ARAN BIOMEDICAL

Bio-XT is a proprietary biomaterials processing technology that optimises the material microstructure to deliver high strength reinforcement of resorbable polymer implants. This paper evaluates its performance and the potential it offers for new product design.

Bio-XT: Maximising the Material Performance of Resorbable Implants

White Paper

Bio-XT: Maximising the Material Performance of Resorbable Implants

SUMMARY: Aran Biomedical Bio-XT processing technology enables the development of considerably higher strength resorbable implantable orthopaedic products, using the same resorbable material grades as those used in current products. Increases in strength and toughness are here quantified, using reliable test methods, to demonstrate the value of Bio-XT processing technology to developers of next generation orthopaedic products.

Comparative mechanical testing was performed, using market leading predicate product as control samples, on a biocomposite threaded suture anchor screw. Clinically relevant mechanical specifications were evaluated, with particular focus on torsional strength. *Torsional strength of the Bio-XT biocomposite suture anchor screw showed an increase of 102%, when compared to a predicate product of identical geometry and material grade* (85% PLLA, 15% β-TCP).

Aran Bio-XT processing technology offers an excellent platform upon which to develop next generation resorbable orthopaedic products. Strength and toughness increases achievable using Bio-XT can facilitate the following disruptive innovations to orthopaedic implants design:

1. Introduction of stronger resorbable products, for load-bearing indications, for which only non-resorbable products are currently considered suitable.
2. Introduction of highly porous products, facilitating osteo-conductivity for higher quality tissue regeneration, without compromising product strength.
3. Introduction of lower profile products compared to currently available resorbable products, using less material, without compromising product strength.

Introduction

This paper presents the effectiveness of Aran Bio-XT, a biomaterial processing technology which significantly reinforces resorbable implants. The technology is tested and evaluated against current devices on the market, thus showcasing the potential for resorbable polymer based new product development in orthopaedics.

The use of resorbable orthopaedic implants can present well-understood clinical benefits compared to use of their non-resorbable counterparts – facilitating tissue regeneration at the surgical site, allowing gradual load transfer onto regenerating osseous tissue, and eliminating the possible need for reoperation to remove a non-resorbable implant[1]. However, the relatively low inherent strength of resorbable polymers presents a roadblock to new product design and limits their adoption in new indications. Bio-XT is a proprietary biomaterials processing technology[2] which delivers high strength reinforcement of resorbable polymer implants. The proprietary processing technology is based on the optimisation of the material microstructure, in which the material is physically orientated and reinforced but chemically unchanged. Resulting performance gains are enabled through maximisation of the inherent material mechanical properties, which are compromised during standard processing such as injection moulding and extrusion.

Bio-XT can be applied to any resorbable polymer or biocomposite blend, enabling its use for improvements of existing product families which leverage material grades that are well understood by the clinical and regulatory community.

Materials and Methods

Comparative torsional strength, identified as a key measurement of clinical relevance, was measured between Aran Bio-XT suture anchors and a market leading predicate of equal material grade and geometry. A market leading suture anchor screw (85% PLLA/ 15% β-TCP; dimensions 5.5 mm ϕ x 15 mm length) was used as a control. The Bio-XT screw was produced using the same material grade as the predicate, and to an identical gross geometry, with two different levels of porosity: one was equal to that of the predicate device, while the other contained a higher porosity to the predicate (Figure 1).

Figure 1: Aran Bio-XT Suture Anchor Screws, Modelled on Market-leading Predicate Product. Circular Porous Design is Replicate of Biocomposite Predicate Product, while Elliptical Porous Design is Replicate of PEEK Predicate Product.

Torsional strength was measured by inserting the screws into a synthetic solid bone block composed of high-density polyurethane foam, equivalent to cortical bone. Screws were inserted into a pre-drilled and tapped hole, using a drive mechanism which served to ensure consistent orthogonal alignment upon insertion, with inbuilt torque measurement capability. Failure torque and mode of failure were recorded for each screw.

Results

Torsional strength of the Bio-XT biocomposite suture anchor screw showed an *increase* of 102% (27.2 lbF.in vs. 13.4 lbF.in), when compared to a predicate product of identical geometry and material grade (85% PLLA, 15% β-TCP). Bio-XT screws demonstrated a torsional shear failure mode, consistent with predicate devices.

Specimen	Description	Torsional Strength (lbF.in)					
		Average	Std Dev	n=1	n=2	n=3	% Increase
1	Market-leading Predicate Biocomposite (Circular Pores: 7 x Ø1.02mm)	**13.4**	**0.8**	13.5	14.2	12.6	-
2	Aran Bio-XT Biocomposite (Circular Pores: 7 x Ø1.02mm)	**27.2**	**0.98**	26.6	28.3	26.6	**102%**
3	Aran Bio-XT Biocomposite (Elliptical Pores: 14 x Ø(1.02 x 2.03) mm, equivalent to PEEK porous design)	**13.9**	**1.4**	12.5	15.3	13.9	**3%**

Table 1: Comparative Torsional Strength of Various Biocomposite Screws, of Identical Gross Geometry and Material Grade.

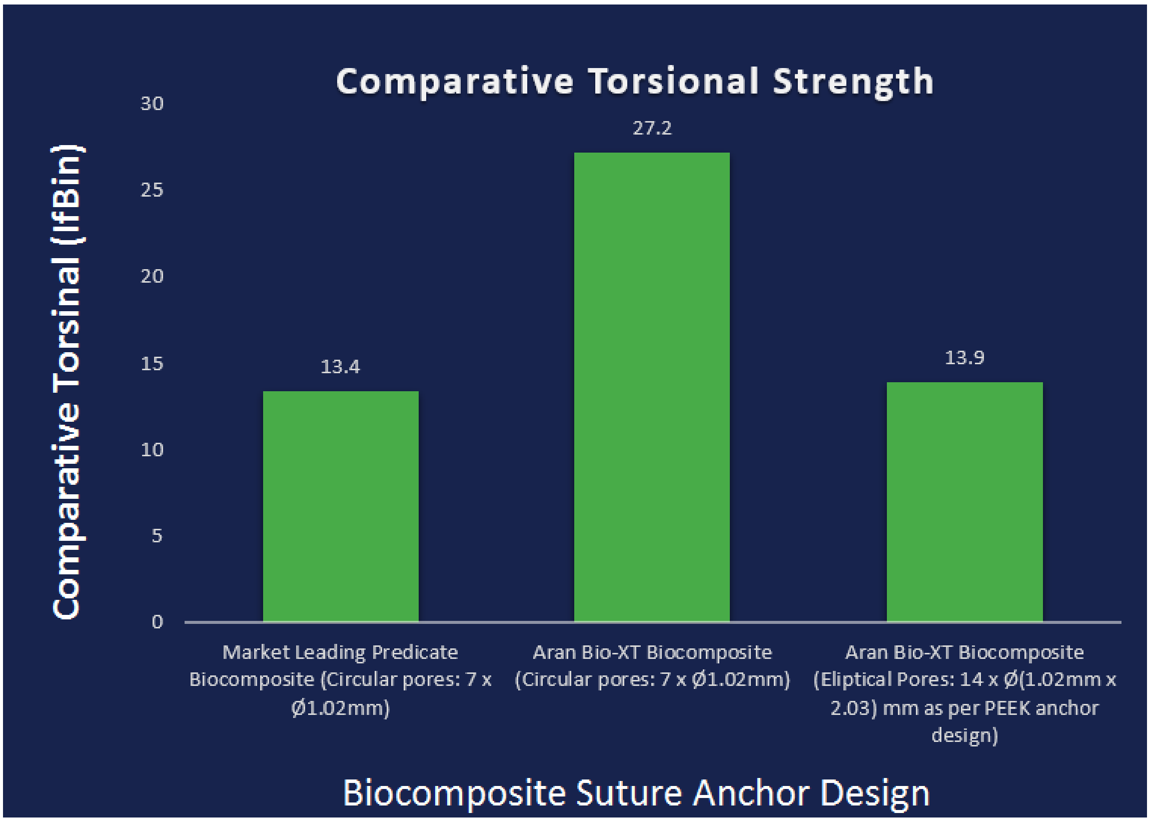

Figure 2: Comparative Torsional Strength of Biocomposite Screws: Aran Bio-XT Circular Pore & Elliptical Pore Designs vs. Market-leading Circular Pore Predicate.

Discussion

The results conclusively indicate that resorbable implants manufactured using Bio-XT are significantly stronger than predicate devices, with a torsional strength increase of 102%. The benefit of this additional strength gain can be manifested in a range of design options, yielding higher performance resorbable implants.

In particular, the Aran Bio-XT processing technology platform enables three discrete performance enhancements: (i) *stronger*, (ii) *more porous* or (iii) *lower profile* products. Clinicians and developers of next generation orthopaedic products can recognise the limitations of current designs and the potential for improvements: the performance advantage of Bio-XT can be adopted into customised design solutions in a manner that best delivers functional performance and clinical outcome improvement.

Stronger resorbable products, with 102% higher strength, offer greater suitability in partially load-bearing indications such as spinal or extremities repair; and can offer a resorbable alternative to currently non-resorbable product solutions. Meanwhile, ***higher porosity*** resorbable products, with uncompromised strength, facilitate greater osteoconductivity through the introduction of appropriately-dimensioned porous channels. These provide an architecture which promotes the ingrowth and regeneration of higher-quality osseous tissue, understood to improve long-term clinical outcome[3-5]. Remarkably, a Aran Bio-XT biocomposite screw, containing large elliptical pores – currently feasible only in a PEEK predicate – still outperformed the considerably less porous predicate device with circular pores (Figure 2), in terms of torsional strength. Of course, alternative pore configurations may be considered, in which the porosity allowance can exhibit greatest osteoconductive performance. Finally, ***lower profile*** products, with uncompromised strength, offer the potential for less invasive surgical delivery, a smaller volume into which tissue needs to regenerate, less degradation by-product, and potentially larger internal diameters for related insertion driver instrumentation, thus preventing insertion driver stripping.

Aran Bio-XT processing technology is a compelling, material-grade-non-specific, strength reinforcing technology, providing a valuable solution to developers of next generation resorbable orthopaedic products.

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For enquiries, contact: info@aranbiomedical.com