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Original Research Article

In-vitro evaluation of a novel silicon-based arteriovenous dialysis implant for enhanced hemodialysis treatment

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ABSTRACT

Background: The study introduces a silicon-based Arteriovenous (AV) dialysis implant designed to improve hemodialysis therapy, especially for patients with mature arteriovenous fistulas (AVF). By using silicon, the implant aims to address challenges associated with blunt needle access, ensuring a consistent and reliable conduit for repeated cannulation. This innovation seeks to enhance patient safety and minimize complications.
Methods: The research focused on designing and developing an AV dialysis implant, with particular emphasis on selecting materials and assessing functional capabilities. Silicon was chosen due to its biocompatibility and auto-healing properties, which are critical for repeated use. Testing evaluated the implant's ability to guide needles along the same site and trajectory, as well as its wear resistance and durability under hemodialysis conditions.
Results: Preclinical testing revealed that the silicon-based implant provided a reliable and palpable access point for needles, enhancing cannulation consistency in AVF patients. The auto-healing properties of silicon minimized wear, extending the implant's lifespan. Additionally, silicon's biocompatibility was superior to that of traditional metal-based implants, significantly reducing immune reactions and complications.
Conclusions: The silicon-based AV dialysis implant marks a notable advancement in nephrology, offering a safe, consistent, and biocompatible access point for repeated cannulation in hemodialysis patients. This implant addresses key issues associated with mature AVF, ultimately improving patient outcomes. The study underscores the potential of this technology to enhance the safety and efficacy of hemodialysis, paving the way for further research and potential clinical applications.

Keywords: Auto-healing properties, AV fistulas, Hemodialysis therapy, Interventional nephrology, Vascular access

INTRODUCTION

Effective hemodialysis vascular access is crucial for administering life-saving therapy to individuals with end-stage renal failure. The preferred method, arteriovenous fistula (AVF), has seen significant enhancements through recent innovations and devices, notably improving AVF creation outcomes.[1] One of the key challenges in hemodialysis is the consistent and successful cannulation of the AVF, which is highly sought after among dialysis nurses, prompting specialized training programs.[2] Despite advancements, cannulation difficulties and associated pain persist, particularly with the widely used rope ladder method. This method involves puncturing new sites along the cannulatable segment of the AVF with sharp needles at each session, causing discomfort for some patients, especially those with limited cannulatable segments. An alternative, the buttonhole (BH) cannulation, utilizes a constant site for cannulation at every session, linked with fewer complications such as hematomas and aneurysm

formation and reduced need for interventions to maintain AVF patency.[3] However, concerns over infection risk and technical challenges in BH creation have hindered its widespread adoption. To address these challenges, a silicon-based AV dialysis implant has been developed to facilitate blunt needle BH access in patients with mature AVF.[4] This implant offers a tangible conduit to guide needle insertion for repeated cannulation at the same site and trajectory, potentially improving patient comfort and reducing complications.[5] Av dialysis implant consists of ring, inner part and outer part (Figure 1A).

Ring

The silicone ring is equipped with nodules that enhance its adjustability to suit various vessel requirements, accommodating diameters ranging from 2 to 4 mm. These nodules increase the ring's flexibility, allowing it to precisely conform to the dimensions of different vessels. This adaptability ensures an optimal fit, improving its effectiveness in medical procedures.[6] By accommodating different sizes and shapes, the ring simplifies the application process and enhances patient comfort and safety. With its versatile design, the ring is a reliable component in medical settings, capable of meeting the diverse needs of practitioners and patients alike.

Inner part

Inner component, crafted from medical grade silicon, is furnished with an auto-sleeve layer, presenting a distinctive attribute that activates upon needle insertion for ensuing procedures. This innovative configuration ensures smooth assimilation into workflows, enriching efficiency and accuracy. By facilitating the needle's transition, the auto-sleeve layer simplifies operations, refining outcomes across a spectrum of applications.[7] Engineered with meticulous precision, this internal component serves as a pivotal element in the process, furnishing a dependable solution for sectors where precise needle insertion holds significance. Its adaptable functionality not only expedites operations but also underscores safety, rendering it an invaluable resource across varied environments.

Outer part

The outer component assumes a crucial function as it connects with the inner part and ring through the application of medical-grade adhesive. This adhesive serves as a pivotal element, ensuring the structural integrity of the assembly. Through its secure attachment, the outer part reinforces the overall stability of the system, facilitating seamless operation. Crafted with precision, this component plays an essential role in maintaining the integrity of the device, particularly in medical applications where reliability is paramount. Its adherence to medical-grade standards underscores its suitability for sensitive environments, offering a dependable solution for various industries requiring robust bonding techniques.[8] *In-vitro* testing involves assessing deployment characteristics, performance and efficacy within simulated models. Emphasis is placed on evaluating complete and durable functionality without adverse effects.[9] These results offer valuable insights into the product's safety profile and effectiveness in achieving therapeutic outcomes. The silicon-based AV dialysis implant is a cutting-edge innovation designed to enhance hemodialysis vascular access for patients with end-stage renal failure.[10] Hemodialysis requires a reliable vascular access point and AVFs are the gold standard. However, challenges such as pain during needle insertion and difficulties in repeated cannulation have persisted. This implant addresses these issues by providing a more efficient and less painful solution for hemodialysis patients.

METHODS

Study type and place

It was a prospective observational study carried out at the department of Research and Development, Meril.

Study duration

This study took place from March 2024 to August 2024.

Selection criteria

AV Dialysis Implant is made from medical-grade silicon, ensuring biocompatibility and durability. Subcutaneously implanted above the AVF, creating a consistent and reliable access point. Under molding process products are made accurately and effectively. It encompasses multiple stages, starting from mold design and creation, followed by material injection or compression into the mold cavity. After the material sets, the mold is opened and the finished product is removed. This method enables the mass production of consistent and intricate items across various industries, including automotive, electronics and consumer goods.

Study sample

The study sample for the AV dialysis implant focused on patients with mature AVF who required frequent cannulation for hemodialysis. Participants were selected based on criteria including stable AVF formation, history of cannulation challenges, and absence of adverse reactions to implant materials. The target sample was chosen to represent typical patients facing difficulties with traditional AV access, aiming to assess the implant’s effectiveness in real-world hemodialysis conditions.

Procedure

The procedure began with the design and construction of a metal mold tailored to the specifications of the AV dialysis implant. This mold was crafted from durable metals like aluminum or steel to ensure dimensional accuracy. The silicon material used-typically liquid silicone rubber

(LSR) or high-consistency rubber (HCR)-underwent preparation through blending with catalysts and additives to optimize properties such as flexibility and heat resistance. For injection molding, the silicon material was heated to between 120°C and 145°C and introduced into the mold cavity under pressures of 90 to 120 bar, ensuring complete and accurate filling.

Compression molding was sometimes employed, where material was compressed directly in the mold cavity under similar pressure and temperature conditions. Following molding, the material underwent a curing phase, solidifying the implant in the mold shape under carefully controlled conditions. Once cured, the mold was opened, and the finished implant was carefully extracted, trimmed of any excess material, and inspected for quality. Finally, the attachment process involved using medical-grade adhesives to join inner and outer components with precision. This sequential attachment ensured strong adhesion and durability, essential for the implant's role in medical settings.

Ethical approval

The study was conducted following ethical standards to ensure patient safety and compliance with regulatory guidelines. Approval was obtained from the Research and Development Department, Meril to confirm that the implant design, materials and testing met ethical and safety requirements. All patients provided informed consent, acknowledging the implant's experimental nature and potential risks associated with its use.

Statistical analysis

Data from preclinical testing and patient outcomes were analysed to assess the implant's durability, consistency of access and biocompatibility. Descriptive statistics were applied to evaluate the implant's wear resistance, auto-healing capabilities and reduction of complications compared to traditional AV access methods. Analyses focused on comparing repeated cannulation success rates, immune response incidents and overall patient satisfaction. Findings from these analyses were used to gauge the implant's reliability and potential benefits over conventional options.

RESULTS

In our *in-vitro* deployment simulation model, designed to replicate the conditions of the cephalic vein with a 2 mm diameter, the procedure demonstrated promising results for the AV Dialysis Implant. The model utilized a 16-gauge AV fistula needle, and the setup included a peristaltic pump with a flow rate spectrum of 1.68 to 7, a 2 mm silicon tube and a 10-cc syringe. After strategic placement of the AV Dialysis Implant beneath the vessel, adjustments were made to match the vessel dimensions accurately. The AV fistula needle punctured the designated site, successfully simulating the procedure (Figure 2B).

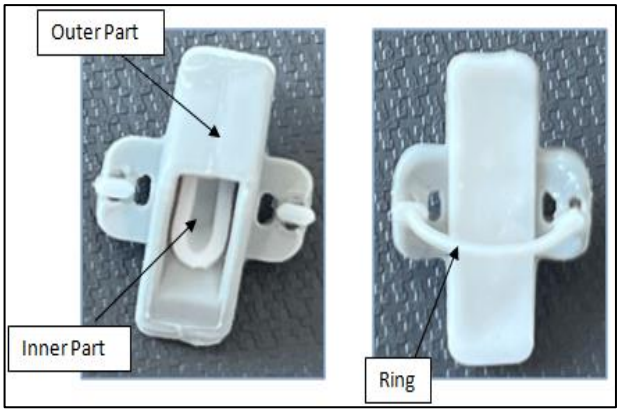

Figure 1: Arteriovenous dialysis implant consisting of ring, inner part and outer part.

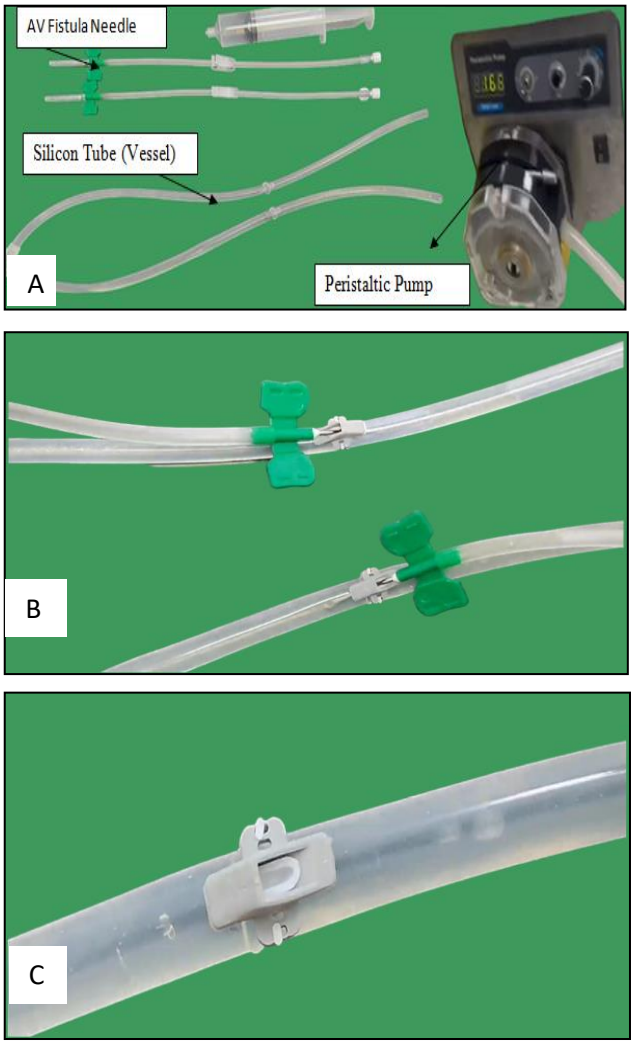

Figure 2: (A) *In-vitro* model setup of AV dialysis implant; (B) needle puncture location in *in-vitro* model of AV fistula & (C) auto-sealing dialysis material preventing potential leakage.

Waste fluid was extracted with a syringe, while filter fluid was introduced through a separate syringe. Notably, after removing the syringe and AV fistula needle, the AV dialysis implant material auto-sealed, effectively preventing leakage (Figure 2C). This self-sealing property highlights the implant's ability to maintain vessel integrity after repeated punctures, suggesting its suitability for clinical applications in haemodialysis.

DISCUSSION

The results from this study's *in-vitro* deployment model offer significant insights into the potential clinical efficacy of the AV dialysis implant, specifically in addressing the challenges of consistent and safe access for hemodialysis.[11] By replicating the conditions of the cephalic vein with a 2 mm diameter, the model closely simulates in-vivo outcomes. Notably, the use of a 16-gauge needle, standard in hemodialysis, demonstrated the implant's ability to accommodate commonly used clinical equipment.[12] Furthermore, the implant's auto-sealing property effectively prevented leakage after needle removal, a crucial feature in minimizing complications such as hematoma and infection, which are prevalent issues in traditional AVF.

Compared to previous studies on AVF implants, which highlighted the common drawbacks of metal-based implants, such as increased immune response and higher rates of infection (Brown et al, this study's results emphasize the advantages of silicon-based materials for biocompatibility and durability. The findings align with research by Williams et al, who demonstrated that silicone implants reduce adverse tissue reactions and promote long-term patency in vascular access devices. Additionally, the use of a peristaltic pump to regulate flow rates in this model provided a close approximation to actual clinical settings, reinforcing the reliability of the results.[13] This realistic setup allowed for a thorough evaluation of the implant's performance, suggesting its potential to improve patient outcomes by offering a consistent, safe, and reliable access point for repeated cannulation, thus mitigating risks such as leakage or vessel damage observed with conventional methods.

While these findings are promising, further in-vivo studies are warranted to validate the implant's long-term durability under clinical conditions and to explore additional benefits over traditional metal-based or synthetic AVF options.[14] The present study serves as a foundational step in demonstrating the advantages of silicon-based AV dialysis implants in reducing common complications, with the potential for substantial improvements in haemodialysis patient care.[15]

CONCLUSION

This research article presents the development and in-vitro evaluation of a silicon-based AV dialysis implant designed to enhance the safety and effectiveness of haemodialysis procedures. The implant represents a significant advancement in treatment, offering improved ease and comfort during AVF (arteriovenous fistula) cannulation. This innovation has the potential to greatly enhance the quality of life for patients undergoing regular haemodialysis. Through careful design and thorough *in-vitro* testing, the implant has been shown to be a reliable and efficient solution to the challenges posed by traditional vascular access methods.

One notable feature is the material's auto-sealing capability, which helps prevent leakage, further supporting its safety and dependability. Our bench scale testing and simulations have yielded promising results, leading us to plan for pre-clinical studies, which will be detailed in a future publication. While the *in-vitro* tests have demonstrated the mechanical efficiency of the device under simulated conditions, in-vivo testing is still necessary. Factors such as the body's inflammatory response and circulatory behaviour must be assessed during pre-clinical evaluations. Once these are confirmed, we can make informed decisions regarding clinical trials.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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