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Instrumented Spinal Stabilization without Fusion for Spinal Metastatic Disease

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Abstract

Objectives—Spinal stabilization surgery is an integral part of the treatment of spinal metastatic disease. Bony fusion is the hallmark of spinal stabilization in non-oncology patients. Spinal oncology patients are unlikely to achieve bony fusion due to their overall prognosis and concurrent therapies. Stabilization surgery without fusion may be a reasonable approach for these patients. Literature evaluating the effectiveness of this approach is limited. The object of this study was to investigate the rate of instrumentation failure in patients undergoing posterior spinal instrumented stabilization without fusion for spinal metastatic disease.

Methods—Data from consecutive cases of spinal surgery at our institution during an 81-month period were reviewed. Demographics, clinical notes, and computed tomography (CT) findings were recorded and used to evaluate instrumentation failures. Patients who underwent separation surgery that included laminectomy and posterior spinal instrumentation without fusion for spinal metastatic disease and had follow-up CT scans >3 months postoperatively were selected for the study.

Results—Twenty-seven patients were included in the study. Mean age was 64.85±6.53 years. Nine patients were women. A mean of 1.61±0.96 laminectomy levels was performed. A mean of 8.26±1.48 screws was inserted. The mean postoperative discharge date was 5.07±1.47 days. Mean follow-up duration was 12.17±11.73 months. None of the patients had a change in instrumentation position, pedicle screw pullout, change in spinal alignment, or progressive deformity. No patient required reoperation or instrumentation revision or replacement.

Conclusions—Our experience suggests that instrumented spinal stabilization without fusion is an acceptable approach for patients with spinal metastatic disease.

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Keywords

fusion; instrumentation; metastases; spine; spinal metastatic disease; spinal stabilization

INTRODUCTION

The spinal column is the most common site of metastatic bone disease.[1] It is also the third most common site for solid tumor metastatic disease, following the lung and the liver.[1] Metastatic lesions account for more than 90% of spinal tumors, and the most common origins of metastasis are lung, breast, prostate, and kidney.[2–6] The most frequent locations for metastases within the spinal neural axis are the thoracic and thoracolumbar spine (70%), followed by the lumbar spine and sacrum (20%), whereas the least frequent location is the cervical spine.[6–8] Spinal metastases may cause neural compression and spinal fracture and can lead to debilitating pain and neurological deterioration. Surgical decompression and spinal stabilization are integral components of the treatment of spinal metastatic disease.[6, 7, 9]

The hallmark of spinal stabilization surgery in non-oncology patients is the achievement of solid bony fusion.[10] Studies have shown that patients with degenerative spinal disease, spinal stenosis, adult scoliosis, spondylolysis, or spondylolisthesis who underwent spinal decompression and fusion and achieved fusion had a better clinical outcome than those who did not achieve spinal fusion.[11–26] This improved outcome is due to the lasting spinal stability provided by bony fusion.[10] Spinal fusion indications and success rates have evolved in the past 2 decades as an increasing variety of titanium instrumentation and fusion substrates has become commercially available.[24, 27–29]

The goals of care for spinal oncology patients can differ from those for non-oncology patients due to their overall prognosis and concurrent therapies.[30–32] Patients treated for spinal metastatic disease may not live long enough to achieve bony fusion or develop hardware failure.[33–35] The healing capacity of their bone is often reduced as a result of continuous chemotherapy, radiation therapy, and poor nutritional status.[10, 36, 37] Furthermore, the decortication procedure that is required to stimulate fusion may disturb the body's natural anatomic barriers that prevent the tumor from additional spread.[38] For these reasons, the goals of spinal stabilization in oncology patients include pain relief, preservation of neurological function, prevention of progressive spinal deformity, and improvement of overall survival and quality of life.[1] In patients with spinal metastatic disease, fusion might not be essential to achieving these goals. However, instrumented internal bracing of the spine is effective.

The use of instrumented stabilization without fusion has been described for other spinal diseases or disorders. Studies in the spinal trauma literature describe the satisfactory outcome of spinal stabilization without fusion in the management of vertebral fractures.[39–45] These studies included the treatment of fractures specifically by posterior instrumentation. Further, a 10-year follow-up study of patients who underwent posterior instrumentation without fusion for traumatic thoracic and lumbar spine fractures supported the effectiveness of non-fusion stabilization.[46]

Nevertheless, several authors have reported failure of instrumentation in non-oncology patients who underwent stabilization without fusion.[47–49] These findings suggest that instrumentation can only stabilize the spine and maintain its alignment while the spine is being fused. The findings further assert that bony elements of the spine cannot be replaced by implanted hardware.[48, 50] In addition, other authors suggest that the amount of stress at the bone-screw interface can increase in the absence of a fusion construct, which can lead to instrument loosening or fracture.[51]

Literature evaluating the effectiveness of spinal stabilization without fusion in patients with spinal metastatic disease is limited. Studies evaluating outcomes of separation surgery likely include many patients that did not achieve bony fusion; however, to the best of the authors' knowledge, this patient population has yet to be specifically evaluated. The aim of the present study was to evaluate the rate of instrumentation failure in spinal oncology patients undergoing posterior spinal instrumented stabilization without fusion.

MATERIALS AND METHODS

Population, Setting, and Study Design

Consecutive spinal operations performed by a single neurosurgeon over an 81-month period (January 1, 2010 – September 30, 2016) at our institute were reviewed to reduce the possibility of selection bias in this study. Data from patients undergoing surgery before November 11, 2015 were retrospectively collected. After that date, data were prospectively collected. The Research Electronic Data Capture (REDCap) system (Vanderbilt University, Nashville, TN) was used to manage the data. This chart review was conducted after obtaining institutional review board approval. The approval included a Health Insurance Portability and Accountability Act waiver of patient authorization owing to the retrospective nature of and use of de-identified data in this study.

Patients undergoing separation surgery consisting of laminectomy and posterior spinal instrumentation for spinal metastatic disease who had a follow-up computed tomographic (CT) scan >3 months after the surgery were included in the study. Patients with non-metastatic cancer, anterior instrumentation, use of any fusion substrate at surgery, or previous radiation therapy or surgery on the same spinal level were excluded. Partial corpectomy was performed on some study participants. Less than 50% of the vertebral body was removed during corpectomy and no anterior construct was placed. All included patients underwent posterior pedicle screw stabilization with bilateral screw-rod constructs.

Demographic data such as sex, age at the time of surgery, origin of primary carcinoma, and comorbidities were obtained from each patient's electronic medical record. The number of pedicle screws placed and number of laminectomy levels were also documented. In addition, duration of the surgical procedure, estimated blood loss, type of guidance used for pedicle screw placement (2D fluoroscopy or 3D fluoroscopy with spinal neuronavigation), postoperative date of discharge, and follow-up data and duration were recorded. Any case of postoperative radiation at the same spinal level, postoperative infection, or reoperation for instrumentation revision was documented.

Evaluation of Instrumentation Failure

Preoperative, immediate postoperative, and follow-up CT scans were obtained and reviewed by a neuroradiologist and a neurosurgeon. Patients typically underwent postoperative CT scans at 6 weeks, 3 months, 6 months, and 1 year and were then followed with a CT scan biannually. Criteria for instrumentation failure were identified on CT imaging. The criteria included any change in instrumentation position, pedicle screw pullout, change in spinal alignment, or progressive deformity. Patients were further evaluated during follow-up office visits to assess for any instrumentation failure and need for reoperation and instrumentation revision. Postoperative CT scans were evaluated for any evidence of new bone growth or fusion between the stabilized levels.

Statistical Evaluation

Differences between patient groups who experienced instrumentation failure and those without instrumentation failure were compared using a Student's t-test.

RESULTS

One hundred and thirty-nine consecutive patients were evaluated. One hundred and twelve of the evaluated patients were excluded from the study. The patients excluded did not require instrumentation (n=63), had non-metastatic disease (n=17), had anterior instrumentation (n=3), did not have a 3-month follow-up examination (n=15), or received fusion material (n=11). One patient underwent a previous surgery on the same spinal level. Finally, 2 additional patients were excluded because they had multiple separate laminectomies on different spinal levels.

The study group was comprised of the remaining 27 patients, 9 of whom were women. The mean age of the patients at the time of surgery was 64.85±6.53 years (Table 1). All included patients had an expected prognosis of 6 months or more as determined by their primary medical oncologist. The primary disease sites and their prevalence in the study group patients were as follows: lung (n=10; 37.0%), kidney (n=10; 37.0%), prostate (n=3; 11.1%), breast (n=1; 3.7%), colon (n=1; 3.7%), thyroid (n=1; 3.7%), and adrenal glands (n=1; 3.7%). The types of comorbidities with their prevalence were diabetes (n=2; 7.4%), hypertension (n=20; 74.1%), renal insufficiency (n=1; 3.7%), heart failure (n=1; 3.7%), and coronary artery disease (n=2; 7.4%). The indication for surgery was the presence of a neurologic deficit, myelopathy, or spinal instability secondary to spinal metastatic disease in a patient with an overall prognosis of >6 months as determined by the patient's medical oncologist. Operations were performed with 2D fluoroscopy in 5 cases (18.5%) and 3D fluoroscopy with spinal neuronavigation in 22 cases (81.5%). Constructs included 1 (3.7%) cervicothoracic (C7 pedicle fixation), 18 (66.7%) thoracic, 1 (3.7%) thoracolumbar, and 7 (25.9%) lumbar. The mean number of laminectomy levels was 1.61±0.96; the mean number of screws inserted was 8.26±1.48; the mean duration of the surgical procedure was 198.74±43.15 minutes; and the mean estimated blood loss was 836.11±1239mL. Images from a representative case are shown in Figure 1. Partial corpectomy at one vertebral level was performed on 4 patients (14.8%). None of the study patients had a major perioperative complication. Patients were discharged a mean of 5.07±1.47 days after surgery, and there

were no postoperative wound infections. The mean follow-up duration was 12.17±11.73 months postoperation. Twenty-four patients (88.9%) underwent postoperative radiotherapy.

None of the 27 patients experienced any instances of instrumentation failure such as pedicle screw pullout, rod bending, or rod breakage. No changes in spinal alignment, development of kyphosis, or progressive deformity were observed on the follow-up CT scans (Figure 1). As a result, none of these patients required reoperation for instrumentation revision, removal, or replacement. There was no evidence of new bone growth or bony fusion for any of the postoperative CT scans analyzed. No instances of pain or neurologic deficit attributed to spinal instrumentation were noted during clinical evaluations.

DISCUSSION

This study describes a cohort of patients with spinal metastatic disease who underwent instrumented surgical stabilization without fusion. The patients were assessed clinically and with postoperative CT imaging. Instrumentation failure was not identified in any of the patients. The average follow-up time was 12.17 months.

Several characteristics of patients with spinal metastatic disease make them unlikely to achieve bony fusion following surgery. Fehlings et al. reported a median survival time of 7.7 months for patients undergoing surgery for spinal metastatic disease in a prospective, multicenter trial.[52] Similar median survival data has been observed in other studies.[53–57] In our study, the mean follow-up time was 12.2 months. This contrasts with the process of bony fusion that may occur over 1 year or longer.[58, 59] Patients with spinal metastatic disease typically receive postoperative radiation and chemotherapy that may impair new bone formation.[36, 37, 60–62] Corticosteroid administration can decrease bone mineral density and compromise osseous healing capacity.[63–65] The nutritional compromise observed in oncology patients may further preclude fusion occurrence.[38, 61]

A potential disadvantage of the lack of fusion in oncology patients is instrumentation failure. Instrumentation failure has been reported in the degenerative and trauma spinal literature; however, it often occurs in a delayed fashion and is unlikely to impact patients with a limited survival expectation.[66–69] Screw loosening also typically occurs in a delayed fashion and may not be clinically significant in patients with spinal metastatic disease.[51] Rod breakage is a rare event.

There are some potential advantages to eliminating fusion. Operative time, as well as total blood loss, may decrease.[44] The risk of further destabilization of the spinal column caused by posterolateral decortication as part of the fusion procedure is eliminated. The possibility that the fusion substrate could stimulate the growth of cancer cells is removed.[70–73] Finally, fusion materials are expensive. Cellular allograft and demineralized bone matrix are fusion substrate options in cancer patients; however; they carry a substantial financial cost. List prices for commonly used fusion substrates may be as much as $5,000 (USD).[74–76] Excluding these materials represents a substantial cost saving, particularly in high-volume oncology settings.

Surgical outcome studies can be challenging when examining a disease with a relatively short survival rate. Hardware failure is more likely to occur with increasing time from surgery.[66] Therefore, we selected patients with >3 months follow-up because they were more likely to develop instrumentation issues. Our median follow-up of 7 months and mean follow-up of 12.17 months is comparable to the results achieved by Fehlings et al.[52] in a study with similar group of patients. This represents an adequate follow-up time for the condition studied. Clinical and radiographic data were utilized to assess patients for instrumentation failure. CT imaging accurately detects hardware issues;[51, 77–80] and, therefore, it was used to assess instrumentation integrity and spinal alignment for all of the patients in our study.

In most of the patients, the spine was stabilized with long-segment fixation. Pedicle screws were typically placed from 2 levels above to 2 levels below the affected vertebral segment. An average of 8.3 pedicle screws was placed per patient. Following this classic approach to spinal stabilization was likely a contributing factor to the lack of hardware failures. Although an increasing trend exists toward minimally-invasive and short-segment constructs,[81, 82] such surgical techniques can result in hardware failure.[81, 83] Further, bilateral screw rod constructs were placed in all cases, and the authors would discourage unilateral fixation in the setting of spinal metastatic disease.

The patients included in this study underwent a posterior separation surgery involving posterior and posterolateral decompression of the neural elements and spinal stabilization.[9] Many of these patients had significant anterior vertebral body disease, and 4 patients had a partial corpectomy performed from a posterolateral approach without cage placement. Presumably, patients with anterior disease, a posterior and posterolateral decompression, and a long posterior construct would be at risk for hardware failure. However, hardware failure in this setting was not observed. Patients undergoing surgery for spinal metastatic disease are unlikely to achieve bony fusion or hardware failure regardless of the technique/substrate employed in large part due to their life expectancy.

The heterogeneity of patients with spinal metastatic disease makes them a difficult population to study because characteristics such as pathology, chemotherapeutic regimens, sites of distant metastases, and patient treatment goals vary. Studies of diverse populations can be limited by selection bias. We restricted the population to those patients with adequate follow-up who met our selection criteria; however, this inclusion process also limited our study population. There were no instances of instrumentation failure in our study group so a true failure rate could not be determined.

Recent advances in immune therapy and targeted therapy for systemic cancers has improved the expected survival for certain cancer types.[84–86] If significant survival improvements occur for patients with spinal metastatic disease, long-term bony fusion may become achievable and also necessary. The spinal surgeon should work closely with a medical oncologist to accurately assess a patient’s prognosis given the available therapies and determine the spinal treatment goals.

CONCLUSIONS

Instrumented spinal stabilization without fusion is an acceptable surgical approach for the treatment of spinal metastatic disease. The risk of hardware failure or progressive deformity following posterior spinal instrumentation without fusion for spinal metastatic disease is low. Spinal surgeons, particularly those accustomed to routinely performing fusion procedures in non-oncology patients, should be aware of these findings.

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Abbreviations

CT	computed tomographic
REDCap	Research Electronic Data Capture

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Highlights

- To the best of our knowledge, this is the first reported analysis of spinal instrumentation without fusion for spinal metastatic disease.
- Our report provides a useful outcomes analysis for a cohort of patients with spinal metastatic disease undergoing surgical stabilization.

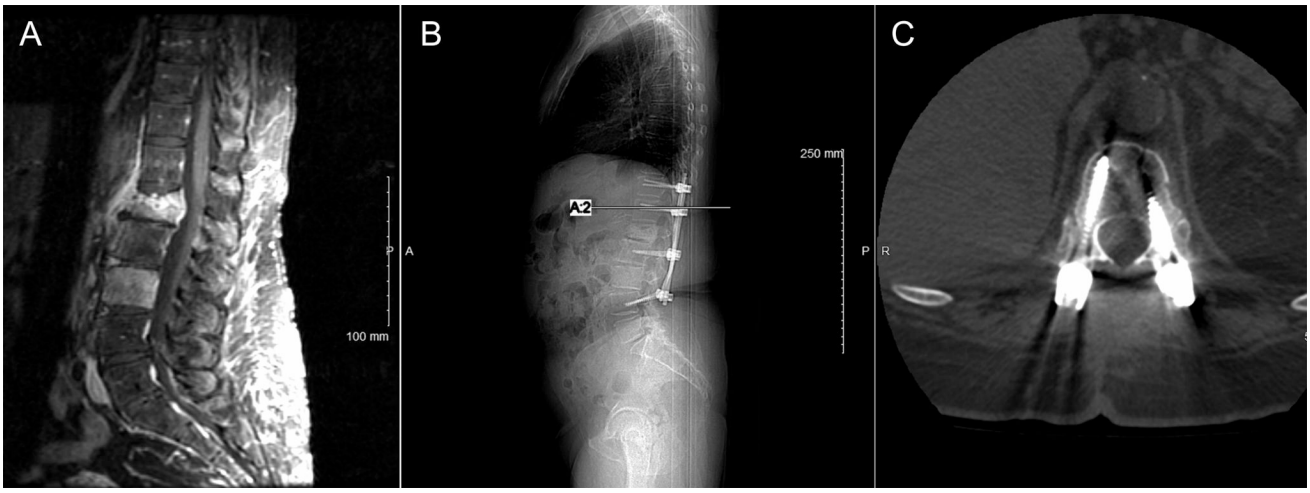

Figure 1.

Representative images from a 61-year-old woman with renal cell carcinoma who presented with intractable axial loading back pain. The patient had an L1 pathologic compression fracture and L3 vertebral body tumor involvement (A, sagittal T1- weighted gadolinium-enhanced magnetic resonance image). She underwent a separation surgery that included an L1 laminectomy and T11–L4 posterior spinal stabilization without fusion. The patient underwent postoperative fractionated radiotherapy. Follow-up spinal CT scan 16 months after the surgical procedure shows stable spinal alignment without evidence of instrumentation failure (B, sagittal and C, axial).

Table 1

Summary of Results

	Summary of Results
Mean Age	64.85±6.53 years
Primary Disease Site	Lung (10), Kidney (10), Prostate (3), Breast (1), Colon (1), Thyroid (1), Adrenal Glands (1)
Mean Laminectomy Levels	1.61±0.96
Mean Pedicle Screws Placed	8.26±1.48
Spinal Segment Instrumented	Cervicothoracic (1), Thoracic (18), Thoracolumbar (1), Lumbar (7)
Average Postoperative Discharge Day	5.07±1.47
Average Follow-up	12.17±11.73 months