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### Summary

- The Oxford unicompartmental knee replacement is a reliable treatment for medial knee compartment osteoarthritis, provided patients with the correct indications are chosen and the appropriate surgical expertise is available.
- The Oxford knee has been available since fall 2000 in Canada and since the early 1980’s in Europe.
- The latest version, Phase III, has generated interest since it uses both a minimally invasive surgical technique, as well as a free-floating, fully congruent meniscal bearing. This has the potential for faster recovery of the patient, as well as improved wear characteristics.

### The Technology

Unicompartmental knee arthroplasty (UKA)* is a surgical technique involving partial replacement of the knee joint to treat osteoarthritis. The Oxford Unicompartmental Knee Arthroplasty is a UKA that was developed in Britain in 1978. Available throughout Europe since the early 1980s, its first introduction in North America came in the fall of 2000 at the Scarborough Hospital, in Ontario.

Osteoarthritis is a disease of joint cartilage, associated with secondary changes in the underlying bone, which causes pain and impairs the function of the affected joint. Knee osteoarthritis usually occurs in the medial compartment as this side of the knee bears most of the weight.

The Oxford Knee has gone through three phases; all versions with the same basic implant construction. It has a spherical femoral component and a flat tibial component that are cemented to the bone. In between there is an unconstrained polyethylene mobile bearing. The upper surface of the bearing is spherically concave and the lower surface is flat, making it fully congruent in all positions.

The Oxford Knee is manufactured for sale in Canada by Biomet Merck Limited of Bridgend, South Wales, U.K. Of the UKAs marketed in Canada, the Oxford Knee is the only one with a mobile, free-floating, fully congruent bearing. The others use a cemented, fixed bearing. The congruent bearing gives a bearing surface that mimics the natural meniscus. Since the load is evenly distributed over the bearing surface as opposed to a fixed bearing knee, it may improve wear characteristics.

Surgical technique is important for UKA, particularly when a mobile bearing is used, as in the Oxford Knee. The stability of a mobile bearing depends on ligament balance. With the initial design of the Oxford Knee™ (Phase I), the femur was prepared with a saw, and precise ligament balance was difficult to achieve. As a result, bearing dislocation could occur. In 1989, the Phase II innovation was introduced: the femur is now prepared with a mill. Bone is removed in 1 mm increments allowing a more accurate ligament balance.

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* Acronyms used in this report: UKA - unicompartmental knee arthroplasty; TKR - total knee replacement; HTO - high tibial osteotomy
balance of the ligaments. Bearing dislocation is less frequent and knee kinematics is improved compared to the Phase I version.\textsuperscript{5,7}

The main innovation of Phase III over Phase II in 1998 was a minimally invasive surgical technique and associated instrumentation. The operation is now performed through a short incision (6-8 cm) from the medial pole of the patella to the tibial tubercle. Compared to the longer incision used for TKRs, there is less damage to the extensor mechanism, as the patella is not dislocated and the suprapatellar synovial pouch remains intact.\textsuperscript{7}

### Regulatory Status

On May 29, 2000 Health Canada issued Biomet Orthopedics Inc. a device class 3 license for the sale of the Oxford\textsuperscript{TM} Phase III Unicompartmental Knee System. The license covers the femoral component, the tibial tray, and the polyethylene meniscal bearing.

### Patient Group

The main indication for the Oxford Knee is medial knee compartment osteoarthritis. The anterior cruciate ligament must be functionally intact with a fixed flexion deformity less than 15 degrees. Any varus deformity should be passively correctable preoperatively, and there should be full thickness cartilage in the lateral compartment. 19,709 knee replacements were done in Canada in 1997/1998, and 86% of these patients were 60 years or older. This suggests the Oxford Knee patient group will be predominantly elderly.\textsuperscript{7,10}

### Current Practice

Surgical treatments for osteoarthritis of the knee include: arthroscopic debridement, high tibial osteotomy (HTO), total knee replacement (TKR), and unicompartmental knee arthroplasty (UKA).\textsuperscript{11-15} HTO has good short-term results, but deterioration of the knee joint continues. Rehabilitation is more extensive than that required for arthroplasties. Adjustments to the original surgical procedure after HTO have shown a greater clinical success rate than revisions after UKA or TKR. However, studies comparing UKA and HTO have found UKA provides better pain relief.\textsuperscript{13}

The evidence suggests that overall, the cumulative failure rates of UKA tend to be higher than TKR. However, the UKA has potential advantages that make it an attractive alternative to TKR for properly selected patients. These include: lower morbidity, quicker recovery, minimal loss of bone stock, preservation of both cruciate ligaments, complete preservation of the patellofemoral articulation, and increased range of motion.\textsuperscript{4,13,16}

Several UKAs are currently available in Canada. The products implanted with minimally invasive surgical techniques are the Oxford\textsuperscript{TM} Knee Phase III (Biomet), and the Repici II\textsuperscript{TM} (Biomet). UKAs implanted with standard surgical techniques include the PFC\textsuperscript{®} UKA (Johnson & Johnson/Dupuy), the Genesis II UKA (Smith & Nephew Richards), the Miller Galante II (Zimmer) and the LCS UKA (Johnson & Nephew Johnson/Deupy). Each of these products has a minimally invasive surgical technique under development. There is no clear evidence that one UKA design is superior, and a prospective randomized trial would be required to demonstrate any differences.

Non-surgical treatments for knee osteoarthritis include cartilage transplantation, meniscal allografts and other injectables.

### Potential Cost

The direct medical costs associated with the Oxford\textsuperscript{TM} Knee Phase III procedure include: the charge to the hospital for the prosthesis (list $3,200); the surgeon billing rate for a UKA ($425 in Ontario), and hospital costs. The instruments for implanting the Phase III system are typically consigned to the hospital, or brought in on a case-by-case basis, with no charge to the hospital or physician.
Projected Rate of Diffusion

The first Canadian Oxford Knee procedures were performed in Ontario in the fall of 2000. Following a training course given in Vancouver in June 2001, there have been Oxford™ Knee Phase III surgeries in every province in Canada. Estimates of the proportion of knee replacements that meet the Oxford Knee indications range from 10% to 25%, implying that 2,000 to 5,000 patients per year could be candidates for the Oxford Knee. A key factor for dissemination will be the availability of surgeons trained to implant the system.

Assessing the Evidence

Long-term follow-up studies are needed to evaluate the success of knee prostheses. We report on three studies assessing the long-term survival of the Oxford™ Knee Phase I & II. First, the Swedish National Arthroplasty Study reported a five-year survival rate for the prosthesis of 90%. The failure rate (defined as the rate of revision of the prosthesis for any reason) from centre to centre ranged from 0% to 30%.1

In another study the designers of the prosthesis performed the surgery and the analysis. This was a ten-year survival study with the standard Oxford™ Knee Phase I and II approach. The sample included 144 knees with one lost to follow-up. There was one bearing dislocation in a Phase I knee, which was reduced by manipulation. There were no dislocations of Phase II knees. The 10-year survival rate of the arthroplasty was 98% (95% confidence interval 93%-100%). At 10 years the worst-case survival rate, assuming all knees lost to follow-up had failed, was 97%.9

An independent review of a series of patients, treated by three surgeons at a non-teaching hospital in Sweden, reported similar results. In this series, there were 378 patients with no loss to follow-up. The 10-year survival rate was 95% (95% confidence interval 93%-98%). There were three bearing dislocations in Phase I knees and no dislocations of Phase II knees.5

Currently, long-term survival evidence using the Phase III approach is not available due to its recent development (1998). However, a study has compared the traditional Oxford Phase I and II process (with midline incision and lateral dislocation of the patella) to the minimally invasive Phase III procedure. Ten patients were in each group, all operated on by the same surgeon. Post-operative recovery of straight leg raising, flexion to 90 degrees, and time to discharge were all improved compared to the Phase I and II patients. Patients were discharged on average 1-2 days post-operatively with the minimally invasive procedure. No complications occurred and three months after surgery the two groups had achieved similar recovery. There was no radiological evidence of impaired cementation or orientation of the prostheses implanted through the smaller incision.17

Adverse Effects

Serious complications with the Oxford Knee are rare. UKA has had, in general, a higher revision rate than TKR. The Oxford Knee has attempted to minimize the failure rate by addressing implant design, indications, and surgical technique. Proponents of UKA believe that improper patient selection is a leading cause of UKA failures. Because the selection of appropriate patients is critical to the long-term success of UKA, efforts have been made to develop careful selection criteria.4,11,18

Implementation Issues

Patient selection is clearly a key factor for the Oxford Knee. Precise indications are important in unicompartmental arthroplasty, more particularly in a prosthesis with a mobile bearing (as in the Oxford Knee) than in one in which it is fixed.5,8

The success rate for orthopedic prostheses is highly surgeon dependent, and the relatively high failure rate found in the Swedish National Arthroplasty Study may be due to poor early technique and poor patient selection involving a
few specific centres. The technique of implantation of the Oxford Knee is demanding and very different from that of TKR and other unicompartmental implants. The data from the Swedish National Register show that the method has not been successful everywhere and suggests that it should only be employed by surgeons who have been appropriately trained in its use.\(^5\)\(^{17}\) Although strongly recommended by the manufacturer, an Oxford Phase III training program is not a requirement for the surgeon in order to implant the device.

**References**


This brief was prepared by Allan Brown, BSc, MBA, MA; CCOHTA and has been peer reviewed. The contents are current as of September 2001.

For updates to the regulatory status of this technology, check the sites in the Links (Regulatory Status) section of our website: [www.ccohta.ca](http://www.ccohta.ca).

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