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Assessment of quality of life after the DIAM™ spinal stabilization system

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Assessment of quality of life after the DIAM™ spinal stabilization system

Purpose. The Device for Intervertebral Assisted Motion (DIAM™) is a method that has been recently applied for the operative treatment of low back pain. The aim of this study was to assess the quality of life in patients with low back pain during the course of a single-level discopathy performed using the DIAM™ system, who previously had not undergone any surgical procedure within the lumbar spine.
Methods. The study group consisted of 23 selected patients (15 women and 8 men) with a mean age of 47 years. All subjects underwent single-level fenestration with discectomy and DIAM™ system implantation. The level of pain and disability at rest and movement were evaluated at baseline (pre-surgery) and at 6 months after surgery. All patients underwent a post-operative rehabilitation programme. Patients were evaluated using a Visual Analogue Scale (VAS) –pain's level at rest and movement, a modified Oswestry Disability Index (ODI) and the Melzack Pain Questionnaire (MPQ).
Results. Pain's level reduction was observed in 78% of patients at rest and in 88% of patients at movement. 79% of patients presented an improvement in their ODI score, but disability still persisted in pain intensity and during lifting. All MPQ indicators also improved, but mostly in the psychological dimensions of pain.
Conclusions. It was found that during the 6 months following a single-level DIAM™ implantation a greater decrease in pain at rest than at movement was recorded.

Key words: quality of life, DIAM™, spinal stabilization

INTRODUCTION

Surgical fusion of the spine is carried out to reduce pain resulting from instability, degenerative changes in the intervertebral joints (IJ) and interwertebral discs (ID), spondylolisthesis, pathological deformity or injury. Studies on the long-term outcomes have demonstrated that spine segment arthrodesis accelerates degenerative changes in adjacent segments [1]. A dynamic stabilization is referred to as soft and was introduced as the result of trying to apply a different treatment approach than spondylodesis. The aim is to reduce pain in a vertebral segment to simultaneously allow mobility and the unloading of the ID. In treatments of this type of pain syndromes, devices that maintain mobility of the operated segment are applied [2-4].

One of the solutions is the Device for Intervertebral Assisted Motion (DIAM™). A flexible, silicone-interspinous spacer is implanted into the interspinous ligament between the spinous processes. The indications include: degenerative syndromes of the IJ, foraminal stenosis and support of the degenerative disc. Positioned spacer unloads the facet IJ and distracts the intervertebral space and neural foramina. This results in an unloading of the pathologically changed ID, reduces pressure at the nerve roots. A dynamic stabilization, in contrast to transpedicular fusion, diminishes mechanical stress affecting the disc and thereby protects adjacent tissue from too rapid degeneration. Due to the materials used in the stabilizer the implant has compression properties and therefore can act as a shock absorber. It can be also implanted without discectomy being performed at the same time [2,4-7].

The subject literature assess various aspects of the use of DIAM™ and analysed the efficacy of this type of treatment in various syndromes and clinical aspects [8-12]. These

studies include patients with spinal stenosis, single or double-level disc herniation, one re-operated on once or more times. The analyses were conducted for various periods of time after implantation - from several time [8]. Some compare various types of dynamic stabilization, but only with regards to the radiological aspects. They relate to the misalignment of the implant, changes in the bone structure of the spine, and other related issues [9,10]. Furthermore, microdiscectomy alone is compared to those with DIAM™ implantation in patients with disc herniation [8]. In contrast to other, this study included a homogenous group of patients, who underwent the same surgical procedure, had the similar type of single-level pathology and the number of surgical interventions, all patients participated in the same physiotherapy programme. Their treatments were compliant with the respective phases of the process of tissue healing and were consistent with the rules [13-19]. The programme was tailored to the current clinical status and carried out under the supervision of a physiotherapist.

It was assumed that a single-level implantation of the DIAM™ would result in pain reduction at rest and movement, the level of disability in the study group within, a period of 6 months after surgery. The aim of this study was to assess the differentiation of selected parameters of quality of life in patients suffering lumbar degenerative disc disease at baseline and 6-month after implantation of the DIAM™ and physical therapy schedule recommended to continue at home.

METHODS

It was selected a group of 23 patients of DIAM™ implantations performed in 2008-2010. A DIAM™ was performed in all patients for the treatment of a single-level disc degeneration disease confirmed by magnetic resonance imaging (MRI) and the instability in this segment. All underwent surgical intervention by means of the fenestration technique with discectomy. In the study group the largest number of implantations was performed at segment L4-L5 (n=13), 6 at segment L3-L4, and 4 at L5-S1.

Among the 23 subjects: 15 women (65.4%) and 8 men (35%), the mean age of patients was 47 years (SD 10.2) – women - 49 (SD 10.6); men 43 (SD 8.7). The average body weight of the women was: 76.3 kg, (SD 14.2) and 165 cm (SD 7.81); men 95 kg (SD 12.8) and 177 cm (SD 4.53). The mean value of BMI - women: 27 (SD 3.03); men 30.4 (SD 4.47). Prior to surgery these patients underwent ineffective conservative treatment for a minimum of 6 months. On physical examination neurological symptoms were detected. A sign of Lasèque was present in 19 patients; in 10 of these the symptom was unilateral, while in the remaining 9 it was bilateral. Examination indicated a slight paresis in 6 patients dependent on the level of damage.

Excluded from the study: multilevel degenerative disc disease, adjacent level degeneration, the implantation of more than one device, the need to broaden their spinal canal, previous and/or other spinal surgery at any level, advanced degenerative changes within the lumbosacral spine, previous spinal trauma, spondylolisthesis, scoliosis, other causes of stenosis than degenerative disc disease stenosis, osteopenia, osteoporosis, any metabolic disease, spinal tumours, inflammations, infection, fever, BMI>39.9, and those who did not complete the questionnaires were.

All participants provided written informed consent prior to their enrolment in the study. Prior to surgery they underwent a standard neurological examination and the data from their medical history was collected. After admission to the ward were examined for the first time (Examination I). Patient received ODI and a MPQ. The intensity of pain was measured at rest and at movement using the VAS. The examination was repeated after a period of 6 months (Examination II).

In hospital a physiotherapy programme was introduced. On discharge all patients received a 6-month physical therapy schedule which allowed them to continue. They were advised to exercise twice a day for 15-20 minutes. The program was compliant with the respective phases of the physiological process of tissue healing [5].

1) Preoperative phase: cognitive approach, behavioural education about surgery treatment, presentation and explanation of post-operative low back pain protection rules, introduction into post-operative physiotherapy.

2) Acute post-operative phase: important healing tissue process the phase was performed in the hospital up until about the 7th day, during the programme's duration it was supervised by a physiotherapist and included indicated and contraindicated activities.

Bleeding phase: not using a back lying position for one week. Standing position and walking on the first post-operative day to be achieved only from a side lying position using an orthopaedic walker to increase the base of support, posture correction, ventral muscle group identification on the front lying position; as well as teaching about such 'don't' as: no sitting position for 2-4 weeks, no lumbar part rotation for the next 3 weeks, avoid flexion, hyperextension and dynamic abdominal exercise for 6 weeks. The programme included activities connected with ventral muscle group identification (lying prone and lying prone with forearm support) and the need for the restoration of the mechanical properties of the nerve using the neuromobilization (anti-adhesive) technique. For the week of hospitalization the patients were taught how to exercise. These exercises were prescribed as a home-based physiotherapy programme for the next 6 months.

Cell proliferation phase - healing by first intention that lasted from the 3rd to the 4th post-operative day – lumbar roots autoneuromobilization in a front and side lying position along with non-weight lifting exercises. Ventral muscle group identification on lying prone with forearm support through a pelvis posterior tilt (learning to feel pelvic floor tension), exercises in a knees-supported position from the 2nd week, walking several times a day without an orthopaedic walker, discharge from hospital on the 6th to 7th day, contraindications as in the bleeding phase.

Phase of tissue remodelling and secondary prevention (5-16 weeks) – the adhesion maturation phase. Early protective phase (up to 6 weeks) - contraindications as above, ventral muscle group pelvic tilt exercises in several positions, weekly contact with a department of physiotherapy. Dynamic prevention phase (6 weeks to 6 months) – dynamic lumbar spine stabilization exercises, proprioception training.

The VAS was used to assess the intensity of pain felt at rest and during daily activities – walking [20]. The ODI was used to assess disability caused by lumbar spine disorders. In the modified version of the questionnaire used in this study the question regarding sexual life was replaced by the question on career/family responsibilities. On the basis of the percentage disability score patients were classified into one of five groups according to their disability level: minimal, moderate, severe, crippled, bed-bound [21]. The MPQ was used too. This consisted of 20 subclasses of adjectives describing the sensations of pain. Each expression was assigned to a numerical value. All descriptors were divided into 4 major categories: sensory, affective, evaluative, and miscellaneous. The patients were asked to select those words that describe the best their feeling of pain and experiences during the past week. Only one word could be chosen from one subgroup. The sum of scale values were used to calculate the Pain Rating Intensity Score (PRIS). The separate scale values were used in categories to calculate the sensory, affective, evaluative, and miscellaneous ratings [3,9].

Statistical analysis was performed using the Statistica 10. Where necessary, the arithmetic mean, maximal and minimal values, median and standard deviation (SD) were used to describe the inter-variability within parameters. Gaussian-normality was assessed with the Shapiro-Wilk statistical test. Nonparametric statistics were used for the abnormal distribution.

The Wilcoxon nonparametric test was used to assess statistical significance in data groups for dependent variables or the Mann-Whitney U-test for independent variables. P values≤0.05 were considered to be statistically significant

RESULTS

The analysis of pain levels showed no significant differences between the results for women and men (Mann-Whitney U-test). Perception results of the level of subjective pain in patients before surgery are presented in Table 1.

Table 1. Levels of pain in VAS score distribution at Examinations I and II

Variable	Examination I			Examination II			Wilcoxon test
	Median	Max	Min	Median	Max	Min	P
VAS at rest	6.0	8.5	0.0	2.0	8.5	0.0	0.001*
VAS at movement	8.0	10	5.0	4.0	10	1.8	0.01*

* p≤0.05; VAS - Visual Analogue Scale

The reduction of pain was significant both at rest and at movement. Reduction in the pain level at rest was observed in 78% patients, while improvement at movement occurred in as many as 88% of patients. The level of pain in the total study group was reduced at rest by 56.3% and at movement by 36%.

The ODI percentage score indicating the disability level of patients was on average 53% (median 51) at the time of Examination I. After a six-month period following surgery, scores on the questionnaire showed a significant improvement (p<0.01). The ODI percentage score was reduced to the level of 35.78% (median 38) on Examination II (Table 2). The analysis of the study showed that the level of disability was reduced in 18 patients (79%), increased in 4 patients (17%), and did not change in 1 person (4%). It was found that before surgery the patients were limited the most in terms of lifting and pain intensity, while sleeping and walking were the least limited by pain. The Wilcoxon test showed significant differences in the overall result of the ODI scores between Examination I and II. In comparing changes in pain during typical daily activities, significant differences were found in all scales excluding personal care activities (p>0.05) and lifting (p>0.05) (Table 2).

Table 2. Disability ODI score distribution at Examinations I and II

Variable	Examination I			Examination II			Wilcoxon test
	Median	Max	Min	Median	Max	Min	P
ODI [%]	51	74	40	38	58	12	0.01*
Sections by ODI:							
1. pain intensity	3.0	4.0	1.0	2.0	4.0	0.0	0.001*
2. personal care	2.0	5.0	0.0	2.0	4.0	0.0	0.12
3. lifting	4.0	5.0	1.0	3.0	4.0	1.0	0.09
4. walking	2.0	4.0	1.0	1.0	3.0	0.0	0.01*
5. sitting	3.0	5.0	1.0	2.0	3.0	0.0	0.01*
6. standing	3.0	4.0	1.0	2.0	4.0	0.0	0.01*
7. sleeping	2.0	3.0	0.0	1.0	2.0	0.0	0.001*
8. social life	3.0	4.0	1.0	2.0	4.0	0.0	0.01*
9. travelling	3.0	5.0	1.0	2.0	4.0	0.0	0.001*
10. employment	3.0	5.0	1.0	2.0	3.0	0.0	0.04*

*p≤0.05; ODI - Modified Oswestry Disability Index

The results of comprehensive therapy using the DIAM™ influenced the size of disability groups according to the ODI score before and after surgery. At baseline, as many as 92% of patients were included in the severe disability and crippled group, while after the six-month period a significant improvement was observed. At Examination II, 52% of patients were eligible for groups of minimal and moderate disability (Table 3).

Table 3. ODI scores distribution according to disability groups at Examinations I and II

Level of disability	Examination I n (%)	Examination II n (%)
0-20% - minimal disability	0	4 (17%)
21-40% - moderate disability	2 (9%)	8 (35%)
41-60% - severe disability	16 (69%)	11 (48%)
61-80% - crippled	5 (22%)	0
81-100% - bed-bound	0	0

ODI - Modified Oswestry Disability Index*****p≤0.05

Analysis of pain quality and its intensity based on MPQ showed that during the 6 months after surgery average scores decreased significantly in all the tested scales ($p<0.01$). The biggest change was found in the affective dimension, where the pain score decreased by 48%. Evaluative score decreased by 25%. The smallest change occurred in the sensory dimension, where the score fell by 25%. The PRI decreased from 33.34 to 24.08 (28%). The PRI was reduced in 78% of patients (Table 4).

Table 4. Differentiation of pain dimension scores according to MPQ at Examinations I and II

Variable	Examination I			Examination II			Wilcoxon test
	Median	Max	Min	Median	Max	Min	p
PRIS	33.0	54.0	13.0	23.0	56.0	4.0	0.001*
Sensory scale	18.0	32.0	2.0	14.0	30.0	3.0	0.01*
Affective scale	6.0	10.0	0.0	2.0	11.0	0.0	0.01*
Evaluative scale	3.0	5.0	0.0	3.0	4.0	0.0	0.001*

*****p≤0.05; PRIS - Pain Rating Intensity Score; MPQ - Melzack Pain Questionnaire

DISCUSSION

It has been shown that reduction of the level of pain and disability after 6 months after operation occurred in a comparable number of patients when using the two questionnaires. Changes were significant, establishing the comparable sensitivity of both methods. The lack of improvement or deterioration observed in some instances can be for various reasons. MRI examination revealed some degenerative changes at more than one level in all patients, but the surgical intervention was necessary only at one level. Moreover, the results could influenced by patients' psychological predisposition and social and living situations. Deterioration observed in patients could also be due to incorrect performance of home physical therapy. Many patients expect pain and disability to cease after surgery. But despite the improvements that occur in a high percentage of patients, it should be noted that some of them can still suffer from pain in their spine and their physical ability is limited. Perhaps this is due to the diversity

of the initial clinical symptoms of these patients and their individual response to therapy. Differences in pain perception at rest and at movement, both before and after surgery are caused by different ID loads depending on the particular position of the body. Lying supine releases pressure from the ID, and thus the patient feels minimal pain. The ID are subjected to the highest load when taking a sitting position, in particular with bending the body to the front and during weight lifting with a bent back in a forward stooping position. This type of body position is often involved in many activities performed repeatedly during the day, which can cause additional pain [3].

Pain assessment with the MPQ showed that after surgery the affective component of pain fell to a greater extent and the sensory index presented the least reduction, which can be attributed to an increase in the emotional dimension during Examination I. This can be also affected by a change in environment. Staying in hospital is a common stressful situation resulting from *inter alia* the fear of surgery. In Melzack's opinion, somatic factors in chronic pain become less important as its duration and emotional responses to pain increase. They produce negative emotions in the patient such as fear, anger, often leading to depression [22]. The reduction of pain in patients undergoing surgery allowed the emotional response to pain to decrease, and thus improve patients' psycho-emotional balance. This aspect of life was improved the most according to the disability rating on the ODI. Statistical analysis demonstrated that there were no differences in the level and nature of pain and disability between men and women. The study results indicate the effectiveness of a single-level DIAM™ implantation, but require further investigation because of the small number of patients included in the study and the relatively short time period between Examination I and II.

The effectiveness of the DIAM™ was evaluated by Hrabálek et al., (2009) who examined a group of 68 patients. This treatment improved patient status according to the disability rating on the ODI from 60.44% to 21.85% (a difference in mean: 38.59), while the level of pain decreased from 7.18 to 2.10 (an improvement of 5 points gives 70.75%). All patients achieved an improvement. There was an increase in disability. It should be noted that there were greater differences during qualification for surgery in the study group [11]. Taylor et al.,(2007) performed a retrospective study. Examinations were conducted 6 and 18 months post-operatively. The authors reported that a greater improvement was obtained after a longer period of time following surgery. In the study the pain level showed an improvement in 88.5% of patients operated on. The disability level measured by a self-modified Dallas Questionnaire decreased in 63.1% patients, while increasing in 12.3%. In the questionnaire was evaluated 16 aspects of their life on a visual analogue scale. After 6 months of observation the questionnaire revealed that the quality of sleep had improved in 64% of patients, of sitting in 54%, and in 51% of discomfort during occupational activities had been reduced [23]. It is worth noting that these values are highly similar to the results of the present study. Both studies, indicate that one of the biggest improvements was recorded in the quality of sleep and social relations: aspects of daily life that do not require much activity. This observation is also confirmed by the change in the pain level rating in VAS. The change in pain experienced at rest is much higher than the change of pain intensity at movement. Furthermore, tasks that require great physical activity on the basis of the ODI the slightest change and were not statistically significant. This suggests the occurrence of musculoskeletal functional disorders.

The most recent study conducted by Crawford et al.(2012) reported a clinical improvement achieved in a prospective observation of 81 consecutive patients after a DIAM™. Two years after surgery they reported a significant improvement in back and leg pain in VAS and disability reduction in the ODI score. Although the outcomes are promising, the study included patients with various diagnoses and multiple adjunctive surgical

decompressions in addition to a DIAM™ [24]. Summara et al.(2009) in a retrospective study (n=73) indicated on an improvement in 90% operated patients [5]. Similarly, Buric et al.(2011) performed a two-year observation of patients after a DIAM™. The results were promising because of the high level of patient satisfaction and improvement in their quality of life. Nevertheless, it is not known exactly what type of clinical syndromes were exactly present in the patients included in the study group [12].

CONCLUSIONS

Single-level DIAM™ implantation results in pain and severe to moderate disability in 52% of patients of the study group during a 6-month period following surgery. The results are not entirely satisfactory because pain and severe disability persisted in 48% of patients. It was found that during the 6 months following a single-level DIAM™ implantation a greater decrease in pain at rest than at movement was recorded. It was found according to MPQ that amongst the three components the emotional response to pain diminished to the greatest extent.

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