

# Leading surgeons warn against media hype about tracheal regeneration

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Reports of the two earliest tissue-engineered whole organ transplants using a windpipe, or trachea, created using the patient's own stem cells, were hailed as a breakthrough for regenerative medicine and widely publicized in the press. However, two leading transplant surgeons in Belgium warn of the dangers of media attention, and urge that tracheal bioengineering be demonstrated as both effective and safe before further transplants take place. Their views are published in an Editorial in *The Journal of Thoracic and Cardiovascular Surgery*, an official publication of the American Association for Thoracic Surgery.

In 2008, surgeons repopulated a donor trachea with cells from a 30-year-old woman, which they then transplanted into the patient. In 2011, a 36-year-old man who had been suffering from late-stage tracheal cancer was given a new trachea made from a synthetic scaffold seeded with his own [stem cells](#). Both procedures were carried out by Professor Paolo Macchiarini and colleagues (Barcelona, 2008, and Sweden, 2011).

In 2012, an article in The New York Times, "A First: Organs Tailor-Made With Body's Own Cells," recognized tracheal regeneration as the first [regenerative medicine](#) procedure designed to implant "bioartificial" organs. The achievement was touted as the beginning of complex organ engineering for the heart, liver, and kidneys, and it was suggested that allotransplantation along with immunosuppression might become problems of the past.

"Major medical breakthroughs deserve the necessary press attention to

inform the medical community and public of the news," say Pierre R. Delaere, MD, PhD, and Dirk Van Raemdonck, MD, PhD, from the Department of Otolaryngology Head & Neck Surgery and the Department of Thoracic Surgery, University Hospital Leuven, Belgium. "Unfortunately, misrepresentation of medical information can occur and is particularly problematic when members of the professional and public press are misled to believe unrealistic medical breakthroughs."

The authors raise doubts regarding whether a synthetic tube can transform into a viable airway tube, pointing out that the mechanism behind the transformation from nonviable construct to viable airway cannot be explained with our current knowledge of tissue healing, tissue transplantation, and tissue regeneration. "Cells have never been observed to adhere, grow, and regenerate into complex tissues when applied to an avascular or synthetic scaffold and, moreover, this advanced form of tissue regeneration has never been observed in laboratory-based research," say the authors.

Delaere and Van Raemdonck reviewed the information gathered from published reports on three patients who received bioengineered tracheas and unpublished reports on an additional 11 patients. Although there were differences between the techniques used, production of the bioengineered trachea in all cases produced similar results, and the different approaches worked in comparable ways.

"The results show that mortality and morbidity were very high. Several patients died within a three-month period, and the patients who survived longer functioned with an airway stent that preserved the airway lumen," they observe.

They also question whether the [trachea](#) can really be considered to be the first bioengineered organ. From the 14 reports reviewed, they concluded that the bioengineered tracheal replacements were in fact airway

replacements that functioned only as scaffolds, behaving in a similar way to synthetic tracheal prostheses.

Publication of these papers in highly ranked medical journals is attributable to the media hype regarding "stem cells" and the work done on an airway that is less accessible for direct visualization, say Delaere and Van Raemdonck.

"In conclusion, the ethical justification of tracheal replacement with a synthetic prosthesis or with a decellularized allograft in humans is questionable, because there are no available experimental data describing a possible successful outcome," Delaere and Van Raemdonck remark. "The currently available published articles on bioengineered tracheas and the resulting media attention endanger the field of tracheal replacement and the field of tissue engineering as a whole. For patient safety, tracheal bioengineering must be demonstrated as being efficacious and safe before further transplants," they conclude.

**More information:** "The trachea: The first tissue-engineered organ?" by Pierre R. Delaere, MD, PhD, and Dirk Van Raemdonck, MD, PhD (DOI: [dx.doi.org/10.1016/j.jtcvs.2013.12.024](https://doi.org/10.1016/j.jtcvs.2013.12.024)). *The Journal of Thoracic and Cardiovascular Surgery*, Volume 147, Issue 4 (April 2014), published by Elsevier.

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