WEAR CHARACTERIZATION OF A TOTAL WRIST REPLACEMENT PROSTHESIS

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ABSTRACT

A wear testing machine was designed to simulate the loading and motion of the wrist joint resulting from flexion, extension, radio -ulnar deviation and axial rotation that an individual may experience during normal daily activity. This machine was then used to evaluate a newly developed total wrist joint replacement prosthesis. Six prosthesis specimens underwent 5 million cycles at a frequency of 1.5 Hz while a compressive axial load of 20 lb was constantly applied to the articulating surface. Weight and dimensional changes due to wear were examined. The result showed a maximum wear loss rate of 0.0006 inch per year, which corresponds to an implant life as 65 years from a structural standpoint.

METHODS

Implant Description

The total wrist joint replacement prosthesis (Avanta Orthopaedics, San Diego, CA) is made up of three primary articulating components and two screws (Figure 1). The elliptical surface of the polyethylene ball and the radial component articulate against each other along two perpendicular axes of rotation replicating flexion-extension and radio-ulnar deviation. An additional degree of freedom is incorporated on the carpal side of the implant where the articulating ball is allowed to rotate against the carpal component with a rotation angle of ± 5°. The head of each screw governs the rotational extremes. The articulating ball and carpal component are joined using an interference snap fit spherical stem. The radial, carpal, and screw components are fabricated from implantable grade cobalt chrome alloy per ASTM F-1537. The articulating ball component is fabricated from implantable grade extruded ultra-high molecular weight polyethylene (UHMWPE) per ASTM F-648. Each metallic component is machined from wrought material and is ultrasonically cleaned and passivated in accordance to ASTM F-86. The articulating ball is machined from wrought material and is ultrasonically cleaned in de-ionized/distilled water. The articulating surfaces of the metallic components are polished to a mirror finish with a maximum of a 4 micro inch surface finish. The articulating ball is machined to a maximum of 32 micro-inch surface finish. All components that make up the total wrist joint prosthesis are sterilized using ethylene oxide gas (EO).

Figure 1. Avanta total wrist joint prosthesis

Test Description

The wear test was performed using a custom made six station reciprocating machine (Figure 2). The prosthesis was cyclically actuated in a circular fashion at a rate of 1.5 Hz creating a conical envelope of 40° while a constant compressive force of 20 lb was applied to the bearing surfaces of the prosthesis via a compressive spring housed on the top of each station. An uni-axial compression load cell was incorporated into the base of each station to monitor the implant loading during the course of testing. The test specimen underwent 5 million cycles. A non-contact reed switch was used to record the number of cycles. Force data and number of cycles was collected with a custom data acquisition program in a personal computer. Implants were submerged in a properly sterilized 25% bovine serum (Grottkau, 2002) at 37 °C. Solution was replaced weekly. Three UHMWPE control samples were submerged in the bovine solution for a time period equivalent to the wear test. After test completion, the mass of each articulating UHMWPE ball was weighed on a microscale. The radii and exterior features were measured with an optical comparator (Jones & Lamson EPIC 30E, 20X Lens, Springfield, VT). Diameters and internal features were inspected with a coordinate measuring machine (SmartScope, Rochester, NY). The spherical diameter features were inspected with a contour measurement (Mitutoyo Contour Tracer CV-500, Aurora, IL).

Figure 2. Wear testing machine

RESULTS

Weight and dimensional changes of the test and control samples were compared to eliminate the effect of water absorption. The pre- and post-test weights and dimension of the articulating balls were compared to determine the weight and dimensional loss (Tables 1 and 2) due to wear. Visually no wear nor scratch on the metal components.

Original Measurement (inch)	wear (1/1000 inch)					
	I	II	III	IV	V	VI
Total height (.406±.010)	3	1	1	1	1	3
Total length (1.136±.010)	1	2	0	2	1	2
Chamfer for relief for screw head (.020 X 45°)	1	1	0	0	1	0
Diameter of the neck of articulating ball (∅.231 + .002 /-.000)	3	4	2	5	4	5
Center of articulating ball (.093 + .002 /-.000)	2	2	2	1	2	0
Round of relief (R.030±.005 2X)	1	2	1	2	2	1
Spherical diameter of articulating ball (S∅ .255 + .002/-.001)	2	1	0	1	1	0
Articulating ball-relief center distance (.306± .002 2X)	2	1	0	0	1	1
Curvature of relief for screw head (.242 + .003 /-.000 TYP)	4	1	6	3	6	4
Curvature of the ellipse body (R.706±.010)	1	3	2	2	4	4
Total width (.681±.010)	4	3	3	1	2	2
Curvature of the ellipse tip (R.153±.010 2X)	5	2	3	7	5	2
Curvature of the bottom Surface (R.005 .002)	1	1	1	1	1	0

Table 1. Dimensional changes of articulating ball samples

DISCUSSION

The range of motion required for daily activity is dependent upon the specific task that each individual may be performing. The orthopaedic hand surgeons participating in the design of this prosthesis determined that restoring 40° of flexion, 40° extension, 10° radial deviation, and 20° ulnar deviation would satisfy the needs for performing most tasks (Ryu, 1991). Therefore, the relative positions used in this study replicate common limits of daily motion.

Sample	Pre-test weight (g)	Post-test weight (g) *	Percentile change
I	2.1893	2.1831	0.2832%
II	2.2077	2.2010	0.3035%
III	2.2070	2.200	0.3172%
IV	2.2047	2.1893	0.6985%
V	2.2004	2.2000	0.0182%
VI	2.2040	2.1997	0.1951%

* Average weight gain (0.0008 g) of soak samples subtracted

Table 2. Pre- and post-wear weight of the articulating ball samples

The loading scenario was based on three studies. Putnam et al. (2000) reported that for every 1 unit of force achieved during grip there was approximately 5 times that magnitude of force transferred to the distal radius, ulna, and surrounding ligaments. Trumble et al. (1987) reported that approximately 18% of the total axial load across the wrist was transmitted to the distal ulna. Hence, 82% of axial load is transferred through the radius. Chao et al. (1989) estimated the maximum force across the wrist due to the flexors as 45 lb ? 5=225 lb. Using the above results, 80% of that force or 180 lb would be transferred through the prosthesis. This is at maximum contraction, and it is expected that the prosthetic components will be subjected to 10% of the maximum force through the radius (i.e. 18 lb) in daily activities. Therefore, the loading scenarios in our study (i.e. 20 lb) is rigorous in comparison to the normal physiologic requirements. This is particularly true for a patient population with arthritic deformities.

It is generally accepted that the frequency of motions of the wrist joint at normal condition is roughly 1 million cycles per year. Of the six implants tested in the current study, the maximum loss in depth is 0.003 inches. Using the 1 million cycle equivalent to one year analogy, this corresponds to a maximum loss of 0.0006 inch/year. The designed thickness of the articulating ball at its thinnest load bearing portion is 0.039 inch when measured in the transverse direction. Based on these figures, the estimated implant life from a structural standpoint is 65 years. The investigators feel that the tests used to evaluate the total wrist joint prosthesis provide an accurate, although rigorous, appraisal of the wear characteristics of the implant components in a reasonably close simulation of the in vivo experience.

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