Cervical Interbody Fusion Devices: A Load-Induced Subsidence Resistance Evaluation

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Introduction:
Cervical interbody fusion devices (CIFDs) are inserted between vertebrae to restore the original intervertebral height and lead to bone fusion. However, current cervical cages have been associated with clinical outcomes such as segmental instability and device subsidence. In this study, a porous nitinol cervical implant was evaluated for resistance to load-induced subsidence. Its performance was compared to different cervical spine fusion devices.

Materials and methods:
Biomaterials: Standard windowless Actipore™ Anterior Cervical Fusion (ACF) devices (w=12-15mm, L=13.5mm, h=3-4.5mm; n=5; Biorthex Inc., Fig. 1) present a double-dome top with a flat bottom shape for an adequate intervertebral fit without the requirement for a bone graft. They were produced by self-propagated high-temperature synthesis (SHS), machined from raw material (porous nitinol; ∅230±130-µm pores, 65±5% porosity) and were tested in load-induced subsidence.

Controls: Their performance was compared to that of current hollow cervical devices: expandable threaded cylindrical (TiAlV, CIFEC; Proconcept SA), domed top and flat bottom (TiAlV, SynCage-C; Synthes-Stratec), waved top and bottom (porous tantalum, Hedrocel cervical fusion; Implex), and expandable waved top and bottom (TiAlV, C-Varlock, Kiscomedica) cages.

Load-induced subsidence testing: All cervical devices were evaluated using a universal testing machine (INSTRON 8521) following ASTM F1839-01 [1]. The CIFDs were positioned between two grade-15 polyurethane blocks in order to achieve device subsidence. The intervertebral body fusion devices were then assessed for their degree of subsidence under uniaxial compressive stress. According to ASTM F2077-01 [2], the suggested intradiscal height for the intended level of application is 4mm. In this study, the failure criterion was set to a 50-% loss of initial disc height (2mm). This value was chosen in case of failure due to distraction loss associated with reoccurrence of pain and function deficits.

Statistical analysis: One-way analyses of variance (ANOVA) were performed to determine if any statistically significant difference existed between cervical cages.

Results:
All cages obtained a similar behavior in subsidence testing using a 2-mm failure criterion. In fact, in all cases, load *vs*. displacement curves showed a similar phenomenon: displacement was directly proportional to load (Fig. 2). Moreover, Actipore™ ACF specimens (Fig. 1) obtained a significantly superior slope corresponding to resistance to subsidence when compared to other current cervical cages (Fig. 2) according to a one-way ANOVA. Regardless of CIFD type, there was no particle detachment from the blocks. No failure was observed with any cages.

Discussion:
Subsidence and migration both represent well-known clinical complications that were observed in the past with intervertebral fusion cages [3]. In some cases, the cage structure had a tendency to sink through the vertebral endplate and progress into cancellous bone [4,5]. The excellent resistance to load-induced subsidence in the case of Actipore™ ACF is hypothesized to be a consequence of its shape design. The ACF device seems to mimic the intervertebral space: its flat bottom permits maximal contact to the inferior endplate. The device double-dome top additionally follows the concavity of the superior vertebra. Actipore™ ACF therefore offers a better support to vertebral end-plates and consequently permits to reduce the subsidence phenomenon. Moreover, the Actipore™ ACF bulk porosity did not seem to affect block support in this study. Porous nitinol interconnected porosity will additionally permit rapid bone integration without the necessity for bone grafting.

Fig. 1. Actipore™ Anterior Cervical Fusion implants.

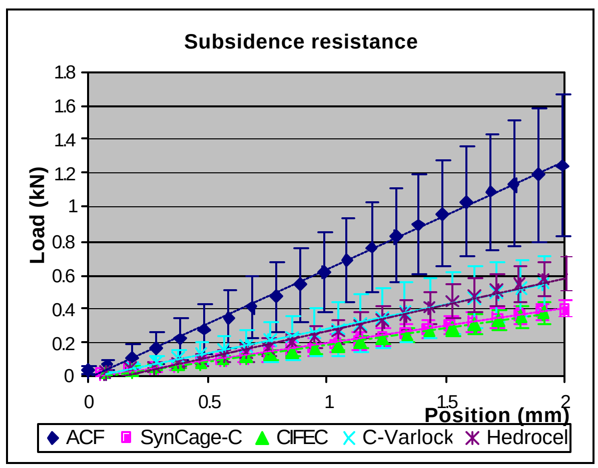

Fig. 2. Subsidence resistance to load-induced subsidence.

References:
[1] ASTM F1839-01, 2001.
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