Factors associated with spinal fixation mechanical failure after tumor resection: a systematic review and meta-analysis

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Abstract
Background: No available meta-analysis has been published that systematically assessed spinal fixation mechanical failure after tumor resection based on largely pooled data. This systematic review and meta-analysis aimed to investigate the spinal fixation failure rate and potential risk factors for hardware failure.

Methods: Electronic articles published between January 1, 1979, and January 30, 2021, were searched and critically evaluated. The authors independently reviewed the abstracts and extracted data on the spinal fixation failure rate and potential risk factors.

Results: Thirty-eight studies were finally included in the meta-analysis. The pooled spinal fixation mechanical failure rate was 10%. The significant risk factors for hardware failure included tumor level and cage subsidence. Radiotherapy was a potential risk factor.

Conclusion: The spinal fixation mechanical failure rate was 10%. Spinal fixation failure is mainly associated with tumor level, cage subsidence and radiotherapy. Durable reconstruction is needed for patients with these risk factors.

Keywords: Spinal tumor resection, Spinal fixation mechanical failure, Risk factors, Tumor level, Cage subsidence, Radiotherapy, Meta-analysis

Introduction
The spine is a common site of musculoskeletal tumors, and spinal tumor patients must undergo spinal surgery to relieve neural compression, control local tumors and prolong survival [1, 2]. After resecting the tumor, internal fixation is used to attain spinal stability [3, 4]. Given the increased survival of patients, there is a growth trend of fixations experiencing failure. Spinal hardware failure could cause spinal instability and decrease the quality of life of patients [5–10]. To avoid the mechanical failure of spinal fixation, it is important to study factors related to the current situation.

Although some studies [7, 11–16] on spinal fixation mechanical failure after tumor resection have been published, some questions remain unanswered. First, most current studies describe only the rate of spinal hardware failure and the potential risk factors based on clinical experience, and these studies lack statistical risk factor analyses [13, 16, 17]. Second, statistical analysis was only performed in a few studies, and the population of included patients was small, which may affect the results [3, 4, 18]. In addition, not all studies included vertebral location [3–5, 11] as a risk factor. Therefore, to better guide clinical therapy, a meta-analysis is urgently needed to investigate the factors associated with spinal fixation mechanical failure.
Materials and methods

Search strategy
A comprehensive literature search was performed using the PubMed, EMBASE, Web of Science, and Cochrane Library databases for studies published between January 1, 1979, and January 30, 2021. The following MeSH terms and their combinations were searched: ((Spine[MeSH Terms]) AND (((Neoplasms[MeSH Terms]) OR (Sarcoma[MeSH Terms]) OR (Carcinoma[MeSH Terms]))) AND (((instrumentation failure) OR (fixation failure)) OR (hardware failure)) OR (Rod fracture)). Two authors independently reviewed the titles and abstracts to screen and extract relevant articles.

Selection criteria
The PICOS criteria for inclusion and exclusion were as follows:

P (participants): Studies of spinal tumor surgery were included.
I and C (intervention and control): Studies in which spinal tumor patients received tumor resection and spinal fixation were included. If some studies included partially duplicated patients, only the studies that used large and advanced data were included.
O (outcome): Studies that included patients with spinal fixation mechanical failure with or without the following clinicopathologic factors were included: sex, age, chemotherapy, radiotherapy, tumor histology, location, surgical approach, number of vertebrae resected, rod diameter, constructed length and cage subsidence. For risk factor analysis, only the studies reporting fixation failure rates stratified by each risk factor were included. When a study reported the results on different subpopulations, we regarded data from the subpopulations as separate studies in the meta-analysis.
S (study type): Research articles published between January 1, 1979, and January 30, 2021, were included. All review papers, meta-analyses, and case reports were excluded.

Quality assessments
The quality of each eligible study was rated independently by two reviewers using the modified Newcastle–Ottawa scale 27. A score of 0–9 was assigned to each study.

Data extraction
A data collection sheet was developed to record the level of evidence, study quality, available outcomes, and risk factors. Two investigators independently extracted data from these studies. If the variable was divided into dichotomous subgroups, data from the two subgroups were included regardless of the cutoff value. If the variable was divided into polytomous rather than dichotomous subgroups, only the data of subgroups in both ends were included.

Statistical analysis
The analyses were performed using Stata 14.0 (StataCorp, College Station, TX, USA). We used a random-effects model to produce a pooled overall estimate for the spinal fixation failure rate with Stata 14.0. The OR was used to compare dichotomous variables. All results were reported with 95% CI. Statistical heterogeneity between studies was assessed using the Chi-square test and quantified using the $I^2$ statistic. If $p < 0.1$ and $I^2 \geq 50\%$, the random-effects model was used to merge the ORs. If $p > 0.1$ and $I^2 < 50\%$, the fixed-effect model was used to merge the OR values. When OR > 1, the factors were accepted as risk factors resulting in fixation failure. When OR < 1, the factors were accepted as protective factors avoiding fixation failure. If significant heterogeneity was noted, an increased quantity of included studies was necessary.

Sensitivity analysis and publication bias
Sensitivity analysis was performed to evaluate whether the results of the meta-analysis changed after the removal of any one study. To assess the presence of publication bias, we used funnel plots and Egger’s test. A value of $p < 0.05$ indicated statistically significant publication bias.

Results

Study characteristics
We preliminarily screened 348 studies from the PubMed, Embase, Web of Science, and Cochrane Library databases. After reading the articles, 310 studies did not conform to the inclusion criteria. Therefore, 38 studies [1–38] were finally included in the meta-analysis. All the included studies were retrospective and had evidence of 3B or 4 according to the criteria of the Center for Evidence-Based Medicine in Oxford, UK. All observation studies had a quality score of 5 or greater on the Newcastle–Ottawa scale and were considered to have high quality (Fig. 1; Table 1).

Spinal fixation mechanical failure rate
The pooled data on the spinal fixation mechanical failure rate consisted of 35 [1–3, 5–10, 12–37] studies with 2689 patients. The pooled failure rate was 10% (95% CI 8–12%) and is shown in Fig. 2.
The prognostic factors with similar variables were pooled in the meta-analysis. The details of the meta-analysis results are shown in Table 2.

**Age**

Seven studies [3–6, 8, 11, 18] compared the spinal fixation failure rate between the older and younger subgroups. Values of $I^2 = 0.0\%$ and $p = 0.945$ were obtained after the OR values of the failure rate were merged, indicating that no heterogeneity existed. A fixed-effect model was used to merge the data (OR = 1.01, 95% CI 0.97–1.05 and $p = 0.634$), showing no significant difference in the failure rate between the older and younger subgroups.

**Sex**

Seven studies [3–6, 8, 11, 18] comparing the failure rate between males and females were included. Values of
| Study               | Year   | Time frame       | Level of evidence | Quality score | Country | Age (years) | Total pts. (n) | Male | Female | Median follow-up (months) | Fixation failure rate (%) |
|---------------------|--------|------------------|-------------------|---------------|---------|-------------|----------------|------|--------|--------------------------|---------------------------|
| McLain, R. F        | 1991   | 1984–1989        | 4                 | 7             | USA     | 49.55       | 11              | 7    | 4      | 17                       | 36.36                     |
| Dickman, C. A       | 1992   | 1987–1991        | 4                 | 7             | USA     | 47          | 104             | 55   | 49     | 20                       | 17.31                     |
| Rompe, J. D         | 1993   | 1987–1991        | 4                 | 7             | Germany | 61          | 50              | 23   | 27     | ≥ 12                      | 645.5                     |
| Bilsky, M. H        | 2002   | 1985–1999        | 4                 | 7             | USA     | 54          | 42              | 28   | 14     | 35                       | 4.76                      |
| Vrionis, F. D       | 2003   | 2000–2003        | 4                 | 7             | USA     | 53          | 96              | 56   | 40     | NA                       | 3.10                      |
| Mazel, C            | 2004   | 1994–2000        | 4                 | 7             | France  | 52          | 34              | 27   | 5      | 15                       | 5.88                      |
| Villavicencio, A. T | 2005   | 1993–1999        | 4                 | 6             | USA     | 51          | 58              | NA   | NA     | NA                       | 3.50                      |
| Bilsky, M. H        | 2005   | 1996–2003        | 4                 | 7             | USA     | 53          | 41              | 22   | 19     | NA                       | 7.32                      |
| Street, J           | 2007   | NA               | 4                 | 6             | Canada  | NA          | 96              | NA   | NA     | NA                       | 1.04                      |
| Placantonakis, D. G | 2008   | 1996–2006        | 4                 | 7             | USA     | 52          | 90              | 58   | 32     | 21                       | 12.00                     |
| Stevens, Q. E       | 2009   | 2003–2006        | 4                 | 7             | USA     | 56.3        | 34              | 17   | 17     | 12                       | 5.88                      |
| Matsumoto, M        | 2011   | 1997–2009        | 4                 | 7             | Japan    | 46.5        | 15              | 12   | 3      | 41.5                     | 4.00                      |
| Rajpal, S           | 2012   | 1995–2009        | 4                 | 7             | USA     | 56.3        | 37              | 20   | 17     | 21                       | 2.70                      |
| Jandial, R          | 2013   | 2008–2010        | 4                 | 7             | USA     | 5664        | 11              | 6    | 5      | 14                       | 9.09                      |
| Matsumoto, M        | 2013   | 1997–2009        | 4                 | 7             | Japan    | 55.3        | 8               | 5    | 3      | 768                      | 37.50                     |
| Yoshioka, K         | 2013   | 2006–2012        | 4                 | 7             | Japan    | 496         | 26              | 11   | 15     | 26.5                     | 3.85                      |
| Bellato, R. T       | 2015   | 2009–2014        | 4                 | 7             | Brazil   | 5671        | 105             | 54   | 51     | 74                       | 8.57                      |
| Luzzatti, A. D      | 2015   | 1994–2011        | 4                 | 7             | Italy    | 48          | 38              | 18   | 20     | 39                       | 2.60                      |
| Mesfin, A           | 2015   | 2001–2013        | 4                 | 7             | USA     | 50.7        | 10              | 9    | 1      | NA                       | 10.00                     |
| Sellin, J. N        | 2015   | 1993–2010        | 4                 | 7             | USA     | 59          | 43              | 26   | 17     | NA                       | 4.65                      |
| Boriani, S          | 2016   | 1990–2015        | 4                 | 7             | Italy    | 44.1        | 216             | 113  | 103    | 45                       | 10.19                     |
| Glorion, M          | 2016   | 1992–2004        | 4                 | 7             | France   | 45.9        | 88              | 60   | 28     | 49.4                     | 9.09                      |
| Goodwin, C. R       | 2016   | 2004–2014        | 4                 | 6             | USA     | NA          | 21              | NA   | NA     | 51                       | 38.10                     |
| Sciubba, D. M       | 2016   | 2004–2014        | 4                 | 7             | USA     | 47          | 23              | 15   | 8      | 50                       | 39.10                     |
| Pedreira, R         | 2017   | 2003–2013        | 4                 | 7             | USA     | 60/65       | 159             | 85   | 74     | ≥ 3                      | 1.90                      |
| Scotto, G           | 2017   | 1992–2017        | 4                 | 7             | Italy    | NA          | 518             | NA   | NA     | NA                       | 5.10                      |
| Shah, A. A          | 2017   | 2010–2016        | 4                 | 7             | USA     | 58          | 33              | 20   | 13     | 18                       | 25.00                     |
| Yoshioka, K         | 2017   | 2006–2010        | 4                 | 7             | Japan    | 53.3        | 47              | 20   | 27     | 71.3                     | 17.00                     |
| Shimizu, T          | 2018   | 1993–2015        | 4                 | 7             | Japan    | 38          | 30              | 13   | 17     | 87                       | 20.00                     |
| Sugita, S           | 2018   | 1992–2008        | 4                 | 6             | Japan    | 63          | 191             | NA   | NA     | 9.9                      | 27.00                     |
| Barzilai, O         | 2019   | 2016–2017        | 4                 | 8             | USA     | 63.5        | 53              | 30   | 23     | 4.93                     | 6.00                      |
| Barzilai, O         | 2019   | 2010–2015        | 4                 | 7             | USA     | 61          | 88              | 44   | 44     | 44.6                     | 12.50                     |
| Study      | Year | Time frame       | Level of evidence | Quality score | Country    | Age (years) | Total pts. (n) | Male | Female | Median follow-up (months) | Fixation failure rate (%) |
|------------|------|------------------|-------------------|---------------|------------|-------------|---------------|------|--------|--------------------------|--------------------------|
| Park, S. J | 2019 | 2002–2015        | 4                 | 7             | Korea      | 49          | 32            | 18   | 14     | 49.8                     | 37.50                    |
| Li, Z. H   | 2020 | 2009–2017        | 4                 | 7             | China      | 37.1        | 30            | 20   | 10     | 41.8                     | 26.67                    |
| Park, S. J | 2020 | 2010–2017        | 4                 | 6             | Korea      | NA          | 136           | NA   | NA     | 16.5                     | 662                      |
| Shinmura, K| 2020 | 2010–2015        | 4                 | 7             | Japan      | NA          | 61            | NA   | NA     | > 24                     | 42.60                    |
| Wei, H. Y  | 2020 | 2015–2018        | 4                 | 7             | China      | 45.5        | 15            | 7    | 8      | 31.1                     | 667                      |
| Wong, Y C  | 2020 | 2007–2017        | 4                 | 7             | China      | 57.3        | 88            | 45   | 43     | NA                       | 1020                     |

a Level of evidence: according to the criteria of the Centre for Evidence-Based Medicine
b Quality score: the score of the study using the Newcastle–Ottawa Scale
c Age is represented by the median or the average age of the study population
I^2 = 0.0\% and p = 0.694 were obtained after OR values of failure rate were merged, indicating that no heterogeneity existed. A fixed-effect model was used to merge the data (OR = 1.17, 95\% CI 0.67–2.04 and p = 0.591), suggesting that the failure rate did not significantly differ based on sex.

**Chemotherapy**

Four studies [3, 6, 11, 18] evaluated chemotherapy as a risk factor for spinal fixation failure. Values of I^2 = 8.8\% and p = 0.349 were obtained after OR values of failure rates were merged, indicating that no heterogeneity existed. A fixed-effect model was used to merge the data (OR = 1.77, 95\% CI 0.83–3.78 and p = 0.142). The results showed no significant difference in the failure rate between patients who received chemotherapy and those who did not receive chemotherapy.

**Radiotherapy**

A total of 8 studies (including subgroups) [3–6, 8, 11, 18] assessed the association between radiotherapy and failure rate. Values of I^2 = 56.0\% and p = 0.415 were obtained...
Table 2  Show results of meta-analysis including pooled OR, 95% CI, sensitivity analysis, and publication bias

| Prognostic factors | N  | OR range | Pooled OR | Pooled 95% CI | Heterogeneity (I^2) (%) | Model | p     | Sensitivity analysis | Affected study | Publication bias (Egger’s test) |
|-------------------|----|----------|-----------|---------------|-------------------------|-------|-------|---------------------|----------------|---------------------------------|
| The older versus the younger [3–6, 8, 11, 18] | 7  | 0.73–2.55 | 1.01      | 0.97–1.05     | 0.0                     | Fixed | 0.634 | No effect           | None           | 0.634                           |
| The female versus the male [3–6, 8, 11, 18] | 7  | 0.44–12.75 | 1.17      | 0.67–2.04     | 0.0                     | Fixed | 0.591 | No effect           | None           | 0.455                           |
| With versus without chemotherapy [3, 6, 11, 18] | 4  | 0.19–2.59 | 1.77      | 0.83–3.78     | 8.8                     | Fixed | 0.142 | Effect              | Matsumoto, M  | 0.183                           |
| With versus without radiotherapy [3–6, 8, 11, 18] | 8  | 0.09–1089 | 2.56      | 0.99–6.62     | 56.0                     | Random | 0.053 | No effect           | None           | 0.894                           |
| Primary versus metastatic tumor [3, 4, 11] | 3  | 0.57–213  | 0.93      | 0.46–1.87     | 0.0                     | Fixed | 0.834 | No effect           | None           | 0.750                           |
| Thoracic/lumbar versus thoracic level [4, 5, 11] | 3  | 1.75–4.25 | 2.26      | 1.07–4.77     | 0.0                     | Fixed | 0.032 | No effect           | None           | 0.642                           |
| Lumbar versus thoracic level [3–5, 11] | 4  | 1.40–729 | 2.49      | 1.37–4.53     | 0.0                     | Fixed | 0.003 | No effect           | None           | 0.890                           |
| Posterior only versus combined approach [3, 11] | 2  | 1.14–4.76 | 1.46      | 0.47–4.50     | 0.0                     | Fixed | 0.514 | Effect              | Matsumoto, M  | –                               |
| Multiple versus single vertebrae resection [3–5, 8, 11, 18] | 6  | 0.22–210 | 0.97      | 0.48–1.94     | 0.0                     | Fixed | 0.930 | No effect           | None           | 0.726                           |
| Thin versus thick rod [4, 11] | 2  | 1.08–1.50 | 1.27      | 0.54–2.96     | 0.0                     | Fixed | 0.587 | No effect           | None           | –                               |
| Longer versus shorter constructed length [3, 8, 11, 18] | 4  | 0.91–3.25 | 1.13      | 0.79–1.61     | 47.9                     | Fixed | 0.498 | Effect              | Wong, Y. C     | 0.365                           |
| With versus without cage subsidence [5, 11] | 2  | 4.05–1463 | 5.46      | 1.48–20.17    | 0.0                     | Fixed | 0.011 | No effect           | None           | –                               |
after the OR values of the failure rate were merged, indicating that heterogeneity existed. The pooled result via a random-effects model minimally indicated that patients with radiotherapy had a higher risk of fixation failure than patients without radiotherapy (OR = 2.56, 95% CI 0.99–6.62, p = 0.053).

Tumor histology
Three studies [3, 4, 11] evaluated the relationship between tumor histology and failure rate. Values of $I^2 = 4.50$ and $p = 0.500$ were obtained after the OR values of the failure rate were merged, indicating that heterogeneity did not exist. Thus, a fixed-effect model was applied. No significant difference in tumor histology was observed (OR = 0.93, 95% CI 0.46–1.87, $p = 0.834$).

Tumor site
Four studies [3–5, 11] evaluated the relation between the tumor site and failure rate. Three studies [4, 5, 11] compared the failure rate between thoracic-lumbar and thoracic levels with no heterogeneity ($I^2 = 0.01$ and $p = 0.972$). Thus, a fixed-effect model was applied. Thoracic-lumbar level had an increased risk of fixation failure (OR = 2.26, 95% CI 1.07–4.77, $p = 0.032$). Four studies [3–5, 11] compared the failure rate between the lumbar and thoracic levels, with heterogeneity existing ($I^2 = 0.00$ and $p = 0.500$) and a fixed-effects model applied. Lumbar level exhibited an increased risk of fixation failure (OR = 2.49, 95% CI 1.37–4.53, $p = 0.003$).

Surgical approach
Two studies [3, 11] explored the failure rate and surgical approach included, and no heterogeneity was noted ($I^2 = 0.00$ and $p = 0.350$). Thus, a fixed-effect model was applied. The failure rate was not significantly different based on the surgical approach (OR = 1.46, 95% CI 0.47–4.50, $p = 0.514$).

Vertebrae resection
Six studies [3–5, 8, 11, 18] evaluated the relation between vertebrae and failure rate. Values of $I^2 = 0.97$ and $p = 0.671$ were obtained after the OR values of the failure rate were merged, indicating that heterogeneity did not exist. Thus, a fixed-effect model was applied. A significant difference was not found in the number of vertebrae resected (OR = 0.97, 95% CI 0.48–1.94, $p = 0.930$).

Rod diameter
Two studies [4, 11] evaluated the relation between rod diameter and failure rate. Values of $I^2 = 0.00$ and $p = 0.705$ were obtained after the OR values of the failure rate were merged, indicating that heterogeneity did not exist. Thus, a fixed-effect model was applied. No significant difference in rod diameter was noted (OR = 1.27, 95% CI 0.54–2.96, $p = 0.587$).

**Conducted length**
Four studies [3, 8, 11, 18] included the failure rate and constructed length. No heterogeneity was noted ($I^2 = 47.99$% and $p = 0.124$), and a fixed-effect model was applied. The meta-analysis failed to find significance among different constructed lengths (OR = 1.13, 95% CI 0.79–1.61, $p = 0.498$).

**Cage subsidence**
Two studies [5, 11] evaluated the relation between cage subsidence and failure rate. Values of $I^2 = 0.00$ and $p = 0.416$ were obtained after the OR values of the failure rate were merged, indicating that heterogeneity did not exist. Thus, a fixed-effect model was applied. Collectively, cage subsidence is a significant risk factor for spinal fixation failure (OR = 5.46, 95% CI 1.48–20.17, $p = 0.011$).

**Sensitivity analysis and publication bias**
Sensitivity analysis was performed in these groups. The pooled OR of chemotherapy changed significantly when excluding the study by Matsumoto [11]. The pooled OR of the surgical approach changed significantly when excluding the study by Matsumoto [11]. The pooled OR of constructed length changed significantly when excluding the study by Wong [8]. The results of the other meta-analysis did not change after removal of any one study.

Egger’s test was completed to examine the existence of publication bias. Publication bias failed to evaluate the surgical approach, rod diameter and cage subsidence because these subgroups only included two studies. Egger’s test resulted in $p > 0.05$ in the other groups and indicated that the possibilities of publication bias can be excluded.

**Discussion**
Durable reconstruction is required to achieve spinal stabilization after tumor resection [3, 4]. Fixation failure is a troubling complication for tumor patients who acquire long-term survival with effective therapy [10–12]. Therefore, it is important to identify risk factors affecting spinal fixation and optimize reconstruction proposals. In this study, we performed a systematic review and meta-analysis to evaluate the failure rate of spinal fixation after tumor resection and to investigate the related risk factors for spinal fixation failure.

Although complications, including fixation failure, have been reported in numerous studies, the incidence varies. Thus, the practical fixation failure rate remains unclear. Sciubba et al. [18] studied 23 patients who underwent TES of the lumbar spine and reported that
In our study, we found that the tumor level was a risk factor for spinal fixation failure, which was consistent with most of the literature.

**Cage subsidence**
Matsumoto et al. mentioned that cage subsidence resulted in the failure of loading sharing in the anterior spinal column, leading to an increased force imposed on the posterior fixation. In this study, they reported that cage subsidence was significantly related to instrumentation failure [11]. However, Yoshioka et al. [5] did not find a relationship between cage subsidence and instrumentation failure and insisted on the importance of eventual bony fusion, which prevented instrumentation failure despite cage subsidence. Our study found that cage subsidence is one of the reasons for fixation failure.

**Limitations**
This meta-analysis had some limitations. First, our meta-analysis was based on retrospective studies, so selection bias was possible. Second, prognostic factor analysis included some studies with small samples, which might result in publication bias and affect sensitivity. Further studies may be needed to verify our conclusions. Furthermore, the follow-up time varied in each study. Despite these limitations, this study applied a series of measures and strict standards to evaluate the quality of these studies.

**Conclusion**
In conclusion, our results indicate that the spinal fixation mechanical failure rate was 10%. Spinal fixation failure is mainly associated with tumor level, cage subsidence and radiotherapy. Durable reconstruction is needed for patients with these risk factors.

**Authors’ contributions**
Data Extraction, ZC and YZ. Quality assessments, ZC and XT. Data analysis, ZC and YZ. Writing-origin draft, ZC. Writing-review and editing, ZC, YZ, XT, RY, TY and WG. All authors read and approved the final manuscript.

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**Availability of data and materials**
Please contact the authors for data requests.

**Declarations**
This study obtained approval from the institutional review board of Peking University People’s Hospital.

**Consent for publication**
Not applicable.
Competing interests
The authors declare that they have no competing interests.

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