National Institute for Health and Care Excellence

IP958– Implantation of a shock or load absorber for mild to moderate symptomatic medial knee osteoarthritis
Consultation Comments table

IPAC date: Thursday 13th November 2014

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 NHS Professional	**1**	I have been impressed with the early to mid-term results now we have defined the selection criteria and strongly support the on-going evaluation of this device. I would suggest that the device is approved for use in appropriately selected patients who are monitored by an independent registry in order to achieve medium to long-term data on an appropriately large cohort of patients.	Thank you for your comment. The NICE IP Programme will only recommend submission of data to registers for procedures with “research only” recommendations, if the registry data collection has received research governance and ethics approval.
2	Consultee 5 NHS Professional	**1**	It is crucial that surgeons are trained adequately to perform this procedure and I have been directly involved with such cadaveric training programmes that are well established for this device.	Thank you for your comment. IPAC does not routinely stipulate training requirements for procedures with “research only” recommendations. Training for performing the procedure is normally covered by research governance and ethics committee approvals.

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3	Consultee 6 NHS Professional	**1, 4, 5**	The provisional recommendations are reasonable and there are no factual inaccuracies. I would suggest these should only be done by pure knee subspecialists who also have high tibial osteotomy (as well as unicondylar arthroplasty) in their management arsenal as undoubtedtly patient seclection is key. I have implanted these in 7 patients as part of the international longitudanal study. There have been no complications and no device removals. One patient did have a subsequent arthroscopy and is doing well. I have not had time to collate their individual knee scores prior to the deadline for comments passing but anecdotally all have said they would have the procedure again and one is listed to have the other side done.	Thank you for your comments. This is a “research only” recommendation. Patient selection and who should perform the procedure will be covered by research governance and ethics committee approvals.

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4	Consultee 3 Manufacturer	**1**	[redacted] have two publications that we would like the Committee to consider as further evidence relating to the above requirements for two year follow up data and comparative studies: 1. *Unloading the Osteoarthritic Knee with the [redacted] System: Surgical Technique and Early Clinical Results.* *David Hayes, Craig Waller and Nicolas London* 2. *Conservative Treatments , Surgical Treatments and the [redacted] Knee Implant System for Knee Osteoarthritis : A Systematic Review* *Chuan Silvia Li, Olufemi R Ayeni, Sheila Sprague, Victoria Truong & Mohit Bhandari* We are also submitting a final manuscript for consideration in response to requirements for two year follow-up data. This manuscript will be submitted for publication to Clinical Interventions in Aging in September 2014 • *Joint uploading implant modifies subchondral bone trabecular structure in medial knee osteoarthritis: 2 year outcomes of a pilot study using fractal signature analysis. Larry Miller, Jon Block.*	Thank you for your comment. Hayes et al. is a chapter and not a published article in a peer reviewed journal. Therefore IPAC will not consider efficacy data from this paper. Chuan Siliva Li et al., 2013 is an overview of systematic reviews for different knee treatments and indirect comparison with OASYS trial ([redacted]) data which was already included in table 2. IPAC only considers efficacy data from studies published in peer reviewed journals. Open unpublished research data, prior to peer review is not included, unless it raises new safety concerns or is from a national register that is supported by a professional body or society.

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5	Consultee 3 Manufacturer	**2**	[redacted] are submitting an overview presentation that summarises results showing: Clinical experience to date demonstrates an effective treatment option Significant pain relief Significant functional improvements Consistent improvement across all outcome measures [redacted] compares favorably to HTO and UKA Literature [redacted] safety compares favorably to HTO	Thank you for your comment. Additional clinical data presented in the presentation is unpublished efficacy data and cannot be considered for inclusion in the guidance.
6	Consultee 3 Manufacturer	**4**	[redacted] is a safe procedure offering an attractive treatment option for patients with mild to moderate OA, who hope to avoid or delay knee replacement. The implant has been designed to have a reversible surgical procedure that preserves downstream treatment options.	Thank you for your comment. Section 3.1 states that 'the device can be removed at a later date'.

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7	Consultee 3 Manufacturer	**5**	In response to the anecdotal and theoretical events reported by the specialist advisors it should be noted that with reference to bone loss adjacent to anchoring sites, compromising future salvage surgery including joint replacement, data collected from patients who have had [redacted] removed does not support this. [redacted] [redacted] is required to collect complaint handling data as part of its reporting requirements to Notified Bodies and Government Agencies, as is standard practice in medical device companies. [redacted] are required to report potential and confirmed occurrences of which they become aware, as described in the company Quality System. In over 800 implants of the [redacted] System, none of the anecdotal or theoretical adverse events listed had occurrence levels high enough to warrant regulatory action. Those events listed above either did not occur or occurred with rates low enough to be deemed acceptable by the quality and regulatory compliance team.	Thank you for your comments. IPAC routinely seeks advice from Specialist advisors on both efficacy and safety of the procedure. The additional anecdotal and theoretical outcomes in 5.6 are listed by Specialist Advisers and there are no reports of these in the literature.

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8	Consultee 4 NHS Professional	**4,5**	Whilst I was initially sceptical about this device I have watched carefully and have now used this on a few occasions. I believe in offloading and maintaining the native joint for as long as possible both to reduce risks and lower the impending burden of revision in the future if we continue to implant arthroplasties into younger patients	Thank you for your comment. The committee discussed the role of this procedure and device in the management of younger patients and added a Committee comment in 6.1 which states that: *The Committee was advised that there are few treatment options for younger patients with osteoarthritis of the knee and implantation of a shock or load absorber may offer an option for these patients, and may potentially delay the need for joint replacement.*
9	Consultee 4 NHS Professional	**4, 5**	Osteotomy is my standard treatment to offload in the younger patient, but this is not always possible in view of individual patient anatomical variation. In addition osteotomy is much less easily reversible. In my limited experience (only two cases) of this product so far I have had no problems with wound healing (this was a concern of mine from the size of the implant) both patients have noticed benefit from the device, and there have been no complications with the implant itself. We are considering enrolment into the GOAL study - HTO v [redacted]	Thank you for your comment. The committee discussed the role of this procedure and device in the management of younger patients and added a Committee comment in 6.1 which states that: *The Committee was advised that there are few treatment options for younger patients with osteoarthritis of the knee and implantation of a shock or load absorber may offer an option for these patients, and may potentially delay the need for joint replacement*. GOAL (post-market) study is a global, prospective, multicentre, non-randomised, controlled non-inferiority trial to evaluate symptom relief in patients with medial knee osteoarthritis treated with the [redacted] knee implant for load reduction compared with HTO; estimated enrolment: 225; estimated completion date: June 2018.

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10	Consultee 5 NHS Professional	**5**	In my opinion, some of the early failures seen with this device in the COAST trial were due to a combination of poor patient selection and the inevitable learning curve that is involved when a surgeon takes on a new procedure. Along with my senior colleague in the trust, I am currently applying for approval from commissioners to perform this procedure as I commonly see patients in clinic who would benefit from this surgical option.	Thank you for your comments. COAST study is a multicentre open-label interventional study of patients with medial compartmental knee osteoarthritis symptoms treated with the [redacted] Unicompartmental Knee Arthroplasty (UKA) System. Results from COAST study were included in table 2 (study 2,3).
11	Consultee 1 NHS Professional	**General**	I am a specialist knee surgeon with an interest in the management of young (30-55yrs) patients with osteoarthritis of the knee and have evaluated this device for more than 4 years implanting devices into 42 patients initially as part of a multi-centre study and more recently independently with the support of my NHS Foundation Trust. There are few treatment options for these patients once they have exhausted simple procedures especially as most specialists are reluctant to offer joint replacement to the younger age-groups. This load absorber offers the opportunity for surgeons to drastically reduce pain, improve function and delay the use of joint replacement. Critically, however, I believe it should not reduce the future effectiveness of joint replacement which is where it stands apart from other joint or bone-altering alternatives.	Thank you for your comment. The committee discussed the role of this procedure and device in the management of younger patients and added a Committee comment in 6.1 which states that: *The Committee was advised that there are few treatment options for younger patients with osteoarthritis of the knee and implantation of a shock or load absorber may offer an option for these patients, and may potentially delay the need for joint replacement*. The Committee noted the lack of evidence on the potential impact of the procedure on future surgery, including joint replacement when the overview was presented. Thus, in section 1.2 it is recommended that: "Clinicians should report the nature and timing of any further surgery on the knee and the effect of removing the device."

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12	Consultee 1 NHS Professional	**General**	I was asked to forward questionnaires to all non-study patients of mine who have been treated with this device so independent feedback could be sought. Unfortunately (due to an error at the National Institute) the sealed envelopes we sent out contained a questionnaire about cholecystectomy and not the load absorber. By the time this error was realised, and we had the opportunity to send out the correct questionnaire, the open hearing deadline was less than a week away. I am concerned that this critical patient feedback may not have been reviewed due to this error. If this is the case then important outcome information from UK patients may not have been taken into account when completing the guidance.	Thank you for your comment. An administrative error occurred when obtaining patient commentary for this procedure, which led to the wrong questionnaires being sent. This was an unfortunate mistake for which we apologise. To address this error, the deadline for obtaining patient commentary was extended, and patient commentaries were sought using the correct questionnaire. These were made available to IPAC to consider at the November IPAC meeting. Based on the patient commentaries received for this procedure, a Committee comment was added to guidance in section 6.2: *The Committee noted commentary from patients that described benefit. The time to recovery was relatively long for these patients: up to a year. Some patients noted that the device was bulky.*
13	Consultee 1 NHS Professional	**General**	Please see the attached file for a patient review on the [redacted] which was implanted more than 4 years ago: https://www.youtube.com/watch?v=BVFxARbhnww	Thank you for your comment. Patient views or statements made on social networking websites cannot be considered as evidence. All relevant published evidence (which has been subject to peer review) has been included in the overview. Based on the patient commentaries received for this procedure, a Committee comment was added to guidance in section 6.2: *The Committee noted commentary from patients that described benefit. The time to recovery was relatively long for these patients: up to a year. Some patients noted that the device was bulky.*

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14	Consultee 2 NHS CEO	**General**	I had this implantation operation last December and it has been a great success. I had reached a stage where walking had become quite painful because of arthritic deterioration. The [redacted] has both alleviated the pain and allowed a return to regular walking and excercise. Commenting from a professional perspective as an NHS CEO , I think this is a very simple procedure with potentially strong economic benefits for the group of patients who are likey to benefit from this treatment. I would strongly recommend continued support for the development of this procedure.	Thank you for your comment. The Committee very much welcomes hearing from patients who have undergone this procedure and considered your experience and views in their deliberations. A committee comment was added to section 6.2: *The Committee noted commentary from patients that described benefit. The time to recovery was relatively long for these patients: up to a year. Some patients noted that the device was bulky.* IPAC supports research by identifying key outcomes for future studies as the current published evidence for this technology is limited in quality and quantity.
15	Consultee 5 NHS Professional	**General**	I note on page 14 that a recommendation has been made to add patient data to the national osteotomy register that is in progress. I would also advocate the use of a register for the load absorber patients to collate data. The data collection forms for this procedure are already in use.	Thank you for your comment. In Specialist advice summary (page 14 of the overview), one of the advisers suggested submitting patient data to the national osteotomy register that is being planned with support by British Association for Surgery of the Knee (BASK). BASK informed that 'the national osteotomy register is not at the stage of recruiting and will take a minimum of 1 year to start'. They also said that 'the load absorber would not be considered appropriate for recording in the database as currently constructed, but has merit as an idea. At this stage this is theoretical and cannot be used in the NICE guidance'.

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16	Consultee 1 NHS Professional	**NOTE**	I have worked in the past on a research study funded by the manufacturer which is now complete. I was involved in the first European multi-centre trial of this device	Thank you for your comment.
17	Consultee 5 NHS Professional	**NOTE**	I have worked as an instructor on the cadaveric course and performed consultancy work for [redacted] inc. I was a senior knee fellow between 2010 and 2012 working with [redacted] in Harrogate and [redacted] at Royal Derby. I was closely involved with the COAST trial from the start in 2010. I now work as a consultant in Yorkshire.	Thank you for your comment.

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