Clinical Evaluation of Porous Nitinol as a Cervical Fusion Device

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Introduction:
Interbody fusion devices (IFDs) represent a surgical solution to treat degenerative disc diseases (DDDs). The objective is to re-establish the intervertebral height and eliminate segmental mobility by inducing an intervertebral fusion. Technological development in implant design arose from the high rate of failure reported when allo- and autograft were used without instrumentation [1-3]. Many IFDs were therefore developed using additional spinal fixation. The objective of this study was to examine patients suffering from cervical DDDs and instrumented with a porous nitinol (PNT) IFD, which does not require bone grafting or supplemental instrumentation. The data were collected from clinical and radiological observations.

Materials:
Biomaterials: Porous nitinol implants were produced by self-propagated high-temperature synthesis and machined from raw material (Ø230±130-μm pores, 65±5% porosity; Actipore\textsuperscript{TM}, Biorhex Inc., Montreal, QC, Canada).

Methods:
Surgical technique: 39 patients suffering from DDDs at cervical level(s) were instrumented using an anterior cervical interbody fusion (ACIF) technique. The group included 23 males and 16 females (mean age: 49.7±8.3 y.o.). A significant follow-up of 5 months or more was chosen. Patients were instrumented between C3-T1 at either 1, 2 or 3 contiguous or non-contiguous levels. The inclusion criteria were the following: instability of cervical segment, osteophyte formation in facet joints or endplates, decrease in cervical disc height, scarring of ligaments, annulus or facet joint capsule, herniated nucleus pulposus, first surgery involving nitinol material, and no additional anterior instrumentation. The study exclusion criteria were the following patients with heart diseases, diabetes or osteoporosis and/or showing vertebral fracture were not selected. Radiological evaluation A retrospective post-op radiological evaluation consisted of standing antero-posterior and lateral films, as well as supine flexion and extension x-ray analyses. The relative orientation between the anterior face of the upper vertebra and the anterior face of the lower vertebra was measured on flexion and extension x-rays. The displacement was calculated as the difference between both orientations. Instrumented levels with a displacement inferior to 5° were considered fused.

Pain and symptoms: At the follow-up visit, patients quantified the level of pain that they experienced (both at follow-up time and retrospectively, prior to the surgery). Neck pain was assessed using a 6-point scale: 0 representing no pain and 6, an unbearable pain. Any significant change in pain condition was then evaluated using the Student’s t-test.

Patient function: Functional outcome was assessed through an 11-item questionnaire (MOS SF-36). The patient was asked to evaluate both his actual condition and that observed during the 4 weeks preceding surgery. The condition was recorded following a 6-point scale.

Results:
Twenty-three patients (59.0%) were instrumented at a single cervical level. Thirteen others (33.3%) were implanted at 2 levels, while three patients (7.7%) were instrumented at 3 cervical levels. The average postoperative follow-up was 29.5 months. A total of 38 patients (97.4%) showed a displacement inferior to 5° between flexion and extension radiographs (C6-C7, Fig. 1). One patient (2.6%) showed a displacement superior to 5°, therefore failing the fusion criteria after 28 months of follow-up. Complications were reported in six patients (15.4%), however they were not related to the use of PNT devices: patients managed to develop complete fusion and did not require reoperation. The evaluation of preoperative pain was relatively high: 3.1±0.7 on a maximum of 5 points. The postoperative score was low: 1.1±0.0 for an average pain reduction of 2.0 points. Prior to the surgery, 67.5% of the patients rated their general health as fair to poor. One year after the implantation of the PNT cervical implant, 72.5% of the patients were feeling better than before surgery took place.

Discussion:
The results obtained with PNT IFDs support the fact that the new biomaterial is effective for the treatment of DDDs reported in the cervical spine. PNT safety and efficacy was previously demonstrated to possess unique properties in order to fulfill the requirements for vertebral distraction and support. Moreover, its interconnected porosity also permitted osseointegration and reduced migration possibilities [4]. PNT capillarity and superelasticity also permit quick bone formation and long-term positive bone remodeling. An advantage in the case of PNT IFDs is certainly the rapid osseointegration without the requirement for bone graft. It should also permit the use of stand-alone implants without the requirement for anterior instrumentation therefore reducing surgery time.

References: