Arthrex 7 mm x 23 mm BioComposite Interference Screw vs. DePuy Mitek 7 mm x 23 mm Milagro Screw

Arthrex Research and Development

Objective

A twelve week *in vitro* degradation study was performed comparing rope pull-out, polymer degradation, mass loss, changes in pH, and gross morphological observations of the Arthrex 7 mm x 23 mm BioComposite Interference Screw (70% PLDLA, 30% biphasic calcium phosphate) and the DePuy Mitek 7 mm x 23 mm Milagro Interference Screw (70% PLGA, 30% β-Tricalcium Phosphate).

Methods and Materials

Accelerated Study

Each BioComposite Interference (n=2) and Milagro (n=2) screw was weighed, placed into a sealed glass container, and filled with 75mL of phosphate buffered normal saline, pH 7.4. All of the containers were placed into an incubator set to 47°C. Based on the empirical observation that increasing the temperature by 10°C roughly doubles the rate of many polymer reactions, the accelerated time point equates to roughly double the real-time time point.[1] Saline pH was measured weekly, recorded, and replaced when outside the physiological range (pH 7.4 ± 0.2, ASTM F 1635-95). After soaking in saline for the proper time interval, the screws were removed from the incubator, rinsed with deionized water, dried in a lyophilizer for 48 hours, and weighed to account for mass loss.

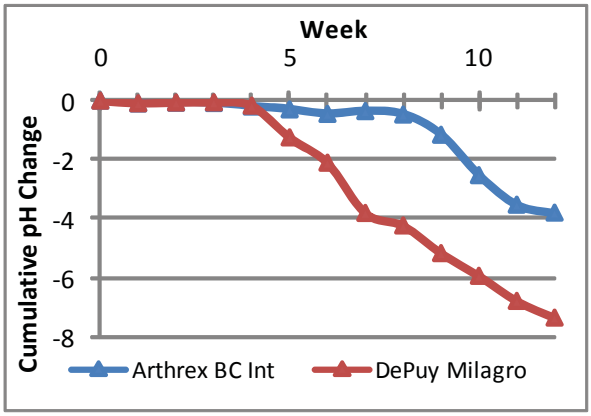
Real Time Study

Each BioComposite Interference (n=6) and Milagro (n=6) Screw was inserted with an appropriate driver into an 8 mm pilot hole in 20 lb/ft^3 polyurethane foam block with 6.4 mm nylon rope to simulate a tendon. The foam block assemblies were placed into sealed glass containers and filled with 75mL of phosphate buffered normal saline, pH 7.4. All of the containers were placed into an incubator set to 37°C. Saline pH was measured weekly and replaced when outside physiological range. After soaking in saline for the proper time interval, the foam block assemblies were rinsed with deionized water, dried in a lyophilizer for 48 hours, and tested for ultimate rope pull-out strength on an Instron 5544 electromechanical materials testing system by pulling on the nylon rope. Polymer analysis consisted of prepping the center portions of the BioComposite Interference and Milagro Screws at a 1:1 ratio in chloroform and analyzed on a ViscoSystem AVS 370 for inherent viscosity (IV). IV is indicative of polymer chain length; decreases in IV suggest polymer degradation.

Results

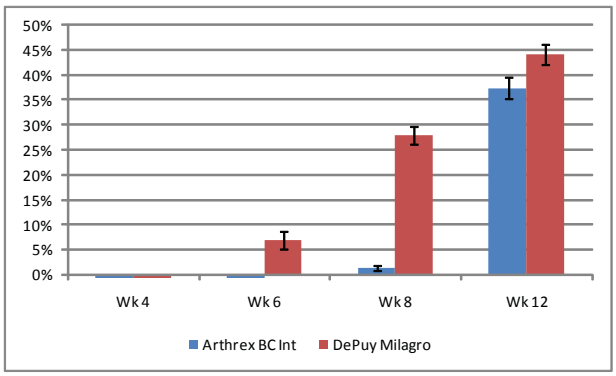
Changes in pH: Figure 1 depicts the cumulative change in pH of the BioComposite Interference and Milagro Screws through 12 weeks of accelerated degradation. The rate of acidosis of the Milagro was higher than the BioComposite Interference at weeks 5, 6, 7, and 8; equivalent at weeks 10-16 ($p<0.05$ for all groups). Through 12 weeks, the saline solution containing the Milagro Screw became nearly twice as acidic as that of the BioComposite Interference Screw.

Figure 1: Cumulative Change in pH of the BioComposite Interference and Milagro Screws



Mass Loss: Figure 2 illustrates the mass loss of the BioComposite Interference and Milagro Screws through 12 weeks of accelerated degradation.

Figure 2: Mass Loss of the BioComposite Interference and Milagro Screws



Gross Morphological Observations: Table 1 depicts the BioComposite Interference and Milagro Screws through 12 weeks of accelerated degradation. Representative screws at dynamic time points for both groups are shown. By week 8, one Milagro screw had cracked. By week 12, both Milagro screws had cracked. Through 12 weeks of accelerated degradation, the BioComposite Interference screws remained intact.

Table 1: Gross Morphological Observations of the BioComposite Interference and Milagro Screws

	BioComposite Interference	Milagro
Wk 0		
Wk 8		 
Wk 12		 

Rope Pull-out: Through 12 weeks of real-time degradation, there was not a significant change in rope pull-out strength of the BioComposite Interference or Milagro Screws when compared to time zero ($p = 0.714$ and $p = 0.838$, respectively).

Polymer Analysis: Table 2 depicts the inherent viscosity of the BioComposite Interference and Milagro Screws through 12 weeks of real-time degradation. The 10% decrease in IV of the BioComposite Inteference Screw is significant ($p = 0.036$). The 53% decrease in IV of the Milagro is significant ($p < 0.001$).

Table 2: Polymer Analysis of the BioComposite Interference and Milagro Screws

Inherent Viscosity (dl/g)	BioComposite Interference Screw	Milagro Screw
Wk 0	2.16 ± 0.07	1.34 ± 0.02
Wk 12	1.95 ± 0.15	0.63 ± 0.12
% Decrease	*10%*	*53%*

Conclusion

Composite screws should be optimized for mechanical strength and material behavior while being benign. Polymer degradation that occurs too quickly may decrease the local pH at the surgical repair site, thereby increasing the activity of osteoclasts to resorb tissue and screw material, weakening the interface, and inducing inflammation.[2,3] Healing at the surgical site begins quite rapidly: After surgery, weeks 8 through 12 are associated with key healing pathways in the development of soft tissue, including the maturation of collagen and improved cellular organization.[4,5,6]

The rate of polymer degradation associated with the Milagro screw accounts for the high level of acidosis observed in the accelerated study. A significant portion of the Milagro's acidosis occurs during the equivalent of weeks 8 through 12 real-time, and may delay healing as well as inducing inflammation at the surgical site. The BioComposite Interference Screw begins acidosis during the equivalent of weeks 16 through 20 real-time, after a significant portion of tissue regeneration has occurred. It has been shown that the composite material used in the BioComposite Interference Screw acts as a pH buffer, reducing the concern that any adverse reaction, associated with local acidosis, may occur.[7]

References

1. Hemmerich, Karl J., General Aging Theory and Simplified Protocol for Accelerated Aging of Medical Devices, *Med. Plastics and Biomaterials,* July 1998.
2. Komarova et al, *Proc Natl Acad Sci USA*, 102:2643-2648, 2005.
3. Hunt et al, *Knee Surg Sports Traumatol Arthrosc,* 6:655-660, 2008.
4. Bos et al, *Biomaterials*, 1:32-36, 1991.
5. Gutwald et al, *J Mater Sci Mater Med,* 5: 481-490, 1994.
6. Pierre et al, *J Shoulder Elbow Surg,* 5:58, 1996.
7. Agrawal et al, *J Biomed Mater Res,* 38:105-114.