IdentiPol QA2 application for biomedical material assessment

This abstract and poster paper show how the identiPol was used to measure the glass transition temperatures of the formulations in order to ensure they had the correct performance used in Body-temperature reverting, plasticised shape-memory polymers for the healing of fractures.

COMPRESSION SCREWS FOR THE FIXATION OF SMALL BONES AND BONE FRAGMENTS USING BIOCOMPATIBLE, BIORESORBABLE, BODY-TEMPERATURE REVERTING, PLASTICISED SHAPE MEMORY POLYMERS

B.M. Thomson[1], G. Thompson[1], D. Vgenopoulos[1], K. Nair[1], J. Duncan[2], K. Howell[1], M. Martyn[1] and P. Coates[1]
[1]School of Engineering and Informatics, Bradford University [2]Lacerta Technology, Leicestershire

Orthopaedic compression screws promote fracture healing by drawing-together and stabilising adjacent bone fragments (e.g. Herbert screws in scaphoid repair).

Shape memory polymers are materials that switch from one macroscopic shape to another following the application of external 'triggering' stimuli (e.g. by shrinking in length when heated). A shape memory compression screw could therefore potentially be used to pull bone fragments together.

The shape memory phenomenon occurs because when polymers solidify from a melt (or dry from solutions), the molecules form tangled networks in which individual molecules adopt conformations with the lowest available energies. If a solid polymer is (i) heated to a temperature above the point where the polymer chains are able to begin to move relative to one another (called Tg) but below its melting point; (ii) stretched; and then (iii) rapidly cooled below Tg without releasing the tension, then the polymer's chains become 'locked' into energetically unfavourable conformations, (analogous to frozen, stretched rubber bands). As long as the polymer remains below Tg then its molecules remain locked in these energetically unfavourable conformations. However, if the polymer is heated above Tg, then molecules will move relative to one another and revert to their original energetically favourable conformations (e.g. re-heating a stretched shape memory polymer above Tg will cause it to shrink in length).

The biocompatible, bioresorbable polymer polylactic acid can show shape memory properties and could therefore potentially be used to make a shape memory compression screw. Unfortunately, the triggering temperature required to initiate shape reversion in unmodified PLA is too high to be conveniently incorporated into routine clinical practice.

The value for Tg for a particular polymer can be reduced by adding plasticisers, low molecular weight compounds that facilitate the movement of molecular chains within solid polymers. To identify plasticisers that can reduce the Tg of PLA to 37C (i.e. physiological temperatures), standardised mixtures of PLA, plasticiser and solvent were added to moulds and dried in a computer controlled oven to produce plasticiser-polymer films. The Tg of these materials was determined using an identiPol machine. The films' shape memory properties were assessed by (i) heating 10 mm long pieces of film to 85C in water; (ii) stretching them to 20mm long; (iii) rapidly cooling them to 5C without releasing the tension; and then (iv) attempting to trigger shape memory reversion by brief immersion in water at 10C – 60C or more prolonged immersion in saline at 37C.

Results showed that two reportedly biocompatible plasticisers, Triacetin and Tributyl *O*-acetylcitrate reduced PLA's Tg in a dose dependant manner and that shape memory reversion could occur at 37C in saline. Such materials could potentially be used to form compression screws that shrink in length post-implantation and pull bone fragments together.

Ongoing work aims to optimise the conditions required to produce the shape memory plasticised PLA. Future work will use the manufacturing and characterisation equipment available at Bradford (e.g. injection moulding, extrusion and machining) to produce compression screws from these shape memory materials.

COMPRESSION SCREWS FOR THE FIXATION OF SMALL BONE FRAGMENTS USING BIORESORBABLE, BODY-TEMPERATURE REVERTING, PLASTICISED SHAPE-MEMORY POLYMERS

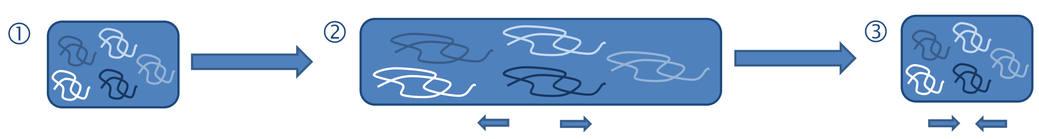
B.M. Thomson[1], G. Thompson[1], D. Vgenopoulos[1], K. Nair[1], J. Duncan[2], K. Howell[1], M. Martyn[1] and P. Coates[1]

Faculty of Engineering & Informatics, School of Engineering, University of Bradford[1], Lacerta Technology[2]

Introduction

OBJECTIVE: Make orthopaedic compression screws from stretched Shape Memory Polymers (SMP) and promote bone healing by using SMP's reversion force to gently pull bone fragments together

Underlying principle behind Shape Memory Polymers:



In normal polymers, molecules adopt minimal energy conformations

Heat polymer > T_g (temperature at which molecules can move within a solid polymer), stretch and cool under tension. Locks molecules in energetically unfavourable conformations, like frozen, stretched rubber bands

Re-heat above T_g and entropy drives molecules back to original conformations – polymer reverts to original shape

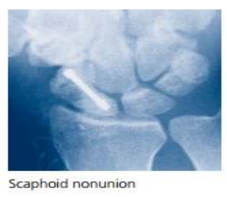
- The biocompatible, bioresorbable polymer polylactic acid (PLA) can show shape memory effects, but its T_g is too high for routine clinical use (~65°C).
- Plasticisers are small molecules that reduce a polymer's T_g

➔ Find a biocompatible PLA-Plasticiser combination that reverts under physiological conditions and use this material to make an orthopaedic compression screw

Concept:

Stretched SMP screw on implantation ①

Post-implantation ② Reversion above Tg

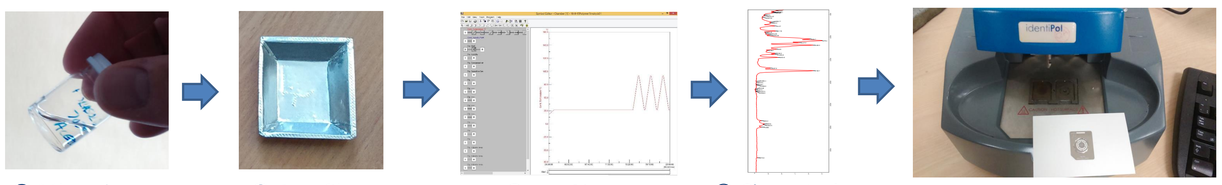


➔ **SMP's reversion force gently pulls bone fragments together**

Experimental

Identify a biocompatible Polylactate-Plasticiser SMP that reverts under physiological conditions

Screening method for measuring T_g of polymer-plasticiser-solvent cast films



① Mix polymer, plasticiser and solvent

② Cast film in disposable mould

③ Dry film in computer controlled oven

④ Characterise if required

⑤ Measure T_g using identiPol machine

Screening method for assessing reversion of polymer-plasticiser SMP films

① Cut 10 x 3 mm piece of plasticised polymer film

② Heat above Tg (85°C), stretch to ~ 20 mm, cool in water (5°C) whilst maintaining tension to form SMP

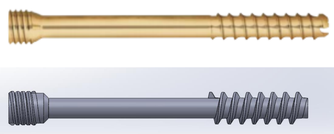
③ Revert by brief immersion in water (0 - 85°C) or more prolonged incubation at 37°C in saline. Measure change in length

For implants that exploit SMP phenomenon clinically, we want shape-memory polymers that are:

1. **Dimensionally stable at room temperature when dry**
2. **Revert under physiological conditions (i.e. saline and 37°C)**

Results

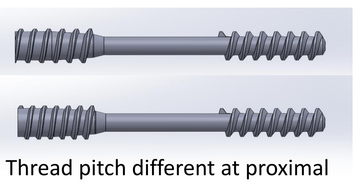
Design of compression screw



Typical existing design: Synthes 3.0mm Headless Compression screw, long thread and Solidworks model based upon several existing designs

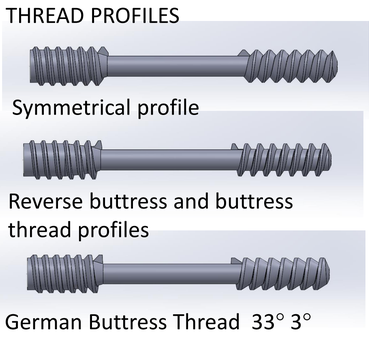
Possible design criteria

THREAD PITCH



Thread pitch different at proximal and distal ends to produce compression

THREAD PROFILES

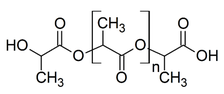


Symmetrical profile

Reverse buttress and buttress thread profiles

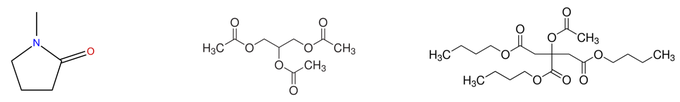
German Buttress Thread 33° 3°

Use of biocompatible plasticiser to lower the T_g of polylactate so that SMP reversion occurs under physiological conditions



Polylactate

Plasticisers



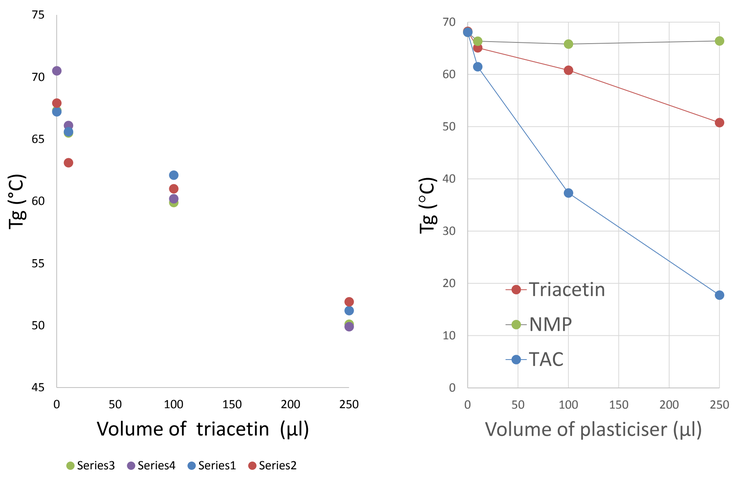
N-Methyl-2-Pyrrolidone

Triacetin

Tributyl *O*-acetylcitrate (TAC)

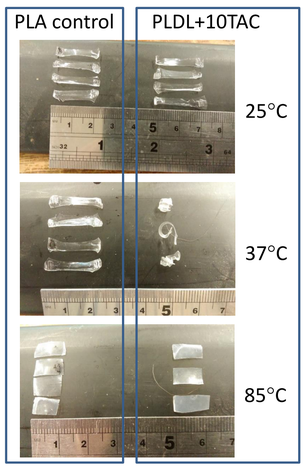
Safety/ regulatory: Triacetin and Tributyl *O*-acetylcitrate are not hazardous according to Regulation (EC) No. 1272/2008 or classified as dangerous according to Directive 67/548/EEC.

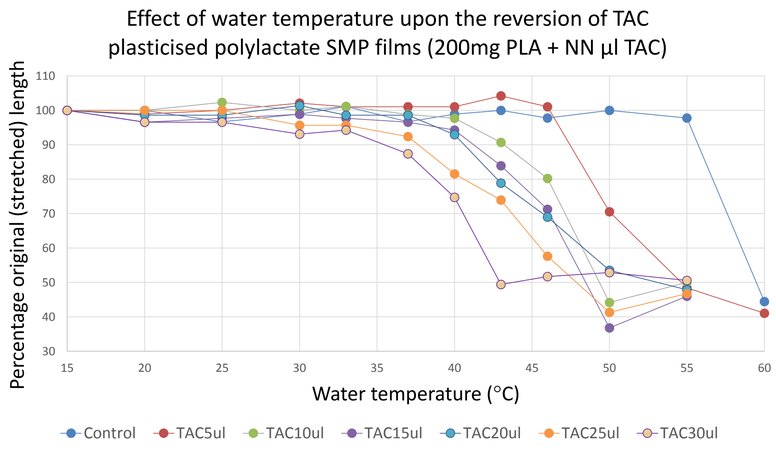
Effect of plasticisers on Tg of polylactic acid (200mg)



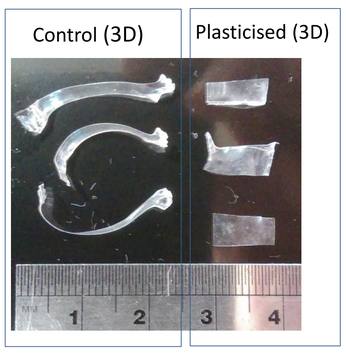
Effect of Tributyl *O*-acetylcitrate (TAC) on reversion temperature of polylactate SMP

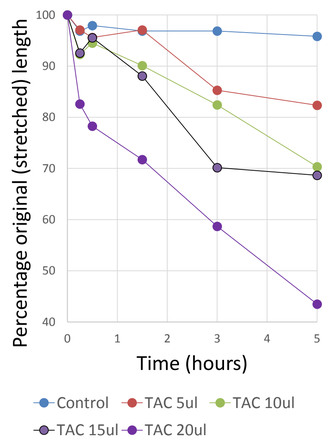
Reversion of plasticised polylactate SMP following 10 second immersion in water at 0-60°C

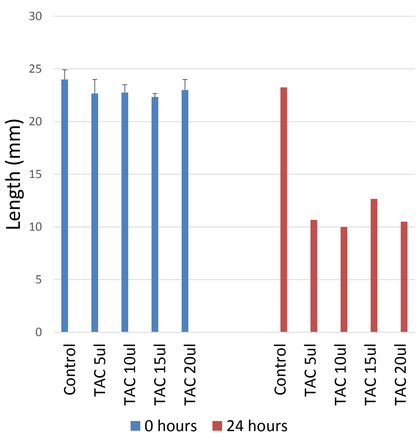




Reversion of plasticised polylactate SMP films (200mg PLA + NN µl TAC) at 37°C in saline







Conclusions

- Results showed that two reportedly biocompatible plasticisers, Triacetin and Tributyl *O*-acetylcitrate could reduce PLA's T_g in a dose dependant manner
- Shape memory polymers formed from Tributyl *O*-acetylcitrate plasticised PLA reverted under physiological conditions (37°C in saline).
- **Such materials could potentially be used to form compression screws that shrink in length post-implantation and pull bone fragments together.**