Revolutionary bioengineered trachea transplants under investigation

One of Europe's most prestigious medical universities, the Karolinska Institute in Stockholm, has launched two investigations into the clinical procedures of a doctor famed for performing potentially revolutionary, bioengineered tracheal transplants.

Since 2008, Paolo Macchiarini, a thoracic surgeon at the Karolinska Institute, has replaced parts of airways damaged by injury, cancer or other disorders in 17 patients. In the earlier cases, he transplanted parts of tracheas taken from cadavers; in his later work, he transplanted synthetic tracheas. In both procedures, before transplantation, he would treat the tracheas with stem cells taken from the patient's bone marrow, which he says helps the transplants to act like biological tissue.

Bioengineering experts contacted by *Nature* say that Macchiarini's procedures were considered a great leap for their nascent field because tracheas demand a high level of biological function — including the ability to defend against the constant assault of inhaled bacteria and to form a seal with the adjoining airway tissue.

Macchiarini's reports were a "bright spot" for the field, says David Mooney, a bioengineering specialist at Harvard University in Cambridge, Massachusetts.

One of the investigations is being conducted by an external expert in the relevant fields, who is due to report the findings on January 15. It focuses on the three procedures that Macchiarini carried out at the Karolinska Institute, all of which involve artificial tracheas.

The investigation comes in response to a report filed in August by four thoracic doctors at the affiliated Karolinska Hospital — Matthias Corbascio, Thomas Fux, Karl-Henrik Grinnemo and Oscar Simonson — who helped to treat the three patients.

The doctors compared results in a paper Macchiarini published in *The Lancet*, describing the first use of a synthetic trachea seeded with stem cells, with the medical records of the patient. According to the doctors, there are discrepancies.

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