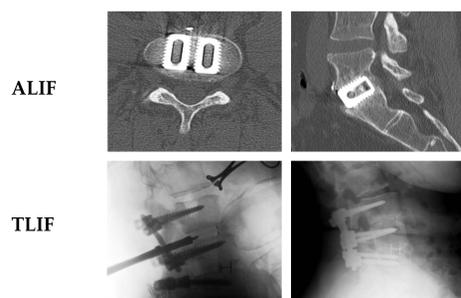


INTRODUCTION

Spinal fusion surgery has shown to be an effective treatment of lumbar instability, deformity, and debilitating lower back pain when unresponsive to non-surgical techniques¹. Spinal interbody fusion involves the removal of the intervertebral disc and scraping of the bony endplates to promote fusion of the vertebrae across the disc section after cages or screws are inserted. The most common techniques for interbody fusion include: Anterior Lumbar Interbody Fusion (ALIF) and Transforaminal Lumbar Interbody Fusion (TLIF). For these procedures, *in vitro* models have shown that disc removal greater than 30% is needed to promote fusion supporting loads greater than 600N². Unfortunately, no clinical validation exists comparing disc volume removed to clinical outcomes.



The objective of this study was to identify the relationship between the percentage of disc material removed intra-operatively and clinical outcomes for interbody fusion procedures.

METHODOLOGY

Study Design:

A retrospective correlation study was performed comparing image-based disc volume measurement with intra-operative disc volume measurement and correlating with clinical outcomes.

- 22 subjects were evaluated in this IRB approved study.
- The patients' pre-operative disc volume was computed using MR images and a semi-automated software algorithm.
- The percent disc volume removal as calculated from the intra-operative volume and pre-operative volume was then compared with post-surgical outcomes.

Intra-operative Disc Volume Measurement:

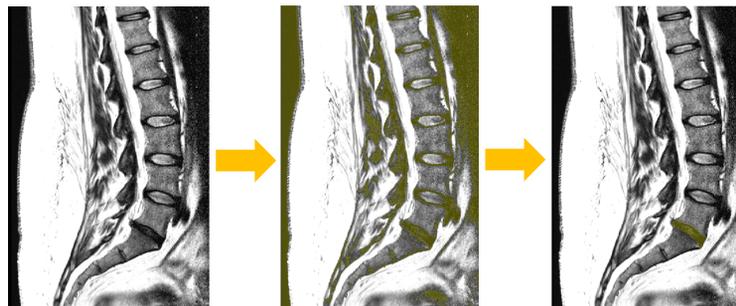
During spinal fusion surgery, disc material removed was placed into a 30 mL syringe and compressed forcefully to remove excess liquids. Measurements were made with 1.0 mm³ precision.



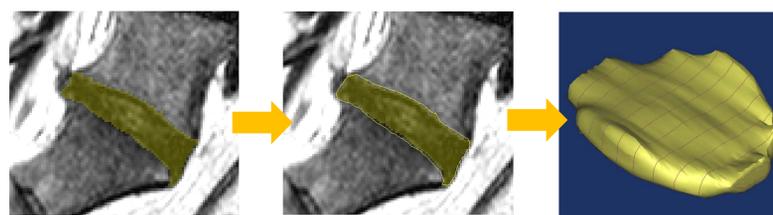
All disc material removed during surgery was placed in a graduated syringe and measured in cubic centimeters

Image-Based Disc Volume Measurement:

Disc volume measurements were obtained by analyzing pre-operative MRIs with Mimics version 12.01 software. Thresholding was used to differentiate between pixels belonging to the disc and those of surrounding tissues and then edited by hand to ensure inclusion of only disc material. The area of the pixels were automatically integrated over all slices to obtain a 3-D model and disc volume measurement with 0.01 mm³ precision.



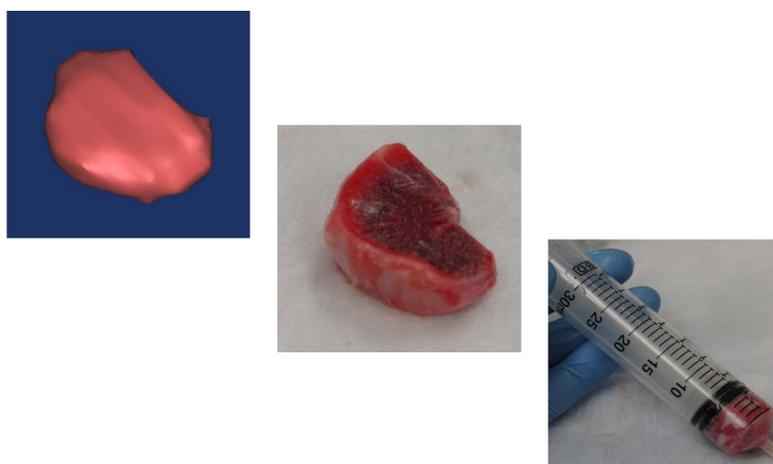
MRI image stacks are loaded into Mimics analysis software where a threshold is applied to a level which selects the intervertebral disc. The image is then edited by hand to identify only disc material.



Once the disc is isolated, the software uses an internal algorithm to trace the surface. This spline fit is used to calculate the area at each slice and is integrated over all slices to obtain the volume. The outlined sections are also used to generate a three dimensional representation of the intervertebral disc.

Volume Measurement Validation:

Porcine spines were used to validate the image-based and intra-operative measurement methods. MRIs from two porcine spines were analyzed using pre-operative image-based protocols. Five discs from each spine were removed *en bloc*. Water volume displacement of each disc was found using a 50 mL graduated cylinder. This gold standard was used to compute the error of the other volume measurement techniques. To validate intra-operative syringe measurements, each disc was fragmented and measured using intra-operative protocols.



RESULTS

Volume Measurement Validation:

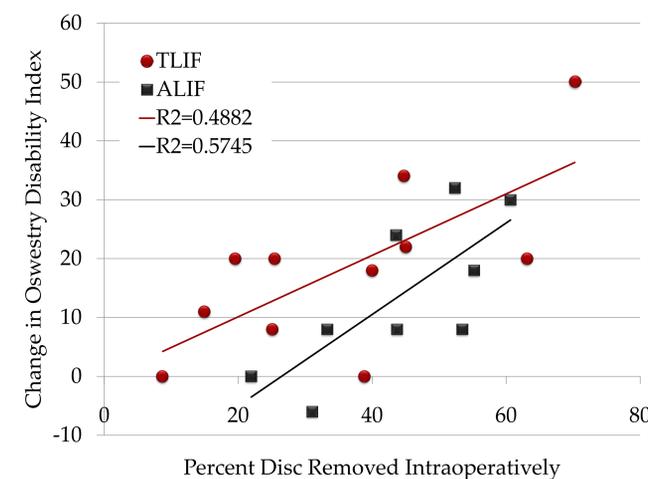
- Technique validation demonstrated the image-based MRI error compared with the gold standard to be 1.7%.
- Similarly, the intra-operative syringe volume measurement error was accurate within 2.1% of gold standard.

Patient Sample:

- 11 TLIF and 9 ALIF cases included in the analysis.
- Oswestry Disability Index data collected on all cases demonstrated the functional outcome for each patient.

Surgical Disc Volume Measurement and Outcomes Correlation:

- Disc volume removed during surgery ranged from 9% to 70%
- The percent disc volume computed to be removed in ALIF 38.96% (± 24.01) and TLIF 43.28% (± 12.21) cases was not statistically distinct by surgical procedure ($p=0.5736$).
- A correlation was found between clinical outcomes as measured by the change in ODI score and the percentage of disc removed intra-operatively



DISCUSSION

- This study identified the relationship between the percentage of disc material removed intra-operatively and clinical outcomes from interbody fusion procedures.
- Since clinical outcome is a multifactorial concept including both surgical components and patient history, compliance, and psychosocial factors, the correlation of surgical outcomes and specific surgical criteria is difficult.
- Limitations of this study include the use of a convenience sample of patients who had pre-operative MR and intra-operative syringe measurements.
- Image-based volume measurements were scaled similar to other studies due to the spline fit's minimization function in the computer software.
- Syringe validation was controlled to minimize the loss of tissue, which may be impossible to reproduce intra-operatively.
- In spite of limitations, these data support a more widespread investigation into the role of percent disc removal in surgical outcomes.

In conclusion, we have developed a validated MRI methodology to assist surgical planning and a research design for capturing longitudinal data which may assist the improvement of spinal minimally invasive techniques

REFERENCES

- [1] Fritzell P et al. *Spine*. Jun 1 2002; 27(11):1131-1141.
 [2] Closkey R et al. *Spine*. Jun 15 1993; 18(8):1011-1015.

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