

Orthopaedic Research Society
48th Annual Meeting
Dallas, Texas / February 10-13, 2002
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ABSTRACT NO. _____

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Porous [TiNi] device for degenerative disc diseases: Pre-clinical study

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Keywords (Primary;Other):

Intervertebral Disc;Low back pain;Lumbar spine;Spine fusion;Titanium alloy

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• **POROUS TiNi DEVICE FOR DEGENERATIVE DISC DISEASES: PRE-CLINICAL STUDY**

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INTRODUCTION

Degenerative disc diseases (DDD) that induce back pain through a degenerative collapse of the disc and the consequent increase of segmental instability represent a major concern for spinal surgeons. The development of cages arises from the high rate of failure reported when allograft or autogeneous graft was used without instrumentation. Despite the numerous options for lumbar interbody fusion, cages have been reported to subside, migrate, break or fail to induce fusion [1, 2].

To improve the relation between the implant and the biological structures, a new porous metal has been developed for medical applications. Using porous TiNi, biological tissues take advantage of the network of interconnected fenestration that extend throughout all this osteoconductive material [3]. An interbody fusion implant made of porous TiNi should permit the fusion of adjacent vertebral bodies without the requirement for additional bone graft. The objective of this study was to examine the outcome of a group of patients suffering from degenerative disc disease and instrumented with TiNi interbody fusion devices. This study is retrospective for the preoperative evaluation of the patients and the surgical instrumentation, and mainly prospective for the postoperative measurements.

MATERIALS AND METHODS

Patients

Patients instrumented with TiNi interbody fusion devices (IFD) at the Novosibirsk Research Institute of Traumatology and Orthopaedics were identified based on the following criterion. Patients were instrumented at the lumbar level (L4 and/or L5) following DDD diagnosis. A posterior lumbar interbody fusion (PLIF) technique was used with cylindrical implants with no supplemental posterior instrumentation. From the 55 patients identified, 39 had a minimum postoperative follow-up of six months and accepted to participate. The group included 27 males and 12 females having a mean age of 43.2 years.

The implants were machined from porous TiNi alloy produced following a self-propagating high temperature technique [4]. This material showed 74% of porosity and an average pore size of 297 µm (SD: 165 µm). The dimensions of the implant (diameter and length) were specified following the evaluation of the specific spinal geometry of each patient: 12mm (n = 29, 64%) or 14mm (n = 16, 36%) diameters; 21-25mm in length.

Evaluation parameters

The standard radiological evaluation consisted of standing postero-anterior (PA) and lateral films, and spine flexion and extension films. Fusion was quantified by the difference between adjacent vertebrae relative orientation on flexion and extension radiographs. An instrumented level showing a displacement of less than 5 degrees was considered fused.

Low back pain was assessed using a 6point scale: 0 representing no pain and 6 corresponding to unbearable pain. Functional outcome was assessed through a 24-binary statement questionnaire. Patient's condition self-rating was also recorded following a 5point scale: worse, not improved, mildly improved, marked improvement, complete recovery. Complications and secondary operations were also reported.

Five-ml blood samples were taken to quantify the nickel ions levels using inductively-coupled plasma mass spectrometry (ICP-MS).

RESULTS

A single level was instrumented in 33 patients (85%): the L4 disc in 13 patients and the L5 disc in 20 patients. Both L4 and L5 discs were instrumented in 6 other patients (15%). The average postoperative follow-up for these patients was 13.1 months (SD: 4.5 months). 32 patients were instrumented with additional bone graft packed anterior to the implant and 7 patients were instrumented without any bone graft. No difference was found between the two groups.

Complications were reported in 5 patients. All complications resolved shortly after the surgery and all involved patients developed interbody fusion. 36 patients (95%) showed interbody fusion with a displacement smaller than 5 degrees (average: 2.4 degrees). The average nickel content was 2.7 µg/L (SD: 3.4 µg/L) and it corresponded very well with the basal 15 µg/L blood concentration reported [5].

Patients' preoperative pain was high: 4.2 points (SD: 0.8 points) on a maximum of 5. The postoperative score was low: 0.6 (SD: 0.8) for an average pain reduction of 3.6 points (p < .001). Patients' postoperative condition self-rating was also high, ie. 4.5 points (SD: 0.7 point) on a 5-point scale. 23 patients claimed a complete recovery, 12 others claimed a marked improvement, and 4 patients condition was mildly improved.

Preoperative results of the disability questionnaire revealed that patients' condition was not very good before the surgery with 89% of the statements answered as "relevant". On the other hand, postoperative results show that the patients are in a better condition with only 6% of statements identified as "relevant". After grouping all statements across patients, 83.8% of the items have improved. None of the items showed deterioration and only 5.8% did not improve.

DISCUSSION

Disc collapse often results into segmental instability and low back pain. Instrumentation with intervertebral implants and fusion is the prevalent treatment. Numerous implant designs are available on the market, but very few permit osseointegration that improves interbody fusion. In the present study, only two patients (5.1%) showed non-fusion at follow-up. This result is comparable to those presented in the literature. Kuslich et al. [6] reported a four-year follow-up of patients instrumented with the BAK lumbar fusion cage. They have shown 91.7% and 95.1% fusion rates after two and four years respectively. These results were obtained following addition of bone graft. In the present study, 7 patients were instrumented without bone graft and all showed fusion with an average intervertebral displacement of 2.7 degrees (1.6 degrees). The use of bone graft does not seem to make any difference in the fusion process. These results support the existence of the TiNi osteoconduction properties. Additionally, nickel concentration levels compared very well with human normal blood levels.

Complications observed in the present study were similar to those reported in literature. Out of the 39 patients instrumented, only two inadvertent dural lacerations (5.1%) were noted. No additional surgery was required, but the mean follow-up is relatively short.

All patients felt important pain relief after the surgery. None experienced "very bad pain" or "almost unbearable pain". Among the group, 23 patients (59%) did not experience any pain, 11 patients (28%) had little pain, 4 patients (10%) had moderate pain, and only 1 patient (3%) still experienced bad pain. The decrease in pain also results into important improvement of patient's function (83.8%).

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