

# AN INVESTIGATION INTO MINIMISING MECHANICAL FAILURES IN SPINAL FUSION SURGERY

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## Introduction

Spinal surgery is one of the most complex forms of surgery currently performed, in part due to the irregular anatomy of the vertebrae as well as the complexity of the surgery itself. Spinal fusion is a commonly used procedure which aims to stabilise the spinal column whilst alleviating the pain observed by the patient. The procedure involves the fusion of multiple vertebrae in the spine to reduce the movement of the vertebrae. However the procedure does face numerous complications such as hardware failure (fracture and loosening), surgical error (fusion at the wrong level and misplaced pedicle screws) and biological failure (rejection of bone graft). This study investigates the causation of premature failure within spinal fusion devices and aims to devise a method to help reduce failure in spinal fusion procedures whilst also allowing early detection of the onset of hardware failure.

## Materials and Methods

A literature review and the FDA's MAUDE system was used to determine the main failure modes of spinal fusion, how frequently the procedure is performed and to determine the cost of the procedure as well as the cost of re-operating on failed surgeries. Questionnaires were sent to 50 surgeons to establish insight into spinal fusion from a surgeons' point of view. In-vitro experiments were also carried out in the form of a simulated spinal fusion procedure. This further outlined issues which may be faced by physicians.

## Results

The literature review highlighted that approximately 6.5% of studied spinal fusion failures can be attributed to screw misplacement. Other literature outlined an investigation into screw misplacement and found that out of 2,201 pedicle screws the misplacement rate was 14% (308 individual screws). A review of the FDA's MAUDE system showed that fracture and breakage attributed to 22% of all 500 pedicle screw entries. Furthermore, other common modes of failure were investigated such as rod failure and loosening were observed with 46% (out of a sample of 100 patients) spinal fusion failures related to the rod hardware.

Feedback from the surgeon questionnaire described the surgeons' insights into main complications with spinal surgery. The three main insights were developed which were; patient biology is a defining factor within the success or failure of spinal fusion,

inevitable procedural error is likely to occur due to the length and complexity of the procedure and preoperative factors such as being a smoker greatly affect the outcome of spinal fusion surgery.

The in-vitro experiment highlighted the complexity of the surgery primarily due to the irregular geometry of the vertebrae which alters at each vertebral level and from patient to patient.

## Discussion

From a combination of the literature review, surgeon questionnaires and in-vitro experiments it was decided that a potential problem which can be improved upon is the placement of the pedicle screw itself. The nature of the spinal fusion operation means that one of the most critical components (accurately drilling into the vertebra) is one of the final steps of the procedure, meaning that fatigue may be an issue.

To lessen the effect of this a device to aid alignment and limit procedural error was generated. With an aim of creating accurate drilling into the pedicle and potentially improving patient outcomes by limiting failure due to pedicle screw misplacement.

## Conclusion

In conclusion spinal fusion is a highly complex surgical procedure which has multiple failure modes. This study highlighted an opportunity to create a device which can reduce the amount of fusion failures which are attributed to screw misplacement and to improve patient outcomes.

## References

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