A New Approach: The Rise of Bioabsorbable Implants in Veterinary Orthopedic Surgery

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The Background:

Medical devices have been implanted in both humans and animals to successfully treat a vast array orthopedic conditions for almost a century. A similarity shared by a wide variety of implants is that their function to support bone healing is usually temporary; they are superfluous once a patient’s tissues have fully healed. Elective removal of implants is often recommended in humans once the device’s role in healing is complete (e.g. a fracture has healed). The rationale is to prevent the rare, but potentially significant complications associated with the long-term presence of an implant in the body. By contrast in veterinary medicine, the majority of implants are expected to remain in the body indefinitely in part because of the added expense/ morbidity removal entails but
also because animals have shorter life spans. Removal is usually limited to cases where the implant is associated with complications such as infection, local tissue irritation/pain, and implant loosening. An ideal implant would “go away” once it is no longer needed by the patient rather than require surgical removal or cause complications by its persistent presence.

After decades of research and clinical testing, bioabsorbable implants are now commonly used in a number of human orthopedic procedures. Applications continue to expand rapidly in the areas of craniomaxillofacial, spinal, and orthopedic surgery. Novel uses for bioabsorbable implants are also evolving including the additions of bone morphogenetic proteins and bone graph extenders to speed bone healing. Despite these advancements and research, nearly all veterinary orthopedic implants are still manufactured using stainless steel, titanium or titanium-based alloys. Only recently have bioabsorbable implants garnered consideration for use in veterinary patients and surgical techniques.

The Function
The bioabsorbable implants being introduced in the veterinary industry today are currently being used in tibial tuberosity advancement (TTA) procedures. This well-established surgical procedure treats cranial cruciate ligament (CrCL) deficient stifle joints by advancing the tibial tuberosity until the attached patellar ligament is perpendicular to the top of the tibia (tibia plateau). This neutralizes the unrestricted tibio-femoral shear force generated during load bearing in knees with CrCL tears. One of the implants used to stabilize the tibial tuberosity is a “cage” like device that previously has been manufactured using stainless steel or titanium. Bioabsorbable cages offer a number of unique advantages over previous implants.

The Chemistry
Polymers are macromolecular structures that contain large numbers of long chain molecules. If polymer chains are effectively arranged side by side with regularity and symmetry, the polymer will have a crystalline or semi-crystalline structure. Solid polymers, such as this, will form as opaque, and this configuration is the primary make up of the TTA cages currently being introduced into the veterinary field.

The composition of the single atoms and groups within the structure, and the manner in which they are arranged within these molecular and crystalline structures, control most of the properties of the resulting material. For example, amorphous polymers and highly cross-linked polymers are usually brittle because their molecular form cannot be easily re-arranged when mechanical forces are applied, and they break rather than deform. Highly crystalline polymers usually have high strength and elasticity.\(^1\) Crystallinity varies with temperature as well and behaviors of the polymers will vary based on temperature and the polymers will often look and behave like a standard plastic at room temperature, such is the case with the TTA cages being introduced into veterinary orthopedic market. The term ‘resorbable’ or ‘bioresorbable polymer’ can be

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\(^1\) The Biocompatibility, Biological Safety and Clinical Applications of PURASORB® Resorbable Polymers, Professor David Williams, Ph.D., D.Sc., FREng.
A New Approach (continued)

defined as a polymer, which is capable of removal, by cellular activity and/or dissolution in a biological system.\textsuperscript{2} Polymers, by their very nature, are prone to degradation from various environmental factors, such as heat, light, and certain chemical environments. As medical implants are in constant contact with body fluids, and largely devoid of light or heat fluctuations, the degradation is almost completely dependent on the interaction between the fluids and the molecules of the polymer. This is a form of hydrolysis and this is what will facilitate the absorption of surgically implanted devices.

Biocomposites are formed when a polymer is reinforced with a biologic substrate. The biocomposites currently used to produce the TTA cages being introduced into the veterinary market are comprised of 30% biphasic calcium phosphate (biologic substrate) and 70% PLDLA, or Poly-L/D-lactide (polymer). The biphasic calcium phosphate provides well-documented osteoconductive properties, controlled solubility and the release of calcium ions to support balanced osteogenesis; all of which promotes a strong interface with bone. The PLDLA is a polymer that absorbs predictably over time (see graph below), shows no crystalline degradation buildup at the site of the implant, and has a proven track record as a bioabsorbable polymer.

The Breakdown

The graph below depicts a typical trend curve for molecular weight vs. time and mass loss vs. time for a semi-crystalline polymer. Also overlaid in the graph is the projected support curve over time. Up until a critical point, the observed mass loss is relatively low, but increases as the material becomes more friable.

Poly(lactides) exhibit bulk degradation via hydrolysis of the ester group. The rate at which the product degrades is governed by the level of crystallinity in the structure. Because the biocomposite formulation used in the TTA cages is amorphous and lacks an ordered crystalline structure, a faster more uniform degradation profile would be expected. Preliminary studies project a 12-15% reduction in molecular weight (determined through inherent viscosity) between 0 and 6 weeks, a 31-32% reduction after 12 weeks, and an 88- 92% reduction after 48 weeks.

The Rationale

In 2003, 1.3 billion dollars was spent to surgically treat canine CrCL disease in the United States alone and by all estimates this amount has only increased over the past 10 years. Although there are numerous methods of surgical repair, TTA has proven to be an effective and popular surgical option. To date, TTA infections rates are reported to be between 2.6-8.7\%. When short or late-term infections occur it is often necessary to remove all implants for definitive resolution. Bacteria form a protective glycocalyx layer (polysaccharide fibers) on metallic implants which makes them highly resistant to antibiotics and the patient’s immune response. Essentially, implants act as a “protective oasis” for bacteria to persist within the body, making resolution of infection difficult or impossible. By contrast, the surface of the bioabsorbable implant is constantly changing, so it is difficult for bacteria to persist on its surface. Additionally patient cell can infiltrate the biocomposite directly potentially allowing for an enhanced immune response to any bacteria present.

\textsuperscript{2} The Biocompatibility, Biological Safety and Clinical Applications of PURASORB® Resorbable Polymers, Professor David Williams, Ph.D., D.Sc., FREng.
Lastly, the challenges and morbidity associated with metallic TTA cage removal are eliminated since the biocomposite cage is not permanent also eliminating the possibility of late-stage postoperative cage infection.

The Outcomes
To date, bioabsorbable TTA cages have been used in over 30 dogs as part of an ongoing clinical evaluation. Initial findings and 6 month evaluations have been positive. No differences are apparent relative to radiographically observed mechanical stability between the biocomposites and metal cages and osteotomy healing has been very good. Six month postoperative radiographs demonstrate progressive osteointegration. Additionally, the new cages seamlessly integrate into the previously described TTA surgical technique so there has been no need to alter anything in order to implant the device.

The Future
Bioabsorbable polymer implants will continue to make inroads into many orthopedic applications. Surgeons who have been long familiar with the properties and handling characteristics of metal implants, may find it advantageous to familiarize themselves with the unique characteristics and advantages of these new types of biomaterials. Like with any implant, better understanding the science behind them will allow for the best decisions regarding their usage and implantation.

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A New Approach (continued)

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