Low Implant Failure Rate of Percutaneous Fixation for Spinal Metastases: A Multicenter Retrospective Study

Alvaro Silva[1], Ratko Yurac[1], Alfredo Guiroy[2], Oscar Bravo[1], Alejandro Morales Ciancio[2], Federico Landriel[3], Santiago Hem[3]

■ OBJECTIVE: **To evaluate incidence and types of implant failure observed in a series of patients with spinal metastases (SM) treated with minimally invasive stabilization surgery without fusion.**

■ METHODS: **In this multicenter, retrospective, observational study, we reviewed the files of patients >18 years old who underwent surgery for SM using percutaneous spinal stabilization without fusion with a minimum 3-month follow-up. The following variables were included: demographics, clinical findings, prior radiation history, SM location, epidural spinal cord compression scale, Spinal Instability Neoplastic Scale, neurological examination, and surgery-related data. Primary outcome measure was implant failure rate, as observed in patients' last computed tomography scan. Multivariable analysis was performed to identify baseline factors and factors associated with implant failure.**

■ RESULTS: **Analysis included 72 patients. Mean age of patients was 62 years, 39 patients were men, and 75% of patients had an intermediate Spinal Instability Neoplastic Scale score. Tumor separation surgery was performed in 48.6% of patients. Short instrumentation was indicated in 54.2% of patients. Three patients (4.2%) experienced implant failure (2 screw loosening, 1 screw cut-out); none of them required revision surgery. In 73.6% of cases, survival was >6 months. No significant predictors of failure were identified in the multivariate analysis.**

■ CONCLUSIONS: **A low implant failure rate was observed over the short and medium term, even when short instrumentations without fusion were performed. These findings suggest that minimally invasive stabilization surgery without fusion may be an effective and safe way to treat complicated SM.**

INTRODUCTION

Spinal metastases (SM) are the most frequent osseous metastases and a major source of morbidity in patients with cancer.[1] SM cause pain as well as neurological compromise in up to 14% of cases and thereby can significantly impact patients' quality of life.[2-4] The emergence of new oncologic therapies has led to significant improvements in patient survival, which has resulted in an increasing number of patients with vertebral metastases that require medical treatment, radiotherapy, or surgery.[5,6]

The main objectives of surgery for SM are pain relief and management of neurological compromise, which are achieved by mechanical spinal stabilization and neural decompression.[5] These goals focus both on improving patients' quality of life and on minimizing treatment-related complications.[7] Conventional open fixation and decompression surgery has been proven effective at improving neurological status, but complication rates are high (25%–40%) and can themselves worsen patients' quality of life.[3] The development of minimally invasive spine surgery (MISS) has changed the treatment paradigm for SM, owing to its low complication rate despite outcomes comparable to those of open surgery.[8-10]

Percutaneous spinal fixation techniques—with or without decompression—in combination with postoperative conventional

Key words
■ Implant failure
■ Minimally invasive spine surgery
■ Percutaneous spinal fixation
■ Spinal metastases

Abbreviations and Acronyms
AIS: American Spinal Injury Association Impairment Scale
CT: Computed tomography
ESCC: Epidural spinal cord compression
MISS: Minimally invasive spine surgery
SM: Spinal metastases

From the [1]Facultad de Medicina, Clínica Alemana Universidad del Desarrollo, Santiago, Chile; [2]Spine Unit, Orthopedic Department, Hospital Español de Mendoza, Mendoza, Argentina; and [3]Neurosurgery Department, Hospital Italiano de Buenos Aires, Buenos Aires, Argentina

To whom correspondence should be addressed: Alvaro Silva, M.D. [E-mail: asilvag@alemana.cl]

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or stereotactic radiation therapy accomplish the treatment goals for SM with a lower risk of complications, despite usually adequate tumor resection and a local recurrence rate of <5% per year.[11,12] Patients with SM undergoing surgical stabilization have multiple risk factors that predispose them to implant failure, including poor bone quality owing to tumor infiltration, previous vertebral irradiation, high stress of posterior implants owing to insufficient anterior support at the level of the metastatic vertebra, and a higher risk of local infection secondary to nutritional and/or immunologic compromise, among others.[13-15]

Implant failure is a complication that may affect the outcome of patients and occasionally may require revision surgery. During percutaneous fixation surgery for SM, normally no fusion is performed, leading to a theoretically higher risk of implant failure.[16-18] This being said, the literature on implant failure rates following percutaneous SM fixation is extremely limited.[18-22] The aim of this study was to evaluate the incidence and types of implant failure observed in a series of patients with SM treated with minimally invasive stabilization surgery.

MATERIALS AND METHODS

After our protocol received approval from the institutional review board, we reviewed the medical records of all patients who underwent percutaneous spinal fixation with or without separation surgery and without spinal fusion for the treatment of symptomatic SM between 2011 and 2019 at 2 hospitals in Chile and 2 hospitals in Argentina. We included in our analysis patients >18 years old who were operated on for SM using a minimally invasive percutaneous screw system, with or without separation surgery and without fusion, who had a minimum follow-up of 3 months and had complete medical and imaging records. We excluded patients with previous spinal surgeries for their oncologic disease and patients who had undergone anterior column surgery (e.g., cage, mesh, bone graft).

We use the neurologic, oncologic, mechanical, and systemic decision framework by Laufer et al.[5] from Memorial Sloan-Kettering Cancer Center for treating patients with SM. To decide between cement augmentation versus percutaneous screws, we consider the Spinal Instability Neoplastic Scale score, extent of the compromise of the posterior vertebral wall, compromise of posterior elements, and, in the thoracic spine, the compromise of the costovertebral joint.

For percutaneous fixation and MISS decompression, we use the following technique: using C-arm guidance, we put the Kirschner wires into the pedicles. Depending on the extension and localization of the tumoral compression, we can approach the spine by a paramedian mini-open transmuscular incision to access the lamina and the articular process. If the compression is bilateral, a mini-approach over the midline can be used. We use a speculum or tubular retractors and a microscopic view. With a high-speed drill, the lamina, joint, and pedicle are drilled; the dural sac is exposed; and a pedicle-to-pedicle decompression is performed. Tumor is removed from the medial pedicle wall, and a tilt of the operating table helps to access the tumor under the posterior longitudinal ligament. If the compression is bilateral, the procedure is repeated on the other side. Then the screws are placed, and the percutaneous rod is locked. We do not decorticate the facet joints or insert any bone graft.

Recorded Data

Our primary outcome measure was implant failure, observed in the patient's last computed tomography (CT) scan, defined as construct failure and/or mechanical failure of the vertebrae. We used a classification system that we modified from the one originally published by Kumar et al.,[13] based on the different possible mechanisms of failure (Table 1).

We collected the following patient data: age, sex, comorbidities, primary tumor origin, symptoms (mechanical pain, radiculopathy, or myelopathy), history of prior radiation therapy, time from cancer diagnosis to symptomatic metastases, metastases location, epidural spinal cord compression (ESCC), Spinal Instability Neoplastic Scale score, surgery-related data (instrumentation levels), and type of surgery performed (percutaneous fixation alone, percutaneous fixation with vertebroplasty/kyphoplasty, or percutaneous fixation with tumor separation surgery). Patients also were assigned an American Spinal Injury Association Impairment Scale (AIS) score based on their neurological examination, rated from A (complete impairment, with no motor or sensory function below the level of injury) to E (normal function). Secondary outcome measures were intraoperative and postoperative complications, neurological status, and patient survival.

Statistical Analysis

Continuous variables were summarized as means, with standard deviations and ranges, while categorical variables were summarized as absolute numbers and percentages. The normality of distribution was tested for all continuous variables using the Shapiro-Wilk test. During intergroup comparisons, all of which involved just 2 groups, normally distributed continuous variables were assessed using nonpaired t tests, while non—normally distributed continuous variables were assessed using the Mann-Whitney U test. For intergroup comparisons of categorical variables, Pearson χ^2 analysis was used. All tests were 2-tailed, with a Bonferroni-adjusted P threshold of 0.001 used to account for multiple comparisons. Multivariable analysis was performed to identify baseline and perioperative factors associated with implant failure, employing binary logistic regression analysis. For the model, independent variables with univariate P values < 0.10 were introduced by forward entry and excluded from the final model when P was > 0.10. All analyses were performed using IBM SPSS Version 26.0 software (IBM Corporation, Armonk, New York, USA).

RESULTS

Baseline Demographic Data

Our analysis included 72 patients. Mean age of patients was 62 years (range, 25—90 years), and 39 patients were men (54.2%). All patients had mechanical pain. Data on neurological compromise, comorbidities, primary tumor, and prior radiation background are summarized in Tables 2 and 3.

Metastases-Specific Data

In 80.5% of patients, the metastases were located either at the thoracolumbar junction or in the lumbar spine; 48.6% had a radiologic ESCC grade of 2 or worse; and 75% had an intermediate Spinal Instability Neoplastic Scale score (Table 4).

Table 1. Implant Failure Scale

Type 1	Screw loosening (peri-screw radiolucency)
Type 2	Screw pull-out (translation of screw on its axis) or screw cut-out (screw violates the margins of the pedicles or vertebral end plates after repeated movements)
Type 3	Screw/rod breakage
Type 4	Angular deformity: sagittal angulation increased >10°, measured between the upper end plate of the upper vertebra and the lower end plate of the lower vertebra

Surgical Data

In 29.2% of patients, a kyphoplasty was added for additional mechanical support. In 48.6% of patients, tumor separation surgery for epidural compression was performed. Instrumentation of 1 level above and 1 level below the levels of SM was performed in 54.2% of patients (Table 5).

Table 2. Characteristics of Patient Sample ($N = 72$)

Variable	Number (%)
Age, years	
≤55	17 (23.6%)
56–65	31 (43.1%)
≥66	24 (33.3%)
Sex	
Female	33 (45.8%)
Male	39 (54.2%)
Number of comorbid illnesses	
0	23 (31.9%)
1	27 (37.5%)
2	22 (30.6%)
>2	0 (0.0%)
Hypertension	30 (41.7%)
Diabetes mellitus	10 (13.9%)
Heart disease	5 (6.9%)
Preoperative AIS score	
E	44 (61.1%)
Isolated radiculopathy	8 (11.1%)
Cauda equina syndrome	1 (1.4%)
D	9 (12.5%)
C	9 (12.5%)
B	1 (1.4%)
A	0 (0.0%)

AIS, American Spinal Injury Association Impairment Scale.

Table 3. Characteristics of Cancer and Preoperative Treatment ($N = 72$)

Variable	Number (%)
Primary tumor	
Breast	19 (26.4%)
Lung	19 (26.4%)
Kidney	8 (11.1%)
Prostate	7 (9.7%)
Multiple myeloma	4 (5.6%)
Colorectal	3 (4.2%)
Uterine	2 (2.8%)
Neuroendocrine	2 (2.8%)
Bladder	2 (2.8%)
Other, single cancers*	4 (5.6%)
Multiple cancers (melanoma and kidney)	1 (1.4%)
Unknown primary	1 (1.4%)
Cancer known when SM identified	64 (88.9%)
Prior radiation therapy	9 (12.5%)
Time from cancer diagnosis to SM symptoms	
≤6 months	53 (73.6%)
7–12 months	5 (6.9%)
1–2 years	5 (6.9%)
>2 years	9 (12.5%)

SM, spinal metastases.
*Gastric cancer, pancreatic cancer, Hodgkin lymphoma, ocular melanoma.

Intraoperative and Postoperative Complications

In 4 patients, accidental dural tears occurred during separation surgery; all resolved intraoperatively. Three patients experienced wound dehiscence, and 2 had epidural hematomas that required revision surgery. No wound infections were observed. After SM surgery, 53 patients lived >6 months; of these patients, 18 lived >2 years (Table 6).

Neurological Outcomes

All 44 patients with a preoperative AIS rating of E (full neurological function) maintained that score postoperatively. All 9 patients with either an isolated radiculopathy ($n = 8$) or cauda equina syndrome ($n = 1$) improved completely. Among the 9 patients with a preoperative AIS score of D, 7 improved to AIS E, while 2 remained unchanged. Among the 9 patients with a preoperative AIS C score, 5 improved to AIS E, 3 improved to AIS D, and 1 deteriorated to AIS A. The 1 patient whose neurological status was rated AIS B preoperatively improved to AIS C postoperatively.

Implant Failure

Three patients (4.2%) experienced implant failure: 2 patients experienced type 1 failure, and 1 patient experienced type 2. None

Table 4. Characteristics of Metastases ($N = 72$)

Variable	Number (%)
Location	
Upper thoracic spine (T1-T6)	14 (19.4%)
Lower thoracic spine (T7-T12)	32 (44.4%)
Lumbosacral spine (L1-S1)	26 (36.1%)
ESCC grade	
0	9 (12.5%)
1a	10 (13.9%)
1b	13 (18.1%)
1c	5 (6.9%)
2	19 (26.4%)
3	16 (22.2%)
SINS score	
1–6	0 (0.0%)
7–12	54 (75.0%)
13–18	18 (25.0%)

ESCS, epidural spinal cord compression; SINS, Spinal Instability Neoplastic Scale.

of these patients required revision surgery (Figures 1 and 2). The first patient was a 43-year-old woman with a neuroendocrine tumor that had been diagnosed 545 days before SM were found at T11 (ESCC grade 3, AIS score C). She underwent percutaneous fixation, cemented screw placement, kyphoplasty support, and MISS decompression. At 841 days after surgery, in a routine follow-up check of her neoplasm, CT scan showed asymptomatic type 1 loosening. The patient is still alive and remains asymptomatic. The second patient was a 71-year-old man with lung cancer, which was discovered with SM at L2 (ESCC grade 2, AIS score C). He underwent percutaneous fixation, cemented screw placement, kyphoplasty support, and MISS decompression. At 573 days after surgery, in a routine follow-up check of his neoplasm, CT scan showed asymptomatic type 1 loosening. The patient died 675 days after surgery. The third patient with implant failure was a 57-year-old woman with lung cancer that had been diagnosed 1460 days before SM were found at T5 (ESCC grade 1b, AIS score E). She underwent percutaneous fixation, and kyphoplasty support. She presented with dorsal pain and mild lower limb paresis 121 days after surgery. CT scan and magnetic resonance imaging were performed, and type 2 loosening was found: pedicular fracture owing to marginal progression of the tumor. The patient had end-stage lung cancer and died 191 days after surgery.

Table 5. Characteristics of Surgery ($N = 72$)

Variable	Number (%)
Percutaneous screws	72 (100.0%)
Kyphoplasty	21 (29.2%)
Separation surgery	35 (48.6%)
Screw augmentation	6 (8.3%)
Instrumentation levels	
2	39 (54.2%)
3	6 (8.3%)
4	22 (30.6%)
5	4 (5.6%)
6	1 (1.4%)

Table 6. Surgical Complications, Postoperative Radiation Therapy, and Patient Survival ($N = 72$)

Variable	Number (%)
AIS score	
Improved	25 (34.7%)
Unchanged	46 (63.9%)
Worse	1 (1.4%)
Postoperative complications	10 (13.9%)
Wound dehiscence	3 (4.2%)
Pneumonia	2 (2.8%)
Epidural hematoma	2 (2.8%)
Paraplegia	1 (1.4%)
Urinary tract infection	1 (1.4%)
Deep venous thrombosis	1 (1.4%)
Postoperative radiation therapy	62 (86.1%)
Survival	
≤6 months	19 (26.4%)
6–12 months	18 (25.0%)
1–2 years	17 (23.6%)
≥2 years	18 (25.0%)

AIS, American Spinal Injury Association Impairment Scale.

When analyzing for potential predictors of implant failure, on univariate analysis, a potential association was observed with a preoperative AIS score of C or worse, the addition of kyphoplasty during surgery, and any postoperative complication (Table 7). However, on multivariable analysis, no significant predictors were identified (Table 8).

DISCUSSION

Percutaneous MISS has become a widely used technique for surgical management of SM owing to its low complication rate and outcomes similar to open surgery.[19,20] The hardware failure rate reported in large series of patients with metastatic spinal tumor is 2%–16%.[16] Most of these series have included open surgery

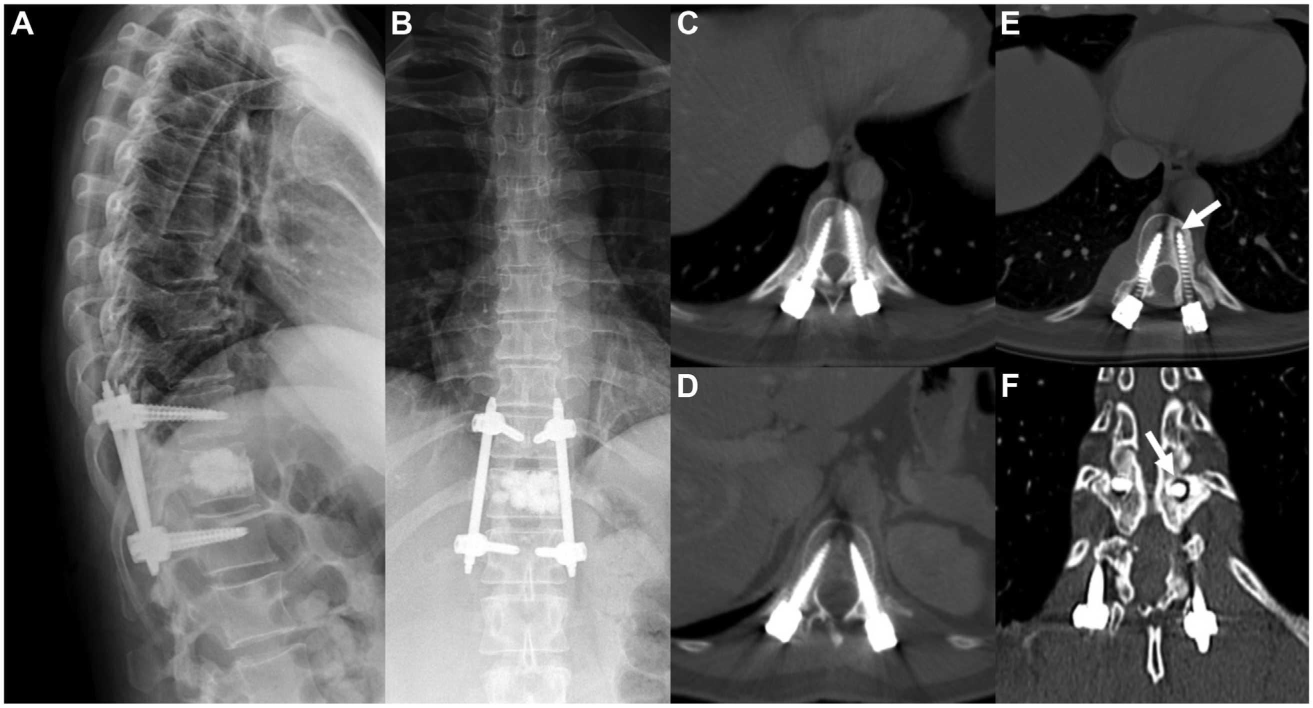

Figure 1. (**A** and **B**) A 43-year-old woman with a T11 neuroendocrine metastatic tumor underwent percutaneous fixation with decompression. (**C** and **D**) CT scan obtained 3 months postoperatively showing proper screw placement. (**E** and **F**) Asymptomatic type 1 implant failure (peri-screw radiolucency) visible 2 years later (*white arrows*).

techniques, and others have included patients treated with both open surgery and MISS. The study by Versteeg et al.[18] and the present study are the 2 largest reported series of patients with SM treated exclusively with MISS. Similar to our own hardware failure rate of 4.2%, Versteeg et al.[18] had a 3.9% implant failure rate, with 0.9% of all patients requiring revision surgery: specifically, 2 patients required surgery because a screw became dislodged and 1 patient required surgery because of a broken pedicle screw.

Our 4.2% implant failure rate is low, considering that neither arthrodesis nor anterior column restoration was performed in any patient. As stated above, this rate resembles others reported in the literature. Moreover, in 2 of our 3 patients in whom implant failure occurred, it was only a radiologic finding (type 1 implant failure). In the 1 remaining patient, the patient reported dorsal pain and exhibited mild lower limb paresis, after which both magnetic resonance imaging and CT scan revealed a pedicular fracture (type 2 implant failure) owing to marginal progression of the tumor in end-stage lung cancer. In addition, this patient had a history of prior thoracic surgery, a condition previously described by Amankulor et al.[16] as a risk factor for instrumentation failure.

Quraishi et al.[23] reported a 10.7% overall reoperation rate for SM, with 3.1% due to implant failure.[17] Amankulor et al.[16] noted a similar implant failure rate of 2.8%. Both authors used revision surgery as their criterion to define hardware failure. As far as we know, implant failure that requires revision surgery usually is symptomatic and worse overall, in terms of the degree of failure, than failure diagnosed purely as an imaging finding in an asymptomatic patient. Consequently, this leads us to believe that the implant failure rate we observed in our series could be lower than rates previously published.

We were unable to identify any factor that could be significantly associated with implant failure, probably owing to the small number of patients with this complication in our series. However, variables such as instrumentation over >6 levels, a history of chest wall resection, preoperative radiation, and positive sagittal balance have been mentioned in the literature as possible contributors.[9,16] The 1 patient in our series with type 2 implant failure had a history of thoracic surgery, a condition previously described as a very significant risk factor for instrumentation failure,[9,16] in addition to prior radiation, another condition significantly associated with hardware failure.[24] Although conventional radiotherapy has been shown to recalcify tumor-infiltrated vertebrae and increase

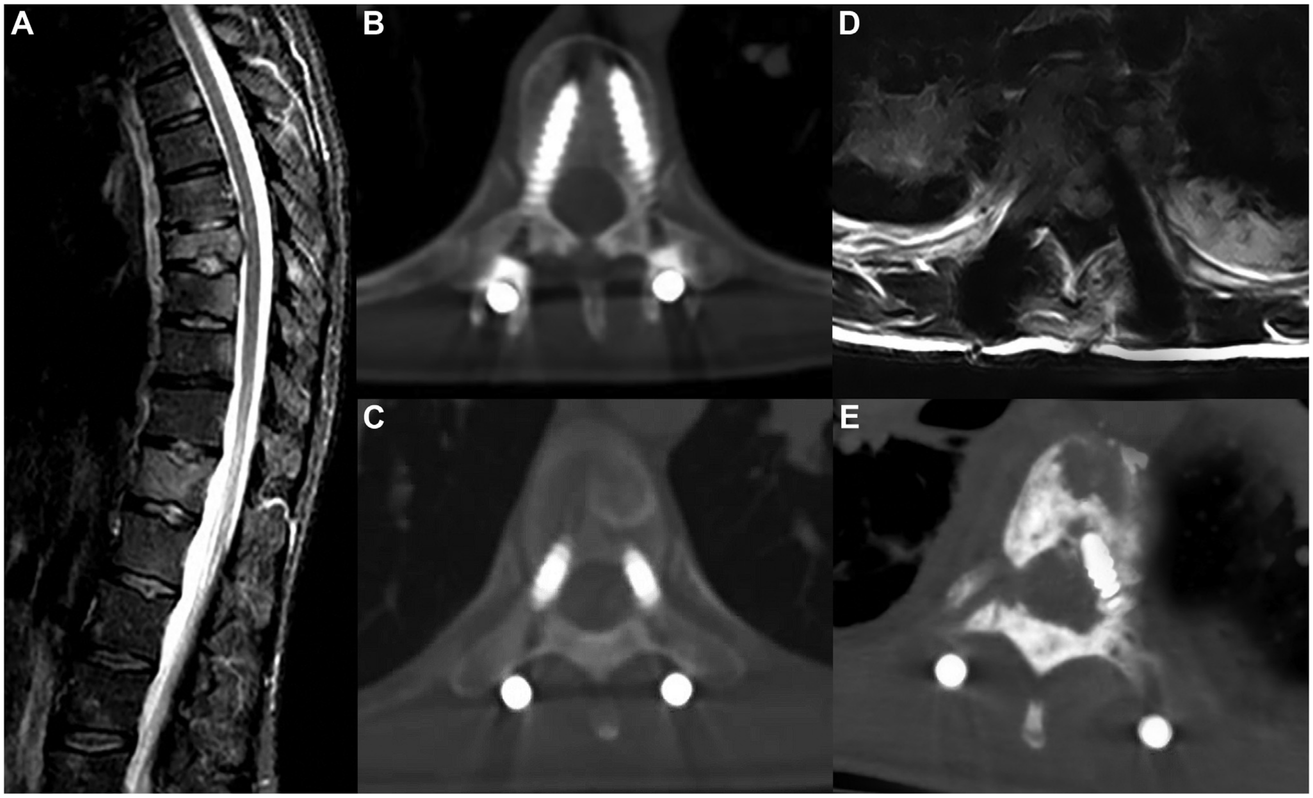

Figure 2. (**A**) A 57-year-old woman with T5 lung metastatic tumor underwent T4-T6 percutaneous fixation. (**B** and **C**) Postoperative CT scan showing accurate instrumentation placement. (**D** and **E**) Symptomatic type 2 implant failure (screw cut-out) 121 days after surgery owing to local tumor progression in the final stage of lung cancer.

their bone mineral density,[25,26] it decreases the strength of normal adjacent vertebrae, elevating the risk of late periconstruct failure.[24,27] With the emergence of stereotactic radiation therapy, radiation can now be targeted to the affected vertebral body, limiting radiation to the peripheral normal vertebrae. Although it is known that radiosurgery increases the risk of vertebral compression fracture after its application, it also is associated with a lower rate of implant failure than that observed after conventional radiotherapy, owing to the reduced osteoporotic side effects of stereotactic radiation therapy on vertebrae adjacent to those infiltrated by tumor.[28,29]

Longo et al.[30] reported a 13.8% hardware failure rate in a series of 58 patients; however, the operative revision rate for failure was limited to 3.4%, with poor preoperative spinal functional status and multiple myeloma considered potential contributors to instrumentation failure. In our series, 4 patients had multiple myeloma, none of whom experienced implant failure over the course of follow-up.

It is unclear why the implant failure rate is lower than expected in this particular patient population, considering that osteopenia and osteoporosis are common among patients with cancer.[9,31] In addition, the healing capacity of the spine is particularly affected by tumors, systemic therapies, irradiation, and the generally reduced health status and nutritional compromise exhibited by many patients with cancer. The protective effect of MISS on the posterior tension band might be one explanation for the lower failure rates documented with MISS relative to open surgery.[32]

With advances in instrumentation, the incidence of implant failures has declined,[11,24] as we observed in our series, despite the prolonged survival and enhanced functional capacity some patients experience, which would imply greater cyclic load on the screws and rods. However, in the last few years, short fixations (1 level above and below the tumor) have been used for SM fracture stabilization. Although the risk of screw pull-out could increase with short versus longer fixations and the region of the spine affected, such as mobile and transitional spine

Table 7. Comparing Baseline and Intraoperative Characteristics in Patients with versus without Implant Failure

Variable	Implant Failure	No Implant Failure	*P* Value
Total number	3	69	
Time to spinal metastases, mean	668	351	0.56
SINS score	11.7	10.9	0.59
Preoperative ASIA grade C or worse	66.7%	11.6%	0.007*
Instrumentation levels, mean	2.33	2.00	0.66
Percutaneous screws	100.0%	100.0%	1.00
Kyphoplasty	100.0%	26.1%	0.006*
Separation surgery	66.7%	47.8%	0.52
Screw augmentation	0.0%	8.7%	0.59
Intraoperative complications	0.0%	5.8%	0.67
Postoperative complications	66.7%	11.6%	0.007*
Survival days, mean	618.3	541.4	0.56
Days to final imaging, mean	511.7	336.7	0.56

SINS, Spinal Instability Neoplastic Scale; ASIA, American Spinal Injury Association.
*Significant value.

regions, short fixations have been shown to be effective at providing the stabilization needed. To reduce the rate of construct failure, some authors used cement screw augmentation or vertebral body augmentation, both of which could decrease pedicle screw pull and increase the anterior mechanical support to shortening construct length, permitting less aggressive surgery and saving mobile segments in the lumbar spine.[16,21] In our study, probably owing to the size of the sample group, we did not find any significant difference in implant failure rate with kyphoplasty or screw augmentation between short fixation versus long fixation procedures. Because this was a multicenter, retrospective study, there is a variability in the decision making for the length of the construct.

The present study has some limitations, including the retrospective nature of data collection and analysis. The duration of patient follow-up also was heterogeneous owing to the heterogeneity in primary tumor prognosis in our patient sample. However, almost half of the patients (48.6%) were observed for >1 year. We also excluded patients with follow-up times <3 months; consequently, some early implant failures might have been missed. Finally, we generally do not routinely order CT scans after surgery for patients with SM, unless there is a clinical need to do so, but frequently, our patients had scans ordered by their oncologist as part of routine cancer follow-up, so the duration of time between surgery and when CT scans were performed varied among our patients. This is a limitation because we cannot determine clearly at what time point the failure occurred.

Table 8. Baseline and Perioperative Predictors of Implant Failure

Variable	*P* Value
Kyphoplasty	0.997
Postoperative complications	0.225
Preoperative AIS score	0.483

AIS, American Spinal Injury Association Impairment Scale.

CONCLUSIONS

In our series of 72 patients undergoing surgery for SM, minimally invasive spinal fixation without fusion exhibited a low implant failure rate over both the short and the medium term, even when short instrumentations were performed. There was also a negligible infection rate. These findings suggest that this technique may be an effective and safe way to treat complicated SM in patients with cancer. Nonetheless, longer-term, more methodologically robust studies are necessary to validate and expand on our findings.

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