National Institute for Health and Care Excellence

IP1193 - Minimally Invasive Sacroiliac joint fusion Surgery for Chronic Sacroiliac Pain Consultation Comments Table

IPAC date: 9 February 2017

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 AXA-PPP healthcare	1	We do not agree with your conclusion that the “Current evidence on the safety and efficacy of minimally invasive sacroiliac (SI) joint fusion surgery for chronic SI pain is adequate to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit” We would ask you to reconsider and instead recommend ongoing special arrangements for clinical governance, consent and audit. Our rationale for this recommendation is outlined in the points below:	Thank you for your comments. The Committee considered this comment but decided not to change the guidance.

2	Consultee 1 AXA-PPP healthcare	4	**Efficacy** We have concerns over the limited quality of the studies that include three randomised controlled trials, both sponsored by the device manufacturer but with very limited follow up because of their crossover design. • The evidence on which you have based your conclusions comes primarily from 2 randomised controlled trials from Polly et al. (2016) and Stureson et al. (2016), 2 systematic reviews one of which (Zaida et al. 2015) has not included any high quality RCTs and the other (Heiney et al. 2016) included one short RCT with 6 month follow up (Whang et al. 2015). • There are 3 RCTs but none have sufficient control group participants beyond 6 months because of crossover into surgical arms • More than half of operated patients continued to use opioids at the end of the follow up period for SIJ or back pain (in those studies reporting this) • A significant proportion (35-44% where reported) of patients had already undergone lumbar fusion surgery prior to this intervention. This raises concerns about the efficacy of any fusion surgery carried out primarily for pain (as opposed to cancer or trauma).	Thank you for your comments. The committee has reached its draft recommendation based on evidence from peer reviewed published sources (see overview and section 4 and 5 of the guidance). The aim of the programme is to describe the conditions under which the procedure may be used in the NHS based on a review of its efficacy and safety. The committee members are aware of the potential limitations of studies which are not independent of the manufacturer (sponsored mainly by companies directly or indirectly), and of studies which do not have long follow-up periods, but nevertheless they made the recommendation for standard arrangements. Another publication reporting referred leg pain (Dengler 2016) has been identified in our update searches. Data from this study has been added to study 2 in table 2 in the overview. Data on prior lumbar fusion are reported in table 2 in the overview.

3	Consultee 1 AXA-PPP healthcare	General	You may be interested in recent editorials from Prof Haddad and Roberts et al. who report the general poor level of evidence in orthopaedic research. Roberts et al. report that more than two thirds of studies presented at major spinal conferences in 2015 and 2016 were case series rather than level 1 evidence. Case series are subject to bias that makes it very difficult to ascertain whether and intervention is effective. These authors write: “Case series are not included as evidence in guidelines because of the methodological limitations and, it is unclear why surgeons persist in undertaking small case series and claiming efficacy This practice is hindering our specialty in achieving academic potential and should stop. ..” http://www.bjj.boneandjoint.org.uk/content/99-B/1/1 http://www.bjj.boneandjoint.org.uk/content/99-B/1/3?etoc	Thank you for your comments. Thank you for bringing these editorials to our attention. The committee members are aware of the varying quality of evidence available on different interventional procedures, and on the biases and limitations of different study designs. In considering safety and efficacy IPAC often uses data from non-randomised and observational studies, including case series, when other evidence is lacking. In this case there was a well conducted randomised study with clear entry criteria in addition to case series. IPAC does not produce treatment guidelines. It considers the evidence for safety and efficacy of specific interventions for specific conditions and do not compare one treatment with another.

4	Consultee 1 AXA-PPP healthcare	5	Safety • 25% of patients required further surgery to the spine or hip and 13.1% required contralateral surgery during the follow up period in the Sachs study (see below) • Complication rates of 13 and 16% at 90 days and 6 months in the Schoell study suggests that it is too early to conclude that this intervention is safe in the short to medium term.	Thank you for your comment. Data on additional and bilateral procedures (from Sach's study) are presented in table 2 in the overview. The complications are specifically recorded and discussed in sections 5.4-5.7. A discussion of these potential complications would be part of "normal arrangements" when consenting for surgery. These problems were discussed in committee. Data on 90 days and 6 month complication rates (from Schoell study) are presented in study 9 in table 2 in the overview. The commonest complication is failure to resolve symptoms or recurrent back problems. These problems are present with most treatments for back pain.

5	Consultee 1 AXA-PPP healthcare	General	All important studies appear to have been funded by a device manufacturer. There is no independent research. Many authors of these studies have conflicts of interests and some were paid substantial sums of money by the device manufacturer.	Thank you for your comment. Information about conflicts of interest and source of funding for the included studies are reported in table 2 in the overview and the committee were aware and discussed these when coming to their decision.
6	Consultee 2 Manufacturer SI-BONE	6.1	I am writing to comment on the Interventional procedure consultation document “Minimally Invasive Sacroiliac joint fusion Surgery for Chronic Sacroiliac Pain.” I am an orthopedic spine surgeon with 20 years in clinical practice. I am currently the VP of Medical Affairs for SI-BONE, Inc. the manufacturer of the iFuse Implant System®. In the consultation document, dated December 2016, the committee comments “the committee noted that the evidence reviewed by the committee was mainly from 1 device, but that there is more than 1 device available. The committee also noted that there was a lack of evidence beyond 3 years of follow-up.” There have been two articles that were recently accepted for publication that address these issues.	Thank you for your comment. See response to comment 9 about the 2 recently accepted publications.

7	Consultee 2 Manufacturer SI-BONE	3,4, 5	The committee has recognized the significant differences between the lateral and the dorsal approaches for minimally invasive (MIS) SI joint fusion. There are significant differences between these two approaches especially with respect to the anatomy/surgical approach, risk profile, stabilization strategies, fusion strategies, and most importantly the evidence base. There is a significant body of literature documenting the safety, effectiveness and durability of lateral trans-articular MIS SI joint fusion performed with the iFuse Implant System. There is a paucity of literature supporting the dorsal approach. The results of lateral MIS SI joint fusion with the iFuse Implant System are not generalizable to the dorsal approach.	Thank you for your comments. The 'overview' of evidence and the 'draft guidance' focused on the lateral transarticular approach. The procedure description is also based on this approach. IPAC amended committee comment 6.1 to state that there is more than 1 device and surgical approach.

8	Consultee 2 Manufacturer SI-BONE	6.1	As noted by the committee there are several lateral "products" for MIS SI joint fusion. The vast majority of these products are "screws" of some sort. Some of them have fenestrations for placement of bone graft, (no published clinical literature supports this fusion strategy) some have variably pitched threads (no supporting evidence), and one is coated with hydroxy appatite (HA), but all of them are screws. HA is a surface coating that is reabsorbed with time. HA coating has not been shown to be effective when in contact with cancellous bone, for example HA on an acetabular prosthesis. The iFuse implant is quite unique when compared to a screw. The iFuse Implant is designed with a different stabilization strategy and utilizes a different fusion strategy. The iFuse Implant is triangular in cross section and is impacted across the joint (not threaded). The triangular implant is 30 times more resistant to rotation than a similarly sized screw. The iFuse Implant is manufactured with a porous surface that allows for bone ingrowth and bone ongrowth. This surface is an integral and permanent part of the implant. The surface does not reabsorb or dissolve over time. The surface of the iFuse Implant is the same porous surface technology that has been used in orthopedic joint arthroplasty and in dental implants for over 25 years. The longevity and durability of these implants is well documented.	Thank you for your comments. The IP programme issues guidance on procedures rather than individual devices. Section 6.1 in the guidance states that 'the evidence reviewed by the committee was mainly from 1 device using a lateral transarticular approach, but there is more than 1 device and approach available'.

9	Consultee 2 Manufacturer SI-BONE	5.5 & 4	Dr. Holt has compared his experiences with the iFuse Implant System and orthopedic screws (the implants he used for SI joint fixation prior to availability of iFuse). His paper was recently accepted for publication http://www.ijssurgery.com/10.14444/4005. (PDF attached). This paper documents a 30% revision rate for screws compared to a 5% revision rate for iFuse at four years. This paper provide support for the significant differences in outcomes between the iFuse Implant system and screws. In addition, the paper provides additional "longer term" follow-up with documentation of an acceptable revision rate at 4 years. A second paper evaluating three treatment cohorts of patients with SIJ dysfunction was recently accepted for publication at the Journal Neurosurgery. I apologize for not having a link. I will send it when available. I have attached a PDF copy of the "accepted" publication. This paper follows three treatment cohorts; 1) Conservative care (Physical Therapy), 2) Radiofrequency Ablation (RFA), and iFuse (MIS SIJ Fusion). This paper provides additional evidence to support the durability of the iFuse procedure out to 6 years.	Thank you for your comment and sharing information about the 2 recently accepted publications. **Spain K 2017** is a retrospective comparative study reporting surgical revision rates for fixation with screws (n=38) compared to SIJ fusion with triangular titanium implants (n=274). Using survival analysis techniques, the 4 year cumulative probability of revision in the fixation group was 30.8% and 5.7% for fusion. Revision rates are already reported in section 5.5 in the guidance. Because of the mismatch groups and different follow-up periods, this study has been added to appendix A in the overview. **Vanaclocha VV 2017** is a retrospective comparative study reporting pain and functional outcomes for SIJ fusion (n=27) compared to either conservative management (n=63) or SI denervation (n=47) (mean follow-up 3.5 years). Pain and functional outcomes are reported in section 4.3, 4.4 in the draft guidance. There are huge losses to follow-up, therefore this study has been added to appendix A in the overview.

10	Consultee 2 Manufacturer SI-BONE	6.3 & 4.2	The committee also noted that “while this procedure achieves stabilization of the joint, there was evidence that fusion of the joint does not occur in many patients.” The 2 year SIFI study (Duhon, IJSS 2016) included a radiographic analysis by an independent reviewer. This CT analysis demonstrated a high rate of bony adherence (97%) to the implants on both the iliac and the sacral sides of the SI joints. If the iliac bone and the sacral bone are firmly attached to the implants via the porous surface, then the bone are united, joined together, or in a word fused. A paper evaluating the CT scans from the SIFI prospective study (1 year CT scans) and the INSITE RCT (2 year CT scans) is currently under review at IJSS. Hopefully this paper is accepted for publication in the very near future. What this paper shows is that “bridging bone” or osseous fusion of the joint occurred in 27% of patients at 1 year and in 55% percent of patients at 2 years. The Rudolf (Rudolf, Open Orthopedic Journal 2014) paper documented bridging bone in 87% of patients at 5 years. There is significant literature to support the durability and long term fusion of the SI joint with the iFuse Implant procedure.	Thank you for your comment and sharing information about relevant upcoming publication. Radiographic outcomes (from Duhon 2016) have been reported in section 4.2 in the draft guidance. Rudolf L 2014 paper has been included in the systematic review (Heiney 2015) in table 2 of the overview. Efficacy data that have not been published or accepted for publication by peer reviewed journals are not normally selected for presentation to the committee. IPAC may review the guidance upon publication of substantive new body of evidence in peer reviewed journals.
11	Consultee 2 Manufacturer SI-BONE	General	I would also like to share a box link https://app.box.com/v/iFuse-KeySIJ-pubs with a complete bibliography and copies of the published clinical literature demonstrating the safety, effectiveness, durability and cost benefit of MIS SI Joint fusion with the iFuse Implant System. Please download any of the publications that are not currently in the committee’s bibliography for this procedure.	Thank you for your comments and sharing the bibliography of published literature. The team has verified this list and added missing papers to the overview.