

Peer-Reviewed Article Shows Superior Hemolysis Profile in Realheart[®] TAH Compared to Market-Leading Device

Västerås, Sweden, April 21, 2026 – Scandinavian Real Heart AB (publ) announces today that a new in vitro study, published in the peer-reviewed journal *Artificial Organs*, demonstrates that the Realheart[®] TAH causes approximately half the level of hemolysis – the mechanical destruction of red blood cells – compared with the only FDA-approved artificial heart device currently in wide clinical use. The differences across all primary endpoints were statistically significant ($p < 0.05$).

Hemolysis is a well-documented complication in patients with mechanical heart pumps. When red blood cells are damaged as they pass through a device, hemoglobin is released into the bloodstream, which over time can contribute to kidney injury, anaemia and other organ complications. Despite the clinical relevance of hemolysis, no in vitro hemolysis data for the approved device have previously been published – making this the first head-to-head laboratory comparison of two total artificial hearts using fresh human blood.

The study was conducted using human whole blood which was circulated through each device in a circulation model mimicking half of the human cardiovascular system (left side, or systemic, circulation). The results show that Realheart[®] TAH produced a significantly lower normalised hemolysis index (mgNIH), 18.11 ± 3.53 mg/100 L, compared with 37.15 ± 12.42 mg/100 L, than the comparator ($p < 0.05$). Further, plasma free hemoglobin, a direct marker of red blood cell destruction, was nearly twice as high in the comparator samples after six hours, and only the comparator significantly reduced the number of intact red blood cells relative to both the Realheart[®] TAH and the static control. In summary, Realheart[®] TAH causes significantly less harm to red blood cells than the market-approved alternative.

These results add to a growing body of experimental preclinical evidence, as well as computational modelling, indicating a favourable hemolysis profile for the Realheart[®] TAH design. The current study confirms that pattern in human blood, which is roughly twice as sensitive to mechanical damage as alternative experimental options (e.g. bovine blood). The tests in this study were limited to systemic circulation, and in the next step full-body circulation testing will bring the preclinical evaluation closer to the conditions the device will face in patients.

"This was our first study on human blood, and these data show that the Realheart[®] TAH causes significantly less blood damage than the only market-approved alternative, which is a critical biomarker evaluated by regulatory agencies. With this piece of the puzzle in place, we have moved on to more comprehensive evaluations, including full-body circulation testing, as part of our stepwise preparation for late-stage testing of our product. We have chosen to use human blood as this is more easily damaged than animal blood, which is typically used, thus giving a more clinically relevant risk assessment" says Ina Laura Perkins, CEO, Realheart.



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Read the full study: <http://doi.org/10.1111/aor.70149>

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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