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ORIGINAL RESEARCH

MANUSCRIPT SUBTYPE

AN EXTENDED FOLLOW-UP OF SPINAL INSTRUMENTATION RESCUE WITH CEMENT AUGMENTATION

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ABSTRACT

BACKGROUND AND PURPOSE: Percutaneous cement augmentation has been reported as an effective salvage procedure for frail patients suffering with spinal instrumentation failure, such as screw loosening, hardware breakage, cage subsidence, and fractures within or adjacent to stabilized segments. Favorable results were reported over a median follow-up period of 16 months in a retrospective analysis of 31 consecutive procedures performed in 29 patients. In the present study, the long-term effectiveness of this treatment in avoiding or postponing revision surgery is reported.

MATERIALS AND METHODS: Clinical and radiological data of our original cohort of patients were retrospectively collected and reviewed to provide an extended follow-up assessment. The need for revision spinal surgery was assessed as the primary outcome and the radiological stability of the augmented spinal implants was considered as the secondary outcome.

RESULTS: An extended radiological follow-up was available in 27/29 patients with an average of 50.9 months. Overall, 18/27 (66.7%) patients, originally candidates for revision surgery, avoided a surgical intervention after a cement augmentation rescue procedure. In the remaining patients, the average interval between the rescue cement augmentation and the revision surgery was 22.5 months. Implant mobilization occurred in 2/27 (7.4%) patients, rod breakage in 1/27 (3.7%), a new fracture within or adjacent to the instrumented segment occurred in 4/27 (14.8%) patients and screw loosening at rescued levels occurred in 5/27 (18.5%) patients.

CONCLUSIONS: In this cohort, cement augmentation rescue procedures were found to be effective in avoiding or postponing revision surgery during long-term follow up.

ABBREVIATIONS: N/A

Received month day, year; accepted after revision month day, year.

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SUMMARY SECTION

PREVIOUS LITERATURE: Cement augmentation has been shown to be a potential alternative to revision surgery, in the short term, for fragile and elderly patients with spinal implant failures or new fractures. A recent systematic review of case series on cement rescue augmentation by Cawley et al. included studies with a median follow-up of 12 months, suggesting that cement augmentation in selected patients can help in stabilizing loosened screws and treating vertebral fractures.

KEY FINDINGS: The present study, with an average follow-up of 50.9 months, found that 66.7% of patients avoided surgery, and for those who required revision surgery, it was postponed by an average of 22.5 months. This delay could significantly improve quality-adjusted life years for patients with low life expectancy.

KNOWLEDGE ADVANCEMENT: The extended follow-up period in this study demonstrates the long-term efficacy of percutaneous salvage procedures, establishing cement augmentation as a practical and less invasive alternative to avoid or postpone revision surgery for selected and fragile patients.

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INTRODUCTION

Instrumented spinal surgery is widely used in the treatment of degenerative, traumatic and neoplastic pathologies of the vertebral column. As patients undergoing spinal surgery increase in age, concurrent osteoporosis has become a frequent comorbidity and is one of the main causes of spinal instrumentation failure. Bone mineral density of the spine has been shown to affect the stability of pedicle screws[1,2] with loosening in up to 25% of patients with reduced bone mineral density[3]. The length of the stabilization[4], sagittal and frontal imbalance, and thoracic localization are further factors influencing the stability of the spinal constructs[5]. In addition to bone resorption and screw loosening, cage subsidence and fractures both in the instrumented segment and at junctional levels, represent the most common delayed causes of instrumentation failure. These occurrences are often associated with recurrent pain and may require revision surgery[6,7]. Revision surgery remains the gold standard for implant failure, but it is associated with further potential morbidity and increased costs[8]. Moreover, revision surgery may not be suited for patients with significant comorbidities in whom such a procedure – often more invasive than the index operation – may represent a significant risk. Accordingly, percutaneous cementation has been reported as a salvage procedure for this elderly and frail patient group, and may represent a safe and effective alternative to surgical revision[9–11].

Our group has previously reported on cement augmentation in the treatment of clinically relevant implant failure in a retrospective analysis of 31 consecutive procedures performed in 29 patients, with favorable results found over a median follow-up period of 16 months[12]. Subsequent publications from other centers have reported similar observations in terms of feasibility and safety of cement augmentation in frail and elderly patients[11,13–15], even in complex instrumentation cases such as intervertebral body implant failure[16]. A recent systematic review has been published on salvage cement augmentation in cases where surgical revision is not considered a viable option[9].

It is however not yet known whether these favorable outcomes remain sustained in the long-term. To address this question, we conducted an extended follow-up study based on a retrospective analysis of medical records of our original patient series.

MATERIALS AND METHODS

General methods

In our previous study, 29 patients were treated between May 2013 and October 2016 with rescue cement augmentation for clinically relevant screw loosening with bone resorption, cage subsidence, and vertebral fracture within or adjacent to the instrumented segment(s). Instrumentation failure was deemed clinically relevant if associated with new or recurrent pain correlated with imaging findings, or if deemed a threat to spinal biomechanical stability. Indications for primary spinal instrumentation included traumatic, degenerative, and neoplastic conditions.

We retrospectively collected and reviewed all available clinical and radiological data related to any spinal interventions until November 2023, defined as extended long-term follow-up.

The details of the rescue procedures were described in the original study, which included 13 procedures with cement augmentation of fractures within or adjacent to the instrumented segment, 9 procedures with augmentation around loosened screws and 8 with both. One procedure was aborted.

Informed consent was obtained from all patients. Local ethical committee approved this retrospective study.

The primary outcome assessed in this long-term follow-up study was the effectiveness in avoiding or postponing revision spinal surgery at the previously instrumented spinal segment or at adjacent levels following the cement augmentation rescue procedure. The time interval between the cement augmentation and the revision surgery, as well as the indication and the type of new surgical intervention were also recorded. ASA physical status classification system was adopted as a general indicator of patients' physical status.

The secondary outcome was the radiological outcome of the previous cement augmentation procedures and implant stability assessment, on the basis of long-term imaging follow-up performed for the index spinal pathology or for unrelated reasons. The duration of radiological follow-up was defined as the time between the original rescue procedure and the last available imaging follow-up.

Long-term imaging follow-up consisted of conventional radiograms, CT scans and MRI studies including the spinal segment of interest.

The radiological images were reviewed by a neuroradiologist and a neurosurgeon in consensus, defining the radiological outcome of the previous percutaneous cement augmentation procedures in terms of implant mobilization and integrity, further cage subsidence, new fractures or spinal deformity. For patients with an available CT scan, onset or progression of screw loosening was also recorded.

Statistical methods

Characteristics of all included patients are described as mean and standard deviation (SD) or median and 1st and 3rd quartile, and as count and percentage. Follow-up data are described as count and percentage. The Kaplan-Meier method was used to compute the cumulative probability of being free from revision surgery (i.e 'avoided surgery') over more than 4 years of follow-up. Patients who remained free from surgery were censored at the last follow-up moment.

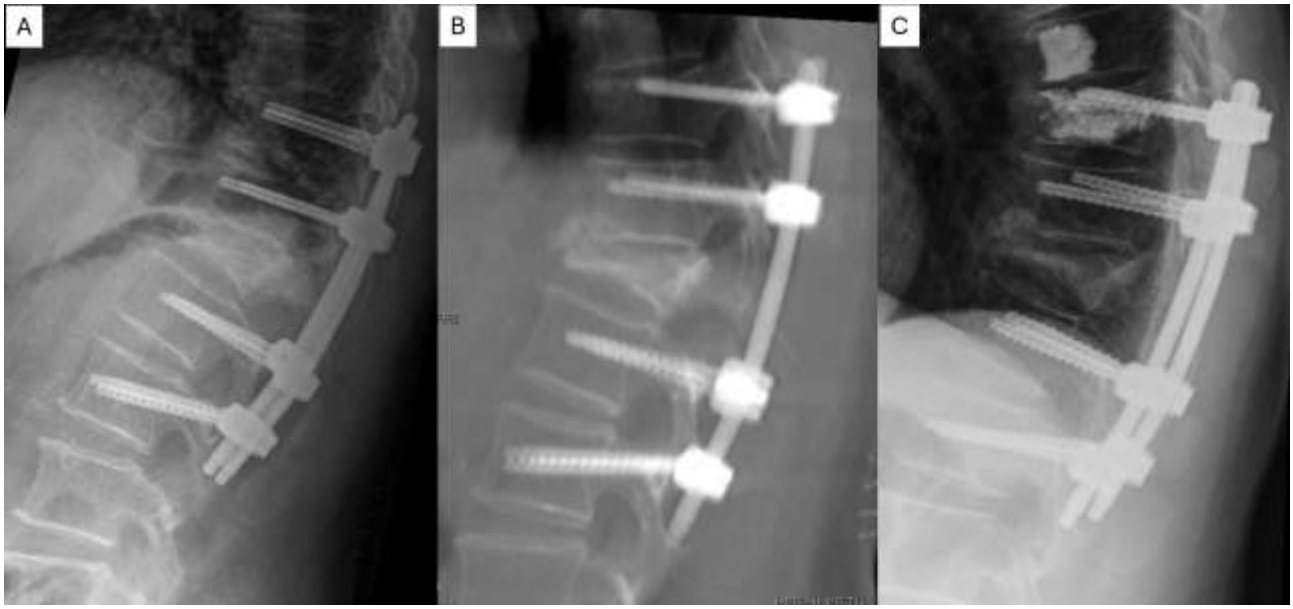

Figure 1: Standing lateral radiograph (A) of a 76 year-old patient with T10-L2 posterior fixation and decompression for treatment of a burst vertebral body fracture of T12 with posterior wall retropulsion and central canal stenosis. Sagittal thick layer MPR reconstruction from CT scan (B) shows new fracture of T10 with initial "pullout" of the screws one month after surgery. The patient was treated with rescue cement augmentation on the fractured vertebral body and prophylactic augmentation at the level above. Standing lateral radiograph (C) performed 3 months after the rescue augmentation shows stability of the treatment. The patient was followed up to 85 months after surgery and no further invasive procedure was needed.

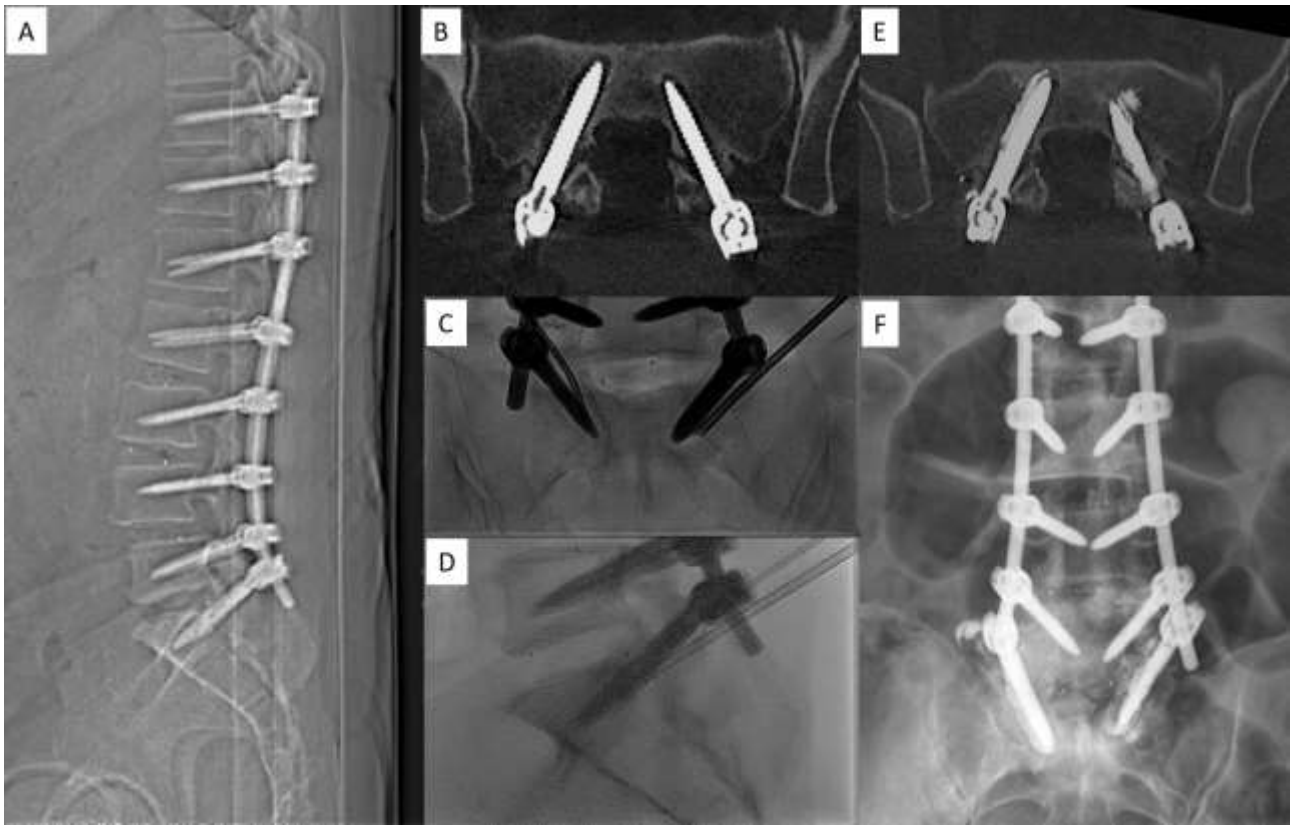

Figure 2: Standing lateral radiograph (A) of a 57 year-old patient with T12-S1 posterior fixation and decompression for treatment of a multi-level central canal stenosis. CT axial image (B) shows bilateral screw loosening at S1, deemed symptomatic. Intraprocedural fluoroscopy (C, D) of rescue cement augmentation procedure performed bilaterally at S1. CT axial image (E) and radiograph (F) follow-up after 20 months showing stability of the construct. Patient improved clinically after augmentation rescue procedure, and no surgical intervention was necessary.

RESULTS

Basic characteristics of the study population are summarized in Table 1. An extended follow up was available in 27/29 patients; male/female ratio: 10/17; age range at time of the original treatment: 50-82 years; average age: 71.3. For one patient an extended follow-up was not recorded because the rescue procedure was aborted due to technical reasons, while another patient moved abroad, and no follow-up data could be collected. The median follow-up time of our cohort was 54 months (1st quartile: 21 months; 3rd quartile: 78 months).

17/27 patients were still alive at the time of medical record analysis, while 10/27 had died due to causes unrelated to the spinal pathology and to the cement augmentation (3 oncologic progression, 3 acute coronary syndrome, 2 trauma, 1 COVID-19, 1 sepsis unrelated to spinal surgery and intervention). 15/27 patients were identified as “ASA 2”, and 12/27 patients were identified as “ASA 3”.

An extended radiological follow-up was available for 27 patients with an average of 50.9 months at the last imaging study (range 2 to 103 months, SD 32.2). In 16 patients (59.3%), follow-up imaging was available beyond 4 years.

Overall, the instrumentation was in the thoracic segment in 1/27 patients, in the thoraco-lumbar segment in 16/27 (Figure 1) and in the lumbo-sacral segment in 10/27 (Figure 2). There was no significant correlation between instrumented segment and need of revision surgery. The average length of the instrumentation was 5.7 levels (range 2-14). Available follow-up imaging was a CT scan in 17 patients, an MRI scan in 2 patients, conventional radiographs in 6 patients, CT + MRI in 1 patient, and CT + conventional radiographs in 1 patient.

During the extended follow-up interval, imaging revealed implant mobilization in 2/27 (7.4%) patients, rod breakage in 1/27 (3.7%), and a new fracture within or adjacent to the instrumented segment occurred in 4/27 (14.8%) patients. Fractures were located at the adjacent segments in 2 cases, within the instrumented segments in 1 case, and in both the adjacent segments and within the instrumented segment in 1 case. Among patients with a CT scan during the extended follow-up interval, screw loosening in rescued segments was observed in 5/19 patients. No further cage subsidence nor new relevant spinal deformity occurred.

Overall, 9 patients needed revision surgery at the instrumented segment or adjacent levels. The average time interval between the rescue cement augmentation and the revision surgery was 22.5 months (range 2-47 months).

Reasons for revision surgery were adjacent segment degeneration in 3/9 cases, screw loosening in 1/9 case, both implant mobilization and new fracture in 1/9 case, both screw loosening and implant mobilization in 1/9 case and infection in 1/9 case. In 2/9 cases reasons for revision surgery were unknown (surgery performed at other centers).

Among the 9 patients requiring a surgical revision, 2 were treated with extension of the instrumentation due to adjacent segment degeneration, 3 with implant removal, and 3 patients with both implant removal and extension of the stabilization. One patient treated at another center with implant removal, also underwent cement-augmentation for a new vertebral fracture within the instrumented segment. One patient underwent multiple unspecified revision procedures at different hospitals abroad. The new fractures were treated in 2/4 cases with cement augmentation vertebroplasty, associated with implant removal in one case due to implant mobilization. A conservative approach for the remaining 2 fractures was adopted.

Overall, the probability of being free from revision surgery following the cement augmentation rescue procedure was 79.6% at 3 years (95% confidence interval: 64.8% to 97.7%), despite being originally candidates for revision surgery (Figure 3).

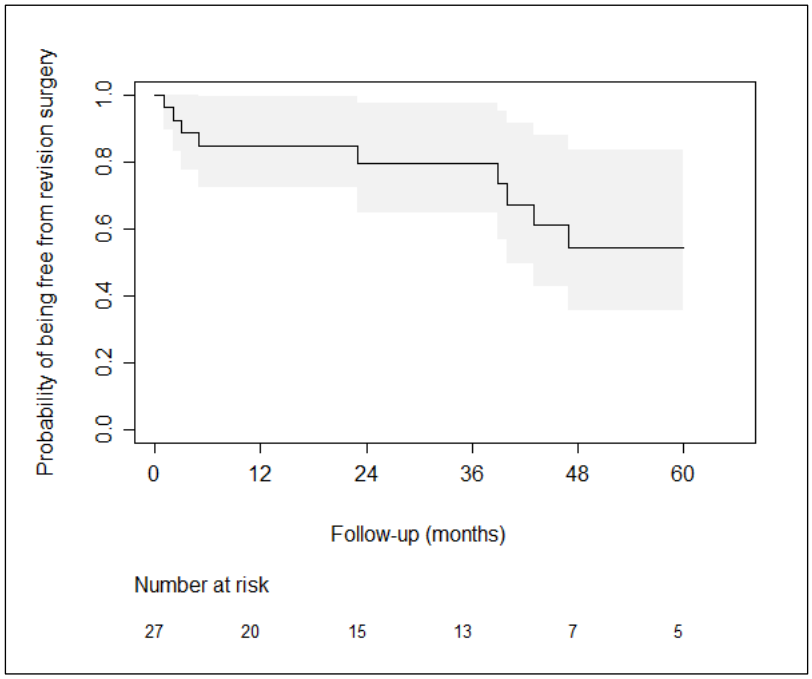

Figure 3: Kaplan-Meier curve with 95% confidence interval band and an at-risk table.

In the subgroup of patients that did not underwent revision surgery the average length of instrumentation was 5.3 levels, while it was 6.4 levels for patients that underwent revision; the difference was not statistically significant.

Main results are summarized in Table 2.

DISCUSSION

Rescue cement augmentation, in selected fragile patients with implant failure or new fractures after spine surgery, may represent a safe and effective technique to avoid or postpone revision surgery: on an average follow-up interval of 50.9 months after a rescue augmentation, 66.7% of patients in our series had avoided surgery and, for those who required revision surgery, the intervention was postponed for almost 2 years (22.5 months).

Revision surgery remains the first treatment option for symptomatic implant mobilization, with the aim of easing pain and ensuring the stability of the posterior fixation[17]. The surgical treatment is also useful in collecting material for microbiological analysis in order to provide information regarding low-grade infection, which is present in up to 29% of cases with implant mobilization[18,19]. On the other hand, conservative management is an option in asymptomatic patients[20]. Surgical treatment usually involves implant removal and replacement using larger screws (a 2 mm increase in diameter significantly enhances the resistance to pullout[17]), utilizing allograft bone[21] or cement[22], with or without prolongation of the stabilization. Since the anatomy can be distorted and scar tissue is present, these revision surgeries are usually more invasive, last longer, and come with a higher risk of complications[23,24] compared to index surgeries. Cement augmentation techniques may therefore offer an alternative option to surgery in fragile patients. Their aim is to stabilize loosened screws and mobilized implants and treat vertebral body fractures within the fixation segment or at the adjacent levels, with the aim of avoiding or at least delaying revision surgery in patients in whom open surgery is deemed dangerous or too invasive. Of note, cement augmentation has been demonstrated as not being inferior to revision surgery from a biomechanical perspective[25]. Our results seem to align with the biomechanical characteristics of cement salvage, seeing that no new deformities were observed during our long-term follow-up.

Our original patient cohort presented with clinically relevant screw loosening with bone resorption, cage subsidence or vertebral fractures within or adjacent to the instrumented segments and had a surgical indication, either due to their biomechanical situation or because of pain symptoms, yet they were not considered good surgical candidates. It is conceivable that without a minimally invasive possible solution at hand, as cement augmentation rescue, some of them would have been managed conservatively.

Because of their general conditions and/or advanced age, rescue cement augmentation was found to be indicated instead of surgical revision after multidisciplinary spine board discussion with spine surgeons, neuroradiologists, and pain physicians.

Our follow-up interval (50.9 months on average) is longer than that of other studies published to date. In a recent review by Cawley et al[9] that included our previous report and 10 other studies regarding cement augmentation, a median follow-up period of 12 months was reported (average 12.1 months; 3-24 months range).

Of the 27 patients included in our cohort, a total of 9/27 patients required revision surgery.

The most common reason to repeat surgery was adjacent segment degeneration (3/9). Infection was the indication in another patient (1/9). 1 patient (1/9) was re-operated due to screw loosening, another (1/9) due to implant mobilization and another (1/9) due to both screw loosening and implant mobilization. Two cases were operated in other centers and underwent revision surgery for unknown indications. For one of these two cases, the type of surgery is also unknown, while the second patient underwent implant removal, extension of the stabilization and cementoplasty for an adjacent segment vertebral body fracture. 2/9 patients were subsequently operated in our center and underwent implant removal and extension of the stabilization, whilst 3/9 underwent implant removal only and 2/9 extension of the stabilization only.

Vertebral fracture at the level of the loosened screws or adjacent to the instrumented segments is a well-known complication for which percutaneous vertebroplasty has been already described as a treatment option[26]. In a total of 4/27 of our patients (14.8%) a new fracture was diagnosed within the instrumented levels (2 patients), at a junctional level (1) or both (1). In two cases a cementoplasty was carried out, in one case a surgical intervention was performed, and, in the last case, no further treatments were performed due to lack of symptoms.

The fragility of our population is highlighted by the finding that more than 1 out of 3 patients (37% - 10/27) died during the extended follow-up period due to causes unrelated to the surgery or the cement augmentation. Among the patients who required a surgical revision after rescue cement augmentation, the median time between cement augmentation and the new surgical intervention was 22.5 months. Delaying surgical treatment for a few months or years may be beneficial in terms of quality adjusted life years (QALY), or may be helpful to entirely avoid surgery in patients with a low life expectancy.

The present study lacks clinical outcome scores; this is in contrast with our previous work where clinical outcome had been reported [12]. Our previous results, in line with Wang et al.[13], demonstrate that rescue cement augmentation favorably impacts short-term clinical outcome. In the present study clinical scores – such as the NRS pain scale – were not reported because patients were no longer being routinely followed at that point, for some patients several years after their procedures. Moreover, pain scores may not be a reliable outcome parameter, as they may well reflect the wider influence of failed back surgery cases; also, the association between the procedure and the clinical outcome may be difficult to assess after 10 years post-procedure. Our clinical endpoint was therefore the need for revision surgery,

which in our opinion is a more relevant clinical variable.

Other limitations of our study are its retrospective analysis, the absence of sagittal balance measurements and DEXA scores, and the lack of a control group.

A prospective randomized trial (revision surgery versus rescue cement augmentation versus conservative management) would be ethically questionable and difficult to perform due to the fragility of these patients together with the variable complexity of biomechanical, clinical and surgical aspects.

Table 1: Baseline characteristics of the population.
*At study completion (November 2023).

Baseline Characteristics	
Number of patients	27
Age at treatment	
average (range) –years	71.3 (50-82)
Sex	
Female	17 (63%)
Male	10 (37%)
ASA Score	
1	0
2	15 (55.6%)
3	12 (44.4%)
4	0
Alive*	17 (63%)
Dead*	10 (37%)
Follow-up -months	
Average (range)	50.9 (2-103)
Standard Deviation	32.2
Instrumented levels	
Thoracic	1 (3.7%)
Thoraco-lumbar	16 (59.3%)
Lumbo-sacral	10 (37%)

Table 2: Technical information regarding the procedures

Technical Details Regarding Surgery And Rescue	
Instrumentation failure	
Screw loosening	5 (18.5%)
Implants mobilization	2 (7.4%)
Broken implants	1 (3.7%)
New fractures	4 (14.8%)
Adjacent segment (A)	2 (7.4%)
Instrumented segment (I)	1 (3.7%)
A+I	1 (3.7%)
Revision surgery	
Total	9 (33.3%)
> 1 surgery	2 (7.4%)
Time interval, rescue to revision surgery	
Average -*months*	22.5
Indication to revision surgery	
Adjacent segment degeneration	3 (11.1%)
Screw loosening	1 (3.7%)
Implants mobilization + new fracture	1 (3.7%)
Screw loosening + implants mobilization	1 (3.7%)
Infection	1 (3.7%)
Unknown (Surgery at outside institution)	2 (7.4%)
Type of revision surgery	
Implants removal	3
Extension of the stabilization	2
Implants removal and extension of the stabilization	3
No data available	1
New fractures treatment	
Cementoplasty	2
Conservative treatment	2

CONCLUSIONS

Cement augmentation performed to salvage spinal hardware failure allowed to avoid or delay revision surgery during long-term follow-up in a large proportion of frail patients in our cohort, in whom revision surgery was deemed to come with a significant risk of morbidity. The indication for cement salvage procedures should be reached after multidisciplinary discussion and tailored to the requirements of individual patients who present with a higher surgical risk.

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