

A faint, grayscale illustration of a human spine is positioned on the left side of the slide, extending from the top towards the bottom. It shows the vertebrae and intervertebral discs in a slightly curved perspective.

Total Disc Replacement

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Disclosures



Artificial Cervical Discs

- Prodisc-C



- Prestige LP



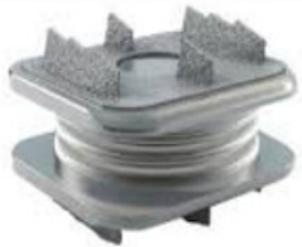
- MobiC



- Discover



- M6



- ActivC



- Discovery



- Bryan





Industry Study - Mobi-C: A Randomized, Prospective, Multicenter Clinical Trial with Seven-year Follow-up

- Patients with symptomatic cervical degenerative disc disease (DDD) at one or two levels were allowed into the study
- Outcomes, adverse events, and reoperations were collected
 - Primary endpoint was patient success (clinical improvement and absence of complications and secondary surgery events)
 - Testing the non-inferiority and superiority of TDR versus anterior cervical discectomy and fusion (ACDF)
- 599 patients enrolled and treated (overall follow-up rate of 80.2%)
 - Patients were randomized in a 2:1 ratio (investigational: control)
 - 164 one-level TDR
 - 225 two-level TDR
 - 81 one-level ACDF
 - 105 two-level ACDF

Radcliff, K., Davis, R. J., Hisey, M. S., Nunley, P. D., Hoffman, G. A., Jackson, R. J.,...& Coric, D.



Mobi-C Study Results

- All treatment groups saw improvement in pain and function outcomes compared to baseline
 - Improvement was maintained for 7 years
- Disability improvement was recorded in 70.2% - 80.8% of two-level surgeries and 84.6% - 84.8% of single-level surgeries
- Neck pain improvement was recorded in 77.7% - 86% of two-level surgeries and 83.3% - 87.5% of single-level surgeries
- One-level TDR and ACDF patients had comparable levels of improvement while two-level TDR patients showed more improvement in pain and function assessments than two-level ACDF patients
 - One- and two-level TDR groups had a significantly lower incidence of second surgery than the ACDF groups

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LSI: TDR Performed in an Ambulatory Surgery Center (ASC) - Background

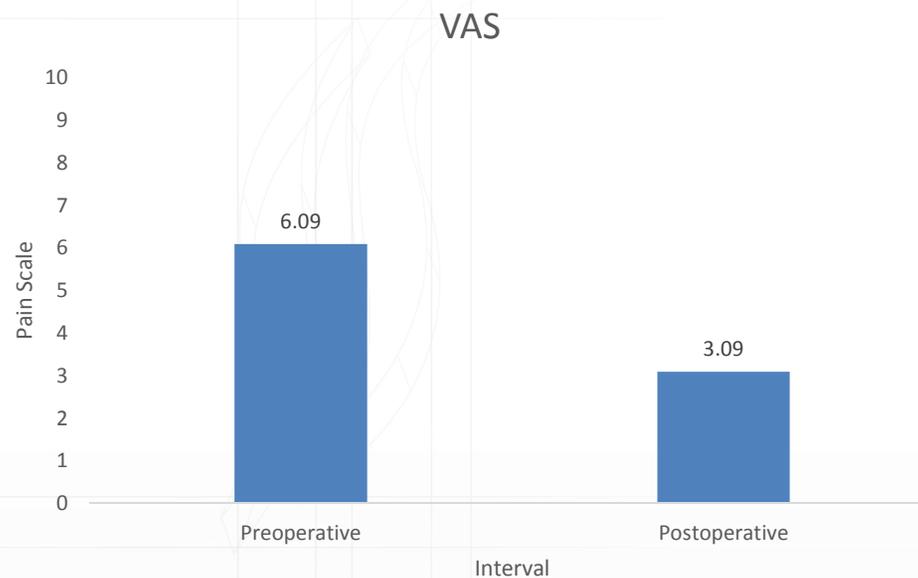
- A retrospective review of prospectively collected outcomes for 11 patients
- Cervical artificial disc replacements took place between January, 2014 and October, 2015 at one of LSI's ASCs
- Visual analog scale (VAS), neck disability index (NDI), and return to work (RTW) metrics were collected for each patient
 - Average follow-up was 219 days (range = 3-12 months)





Preoperative & Postoperative VAS

Measure	N	Mean	Std. Dev.	P-Value
VAS				
Preoperative	11	6.09	1.64	0.004*
Postoperative		3.09	1.97	

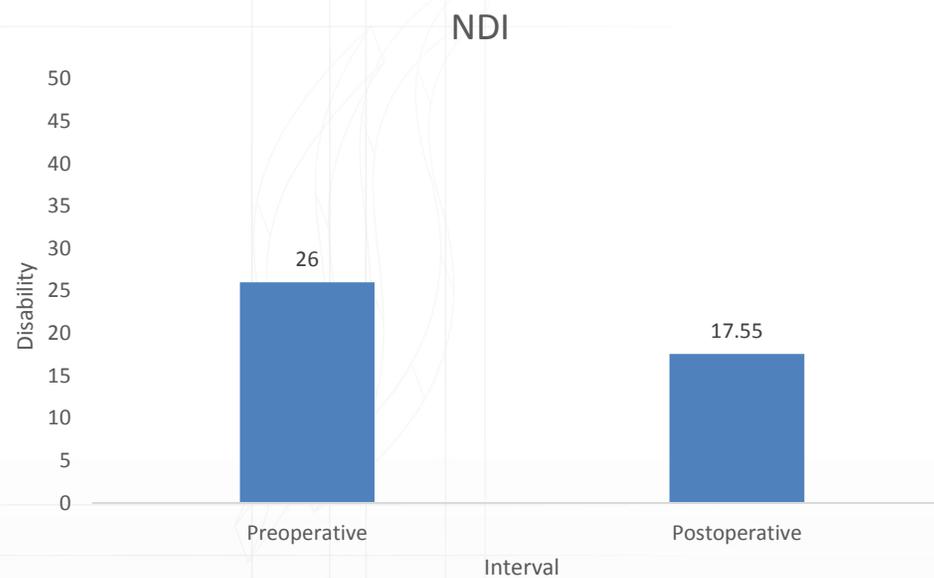


*Calculated using Student t-test in Stata



Preoperative & Postoperative NDI

Measure	N	Mean	Std. Dev.	P-Value
VAS				
Preoperative	11	26	8.82	0.005*
Postoperative		17.55	9.97	



*Calculated using Student t-test in Stata



Return to Work

- 10 patients were included in the analysis
 - 1 patient was removed from the sample for indicating *homemaker*
 - 7 (70%) patients reported returning to their usual occupation at follow up
 - 2 returned in less than 1 month, 3 returned within 1-2 months, and 2 returned within 2-3 months

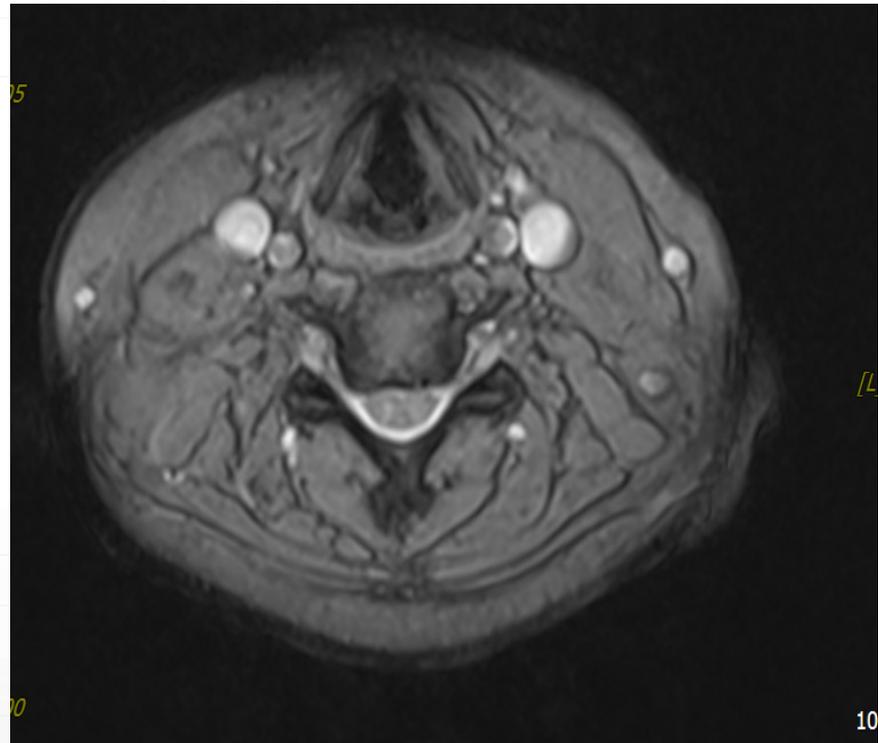
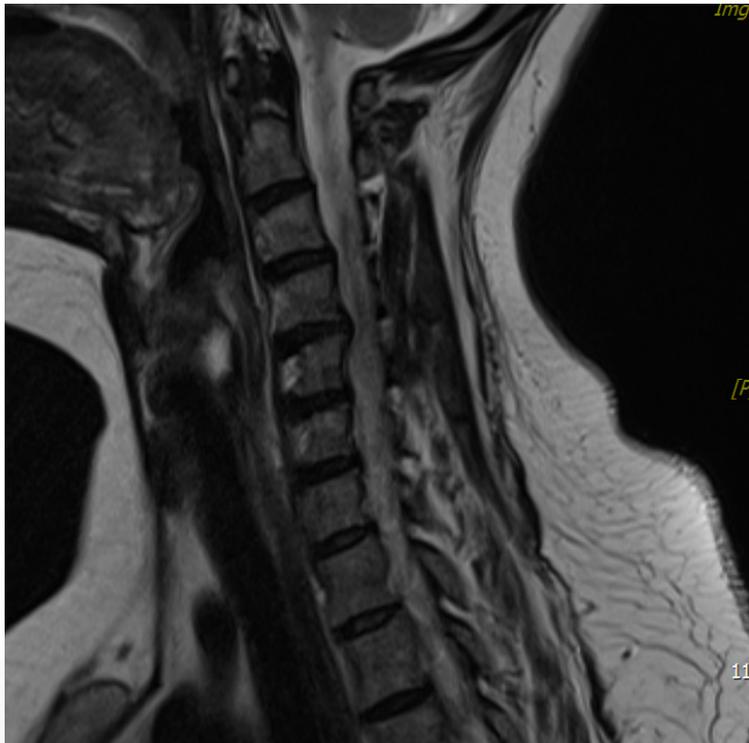


Case Study

- A 42-year-old White female, who underwent a previous lumbar spine surgery at LSI, presented with numbness, tingling, and weakness in both arms and hands. The patient also experienced frequent headaches.
- MRI confirmed that at C3/4 there was mild to moderate left-sided uncovertebral arthropathy and neural foraminal narrowing. At C4/5 there was a broad-based central soft disc protrusion and moderate bilateral uncovertebral arthropathy and neural foraminal narrowing. Findings at C5/6 were insignificant.
- These findings led to the recommendation that the patient undergo a cervical disc arthroplasty with possible spinal cord decompression and total disc replacement



Case Study Preoperative Imaging



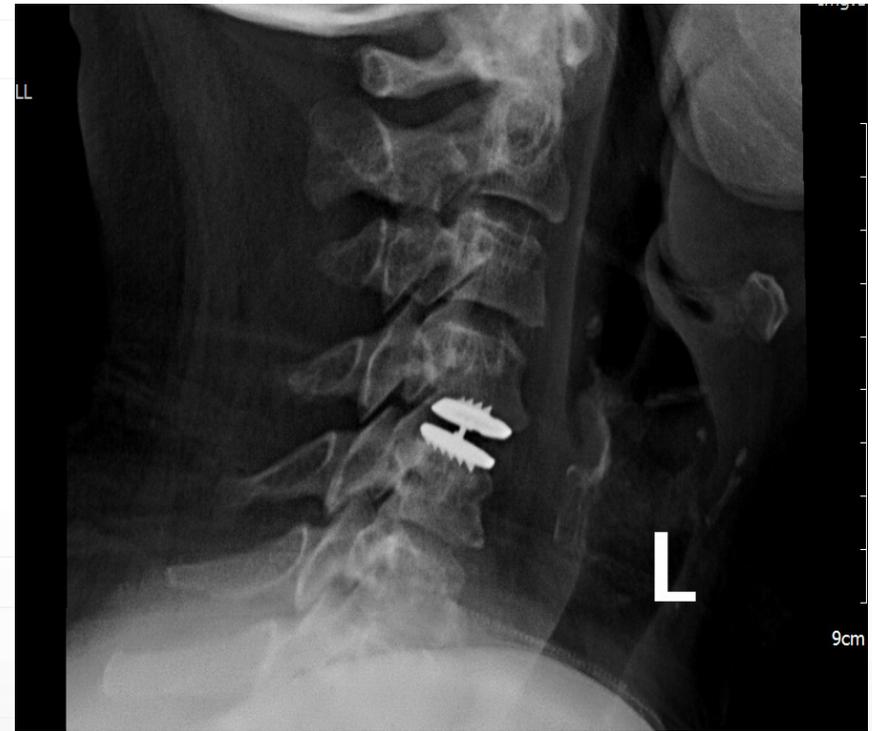
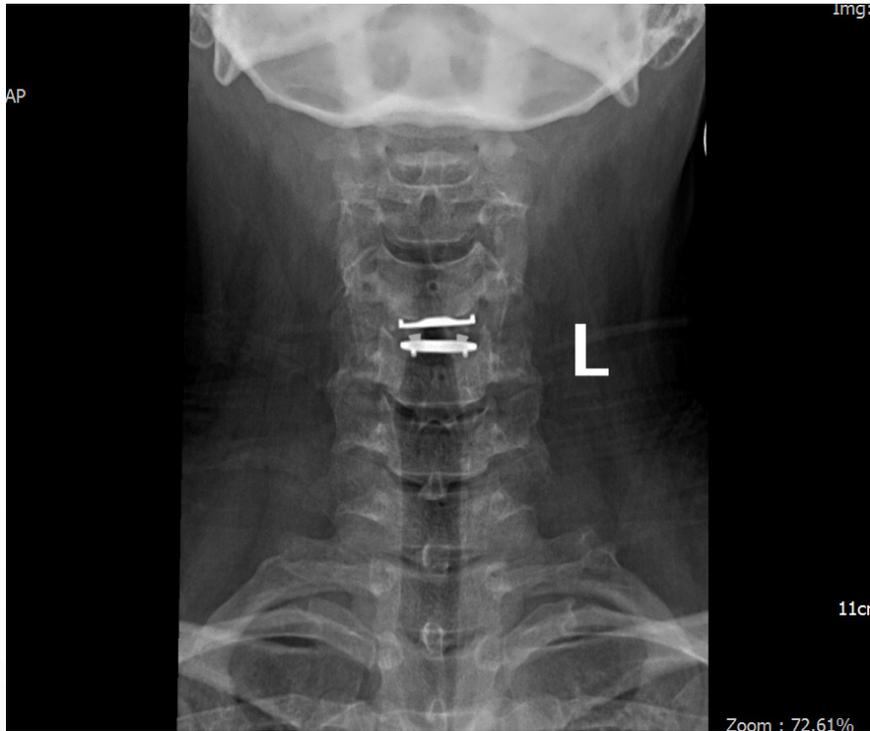


Case Study Cont'd

- The patient underwent outpatient minimally invasive cervical discectomy and total disc arthroplasty Mobi-C at C4/5, which took one hour and forty nine minutes to complete
- There were no operative complications and an estimated blood loss of 25 ml
- The patient tolerated the surgery well and was released two hours and fifty three minutes postoperative, awake and in stable condition



Case Study Postoperative Imaging





Conclusions

- Industry outcomes coupled with Laser Spine Institute's preliminary study suggest that artificial disc replacement is a safe and effective surgical intervention that produces similar results to ACDF
- Outside literature reinforces the notion that total disc arthroplasty provides comparable results to ACDF while demonstrating a decreased probability of subsequent surgery, proposing that total disc arthroplasty may slow the rate of adjacent-level disease*
 - After seven years of follow-up, a total of 30 secondary surgeries were performed on 19 (18%) of the 106 patients in the ACDF group compared to seven secondary surgeries performed on 7 (7%) of the 103 patients in the ProDisc-C group

*Janseen ME, Zigler JE, Spivak JM, et al. ProDisc-C Total Disc Replacement Versus Anterior Cervical Discectomy and Fusion for Single-Level Symptomatic Cervical Disc Disease. *The Journal of Bone and Joint Surgery*. 2015;97:1738-47.

