Blood Trauma Testing for a Total Artificial Heart

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Total artificial hearts (TAHs) are 70cc in size but, in recent, a 50cc TAH has been developed. This smaller device could cause an increased percent of hemolysis due to greater pressure and turbulence shear stress applied. It was hypothesized that the 50cc TAH will induce equivalent or less hemolysis than the 70cc TAH. The study was conducted per ASTM and FDA guidelines. Twenty- four flow mock loops were constructed to simulate left and right ventricle patterns with the two different TAHs. At the 0, 5, 90,180, 270, and 360 minute marks, 5cc of blood was drawn and underwent three tests; ACT (activated clotting time) to ensure a clotting time of at least 600 seconds, pfHb (plasma-free hemoglobin), and CBC (complete blood chemistry). The NIH (normalized index of hemolysis) and MIH (modified index of hemolysis) values were calculated for better comparison to in vivo values. Two parametric and two non-parametric tests, which were to account for a smaller sample size, were performed; an unpaired t-test, two one-sided test (TOST), Mann-Whitney, and non-parametric two one-sided test (NPAR). The overall t-test p-values, greater than 0.05, for both the NIH and MIH values showed no statistical difference. In the TOST test, the upper and lower limits for the NIH and MIH values did not fit within the confidence intervals of the TOSTs, the devices are not statistically equivalent. From the Mann-Whitney tests of the NIH values proved to be significant with a p-value of 0.0008 but the MIH values proved to be not significant with a p-value of 0.17384. The p-values of the NPAR tests were all >0.05, meaning the two devices are statically equivalent. From the NIH and MIH calculations, the hypothesis was proven. From these tests, the 50cc can be approved for human implantation by the FDA.

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