An Evaluation of A Modified Cobe Cardiotomy Reservoir

David Ogella, A.A.; Ronald G. Ronald, B.S.; John Meserko, B.S.

Cleveland Clinic Foundation, Department of Cardiac Surgery
9500 Euclid Avenue, Cleveland, Ohio 44106

INTRODUCTION

Since early 1967, a standard component of the pump set-up at the Cleveland Clinic's Department of Cardiac Perfusion was Travenol's Flexible Cardiotomy Reservoir equipped with a defoamer of siliconized stainless steel wire. This reservoir is furnished with a gross inline filter rated at 125 microns in density.

Even though the unit was in use for approximately 8 years with no apparent difficulties, awareness of the benefits of blood filtration were becoming obvious. Many groups across the country were beginning, along with the Cleveland Clinic, to investigate the benefits of blood filtration in all phases of patient care including open heart surgery. This investigation was prompted by the high incidence of postoperative cerebral and pulmonary complications and the concern that they might be caused by gaseous and/or particulate matter generated by bubble oxygenators and sterile suction blood. [1,2,6]

This brought about numerous investigations and evaluations of the arterial filters available on the market at that time. Through the use of sophisticated ultra-sound equipment it became immediately obvious that the use of an arterial filter in conjunction with a bubble oxygenator was an absolute necessity.[5] To eliminate particulate matter from entering the oxygenator, we further evaluated all of the different in-line cardiotomy filters commercially available at that time.

Problems with these units quickly became obvious. The units had to be unwrapped and installed at the time of set-up. This was not only inconvenient but compromised the sterility of our set-up. Also, the in-line units would constantly hang-up as much as two hundred cc.'s of volume at a time, causing fluid maintenance difficulties. Finally, in-line filtration was dropped as an effective means of filtering cardiotomy blood during total bypass.

It was about this time that Cobe Laboratories introduced their hard shell cardiotomy reservoir with an integrated Swank Cardiotomy filter (Figure 1). Through our ultra-sound studies, we already were familiar with the favorable capabilities of the Swank Filter. There was some skepticism since the Swank Arterial filter had a tendency to totally occlude about 2% of the time. Of course, this would not be as critical a problem in the filters position as a cardiotomy filter since the entire unit could be quickly replaced, even during total bypass, without endangering the patient. We decided we would try a few units as a clinical evaluation. This was the first major component change in our set-up in nearly eight years.

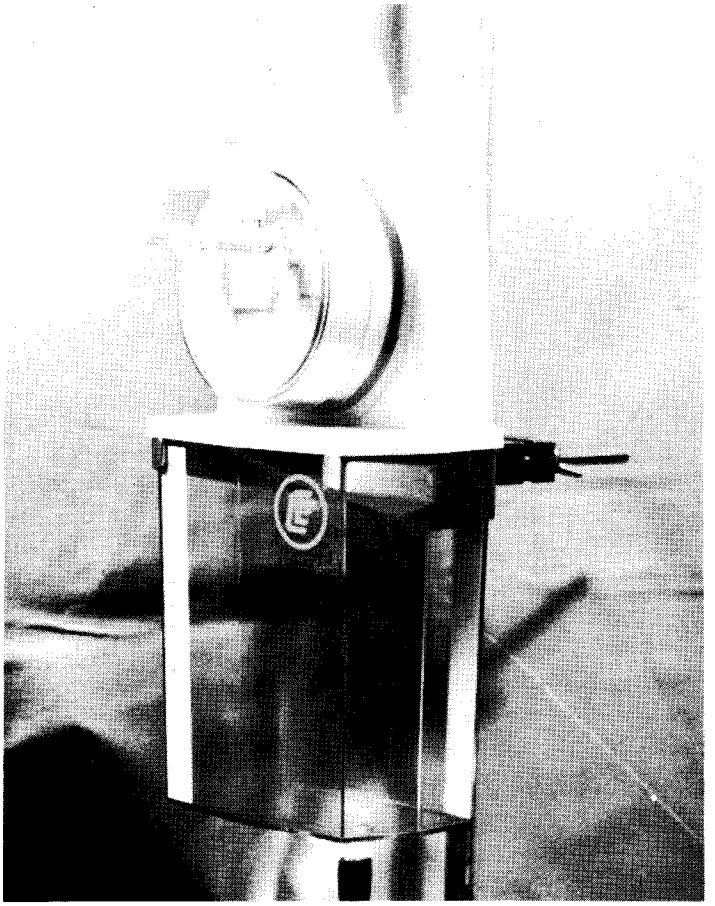

Figure 1. Cobe Cardiotomy Reservoir #42-300 with Integrated Swank Filter.

The advantages of the Cobe reservoir became obvious to us immediately, especially since we were changing from a soft unit to a hard-shell. It was quick and easy to hang on to its specially made bracket. It was marked in 100cc increments that were easy to read and offered us an idea of how much volume was entering the reservoir from the sterile suction and left heart. Most importantly, we saw fat and tissue emboli, suture material and even foamy residue being stopped by the Swank filter. One disadvantage noted at this time was the tendency for some volume to hang-up in the reservoir during high volume return situations. This was supposedly due to a vacuum being created in the cardiotomy return line. We corrected this situation by lifting the return line above the level of the fluid and lowering it again rapidly.

It was a short time later that we introduced the Cobe cardiotomy reservoir into our system permanently. We now felt the addition of filtered cardiotomy, arterial and bank blood would offer a significant benefit to the postoperative morbidity of our patients.

MATERIALS

The set-up used to conduct this cardiotomy study consisted of: the Travenol pump consisting of three modular heads *5M6050 (an arterial, sterile suction *5M0925 and left heart) and a Sarns Normothermia unit. The Travenol Bubble Oxygenator* was also used. The tubing used consists of Cobe's† custom pack comprised of Tygon° tubing formulation S50HL. On our arterial side, we incorporated the Johnson and Johnson arterial Filter #1330. Dimensions of the Cobe cardiotomy reservoir are 15 inches by six inches deep by six inches wide.

Our original carditomy consisted of the Swank filter made of compressed Dacron wool mounted on the face of the cardiotomy reservoir, encased in a clear plastic shell. There are two entry ports that can accept quarter inch tubing for the sterile suction and left heart. There is also a luer lok stopcock with two entry ports for fluid administration directly into the filter.

Behind the Swank filter there is an air interface of about a quarter inch followed by a defoaming pad. From the defoaming pad the fluid path drops to a splash plate which directs it to the back wall of the unit. It then cascades to the bottom of the reservoir and exits via a three-eighths inch straight plastic port. There are four additional ports at the top of the reservoir which accept I.V. tubing and can be used for

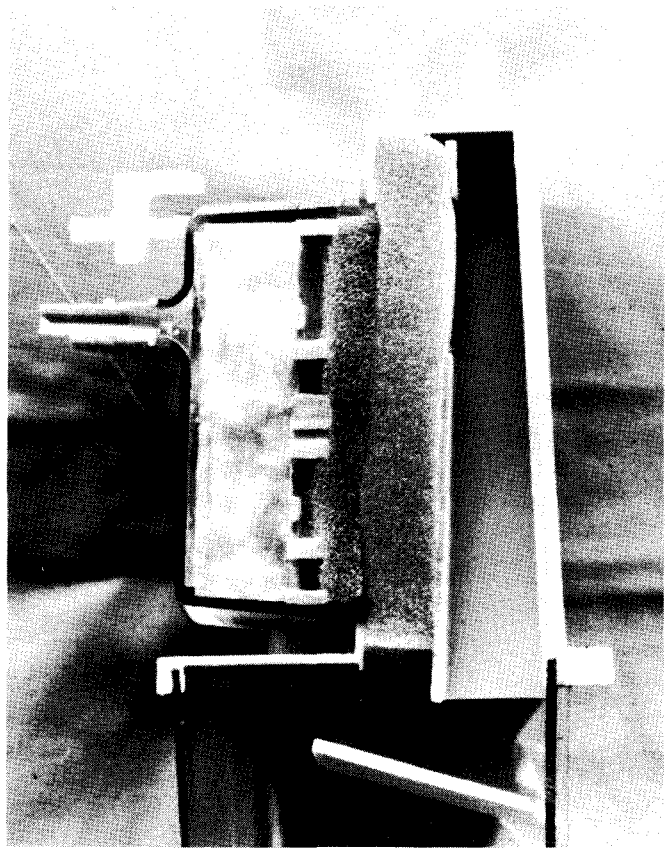

Figure 2. The Addition of An Extra Defoaming Pad Created A More Homogenous Fluid Path.

the addition of solution to the system. A quarter inch vent port between these four ports can be used as a rapid prime system. A strip of paper on the left side of the reservoir marks 1500 cc of volume in 100 cc increments. The Swank filter performs in two ways. First it acts as a trapping mechanism featuring compressed Dacron wool as a dense, depth filter. Second, it features a unique property which causes particles to become electrostatically attracted to the strands of Dacron.[1,6] It has the capabilities of filtering to 20 microns.

Our Standard unmodified Cobe cardiotomy consisted of a hand fluffed Swank filter followed by an air interface followed by a defoaming sponge. The first structural change made was a switch from hand fluffing and inserting the Dacron wool to machine fluffing of this material. The second was the addition of a defoaming pad to fill the air space between the filter and the defoaming pad (Figure 2).

For our evaluation, a series of cardiotomies with each individual modification were run to test for possible problems on an individual basis.

For purposes of comparison the Bentley carditomy model Q220F* with a three-phase polyfilter was used (Figure 3). The Bentley was evaluated with and without an additional splashguard located in the satellite. The basic configuration is that of a dome shape with three quarter inch inlet ports for the sterile suction and left heart

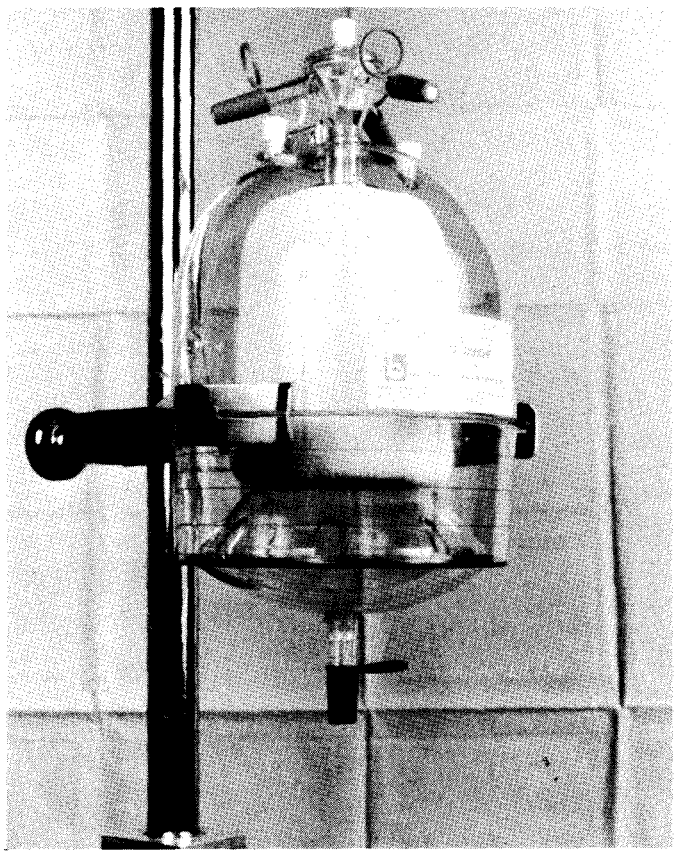

Figure 3. Bentley Cardiotomy Reservoir #Q220F.

suction emptied into one common area from which the fluid then passed over the filter to the bottom of the reservoir to empty out into three-eighths inch tubing. The holding volume capacity is 2000 cc. which is marked in graduated 100 cc increments. The Bentley Polyfilter is made of a specially processed polyester that is formed into a three-stage gradational filter (Figure 4). These three layers of urethane foam offer 150 micron, 73 micron and finally a fine 27 micron filter.[3]

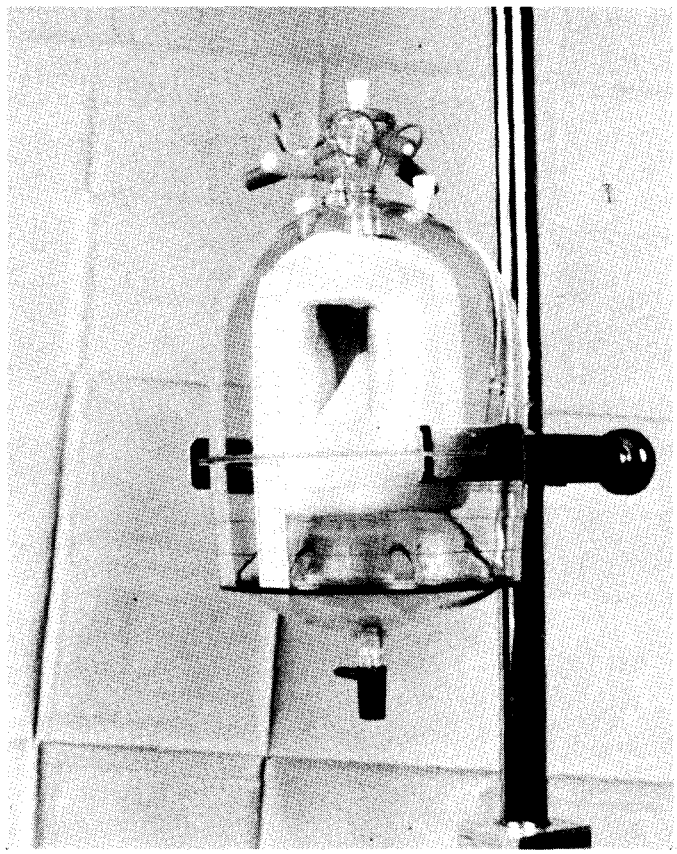

Figure 4. Cross Section of Bentley Reservoir Illustrating Three Phase Polyfilter.

METHODS

The methods utilized for this study were comprised of actual visual changes observed during the cases versus actual laboratory data collected.

Our visual observation method was basically determining if there was less foaming of the blood occurring pre-filter, post-filter, pre-defoaming pad and post-defoaming pad. Also, we noted the variability of flow patterns of the fluids. The purpose for utilizing this method of observation was to eventually aid us in determining which modification was best able to insure a steady fluid path through the filter and defoaming pad to the reservoir.

The laboratory data collected was mainly the result of four tests. Preoperative plasma hemoglobin and platelet counts as well as repeating these tests again 24 hours after heparin reversal.

RESULTS

During the original discussion in reference to the evaluation of the reservoirs it was decided by Cobe labs that the above-mentioned blood work would be examined in all the subsequent studies to see if there would be any deviations from the norm. We were supplied at this time with 20 reservoirs of each design which were to be used for evaluation purposes. Later when we decided to include the Bentley reservoirs in our study, we purchased 20 units for examination.

After collecting and carefully evaluating the lab data it was found that the results were not statistically significant since the figures did not deviate from what we were used to seeing.

This is by no means a definitive study. There certainly are possibilities for further evaluation of this product or any other product involved in extracorporeal circulation. More elaborate blood testing might have been utilized to pinpoint hemolysis or particulate matter counts in the cardiotomy blood. We would have liked to have increased the number of cases in each study. Unfortunately, time and resources did not allow this more extensive data collecting process.

However, though we were unable to point to specific data to prove differences in the changes made to Cobe and Bentley reservoirs, we feel we can make significant visual observations which may lend support to our study. For instance, we noted that following entry of the blood from the ports to the filter, the fluid was rapidly transported across the filter generally in the area at the bottom of the filter. It was noted that the hand fluffed Swank filter tended to increase the incidence of low fluid resistance, that is, it tended to seek the path of least resistance, therefore, not utilizing much of the surface area of the filter.

It was also noted that past the filter, in the area between the filter and defoaming pad, there was a great deal of percolating or bubbling of the fluid. This fluid, however, was satisfactorily debubbled following the defoaming pad.

The first structural change incorporated in the Cobe cardiotomy was the machine fluffed filter. Upon visual examination, we noted the fluid entering from the ports now tended to be dispersed more evenly across the entire face of the filter.

The last structural modification incorporated in the Cobe cardiotomy was the machine fluffed Swank filter with an added defoaming pad. Air in contact with blood, of course, will cause hemolysis, but we felt that the addition of this defoaming pad eliminated this bubbling of blood and created a more homogenous fluid path. Because of this improvement, we feel that the blood is subjected to less damage in the new model. This in conjunction with the improved blood distribution through the machine fluffed filter, in our opinion, warranted a production change in the Cobe cardiotomy reservoir.

As stated previously, the Bentley cardiotomy was also studied for purposes of comparison. At the inlet ports the blood comes in contact with a small triangular piece of plastic which prevents it from entering the other ports instead of being directed downward in its regular fluid path. The blood then descends via a tube to the filter

upon which gravitational pull allows the blood to pass through the filter to the reservoir and out via the three eighth inch port at the base of the Cardiotomy. The drainage capabilities with respect to the angulation at the base of the cardiotomy. As mentioned previously, this was a disadvantage with the Cobe cardiotomy.

We were impressed at the willingness of the manufacturers and their representatives to cooperate with us to make improvements on their products for the good of the patient. It was gratifying to work with Cobe and Bentley Laboratories in this evaluation. We realized that by cooperating with the manufacturers we had established a rapport that allowed us to test and evaluate changes that we had a hand in initiating and were fortunate enough to see these products incorporated in the future models.

This then we feel might be another goal of Clinical Perfusionists to recognize where improvements are necessary, to make logical suggestions to manufacturers and follow-up with careful evaluations and eventual incorporation of the product into the extracorporeal circuit.

REFERENCES

1. Connell, R.S. et al: The Effect on Pulmonary Ultrastructure of Dacron-Wool Filtration During Cardiopulmonary Bypass. *The Annals of Thoracic Surgery,* 3:217-229, 1973

2. Dunbar, R.W., et al: Microaggregate Blood Filters: Effect On Filtration Time, Plasma Hemoglobin, and Fresh Blood Platelet Counts. *Anesthesia and Analgesia,* 4:577-583, 1974

3. Ionescu, M.I., Wooler, G.H.: *Current Techniques in Extracorporeal Circulation:* Great Britain: Butterworth & Co. Ltd., 97, 297-319, 1976

4. Galletti P.M., Brecher, G.A.: Heart-Lung Bypass: New York: Grune and Stratton, Inc., 154-170, 1962

5. Loop, I.D., et al: Events Related to Microembolism during Extracorporeal Perfusion in Man: Effectiveness of In Line Filtration Recorded by Ultrasound. *The Annals of Thoracic Surgery.* 21:412-420, 1976

6. Osborn, J.J., et al: Clinical Use of Dacron Wool Filter During Perfusion for Open-Heart Surgery. *The Journal of Thoracic and Cardiovascular Surgery,* 4:575-581, 1970

7. Reed, C.C., Clark, D.K: Cardiopulmonary Perfusion: Texas: *Texas Medical Press, Inc.* 257-270, 1975

*Travenol Laboratories, Morton Grove, Illinois
†Cobe Laboratories, Lakewood, Colorado
°Norton Company, Akron, Ohio
#Surgikos, New Brunswick, New Jersey
**Bentley Laboratories, Irvine, California