Hemodialysis Needle Redesign for Improving Patient Compliance

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Traditional hemodialysis needles often cause significant patient discomfort and vascular injuries due to their rigid design. This study introduces a novel needle made from a thermoplastic polymer blend of Poly(methyl methacrylate) (PMMA), Polypropylene carbonate (PPC), and Polyvinyl acetate (PVAc). The needle transitions from rigid to flexible at body temperature, providing precise directional control similar to steel needles during insertion while conforming to the vasculature. This design minimizes tissue trauma and discomfort, aiming to improve patient comfort and reduce complications such as needle dislodgement and vascular trauma. Tensile testing revealed a tensile modulus of 1.8 GPa at room temperature, decreasing to 135 MPa at body temperature due to the glass phase transition of the polymer blend, which occurs between 24°C and 37°C. This significant drop in tensile modulus ensures the needle maintains sufficient rigidity for insertion and becomes flexible enough to conform to the vein, reducing mechanical mismatch and potential injury. By addressing the mechanical compatibility between the needle and vascular tissues, this design enhances patient adherence to treatment and overall hemodialysis outcomes. This innovative approach aims to mitigate common issues associated with needle insertion in hemodialysis, potentially improving patient compliance and reducing the risk of adverse health outcomes.

Keywords: Hemodialysis, Arteriovenous Fistula, AVF Access Devices, Thermoplastic Elastomers, Patient Comfort, Conforming, Stenosis, Kidney dysfunction, Blood, Needle, Cannulation, Catheter tubes, Veins, Arteries, Hematology

1 Introduction

Chronic Kidney Disease (CKD) affects 40% of individuals over 65 in the United States. As CKD progresses to End-Stage Kidney Disease (ESKD), nearly half a million Americans require hemodialysis, a process where blood is filtered externally through an arteriovenous fistula (AVF) [1]. However, this treatment often leads to patient discomfort, vascular injuries, and adherence challenges.

A significant complication in hemodialysis is vascular injury and stenosis, often caused by rigid stainless steel needles that do not conform to vascular tissues. This mismatch results in friction, stresses, tissue trauma, discomfort, inflammation, and complications such as infiltrations, scarring, and stenosis. While flexible catheters can reduce these issues, their use requires the Seldinger technique for accurate placement, demanding comprehensive training for nurses accustomed to using standard stainless steel needles, the standard for hemodialysis in the United States.

Hemodialysis sessions in the United States last three to five hours, three times a week, or indefinitely for ESKD patients. Micro-movements during sessions cause needle agitation, contributing to vascular complications and discomfort. Pain from needle insertion is a significant factor in non-compliance, with about 30% of patients skipping or shortening sessions due to pain, increasing their risk of hospitalization and mortality [1]. Approximately 20% of hemodialysis patients experience severe pain during needle insertion, even with analgesics, due to fistula infiltration, increasing the risk of needle dislodgement [2]. Needle agitation and patient movement contribute to vascular infiltration and needle dislodgement, causing inflammation and increasing the risk of stenosis or thrombosis. Prolonged pain is commonly associated with vascular swelling and endothelial damage.

To address these issues, this study proposes an innovative needle design that starts rigid for controlled insertion but becomes flexible at body temperature due to a sharp drop in tensile modulus at the glass transition phase. The needle uses a thermoplastic polymer blend of polymethyl methacrylate (PMMA), polypropylene carbonate (PPC), and polyvinyl acetate (PVAc) as a compatibilizer. Our needle design geometry matches medical-grade stainless steel 15-gauge needles used in hemodialysis for mature fistulas.

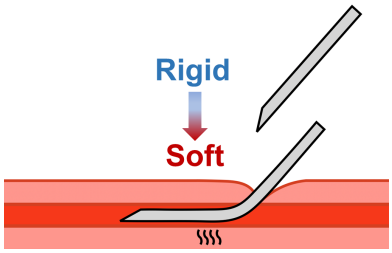

Fig. 1 Concept Illustration of our Polymer Composite Needle Design

2 Materials and Methods

2.1 Needle Material. Our polymer blend consists of Polypropylene Carbonate (PPC), Polymethyl Methacrylate (PMMA), and Polyvinyl Acetate (PVAc), each contributing unique properties to the mix: PPC serves as the plasticizer in this composition, while the PVAc enhances the interface adhesion with its modulus of 3.4 GPa [3]. These polymers are biocompatible and hemocompatible individually, and they do not polymerize when mixed [4][5][6].

To find the thermal time constant, a conservative estimate is taken by choosing the smaller density and specific heat capacity values from each of the three components of our composite.
The thermal time constant is about 20 seconds, according to Equation 1. The highest applicable forced convective heat transfer coef-

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Table 1 Properties of Different Materials

Materials	ρ [g/mL]	c_p [J/g]
PVAc	1.17	1.63
PMMA	1.17	1.48
PPC	1.26	1.70

ficient was chosen for the fastest response time, at about 30 $\frac{W}{m^2 \cdot K}$.

$$\tau = \frac{\rho V c_p}{hA} \tag{1}$$

The τ constant can model how long it takes for the polymer mix to reach the glass phase temperature. From Equation 2, it takes 6 seconds for the needle to reach glass phase temperature at 24 °C for a polymer composite [3], sufficient for needle insertion and adjustments before being clamped down. Needle insertion typically lasts for a few seconds.

$$T(t) = T_\infty + (T_0 - T_\infty) \cdot e^{\frac{-t}{\tau}} \tag{2}$$

The exponential heating equation can generate a plot of the overall needle in Figure 2.

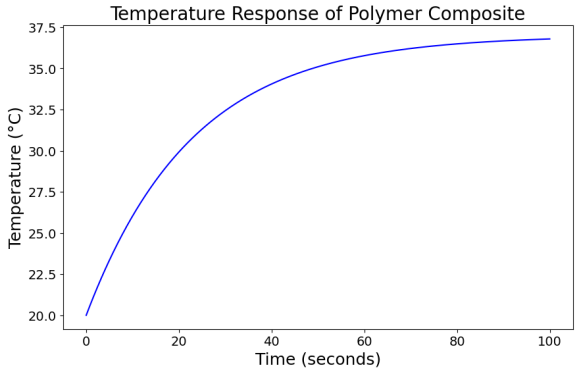

Fig. 2 Theoretical Thermal Response of 15-gauge needle at Human Body Temperature (37°C)

2.2 Thermoplastics. The specific formulation consists of a 70:30 weight ratio of PMMA to PPC with 5 phr PVAc, which can be optimized based on the application.

$$P_{cr} = \frac{\pi^2 EI}{(KL)^2} \tag{3}$$

For a typical 15-gauge needle geometry to withstand buckling, the tensile modulus must be at least 1.52 GPa for a 2 N insertion force, as determined by Equation 3. Insertion forces range from 1.5 N to 2 N [7].

Conversely, the polymer composite at ambient temperature, represented by the blue bar in Figure 3 , with a high Young's modulus of 1.8 GPa, offers substantially greater stiffness. This property is essential for applications that demand precise catheter placement, particularly in challenging vascular interventions where navigational accuracy is critical and a higher degree of rigidity is beneficial.

The red bar in Figure 3 , which reflects the polymer composite warmed to 37 °C with Young's modulus of 135 MPa, compromises flexibility and stiffness. This medium stiffness is advantageous when rigidity is necessary to prevent kinking, but complete rigidity could be detrimental.

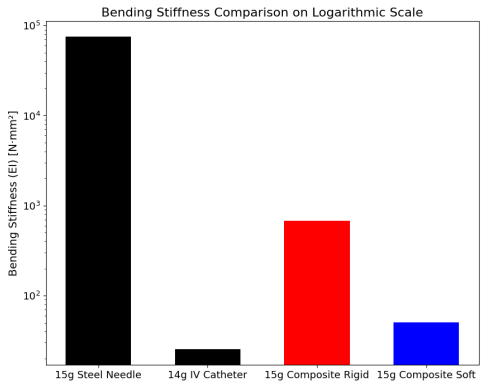

Fig. 3 Bending Stiffness Chart between Commonly used Fluid Delivery Devices

Table 2 Design Criteria

Design Criteria	Young's Modulus (E)
Minimum @ 20 °C	1.52 GPa
70:30 (PMMA: PPC)	1.8 GPa
w/ 5 phr PVAc @ 20 °C	
Target Minimum @ 37 °C	86-134 MPa
70:30 (PMMA: PPC)	135 MPa
w/ 5 phr PVAc @ 37 °C	
PMMA	2.9 GPa
PPC	34-41 MPa

14-gauge IV catheters are designed to minimize kinking and feature a larger inner diameter than conventional medical-grade stainless steel 15-gauge needles. Additionally, 16-gauge IV catheters are widely used. To achieve the same bending stiffness as a 16-gauge IV catheter, a 15-gauge needle would require a tensile modulus of approximately 28.75 MPa. In hemodialysis treatment, it is crucial to maintain the lumen, ensuring that cross-sectional deformation does not result in more than a 50% reduction in flow rate, which is considered kinking [8]. Given that arteriovenous fistula (AVFs) have a tensile modulus at least 2-3 times greater than regular tissue, a tensile modulus between 86 and 134 MPa is ideal for the polymer composite in its soft mode based on achieving a bending stiffness that is 2-3 times more than 14-gauge IV catheters [9].

3 Material Testing

The data presented in Figure 4 shows the results of a tensile test conducted on a dog bone specimen of the polymer composite. The specimen had a cross-sectional area of 3 mm x 14 mm and an unclamped length of 38 mm. The testing was performed using an Instron 34TM-50.

The rule of mixtures was used to estimate the tensile modulus of a solvent-blended polymer composite. The polymers were blended in acetone, which was later evaporated. Given that acetone does not contribute to the stiffness of the composite, it was necessary to normalize the cross-sectional area to reflect only the remaining polymer content. The tensile modulus calculation estimates the polymer composite by adjusting the cross-sectional area to match the actual volume fraction of the polymer blend post-evaporation. This normalization ensures that the calculated tensile modulus reflects the material's behavior after acetone evaporation. Considering this value as an upper bound estimate of the tensile modulus is important, as it assumes ideal conditions with complete acetone evaporation and perfect distribution of the polymer blend without any residual voids or imperfections. However, it is worth noting that the proper addition of PVAc through a Brabender may multiply the tensile modulus [3]. Figure 5 showcases the polymer composite's outer surface temperature dynamics over

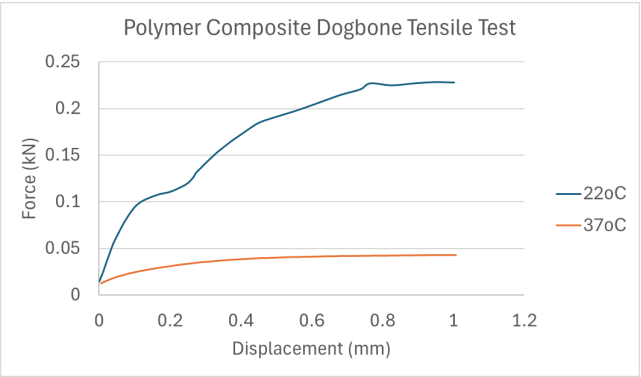

Fig. 4 Instron Tensile Testing of Polymer Composite at Rigid and Soft State

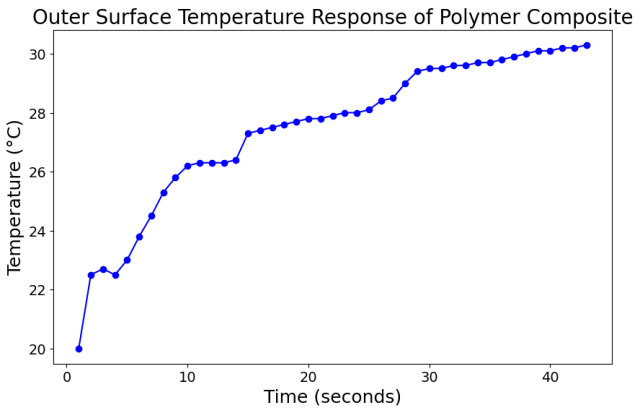

Fig. 5 Surface Temperature Response of Dogbone mold using FLIR Camera

time, captured using a Forward Looking Infrared (FLIR) thermal camera.

The glass phase temperature of PPC is 23°C, but it marginally increases with the addition of PMMA and PVAc, whose property is significant during the insertion of hemodialysis needles.

In our experimental setup, we investigated the thermal response of our polymer composite by placing it in a controlled thermal bath. Initially, the polymer composite was at a starting temperature of 20°C, reflecting common ambient conditions. We then immersed the polymer composite in a thermal bath set To simulate the conditions upon insertion into the body, 37°C is the typical human body temperature. This method allowed us to closely monitor how quickly the polymer composite adapts to the warmer environment. It is critical for assessing its performance characteristics, such as flexibility and thermal stability under operational conditions. This approach provides precise control over the heating rate and uniform temperature exposure, ensuring that our observations and measurements of the polymer's thermal behavior are accurate and reproducible.

3.1 Computational Simulations. ANSYS Workbench was used to conduct the deflection and buckling finite element analysis (FEA) simulations for the various materials before and after skin puncturing. The ambient temperature was set to 22°C, and the body temperature was set as 37°C during all simulations.

Table 3 outlines the combined properties of the polymer composite, as determined using the manufacturing and testing procedures outlined in the Material and Methods section. With these values, the force required at a fixed displacement value of the soft and rigid state were compared to showcase the desired reduction in bending stiffness showcased in Figure 6 where both side and top

Table 3 Mechanical Properties at Different Temperatures

Temperature (°C)	Young's Modulus (MPa)	Poisson's Ratio
22	1800	0.32
37	135	0.32

views are shown at the given loading.

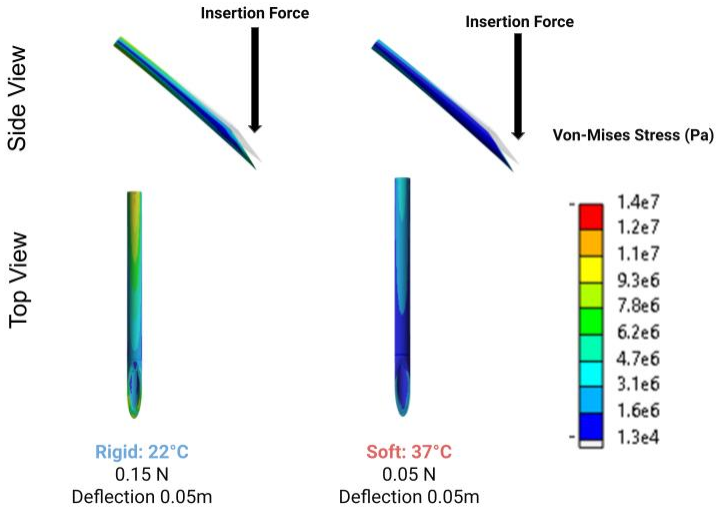

Fig. 6 Stress Contour Plots of Polymer Composite Needle at Different Temperatures

3.2 Polymer Blend Eigenvalue Buckling Analysis. The FEA ANSYS simulations indicated that the polymer blend would not buckle for the eigenvalue buckling tests. The expected insertion force of 1.5 N would not cause buckling as it was less than the critical buckling load in Table 4 found in Appendix II. The insertion force of 2 N was previously mentioned; however, this is more typical of a stainless steel needle.

4 Experimental

The polydimethylsiloxane (PDMS) phantoms were designed to assess the insertion dynamics and vascular interaction of hemodialysis needles under various conditions. By adjusting the bend radius of the phantom channel, the setup could simulate different anatomical scenarios, allowing for the testing of needle adaptation to varying vascular curvatures. This method was used to determine how well the needle performs during insertion at different angles and radii, which is critical for evaluating the risk of needlestick injuries and other vascular damage associated with traditional rigid stainless steel needles.

4.1 Vein Phantom. To further model arteriovenous fistulas (AVFs) effectively for evaluating hemodialysis needle designs, vein phantoms were cast from a polydimethylsiloxane (PDMS) mixture, chosen for its elastomeric properties that closely mimic the stiffness of human fistulas. The phantom is fabricated from a Sylgard 184 kit, employing a 10:2 weight ratio of PDMS to curing agent for the desired 1.5MPa stiffness of a human fistula [13]. This mixture is poured into a 3D printed PLA mold with an internal rod. It was allowed to cure at room temperature for 24 hours. After curing, the PDMS was removed from the mold, and the rod was extracted, leaving a channel that simulated the AVF's lumen. Figure 7a shows a medical-grade stainless steel needle puncturing through the opposite wall, while Figure 7b depicts the needle being dislodged

during different vein movements. Figure 7c shows the needle inserted into a straightened vein phantom. In contrast, Figures 8a and 8b demonstrate the softened needle composite adapting to the same vein movements without puncturing the opposite wall or becoming dislodged, respectively. Figure 8c illustrates the needle conforming to a straightened vein phantom.

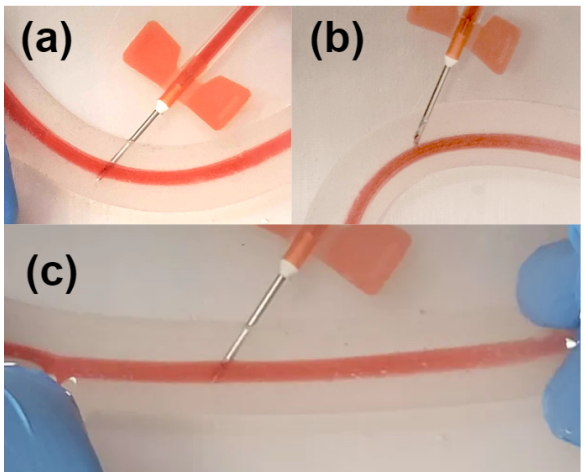

Fig. 7 Medical-grade Stainless Steel Needles Inserted into Vein Phantoms

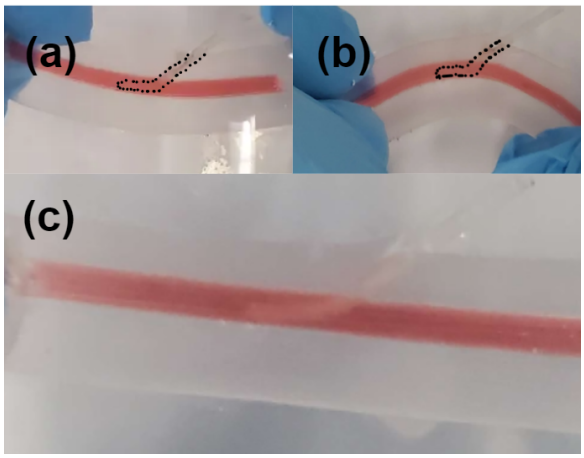

Fig. 8 Softened polymer composite needles are inserted into vein phantoms

4.2 AVF Phantom. Arteriovenous fistula (AVF) phantoms were used to test for needle buckling by simulating the mechanical behavior and vascular response during needle insertion by using an Instron compression test. These phantoms were constructed using the same PDMS mixture discussed in the Vein Phantom section. Figure 9 illustrates this experimental setup: the PDMS buckling phantom is designed to mimic the stiffness of human fistulas and needle puncture testing.

4.3 Flow Considerations. Blood flow in an AVF is typically laminar, with a Reynolds number of approximately 730 at the inflow artery during the first week, indicating laminar flow. Increasing blood draw into the turbulent threshold raises the risk of coagulation and clotting.

Higher flow rates lead to increased shear and pressure, elevating the risk of hemolysis and stenosis, respectively. Hemolysis occurs when red blood cells are destroyed under high shear, exceeding their deformation capacity. To prevent this, blood draw

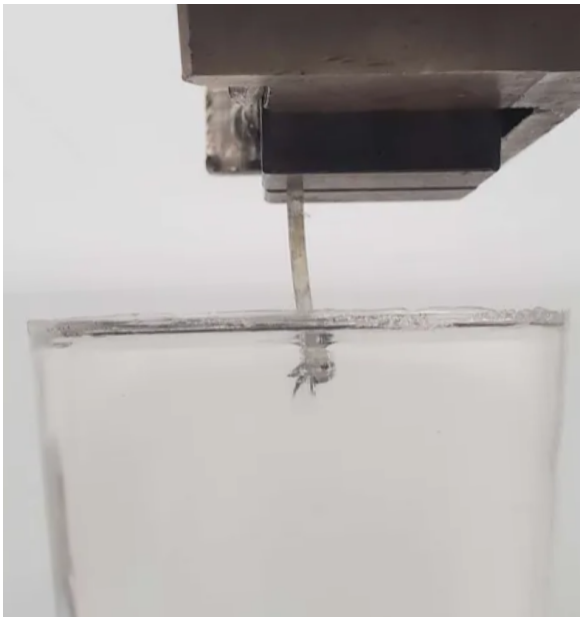

Fig. 9 AVF Buckling Phantom With Instron Inserting Polymer Composite Needle

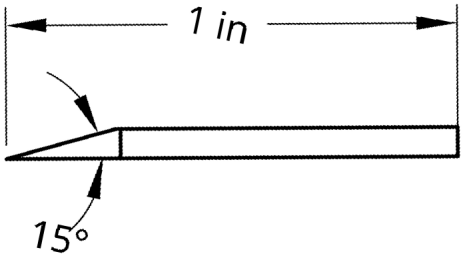

Fig. 10 Hemodialysis Scaled Needle Being Used

rates must remain within an optimal range, typically between 300 and 500 mL/min, as prescribed based on the patient's AVF maturity and health. Maintaining this flow rate throughout a session is challenging due to various factors affecting flow quality.

FDA guidelines for 501(k) Premarket Notification for intravenous catheters highlight kinks and breaks as critical concerns. Kinking, defined as a minimum 50 percent reduction in flow due to passageway narrowing, renders catheters and related devices non-viable.

Considering these fundamental issues, the material and geometry of a novel needle design are crucial for effectively controlling blood flow.

5 Needle Design

For the needle geometry and design, Wang et al [9] identify the optimal zeta angle for IV needle tips at 15 degrees, which is achieved by angling a cylindrical needle against a grinding stone, thus producing specific tip geometries. The zeta angle refers to the specific angle at which the tip of an intravenous (IV) needle is shaped or sharpened. While typically pointed for rope ladder cannulation techniques, buttonhole blunt needles had the lowest risk of complications and did not significantly increase the infection rates when employed [10]. Figure 10 visually outlines the zeta angle. This study selected a 15 gauge (15G) needle based on its ability to meet the buckling constraints critical in dialysis treatments for withstanding axial loads without bending or collapsing. The larger diameter of the 15G needle allows for higher blood flow rates, which is essential for efficiently removing toxins and excess

fluids from the blood. These higher flow rates are particularly advantageous in patients with well-matured and robust AVFs, where the vessel's structural integrity can withstand the larger puncture required by a 15G needle. In the initial stages of the hemodialysis treatments, smaller gauges such as 17G are preferred to minimize trauma to the newly created, fragile AVF. Once the AVF matures and develops, larger gauges, like the 15G, facilitate the higher blood flow rates required for effective dialysis and treatment time reduction.

5.1 Needle Manufacturing. We used an aluminum injection mold manufactured using CNC machining techniques. This mold is specifically designed to fabricate components with geometries mimicking those of 15 gauge needles,with an inner central rod to capture the needle geometry . For the injection molding, a Morgan Press was utilized along with the prepared polymer composite and injection mold, ensuring the production of high-precision medical needle parts. The aluminum construction of the mold facilitates excellent thermal conductivity so a hotplate or oven can be used to warm the injection mold and facilitate more flow of the polymer composite.

6 Conclusion

This study presents an innovative approach to improving hemodialysis needles by integrating a polymer composite that transitions between rigid and flexible states based on temperature. The proposed needle design aims to reduce complications such as vascular trauma, infiltration, and pain, which are prevalent with conventional stainless steel needles. Our findings indicate that a tensile modulus between 86 and 134 MPa is ideal for the polymer composite's soft mode, aligning closely with the mechanical properties of arteriovenous fistulas (AVFs). Flow rate testing, insertion force analysis, and infusion testing are planned further to validate the needle's performance under clinical conditions. By addressing the mechanical compatibility between the needle and vascular tissues, this design can enhance patient comfort, adherence to treatment, and overall hemodialysis outcomes, paving the way for significant advancements in dialysis care.

7 Future work

Future plans include flow rate testing with a peristaltic pump at varying needle bend radii to assess kinking.

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Appendix

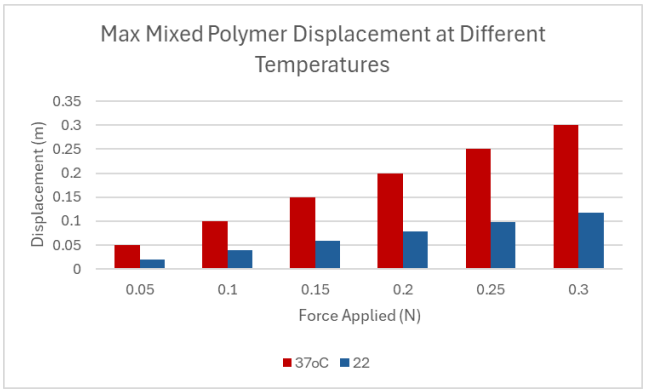

Fig. 11 Appendix I: Max Displacement for Polymer Needle Material with Force Applied to tip

Table 4 Appendix II: Eigenvalue Buckling Analysis Results

Force (N)	Mode Number	Load Multiplier	Critical Buckling Load
2	1	0.79524	1.6
2	2	0.83089	1.7
2	3	1.0754	2.2

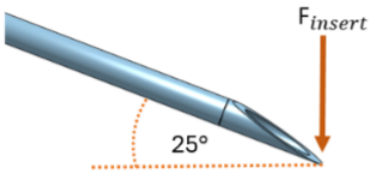

Fig. 12 Insertion force FEA Simulation Setup

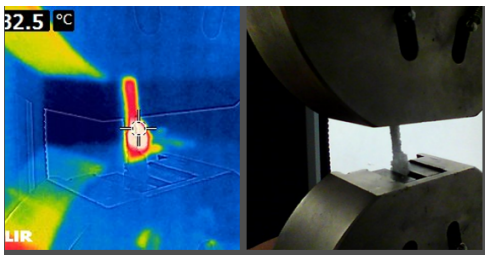

Fig. 13 Polymer Composite Dogbone in the Instron Machine at its soft state

Fig. 14 This dogbone was used to test all polymer composite according to the ASTM D638 Type IV

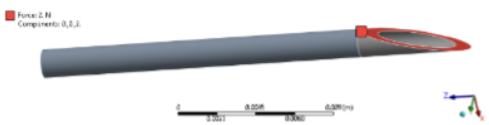

Fig. 15 Needle Loading for Buckling Simulations FEA

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