In Vitro Analysis of the Physical Characteristics of Femoral Bypass Cannulae

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ABSTRACT

The physical dimensions and flow characteristics of arterial and venous femoral cannulae were evaluated. An in vitro femoral bypass simulator was employed to measure pressure drop across various O.D. arterial and venous cannulae from Cook Inc., C.R. Bard Inc., D.L.P. Inc., Shiley, Inc. and BioMedicus Inc. 30°C, 40% hematocrit bovine blood was employed with a Biomedicus BP-80 vortex pump. Pressure drop, peak flow velocity, shear rate, and Reynold's numbers were statistically compared. The maximum "safe" flow rate for each cannula was determined. The blood flow rate that yielded a pressure drop greater than 200 mmHg for the arterial cannulae, and the blood flow rate achieved at 300 mmHg Bio-pump inlet pressure for the venous cannulae are:

Arterial Cannula	Blood Flow L/min @ 200 mmHg	Venous Cannula	Blood Flow l/min @300 mmHg
16 Fr. Biomedicus	3.5	18 Fr. Biomedicus	3.0
20 Fr. Canyon	4.0	20 Fr. Canyon	4.0
19 Fr. Biomedicus	5.0	18 Fr. Bard	4.5
20 Fr. Cook	6.0	20 Fr. Bard	6.5
17 Fr. CR Bard	6.0	21 Fr. DLP	6.5
20 Fr. Shiley	>6.5	26 Fr. Shiley	>6.5
20 Fr. C.R. Bard	>7.0	24 Fr. Biomedicus	>7.5
21 Fr. DLP	>7.0	29 Fr. Cook	>8.0

For the smallest Fr. O.D. to facilitate insertion and to yield the maximum safe (turbulence and friction) blood flow rate, the 20 Fr. C.R. Bard arterial cannula in tandem with the 20 Fr. C.R. Bard, or 21 Fr. DLP venous cannula, appear to be the optimal choice for full-flow femoral bypass.

INTRODUCTION

The Cardiopulmonary Support System (CPS) is designed to provide total circulatory and respiratory support in an emergency setting (Bard Cardiopulmonary Support System Description and Directions for Use)[a]. CPS can be used as a bridge to surgery for the unstable patient, as a resuscitative tool in the event of cardiac and/or respiratory arrest, and to support the 3.5% of percutaneous transluminal coronary angioplasty patients that require emergency bypass surgery every year.[1,5] The American College of Cardiology and the American Heart Association recommend that a cardiovascular surgical team stand by for all angioplasty procedures.[1,5] Femoro-femoral cannulation of arterial and venous sites should provide adequate flow for cardiopulmonary support and cardiac decompression in compromised, normothermic patients. The specific qualities of the femoral cannulae which minimize the risks associated with this cannulation procedure are: 1) smooth, tapered tip, 2) thin-walled, yet non-collapsible, and 3) smooth blood interface continuation with minimal stagnation.[2] **Table One** lists the test cannulae manufacturers and physical dimensions which were compared in this study. Evaluating the results with regard to fluid dynamics and the possibilities of limited blood flow, excessive pressure drop, and estimated blood component damage will allow an appropriate clinical choice of femoral cannulae.

BACKGROUND

Pfaender[2] and Riley, et al.[3] list possible physiologic complications with regards to the inappropriate use of cannulae. These complications may include limited perfusion capabilities with possible neurologic or renal sequelae, dissection or transection of the vessel and possible intimal damage.

The ideal cannula will provide maximal flow at minimal pressure drop, Friction Coefficient (energy loss or drag at blood surface interface) and Reynold's number (conversion from laminar to turbulent flow), with the smallest outside diameter.[6,7] The purpose of this observation is to evaluate currently available arterial and venous femoral cannulae in regard to pressure drop generated, maximum safe flow achieved, and estimated blood handling ability.

MATERIALS AND METHODS

The in vitro circuit in **Figure One** accommodated the venous and arterial cannulae and was primed with 40% hematocrit bovine blood at 30°C.[3] The bovine blood was heparinized sufficiently to maintained ACTs greater than 500 seconds. The CVP was maintained at 7-10 cm, RPMs were varied to increase blood flow in 0.5 L/min increments. Pressure measurements were obtained using Gould[b] and ValiDyne[c] monitors calibrated according to manufacturers' instructions for use.

Three repetitions of observations of cannulae inlet and outlet pressure, vortex pump[d] RPM and blood flow, and CVP at each flow increment were recorded for all cannulae pairs. The

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a. Bard Cardiopulmonary Division, Billerica, MA observations were entered into a computer spreadsheet[e] for further computation and statistical analysis.[f] The mean and standard deviation for each of the three observed cannula pressure drop at test flow increments were calculated. Two way analysis of variance was employed to confirm data trends and specific flow test increment pressure drop points were compared by hypothesis tests between means with known variances.[f]

The cannulae dimensions and mean pressure drops were employed to estimate individual cannulae flow velocity, Reynolds' Number, and Friction Coefficient with the following algorithms.[4,6-7]

RE=VEL*1.08*(ID/2))/.04 - Eq.1

FC=(DP*1.36/.5*1.08*VEL^2)*((ID/2)/LEN) - Eq. 2

where: RE = Reynolds' No.
VEL = velocity cm/sec
1.08 = density gm/cm^3
ID = Inside Diameter cm
.04 = viscosity in poise
FC = Friction Coefficient (unitless)
LEN = insertable length cm
DP = pressure drop mmHg
1.36 = cm blood/mmHg

A cannula Efficiency Index (EI) was calculated to include the influence of pressure drop, operating size (O.D.), at a specific blood flow:

EI=DP*OD/BF - Eq. 3

where: EI = mmHg*cm/L/min
BF = blood flow L/min
OD = Outside Diameter cm

The Friction Coefficient versus the Reynolds' Number was plotted on a log-log scale to discover the blood flow where turbulence began for each cannula design.[7] The cannulae were ranked and plotted for lowest Efficiency Index and highest blood flow where turbulence began.

RESULTS

Appendix One lists the raw data for the simulator cannulae observations. Appendix Two lists the flow dynamics computations for each cannula design. **Figures 2, 3, 4 and 5** track and rank the pressure drop versus vortex pump flow for each cannula. **Figures 6** and **7** plot and rank individual cannula Efficiency Index and operating size. **Figure 8** illustrates an example of the slope change that indicates the beginning of turbulent blood flow.

Figures 9 and **10** represent and rank the cannula blood flow where turbulence begins. **Figures 11** and **12** compare vortex pump RPM and cannulae blood flow rates.

DISCUSSION

Figures 2 and **4** present cannulae indicated for partial bypass with pressure drops greater than -300 mmHg for venous cannula blood flows 4.0 L/min and greater, and pressure drops greater than 200 mmHg for arterial cannula blood flows 4.0 L/min and above. The simulator test blood with hematocrit of 40% at 30°C was high viscosity by clinical standards. **Figures 3** and **5** illustrate cannulae indicated for total bypass with pressure drops less than -300 mmHg for venous cannula blood flows of 5.0 to 8.0 L/min and less than 200 mmHg for arterial cannula blood flows of 6.0 to 7.5 L/min .

The Canyon 20 Fr[g] and Biomedicus 16 Fr femoral arterial cannulae are not competitive in **Figure 7** that ranks the test cannulae for pressure drop efficiency and operating outside diameter. The CR Bard 18 Fr, Canyon 20 Fr, and Biomedicus 18 Fr femoral venous cannulae are not competitive in **Figure 6** that ranks the test cannulae for pressure drop efficiency and operating outside diameter. The Cook 29 Fr venous[j] cannula demonstrated competitive efficiency measures, however, the O.D. will limit its application.

Figure 8 illustrates that the blood flow where turbulence occurs is near a Reynolds' number of 1000 and a Friction Coefficient of 1*10^4.[6,7] Coulter and Papenheimer[6] state that significant hemolysis occurs after 60 to 100 minutes of flow at Reynolds' Numbers greater than 1000 - 2000 and blood velocities greater than 100 - 120 cm/sec. The simulator direct cannulae pressure and flow measurements conformed with published mathematical models for turbulence and energy loss. Low pressure drop measurements alone correlate with the more complex turbulence equation results, if the test cannulae have the same physical geometry. **Figures 9** and **10** suggest the cannulae blood flows where measurable clinical hemolysis will be observed.

Figures 9 and **10** which rank the cannulae blood flows where turbulence begins, corroborate the cannulae efficiency ranking in **Figures 6** and **7.** Examination of the generated cannulae pressure drops and the estimations of Friction Coefficient and Reynolds' number, and consideration of cannulae outside diameter indicates the CR Bard 20 Fr venous and CR Bard 20 Fr arterial cannulae will provide full flow femoral cardiopulmonary bypass with minimal estimated damage to blood components and femoral vessels. The DLP 21 Fr Venous[h] and Shiley 20 Fr arterial[i] cannulae will provide comparable performance.

b. Gould Inc. Oxnard, CA
c. ValiDyne Engineering Corp., North Ridge, CA
d. BioMedicus, Eden Prairie, MN
e. Lotus Development Corp., Boulder, CO
f. Ecosoft, Inc., Indianapolis, IN
g. Canyon Medical Products, Salt Lake City, UT
h. DLP, Inc., Grand Rapids, MI
i. Shiley, Inc., Irvine, CA
j. Cook Inc., Bloomington, IN

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TABLE 1 - MANUFACTURER O.D., WALL THICKNESS AND INSERTABLE LENGTH OF TEST CANNULAE

FEMORAL CANNULAE

ARTERIAL AND VENOUS

CANNULA MANUFACTURER:	OUTSIDE DIAMETER:	WALL THICKNESS:	INSERTABLE LENGTH:
BIOMEDICUS	16 Fr Art	.072 In	10.4 cm
	19 Fr Art	.085	16.4
	18 Fr Ven	.085	45.6
	24 Fr Ven	.085	38.6
DLP	21 Fr Art	.071 In	10.8 cm
	21 Fr Ven	.072	53.6
C.R. BARD	17 Fr Art	.034 In	16.5 cm
	20 Fr Art	.043	13.1
	18 Fr Ven	.042	59.0
	20 Fr Ven	.047	59.2
CANYON	20 Fr Art	.068 In	30.5 cm
	20 Fr Ven	.071	61.0
COOK	20 Fr Art	.055 In	15.3 cm
	29 Fr Ven	.054	54.9
SHILEY	20 Fr Art	.059 In	8.0 cm
	26 Fr Ven	.073	67.0

Direct Caliper Measurement

FIGURE 1 - IN VITRO FEMORAL CANNULAE, ECC SIMULATOR CIRCUIT

FIGURE 2 - PRESSURE DROP ACROSS FEMORAL VENOUS CANNULAE FOR PARTIAL BYPASS

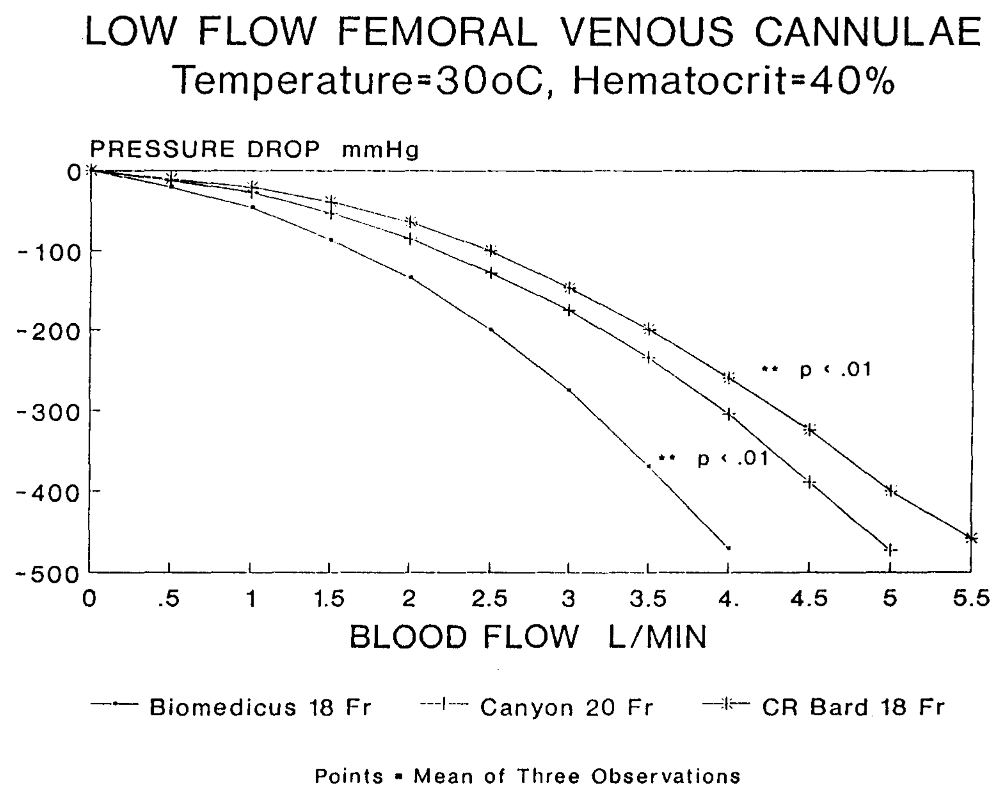

FIGURE 3 - PRESSURE DROP ACROSS FEMORAL VENOUS CANNULAE FOR TOTAL BYPASS

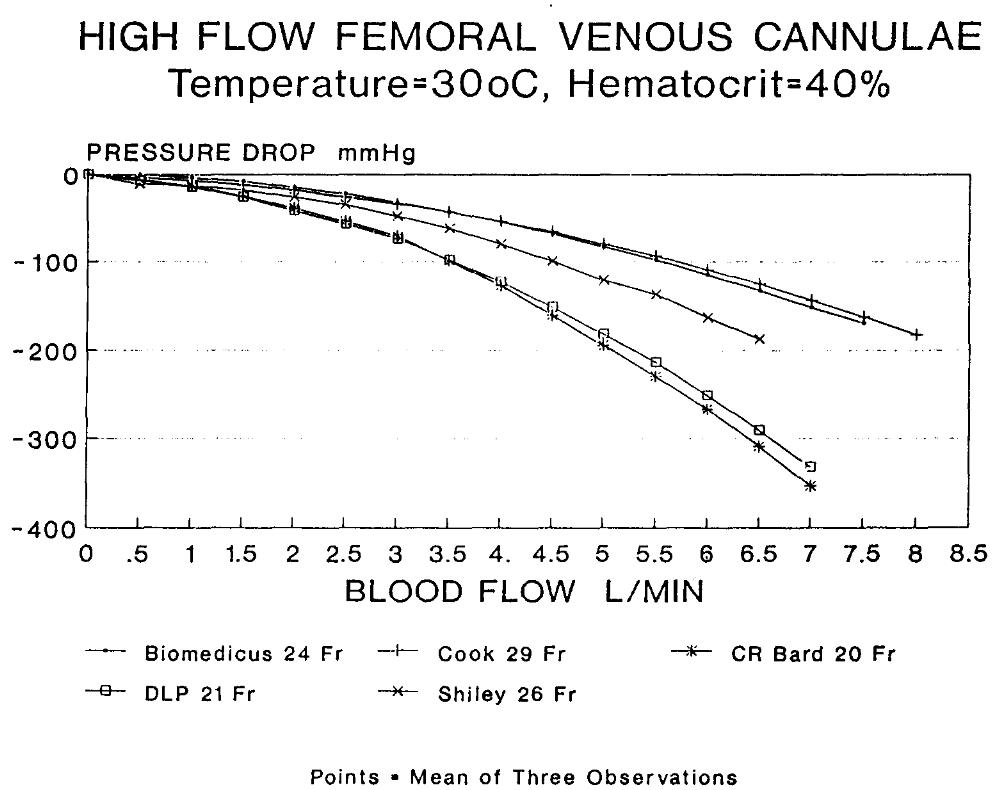

FIGURE 4 - PRESSURE DROP ACROSS FEMORAL ARTERIAL CANNULAE FOR PARTIAL BYPASS

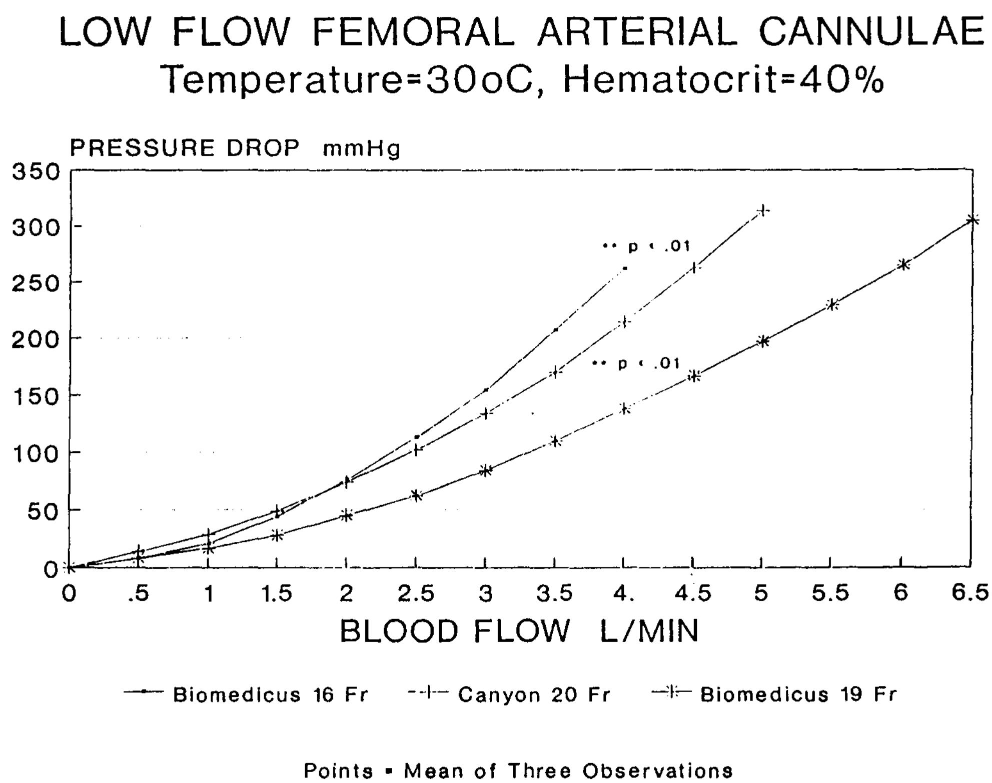

FIGURE 5 - PRESSURE DROP ACROSS FEMORAL ARTERIAL CANNULAE FOR TOTAL BYPASS

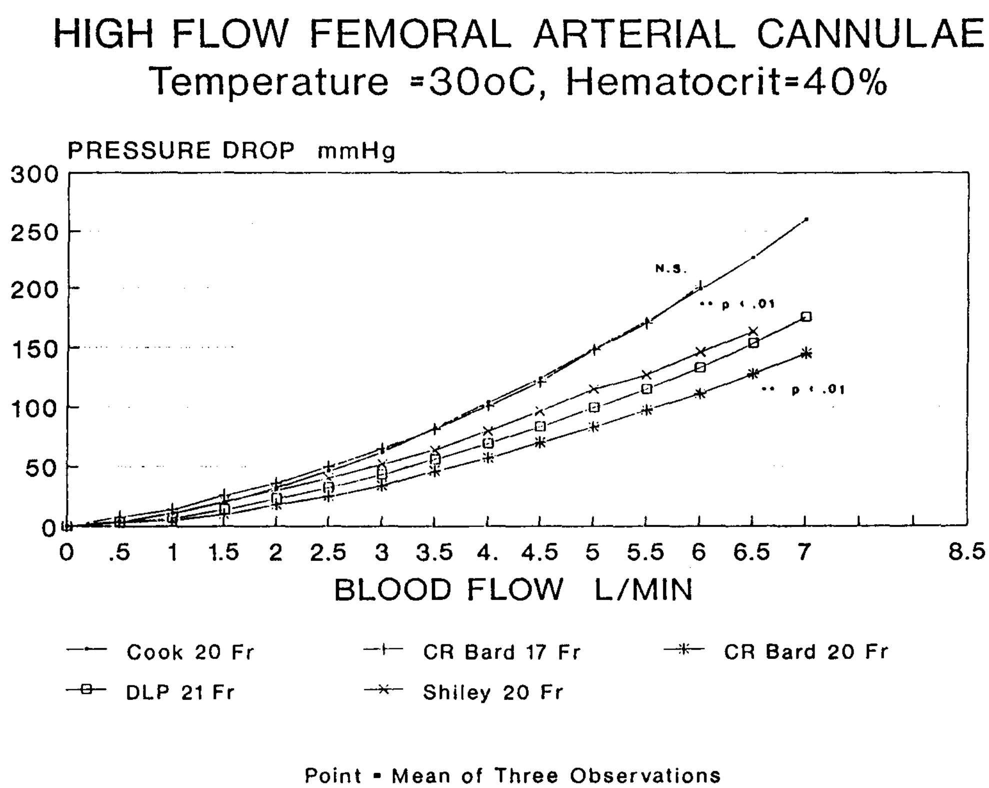

FIGURE 6 - EFFICIENCY INDEX AT FOUR LITERS PER MINUTE (HCT = 40%, TEMP = 30°C) FOR TEST VENOUS CANNULAE

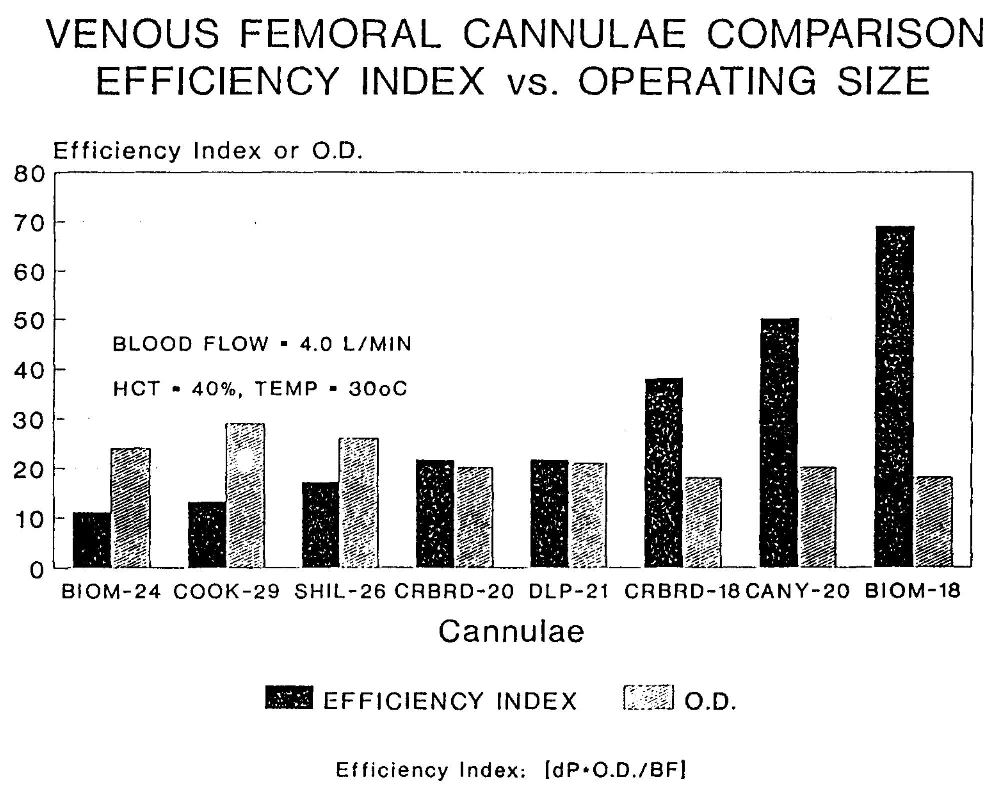

FIGURE 7 - EFFICIENCY INDEX AT FOUR LITERS PER MINUTE (HCT = 40%, TEMP = 30°C) FOR TEST ARTERIAL CANNULAE

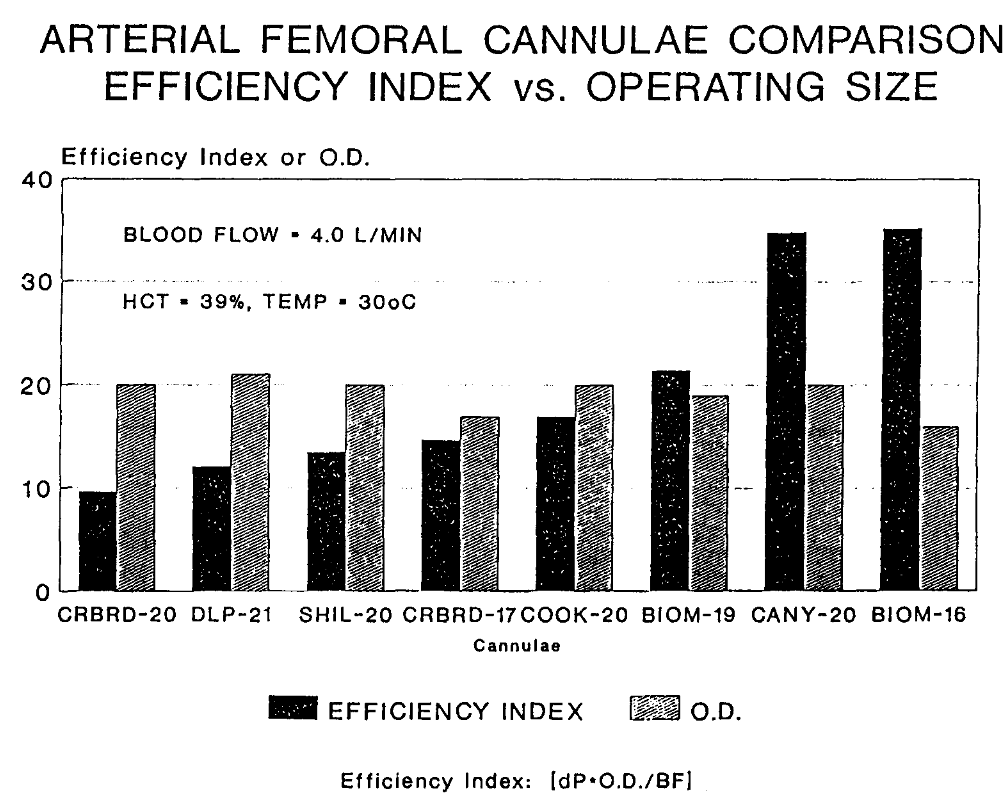

FIGURE 8 - FLOW POINT (2.5 L/MIN, HCT = 39%, TEMP = 30°C) WHERE TURBULENCE BEGINS FOR SHILEY 26 FRENCH VENOUS CANNULAE

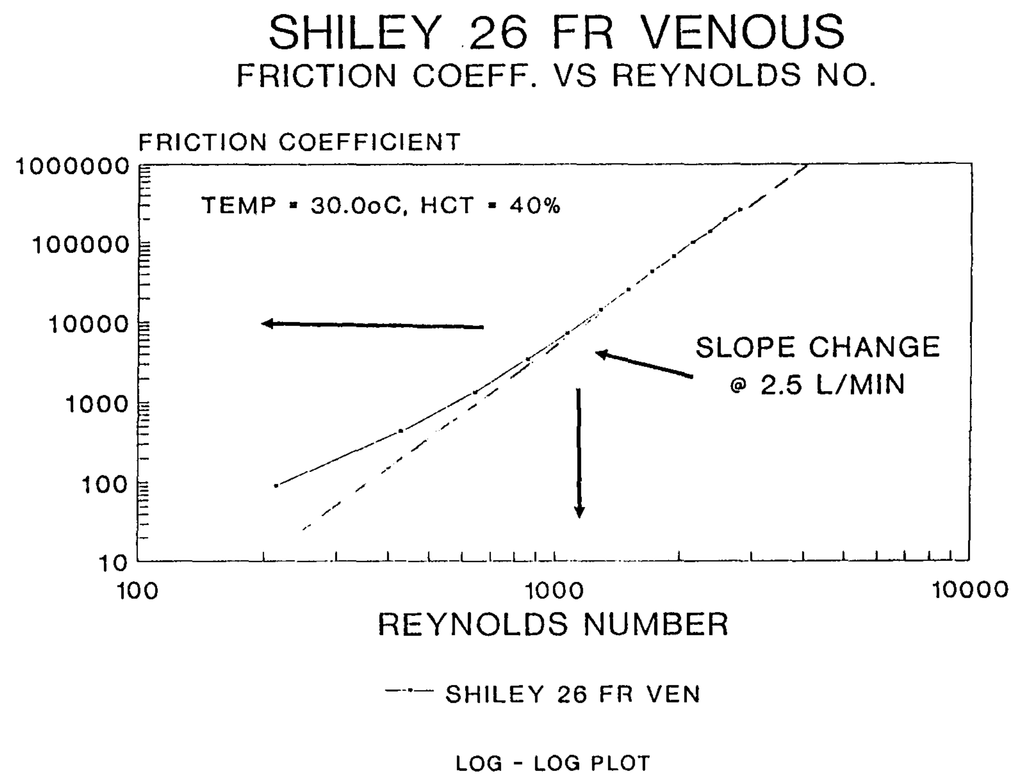

FIGURE 9 - BLOOD FLOW RATE (HCT = 40%, TEMP = 30%) WHERE TURBULENCE BEGINS FOR TEST VENOUS CANNULAE

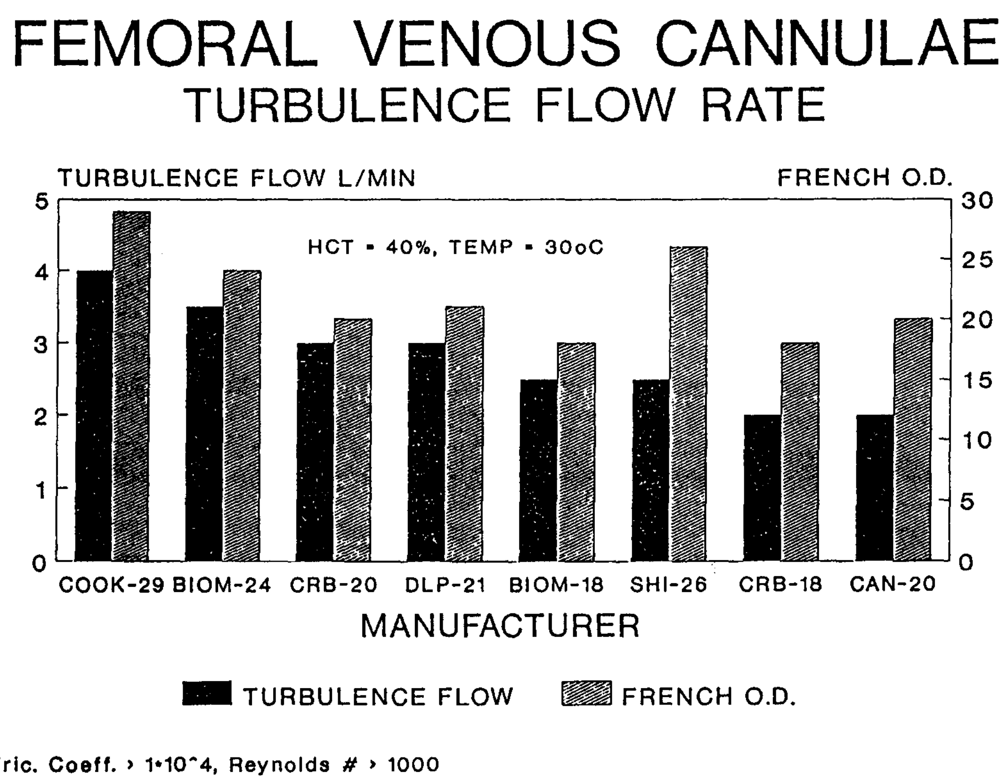

FIGURE 10 - BLOOD FLOW RATE (HCT = 40%, TEMP = 30°C) WHERE TURBULENCE BEGINS FOR TEST ARTERIAL CANNULAE

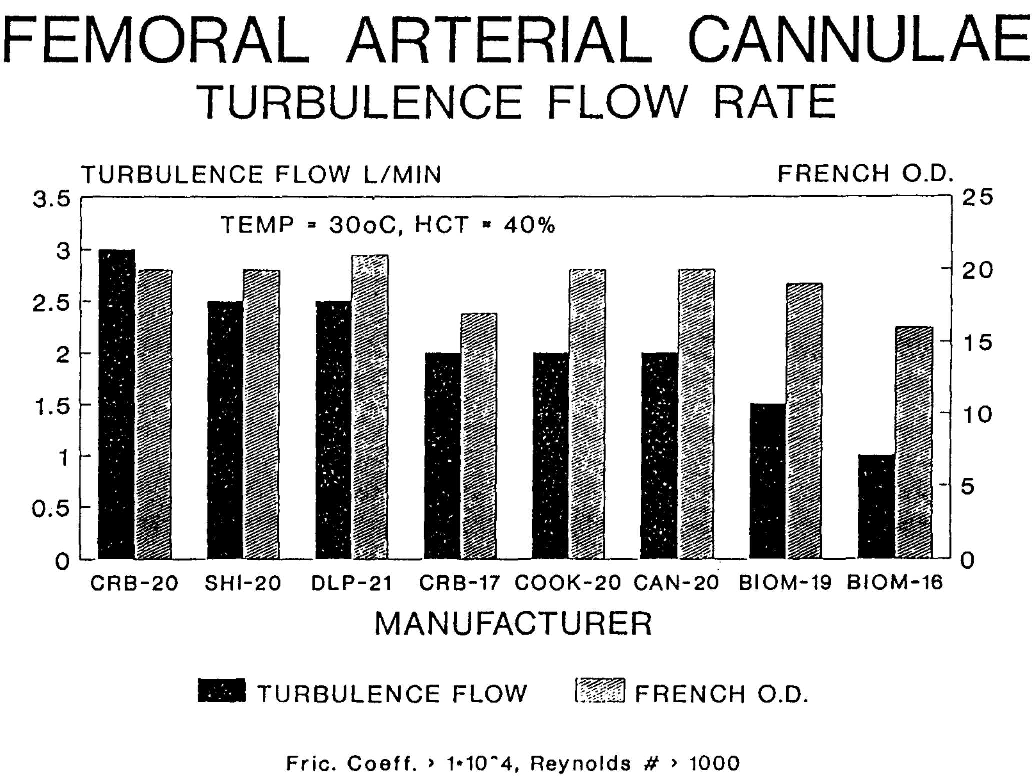

FIGURE 11- VORTEX PUMP RPM'S FOR BLOOD FLOW RATES (HCT = 40%, TEMP = 30°C) FOR TEST VENOUS CANNULAE. CANNULA PRESSURE DROP MAY BE READ FROM FIGURE FOUR OR FIVE.

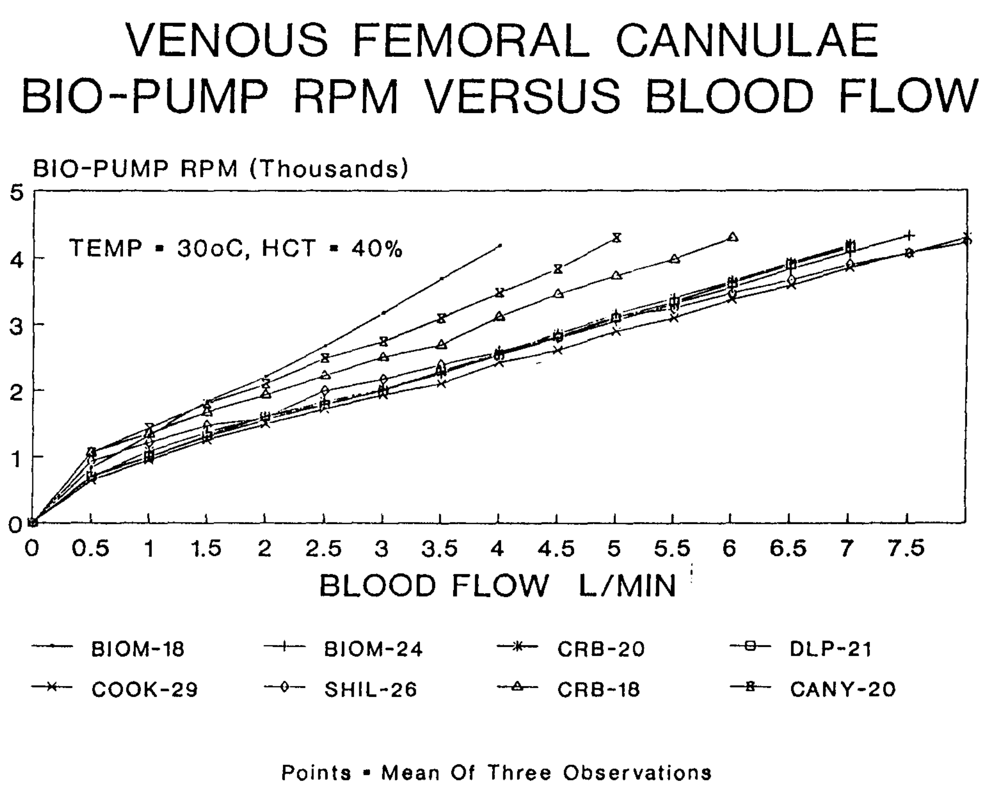

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FIGURE 12 - VORTEX PUMP RPM'S FOR BLOOD FLOW RATES (HCT = 40%, TEMP = 30°C) FOR TEST ARTERIAL CANNULAE. CANNULA PRESSURE DROP MAY BE READ FROM FIGURE FOUR OR FIVE.