WEAR ANALYSIS OF THE BRYAN CERVICAL DISC PROSTHESIS

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PURPOSE:
To measure the in vitro and in vivo wear properties of the Bryan Cervical Disc Prosthesis.

METHODS:
Cervical Simulator: In vitro wear was measured in a custom cervical spine simulator. The testing assemblies were identical to the sterilized prostheses in materials and processing with the exception of end plates which were modified for fixturing purposes. A polymeric nucleus was placed between the metallic end plates and surrounded by a sealed polymeric sheath. All nuclei were hydrated with saline for a minimum of 72 hours prior to testing. Six assemblies were tested to 10,000,000 cycles at 37°C in bovine serum with the following load and motion profile: 130 (N) constant load with simultaneous ± 4.9° flexion/extension and ± 3.8° axial rotation at 4 Hz. Three additional load soak control assemblies were subjected to only load for the same duration. These were used to determine fluid absorption and creep effects on height and mass of the nucleus. An additional three assemblies and two load soak controls were tested for long term wear, with the endpoint being when wear of the prosthetic nucleus was sufficient to allow prosthesis endplate-to-endplate contact.

Before testing and following testing the nuclei were visually inspected microscopically and the mass, height, and diameter were characterized. Additionally, wear debris from two samples were analyzed microscopically at 100X and 400X in accordance with ASTM F1877.

Caprine Model: Fifteen skeletally mature Nubian goats had anterior discectomy at C4-C5. Eleven had reconstruction with the Bryan Cervical Disc and four with iliac crest allograft and titanium cervical plates. Animals were divided into the following groups: Group I baseline n =1, Group II Bryan 3 month n =4, Group III Bryan 6 month n =3; Group IV Bryan 12 month n=3; Group V plated control 12 month n =4. One animal in the plated group sustained a cervical fracture and was euthanized before completion of the study. One animal in Group II died the first postoperative day from gastrointestinal complications and was excluded from analysis. The animal protocols were approved by the local animal care committee.

After sacrifice, the following samples were analyzed: Periprosthetic, spinal canal at the surgery site and cranial and caudal sites, draining lymph nodes, liver, and spleen. All tissues were subjected to histopathologic examination to estimate the degree of inflammatory response and to identify any polymeric or metallic wear debris per ASTM and ISO standards. The sections were stained by H&E and were assessed under microscopy by a blinded veterinary pathologist. The polymeric materials produce polarizable particles that are easily identifiable using polarizing light microscopy.

RESULTS:
Cervical Simulator: All assemblies maintained functionality to 10 million cycles. Uniform wear was observed except in one specimen where four indentations were observed on the nuclear surface. No metallic wear debris was noted. The mean load soaked adjusted mass loss was 1.76%. The average height loss was 0.75%. The particulate debris analysis is given in Table 1. The mean particulate size was 3.9 μm.

In long-term wear testing, endplate contact occurred 37.7, 39.7 and 40 million cycles. An average of 18.2% of nuclear mass was lost at this point. Despite the contact the prosthesis remained functional.

Caprine Model:
Periprosthetic Tissue, Bryan:
Polarizable particulate debris was seen in three of nine animals. The debris was extracellular and present in small quantities not associated with any inflammatory reaction.

Periprosthetic Tissue, Plated:
Many macrophages containing dark nonpolarizable material (titanium) were observed in all sections of all three animals.

Lymph Tissue Bryan:
No particulate debris or inflammatory response secondary to surgery or the Bryan disc were observed. Lymphadenitis was observed in the majority of animals and was secondary to green identification tattoo pigment used by animal care givers. This was similar histologically to specimens obtained from the pinna and in the control animals.

Lymph Tissue Plated:
No debris or inflammatory reactions related to the surgery or implant were identified. Other findings of lymphadenitis were thought to be secondary to tattoo pigments and/or chronic parasitism.

Neural Tissues Bryan:
Three of the nine Bryan animals had polarizable material anterior to the dura mater in the cervical spine and one in the lumbar spine. The material was loose in the adipose tissue and not associated with any cellular response.

Neural Tissues Plated:
No particular matter or inflammatory process was identified.

Distance:
The liver and spleen from Bryan disc and control animals did not demonstrate any particulate matter or obvious inflammatory reaction. Findings such as hyperplasia were thought to be nonspecific and unrelated to the surgery or prosthesis.

CONCLUSION:
Wear of the polymeric bearing surfaces has been associated with long-term failure and, in particular, to adverse inflammatory reactions of joint prostheses. This study utilized protocols similar to standards established for large joint arthroplasty. Wear was observed and resulted in 1.76% mass and 0.74% height loss of the polymeric nucleus. This wear rate may not be representative of human wear rates due to multiple factors. For example, the animals continued to head-butt to establish herd dominance and the biomechanics of the goat force the device through a larger range of motion while under a higher load. In these studies, wear particles were observed in the periprosthetic and the epidural space of three of nine goats. No inflammatory reaction was observed. A more severe inflammatory reaction was seen in the periprosthetic tissue in the fused and plated control animals. No distant effects in lymph nodes or liver and spleen were observed.

Based on these studies, the Bryan cervical disc prosthesis has acceptable wear characteristics to predict satisfactory long-term performance.

Table 1 Particulate analysis after 10 million simulator cycles.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Min</th>
<th>Max</th>
<th>Average</th>
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</thead>
<tbody>
<tr>
<td>Feret Diameter, μm</td>
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<td>Equivalent Circle Diameter, μm</td>
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<td>Aspect Ratio</td>
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<td>Elongation</td>
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<tr>
<td>Form Factor</td>
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</tr>
</tbody>
</table>

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