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The Diam Interspinous Stabilization for Low Back Pain: 5 Years Follow-up

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Objective: To evaluate the usefulness of the DIAM (dynamic interspinous amortization device) device in patients affected by low back pain (LBP) due to degenerative disc disease (DDD). Prospective non controlled case series.

Background: Recently a number of interspinous devices for dynamic interspinous distraction-stabilization have entered the clinical practice in Europe. All of these devices have a common property of acting on the posterior part of the functional spinal unit by distracting the spinous processes and avoiding extension of the treated segment. Consequently, these systems seem to improve the cross-sectional area of the thecal sac and enlarge the diameter of the intervertebral foramina. What was found as a collateral observatin after implantation of these devices was that those patients affected by degenerative disc disease and low back pain, improved significantly in their pain level.

Methods and materials: This study is a report of 5 years follow-up of a consecutive series of 52 subjects treated for low back pain due to degenerative disc disease between December 2003 and December 2004.

All subjects presented with low back pain with 19 subjects complaining also of slight pain irradiating to buttock and thigh. The pre-operative symptom duration ranged from 6 to 84 months (mean 31.8, SD 20.2, median 24). All subjects reported some type of conservative treatment modality performed in the past, mainly physical therapy and exercises addressed to their low back pain problem. Almost all subjects had occasionally and on need been taking NSIADs during the period of their sickness. Ten subjects had a history including discectomy without recurrence but later developed back pain. There were 29 females and 23 males, aged between 29 and 77 years (mean 49.4, SD 12.4). Twenty-five subjects were sedentary workers, 19 were heavy duty workers while the rest of subjects were in retirement. The disc degeneration included was of type 3 and 4 (Pfirmman classification).

The patients were followed for pain by Visual Analogic Scale and for functional status by self-reported Roland-Morris Disability Questionnaire. The minimum follow-up was 60 months. The intermediate follow-up at two, six, twelve, twenty-four and forty-eight months was tested for, too.

Results: To determine the number of improved patients we have arbitrarily selected a cut-off criteria based on a 50³% of improvement as calculated on the VAS scale comparing the 60 months VAS values to the VAS baseline values. Thirty-nine patients (75%) reported an improvement superior to 50%. Nine patients (17%) had an imporvement of less then 25% and 4 patients (8%) showed an improvement between 25 and 50%. Including all of the patients, the values for the VAS at time 0 was 6.0 ± 1.9 while at 60 months the VAS values was 2.3 ± 1.9 . The mean functional status at time 0 was 13.7 ± 4.7 and on 60 months was 5.1 ± 4.9 .

Conclusions: This prospective, long term, clinical series indicates that the DIAM device is a usefull treatment option for patients affected by LBP due to DDD of mild and moderate degree. Further research with RCT is necessary to confirm these preliminary results.