MULTI-MATERIAL 3D PRINTING FOR PERCUTANEOUS SURGICAL DRAINS

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MULTI-MATERIAL 3D PRINTING FOR PERCUTANEOUS SURGICAL DRAINS

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ABSTRACT

A Percutaneous drain is a medical catheter used by Interventional radiologists to drain abscesses or cysts within the human body. The purpose of drainage is to reduce the need for open surgery, decreasing infections and recovery time. Percutaneous drains were initially designed for irrigation, not drainage; a contributing factor to the current 50% procedural fail rate. Alongside; clogging, kinking and infection.

The focus of the project is to mitigate failure with a fundamental redesign of the percutaneous drain, utilising a multidisciplinary research team from various organisations that work in conjunction to address this Issue*.

This thesis, while a component of a more significant study, asks the question, 'how can design research and multi-material 3D printing, provide innovative insights to improve the clinical performance of percutaneous drains?'

Three elements of the overall drainage procedure are focused on; the efficiency of the drains drainage, the insertion and removal procedure, and simulated anatomy models to provide context to each design. These are explored using multi-material 3D printing as a design tool to investigate new geometries, material combinations and dynamic qualities. Multi-material 3D printing is a design enabler which produces fast and accurate prototypes to explore ideas and communicate intentions to the research team.

The overall aim of this thesis project is to work alongside healthcare professionals cohesively, to develop novel drainage catheter prototypes. This aim will be achieved by utilising multi-material 3D printing for communication, discussion, rapid prototyping, and development. The primary outputs are innovative designs concepts for percutaneous drains, in the form of CAD files and 3D printed prototypes; while the written thesis documents research outcomes, outputs and process.

*NB: This thesis is derived from of a funding proposal submitted to the Ministry of Business, Innovation and Employment (MBIE).

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All figures not cited here have been produced by the Author.

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GLOSSARY

Anatomy - the bodily structure of humans, animals, and other living organisms.
Bilateral - having two sides
Bioprinting - three-dimensional printing of biological tissue and organs through the layering of living cells.
Catheter - a flexible tube inserted through a narrow opening into a body cavity for removing fluid.
Cavity - a space within a solid object.
Composites - something made up of several parts or elements.
Connex - The multi-material Stratasys Connex Objet350 3D printer.
Customisation - a modification made to something to suit a particular individual or task.
Digitisation - the conversion of text, pictures, or sound into a digital form that can be processed by a computer.
Dissemination - spreading.
FDA - Food and Drug Administration is a federal agency of the United States Department of Health and Human Services.
Incision - a surgical cut made in skin or flesh.
Innovation - introducing new ideas; original and creative thinking.
Irrigant/ Irrigation - the process of washing out an organ or wound with a continuous flow of water or medication.
Lumen - internal passage within a catheter.
Mitigate - make (something wrong) less severe, dangerous, or painful.
Multi-disciplinary - combining or involving several academic disciplines or professional specialisations in an approach to a topic or problem.
Multi-material - A combination of two or more materials in one single 3D print.
Necrotic - dead matter such as pus.
Novel- interestingly new or unusual.
Percutaneous - through the skin.
Peritoneum space - the serous membrane lining the cavity of the abdomen and covering the abdominal organs.
Polymers - a substance which has a molecular structure built up chiefly or entirely from a large number of similar units bonded together.
Procedure - a surgical operation.
Prototype - a first or preliminary version of a product from which other forms are developed.
Reiterated - repeat something or many times, typically for emphasis or clarity.
Saline - a solution of salt in water.
Septic - a painful infection in a joint.
Simulation/ Simulated Anatomies - to create a simulation, likeness, or model of a situation or system.
Software - programs and other operating information used by a computer.
Unilateral - having only one side or surface; without a reverse side or inside.
Viscosity - the state of being thick, sticky, and semi-fluid inconsistency.

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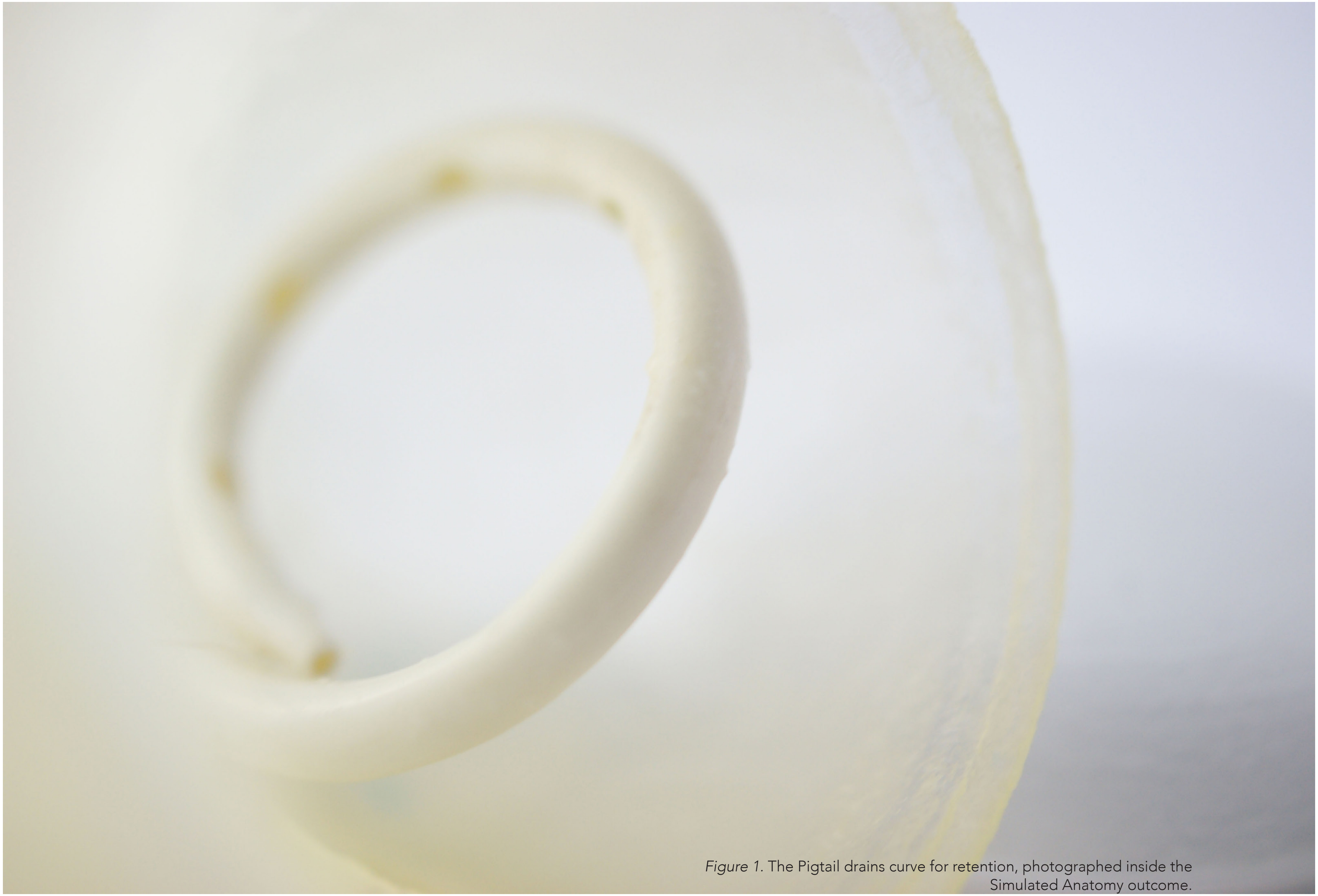

Figure 1. The Pigtail drains curve for retention, photographed inside the Simulated Anatomy outcome.

INTRODUCTION

THE PERCUTANEOUS DRAIN

The percutaneous drain is a medical catheter used to drain abscesses or cysts within the human body (see figure 2). An abscess is a collection of infected fluid, ranging from blood to pus. Interventional radiologists most commonly remove these collections using image guidance to accurately insert a needle or catheter through the skin and into the infected area. This process is called the percutaneous drainage procedure. This procedure is favoured over others such as open surgery, as it offers fewer complications and recovery time. Although preferred, the current percutaneous procedure was previously designed for irrigation, not drainage, which is a contributing factor as to why the drains fail rate is so high (50%). As well as;
-clogging;
-kinking;
-loosening of the catheter or needle; and
-leakage of necrotic matter.

Figure 2. Percutaneous surgical drain in scale.

THE GREATER PROJECT

In response, a funding proposal was submitted to the Ministry of Business, Innovation and Employment (MBIE). Creating a project that focuses on the fundamental redesign of the current percutaneous drain, to mitigate failures and improve the overall efficiency. This project will allow a multi-disciplinary research team from various organisations around New Zealand to work in conjunction to address this issue.

The focus of the project is a combination of four elements. These elements include:
- new geometries based on computer simulation and fluid modelling;
- micro-grooved surfacing for reduced adherence of debris;
- incorporation of antimicrobial agents for reduced biofilm formation; and
- multi-material 3D printing to allow rapid iterative testing of prototypes and increased speed to market.

Each of the four elements was assigned to different groups or individuals within the larger team. This individual thesis is undertaking the fourth element of the project, utilising multi-material 3D printing to develop and improve three aspects of the percutaneous drainage procedure; The efficiency of the catheters drainage speed, the insertion and removal of the drainage catheters tip and simulated anatomy models. As there have been no developments or patents for the percutaneous drain in over a decade, there is a unique opportunity for an introduction of novelties that will assist in the improvement of the procedure. While a component of a more significant study, this thesis asks the question,'How can design research and multi-material 3D printing, provide innovative insights to improve the clinical performance of percutaneous drains?'

This thesis, therefore, aims to identify areas where the researcher's expertise and resources can foster innovation. It proposes creative methods of idea generation, prototyping and communication that can, with 3D printing, be a design enabler within a larger collaborative project. Utilising 3D printing to develop the catheters drainage speed, insertion process and procedural planning will improve the efficiency of the overall procedure by; decreasing patients surgical and recovery time, procedural issues, as well as introduce the potential for customisation. The personal approach of this thesis is to work alongside healthcare professionals cohesively, to produce an efficient and novel drainage catheter design, through the extensive use of multi-material 3D printing.

OVERVIEW OF CHAPTERS

Chapter one: Background Research
Background research was undertaken to understand the advantages and disadvantages of the current percutaneous drainage procedure. 3D printing was also analysed to acknowledge the level of incorporation already within the medical industry, using case studies to strengthen the research.

Chapter two: Methodology
Two main methodologies were used in this thesis; research for design and research through design. This chapter discusses the chosen methods to understand the topic, as well as create an improved product from the proposed question.

Chapter three: Design composition
The design composition chapter is the largest as it covers all three design areas; simulated anatomy, drainage efficiency and the drainage tip. All three areas are cohesively developed through 3D printed iterations, analysis and innovative thinking.

Chapter four: Conclusion
The conclusion chapter of this thesis discusses the personal journey, 3D printing technologies and collaborations that have assisted in the development of designs and the results equated through research and rapid prototyping.

Figure 3. The current Pigtail catheters drainage holes.

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BACKGROUND

This background review explores and discusses three key themes;
- current percutaneous drains and procedures;
- additive manufacturing on a Global and National scale; and
- medical applications of 3D printing.

The literature discussed within this review aims to explore existing percutaneous drainage information and experiments, as well as gaps in the current research which requires further investigation. Research will be conducted using scholarly sources, alongside case studies covering the current percutaneous drain and the issues surrounding the procedure.The dynamics of 3D printing will also be discussed, why it is advantageous and how 3D printing is utilised in the medical industry.

Gaining clarity on the current research and competing products will generate new ways of thinking in response to the proposed research question. This information is essential as it ensures the same mistakes will not be made throughout the design process, creating a product that improves on the discussed issues regarding the current percutaneous drainage procedure.

1.1 PERCUTANEOUS DRAINAGE PROCEDURE

An abscess is an infected fluid collection within the body that causes pain, fever and chills (Charles, 2012). As seen in figure 5, percutaneous drainage is a medical procedure where Interventional radiologists use live image guidance, such as computed tomography (CT) or ultrasound, to place a thin needle and catheter into the abscess to drain the infected fluid from an area of the body (Meyer, Schaller, Rohde, & Hassler, 1994).

The percutaneous procedure has rapidly become the procedure of choice, proving to be more advantageous in comparison to the only alternative, open surgery (Meyer et al., 1994). However, while percutaneous procedures are advantageous in some ways, the success rate of the procedure can still be developed and improved, which would minimise common complications (Lambiase, 1991).

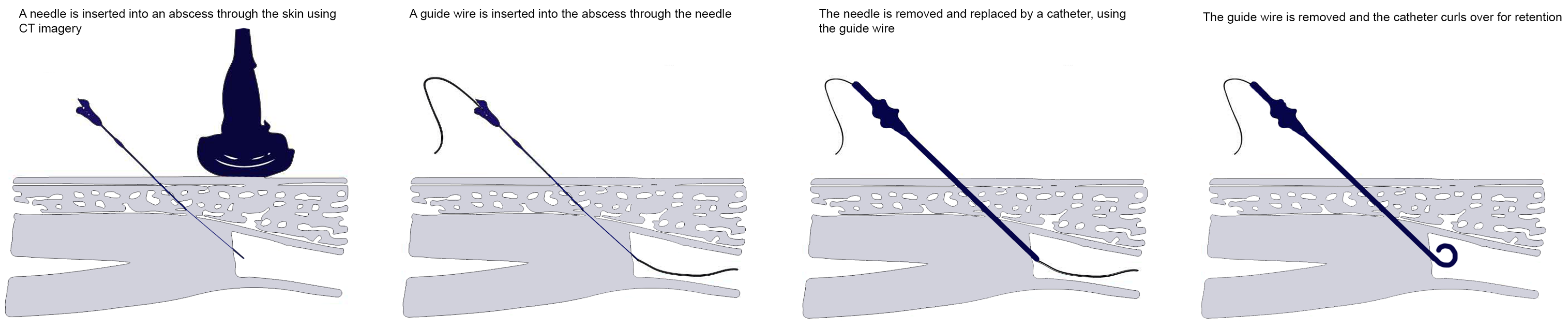
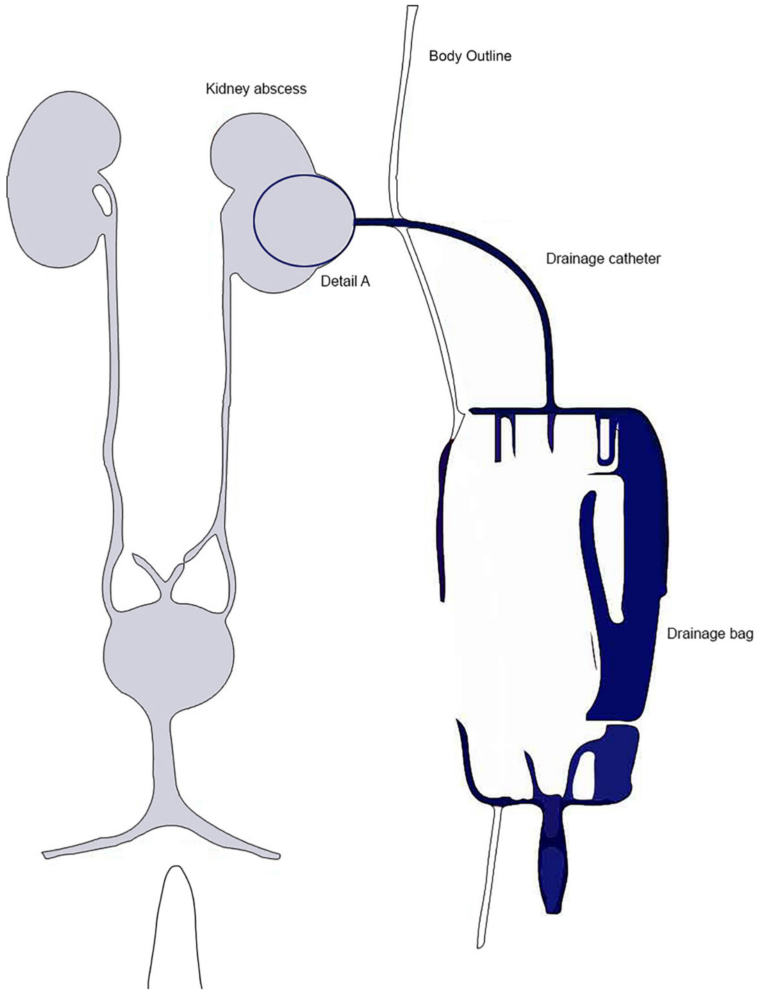


Figure 4. Diagram explaining how the Pigtail catheter is inserted, using CT imagery for guidance.



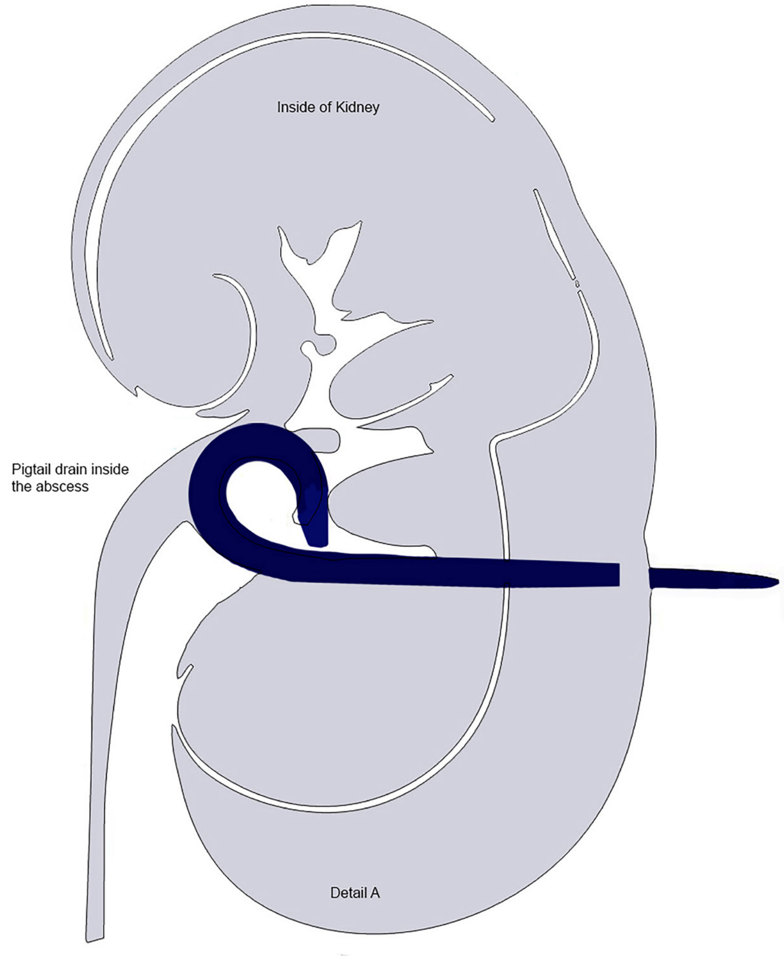


Figure 5. Diagram of the Pigtail drain inside an abscess, showing the drains entire shape and how it secures within.

CASE STUDIES

The most commonly used drainage catheter is the Pigtail drain (see figure 7). These must be cleaned or replaced at least once a day (Macha, Thomas, & Nelson, 2006). While there has been no recent development of the percutaneous drains, some tests and experiments have been undertaken to improve drainage flow, size and shape of current drainage catheters. However, these tests have not resulted in the emergence of a new drain design.

One specific experiment tested and compared different brands of single-lumen catheters to evaluate and determine whether the size and shape of the catheter can improve the drainage flow rate. The following parameters are some of the comparisons within this experiment;

- flow rates between catheters of the same size;
- whether changing the fluid viscosity (consistency) has a substantial effect on the flow rates; and
- the tendency of catheters to kink (Macha et al., 2006).

The results produced from this experiment were as expected, with the larger catheters producing the most efficient drainage flow rate between the different catheter brands. However, when a thicker viscosity of the fluid is introduced, this difference disappears. The use of a more viscous liquid decreases the drainage speed, resulting in the flow rate being the same between the catheter sizes (Macha et al., 2006). These results were informative as the majority of fluid within an abscess is thicker, consisting of combinations of blood and pus, therefore the size of the catheter does not create a large enough difference for drainage.

A separate experiment tested the influence that the number of catheter holes has on the drainage efficiency (Ballard, Alexander, Weisman, Orchard, Williams & D'Agostino, 2015). Three different drainage catheters were constructed and tested (see figure 6):

- an open-ended model with no side holes;
- bilateral side hole model; and
- unilateral side hole model.

The evacuated water from a reservoir was tested and measured at ten-second intervals. The results from all three catheter models were later analysed (Ballard et al., 2015). The results suggest that beyond the side hole number threshold (three), adding more side holes does not improve the catheters drainage efficiency for any of the catheters (Ballard et al., 2015). The results of this experiment are beneficial; however, water is not an accurate testing substitute for the necrotic matter. The results might have been different if thicker viscosities were tested for validation.

Despite these drainage efficiency experiments, there is still a significant gap in the research. The efficiency of the drain has been evaluated covering the number of holes and the size of the catheter. However, there are many other approaches to efficiency that have the potential for improvement. Which include, developing and testing the size and shape of the catheters side holes, more comfortable insertion and removal of the catheter for maximum comfort and the security of the drain.

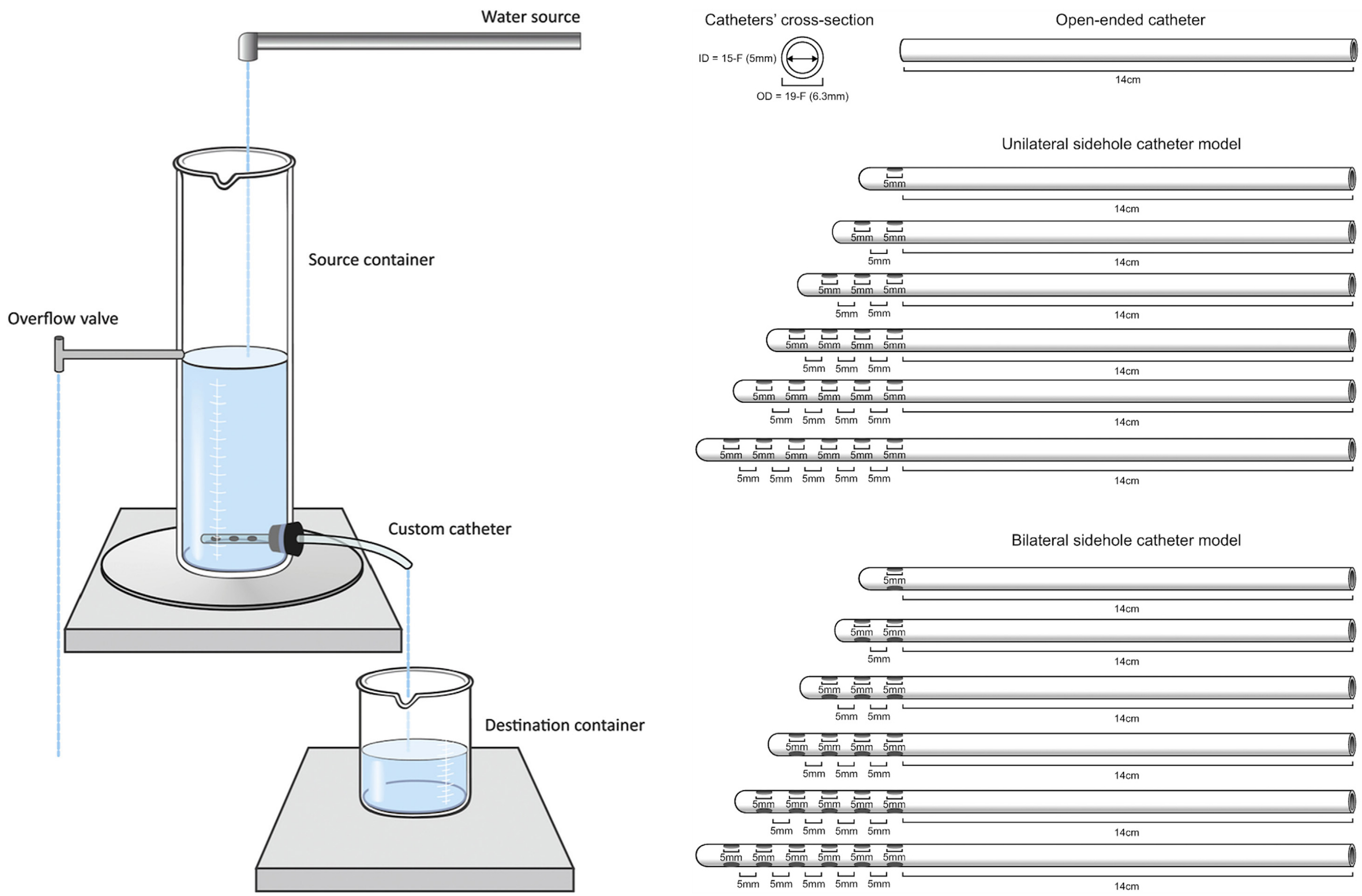


Figure 6. Schematic diagram of the drainage output-measuring device in which the custom drainage catheters were inserted. Alongside catheters and dimensions that were tested and analysed (Ballard et al., 2015).

ISSUES AND COMPLICATIONS

With every medical procedure, some complications and issues arise due to various reasons. Difficulties need to be made aware of for the safety of the patient. Such as;

- it is vital for the body to be positioned correctly to prevent organ damage for example when a lung or other organ is accidentally punctured (Matlaga, Shah, & Assimos, 2006);
- during the drainage procedure, saline solution is used as an irrigant, and occasionally the body can absorb high levels of fluid causing fluid overload (Charles, 2012);
- infection is one of the primary health issues as the needle can come loose and introduce bacteria into the wound; and
- methodological issues regarding the percutaneous drainage procedure are the drainage flow, clogging of the drainage catheter holes and the internal string loosening (see figure 7), which can cause bleeding, sepsis and infection (Charles, 2012). Nonetheless, it is inevitable that complications may occur during or after percutaneous surgeries (Matlaga et al., 2006).

While the complications for the patient are apparent, the percutaneous procedure requires less surgical and recovery time due to smaller incisions than open surgery (Charles, 2012). The antibiotic availability has much broader coverage, resulting in easier penetration of the abscess walls. This allows the drainage procedure to be applied on a broad range of body parts and organs with relative success (Lambiase, 1991). Some of these procedures include neck infections, ovarian abscesses and occasionally septic joints, with other areas continuing to be explored (see figure 8).

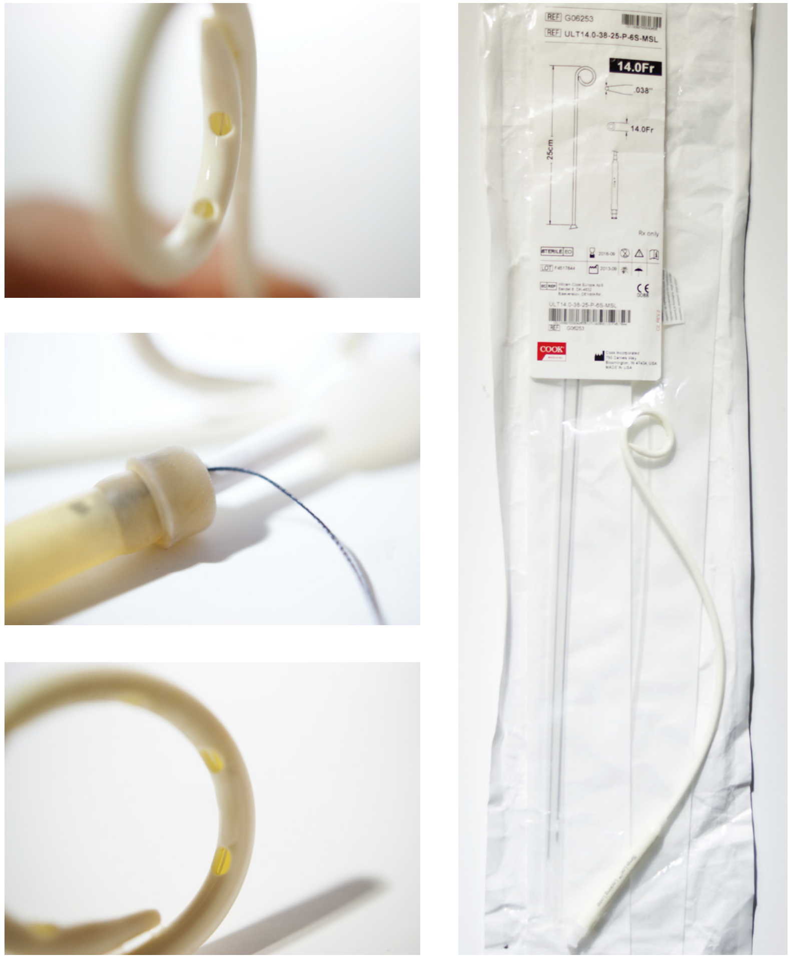


Figure 7. Three views of the current Pigtail drain, highlighting the internal string and drainage holes. As well as the catheter packaged for use.

OVERVIEW OF ABSCESS LOCATIONS

The below overview of abscess locations is an anatomical map of the potential areas of the body an abscess or cyst may develop. During the drainage procedure, every individual's body is different; including the amount of fat or tissue that is penetrated or the internal pathway the catheter takes. The map (figure 8) below, reveals that an abscess can develop in a variety of locations in the body.

Therefore, the design of the catheter needs to be suitable for a range of viscosities of liquid, wall thicknesses and bodily movements. Figure 8 shows collections inside the peritoneum space, under the skin, in the scalp, stomach, pancreas and neck as well as near the kidney and spinal cord . Thus, highlighting the areas of the body that allow for abscesses to accumulate in conjunction with the surrounding organs.

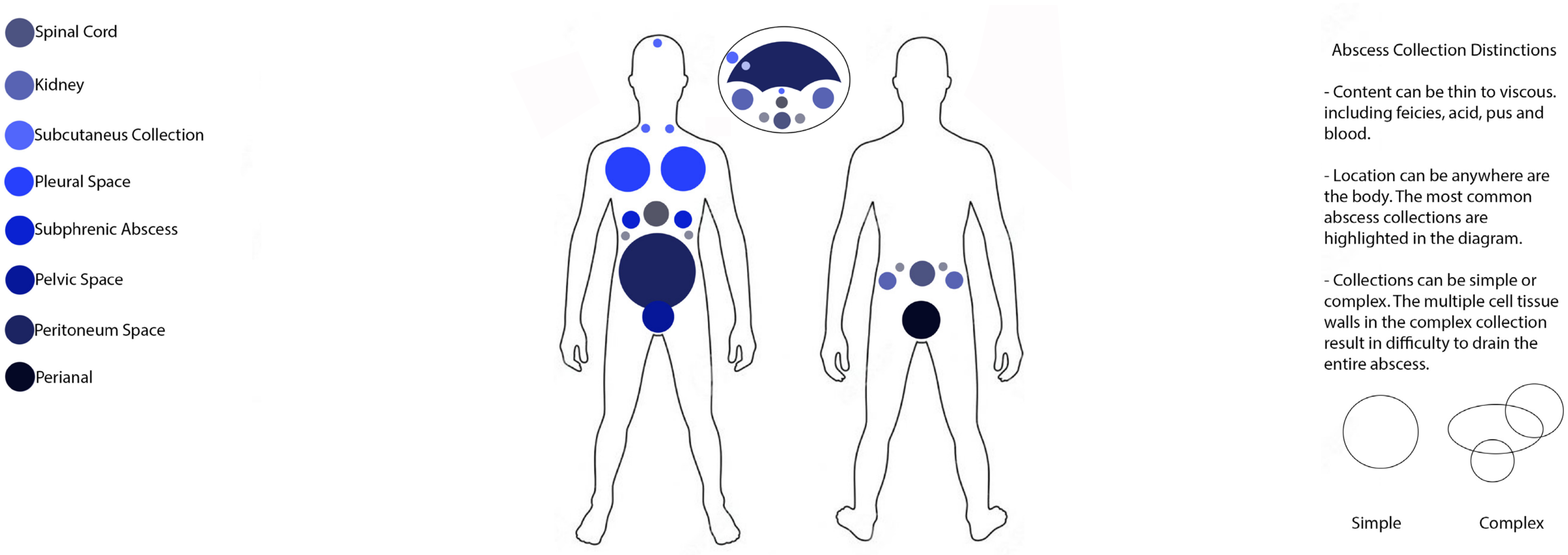


Figure 8. Anatomical map visualising the variation of abscesses locations.

1.2 3D PRINTING: GLOBAL USES AND ADVANTAGES

Additive manufacturing (AM), more commonly known as 3D printing, was invented by Charles Hull in the early 1980's and has been revolutionising the world of design since (Campbell, Williams, Ivanova & Garrett, 2011). 3D printing produces forms and products layer by layer (additively), creating three-dimensional objects on demand (Ford & Despeisse, 2016). 3D printing offers many distinct advantages. Firstly, because of the additive building process, 3D printing processes can generate complex geometries that cannot be fabricated by any other means (Lipson and Kurman, 2013). Additionally, 3D printing provides the opportunity for customisation and personalisation within designs that can target specific individuals. Through technology such as 3D scanning, individuals can print forms to the exact size and shape they desire. "3D printing offers us the promise of control over the physical world" (Lipson and Kurman, 2013, pg11).

As well as this, the 3D printing process has the potential to reduce waste, thus providing the opportunity for sustainable design and production processes. Rejected prototypes can be shredded and recycled, creating a life cycle for each design and reducing the amount of non-recyclable waste. 3D printing, if utilised correctly, could significantly reduce resource and energy demands as well as process-related CO2 emissions (Gebler, Schoot Uiterkamp, & Visser, 2014). Especially when compared to traditional subtractive techniques where the shape is cut from an existing billet, leaving behind material chips that cannot be reused. 3D printing does not only provide materialisation advantages, but it also provides the opportunity for instant production on a global scale. The designs, in file form, can instantly travel around the world to be printed or edited (Campbell et al., 2011). Because of these advantages, 3D printing will provide profound ecological and environmental improvements within the design industry.

3D PRINTING DISADVANTAGES

Although 3D printing provides many advantages, with any innovative technology there are barriers and challenges to exploit the technologies advantages fully. 3D printing is entering the mass production market; however, 3D printers can only produce one 1.5-inch cube in an hour (Campbell et al., 2011). Other techniques such as injection moulding can produce several cubes in under a minute. 3D printing does not have the capabilities to keep up and compete with these time constraints for mass production. Therefore, the use of 3D printing is essentially for lower production rate products such as customisation tools (Campbell et al., 2011.

Polymers, alloys of aluminium, steel and titanium, as well as ceramic and wooden composites are currently printable materials. However, the use of the variety of materials is dependable on the type of 3D printing used and can decrease the prints overall strength and detail (Gebler et al., 2014). Polymers are also very slow to biodegrade without the help of other chemicals. Because of this, additional materials will be continuously developed so they can either be recycled and reprinted or biodegrade more efficiently (Campbell et al., 2011).

MULTI-MATERIAL 3D PRINTING

Multi-material 3D printing is an intriguing and successful aspect of the Additive Manufacturing industry. There are various multi-material 3D printers including the Connex Objet350 printer, the Stratasys J750 and 3D systems, which can utilise up to ten variations of materials in one single print (Reichl & Inman, 2016). The printer has two base materials: VeroWhitePlus, which is a rigid material, and TangoPlus, which is a flexible translucent material (Reichl & Inman, 2016). These printers produce dynamic, high-quality forms that other applications of additive manufacturing cannot (see figure 9).

3D printing is only made possible through the digitisation of design and manufacturing. Associated technologies such as 3D scanning and online platforms, allow for Computer Aided Drawings (CAD) to be generated using software and online systems (Lipson and Kurman, 2013). These systems of 3D modelling include Solidworks, Fusion, Rhino and online sources such as Autodesk.

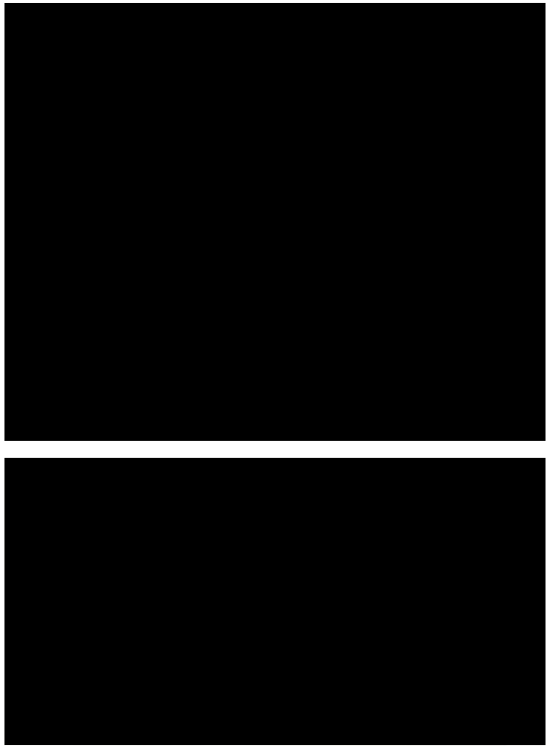


Figure 9. Connex prints of a human skull and foot to portray the difference between hard and soft materials ("Biomimetic Anatomical Models | Stratasys", 2018).

MEDICAL 3D PRINTING APPLICATIONS AND ADVANTAGES

3D printing practices are rapidly expanding within the medical industry, and are expected to revolutionise the current and future application of medical tools (Ventola, 2014). 3D printing within this field is best suited for custom prosthetics, implants, anatomical surgical planning and prototyping of medical devices (Stratasys, 2018). There are many advantages to incorporating 3D printing into the medical industry, including the customisation for individual patients, cost effectiveness, increased productivity and enhanced collaborations with other fields (Ventola, 2014).

The customisation is the most advantageous aspect of 3D printing, benefiting the medical industry as every patient's anatomy is unique. 3D printing will provide the opportunity to customise prosthetics and equipment to suit every procedure efficiently. Also, customised surgical tools can reduce recovery time, surgery time and the overall surgeries success (Ventola, 2014).

Having the ability to re-design and improve equipment and procedures can speed up waiting times and improve patient care. STL (Standard Tessellation Language) files also provide the opportunity to share designs amongst fellow researchers with ease, as well as publish the files online to the public, allowing the data to be shared on a global scale with no shipping costs (Rengier et al., 2010).

Another benefit of 3D printing provides the medical industry is cost efficiency. Smaller production runs for personalised printing increases profitability due to the need for continuous prototyping and customisable attachments (Ventola, 2014). As well as efficiency, 3D printing within the medical manufacturing field will increase accuracy, reliability and resolution (Rengier et al., 2010). These improvements will be particularly beneficial for personalised medical equipment.

MEDICAL 3D PRINTING DISADVANTAGES

Although there are many benefits to medical 3D printing, the issue of safety and security continues to arise. There is the possibility for substandard medical equipment to be developed which has the potential to cause damage to the industry and its reputation. 3D printing does not always produce products with the same surface finish or strength that other materials and techniques may provide (Berman, 2012). Developed materials that benefit the medical industry are difficult to gain approval (Ford & Despeisse, 2016). Although medical materials and products have been 3D printed and approved in the past, the FDA (Food and Drug Administration) demands may complicate 3D printed medical products on a larger production scale (Ventola, 2014). The FDA has developed a working group to evaluate technical and regulatory considerations regarding 3D printing in the medical industry (Ventola, 2014).

The use of custom 3D-bioprinted implants is a procedure that is applied to orthopaedic surgeries with increasing frequency. Non-custom made implants do not necessarily match the patient and often require excision of significant quantities of bone (Parvizi, 2017). Companies such as Ossis, a Christchurch based company, manufactures and customises human joints for implants or replacements. The implants are fabricated through CT scanning and CAD software and 3D printed in titanium (see figure 10). At Ossis, each implant is individually modified for every patient by the surgeon and engineer to ensure a perfect match, reducing issues and increasing each surgeries accuracy ("Ossis", 2018).

3D printing applications have been investigated on several levels through the Victoria University of Wellington Design Masters programme. The MADE (multi-property additive-manufacturing design experiments) research stream allows students to explore multi-material technologies to produce products such as 3D printed prosthetics and anatomies that are customised for specific clients ("Designed Prosthetics | MADE," n.d.).

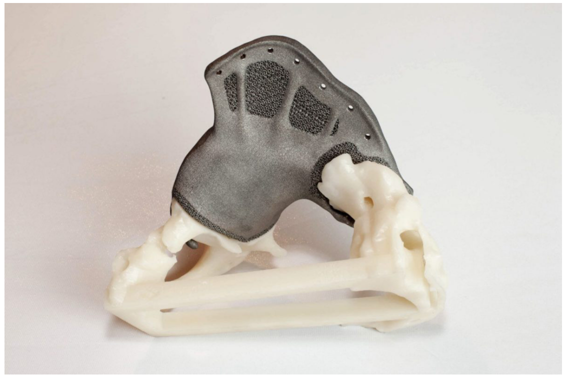


Figure 10. Customised 3D printed hip joint using titanium polymers ("Ossis", 2018).

SIMULATED ANATOMY

The topic of 3D printing has gained interest in the medical industry because of the increasing potential it offers surgeons, radiologists and patients (Ballard, Trace, Ali, Hodgdon, Zygmont, DeBenedectis & Lenchik, 2018). The most immediate possibility being presurgical planning, teaching and customisation (Ballard et al., 2018). Procedural planning models can be 3D printed using multi-material printers for surgeons to practise complex procedures (see figure 11). Not only potentially reducing human error, but also providing the opportunity to foresee theoretical issues during or after the procedure, as the complex anatomy is unique to each patient (Ventola, 2014). "Normally, if you make a mistake, you're making it on a baby. Here's an opportunity with 3D models to make the mistakes on the models . . . So when you perform on a baby, you're already an expert" (Stratasys.com, 2018). Treatment planning allows radiologists to organise the safest option for each patient before the surgery, to save operational time (Ballard et al., 2018).

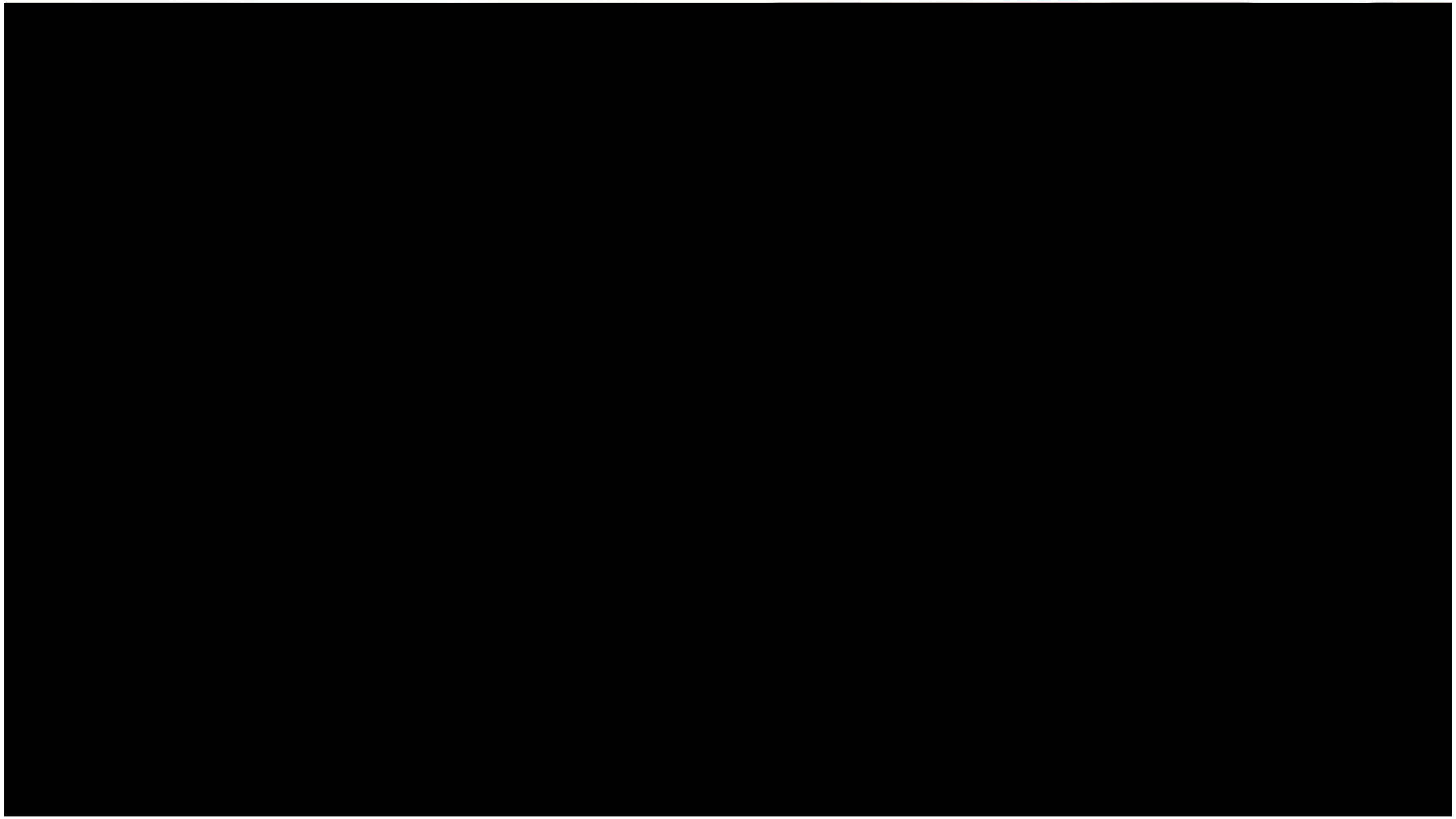


Figure 11. Simulated anatomy model for planning procedures (Medicine, 2018).

SIMULATED ANATOMY

Simulated Anatomy is a Victoria University of Wellington Masters project by Hamish McIntosh (2015). McIntosh focused on multi-material 3D printing to simulate the human anatomy. Hamish experimented with the multi-material 3D printer to create a lifelike model of the human neck, including the skin, muscles and windpipe (see figure 12). This outcome was through an experimental process of material tests which were consistently reviewed by clinicians. The idea behind the project was to create customised 3D printed models for medical training and an anatomical understanding (McIntosh, 2018).

Figure 12. 3D Connex printed model of a human neck, highlighting the variation in materials (McIntosh, 2018).

BIOMIMICS

BioMimics are highly realistic 3D printed models of human anatomy for Physician training and medical testing (see figure 13). BioMimics models eliminate restrictions associated with current training techniques on animals or mannequins, as the multi-material technology can effectively mirror the soft tissue and hard bone of the human anatomy that other means may not (Stratasys, 2018). Animal’s anatomy does not perfectly match that of humans, and the mannequins do not cohesively recreate the live-tissue feel. Stratasys is one of the leading companies to 3D print tools and anatomies to incorporate into the medical environment (Stratasys, 2018).

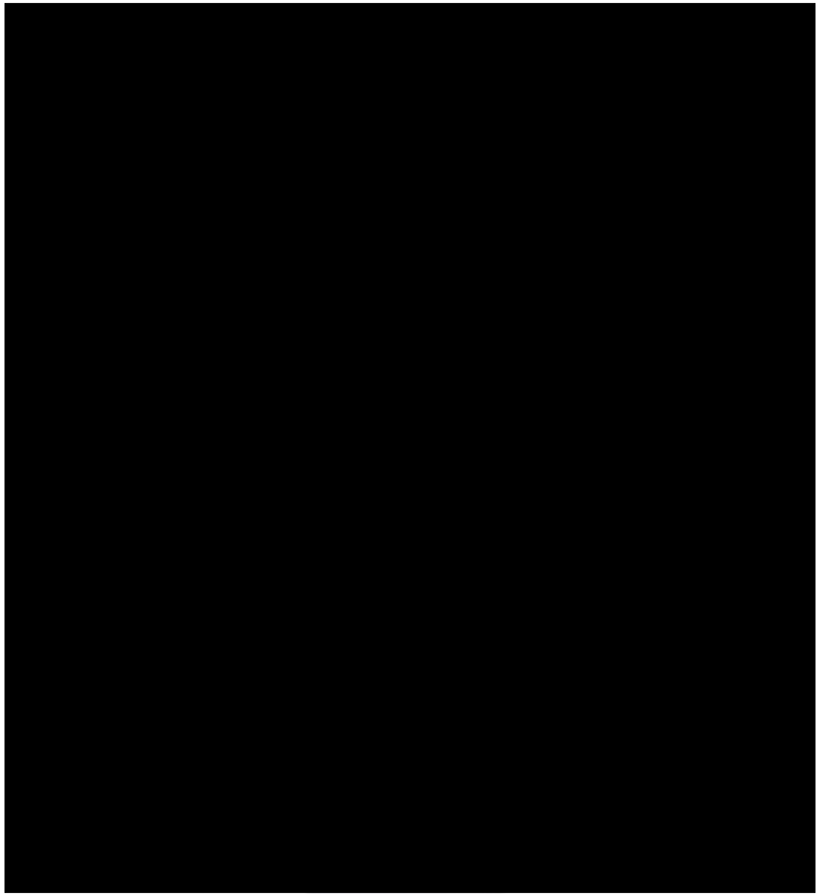


Figure 13. 3D printed human anatomy models of various parts (“Biomimetic Anatomical Models | Stratasys”, 2018).

1.4 OVERVIEW OF CURRENT DRAINAGE CATHETERS

Cook Medical is New Zealand's leading catheter design and production company and is the primary catheter distributor for Auckland Hospital. Cook Medical has 189 drainage catheters and supporting tool designs currently on the market ("Products - Cook Medical", 2018). A competitor analysis is paramount in this thesis to avoid repetition. It also provides insight as to how the designs can be developed to include novel geometries while still being accepted into the industry. Many of these products, including the Pigtail, Malecot and aspects from the more novel catheters were precedents for the design phase of this thesis. The information and images in figures 12-16 are all gathered through the Cook Medical website (2018).

Biliary Catheter

The Biliary catheter is inserted into the bile duct when it becomes blocked. The drainage tube is penetrated through the skin into one of the livers bile ducts for drainage, assisting in patient relief.

Figure 14. Cook Medical Biliary catheters ("Products - Cook Medical", 2018).

Balloon Catheter

[redacted]

The Balloon catheter is used to clear an obstructed or narrowed region; achieved through the insertion of a small inflatable balloon into the canal, duct or blood vessel.

Malecot Catheter

[redacted]

The Malecot catheter is used post surgeries, for drainage. The soft latex shape is incorporated to enhance retention and promote drainage.

Figure 15. Cook Medical Balloon catheters (“Products - Cook Medical”, 2018).
Figure 16. Cook Medical Malecot catheters (“Products - Cook Medical”, 2018).

Novel catheter forms

[redacted] [redacted]

The novel catheter forms use a variety of shapes for retention and drainage. These catheters were chosen for the competitor analysis because of the hole shape and orientation.

Pigtail Catheter

[redacted] [redacted]

The Pigtail catheter is the most commonly used catheter. Its purposes is to drain thin to thick mucus within an abscess or cyst.

Figure 17. Cook Medical novel catheters ("Products - Cook Medical", 2018).
Figure 18. Cook Medical Pigtail catheters ("Products - Cook Medical", 2018).

1.5 BACKGROUND CONCLUSION

3D printing is expected to play a significant part in the inclination toward personalised healthcare applications. Furthermore, 3D printing has become a valuable and potentially transformative tool within the medical industry. The applications developed are due to an increase in printer performance, resolution and availability of materials (Michalski & Ross, 2014). The medical innovations that have been created using 3D printing are incredibly significant and will continue to develop in the future.

3D printing can improve the percutaneous drainage procedure in many ways, specifically the drainage catheters. 3D printing allows for cost-effective, accurate prototyping, which produces developments efficiently. The personalisation aspect of additive manufacturing is a vital method to customise catheters for specific body parts, organs or people. In doing so, this can reduce the risks and dangers involved in the procedure as they are explicitly designed for that process. The connex printer allows multi-material products to be made, which can contribute to an innovative and successful catheter design that can bend and mould to the human body. As continuous developments are made, the FDA will approve these before human testing, which previous research has shown is vital.

The next chapter is Methodology, which explains and justifies which methods will be used for each of the above project aspects.

Figure 19. 3D printed iteration models from all development phases.

2

METHODOLOGY

This thesis conducted an exploration of multiple research design approaches, including research for design and research through design. This thesis primarily focuses on Research through design, annotated using visual and verbal documentation, together with collaboration methods. These methods have been implemented to assist in clear communication between various medical, scientific and design fields. Both research for design and research through design are part of the 'Double Diamond' design process model (see figure 20) developed by Design Council (2018).

Discover- Learning and understanding
Define- Gaining Focus
Develop- Generating possible solutions
Deliver- Refining solutions that work

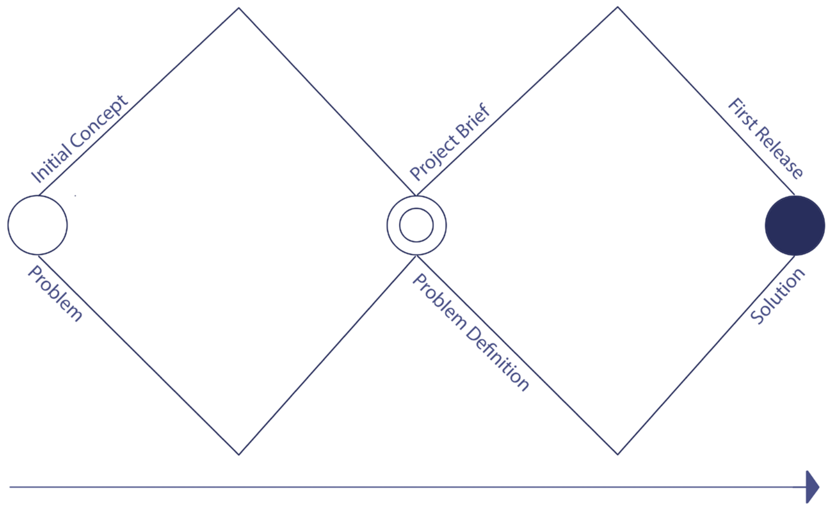


Figure 20. Double Diamond Design process model (Design Council, 2018).

2.1 RESEARCH FOR DESIGN

Research for design (RfD) is phase one of the Double Diamond diagram (see figure 20) and is often used in collaboration with the word development. This directly relates to design, as it means (according to the Old English Dictionary) 'work directed towards innovation, introduction and improvements of products and processes' (Frayling, 1994). RfD has many benefits for the design process as a whole. It improves the relevance of the finalised design, increases the robustness of the design practice and improves the designers understanding on current theories and common mistakes (Akker, Gravemeijier, McKenney, & Nieveen, 2006). Within this thesis, background research is also necessary to understand the current medical procedure of the percutaneous drain, through scholarly sources and more importantly, collaborations with professionals within the medical industry.

BACKGROUND RESEARCH

The aim of the initial background research displayed in this thesis was to understand the entire drainage procedure, the current drainage catheters on the market, human anatomy and how 3D printing could benefit the medical industry. This was achieved through an extensive literature review, competitor analysis of the current catheters on the market and case studies highlighting current uses of 3D printing within the medical industry.

COLLABORATIONS

The collaboration and input from a range of healthcare professionals provided crucial support within this project. Meetings and skype calls were conducted with the medical personnel to discuss the personal direction within the greater team. As well as informational meetings about the human anatomy and the location of abscesses (see figure 8), as well as receiving results from their testing process (see appendix 1). Observations of percutaneous medical procedures took place at Auckland Hospital to gain on hand experience of the drainage procedure, the insertion and removal of the catheter as well as issues with the current catheter that may arise during or after the procedure. Clinical observations provide information and experience that written literature cannot. Design applications such as 3D printed objects, which can be seen and felt, also act as a communicative tool between the different industries, allowing individuals to gain a more comprehensive understanding than words and images allow.

Figure 21. Issy Hawkins in the operation theatre to gain a comprehensive understanding of the percutaneous drainage procedure.

2.2 RESEARCH THROUGH DESIGN

Research through design (RtD) is the second, third and final step of the Double Diamond diagram. RtD allows analysis of ideas through initial idea generation, 3D Computer Aided Drawings (CAD) or renders and 3D printed physical models. This allows for a comprehensive review of material quality and strength, movement and form shape and size. The information gathered from each set of iterations becomes the basis for the development of each design. This specific design approach is practice based. It is concerned not only with creating physical iterations but also with the overall method of evaluating the process through reflections, discussions and inquiry (Miltons & Rodgers, 2013).

IDEA GENERATION

Idea generation is at the forefront of the design process. Initial work for this project began with sketches (see figure 22) and discussions to develop an understanding of what is expected, as well as what has the potential for improvement.

Figure 22. Idea generation in the process, through sketches inside a design log book.

CAD MODELLING

CAD (Computer Aided Drawings) modelling, also known as 3D modelling, can be achieved through software such as SolidWorks, Rhino and Keyshot. This software produces 3D models to 3D print or render (see figure 23). CAD modelling is also a crucial step for analysis, allowing the models to be evaluated and developed physically regarding form shape.

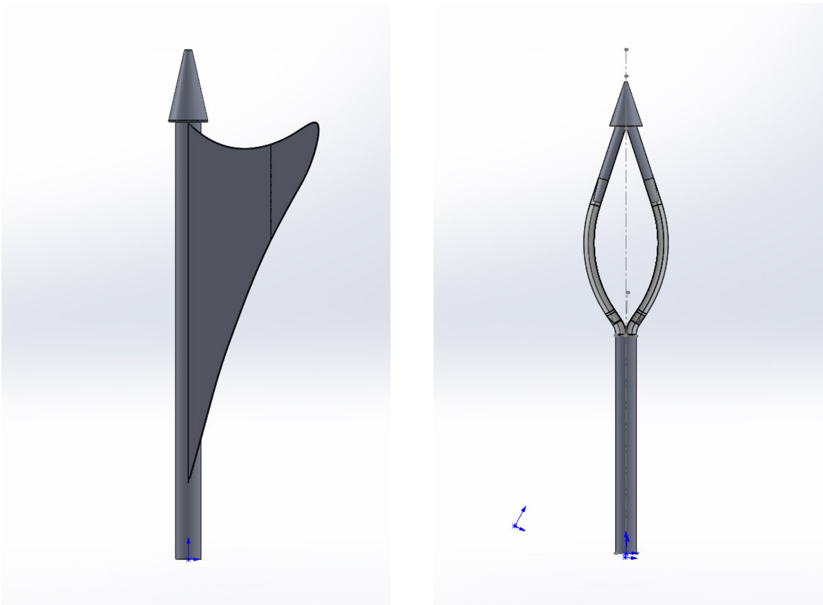


Figure 23. The Twist and Eggbeater drain in CAD form. These models are developed on Solidworks and then 3D printed.

3D PRINTING

3D printing could not be achieved without the use of CAD files. 3D printing has been utilised heavily throughout this thesis as a frame of reflection and inquiry. The physical models allow for evaluation of the materials strength and durability regarding the forms shape as well as the intended application (see figure 24). Multi-material 3D printing has been utilised in this project, providing many options for the materials development.

Figure 24. 3D printed downward expansion model, experimenting with multi-material properties.

ANALYSIS

Each step of the design process highlights attributes and aspects that require reflection to ensure the best possible design outcome. This analysis could be achieved through discussions or individual thinking. The below figure (25), portrays overlaying sketches to understand and visualise analysis ideas for each proposed concept.

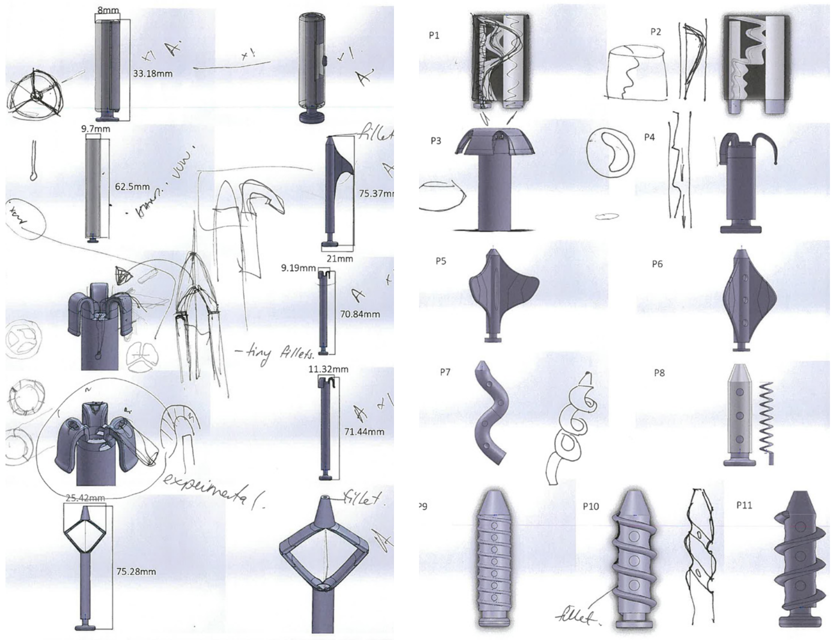


Figure 25. CAD models of multiple iterations. The physical models are analysed and developed accordingly.

Figure 26. The final Eggbeater drain, highlighting the forms external design and the internal cavity.

3

DESIGN OUTPUTS

Simulated anatomy model

Drainage efficiency model

Catheter tip model

Figure 27. 3D printed iterations of the simulated anatomy, drainage efficiency and catheter tip models; all design outputs.

This chapter describes the design process in detail and divides the investigation into three elements.
The three elements (as seen in figure 27) are:
3.1 Simulated anatomy models;
3.1 Efficiency drainage models; and
3.3 Innovative pathway and retention models.

The simulated anatomy models utilise form design and multi-material properties that provide context for the new drains, gaining justification for design adjustments during the development phase.

The efficiency drainage models are a testing tool that presents multiple hole configurations to understand which combination of size, shape and hole orientations create the most efficient drainage speed.

The innovative pathway and retention models incorporate novel form designs and 3D printed material structures. These designs range from innovative developments on the current pigtail drain to a complete restructure of the drainage catheter and the overall procedure.

Figure 28. Visualising the Pigtail catheter through the simulated anatomies clear lid, for pre-surgical planning and context for design developments.

3.1 SIMULATED ANATOMY

The simulated anatomy model (see figure 28) creates a fluid form that emulates an abscess, visualising how the drain reacts during the drainage procedure. The developed drains cannot be tested on humans. Therefore the SAM provides an innovative method of design validation through analysis of the form during the synthesised procedure. To create a more realistic representation of an abscess, internal cavities that fill with air were introduced within the forms walls. The SAM has the potential for additional use including, student learning, patient understanding and pre-surgical planning. This form of communication will create a comprehensive knowledge for the patient to visualise the precautions they will need to take before and after the surgery.

The SAM could also be used by surgeons and radiologists to foresee theoretical issues. Especially for complex abscess procedures, where the drain has to pierce through multiple layers of tissue (Ventola, 2014). 2D imagery does not always provide enough information to anticipate procedural issues. However, with models derived from patient scans, refined therapeutic approaches can be generated before entering the operating theatre (Stratays, 2018). The simulated anatomy models were created using CAD modelling software and were 3D printed using the Connex multi-material 3D printer.

The design process is established through initial model sketches (see figure 29) and CAD modelled forms (see figure 30) to decipher whether the idea has potential. The early designs utilise a rounded shape designed to fit the current standard Pigtail drains (6.0mm in diameter). The drain enters the SAM using the same method as it would insert into an abscess; by being elongated over a stent or guide wire (Meyer, Schaller, Rohde, & Hassler, 1994).

The overall purpose of this design is first, to visualise the new drains properties within a similar environment to an abscess and secondly, to test the endurance of each drains external forms retention techniques. The lid is 3D printed using a veroclear (hard) material for the patient or radiologist to cohesively understand the drain while it is in use, to observe how it may move within a cavity. The lid is also designed to click on an off as another option for a more evident viewpoint.

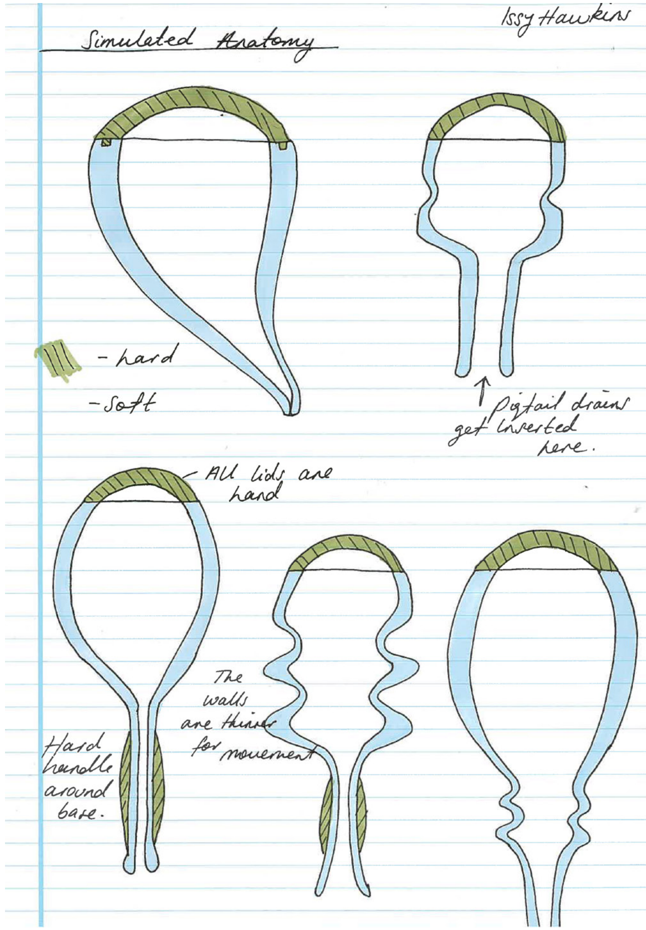


Figure 29. Simulated anatomy sketches of the initial model ideas.

The SAMs external form is the next area of focus, concentrating on a more abstract structure that represents the unsystematic attributes of an abscess more realistically. In the future, these designs could be created using CT or 3D scans of abscesses and 3D printed. The SAM would be a replica of each patient's unique internal form.

These unusual shapes test the variated conditions a drain could be inserted into successfully before the procedure begins. Thus eliminating potential procedural issues that could arise before or after the operation. The SAM provides a means for radiologists to safely practice or teach complex procedures on, reducing risks involved for the patient.

Following this development, rippled edges are established around the abscesses body to enhance the bendability of the form and increase the fluidity of the movement. This requires experimentation to work, as the softness of the available 3D materials also determine the flexibility of the structure's walls.

The softer materials influence kinking, preventing further drainage. The thicker or harder forms create forced movements due to stiffer edges. Therefore, balancing the two result in fluid actions without damaging the overall drainage flow.

Figure 30. CAD modelled simulated anatomy forms for 3D printing rapid prototyping.

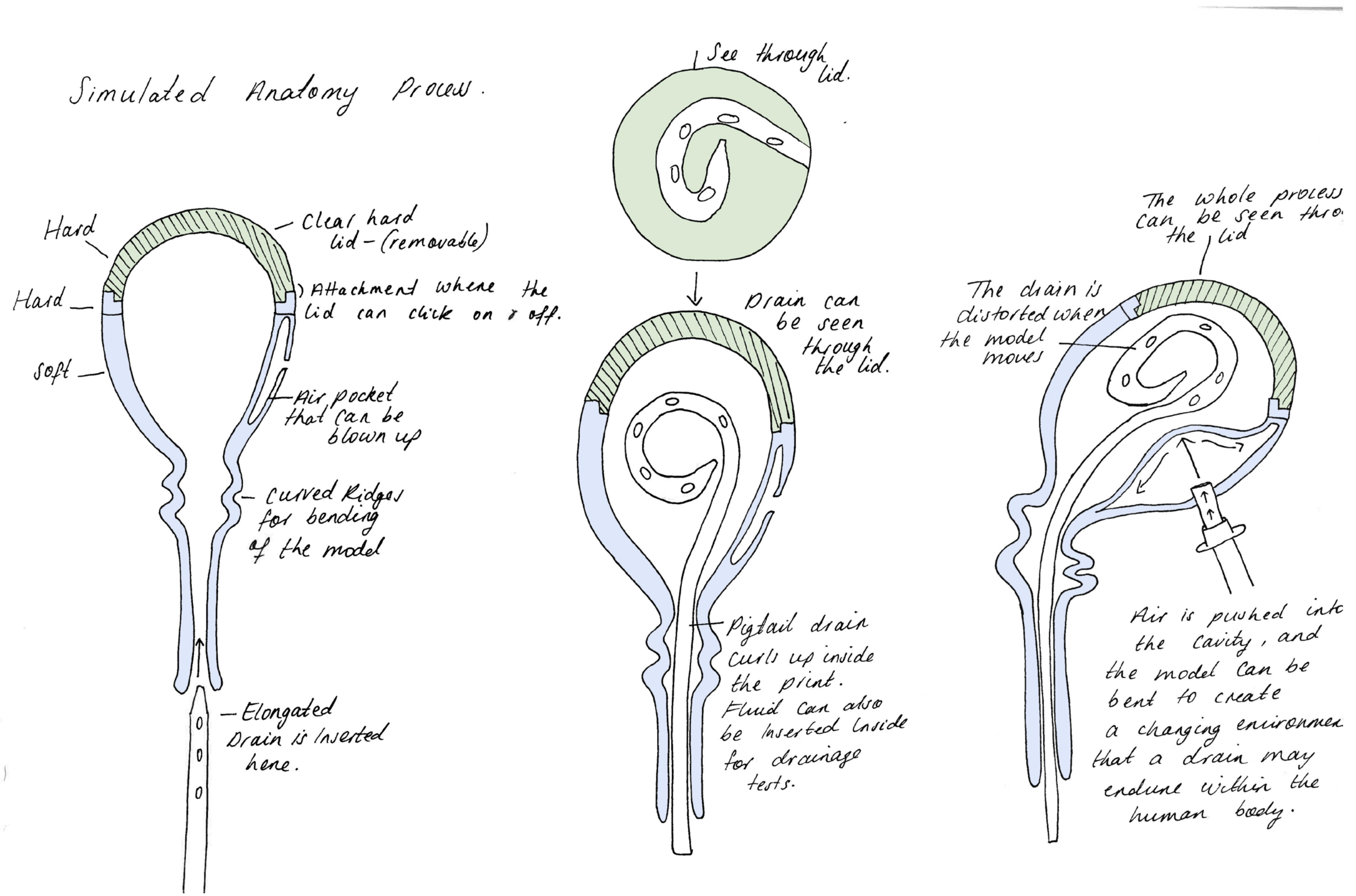


Figure 31. Developed simulated anatomy sketches, determine how the internal cavity may work. These sketches are the basis for useful design developments.

Due to an analysis of the preliminary designs, the next development stage is an introduction of active movement within the SAM (see figure 31). An internal cavity is established inside the walls of the model for inflation, to change the shape of the form abruptly (see figure 32). The inflation simulates breathing and physical movements that naturally occur within the human body. The pressure the drain has to endure during the procedure continuously changes, therefore It is essential to understand what conditions the drains can withstand for a higher success rate within the body.

Currently, mannequins or animals are exploited to simulate the human body, which does not accurately mimic human-like qualities (Stratasys, 2018). Therefore the SAM would be a beneficial contribution to the market. The internal cavity is an intricate design addition due to the required movement in conjunction with the available 3D materials. The wall needs to be thin enough to allow movement, while also acquiring strength during excessive stretching and pressure.

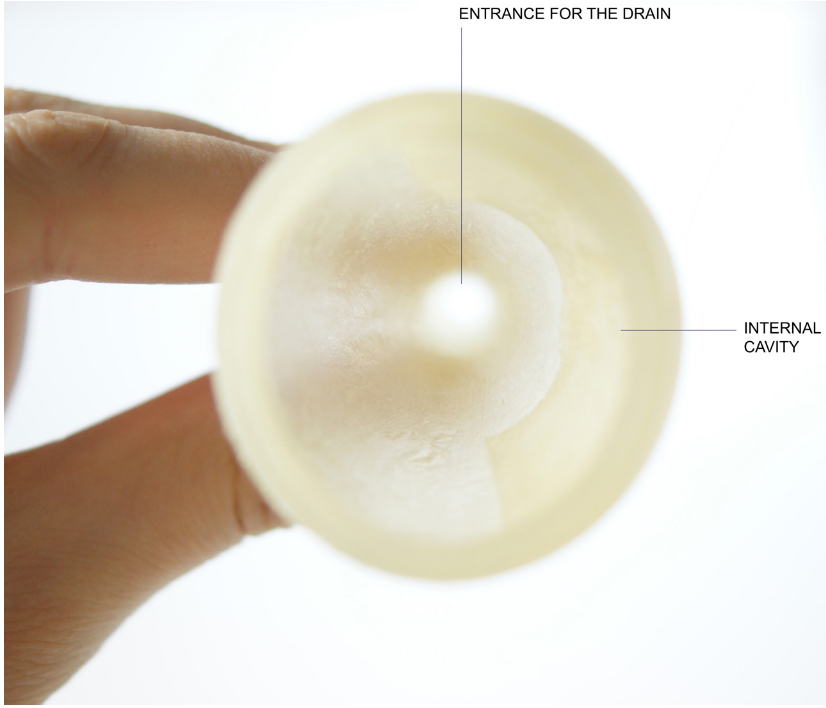


Figure 32. Bird's eye view of the simulated anatomy model, highlighting the 3D printed internal cavity.

SIMULATED ANATOMY FINAL OUTCOME

Figure 33. Simulated anatomy model rendered, with the Pigtail drain inserted to visualise the context of the human body.

Figure 34. The simulated anatomy model with the Pigtail drain inserted, with the rippled edges for fluid movement highlighted.

Figure 35. Pigtail drain inside the simulated anatomy. Visualising how the internal string can become loose or tangled before the procedure begins.

REFLECTION

The simulated anatomy model's final outcome encompasses many different features that were established during the experimentation process. These features include a generic bulbous head that can fit the current Pigtail drain and developed designs inside (see figure 33). This form has also incorporated an internal cavity into the walls, which expands when pumped with fluid to create a breathing effect. The structure has rippled edges along the body of the drain to enhance fluid movements and to make the conditions more drastic for the drain to withstand (see figure 34). Also, the removable lid of the SAM is clear and hard, so the user can observe the up and coming procedure, as well as remove it when necessary.

The fluid movements and geometric shapes the SAM portrays was managed through the extensive use of 3D modelling and printing. 3D printing is a platform for innovative thinking and rapid prototyping which creates unlimited opportunities for development. Although multi-material 3D printing can create issues with physical integrity and strength, it has granted an idea to form which has the potential to be used within a clinical setting, to help improve the efficiency, safety and patient understanding of the percutaneous drainage procedure specifically (see figure 35).

Alongside the Simulated Anatomy model, straight catheter forms were designed using a variation of hole combinations. These variations include size, shape and orientations which are tested against each variable to decipher the most efficient combination. The results are analysed within the next subchapter, and the most efficient combination will be incorporated into the developed drain design.

Figure 36. 3D printed efficiency drainage models for testing.

3.2 DRAINAGE EFFICIENCY

Drainage efficiency is a prominent issue with the current percutaneous drains on the market due to insufficient drainage speed and a high percentage of clogging of the catheter (Ventola, 2014). Therefore, 3D printing is introduced as a prototyping and communicative tool to provide models for testing and evaluation to improve these issues (see figure 36).

This subchapter focuses on the design, test results and development of the catheters drainage efficiency using hole design as the prominent feature. Each set of hole designs are tested using a variety of viscosities of liquid to determine the peak flow and dynamic flow rate. The hole designs tested are hole sizes, shapes and orientations. The 3D printed drains are sent to Auckland for testing. The results are received for analysis within this chapter to ensure accurate developments.

TESTING PROCESS

The designed drainage models are created using Solidworks, and 3D printed using a vero (hard) 3D printed material. Although the current drainage catheter is not rigid, the testing process requires a hard surface for stability to accurately measure the drainage flow speed. The tests include a variety of hole shapes (circle, oval, slot and teardrop), sizes (small, medium and large) and orientations (scattered, straight and spiral).

Information gathered during the Research For Design phase of this thesis, provides few results, highlighting the limited research within this field. These results include;
- large catheters drain more efficiently than smaller catheters, depending on the liquid's viscosity (Macha et al., 2006); And
- the introduction of more than three holes makes no difference to the drainage speed (Ballard et al., 2015).

Although these results could have been hypothesised, they still allow for an elimination of tests of required information.

This thesis is part of a larger teams project from various organisations. Within the group, multiple individuals are working on separate aspects of this project. At AUT, there is a small team working on the testing of the efficiency drains using 3D prints to ensure scientifically accurate results.

The test rig is designed to produce substantial pressure to simulate the force the body naturally provides, coercing the liquid to exit the drain. As water has such a low viscosity, glass beads and oil mixtures are combined with water to create a more realistic reproduction of necrotic matter (dead cells and pus). The information gathered from the test rig is analysed, to identify the most beneficial attributes while discarding the least favourable.

The current testing process produces relevant and accurate data, however, takes time. The process is as follows;
1. Each drain is inserted into the end of the drainage tube;
2. The liquid is poured into the funnel end of the drain, which then runs down the tunnel to exit.
3. The speed the liquid exits the drain is measured through weight sensors caught in the black bucket (see figure 37).

This process is repeated three to five time per drain, to create a fair and valid testing procedure.

The efficiency drains are designed and printed in a rigid material to precisely fit the connection at the end of the testing tube. Each drains iteration has the same area for drainage. However, the shape, size and number of holes differ to determine desirable attributes. Once the most desirable characteristics are deciphered, these holes will be incorporated into the catheters final design.

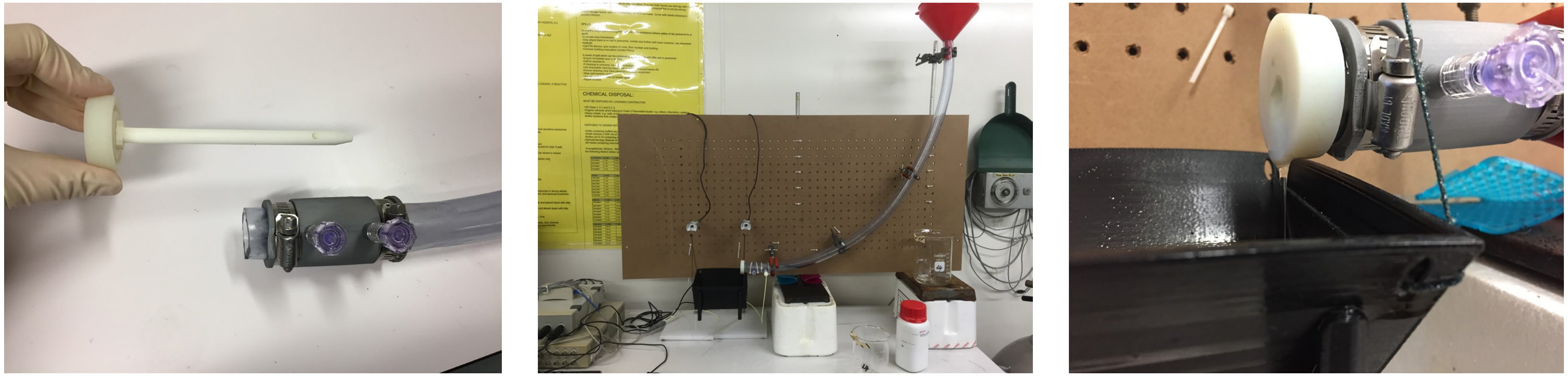


Figure 37. Three steps of the efficiency drain testing procedure.

TEST 1: HOLE SIZE AND ORIENTATION

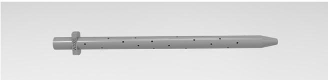
CATHETER TESTING MATRIX: HOLE SIZE COMPARISONS							
LARGE CATHETER	CODE	DRAIN HOLE SIZE	DRAIN HOLE SHAPE	DRAIN HOLE NUMBER	ITERATION NUMBER	ORIENTATION	NOTES
	WZ001	SMALL	CIRCLE	36	1	SPIRAL	Mass = 3.11 grams Volume = 3107.89 cubic mm³ Surface Area = 6268.08 mm²
	WZ002	MEDIUM	CIRCLE	10	2	SCATTERED	Mass = 3.11 grams Volume = 3107.16 cubic mm³ Surface Area = 6205.2 mm²
	WZ003	LARGE	CIRCLE	5	3	STRAIGHT	Mass = 3.11 grams Volume = 3107.09 cubic mm³ Surface Area = 6187.43 mm²
	WZ004	SMALL AND LARGE	CIRCLE	38	4	SCATTERED	Mass = 3.11 grams Volume = 3107.2 cubic mm³ Surface Area = 6251.51 mm²

Figure 38. Catheter testing matrix of hole size and comparisons.

TEST 1: HOLE SIZE AND ORIENTATION RESULTS

The hole size and orientation drains were developed (see figure 38) to understand whether a combination of hole sizes would drain more efficiently than drains with one standard size (large or small). A variation of sizes creates potential for hierarchy during drainage, with the thicker matter gravitating towards larger holes and the less viscous matter draining through the smaller holes. It would also allow for constant drainage if the larger holes get prematurely blocked.

Each graph is titled using codes. These codes represent a viscosity of fluid that has been tested ranging from water like substances to oil/pus that have been made using hydrocarbons and tested at 37 degrees.
D500 = (219 mPa)
N75 = (66.82 mPa)
N35 = (30.12 mPa)
S3 = (2.434 mPa)
mPa = Measure of pressure

The dynamic flow and peak flow have been tested and recorded for each set of results. Peak flow is measured using the top drainage speed. The dynamic flow slope marks each catheters pressure drop per-flow rate. A smaller flow slope is more advantageous for a catheter because it creates a higher pressure that would assist in the drainage efficiency.

The mixed combination of hole sizes produced the most efficient results as seen in figures 39-42. Creating this set of test drains was challenging to ensure each designs surface area was the same. However, they are sufficient to infer a favourable result at this stage. These results will be reconfirmed with moderated models. These results show an improvement to the current pigtail drains design, which utilises the single sized holes.

HOLE SIZE AND ORIENTATION DYNAMIC FLOW SLOPE COMPARISONS

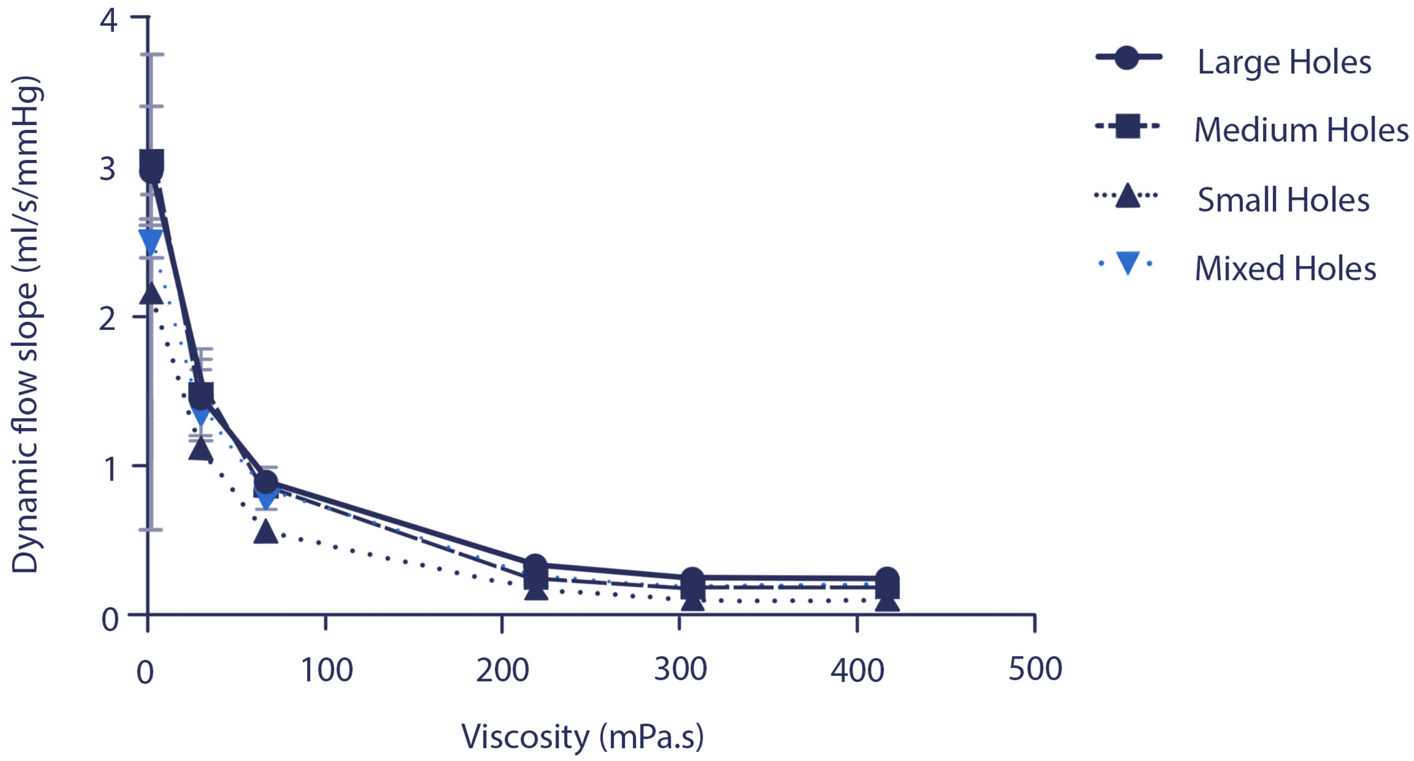


Figure 39. Hole size and orientation dynamic flow slope comparisons.

HOLE SIZE AND ORIENTATION DYNAMIC FLOW SLOPE OF MULTIPLE VISCOSITIES

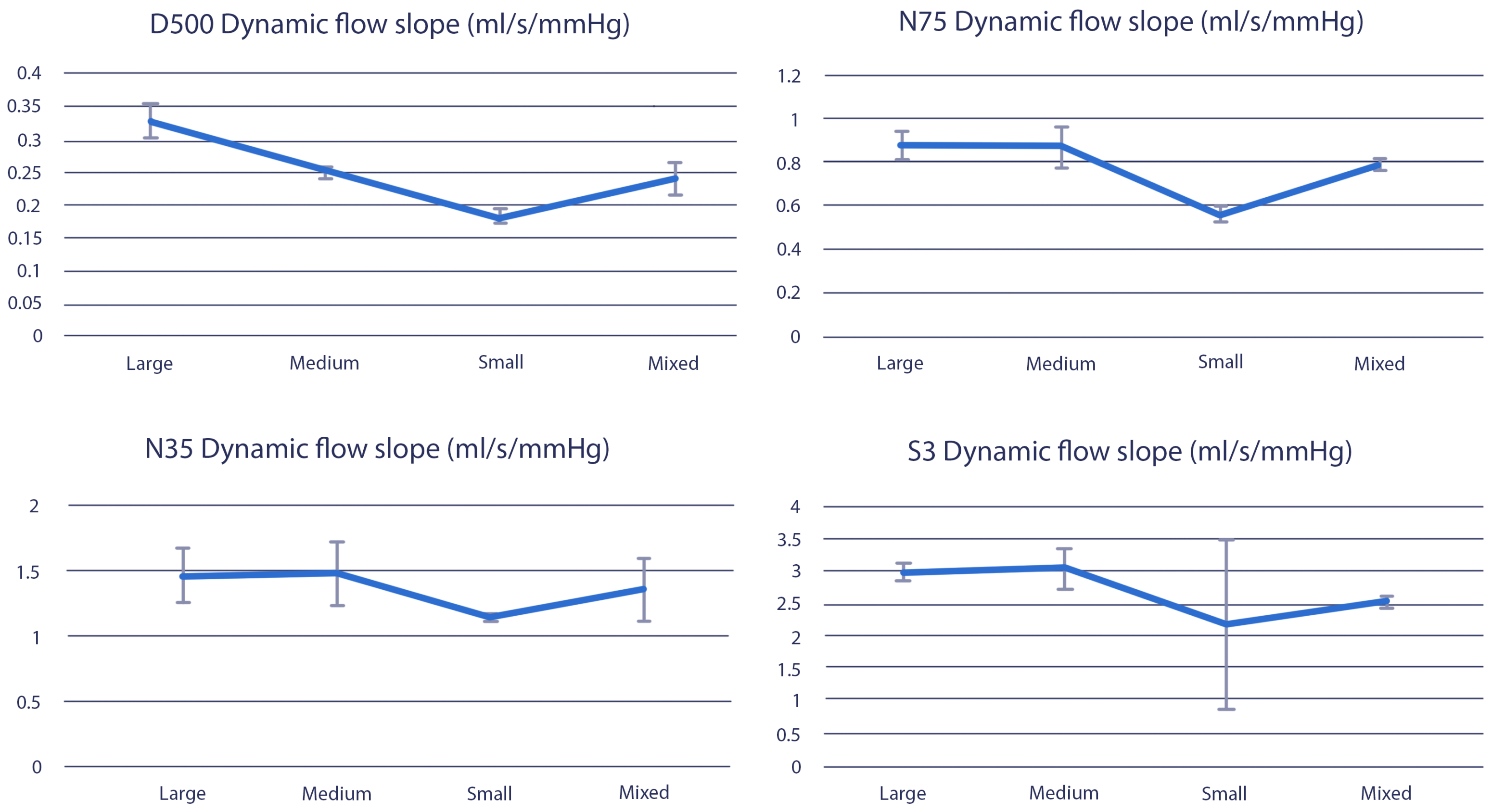


Figure 40. Hole size and orientation dynamic flow slope of multiple viscosities.

HOLE SIZE AND ORIENTATION PEAK FLOW COMPARISONS

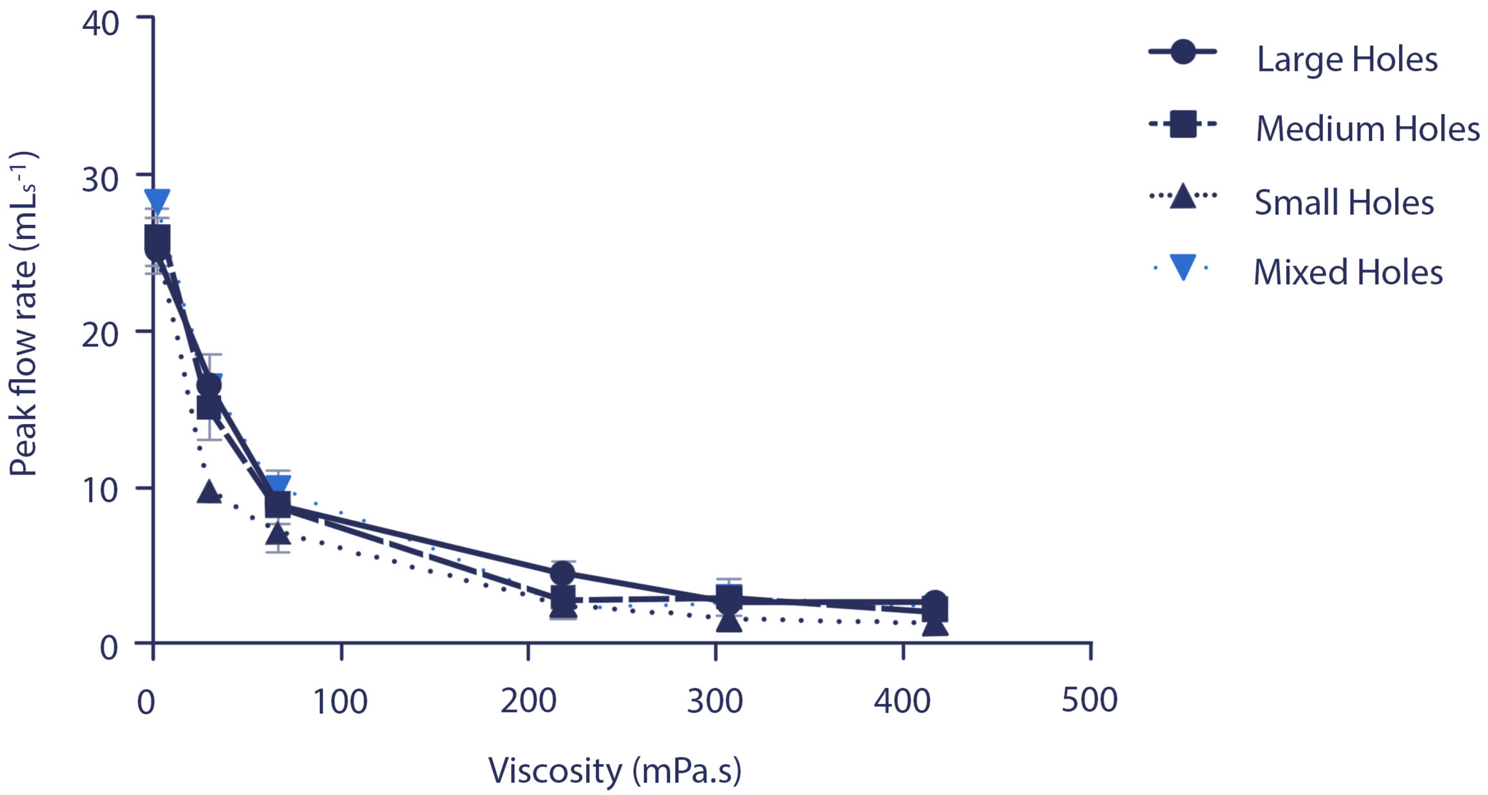


Figure 41 Hole size and orientation peak flow comparisons. .

HOLE SIZE AND ORIENTATION PEAK FLOW OF MULTIPLE VISCOSITIES

Figure 42. Hole size and orientation peak flow of multiple viscosities.

TEST 2: HOLE SHAPE AND SIZE

CATHETER TESTING MATRIX: HOLE SHAPE AND SIZE

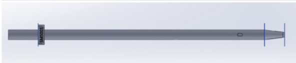
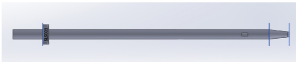
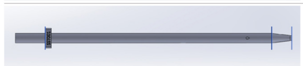
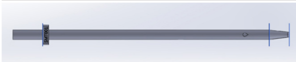
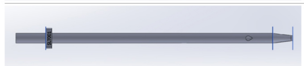
SMALL CATHETER	CODE	CATHETER SIZE	DRAIN HOLE SIZE	DRAIN HOLE SHAPE	ITERATION NUMBER	NOTES
	SSC001	SMALL	SMALL	CIRCLE	1	Mass = 1.77 grams Volume = 1769.25 cubic mm^3 Surface area = 3515.14 mm^2
	SMC001	SMALL	MEDIUM	CIRCLE	1	Mass = 1.77 grams Volume = 1767.67 cubic mm^3 Surface area = 3515.21 mm^2
	SLC001	SMALL	LARGE	CIRCLE	1	Mass = 1.77 grams Volume = 1765.09 cubic mm^3 Surface area = 3511.32 mm^2
	SSO001	SMALL	SMALL	OVAL	1	Mass = 1.77 grams Volume = 1769.32 cubic mm^3 Surface area = 3516.08 mm^2
	SMO001	SMALL	MEDIUM	OVAL	1	Mass = 1.77 grams Volume = 1767.77 cubic mm^3 Surface area = 3516.37 mm^2
	SLO001	SMALL	LARGE	OVAL	1	Mass = 1.77 grams Volume = 1765.42 cubic mm^3 Surface area = 3512.71 mm^2
	SSS001	SMALL	SMALL	SLOT	1	Mass = 1.77 grams Volume = 1769.27 cubic mm^3 Surface area = 3515.75 mm^2
	SMS001	SMALL	MEDIUM	SLOT	1	Mass = 1.77 grams Volume = 1767.75 cubic mm^3 Surface area = 3516.08 mm^2
	SLS001	SMALL	LARGE	SLOT	1	Mass = 1.77 grams Volume = 1765.34 cubic mm^3 Surface area = 3512.47 mm^2
	SST001	SMALL	SMALL	TEARDROP	1	Mass = 1.77 grams Volume = 1769.23 cubic mm^3 Surface area = 3515.32 mm^2
	SMT001	SMALL	MEDIUM	TEARDROP	1	Mass = 1.77 grams Volume = 1767.68 cubic mm^3 Surface area = 3515.56 mm^2
	SLT001	SMALL	LARGE	TEARDROP	1	Mass = 1.77 grams Volume = 1765.20 cubic mm^3 Surface area = 3511.83 mm^2

Figure 43. Catheter testing matrix of hole shape and size.

TEST 2: HOLE SHAPE AND SIZE RESULTS

The second set of efficiency drains tested the difference between a variety of hole shapes, testing one hole per catheter (see figure 43). These were tested using large and small catheters with small, medium and large holes. The multiple shapes tested were oval, circle, slot and teardrop.

Comparing the results from each shapes testing process highlights specific dimensions that allow the dead matter to drain more efficiently than others. These shapes were also altered in size to see how small the hole can be while still draining efficiently. Although the hole sizes and shapes change, each sized catheter had the same overall surface area and were, therefore, able to be compared.

The following graphs in figures 44-47, highlight the difference in results between the large holes in the large catheter. The large catheters test results have been elaborated as there is a more significant difference between each shape, creating a more straightforward analysis of results. The test results established using the small catheters validate these results.

The below graphs show that the oval holes have the most efficient drainage flow with the lowest dynamic flow slope (DFS). The results are highlighted in bright blue to create a distinct difference and allow for precice analysis.

HOLE SHAPE AND SIZE DYNAMIC FLOW SLOPE COMPARISONS

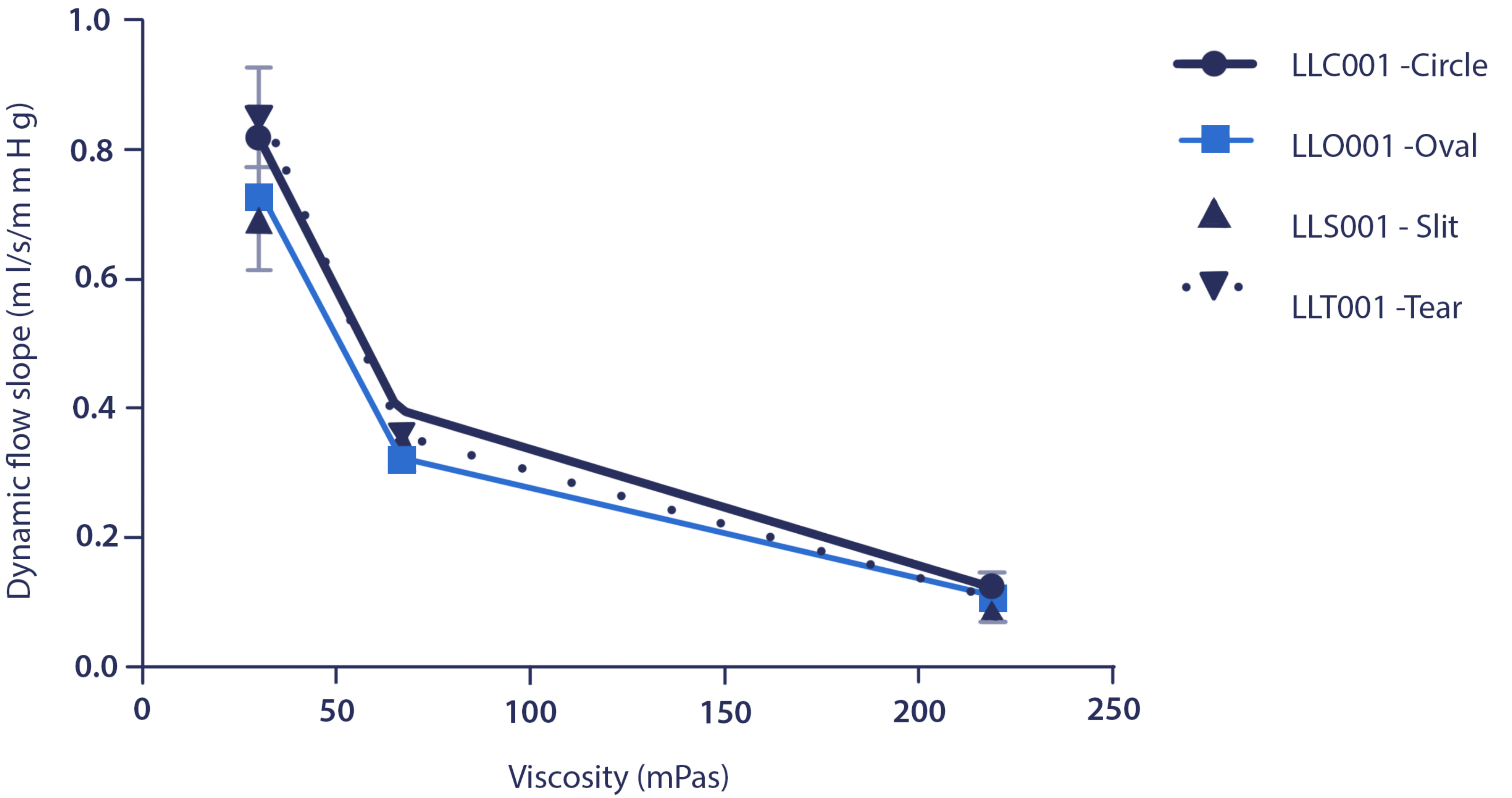


Figure 44. Hole shape and size dynamic flow slope comparisons.

HOLE SHAPE AND SIZE DYNAMIC FLOW SLOPE OF MULTIPLE VISCOSITIES

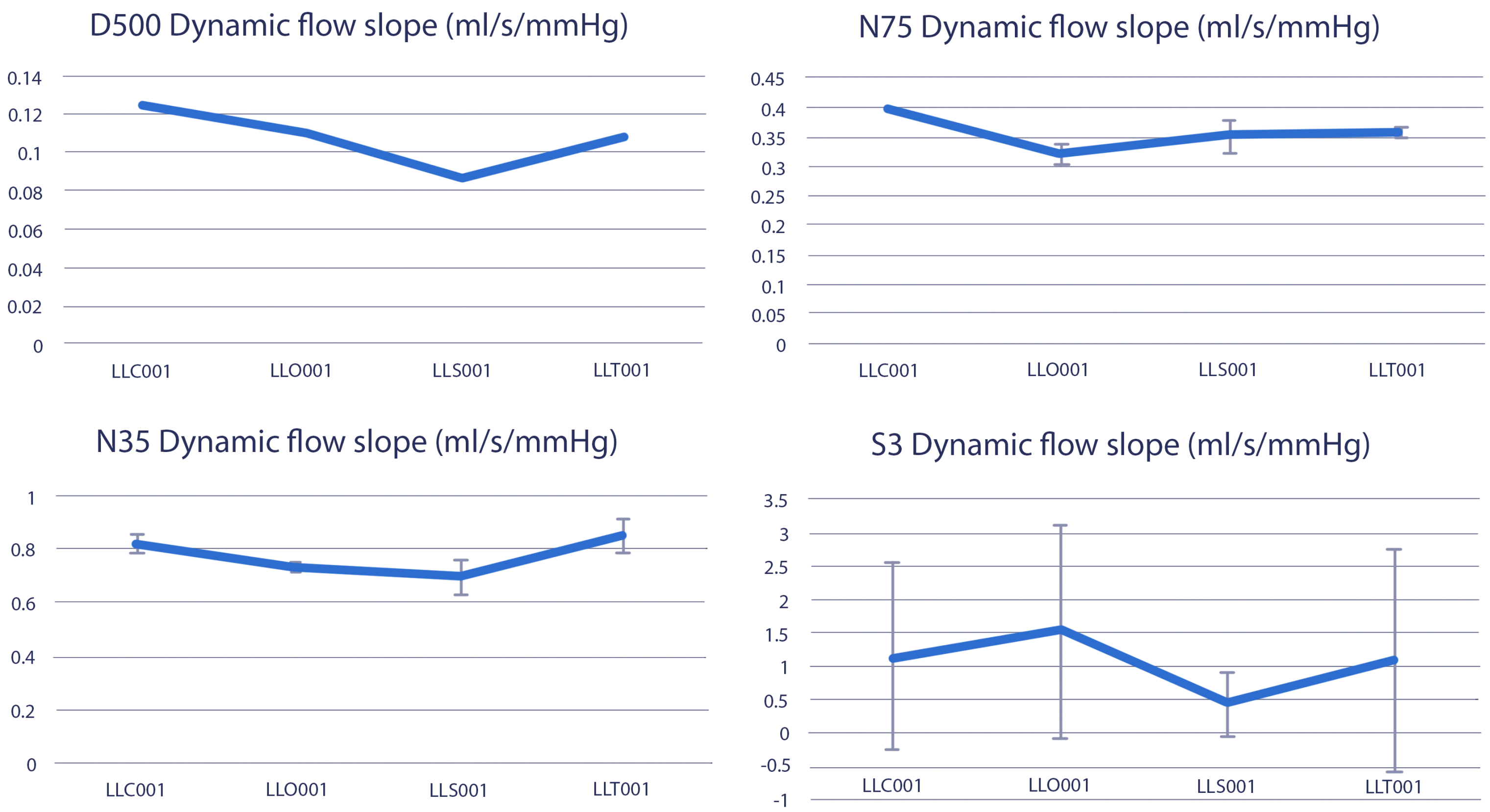


Figure 45. Hole shape and size dynamic flow slope of multiple viscosities.

HOLE SHAPE AND SIZE PEAK FLOW COMPARISONS

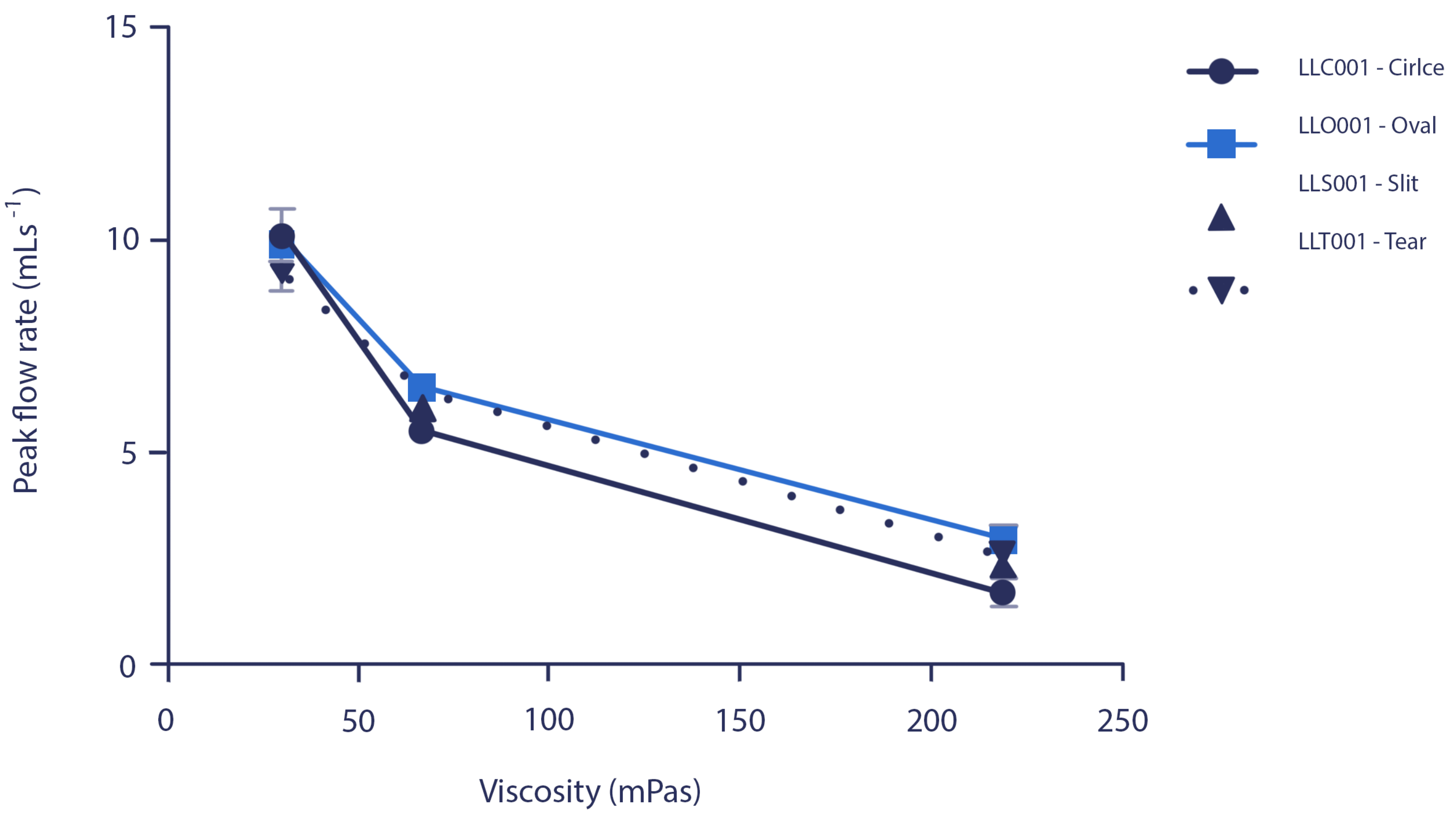


Figure 46. Hole shape and size peak flow comparisons.

HOLE SHAPE AND SIZE PEAK FLOW OF MULTIPLE VISCOSITIES

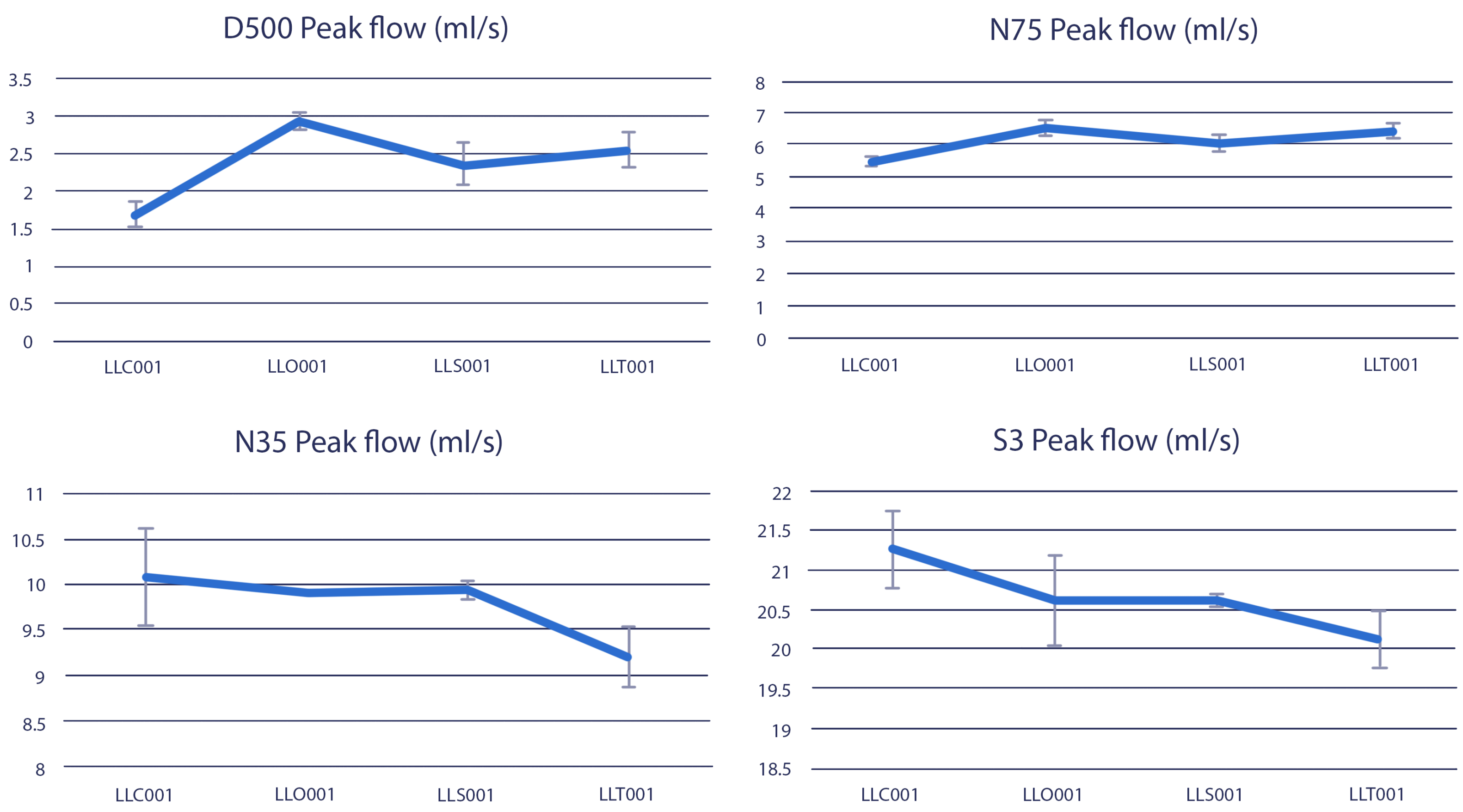


Figure 47. Hole shape and size peak flow of multiple viscosities.

TEST 3: HOLE SHAPE AND ORIENTATION

CATHETER TESTING MATRIX: 4 HOLE SPIRAL AND LINE PATTERN

LARGE CATHETER	CODE	CATHETER SIZE	DRAIN HOLE SIZE	DRAIN HOLE SHAPE	ITERATION NUMBER	ORIENTATION	NOTES
	LLC002	LARGE	LARGE	CIRCLE	2	SPIRAL	Mass = 3.1 grams Volume = 3096.1 cubic mm^3 Surface Area = 6125.94 mm^2
	LLO002	LARGE	LARGE	OVAL	2	SPIRAL	Mass = 3.1 grams Volume = 3097.46 cubic mm^3 Surface Area = 6131.89 mm^2
	LLS002	LARGE	LARGE	SLOT	2	SPIRAL	Mass = 3.1 grams Volume = 3097.78 cubic mm^3 Surface Area = 6135.43 mm^2
	LLT002	LARGE	LARGE	TEARDROP	2	SPIRAL	Mass = 3.1 grams Volume = 3096.91 cubic mm^3 Surface Area = 6130.12 mm^2
LARGE CATHETER	CODE	CATHETER SIZE	DRAIN HOLE SIZE	DRAIN HOLE SHAPE	ITERATION NUMBER	ORIENTATION	NOTES
	LLC003	LARGE	LARGE	CIRLCE	3	STRAIGHT	Mass = 3.1 grams Volume = 3096.04 cubic mm^3 Surface Area = 6126.33 mm^2
	LLO003	LARGE	LARGE	OVAL	3	STRAIGHT	Mass = 3.1 grams Volume = 3097.34 cubic mm^3 Surface Area = 6131.78 mm^2
	LLS003	LARGE	LARGE	SLOT	3	STRAIGHT	Mass = 3.1 grams Volume = 3097.76 cubic mm^3 Surface Area = 6135.58 mm^2
	LLT003	LARGE	LARGE	TEARDROP	3	STRAIGHT	Mass = 3.1 grams Volume = 3096.58 cubic mm^3 Surface Area = 6131.86 mm^2

Figure 48. Catheter testing matrix of hole shape and orientation.

TEST 3: HOLE SHAPE AND ORIENTATION RESULTS

The orientation catheters were designed using four holes of the same four shapes and sizes that spiral around the lumen of the catheter. These were each tested against the same sized shaped holes oriented in a straight line (see figure 48). Each individual catheters surface area is equal. During the current drainage catheters procedure, the dead matter congregates around the first drainage hole and neglects any other, slowing down the drainage process as well as heightening the chance of clogging. This test is to understand whether a change in the orientation could make a difference in the drainage efficiency by spreading out the use of drainage holes, thus, reducing clogging.

The results seen in figures 49 and 50, highlight no valid difference in results between the oval shape orientations. Although the straight drains results are drawn in bright blue, this was not to highlight the most efficient results, only for an easier differentiation between the two. The straight and spiral designs both produced equal results, therefore no preference can be infered. The same test will be undertaken between the cirlce, slot and tear drop designs for validation, however, will not be analysed within this thesis.

HOLE SHAPE AND ORIENTATION DYNAMIC FLOW SLOPE COMPARISONS

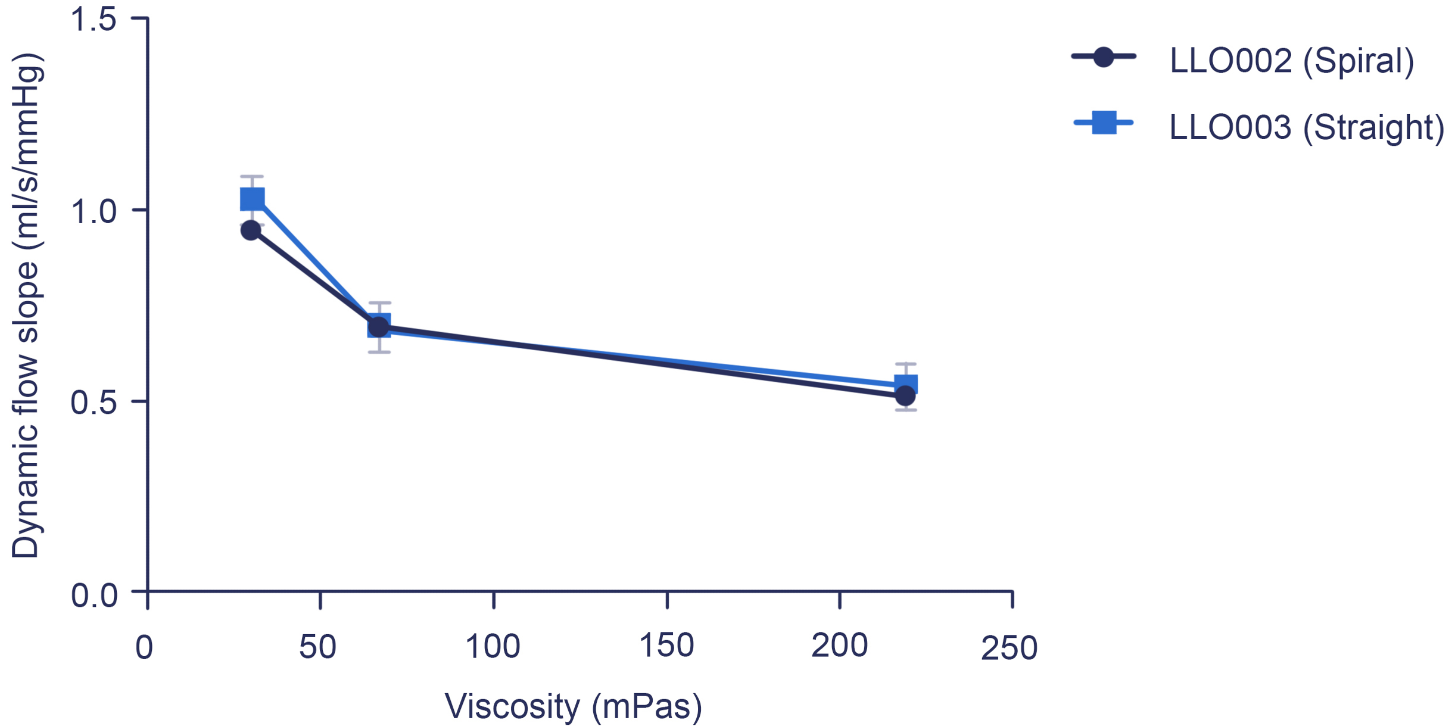


Figure 49. Hole shape and orientation dynamic flow slope comparisons.

HOLE SHAPE AND ORIENTATION PEAK FLOW COMPARISONS

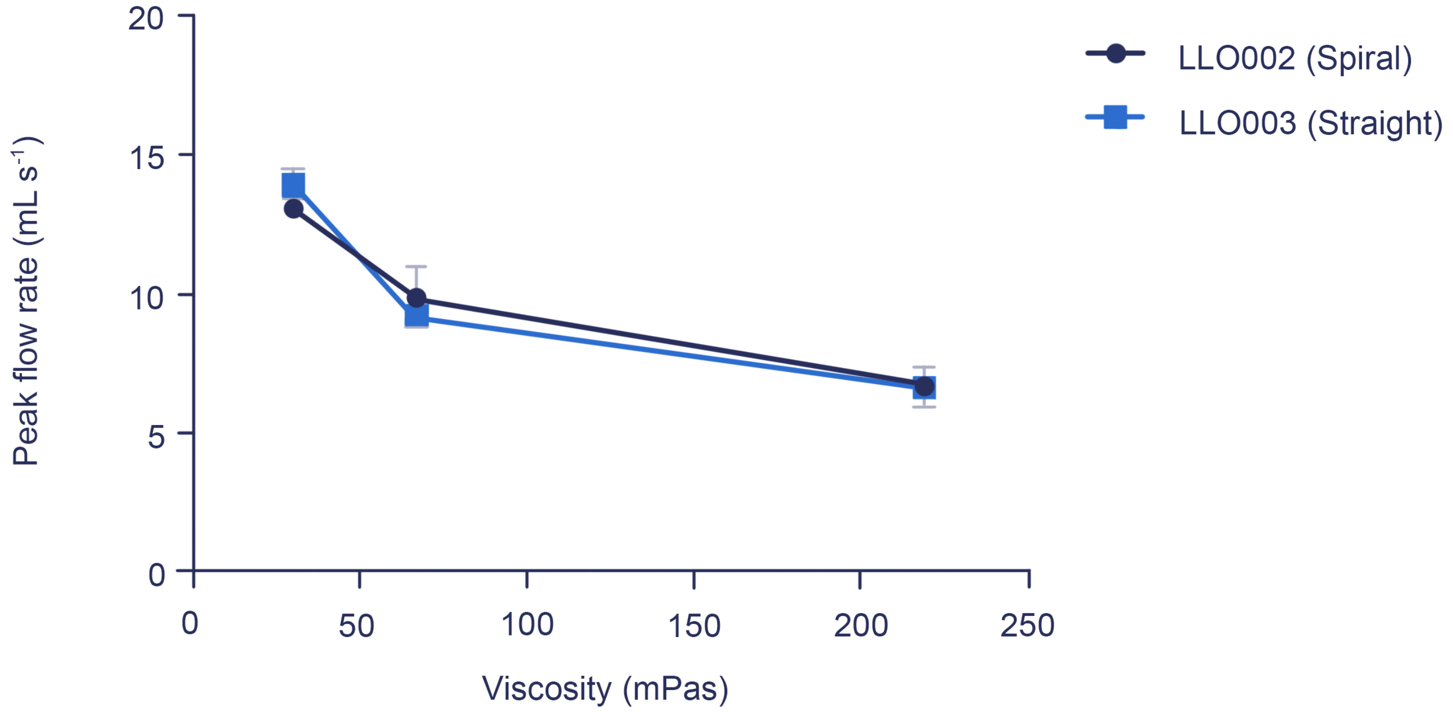


Figure 50. Hole shape and orientation peak flow comparisons.

FINAL DRAINAGE HOLE DESIGN

The final drainage hole design incorporates the oval shape and mixed hole sizes in a straight orientation. These parameters have been chosen because of the results gained from the testing procedure. The following renders is figures 51 and 52, highlight these hole designs as a preliminary outcome.

Figure 51. Pigtail drain utilising the final drainage hole designs; to be tested.

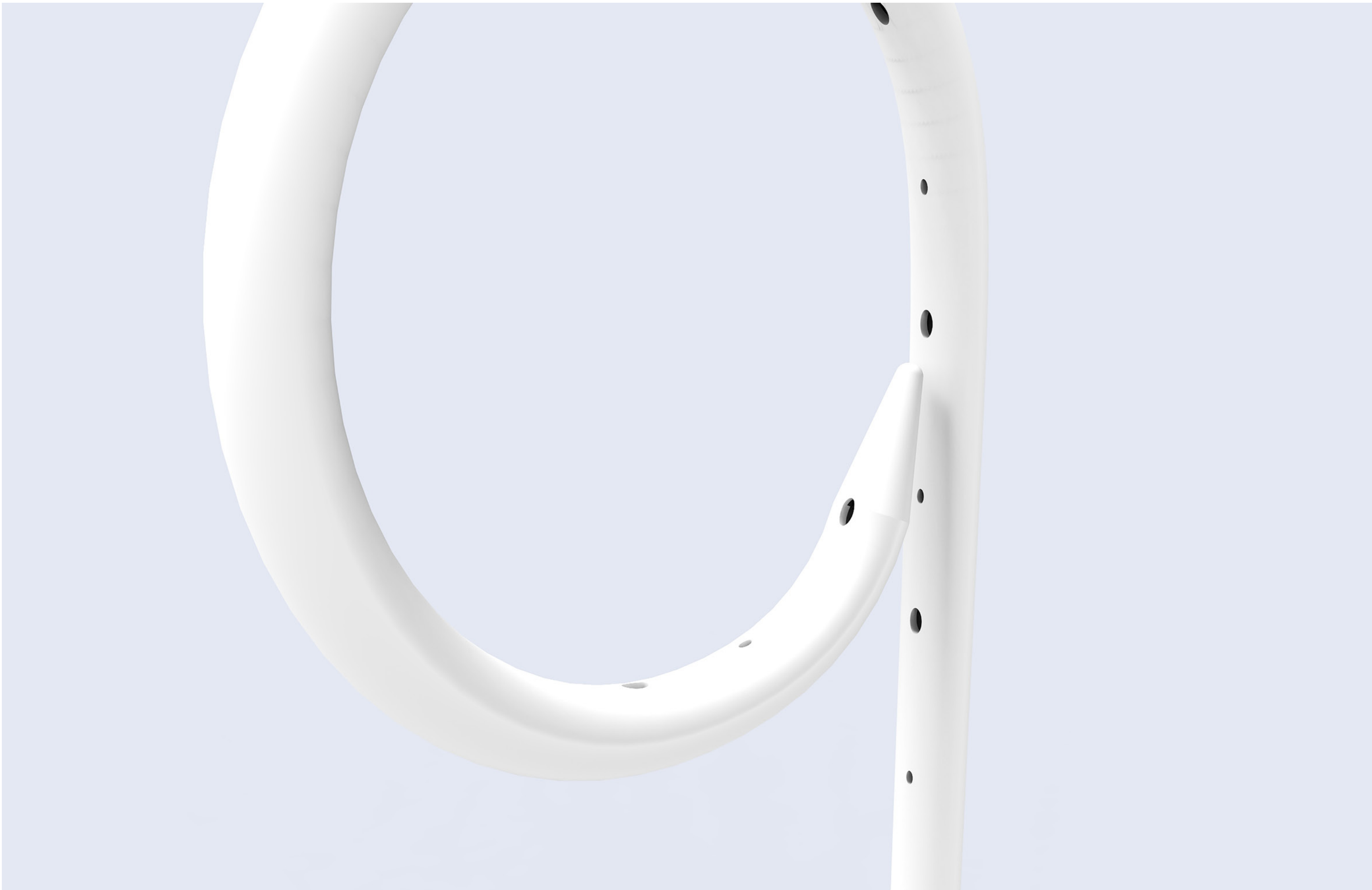


Figure 52. Pigtail drainage hole design, highlighting the oval holes and varied sizes.

REFLECTION

Although the testing procedure was not complete during the writing of this thesis, a new methodology has been implemented during its completion which will continue to gain valid results as the project evolves. This methodology includes;
- a variety of designs created using CAD software;
- 3D printed;
- strategically cleaned;
- sent to Auckland for testing;
- results analysis; and
- developed drains based on the feedback and results.

3D printing provides speed and accuracy to the development process that other means can not. Once the limitations are set, the hole designs can be modelled and produced to continue the testing procedure efficiently. 3D printing is utilised within environments where rapid prototyping is necessary for increased speed to market.

The results accumulated from all three tests, include the oval shape, mixed combination of hole sizes and either a straight or spiral orientation. The results gained from these tests are accurate and will continue to gain quantitative data to improve the drains overall efficiency. Although this thesis has incorporated a scientific route for testing, it is on going as other parameters need to be met, however, these final hole designs will be incorporated into the pigtail drain designs to justify the testing procedure.

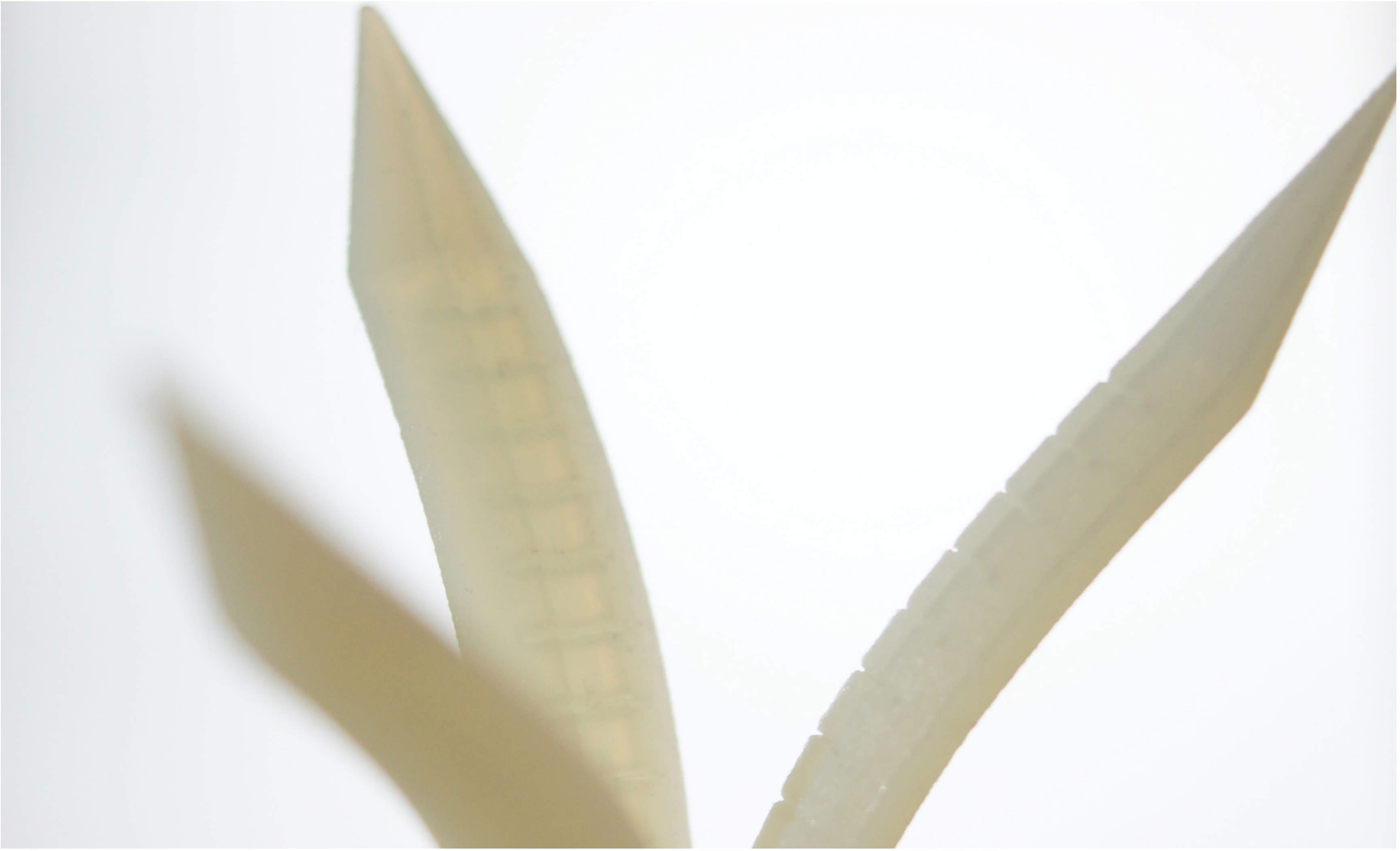


Figure 53. The Anchor drain expanding, exposing the cavity details.

3.3 CATHETER TIP DESIGN CONCEPTS

The current Pigtail drains insertion tip is round which is secured tightly using an internal string (see figure 7). The Pigtail drain straightens over a guide wire or internal stent for insertion and removal, which allows the drain to enter the abscess accurately and smoothly. Once inside the abscess, the guide wire is removed, which causes in the Pigtail to curl back over naturally. The Pigtails internal string is then pulled tight and secured for strength and retention.

This process, although heavily practised, is flawed in the following areas:

- the internal string can loosen, causing the catheter to fall out or generate an infection (see figure 35);
- the string is an obstacle for the infected fluid, causing clogging of the catheter, which can also contribute to an infection;
- the holes can become blocked due to a collapse in the abscess or thick mucus obstructing the opening; and
- the catheter can kink around areas of impact or drainage holes (Charles, 2012).

This thesis, therefore, explores the removal of the internal string by introducing multi-lumens and multi-material qualities into the Pigtail drain design (see figure 53). The drains retention technique will also be developed, employing original design qualities to create an efficient drainage flow and improve the drains security within an abscess.

3D printing has been incorporated into this aspect of the thesis purely as prototyping, communication and development method. The 3D printing connex material has not been FDA approved. Therefore no testing will be done on animals or humans. The material could not withstand human conditions, and consequently, other production techniques will be employed once successful models enter the production phase.

Prototypes were created using Solidworks, and 3D printed using a variety of vero (hard) and tango+ (soft) multi-materials. Utilising 3D printing creates an opportunity for complex geometries and customisation that current prototyping techniques do not provide (Lipson and Kurman, 2013). As seen in figure 8, the location and condition of each patients abscess can be extremely varied; therefore the drain needs to be able to gain entry no matter the complexity of the area. The use of multi-materials allows the drain to be flexible while also holding shape and strength to gain entry into multiple bodily conditions.

The design process is achieved predominantly using the Research Through Design methodology. This methodology requires continuous printing and development of each idea throughout the design phase. These are then analysed and discussed alongside the broader team to identify areas of potential. The initial themes were;
- the internal non-removable stent;
- internal removable stent;
- removable outer tube;
- assisted drainage; and
- pigtail drains.

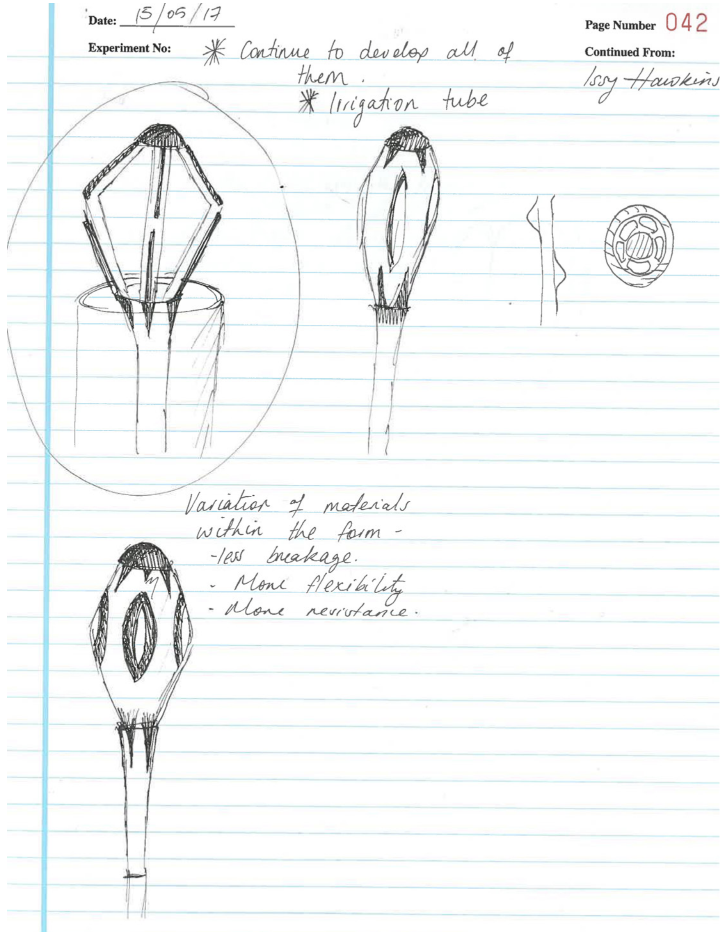


Figure 54. Initial form sketches, incorporating multi-materials within the idea generation.

These designs have been laid out using a matrix (see appendix one) that assisted in the differentiation of models and the decisions of which ones to continue with and which ones to cut. The design matrix is a useful tool to help understand where the designs have been and the direction in which they are going. The matrix is necessary to eliminate the risk of duplicating ideas and following the design progress.

The more successful designs were ordered into two less specific categories. The first category was the Pigtail drain designs, which focused and developed the Pigtail shape by introducing double lumens and multi-material configurations. The second category was novel designs, which completely reshaped the catheters form as well as the application.

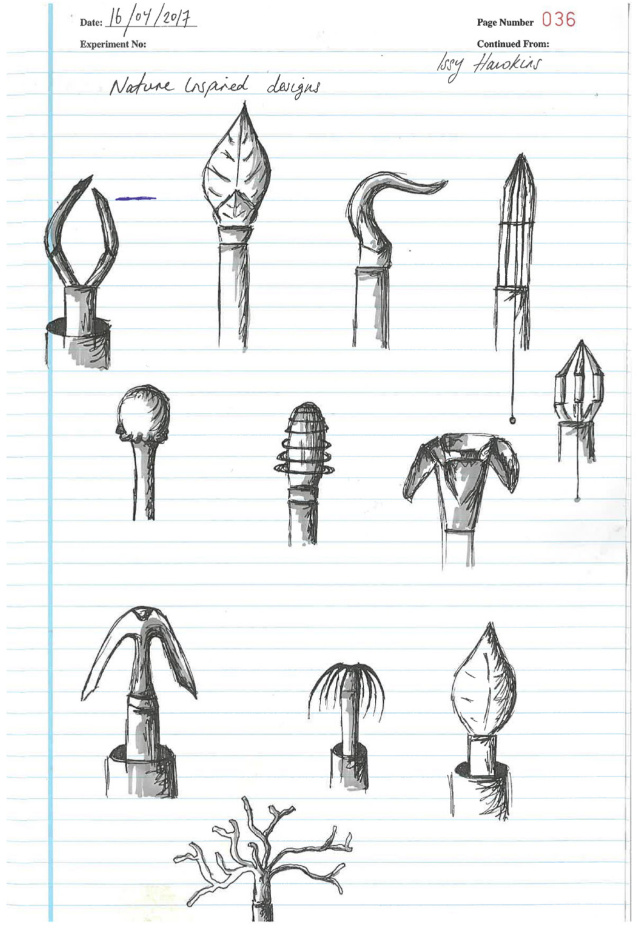


Figure 55. Nature inspired sketches, experimenting with forms for retention.

NON-REMOVABLE INTERNAL STENT

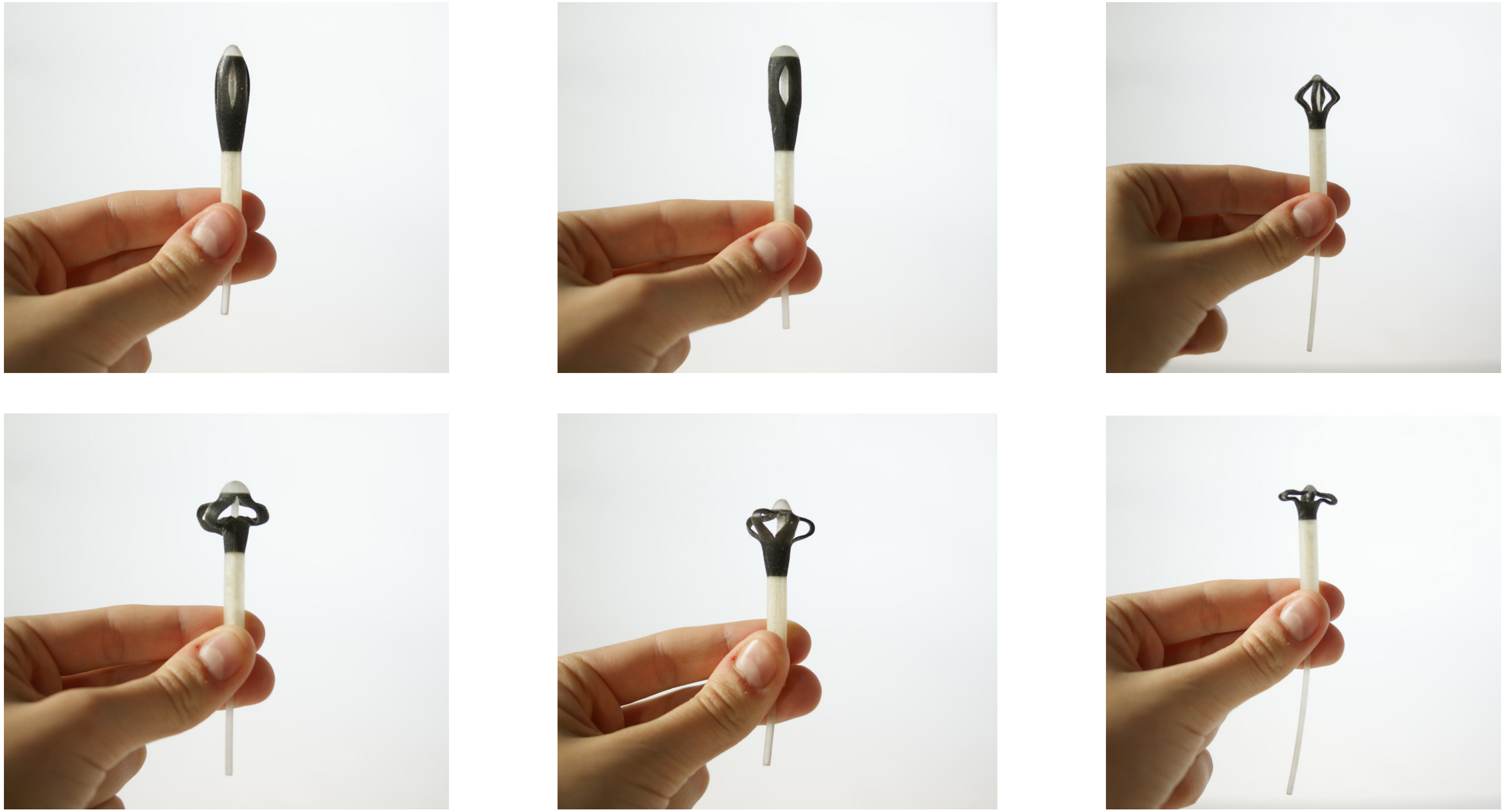


Figure 56. 3D printed non-removable internal stent iterations, showing how the form expands within an abscess.

The non-removable internal stent mainly focuses on a streamline insertion and removal, while aiming to create secure retention. Constant pressure is required to ensure the drainage tip expands using the internal stent, which would be executed by the radiologist.

Figure 57. Most successful non-removable internal stent design. The form is streamlined and creates significant drainage holes once the stent is activated.

However, this design has the potential to be counterproductive, as the stent sits inside the drainage lumen which could decrease drainage efficiency. Nevertheless, the large holes created through the downward expansion, also invite the fluid to enter the drainage catheter.

REMOVABLE INTERNAL STENT

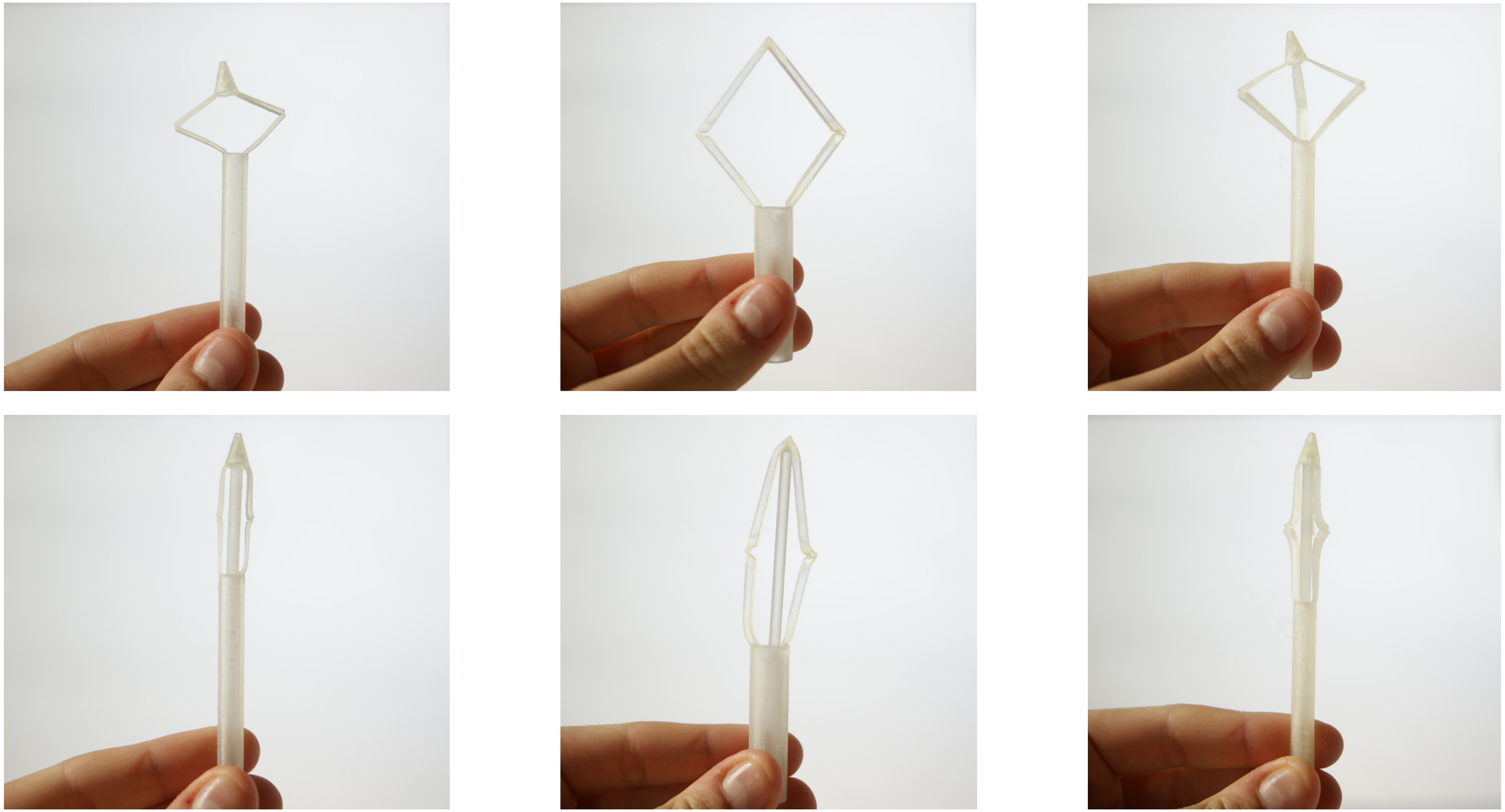
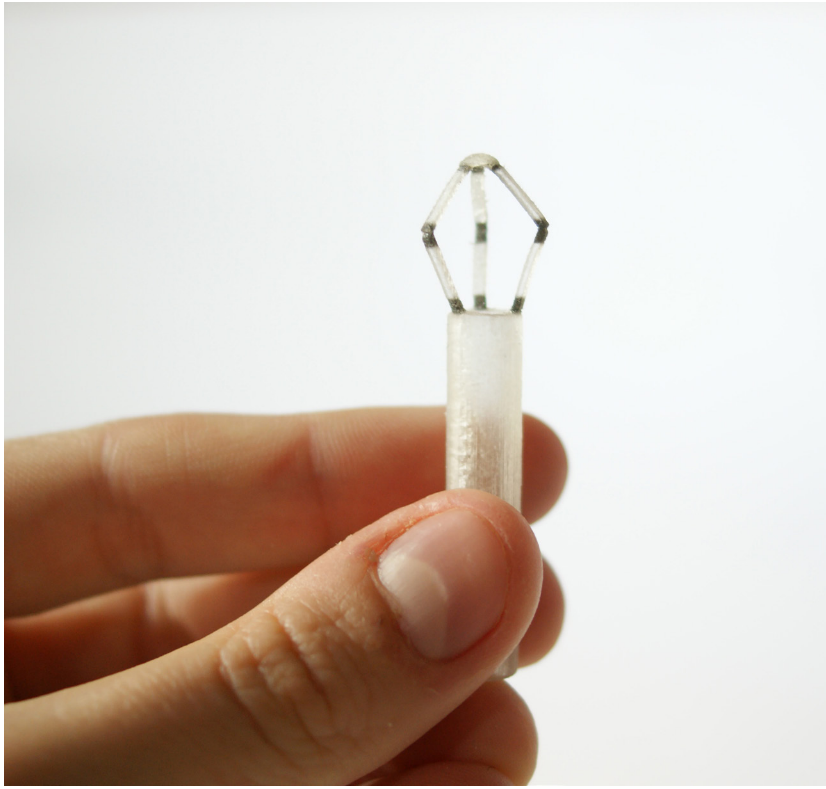


Figure 58. 3D printed removable internal stent iterations; the inner stent creates a streamline form for insertion and removal.

The removable internal stent design utilises a rigid insert used to elongate the drain's tip for the insertion process. Although innovative, this design creates a risk of puncturing surrounding organs if the radiologists were to miss the drain for elongation.

It would be increasingly difficult to use this method for insertion and especially removal, the longer the catheter was inside the body. However, overall, the internal stent design highlights how multi-material properties can create fluid movements and increase form durability.



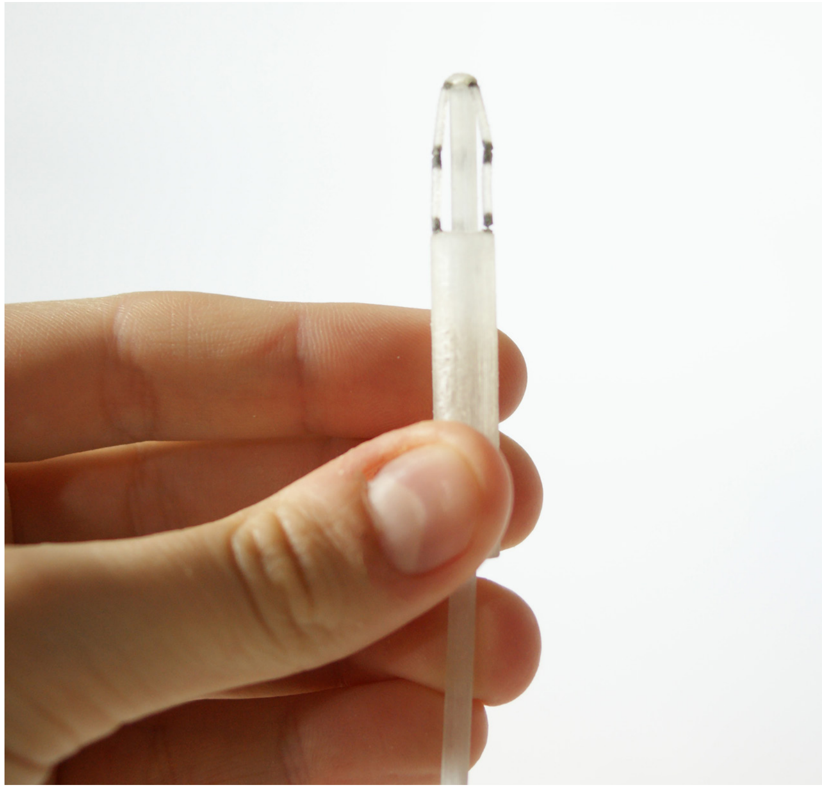


Figure 59. Most successful removable internal stent design. The forms colours portray the difference between material strengths, allowing the structure to straighten.

EXTERNAL TUBE

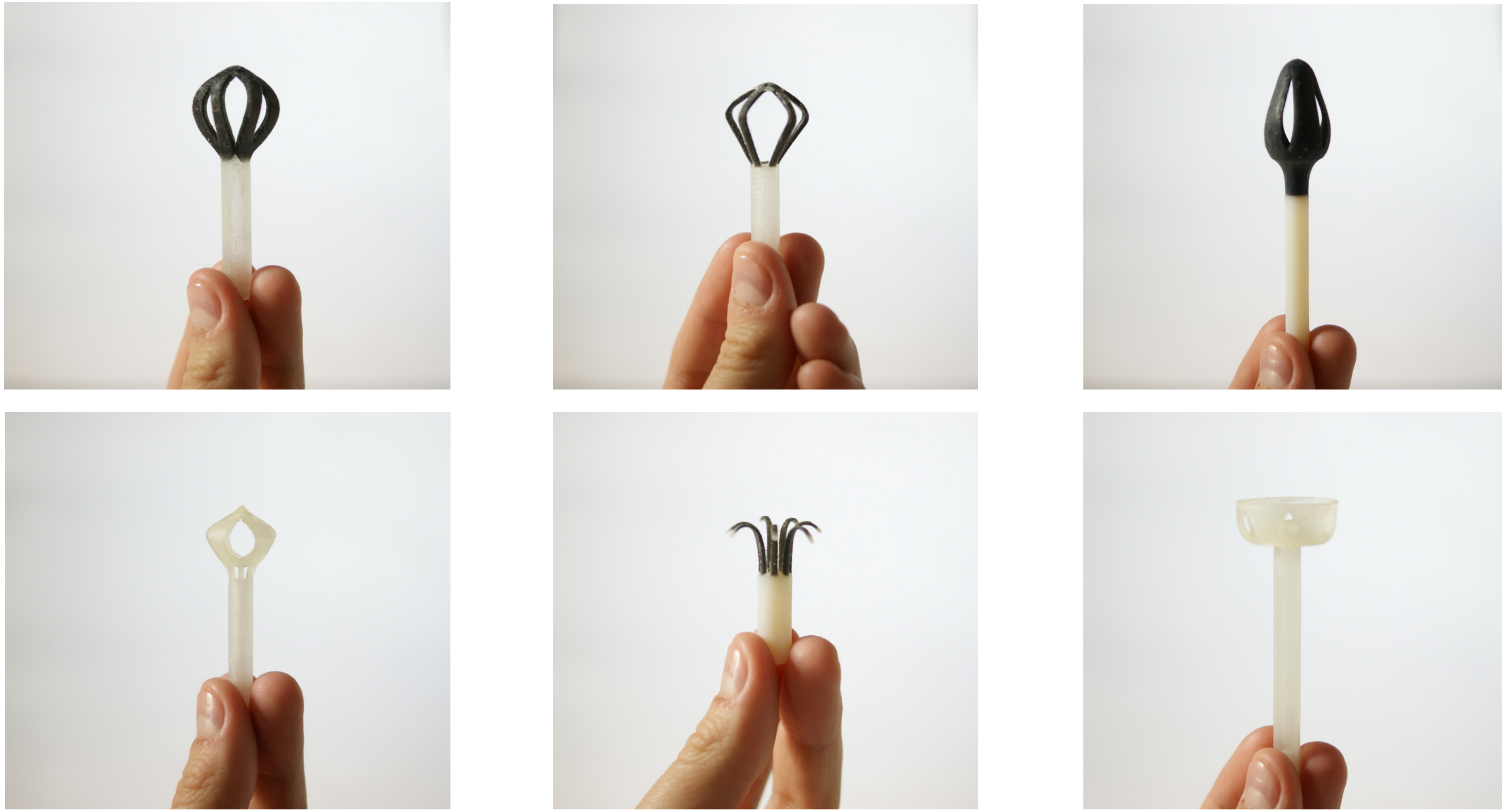


Figure 60. 3D printed external tube iterations. These forms are designed to protrude into the body and inserted using an outer tube.

The external tube drains incorporate novel designs that protrude externally into an abscess. An outer tube then shrinks the form into a streamline position for smooth entry into the body. The external tube potentially increases the insertion wound for the patient, consequently increasing recovery time. However, this design eliminates the need for the internal string which causes issues and infections within the current procedure.

Figure 61. Most successful external tube design, showing the three stages of the insertion process on how the form contracts within the outer tube.

ASSISTED DRAINAGE

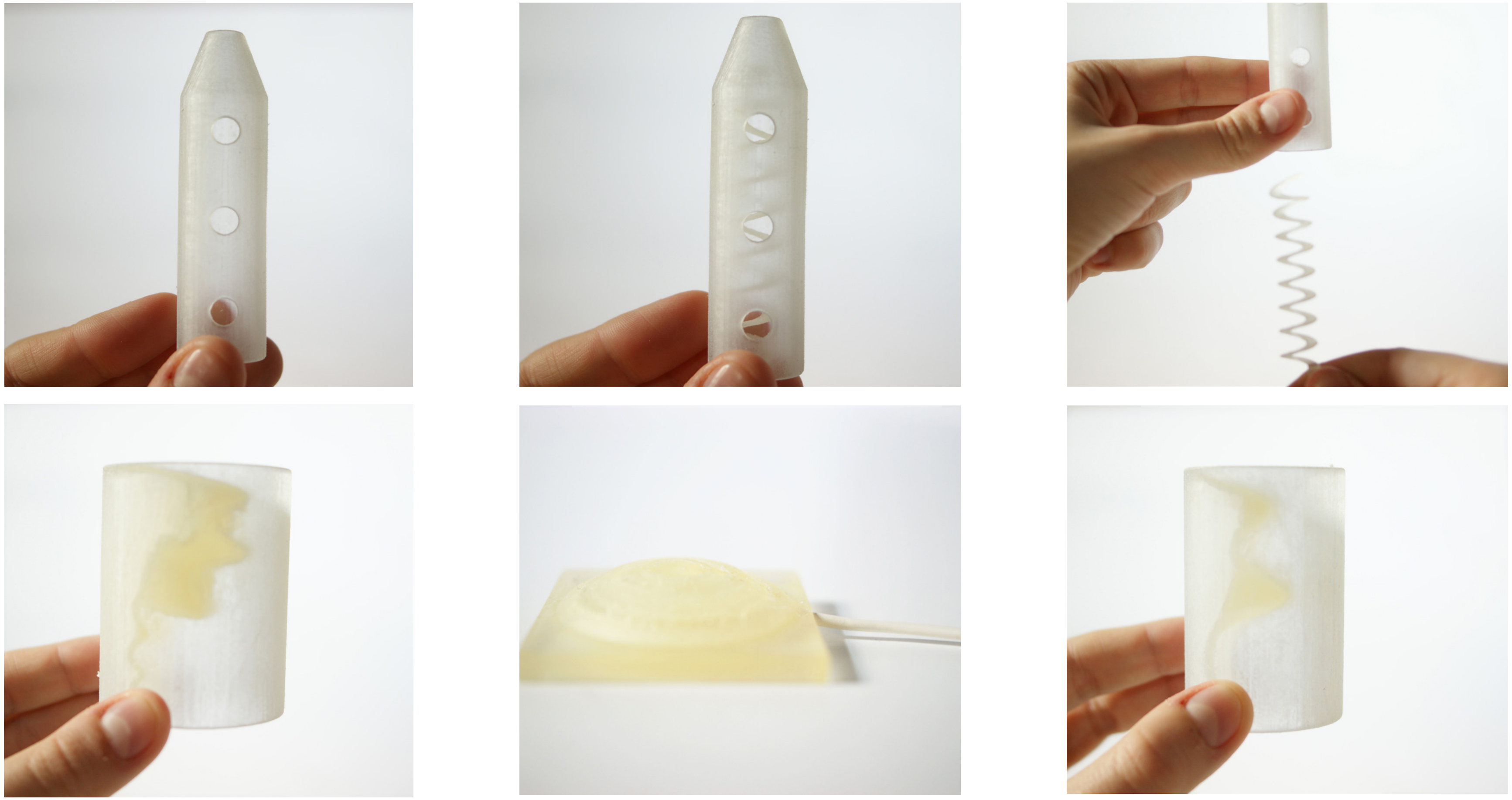


Figure 62. 3D printed assisted drainage iterations. Highlighting the Archimedes screw insert, as well as the blow-up models to comprehend how they may work, in conjunction with the multi-material properties.

The assisted drainage designs focus on fluid movements that can be utilised within the catheter to benefit the drainage efficiency. These designs incorporate manual controls from the radiologist to either blow up the inside of the catheter walls, creating a breathing effect, or to manually rotate an Archimedes screw to loosen the clogged dead matter. Although materiality issues create challenges for developments, these designs are beneficial due to the unique movements which focus on targeted issues.

Figure 63. 3D printed Archimedes screw inside the drain, and a view of the blow-up drains internal cavity.

PIGTAIL DRAINS DOUBLE LUMEN

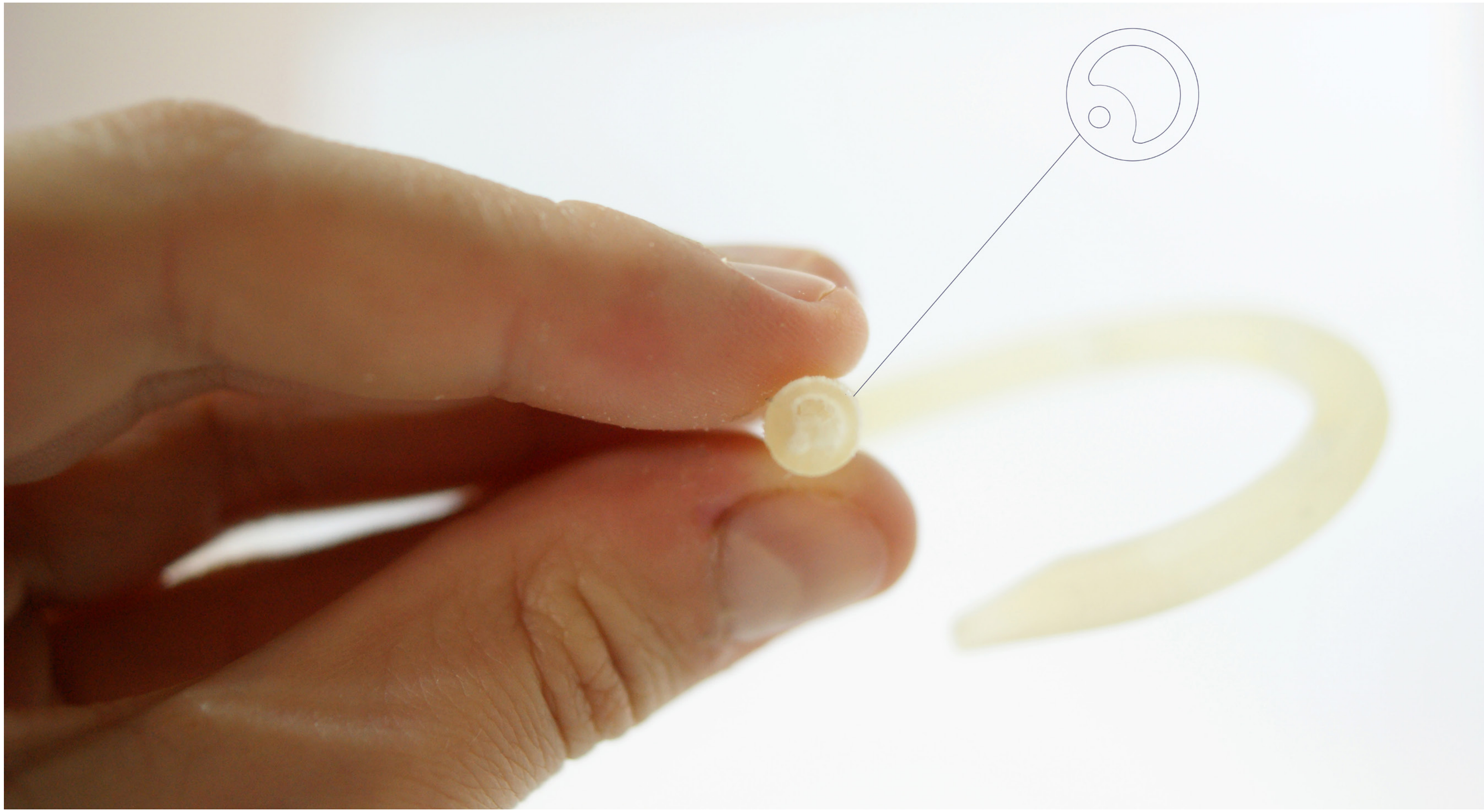


Figure 64. View of the multi-material pigtail drains various lumens.

The Pigtail catheter designs utilise the standard Pigtail drain's shape, to introduce multi-material properties and complex multi-lumens for increased strength and drainage speed. The prominent reasoning behind these forms is to eliminate the current Pigtail drain's internal string.

These forms create a challenging post-printing cleaning process, which causes difficulties during analysis and development. However, these designs have potential as multi-lumens can target multiple issues including drainage efficiency, clogging and irrigation.

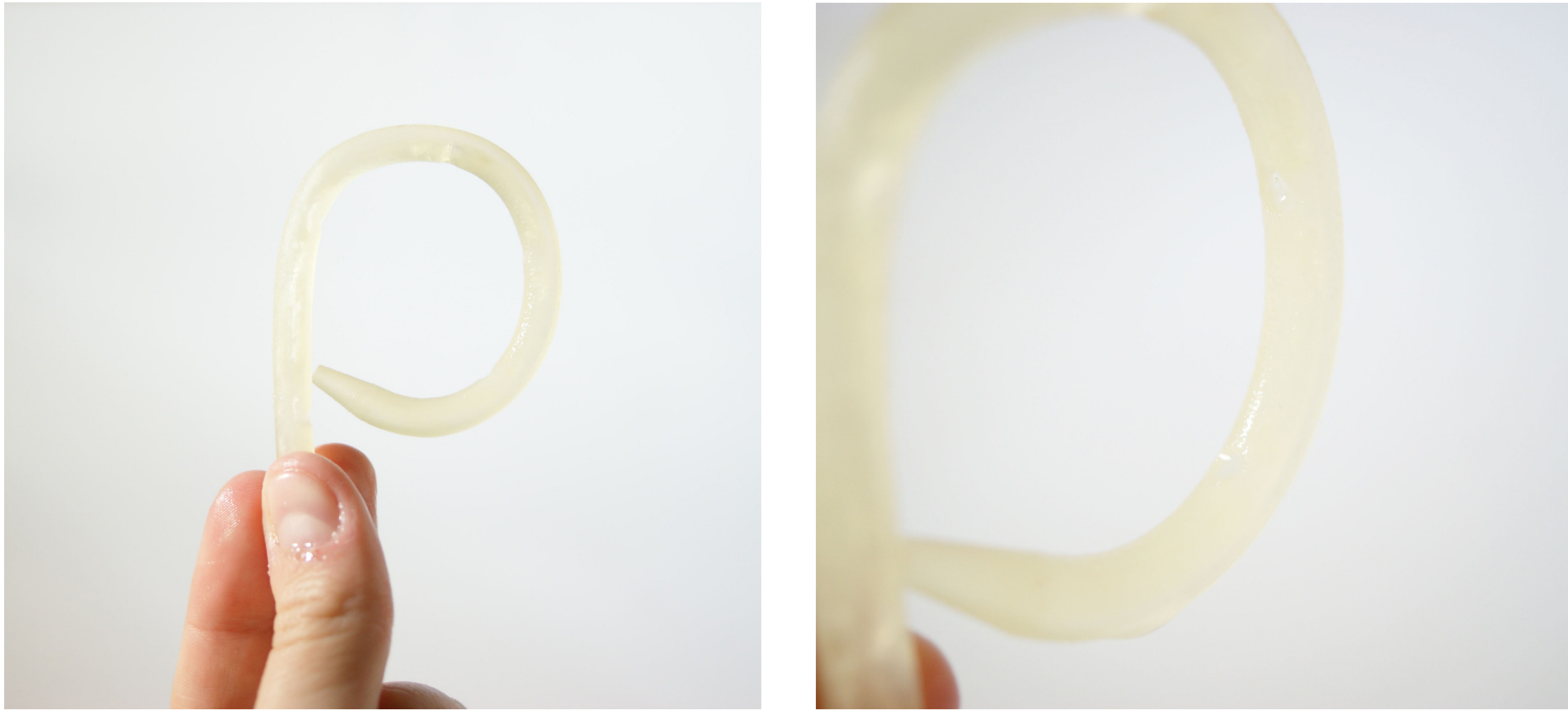


Figure 65. 3D printed Pigtail drain iteration, highlighting the drainage holes.

CLINICAL EVALUATION ONE

The following evaluation includes feedback from a group of radiologists as well as the medical and scientific professionals within the project's larger team. This feedback created expectation guidelines for the new percutaneous drain design, as well as unrecognised clinical issues with the models thus far.

Overall, the clinical feedback resulted in the internal stent designs (see figures 96-99) discontinuation because they created an obstacle that the fluid would struggle to pass, making the overall idea counteractive. The external tube, assisted drainage and Pigtail drain designs (see figures 100-103) continued, however, needed developments as they were the furthest from being resolved.

These designs have immense potential and room for innovation. The professional opinion of the larger team allows hypotheses to be clarified and act as an informative method of testing to gain qualitative data.

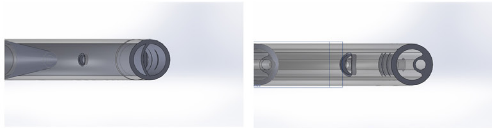
For the next development phase, the separation of the initial themes generated two main categories. The first category is Pigtail designs, which includes the Assisted drainage and Pigtail designs. The second category is the Novel designs, consisting of the External tube drains. These designs will be developed further in the next stages and reevaluated for another analysis and discussion with the team in May 2018.

PIGTAIL DESIGN ITERATIONS

DOUBLE LUMEN PIGTAIL DRAIN

IRRIGATION

The double lumen pigtail drain has been incorporated to irrigate the abscess through the catheter. The multi-lumens also allow for various insertion methods without having to change the orientation or size of the holes.



MULTI-MATERIAL

The multi-material pigtail drain is utilised to eliminate the internal string. The thicker and harder material used as a spine down the catheter holds the form in place securely.

ASSISTED DRAINAGE

ARCHIMEDES SCREW

The Archimedes screw drain incorporates an internal twist to loosen and remove thick matter from the catheter. This reduces clogging and infection of the patient's cavity.

INTERNAL BLOW-UP

The internal blow-up drain incorporates cavities inside the catheters walls to make them 'breathe'. This prevents blockages as well as ensuring the liquid exits the drain efficiently.

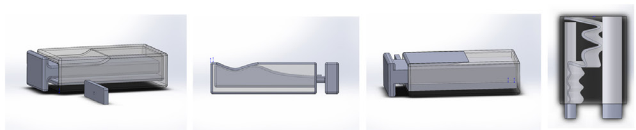
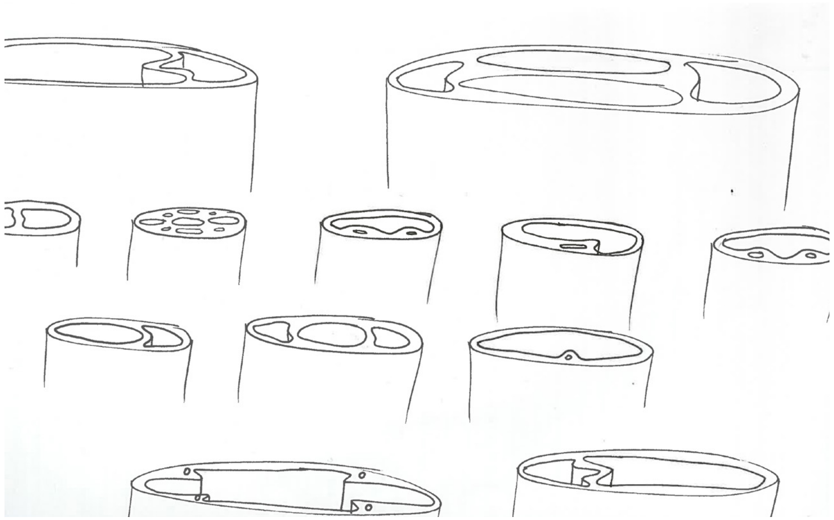


Figure 66. Pigtail design iteration matrix, to understand the design process.

3D PRINTED PIGTAIL DRAINS



The 3D printed pigtail drains incorporate less drastic developments and processes based around the current Pigtaildrain shape, therefore predominantly appeal to medical professionals. For radiologists, the transition between drains would be minimal and would require less training than a complete procedural restructure. As seen in figure 66, multi-material properties, double lumens, internal cavities and redesigned stents have been explored and elaborated in the following subchapter.

Figure 67. Double lumen section views for idea generation.

DOUBLE LUMEN PIGTAIL DRAIN

The primitive form of development is through applying double lumen designs alongside new hole orientations. The current pigtail drain implements a single lumen, used for multiple applications; insertion, drainage and irrigation. The advantage of introducing double lumens is simultaneous irrigation and drainage, creating a more efficient drainage procedure.

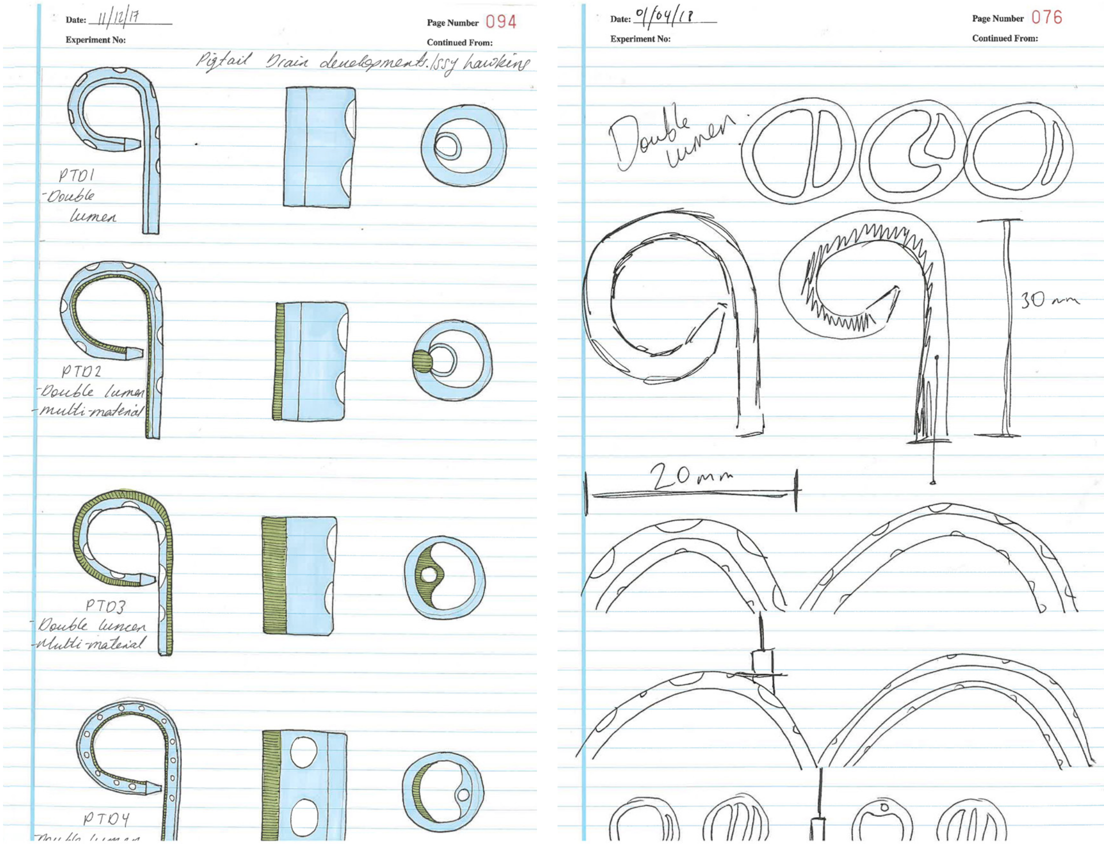


Figure 68. Double lumen sketches to experiment with hole orientations, to improve the overall drains performance.

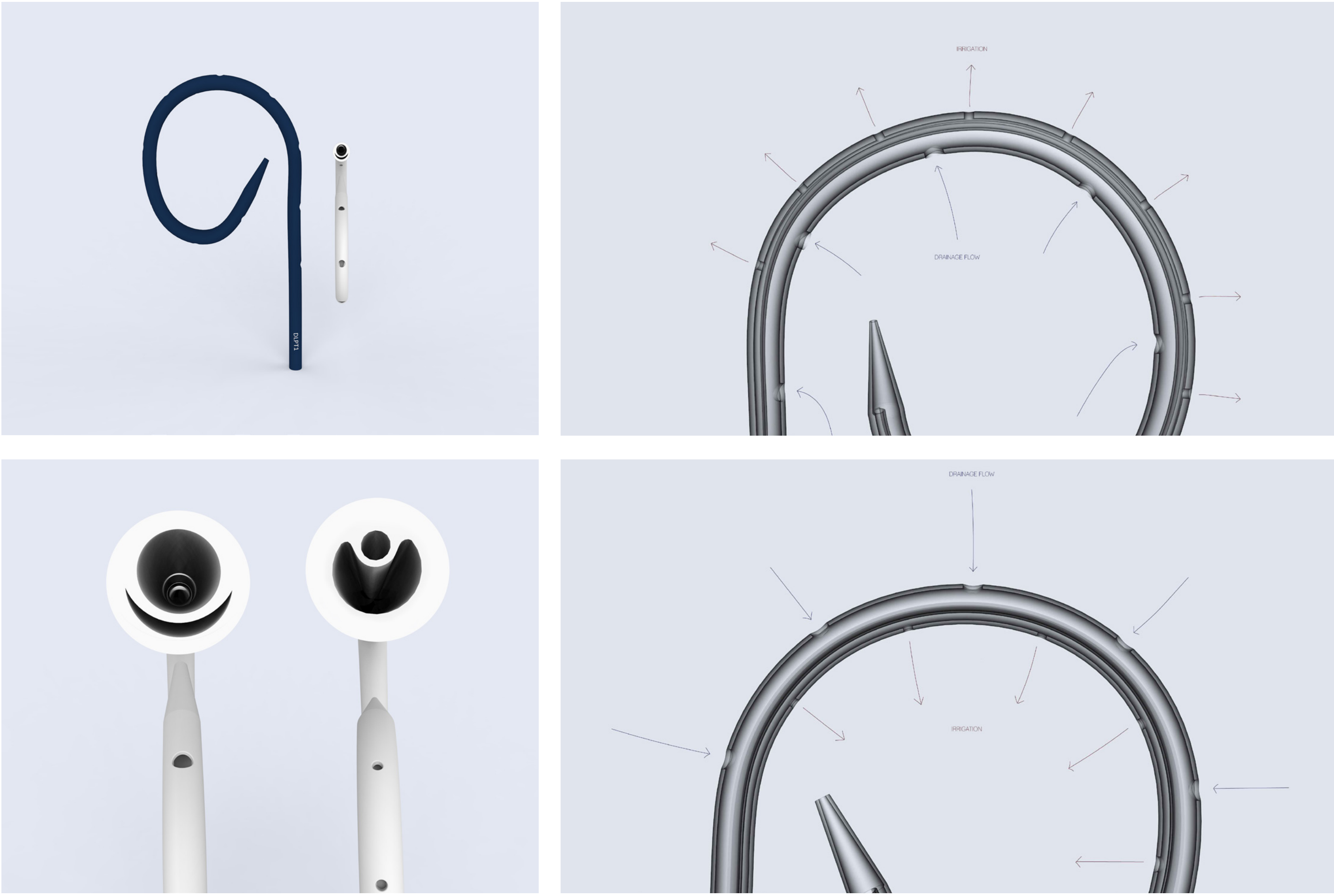


Figure 69. Double lumen initial renders and flow diagrams, for a clear vision of the dual lumen configurations, as well as an understanding of how the drain would work during the drainage procedure.

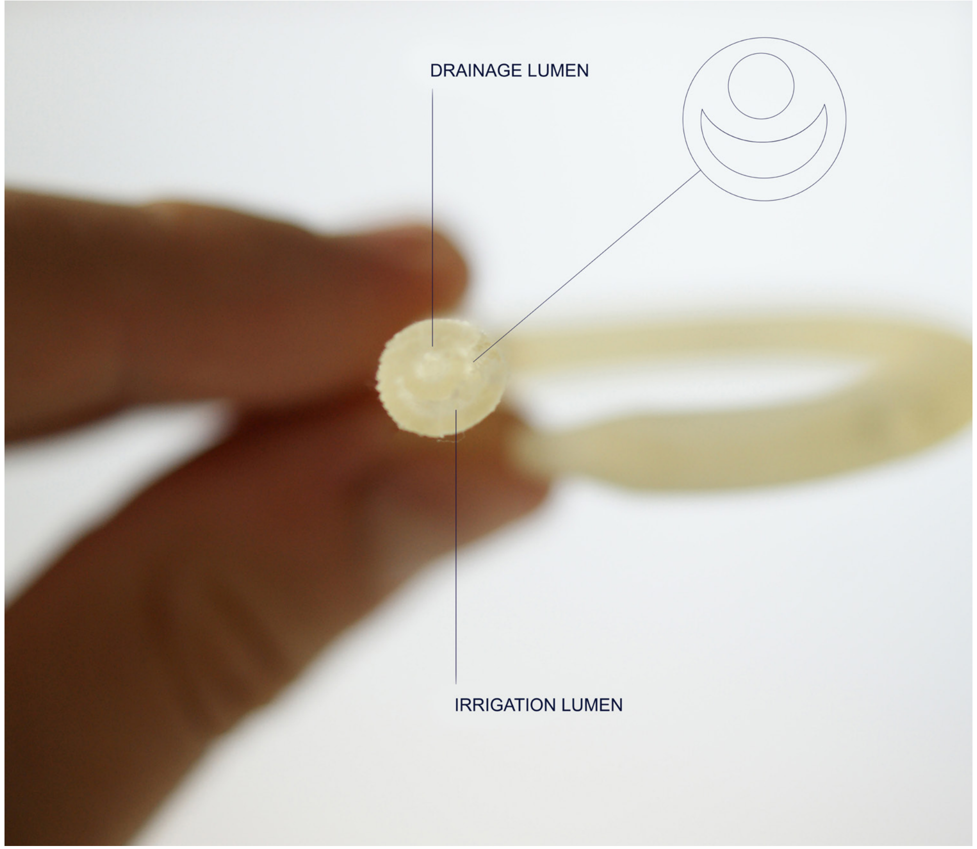
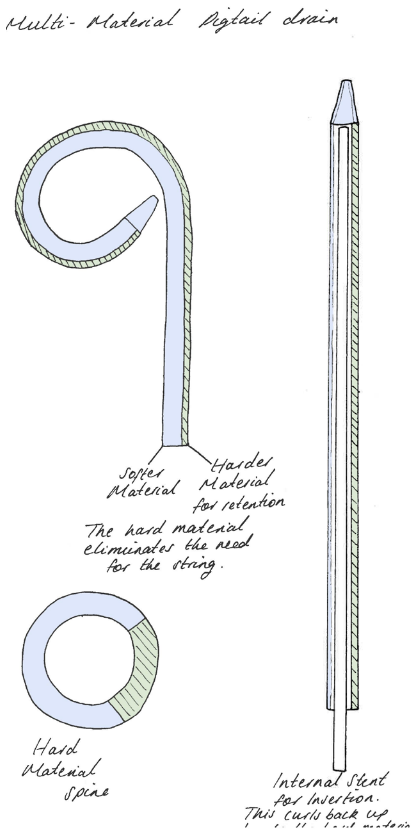


Figure 70. Developed 3D printed double lumen drain, after experimenting with lumen shapes, hole configurations and pigtail sizes.

MULTI-MATERIAL PIGTAIL DRAIN

The multi-material Pigtail drain eliminates the internal string by adding multi-material properties as a spine for retention. The drains spinal material sustains a more advanced memory than the current silicone catheters. The Pigtail drain is elongated for insertion and removal using a guide wire or stent. Which, once removed, causes automatic curling for security within the abscess without the need for an obstructive string.



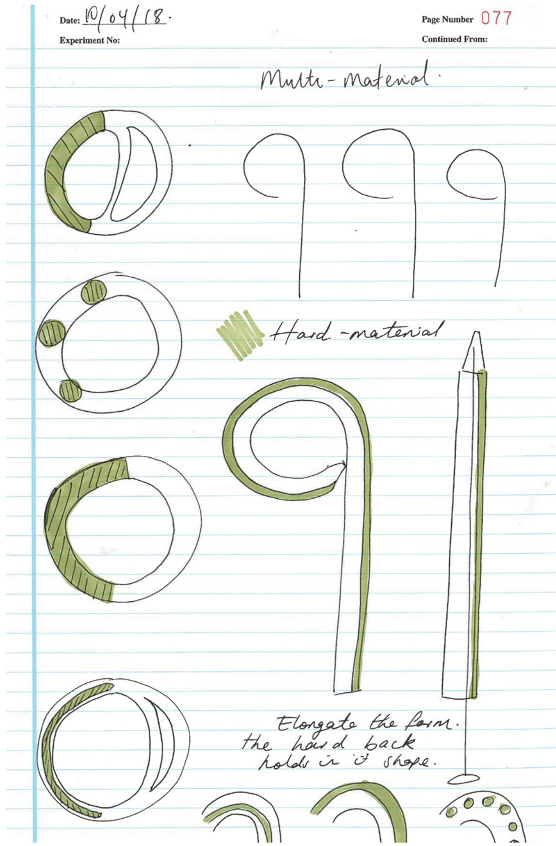


Figure 71. Multi-material sketches to experiment with the thickness, shape and location of the Pigtail drains spine, to heighten strength.

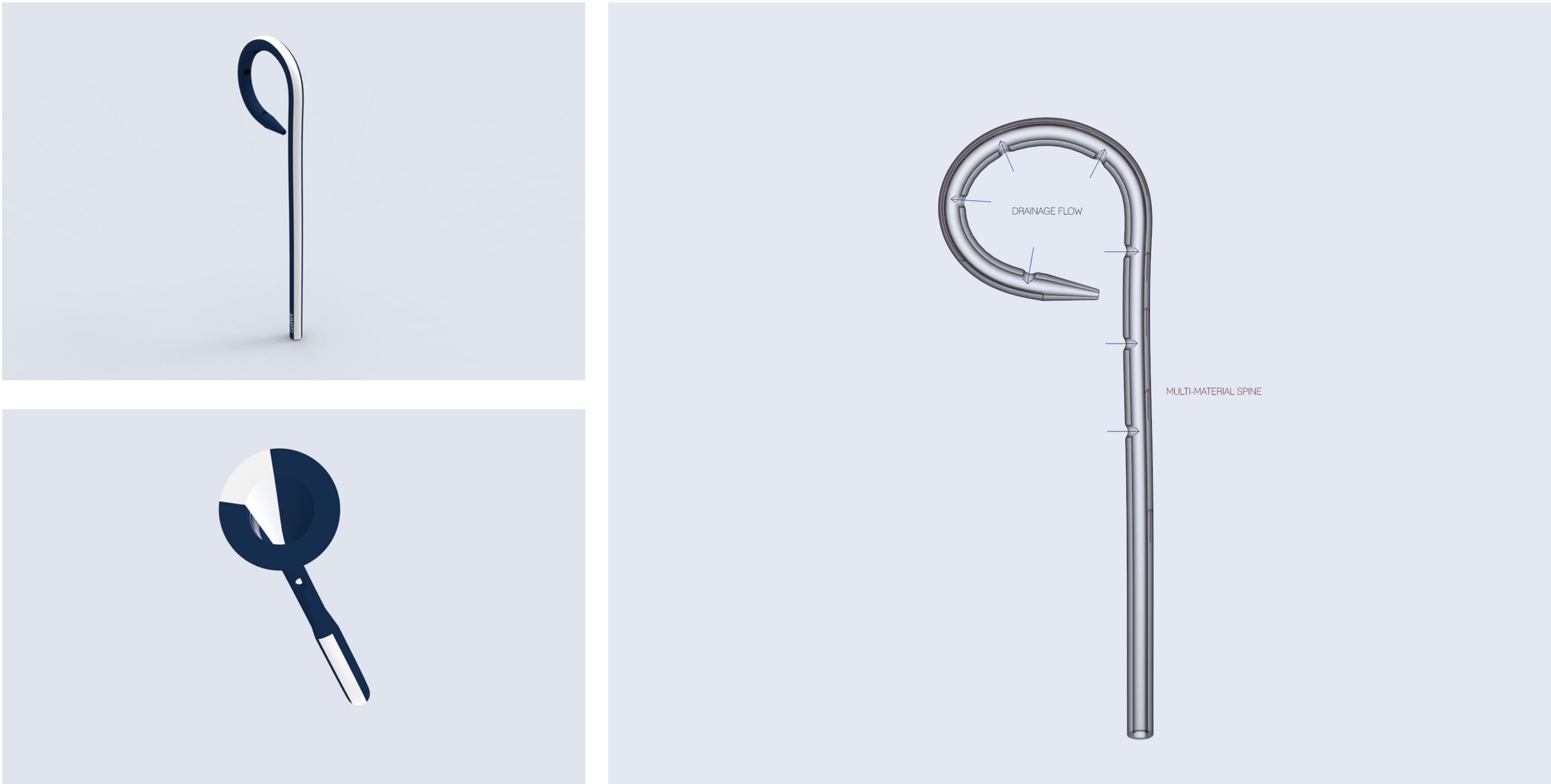


Figure 72. Multi-material initial renders and flow diagrams, to visualise the difference in material strength.

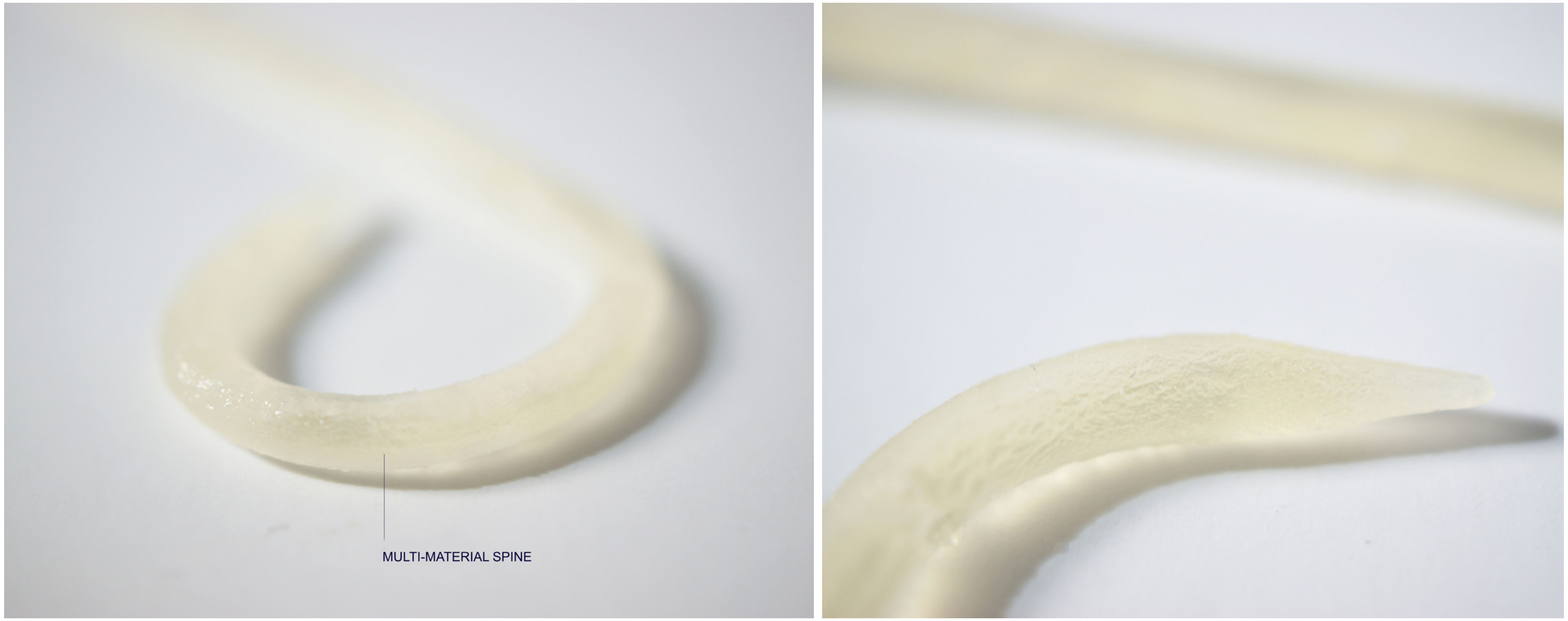
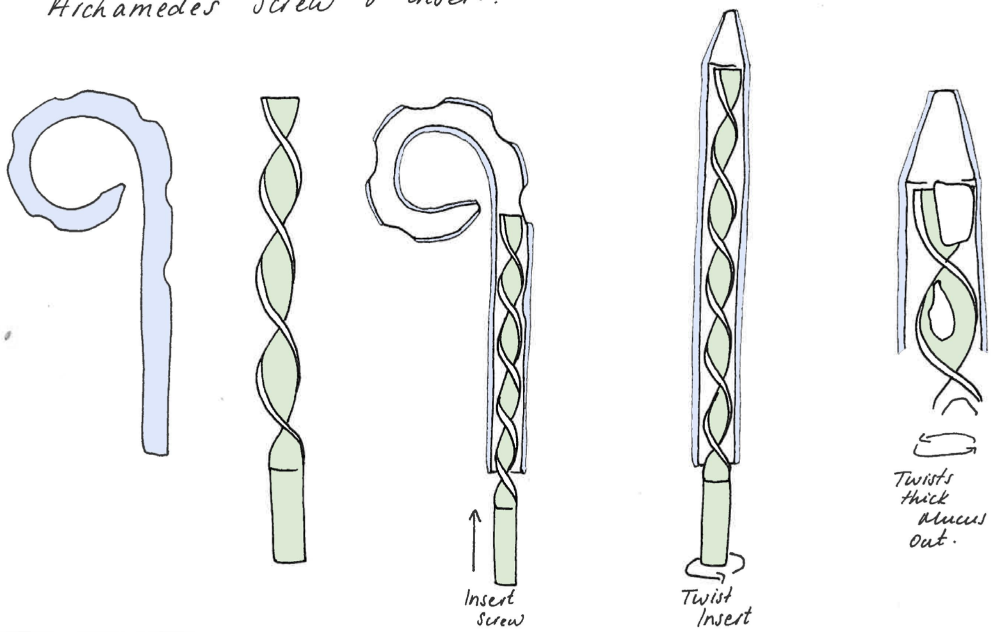


Figure 73. Developed 3D printed multi-material model. The materials opacity changes depending on the strength, which is highlighted using annotations.

ARCHIMEDES SCREW

The Pigtail drain has implemented innovative applications to assist in an increase in the catheters drainage. The Archimedes screw includes a corkscrew insert to physically rotate and break up the thicker matter to remove it and prevent premature blockages. This technique is beneficial as the stent can be controlled manually by the radiologist and removed when the drainage flow becomes steady.

Archamedes Screw o Insert.



The archamedes screw eliminates clogging as the thicker matter can be twisted out. This can reduce infection and the need for changing catheters.

Figure 74. Archimedes screw sketches for design planning and logistical understanding.

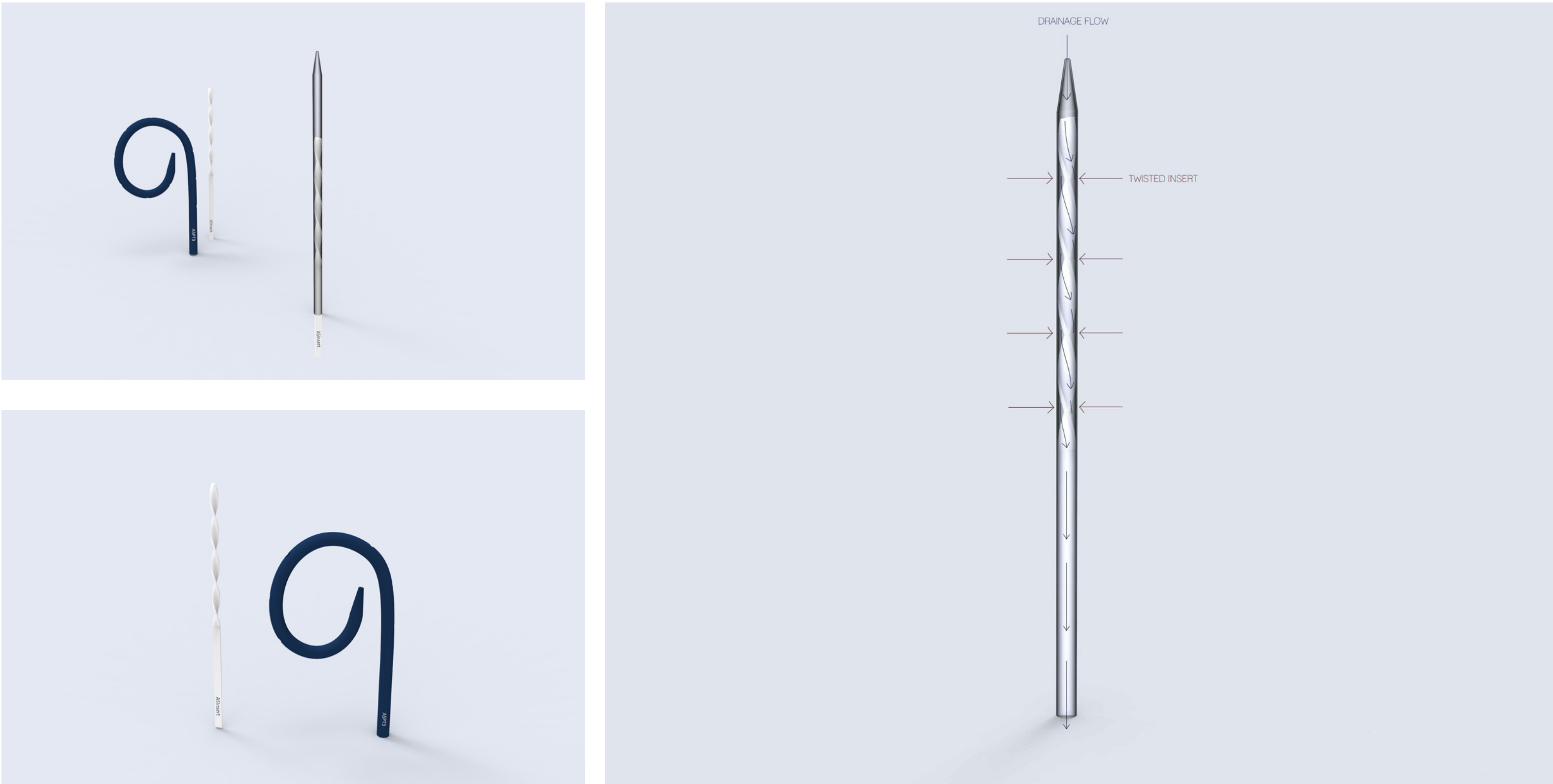


Figure 75. Developed model renders and flow diagram, justifying the idea, by portraying how the screw will assist in the drainage efficiency.

Figure 76. The developed Archimedes screw model shows the inserted screw inside the pigtail drain, portrayed using image annotations.

BLOW UP PIGTAIL DRAIN

The Blow-up Pigtail drain incorporates an internal cavity design within the catheters walls, to manipulate thicker mucus to exit the body. The cavity is a hollow tunnel that runs down the length of the drain that varies in thicknesses. A needle or syringe inserts fluid into the cavity, creating a rippling movement down the side of the lumen. The thinner areas of the cavity are areas that 'breathe', while thicker regions create avenues for the fluid to descend. This motion is continuous throughout the length of the catheter which creates a constant flow of movement. The Blow-up drain will increase the drainage efficiency and reduce adherence of debris, as the dead matter is less likely to accumulate on an unstable form.

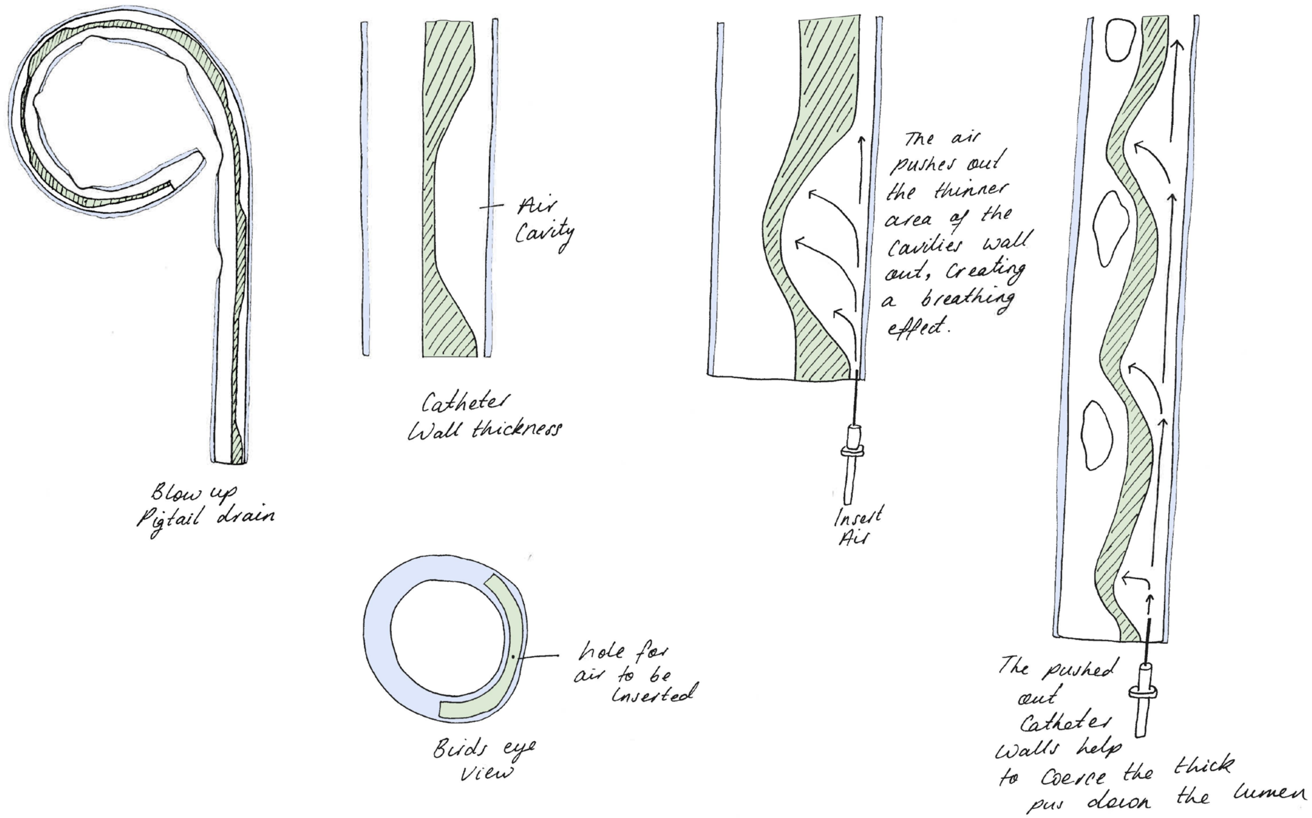


Figure 77. Internal blow-up Pigtail drain sketches. These sketches create a more comprehensive understanding of the blow-up process, portraying the variation in material thicknesses.

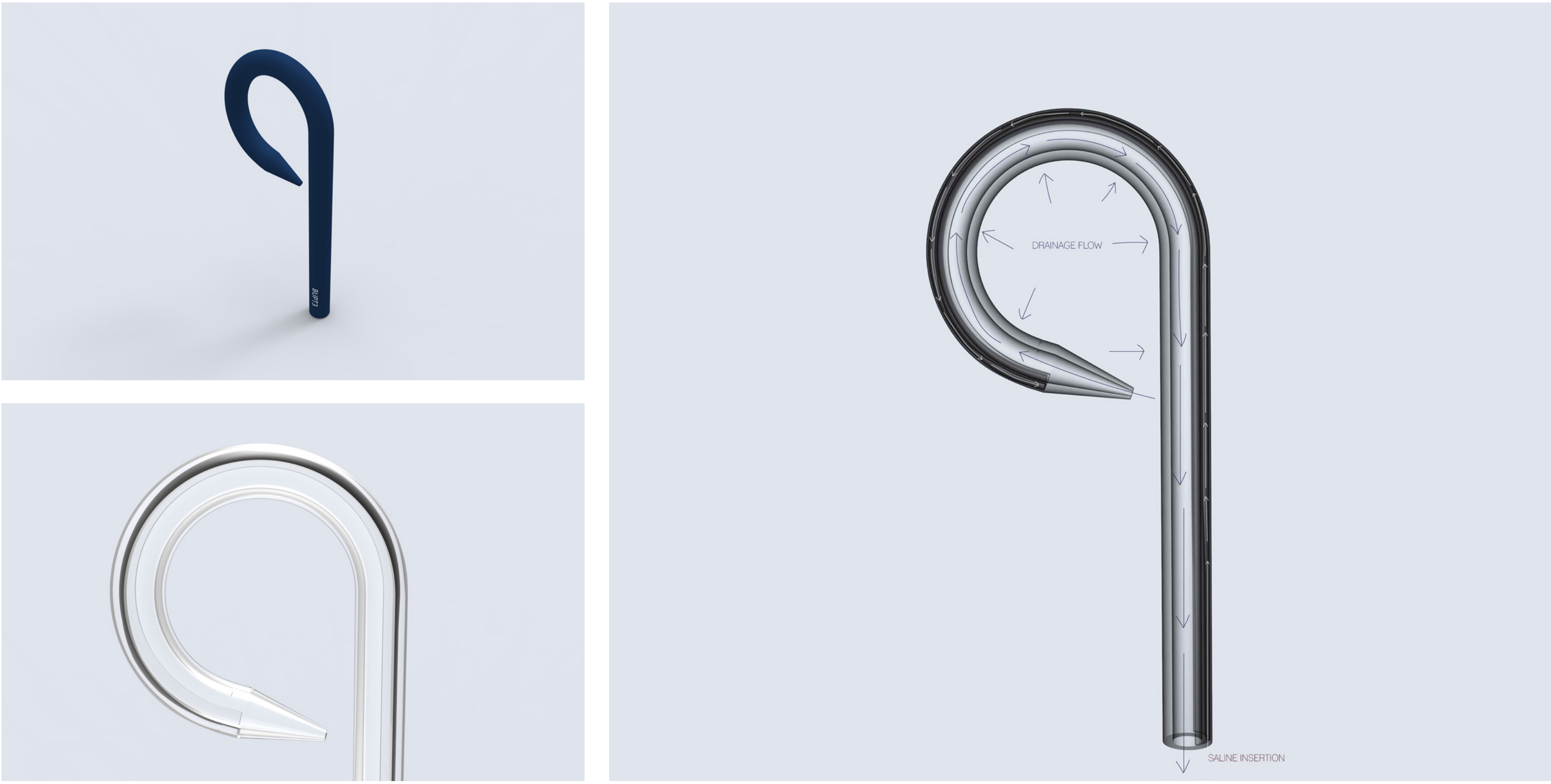
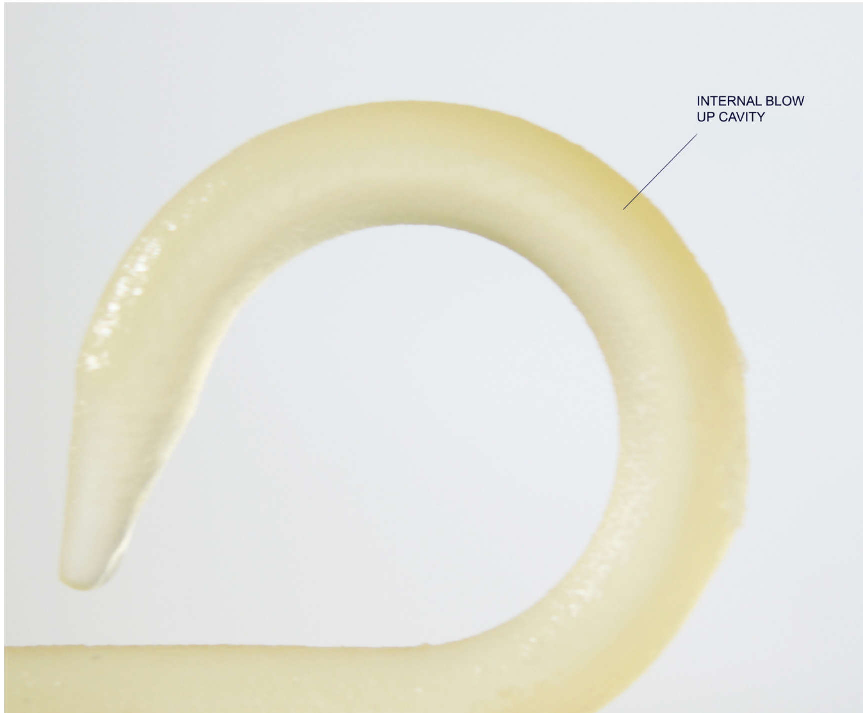


Figure 78. Developed blow-up Pigtail renders and flow rate diagram, creating an understanding of how the cavity within the walls, creates a breathing effect through fluid or air and material manipulation.



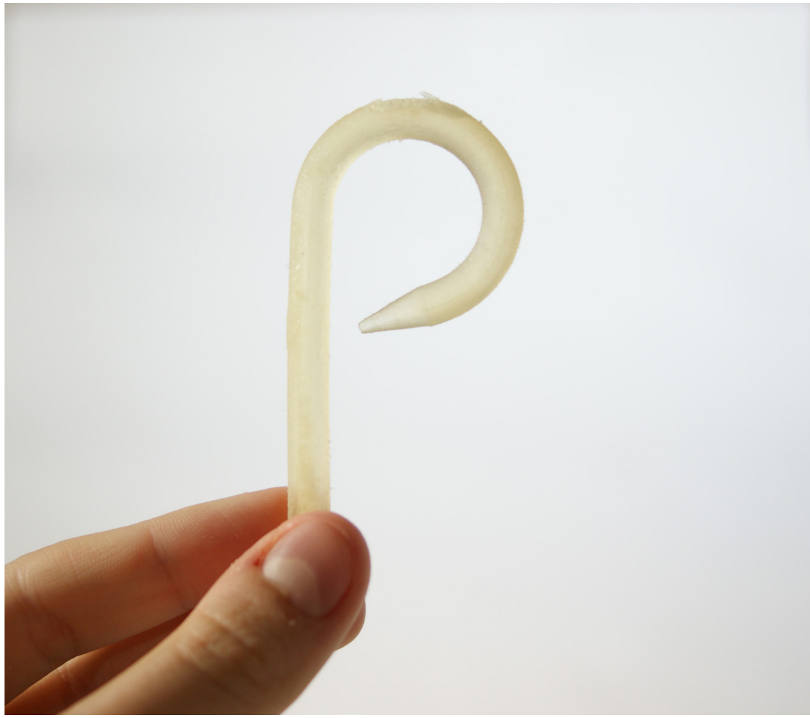


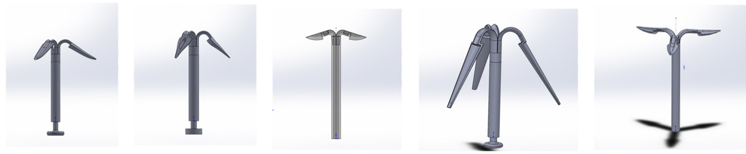
Figure 79. Developed multi-material blow-up Pigtail drain. The internal cavity creates a slight colour change, visualised through imagery annotations.

NOVEL DESIGN ITERATIONS

EXTERNAL TUBE

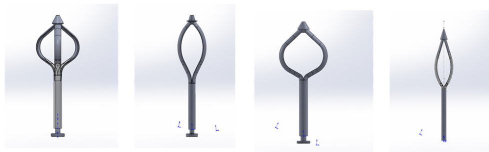
ANCHOR

The Anchor drain incorporates an external tube that allows the form to elongate for insertion and removal. The form then opens inside the abscess for retention methods. The multi-material properties create memory within the form.

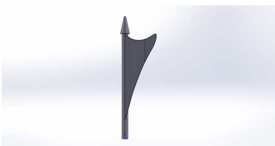


EGGBEATER

The eggbeater form utilises the same idea as the anchor, although a different form. The rounded edges bend inside the external tube due to the multi-material properties. These edges protrude back out once the external tube is removed.



TWIST



The twist drain incorporates a physical motion to twist the wing inside the external tube. This then unravels back out into the cavity which is afforded due to the multi-material properties. The shape of the form is unique, making it difficult for the patient to accidently rip it out after the procedure.

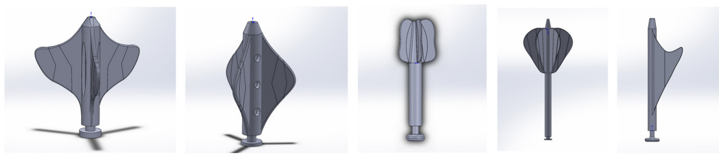
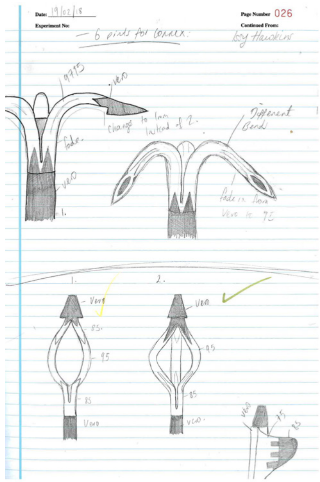


Figure 80. Novel design drain iterations.

3D PRINTED NOVEL DRAINS

The introduction of novel developments advances forms and processes that improve the drains overall performance. These forms aim to implement unique construction techniques to add strength for successful insertion, removal and secure retention (see figure 80). The generation of catheter retention is through forms that expand inside the abscess, however, do not pierce the tissue or organs. The extended forms open the abscess and clear surrounding obstacles for a clear drainage pathway. Each of the novel drain designs utilises an external sheath for insertion and removal as the designs require assistance to become streamlined. They all also incorporate multi-material 3D printing for rapid prototyping, added strength, fluid movements and physical material memory.



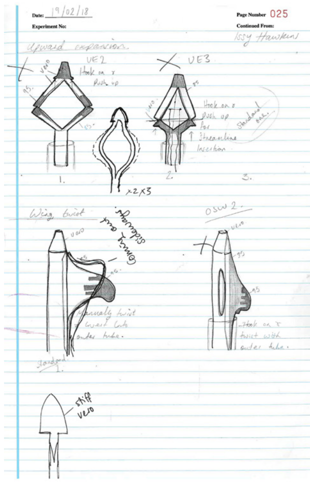


Figure 81. Novel sketch iterations create visual brainstorms for drain developments.

ANCHOR DRAIN

The Anchor drain is a novel design that focuses predominantly on smooth insertion and secure retention within an abscess. Multi-material properties allow for an external sheath to reform the Anchor into a straight line when required. However, once removed, the material memory enables the form to readjust into the original open state. When the Anchors form closes, the tips are designed to create a hole for the guide wire to thread through, to prevent the need to adjust the procedure. This design will also assist in the drainage efficiency due to the more significant point of entry for the thicker dead matter.

The current Pigtail drain incorporates holes on the underside of the catheter for drainage. The Anchor design, however, will assist in the drainage efficiency due to the more significant point of entry for the thicker dead matter. The open arms inside the abscess create a clear pathway into the lumen with no obstacles to slow down the drainage process.

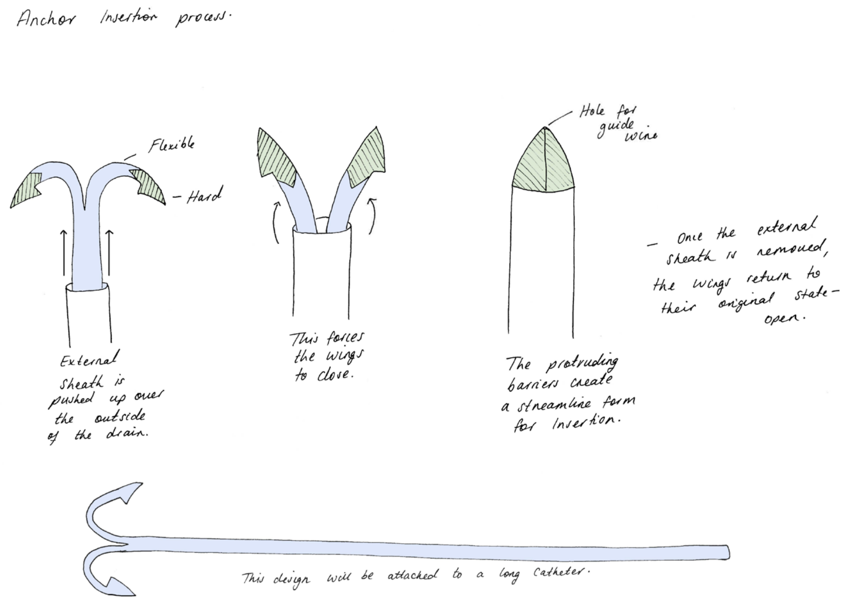


Figure 82. Detailed sketches to decipher how the Anchor drain can elongate for insertion and removal.

Figure 83. Developed Anchor drain renders and flow rate diagram, portraying how the open state invites the fluid to exit the catheter.

ANCHOR DRAIN ITERATIONS

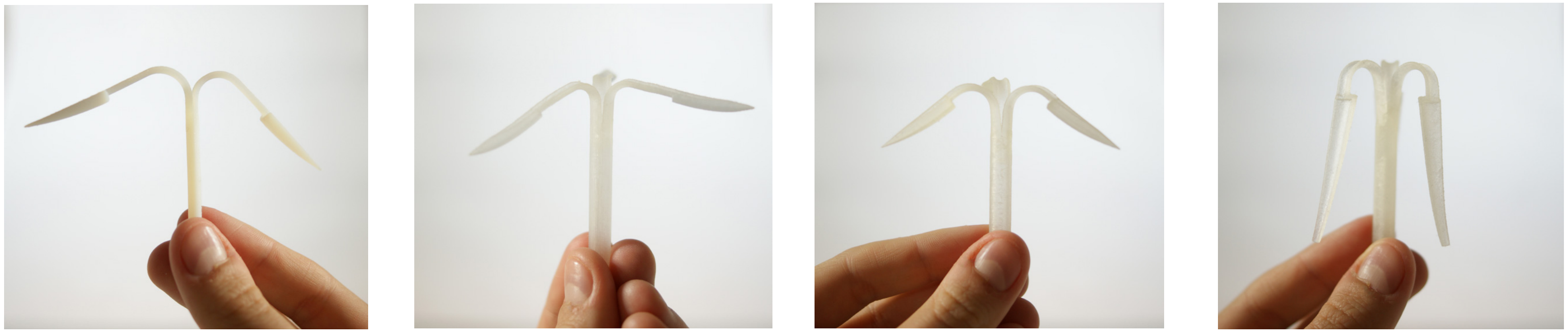


Figure 84. Anchor drain 3D printed iterations to develop the wing size, shape and material strength.

ANCHOR DRAIN INSERTION AND REMOVAL PROCESS

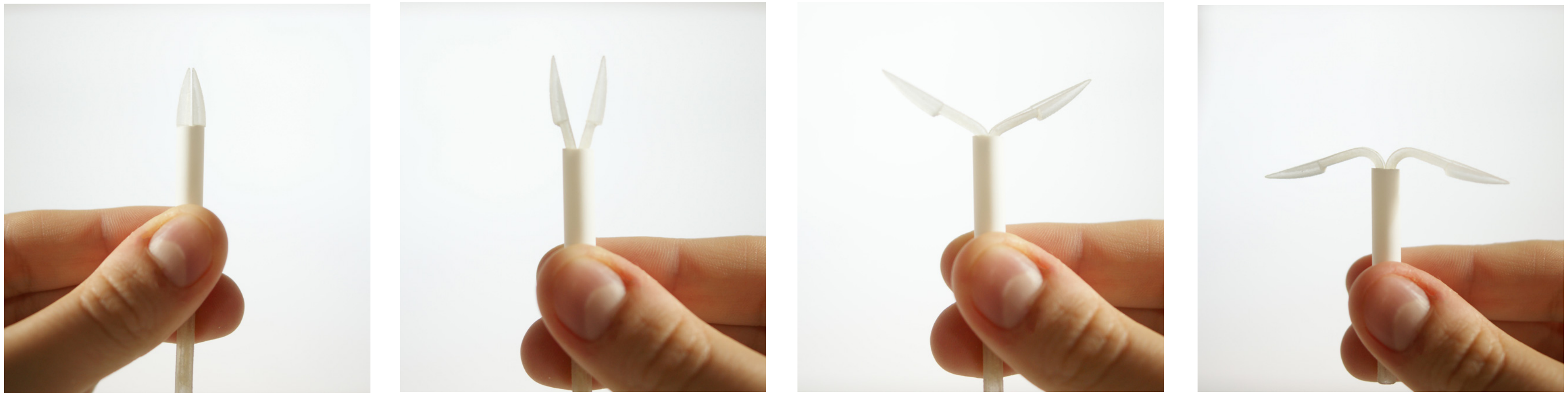


Figure 85. 3D printed Anchor final iteration, portraying how the multi-material forms can move within the external sheath.

EGG BEATER DRAIN

The Eggbeater drain, alongside the Anchor, initially focused on the insertion and retention of the catheter within an abscess. The shape of this drain has the highest potential for success due to the forms open, yet stable configuration. The incorporation of hard and soft materials supports fluidity, enabling flexible movements throughout the structure inside and out of the external sheath.

During the drainage procedure as the abscess contracts, the tissue can inadvertently block the catheters drainage holes and prevent the drainage to commence (Charles, 2012). The Eggbeater's shape, however, will prevent blockages and therefore has the opportunity to mitigate another current procedural issue.

This design idea derived from the current Malecot catheter (see figure 16). The Malecot drain focuses specifically on the retention of the tip through the shape of the form. However, the silicone material is not as reliable as the Eggbeater drain, which utilises stronger materials, eliminating the need for other retentive techniques.

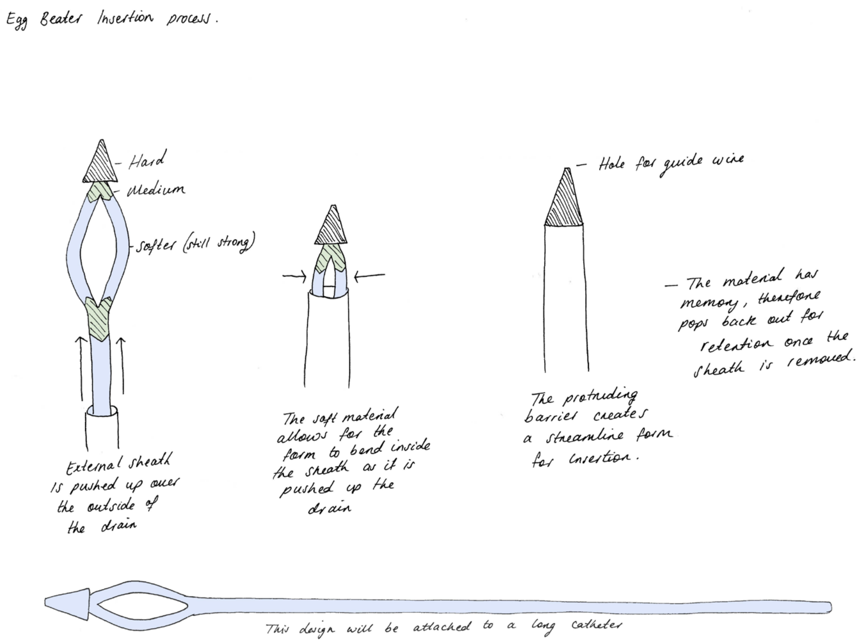


Figure 86. Detailed sketches to decipher how the Eggbeater drain can elongate for insertion and removal.

Figure 87. Developed Eggbeater drain renders and flow rate diagram, to understand how the large drainage holes can increase drainage efficiency.

EGG BEATER DRAIN ITERATIONS

Figure 88. Eggbeater drain 3D printed iterations to develop the drainage tip, wing numbers and material strength.

EGG BEATER DRAIN INSERTION AND REMOVAL PROCESS

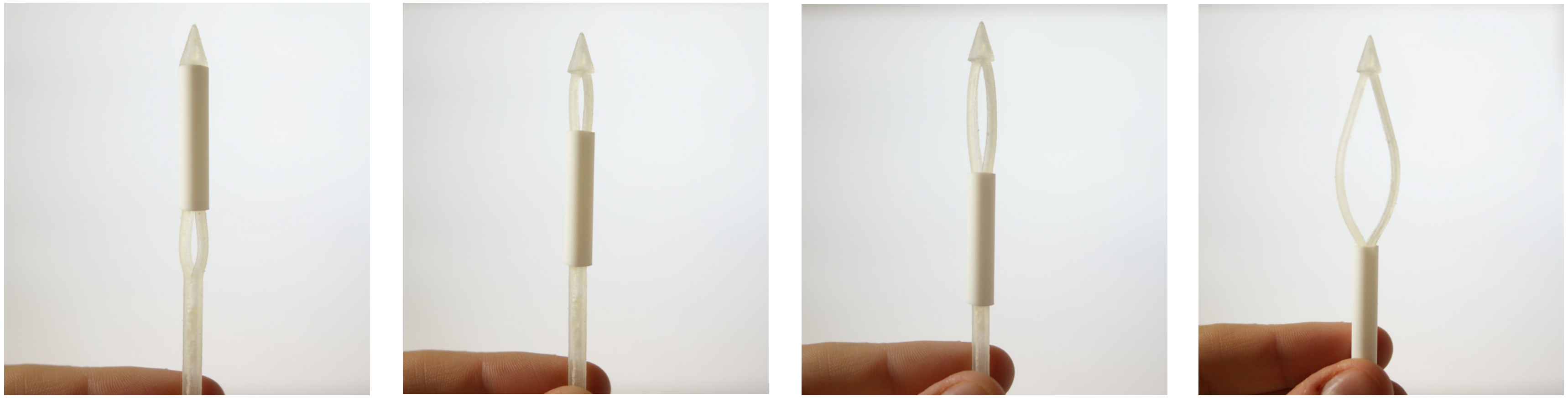


Figure 89. 3D printed Eggbeater final iteration, portraying how the multi-material properties within the wings, can allow for movement within the external sheath.

TWIST DRAIN

The final novel drainage design is the Twist drain. The Twist drain has a unique one-sided form that provides additional retention inside the abscess. The forms wing is layered using a variety of soft and hard materials, to allow fluidity while also retaining the shape of the form, which will reduce the catheter being unintentionally ripped out. The wing requires a manual motion to wrap around the catheter tightly, which is inserted using an external sheath. The wing then readjusts to its original open form once inside the abscess.

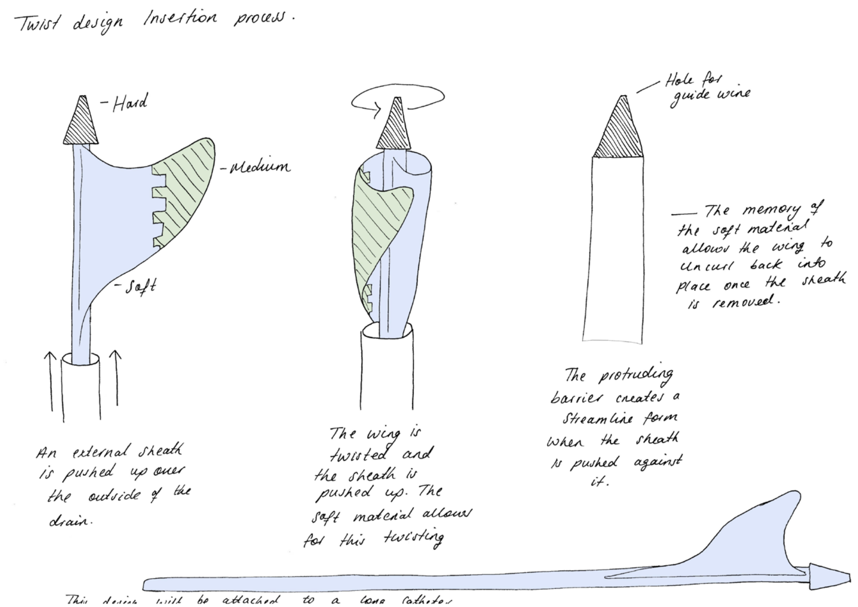


Figure 90. Detail sketches understanding how the Twist drain can manipulate the multi-material properties, to create fluid movements within the external sheath.

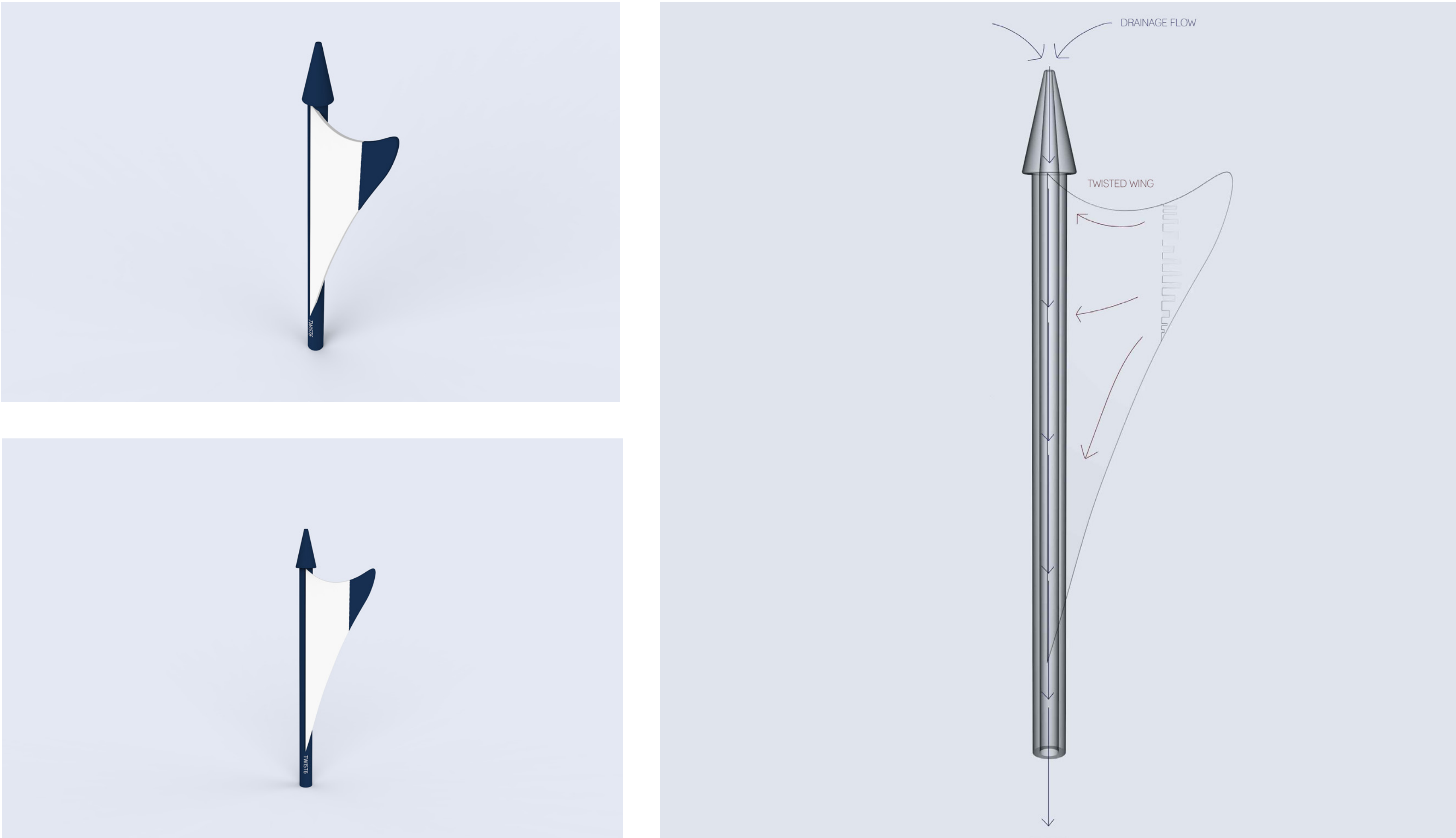


Figure 91. Twist drain renders and flow rate diagram, to develop the wing material and form shape for heightened retention.

TWIST DRAIN ITERATIONS

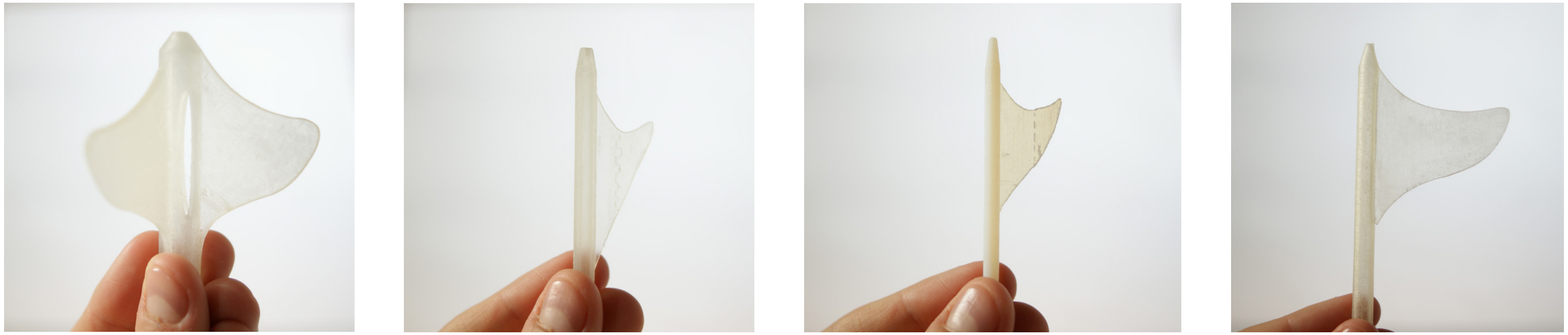


Figure 92. Twist drain 3D printed iterations to develop the form shape and size of the drains retention wing.

TWIST DRAIN INSERTION AND REMOVAL PROCESS

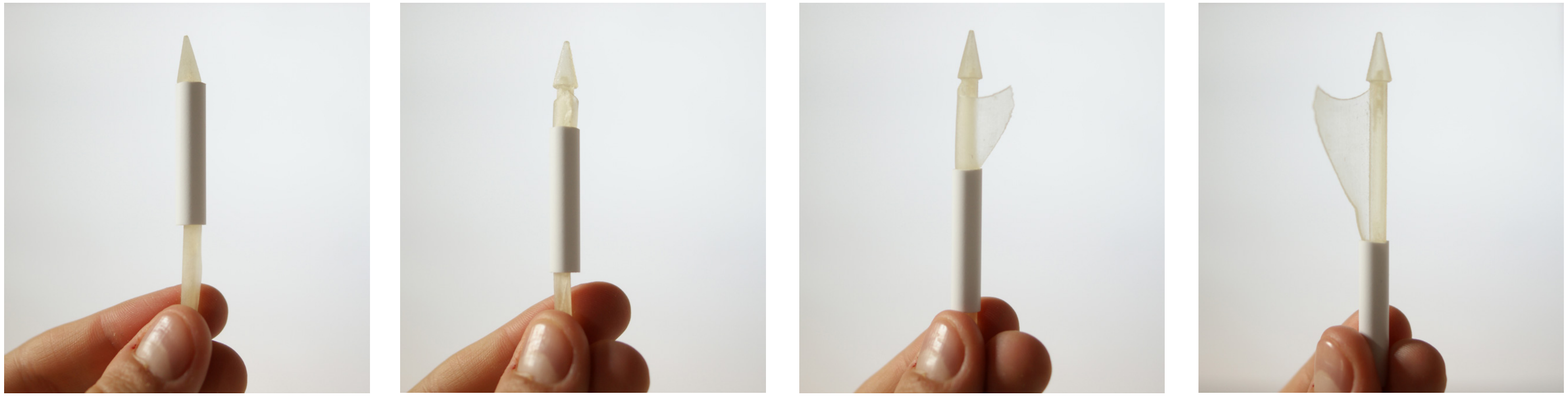


Figure 93. 3D printed Twist drain final iteration, showing the fluid movements within the Twist drains wing and how it fits within the external sheath.

CLINICAL EVALUATION TWO

The second clinical evaluation was gained through a group of radiologists to understand the advantages and disadvantages of each proposed design. The radiologists interacted with physical models and imagery to comprehend the model's ideas and their novelties.

Through discussions, the external sheath designs (see figures 128-139) need to be reevaluated. This is because the elongation of a 6-week old drain using an outer sheath would not work effectively, as the forms movements and responses become increasingly more difficult to predict. The incision for an external tube design would also become more invasive, adding to the patient's recovery time. The multi-material properties were utilised well in conjunction with the forms shapes; however, these forms would need more than the material memory to create secure retention. The radiologists did favour the eggbeater form as this shape would have the most robust retention once developed.

Following further discussions, it became clear the need for irrigation and cleaning is prominent within the procedure, which can be achieved through the incorporation of a double lumen drain (see figures 68-70). Feedback on the Pigtail drain designs also highlighted that eliminating the internal string for retention was a definite idea as this currently causes many issues during or after the procedure.

The Archimedes screw, blow-up and multi-material drains (see figures 71-79) were not discussed in detail during the clinical evaluation, however, based on the overall feedback these drains would not create a significant improvement to the current Pigtail drains, therefore, will not continue development.

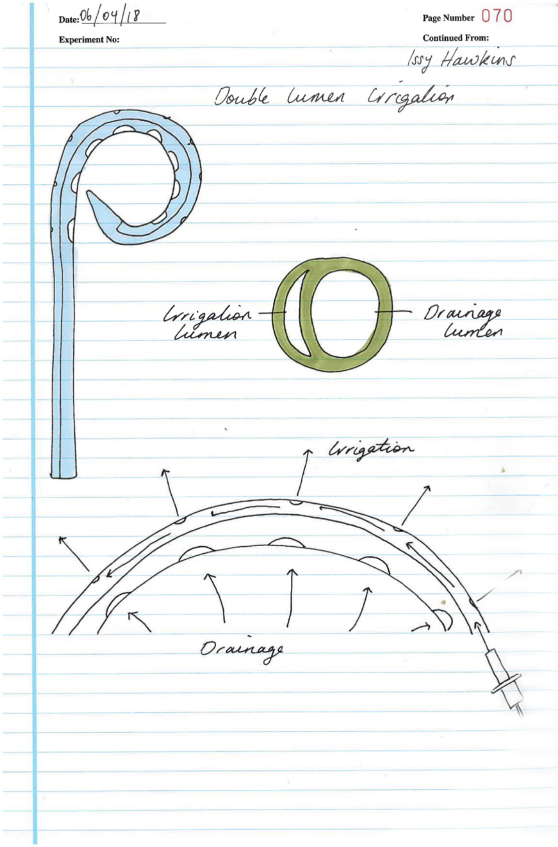
After reflecting on the radiologist's feedback, the novel design forms and Pigtail double lumen drains will continue development. The need for assisted retention prompted an idea to incorporate fluids within the designs to strengthen and manipulate the structures.

FINAL DESIGNS PIGTAIL DRAINS

Figure 94. Final Pigtail drain design iterations matrix.

PIGTAIL DRAIN IRRIGATION

The first final Pigtail design is the Irrigation drain. The Irrigation drain focuses specifically on an introduction of a second lumen, in conjunction with the location of smaller holes. The outward position of the additional features creates an even spread of saline and fluid around the abscess. Saline assists in the break up of thick pus and dead matter, which coerces the fluids to enter the large lumen through the drainage holes. Having the ability to irrigate and simultaneously drain the abscess, will reduce clogging and increase the drainage speed.



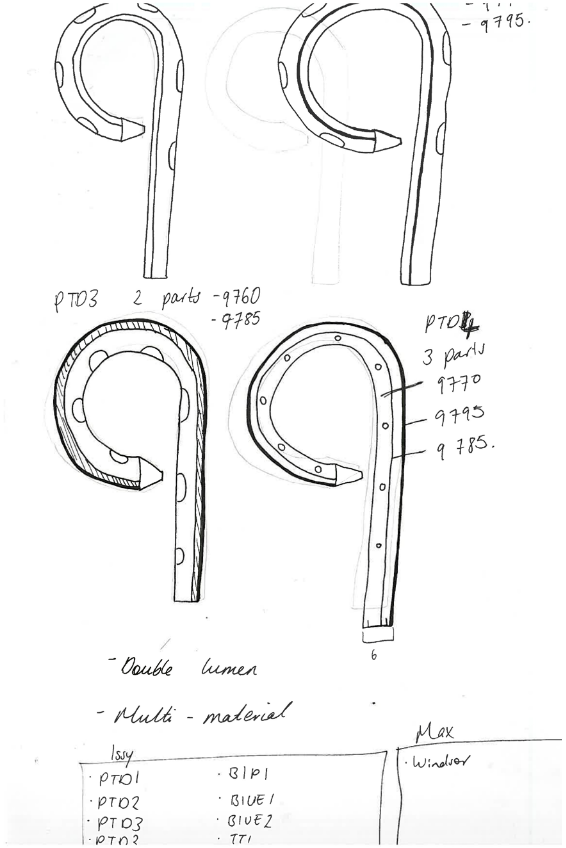


Figure 95. Double lumen Irrigation drain sketches, experimenting with lumen shapes and hole orientations.

Figure 96. Double lumen irrigation renders and flow diagram, to understand the most efficient configurations for irrigation and drainage.

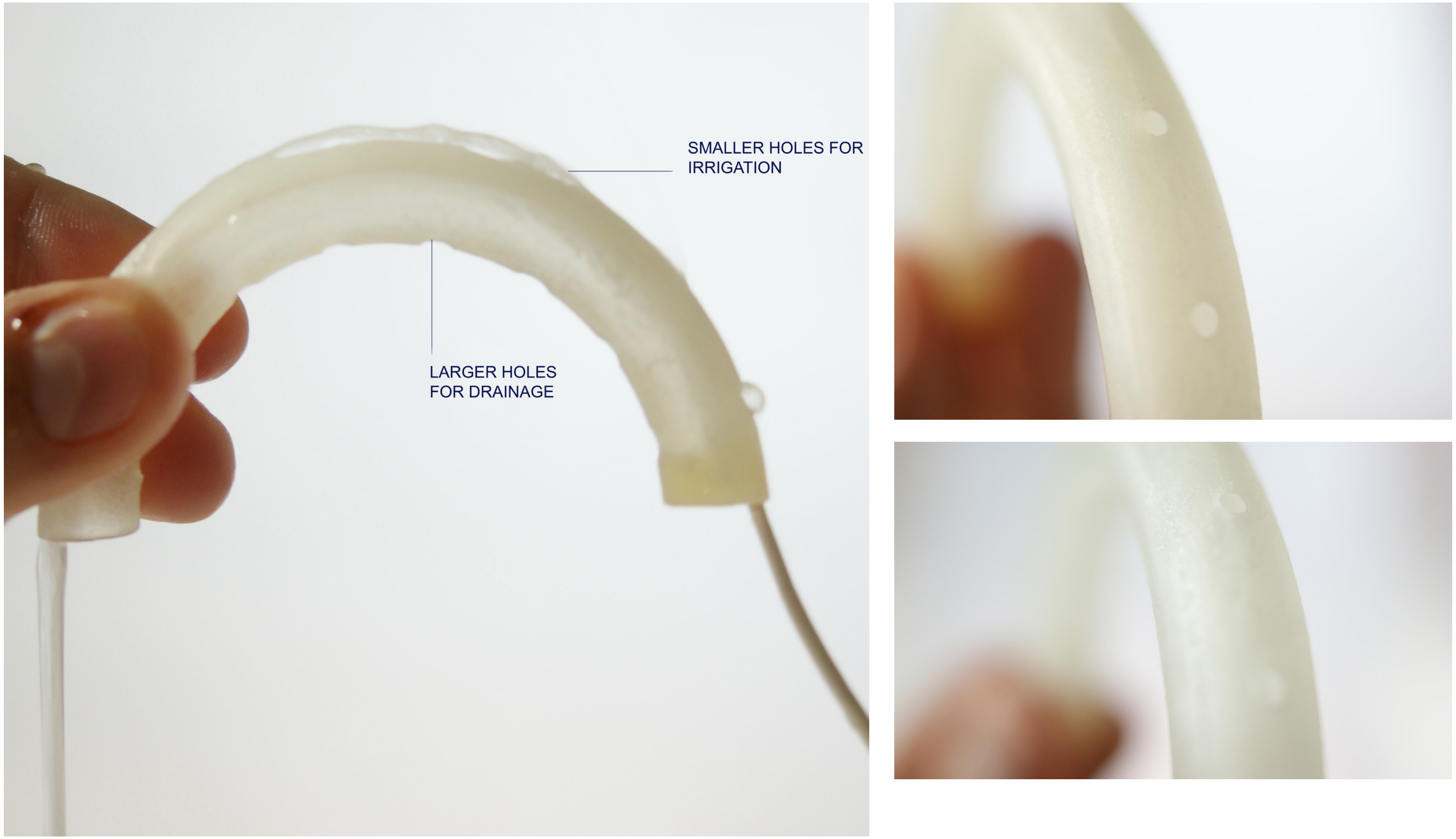
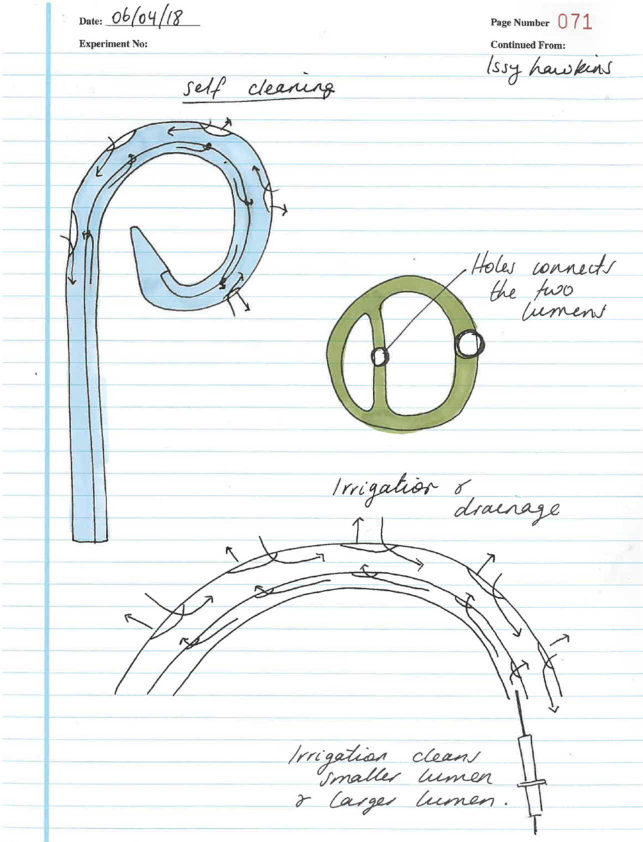


Figure 97. 3D printed Irrigation model, to experiment with water inside the double lumens and develop accordingly.

PIGTAIL DRAIN SELF CLEANING

Experimenting with hole orientations resulted in the development of a self-cleaning Pigtail drain. As seen in figure 98, the large and small lumens connect through irrigation holes. During the drainage procedure, saline or other fluid is inserted into the smaller lumen. However, the liquid does not instantly travel into the abscess, instead, flows through the large lumen and then into the infected area. This process therefore not only irrigates the abscess, but it also cleans the larger lumen on the journey out. The overall drainage efficiency of the catheter will improve, as well as decrease the catheters blockages.



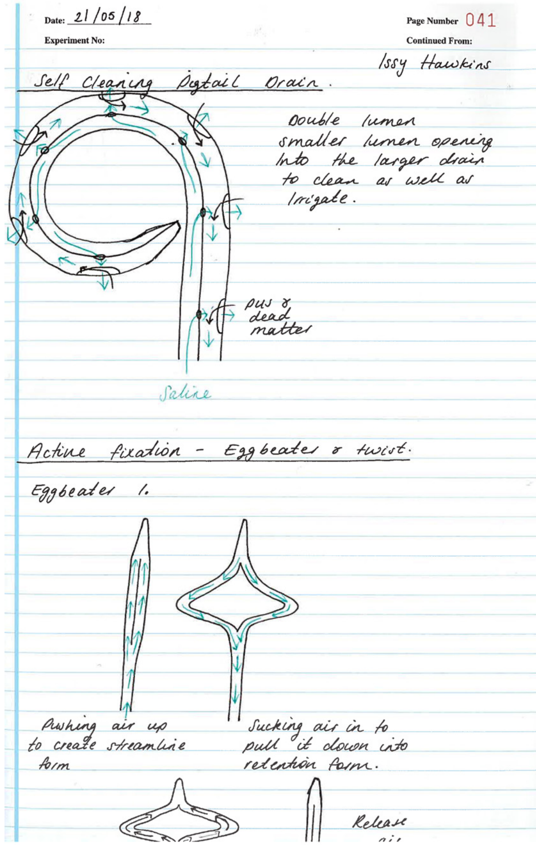


Figure 98. Double lumen Self-cleaning drain sketches, experimenting with hole placements within the inside of the catheter.

Figure 99. Double lumen Self-cleaning renders and flow diagram, to visualise the idea and understand if it was applicable.

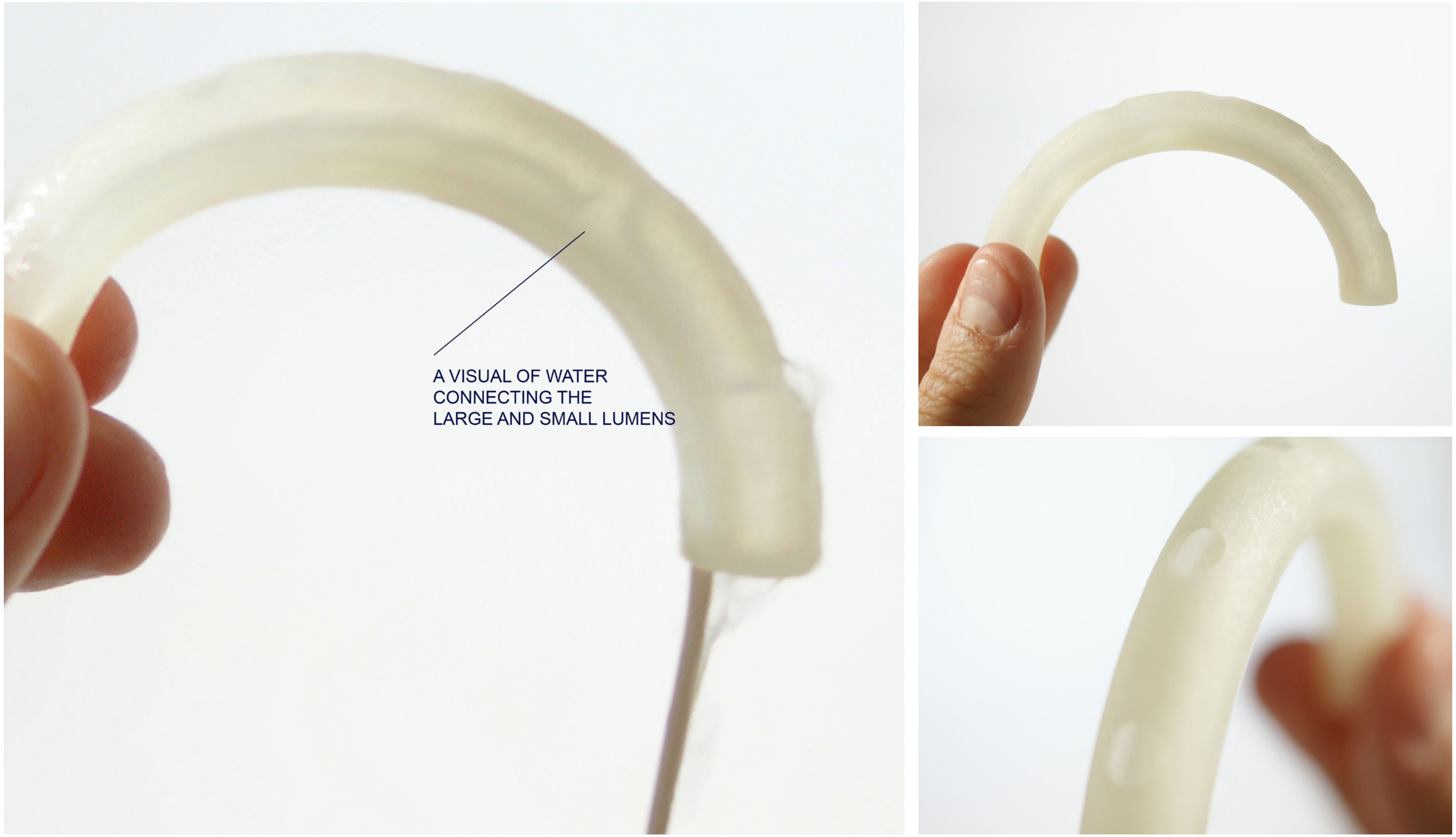


Figure 100. 3D printed Self-cleaning model, to test water in conjunction with hole locations, resulting in the smaller lumen cleaning and draining through the large.

PIGTAIL DRAIN DESIGNS WITH FINAL ORIENTATION HOLES INCORPORATED

IRRIGATION

Figure 101. Small and large oval holes incorporated into the Irrigation drain.

SELF CLEANING

Figure 102. Small and large oval holes incorporated into the Self-cleaning drain.

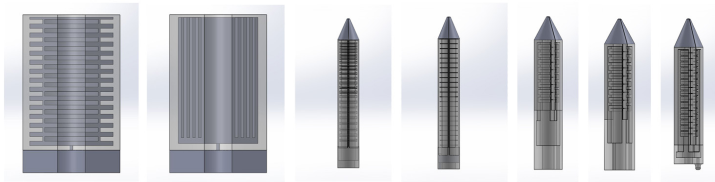
FINAL DESIGNS NOVEL DRAINS

NOVEL DESIGN ITERATIONS

ACTIVE FIXATION

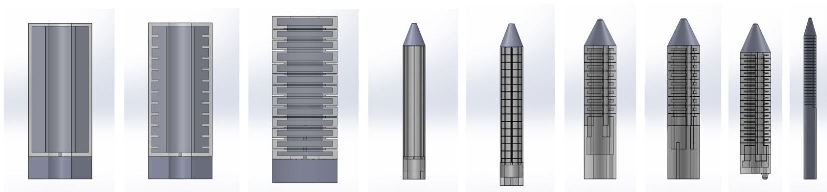
ANCHOR

The incorporation of active fixation is vital in the development of the designs. Using water pumps and unique internal cavities, the Anchor form folds out into the abscess and is held securely using the liquid. Once the liquid is extracted, the form returns to its streamline position for removal.



EGGBEATER

The eggbeater drain uses the same developments as the anchor, however, in a different form. The design alters depending on the direction the form needs to bend. This design can incorporate two or three wings.



TWIST

The twist drain also incorporates the developed designs however the form cuts are orientated vertically rather than horizontally. Once the wing is pumped with liquid, the wing will spiral securely around the waist of the catheter for insertion and removal. This wing will unwind when the liquid is removed for retention.

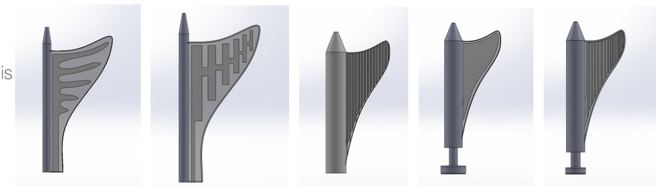


Figure 103. Novel drain design iterations matrix, shown using CAD modelled images.

After discussions with the radiologists, the introduction of developments utilising active fixation methods into the novel drains is apparent. By incorporating this method, the external sheath is eliminated, and the mode of retention is intensified. These designs no longer focus specifically on introducing multi-material properties, however, utilise these properties to create fluid movements that move and bend once cavities are inserted with liquid (see figure 103).

The current balloon catheter (see figure 15) has been a precedent for the active fixation technique. However, due to materiality and internal cavity designs, the forms move directionally for retention rather than being used as a tool to only prevent blockages ("Products - Cook Medical", 2018).

As seen in figure 104, throughout the design process, many iterations have been developed to create a retentive curve, to ensure the form does not split and break once the cavity is activated. This was achieved through experimentation of material strength, wall thicknesses and cavity filleting. Filleting is when the model's edges are curved to prevent the sharp corners from ripping when placed under pressure. Connex printing material was not initially designed for excessive stretching. Therefore curved edges create less pressure for the form to withstand.

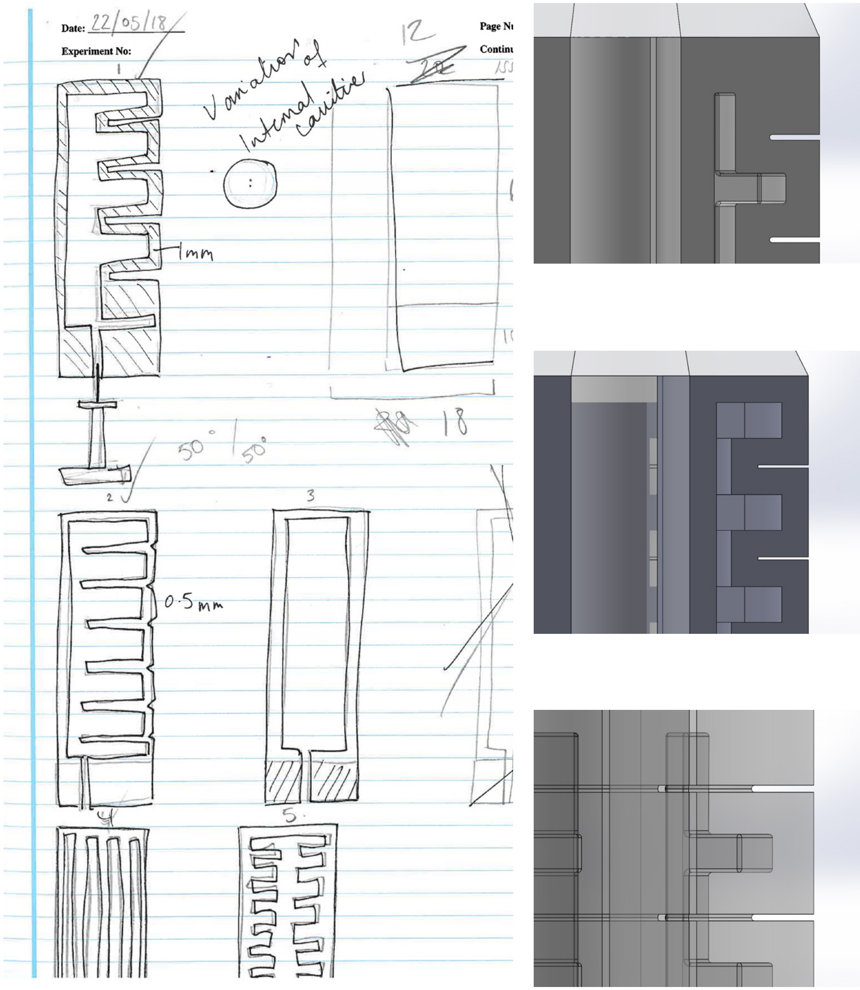


Figure 104. Variations of catheter wall thicknesses and filleted edges for successful developments.

ACTIVE FIXATION ANCHOR DRAIN

The Anchor drain incorporated the active fixation method through form explorations and internal cavity designs. The configurations and cavities allow the drain to reform (see figure 106) entirely, creating a secure open tip that assists in the drainage efficiency. The 3D printed catheter's original state is streamlined for the insertion and removal. However, the fluid is inserted once inside the abscess, causing the Anchor's wings to extend out. While the liquid is inside the cavities, the materials ability to move is disabled, creating solid retention.

This design's iterations were in response to the materials reactions to the pressure of the water. The thickness of the internal cavities walls (1mm) is designed to allow for fluid movements, while also having the strength to hold the expanded position under stress.

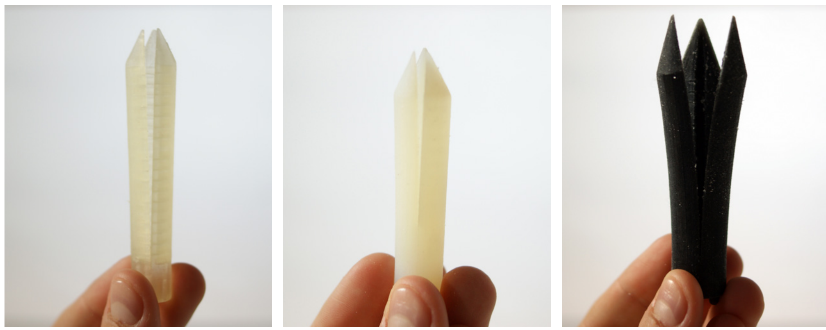


Figure 105. 3D printed Anchor drain active fixation iterations. Experimenting with cavity sizes and material strength.

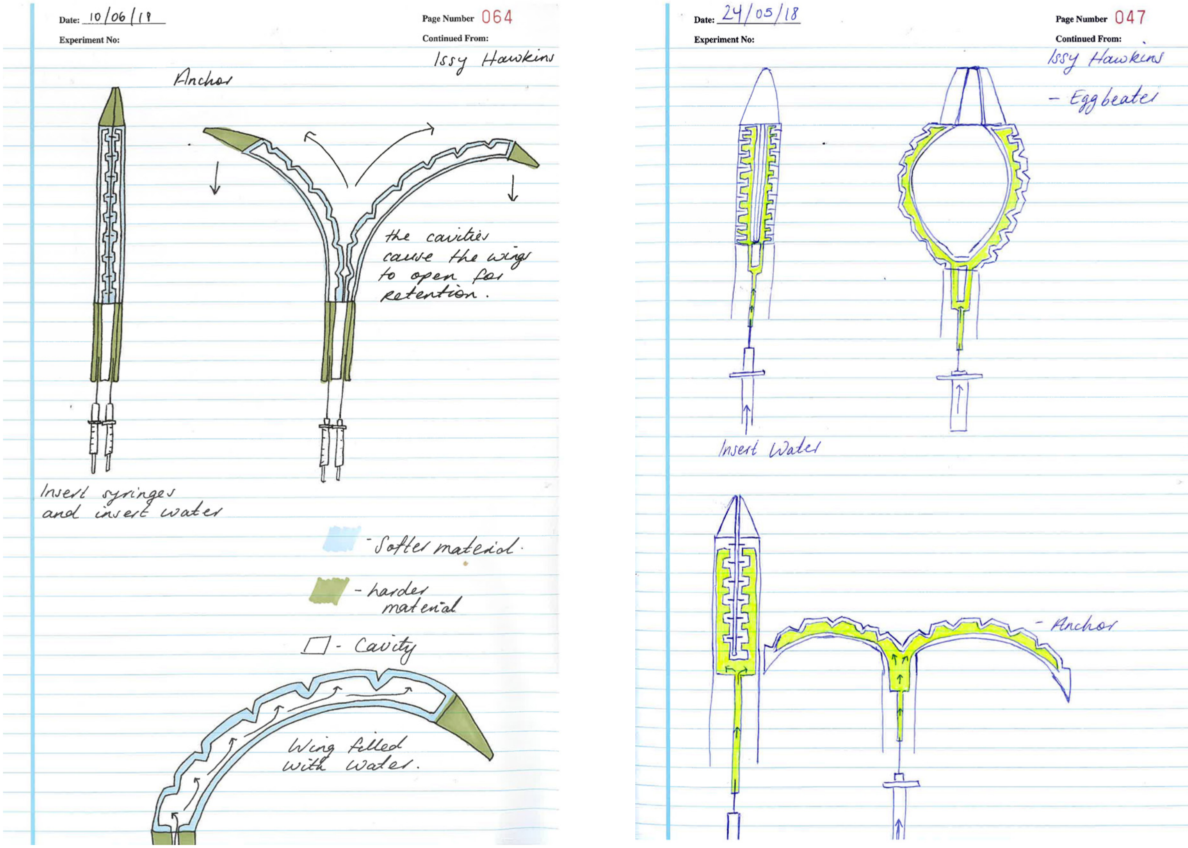


Figure 106. Anchor drain internal cavity developments.

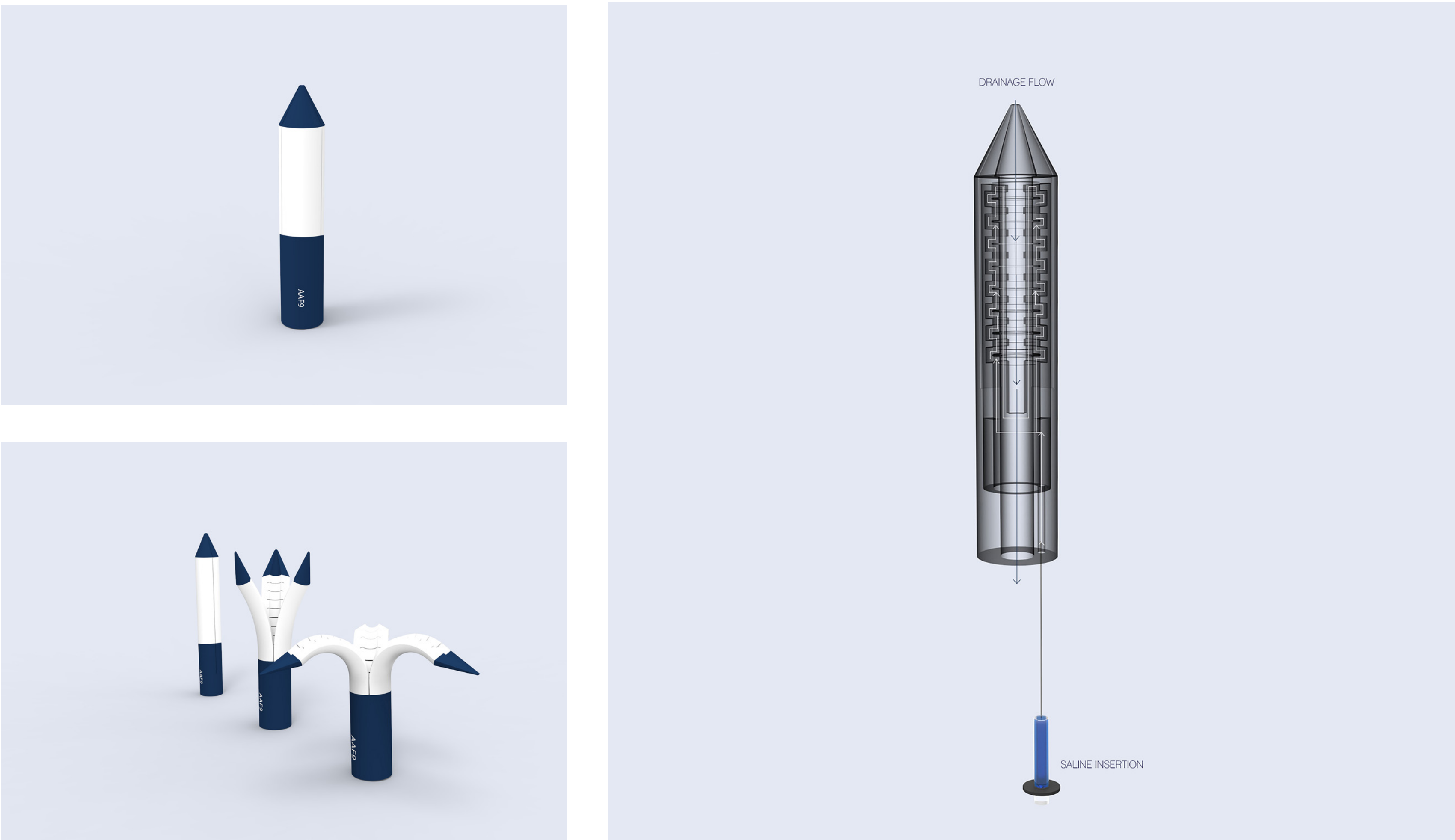


Figure 107. Anchor drain active fixation renders, visualising how the form will expand once the fluid is inserted.

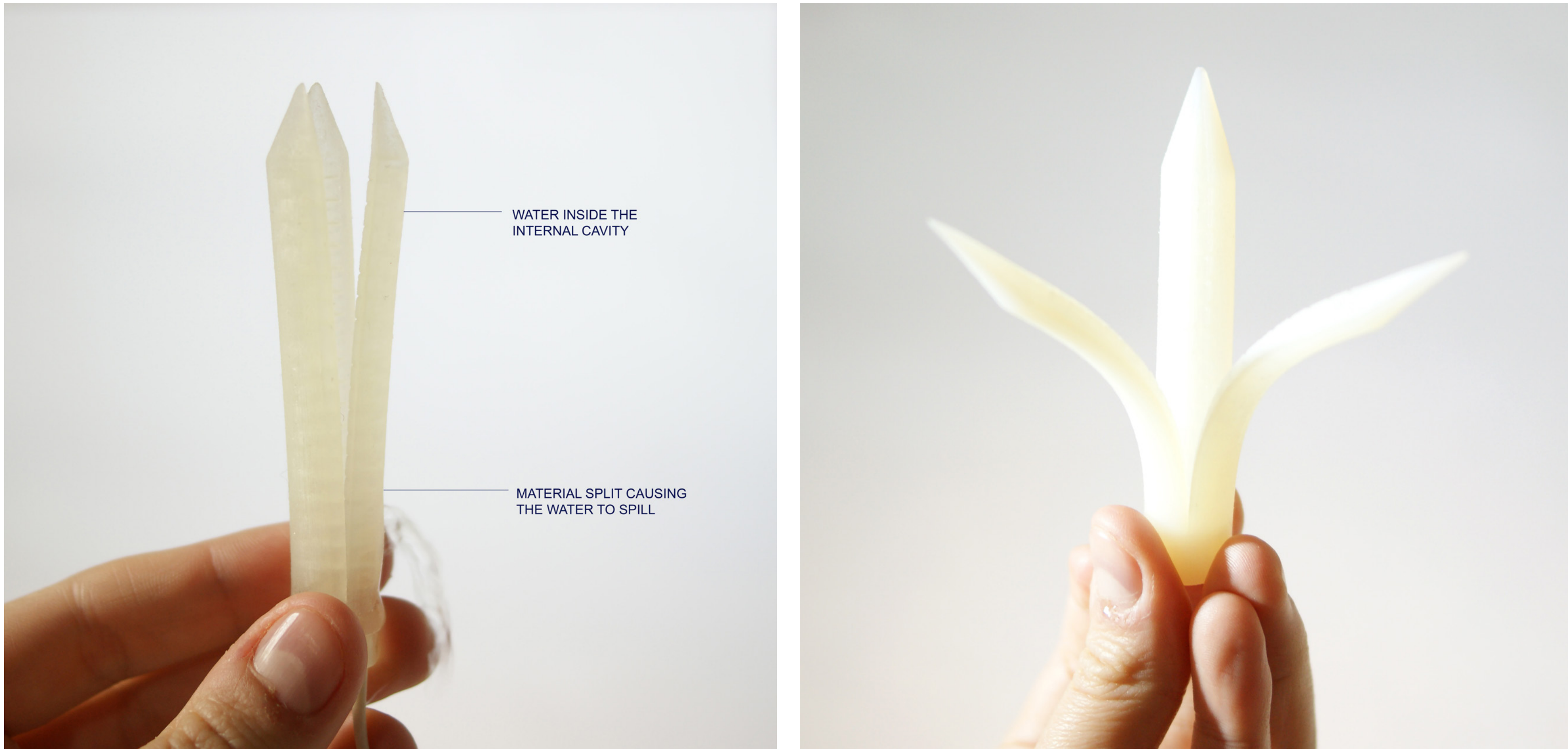


Figure 108. Anchor drain 3D prints. As seen in the left image, when the wall thickness is too thin, the water breaks through. The right image shows all three wings expanding.

ACTIVE FIXATION EGG BEATER DRAIN

The Eggbeater drain has also combined the active fixation method into the final design. Similar to the Anchor, the Eggbeater is 3D printed in an elongated state for smooth insertion, which incorporates a passage for the guide wire to pass through for precise positioning. Once inserted into the body, the fluid is injected, causing the wings to expand externally into the abscess. The shape of the Eggbeater clears the internal pathway for drainage, as large open holes appear. These holes will reduce premature blocking of the catheter, resulting in a more reliable and efficient procedure.

The internal cavities for the Eggbeater are put under less pressure, as the movement does not require as much force to create a retentive form. With that being said, many iterations were 3D printed to ensure the structure expands sufficiently for security. Fluid insertion cavity designs were undertaken to inject all three wings simultaneously. Because of the material, however, extending these wings individually creates a more retentive curve for demonstration.

Figure 109. 3D printed Eggbeater drain active fixation iterations, experimenting with cavity thicknesses and shapes.

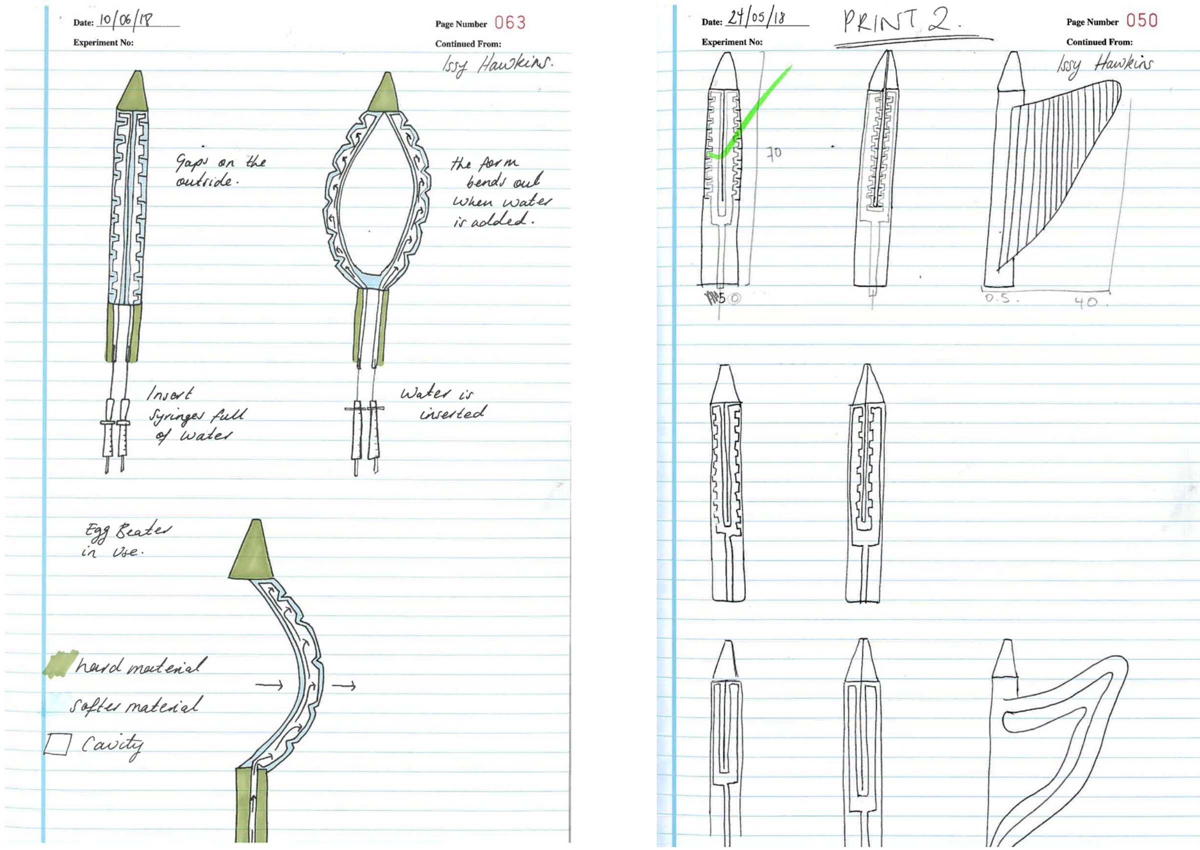
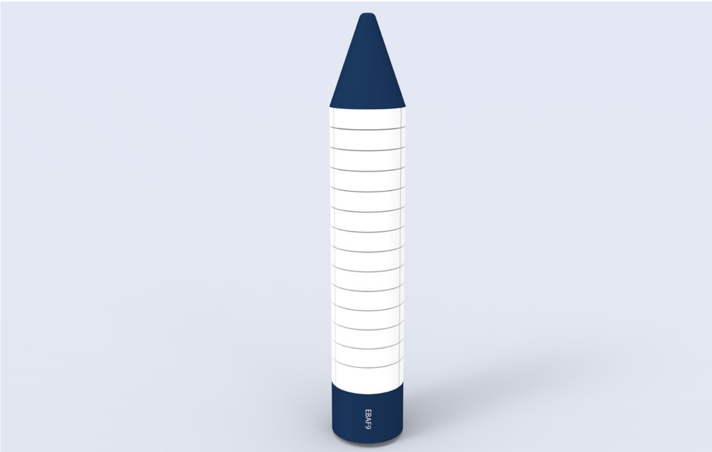
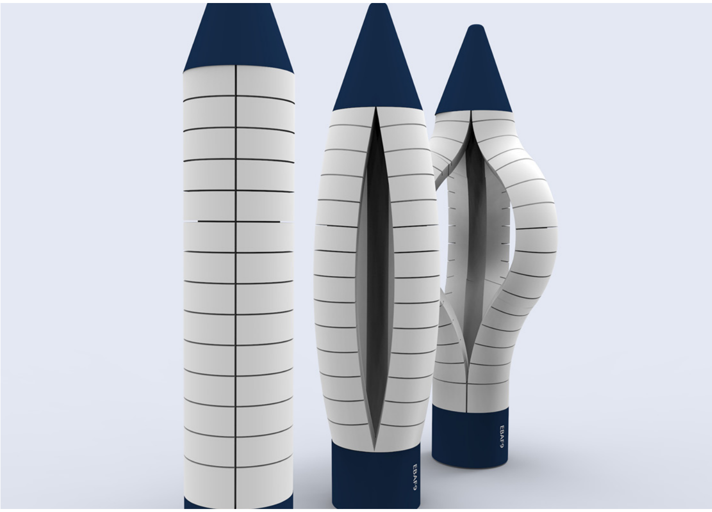


Figure 110. Eggbeater drain internal cavity developments.





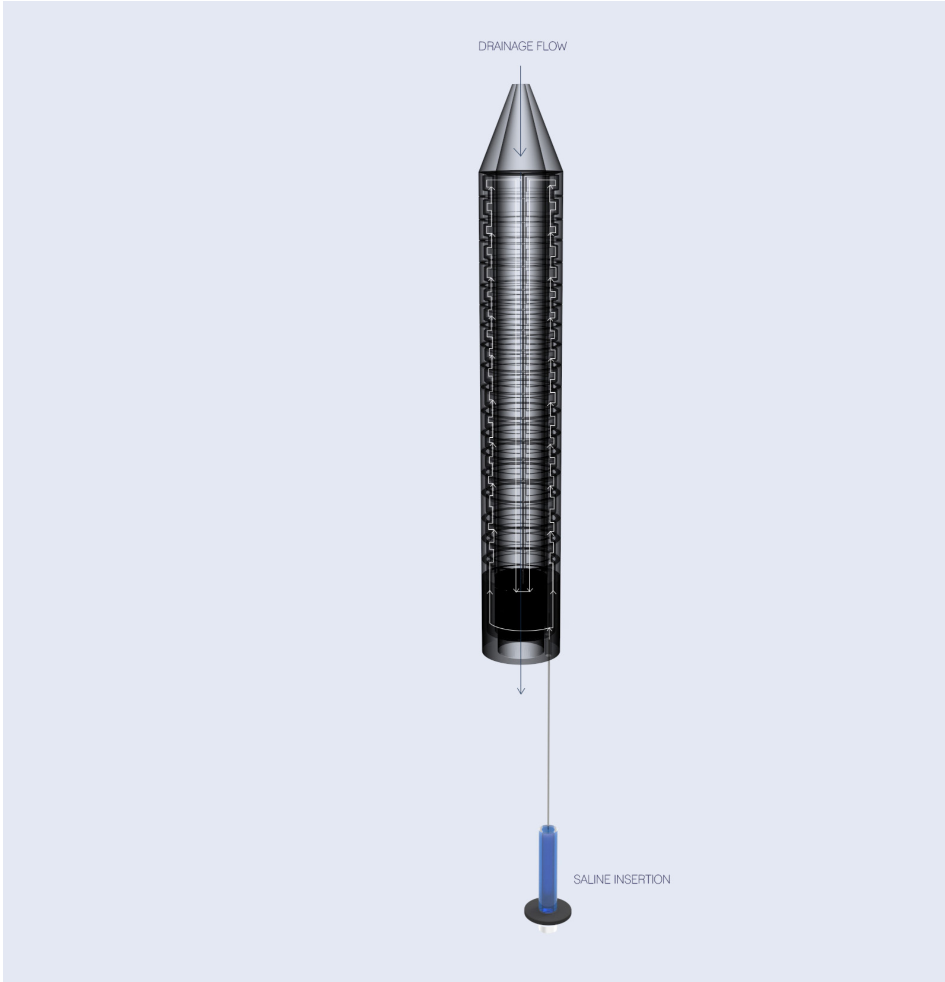


Figure 111. Eggbeater drain active fixation renders and flow diagram, visualising how the form will externally protrude once the fluid is inserted.

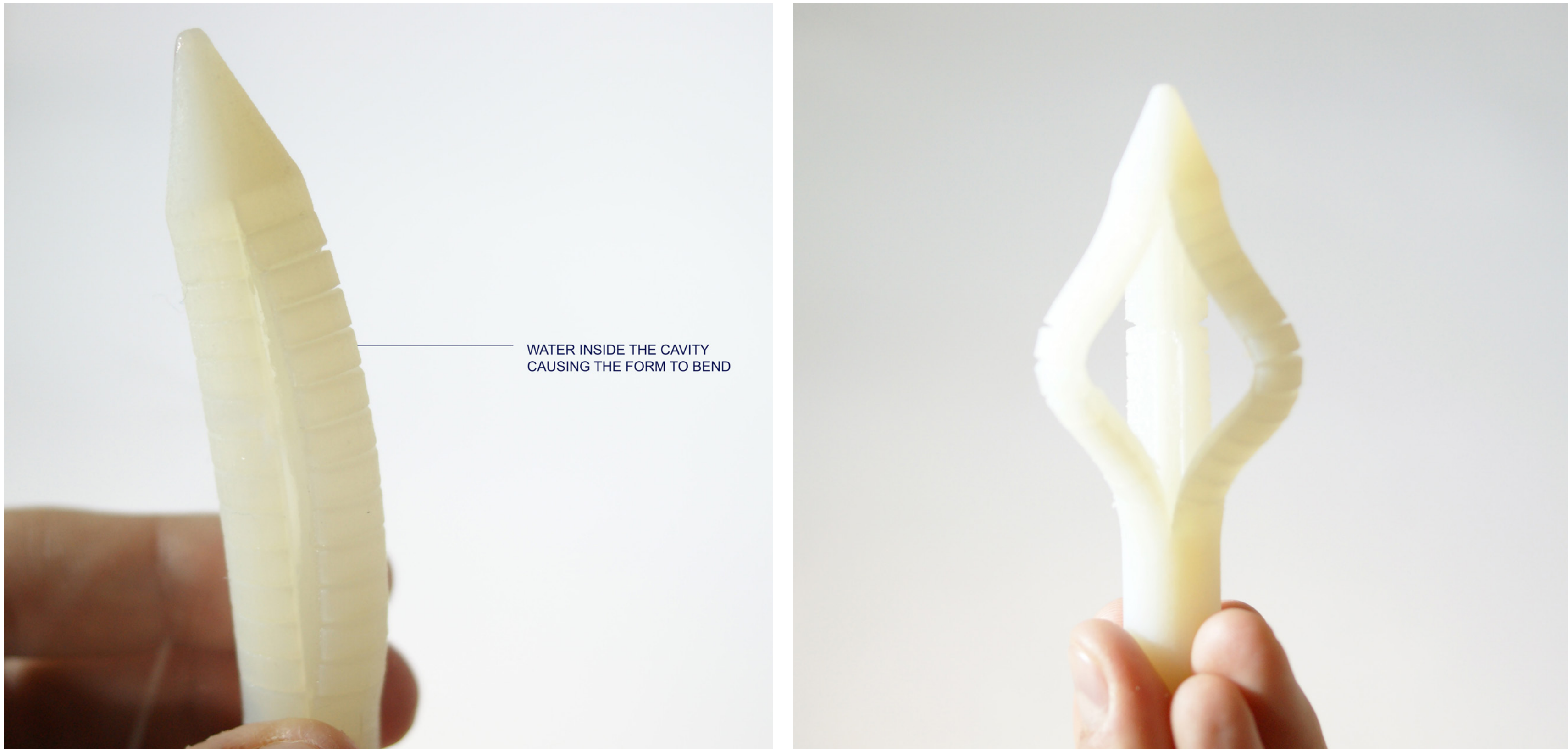


Figure 112. Eggbeater drain 3D prints. As seen in the left image, when water is inserted into the cavity the form bends for retention. The right image shows all three wings protruding.

ACTIVE FIXATION TWIST DRAIN

The Twist drain incorporates the active fixation methods within the design. The Twist drain is 3D printed in the retentive form, using active fixation to insert liquid into the cavity to shrink the wing compactly around the catheter. Once compressed, the drain is inserted into the body. The fluid is then removed, allowing the wing to reopen into the abscess for retention.

Patient care is the most critical aspect of any procedure; therefore, although innovative, this idea is discontinued because the wing will not contract adequately to become streamlined and thus would not create a smooth insertion.

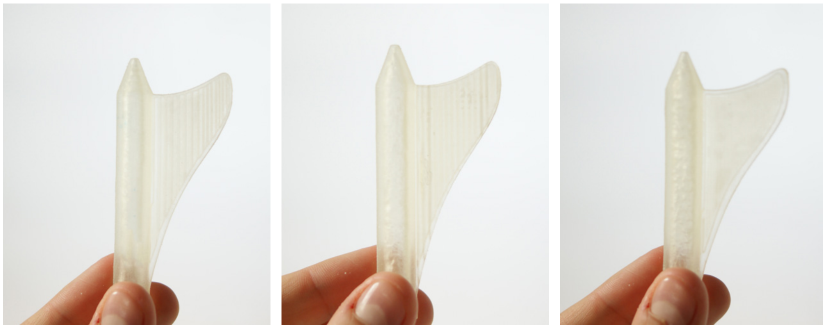


Figure 113. 3D printed Twist drain active fixation iterations, experimenting with cavity thicknesses and external wing shapes.

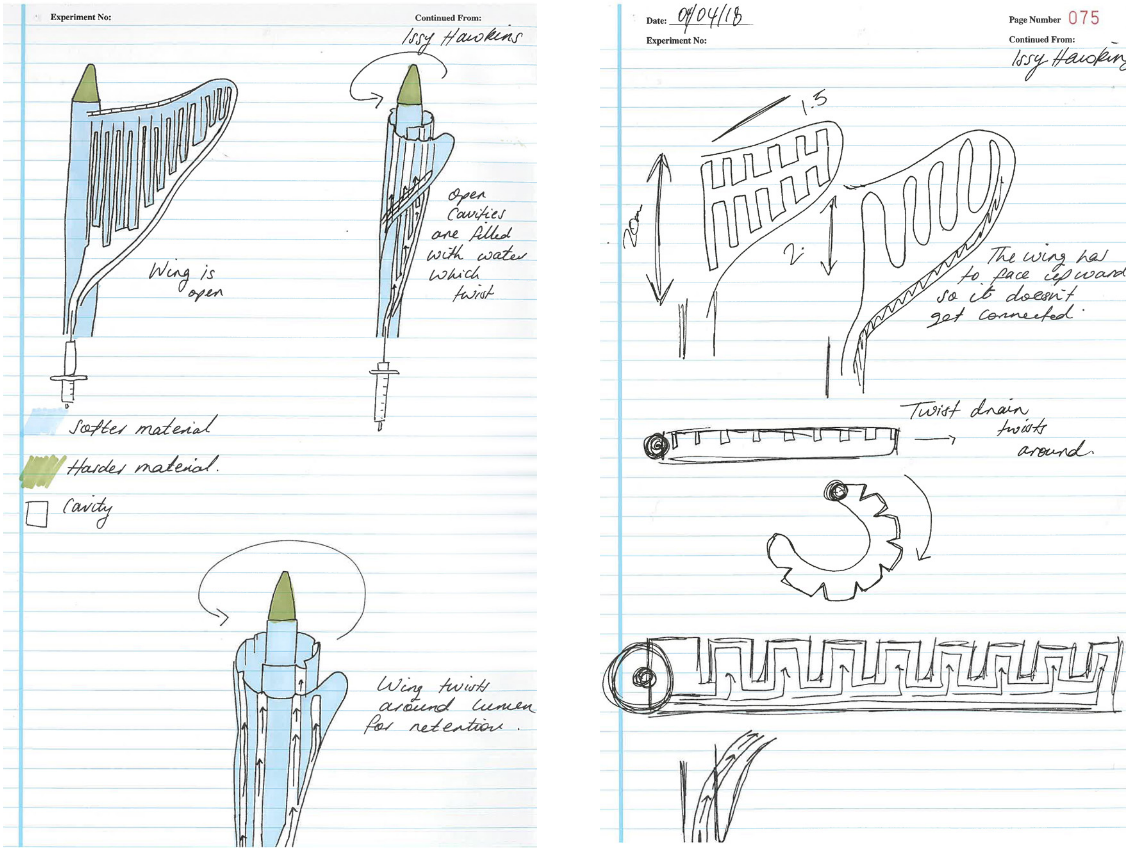
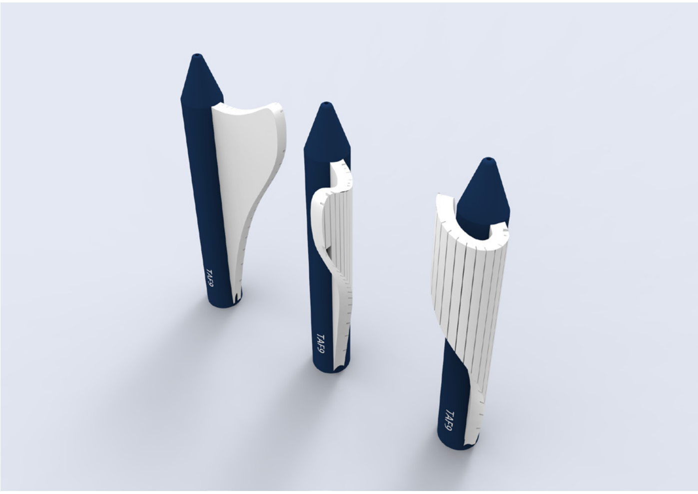


Figure 114. Twist drain internal cavity designs and insertion process developments.



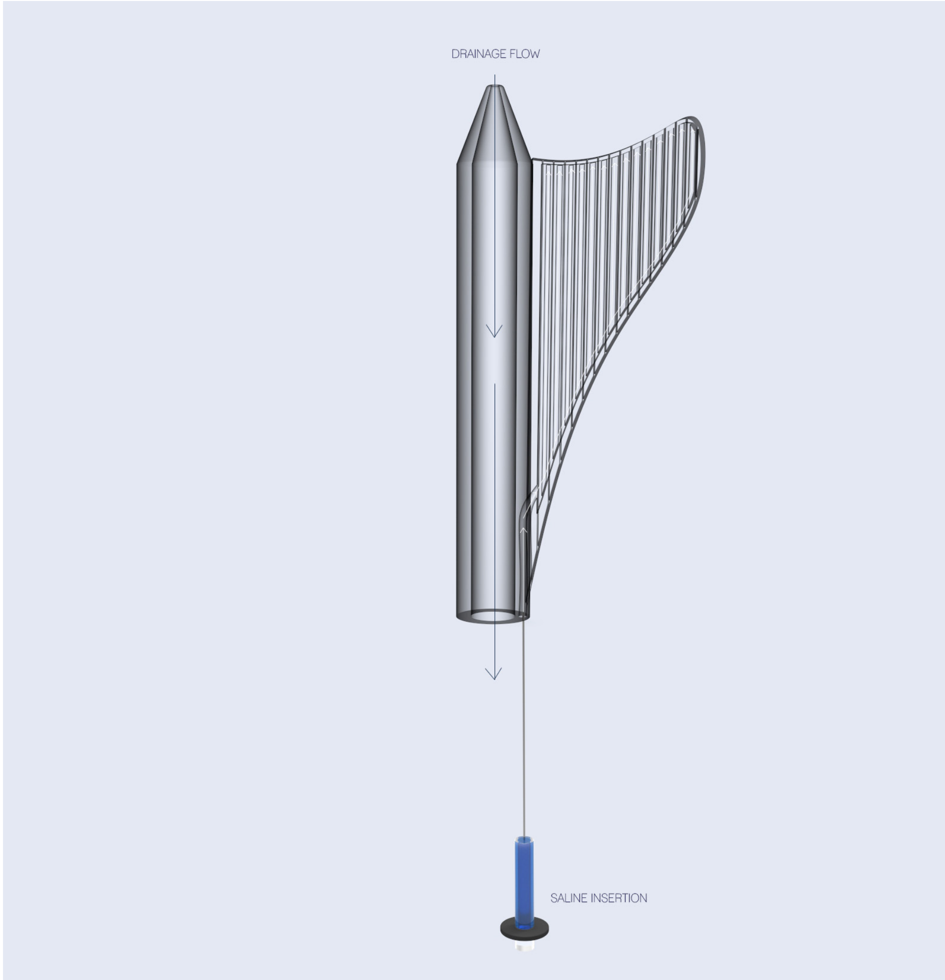
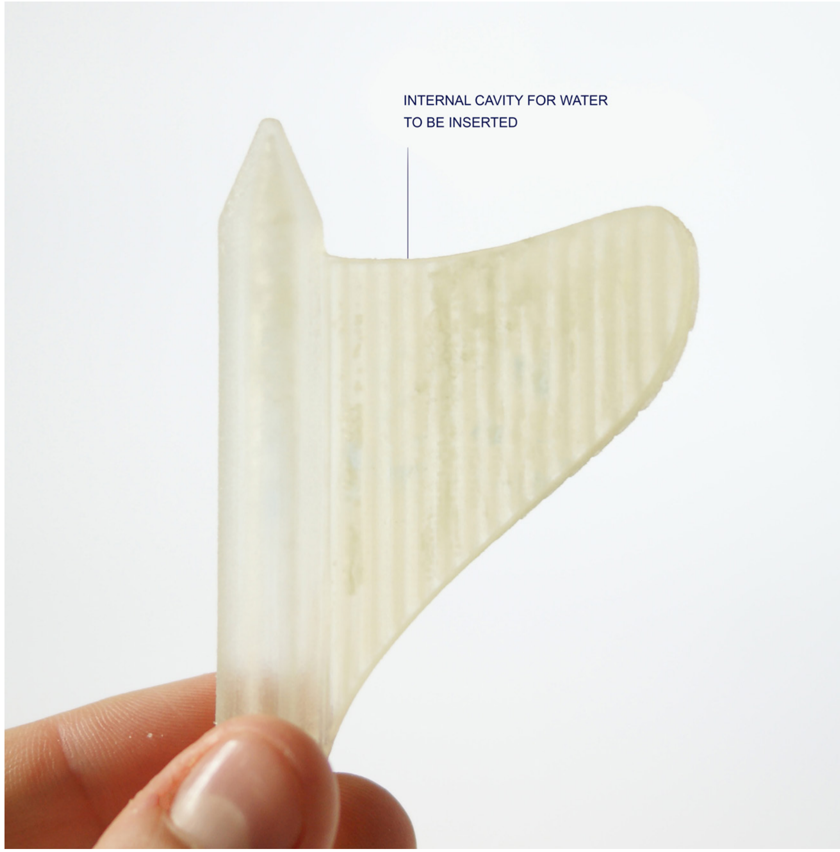


Figure 115. Twist drain active fixation renders and flow diagram, visualising how the form will wrap around the cavity once the fluid is inserted for insertion and removal.



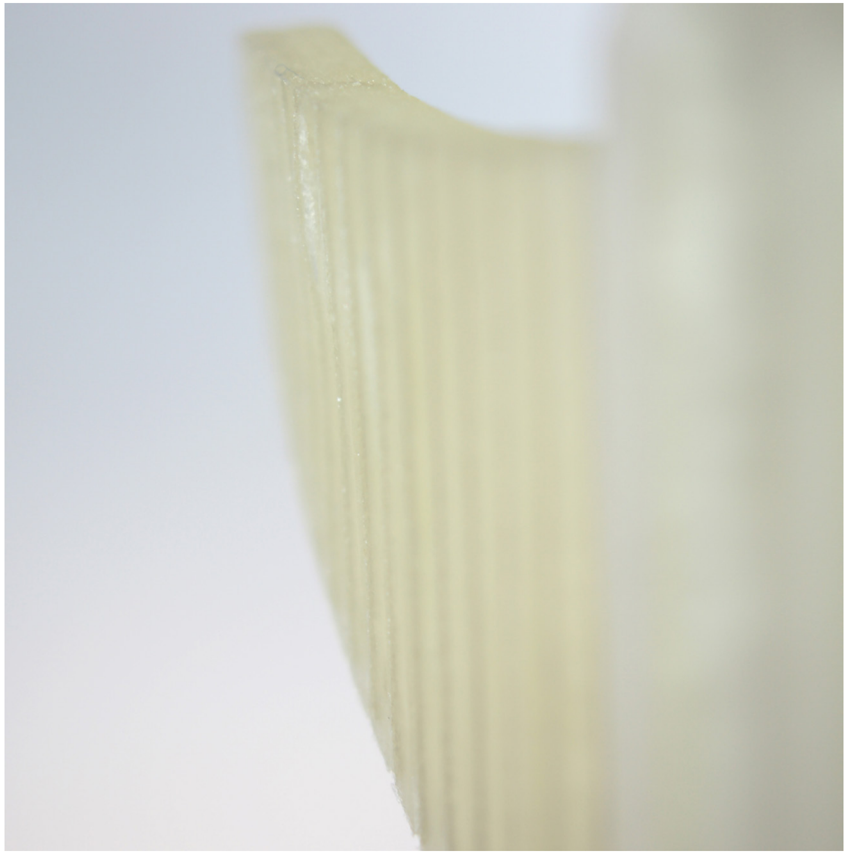


Figure 116. The Twist drains 3D prints, highlighting the wings internal cavity and multi-material properties to allow fluidity.

ACTIVE FIXATION FINAL DESIGN

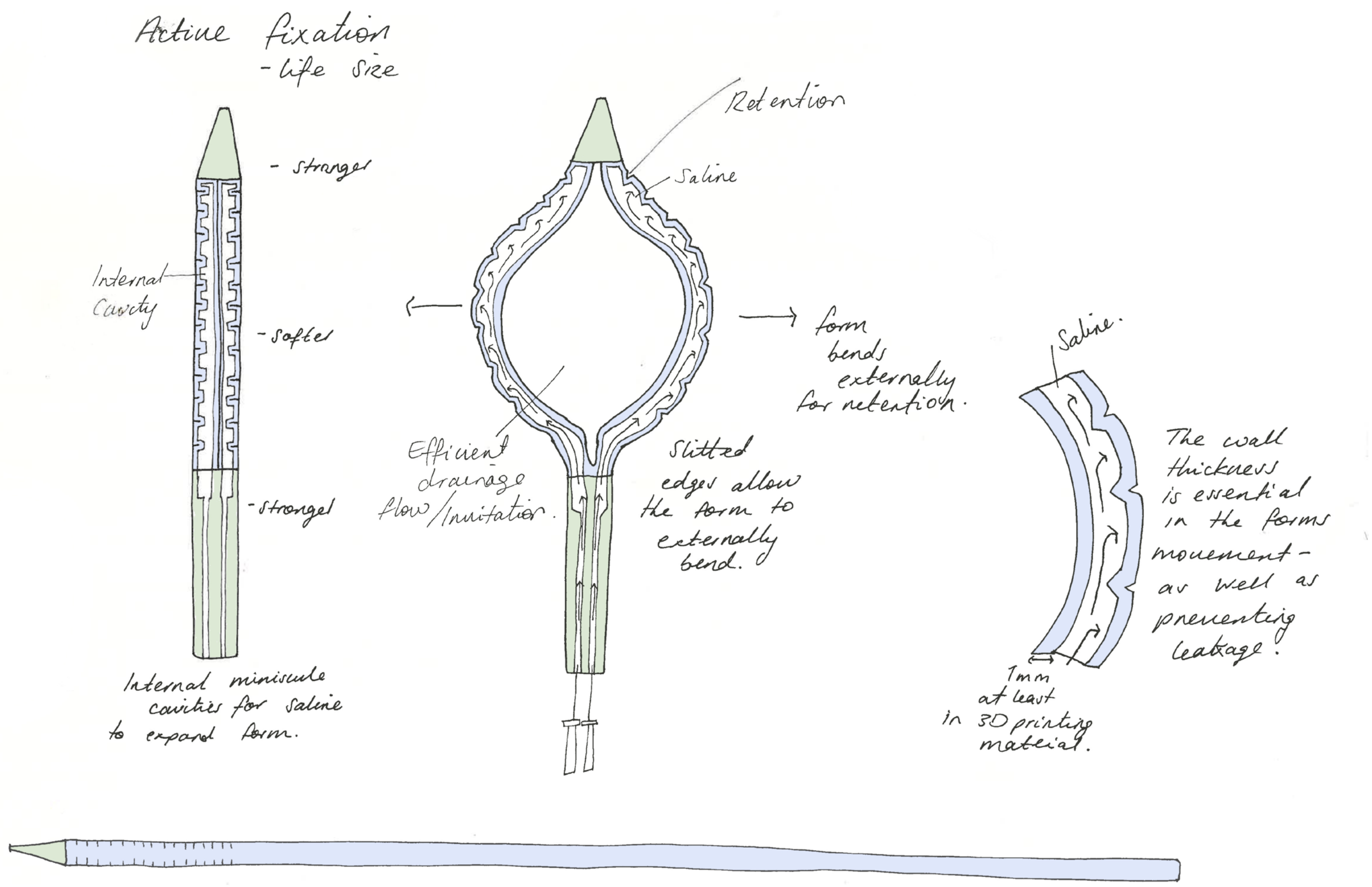


Figure 117. The Eggbeater drains final development sketches. Altering the forms overall size and internal cavity configurations.

EGG BEATER LIFE SIZE

Figure 118. The Eggbeater drain rendered in life-size, showing the form blown up for retention and inside the simulated anatomy model for context.

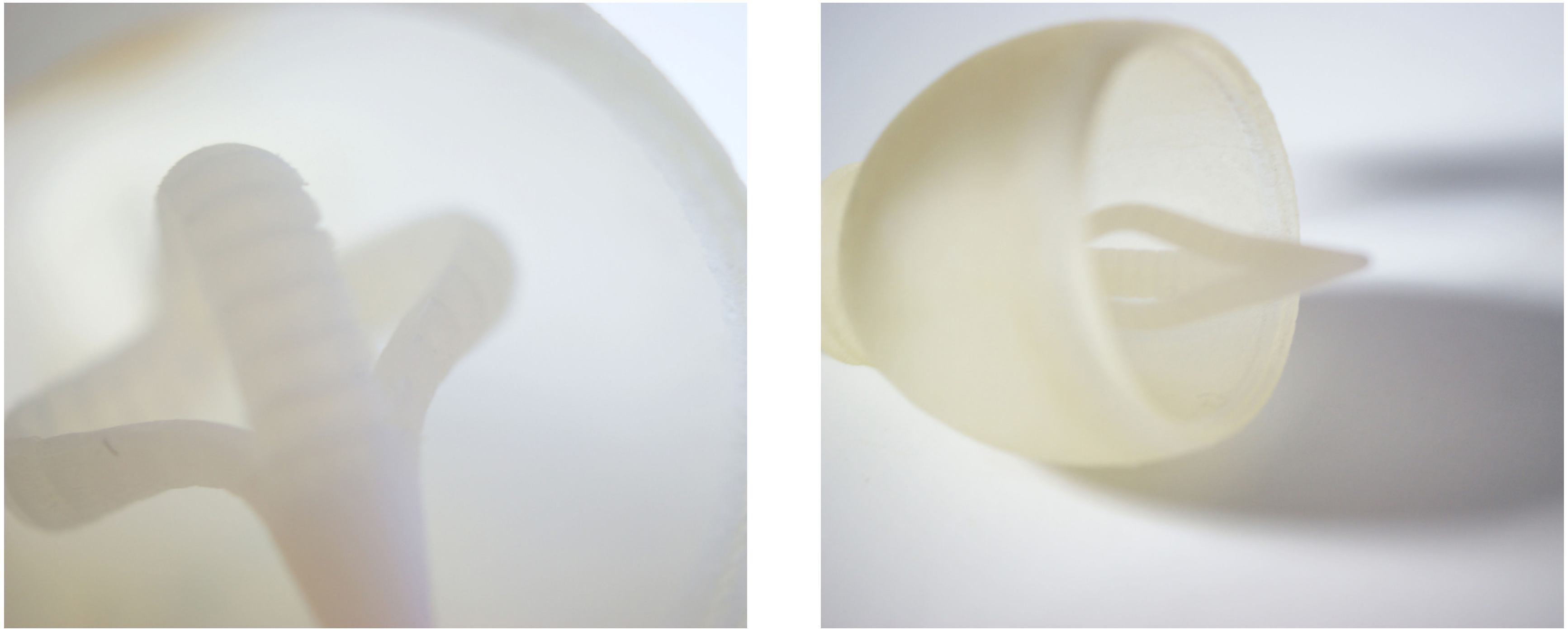


Figure 119. 3D printed life-size Eggbeater model, incorporated into the simulated anatomy model.

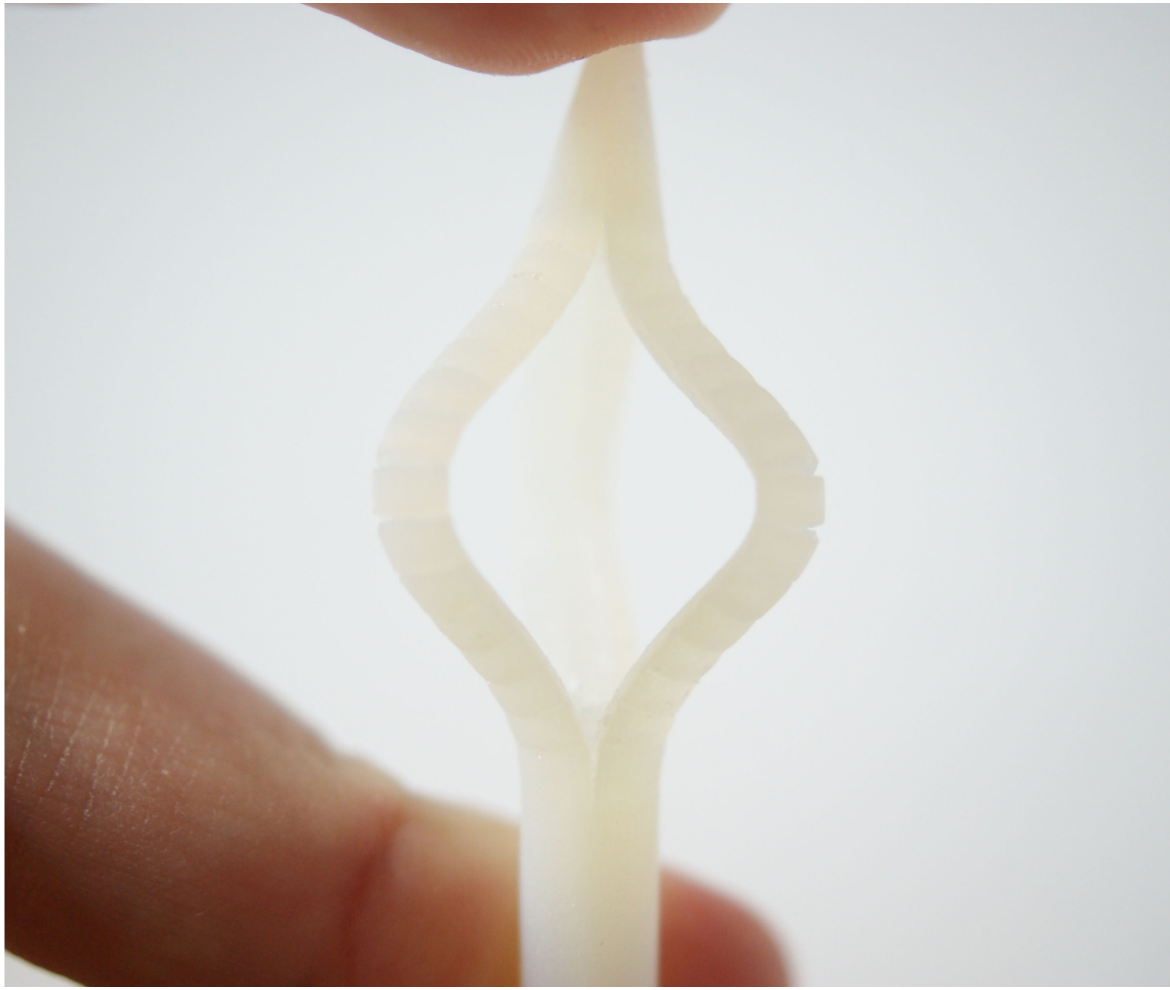


Figure 120. 3D printed Eggbeater model, highlighting the fluid movement for retention, afforded by muli-material 3D printing.

REFLECTION

The double lumen and active fixation models have created new opportunities for the project to explore. Incorporating active fixation resulted in an elimination of the external sheath for insertion and removal, as suggested by the radiologists. However, feedback also indicated the multi-material properties would struggle to improve retention. Therefore, incorporating active fixation methods alongside 3D printing provides the potential for safe and smooth insertion, as well as reliable retention once the fixation method is activated. The activation of the models was through a syringe, inserting water into individual cavities within each model. These cavities will be connected to ensure the model's wings expand simultaneously (see figures 108 and 112) when required throughout the drainage procedure.

The Eggbeater drain was the most successful final development (see figure 109-112), due to the multi-material wing's ability for security, and fluid movement. The developed working model is overscaled to 13.5mm in diameter, for design clarification and idea communication and understanding. For use inside the body, the drain needs to be 6mm in diameter or less. The final scaled down Eggbeater drain (see figure 117-120) has not incorporated the internal cavities. However, the model was 3D printed to understand the form at the predetermined size to visualise how the drain may work when fully developed.

Both double lumen designs have excellent potential for introduction into the medical environment (see figures 95-100) using existing manufacturing methods. The hole orientations have assisted in drainage flow, reducing the chance of lumen clogging and improving the efficiency of the overall procedure. Figures 101 and 102 introduce the most successful results from the testing process (3.1), in the Irrigation and Self-cleaning drains.

Figure 121. Final double lumen Irrigation drain

4

CONCLUSION

This thesis has been a personal journey , accumulating knowledge, skills and experience which has resulted in a range of design outcomes in response to Clinical Feedback Two. This includes, proposals that stretch 3D printing technology as a new form of production, through to proposals that can be manufactured with conventional manufacturing techniques. The feedback inspired further exploration, addressing the notion of 'active retention' as seen in figures 105 to 116. The developed experiments create new territory of active retention and fluidics that stretch the current capabilities of 3D printing technologies. Although the final dynamic drains are not fully resolved as a manufacturable catheter, the models signal new research (responsive soft robotics) yet to be explored in greater depth by others. The feedback also confirmed the value of a range of design proposals that can be achieved through conventional manufacturing processes, yet nevertheless offer improved drainage efficiency. Such as the double lumen Self-cleaning and Irrigation Pigtail drains (see figures 95-100).

In both instances, multi-material 3D printing proved to be an invaluable tool for rapid prototyping and evaluation of each design concept. While the 3D printing materials available, currently lack structural integrity and durability needed for production parts, the project is working at the cutting edge of rapidly developing technology in the pursuit of innovation; and the situation is expected to change swiftly.

Throughout the completion of this thesis, clinical input from scientists and medical professionals has been paramount in the ongoing development of designs. Multi-disciplinary projects produce a wide variety of ideas and contributions as a result of the many different perspectives that need to be accommodated, in the search for a successful outcome. In this unusual alliance between design, science and medicine, design provided a new means of discussion and communication by calling on technologies that other disciplines do not necessarily have access. However, this project would not have been a success without each discipline, as they individually generate expertise, opinions and solutions, which together, can improve an underlying problem.

While a multi-disciplinary collaboration can at times result in confusion or misunderstandings through, for example, differences in terminology, it became evident that design provides a shared understanding of ideas through the use of physical prototypes. 3D printing proved to be most beneficial in that respect, by allowing the team to interact with the 3D printed models and follow the proposed ideas. Multi-material 3D printing, in particular, has been an extremely beneficial tool to overcome the interdisciplinary communication, as the physical prototypes and their dynamic properties could be understood, manipulated and analysed with ease, rather than having to decipher how the form may work through static images and written descriptions.

To conclude, while this thesis focused on a particular aim, the perspective gained applies to a wide variety of design projects as a transferable process of investigation. The research question asks ‘How can design research and multi-material 3D printing, provide innovative insights to improve the clinical performance of percutaneous drains?’. The resulting range of design outcomes demonstrates how rapid prototyping and multi-material 3D printing can be used to develop innovative, minimally invasive, drainage catheters, to incorporate into the medical environment.

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APPENDIX ONE: INITIAL ITERATION MATRIX

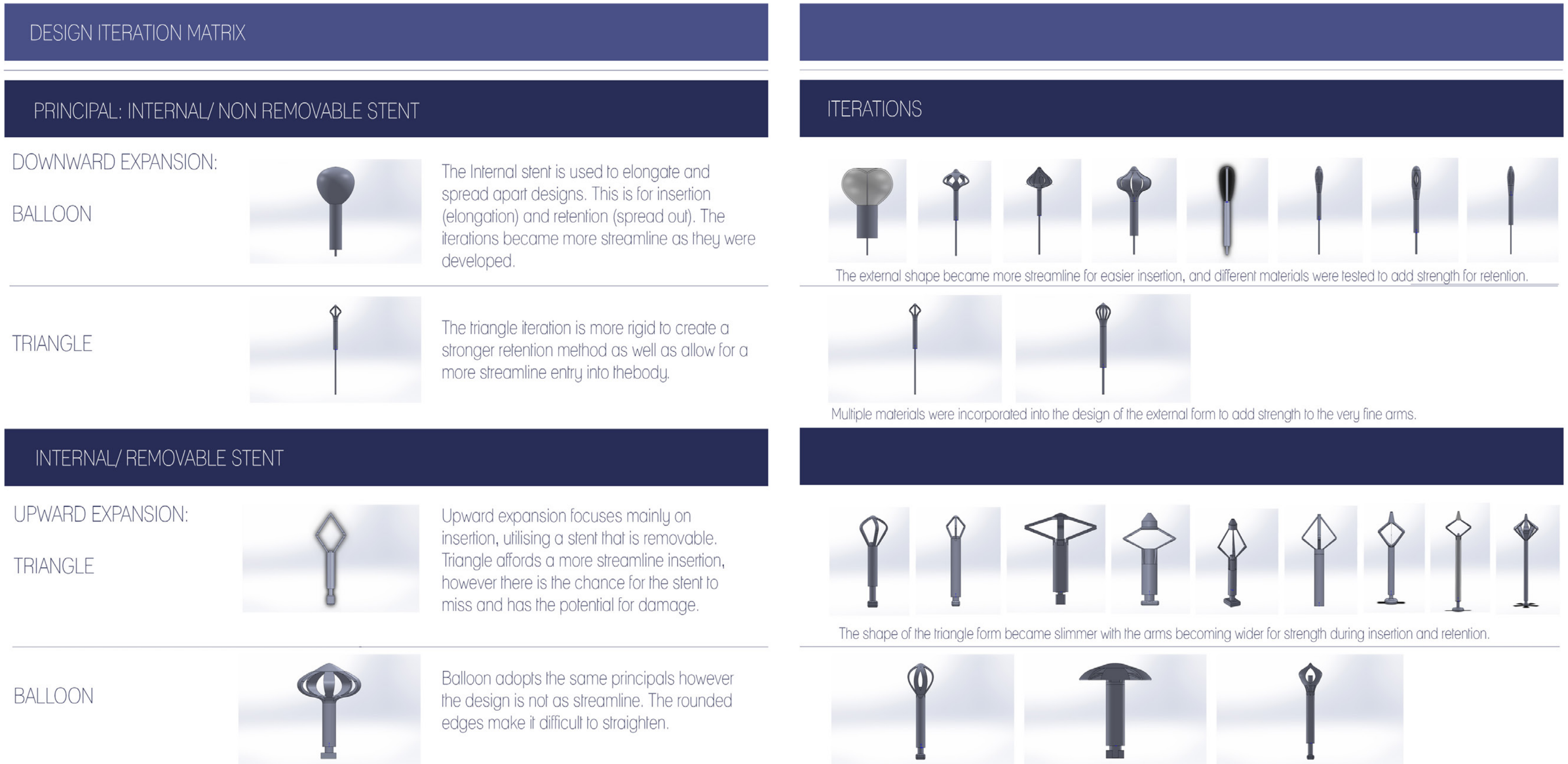


Figure 122. Initial design iteration matrix: left-hand side.

The form was iterated however the removable stent did not work with each shape as it did not become streamline for insertion.

EXTERNAL TUBE

TUBULAR EXPANSION: PEN

Tubular expansion slides over the outside of the catheter allowing for easy insertion, however creates a larger form. The pen design was difficult to straighten, and did not provide enough retention.

The pen forms shape struggled to make it through the tube for insertion because of the ammount of excess material.

OUTWARD BEND

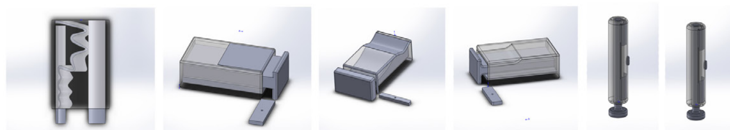
The 'ear' design creates retention for inside the catheter that hide within the external tube and release once the external tube is released. However, because of the small arms, they can become very weak.

The outward bend design was developed to try and make the wings stronger to create firmer retention.

ASSISTED DRAINAGE

INTERNAL WALL BLOW UP

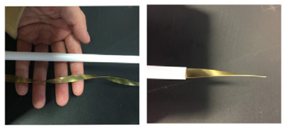
Assisted drainage is an external way of increasing the drainage flow. The internal blow up consists of small cavities that blow up within the catheters walls that creates a breathing effect down the side of the drain. This helps loosen the dead matter to help it exit the drain.



The internal blow up has been developed using different shapes and materials to understand how the idea could work within a catheter.

ARCHIMEDES SCREW

The archimedes screw is a removable stent that can loosen and remove thicker matter that would normally clog a catheter. This design is very fragile and more iterations can be made physically.



The archamedes screw was 3D printed first, and then modelled using other materials to allow for durability when analysing.

DOUBLE LUMEN PIGTAIL DRAIN

PIGTAIL DRAINS

The current pigtail drains have one lumen, however I have been developing some concepts with double or more lumens with different materials. This can be used as a retention tool or for itigation.

The pigtal drains were developed with different configurations of lumens inside. However because of the size, the lumens were very fragile during the cleaning proccess.

Figure 123. Initial design iteration matrix: right-hand side.