

**Effect of the CLC2000™
on Hematocrit, Hb, Free Hb, and LDH
in an in-vitro dialysis system.**

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Introduction

The CLC2000, a novel intravenous device (ICU Medical Inc., San Clemente, CA), has been designed to eliminate retrograde blood in the catheter lumen and reduce overall complications related to catheter occlusion.

Objective

The aim of this study, performed at the Renal Research Institute (New York), was to evaluate the CLC2000 using Hematocrit (Hct), Hemoglobin (Hb), Free Hemoglobin (FHgb) and Lactic Dehydrogenase (LDH) as parameters of hemolysis. The CLC2000 was then compared to the Hub to Hub connection in an in-vitro Hemodialysis (HD) setting.

Design

Seven sets have been tested. Each set consisted of two sessions, one with a direct link between arterial and venous line (Hub to Hub), and the other with the CLC2000 inserted.

Materials

- a. Fresenius 2008H HD-machine
- b. Standard extracorporeal tubing
- c. F5 or F6 Hemodialyzers
- d. CLC2000 Samples
- e. Four units of human blood from blood bank tested negative for HIV and Hep. C
- f. Saline
- g. Recommended collection tubes (lavender, red top)
- h. Scale/weights
- i. Disposables: syringes, saline bags etc.

Methods

Experimental Steps:

1. Setup HD-system and prime with saline.
2. Prepare blood bag which will serve as blood pool.

- 2.1. Dilute one unit blood with saline (approximately 500 ml) to 750 ml; add 5000U (units) heparin.
- 2.2. Split blood into 2 portions:
First portion=Control
Second portion=CLC2000
3. Connect blood pool to HD-machine.
- fill extracorporeal system (no dilution!)
4. Connect arterial and venous sides.
 - 4.1. Control = Hub to Hub
 - 4.2. CLC2000
5. Simulate dialysis for 3 hours at a blood flow $Q_b = 300$ ml/min, dialysate flow $Q_d = 800$ ml/min, Ultrafiltration rate $UFR = 0$.
6. Retrieve samples for Hct, Hb, FHgb and LDH: 0 min, 15 min, 60 min, 120 min and 180 min for each test system.
 - 6.1. Add 2000U heparin to pool at 120 min elapsed dialysis time.

Calculations

Priming volume extracorporeal system: 250ml
Samples: +50 ml
Recirculation volume / dilution: +75 ml
per set 2x 375 ml

In a normal patient approximately 4L blood are being accessed. At a $Q_b = 400$ ml/min - 72L blood get dialyzed or the 4L get cleaned 18 times during 3 hours.

350mL blood circulates for 3 hours. In order to reach the same proportions this sized down in vitro setup should run at $Q_b = 35$ mL/min. A $Q_b = 300$ mL/min equals a 7x greater force.

Statistics

Data are expressed as mean \pm standard deviation. Hub to Hub and CLC2000 Hb- and LDH-data were compared using the two-tailed t-test and a probability ($P > 0.05$) was considered significant to reject the null hypothesis.

Table 1:

Mean Hematocrit [%]; Hb [g/dL]; Free Hb [g/dL]; LDH [U/L]) values \pm standard deviation

	0 min	15 min	60 min	120 min	180 min
Hct CLC	27.3 \pm 3.45	26.2 \pm 4.03	28.8 \pm 4.30	32.6 \pm 4.37	37.5 \pm 8.09
Hct Hub	27.4 \pm 5.52	26.9 \pm 3.95	29.6 \pm 4.38	33.2 \pm 4.89	36.2 \pm 4.35
Hb CLC	9.2 \pm 1.23	9.0 \pm 1.28	10.1 \pm 1.42	11.2 \pm 1.36	12.9 \pm 2.67
Hb Hub	9.0 \pm 1.74	9.2 \pm 1.41	10.3 \pm 1.55	11.6 \pm 1.68	12.6 \pm 1.51
FHgb CLC	21.8 \pm 18.55	60.0 \pm 46.73	102.3 \pm 57.0	135.9 \pm 75.36	236.2 \pm 212.83
FHgb Hub	17.3 \pm 11.94	33.1 \pm 27.77	54.6 \pm 63.66	62.8 \pm 58.53	112.2 \pm 137.43
LDH CLC	246.7 \pm 85.48	317.4 \pm 148.62	414.7 \pm 144.90	534.1 \pm 203.89	764.6 \pm 506.35
LDH Hub	231.6 \pm 86.67	292.7 \pm 112.42	367.3 \pm 172.79	457.1 \pm 201.86	567.4 \pm 305.72

Figure 1: Mean Hct [%] vs time

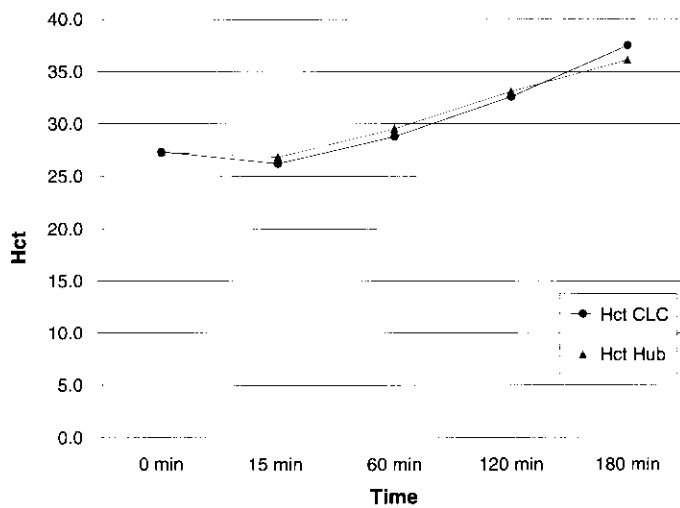


Figure 2: Mean Hb [g/dL] vs time

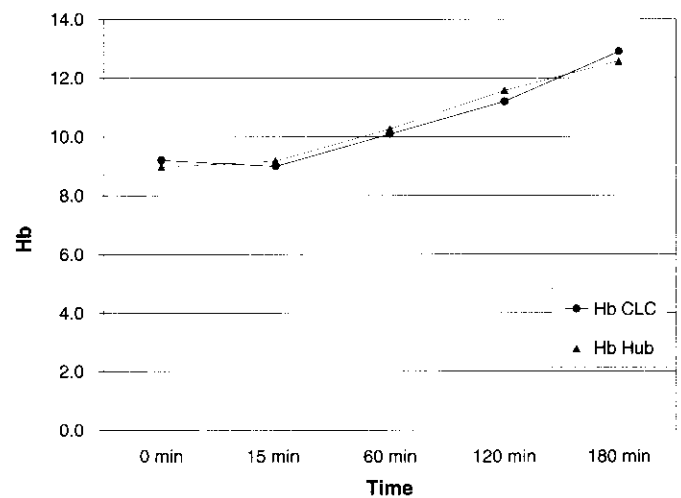


Figure 3: Mean FHgb [g/dL] vs time

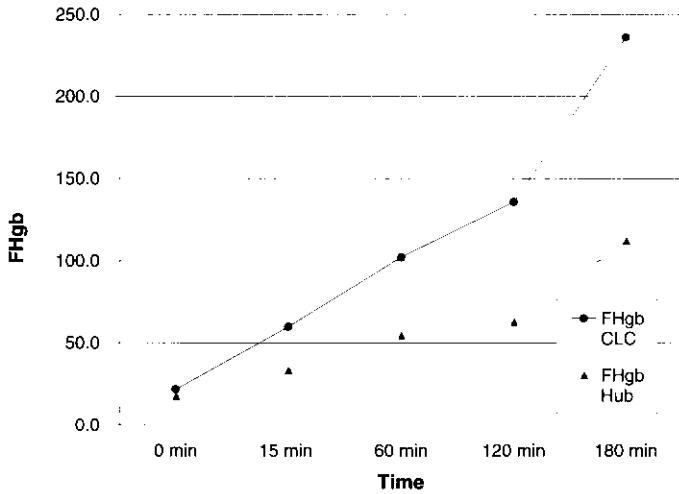


Figure 4: Mean LDH [U/L] vs time

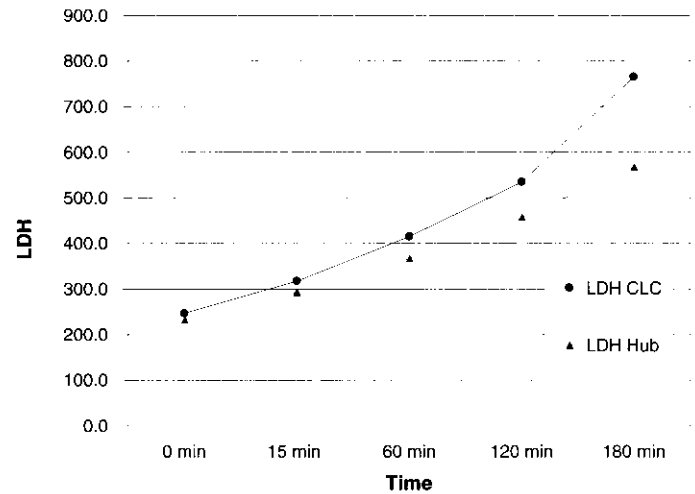


Table 2:

Sample times and statistical analysis of the CLC2000 data using the two-tailed t-test given in table 2. (Probability P>0.05)

(II-Hb [g/dL]; III-Free Hb [g/dL]; IV-LDH [U/L])

<i>Time in min</i>	<i>II P-value</i>	<i>III P-value</i>	<i>IV P-value</i>
0= pre	0.93	0.640	0.79
15	0.77	0.087	0.60
60	0.77	0.098	0.43
120	0.69	0.089	0.36
180= post	0.62	0.260	0.36

Conclusions:

There was no significant difference between the mock dialysis using the control (hub to hub) and the CLC2000. The data shows that no significant hemolysis occurred in the CLC2000 during extreme in-vitro conditions, which were equal to seven times the stress of regular dialysis.