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Design and Development of Pre-Shape Guidewire Technology for Transcatheter Aortic Valve Implantation

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Abstract: In the current study, we present a guidewire that is configured for insertion into the heart of a patient during a procedure such as a transcatheter aortic valve replacement procedure. A guidewire device has a core with a tapered distal section and a proximal section. The medical guidewire in the current invention has better torque transfer from the guidewire's proximal end to its distal end. To increase the safety of transcatheter aortic valve implantation (TAVI) procedures, a new tool called the Pre-Shape TAVI Guidewire was developed. Guidewire entanglement risk and other procedure-related issues are intended to be decreased by the device. The single-wire device is pre-shaped to fit the aortic annulus, making the valve implantation process simpler and more effective. The device significantly speeds up procedures and lowers the possibility of paravalvular leak. The Pre-Shape TAVI Guidewire is anticipated to enhance patient outcomes while lowering procedure risks.

Keywords: Pre-Shape, TAVR/ TAVI Guidewire, Pig-Tail Guidewire, PTFE Guidewire

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1. Introduction

A guidewire is a thin, flexible, medical wire inserted into the body to guide a larger instrument, such as a catheter, central venous line, or feeding tube. The Pre-shape TAVI (Transcatheter Aortic Valve Implantation) Guidewire is a new, innovative medical device designed to provide physicians with a more efficient and accurate way to implant transcatheter aortic valves. The Pre-shape TAVI Guidewire is constructed from a unique combination of Nitinol and stainless steel, which together provide a flexible and resilient guidewire that can be quickly and accurately advanced through complex aortic anatomy. The guidewire's pre-shaped tip allows it to be placed directly into the valve implantation site, and its unique design allows it to be manipulated in the aortic anatomy with precision and accuracy. This device is designed to improve the accuracy and efficiency of transcatheter aortic valve implantation, resulting in better outcomes for patients.

Transcatheter aortic valve implantation (TAVI) is a minimally invasive procedure used to replace a damaged or diseased aortic valve in patients with severe aortic stenosis [2]. A pre-shape guidewire is an important tool used in the TAVI procedure to assist in the successful delivery of the prosthetic valve. Transcatheter Aortic Valve Implantation (TAVI) is a minimally invasive procedure used to treat aortic valve stenosis. It has been shown to be equally effective to traditional open-heart surgery, with fewer risks and a shorter recovery period. One major limitation of TAVI is the difficulty of navigating through the aortic arch into the left ventricle to implant the prosthetic valve. Guidewires are thin, flexible wires that can be manipulated through the aortic arch to create a passage for the placement of the prosthetic valve. This review examines the current state of guidewire technology used in TAVI, including Material, their design features, and the advantages and disadvantages of each.

SS, Ni-Ti, Pl, and/or alloy metals are used to make guide wires. The basic framework of a wire is made up of an inner safety ribbon surrounded by a core, which is then wrapped in a braid, though the makeup of each component of the wire frequently varies. Various levels of stiffness are possible for wire shafts, which helps maintain structural integrity while using wires. The metallic type and core thickness are principally responsible for the shaft's rigidity. The distal portion of the wire, which forms a spring tip, is generated by a tapering core. This region has a thinner core, which enables greater flexibility and moulding capacity.

2. Discussion

The guidewire must guard against severe device distortion during delivery so that all parts are operational upon deployment. Stiffness is the primary guidewire characteristic that makes these goals possible. Vascular trauma could happen as a gadget is tracked through the vascular tree if an insufficiently stiff wire is employed.

The Pre-shape TAVI guidewire is a new medical device designed to help guide the placement of transcatheter aortic valve implants (TAVI). The device is designed to help reduce the risk of malpositioning of the valve and improve the overall success of the procedure. Additionally, the device will be found to be highly cost effective, making it an attractive option for physicians and healthcare facilities. Overall, the Pre-shape TAVI guidewire appears to be a promising new device that could potentially improve the safety and efficacy of TAVI procedures.

Guidewires used in TAVI typically have an inner core of stainless steel or nitinol, a flexible outer layer of polyurethane or polyethylene, and a tip that is either straight or curved. The tip is designed to help the guidewire navigate through the aortic arch and into the left ventricle.

The condition known as aortic stenosis results in the aortic valve's leaflets thickening, which is frequently brought on by an accumulation of calcium on the leaflet. As a result, the valve cannot fully open. The thickness makes it harder for the valves to open and close, which lowers the amount of blood that the heart pumps to the tissues. To introduce this, PTFE Pre-shaped Guidewire is placed before delivering (TAVI/R). The Pre-shape wire guide is made to offer the greatest assistance possible while performing endovascular treatments on convoluted anatomy. Guidewire offers three extremely flexible guidewire end designs that offer unparalleled flexibility and assistance.The Pre-Shape Guidewire are available in different lengths, shapes, etc. to accommodate different anatomical applications.

The outer diameter of it is 0.031- 0.038 inches and 260-300 cm in length. In which the core wire and spring coil material is made up of Stainless Steel, Dura steel & Nitinol (nickel and titanium).PTFE, Hydrophilic, Hydrophobic, and Hybrid materials make up the spring coil coating. The guide wire is provided in three different curves such as Extra Small, Small Medium and Large.

PTFE Pre-shape guidewire is a medical device used to guide and support the insertion of catheters and other medical instruments into the body during medical procedures. It is used for a variety of procedures in the cardiovascular, gastrointestinal, and urological systems. The PTFE Pre-shape guidewire is made of PTFE (polytetrafluoroethylene) which is a highly flexible, durable, and inert material. It is designed to be flexible enough to navigate through tight spaces in the body while remaining strong enough to support the catheter or other instruments. It is also resistant to corrosion, wear, and abrasion. The PTFE Pre-shape guidewire is available in a variety of sizes and shapes to accommodate the specific needs of the procedure.

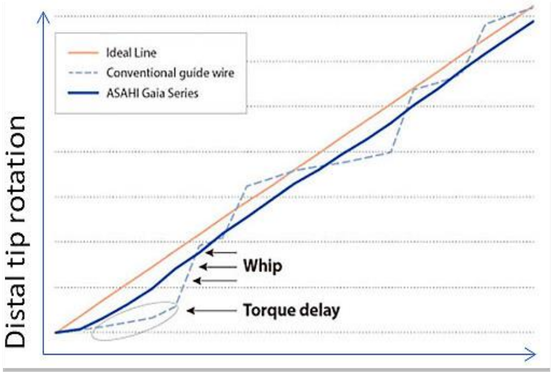

Figure 1. Tip Load

2.1 Tip Load: The factors that primarily influence tip load are core thickness and material, having stainless steel core-to-tip design being employed for tip loads up to the highest levels.

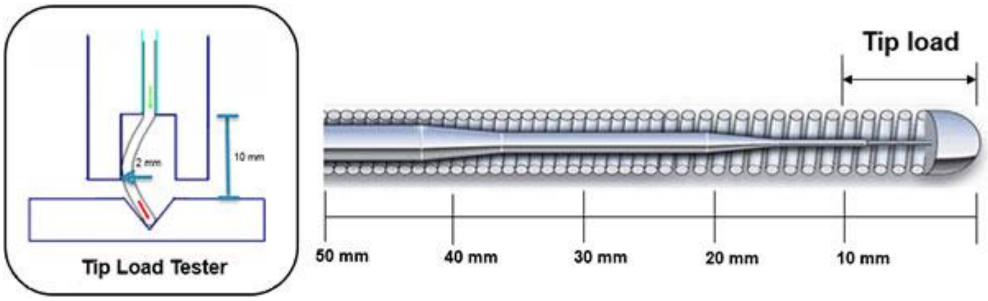

Figure 2. Input rotation at proximal end

2.2 Whip: A smooth operator torque input causes the distal end of the wire to jerk abruptly. This impact can be diminished by utilizing polymer covers and sleeves and hydrophilic coatings. In the graph below, a whip reaction is represented as a dotted line. The y = x line illustrates a flawless guidewire by displaying a 1:1 torque response in contrast to the dotted line's unpredictable whip.

2.3 Tip: The tip of the wire denotes its distal end. If the core of a design reaches the tip of the wire, it is referred to as "core-to-tip" design. This design has a torque rate that is amazingly close to 1:1 with great tactile feedback and tip control (Figure 2.3A). If the core does not go all the way to the wire's distal tip, a little metal ribbon assures continuity (Figure 2.3B). With more specialized tools, penetration is facilitated by the tip's tapering.

The "core-to-tip" design has a core that extends all the way to the tip

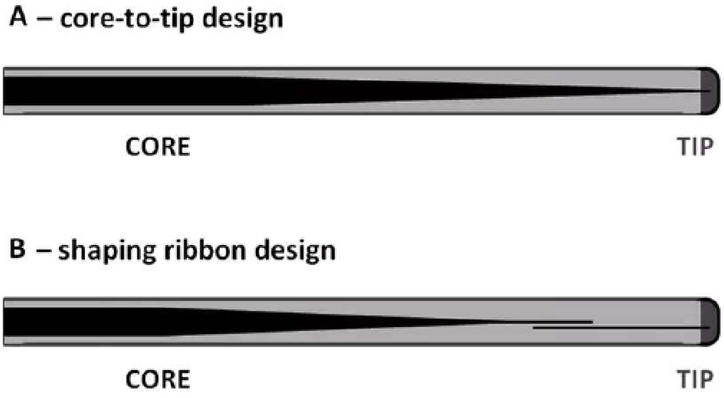

Figure 3. A & B Core to Tip design**.**

2.4 Basic Components of Guidewire

- A central shaft (core) made of Stainless Steel or Nitinol.
- Body which surrounds the core and is usually made of coils or polymers.
- A distal flexible tip made up of Stainless Steel.
- Surface coating with Polytetrafluoroethylene (PTFE).

2.5 Basics of Guidewire

- Flexibility: The flexibility of a guide-wire is determined by the core of the wire, which is either made of rigid stainless steel or exceedingly elastic nitinol.

- Tip Style: With shape ribbon utilized at the end to make the end more flexible, guidewires include a core wires that either terminates short of the tip or tapers down to the end for added support. This's design aids in regulating torqueability.
- Tip Load: This is a measurement of the strength and stiffness of the tip based on how much pressure is required to bend or collapse the tip.
- Core-to-Tip: The wire's tip is where the core finishes. In addition to increasing the wire's diameter and stiffness to aid cross-resistant lesions, this design offers fine tip control.

2.6 Classification of Guidewire

By Tip Style:

- Straight tip: that has elastic, straighter tips on both ends to lessen the chance of blood vessel trauma.
- J tip: Even additional elasticity and security for the artery during placement is offered by the J tip, which has a straight, flexible tip at the proximate end and a bending tip at the distal end.
- Angled tip: The guidewire is made to steer during placement by having an angle tip with a straighter, flexible end at the proximate portion and a bend of less than 90 degrees at the distally point.
- Pre - Shaped with the core wire and spring coil material is made up of Stainless Steel, with PTFE Coating on spring coil.

2.7 Literature Review

Mathews et. al. [2] First of all, by gradually shrinking the cross-sectional diameter of corewire, the stiffness of the guidewire is frequently subtly lessened near the distal end. Prior to surgery, the doctor will frequently modify the distal portion of corewire to include a lengthy, gentle bend. This reduces the chance of damaging sensitive tissue when inserting and setting the guidewire within the patient.

Fu Xuesen et. al. [3] In the current embodiment, tip end cap 5 and tail end cap 6 both have a circle inside them and are put on the other end of push rod section 1, the other side of push rod section 1, and the tail end cap 6. By positioning the tail end cap 6, the hole can securely install and fix the guide wire sheath 4. In the current embodiment, the guide wire sheath 4's surface has been hydrophilically coated. This improves instrument communication, lessens the wire's frictional force against the blood vessel wall, and makes the wire easier to track inside blood vessels.

Dongming Hou et. al. [4] A TAVI device may be slidably positioned on a guidewire with a distal part that is pre-configured to produce more than one distal loop and a guidewire with a proximate end, a distally end, and a length that extends there between. The guidewire may have a relatively stiff proximal section and a relatively flexible distal section joined by a transition region. A guidewire with an expandable element positioned around the transition region, a comparatively flexible distal section linked to the proximity section by a transition region, and a comparatively stiff proximity part may be introduced in upstream through the client's aorta and into the ventricle on the left during a TAVI procedure.

Phuoc V et. al. [8] This study came to the conclusion that the shape of a guidewire in the heart valve was substantially regulated by the geometries of the client's aorta and the inserting conditions. Aortic valve Trans Catheter implantation is a current minimally invasive technique for implanting a heart valve prosthetic. The position of the prosthesis appears to have a major impact on TAVI success. We developed a client Finite Element framework to predict the positioning of the rigid guidewire required to position the heart valve. They also investigated the impact of the modeling parameters. The model's accuracy was quantified by the difference in distance and angle between both the simulated guide-wire and the intraoperative ones. There was a good deal of agreement between both the predicted values and the intra-operative observations that were provided for 2 clinical cases.

Gareth J. Harrison et. al. [14] If a particular type of guidewire is advised while delivering intravascular devices, the Guidelines use for should be followed when selecting a supporting wire guide. Alternatively, the choice would be determined by the operator's experience and the stock at hand. Although there isn't a standard terminology to define the rigidity of wires guide, many of them have names that include words like "stiff," "super stiff," "extra stiff," and "ultra stiff" without any obvious scientific significance. The Amplatz Extra Stiff and Lunderquist Extra Stiff wires are illustrations of wire groups for which these words are also employed. Thus, stiffening needs to have a better explanation. A technical term relating to a wire's resistant to bend is the flex modulus. The purpose of this study was to determine the flex stiffness, which is a measure of stiffness, for a few regularly used stiff guidewires.

Benjamin Faurie, et. al. [19] This study aimed to demonstrate that rapid left ventricle (LV) paced via the wire guide is safe and efficient when combined with balloon aortic valvuloplasty and transaortic valve implantation. (TAVI). Background: Temporary right ventricular pacing is difficult and associated with pericardial and vascular problems during TAVI and BAV. The techniques the backup 0.03500 guidewire was used to deliver rapid left ventricular pacing. The anode of an external pacemaker was attached to a needle that was inserted into the groyne, and the cathode was attached to the tip of the 0.03500 wire. The TAVI catheter or balloon provided insulation.

2.8 Comparison with the nearby device

Table 1. Guidewire Parameter

Parameter	Subject Device	Nearby Device
Guidewire Length	275 cm	260 cm
Size Matrix (hxw)	50cm x 4.9cm,	3.0cm x 3.0cm
Outer Diameter	0.035”/0.89 mm	0.035”/0.89 mm
Core Material	Stainless Steel	Stainless Steel
Coil Coating	PTFE	PTFE
Coiling Wire	Round spring coiling	Flat coiling

2.9 Constraints

a) The guidewire must be made of PTFE material.

b) The guidewire must be able to navigate a variety of narrow and blocked arteries.

c) The guidewire must be easy to use and maneuver.

d) The guidewire must be cost-effective and affordable.

e) The guidewire must be safe and have minimal risk of damaging the artery or causing harm to the patient.

3. Aims and Objective

The main aim of the research is that the guidewire should able to be smoothly passed through tracking location.

The project objectives of this study are as follows:

a) To provide a safe and effective means of delivering medical devices to the target site without damaging the surrounding tissue or organs.

b) To aid in the navigation of curves and tight turns in the vascular system.

c) To reduce the risk of valve malpositioning and improve clinical outcomes.

d) To reduce the risk of perforating the wall of the vessel and the risk of vessel damage from improper placement of the device.

e) To reduce the amount of force needed to advance the device through the body.

4. Methodology

4.1 Manufacturing Process

The manufacturing process of PTFE pre-shaped guidewires involves several steps. First, a mandrel is created from a drawn wire stock. This mandrel is then placed into a pre-formed PTFE tube and heated in order to soften the PTFE.

The heated tube is then extruded through a die to create the desired shape of the guidewire. After the wire is extruded, it is cooled and inspected. Finally, the guidewire is cut to the desired length and finished with the application of a lubricant.

The manufacturing process of pre-shaped guidewires involves the following steps:

1. *Raw Material Preparation:* Nitinol or stainless steel are the primary basic materials utilised to create pre-shaped guidewires. In order to fit the pre-shaped guidewire to the necessary length, the raw materials are divided into small pieces.

Depending on the desired qualities of the guidewire, any material appropriate for use may be used to create the guidewire. Metals, metal alloys, polymers, composites, or similar materials, as well as their combinations or mixtures, are a few examples of acceptable materials. SS, such as 304-V, 304-L, and 316 SS, and metal like NI-Ti metal are a few examples of acceptable metals and metal alloys.

However, stainless steel is still a viable option for short-term guidewires and other medical devices. The 0.035” of SS304 wire is suitable for pre-shape guidewire due to its properties. SS304 is a stainless steel alloy that is corrosion-resistant and has a high strength-to-weight ratio.

This makes it a great choice for forming guidewires that need to be both durable and lightweight. Additionally, SS304 is also non-magnetic and has excellent ductility, making it ideal for forming complex shapes.

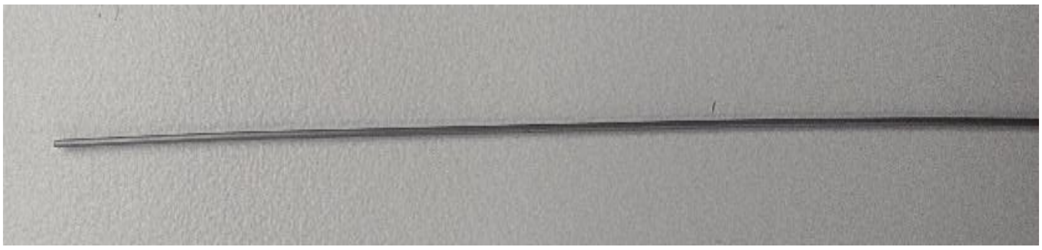

Figure 4. SS 304 wire.

2. *Tapered wire:* SS304 is a type of stainless steel. It is a popular choice for guidewires because it is strong and Corrosion-resistant. Its tapered shape makes it easier to navigate through the body and navigate around obstacles. It is frequently employed in numerous medical procedures, including as endoscopic surgery, angioplasties, and various other less-invasive operations.

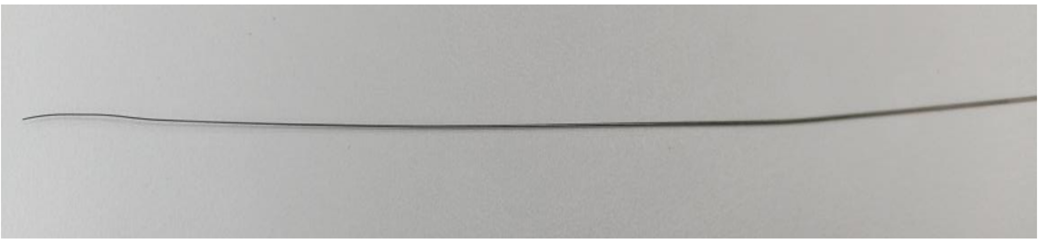

Figure 5. Tapered wire.

3. *Pre-forming:* The raw material pieces are heated during the pre-forming process and then formed into the **a**ppropriate **pre**-shaped design.

Figure 6. Small curve

Figure 7. Large curve

4. *Coil:* A ribbon or wire used for shaping that connects the distal tip to the distal portion may be covered by an elastic element, such as a coiling spring, helix winding, polymeric sheath, or other suitable flexibility component. Some variations of the distally segment may have a distal tapering piece connecting it to the shape ribbons and/or the distally end. Metals, alloys, polymers, and other suitable materials, such as those mentioned above, can all be used to create the structure.

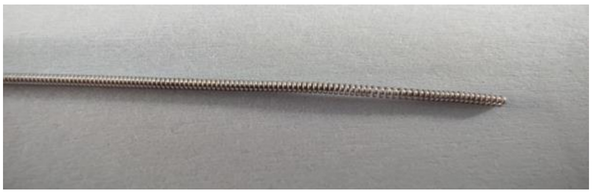

Figure 8. Coiling.

The structure's cross section, which includes the flexible part and/or the shaping ribbon, can have any suitable shape, such as a circle, oval, flat, ribbon-shaped, rectangular, square, or a mix of such shapes.

5. *Welding:* The PTFE Pre-shape guidewire is created by welding the formed parts together.

In some implementations, the attachment can be completed via laser or plasma welding. In laser welding, the required heat is provided by a light beam. Because to the significant accuracy that may be achieved when using a LASER light heat source, LASER welding may be advantageous in the operations that the invention contemplates. It should be noted that other parts of the gadget can also be attached using similar laser welding. Additionally, infrared light can occasionally be used as an energy source for welding, the solder process or other processes that attach different guidewire assemblies or components together. Again, because the light from a laser heating element may provide an excellent level of precision, using one for these connection operations can be beneficial. Soldering laser diodes is a specific instance of such a method.

6. *Coating:* After that, a lubricious coating is applied to the pre-shaped guidewires to lessen friction and enhance the device's functionality.

PTFE (Polytetrafluoroethylene) coating on pre-shape guidewires can provide a number of benefits, including increased lubricity, improved torque-ability, enhanced tensile strength, and improved guide catheter compatibility. The PTFE coating also resists chemical biological, and thermal degradation, making it a viable option for many medical applications. PTFE coatings also provide a protective barrier against wear and tear. This is especially beneficial when used in conjunction with guidewires that require frequent manipulation during procedures. In addition, PTFE coatings can reduce the friction between the guidewire and the surrounding structures, making them easier to maneuver and control during surgical procedures.

Figure 9. Coating

7. *Finishing:* After quality control, the finished, pre-shaped guidewires are packaged for transportation.

8. *Raw Material Procurement:* PTFE (polytetrafluoroethylene), stainless steel, and titanium are the basic materials required to make PTFE Pre-shape guidewire. These materials come from trustworthy suppliers.

4.2 Materials and methods

The model's objective is to forecast the shape of a rigid guidewire put into an aortic and ventricular geometry unique to the patient. Identifying the stresses and strains of a beam (the guidewire) limited to fit inside a cavity is the mechanical problem (aorta and left ventricle). The Finite Element (FE) method is used with an implicit strategy to resolve the issue.

4.3 Assumption on motions

The entire structure may be distorted by cardiac and respiratory motions. The suggested method, nevertheless, ignored the dynamic implications of this motion on the guidewire. Also, because of the guidewire's low mass and tiny inertial force in comparison to the contact forces, it was presumed that its motion was quasi-static. The simulation's final static equilibrium only correctly anticipated the guidewire's final position.

4.4 Mechanical properties

According to intra-operative observations, the insertion of a strong guidewire caused minor aortic deformations. The ventricle and aortic wall were therefore thought to stay stiff. The influence of blood pressure, pre-stress inside the vascular muscles, and the non-linear behaviour of the aorta wall across substantial deformations were not necessary to model under this supposition. Nonetheless, a model with linear elastic tissues was put to the test to demonstrate its viability.

We found no evidence that the intervention caused the strong guidewire to permanently distort. We postulate that, with the exception of gothic aortic arches, the typical curvature of the aortic arch is insufficient to result in plastic strains.

The guidewires may puncture the ventricular wall because of their straight design. Before the intervention, the guidewire must be bent at its end to reduce the possibility of perforation. Clinicians manually bend the guidewire to create a curved end for that reason. The acquired deformity is irreversible (plastic deformation).

4.6 Contacts and boundary conditions

Contact forces are produced by the guidewire's interactions with the aortic wall. Because the guidewire was coated with PTFE to lessen friction, tangential contact forces were ignored.

The proximal end (base) of the guidewire's orientation in the thoracic aorta was controlled in the model by a slipping rail. The operator's translations and rotations were modelled as Dirichlet boundary conditions that were applied at the guidewire's furthest distal node.

The guidewire's proximal end is left free in the left ventricle during actual TAVI procedures, while the operator moves the distal end. Typically, when it is introduced via a femoral dilator.

The guidewire's curved end can be oriented in a variety of ways, but once it enters the ventricular chamber, it is still possible to change the orientation. We created the model to account for the potential for various orientations in the ventricular cavity.

5. Results and Discussion

5.1 Track ability Testing

The analysis was conducted on total three samples of “Pre-Shape Guidewire”.

Pre-shaped guidewires, which are typically constructed of PTFE, are tested for trackability using the interventional device testing apparatus (Polytetrafluoroethylene). Using this apparatus, a simulated vessel is utilised to test the guidewire's manoeuvrability in order to gauge how trackable it is.

Several variables, such as fluctuating pressure, flow rate, and vessel curvature, are used to assess the guidewire's trackability. The guidewire's performance is assessed by timing how long it takes to execute the manoeuvre and how far it travels inside the model ship.

The pre-shaped guidewire's suitability and effectiveness for its intended usage can be assessed using the results of the trackability testing.

Figure 10. Experimental Set-up for “Trackability”.

5.2 Test Result

Test results of the Trackability test of “Pre-Shape Guidewire” is given in below Table - 6.1.

Table 2. Track ability Test Result

Sr. No.	Guidewire Size	Maximum Force (N)
1.	50 mm x 49 mm x 0.035” x 275 cm	400
2.		380
3.		385

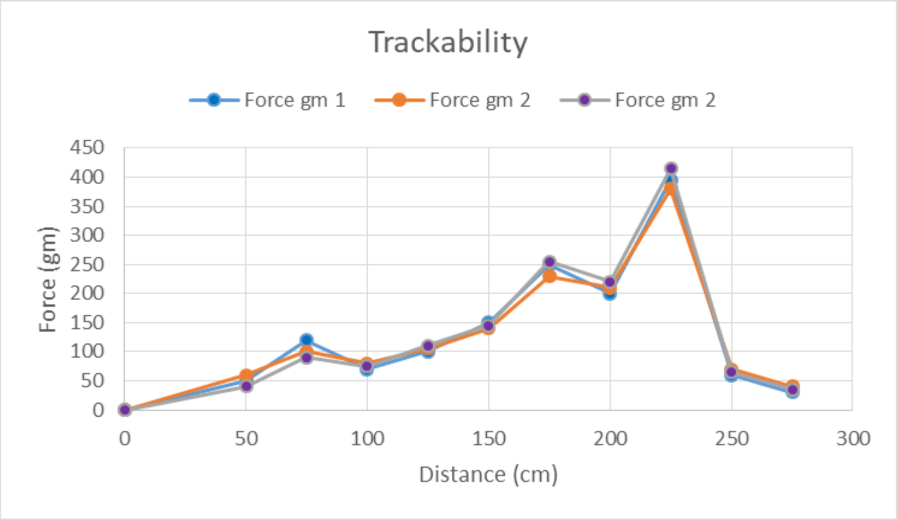

Table 11. Force vs Distance

5.3 Calculation

Newton force is calculated using the formula F = μ * A * v, where μ is the coefficient of friction, A is the area of contact between the wire and the medium, and v is the velocity of the wire. In this case, the coefficient of friction for PTFE in water is 0.02.

The area of contact is calculated by multiplying the circumference of the guidewire (2πr) by its length, or 2π(0.889/2) * 260 cm = 726.596 cm2. The velocity of the wire is 30 cm/min. Substituting these values into the formula, the Newton force is 0.02 * 726.596 cm2 * 30 cm/min = 435 gm.

For water at 25°C, the dynamic viscosity is 0.001 Pa*s and the density is 1000 kg/m3.

5.4 Formula

F = Newton force

μ = Coefficient of friction

A = Area of contact between the wire and the medium v = Velocity of the wire

$F = \mu * A * v \quad \mu = 0.02 \qquad (1)$

$A = 2\pi rl \qquad (2)$

$A = 2\pi\ (0.889/2) * 260\ \text{cm} \quad A = 726.596\ \text{cm2}$

$v = 30\ \text{cm/min}$

So now substituting above values,

$F = \mu * A * v$

$F = 0.02 * 532.7\ \text{cm2} * 30\ \text{cm/min} \qquad (3)$

$F = 435\ \text{gm}$

5.3 Kink Resistance

The purpose of this report is to determine the kink radius of “Pre-shape Guidewire”. Kink radius is the minimum radius at which wire would not kink.

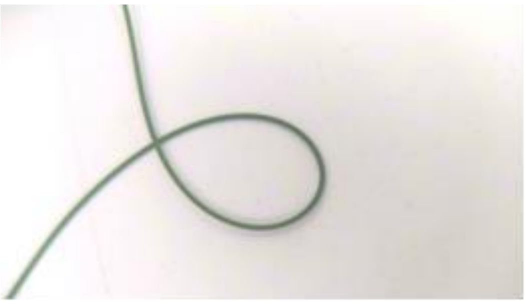

Figure 12. Before Kink Test.

Figure 13. Before Kink Test.

5.4 Tensile Test

This test method is intended to determine tensile test of “Pre-shape Guidewire”.

5.5 Test Method

- Measure the Tensile strength of the samples using a Tensile Testing Machine
- Enter Test Type as “Tensile Strength” from the drop down list.
- Sample length 100 mm.
- Test speed 30 mm/min.

5.6 Acceptance criteria

The Strength NLT 20 N.

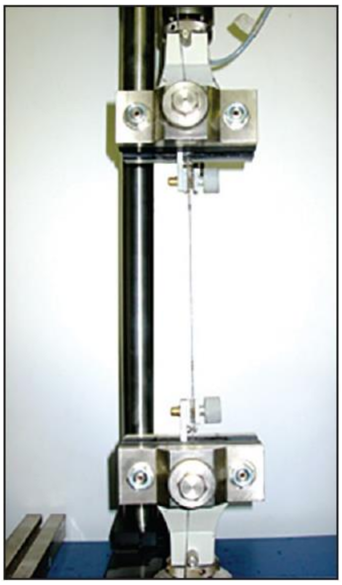

Figure 14. Tensile Testing of Guidewire

5.7 Test results

Table 3. Tensile Test Result

Sr. No.	Guidewire size	Result
1	50 mm x 49 mm x 0.035” x 275 cm	Complies
2		Complies
3		Complies

6. Conclusions

1. Pre-shaped guidewires are an essential component of TAVR procedures and are used to navigate through difficult, tortuous vessels and maintain a shape in the vessel.
2. Pre-shape guidewires provide improved accuracy, safety, and control compared to other guidewires, and they are available in a variety of shapes to meet the needs of various clinical procedures.
3. Pre-shaped guidewires can reduce the number of attempts needed to navigate a catheter, resulting in shorter procedure times and are also more cost-effective compared to other guidewires.
4. Due to the rising frequency of structural heart illnesses and the rising demand for minimally invasive procedures, the market for pre-shaped guidewires is anticipated to expand in the next few years.
5. With the advances in materials and design, pre-shaped guidewires will continue to be a valuable tool in the placement of interventional devices within the chambers of the heart.

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