computer-navigated TKA would lead to better alignment and henceforth a decrease in revision rates. Whilst it was acknowledged that there was an absence of direct comparative data to support this assumption, an economic analysis was nonetheless undertaken to determine what reduction in revision rates would be required to make computer-navigated TKA cost-effective.

At the increased cost proposed, computer-navigated TKA is unlikely to be cost-effective unless it achieves a 50% relative risk reduction (at least a 2-3% absolute risk reduction) in revision rates.

6. Rationale for MSAC's Advice

MSAC agreed that there are no safety issues relating to the use of this procedure, and that computer navigation improved post operative mechanical axis alignment of the knee as assessed by radiological measures.

MSAC found, however, that there was insufficient evidence to support the claim that reducing the rate of knee malalignment will decrease total knee arthroplasty revision rates and lead to significant improvements in health outcomes.

MSAC considered that the economic analysis demonstrated that the procedure is not cost-effective in the general population undergoing TKA; and that large changes in revision rates would be required to make computer-navigated TKA a cost effective intervention.

MSAC also noted that the base case used in the economic model appeared to favour the proposed intervention because of significant incremental gains in utility with computer navigated TKA in the model and the long time horizon (15 years) applied.

MSAC members postulated that if the procedure were perhaps confined to high volume centres, the economic case may become more attractive, but at this stage the lack of evidence to support a significant gain in health outcomes could not allow this conclusion to be drawn.

MSAC also noted that, while the Advisory Panel report suggested some sub-groups of patients (specifically complex knees and deformed knees) might gain considerable benefit from computer navigated TKA, there were no data presented to demonstrate that these sub groups of patients would derive such a benefit.

On this basis MSAC did not recommend any change to the current public funding arrangements for TKA, and concluded that the current MBS arrangements for TKA not be changed.

All 17 members present for this discussion were in favour of the motion that the Minister be advised that there should be no change in public funding arrangements for total knee arthroplasty.

MSAC advises that it does not support a change in public funding arrangements, and that there should be no differential reimbursement for computer-navigated total knee arthroplasty.

7. Context for Decision

This advice was made under the MSAC Terms of Reference:

- Advise the Minister for Health and Ageing on the strength of evidence pertaining to new and emerging medical technologies and procedures in relation to their safety, effectiveness and cost-effectiveness and under what circumstances public funding should be supported.
- Advise the Minister for Health and Ageing on which new medical technologies and procedures should be funded on an interim basis to allow data to be assembled to determine their safety, effectiveness and cost-effectiveness.
- Advise the Minister for Health and Ageing on references related either to new and/or existing medical technologies and procedures.
- Undertake health technology assessment work referred by the Australian Health Ministers' Advisory Council (AHMAC) and report its findings to the AHMAC.

8. Linkages to Other Documents

The MSAC Advisory Panel Report is available at <http://www.msac.gov.au/internet/msac/publishing.nsf/Content/MSACCompletedAssessments1120-1140>