National Institute for Health and Clinical Excellence

705 – Insertion of individually magnetic resonance imaging designed unicompartmental interpositional implant in osteoarthritis of the knee

Consultation Comments table

IPAC date: Thursday 16th July 2009

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1, Notifier	**1**	i agree that prospective data collection continued audit should be part of this procedure.	Thank you for your comment.

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2	Consultee 2, Clinician (international)	**1**	I am the Chairman of the Department of Orthopedic Surgery at the University of Regensberg in Germany and immediate past president of the German Orthopedic Society (Deutsche Gesellschaft Orthopadie und Orthopaedische Chirurgie e. V.). I recently learned of the NICE recommendations and hoped to provide some results from our clinical experience which may help in your deliberations. Our department staff surgeons have used the iForma in the treatment of over 50 patients with mild-to-moderate unicompartmental osteoarthritis of the knee since 2006. We have also been a lead investigator site in a multi-center trial reviewing the performance of the device. Based on our direct clinical experience and review of data available from the trial, we believe that the MRI based custom interpositional device offers a reasonable and appropriate treatment option for select patients with early to moderate stage unicompartmental osteoarthritis. Further, the patient-matched design of the device and the diagnostic information provided by the MRI scan, in our experience, supports outcomes that are significantly better than reported with predecessor interpositional devices.	Thank you for your comment. The NICE Interventional Procedures Programme Methods Guide highlights that efficacy outcomes from non peer-reviewed studies are not normally presented to the Committee. The Committee did however have sight of all the data submitted as part of public consultation. The guidance will not be changed.

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2 cont.	Consultee 2, Clinician (international)	**1 cont**	Our basis for this view includes the results from our clinic as well as the trial data which is being submitted to JBJS British edition for possible publication. From June 2005 to April 2008, 84 subjects received an iForma implant as part of a post market registry. Â The study group included 45 men and 39 women with a mean age of 53 years (37 to 71) and a mean Body Mass Index (BMI) of 29.5 (14.7 to 50.0). The treated compartment included both medials and laterals, with laterals comprising approximately 5% of all implants. The mean WOMAC knee scores for these patients increased from 47.5 before surgery to 70.7 at 3 months (p0.007). This improvement remained statistically significant through 12 and 24 months of follow-up. Statistically significant ($p<0.05$) reduction in pain assessed using a standard visual analog scale (VAS) was achieved for all five of the predefined pain measures. Complications have included general surgical complications, such as infections, as well as dislocation or subluxation of the implant and persistent pain. The rate of revision in the clinical trial has run at approximately 5%. All revisions at our institution have been to a new interpositional device (in one case of dislocation) or to a primary knee replacement. It is our understanding from the company that there have been over 800 implantations of the device since introduction with the earliest patients out almost 5 years. While we do not have data to comment on the experience of others, the complication rate in the broader commercial experience appears to be running at about 10%, perhaps due to less stringent patient selection criteria.	

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3	Consultee 3, Private Sector Professional	**1**	*[CONFLICT: Advisor/Consultant for ConFormis. I have given many seminars and teaching labs for ConFormis regarding the use and implantation of this iForma devise to physicians all across the United States.]* The iForma represents, in my opinion, the third generation of interpositional arthroplasty. The previous generations being the "McKeever" type and the "UniSpacer" implants. If the literature of the McKeever is reviewed, it is found to be very successful in the single compartment OSTEOARTHRITIS patient. The UniSpacer had issues with dislocation early because they were being grossly undersized to the tibial anterior/poterior dimension, but after this was realized and sizing changed, outcomes improved. Building on past experience CUSTOM or correctly sized implants such as the iForma, used in a NON-RHEUMATOID, PHYSICALLY YOUNG patient, with SINGLE COMPARTMENT DISEASE, is an excellent conservative option. My clinical experience of having implanted 60+ knees with iFormas to date, I feel, gives enough support to justify the iForma in the correct patient population.	Thank you for your comment. The Interventional Procedures Programme has been advised that McKeever and Unispacer are no longer being used in the UK. Section 1.1 includes a request for 'clear descriptions of patient selection' in future research.
4	Consultee 1, Notifier	**2.1**	all options of surgical and non-surgical treatments should be informed to the patient. it is not a procedure for end stage OA, but early OA in YOUNG ADULT population, who do not wish for a replacement.	Thank you for your comment. The list of current treatments and alternatives is not intended to be definitive. Section 1.1 includes a request for more information on patient selection.

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5	Consultee 2, Clinician (international)	**2.1**	Our indication for the custom interpositional device is typically for patients who have stopped responding to conservative therapy options such as viscosupplementation but are not yet indicated for traditional knee replacement. The interpositional device can be considered an effective alternative to tibial osteotemy and unicompartmental knee replacement in arthritic patients with intact ligaments and intact subchondral bone plate in the femur and tibia. Â One additional aid we use in patient selection is an Independent Radiology Review report that is provided by the company. The report provides a reading of the MRI for each patient covering a standard set of diagnostic factors that can affect the performance of the implant, including findings that would be difficult or impossible to assess using x-rays alone. We have found that with close attention to patient selection, the custom interpositional device, can be comparable in efficacy to well-accepted procedures such as HTO but with significant surgical advantages (e.g., blood loss, surgical time, incision length).	Thank you for your comment. The list of alternative treatments is not intended to be exhaustive.

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6	Consultee 3, Private Sector Professional	**2.1**	While iForma is a surgical procedure it should be considered conservative. Usually done in conjunction with arthroscopy and limited arthrotomy as an outpatient or overnight stay. No subchondral bone is removed, only remnants of damaged meniscus and marginal osteophytes are removed, therefore patients can bear weight immediately without fear of subsidence as in UKRs or complications related to osteotomy as in HTOs. iForma "burns no bridges" in treatment of single compartment osteoarthritis. HTOs have well documented risks, including conversion to TKR being much more difficult and longevity of symptomatic relief not being as long as hoped for in a large percentage of patients. "Bridge burned". UKR replacements in overweight or physiologically young active patients is inappropriate. The only salvage of a failed UKR is a TKR and these two groups of patients are at high risk of failure with TKRs. "Bridge burned". iForma represents a conservative alternative to HTOs and UKRs that will not make future treatment more difficult, providing this patient population with many years of symptomatic improvement so they can continue to be very active in work and play.	Thank you for your comment. The Committee considered this comment but decided not to change the guidance.
7	Consultee 1, Notifier	**2.2**	the surgery is performed as day case,unless bilateral.fluroscopy is always used to check stability of implant. the implant should be inserted within 6 months of the MRI.The implant is much more congruent than the other similar implants,on the market, which are off the shelf implants.	Thank you for your comment. Section 2.2 of the guidance states that this may be performed as a day case and this section is intended to be a summary of the procedure. The guidance will not be changed.

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8	Consultee 2, Clinician (international)	**2.2**	Two comments of clarification. The aim of the procedure is to provide pain relief and function such that the patient can engage in typical activities of daily living and return to work. Most of the patients who have had the procedure are not yet at retirement age, so this is an important objective of the treatment. Leg axis correction is one of the mechanisms by which the pain relief is provided, but not the main aim of the procedure. On the procedure itself, we have not found general anaesthesia to be necessary in most cases. The surgery is always performed using an arthroscopic approach, for full removal of the meniscus, before the arthrotomy is made for device insertion.	Thank you for your comment. Section 2.2.1 of the guidance will be changed. Section 2.2.2 of the guidance states that this procedure is 'usually performed with the patient under general anaesthesia'.
9	Consultee 3, Private Sector Professional	**2.2**	Based on the MRI, ConFormis can determine the amount of cartilage loss so an appropriate thickness of the implant can be made to restore anatomic alignment for each individual. The surface geometry of the tibia is also determined so the implant anatomically "locks" into place on the tibia in weight bearing. This is key to why no bone or cartilage has to be removed to fit the patient to the implant, the implant fits the patients anatomy with full coverage of the tibial plateau. This reduces the risk of dislocation and greatly reduces surgical time.	Thank you for your comment. Section 2.2 of the guidance is intended to be a summary of the procedure.

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10	Consultee 1, Notifier	**2.3**	The implant reduces pain over a period of time. it cannot be compared to a full total knee replacement,and should be included in a pre-TKR/UKR surgical option given to a patient.Loosening of the implant(if it happens) will not lead to any significant bone loss,compromising further surgery(similar to conversion from Uni knee to total knee),also there is no added complication as in a post-HTO conversion,which may lead to malrotation or malaligned proximal tibia.	Thank you for your comment. Section 2.4.2 is the opinion of the Specialist Advisers.
11	Consultee 3, Private Sector Professional	**2.3**	As I've stated previously, iForma will not over correct alignment, like HTO's will, but will restore 2-3 degrees of correction per millimeter of thickness and place the patient at their prior anatomic alignment. Most iFormas are 2.5-3 milimeters thick. IForma is not without risk, but compared to the alternatives in this patient population, a procedure that is conservative, i.e. "Burns no bridges", and allows immediate full weight bearing with quick return to work and play has to be considered at least with HTO's and UKR's, if not before. Regarding concerns about converting from iForma to a UKR or a TKR, these surgeries will not be any more difficult if additional surgery is needed.	Thank you for your comment.

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12	Consultee 2, Clinician (international)	**2.3**	Our department's clinical experience runs counter to the observations of the Specialist advisers. The MRI based interpositional device has provided good pain relief and a return to function for most of the patients who have been treated with the device. In the cases where a revision was necessary, the re-intervention was to the original alternative surgery (e.g., primary total knee replacement) being considered. These results are far better than the published results using non-customised free floating interpositional spacers such as the Unispacer. Our surgeons do not consider this device as an alternative to traditional knee replacement surgery for most patients that come to our institution. Total or partial knee replacement remains the preferred option in the majority of situations. But there are a targeted group of patients who have early osteoarthritis and debilitation for whom we believe this is a very reasonable and attractive option. If there is benefit to avoiding bone cuts due to early age, comorbidities such as obesity, or lifestyle considerations such as smoking, the interpositional device becomes an attractive option.	See response to comment no, 2.
13	Consultee 1, Notifier	**2.4**	apart from the standard complications, the risks of 1.dislocation are less as this is implant is contoured to fit the knee of that patient, 2. persistence of pain only when recommended guideleines are not followed. i cannot see the relevance of the paragraph 3.2 for this procedure.	Thank you for your comment. The guidance will not be changed. Section 3 is a standard section included in every piece of IP guidance referring to related NICE guidance.

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14	Consultee 2, Clinician (international)	**2.4**	See previous comments.	Thank you.
15	Consultee 3, Private Sector Professional	**2.4**	Regarding safety. In my practice I have over 60 knees implanted with iForma, dislocation has occurred in 4 knees. Infection and DVT is not a direct risk of iForma but a risk of any knee surgery. Since surgical time with iForma is short, usually 20 minutes for arthrotomy and implantation, risk of infection and DVT should be greatly reduced. The theoretical risk of CVAs and MIs in my opinion should be very small because of the patient population being considered for iForma.	Thank you for your comment. The NICE Interventional Procedures Programme Methods Guide states that the Committee may consider evidence on safety that has not been peer reviewed so these safety data describing dislocations will be added to the guidance. Section 2.4.2 of the guidance includes theoretical adverse events listed by our Specialist Advisers.