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Chiropractic management of a Veteran with persistent spinal pain syndrome-2 status-post L3-L5 laminectomy and Coflex interlaminar stabilization: a case report

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Background*: Coflex interlaminar stabilization (CIS) is a second-generation interspinous implant that promotes intersegmental flexion following decompression for moderate to severe lumbar spinal stenosis. We describe the management of a patient with persistent spinal pain syndrome-2 (PSPS-2) status-post CIS implant presenting to a chiropractor's office.*

Case presentation: *A 77-year-old Hispanic male Army veteran presented with PSPS-2 status-post L3-L5 laminectomy and CIS for lumbar spinal stenosis. A 4-visit trial care plan ensued with flexion-distraction*

Gestion chiropratique d'un vétéran atteint du syndrome de douleur spinale persistante-2 après laminectomie L3-L5 et stabilisation interlaminaire Coflex: un rapport de cas

Contexte: *La stabilisation interlaminaire Coflex (CIS) est un implant interépineux de deuxième génération qui favorise la flexion intersegmentaire après décompression pour une sténose spinale lombaire modérée à sévère. Nous décrivons la prise en charge d'un patient atteint du syndrome de douleur spinale persistante-2 (SDPS-2) après un implant CIS, qui se présente au bureau d'un chiropraticien.*

Présentation de cas: *Un vétéran de l'armée hispanique âgé de 77 ans s'est présenté avec un statut PSPS-2 après une laminectomie L3-L5 et une CIS pour sténose spinale lombaire. Un plan de soins d'essai de 4 visites a été*

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Veteran provided approval for publication of this report and associated images. The patient's consent to publish was obtained and submitted.
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manipulation, drop-assist spinal manipulation, patient education, and repeated lumbar flexion-based stretches. No adverse events occurred. On re-evaluation, the numeric pain rating and Oswestry Disability were unchanged.

Summary: *We describe the multimodal management of a PSPS-2 patient with a CIS implant presenting to a chiropractic clinic. While no clinically meaningful improvement was observed, no adverse events were reported. Further investigation is needed to evaluate the safety and clinical effectiveness of multimodal manual therapy and exercise-based care in patients with PSPS-2.*

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KEY WORDS: case report, Coflex, chronic lower back pain, persistent spinal pain syndrome, chiropractic, spinal manipulation

mis en place avec manipulation par flexion-distraction, manipulation vertébrale par assistance par chute, éducation du patient et étirements répétés basés sur la flexion lombaire. Aucun événement indésirable n'est survenu. Lors de la réévaluation, l'évaluation numérique de la douleur et l'Indice de handicap d'Oswestry sont restés inchangés.

Résumé: *Nous décrivons la gestion multimodale d'un patient PSPS-2 ayant un implant CIS, qui se présente dans une clinique chiropratique. Aucune amélioration cliniquement significative n'a été observée, aucun événement indésirable n'a été signalé. Des examens supplémentaires sont nécessaires pour évaluer la sécurité et l'efficacité clinique de la thérapie manuelle multimodale et des soins basés sur l'exercice chez les patients atteints de PSPS-2.*

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MOTS CLÉS : rapport de cas, Coflex, douleur chronique du bas du dos, syndrome de douleur spinale persistante, chiropratique, manipulation vertébrale

Introduction

Lumbar spinal stenosis (LSS) is a degenerative condition pervasive among older adults.[1] LSS, defined as a narrowing of the central canal, lateral recess, or neural foramen of the spinal canal in the lower back is often associated with increased disability, limited walking capacity, and increased fall risk.[2,3] LSS is the most common reason for spinal surgery in older adults over the age of 65.[4] The management of LSS varies from non-pharmacological therapies, such as spinal manipulation and rehabilitative exercise, medication management, or surgical intervention, such as decompression and fusion.[5,6]

Coflex interlaminar stabilization (CIS) uses a new generation of interspinous device alternative to posterior lumbar interbody fusion (PLIF) following decompression for the management of moderate to severe LSS.[7,8] The Coflex device (Paradigm Spine, LLC, New York, New York) implanted for CIS is a U-shaped compressible titanium device that is interposed between the lamina and the spinous processes after surgical decompression (Figure 1). Compared to PLIF, CIS is less invasive and preserves the motion of intersegmental flexion at the affected and adjacent levels.[7,9] Compared to traditional lumbar decompression and fusion surgeries, CIS is favored because of shorter operation times, decreased intraoperative bleeding, and faster recovery periods.[10]

Persistent post-surgical spinal pain is common, with 20 to 40% of patients developing persistent spinal pain syndrome type 2 (PSPS-2) after lumbar surgery.[11,12] PSPS-2 is defined as recurrent or chronic axial or radicular spinal pain in patients with a history of spinal surgery, previous-

Figure 1.
Coflex interlaminar stabilization device. With permission from Errico TJ et al.[32]

ly referred to as failed back surgery syndrome.[12,13] The etiology of PSPS-2 is not well understood but is likely multifactorial. Postoperative factors like recurrent disc herniation, adjacent segment disease, and nerve root irritation, along with psychosocial factors such as depression, anxiety, and socioeconomic stress, can negatively impact surgical outcomes and recovery.[12,14]

Non-surgical therapies such as exercise, pharmacological management, and interventional injections are often recommended for PSPS-2.[5,11] Descriptions of multimodal manual therapy and exercise-based management of PSPS-2 delivered by a chiropractor are sparse.[15–19] Thus, we aim to describe a multimodal approach of manual therapy and exercise for the management of a patient with PSPS-2 and a novel CIS implant presenting to a chiropractor.

Case presentation

This case was approved by the Miami VA Health Care System Privacy Officer. The patient provided consent for publication. This report followed the CARE guidelines for reporting case reports.[20]

Background

A 77-year-old Hispanic male United States Army veteran was referred by their Veterans Health Administration (VA) primary care physician to a VA chiropractic clinic for chronic low back pain. Four years before his presentation to the chiropractic clinic for evaluation, the veteran had undergone an L3-L4 to L4-L5 laminectomy with L3-4 to L4-5 CIS for right-sided lower extremity radiculopathy and weakness due to LSS. The veteran's right lower extremity radicular pain responded positively to surgical intervention, but axial lumbar pain persisted.

On initial presentation, the veteran described persistent back pain as constant aching with intermittent sharp pains. His pain was localized to the right more than the left side of the axial lumbar spine area. He experienced weekly flare-ups of increased pain intensity described as "sharp and spastic". The veteran denied lower extremity radiation or saddle anesthesia. His back pain was provoked by walking and ascending stairs and was reduced with anti-inflammatory medication, lidocaine patches, heat, and lumbar flexion-biased stretches. His walking was limited to approximately one-quarter mile due to axial lumbar pain. The Oswestry Disability Index (ODI) rated his function as "moderate disability" (17 out of 50 [34%])[21] and his pain rating on a Visual Analog Scale was 6/10.

He attempted multiple management strategies for his back pain since completing surgery in 2019. He trialed 300 mg of Gabapentin three times a day but discontinued due to a lack of efficacy. He received multiple transforaminal epidural steroid injections for lumbosacral pain, with significant relief (percent improvement unknown) from the last injection, but the reason for discontinuing further intervention is unknown. He trialed physical therapy after spinal surgery to return to activity status and later for chronic pain management with benefit.

Prior lumbar plain films on record demonstrated mild levoscoliosis with associated multilevel lumbar degenerative changes, a laminectomy with CIS at L3-5, and a stable grade 1 degenerative anterolisthesis of L4 on L5 (Figure 2). Prior magnetic resonance imaging revealed multilevel degenerative disc disease and facet hypertrophy, a right subarticular disc protrusion at L1-2, a central to right central disc protrusion at L5-S1, moderate spinal canal stenosis at L3-4, and left lateral stenosis at L4-5 (Figure 3).

Medical history was remarkable for type 2 diabetes, prostate cancer treated to remission, giant cell arteritis with polymyalgia rheumatica, and gout. His current medication list included 200 mg Celecoxib, 81 mg aspirin, 1000 mg Metformin HCl, and 300 mg Allopurinol.

Examination

The veteran's gait was steady, characterized by a left antalgic lean and a mild right-sided limp. No lower extremity muscle atrophy was observed. Lumbar range of motion was moderately restricted with lumbar flexion and severely restricted with extension, both of which provoked his lumbosacral pain. Other lumbar planes of motion were moderately limited but did not provoke his back pain. Heel and toe walk, Romberg's test, and heel-to-shin test were performed without difficulty. Neurological examination revealed asymmetry, including decreased sensation in the right L1–L4 dermatomes, reduced muscle strength (4/5) in the right hip flexors, abductors, adductors, knee flexors and extensors, dorsiflexors, hallux extensors, and plantar flexors, along with hyporeflexia (0+) of the right L4 and S1 deep tendon reflexes, otherwise, the left lower extremity was intact neurologically (5/5 muscle strength, 1+ deep tendon reflexes, sensation intact). Both Hoffman's reflex and ankle clonus were absent bilateral-

ly. His lumbosacral pain was elicited with facet loading via Kemp's test, right-sided Gaenslen's test, right-sided thigh thrust, and a supine straight leg raise to 65 degrees. Hip and sacroiliac orthopedic testing with FABER, FADIR, pelvic compression, and sacral thrust tests were unremarkable for his concordant lumbosacral pain. Hip internal and external rotation were limited bilaterally but did not provoke his lumbosacral pain. Segmental joint play was restricted in the thoracic, lumbar, and right sacroiliac regions and caused localized discomfort. On myofascial palpation, hypertonicity was observed in the lumbar paraspinals, quadratus lumborum, and hip external rotators, bilaterally.

Clinical impression

The veteran's working diagnosis was PSPS-2 status-post L3-L5 laminectomy and CIS with associated myofascial and segmental restrictions in the setting of LSS and a lumbar flexion bias.

Treatment recommendations

A recommendation was made to trial multimodal chiropractic care to include manual therapy, therapeutic exercise, and patient education. Manual therapies included: flexion-distraction technique applied to the lumbar spine, drop-assist spinal manipulative therapy of the thoracic region and right sacroiliac joint, manual myofascial release,

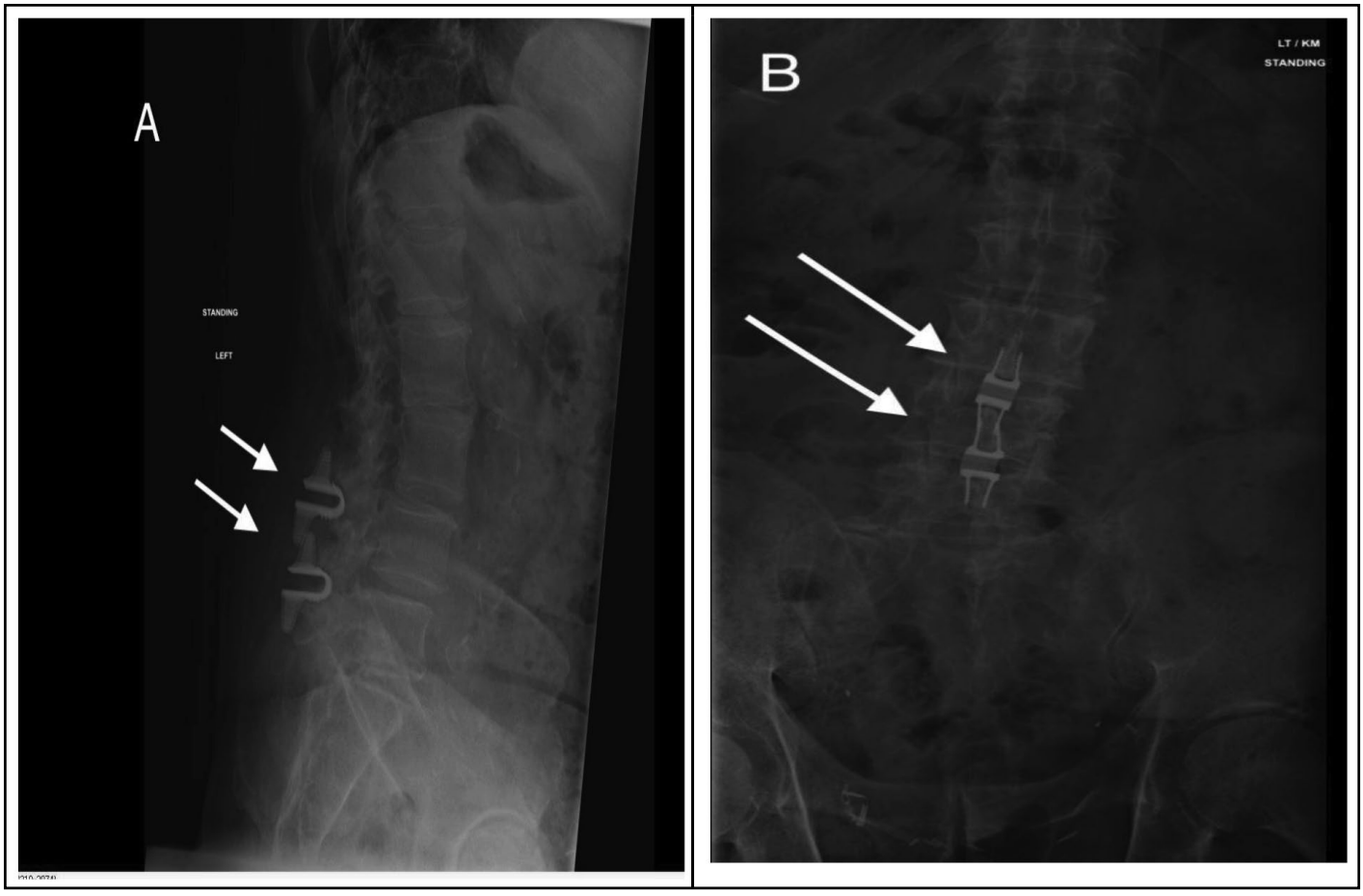

Figure 2.

Case presentation postoperative plain film radiographs of the lumbosacral region with lateral (A) and posterior to anterior views (B) demonstrate an L3 to L5 laminectomy and Coflex interlaminar stabilization (CIS). The CIS implant is demonstrated at L3/L4 and L4/L5 (white arrows). Additional imaging findings include Grade 1 degenerative anterolisthesis of L4 on L5 and left hip osteoarthritis.

and post-isometric relaxation technique applied to lumbar paraspinals, quadratus lumborum, and hip external rotators, bilaterally. At each visit, the veteran was provided home exercise instructions in repetitive lumbar flexion and core stabilization. Exercises included supine double and single knee-to-chests, hook-lying gluteus bridges, bird-dog exercise, and dying bug.[18,22,23]

Re-evaluation

At his fourth visit in five weeks, a re-examination was performed. His lumbar extension range of motion improved to a mild restriction with pain. All other planes of motion remained unchanged and were moderately limited without painful provocation of his chief complaint. Neurological and orthopedic exams were reassessed without significant changes from the baseline evaluation. Repeat ODI rated function "moderate disability" (16 out of 50 [32%]) and Visual Analog Scale pain rating was 6 out of 10, indicating no improvement in his functional status. Due to the lack of improvement following a short trial of care, the patient was discharged from the chiropractic clinic and instructed to follow up with his referring primary care provider.

Discussion

This case report describes multimodal chiropractic management for PSPS-2 with CIS. The existing evidence on chiropractic treatment for PSPS-2 is limited[15,19,24,25] and none of these studies have addressed the condition in the context of CIS. This case adds to the body of post-surgical spine pain management by introducing a new surgical implant that tolerates multimodal manual therapies. While the results of the trial of care were not favorable for the patient's disability or pain intensity, no adverse events or

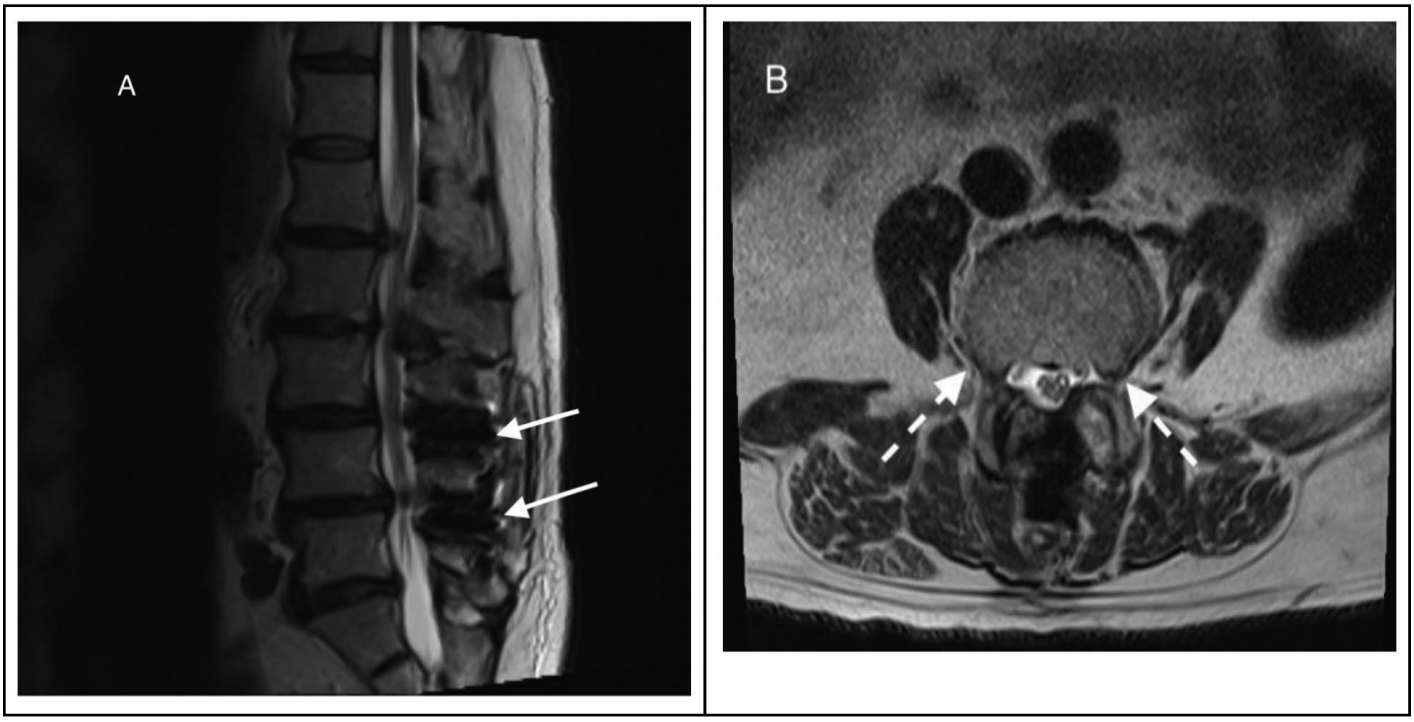

Figure 3.

Case presentation lumbar magnetic resonance imaging demonstrates multilevel degenerative disc disease and moderate spinal canal stenosis on sagittal view (A). The Coflex interlaminar stabilization (CIS) implant is demonstrated at L3/L4 and L4/L5 (A: white arrows) as a signal void. On axial view (B), moderate spinal canal stenosis at L3-4 with a subarticular bugle and left central to foraminal disc extrusion are demonstrated. (B: white dashed arrows highlight the subarticular bulge and disc extrusion).

exacerbations of his condition were reported. In contrast to Chu and Trager, our course of care was limited to four visits over five weeks, where their cohort's mean number of chiropractic visits among 31 patients with PSPS-2 was 21.5±8.7, which occurred over a mean duration of 2.5 ±1.5 months.[19]

As spinal condition experts, chiropractors need to familiarize themselves with the indications for and complications of CIS to support appropriate referral, post-surgical co-management, effective interdisciplinary communication, and optimal patient care outcomes. CIS is an alternative to PLIF for stabilization after decompression of the lumbar spine. As a second generation interspinous device, the primary clinical indication for CIS is LSS and the therapeutic intention is to "offload" pressure on the disc space, increase intervertebral foraminal surface area,

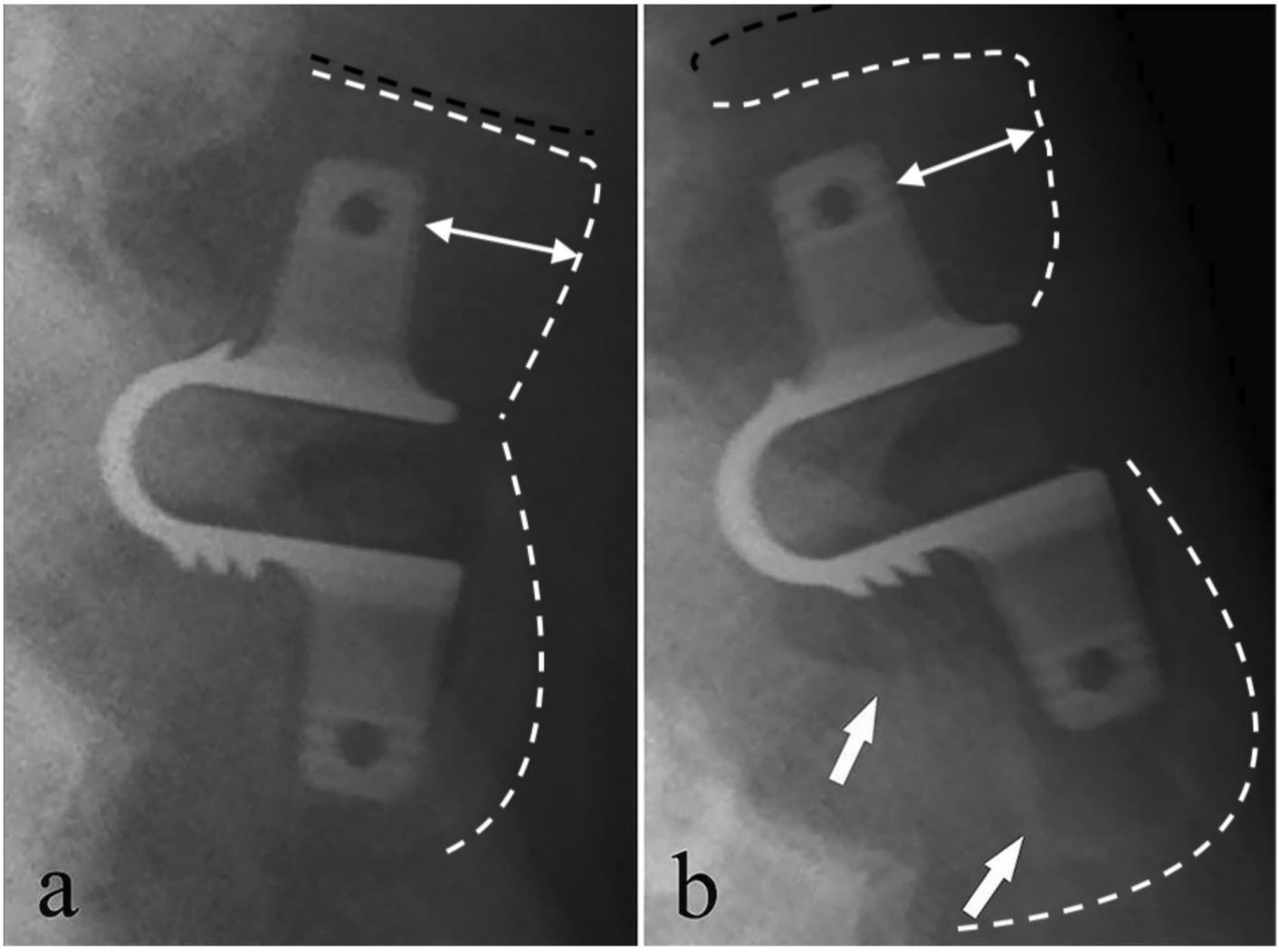

Figure 4.

Example of Coflex interlaminar stabilization (CIS) implant loosening on lateral view plain films. Lateral (a) and over-flexion (b) radiograph views demonstrating areas of CIS implant loosening in an over-flexion position identified by single head white arrows placed by Li et al.). Dashed white lines outline the spinous processes of involved segments. Dashed black lines outline non-involved segment spinous processes. The superior aspect of the implant is stable as indicated by double-headed white arrows. Modified and with permission from Li et al. [28]

increase disc space heights, reverse or preserve lordosis, limit range of motion and stabilize the surgical level(s), and reduce risk of adjacent segment disease.[7,8,26] With CIS, the Coflex device (Figure 1) is placed between the spinous processes of adjacent lumbar vertebrae, after a decompression procedure, and induces a 'flexed' orientation between the segments.

It is also prudent to acclimate to the typical post-operative imaging presentations of CIS to assist with differentiating normal postoperative findings from pathological changes and potential complications of the hardware. Due to its titanium composition, the Coflex device will appear as a bright white structure on plain film imaging. In a lateral view, it appears as a U-shaped device interposed between spinous processes. On posterior-to-anterior view, the CIS implant appears as a symmetrical, radiopaque density midline over the spinous processes (Figure 2). On magnetic resonance imaging, the CIS implant will appear as a void signal (Figure 3) because the titanium does not emit a signal.[27] The void signal and artifact can mimic pathology or obscure structures. Regarding complications, hardware loosening (4.7% to 60%; Figure 4) and osteolysis (39.4%) have been reported.[28,29] Depending on the follow-up period, 42% to 89% of cases develop heterotrophic ossification of the stabilized spinal segments (Figure 5), which has been hypothesized to be due to aseptic inflammation secondary to prolonged friction between CIS implant and surrounding tissues from daily activities.[28,30,31] Extremely rare instances of hardware fracture[28] (Figure 6) and spinous process fracture[29] have been reported.

Although current literature does not specifically consider CIS, conservative treatments are preferred for PSPS-2, including exercise, spinal manipulative therapy, medication, and epidural steroid injections.[11,24] Several studies have found that a multimodal approach of manual care methods, including flexion-distraction technique and active care exercises has been effective in reducing patient-reported disability.[19,30,31] For adults at least 1 year after lumbar spine discectomy, those who received spinal manipulation had lower rates of lumbar spine reoperation compared to controls, which may indicate the potential

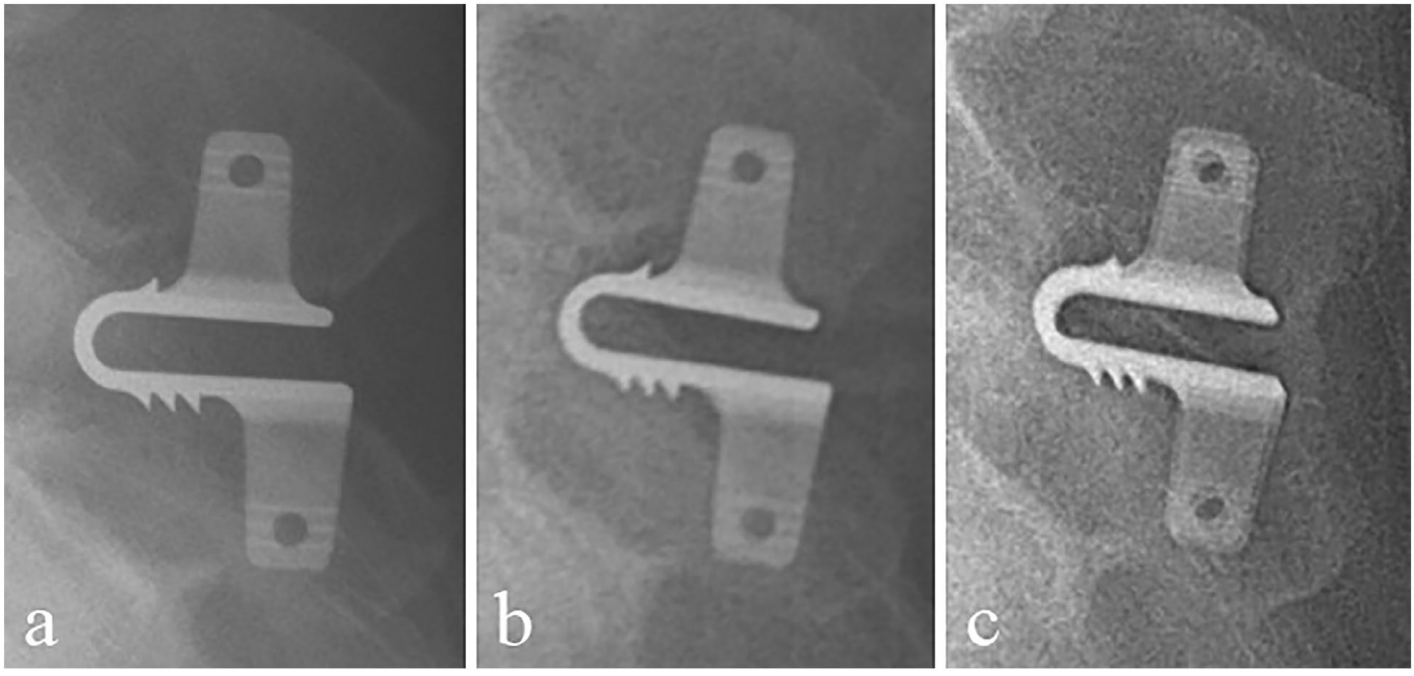

Figure 5.
Example of heterotrophic ossification (HO) at Coflex interlaminar stabilization (CIS) implant site. Lateral view radiograph of one patient with no HO seen immediately after surgery (a.), Grade 1 HO seen at one year after surgery (b), and interspinous fusion at the final follow-up visit (c.). With permission from Li et al.[28]

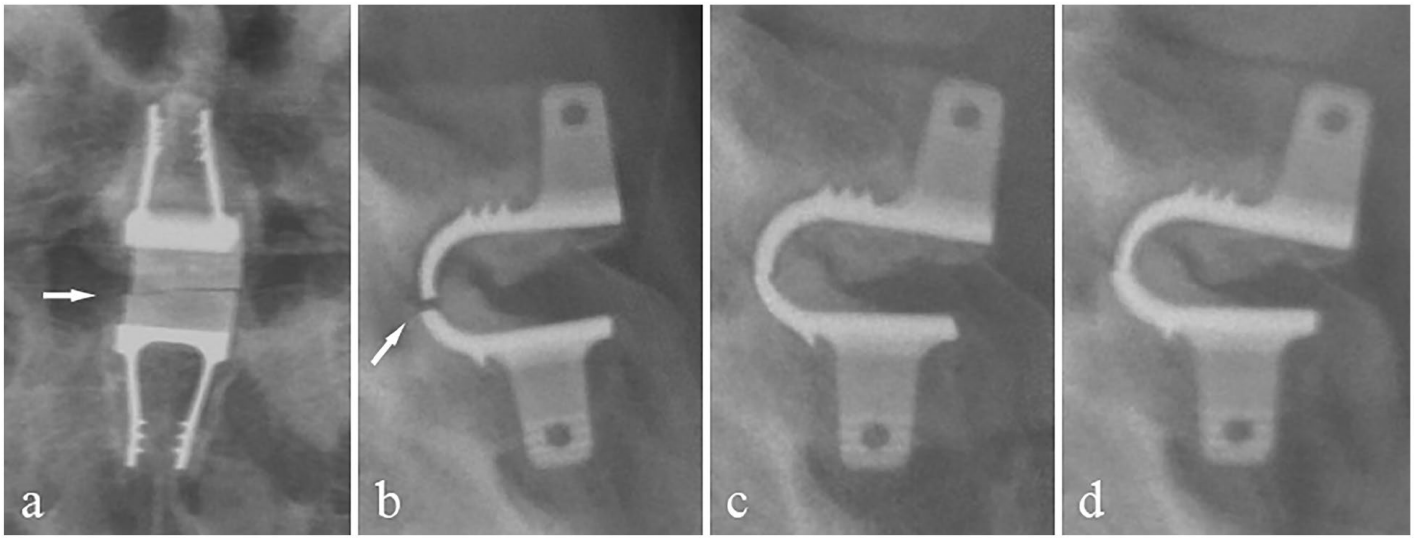

Figure 6.
Example of a Coflex interlaminar stabilization (CIS) implant fracture 14 years post-surgery. Posterior to anterior (a) and lateral view (b,c,d) radiographs demonstrate CIS implant failure with hardware fracture (white arrows placed by Li et al.). With permission from Li et al.[28]

marker of safety of this treatment for this population.[18] As the patient presented several years post-surgery without progression of neurological signs and symptoms, the patient was considered stable and a trial of care was initiated. At the initial visit, the patient was evaluated for the suitability of high-velocity, low-amplitude lumbar spinal manipulation by using pre-loading positioning specific to the technique and obtaining patient feedback on comfort and tolerance. Given the case complexity of the PSPS-2 presentation and patient intolerance to pre-load positions for side-posture high-velocity low-amplitude lumbar manipulation, we elected to trial care utilizing lumbar spine flexion-distraction technique and prone high-velocity, low-amplitude drop-assist thoracic spinal and sacroiliac joint manipulation.[19] The veteran was instructed in flexion-based exercises and core stabilization exercises, given his history of LSS and continued poor tolerance to standing postures accentuating lumbar extension. These exercises encourage independent self-management and are considered safe, low-load movements that focus on spinal stability and motor control.[19,22,23]

Although we report a single case without adverse events, the safety and effectiveness of multimodal conservative care management for patients with PSPS-2 and surgical implants is largely uncertain. Retrospective cohorts or prospective registries should evaluate cost differences, medication utilization, reoperation rates, engagement with health care services, as well as clinical and safety outcomes for patients with PSPS-2 and surgical implants such as CIS. The association between multimodal care and clinical outcomes in patients with PSPS-2 and surgical implants should be explored further with a randomized controlled trial with comparator groups such as physical therapy, medication management, or behavioral intervention.

Limitations

There is limited research on chiropractic care in the management of PSPS-2. This case report is limited to the specific patient encounters during this trial of care and may not necessarily be extrapolated to the general population. There are further nuances related to the PSPS-2 population due to the variety of surgical hardware that may be used, and we described only one type of surgical hardware, CIS. We also recognize the trial course of care may have been insufficient in the dosage of care to effect clinical change on the condition.

Summary

PSPS-2 is a common condition following decompression and fusion lumbar spinal surgery. This study described a case of PSPS-2, specifically with a second-generation interspinous device, CIS, and highlights its characteristic presentation on imaging and potential complications. While the outcomes of the care trial were limited, they underscore the need for further research into the role of chiropractic management in patients with PSPS-2 and subtypes of surgical implants such as CIS.

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