

Peer-Reviewed Study Shows Six Times Lower Blood Damage in Realheart® TAH Than Market-Leading Device in Vitro

Västerås, Sweden, September 16, 2026 – Scandinavian Real Heart AB (publ) announces today that a study sponsored by the company has been published in the peer-reviewed journal Nature Scientific Reports, showing that the Realheart® TAH causes about six times less blood damage (hemolysis) than the only FDA-approved artificial heart device currently in wide clinical use. The study was carried out in a lab-based system mimicking full body circulation. Further, the study shows that the Realheart® TAH preserves a protein essential for blood coagulation and the prevention of internal bleeding.

In the current study, complete devices were tested in a laboratory circuit simulating both systemic circulation and lung circulation and under the test conditions, there was clear difference between the devices. The Realheart® TAH generated about six times less hemolysis than the comparator device (normalized hemolysis index, mgNIH: 35.5 ± 4.3 versus 226.0 ± 30.6 mg/100 L; $p = 0.002$), with significantly lower blood damage at every measurement point after five minutes. Additionally, the comparator produced significantly higher levels of cell fragments – debris from damaged blood cells – whereas no corresponding increase was observed with the Realheart® TAH.

The study also evaluated the function of the coagulation protein von Willebrand factor, which is typically damaged in patients with continuous flow heart pumps leading to increased risk of the bleeding disorder acquired von Willebrand syndrome. Both pulsatile artificial hearts fully preserved von Willebrand factor function, in contrast to a continuous-flow blood pump used as reference ($p = 0.023$ for both pulsatile devices). The findings confirm a fundamental advantage of the pulsatile operating principle on which the Realheart® TAH is built, and are believed to be an indicator of a lower risk of device-related bleeding complications.

“When we published our first head-to-head study on human blood in April, we communicated that more comprehensive full-body circulation testing would follow. We added lung circulation to the model and have now delivered on that step – and under these more clinically relevant conditions, the difference grew to more than six-fold in favour of the Realheart® TAH. Together with the preserved function of von Willebrand factor, an important indicator of bleeding risk, these results further strengthen the safety documentation we are building ahead of the clinical evaluation of our artificial heart,” says Ina Laura Perkins, CEO, Realheart.

The article, “Hemocompatibility of the Realheart TAH against SynCardia TAH in Full-Body Circulation with Human Blood”, is available at <https://www.nature.com/articles/s41598-026-68178-2>



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About Us

Scandinavian Real Heart AB (publ) is developing the first artificial heart that mimics the shape, function, and blood flow pattern of the human heart. These unique product features provide completely new opportunities to save lives and give patients a good quality of life while waiting for a heart transplant. In the future, artificial hearts may also become an alternative to transplantation for broader groups of patients with severe heart failure. Realheart® TAH (Total Artificial Heart) is now being evaluated in extensive preclinical trials ahead of a first clinical study in patients. The company's shares are traded on Nasdaq Stockholm First North Growth Market. For more information, visit www.realheart.se