Retrieval Analyses of Dynesys® Polymeric Implants from a United States Investigational Device Exemption Study

[1]Kai Zhang; [2]Ming Shen; [1]John M Dawson
[1]Research and Emerging Technologies, Zimmer Spine Inc., Minneapolis, MN, [2]Research, Zimmer Inc., Warsaw, IN

INTRODUCTION

The Dynesys System (Zimmer GmbH, Winterthur, Switzerland) is a dynamic stabilization device developed for treating lumbar degenerative disease. The system has pedicle screws that are manufactured from Ti-6Al-7Nb, a titanium alloy that has been in clinical use in many other orthopedic devices; spacers that are manufactured from polycarbonate urethane (PCU); and cords that are manufactured from braided polyethylene terephthalate (PET).

The system was first implanted in Europe in 1994 and introduced to the European market in 1999. To date it has been implanted in over 42,000 patients worldwide. In 2003, an FDA approved, prospective, randomized Investigational Device Exemption (IDE) clinical trial of the system began. The objective of the study was to compare non-fusion using the Dynesys System with fusion using pedicle screws and metal rods. Enrolled patients suffered from leg and lower lumbar symptoms and presented with evidence of spinal stenosis with up to grade I degenerative spondylolisthesis.

Of the 253 study patients who had received one or two-level Dynesys implants, 22 patients underwent re-operation. None of the reoperative cases were performed due to implant failure. Of the 22 re-operations, Dynesys devices were explanted from 11 cases. Four of the 11 cases were returned to the manufacturer with sufficient history and in storage conditions that permitted inclusion in this study. *In vivo* component duration of the four cases ranged from 9 to 19 months. The implants were retrieved for reasons apparently unrelated to the failure of PCU spacers or PET cords.

The current study characterized the explanted condition of retrieved spacers and cords to provide evidence of their biostability.

MATERIALS AND METHODS

Materials

Explanted parts (10 PCU spacers and 16 PET cords) with in vivo time from 9 to 19 months and the non-implanted, lot-matched, shelf-aged controls were studied. Explanted spacers and cords were cleaned and dis-infected per internal operational procedures, which have been proven not to affect the future material analyses. An optical microscope (Nikon SMZ-U, Tokyo, Japan) with magnifications up to 40X and equipped with a digital camera was used to inspect all explants for cuts, abrasions, cracks, and potential wear patterns after cleaning and disinfection and before other characterization procedures.

ATR-FTIR and GPC Analyses of PCU Spacers

The ATR-FTIR analysis was performed using a diamond Golden Gate ATR cell (Specac Ltd, Orpington, United Kingdom) and the spectra were recorded using a Bio-Rad FTS-45 (Bio-Rad Laboratories Europe, Hertfordshire, United Kingdom) with a scan range of 400-4000 cm^{-1} and a resolution of 4 cm^{-1}. The PCU spacers were analyzed from three depths: 1) on the spacer surface, 2) 100 µm below the spacer surface and 3) in the center (bulk) of the spacer that was approximately 2000 µm below the surface.

The GPC analyses of the PCU spacers were performed with a Spectra Physics Isochrom TSP P1000 system (Thermal Separation Products, San Jose, California). Molecular weight (MW) values for representative PCU samples of the surface (0 – 100 µm) and in the center (bulk) were PCU were reported as polystyrene equivalent molecular weights.

ATR-FTIR and GPC Analyses of PET Cords

ATR-FTIR analyses of PET cords were performed in two positions each on the outer (superficial) woven fibers and on the center (core) fiber. The samples were placed on a diamond Golden Gate ATR cell and the spectra were recorded using a Bio-Rad FTS-45 FTIR.

The GPC analysis of the PET cords was also performed by a Spectra Physics Isochrom TSP P1000 system. MW values for representative PET outer and core fibers were reported as PMMA equivalent molecular weights.

SEM Observation of PCU Spacers

Scanning electron microscopy (Amray 1830, Amray, Bedford, MA) was also used to examine the surfaces of PCU spacers. The samples were sputter coated with gold.

RESULTS

Figure 1 shows the overview of all explants from the four cases. The spacers and cords exhibited variable superficial damage, such as cuts and scratches that are attributed to the explantation process.

Figure 2A shows the surface ATR-FTIR spectra of all PCU spacers. No new peaks at 1650 cm^{-1} or 1174 cm^{-1} were present, where the 1650 cm^{-1} peak was attributed to a potential degradation product of aromatic amine in hard segments[2], and the 1174 cm^{-1} peak was attributed to branched ether peak due to a potential crosslinking during the biodegradation process in soft segments.[2] The spectra of 100 µm below the surface and in the bulk (not shown) were nearly identical to the controls. Although the FTIR spectra showed that explanted PCU spacer surfaces had slight (< 10%, before considering the detection limit of 5%) peak height changes for bands at wave numbers of 1740 cm^{-1} (free C=O of carbonate soft segment) and 1248 cm^{-1} (C-O-C of carbonate soft segment), the IR spectra were unchanged below the surface and in the center. Furthermore, no identifiable IR peaks were observed at wave numbers that would be attributed to PCU degradation processes. The FTIR analyses of the retrieved PET cords (data not shown) also demonstrated that the PET cords were chemically unchanged at both the surface and the interior.

Figure 2B shows the GPC molecular weight distributions of the PCU spacers in Case 4 and the lot-matched control. The GPC results of the other spacers were very similar to the results shown in Figure 2B; therefore, the GPC results of the other spacers have been omitted for simplicity in data presentation. The GPC analyses of PCU and PET explants (data not shown) demonstrated the absence of shoulder-peaks in lower Mw regions that might be attributed to any biodegradation.

DISCUSSION

Explanted Dynesys PCU spacers and PET cords that had been implanted in four IDE re-operation cases from 9 to 19 months were analyzed. The biostability of the explants was supported by the above analytic results.

Limitations of the present study included a small number of cases; a short implantation period between 9 and 19 months, and limited numbers of available, lot-matched controls. Despite the study limitations, results of the retrieval analyses demonstrated biostability of PCU spacers and PET cords up to 19 months *in vivo.* Continued monitoring of retrieved PCU spacers and PET cords from cases with longer *in vivo* component durations is warranted.

REFERENCES

[1] Trommsdorff et al., *Pro. Society for Biomaterials Meeting*, 2003.
[2] Christenson et al. *Corrosion Engi, Sci and Tech* 2007;42(4):312-23.

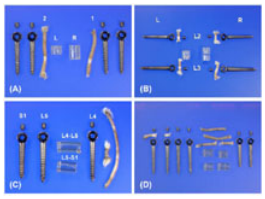

Figure 1. Overview of the four cases of retrived Dynesys systems: (A) Case 1 (9 month in vivo), (B) Case 2 (11 m), (C) Case 3 (16 m) and (D) Case 4 (19 m).

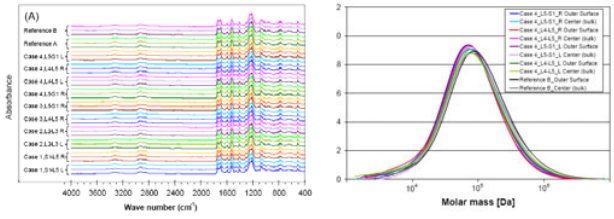

Figure 2. (A) FTIR spectra of PCU spacers: all four cases with two reference controls and (B) Representative GPC results of PCU spacers.