What Are the Risk Factors for Mechanical Failure in Spinal Arthrodesis? An Observational Study

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Posted Date: 22 November 2023

doi: 10.20944/preprints202311.1200.v1

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Article

What Are the Risk Factors for Mechanical Failure in Spinal Arthrodesis? An Observational Study

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Abstract: PURPOSE: The aim of this study was to identify the incidence of early mechanical failure in the first post-surgical year in patients who had undergone spinal surgery, and to assess the related risk factors. METHODS: Retrospective observational study of a prognostic cohort was conducted at an orthopaedic hospital, examining all patients with spine degenerative disease who consecutively underwent arthrodesis surgery between March 2018 and March 2019. The incidence of postoperative mechanical failure during the first year was calculated as primary outcome; the time between the date of the implant surgery and diagnosis of the mechanical failure was calculated as secondary outcome. RESULTS: A total of 237 patients were identified for statistical analysis. The median age of the group of patients was 47 years (IQR of 44), and 66.6% were female. The incidence of mechanical failure in the first postoperative year was 5.1% overall with 12 events and the median time between surgery and the need for revision surgery was 5 months (IQR=7.75). ASA score (OR= 2,39; p=0.134), duration of the surgical procedure (OR=1,27; p=0,006) and inability to walk at discharge (OR=7,86; p=0,072) were independent risk of factor associated with the mechanical failure. CONCLUSION: Higher ASA score and longer duration of surgery are risk factors for mechanical failure in the first year in patients who had undergone spinal surgery and must be carefully considered when planning spinal surgery. During hospitalization, recovery of ambulation must be encouraged to prevent mechanical failure. All these factors are useful in identifying patients with a closer follow-up is needed.

Keywords: spinal fusion; mechanical failure; risk factor; spine arthrodesis

1. Introduction

In recent decades, thanks to improvements in the surgical techniques and instrumentation available, there has been a considerable increase in the use of spinal fusion surgery for the treatment of degenerative spinal pathologies [1,2]. Such surgery seeks to limit movement of spinal segments that cause pain after spinal fusion. The main pathologies in which this procedure is indicated are adult scoliosis, kyphosis, disc herniation, vertebral fractures, spinal stenosis, and spondylolisthesis [3,4].

Spinal fusion is surgery to connect two or more bones in any part of the spine using metal plates, screws or rods might hold the bones together.

The outcomes following such procedures, which often vary widely in terms of the type and number of vertebrae involved, are not clear and, to date, no true postoperative care best practice has been identified to achieve the best results.

In the post-operative period, a significant number of patients may experience postoperative mechanical complications such as implant breakage and proximal or distal junctional syndrome, i.e., degeneration of the vertebral segment adjacent to the stabilised district. In a systematic review of

 doi:10.20944/preprints202311.1200.v1

2021, Noh et al. report an overall incidence of rod breakage of 12% with a variability of 7 to 18% [5]. Such an event has a negative impact on the patient's health and often makes new instrumental revision necessary [6,7]. Mohi Eldin et al. report that, in procedures using pedicle screws in the lumbar region, mechanical failure occurs early, within the first six months after surgery [8]. Therefore, an understanding of the relative risk factors associated with mechanical failure of the systems used is increasingly important. [9–11]. The most frequently investigated risk factors are related to patient demographics and to radiological and surgical techniques [12–14]. Old age, a higher body mass index (BMI), prior spinal surgery and pedicle subtraction osteotomy are the risk factors identified by NoH et al. [5]. Early recovery of ambulation after such surgeries is encouraged in the clinical practice [15], playing an important preventive role of postoperative complications [16–18]. In contrast, the role of such recovery in relation to possible mechanical failure in the first year after surgery is poorly described in the literature .

The aim of this study was to identify the incidence of early mechanical failure in the first post-surgical year in patients who had undergone spinal surgery for degenerative disease and to assess the related risk factors.

2. Materials and Methods

2.1. Study Design

Retrospective observational study.

2.2. Setting and Patients

The study was conducted at a spinal surgery Unit of an Italian single-speciality, orthopaedic hospital, examining all patients who consecutively underwent surgery between March 2018 and March 2019. A computerised system was used to identify patients who could be possible candidates for the study. The inclusion criteria were: patients who had undergone for first time spinal arthrodesis for degenerative disease involving the use of some form of instrumentation (rods or screws). All patients were included irrespective of the diagnosis that led to the need for such surgery. The exclusion criteria were: patients who had undergone a spinal procedure without application of any instrumentation—i.e., herniectomy, vertebroplasty and laminectomy — and subjects admitted for mechanical dysfunction and undergoing revision surgery for a previous failed surgery.

The study was approved by the Ethics Committee with protocol number 0007166 and was registered on the Clinicaltrials.gov database (NCT04983576).

2.3. Surgical Procedure

The posterior arthrodesis procedure consisted of applying screws inside the pedicles, which were then connected with a rod and securing nuts to ensure the implant's biomechanical tightness and promote vertebral fusion. Based on the clinical evaluation and biomedical imaging, a team of experienced orthopaedic surgeons determined the most appropriate surgical modalities such as the number of levels to be stabilised and the best surgical approach.

2.4. Postoperative Care and Rehabilitation

In the postoperative phase the patients were followed by a multidisciplinary team of orthopaedic surgeons, physiatrists, nurses and physiotherapists. During daily meetings, the patients were accepted by a multidisciplinary team of orthopaedic surgeons, nurses, physiatrists and physiotherapists. This team was tasked with discussing the most suitable surgical treatment, any problems that may have arisen during the course of post-operative treatment and monitoring of the patient's recovery, establishing the timing of discharge and any orthosis prescription. The surgical team was the same for all patients who had undergone surgery enrolled in the study. Physiotherapy included two exercise sessions per day, Monday through Friday, and an additional session on Saturday morning. The aim of rehabilitation was to recover basic autonomy, and early walking. The rehabilitation plan included bedside exercises, assistance with verticalization manoeuvres to sit up

 doi:10.20944/preprints202311.1200.v1

and stand upright, walking and training on climbing stairs, as well as instruction for postures and movements allowed or not.

2.5. Outcomes

The primary outcome was the incidence of postoperative mechanical failure during the first year was calculated as the ratio between the number of diagnoses of mechanical failure and the total number of arthrodesis procedures performed. The diagnosis of mechanical failure included the diagnosis of rod and/or screw breakage (bilateral or unilateral), vertebral fracture proximal or distal to the instrumentation, mobilisation of the fixation device without breakage thereof and junctional syndrome for which the instrumentation required revision. The diagnosis was collected by the physiotherapist in charge of the research by consulting the patient's medical records. The diagnosis had to be made during the first year after surgery. The secondary outcome was the assessment of time elapsed between the date of surgery and the diagnosis of mechanical failure.

2.6. Variables Collected

Possible risk factors were identified through literature and multidisciplinary discussion among professionals (nurses, physiotherapists, physiatrists, orthopaedists) [13]. The variables collected were summarised in three groups:

- demographic variables: age, sex, body mass index (BMI), smoking, diagnosis of diabetes, diagnosis of depression, osteoporosis, anaesthesiologic risk defined pre-operatively with the ASA score, anamnesis of previous spinal surgery but not arthrodesis, the diagnosis that led to surgery.
- Surgical and postoperative variables: number of spinal levels involved in the stabilisation, involvement of the lumbosacral vertebrae, length of surgery (calculated at 15 min intervals), surgical approach (posterior and other), ability to walk more than 10 meters at hospital discharge without aids, and time between surgery and walking recovery.

The data were collected by consulting the patients' clinical records, available on the computer system. From each file, information was gathered starting from the day of admission to the ward up to the day of discharge and any subsequent re-admissions or outpatient visits.

2.7. Statistical Analysis

A descriptive analysis of the data was performed using the central trends, frequencies and relative dispersion measures for the individual outcomes and variables. The relationship between the primary outcome and the other variables was investigated using an ordinal logistic regression model and the independent variables were selected applying a backward procedure, first limiting any confounding by including all variables in the model and then adjusting the effects for all the factors analysed. The variables were then removed individually at each step starting with those with the highest p-value. The selection process was suspended until all variables included in the model proved significant. The level of significance was set at $p < 0.157$. Receiver operator characteristic (ROC) curve analysis was used to check the logistic regression model. Statistical interpretation of the data was performed using SPSS software.

A post hoc power calculation was undertaken, as a convenience sample was being used. In the unmatched cohort, assuming type I error of 0.05, as well as the rate of primary outcome and study group size as reported in the results, the analysis had 95% power, adequate to undertake and report on the analyses of interest. With a sample size of 250 patients eligible for inclusion in the study and with the incidence of mechanical problems expected according to data available in the literature ranging from 7–12%, 18 to 30 events are to be expected.

3. Results

306 patients eligible for the study were identified. Of these, 7 could not be enrolled for data loss, 26 were lost to the study as they did not show up for their follow-up visits and 36 were admitted for

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mechanical dysfunction and undergoing revision surgery for a previous failed surgery. Statistical analysis was therefore conducted on a total of 237 patients. Figure 1 shows the relevant flow chart.

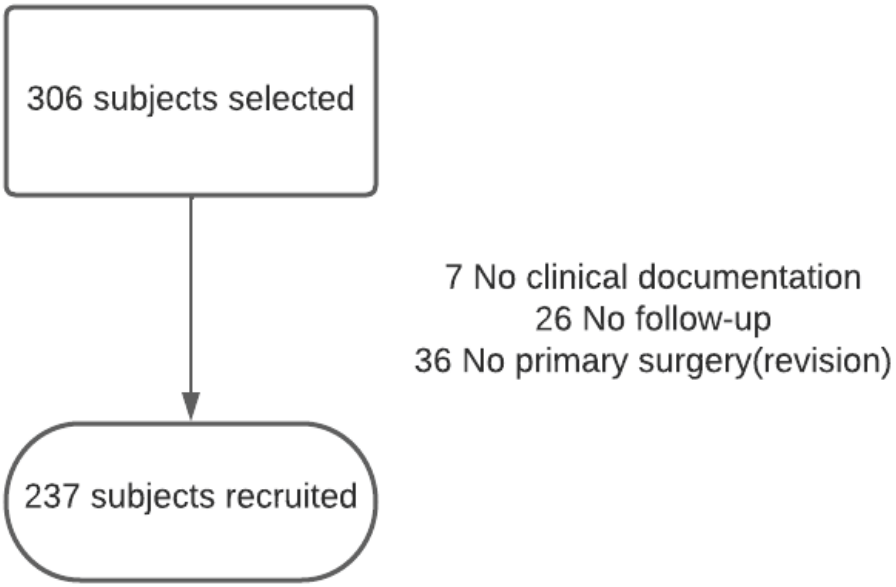

Figure 1. Enrollment process.

The mean age of the group of patients was 47 years (IQR of 42), and 66.2% were female. The baseline characteristics and the variables gathered for all patients enrolled are summarised in Table 1. The incidence of mechanical failure in the first postoperative year was 5.06% overall with 12 events. If considering the implant breakage alone, the incidence is 2.2%, for screws loosening is 1,6 % and for junctional fracture is 1.3%. The median time between surgery and the need for revision surgery following the diagnosis of mechanical failure was 5 months (IQR=7.75). Among the 12 patients diagnosed with mechanical failure and undergoing a first surgical revision, a second surgical revision was required for 4 patients (or 33.3%). From the multivariate analysis (Table 2), ASA score (OR= 2.396; p=0.134), duration of the surgical procedure (OR=1.27; p=0.006) and achievement of walking (OR=7.86; p=0.072) were the independent risk factors for mechanical failure.

Table 1. Patient's characteristics. Data were n (%) for categorical variables and pct25/median/pct75 for continuous variables.

Variable		Total N=237	Not mechanical failure N=225	Mechanical failure N=12
Age, median (IQR)		20.5-47-62.5	46 (42)	60.5 (35)
Sex	Female	157 (66.2)	151 (67.1)	6 (50)
	Men	80 (33.8)		
Body Mass Index (BMI), median (IQR)		20-23-27	23 (7)	26 (12)
Smoking	Yes	64 (27)	60 (26.7)	4 (33.3)
	No	173 (73)		
Diabetes	Yes	14 (5.9)	12 (5.3)	2 (16.7)
	No	223 (94.1)		
Depression	Yes	25 (10.5)	23 (10.2)	2 (16.7)
	No	212 (89.5)		

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Osteoporosis	Yes	26 (11)	23 (10.2)	3 (25)
	No	211 (89)		
ASA Score, median (IQR)		1-2-2	2 (1)	2.5 (1)
Anamnesis of Spine surgery	Yes	48 (20.3)	42 (18.7)	6 (50)
	No	189 (79.7)		
Diagnosis				
• Scoliosis		112 (47.3)	107	5
• Discopathies		45 (19.0)	43	2
• Stenosis		26 (11.0)	25	1
• Spondylolisthesis		27 (11.4)	26	1
• Other (fractures/..)		27 (11.4)	24	3
Time operation (hours), median (IQR)		3-4-4	4 (1)	3.5 (4)
Surgery access	Posterior	221 (93.2)	211 (93.8)	10 (83.3)
	other	16 (6.8)		
Nr fused levels, median (IQR)		2-5-12	5 (10)	8 (10)
Lumbosacral arthrodesis	Yes	81 (34.2)	77 (34.2)	4 (33.3)
	No	156 (65.8)		
Free walking recovery at discharge	Yes	50 (21.1)	41 (18.2)	9 (75)
	No			
Time from surgery to recovery ambulation, median (IQR)		2-3-5	3 (3)	4.5 (6)

Table 2. Logistic regression for 1-year failure. Factors included according to a backward * procedure with a p-for removal fixed at 0.157.

	Wald	**Sig.**	**Exp(B)**	**95% CI per EXP(B)**	
				Lower	Upper
Time operation	**2,442**	**,006**	1,273	,940	1,723
ASA score	2,250	,134	2,396	,765	7,506
Free walking recovery at discharge	7,351	,077	7,863	1,771	34,914

4. Discussion

The incidence of mechanical failure in the first year after surgery was 5,06%, with the time to diagnosis of the issue from the time of surgery being a median of 5 months. This is below the overall incidence presented by Noh et al. in their systematic review of the literature, which reported a rate of 12% for implant breakage alone. This difference can be explained by a much longer follow-up for the studies selected by Noh et al. where the average time to breakage was calculated to be 23.4 months after surgery.

The independent risk factors for mechanical failure revealed by the multivariate analysis were ASA score, duration of surgery, and failure to recover ambulation without aids during hospitalization.

Lynch et al. [19] showed a result in opposite direction. In patients who underwent single-level lumbar spine fusion surgery, the ASA score was not a significant risk factor for possible complications

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or functional recovery of patients in the first two postoperative years. This difference in outcome could be explained precisely in the population considered. In the present study, the median number of spinal levels involved in the surgery was 5 with a range from 2 to 12, thus with a type of surgery certainly more important and different from the Lynch study. In line with this hypothesis, it should be noted that also in the study by Phan et al. [20] it was shown, for patients undergoing cervical arthrodesis, that the American Society of Anesthesiologists (ASA) score could be a valuable tool in identifying patients most at risk of hospital readmission in the first 30 days after surgery. Among the independent predictors of implant-related complications identified by Soroceanu et al. [11], the ASA score was also significant.

Among the surgical variables, the longer length of the arthrodesis and the longer length of the surgical procedure were risk factors for mechanical failure. Specifically in our study length of surgery (calculated at 15 min intervals) increases the risk of rupture by more than twofold after a certain threshold. Several authors [13,14,21] report this association in the literature. Aldebayan et al. [21] reported that operations lasting at least 4 hours e 19 minutes were associated with poorer functional outcomes at discharge, thus it was more likely that the patient would be discharged to a healthcare facility rather than to their own homes. Demura et al. [14], in a pediatric population, identified a slightly higher cut-off with surgery duration greater than 5 hours as a predictor of postoperative complications.

Among the variables involving postoperative care, the inability to regain ambulation proves to be a significant risk factor. The importance of early recovery of ambulation after spine surgery was reported by several authors [16,17]. Lovecchio et al. [18], considering a population of adults diagnosed with spinal deformity, reported on multivariate analysis the recovery of ambulation as a protective factor for postoperative complications. In the present study, recovery of ambulation also plays an important role in the medium and long term. It can be assumed that early verticalization provides a mechanical stress on the vertebral bony tissue, thus stimulating the calcification process, and this most likely facilitates stabilisation of the instrumentation inserted during the arthrodesis procedure. The importance of loading in healing after stabilization surgery has already been highlighted in other types of interventions, such as stabilization after tibial diaphysis fracture [22–25]. Further studies on a specific population such as those undergoing spinal arthrodesis surgery are needed to better understand the role of loading in the postoperative calcification process. This indication should be taken into account when planning the postoperative course of care and implementing physiotherapy treatment.

Limits: the study does have some limitations. First of all, the relatively low incidence of the primary outcome suggests the need to plan study protocols with a larger sample size. Likewise, a longer follow-up period would also facilitate detection of a higher incidence of the results. Secondly, the patient's lifestyle during the postoperative period is a factor that should be considered as a possible predictor.

5. Conclusions

After spinal arthrodesis, in the first postoperative year, higher ASA score and longer duration of surgery are risk factors for mechanical failure and must be carefully considered when planning spinal surgery. During hospitalization, recovery of ambulation must be encouraged to prevent mechanical failure. All these factors are be useful to better identify patients with a closer follow-up is needed.

Author Contributions: Conceptualization, methodology , writing and validation: V.P. and A.C.; software, validation: A.E.; formal analysis, investigation: M.M.; data curation, writing—original draft preparation: R.R. and F.A.; review and editing, visualization, supervision: M.G.B and M.G. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Review Board (or Ethics Committee) of Istituto Ortopedico Rizzoli (CE-AVEC 354/2021/Oss/IOR approved in 22/04/2021).

Informed Consent Statement: Not applicable because for Italian law informed consent is not required for retrospective observational studies.

Data Availability Statement: Data available on request due to restrictions e.g., privacy or ethical. The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: On behalf of all authors, the corresponding author states that there is no conflict of interest.

Abbreviations

BMI : body mass index
PSO: pedicle subtraction osteotomy
ROC : Receiver operator characteristic

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