

Stand-Alone Technology

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Disclosures



Stand-Alone Devices

Optio-C



Stalif C



Coalition



Prevail



ROI-C





Technology Descriptions

- Optio-C
 - A no profile, modular stand-alone cervical device that offers allograft and PEEK options
 - Alternative to ACDF
 - Allograft/Autograft option is intended for one-level anterior screw to provide stabilization as an adjunct to cervical fusion
 - PEEK option becomes an anterior cervical intervertebral body fusion device
- Stalif C
 - An integrated cage system and 3 screw construct allowing it to nest within the confines of the vertebral body without compromising the anatomy external to the interbody
 - Produces a lag effect between the vertebral body and the implanted device which provides constant compressive forces against the implant



Industry Outcomes

- Study comparing zero-profile fixation (group A) and stand-alone PEEK cages (group B) for 3- and 4-level cervical disease
- Group A contains 33 (27 3-level and 6 4-level) patients who received zero-profile devices that involved fixation while group B contains 35 (30 3-level and 5 4-level) patients who received stand-alone PEEK cages
 - In group A, 12 patients received Stalif C and 21 received Optio-C
- The average patient age was 60 and 52 years with respect to groups A and B

Gerszten P C, Paschel E, Mashaly H, et al. (September 10, 2016) Outcomes Evaluation of Zero-Profile Devices Compared to Stand-Alone PEEK Cages for the Treatment of Three- and Four-Level Cervical Disc Disease. *Cureus* 8(9): e775. DOI 10.7759/cureus.775



Industry Outcomes Continued

- The average preoperative VAS Arm in groups A and B were 6.4 and 7.1, respectively
- The average postoperative VAS Arm in groups A and B were 2.5 and 2, respectively
 - Delta of 3.9 in group A and 5.1 in group B
- There was a higher occurrence of both symptomatic subsidence and adjacent level degeneration with PEEK cages compared to zero-profile devices

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LSI's Stand-Alone Technology Study

- A retrospective review of 13 patients that underwent outpatient minimally invasive cervical spine surgery using stand-alone technology (Optio-C and Stalif C)
 - Surgeries took place between March, 2015 and April, 2016
 - Population comprised of 4 males and 9 females
 - Average age is 52.7 (SD = 9.2) years
 - Average BMI is 30.73 (SD = 6.49)
- Visual analog scale (VAS), neck disability index (NDI), and return to work (RTW) metrics were collected for each patient
 - Average follow-up was 246 days (range = 90 – 540 days)



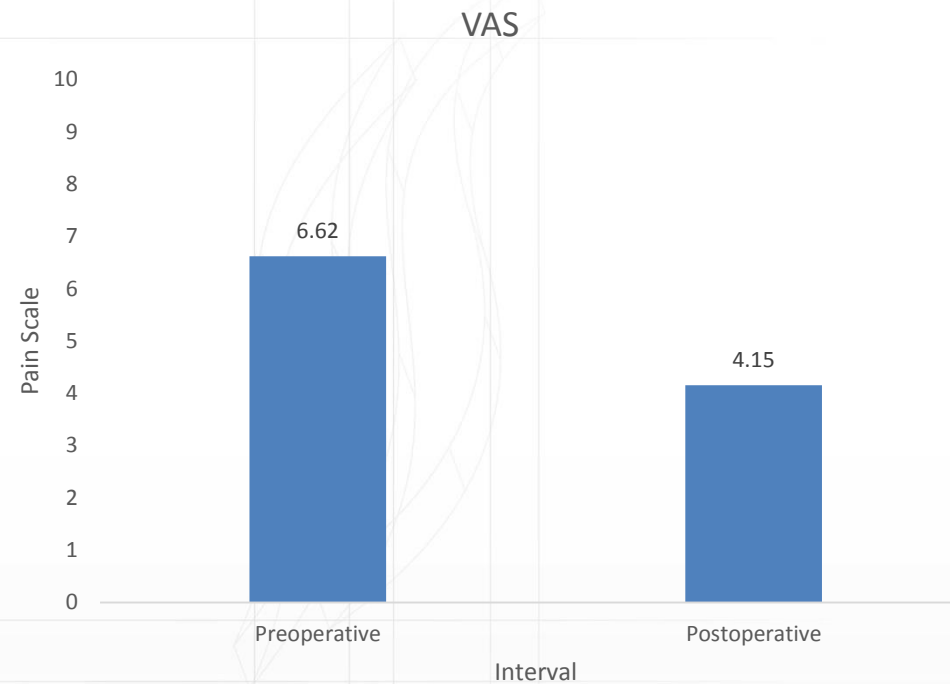
Surgical Variables

- Average length of surgery was 111.9 min (SD = 44)
- Average estimated blood loss was 32.3 ml (SD = 16.2)



VAS

Measure	N	Mean	Std. Dev.	P-Value
VAS				
Preoperative	13	6.62	2.29	0.016*
Postoperative		4.15	3.89	

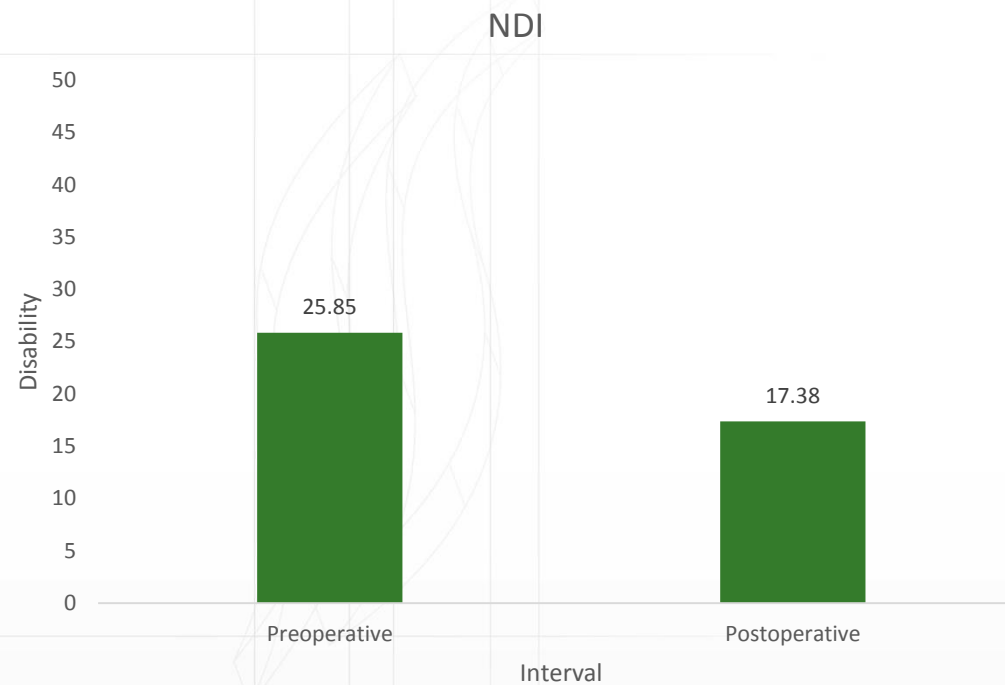


*Calculated using Student t-test in Stata



NDI

Measure	N	Mean	Std. Dev.	P-Value
VAS				
Preoperative	13	25.85	10.76	0.003*
Postoperative		17.38	13.97	



*Calculated using Student t-test in Stata



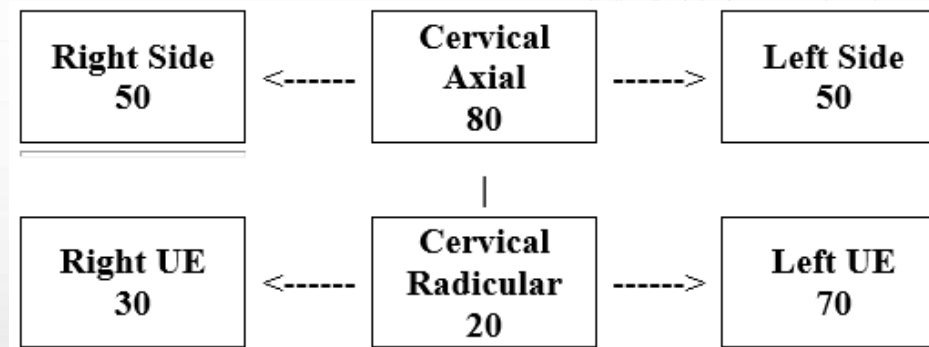
Return to Work

- 8 patients were included in the analysis
 - 5 patients were removed for indicating *retired*, *disabled*, or *homemaker*
- 6 (75%) patients reported returning to their usual occupation at follow-up



Case Study - History

- 61 y/o male with recurrent cervical spine discomfort
- BMI of 27.43
- Prior cervical decompression in 2006
- **CHIEF COMPLAINT:** Neck pain with numbness and tingling down the arms to the hands. Conservative treatments following his 2006 surgery are not helping and his activities of daily living have been significantly impacted. Patient also suffers from headaches.
- Looking up and sitting increases the pain





Physical Examination

- Spinal Exam
 - No scar
 - Deep Tendon Reflexes = Biceps left: 3+. Biceps right: 3+. Brachioradialis left: 3+. Brachioradialis right: 3+. Patellar left: 3+. Patellar right: 3+. Triceps left: 3+. Triceps right: 3+. Achilles left: 3+. Achilles right: 3+.
 - Pedal Pulses = Dorsalis Pedis: 2+. Posterior Tibial: 2+.
 - No LE Edema, no UE Edema
 - No atrophy
 - Heel walk = Left: Normal. Right: Normal
 - Toe Walk = Left: Normal. Right: Normal.
 - Gait = Normal



Physical Examination Continued

- Spinal Exam – Sensory/Palpation

- Dermatomes

- Left – Cervical = C1: Normal. C2: Normal. C3: Normal. C4: Normal. C5: Hypo-esthetic. C6: Hypo-esthetic. C7: Hypo-esthetic. C8: Hypo-esthetic.
 - Right – Cervical = C1: Normal. C2: Normal. C3: Normal. C4: Normal. C5: Hypo-esthetic. C6: Hypo-esthetic. C7: Hypo-esthetic. C8: Hypo-esthetic.

- Spinal Tenderness

- Cervical: Normal

- Spinal Exam – Range of Motion

- Cervical: Flexion painful. Flexion limited. Hyperextension limited. Hyperextension painful. Lateral Flexion painful: Bilateral. Lateral Flexion limited: Bilateral. Rotation painful: Bilateral. Rotation limited: Bilateral.
 - Shoulder: Flexion normal. Hyperextension normal. Abduction normal. Adduction normal.
 - Elbow: Flexion normal. Hyperextension normal.
 - Wrist: Flexion normal. Extension normal. Radial Deviation normal. Ulnar Deviation normal.



Physical Examination Continued

- Spinal Exam – Provocative Tests

- Cervical Tests

- Clonus Test – Left: Positive. Right: Positive. Notes: Sustained.
- Hoffman's Test – left: Positive. Right : Negative.
- Adson's Test – Left: Negative. Right: Negative.
- Spurling's (Foraminal Compression) Test – Left: Positive. Right: Negative.

- Spinal Exam – Muscle Strength

- Cervical

- Deltoid Left: 5. Deltoid Right: 5. Biceps (Elbow Flexion) Left: 4. Biceps (Elbow Flexion) Right: 5. Triceps (Elbow Extension) Left: 5. Triceps (Elbow Extension) Right: 5. Trapezius Left: 5. Trapezius Right: 5. Wrist Flexion Left: 5. Wrist Flexion Right: 5. Wrist Extension Left: 5. Wrist Extension Right: 5. Extrinsic Left: 5. Extrinsic Right: 5. Intrinsic Left: 5. Intrinsic Right: 5. Motor Grip Left: 4. Motor Grip Right: 5.



Imaging Dictation

- C2-C5 are unremarkable
- At C5/6 there is a disc bulge with a left central disc herniation identified with mild canal stenosis. There is foraminal narrowing bilaterally moderate to severe towards the left and moderate towards the right.
- At C6/7 there is a focal disc herniation without canal stenosis. Neural foramina are patent.
- C7/T1 is unremarkable

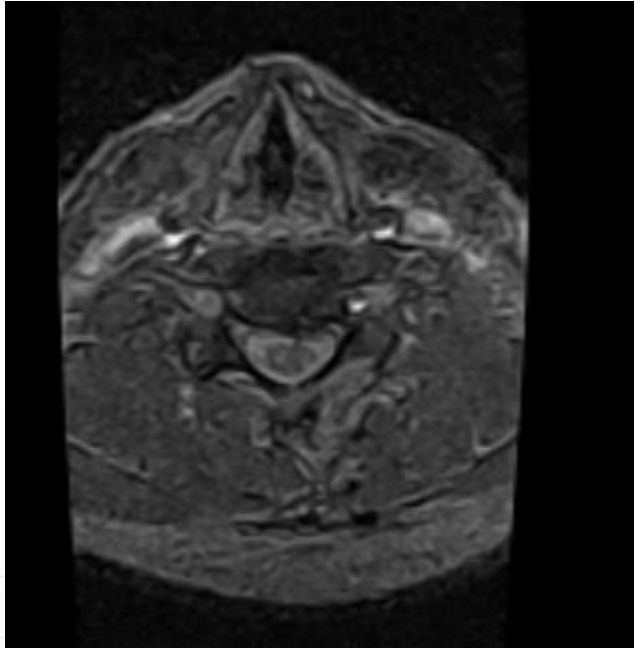
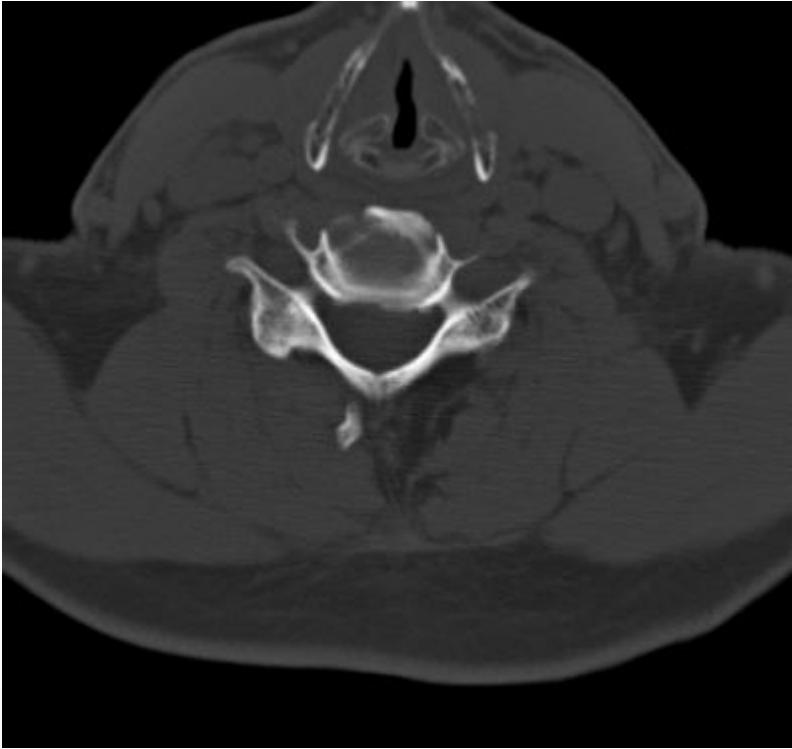


Preoperative Images





Preoperative Images Continued





Surgery

- C5-6 anterior cervical discectomy and fusion
 - C5-6 placement biomechanical device and fusion PEEK spacer
 - C5-6 non-segmental fixation using Optio-C plate and screws
 - Harvesting of local bone for morcellized arthrodesis
 - Anterior cervical microscopic dissection
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- The surgery took 72 minutes to complete with an estimated blood loss of 50 ml

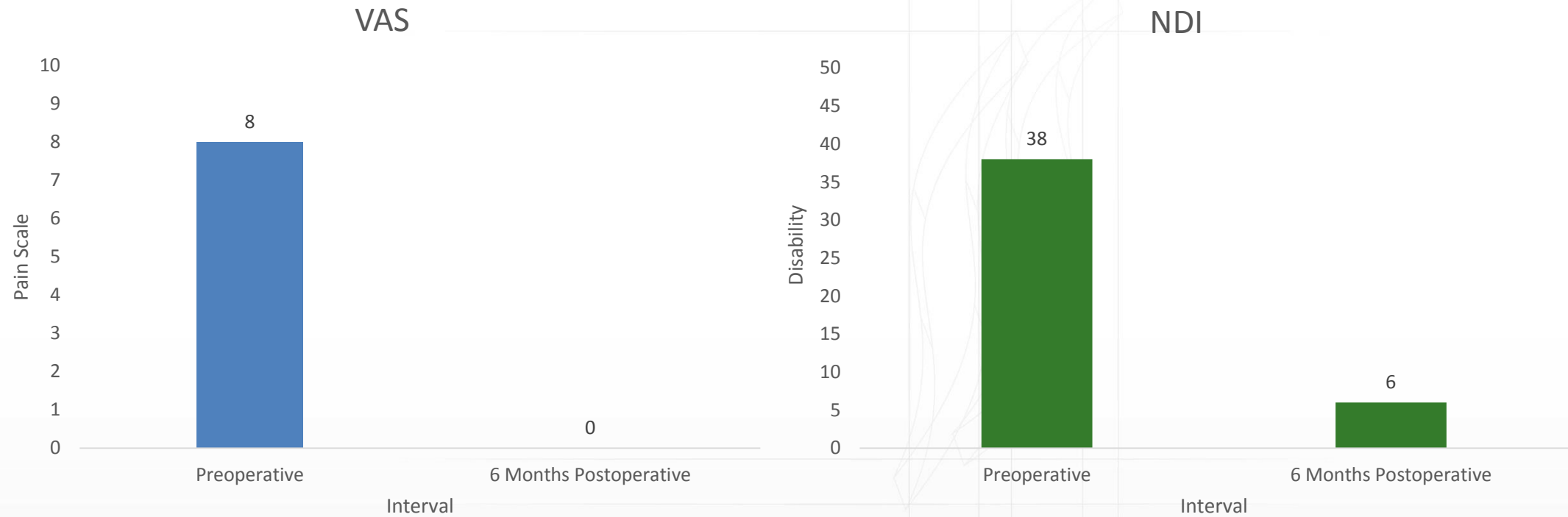


Postoperative Images





Outcomes





Conclusion

- Industry studies coupled with LSI's outcomes suggest that stand-alone technology is an effective alternative to fusion plating systems
- LSI's study also suggests that it is feasible to use cervical stand-alone technology in an ambulatory surgery center

