

# Technical Monograph

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## **BRYAN<sup>®</sup> Cervical Disc Prosthesis**

### **Biomechanical Testing**

**Paul A. Anderson, M.D.**  
University of Wisconsin  
Madison, Wisconsin USA

**John G. Heller, M.D.**  
Emory University Hospital  
Atlanta, Georgia USA

**Bengt Lind, M.D., Ph.D.**  
Sahlgrenska University Hospital  
Göteborg, Sweden

**Bryan<sup>®</sup>**  
Cervical Disc System

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## SUMMARY

The preclinical safety of the BRYAN® Cervical Disc Prosthesis has been thoroughly evaluated over a span of five years (1998 – 2003) in a rigorous series of mechanical tests, cadaveric experiments, and *in vivo* animal models. Device integrity was demonstrated in multiple loading modes, including shear, tension, torsion, compression, creep, and wear during simulated activities of daily living. Animal models confirmed that the biologic response to the device was acceptable. Following successful completion of these tests, a clinical trial was initiated to evaluate safety and efficacy. Clinical studies continue to investigate device migration, subsidence, and range of motion, using state-of-the-art radiographic techniques.

## DEVICE DESCRIPTION

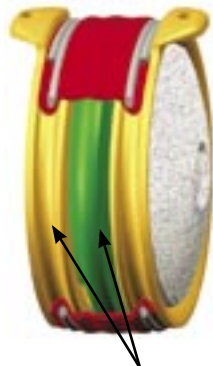
The BRYAN® Cervical Disc Prosthesis, manufactured by Medtronic Sofamor Danek USA, Inc., is a cervical intervertebral disc prosthesis designed to permit motion similar to the normal cervical functional spine unit. The prosthesis (see Figure 1) is intended to treat stable cervical disc disease without fusion, thereby providing the patient with the capability for motion at the treated level.

The device consists of a polyurethane nucleus designed to fit between two titanium alloy surfaces (shells). The bone-contacting surface of each shell includes a titanium porous coating to facilitate bone ingrowth and long-term stability. A polyurethane sheath surrounds the nucleus and is attached to the shells, forming a closed compartment. Titanium alloy seal plugs provide for retention of a lubricant. Anterior stops on each shell are designed to prevent posterior migration of the device.

The prosthesis is currently available in five diameters: 14, 15, 16, 17, and 18mm.

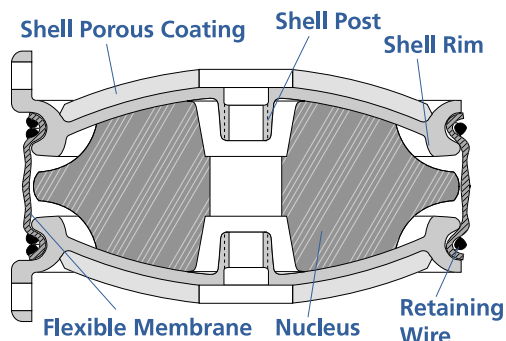


Figure 1  
BRYAN® Cervical  
Disc Prosthesis



Shell/Nucleus  
Interface

- Nucleus
- Shell with Rigid Wings
- Porous Coating on Shell Dome
- Sheath (shown cut away)
- Retaining Wires (shown cut away)



## LABORATORY AND CADAVER TESTING

In order to establish the safety of the BRYAN® Cervical Disc Prosthesis, potential failure modes were identified, and each was assessed in a specifically designed experiment where the severity of the test was increased until the prosthesis failed. Tests were initiated after several years of prosthesis development and were performed over a period of five years. In order for the device to pass each test, the failure level must exceed the *in vivo* load requirement with an adequate factor of safety.<sup>1</sup> A subset of the tests completed to date are listed below.

### Compression Tests

The metallic prosthesis shell was tested in compression fatigue to verify that the porous coated prosthesis would be able to carry the expected clinical load for 10 million cycles. The shell passed with a factor of safety of three.

The nucleus was evaluated under static compression to verify that extreme one-time loads will not cause prosthesis failure. The load-carrying capacity of the device exceeded by a factor of 11 the maximum published compression for voluntary activities, which range from 55 to 1164 Newtons.<sup>2,3</sup> Subsequent compression fatigue testing of the nucleus for 10 million cycles demonstrated that the factor of safety was greater than 12 in this fatigue loading mode.

### Shear Tests

The prosthesis was implanted in the cervical spines of cadavers. Under the axial compression associated with typical neutral zone activities, the caudal vertebral body was forced anteriorly at a constant displacement rate. The prosthesis did not migrate from the vertebral bodies, and implanted levels tested to failure were able to carry loads at approximately 83% of the unoperated levels in spite of the lack of bony ingrowth into the device. The shear displacement for additional tests was halted at a load level corresponding to a factor of safety of four; no devices failed at this load level.

The seal plug post in the prosthesis shell was tested in shear fatigue to assure that the post has adequate fatigue strength to withstand 10 million load cycles. In order to increase the severity of the test, it was assumed that 100% of the shear load would be carried by the shell post and 0% would be carried by the shell inner lip. In spite of these harsh test parameters, the device passed with a factor of safety over 2. *In vivo* cervical shear loads are reported to range from 0 to 135 Newtons.<sup>2</sup>

### Tensile Tests

The assembled prosthesis was distracted at a constant rate to assess the ability of the sheath to maintain mechanical integrity. The sheath was able to maintain a seal after a displacement of 10mm and was not ultimately ruptured until a displacement of 16mm was reached, suggesting

<sup>1</sup>Factor of safety is the ratio of the failure load to the maximum expected *in vivo* load.

that the measured factor of safety greater than 7 for device integrity is more than adequate.

### Torsion Tests

The porous coating of the prosthesis shells was rotated under a constant compression against bone, and the torsional resistance was compared to that required to rotate a shell on a nucleus under the same compressive load. Due to the inherent stability of the porous coating combined with the low friction of the nucleus and the highly polished inner surface of the shells, the porous coated shells have a greater tendency to rotate at the shell/nucleus interface than at the shell/bone interface immediately post-implantation. After ingrowth of bone into the porous coated surface of the implant, the probability of shell migration is remote.

The assembled prosthesis was subjected to 90° of axial rotation under normal neutral zone compression. The interior seal of the prosthesis was maintained even though the human range of motion in axial rotation for the middle and lower cervical spine is 7°.

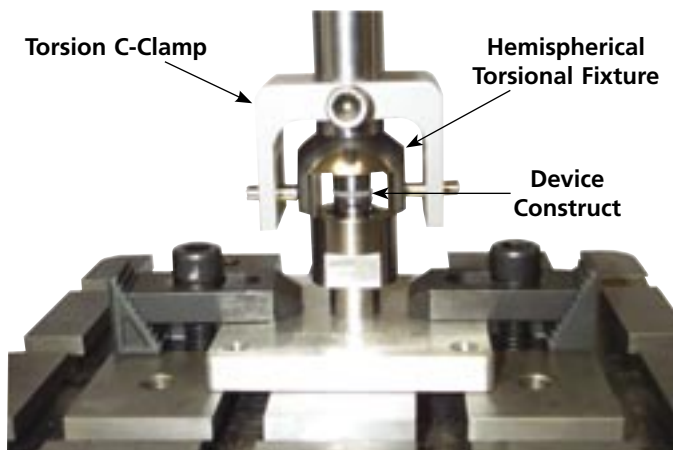


Figure 2  
Test configuration for torsion/compression testing

### Creep Tests

Prosthesis nuclei were subjected to constant axial compression expected during neutral zone excursions of the cervical spine. The test was performed in 0.9% saline at body temperature for 700 hours while continuously monitoring axial displacement. Creep was limited to 4.3% under these harsh loading conditions.

### Wear Tests

Custom cervical spine simulators were designed and built to reproduce the loads and motions of the cervical spine. With the care of custom computer-controlled motors, the system is capable of applying axial compression while performing axial rotation and flexion/extension or lateral bending motions. Tests were performed at body temperature in bovine serum to replicate the degradative effects of extracellular fluids on the prosthesis materials, if any.

Six nuclei were tested to 10 million cycles of flexion/extension and 10 million cycles of concurrent axial rotation to evaluate the durability of the prosthesis. Three

additional samples were subjected to the compressive loads without the motions in order to adjust for any gravimetric changes due to hydration rather than nucleus wear. A full characterization of particulates generated during the experiment was performed, and the ability for the sheath to restrict movement of any particulates generated was assessed.

The nuclei had lost less than 2% of their mass due to wear at the conclusion of the test. All prostheses were fully functional and demonstrated no indications of impending failure. Every sheath was able to maintain air pressure, suggesting that no particulates from the nucleus were allowed to migrate from the inner portion of the device. Particle analysis showed that the wear particulate was generally globular in nature with an average diameter of 3.9 microns. In contrast, traditional polyethylene hip and knee prostheses produce particles that average less than two microns in diameter. Less than 5% of hip particles and 25% of knee particles are more than two microns in diameter.<sup>4,5</sup> Recent studies have shown that submicron particles can initiate cytokine release, whereas larger particles (greater than two microns) produce either no activity or activity only at high doses.<sup>6,7</sup>



Figure 3  
Front view of a custom Cervical Spine Simulator

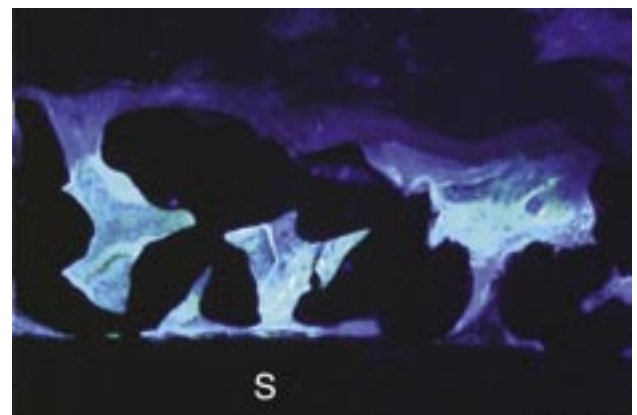


Figure 4  
Tetracycline-labeled bone ingrowth into the shell's porous coating

## ANIMAL STUDIES

First generation devices were implanted into six large primates for a period of six months. While the biomechanical and anatomical similarities would suggest that the choice of primates was appropriate, the animal model proved to be extraordinarily harsh. Within a few hours after the surgical procedure, the animals resumed daily activities without restriction. In spite of the severity of the model, safety was demonstrated; no device migration or disc space collapse was detected. All animals were successfully fused following explantation and were returned to their colonies. Modifications were made to improve the bone preparation process and to improve the bone ingrowth surface of the prosthesis. These modifications were evaluated in a follow-up large primate study with four additional animals. In spite of this lack of post-operative immobilization, the prosthesis demonstrated bone ingrowth in all device-to-vertebral-body interfaces. This observation was supported by the histologic observation of tetracycline-labeled bone ingrowth through all bead layers to the shell substrate. Further direct evidence in the form of radiographic stability under passive spinal manipulation indicated that there was no motion of the shell at the vertebral endplate and confirmed intended implant function throughout the range of motion.



**Figure 5**  
Anatomical comparison of the vertebral body of the human (left) and the large primate (right)

Recent efforts have sought to identify the local and distant biologic response to the prosthesis in a goat model. This long-term study of three animals each at three months, six months, and twelve months characterized the response to the device in the periprosthetic tissues, spinal canal tissues, lymph nodes, liver, and spleen. No inflammatory response to the bulk device was observed at any time point. A limited number of particles (typically 2 to 4 per  $\text{cm}^2$ ) were observed in periprosthetic tissue at six and 12 months but there was no inflammatory response.

## CLINICAL STUDIES

Having successfully completed testing in the laboratory and in animal models, clinical trials were initiated in Europe in January, 2000. Several supplemental clinical evaluations were performed on a subset of these patients in order to establish safety and efficacy in humans. A two-year RSA (radiostereometric analysis) study is

ongoing to assess device subsidence and migration. This advanced technique uses small radio-opaque markers to assess the position of each prosthesis shell with respect to the adjacent bone. All components were stable ( $<100$  microns of migration or subsidence) within three to six months in the 11 patients studied. The six-month prosthesis stability in the eleventh patient will be assessed when adequate follow-up is reached.

An additional clinical study was initiated in 40 patients to evaluate the ability for the cervical disc prosthesis to maintain cervical motion at long follow-up periods. To date, dynamic fluoroscopy has shown that all C5/C6 disc-replaced patients demonstrate cervical spine motion at one-year follow-up that is statistically similar to that observed in normal volunteers but statistically different than both C5/C6 degenerative and C5/C6 fused patients.

## CONCLUSIONS

The BRYAN<sup>®</sup> Cervical Disc Prosthesis has been extensively evaluated in the laboratory in a series of worst-case mechanical challenges. The evaluation included the development and implementation of custom test equipment to verify adequate durability of the prosthesis through 10 million simulated load and motion cycles. The device passed this and all other tests with an adequate factor of safety, suggesting that mechanical failure of the device *in vivo* is unlikely. Animal models were subsequently employed to further evaluate the safety of the prosthesis. Again, the device demonstrated excellent mechanical integrity and excellent resistance to subsidence and migration. Finally, ongoing clinical studies are confirming that the results from the animal studies do apply to humans. Device stability has been demonstrated in an RSA study, and the ability of the device to preserve motion has been confirmed in a dynamic fluoroscopy study.

## REFERENCES

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- <sup>6</sup> Green T.R. *et al.*: J. Biomed. Mater. Res. 53: 490-497, 2000.
- <sup>7</sup> Matthews J.B. *et al.*: J. Biomed. Mater. Res. 52: 296-307, 2000.



**THE BRYAN<sup>®</sup> CERVICAL DISC PROSTHESIS IS NOT FOR DISTRIBUTION IN THE USA OR ITS TERRITORIES.**