CLINICAL EVALUATION STUDY





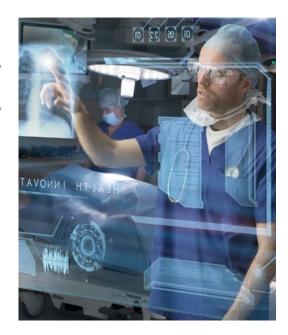
FeelTect is a medical device start-up based in Galway, Ireland. Their flagship technology, Tight Alright, was developed with a mission to improve the application of compression therapy, primarily for the millions of people worldwide with active Venous Leg Ulcers (VLUs). FeelTect aim to address this poorly addressed clinical need via Tight Alright's ability to accurately measure and continuously monitor sub-bandage pressure. In addition to ensuring safety and efficacy through the consistent provision of evidencebased therapy, other key benefits include the ability to monitor compliance and to empower patients to engage in their own therapy. Ultimately, Tight Alright will facilitate reduced VLU healing times by enabling users to consistently apply compression therapy correctly and confidently.

About Health Innovation Hub Ireland

Health Innovation Hub Ireland (HIHI) was established by the Department of Business, Enterprise and Innovation and the Department of Health, supported by Enterprise Ireland (EI) and the Health Service Executive (HSE) to drive collaboration between the health service and enterprise.

We offer companies the opportunity for pilot and clinical validation studies and the health service access to innovative products, services and devices that they may not otherwise be exposed to.

HIHI is built on the recognition that collaboration with enterprise can benefit patient care, patient pathways and outcomes.



The Healthcare Challenge

Compression therapy is the cornerstone of Venous Leg Ulcer (VLU) treatment, helping to overcome venous insufficiency, restoring circulation, and achieving successful healing. VLC is a long lasting (chronic) sore that takes between three to four months to heal if treated by a healthcare professional trained in compression therapy. However, some ulcers may take longer to heal, and some never heal. The global VLU treatment market is estimated to reach \$32 billion by 2026.

The current gold-standard treatment for VLUs is graduated compression therapy. If compression is too loose, the therapy is ineffectual, and if it is too tight, it is dangerous. Despite this, there is currently no accurate feedback on the level of pressure applied during routine compression therapy, making it difficult to determine if gold standard therapy is achieved. Furthermore, there is no means of monitoring this pressure over time, which can be affected by factors such as a reduction in swelling due to the compression therapy.



The Healthcare Solution

Tight Alright is a pressure sensing device that can be easily and securely attached to a compression bandage, where it measures and monitors sub-bandage pressure. The device wirelessly transmits pressure signals to a user-friendly app for viewing live readings or recorded data. In addition to the Tight Alright pressure-sensing device, FeelTect are developing a digital platform that can be used to monitor patients remotely, ensuring therapy is maintained. Using this information, healthcare professionals can address issues with compliance or make informed decisions on changes in compression regimens, while patients can become empowered to actively participate in their treatment at home. This ability for self-care can avoid unnecessary visits to wound clinics or visits from the clinical team unless necessary. In light of the growing aging population and the increase of chronic disease, FeelTect strive to reduce the burden on the acute healthcare system while empowering people to manage their own condition.



HIHI Role

HIHI facilitated a functional assessment of the Tight Alright device by a number of healthcare professionals with experience in wound management. This included practical bandage application and a feedback session about the use and design of the product. HIHI supported the development of protocols and ethics submissions, coordinated surveys and feedback, reviewed the study data and completed a final Project Report.



Outcome Report

FeelTect's Tight Alright device should be considered as a device capable of achieving the gold standard target pressure in bandage application. There are many potential benefits for a device like this on the market such as ensuring the correct pressure is reached when applying the bandage leading to patients receiving the recommended standard of care thus reducing the risk of prolonged treatment time. This in turn could reduce the visits to and from healthcare professionals based on a proper initial application and potential real time telemetry from the device. A reduction in recurring admittance to hospital would provide savings to the public healthcare sector. This will reduce the burden on the healthcare system while improving patient outcomes and experience, and allowing healthcare professionals to concentrate on other tasks.

Testimonial

The collaborative project with the HIHI in University Hospital Galway provided our first stages of clinical validation of the Tight Alright technology. HIHI were instrumental in instigating the engagement with participants (i.e. wound care nurses) and supporting the development of protocols and ethics submissions. The results from our project provided confirmation of the clinical need, evidence for Tight Alright as a solution, and valuable user feedback. Furthermore, the study also gave FeelTect invaluable exposure to potential investors, industry representatives, and healthcare professionals. Ultimately, this study has formed the foundation of our clinical validation plan, we are extremely grateful for the support provided by HIHI.

Dr Andrew Cameron, Founder and CEO

