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Hydrolytic degradation of the continuous fiber composites of the Evolvecomp™ family

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Introduction

Conventional bioabsorbable polymer implants have lacked the mechanical properties to be applied in load bearing applications in human body. Bioactive natural mineral fiber reinforced composites offer improved mechanical properties. Additionally, bioactive natural mineral fiber component offers another great advantage, bioactivity. This means that it promotes bone healing and bone growth. Continuous fiber reinforced composites elevate the bioabsorbable implant material properties to a whole new level.

This white paper summarizes hydrolytic degradation properties of the three composites belonging to the Evolvecomp composite family with the Arctic Biomaterials' proprietary bioactive X3 natural mineral fiber as continuous fiber reinforcement.

Materials and methods

In this study, the samples were composites of lactide based copolymers and continuous natural mineral fiber. They present the three compositions of the Evolvecomp composite family. The compositions and dimensions of the samples are presented in Table 1.

Table 1. *Sample properties.*

Product	Evolvecomp™ GF40PLD96	Evolvecomp™ GF40PLD85	Evolvecomp™ GF40PLG85
Polymer	P(L/DL)LA 92/8	P(L/DL)LA 70/30	PLGA 85/15
Natural mineral fiber content (wt-%)	40	40	40
Inherent viscosity (dl/g)	2.1	2.0	1.7
Test sample diameter (mm)	1.8-2.0	1.8-2.0	1.8-2.0
Test sample length (mm)	50	50	50

Hydrolytic degradation of the samples was studied in a two-year *in vitro* (37°C, pH 7.4) study according to ISO 15814 [1] and ISO13781 [2]. At predetermined time points, mass loss, water absorption, mechanical properties (shear strength and bending strength), inherent viscosity and residual monomers were measured. Additionally, photos and SEM images were taken on selected samples. One of the studies (Evolvecomp GF40PLD96) was extended to three years. All samples were EtO sterilized.

Results and discussion

Overall, the results show that the Evolvecomp GF40PLG85 composite loses its properties faster than the two other composites. This was an expected outcome because the matrix polymer of the GF40PLG85, namely PLGA, degrades faster than PLDLA due to its greater hydrophilicity.

Mass loss and water absorption results of the composites are presented in Figure 1 on the left. The results are shown as relative mass change, water absorption upwards and mass loss downwards. It can be noted that the mass loss behaviour of the two composites with PLDLA as polymer matrix is practically identical but a slight difference in the water absorption can be noted. The faster degradation and water absorption of the GF40PLG85 compared to the two other composites can be seen very well. The filler content of the composites during the in vitro test series is shown on the right in Figure 1. The polymer component of the Evolvecomp GF40PLG85 degrades remarkably faster than those of the two other composites.

The progress of the degradation can also be observed in the SEM images shown in Figure 2, Figure 3 and Figure 4. Figure 2 shows SEM images of Evolvecomp GF40PLD96 composite pin ends where the degradation of the natural mineral fibers can be seen well. At later time points, there are empty holes in the places of fibers. Figure 3 shows Evolvecomp GF40PLD85 and Figure 4 the Evolvecomp GF40PLG85 fractured cross section of a composite pin. It can be noted that towards the end of the test series, there are less polymer around the fibers. When compared with the filler content data shown in Figure 1, the polymer matrix degradation of the GF40PLG85 is evident.

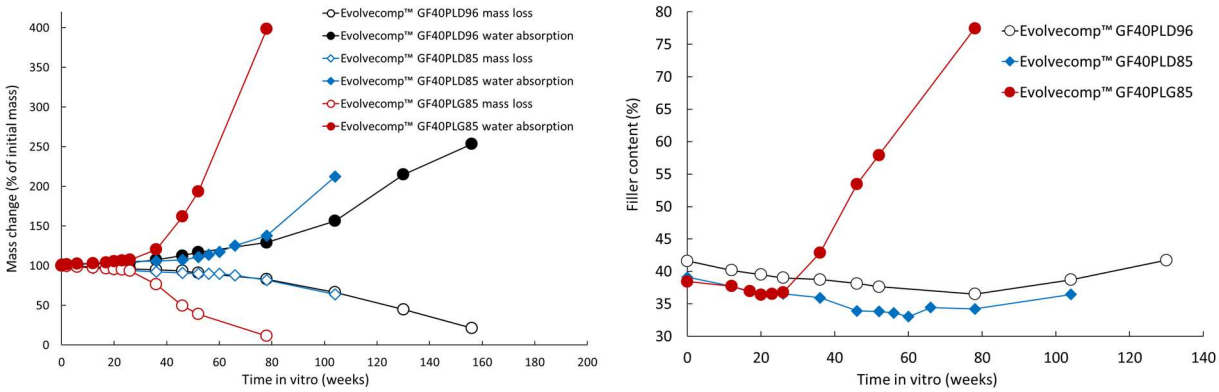

Figure 1. *Mass loss and water absorption results on the left and filler content on the right as a function of time in vitro.*

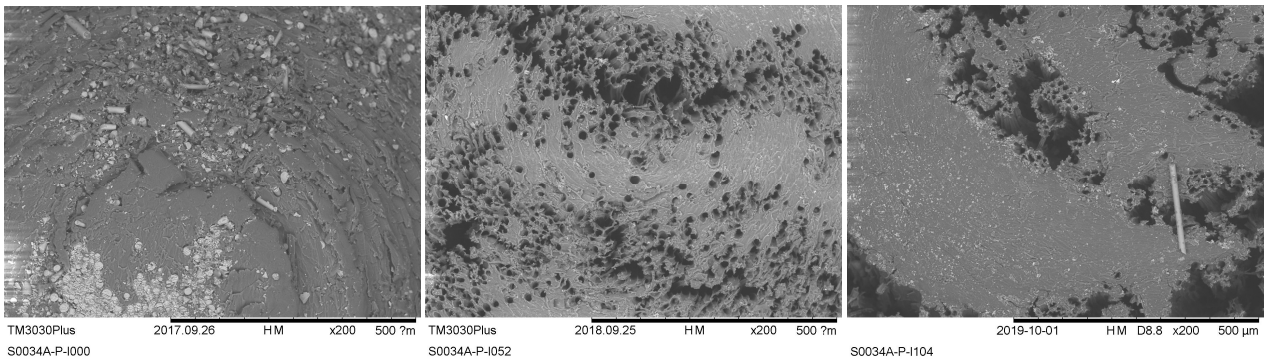

Figure 2. *SEM images of Evolvecomp GF40PLD96 composite pin end at the time points of 0 weeks (left), 52 weeks (middle) and 104 weeks (right).*

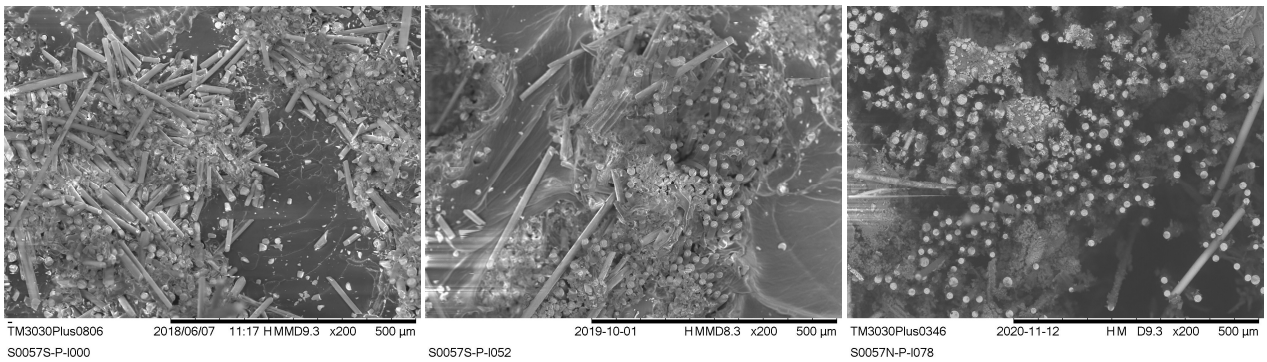

Figure 3. *SEM images of Evolvecomp GF40PLD85 composite pin fractured surface cross section at the time points of 0 weeks (left), 52 weeks (middle) and 104 weeks (right).*

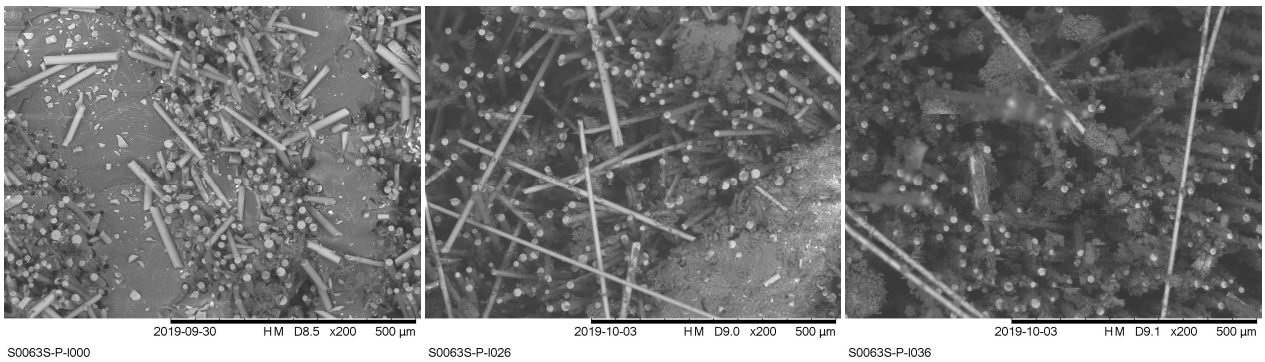

Figure 4. *SEM images of Evolvecomp GF40PLG85 composite pin fractured surface cross section at the time points of 0 weeks (left), 26 weeks (middle) and 36 weeks (right).*

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Mechanical properties of the samples were tested after their withdrawal from dissolution medium, i.e. they were tested wet except the 0-week time point. Bending strength results are shown in Figure 5 and shear strength results in Figure 6. The results of the Evolvecomp GF40PLG85 are shown only up to 36-week time point due to the fact that after that time point the samples were too degraded to be tested.

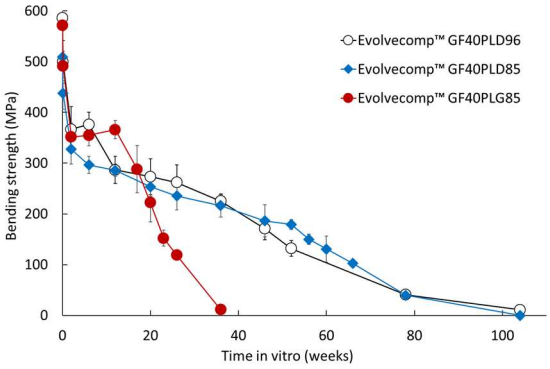

Figure 5. Bending strength of the composite samples in vitro.

There is a notable decrease in the bending and shear strength of the composites during the first 24 hours in vitro. It must be noted however, that the initial properties of the composite samples (i.e. 0-week samples) were measured dry whereas the one day in vitro time point samples were measured wet. 0-week time point corresponds to the situation just before insertion of the material to human body, when the material is dry and at room temperature. The time point of day one corresponds to the situation when the material has been inserted and has reached equilibrium in human body, at 37°C and has absorbed water. Absorbed water in the composites acts as plasticizer and thus has an effect on the mechanical properties.

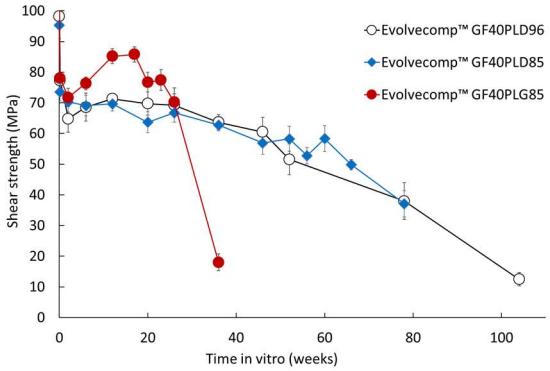

Figure 6. Shear strength of the composite samples in vitro.

The results show that the mechanical properties decline almost linearly for the two composites with PLDLA as the polymer matrix. The Evolvecomp GF40PLG85 degrades faster and thus also the mechanical properties decline faster.

Inherent viscosity of a polymer is dependent on the molecular size of the polymer and thus gives an approximation of the molecular size. The smaller the molecules are in the polymer, the smaller is the inherent viscosity. Inherent viscosity results are presented in Figure 7. The decline in the inherent viscosity is practically identical for the Evolvecomp GF40PLD96 and GF40PLD85 and significantly faster for GF40PLG85.

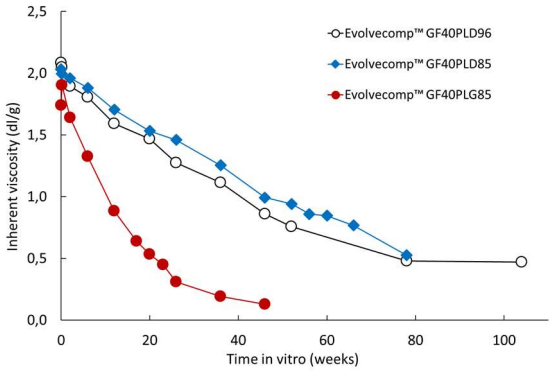

Figure 7. Inherent viscosity of the Evolvecomp composites in vitro.

Residual monomers were low throughout the study and thus can be assumed not to have an effect on the polymer degradation.

Conclusions

Overall, the GF40PLG85 composite degraded faster than the GF40PLD96 and GF40PLD85 composites. This was an expected outcome because PLGA is known to degrade faster than PLDLA. The Evolvecomp GF40PLG85 is suitable for applications where fast degradation is desired whereas the other two composites are more suitable for use in applications where good mechanical property retention for longer time periods is wanted.

References

1. ISO 13781:2017 Implants for surgery – Homopolymers, copolymers and blends on polylactide - In vitro degradation testing
2. ISO 15814 Implants for surgery – copolymers and blends based on polylactide – in vitro degradation testing