

# PSYCHOSOMATIC AND CLINICAL PROGRESSION OF PATIENTS WITH STENOSIS OF LUMBAR CANAL UNDERGOING SURGERY WITH INTERSPINOUS SYSTEM

*EVOLUÇÃO PSICOSSOMÁTICA E CLÍNICA DE PACIENTES COM ESTENOSE DO CANAL LOMBAR OPERADOS COM SISTEMA INTERESPINOSO*

*EVOLUCIÓN PSICOSOMÁTICA Y CLÍNICA DE LOS PACIENTES CON CIRUGÍA DE ESTENOSIS DEL CANAL LUMBAR CON SISTEMA INTERESPINOSO*

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## ABSTRACT

**Objective:** The goal of this study was to evaluate the efficacy of interspinous spacers in degenerative lumbar disease and the evolution of patient's depression status and somatization preexisting symptoms. **Methods:** 20 patients with degenerative lumbar spinal stenosis were evaluated. Considering the different inclusion criteria, patients agreed to participate in the study by signing the written consent form. For clinical and psychosomatic assessment we used Euroqol Score (EQ-5D) for lumbar spine and lower limbs, Visual Analogue Scale (VAS); Oswestry Disability Index version 2.0 and Modified Somatic Perception Questionnaire (MSPQ); and Zung Self-Rating Depression Scale (ZDS). Statistical analysis was performed using Friedman and Wilcoxon tests, with significance level of 0.05. **Results:** There was an improvement in EQ-5D ( $p < 0.001$ ), VAS for lumbar spine and lower limbs ( $p < 0.001$ ), ODI ( $p < 0.001$ ), without significant changes in MSPQ ( $p = 0.197$ ). **Conclusion:** In patients with degenerative lumbar disease (Benzel grade 2, 3 and Pfirrmann grade 3, 4) and stable in psychosomatic terms, the use of interspinous spacers proved effective clinical progression and improved the rate of depression related to the pre-existing pathology.

**Keywords:** Spine; Quality of live; Depression; Orthopaedic fixation devices; Lumbar vertebrae/surgery.

## RESUMO

**Objetivo:** Procuramos avaliar a eficácia terapêutica de estabilizadores interespinosos na doença degenerativa lombar, e a evolução do índice de depressão e somatização de sintomas preexistentes nesses pacientes. **Métodos:** Estudamos 20 pacientes com estenose de canal lombar. Considerados diversos critérios de inclusão, os pacientes concordaram em participar do estudo assinando o consentimento livre e esclarecido. Na avaliação clínica e psicossomática utilizamos: Escore Euroqol (EQ-5D); escala visual analógica (EVA) lombar e dos membros inferiores; Oswestry Disability Index versão 2.0 e Modified Somatic Perception Questionnaire (MSPQ) e Zung Self-Rating Depression Scale (ZDS). A análise estatística foi realizada com os testes de Friedman e Wilcoxon, sendo o nível de significância 0,05. **Resultados:** Existiu uma melhoria em EQ-5D ( $p < 0,001$ ), EVA lombar e dos membros inferiores ( $p < 0,001$ ), ODI ( $p < 0,001$ ), sem alterações significativas no MSPQ ( $p = 0,197$ ). **Conclusão:** Em pacientes com doença degenerativa lombar (grau 2 e 3 de Benzel e 3 e 4 de Pfirrmann), estáveis em termos psicossomáticos, o uso de estabilizadores interespinosos revelou-se eficaz considerando a evolução clínica e o índice de depressão preexistente relacionado com a patologia diagnosticada.

**Descritores:** Coluna vertebral; Qualidade de vida; Depressão; Dispositivos de fixação ortopédica; Vértebras lombares/cirurgia.

## RESUMEN

**Objetivo:** Intentamos determinar la eficacia de estabilizadores interespinosos en patología degenerativa lumbar, y la evolución de los síntomas de depresión y somatización preexistentes en los pacientes. **Métodos -** Estudiamos 20 pacientes con estenosis del canal lumbar. Después de considerar varios criterios de inclusión todos los pacientes dieran su consentimiento libre, previo e informado. Para la evaluación clínica y psicossomática se utilizaron: Puntuación EuroQol (EQ-5D), Escala Visual Analógica (EVA) de la columna lumbar y de as miembros inferiores, Oswestry Disability Index versión 2.0 y Modified Somatic Perception Questionnaire (MSPQ), y Zung Self-Rating Depression Scale (ZDS). El análisis estadístico se realizó a través de pruebas de Friedman y Wilcoxon, con nivel de significancia 0.05. **Resultados:** Hubo una mejora en la EQ-5D ( $p < 0,001$ ), EVA de columna lumbar y miembros inferiores ( $p < 0,001$ ), ODI ( $p < 0,001$ ), sin cambios significativos en MSPQ ( $p = 0,197$ ). **Conclusión:** En pacientes con enfermedad lumbar degenerativa (grado 2/3 de Benzel y 3/4 de Pfirrmann) y estabilidad psicossomática, los estabilizadores interespinosos fueron eficaces, mejorando también la tasa de depresión relacionada con la patología preexistente.

**Descriptores:** Columna vertebral; Calidad de vida; Depresión; Dispositivos de fijación ortopédica; Vértebras lumbares/cirurgia.

## INTRODUCTION

When the degenerative cascade reaches high levels of progression, the therapy solution usually proposed is direct decompression, often associated with arthrodesis. This approach has been validated by various publications<sup>1-4</sup> and by our clinical practice. However,

when degenerative changes are only moderate, the selection of an appropriate therapy is never linear.<sup>5,6</sup>

As for arthrodesis, it always somewhat restricts the mobility of the intervened segment, changing the local biomechanics<sup>7-9</sup> in a way that often seems disproportionate to the pathology we are seeking to

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treat. This may contribute to a less favorable clinical outcome, which somehow gives way to a search for new solutions.<sup>10,11</sup>

Whereas the intervertebral mobility contributes decisively to the functional harmony of our spine, it seems logical to us to look for alternatives that preserve it as much as possible. It is in this context that alternative techniques seeking to combine therapeutic efficacy and retention of mobility have emerged.

Interspinous instrumentation cannot be considered an alternative to arthrodesis, but can be used prior to decompression alone or other dynamic stabilization techniques, or even non-surgical treatment.<sup>12,13</sup> It is therefore important to realize its possible effectiveness in treating lumbar degenerative disease and the consequent influence on the natural evolution of its pathology. It is precisely its simplicity and reported low morbidity that, coupled with the favorable results we have been obtaining, led us to assess the therapeutic efficacy of these devices.

Thus, the aim of this work was to evaluate the therapeutic clinical efficacy of semi-rigid interspinous dynamic stabilizers when used in patients with lumbar canal stenosis and degenerative vertebral disc disease, and the variations of the psychosomatic profile.

## MATERIAL AND METHODS

The study was conducted on a series of 20 patients with degenerative lumbar disease, selected according to the following inclusion criteria: over 40 and under 80; gender and race considered irrelevant; body mass index (BMI) less than 40; chronic pain during the last year and classified as greater than grade four according to the visual analog scale of pain (VAS) in the lower limbs or in the lumbar spine; acute pain of intensity greater than grade six (VAS) in the lumbar spine or in lower limbs as long as preceded by chronic pain for the last year (VAS 4 or higher); functional impairment as measured by the Oswestry Disability Index (ODI)<sup>14</sup> always above 30%; moderate lumbar degenerative disc disease located on the cranial caudal side always after disc L2-3 and classified as grades three and four according to Christian and Pfirmann;<sup>15</sup> possibly associated with disc prolapse; Meyerding grade one spondylolisthesis as long as the etiology is degenerative, segmental instability confirmed by radiological dynamic exams with posterior misalignment of less than 2 mm; having undergone nonsurgical treatment (physical therapy and medication) for six months without clinical and functional success; not having undergone other lumbar spine surgeries; a Zung ZDS (Zung Self-Rating Depression Scale)<sup>16</sup> index less than 50 and a MSPQ (Modified Somatic Perception Questionnaire)<sup>17</sup> symptoms somatization index less than 15, confirming the absence of depressive tendencies or exacerbated somatization of symptoms; not being involved in litigation of any nature.

All patients agreed to participate in the study by completing the appropriate informed consent form.

The study group (SG) thus included six males (30%) and 14 females (70%), 16 (85%) of whom were Caucasian and three (15%) of whom were African.

At surgery their ages ranged between 43 and 76 years, body weight ranged between 48 kg and 88 kg, and height ranged between 1.47 m and 1.73 m.

Twelve patients had been retired with ages 35 to 68 years old. Of the 14 women evaluated, 13 were already in menopause that occurred between 42 and 55 years.

The members of this study group (SG) were all operated by the present author using a semi-rigid interspinous (DIAM-Medtronic™) dynamic stabilization system. (Figure 1) The surgery was performed on L4-L5 in 16 patients (75%), L4-L5-S1 in one patient (5%), and L3-L4-L5 in four patients (20%). In 11 patients (55%) a foraminectomy for decompression was also performed.

Patients were subjected to complementary tests to assess their medical condition pre-surgery, and thromboembolism prophylaxis was performed by administration of 40 mg subcutaneous enoxaparin daily, supplemented by compression stockings during surgery, and until the normalization of the activities of daily living.

The operations were performed under general anesthesia in a Wilson splint, after infiltration of the skin and subcutaneous tissue with a 1% diluted adrenaline solution.

All patients were operated using a minimally invasive technique and a tubular approach was used in 11 patients. (Figures 2 and 3)

Hospital discharge occurred invariably at 24 hours after surgery. No noteworthy complications occurred during the procedures.

A record was kept of all of the elements collected (pre-, 1 year, and 2 years after surgery) in accordance with the universally recognized rules for an orthopedic clinical evaluation.

In patients with degenerative lumbar pathology, general health was measured in terms of quality of life, using an official form in Portuguese, with its evaluation algorithm provided by Euroquol group 1990 (EQ-5D), and towards this end the study



Figure 1. Lateral X-ray of the lumbar spine revealing dual system DIAM (L4-L5-S1).



Figure 2. Tubular approach of the lumbar spine (Medtronic©) for decompression and DIAM application.

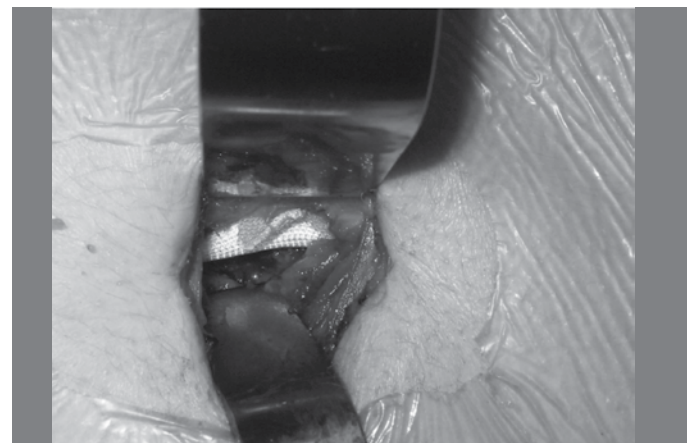


Figure 3. "DIAM" inserted.

was registered in the central Dutch database; acute and chronic pain in the lower back and lower limbs was measured with the visual analog scale of pain (VAS); the degree of lumbar disability was measured using the ODI (Oswestry Disability Index) version 2.0 duly validated in Portuguese; the likelihood of somatization of symptoms was measured by the MSPQ (Modified Somatic Perception Questionnaire); and depressive tendencies were measured with ZDS (Zung Self-Rating Depression Scale).

Statistical analysis of the collected data was carried out with specialized support in this area, and adapted to the specific work to be performed.

Thus, the Lillieford and Shapiro-Wilk test was first used to assess the possibility that the data had a Gaussian distribution. Since such distribution did not seem to exist, nonparametric tests (Friedman and Wilcoxon) were then selected for the two-year clinical evaluations.

It should be noted that the level of significance was set at 0.05.

## RESULTS

The results of the clinical and functional assessment are referred to in means and standard deviations as well as their time of evolution and are presented in Table 1.

The quality of life measured by the EQ-5D was  $0.339 \pm 0.235$  preoperatively and this value changed to  $0.849 \pm 0.070$  after the first year, with  $p < 0.001$ . Importantly, this trend seems to have been maintained over time, since in the second year, we obtained  $0.843 \pm 0.057$  with  $p < 0.001$  compared to preoperative values, and  $p = 0.684$  compared to the first year.

The value obtained for VAS in the lumbar region on average and standard deviation preoperatively was  $6.60 \pm 2.25$ , constituting a  $1.00 \pm 0.77$  improvement in the first year, with  $p < 0.001$ . In the second year, we obtained  $0.80 \pm 0.68$ , with  $p < 0.001$ , compared to the preoperative score, and  $p = 0.406$  in the comparison between the first and second years. Regarding the VAS for the lower limbs it was  $6.10 \pm 2.61$  preoperatively,  $1.20 \pm 1.37$  in the first year, and  $1.10 \pm 0.69$  in the second year. Comparative analysis of these values resulted in  $p < 0.001$  between the preoperative and both the first and second years, and  $p = 0.958$  between the first and second years. We believe that very significant improvements were observed in both locations in some way that were maintained throughout the study.

The evaluation revealed a preoperative ODI value of  $55.00 \pm 16.67$ , which changed to  $13.00 \pm 10.13$  and  $13.00 \pm 10.18$  in the first and second years, respectively. Comparative statistical analysis of these values showed  $p < 0.001$  in the first and second years compared to preoperative values, with  $p = 0.493$  when comparing with each other the values obtained in the first and second years.

Again we find a significant improvement which was maintained throughout our study.

In the assessment of depressive tendencies with ZDS, we obtained  $30.36 \pm 5.6$  preoperatively, which changed to  $27.40 \pm 6.40$  in the first year ( $p = 0.004$ ) and  $27.08 \pm 6.38$  in the second year ( $p = 0.006$ ). When we comparatively analyzed the values in the first

and second years, we obtained  $p = 0.172$ . In line with that described for other parameters, we had a clear improvement after the first year, which continued to be observed at the end of our study.

As for the MSPQ, which measures the possible somatization of symptoms, we found a value of  $5.60 \pm 4.16$  preoperatively and  $5.00 \pm 4.14$  and  $5.00 \pm 4.06$ , respectively, in the first and second years, but with a  $p = 0.197$  throughout the study, revealing a stability of our sample with regards to this parameter.

## DISCUSSION

During the last decade, we have witnessed remarkable technological development, which curiously does not seem to be accompanied by an equal scientific production. This clear disparity between clinical practice and research should be changed in the short term, especially for ethical, but also economic reasons. Effective scientific evaluation governed by reliable scientific principles is essential.<sup>18,19</sup> Thus, we fully agree with those<sup>20-27</sup> who recommend the use of multiple means of measurement that respect cultural, social, and personal differences present in the patients that we propose to evaluate, and it is in this manner that we developed this prospective study.

Data were collected over the course of two years, usually considered the minimum assessment period for patients with lumbar pathology, far outlasting the healing time of muscles that may be affected by the surgical approach.<sup>28-31</sup>

The fact that we measured a dynamic stabilization technique made it essential to include only patients with moderate lumbar pathology, who had somehow retained the segmental mobility of their spine. We then selected Benzel lumbar degenerative bone pathology types 2 and 3, and Pfirrmann degenerative disc disease types 3 and 4.

To clinically and functionally evaluate the patients of the study group, we measured the quality of life, pain intensity, lumbar disability, and psychological profile, selecting the tests we deemed most appropriate for this purpose, bearing in mind the designated minimum clinically important difference (MCID) for each test.<sup>30,32-34</sup>

Quality of life, in terms of overall health, can be defined as the self-perception of the functional effects attributed to any pathology and its corresponding treatment, basically reflecting how an individual perceives to have gained or lost quality of life. To this end, we selected the Euroqol (EQ-5D) form due to its reliability and validation in the Portuguese language.<sup>35-49</sup> In our patients preoperatively, the result was on average 0.339, indicating a notorious decrease in the expected quality life. With the passage of time, the postoperative evaluation showed an unquestionable substantial improvement, with results representing increases in the order of 250% ( $p < 0.001$ ). To reinforce the importance of this, it should be noted that the MCID set for this parameter equals any increase.

Mariotti et al.<sup>50</sup> had already described a positive result when studying the quality of life of a group of patients with lumbar stenosis that had surgery with interspinous systems, having however used the Dallas Pain Questionnaire.

**Table 1.** Results of clinical and functional evaluation of the study group (mean and standard deviation) and its comparative analysis.

Variable	Pre-surgery	After 1 year	After 2 years	Global comp. p value*	Comp. of Pre-1 year p value **	Comp. of Pre-2 years p value **	Comp. of 1 year 2 years p value **
EQ-5D	$0.339 \pm 0.235$	$0.849 \pm 0.070$	$0.843 \pm 0.057$	<0.001	<0.001	<0.001	0.684
Oswestry (ODI)	$55.00 \pm 16.67$	$13.00 \pm 10.13$	$13.00 \pm 10.18$	<0.001	<0.001	<0.001	0.493
Lumbar VAS	$6.60 \pm 2.25$	$1.00 \pm 0.77$	$0.80 \pm 0.68$	<0.001	<0.001	<0.001	0.406
LL VAS	$6.10 \pm 2.61$	$1.20 \pm 1.37$	$1.10 \pm 0.69$	<0.001	<0.001	<0.001	0.958
Zung	$30.36 \pm 5.06$	$27.40 \pm 6.40$	$27.08 \pm 6.38$	0.004	0.004	0.006	0.172
MSPQ	$5.60 \pm 4.16$	$5.00 \pm 4.14$	$5.00 \pm 4.06$	0.197	—	—	—

Significance  $p \leq 0.05$ . \* Friedman test; \*\* Wilcoxon test.

The following year, Hsu et al.<sup>51</sup> confirmed that described by Mariotti, finding significant improvement in SF-36, studying patients with the same pathology operated with an identical technique. It should be noted that this improvement was also observed by Anderson et al.<sup>52</sup> and Siddiqui et al.<sup>53</sup>

Although we used the EQ-5D, our results resemble those of the authors mentioned, though none reported an improvement as significant as that which we obtained.

Uncontrollable pain is often a determining factor for performing surgery. It is essential to assess its severity and evolution,<sup>54</sup> measured by its observed intensity and the functional disability it creates. Note that although this last detail is the most difficult to obtain<sup>55-57</sup>, for a correct characterization of the latter, both symptoms should be evaluated together.<sup>61-58</sup> For an appropriate quantification of pain reported by our patients, we used the VAS, which has widespread use and is recommended for this type of study,<sup>62-64</sup> associated with a topographical representation of location made by the patients themselves, complementing its desirable psychological characteristics.<sup>65,66</sup> As is known, this aspect has an especially important role in situations of chronic pain.<sup>67,68</sup> We also evaluated pain at the time it was felt, and over the two years post-surgery as some authors have recommended.<sup>69</sup> The VAS value obtained preoperatively averaged higher than six in all of the areas studied, regressing 5.6 points ( $p < 0.001$ ) in the lower limbs and 4.9 points ( $p < 0.001$ ) in the lumbar region. It is a very favorable evolution, especially if we remember that the MCID for this parameter is only two points (20%). It should be noted that even an exaggerated MCID of four points, as suggested by Carragee,<sup>70</sup> is below the value described in our study.

Wiseman et al.<sup>71</sup> reported that interspinous systems positively influenced pain, especially if it had a facet origin, since they decrease the pressure on these joints during different activities of daily living. Senegas et al.<sup>72</sup> had already confirmed the improvement of low back pain and radiculalgia in a series of 300 patients studied, attributing it to the central and foraminal resizing inherent in interspinous instrumentation. More recently, Laurysen<sup>73</sup> and Taylor et al.<sup>74</sup> reiterated these statements. However, none of these evaluated patients for a period similar to ours, or referred to an equal percentage of improvement. Our result may also be related to the same biomechanical effect, but it should be noted that it resulted from the use of the analog scale of pain, and not a verbal scale such as that which Taylor used. Thus, we consider that the values described are broadly in line with what is published by the authors cited, but they outnumber us in certain aspects underlining the therapeutic efficacy of the technique employed.

The degree of lumbar disability is one of the fundamental parameters of the clinical assessment of patients with lumbar degenerative disease. Although Müller et al.<sup>27</sup> mention that 82 questionnaires exist that are used in this type of pathology, the ODI, besides being widespread, won our preference since we were evaluating patients with severe pain. The 2.0 version selected is validated for the Portuguese language, and has been regarded as more effective the greater the severity of symptoms.<sup>3,36</sup>

On average, we obtained a preoperative value of 55% for the ODI, which reflects that we are dealing with individuals with disabilities significantly higher than our inclusion criteria (30%). A very significant improvement recorded shortly after the first year (76% with  $p < 0.001$ ) remained in the assessment at two years, and is well above the 18% referred MCID for this test.<sup>33</sup>

Several studies that assess physical disability with degenerative lumbar disease treated with interspinous systems are known, but in many cases the ODI was not used, which imposes some constraints in comparing them with our study. Anderson et al.<sup>52</sup> describe a 63.4% improvement using the Zurich Claudication Questionnaire (ZCQ) while Zucherman et al.<sup>75,76</sup> with the same survey found 44.3% in two multicenter prospective and randomized studies. Even knowing that the ZCQ is not one of the most widely used tests for this type of evaluation,<sup>27</sup> and that the patients were operated using rigid and not semi-rigid interspinous systems, it should be noted that our result seems to be superior to that described by these authors, including

the study by Siddiqui et al.<sup>53</sup> who are known to have combined the ZCQ with the ODI, and mention an improvement of 43%.

Kondrashov et al.<sup>77</sup> used the ODI exclusively for patients with a mean age of 67 years reporting, after four years of evolution, an improvement from 45 to 15, constituting a change of 30, well above the MCID of 15 under consideration. This is the study that is best suited to a comparison with our study, which still had superior results, reinforced by the greater previous limitation of patients which, as mentioned, allows for a greater effectiveness of the ODI.

We consider psychosomatic evaluation of our patients to be fundamental, considering its potential influence on the outcome of patients undergoing lumbar surgery.<sup>78,79</sup> However, it should be noted that this may be made possible by the intensity of symptoms present, especially when dealing with situations of chronic pain.<sup>80</sup> Because this is precisely our case, we decided to conduct the test, selecting the Zung Self-Rating Depression Scale (ZDS) as an index of depression, and the Modified Somatic Perception Questionnaire (MSPQ) as an index for the somatization of symptoms. These tests are included among those that are usually recommended when seeking to evaluate patients with degenerative lumbar disease.<sup>33</sup>

In our study and on average both the ZDS and the MSPQ values were far from the inclusion criteria, considered 49 and 36 respectively, which seems interesting to us, because it reveals a crucial psychological stability in candidates for lumbar surgery.<sup>30,81</sup> We found a 9.7% improvement in the ZDS, with  $p = 0.004/p = 0.006$ , and 10.7% improvement for the MSPQ, although  $p = 0.197$ . It should be noted that as is known the MCID for these parameters is any resulting improvement.

Hobby et al.<sup>78</sup> and Mannion and Elfering<sup>33</sup> have mentioned that a possible psychosomatic dysfunction may by itself not be a factor that would contraindicate lumbar surgery, mentioning the improvement of clinical parameters after surgery, which seems to indicate that poor surgical outcomes increase the rate of depression. When we look at our results, we found that the unequivocal clinical and functional improvement obtained was accompanied by the improvement of one or both of the ZDS and MSPQ. However, if the ZDS improvement was obtained with statistical significance, that was not confirmed with the MSPQ, where improvement was not obtained, becoming, on the other hand, an indicator of prior emotional stability that remained unchanged throughout the study, reinforcing our research interest.<sup>32,33,82</sup> In summary, we obtained a clear clinical and functional improvement of our patients that was maintained throughout the two years of assessment and was significantly accompanied by the rate of depression (ZDS), while the MSPQ remained within the normal range, while showing no significant improvement after surgery.

We know that both Taylor et al.<sup>74</sup> and Kim et al.<sup>83</sup> reported a similar result. However, it should be clarified that neither evaluated psychosomatic function of their patients separately, and also showed follow-ups of only 18 and 12 months respectively, which seems insufficient to us. We recall that our study was performed during the minimum recommended period (two years), and used a psychosomatically stable sample, enhancing the interest and validity of the results.

## CONCLUSION

We conclude that in situations of moderate lumbar bone (Benzel type 2/3) and disc (Pfirman type 3/4) disease, the use of a semi-rigid interspinous system was effective in the symptomatic and functional improvements of patients. Furthermore, in psychosomatically stable patients, the depression index improved along with clinical and functional improvements.

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All authors declare no potential conflict of interest concerning this article.

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