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REVIEW ARTICLE

iFuse Implant System for Treating Chronic Sacroiliac Joint Pain: A NICE Medical Technology Guidance

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Abstract
Treatment and management of sacroiliac joint pain is often non-surgical, involving packages of care that can include analgesics, physiotherapy, corticosteroid injections and radiofrequency ablation. Surgical intervention is considered when patients no longer respond to conservative management. The iFuse Implant System is placed across the sacroiliac joint using minimally invasive surgery, stabilising the joint and correcting any misalignment or weakness that can cause chronic pain. The iFuse system was evaluated in 2018 by the UK National Institute for Health and Care Excellence (NICE) as part of the Medical Technologies Evaluation Programme (MTEP). Clinical evidence for iFuse suggests improved pain, Oswestry disability index (ODI) and quality of life compared to non-surgical management. The company (SI-Bone®) submitted two cost models indicating that iFuse was cost saving compared with open surgery and non-surgical management. Clinicians advised that non-surgical management was the most appropriate comparator and Cedar (a health technology research centre) made changes to the model to test the impact of higher acquisition and procedure costs. Cedar found iFuse to be cost incurring by approximately £560 per patient at 7 years. During the consultation period, the company reduced the cost of some iFuse consumables, and Cedar extended the time horizon to test the assumption that iFuse would become cost saving over time. These changes indicated that iFuse becomes cost saving at 8 years (approximately £129 per patient), after which the cost saving continues to increase. NICE published guidance in October 2018 recommending that the case for adoption of the iFuse system in the UK National Health Service (NHS) was supported by the evidence.

1 Introduction

The National Institute for Health and Care Excellence (NICE) produces guidance on new or innovative medical devices or diagnostics, Medical Technologies Guidance (MTG). The aim of the guidance is to support adoption of clinically effective and cost-saving technologies in the UK National Health Service (NHS).

This paper summarises the evidence base for iFUSE as reported in Cedar's assessment report and how it was used to inform the NICE MTG on the iFuse Implant System for treating chronic sacroiliac joint pain (MTG39). Cedar is a healthcare technology research centre formed through collaboration between the Cardiff and Vale University Health Board and Cardiff University. The paper is part of a series that provide an insight into the development of NICE MTG [1].

1.1 Background to Condition and Technology

The sacroiliac joint (SIJ) is the joint between the sacrum and ilium bones of the pelvis. The SIJ supports the weight of the upper body and its primary function is in shock absorption and stability. Functioning of the SIJ can be altered as a result of a specific traumatic incident or as a result of wear and tear over time, resulting in pain in the groin, buttocks, lower back or legs [2–4]. Chronic SIJ pain can make it difficult

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Key Points for Decision Makers

The iFuse system shows potential for long-term cost savings in the UK National Health Service (NHS) due to the reduced requirement for ongoing treatment and pain management costs associated with non-surgical treatments for sacroiliac joint pain.

There is high-quality evidence that the iFuse system leads to improved pain, Oswestry disability index (ODI) and health-related quality of life when compared to conservative/non-surgical management. The longest follow-up available in the included evidence was for 6-year outcomes.

to carry out usual tasks and can severely impact patients' quality of life [5].

SIJ pain is usually treated in a stepped approach, starting with less invasive options such as non-steroidal anti-inflammatory medications and/or opioids and physiotherapy [2, 6]. For patients who do not respond to first-line measures, additional, more invasive procedures are prescribed, typically SIJ corticosteroid injections followed by SIJ radiofrequency ablation (RFA) [2, 7, 8]. If these procedures also fail to alleviate patients' pain then minimally invasive SIJ fusion (MISIJF) is considered [9].

There are a number of CE-marked devices that could be used for MISIJF, including the iFuse Implant System (SI-Bone®, Inc., San Jose, CA, USA) [8]. The iFuse Implant System consists of sterile, cannulated triangular titanium implants with a porous surface, and a surgical instrument system for implantation. The instrument system uses guide pins for accurate placement of the implants [10].

The device is implanted during a minimally invasive surgical procedure under general or spinal anaesthesia, involving a small incision made over the lateral buttock to allow entry to the lateral access of the ilium. The iFuse implants are then placed across the SIJ and remain in place permanently. Typically three implants are used depending on the size of the patient [10, 11].

2 Decision Problem (Scope)

In their evidence submission, the manufacturer must keep within the scope of the evaluation. The scope is defined by NICE in the form of a PICO table (population, intervention, comparator, outcomes, plus cost analysis and subgroups to be considered).

2.1 Population

The population was defined as people with unresolved SIJ dysfunction. A number of population subgroups of interest were identified, including women of reproductive age, number of implants inserted, unilateral versus bilateral SIJ implants and patients who had previous lumbar surgery.

2.2 Intervention

The intervention was defined as SIJ fusion using the iFuse Implant System.

2.3 Comparator

The comparator was defined as non-surgical or conservative management; open SIJ fusion surgery, using screw or cage systems; SIJ denervation; or RFA. Non-surgical or conservative management included optimisation of medical therapy; individualised psychological and physical therapy with provision of adequate information and reassurance; and corticosteroid injections.

2.4 Outcomes

The following patient outcomes were included in the scope: back and SIJ pain relief; improvement in function and disability from back pain (Oswestry disability index [ODI] or other valid disability scale); blood loss during surgery; patient satisfaction; patient health-related quality of life; radiographic evidence of union and absence of loosening (x-ray or computerised tomography [CT] scan to measure bone growth across the fused joint); time to return to work/normal activities; perioperative morbidity and device-related adverse events; postoperative infection or complications; and reoperation rates and medication (opioid) use. System outcomes included procedure time and resources and length of hospital stay.

3 Cedar's Review of the Evidence

The company provided an evidence submission to NICE presenting the available clinical and cost evidence, alongside a de novo cost model produced by the company. Cedar's assessment report aimed to provide the NICE Medical Technologies Advisory Committee (MTAC) with a balanced, fair and independent appraisal of the evidence surrounding use of the iFuse Implant System for chronic SIJ pain [10].

3.1 Review of Clinical Effectiveness Evidence

The company identified 28 publications as relevant and narrowed this to three studies reported in multiple publications (INSITE [INvestigation of SacroIliac fusion TreatmEnt] [12–14], iMIA [iFuse Implant System Minimally Invasive Arthrodesis] [15–17] and SIFI [Sacroiliac Joint Fusion with iFuse Implant System] [18–20]); Long-term follow-up in INSITE/SIFI (LOIS) study (unpublished); a pooled analysis of INSITE, iMIA and SIFI [21]; and a retrospective study [22].

To ensure that all key studies were identified, Cedar undertook a comprehensive search [10] and selection process (Fig. 1). Cedar considered 12 publications (of 11 studies) to be relevant to the decision problem and all of these had been identified by the company. These consisted of two randomised controlled trials (RCTs) (iMIA [15] and INSITE [12]), two retrospective comparative studies [22, 23], seven non-comparative studies [18, 24–29] and a subgroup analysis [30] of one of the non-comparative studies [18] of SIJ pain dysfunction in women with postpartum girdle pain.

The patient population in the RCTs and comparative studies varied and included SIJ dysfunction [12], lower back pain originating from the SIJ [15], unresolved pain [22] and revision for pain recurrence [23]. All of these studies were conducted outside the UK and three were sponsored by the manufacturer. All compare iFuse to non-surgical

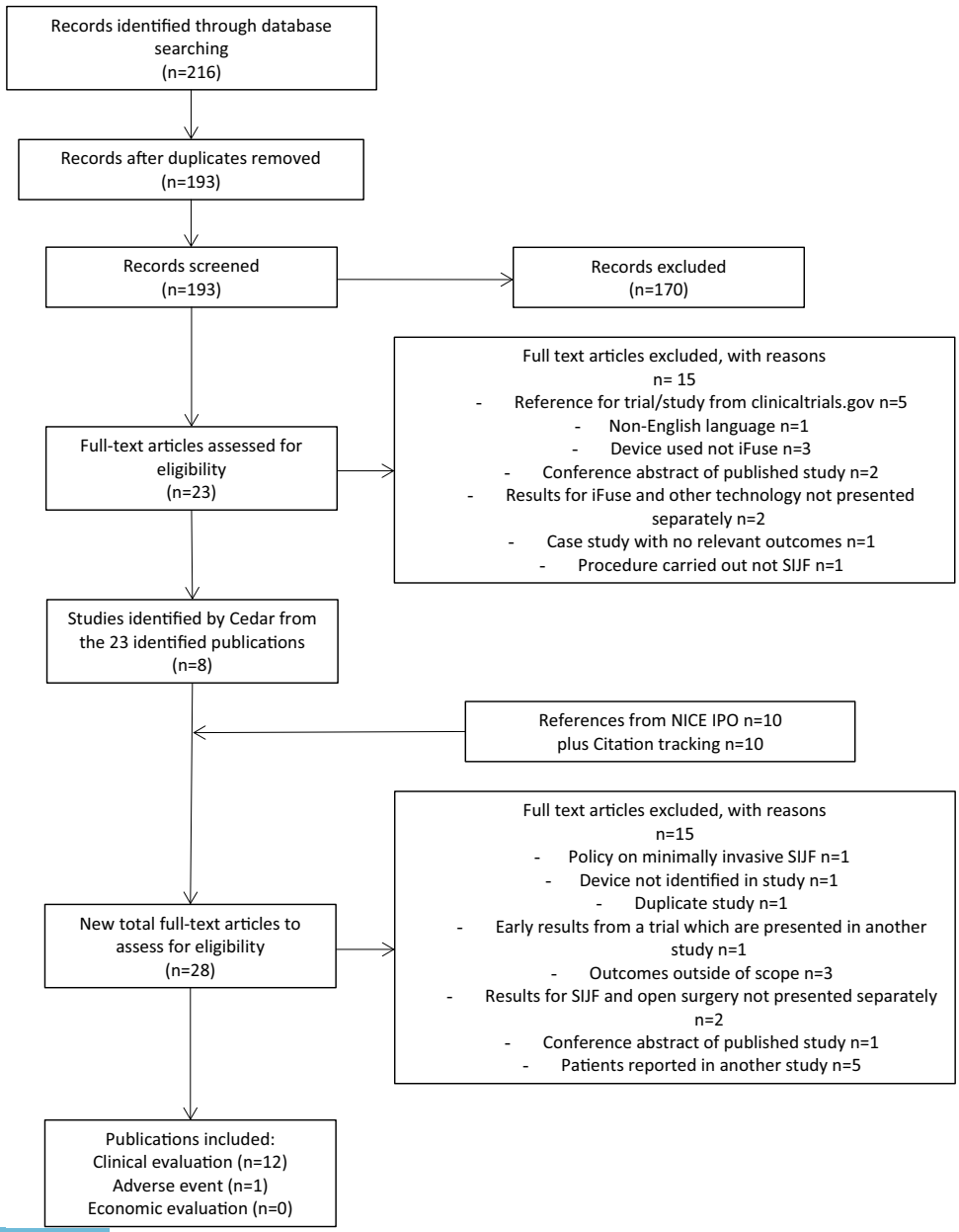

Fig. 1 Publication identification and selection process. *IPO* interventional procedure overview, *NICE* National Institute for Health and Care Excellence, *SIJF* sacroiliac joint fusion

management, except for one study [23] that compared revision rates for iFUSE versus SIJ fixation using screws.

Cedar considers that the evidence base for the use of iFuse is quite strong. The two RCTs present outcomes at 12 [15] and 24 months [12] for iFuse compared with conservative/non-surgical management. It is worth noting that in one RCT [15] the study protocol did not allow patients receiving conservative management to receive SIJ corticosteroid injections or sacroiliac denervation (SID) through RFA but did allow them to receive cognitive behavioural therapy (CBT), if available at their site. In the other RCT [12] the study protocol allowed patients receiving non-surgical management to receive SIJ corticosteroid injections or SID through RFA but did not include CBT. Note that neither RCT was blinded, as surgery is required to place the iFuse implant and conservative management does not include surgery. Although this may present a risk of bias, Cedar considers this to be an unavoidable limitation. One retrospective comparative study [22] presented outcomes at 6 years for iFuse versus conservative management or SID through RFA. There was a lack of comparative evidence for the use of iFuse versus SIJ fixation using screws, and the single study [23] comparing these two treatments presented revision rates only.

The clinical evidence demonstrated that iFuse improved pain, ODI and health-related quality of life when compared to conservative/non-surgical management. Included comparative studies are listed in Table 1. Non-comparative included studies are summarised in Cedar's assessment report [10].

3.2 Safety Outcomes

A low number of adverse events were reported [12, 15, 22] (Table 1); this is reiterated by a pooled analysis of three trials [21]. Of the 326 patients [21] undergoing SIJF, four (1.2%) underwent early surgical revision. In each case, one implant was inadvertently placed into the sacral foramen causing postoperative neuropathic symptoms and requiring surgical repositioning of the implant. Late revision surgery was performed for nine (2.8%) patients, typically done to address pain and sometimes associated with poor implant position. Overall, eight (2.5%) patients had wound-related issues, including surgical washout of deep wound infection ($n=1$), drainage from wound treated with antibiotics ($n=3$), redness treated with antibiotics ($n=3$) and slow healing treated with antibiotics ($n=1$). No patient had bony infection or implant removal for infection.

3.3 Review of Economic Evidence

Neither the company nor Cedar identified any published economic evidence relevant to the decision problem. The company submitted two cost models, the first comparing iFuse with open surgery and the other comparing iFuse with non-surgical management.

3.3.1 iFuse Model Structure

Both models have a Markov structure, with an NHS and personal social services perspective, 6-month cycle length and a 7-year time horizon. The modelled pathway for open surgery and iFuse is similar. Both procedures can have two outcome states: chronic pain or a good response that requires no further treatment. Both outcome states have a constant risk of revision, and each revision can result in either chronic pain or a good response. Clinical experts advised that open surgery was no longer common practice in the NHS, and Cedar determined that non-surgical management was a more appropriate comparator.

Non-surgical management takes all patients through a first corticosteroid injection; following this they may progress to recurrent corticosteroid injections, and then may progress further to RFA. From any of these states, patients may move to the final modelled state of chronic pain, and at 7 years 92% are in this state, requiring pain medication.

This structure means that for open surgery or iFuse the majority of the costs are at the start of the model, with only the patients in chronic pain having ongoing costs. For non-surgical management, costs continue for patients in all states for the duration of the model. Consequently, the longer the model duration, the more likely that iFuse will be cost saving compared to non-surgical management.

3.3.2 Key Assumptions

The following assumptions are made in both the submitted and ammended cost models. For all arms of the model:

- All patients in chronic pain receive an opioid-based regimen and see the general practitioner (GP) every 6 months; 50% are on strong opioids and attend outpatient clinics every 6 months.

For the open surgery and iFuse arms:

- Chronic pain is not a final state; all patients have an equal chance of revision surgery for the duration of the model.
- Physiotherapy post operation is not included.
- Patients with good outcomes require no pain medication, and continue in this state unless requiring a revision.
- Post revision, 50% of patients are in chronic pain.
- Revision surgery has the same costs as the initial procedure.

For non-surgical management:

Table 1 Summary of studies comparing iFuse with conservative management/non-surgical management

Study (year) and design	Participants, setting, intervention and comparator	Outcomes, follow-up and withdrawals	Results	Comments
Dengler et al. (2017) [15] RCT (iMIA trial: ClinicalTrials.gov identifier NCT01741025)	109 patients with chronic LBP originating from SIJ attending spine clinics (Belgium $n=2$, Germany $n=3$, Italy $n=3$, Sweden $n=1$) were randomized 52 patients received SIJF with iFuse, mean age 49.4 years (range 27–70), 38 (73.1%) females 51 patients received CM (medical therapy and physiotherapy), mean age 46.7 years (range 23–69), 37 (72.5%) females At 6 months CM patients who were not benefiting from treatment were allowed to crossover to receive SIJF	LBP VAS, ODI, SIJ function via ASLR, EQ-5D TTO, EQ-5D VAS, Zung depression scale, patient satisfaction, AEs 12 months' follow-up For crossover patients the last observation carry forward imputation method was used to estimate 12-month values, 21/49 (43%) patients crossed-over at 6 months Withdrawals—SIJF group: 2 after randomization and prior to treatment, 2 during months 6–12; CM group: 4 after randomization and prior to treatment, 1 during months 1–3 and 1 during months 6–12	LBP VAS improvement mean score (SD)—SIJF group: 41.6 (27); CM: 14.0 (33.4), $p<0.0001$ ODI mean score (SD)—SIJF group: 32.1 (19.9); CM group: 46.9 (20.8), $p<0.0001$ SIJ function improvement at 6 months—SIJF group: 2 points, $p<0.0001$; CM group: 0.2 points, $p=0.3247$ EQ-5D TTO mean score (SD)—SIJF group: 0.74 (0.25); CM group: 0.54 (0.33), $p=0.0009$ EQ-5D VAS mean score (SD)—SIJF group: 53.5 (23.8); CM group: 64.9 (20.9), $p=0.0005$ Zung depression scale mean score (SD)—SIJF group: 39.6 (9.2); CM group: 44.4 (9.6), $p=0.0035$ Patient satisfaction at 6 months was greatest in the SIJF group, $p<0.0001$ AEs (severe device or procedural events)—SIJF group: 4 patients (recurrent SIJ pain attributed to device loosening in the sacrum $n=2$, postoperative new-onset leg pain related to implant malposition $n=1$, postoperative haematoma $n=1$); CM crossover group: 2 patients (SIJ pain attributed to device loosening $n=1$, postoperative haematoma $n=1$)	The study was sponsored by SI-Bone®, iFuse manufacturer. One author is an employee of SI-Bone®. Another four authors are consultants to SI-Bone® Appears to be a per protocol analysis of outcomes rather than intention to treat

Table 1 (continued)

Study (year) and design	Participants, setting, intervention and comparator	Outcomes, follow-up and withdrawals	Results	Comments
Polly et al. (2016) [12] RCT (INSITE trial: ClinicalTrials.gov identifier NCT01681004)	158 patients with chronic SIJ dysfunction (19 centres in the USA) were randomised 102 patients received SIJF with iFuse, mean age 50.2 years (range 25.6–71.7), 75 (73.5%) females 46 patients received NSM (stepwise medical therapy, physiotherapy, intra-articular SIJ corticosteroid injections and RFA of lateral branches of the sacral nerve roots), mean age 53.8 years (range 29.5–71.1), 28 (60.9%) females At 6 months NSM patients who were not benefiting from treatment were allowed to crossover to receive SIJF	SIJ VAS, ODI, EQ-5D TTO, SF-36 PCS, AEs 24 months' follow-up For crossover patients the last observation carry forward imputation method was used to estimate 12-month values, 39/46 (84.8%) patients crossed-over at 6 months Withdrawals—at 6 months 145/158 (92%) completed trial. SIJF group: 7 withdrew after randomization and prior to treatment, 1 during months 3–6, 1 during months 6–12, 2 during months 12–18 and 9 during months 18–24; NSM group: 3 withdrew after randomization and prior to treatment, 2 during months 1–3; NSM crossover group (from time of crossover): 1 withdrew during months 1–3, 1 during months 3–6, 1 during months 6–12, 4 during months 12–18 and 1 during months 18–24 s	SIJ VAS improvement at 6 months, 38.2 points greater for SIF group compared to NSM group, $p < 0.0001$ ODI mean score—SIJF group at baseline, 6, 12 and 24 months: 57.2, 29.9, 28.3 and 28.7, respectively, $p < 0.0001$; NSM mean ODI decreased by only 4.6 points at 6 months, $p = 0.0537$ EQ-5D TTO index improvement mean score—SIJF group at 6, 12 and 24 months: 0.29, 0.31 and 0.28 points, respectively, $p < 0.0001$; NSM group at 6 months: 0.06 points, $p = 0.1740$; $p < 0.0001$ for difference in change score NSM vs. SIJF SF-36 PCS improvement mean score—SIJF group at 6, 12 and 24 months: 12.5, 12.8 and 11.2 points, respectively, $p < 0.0001$; NSM group at 6 months: 3.9 points, $p = 0.299$; $p < 0.0001$ for difference in change score NSM vs. SIJF AEs—3 SIJF group patients and 1 from NSM crossover group required revision surgery during 24-month follow-up period; 5/55 severe events in the SIJF group were device or procedure related	The study was sponsored by SI-Bone®, iFuse manufacturer. The study manuscript was written jointly by the authors and SI-Bone®; statistical analyses were completed by SI-Bone®. Two of the study authors are paid consultants to SI-Bone® and another two are employees of SI-Bone® An intention to treat approach was used for the 6-month primary endpoint of binary success/failure composite measure. For other outcomes it appears that a per protocol rather than an intention to treat analysis was conducted Unlikely that the study had statistical power

Table 1 (continued)

Study (year) and design	Participants, setting, intervention and comparator	Outcomes, follow-up and withdrawals	Results	Comments
Vanaclocha et al. (2018) [22] Retrospective comparative study	152 patients with chronic SIJ pain from 1 outpatient neurosurgery clinic (Spain) 27 patients received SIJF with iFuse, mean age 48.0 years (range 25–69), 19 (70.4%) females 74 patients received CM (counselling, physiotherapy, medical therapy), mean age 51.4 years (range 29–70), 36 (57.1%) females 51 patients received SID, mean age 48 years (range 24–70), 25 (53.2%) females	VAS SIJ pain score, ODI, pain medication use Patients receiving an interventional treatment were assessed 1 month after treatment and every 6 months thereafter for 6 years; patients receiving CM were assessed every 6 months. Mean follow-up time—CM group: 44 months; SID group: 39 months; SIJF group: 41 months At 6 years' follow-up data only available for 16 patients in CM group, 2 in SID group and 1 in SIJF group	Difference in VAS at 6 months and beyond: SIJF vs. CM 6 points, $p<0.001$; SIJF vs. SID 4.5 points, $p<0.001$ Mean ODI difference beyond 6 months: SIJF vs. CM 24 points, $p<0.001$; SIJF vs. SID 17 points, $p<0.001$ All SIJF patients showed at least a 15-point improvement at year 4 ($p<0.001$ between baseline and year 4). No patient in the CM or SID groups had an improvement in ODI of at least 15 points at year 4 Medication use, last follow-up vs. baseline—SIJF group: opioid use decreased over time and was low (7%) at last follow-up, $p=0.0003$; SID group: opioid use decreased rapidly but increased at last follow-up to over 80%, $p=0.0012$; CM group: opioid use was unchanged in the first 6 months, by last follow-up > 80% were taking opioids, $p<0.001$ AEs—SIJF group: no major complications were observed and no patients treated required a surgical revision	

AEs adverse events, *ASLR* active straight leg raise test, *CM* conservative management, *LBP* lower back pain, *NSM* non-surgical management, *ODI* Oswestry disability index, *PCS* physical component summary, *RCT* randomised controlled trial, *RFA* radiofrequency ablation, *SD* standard deviation, *SF-36* 36-Item Short Form Health Survey, *SID* sacroiliac denervation, *SIJ* sacroiliac joint, *SIJF* sacroiliac joint fusion, *TTO* time trade-off, *VAS* visual analogue scale

- Chronic pain is a final state, with 92% of patients in this state after 7 years.
- Patients on corticosteroid injections require no pain medication, for the whole of the 6-month cycle.
- The probability of continuing a treatment is constant over time, whereas in practice they are likely to be temporary.

3.3.3 Data Sources for Outcomes and Resources

The company commissioned interviews of four clinicians to validate clinical parameters from the literature, the care pathway and to obtain response rates for corticosteroid injections and RFA.

The length of stay data were taken from selected non-comparative papers.

3.3.4 Changes by Cedar

Where possible, Cedar used evidence from published studies to base model results on meaningful data. The changes are presented in Table 2. Cedar also addressed two minor errors in the calculation of the transition probabilities in the model.

The success rates used in the model for response to iFuse or open surgery were taken from a review that reported patient satisfaction [31] based on a mix of ODI, visual analogue scale (VAS) scores and 36-Item Short Form Health Survey (SF-36) measurements in different studies. The review was not included in the clinical evidence. The submitted model uses this value as a proxy for "good response to treatment", meaning that no further treatment or pain medication is required. Cedar felt that this was not appropriate and found alternative sources of information. A study in the clinical evidence reported a success rate for iFuse surgery [18]. For open surgery, Cedar used a study that reported "good response to treatment" [32].

Table 2 Key external assessment centre (EAC) changes to model parameters

Variable	Company value	EAC value	EAC source and comments
Length of stay for open surgery (anterior)	8 days	6.7 days	Submitted model used data from 1 paper [33]. Cedar calculated a weighted average length of stay from 2 papers [33, 34]. None of the studies were included in the clinical evidence
Length of stay for open surgery (posterior)	5.1 days	4 days	Company: calculation reported in review [35] Cedar: calculated a weighted length of stay based on data from 4 studies [36–39] reported in the review that reported average length of stay [35]
Length of stay for iFuse	1.7 days	0.8 days	Company: poor-quality review [40] Cedar: calculated a weighted average length of stay from 4 papers included in the clinical evidence reporting mean length of stay [12, 18, 29, 30]
Procedure time for open surgery (anterior)	104 min	110.9 min	Company: data from 1 paper [33] Cedar: weighted mean from 2 papers [33, 34]
HRG codes used for open surgery and iFuse (cost of bed day)	Open surgery: £380.99 iFuse: £272.32	Open surgery: £272.32 iFuse: £380.99	NHS reference costs for 2015/2016 Cedar changed the cost of a bed day for open surgery and iFuse to agree with value in the company's submission
Cost of corticosteroid injections	£637	£500	NHS reference costs for 2015/2016 Company: weighted average of HC29B and HN16A Cedar: HC29B HRG code only
Low-cost drug regimen	£63.25	£27.38	Cedar found lower costs for the drugs listed by the company in the December 2017 BNF/drug tariff
High-cost drug regimen	£692.98	£669.78	Cedar found lower costs for the drugs listed by the company in the December 2017 BNF/drug tariff
Good response to treatment: iFuse	84%	79.9%	Cedar obtained a figure for success rate from 1 paper [18] at 12 months post-procedure, which was deemed to be a more accurate estimate
Good response to treatment: open surgery	54%	48%	Cedar obtained a more appropriate figure for success rate from 1 paper [32]
Procedure time: open, posterior	104 min	110.9 min	Cedar calculated a weighted average procedure time from 2 papers [33, 34]

BNF British National Formulary, *HRG* Healthcare Resource Group, *NHS* National Health Service

3.3.5 Results from the Model Following Changes

The model submitted by the company found iFuse to be cost saving when compared to either open surgery or non-surgical management at 7 years.

After the changes made by Cedar, the model showed iFuse to remain cost saving compared to open surgery, but to incur a cost of £557.22 per patient at 7 years when compared to non-surgical management. Extending the time horizon would result in iFuse becoming cost saving compared to non-surgical management after 9 years.

Both versions of the model showed that iFuse was a less expensive initial procedure than open surgery, and had improved patient outcomes for the length of follow-up available. However, clinical experts advised that open surgery was no longer common practice in the NHS.

The iFuse system has higher initial costs (including acquisition and procedure costs) than non-surgical management. However, Cedar also noted that as time passes, the costs associated with non-surgical management continue to be accrued for all patients. For iFuse most of the costs are in the initial procedure, with only those patients in chronic pain having ongoing costs for the remainder of the model. Cedar judged this to be relevant to the cost consequences because lifelong management is normally needed for chronic SIJ pain and people are likely to have iFuse in place for the rest of their lives. Cedar therefore considered that cost savings with iFuse were plausible beyond the time horizon of the company's model.

3.3.6 One-Way Sensitivity Analysis and Key Drivers

Comparing iFuse to non-surgical management, the main drivers of cost were the cost of pain management and the number of corticosteroid injection procedures in each 6-month cycle. Clinical experts advised that patients would typically receive one injection during 6 months, as calculated in the submitted model.

Other important drivers include the length of stay for iFuse, the response rate to corticosteroid injections, cost of theatre time and cost of corticosteroid injections.

4 National Institute for Health and Care Excellence (NICE) Guidance

4.1 Preliminary Guidance

The NICE MTAC met in April 2018 and considered evidence from a range of sources, including the company's submission, Cedar's report and additional economic modelling, and testimony from clinical and patient experts. The Committee made provisional recommendations that went to public consultation. The Committee considered the overall quality and quantity of the evidence to be quite high and favoured the use of the iFuse Implant System and considered that use of the iFuse system would be cost saving over time.

4.2 Consultation

During the consultation process, NICE received 13 comments [41] from five consultees (company representative, competitor manufacturer, NHS professional, private healthcare professional and other). Comments covered comparators, costs, corrections and clarifications. One comment from the company informed that it intended to lower the price of iFuse consumables from £275 to £136, making a small reduction in the modelled cost of iFuse. Cedar reviewed the information provided in the comments and updated the extended cost model with the new consumable price. In this scenario, the model shows that iFUSE is cost saving by £129 per patient after 8 years. This information was presented to MTAC in July 2018.

4.3 Recommendations

The evidence submitted by the company and Cedar's assessment report were presented to MTAC, who produced the following recommendations:

- The case for adopting the iFuse Implant System to treat chronic SIJ pain is supported by the evidence. Using iFuse leads to improved pain relief, better quality of life and less disability compared to non-surgical management.
- iFuse should be considered for use in people with a confirmed diagnosis of chronic SIJ pain (based on clinical assessment and a positive response to a diagnostic injection of local anaesthetic in the SIJ) and whose pain is inadequately controlled by non-surgical management.
- Cost modelling indicates that after 8 years, using iFuse instead of non-surgical management will save the NHS around £129 per patient. It is likely that savings will then increase over time. Savings mainly come from fewer corticosteroid joint injections and less pain relief medication with iFuse than with non-surgical management.

5 Key Challenges and Learning Points

SIJ pain is debilitating and can restrict daily activities, impair sleep and affect mood. It is likely to be undiagnosed or misdiagnosed as pain originating from the lumbar spine or hip joint. An increased awareness of the condition among clinicians when assessing and treating low back pain would be beneficial for patients.

Studies reported outcomes for the same patients across multiple publications without explicitly indicating they were the same patients. This proved a challenge when evaluating the clinical evidence. We had to compare baseline characteristics of treatment groups across included studies in order to exclude studies where results for patients had been presented previously.

Modelling the appropriate pathway was complex, as there is not a clear point at which iFuse would be offered. In reality some patients may progress through several non-surgical treatments and then receive surgery.

6 Conclusions

NICE has assessed iFuse for treating chronic SIJ pain to help the NHS decide whether to use this product. Evidence suggests that using iFuse leads to improved pain relief, better quality of life and less disability than non-surgical management. Cost modelling indicates that using iFuse instead of non-surgical management for people with chronic SIJ pain will save the NHS around £129 per patient after 8 years and these savings will increase over time. Therefore, NICE have concluded that iFuse should be considered as an option for people with chronic SIJ pain when non-surgical management is not effective.

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Author Contributions MD, JE, SOC, HM, KC and GCR contributed to the preparation of the manuscript. GCR reviewed the full assessment report and this article, and can act as a guarantor for the overall content.

Compliance with Ethical Standards

Conflict of interest At the time of completing the assessment report, JE and HM were Cardiff University employees and had no conflict of interest. KC is a NICE employee and had no role in the production of the assessment report but contributed to the preparation of this manuscript.Cedar was funded by the NICE Medical Technologies Evaluation Programme for their work. MD, SOC and GCR are NHS employees, and the NHS has a financial interest in the guidance on which this project is based.

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