DIAM (Device for Interspinous Assisted Motion)

Interspinous device

Case series

2013

Although posterior lumbar interbody fusion (PLIF) has a successful fusion rate, the long-term outcome of PLIF is occasionally below expectations because of adjacent segment degeneration (ASD).

OBJECTIVE: To evaluate the ability of hybrid stabilization using DIAM (Device for Interspinous Assisted Motion) to delay ASD. METHODS: An intervention comparison study of 75 patients (hybrid, 25; PLIF, 50) was performed. The indications for hybrid stabilization were facet joint degeneration, Pfirrmann grade II to III, and stenosis at the rostral adjacent segment. The PLIF group consisted of patients matched for age, sex, and fusion. The hybrid stabilization procedure included traditional PLIF and DIAM installation at a superior adjacent segment. The outcomes were analyzed with a linear mixed model analysis. Conditional logistic regression was performed to calculate the odds ratio for the association of surgical methods. RESULTS: The hybrid group (24%) revealed fewer ASDs than the PLIF group (48%). Among ASDs, spondylolisthesis occurred more frequently in the PLIF group than the hybrid group. Hybrid surgery was significantly associated with ASD; the odds ratio for hybrid surgery was 0.28 compared with PLIF. Foraminal height of the PLIF group decreased more than the hybrid group (P = .01). Segmental mobility showed a greater increase in the PLIF group than the hybrid group (P = .04). However, the clinical outcomes did not show significant differences between the groups. CONCLUSION: Hybrid stabilization with DIAM and pedicle screws can be used for patients with facet degeneration at adjacent segments but should be further investigated.

2009

A total of 68 patients aged 23 to 75 (average age, 50.01) years, including 39 men (average age, 50.44) and 29 women (average age, 49.45), were followed up for 1 to 3 years and evaluated.

All patients underwent a standard pre-operative clinical and neurological examination. Each patient assessed pain intensity using a Visual Analogue Scale (VAS) and, with an Oswestry Disability Index (ODI) questionnaire, evaluated their functional state. In the case of disc herniation recurrence, a sequester was removed; for foraminal stenosis, foraminotomy and partial medial facetectomy was performed. After this decompression of nerve structures, a spacer was implanted. Follow-up included clinical and neurological examination at 6 weeks, 6 months and 1 - 3 years post-operative. At 6
months and between 1 and 3 years after surgery, pain intensity and functional outcome using VAS and ODI assessments were measured by the patients, and antero-posterior and lateral skiagrams of the lumbosacral spine were made. The X-ray examination was made to reveal a potential implant dislocation. The VAS and ODI values at 1-3 post-operative years were compared with those before surgery and the results were statistically analysed. The surgeon evaluated the outcomes at 1-3 years of follow-up according to the Odom criteria.

The average ODI of the group was 60.44 % before and 21.85 % after surgery, which showed an improvement by 63.85%. The average VAS was 7.18 points before and 2.10 points after surgery, showing an improvement by 70.75 %. A comparison of the pre- and post-operative results showed, in the average ODI differences of 38.24 % and 39.44 % in women and men, respectively; and in the average VAS value, 5.00 in women and 5.19 in men. The results evaluated according to indication for surgery were as follows: in patients with disc hernia, the difference in ODI was 39.62 % on average, and in VAS it was 5.42 points on average. In patients with disc herniation recurrence, the differences between pre- and post-operative average values were 41.50 % for ODI and 5.00 points for VAS. In patients treated for foraminal stenosis, these differences were 39.79 % for ODI and 5.18 points for VAS. The results for the level treated showed that at L5/S1 the average difference for ODI was 46.75 % and 4.50 points for VAS; at L4/5 it was 35.52 % for ODI and 5.12 for VAS; at L3/4 it was 48.00 % for ODI and 5.78 for VAS; and at L2/3 it was 39.00 % for ODI and 4.50 for VAS. The results related to the method of nerve root decompression included the average differences of 40.00 % in ODI and 5.17 in VAS for removal of a disc sequester; and average differences of 32.89 % in ODI and 4.78 in VAS for foraminotomy and partial medial facetectomy. The results evaluated for the duration of pre-operative complaints were as follows: surgery by 3 months, average ODI, 44, 53 % and average VAS, 5.25; surgery between 3 and 6 months, average ODI, 37.65 % and average VAS, 4.71; and surgery after 6 months, average ODI, 35.60 % and average VAS, 5.28. The Odom criteria showed results as excellent in 41 %, good in 51.5 % and fair in 7.5 % of the patients. No poor result was recorded. There were no early complications such as haematoma, wound seroma or deep subfascial infection, and no implant dislocation. One patient had to undergo repeat surgery for subcutaneous infection without affecting the implant. Until the end of the study, no signs of herniation recurrence at the segment stabilised with a Diam interspinous spacer had been found.

The fact that none of the patients in this study required revision surgery or had a recurrence of disc herniation provides evidence for the effectiveness of the DIAM interspinous spacer. This also suggests that the implant protects the whole operated spinal segment, i.e., both intervertebral joints and discs, from being overloaded. Lesser mechanical stress applied to intervertebral facets may slow down degenerative processes and reduce their signs.

The implantation of a DIAM interspinous spacer is a less invasive and safe method of dynamic stabilisation of the spine without intra- or post-operative complications that is well tolerated by the patient. At 3-year follow-up the patients reported improvement in their functional state, as measured with an ODI, by 64 % on the average. Their axial and nerve root pain was reduced by 71 % on the average. All patients showed improved clinical conditions and the outcomes were evaluated as excellent in 41 %, good in 51 % and fair in 7.5 % of the patients. The results of implantation were not significantly related to age, gender, operative indications, operated lumbosacral level, method of nerve root decompression or duration of pre-operative problems. No patient treated by the DIAM spacer had any recurrence of disc herniation 2).

Case reports

A case of an extremely late complication (after 10 years) in the form of intra- and extrafascial...
dumbbell abscesses, concomitantly appearing at both levels treated with the DIAM spacer. The paper presents the existence of a significant correlation between CT and MRI findings as well as the deterioration in Oswestry Disability Index and visual analog scale scores. Over time, dynamic spine stabilization might possibly impact reactive accumulation of sterile fluid in the vicinity of an implant and could therefore be related to delayed complications even 10 years after surgery. The finding of a growing layer composed of thick aseptic fluid around the DIAM implant, with a simultaneous occurrence of spinous process osteolysis and formation of a mineralized pseudocyst, bears a considerable risk of delayed inflammatory complications, including abscess, and therefore requires the explantation of the DIAM implant 3).

