Paper #30 2003

Porous Coated Motion Cervical Disk Replacement: A Biomechanical, Histomorphometric, and Biologic Wear Analysis in a Caprine Model

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INTRODUCTION: The current study was undertaken to investigate the biomechanical and biologic in-growth characteristics of the Porous Coated Motion cervical disc prosthesis following a six and twelve-month implant duration using an in-vivo caprine model (n=12). As a secondary objective, the caprine model was evaluated for suitability as an animal model for evaluation of total disc replacement arthroplasty, motion preservation and biocompatibility.

METHODS: Twelve mature Nubian goats were equally divided into two groups based on post-operative time periods of six-months (n=6) and twelve months (n=6). Using an anterior surgical approach, a complete diskectomy was performed at the C3-C4 level followed by implantation of the Porous Coated Motion cervical disc prosthesis. The prosthesis contains an electrochemically bonded TiCaP coating at the implant surface, which serves to optimize mineralized anchorage at the vertebral endplates. The animals were euthanized at the appropriate post-operative time interval with status of the disc prothesis based on computed tomography (CT), multi-directional flexibility testing, undecalcified histology, histomorphometry and immunocytochemical analyses.

Animal Research Permission: The institutional animal care and use committee (IACUC) granted approval for this project.

RESULTS: All twelve animals undergoing porous coated motion cervical disc replacement had no evidence of prosthesis loosening, neurologic or vascular complications. Computed tomography scans obtained six-months post-operatively demonstrated the ability to image and assess the cervical spinal canal for the presence of compressive pathology in the area of a CoCrMo prosthesis (previously only shown for titanium implants). CT scan axial images through the maximum mass of the prosthesis showed the preserved ability to evaluate the spinal canal and rule out further compressive spinal cord lesions. Multi-directional flexibility testing indicated no differences in full range of intervertebral motion between the Porous Coated Motion prosthesis and the normal cervical spine (n=7) under axial rotation, flexion/extension or lateral bending conditions (p>0.05) (Figure 1). Based on immunohistochemical and
routine histologic analysis, there was no evidence of particulate debris, membrane-bound cytokines or cellular apoptosis within the local or systemic tissues. Moreover, review of the spinal cord at the operative levels indicated no evidence of cord lesions, inflammatory reaction, wear particles or significant pathologic changes in any treatment. Histomorphometric analysis at the metal-bone interface (bone contact area / total endplate area) indicated the mean trabecular ingrowth of 40.5±24.4% (Figure 2). This was more favorable porous ingrowth than reported for acetabular, femoral, patellar, and tibial conventional joint prostheses in arthroplasty literature.

CONCLUSIONS: All twelve goats undergoing porous coated motion cervical disc replacement had no evidence of prosthesis loosening, neurologic complications or experienced inflammatory reactions from particulate wear debris – after six and twelve month implantation intervals. Segmental intervertebral motion was preserved based on multi-directional flexibility testing. The TiCaP porous ingrowth surface provided some immediate advantages with friction during press-fit applications and there was no significant anterior prosthesis subluxation despite immediate post-operative unrestricted cervical activity. The current study establishes a challenging biomechanical model for evaluation of cervical disc prostheses. At 6 months follow up in the caprine model there was an absence of cellular reaction and no granulation tissue response to any particulate wear debris.

![Multi-directional Flexibility Testing](image)

**Figure 1: Biomechanical Loading Mode**

One-Way ANOVA:
- Axial Rotation: F=0.08, p=0.968; NSS
- Flexion Extension: F=3.67, p=0.029
- Lateral Bending: t=1.00, p=0.412; NSS

* - indicates statistical differences from all groups

Non-Union Rate:
- Autograft - 57%
- Autograft + Plate - 43%
• If noted, the author indicates something of value received. The codes are identified as: a - research or institutional support, b - miscellaneous funding, c - royalties, d - stock option, e - consultant or employee. For full information, refer to inside back cover.

• The FDA has not cleared the drug and/or medical device for the use described in this presentation (i.e., the drug or medical device is being discussed for an “off label” use). For full information, refer to the disclaimer information at the back of the book.