TITLE: MAKO’s RESTORIS Implants and MAKoplasty Procedure for Early to Mid-Stage Osteoarthritic Knee Disease: A Review of the Clinical and Cost-Effectiveness and Safety

DATE: 27 April 2011

CONTEXT AND POLICY ISSUES

The MAKoplasty® procedure is a minimally invasive, robot-guided partial knee resurfacing arthroplasty that may be suitable for patients with early to mid-stage osteoarthritis. The MAKO RIO® Robotic Arm Interactive Orthopedic System provides tactile guidance to the surgeon to direct the insertion and alignment of the unicompartmental (RESTORIS®), bicompartmental (RESTORIS® MCK), or other manufacturer’s implants. Unicompartmental resurfacing involves replacement of the the medial (inner) portion of the knee and the bicompartmental procedure involves replacement of the medial, patellofemoral (top) or both components of the knee. Insertion of the unicompartmental or bicompartmental prosthesis preserves the cruciate ligaments and requires less bone resection than total knee arthroplasty, where all cartilage is replaced.

In preparation for the MAKoplasty procedure, pre-surgical computed tomography (CT) scans are done and a patient-specific three dimensional model is created. This model is used to plan and guide the device implantation during the procedure. The system provides visual, tactile and auditory feedback to the surgeon during the procedure (Tactile Guidance System™) to prevent removal of bone outside of the planned surgical boundaries.

The MAKoplasty procedure does not require the patient’s leg to be rigidly fixed during the surgery, unlike the Acrobat robotic system, which is also used for minimally invasive partial knee arthroplasty. This allows the limb to be moved through the range of motion to assess implant alignment, and may avoid some complications related to the procedure. After the bone is prepared and implants aligned, they are cemented in place. A more detailed description of the procedure is provided in the article by Pearle et al.

It is estimated that 8% to 10% of knee arthroplasties in the US are unicompartmental. Long-term survival rates have been inconsistent and depend on patient-specific factors, such as age, weight and comorbidities, and factors related to the device, its alignment, and the surgical

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approach (conventional or minimally invasive technique). Limb or implant misalignment can jeopardize the long-term survival of the prosthesis. Revision rates of 10% to 20% have been reported for unicompartmental implants. Data on the frequency of bicompartamental arthroplasty were not readily available in the published literature search. This report will review the clinical and economic evidence specific to the MAKO prostheses and robotic arm assisted knee arthroplasty procedure.

RESEARCH QUESTIONS

1. What is the clinical effectiveness of MAKO’s RESTORIS line of implants and MAKOplasty procedure for patients with early to mid-stage osteoarthritic knee disease?

2. What is the clinical evidence regarding the safety of MAKO’s RESTORIS line of implants and MAKOplasty procedure for patients with early to mid-stage osteoarthritic knee disease?

3. What is the cost-effectiveness of MAKO’s RESTORIS line of implants and MAKOplasty procedure for patients with early to mid-stage osteoarthritic knee disease?

KEY MESSAGE

There is insufficient evidence on the clinical effectiveness and safety of the MAKOplasty procedure and MAKO’s RESTORIS implants. No information on the cost-effectiveness of the MAKOplasty procedure was identified.

METHODS

A limited literature search was conducted on key resources including PubMed, The Cochrane Library (2010, Issue 2), University of York Centre for Reviews and Dissemination (CRD) databases, Canadian and major international health technology agencies, as well as a focused Internet search. No filters were applied to limit the retrieval by study type. Where possible, retrieval was limited to the human population. The search was also limited to English language documents published between January 1, 2006 and April 4, 2011. Reference lists of articles were hand-searched.

Rapid Response reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials, non-randomized studies, and economic evaluations.

SUMMARY OF FINDINGS

One retrospective study was found in the published literature. No health technology assessments, systematic reviews, meta-analyses, randomized controlled trials or economic evaluations of MAKOplasty or MAKO RESTORIS implants were identified. Articles of potential interest are provided in the appendix.
Non-randomized studies

One retrospective cohort study assessed the alignment of the tibial component in minimally-invasive unicompartmental knee arthroplasties performed with or without robotic assistance. In this study, 31 patients underwent arthroplasty by one surgeon using the MAKO robotic arm. These were compared to a retrospective control group of 27 consecutive unicompartmental knee arthroplasties performed by the same surgeon using conventional manual surgical methods. In the robotic-arm group the average age was 64 years (range 46 to 82), body mass index (BMI) was 30 kg/m², and 52% were female. In the control group, the average age was 57 years (range 36 to 80), BMI was 28 kg/m² and 37% were female. There were no statistically significant differences between groups on height, weight, or BMI (statistical testing on age or underlying diagnosis were not reported). In 28 of 31 patients in the robot-assisted group, a polyethylene inlay-design tibial component was implanted. In all other control and study group patients, a metal-backed onlay-design tibial component was implanted. Radiographs at two or six weeks post-surgery were used to compare the differences in the pre-operative planned position of the tibial implant with the post-operative position. The error and variance in the alignment were calculated and compared between groups. The study found that both the error and variance in alignment were lower among those who had robot-assisted arthroplasty than those who had conventional manual surgery. One patient in the robot-assisted group developed pain at three months post-operatively and had tibal loosening of the implant. No other cases of loosening were reported. The study failed to report the patients’ underlying diagnosis or the duration of follow up, and did not assess femoral or limb alignment, or clinical outcomes. The authors concluded that further study is needed to determine if a reduction in alignment error is associated with improvement in implant function or survival.

Limitations

The available evidence was limited to one retrospective cohort study, which may be considered one of the weakest levels of evidence with a high risk of selection and information bias. The study provided information on surrogate outcomes, such as alignment of the prosthesis.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

No randomized controlled trials or high quality non-randomized studies were found on the MAKOplasty procedure or MAKO implants. There was insufficient evidence on the safety and efficacy of this surgery. No economic studies were identified.

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REFERENCES:


APPENDICES:

Health technology assessments not specific to MAKO products.


Refer to page 13, 41 and 42 for information on unicompartmental knee arthroplasty.

Case series


The outcomes of unicompartmental knee arthroplasties (UKAs) have demonstrated inconsistent long-term survival. We report the first clinical series of UKA using a semiactive robotic system for the implantation of an inlay unicompoylar knee arthroplasty. Ten patients were selected for this study. Preoperative mechanical leg alignment values ranged from 0.3 degrees varus to 9.8 degrees varus. A haptic guidance system was used; a detailed description is given in the manuscript. The setup time for the robot was 41 minutes; intraoperative registration process, 7.5 minutes (6-13 minutes); skin incision, 8 cm; robot-assisted burring, 34.8 minutes (18-50 minutes); mean tourniquet time, 87.4 minutes (68-113 minutes); and overall operation time, 132 minutes (118-152 minutes). The planned and intraoperative tibiofemoral angle was within 1 degrees. The postoperative long leg axis radiographs were within 1.6 degrees. Haptic guidance in combination with a navigation module allows for precise planning and execution of both inlay components in UKA


Modular bicompartmental arthroplasty is an emerging knee-resurfacing approach that provides a conservative alternative to total knee arthroplasty. Isolated bicornpartmental arthritis involving the medial or lateral and patellofemoral compartments, but with no significant deformity or bone deficiency, preserved motion, and intact cruciate ligaments, can be effectively managed with this treatment method. For the many young and active patients with isolated bicornpartmental arthritis, given the potential durability of the procedure and the prosthesis, it is appropriate to use an approach that is more conservative than total knee arthroplasty. Robotic arm assistance for modular bicornpartmental arthroplasty optimizes component position and alignment, which may improve system performance and long-term durability. In addition, a percentage of patients who undergo isolated unicompartmental or patellofemoral arthroplasty may later develop progressive arthritis in an unresurfaced compartment. Their cases may be effectively managed with a staged modular approach to resurfacing the degenerating compartment, but additional study is needed

Early outcomes of unicompartmental knee arthroplasty performed with a robotically assisted navigation system have been favorable. The surgical technique enhances accuracy of bone preparation and component positioning. Technical errors of the system have been minimal. The surgeon’s learning curve is not adversely affected. Early patient outcomes are excellent and complications minimal. Further follow-up and study will help to determine whether these early outcomes are sustained over time.
