

Five years on, first ever tissue-engineered airway transplant remains successful

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New results published in *The Lancet* today [Wednesday 23 October] reveal that five years after the first successful transplantation of a tissue-engineered airway (reported in *The Lancet* in 2008 [1]) the recipient continues to enjoy a good quality of life, and has not experienced any immunological complications or rejection of the implanted airway.

The pioneering operation allowed a 30-year-old Colombian mother of two to receive a new section of tissue engineered trachea (windpipe), after part of her own trachea collapsed due to [complications](#) from tuberculosis. An international team of researchers, led by Professor Paolo Macchiarini from the Karolinska Institutet in Stockholm, Sweden (then at the Hospital Clínic of Barcelona in Spain), implanted a tissue engineered trachea, produced by removing the cells from a human donor trachea, which was then recellularised with cartilage cells (chondrocytes) derived from the patient's own stem cells, and epithelial cells taken from a healthy part of her trachea.

The recipient had no complications from the operation and was discharged from hospital on the 10th postoperative day. As reported in 2008, after 4 months, the graft had a normal appearance and properties, and the patient had no anti-donor antibodies and did not need to take immunosuppressive drugs. However, at the time of publication, researchers cautioned that longer follow-up of the patient would be needed to judge how successful the operation had been.

Now, Professor Macchiarini and colleagues present five year follow-up

data from the operation, reporting that the recipient continues to enjoy a good quality of life, including a normal social and working life.

Moreover, regular testing of lung function, immunological response to the transplant, and other key indicators reveal that the recipient has retained good [lung function](#) and has not experienced any immunological complications.

In addition to regular testing of the implanted trachea's function, the researchers also examined the internal structure of the transplant area using CT scans and bronchoscopy. Six months after surgery, scarring in the area of the graft became apparent, which gradually led to narrowing of part of the airway, resulting in a persistent and worsening cough. This was addressed by implantation of a stent (a scaffold which holds the airway open), and although some scarring remains—and is monitored by regular bronchoscopies—the patient no longer experiences any symptoms.

According to Professor Macchiarini, "These results confirm what we – and many [patients](#) – hoped at the time of the original operation: that tissue engineered transplants are safe and effective in the long term. However, the scarring which occurred in this patient shows that long-term biomechanical stability can be improved, something which is currently under active pre-clinical investigation. The results of a first-in-man active clinical trial will soon provide the definitive evidence that is needed before this stem cell based tissue engineering technology can be translated into routine clinical practice."*

In a linked Comment, Professor Alan Russell of the Disruptive Health Technology Institute, at Carnegie Mellon University and the Allegheny Health Network, in Pittsburgh, USA, writes that this is, "the end of the beginning for tissue engineering; the groundwork has been laid for clinical implementation in other specialties....Whole organ tissue engineering is akin to converting a Ford into a Ferrari while driving at

top speed. The approach is elegant but fraught with challenges and opportunities for improvement; few medical advances have needed a complete biological understanding before implementation.....[but the authors] present compelling evidence that the tracheal graft is now naturalised."

He adds, "Excitement about tracheal regenerative therapy might be muted by realisation that the patient in this study was not restored to full health. Although heroic in complying with the needs of a research study, the patient is suffering from ongoing complications from scarring at the proximal anastomotic site. There is nothing unusual about a tracheal stricture forming at a surgical site and, in fact, this patient had already had such a post-surgical stricture. Rather, the formation of a stricture shows that the remaining challenges for [tissue engineering](#) of thin hollow organs such as [trachea](#), oesophagus, intestine, blood vessels, and bladder relate to how neo-tissues are incorporated into existing structures."

More information: [1] [www.thelancet.com/journals/lan ... \(08\)61598-6/fulltext](http://www.thelancet.com/journals/lan/article/PIIS0140-6736(08)61598-6/fulltext)

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