

Porous Nitinol for Intervertebral Fusion: A Histomorphometry and Radiological Study in Sheep

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INTRODUCTION

Intervertebral disc degeneration with consequent chronic low back pain and lumbar dysfunction represents a major affliction within the working population. In particular, cases of internal disc instability, height reduction, herniation, infection, and disruption are often observed. Treatment with spinal fusion cages was therefore introduced to provide immediate interbody fixation, mechanical stability, intervertebral fusion, disc height distraction, and consequent pain relief. Some disadvantages of spinal cages with autologous bone grafting were however noticed: long operative time, significant blood loss, graft harvest site morbidity, and high non-union rates. Porous osteogenic materials represent an alternative to traditional cage implants. For example, porous Nitinol (PNT) and its interconnected fenestration trigger cellular capillarity. Therefore, PNT should promote bone ingrowth, immediate fixation, and eventual intervertebral fusion without the need for bone grafting. The objective of this study was therefore to compare a PNT interbody fusion device to a commercially available hollow TiAlV cage based on osseointegration capacity, fusion success and distractive properties.

MATERIALS AND METHODS

Experimental design and surgical technique

Mature female sheep (1-2 years old) simultaneously underwent 2-level interbody surgery (retroperitoneal approach; left lumbar regions L2-L3 and L4-L5) with one PNT implant ($\phi 11\text{mm} \times 20\text{mm}$, $230 \pm 130\mu\text{m}$ pores, 68% porosity; Biorthex Inc., Montreal, Canada) and one hollow threaded TiAlV fusion cage ($\phi 11\text{mm} \times 20\text{mm}$). The TiAlV cage was first filled with iliac crest bone chips, then screwed into position using slightly modified PLIF instrumentation. The PNT implant was inserted in the second intervertebral space in absence of autograft seeding. The wound was closed in layers and the sheep were allowed to recover for 3, 6, and 12 months (4-6 sheep/time point).

Evaluation protocol

Histomorphometry: The spinal columns were removed as units (L1-L6), placed in neutral formalin (10%), and prepared for ground sectioning. After fixation, L2-L3 and L4-L5 segments were isolated. Implants were then sectioned at increments of 5mm. Following trimming, specimens were dehydrated in ethanol and cleared with xylene. Undecalcified tissues were then embedded in MMA. 100 to 300- μm sections were taken using an EXAKT saw and ground to 60 μm . Each section was then stained with Stevenel's blue and van Gieson's picrofuchsin. All individual 100 \times histological fields, contained within the metal perimeter, were acquired using light microscopy combined to a 3axis motorized stage. In parallel, an image analysis program was developed to sequentially acquire bone, soft tissue, and metal respective surfaces. For each entire histological slide, osseointegration was then obtained: [bone area%/(100%-metal area%)].

Radiological fusion analysis and interbody distraction index :

Frontal and lateral x-rays of specimens were evaluated for radiolucent halo and bone bridging by 3 surgeons in a blind fashion. A radiological fusion score (RFS) was developed: 12 points (max. 24) was considered fusion success. Pre-op and post op lateral x-rays were then numerized. An interbody (IB) distraction index was adapted from Sandhu et al. [1] using vertebral body and disc height measurements along the lumbar spine. The IB index was defined as [fusion height - (L1 + L6 height)]/average body height. Post-op IB index was pressed as a ratio to the pre-op IB index.

RESULTS

Based on histology assessment, PNT demonstrated a faster endoprosthetic ossification rate than the TiAlV cages. Indeed, PNT implant osseointegration gradually increased from 21.4% to

37.6% (3-12 mo., Fig. 1a) and was systematically higher than that of TiAlV (22.8%-25.4%; 3-12 mo.; Fig. 1a). Moreover at 6 and 12 months, PNT mineralized bone content (MBC) was even higher than basal cancellous bone MBC (28.8%; Fig. 1a). Based on bone bridging and absence of radiolucency criteria, PNT radiological fusion evaluation also increased with time (mean RFS : 12.5-18.5; 3-12 mo.; Fig. 1b) and was systematically higher than that of TiAlV cages (mean RFS: 2.0-15.0; 3-12 mo.; Fig. 1b). Regardless of implantation time, 81.25% of PNT implants (13/16) obtained fusion success, as opposed to 25% of TiAlV cages (4/16). Additionally, both implants obtained similar success in distraction from pre-op disc height levels until 6 months post-op (Fig. 1c): regardless of material type post-op IB index was higher than the pre-op level at all times except at 12 months.

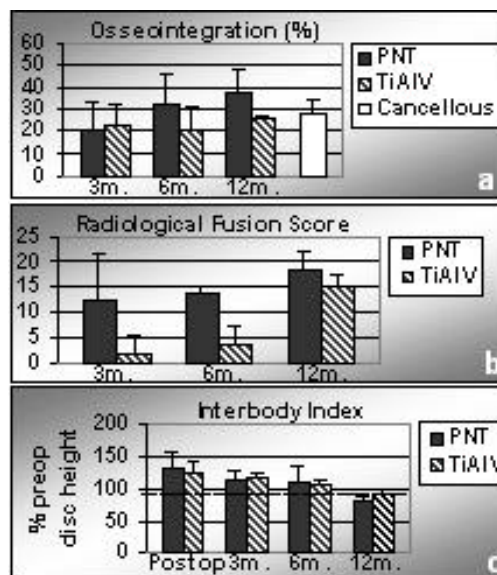


Fig. 1. Mineralized bone integration (a), radiological fusion score (b), and interbody index (c) according to implantation time.

DISCUSSION

Porous Nitinol constituted an excellent substrate for woven bone and osteogenic cells integration. PNT bulk structural properties such as high porosity percentage (mean: 68%) and adequate pore size (mean: 230 μm) for capillarity wicking forces, triggered high bone filling percentages reaching up to 37.6% of mineralized bone matrix after a year of sheep implantation. Similarly to osseointegration results, PNT radiological fusion scores compared favorably with the commercially available non-porous hollow TiAlV control cage currently used for lumbar interbody fusion. Moreover, autologous bone grafting did not confer TiAlV cages any advantage over PNT regardless of implantation time. Therefore, porous Nitinol represents a new biomaterial with osteoconductive properties for bone fusion. Potential applications include carrier materials and bone graft substitutes for guided bone regeneration. Soft tissue attachment and repair also represent potential applications of porous Nitinol. Additional mechanical characterization is currently being performed.

REFERENCES

[1] Sandhu HS et al. (1996). Spine 21(10):1201-1210.

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