Arctic Biomaterials Oy
Arvo Ylpön katu 41
33520 Tampere, Finland
www.abmcomposite.com
VAT no. FI 26340038

Degradation characteristics of injection molded Evolvemer™ TCP30PLGA products

Arctic Biomaterials Research and Development

Objectives

The objective of this white paper is to present the degradation characteristics of injection molded implant prototypes composed of Evolvemer™ TCP30PLGA composite material. *In vitro* degradation analysis was conducted according to [1,2]. Similar *in vitro* analyzes have been widely used to evaluate the degradation characteristics of similar composite materials and various implant prototypes [3-5]. Composite materials composed of calcium phosphates (CaP) and PLA/PGA polymers have proven to be osteoconductive [4, 5, 6] and they have been used with clinical success [7, 8]. One advantage of these materials over plain PLA/PGA polymers is that the CaP component (such as beta-TCP) can provide a suitable base for cell bonding.

Materials and Methods

The investigational 4.5 mm diameter suture anchor implant prototypes used in this analysis were injection molded from Evolvemer™ TCP30PLGA pellets. The design of the used samples was created by a customer of Arctic Biomaterials and thus it is not opened in this paper. Initial inherent viscosity, initial residual monomer content and surface/volume ratio of manufactured implants are listed in Table 1.

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-%)	Beta-TCP content (wt-%)
4.5	3.37	2.25	< 0.1	30

The samples were EtO sterilized prior to study.

The *in vitro* degradation study was conducted in order to analyze the degradation characteristics of suture anchor prototypes. Real time (37°C) *in vitro* degradation analyses in Sörensen buffer solution were conducted according to standard [9]. During the *in vitro* degradation, diameter of investigational implants, mass loss, inherent viscosity and strength retention were measured.

Results

The results are presented in Figures 1-4. The dimensional changes and mass loss were measured. It was found that during the follow-up, the diameter of suture anchor prototypes increased by ca. 15%. The mass loss samples revealed that the remarkable mass loss started after 26 weeks degradation *in vitro*. At 2 years (104 weeks) time point only 35 % of initial mass was remaining.

Inherent viscosity and mechanical strength during the degradation were analyzed *in vitro.* Mechanical testing was eyelet testing.

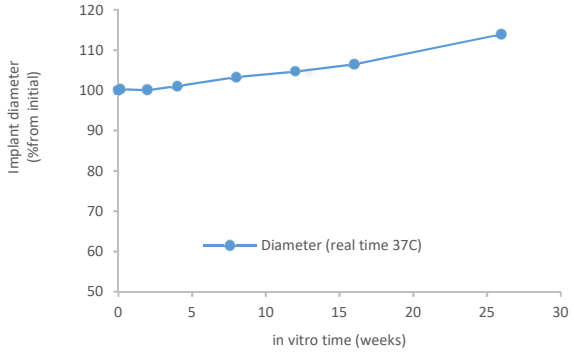

Figure 1. *Dimensional changes during in vitro degradation.*

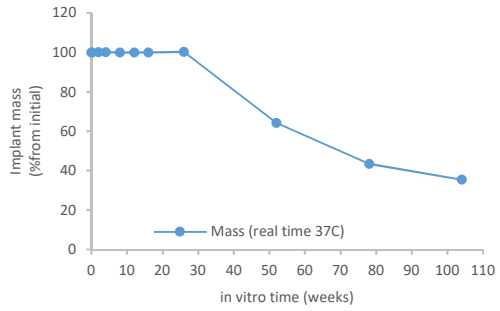

Figure 2. *Mass loss during in vitro degradation.*

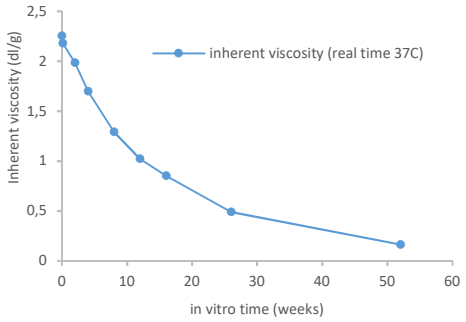

Figure 3. *Reduction of inherent viscosity during in vitro degradation.*

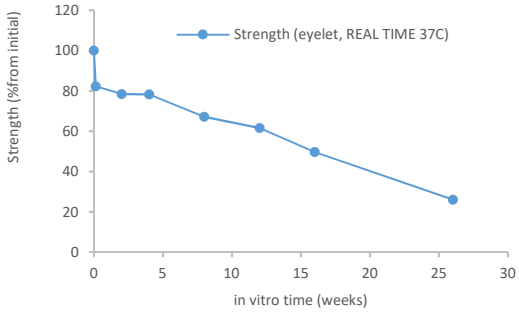

Figure 4. *Reduction of mechanical strength during in vitro degradation.*

Conclusions

This white paper presented degradation properties for investigational suture anchor products composed of Evolvemer™ TCP30PLGA composite material.

The outer dimension of the suture anchors gradually increased during the *in vitro* degradation, ending up 14% higher than the initial diameter at week 26.

The mass loss started between weeks 26 and 52, being 35% of the initial mass at 104 weeks.

The mechanical strength retention and the inherent viscosity data show that for the first 12 weeks of *in vitro* degradation, the mechanical properties remained above 60% of the initial dry strength and above 75% of the initial wet strength and the inherent viscosity was above 1.0 dl/g. This is still at the safe level compared to 0.8 dl/g threshold of more significant mechanical property reduction. [10]

All the results presented in this paper pertain to an example case using a prototype investigational suture anchor implants. When proving the behavior of actual products composed of Evolvemer™ TCP30PLGA composite material, similar studies and possible further analyses need to be conducted in order to verify the degradation 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. Aunoble S et al, Journal of Biomedical Materials Research Part A 2006;78A:416-422.
4. Kobayashi S et al, Journal of Materials Science: Materials in Medicine 2009;20(1):379-386.
5. Ignatius AA et al, Journal of Biomaterials Science, Polymer Edition 2001;12(2):185-194.
6. FDA Guidance: Bone Anchors - Premarket Notification (510(k)) Submissions
7. Daculsi G et al, Biomaterials 2011;32:3166-3177.
8. Barber FA et al, Arthroscopy 2011;27(5):637-643.
9. ISO 15814:1999 Implants for surgery - Copolymers and blends based on polylactide - In vitro degradation
10. Paakinaho K et al, Journal of the mechanical behavior of biomedical materials. 2011;4(7):1283-1290.