

Review Article

Fiber Manufacturing, Membrane Classification, and Winding Technologies Associated with Membrane Oxygenators

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ABSTRACT

Fiber bundling refers to the process of winding hollow polypropylene fibers onto the central core of a membrane oxygenator. Identifying the various bundling techniques serves to facilitate the clinician's understanding of unique device characteristics and the subsequent manufacturing process. This technical information has been voluntarily provided by the product managers and engineers of current membrane manufacturers. Currently the industry employs four primary bundling techniques: single strand, mat configuration, tape and helical.

Single strand wraps one fiber at a time, up and down a central core to create the fiber bundle. A modification of the single strand technique is the single strand multi toe, where multiple fibers are wound at a time. Mat technology wraps a large, woven sheet consisting of uniformly placed fibers and spacing filaments, around the oxygenator core. A modification is the double mat, where two sheets of fibers oriented at a specific bias to each other, are wrapped to yield a fiber bundle. Tape technology involves evenly spaced fibers, 5 to 10 fibers wide, wrapped up and down the length of the core. Helical utilizes a spacing filament that is spiraled around each individual fiber and then around the core of the device.

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INTRODUCTION

The features of the blood flow path of a membrane oxygenator directly influence the amount of gas transferred to the blood. Each oxygenator accomplishes this goal through various design innovations that distinguish one manufacturer's membrane from another. Secondary flow characteristics, or turbulence, provide the primary means to optimize gas transfer. However, additional parameters that enhance the transfer efficiency of an oxygenator are diffusion gradients, the choice of fiber manufacturer, classification or type of oxygenator and the fiber winding technology. This paper describes these parameters.

DIFFUSION GRADIENTS

The ability to manipulate gas transfer via altering the diffusion gradient is limited. The upper limit for the diffusion gradient is the FIO_2 of the ventilating gas, which is 100%. The venous oxygen levels regulate the lower limit of the diffusion gradient and during normal physiologic circumstances and controlled cardiopulmonary bypass (CPB), do not readily fluctuate. Clearly, the diffusion gradient does not provide a means by which oxygen transfer can be altered by the clinician.

FIBER MATERIAL AND MANUFACTURING PROCESS

The fibers used in membrane oxygenators are of a hollow fiber type configuration. There are four manufacturers responsible for the production of hollow fibers used in membrane oxygenators: Mitsubishi^a, Hoechst Celanese^b, Akzo Nobel^c, and Terumo^d. These fibers are made from polypropylene, have varying pore sizes and range in internal diameter from 200-280 μ with a wall thickness of 25 to 50 μ (Figure 1) (1).

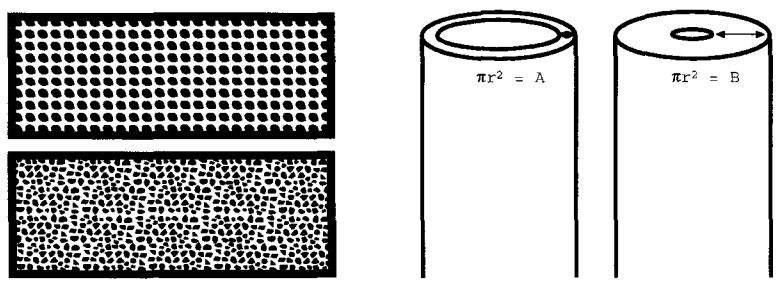
AZKO NOBEL FIBER MANUFACTURING PROCESS

The Akzo Nobel hollow fiber membranes are made by a thermally induced phase separation process (2). During this process the polymer is melt mixed with a defined mixture of seed oils (soy and castor). The resultant fiber is formed from this solution by a process of spinning and cooling. During cooling, a phase separation is initiated leading to the formation of pores filled with oil on a solid polymer. After removal of the residual oil using hot alcohol and then drying, the fiber manufacturing process is complete.

CELANESE FIBER MANUFACTURING PROCESS

The Celgard process uses semicrystalline films or fibers composed of polypropylene. The polypropylene is melted and spun into an undrawn fiber, a process called extrusion. A heat treatment, annealing, then occurs where the polypropylene tub-

Figure 1: Various pore sizes and fiber dimensions used in membrane oxygenator construction



ing is longitudinally expanded by a controlled expansion process referred to as mechanical drawing. The extent of stretching controls both pore size and pore size distribution(3). This unique process yields pore like structures by inducing small slits in the tube wall. While the fiber is still under tension, it is heat set to minimize the loss of porosity.

MITSUBISHI FIBER MANUFACTURING PROCESS

Mitsubishi's manufacturing process uses a sophisticated melt spin technology to form an arrangement of periodical dense and coarse structures along a polypropylene fiber. This fiber is then heated and pores are formed by a drawing technique, i.e., an expansion method. The pores are stabilized via heat and safety tested using a pin hole test (4).

TERUMO FIBER MANUFACTURING PROCESS

Terumo uses a thermally induced micro phase separation process. Liquid paraffin and polypropylene are mixed together and then melt spun. The mixture is then extruded and goes through a cooling process where the paraffin is removed. The membrane obtained by this method has a microporous structure consisting of a three dimensional network consisting of highly tortuous continuous channels (5). This is different from the slit like pores of the microporous membranes obtained by the expansion method.

The particular manufacturing process will determine the tensile strength, porosity, fiber thickness and dimensions, plasma break through, explosion pressure and gas flux of the fibers (2,3,4,5). This coincides with the membrane oxygenator's gas transfer ability, plasma leakage and device safety and durability during oxygenator handling, production and shipping (2,3,4,5). Once the manufacturing process is complete the fibers are wound on single thread or multi-thread bobbins, or woven mats on spools and then shipped to the membrane oxygenator manufacturer. The spools are stored at specific conditions, until

- a Mitsubishi-Rayon, Co., Tokyo, Japan
- b Hoechst Celanese, Charlotte, NC
- c Akzo Nobel, Wuppertal, Germany
- d Terumo Corporation, Tokyo, Japan

used, as the fibers are sensitive to ultraviolet light, humidity, static electricity and foreign materials (2,4).

In order to give more information for use with applications involving blood, the following biological safety tests must be conducted: cytotoxicity, hemolysis, mutagenicity, in addition to concurrence with the requirements of the US Pharmacopeia XXII<88>, Class VI. However, oxygenator manufacturers must conduct their own studies to assure themselves of the stability of this material for its specific application, and its safety and efficacy in their device (2).

MEMBRANE CLASSIFICATION

Membrane oxygenators consist of two types based on the material and mechanism for gas transfer (6). They are: true membranes and microporous membranes.

TRUE MEMBRANES

A true membrane is made of silicone and is configured in a jelly roll. It is termed a true membrane because there is a complete barrier between blood and gas, as there is in vivo. This type of membrane oxygenator is primarily used for long term applications and is the only one approved by the Food and Drug Administration (FDA) for this purpose.

MICROPOROUS MEMBRANES

Microporous membranes constitute the majority of membrane oxygenators used for short term bypass procedures. The term microporous refers to membranes made of polypropylene with pores integrated into the surface of the fiber during the manufacturing process. The pore size is less than 1 micron, and will vary depending on the specific manufacturing technique used (7). Gas transfer occurs through the micropores and initially has direct blood/gas contact upon the beginning of CPB. Blood proteins immediately coat the fibers, eliminating the direct blood/gas interface, allowing gas to exchange via diffusion. In these oxygenators, the surface tension of the blood prevents large amounts of fluid from seeping through the pores during the procedure. The pore size must be less than one micron to inhibit both gas and serum leakage across the membrane (7).

Microporous membranes have several configurations based

Figure 2: The flat plane membrane

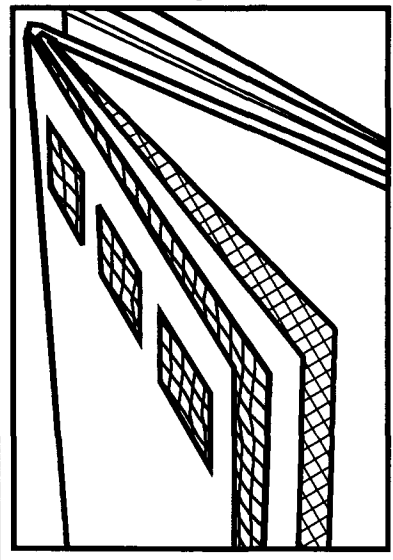


Figure 3: Hollow fiber orientation with blood on the inside, gas on the outside. Reverse hollow fiber, with blood flow on the outside and gas on the inside.

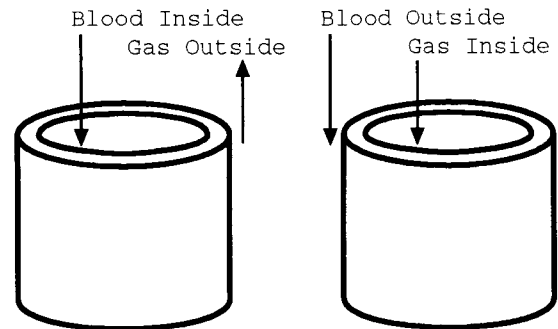
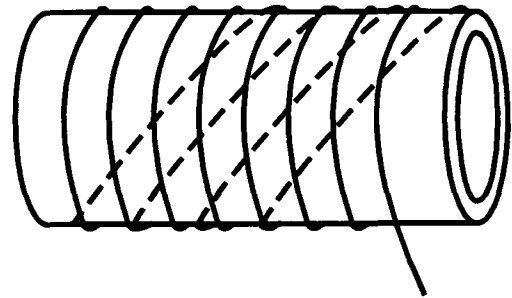


Figure 4: Single strand technology



on their arrangement of fibers and blood flow. They include the flat plane membrane and the hollow fiber membrane. The hollow fiber membranes can be further subdivided according to the orientation of blood flow either inside or outside of the fiber matrix (6).

The flat plane membrane consists of a polypropylene membrane sheet with alternating layers of screen spacers (Figure 2). This arrangement produces a device with uniform cross sectional flowpaths in both the blood and gas phases. The distance between layers is kept at a minimum to eliminate volume compliance effects (1). The use of the screen spacers creates gentle mixing at the membrane surface to optimize mass transfer. The surface area of this membrane is achieved by arranging a number of these membrane layers in parallel.

The other type of microporous membranes are the hollow fiber and reverse hollow fiber configuration. Hollow fiber refers to the blood flowing inside the lumen of the fiber and the countercurrent gas flow on the outside. The term reverse hollow fiber denotes blood flowing on the outside lumen of the fiber, with gas flow inside (Figure 3).

Hollow fiber devices with blood on the inside and gas on the outside cannot utilize secondary flow characteristics. Membranes of this arrangement must rely on other means to increase

gas transfer, such as a greater membrane surface area and diffusion gradients. With regard to the efficiency of this configuration, approximately 90% of the total mass transfer resistance resides in the blood phase, due to the laminar streamlined blood flow within the fibers (1). Higher mass transfer rates per unit area could be achieved by reducing the internal diameter of the fibers. However, this has not yet been put into practice, as it is more difficult and hence more expensive to manufacture fibers with an internal diameter of less than 200μ (1).

Membranes of the reverse hollow fiber design dominate the market for short term extracorporeal use. Reverse hollow fiber devices have blood flowing on the outside of the fiber. Blood can flow perpendicular or cross current to the fiber bundle, which induces secondary flow characteristics, thus increasing gas exchange. However, the blood flow may flow parallel to the gas flow. In this case, blood usually flows in the opposite direction, or countercurrent, to the gas flow. Reverse hollow fiber units rely on the blood flow path to generate secondary flow characteristics and to minimize shunting within the device. These devices typically have high mass transfer rates and require smaller surface areas due to the secondary flow characteristics created. At present, those membranes that are of the reverse hollow fiber configuration appear to be the most efficient and most abundant (1).

FIBER BUNDLING TECHNIQUES

One of the most distinguishing features of oxygenators is their bundling techniques. The choice of fiber combined with a specific bundling technique enables the manufacturer to customize an oxygenator's design to provide what they believe to be optimum performance. Bundling technique refers to the process of winding the fibers, either from mats or bobbins, onto a central core. The bundling technology is a primary factor that influences gas transfer and blood handling characteristics of a device. Currently, there are four bundling techniques used: single strand, mat configuration, tape and helical.

SINGLE STRAND TECHNOLOGY

Single strand technology wraps one strand of fiber at a time around a center core to create the fiber bundle (Figure 4). With this configuration the fibers may be aligned but the spacing in between may vary. This scenario may create areas within the fiber matrix where increased resistance and shunting can occur. Clinically, this may alter performance, specifically during periods where viscosity changes, i.e., cooling.

SINGLE STRAND MULTI TOE

A modification of the single strand technique designed to improve consistency is to wrap multiple fibers at one time (Figure 5). These fibers are at a fixed distance from each other and come off a 6 or 7 toed spool instead of a single fiber spool. A cross section of this fiber bundle would yield a more consistent wrap and, therefore, better clinical performance. It has been

Figure 5: Single strand multi toe

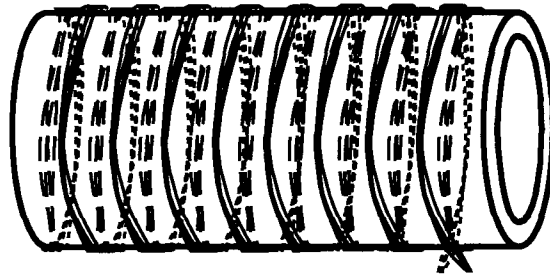


Figure 6: Mat technology

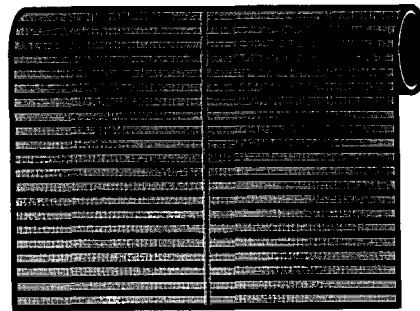
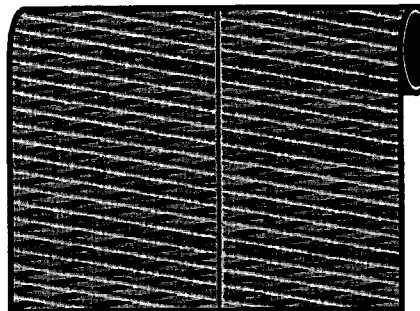


Figure 7: Double mat

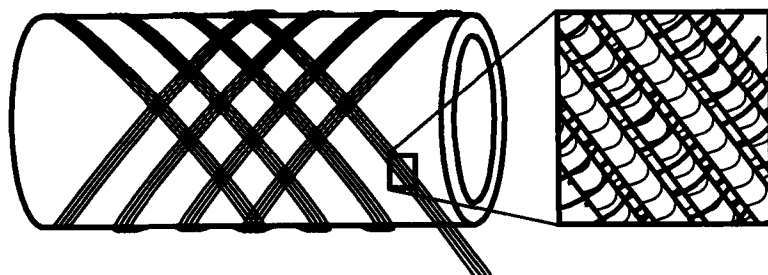
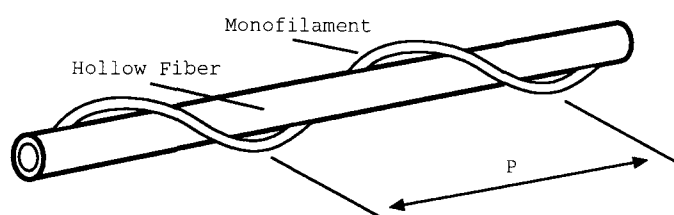


shown that modules constructed with very uniform inter-fiber spacing possess higher mass transfer efficiencies than modules with uneven fiber spacing (1).

MAT TECHNOLOGY

A mat configuration consists of fibers uniformly spaced by the use of a polypropylene filament that runs perpendicular to the fiber matrix (Figure 6). This filament assures even spacing between the fibers and does not participate in gas exchange.

The manufacturers can specify the number of fibers per square inch, the particular dimensions of the fiber, and the bias

Figure 8: Tape technology**Figure 9: Helical configuration**

or angle of fibers relative to the blood flow.

A variation of this technique is a double layer mat pattern. Instead of one mat unwinding from a spool there are two sheets of the mat fibers (Figure 7). These two fiber sheets are at a specific bias to each other which the manufacturer determines. Thus, two sheets of fibers at a fixed angle wrap around a center core to yield the fiber bundle.

Theoretically, the efficiency varies depending on the angles that the fiber sheets are placed relative to each other. The angle of the fiber planes influences mass transfer as it regulates secondary flow characteristics. Both single and double mat fiber bundling techniques utilize a width of fibers the same dimension or larger than the core. This should eliminate the potential variations in fiber spacing associated with inconsistent performance.

TAPE TECHNOLOGY

Tape technology resembles the mat configuration (Figure 8). This method of fiber bundling involves evenly spaced fibers, 5 to 10 fibers wide, that are wrapped around a core, much like tape being pulled of a dispenser. This is similar to the mat with the exception that the mat is the entire width or larger than the core, while the tape technology is a fixed width of only several fibers. Since the width is fixed, the fibers must be wound up and down the length of the core which may create some areas of overlap and uneven spacing.

HELICAL CONFIGURATION

The helical technique utilizes the wrapping of a single fila-

ment around each fiber (Figure 9). This configuration alters the blood flow path in order to enhance gas exchange. The fiber strands are then wound around a center core in the same fashion as the single strand technique.

CONCLUSION

Optimal clinical outcomes are contingent upon the reliability of a membrane oxygenator to maintain consistent gas transfer. Oxygenator manufacturers specify ranges for deviations in fiber dimensions, inner and outer diameter, winding specifications and packing density, i.e., the number of fibers per square inch. This provides a means for establishing gas transfer capacities and limitations.

However, alterations in the fibers may occur due to less than optimal shipping, handling, and storage conditions which may result in substandard performance of an oxygenator. In addition, varying patient parameters and clinical protocols may also influence the gas transfer capabilities of these devices.

REFERENCES

1. Gaylor JDS, Hickery S, Bell G, and Pei JM. Membrane oxygenators: influence of design on performance. *Perfusion*. 1994; 9(3): 173-180.
2. Akzo Nobel. Technical products reference manual (brochure). Wuppertal, Germany: 1995.
3. Kesting RE. *Synthetic Polymeric Membranes*, 2nd ed. New York: John Wiley & Sons; 1985: 290-296.
4. Mitsubishi-Rayon. Polyolefin Hollow Fiber Membrane Technical Information (brochure). New York; 1993.
5. Terumo. Development of a new microporous hollow fiber membrane for oxygenators (brochure). Muramoto T, Tatebe K, Nogawa A, et al. Somerset, NJ: 1994.
6. Beckley PD, Holt DW, and Tallman RD. Oxygenators for extracorporeal circulation. In: CT-Mora, ed. *Cardiopulmonary Bypass Principles and Techniques of Extracorporeal Circulation*. New York: Springer Verlag. 1995; 199-219.
7. High KM, Snider MT, and Bashein G. Principles of oxygenator function:- Gas exchange, heat transfer, and blood artificial surface interaction. In:-GP-Gravelee, RF-Davis, and JR-Utley eds. *Cardiopulmonary Bypass Principles and Practice*. Baltimore, MD: Williams and Wilkins. 1993; 28-54.