Introduction: Cervical total disc replacement (TDR) procedures are an option for treatment of cervical spinal disc degeneration. The goal of TDR replacement is to replace the painful and degenerated TDR with a new bearing unit to enable pain free motion. A young and active patient population demands a proven durable replacement bearing surface to accomplish this goal. The wear of that surface may be dictated by design considerations such as bearing surface material or designed constraints. The Prodisc-C device is an example of a semi-constrained metal-on-polyethylene (PE) cervical TDR replacement based on past highly successful total joint replacement models. PE wear debris should be well characterized during cervical TDR replacement design. Currently, cervical TDR replacement wear data exists for several design and material combinations [2]. It is important to document the in-vitro wear performance for cervical TDR replacement designs, and to verify this work through patient follow-up and finally retrieval analyses. An ISO input parameter set for simulation of cervical TDRs exists [3]. Current information on PE wear in cervical TDR replacements based on ISO inputs has not yet been published.

The purpose of this investigation was to assess the in-vitro wear performance of an articulating, semi-constrained, metal on polyethylene cervical TDR replacement when experiencing ISO cervical load and motion conditions.

Materials and Methods: Two temperature controlled, eight station spine simulators (Endolab, Germany), designed according to ISO/DIS 18192, were mounted with 4 Prodisc-C (Synthes, USA) cervical artificial discs per simulator. The Prodisc-C articulation surface is a CoCr alloy/UHMWPE couple that represents a semi-constrained design. The implants were fixed with polyurethane, and care was taken to assure proper center of rotation alignment. Two specimens served as loaded soak controls.

The ISO cervical wear test inputs a “cross-shear” motion profile. The magnitudes and frequencies of the ISO loading and motion profiles experienced by the implants on this simulator are shown in Fig 1. The cross-shear motion pattern is based upon literature values for physiologically based loads and motions in the cervical spine [3].

All PE inlays were pre-soaked in distilled water at a temperature of 37±2°C for at least 2 weeks. The testing temperature of the test medium was 37±2°C. Calf serum according to ISO/DIS 14242-1 with a protein content of 30 g/L, and EDTA content 20 mMol was used. Patricin (50μg/mL) has been added to retard bacteria-induced degradation. Test serum was exchanged and a thorough apparatus cleaning was conducted every half million cycles.

An analysis of each dismounted cleaned prosthesis was conducted before the test, at 500k cycles, at 1 million cycles, and at 1 million cycle intervals thereafter for a minimum of 6 million cycles. The PE parts were cleaned, dried, and the gravimetric wear rate was determined, adjusted with the load-soak control weight change, according to ISO 14242-2. The average wear was calculated using a linear regression analysis. Wear surfaces were described. Wear particle size (ECD) and shape factor were determined based on published methodology [4,5].

Results: A mean soak controlled gravimetric wear rate of 1.99±0.15 mg/milion cycles was determined for the Prodisc-C PE components subjected to the ISO input profile (Fig 2). The PE contact surfaces for all implants tested showed highly polished areas, machine mark residuals, and light surface scratches. No plastic deformation or implant failure occurred. Particle analyses showed a mean ferret diameter ranging from 0.172 to 0.326μm (Fig 3) with >90% of the particles being submicron in size. Shape factors ranged form 0.771 to 0.878, indicating particles were generally spherical in nature.

Discussion: The wear performance of the Prodisc-C has been simulated in vitro according to ISO specified parameters, and the resultant PE wear rates, contact surface analyses, and particle sizes have been reported. Wear rates are considerably below that of other Metal on PE lumbar discs and total hips. The components experienced multi-directional motions that are likely to occur in a young and active patient’s cervical spine [7]. To the author’s knowledge, this is the first cervical TDR replacement PE wear rate reported using the ISO inputs. When compared to the lumbar input parameters, the cervical incorporates a much lower peak load (150N vs 2000N), and a greater range of motion. Prosthesis performance in this unique environment should be more thoroughly characterized in the future as retrievals become available in order to further optimize cervical prosthesis designs.