Objective: To identify the incidence and possible risk factors associated with rod breakage in patients who underwent vertebral column resection (VCR) or pedicle subtraction osteotomy (PSO) to treat complex deformities of the spine. Methods: Retrospective analysis of a series of 32 patients operated from 2014 to 2018 in a single center. The patients were analyzed for demographic (sex, age), biometric (BMI), radiographical (pre- and postoperative angular variations), and surgical (arthrodesed and osteotomized levels) characteristics. Descriptive analyses were performed for the numerical variables (mean, standard deviation, maximum, median, and minimum) and frequency analysis was performed for the categorical variables. Logistic regression analysis was performed for the dependent variable “rod breakage”, using a stepwise technique to select the variables for the best model, assuming statistical significance of 0.05. Results: Of the 32 patients selected, rod breakage occurred in 34.4%. Mean age was 36.6 years (±19.8), ranging from 10 to 74 years, and the mean BMI was 25.1 (±6.0). Most patients were subjected to VCR (75.0%), were males (56.2%) and did not smoke (90.6%). Logistic regression analysis showed that “arthrodesed levels” were positively associated with rod breakage (OR 1.72; CI95%: 1.13-3.10; p<0.05). The other factors were not associated with breakage. Conclusion: Rod breakage is a frequent complication after three-column osteotomy, especially in long constructions. Level of evidence III; Retrospective Study.

Keyword: Failed Back Surgery Syndrome; Spinal Curvatures; Spinal Diseases.
rotura fue de 34.4%. Se observó que el promedio de edad fue de 36.6 años (± 19.8 años), distribuyéndose entre 10 a 74 años, y el IMC promedio fue de 25.1 (± 6.0). Se verificó que la mayor parte de los individuos fue sometida a la técnica RCV (75.0%), era del sexo masculino (56.2%) y no fumaba (90.6%). En el análisis de regresión logística, los “niveles artrodesados” se asociaron positivamente a la rotura (OR 1.72; IC 95%; 1.13-3.10; p < 0.05). Los otros factores no se asociaron a la rotura. Conclusión: La rotura de varillas es una complicación frecuente de las osteotomías de tres columnas, principalmente en reconstrucciones largas. Nivel de evidencia III; Estudio Retrospectivo.

INTRODUCTION

Major improvements in surgical techniques, the development of new instrumentation materials, and multimodal neuromonitorization have made procedures like pedicle subtraction osteotomy (PSO) and vertebral column resection (VCR) increasingly common in the treatment of complex and rigid spinal deformities. Both PSO and VCR are called three-column osteotomies (3CO) because they extend from the posterior to the anterior spine.1

These techniques are valuable tools in the treatment of severe deformities. They allow for large angular corrections and, in some cases, are the only available therapeutic resource.2 It should be noted, however, that they are not without risks. The literature reports high rates of complications, such as neurological injuries, fractures at adjacent levels, consolidation defects, and instrumentation failure.3–5

Fatigue, with the consequent failure of the instrumentation material, is a characteristic of the appearance of pseudoarthrosis, which in turn is associated with significant impact on the quality of life of the patient. It is related to the presence of pain, loss of the correction obtained, the possibility of neurological deficit, and the need for revision surgery, in some cases with catastrophic outcomes. Although breakage of the instrumentation can cause important complications in patients, literature on the subject is very limited, especially when only cases in which 3CO was performed are analyzed. Thus, the objective of this study was to evaluate factors related to rod breakage in patients who underwent PSO and VCR.

METHODS

This is a retrospective evaluation of patients who underwent surgery at a single center during the period from 2014 to 2018. All the patients were submitted to 3CO (PSO or VCR), most of them with initial instrumentation with two 5.5 mm titanium rods, performed by the same surgical team. Only two received PSO with three-rod instrumentation. An analysis of the medical records and simple radiography and computed tomography examinations of the spine was conducted. The inclusion criteria were complex pathologies, five or more levels of posterior arthrodesis, 3CO performed, patient older than 10 years of age at the time of surgery. We obtained a total number of 32 patients, all of whom were followed-up for at least two years after surgery.

The patients included in the study were evaluated on demographic, clinical, social, and surgical aspects. Descriptive (body mass index, age, coronal correction, sagittal correction, arthrodesed levels, osteotomized levels) and categorical (sex, tobacco use, PSO or VCR performed) variables were assessed as possible predictors of rod breakage. Arthrodesed levels was defined as the levels included in the initial instrumentation aimed at arthrodesis. The occurrence of pseudoarthrosis was not evaluated in this study.

The pre- and post-correction angle variations were evaluated in panoramic orthostatic radiographs using the Cobb measurement method of the main rigid curve and Surgimap® software. The diagnosis of rod fracture was made using orthostatic radiographs.

The descriptive analyses were performed through summaries of the numerical variables (mean, standard deviation, maximum, median, and minimum) and frequencies of the categorical variables. Logistic regression analysis was performed for the dependent variable “breakage”, using the stepwise technique to select the variables that make up the best model, assuming a significance level of 0.05. All the analyses were conducted using R 3.6.0 software (Planting of a Tree).

RESULTS

Out of the group of 32 patients selected, 34.4% had experienced breakage. We observed that the mean age was 36.6 years (± 19.8 years), ranging from 10 to 74 years of age, and the mean BMI was 25.1 Kg/m² (± 6.0). We confirmed that most of the patients had been submitted to the VCR technique (75%), were male (56.2%), and did not smoke (90.6%), as displayed in Tables 1 and 2.

As Table 3 shows, in the logistic regression analysis “arthrodesed levels” were positively associated with breakage (OR 1.72; CI95%; 1.13-3.10; p < 0.05). Factors like surgical technique, sex, age, BMI, Delta Sagittal Cobb, Delta Coronal Cobb and osteotomized levels were not associated with breakage. The OR for tobacco use could not be estimated, for there were no cases of tobacco users without breakage.

In the multivariate analysis, considering the effect of the variables simultaneously, no model presented statistical significance for the characteristics analyzed. We found that the model with “arthrodesed levels” and “tobacco use” presented the lowest AIC (Akaike information criterion), however, without statistical significance of the odds ratios. Therefore, the univariate with the characteristics “arthrodesed levels” (model 1) remained the most suitable for the study in question (Table 4 and Figure 1).

Table 1. Absolute and relative frequencies of the categorical variables.

| Variables                | n (%) |
|--------------------------|-------|
|                          | Yes 11 (34.4) | No 21 (65.6) |
| Technique                | PSO 8 (25.0) | VCR 24 (75.0) |
| Sex                      | Female 14 (43.8) | Male 18 (56.2) |
| Tobacco use              | Yes 3 (9.4) | No 29 (90.6) |
| Arthrodesed levels       | 8 7 (21.9) | 9 7 (21.9) |
|                          | 10 6 (18.8) | 11 2 (6.2) |
|                          | 12 3 (9.4) |
| Osteotomized levels      | 15 1 (3.1) | 1 10 (31.2) |
|                          | 2 14 (43.8) | 3 7 (21.9) |
|                          | 5 1 (3.1) |

Table 2. Descriptive measurements (mean, standard deviation, minimum, median, maximum) of the numerical variables.

| Variables        | Mean (SD) | Minimum | Median | Maximum |
|------------------|-----------|---------|--------|---------|
| Age              | 36.6 (19.8) | 10 | 28 | 74 |
| BMI              | 25.1 (6.0) | 15.2 | 24.2 | 38.2 |
| Delta Sagittal Cobb | 37. (23.8) | 2 | 32 | 80 |
| Delta Coronal Cobb | 25.2 (28.0) | 0 | 12 | 92 |
According to the odds ratio of model 1, for each increase of one unit in the arthrodesed levels, a 72.32% increase in the breakage odds ratio is expected.

Model 1 presents a high degree of separability (AUC=0.8074), that is, the ability to predict breaks from arthrodesed levels is 80.74% (Appendix 1).

We also present the residual statistical analysis in the appendix of this work.

Table 3. Odds ratio (confidence interval of 95%) of the univariate logistic model for breakage.

| Characteristics       | Odds ratio (OR) | CI 95%                  | p-value |
|-----------------------|-----------------|-------------------------|---------|
| Technique             | PSO             | 1.0000                  |         |
|                       | VCR             | 0.9330                  | 0.1598 – 4.8914 | 0.8300 |
| Sex                   | Female          | 1.0000                  |         |
|                       | Male            | 0.9000                  | 0.2046 – 4.0303 | 0.8880 |
| Tobacco use           | Yes             | 0.0000                  | 0.0000 – Not available | 0.9935 |
|                       | No              | 1.0000                  |         |
| Age                   |                 | 1.0214                  | 0.9983 – 1.0626 | 0.2729 |
| BMI                   |                 | 1.0008                  | 0.9781 – 1.1322 | 0.9900 |
| Delta Sagittal Cobb   |                 | 1.0092                  | 0.9780 – 1.0424 | 0.5670 |
| Delta Coronal Cobb    |                 | 0.9936                  | 0.9640 – 1.0203 | 0.6740 |
| Arthrodesed levels    |                 | 1.7232                  | 1.1316 – 3.1046 | 0.0298 |
| Osteotomized levels   |                 | 0.8384                  | 0.3333 – 1.8934 | 0.6810 |

Table 4. Odds ratio (confidence interval of 95%) of the logistic model adjusted for breakage.

|               | Model 1          | Model 2          |
|---------------|------------------|------------------|
| (Intercept)   | 0.0035**         | 0.0006**         |
| Arthrodesed levels | 1.7232**        | 1.578*           |
| Tobacco use   | (1.1316 – 3.1046) | (1.0337 – 2.8614) |
|               | 0.000            | (0.000 – Not available) |
| AIC           | 38.24            | 35.63            |
| BIC           | 41.17            | 40.02            |
| Log Likelihood| -17.12           | -14.81           |
| Deviance      | 34.24            | 29.63            |
| Number of observations | 32              | 32               |

p < 0.05 and p < 0.10

Figure 1. ROC curve of model 1.

DISCUSSION

Although three-column osteotomies are an important resource in the surgical treatment of severe spinal deformities, several complications may result from this approach. Among them, failure of the material stands out in this study. The literature on the subject is still controversial. High BMI, advanced age, and physical properties have been indicated as increasing the risk of breakage. Of these, only those relating to the physical properties of the material and the number of rods used did not lose statistical significance in other studies.

In this study, we investigated the anthropometric, social, and surgical characteristics of a series of patients submitted to 3CO in a single center in order to identify possible risk factors for a specific complication, rod breakage. We observed an incidence of 34% for this outcome: of the 32 patients evaluated, 11 had rod breakage.

This value is like that commonly found in similar study series, in which there is an approximate variation of between 25 and 40%. The high frequency of material breakage in these surgeries suggests that the biomechanical demand on this surgery is high.

Along these same lines, studies show that constructions using more than 2 rods have a lower failure rate. The work of Gupta et al. suggested a new way of using four rods following PSO and reported a significant reduction in the occurrence of failure.

Studies evaluating rod breaking strength have shown that cobalt chromium rods withstand around three to five more stress cycles than titanium alloy rods and support a higher load up to breakage. In addition, they showed that larger diameter rods are more resistant.

Another aspect pointed out by these studies is that titanium alloys break at the point of curvature induced by stress forces. The failures observed in cobalt chromium constructions break more often at the body or tulip of the polyaxial screw, revealing the greater strength and reliability of this material.

However, the higher rigidity of the cobalt chromium alloy was associated with a higher incidence of adjacent levels disease. This is compatible with the concept that the transition zones between very discrepant elastic coefficient areas are submitted to high mechanical stress. This should be considered when choosing the implant to be used in each patient.

Our analysis showed that the number of levels involved in the arthrodesis is directly related to the increased incidence of material breakage. The chance of this complication occurring increases considerably with each additional level involved in the initial surgery. This may be due to the greater length of the rod, with the resulting increase of the lever arm in the osteotomized area, creating an overload on the material. Another plausible hypothesis would be the greater likelihood of pseudoarthrosis occurring in long constructions. In fact, both explanations are complementary to each other in terms of causality related to breakage of the material.

As a limitation of this study, we highlight the lack of assessment of the occurrence of pseudoarthrosis through imaging examinations. Such an analysis could possibly help to explain more clearly why an increase in the number of levels involved in the surgery generates a higher incidence of breakage, as explained in the previous paragraph.

Therefore, we conclude that three-column osteotomy is an important tool, but often implies breakage of the implant used. A material failure rate is expected to be observed in 25 to 50% of the cases in which these techniques were used. Considering our findings, we suggest increased vigilance in cases where the inclusion of many levels of arthrodesis is expected. In these cases, the possibility of using more suitable constructions with stronger metal alloys and multiple rods of greater diameters should be evaluated.

CONCLUSION

Material failure after performing three-column osteotomies, especially in long two-rod constructions, was a frequent complication, even during short- and medium-term follow-up.

All authors declare no potential conflict of interest related to this article.
EVALUATION OF ROD BREAKAGE AFTER THREE-COLUMN OSTEOTOMY

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Appendix 1. Residuals Analysis of Model 1.