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MEDIA RELEASE

Kangaroo tendon to disrupt orthopaedic ligament market: world first

Manufacturing new and uniquely Australian bone and ligament materials

The University of Sydney and three industry partners plan to disrupt the billion-dollar orthopaedic ligament-replacement market with new and uniquely Australian bone and ligament materials.

Funded with \$2.4 million cash invested by <u>Allegra Orthopaedics</u>, Bone Ligament Tendon (BLT) Pty Ltd and the <u>Innovative Manufacturing CRC Limited</u> (IMCRC), the medical and manufacturing project targets the need for better materials than current ligament graft and bone-fixation solutions.

Over the next three years, the project led by orthopaedic surgeon and head of BLT, Dr Nick Hartnell, will lab-test two pre-clinical projects in tandem, with the intent to create a global supply opportunity through Australian medical and manufacturing innovation.

In a world-first, researchers will test the efficacy of kangaroo tendons for eventual use in knee, ankle and shoulder ligament-replacement procedures. Early proof of concept testing has shown kangaroo tendon is six times stronger than human cruciate ligament.

The second element is to manufacture and test the viability of 3D-printed biodegradable screws made from a ceramic material (<u>Sr-HT-Gahnite</u>) to fix kangaroo tendon to bone in patient ligament-repair procedures.

Together, the ligament and bone-fixing projects will bring a unique Australian solution to a global ligament and tendon repair market estimated at \$10bn annually.

As an indication of the size and challenges inherent in this market, some 15,000 primary anterior cruciate ligament (ACL) <u>knee reconstructions</u> are done annually in Australia.

Kangaroo tendon brings bounce to ligament challenge

"Materials used in ligament reconstructions come from three sources: humans, pigs, and synthetic constructs, and each has drawbacks," says <u>Dr Elizabeth Clarke</u>, who leads the kangaroo tendon-testing project with <u>Professor Christopher Little</u>, both of the University of Sydney.

The kangaroo tendon being tested as a future graft material was developed by BLT headed by <u>Dr</u> <u>Nick Hartnell, an orthopaedic surgeon and Sydney Medical School graduate</u>. Its use in the project is covered by an Australian Provisional Patent owned by BLT.

"Kangaroo tendon has a similar composition to humans but is longer and has better mechanical properties, which makes it an exciting natural product that could be used in a range of surgical procedures," says Dr Hartnell.

Kangaroo tendons used in the project will be salvaged from kangaroo tails and Achilles tendons discarded as waste from the kangaroo meat industry and annual culling.

"Synthetic graft materials provide a reproducible option for ligament replacement procedures but have relatively poor performance due to material failures that result in debris being deposited inside a joint, which cause cartilage and synovial damage," Dr Hartnell adds.

imcrc.org ABN 24 607 527 499 As a result, synthetic graft material is being disregarded in Australia as a viable graft material.

Another human source of ligament replacement involve autografts—where a patient's own tissue is grafted from one body site, such as a hamstring or thigh, to another, such as the knee. This approach has risks and downsides, such as problems at the donor site and increased recovery time.

Ligament allografts from human-cadaver have limitations too: they fail to provide consistently high-quality implants, suffer from poor surgical performance, and have impaired mechanical properties due to sterilisation and preservation requirements.

Xenografts involve graft tissue donated from one species for use in another. In human ligament reconstructions, xenografts were introduced to address mechanical and biological concerns with synthetic materials, including safety, quality and availability problems.

Currently, the only non-human source of ligaments for use in ligament reconstructions come from pig tissue and these are used only for multi-ligament and revision cases, not primary surgeries. The short (3cm) length of pig tendon also restricts its use in human ligament reconstructions.

Sr-HT-Gahnite: super strong biocompatible material

Strontium-hardystonite-Gahnite (Sr-HT-Gahnite) is a world-first material developed by the University of Sydney licensed exclusively to Allegra Orthopaedics.

A highly porous and biocompatible calcium silicate, it has many advantages over existing synthetic bone materials, including strength, being antimicrobial, having the capacity to be reabsorbed into bone and the ability to be 3D printed.

"This project represents a global high-tech manufacturing opportunity for Allegra and Australia," says Allegra chief executive, Jenny Swain. "Developing Sr-HT-Gahnite as a fixation and bone screw material for this project expands the commercial applications of this unique material.

"We believe our collaboration with BLT, Sydney University and the IMCRC will see Australian companies achieve considerable recognition for our innovative capabilities.

Our Innovation Manager, Ameneh Sadeghpour will be working closely to ensure the successful development of the kangaroo xenograft and the Sr-HT-Gahnite screws.

"This project will expand Allegra's range of commercialised medical devices, adding new product lines to our sales and distribution division, in turn driving the company's global competitiveness and position, and revenue."

This element of the project will be led by <u>Professor Hala Zreiqat</u>, inventor of the Sr-HT Gahnite ceramic and Director of the Australian Council Research Centre for Innovative Bioengineering at the University of Sydney. Her expertise spans new engineered materials and 3D-printed platforms for regenerative medicine in orthopaedic, dental, and maxillofacial applications

Unique global opportunity

David Chuter, CEO and Managing Director at the IMCRC, sees Australia leading the way in developing and implementing new manufacturing models and technology in the medical space to create new market opportunities.

"Key to this project is the development of advanced manufacturing and supply chain solutions to enable successful production and upscaling, and to realise potentially significant commercial outcomes both locally and through export," he said.

"The delivery of the kangaroo xenograft with unique 3D printed screws as an off-the-shelf product would be a world-first breakthrough in the global orthopaedic medical device industry – developed and manufactured in Australia, using home grown materials and know-how."

Fast facts

ACL reconstructions in people aged 16 and above have tripled in the decade to 2013 according to Australian Medicare data.

In the United States, 200,000 ACL ruptures occur annually, with up to a quarter needing additional or revision surgery. In the 12 years from 1994 to 2006, the incidence of ACL reconstructions in the US climbed from 87,000 to 130,000.

Further, the professionalisation of sport and an ageing population are seeing more frequent ACL injuries, especially in the under-20 and over-40 age populations.

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