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Successful Intradiscal Treatment of Adjacent Segment with VIA Disc® NP Allograft in a 65-Year-Old Woman with L4-Sacrum Laminectomy and Posterior Fusion

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Background: Adjacent segment disease is a major long-term complication after surgical treatment of lumbar disc disease. When conservative management fails, the predominant treatment is further surgery. Safe and effective nonsurgical intervention for adjacent segment disease is an unmet medical need.

Case Report: A 65-year-old woman with a history of L4-S fusion was referred for evaluation of worsening pain affecting the lumbar spine after conservative measures failed to provide meaningful improvement. She was treated with an injection of VIA Disc® NP, a processed human nucleus pulposus tissue allograft intended to supplement degenerated intervertebral discs. She reported 80% pain relief 4 weeks after injection with further improvement through 8 months, including restored ability to perform her usual activities with minimal discomfort.

Conclusion: A single intradiscal injection of VIA Disc® NP successfully relieved pain and improved function in a patient with prior L4-S fusion who presented with adjacent segment disease at L3-4.

Key words: Adjacent segment disease, allogeneic disc tissue, allograft, case report, degenerative disc disease, intradiscal injection

BACKGROUND

Adjacent segment disease is a major long-term complication after surgical treatment of lumbar disc disease (1-3). Although surgical interbody fusion as a treatment for discogenic back pain is often successful, up to one in 5 patients will need additional surgery within 4 years after lumbar instrumentation (3-5). There are multiple risk factors for adjacent segment disease in patients undergoing lumbar fusion surgery, including body weight, age, lumbar anatomy, and the number of levels of fusion contributing to biomechanical stiffness (6-10). The predominant treatment modality for adjacent segment disease when conservative management yields inadequate pain relief is further surgery (11,12). There is an unmet medical need for safe and effective nonsurgical intervention for adjacent segment disease.

Supplementing the intervertebral disc in an intermediate stage of intervertebral disc degeneration with processed allogeneic disc tissue may support biomechanical function and overcome a loading imbalance resulting from tissue loss and disruption. VIA Disc® NP (VIA Disc Allograft, Vivex Biologics, Inc, Miami, FL) is a processed human nucleus pulposus tissue allograft intended to supplement degenerated intervertebral discs. The first large, randomized controlled trial studying intradiscal supplementation was the Viable Allograft

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Supplemented Disc Regeneration in the Treatment of Patients with Low Back Pain With or Without Disc Herniation (VAST) Trial (NCT03709901) (13-15). The safety profile of the supplemental allograft demonstrated risk similar to discography, and clinical outcomes data provide preliminary evidence for efficacy with respect to pain reduction and improved functional status (13-15). Patients over the age of 60 years or with a history of prior lumbar fusion surgery, however, were not eligible to participate in the trial (16).

To date, no published reports have documented the use of this particular form of intradiscal therapy to treat adjacent segment disease. Here, a case of adjacent segment disease successfully treated with a single intradiscal injection of VIA Disc NP to the affected adjacent disc is detailed.

CASE

A 65-year-old woman presented for a new patient evaluation and treatment with a chief complaint of lumbar back pain. Past medical history was positive for skin cancer, and past surgical history included a cervical anterior cervical discectomy and fusion procedure and L4 to sacrum laminectomy and fusion 9 years earlier. She was a prior smoker with 30 years of abstinence. She reported pain being about 75% central and 25% radiating into bilateral posterior thighs and buttocks, right greater than left, in a nonspecific dermatomal distribution.

The patient recovered reasonably well from the L4-S fusion and had minimal to no low back pain for a period of 3 to 4 years. Subsequently, there was a gradual increasing of pain affecting primarily the lumbar spine. Her pain worsened significantly from what had been a tolerable level of 3 of 10 on the Numeric Pain Rating Scale (NPRS) for daily pain to an intolerable level of 7 of 10 subsequent to a rear-impact motor vehicle accident 6 months before the initial consultation. During the preceding 6 months the patient sought relief through physical therapy, chiropractic care, medications, epidural injections, and medial branch blocks above the level of her fusion, without meaningful improvement. She consulted with an orthopedic spine surgeon at this point, who discussed with her the option of consulting with an interventional pain medicine specialist regarding nonsurgical treatment options before intervening surgically to extend her fusion.

At her initial consultation she felt dejected about her pain and was fearful it would become permanent. Aggravating factors were prolonged sitting, as well as bending, lifting, and twisting maneuvers. Alleviating factors were lying down, rest, and epidural steroid injections that provided short-term significant relief. Functional limitations included inability to complete her activities of daily living without significant pain, including sweeping, cooking, cleaning, and yardwork/gardening.

Physical examination revealed an otherwise well-appearing 65-year-old woman with a normal gait and no obvious neurologic deficit. Strength and sensation were normal at the hip, knee, and ankle bilateral with a slight paresthesia in the right posterolateral thigh. Examination of her lumbar spine demonstrated a well-healed posterior midline incision consistent with her surgical history. Her skin was intact with no swelling, skin breakdown, erythema, or rash. She was tender to palpation about her prior surgical incision centrally as well as bilateral from approximately L2 to sacrum, worst from L2-4. Pain was most replicated with forward flexion and prolonged sitting. The patient preferred to stand versus sit for prolonged periods. Faber test was mildly positive bilaterally. Straight leg raise was negative bilaterally. Sustained hip flexion was positive bilaterally. Facet loading was mildly painful.

She presented with recent imaging studies, including flexion-extension x-rays that demonstrated a slight retrolisthesis of L3-4 with no motion and subtle spondylosis, and magnetic resonance imaging of the lumbar spine that demonstrated a posterior L4-S posterior fusion with pedicle screws and rods in place (Fig. 1). There were decompressive laminectomies at L4, L5, S1. She was widely decompressed from L4-S. At the L3-4 level she had moderate disc height loss, broad mild disc bulge, vertebral body endplate changes, facet hypertrophy, and grade 1 retrolisthesis. There was moderate neuroforaminal stenosis without canal stenosis at L3-4.

She was diagnosed with L3-4 disc disorder with annular fissuring and bulge, L3-4 facet arthropathy, prior L4 to sacrum laminectomy and fusion. An order was then placed for a L3-4 diagnostic analgesic disc injection with 4% lidocaine, which was performed 2 weeks later. The patient demonstrated near complete 95% relief for the first 6 hours. Given the excellent response to the analgesic disc injection, the patient was offered an injection of VIA Disc NP to supplement the tissue loss in the degenerative L3-4 disc. The purpose of this intradiscal therapy was explained to her, noting that supplementing the tissue loss may restore hydration and improve biomechanics, and thereby improve pain and function. The patient agreed to the procedure,

which was performed one month after the diagnostic evaluation. The patient experienced minimal injection site soreness; no other procedure-related adverse events were noted (Figs. 2 and 3).

She returned for follow-up at 4 weeks after injection reporting 80% improvement in pain as well as function, with a NPRS score of 2 of 10. Being able to sit for prolonged periods without having to stand and pace, she was better able to complete daily activities with minimal pain. At her 3-month follow-up she reported 90% pain relief with an NPRS score of 1 of 10 and ongoing improvement in function. This improvement was sustained at the 6-month follow-up, when she said that the disc injection provided "tremendous" pain relief. At her most recent follow-up (8 months after the procedure), she reported 0 of 10 pain most of the time with at most 1 of 10 "achiness" when gardening, walking long distances, or doing yardwork, all of which she described as a "normal discomfort" (Fig. 4). She reported happily that she has been able to take walks with her grandson, garden, and do yardwork without any pain.

DISCUSSION

This case report documents successful treatment of the adjacent segment in a 65-year-old woman who had undergone lumbar spinal fusion surgery 9 years prior. The treatment was well tolerated, with pain relief and marked functional improvement noted at 4 weeks after treatment and further improvement through the 8-month follow-up. The patient's medical history,

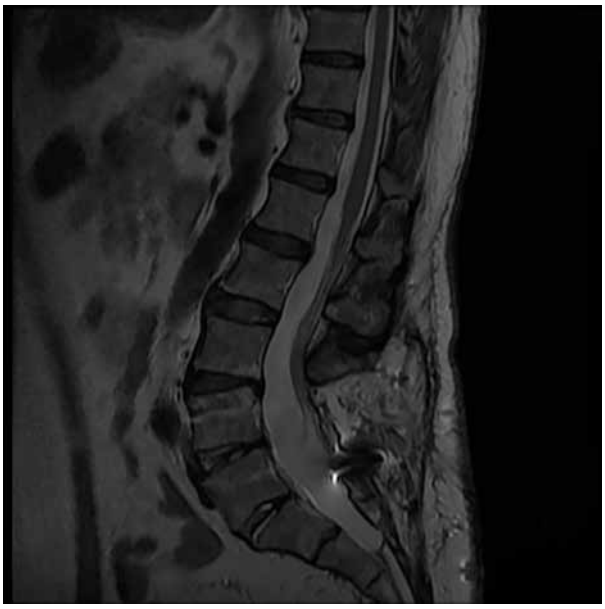

Fig. 1. T2 magnetic resonance imaging demonstrating L4-S fusion with wide decompression.
The L3-4 disc is degenerative with posterior height loss and loss of central hyperintensity consistent with desiccation. Modic vertebral body changes are present.

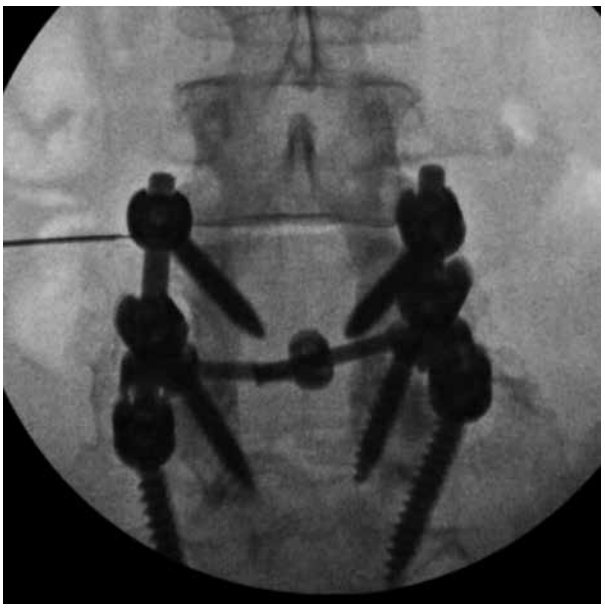

Fig. 2. Fluoroscopic procedural imaging showing 18-gauge introducer needle approaching the L3-4 disc.
The 18-gauge introducer needle is shown approaching the L3-4 disc from the patient's left side. Disc height and vertebral body irregularities are evident when comparing the disc of interest with the L2-3 disc above.

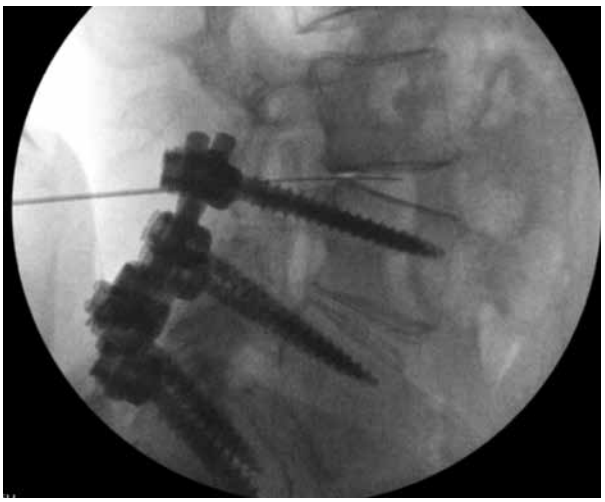

Fig. 3. Lateral fluoroscopic imaging showing intradiscal placement of needle tip.
VIA Disc® NP injected with 2-needle technique utilizing an 18-gauge introducer needle followed by a 20-gauge spinal needle into the disc.

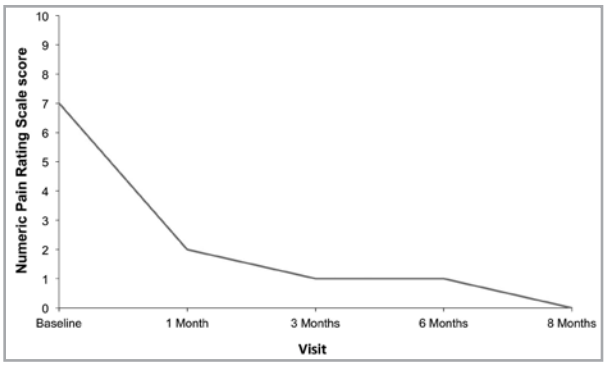

Fig. 4. Numeric Pain Rating Scale score at baseline and follow-up.

demographic profile, clinical symptoms, and imaging studies are all broadly typical of adjacent segment disease. Nonsurgical management had been pursued appropriately, including physical therapy, chiropractic care, medications, epidural injections, and medial branch blocks above the level of her fusion, but without any meaningful pain relief. The next step for this patient would have been surgical intervention had she not been referred to consider the option of intradiscal therapy.

Patients who develop painful adjacent segment disease are left with few options to achieve meaningful pain relief. Nonoperative treatment is recommended, which typically consists of physical therapy and medication (17). In cases where conservative management fails to provide adequate pain relief, revaluation, examination, and imaging are indicated to identify the most likely pain generator (18). Interventional treatment options targeting the most likely pain generator include epidural steroid injections, lumbar facet blocks, and ablations (19). However, interventional treatment options are limited when the disc is the primary pain generator, as was determined in this case by lack of efficacy of radiofrequency ablation of the medial branches and confirmation with analgesic injection. Targeted therapy for the disc is indicated in these cases, but there is limited evidence of efficacy for these therapies (20). Consequently, this gap in evidence-based treatment often leads to the decision to extend the fusion surgically (17) or to consider a trial of dorsal column stimulation (21). Although these therapies may benefit patients, they are more invasive. A targeted treatment that is simpler and less invasive is desirable.

To the best of my knowledge, there are no other case reports in the published literature with which to compare this one. Treatment of adjacent segment disease after fusion is typified by progressively more aggressive care, beginning with a foundation of physical therapy, strengthening exercises, and rest and restriction of physical activity, often escalating to corticosteroid injections and analgesic medications to help reduce the pain and swelling, and finally to more invasive therapies, such as nerve blocks or spinal stimulation (21). Although precedent exists in the VAST trial for allograft supplementation (13,14), the upper limit of the age range was 60 years, and any surgical intervention in the lumbar spine (L1-S) was an exclusion criterion; therefore, no patient older than 60 years or suffering from adjacent segment disease was included. The main limitation of this case report is the relatively short follow-up time. To make a stronger argument for the feasibility of this treatment modality, longer-term outcome data are required.

CONCLUSION

This case report of intradiscal injection of human allograft nucleus pulposus disc tissue to supplement and treat the adjacent degenerative L3-4 disc in a patient with prior L4-S fusion provides preliminary proof of concept that adjacent segment disease can be effectively treated with this nonsurgical intervention. The major limitations of this case report are the sample size of one and the relatively short-term duration of follow-up. Long-term follow-up and additional case reports are needed to support this hypothesis.

REFERENCES

1. Ouchida J, Nakashima H, Kanemura T, et al. Adjacent segment degeneration after short-segment lateral lumbar interbody fusion (LLIF). *Biomed Res Int* 2022; 2022:5161503.
2. Chen KJ, Lai CY, Chiu LT, et al. Adjacent segment disease following Dynesys stabilization for lumbar disorders: A case series of mid- and long-term follow-ups. *World J Clin Cases* 2021; 9:10850-10860.
3. Jeong TS, Son S, Lee SG, Ahn Y, Jung JM, Yoo BR. Comparison of adjacent segment disease after minimally invasive versus open lumbar fusion: A minimum 10-year follow-up. *J Neurosurg Spine* 2022; 36:525-533.
4. Irmola TM, Hakkinen A, Jarvenpaa S, Marttinen I, Vihtonen K, Neva M. Reoperation rates following instrumented lumbar spine fusion. *Spine (Phila Pa 1976)* 2018; 43:295-301.
5. Fritzell P, Hagg O, Wessberg P, Nordwall A; Swedish Lumbar Spine Study Group. 2001 Volvo Award winner in clinical studies: Lumbar fusion versus nonsurgical treatment for chronic low back pain: A multicenter randomized controlled trial from the Swedish Lumbar Spine Study Group. *Spine (Phila Pa 1976)* 2001; 26:2521-2532; discussion 2532-2524.
6. Kodsy MM, Freitag HE, Winkelman RD, et al. A retrospective analysis of the L3-L4 disc and spinopelvic parameters on outcomes in thoracolumbar fusion: Was Art Steffee right? *World Neurosurg* 2022; 159:e399-e406.
7. Yun YI, Jeon I, Kim SW, Yu D. Risk factors for adjacent segment disease requiring reoperation after posterior lumbar interbody fusion with screw fixation: Focus on paraspinal muscle, facet joint, and disc degeneration. *Acta Neurochir (Wien)* 2022; 164:913-922.
8. Lau KK, Samartzis D, To NS, Harada GK, An HS, Wong AY. Demographic, surgical, and radiographic risk factors for symptomatic adjacent segment disease after lumbar fusion: A systematic review and meta-analysis. *J Bone Joint Surg Am* 2021; 103:1438-1450.
9. Okuda S, Yamashita T, Matsumoto T, et al. Adjacent segment disease after posterior lumbar interbody fusion: A case series of 1000 patients. *Global Spine J* 2018; 8:722-727.
10. Wang T, Ding W. Risk factors for adjacent segment degeneration after posterior lumbar fusion surgery in treatment for degenerative lumbar disorders: A meta-analysis. *J Orthop Surg Res* 2020; 15:582.
11. Amini DA, Moser M, Oezel L, et al. Early outcomes of three-dimensional-printed porous titanium versus polyetheretherketone cage implantation for stand-alone lateral lumbar interbody fusion in the treatment of symptomatic adjacent segment degeneration. *World Neurosurg* 2021. doi:10.1016/j.wneu.2021.11.122.
12. Brox JI, Nygaard OP, Holm I, Keller A, Ingebrigtsen T, Reikeras O. Four-year follow-up of surgical versus non-surgical therapy for chronic low back pain. *Ann Rheum Dis* 2010; 69:1643-1648.
13. Beall DP, Davis TT, DePalma M, et al. Viable disc tissue allograft supplementation; one- and two-level treatment of degenerated intervertebral discs in patients with chronic discogenic low back pain: One year results of the VAST randomized controlled trial. *Pain Physician* 2021; 24:465-477.
14. Beall DP, Wilson GL, Bishop R, Tally W. VAST clinical trial: Safely supplementing tissue lost to degenerative disc disease. *Int J Spine Surg* 2020; 14:239-253.
15. Hunter CW, Guyer R, Froimson M, DePalma MJ. Effect of age on outcomes after allogeneic disc tissue supplementation in patients with chronic discogenic low back pain in the VAST trial. *Pain Manag* 2022; 12:301-311.
16. ClinicalTrials.gov. Viable allograft supplemented disc regeneration in the treatment of patients with low back pain (VAST). https://clinicaltrials.gov/ct2/show/NCT03709901. Date Updated 07/07/2021. Date Accessed 05/03/2022.
17. Tobert DG, Antoci V, Patel SP, Saadat E, Bono CM. Adjacent segment disease in the cervical and lumbar spine. *Clin Spine Surg* 2017; 30:94-101.
18. Waguespack A, Schofferman J, Slosar P, Reynolds J. Etiology of long-term failures of lumbar spine surgery. *Pain Med* 2002; 3:18-22.
19. Cohen SP, Bhaskar A, Bhatia A, et al. Consensus practice guidelines on interventions for lumbar facet joint pain from a multispecialty, international working group. *Reg Anesth Pain Med* 2020; 45:424-467.
20. Meisel HJ, Agarwal N, Hsieh PC, et al. Cell therapy for treatment of intervertebral disc degeneration: A systematic review. *Global Spine J* 2019; 9:39S-52S.
21. Grider JS, Manchikanti L, Carayannopoulos A, et al. Effectiveness of spinal cord stimulation in chronic spinal pain: A systematic review. *Pain Physician* 2016; 19:E33-E54.