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Degradation characteristics of injection molded Evolvecomp™ GF40PLD96 products

Arctic Biomaterials Research and Development

Objectives

The objective of this white paper is to present the degradation characteristics of investigational implant prototypes injection molded from Evolvecomp GF40PLD96 and 70L/30D,L PLA (RESOMER LR 708).

Materials and Methods

The investigational implant prototypes used in this evaluation were injection molded from a blend of Evolvecomp GF40PLD96 pellets and 70L/30D,L PLA (RESOMER LR 708) granules. Figure 1 presents an example of an interference screw type implant used in this study. Initial inherent viscosity, initial residual monomer content and surface/volume ratio of manufactured implants are listed in Table 1. The samples were EtO sterilized prior to study.

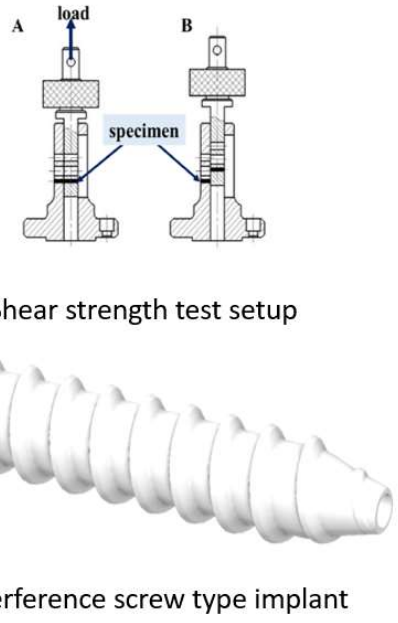

Figure 1. *Interference screw type implant and shear test setup.*

Table 1. *Initial properties of manufactured implant prototypes.*

Implant diameter (mm)	Area/volume ratio (1/mm)	Initial inherent viscosity (dl/g)	Residual monomer content (wt-%)	Glass fiber content (wt-%)
4	3	2.12	<0.1	20
6	2.2	2.14	<0.1	23
12	1.14	2.25	< 0.1	21

The *in vitro* degradation study was done according to [1-3] in order to analyze the degradation characteristics of implant prototypes. During the *in vitro* degradation, diameter of investigational implants, mass loss, inherent viscosity and shear strength retention were measured.

Results

The results are presented in Figures 2-6. It was found that during the 52-week follow-up, the diameter of implant prototypes increased by ca. 14-18% (Figure 2). The diameter increase was similar for all analyzed implant sizes. The mass loss samples revealed that the remarkable mass loss started after ca. 26-52 weeks degradation *in vitro* (Figure 3). At 2 years (104 weeks) time point, ca. 10 - 25 % of initial mass was remaining. The remaining mass seemed to depend on the implant diameter. The largest implant prototypes retained their mass slightly longer than the smaller implant prototypes.

Reduction of inherent viscosity during the degradation followed similar trend (Figure 4) regardless of the implant size and slight variations in initial chemical properties (see Table 1). During the first 24h of degradation analysis, all samples lost ca. 30% of their dry shear strength (these results are not shown here, data on file). This initial strength loss was caused by the penetration of incubation

media inside the implants. The evaluation presented in this paper is focused on strength retention beginning from this 24h time point. These "wet strength" retention results are presented in Figure 5. The wet strength data revealed that for the first 16 weeks of *in vitro* degradation, the mechanical properties remained above 80% of the initial (time point 24h) wet strength (Figure 5).

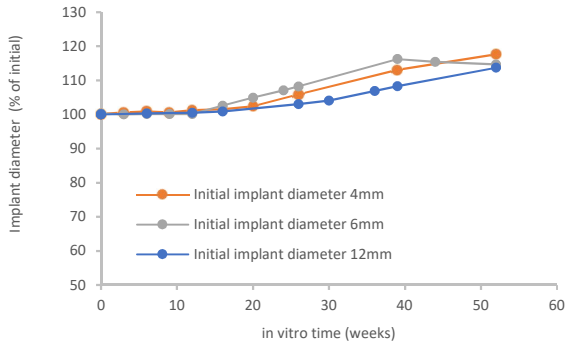

Figure 2. *Dimensional changes during in vitro degradation.*

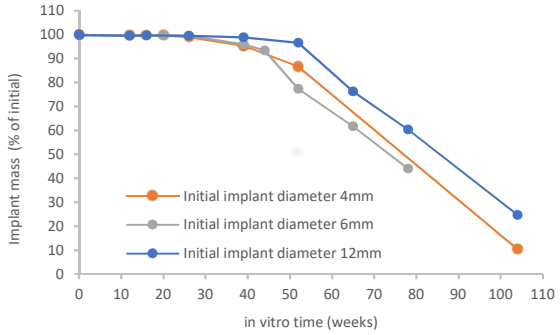

Figure 3. *Mass loss during in vitro degradation.*

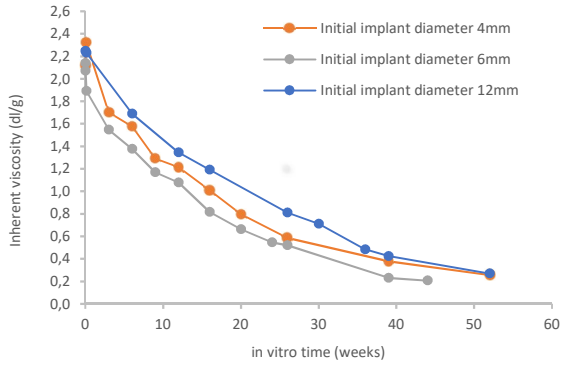

Figure 4. *Reduction of inherent viscosity during in vitro degradation.*

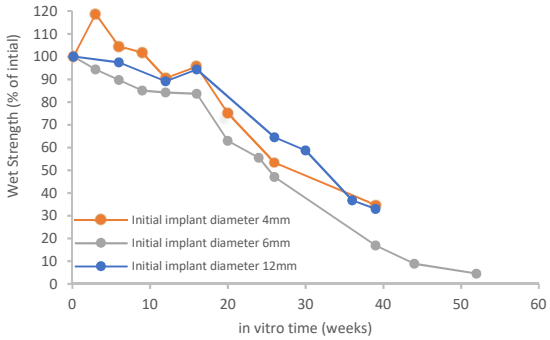

Figure 5. *Reduction of "wet strength" during in vitro degradation.*

Conclusions

This white paper presents degradation properties of investigational interference screw prototypes composed of a blend of Evolvecomp GF40PLD96 pellets and 70L/30D,L PLA (RESOMER LR 708) granules.

The outer dimension of the implant prototypes gradually increased during the *in vitro* degradation, ending up 14 - 18% higher than the initial diameter at week 52.

The mass loss started between weeks 26 and 52, being 10 – 25 % of the initial mass at 104 weeks. The largest implant prototypes retained their mass slightly longer than the smaller implant prototypes.

Reduction of inherent viscosity during degradation followed similar trend regardless of the implant size and slight variations in initial chemical properties.

Shear strength retention analysis revealed that for the first 16 weeks of *in vitro* degradation, the mechanical properties remained above 80% of the initial wet strength.

All the results presented in this paper pertain to an example case using a prototype investigational implants. When demonstrating the behavior of actual products composed of Evolvecomp GF40PLD96 composite material, similar studies and possible further analyses need to be conducted in order to verify the characteristics of actual products.

References

1. F2502-11 Standard specification and test method for absorbable screws and screws for internal fixation implants
2. FDA Guidance (draft): Guidance document for testing biodegradable polymer implant devices
3. ISO 15814:1999 Implants for surgery - Copolymers and blends based on polylactide - In vitro degradation