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Biomechanics

A comparison of the shock-absorbing properties of cervical disc prosthesis bearing materials

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Abstract

Background Data: Cervical arthroplasty offers theoretical advantages over traditional spinal fusion, including elimination of adjacent segment disease and elimination of the risk of pseudoarthrosis formation. Initial studies of cervical arthroplasty have shown promising results, however, the ideal design characteristics for disc replacement constructs have not been determined. The current study seeks to quantify the differences in the shock absorption characteristics of three commonly used materials in cervical disc arthroplasty.
Methods: Three different nucleus materials, polyurethane (PU), polyethylene (PE) and a titanium-alloy (Ti) were tested in a humidity- and temperature-controlled chamber. Ten of each nucleus type underwent three separate mechanical testing protocols to measure 1) dynamic stiffness, 2) quasi-static stiffness, 3) energy absorption, and 4) energy dissipation. The results were compared using analysis of variance.
Results: PU had the lowest mean dynamic stiffness (435 $\pm$ 13 N/mm, $P < .0001$) and highest energy absorption (19.4 $\pm$ 0.1 N/mm, $P < .0001$) of all three nucleus materials tested. PU was found to have significantly higher energy dissipation (viscous damping ratio 0.017 $\pm$ 0,001, $P < .0001$) than the PE or TI nuclei. PU had the lowest quasi-static stiffness (598 $\pm$ 23 N/mm, $P < .0001$) of the nucleus materials tested. A biphasic response curve was observed for all of the PU nuclei tests.
Conclusions: Polyurethane absorbs and dissipates more energy and is less stiff than either polyethylene or titanium.
Level of Evidence: Basic Science/Biomechanical Study.
Clinical Relevance: This study characterizes important differences in biomechanical properties of materials that are currently being used for different cervical disc prostheses.

Keywords: Cervical Disc Arthroplasty; Shock Absorption; Degenerative Disc Disease; Cervical Spine

Cervical discectomy and fusion have provided reliable and satisfactory results for patients with radiculopathy and myelopathy due to single-level degenerative disc disease. Despite the effectiveness of the procedure, there are drawbacks. After fusion, the kinematics and kinetics of the adjacent segments of the spine are altered.[1–3] The result is that as many as 92% of patients undergo degenerative changes at adjacent segments, with 1 in 4 having symptomatic disease in the first 10 years after fusion.[4–6] Cervical disc arthroplasty offers the possibility of mitigating these problems by mimicking the natural properties and by maintaining the natural motion (flexion/extension, lateral side bending, and axial rotation) of intact cervical intervertebral discs.[7] Although cervical arthroplasty range-of-motion studies are numerous,[8–11] studies of axial motion and load transfer are few. This is unfortunate because one of the functions of the normal, healthy intervertebral disc is to provide shock absorption. Axial kinetics of artificial discs has received little attention until recently because of the prevailing belief that, unlike intact human discs, artificial discs could not provide any appreciable measure of shock absorption. With the advent of newer bearing surface materials, a closer look at the shock-absorbing characteristics of cervical discs is warranted.

To achieve the appropriate functional characteristics, prosthetic discs are generally composed of different materials. Typically, there is a metal component, which facili-

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tates osteointegration with the vertebral body, and a bearing surface, which enables motion in different planes and axial load absorption. Devices currently being used have important differences in the type of bearing surface utilized. Examples of different interfaces include metal on metal, metal on polyethylene (PE), and metal on polyurethane (PU). The mechanical properties of the human intervertebral disc have been well characterized.[12,13] There are, however, few data in the literature that evaluate the shock absorption characteristics of the materials used in spinal arthroplasty. LeHuec et al.[14] evaluated the dynamic properties of lumbar disc replacements. They reported no difference between a metal-on-metal disc and a metal-on-PE disc. There was no comparison of these discs to intact or fused segments.

The loads borne in the lumbar spine differ dramatically from those in the cervical spine. Aside from the study by Dahl et al.,[15] we are unaware of any other in vitro studies that have investigated the shock-absorbing characteristics of the prosthetic cervical disc. Dahl et al. examined implanted discs in cadaveric functional spinal segments, comparing a metal-on-PU construct with both a fusion construct and intact human discs with respect to axial stiffness, energy absorption, and viscous damping. They concluded that the metal-on-PU disc was a more dynamically biofidelic alternative to cervical fusion.

A finite element study by Kang et al.[16] suggests that systems that are unable to reproduce adequate shock absorption alter the load-bearing relationships of the posterior elements. This prevents them from participating in normal axial load sharing. A stiffer construct also places significantly higher stresses across the vertebral endplate.[17] This can lead to problems such as subsidence. A shock-absorbing material is therefore potentially beneficial to restoring normal load-bearing relationships. A comparison of shock-absorbing characteristics of common prosthetic materials used in cervical disc arthroplasty, however, is lacking. The question remains as to how much load different biomaterials will absorb. The materials used in current cervical discs vary widely, and comparisons need to be made to fully evaluate them.

The goal of this study is to quantify and compare the shock-absorbing properties of PU, PE, and titanium-alloy (TI) cervical disc nucleus materials to determine whether they differ significantly.

Methods

Specimen preparation

Three different materials were tested and compared: PU (Bionate-S), ultrahigh–molecular weight polyethylene (UHMWPE) and TI (Ti6A14V, Bionate-S, DSM PTG, Berkeley, CA) (Fig. 1). The TI was used to represent the characteristics of a metal-on-metal disc. The rationale for the use of titanium is explained further in the "Discussion" section. The PU that was used was Bionate-S (99% polycarbonate urethane, 1% silicone), and the PE was UHMWPE. Ten nuclei of each material were created measuring 14 mm in diameter. The nuclei were sterilized twice with ethylene oxide. The specimens were immersed in 0.9% saline solution for a minimum of 58 hours at body temperature (37°C ± 3°C), the period of time necessary to achieve saturation of the nuclei. Before testing, each nucleus underwent preconditioning to 100 N of compression at 1 Hz for 10 cycles. Ten nuclei of each material were tested for each of the following loading modes: quasi-static axial compression, dynamic testing, and impact testing.

Equipment

Testing was performed with a custom high-speed MTS servohydraulic system (model 318.10S; MTS Corp., Eden Prairie, Minnesota). To preclude inertial issues with testing in a water bath, an environmental chamber was designed and manufactured to provide a controlled temperature (37°C ± 3°C) and humidity (99% relative humidity) environment (Fig. 2). Stainless steel mandrels (Medtronic, Memphis, Tennessee) with identical surface geometry and material (Ti6Al4V) were mounted to the MTS actuator and baseplate of the chamber to test the individual nuclei. A load cell (model 4526; Robert A. Denton, Inc., Rochester Hills, Michigan) mounted between the environmental chamber

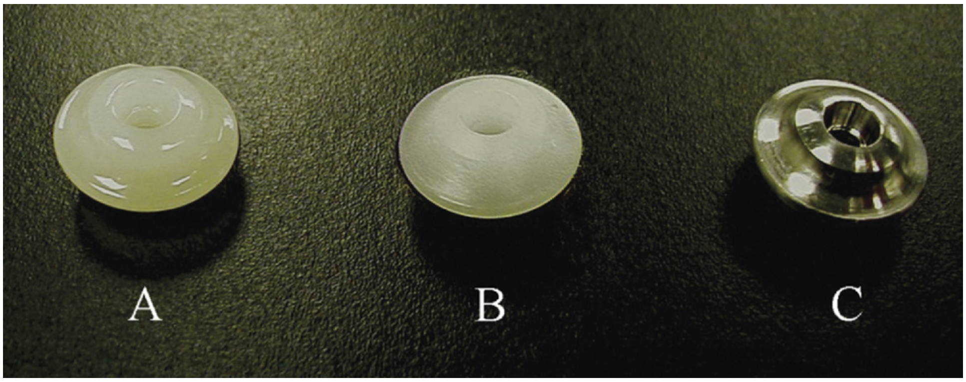

Fig. 1. Three different nucleus materials with identical geometry were tested: (A) PU, (B) UHMWPE, and (C) TI.

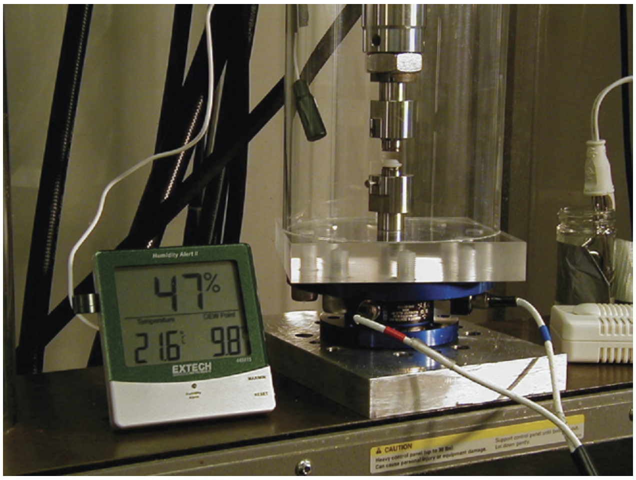

Fig. 2. Environmental chamber and load cell mounted within MTS system.

and the MTS base recorded the forces applied to the nuclei, and the integral MTS linear variable differential transformer (model 490.01; MTS Corp.) recorded the actuator displacements.

Test protocol

Ten nuclei of each material type—PU, ultrahigh–molecular weight PE, and TI—were individually characterized by use of 3 separate mechanical testing protocols: dynamic, impact, and quasi-static.

Dynamic testing

The dynamic test protocol was a cyclic sinusoidal frequency sweep from 0.25 to 20 Hz (0.25, 0.5, 0.75, 1, 2, 5, 10, 15, 20 Hz) to a peak load of 100 N. This test was performed to provide a measure of the dynamic stiffness and viscous damping ratios of the different nucleus materials. The dynamic stiffness was determined by calculating the best-fit slope of the force-displacement curve through the range of frequencies tested. The viscous damping ratio is a unit-less measurement represented by ζ that quantifies the ability of a substance to absorb energy without transmitting it to the surrounding environment. It ranges from 1.0 to 0.0, with 1.0 being total energy absorption with no transmission of energy and 0.0 being complete transmission of energy. Thus the higher the viscous damping ratio a substance has, the better it is at shock absorption.

Impact testing

The impact protocol examined the response of the nucleus materials to a 100-millisecond impulse with a peak load of 300 N. This was chosen to represent approximately 75% of the force generated by a person rapidly going from a standing position to a seated position ("plopping down" into a chair) as described by Allen et al.[18] This protocol enabled the measurement of the impulse dynamic stiffness, hysteresis (energy absorption), and viscous damping ratio for each material.

Quasi-static testing

This test protocol compresses the nuclei at a predetermined displacement rate. The stiffness of the samples was determined with a quasi-static testing method to minimize viscoelastic effects. Because stiffness in shock-absorbing materials is dependent on rate of loading, this test will determine the compliance of the material at minimal loading speed in contrast to the impact and dynamic testing methods. The nuclei were axially compressed at 12.0 $\pm$ 1.2 mm/min (0.50 $\pm$ 0.05 in/min). Testing was stopped at a clinically relevant load level of 558 N as reported in Moroney et al.[19] This is the load produced by subjects in maximal voluntary loading in flexion, where all of the load would be borne by the disc and not shared with any adjacent structures.

Statistical methods

Comparisons were made between the 3 nucleus material groups for the metrics of impulse (dynamic) stiffness, quasi-static stiffness, impulse hysteresis, and viscous damping ratio. Because of the presence of multiple groups, a single-factor analysis of variance was performed to determine statistical significance based on $\alpha = .05$. Given analysis of variance statistical significance, subsequent pair-wise comparisons between individual groups were made by use of Bonferroni corrected *t* test analyses (correcting α to .0167) to account for multiple comparisons (type I error).

Results

A total of 30 nuclei were tested, 10 of each material type, in each of 3 different test protocols. None of the test nuclei failed under the subjected loads.

Dynamic testing

Among the 3 nucleus materials tested, PU was found to have a higher viscous damping ratio (0.017 $\pm$ 0.001) than the PE (0.002 $\pm$ 0.001) or TI (0.003 $\pm$ 0.003) nuclei. This was a statistically significant difference ($P < .001$). In addition to the viscous damping ratio, the dynamic stiffness was also computed as a function of frequency. This allowed for direct comparisons of stiffness as they changed with varying frequencies (Fig. 3). PU had the least dynamic stiffness across the entire range of frequencies tested, by 1 order of magnitude.

Impact testing

Impact testing enabled the calculation of impulse dynamic stiffness and impulse hysteresis for each of the 3 different nucleus materials (Fig. 4). PU had the lowest mean dynamic stiffness (435 $\pm$ 13 N/mm), whereas PE (5029 $\pm$ 200 N/mm) and TI (7398 $\pm$ 217 N/mm) were similar. The PU nucleus was significantly less stiff than the other materials ($P < .0001$). PU had the highest energy absorption (19.4 $\pm$ 0.1 N/mm, $P < .0001$) of all 3 nucleus materials tested.

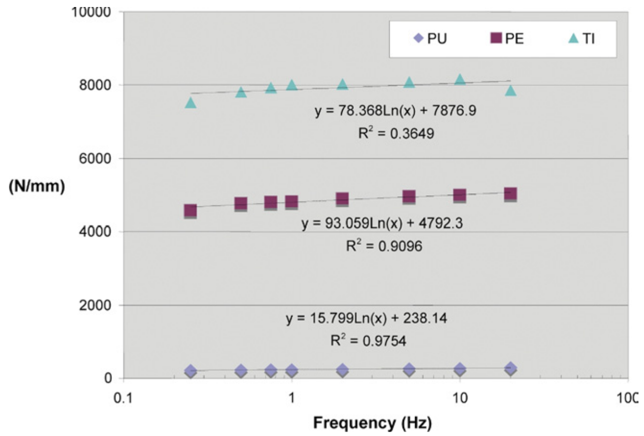

Fig. 3. Plot of dynamic stiffness as a function of frequency for each group of nucleus materials (n = 10 each). The equation of each line of best fit and its associated correlation coefficient (R^2) are included underneath the lines.

Quasi-static testing

Quasi-static testing enabled the calculation of quasi-static stiffness for each of the 3 different nucleus materials (Fig. 5). PU had the lowest quasi-static stiffness (598 ± 23 N/mm) when compared with PE (4402 ± 95 N/mm) and TI (7647 ± 321 N/mm). Consistent with the previous dynamic stiffness results of the tested nucleus materials, this was a statistically significant difference ($P < .0001$). A biphasic response curve was observed for all of the PU nucleus tests. This was not seen in either the PE or TI nuclei. Hysteresis plots of the 3 different nuclei in both the dynamic and quasi-static testing protocols were constructed (Fig. 6). These plots show a loop in which the area under the curve quantifies the amount of energy absorbed by the material. The biphasic response of the PU nuclei was characterized by computing the initial stiffness (K_1) and secondary stiffness (K_2) compared with the overall average stiffness (K_{ave}) (Fig. 7).

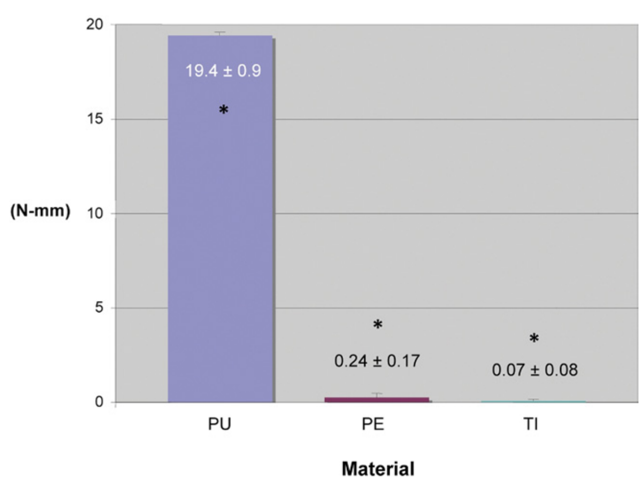

Fig. 4. Plot of viscous damping ratio for each group of nucleus materials (n = 10 each). The value in newton-millimeters is included for each material, along with the standard deviation. An asterisk indicates that a group is statistically different from the other groups.

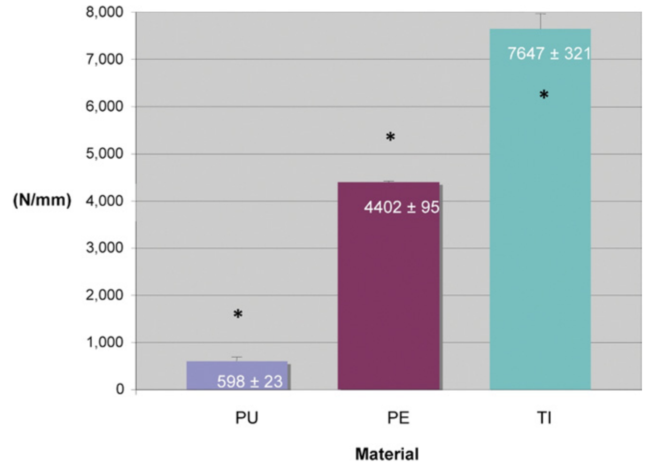

Fig. 5. Plot of dynamic stiffness for each group of nucleus materials (n = 10 each). The value in newtons per millimeter is included for each group, along with the standard deviation. An asterisk indicates that a group is statistically different from the other groups.

Discussion

In this study the shock-absorbing qualities of 3 different materials were tested. PU and PE are biomaterials that are components of metal-on-polymer cervical discs that are currently in use. The TI was used as a reference for all metal-on-metal prosthesis designs. Although titanium is not commonly used as a metal-on-metal articulation, it was selected in this case to serve as a reference metal because of its availability. In addition, titanium has a relatively lower stiffness when compared with other metals such as cobalt-chrome, which is more commonly used in articulating surfaces. Given its relatively lower stiffness, titanium will encompass the low end of the implantable metals spectrum in the study metrics measured.

The results of our study indicate that in both the dynamic and quasi-static testing protocols, PU is significantly less stiff than either PE or TI. There were statistically significant differences between PE and TI but on a much smaller order of magnitude. The dynamic stiffness of the PU nuclei was 1 order of magnitude less stiff than the PE and TI nuclei over the entire range of frequencies tested (0.5–20 Hz).

Impulse hysteresis provides a measure of the energy absorption capability of a material or system. In this study the impulse hysteresis of the PU nuclei was found to be significantly greater than both the PE and TI nuclei by nearly 1 order of magnitude. This outcome suggests that a PU nucleus would provide much greater shock-absorbing capability than a nucleus manufactured from PE or a metal-on-metal joint configuration.

Damping is used to characterize a system's ability to reduce the amplitude (ie, dissipate the energy) of a vibratory response, and the damping ratio is a non-dimensional ratio of the system's actual damping compared with a critically damped response. As stated earlier, a damping ratio of 1.0 would indicate a critically damped response in which the system optimally dissipates energy

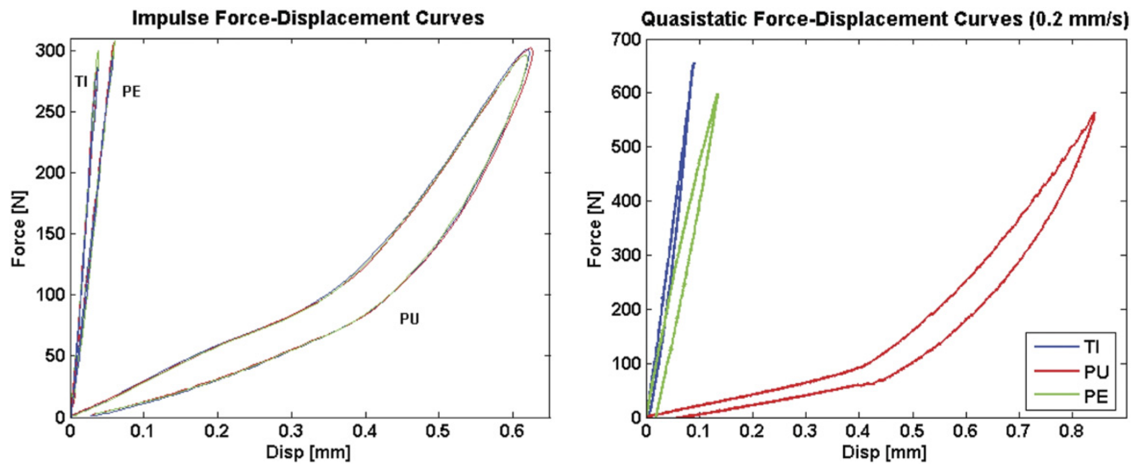

Fig. 6. Force–displacement (Disp) plots of impulse and quasi-static tests showing biphasic response of PU material. The graph on the left shows the displacement of each material in millimeters as a function of the single impulse force in newtons applied to it. The graph on the right shows the force-displacement curves that resulted from a slow compression of 0.2 mm/s (12 mm/min).

without oscillation. In this study all 3 nucleus materials resulted in under-damped responses ($\zeta < 1$), but the PU nucleus had the highest damping ratio by nearly 1 order of magnitude. This result again supports that a PU nucleus would be better at dissipating energy than one manufactured with PE or TI.

The PU nuclei displayed a biphasic load-displacement response to both quasi-static and impulse loading. This biphasic curve was not seen with either PU or TI. We believe the biphasic load-displacement response of the PU nuclei can be attributed to the large deformation of the more compliant PU material within the mandrels at higher loads (>100 N). As the PU nucleus undergoes this deformation, the outer "flange" of the nucleus comes into contact with the mandrels and begins to carry load, thus stiffening the construct as the load is carried by more material (ie, greater cross-sectional area). This was not observed for either the PE or TI nuclei because they were much stiffer and were only loaded through the thicker center region of the nucleus. Therefore the initial stiffness (K_1), secondary stiffness (K_2), and average stiffness (K_{ave}) were reported only for the quasi-static PU tests.

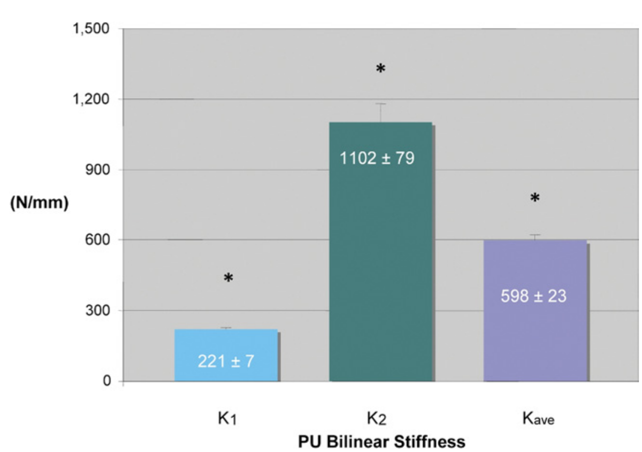

Fig. 7. Plot of initial (K_1), secondary (K_2), and average (K_{ave}) quasi-static stiffness for PU nuclei (n = 10). The value in newtons per millimeter is included for each group, along with the standard deviation. An asterisk indicates that a group is statistically different from the other groups.

In a previous in vitro study examining the mechanical properties of the cervical spine, Moroney et al.[20] reported that the compressive stiffness of the intact (natural) intervertebral disc was 492 ± 472 N/mm (n = 28). These data were for individual body-disc-body preparations tested under quasi-static loading. If we assume that the compressive stiffness of cervical vertebral bodies is significantly greater than that of the intervertebral disc, then the quasi-static stiffness of the PU nuclei in this study (598 ± 23 N/mm) compares favorably with the intact intervertebral disc as reported by Moroney et al. Furthermore, Moroney et al. reported that the compressive stiffness for grade 1 discs (no degeneration) was 737 ± 885 N/mm (n = 4), which suggests that the compressive stiffness of the PU nuclei was clearly in the range of compressive stiffness for normal healthy discs. On the other hand, the quasi-static compressive stiffness results (Fig. 7) for the PE nuclei were 7 times higher than that of the PU nuclei and substantially outside the range of the normal intact cervical disc.

An in vitro study comparing the response of a metal-on-PU system implanted into 3-segment cervical spines with a fusion construct and intact human discs found that the dynamic stiffness of the metal-on-PU disc was similar to that of the intact disc. The energy absorption and viscous damping exceeded those of both the intact and fusion constructs.[15] This study points toward important characteristics of a PU-based system. The results indicate that if the goal of disc arthroplasty is to mimic the natural state as closely as possible, a metal-on-PU system comes very close with respect stiffness and shock absorption. Whereas the functional characteristics of the intact human disc may change with advancing age, the cadaveric specimens in this study are likely close in age to the majority of patients undergoing disc arthroplasty. Whether this is the most clinically desirable amount of load dampening for a disc replacement or whether there should be different dampening properties depending on the age of the patient is currently unknown. Long-term clinical research into this area is necessary to fully answer these questions.

The findings of this study are limited in scope to the mechanical tests that were performed. There are further aspects of cervical discs that need to be examined. Even though this study only examined shock absorption, a discussion of compliance inherently leads into questions about aspects of biologic durability. There have been numerous investigations into the biologic durability of PU. From a wear-rate standpoint, published studies of simulated wear indicate that PU has excellent wear properties and produces wear particles that do not incite a robust inflammatory response.[21] Animal and retrieval studies would suggest that PU compares favorably with PE with respect to wear rates, debris, and inflammatory response of the host.[22–25] These studies suggest that although PU is more prone to degradation than metal, highly compliant PU materials may express favorable wear and inflammatory response characteristics. Despite favorable biocompatibility and biologic stability profiles, polymers of PU can be susceptible to in vivo degradation through processes such as stress cracking and oxidation.[26–28] Fortunately, the wide variability in PU formulations allows for the ability to control these effects and design for robustness in specific applications.

Another limitation of this study is the testing apparatus. Although the MTS system does provide accurate and reproducible results, it does not completely mimic an actual human cervical spine and the complex loading that occurs. The addition of surrounding soft tissues and bony structures would undoubtedly have an effect on the loading of the material. In addition, because of the geometric configuration in which the titanium implant was tested, compliances inherent in the mounting apparatus decreased the actual stiffness of the titanium specimen, which normally would be significantly higher. However, including the mounting compliances, the titanium exhibited characteristics that were significantly altered from both the PE and PU specimens.

Finally, it should be acknowledged that shock absorption is a theoretic benefit to an artificial disc. No clinical study has shown an incontrovertible benefit to a shock-absorbing device versus a non–shock-absorbing device. This is why continued clinical investigation into this area of disc arthroplasty is important and, indeed, ongoing.[29]

Conclusion

The findings of this study suggest that the PU nucleus material provides statistically significantly lower stiffness and greater energy absorption and damping characteristics than the UHMWPE nucleus material. Conversely, the UHMWPE nucleus material behaved much more similarly to the TI (metal-on-metal) nucleus in all of the mechanical tests performed. With respect to shock absorption, a device construct incorporating PU would likely provide characteristics more similar to those of the natural intervertebral disc than a construct incorporating PE or titanium.

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