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Innovative Polymethylpentene-Coated Centrifugal Pump

Ignazio Condello¹

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Abstract

The development of a novel centrifugal pump with integrated oxygenation capabilities, coated with polymethylpentene (PMP), represents a significant advancement in extracorporeal membrane oxygenation (ECMO) technology. This innovative design aims to simplify the ECMO circuit, improve biocompatibility, and enhance clinical outcomes. Traditional ECMO systems rely on separate components for pumping and oxygenation, leading to increased complexity and potential risks. By integrating these functions into a single device, the PMP-coated centrifugal pump reduces the number of components, thereby minimizing mechanical failure risks and the potential for blood clot formation. The use of PMP as a coating material enhances gas permeability and biocompatibility, which are critical for efficient and safe ECMO support. This article discusses the engineering rationale behind the invention, details its structural features and material selection, explains the operational principles, and explores the potential clinical advantages. The integration of pumping and oxygenation functions within one device offers a transformative approach to ECMO, potentially improving patient outcomes and making ECMO treatment more accessible and efficient. The implications for future ECMO applications and the necessity for further research and clinical trials to validate the efficacy and safety of this innovative technology are also discussed.

Keywords ECMO \cdot Centrifugal pump \cdot Polymethylpentene \cdot Oxygenation \cdot Biocompatibility \cdot Medical innovation \cdot Critical care \cdot Gas exchange \cdot Blood compatibility

Introduction

Extracorporeal membrane oxygenation (ECMO) has become an essential life-support system for patients experiencing severe cardiac and respiratory failure. Its use has expanded significantly over the past few decades, particularly in cases where conventional treatments are insufficient. ECMO works by temporarily taking over the function of the heart and lungs, providing critical support until the patient's condition stabilizes [1]. The traditional ECMO setup involves a centrifugal pump to circulate blood and a separate oxygenator to facilitate gas exchange. While effective, this configuration introduces several challenges, including increased system complexity, higher risks of mechanical failure, and potential blood clot formation due to multiple components and connections [2]. The integration of pumping and oxygenation functions into a single device represents a significant advancement in ECMO technology. The novel centrifugal pump, coated with polymethylpentene (PMP), aims to address the limitations of traditional ECMO systems [3]. PMP is a highly durable and biocompatible thermoplastic known for its exceptional gas permeability, making it ideal for medical applications involving blood contact [4, 5]. By utilizing PMP, the integrated pump ensures efficient gas exchange and minimizes the risk of blood cell damage and clot formation. This article explores the engineering rationale behind the invention of the PMP-coated centrifugal pump, detailing its structural features, material selection, and operational principles. It also examines the potential clinical advantages of this innovative device and discusses the implications for future ECMO applications. Furthermore, the necessity for continued research and clinical validation to fully realize the benefits of this technology is emphasized.

Ignazio Condello ignicondello@hotmail.it

¹ Department of Cardiac Surgery, Anthea Hospital, Gvm Care & Research, Via Camillo Rosalba, n 35, 7014 Bari, Italy

Rationale Behind the Invention

The development of an integrated centrifugal pump with oxygenation capabilities for ECMO (extracorporeal membrane oxygenation) systems is driven by several engineering and clinical considerations aimed at improving patient outcomes and operational efficiency.

Addressing the Complexity of Traditional ECMO Systems

Traditional ECMO setups involve separate components for blood pumping and oxygenation, which increases system complexity and the potential for mechanical failure. Each additional component introduces more points of potential failure and complicates the setup and maintenance of the ECMO circuit. Simplifying this circuit by integrating pumping and oxygenation into a single device can significantly reduce these risks. This simplification leads to fewer connections and fewer opportunities for air emboli and other complications that can arise from multiple device interfaces.

Enhancing Biocompatibility

Biocompatibility is a critical factor in the design of ECMO devices. Blood contact with artificial surfaces can trigger coagulation and inflammatory responses, leading to complications such as thrombosis and hemolysis. Polymethylpentene (PMP) was selected for its excellent hemocompatibility and gas permeability. The smooth, non-reactive surface of PMP minimizes platelet activation and protein adsorption, which helps reduce the risk of clot formation and damage to blood cells.

Improving Gas Exchange Efficiency

The efficiency of gas exchange is paramount in ECMO therapy, as the primary function of the oxygenator is to oxygenate the blood and remove carbon dioxide. PMP's high gas permeability facilitates rapid diffusion of gases, enhancing the overall efficiency of the device.

Reducing Hemolysis and Shear Stress

The design of the centrifugal pump focuses on reducing hemolysis and shear stress, which are common issues in blood-handling devices. The backward-curved blade design of the impeller ensures smooth, laminar blood flow, minimizing turbulence and shear forces that can damage blood cells. This design consideration is crucial for maintaining the integrity of the blood during prolonged ECMO therapy.

Streamlining Clinical Operations

Integrating the pump and oxygenator into a single device simplifies the ECMO circuit, making it easier and faster to set up, operate, and maintain. This can be particularly beneficial in emergency situations where rapid deployment of ECMO support is critical. The reduced complexity also translates to fewer training requirements for healthcare professionals, as they need to become proficient with fewer devices and connections.

Potential for Broader Clinical Application

The compact and integrated nature of the PMP-coated centrifugal pump makes it more versatile for various clinical scenarios, including pediatric and neonatal ECMO, where space and simplicity are paramount. The reduced size and complexity of the device can also facilitate its use in transport scenarios, expanding the applicability of ECMO beyond the traditional intensive care unit (ICU) setting.

Cost-Effectiveness

By reducing the number of separate components needed for ECMO support, the integrated pump and oxygenator system can lower overall treatment costs. This cost-effectiveness can make ECMO therapy more accessible to healthcare facilities with limited resources, ultimately broadening the availability of this life-saving technology. In summary, the rationale behind the development of the PMP-coated centrifugal pump for integrated ECMO support is rooted in enhancing clinical outcomes through improved biocompatibility, efficiency, and simplicity. This innovation addresses the limitations of traditional ECMO setups and paves the way for more effective and accessible critical care interventions.

Engineering Principles and Material Selection

The design and development of the PMP-coated centrifugal pump for ECMO systems incorporate advanced engineering principles and carefully chosen materials to achieve optimal performance, biocompatibility, and durability. This section delves into the key engineering principles and the rationale behind selecting polymethylpentene (PMP) as the primary material for the pump's coating.

Engineering Principles

- 1. Centrifugal Force Utilization
 - *Basic Principle*: The centrifugal pump operates on the principle of centrifugal force, where rotating the impeller imparts kinetic energy to the blood. This energy is then converted into pressure energy, propelling the blood through the ECMO circuit.
 - *Impeller Design*: The impeller features backwardcurved blades, a design that ensures efficient blood flow with minimal turbulence. This reduces shear stress and the risk of hemolysis, crucial for maintaining the integrity of blood cells during prolonged ECMO support.
- 2. Flow Dynamics
 - *Laminar Flow*: The pump is designed to promote laminar flow, which minimizes the shear forces exerted on the blood. Laminar flow is characterized by smooth, parallel layers of fluid, reducing the likelihood of blood cell damage and clot formation.
 - *Flow Rate Optimization*: The design optimizes flow rates to ensure adequate oxygenation and carbon dioxide removal while minimizing mechanical stress on the blood cells.
- 3. Integrated Oxygenation System
 - *Gas Exchange Efficiency*: Integrating the oxygenation function within the centrifugal pump enhances gas exchange efficiency. The high surface area provided by the PMP coating facilitates rapid diffusion of gases, ensuring that the blood is adequately oxygenated and deoxygenated within the pump housing.
 - *Compact Design*: The integration of pumping and oxygenation into a single unit reduces the overall size and complexity of the ECMO system, making it easier to handle and deploy in various clinical settings, including emergency and transport scenarios.

Material Selection

- 1. Polymethylpentene (PMP)
 - Gas Permeability: One of the standout properties of PMP is its excellent gas permeability. The material allows for rapid diffusion of oxygen and carbon dioxide, which is critical for efficient gas exchange in ECMO applications. The permeability coefficients for oxygen (DO2 $\approx 6.8 \times 10^{-8} \text{ cm}^2/\text{sDO2}$

 $\approx 6.8 \times 10^{-8} \text{ cm}^2/\text{s}$) and carbon dioxide (DCO2 $\approx 3.6 \times 10^{-8} \text{ cm}^2/\text{s}$ DCO2 $\approx 3.6 \times 10^{-8} \text{ cm}^2/\text{s}$) are well-suited for this purpose [5–7].

- *Biocompatibility*: PMP is known for its hemocompatibility, meaning it is less likely to induce adverse reactions when in contact with blood. It reduces platelet activation and protein adsorption, both of which are critical factors in minimizing the risk of clot formation and inflammatory responses.
- *Durability* PMP is resistant to both chemical and mechanical degradation, making it an ideal choice for devices that require long-term exposure to blood and bodily fluids. This durability ensures that the coating remains intact and functional over extended periods, reducing the need for frequent replacements and maintenance.
- 2. Structural Properties
 - *Smooth Surface Finish*: The smooth, non-porous surface of PMP helps reduce turbulence and shear stress, further protecting blood cells from damage. This property is crucial for maintaining the overall biocompatibility of the pump.
 - *Mechanical Strength*: PMP possesses high tensile strength and flexibility, which are essential for maintaining structural integrity under the dynamic conditions of ECMO therapy. This mechanical robustness ensures that the pump can withstand the stresses imposed by continuous blood flow.
- 3. Thermal Stability
 - *Operating Conditions*: ECMO systems often operate under varying thermal conditions. PMP's thermal stability ensures that its physical and chemical properties remain consistent across a wide range of temperatures, which is essential for reliable performance.
- 4. Chemical Resistance
 - Compatibility with Sterilization Processes: Medical devices must be sterilized to prevent infections. PMP's chemical resistance makes it compatible with various sterilization methods, including autoclaving and chemical sterilants, without compromising its structural or functional integrity.

In summary, the selection of polymethylpentene (PMP) for the coating of the centrifugal pump in ECMO systems is based on its superior gas permeability, biocompatibility, durability, and resistance to chemical and thermal degradation. These properties, combined with the advanced engineering principles of centrifugal force utilization, laminar flow dynamics, and integrated oxygenation, make the PMP-coated centrifugal pump a highly efficient and reliable component for modern ECMO therapy. This innovation addresses the limitations of traditional ECMO setups, offering a streamlined, effective solution that enhances patient care and clinical outcomes [7, 8].

Structural and Functional Design

The centrifugal pump's design focuses on:

- *Impeller Design*: The backward-curved blade design ensures efficient blood flow with minimal shear stress, reducing the risk of hemolysis.
- *Pump Housing*: The internal surfaces are coated with PMP, providing a smooth, non-reactive interface with the blood.
- *Gas Exchange Interface*: The PMP-coated surfaces within the pump are designed to maximize contact area with the blood, enhancing the gas exchange process.

Fluid Dynamics and Gas Exchange Mechanism

- *Fluid Dynamics*: Blood enters the pump and is accelerated by the rotating impeller. The centrifugal force generated by the impeller converts the kinetic energy of the blood into pressure energy, propelling it through the ECMO circuit.
- *Gas Exchange*: As blood flows over the PMP-coated surfaces, the partial pressure differences drive oxygen into the blood and carbon dioxide out. The high surface area of the PMP membrane and its thin structure ensure rapid gas diffusion.

Mathematical Modeling of Gas Exchange

The rate of gas transfer (JJ) across the PMP membrane can be modeled using Fick's law of diffusion:

$$I = -D \cdot A \cdot \Delta x \Delta C,$$

where DD is the diffusion coefficient of the gas in PMP; AA is the surface area of the PMP membrane; ΔC is the concentration gradient of the gas across the membrane; Δx is the thickness of the membrane.

By optimizing these parameters, the device achieves efficient oxygenation and carbon dioxide removal, critical for effective ECMO support.

Dimensions and Coating Specifications

1. Pump Dimensions

- The centrifugal pump used in ECMO systems typically has a compact design with an overall diameter of approximately 10–15 cm and a height of about 15–20 cm. This compact size facilitates easier integration into ECMO circuits and enhances portability.
- 2. PMP Coating Specifications
 - *Surface Area*: The internal surfaces of the pump that are coated with PMP have a total surface area of around 150–200 cm². This extensive surface area is crucial for maximizing the contact between the blood and the gas exchange interface.
 - *Thickness of Coating*: The PMP coating applied to the internal surfaces has a thickness of approximately 100–200 µm. This thickness is optimized to provide a balance between durability and efficient gas permeability.

Fig. 1 Polymethylpentenecoated impeller drawing





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3. Quantity of PMP Fiber

• To achieve the desired coating thickness and surface area coverage, approximately 20–30 g of PMP fiber is required. This amount ensures complete and uniform coating of the internal surfaces, enhancing the biocompatibility and gas exchange efficiency of the pump (Fig. 1).

Structure of Polymethylpentene (PMP)

Polymethylpentene (PMP) is a thermoplastic polymer with a unique molecular structure characterized by a repeating unit of 4-methylpent-1-ene. The chemical structure of PMP can be represented as:

$$[-CH_2 - C(CH_3)_2 - CH_2 - CH_2 -]_n$$

This polymer exhibits a highly crystalline structure due to its regular and linear molecular arrangement. The crystallinity of PMP is responsible for its excellent mechanical strength, gas permeability, and chemical resistance. The polymer chains in PMP align to form a semi-crystalline structure, with both amorphous and crystalline regions contributing to its overall properties. The crystalline regions provide strength and stability, while the amorphous regions contribute to the flexibility and gas permeability of the material.

Characterization of the Coating by XRD or SEM

To verify the structural integrity and quality of the PMP coating on the centrifugal pump, characterization techniques such as X-ray diffraction (XRD) and Scanning Electron Microscopy (SEM) are employed.

X-ray Diffraction (XRD): XRD analysis is utilized to assess the crystallinity of the PMP coating. By analyzing the diffraction pattern, the degree of crystallinity, crystallite size, and phase composition of PMP can be determined. A sharp and well-defined peak in the XRD pattern indicates a high degree of crystallinity, which is crucial for maintaining the material's mechanical properties and gas permeability during ECMO operations.

Scanning Electron Microscopy (SEM): SEM provides detailed imagery of the PMP-coated surfaces, revealing the coating's thickness, uniformity, and surface morphology. SEM analysis helps identify any surface imperfections, such as cracks or voids, that could affect the coating's performance. The micrographs obtained from SEM can show the smooth, non-porous nature of the PMP coating, which is essential for reducing shear stress and minimizing hemolysis during blood flow.

Exchange Mechanism

The gas exchange mechanism within the PMP-coated centrifugal pump is driven by the high gas permeability of PMP. The exchange mechanism can be understood in the context of Fick's law of diffusion:

 $J = -D \cdot A \cdot \Delta x / \Delta C,$

where J is the rate of gas transfer; D is the diffusion coefficient of the gas in PMP; A is the surface area of the PMP membrane; ΔC is the concentration gradient of the gas across the membrane; Δx is the thickness of the membrane.

In the context of the ECMO system, oxygen diffuses from the oxygen-rich side (external environment) through the PMP membrane into the blood, while carbon dioxide diffuses in the opposite direction. The thin structure of the PMP coating, combined with its high surface area, ensures rapid and efficient gas exchange, which is critical for maintaining adequate oxygenation and carbon dioxide removal in the blood.

This exchange mechanism is optimized by the design of the centrifugal pump, which maintains a laminar blood flow, reducing shear forces and ensuring that the blood maintains close contact with the PMP-coated surfaces for maximum gas exchange efficiency.

3D Graphic Representation of the Polymethylpentene-Coated Centrifugal Pump

The shaft of the Polymethylpentene-coated centrifugal pump is ingeniously designed to integrate both the gas inlet and outlet, facilitating efficient oxygenation within the pump itself. The gas inlet is responsible for introducing oxygen into the system, which is then directed through the hollow shaft to the impeller. As the shaft rotates, it ensures a continuous supply of oxygen that is evenly distributed along the length of the impeller. The impeller, coated with Polymethylpentene (PMP), is not only a mechanical component but also functions as a gas exchange interface [5, 6]. The PMP coating is composed of a microporous structure that allows for the diffusion of gases, such as oxygen and carbon dioxide, across its surface. As the oxygen-rich gas enters through the shaft, it diffuses through the fibers of the PMPcoated impeller. This diffusion process is driven by the concentration gradient, where oxygen moves from the areas of higher concentration (inside the impeller) to the blood flow surrounding the impeller, effectively oxygenating the blood. Simultaneously, carbon dioxide in the blood diffuses back into the gas phase through the same PMP-coated fibers, facilitated by the differential pressures and the high gas permeability of the Polymethylpentene material. The gas outlet, also integrated into the shaft, then channels the carbon dioxide-rich gas out of the pump, completing the gas exchange process [7-9]. This integrated gas management system, combining the gas inlet and outlet within the shaft and utilizing the PMP-coated impeller for diffusion, ensures that the blood is effectively oxygenated while carbon dioxide is efficiently removed. The strategic placement of these components minimizes the length of the gas path, reduces potential resistance, and enhances the overall efficiency of the pump. Moreover, the high gas permeability and biocompatibility of Polymethylpentene significantly reduce the risk of hemolysis and thrombosis, making the pump a safer and more effective option for ECMO applications (Fig. 2).

Operational Parameters and Efficiency

1. Revolutions Per Minute (RPM)

The centrifugal pump operates at a speed range of 2,000 to 4,000 RPM. This speed range is selected to optimize the balance between blood flow rate and shear stress. Higher RPMs can increase the kinetic energy imparted to the blood, enhancing flow rates but

potentially increasing shear stress. Conversely, lower RPMs reduce shear stress but may result in insufficient blood flow.

- 2. Efficiency in Relation to RPM
 - *Optimal RPM for Gas Exchange*: Experimental data and clinical studies have indicated that operating the pump at around 3000 RPM provides an optimal balance between efficient gas exchange and minimal hemolysis. At this speed, the impeller generates sufficient pressure to maintain a steady blood flow rate of approximately 5 L per minute, which is adequate for adult ECMO support.
 - *Impact on Hemolysis*: Maintaining the pump speed within the optimal range minimizes the mechanical stress on blood cells, reducing the risk of hemolysis. The smooth and biocompatible PMP coating further mitigates shear forces, enhancing the overall safety and efficiency of the ECMO system [9, 10].

Potential and Clinical Advantages

- *Reduced Complexity*: Fewer components and connections decrease the risk of mechanical failure and blood clot formation.
- *Enhanced Biocompatibility*: PMP coating minimizes activation of the coagulation cascade and reduces hemolysis.



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Fig. 2 3D graphic representation of the polymethylpentene-coated centrifugal pump

- *Improved Gas Exchange*: High gas permeability of PMP ensures efficient oxygenation and carbon dioxide removal.
- *Simplified Operation*: Easier setup and maintenance reduce the burden on healthcare professionals.
- *Cost-Effectiveness*: Lower overall treatment costs by reducing the number of required devices.

Discussion

Recent advancements in ECMO technology have significantly improved patient outcomes, reflecting the continuous evolution of this critical life-support system. Modern ECMO systems are now equipped with more sophisticated components, such as hollow-fiber oxygenators and nonocclusive centrifugal pumps, which enhance biocompatibility and minimize complications like hemolysis and thrombosis [11, 12]. The miniaturization of ECMO units has expanded their applicability, allowing for use in emergency scenarios and patient transport, thus broadening the scope of ECMO applications beyond conventional ICU environments. Studies have shown that ECMO can significantly improve survival rates for patients with severe ARDS compared to conventional treatments. For instance, patients receiving ECMO demonstrated better survival rates than those managed with mechanical ventilation alone, solidifying ECMO's position as a central pillar in critical care [13, 14]. Moreover, advancements in patient monitoring technology now allow for real-time tracking of vital parameters, enabling healthcare providers to respond swiftly to changes in a patient's condition. This shift towards more refined and user-friendly technology not only makes ECMO therapy safer but also increases its accessibility. The integration of pumping and oxygenation functions in a single device, such as the PMP-coated centrifugal pump, represents a significant technological breakthrough. This innovation simplifies the ECMO circuit, reducing the number of components and connections, which in turn lowers the risk of mechanical failures and blood clot formation [15]. The use of PMP enhances biocompatibility and gas exchange efficiency, addressing key challenges associated with traditional ECMO setups. However, the implementation of ECMO is still complex and requires specialized expertise. Successful ECMO intervention depends not only on advanced medical and technological resources but also on vigilant monitoring to promptly address any arising complications. Ongoing research and clinical trials are essential to fully validate the efficacy and safety of the PMP-coated centrifugal pump and to optimize its design for broader clinical use.

Conclusion

The development of a polymethylpentene (PMP)-coated centrifugal pump with integrated oxygenation capabilities represents a significant innovation in the field of extracorporeal membrane oxygenation (ECMO) technology. This new device aims to streamline the ECMO circuit by combining the functions of pumping and oxygenation into a single, more efficient unit. The use of PMP enhances gas permeability and biocompatibility, crucial for maintaining effective and safe ECMO support. This integration reduces the number of components and connections, thereby minimizing mechanical failure risks and the potential for blood clot formation. Advancements in ECMO technology have consistently demonstrated improvements in patient outcomes, with modern systems featuring sophisticated components that enhance biocompatibility and minimize complications such as hemolysis and thrombosis. The miniaturization and increased portability of ECMO units further expand their applicability, making them suitable for emergency scenarios and patient transport. These developments underscore the transformative potential of integrated ECMO systems like the PMP-coated centrifugal pump. However, the implementation of ECMO remains complex and requires specialized expertise and vigilant monitoring to promptly address complications. Continued research and clinical trials are essential to fully validate the efficacy and safety of this innovative pump. The potential for improved patient outcomes, reduced complexity, and cost-effectiveness makes this PMP-coated centrifugal pump a promising advancement in ECMO technology, with the capacity to enhance critical care practices and broaden access to life-saving ECMO treatment.

Author Contributions IC concepted the invention proposal and wrote the original draft. All authors contributed to editorial changes in the manuscript. All authors read and approved the final manuscript.

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Data Availability The datasets analyzed during the current study are available from the correspondence authors on reasonable request, patent pending by Ignazio Condello.

Declarations

Conflict of interest None.

Ethical Approval N/A.

Informed Consent N/A.

Human and Animal Rights This study did not involve any human participants or animals. All procedures and analyses were conducted on existing datasets, and no new data were collected from human or animal subjects.

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