

IN VITRO MECHANICAL EVALUATION OF SPINAL FIXATION ROD CONNECTORS

AVALIAÇÃO MECÂNICA IN VITRO DE CONECTORES DAS HASTES DE FIXAÇÃO VERTEBRAL

EVALUACIÓN MECÁNICA IN VITRO DE CONECTORES DE VARILLAS DE FIJACIÓN DE LA COLUMNA

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ABSTRACT

Objective: Evaluate and compare the mechanical resistance and the fatigue behavior associated with the use of three different modalities of vertebral fixation system rod connectors through in vitro pre-clinical mechanical tests developed specifically for this application (linear, lateral with square connector and lateral with oblique connector). **Methods:** Cobalt chromium rods 5.5 mm in diameter were used and coupled with three types of connectors: a) side rod with oblique connector, b) side rod with square connector, and c) rod and linear connectors. Quasi-static mechanical four-point bending and fatigue tests were performed. The variables measured were (I) the bending moment at the yield limit, (II) the displacement at the yield limit, (III) the rigidity of the system in flexion and (IV) the number of cycles until system failure. **Results:** The linear system presented the greatest force and the greatest moment at the yield limit, as well as the greatest stiffness equivalent to bending. All specimens with square and oblique connectors endured 2.5 million cycles in the minimum and maximum conditions of applied moment. The specimens with linear connector endured 2.5 million cycles with fractions of 40.14% of the bending moment at the yield limit, but failed with levels of 60.17% and 80.27%. **Conclusions:** Systems with linear connectors showed greater mechanical resistance when compared to systems with square and oblique connectors. All systems supported cyclic loads that mimic in vivo demands. **Level of evidence V; In vitro research.**

Keywords: Spinal Fusion; Essay; Experimental Implants; Arthrodesis.

RESUMO

Objetivo: Avaliar e comparar a resistência mecânica e o comportamento em fadiga associados ao uso de três modalidades distintas de conectores de hastes do sistema de fixação vertebral por meio de ensaios mecânicos pré-clínicos in vitro desenvolvidos especificamente para essa aplicação (linear, lateral com conector quadrado e lateral com conector oblíquo). **Métodos:** Foram usadas hastes de Cromo-cobalto de 5,5 mm de diâmetro acopladas a três modalidades de conectores: a) haste lateral com conector oblíquo, b) haste lateral com conector quadrado e c) haste e conector lineares. Foram realizados ensaios mecânicos quase-estáticos e de fadiga sob flexão em quatro pontos. As variáveis medidas foram (I) o momento fletor no limite de escoamento, (II) o deslocamento no limite de escoamento e (III) a rigidez do sistema em flexão e (IV) número de ciclos até a falha do sistema. **Resultados:** O sistema linear apresentou a maior força e o maior momento no limite de escoamento, bem como maior rigidez equivalente à flexão. Todos os corpos de prova com conectores quadrados e oblíquos suportaram 2,5 milhões de ciclos nas condições mínimas e máximas de momento aplicado. Os corpos de prova com conector linear suportaram 2,5 milhões de ciclos com frações de 40,14% do momento fletor no limite de escoamento, porém falharam com níveis de 60,17% e 80,27%. **Conclusões:** Os sistemas com conectores lineares apresentaram maior resistência mecânica quando comparados aos sistemas com conectores quadrados e oblíquos. Todos os sistemas suportaram carregamentos cíclicos que mimetizam as solicitações in vivo. **Nível de evidência V; Pesquisa in vitro.**

Descritores: Fusão Vertebral; Ensaio; Implantes Experimentais; Artrodese.

RESUMEN

Objetivo: Evaluar y comparar la resistencia mecánica y el comportamiento de fatiga asociado al uso de tres modalidades distintas de conectores de varilla del sistema de fijación vertebral a través de ensayos mecánicos preclínicos in vitro desarrollados específicamente para esta aplicación (lineal, lateral con conector cuadrado y lateral con conector oblicuo). **Métodos:** Se utilizaron varillas de cromo-cobalto de 5,5 mm de diámetro acopladas a tres tipos de conectores: a) varilla lateral con conector oblicuo, b) varilla lateral con conector cuadrado y c) varilla y conector lineales. Se realizaron ensayos mecánicos y de fatiga cuasi-estáticos y ensayos por flexión de cuatro puntos. Las variables medidas fueron (I) el momento flector en el límite elástico, (II) el desplazamiento en el límite elástico y (III) la rigidez del sistema en flexión y (IV) el número de ciclos hasta la falla del sistema. **Resultados:** El sistema lineal presentó la mayor fuerza y el mayor momento en el límite elástico, así como la mayor rigidez equivalente a la flexión. Todas las probetas con conectores cuadrados y oblicuos soportaron

Study conducted at the Biomechanical Engineering Laboratory of the Universidade Federal de Santa Catarina, Florianópolis, SC, Brazil.

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2,5 millones de ciclos en las condiciones mínimas y máximas de momento aplicado. Las probetas con conector lineal soportaron 2,5 millones de ciclos con fracciones del 40,14% del momento flector en el límite elástico, pero fallaron con niveles de 60,17% y 80,27%. Conclusiones: Los sistemas con conectores lineales mostraron mayor resistencia mecánica en comparación con los sistemas con conectores cuadrados y oblicuos. Todos los sistemas admitían cargas cíclicas que imitan las solicitudes in vivo. **Nivel de Evidencia V; Investigación in vitro.**

Descriptor: Ensayo, Implantes Experimentales; Artrodesis.

INTRODUCTION

Rigid, larger-diameter rods have been widely used in vertebral fixation systems for posterior spinal stabilization in recent decades. The rods have been used as connection components in vertebral fixation systems, usually coupled to the hooks or screws, which are the bone anchoring elements of these systems. This vertebral fixation modality has been widely used in the treatment of degenerative, tumoral, and traumatic diseases and deformities of the spine.¹

In revision surgeries, the extension of the vertebral fixation can be performed by surgical exposure of the initially operated vertebral segment, removal of the rod, and its replacement with a longer rod. Another technical option is the use of an additional rod connected to the rod of the primary vertebral fixation system. Connecting the rods allows the procedure to be performed with less morbidity, avoiding surgical exposure of the previously fixed vertebral segment.^{2,3} The connection is also used for multi-rod constructs, in which additional rods are used to increase biomechanical stability.⁴

The connection of the vertebral fixation system rods can be accomplished with linear or lateral connectors, which must be designed so the biomechanical stability of the vertebral fixation system is maintained. The alignment of the fixation system screws determines the choice of the rod connector modality. Linear connectors have been used when screws are aligned, and lateral connectors when the screws are misaligned and linear connection of the rods is not possible.⁴⁻⁶

With the goal of mitigating the risk of adverse events during the use of these systems, technical standard ASTM F2193-18a (*Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*), defines a clinically relevant *in vitro* testing method for verifying the safety of straight rod vertebral fixation system designs. However, there is no testing method described in the world literature that considers the effect of connector use on rod fatigue life in vertebral fixation systems. The objective of the present original experimental study is to evaluate and compare the structural characteristics and fatigue resistance associated with the use of three different modalities of vertebral fixation system rod connectors (linear, lateral with square connector, and lateral with oblique connector). The authors' hypothesis is that different connector models result in different fatigue performance of connected rod systems.

METHODS

Approval of this study by an institutional review board was not required since the research was not conducted in human or live animals. Sixty-six (66) longitudinal CoCr rods (ASTM F1573) measuring 5.5 mm in diameter and 100 mm in length (Safe System, Víncula, Brazil) and 33 titanium connectors (ASTM F136) were used to form three (3) experimental groups defined by the rod connector modality used, i.e., oblique, square or linear (Figure 1). Each specimen was made up of two rods joined by the respective connector. The oblique connector joins the rods obliquely by means of two locking counter screws. The square connector joins the rods laterally by means of four locking counter screws. The locking counter screws were tightened with a torque wrench and standardized at 12000 N.mm.

For each group, a total of eleven (11) specimens were used. Five (5) specimens were used in quasi-static four-point bending tests to determine the relevant structural characteristics for ensuring system functionality, while six (6) specimens from each group were submitted to fatigue tests. The experimental study was conducted at the Biomechanical Engineering Laboratory at the Universidade Federal de Santa Catarina (LEBm/HU-UFSC).

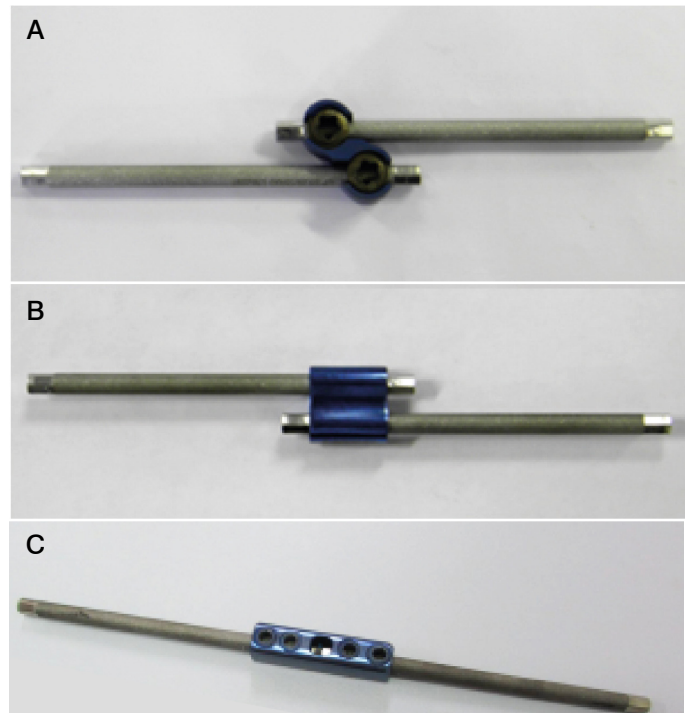


Figure 1. Rod system with oblique (A), square (B), and linear (C) connectors.

Mechanical four-point bending test

The parameters used in the tests are described in technical standard ASTM F2193-18a (*Standard Specification and Test Methods for Components Used in the Surgical Fixation of the Spinal Skeletal System*) for bending testing of straight rods used in spinal fixation systems. The novel change proposed here involved positioning the connection region of the rods at the location of the maximum bending moment (Figure 2) during the loading application phase in the quasi-static four-point bending test.

The device was adjusted so that the distance between two support points (L) was equal to 129 mm and the distance between the two load application points, as well as the distance between the load application point and the closest support, was equal to 43 mm. The support and load application rollers used are made of SAE 1040 steel and are 9.5 mm in diameter with a V-shaped notch at the midpoint of their length to better accommodate the specimen. After a pre-load of 10 N was applied to the specimen, the test was conducted under displacement control at a speed of 10 mm/min, and the Force (N) x Displacement (mm) curve was obtained for each of the specimens tested. The variables measured were (I) force at the yield point (N), (II) bending moment at the yield point (N.mm), (III) displacement at the yield point (mm), (IV) maximum force (N), (V) bending moment at the resistance limit, (VI) displacement at the resistance limit, the bending stiffness of the system. The 0.2% offset method and linear regression of the initial force x displacement curve were used to determine the yield point. The tests were performed using a universal testing machine (DL3000, EMIC, Brazil).

To perform the cyclic fatigue test, loadings of 50.00%, 75.00% and 90.00% of the mean bending moment in the yield were applied to the system with oblique connector, of 75.00%, 85.00% and 95.00% to the square connector group, and of 40.14%, 60.17%

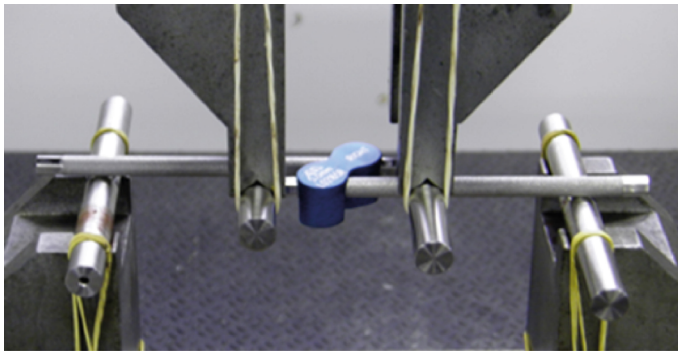


Figure 2. Example of the positioning of the specimens for conducting the mechanical tests.

and 80.27% to the group with the linear connector, calculated from the results of the quasi-static test for each group. A frequency of 5 Hz for 2.5×10^6 cycles was used to test the systems with square and oblique connectors. For the systems with a linear connector, however, a frequency of 6 Hz was applied. Two specimens were used for each loading configuration in each group. The tests were conducted using a servo-hydraulic fatigue testing machine (BME, Brasvulvas, Brazil).

Statistical analysis

For the statistical analysis of the results of the variables measured in the quasi-static four-point bending test, Bartlett’s tests were performed to evaluate the homogeneity of variance and one-way analysis of variance (ANOVA) with Tukey’s test were performed for paired comparisons. In the situation where the condition of homogeneity of variance was not satisfied, the ANOVA test with Welch correction was applied. The level of significance applied was equal to 0.05.

RESULTS

The results obtained in the quasi-static test are described in Table 1 and Figure 3. The linear connector systems presented the greatest force and the greatest moment at the yield limit than the other connection philosophies. The square and oblique connector systems showed no difference in maximum force, and both presented greater maximum force than the linear connector systems. The square connector system presented the greatest moment at the resistance limit, followed by the systems with linear and oblique connectors, respectively. Stiffness was greater in the square connector system, followed by the oblique and linear systems. As regards equivalent bending stiffness, however, the system with the greatest magnitude used the linear connector, followed by the square and oblique connector systems.

All the oblique and square connector system specimens withstood all the moments applied during 2.5 million cycles (Table 2). The linear connector system specimens withstood the bending moment of 6101.00 N.mm (40.14% of the bending moment at the yield limit) during 2.5 million cycles and failed before reaching 2.5 million cycles when subjected to bending moments of 9010.00 N.mm and 12020.00 N.mm (60.14% and 80.27% of the bending moment at the yield limit), respectively.

DISCUSSION

The literature has shown that the risk of rod breakage following surgery to restore the natural curve of the spine increases considerably when connectors are used.⁸ Connector failure accounts for 12.2% of all spine correction surgery failures and on average occurs after 2 years of implantation.⁹ However, it has been shown that the loads experienced by rods subject to daily physiological conditions are not sufficient to warrant the failure rate observed.¹⁰ Rod fractures can occur due to bending fatigue and the concentration of stress at specific points of the rod. The presence of

Table 1. Mean (standard deviation) values resulting from the quasi-static mechanical test.

	Oblique connector	Square connector	Linear connector
Force at the yield limit (N)	439.25 (11.11)	465.93 (15.96)	544.20 (14.89)
Moment at the yield limit (N.mm)	9447.23 (238.84)	10250.55 (351.14)	14974.00 (409.80)
Maximum force (N)	1384.14 (11.28)	1385.24 (6.00)	1092.20 (8.55)
Moment at the resistance limit (N.mm)	29759.01 (242.46)	30475.28 (132.04)	30036.00 (239.75)
Stiffness (N/mm)	253.41 (5.55)	302.33 (3.28)	171.00 (7.31)
Equivalent bending stiffness (N.m ²)	8.40 (0.18)	10.73 (0.12)	11.86 (0.51)

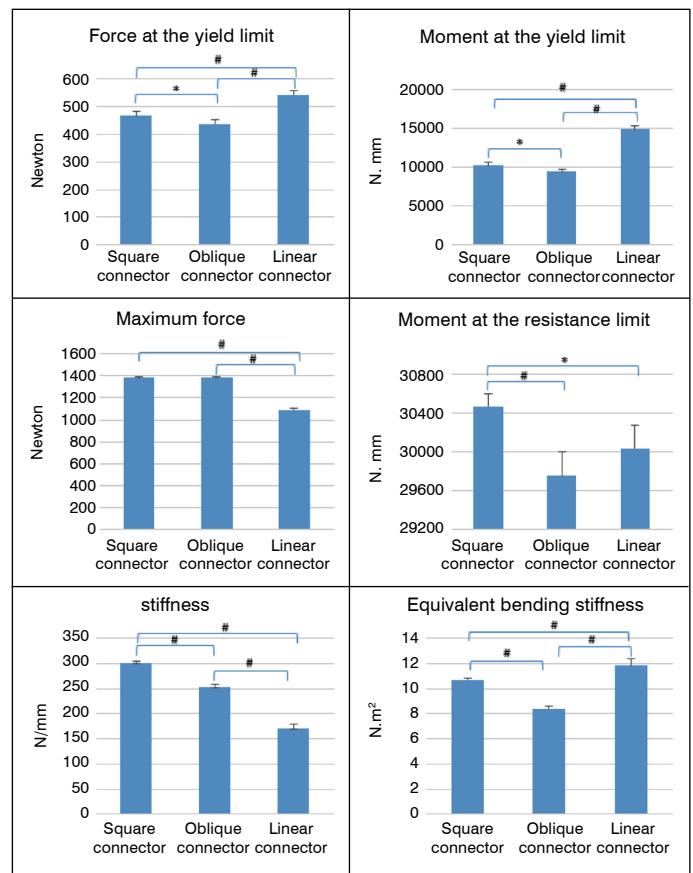


Figure 3. Quasi-static test results. * - $P < 0,05$, # - $P < 0,01$.

connectors in rod systems generates stress concentrators in the associated rods.

In the present study, a method was developed to evaluate the effect of different connectors on the fatigue performance of long constructions. In the quasi-static tests, the linear connector system showed the greatest force and greatest moment at the yield limit by a significant margin when compared to the systems with square and oblique connectors. Comparing the last two systems, both force and moment at the yield limit were greater using the square connector system. The square system also presented the greatest moment at the resistance limit and the greatest stiffness as compared to the other systems. The linear

Table 2. Fatigue test results.

Oblique connector			
Fraction of the moment at yield	Moment applied (N.mm)	Specimen	Life cycles
50.00%	4723.62	Sp 1. Sp 2	> 2.5 10 ⁶
75.00%	7085.42	Sp 1. Sp 2	> 2.5 10 ⁶
90.00%	8502.51	Sp 1. Sp 2	> 2.5 10 ⁶
Square connector			
Fraction of the moment at yield	Moment applied (N.mm)	Specimen	Life cycles
75.00%	7687.91	Sp 1. Sp 2	> 2.5 10 ⁶
85.00%	8712.97	Sp 1. Sp 2	> 2.5 10 ⁶
95.00%	9738.02	Sp 1. Sp 2	> 2.5 10 ⁶
Linear connector			
Fraction of the moment at yield	Moment applied (N.mm)	Specimen	Life cycles
40.24%	6010.00	Sp 1. Sp 2	> 2.5 10 ⁶
60.17%	9010.00	Sp 1	198613
60.17%	9010.00	Sp 2	210351
80.27%	12020.00	Sp 1	28946
80.27%	12020.00	Sp 2	30132

system had less stiffness than the oblique system but there was no difference between them in the moment at the resistance limit. However, considering the equivalent bending stiffness, the system with the linear connector had the greatest magnitude, followed by the square and oblique systems, respectively. In view of the results obtained in the quasi-static tests and using resistance to permanent deformation as the failure criterion, the best mechanical performance was achieved with linear connector systems. It should be noted, however, that systems assembled with a linear connector have the least stiffness among the systems analyzed. Therefore, the relationship of compromise established for this alternative must be considered: greater range of elastic behavior, a fundamental requirement for maintaining the functionality of the system, at the expense of less system rigidity.

Although a relevant role is frequently assigned to maximum force or to the maximum bending moment withstood by spinal implants, the rods are characterized as elements that must act within the scope of the elastic behavior regime of the material. In the case that this components yields, the system will not return to the original position, maintaining the permanent residual deformation that will change the conditions for the occurrence of intervertebral arthrodesis. These implants lose functionality if the value of the bending moment applied to them exceeds the yield moment of the connected rods. Additionally, the stiffness of rods connected by longitudinal connectors is associated with the level of lateral displacement that will be experienced when using them under the mechanical demand of the spine. The variables analyzed in the quasi-static tests in the present work reflect these assumptions. The value of the bending moment at yield and the magnitude of the lateral displacement of the rod-connector system indicate the limit of use without the occurrence of permanent deformation of these systems. Stiffness indicates the greater or lesser ease of generating deflexion of these systems under bending load.

Using instrumented implants *in vivo*, we observed that the gait and the ventral flexion of the trunk are activities with the potential to cause the failure of the fixation.⁷ The bending moment measured in the standing position was 6900 N.mm and approximately 120% (8280 N.mm) of this value was measured during the gait cycle. Because, in spine fixation systems, this moment is shared by the spine itself and the two rods connecting each vertebra, it can be estimated conservatively that each rod can withstand a load on the order of 4140 N.mm.

The results obtained indicate that all the systems analyzed have a moment at the yield limit greater than 4140 N.mm. Adopting this value as the biomechanical criterion for acceptance of the design, the

oblique connector presents a safety coefficient (SC) equal to 2.28, the square connector presents an SC of 2.47, and the linear connector presents a SC of 3.61 for the parameter moment at the yield point.

The increasing use of longitudinal rod connectors in vertebral fixation systems is directly related to the degeneration of the vertebral segment adjacent to the arthrodeses, which has been observed in 5.2 to 36.1% of arthrodeses of the lumbar and lumbosacral spines,¹¹⁻¹⁷ and surgical revision is required in 7.5 to 11% of patients.^{18,19} Surgical reintervention to treat adjacent disc degeneration can be performed by connecting the system rods or using a single rod. From a biomechanical point of view, no difference between these two fixation modalities has been observed²⁰⁻²² and the use of rod connectors results in less surgical morbidity without the need for exposure of the previously fixed vertebral segments. However, a higher risk of rod fracture has been reported with the use of connectors.²³

Connector failure accounts for 12.2% of all spinal correction surgery failures and on average occurs after two years of implantation. Rod fractures can occur due to fatigue from bending and the concentration of stress at specific points on the rod.²⁴ However, the main fixation failure mechanism is caused by fatigue of the material with the application of load while performing daily tasks. Considering that a person takes an average of 1.0 to 1.5 million steps per year and that each step corresponds to 2 peak loads on the spine, one year of daily walking activities corresponds to 3 million peak loads on the spine. Considering that the consolidation of spinal arthrodesis occurs over a period of 4 months, 1 million load cycles need to be safely supported by the vertebral fixation system rods.

Implant fracture, mainly in pedicle screws and rods, is a recognized complication following spine surgery and can be attributed to pseudoarthrosis, improper implant selection, inadequate fixation points (resulting in long lever arms, for example, due to bone resections), corrosion of the implant, and excessive loads caused by the patient's habits. Rod fracture is more commonly seen in high mechanical demand applications, such as pedicle subtraction osteotomies (PSOs) in adult spinal deformities and the use of growth rods for early onset scoliosis. Fatigue failure occurs when repeated loading creates alternating stresses on the instrumentation. The fatigue failure process is generally imperceptible to the patient until the catastrophic failure of the component occurs. Studies have examined the role of fatigue in spinal instrumentation; however, these fatigue studies limited their investigations to the behavior of fatigue in straight rods, without considering the possibility of using connectors.²⁵⁻²⁷

The results obtained indicate that all the systems analyzed withstand, without failure, more than 2,500,000 cycles under a bending moment higher than 4140 N.mm.

Safety and efficacy are fundamental requirements that need to be ensured in the design and manufacture of healthcare products so that the intended use for the medical device is satisfactorily achieved. The three vertebral fixation system connector rod modalities used in the study present structural behaviors that demonstrate the safety of the designs. The preclinical fatigue test results are a preliminary indication that the connector systems have the safety necessary to be applied *in vivo*.

The present study has some limitations. First, the mechanical tests were not conducted in a saline bath at a temperature of 37° C, creating conditions different from *in vivo* conditions. The use of a pH-controlled liquid bath would add corrosion effects to the analysis, more closely approximating reality. However, for the purpose of comparing the designs of different connectors, the same comparative basis was used (open air test/room temperature), validating the results obtained. In addition, only the bending of the systems was analyzed. Rods are subject to the effects of torsion, which can also impact system fatigue resistance. However, bending is the main loading mode supported by these medical devices.

The study hypothesis, that different connector models imply different fatigue performance in connected rod systems, was confirmed.

CONCLUSION

Rod systems connected by linear connectors support greater bending moments before they suffer permanent deformation than square and oblique connector systems, even though they are less rigid. All the systems have fatigue resistance deemed acceptable

for their intended use according to the bending moment applied during a gait cycle.

All authors declare no potential conflict of interest related to this article.

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