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Mechanical and Aerospace Engineering

**DESIGN AND DEVELOPMENT OF A PROTOTYPE
OF A CATHETER FOR THORACENTESIS**

(Final Report for Capstone Project)

by

Alisher Sabigaliyev

Aruzhan Ashimova

Rakhymzhan Orazgali

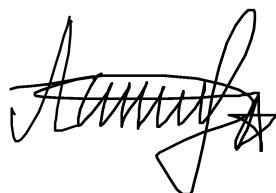
Principal Supervisor: Didier Talamona

Co-supervisor: Asma Perveen

April 2026

Declaration

We hereby declare that this report entitled “Design and Development of a Prototype of a Catheter for Thoracocentesis” is the result of our own project work except for quotations and citations that have been duly acknowledged. We also declare that it has not been previously or concurrently submitted for any other degree at Nazarbayev University.



Names: Ashimova Aruzhan

Date: April 2026



Names: Alisher Sabigaliyev

Date: April 2026



Names: Rakhymzhan Orazgali

Date: April 2026

Abstract

While thoracentesis and diagnostic and therapeutic drainage of pleural effusions have been performed routinely, catheter systems in use today do not provide much more than blocking off the area of catheter placement with limited reliable samples, introducing air into the pleural space and uncontrolled conditions when the catheter is inserted. Therefore, this Capstone project was designed to develop a prototype thoracentesis catheter that is safe for use, easy to operate, and provides superior functionality to existing catheters. Literature-based requirement definition, CAD concept implementation, material choice, additive-manufacturing-based prototyping, tensile testing, finite element analysis, and fluid-flow simulation were used to implement the project. SolidWorks was used to develop three design iterations, one being a single-lumen concept and two modified to have a flushing capability. Flexible 80A resin was selected as the initial prototype resin to SLA print and BioMed Flex 80A and AISI 316L were suggested as the possible material to develop into clinical grade. The catheter print was tested in two orientations and it was discovered that there was a trade-off between the quantity volume of resin applied and the quality of the print. Tensile testing with ASTM D412 Die-C specimen revealed that the time elapsed after the curing process had a significant impact on the mechanical response and the ultimate tensile strength mean was maximum at 15 min of the curing process. Simulation was conducted by use of finite elements to demonstrate that the most mechanically sensitive region of the distal perforated region during insertion and removal had von Mises stress of maximum 1.22 MPa and 0.606 MPa respectively. The simulations of the fluid revealed that the lumen was functional in real-life manual aspiration and in hypothetical maximum suction conditions. On the whole, the project confirmed the technical feasibility of the recommended concept of the catheter on the prototype level and established an engineering platform to further optimization, validation, and development of the catheter to a more clinically developed thoracentesis device.

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1 Introduction

Thoracentesis is a percutaneous, where a needle or catheter is inserted in the pleural space to remove any collected air or more often pleural fluid so that they can be analyzed diagnostically and/or drained therapeutically. It has become an essential procedure in interventional pulmonology and in most cases is done under the guidance of ultrasound to ensure optimality of safety and success of the procedure (Nicholson et al., 2023; Roberts et al., 2023).

The relevance of thoracentesis devices is highlighted by their current needs due to the epidemiology burden of the pleural disease. Pleural effusion occurs in about 1.5 million patients each year in the United States alone, and thoracentesis is done in approximately 178,000 cases each year (Nicholson et al., 2023). Malignant pleural effusion: malignancy and cohort Malignancy caused approximately two-thirds of chronic pleural effusions, and on a global scale, about 150,000 new malignant pleural effusions and 100,000 each year in the United States and Europe respectively (Shirzadi et al., 2025).

Combining these facts, one can conclude that nowadays the thoracentesis and the drainage of pleura can be used safely and efficiently, which makes the creation of better thoracentesis catheters like the one studied in the given project possible.

1.1 Requirements

Recent catheter technology presents a series of issues. Even with the application of ultrasound guidance, thoracentesis is still linked to iatrogenic pneumothorax and air entry, bleeding and re-expansion pulmonary oedema (Cantey et al., 2016). Recent meta-analysis stated the general complication rates of approximately 20% with most being caused by infection or catheter abnormalities including blockage, kinking, and dislodgement (Wang et al., 2023). The narrative reviews explain the common catheter clots caused by fibrins or tumour debris, poor drainage and sampling, and superficial or deep infections which occasionally lead to removal of the catheter (Lui et al., 2016).

These problems represent some of the shortcomings of their current systems: They are vulnerable to air during insertion, the lumens and side holes are easy to block, and they have external connectors that are hard to maintain sterility. Patients and clinicians are still exposed to recurrent blockage, infection, air entry and unreliable sampling, and this necessitates redesigned thoracentesis and pleural catheter solutions that reduce

complications and maintain patency and reliable sampling of pleural fluid in a hospital or community setting.

1.2 Aim and Objectives

This Capstone Project aims to design and develop a novel prototype of the catheter system for thoracentesis with modification that improves safety, usability, and procedural precision of the sampling compared with current devices.

For this project next objectives were identified:

1. To define requirements based on literature review;
2. To design concept development and prototype;
3. To select biocompatible material;
4. To define manufacturing methods;
5. To perform tensile testing of material;
6. To evaluate insertion/removal simulations;
7. To conduct fluid distribution simulation;

1.3 Industrial and Institutional Context

IHT Central Asia LLP is a Spanish-Kazakh medical device producer that is located in Technopark of Nazarbayev University in Astana. It concentrates on the development and production of medical devices technologies manufactured through the European technology transfer and functions as the member of the Galamat Group cluster of medical technologies. In this portfolio, the IHT Central Asia will localise the high-value single use device production in line with the regional clinical requirements and assist in import substitution.

The idea is based on the practical experience of Dr. Akhmatkul Rakhmankulovich Dzhaparov, a thoracic surgeon from Shymkent. The current capstone project is a part of this industrial setting because it is a prototype of a new disposable thoracentesis catheter. The main industrial technical specification of IHT Central Asia LLP. The designed prototype of the thoracentesis catheter has to follow all requirements from this technical specification.

1.4 Limitations and Constraints

Various technical and practical constraints are set on the development of the proposed thoracentesis catheter. To begin with, the project is limited by a fixed capstone period, which limits the quantity of refinements of the design, prototyping, and repeatable

experimental validations. Consequently, this finished design is more of a proves-of-concept and not an optimized medical device. Second, there is low access to high level of engineering and medical facilities. Sterilization, precision manufacturing and certified testing of biocompatibility and other industrial grade equipment are not present within the university environment. Moreover, non-industrial 3D printing systems are limiting prototyping possibilities, and can add dimensional errors and material variances. There were also occasional technical failures of the 3D printer which provided additional limitations to the capability of creating consistent and repeatable prototypes. Lastly, our project is not going to involve any human clinical testing, and only some initial validation can be conducted in simplified circumstances. Thus, usability, safety, and performance of the offered design cannot be completely verified, and the results are not enough to approve the design by the regulatory body and use it commercially.

1.5 Engineering Ethics and Standards

Ethics of engineering are critical to the development of medical device engineering because their performance as an invasive device directly correlates with the quality of care to patients. To use the example of a thoracentesis catheter, engineering ethics dictate that the design and production process should include minimization of harm to patients, accurate communication of the limitations found during prototyping, responsible interpretation of the resulting data from various tests, and a general avoidance of misleading claims about the clinical readiness of any new prototype. This project of thoracentesis catheter developed only as a proof-of-concept and initial prototype. This project includes prototype testing only and clinical trials will not be performed.

Engineering standards provide a technical and regulatory framework that helps develop devices safely. For this project specifically, ISO 10993 (the biological assessment of materials), ISO 14971 (the assessment of risk associated with medical device development), ISO 9626 (tubing used for stainless steel needles) and ASTM D412 (tensile testing), collectively ensure that the selection of materials, risk assessment and mechanical validation are all done in an orderly, internationally accepted manner. Thus, both will be used to support the safe design of the thoracentesis catheter outlined here, and how it will be used to develop the next generation of thoracentesis catheters through engineering standards (ASTM International, 2006; ISO, 2016; ISO 10993-1, 2025; ISO 14971, 2019).

2 Literature Review

Thoracentesis is primarily a treatment and assessment method in the evaluation of pleural effusion caused most commonly by heart failure, pneumonia and malignancy (Nicholson et al., 2023; Shirzadi et al., 2025). Thoracentesis is part of treating the parapneumonic effusion, and empyema, and in these cases, it is necessary to drain the infected collections at an early stage to avoid the development of the complex, loculated infection of the pleura (Abdulelah et al., 2024).

The visceral and parietal pleura cover the lungs and the area between the two areas is referred to as the pleural space. There is a thin fluid in this space, which however under the influence of pneumonia, cancer, congestive heart failure and many more, may lead to excess fluid development. (Boccatonda et al., 2024). The patient is typically sat upright or semi-recumbent and the place of insertion is chosen in the triangle of safety or in a lateral infrascapular intercostal space and not in the paraspinal area where the intercostal artery is more open (Christopher et al., 2024) (Figures 1, 2 and 3).

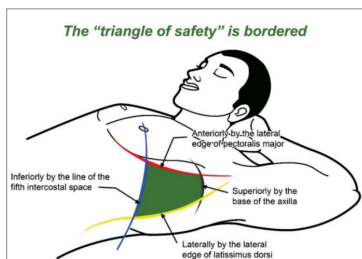


Figure 1. Triangle of safety

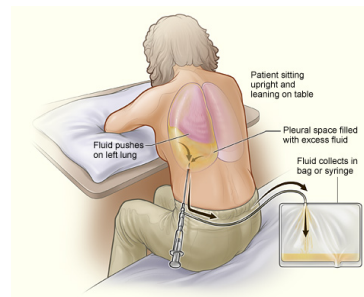


Figure 2. Thoracentesis procedure

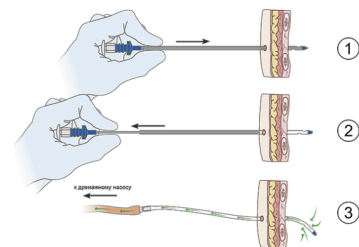


Figure 3. Catheter insertion procedure

According to Nicholson et al. (2023), thoracentesis is a procedure that is ultrasound-guided and structured. Ultrasound is initially to ensure that there is a sufficient amount of fluid pocket and determine the safe point to puncture: a low-frequency probe is used to identify the location of the effusion, diaphragm and the lung, after which a high-frequency linear probe is used to identify the precise location of the intercostal point of puncture. Two ultrasound methods are identified real-time needle guidance, whereby the visualisation of the needle is continuous, and site-marking method, whereby a target point is marked on the skin prior to the procedure. They both achieve a significant reduction of

pneumothorax and dry taps in comparison to blind thoracentesis by providing sufficient fluid depth and preventing the abdominal organs (Nicholson et al., 2023).

To collect 50-60 mL of pleural fluid, diagnostic thoracentesis is typically done with 20 -22 G needle, with a 60 mL Luer-lock syringe, but for therapeutic purposes a 6-8 Fr catheter-over-needle system is commonly used and is left in the pleural space (Nicholson et al., 2023). The drainage process can be done either by gravity, manually through a three way stopcock or vacuum/wall suction with the fluid being removed gradually and in most cases no more than 1.5L per session to minimize the chances of re-expansion pulmonary oedema. The workflow outlines the most important design guidelines of pleural access devices; they are compatible with ultrasound-guided intercostal insertion, atraumatic access, controlled drainage with air-entry guard, and dependable sample collection ports to be examined in the laboratory.

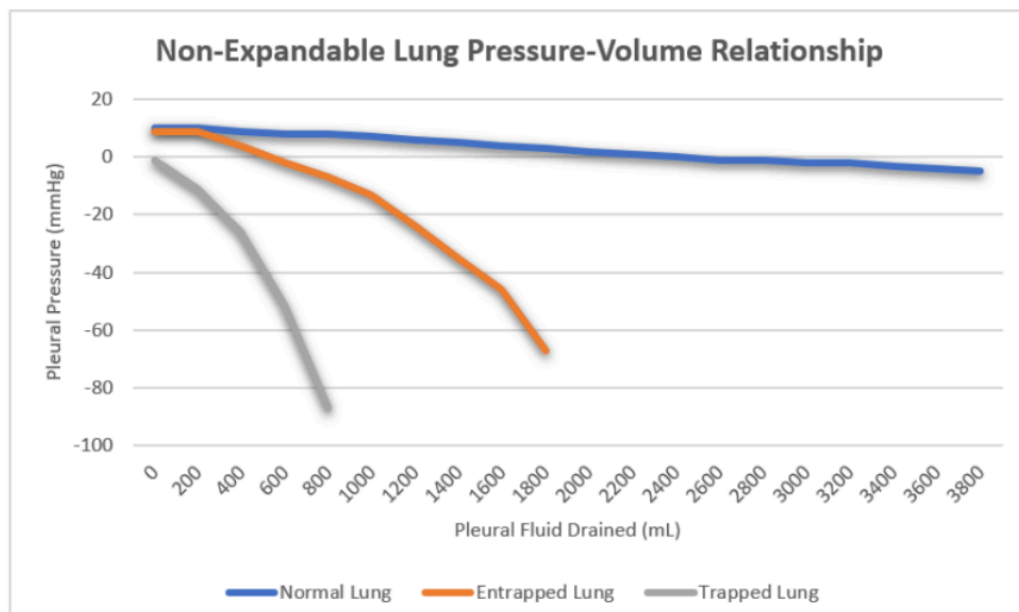


Figure 4. Three cases of pressure/volume curves representing the removal from the pleural effusions in normal, entrapped and trapped lungs respectively.

Pleural pressure-volume curves (Figure 4) help in differentiation of normal and non-expandable lung during thoracentesis (Nicholson et al., 2023). In a normal lung the production of fluid begins with a slightly positive pleural pressure and is followed by a shallow nearly linear descent of the pressure during the re-expansion of the lung which fills the pleural space. Pleural elastance (pressure change/unit volume removed) is not much,

and post-procedure pressures are typically not very negative indicating a compliant, fully expandable lung.

On the contrary, the non-expandable lung demonstrates more splendid curves characteristically. The active pleural inflammation or malignancy leads to lung entrapment, which, in general, exhibits an early normal-like stage of gradual decrease in pressure, and then an inflection point, beyond which any subsequent drainage results in a sharp reduction in the pressures to distinctively negative values. A chronic fibrous visceral peel causes trapped lungs to start with a negative baseline pressure and has a steep drop in pressure, suggesting that it has high pleural elastance and low expansion capacity. The specific patterns assist in distinguishing between normal lung, lung entrapment and trapped lung during thoracentesis and the reason why patients with non-expandable lung tend to experience early chest pains or limited volume of tolerable drainages (Nicholson et al., 2023).

2.1 Existing Catheters

First of all, catheters have their own measurement of the outer diameter, and here is the following explanation. The sizes of catheters used in thoracentesis and pleural drainage are normally given in French (Fr), not in millimetres (Figure 5). The French gauge is stipulated in such a way that the outside diameter measured in millimetres corresponds to one third of the French size ($D[\text{mm}] = \text{Fr}/3$) (Dodds, 1989). Therefore a 6 Fr catheter will have external diameter of about 2.0 mm and common indwelling pleural catheters of 15.5 Fr will be about 5.2 mm in the case of this project.

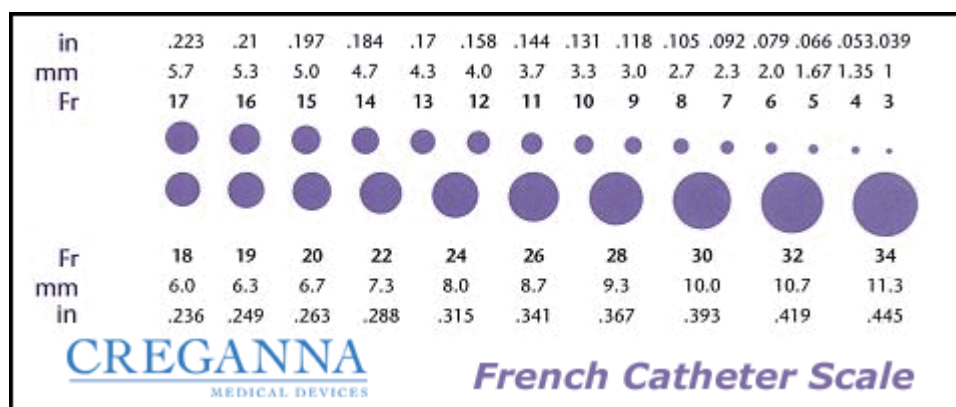


Figure 5. French Catheter Sizing system

Thoracentesis catheters and pleural drainage commercial products can be classified into three largest categories: (i) single-use thoracentesis catheter sets, typically 5-8 Fr catheter-over-needle or pigtail-based, used in both diagnostic and short-term therapeutic aspiration; (ii) small-bore chest tubes, typically 14 Fr straight or pigtail drains placed with the Seldinger technique and left in place several days; and (iii) tunnelled indwelling pleural catheters (These categories are the reference points against which any new thoracentesis catheter could be compared).

Thoracentesis instruments (Rocket(r) Thoracentesis Set, BD Safe-T-Centesis™ and Thora-Paratm) are a combination of small-bore catheter and introducer needle, safety valve, stopcock and drainage accessories. Various design characteristics are multi-fenestrated distal segments, radiopaque stripes and length markings, Luer-lock interfaces and one-directional air and fluid valves. Smaller chest tubes like Cook(r) Fuhrman Pleural Drainage Set include 5-12 Fr pigtail catheters having side holes in the pigtail loop, centimetre marking and radiopaque material and are provided with needles, guidewires and sheaths. IPC systems (PleurX™, Aspira(r)) are long, multi-fenestrated distal node and proximal one-way valve cuffed silicone catheters, which are delivered via tunnellers, peel-away sheaths and home drainage systems (Narayanan et al., 2014; Porcel, 2018).

Irrespective of these features, there are still significant performance problems. The small-bore drains are also likely to become obstructed with fibrin, clots or viscous pus, kink or malposition resulting in poor drainage (Porcel, 2018). IPCs present with non-trivial pleural and exit-site infection, symptomatic loculations, catheter blockage, and catheter dislodgement rates, catheter-tract metastases and catheter fractures (infrequent) (Lui et al., 2016; Yagnik et al., 2018). All in all, current catheters offer good access and drainage although they are mostly single-lumen systems with minimal capacity of controlling blockage, accommodate diagnostic and therapeutic manoeuvres in parallel, and reduce tract-related complications. Such constraints are driving the implementation of the altered design of a thoracentesis catheter that has a superior architecture of access ports and safety measures within the project.

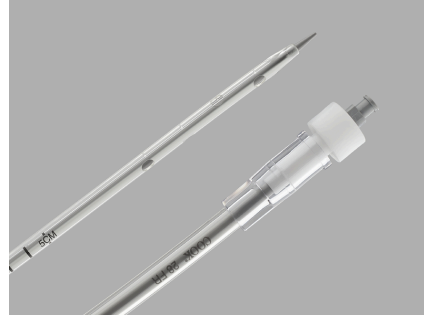


Figure 8. PleurX™ 15.5 Fr catheter

2.2 Materials and Biocompatibility

Biocompatibility is the property of a material to execute its desired action in the body and have the proper biological response. This is relevant in medical engineering since the safety of a device is not merely determined by the mechanical performance of the device, but also the response of the body to the device. What is acceptable in one scenario might not be acceptable in another, due to the fact that biocompatibility is always specific to the nature of contact, length of contact and clinical intent of the device (Williams, 2019).

In the case of medical devices, biomaterials are chosen based on established standards and a risk-based assessment procedure. The primary standard is the ISO 10993 series that is employed to evaluate the biological safety of a device based on the purpose of use, the character of contacts with the body, and the duration of contacts. Practically, endpoints to determine this evaluation usually include cytotoxicity, irritation, sensitization, and systemic toxicity or hemocompatibility (where applicable) (FDA, 2023).

Besides biological testing, more extensive performance criteria are also considered to select biomaterials. These are chemical stability, potential leakage of toxic substances,

compatibility with the manufacturing and sterilization procedures, and the capability of the end device to stay safe and functional in the biological environment. That is why, contemporary biocompatibility evaluation is not specific to a single material property, but is a mixture of biological, and chemical, and practical considerations in the eventual medical device design (Rosa et al., 2024)

2.2.1 Biocompatible Materials for the Catheter

The choice of chest and pleural drainage catheters must be made within the biological assessment of ISO 10993 since the safety of a catheter is not only determined by the drainage ability of the catheter, but also by the reaction of the body to the ultimate equipment in clinical practice. In the engineering aspect, the choice of catheter materials is a trade-off between biocompatibility, mechanical performance, processability and sterilization stability and service-environment stability (FDA, 2023; Yang et al., 2019).

Polyurethane (PU), silicone elastomers and polyvinyl chloride (PVC) are common polymers used in medical catheters. The popularity of such materials is due to the ability to give them the flexibility and structural strength needed by drainage devices, but each polymer has its benefits and drawbacks (Yang et al., 2019). Polyurethane continues to be of significant interest as a catheter material since medical grade thermoplastic polyurethane is already utilized in medical devices like catheters that are in contact with blood and that it possesses convenient mechanical tunability and manufacturability (M'Bengue et al., 2023).

Silicone is also popular due to its high biocompatibility and the low associated tissue toxicity and a comparatively low inflammatory reaction of the material, which contributes to the fact that it can be used in the case of longer-term contacts (Jeong & Oh, 2019). PVC is cheap and commonly utilized in the production of catheters and tubing, but is usually harder than silicone-based materials (Jeong and Oh, 2019). Moreover, the issues of plasticizers are also significant with certain PVC medical products, as plasticizers can escape the material and cause exposure to patients (Šimunović et al., 2022). Other polymers are also under consideration, including thermoplastic elastomers (TPEs), since these can provide both the elastic properties and thermoplastic processing, and can potentially provide convenient flexibility in biomedical device applications (Schneider et al., 2021).

Catheter performance is also dependent on surface properties. The hydrophilic and antimicrobial coating is a topic of growing interest due to the ability to decrease the friction

and microbial adhesion and biofilm formation on the catheter surface (Yang et al., 2019). Hydrophilic biomaterial catheters exhibited significantly reduced thrombotic and microbial adhesion compared to thermoplastic polyurethane catheters in an in vitro catheter model of the venous system (LeRoy & Donahue, 2025). Plastic catheters also have been tested in silver nanoparticle coats that have been demonstrated to reduce the growth of bacteria and catheter biofilm formation (Roe et al., 2008).

On the whole, there is no single polymer, which is universally the best in all catheter uses. The material of the catheter must be able to balance handling, flexibility, surface compatibility, manufacturability, and the particular clinical use of the device (Gambrill et al., 2024).

2.2.2 Biocompatible Materials for the Needle

Pleural or vascular catheter introducer needles and stylets are typically made out of rigid austenitic stainless-steel tubing. The use of ISO 9626 is specifically applied to stainless-steel tubing that is aimed at use in hypodermic needles and other associated medical devices, and more recent studies concerning biomedical stylets observe that 304, 304L, and 316L grades are frequently used due to offering a realistic balance of rigidity, formability, and corrosion resistance to short-term invasive components

The reason stainless steel is still used to produce the needles is that it can be shaped into thin beveled pieces and can be subjected to traditional finishing techniques including polishing, passivation and sterilization. The importance of these surface treatments is that the manufacturing route may affect corrosion behavior, metal-ion release, and that electropolishing is often applied to achieve smoother and more passive stainless-steel surfaces in medical devices (Eliaz and Nissan, 2007; Reclaru et al., 2025).

Nevertheless, not all designs can be made with rigid stainless steel. In cases where more flexibility and recoverable deformation is needed, nitinol is also a key choice due to its superelastic behavior, kink resistance and physiological compatibility that has found application in numerous minimally invasive medical devices (Duerig et al., 1999). Other titanium alloys including Ti- 6Al-4V have also been identified as biomedical metals due to their excellent performance in corrosion resistance and biocompatibility. However, in this regard, they should not be called the conventional rigid needle tubing biomaterials but

instead as alternative biomaterials, because the conventional standard of tubing in the region is still centered on stainless steel (Geetha et al., 2009; ISO, 2016).

All in all, stainless steel is the best-established material family of conventional introducer needles and stylets, with alternative alloys primarily being sought out when greater flexibility or other specific performance is necessary.

2.3 Additive Manufacturing of Medical Devices

The process of 3D printing, also referred to as Additive Manufacturing (AM), is a layer-by-layer fabrication whereby one creates three-dimensional objects directly manufactured out of digital models. In contrast to the traditional manufacturing that is subtractive, AM is a type of manufacturing that can deposit materials in layers, allowing high geometric complexity, internal structures, and rapid product development (Gibson et al., 2021). The overall AM process involves the creation of CAD models, conversion into STL, division into individual layers, creation of the layers layer by layer, and after-processing, involving cleaning and curing. Rapid prototyping and customization is possible using this digital-to-physical pipeline, which is especially useful in the medical field.

Stereolithography (SLA) has become the most popular in medical prototyping because of its high resolution and capacity to create complicated geometries with a smooth surface finish (Ali et al., 2020). This renders it particularly appropriate to medical prototypes and models of anatomies. Fused Deposition Modeling (FDM), Selective Laser Sintering (SLS) are other approaches, which vary in terms of material type and the production mechanisms, but provide an opportunity to produce various kinds of medical parts (Jorge et al., 2024). AM finds extensive application in medical practice in the creation of anatomical models, surgical planning, prosthetics, and preliminary devices prototypes.

Additive manufacturing, despite its benefits, has major shortcomings. The layer-by-layer fabrication method can also form anisotropic mechanical behavior, potentially limiting the uniformity and predictability of parts manufactured by this method, in comparison with traditionally manufactured components. Moreover, printable materials that meet the appropriate mechanical properties and long-term biocompatibility and sterilization compatibility are scarce in several medical applications. That is why AM continues to be applied primarily to prototyping, but not a universal substitute to

conventional manufacturing. However, it is also a useful method of quick design fabrication and personalization in the medical field, and stereolithography is particularly appealing when the precision and fineness of the structure are needed (Salmi, 2021; Melchels et al., 2010).

2.4 Pressure in Pleural Space

The pleural pressure has a significant role in the physiology of thoracentesis since it can be used to determine the pressure gradient within which the pleural fluid will flow into the catheter during the aspiration process. The pleural pressure is slightly subatmospheric (negative) under normal conditions. When the lung is functioning normally and resting at functional residual capacity, the pleural pressure can be expected to be in the approximate range of negative pressure -294 to -490 Pa (Zielińska-Krawczyk et al., 2018). When pleural fluid accumulates, however, this pressure can become less negative or possibly even positive as a result of an alteration of the normal balance between the lungs and the chest wall. In fact, research using pleural manometry in individuals with pleural effusions shows that the initial pleural pressure (prior to drainage) for these individuals ranged from $+785$ Pa to -2.06 kPa prior to drainage (Light et al., 1980).

Pleural pressure is variable and changes continuously with drainage during thoracentesis. Light et al. (1980) reported that pleural pressure less than approximately -1.96 kPa at which point the drainage procedure should be discontinued; when a patient develops any symptoms; and/or when further aspiration of the pleural fluid is no longer possible are all factors that will cause a drainage to be discontinued. Another crucial variable is the pleural elastance per unit volume removed (the change in the pleural pressure per millilitre (mL) of fluid removed); and the normal pleural elastance has been determined to have an upper limit of about 1.42 kPa/L, above which indicates insufficient inflation of the lungs (Hu et al., 2020; Nicholson et al. 2023). Therefore, from an engineering perspective, a thoracentesis catheter has a variable hydraulic boundary condition instead of a fixed and stable pressure for use with the pressure based flow simulation in this project.

2.5 Requirements and Technical Specifications

The main design input of this project is an industrial technical specification of IHT Central Asia LLP of a single use thoracentesis catheter system with the additional port of

access. It should be used to drain the pleural, air, and pus of adult patients in different clinical settings and should be made up of a flexible, radiopaque catheter (approximately 250-300 mm) with a perforated distal area, metric, and radiopaque impressions and a side branch that leads to the sample and cleanses the lumen but avoids the entry of the air. All its parts can be used as any other drainage that fits in standard drainage.

The project should provide a prototype thoracentesis catheter system that:

1. resembles the total geometry (250-300 mm long, 29 mm distal punched area);
2. is marked with complete radiopaque and metric scales;
3. has a side-access port of proximal 5 mm diameter, having a one-way valve in-built;
4. is made of a dynamic, radiopaque, medical polymer (PU or PVC surrogate prototype);
5. is intended to operate as a single-use drainage assembly with a suitable puncture needle and external drainage outlets.

3 Methodology: Concept Development and Design

The technical and time limitations mentioned in the Scope and Limitations section simplified the methodology of this capstone project and thus it is mainly literature-review based with specific engineering validation. Capstone's methodology flow chart is demonstrated in Figure 9.

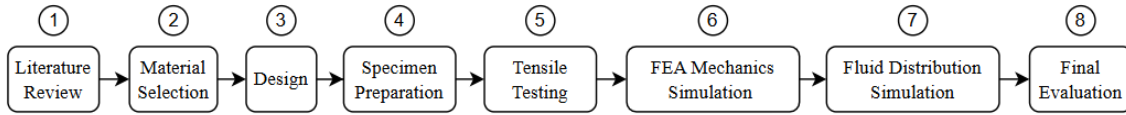


Figure 9. Methodology Flow Chart

The literature review is structured in the first place to summarise existing practice of thoracentesis, the most common types of catheter designs, selection of materials, and known complications of the devices and to find the quantitative data that will be used later in the modelling and testing process. Second, the selection of materials is carried out based on the published evidence and the general practice in the industry, where the biocompatibility, mechanical suitability, manufacturability, and compatibility with sterilisation are given preference. Third, prototype catheter design is created in SolidWorks according to the technical requirements received by IHT Central Asia LLP, to translate the specification to specific CAD geometry and assembly features. Fourth, specimen preparation will be performed by consulting the applicable ASTM tensile-testing standards and choosing a geometry of the specimen that will be used in the experiment and is compatible with the selected polymer and the manufacturing techniques at its disposal; the chosen specimen will then be modeled and fabricated in large enough quantities to be tested comparatively. Fifth, tensile testing is conducted to ensure that the chosen polymer fulfills the mechanical requirements of a catheter prototype; engineering stress-strain curves are applied to determine tensile strength, strain at break and Young's modulus and the identical test programme is repeated to compare curing times to identify a curing condition which enhances mechanical performance of the final prototype. Sixth performance test of FEA insertion and removal mechanics simulations to determine the required applying forces. Seventh, fluid distribution simulation is performed to determine the approximations of pressure distribution, flow rate, and velocity profiles during drainage based on governing equations and boundary conditions of peer-reviewed research. Eventually, the results of all

experiments and simulations are integrated in a conclusive analysis to determine whether design and material selection can address the project requirements and provide a definite guideline as to the following step in the project line of the industrial partner.

3.1 Concept Generation and CAD Model

The original design, which was meant to be an improvement over a typical thoracentesis catheter, keeps its crucial draining function. A proximal side access port for flushing and emergency access, a full-length millimeter depth measuring scale along the catheter's length to control depth during insertion, and a distal perforated drainage zone with a tapered tip that permits fluid drainage with less damage to surrounding tissue were among the features added to improve the catheter's usability and safety while maintaining its basic cylindrical single-lumen design. Two radiopaque marker bands were added to the distal end of the catheter to improve imaging visibility of the device. The design features were then used to develop a CAD model of the catheter, which contains the dimensions and geometric specifications needed to evaluate and prototype further.

A technical drawing (Figure 10) has been prepared to produce this catheter design based on the orthographic projection of three dimensions. These views provide information regarding the geometric layout of the complete catheter body, distal portion of the catheter, and proximal access-port configurations. The drawing also serves as the basic engineering drawing to be used for further evaluation using computer-aided design (CAD) software.

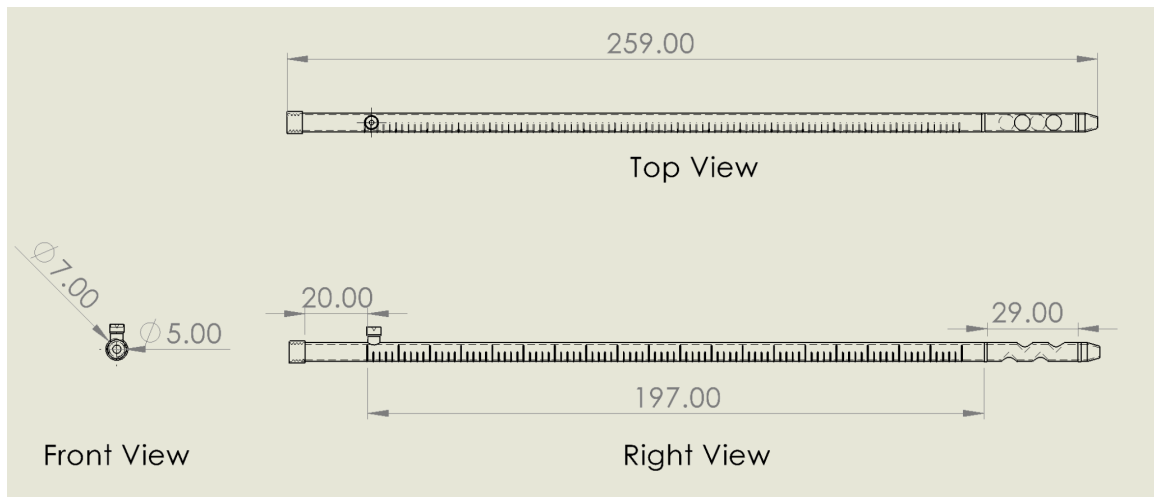


Figure 10. Final Technical Drawing

The concept generation led to the creation of a CAD (computer-aided design) model (Figures 11-13) using the SolidWorks software program, which included defining the major geometrical characteristics of the final product (Table 1).

Table 1. Main dimensions of first design catheter.

Characteristic	Dimension, mm
Total length of catheter	259
Outer diameter	7
Inner diameter	5
Additional port outer diameter	5
Distal perforated portion	29

As a result, this CAD model enables for additional evaluation of design, manufacturing, and prototype viability in addition to representing the engineering realization of the original concept.

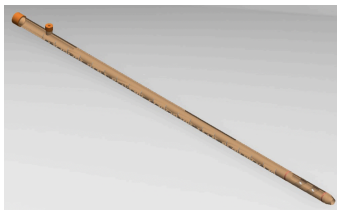


Figure 11. Isometric View of First Design Catheter

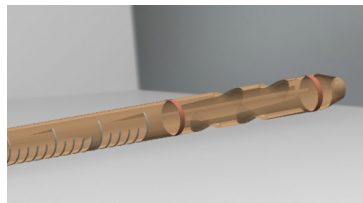


Figure 12. Perforated Zone of First Design Catheter

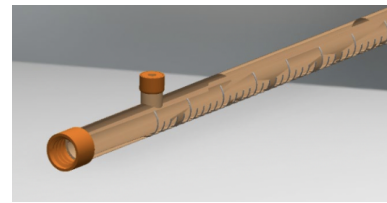


Figure 13. Additional Port of First Design Catheter

Once the first design was developed, a new concept was suggested on the basis of further clinical suggestions by the thoracic surgeon Dr. Akhmadkul Dzhaparov. This second design has an addition of an internal flushing tube within the main catheter body (Figures 14-16). This design allowed the catheter to be bidirectional: water could be introduced to the pleural space to clean it, while the principal lumen would fill the body with pleural fluid. This idea had a clinical use, but was extremely difficult to manufacture as the individual cylindrical internal tube complicated the geometry and decreased the effective drainage capacity of the main lumen.

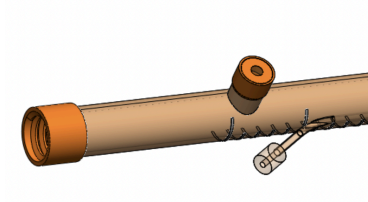


Figure 14. Additional Flushing Tube Connection of Second Design Catheter

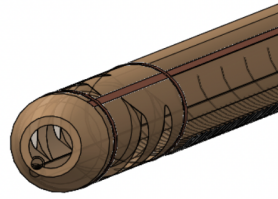


Figure 15. Detailed View of Second Design Catheter

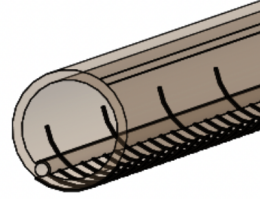


Figure 16. Cross-section View of Second Design Catheter

Therefore, a third design was developed that improved manufacturability and flow capacity while maintaining the cleansing capabilities. In this design, the cylindrical secondary tube that ran the length of the catheter wall was replaced with a crescent-shaped internal channel (Figures 17-19). This shape might offer a larger effective drainage area in the major lumen and was easier to fabricate. Therefore, it was thought that the crescent-channel design was a more practical engineering choice to move forward with development and prototyping.

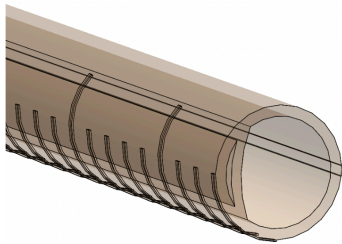


Figure 17. Cross-section View of Third Design Catheter



Figure 18. Front View of Third Design Catheter

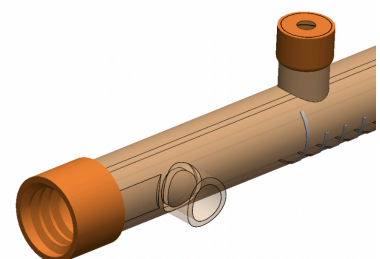


Figure 19. Additional Port of Third Design Catheter

3.2 Material Selection

The choice of materials of the prototype system was guided by the literature analysis and technical specifications of the project, which included Flexible 80A Resin to make the catheter body and AISI 316L stainless steel to make the puncture needle (stylet). Moreover, BioMed Flex 80A was found as the clinically oriented analogous material to be used in the subsequent development phases. In this capstone, specimen preparation and tensile testing were performed with Flexible 80A Resin only and 316L and BioMed Flex 80A are characterised as the material choices to be used when developing the device concept and in the research, respectively, and are outlined in the subsequent subsections.

Material selection for the catheter body was informed by the literature review on commonly used catheter polymers (e.g., polyurethane, silicone elastomers, and PVC) and the typical trade-off between biocompatibility, mechanical performance, processability, and sterilization stability for clinical use (FDA, 2023; Yang et al., 2019; Jeong & Oh, 2019). As a part of the capstone constraints, the catheter material needed to be compatible with SLA prototyping and in large enough supply to repeat the printing process and tensile tests.

For prototyping, Formlabs Flexible 80A Resin was selected as the main catheter-printing material because it provides elastomeric behaviour close to “rubber/TPU-like” stiffness, with a post-cured Shore hardness of 80A, ultimate tensile strength (UTS) of 8.9 MPa, and elongation at break of 120%, measured using ASTM D412-06 (A) (Formlabs, 2024). The reference post-processing conditions (Form 3, 100 um settings, 10 min wash, and post-cure at 60 C 10 min) are also recorded in the Technical Data Sheet and it specifically states that properties may change with geometry, orientation, print settings and temperature (Formlabs, 2024). Such features render Flexible 80A an appropriate material to develop a workable proof of concept catheter geometry as well as allowing controlled mechanical experimentation within the context of this project.

For the further research of the capstone, BioMed Flex 80A was indicated as the biocompatible relevant material. The BioMed Flex 80A TDS states that it is ISO 10993 and USP Class VI certified, manufactured in an FDA-registered, ISO 13485 facility, and intended for long-term skin contact (>30 days) and short-term mucosal contact (<24 h) (Formlabs, 2023). It also includes listed sterilization compatibilities (E-beam, ethylene oxide, gamma, and steam sterilization/autoclave) and reports elastomeric mechanical performance (e.g., Shore 77–80A, UTS 7.2 MPa, elongation at break 135%, ASTM D412-06 (A)) (Formlabs, 2023).

However, using BioMed Flex 80A for this capstone’s prototyping and tensile testing was not considered rational because the prototype is not intended for clinical testing, and material availability/cost constraints required efficient use of resin. Thus, Flexible 80A Resin was selected to prototype and test its mechanical features, and BioMed Flex 80A is suggested to be applied in the further research, because of biocompatibility, sterilization effect validation, and compliance with regulations of the material.

3.3 Design for Manufacturability and Assembly (DFMA)

In order to maintain SLA printing limits, the catheter body's geometry was altered to ensure that the walls' thickness was as consistent as possible. This increased print stability and decreased the possibility of local deformation both during and after curing. In order to lessen local stress concentrations and enable more dependable production close to the access-port region and the distal perforation zone, geometrical transitions were kept as smooth as feasible. In order to lower local stress concentrations and enable more dependable production close to the access-port region and the distal perforation zone, geometrical transitions were kept as smooth as feasible. The access port and perforations were designed to be within the constraints of SLA printing capabilities.

Key functional aspects of the catheter, including as the distal end, perforation zone, millimeter markings, and access port, were developed to minimize post-processing after fabrication and prevent unnecessary support contact during SLA print setup by incorporating DFMA concepts. Additionally, the access port's design makes it compatible with typical medical tubing and connection interfaces, reducing the need for additional modifications. By designing the catheter to remain a mostly one-piece component and making sure that its geometry would be suitable for both prototype printing and eventual scale up from extrusion to injection molding, assembly complexity was also reduced.

3.4 Tensile Testing

Tensile testing is one of the common mechanical characterisation techniques where a specimen is pulled in a uniaxial mode to failure in order to measure the resistance of the specimen to deformation and fracture. The general objective of the test is to achieve a stress strain response that is indicative of the behavior of a material under tension that enables comparison of candidate materials and confirmation that a material of choice meets design specifications of strength and ductility. In the test, the universal testing machine measures the applied load F vs. time and the corresponding crosshead displacement/extension ΔL (or gauge extension in case of an extensometer) as a function. These are the main measurements that are transformed into engineering stress and strain to assess material performance in a standardised manner.

The measured load/initial cross-sectional area of the specimen σ is used to determine engineering stress A_0 :

$$\sigma = \frac{F}{A_0} \quad (1)$$

The change in gauge length, divided by the initial gauge length L_0 , results in the engineering strain ε :

$$\varepsilon = \frac{\Delta L}{L_0} \quad (2)$$

Based on the resultant stress-strain curve, the final tensile strength (UTS) is considered as the highest engineering stress attained during the test:

$$UTS = \max(\sigma) \quad (3)$$

The strain value at the instant of fracture can be used to obtain the elongation at break (engineering strain at failure) which may be presented as a percentage:

$$Elongation\ at\ break\ (\%) = \varepsilon_f \times 100\% = \frac{\Delta L_f}{L_0} \times 100\% \quad (3)$$

and ΔL_f is the extension at fracture.

In this capstone, tensile test is needed to ensure that the chosen polymer (Flexible 80A Resin) has a sufficient tensile strength to sustain a working thoracentesis catheter prototype where increasing tensile strength may be compromised in order to tear or permanently deform and to fail when handled and used. The measured ultimate tensile strength and elongation at break are compared directly with the manufacturer's reported values for BioMed Flex 80A in the Formlabs Technical Data Sheet (UTS = 8.9 MPa; elongation at break = 120%) to check consistency and to assess the reliability of our specimen preparation and test procedure (Formlabs, Technical Data Sheet). Moreover, the specimens that are cured at various post-processing times are also tested in order to determine the optimal time of curing that would perform the optimal mechanical performance, such that the chosen curing condition can be used as a controlled post-processing parameter of the final catheter prototype.

3.4.1 Specimen Selection

For Flexible 80A Resin, the tensile specimen geometry was selected to match the manufacturer's approach in the Technical Data Sheet, which reports tensile properties using

ASTM D412-06, Test Method A (dumbbell specimens). ASTM D412 is used to measure the tensile of vulcanized thermoset rubbers and thermoplastic elastomers, and the test is specifically intended to be used with high-elongation materials as opposed to hard, low-elongation rubbers (ASTM International, 2006). This makes it appropriate for an elastomeric catheter prototype material, where strains before rupture are expected.

A 3.0 mm specimen thickness was chosen based on the nominal geometry suggested by ASTM D412 to tensile test thermoplastic elastomer-type materials, in which the standard suggests 3.0 ± 0.3 mm thickness and cautions that other thicknesses might not yield similar results. Moreover, ASTM D412 stipulates that dumbbell specimens must be within a reasonable range of thickness (no more than 3.3 mm), thus 3.0 mm is fully compliant with the standard but offers enough rigidity to ensure reliable gripping and consistency in testing (ASTM International, 2006).

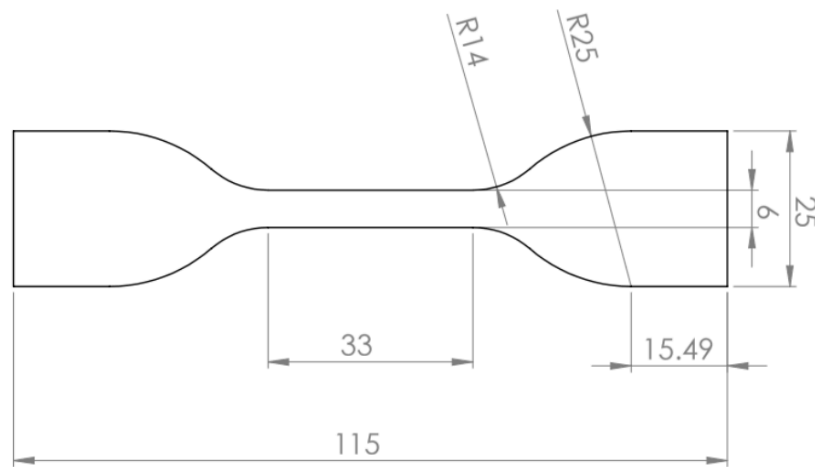


Figure 20. ASTM D412 (A) Die C Specimen Drawing

Die C was selected that defines a short bench-mark distance suitable for elastomers: for Die C the between-bench-mark distance is 25.00 ± 0.25 mm, which is used for strain/elongation calculation (ASTM International, 2006). The die dimensions needed for CAD modelling are provided in Figure 20 of the standard (metric table), where Die C has a reduced-section width $W = 6$ mm and reduced-section length $L = 33$ mm (ASTM International, 2006). These dimensions were used to generate the specimen sketch in SolidWorks (Figure 20).

3.4.2 Specimen Preparation

In SolidWorks, tensile specimens were initially modeled until there was the selected ASTM D412 Die C geometry. PreForm (Formlabs) was subsequently used to import the CAD files to generate support, slice, and orient. Specimens were made with the standard 0.100 mm (100 μ m) layer thickness Flexible 80A Resin in 0.100 mm (100 μ m) consistent with the testing conditions reported by the manufacturer of Flexible 80A Resin (Figure 23).

Specimens were produced in a Formlabs Form 3L printer (Figure 21) through stereolithography (SLA) where light selectively cures liquid resin layer-by-layer to build the part. Form 3L Resin Tank V3 was used in printing; this is a flexible-film tank that is part of the Low Force Stereolithography process and is used on the Form 3L platform. Flexible 80A Resin is compatible with the Form 3L ecosystem, which includes the Form 3L Resin Tank V3 (Figure 22).



Figure 21. Formlabs Form 3L SLA Printer (Formlabs)



Figure 22. Formlabs Form 3L Resin Tank V3 (Formlabs)

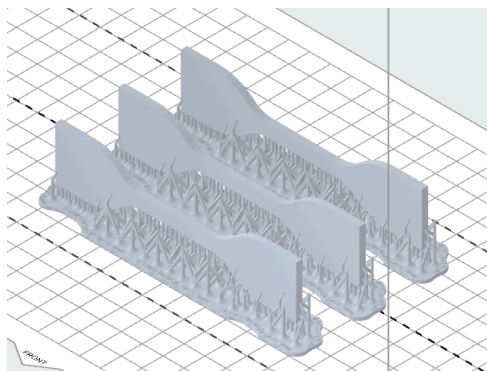


Figure 23. Import into PreForm



Figure 24. Printed Specimens

Specimens were washed with Form Wash V2 (Figure 25) after printing (Figure 24) to take off remaining uncured resin on the surface. Formlabs states that all SLA parts need to be washed and adds that Form Wash V2 will automatically clean with IPA (isopropyl alcohol) or other solvents, controlled agitation, and automatic lift-out step to minimize over-soaking and risk of deformation. The default condition of fresh IPA was a 10-minute wash as recommended in the Formlabs documentation and the post-processing conditions used in the Flexible 80A material data (Figure 27).

Finally, to cure the sample, Form Cure V1 (Figure 26) was used, which is a combination of controlled heat and 405 nm light to complete the polymerisation process and stabilise the final material performance (Figure 28). The temperature of the curing machine was set 60°C for all specimens. The curing time was used as an experimental variable in this project because the Engineering and Specialty resin will not be at full strength and functionality until they are post-cured; therefore, tensile testing was conducted at the same conditions by using 10, 15, 20 and 25 minutes of curing time under the same conditions.



Figure 25. Formlabs Form Wash V2 (Formlabs)



Figure 26. Formlabs Form Cure V1 (Formlabs)



Figure 27. Washing Post-process



Figure 28. Curing Post-process

3.4.3 Test Procedure with MTS Criterion C41.103

An MTS Criterion 40 electromechanical universal test system Model C41.103 was used to perform tensile tests (Figure 29).

The reason behind the choice of this particular machine is that its maximum rated force capacity is 1 kN which is suitable when dealing with low-strength elastomeric specimens and prevents loss of resolution that might occur when measuring small forces on a higher capacity frame (e.g. 5-10 kN) (MTS Systems Corporation, 2026).



Figure 29. MTS Criterion C41.103 (MTS Systems Corporation, 2021)

To minimize grip slipping, which is a critical concern of elastomers, pneumatic grips were used to hold the specimens in place, as it offers constant force and is the preferred choice in this type of application (MTS Systems Corporation, 2021) as demonstrated in Figure 30 and 31.

The control of tests and data collection were conducted in TestSuite TW Elite with the assistance of a standards-based workflow (ASTM D412 template). The template will assist in automated reporting of important tensile results after gathering the force- extension data (MTS Systems Corporation, 2021). The first grip separation was to be 60 mm. Specimen dimensions and test/environment parameters were inputted as pretest values in TW Elite before each run; these values are summarised in Table 2.



Figure 30. Fixing specimen (10 min. curing-time)

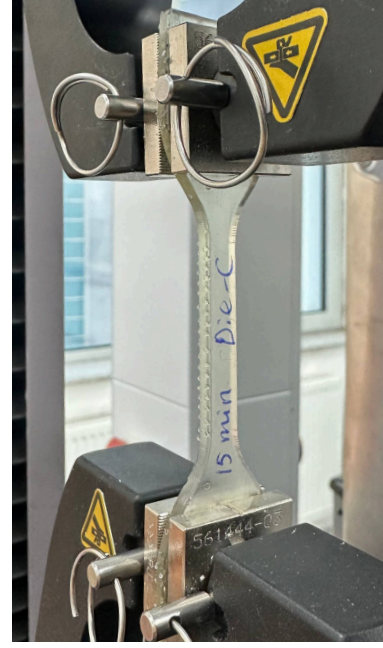


Figure 31. Fixing specimen (15 min. curing-time)

Table 2. Input parameters in TestSuite TW Elite (ASTM D412 template).

Pretest parameter	Value	Unit
Width	6.000	mm
Thickness	3.000	mm
Specimen gage length	25.000	mm
Mark length	25.000	mm
Test rate	8.300	mm/s
Elongation point 01	0.500	mm/mm
Elongation point 02	1.000	mm/mm
Temperature	23.0	°C
Humidity	50.0	%
Data acquisition rate	30.0	Hz

Raw data of each tensile test were exported from TestSuite TW Elite as time-series data in three variables: crosshead displacement (mm), applied load (N), and time (s). These

represent the main experimental record employed in post-processing and calculation for engineering strain and stress, which allows plotting the stress-strain curve and extracting significant tensile properties (MTS Systems Corporation, 2021; ASTM International, 2006).

3.5 FEA Insertion and Removal Mechanics Simulation

Using the structural finite element analysis (FEA) program Abaqus, the mechanical response of the catheter was examined for two distinct loading scenarios associated with the procedure: insertion and removal. To address the procedure sequence, the simulation was divided into two halves. Since both parts are advanced simultaneously when the pleural area is accessible, the catheter and needle were assembled jointly for the insertion case. Since the introducer needle is removed after insertion and the catheter is left in the body, the removal case involved removing the needle from the assembly and modeling the catheter alone. This analysis division is significant to create two different structural conditions for the device during application and to ensure clinical realism of the FEA.

In the insertion simulation case, the proximate part of the catheter and needle assembly was loaded axially with an optimal compressive load of 60 N. This load was taken from experimental values measured by Watanabe et al. (2011) for the insertion of a catheter into a human body, who reported a mean maximum insertion force of 71.4 N at the peri-umbilical port and an average of 65.3 N at any other port site, with ranges of 63.9 N – 75.5 N and 31.8 N – 83.8 N, respectively. Since there is enough stress on the prototype to prevent underestimating the amount of stress it endured, 60 N was selected as a mid-range value design load because, despite being above the upper bounds of the reported range, it does not represent extreme, unusual, or uncommon penetration conditions. As a result, 60 N strikes the ideal balance between physiological realism and careful evaluation of a prototype's design.

As for the removal of the catheter, only the catheter was modelled without a needle, since the needle is removed during the operation after the insertion into the body. The catheter was applied to a tensile force of 30 N (nominal withdrawal load). Published data show that the maximum axial pulling forces needed to remove the catheter from the human body vary from about 34.0 to 40.9 N and the peak axial pulling forces used to secure a surgically inserted catheter using suture in an in-vivo model are about 27.6 N, 30 N is

considered an optimal lower load for estimating the catheter integrity due to pulling force during removal without creating an increased level of severity for the pull force scenario, this load was representative of a moderate degree of mechanical relevance.

3.6 Fluid Distribution Simulation

Software SolidWorks Flow Simulation is applied to define two cases for assessing the internal catheter pressure distribution during a fluid flow simulation. Using a fluid flow rate of 120 mL/min, the first clinical will simulate a situation where the catheter is used with a suction pressure of 19.4 kPa, which is the average negative manual aspiration pressure of about 146 mmHg; the second condition will simulate the maximum aspirator suction pressure at 95 kPa, which represents the maximum negative pressure of near peak syringe aspiration (about -718 mmHg) based on investigations using a syringe with 60 mL of liquid (Capp et al., 2024; Haseler et al., 2011).

Since a sustained clinical case was not represented by the critical maximum suction conditions, the two scenarios were modelled independently. In the real world, syringe-generated negative pressures fluctuate because they mostly depend on how much the plunger has been drawn back. It was expected that the pressure would decrease from its maximum rather than remain at its maximum as aspiration advanced and the plunger location changed. As a result, the loading condition of 19.4 kPa was applied to be clinically relevant, and the theoretical top limit of 95 kPa was utilised for comparison. A 60 mL syringe was chosen as the reference aspiration tool because it is frequently used to remove pleural fluid during thoracentesis. The purpose of the simulation was to assess the pressure distribution, local pressure concentration, and flow characteristics in the catheter lumen, with an emphasis on the perforation zone, the tip region, and any additional drainage access sites. This simulation was designed to evaluate the stability of drainage provided by the suggested geometry under both normal and high suction conditions.

3.7 Prototype Manufacturing

The process of prototype manufacturing is an important phase in the design and development of medical devices because the prototype component is the physical manifestation of the computer-aided design (CAD). This allows for confirmation of geometry, feasibility of production, handling, and functionality of your proposed final design before actual material production occurs. The purpose of this project was to utilize

prototype manufacturing to determine if the proposed thoracentesis catheter design (including lumen size, perforation area, supplemental access port, and overall dimensions) could be produced with sufficient accuracy, allowing for mechanical and functional evaluation.

Because a Formlabs Form 3L printer can create thin-walled hollow geometries, smooth surfaces, and small features required for the catheter lumen, perforation zone, access port, and exterior marks, catheter prototypes were made using stereolithography (SLA). PreForm software was used to prepare the CAD model for printing once it was exported from SolidWorks as an STL file. This program allowed for orientation, slicing, and support generation before printing. Flexible 80A V1 resin served as the main prototype material because the 80 shore The resin's hardness would enable the printed prototype to more closely resemble the compliance of elastomeric catheter components than any other material could. The printed prototypes were produced with a 0.1 mm layer thickness. Two print iterations were evaluated in order to determine the effects of build orientation on manufacturability and prototype quality. The catheter was printed horizontally in the first iteration in order to reduce the amount of support material consumed and improve material conservation. According to the printer job report, this build utilized a total of 9 mL of Flexible 80A V1 resin, consisted of 181 layers, and had a total print time of 3 h 24 min.

In order to better facilitate the formation of the long rectangular structure of the catheter, help expel uncured resin that accumulates inside the internal channel during printing, and lessen the possibility of resin becoming trapped within the lumen, the second print iteration of the catheter prototype was oriented 45° from the surface of the print bed. However, this orientation did require a significantly larger amount of support material than the previous print iteration. This angled build required the creation of 1660 layers, each measuring 0.1 mm. Following printing, both prototypes underwent the same post-processing steps using Form Wash V2 (Figure 25) and Form Cure V1 (Figure 26). Specifically, each prototype was washed in Form Wash V2 for ten minutes to remove uncured resin and cured in Form Cure V1 for ten minutes at 60°C to fully polymerize and solidify mechanical properties. The wash and cure times and temperatures followed the manufacturer's instructions for Flexible 80A resin. After being post-processed, the prototypes were evaluated for lumen continuity, integrity of perforation, geometric

accuracy, surface finish, and overall print quality compared to each other to determine which print orientation was more appropriate for the manufacturability of the thoracentesis catheter prototype.

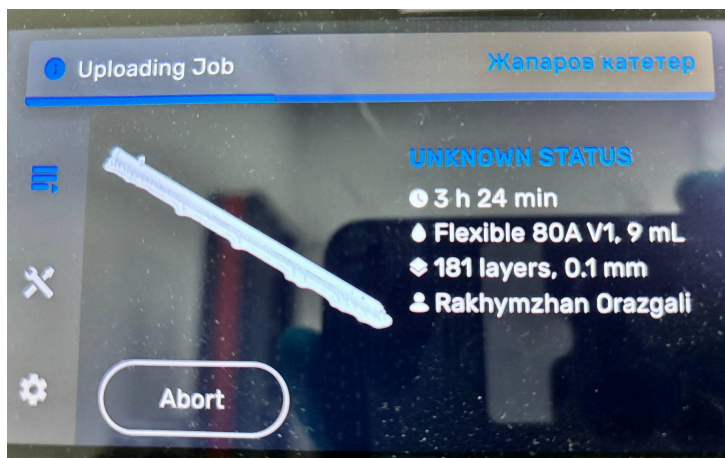


Figure 32. Print Job Screenshot First Iteration.

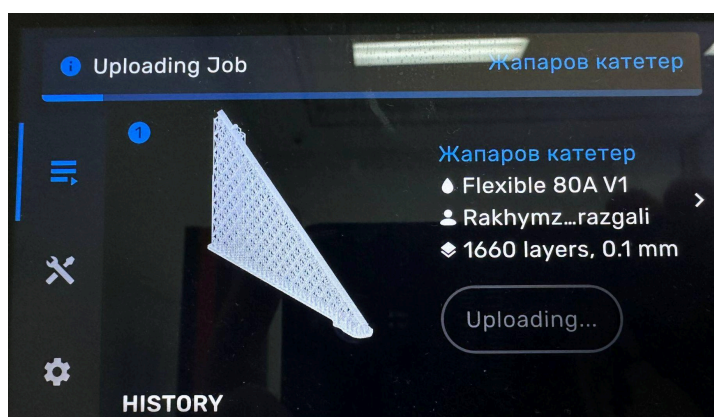


Figure 33. Print Job Screenshot of Second Iteration.

3.8 Preliminary Risk Analysis

A risk analysis was undertaken to ascertain the major technical risks affecting the reliability of the prototype tier results. Major manufacturing risks included the unsuccessful printing of the prototypes by SLA, dimensional accuracy issues, the presence of trapped uncured resin in the lumen, and surface defects due to print orientation and support strategies (Figures 32–35). The major risks affecting the tensile testing of the prototypes included variability in preparation of the specimens, the potential for grip slippage, and measurement uncertainty due to pretest input or machine setup which were reduced by the

standardisation of specimen geometry, fixed test parameters, and the correct use of a pneumatic grip (Section 3.4.1–3.4.3; Figure 29; Table 2).

The number of specimens tested and included in the results also increased uncertainty related to the average tensile values represented in Table 3. Moreover, the risk of using simplified material models and boundary conditions for the FEA and fluid simulations means that the numerical results should only be viewed as preliminary engineering estimates, rather than final clinical performance data. Overall, although these risks do not preclude the study, they indicate that further refinement of the prototype, retesting and additional validation may be required.

4 Results

Prototypes of both catheters were made successfully using Flexible 80A V1 Resin and the SLA process described in Section 3.7.1. Both prototypes were manufactured without any major visible defects (extra holes, gross deformation, misalignment of the additional access port and distal features) and are therefore consistent with CAD (Figures 34 and 35). After printing, both prototypes were soft and easily deformable, but after the desired cleaning/curing cycle outlined in Section 3.7.1, they became rigid enough to handle and visually inspect. The first prototype was printed in a horizontal orientation and used 9 mL of resin, however, contained a large amount of excess resin remaining in and around the internal structures. The second prototype was printed at a 45° angle and exhibited less excess resin within its geometries, indicating improved drainage of resin inside the lumen; however, more resin was consumed in building this prototype (38.7 mL) because of the additional support structure required for manufacture at an inclined angle (Figures 32 - 35). Overall, printing results were a trade-off between efficient use of materials and quality of prototype as the second prototype iteration (inclined) was cleaner.

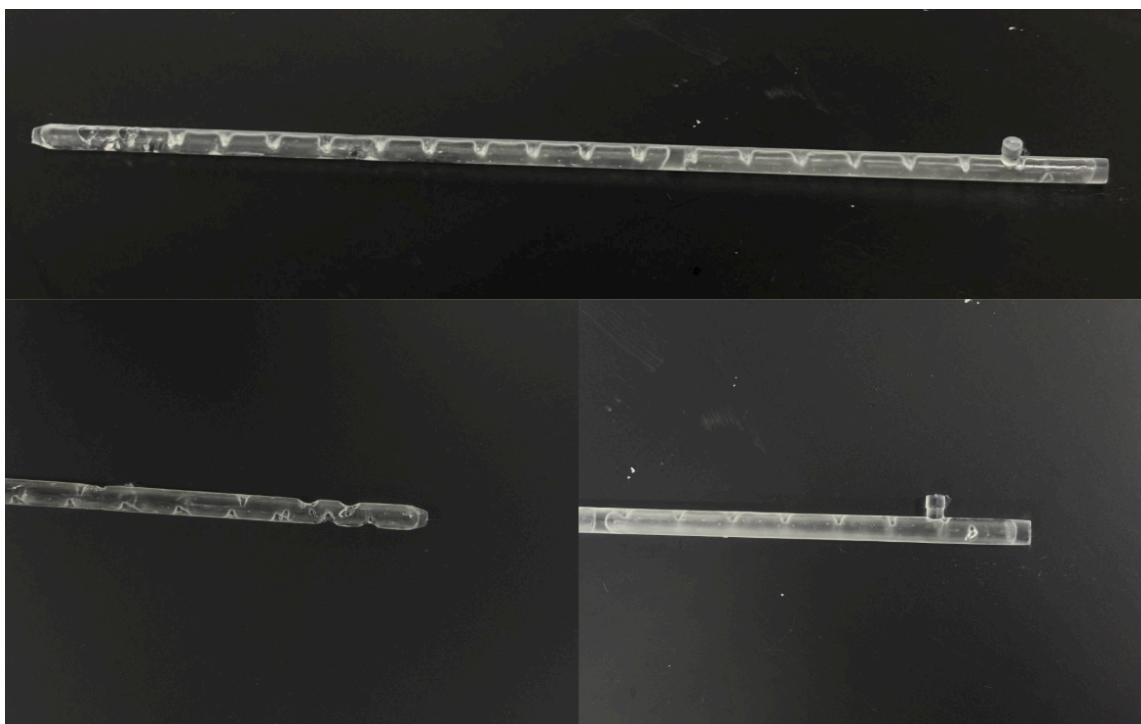


Figure 34. First Printing of Catheter

The first prototype of Flexible 80A printed in horizontal alignment successfully reproduced the primary geometry of a catheter, but a larger volume of residual resin was left inside the printed structure when compared to the second prototype.

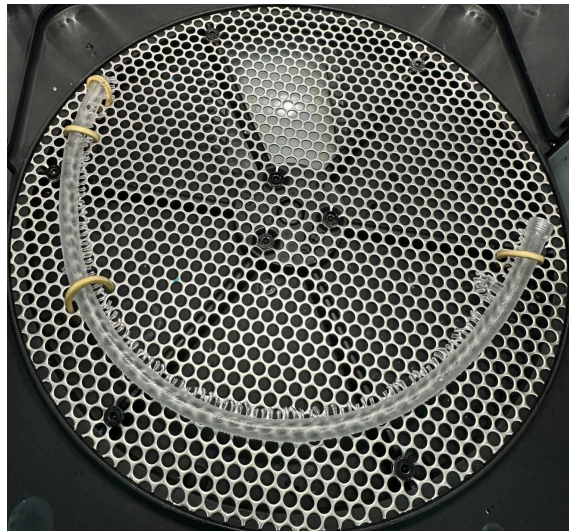
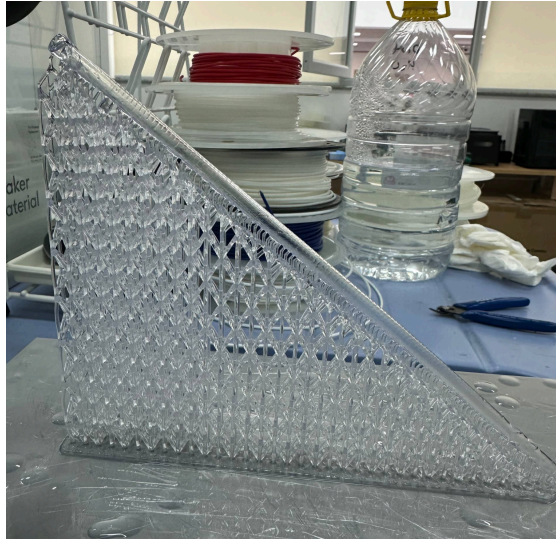


Figure 35. Second Printing of Catheter

The second prototype of Flexible 80A printed at a 45-degree angle had a cleaner internal geometry and a smaller volume of residual resin due to greater drainage of resin during the printing process. However, there was a much greater consumption of resin for this print orientation because of the additional support volume.

4.1 Tensile-Testing

Following the export of the raw outputs (displacement, load, and time) of MTS system, the data were spreadsheet processed in Microsoft Excel to obtain engineering stress-strain and the main tensile parameters of each curing condition. The processed values are summarised in Table 3, reporting the results per specimen and the average results per curing time.

Table 3. Tensile-Testing Results.

Specimen ID	Run	Curing , min	Elongati on, %	Displace ment, mm	Load, N	Time , s	Strain	Stress , Mpa
1802-1	1	10	112	56.03	75.87	7.59	2.24	4.22
1802-2	2		113	68.04	94.57	9.15	2.72	5.25
Average (1-2)			113	62.03	85.22	8.37	2.48	4.73
1802-3	3	15	132	79.29	123.06	10.65	3.17	6.84
1802-4	4		124	74.53	113.38	10.01	2.98	6.30
Average (3-4)			128	76.91	118.22	10.33	3.08	6.57
1902-3	5	20	110	65.80	101.17	8.85	2.63	5.62
1902-4	6		128	76.58	125.46	10.29	3.06	6.53
Average (5-6)			119	71.19	113.32	9.57	2.85	6.07
1902-5	7	25	126	75.78	115.41	10.18	3.03	6.41
1902-6	8		111	66.79	99.51	8.98	2.67	5.53
Average (7-8)			119	71.29	107.46	9.58	2.85	5.97

Figure 36 shows photographs of the printed ASTM D412 Die C specimens before and after testing and fractured specimens after testing to record the condition of the specimen, the fracture appearance and the reproducibility of the location of failure between runs.

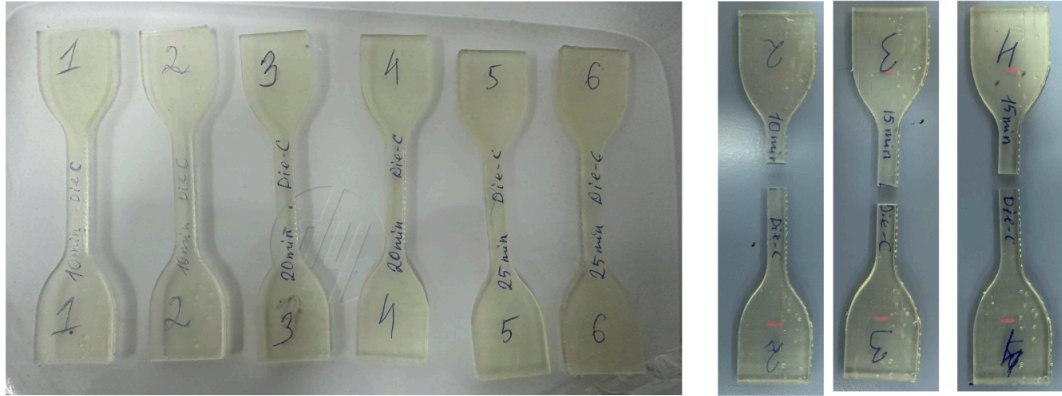


Figure 36. Printed ASTM D412 (A) Die C Specimens of Different Curing Time

The load-displacement curves exhibit a gradual non-linear tensile behavior with a gradual stiffness increase and sudden drop in load at fracture. The 10 min curing group failed at lower loads: Specimen 1802-1 reached 75.87 N at 56.03 mm, while Specimen 1802-2 reached 94.57 N at 68.04 mm (average peak load 85.22 N, average displacement 62.03 mm). The 15 min group produced the highest overall loads and extensions: Specimen 1802-3 reached 123.06 N at 79.29 mm, and Specimen 1802-4 reached 113.38 N at 74.54 mm (average 118.22 N, 76.91 mm). For 20 min, results were mixed: Specimen 1902-3 failed at 101.17 N and 65.80 mm, whereas Specimen 1902-4 reached the highest single-run load, 125.46 N at 76.58 mm (average 113.32 N, 71.19 mm). For 25 min, Specimen 1902-5 reached 115.41 N at 75.78 mm, and Specimen 1902-6 reached 99.51 N at 66.79 mm (average 107.46 N, 71.29 mm) (Table 3 and Figure 37).

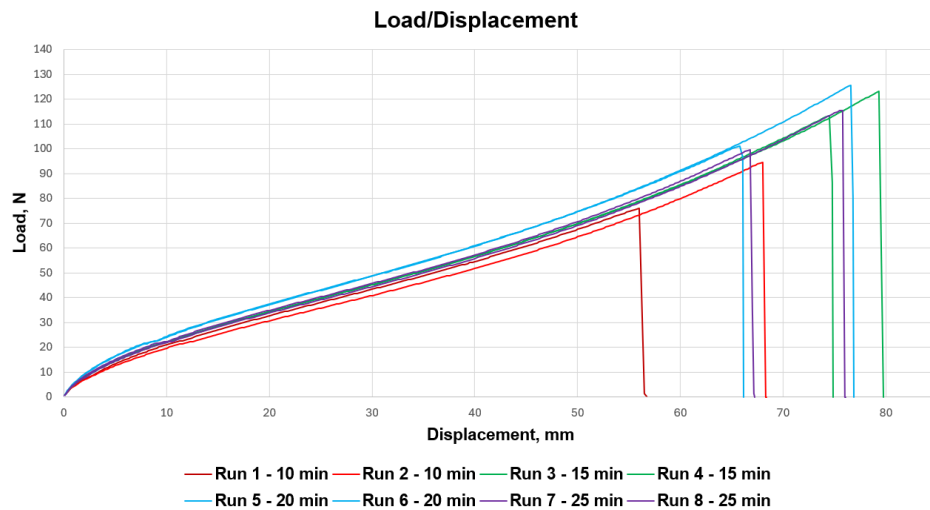


Figure 37. ASTM D412 (A) Die C Flexible Resin 80A Load/Displacement

The stress strain curves also trend as the force curves do with fracture occurring at strains of around 2.24-3.17. In the 10 min group, Specimen 1802-1 reached 4.22 MPa at $\epsilon = 2.24$, while Specimen 1802-2 reached 5.25 MPa at $\epsilon = 2.72$. In the 15 min group, Specimen 1802-3 achieved the highest stress of the entire dataset (6.84 MPa at $\epsilon = 3.17$), and Specimen 1802-4 reached 6.30 MPa at $\epsilon = 2.98$. In the 20 min group, Specimen 1902-3 reached 5.62 MPa at $\epsilon = 2.63$, while Specimen 1902-4 reached 6.53 MPa at $\epsilon = 3.06$. For 25 min, Specimen 1902-5 reached 6.41 MPa at $\epsilon = 3.03$, and Specimen 1902-6 reached 5.53 MPa at $\epsilon = 2.67$ (Table 3 and Figure 38).

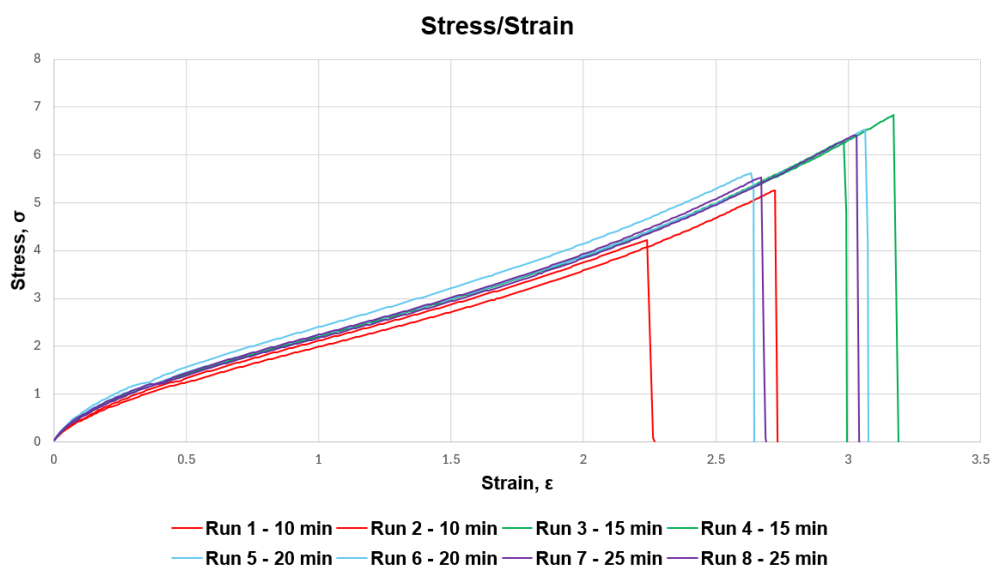


Figure 38. ASTM D412 (A) Die C Flexible Resin 80A Stress/Strain

There was a positive increase in ultimate tensile strength (UTS) between 10 min and 15 min curing followed by slight decrease in longer curing periods. The 10 min specimens had UTS values of 4.22 MPa (1802-1) and 5.25 MPa (1802-2), giving an average of 4.73 MPa. The 15 min group produced the highest mean UTS: 6.84 MPa (1802-3) and 6.30 MPa (1802-4), average 6.57 MPa. At 20 min, UTS values were 5.62 MPa (1902-3) and 6.53 MPa (1902-4), average 6.07 MPa. At 25 min, UTS values were 6.41 MPa (1902-5) and 5.53 MPa (1902-6), averaging 5.97 MPa. To compare, the manufacturer has a declared post-cured UTS of 8.9 MPa of Flexible 80A Resin at their stated processing conditions (curing at 60 °C for 10 minutes.) (Table 3 and Figure 39).

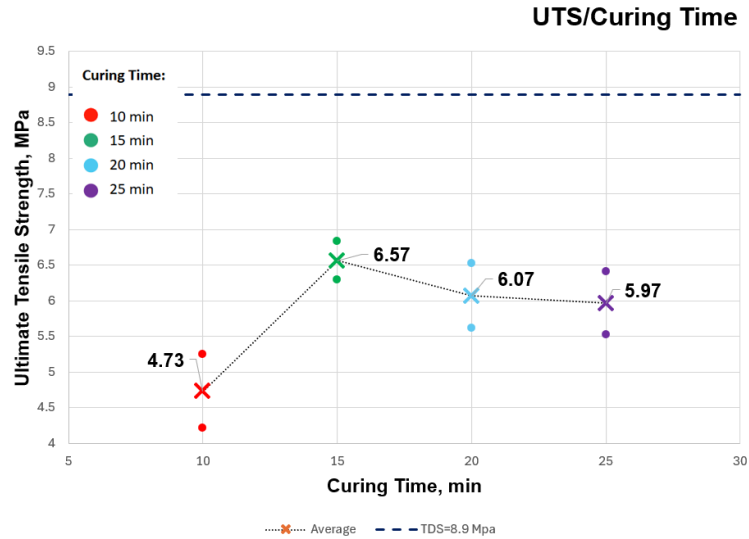


Figure 39. ASTM D412 (A) Die C Flexible Resin 80A UTS/Curing Time

Break elongation was similar to the manufacturer benchmark, where the maximum was at 15 min curing. The 10 min group showed 112% (1802-1) and 113% (1802-2), average 113%. The 15 min group showed 132% (1802-3) and 124% (1802-4), average 128%. The 20 min group showed 110% (1902-3) and 128% (1902-4), average 119%. The 25 min group showed 126% (1902-5) and 111% (1902-6), average 119%. Formlabs indicates elongation at break of 120 percent in post-cured Flexible 80A Resin (curing at 60 °C for 10 minutes), and also indicates that the properties are subject to change with print orientation, settings and temperature (Table 3 and Figure 40).

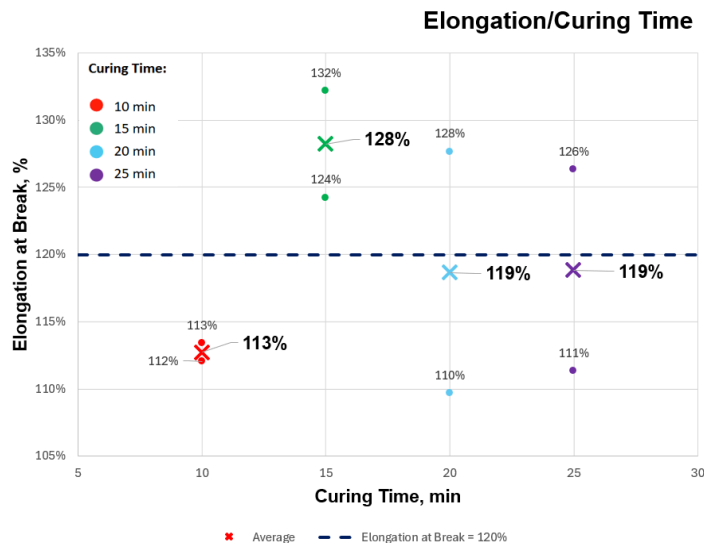


Figure 40. ASTM D412 (A) Die C Flexible Resin 80A Elongation/Curing Time

4.2 FEA Insertion and Removal Mechanics Simulation

The analysis that was performed using the finite method (Abaqus) showed that a maximum von Mises stress of 1.22 MPa was created in the catheter-needle assembly under insertion loading and with an axial force of 60 N (Figure 41). The highest values of stress were found at the distal perforated portion of the catheter where the perforations or holes exist. The lowest values of stress were found in the needle and in the proximal tail section of the catheter.

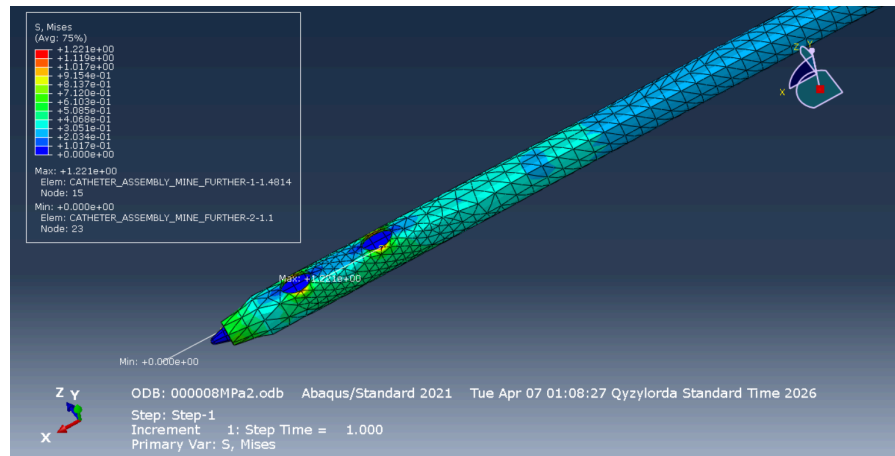


Figure 41. FEA Insertion Mechanics Simulation (1.221 MPa, E = 2.59 MPa, 60N)

As shown in Figure 42, under the removal loading condition where an axial load of 30 N was applied to the catheter alone, the maximum von Mises stress was 0.606 MPa. Again, the highest stress concentrations occurred in the distal perforated area surrounding the perforation holes, with the lowest stress concentrations occurring at the proximal end of the catheter.

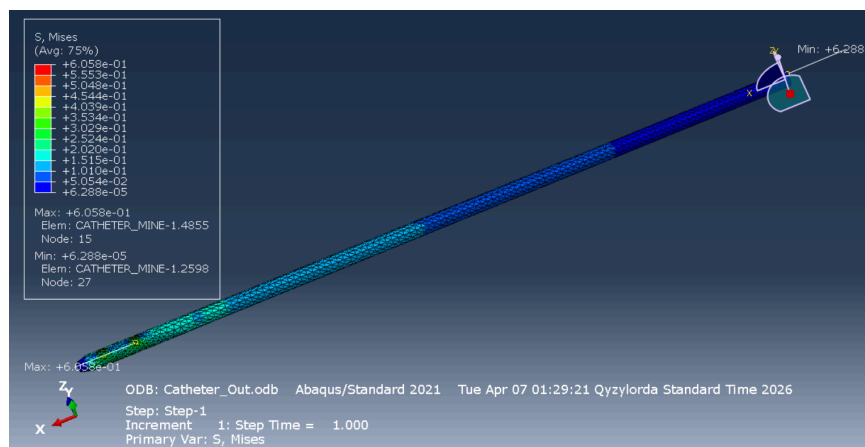


Figure 42. FEA Removal Mechanics Simulation (0.606 MPa, E = 2.59 MPa, 30N)

The same stress concentration occurred at the same critical regions of designs in both simulations. However, there was a higher peak stress for the insertion situation than the removal situation as identified by the values of 1.22 MPa and 0.606 MPa, respectively.

4.3 Fluid Distribution Simulation

Two suction conditions were simulated in SolidWorks fluid flow simulation program: real manual aspiration and theoretical aspirate maximum. For the actual manual aspirate condition tested, 120 ml/min flow rate with 19.4 kPa syringe pressure, max catheter pressure was 81.97 kPa (shown in Figure 43). Pressure distribution along the flow trajectories concentrated at distal end of catheter as well as within (DSA).

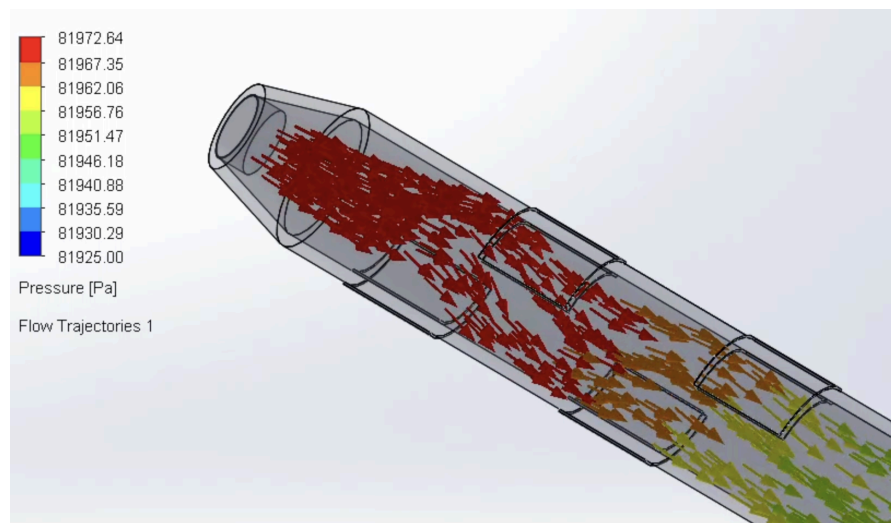


Figure 43. Real Manual Aspiration Case (flow rate = 120 mL/min, pressure from syringe = 19.4 kPa)

Under ideal hypothetical conditions at a flow rate of 580 mL/min with an injection pressure of 95 kPa, there was a maximum pressure exerted at the catheter of 6.74 kPa (Figure 44). The pressure distribution mirrored that exhibited during the lower total applied pressure case since the flow trajectories again flowed along the internal lumen of the catheter.

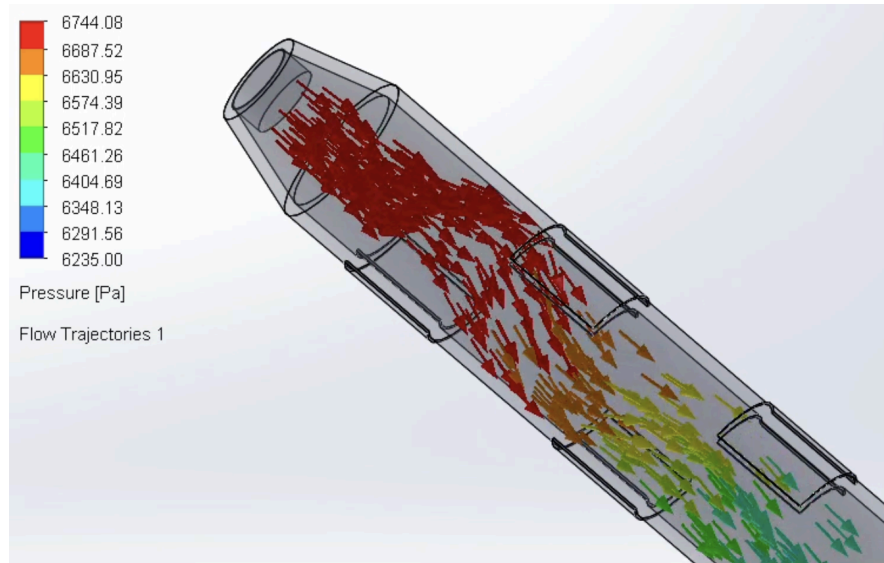


Figure 44. Critical Maximum Case (flow rate = 580 mL/min, pressure from syringe = 95 kPa)

As a result, this CAD model enables for additional evaluation of design, manufacturing, and prototype viability in addition to representing the engineering realization of the original concept.

5 Discussion

The engineering elements of this project will be addressed in this section, and how they relate back to the original design goals developed for the thoracentesis catheter. The discussion will evaluate how these engineering components, including tensile test results, prototype manufacturing results, insertion and removal simulation results and fluid distribution results given from prototype testing demonstrate that the proposed design is feasible. This discussion will also highlight limitations with the current proof-of-concept prototype and indicate where refinements are necessary for future validation.

5.1 Tensile-Testing

The reported ultimate tensile strength (UTS) was not close to the 8.9 MPa of the Formlabs Technical Data Sheet (TDS), and the elongation at break was nearly the same as the reported 120% (Formlabs, 2024). This combination implies that the test was able to obtain the desired high-ductility behaviour, however the strengths values cannot be directly compared to the TDS since the manufacturing and preparation conditions were not identical.

The main limitation is specimen preparation. ASTM D412 is composed of dumbbell specimens that are ideally cut out of a flat sheet and standard emphasizes that tensile values are determined by the geometry of the specimen and test conditions (ASTM International, 2006). Formlabs also adds that they employed Die C specimens in their tensile tests and these specimens were cut out of sheets (Formlabs, 2024). In our final project, specimens were printed directly since a cutting die/clicker press was not accessible and the use of resin had to be limited due to its cost, accessibility in Kazakhstan and limited material allocation by IHT Central Asia LLP. Direct printing has the potential to add orientation and surface effects which decrease measured strength, which is consistent with the TDS note that properties depend on geometry, orientation, settings, and temperature (Formlabs, 2024).

The other limitation is that there are few runs incurred per curing time, which limits statistical reliability. According to ASTM D412, tensile will be sensitive in terms of testing conditions and will only be compared under the same testing conditions (ASTM International, 2006). Regardless of these limitations, the testing could be described as successful in terms of project objectives since it was able to reproduce elongation values close to the TDS benchmark and show a strong dependence of mechanical performance on

curing period, giving a useful foundation of selecting post-processing parameters in the catheter prototype.

5.2 FEA Insertion and Removal Mechanics Simulation

The finite element analysis finds that the distal perforated zone is also the most mechanically damaged part of the catheter (both when trying to insert and remove it). Maximum von Mises stress in both cases occurred in the area around the perforation. This indicates that this area is where most of the local mechanical performance of the structure occurs. This aligns with what would be expected from an engineering perspective because when a doctor perforates a tube, it destroys the continuity of the tube wall, decreases the effective load carrying cross section, and creates localized geometric discontinuities resulting in areas where stress accumulates. Therefore despite the need for perforations to allow for drainage, the perforations also represent the area of the design that has the least resistance to structural failure.

Comparison of maximum stress produced by insertion (1.22 MPa) compared to maximum stress from removal (0.606 MPa) indicates that insertion produces greater stress due to the higher load during insertion (60 N) versus load during removal (30 N). Further, due to involvement of the catheter-needle assembly when inserting, load is transferred through the distal end during penetration resulting in greater stress development in the area immediately surrounding the perforated portion of the catheter. Conversely, for removal loading, only the catheter itself is loaded and the lower tensile forces result in less overall stress on the catheter. Peak stresses in the same distal location under both loading conditions indicates that portion of the design is the primary structural control point for the catheter.

This is consistent with engineering expectations since perforating a tube results in the destruction of the tube wall's continuity, a reduction in the effective load carrying cross section, and the creation of localized geometric discontinuities that lead to stress-accumulating areas.

5.3 Fluid Distribution Simulation

According to fluid distribution tests, the catheter's present internal flow characteristics will allow it to operate as intended in both a theoretical and real world manual aspiration scenario. In contrast to using a syringe to create a negative pressure equal

to the syringe's theoretical maximum suction, the real-world case is crucial from an applied clinical perspective because it is based on reported manual aspiration pressures that will closely resemble a typical thoracentesis procedure. The literature suggests that manual aspiration is typically associated with using less negative pressure and therefore greater variability than would be seen if the maximum suction of a syringe was applied; this has primarily to do with how far back the plunger on a syringe is pulled and the operator's technique.

The results from our simulations show that pressure is not uniformly distributed along the catheter. Instead, pressure varies throughout the flow path of the catheter primarily since the distal region contains a change to the geometry of the lumen and represents the entry point to the catheter. The hydraulic behaviour of the region around the internal geometry is then dictated by the internal geometry of the catheter in the distal region, and the flow path. The results of the simulation demonstrate that under both normal and great suction flow, the flow trajectories are as we would expect, suggesting that the lumen was still open and functioning as a continuous conduit in both flow scenarios.

In comparison to the critical theoretical trial, the maximum pressure recorded during the actual case trial was higher. Rather than taking this finding to mean that the real case had more severe mechanical conditions, this demonstrates that local internal pressures in the model were dependent upon a complete set of flow boundary conditions, defined as prescribed flow rate, suction condition and reference used by the software to calculate pressures. As a result, the two simulations are best viewed as hydraulic case comparatives and not as a simple linear ranking of severity. As such, although the real case represents the most clinically relevant example of catheter behaviour during use, the critical case represents a theoretical to enable comparison of actual and potential catheter performance.

Based on the internal flow capacity of the lumen design under realistic and upper limit vacuum settings, fluid simulation results show that the catheter suggested for drainage is a successful design. The difference seen between these two cases warrants further experimentation on the characteristics of pressure behaviour to validate the numerical modelling and provide the hydraulic limitations for catheters in clinical practice.

6 Conclusions

This capstone project provided a systematic, requirements-based foundation to design a prototype thoracentesis catheter and confirmed the viability of SLA-printing Flexible 80A Resin to prototype on a small scale within the confines of the university. Tensile testing also gave us a convenient check of post-processing conditions of our workflow, as well as showed that the curing time influences the mechanical response of the printed elastomeric specimens. According to tensile performance measured in all the experimented conditions, the proposed post-curing time of the next catheter prototype version would be 15 minutes since it provided the highest overall tensile response out of the tested curing configurations and thus provided the most conservative margin in handling and usage between prototyping and actual use.

The capstone project provided an engineering base to plan and develop a prototype thoracentesis catheter with enhanced clinical functionality. Beginning with the first idea of a standard single-lumen catheter, the design was incrementally developed with several iterations based on clinical and engineering feedback. The last concept had the essential features aimed to enhance the usability and safety of the procedures such as proximal access port, millimeter depth markings, distal perforable drainage area, radiopaque marker bands, and altered internal flushing-channel concept. CAD development, DFMA, SLA-prototyping proved that the geometry under consideration could be developed into a prototype that could be produced and tested at the university level.

The finite element insertion and removal simulations demonstrated that the perforated distal area is the most mechanically demanding of the catheter and the flow simulations demonstrated that the inner lumen geometry is capable of sustaining fluid flow in both a realistic manual aspiration and a theoretical maximum suction environment. On the whole, the work demonstrated the concept of the proposed catheter to be technically viable like a prototype and that the integration of clinical support, CAD, additive manufacturing, and simulation can be successfully applied to the process of developing a better thoracentesis device.

6.1 Limitations

This project has many limitations which must be considered while interpreting the results. The prototype catheter was evaluated only at the prototype-level, no clinical,

in-vivo, or ex-vivo demonstrations were made and, therefore, the safety and performance of this device has not yet been verified for actual medical use. The number of tensile specimens which were tested under each curing condition was also limited, which lowers the statistical reliability of evaluating the average values. Also, Flexible 80A resin was the primary material that was tested for the experimental portion of the project and was intended only for proof-of-concept prototyping; therefore, a more appropriate BioMed Flex 80A material has been identified for future work but was not available to test during the construction of a prototype. Additionally, FEA and fluid simulations were completed using simplifications of the materials properties, loading conditions, and boundary conditions used in each of the simulations, thus they represent preliminary engineering estimates and not accurate representations of clinical behaviour. Finally, the fluoroscopic imaging of the radiopaque-marker design would need to be performed to verify the imaging visibility of the design.

6.2 Further Research and Improvements

In the future, the current proof of concept for this device will need to be developed into a more clinically relevant and validated device. Initially, the catheter must be manufactured with BioMed Flex 80A or some other medically certified elastomer so we can evaluate how this material affects manufacturability, post-processing characteristics and mechanical properties from a more clinically appropriate material. The mechanical testing program must be expanded by increasing the number of specimens used in testing and adding tests, e.g., kink resistance, bending response, fatigue resistance, tear resistance. The prototype will require fluoroscopic verification of the radiopaque markers, functional drain testing under more physiologic pleural flow conditions, refinement of current FEA and flow simulations using more representative material models, and utilization of clinically validated boundary conditions. Finally, future development should involve ex vivo, in vivo or preclinical testing and continue optimizing the distal perforated area, flushing channel design, and manufacturing process, including a potential transition from SLA prototyping to scalable industrial processes like extrusion or injection molding.

7 Project Management

Figure 45 demonstrates the schedule of the project. The capstone started in August with literature review which lasted into August-April since it is literature-review based project and needed regular updates provided by academic sources. Consultations with Dr. Akhmed Japarov were also preserved during the whole milestone.

The main development work started with prototype design in October–November, followed by iterative prototype printing in November–February. Additional printing time was required since the geometry of the catheters is complicated and there are internal diameters that are very small and it took several runs to get to acceptable print quality. Preparation of specimens was done in the period of January-February and tensile tests done in the period of February-March. FEA of insertion/removal mechanics and fluid distribution were simulated in March-April. The process of data analysis and validation began with the initial tensile tests and went on until all the experiment and simulation results were integrated (February-April). In March-April, the final report was brought together and the final presentation will be prepared and delivered in May.

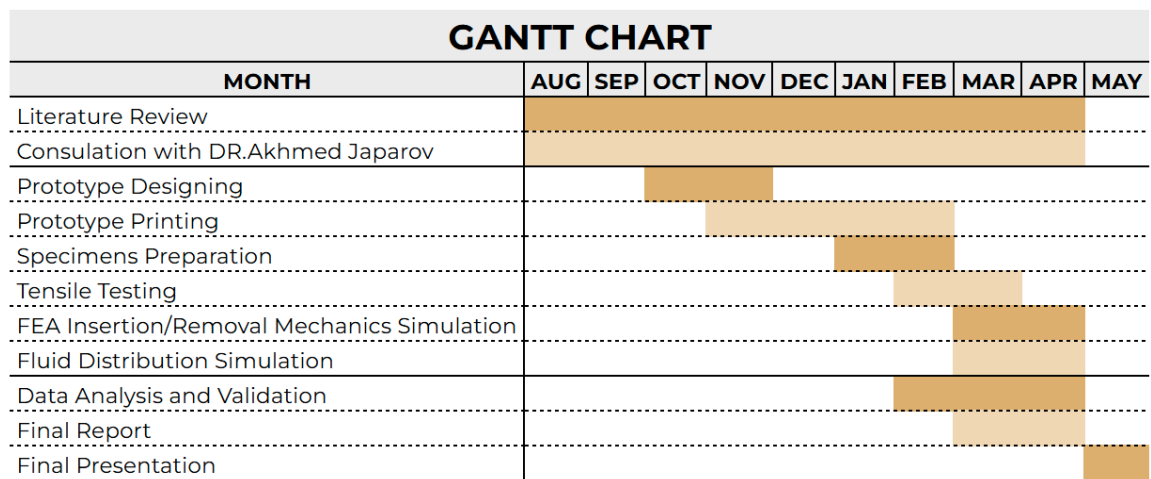


Figure 45. Capstone Gantt Chart

7.1 Team Members' Contributions

All roles and assignments were allocated between all group members. Stages of the capstone project were divided by responsibilities and interests that contributed to the development of this project.

7.1.1 Alisher Sabigaliyev's Contribution.

During the capstone development Alisher Sabigaliyev worked as a core member dealing with both the technical and documentation components of the project. He was leading the concept development of the thoracentesis catheter, creating and developing ideas of design as per the industrial specification. Simultaneously, He assumed the major part in the general organization, design and structure of the written report, which implies setting the order of sections and subsections and providing the uniformity of academic style and formatting of figures and tables and references.

Alisher was the lead writer of the report's technical content, drafting and incorporating Section 1 (Requirements; Aim and Objectives; Industrial and Institutional Context; Limitations and Constraints) and most of Section 2 (Literature Review) including the review of pleural disease and thoracentesis methods, various catheter systems, catheter material and biocompatibility, dedicated sub-sections describing catheter and needle material selection, and the Requirements and Technical Specifications derived from the industrial input document. He also contributed to the drafting of the key sections of Section 3 (Methodology: Concept Development and Design) - the methodology map, Material Selection, and the full description of the Tensile Testing process (including the selection of the specimen standard, specimen preparation, and the testing procedure using the MTS Criterion C41.103 system). Moreover, he wrote the analytical report for Section 4 (Results: Tensile Testing), Section 5 (Discussion: Tensile Testing) and Section 6 (Conclusions: Tensile Testing), including consistency between the raw results from the machine, processing in Excel, final plots and analysis. He also developed Section 7 (Project Management) including the project schedule, milestones and Gantt chart, and the APA reference list. Apart from the writing, Alisher was the main visual communicator for the project: he prepared the slide deck and posters (both landscape and horizontal) individually, keeping the technical style of the report, slides, and posters consistent and coherent.

7.1.2 Aruzhan Ashimova's Contribution.

Aruzhan Ashimova conducted research on ISO sterilization requirements, ensuring the design met safety and medical standards. Aruzhan contributed to the development of the concept by working closely with peers to ideate and ensure technical feasibility of the proposed ideas. Aruzhan also performed a literature review on recent works in the field of

catheter design and requirements to choose materials and perform the design based on evidence.

Aruzhan selected the materials from the perspective of mechanical, chemical and biocompatibility characteristics of the components. Also, she conducted CAD modelling to ensure accurate representation of the geometry of the system and was involved in preparation of simulation and the design optimisation process. Aruzhan also contributed to the technical reporting by documenting various analyses, providing interpretations and effectively communicating engineering insights in reports.

7.1.3 Rakhymzhan Orazgali's Contribution.

Rakhymzhan Orazgali was also in the field of design and practical implementation. He helped to formulate concepts and also helped in choosing appropriate materials of different project elements. The coordination of communication within the team by Rakhymzhan also helped in ensuring that activities were done in time and information disseminated among team members. He was also an active worker in CAD modelling and drawings that were used to prepare in-depth designs of mechanical parts. Moreover, he did the 3D printing of parts and the conversion of CAD models to physical models to test and demonstrate the functionality.

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