## INNOVATION IN BONE REPLACEMENT



SMALL SAMPLE

70µm

An innovative synthetic bone substitute 100 times stronger than those currently in clinical use, developed using Microscopy Australia's facilities, is being brought to global markets.

2mm

Image: Scanning electron micrograph of bone scaffold imaged at the University of Sydney



### BREAKTHROUGH IN BONE REPLACEMENT

#### CHALLENGE

There is no synthetic bone scaffold strong enough to grow large, loadbearing bones such as the spine and leg bones.

When large areas of bone are damaged, surgeons insert porous templates to guide the growth of regenerating bone tissue. Current bone scaffolds have a variety of issues:

- Patients' own bone from elsewhere in their body – only suitable when the damaged area is small.
- Donor bone associated with rejection and potential infection
- Synthetic bone not strong enough for load-bearing bones

Large bone defects and loss due to cancer or trauma can result in scar tissue that impairs the bones' ability to repair and regenerate even with a scaffold. To encourage growth a transplant of the patients own bone is used. This has several complications including risk of chronic pain and morbidity at the donor site.

#### RESEARCH

A 3D printable ceramic bone scaffold, with the strength and elasticity of healthy bone, has been developed by Prof. Hala Zreiqat's team at the University of Sydney. They incorporated trace elements that are important in bone formation into a biocompatible ceramic. This material was then tweaked mechanically and chemically to make it 100 times stronger than the bone substitutes in clinical use today. The scaffold slowly dissolves into the body as the bone regenerates.

Recently the researchers have also developed a new method that can turn patient skin cells into bone cells. These have the potential to be embedded into the bone scaffold to facilitate healing.

Scanning electron microscopy at Microscopy Australia's University of Sydney facility provided essential information by revealing the structure and biocompatibility of the materials. In-vivo X-ray microtomography at Microscopy Australia at the University of Adelaide enabled the evaluation of the scaffold's bone-healing potential in animal models.

## **2.2**m

The number of bone graft surgeries performed each year worldwide

# **\$5.8**bn

The projected market size for bone grafts & substitutes by 2026

#### **IMPACT**

New stronger bone scaffolds will meet the need for load-bearing bone substitutes.

The University of Sydney has granted an exclusive licence to Australia's largest manufacturer of orthopaedic devices, Allegra (previously ASDM), to bring the bone scaffold to market.

They are currently undertaking a preclinical large animal study to test the performance of this material in a spinal fusion device in sheep, whose spines are very similar to human spines. This trial will form the basis for FDA approval of the medical device. Success at the 6 month mark will lead to human clinical trials.

"This is an exciting project for ASDM and fits our strategy of developing a portfolio of products in orthopaedics. This material is a novel breakthrough technology with huge global potential." – Allegra CEO Tom Milicevic

