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Review Article

Medicolegal corner (spine): Contraindicated use of DuraSeal in anterior cervical spine led to quadriplegia

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ABSTRACT

Background: The package insert for DuraSeal (Integra LifeSciences, Princeton NJ) states it is **Contraindicated** for use in the anterior cervical spine (confined space): "Do not apply DuraSeal® hydrogel to confined bony structures where nerves are present since neural compression may result due to hydrogel swelling (…up to 12% of its size in any direction)." Further, it should not be used to treat massive unrepaired cerebrospinal fluid (CSF) leaks in any location; "…(it) is indicated as an adjunct to sutured dural repair during spine surgery to provide watertight closure," but it is not to be used "...for a gap greater than 2 mm…."

Methods: A spinal surgeon interpreted a geriatric patient's MR as showing severe C3-C4 to C5-C6 anterior cord compression due to disc disease/spondylosis. However, he never reviewed the CT report/images that documented marked ossification of the posterior longitudinal ligament (OPLL) with multiple signs of dural penetrance.

Results: The anterior C4, C5 corpectomy, and C3-C6 strut fusion/plating resulted in a massive, irreparable cerebrospinal fluid (CSF) leak. Despite the contraindications, the surgeon mistakenly applied DuraSeal which caused the patient's postoperative quadriplegia (i.e., as documented on the delayed postoperative MR scan). Following a secondary surgery consisting of a laminectomy/posterior fusion, the patient was still quadriplegic. Further, as he requested no postoperative MR scan and performed no subsequent corrective surgery (i.e., anterior removal of DuraSeal), the patient remained permanently quadriplegic.

Conclusion: DuraSeal is directly contraindicated for use in the anterior cervical spine, with/without a CSF leak. Here, utilizing DuraSeal for anterior cervical OPLL surgery resulted in permanent quadriplegia, and was below the standard of care.

Keywords: Anterior cervical surgery, Cerebrospinal fluid leak, Corpectomy, DuraSeal, Fibrin sealant, Fusion, Ossification of the posterior longitudinal ligament, Quadriplegia

INTRODUCTION

The use of DuraSeal in the anterior cervical spine is directly contraindicated as this is considered a "confined space." The package insert states: "Do not apply DuraSeal® (Integra LifeSciences, Princeton NJ) hydrogel to confined bony structures where nerves are present since neural compression may result due to hydrogel swelling (…up to 12% of its size in any direction)." Further, DuraSeal should not be applied over an unrepaired dural tear. Rather, DuraSeal "… is indicated as an adjunct to sutured dural repair during spine surgery to provide watertight closure," but "…(not for) a gap greater than 2 mm…." Here, we present a geriatric patient whose surgeon performed an anterior cervical C4, C5 corpectomy with C3-C6 strut fusion causing

quadriplegia due to the contraindicated anterior cervical use/application of DuraSeal.

PATIENT'S PREOPERATIVE EVALUATION

An elderly patient was originally seen by an otolaryngologist who ordered a neck CT scan. It showed multilevel continuous cervical OPLL extending from C3-C6, resulting in marked anterior cord compression with accompanying signs of dural penetration [Figures 1 and 2]. The patient was referred to a spinal surgeon. Although the surgeon ordered an MR that he interpreted as showing multilevel cervical disc disease alone, he neither reviewed the report or images of the previously performed CT [Figures 1-4].

FAILURE TO ASSESS PREOPERATIVE CT THAT SHOWED OPLL AND DURAL PENETRANCE

The best way to document the presence of OPLL is with a CT study, but MR's can also show changes indicative of OPLL's presence [Figures 1, 2, 5, 6] [Tables 1 and 2].[1-6] Although MR examinations may show hypertrophied posterior longitudinal ligament (PLL) typically at multiple disc spaces (i.e., a form of HPLL), mixed HPLL/OPLL masses can extend behind single/multiple vertebral bodies. Here, the preoperative MR clearly indicated the presence of multilevel OPLL spanning the C3-C4 through the C5-C6 levels [Figure 3 and 4]. CT's usually provide a more direct image of punctate ossification/calcification within HPLL, or frank ossification/calcification within mature OPLL [Figures 1, 2, 5, 6].[2-6] In this case, the surgeon failed to read the report or review the previously obtained CT images. Had he done so, he would have seen the various signs of dural penetration present at multiple levels from C3-C6 (i.e. single layer signs often with postiive C signs, and double layer signs) [Tables 1 and 2] [Figures 1 and 2].[1-6]

FAILURE TO USE INTRAOPERATIVE NEURAL MONITORING (IONM); SEP (SOMATOSENSORY EVOKED POTENTIALS), MEP (MOTOR EVOKED POTENTIALS), EMG (ELECTROMYOGRAPHY)

This very complex multilevel anterior cervical corpectomy C4, C5 with C3-C6 fusion for OPLL was, unfortunately, performed without the benefit of intraoperative SEP, MEP or EMG monitoring. Had IONM been utilized, the MEP/SEP potentials would probably have been lost shortly after the DuraSeal was applied (i.e. the hydrophillic DuraSeal takes several minutes to expand), and would, to a reasonable degree of medical probability, have prompted the surgeon to remove the anteriorly compressive DuraSeal mass. Certainly, the MEP/SEP signals would have dropped out by the time the patient was closed. IONM loss along with the patient's postoperative severe quadriparesis should have led to an emergent postoperative cervical

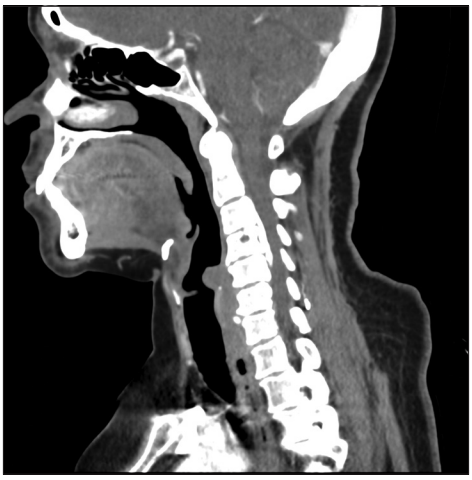

Figure 1: Preoperative paramedian sagittal soft-tissue CT study showing classical cervical OPLL extending superiorly behind the C3 vertebral body, and inferiorly all the way to the mid portion of C5. The hypodense areas represented dural incorporation between the posterior vertebral bodies and the ossified OPLL. The different configurations represented the single, C, and double layer signs of dural penetrance. Anterior cervical surgery was, therefore, more likely than not, to result in an anterior intraoperative cerebrospinal fluid (CSF) leak. Anticipating this leak would have probably resulted in correctly planning it's appropriate intraoperative/postoperative management. Further, the negative K sign (measured from the middle of the canal at C2 to the middle of the canal at C7 with a vertical line between the two points) confirmed that a direct anterior approach (i.e., consisting of a corpectomy) would be warranted to adequately resect the ventral OPLL mass, and decompress the cord.

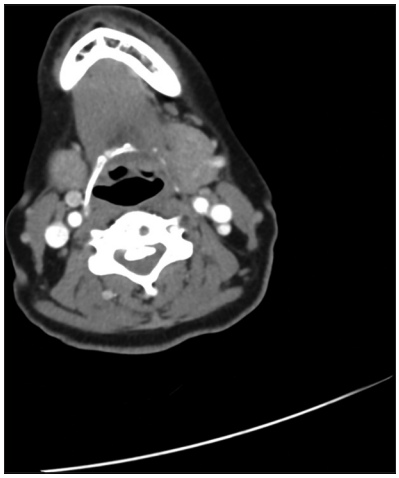

Figure 2: Preoperative axial CT scan obtained at the mid C4 level showed the classical single layer and bilateral C signs contributing to ventral cord compression. Furhter, these signs had likely already penetrated the ventral dura and surgical resection would more likely than not result in a CSF leak.

MR. This would have documented massive anterior cord compression from DuraSeal, and should have led to

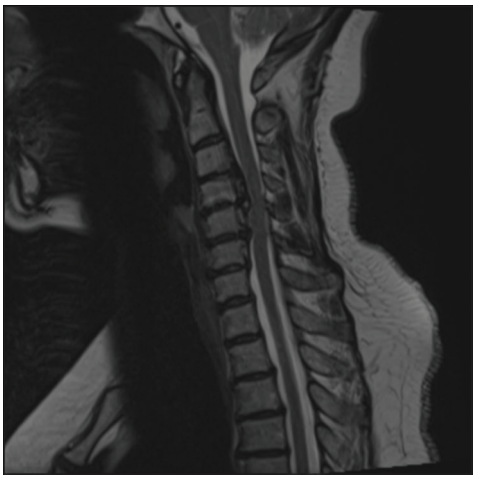

Figure 3: Preoperative midline sagittal T2-weightd MR of C3-C4 to C5-C6 OPLL. This study confirmed the massive ventral OPLL C3-C6 and the resultant increased cord signal extending from above the C3-C4 level down to the mid C5 level. Further, the inhomogeneous, signal within the OPLL mass reflected active bone marrow production occurring in Haversian canals. This study also showed the negative K sign (vertical line between midpoint C2 to mid-point C7) indicating that a direct anterior approach to OPLL was warranted.

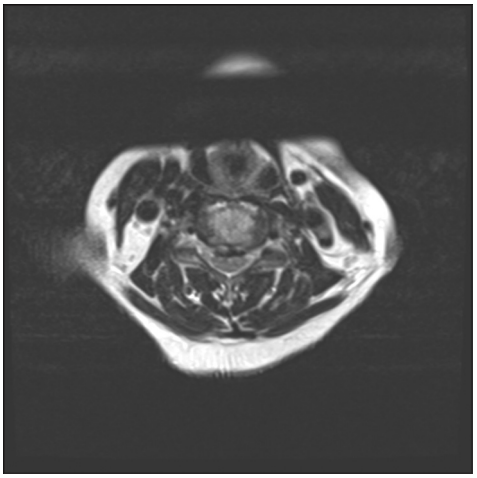

Figure 4: Axial T2 weighted MR at the C4-C5 level showing massive ventral OPLL resulting in cord compression. Note the inhomogeneity of the ventral mass that indicated active boen marrow production occurring in Haversian canals. There is also some high signal intensity within the cord itself reflecting the severity of cord compression at this level.

DuraSeal's immediate anterior removal. Unfortunately, the postoperative MR was delayed until 9 hours following surgery, by which time the patient was fully quadriplegic. Further, the patient underwent the wrong secondary surgery (i.e. laminectomy/posterior fusion). In short, the lack of IONM contributed to this patient's postoperative permanent neurological injury.

SPINE SURGEON'S NEGLIGENT SURGERY WITHOUT AN OPERATING MICROSCOPE

In this case, the surgeon performed a multilevel anterior corpectomy (C4, C5) and fusion (C3-C6) for OPLL without an operating microscope. This certainly increased the probability of a CSF fistula, as makes it even more difficult to define a plane between the underlying dura and the overlying OPLL mass (anterior exposure).

SPINE SURGEON'S NEGLIGENT SURGERY WITHOUT AN ARTERIAL LINE

The surgeon proceeded to negligently perform the C4 and C5 anterior corpectomy with C3-C6 strut/plated fusion without insisting that anesthesia place an arterial line. Notably, during the first surgery, the patient lost over 1000 cc of blood over 15 minutes, resulting in at least 30 minutes of severe hypotension requiring massive repeated doses of pressors. Such hypotensive events can readily occur during anterior OPLL resection, not only due to direct bleeding from the OPLL mass itself (i.e. open Haversian canals), but also to increased bleeding from the valveless epidural veins (Batson's plexus) with/without a CSF leak, or to a potential vertebral artery injury. Here, an arterial line was finally placed 3 hours following the end of the first operation.

ANTERIOR SURGERY RESULTED IN MASSIVE CSF LEAK THAT THE SURGEON NEGLIGENTLY TREATED WITH CONTRAINDICATED GELFOAM/FLOSEAL, DURAGEN, AND DURASEAL

The surgeon performed a C4 and C5 anterior corpectomy, and C3-C6 fusion with plating for what he wrongly diagnosed as disc disease with osteophytes. However, he encountered severe OPLL that he should have known about had he read or reviewed the preoperatively available CT scan. Further, he misleadingly recorded in his operative note that the CSF fistula was just a few mm in size. Nevertheless, during his deposition he finally acknowledged that the dural defect was much larger than that, comprising 50-100% of the C4 and C5 corpectomy expanse.

Use of Contraindicated Gelfoam and FloSeal

When the CSF leak occurred, resulting in copious epidural bleeding (i.e., loss of the dural tamponade of the valveless epidural venous plexus), the spine surgeon placed Gelfoam (Pharmacia & Upjohn Co., Division of Pfizer Inc., NY, NY) and Floseal (Baxter Healthcare Corporation, Hayward, CA). The operative note stated: "Venous bleeding from epidural venous plexus was stopped with Gelfoam/Thrombin and Floseal." Notably, the warning on the package insert for FloSeal states it is not a substitute for meticulous hemostasis, and should be removed to avoid swelling (i.e., 10-20% after application to surrounding

Table 1: Summary of Epstein's studies.

Author Reference Journal	Study Design	Parameters	Parameters	Parameters	Conclusions
Epstein[1] 1999 Surg Neurol	Anterior Cervical Microdural Repair CSF Fistula/OPLL Case: 59 yo OPLL	OPLL to/Through Dura SLS +C Signs DLS	DT/DF Manage Suture FS-Tisseel Muscle Graft LD, WPS, LPS	ACF C3-C7 PF C3-T1 Halo 5 mm Anterior CSF Leak C4-C5	Surgery: LPX Microscope MDS,BPG, FS=Tisseel, MFC=Duragen
Epstein[2] 2001 Spine	Dural Penetration in 54 OPLL Pts ACF/PF Surgery	1 of 12 SLS (+C Sign) 1 of 4 DLS DT/DF/No Dura	2 DT/DF Out of 54 ACF/PF OPLL	38 Patients Smooth Layer Sign	22 Classic OPLL 16 Early OPLL
Epstein[3] 2009 Surg Neurol Int	82 OPLL Pts WPS/LPS Shunts	ACF (avg 2.6 Levels) PF (avg 6.6 Levels)	Patients DF Dural Penetrance 2 SLS 3 DLS	Complex Dural Repair SP FS (Tisseel) MFC (Duragen)	5 Dural Repairs WPS/LPS Shunts Plus SP, FS, MFC
Epstein[4] 2013 Surg Neurol Int	Diagnosis Treatment CSF Fistulas DT Spine Surgery	DT/DF Tumors Shunts Cysts Trauma ESI	DT/DF OPLL OYL Diagnosis MR/CT	Repair 7-0 Gore-Tex MPG MFC FG (Tisseel)	Adjuncts Lumbar Drain WP/LP Shunts
Epstein[5] 2014 Surg Neurol Int	Manage OPLL Anterior, Posterior, AP SEP, MEP, EMG, TIVA	Best MR/CT Both Studies MR Best ST CT Ossified	CT Shows Signs Dural Penetration SLS + C Sign DLS	Anterior Surgery Kyphosis Positive K Sign More DF/DT Vascular Injuries	Posterior Surgery Lordosis Negative K Sign
Epstein[6] 2014 Surg Neurol Int	Need to Know About Anterior OPLL Surgery TIVASEP, MEP, EMG	MR: Look for High T2 Preop Cord Signal Preop CT Early or Classical OPLL	CT Signs of Dural Penetration SLS +C Sign DLS	ACF Corpectomy Typically Avoid ACDF Leaving OPLL Behind	PF-Good Lordosis Laminectomy Fusion Laminoplasty
Epstein[7] 2020 Surg Neurol Int	RPI/WCS Rare-Acute Postop Deficits 7 Cases English Literature	RPI/WCS Immediate Restoration Blood Flow to CC/IC	P=MR: New F or D High T2 MR Cord Signal	High T2 Sinal: E, I, S, H	Exclude Extrinsic Pathology

RPI: Reperfusion injury, WCS: White cord syndrome, CC: Compressed cord, IC: Ischemic cord, P-MR: Postoperative MR, high intramedullary cord signal, F: Focal, D: Diffuse, E: Edema, I: Ischemia, S: Swelling, H: Hematoma, Pts: Patients, OPLL: Ossification posterior longitudinal ligament, WPS: Wound-peritoneal shunt, LPS: Lumboperitoneal shunt, ACF: Anterior corpectomy and fusion, PF: Posterior fusion, avg: Averages, DF: Dural fistulas, SLS: Single layer sign (large central mass), DLS: Double layer sign (large central hyperdense mass on CT interrupted with hypodense dura), DR: Dural repair, SPG: Sheep pericardial graft, FS: Fibrin sealant (Tisseel), MFC: Microfibrillar Collagen-Duragen, Postop: Postoperative, SS: Spine surgery, CSF: Cerebrospinal fluid, DT: Dural tears, ESI: Epidural steroid injections, OYL: Ossification yellow ligament, MPG: Muscle patch grafts, C Sign: Typically bilateral imbrication of dura in C configuration with central SLS, AP: Anterior/posterior, ST: Soft tissue, Positive K Sign: Vertical line drawn from Mid C2 and mid C7 points in canal: OPLL mass anterior to line, Negative K Sign: Vertical line drawn from mid C2 and mid C7 points in canal: OPLL mass posterior to line, LD: Lumbar drain, SEP: Somatosensory evoked potentials, MEP: Motor evoked potentials, EMG: Electromyography, TIVA: Total intravenous anesthesia, BPG: Bovine pericardial graft, ACDF: Anterior diskectomy/fusion, MDS: Microdural Stapler 1.4 mm, yo: Year old

anatomic areas) in confined spaces. The package insert further warns that it's safety has not been established in neurosurgery.

Contraindicated Application of Duragen

Although the surgeon claimed the intraoperative cerebrospinal fluid leak/fistula (CSF) was readily controlled with a "small cottonoid" (i.e., direct quote from operative report), in fact, there was a major dural tear without any approximated dural edges. Further, during his deposition, the surgeon finally acknowledged he could not close the dura as it was "incompetent," had "irregular edges," and could not be "sewn primarily." Additionally, he "...could not tell the full extent of the dural breach...," but ultimately admitted it could have been between 50-100% of the length of the 2-level corpectomy. Next, the surgeon placed Duragen (Integra LifeSciences, Plainsboro, NJ) over the massive dural defect despite the warnings of the package insert that state: "DuraGen Secure Dural Regeneration Matrix is not designed, sold or intended for use except as described in the Indications for Use and is contraindicated in the following situations." One of these included; "For repair of spinal neural tube defects or anterior spinal surgery with dural resection."

Table 2: Summary of failures/negligence in this case.

Failures	Summary
Failure to Review Films/ Report of Preoperative CT To Know OPLL was Present	Failure to review/read report of available preoperative CT showing OPLL to/through the dura (dural penetrance signs: single layer, C, and double layer signs) Failure to anticipate/plan to treat a complex intraoperative CSF leak If anticipated CSF leak due to OPLL, Surgeon should/would have read "contraindications" to using anterior cervical DuraSeal and avoided using it
Failure to Anticipate/Treat Massive CSF Leak	If CT had been reviewed (report read/films evaluated) the surgeon have prepared for a large intraoperative CSF Leak Surgeon could have; preoperatively education family of risks/treatment of CSF leak, anticipated need for lumbar drain, possible wound-peritoneal shunt and/or lumboperitoneal shunt
Failure to Use Intraoperative SEP, MEP and EMG Monitoring for Anterior Corpectomy/Fusion ACF C4, C5 with C3-C6 Fusion for OPLL	Had intraoperative IONM been utilized, the surgeon would have recognized that the loss of SEP/MEP potentials signaled severe anterior cord compression from DuraSeal, and immediately removed the it. Alternatively, had signals dropped out at any time during and immediately following closure, the surgeon would have been alerted to obtain an emergent MR. Note, in this case, more than 9 hours intervened between the end of surgery and the surgeon's ordering a STAT MR once the patient was fully quadriplegic. When that MR showed a huge anterior compressive DuraSeal mass, it should have prompted the surgeon to remove the anterior DuraSeal. Instead, he performed a laminectomy/posterior fusion. Further he never repeated a postoperative MR for 6 months and never reoperated on the patient. Therefore, the failure of the spine surgeon to utilize IONM significantly contributed to this patient's permanent postoperative quadriplegia
Failure to use a microscope	Without an operating microscope, operative dissection and resection of such severe OPLL as in this case, lead to a guaranteed intraoperative CSF leak, as noted in this case
Failure to use an arterial line	An arterial line should have been used during the first operation to monitor blood pressure. Rather, there was an acute estimated 1000 cc blood loss occurring over a 15 min interval that
Contraindicated Spine Surgeon's Use of Anterior Cervical Gelfoam, and Floseal (i.e., Use in Contained Space/ Not Washing It Out)	When the CSF leak occurred, resulting in copious epidural bleeding (i.e., loss of the dural tamponade on the epidural venous plexus), the spine surgeon placed Gelfoam and Floseal (Baxter Health Corporation, Hayward CA). Both are both directly contraindicated for use "…near confined neural structures "(i.e., particularly when combined with both Duragen and DuraSeal). The package insert for FloSeal states under Warnings: Excess FLOSEAL Matrix (material not incorporated in the hemostatic clot) should always be removed by gentle irrigation and suctioned out of the wound. Meticulous irrigation is required when used in, around, or in proximity to foramina in bone, areas of bony confine, the spinal cord, the brain and/or cranial nerves FLOSEAL Matrix swells by approximately 10–20% after product is applied and surgeons should consider its potential effect on the surrounding anatomic areas. Maximum swell volume is achieved within about 10 min The safety and effectiveness for use in neurosurgical and urological procedures has not been established through randomized clinical studies
Contraindicated application of Duragen beneath DuraSeal	The surgeon acknowledged the size of the defect was large, not just a few mm, but about the length of the 2-level corpectomy. He, therefore, placed Duragen (Integra LifeSciences, Plainsboro, NJ) over the massive dural defect despite its contraindications (i.e., package insert). However, the package insert itself states: "DuraGen Secure Dural Regeneration Matrix is not designed, sold or intended for use except as described in the Indications for Use and is contraindicated in the following situations: For repair of spinal neural tube defects or anterior spinal surgery with dural resection."
"Contraindicated" Use of DuraSeal in Anterior Cervical Spine and With Unrepaired CSF Leak (Package Insert)	DuraSeal directly contraindicated for use in anterior cervical spine (i.e., confined space) resulting in a compressive lesion DuraSeal: do not apply without adequate dural closure Package Insert (Integra LifeSciences, Princeton, NJ): CONTRAINDICATIONS: Do not apply the DuraSeal® Exact hydrogel to confined bony structures where nerves and spinal cord are present since neural compression may result due to hydrogel swelling. The hydrogel may swell up to 12% of its size in any dimension Intra-operative exclusion criteria: Patient has a gap greater than 2 mm remaining after primary dural closure
Failure to use of postoperative lumbar drain to treat CSF fistula rather than DuraSeal	Had the spinal surgeon read the report and/or reviewed the films, he would have anticipated an intraoperative CSF fistula due to OPLL. More likely than not, he could have planned to treat this with a postoperative lumbar drain for CSF diversion, and avoided the anteriorly compressive DuraSeal mass

(Contd...)

Table 2: *(Continued)*

Failures	Summary
Failure to order STAT postop MR after first surgery	The surgeon waited until the patient was fully quadriplegic, a full 9 hours after the first surgery ended, and 6 hours following the postoperative STAT CT scan that the surgeon interpreted as ruling out an epidural hematoma. Notably, there were no medical/surgical factors (i.e., respiratory and/or metabolic issues)or other factors that precluded in any way taking the patient down for a STAT MR scan. Again, this markedly delayed postoperative MR study, delayed the second surgery which should have been direct anterior removal of compressive DuraSeal rather than the wrong operative choice for laminectomy/posterior fusion
Failure to perform correct second operation in a timely fashion	This second surgery should have been for anterior cervical removal of compressive DuraSeal Rather, the surgeon wrongly/mistakenly chose to perform a laminectomy/y posterior fusion that failed to decompress the cord/failed to remove anterior DuraSeal/left patient quadriplegic
Failure to obtain STAT MR scan after the second surgery	Had the surgeon obtained a timely MR following the second surgery (i.e., STAT or even within 24 hours) he would have identified residual anterior cord compression from DuraSeal, and more likely than not, performed a third procedure to remove it However, he failed to obtain a postoperative MR for 6 months, thus leaving the patient with a permanent/irreversible quadriplegic deficit
Failure to perform third surgery consisting of anterior removal of DuraSeal	The patient underwent the wrong second operation, a laminectomy with posterior fusion. Had a STAT postoperative MR scan been performed following that second surgery, more likely than not, a third operation consisting of direct anterior removal of the DuraSeal would have been performed. To a reasonable degree of medical probability, even though that direct anterior cord decompression was delayed, it would have resulted in some degree of neurological recovery. Alternatively, with no repeat MR and no reoperation, the patient was left permanently quadriplegic

SEP: Somatosensory evoked potentials, MEP: Motor evoked potentials, EMG: Electromyography, IONM: Intraoperative neural monitoring, OPLL: Ossification of the posterior longitudinal ligament, Postop: Postoperative, PT: Physical therapy, OT: Occupational therapy, MD: Medical doctors, SOC: Standard of care

Contraindicated Application of DuraSeal

Next, the surgeon ignored the clear contraindication to applying DuraSeal over Duragen in the anterior cervical spine. He specifically stated: "A piece of Duragen was placed over thecal sac and reinforced with Dural Sealant." Here, the application of DuraSeal (Integra LifeSciences, Princeton NJ) in the anterior cervical spine was neglitent. It was a direct contraindication to use DuraSeal in a "...confined space...", that here included the anterior cervical spine. The package insert states: "Do not apply DuraSeal® (Integra LifeSciences, Princeton NJ) hydrogel to confined bony structures where nerves are present since neural compression may result due to hydrogel swelling (…up to 12% of its size in any direction) that it should not be applied over an unrepaired dural tear."

Failure to Consider Use of Postoperative Lumbar Drain to Treat CSF Fistula

Had the spinal surgeon read the report or reviewed the preopereative CT images, he would have known that the patient had OPLL. This would have enabled him to anticipate and plan to treat an intraoperative CSF fistula. More likely than not, he would have opted to use a postoperative lumbar drain for CSF diversion, and avoided using the directly contraindicated Gelfoam/Floseal, Duragen, and most critically, the DuraSeal.

SPINE SURGEON'S FAILURE TO DIAGNOSE IN A TIMELY FASHION AND APPROPRIATELY TREAT POSTOPERATIVE QUADRIPARESIS/ QUADRIPLEGIA

Following surgery, which included a major intraoperative CSF leak, the patient was taken back to the postoperative care unit "deep" following extubation. Instead of waiting to examine the patient himself once the anesthetic wore off, the surgeon went directly into his next case. This left the anesthesiologist to examine the patient who was severely quadriparetic when she was finally awake. When informed of her paralysis, the surgeon asked for a STAT non contrast scan. This was performed within approximately 2 postoperative hours; he interpreted it as showing no postoperative epidural hematoma. However, even the radiologist commented that the CT's significant metallic artifact interfered with adequately assessing what was going on within the spinal canal [Figures 5 and 6]. Nevertheless, the surgeon did not order a STAT MR, but rather recommended it be done sometime overnight. Additional recommendations included the administration of intravenous steroids, and keeping the mean arterial blood pressure between be maintained between 70-90 mm Hg.

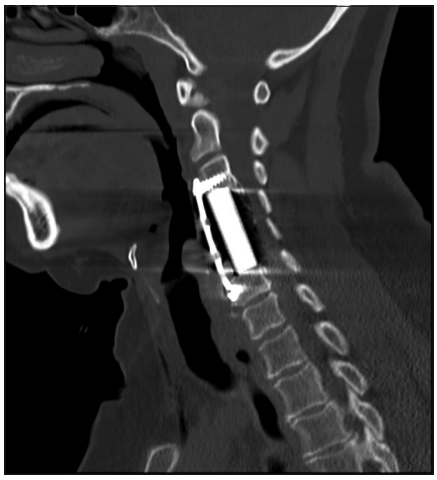

Figure 5: This STAT postoperative parasagittal cervical non-contrast CT study showed the C3-C6 anterior strut graft in place along with the anterior plate. The hypodense mass dorsally extending from the C3-C4 through the C5-C6 levels (i.e. posterior to the graft and anterior to the cord itself) contributed to marked ventral cord compression (i.e., this was due to Duraseal as confirmed on the postoperative MR). Further, the spinal surgeon simply read this STAT postoperative CT study as ruling out an anterior epidural hematoma despite the radiologist's statement that he (the radiologist) could not discern what was going on inside the spinal canal due to marked metallic artifact, thus indicating an additional MR was warranted.

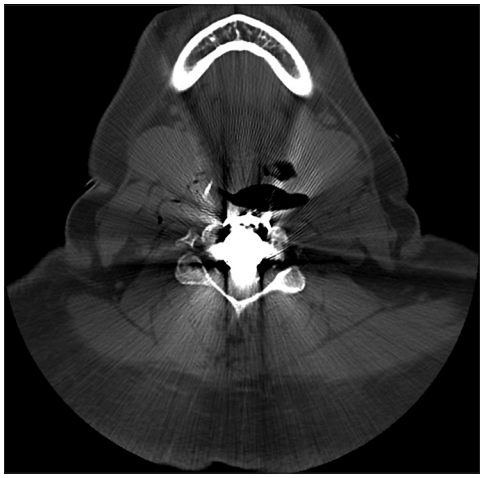

Figure 6: STAT postoperative axial non-contrast CT scan at mid C4 level showing marked metallic artifact from cervical disc arthroplasty device. The presence of the device made it difficult for the radiologist to interpret/identify any pathology within the spinal canal. This further confirmed that a STAT MR was warranted.

POSTOPERATIVE MR DELAYED FOR OVER 9 HOURS ALLOWING QUADRIPARESIS TO EVOLVE TO QUADRIPLEGIA

When the patient became fully quadriplegic 9 hours postoperatively, a STAT MR was finally obtained. Notably, there was no adequate explanation for this delay other than the surgeon having just ordered it be done "sometime overnight". The MR documented massive anterior cord compression due to DuraSeal (i.e., 33 mm cephalad/caudad, and axially 8–13 mm) [Figures 5-8].

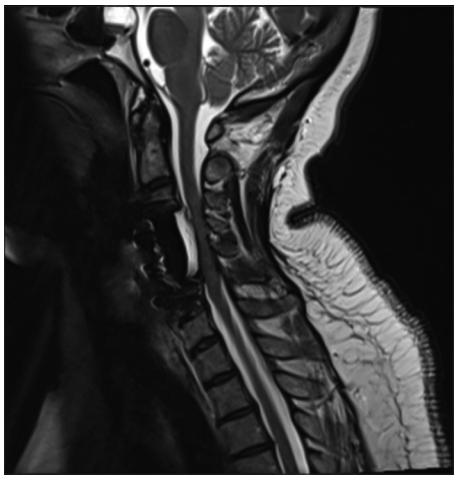

Figure 7: Delayed postoperative sagittal MR confirming massive anterior cord compression from the C3-C4 through the C5-C6 levels due to hyperintense DuraSeal. This midline sagittal postoperative MR scan, unfortunately obtained another 6 + hours after the CT scan but 9 + hours after the first surgery ended, showed massive anterior cord this postoperative midline sagittal MR scan showed massive anterior cord compression/edema attributed to the hyperintense DuraSeal Mass. Also note the new diffuse increased signal within the cord extending from C3-C6 consistent with acute cord edema.

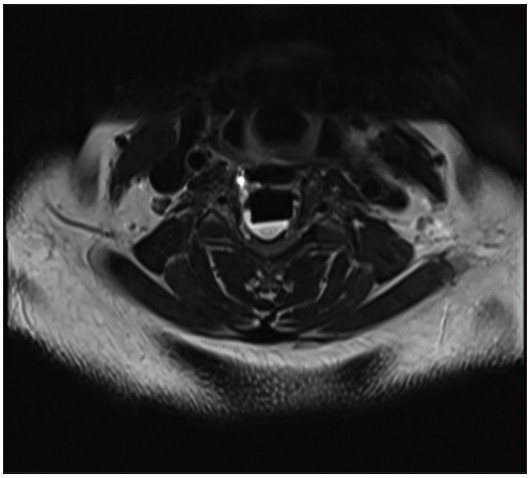

Figure 8: Delayed postoperative axial MR at the mid C4 level showing massive ventral cord compression due to DuraSeal.

FAILURE TO REOPERATE IN A TIMELY FASHION AND TO PERFORM THE CORRECT SECOND SURGERY: DIRECT ANTERIOR REMOVAL OF COMPRESSIVE DURASEAL

The surgeon then mistakenly performed the wrong second operation despite the clear MR documentation of a huge anterior DuraSeal Mass compressing the spinal cord. His second surgery consisted of a laminectomy/

posterior fusion rather than directly and correctly removing the anteriorly compressive DuraSeal.

FAILURE TO OBTAIN AN IMMEDIATE POSTOPERATIVE MR SCAN FOLLOWING THE SECOND SURGERY, AND FAILURE TO PERFORM AN ACUTE THIRD OPERATION TO REMOVE ANTERIOR DURASEAL RESULTED IN THE PATIENT'S PERMANENT AND IRREVERSIBLE QUADRIPLEGIA

The spine surgeon failed to order a STAT MR scan following the 2nd surgery, despite the fact that the patient remained quadriplegic. In fact, the only postoperative MR study the surgeon requested/performed was obtained 6 months later. Therefore, the patient received no emergent third operation (i.e. to remove the anteriorly compressive DuraSeal), thus leaving her fully and completely quadriplegic [Figure 9]. Had a STAT MR been performed after the second surgery, and had she undergone a third surgery consisting of direct resection of the anteriorly compressive DuraSeal, she, to a reasonable degree of medical probability, would have sustained some greater degree of neurological recovery.

DISCUSSION

Limitations of MR in the Documentation of OPLL

MR examinations show OPLL, particularly when there is retrovertebral extension of isointense/hypointense masses consisting of either hypertrophied or ossified posterior longitudinal ligament [Figures 3, 4, 7, 8].[1-6] Further, on MR, OPLL often contains inhomogeneous/isointense/hyperintense components consistent with active bone marrow production (i.e., fat content) within Haversian canals.

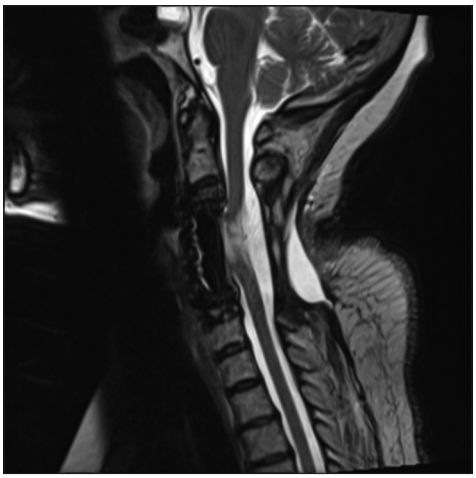

Figure 9: Six month postoperative T2 midline sagittal MR study showing cord atrophy/myelomalacia and ventral adherence of the cord to the previously placed DuraSeal. Note the capacious canal at this point due to the marked cord atrophy. There is also a residual hyperintense posterior fluid-signal collection likely attributed to the prior cervical laminectomy.

CT: Best Documentation of OPLL (Hypertrophy (HPLL)/ Classic Ossification)

CT scans more typically provide clearer, more direct, hypo-isodense (hypertrophied PLL) or hyperdense (mature classical OPLL) images of HPLL/OPLL.[2-6] Here, however, the surgeon did not review the CT report or mages that clearly showed classical OPLL with multiple signs of dural penetrance [Figures 1, 2, 5, 6] [Tables 1 and 2].[1-6]

Contraindicated use of Gelfoam/FloSeal, Duragen and DuraSeal to Treat Massive Anterior Cervical CSF Leak: Placement of a Postoperative Lumbar Drain Would Have Temporarily Sufficed

The spine surgeon was negligent in his "contraindicated" application of Gelfoam/FloSeal, Duragen, and DuraSeal to the anterior cervical spine, in a "confined space" where all of these products could substantially swell. Further, the latter two were directly contraindicated for use in the presence of a massive, unrepaired anterior cervical dural leak. Hence, the choice to apply Duragen followed by DuraSeal resulted in MR-documented severe anterior cord compression and resultant edema, causing the patient's postoperative quadriparesis/plegia [Figures 1-9] [Tables 1 and 2].[1-6]

The Patient's Postoperative Quariplegia was Not Due to a Reperfusion Injuyr (RPI) or White Cord Syndrome (WCS)

RPI/WCS is an extremely rare diagnosis attributed to an acute reperfusion of previously markedly compressed/ischemic spinal cord tissues [Table 1].[7] The classical MR findings include; "…new or expanded, and focal or diffuse intramedullary hyperintense cord signals consistent with edema/ischemia, swelling, and/or intrinsic hematoma."[7] However, as a diagnosis of exclusion, it is only applicable to patients who develop new neurological deficits following cervical surgery where new/residual extrinsic pathology responsible for and/or contributing to neural compromise have been excluded/ruled out. In this case, the "contraindicated" anterior cervical application of DuraSeal (i.e., to a confined space with an unrepaired CSF fistula) resulted in massive anterior cord compression, causing the patient's quadriplegia [Tables 1 and 2]. Further, the surgeon failed to postoperatively obtain a STAT MR scan and perform the right second operation (i.e. direct anterior resection of the DuraSeal mass), thus leaving the patient permanently quadriplegic.

CONCLUSION

After the first surgery, the "contraindicated anterior cervical application of DuraSeal into a confined space to

treat a massive, unrepaired CSF leak caused the patient's quadriplegia [Tables 1 and 2].[1-6] Additional failures included; the failure to obtain a STAT MR after the 1st surgery, failure to perform the correct 2nd surgery, failure to obtain a STAT MR after the 2nd surgery, and failure to perform an emergent correct 3rd surgery to remove the anterior DuraSeal. All of these errors contributed to the permanence of the patient's DuraSeal-related postoperative quadriplegia.

Declaration of patient consent

Patient's consent not required as patient's identity is not disclosed or compromised.

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Conflicts of interest

There are no conflicts of interest.

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Commentary

Contraindicated Use of DuraSeal In Anterior Cervical Spine Led to Quadriplegia

This Medicolegal Corner (Spine) highlights the issues of complex spine surgery in this complicated OPLL case. The failure to recognize OPLL and underestimate the degree of difficulty in a case that was destined to be problematic from the start was a big issue in this case. The lack of intraoperative monitoring brings into question if this SCI occurred during the case or with the hydrophilic expansion of the DuraSeal at the end of the case. Our group has experienced five complications using a similar tissue sealant. BioGlue is FDA and CE Mark approved as an adjunct to standard methods of surgical repair to band seal and/or reinforce soft tissues. Dural repair is listed in the soft tissue indications. Five patients were re-operated for neural compression secondary to an inflammatory mass within 6-50 weeks following spinal surgery (& 1 following cranial surgery for frontal sinus repair). In our cases the weakness appeared in a more delayed fashion after the product expanded. With quick MRI identification of the mass compressing the cord, we were able to remove the mass with urgent surgery and restore neurologic function. Pathology revealed an aseptic mass with reactive granulation tissue.

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