

Sacroiliac Joint Fusion: Upending Decades of Research

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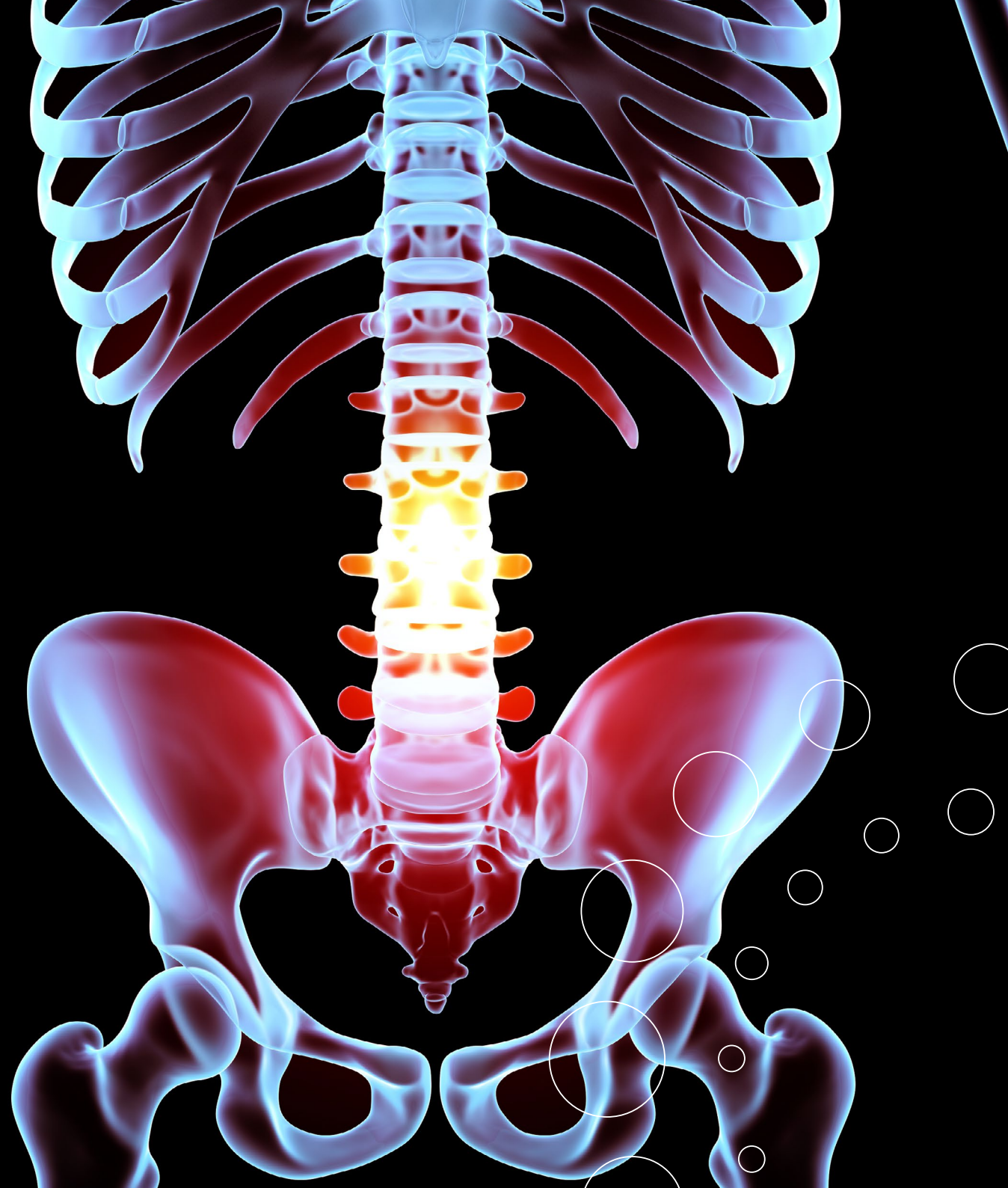
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Sacroiliac Joint Fusion: Upending Decades of Research

Sacroiliac joint fusion is a popular surgical procedure to address lower back pain. Despite this, a careful review of the literature shows that we have little solid evidence to confirm that the procedure is particularly effective at reducing pain. Dr Engelke Marie Randers and Dr Thomas Johan Kibsgård at the University of Oslo conducted a thorough trial to determine the real-world therapeutic benefit of this surgery – with important results.

Sacroiliac Joint Fusion: Why and How?

Lower back pain is a major cause of disability. It's an expected part of ageing, serving practically as shorthand for debilitating or chronic discomfort. It is in the interest of millions worldwide that effective interventions are found to alleviate this source of physical and mental anguish. One of the major causes of lower back pain lies in the sacroiliac joints, which connect the spine to the pelvis. Issues stemming from these joints are thought to underly from 10% to 30% of all lower back pain cases.

The first surgical interventions attempted to address sacroiliac joint-associated pain included open surgery, with the high rates of complications and lengthy recovery times typical of such procedures. Then, in the early 2000s, minimally invasive techniques were introduced.

Minimally invasive surgery has since become increasingly commonplace. The iFuse implant, for example, has found application in over 80,000 procedures globally. Compared to non-operative options, these surgeries are believed to reduce lower back pain and improve patient function.

What Does the Literature Tell Us?

Despite their popularity, many academics have noted that the evidence for their superiority is lacking. In 2022, Dr Eva Chang and colleagues published a review in *The Spine Journal* in which they found much of the literature ostensibly supporting these surgeries to be of low methodological quality.

They found only two randomised control trials (RCTs) comparing surgery to non-operative treatment had been completed, one from Europe and one from America. Both reported that surgery was more effective at reducing pain, and further than non-operative options were, in fact, ineffective. However, neither study has been

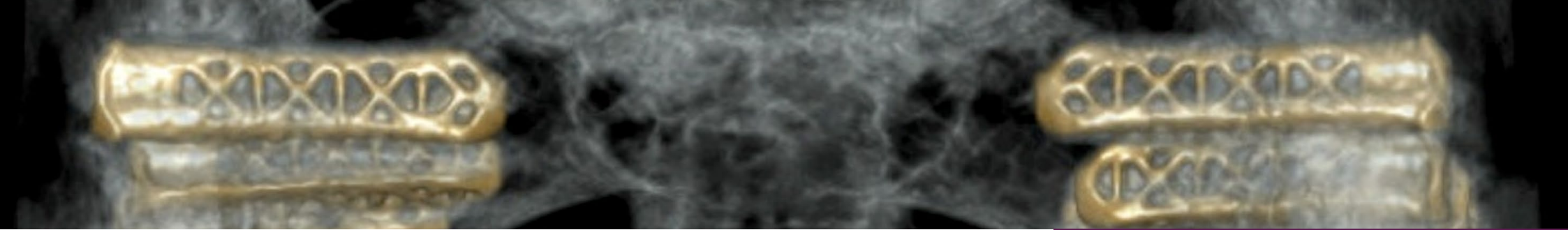
able to account for the potential placebo effect. As surgical interventions are associated with a great degree of expectation and ritual for patients, there remains the possibility that patients may perceive benefits in the absence of genuine efficacy of the procedure undertaken.

Sham Surgery as a New Experimental Control

To address the gap in the clinical literature, Dr Engelke Marie Randers, Dr Thomas Johan Kibsgård (both at Oslo University hospital and the University of Oslo), and their colleagues carried out the first sham surgery-controlled RCT to compare the efficacy of surgery versus non-operative treatment in reducing sacroiliac joint pain.

A sham surgery is, simply put, a fake surgical procedure. All the usual preparation is performed, and even some genuine aspects of the real procedure, but the fundamental elements of the surgery are not performed. By using sham surgery as a control, it is reasoned that patients cannot tell whether or not they received the focal procedure of the trial. Therefore, the placebo effect cannot interfere with the trial's results.

Dr Randers and Dr Kibsgård planned a double-blind, randomised, multicentre trial in which patients were assigned either to receive minimally invasive sacroiliac joint fusion surgery or a sham surgery. Between September 2018 and October 2021, 63 adult patients with severe sacroiliac joint pain lasting more than six months were evaluated and randomised at Oslo University Hospital in Norway and Karolinska University Hospital in Sweden. It was planned that 32 would be assigned sacroiliac joint fusion, while 31 would receive sham surgery.



Going Under the Knife

Before the procedures, patients completed questionnaires on their pain at baseline, as well as a series of functional tests. They then repeated these measures just before a numbing agent was injected to diagnose sacroiliac joint-associated pain, just before the operation, just after the operation, three months post-operation, and six months post-operation. At this time, patients were informed about the procedure they had actually received, and those in the sham group were allowed at this point to undergo the genuine surgery. After that, the researchers checked in with patients two and five years after surgery.

The surgery was performed under general anaesthesia, during which a 3–5cm incision was made over the posterolateral aspect of the pelvis on one side. Guide pins were inserted over the sacroiliac joint and verified by fluoroscopy imaging. The surgeon drilled and broached over the pins, and inserted three triangular, titanium iFuse implants over the joint. The wound was then closed, and a local anaesthetic was injected subcutaneously.

The sham procedure was similar, but after the initial incision, a blunt guide pin was instead inserted through the muscle to the cortical ilium and then removed. The wound was closed, and anaesthetic was administered as with the genuine surgery.

Did the Type of Surgery Matter?

The study's primary endpoint was the difference between the groups in sacroiliac joint pain on the operated side from baseline to six months post-operation. This was assessed with a patient-reported numeric scale rating from 0 to 10, with 0 being no pain and 10 being the worst imaginable pain.

The average ratings on the numerical scale between the surgical and sham groups differed by 1 point. While the greatest improvement was seen for the surgical compared to the sham-surgical patients, this wasn't statistically significant. For all

functional tests, both groups showed slight improvements six months post-surgery without significant differences between groups.

Interpretation

Based on these findings, the researchers concluded that their trial 'could not prove that minimally invasive fusion of the sacroiliac joint was superior to sham surgery at six months postoperative'. Why their findings conflict with previous research remains a topic for further investigation.

The researchers note that when sham results don't support existing literature, it is often claimed the study population doesn't represent real-world patients. However, Dr Randers and Dr Kibsgård used the same diagnostic criteria for sacroiliac joint pain as the previously published European RCT. Furthermore, the American RCT excluded patients for various non-clinical reasons, raising questions about its representativeness.

The researchers also considered whether patients might somehow know which intervention they received. They found that 59% of the surgery group and 48% of the sham group correctly guessed which group they belonged to before unblinding, and the 50-50 guessing is to be expected for a properly blinded trial.

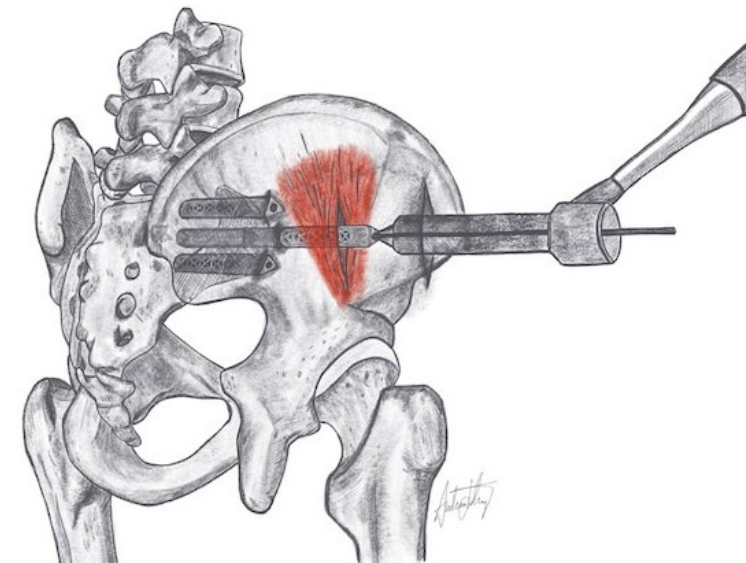
The length of follow-up could be considered another limitation. Dr Randers and Dr Kibsgård chose six months to align with the other two RCTs. Additionally, it has been shown that most of the clinical benefit of this surgery is concentrated within the first six months post-operation, not justifying a longer follow-up.

Perhaps most critically, this trial shows that properly conducted sham trials can be powered to uncover clinical trends and challenge a quorum of erroneous literature. Most pertinent to lower back pain sufferers, the study prompts a discussion on whether the risks and complications of irreversible surgery are worth it when measured efficacy can be so small and perhaps simply the result of the placebo effect.



Dr Randers and Dr Kibsgård planned a double-blind, randomised, multicentre trial in which patients were assigned either to receive minimally invasive sacroiliac joint fusion surgery or a sham surgery.

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MEET THE RESEARCHERS



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Dr Engelke Marie Randers graduated from the University of Oslo in 2009 with an MD. From 2011, she worked as an orthopaedic surgeon at the Vestre Viken Hospital Trust until 2016, when she was recruited to Oslo University Hospital to work as a spine deformities consultant in its Division of Orthopaedic Surgery. Simultaneously, she is completing her PhD thesis at the University of Oslo on the surgical treatment of the sacroiliac joint. She has already published four research papers on her work on sacroiliac joint fusion.

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<https://www.med.uio.no/klinmed/english/about/organization/divisions/orthopaedic-surgery/research-groups-opk.html>

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FURTHER READING

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Dr Thomas Johan Kibsgård completed his PhD thesis on sacroiliac joint fusion and biomechanical sacroiliac joint motion titled 'Radiostereometric analysis of sacroiliac joint movement and outcomes of pelvic joint fusion' in 2014 at the University of Oslo. He works there today, where, since 2016, he has held an Associate Professorship in the Orthopaedics Department. In this capacity, he researches sacroiliac joint fusions and spinal deformities. He also works as a consultant in spine deformities with the Division of Orthopaedic Surgery at Oslo University Hospital. He has published over 20 papers on his work spanning sacroiliac joint injury, total knee arthroplasty, and idiopathic scoliosis.

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