Blood Volume Sequestration in Cardiotomy Reservoirs: An In-Vitro Evaluation

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Abstract

An in-vitro evaluation of the dynamic volume loss of several clinically available cardiotomy reservoirs was conducted. The reservoirs were grouped according to microfiltration rating (20 to 40 u) and the dynamic sequestration of each was examined over a blood flow range of 0 to 8 L/min. A statistically significant decrease in both static and dynamic volume loss was found to be associated with increasing microfiltration pore size. Furthermore, significant differences in volume sequestration were demonstrated between devices within each group over the blood flow range of 0 to 3200 ml/min. The Dideco D-744 reservoir was found to produce the least volume sequestration over this flow range. The Dideco D-742 and Bard H-710F exhibited somewhat greater volume losses over the same flow range. The Bard H-700F and American Bentley BCR-3500 and Q-220F exhibited the greatest static and dynamic volume losses of the reservoirs tested. Total recoverable blood volume was evaluated and the Dideco D-744, D-742 and Bard H-710 were found to be superior, in this respect, to the other devices examined in this series.

The data presented demonstrates that, of the devices tested, the D-744, D-742 and H-710F are superior to the others in high cardiotomy flow applications where sequestration may be of significant concern.

Introduction

Many devices incorporated into extracorporeal support systems, of necessity, incorporate a "defoaming chamber" design for phase separation. This chamber usually consists of a mass of reticulated foam (onto which is coated a measured quantity of antifoam compound), contained by a woven fabric "sock." The air/blood foam mixture introduced into this chamber passes radially through the foam matrix pores, allowing exposure to surface active agents to return the blood to its normal suspension state. Depending upon design and application considerations, a filter matrix may also be included to provide for microfiltration of the blood suspension.

Interposition of any material, through which blood must flow, creates an impediment to such flow, resulting in inlet side sequestration and/or increasing differential pressure across the intervening matrix. This characteristic has been repeatedly described in discussions of bubble oxygenator performance[1,2,3,4,5] and occasionally with reference to cardiotomy reservoir performance[3]. In the authors' experience, the primary design considerations which determine the extent of operational sequestration (dynamic loss) are porosity, thickness and frontal surface area of the interposed matrix.

Although dynamic loss within cardiotomy reservoirs may be minimal during cardiopulmonary bypass involving relatively low flow suction return, its importance can become quite significant during high flow utilization such as autotransfusion. With the development of microfiltration cardiotomy reservoirs, an additional barrier to unimpeded blood flow has been introduced into the cardiotomy system.

This study was undertaken to evaluate the combined effects of design configuration and materials selection, in some of the currently available cardiotomy reservoirs, with respect to this sequestration phenomenon. Although we have not, by any means, examined all devices currently available in the clinical market, we have attempted to evaluate a representative sampling of varied design and microporosity.

Methods

A series of clinically available filtered cardiotomy reservoirs were examined to establish the extent of volume retention at operational flow rates and the

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Table 1
Composition of Test Device Groups

	Group A				Group B			
Manufacturer	Device	# Tested	Pore Size (u)	Matrix Type	Device	# Tested	Pore Size (u)	Matrix Type
Bard Cardiopulmon.	H-700F	2	20	Screen	H-710F	3	40	Screen
Electromedics	D-742	2	20	Screen	D-744	3	40	Screen
American Bentley	BCR-3500	2	20	Foam	D-220F	3	27	Foam

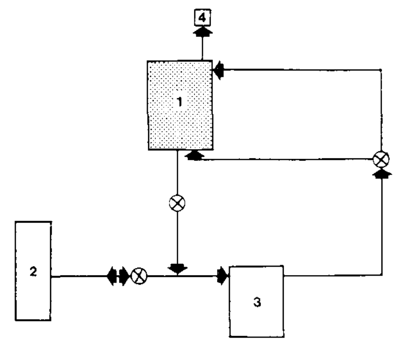
amount of unrecoverable volume following use. The type and number of devices tested, as well as their design specifications are detailed in Table 1.

Each device was examined by inclusion in an in-vitro circuit constructed as depicted in Figure 1. The circuit provides for direct, retrograde priming of the cardiotomy reservoir from a laboratory graduate, thereby insuring precise, comparable prime volume administration to each device examined. The reservoirs were grouped into two test groups (Group A and Group B) according to their microfiltration rating (as defined by manufacturer's specifications). The order of examination within each group was altered, such that devices of a given manufacturer were interspersed throughout the testing of the group, to ensure that unidentified changes in blood pool characteristics would not preferentially affect any particular set of test devices.

Prior to priming of the circuit, 4 liters of fresh, heparinized bovine blood was prefiltered by recirculation (5 L/min) through a cardiotomy reservoir of the same microfiltration class as the group to be tested (Group A: Harvey H-700F[a]; Group B: Bentley Q-220F[b]. The prefiltered blood pool was then sequestered in a 10 liter Nalgene reservoir[c].

The device was primed with 1200 ml of prefiltered blood (Hct=34%) by retrograde transfer to the reservoir from a laboratory graduate utilizing a manually advanced roller pump.

Recirculation was initiated at 1600 ml/min to establish "wetting" of the reservoir defoamer. Following 3 minutes of recirculation, flow was stopped and reservoir blood level was allowed to equilibrate for 5 minutes prior to determination of baseline volume. All operational volumes were determined by comparison of meniscus position against the reservoir volume calibration scale. When meniscus level was found to be between



CARDIOTOMY RESERVOIR TEST CIRCUIT

LEGEND

1. Test reservoir
2. Laboratory graduate
3. Roller pump
4. Aneroid manometer

FIGURE 1: Test circuit schematic diagram

calibration marks, a metric ruler was utilized to interpolate, and the volume reported to the nearest 25 ml.

Following establishment of baseline level, recirculation was resumed at 800 ml/min for a 5 minute equilibration period prior to determination of reservoir blood volume under conditions of active flow. Pressure drop across the cardiotomy filter/defoamer was determined utilizing an aneroid manometer attached to a luer port in the top of the defoamer inlet chamber.

This procedure was repeated at flow increments of 800 ml/min to a maximum flow of 8 L/min. At the conclusion of flow tests, flow was terminated and blood from the reservoir returned to the graduate by gravity drainage. To ensure maximum recovery, cardiotomy inlet ports were opened to atmospheric pressure and the reservoir allowed to drain freely for 5 minutes. Recovered volume was then determined by graduate measurement.

Following recovered volume determination, the blood was returned to the "pool" reservoir and mixed

a Bard Cardiopulmonary, Santa Ana, CA 92705
b American Bentley, Irvine, CA 92714
c Fisher Scientific, Tustin, CA 92680

by gentle agitation. A new aliquot of blood was then introduced into the graduate in preparation for the next test.

Results

The mean volume loss data obtained during testing of GROUP A and GROUP B reservoirs are presented in Tables 2 and 4 respectively, while the statistical comparison of that data will be found in Tables 3 and 5. The graphic representation of the relationship between blood flow rate and dynamic volume loss is presented in Figure 2 (GROUP A devices) and Figure 3 (GROUP B devices).

The blood volume recovered following use of each device tested is presented in Table 7 and graphically depicted in Figure 4.

Examination of the data collected for GROUP A devices (Table 2 and Figure 2) clearly shows that the D-742 reservoir[d] demonstrates the lowest dynamic loss over the manufacturer's recommended operational flow range (0 to 5 L/min). This reservoir showed a 75 ml static loss (6.3% of prime volume) as compared to 187.5 ml (15.5%) for the H-700F[e] and 200 ml (16.7%) for the BCR—3500[f].

Under low flow conditions (800 ml/min) the D-742 exhibited a dynamic loss of 125 ml (10.4% of prime volume) increasing to 575 ml (47.9%) under high flow conditions (4800 ml/min). Similar data for the H-700F demonstrates a 187.5 ml static loss (15.6%), 462.5 ml (38.5%) low flow dynamic loss and a high flow dynamic loss of 775 ml (64.6%). A static loss of 200 ml (16.7%) was exhibited by the BCR-3500 reservoir, with low flow and high flow dynamic losses being 637.5 ml (53.1%) and 825 ml (68.8%) respectively. The data collected for GROUP A devices was statistically compared (Table 3) by construction of confidence intervals and compared by two sample t-test[6]. Such analysis demonstrated a highly significant ($p < 0.0010$) trend of improvement in dynamic (and static) losses when comparing the D-742 to either the H-700F or the BCR-3500 reservoirs over an operational flow range of 0-3200 ml/min. Similar comparison of H-700F and BCR-3500 reservoirs demonstrated a significant ($p<0.0500$) difference at flow ranges between 1600 and 3200 ml/min. It should be noted, however, that the excessive standard deviation experienced with the H-700F tests at low flow rates (800-1600 ml/min) adversely affected statistical comparison of *all* GROUP A devices. Testing of a larger sample population would probably have allowed the establishment of statistical significance within this flow range.

Examination of GROUP B devices yielded results generally similar to that experienced in GROUP A testing. The D-744[d] reservoir exhibited the lowest static and dynamic loss over the range of 0-3200 ml/min. The losses demonstrated with the H-710F[e] were greater than those experienced with the D-744 and less than those observed with the Q-220F[h]. Statistical comparison (Table 5) shows statistically significant ($p<0.0100$) differences between all devices in GROUP B through the flow range of 0 to 3200 ml/min.

Comparison of GROUP A and GROUP B data demonstrates a significant improvement in static and dy-

d Electromedics, Inc., Englewood, CO 80012
e Bard Cardiopulmonary, Inc., Santa Ana, CA 92705
f American Bentley, Inc., Irvine, CA 92714

Table 2
Mean Cardiotomy Reservoir Data (Group A)

		H700F				BCR-3500				D-742			
Flow Rate (ml/min)	Prime Volume (ml)	Inlet Pressure (Torr)	Dynamic Volume (ml)	Dynamic Loss (ml)	Std. Deviat.	Inlet Pressure (Torr)	Dynamic Volume (ml)	Dynamic Loss (ml)	Std. Deviat.	Inlet Pressure (Torr)	Dynamic Volume (ml)	Dynamic Loss (ml)	Std. Deviat.
0	1200	0	1012.5	187.5	12.5	0	1000	200	0	0	1125	75	0
800	1200	0	737.7	462.5	112.5	0	562.5	637.5	12.5	0	1075	125	0
1600	1200	0	650	550	50	0	487.5	712.5	12.5	0	975	225	0
2400	1200	0	587.5	612.5	12.5	0	450	750	0	0	900	300	0
3200	1200	0	500	700	25	0	425	775	0	0	812.5	387.5	12.5
4000	1200	5	462.5	737.5	37.5	0	400	800	0	0	712.5	487.5	12.5
4800	1200	5	.425	775	25	0	375	825	0	0	625	575	0
5600	1200	5	400	800	25	0	350	850	0	0	512.5	687.5	12.5
6400	1200	5	362.5	837.5	12.5	0	325	875	0	0	437.5	762.5	12.5
7200	1200	10	300	900	0	0	300	900	0	0	400	800	25
8000	1200	10	287.5	912.5	12.5	0	300	900	0	0	400	800	25

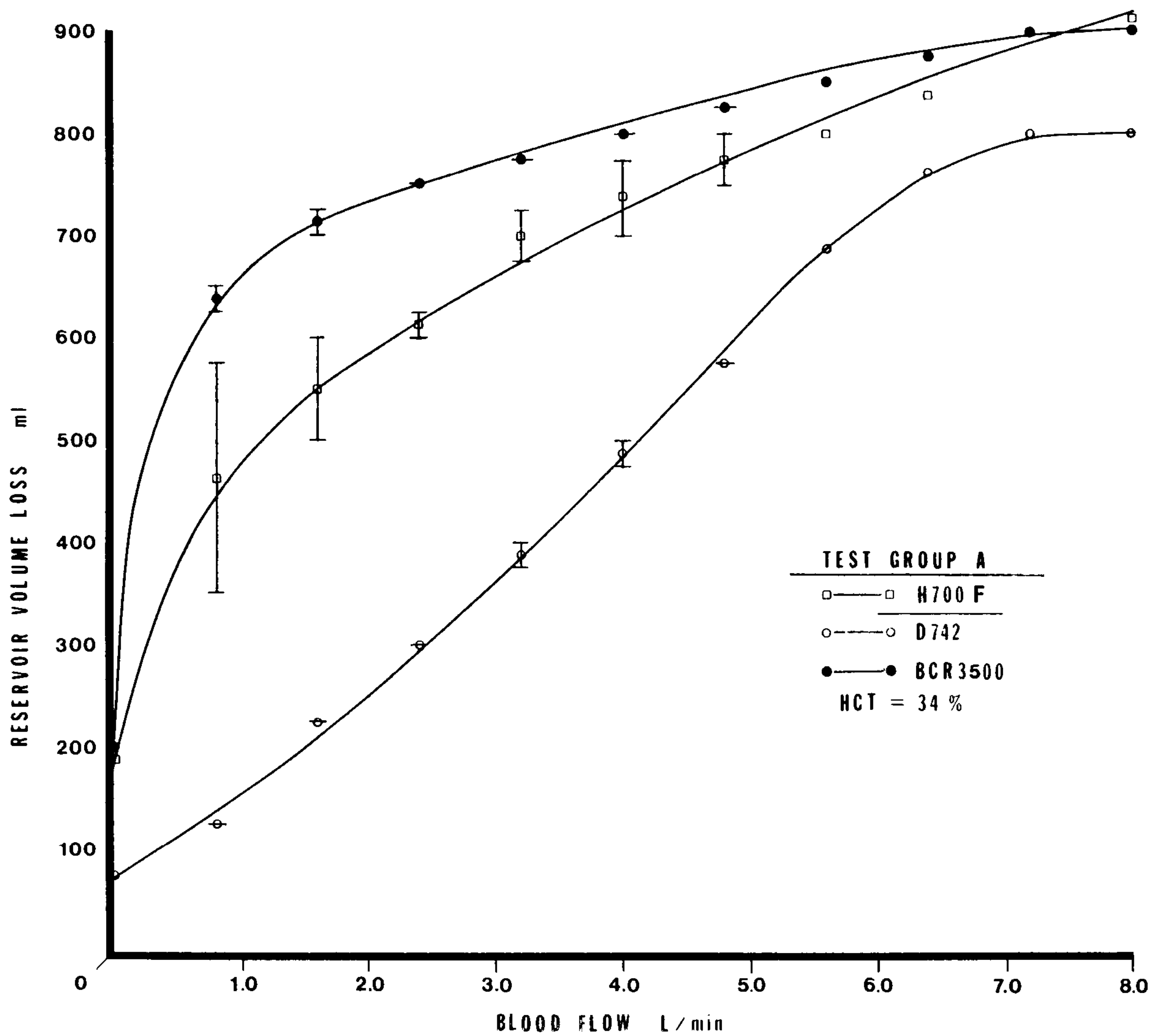


FIGURE 2: Relationship between flow rate and reservoir dynamic loss in GROUP A devices

Table 3
Cardiotomy Data Statistical Analysis (Group A)

Two Sample T-Test N.S. = Not Significant (P0.0100)

	....H-700F Versus D-742..			..H-700F Versus BCR-3500..			....D-742 Versus BCR-3500.		
Flow Rate (ml/min)	# Observ.	T-Stat.	Signif.	# Observ.	T-Stat.	Signif.	# Observ.	T-Stat.	Signif.
0	2	12.72792	<0.005	2	-1.41421	N.S.	2	Error	<0.0005
800	2	4.242641	N.S.	2	-2.18643	N.S.	2	-57.9828	<0.0005
1600	2	9.192388	<0.0100	2	-4.45896	N.S.	2	-55.1543	<0.0005
2400	2	35.35534	<0.0005	2	-15.5563	<0.0025	2	Error	<0.0005
3200	2	15.81139	<0.0025	2	-4.24264	N.S.	2	-43.8406	<0.0005
4000	2	8.944272	<0.0100	2	-2.35702	N.S.	2	-35.3553	<0.0005
4800	2	11.31371	<0.0050	2	-2.82843	N.S.	2	Error	<0.0005
5600	2	5.692100	N.S.	2	-2.82843	N.S.	2	-18.3848	<0.0025
6400	2	6.000000	N.S.	2	-4.24264	N.S.	2	-12.7279	<0.0050
7200	2	5.656854	N.S.	2	Error	<0.0005	2	-5.65685	N.S.
8000	2	5.692100	N.S.	2	1.414214	N.S.	2	-5.65685	N.S.

Table 4
Mean Cardiotomy Reservoir Data (Group B)

		H-710F				Q-220F				D-744			
Flow Rate (ml/min)	Prime Volume (ml)	Inlet Pressure (Torr)	Dynamic Volume (ml)	Dynamic Loss (ml)	Std. Deviat.	Inlet Pressure (Torr)	Dynamic Volume (ml)	Dynamic Loss (ml)	Std. Deviat.	Inlet Pressure (Torr)	Dynamic Volume (ml)	Dynamic Loss (ml)	Std. Deviat.
0	1200	0	1100	100	0	0	975	225	0	0	1175	25	0
800	1200	0	1066.7	133.3	11.8	0	833.3	366.7	11.8	0	1133.3	66.7	11.8
1600	1200	0	1000	200	0	0	725	475	20.4	0	1100	100	0
2400	1200	0	925	275	0	0	683.3	516.7	31.2	0	1100	100	73.6
3200	1200	0	825	375	20.4	0	659.3	541.7	23.6	0	933.3	266.7	11.8
4000	1200	0	675	525	0	0	616.7	583.3	11.8	0	633.3	566.7	11.8
4800	1200	5	600	600	0	0	608.3	591.7	11.8	0	450	750	35.4
5600	1200	10	550	650	0	0	558.3	641.7	11.8	0	508.3	691.7	11.8
6400	1200	13.3	508.3	691.7	11.8	0	533.3	666.7	11.8	0	508.3	691.7	11.8
7200	1200	21.7	466.7	733.3	23.6	0	508.3	691.7	11.8	0	491.7	708.3	11.8
8000	1200	25	433.3	766.7	11.8	1.7	483.3	716.7	11.8	0	475	725	0

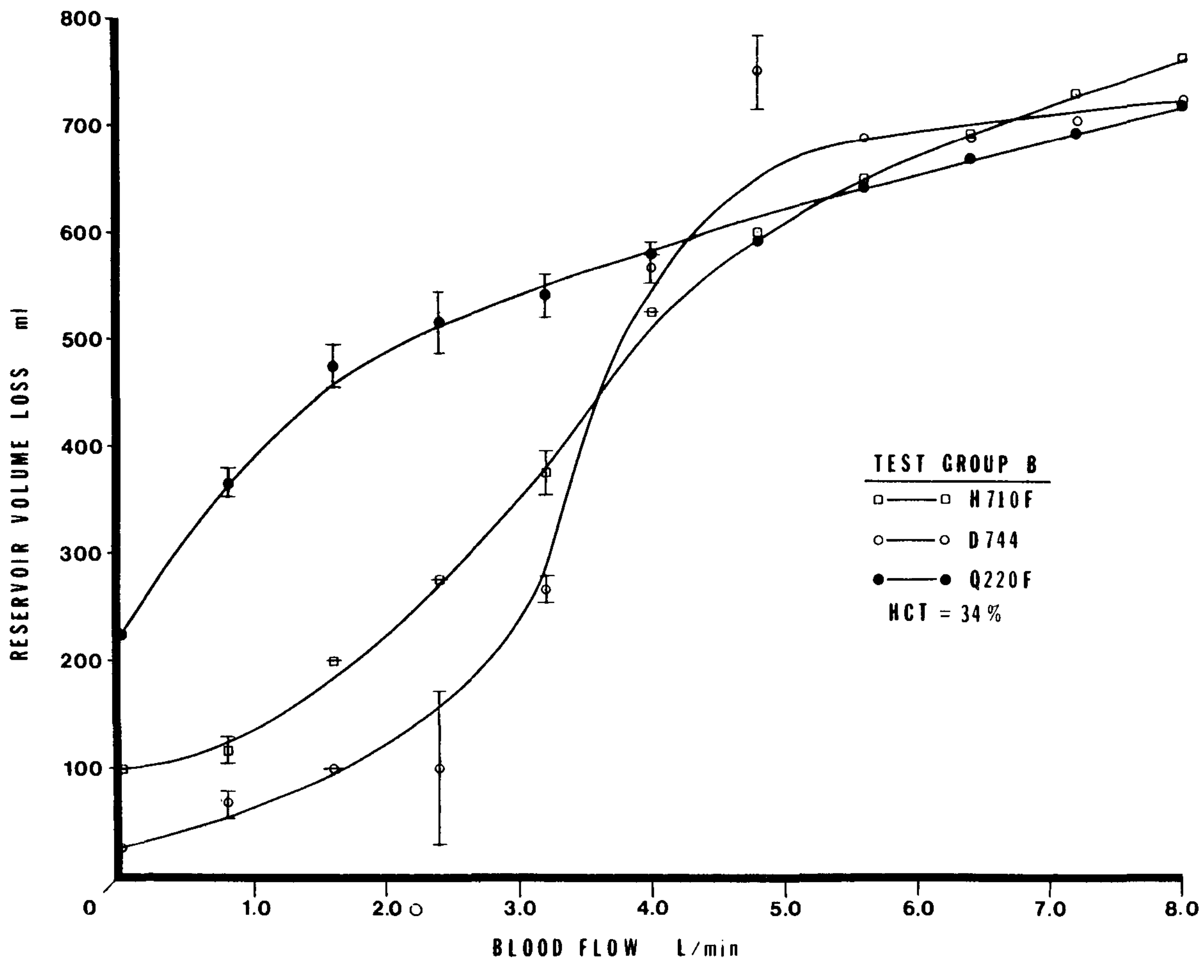


FIGURE 3: Relationship between flow rate and reservoir dynamic loss in GROUP B devices

Table 5
Cardiotomy Data Statistical Analysis (Group B)

	....H-710F Versus D-744..			...H710F Versus Q-220....			....D-744 Versus Q-220F..		
Flow Rate (ml/min)	# Observ.	T-Stat.	Signif.	# Observ.	T-Stat.	Signif.	# Observ.	T-Stat.	Signif.
0	3	Error	<0.0005	3	Error	<0.0005	3	Error	<0.0005
800	3	6.912543	<0.0025	3	-24.2250	<0.0005	3	-31.1376	<0.0005
1600	3	Error	<0.0005	3	-23.3487	<0.0005	3	-31.8392	<0.0005
2400	3	4.118327	<0.0100	3	-13.4178	<0.0005	3	-9.02859	<0.0005
3200	3	7.959507	<0.0010	3	-9.25578	<0.0005	3	-18.0520	<0.0005
4000	3	-6.12089	<0.0025	3	-8.55751	<0.0010	3	-1.72295	N.S.
4800	3	-7.33920	<0.0010	3	1.218307	N.S.	3	7.347837	<0.0010
5600	3	-6.12089	<0.0025	3	1.218307	N.S.	3	5.189597	<0.0050
6400	3	0	N.S.	3	2.594798	N.S.	3	2.594798	N.S.
7200	3	1.641095	N.S.	3	2.730781	N.S.	3	1.722946	N.S.
8000	3	6.120891	<0.0025	3	5.189597	<0.0050	3	1.218307	N.S.

Table 6
Cardiotomy Statistical Analysis (Group A & Group B Comparison)

Two Sample T-Test N.S. = Not Significant <P 0.0100)

	H-700F VS H-710F		BCR-3500 VS Q-220F		D-742 VS D-744	
Flow Rate (ml/min)	T-Stat.	Signif.	T-Stat.	Signif.	T-Stat.	Signif.
0	13.28157	<0.0005	Error	<0.0005	Error	<0.0005
800	5.492024	<0.0100	24.64280	<0.0005	6.628615	<0.0050
1600	13.28157	<0.0005	14.33214	<0.0005	Error	<0.0005
2400	51.22890	<0.0005	10.03221	<0.0010	3.645763	N.S.
3200	16.15315	<0.0005	13.26292	<0.0005	10.99280	<0.0010
4000	10.75174	<0.0010	24.63844	<0.0005	-7.20720	<0.0050
4800	13.28157	<0.0005	26.52583	<0.0005	-6.63241	<0.0050
5600	11.38420	<0.0010	23.68337	<0.0005	-.382200	N.S.
6400	13.26780	<0.0005	23.68337	<0.0005	6.442801	<0.0050
7200	9.476759	<0.0025	23.68337	<0.0005	5.788437	<0.0100
8000	13.26780	<0.0005	20.84091	<0.0005	5.692100	<0.0100

namic volume losses associated with the D-744 reservoir over all other reservoirs examined. However, the D-742 and H-710F reservoirs also demonstrated significant improvement in such parameters over the remaining devices tested (H-700F, BCR-3500 and Q-220F).

As may be seen from Table 7 and Figure 4, the total recoverable blood volume, following use, demonstrated that the greatest return can be anticipated from the D-744 (1150 ml; 96%) and the H-710F (1100 ml; 92%).

Discussion

With increasingly frequent use of cardiotomy reservoirs in procedures involving high rates of salvaged blood return, the selection of devices by performance criteria has become of greater significance. Previously, the examination of cardiotomy reservoir performance has generally focused upon its filtration efficiency and the device contribution to overall blood trauma[7]. While the importance of these factors cannot be denied, the effect of reservoir design and materials selection on free blood flow within the device may be of critical importance when faced with the need to rapidly, and completely, return the processed volume to the patient. While, in contrast to the data presented herein, a recent clinical study report states that no significant difference in dynamic loss was demonstrated among several cardiotomy models, it should be noted that such results were obtained under intraoperative, clinical conditions

Table 7
Mean Recovered Volume (Group A & Group B)

	.........Group A.........				.........Group B.........	
	H-700F	D-742	BCR-3500	H-710F	D-744	Q-220F
Prime Volume (ml)	1200	1200	1200	1200	1200	1200
Recovered Vol. (ml)	975	1012.5	975	1100	1150	950
% of Total Prime	81	84	81	92	96	79

which preclude the precise control of variables which may significantly affect such data. Variables such as hematocrit, viscosity, flow rate, microaggregate content and temperature were rigidly controlled in the present in-vitro study. The resultant data demonstrates significant differences in static, dynamic and residual blood loss amongst the reservoir models examined.

The dynamic volume loss, at any operational flow, was demonstrated to increase as microfilter media pore size was decreased, an expression of increased blood flow resistance. The dynamic loss of blood volume, however, cannot be totally explained by the porosity of the microfilter media, as may be seen from comparison of results obtained with devices of similar filtration materials (H-700F/D-742 and H-710F/D-744). Such data demonstrates significant differences between similar devices. It is of interest to note that the three devices demonstrating the least dynamic loss also exhibit a general "curve characteristic" approximating a sigmoid shape, whereas the remaining devices exhibit totally dissimilar "curve characteristics." The authors are unprepared, at this time, to present a conclusive explanation for such observations, other than to conclude that factors other than microfilter porosity contribute to the overall dynamic loss. Such factors may include total microfilter surface area, the quantity and type of reticulated foam incorporated in the design and the size and configuration of chambers proximal to the filter media. The definition of the relationship between each of these factors and the observed dynamic loss is, however, beyond the scope of the data presented.

Examination of the data demonstrates that devices exhibiting greater dynamic losses under active flow conditions also exhibit increases in non-recoverable blood loss under static conditions. Thus, the data presented defines performance criteria which may be of significance in the choice of cardiotomy reservoirs for applications involving high rates of blood return.

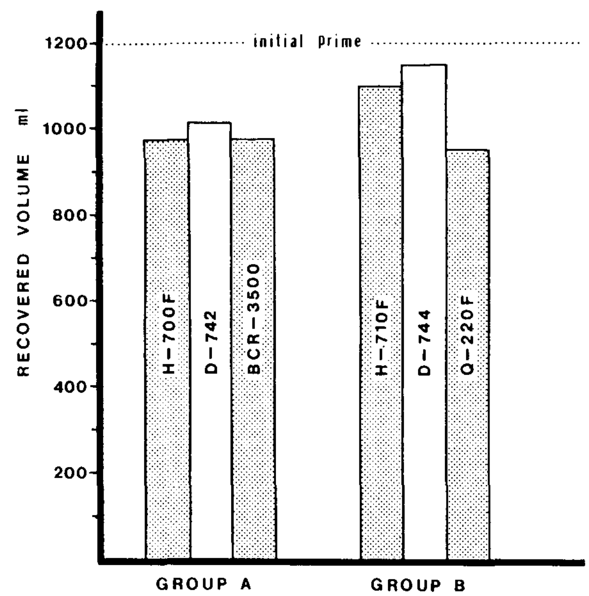


FIGURE 4: Volume recovery in cardiotomy reservoirs tested

References

1. Reeder, G.D.: Initial Evaluation of a New Bubble Oxygenator, presented at 11th International Conference of the American Society of Extracorporeal Technology, 1973.
2. Pfefferkorn, R.O.: Galen Optiflo—A Clinical Evaluation, presented at Region III Scientific Workshop, American Society of Extracorporeal Technology.
3. Reed, C.C. and D.K. Clark: Cardiopulmonary Perfusion, Texas Medical Press, Houston, p. 254, 1975.
4. Reeder, G.D., R.O. Pfefferkorn and S.E. Newton: In-Vitro Performance Evaluation of the Dideco Bubble Oxygenator, (submitted for publication, *JECT*, June, 1984).
5. Burgess, F.M.: Evaluation of the New Harvey Bubble Oxygenator, presented at 11th International Conference of the American Society of Extracorporeal Technology, 1973.
6. Eason, G., C.W. Coles and G. Gettinby: Mathematics and Statistics for the Bio-Sciences, John Wiley & Sons, New York, p. 475-478, 1980.
7. Meserko, J.J. and M.G. Sinkewich: Comparison of Cardiotomy Reservoirs With Microaggregate Filters, Proc. AACP 1, p9-14, 1980.