

MECHANICAL TESTING OF POROUS NITINOL FOR INTERVERTEBRAL FUSION DEVICES

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INTRODUCTION:

Optimum orthopaedic devices in contact with hard tissue require the capacity to establish rapid bone fixation and ingrowth in order to ensure an adequate healing response and to avoid rejection of the implanted material within the long-term perspective. Very few engineered materials possess high strength, high recoverable deformation and substantial strain to failure in order to be applied in conjunction with bone tissue. Porous nitinol (PNT) holds great promise for clinical applications such as interbody fusion devices (IFDs) since its osseointegration and fusion capacities have been successfully demonstrated [1]. In this study, porous nitinol mechanical characteristics under static compression, tension and torsion were evaluated in order for the PNT IFD to eventually prevent subsidence and facilitate bone remodeling phenomena.

MATERIALS AND METHODS:

Biomaterials: Porous nitinol specimens were produced by self-propagated high-temperature synthesis (SHS) and machined from raw material ($\varnothing 230 \pm 130$ - μm pores, $65 \pm 5\%$ porosity; Actipore™; Biorthex Inc., Montreal, QC, Canada). Standard cylindrical PNT materials with a constant cross-section ($\varnothing = 12.5 \pm 0.25\text{mm}$; $L = 30.0 \pm 0.1\text{mm}$; $n = 10$ all tests) were tested in compression and torsion. Round shouldered PNT specimens (reduced cross-section: $\varnothing = 8.89 \pm 0.2\text{mm}$) were also evaluated for tensional strength.

Apparatus: PNT specimens were evaluated using a universal testing machine (INSTRON 8521) following ASTM E6 [2] and E8 [3] standards. Parallel plates were used for even distribution of compressive load (perpendicular pins were added to transmit torque during torsion testing). Cylindrical and shouldered specimens were loaded along the specimen longitudinal (z) axis (compression and tensional strength respectively). Cylindrical specimens with square ends were loaded with a torque in the longitudinal (z) direction (torsional strength). The rate of rotation of the machine heads was predetermined to $6^\circ/\text{min}$. In all cases, the application range of the force acquisition was 22,000N. Load/deflection curves were recorded and tests were performed until specimen failure, which was defined as a visible crack developing through the material struts or a noticeable decrease in the stress beyond the elastic period.

Compressive and tensional strength: PNT strength was calculated by dividing the maximum force carried by the original cross-sectional area of the specimen. The modulus of elasticity was determined from the slope of the stress-strain diagram in the linear elastic region. Yield strength was determined by the offset method.

Torsional strength: The torsional strength was calculated by multiplying the maximum torsion moment by the original outer radius and the polar moment of inertia of the original cross-section. The torsional modulus of elasticity was determined from the slope of the stress-strain diagram in the linear elastic region. Yield strength was also determined by the offset method.

RESULTS:

Compressive strength: All PNT specimens showed a similar compressive characteristic behavior during load application. A progressive deformation was obtained, followed by a buckling phenomenon. PNT is a ductile material and showed a pronounced plastic and accentuated deformation (Fig. 1). A continuous enlargement of cross-section resulted in an "S"-shaped device after testing. PNT did not demonstrate any brittleness or fracture up to 22,000N: No particle was observed to detach before high non-physiological loads were reached ($> 20,000\text{N}$). Compared to Bobyn et al. [4], PNT compressive strength (180-218MPa, Fig. 2) seemed to be superior to that of cortical bone (130-150MPa, Fig. 2), as opposed to porous ceramics for example (3-30MPa, Fig. 2) which are considered very brittle.

Tensional strength: Porous nitinol devices again showed a consistent rupture pattern. Specimens fractured with a less ductile behavior however and a relatively low deformation at failure was obtained under tension (6.0%, Table 1).



Figure 1. Porous nitinol ductility capacity under compression.

Torsional strength: PNT materials systematically fractured following a relatively large deformation (6°). They presented a roughly oblique fracture cracking, which was not visible until failure. The resulting broken pieces were demonstrated to possess a spiral shape. Average ultimate strength values (524MPa, Table 1) were in the acceptable range for interbody fusion devices.

Table 1. Porous nitinol mechanical properties.

Property	Compression	Tension	Torsion
Elastic modulus (GPa)	3.7	4.6	13.4
Yield strength 0.2% (MPa)	42.7	9.0	214.0
Max. elastic deformation (%)	6.6	2.3	1.4 ($^\circ$)
Ultimate strength (MPa)	213.4	16.2	524
Strain to failure (%)	52.3	6.0	5 ($^\circ$)

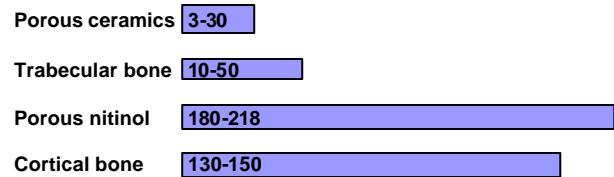


Figure 2. Compressive strength (MPa) of porous materials.

DISCUSSION:

Similar to other biomaterials with intervertebral fusion applications, porous nitinol must be able to sustain biomechanical stress and resist strain found in the spinal column environment. PNT mechanical testing allowed to provide necessary information on strength and ductility, as well as a solid base for the possible design applications of the alloy. Compression, tension and torsion testing therefore permitted to evaluate some mechanical conditions to which PNT IFDs are exposed in clinical service. For example, porous nitinol showed suitable properties for an interbody fusion implant, being stronger in compression than cortical bone (Table 1; Fig. 2) while showing an elastic modulus similar to trabecular bone. It certainly explains the excellent osseointegration, bone bridging and remodeling phenomena obtained with porous nitinol implants in the past [1]. With similar mechanical properties to bone, it is possible to expect that porous nitinol devices will rapidly develop bone anchoring, fusion, consolidation properties and therefore mature bone formation will follow.

REFERENCES:

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