An Evaluation of

Silicone Membranes

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At this writing, our knowledge of silicone rubber membranes and its properties are becoming known to us rapidly. We have acquired sufficient data to begin to make the membranes do some fairly startling things for us. However, we are actually just beginning to penetrate the fog to make out shapes of things we can use and put to work for us. In the near future, the new silicone membrane products we haven't laid our hands on yet will become well known to us much as the use of silicone membranes for oxygenation is just of late being understood by a number of people.

Gas studies done by Dow Corning*, et al.,[1] have shown that silicone rubber membranes of comparable thickness to teflon membranes pass 02 10 times better and Co2 18 times better. For this reason, silicone is the membrane of choice for gas exchange not to mention the practical side of silicone insofar as it can be used as a much stronger membrane than the teflon that tears quite easily and can be prefabricated by gluing sheets together to form blood sacs.

Fallacies

As with any new discovery, we have had to try to wade through to the basic knowledge discarding fallacies based on theories expressed in good faith from seemingly well thought out assumptions but nonetheless erroneous and greatly misleading. For instance, the idea was expounded upon by many that the number of threads per inch of a given piece of silicone membrane directly affects its oxygenation characteristics adversely as the number of threads increases per sq. inch. For a number of years, everyone accepted this principle as valid and a well conceived notion. It seemed to make sense.

When we started to doubt this bit of misunderstood information, it became mandatory to test its validity. However, before it was possible to arrive at answers on this test, we found it necessary to develop a simple yet quantitative and qualitative procedure of insuring that each batch of membrane would be the same in terms of oxygenation, thickness and burst strength.

We thus established that for a given measured thickness of membrane in the interstices or area between the threads that you would get a constant breakout pressure when applying air pressure to a sample of cloth in question and that this would give a constant amount of oxygenation passage.

Standards

It was established that from 31 to 36 ml. of oxygen per sq. meter would pass through a ½ mil silicone membrane; the interstices of the membrane having .0330 grams of silicone per sq. inch and .0710 grams of cloth per sq. inch. The measurement over the individual thread is approximately 6 mils after coating, the breakout pressure is 18 to 22 lbs. per sq. inch. This has been Medical Monitors standard cloth that they have been calling ½ mil membrane and manufactured since 1962. This cloth has approximately *.025* millimeters of space between the threads.

We then selected a cloth that has a weight of .0220 grams per sq. inch of thread and we added .0190 grams of silicone or slightly more than half the amount of silicone as on the previous cloth. The breakout pressure was then established at 22 to 28 lbs. per sq. inch and the oxygenation was established at 46 ml. of oxygen per sq. meter by the method described by Crystal, Day and Kranz.* [2, 3]

The reason for the greater breakout pressure or greater strength even though less silicone is applied is fairly clearly understood. There is simply a much greater surface or matrix for the silicone to bond on and add support.

It is virtually impossible to find a practical method of measuring the thickness of silicone between the threads of the new cloth since the threads are less than *.006* mils apart. The thickness of the cloth uncoated is *.0045*; the thickness of the cloth over the thread after coating is *.0045+* with burst pressure of 26 lbs.

A New Thought

At this point, I wish to offer a new reason for what I find as to the greater oxygenation even though there are a greater number of threads more closely spaced. The dacron is a multi-filament thread which must in reality have many spaces which oxygen can pass through. Although this thread is coated with silicone, it must not be an impediment to the passage of the oxygen but even perhaps it is actually through the thread itself that most of the oxygen is passing and not through the silicone between the thread which is much more dense in comparison to the amount of silicone on the thread.

It seems reasonable that this is where the thinking that the more threads per sq. inch, the less oxygenation has gone astray. If the threads were more solid matter, such as a mono-filament fish leader, then oxygen could not pass through. When one realizes that each thread is a multi-filament with huge spaces in terms of an oxygen molecule to pass through, then it becomes quite evident that oxygen is passing through the thread more than it is the silicone.

Another test that helps to prove this theory was to coat some of this new cloth with the same amount of silicone by weight per sq. inch as the old wider spaced dacron threads. The oxygena-

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tion passage through this more heavily coated cloth was approximately the same as per the old dacron. However, it was quite obvious that the silicone in the interstices of the new cloth was much heavier although the silicone over the thread itself is approximately the same as some of the new cloth coated with less silicone between the interstices.

Nature of Silicone

In the manufacture of this membrane, it's the nature of the silicone to shrink closely around the thread on vulcanization. Therefore, in putting a very small amount of silicone on this cloth, the silicone adheres to a single thread surrounding it and leaving a film between the two threads that is quite thin. As you increase silicone, you increase this thickness of silicone in the interstices.

However, the silicone on the thread itself, until it builds up to the height of the thread when laid flat, remains approximately the same. Thus the surface area that oxygen can pass through is increased in direct proportion to the amount of silicone that you allow to build up in the valleys between the threads.

"Leaks"

We would like to try to clear up some of the misunderstanding that has been created in terms of thinking about leaks as far as membranes are concerned. When you say leaks, you mean many things to many different people. When you use the term leaks to the physician, he thinks in terms of blood getting out or possibly bacteria getting in through the membrane. Of course in a heart-lung machine, this is the most important criteria to consider.

However, this is far too simple a determination of leaks as far as the manufacture of the membrane is concerned since in testing the membrane for leaks, one must determine at what point fluid will start moving through the membrane and at what point gases will merely be accelerated through the membrane. Thus, we can see that a membrane coated with *.0140* grams of silicone per sq. inch will have a burst pressure of approximately 14 lbs. per sq. inch yet will not allow fluid to pass through the membrane.

Air molecules will pass through readily so that a bag blown up with air and sunk under water will appear to be completely full of pinholes as air will be bubbling up over the entire surface of the bag. This same bag filled with water and held up will not have water leaking out of the bag although the surface will feel moist.

Other tests have been described such as the one done by General Electric using vacuum and a keystone solution to show pinholes on a blotter. This test will show liquid that will move through the membrane of the solvent nature. However, water would not move through this same membrane under the same vacuum. As the liquids get closer to the gaseous state having molecules further apart, obviously more liquid is going to pass through a given molecular weight of silicone than one with a higher density of molecules and silicone.

Gas Passage

As one moves into the gaseous state of testing, one finds that by blowing a bag up with air and testing the gases that come through, the pinholes can be determined in terms of the amount of oxygen that comes through and the amount of air. That is, a membrane that has a higher gradient of oxygen than nitrogen passing through will obviously be considered to be a membrane that is more free of pinholes.

Thus you see, asking about pinholes could be a little bit like asking "how high is the sky". It then becomes necessary to qualify the statement with what kind of gas or molecule do you wish to pass through the membrane and how much liquid do you wish to keep from passing through at what pressure gradient since obviously the membrane passes a water molecule and a gas molecule extremely rapidly.

It may be hard to detect in this text but what I am trying to say is that it becomes a question of what is practical in terms of oxygen passage, water molecule passage or blood molecule passage through the membrane itself in terms of practical usage rather than what can you bench test and get through it?

What Is a Pinhole?

During the procedure of establishing a proper thickness or thinness of silicone to apply to the new cloth, it became apparent that we must establish a criterion for what a pinhole really was in terms of our proposed usage of the membranes. When tested under water for pinholes, air bubbles formed on the surface rather rapidly if coated extremely thin; therefore: what was an air leak? what was a water leak? and what was a blood leak? became the primary questions we were concerned with.

First we had to establish the true breakout pressure of air against the membrane when the membrane was held under water at which point the pressure meter fell sharply and bubbles spurted out of the pressure chamber at a pinhole point that had not been there up until that pressure point had been reached. The bubbles that formed slowly on the surface of the membrane were not necessarily pinhole leaks as far as a membrane oxygenator for blood was concerned.

It has been a well known fact that one of the problems of a membrane oxygenator, heretofore, has been its leaks. In looking at the old membrane material, we can see that the two threads supporting the silicone act as a suspension bridge and that the silicone is suspended between the two columns. If we destroy the integrity of the membrane film between these columns or in the interstices, it will open up a hole far bigger than the pinpoint we originally poked through it, thus leaving a leak of considerable size. Although this is proven not too troublesome with our older membrane, we will not deny that leaks have occurred although they are of a rare nature.

The New Membrane

The occurrence and the effects of leaks in the new membrane are greatly reduced since the point of the pin we used to penetrate the membrane will actually touch the threads on either side of the pinpoint by the time it is pierced through and move these threads aside which will close back up on withdrawal of the pin since the rubber on the opposite sides of the threads has a memory which will push the hole closed in returning the thread. Thus a leak of any consequence is virtually impossible to create by simply putting a pin through the membrane since it has a selfsealing characteristic.

The advantages of the newly described membrane are:

1. Safer from a leakage standpoint.
2. Not as delicate; can withstand greater abuse in handling.
3. Does not present as rough a surface to the blood cells to impinge upon.
4. Takes a more even coat of silicone membrane on the threads.
5. Gives a higher burst pressure point per the amount of silicone applied to them.
6. Allows an increased passage of oxygen gas across into the blood and Co_2 gas passage out of the blood.

Summary and Conclusion

A false understanding about the number of threads per inch effect on a membrane used for oxygenation has been laid bare and cleared up. From the findings gathered from actual oxygenation studies with a multi-filament dacron cloth, a new and much improved oxygenation membrane has been developed.

References

[1] Gas transmission rates of plastic films, Dow Corning, 7/1/59.

[2] Combination membrane oxygenator-dialyzer, Day, Crystal, et al.—Vol. X Trans. Amer. Soc. Artif. Int. Organs, 1964.

[3] Comparison of gas transferring capabilities of membranes in vivo Kranz, Day, et al., American College of Surgeons, 1965.

MEDICAL MONITORS

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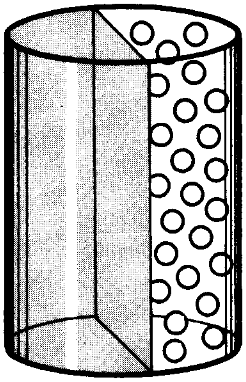
Pump-Tech Wanted

On or about July 1st, 1969, a pump-oxygenator technologist is needed in Houston, Texas. Anyone who is interested in this position may contact Beryl Harberg, M.D., at 1418 Medical Towers Building, Houston, Texas 77025. A clinically qualified individual is desired.



Dialysis

The removal of toxins and substances capable of reaching toxic levels in the bloodstream of man is not a new concept. But, indeed, the technique of dialysis has reached practicality only within this decade. The technique is applied to those individuals who have ingested a dialyzable poison or who have suffered the loss of normal kidney function. Of these patients, some have only acute or short term disorders which can be corrected by only a few treatments.

Those who are chronically ill and have suffered permanent renal impairment must undergo dialysis on a continuing basis, receive a kidney transplant, or die. This opens the door to many questions, some old and some new, to evaluate the application of the concept and the inter-relationship of the complex factors which affect it.

The basic techniques are two: hemodialysis utilizing an "artificial kidney" machine, and peritoneal dialysis, in which the patient's peritoneum acts as the membrane awash with the dialyzate solution. Are these techniques clinically applicable as "treatments of choice" for renal disorders and certain poisonings? Is chronic dialysis, as practiced today, an accepted clinical entity or still in a highly experimental stage?

In disrupting the body's delicate balances by the introduction twice-weekly of an extra-corporeal circuit composed of foreign bodies, certain physiologic parameters shift in response to dialysis. Is medicine, at the present state of the art, fully capable of diagnosing, evaluating, and compensating for these shifts and/or metabolic imbalances? What chance does the patient have to lead a normal, productive life though dependent upon treatment?

In institutional programs, the personnel cost is the greatest cost factor while in home programs it is the cost of materials. The psychological makeup of the patient and his family are a limiting factor in determining whether he remains institutionally oriented or can attempt home dialysis. What percentage of the existing chronic dialysis patients could benefit from home dialysis and be released from the more expensive institutional programs? Would it be possible to dialyze more people at home if a technician could assist with their treatments?

The Wall Street Journal article, which has been reprinted in this issue, emphasizes the cost factor in dialysis. This has been of great concern ever since Dr. Scribner completed his first time/efficiency studies. What are all of the factors that affect cost? What areas can and are being investigated to lower the cost per treatment per patient? Could the application of sound business practices, such as volume group purchasing, etc., reduce costs?

What part can the engineer and manufacturer play in making affordable dialysis treatment available to a greater number of candidates? Could an industry-wide price cut see its compensation in profits from increased volume? Are there any steps industry can take in the future to assist in this cost reduction? Would government subsidies to industry to reduce equipment prices coupled with private or insurance funds for the patient have any merit?

The technologist enters as the individual most familiar with the details of operation and the opportunity to develop an insight into improvements in the technique and equipment. What can