

Original Article

## *An Under-Occluded Roller Pump is Less Hemolytic Than a Centrifugal Pump*

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Keywords: index of hemolysis, roller pump, occlusion, centrifugal pump, extracorporeal circulation, plasma-free hemoglobin, in-vitro study

### ABSTRACT

The purpose of this study is to measure and compare the hemolysis produced by roller pumps with varied occlusion settings and a centrifugal pump. The null hypothesis is that there is no difference in the Index of Hemolysis (IH=gm Hb/100 L pumped) produced by a roller pump (RP) at four different occlusion settings and a centrifugal pump (CP) at the same blood flow rate (4.5 L/min) and afterload (250 mmHg,  $\pm 10$  mmHg) over three hours.

Five identical closed-loop circuits were assembled and primed with saline. The pumps were then calibrated and occlusions were set. In three circuits, the occlusion for the RP was opened at 5 RPMs to support 150, 225, or 300 mmHg ( $\pm 10$  mmHg) against a clamped line. In one circuit, a RP was adjusted to a barely non-occlusive setting (1 cm drop/30 inch gradient). The fifth circuit employed a CP. Prior to testing, the saline in each circuit was replaced with one liter of fresh bovine blood (Hct=22 $\pm$ 2%). The IH for each treatment was compared in six trials yielding a statistical power > 0.80.

Analysis of variance with multiple comparison ( $p \leq 0.05$ ) demonstrated that compared to the barely non-occlusive setting, the IH in the centrifugal pump was not significantly greater. Under-occluded RP settings yielded IHs significantly less than the CP. It appears that opening the occlusion on a roller pump allows a lower IH compared to traditional RP occlusion setting or centrifugal pumping.

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## INTRODUCTION

Cardiopulmonary bypass (CPB) may precipitate many problems including hematologic complications (1,2). Hemolysis is a hematologic complication commonly observed during CPB procedures and is related to the exposure of blood to the extracorporeal circuit (ECC) (1,3,4). The damage caused by mechanical stress may be manifested in shortened red blood cell survival time, increased cellular aerobic metabolism and red blood cell membrane alterations (4,5). The occlusion setting of the blood pump is a primary factor causing surface-induced damage associated with the extracorporeal circuit (5,6). The significant factor responsible for hemolysis in roller pumps (RPs) is the compression of the tubing in the pump chamber by the rollers (4,6). Variables such as stroke volume and the pressure gradient across the arterial cannula have minimal contribution to the total hemolysis produced during CPB, while the combined use of suction systems, filtration devices, and the pump-oxygenator system produce the greatest amount of hemolysis (1,2,5,6).

A blood pump must provide adequate control of forward flow (7,8). The exact output of the blood pump may vary during CPB, and it may be difficult to determine the exact flow output due to occlusion variance throughout the bypass run (8). The output variance observed in roller pumps may be caused by slight changes in the original occlusion setting. Studies have shown that at non-occlusive settings, roller pump output is sharply decreased, and decreased output may result in hypoperfusion of the patient (3,4,7). The output of the centrifugal pump varies with changes in systemic vascular resistance. The optimal blood propulsion device will maintain adequate and predictable pump output while minimizing hemolysis. Hemolysis caused by different roller pump occlusions and by the centrifugal pump can be quantified by measuring the change in plasma free hemoglobin levels over time (1,2,3,4,7). The index of hemolysis has been used as the criteria for evaluating blood damage, but is only an indicator of the total damage to the erythrocyte (4). Free plasma hemoglobin is normally removed by the reticuloendothelial system (RES). However, rapid increases in the amount of plasma hemoglobin produced due to CPB may exceed the RES and renal threshold for removal of free plasma hemoglobin causing hemoglobinuria. During CPB, plasma hemoglobin is removed by the kidneys and phagocytes. When evaluating hemolysis clinically, the amount of hemoglobin detected does not reflect the total quantity produced, but is a result of the balance between the rate of formation and the rate of elimination of free hemoglobin.

Use of in-vitro extracorporeal test circuits controls for the effects of the volume, flow rate, and hematocrit. When the quantity of hemoglobin produced per volume of blood is measured at a con-

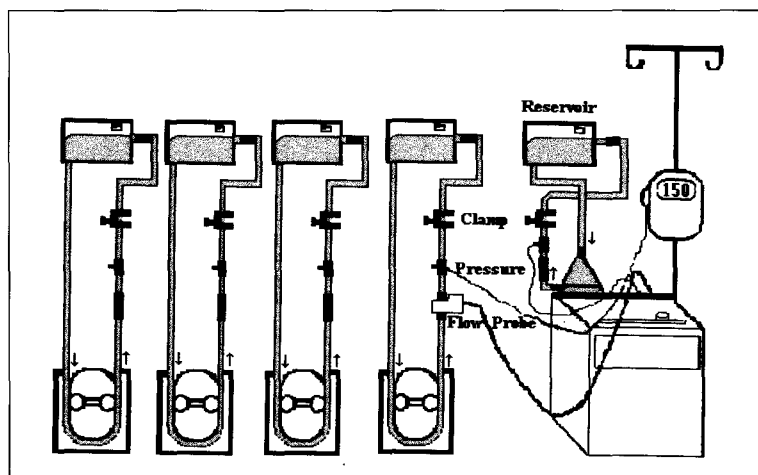
stant flow rate over a set period of time, it is referred to as the index of hemolysis. This value represents the grams of hemoglobin freed per 100 liters of pumped blood. In vitro, variance in blood volume and hematocrit can be minimized by priming the experimental circuits with equal volumes drawn from the same blood pool. The purpose of this study is to measure and compare the hemolysis produced by roller pumps with different occlusion settings and a centrifugal pump. The null hypothesis is there is no difference in the index of hemolysis produced by an RP at four different occlusion settings and a centrifugal pump (CP) at the same blood flow rate and afterload over three hours.

## METHODS AND MATERIALS

Five identical closed-system circuits were assembled (Figure 1)<sup>a</sup>. Four were loaded into Stockert-Shiley® roller pumps<sup>b</sup> and the fifth was assembled using a Biomedicus® console<sup>c</sup> and a centrifugal pump<sup>d</sup>. A blood reservoir was filled with an identical amount of blood and left static to serve as a control throughout the duration of testing. Four and one-half feet of 3/8" diameter polyvinyl chloride tubing<sup>e</sup> was fed from the blood reservoir<sup>f</sup> into each of the roller heads and the centrifugal pump. The blood reservoirs used were 1000 ml bags adapted with a 1/2" x 3/8" connector<sup>g</sup> on the inlet of each bag. Each reservoir was mounted one foot above its respective pump yielding an approximate preload of 25 mmHg. On the positive pressure side of the roller pumps and outlet line of the centrifugal pump, a 3/

- a Paintbrush, Microsoft Corp., Redmond, WA 98073
- b Sorin Biomedical, 176200 Gillette, Irvine, CA 92714
- c Medtronic Bio-Medicus, Inc., Model 540B, Eden Prairie, MN 55344
- d Medtronic Bio-Medicus, Inc., Model BP-80, Eden Prairie, MN 55344
- e Gish Biomedical, Inc., Mediflex MT2007, Irvine, CA 92714
- f Sarns 1000 ml venous reservoir, Ann Arbor, MI 48103
- g Gish Biomedical, Inc., Model EC2145 S, Irvine, CA 92714

Figure 1:



8" x 3/8" connector<sup>h</sup> with luer lock, a 3/8" in flow probe<sup>i</sup> and a hose-cock clamp<sup>j</sup> were placed in-line to measure pressure and flow respectively and to facilitate the application of afterload. A transducer<sup>k</sup> was attached to the 3/8" x 3/8" LL connector on each circuit and primed. Oc-

clusion was set on three roller pumps at a rate of 5 RPMs until pressures of 150, 225, and 300 mmHg ( $\pm 10$  mmHg) were seen respectively, the fourth pump occlusion was set per protocol at the Medical University of South Carolina (30 inch above reservoir for a 1 cm/min drop in fluid).

A back pressure of 250 mmHg ( $\pm 10$  mmHg) was applied to all test circuits. The flow probe from the Biomedicus console was connected and flow was then adjusted to 4.5 LPM for each circuit. Each roller pump had been calibrated prior to the introduction of blood to the circuit using saline solution and flow was determined with a Biomedicus flow-probe that had been zeroed.

Once each circuit was assembled, 6 liters of fresh heparinized (4.0 IU/ml) bovine blood was diluted to a hematocrit of  $22 \pm 2\%$  and filtered through a 40 micron arterial filter into each blood reservoir. The blood within each circuit was then circulated at room temperature and samples were taken at 1/2, 1, 1 1/2, 2 and 3 hour increments. One sample was taken from each circuit, including the control, during each time interval in a quantity sufficient to yield 3 mls of plasma after centrifugation. This allowed each sample to be tested in triplicate, with the mean of the 3 values recorded at each time sample. Six trials were performed on each of the circuits, yielding a total of 90 samples (15 per pump). Each sample was analyzed for plasma-free hemoglobin levels by the Harboe (9) method and the index of hemolysis (10) for each three hour trial was calculated for each treatment group.

$$IH (mg/100L) = \frac{1000 [\Delta PfHgb * Volume * (1-Hct)]}{Flow * \Delta t}$$

Data analysis was accomplished using a statistical software package<sup>l</sup> to perform analysis of variance of the treatments undergoing testing.

## RESULTS

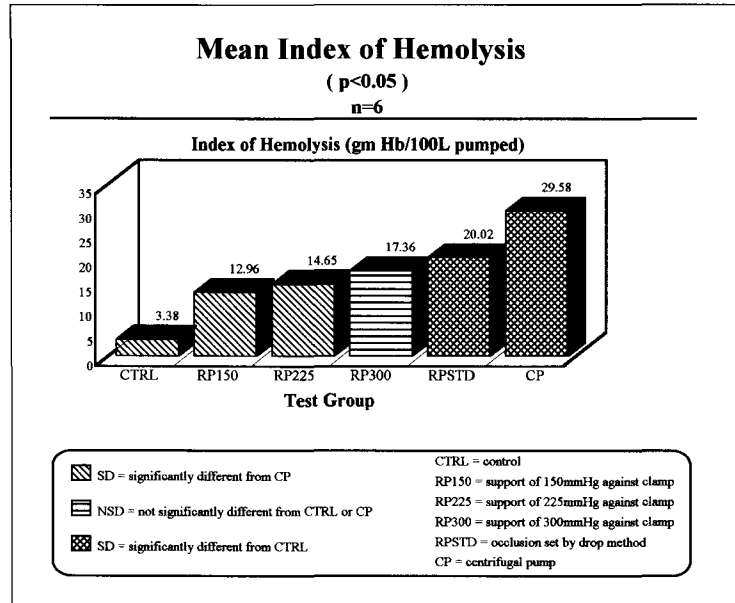
Analysis of variance revealed a significant difference ( $p \leq 0.001$ ) among the treatments tested. Table 1 shows the mean

Table 1:

	CTRL	RP150	RP225	RP300	RPSTD	CP
MEAN	3.38	12.96	14.65	17.36	20.02	29.58
STDEV	1.28	8.23	7.97	7.99	10.92	10.59

Mean IH (gm Hb/100L pumped) and standard deviation for each test group

Figure 2:



IHs and standard deviations for each test group. The calculated IHs were compared by ANOVA and Tukey's multiple comparison procedure whereby  $p \leq 0.05$  was considered to be significant. The results of the comparison tests and the differences between the test groups are graphically<sup>m</sup> depicted in Figure 2.

## DISCUSSION

The results of this in-vitro evaluation demonstrate that there is no difference in hemolysis rate between a roller pump with a standard set occlusion and a centrifugal pump at 4.5 L/min blood flow rate with an afterload of 250 mmHg ( $\pm 10$  mmHg). Open-

h Gish Biomedical, Inc., Model EC125 S, Irvine, CA 92714  
 i Medtronic Bio-Medicus, Inc., Model DP38, Eden Prairie, MN 55344  
 j Curtin Matheson Scientific, Inc., Model 059188  
 k DLP, Inc., Grand Rapids, MI 49501  
 l Minitab, Minitab, Inc., State College, PA 16801  
 m Harvard Graphics, Software Publishing, Inc., Mountain View, CA 94039

ing the occlusion on a roller pump decreases the rate of hemolysis (3,4,7). When the roller pump occlusion is opened such that 5 RPMs against a clamp supports a pressure of 150-225 mmHg ( $\pm 10$  mmHg), the roller pump hemolysis rate is significantly less than the IH of the CP. This is consistent with the findings of Lee-Sensiba, Tortolani, and Tamari, where a non-occlusive roller pump produced significantly less ( $p < 0.02$ ) hemolysis than a centrifugal pump (communication with Yehuda Tamari, 3/14/95). In this study an afterload of 250 mmHg ( $\pm 10$  mmHg) resulted in significantly greater IH in the CP compared to the RPs set to be non-occlusive. The pressure/flow relationship for each pump evaluated was 0.05 mmHg/ml/min. These results prove to be inconsistent with a study from Tamari, et al (5), where it was shown for pressure/flow ratio below 1 mm/ml/min, a CP proved to be less hemolytic, and above 1 mmHg/ml/min, a roller pump demonstrated less hemolysis. The standard roller pump occlusion setting was not significantly different from the CP and the other roller pump occlusion settings. However, the very non-occlusive settings (RP-150, RP-225) resulted in significantly lower IH than the CP.

Based on these results, one is encouraged to perform a clinical study to measure the effect of opening the occlusion setting. Issues of hemolysis and other cell destruction, and accuracy and safety of predicting blood flow rate as afterload varies should be explored.

## CONCLUSIONS

1. The barely non-occlusive roller pump is not significantly different in rate of hemolysis from the centrifugal pump.
2. An under-occluded roller pump is less hemolytic than a centrifugal pump at 4.5 liters of blood flow per minute and an afterload of 250 mmHg.
3. The hemolysis caused by an under-occluded roller pump is not significantly different from the hemolysis caused by a barely non-occlusive pump.
4. The quantity of backward flow set in the non-occlusive groups is constant at a given afterload over the range of RPMs and blood flows employed in this study.

## ACKNOWLEDGMENTS

We wish to express our appreciation to Medtronic, Inc. for donating the centrifugal pump heads and flow probes used in this study. We also take this opportunity to thank Sorin, B.A. for loaning the roller pumps used in this application.

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