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Premature failure of poly-L/D-lactide bioresorbable spinal cages

Pitfalls in designing in time-dependent materials

Stefan W. Sturm¹, Tom A.P. Engels¹, Theo H. Smit² and Leon E. Govaert¹

¹ *MaTe, Eindhoven University of Technology*
² *Skeletal Tissue Engineering Group Amsterdam*

The premature in-vivo mechanical failure of PLDLA bioresorbable spinal cages is investigated. The instantaneous strength of the cages is more than adequate to sustain the forces encountered in the specific loading condition. It is now shown that the high rate dependence of the material is the cause of the failure, pointing out that the time-dependent nature of polymeric materials can lead to unexpected failure.

Introduction

In spinal diseases leading to degeneration or instability, fusion of one or more spinal segments may be indicated. Devices used for this purpose not only should maintain or restore the normal distance between vertebrae, but also stabilize the vertebral segment in order to allow bony fusion. Since the 1980's, spinal fusion with so-called interbody cages has evolved into a routine procedure. Bioresorbable polymers made an impressive development during the last three decades, providing a real alternative to traditional non-resorbables. The main advantage of bioresorbables is that retrieval operations are no longer necessary: long-term complications such as corrosion, wear, foreign body reaction, and the risk of infection are prevented. Furthermore, polymeric implants have an elastic modulus close to bone, and functional forces are gradually transferred to the underlying bone as the material degrades, thereby reducing the fusion-delaying stress-shielding effect generally observed by metal implants.

Bioresorbables, however, have their own drawbacks and pitfalls. An important issue is that bioresorbables should behave in a predictive way: they should maintain their mechanical integrity for a minimal period of time, and then degrade slowly in order to avoid tissue reactions. A recent pilot study on goat models [1], involving PLDLA spinal cages, indicated that traditional design approaches do not apply. In this study cage failure could already be observed 3 months after implant, whereas traditional design approaches indicated a life-time of at least a year.

Initial design approach and validation of material- and loading conditions

To determine the ultimate force which a vertebral body of the goat can endure, a few specimen were compressed until failure. The ultimate load level was determined to be approximately 3.5 kN, the load at which the bone marrow was pushed out. The strength of the prototype of the spinal cage was determined to be approximately 6 kN in a uniaxial compression test. Since it is not expected that the ultimate strength of the vertebral body will be reached (in real-(goat)-life), this implies that at least a safety factor of two is present. To investigate the actual forces occurring in the spinal column of a goat, a spinal cage equipped with strain gauges was implanted. The study showed that the peaks in the dynamic forces were around 900 N, far less than the 6 kN load the spinal cage could endure (safety factor of at least 6).

Since poly-lactic acids are biodegradable, the influence of progressive degradation was investigated in an in-vitro study with spinal cages. Spinal cages were placed in a PBS (Phosphate Buffered Saline) solution at 37°C for increasing aging times prior to testing; the results are presented in Figure 1. It is clear that, despite the strong decrease in weight-average molecular weight, the strength of the cage was not affected within a period of a year. As a result, it was anticipated that failure would not occur within the experimental timescale of the goat study which was one year. Mechanical failure, nonetheless, did occur.

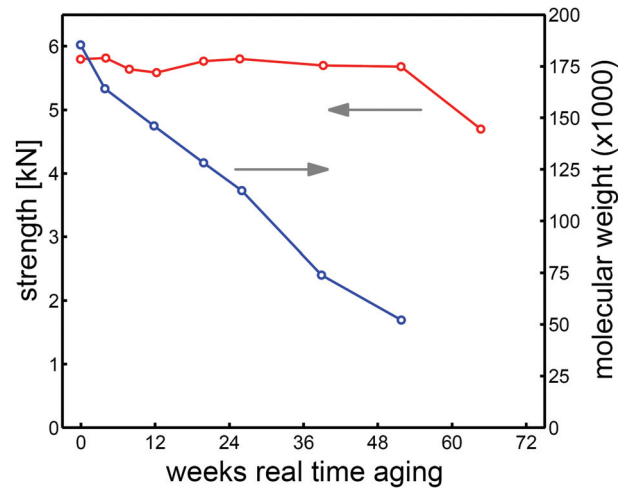


Figure 1: Molecular weight reduction and cage strength versus aging time.

Time dependent failure in PLDLA

To resolve the issue of the (apparently) unexpected premature failure of the PLDLA cage, we investigated the long-term failure response of PLDLA. For this we use the constitutive framework we developed earlier and which is given in its latest form by Klompen et al. [2]. In this work a constitutive model is presented that describes the large strain deformation of amorphous polymers for different thermodynamic states. An amorphous polymer is in the model fully described by a set of parameters of which only a single parameter, S_a , depends on thermal history. It was demonstrated previously [3] that this model can also be employed to quantitatively predict the long-term failure of glassy polymers. Basic assumption in this approach is that failure is governed by accumulation of plastic strain that eventually triggers strain softening and initiates strain localization phenomena. This view is supported by the fact that the dependence of time-to-failure on applied stress is equivalent to the dependence of yield stress on applied strain rate [3]. Here we will use the same modeling approach with a small adaptation to the viscosity definition to take into account the contribution of a second process in the rate dependence of the material [4,5].

The material used in this study is an amorphous polylactic acid. Lactic acids come in two isomeric configurations: a levorotary (L) and a dextrorotary (D) configuration. Polylactic acids made from D-lactide are amorphous, whereas polylactic acids made from L-lactide are semi-crystalline. However, polylactic acids can be made containing both D- and L-lactide, and the ability to crystallize depends on the total amount of D-lactide. When the D-lactide content is around, or greater than 10% no crystallization will occur and the polymer will be amorphous. The polylactic acid used in this study is a copolymer of 70:30 Poly(L-lactide-co-D,L-lactide), where the poly(D,L-lactide) is a racemic homopolymer. The overall D-lactide content is 15%, rendering the material incapable of crystallization.

In Figure 2 the description of the model of compression experiments performed at 25°C and 37°C for true strain rates of 10^{-2} , 10^{-3} and 10^{-4} s $^{-1}$ can be seen. For both temperatures the model can give an accurate description of the large strain response. In Figure 3 (left) the yield stresses versus logarithm of strain rate can be seen for both temperatures. From this figure it becomes apparent that the rate dependence of the yield stress for PLDLA, i.e. 13 MPa/decade, is much higher than the rate dependence normally encountered for amorphous polymers, i.e. 3-6 MPa. This high rate dependence can thus also be found for the applied stress versus time-to-failure, as can be seen on the right hand side of Figure 3. It can be seen in this figure that the model underestimates the time-to-failure somewhat, but it has to be born in mind that these are true predictions and that they only fall about 5-10% short of the experimental values.

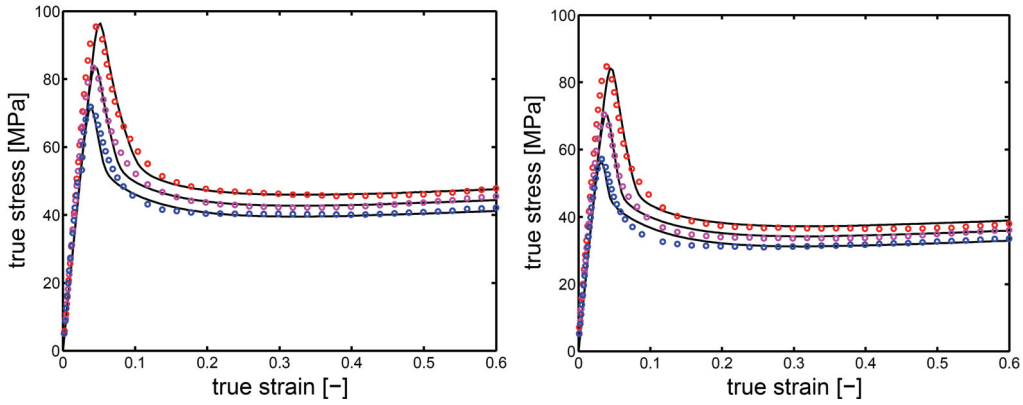


Figure 2: Model results versus experimental results for compression tests performed at 25°C (left) and 37°C (right).

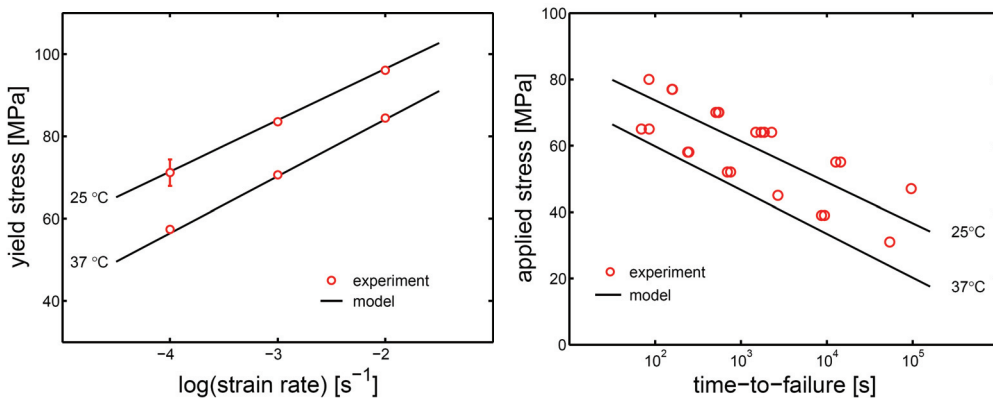


Figure 3: Yield stress versus logarithm of strain rate (left); applied true stress versus logarithm of time-to-failure (right).

Application to spinal cages

From the performed (intrinsic) characterization of PLDLA it is apparent that the sensitivity of the material for the applied stress under constant loading conditions is much higher than is expected. Therefore, normal design considerations will lead to a considerable overestimation of the life-time of any product made from PLDLA and used in a structural application. To verify this we performed a compression test on a PLDLA spinal cage at 37°C in air, see Figure 4 (left), to determine the thermodynamic state, S_a , of these type of cages, giving a consistent set of parameters which enables us to predict the long-term behavior of these spinal cages. In Figure 4 (right) the resulting long-term prediction can be seen. From this prediction it becomes obvious that when the predicted stress dependence is extrapolated to low stresses, failure will occur in a matter of days to weeks, instead of the expected years. However, a subtle distinction has to be made with respect to this extrapolation. In the compression results of Figure 2 it can be seen that the rate dependence is not the same over the whole stress response. In the softening and hardening region the rate dependence is notably lower than in the yield region. This indicates that at low strain rates and long loading times a change of behavior which can be characterized by only a single process should be expected. Such a change in behavior will change the slope of the curve of Figure 4 (right) to a lower value for low applied stresses and long failure times, and will thus shift the failure times to longer times.

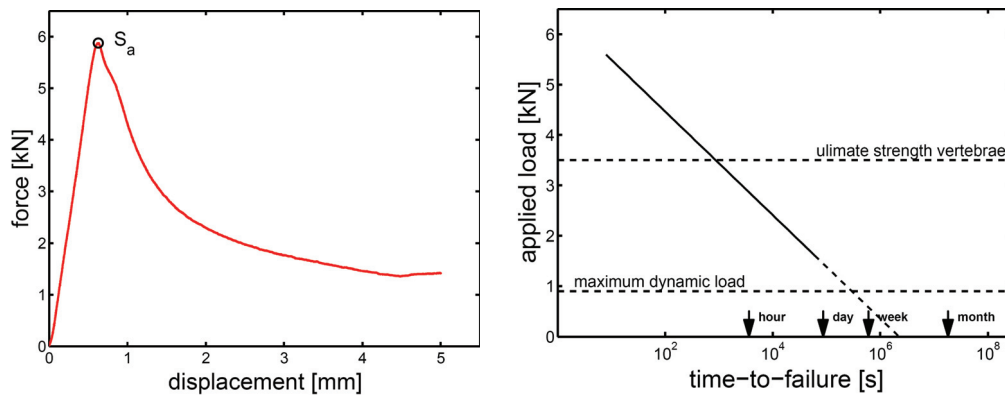


Figure 4: Compression test of a spinal cage (left); prediction of long-term failure of a spinal cage (right).

Conclusions

In conclusion it can be said that the in-vivo failure of the PLDLA cages is due to mechanical failure. It has been shown that the high rate dependence of PLDLA is the cause of this premature failure. From this study it becomes apparent that when designing in time-dependent materials one should be very hesitant in using standard design approaches. A solid understanding of the time-dependence of the material being used is of utmost importance.

References

- [1] Krijnen, M.R., Smit, T.H., Strijkers, G.J., Nicolay, K., Pouwels, P.J.W., and Wuisman, P.I.J.M., *Neurosurg Focus* **2004**, *16*(3), Article 3.
- [2] Klompen, E.T.J., Engels, T.A.P., Govaert, L.E., Meijer, H.E.H., *Macromolecules* **2005**, *38*(16), 6997-7008.
- [3] Klompen, E.T.J., Engels, T.A.P., van Breemen, L.C.A., Schreurs, P.J.G., Govaert, L.E., Meijer, H.E.H., *Macromolecules* **2005**, *38*(16), 7009-7017.
- [4] van Breemen, L.C.A., Poster, this conference
- [5] Janssen, R.P.M., Poster, this conference