In Vitro Evaluation of a Range of Bioabsorbable Composite Interference Screws designed for Anterior Cruciate Ligament Reconstruction

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Introduction: Bioabsorbable polymers have gained popularity in anterior cruciate ligament (ACL) reconstruction to overcome the limitations with metal devices. Polymers also have limitations. Like metal they do not 'integrate' with the adjacent bone and can elicit a foreign-body reaction that manifests as fibrous encapsulation. Acid release during polymer degradation, particularly for the more rapidly resorbing polymers such as PGA, will lower the pH and may exceed the local tissue tolerance and clearing capacity of the bone, resulting in 'acidosis' effects. Also, a number of long-term studies show that replacement by bone does not occur with polymer screws (1-3).

A new generation of composite interference screws are becoming available with osteoconductive calcium salts added to the polymer component. It is claimed this improves the hard-tissue response and leads to eventual bony replacement of the device. It is also claimed that the calcium salts provide a pH buffer for the acid released during polymer degradation(4).

Very limited data is available relating to different composite screws and in particular their ability to achieve their primary function of providing rigid graft fixation without complication throughout the healing period. The aim of this study was to compare the behaviour of a number of composite screws in an invitro environment, designed to approximate human invivo conditions, during the biological healing period.

Materials and Methods: Four commercially available composite interference screws were tested. Similar sizes were used to enable a more meaningful comparison. Table 1

Screw	Supplier	Polymer	Filler	% Fill
Bilok 7 x 20mm	Arthrocare	PLLA	beta TCP	25
Biosteon 7 x 23mm	Stryker	PLLA	HA	25
Calaxo 7 x 20mm	Smith&Nephew	PLDLLA/PGA	CC	35
Milagro 8 x 23mm	Depuy Mitek	PLLA/PGA	beta TCP	30

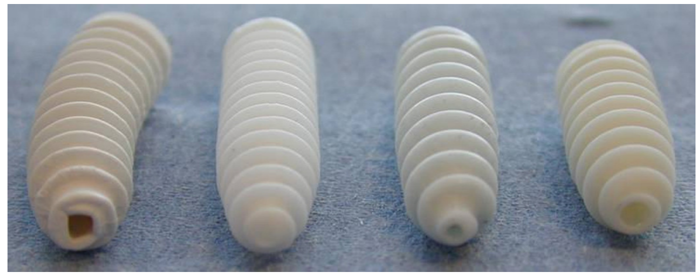
Poly-L lactic acid – PLLA
Poly-L/DL lactic acid – PLDLLA
Poly glycolic acid – PGA
Tri-calcium phosphate (TCP)
Hydroxyapatite (HA)
Calcium carbonate (CC)

Screw ageing was undertaken by submersing each screw in 200ml of phosphate buffered saline (PBS) solution at a pH of 7.36 and a temperature of 37oC for up to 12 weeks. The dimensions of each screw, length and diameter, were taken using a digital micrometer to the nearest 0.01mm. Screw weights were measured on a 3 decimal figure laboratory balance to the nearest 0.001gm following removal of surface water on a paper towel. The pH of the PBS solution was measured using a standard laboratory pH meter and gel-filled electrode. All measurements, apart from molecular weight, were taken at weekly intervals up to and including 12 weeks. The molecular weight was determined at 0 and 12 weeks. Molecular weight was determined by Gel permeation chromatography (GPC) in chloroform solution using a polystyrene calibration standard and refractive index detector.

Results: The mean dimensions, wet weight, molecular weight (Mw) and pH of the buffer solution at 0, 6 and 12 weeks ageing are shown below.Table 2

Screw	Weeks	Diameter mm	Length mm	Wet Weight gm	pH of solution	Molecular Weight Mw
Bilok	0 6 12	7.17 7.29 7.22	20.08 20.08 20.12	0.651 0.659 0.666	7.36 7.29 7.28	84127 46486
Biosteon	0 6 12	6.91 6.90 6.90	22.66 22.58 22.59	0.560 0.563 0.566	7.36 7.34 7.32	86440 66675
Milagro	0 6 12	8.04 8.27 8.38	23.19 23.03 23.22	0.967 1.010 1.038	7.36 7.34 7.34	114286 37775
Calaxo	0 6 12	7.38 8.93 11.82	20.03 23.46 29.21	0.666 1.146 2.167	7.36 7.13 6.86	93952 15500

Following 6 weeks of ageing, an image was taken of the 4 screw types to illustrate the observed morphological changes.



6 weeks invitro. From left to right: Calaxo, Bilok, Biosteon and Milagro

It was noted that following the 12 weeks of ageing and then drying, the Calaxo screw was mechanically weak and easily crushed between thumb and forefinger.

Discussion: The dimensional changes for the Bilok, Biosteon and the Milagro screw were small, non isotropic and are probably indicative of polymer chain orientation effects due to flow patterns in the moulded components. The Calaxo screw, however, showed a diameter increase of 4.4mm and a length increase of 9.18mm. Any substantial increase in length of an interference screw could be of particular relevance with regards to the placement of the screw relative to the joint space. The curvature to the Calaxo screw was clearly noted after just 1 week in the PBS solution (see image 1). The interference fit of the screw to the tunnel/graft should help to minimise the potential to distort clinically.

The overall weight gain, which is due essentially to moisture up-take, amounted to 2.3%, 1.1%, 7.3% and 225% for Bilok, Biosteon, Milagro and Calaxo respectively. The Calaxo screw wet weight, which increased significantly from 0.666 to 2.167 grams over the 12 weeks, correlates with the observed increase in size of the screw and may be attributed to the more hydrophilic nature of the composite.

Bilok had a 44.7% decrease in Mw over the 12-week period, Biosteon 22.9%, Milagro 66.9%, and Calaxo 83.5%. As molecular weight falls to below 60% of its initial value, significant strength loss begins to take place(5).

The pH of the PBS solution did, to varying degrees reduce during the test period. For the Bilok, Biosteon and Milagro screws the pH drop was small, less than 0.1 units over 12 weeks, and the final pH of the PBS solution was still within the physiologic range 7.2 – 7.4. For the Calaxo screw, however, the pH of the PBS solution fell below 7.2 at 4 weeks and reached an acidic 6.86 at 12 weeks. Quite clearly the acid released during degradation overwhelmed the buffering effect of both the CC within the Calaxo screw and the PBS solution. These large and rapid changes seen in the Calaxo screw may have significant clinical consequences.

The risks to the patient of using rapidly resorbing polymers such as PGA in specific indications may outweigh the claimed benefits.

References: .

1. Warden WH, Chooljian D, Jackson DW. Ten-year Magnetic Resonance Imaging Follow-up of Bioabsorbable Poly-L-Lactic Acid Interference Screws After Anterior Cruciate Ligament Reconstruction. Corrected Proof. Arthroscopy. 25 April 2007. DOI: 10.1016/j.arth.2006.12.032

2. Barber FA, Dockery WD. Long-term absorption of Poly L lactic acid interference screws. Arthroscopy. 2006 Aug;22(8): pp 820-6.

3. Radford MJ, Noakes J, Read J, Wood DG. The natural history of a bioabsorbable interference screw used for anterior cruciate ligament reconstruction with a 4-strand hamstring technique. Arthroscopy. 2005 Jun;21(6):707-10.

4. Agrawal CM, Athanasiou KA. Technique to control pH in vicinity of biodegrading PLA-PGA implants. J Biomed Mater Res. 1997 Summer;38(2):105-114.

5. Middleton JC, Tipton AJ: Synthetic biodegradable polymers as orthopedic devices. Biomaterials 2000; 21: pp 2335–2346.