

Case Series

Contaminated bone grafts and tuberculosis in three spine surgery patients: a case series

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Received: 16 August 2023

Revised: 29 August 2023

Accepted: 31 August 2023

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ABSTRACT

Tuberculosis (TB) is a global health issue affecting millions of people every year. Previous articles displayed cases of TB resulting from contaminated bone grafts used in spinal surgeries. However, deeper understanding about the serious health consequences for patients affected by TB-infected bone grafts is lacking. Here, we discuss three unique patients who contracted TB after undergoing lumbar spinal surgery. We describe three patient cases in which individuals initially presented with back pain, underwent required lumbar spinal fusion surgery with bone graft implants, and, afterwards, contracted TB. All patients were given RIPE therapy, had additional surgery to remove the faulty hardware, and lived with significant and prolonged pain. In addition, patient X experienced night sweats, patient Y had a subcutaneous abscess positive for TB, and patient Z had severe burning pain, rash, and sweats. Altogether, we emphasize the importance of increasing our awareness about the potential risks and complications associated with utilizing contaminated surgical products. We encourage healthcare professionals to take necessary precautions to ensure the safety of their patients by screening bone grafts for potential pathogens and practicing proper sterilization techniques.

Keywords: *Mycobacterium tuberculosis*, Bone graft, Lumbar interbody fusion, Contamination, Spinal surgery, Infection, Risk management

INTRODUCTION

Spinal fusion is a surgery that joins at least two vertebral bodies together with the goal of maintaining appropriate motion of the spine and alleviating pain symptoms.^{1,2} Donor bone grafts are implanted between vertebrae to enhance the structural support of the spine.^{3,4} Spinal fusion surgery is beneficial to patients due to its positive effect on quality of life including pain and disability reduction.

The quality of implanted bone grafts plays an important role in the recovery process and vitality of health in patients suffering from low back pain. Bone graft contamination can lead to life-threatening infections and complications, further deteriorating patients suffering from debilitating diseases.⁵ In 2021, seven patients who

underwent spinal surgery involving placement of a bone allograft tested positive for spinal and disseminated tuberculosis at a single hospital.^{6,7} *Mycobacterium tuberculosis* was transmitted via a compromised FiberCel bone matrix allograft derived from product lot #NMDS210011 from Aziyo Biologics, Inc.⁸ The contaminated bone grafts were recalled on June 2, 2021. Quadruple tuberculosis drug therapy was administered to patients who tested positive for tuberculosis, asymptomatic patients with contaminated bone graft placement, and exposed healthcare workers.

Tuberculosis is a bacterial infection primarily affecting the lungs, resulting in symptoms of fever, night sweats, weight loss, persistent cough, and lymphadenopathy.⁹ Diagnosis of tuberculosis is performed using bodily secretions or

tissue biopsy that shows characteristic inflammatory findings of macrophages, T cells, and granuloma. Tuberculosis can have extrapulmonary manifestations including skeletal tuberculosis, involving infection of the bones and joints. Skeletal tuberculosis presents as Pott's

disease, arthritis, and osteomyelitis. Quadruple antimicrobial therapy targeted against both pulmonary and skeletal tuberculosis includes oral administration of rifampin, isoniazid, pyrazinamide, and ethambutol for six to nine months.

Timelines of Patients X, Y, and Z

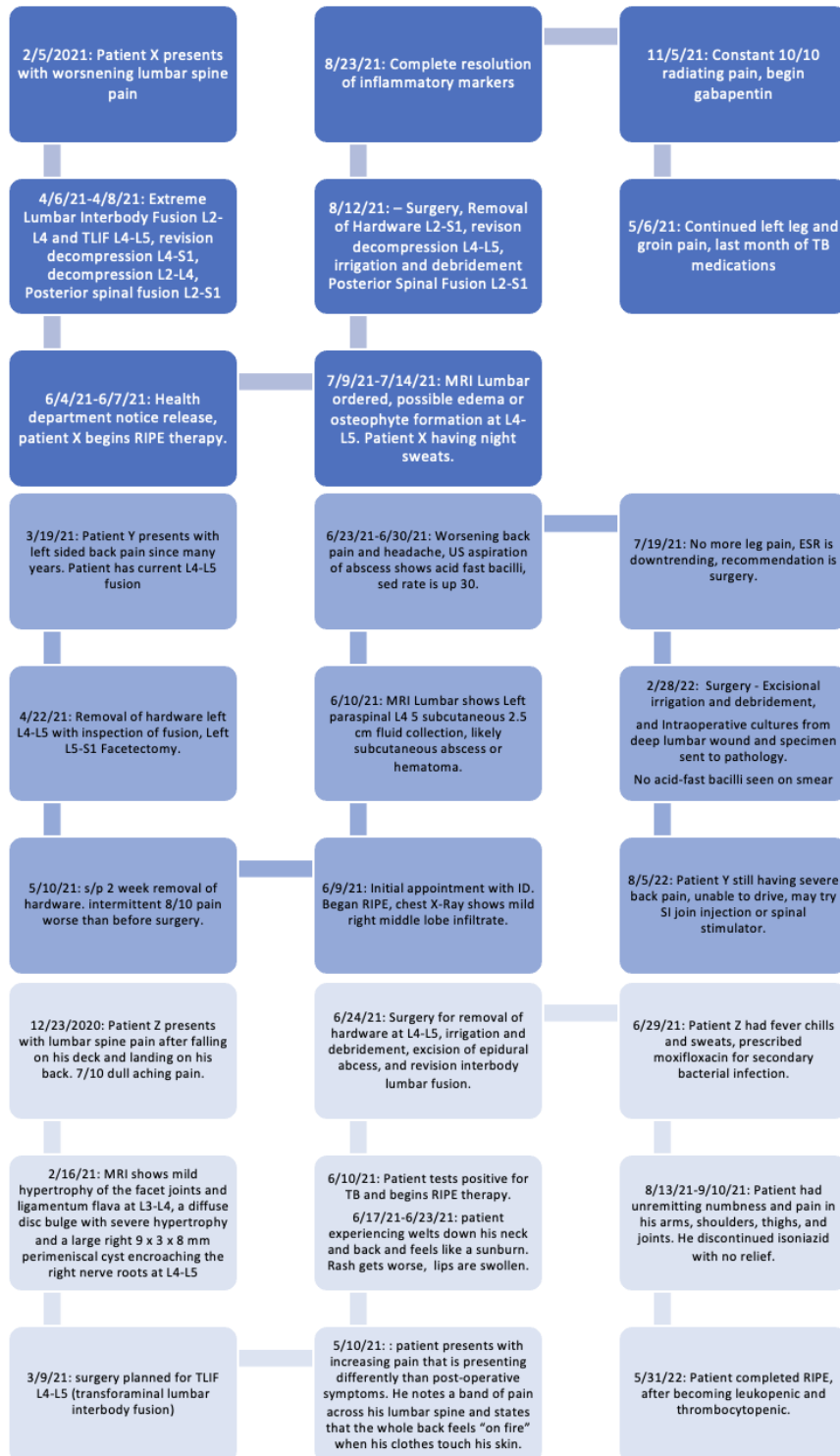


Figure 1: Timelines of patients x, y and z.

We present a case report of three patients who received tuberculosis-contaminated bone graft implantation during spinal surgery and afterwards, tested positive for tuberculosis. Our case report demonstrates the grave impact that infected surgical products can have on the health of our patients.

CASE SERIES

Patient X

Patient X, a 59-year-old female, presented to the spine clinic on 2/5/2021 with constant back pain that had been ongoing for over a year. The pain was described as an aching, shooting, and stabbing sensation, which radiated to her left knee, thigh, and foot. The patient reported a pain level of 5/10, which was worsened by a change in position, and stiffness was present constantly. The patient had tried several treatments such as NSAIDs, muscle relaxants, physical therapy, and epidural steroid injections, which provided only mild relief. The patient's medical history included degenerative joint disease, arthritis, obesity, spinal stenosis, and spondylarthritis.

Clinical findings

On physical examination, the patient was positive for lumbar tenderness, and abnormal extension, flexion, lateral bending, and rotation bilaterally. The patient had an abnormal gait, positive straight leg raise on the left, and left ankle dorsiflexion and big toe extension were both +4/5.

Diagnostic assessment



Figure 2: MRI Lumbar dated 2/2/2021 shows multilevel degenerative changes with varying degrees of spinal canal and neural foraminal stenosis. It also shows a disc bulge at T12/L1 with moderate spinal canal stenosis and mild mass effect on the nerve roots in anterior left spinal canal. In addition, it shows a mild mass effect on the bilateral L3 nerve root within the L3-4 neural foramina and an L4-5 left hemilaminotomy with no significant residual or recurrent stenosis seen. Results of pathologic tests and imaging show diagnoses of lumbar degenerative disc disease, history of lumbar laminectomy, spinal stenosis of the lumbar region with neurogenic claudication, and lumbar herniated nucleus pulposus.

Therapeutic intervention

Surgery was planned for 4/6/2021 and 4/8/2021, including an extreme lumbar interbody fusion (XLIF) L2-L4 initially, and transforaminal lumbar interbody fusion L4-L5 (TLIF), revision decompression L4-S1, decompression L2-L4, and the posterior spinal fusion L2-S1 two days later.



Figure 3: X-ray with 2 views of the lumbar spine including AP and lateral was obtained on 4/26/21. There is an L2-S1 fusion with interbodies at L2-L5. There are no signs of hardware failure.

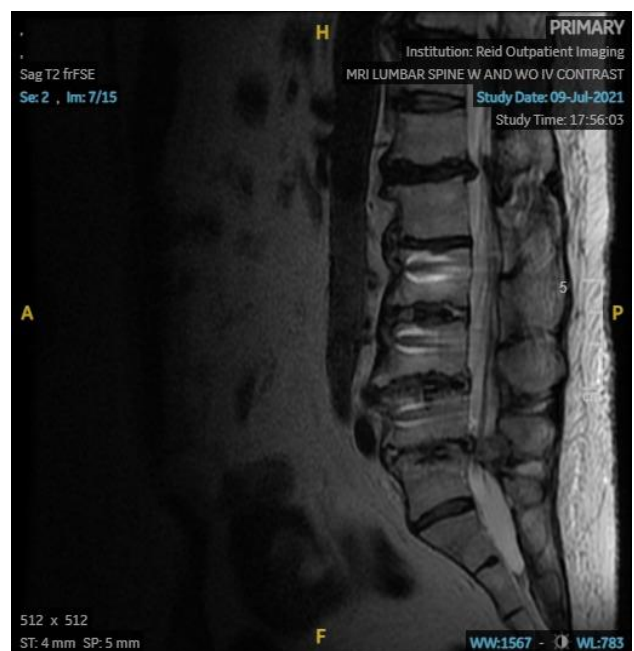


Figure 4: T2 weighted MRI showed no abnormal areas of enhancement are appreciated to suggest an acute infectious process. Irregularity involving the superior endplate of T11 could represent a compression fracture without significant height loss. Difficult to determine acuity. No STIR series was obtained. Disc protrusion and disc osteophytes T12-L1 results in significant spinal canal stenosis. Post-operative changes are present at the posterior lateral left side L5 level; however, this is chronic in nature. This is not an acute process.

Follow up and outcomes

On 4/26/21, the patient presented post-surgery with 3/10 pain, left leg weakness, and PT going well. On 5/24/21, the patient's pain worsened to 6/10, and it was discovered that she had DISH syndrome, requiring more recovery time. On 6/4/21, it was discovered that the bone grafts used in the surgery were contaminated with TB, and the patient was scheduled for an infectious disease appointment on 6/7/21. At the appointment, she tested positive on TB QuantiFERON gold and started RIPE therapy per health department guidelines.

On 7/14/21, the patient reported 2/10 intermittent pain and night sweats 2-3 times a week. An MRI of her lumbar spine was ordered to check for active infection, and on 7/28/21, the physician recommended removal of hardware L2-S1 with revision decompression L4-L5 with irrigation and debridement, posterior spinal fusion L2-S1, which was scheduled for 8/12/21.

On 11/5/21, the patient reported constant 10 out of 10 pains radiating down to her left buttock and anterior leg, and the recommendation was to start a gabapentin protocol. On 5/6/22, she was still experiencing groin and left leg pain and weakness, and it was noted that she was on her last month of RIPE therapy. As of the last follow-up appointment on 5/6/22, the patient continued to experience pain and other symptoms associated with the TB contamination.

Patient Y

On 3/19/21, a 57-year-old male, patient Y, presented to a spine clinic with a chief complaint of low back pain that he had been experiencing for years with no known cause. The patient rated his pain as 7 out of 10, and it varied in intensity. He had previously undergone medial and lateral branch blocks but was interested in discussing surgical options. The patient reported that the pain was on the left side of his back and did not radiate to his legs, groin, or buttocks. He also denied any loss of bowel or bladder control. His medical history included hyperlipidemia, hypertension, and spinal stenosis, and he was a current smoker but did not use alcohol or drugs.

Clinical findings

A physical examination revealed lumbar tenderness with a normal gait.

Diagnostic assessment

Pathologic test and imaging reveal diagnoses of lumbar spine pain and a history of lumbar spinal fusion.

Therapeutic interventions

The patient's surgery was scheduled for 4/22/21, which involved the removal of hardware from the left L4-L5

region with an inspection of the fusion and a left L5-S1 facetectomy.

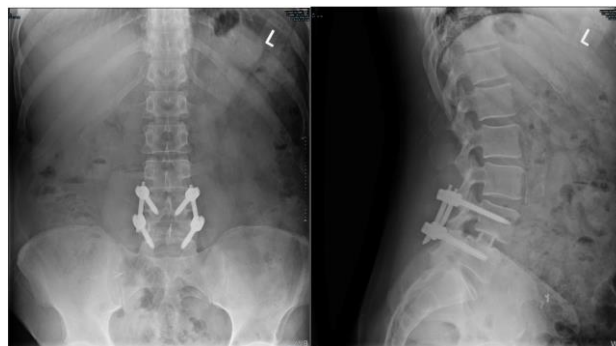


Figure 5: On 3/19/21, 4 views of the lumbar spine were obtained on X-ray, including AP, lateral, flexion, and extension. There is an L4-L5 fusion with interbody and no signs of hardware failure.

Follow-up and outcomes

However, when the patient presented to the clinic for his two-week follow-up on 5/10/21, he reported intermittent eight out of 10 pain that was worse when standing, and he experienced little relief from muscle relaxants and analgesics. On 6/9/21, patient Y had an initial appointment with an infectious disease specialist, where he tested positive for QuantiFERON gold, and his erythrocyte sedimentation rate was 16. He began RIPE therapy, and a chest x-ray showed a mild right middle lobe infiltrate.

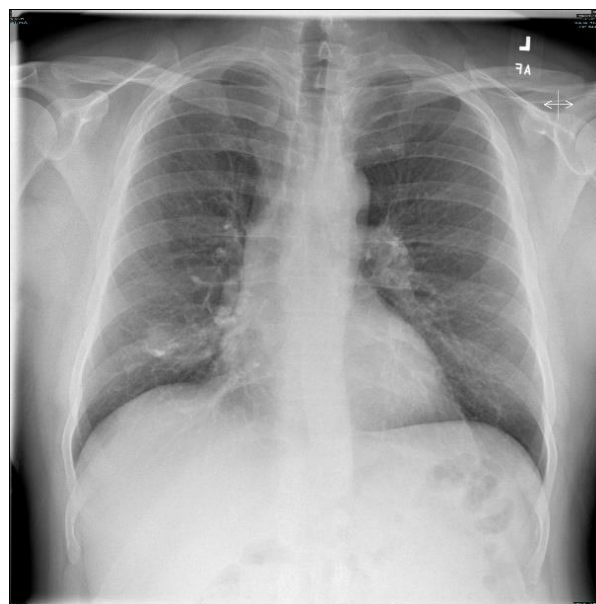


Figure 6: Chest X-ray, with a mild right middle lobe infiltrate.

On 6/23/21, the patient reported worsened back pain and a headache, but he remained compliant with the RIPE therapy. On 6/25/21, he underwent US-guided aspiration of his spinal abscess, which showed 0-1 acid-fast bacilli

per high-power field. By 6/30/21, his sedimentation rate had elevated to 30, and another MRI of his lumbar spine showed an interval decrease with a left L4-5 subcutaneous abscess measuring 1.3 cm. On 7/12/21, he had a negative chest x-ray.

By 7/19/21, patient Y's leg pain had resolved, and he was only experiencing back pain near his incision. He was using gabapentin and percocet for the pain, and his sedimentation rate was trending downwards. However, he had a persistent fluid accumulation, and surgery was recommended.

On 1/18/22, patient Y presented to the infectious disease clinic with daily severe headaches, nausea, blurred vision, light and sound sensitivity, and severe back pain. He was advised to hold isoniazid for three days to monitor headaches, but they persisted, and his blood pressure began to spike. He was instructed to stop taking rifampin and was later advised to restart it.

On 2/18/22, patient Y followed up with the spine clinic and reported a burning sensation around his incision. The fluid collection had possibly remained unchanged, and outpatient surgery was scheduled for 2/28/22. On that day, he underwent excisional debridement of granulation tissue in the thoracolumbar fascia, irrigation, and debridement of lumbar skin, subcutaneous tissue, fascia, and muscle. Intraoperative cultures were taken from deep lumbar wounds, and a specimen was sent to pathology. No acid-fast bacilli were seen on the smear.

Patient Y finished his RIPE therapy at the end of May 2022, and he continued to experience back pain. He was willing to try a spinal cord stimulator or SI joint injections.

Patient Z

On 12/23/2020, a 55-year-old white male presented with lumbar spine pain that began in November 2020 due to falling on his deck and landing on his back. The patient tried diclofenac with no relief. He also tried walking, icing, and heat with mild relief. The pain radiated from the back down the right leg to the mid-calf region, and there was numbness and tingling present down the legs to the toes. The patient described the pain as dull, aching, and burning. The patient rated severity seven on a 10-point scale, and the symptoms were aggravated by twisting, standing, and positioning. There was no relevant medical, family, or psychosocial history.

Clinical findings

On physical exam, the patient had a positive straight leg raise on the right, right paraspinal spasms, tenderness, and signs of injury on the right lumbar spine. Additionally, he was positive for sensory deficit and weakness. The physical exam also included mild weakness in plantarflexion and dorsiflexion on the right.



Figure 7: Magnetic resonance imaging (MRI) results dated 2/16/21 showing mild hypertrophy of the facet joints and ligamentum flava at L3-L4, a diffuse disc bulge with severe hypertrophy and a large right 9x3x8 mm peri meniscal cyst encroaching the right nerve roots at L4-L5, and a diffuse disc bulge with moderate hypertrophy of the facet joints and ligamentum flava at L5-S1.

Diagnostic assessment

The spinal surgeon diagnosed the patient with a grade 1 spondylolisthesis, degenerative disc disease of the lumbar spine with spinal stenosis, and synovial cyst of the lumbar facet joint.

Therapeutic intervention

The patient's treatment plan included an L4-L5 transforaminal lumbar interbody fusion (TLIF) on 3/9/21.



Figure 8: X-ray results dated 3/24/21 showing two views (AP and lateral). The images show an L4-L5 lumbar fusion with four screws, two vertical radiopaque rods, and a single intervertebral spacer. All hardware is in its intended position with no signs of complication. Lumbar anatomy has been restored overall and there is adequate lumbar lordosis.

Follow-up and outcome

On 5/10/21, the patient experienced increasing pain that was presenting differently than his post-operative symptoms. He noted a band of pain across his lumbar spine and stated that the whole back feels "on fire" when his clothes touch his skin. On 6/7/21, the hospital confirmed the patient's exposure to TB, and the patient tested positive

for QuantiFERON Gold. On 6/23/21, the patient continued to experience pain in his lower back that radiated down his legs to his feet, and pertinent positives included back and joint pain and weakness. Additionally, on 6/10/21, the patient started on RIPE therapy (rifampin, isoniazid, pyrazinamide, ethambutol) to treat TB per the centers for disease control and prevention (CDC) guidelines.

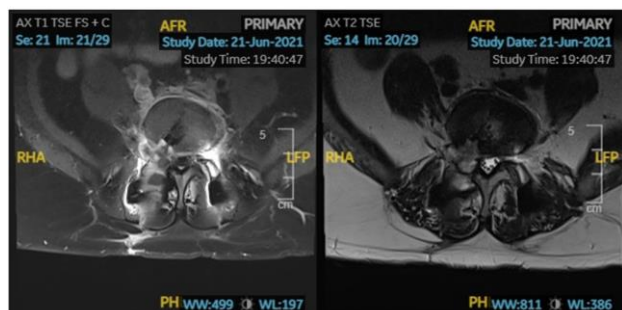


Figure 9: MRI images dated 6/21/21 showing spinal fusion present at L4-L5. There is edema and enhancement within L4-L5 vertebral bodies. There is also cortical irregularity involving the superior and inferior endplates at which was not present on the prior exam. In addition, there is bowing of the posterior cortex of L5 vertebral body and postoperative fluid collections involving the right side of the thecal sac with peripheral enhancement. Given the patient's history, this could represent small areas of infection and/or abscesses. The degree of bone marrow edema and enhancement likely represents osteomyelitis.

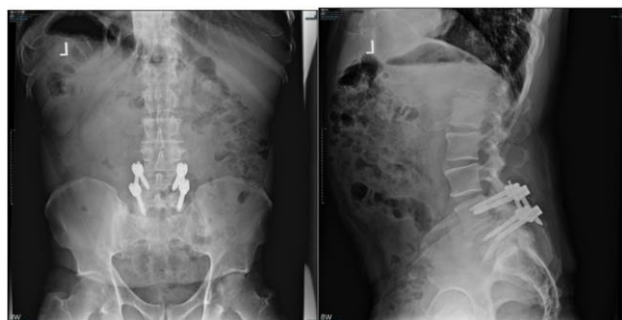


Figure 10: Post-revision X-rays dated 7/9/21 showing two views of the lumbar spine. Images show L4-L5 fusion with no signs of complication. Vertebral bodies of L4 and L5 show no signs of gross infection. No gas or fluid levels are appreciated in the soft tissue. Images show the removal of spacer as intended from the intervertebral space.

On 6/24/21, surgery was performed for the removal of the spinal hardware. The procedure included removal of the hardware at L4-L5 along with the peek interbody spacer sent to pathology with the bone graft. The surgery also included irrigation and debridement of the skin, subcutaneous tissue, muscle, and bone at L4-L5, excision of the epidural abscess, revision transforaminal lumbar

interbody fusion, posterior lateral fusion, revision decompression with revision laminectomy, facetectomy, and foraminotomy, and the use of the microscope for lysis of neurovascular adhesions and excision of the epidural abscess.

DISCUSSION

Our case study demonstrates the grave impact of contaminated donor bone grafts on the health outcomes of patients undergoing spinal fusion surgery. All three patients had standard spine surgery to alleviate their pain and associated symptoms but instead faced the burden of getting infected with systemic tuberculosis, having additional surgical interventions to remove the faulty hardware, and facing complications such as spinal abscesses. These patients were harmed, their pain was prolonged, and their quality of life was diminished due to the stress of a longer hospital stay and extensive treatment.

Our findings are consistent with previously published articles. Issa et al reported two patient cases in which tuberculosis-infected bone graft resulted in patients contracting disseminated tuberculosis, presenting with osteomyelitis, discitis, and abscess.¹⁰ In these patients, the infected bone was surgically removed and thoroughly debrided. These two patients, along with the three patients in the present study, all have one thing in common: a single source of infection. Tuberculosis transmitted via FiberCel bone matrix allograft from Aziyo biologics, Inc was later recalled.

The overall implications of this report are significant for both patients and clinicians. We show the potential risks associated with utilizing contaminated surgical products and emphasize the need for strict quality control measures to prevent future occurrences of similar incidents. We advocate for patient safety and healthcare worker safety by encouraging continued monitoring and surveillance of bone graft sources, adequate donor screening and selection, and proper sterilization process.¹¹ Further, patients should be informed about these risks when considering spinal fusion surgery and clinicians should raise their awareness about the consequences of implanting nonsterile surgical products.

The strengths of this case report include the detailed descriptions of clinical presentations, thorough diagnostic evaluations, and appropriate management strategies for the three cases. The limitations of this report include the retrospective nature of the study and the small sample size, which limits generalizability.

CONCLUSION

Spinal fusion surgeries involving donor bone graft placements carry the risk of undesired infections and adverse health outcomes. Patients affected by contaminated grafts exhibit symptoms of disseminated tuberculosis, complications including spinal abscesses,

and additional long-term, dire consequences affecting their quality of life. Future efforts should focus on ensuring the safety and sterility of surgical products, quickly identifying affected patients, and rectifying the issue.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: Not required

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Cite this article as: Naveed M, Ruan T, Sharma V, Vien H. Contaminated bone grafts and tuberculosis in three spine surgery patients: a case series. *Int J Res Orthop* 2023;9:1247-53.