Case Report

Total joint replacement of the lumbar spine: report of the first two cases with 16 years of follow-up

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Background: Total joint replacement (TJR) of the lumbar spine is a revolutionary procedure that couples the clinical benefits of neural decompression with preservation of natural motion and sagittal balance at the operative level. The TJR procedure involves reconstruction of the entire motion segment using a posterior bilateral transforaminal approach to access the disc space. The TJR implant (MOTUS, 3Spine, Chattanooga, TN, USA) replaces the function of the intervertebral disc and facet joints, performing biomechanically as a new articulation for the resected, degenerated disc and facets. The implant has been optimized to simulate the kinematic characteristics of the three-joint complex.

Case Description: Two male patients, ages 32 and 38 years, underwent the first TJR procedures in 2007 in South Africa. Both patients had imaging evidence of advanced spinal degeneration with unremitting back and leg pain refractory to conservative management. Symptom amelioration was achieved postoperatively with markedly reduced pains scores and improved function at clinical follow-up. Both cases were recently re-examined after 16 years and the patients reported that the procedure significantly changed their lives. Neither believes they have a lingering back condition and they have been able to fully participate in all functions related to work, family and recreation. There was little to no imaging evidence of adjacent segment disease or arthritic changes at this long-term follow-up interval.

Conclusions: After 16 years of clinical follow-up, the implant continues to function normally, without evidence of adjacent segment degeneration and both patients continue to enjoy activities of daily living without back or leg pain or other functional impairments.

Keywords: Degeneration; joint replacement; MOTUS; case report

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Introduction

Degeneration of the lumbar spine is an almost ubiquitous phenomenon with aging in humans (1-6), and the associated osseo-ligamentous deterioration can impact the entirety of the vertebral motion segment including the intervertebral disc and the two synovial facet joints (7-9). In fact, recent evidence underscores the biomechanical interdependence and pathophysiological overlap of degeneration across the three-joint complex, with disc degeneration and facet arthrosis typically occurring in tandem (10).

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Disc and facet degeneration, along with compression of the nerve roots can produce intractable symptoms of low back pain, radiculopathy and/or neurogenic claudication. When pain and functional impairment become chronic and refractory to conservative measures, surgical decompression of the offending structures provides relief (11).

Although decompression of the neural elements provides symptom amelioration, the removal of bone and ligamentous tissue disrupts the natural biomechanical stability of the spine, with more aggressive decompression resulting in greater instability (12,13). Consequently, instrumented fusion is often performed in conjunction with decompression to re-establish stability across the vertebral motion segment (14). Unfortunately, not only does this surgical approach essentially eliminate natural motion at the operative level but it also has the untoward consequence of exacerbating the stresses across the joint which very often results in adjacent segment disease (15).

Twenty years in development, total joint replacement (TJR) of the lumbar spine is a revolutionary procedure that couples the clinical benefits of decompression with maintenance of natural motion at the operative level via the implantation of a device that functions biomechanically as a new articulation for the resected, degenerated disc and facets and is optimized to mimic the kinematic characteristics of the three-joint complex (16,17).

We report on 16 years of follow-up of the first two cases treated in Pretoria, South Africa in September 2007 with TJR. We present these cases in accordance with the CARE reporting checklist (available at https://jss.amegroups.com/article/view/10.21037/jss-24-50/rc).

Highlight box

Key findings

- 16-year follow-up of the first-in-human total joint replacement (TJR) of the lumbar spine in two cases.
- The implant continues to function normally with no evidence of adjacent segment degeneration and both patients continue to enjoy activities of daily living without back or leg pain or other functional impairments.

What is known and what is new?

- Surgical decompression and instrumented lumbar fusion adversely affect the natural biomechanics of the three-joint complex and increase the risk of adjacent segment disease.
- Lumbar TJR is a motion segment reconstruction that utilizes a motion-preserving implant (MOTUS) that functions biomechanically as a new articulation for the resected, degenerated disc and facets.

What is the implication, and what should change now?

- TJR may offer a viable surgical alternative to instrumented fusion for treatment of chronically symptomatic spinal degeneration.

Case presentation

Surgical procedure synopsis

TJR is indicated for the biomechanical reconstruction and stabilization of a spinal motion segment following decompression at one lumbar level from L1/L2 to L5/S1 for skeletally mature patients due to symptomatic lumbar degeneration with or without foraminal or lateral recess spinal stenosis confirmed by radiographic imaging including computed tomography (CT), magnetic resonance imaging (MRI), and standard plain film radiography, with no more than a Grade 1 spondylolisthesis at the involved level.

The TJR procedure is a lumbar motion segment reconstruction that involves device implantation using a bilateral transforaminal lumbar interbody approach to access the disc space. Laminectomy, bilateral facet removal, and partial discectomy are used to achieve a wide central and bilateral decompression of the neural elements. The lateral annulus and anterior longitudinal ligament are preserved to maintain soft tissue tension and stability when disc height is restored. Additional surgical preparation includes three-column corrective pedicle vertebral body osteotomy (PVBO) of the superior portion of the inferior vertebral body, keel cuts, soft tissue tensioning, distraction of collapsed disc space as well as height and length trialing. The treated segment receives two implants, inserted bilaterally along the trajectory of the pedicles, such that the midpoint of the ball of the implant is approximately 40% ventral to the posterior vertebral body which is consistent with the physiologic center of rotation. The implant has a titanium plasma spray ingrowth surface at the keel/bone interface and initial fixation is achieved by press-fit as well as via the placement of a retention screw into the caudal portion of the implant which passes obliquely through the pedicle and into the vertebral body of the caudal level. TJR involves the implantation of the MOTUS device (3Spine, Chattanooga, TN, USA) which has been refined to simulate the kinematic characteristics of the three-joint complex (*Figures 1*,*2*).

With this procedure patients can be mobilized and often discharged the same day as surgery. Postoperative drains are rarely required, but this should be based on the surgeon's

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Figure 1 The MOTUS device (3Spine, Chattanooga, TN, USA) (https://www.3spine.com/).

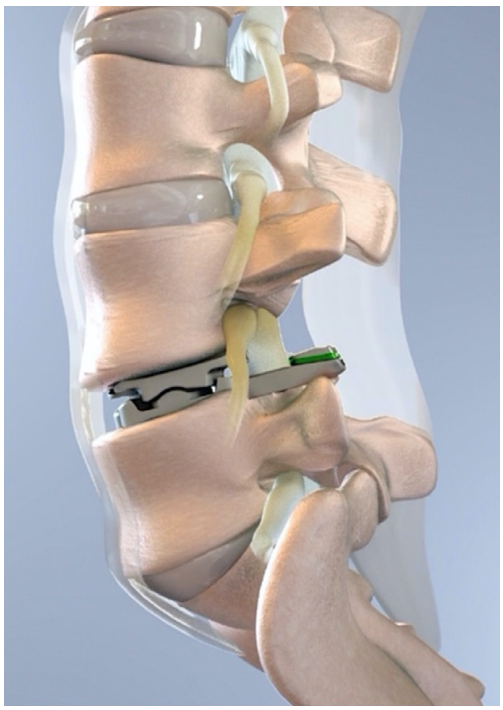

Figure 2 Lateral view rendering depicting total joint replacement at the L4/L5 vertebral level (https://www.3spine.com/).

clinical judgement. Before discharge, the patient should be able to urinate, and be safely ambulating. Patients should be routinely checked on that evening and the following day.

Controlled activity is recommended for the first 12 weeks, including supportive stretching (seated or lying supine). Only non-stressed lifting should be employed for the first 4 weeks which consists of minimal bending, lifting, twisting. After 4 weeks, patients can be allowed to initially bend and twist gently while avoiding complex motions such as lifting and twisting forcefully until their strength improves. Patients should progress slowly to increase range of motion through supported stretching until 12 weeks. At 12 weeks, formal physical therapy can be initiated.

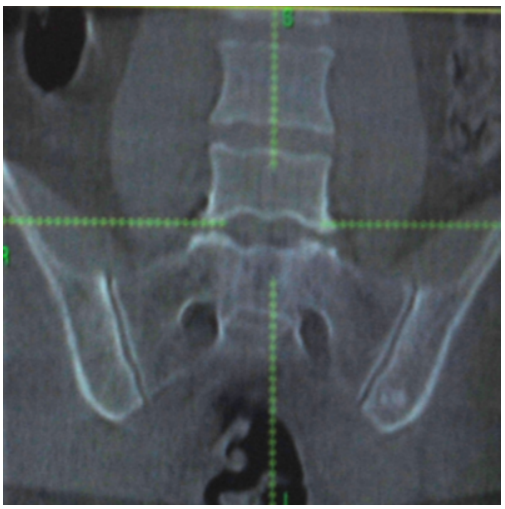

Figure 3 Preoperative imaging for Case 1. AP radiograph demonstrating degenerative changes with osteophytes at the lateral borders of L5/S1 (green dotted lines indicate the center of the image). AP, anteroposterior.

Case 1

This case represents a 32-year-old male patient who presented with severe lumbar discogenic back and bilateral leg pain which was unremitting and prevented him from working as a canine police officer. His work was rigorous and physical. Training and caring for a police dog included 15-hour round trip car rides from Johannesburg to Cape Town weekly. At baseline, the patient reported a back pain severity score of 9, and a back function score of 54 by Oswestry Disability Index (ODI) representing severe disability.

At the time of surgery, the patient was single, very healthy and employed. The patient had not had previous orthopedic or spine surgery and had exhausted conservative management including physical therapy, non-narcotic pain medications, corticosteroid injections, and activity modification. Preoperative imaging demonstrated disc degeneration with lateral recess stenosis at L5/S1 (*Figure 3*).

After providing informed consent, this patient underwent TJR on September 9, 2007 with the MOTUS device implanted at L5/S1 and recovered over 6–12 months following surgery. Postoperative management included physical therapy, non-addictive pain medications and muscle relaxers, rest, activity modification, and injections where indicated. Through the initial 12 months of follow-up, back and leg pain severity and ODI scores diminished

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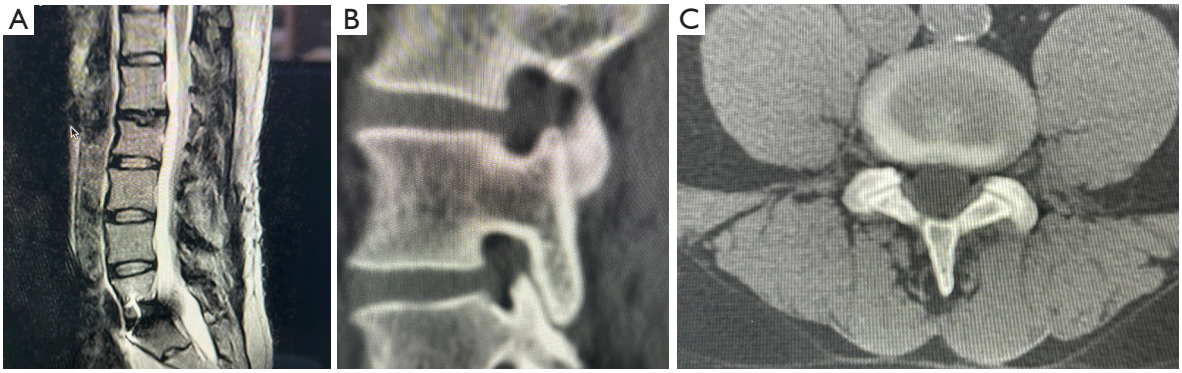

Figure 4 Postoperative imaging for Case 1. Sagittal (A) MRI view of the lumbar spine showing normal intervertebral disc morphology at the superior level (L4/L5) (arrow: N/A). Sagittal (B) CT image of the adjacent superior vertebral level to the TJR implant illustrating a lack of osseous arthritic changes. Axial (C) CT image through the L4/L5 intervertebral space. No arthritic changes are evident. MRI, magnetic resonance imaging; N/A, not applicable; CT, computed tomography; TJR, total joint replacement.

significantly. At 3 months, back pain severity was 3.5 and ODI was 32. Complete symptom amelioration was realized by 12 months with pain and ODI scores of 0. Absence of symptoms has been maintained through 16 years of follow-up.

Today, this patient is married, has a young daughter, and still works as a police officer in the canine division. He states that every 6 months he has to pass an extensive physical and he has no limitations in any areas, especially the shuttle runs. This level of well-being has been sustained through 16 years with full resumption of normal activities of daily living and sport. The patient currently reports no back or leg pain and no back-related functional impairment.

Postoperative 16-year MRI and CT scans show the implant fully functional with no evidence of adjacent level degeneration (*Figure 4*).

Case 2

This is a case of a 38-year-old male with intractable back and leg pain who worked in the mining industry. He was unable to work, and lifting or bending maneuvers were severely curtailed. He led a very active lifestyle before symptoms including golfing, running, and participating in several Cape Epic bike races, which entail an 8-day, 700 km, 16,000 m climb. The race is grueling and exhausting, both physically and mentally. For 9 years, he had symptoms of lumbar and leg pain before surgery. He was married, very healthy and employed but was unable to participate in family outings, even holding his then 9-month-old child was impossible. At initial presentation, the patient reported a back pain severity score of 6, and a back function score of 28 by ODI. Preoperative imaging demonstrated degenerative changes at L5/S1 and a subtle spondylolisthesis with stenosis at L4/5 (*Figure 5*).

The patient had not had previous orthopedic or spine surgery and had exhausted conservative management including physical therapy, non-narcotic pain medications, corticosteroid injections, and activity modification.

One day following Case 1 (September 10, 2007), this patient also provided informed consent and underwent an anterior lumbar disc replacement at L5/S1 (Maverick™, Medtronic, Inc.) with intact facets and TJR with posterior placement of the MOTUS implant at L4/L5 under the same anesthesia. This patient had a similar recovery period spanning 6–12 months, postoperatively. Postoperative management included physical therapy, non-addictive pain medications and muscle relaxers, rest, activity modification, and injections where indicated. This case did undergo facet (medial branch block) injections at the caudal level involving the disc arthroplasty within 6 months of surgery but this pain episode was isolated and resolved without the need for additional injections. Through the initial 12 months of follow-up, the back pain severity score and ODI showed marked improvement with values of 1 and 6, respectively. Symptom amelioration was maintained through 16 years with full resumption of normal activities of daily living and sport. The patient currently reports no back or leg pain (back pain severity =0) and no back-related functional impairment (ODI =0).

Postoperative MRI and CT scans at 16 years show the implant fully functional with normal adjacent segment

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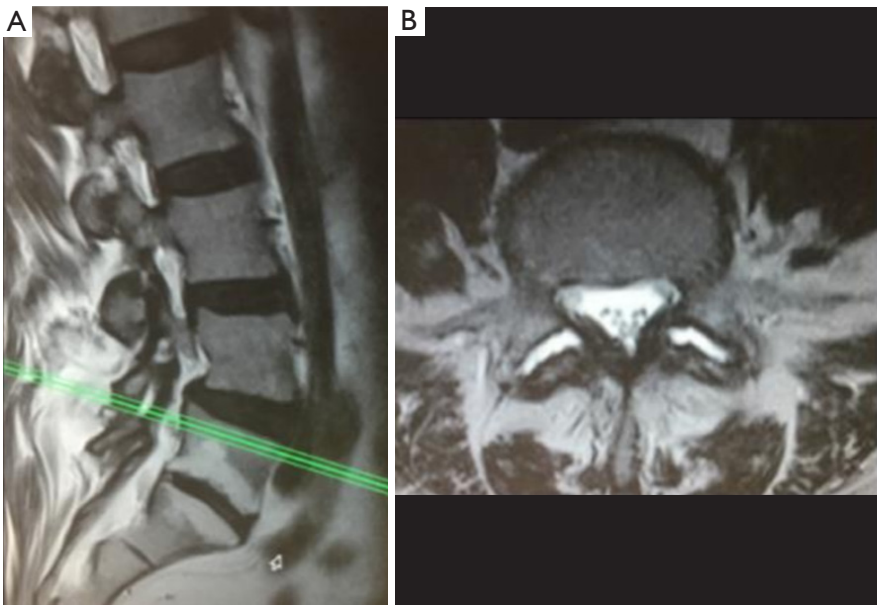

Figure 5 Preoperative imaging for Case 2. Sagittal (A) MRI view of the lumbar spine showing mild spondylolisthesis at L4/L5 (2 mm) with concomitant Modic changes at L5/S1 (green line indicates axial slice location). Corresponding axial (B) MRI view identifying fluid accumulation in the bilateral facet joints. MRI, magnetic resonance imaging.

vertebral and disc morphology and no evidence of degeneration at adjacent levels (*Figure 6*).

Ethical consideration

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the two patients for publication of this case report and accompanying images. A copy of the written consent is available for review by the editorial office of this journal.

Discussion

This case report offers the unique opportunity to evaluate the first in human use of the MOTUS implant for TJR of the lumbar spine. These two patients provide a remarkable 16-year duration of postoperative follow-up without resumption of symptoms, surgical revision, or evidence of degeneration or arthritic involvement at adjacent levels. Radiographic assessments, including CT scan, MRI, and plain radiographs taken in June, 2023 displayed consistent and stable implant positioning, with no signs of implant wear, loosening, or failure. Both patients reported that the TJR procedure significantly changed their lives for the better. At this juncture, neither believes they have a back problem, and they have been able to fully participate in all functions related to work, family and recreation.

The implant used in these operations was an earlier prototype of the current design with the primary difference being a metal-on-metal articulation which was modified subsequently to include a metal-on-cross-linked antioxidant vitamin E polyethylene (*Figure 1*) (18).

The design of this implant functions biomechanically as a new articulation for the resected, degenerated disc and facets. We postulate that the ability to maintain relatively normal flexion/extension motion at the treated level after implantation provides more physiologic stress transfer across the adjacent levels that acts to minimize wear and prevent a degenerative cascade requiring further surgeries. The zero-profile feature of the implant, which preserves normal kinematic joint functioning, may have the additional theoretical benefit of minimizing pain due to the reduced prominence of the hardware.

In contrast, the mainstay surgical option for advanced lumbar spinal degeneration, surgical decompression coupled with instrumented fusion, fundamentally alters the biomechanics of the three-joint complex by eliminating all motion at the operative level(s), creating aberrant stress

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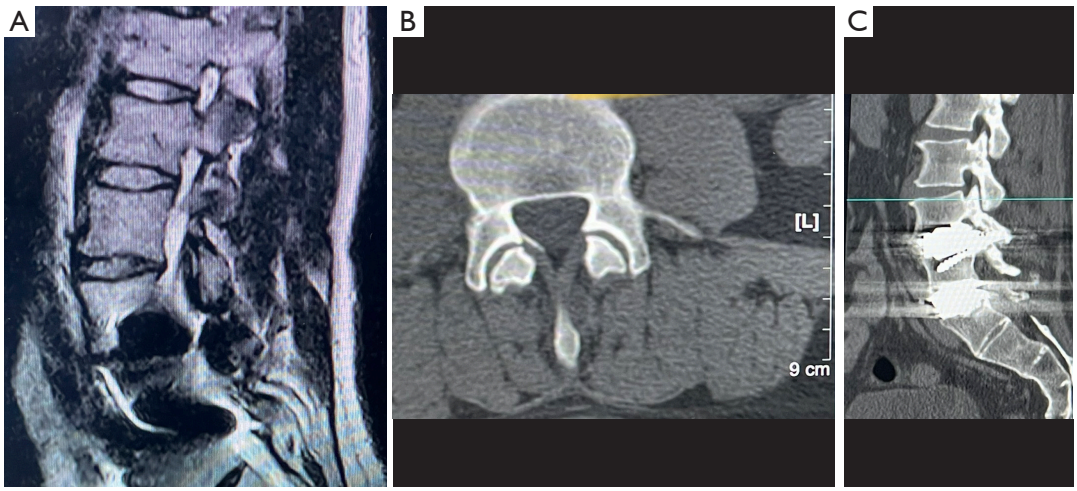

Figure 6 Postoperative imaging for Case 2. Sagittal (A) MRI view of the lumbar spine showing normal intervertebral disc morphology at the superior level (L3/L4). Axial (B) (L indicates left) and sagittal (C) CT images through the L4 superior endplate without evidence of degenerative spondylosis (blue line indicates axial slice location). MRI, magnetic resonance imaging; CT, computed tomography.

distributions that can lead to adjacent segment disease (15). In fact, the incidence of revision surgery to managed a failed primary arthrodesis has been reported to be as high as 25% at 10 years after the index surgery (19).

An initial pilot investigation of this novel implant showed encouraging results. Using a propensity-matched study design involving 156 patients treated with transforaminal lumbar interbody fusion (TLIF) compared with 52 MOTUS-treated patients, Alex Sielatycki *et al.* (16) reported comparative ODI responder rates for back function of 72% and 90% (P=0.008), respectively. The implant is currently being investigated under an Investigational Device Exemption (IDE) trial protocol at multiple clinical sites in the US (ClinicalTrials.gov, NCT05438719).

Conclusions

First-in-human TJR of the lumbar spine was performed successfully in two patients that have been followed clinically for 16 years. At this long-term follow-up, the implant continues to function normally, there is no evidence of adjacent segment degeneration and both patients continue to enjoy activities of daily living without back or leg pain or other functional impairments.

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Footnote

Reporting Checklist: The authors have completed the CARE reporting checklist. Available at https://jss.amegroups.com/article/view/10.21037/jss-24-50/rc

Peer Review File: Available at https://jss.amegroups.com/article/view/10.21037/jss-24-50/prf

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jss.amegroups.com/article/view/10.21037/jss-24-50/coif). All authors reported that this work was supported by 3Spine, Inc. (Chattanooga, TN, USA). J.E.B. received consulting fees for medical writing from 3Spine. S.C.H. and S.D.H. are patent holders in 3Spine. S.C.H., J.A.S. and S.D.H. are stockholders in 3Spine. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from the two patients for publication of this case report and accompanying images. A copy of the written consent is

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available for review by the editorial office of this journal.

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