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Preliminary results of a soft novel lumbar intervertebral prosthesis (DIAM) in the degenerative spinal pathology

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Summary

The authors report a series of 43 patients suffering from lower limb pain, almost constantly associated with chronic or acute backpain, treated by microsurgical nerve root decompression and by implantation of a soft intervertebral prosthesis (DIAM). Satisfying results were obtained in 97% of cases, inducing the authors to consider the device a reliable tool for curing low-back pain and sciatica. Selection criteria are exposed and discussed.

Keywords: Spinal degenerative pathology; spinal instability; soft lumbar prosthesis; DIAM.

Introduction

Correction of lumbar vertebral instability remains a major challenge in spinal degenerative pathology. Clinical evidence of pain relief when pathologic motion is eliminated by immobilization or arthrodesis has led to consider spinal fusion as the method of choice for surgically relieving spinal pain. Consequently, a plethora of techniques have been introduced involving transpedicular screws, plating and wiring. Despite these concerns, the outcome is not successful in all patients. That is particularly true in cases of minimal instability as rigid fixation leads to many problems concerning: a) the surgical insertion of the devices as well as all the inherent complications associated with mechanical failure and loosening; b) the long-term stiffness either of the stabilized segment or the adjacent levels.

In order to obviate these drawbacks, we have used a novel soft implant [5] (DIAM*) in 51 patients suffering from lower limb pain, almost constantly associated

with chronic or acute backpain, and suspected of harbouring low grade spinal instability.

Clinical materials and methods

Fifty-one patients with pain in the lower limbs, very frequently accompanied by persistent low-back pain, were admitted to our Neurosurgical Institute during the period May 1999 to February 2004. As first useful follow-up examination the one at 12 months after surgery was chosen, 8 patients were excluded from the study. Of the remaining 43, 26 were male and 17 female, with age varying from 34 to 80 years; mean age was 54,49 years. Clinical complaints ranged from low-back pain (39 cases) to sciatica (31 cases), cruralgia (2 cases), lower limb paresthetic sensations (7 cases). The diagnostic work-up variously included the clinical examination, plain and dynamic radiological x-rays, neuroradiological (CAT and MRI) studies, trial external immobilization in plastic jacket. In the last 30 patients an intra-operative evaluation concerning the mutual articular relationship between contiguous vertebral bodies (by pulling up the spinous process through clamping their proximal extremities) became an integral part of the patient's whole examination. Pathological entities discovered during neuroradiological assessment were: significant disc prolapse associated with lateral and foraminal stenosis (36 cases), single level or multilevel narrowing of the spinal canal (7 cases). Mild degenerative spondylolisthesis grade 1, never reaching the extreme dislocation, was found in 8 patients affected either by herniated disc or spinal stenosis. Minimal or mild retrolisthesis was found in other 15 cases. All the patients were operated on by the same surgeon (A. M.) using microsurgical discectomy or multiple microsurgical interhemilaminectomy. The soft prosthesis implantation was single-level in 31 cases and multiple in the remaining patients. Pre and post-operative pain and quality of life of patients were evaluated using the Dallas Questionnaire [3]. Results were further refined integrating them into the four categories of the Henderson Classification of Functional Results (Table 1). The post-operative time of observation varied between 12 months and 5 years (mean: 34,7 months). Two patients were lost at follow-up and excluded from the study.

Results

With regard to symptoms best results were collected in patients suffering from low-back pain with (27

* Cousin Biotech, France

Table 1. *Functional results according to Henderson*

Level	Functional capacity
Excellent class 1	no pain no restriction regarding precedent activity no limitation for physical activity
Good class 2	occasional pain (< 12 hour) possibility to take up again precedent work minimal limitation for physical activity
Middle class 3	pain reduced by intervention reduction of professional activity reduction of physical activity
Bad class 4	identical symptoms as preoperatively not able to work necessity for a continuous pharmacological support

cases) or without (8 cases) sciatica. Half of the subjects were in class 1, the remaining in Class 2. The four patients complaining of sciatica without back pain did well, only one patient was in class 1, the others in class 2. Patients with low-back pain and cruralgia did worse: one was in class 2, the other in class 3.

In relation to spinal pathology, 67% of patients harbouring spinal stenosis were in class 1, all the others in class 2. Patients suffering from herniated disc prolapse were either in Class 1 (43%) or in class 2 (57%), while those with disc herniation and canal stenosis had a wider distribution: 36% in class 1, 57% in class 2, 7% in class 3.

Overall analysis of the data rendered the following information: 18 patients (44%) are in class 1, 22 patients (53%) are in class 2, the remaining patient (2,3%) is in class 3.

Assuming as satisfying results the first two classes of Henderson, we collected useful outcomes in 97% of cases.

Discussion

Clinicians think that they know the cause of sciatica and treat it by surgical removal of whatever is pressing on the nerve root, emphasizing to the patient that the procedure is to relieve leg pain and not back pain. Consequently, many patients are left with debilitating back pain after surgery and the options of anti-inflammatory medications, additional surgery and/or physical therapy. In these conditions segmental instability of the lumbar spine is regarded as one of the sources of low back-pain. Indeed, when the abnormal motion between two or more vertebrae is extensive, the

movement may cause mechanical deformation of the intraspinal nerve tissue and, thereby, induce pain and/or neurological deficits. But even minor instability may cause irritation of receptors related to facet joints or other components of the motion segment, resulting in local pain and/or painful muscular reflex spasm.

This may especially concern patients operated upon both at single or multiple levels, but is very frequently observed also in degenerative conditions. Although the disc is a major structural component of the spinal column, a spinal segment should be viewed as a three-joint complex consisting of the disc and the two facet joints. Disc degeneration is thought to precede all other changes within aging motion segment [1]. With disc dehydration and narrowing of the disc space, the anular fibres of the disc are no longer under tension loading but, rather, sustained compression loading from the vertebra above. Furthermore, the alignment between the facets change with reduced disc height and the facets begin to undergo subluxation until the tip of the inferior facets impinges on the lamina below. Throughout movement, the center of rotation within the motion segment no longer follows its expected path and subsequently becomes erratic. At that time, a patient not only may have back pain at forward flexion but also may have significant reproduction of pain when attempting to extend from a forward-bent position. This satisfies the three criteria of instability suggested by Kotilainen and Valtonen [2]: 1) instability catch; 2) painful catch; 3) apprehension.

During the process of three-joint complex degeneration, surgical intervention may be necessary to alleviate disabling symptoms but we must consider that all surgical interventions, violating the integrity of the three-joint complex, affect the biomechanical stability of the motion segment. Consequently, the surgical procedure may exaggerate a pre-existing degenerative instability, maintaining low-back discomfort.

It is obvious that procedures performed for pathologic alterations in the late degenerative phase, such as wide decompressive laminectomies or facetectomies, disturb load-bearing ability significantly and may lead to clinically relevant instability. In these instances, it may be necessary to perform a fusion to stabilize the unstable spine. Procedures performed for pathologic changes occurring during early degenerative and early instability phases, such as partial laminectomies and discectomies for disc herniations, cause only low-grade segmental instability. Such cases are more difficult to treat as rigid fixation represents an overtreatment

while the mere discectomy may be insufficient to cure backache.

In order to reduce the failed-back surgery rate in the latter group of patients, we tried to improve patient selection by forcing especially clinical examination of the back. Even though lumbar instability can be verified both clinically and radiologically, radiological findings do not always correlate with clinical symptoms and vice versa.

In our study spinal instability was evaluated by the three criteria mentioned previously: 1) instability catch; 2) painful catch; 3) apprehension. A further evaluation was made directly in the operative room inspecting the mutual relationship between the operated vertebral bodies. Patients with spinal instability present an abnormal excursion of the vertebrae when these are pulled up by a clamp branching their spinous processes.

In addition to nerve root decompression, all patients suffering from nerve root pain associated with significant low-back pain and satisfying the above mentioned four criteria, were stabilized by DIAM prosthesis, which was implanted into the segment affected by the disc-root conflict. Indeed, biomechanic tests [4] have demonstrated that a posterior shock-absorbing implant in lumbar spine is able to: 1) reduce intradiscal pressure; 2) re-tighten posterior elements of the vertebral bodies; 3) reduce rotatory dislocation. This represents an attractive alternative for stabilizing the painful segment and yet allow some spinal mobility. Also, the soft device is able to maintain the disc height and to prevent the facet impingement.

Although results of this study are very favourable, we realize that our procedure is somewhat empirical and lacking constant sensitivity. Nevertheless, the

DIAM prosthesis has demonstrated to be very biocompatible and either safely or easily implantable. Thus its use is not a harmful procedure. Consequently, we assume that whenever the diagnosis of back pain remains in doubt it is more useful for the patient to be implanted. No negative consequences can arise from the prosthesis even if the patient has not been selected correctly. It would be much worse to prevent using DIAM in an unstable patient who remains undetected by clinical and radiological selection.

This is our experience and the satisfying operative results seem to support our judgement. Nevertheless, improvements are necessary to further our knowledge on selection criteria. This is in the foreground for developing techniques with highest probability for success in a given low-back pain disorder.

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