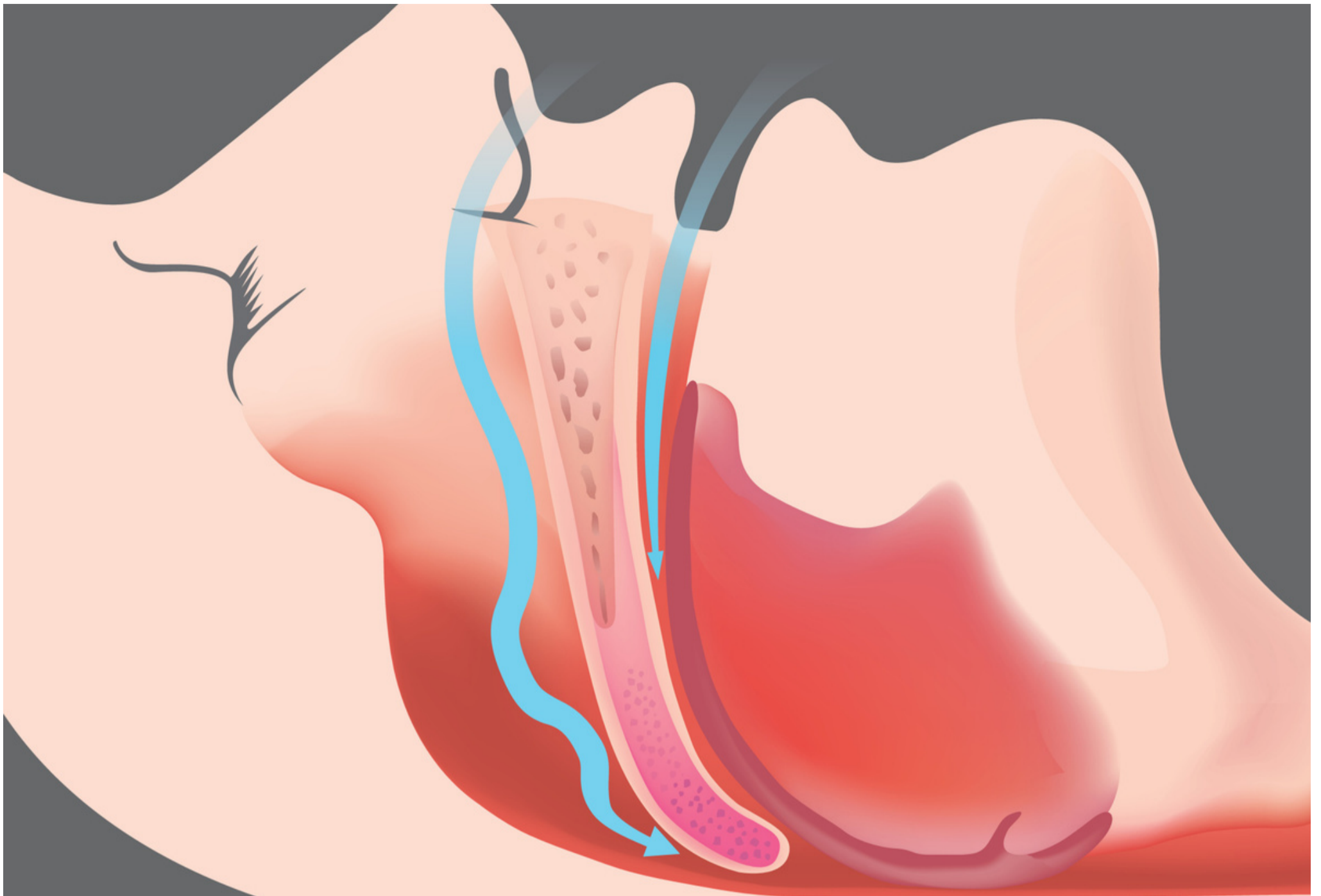


Device to Treat Sleep Apnoea

An implantable device that advances the sufferer's tongue to address obstructive sleep apnoea

Published: 8th March 2021



PATTARAWIT, stock.adobe.com

Background

Obstructive Sleep Apnoea (OSA) is a debilitating condition with significant morbidity and mortality characterized by blockage of the upper airway during sleep as a result of collapse of the soft tissues in the throat. OSA affects approximately 6-8.5% of the adult population in western countries.

Patients suffering from OSA have sleep fragmentation and deprivation, as they are unable to achieve adequate rapid eye movement sleep resulting in a non-refreshing sleep pattern. The major symptom of OSA is excessive daytime sleepiness (EDS) or daytime functional impairment. As a result, lack of concentration and memory, changes in mood and personality, and an increase in workplace and traffic accidents have been linked to EDS.

If OSA is untreated, the effects are obesity, cardiovascular (hypertension, cardiac arrhythmias and failure), cerebrovascular (depression and stroke), endocrine/metabolic (renal failure, diabetes and impotence) and premature death.

Technology Overview

The University of Cape Town's solution to treat OSA is a device that is implanted below the tongue with one end fixed to the chin bone and the other to the base of the tongue.

The device acts as a scaffold for the growth of a biological tendon from the patient's own stem cells. The bio-sorbable material is eventually replaced by a tendon, that is strong enough to hold the base of the patient's tongue in the advanced position.

The resulting gain in air flow in upper airway, provided by the new tendon would replace the need for positive pressure to be delivered to the patient's airway during sleep or other invasive surgical procedures such as splinting the tongue or reducing the length of the tongue with radiation and laser surgery.

The inventors have demonstrated:

- proof of principle that advancing the patient's tongue overcome sleep apnoea
- functionality of the device in a prototype
- growth of the biological ligament and bio-sorption of the device over time in animal trials. The trials were conducted in sheep and the biological tendons harvested and had a strength of 70N. The picture above depicts a cross-section of the biological tendon demonstrating the replacement of the delivery vehicle and the vascularization of the grown biological tendon

- the surgical implant procedure was proven to be simple and effective in the sheep trials

More data and pictures of the tendon and results can be shared with a follow-up.

Benefits

The benefits of the UCT sleep apnoea device are the following:

- the base of the apnoea sufferer's tongue is advanced sufficiently to open the airways and overcome the obstruction experienced during OSA
- removes the patient's dependence on air passage management technologies to assist the patient to breathe
- the patient's quality of life improves as the advanced airway facilitates the oxygenation of the bloodstream; preventing the co-morbidities associated with OSA
- the biological tendon is grown from the patient's own tissue and becomes a permanent feature within the patient's anatomy. The tensile strength of the sheep tendon was measured at 70N
- the materials are readily available and can be packaged as a kit that could be supplied to surgeons

Applications

The technology is intended as:

- Treatment for the permanent alleviation of severe OSA
- As a less invasive single surgical intervention for the treatment of OSA

OSA is treated by a variety of health professionals including Ear Nose and Throat specialists, Maxillo-facial surgeons and Pulmonologists.

The solution is envisioned as a kit with the active components pre-packaged and ready for implant into a patient.

Opportunity

The product development is complete and a preliminary surgical kit has been prepared and will be manufactured by manufacturing partner. The components of the device and the kit are generally available and do not comprise novel materials. A human clinical trial is the next step.

UCT and the inventor are seeking a mutually-beneficial partnership with a company willing to license the technology and with the following expertise and resources:

- understanding of the industry value chain to bring an implantable OSA treatment device to market
- experience in conducting similar human clinical trials
- a track record in obtaining requisite regulatory approval for similar devices
- access to capital for the clinical trial

UCT's inventor is an experienced maxillo-facial surgeon with his own private practice. He is willing to work with the company through the clinical trial.

Animal trials have been successfully completed and a publication of the results is available.

Patents

- [PCT/IB2017/053421](#)

IP Status

- Patent application submitted

Seeking

- Commercial partner
- Development partner
- Licensing
- Seeking investment