In vivo biostability of polymeric spine implants: retrieval analyses from a United States investigational device exemption study

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Abstract The Dynesys System for stabilizing the lumbar spine was first surgically implanted in Europe in 1994. In 2003, a prospective, randomized, investigational device exemption clinical trial of the system for non-fusion dynamic stabilization began. Polycarbonate urethane (PCU) and polyethylene terephthalate (PET) components explanted from four patients who had participated in the study were analyzed for biostability. Components had been implanted 9–19 months. The explanted components were visually inspected and digitally photographed. Scanning electron microscopy was used to analyze the surface of the spacers. The chemical and molecular properties of the retrieved spacers and cords were quantitatively compared with lot-matched, shelf-aged, components that had not

been implanted using attenuated total reflection Fourier transform infrared (FTIR) and gel permeation chromatography (GPC). FTIR analyses suggested that the explanted spacers exhibited slight surface chemical changes but were chemically unchanged below the surface and in the center. New peaks that could be attributed to biodegradation of PCU were not observed. The spectral analyses for the cords revealed that the PET cords were chemically unchanged at both the surface and the interior. Peaks associated with the PET biodegradation were not detected. GPC results did not identify changes to the distributions of molecular weights that might be attributed to biodegradation of either PCU spacers or PET cords. The explanted condition of the retrieved components demonstrated the biostability of both PCU spacers and PET cords that had been in vivo for up to 19 months.

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Introduction

The Dynesys System (Zimmer GmbH, Winterthur, Switzerland) is a dynamic stabilization device developed for treating lumbar degenerative disease. The system (see Fig. 1) has pedicle screws that are manufactured from of Ti-6Al-7Nb, a titanium alloy that has been in clinical use in many other orthopedic devices [1, 2]; 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. Clinical studies

Fig. 1 The Dynesys™ system is composed of pedicle screws and set screws, universal spacers and cords

have been conducted in Europe to test the efficacy of the system in treating various pathologies related to lumbar spine instability [3–6]. To date it has been implanted in over 42,000 patients worldwide.

In 2003, an approved United States Food and Drug Administration, prospective, randomized clinical trial of the system began. The objective of the FDA 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. The safety and efficacy of this clinical study has been reported separately [7].

Of the 253 study patients who had received one or two-level Dynesys implants, 22 patients underwent re-operation. 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 (Table 1). Nevertheless, the biostability of PCU and PET may have been a concern; the literature [8, 9] has reported biodegradation of PCU material at 20 weeks in an animal model and long-term in vivo chemical changes of PET.

The current study characterized the explanted condition of retrieved spacers and cords to provide evidence of their biostability. The biostability of Ti-6Al-7Nb was not in the scope of this study because of its long and successful history as an implant material.

Materials and methods

Materials

Table 1 lists the details of the explanted parts and the non-implanted, lot-matched, shelf-aged controls.

Cleaning and disinfection of the explants

Explanted spacers and cords were cleaned four times by soaking at room temperature in a 4% disinfecting solution (Deconex 53 plus, Borer Chemie AG, Zuchwil, Switzerland) for 30 min and then by rinsing with tap water. When adherent contaminations such as blood residues were observed, the explants were soaked in a 5% cleaning solution (Deconex 11 UNIVERSAL) for 6 to 12 h.

Optical inspection of as-received PCU spacers and PET cords explants

An optical microscope (Nikon SMZ-U, Tokyo, Japan) with magnifications up to 40× 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.

Sample preparation for ATR-FTIR and GPC analyses

Prior to attenuated total reflection Fourier transform infrared (ATR-FTIR) and gel permeation chromatography (GPC) analyses, the PCU spacers were flushed with deionized water and dried over silica gel at room temperature in a desiccator for at least 5 days. For PET cords, the following preparation steps were performed [9]:

1. Cleaned enzymatically to eliminate proteins and fatty residues.
2. Cut using a scalpel.
3. Cleaned ultrasonically, 15 min, Terg-A-Enzyme, 7.5 g/L deionized water (Alconex Inc, White Plains, NY).
4. Stored for 3 days at 45°C in the enzyme solution.
5. Rinsed with deionized water and ethanol, followed by 10 min ultrasonic bath.
6. Stored in fresh enzyme solution for another 2 days at 45°C.
7. Rinsed with deionized water and ethanol.
8. Dried in a desiccator for at least 3 days (30 mbar).

ATR-FTIR and GPC analyses of PCU spacers

The ATR-FTIR analysis was performed using a diamond Golden Gate ATR cell (Specac Ltd, Orpington, UK) and the spectra were recorded using a Bio-Rad FTS-45 (Bio-Rad Laboratories Europe, Hertfordshire, UK) with a scan range of 400–4,000 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 2,000 μm below the surface. Spectra from three

Table 1 Basic clinical information of the four revision cases and control parts

Case #	Primary indication	In vivo time (months)	Reason of revision	Levels	Retrieved parts		
					Pedicle screws	Spacers	Cords
1	Central stenosis	9	Continued leg and back pain	L5–S1	4	2	2
2	Central stenosis	11	Pedicle screw loose	L2–L3	4	2	4
3	Other herniated nucleus pulposus	16	Pedicle screw loose	L4–L5 R, L5–S1 R	3	2	2
4	Central Stenosis	19	Increased low back pain	L4–L5, L5–S1	6	4	6
Lot-matched Controls							
Ref A	Same PCU lot as in Case 2						
Ref B	Same PCU lot as in Case 4						
Ref C	Same PET lot as in Case 1						
Ref D	Same PET lot as in Case 2						
Ref E	Same PET lot as in Case 4						

The lot-matched controls are unimplanted, shelf-aged parts

different positions were taken at each depth. At each position, the PCU sample was placed on the ATR cell to detect surface chemistry in a thin surface region (1–5 μm) [8, 10]. Because the surface chemistry of polyurethanes may vary in the open-air environment, [11] spectra of the bulk spacer samples were recorded immediately after cutting.

Representative IR spectral peaks (chemical fingerprints) of PCU are listed in Table 2. Spectra were normalized to the chemically stable aromatic group at 510 cm^{-1} . Subsequently, the spectra were compared with the spectra of non-implanted controls (Table 1). The percentage of differences in IR peak height of the explanted to the control samples was quantified using the following peaks: (1) NH ($3,340\text{ cm}^{-1}$), (2) hydrogen-bonded C=O ($1,701\text{ cm}^{-1}$) of urethane hard segment, [12] (3) free C=O ($1,740\text{ cm}^{-1}$), (4) C–O–C ($1,248\text{ cm}^{-1}$) of carbonate soft segment, [12] and (5) the broad band at $3,200\text{--}3,500\text{ cm}^{-1}$ (measured at $3,280\text{ cm}^{-1}$) that corresponds to the increase in NH and OH of degraded urethane and carbonate or to absorbed biofluid [13, 14]. The detection limit of the IR spectroscopy was 5%.

The GPC analyses of the PCU spacers were performed with a Spectra Physics Isochrom TSP P1000 system (Thermal Separation Products, San Jose, California) equipped with a refractive index detector RI 71 (Shodex Ltd, Tokyo, Japan) using three PSS-GRAM $10\text{ }\mu\text{m}$ GPC columns: $30\text{ }\mu\text{m}$ $8 \times 50\text{ mm}$, $30\text{ }\mu\text{m}$ $8 \times 300\text{ mm}$ and $3,000\text{ }\mu\text{m}$ $8 \times 300\text{ mm}$ (PSS Polymer Standards Service GmbH, Mainz, Germany). Representative samples of the surface (0–100 μm) and in the center (bulk) were dissolved in dimethylacetamide with 0.1% of lithium bromide at 80°C [15, 16]. The sample concentration was 3 g/L. For calibration, 12 polystyrene standards ranging

from 10^2 to $2 \times 10^6\text{ g/mol}$ were used, thus all molecular weight values for PCU were reported as polystyrene equivalent molecular weights. The weight average molecular weight, Mw, was calculated. The measurement uncertainties were 10%.

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. IR peaks of PET are listed in Table 2. To evaluate the differences, all spectra were normalized to the band of a chemically stable aromatic group at 725 cm^{-1} and compared with the spectra of non-implanted controls. To evaluate potential hydrolytic degradation, the carboxyl index that is defined as the absorbance ratio of the carboxylic acid ($1,640\text{ cm}^{-1}$) to the carbonyl group ($1,713\text{ cm}^{-1}$) was calculated [9]. The detection limit of the IR spectroscopy was 5%.

The GPC analysis of the PET cords was also performed by a Spectra Physics Isochrom TSP P1000 system equipped with a refractive index detector RI 71 using two PSS-PFG $7\text{ }\mu\text{m}$ columns: $100\text{ }\mu\text{m}$ $8 \times 300\text{ mm}$ and $1,000\text{ }\mu\text{m}$ $8 \times 300\text{ mm}$. Representative samples of the PET outer and core fibers were completely dissolved in the GPC eluent (0.05 M potassium-trifluoroacetate in hexafluoroisopropanole) [17]. The sample concentration was 3 g/L. For the calibration, 12 poly(methyl-methacrylate) (PMMA) standards ranging from 10^3 to 10^6 g/mol were used, thus all molecular weight values for PET were reported as PMMA equivalent molecular weights. The Mw was calculated. The measurement uncertainties were 10%.

Table 2 Representative IR peaks for PCU and PET

Polymer	Wave number of the IR bands (cm^{-1})	Attribution to functional chemical groups in the polymer
PCU	3,340–3,330	Stretching N–H of urethane
	2,940–2,920	Stretching C–H ₂ of soft segment
	1,740–1,737	Stretching C=O of free carbonate
	1,720	Stretching C=O of hydrogen-bonded carbonate
	1,705–1,701	Stretching C=O of hydrogen-bonded urethane
	1,598–1,596	Stretching of aromatic C=C
	1,530–1,527	Bending C–H ₂ of soft segment/stretching C–N of urethane
	1,254–1,248	Stretching C–O–C of carbonate/wagging C–H ₂ of soft segment
	1,223–1,220	Bending N–H and stretching C–N of urethane
	1,077–1,065	Stretching C–O–C of carbonate
	510	Torsion of aromatic group
PET	1,713	Stretching C=O of ester group
	1,640	Carboxylic acid of hydrolyzed ester
	ca. 1,250	Stretching COO of ester
	ca. 1,100	Stretching C–O of ester/deformation of aromatic C–H
	725	Deformation of aromatic group
	1,640	Carboxylic acid of hydrolyzed ester

SEM observation of PCU spacers

After FTIR and GPC analyses were complete, areas of defects and potential wear patterns visually identified on the PCU spacers by optical microscopy were further examined using an Amray 1830 scanning electron microscope (SEM) (Amray, Bedford, MA) at 15 kV accelerating voltage. The samples were sputter-coated with gold.

Results

Visual inspection of the explants

Figure 2 shows the overview of all explants from the four cases. Nine of the ten spacers demonstrated variable amounts of permanent curvature (Fig. 3a). Imprints of the pedicle screw heads were present in the end surfaces (Fig. 3b). Imprints of contact with the cord were also visible along the inner wall of the spacers (Fig. 3c). The spacers exhibited variable superficial damage, such as cuts and scratches, likely due to the removal procedures during the revision surgeries. Small, localized wear zones were present on the outer surfaces of eight out of the ten spacers (Fig. 3d), but the locations and amounts of wear varied among retrievals. The wear zone for the spacer of Case 2 (Fig. 3d), though pronounced, was estimated by image analysis to be only about 0.05 wt% of an intact spacer. Most surfaces of the spacers did not exhibit any damage but were smooth and unremarkable (Fig. 4a); wear zones,

when presented displayed a wavy pattern typical of abrasive wear in elastomers (Fig. 4b); [18].

The locations of the wear patterns suggested that the source of wear was abrasion between the spacer and vertebral bone. There was no evidence of wear due to relative motion between the spacer and cord. Only one spacer showed slight wear marks on the front surface. The connection site between screws and cords could not be identified clearly in all explanted cords. When the site could be identified, damage was limited to breakage of some outer fibers (Fig. 5).

ATR-FTIR and GPC analyses of PCU spacers and PET cords

PCU spacers

Figure 6 shows the surface ATR-FTIR spectra of all PCU spacers. No new peaks at 1,650 or 1,174 cm^{-1} were present (Fig. 6b), where the 1,650 cm^{-1} peak was attributed to a potential degradation product of aromatic amine in hard segments [8], and the 1,174 cm^{-1} peak was attributed to branched ether peak due to a potential cross-linking during the biodegradation process in soft segments [15]. The spectra of 100 μm below the surface and in the bulk (not shown) were nearly identical to the controls.

The percentage of changes in peak height, averaged by the three positions in each spacer, is listed in Table 3. On the surfaces of the explanted spacers, changes of <10% in the soft segments (1,740 and 1,248 cm^{-1}) occurred

Fig. 2 Overview of the four cases of retrieved Dynesys systems: **a** Case 1 (9 months in vivo), **b** Case 2 (11 months in vivo), **c** Case 3 (16 months in vivo) and **d** Case 4 (19 months in vivo)

while nearly no noticeable change occurred in the hard segments ($3,340$ and $1,701\text{ cm}^{-1}$). At depths of $100\text{ }\mu\text{m}$ below the surface and in the bulk of the explanted spacers, changes were mostly below the detection limit of 5%, suggesting that no detectable changes had occurred.

Figure 7 shows the GPC molecular weight distributions of spacers in Case 4 and the lot-matched control. The GPC results of the other spacers were very similar to the results shown in Fig. 7; therefore, the GPC results of the other spacers have been omitted for simplicity in data presentation.

Quantitative results of the GPC analysis are included in Table 4. Differences in the Mw were present between different spacer lots and within the lot. The Mw of the 10 retrieved spacers were between $110,000$ to $170,000\text{ g/mol}$ and the Mw of the two controls were between $131,000$ to $193,000\text{ g/mol}$. The surface-to-bulk differences in the two controls were -8 and -1% , respectively. The data comparisons listed in Table 4 were made only for surface-to-bulk differences in the individual explanted spacers instead of a comparison against the controls. Accordingly, the surface-to-bulk changes of Mw in the explanted spacers

ranged between 1 to -16% without considering the potential detection error of 10% .

PET cords

Figure 8 shows the ATR-FTIR spectra of the outer surfaces of all cords. The spectra of all central fibers were nearly identical to the spectra shown in Fig. 8, thus the results are not presented here. Hydrolytic biodegradation [19] (evidenced by the formation of a carboxyl peak at $1,640\text{ cm}^{-1}$) was absent in the spectra of both outer and central fibers. The carboxyl indices of both outer and central fibers were all less than the detection limit of 5% ; therefore, no structural chemical changes associated with hydrolytic biodegradation were identifiable in the explanted cords.

Figure 9 shows the GPC molecular weight distributions of explanted cords from Cases 2 and 4 with lot-matched controls. The GPC cord results from Cases 1 and 3 and from the Reference C cord were quite similar to the results shown in Fig. 9. No apparent changes were discernable between the reference and explanted cords. The comparative GPC results listed in Table 5 showed that all Mw

Fig. 3 Typical visual observations of explanted PCU spacers: **a** permanent bend along longitudinal axis (Case 3), **b** imprint of pedicle screw on the end face of a spacer (Case 4), **c** contact imprint by the PET cord along the inner wall (Case 3), and **d** a wear scar (Case 2)

Fig. 4 **a** Typical smooth surface feature (spacer in Fig. 3b) and **b** typical wear scar features observed by SEM (spacer in Fig. 3d)

changes from the outer to the central fibers were below the detection limit of 10%.

Discussion

The distinct imprints of a screw on the end face of a spacer (Fig. 3b) and of a cord on the inner wall of a spacer (Fig. 3c) demonstrated that these implants did not

experience much motion relative to each other in situ. These findings suggested that cord tension was reasonably maintained, restricting relative sliding movements at the screw head-spacer and spacer-cord interfaces.

Rubbing of a spacer against a facet joint nearby was likely the cause of the observed wear pattern (Figs. 3d, 4). This was not an intended function of the system and did not occur on all spacers. Moreover, the observations of these explants are not uncommon when compared with other

Fig. 5 Connection site with the pedicle screw in explanted PET cords (Case 1)

Fig. 6 FTIR spectra of PCU spacers: **a** all four cases with two reference controls and **b** overlay of all spectra in **a**

implants retrieved outside this study (European data not presented here).

Polyurethane can be viewed as a block copolymer of hard and soft segments arranged in alternating structures. Polyurethanes have been used in medical devices since the 1970s and the literature has reported on the biostability of polyurethanes [20–25]. Generally, the biostability of polyurethanes is strongly affected by multiple factors. For example, polycarbonate soft segments are chemically more stable than either polyether or polyester counterparts and the biostability of a Shore 55D polyurethane is quite different from that of Shore 80A one [25]. The annealing process reduces environmental stress cracking (ESC) [20–23] while appropriate sterilization methods maintain the biostability of polyurethanes [20]. Bulky and dense polyurethanes are more stable than thin, porous or fibrous

Table 3 Changes in characteristic IR peaks of PCU spacers

Level	Case 1			Case 2			Case 3			Case 4		
	S1-L5 L	S1-L5 R	L2-L3 L	L2-L3 R	L4-L5 R	L5-S1 R	L4-L5 R	L5-S1 R	L4-L5 L	L4-L5 R	L5-S1 L	L5-S1 L
NH, OH increase of degraded urethane, carbonate, absorbed biofluid, tissue ($3,280\text{ cm}^{-1}$)	S 5	6	6	6	*	6	*	6	6	*	9	
	I *	*	*	*	*	*	*	*	*	*	*	*
	B *	*	*	*	*	*	*	*	*	*	*	*
Carboxyl NH of urethane hard segment ($3,340\text{ cm}^{-1}$)	S 6	*	*	*	*	*	*	*	*	*	*	*
	I *	*	*	*	*	*	*	*	*	*	*	*
	B *	*	*	*	*	*	*	*	*	*	*	*
H-bonded C=O of urethane hard segment ($1,701\text{ cm}^{-1}$)	S -5	-6	*	*	*	*	*	*	*	*	*	*
	I *	*	*	*	*	5	*	*	*	*	*	*
	B *	*	*	*	*	7	*	*	*	*	*	*
Mean of hard segment changes ($3,340, 1,701\text{ cm}^{-1}$)	S -6	*	*	*	*	*	*	*	*	*	*	*
	I *	*	*	*	*	*	*	*	*	*	*	*
	B *	*	*	*	*	6	*	*	*	*	*	*
Free C=O of carbonate soft segment ($1,740\text{ cm}^{-1}$)	S -6	-7	-9	-9	*	*	*	*	-6	*	-6	*
	I *	*	*	*	*	*	*	*	*	*	*	*
	B *	*	*	*	*	6	*	*	*	*	*	*
C-O-C of carbonate soft segment ($1,248\text{ cm}^{-1}$)	S -6	-7	-7	-7	-5	*	*	*	*	*	*	*
	I *	*	*	*	*	*	*	*	*	*	*	*
	B *	*	*	*	*	*	*	*	*	*	*	*
Mean of soft segment changes ($1,740, 1,248\text{ cm}^{-1}$)	S -6	-7	-8	-8	*	*	*	*	-6	*	-5	*
	I *	*	*	*	*	*	*	*	*	*	*	*
	B *	*	*	*	*	*	*	*	*	*	*	*

S surface, I 100 μm below surface, B bulk (approximately 2,000 μm below surface)

* Below detection limit of 5%

Fig. 7 Representative GPC results of PCU spacers

polyurethanes [22]. The states of stress, compression versus tension, impacts differently on biostability characteristics [24].

Biostability of the retrieved Dynesys spacers was suggested in the IR results, particularly due to an absence of peaks at $1,650$ and $1,174\text{ cm}^{-1}$ (Fig. 6), which would be attributed to the biodegradation process and products if present [8]. Table 3 shows that any as-characterized chemical changes were minor and limited to the PCU surfaces at the 5% systematic detection limit of the FTIR spectrometer and that nearly no changes occurred below the surface of PCU spacers.

The IR findings of PCU components that had been in vivo for 9–19 months differ from the results reported in the Christenson et al. study. Christenson et al. [8] reported that PCU 80A was susceptible to biodegradation after implantation for 20 weeks in a rat model. In comparison with the PCU material used in Dynesys, PCU 80A has a different hard-soft segment ratio and molecular weights. Differences in other factors also existed, such as extrusion versus injection-molding processes, thin- versus thick-walled device designs, and in vivo biaxial versus primarily compression bending in Dynesys. These differences make a direct comparison very difficult.

Consistent with FTIR findings, the GPC results suggested the biostability of the retrieved Dynesys PCU spacers. There were only minor Mw changes detected at the spacer surfaces. Given a surface-to-bulk Mw difference of 1 and 8% in the two controls and the 10% measurement uncertainties, those differences could be introduced by the detection limit and/or lot-to-lot differences in the raw material. Accordingly, the retrieved spacers exhibited lot-to-lot and same lot Mw variations that was exemplified in the 16% Mw variation in Case 4 spacers. Combining the

8% decrease in the control and the 10% uncertainty, the in vivo Mw changes in the surface of the explanted spacers were marginal. In addition, the absence of shoulder-peaks in lower Mw regions that would be attributed to degradation products also confirmed the biostability of the explanted spacers [26]. Overall, results of the analyses suggested that the Mw differences in PCU retrievals were only minor and mostly due to lot-to-lot or within lot differences but not to in vivo changes.

Hydrolysis has been considered a predominant degradation mechanism for PET in an aqueous environment. The polymer chains may be cleaved at the ester groups resulting in two fragments of carboxylic acid and hydroxyl groups [9, 27, 28]. Long-term in vivo chemical changes of PET vascular grafts have been attributed to hydrolytic degradation [9]. The severity of degradation depends upon the surface area exposed to the biological fluids and the implantation duration.

The vascular graft retrievals studied by Riepe et al. [9] were subjected to a pulsatile blood flow environment and shear stress conditions.

These factors, which resulted in hydrolytic degradation of vascular grafts, do not describe the environment, loading, and exposure of the Dynesys PET cords, and no in vivo changes in the retrieved PET cords were evident in the present study. The FTIR spectra showed no detectable formation of a carboxyl peak, either in the outer or central fibers. The carboxyl indices of all cords and at all locations were below the detection limit of 5%. The GPC analyses suggested no decrease in Mw, either in the outer or central fibers, and demonstrated the absence of broadened Mw distributions, which was indicative of no noticeable molecular cleavage in the explanted cords during in vivo use.

Table 4 Molecular weight changes in PCU spacers

Level	Case 1		Case 2		Case 3		Case 4		Ref A		Ref B	
	S1–L5 L	S1–L5 R	L2–L3 L	L2–L3 R	L4–L5 R	L5–S1 R	L5–S1 R	L4–L5 L	L4–L5 R	L5–S1 L	NA	NA
Average M_w in the bulk (g/mol)	146,200	145,600	142,500	147,700	139,700	131,900	154,800	162,500	145,300	168,200	142,800	192,600
Average M_w at the surface (g/mol)	129,600	125,300	130,400	124,000	123,200	110,800	135,000	164,100	125,800	144,800	131,000	190,900
Average M_w difference of Surface/Bulk (%)	–11	–14	–8	–16	–12	–16	–13	1	–13	–14	–8	–1

NA not applicable

The biodegradation is a breakdown process of materials or components with the participation of biological agents such as enzymes and cells [29]. Biodegradation of a supposedly biostable material or component will result in undesirable chemical, mechanical, and biological responses. The biostability and mechanical performance of polymeric implant components correlate to each other via molecular weight [20]. Biostable polymeric components with stable molecular chemistry and structures provide stable molecular weight of polymers, which in turn maintains the as-designed and appropriate mechanical performance of the implants. The Dynesys dynamic stabilization system is designed to conform to the anatomy. Previous in vitro biomechanical, cadaveric tests and clinical studies have demonstrated the system's mechanical stability and positive effects on spinal correction [7]. Though the investigation of biomechanical performance of the explanted components is outside the scope of this current study, the biostability of the retrieved components suggests that they maintained their normal mechanical function, which was also demonstrated by a previous retrieval study on the PCU spacers [30] and multiple in vitro biomechanical tests [7].

The analytic results described above regarding the in vivo changes in the Dynesys explants showed marginal or no evidence of biodegradation. 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.

A recent publication in Spine by Ianuzzi et al. [31] also reported the retrieval analyses of Dynesys explants with a focus on PCU spacers. Ianuzzi's general observation of localized wear and surface damage, as well as bending of explanted PCU spacers agree with the results of this current study. Differences in results between the studies may be attributed to differences in location, in vivo time, and methods of characterization (cleaning, GPC, and FTIR). With regard to location, Ianuzzi analyzed surfaces exposed to body fluid and tissues but sub-surface and bulk locations were not studied. Reports of changes to the surface chemistry for explanted PCU spacers are not new [32]. This study includes results for sub-surface locations (100 microns below the surface) and bulk locations of the explants. With regard to in vivo time, the explants presented in this manuscript have an average in vivo time of 1.1 years while the average time in vivo of Ianuzzi is 4.3 years. Because FTIR signals of potential chemical changes on exposed implant surfaces depend upon implantation time, it is expected that the results of Ianuzzi may show greater changes than the current manuscript.

Fig. 8 FTIR spectra of PET cords: **a** all four cases with three reference controls and **b** overlay of all spectra in **a**

Fig. 9 Representative GPC results of PET cords

Table 5 Molecular weight changes in PET cords

Level	Case 1			Case 2			Case 3			Case 4			Ref C	Ref D	Ref E
	L5-S1	cord 1	L5-S1 cord 2	L2-L3	L2 L	L2-L3 L3 R	L4-S1	R	L4-S1 cord 1	L4-S1 cord 2	L4-S1 cord 2	L4-S1 cord 2	NA	NA	NA
Average M_w of outer fibers (g/mol)	71,640		70,090	73,600		74,390	73,180		73,090		73,380	73,330		73,740	75,020
Average M_w difference to reference (%)	*		*	*		*	*		*		*	NA		NA	NA
Average M_w of inner fibers (g/mol)	74,180		71,180	74,710		74,770	73,290		71,310		71,490	72,190		75,490	73,540
Average M_w difference to reference (%)	*		*	*		*	*		*		*	NA		NA	NA

* Below measurement uncertainty of 10%

NA not applicable

With regard to differences of methods, (1) the study of Ianuzzi does not disclose cleaning techniques. Thus, the effects of residual body fluids and tissues cannot be fully assessed. As mentioned in a previous study, [32] residuals may generate FTIR bands that overlap the bands of PCU degradation byproducts. (2) The study of Ianuzzi lacks GPC analyses and results like those presented in this study. GPC analysis can confirm the presence of low-molecular degradation byproducts, if any. (3) The study of Ianuzzi assumes certain bands are related to degradation of PCU. This band assignment was originally proposed by Christensen [8, 25] based on in vitro and in vivo rat studies. The present study did not reveal the appearance of any such bands and a previous study [32] suggested that these bands may overlap with the bands from tissue and body fluid residues (mainly for protein content). Taken together, as suggested by both groups, further investigation and monitoring of the retrieved DynesysTM systems is warranted.

In summary, 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 following results. The FTIR analysis showed that explanted PCU spacers had slight chemical changes on the surface but were chemically unchanged below the surface and in the center. No identifiable IR peaks were observed at wavenumbers that would be attributed to PCU biodegradation processes. The FTIR analyses showed that the retrieved PET cords were chemically unchanged at both the surface and the interior and demonstrated an absence of biodegradation peaks. The GPC analyses of PCU and PET explants showed the absence of shoulder-peaks in lower M_w regions that might be attributed to biodegradation.

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Conflict of interest The author(s) has/have received or will receive benefits for personal or professional use from a commercial party related directly or indirectly to the subject of this manuscript.

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