In vitro Degradation Behavior of Poly(*p*-dioxanone) Films: Effects of Temperature on Physical Properties

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Statement of Purpose: Poly(*p*-dioxanone) (PDS) is a synthetic bioabsorbable polymer with excellent properties and has been used in sutures for many years. The polymer with a glass transition temperature (T_g) of about -10°C is much more flexible than poly(lactic-co-glycolic acid) (PLGA) at body temperature. Therefore PDS in the form of flexible film or thin sheeting finds increased use in areas such as plastic surgery (e.g., septoplasty).[1] PDS is designed to degrade in a biological environment and it will take about 10 weeks for the polymer to lose its mechanical strength *in vitro* and *in vivo* at 37°C.[2] On the other hand, it is always desirable that the degradation behaviors of a polymer can be predicted with accelerated test methods so that the development cycle of an absorbable medical device can be shortened. One method that is frequently used to accelerate the degradation is to perform the tests at elevated temperatures. As such, the present study examines the effects of temperature on the *in vitro* degradation of PDS film.

Methods: *In vitro* degradation was performed by submersing 0.5x4x50 mm strips of dyed PDS film[2] (initial properties shown in Table 1) in a phosphate buffer solution of pH 7.3 at 37, 45, 55 and 65 °C for up to 10 weeks. At each pre-determined time interval, the samples were removed and tensile-tested first to evaluate breaking strength with an Instron 5544 using either a 100- or 500-N load cell at 10 mm gage length and 20 mm/min loading rate. Changes in crystallinity and T_g were obtained by analyzing Differential Scanning Calorimetry (DSC) curves of first scan at 20°C/min. A Nikon SMZ-U optical microscope with a DXM1200F digital camera and NIS-Elements Imaging software was used to examine specimen surface morphology. A Veeco Model 1650 atomic force microscope with a Si probe was used to evaluate the changes in surface morphology and roughness in tapping mode.

Results: This study investigated the interrelationships between material properties, *in vitro* time and temperature. Figure 1 shows the degradation profiles for breaking strength retention (BSR) at 37, 45, 55 and 65°C reported as percentages of the control. The results showed that the PDS films gradually lost their strength with increasing *in vitro* time. The degradation was significantly accelerated from low to high temperatures that could be predicted by an Arrhenius relationship, from which activation energy was derived and ranged ~9.7-13.8 kJ/mol (Figure 2). Therefore a 10-week in vitro study at 37°C may be greatly shortened by performing the study at elevated temperature. DSC results showed there was an increase in percent crystallinity with degradation but Tg was seldom affected. AFM showed an increase in surface roughness with *in vitro* time and the presence of spherulite-like crystals (Figure 3).

Conclusions: This study determined degradation profiles for PDS at elevated temperatures and explored the interrelationships between material properties, *in vitro* time and temperature. Tensile strength decreased with *in vitro* time and polymer morphology changed during degradation. Elevated temperature significantly accelerated the *in vitro* degradation and therefore may be used to predict material behavior at body temperature.

Table 1. Initial Properties of Poly(*p*-dioxanone) Film

Max Stress (MPa)	Yield Stress (MPa)	Modulus (MPa)
56±1.9	43±4.4	450±10.3

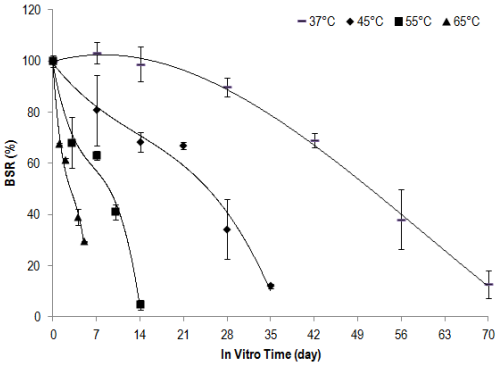

Figure 1. Effect of temperature on BSR.

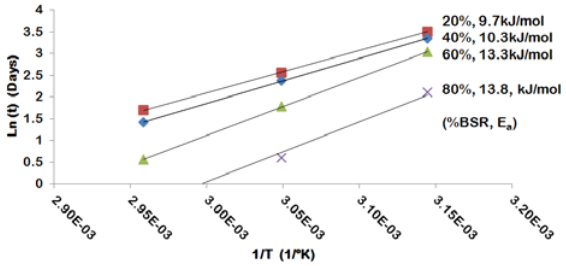

Figure 2. Arrhenius plots showing *in vitro* time needed to reach 20, 40, 60 and 80% BSR.

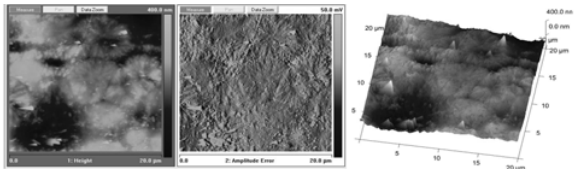

Figure 3. AFM images showing the height, amplitude and 3-D topographic AFM images (left to right) of PDS films degraded at 55°C for 3 days

References:

1. Boenish, M. and G. Trenite. Arch Facial Plast Surg. 2010: 12(1): 4-10.
2. Deng, M., etc, 34th SFB Annual Meeting. 2010; Vol. 2; p586.

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