 Acta Chir. orthop. Traum. čech., 83, 2016, No. 4
p. 263–268

ORIGINAL PAPER
PŮVODNÍ PRÁCE

Radiological Changes after Interspinous Dynamic Stabilisation for Lateral Stenosis of Lumbar Spinal Canal: A Parallel Group Randomised Trial

Radiologické změny po interspinózní dynamické stabilizaci pro laterální stenózu páteřního kanálu: randomizovaná studie paralelně léčených skupin

J. MOHAR[1], M. CIMERMAN[2]

[1] Department of Spine Surgery and Paediatric Orthopaedics, Valdoltra Orthopaedic Hospital, Ankaran, Slovenia
[2] Depratment of Traumatology, Ljubljana University Medical Centre, Ljubljana, Slovenia

ABSTRACT

PURPOSE OF THE STUDY

Interspinous dynamic stabilisation devices (IDSDs) are used for stabilisation and indirect decompression of the spinal motion segment in minimally invasive treatment of degenerative conditions of lumbar spine. Good methodological quality studies on biomechanical effects of IDSDs are lacking in scientific literature. The purpose of this study was to evaluate the biomechanical effect of dynamic IDSD implantation on a spinal motion segment.

MATERIAL AND METHODS

We conducted a parallel group randomised trial (RT) on twelve patients, comparing radiological stabilisation and indirect decompression outcome measures between groups of patients with an isolated degenerative condition of L4-L5 motion segment and unilateral L5 nerve root radiculopathy. One group of six patients was operated by decompression and dynamic IDSD implantation and the other group of six patients by decompression alone. The radiological assessment was performed 6 months postoperatively in all patients.

RESULTS

Dynamic IDSD implantation significantly decreased segmental intervertebral angle (IA) and significantly increased segmental foraminal height (FH) and foraminal width (FW). The implantation had no effect on segmental range of motion (ROM) and posterior disc height (PDH).

CONCLUSIONS

The studied dynamic IDSD improved radiological indirect decompression outcome measures while only partially improved radiological stabilisation outcome measures.

Oxford Centre for Evidence-Based Medicine 2011 Level 3: randomised trial with small effect size.

Key words: lumbar spine, degenerative lateral stenosis, interspinous dynamic stabilisation, DIAM, randomised trial.

INTRODUCTION

Degenerative lateral stenosis (DLS) of lumbar spinal canal is defined as an anatomical variation of spinal canal stenosis in the area where a nerve root passes from the thecal sac to the exiting zone of the intervertebral foramen (11). The predominant clinical manifestation of DLS are symptoms and signs of radiculopathy that are exacerbated in lumbar extension and relieved in lumbar flexion as a result of either increase or decrease of a nerve root and vascular tissue compression in the intervertebral foramen, respectively (6, 14). The incidence of DLS ranges between 8% and 11% and the gold standard of its treatment is currently a direct surgical nerve root decompression (7).

In recent decade and a half, IDSDs have been used for stabilising the spinal motion segment by distraction of the interspinous space and limitation of extension and for indirect decompression of the intervertebral foramina (3, 8, 15). This heterogeneous group of implants functions as either dynamic (deformable) or static (rigid) spacer and the implants are either stand-alone devices or act as an adjunct to a decompressive procedure. IDSDs have been used for minimally invasive treatment of various diseases in the continuum of lumbar spine degeneration pathology (5, 23). To this day there exists only one RT on biomechanical effects of an IDSD and only one clinical RT comparing decompression and static IDSD implantation with decompression alone (13, 24). With the lack of good methodological quality clinical studies on IDSDs and scientifically based consolidation of proper indications, and, furthermore, due to recent reports of complications, revisions and higher costs of implantation compared to standard decompression procedures, the use of IDSD has been somewhat falling out of use in the last years (4, 19, 20).

To our knowledge no dynamic IDSD has ever been biomechanically studied in an RT and no RT has ever compared decompression and a dynamic IDSD implantation with decompression alone. We conducted a parallel group RT in order to assess the biomechanical effects of a dynamic IDSD implantation on an isolated spinal motion segment and we hypothesised that radiological stabilisation and indirect decompression outcome measures would be significantly improved in a group with dynamic IDSD.

MATERIAL AND METHODS

Study design

After having granted approval from National Medical Ethics Committee we conducted a single-centre parallel group RT. The study time-frame from the first enrolment to the last follow-up spanned from August 2013 to July 2015. A total of twelve consecutive patients with clinical and MRI diagnosis of L4-L5 motion segment DLS and unilateral L5 nerve root radiculopathy were recruited from the first authors affiliated medical institution with allocation ratio of 1:1 as shown in Figure 1. The clinical diagnosis was made by an orthopaedic surgeon and the radiological diagnosis by a radiologist independently. The key inclusion criteria were: the age over eighteen

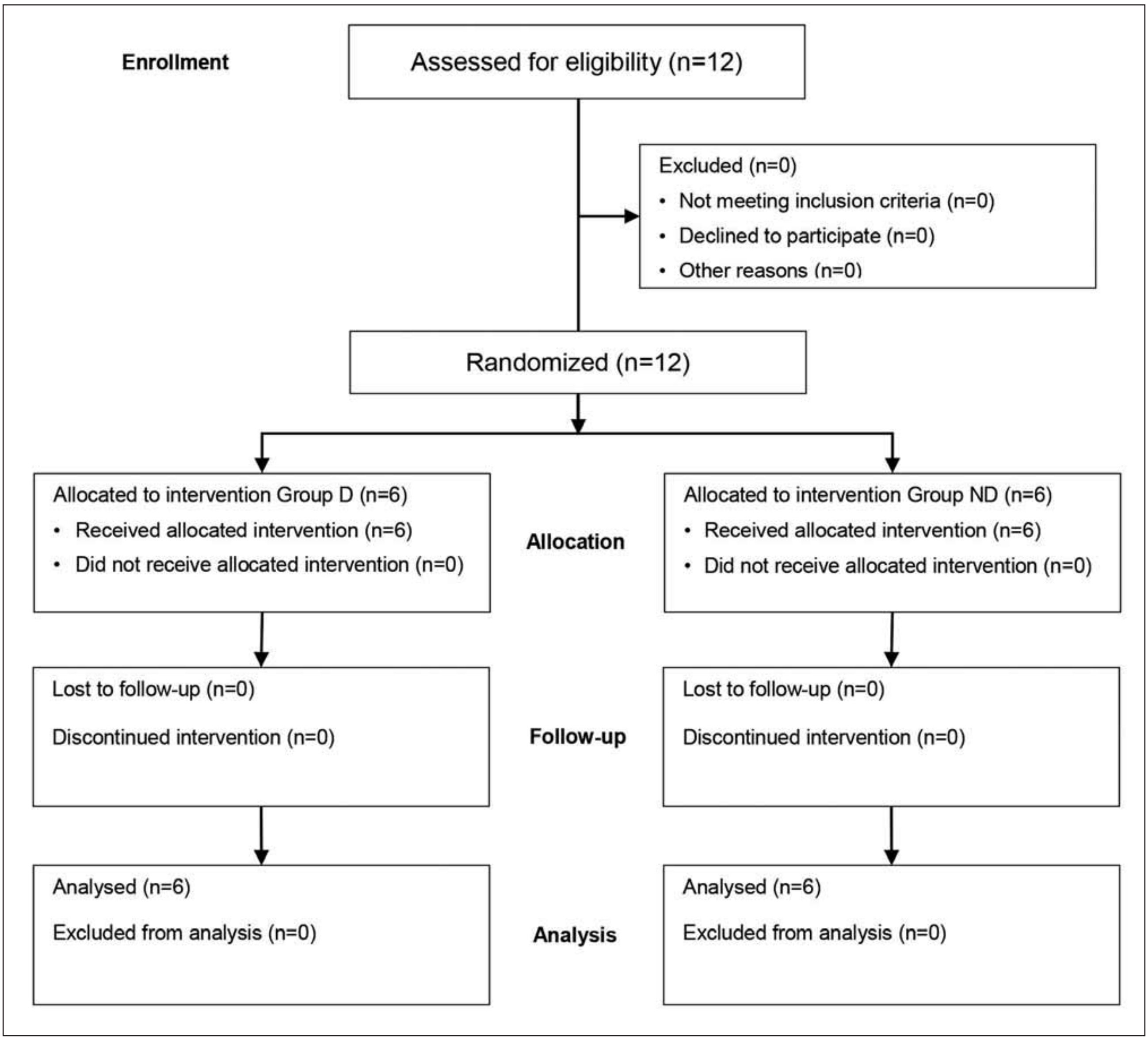

Fig. 1. RT participant flow diagram

years, at least six months of unsuccessful conservative treatment, Pfirrmann gr. I–IV disc degeneration, Schizas gr. A central spinal stenosis, Fujiwara gr. 1–3 facet joint osteoarthritis, ASA general health gr. 1–3. Key exclusion criteria were: peripheral arterial occlusive disease, peripheral neuropathy, hip pathology, symptoms of neurogenic intermittent claudication, disc herniation on any lumbar level, previous spinal operation, spinal instability or deformation, previous trauma, tumor, infection or metabolic bone disease of the spine. Patients were assigned consecutively to Group D or Group ND by a method of nonalgorithmic simple randomisation and they were blinded to interventions after assignment. The patients in Group D received a decompressive procedure (posterior midline approach, flavectomy and laminotomy with possible additional partial facetectomy and/or foraminotomy) and IDSD implantation – DIAM™ Spinal Stabilization System (Medtronic, USA). An IDSD implantation was performed according to manufacturer's instructions. The patients in Group ND received a previously described decompressive procedure without an IDSD implantation. All operations were performed by a single surgeon (first author). All patients received a standardised rehabilitaiton and were assessed a few days preoperatively and six months postoperatively by a standardised lateral radiographic image of lumbar spine in a standing position of neutral, flexion and extension. At the time of pre- and postoperative radiological assessment, the patients also completed the standardised forms of Oswestry Disability Index (ODI) questionnaire and Visual Analog Scale for lumbar (VAS-lumbar) and leg (VAS-leg) pain. The average time of postoperative radiological and clinical assesment was 196 days for group D and 188 days for group ND, respectively.

Demographics

The study cohort consisted of 6 males (50%) and 6 females (50%). There were 4 males and 2 females in Group D and 2 males and 4 females in Group ND. The average age of the study cohort was 50 years (range 36 to 61) with the average age of 49 years (range 36 to 55) and 51 years (range 39 to 61) for Group D and Group ND, respectively. The groups were compared for age, height, weight and Body Mass Index (BMI) using a χ^2 test and they were homogeneous ($p = 0.35$). Table 1 represents the baseline demographic characteristics of studied groups.

Outcome measures

The radiographic images in a DICOM format were exported to the EBS program (Ekliptik, Slovenia) and all measurements were conducted by an independent observer. The radiological stabilisation outcome measures were IA in neutral, formed by lines drawn on the upper endplates of adjacent vertebra, segmental ROM in flexion (ROM-F), calculated as the difference between IA in neutral and IA in flexion, segmental ROM in extension (ROM-E), calculated as the difference between IA in extension and IA in neutral, total segmental ROM (tROM), calculated as the difference between IA in extension and IA in flexion and PDH in neutral. The radiological indirect decompression outcome measures were FH in neutral, measured as the distance between the most upper and the most lower point of the intervertebral foramen, and FW in neutral, measured as the distance between the most anterior and the most posterior point of the intervertebral foramen. All data were collected in the first author's affiliated institution with no data being excluded for any reason.

Statistical analysis

The radiological stabilisation and indirect decompression outcome measures were compared as differences in pre- and postoperative means within groups using a paired t-test and between groups using a t-test for independent samples. The effect size was interpreted according to Cohen 1998 classification with small, medium and big effect sizes at $d < 0.2$, $d \cong 0.5$ and $d > 0.8$, respectively. The statistical significance was set at $p \leq 0.05$. SPSS software package, version 22.0 (IBM, USA) was used for all statistical analysis.

RESULTS

Analysis of outcome measures within groups

The difference between the pre- and postoperative IA in neutral within Group D showed a statistically significant ($p = 0.014$) decrease of IA postoperatively. The same difference was also statistically significant within Group ND ($p = 0.037$), corresponding to a slight increase in the postoperative IA. The differences between the pre- and postoperative ROM-E, ROM-F, tROM and PDH in neutral were not statistically significant in either group. The differences between the pre- and postoperative FH in neutral and FW in neutral within Group D were both statistically significant with p values 0.031 and 0.018, respectively, corresponding to the postoperative increase of FH and FW. The same differences were not statistically significant within Group ND.

Analysis of outcome measures between groups

The comparison of the differences between the pre- and postoperative IA in neutral showed a significant

Table 1. Baseline demographic caracteristi cs of Group D and Group ND

	n	Age [year]		Height [cm]		Weight [kg]		BMI [kg/m²]	
		M	SD	M	SD	M	SD	M	SD
Group D	6	49.2	7.4	174.2	9.2	82.8	10.2	27.4	3.7
Group ND	**6**	**51.2**	**9.1**	**169.5**	**10**	**72.7**	**20.4**	**25**	**5.3**
Combined	12	50.2	8	171.8	9.5	77.8	16.3	26.2	4.5

Table 2. Comparison of radiological outcome measures between groups

OUTCOME MEASURE	M	SD	M	SD	F	t	p	d
IA difference [°]	4.03	2.66	-0.93	0.81	2.193	4.373	0.001*	2.76
ROM-E difference [°]	**-1.18**	**2.25**	**0.9**	**1.2**	**3.373**	**-2**	**0.073**	**-1.26**
ROM-F difference [°]	0.65	3.14	-0.8	1.8	2.406	0.981	0.35	0.66
tROM difference [°]	**-0.53**	**3.79**	**0.1**	**2.5**	**0.774**	**-0.342**	**0.74**	**-0.21**
PDH difference [mm]	-0.73	1.66	0.47	1.78	0.02	-1.555	0.151	-0.76
FH difference [mm]	**-2.63**	**2.16**	**1.02**	**2.14**	**0.014**	**-2.96**	**0.014***	**-1.86**
FW difference [mm]	-1.68	1.19	1.18	1.37	0.853	-3.539	0.005*	-2.44

difference between groups, corresponding to the decrease of the postoperative IA in Group D. The pre- and postoperative differences in ROM-E, ROM-F, tROM and PDH in neutral between groups were not statistically significant. The pre- and postoperative differences in FH and FW were both statistically significant, corresponding to the increase of postoperative FH in neutral and FW in neutral in Group D. There were no complications and no reoperations in either group. Table 2 and Figure 2 represent the comparison of radiological outcome measures between groups.

There were no statistically significant differences in pre- and postoperative ODI, VAS-lumbar and VAS-leg scores between groups.

DISCUSSION

The biomechanical effects of DIAM implantation on a lumbar motion segment had been studied previously on cadaver and finite element models (1, 2, 16, 22). Anasetti et al. reported a shift of a motion segment toward kyphosis in the neutral position after a DIAM implantation, a finding that was confirmed by our study as well as other, methodologically lower quality studies on the same IDSD (9, 18, 23). A slight kyphotic position of a motion segment after an implantation of IDSD would theoretically suggest a possible deterioration of a spinal sagittal alignment, yet an analysis of a prospective case series showed an average improvement in a sagittal

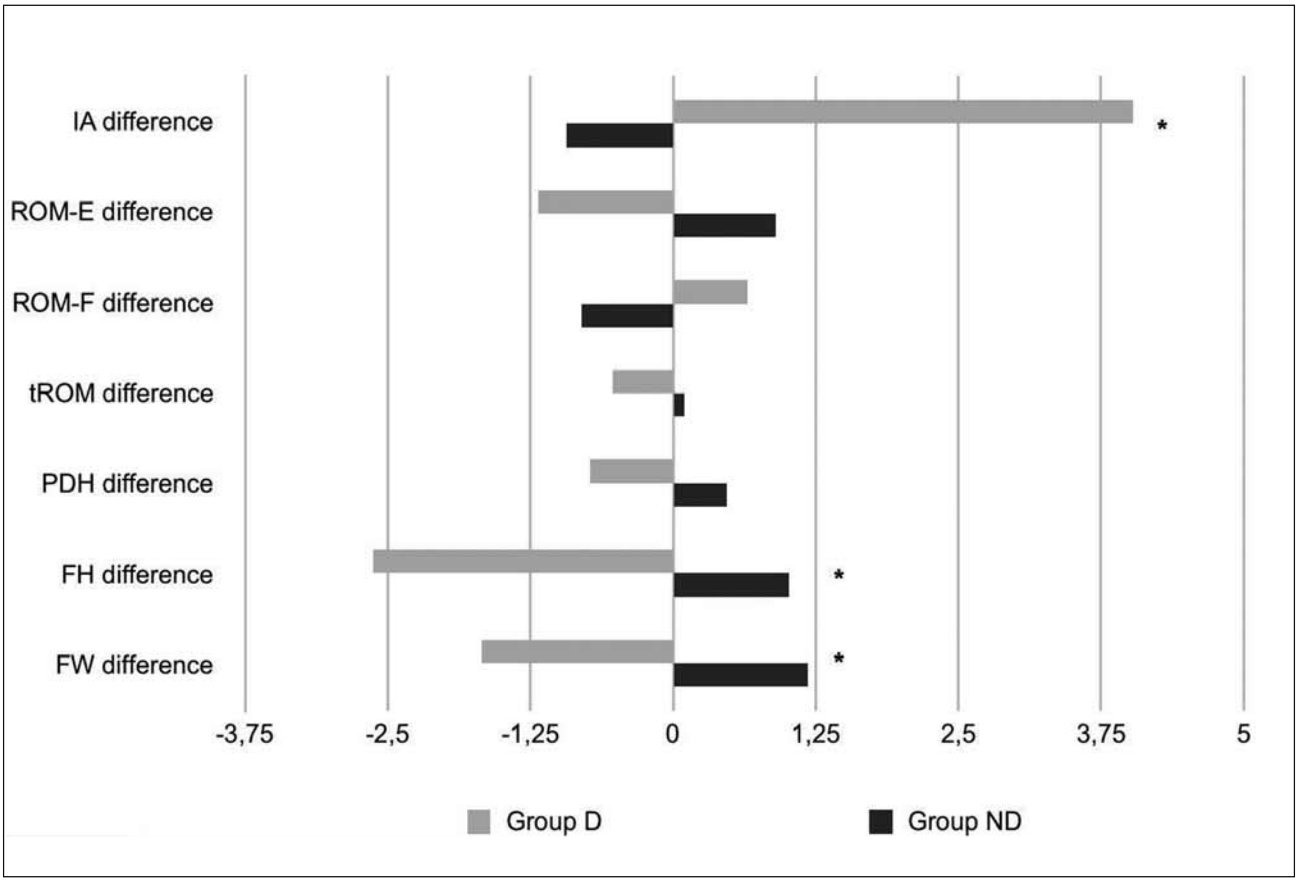

Fig. 2. Graphical representation of radiological outcome measures between groups. The graphical representation of radiological outcome measures between groups shows a statistically significant decrease of the postoperative IA and a statistically significant increase of the postoperative FH and FW in Group D. There were no statistically significant differences in ROM-E, ROM-F, tROM and PDH between groups.

alignment after a static IDSD implantation in patients with spinal stenosis (17). The reasoning behind this is the restitution of global lordosis after a relief the symptoms as a result of an IDSD implantation. DIAM is a dynamic IDSD with a deformable silicone core and functions as a shock absorber, therefore potentially lessening the kyphotic position of a motion segment compared to static IDSDs under loading conditions. Future studies should focus on comparing biomechanical effects between dynamic and static IDSDs. Studies on models have reported a decrease in a segmental tROM after a DIAM implantation on intact and partially destabilised motion segment with the segmental ROM-E being more affected than the segmental ROM-F (2, 16, 22). Our literature search did not present any patient-based biomechanical studies on the effect of a DIAM implantation on a segmental ROM, yet a retrospective case series by Kong et al. found that an implantation of another, shape-based type of a dynamic IDSD significantly reduced the segmental tROM (10). Based on our results, a DIAM implantation does not significantly change the segmental tROM, ROM-E and ROM-F. Our study did not find any statistically significant change in the postoperatve PDH within Group D as well as between groups. Similar results were reported by Kim et al. who stratified and matched patients receiving a DIAM implantation with patients receiving a decompressive procedure (9). Sobottke et al. on the other hand reported a significant increase of the PDH after a DIAM implantation, although they noted a decrease in the PDH at an average of six and seventeen month follow-up time points (18). They suggested that this "loss of correction" was caused by an implant breakdown, however, no further evidence was given to support this claim. Our explanation of a DIAM implantation not affecting the PDH is that under loading conditions, this material-based dynamic IDSD is not able to increase the PDH because of its deformability. The instantaneous center of rotation is shifted posteriorly after an IDSD implantation and lies closely to the PDH, therefore a deformable silicone implant would not be able to increase it (1). Finally, our results confirm that a DIAM implantation significantly increases indirect decompression outcome measures of the FH and FW as it had been proven previously in a retrospective case series (18). This effect is, in our opinion the main reason for an IDSD implantation as it decompresses nerve roots in foramina by the no-see-no-touch technique. The procedure of one segment IDSD implantation, combined with the direct surgical decompression of recess stenosis of the lower vertebral level nerve root pair, can therefore elegantly decompress four nerve roots. Comparing randomised patients with a static IDSD and conservatively treated patients with neurogenic intermittent claudication as a control group, Zucherman et al. reported no significant differences in the IA, PDH and FH at one and two year follow-up (24). Other studies on the same IDSD did not confirm these findings and reported a significant decrease in the IA and increase in the PDH and FW (12, 21). It is possible that the differences in implant sizing between users or postoperative subsidence of implants after a longer follow-up are the reasons for different results between the studies.

There are some limitations to our study. The method we used to generate the random allocation sequence is usually reserved for studies with large sample sizes. Nevertheless, this type of randomization process eliminates selection and accidental biases found in restricted and adaptive randomization procedures and both groups represented in our study were well balanced and homogeneous. No sample size calculation was made prior to beginning of this study, which can lead to potential reliability problems. Furthermore, the sample size was small due to short enrollment time-frame and strict inclusion and exclusion criteria which can lead to potential statistical analysis errors. Nevertheless, this single-centre time-framed RT is to our knowledge the first to study the biomechanical effects of a dynamic IDSD. Due to these limitations, we rank this study as Level of Evidence 3 on the Oxford Centre for Evidence-Based Medicine 2011 criteria.

CONCLUSIONS

The short-term biomechanical effect of a DIAM implantation on an isolated lumbar motion segment under loading conditions is a decrease in the segmental IA and an increase in the segmental FH and FW. The implantation has no effect on the segmental ROM and PDH. This dynamic IDSD therefore improves radiological indirect decompression outcome measures while only partially improves radiological stabilisation outcome measures. To our knowledge this is the first RT on biomechanical effects of a dynamic IDSD.

Acknowledgement

The authors did not receive any funding in support of their research and report no conflicts of interest.

References

1. ANASETTI, F., GALBUSERA, F., AZIZ, H. N., BELLINI, C. M., ADDIS, A., VILLA, T., TELI, M., LOVI, A., BRAYDA-BRUNO, M.: Spine stability after implantation of an interspinous device: an in vitro and finite element biomechanical study. J. Neurosurg. Spine, 13: 568–575, 2010.
2. BELLINI, C. M., GALBUSERA, F., RAIMONDI, M. T., MINEO, G. V., BRAYDA-BRUNO M.: Biomechanics of the lumbar spine after dynamic stabilization. J. Spinal Disord. Tech., 20: 423–429, 2007.
3. BORG, A., NURBOJA, B., TIMOTHY, J., CHOI, D.: Interspinous distractor devices for the management of lumbar spinal stenosis: a miracle cure for a common problem? Br. J. Neurosurg., 26: 445–449, 2012.
4. GAZZERI, R., GALARZA, M., NERONI, M., FIORE, C., FAIOLA, A., PUZZILLI, F., CALLOVINI, G., ALFIERI, A.: Failure rates and complications of interspinous process decompression devices: a European multicenter study. Neurosurg. Focus, 39 (E14): 1–9, 2015.
5. HRABÁLEK, L., MACHÁC, J., VAVERKA, M.: The DIAM spinal stabilisation system to treat degenerative disease of the lumbosacral spine. Acta Chir. orthop. Traum. čech., 76. 417–423, 2009.

6. INUFUSA, A., AN, H. S., LIM, T. H., HASEGAWA, T., HAUGHTON, V. M., NOWICKI, B. H.: Anatomic changes of the spinal canal and intervertebral foramen associated with flexion-extension movement. Spine, 21: 2412–2420, 1996.
7. JENIS, L. G., AN, H. S.: Spine update. Lumbar foraminal stenosis. Spine, 25: 389–394, 2000.
8. KABIR, S. M., GUPTA, S. R., CASEY, A. T.: Lumbar interspinous spacers: a systematic review of clinical and biomechanical evidence. Spine, 35: E1499–1506, 2010.
9. KIM, K. A., MCDONALD, M., PIK, J. H., KHOUEIR, P., WANG, M. Y.: Dynamic intraspinous spacer technology for posterior stabilization: case-control study on the safety, sagittal angulation, and pain outcome at 1-year follow-up evaluation. Neurosurg. Focus, 22: E7, 2007.
10. KONG, D. S., KIM, E. S., EOH, W.: One–year outcome evaluation after interspinous implantation for degenerative spinal stenosis with segmental instability. J. Korean Med. Sci., 22: 330–335, 2007.
11. LEE, C. K., RAUSCHNING, W., GLENN, W.: Lateral lumbar spinal canal stenosis: classification, pathologic anatomy and surgical decompression. Spine, 13: 313–320, 1988.
12. LEE, J., HIDA, K., SEKI, T., IWASAKI, Y., MINORU, A.: An interspinous process distractor (X STOP) for lumbar spinal stenosis in elderly patients: preliminary experiences in 10 consecutive cases. J. Spinal Disord. Tech., 17: 72–77, 2004.
13. MARSH, G. D., MAHIR, S., LEYTE, A.: A prospective randomised controlled trial to assess the efficacy of dynamic stabilisation of the lumbar spine with the Wallis ligament. Eur. Spine J., 23: 2156–2160, 2014.
14. MORISHITA, Y., HIDA, S., NAITO, M., ARIMIZU, J., MATSUSHIMA, U., NAKAMURA, A.: Measurement of the local pressure of the intervertebral foramen and the electrophysiologic values of the spinal nerve roots in the vertebral foramen. Spine, 31: 3076–3080, 2006.
15. PARCHI, P. D., EVANGELISTI, G., VERTUCCIO, A., PIOLANTI, N., ANDREANI, L., CERVI, V., GIANNETTI, C., CALVOSA, G., LISANTI, M.: Biomechanics of interspinous devices. Biomed. Res. Int., 2014: 1–7, 2014.
16. PHILLIPS, F. M., VORONOV, L. I., GAITANIS, I. N., CARANDANG, G., HAVEY, R. M., PATWARDHAN, A. G.: Biomechanics of posterior dynamic stabilizing device (DIAM) after facetectomy and discectomy. Spine J., 6: 714–722, 2006.
17. SCHULTE, L. M., O'BRIEN, J. R., MATTEINI, L. E., YU, W. D.: Change in sagittal balance with placement of an interspinous spacer. Spine, 36: E1302–1305, 2011.
18. SOBOTTKE, R., SCHLÜTER-BRUST, K., KAULHAUSEN, T., RÖLLINGHOFF, M., JOSWIG, B., STÜTZER, H., EYSEL, P., SIMONS, P., KUCHTA, J.: Interspinous implants (X Stop, Wallis, Diam) for the treatment of LSS: is there a correlation between radiological parameters and clinical outcome? Eur. Spine J., 18: 1494–1503, 2009.
19. TAMBURRELLI, F. C., PROIETTI, L., LOGROSCINO, C. A.: Critical analysis of lumbar interspinous devices failures: a retrospective study. Eur. Spine J., 20 (Suppl. 1): S27–35, 2011.
20. VAN DEN AKKER-VAN MARLE, M. E., MOOJEN, W. A., ARTS, M. P., VLEGGEERT-LINKAMP, C. L., PEUL, W. C.; Leiden-The Hague Spine Intervention Prognostic Study Group (SIPS).: Interspinous process devices versus standard conventional surgical decompression for lumbar spinal stenosis: cost utility analysis. Spine J., 2014. [Epub ahead of print]
21. WAN, Z., WANG, S., KOZANEK, M., XIA, Q., MANSFIELD, F. L., LÜ, G., WOOD, K. B., LI, G.: The effect of the X-Stop implantation on intervertebral foramen, segmental spinal canal length and disc space in elderly patients with lumbar spinal stenosis. Eur. Spine J., 21: 400–410, 2012.
22. WILKE, H. J., DRUMM, J., HÄUSSLER, K., MACK, C., STEUDEL, W. I., KETTLER, A.: Biomechanical effect of different lumbar interspinous implants on flexibility and intradiscal pressure. Eur. Spine J.: 17: 1049–1056, 2008.
23. ZHAO, Y., WANG, Y. P., QIU, G. X., ZHAO, H., ZHANG, J. G., ZHOU, X.: Efficacy of the Dynamic Interspinous Assisted Motion system in clinical treatment of degenerative lumbar disease. Chin. Med. J., 123: 2974–2977, 2010.
24. ZUCHERMAN, J. F., HSU, K. Y., HARTJEN, C. A., MEHALIC, T. F., IMPLICITO, D. A., MARTIN, M. J., JOHNSON, D. R. 2nd., SKIDMORE, G. A., VESSA P. P., DWEYER, J. W., PUCCIO, S. T., CAUTHEN, J. C., OZUNA, R. M.: A multicenter, prospective, randomized trial evaluating the X STOP interspinous process decompression system for the treatment of neurogenic intermittent claudication: two-year follow-up results. Spine, 30: 1351–1358, 2005.

Corresponding author:
Janez Mohar, MD
Head of C1 Department of Spine Surgery and Paediatric Orthopaedics
Valdoltra Orthopaedic Hospital
Jadranska c. 31
6280 Ankaran, Slovenia
E-mail: janez.mohar@ob-valdoltra.si