

## Original article

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## Risk factors for hardware failure after total spondylectomy in patients with spinal tumors

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### Abstract

**Introduction** Total spondylectomy for spinal tumors provides optimal local control and is associated with a high risk of implant instability.

The **objective** was to determine risk factors for implant instability after spondylectomy in patients with neoplastic lesions of the spine.

**Material and methods** A retrospective cohort study included patients with spinal tumors treated with tumor resection between 2007 and 2023. Inclusion criteria were spondylectomy and vertebral body replacement, thoracic or lumbar spine localization, follow-up period  $\geq 12$  months. LASSO regression and Random Forest methods and multivariate analysis were used to identify instability predictors.

**Results** Implant instability was observed in 16 patients (18.4 %). Risk factors included the use of bone cement instead of allograft (OR = 0.125,  $p = 0.014$ ), contact surface mismatch  $> 10^\circ$  (OR = 0.214,  $p = 0.026$ ), prosthesis subsidence  $> 2$  mm at 3 months (OR = 4.497,  $p = 0.023$ ).

**Discussion** The risk factors identified had a great clinical role for the prevention of implant instability. The use of bone graft instead of cement, precise matching of contact surfaces and control of early prosthetic subsidence can significantly reduce the risk of metal construct failure. Careful preoperative planning and regular postoperative monitoring are essential for the outcome.

**Conclusion** Three independent risk factors for implant instability after spondylectomy identified in patients with spinal tumor lesions included the use of bone cement instead of allograft, a discrepancy between the contact prosthetic surfaces of more than  $10^\circ$ , and an implant subsidence of more than 2 mm after 3 months. These factors are important for planning of the surgical intervention and postoperative monitoring to prevent metal construct instability.

**Keywords:** spinal tumors, spondylectomy, implant instability, risk factor, vertebral body replacement

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## INTRODUCTION

According to oncological concepts, total en bloc spondylectomy (TES) for spinal tumors provides adequate local control [1–4]. The influence of TES on spinal stability is substantial, necessitating careful planning of the reconstructive stage of the intervention [5–7].

Modern principles of reconstruction after TES are based on the concept of circular stabilization of the spine [8]. The vertebral body replacement is essential for the reconstruction of the anterior column, providing adequate anatomical height of the interbody space and distribution of axial load [9]. Posterior instrumentation can ensure the fixation strength that would prevent excessive mobility in the operated segment [10].

Despite advancements in implant technology and surgical techniques, implant failure remains a significant concern [11]. Most serious complications include instability of the metal construct, migration of the vertebral body replacement implant and formation of pseudoarthrosis [12, 13]. The complications can lead to the need for repeated operations, deterioration in quality of life and lower cancer treatment effectiveness [14, 15].

Understanding the factors that influence the development of implant instability is critical for optimizing surgical strategy and improving long-term treatment outcomes.

The **objective** was to determine risk factors for implant instability after spondylectomy in patients with neoplastic lesions of the spine.

## MATERIAL AND METHODS

The retrospective cohort study included patients with spinal tumors who underwent tumor resection between 2007 and 2023. The study was approved by the local ethics committee.

The inclusion criteria included (1) previous spondylectomy, (2) vertebral body replaced with mesh cage, (3) thoracic or lumbar location; (4) complete information on the hardware status; (5) follow-up period  $\geq 12$  months.

Exclusion criteria included (1) patients with more than 20 % missing values in the dataset; (2) non-aggressive benign tumors; (3) pathological vertebral fractures unrelated to tumors.

The study included 87 patients who underwent surgical treatment between 2007 and 2023. Incomplete data (no more than 20 % missing values) were identified in 8 cases (9.2 %) without instability which was adjusted using the multiple imputation method. The majority of the patients were males (60 %). The median age was 56 (48.5; 62) years. Most patients (63 %) were able to ambulate unassisted prior to surgery, 17 % used additional support devices, and 20 % could not ambulate. Sixty-seven per cent of patients scored 1–2 points on the ECOG scale. The median time from diagnosis of the pathology to surgery was 4 (2; 6) months (Table 1).

Total en bloc spondylectomy was produced for tumor resection. Wide en bloc resection was performed in cases where it was technically possible without compromising significant structures. Meningiolysis, vessel isolation, elective marginal or intrafocal en bloc spondylectomy with maximum possible tumor removal (intentional transgression) were performed in case of epidural spread of the tumor or involvement of major vessels. After spondylectomy, the post-resection defect was replaced with a mesh of the vertebral body and a transpedicular fixation system was used for reconstruction of the spine. The prosthesis was filled with bone cement or allogeneic bone graft. The posterior approach was employed for the thoracic spine surgery; a combined approach was used in some cases to mobilize massive tumors. The lumbar spine was approached in two stages using the posterior and anterior aspects. Post surgery, patients were referred to an oncologist to decide on adjuvant therapy.

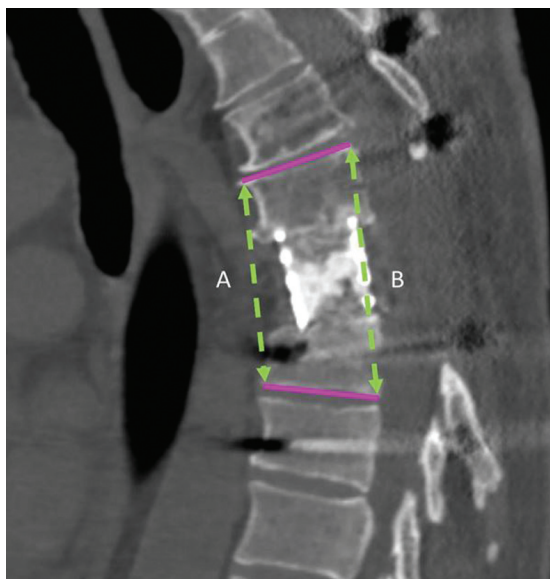
Table 1

## General characteristics of patients

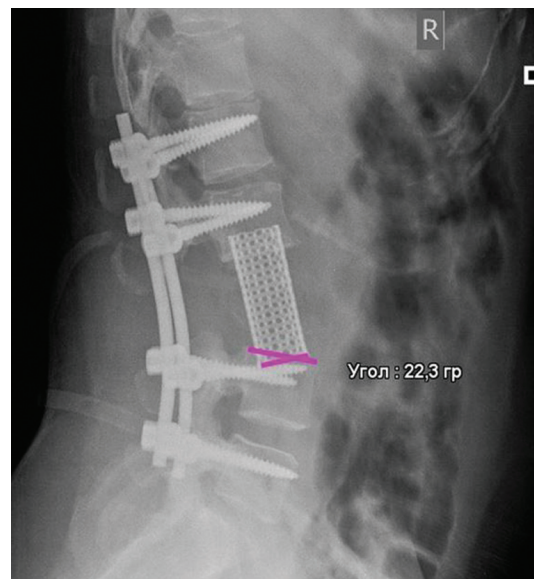
Description		Indicators		
		The median	abs.	%
Number of patients			87	100
Females			35	40.2
Males			52	59.8
Age, years		56 (48.5; 62.0)		
Body mass index		23.9 (21.9; 26.5)		
Comorbidity index, score		7 (2.0; 8.5)		
Ambulation prior to surgery	Unable to walk		17	19.5
	Walking using additional support		15	17.2
	Walking unassisted		55	63.3
ECOG status	0		3	3.4
	1		27	31.0
	2		31	35.6
	3		16	18.4
	4		10	11.6
Sacropeine index		0.7 (0.7; 0.8)		
Time before surgery, months		4 (2; 6)		

The data contained both quantitative and qualitative variables including age, gender, spinal lesion level, tumor characteristics, preoperative neurological function, surgical parameters, blood loss volume, intraoperative and postoperative complications and outcomes such as ambulatory status and presence of mechanical instability of the construct. A total of 42 variables were analyzed.

The sacropeneia index was assessed as the ratio of the transverse area of the iliopsoas muscle to the area of the L4 vertebral body [16], tumor invasion evaluated with the Tomita score [17], bone density measured in Hounsfield units (HU) at the L1 level [18], surgical invasiveness assessed with a scoring system reported by Kumar et al. [19], radiological parameters measured in the midsagittal projection in the operated segment (affected level and adjacent vertebrae) using CT scan. The local angle was considered as the Cobb angle between the upper endplate of the cranial vertebra adjacent to the prosthesis and the lower endplate of the caudal vertebra adjacent to the prosthesis [20]. The segment height (the average height of the segment with the prosthesis) was calculated as the arithmetic mean of two values. The anterior distance was defined as the distance from the upper anterior edge of the adjacent cranial vertebra to the lower edge of the caudal vertebra, the posterior distance was defined as the distance from the upper posterior edge of the adjacent cranial vertebra to the lower edge of the caudal vertebra (Fig. 1). Prosthesis subsidence was considered as a decrease in segment height compared to postoperative values, and contact surface mismatch was considered as an angle greater than 10° between the contact surface of the prosthesis and the endplate (Fig. 2) [21]. Complications were assessed using the SAVES 2 system [22]. Overall survival was calculated as the time from spinal surgery to death or the end of follow-up; survival without local recurrence was calculated as the time from surgery to diagnosis of recurrence based on instrumental research methods. Late postoperative complications and the functional outcome of the patient's ability to ambulate unassisted (the degree of recovery of the neurological status) were also monitored.



**Fig. 1** CT scan of the thoracic spine, midsagittal section showing condition after resection of chondrosarcoma of Th7 vertebra: (A) anterior distance of the segment, (B) posterior distance of the segment with vertebral body prosthesis



**Fig. 2** Lateral radiograph of the lumbar spine showing condition after resection of hemangioendothelioma of the L3 vertebra; angle of 22° discrepancy between the contact surfaces of the prosthesis and the endplate of the L3 vertebra

The R language version 4.3.3 and the R. Studio development environment were used for data analysis [23]. Missing values in the data were processed using the multiple imputation method and the PMM (Predictive Mean Matching) algorithm from the mice package for R. Five imputations were performed for each missing variable to consider the uncertainty associated with missing data [24]. The mean values were presented as the median, the interval estimate the interquartile range (25 %; 75 %).

Regularized logistic regression was employed using the LASSO (Least Absolute Shrinkage and Selection Operator) method to reduce the dimensionality of the data and select significant predictors. This method allows for reducing the number of variables and eliminating multicollinearity issues [25]. LASSO regression was performed using the **cv.glmnet** function from the **glmnet** package in the R environment. The optimal value of the regularization parameter  $\lambda$  was selected based on cross-validation. Variables with non-zero coefficients selected using LASSO were employed to build the final model.

Additionally, the Random Forest method was employed using the **ranger** package to validate the LASSO results and identify potential nonlinear interactions between variables. This method allowed us to estimate the importance of variables taking into account their mutual influence and nonlinear relationships [26]. The results of Random Forest were used to confirm the choice of predictors obtained by the LASSO method.

Firth logistic regression was used to simulate risk factors for metal construct instability to eliminate the problem of bias in small samples and rare outcomes [27]. The regression was performed using the **logistf** package in R. The quantitative assessment of risk factors was presented as an odds ratio.

## RESULTS

The majority of patients (67 %) had solitary metastatic lesions of the spine. The thoracic spine was affected in 68 %, the lumbar involvement observed in 28 %. The localization classified with SINS was distributed between the transitional (39 %), semi-rigid (37 %) and mobile (24 %) regions. The majority

of patients (86.2 %) had lesions of one segment. Mechanical pain was diagnosed in 83 % of patients. The lytic type of bone lesion was predominant (61 %). The spine axis was normally aligned in 67 % of patients. Tomita type 4 lesion with epidural compression was seen in 56 % (Table 2).

Table 2

## Characterization of the tumor

Description		Parameters ( <i>n</i> = 87)		
		The median	abs.	%
WHO tumor type	metastasis		58	66.7
	primary malignant		22	25.3
	primary benign (aggressive)		7	8.0
Spine section	thoracic (Th3–10)		59	67.8
	thoracic-lumbar (Th11–L1)		4	4.6
	lumbar (L2–L5)		24	27.6
Localization classified with SINS	transitional		34	39.1
	mobile		21	24.1
	semi-rigid		32	36.8
Number of segments	more than 1 segment		12	13.8
	1 segment		75	86.2
Mechanical pain	pain free		12	13.8
	there is		72	82.8
	none		3	3.4
Type of bone involvement	lytic		53	60.9
	mixed		34	39.1
Presence of deformity	De novo kyphosis or scoliosis		19	21.8
	normal alignment		58	66.7
	subluxated or translated		10	11.4
Tumor invasion evaluated with the Tomita score	3		7	8.1
	4		49	56.3
	5		12	13.8
	6		19	21.8
HU in L1		103 (83.5; 122.5)		
Preoperative radiation therapy			7	8.1

A combined surgical approach was used in 66 % of cases. The median operation time was 270 (227.5–360.0) min, the median blood loss was 1700 (1000–2500) mL. Spinal fixation was performed 2 levels above and 2 levels below the affected segment in 55 %. Titanium rods with a diameter of 5.5 mm were used in 82 %. Spinopelvic fixation was required for one patient. Bone graft was used as a common filling material for the bone contact area (62 %) and bone cement was employed in 38 %. The median prosthesis height was 40 (29–54) mm, the median support surface area measured 420 (280–450) mm<sup>2</sup>. A discrepancy of more than 10° between the contact surface of the prosthesis and the adjacent endplate was observed in 46 % of cases. A change in the local angle (median 3 (0–6.5)°) and the height of the operated segment (median 0.0 (–1.0–1.5) mm) was observed after the operation (Table 3).



Table 3

## Surgical treatment and implant parameters

Description		Parameters ( <i>n</i> = 87)		
		The median	abs.	%
Surgical approach	posterior		30	34.5
	combined		57	65.5
Blood loss, mL		1700 (1000; 2500)		
Operating time, min		270 (227.5; 360.0)		
Surgical invasiveness index		17 (16; 20)		
Length of fixation, segments	3		8	9.2
	4		2	2.3
	5		48	55.3
	6		9	10.3
	7		15	17.2
	8		3	3.4
	9		2	2.3
Type of rods	5.5 mm		71	81.6
	6 mm		13	14.9
	additional rods		3	3.4
Prosthesis filling material	cement		33	37.9
	bone graft		54	62.1
Height of prosthesis, mm		40 (29; 54)		
Mismatch of contact surfaces > 10°			40	46.0
Changing local angle, °		3 (0; 6.5)		
Change in segment height, mm		0.0 (−1.0; 1.5)		

The treatment results indicated the median prosthesis subsidence of about 1 (0; 2) mm after 3 months and about 2 (1; 3) mm at the last observation. The majority of patients (76 %) experienced no complications evaluated with Spinal Adverse Events Severity System, version 2 (SAVES-V2). Postoperatively, 20 % of patients received bisphosphonate therapy and 14 % received radiation therapy. Improved motor function was noted three months after surgery and 77 % of patients were able to ambulate unassisted. Local tumor recurrence developed in 23 (26 %) patients. The median overall survival was 28 (16; 55.5) months.

Table 4

## Treatment outcomes and survival rates

Description		Parameters ( <i>n</i> = 87)		
		The median	abs.	%
Subsidence of the prosthesis after 3 months.	> 2 mm		29	33.3
	≤ 2 mm		58	66.7
	prosthesis subsidence at last follow-up, mm	2 (1; 3)		
Severity of complications SAVES v.2, degree	1 (complications)		66	75.9
	2		6	6.9
	3		10	11.5
	4		1	1.1
	5		4	4.6
Postoperative bisphosphonates			17	19.5
Postoperative radiation therapy			12	13.8
Ambulation at 3 months	no ambulation		7	8.0
	walking using additional support		13	14.9
	walking unassisted		67	77.1
Local recurrence			23	26.4
Overall survival, months		28 (16.0; 55.5)		

Implant instability requiring revision surgery developed in 16 patients (18.4 %). Instability was caused by broken rod ( $n = 6$ ; 36.5 %), screw loosening and development of transitional kyphosis ( $n = 8$ ; 50 %) and vertebral body prosthesis migration ( $n = 2$ ; 12.5 %). Cases of broken rod and screw loosening were accompanied by prosthesis subsidence of greater than 4 mm into the bodies of adjacent vertebrae. Pseudoarthrosis was noted in 75 % of cases in patients with implant instability. The results of LASSO regression ( $\lambda = 0.036$ ) indicated most significant associations with the risk of implant instability out of 42 initial predictors:

- prosthesis filling material ( $\beta = -0.984$ );
- mismatch of contact surfaces more than  $10^\circ$  ( $\beta = 0.448$ );
- prosthesis subsidence of more than 2 mm after 3 months ( $\beta = 0.188$ );
- length of fixation ( $\beta = -0.114$ );
- number of operated segments ( $\beta = -0.104$ );
- difference in segment height before and after surgery ( $\beta = 0.116$ );
- functional status after 3 months ( $\beta = 0.113$ );
- prosthesis subsidence observed at the last follow-up ( $\beta = 0.081$ );
- age ( $\beta = 0.010$ );
- overall survival ( $\beta = 0.006$ );
- time before surgery ( $\beta = -0.004$ );
- duration of operation ( $\beta = -0.004$ ).

Additional analysis was conducted using the Random Forest method to confirm the choice of predictors and assess the importance of variables taking into account the nonlinear interactions.

From the 42 characteristics, the following parameters appeared to be most important:

- prosthesis subsidence observed at the last follow-up (importance score = 0.031);
- prosthesis filling material (0.008);
- difference in segment height before and after surgery (0.007);
- overall survival (0.007).

Prosthesis subsidence of more than 2 mm after 3 months (0.007) and contact surface mismatch (0.005) were among the most significant factors that are partially consistent with the results of LASSO regression.

Three predictors with the highest LASSO regression coefficients were selected for multivariate analysis using Firth regression. Limiting the number of predictors to three allowed us to avoid overfitting the model, given the size of the sample [28]. The factors selected were of great clinical significance characterizing major biomechanical parameters of the design. Multivariate analysis using Firth regression revealed the following independent risk factors for implant instability (Fig. 3):

- the use of bone graft instead of cement reduced the odds of instability by 8 times (OR = 0.125, 95 % CI: 0.026–0.475,  $p = 0.014$ );
- absence of contact surface mismatch was associated with a lower risk (4.7 times lower odds) of instability (OR = 0.214, 95 % CI: 0.047–0.815,  $p = 0.026$ );

—Prosthesis subsidence of more than 2 mm after 3 months increased the likelihood of instability by 4.5 times (OR = 4.497, 95 % CI: 1.224–18.41,  $p = 0.023$ ).

The model demonstrated statistically significant predictive value (LR  $\chi^2 = 24.74$ ,  $df = 3$ ,  $p < 0.001$ ).

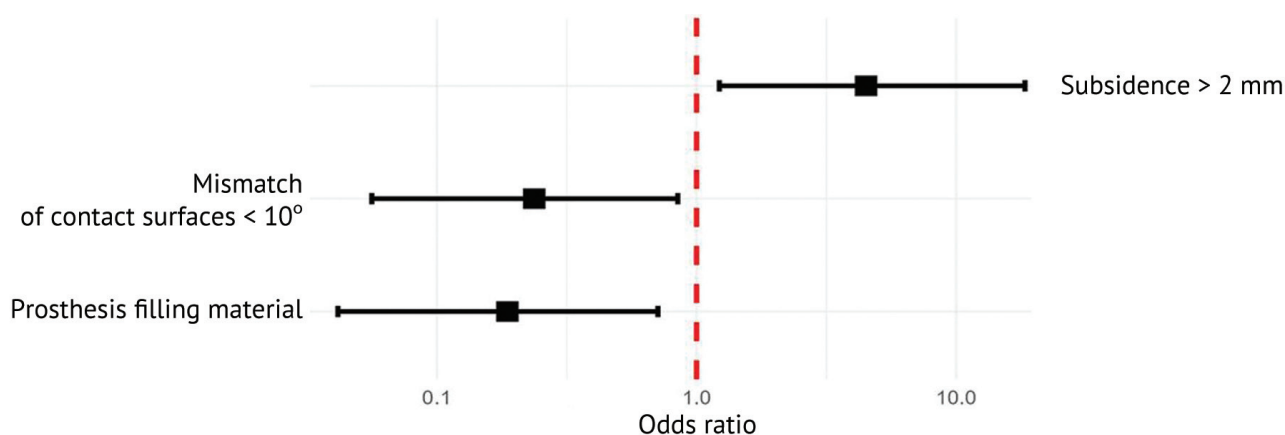


Fig. 3 Firth regression results

## DISCUSSION

Risk factors for implant instability in patients with spinal tumors after spondylectomy were reviewed in the series. The instability rate was 18.4 %, which is Yoshioka et al. reported significant differences in the frequency of instability depending on the level of intervention with instrumentation failure occurred in 5.9 % after thoracic multilevel TES to 42.9 % after lumbar multilevel TES [30]. Hardware failures were associated with broken rods (36.5 %), screw loosening and junctional kyphosis (50 %), and cage migration (12.5 %). These data are consistent with those reported in the systematic review by Li et al. with hardware failure of 12.1 % as one of the most frequent complications [31].

Multivariate analysis revealed three independent predictors of implant instability. The choice of filling material for the prosthesis was most significant factor with the bone graft reducing the risk of instability by eight times compared to cement. This is consistent with the concept offered by Akamaru et al. who reported better bone integration with bone graft in cases of benign or primary malignant tumors [32]. Melcher and Harms reported the use of bone cement as an acceptable option for anterior reconstruction in cases of metastatic lesions or severe osteoporosis [33]. The strategy is practical for patients with limited life expectancy. However, modern advances in the treatment of cancer patients have led to a significant increase in survival, including patients with metastatic lesions of the spine [34]. In our series, the overall median survival was 28 months creating preconditions for the development of late complications. With use of cement, patients can survive to the development of pseudoarthrosis and hardware failure, which is confirmed by the high frequency of pseudoarthrosis (75 %) in patients with implant instability.

A discrepancy between the contact surfaces of the prosthesis and adjacent endplates of more than 10° increased the risk of instability by 4.7 times. Mohammad-Shahi et al. reported the critical importance of this factor, demonstrating the risk of hardware failure at angular mismatch from 0° to 10° [35]. This factor is very important in multilevel resections [36], and Yoshioka et al. reported higher risk of instability with increasing length of reconstruction [30]. This may be explained by the fact that the increase in the number of contact points during multi-level reconstruction creates a more complex biomechanical system in which small deviations in the positioning of the prosthesis at each level can add up and lead to a significant redistribution of loads on the entire construct. In this case, uneven



distribution of forces on the contact surfaces can create zones of local overstress accelerating wear of the rods.

Subsidence of the prosthesis by more than 2 mm 3 months after surgery increased the likelihood of instability by 4.5 times. Shimizu et al. identified early subsidence ( $\geq 2$  mm after 1 month) as an independent risk factor for instrumentation failure [29]. Vaccaro et al. suggested early subsidence could be influenced by several factors including bone quality, the area of contact between the implant and the vertebral body, the extent of intraoperative distraction, the technique of preparation of the endplates and the correspondence of the mechanical properties of the implant and bone (modulus of elasticity) [37]. Interestingly, all these factors are interrelated and can enhance each other's influence. For example, with reduced bone mineral density, increasing contact area of the implant with the vertebral body is essential for better load distribution [38]. Excessive intraoperative distraction can lead to injury to the endplates, which, in combination with the mismatch between the elastic modulus of the implant and the bone, can create preconditions for early subsidence even with initially correct positioning of the prosthesis.

The findings and literature analysis allowed us to formulate practical recommendations to reduce the risk of implant instability:

- bone graft is to be considered as a method of choice in the absence of contraindications, taking into account its ability for biological integration and remodeling;
- preoperative planning suggests careful consideration of the fixation points, contact zones of the prosthesis; imaging is practical for assessment of the bone quality and preoperative modeling of implant placement;
- the most accurate fit of the contact surfaces is to be ensured intraoperatively avoiding excessive distraction and minimizing damage to the endplates when preparing the prosthetic bed;
- careful radiological monitoring and control of osseointegration are important postoperative steps;
- rods of greater diameter, lengthening of the fixation zone and additional rods can be used in the presence of risk factors (osteoporosis, multi-level lesions, localization in transitional areas);
- individual vertebral body prostheses manufactured with 3D printing can be used to prevent instability, optimize load distribution due to precise conformity with the patient's anatomy, creating additional fixation points in the implant construct and using materials with an elastic modulus close to bone tissue (PEEK composites).

Individualization of surgical treatment with the above recommendations can help reduce the incidence of implant instability and improve long-term treatment outcomes in patients with spinal tumors.

The study has several limitations. The retrospective nature of the study prevents control of the quality of the data collected and increases the risk of systematic errors. The single-center design may reduce the external validity of the results. The relatively small sample size (87 patients) limits the statistical power of the study, given the heterogeneity of the population by tumor types (metastatic, primary malignant and aggressive benign tumors). The long period of material recruitment (2007–2023) could be accompanied by changes in surgical technique and perioperative patient management. Despite the use of modern statistical processing methods missing data (9.2 % of cases) could have affected the results of the analysis. Although justified by the sample size limiting the number of predictors to three variables in the final model could have led to the loss of potentially significant risk factors. In addition to that, the potential influence of competing risks (e.g., death) limits the assessment of the incidence of instability at a long term.

## CONCLUSION

Three independent risk factors for implant instability after spondylectomy identified in patients with spinal tumor lesions included the use of bone cement instead of allograft to fill in the vertebral body prosthesis, mismatch of the contact surfaces of the prosthesis with the adjacent endplates by greater than 10°, and an implant subsidence of more than 2 mm 3 months post surgery. These factors are important for planning of the surgical intervention and postoperative monitoring to prevent metal construct instability.

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**Ethical review** All patients signed informed consent for the use of information for educational and scientific purposes.

**Informed consent** The study was approved by the local ethics committee and conducted in accordance with the principles of the Declaration of Helsinki.

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