



Early results with a patient specific interpositional knee device

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The iForma® ConforMIS Interpositional knee device is a recently developed patient specific implant used for the treatment of mild to moderate uni-compartmental osteoarthritis. The benefits over traditional methods of surgical management are: it is less invasive, can be performed as a day procedure and does not limit future options. Bespoke implants are produced from data extracted from MRIs.

Twenty-six patients with the iForma® ConforMIS interpositional knee implant from November 2007 were retrospectively reviewed. The average age was 54.7 years, The average pre-operative WOMAC score was 37.8 improving to 67.6 post-operatively. Five patients required revision. No dislocations were reported.

Our early experience suggests this device is a viable and safe treatment option. However, patient selection plays an important role in the outcome following surgery and long term results should be awaited.

Keywords: knee hemiarthroplasty; interpositional device; patient specific; young patients; osteoarthritis.

and poorer outcome score (15). High tibial osteotomy (HTO) is another surgical option for correction of malalignment with excellent results. Osteotomy does not appear to prevent the progression of the disease and can make future total knee replacements (TKR) challenging (6). Evidence from the Swedish Knee Register shows revision rates of 9% for TKR, 24% for UKR and 17% for HTO in patients under the age of 55 (21). With such high revision rates, there is a need for a more successful operation in the young, high demand patients.

In recent times there has been a return to metal hemiarthroplasties which previously have had excellent results (18); however the recent Unispacer® (Zimmer, Warsaw, IN, USA) implant had poor results with high rates of post-operative pain (1,19). Recently patient specific implants have been developed. This article presents early results with the ConforMIS interpositional knee prosthesis.

INTRODUCTION

Management of young, active patients with medial compartmental osteoarthritis is a controversial topic. Due to their young age and the high chance of a revision, a total knee arthroplasty is not always recommended (7). Unicompartmental knee replacements (UKR) are controversial with good results shown in numerous joint registers (14). There is concern in young patients about the need to perform bone cuts and about the higher revision rates

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Fig. 1. — A prototype of the iForma implant

The ConforMIS iForma® interpositional knee device is a chromium cobalt molybdenum patient specific implant (5). It uses CAD/CAM technology which allows the specific dimensions of the patient's knee to be extracted from information in their MRI scans to produce a bespoke implant to the patient's knee. Advantages of the implant are that it is bone preserving and no bony cuts are required for placement of the prosthesis. The use of this implant does not limit future surgical options with revision to both UKR and TKR possible post interpositional knee device. Due to the patient specific design it can help correct mal-alignment of the patient's mechanical axis.

MATERIALS AND METHODS

From November 2007 till July 2009, 26 patients were treated with the iForma® interpositional knee device (ConforMIS, Burlington, MA, USA) (Fig. 1) at Princess of Wales hospital, Bridgend and at the Royal Glamorgan hospital, Llantrisant, United Kingdom. The introduction of the new prosthesis was approved by the Local Clinical research and Ethics committee. National Institute of Clinic Excellence (NICE) was informed prior to their current guidelines being produced. All patients provided their informed consent for the procedure.

All the patients were evaluated pre-operatively with a history, physical examination, plain radiographs and an

MRI scan. All patients completed a pre and post-operative WOMAC (Western Ontario and McMaster universities) questionnaire and post-operatively they were asked about their hospital experience (2). The indications for the procedure are the same as those for UKR : unicompartmental disease, clinically correctable varus/valgus malalignment, intact anterior cruciate ligaments and no fixed flexion deformity (20). The patients had grade II-IV Osteoarthritis (OA) in either the medial or lateral compartment with no more than grade II in the other compartment or the patellofemoral joint. Grading was based on the radiological classification by Kellgren (11) and on arthroscopic findings. Standard antero-posterior, lateral and skyline views were performed. Rosenberg views (16) were performed of the other non-affected compartment for assessment of a viable joint space. Not all had long leg alignment views (Table II).

Patients were excluded if they presented with an uncorrectable varus/valgus malalignment, active infection, fixed flexion deformity or severe multi-compartmental arthritis, if they did not give their informed consent or if the MRI showed areas of abnormal tibial stress or an abnormal tibial slope.

Our population consisted of 17 males and 9 females with an average age 54.7 years (41-69 yrs). The patient demographics are displayed in table I. We implanted a total of 34 implants (29 medial, 5 lateral implants). Of these 7 were bilateral. Our average follow-up was 43 months (27-51 months).

One patient had a previous high tibial osteotomy. The arthritis had deteriorated to grade IV but a UKR was contraindicated as per the Oxford protocol due to previous posterior cruciate injury. All patients had been tried with non-operative management (analgesia, anti-inflammatories, intra-articular injection, physical therapy and activity modification).

An MRI scan was performed with the appropriate software for image manipulation as required by the manufacturer. Patients were informed that their images would be sent via a secure channel to the manufacturing company in the USA. The images were reviewed by a radiologist for the company, who provided a comprehensive report regarding the patient's suitability for the prosthesis. Further discussions regarding suitability of the patient or the implant took place between the surgeon and the radiologist for the early cases. Once the procedure was considered to be suitable, the implant was manufactured, size and thickness of the implant being pre-determined according to the cartilage damage. The surgical procedure was performed within 6 weeks of the MRI scan.

Table I. — Table showing patient demographics from our study

Age	54.7 yrs (41-69 yrs)
Sex	9 females 17 males
Side	24 medial 5 lateral
BMI	32 kg/m ² (23.5-38 kg/m ²)
Follow-up	19 months (10-27 months)

Surgical technique

All patients were treated according to the company's recommended surgical technique. All patients received one dose of prophylactic antibiotic, cefuroxime 1.5 g was given. In all cases a tourniquet was used. All procedures were performed under fluoroscopic control in the supine position and a side support was used for controlled opening of the joint.

An examination under anaesthesia was performed to check for stability, correction of deformity and range of movement. A standard knee arthroscopy was then performed. Non-affected compartments were checked to confirm the MRI findings and to ensure that there had been no progression of OA since the patient was listed. For the affected compartment, a complete arthroscopic meniscectomy was performed (Fig. 2). Tears of the meniscus in the opposite compartment were trimmed. Any prominent ridges on the opposing surfaces were smoothed with arthroscopic shavers and burrs. Any step-offs between the bare bone and the remaining articular cartilage were levelled for better seating of the implant. Following this a mini parapatellar lateral or medial arthrotomy was performed measuring approximately 5 cm. Through this incision any remaining visible osteophytes, especially on the femoral condyle, were removed. The remaining anterior horn of the meniscus was also removed. These are important steps to allow the proper seating of the prosthesis on the tibial plateau. No medial releases were required in the patients included in



Fig. 2. — Intra-operative arthroscopic picture of the medial condyle in one of our patients under-going the procedure.

this study. The patient specific implant was then checked to ensure that it was for the correct patient and laterality and compartment. The implant was held with a special instrument for manipulation. It was then inserted with the knee flexed between 30-50° and touching the femoral condyle, the knee was then extended on to the implant with a varus or valgus stress being simultaneously applied. Once the implant was seated a fluoroscopy was performed to confirm proper positioning of the implant (Fig. 3). The knee was evaluated for stability and range of movements. The wounds were closed in the routine manner and dressings applied.

All patients had one intra-articular drain inserted and a cryo/cuff was used. These were removed after 4 hours. The patients were allowed to mobilise fully weight bearing with crutches immediately after the procedure. All patients had post-operative analgesia and were discharged on the day of the procedure. The patients were reviewed in the clinic after 3 weeks, with radiographs, and at regular intervals after that. All patients were independently assessed by the operating consultant with up to date radiographs and clinical scoring. The WOMAC scores were filled up at the last follow-up appointment.

Table II. — Pre- and post-operative alignment and ROM

	Pre-Op average (Range)	Post-Op Average (Range)
Extension	2.05° (-10-10)	1.57° (0-10)
Flexion	116.3° (80-140)	119° (90-135)
Clinical assessment of alignment	4.6° (0-10)	3° (0-5)



Fig. 3. — Intra-operative fluoroscopy confirming correct sitting of the implant.

RESULTS

No patient had a DVT or post-operative wound complications.

The average WOMAC score pre operatively was 37.8 improving post-operatively to 67.6 ($p < 0.001$). There were improvements in all three aspects of the WOMAC score. Pain improved from 7.8 to 14 ($p < 0.001$), function improved from 26.5 to 47.8 ($p < 0.0002$) and stiffness also improved from 3.1 to 5.6 ($p < 0.0003$).

We had no infection in our series. There were no reported dislocations from this cohort. Several patients reported that they were able to return to high level of activities and there was an overall patient satisfaction with the procedure of 82%. One patient reported that he had noticed significant improvements with his gait post surgery. There were a total of 5 failures resulting in either revision or removal of the implant giving a revision rate of 19.2% within the first year. All these patients had the implant removed due to persistent post-operative pain. Three patients were revised to TKRs, one was revised to UKR and later to TKR and one patient had the implant removed and is cur-



Fig. 4. — Post operative radiographs of one of our patients who received bilateral implants.

rently awaiting a TKR. A review of the pre-operative MRI scan revealed that three of these patients had shown areas of increased tibial stress and the report suggested that such patients may experience ongoing pain post operative. These implants were also inserted whilst in the surgeon's learning curve and this may account for their subsequent failure. All these implants were removed at an average of 10.2 months post-operative (5-13 months). One patient who experienced bilateral implants at the same sitting said he would have the implants again but on separate sittings (Fig. 4).

DISCUSSION

The re-emergence of hemiarthroplasty for knees is no surprise with the excellent results of Scott, McKeever and Macintosh (18). Studies have shown that correction of medial osteoarthritis can be achieved with interpositional knee devices (4).

The interposition hemi-arthroplasty procedure allows the patient to mobilise early and has good results in terms of range of movement and function as demonstrated by the WOMAC score. The major advantage of the interposition hemiarthroplasty procedure is that it is a bone preserving operation and it does not limit future surgical options (18).

Koeck *et al* (12) in their series of 28 patients have shown very promising results with interpositional arthroplasty as a means of correction of malalignment in comparison to HTO. They found that the iForma® implant was able to achieve a good correction in deformities up to 15°. The recently published results of Koeck *et al* single arm multi centre trial using the same prosthesis found similar results to ours (13). They had a revision rate of 24% in 16 months whilst ours is slightly lower at 19.2% in the first year.

The concerns with the Unispacer® were the high rates of dislocations and the amount of persisting pain giving a revision rate of 44% in the first 2 years (1). Sisto *et al* attributed the failure of the Unispacer® to dislocation, persistent severe pain and failure of the implant to internally and externally rotate (14). We found no evidence of problems with the articulation of the iForma® implant or of dislocation. We believe this is a result of the patient specific design of the implant that it is able to interlock on the tibial surface thus limiting its movement. We had a lower rate of revision than Sisto *et al* did with the Unispacer®.

Conversion of HTO to TKR may involve complex ligament balancing problems and complex centring problems of the tibial implant due to truncation (10). Several recent studies though have shown that after HTO knee replacements are as successful (8). Conversion of a UKR to a TKR may need metallic augmentation or bone grafting (17) and there are contradictory reports of the success of revision to TKR from UKR (9).

We found that it took up to one year before the true beneficial effects of the implant were known. We feel that some of the earlier revisions may not have been revised if more time was given to allow the implant to bed in. It is worth noting that in this study, the revision rate was 16% with surgeons performing more than 10 and 45% in those surgeons performing less than 10. We had 3 surgeons performing 34 operations in total and therefore our revision rate may be accounted by the learning curve of this implant.

We found that this implant may have worse results when implanted in middle aged women. The hypothesis that this could be due to an increased

rate of osteoporosis in these patients was not confirmed by DEXA scanning.

Our results are inconclusive towards the benefit of this patient specific implant. This is most likely down to patient selection and would represent the early experiences of the senior authors. Other series have similar failure rates (12). The cost is a further disadvantage to the use of this implant. It is approximately 3 times the cost of the UKR. But none of our patients required in-hospital stay post operatively. The final cost can be estimated to be similar to a HTO, UKR or TKR procedure. This was also the experience of Koeck *et al* in 2011 (12).

CONCLUSION

We feel that these early preliminary results (43 months) do not offer strong enough evidence to make a conclusion on the overall use of the patient specific interpositional implants. The failure rate is still too high. Whilst it appears to overcome some of the criticisms of previous design implants we have found it still to require time before it embeds within the knee and that ongoing pain can still be an issue. A larger multi-centred randomised control trial should be performed to ascertain the true effect of this implant.

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