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USE OF THE uCentum SYSTEM IN THE SURGICAL TREATMENT OF DISEASES OF THE VERTEBRAL SPINE

UTILIZAÇÃO DO SISTEMA uCentum NO TRATAMENTO CIRÚRGICO DAS DOENÇAS DA COLUNA VERTEBRAL

USO DEL SISTEMA uCentum EN EL TRATAMIENTO QUIRÚRGICO DE ENFERMEDADES DE LA COLUMNA VERTEBRAL

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ABSTRACT

Objectives: Evaluate the treatment outcome and the performance of the uCentum spinal fixation system in treating traumatic, degenerative, and tumoral diseases of the spine. Methods: This is a therapeutic study to investigate treatment outcomes and level of evidence III, including twenty-three adult patients of both sexes undergoing surgical treatment of degenerative (13 patients), traumatic (04 patients), or tumor diseases (06 patients). Patients were prospectively evaluated using clinical parameters: pain (visual analog scale), clinical and functional assessment questionnaires (SF-36, Oswestry and Roland-Morris), and radiological criteria (arthrodesis consolidation, loosening, breakage or deformation of the implants). Results: Twenty patients were followed for a period of 01 month to 12 month (mean 6,5±7,77). Three patients died due to complications unrelated to the primary disease (traumatic brain injury, septicemia, and lung tumor). Improvements were observed in clinical parameters and scores of the evaluation questionnaires used. No implant-related complications (breakage, loosening, deformation) were observed. Conclusion: the uCentum fixation system showed great versatility for performing the surgical treatment, allowing the performance of open, percutaneous procedures, the introduction of acrylic cement inside the implants, and conversion of polyaxial screws into monoaxial screws intraoperatively. ***Level of Evidence III; Therapeutic Studies - Investigating the Results of Treatment.***

Keywords: Spine Neoplasms; Surgical treatment; Percutaneous Fixation.

RESUMO

*Objetivos: Avaliar o resultado do tratamento e o desempenho do sistema uCentum de fixação vertebral no tratamento de doenças traumáticas, degenerativas e tumorais da coluna vertebral. Métodos: Trata-se de um estudo terapêutico de investigação dos resultados do tratamento e nível de evidência III, incluindo vinte e três pacientes adultos de ambos os sexos submetidos ao tratamento cirúrgico de doenças degenerativas (13 pacientes), traumáticas (04 pacientes) ou tumorais (06 pacientes). Os pacientes foram prospectivamente avaliados por meio de parâmetros clínicos: dor (escala visual analógica), questionários de avaliação clínica e funcional (SF-36, Oswestry e Roland-Morris), e critérios radiológicos (consolidação da artrodese, soltura, quebra ou deformação dos implantes). Resultados: vinte pacientes foram seguidos por um período de 01 a 12 meses (média 6,5 ± 7,77). Três pacientes foram a óbito devido a complicações não relacionadas com a doença primária (trauma cranioencefálico, septicemia e tumor pulmonar). Foi observada melhora dos parâmetros clínicos e escores dos questionários de avaliação utilizados. Não foram observadas complicações relacionadas com os implantes (quebra, soltura, deformação). Conclusão: o sistema de fixação uCentum apresentou grande versatilidade para a realização do tratamento cirúrgico, permitindo a realização de procedimentos abertos, percutâneos, introdução de cimento acrílico no interior dos implantes e conversão dos parafusos poliaxiais em monoaxiais no intra-operatório. **Nível de Evidencia III; Estudos terapêuticos - Investigação dos resultados do tratamento.***

Descritores: *Neoplasias da Coluna Vertebral; Tratamento Cirúrgico; Fixação Percutânea.*

RESUMEN

Objetivos: Evaluar el resultado del tratamiento y el desempeño del sistema de fijación vertebral uCentum en el tratamiento de enfermedades traumáticas, degenerativas y tumorales de la columna vertebral. Métodos: Este es un estudio terapéutico para investigar los resultados del tratamiento y el nivel de evidencia III, que incluye veintitrés pacientes adultos de ambos sexos sometidos a tratamiento quirúrgico de enfermedades degenerativas (13 pacientes), traumáticas (04 pacientes) o tumorales (06 pacientes). Los pacientes fueron evaluados prospectivamente mediante parámetros clínicos: dolor (escala analógica visual), cuestionarios de evaluación clínica y funcional (SF-36, Oswestry y Roland-Morris) y criterios radiológicos (consolidación de artrodesis, aflojamiento, rotura o deformación de los implantes). Resultados: veinte pacientes fueron seguidos durante un período de 1 a 12 meses (media 6,5 + 7,77). Tres pacientes fallecieron por complicaciones no relacionadas con la enfermedad primaria (lesión cerebral traumática, septicemia y tumor pulmonar). Se observaron mejoras en los parámetros clínicos y puntuaciones de los cuestionarios de evaluación utilizados. No se observaron complicaciones relacionadas

Study conducted by the School of Medicine of Ribeirão Preto (Ribeirão Preto/SP).
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con el implante (rotura, aflojamiento, deformación). Conclusión: el sistema de fijación uCentum mostró una gran versatilidad para realizar el tratamiento quirúrgico, permitiendo la realización de procedimientos abiertos, percutáneos, introducción de cemento acrílico en el interior de los implantes y conversión de los tornillos poliaxiales en tornillos monoaxiales en el intraoperatorio. ***Nivel de Evidencia III; Estudios terapéuticos - Investigación de los resultados del tratamiento.***

Descriptores: *Neoplasias de la Columna Vertebral; Tratamiento quirúrgico; Fijación Percutánea.*

INTRODUCTION

Arthrodesis has been the most commonly used surgical procedure in the surgical treatment of spinal diseases, although new technologies have been developed to preserve the mobility of the vertebral segment.[1,2] Spinal fixation systems have been developed and improved to keep pace with trends in surgical treatment, and spinal fixation systems have been refined to keep pace with the demands and needs of surgical procedures.[3-5]

Less invasive surgery has been a growing trend in spine surgery.[6-8] The development of fixation systems that can meet the widest spectrum of procedures, from classic open procedures to the percutaneous ones that have been recently introduced, has been occurring in parallel so that the same fixation system can meet the widest spectrum of surgical procedures. The development of universal systems that can more broadly meet the technical needs of surgical procedures has technical, logistical, and economic advantages.

The uCentum system (Ulrich® - Ulm-Germany) was developed to meet the different requirements of open or percutaneous spine procedures so that large spectrums of procedures can be performed with the same spine fixation system. The uCentum system (Ulrich® - Ulm-Germany) is universal. Its versatility is characterized by its open or percutaneous use, complementation with acrylic cement for fixing the fenestrated screws, conversion of the polyaxial implant into a monoaxial one during surgery, and corrective maneuvers. (Figure 1)

The study aimed to evaluate the versatility and results of treating the spine's degenerative, traumatic, and tumor diseases using the uCentum (Ulrich®- Ulm-Germany) spinal fixation system.

MATERIAL AND METHODS

The Ethics Committee of HCFMRP-USP approved the study under No. 16606/2012. Twenty-three patients underwent surgical treatment using the uCentum spinal fixation system (Ulrich).

The uCentum system is a method of titanium vertebral fixation consisting of screws and hooks. It is indicated for treating diseases of the thoracic and lumbar segments that require stabilization or correction. The screws are polyaxial, monoaxial, and polyaxial screws that can be converted to monoaxial screws at the time of fixation. The implants are low profile and can be used along the entire length of the thoracic, lumbar, and sacral spine. All the system's screws are cannulated and fenestrated, allowing percutaneous use, use of guide wire, and infusion of acrylic cement inside. The diameter of the screws varies from 4.5 mm to 10 mm, and the length from 25 mm to 60 mm. The connecting rods of the system has a diameter of 5.5 mm. The system requires classical technical conditions such as fluoroscopy or navigation, and the supporting instruments are used according to the selected technique (open, percutaneous, less invasive, acrylic cement infusion).

The patients were evaluated using clinical parameters: pain (visual analog scale), clinical and functional evaluation questionnaires (SF-36, Oswestry, and Roland-Morris), and radiological criteria (consolidation of arthrodesis, loosening, breakage, or deformity of the implants). Evaluations were performed preoperatively, immediately postoperatively, at two, six, and 12 months.

All participating patients read and signed the Informed Consent Form, printed in two copies, which the responsible researcher also signed.

Descriptive statistics (minimum value, maximum value, mean, standard deviation, and confidence interval) were performed. The normality of the sample was assessed using the Kolmogorv-Smirnov test. Mixed effects analysis was used to compare the means of the different evaluation periods, and the significance level was set at 5% ($p < 0.05$).

Figure 1. Implantation of the uCentrum system and its adaptation for percutaneous use.

RESULTS

Of the initial sample, including 23 patients, three died due to complications related to the primary disease: head trauma, sepsis, and lung tumor. Twenty patients were followed up from 01 to 12 months (mean 6.5 ±7.77). Among this group, 09 patients (45%) were male, ranging from 29 to 75 years (mean 52.95 ±12.12). Thirteen patients had degenerative disease of the lumbar spine, three had fractures, and four had spinal tumors. The indication of surgical treatment was related to the presence of pain, instability, or compression of the nerve structures related to the degenerative, traumatic, or tumor disease in the group of patients studied. (Figures 2, 3, 4 and 5)

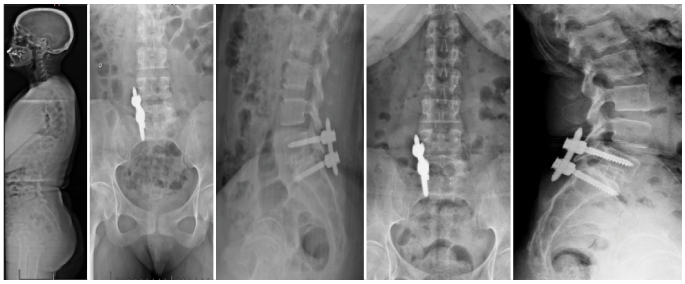

Figure 2. Pre- and post-operative radiographs and at 12-month follow-up, with the radiographic evolution of a patient with degenerative disease and root compression symptoms (pre-operative VAS 10 / post-operative 0).

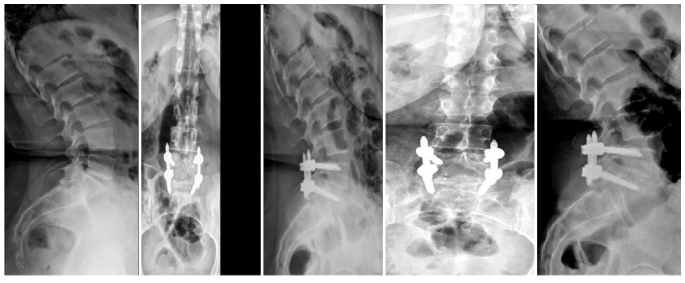

Figure 3. Radiographs of a patient with degenerative disease and symptoms of radicular compression (preoperative VAS 8 / postoperative 0).

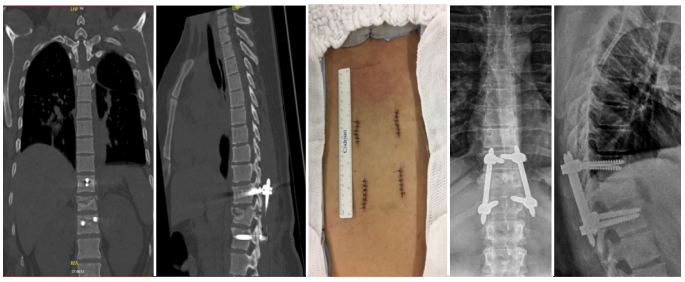

Figure 4. CT scan, post-operative photo, and radiograph at 12 months post--operative of a victim of fall from height with T11 fracture and open fracture of the sacrum.

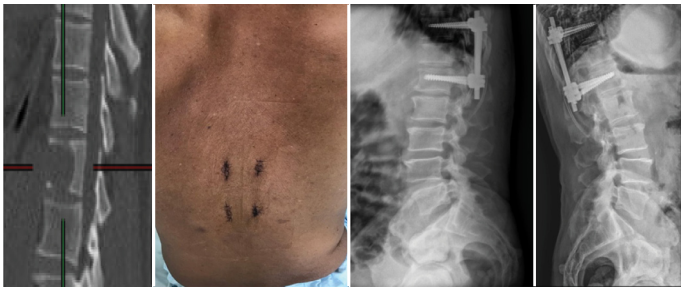

Figure 5. Preoperative tomography, radiography, postoperative clinical appearance, and radiography at 12 months postoperative and supplementary treatment with radiotherapy of a patient with thyroid tumor metastasis.

Pain assessment according to the visual analog scale (VAS) ranged from 7-10 (mean 9.15 ± 0.98) preoperatively, from 1-9 (mean 5.62 ± 2.21) in the immediate postoperative period; from 1-9 (mean 4.92 ± 2.52) at two months; from 0-10 (mean 3.55 ± 2.54) at six months; and from 0-10 (mean 3.38 ± 3.64) at 12 months. The trend of decreasing mean VAS values was observed during the follow-up of the patients. The lack of normality of all sample means and characteristics did not allow comparison by statistical methods. (Figure 6)

The functional capacity domain of the SF-36 questionnaire ranged from 0-40 points (mean 14.40 ± 14.39) preoperatively; from 0-90 (mean 37 ± 26.68) immediately postoperatively; from 0-100 (mean 47.11 ± 34.49) at two months; from 0-100 (mean 58.33 ± 33.61) at six months; and from 5-100 (mean 61.15 ± 31.17) at 12 months postoperatively. A statistical difference was observed between the preoperative values and all postoperative periods: immediate, 2, 6, and 12 months; multiple comparisons test/mixed effects model: $p < 0.05$. (Figure 7)

The physical aspects limitation domain of the SF-36 questionnaire ranged from 0-75 points (mean 7.5 ± 20.03) preoperatively; from 0-100 (mean 43.75 ± 47.21) immediately postoperatively; from 0-100 (mean 51.32 ± 50.33) at two months; from 0-100 (mean 51.39 ± 50.35) at six months; and from 0-100 (mean 57.69 ± 48.29) at 12 months postoperatively. The trend of increasing mean VAS values was observed during the follow-up of the patients. The lack of normality of all sample means and characteristics did not allow comparison by statistical methods. (Figure 7)

The pain domain of the SF-36 questionnaire (SF-32) ranged from 0-41 points (mean 18.10 ± 11.67) preoperatively; from 0-100 (mean 39.40 ± 27.54) immediately postoperatively; from 0-100 (mean 44.84 ± 32.51) at two months; from 0-100 (mean 55.28 ± 30.54) at six months; and from 0-100 (mean 59.08 ± 36.96) at 12 months postoperatively. A statistical difference was observed between the mean pain values preoperatively and at the different postoperative follow-up periods (mixed effects analysis: $p < 0.05$). (Figure 7)

The general health status domain of the S-36 questionnaire ranged from 15-55 points (mean 31.95 ± 11.87) preoperatively; from 22-82 (mean 52.95 ± 19.21) immediately postoperatively; from 22-87 (mean 56.53 ± 25.89) at two months; from 22-70 (mean 62.28 ± 21.49) at six months; and from 15-92 (mean 63.73 ± 36.96) at 12 months postoperatively. The trend of increasing mean VAS

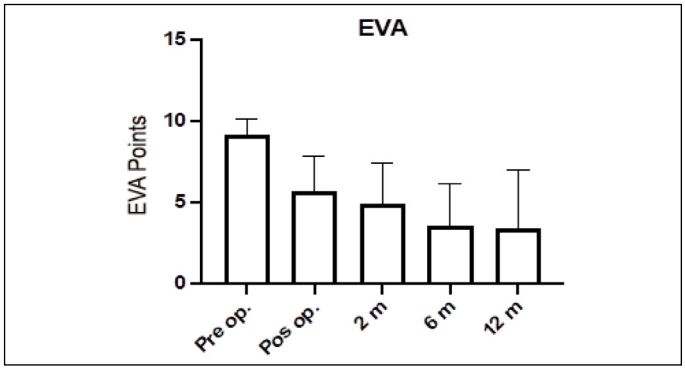

Figure 6. The average visual analog scale values on follow-up periods.

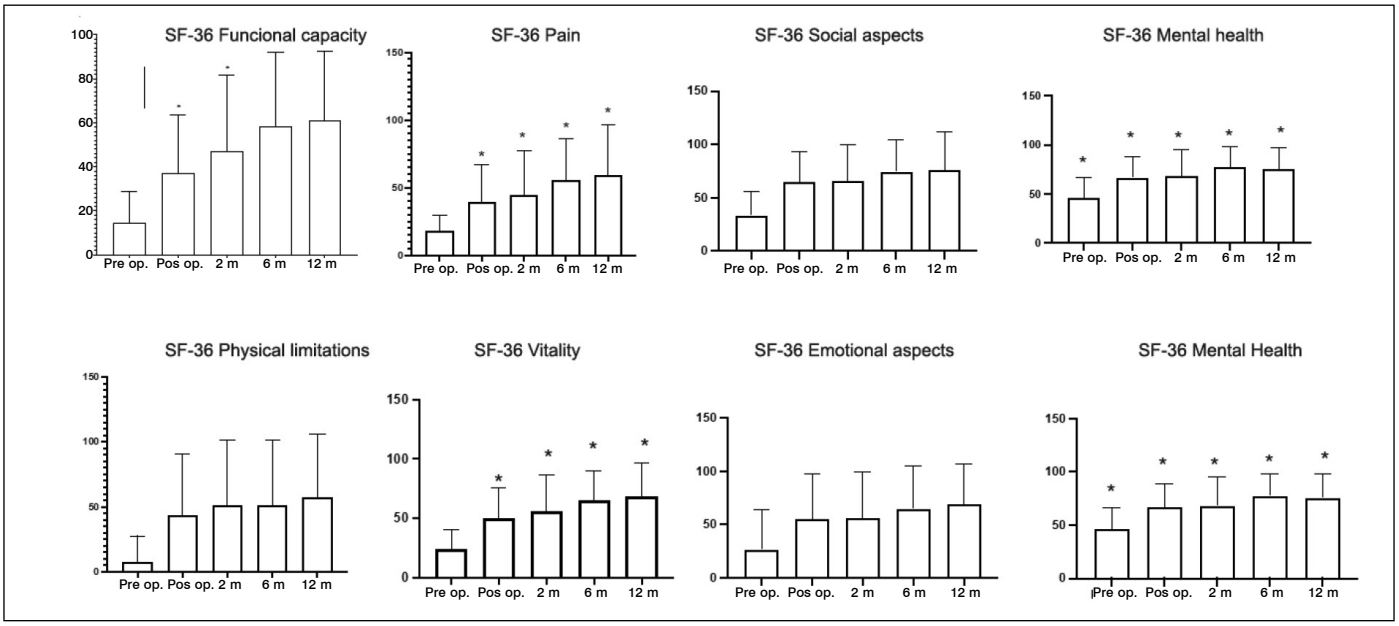

Figure 7. Comparison of the means and standard deviation on SF-36 questionnaire domains. (*): statistical difference.

values was observed during the follow-up of the patients. The lack of normality of all sample means and characteristics did not allow comparison by statistical methods. (Figure 7)

The vitality domain of the SF-36 questionnaire ranged from 0-50 (mean 24 ± 16.11) preoperatively; from 10-100 (mean 50 ± 25.70) immediately postoperatively; from 0-100 (mean 55.53 ± 31.40) at two months; from 10-100 (mean 65.28 ± 24.58) at six months; and 10-100 (mean 68.08 ± 29.05) at 12 months. A statistical difference was observed between the mean preoperative values and postoperative follow-up values (mixed effects analysis: $p < 0.05$). (Figure 7)

The social aspects domain of the SF-36 questionnaire ranged from 0-87.50 (mean 33.48 ± 22.92) preoperatively; from 12.50-100 (mean 65 ± 28.56) in the immediate postoperative period; from 0-100 (mean 65.79 ± 34.32) at two months; from 0-100 (mean 74.31 ± 30.16) at six months; and from 0-100 (mean 75.96 ± 35.89) at 12 months. (Figure 7)

The emotional aspects borderline domain of the SF-36 questionnaire ranged from 0-100 (mean 26.66 ± 36.83) preoperatively; from 0-100 (mean 54.98 ± 42.26) immediately postoperatively; from 0-100 (mean 56.12 ± 43.11) at two months; from 0-100 (mean 64.79 ± 40.38) at six months; and from 0-100 (mean 69.21 ± 37.18) at 12 months. (Figure 7)

The mental health domain of the SF-36 questionnaire ranged from 4-85 (mean 46.45 ± 20.10) preoperatively; from 28-100 (mean 66.80 ± 21.68) immediately postoperatively; from 4-100 (mean 68.21 ± 27.24) at two months; from 28-100 (mean 77.56 ± 20.77) at six months; from 28-100 (mean 75.69 ± 22) at 12 months. A statistical difference was observed between the mean preoperative values and postoperative follow-up values (mixed effects analysis: $p < 0.05$). (Figure 7)

Assessment employing the Oswestry questionnaire ranged from 15-100 (mean 53.74 ± 21.93) preoperatively; from 4-70 (mean 29 ± 19.98) in the immediate postoperative period; from 0-62 (mean 25.11 ± 19.14) at two months; from 18.42-77 (mean 18.42 ± 19.85) at six months; and from 0-77 (mean 22.38 ± 25.88) at 12 months. (Figure 8)

Assessment employing the Roland-Morris questionnaire ranged from 4-24 (mean 17.15 ± 4.92) preoperatively; from 4-24 (mean 10.55 ± 5.47) in the immediate postoperative period; from 0-24 (mean 9.05 ± 6.51) at two months; from 0-17 (mean 7.22 ± 5.14) at six months; and from 0-22 (mean 7.53 ± 7.01) at 12 months. A statistical difference was observed between the mean preoperative values and postoperative follow-up values (mixed effects analysis: $p < 0.05$). (Figure 9)

Radiological evaluation showed no breakage, deformation, loosening of the implants, or other complication related to their use. Arthrodesis consolidation was observed in the arthrodesis; fixation maintenance occurred in patients with tumor disease. In patients with fractures, loss of initial correction resulting from disc injury or accommodation of the vertebral body fracture during the healing process has been observed.

The complications observed were the death of three patients, which was related to the severity of the primary disease. One patient with a metastatic lung tumor progressed with postoperative pain

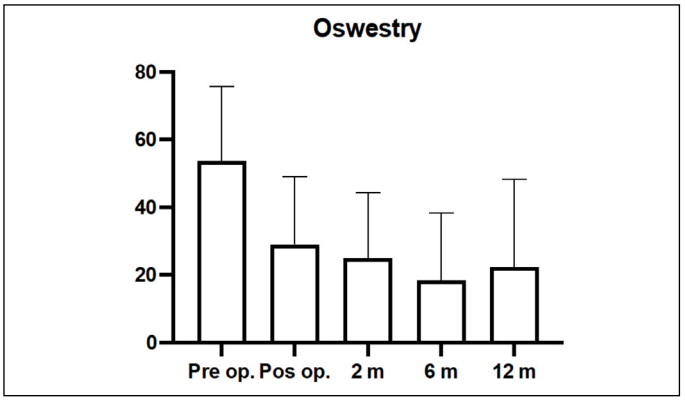

Figure 8. Evaluation using the Oswestry questionnaire.

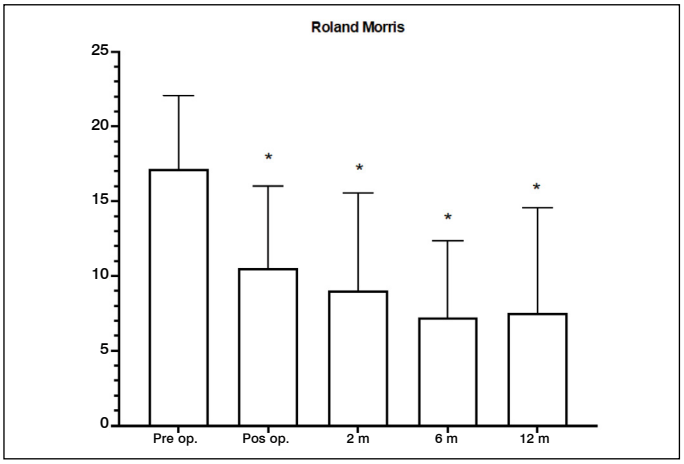

Figure 9. Evaluation using the Roland Morris questionnaire during the follow-up period.

improvement, and the cause of death during follow-up was associated with the primary disease. Another cause of death was sepsis in a patient with degenerative disease and chronic kidney disease undergoing kidney transplantation. The cause of death in the third patient was traumatic brain injury related to the primary trauma.

DISCUSSION

The uCentum fixation system has shown great versatility in the surgical treatment of degenerative, traumatic, and tumor diseases of the spine. It has allowed the performance of classically established open and less invasive or percutaneous procedures. The system also allowed the conversion of polyaxial to monoaxial screws intraoperatively and the introduction of acrylic cement inside the pedicle screws. Cannulated screws allow less invasive or percutaneous procedures and provide greater security for placing the implants inside the vertebral pedicle.[9,10]

The system's versatility for its use in open, less invasive, or percutaneous surgeries and its possibility to treat a wide spectrum of spinal diseases make the system universal with technical, logistical, and economic benefits. Different treatment techniques, such as the classic open, less invasive, or percutaneous, could be used in different diseases with the fixation system.

Percutaneous fixation has been of great use in the treatment of tumor and traumatic lesions, and the stabilization of the vertebral segment, without the need for open exposure, reduces the morbidity of the procedure and accelerates the recovery period, corroborating the growing trend towards less invasive procedures in spine surgery.[11-13] The treatment of unstable thoracolumbar spine fractures has received increasing acceptance and represents a major therapeutic advance, and the reports corroborating the advantages of this treatment modality have increased.[14] Less invasive surgery for treating spine fractures has reduced the complications and shown safety and effectiveness.[14,15] In the presence of associated lesions, as occurred in the group of patients studied who had an open fracture of the sacrum, percutaneous fixation of the fracture reduces the possibility of complications arising from the procedure.

The treatment of spinal metastases also showed a trend toward less invasive techniques due to improving complementary treatments, especially radiotherapy, and introducing new drugs.[16-18] Percutaneous fixation of metastases associated with radiotherapy in lesions sensitive to this treatment modality has significantly reduced postoperative complications. This treatment modality also allows for early complementary treatments, such as radiotherapy.

Unilateral fixation using the less invasive technique we use for the treatment of degenerative diseases allows decompression of the nerve structures, the performance of inter somatic arthrodesis through the posterior approach, and fixation of the vertebral segment. Unilateral fixation using this treatment modality has shown

promising results, and the observed results corroborate the literature reports.[19-21] We have used unilateral fixation using a less invasive approach associated with decompression and reconstruction of the anterior spine in patients with metastases. This treatment modality has been developed following the concept of unilateral fixation, and the preliminary results have been satisfactory.

The group of patients in the study was composed of different diseases. Due to the group's heterogeneity, the evaluation was not performed considering the specific diseases but through the general evaluation questionnaires (visual analog scale, SF-36, Oswestry, and Roland Morris). This modality of evaluation has been prevalent, based on the patient's understanding of his or her clinical situation, and shows the surgeon the real value of the procedure performed.[22,23] Radiographic findings are routinely used in evaluations despite their tenuous correlation with clinical results.[24,25] Clinical evaluation using the study parameters showed improvement in the different parameters selected for the different diseases and treatment methods used by the fixation system.

CONCLUSION

The uCentum spinal fixation system has allowed the surgical treatment of different spinal diseases and the use of various techniques using a single system through the classical open approach, less invasive surgery, or percutaneous surgery.

The versatility and possibility of the application of the system in different disease modalities and treatment strategies cannot be measured, and the examples and results of the application of the system express this attribute of the attachment system.

The limitation of the study consists of the number of patients evaluated and the non-specific evaluation of the use of the fixation system in specific diseases or treatments.

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

CONTRIBUTIONS OF THE AUTHORS: Each author contributed individually and significantly to the development of this article. I define HLA: acquisition, analysis, and interpretation of data for the paper, writing and critical revision of the intellectual content, and substantial contribution to the conception of the paper; Costa HRT: evaluation of patients through clinical parameters, writing and critical revision of the intellectual content; Nascimento LR: acquisition, analysis and interpretation of data for the paper, evaluation of patients through clinical parameters, and revision of the final version of the manuscript to be published. Guarato, MI: acquisition, analysis, and interpretation of data for the paper, evaluation of patients through clinical parameters, and review of the final version of the manuscript to be published.

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Erratum

In the article entitled "USE OF THE uCentrum SYSTEM IN THE SURGICAL TREATMENT OF DISEASES OF THE VERTEBRAL SPINE" authored by Helton Luiz Aparecido Defino, Herton Rodrigo Tavares Costa, Leonardo Ribeiro Nascimento, Izabella Meirelles Guarato, published in Revista Coluna/Columna Vol. 22 N.1/2023, DOI: http://dx.doi.org/10.1590/S1808-185120222201262504, by request of the authors.

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