

5-Year Follow-Up of World's First Regenerated Trachea Transplant

Harvard Bioscience

Harvard Bioscience, Inc. ([Nasdaq:HBIO](#) [1]) and Harvard Apparatus Regenerative Technology jointly announce that five years after a 30-year-old woman was implanted with the world's first tissue-engineered trachea grown in a bioreactor she lives complication-free, according to an article published October 23 in The Lancet.

According to the article, titled "The first tissue-engineered airway transplantation: 5-year follow-up results," the patient, Claudia Castillo, is living normally without any complications or rejection of the implanted airway. In 2008, after part of her own trachea collapsed due to complications from tuberculosis, Castillo underwent surgery led by Professor Paolo Macchiarini and his research team at the Hospital Clinic of Barcelona in Spain.

The replacement tissue-engineered trachea was produced by removing the cells from a human donor trachea, which was then placed inside the bioreactor, where it was recellularized with cartilage cells derived from Castillo's own stem cells and epithelial cells taken from a healthy part of her trachea. Castillo was discharged from the hospital on the 10th postoperative day, and after four months the graft had a normal appearance and properties. This world's first transplant of a regenerated trachea was published in The Lancet in December 2008.

In today's Lancet article, Professor Macchiarini and colleagues write that regular testing of lung function, immunological response to the transplant, and other key indicators reveal that Castillo has retained good lung function five years after the surgery and has not experienced any immunological complications.

In the article, Professor Macchiarini and colleagues conclude, "Our findings provide initial evidence that a tissue-engineering strategy, including decellularization of a human trachea, autologous epithelial and stem cell culture and differentiation, and cell-scaffold seeding using a bioreactor, are safe and promising."

David Green, President of Harvard Bioscience, and CEO of Harvard Apparatus Regenerative Technology (HART), said, "The positive results reported in The Lancet bolster our belief that tissue-engineered transplants, made possible in part by our bioreactor, are safe and effective in the long-term. Although further work must be done before this stem cell-based tissue engineering technology can be translated into routine clinical practice, we are greatly encouraged by these results. They bode well not only for implants involving decellularized human donor organs, but, because the cell-seeding and implant procedures are almost identical, also for the long-term success of organs grown on synthetic scaffolds in our bioreactors--an

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endeavor on which we have collaborated with Professor Macchiarini and his team in recent years."

Mr. Green continued, "Following this pioneering surgery, Harvard Bioscience licensed the bioreactor technology, from which we developed our InBreath (TM) Bioreactor, which has been used in all nine subsequent regenerated trachea transplant surgeries conducted by Prof.

Macchiarini. Since 2011, we have collaborated with him to develop fully synthetic scaffolds. Synthetic scaffolds are preferable to donor scaffolds because the number of donor organs is very limited and the donor scaffold weakened over time in the patient's body. Our current product, the InBreath (TM) Airway Transplant System, which utilizes the InBreath (TM) Bioreactor and the InBreath (TM) Scaffold, has been used in four successful regenerated human airway transplantations."

Harvard Bioscience recently completed the acquisition of all patent rights to synthetic scaffold-based trachea regeneration owned by Professor Macchiarini. Additionally, as previously announced, Harvard Bioscience will spin-off Harvard Apparatus Regenerative Technology on November 1, 2013. Thereafter, HART will be an independent publicly traded biotechnology company focused on developing regenerative medicine therapies, initially for trachea cancer. HART will trade on the NASDAQ market under the ticker symbol HART.

To read the Lancet article, visit

[thelancet.com/journals/lancet/article/PIIS0140-6736\(13\)62033-4/abstract](http://thelancet.com/journals/lancet/article/PIIS0140-6736(13)62033-4/abstract) [2]

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