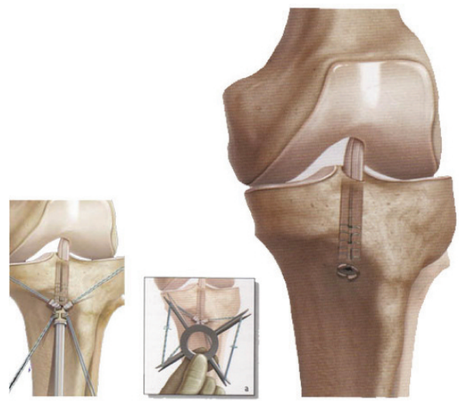
FINALIST IN THE COLLABORATIVE CATEGORY

TrusTECH (North West NHS Innovation Hub) for GraftBolt®: from sketch to product

Anterior Cruciate Ligament (ACL) injury affects 1 in 3500 people with about 200,000 injuries in the US per year. The NHS performs around 11,000 ACL reconstructions annually. ACL reconstruction has failure rates of 5–25% often resulting in further surgery and long term problems. GraftBolt® aims to improve a patient's quality of life by successfully repairing their anterior crucitate ligament injury first time.

Innovation

GraftBolt® allows the graft strands to be separated and tensioned in a controlled manner and provides significant compression of the graft in the bone tunnel, resulting in excellent graft fixation. As a result, GraftBolt® has a higher 'pullout strength' than the main competing product and therefore improves healthcare provision by increasing the reliability of the ACL reconstruction.



Collaboration

Mr Martyn Snow met Dr Bin Wang whilst studying for a Masters, and they devised a way of improving tibial fixation of the graft. TrusTECH and the UMIP (The University of Manchester's technology transfer company) organised a collaboration agreement, and funded the initial development work and testing by Dr Mahmoud Chizari. This work indicated that the device had greater pullout strength than the leading competitor. A UK patent application was filed, followed by a PCT application. Whilst in Canada Martyn was introduced to Arthrex Inc, a major US orthopaedic company. Arthrex's prototype tests were successful, and after they examined the patent applications, a licence was requested.

Knowledge transfer

TrusTECH organised for the University to assign its IP to the NHS Trust, and then drafted and negotiated the licence with Arthrex on behalf of the Trust. Finding a mutually agreeable position was a challenge and the negotiation took about six months. TrusTECH also engaged a US lawyer, in addition to UK solicitors, to ensure the final licence agreement represented a good outcome for the Trust. After signing the licence, Arthrex refined the design for manufacture, gained FDA approval and a CE mark, before placing the device on the market as GraftBolt® in 2010.

Patent protection in a number of territories is now being progressed.

The NHS Trust and the University receive licence fees and royalties on GraftBolt® sales (approx £50,000 to date). TrusTECH and UMIP receive a share of this income which they can use to further the development of new products and services.

Impact

Societal impact: improving quality of life, speeds healing and improves rehabilitation. Economic impact: using GraftBolt® should lead to fewer hospital readmissions for ACL reconstruction failure, which could lead to a cost saving to the NHS and other healthcare providers. An ACL revision operation in the NHS costs £3,000–£3,500 and sometimes two operations are required. Therefore the use of GraftBolt® could save up to £6,000 per ACL reconstruction prevented. Plus, the NHS Trust receives a discount on GraftBolt® purchases.

Key Points

- A model of multidisciplinary working involving clinicians, academics and technology transfer professionals
- Generated £50,000 income from licence fees and product sales to date
- Current treatment method has an associated failure rate of 5–25% – GraftBolt aims to reduce this rate
- Potential savings of up to £6,000 per reconstruction failure prevented

Primary team

Mr Martyn Snow, Orthopaedic Surgeon, University Hospital of South Manchester NHS Foundation Trust

Dr Bin Wang, Senior Lecturer in Applied Mechanics, University of Manchester

Dr Mahmoud Chizari, Research Assistant, University of Manchester

Dr Andrew Maines, Head of R&D, University Hospital of South Manchester NHS Foundation Trust

Dr Joanne Thomas, Senior Technology Manager, TrusTECH (NHS Innovation Hub for the North West)

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