Design of a catheter with variable shape and properties

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Abstract

In medical applications such as medical endovascular catheters, adaptable and morphing devices capable of changing shape and properties such as stiffness become important. These devices allow for safer therapeutic and diagnostic procedures by reducing time to reach target vessels and organs, trauma to the vessel wall and physical stress on the body while increasing the accuracy, benefits and positive outcomes. A catheter with these properties will also reduce X-ray exposure during procedures, recovery time and could save lives in the acute setting.

In the field of emerging materials, several materials demonstrate varying properties when exposed to a stimulus. This, when combined with the field of minimum invasive surgery, holds significant potential for the development of a property morphing endovascular catheter.

This thesis investigates the latest developments in endovascular catheter design through a materials lense. It begins with a thorough examination of material-based advancements in catheters with variable properties, and puts a particular focus on shape memory materials. Using a combination of literature review, field work examination, expert consultations, the design of property morphing catheters is comprehensively analyzed and evaluated.

Prototyping was done to evaluate the potential of two material systems to achieve bending behaviour for the design of a property morphing catheter.

The study presents a conceptual shape memory material-based design for a catheter capable of altering its shape and stiffness as required and demonstrates this with a visual prototype.

Additionally, potential directions for further refinement of this conceptual design are explored. This thesis serves as an initial reference and guiding framework for designers working with emerging materials in the field of medical devices and in particular the development of endovascular catheters with variable properties.

Delft, September 29th, 2023
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This research was made possible with the subsidy of MIT Zuid and the province of Noord-Brabant.

Acknowledgements

This thesis serves as the conclusion of my studies of Industrial Design at Delft University of Technology. During my time of study here, I have gradually developed an interest in materials, particularly emerging materials. Instead of merely selecting a material after the product's design, I have come to appreciate using its inherent properties to create a holistic design—an intersection of technology and embodiment! I am glad that I got the opportunity to carry out my thesis in the field of emerging materials as the project to conclude my studies on.

First and foremost, I wish to express my gratitude to my supervisory team, Sepideh, Sonja, and Jeroen. Their passion, engagement, and expertise have guided me toward a project conclusion that I am proud to present. Their openness to offer guidance and address any questions I had, whether related to the medical domain, materials, research and prototyping, or report writing were highly appreciated.

I would also like to extend my appreciation to the healthcare professionals at the Máxima Medical Centre in Veldhoven and the Herzzentrum Köln for generously dedicating their time and patience to answer all my questions both before, during, and after their procedures.

Lastly, my heartfelt thanks go out to my friends and family for their love and support throughout my time as a student and in this project, whether it involved brainstorming, reviewing my work, or simply sharing a coffee and commiserating about the hardships of having to write a Masters thesis ;).

It has been a privilege to study at a faculty that actively encourages its students to apply their design skills to craft sustainable solutions, be it for the environment, well-being, or inclusivity and I aspire to keep this ethos in my future pursuits.

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Glossary

Actuator: The active component in a material system, which is actuated by a stimulus and therefore controls the dynamic behaviour of the material system.

Austenite phase: The actuated state of an SMA actuator when the activation temperature has been reached.

Bending behaviour: In the context of the material systems, bending behaviour describes the bending performance of the system upon actuation.

Bias spring: A counterforce (spring) to an actuator to recover the material system to a “neutral” non-actuated system state.

Catheter: A flexible tube for medical procedures, fluid delivery, or information collection inside the body.

Coil: A helical or zigzag shaped structure.

Distal end: The tip of the catheter (opposite of proximal end).

Endovascular: Within the blood vessels.

French: The unit describing the diameter of minimum invasive surgical tools.

Guidewire: A thin wire used to guide the placement of a catheter within the body used during minimum invasive surgery.

Interventionalist: Physician trained to perform interventional or minimum invasive procedures.

Lumen: The hollow part of a tube.

Martensite phase: The non-actuated state of an SMA actuator when it is below activation temperature and can be deformed freely.
Material system: A design consisting of multiple material components with different functions.

Minimum invasive surgery: Surgery that is done with only (a) small incision(s) and few stitches.

Neutral state: The material system in its non-actuated state.

Training (in the context of SMA): The process of training or setting the desired shape of an SMA through thermal cycling.

Ground shape: The memorized shape of the SMA after training, to which it returns upon actuation.

Property morphing behaviour: The performance of the material system to show either bending behaviour and/or variable stiffness behaviour.

Proximal end: The end of the catheter located closest to the interventionalist (opposite of distal end).

Sheath: Introducer catheter.

Variable stiffness behaviour: The performance of the material system to change its stiffness upon actuation.

Abbreviations

MS	Material system
PMC	Property morphing catheter
SEA	Superelastic alloy
SMA	Shape memory alloy
SMC	Shape memory composite; material consisting of 2 or more SMMs
SMG	Shape memory gel
SMM	Shape memory material
SMP	Shape memory polymer

1. Introduction

This section introduces the context in which the project is conducted as well as the problem statement, design goal and approach.

1.1 General introduction

There is a growing need for adaptable and morphing devices in various medical applications. This is particularly important for procedures involving medical catheters and endoscopes. The human anatomy varies among individuals, and different shapes are encountered within the body. In the field of catheter-based medical treatments, a range of catheters with varying shapes exists. However, there is currently no catheter that is capable of changing its shape and rigidity on the market.

The development of such a property morphing catheter would greatly enhance the safety and effectiveness of therapeutic and diagnostic procedures. It would potentially reduce the time required to reach target vessels and organs, minimize trauma to the vessel walls and physical stress on the body, while simultaneously improving accuracy and overall outcomes. Additionally, a catheter with these properties would lower X-ray exposure during procedures, shorten recovery times, and potentially save lives in critical situations.

At the Industrial Design Engineering (IDE) faculty of Delft University of Technology, the Emerging Materials Lab focuses on designing shape morphing objects using shape memory materials. These materials belong to the smart materials group, known for their ability to change properties in response to external stimuli like heat or a magnetic field. They exhibit kinetic effects, allowing them to move or change shape. Designers leverage these materials and their creative freedom to develop interactive objects that establish dynamic relationships with users.

1.2 Project introduction

This thesis is the conclusion of my masters at the faculty of IDE at the Delft University of Technology. The master's degree under which this project is executed is Integrated Product Design (IPD). The project is performed with the Emerging Materials Lab at the IDE faculty and in collaboration with Drs. MSc. J. van der Reijden, interventional radiologist at the Máxima Medical Centre.

The goal of the thesis is to explore the opportunities in using shape memory materials at the Emerging Materials Lab to create a property morphing endovascular catheter. This catheter would exhibit the shape memory effect when a stimulus is applied and therefore change its properties such as shape and/or stiffness.

The starting point of the project is an overview of the current developments of property morphing catheters, with an emphasis on catheters using smart materials. This overview sums up important characteristics of the materials, such as biocompatibility and actuation speed, and can be used in future projects as a reference. This project then goes further into designing smart material actuators that enable shape memory effect within the use-context of the endovascular catheter.
Due to the strict medical environment of the device, the design should adhere to the requirements drafted through expert interviews and research. Additionally, the shape memory effect of the materials is explored and compared to decide which material shows the most promise for this application.

The concept design is presented and demonstrated with a prototype. Finally, the project is evaluated and finally recommendations are made for future development.

1.2.1 Problem definition

The manoeuvrability of a catheter decides whether the target area can be reached and hence affects the success rate of a procedure to a great extent. Conventional endovascular catheters are available in many different preformed shapes, sizes and stiffnesses and are selected by the interventionalist based on the anatomical needs.
During complex procedures, the interventionalist might have to exchange catheters multiple times to accommodate to the specific needs for navigating to the target site. Every catheter exchange can cause complications and further increases procedure time, thereby increasing patient trauma (1). There is a clinical need for property morphing catheters that require less frequent exchange to different catheters, allowing adaptable tip shapes, motions in terms of steering and variable stiffness.

The field of property morphing catheters has advanced greatly in the past decade. However, the developments show a gap between what is required and the current state of property morphing catheters. Also, there is no clear systemic approach that specifies design goals or functional requirements and constraints in the case of property morphing catheter development.

This graduation project aims to design a concept with emerging/smart materials that furthers the development towards a property morphing catheter and provide a guideline on this subject for future designers.

1.2.2 Design goal

The goal of this project is to design a proof of concept of a property morphing catheter based on (a) smart material(s). Additionally, a comprehensive review of the state of the art of catheters and developments of material-based property morphing catheters will be delivered to serve as a basis for other designers in this subject.

1.3 Approach

The development of endovascular catheters for interventional procedures starts with a research process to understand their purpose and requirements. This includes communication with professionals in the medical and materials field, observing various procedures and reviewing literature to gain insights. Additionally, data on materials used in catheter manufacturing is obtained from reputable manufacturers like Boston Scientific and Cordis. To supplement this information, the Ansys Granta Edupack 2021 material database is also consulted.
Materials used in the development of property morphing catheters are mapped through literature research. The relevant characteristics are summed up in an overview.
Subsequently, shape memory materials are further investigated through laboratory experiments, prototyping and expert meetings. I evaluated material systems to determine a suitable option with a functional working principle for the property morphing catheter
Once the material(s) and working principle are defined, a design is developed and prototype that demonstrates the functionality of the property morphing endovascular catheter.

1.3.1 Methodology

The double-diamond model (Figure 1) describes the design process in a linear process with two diverging and two converging phases.
It described a research phase (Figure 2) and a design phase (Figure 3), both of which consist of diverging and converging parts.

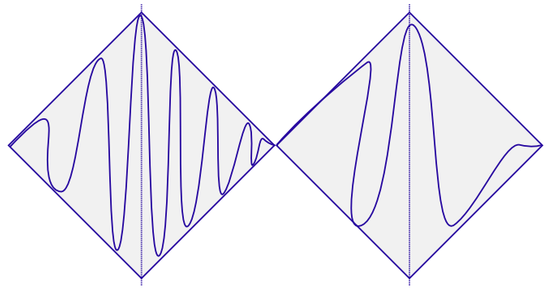


Figure 1: Double diamond model

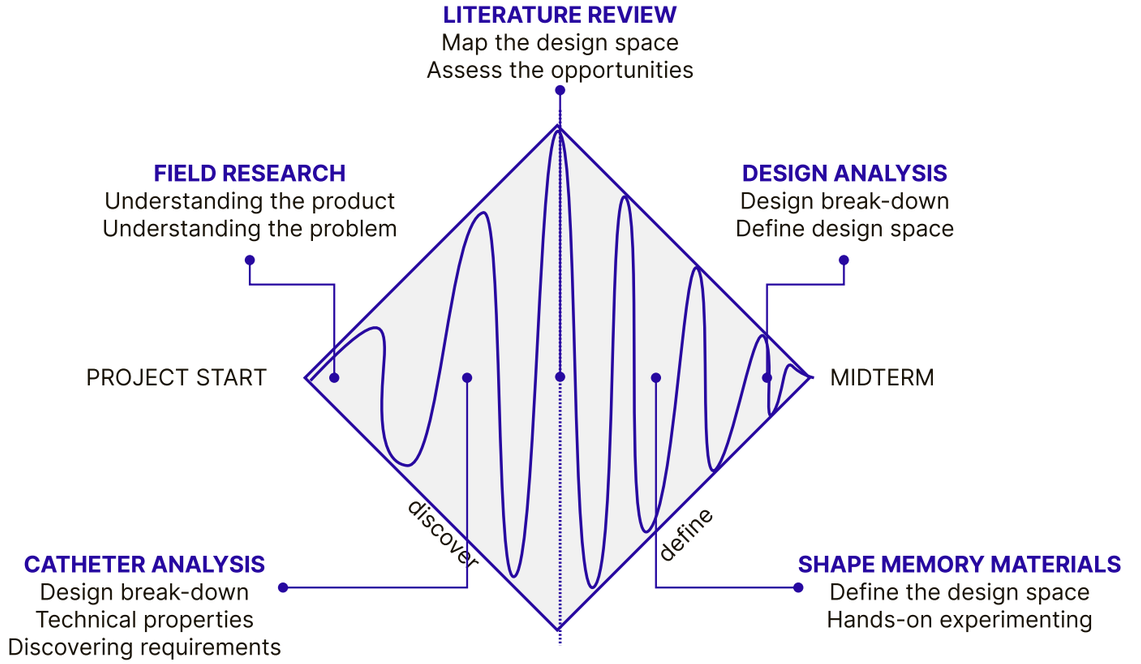


Figure 2: Research phase, double diamond model

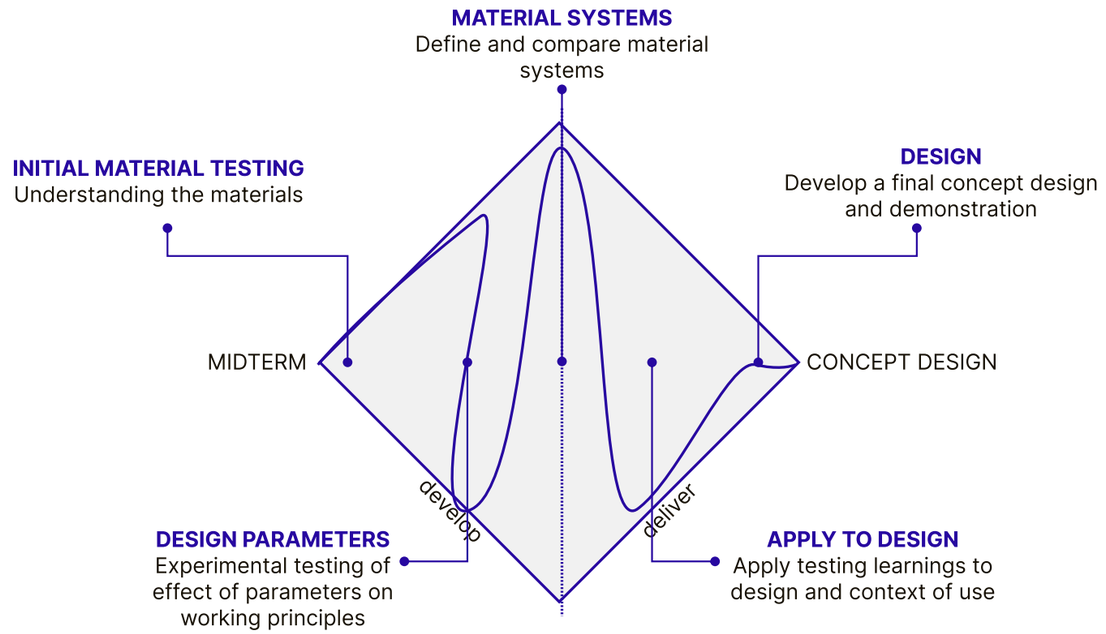


Figure 3: Design phase; double diamond model

2. Background

The background explains the basics of interventional procedures and shape memory materials.

2.1 Interventional radiology

Interventional radiology is similar to surgery but uses minimum invasive procedures to diagnose and treat a variety of medical conditions. Interventionalists use imaging techniques such as X-rays, CT scans, MRI scans and ultrasound to guide small instruments, such as endovascular catheters, through blood vessels or other pathways to deliver treatment directly to the site of the problem (Figure 4).

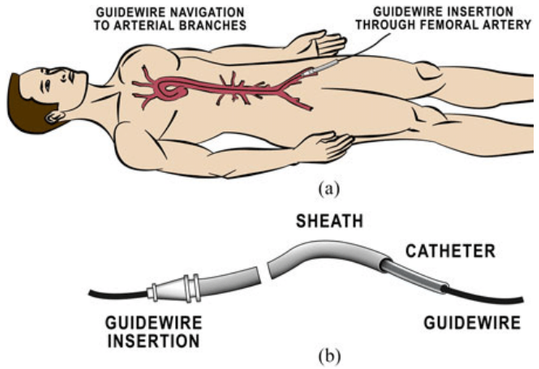


Figure 4: Endovascular catheter insertion (Kilchenmann O'Malley, 2016).

An endovascular procedure typically starts with the interventionalist puncturing the skin of the patient with a needle to reach the femoral artery, located in the thigh area. Other possible entry points are the radial artery in the wrist and the carotid artery located in the neck. A sheath is inserted in the site of puncture which functions as access point to provide access to the femoral artery to the guidewire, catheter and other necessary instruments. The endovascular catheter (Figure 5) is inserted with its distal end (also referred to as the tip) into the artery and navigated to the site of the problem with help of a guidewire. To advance the catheter, the interventionalist pushes, pulls and rotates the catheter from the proximal end which is kept outside the body.

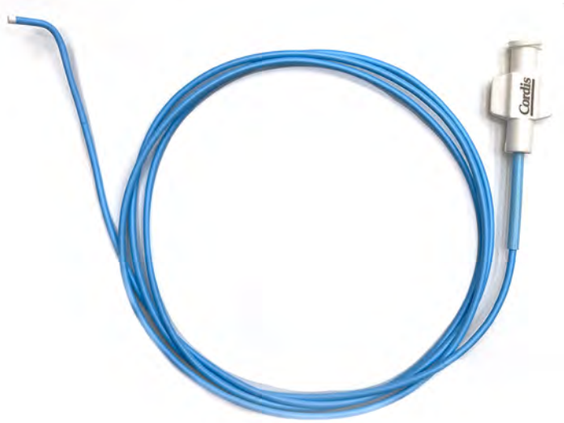


Figure 5: Cordis catheter (photo taken in 2023).

A typical treatment done with minimum invasive surgery is an angioplasty, where a catheter with a balloon is inserted into a obstructed artery due to stenosis. The balloon is then inflated to dilate the stenosis and allow sufficient blood flow (Figure 6).

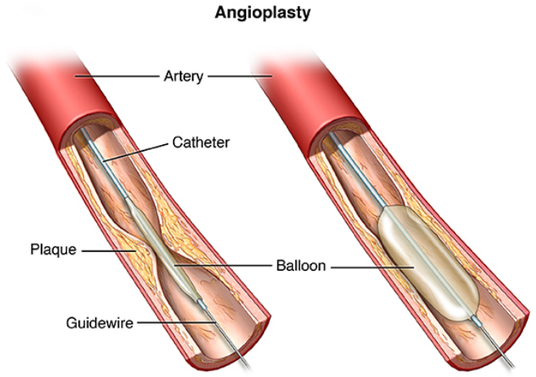


Figure 6: Angioplasty with a balloon catheter (John Hopkins Medicine, n.d.).

Since the anatomy of the blood vessels is complex and patient-specific, selecting a catheter with suitable curvature and stiffness is important for safe and successful navigation of the patient anatomy. Not all curves in the human anatomy can be made with a single catheter so a catheter exchange is likely to be necessary during a procedure. This repeated extraction and insertion of catheters can harm the patient and increase the risk of complications.

An endovascular catheter with property morphing abilities such as variable shape and/or stiffness would allow for safer therapeutic and diagnostic procedures by reducing time to reach vessels and organs, as it increases ease of vessel navigation and the frequency of catheter insertion and extraction can be reduced. A catheter with these properties will also reduce X-ray exposure of the interventionalist and patient during procedure by reducing procedure time (1).

2.2 Shape memory materials

Shape memory materials (SMMs) are a group of emerging materials that respond to particular stimuli by means of transforming their physical and/or chemical properties. SMMs include, amongst others, shape memory alloy (SMA), shape memory polymer (SMP) and shape memory gel (SMG) (2). The stimuli for SMMs include heat, electricity, magnetism, moisture, light and pH. SMMs can switch between a temporary shape and a (trained) ground shape when the stimulus is applied, thereby exhibiting the shape memory effect (3). The shape memory effect of these materials can be used to create new, dynamic devices able to adapt their properties such as the self-expanding SMA stent (Figure 7), which is a tubular wireframe which keeps the patients artery open after angioplasty, activated by body temperature.

Leveraging the shape memory effect of SMMs to develop dynamic medical instruments holds the potential to yield positive outcomes for both patients and healthcare providers.

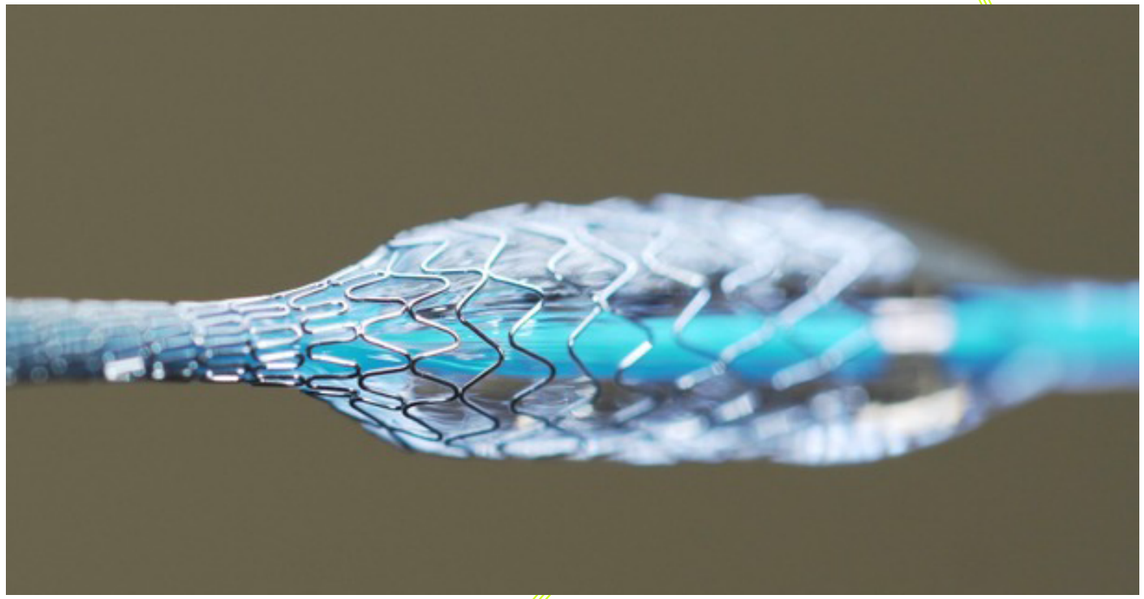


Figure 7: Self-expanding nitinol stent (Shutterstock, n.d.).

3. Analysis

The analysis aims to improve the understanding of the characteristics of an endovascular catheter and its use.
The second part of this analysis consists of a literature review of catheter designs using smart materials. The characteristics of these materials are reviewed including their benefits and limitations.
Methods used in this section are literature review, field research, communication with experts from the medical and materials field and data retrieval from medical device manufacturers Boston Scientific & Cordis.

3.1 The catheter

A catheter is a flexible tube with one or more hollow centres (lumen) that are utilized in minimum invasive surgeries (Figure 8). The catheter can have one or more curves, which are pre-shaped. The curves are referred to as the primary, secondary, tertiary and so forth, counting up from the distal end of the catheter. A catheter with a certain shape is chosen based on the procedure, anatomical needs of the patient and preferences of the interventionalist. Catheters are used in procedures such as stent delivery, drug and contrast injection, a variety of diagnostic activities (4).

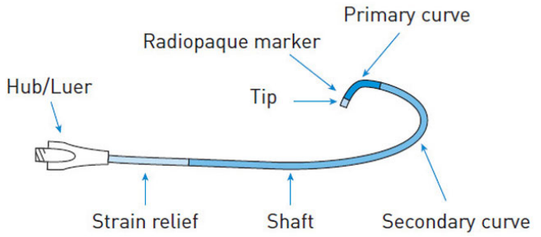


Figure 8: Endovascular catheter (Lim and Koh, 2012).

3.1.1 Catheter types

Catheters exist in many shapes and sizes and are selected specific to the procedure and patient anatomy needs. A catheter has a diameter as small as 1.33mm to as large as 8mm. They are made from flexible polymers and can typically be divided into two types: flush catheters and selective catheters (5).

3.1.1.1 Flush catheters

Flush catheters (Figure 9) allow high-flow injections (e.g. fluoroscopic fluid) into large arteries or veins. They have multiple side holes to prevent vascular damage caused by the tip displacement of the catheter during injection, which would move back due to the force of the injection.

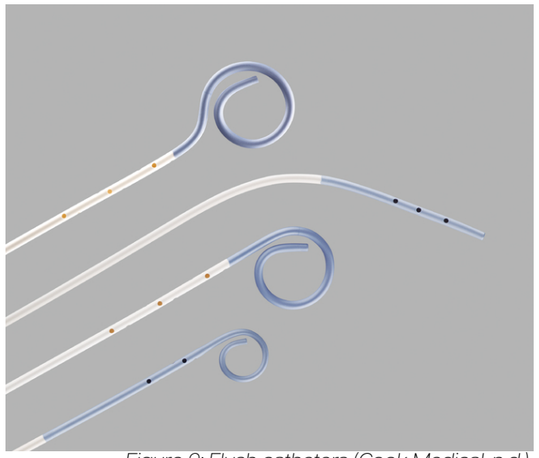


Figure 9: Flush catheters (Cook Medical, n.d.).

3.1.1.2 Selective catheters

Contrarily to flush catheters, selective catheters usually have one end hole. Selective catheters (Figure 10) are designed for rotational stiffness to accurately translate manipulation at the exterior end to the distal end.

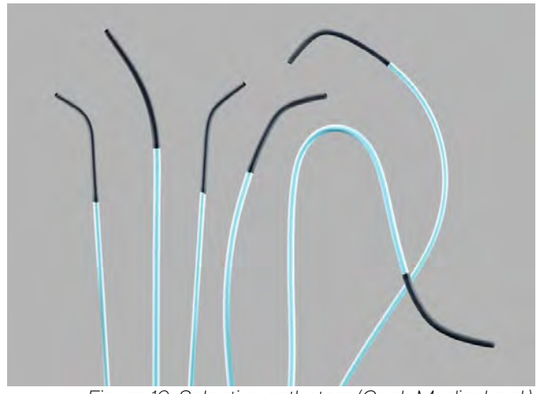


Figure 10: Selective catheters (Cook Medical, n.d.).

3.1.2 Catheter use

Based on my observations of interventional procedures at the Máxima Medical Centre and the Herzzentrum Köln, a procedure description, stakeholder analysis (Appendix 1) and product journey (Appendix 2) were synthesized to gain a better understanding of the use and context of the catheter.
Generally, the use of the catheter can be described in five parts:

1. **Preparation**: The choice for a catheter depends on the interventionalist preferences and anatomical needs of the patient. Before the procedure, the catheters are unpacked and placed on the sterile table. The assistant interventionalist flushes the catheter with physiological saline to make sure the lumen is clear, and the guidewire has limited friction inside the catheter.

2. **Insertion:** The skin is punctured with a needle at the femoral or radial artery, depending on the procedure, and the sheath is placed and the guidewire inserted. The catheter is threaded over the guidewire.

3. **Navigation:** The catheter and guidewire are navigated through the patient anatomy to the target site with help of the imaging technique fluoroscopy. The interventionalist moves the catheter and guidwire by pushing, pulling, and rotating the catheter around its axis.. The catheter tip shape is recovered when the guidewire is retreated and so the interventionalist can use the tip shape to engage with (enter) the vessels to make turns. When the guidewire is advanced through the catheter, the catheter is straightened again.

4. **Delivering treatment or diagnosis:** Upon reaching the target site, the procedure

may involve several approaches, depending on the patient need. In some cases, the guidewire is withdrawn from the patient, and medicine or instruments are delivered through the lumen of the catheter to the target site. Alternatively, the catheter can be exchanged for a different type (e.g. balloon catheter) to administer the necessary treatments.

5. Disposal: the catheter is disposed with medical waste after the procedure.

During the navigation of the catheter to the target site, a catheter exchange might be necessary to reach more difficult-to-reach sites. The following occurrences were observed during my field research, where property morphability might play a beneficial role.

Path selection (Figure 11): When the catheter must deviate from its path into a certain vessel that requires the catheter to bend in a specific direction.

Vessel engagement (Figure 12): If the tip of the catheter is not properly engaged with the target vessel, there is a risk that it could disengage as it is advanced further. The flexibility of the catheter means that the pushing force applied by the interventionalist could cause the catheter to unintentionally move out of the target vessel.

Passing vessel occlusion (Figure 13): A flexible catheter is desirable when navigating through delicate pathways but when there is vessel occlusion, the catheter might not be able to be advanced through the vessel and an exchange to a stiffer catheter is necessary.

3.1.3 Technical characteristics

The technical characteristics of the catheter are used to help determine the requirements for the material and design of the property morphing catheter.

3.1.3.1 Catheter manufacturing and materials

Catheters are commonly fabricated from thermoplastic elastomers (6) through an extrusion process (7). After manufacturing, the catheters are sterilized using ethylene oxide gas which is a process that can take from 1-6 hours, and reach temperatures between 37 to 63°C .

Catheters are available with different constructions, which change the handling of the catheter. The construction involves three basic components (Figure 14).

Liner: A PTFE (Teflon) wall liner to provide chemical resistance and high lubricity due to its hydrophilic nature.

(Optional) Braiding: Stainless steel or polymer braiding to increase torque transmission, wire kink resistance and stiffness.

Outer jacket: A thermoplastic elastomer such as polyethylene or Pebax (polyether block amide) is used for the catheter body. Since a stiff shaft and soft tip are desirable, Pebax is commonly adopted in catheters such as produced by Cordis (and others), as it allows a linear transition stiffness from the soft tip to the hard proximal end within the same material.

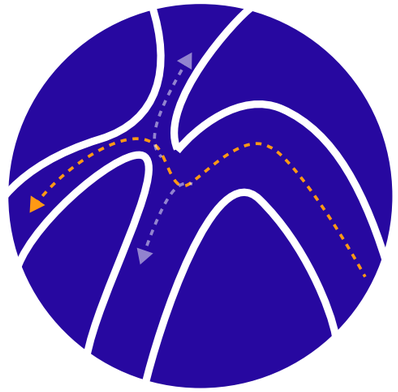


Figure 11: Path selection

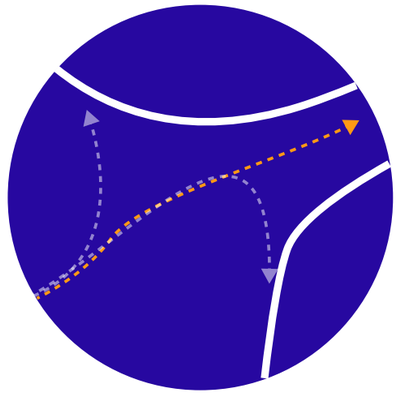


Figure 12: Vessel engagement

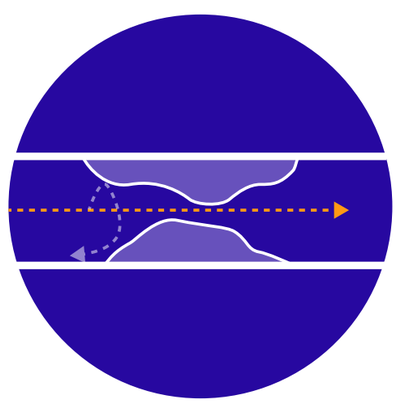


Figure 13: Passing vessel occlusion

3.1.3.2 Mechanical properties of the catheter material

The outer jacket of the catheter construes the largest part of the catheter body and greatly influences its properties. Pebax is a material that can be manufactured with a variable durometer (stiffness) from shaft to tip within one material and is therefore often used for the construction of the outer jacket of the catheter.

The stiffness variation of Pebax material can be used as a guideline for the range of stiffness variation of the property morphing catheter. Pebax material, similar to silicones, undergoes classification using a letter (A-D) along with a numerical value, wherein A and lower numerical values indicate higher flexibility. The material data was retrieved from the Granta Edupack material database (8) and can be found in Appendix 3

It is assumed that the softer durometers (Pebax D25 and D40) are used for the tip while the harder durometers (Pebax D55 and D65) are used for the catheter shaft. Therefore, it is would be desirable that the tip of the property morphing catheter can range between a similar stiffness of 12 to 74 MPa.

Pebax (Type)	D25	D40	D55	D65
$E_{modulus}$ (MPa)	12 - 20	72 - 74	145 - 349	409 - 419

Table 1: Pebax stiffness range for catheters

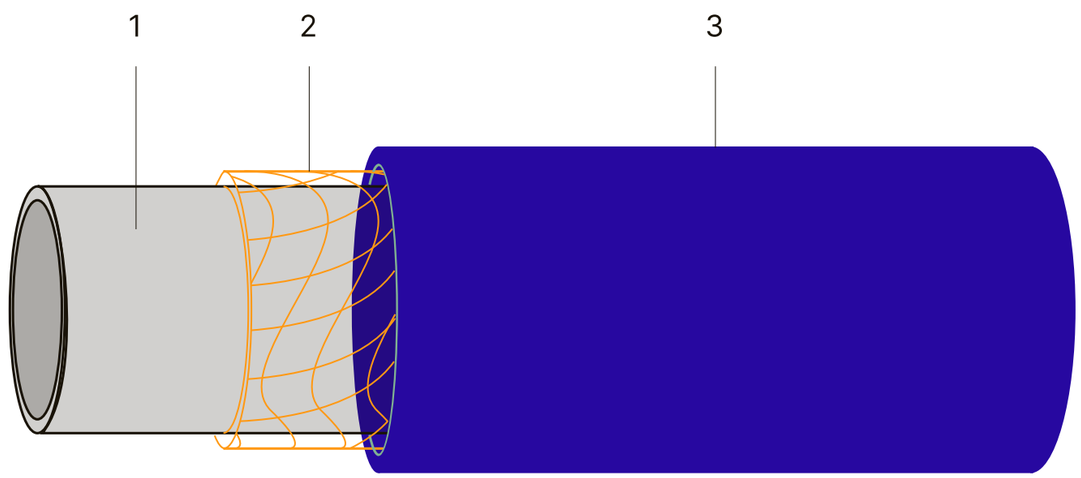


Figure 14: Catheter construction adapted from Zeus Industrial Products: (1) Liner wall, (2) Braiding, (3) Outer jacket

3.1.3.3 Catheter dimensions

Relevant catheter dimensions are the length, inner and outer diameter. Catheter lengths are described in centimetres and are usually between 65 and 100 cm (9). A catheters dimensions are given in its outer diameter size, for which the French (Fr) unit is used, where 3Fr is 1mm (Figure 15). The inner diameter relates to the lumen and is often indicated in inches e.g. a 0.035 catheter will accommodate a guidewire of 0.035 inches or less (10).

In interventional procedures, catheters are commonly in the range of 4-6Fr with a lumen diameter of 0.8mm (van der Reijden, *personal communication*). The size of the sheath required to introduce the catheter into the body depends on the catheter's diameter. For endovascular catheters, it is generally recommended that the outer diameter should not exceed 8Fr as a sheath larger than 8Fr cannot be used in combination with the seal that is used to close the puncture site after the procedure.

In certain procedures like EVAR (Endovascular Aneurysm Repair), larger catheters and sheaths are used in combination with special seals. However, this project's focus is on minimum invasive surgery, and therefore, the endovascular catheter size is limited to a maximum of 8Fr.
The specific size of the catheter depends on the procedure and patient vessel dimensions as it should be suitable for the size of the vessels it will navigate.

3.1.4 Conclusion catheter analysis

The analysis of the conventional catheter provides information used in the requirements. Important characteristics from the analysis are given here.

General characteristics
A catheter has a lumen (hollow center) to enable usage of a guidewire and administration of treatment.

Catheters exist in different sizes and many different tip shapes, which are selected depending on the procedure. The selection of catheters depends on the interventionalists preference and procedure requirements.

Material characteristics
The catheter has a stiff shaft to ensure pushability and torque translation and a softer tip to reduce trauma.

The catheter tip stiffness of a catheter can range between 12 to 74MPa.

The catheter is sterilized using ethylene oxide gas which reaches a sterilization temperature up to 63°C.

Dimensional characteristics
Common endovascular catheters have a maximum size of 8Fr (2.67mm diameter), as with larger dimensions, the regular seals cannot be used anymore.

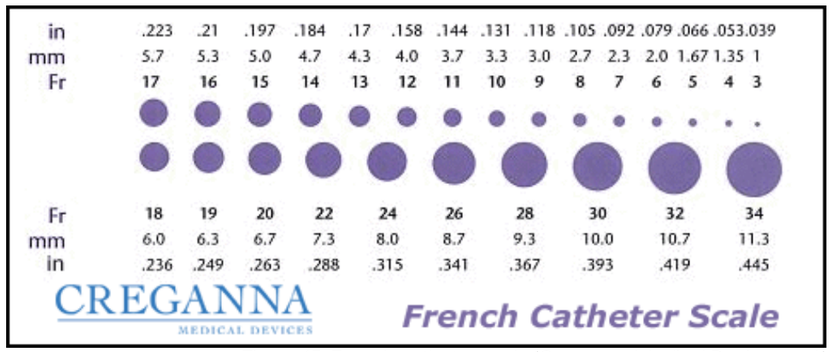


Figure 15: French catheter scale (Creganna Medical Devices, n.d.)

3.2 Literature review of property morphing catheters

The field of property morphing catheters (PMCs) has seen many developments in the past decade. PMCs such as steerable catheters (11, 12, 13, 14, 15, 16, 17) and variable stiffness catheters (11, 14, 18) are actively being researched. In this chapter, I will discuss the different types of catheter developments that are based on smart materials. Then, a summary of the important material characteristics is given per development.

3.2.1 Types of property morphing catheters

An extensive scan was done on the literature of PMCs to understand which developments are made to design such catheters, which material are used for such designs and also to find opportunities for innovation. Based on this scan, PMCs are subdivided into different categories as illustrated in the overview of Figure 16. Mechanical variable stiffness (VS) is not discussed as it is out of scope for this project.

PMCs are either able to select their direction at the tip or have variable stiffness (VS). Steerable catheters are classified by Hu et al. in three categories based on three types of actuation: tendon-driven, magnetically navigated, and soft material driven catheters (1). In variable stiffness catheters, I make the distinction between mechanical variable stiffness which uses mechanisms such as friction and granular-jamming, and material-based variable stiffness which are materials that are able to show a variable stiffness range after activation by a stimulus.

Tendon-driven and magnetically navigated catheters are commercially available steerable catheters.
Tendon-driven catheters (Figure 17)) rely on a bulky spring and pulling wire mechanism attached to the tip end of the catheter (19), and are therefore difficult to miniaturize and control precisely. Additionally, the stiffness properties of the tendon-driven catheter pose a risk of perforation of the vessel wall (20).

Magnetic catheters (Figure 18) are steerable by a small magnet embedded in the catheter tip. They are guided by a magnetic field generated by external magnets. The tip can be steered effectively (21) and they favour miniaturization. The major downside is the large financial and spatial investment that is required for the magnetic system (19). To steer the catheter, the external magnets need to be (re-)positioned and this makes response time slow. Additionally, the magnetic system does not take into account the natural manipulation skills, ergonomic preferences of the interventionalist (22).

There remains a clinical need for improved PMCs (1, 20) that are safe and feasible for implementation in endovascular context

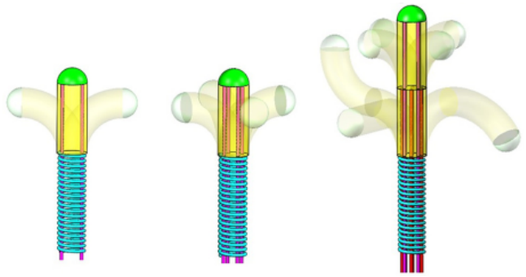


Figure 17: Tendon-driven catheter with multiple steerability axes (Ali et al. 2019)

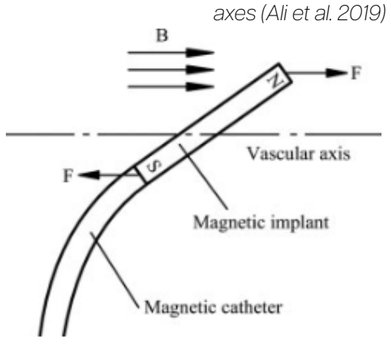


Figure 18: Magnetic catheter (Fu et al., 2009)

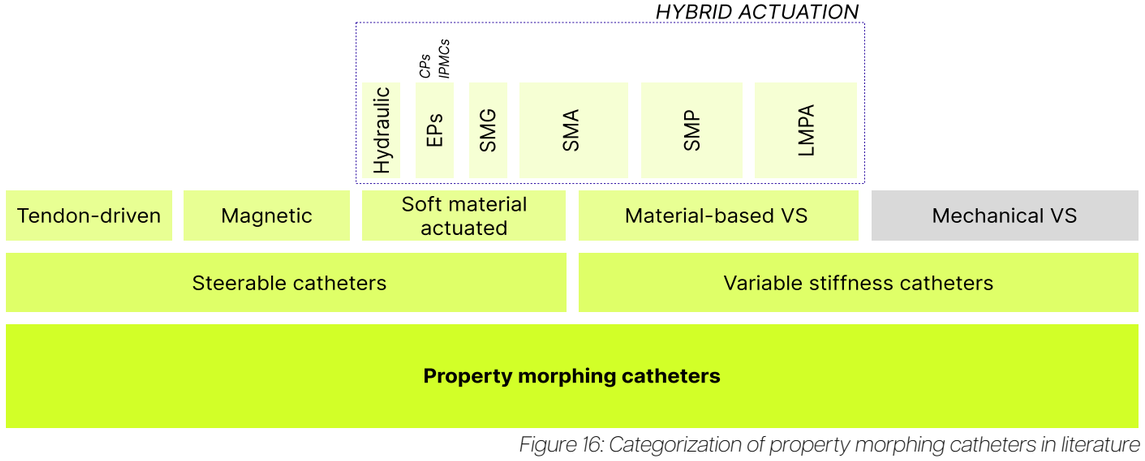


Figure 16: Categorization of property morphing catheters in literature

3.2.2 Material-driven property morphing catheters

Soft material-driven catheters are PMCs whose working principle is based on material properties. This type of catheter includes shape memory effect catheters where steerability and variable stiffness have been achieved with Shape Memory Alloy (SMA) (11), a variable stiffness Shape Memory Polymer (SMP) catheter with embedded magnetic particles for magnetic steering (14), electroactive catheters such as a steerable Conductive Polymer (CP) catheter (12, 13), a steerable Ionic Polymer-Metal Composite (IPMC) actuated catheter (15), a steerable Shape Memory Gel (SMG, hydrogel) based catheter (16), a hydraulically-driven steerable catheter system (17) and a variable stiffness Low-Melting Point Alloy (LMPA) catheter (18). Hybrid-actuation catheters are catheters that use a combination of the above actuation principles to achieve property morphing.

3.2.2.1 Characteristics of material-based property morphing catheters

An overview of the materials used in developments of material-based PMCs is illustrated in Table 2. In Appendix 4 the full literature benchmark of the material-based PMCs can be found.

SMA-driven catheters show promising property morphing ability in both shape and stiffness. A shape morphing catheter was developed by Haga et al. using femtosecond laser manufacturing, which has a diameter below 2mm and demonstrated a bending angle of 90 degrees (23), as well as a variable stiffness catheter that demonstrated a bending angle of 45 degrees and a stiffness change of 20mN (11). The cycle speed of SMAs actuation is higher than that of SMPs because of their good thermal conductivity (24). SMA-driven catheters can be challenging to miniaturize, as coils need to be used to achieve sufficient displacement of the catheter tip (11, 25), and isolation is needed of the coils to protect the patient vessels from thermal damage.

SMP-based catheters have up to now only been designed to have variable stiffness abilities (14). SMPs are able to exhibit shape memory effect although this effect is only significant when no external stresses are applied on the SMP. In the context of the endovascular catheter, this situation is unfeasible due to the radial stress of the vessel on the device. SMPs show variable stiffness at a high glass transition temperature, with a broad glass transition window, meaning there is a need for thermal isolation, therefore slightly complicating miniaturization, although Mattmann et al. have been able to develop a catheter prototype with a diameter of 2.5mm (14). Due to their low thermal conductivity, the cycle speed of SMPs actuation is lower than that of SMAs. SMPs show promise for the application in biomedical devices such as stents, scaffolding and self-tightening sutures, which are activated at body temperature, due to their wide range of biocompatibility (and degradability) as well as ease of manufacturing and low cost (26).

	ACTUATION *behaviour*	**STIMULI** *to elicit actuation*	**CONFIGURATION** *material embodiment*	**APPLICATION** *in PMC*	**BENEFITS** *in PMC*	**LIMITATIONS** *in PMC*
SMA *Shape Memory Alloy*	One-way reversible shape recovery and VS with a factor of 2	Direct or Joule heating	Coil	SMA coil actuator to enable bending and VS	High displacement, shape and stiffness morphability, fast cycle speed	Miniaturization challenge, safety
SMP *Shape Memory Polymer*	One-way reversible shape recovery and VS with a factor of 100-1000	Direct or Joule heating, humidity, light, magnetism, pH	Solid helix	SMP molded over a heating coil to enable VS	High VS potential, miniaturization	Negligible shape recovery, slow cycle speed, safety
SMG *Shape Memory Gel*	Reversible volume change with a factor of 100	Direct heating, electric, humidity, light, magnetism, pH	Gel	Gel layer, on a flexible polymer heater strip to enable bending	Low activation temperature, high demonstrated bending	Sensitive to interference, unclear cycle time, lab synthesis
Hydraulic system *Silicone and physiological saline*	Bending behaviour	Hydraulic actuation	Silicone tubes filled with physiological fluid	Silicone tubes filled with physiological fluid	Instant actuation, accurate, safe	Complex system, miniaturization challenge
CP *Conductive Polymer*	Reversible bending in two directions	Electric	Solid tube	CP outer tube with solid polymer electrolyte inner tube	Actuation speed, miniaturization, low voltage	Toxic electrolyte, only bending performance
IPMC *Ionic Polymer-Metal Composite*	Reversible bending in two directions	Electric	IPMC membrane	Polymer tube coated with noble metal	Almost instant actuation, low voltage	Hysteresis, back relaxation, cost
LMPA *Low Melting Point Alloy*	Reversible VS from solid to liquid	Direct or Joule heating	Encapsulated solid to liquid metal	Tube with an encapsulated LMPA channel	High VS	Requires encapsulation, cost, no shape change

Table 2: Characteristics of material-based catheter developments

An *SMG-based catheter* was developed that showed the highest bending angle recorded of any material-based catheter development within a low response time of 7 seconds (to shrink) and 12 seconds to recover its original volume (16). SMGs such as hydrogels are biocompatible and very similar to human tissue, making them attractive for biomedical applications. The response time of hydrogels is debatable as it can range from anywhere between seconds to hours (Kumru, personal communication). SMGs are not commercially available and need to be synthesized with care in a lab environment as they are sensitive to environmental factors (27). They are relatively more expensive than SMPs but similar to SMAs.

Hydraulically-driven steerable catheters have been studied early-on (28) and are successfully demonstrated in-vivo, showing high manoeuvrability (17) as well as tuneable stiffness by changing the pressure level in the hydraulic chambers. They show almost instant actuation and can utilize biocompatible highly flexible materials like medical-grade silicone. The downside are the advanced manufacturing techniques necessary to allow miniaturization of the hydraulic systems, as well as the cost due to the complex manufacturing process (1).

CP-actuated catheters are only able to show bending behaviour (12) and need toxic high-strain electrolytes to function sufficiently. Because of this, they need encapsulation to become biocompatible which in turn leads to difficulty miniaturizing the device. Almost any polymer can be made conductive so the manufacturability is high and cost is low (29).

IPMC-actuated catheters are also only able to show bending behaviour (15) and are unreliable due to the issue of back-relaxation (1). IPMCs often use toxic and expensive noble-metals, and therefore require encapsulation which in turn hinders miniaturization. Additionally, the polymer component of IPMC needs to be synthesized in a lab and no standardized process is available (30).

Finally, *LMPA-based catheters* demonstrate excellent variable stiffness abilities and no shape changing behaviour (18, 31). The toxicity of LMPAs requires encapsulation to ensure biocompatibility which makes miniaturization difficult. The softening of the LMPA happens through heating and is not instantaneous. Due to their low melting point, LMPAs can be formed easily with casting. The price of LMPAs is dependent on their alloying composition but is generally higher than the price of polymers because of the expensive indium element.

3.2.3 Conclusion literature review and benchmarking

I compared the performance and characteristics of the different materials in the material-based PMC designs of the literature review in Table 3. Every material shows promising features and limitations and there is in the literature no clear trend to one of the materials as being the most promising. For this design project, I take a closer look at the shape memory materials; SMA, SMP and SMG (hydrogel) because of their property morphing abilities and available knowledge and facilities in the faculty of IDE and TU Delft.

	MORPHABILITY *shape*	*stiffness*	**BIOCOMPATIBILITY** *of the material*	**SPEED** *of recovery cycle*	**MINIATURIZATION** *potential*	**FEASABILITY** *for design*	**COST** *of the material*
SMA *Shape Memory Alloy*	++	+	++	++	+	++	-
SMP *Shape Memory Polymer*	--	++	++	+	+	+	++
SMG *Shape Memory Gel*	++	o	++	+	++	-	-
Hydraulic system *Silicone and physiological saline*	++	o	++	++	+	-	+
CP *Conductive Polymer*	-	o	-	++	++	-	++
IPMC *Ionic Polymer-Metal Composite*	-	o	-	++	-	--	--
LMPA *Low Melting Point Alloy*	o	++	--	-	+	+	--

Table 3: Material characteristics in material-based property morphing catheter development (++ excellent, -- poor, o no data found)

3.3 Shape Memory Materials

Shape memory refers to the phenomenon of shape change caused by a certain stimulus. Shape memory materials (SMMs) are smart materials that can “remember” a certain shape they were “trained” to adopt (2). I zoomed in on the SMMs, shape memory alloy, shape memory polymer and shape memory gel, because they have been previously used in the development of property morphing catheters. To grasp the design possibilities of these SMMs, I have researched the characteristics, response time, shape recovery behaviour, range of property change, biocompatibility and feasibility in the use context of these materials.

3.3.1 Shape Memory Alloy (SMA)

Shape memory alloys exhibit the shape memory effect when exposed to heat. SMAs have three temperature phases: the annealing phase, austenite phase and martensite phase (Figure 19). The shape memory effect in shape memory alloys occurs during the transition between the martensite and austenite phases. Within the martensite phase, there are two distinct states: twinned martensite, formed when SMA is cooled from austenite, and detwinned martensite, resulting from mechanical deformation. In the detwinned martensite state, SMA exhibits improved mechanical properties and higher recovery force upon heating, compared to the twinned martensite state.

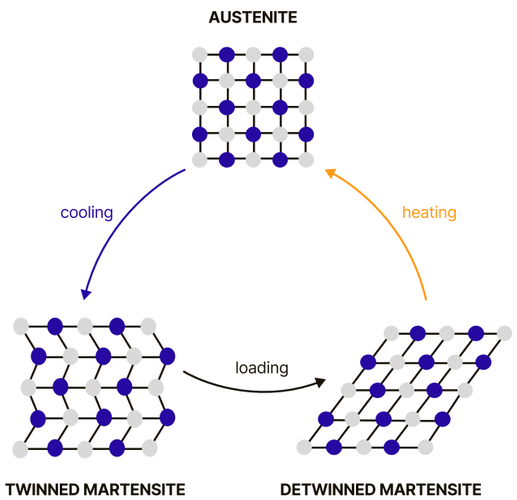


Figure 19: SMA phase transitions

SMA, such as Nitinol, can be trained to a specific shape through an annealing process. During annealing, the SMA “remembers” the shape it is in, which is why it is called a shape memory alloy. For Nitinol, which is widely used due to its affordability and reliability, the annealing process is typically carried out at a temperature of approximately 500°C.
In the rest of this chapter, when referring to SMAs I explicitly mean Nitinol as it is the most common SMA used in the biomedical context.

3.3.1.1 Stimuli of SMA

SMAs are activated by thermal stimuli which can be either direct heating or Joule-heating. The shape memory effect occurs in the austenite phase which, for Nitinol, can range from 30° to 130° C depending on its composition.

3.3.1.2 Response time of SMA

The response time of SMA actuation depends on the composition, size and heating method. When an SMA wire is heated, it can respond faster than a second. With Joule heating, a higher current leads to faster temperature change and therefore faster response time. The actuation can be achieved less than a second (24). The cooling of SMA is generally slower than the heating due to the absence of active cooling elements in most applications.
An SMA with a high transition temperature will have a faster cooling response, as the temperature difference between the transition temperature and room temperature is higher.

3.3.1.3 Shape recovery behaviour of SMA

Various modes of the shape memory effect have been demonstrated in SMAs. These are one-way, two-way shape memory and superelasticity (2).

One-way shape memory
In one-way shape memory, the material is pre-formed to a ground shape at high temperature and then cooled. The part can be deformed to and recover its ground shape when heated to its austenite phase. An illustration of this is given in Figure 20. One-way shape memory is the most common type of actuation for SMAs.

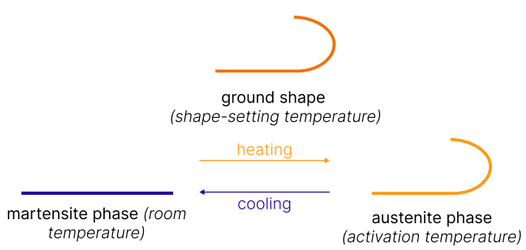


Figure 20: Shape recovery behaviour of SMA

Two-way shape memory
Two-way SMAs possess a high temperature shape and a low temperature shape (2). The time-consuming training requirements, asymmetry between tension-compression cycles, deterioration of strain at high temperatures and significantly lower produces strains make two-way shape memory materials not commercially feasible.

Two-way actuation with one-way SMA
Two-way actuation can be obtained with one-way SMAs using a SMA wire and a bias wire which show opposing shape memory effects, making the shape memory effect reversible. Such bias mechanisms usually come in the form of coil systems such as illustrated in Figure 21.

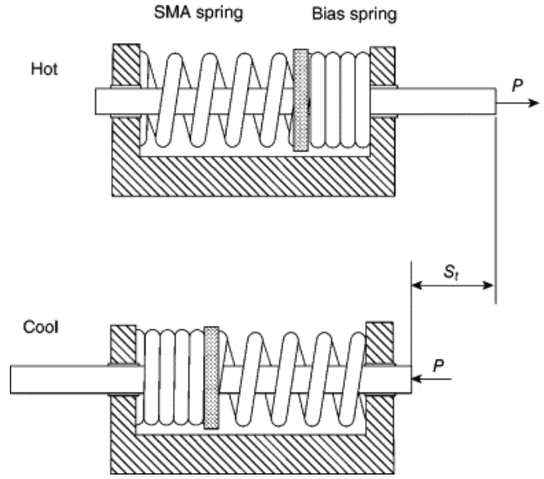


Figure 21: Bias spring mechanism (Nguyen et al., 2010)

Superelasticalloy (SEA)
Superelastic alloy (SEA) is a type of shape memory alloy that exhibit spring-like behaviour. These alloys can recover a significant amount of elastic deformation, up to 8% of their original shape, which is much higher compared to regular steel springs that typically recover only about 0.5%. The shape recovery process does not require heating or cooling as the SEAs undergo a phase transformation under stress. This transformation is reversed when the stress is removed.

3.3.1.4 Range of property change of SMA

SMAs are able to exhibit shape recovery as well as variable stiffness.

Shape recovery properties
SMA is easy to deform and generates force upon shape recovery. The deformation stress of SMA ranges from 50 to 200 MPa and its recovery stress ranges from 150 to 300 MPa (24). Nitinol can recover deformations up to 8% strain (2).
SMAs have a high cycle-life, maintaining their shape fixity and shape recovery in thousands or more deformation cycles before degrading occurs (32).

Variable stiffness properties
In the austenite phase, the SMA exhibits an elastic modulus (stiffness) that is about two times higher than in its martensite phase (33), meaning the SMA stiffens in its activated state. In the activated austenite phase the elastic modulus is found to be 70 GPa while in the not-activated martensite phase the elastic modulus can be as low as 40 GPa which means Nitinol SMA can exhibit a stiffness change of a factor close to 2.

3.3.1.5 Biocompatible SMAs

Nitinol SMA is the most commercially used type of SMA and is biocompatible. Other types of SMAs are rarely used as they are either more difficult to machine (as with Cu-based SMA’s) or show poor shape recovery behaviour (as with Fe-based SMAs).

3.3.1.6 Feasibility for design

Nitinol is commercially available in wire form in many different thicknesses. At the IDE faculty, there is a dedicated area for designing with SMA, along with abundant knowledge about the material. SMA is a popular choice for developing PMCs due to its excellent shape recovery, quick response time, and adjustable stiffness when activated. However, miniaturization remains a challenge as thermal insulation is required, and coils are used to achieve the desired displacement. However, an SMA-actuated PMC was developed by Haga et al. which is less than 2mm in diameter. Therefore, the miniaturizing of such a design is possible (11).

3.3.2 Shape Memory Polymer (SMP)

Shape memory polymers (SMPs) are widely studied because they offer more flexibility in design, manufacturing and are less costly than SMAs. Almost any polymer can become an SMP by physical crosslinking or chemical crosslinking (2). This provides us with a very wide range of materials and tuneable properties.
SMPs exhibit the shape memory effect through a range of stimuli such as thermal, electric, magnetic field, ions etc., of which thermal stimulation is the most commonly used (34). Under specific conditions where thermal stimulation is unsuitable, it might be necessary to fill the SMP with particles so that electrical or magnetic stimulation can evoke the shape memory effect.
Similarly to SMAs, SMPs can recover their permanent shape upon exposure to such stimuli (Figure 22). SMPs have a two-phase structure: a fixed phase and reversible phase. In the fixed phase, the glass transition temperature (Tg) is higher than in the reversible phase. In the reversible phase, the SMP may undergo reversible changes of softening and hardening by altering the stimulus (e.g. temperature).

3.3.2.1 Stimuli of SMPs

Depending on the composition of the SMP, multiple stimuli such as temperature, electricity, light, humidity, magnetism and changing pH-value can be used to activate the shape memory effect(s) of the material. Thermal stimulation is the most commonly used for SMP activation (26). The activation temperature of the SMP is the glass transition temperature, or Tg. Since the Tg of most polymers lies around 60° C according to experts, so they have to be thermally isolated to protect the human tissue when thermally stimulated.

3.3.2.2 Response time of SMPs

Recovery speed of SMPs is stated to be <1 s to several min (24) and is dependent on the thermal conductivity of the material, the thickness and shape, as well as the cooling method and ambient temperature. SMPs will have a slower cycle time than SMAs because of their lower thermal conductivity and therefore longer cooling time.

3.3.2.3 Shape recovery behaviour of SMPs

The most common type of shape memory behaviour in SMPs is the dual-shape memory effect. These SMPs have a permanent and temporary shape, where the temporary shape is a deformation of the permanent shape caused by an external force . Shape recovery occurs from the temporary to the permanent shape under stimulation by the appropriate stimuli (Figure 23), as long as there are no external forces preventing recovery (2). This could be challenging to design with in the biomedical context where there is a need for recovery against mechanical constraints of the surrounding tissue (34).
Conventional SMPs are capable of one-way shape recovery, meaning they can recover from a deformation at high temperature to their original shape. Research is being done to achieve reversible shape change in SMPs and has been achieved with various successful outcomes, most notably in pNIPAM hydrogels and liquid crystal elastomers (24).

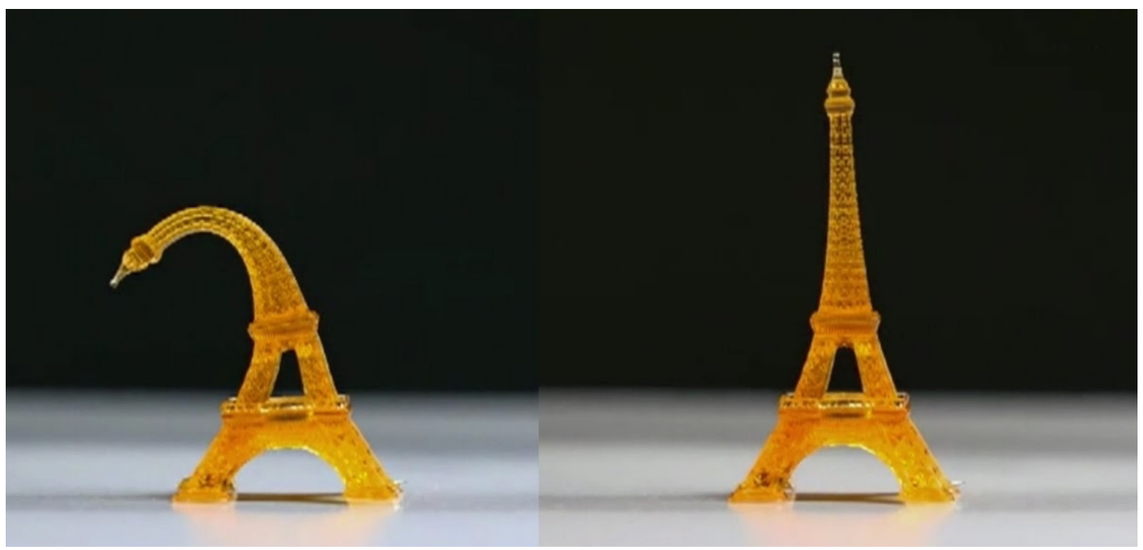


Figure 22: Shape recovery of SMP (Ge et al., 2016)

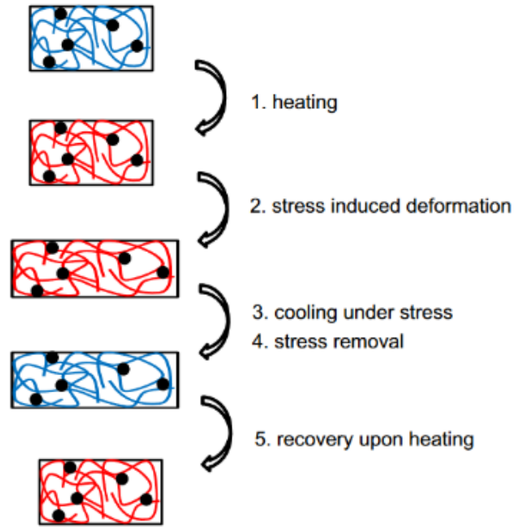


Figure 23: Shape recovery mechanism of SMP (Xie, 2011)

3.3.2.4 Range of property change of SMPs

Similar to SMAs, SMPs are also able to exhibit shape recovery as well as variable stiffness.

Shape recovery properties
The stress required to deform SMPs ranges between 1 - 3 MPa and stress generated during recovery ranges between 1 - 3 MPa which is significantly lower than the generated stress of SMAs during recovery. Strain recovery of SMPs can be up to 400%, and possibly above 800% (24). This results in the SMP only being able to fully recover its shape when no external stress is applied to the material.
SMPs have low cycle life meaning their shape morphing performance will degrade over a small amount of cycles. Most SMPs experience degradation in shape memory performance after more than 5 cycles. Cycle life is dependent on the composition of the polymer and efforts have been made to increase SMP cycle life from the range of tens to the range of thousands (35).

Variable stiffness properties
SMPs Young's modulus has a variation range between 0.01 – 3 GPa below glass transition temperature (when no stimulus is applied) to (0.01-10) × 10-3 GPa above glass transition temperature (when the stimulus is applied). SMPs stiffness decreases when temperature increases contrarily to SMAs which show stiffness increase at higher temperature.

3.3.2.5 Biocompatible SMPs

There is a wide range of polymers that are biocompatible and show shape memory behaviour, although they are not marketed so. Polyurethanes have stood out because of their biocompatibility as well as their favourable mechanical properties (36). Additionally, they have a transition temperature closer to human body temperature than other shape memory polymers, which increases safety for use inside the human body.

3.3.2.6 Feasibility for design

Many polymers show property morphing behaviour such as the commercially available polyurethane. However, the temperature needed to utilize the property morphing behaviour, in this case variable stiffness is very high (Jansen, *personal communication*). To make use of the variable stiffness in an efficient way, a cooling mechanism has to be included in the design such as is demonstrated in the research of Mattmann et al. (14) which can be challenging to miniaturize.

3.3.3 Shape Memory Gel (SMG)

Hydrogels are a type of shape memory gel that exhibit extreme volume change, by swelling (absorbing water) and shrinking (expelling water), in response to stimuli such as pH or temperature (2). Hydrogels show a reversible volume change which can be used to design actuation behaviour (Figure 24).

Hydrogels are very soft and easily damaged, which limits their application, although, research is being done that drastically improves the mechanical properties of hydrogel (Kumru, *personal communication*). Nonetheless, it can be advantageous to integrate hydrogel structures with other hard SMPs. Implementing hydrogel in SMPs, such as in a layered composite, eliminates the training steps necessary for SMP to achieve a temporary shape which can transform to a permanent shape (2).

Commercially available hydrogels are in the shape of beads, often used in toys and can be used to make cheap hydrogel actuated prototypes (37) (Figure 25).

3.3.3.1 Stimuli of hydrogels

Hydrogels can be actuated by a range of stimuli including temperature, electricity, light and pH change (38). Thermoresponsive gels can either show a lower critical solution temperature (LCST) or an upper critical solution temperature (UCST); LCST hydrogels collapse above their critical temperature where UCST hydrogels expand above their critical temperature (27). The UCST and LCST of hydrogels can be tuned depending on their composition.

3.3.3.2 Response time of hydrogels

The response time of hydrogels can be between seconds and hours. The response time of hydrogels is very dependent on the presence of water and the volume of the hydrogel and is significantly slower in air than in water. Hydrogels with the size of several centimeters can have a response time as large as several hours (38). However, the research by Selvaraj & Takahata demonstrated a thin embedded hydrogel actuator which was able to actuate to a bending angle of 170° within 7 seconds by shrinking and recovering its original volume in 12 seconds (16).

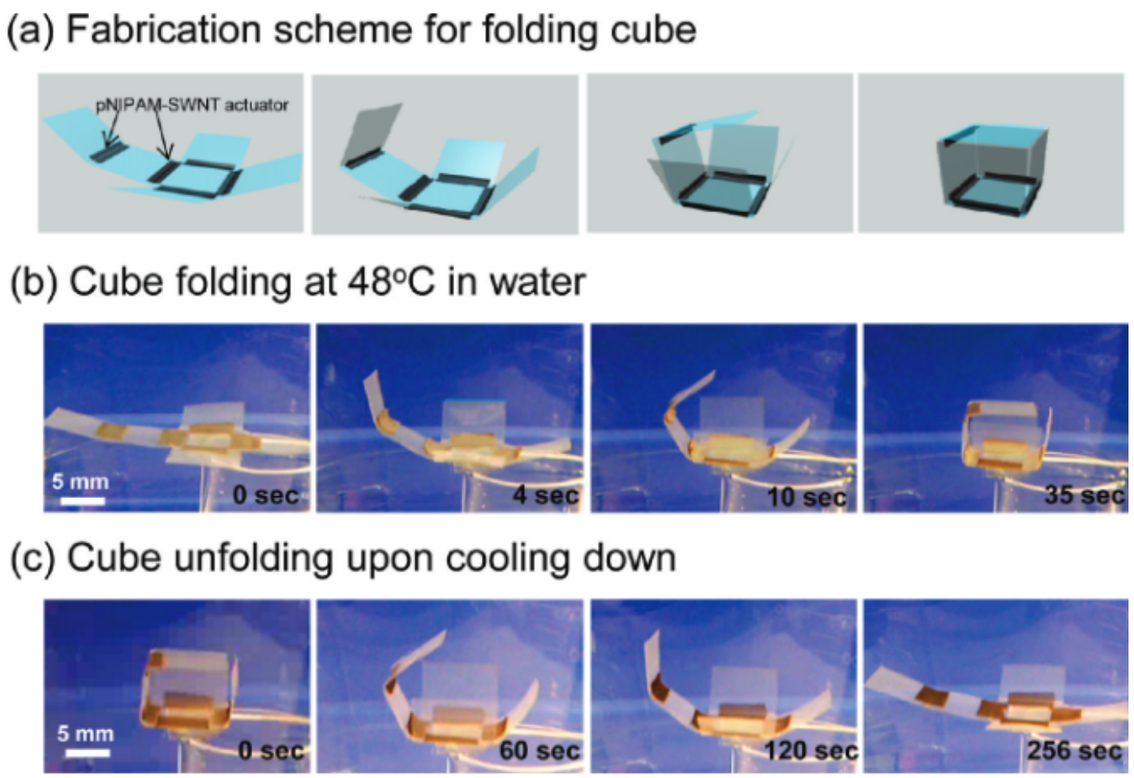


Figure 24: Folding cube based on thermal responsive hydrogel (Zhang et al., 2011)

3.3.3.3 Shape recovery behaviour of hydrogels

Hydrogels can exhibit a volume change up to several hundred fold of their original volume. Under a heightened temperature, this volume change can be sped up. The volume change of hydrogel can be used to enable shape morphing such as illustrated in Figure 24. The response of the hydrogel is reversible (39). Selective patterning enables localized swelling of hydrogels in specific regions. This controlled swelling and collapse of hydrogels results in significant shape changes, such as out-of-plane bending, curving, twisting, and folding (40).

3.3.3.4 Range of property change of hydrogels

It is difficult to precisely determine the range of property change of hydrogels during actuation. Their volume change is a factor of several hundred compared to their original size, and can be used to design variable shape and stiffness. Reportedly, shape memory gels have a stiffness change of 10 to 0.1 MPa between shrunk and swollen state respectively (24).

3.3.3.5 Biocompatible hydrogels

The thermoresponsive hydrogel pNIPAM (poly(N-isopropylacrylamide)) has been mostly studied because it shows reversible massive volume change at a relatively low temperature of around 32° C and it is biocompatible.

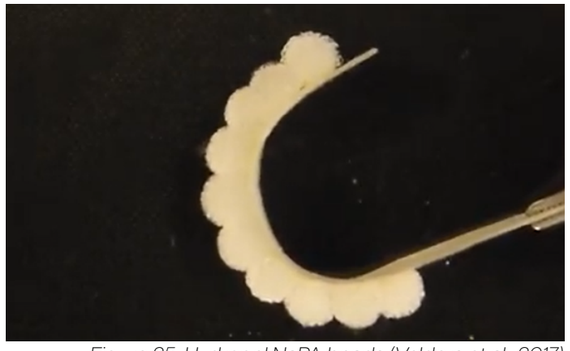


Figure 25: Hydrogel NaPA beads (Velders et al., 2017)

3.3.3.6 Feasibility for design

The synthesis of hydrogel is a lab-based process and is not standardized yet. At the faculty of IDE there is no expertise in the design with hydrogel, however at the faculty of Aerospace Engineering there is. Together with the expert from Aerospace Engineering I synthesized a hydrogel. The process (described in Appendix 6) is relatively easy, being very similar to mixing silicones. Regarding the time-frame for this thesis project, it was unfeasible to implement the hydrogel in a catheter prototype, as the properties of the hydrogel are very dependent on the mixing ratios of the different components. This would have to be researched first to be able to determine the suitable composition.

3.3.4 Conclusion SMMs

Shape memory materials offer many opportunities for the creation of products with dynamic relastionships with the user and their environment. Within the development of PMCs, there is no clear trend towards one material as all materials show different benefits and limitations. In Table 4, the quantified data of the property morphing behaviour of the SMMs is given, as found in literature. The reversibility (cycle stability) indicates the number of actuation cycles the material can go through before performance deterioration occurs.

I used a Harris profile (Figure 26) to make a choice of material to focus on for the prototyping of the design. The Harris profile is based on Table 4 and communication with materials experts (Ghodrat, Jansen & Kumru).
From the Harris profile, SMA is the best option to design the actuation with regarding their high shape recovery, variable stiffness within the range of catheter stiffness, cycle speed and reliability. In the faculty of IDE I have access to the necessary equipment to design with SMA, which is not the case for SMGs. However, SMG is an interesting material which shows promise in the biomedical application (Table 2; Table 3) so I did the synthesizing process together with B. Kumru from the faculty of Aerospace Engineering at a later stage in the project and it is fairly uncomplicated (Appendix 6). Considering the time constraints of this project, I recommend a next project that specifically focuses on applying SMG in this specific design context.

	RECOVERY STRESS *in MPa*	**VOLUME CHANGE** *factor*	**STIFFNESS CHANGE** *factor*	**SPEED** *of recovery cycle*	**REVERSIBILITY** *cycle stability*
SMA *Shape Memory Alloy*	150-300	o	<2	<1s	>1000
SMP *Shape Memory Polymer*	1-3	o	100-1000	<1s - several minutes	10-100
SMG *Shape Memory Gel*	o	100-<1000	100	<1s - 10s	o

Table 4: Quantified data property morphing ability of SMMs

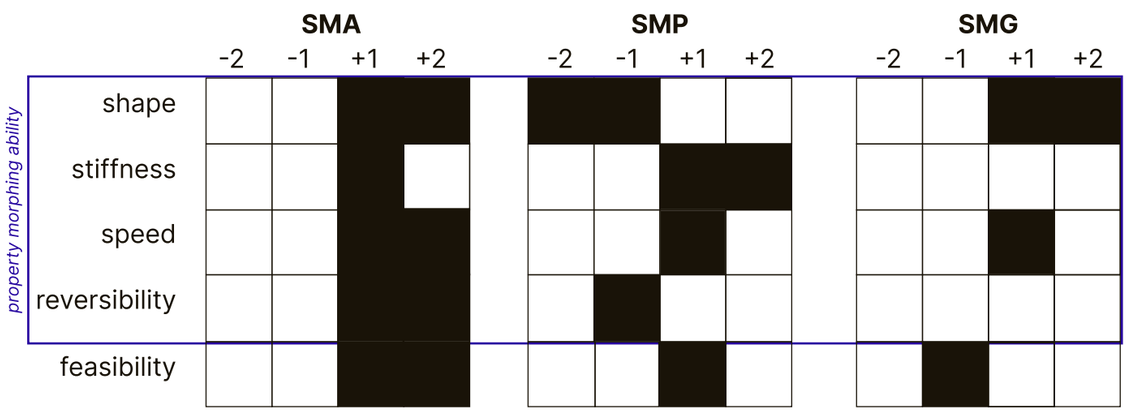


Figure 26: Harris profile of SMMs characteristics

4. Design Requirements

The design requirements are drafted from the research. They serve as a guideline of what the design of the property morphing catheter should comply to. The requirements can be used in future projects of this subject.

To draft the list of requirements, I used the Delft Design Guide (41). The requirements are based on all the previously discussed findings in literature, observations and communication with experts. Because this project will result in a proof of concept, the requirements will be most centred around the property morphing ability and biocompatibility requirements rather than for example ergonomics and user-centredness. Some requirements regarding safety from the European Union Medical Device Regulation (MDR(EU)2017 745) (42) are also taken into account.
Other relevant requirements for further development are reformulated as wishes. They are kept in mind but not stated as requirements to prevent overly limiting the design possibilities in this early stage of development.

4.1 Property morphing performance

- The design should be able to morph its stiffness and/or shape properties on demand when a stimulus is applied.
- The design's property morphing ability should be reversible.
- The design's property morphing ability should be repeatable.
- The actuation response time must be within seconds.

4.2 SMA characteristics

- The coil elongation should not exceed 100% of its trained coil length.
- Flat coil actuators should be used for bending actuation to minimize the device cross-section.
- The device should include a bias spring to enable reversible actuation.
- The bias spring should be made from superelastic alloy.

4.3 Usability

- The design allows a lumen to enable usage of a guidewire and administration of treatment.
- The design has a stiff shaft to ensure pushability and torque translation.
- The design has a variable stiffness tip to ensure safe vessel navigation.
- The design does not require spatial changes to the operating room.
- The design should ensure familiarity for the interventionalist, minimizing the need for re-training or specialized education to use it.

4.4 Medical regulations

The regulatory requirements for this project are derived from Annex I of the European Union Medical Device Regulation (MDR(EU)2017 745) (42). These requirements are based on the medical device classification of an endovascular catheter and have been paraphrased to ensure clarity and readability. The classification and other relevant regulatory requirements can be found in Appendix 5.

- The design is biocompatible in all part that are in contact with the exterior.
- The design is non-toxic in all parts that are in contact with the exterior.
- The parts of the design in contact with the exterior are compatible with biological tissue.
- The design is sterilizable with conventional methods (such as ethyleneoxide sterilization).
- The design is made as to prevent as much as possible the risk of thermal, and electrical damage to the user and other stakeholders.
- The design's surfaces shall not exceed a temperature of over 41 degrees Celsius (for endovascular applications specifically) (14).

4.5 Wishes (future development)

- The design can achieve a minimum bending radius of 10 mm in order to be able to manoeuvre through most vessel branches (43).
- The design is as small as possible, maximally 8Fr.
- The design of the device aims to balance miniaturization and property morphing performance.
- The tip stiffness can range between 12 to 74MPa.

5. Design Exploration

The design exploration is divided into three parts. First, existing SMA property morphing catheter designs are analysed and broken down into their (changeable) component parameters. A first prototyping phase is conducted which consists of hands-on material experimentation and prototyping mock-ups of the design. In the second prototyping phase, the working principles and other relevant properties of the material systems are evaluated.

5.1 Design Analysis

The existing SMA catheter designs from literature are analysed and broken down to separate design parameters. Based on these design parameters, knowledge gaps are identified. These knowledge gaps serve as the starting point for the first prototyping phase.

5.1.1 Design of an SMA actuated catheter

SMA has been used in the development of multiple property morphing catheter designs (3.2 Literature Review). Almost all designs are based on the design of Park and Esahi from 1999 (Figure 27) which uses coil actuators (44).
The designs can be broken down into five basic components as illustrated in Figure 28:

(1) The flexible inner tube which acts as the lumen of the catheter;
(2) A bias or liner coil which acts as the counterforce to restore the catheter to its neutral state and therefore enables two-way actuation;
(3) The SMA actuators, which can be wires or coils;
(4) (Optionally) Polymer links to which the actuators and bias spring are attached. Although eliminating the polymer link has resulted in more free movement of the SMA catheter (11);
(5) A flexible outer tube, encasing the whole system.

Advancements in SMA catheter design have introduced various coil configurations, including zigzag coils and flat helical coils (45, 46). Additionally, some designs have moved away from using polymer links and instead use a steel bias spring to which the SMA actuators are directly attached (11).

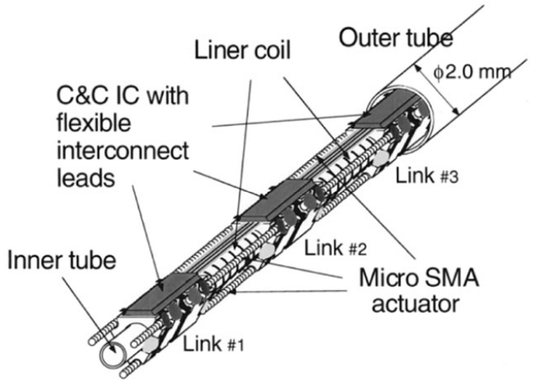


Figure 27: Catheter construction (Park and Esahi, 1999)

5.1.2 Material systems in SMA actuated catheters

From the designs described in the literature, two distinct material systems can be derived which both use SMA coils as their actuating parts.

Material system I achieves bending through actuation of a zigzag or helical coil that contracts upon actuation and therefore contracts the bias spring and creates a bending motion, similarly two the working principle of tendon-driven steerable catheters.

Material system II achieves bending through actuation of a zigzag or helical coil that is trained to show bending behaviour when actuated.

Variable stiffness can be achieved through either the simultaneous actuation of four actuator coils in material system I or the actuation of a helical SMA coil around the bias spring in material system II. SMA hardens when it is reaches its activation temperature and therefore variable stiffness is inherent to the SMA material regardless of its shape or training in the material system (see 3.3.1 Shape Memory Alloy (SMA)). Therefore, my prototyping will be focused on the bending ability of the material systems.
Both material systems are illustrated in Figure 29 on the next page.

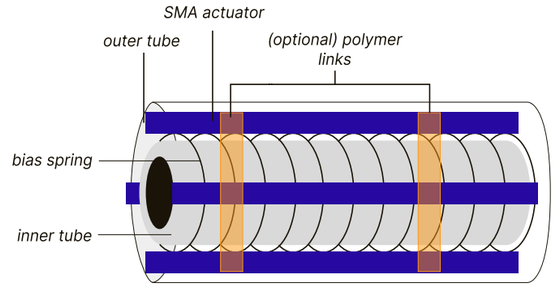


Figure 28: SMA catheter design breakdown

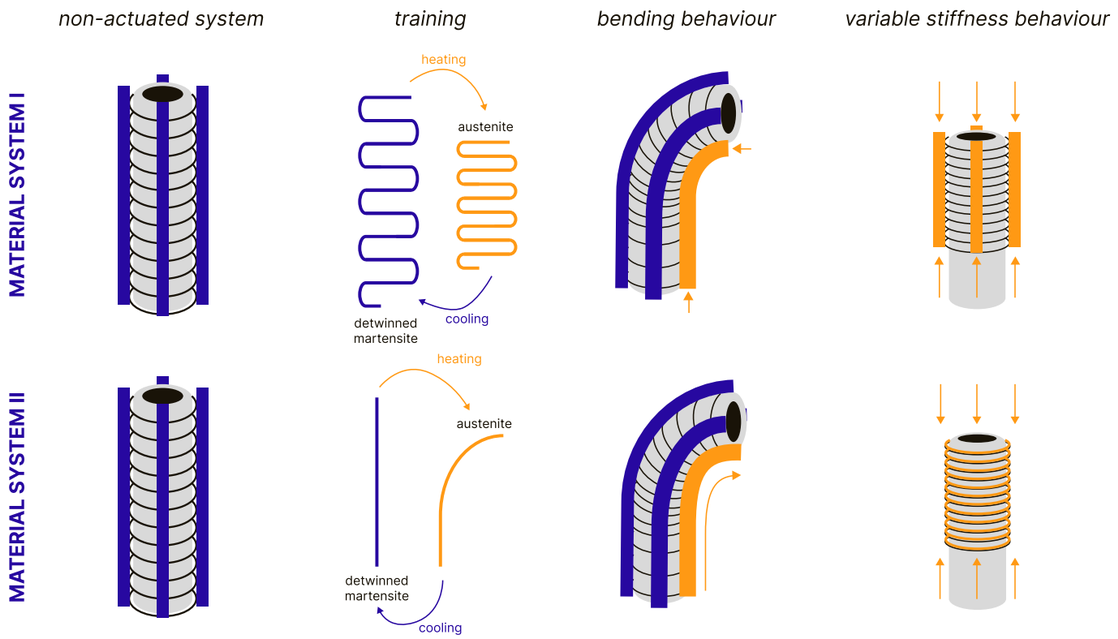


Figure 29: Material systems I and II working principles

5.1.3 Design parameters

Several design parameters (6.7 Design parameters) can be identified from the multiple SMA catheter designs, of which the parameters in the Figure 29 have a large influence on the property morphing behaviour of the PMC.

I organized the design parameters using the Fishtrap model from the Delft Design Guide (41) which can be found in Appendix 8. A simplified overview of the model is shown in Figure 30. The prototyping phases are organized based on the Fishtrap model.

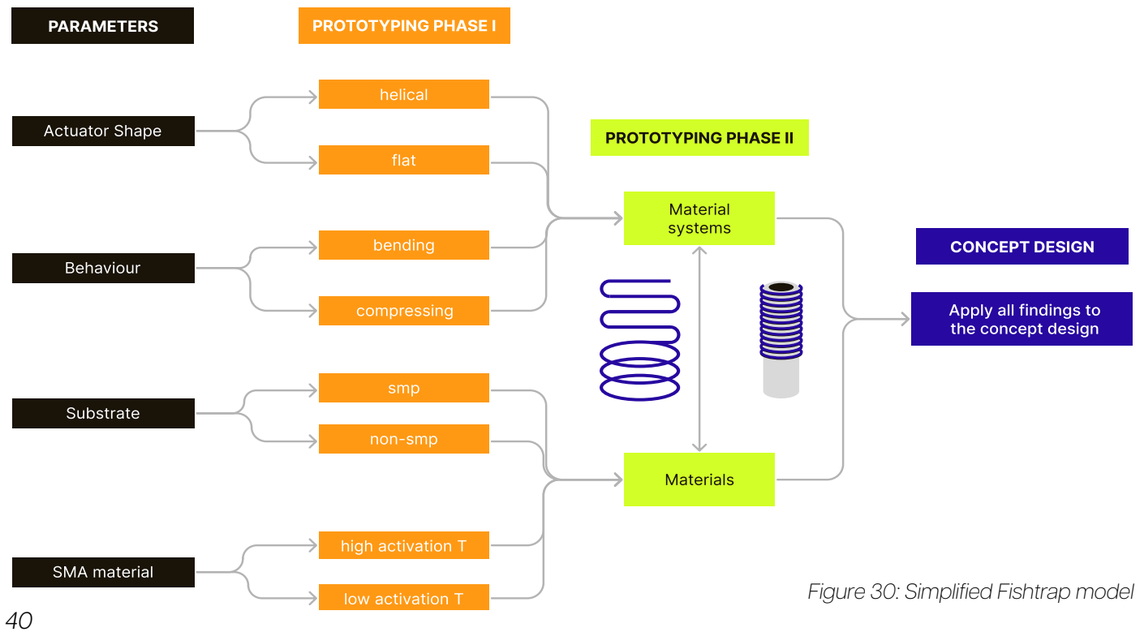


Figure 30: Simplified Fishtrap model

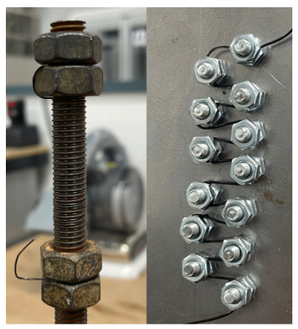
5.2 Prototyping phase I: Material Exploration

In prototyping phase I, the emphasis is on material testing and experimentation to explore the design parameters. The insights gained from phase I serve as the foundation for prototyping phase II, where the material systems are compared and evaluated. Prototyping phase I characterizes the SMA material, determines the difference in actuation behaviour between a helical and zigzag coil and researches the influence of actuator dimensions and substrate coatings on the actuation behaviour. Bending prototypes are made to observe the different forms of bending behaviour of the material systems and the implementation of variable stiffness in the design is briefly discussed.

5.2.1 Training SMA wires

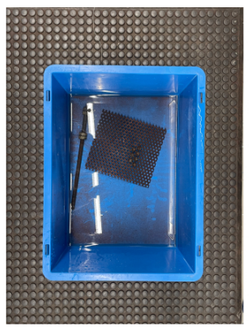
SMA material can be trained to “remember” a certain shape. The remembered shape is called the ground shape of the actuator. The training process is shown in Figure 31. The changeable parameters are the annealing temperature and time which are noted per experiment.

The SMA wire must be clamped in the desired ground shape. For helical coils, this is done using a bolt, while for zigzag coils, a custom mold can be used. It is possible to program the SMA in all kinds of complex shapes, as long as the shape can be fixed in a mold and removed sufficiently without causing plastic deformation.
The wires are annealed in the ceramic oven. The annealing for NiTi-based SMAs usually happens between temperatures of 500-550°C and annealing times of 30-45 minutes. After the annealing process, the materials are quenched in room temperature water. This process results in an SMA actuator with a memorized ground shape.



(a) fixing the SMA in the mold (left helical coil, right zigzag coil)

(b) annealing the SMA in the ceramic oven



(c) quenching the SMA in room-temperature water

(d) removing the SMA from the molds

Figure 31: Training process of SMA into coil shapes

5.2.2 Zwick/Roell test set-up

The test set-up used for experiments involving the measurement of temperature and shape memory effect force generation is based on the Zwick/Roell machine from the Applied Labs. This test set-up has been used in a previous graduation project by Lücker to determine the generated force of SMAs with different activation temperatures (47). As the actuators in the material systems for SMA catheters are fixed at both ends, as is the case in the Zwick/Roell machine, the method serves to determine the generated force of the actuators.

The Zwick/Roell machine (Figure 32) is able to measure tensile forces of samples clamped and stretched in the machine with a tolerance of 0.1% on 500N . SMA generates force when the material is actuated and tries to return to its ground shape from displacement.

A power supply is used to provide the Joule-heating of the SMA actuators and a voltage/current of 2.5V and 1A is applied to all actuators until the activation temperature is reached.
With a K-type thermometer and a FLIR infrared camera, the actuator temperature is monitored. Because the K-type thermometer showed unreliable results during testing, mostly the FLIR camera was used. With my phone camera I recorded the force measurements of the Zwick/Roell machine while I read aloud the temperature measurements corresponding to the amperage.

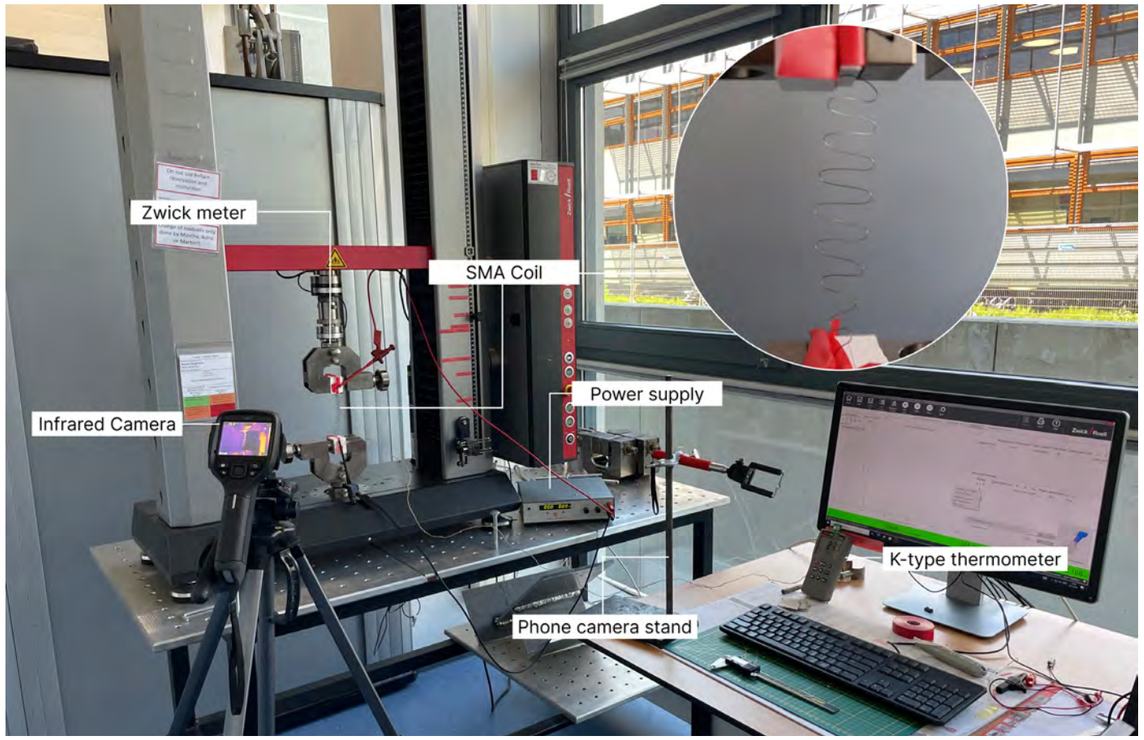
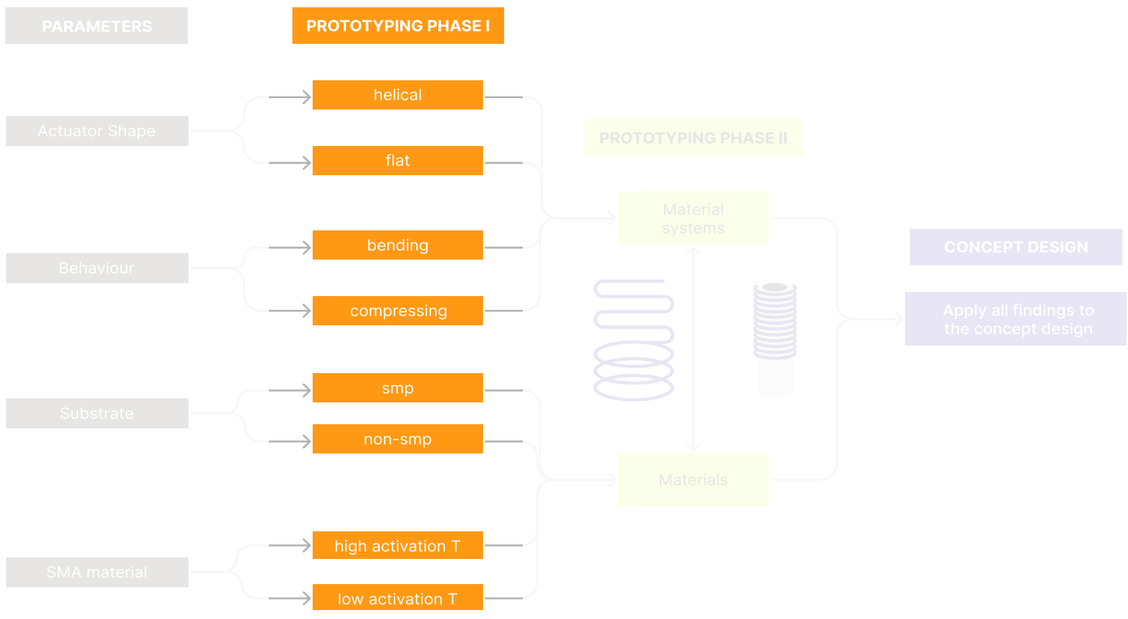


Figure 32: Zwick/Roell test set-up



5.2.3 SMA material characterization

SMAs are available in various alloy compositions, each with different activation temperatures (At). To adhere to medical requirements and prevent tissue damage, the catheter should maintain surface temperatures below 41°C (see 3.5.4 Medical regulations). An SMA with an At of 45° C seems feasible as the At is above body temperature but close to the upper allowable limit. There will be some electrical and thermal isolation provided by the substrate and outer tube (Figure 29). It is assumed that blood flow provides some heat dissipation. Further testing, in vivo or in a simulated environment would be necessary to confirm this assumption. However, within the scope of this design project these assumptions are justified as I focus solely on the design and working principle of the PMC.

For the experiments, SMA wire of a NiTi alloy composition with a diameter of 0.25mm is used. The NiTi wire is manufactured by Kellogg's Research Lab and comes with a given activation temperature of 45°C (48). Table 5 shows the training parameters.

TRAINING PARAMETERS

Alloy; diameter (mm); At (°C)	NiTi; 0.25; 45
Annealing temperature (°C)	500
Annealing time (minutes)	35

Table 5: Training parameters material characterization

5.2.3.1 Determining activation temperature

The SMA is trained into an arbitrary zigzag coil shape such as shown in Figure 31. Because the dimensions of the ground shape are not yet relevant, they are not discussed in this experiment. The zigzag coil is elongated with 50% regarding its trained length and then clamped in the Zwick/Roell. With the power supply, the amperage is slowly increased from 0 to 1A with increments of 0.2A, while the temperature is read from the infrared camera. The force and temperature graph is shown in Figure 33.

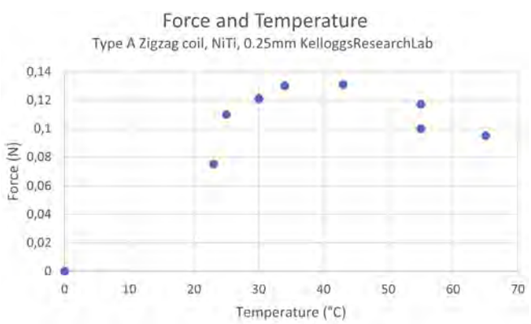


Figure 33: Force and temperature

It can be observed that force generation starts well before 45° C. From 23° C there is force generation within the SMA actuator. The force generation reaches its peak at 32-43° C after which it drops again when the temperature goes beyond 50° C.

5.2.3.2 Cyclic force generation

The SMA actuator is heated to its activation temperature for 10 cycles. After each cycle, the SMA is actuated to recover its original shape before it is elongated to 50% again. Figure 34, shows that the maximum force generate decreases slightly from the initial force of 0.144N to 0.12N by the tenth cycle.

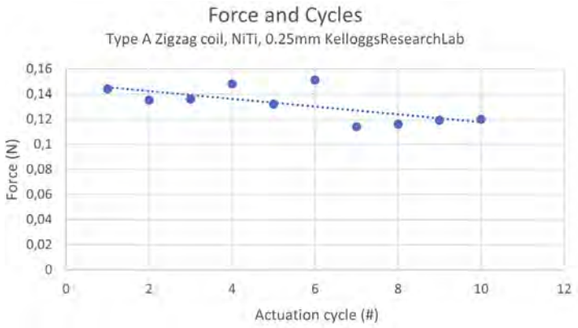


Figure 34: Force and cycles

5.2.3.3 SMA Material: Discussion

By determining the activation temperature of the NiTi wire, it is clear that the actuation starts already at a temperature of 23° C. The generated force reaches its peak at a temperature of 32-43 degrees where it amount to 0,13N. Heating the SMA to 50° and higher resulted in decline in the generated force. This decline might be due to overheating of the SMA.

Some decrease in generated force is noticeable in the force per cycle graph. The decrease could be a consequence of overheating of the actuator in the first test, as temperature fatigue is a common roadblock in SMA actuators. According to literature, the cycle life of SMA actuators is very high, upwards of 1000 deformation cycles when the maximum strain of 8% is respected.

5.2.3.4: SMA Material: Test limitations

The SMA material has superelastic behaviour after the training. This keeps the actuator from staying in its deformed state unless it is clamped. In a later experiment, I found the solution for this problem. The Kellogg's Research Lab NiTi needs to be annealed at a temperature between 200 to 400°C. Another limitation is that with the current Joule-heating method there is no way to stabilize the temperature of the actuator. The actuator can be easily overheated which damages its function.

5.2.3.5: SMA Material: Conclusion

For the application in the PMC design, it is important that actuation does not occur in body temperature as the actuation needs to be controllable by the interventionalist. The starting activation temperature should be above body temperature. According to Kellog's Research Lab, the activation temperature range of SMA can be adjusted by completing a controlled heat treatment during the manufacturing process of the SMA (48). The narrowness of the activation temperature window also differs between manufacturers, as Nextmetal SMA shows an activation start temperature closer to the given activation finish temperature.

SMA generates a higher force when it is immediately heated to its activation temperature. With prolonged heating, the force gradually diminishes, as the SMA actuator starts to overheat. It is necessary to maintain a stable temperature by using a temperature control mechanism, or be able to "freeze" the shape in another way such as in a shape memory polymer composite, as briefly discussed in 4.3.3 Bistable SMA-SMP Composite (Shape Freezing).

5.2.4 Actuator Shape

The SMA actuators in PMC design are coil-shaped to allow extension when the catheter is bending. Wire actuators are less suitable because their fixed length impedes the bending movement of other actuators.
Coil shapes are divided in helical 3-D coils or 2-D zigzag coils. In the context of a catheter design, it is desirable to minimize the cross-section area to allow miniaturization of the catheter. Theoretically, a zigzag coil is preferable over a helical coil for the bending actuators, as with zigzag coils, the cross-section area is minimized (Figure 35).

Regarding variable stiffness, both helical coils and zigzag coils can be used with a minimized cross section area (Figure 36). The helical coil goes around the shaft of the catheter and the SMA stiffens when actuated. Because there is no displacement of the actuator, there is no need for a bias coil, favouring miniaturization. Zigzag coils can be actuated simultaneously to achieve variable stiffness with the same principle as the helical coil design although this set-up requires a bias coil to restore the system after actuation.

In this section the difference in acuation behaviour (i.e. force and cycle time) of a helical and zigzag coil is researched.

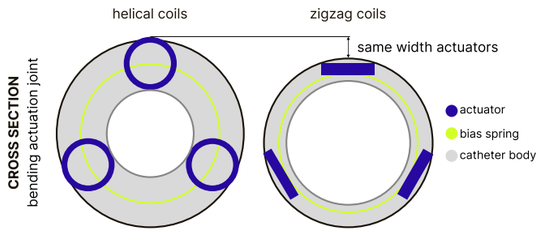


Figure 35: Cross section comparison 3D and 2D actuators

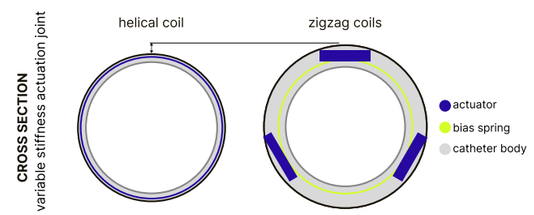


Figure 36: Cross section comparison 3D and 2D actuators

5.2.4.1 Generated force comparison 2D and 3D coil

I fabricated two actuator coils, a 3D and a 2D, with similar dimensions (Figure 37). The zigzag coil with the given dimensions will be referred to now as a Type A zigzag coil, as later on multiple zigzag coils will be introduced with different dimensions from this one.

The training conditions for this experiment and the next are given in Table 6.

The Zwick/Roell test-setup is used with the coils elongated to various percentages with increments of 10% every time (10%, 20%, 30% ...100%). An elongation of 100% is kept as the maximum limit of elongation as a previous graduation project showed that beyond 100% elongation, the SMA actuator is plastically deformed (49). Since the material exhibits some superelastic behaviour when elongated, the spring-like force they exert when not actuated is subtracted from the recorded force generation.

TRAINING PARAMETERS

Alloy; diameter (mm); At (°C)	NiTi; 0.25; 45
Annealing temperature (°C)	500
Annealing time (minutes)	35

Table 6: Test parameters actuator shape

The results (Figure 38) indicate that the Type A zigzag coil exhibits a recovery force of 0.192N when stretched to 100% elongation, while the helical coil generates a force of 0.08N at the same elongation. Throughout all elongation percentages, the zigzag coil consistently demonstrates a higher force generation compared to the helical coil.

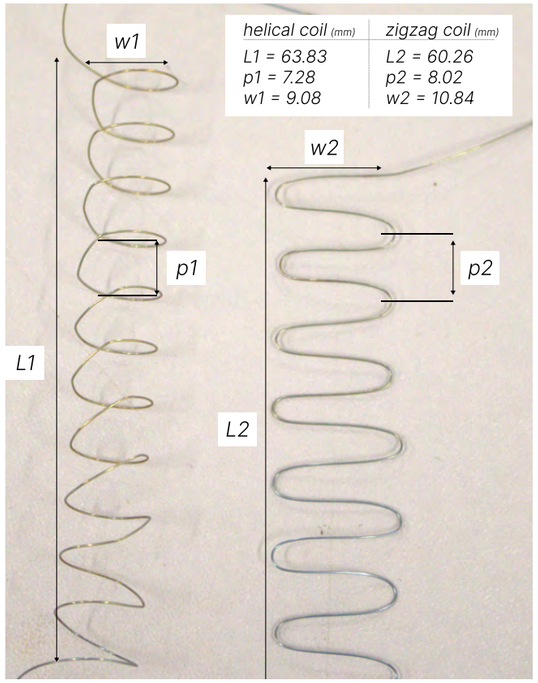


Figure 37: Helical coil (right) and zigzag coil (left)

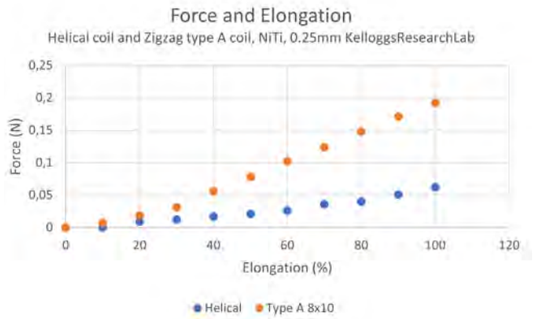


Figure 38: Force and elongation helical and zigzag type A

5.2.4.2 Comparison 2D and 3D coil: Discussion

When comparing a helical coil and a zigzag coil, the helical coil usually has a higher winding density (closer winding spacing) due to its tightly packed windings. As a result, the helical coil has a longer untrained length of wire and needs to be stretched more than the zigzag coil to achieve a similar recovery force. The recovery force of shape memory alloys (SMAs) is primarily determined by the rate of displacement and the amount of stretch (because of it reaching detwinned martensite phase: see 3.4.1.4 Shape recovery behaviour of SMA), rather than the specific shape of the material.

5.2.4.3 Comparison 2D and 3D coil: Limitations

Due to the need for high temperatures during the annealing process, the minimum thickness required for mold designs is 3mm. Consequently, the zigzag mold design is limited to a pitch (distance between windings) of at least 6mm to ensure sufficient space between the bolts, allowing for proper tightening. Replicating the higher pitch of the zigzag coil with a helical coil mold means that for every winding in the bolt, some indentations need to be skipped. This caused an irregular pitch if you would measure every distance between the windings. It would be more accurate to manufacture a custom bolt with the identical pitch to the zigzag coil mold.

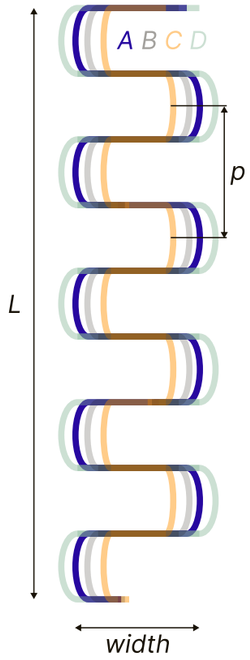
5.2.4.4 Comparison 2D and 3D coil: Conclusion

To obtain a helical coil that offers the same recovery force as the zigzag coil, the helical coil can be shortened, or the amount of windings per mm can be decreased so that a 100% stretch will deliver a higher recovery force.
In conclusion, the recovery force obtainable by helical coils and zigzag coils can be similar, depending on the length of the actuator and density of windings per mm. The zigzag coil is preferable over the helical coil for bending actuators because it favours cross-section area minimization.

CONTINUED

5.2.4.5 Comparing generated forces of zigzags with varying peak heights

This test examines how the dimensions of the actuator influence the actuation behaviour. Zigzag coils with various peak heights were manufactured according to the diagram in Figure 39.



coil width (mm)
Type A = 10
Type B = 8
Type C = 6
Type D = 12

dimensions
width (w) = varying
length (L) = constant
pitch (p) = constant

Figure 39 Dimensions of zigzag types

The molds for the zigzag coils were manufactured on the milling machine to ensure precise dimensioning of the coils (Figure 40). The bolts used are size M3. The length of the actuators is 76 mm and the pitch is 8mm.
Tabel 4 shows the training parameters for this test.

TRAINING PARAMETERS

Alloy; diameter (mm); At (°C)	NiTi; 0.25; 45
Annealing temperature (°C)	500
Annealing time (minutes)	35

Table 7: Training parameters zigzag comparison

The SMA actuators were clamped in the Zwick/Roell machine and stretched to various percentages, ranging from 0 to 100%, with increments of 10%. Because of the superelastic behaviour of the material, the elastic force when not actuated was subtracted from the recorded force to isolate the generated force caused by actuation of the SMA. The actuators were actuated 1A.

The results of the different zigzag coils generated force at different levels of elongation are shown in Figure 41. Based on the results, it is evident that the Type C zigzag coil, the narrowest, consistently demonstrates the highest recovery force, reaching a maximum of 0.516N at an elongation of 100%. Among all the coils, the highest recovery force was observed at an elongation of 100% with the following values: Type A - 0.192N, Type B - 0.296N, and Type D - 0.14N.

5.2.4.6 Comparison generated forces of zigzags with varying peak heights: Discussion

The narrowest zigzag actuator generates the highest force. This is possibily due to the same characteristic of SMA that was discussed in the 3D and 2D coil comparison. The narrow zigzag is further into its detwinned martensite state and therefore generates a higher force upon recovery to get back to ground shape. Extending the wider zigzags past the 100% elongation threshold might result in such a high generated force.

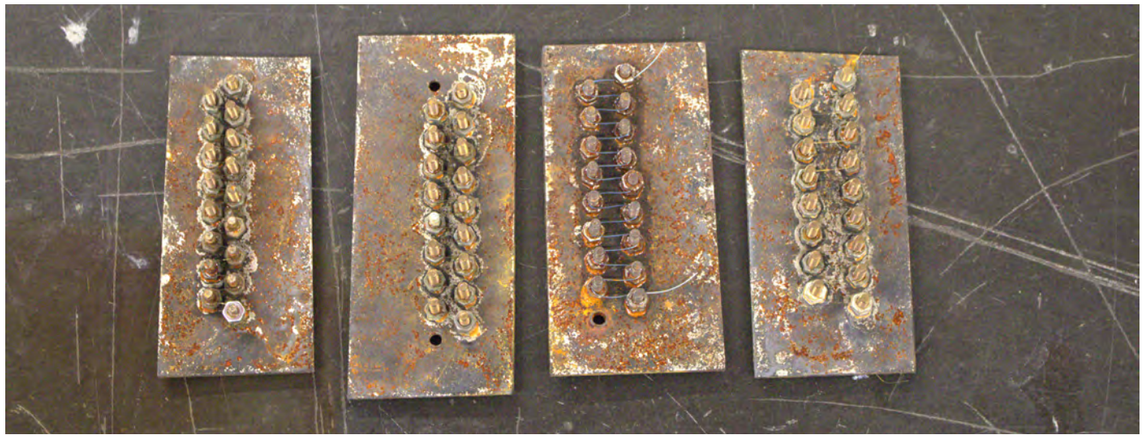


Figure 40: Molds for zigzag coils, Left to right: Type C; Type B; Type A; Type D

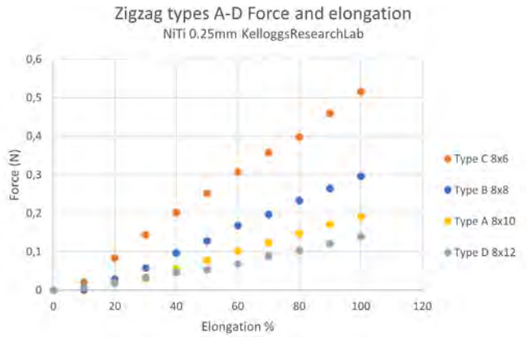


Figure 41: Force and elongation zigzag types

5.2.4.7 Comparison generated forces of zigzags with varying peak heights: Limitations

The elastic behaviour of the SMA was not yet eliminated in these tests, but is is assumed that the relation between the dimension and generated force of the zigzag actuators remains the same also without the elasticity.

5.2.4.8 Comparison generated forces of zigzags with varying peak heights: Conclusion

The results from test show that the zigzag with a smaller peak height generates a larger force upon actuation than zigzags with a larger peak height. This indicates that narrow zigzag actuators are suitable for motions where a high force is necessary. In contrast, narrow zigzag actuators have limitations in the length of their displacement because of their limited wire length. To achieve a large bending radius, it can be advantageous to use an actuator with a larger peak size. Alternatively, multiple narrow zigzag actuators can be placed after each other to increase the total bending radius of the material system such as illustrated in Figure 42.

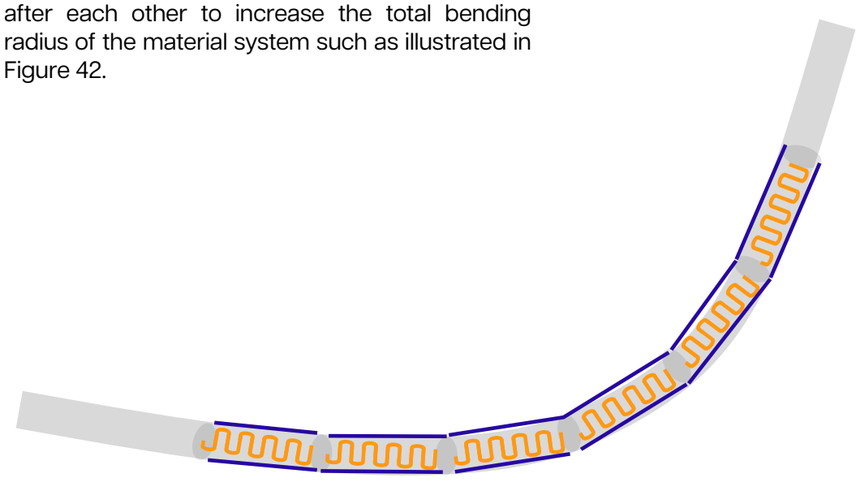


Figure 42: Diagram of multiple actuators achieving a bending angle

5.2.5 Behaviour

Material systems I and II, as described in 5.1.2 Material systems, use the elongation and contraction of actuator coils or the bending and straightening of actuator coils respectively (Figure 43). Thus, the actuators in material systems I and II are differently trained.

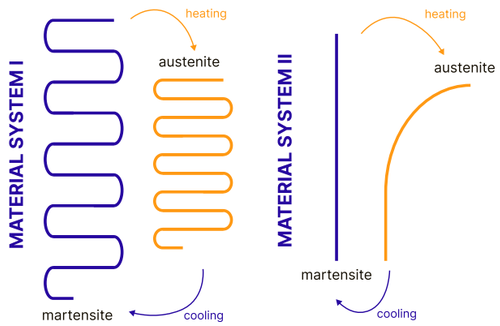


Figure 43: Behaviour of actuators in material systems

5.2.5.1 Prototyping material systems I and II

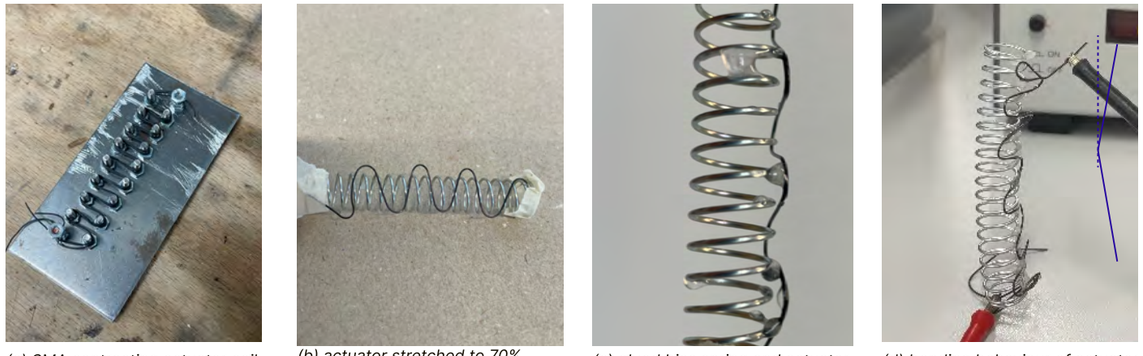
To prototype creating bending with a contracting actuator, a Type A zigzag coil was manufactured. The training conditions are shown in Table 8. These experiments were done before the new SMA material arrived and therefore it uses high-temperature SMA from Flexmet. The prototyping process is shown in Figure 44.

To create bending behaviour with actuators that are trained with bending actuation, a mold needed to be made in which the SMA could be fixed in a bent coil shape. The mold is made by first creating a Type A zigzag coil mold and then bending it 180 degrees. The actuator is trained with the same conditions shown Table 8. In Figure 45 the prototyping process is shown.

TRAINING PARAMETERS

Alloy; diameter (mm); At (°C)	NiTiCu; 0.5; 65-75
Annealing temperature (°C)	550
Annealing time (minutes)	35

Table 8: Training parameters prototyping behaviour



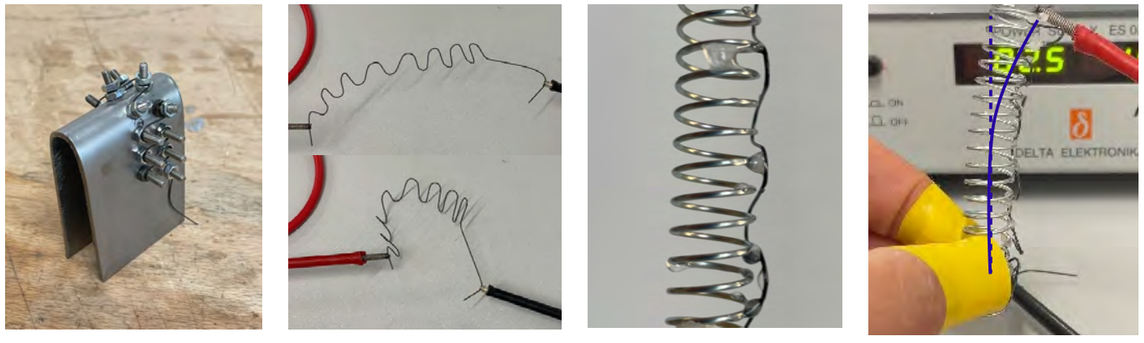
(a) SMA contracting actuator coil mold

(b) actuator stretched to 70% elongation

(c) glued bias spring and actuator coil with non-conductive epoxy

(d) bending behaviour of actuatec system prototype

Figure 44: Process of creating material system I prototype



(a) SMA bending actuator coil mold

(b) non-actuated (top) and actuated (bottom) bending actuator coil

(c) glued bias spring and actuator coil with non-conductive epoxy

(d) bending behaviour of actuated system prototype

Figure 45: Process of creating material system II prototype

5.2.5.2 Behaviour prototyping: Discussion

Both material systems, i.e., the bending actuator and the contracting actuator, can achieve bending behaviour to a certain extent. The bending actuator showed more successful bending performance when using the same bias spring as the contracting actuator, although this result was only observed and not quantifiably recorded.

5.2.5.3 Behaviour prototyping: Limitations

The measure of bending of the material systems was not accurately measured so that it could be compared because this test was more a trial to see whether I could create the bending performance using these types of actuation. It would have been more reliable to have quantifiable measurements. By observation, the material system II showed a larger bending angle.

Glueing the actuators to the bias spring was difficult, as the surface of the bias spring and actuator are both not flat. It helped to tape the actuator first and then apply a generous amount of glue. However, the glueing came loose when at some parts during actuation. This is probably because the glue didn't cure for 24 hours or because of the high heat during actuation of this type of SMA.

5.2.5.4 Behaviour prototyping:Conclusion

From the prototyping it seems that the horizontal displacement of the bias coil requires less force compared to the contraction of the same bias coil, which results in better bending performance for the bending actuator. The bias spring's adjustment to the recovery force of the actuators is crucial for the PMC design.

Commercial availability of custom bias springs is scarce, as indicated through personal communication with PMB staff. To address this, bias springs can be created using superelastic SMA (SEA) (see 3.3.1 Shape Memory Alloy (SMA)). SEA has several advantages, such as a high strain recovery compared to regular steel bias springs. This means that the force required to compress an SEA bias spring can be lower, while still achieving a high strain recovery.

Finally, it is important to understand that SMA actuators lack the ability to finely control the amount of bending, unlike other steerable catheter systems such as hydraulically driven catheters where bending angles can be adjusted by the pressure levels inside the system. SMA actuators can only exist in their distinct martensite or austenite phases and cannot stably maintain intermediate shape changes between the two. This characteristic must be taken into account to ensure effective usage of SMAs in PMC design.

5.2.6 Substrates

Different substrates have been used on actuators in literature such as silicone-based substrates and parylene. In this test, I compare the actuation behaviour of actuators when coated in two different substrates: SMP and non-SMP. This test is done to determine if leveraging the variable stiffness of SMPs offers any advantages compared to non-SMP substrates. Polyurethane-based polymers are used in the medical context, and exhibit repeatable and reliable variable stiffness behaviour (see 3.3.2 Shape Memory Polymer (SMP)). These SMPs have the advantage that they offer variable stiffness at a lower temperature than other SMPs, as their glass transition window starts around 60° C. As a non-SMP, silicone is selected for its wide commercial availability and its use as substrate in previous research documented in literature. The substrates are chosen to have the same shore hardness, A40. The technical datasheets can be found in Appendix 9.

5.2.6.1 Comparing generated force and cycle time of substrate-coated actuators

The generated force of the substrate covered actuators was measured as well as the cycle time. The test was conducted using the Zwick/Roell test set-up. The actuators were both elongated to an arbitrary elongation percentage of 100%. Then, they were actuated for 5 seconds with an amperage of 1A. This was more than enough to reach activation temperature. After 5 seconds, the power supply was turned off (indicated with the black line and word OFF in the graphs) and the actuators were allowed to cool to below 30 degrees. The training conditions of the used SMA coils can be seen in Table 9.
The manufacturing of the substrate-coated actuators can be seen in Figure 46. This process was used to coat the actuators as thinly as possible,

TRAINING PARAMETERS

Alloy; diameter (mm); At (°C)	NiTiCu; 0.5; 65-75
Annealing temperature (°C)	500
Annealing time (minutes)	35

Table 9: Training conditions substrate tests

From the force and cycle time graph (Figure 47), we can observe that there is only a slight difference in the generated force between the PU-coated actuator and the silicone-coated actuator. The maximum generated forces differ by only 0.005N.

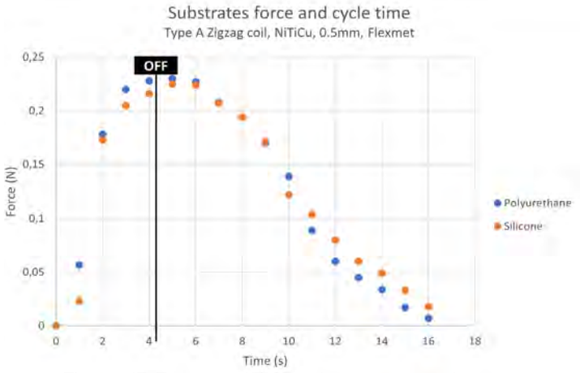
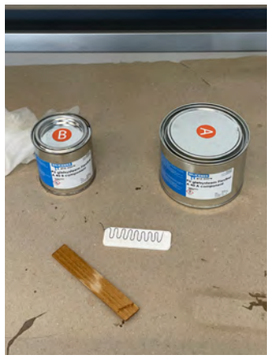


Figure 47: Force and time substrate-coated actuators

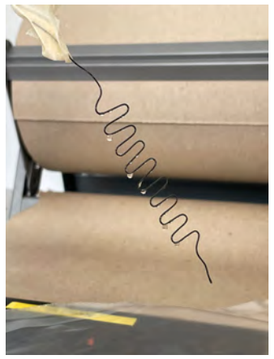
The temperature and cycle time graph in Figure 48 shows that the PU-coated actuator heats up faster, reaching a temperature of +100°C in 5 seconds, whereas the silicone-covered actuator reaches 82.4°C in the same time. The PU-coated actuator shows a steeper cooling curve, leading to a shorter cooling time compared to the silicone-coated actuator.



(a) the components of the substrate are mixed

(b) the mixture is degassed using the vacuum chamber

(c) the substrate is poured over the actuator



(d) the actuator is suspended to let excess substrate drip off

Figure 46: Process of coating the actuators with substrate

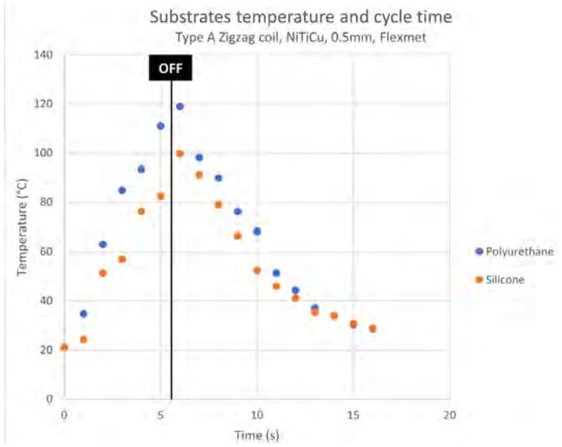


Figure 48: Temperature and time substrate-coated actuators

5.2.6.2 Comparing generated force of bare and substrate-coated actuators

To compare the generated forces of substrate-coated actuators with a bare (uncoated) actuator, three new actuators are manufactured according to the conditions in Table 10 and with the process in Figure 46. The force over elongation is measured from elongation 0 to 100% with increments of 10%.

TRAINING PARAMETERS

Alloy; diameter (mm); At (°C)	NiTi; 0.25; 45
Annealing temperature (°C)	500
Annealing time (minutes)	35

Table 10: Training parameters substrate and bare test

The generated forces over elongation of the substrate-coated actuators and bare actuator are shown in Figure 49.

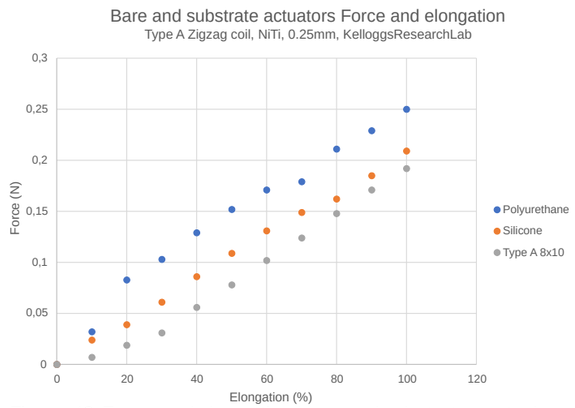


Figure 49: Force and elongation bare and substrate coated actuators

The measurements consistently show that the polyurethane-coated actuator generates the highest force. Specifically, the highest recorded forces are 0.25 N for the PU substrate-coated actuator, 0.209 N for the silicone substrate-coated actuator, and 0.192 N for the bare actuator.
Since the material exhibits superelastic behavior in its martensite state, the spring-like force exerted by the material during the Zwick/Roell test is subtracted from the stress generated during actuation. It's worth noting that the substrate-covered actuators demonstrate a lower spring-like force in their martensite state compared to the bare actuator, as seen in Figure 50.

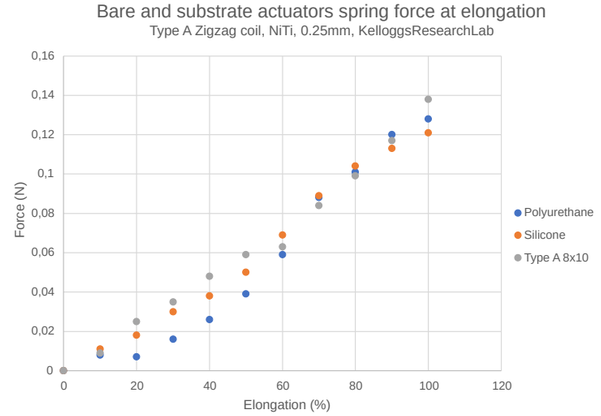


Figure 50: Spring-like force of actuators at elongation

5.2.6.3 Substrate testing: Discussion

The difference in force between the PU and silicone-covered actuators is only about 0.005N. The PU-covered actuator generated more force than the bare actuator, which is unexpected. Looking at Figure 50, it's clear that the difference in spring-like force can't entirely explain the variation in force generation of the actuators. A reason could be that the bare actuator has experienced more cycles, as it was the one I used to determine the activation temperature.

CONTINUED

5.2.6.4 Substrate testing: Limitations

The actuator should be able to extend and contract during actuation and therefore it is important to coat the actuators with a thin layer of substrate. It is unclear whether the actuators are uniformly coated with substrate using this method of coating. Since the substrates polyurethane and silicone are polymers that are not only different in their being a (non)shape memory polymer it is impossible to accredit the better performance of the PU-coated actuator to only the SMP characteristic.

5.2.6.5 Substrate testing: Conclusion

The temperature-dependent variable stiffness characteristic of SMPs is most effective when paired with SMA material whose activation temperature is higher than the SMP's glass transition temperature. However, this poses a challenge when using low-temperature wire to comply with the need to minimize the catheter's surface temperature, as glass transition temperature windows start as low as 60°C. The advantages of the variable stiffness properties should ideally outweigh the thermal risks, or alternatively, the catheter should feature a suitably thick outer tube for actuator insulation. As is described in 5.2.3.5 SMA Material: Conclusion, it would be interesting to test whether the SMP effect of polyurethane, could enable shape freezing of the SMA between its ground shape and its detwinned martensite shape, resulting in a bi-stable SMA actuator This is further discussed in the next prototyping phase.

5.2.7 Conclusions prototyping phase I

SMA Material

The actuation of the low temperature NiTi SMA material takes place within a temperature window, which starts as low as 23°C, with the maximum force generation occurring at temperatures between 34°C to 43°C. This temperature window can be narrowed through the manufacturing process of the SMA and also differs between manufacturers, but this is outside of the scope of this project. It is also important to note that the maximum generated force decreases over multiple cycles due to thermal or mechanical fatigue.
The main insight, considering the present limitations of SMAs, is that they might be best suited for short actuation applications. Prolonged actuation poses potential issues of overheating, unless active temperature sensing and management is implemented in the design, which can be difficult in such a small structure as a PMC.

Actuator shape

The recovery force achievable by both helical and zigzag coils can be comparable, depending on the actuator's length and winding density per length. However, the zigzag coil proves to be more advantageous in this context due to its capability to minimize cross-sectional area. The findings suggest that zigzag coils with smaller peak heights generate greater force compared to those with larger peak heights. This implies that narrow zigzag coils are well-suited for applications requiring higher force generation, while zigzag coils with larger peak heights are preferable when a larger bending radius is necessary.

Behaviour

There is a possible bending behaviour when using contracting actuators. The force needed to contract a bias spring for bending is greater compared to that required for bending a bias spring, therefore the bending actuator performs better in achieving bending of the catheter prototypes. By replacing steel with SEA as the bias spring, the bending behaviour can be improved as less force is required to deform the coil while maintaining the recovery. Another design consideration for incorporating SMA-actuated catheters into the design, is that SMA actuators exhibit two distinct shape states, namely, their austenite and martensite phases. Unlike other systems like hydraulically driven catheters, SMAs lack the ability to stably hold an intermediate position for fine control over bending angles. Thus, the design should take into account these states to ensure effective and reliable control of the catheter's bending behaviour.

Substrates

By using a substrate with a lower glass transition temperature, it is possible to potentially enhance the actuation performance by leveraging the variable stiffness of the polymer. However, it is essential to acknowledge that the experimental results, which showed better actuation performance of the PU-covered actuator compared to the silicone-covered actuator, do not conclusively attribute this performance to the shape memory effect of polyurethane. The concept of using the SMPs shape memory effect for bistability (freezing the ground shape and detwinned martensite shape) is further discussed in 4.3.3 Bistable SMA-SMP Composite (Shape Freezing).

5.3 Prototyping phase II: Material Systems

In this prototyping phase, the material systems bending performance is evaluated and compared on several criteria.
Prototyping phase II results in a recommendation for the most promising material system to be applied to the PMC design. Additionally, a development flowchart illustrates the different design choices (and their associated consequences) that can be made in the process of designing a PMC.

5.3.1 Material systems comparison

Material system I (MS I) depends on the contracting actuation of a stretched SMA coil actuator. Since elongation above 100% will lead to plastic deformation of the actuator, the maximum elongation is 100% and this will be used to achieve the highest possible bending angle for this material system.

Material system II (MS II) depends on the bending actuation of the SMA actuator. To maximize the bending angle of the system, the actuator needs to be trained with the highest possible bending angle, which is a bending angle of 180 degrees.

5.3.1.1 Prototypes of MS I and II

The SMA actuators for this test were made with the following training conditions in Table 10. In the table, the training conditions for the SEA bias spring are shown as well. Note that the actuators have been trained at a temperature of 400° C to eliminate the superelastic behaviour noted earlier.

Prototypes were made according to Figure 51. A flexible PTFE tube functions as the catheter's inner tube. The actuators are fixed to the bias coil using non-conductive epoxy glue. The polymer links, which also function as a base for attaching the bias coil skeleton, clamp the inner PTFE tube in place. The dimensions of the prototype can be found in Table 12.

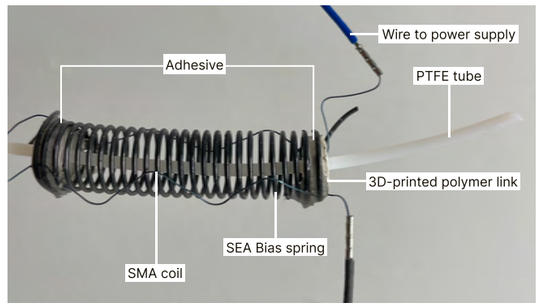


Figure 51: Material system prototype

COMPONENT DIMENSIONS (MM)	
Bias spring: OD; L; p	46; 10; 2
PTFE tube: OD; ID;	2; 1
Polymer link: OD; ID; t	9.7; 1.5; 3

Table 12: Dimensions prototype (OD = outer diameter, L= length, p = pitch, ID = inner diameter, t = thickness)

TRAINING PARAMETERS		
	Alloy; diameter (mm); At (°C)	NiTi; 0.3; 45
	Annealing temperature (°C)	400
	Annealing time (minutes)	45
SEA	Alloy; diameter (mm);	NiTi; 0.8
SEA	Annealing temperature (°C)	550
SEA	Annealing time (minutes)	15

Table 11: Training parameters material systems prototypes

5.3.1.2 Test set-up

The test-setup to monitor the bending of the prototypes is shown in Figure 52. The bending displacement measurement of both material systems is conducted using a grid paper, where each light grey square represents 1mm, and each block represents 5mm. The material systems are secured at one end and left free at the other to be able to measure the displacement during actuation. A power supply is used to actuate the material system with 1A until the activation temperature of 45°C is reached. With the infrared camera, the temperature of the system is monitored so there is no excessive temperature overshoot which might damage the actuators.

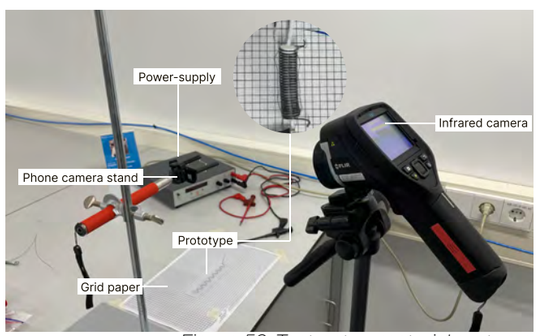


Figure 52: Test-setup material systems

5.3.1.3 Bending performance MS I and II

The actuation performance for both material systems with bare actuators are shown in Figure 53. The left side actuation for both material systems shows no visible displacement for MS I and approximately 2mm for MS II. The right side actuation shows 2mm displacement for MS I and 4mm displacement for MS II.
The cycle speeds for the material system are the heating time until reaching maximum actuation and the cooling time needed to restore the system to its initial position. Please note that the heating response time is dependent on the amperage of the power supply and the resistance of the actuator, which is influenced by its alloy composition, thickness and length.
The cycle speed for MS I is: 2 seconds heating, 10 seconds cooling. For MS II, the cycle speed is: 3 seconds heating, 7 seconds cooling.

5.3.1.4 MS I and II: Discussion

MS II has a higher displacement on both actuation sides with 2mm on left side actuation and 4mm on right side actuation. Therefore, the actuation of the bending actuator results in a better bending performance for the PMC prototype.
MS I exhibits a faster heating reaction than MS II II, with respective heating times of 2 seconds and 3 seconds. The cooling time of MS II is shorter than that of MS I, with respective cooling times of 7 and 10 seconds.
The thermal reaction of the actuators can be optimized through the design of the actuators, taking into account the alloy composition, thickness and absolute length of the wire that is used e.g. the length of the electrical circuit. Minimizing actuator dimensions leads to faster response times as the thermal capacity of the actuator is decreased.

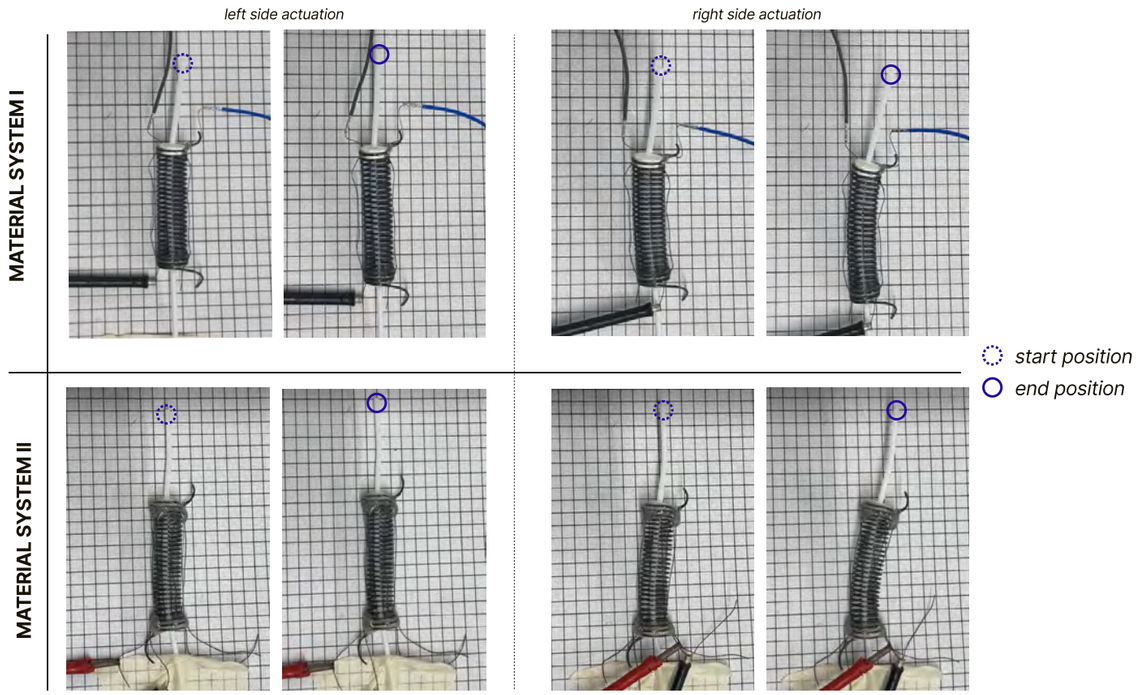


Figure 53: MSI and II bending test performance

5.3.1.5 MS I and II: Limitations

I conducted this test as well with prototypes of the material systems with substrate covered actuators. These tests did not result in any displacement so I did not include them in the results. In the prototypes with bare actuators, there was very little displacement when actuating the left side of the prototype. A reason could be that the stiffness of the PTFE tube and polymer link hinders actuation because of the bias to the right side which is visible in Figure 53 for both prototypes. Another consideration is to make sure to prevent shorts in the electrical circuit. Because both the SMA and SEA of the bias spring are conductive, care should be taken to isolate both.

5.3.2 Bistability (Shape Freezing)

During prototyping phase I, the concept of shape freezing was discussed, which is also known as bistability. Bistability refers to the ability of a shape memory material or composite (SMC) to have two distinct shape states that don't need continuous energy input to maintain their forms. (50). Because the shape memory effects of SMA and SMP are both temperature dependent, they make for a suitable SMC. The working principle of bistability is illustrated in Figure 54.

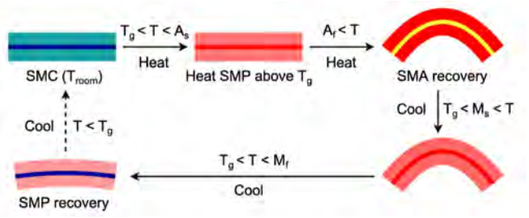


Figure 54: Bistability with shape memory composite (Rajagopalan, 2022).

A bistable SMC requires the starting actuation temperature (As) of the SMA to be higher than the glass transition temperature (Tg) of the SMP. This means that bistability can only be achieved using higher temperature SMA, as the Tg of polymers can only be as low as 60°C.
Bistability is only possible with bending actuation because in compressing actuation, the thickness of the SMP prevents complete compression back to ground shape. I did a short experiment to illustrate this. Because of time contstraints in this project I could not elaborate on this further. Nonetheless, it is included in the assessment in the next section, because it could potentially have benefits for PMC design. The stiffness and continuous actuation increases risks like overheating and vessel perforation in the context of the PMC and bistability might be a solution to these problems.

5.3.2.1 Bistability experiment

Two high temperature SMA actuators were embedded in polyurethane, one being a contracting and the other a bending actuator. Both were actuated to their activation temperature around 70 degrees and cooled down to room temperature. The results are shown in Figure 55.

The results show that the contracting actuator moves sideways due to the space between the zigzags that is now filled with substrate. Upon cooling, the sideways displacement is still slightly present. The bending actuator shows bending upon actuation and stays in the bent shape slightly when cooled to room temperature.
Although this test has its limitations, it is used to demonstrate why bistability in an SMA and SMP composite is unsuitable with contracting actuators. Bending actuators are still able to perform bending in the SMC. For application in a PMC design, further testing is necessary on bistability in an SMA-SMP composite.

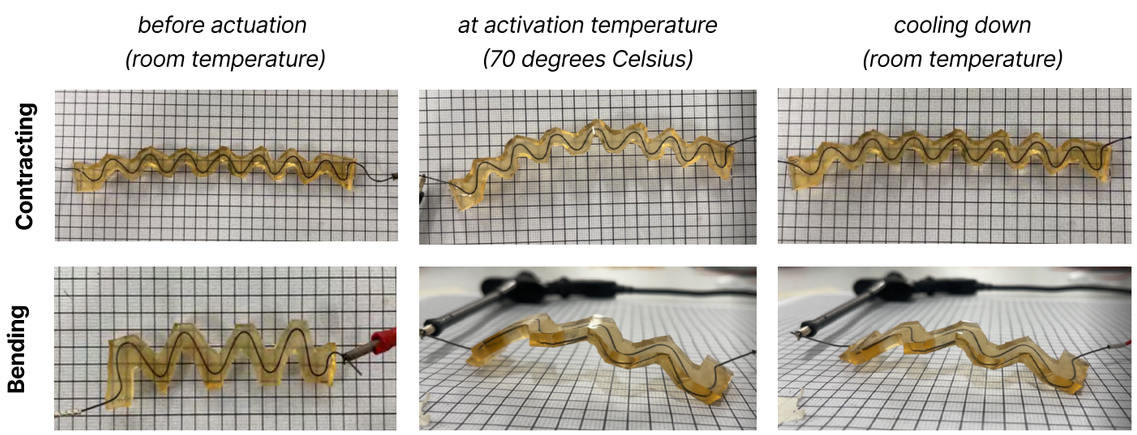


Figure 55: Bistability with SMA-SMP composite experiment

5.3.3 Material systems: Assessment

Property morphing ability

Bending: The prototype of MS II showed a higher displacement in both the left and right side actuation with a respective displacement of 2 and 4mm. To achieve a larger bending angle with MS I, several actuators can be used in a row, which could limit how much the length of the design can be minimized.

Cycle speed: The cycle speed is divided in the heating response and cooling time of the systems. MS I showed a faster heating response compared to MS II with respective times of 2 and 3 seconds. The cooling time of MS II was faster than MS I with respective times of 7 and 10 seconds.

Bistability: The ability to create an SMC with SMA and SMP, enabling shape bistability, is only possible for MS II. Because MS I requires compression, there needs to be free space between the coil peaks between which the actuator can move freely. Aiming for bistability in any system will impede bending performance of the PMC as the thickness of the substrate should exceed the thickness of the SMA (51).

Multifunctionality of the actuator joint: MS I offers the possibility of having a multifunctional actuation joint, where variable stiffness and bending behaviour are integrated. MS II does not have this option.

Manufacturability

Ease of manufacturing: MS I is easier to manufacture as the mold is 2D. This is more space efficient ass well as eliminates a step in the manufacturing process where for a 3D mold, the material needs to be bent before or after cutting. The manufacturing process is discussed further in 7.1 Manufacturing technologies for micro SMA actuators.

The assessment results in the Harris profile in Figure 56. Though both material system designs can lead to a PMC, the assessment recommends MS II as the most effective for implementation in the design of the PMC.

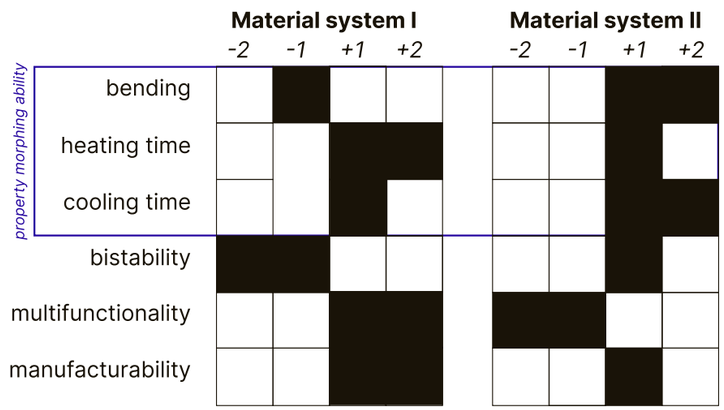
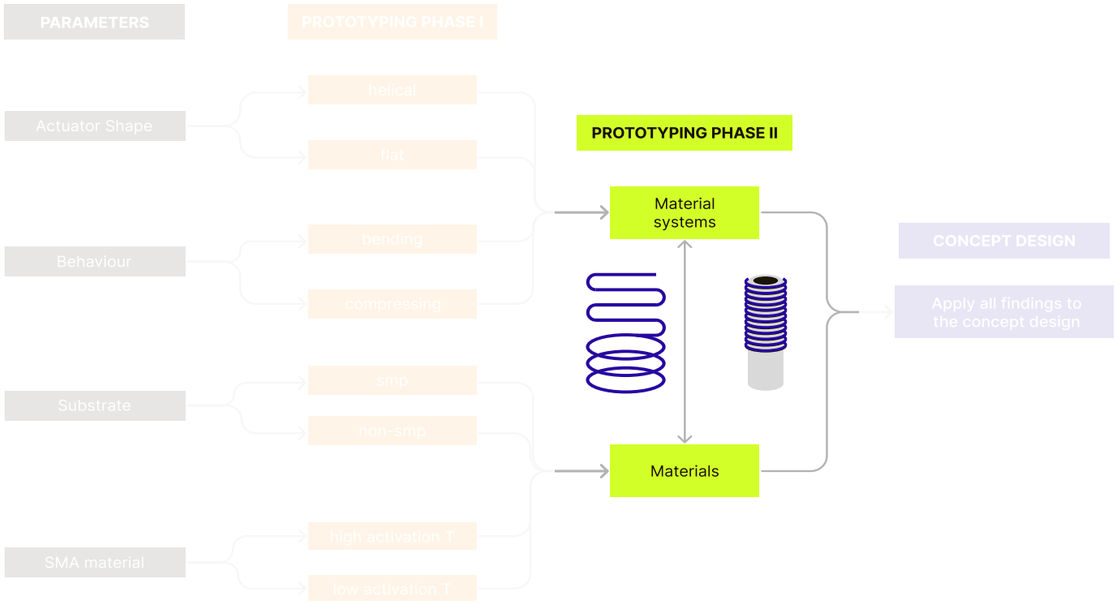


Figure 56: Harris profile assessment material systems

5.3.4 Conclusion prototyping phase II: PMC development flowchart

In the process of research and development of the SMA-driven PMC, I explored many of the different decisions and their associated consequences in the design. To show this process, I visualised a flowchart that is shown on the next page (Figure 57). The flowchart shows the component options and the resulting implications of these choices. This flowchart can serve as a reference for fellow designers in this subject, offering a concise overview of the available alternatives, in as far as I have researched them in this project.

Concluding on prototyping phase II, the concept design will continue with material system II, bending actuators.



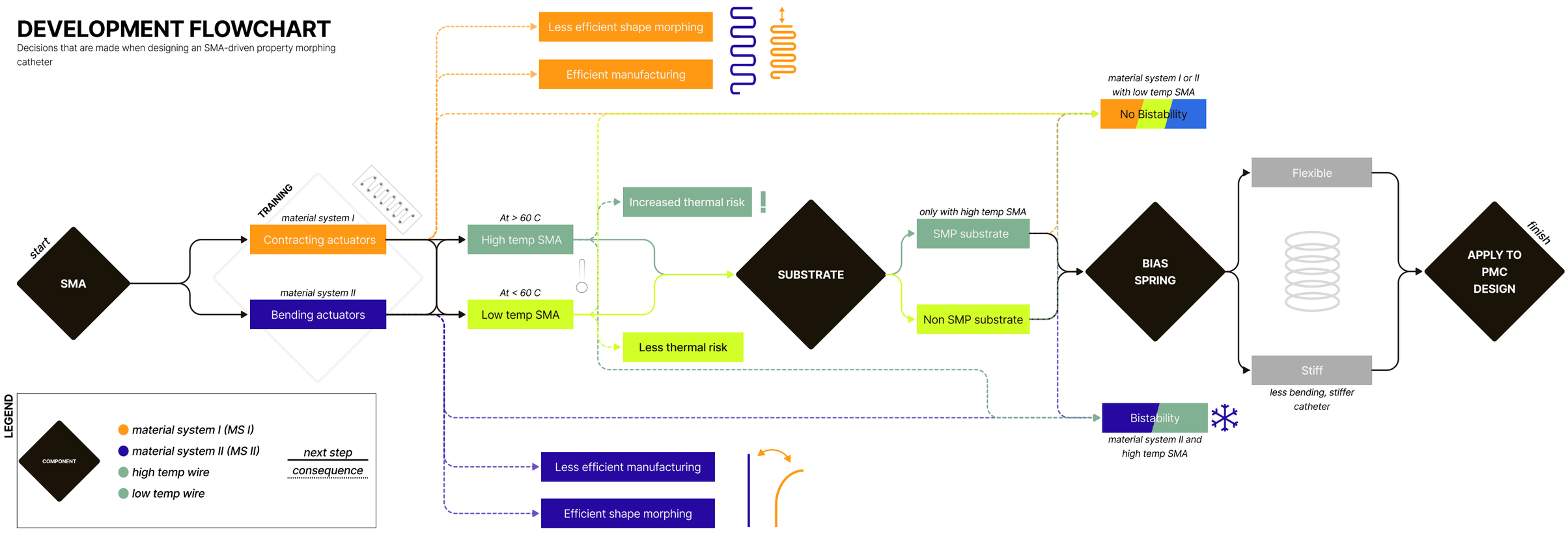


Figure 57: PMC Development Flowchart

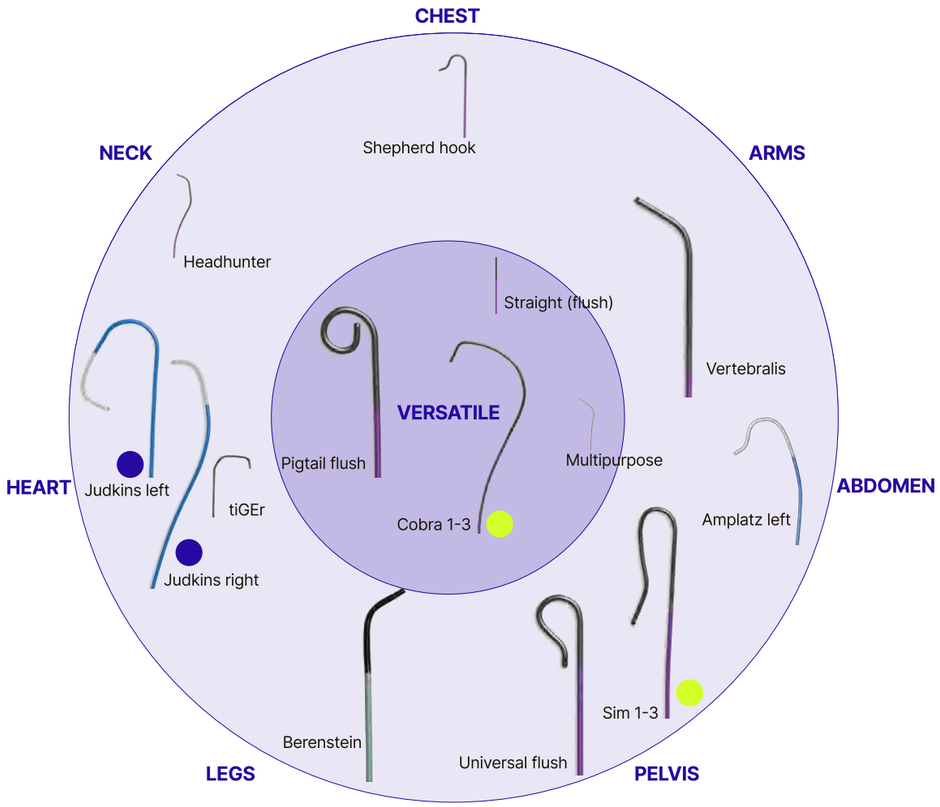
6. Design Embodiment

A fitting application for integrating SMA actuators into a property morphing catheter is put forth as well as a concept design for an SMA-driven PMC. A prototype of the proposed system is presented to showcase its property morphing behaviour.

6.1 Application in the use context

Because of the absence of intermediate phases between martensite and austenite in SMA actuation, the suitability of SMA actuators lies in transitioning between two distinct shapes. In the field of interventional radiology, there is a wide variety of catheter types available, and the selection of a specific catheter depends on factors such as the interventionalist's preference and the patient's anatomy.
I collaborated with van der Reijden to map various catheter types according to the corresponding regions of the body where they are utilized. The catheters are further categorized based on their frequency of use by the interventionalists. This aspect is individual and can vary from one interventionalist to another.

The mapping helps to identify compatible pairs of catheters which can be an opportunity for the design of a PMC. Figure 58 shows a catheter map, where the size of each catheter image corresponds to its frequency of use. Larger catheter images represent frequently used catheters, while smaller ones indicate less frequent usage.
Two promising catheter duo's are marked, which are the Cobra and Sim catheter (van der Reijden, personal communication) and the Judkins left and right catheters (Herzzentrum Köln, personal communication).
Side-note: since flush catheters have (multiple) side-holes, they are not suitable for duo's with non-flush catheters.



Size indicates frequency of use

Figure 58: Catheters mapped to their functional area and frequency of use

While statistics regarding catheterization procedures in the Netherlands is unavailable, in the United States, cardiac catheterization is one of the most frequently performed cardiac procedures, with over 1,000,000 procedures conducted annually. The trend towards minimum invasive surgery has been increasing, accounting for approximately 18% of procedures conducted in major operating rooms as of 2018 (52).

The Judkins left and right catheters are often used in combination when performing a diagnostic cardiac procedure where the interventionalist needs to enter the right and left coronary artery. Additionally, the curves of the Judkins right and left catheters are forgiving, as the primary curve remains curved in the same direction and the secondary curves are less demanding than for the Cobra to Sim duo, providing a feasible application of the SMA in a PMC design (Figures 59 and 60).
The concept design applies material system II to arrive at a property morphing catheter that switches from the Judkins right- to the Judkins left catheter.

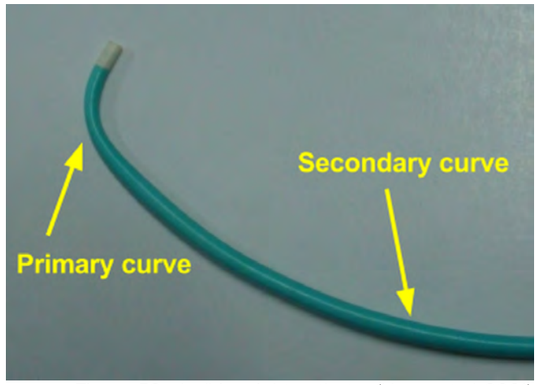


Figure 59: Judkins right catheter (Kwon et al. 2021).

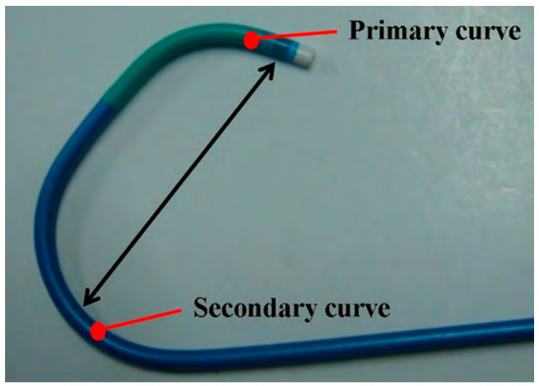


Figure 60: Judkins left catheter (Francis et al., 2016).

6.2 Property Morphing Catheter Concept Design

In the schematic in Figure 61, the concept design of the property morphing catheter is explained.
The catheter has a bending section using the working principles of material system II to achieve shape changing between the Judkins right and Judkins left catheter.
The actuator section at the tip consists of a helical actuator around the catheter shaft that stiffens upon actuation, resulting in a variable stiffness tip, which helps vessel engagement and passing occlusions, as described in 3.1.2 Catheter use.
The exploded view of the design explains the construction of the PMC with all components separated for clarity (Figure 62).

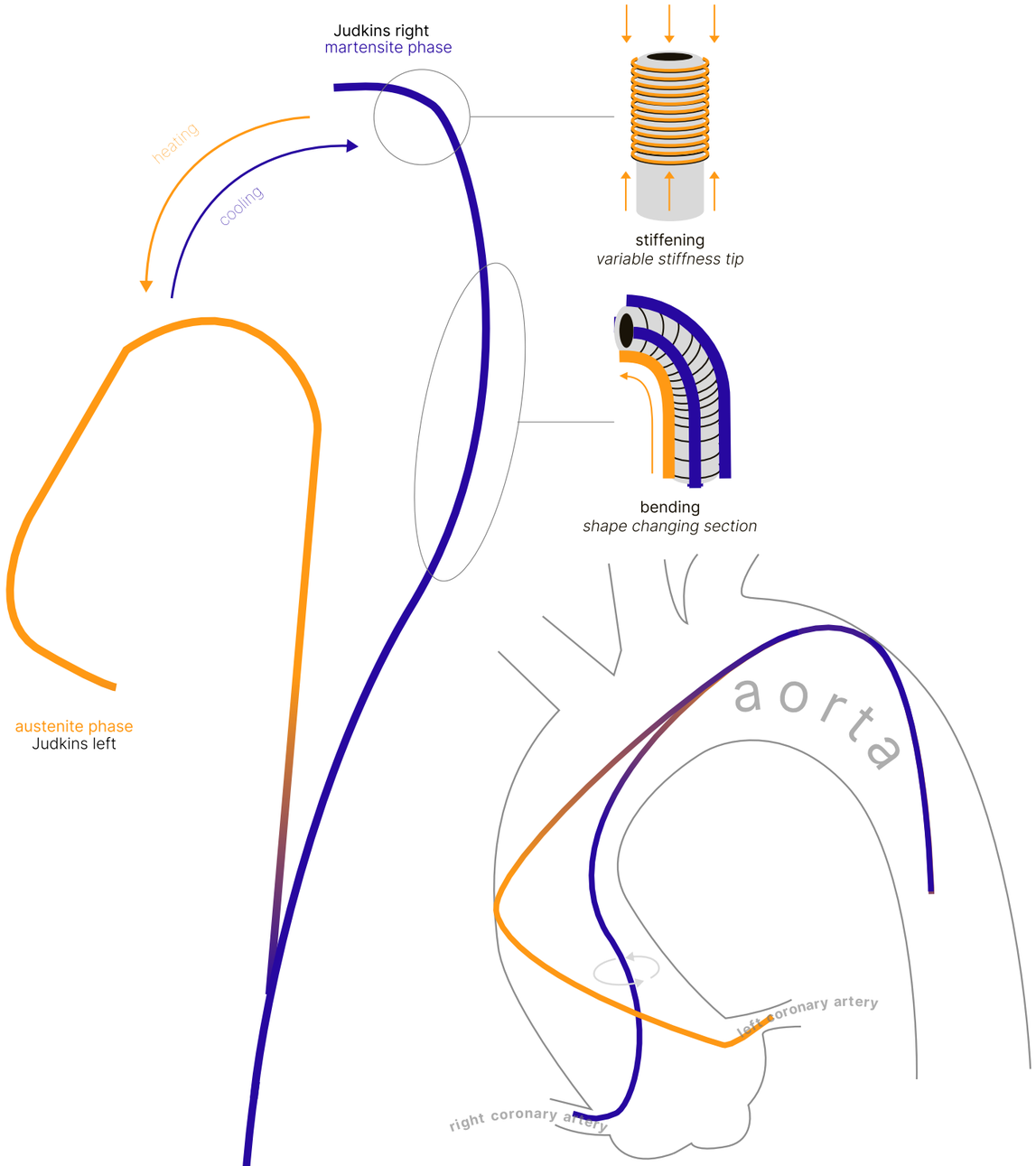


Figure 61: Design diagram of the PMC design

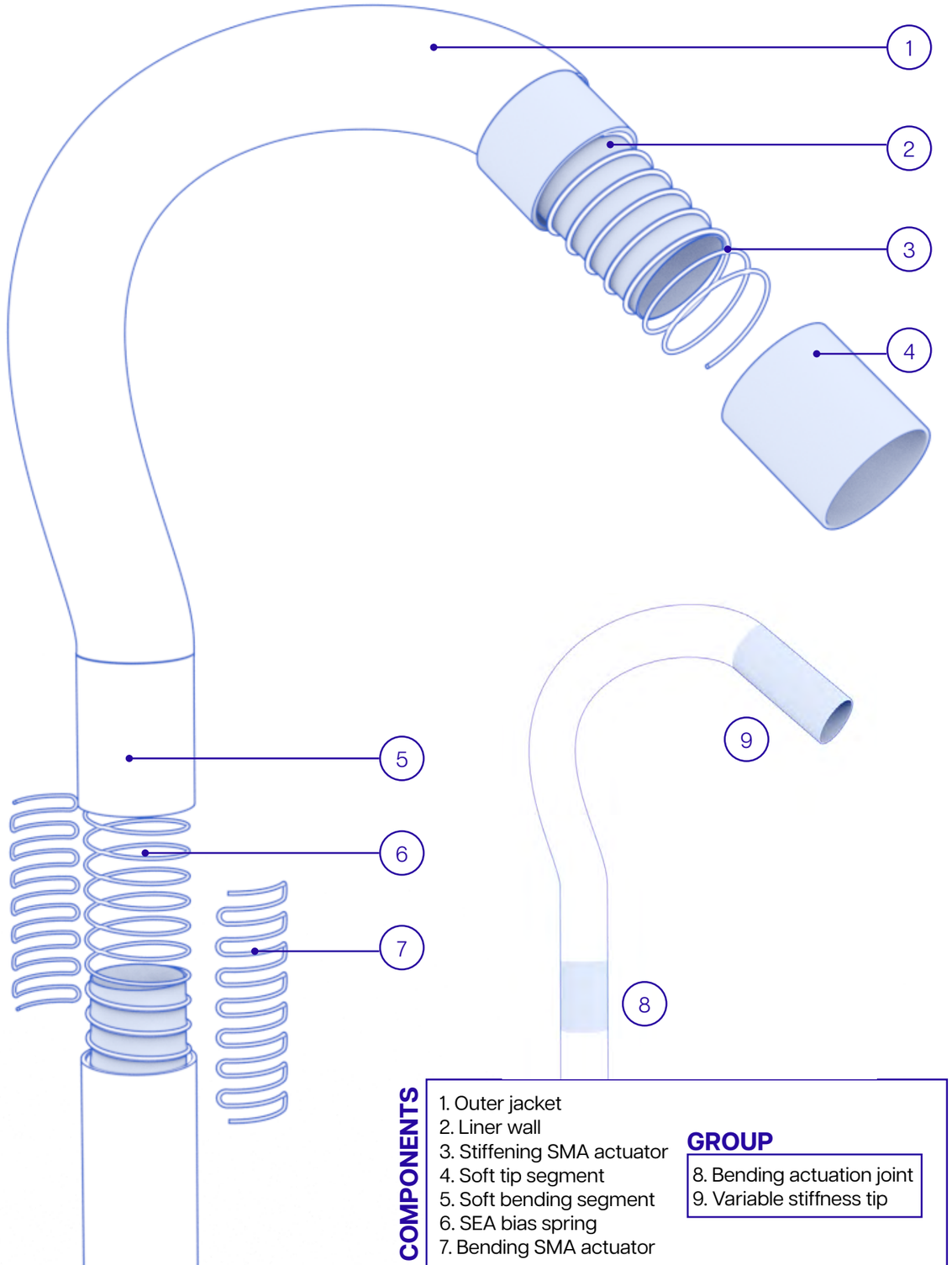


Figure 62: Exploded view of the PMC concept design

6.3 Demonstrator Prototype

A demonstrator prototype was made to show to property morphing ability of an SMA-driven PMC concept in the use context. The demonstrator prototype is not based on the material systems discussed earlier in the project and solely serves as a visual representation of the shape morphing ability of the material.
The demonstration prototype (Figure 63) uses an SMA wire that whose ground shape is the shape of the Judkins left catheter, and placed inside a PTFE tube shaped as the Judkins right catheter.

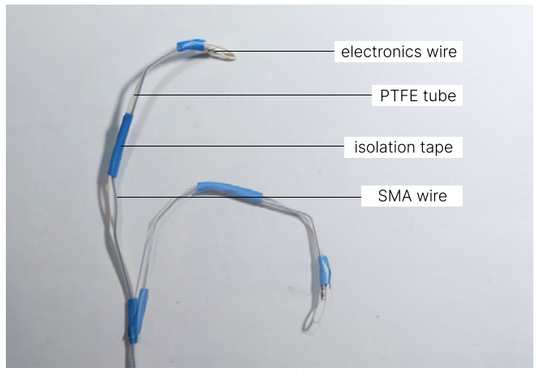


Figure 63: Demonstrator prototype

The demonstration environment is a 3D-printed model of the aortic arch with the right and left coronary artery (Figure 64). The model was printed on the Connex printer at the Digital Fabrication Lab of IDE.
The video for the demonstration prototype can be seen by scanning the QR-code or following this link.

QR code for demo video

Figure 64: 3D-Printed aortic arch model

7. Future Research

In this section I outline some of the future research directions concerning the development of the actuators for an SMA-driven property morphing catheter, including manufacturing technologies for micro SMA actuators and alternative bending actuator designs. Lastly, I briefly discuss other promising material directions regarding PMC design and development.

7.1 Manufacturing technologies for micro SMA actuators

The miniaturization of SMA actuators enables the creation of actuators that require very little space and thermal actuation, while exhibiting a high actuation output. SMAs are considered being materials that are difficult to machine (DTM materials) because of their substantial hardening and high strength. Therefore, advanced machining processes need to be used to reduce any negative effects such as deterioration of the material surface quality and extreme tool wear (53).

A selection of advanced machining techniques that have emerged for SMA machining are electric discharge machining, electrochemical etching and laser machining (Figure 65) for cutting actuators from tubes and sheets. Among these techniques, electrochemical etching is the least impactful on material properties because it machines SMAs without heat effects which can otherwise affect SMA quality (54). The electrochemical etching process can etch conductive metal surfaces which are put under a mild current, with help of electrolytic fluids. In contrast, prolonged exposure to high temperatures, as seen in electric discharge machining and laser machining, can result in the formation of a Heat-Affected Zone (HAZ), altering the chemical composition of SMAs (55).

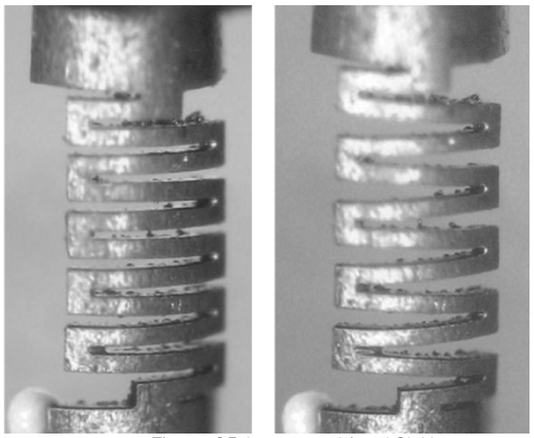


Figure 65: Lasermachined SMA actuators (Tung et al. 2008)

7.2 Bending actuator designs

In this project, the design of SMA actuators has exclusively focused on zigzag-shaped actuators, as they can be easily formed using SMA wire. I conducted a shape exploration within the 2D design realm (Figure 66) to generate alternative actuator designs which could be formed using advanced manufacturing techniques.

The key constraints for this shape exploration were ensuring the possibility of lengthwise extension, symmetry for predictable deformation and limiting the width. In future research, it would be interesting to evaluate the bending performance of different actuator designs.

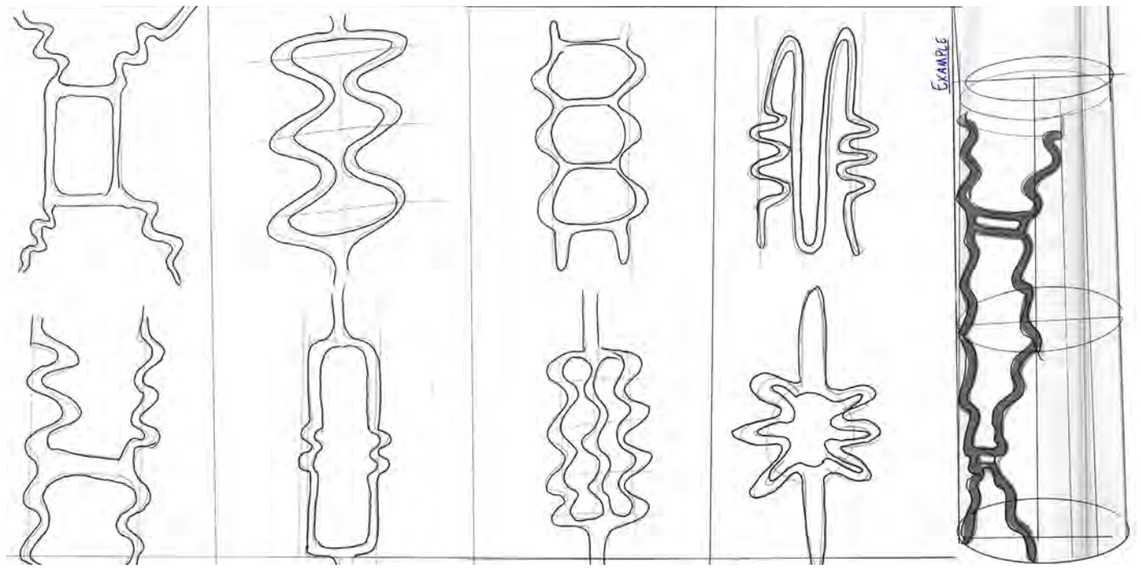


Figure 66: SMA actuator shape exploration

7.3 Other promising material directions

As described in the literature review, material-based catheter developments are extensive. One material direction that is very promising for catheter developments are soft robotics materials, including soft magnetic materials and hydrogels.

Catheters that can be steered magnetically offer a significant safety advantage over other catheter technologies because they don't require heat generation inside the body. However, a major obstacle to their widespread adoption is the substantial financial and spatial investment needed for the external magnets, which are used to manipulate the catheter's magnetic field. Moreover, adjusting the external magnetic field is a time-consuming process, as it requires precise movements of these external magnets.

Currently, magnetic-based technology for steering catheters is the primary method employed in clinical settings. The trend towards technological minimization holds promise for improving the cost-efficiency and space utilization of magnetic catheter systems. Additionally, the emergence of soft magnetic materials, such as magnetic liquid encapsulated in a soft polymer (Figure 67), can help minimize the issues associated with permanent magnets and eliminate the need for wiring and powering of electromagnets in magnetic catheter tips.

Because of their softness and temperature activation close to body temperature, hydrogels pose a promising direction for the development of PMCs. Hydrogels are actively being researched in the field of artificial muscle development, where bending motion is a fundamental application (56). Another promising direction for hydrogel-based PMCs lies in variable stiffness. This potential stems from the fact that hydrogels contract above their activation temperature, and swell under the temperature, which opens up the possibility of engineering structures that can either become stiffer or more flexible. It is essential to research further the activation and deactivation processes of hydrogels, also in liquids mimicking the chemical composition of blood.

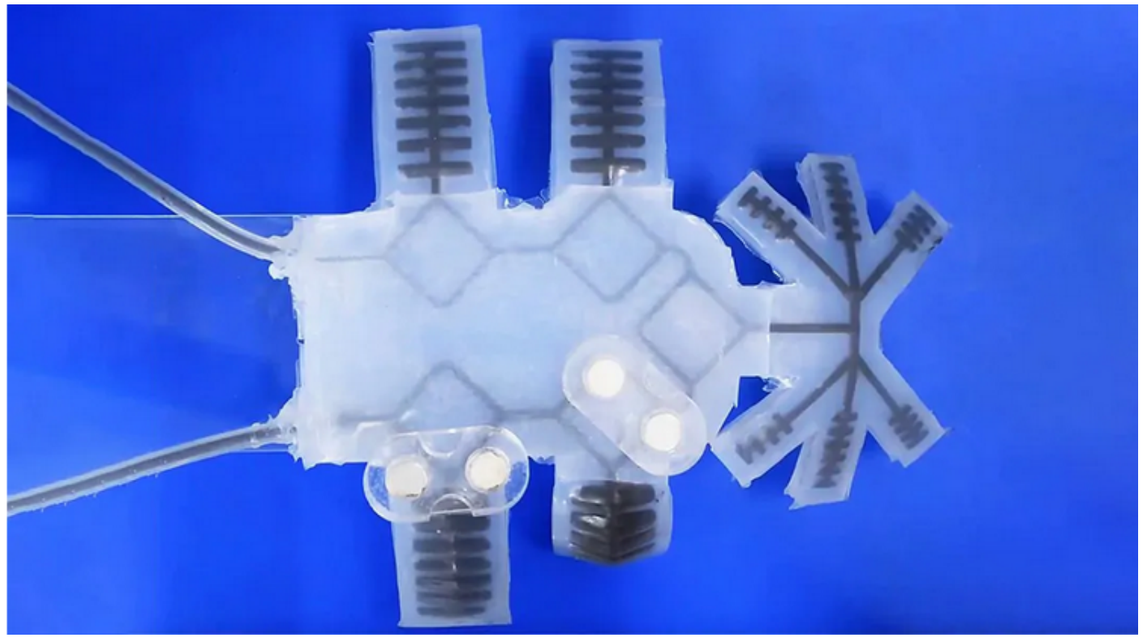


Figure 67: Magnetic liquid encapsulated in silicon (McDonald et al., 2020).

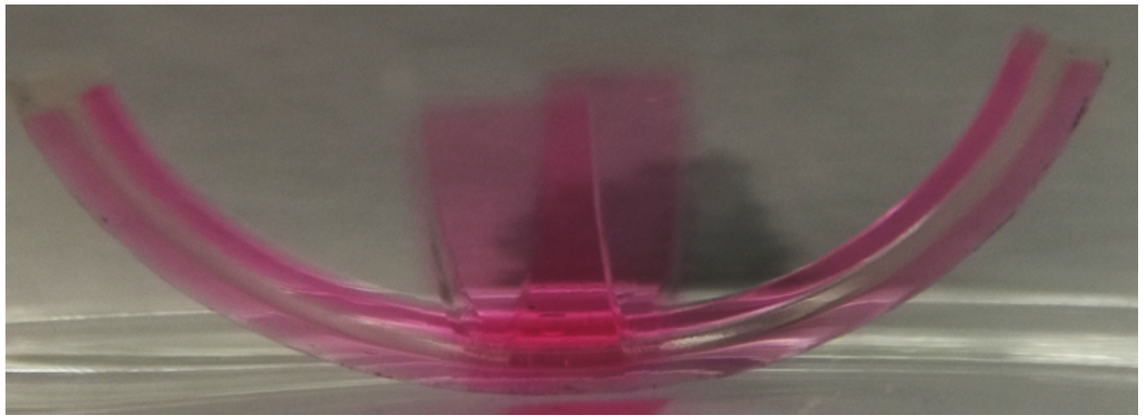


Figure 68: Artificial hydrogel muscle that bends (Ding, 2021)

8. Evaluation

This section mentions issues and potential optimization opportunities for the current design. The evaluation concludes on the initial project brief and what has been accomplished.

8.1 Discussion

The goal of this thesis was to explore the landscape of material-based property morphing catheters and propose a concept design that is able to have varying shape and stiffness properties.

Prototyping with SMAs is a complex process as the material is sensitive to temperature curves used in the training process. The training process in the ceramic oven requires manual attention, as the SMA needs to be removed from the oven in time If I wasn't close to the ceramic oven when the timer went off, some samples spent longer inside. Furthermore, opening and closing the ceramic oven results in a significant temperature drop, sometimes from 500 to 420°C, based on how long the door was open (longer if I had multiple actuators inside). This variability in thermal exposure means that SMAs produced with the same training parameters might show slightly different actuation behaviour.
In addition to these factors, making SMA actuators is a time-intensive process. Each test requires new actuators to ensure that any potential fatigue from previous tests isn't influencing the results, which makes each test time-consuming. This also makes an iterative approach to developing SMA actuators slow, such as finding a balance between the force generated by the actuators and the stiffness of the SEA bias coils. This is especially the case when custom molds are needed to produce the actuators.

The introduction of more automated forming techniques such as discussed in 7.1 Manufacturing technologies for micro SMA actuators, would speed up the iterative process drastically with the trade-off of resulting in higher cost.
Regarding SMA composition TiNiCu can be preferable over TiNi in the use context because of its higher flexibility at low temperatures and large force generation above the phase transformation temperature (57).

The concept of bistability is briefly discussed in this thesis and presents interesting directions for SMA actuators, as implementing it successfully would lead to stable two-way actuation which is currently a limitation in SMAs. Due to the time constraints of the thesis, the exploration was limited and it is therefore recommended that the research on this topic be continued.
Many of the insights in this project were based on a structured trial-and-error. More in-depth research can be done, zooming in on material qualities and how they affect the performance of the material systems for SMA, as well as the optimization of the training for the specific application of the actuators.

Future development must address the safety issues of overheating and electrical leakage, increasing the reliability and predictability of the actuation behaviour of the SMA and the mechanical design of the PMC.
This thesis has resulted in an overview of the possibilities of using SMA for developing a property morphing catheter. I anticipate that future developments in the material science of SMA and miniaturization of technology will yield promising results.

8.2 Conclusion

The initial aim of the project, as described in the project brief, was to design a concept of a (smart)-material driven property morphing catheter. To achieve this goal, first, a comprehensive review of the current landscape of property morphing catheter developments was done. This review included the literature review, where all or most of the material-driven catheter developments in the recent years have been mapped. Also, an analysis of the current state of the art of conventional endovascular catheters was performed including methods like field research and communicating with experts. As a result, a compilation of design requirements was generated that can be consulted by fellow designers aiming to continue in this subject.

SMA, the chosen material to continue with for this project, was thoroughly experimented with and several bending and contracting prototypes were created to understand and evaluate the different material systems available to achieve a property morphing catheter. All the different choices and their consequences in the development of a property morphing catheter were mapped in a development flowchart which also serves as a resource for others. Finally, the learnings were applied to the use context and a concept design was presented for the SMA-driven property morphing catheter.

It is important to note that there isn't a single definitive material direction that can be identified as the most promising for the development of such a catheter. Instead, this project has revealed other potential routes for further investigation. Therefore, future research can be directed towards any of the material directions outlined in this thesis. This thesis can serve as a starting point for other designers and researchers looking to continue research into the possibilities of material-based PMCs and the further advancement of application of SMA actuators in catheter design.

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Appendix

A0. Project brief
A1. Stakeholder analysis
A2. Product journey
A3. Pebax material data
A4. Literature benchmark for material-driven PMC developments
A5. MDR Classification and requirements
A6. Hydrogel synthesis
A7. Design parameters
A8. Fishtrap model
A9. Substrate technical material data

A0. Project Brief

TU Delft

Personal Project Brief - IDE Master Graduation

Design of a catheter with variable shape and properties — project title

Please state the title of your graduation project (above) and the start date and end date (below). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

start date 06 - 04 - 2023 — 25 - 09 - 2023 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

Shape memory materials (SMMs) are materials that respond to particular stimuli by means of transforming their physical and/or chemical properties. These stimuli include heat, electricity, magnetism, moisture and light. The shape memory materials can switch between a temporary shape and their designed shape when the stimulus is applied [1].

Shape memory materials include shape memory ceramics, shape memory alloys (SMAs) and shape memory polymers (SMPs). Multiple shape morphing catheter concepts have arisen using SMAs, SMPs and electroactive polymers (EAPs) but none are commercially available as of yet [2].

In medical applications such as medical endovascular catheters, adaptable and morphing devices capable of changing shape and properties such as stiffness become important. These devices allow for safer therapeutic and diagnostic procedures by reducing time to reach target vessels and organs, trauma to the vessel wall and physical stress on the body while increasing the accuracy, benefits and positive outcomes. A catheter with these properties will also reduce X-ray exposure during procedures, recovery time and could save lives in the acute setting.
Conventionally, endovascular catheters are steered by the interventionalist with a push-pull motion along the shaft and by rotation around the shaft axis. The interaction and feedback between the interventionalist and the catheter is of paramount importance as with accurate feedback, the interventionalist can manipulate the catheter with confidence, minimizing complications and maximizing therapeutic success.

There are limitations that need to be addressed for the application of SMMs. These limitations include the SMMs sensitivity to environmental conditions and the way the shape recovery properties are affected by this. Also safety in the use of these materials and their stimuli should be taken into account [2]. Additionally, SMM sterilization needs to be further investigated for implementation in the biomedical context as traditional methods such as autoclaving or plasma sterilization are detrimental to the mechanical properties and shape memory effects of SMMs [3].

In the Emerging Materials Lab at the Industrial Design Engineering faculty of TU Delft, objects are designed with shape memory materials. In this project we will explore the opportunities of designing such a shape and property changing catheter in collaboration with an interventional radiologist of the Máxima Medical Center in Veldhoven.

[1] Sun et al. (2011). Stimulus-responsive shape memory materials: A review. https://doi.org/10.1016/j.matdes.2011.04.065
[2] Hu, et al. (2018). "Steerable catheters for minimally invasive surgery: a review and future directions." DOI: 10.1080/24699322.2018.1526972
[3] Pineda-Castillo et al. (2022). Shape Memory Polymer-Based Endovascular Devices: Design Criteria and Future Perspective. https://doi.org/10.3390/polym14132526

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Initials & Name F D Sreeram 6487 Student number 4564499

Title of Project Design of a catheter with variable shape and properties

introduction (continued): space for images

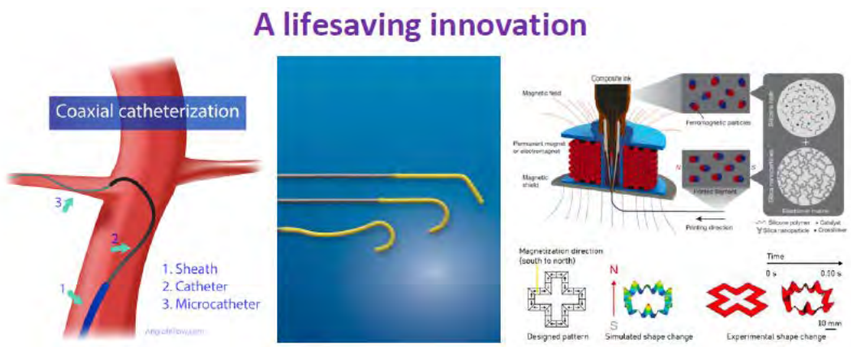


image / figure 1: Catheter diagram from original project brief (Ghodrat, van der Reijden, 2023).

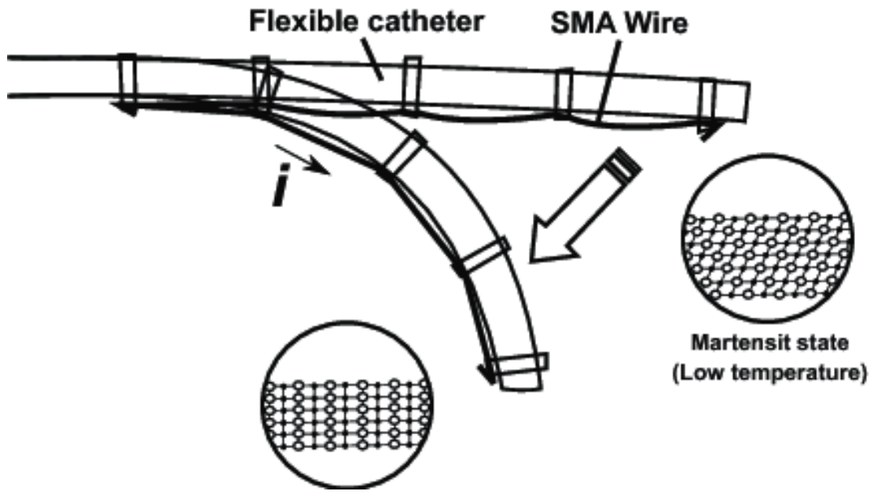


image / figure 2: Bending of a catheter using the shape memory effect of a SMA wire (Szewczyk, 2010).

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The manoeuvrability of a catheter decides whether the target area can be reached and hence affects the success rate of a procedure to a great extent [4]. Conventional endovascular catheters are available in many different preformed shapes, sizes and stiffnesses and are selected by the interventionalist based on the anatomical needs. During complex procedures, the interventionalist might have to exchange catheters multiple times to accommodate to the specific needs for navigating to the target site. Every catheter exchange can cause complications and further increases procedure time, thereby increasing patient trauma. There is a clinical need for smart catheters that require less frequent exchange to different catheters, allowing more complex tip shapes and motions in terms of steering [5].

The field of smart catheters has advanced greatly in the past decade. However, the developments show a gap between what is required and the current state of smart catheters. Also, there is no clear systemic approach that specifies design goals or functional requirements and constraints in the case of smart catheter development [2].

This graduation project aims to design a concept with emerging/smart materials that furthers the development towards a property morphing smart catheter and provide a guideline on this subject for future designers.

[2] Hu, et al. (2018). "Steerable catheters for minimally invasive surgery: a review and future directions." DOI: 10.1080/24699322.2018.1526972
[4] Fu, et al. (2009). "Steerable catheters in minimally invasive vascular surgery." DOI: 10.1002/rcs.282
[5] Ali et al. (2019). "Catheter steering in interventional cardiology: Mechanical analysis and novel solution." DOI 10.1177/0954411919877709

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

To design a proof of concept of a property morphing smart catheter based on smart materials. A prototype will be used to demonstrate the property morphing abilities of the concept in an in-vitro environment. A comprehensive review will be performed on the development of a smart catheter including requirements and material research.

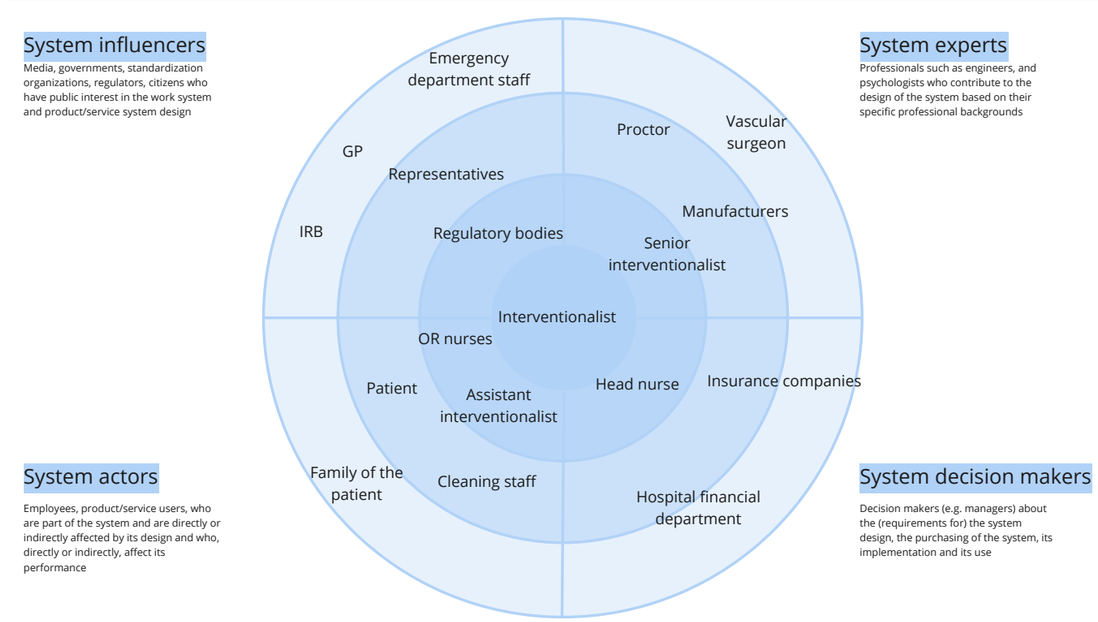
The assignment can be subdivided into the following goals: a. Synthesize requirements for the development of a smart catheter through research and interviews with experts in the medical and material science field.
b. Map the opportunities and limitations in the current state of the art of smart material catheters to provide a guideline for future designers.
c. Create a prototype to demonstrate the property morphing ability of the concept in an in-vitro environment
d. Evaluate the use-safeness of the cocnept through a risk analysis.

The main outcomes will be (1) a concept design of a smart catheter with property morphing abilities (2) an overview of materials and requirements which provides the guideline for future designers based on literature research of the state of the art of smart catheters; and expert interviews (3) a prototype that demonstrates the property morphing abilities in an in-vitro environment.

Methods and tools include a literature review of the state-of-the-art of smart catheter development, interviewing experts from both the medical field and material science, prototyping with shape morphing materials and risk analysis of the concept(s).

A1. Stakeholder analysis

The stakeholder analysis helps to define the requirements per stakeholder and different areas where risks may arise. The stakeholder mapping is done with the 4 actor analysis and is based on interviews with interventionalists as well as observations of procedures. The roles and responsibilities of different stakeholders from the secondary and tertiary ring of the stakeholder map are described.



The interventionalist uses the catheter during procedures. They need to safely and effectively manoeuvre the instrument through the patient anatomy. The choice for the type of catheter is made before the procedure and depends on the type of procedure, the patient-specific anatomy and the preferences of the interventionalist. Certain types of catheters are usually standard for certain procedures e.g. a Judkins left coronary catheter will always be used to investigate the left coronary catheter. If the interventionalist is not the senior surgeon, they will discuss beforehand how the procedure will be executed.
During the procedure, the interventionalist is responsible for manipulating the catheter and guidewire, the foot pedals that regulate the emission of fluoroscopic liquid and the control panel that regulates the operation of the imaging equipment. Additionally, the interventionalist monitors the patient's vital signs and adjust the procedure as needed. The interventionalist and the team work together to ensure a safe and successful procedure.

The assistant interventionalist assists the interventionalist and learns during the process. They follow the instructions of the interventionalist. Their tasks include instrument exchange, holding the guidewire and/or catheter in place, assisting the advancement of the guidewire and/or catheter and using the control panel for the fluoroscopy.

The OR nurses are responsible for setting up the necessary instruments on the sterile table in the operation room (OR), prior to the procedure. They also provide additional instruments during the procedure as requested by the interventionalist, which may include different types of catheters or guidewires retrieved from the OR cabinets. The nurses keep a record of the patient's diagnostics and communicate this information to the interventionalist. Once the procedure is complete, the nurses are responsible for disposing of the used medical instruments and ensuring that OR is prepared for the next procedure. They also assist with discharging the patient from the OR and handing them over to the appropriate department's nurses.

The senior interventionalist will approve the procedure planning (in the case that the interventionalist themselves is not the senior surgeon). The senior surgeon can be present at the procedures to instruct the interventionalist. The level of supervision varies as more experienced interventionalists will not have constant supervision of their senior. It's always the senior interventionalists responsibility that a procedure goes safely as they are the final representative to the patient.

Regulatory bodies such as the European Union are responsible for establishing the rules and regulations governing the development and distribution of medical devices. To ensure compliance with these regulations, notified bodies are appointed by these entities to review and evaluate medical devices for conformity with the law.

The head nurse is responsible for managing instrument availability, ensuring adequate stock, monitoring expiration dates, and overseeing the disposal of expired instruments and materials, thus facilitating the connection between the interventionalist and hospital logistics. The head nurse has an instructing and teaching function to the nurses.

The patient undergoes the procedure. Before surgery, they provide their medical history and inform the interventionalist of the issues that they have which have led to the following procedure. Sometimes there are choices that have to be made by the patient regarding the procedure. The interventionalist will explain the pros and cons of different choices but the final choice is made by the patient. During the procedure the patient must remain still, as any movement can affect the interventionalists ability to perform the procedure accurately. After the procedure, the patient is debriefed by the interventionalist or their assistant. Typically, after the procedure, the patient will be required to stay in the hospital for a minimum of one hour for recovery. During this time, medical professionals closely monitor the patient's condition to ensure everything is well. If the procedure is relatively simple and the patient's condition is stable, they may be discharged to go home after this recovery period. However, in the case of more complex procedures, the patient might need to stay in the hospital for an additional day after the procedure for further observation and care. If the patient is a minor (under the age of 18), the decisions are made by the legal guardian.

The cleaning staff of the hospital enter the OR after the procedure is finished and make sure the waste in the bins is safely disposed. The medical waste is incinerated to ensure biosafety.

The hospital central financial department manages the finances of the hospital which includes the procurement of new medical instruments. If the medical instrument has significant cost, a cost-benefit analysis should be conducted to justify the procurement.

Medical device representatives regularly communicate with interventionalists to introduce new instruments that could be beneficial for specific procedures. To determine the hospital's interest, they arrange a meeting with the (senior) interventionalist and the head nurse. Conversely, the (senior) interventionalist may approach the representatives with a particular issue, and if there is sufficient interest from other interventionalists, the representatives may create an instrument to address the problem. Before their official release, new medical devices undergo clinical testing in selected hospitals.

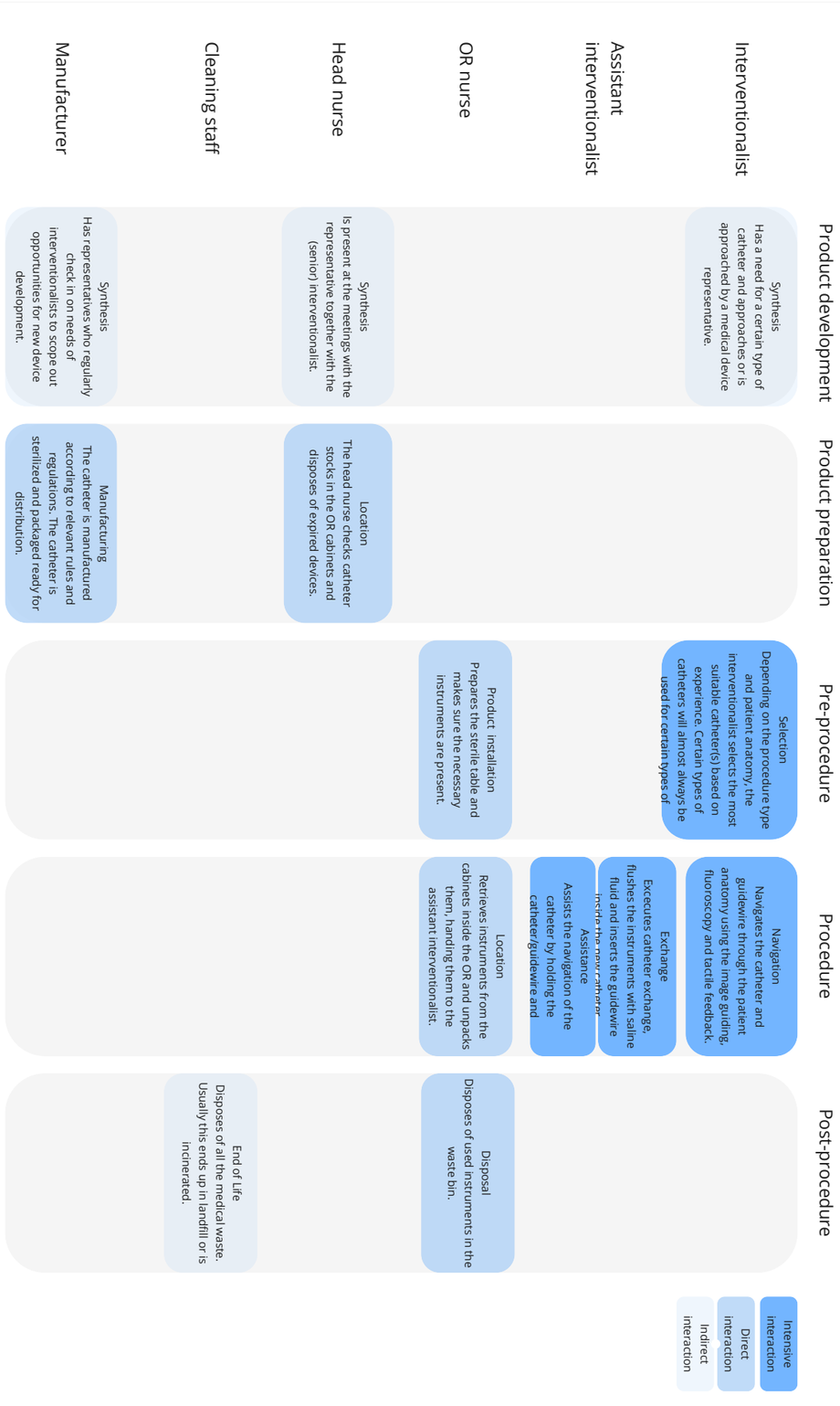
Medical device manufacturers such as Cordis, Boston Scientific, and Johnson & Johnson are engaged in the development and production of a diverse range of medical devices. They are responsible for ensuring that their products comply with applicable medical regulations and standards. In order to maintain their profitability, these companies keep abreast of the latest advancements and trends in the medical field. The profitability versus cost balance of new devices is a deciding factor in the product development.

Proctors are interventionalists who have previously used new medical procedures or devices and are knowledgeable about them. They are selected by medical device manufacturers to test and utilize new devices in a clinical setting. Prior to being used by an interventionalist, the user must be trained and approved by the proctor and manufacturer to ensure competence and safety.

The institutional review board (IRB) assess ethics and (dis)approve of any new treatment which has not previously been executed.

A2. Product journey

The product journey map presents a sequential description of the use of the product, the users involved and the context in which it is used.



A3. Pebax material data from Granta Edupack

Ansys GRANTA EDUPACK

PEBA (Shore D25)

General information

Designation

PEBA (Shore D25), Polyether block amide / Thermoplastic polyamide

Tradenames

Dynastat, Elastamide, Fostalink, Glamide, Grilon, Pebax, Ubesta, Vestamid

Typical uses

Conveyor belts, silent gears, shock-absorber parts, breathable films, soles with studs as well as shells for mountain boots, roofing film, packaging for fresh produce, catheters, surgical gowns, inflators.

Composition overview

Compositional summary

Multiblock copolymer of polyamide (e.g PA12 ~30%) and polyether (e.g polytetrahydrofuran ~70%).

Material family	Elastomer (thermoplastic, TPE)
Base material	TPA (Thermoplastic polyamide-polyether elastomer)
Polymer code	TPA

Composition detail (polymers and natural materials)

Polymer	100	%

Price

Price	* 12,8	-	15,7	EUR/kg
Price per unit volume	* 1,28e4	-	1,58e4	EUR/m^3

Physical properties

Density	999	-	1,01e3	kg/m^3

Mechanical properties

Young's modulus	1,2e7	-	2,06e7	Pa
Specific stiffness	0,012	-	0,0205	MN.m/kg
Yield strength (elastic limit)	* 2,83e7	-	3,17e7	Pa
Tensile strength	2,83e7	-	3,17e7	Pa
Tensile stress at 100% strain	3,68e6	-	6,53e6	Pa
Tensile stress at 300% strain	* 6,25e6	-	1,11e7	Pa
Specific strength	* 28,2	-	31,6	kN.m/kg
Elongation	3,13	-	7,85	strain
Elongation at yield	* 3,13	-	7,85	strain
Compressive modulus	* 1,2e7	-	2,06e7	Pa
Compressive strength	* 3,4e7	-	3,81e7	Pa
Flexural modulus	1,42e7	-	1,62e7	Pa
Flexural strength (modulus of rupture)	* 4,77e7	-	5,28e7	Pa
Shear modulus	* 4,02e6	-	6,94e6	Pa
Shear strength	* 2,26e7	-	3,17e7	Pa

Values marked * are estimates.
ANSYS, Inc. provides no warranty for this data.

General information

Designation

PEBA (Shore D40), Polyether block amide / Thermoplastic polyamide

Tradenames

Dynastat, Elastamide, Fostalink, Glamide, Grilon, Pebax, Ubesta, Vestamid

Typical uses

Conveyor belts, silent gears, shock-absorber parts, breathable films, soles with studs as well as shells for mountain boots, roofing film, packaging for fresh produce, catheters, surgical gowns, inflators.

Composition overview

Compositional summary

Multiblock copolymer of polyamide (e.g PA12 ~50%) and polyether (e.g polytetrahydrofuran ~50%).

Material family	Elastomer (thermoplastic, TPE)
Base material	TPA (Thermoplastic polyamide-polyether elastomer)
Polymer code	TPA

Composition detail (polymers and natural materials)

Polymer	100	%

Price

Price	* 12,8	-	15,7	EUR/kg
Price per unit volume	* 1,28e4	-	1,58e4	EUR/m^3

Physical properties

Density	1e3	-	1,01e3	kg/m^3

Mechanical properties

Young's modulus	7,21e7	-	7,39e7	Pa
Specific stiffness	0,0716	-	0,0735	MN.m/kg
Yield strength (elastic limit)	* 3,39e7	-	3,62e7	Pa
Tensile strength	3,39e7	-	3,62e7	Pa
Tensile stress at 100% strain	1,07e7	-	1,13e7	Pa
Tensile stress at 300% strain	* 1,78e7	-	1,96e7	Pa
Specific strength	* 33,6	-	35,9	kN.m/kg
Elongation	3,79	-	6,78	strain
Elongation at yield	* 3,79	-	6,78	strain
Compressive modulus	* 6,95e7	-	7,67e7	Pa
Compressive strength	* 4,06e7	-	4,34e7	Pa
Flexural modulus	7,21e7	-	1,04e8	Pa
Flexural strength (modulus of rupture)	* 5,59e7	-	5,93e7	Pa
Shear modulus	* 2,39e7	-	2,52e7	Pa
Shear strength	* 2,71e7	-	3,62e7	Pa

General information

Designation

PEBA (Shore D55), Polyether block amide / Thermoplastic polyamide

Tradenames

Dynastat, Elastamide, Fostalink, Glamide, Grilon, Pebax, Ubesta, Vestamid

Typical uses

Conveyor belts, silent gears, shock-absorber parts, breathable films, soles with studs as well as shells for mountain boots, roofing film, packaging for fresh produce, catheters, surgical gowns, inflators.

Composition overview

Compositional summary

Multiblock copolymer of polyamide (e.g PA12 ~65%) and polyether (e.g polytetrahydrofuran ~35%).

Material family	Elastomer (thermoplastic, TPE)
Base material	TPA (Thermoplastic polyamide-polyether elastomer)
Polymer code	TPA

Composition detail (polymers and natural materials)

Polymer	100	%

Price

Price	* 12,8	-	15,7	EUR/kg
Price per unit volume	* 1,27e4	-	1,69e4	EUR/m^3

Physical properties

Density	996	-	1,08e3	kg/m^3

Mechanical properties

Young's modulus	1,45e8	-	3,49e8	Pa
Specific stiffness	0,14	-	0,337	MN.m/kg
Yield strength (elastic limit)	1,11e7	-	1,65e7	Pa
Tensile strength	3,75e7	-	5,48e7	Pa
Tensile stress at 100% strain	1,34e7	-	1,77e7	Pa
Tensile stress at 300% strain	* 2,29e7	-	3,01e7	Pa
Specific strength	10,7	-	16	kN.m/kg
Elongation	4,5	-	5,48	strain
Elongation at yield	0,225	-	0,252	strain
Compressive modulus	* 1,45e8	-	3,49e8	Pa
Compressive strength	* 1,33e7	-	1,98e7	Pa
Flexural modulus	1,62e8	-	1,9e8	Pa
Flexural strength (modulus of rupture)	* 6,14e7	-	8,71e7	Pa
Shear modulus	* 4,95e7	-	1,21e8	Pa
Shear strength	* 3e7	-	5,48e7	Pa

PEBA (Shore D65)

General information

Designation

PEBA (Shore D65), Polyether block amide / Thermoplastic polyamide

Tradenames

Dynastat, Elastamide, Fostalink, Glamide, Grilon, Pebax, Ubesta, Vestamid

Typical uses

Conveyor belts, silent gears, shock-absorber parts, breathable films, soles with studs as well as shells for mountain boots, roofing film, packaging for fresh produce, catheters, surgical gowns, inflators.

Composition overview

Compositional summary

Multiblock copolymer of polyamide (e.g PA12 ~85%) and polyether (e.g polytetrahydrofuran ~15%).

Material family	Elastomer (thermoplastic, TPE)
Base material	TPA (Thermoplastic polyamide-polyether elastomer)
Polymer code	TPA

Composition detail (polymers and natural materials)

Polymer	100	%

Price

Price	* 12,8	-	15,7	EUR/kg
Price per unit volume	* 1,29e4	-	1,59e4	EUR/m^3

Physical properties

Density	1e3	-	1,02e3	kg/m^3

Mechanical properties

Young's modulus	4,09e8	-	4,19e8	Pa
Specific stiffness	0,404	-	0,415	MN.m/kg
Yield strength (elastic limit)	1,66e7	-	1,74e7	Pa
Tensile strength	5,06e7	-	5,54e7	Pa
Tensile stress at 100% strain	2,03e7	-	2,59e7	Pa
Tensile stress at 300% strain	* 3,44e7	-	4,41e7	Pa
Specific strength	16,4	-	17,3	kN.m/kg
Elongation	2,9	-	3,75	strain
Elongation at yield	0,195	-	0,218	strain
Compressive modulus	* 3,94e8	-	4,35e8	Pa
Compressive strength	* 1,94e7	-	2,14e7	Pa
Flexural modulus	3,61e8	-	3,79e8	Pa
Flexural strength (modulus of rupture)	* 8,08e7	-	8,8e7	Pa
Shear modulus	* 1,4e8	-	1,47e8	Pa
Shear strength	* 4,05e7	-	5,54e7	Pa

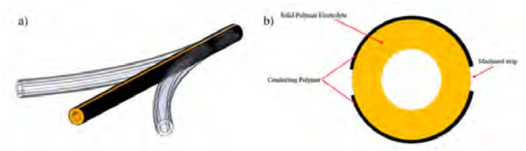
A4. Literature benchmark of material-driven property morphing catheter developments

A4.1 SMA actuated property morphing catheter

Title: Micro-Robotic Medical Tools Employing SMA Actuators for Use in the Human Body
Authors: Yoichi Haga, Takashi Mineta, Tadao Matsunaga and Noriko Tsuruoka.
Year: 2022

Material: NiTi SMA
Biocompatibility: NiTi SMA's are biocompatible and already clinically used in stents.
Manufacturing: Femtosecond laser cutting of a spring-shaped SMA coil.
Actuation speed: The SMAs are actuated in a matter of seconds through Joule heating with a current of 90mA.
Morphability: Multi-directional bending with an angle of 45 degrees was achieved using three SMA coil actuators. Additionally, a design was developed that could bend, extend and control stiffness. The stiffness change recorded was 20mN.
Miniaturization: The developed catheter has an outer diameter of approximately 2mm, although the author mentions the need to increase safety by adding more electrical and thermal insulation.
Benefits: Biocompatibility and ability for a single device to achieve multi-functionality such as extension, twisting and bending.
Limitations: Miniaturization due to low displacement performance of wires, unpredictable actuation behaviour due to hysteretic characteristics of SMA (58), low machineability of SMA (11) and higher cost than SMP (24).
Manufacturability: SMAs are commercially produced in different configurations such as wires, helical springs, torsion springs, cantilever strips and torsion tubes of which wires are the most common. This is because the machineability of SMA is challenging. The heat produced through machining activates the SMA to transform to its stiff (austenite) phase.
Cost: SMAs are more expensive than SMPs but a small amount of material (like a wire) is needed to make use of the shape memory effect.

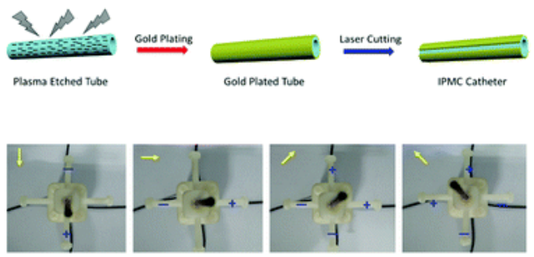
A4.2 Conductive polymer based property morphing catheter



Title: Self-contained tubular bending actuator driven by conducting polymers
Authors: Farajollahi, M., Woehling, V., Plesse, C., Nguyen, G. T. M., Vidal, F., Sassani, F., Yang, V. X. D. and Madden, J. D. W.
Year: 2016

Material: PEDOT (poly(3,4-ethylenedioxythiophene) polystyrene sulfonate) and lithium TFSI salt as electrolyte
Biocompatibility: PEDOT is a biocompatible conductive polymer but the lithium TFSI salt is toxic and needs encapsulation. Other large-strain biocompatible electrolytes could be investigated.
Manufacturing: The PEDOT is laser micromachined on an interpenetrating polymer network (IPN) which was synthesized by chemical polymerization.
Actuation: A voltage of 2V is used to actuate the conductive polymer in a toxic high strain electrolyte. The actuation is in a matter of seconds but faster than SMA actuation (1).
Morphability: The catheter showed a 6.5 mm deflection in open air. CPs are only able to exhibit bending behaviour. Some stiffness change is caused by bending but as it is not mentioned in particular, it is assumed to be negligible.
Miniaturization: The catheter has a 0.9 mm outer diameter and 0.3 mm inner diameter or lumen. However, the electrolyte used here is toxic and requires encapsulation.
Benefits: Low actuation voltage increases safety, relatively easy to manufacture, cheap.
Limitations: Conductive polymers only exhibit bending and they need encapsulation to become biocompatible if the performance is reliant on toxic high strain electrolytes.
Manufacturability: CPs are polymers that are doped through an electrochemical process. The polymers can be formed easily using conventional manufacturing methods such as extrusion and injection moulding.
Cost: Polymers are very cheap (PPy is $3/kg).

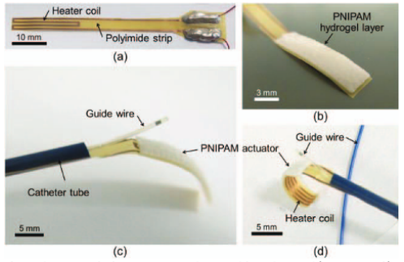
A4.3 Ionic polymer-metal composite property morphing catheter



Title: Cost-effective fabrication of ionic polymer based artificial muscles for catheter-guidewire manoeuvring application.
Authors: Tripathi, A., Chattopadhyay, B. and Das, S.
Year: 2019

Material: IPMC is a sandwich structure consisting of a polyelectrolyte membrane coated with a noble metal layer. Here, a Nafion membrane was gold plated.
Biocompatibility: Nafion and gold are both biocompatible.
Manufacturing: Nafion membrane production requires delicate tuning of variables and is difficult to reproduce. A chromium layer is deposited to increase the adhesiveness between the Nafion and gold. The gold layer is deposited by DC sputtering.
Actuation: At 5V, linear behaviour and maximum (almost instant) actuation was observed. Below 3V, the output was much lower and non-linear. The IPMC shows bending behaviour toward the anode.
Morphability: A maximum displacement of 5 mm is observed with 22 degree bending.
Miniaturization: A specific size is not mentioned but some challenges related to miniaturization. Other research mentions encapsulating the IPMC-actuator as it loses hydration which decreases actuation, and the performance of IPMC-actuators varies with its thickness (30).
Benefits: Rapid response, low actuation voltage, softness of the material reduces risk of vessel wall perforation.
Limitations: Non-linear actuation due to material hysteresis and a problem of back relaxation. The required usage of noble metals significantly increases cost.
Manufacturability: Manufacturing of Nafion membranes poses a reproducibility problem (30).
Cost: The necessity of noble metals makes IPMCs expensive (59).

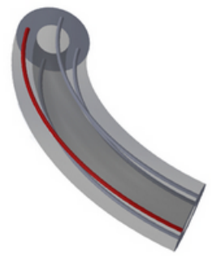
A4.4 SMG actuated property morphing catheter



Title: A steerable smart catheter tip realized by flexible hydrogel.
Authors: Selvaraj, M. and Takahata, K.
Year: 2016

Material: The hydrogel PNIPAM (poly(N-isopropylacrylamide) is embedded in a film and assembled on a commercial catheter.
Biocompatibility: PNIPAM is a biocompatible hydrogel.
Manufacturing: The PNIPAM layer is cast and photo-polymerized. The PNIPAM layer is integrated with a flexible micropatterned heater strip fixed at the tip of a conventional catheter.
Actuation: The hydrogel is actuated through active heating up to 30-32 degrees Celsius where within 7 seconds a bend of 100 degrees was reached. The slow heat dissipation between the hydrogel and the environment causes a slow return to its original shape.
Morphability: A maximum bending angle of 130 degrees observed. An angle of 70 degrees was reached in 3 seconds. This bending performance is higher than other documented shape memory material based catheters.
Miniaturization: The heater strip of the hydrogel actuator is 3.5 mm wide, which exceeds the maximum 2.8 mm [8.5Fr] diameter limit for an endovascular catheter. However, hydrogels can be manufactured in micrometre scale.
Benefits: Hydrogels come close to natural tissue, are biocompatible and actuate in a temperature window close to human body temperature (40).
Limitations: Slow heat dissipation, conventional sterilization is difficult due to the hydrogels high water content. Stimuli-responsive hydrogels are sensitive to interference by other stimuli (27).
Manufacturability: Methods like casting, direct ink writing (DIW) and stereolithography (SLA) printing are used to form SMGs. There is however, no standardized synthesis of SMGs (27).
Cost: The preparation of SMGs is restricted to laboratories and is in most cases expensive.

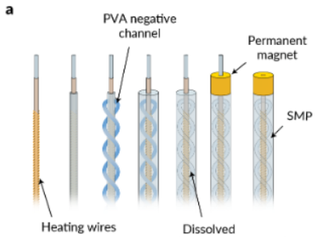
A4.5 Hydraulically-driven property morphing catheter



Title: Soft robotic steerable microcatheter for the endovascular treatment of cerebral disorders.
Authors: Tilvawala Gopesh, Jessica H. Wen, David Santiago-Dieppa, Bernard Yan, J. Scott Pannell, Alexander Khalessi, Alexander Norbash and James Friend.
Year: 2022

Material: Hyperelastic silicone Dragon-Skin 10 SLOW and physiological fluid.
Biocompatibility: The silicon and physiological fluid used are biocompatible.
Manufacturing: A mesoscale molding process was used to cast silicone rubber in polyurethane plastic molds.
Actuation: Almost instantaneous hydraulic actuation. The four channels located radially around the catheter can be filled with physiological fluid up to a pressure of 350 kPa.
Performance: A maximum bending angle of 180 degrees is reached at a pressure of 350 kPa with almost instantaneous actuation speed. The stiffness can be varied by pressurizing the chambers to a set level simultaneously.
Miniaturization: The catheter developed has a diameter of 0.9 mm.
Benefits: Fast actuation and precise control, no electrical or thermal power required as well as the softness of the catheter tip adds to safety.
Limitations: Expensive internal structure manufacturing, not suitable for disposability. The driving tubes are extremely thin and have to be filled and sealed before use, adding to the complexity.
Manufacturability: The manufacturing process of such a small hydraulic system is laborious but possible.
Cost: Silicone material cost are higher than other polymers but cheaper than SMA.

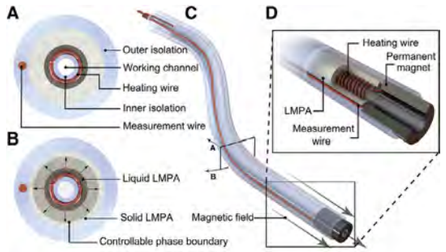
A4.6 SMP-actuated property morphing catheter



Title: Shape memory polymer variable stiffness magnetic catheters with hybrid stiffness control
Authors: Michael Mattmann, Quentin Boehler, Xiang-Zhong Chen, Salvador Pané and Bradley J. Nelson.
Year: 2022

Material: SMP (NOA63, Norland Prod.) with embedded enameled copper wires for heating.
Biocompatibility: The SMP is biocompatible.
Manufacturing: Molding of the SMP layer over the heater coils and inner PTFE liner. After curing with UV-A light for 30 minutes, a second SMP layer is molded over the PVA structure which is then dissolved in a heated ultrasonic bath.
Actuation: Thermal: The SMP is actively heated up to 45 degrees Celsius.
Performance: Sufficient heating is achieved in 6 seconds and cooling in 7 seconds. The catheter is bent by magnetic force, reaching a 60 degree angle with a field of 80 mT. A
Miniaturization: The catheter has an outer diameter of 2.5 mm. The design provides control of more than 90% of the full stiffness transition (between 109 Pa and 108 Pa).
Benefits: The use of SMP enables variable stiffness of the catheter. Compared to LMPAs, SMPs are available biocompatible and the liquid state is avoided and thereby the requirement for encapsulation of the core, which favours miniaturization.
Limitations: Miniaturization still poses a challenge as: active heating and cooling is desirable to achieve a workable actuation response rate (7 s instead of 59 s) and, to utilize the full SMP stiffness range, the SMP volume must be maximized. Shape memory behaviour is extremely limited due to the low force generated during shape recovery.
Manufacturability: SMPs are manufacturable through a wide range of conventional manufacturing methods such as injection moulding and extrusion (24).
Cost: Most polymers can be made into SMPs, resulting in low material cost.

A4.7 LMPA-actuated property morphing catheter



Title: A Submillimeter Continuous Variable Stiffness Catheter for Compliance Control.
Authors: Jonas Lussi, Michael Mattmann, Semih Sevim, Fabian Grigis, Carmela De Marco, Christophe Chautems, Salvador Pané, Josep Puigmartí-Luis, Quentin Boehler and Bradley J. Nelson
Year: 2021

Material: Low-melting point alloy (LMPA) 44.7% Bismuth, 22.6% Lead, 19.1% Indium, 8.3% Tin and 5.3% Cadmium.
Biocompatibility: The LMPA has non-biocompatible components and therefore needs isolation layers able to withstand significant stress to enable biocompatibility.
Manufacturing: Overmolding the polymer lumen and copper heating wire with LMPA through an extrusion process.
Actuation: Thermal: The LMPA is directly heated until 47 degrees Celsius.
Performance: Heated from stiff to flexible state takes 16 s in water. The bulk stiffness change during cool down took place after 30 s of cooling time in water. The controllable stiffness range was between 3 GPa in solid state and stiffness characteristics of a liquid with low viscosity in soft state.
Miniaturization: The outer diameter of the catheter is 1 mm, with a working channel of 180 µm.
Benefits: High stiffness variation from solid to liquid state.
Limitations: The non-biocompatibility of the LMPA requires sufficient isolation.
Manufacturability: Due to their low melting point, LMPAs can be easily cast.
Cost: LMPAs are a combination of metals. Therefore the price is dependent on the alloy composition. In the case-study of the LMPA catheter, cheap metals such as Bismuth, Lead, Tin and Cadmium are alloyed with the more expensive Indium. The price of the cheaper metals is +/-$10/kg while the Indium is $332/kg (8).

A5. MDR Classification and requirements

A5.1 Medical device classification

9.5.1.1 Intended use
The intended use of the catheter is for use in direct contact with the heart or central circulatory system or the central nervous system.

9.5.1.2 Classification
The intended use of the active endovascular catheter dictates by rule 6 that the device is a class III (high risk) medical device according to MDCG 2021-24: Guidance on classification of medical devices, (61).

A5.2 Requirements

These are relevant requirements for this project based on Annex I of the MDR2017/745. They are paraphrased slightly to make them more readable.

1. General requirements
Devices must meet performance expectations, be suitable for their intended purpose, and ensure safety for patients and users.

Manufacturers are required to establish, implement, document, and maintain a risk management system for their devices (i).

10. Chemical, physical and biological properties
The parts of the device in contact with the exterior are biocompatible.

The parts of the device in contact with the exterior are non-toxic.

The parts of the device in contact with the exterior are compatible with biological tissues, cells and fluids (radiopaque dyes, saline, body fluids).

The mechanical properties of the materials used such as strength, ductility, fracture resistance, wear resistance and fatigue resistance are not harmful to any relevant stakeholder in intended use or foreseeable misuse.

The surface properties of the device shall not be harmful to any relevant stakeholder during intended use or foreseeable misuse

10.4.1 Design and manufacture of devices
The device must be designed and manufactured with measures to minimize the risks associated with the release of substances or particles, including wear debris, degradation products, and processing residues. For invasive devices that come into direct contact with the human body, certain substances are restricted to concentrations above 0.1% weight by weight (w/w), provided that the use is justified (ii). these substances include (1) carcinogenic, mutagenic or toxic to reproduction (CMR) substances classified as category 1A or 1B according to Annex VI of Regulation (EC) No 1272/2008; and (2) substances with endocrine-disrupting properties of which evidence exists of probable serious effects on human health.

11. Infection and microbial contamination
Devices labelled as sterile shall be sterilised by means of appropriate validated methods. For heat-sensitive medical devices (such as endovascular catheters), sterilization happens using ethylene oxide gas (EtO).

The material used in the device should therefore be able to withstand a temperature of 63° C without degradation of properties.

14. Construction of devices and interaction with their environment
The device shall be designed and manufactured in a way to remove or reduce as far as possible the risk of injury, in connection with their physical features, including dimensional and ergonomic features;

(i) This includes (1) creating a risk management document specifically for the device; (2) identifying and analyzing known and foreseeable hazards associated with the device; (3) estimating and evaluating risks that occur during intended use and reasonable foreseeable misuse; (4) and applying safety principles to eliminate or control the identified risks.

(ii) The use of such substances require justification based on:
1. Analysis and estimation of potential patient or user exposure.
2. Evaluation of possible alternative substances, materials, or designs, considering independent research, peer-reviewed studies, scientific opinions, and availability of alternatives.
3. Argumentation why alternative substances or design changes are inappropriate while maintaining functionality, performance, and benefit-risk ratios of the product.

The device shall be designed and manufactured in a way to remove or reduce as far as possible risks connected with external influences such as external electrical effects, electrostatic discharge, temperature, pressure and variations in pressure.

18. Active devices and devices connected to them

The device shall be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks to the patient, user or any other person, both during normal use of the device and in the event of a single fault condition in the device.

20. Protection against mechanical and thermal risks

The device shall be designed to protect patients and users against mechanical risks such as resistance to movement, instability and moving parts.

Accessible parts of the device shall not attain potentially dangerous temperatures (over 41 degrees Celsius for endovascular application) under normal conditions of use.

A6. Hydrogel synthesis

(a) The synthesis is performed under a fume hood, although it is not explicitly necessary it increases safety. Gloves, glasses and a labcoat must be worn.

(b) Nipam and methylene are the hydrogel polymer components. Hydrogen peroxide and ascorbic acid are the initiators for the polymerization. These are radical initiators but other types exist such as UV initiators.

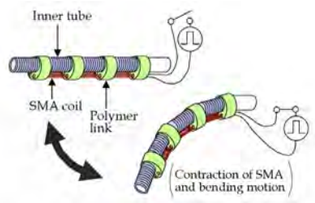
(c) Nipam and methylene are mixed. Since there is no recipe, it is a trial-error process. Methylene is the crosslinker, so the more methylene, the stiffer the hydrogel. The more Nipam, more reactive the hydrogel is upon actuation.

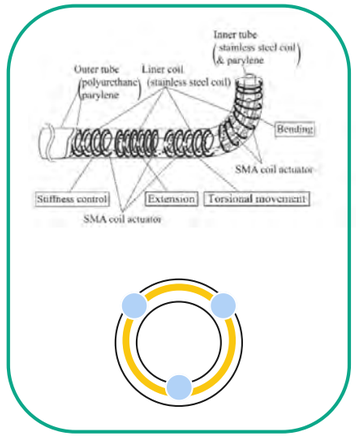
(d) Distilled water is added to mix the Nipam and methylene, until they are both dissolved. The water will be expelled once the hydrogel starts to form.

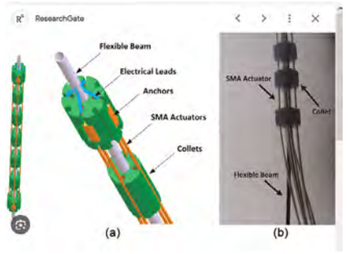
(e) First the ascorbic acid is dissolved in the mixture, then the hydrogen peroxide. The amount of initiator are not that important with reactive initiators, as only The mixture is swirled for around a minute.

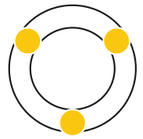
(f) Hydrogel starts to form once it is still. The mixture musn't be touched for 24 hours all the harmful substances are expelled. After removal from the mold (bottle), the hydrogel is washed with water.

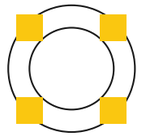
A7. Design parameters











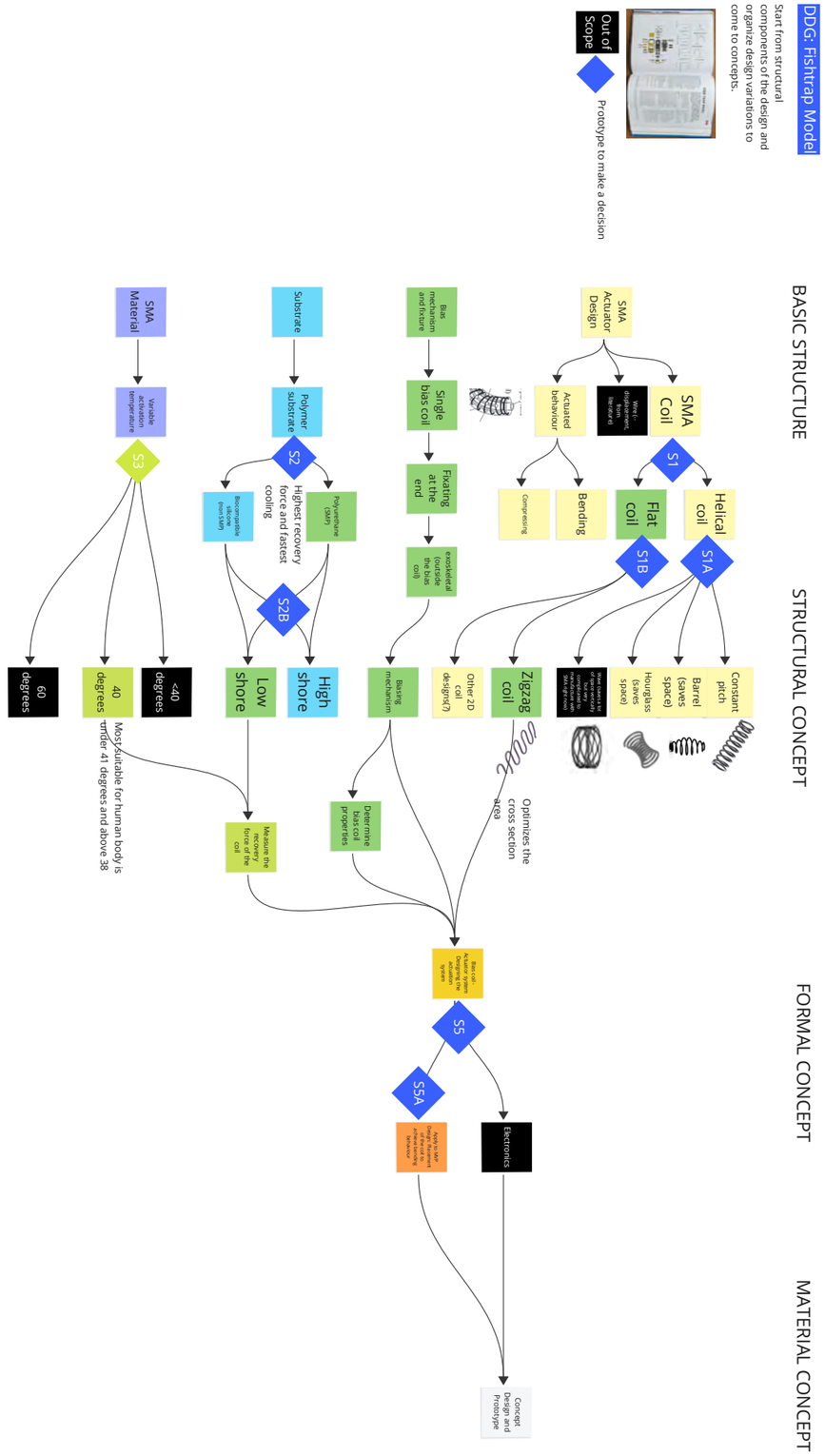
Parameters

- SMA Coil
  - Shape of coil
  - Pitch of coil
  - Length of coil
  - Thickness of coil wire
  - Coil distribution
  - Diameter of coil (6-8Fr)
- Fixation
  - Distribution of points of fixation
  - Number of fixation points
  - Fixation material
  - Liner coil / Bias coil
- Coil placement
  - Location of coil
  - Single or multiple coils
- Substrate
  - Polyurethane (biocompatible and low glass transition temp).
  - Shape memory properties of SMP
  - Substrate mixing ratio (lowering the Tg by having no 1:1 ratio) (See meeting Kasper)
  - Thickness of coating
- SMA Material
  - Low activation temperature SMA

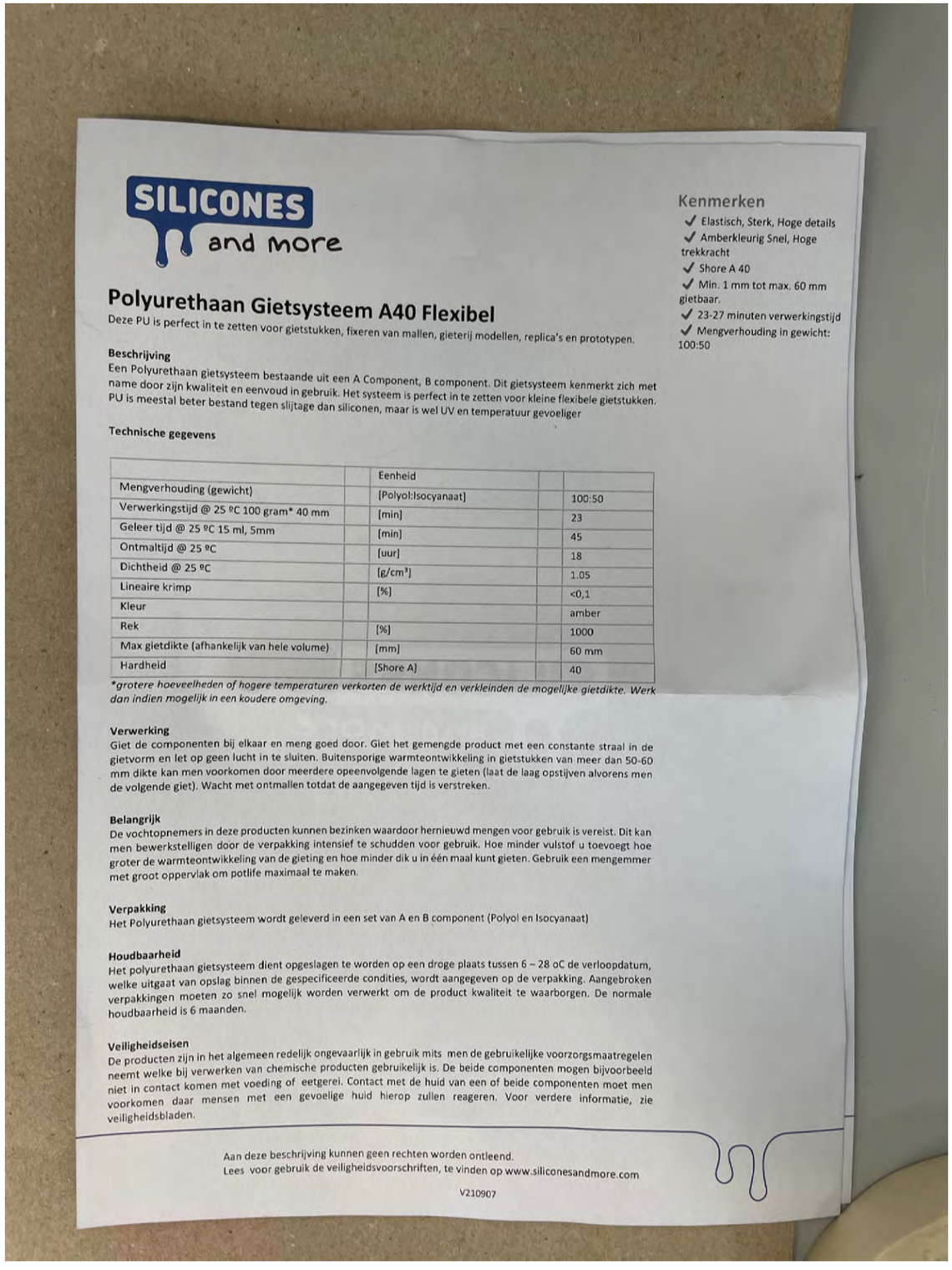
Effects

- Actuation performance
  - How much displacement
  - How much variable stiffness
  - Response time
  - Recovery force
- Functionality
  - Amount of bending
  - Length of variable stiffness section
- Bending actuation
  - Which are the bending points of the catheter
- Actuation performance
  - + Recovery time
  - Material
  - Surface temperature (should be below 41 degr)
- Actuation performance
  - Material
  - Surface temperature (should be below 41 degr)

A8. Fishtrap model



A9. Substrate technical material data



SILICONES and more

Polyurethaan Gietsysteem A40 Flexibel

Deze PU is perfect in te zetten voor gietstukken, fixeren van mallen, gieterij modellen, replica's en prototypen.

Kenmerken

- ✓ Elastisch, Sterk, Hoge details
- ✓ Amberkleurig Snel, Hoge trekkracht
- ✓ Shore A 40
- ✓ Min. 1 mm tot max. 60 mm gietbaar.
- ✓ 23-27 minuten verwerkingstijd
- ✓ Mengverhouding in gewicht: 100:50

Beschrijving
Een Polyurethaan gietsysteem bestaande uit een A Component, B component. Dit gietsysteem kenmerkt zich met name door zijn kwaliteit en eenvoud in gebruik. Het systeem is perfect in te zetten voor kleine flexibele gietstukken. PU is meestal beter bestand tegen slijtage dan siliconen, maar is wel UV en temperatuur gevoeliger

Technische gegevens

	Eenheid		
Mengverhouding (gewicht)	[Polyol:Isocyanaat]		100:50
Verwerkingstijd @ 25 ºC 100 gram* 40 mm	[min]		23
Geleer tijd @ 25 ºC 15 ml, 5mm	[min]		45
Ontmaltijd @ 25 ºC	[uur]		18
Dichtheid @ 25 ºC	[g/cm³]		1.05
Lineaire krimp	[%]		<0,1
Kleur			amber
Rek	[%]		1000
Max gietdikte (afhankelijk van hele volume)	[mm]		60 mm
Hardheid	[Shore A]		40

**grotere hoeveelheden of hogere temperaturen verkorten de werktijd en verkleinden de mogelijke gietdikte. Werk dan indien mogelijk in een koudere omgeving.*

Verwerking
Giet de componenten bij elkaar en meng goed door. Giet het gemengde product met een constante straal in de gietvorm en let op geen lucht in te sluiten. Buitensporige warmteontwikkeling in gietstukken van meer dan 50-60 mm dikte kan men voorkomen door meerdere opeenvolgende lagen te gieten (laat de laag opstijven alvorens men de volgende giet). Wacht met ontmallen totdat de aangegeven tijd is verstreken.

Belangrijk
De vochtopnemers in deze producten kunnen bezinken waardoor hernieuwd mengen voor gebruik is vereist. Dit kan men bewerkstelligen door de verpakking intensief te schudden voor gebruik. Hoe minder vulstof u toevoegt hoe groter de warmteontwikkeling van de gieting en hoe minder dik u in één maal kunt gieten. Gebruik een mengemmer met groot oppervlak om potlife maximaal te maken.

Verpakking
Het Polyurethaan gietsysteem wordt geleverd in een set van A en B component (Polyol en Isocyanaat)

Houdbaarheid
Het polyurethaan gietsysteem dient opgeslagen te worden op een droge plaats tussen 6 – 28 oC de verloopdatum, welke uitgaat van opslag binnen de gespecificeerde condities, wordt aangegeven op de verpakking. Aangebroken verpakkingen moeten zo snel mogelijk worden verwerkt om de product kwaliteit te waarborgen. De normale houdbaarheid is 6 maanden.

Veiligheidseisen
De producten zijn in het algemeen redelijk ongevaarlijk in gebruik mits men de gebruikelijke voorzorgsmaatregelen neemt welke bij verwerken van chemische producten gebruikelijk is. De beide componenten mogen bijvoorbeeld niet in contact komen met voeding of eetgerei. Contact met de huid van een of beide componenten moet men voorkomen daar mensen met een gevoelige huid hierop zullen reageren. Voor verdere informatie, zie veiligheidsbladen.

Aan deze beschrijving kunnen geen rechten worden ontleend.
Lees voor gebruik de veiligheidsvoorschriften, te vinden op www.siliconesandmore.com

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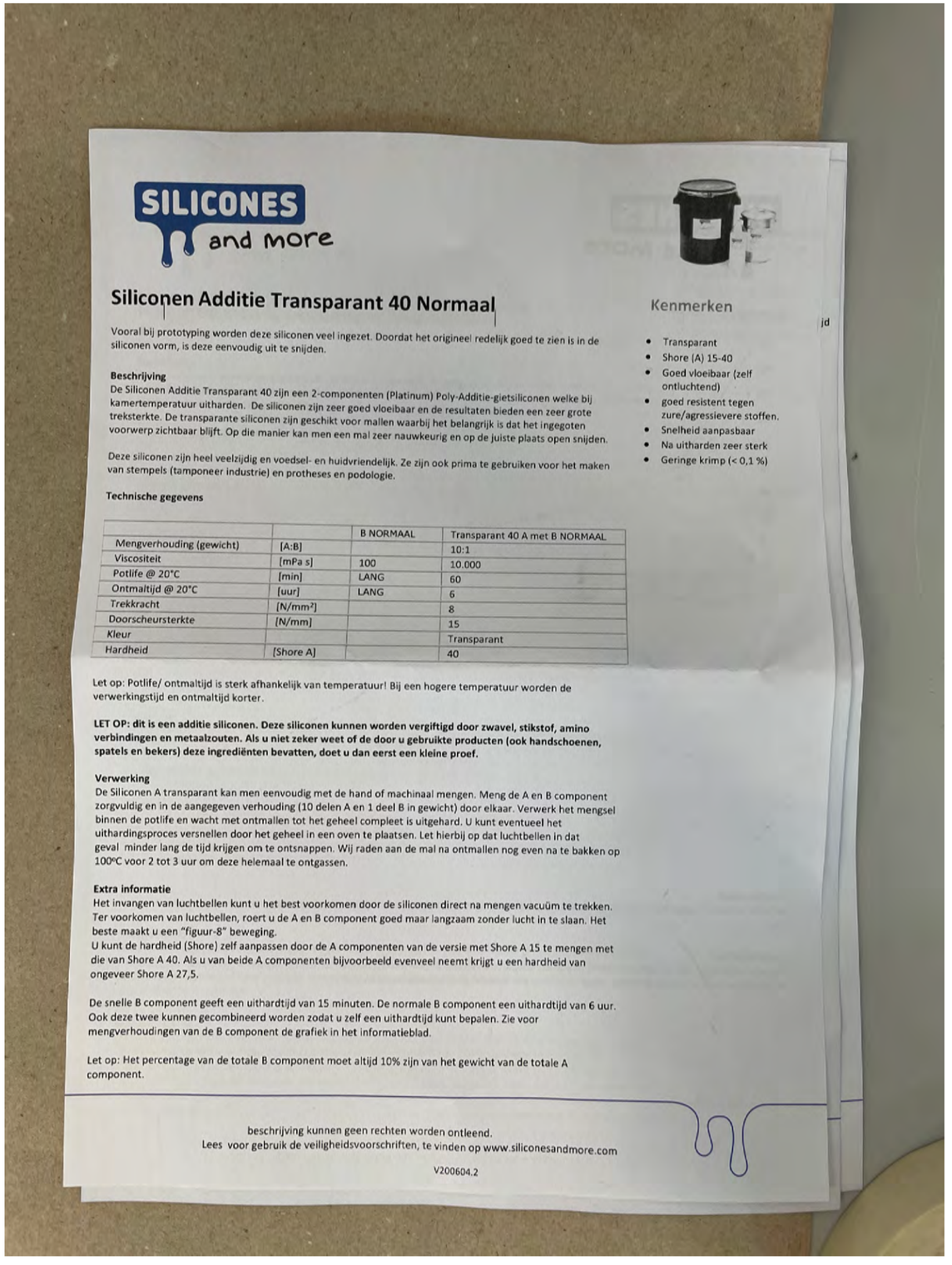

SILICONES and more

Siliconen Additie Transparant 40 Normaal

Vooral bij prototyping worden deze siliconen veel ingezet. Doordat het origineel redelijk goed te zien is in de siliconen vorm, is deze eenvoudig uit te snijden.

Kenmerken

- Transparant
- Shore (A) 15-40
- Goed vloeibaar (zelf ontluchtend)
- goed resistent tegen zure/agressievere stoffen.
- Snelheid aanpasbaar
- Na uitharden zeer sterk
- Geringe krimp (< 0,1 %)

Beschrijving
De Siliconen Additie Transparant 40 zijn een 2-componenten (Platinum) Poly-Additie-gietsiliconen welke bij kamertemperatuur uitharden. De siliconen zijn zeer goed vloeibaar en de resultaten bieden een zeer grote treksterkte. De transparante siliconen zijn geschikt voor mallen waarbij het belangrijk is dat het ingegoten voorwerp zichtbaar blijft. Op die manier kan men een mal zeer nauwkeurig en op de juiste plaats open snijden.

Deze siliconen zijn heel veelzijdig en voedsel- en huidvriendelijk. Ze zijn ook prima te gebruiken voor het maken van stempels (tamponeer industrie) en protheses en podologie.

Technische gegevens

		B NORMAAL	Transparant 40 A met B NORMAAL
Mengverhouding (gewicht)	[A:B]		10:1
Viscositeit	[mPa s]	100	10.000
Potlife @ 20°C	[min]	LANG	60
Ontmaltijd @ 20°C	[uur]	LANG	6
Trekkracht	[N/mm²]		8
Doorscheursterkte	[N/mm]		15
Kleur			Transparant
Hardheid	[Shore A]		40

Let op: Potlife/ ontmaltijd is sterk afhankelijk van temperatuur! Bij een hogere temperatuur worden de verwerkingstijd en ontmaltijd korter.

LET OP: dit is een additie siliconen. Deze siliconen kunnen worden vergiftigd door zwavel, stikstof, amino verbindingen en metaalzouten. Als u niet zeker weet of de door u gebruikte producten (ook handschoenen, spatels en bekers) deze ingrediënten bevatten, doet u dan eerst een kleine proef.

Verwerking
De Siliconen A transparant kan men eenvoudig met de hand of machinaal mengen. Meng de A en B component zorgvuldig en in de aangegeven verhouding (10 delen A en 1 deel B in gewicht) door elkaar. Verwerk het mengsel binnen de potlife en wacht met ontmallen tot het geheel compleet is uitgehard. U kunt eventueel het uithardingsproces versnellen door het geheel in een oven te plaatsen. Let hierbij op dat luchtbellen in dat geval minder lang de tijd krijgen om te ontsnappen. Wij raden aan de mal na ontmallen nog even na te bakken op 100ºC voor 2 tot 3 uur om deze helemaal te ontgassen.

Extra informatie
Het invangen van luchtbellen kunt u het best voorkomen door de siliconen direct na mengen vacuüm te trekken. Ter voorkomen van luchtbellen, roert u de A en B component goed maar langzaam zonder lucht in te slaan. Het beste maakt u een "figuur-8" beweging.
U kunt de hardheid (Shore) zelf aanpassen door de A componenten van de versie met Shore A 15 te mengen met die van Shore A 40. Als u van beide A componenten bijvoorbeeld evenveel neemt krijgt u een hardheid van ongeveer Shore A 27,5.

De snelle B component geeft een uithardtijd van 15 minuten. De normale B component een uithardtijd van 6 uur. Ook deze twee kunnen gecombineerd worden zodat u zelf een uithardtijd kunt bepalen. Zie voor mengverhoudingen van de B component de grafiek in het informatieblad.

Let op: Het percentage van de totale B component moet altijd 10% zijn van het gewicht van de totale A component.

beschrijving kunnen geen rechten worden ontleend.
Lees voor gebruik de veiligheidsvoorschriften, te vinden op www.siliconesandmore.com

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