



Results of Scandinavian Realheart's Total Artificial Heart Demonstrating Lower Rates of Hemolysis, Published in the Journal Artificial Organs

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Scandinavian Real Heart (the "Company") has published results demonstrating that the Company's Realheart Total Artificial Heart (TAH) prototype V11C has lower rates of hemolysis compared to published data from studies of the Reinheart's large and small TAH. The peer-reviewed study titled "In Vitro Hemolytic Performance of the Realheart V11C TAH Prototype with Porcine Blood" was published on-line, ahead of print, in the Journal of Artificial Organs.

The paper summarizes work performed by an international team of researchers led by Drs. Ina Laura Perkins and Azad Najar of Scandinavian Real Heart in collaboration with scientists at the Swansea University Medical School in the United Kingdom.

High rates of hemolysis requiring repeat and frequent blood transfusions are a key factor limiting the utility of currently available TAHs. Furthermore, hemolysis testing is a regulatory requirement for all new devices intended for the treatment of patients with heart failure. In this study, the so called "Aachen Rig" is used as a step towards creating a gold standard for testing pulsatile flow blood pumps.

In order to compare the outcomes of hemolysis testing with data published in the literature, the researchers utilized the Aachen Rig to test the Realheart V11C TAH prototype. By utilizing the continuous flow pump BPX-80 from Medtronic Inc. as a control, the authors demonstrated that the Realheart V11C TAH has a lower absolute and relative rate of hemolysis when compared to published results obtained with both the large and small ReinHeart TAH (ReinHeart TAH GmbH) devices.

"Developing a TAH is a technical and clinical challenge and ensuring that hemolysis is as low as possible is a key factor impacting the design of artificial hearts. It is against this background that we are developing the Realheart TAH with pulsatile blood flow. Thanks to the design of our artificial heart, with two atria, two chambers and an AV plane, we can generate natural blood flow which we expect will contribute to a reduced risk of hemolysis. The research published in this article is the foundation for the methodology we are using in our ongoing comparison with the market-leading pump SynCardia," said Ina Laura Perkins, CEO of Realheart.

Artificial Organs is a peer-reviewed biomedical journal that publishes research in the field of artificial organs and medical technology. The journal was founded in 1977 and is published monthly. The publication can be accessed via:

<http://onlinelibrary.wiley.com/doi/abs/10.1111/aor.14533>

(Access fee may be required).

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Scandinavian Real Heart AB develops a total artificial heart (TAH) for implantation in patients with life-threatening heart failure. Realheart® TAH has a patented design that resembles that of the natural human heart. The artificial heart consists of a four-chamber system (two atria and two ventricles) designed to generate a physiological blood flow pattern that mimics the body's natural circulation. A unique concept in the medical technology world.