
In Vitro Comparison of the Blood Handling by the Constrained Vortex and Twin Roller Blood Pumps

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Abstract

(*J. Extra-Corpor. Technol.* 19[3] p. 316–321 Fall 1987, 30 ref.) Several authors and manufacturers refer to the superior blood handling capability of the constrained vortex blood pump (CVP) design compared to the roller pump (RP). Little, if any, scientific evidence has been presented to support this thinking. The hypothesis that the RP and the CVP are equivalent in regard to trauma to blood cellular elements and proteins was tested. The RP, a Cobe Roller Pump (CRP), was tested utilizing a new long-term formulation of PVC tubing. Two models of the CVP were tested, the Bio-Medicus Centrifugal Pump (BCP) and the Sarns Centrifugal Pump (SCP).

Similar circuits were constructed for the three pumps and fresh human blood was recirculated at 35°C for 48 hours. The circuits allowed control of pH, pCO₂, pO₂ and afterload. An aliquot of test blood was maintained at 35°C for a control. The results from three separate trials were computed.

The BCP test blood exhibited less hemolysis ($p < .05$) than the CRP blood after 16 hours. The contents of all test circuits exhibited a significant increase in hemolysis over time ($p < .01$) and all circuits exhibited more hemolysis than the control ($p < .03$) after 16 hours. All 3 pumps were equivalent in platelet factor IV release. The CRP showed a significant decrease in convertible fibrinogen over time ($p = .02$). There was no significant difference

($p > .05$) in the titer of clottable fibrinogen between the other groups.

The SCP and the CRP were equivalent with regard to blood handling for up to 32 hours of in vitro recirculation. The BCP caused less alteration of red blood cells and fibrinogen than the SCP and CRP.

Introduction

The purpose of this investigation was to compare the twin roller pump (CRP)^a, the Bio-Medicus (BCP)^b and the Sarns (SCP)^c vortex pumps in terms of hemolysis, platelet factor IV release, and fibrinogen destruction in a 48 hour, in vitro test model of a cardiac assist circuit.

There are substantial measurable and perceived differences between vortex type and twin roller pumps.^{1–8,11,16,20,22,25} The pump designs vary in the ability to transfer gaseous micro and gross emboli, produce particulate emboli (e.g., spallation in polyvinylchloride tubing ((PVC)) in the pump head), and in gentleness of blood handling.^{4,6,11,14,18,22–25}

Several authors have demonstrated decreased gaseous embolic activity at the outlet of the vortex pump compared to the roller pump when the inlet and outlet of the pumps are partially occluded.^{6,18} It has been speculated that the inherent vortex design minimizes air emboli from the pump because large volumes of air deprime the vortex pump while smaller volumes of air are displaced to the center of the vortex by the higher density fluid.^{3,6,18}

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a Cobe Laboratories, Inc., Lakewood, CO 80215

b Model BP-50, Bio-Medicus, Minnetonka, MN 55343

c Centrifugal Pump, Sarns Inc./3M, Ann Arbor, MI 48103

The release of particulate matter from PVC tubing (spallation) during roller pumping is well documented.^{3,11,15,17} In this investigation, we employed a more durable PVC polymer (S-65-HL)^d that has longer pump head life than required by present day standards.²³ Figure 1 depicts the amount of spallation of the new formulation and the routinely employed S-50-HL.^d Recent clinical data confirms the longer pump head life and acceptable clinical levels of hemolysis when using the new tubing formulation. Toomasian et al. reported 14, 21, and 28 day in vitro trials with no ruptures.²³ They also present 12 neonatal ECMO cases without excessive hemolysis due to the tubing. Toomasian's photomicrographs of the pump head tubing were consistent with minimal wear and exhibited no tubing breakdown in periods up to 111 hours.²³

The change in plasma free hemoglobin is a useful tool to compare blood pump rates of hemolysis.^{9,25} Investigators have observed low clinical levels of hemolysis with the constrained vortex pump.^{5,9} One European investigator examined the hemolytic differences in the two current vortex pump designs^{b,c} and the twin roller pump in an in vitro model primed with canine blood.⁴ Demierre et al. demonstrated 10 times the hemolysis in the roller pump when compared to

the 2 vortex pump designs.⁴ The authors also measured platelet counts and blood lactate dehydrogenase (LDH) levels but were not able to draw conclusions about the pumps' effects on these parameters. Investigators report lower plasma hemoglobin in sheep and canine long-term experiments when the roller is replaced by the vortex pump.^{5,7,8,20} Clinical trials have yielded lower chest tube drainage volumes and half the hemolysis in vortex pump patients compared to roller pump patients.^{2,3} Data has been presented to prove that a barely nonocclusive roller head setting is least hemolytic.^{9,25}

The arterial blood pump is not the primary source of hemolysis in the extracorporeal circuit (ECC) when coronary suction is employed. However, in cardiac assist circuits, where bypass time may be measured in days rather than hours, the blood pump is the major source of hemolysis.^{10,12,13,26}

Roller pumps may not be the optimal blood pump for long-term support. However, they have been employed in the absence of more expensive devices such as the vortex pump.¹ The purpose of this investigation is to determine at which point roller pump^a hemolysis exceeds vortex pump^{b,c} hemolysis in an in vitro cardiac assist model.

Materials and Methods

Figure 2 shows a schematic of the in vitro circuit. A circuit was constructed for each of the 3 pumps tested (CRP, BCP, SCP). Each circuit was the same in terms of tubing length and circuit elements so the only difference was the means of blood propulsion. Blood was pumped from a 1000 ml. venous reservoir bag, through a Capiiox II 0.8 meter² hollow fiber oxygenator^f and back into the venous reservoir.

Eight units of type specific human blood were collected the day of the experiment. Each 600 ml. collection bag contained 2000 units of heparin for anticoagulation. Each circuit was primed with normal saline prior to the addition of blood. The circuits were interconnected by a recirculation line to ensure uniform mixing. The pH, pCO₂, and pO₂ of the blood^g were measured at all times. Low pO₂s and/or high pCO₂s were regulated by pumping room air through the oxygenator^f; acidosis was corrected with sodium bicarbonate; and it was assumed that equilibrium was attained within 15 minutes. Approximately 600 ml. of circuit perfusate was transferred to a venous reservoir bag for the control aliquot. The volume in each circuit was equilibrated and the recirculation lines clamped to isolate each circuit.

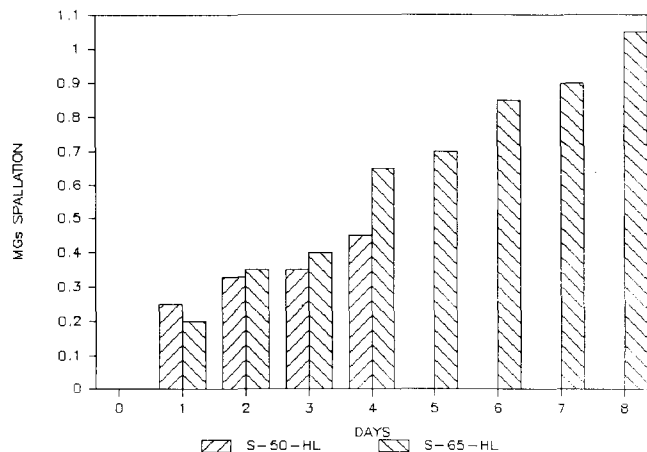


Figure 1: The cumulative spallation of two $\frac{1}{2} \times \frac{1}{16}$ " Norton Plastics tubing types compared in survival tests at 4. L/min. at room temperature with 200 mmHg back pressure and a barely nonocclusive roller setting. The .45 micron prefiltered triple distilled water perfusate was filtered every 24 hours by a 10 micron preweighed filter, the filter was dried and weighed, and the resulting weight reported. (Personal communication, Charton, R.A.: Preliminary life and spallation data of S-65-HL. October 3, 1986). The S-50-HL lasted 96.5 hours before rupture and the S-65-HL lasted 185.3 hours.

^d Norton Company, Akron, OH 44309-3660

^e 1000 ml. venous reservoir bag, Terumo Corp., Piscataway, NJ 08854

^f Capiiox II, Terumo Corp., Piscataway, NJ 08854

^g IL Micro 13, Instrument Laboratories, Lexington, MA 02173

SCHEMATIC

ROLLER VS. BIOMEDICUS

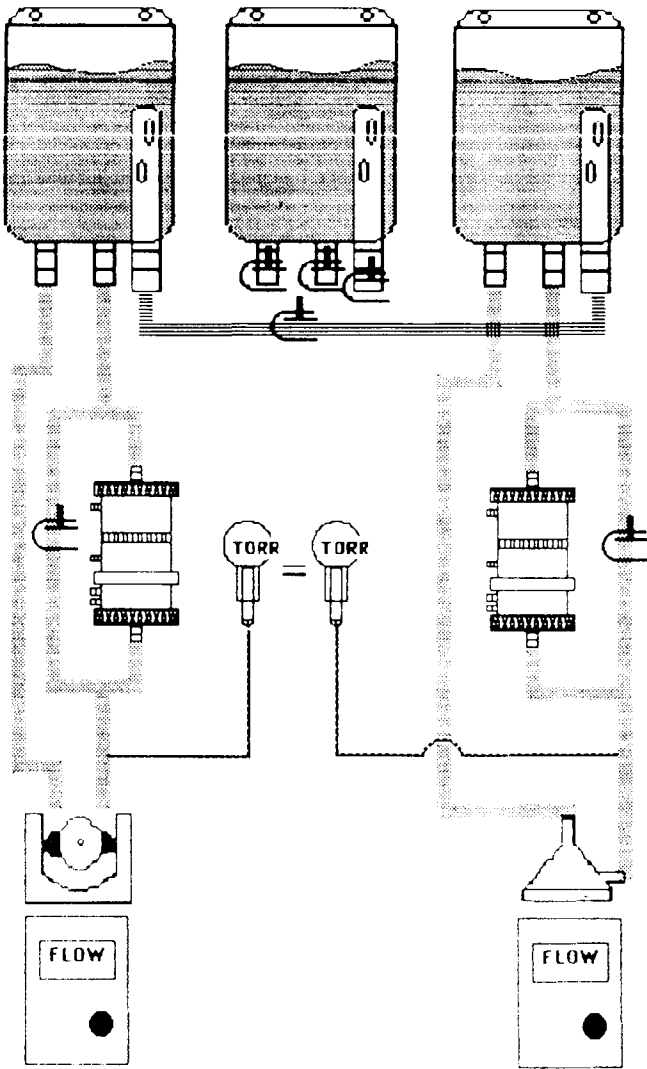


Figure 2: Schematic of in vitro circuit employed to test the two vortex pumps and the roller pump. The in vitro test circuit for the Sarns Vortex Pumps was identical. The test blood was 1000 mls of 27% hematocrit human blood at 35°C.

Occlusion of the CRP was adjusted to a rate of fall (crystalloid) of 1 inch per minute at a height of 36 inches.

A flow rate of 4 liters per minute, as measured with a Bio-Medicus^b in-line flow probe, was established in each circuit. Circuit resistance was adjusted by restricting flow through the oxygenator bypass line; line pressure measured proximally to the restriction was maintained at 150 mmHg. Blood samples were drawn at the following times: baseline (0 hours), 1, 2,

4, 6, 8, 16, 24, 32, 40, and 48 hours. Blood gases were determined using an IL Micro 13 blood gas analyzer^g.

Reptilase time (RT, for fibrinogen), platelet factor 4 (PF4) and plasma free hemoglobin (PFH) assays were performed. Plasma samples for reptilase and plasma free hemoglobin assays were obtained by centrifuging the blood at $1500 \times g$ for 10 minutes. For the platelet factor 4 assay, the sample was drawn into a Diatube-H^h collection tube and centrifuged at 4°C at $2500 \times g$ for 30 minutes. Plasma free hemoglobin was measured as described by Harboe.²⁷ PF4 release was measured using the Asserachrom PF4 enzyme immunoassayⁱ according to manufacturers' directions. Estimation of the clottable fibrinogen levels were obtained by the Reptilase Time^j.

The raw data was entered into a database program^k that allowed the creation of graphic illustrations. Hypothesized differences between the treatment groups (control and types of blood pumps) with respect to elapsed time were analyzed with a One-Way Analysis of Variance,¹ and specific differences between control and blood pump types at a given time were evaluated by a students paired *t*-test.¹

Results

Apparently a seal ruptured in one SCP at 32 hours into the test. Gross hemolysis and a clot were identified in the pump head at the end of the trial. This resulted in a positive skewing of the mean values for PFH, PF4, and RT in the Sarns' data set.

Figures 3 and 4 illustrate hematocrit and blood pH, respectively, during the hemolysis trials. Although control blood pH decreased significantly with time control, PFH values were not affected (Figures 7 and 8).

Figure 5 illustrates changes in PF4 levels during the procedure. The high baseline levels indicate that the blood collection and blood processing procedures caused significant platelet activation and factor release. All pump types appear to cause the release of PF4 at the same rate as illustrated by the similar slopes of the curves. Analysis of variance suggested that there were specific increases in PF4 with elapsed time. However, specific differences ($p < .05$) between pump types could not be demonstrated.

h Diatube H, American Bioproducts Company, Parsippany, NJ 07054

i Diagnostica Stago, American Bioproducts Company, Parsippany, NJ 07054

j Atroxin, Sigma Chemical, St. Louis, MO 63178

k Lotus 1-2-3, Lotus Development Corporation, Boulder, CO 80321

l Microstat Release 4.1, Ecosoft, Inc., Indianapolis, IN 46220

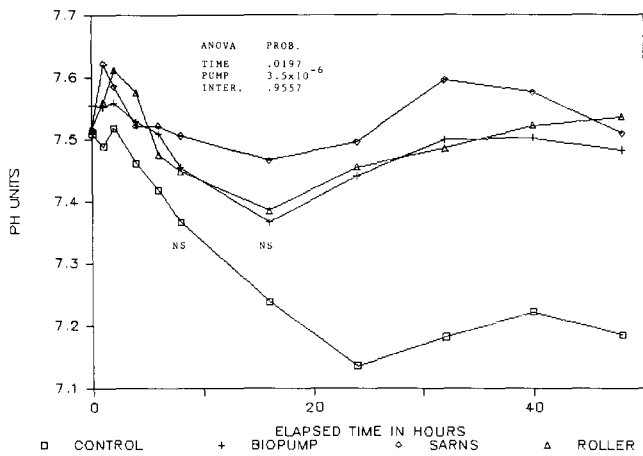


Figure 3: Trends in the mean (n=3) pH in the test blood of each pump circuit during the study. ANOVA = Two Way Analysis of Variance. NS = No Significant difference at $p < .05$. The control blood pH could not be controlled. There were no significant differences between the pH of the test pump circuit bloods.

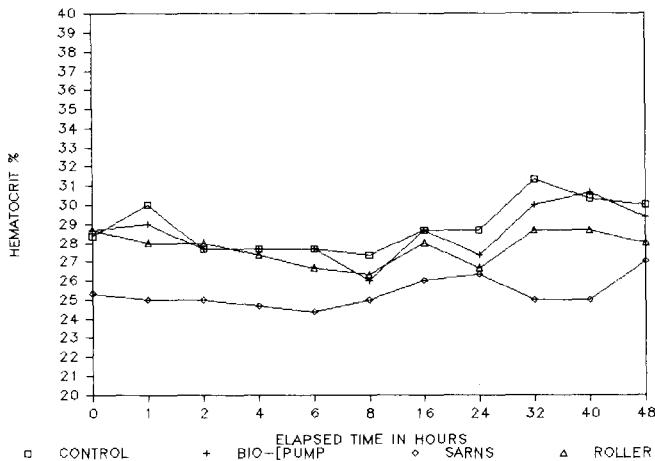


Figure 4: Trends in the hematocrit of the test circuit and control bloods. ANOVA = Two Way Analysis of Variance. There were no significant differences in hematocrit between pump test bloods at $p < .05$.

Figure 6 shows the pump related trends in loss of convertible fibrinogen with time. An increase in RT indicates a decrease in the titer of clottable fibrinogen. The differences between the CRP and control, and between the CRP and the BCP were not significant ($p < .05$) until 32 hours had elapsed. The elevated mean RT for the SCP was not significantly different from other RT values at 48 hours.

Figures 7 and 8 graph PFH values. The SCP trial with the seal leak greatly skewed the PFH curve for SCP (Figure 7). Values from the first two trials for each pump type are plotted in Figure 8, which removes the failed SCP from the analysis.

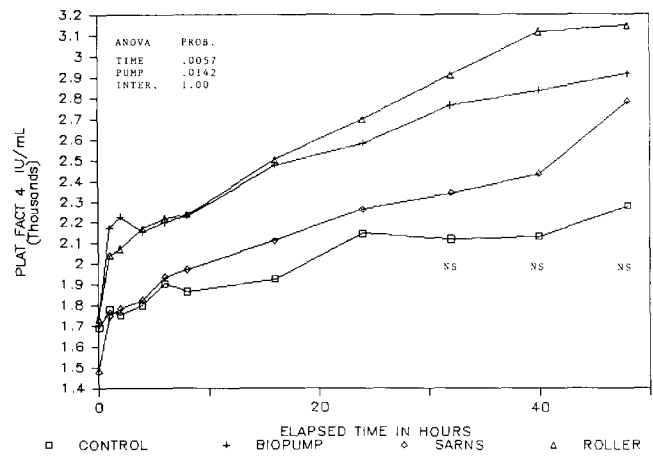


Figure 5: Trends in Platelet Factor Four in the test circuit and control bloods. ANOVA = Two Way Analysis of Variance. NS = No Significant difference at $p < .05$. There was no significant difference between pump test bloods' mean Platelet Factor Four.

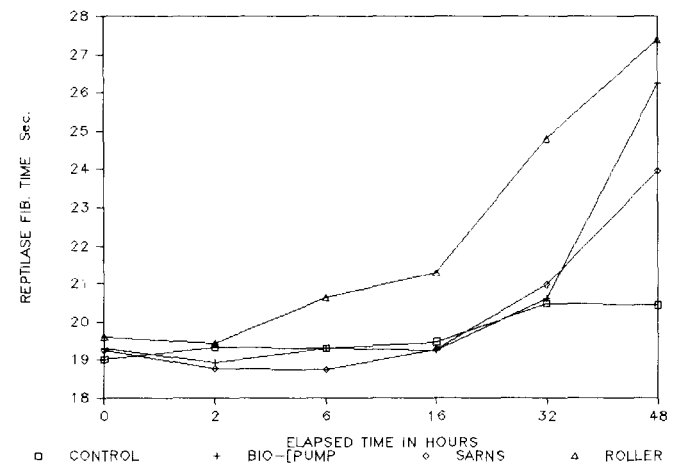


Figure 6: Trends in the Reptilase Time in seconds in the control and pump test bloods. ANOVA = Two Way Analysis of Variance. NS = No Significant difference at $p < .05$. Rise in the Reptilase Time reflects a decay in clottable fibrinogen.

Discussion

Significant changes in hemostasis and the degree of hemolysis are produced by the use of the extracorporeal circuit (ECC) during cardiac surgery.^{29,30,9,25} When the ECC is utilized for long-term cardiac and/or respiratory support, the length of bypass may range from several hours to several days. The purpose of this investigation was to compare the hemostatic and hemolytic changes produced by the Cobe twin roller pump (CRP), the Bio-Medicus centrifugal pump (BCP) and the Sarns centrifugal pump (SCP) over a 48-hour period.

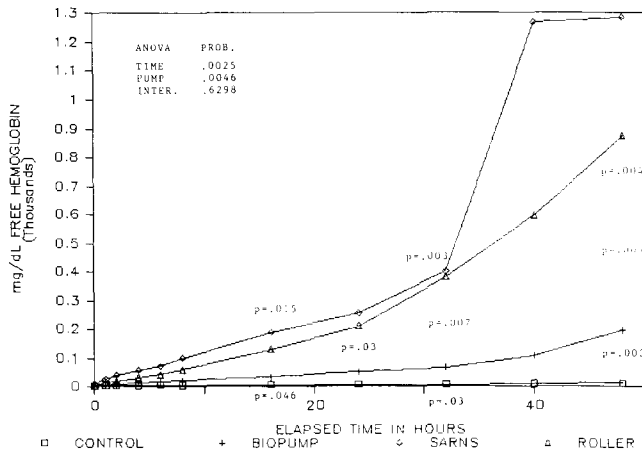


Figure 7: Trends in the plasma free hemoglobin in the control and test circuit bloods. ANOVA = Two Way Analysis of Variance. The sharp increase in the Sarns vortex pump at 32 hours was attributed to the effect of a seal leak in one of the vortex disposables tested.

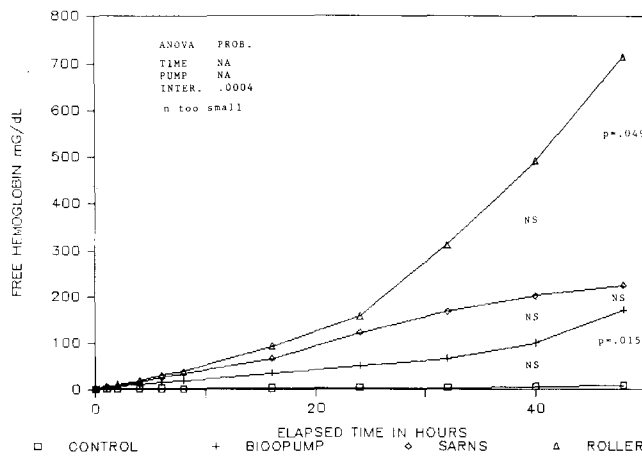


Figure 8: Trends in the plasma free hemoglobin from the first two trials of the control and test pump circuits. The third trial which included the Sarns vortex pump data for the unit that experienced a seal leak was not included. ANOVA = Two Way Analysis of Variance. NS = No Significant difference at $p < .05$.

Mammen et al.³⁰ reported increasing levels of platelet related proteins during bypass, indicating that platelets are activated during this procedure. Bick²⁹ maintains that all patients undergoing cardiopulmonary bypass (CPB) display a platelet function defect. In addition, the majority of patients develop a primary hyperfibrinolytic syndrome. These 2 defects, alone or in combination, are believed to account for the majority of nonsurgical hemorrhage in these patients.

This investigation measured plasma PF4 levels as an indication of platelet activation/damage. The high

baseline levels indicate that the blood collection and processing procedures caused significant platelet activation and factor release (normal plasma PF4 levels: 0–5 ng/ml). All 3 pumps caused more PF4 release than the control, although none of the increases were statistically significant.

The Reptilase Time (RT) was chosen as an index of convertible fibrinogen; a prolongation of the RT reflects a decrease in convertible fibrinogen. Although the exact cause of the observed prolongation cannot be determined, it is most likely due to fibrinolytic activity generated by the extracorporeal circuit (activation of Factor XII with the resultant generation of plasmin).²⁹ All 3 pumps showed an increase in the RT compared to the control. The CRP showed a significant difference at 32 hours ($p = .025$), while the BCP and the SCP paralleled control RT up to 32 hours, after which RT increased, though not significantly.

Plasma free hemoglobin (PFH), used as an index of pump associated hemolysis,^{9,25} increased significantly with time for all 3 pumps. After 6 hours, the CRP was significantly higher than the control ($p = .02$) and after 16 hours it was significantly higher than the BCP ($p = .035$). After 16 hours, the BCP was significantly higher than the control. Although the amount of hemolysis produced by the SCP exceeded that of the BCP, no statistical difference between the SCP and the control was observed. This was probably due to the large variance seen in the SCP samples.

In conclusion, the in vitro human blood cardiac assist model used in this study showed all 3 pump types to be equivalent in terms of hemolysis and preservation of fibrinogen up to 16 hours. After 16 hours, the CRP produced significantly greater amounts of hemolysis than the other pumps, and after 32 hours, the CRP produced a significantly greater decrease in clottable fibrinogen. After 16 hours, the BCP produced significantly more hemolysis than the control. There was no statistical difference between the BCP and the SCP in any of the parameters measured.

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Questions from the Audience

Question: Jack Old, Springfield, MA: Did you do as indicated in the Abstract? Only three samples?

Response: Yes, we did three trials.

Question: Do you think, after you've done more samples, there is an indication you would have seen a significant difference at a shorter interval? Or do you think additional trials would show no more significance?

Response: In looking at the data I don't think it would have shown any significance any sooner—not even by doing more trials.

Question: Robin Sutton, Charleston, SC: I was wondering if you think these results might be clinically significant or not. In vitro they were. But how do you feel about that?

Response: One of the problems with taking it to an in vivo model is that the body has the ability to compensate for some of these problems. Especially there is the body's ability to mask the changes in free hemoglobin. I think in reality the next step is to produce an in vivo model and look at basically the same things. We would do this for the same length of time and see what then is the difference between the in vitro and the in vivo model.