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New Technology for Springs and other Elements in Resuscitation Manikins

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Summary

This master thesis identifies needs for an improved infant CPR manikin through an anatomic study, user empathy and gained knowledge about leading CPR guidelines. The knowledge obtained by needfinding resulted in three possible improvements of the chest compression mechanism, these are:

- Compression mechanism which allows room for implementation of advanced airway management
- Progressive chest stiffness, which is more realistic
- Simulate breaking of ribs

Different technologies, not yet used in training manikins are explored. The possibilities and limitations of these technologies are revealed and evaluated. The most promising technologies are:

- Air spring
- Force regulated linear actuator
- A thin polymer sheet representing the rib cage

The air spring provides a more realistic chest stiffness and is also less space consuming than the current solution. This enables the possibility of implementing an advanced airway.

The force regulated linear actuator concept does not enable more room for an advanced airway. However, it does make it possible to apply any chest characteristic obtained by patient measurements. Moreover, it enables the possibility of simulating breaking of ribs during chest compression, as the stiffness is regulated by software.

The polymer plate concept consumes very little space, thus allowing room for implementation of advanced airway management functionality. Considerable effort is made to verify if this solution will have the desired lifetime by applying mechanics of materials theory and finite element analysis. However, more testing is required to obtain a desired result.

Sammendrag

Denne masteroppgaven tar for seg å finne behovene hos brukere for å forbedre en baby hjerte-lunge rednings dukke. Disse behovene er funnet ved å studere anatomi, kommunisere med brukere og tilegne seg kunnskap om ledende retningslinjer innenfor hjertelungeredning. Kunnskapen fra disse aktivitetene resulterte i tre områder ved dukken som kunne forbedres:

- En kompresjonsmekanisme som muliggjør implementering av funksjonalitet for avansert luftveishåndtering
- Progressiv bryststivhet, noe som er mer lik karakteristikken til menneskers brystkasse
- Simulering av brukne ribbein

Ulike teknologier som ikke ennå er implementert i hjerte- lungeredningsdukker er utforsket. Mulighetene og begrensningene ved disse teknologiene er evaluert opp mot hvordan de tilfredsstiller forbedringsområdene. De mest lovende teknologiene er:

- Luftfjær
- Kraftregulert lineær aktuator
- En polymerplate som representerer brystkassen

Luftfjæren gir en mer realistisk bryststivhet og er mindre plasskrevende enn den eksisterende løsningen. Dermed muliggjør denne teknologien implementering av funksjonalitet for avansert luftveishåndtering.

Den kraftregulerte lineære aktuatoren gir ikke betydelig mye bedre plass for å implementere funksjonalitet for avansert luftveishåndtering. Teknologien muliggjør simulering av hvilken som helst bryststivhet ettersom dette kan reguleres ved programvaren i dukken. Denne løsningen muliggjør også simulering av brukne ribbein, ettersom stivheten kan endres under simulering.

Polymerplatekonseptet er veldig lite plasskrevende ettersom det bare bruker ytterskallet av dukken som det fjærende elementet. Dette konseptet muliggjør derfor implementering av funksjonalitet for avansert luftveishåndtering. Den negative siden ved å implementere denne løsningen er usikkerheten ved hvor lenge polymerplaten vil holde før den blir utsatt for utmattingsbrudd. Derfor er det lagt ned en betydelig innsats for å estimere levetiden til en slik mekanisme ved å bruke mekanikkteori og elementmetode simuleringer. Likevel trengs det mer testing for å oppnå ønsket resultat.

Preface

This report is written by Henrik Aasheim, spring 2017, to fulfil the requirements of a master thesis in a Product Development and Materials specialisation at NTNU's Department of Mechanical and Industrial Engineering, spring 2017. This paper describes the exploration of technologies which might improve an infant manikin used to train medical personnel in CPR and advanced airway management.

The project is created as a collaboration between my supervisor at NTNU, Knut Einar Aasland, representative from Laerdal Medical, Arild Eikefjord and me, Henrik Aasheim.

Initially, I would like to thank my supervisor, Associate Professor Knut Einar Aasland, for guided me through this thesis and been genuinely interested in my work. Secondly, I would like to thank the representative from the company Laerdal Medical, Arild Eikefjord. He have given me valuable feedback from the work that I have done, and guided me towards further work. Thirdly, I would like to thank ”Medisinsk Simulator Senter” and ”Trondheim akuttmedisinske studentforening” (TrAMS) at St. Olavs hospital for letting me observe and gaining knowledge about the use of manikins in health care simulation and first aid training. Finally, I would like to thank my parents and my girlfriend for always supporting me and giving valuable ideas for further investigation. This thesis would not been possible without you.

Thank you.

Stud. Techn. Henrik Aasheim, June 2017

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Chapter 1

Introduction

It is estimated that there were more than 400 000 incidents of cardiac arrests in the US in 2014 [17]. To maximise the chance of survival there are several time-sensitive interventions that must be optimised [2]. This thesis will concern Cardiopulmonary resuscitation (CPR) and advanced airway management training for infants. CPR is an emergency procedure that combines chest compressions with artificial ventilation to circulate blood and supply oxygen to a patient who is in cardiac arrest. This procedure combined with defibrillation are the central elements to restore spontaneous blood circulation and breathing. A visual and easy way to communicate the main elements of high quality CPR is done by using the chain of survival poster [2] (see Figure 1.1).

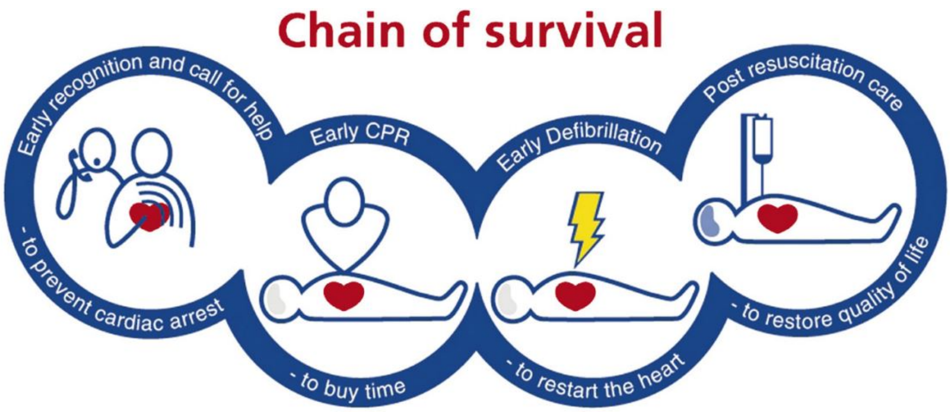


Figure 1.1: Chain of survival [2]

Regularly CPR practice has showed improved quality of CPR performance in terms of adequate ventilation volume and compression depth [18]. Consequently, it is important to provide equipment that enables practice and feedback to both medical personnel and laymen. Such equipment is provided by Laerdal Medical.

1.1 About Laerdal

Laerdal is a world leading company in terms of developing, manufacturing and selling medical equipment for training and clinical usage. The company started of as a toy manufacturer in the 1940s. Laerdal started to focus on first aid and emergency medicine products in the 1960. At that time, pre-hospital emergency medicine began to be seen as an extension of advanced hospital treatment. To teach students mouth-to-mouth resuscitation, a training manikin called Resusci Anne was introduced. Today, Laerdal provides a diversity of products and training programs for emergency care, such as advanced patient simulators for training and various medical equipment for patient treatment. The patient simulators enable training of handling medical conditions that are life threatening without putting patients at risk. The operation unit in Stavanger contains both a manufacturing facility, sales office and a R&D department, which makes cooperation between the departments easy. The core values of Laerdal have remained unchanged since they changed focus to emergency care. These are:

Mission - ”Helping save lives”

Vision - ”No one should die or be disabled unnecessarily during birth or from sudden illness or trauma”

1.2 Background

This master thesis started with the need to reduce the number of infant manikins needed to teach courses in resuscitation for newborns and infants. Laerdal Medical AS provides manikins for the course ”Resuscitation Quality Improvement” developed and taught by the American Heart Association. Feedback from these courses tells us that the practising requires too many different manikins. This has confused both participants and instructors. More functionality in each manikin will decrease the number of manikins required. Consequently, to reduce the number of manikins required, two manikins with some overlapping functionality were identified; the Laerdal Advanced Life Support Baby (Laerdal ALS Baby) and the Laerdal Resussci Baby Quality Cardiopulmonary resuscitation (Laerdal Resussci Baby QCPR). Some initial work was done in the pre-master (see Appendix D). Initially, I learned how critical life saving procedures are conducted. Secondly, I learned about the anatomy required to be imitated in the manikin. Thirdly, I observed the use of an advanced training manikin by medical personnel. Fourthly, I scanned the market for similar products. Fifthly, I established some preliminary product requirements. Finally, I suggested some coarse concepts that fulfill the requirements. To develop a new manikin with today’s standard, regarding accurate feedback and realism, three key functionalities were identified and will now be introduced.

1.2.1 Ventilation volume measurement

The first area of focus is how to accurately measure ventilation volume. Today, a venturimeter measures the flow of air going into the manikin’s lungs. This technology indirectly measures the ventilation volume by integrating the airflow over time. The integration process is prone to integration error, and will be larger in the case of sudden changes in airflow. Instead, measuring the expansion of the lung directly, allows us to know the volume of air in the lung at any time. Consequently, there is no need for an empty lung when turning on the manikin. A proposed technology to measure the expansion of the lung is strain gauges attached to the lung foil. Moreover, using proximity sensors to measure chest rise is another method. The accuracy of these methods is still unknown. It is difficult to measure ventilation volume accurately because the flow of air is transient and the total volume of air is as low as 40 ml.

1.2.2 Realistic airway that allows advanced airway management

The second area of potential improvement is a realistic airway which enables practice in advanced airway management. This includes the use of supraglottic airway devices, and the less used endotracheal tube (ET) [19]. Simulation of tongue edema and infections in the airway would also be valuable for students learning about airway management. The ALS Baby has an advanced airway system with tongue, epiglottis, vocal cords, trachea, left and right main bronchus and esophagus (food pipe) that could be used. With this airway, it is possible to split the lunge in a left part and a right part, indicating correct, or too deep placement of ET. Placing the tube in esophagus (food pipe) is also possible. However, it will be challenging to implement such an airway in a Rususci Baby QCPR, due to a space consuming compression spring in the centre of the manikin.

1.2.3 Compression mechanism

Compressing the chest of a patient who is in cardiac arrest circulates the blood, and keeps the patient artificially alive. Therefore, the compression mechanism is one of the most important functionality of a CPR manikin. The current solution consist of a coil spring located at the centre of the manikin and a sensor detecting the compression depth. The implementation of an advanced airway revealed a need for a compression mechanism which is not located at the centre of the manikin. Therefore, a less space consuming compression mechanism is needed to make room for the realistic airway.

1.3 Problem description

Three functionalities of possible manikin improvement were identified in the pre-master. After discussing with Laerdal, we found that to significantly improve the current manikin, new technologies should be investigated. The official problem description is therefore the following:

> New technologies, such as for example artificial muscles, have the potential to revolutionise resuscitation manikins. Whether they are usable in this kind of product, is unknown, as it has not been studied or tried. In this master thesis, the candidate will scan the market for new technologies with potential to be used in manikins. Based on the results of this scan, he will choose one or a few of the most promising technologies and elaborate the use of them. If

possible, dependent on time and resources, experiments will be done in order to find the properties of the new technologies and to test their usability.

The project will be conducted in close partnership with Laerdal Medical (contact person: Arild Eikefjord), who should be kept in the loop during the entire project to ensure that the chosen technologies are relevant also from an industrial point of view.

As indicated earlier, a less space consuming compression mechanism will make room for implementing an advanced airway. Therefore, this thesis only focuses on solving this issue. Some suggestions of how this can be achieved by conventional technologies are presented in the pre-master (Appendix D). However, after discussing with Laerdal, we found that technologies, not yet used in CPR manikins, should be investigated. Therefore, this master thesis focuses on exploring unconventional technologies with respect to the standard CPR manikins. Hopefully, these new technologies could improve the learning outcome from using the manikins and make the students more satisfied. By using manikins, students can practice on certain procedures repeatedly. This training is key to prepare students for when they must treat real patients. Consequently, an improved manikin will enhance the learning outcome from such training, and make it more effective because the manikin will be more similar to a real patient.

1.4 Project scope

This master thesis is limited to consider the compression mechanism of a CPR manikin. To develop a new improved manikin, I wanted to ensure that I thoroughly understood the requirements for such a manikin. This project gave me the opportunity to rethink what a compression mechanism is. Therefore, I started by investigating the human anatomy which should be imitated. Secondly, I learned about leading guidelines for performing high quality CPR. Thirdly, I acquired knowledge about the usage of manikins in training and education. The acquired knowledge led to some product requirement specifications developed in collaboration with Laerdal. Furthermore, different technologies were investigated. A clear advantage of exploring new technologies is that the hidden opportunities for using these technologies are revealed. A modification of a technology was developed and considerable time was used to elaborate the usage of the technology.

1.5 Objectives

The objectives of the thesis are:

- Verify user needs of training manikins
- Evaluate if new technologies enables a compression mechanism which have similar stiffness characteristic as humans
- Evaluate if new technologies can improve the learning outcome of using CPR manikins

- Develop a compression concept which enables implementation of an advanced airway in a baby CPR manikin.
- Evaluate if the chosen concept is scalable to other CPR manikins
- Evaluate the expected lifetime of such a concept

Chapter 2

Method

There exist several different methodologies of developing products, and all have different advantages and disadvantages. For a developer, the most important is to use methodologies which is beneficial for their project at the current stage. My approach is mainly based on Ulrich and Eppinger's "Product design and development" [3]. This master thesis project will consist of activities included in Ulrich and Eppinger's concept development activities [3] (see Figure 2.1).

2.1 Identify customer needs

During collecting customer needs, I used a method described by Plattner [20], called assume a beginner's mindset. Regardless of that I have considerable knowledge about CPR manikins, after working at Laerdal several summers, I assumed a beginner's mindset. By assuming a beginners mindset during observation of CPR manikins usage in teaching, I opened my mind for understanding the value of the product in a new way.

As knowledge about the user needs is established, initial product demand specification is established. Ulrich and Eppinger emphasises that such specifications are established before the generation of product concepts and therefore, might not be feasible. However, these specifications work as target specifications. They become the working goal of the project. For the usage in this project, there already exist a working product which fulfils most of the target requirements. Consequently, the target specifications can not be changed drastically and consider the new product as an improvement of the existing product.

2.2 Concept generation

To generate concepts, elements from Ulrich and Eppinger's five stage method were used [3], depicted in Figure 2.2. The main focus is to search externally for technologies, and generate concepts with the use of these technologies.

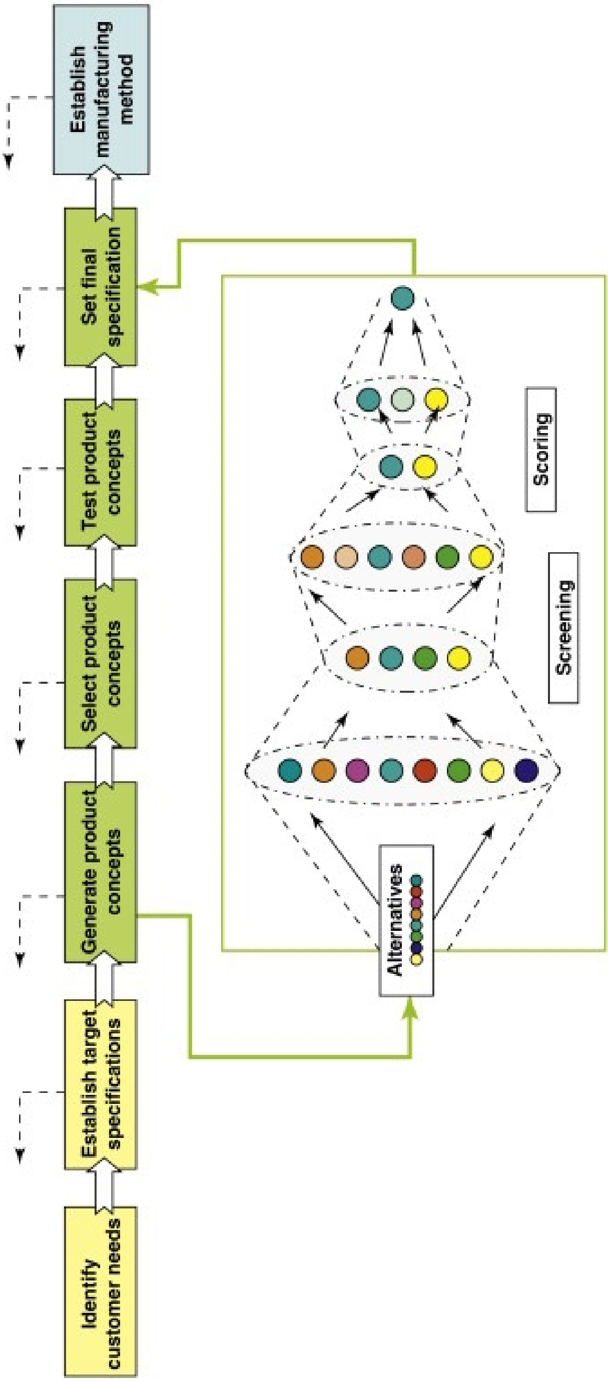


Figure 2.1: Ulrich and Eppinger's main steps applied iteratively[3] [4]

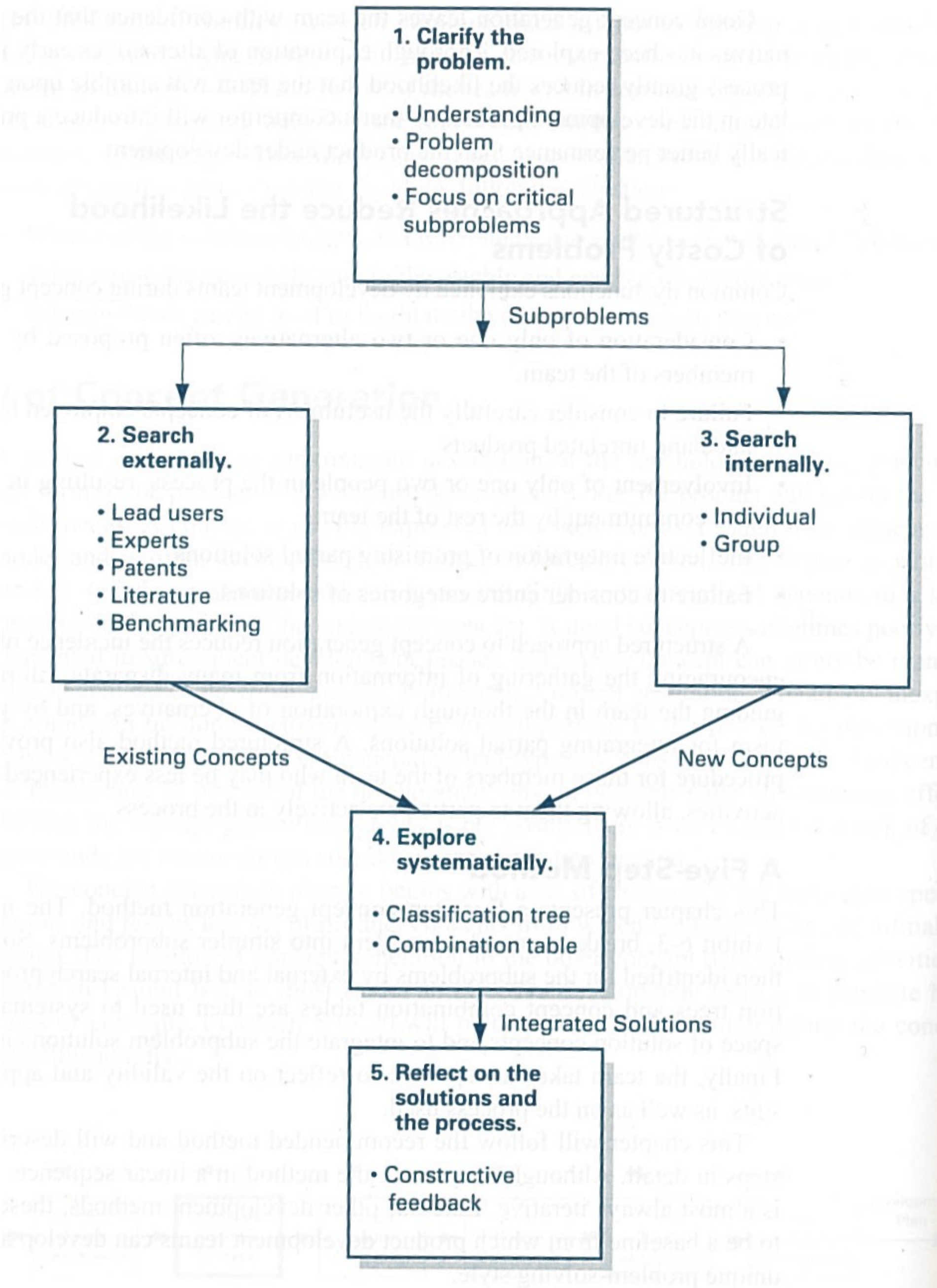


Figure 2.2: Ulrich and Eppinger's concept generation[3]

The project starts off with a broad range of technologies. The assessment of each technology, does not only consider if the concept meet the product specifications. It also explores the technology's ability to further improve the product in terms of learning outcome for the user, or make the training more gripping. The main focus of this thesis is the phases between "generate product concepts" and "set final specifications" as shown in Figure 2.1. The phases in this range are in this thesis applied iteratively. Some technologies have been discarded when theoretical insight is obtained. Some concepts survived until a physical prototype for learning were built and some were more promising. By building coarse prototypes, valuable knowledge is gained fast and a minimum of effort is done in concepts which is not promising. There are strong indications of that the process of building coarse prototypes at an early stage has a positive effect on the final product [21]. The promising concepts were refined through iterative prototyping. The most promising concept were elaborated in detail, and reached to a level where material choosing for fatigue life were considered.

2.3 Reduce risk of producing new products

Welo states that one objective of product development is to reduce the risk of producing new products [22]. A way of reducing the risk of making new products is to obtain knowledge about the product before it is released to market. For this project, gaining knowledge included learning about material behaviour, applying mechanics of material theory, performing finite element analysis and applying fatigue theory.

Chapter 3

Theory

As the main focus in this thesis will be about the chest compression there will be an introduction to the anatomy of the chest, how chest compression are used in emergency care and how chest compressions are taught. The goal of this work is to give knowledge about important aspects and requirements for a compression mechanism in a training manikin.

3.1 Anatomy of a human chest

The chest, or thorax, is the anatomy between the neck and abdomen. It consist of the thoracic cavity and the thoracic wall. The thoracic wall includes the rib cage, muscles and skin which forms a protective cage around the important organs as the lungs and heart. The skeletal part of the thoracic wall consists of the ribs, sternum and thoracic vertebra (see Figure 3.1).The sternum is a short and flat knuckle which consists of three parts connected with false links. These false links becomes bones in the age between 50 and 70, and therefore brittle and prone to breakage during chest compressions. There are 12 pair of ribs in both men and women and are numbered from 1-12, with the topmost rib as number one. In the back, each pair of ribs are connected to a associated thoracic vertebra with a rotation link. In the front the ribs are extended with cartilage. The cartilage of rib 1-7 are connected directly to the sternum, while the 8th, 9th and 10th is connected to the sternum through a cartilage joining. Whereas rib 11 and 12 are not connected to the sternum,and is therefore termed floating ribs.

3.1.1 Breathing

Breathing is primarily due to contraction of the diaphragm. The diaphragm is a skeletal muscle that extends across the bottom of the thoracic cavity. When the diaphragm contracts, abdominal organs is pushed downward, but since the pelvic floor prevents the lowermost abdominal organs from moving in that direction, the abdomen bulges forwards. In this process, the volume of the thoracic cavity increases which leads to a fall in pressure

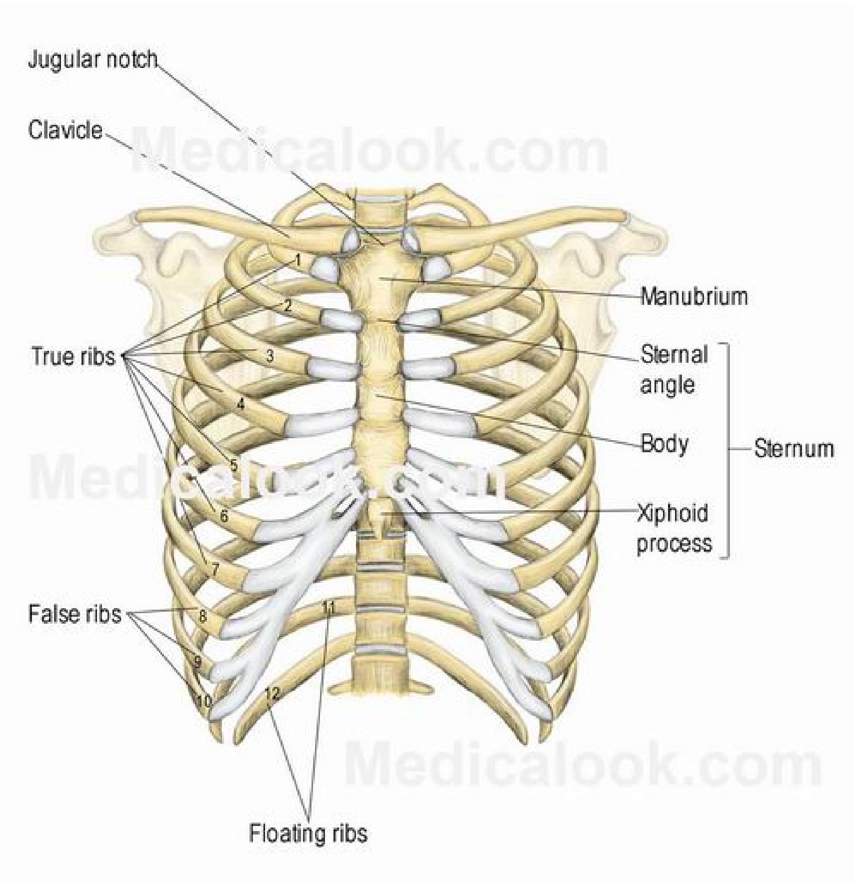


Figure 3.1: Rib cage [5]

of the thorax. The pressure drop causes expansion of the lungs and air is inhaled. During exhalation the diaphragm relaxes, returning the chest and abdomen to its initial position.

During heavy breathing, as for instance during exercise, contraction of the accessory muscles pulls the front of the rib cage upwards. This increases the anterior-posterior diameter of the rib cage, as the initial position of the ribs are tilted downwards. This allows a larger increase of the rib cage and more air is inhaled to the lungs.

Artificial breathing or artificial ventilation are most relevant for this thesis. Methods to do so is listed in the pre-master (see Appendix D). In such a ventilation, all muscles of the patient is assumed to be relaxed. That means the only expansion of the chest is due to the internal pressure of the lungs. The emergency care procedures for both adults and infants [23] [24] states that the ventilation shall last for one second and stop immediately when the chest starts to rise. I assumed that such a ventilation will be similar to a normal breath activated mostly of the diaphragm. To figure out how much the chest expands at normal breath, I measured the circumference of the chest at three different spots during a normal breath. The first measurement point is over the navel, the second, right under the breast muscles, and the third, right over the nipples. The measurement spots are illustrated in Figure 3.2. To discover potential differences between men and women, the measurements were done at one woman and one man. The measurements is presented in Table 3.1.

Table 3.1: Circumference of chest during breathing normally

Man/ woman	Measuring spot	Initial circumference [cm]	Circumference after inhalation [cm]	Circumference increase [cm]	Relative increase
Man	1	81	85	4	4,9 %
Man	2	82	85	3	3,7 %
Man	3	88	91	3	3,4 %
Woman	1	73	76	3	4,1 %
Woman	2	70	73	3	4,3 %
Woman	3	84	86	2	2,4 %

3.1.2 Chest compressions and guidelines

For CPR training manikins, an important feature of the chest is to do chest compressions. In case of a cardiac arrest, the blood stops circulating and to restore the blood circulation, chest compressions can be performed. When compressing the chest, the heart will be compressed and the pumping function of the heart will be restored artificially. Chest compressions does not usually start the heart again, but keeps the patient artificially alive until a defibrillator is available. The importance of defibrillators is addressed by the Norwegian Resuscitation Council in "Guidelines 2015 -BLS with defibrillators" [23]. The starting point of the development is for a infant manikin, so I have used the guidelines for pediatric life support, written by the "European Recucitation Council". For both infants and children the guidelines states that you start of with locating the lower sternum. For children over one year of age this is the detailed description of a chest compression

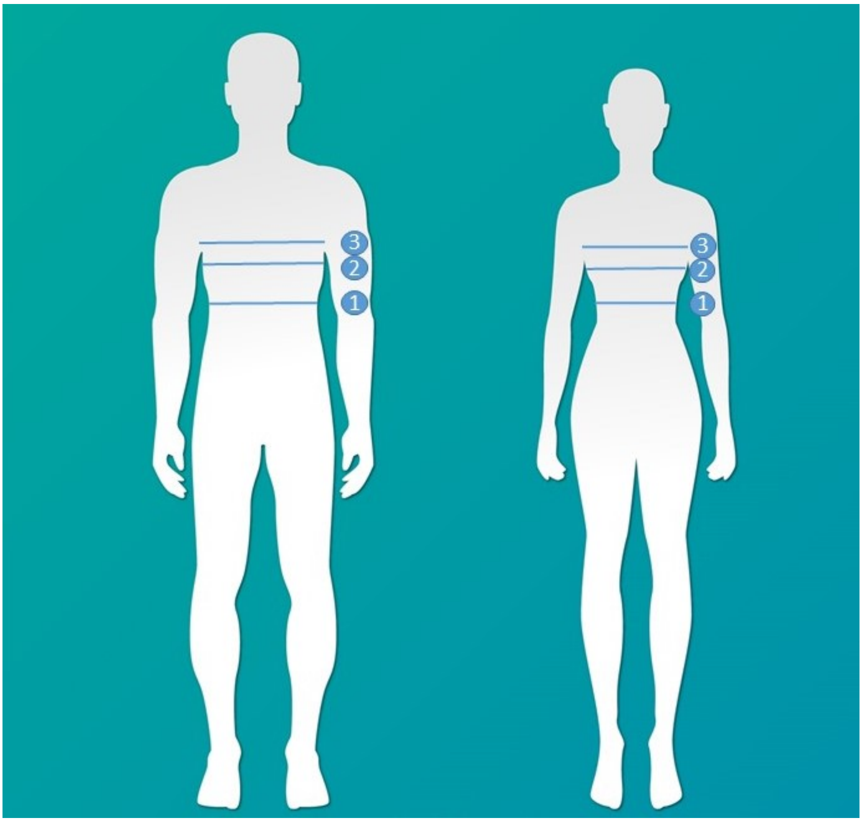
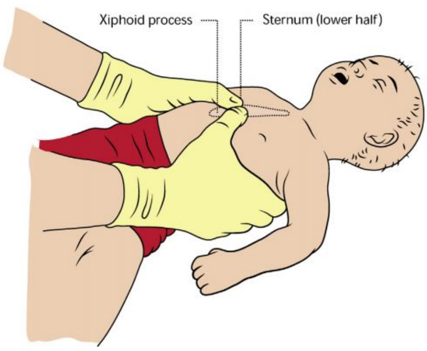


Figure 3.2: Expansion of thorax measurements points while diaphragm breathing [6]

"To avoid compressing the upper abdomen, locate the xiphisternum by finding the angle where the lowest ribs join in the middle. Place the heel of one hand on the sternum one finger's breadth above this. Lift the fingers to ensure that pressure is not applied to the child's ribs. Position yourself above the victim's chest and, with your arm straight, compress the sternum to at least one third of the anterior-posterior dimension of the chest..."[25]

For infants younger than one year, two thumbs placed at the lower sternum is advised. Between each compression, release the pressure completely and repeat at a rate 100-120 /minute.



(a) Chest compression in infant under 1 year

(b) Chest compression in children over 1 year of age

Figure 3.3

Further literature review revealed that the chest stiffness has a progressive characteristic [7]. As far as I know, no training manikin on the market today have a progressive chest stiffness. The manikins on the market have a linear chest stiffness, so trying to implement a characteristic chest stiffness will be interesting. The study providing chest compression force versus depth information measured the performance of 91 adult out-of-hospital cardiac arrest patients. A pad fitted with an accelerometer and a pressure sensor was used to measure the compression depth versus the force applied. The measurements done is illustrated in Figure 3.4. As we see from the measurements, the force applied to the chest is huge. As the bones become more brittle with age, cardiac arrest patients are prone to get ribs and sternum fractures during chest compressions [26]. Breaking of ribs during chest compressions of a unconscious patient can be uncomfortable, but is neccessary to circulate blood. Too shallow chest compressions is seen as one of the big challenges in achieving good CPR [23]. A hypothesis is that too shallow chest compressions are done due to fear of injuring the patient. By simulating broken ribs during a training situation it is believed that medical personnel will get used to the feeling of breaking ribs and to transfer that training to patient situations. It is more important to keep the patient alive with quality chest compressions than to avoid breaking some ribs. Furthermore, we see that the variations between patients are huge. Is should be considered to implement several chest stiffness characteristics in the training situation.

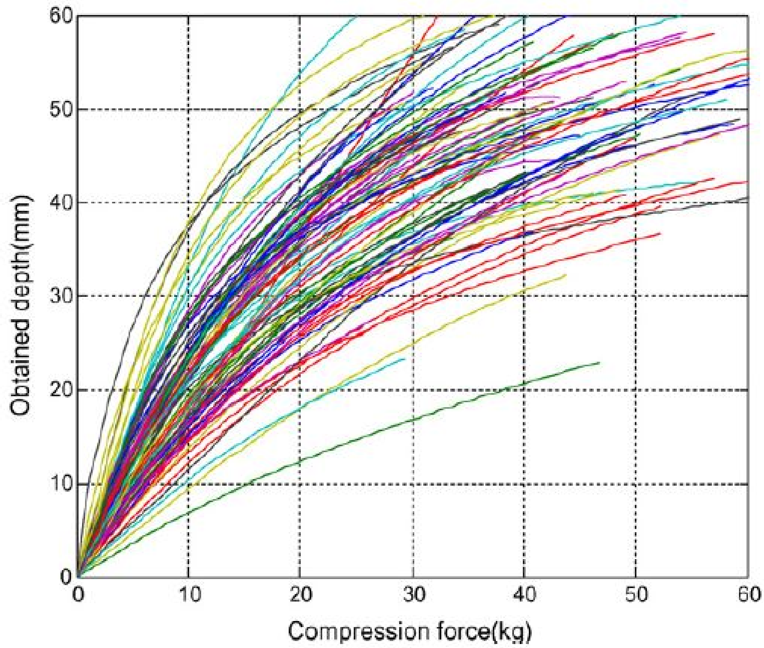


Figure 3.4: Compression force [kg] vs. absolute compression depth [mm] measured at 91 adult out-of-hospital cardiac arrest patients [7]

3.2 Experience during a first aid course held by TrAMS

In the pre-master I did an observation of medical personnel during a simulation training with a baby manikin. In the master thesis work I was a participant of a first aid course as non-medical personnel. This gave insight in how different skill levels of the participants affects how teaching of emergency care are performed. The course was held by Trondheim Akuttmedisinske Studentforening (TrAMS). All trip leaders of the mountaineering and skiing group NTNUI Ski & Fjellsport was invited to participate. Therefore, some extra focus was given to situations that can occur during mountaineering and skiing. The course had elements of theory, practical handling of a Laerdal Little Anne manikin and a situational training. The goal of the course was to teach the participants how to handle a situations where lives are at immediate risk and initial first aid can save those lives. The typical situation is when the patient is unconscious and cardiac arrest is suspected. TrAMS divided the first aid situation into several phases and addressed the key elements of each phase. The phases and key elements of the course are listed in Figure 3.5:

Initial

- Safety of the area
  - is it dangerous for helpers to get to the patients?
- Get an overview of the situation
- Delegate help personell
- Call for emergency help (113 in Norway)

A -airways

- Check if the patient is conscious
- Check the airway of the patient for foreign objects
- Open the airway of the patient by:
  - Extend the neck
  - Chin lift
  - Jaw thrust

B- Breathing

- Check breathing by looking at chest, while having ear close to patient mouth
- A healthy person breathes between 10-20 times per minute
- Count number of breaths for 10 seconds
- If number of breaths is less than 2, classify patient as non breathing and start CPR
- For a cardiac arrest, start with 30 chest compressions, continue with 2 lung ventilations. Repeat this until medical help can assist you. Notice that this procedure is only done to keep the patient artificially alive. To actually start the heart again a defibrillator is necessary.
- If the cardiac arrest is caused by drowning, it is advised to start with five lung ventilations.
- If patient breathes normally, but is unconsious, check again after a minute. If breathing is still normal, you can place patient in lateral position

C- Circulation

- Stop bleeding
  - Apply pressure
  - Rise above heart
- Control pulse

D- Disability

- Alert
- Verbal
- Pain
- Unresponsive

Figure 3.5: TrAMS first aid situation phases

Chapter 4

Requirements

The given information about human anatomy, CPR procedures and user emphasising from pre-master (see Appendix D), observation of a first aid course and some input from Laerdal Medical, lead to some user demands and product requirements which is presented in Figure 4.1, Figure 4.2, Figure 4.3 and Figure 4.4. The current manikins are able to fulfil most of the listed requirements. The requirements which is not yet fulfilled by the current manikins are:

- Compression mechanism which allows room for advanced airway
- Progressive chest stiffness similar as measured at patients
- Simulate breaking of ribs

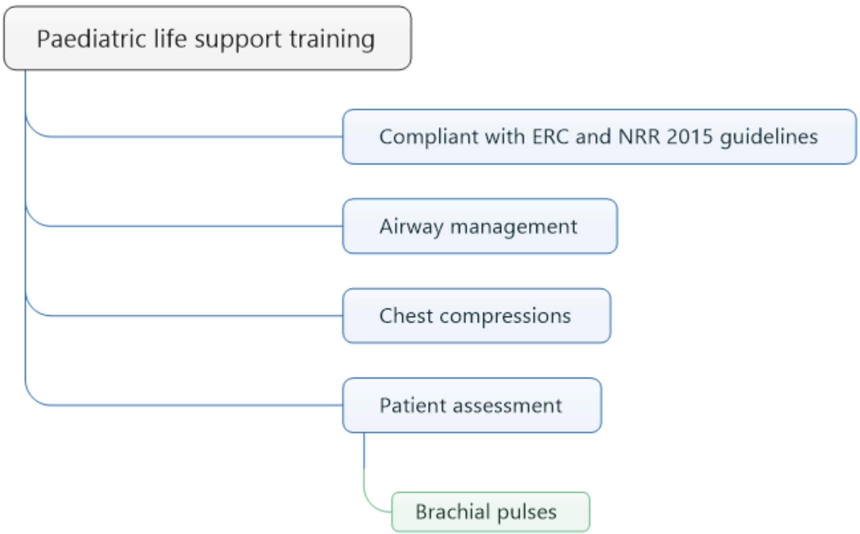


Figure 4.1: Main function tree

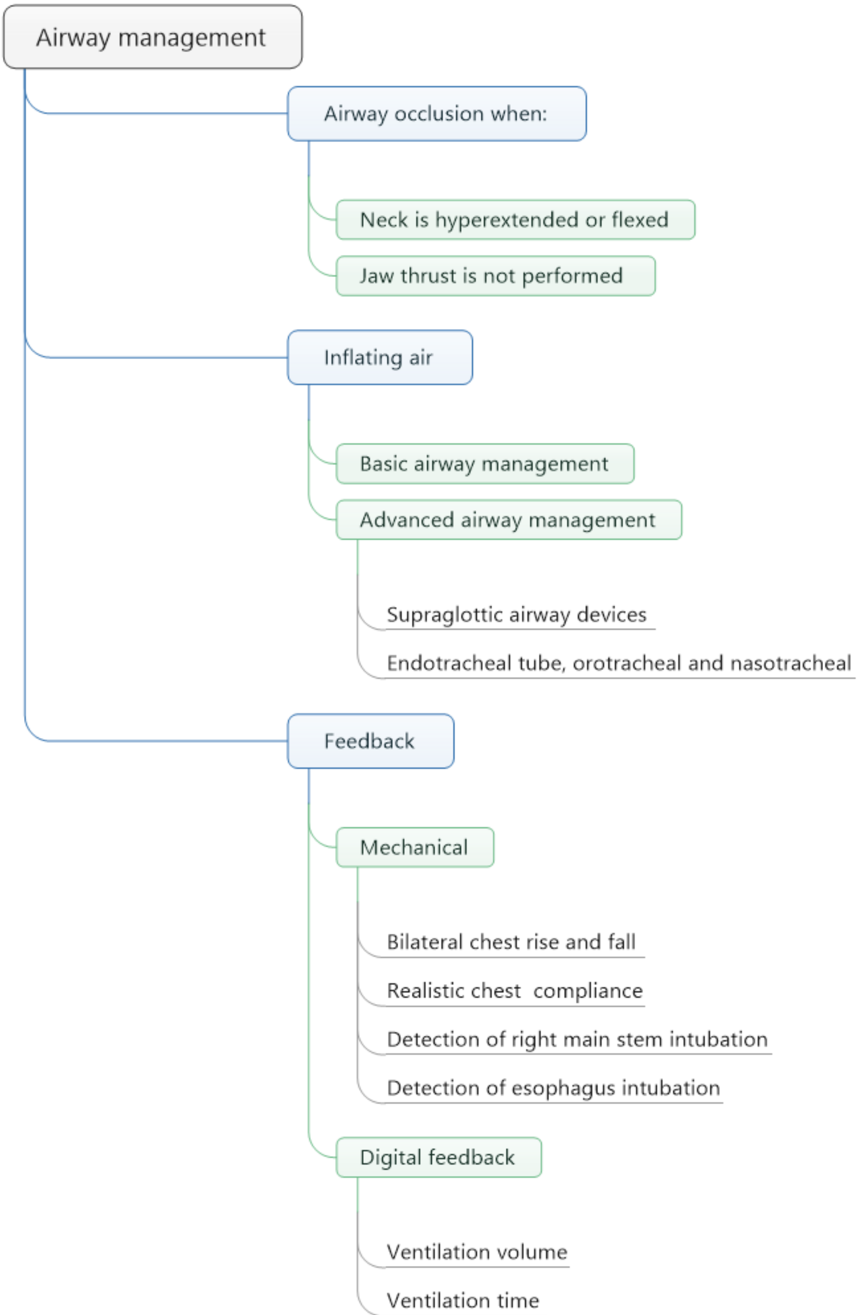


Figure 4.2: Airway function tree

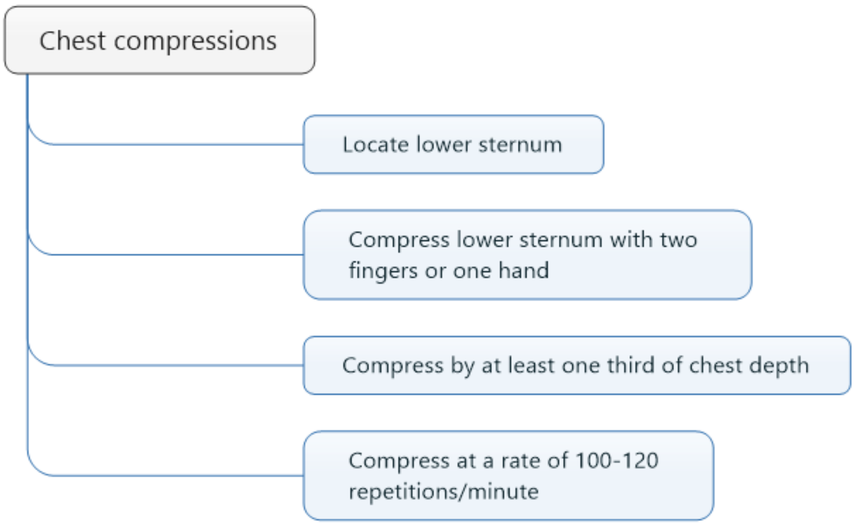


Figure 4.3: Compression function tree

Product target specifications				
Description		Measurements	Must	Should
1	**Chest compression**			
1.1	Compression depth	1/3 of anterior-posterior diameter of chest (1/3 of chest depth)	X	
1.2	Compression rate:	120 repetitions/minute	X	
1.3	Compression force at 1/3 of anterior-posterior diameter of chest:	6-10 kg	X	
1.4	Minimum lifetime	100 000 compressions	X	
1.5	Allows room for advanced airway		X	
1.6	Chest stiffness similar as measured on patients (Tomlinson data)	Progressive stiffness		X
1.7	Simulate breaking of ribs			X
1.8	Anatomically correct surface of thorax/chest including:			
1.9.1	Ribs		X	
1.9.2	Sternum		X	
1.9.3	Xiphisternum			X
1.9.4	Upper Abdomen (belly)		X	

Figure 4.4: Product requirements

Chapter 5

Compression mechanism

The problem of developing a improved CPR manikin is understood well and decomposed into several functions. The critical function to be addressed further is the compression mechanism. At this stage, I see the compression mechanism as a subsystem which functions as a spring inside the manikins chest. In other words, stage one of Ulrich and Eppinger's method of generating new concepts are covered [3]. Three target specifications, which is not yet solved in a current manikin are set. In the further work, the target of allowing room for an advanced airway is set as the most important. This is because it will generate considerable more functionality to the manikin with advanced airway management training. In addition, if a less space consuming compression mechanism is developed, it can be highly valuable for other advanced training manikins. This is because the trend is that users wants more and more functionality included in each manikin, and more functionality requires more space. The next step of Ulrich and Eppinger's generation of concepts is to search externally for solutions solving the target specifications. That was done by analysing products and technologies solving the target specifications.

5.1 Technology analysis

The function of the chest can be decomposed into two sub-functions. The first sub-function is being a spring, and the second sub-function is to imitate the outer anatomy of the chest. Figure 5.1 summarises the technology analysis related to the spring sub-function. Further, the more promising technologies are described more in detail.

5.1.1 Air spring

The air spring idea is inspired by mountain bike suspension. Presumably, this concept could reduce the springs diameter, compared to the current coil springs diameter. Moreover, the air spring will likely have a spring characteristic like the chest compression for real patients. [7]. An air spring functions by compressing air (see Figure 5.2).

	Air spring	Coil spring	Leaf spring	Flexible rib cage structure	Force regulated linear actuator	Cylindrical leaf spring
Compression mechanism						
How	Uses compressed gas as spring	Deflection of spring steel	Bending of steel leafs	Deflection of material in construction	Linear motor with position sensing and adjust force thereafter	Using thin plastic sheet which deflects
Advantage	Possible to achieve progressive spring characteristics	Simple, well known linear behaviour	Progressive behaviour	Anatomically correct	Possible to apply any spring characteristics as wanted	Simple construction which gives space for airway
Disadvantage	Space consuming in airway area	Space consuming in airway area	Small deflection compared to size.	Not found any suitable material that are soft enough yet.	Complicated regulation	Needs additional features to look and feel like a rib cage

Figure 5.1: Morphology of compression mechanism

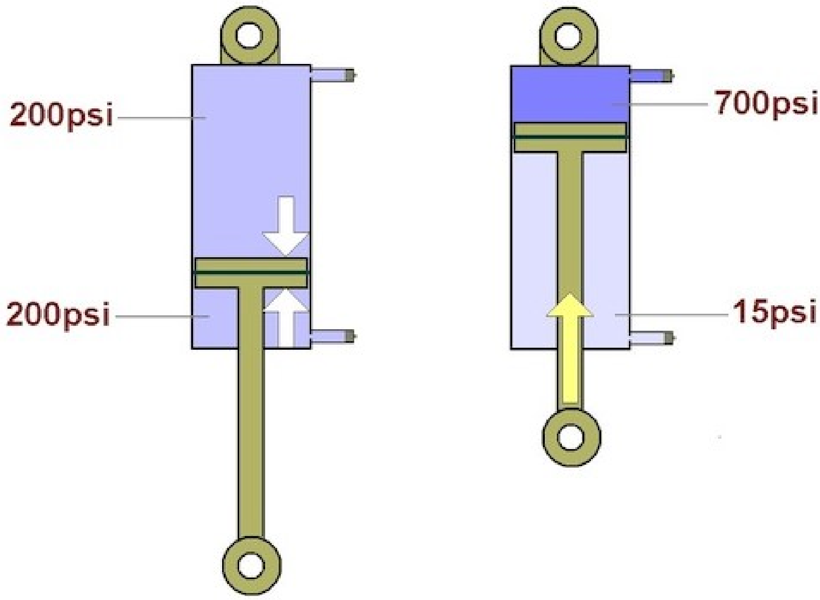


Figure 5.2: Schematics of the air spring [8]

The ideal gas law can be used to verify the working principle and provides information about the air spring's characteristics:

$$PV = nRT \tag{5.1}$$

where:

P - is the pressure of the gas

V - is the volume of the gas

n - is the amount of substance of gas

R - is the gas constant

T - is the absolute temperature of the gas

The objective is to identify the relationship between the force generated by the spring and the displacement of the piston. The force, F, generated by the spring is given by:

$$F = P * A \tag{5.2}$$

where:

P - is the pressure in the pressure chamber

A - is the area of the piston head

In the air spring, the volume of the pressure chamber varies, thus n, R and T remain approximately constant. This gives the equation:

$$P = \frac{nRT}{V} = \frac{c}{V} \tag{5.3}$$

As the piston starts its movement into the cylinder, the change in volume becomes:

$$V = V_i * (1 - \frac{x}{L}) \tag{5.4}$$

where:

V - is the volume of the pressure chamber

V_i - is the initial volume of the pressure chamber

x - is the displacement of the piston

L - is the internal length of the pressure chamber

Hence, the force generated by the spring depends on x:

$$F = \frac{nRT}{V_i * (1 - \frac{x}{L})} * A \tag{5.5}$$

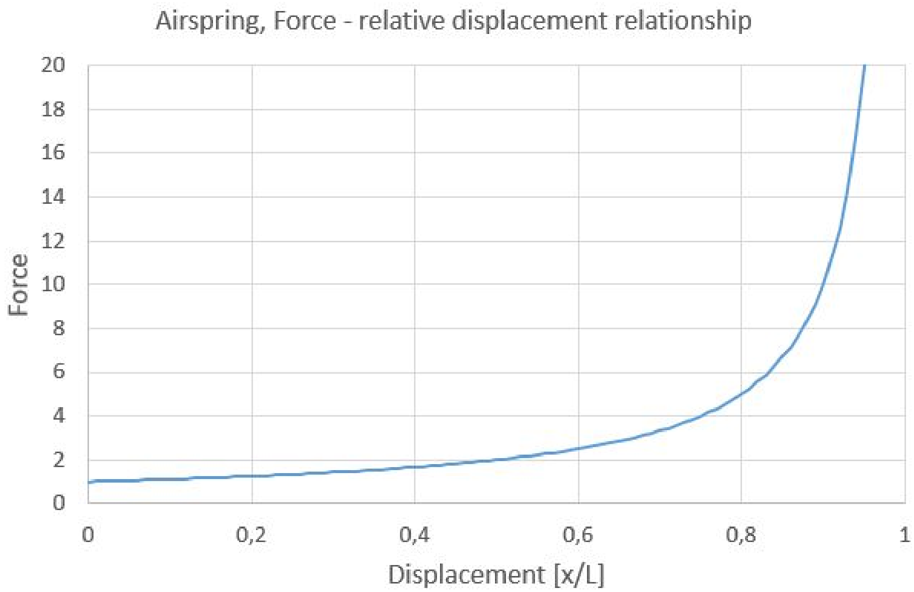


Figure 5.3: Air spring characteristics

By setting all variables to 1 and plotting x from 0 towards L, we get the characteristics of an air spring as shown in Figure 5.3. The plot shows a vertical asymptote at $x = L$.

This characteristic is verified through curves published by the suspension company FOX Factory Inc. as shown in Figure 5.4 [9].

The higher curves have smaller pressure chambers, which makes the characteristic more progressive at the end of the stroke.

According to one of the product requirements, the spring must achieve a force between 6 kg to 10 kg at a chest compression depth $\frac{1}{3}$ of the chest height. I start by checking the pressure applicable to air springs used in bikes. Bike air springs have an initial pressure in the range of 60-130 psi [27], and at a full stroke reach levels at a minimum of 400 psi. With a max pressure at 400 psi $\approx$ 2.76 MPa and a max force generated to be 10kg $\approx$ 100N, I can calculate the radius of the piston head:

$$F = P * A = 100N = 2.76MPa * A \tag{5.6}$$

$$A = \pi r^2 \tag{5.7}$$

$$r = \sqrt{\frac{100N}{2.76MPa * \pi}} = 3.4mm \tag{5.8}$$

Thus, the internal diameter must be $\approx$ 7mm and the outer diameter at a minimum of 10mm. The existing coil spring has a diameter of 20mm, hence the spring diameter is reduced by 50%.

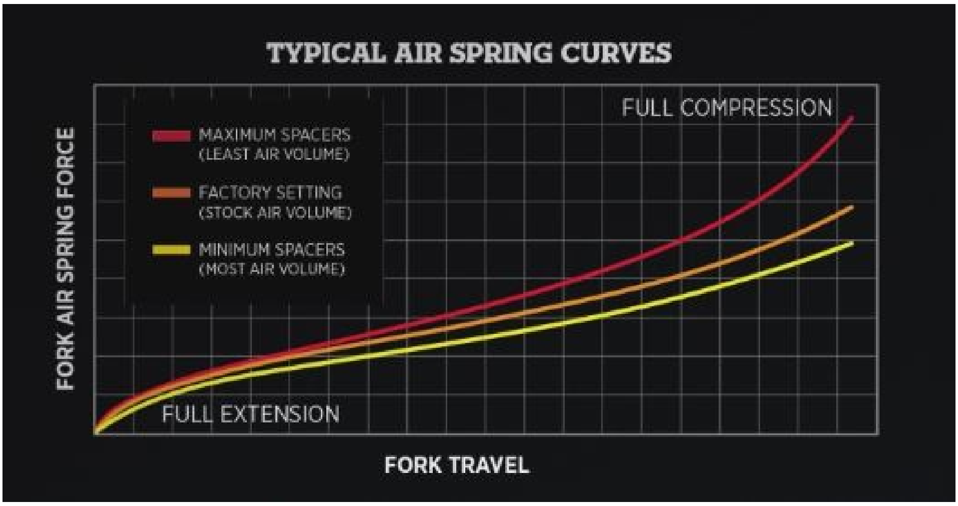


Figure 5.4: Fox air spring characteristics with varying pressure chamber lengths [9]

Furthermore, when I estimated the maximum compression depth possible to achieve with this concept, the travelling of the piston was set to be 90% of the pressure chamber's length. By placing the air spring vertical in the manikin, the air spring had to be at least double the height of the compression depth. In addition, there must be room for a damper when the spring is fully extracted. The damper, which slows down the motion gently while the chest is moving upwards, could be a piece of foam or another pressure chamber as shown in Figure 5.2 [8]. Figure 5.5 illustrates the air spring's required elements. An estimate of the elements height is given in Table 5.1. I used a basis with total chest height of $10cm$. The possible compression depth is given by:

$$10cm = 2 * \text{Compression depth} + \text{Height of elements in manikin} \tag{5.9}$$

This gives a possible compression depth of:

$$\text{Compression depth} = \frac{10cm - \text{Height of elements in manikin}}{2} = \frac{10cm - 2.4cm}{2} = 3.8cm \tag{5.10}$$

When treating real patients, the compression depth is advised to be $\frac{1}{3}$ of the chest depth, according to the European Resuscitation Council [25]. Therefore, this training manikin must have the same qualities, meaning that the piston must be able to travel $\frac{1}{3}$ of the chest depth. The infant manikin's chest depth is 10 cm. To use some of the more progressive part of the curve, I want the piston to travel from $\frac{x}{L} = 0$ to $\frac{x}{L} = 0.9$ to reach the desired 10 kg force. As $\frac{x}{L} = 0.9$ would make the piston's travel to be $x = 3cm$, the total length of the internal pressure chamber would be $L = \frac{3cm}{0.9} = 3.33cm$. In practice, this means that the force applied for compression after 3 cm , will not give a significantly deeper compression depth. Consequently, it is more useful to give feedback on compression force applied, rather than compression depth if the user compresses the manikin too hard.

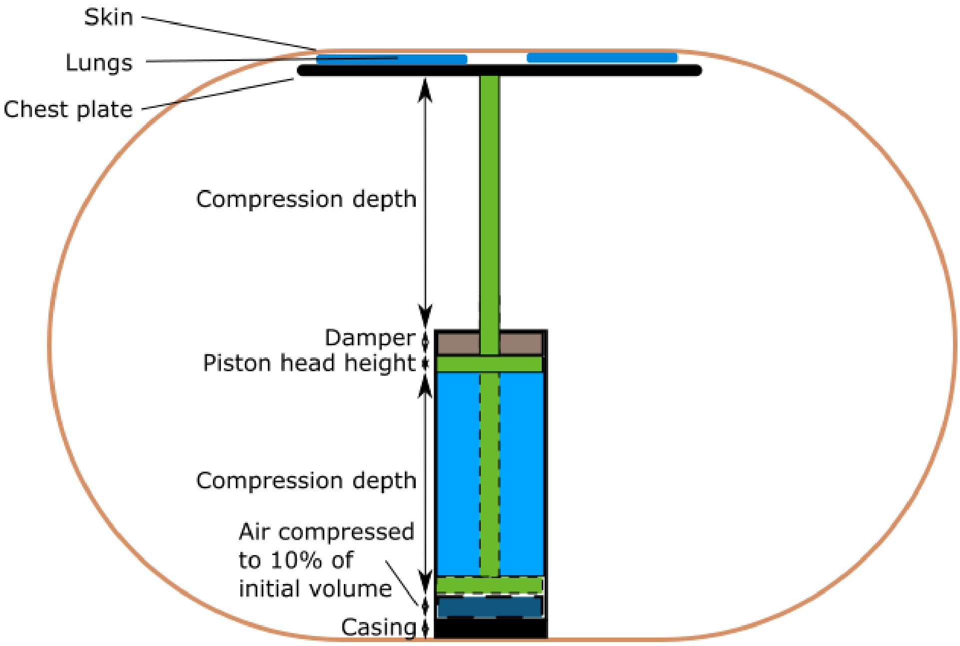


Figure 5.5

The asymptotic behaviour of an air spring seems to be similar to the data obtained from measurements on real patients as illustrated in Figure 3.4. Moreover, the data shows great variance. Variable stiffness in the manikin can be achieved by adjusting the initial air pressure. It is also possible to adjust spring characteristics, as shown in Figure 5.4, by adjusting the internal length of the pressure chamber. The risk of using air springs will also be quite low as the technology is well tested in other applications. However, possible issues of scaling the technology to manikin usage, represents the biggest uncertainty with this solution. As for the users' experience, air springs seem like a good alternative.The key challenge with the current solution to implement an advanced airway system, is the lack of space. The spring's diameter could be reduced by 50%, however, its placement would collide with the advanced airway system's placement. Nevertheless, as the diameter of the air springs required is reduced, it would be possible to place one air spring on each side of the advanced airway.

5.1.2 Coil spring

Contemporary compression mechanisms use a coil spring. In my pre-master, I have suggested how an advanced airway could be implemented while still using a coil spring. However, a coil spring is highly space consuming and thus problematic to use. Still, I came across a highly interesting alternative called "Smalley Wave Spring" [10]. These springs reduce the spring height by 50% compared to coil springs as shown in Figure 5.6. By placing such a spring in the upper part of the manikin, more room is available for the advanced

Table 5.1: Height of elements in air spring manikin

Element	Height [mm]
Skin	3
Lungs	2
Chest plate	5
Damper	3
Piston head height	3
Air compressed to 10% of initial volume	3
Casing of pressure chamber and lower skin	5
Total height of elements	24

airway. This spring's characteristic is linear, as the coil spring, which does not improve the manikin's realism, but it enables the implementation of advanced airway.

5.2 Force regulated linear actuator

During the exploration phase, force regulated linear actuators were studied. Force regulated actuators functioning as springs are interesting because by using these, it is possible to decouple the displacement of the spring and the force generated by the spring. This allows me to apply any desired spring characteristics, and consequently to match the spring's characteristics, to any chest stiffness measured on patients. Such characteristics are shown in Figure 3.4. In a simulation setting, students could thus practice with different chest stiffness characteristics on the same manikin. A good chest compression is determined by the depth of the compression, not the force applied. Therefore, as some patients of the same size have different chest stiffness, students should be trained to compress a certain depth and not a certain force.

Furthermore, by controlling the force working in the spring at any given time or displacement, a sudden drop in the force, which is the nature of broken ribs, would be possible. Breaking of ribs are very common during chest compressions and could be simulated during training.

A linear actuator is any device that creates motion in a straight line. To be force regulated, it must be possible to relocate the movable part of the mechanism by a certain force. The force required to relocate the movable part can be determined by the position. A version of a linear actuator is presented in Figure 5.7. Importantly though, the motion of a linear actuator is not limited to being driven by an electric motor. It could also be possible to regulate the air pressure of an air spring, or control a hydraulic piston.

5.2.1 First model - servo motor

To find out how a force regulated actuator functions I decided to build one. The only goal of the first model was to have a working actuator, which allows displacement of the object

Figure 5.6: Smalley wave spring in the front, compared to a traditional coil spring [10]

controlled when a predefined force is applied to it.

To make the model as rapid as possible, I made it simple and coarse.This was a prototype to learn from, in accordance with the chosen development strategy [28]. A rotational servo motor replaced the linear actuator. To obtain the force applied, a force sensitive resistor (FSR) was used, and to control the movement, an Arduino UNO board was used. I used a kit called MakeBlock to build the physical part. The FSR was placed on a arm attached to the servo. As the force obtained by the FSR exceeded a predefined load, the servo should allow rotation. To make it function as a spring, the predefined load should increase, as the displacement increased. The servo is controlled by choosing an angle the servo moves to. Consequently, the operational range from 0° to 180° is divided into 180 steps. If the force applied to FSR exceeds the threshold force, the servos control system guides the rotation to the next angle-step, which makes the movement uneven. A smooth movement could be achieved by inserting a damper between the force source: the hand compressing and the FSR. A better alternative is to directly control the DC motor in the servo, which will be presented in the second model.

5.2.2 Second model - controlling the DC motor directly

The first model revealed that the servo's motion was uneven. The embedded system of the servo, which actually controls the motor into certain steps, causes this irregularity. To

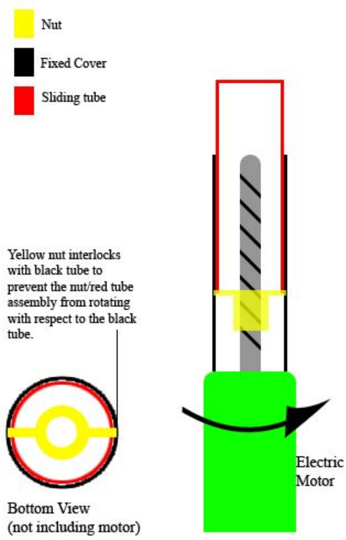


Figure 5.7: A linear actuator [11]

remove the step-wise controlling, I needed to control the DC motor more directly. Firstly, I started to analyse the system that had to be controlled. The DC motor should apply a larger force as the object controlled increases its displacement from an initial position. Therefore, the displacement must be known for the control system. Consequently, I need a closed-loop control system. The schematics of a closed -loop control system is illustrated in Figure 5.9. The working principle is that an error value , e, is continuously calculated, which is the difference between a desired set-point, r and a measured value, y. A correction is applied to the process based on the error value [12]. The set-point of a linear actuator inside a manikin will always be at the chest height of a non-compressed chest. As the chest is compressed the error value increases.

To test a closed-loop control system in practice, I used a motorised linear potentiometer [29]. A motorised linear potentiometer consists of a sled that can move back and forth, activated by a small DC motor. The position of the sled, y, is obtained by a linear potentiometer. The reference value, r, was placed at the very left as shown in Figure 5.10a. The control system, $C(s)$ gives a signal, u to a PWM pin on the Arduino board, telling the DC motor to move the sled towards the left. As addressed earlier, by using linear actuators, it is possible to apply any spring characteristic to the compression mechanism; a key advantage. The first controller, $C(s)$, gave a proportional relationship between e and u. I also tried to make the relationship between displacement, e, and the force, u, progressive by making the controller, $C(s)$, relate the square of the error, e, and the output power, u, proportional. The code to this is shown in appendix A. I tested the system by moving the sled with my fingers, and this verified that the force applied from the sled to my fingers increased as I moved the sled towards the right. This is illustrated in Figure 5.10, by pulling the sled with a spring. The spring is actually a bit stretched in Figure 5.10b. As the DC motor in the model is rather small and weak, the effect is not easily visible. From my

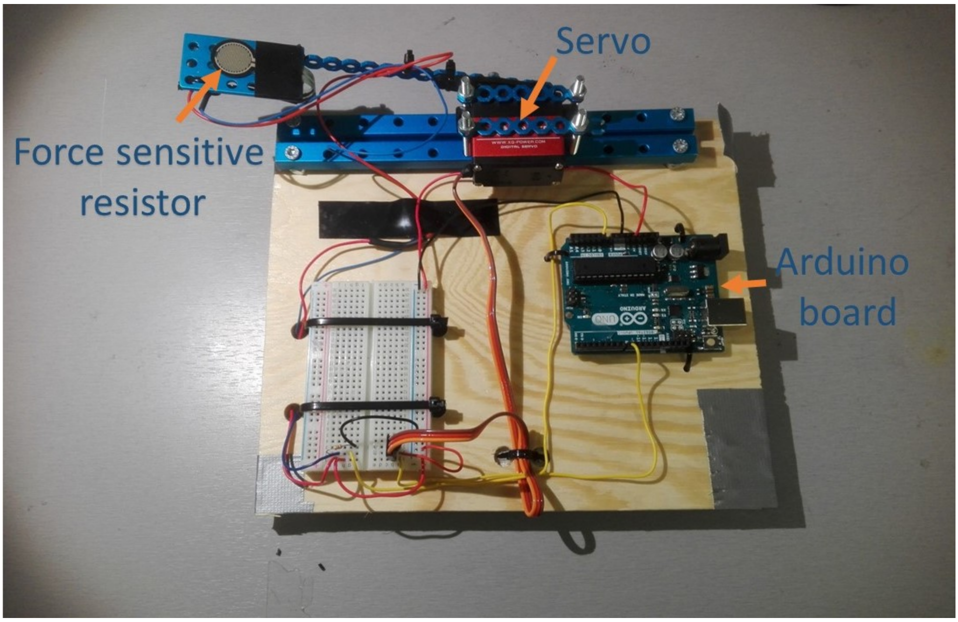


Figure 5.8: First force regulated actuator

understanding, it should be possible to scale this mechanism to work as the main source of deflection in a CPR training manikin.

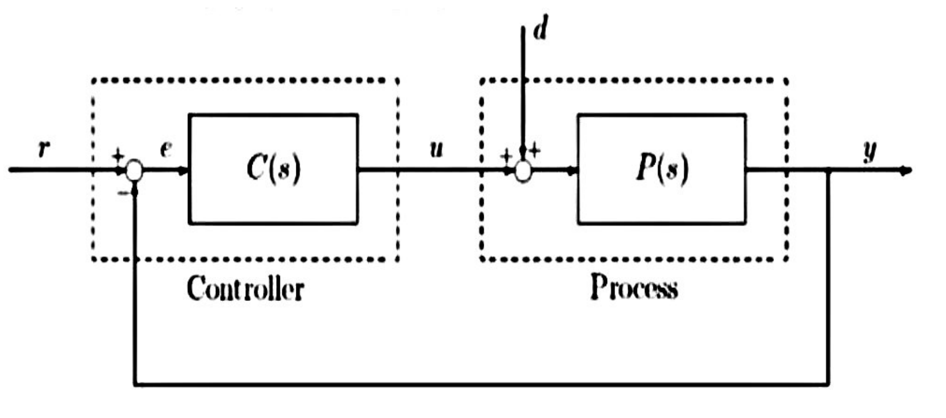
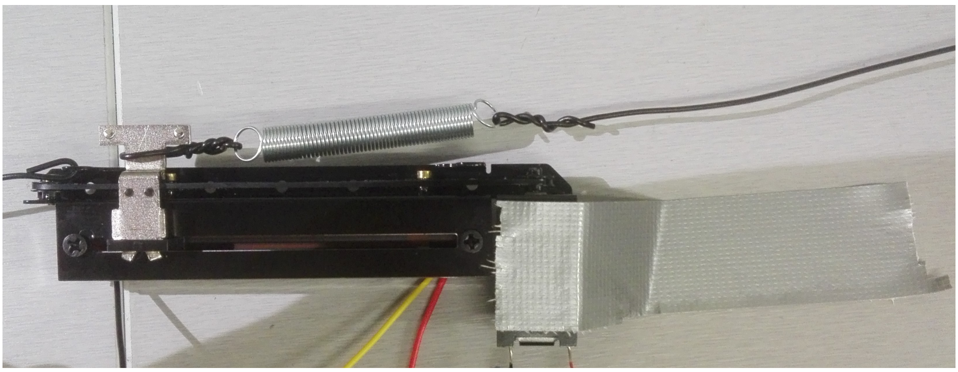
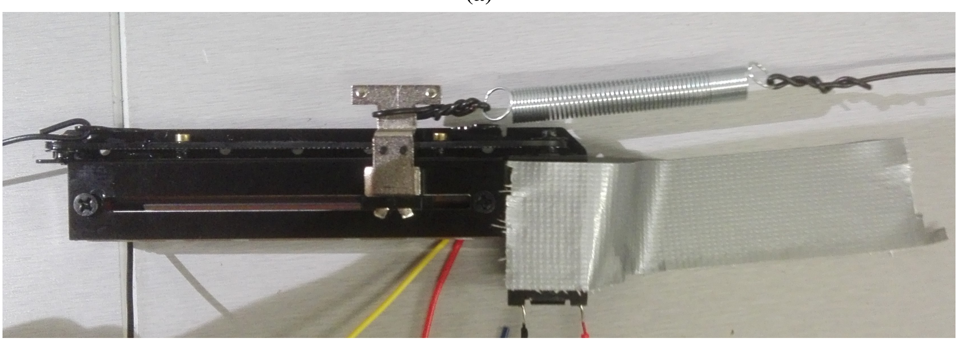


Figure 5.9: Closed-loop control system [12]



(a)



(b)

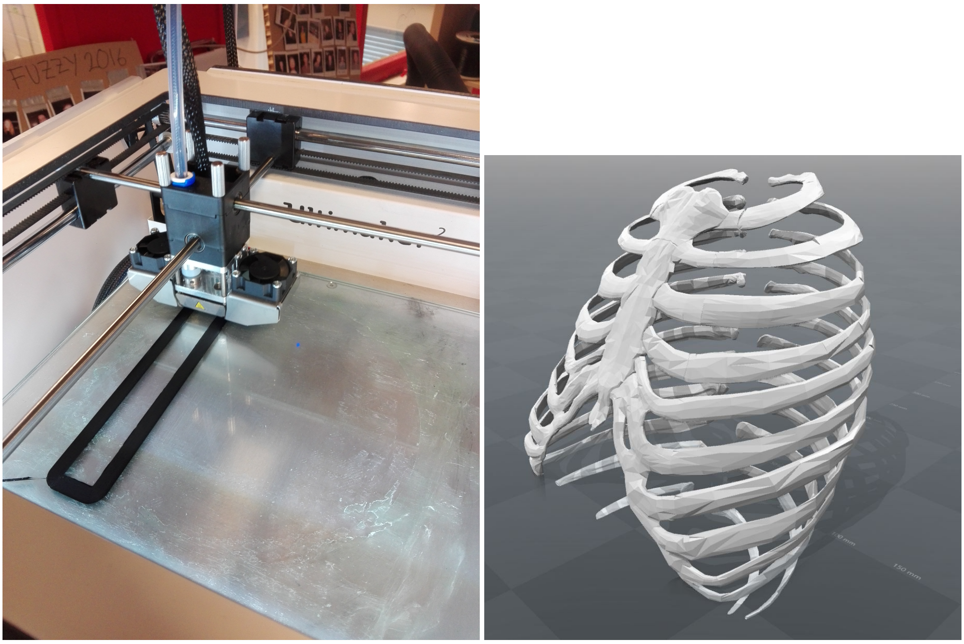
Figure 5.10: Motorised linear potentiometer

5.3 Development of flexible rib cage structure

During this phase of the project I applied rapid prototyping and testing. This approach is inspired by the spiral model for software development proposed by Boehm [30]. The spiral model states that a development process consists of several iterations, and each iteration consists of several basic activities. Throughout this phase, I have utilised these activities: design, build, test and evaluate. The test results decided how I should proceed. Consequently, the improved knowledge could contribute to a new design. This new design could be an incremental improvement of the existing design. Hence, the design will be refined and would lead towards a final product. If the test results are poor, the whole concept could be changed. In this case, to rethink the problem and apply divergent thinking, can contribute to new or additional ideas. Furthermore, these new ideas will be refined through convergent thinking and prototyping. This is illustrated well by Gerstenberg et al. in the article "A Simultaneous, Multidisciplinary Development and Design Journey–Reflections on Prototyping" [28]. Gerstenberg et al. also emphasise the value of using prototypes, called probing ideas. According to Gerstenberg et al., it is possible to create knowledge that is impossible to accurately anticipate regardless of our expectations, by building and testing prototypes [28].

5.3.1 First iteration - Rib Bone model

While trying to make the manikin more realistic, I figured that I wanted to make a flexible rib cage structure. Up until now, the compression mechanism had been a separated part of the manikin. However, now I wanted to investigate if it was possible to integrate the compression mechanism with the anatomic outer of the manikin. To verify that this integrated mechanism would function as expected and required, the material had to be flexible for compression, but also stiff enough to come back to the chests original shape. From the start, spring steel was detected as a too stiff material, but polymer could work. To get a staring point of the rib cage geometry, I found a a .obj file at CadNac.com, shown in Figure 5.11b. At this stage, any indication of the working principle was needed. Using 3D printing is a quick way to get a model of something physical. Thus, since I thought polymer was the adequate material, I wanted to use the 3D printer. To get familiar with the 3D printer, the first piece printed was a simple block with dimensions 2 mm x 15 mm x 150 mm, printed in the material polyactide (PLA). Even with a thickness of 2 mm, the flexibility was much less than expected. I also tested to print with the more flexible material Acrylonitrile Butadiene Styrene (ABS). The ABS material has a higher thermal expansion coefficient than PLA. Therefore, the printed part started warping during the printing process. The warping occurred already at the first layer of printing and the part detached from the printing plate. Thus it was impossible to get finished parts of the dimensions specified in ABS. In 3D printing scale, the length of 150 mm probably caused the warping. Uneven cooling of a material with a high shrinkage percent, such as AB, at large dimensions often results in warping and internal stress. Due to a thin part printed, the stress lead to deformations rather than internal stress. Ideally, the printer should be enclosed, and the air inside the printer should be closer to the printing temperature. That would result in slower and more even cooling, giving less internal stress and deformations. Printing parameters as nozzle temperature, base plate temperature and printing speed were adjusted, but the warping still occurred with the ABS. Thus, it seemed unproductive to continue printing flexible materials. Moreover, other techniques should be explored. It also seemed like there was a need for a much more flexible material with the given geometry. Thus, I wanted to make some changes to the geometry.



(a) First 3D print with the Ultimaker **(b)** 3D model of rib cage [31]

Figure 5.11

5.3.2 Second iteration - Thin plastic sheet with sternum

The hands-on mentality had revealed a need for a thinner flexible structure and a more flexible material. With this knowledge, I could make a better design. The new idea was to make a simple shell of a thin plastic sheet shaped as the outer part of the chest. The sketch for the new design is presented in Figure 5.12. The two hinges in the sketch is meant to function as the more flexible cartilage structure. The stiff part in the middle is meant to represent the sternum.

At the first iteration, the prototype is very coarse. Some key features are addressed to confirm whether it functions or not. The sketch in Figure 5.12 was built to reveal the actual deformation shape and stiffness. To make the first prototype, a PolyMethylMethAcrylate/acrylic (PMMA) plastics plate was thermoformed by heating the material to the glass transition temperature and bending it around a template as shown in Figure 5.13a.

I discovered a possible production process while making the prototype. This hands-on approach is in accordance with the product development approach described by Gerstenberg et al. [28]. The compression mechanism was tested as shown in figure Figure 5.14.

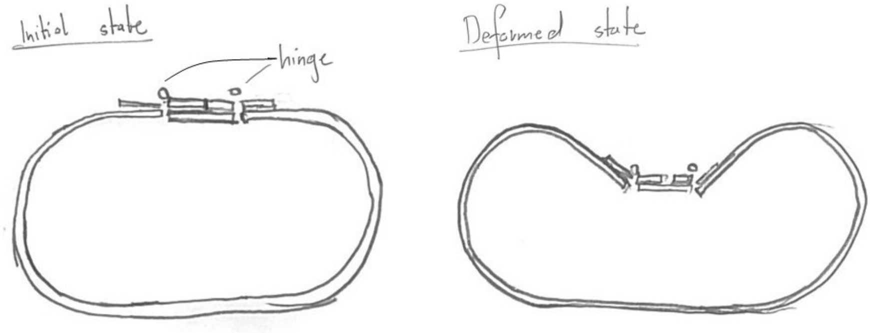
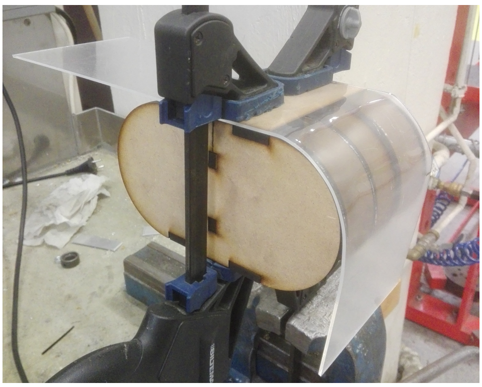
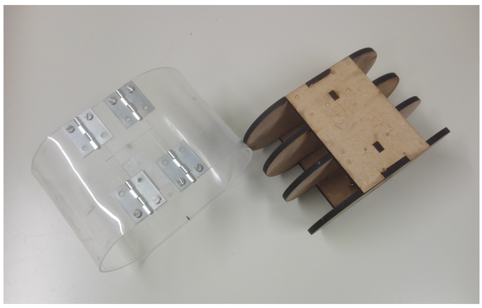


Figure 5.12: First shell sketch



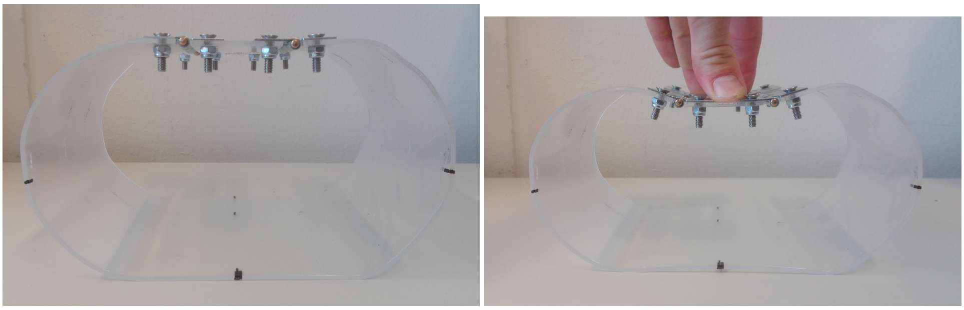
(a)



(b)

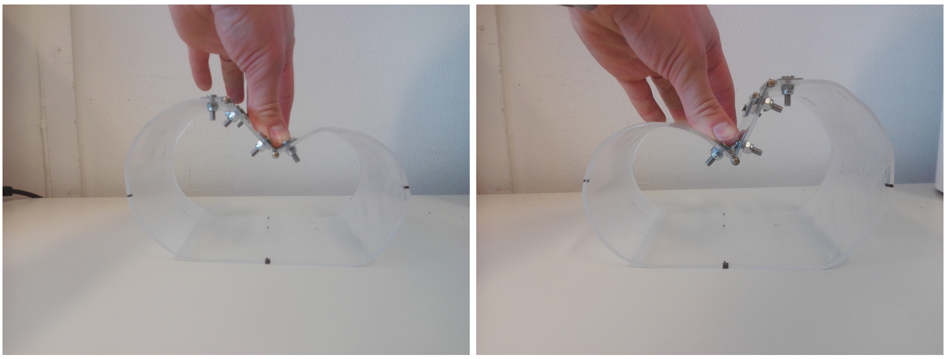
Figure 5.13: Production of PMMA prototype

The testing of this prototype revealed that PMMA is a material with some flexibility, but has a brittle fracture mode. That means, deflection in the elastic area can be repeated multiple times, but as soon as the elastic deformation is exceeded, a brittle fracture will occur. The typical scenario for breaking the structure would be if a user tries to compress the manikin too hard. As these manikins are used for teaching, such a scenario will likely happen several times during the manikin's lifetime. To avoid fracture, compression deeper than what the material can handle must be stopped by some geometrical constraint. Further evaluation revealed that it is easier to compress the chest in the hinge area than at the chest bone. This deformation shape happened as soon as the hand placement was a cm offset from the centre. The deformation shape is shown in Figure 5.15



(a) (b)

Figure 5.14: Intended usage of PMMA model



(a) (b)

Figure 5.15: Deformation mode of PMMA model when compression offset of centre

5.3.3 Third iteration - Thin sheet with one hinge

From testing the current prototype, a new design with only one hinge was designed. The hypothesis for the one hinge prototype was to remove the unstable deformation of the current prototype. The sketch for this design is shown in Figure 5.16

As the current prototype was made of a stiff and brittle material, I found a material which was both softer and had a larger elastic deformation range; High Impact polystyrene (HIPS). HIPS is a non-crystalline thermoplastic with relatively low glass transition temperature (85°C). Due to its low glass transition temperature, it is easy to form it around a template by using a heat gun.

Testing of the HIPS prototype revealed a very sharp angle at the hinge. As a quick fix, I tried to cover up the sharp edge by attaching a sheet of fabric, and placing a plastic piece representing the sternum to see if it would improve the model. This is shown in Figure 5.18a. However, It did not cover up the sharp edge at the hinge sufficiently. By coincidence, I realised that the deformation mode improved significantly by turning the model upside down without any hinge at the compression spot (see Figure 5.18b). This is

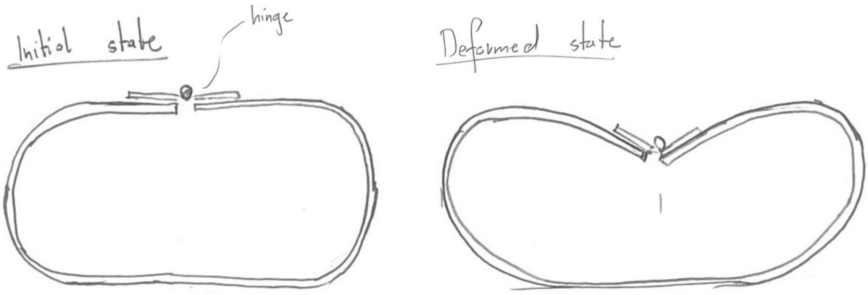


Figure 5.16: Sketch of thin sheet model with one hinge

(a) **(b)**

Figure 5.17: Thin sheet model with one hinge

an example of gaining knowledge through prototyping that is impossible to anticipate as addressed by Gerstenberg [28].

5.3.4 Fourth iteration - Thin sheet without hinges

Consequently, as the main flaws with the design were addressed and solved, I could start to refine the process of the concept. The sketch of the fourth iteration is illustrated in Figure 5.19.

5.3.5 Fifth iteration - trying to make the spring characteristic progressive

A goal in this project has been to match the spring characteristic of the manikin chest with the progressive chest characteristic of patients [7]. Some coarse prototypes have been

(a) (b)

Figure 5.18

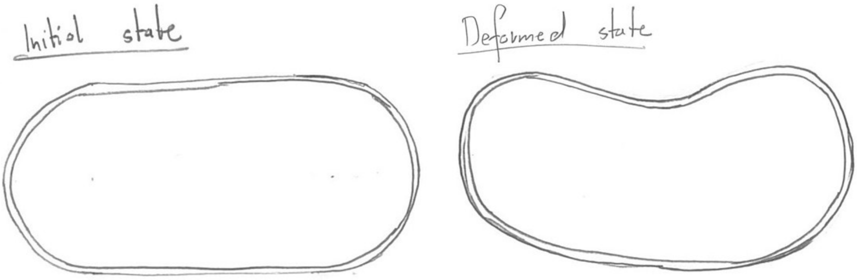


Figure 5.19

tested to get knowledge of some suggested concepts.

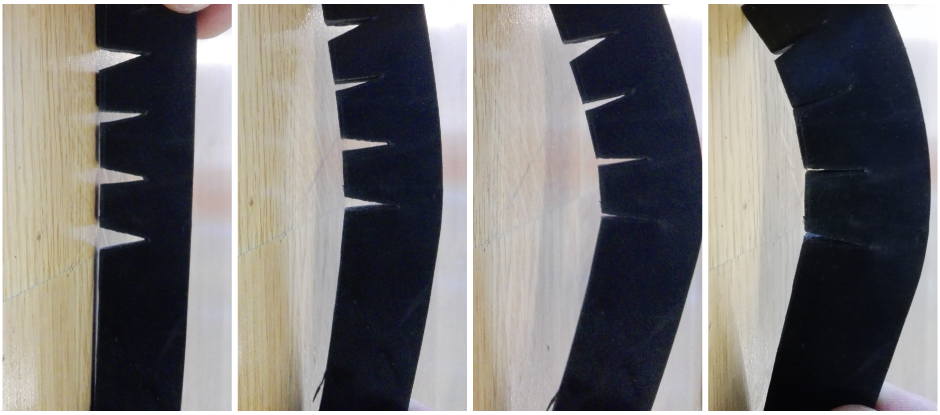
An initial idea was to obtain a progressive characteristic by using the geometry as shown in Figure 5.20. The idea is that the stiffness increases as the curvature increases because more of the V-gaps closes.

The concept was inserted in the current iteration of the compression mechanism as shown in Figure 5.21. The material used is natural rubber, which turned out to be too soft to affect the stiffness of the model.

The same principle was tested by inserting PLA printed parts as shown in Figure 5.22. This solution was more promising, but was not tested in full scale, due to difficulties with attaching the PLA parts to the rest of the compression mechanism. High precision manufacturing is required to do valuable testing. In the case of making a model for testing, the whole concept must be made out of one part.

Testing various material options

To test other types of materials, I contacted Unica AS. This company specialises in vacuum-forming, milling and bending of plastic parts. They recommended me three types of flex-



(a) **(b)** **(c)** **(d)**

Figure 5.20

ible materials which they could provide material tests of. These materials were polycarbonate (PC), Acrylonitrile Butadiene Styrene (ABS) and polyethylene terephthalate glycol-modified (PETG).

Furthermore, backpack buckles also inspired me. These are also designed to apply the flexibility of the plastic. Helsport As, a Norwegian outdoor equipment brand, provided information about how they choose plastic components. They used Nylon in a range of applications, but for components which shall withstand large forces, often in cold conditions, acetal/polyoxymetylen (POM) was their preferred alternative. Therefore, I investigated what processing methods which are available for POM.

Processing of POM

Regarding processing, POM is a versatile material which can be formed by blow-moulding, extrusion and injection moulding [1], where injection moulding is most commonly used. Mould shrinkage is typically in the range of 1.9% to 2.3%, which is quite high and makes the mould design complicated [13]. POM has excellent properties for machining processes such as milling and turning, which allows for high cutting speed without coolants. Thermoforming, as used earlier to make prototypes, will not be possible with POM due to a highly crystalline molecular structure. The highly crystalline structure explains why the material has a defined melting point. At this melting point, the material turns abruptly from solid to liquid. The thermoforming process requires that the material has a temperature range from solid state to liquid, where the material is soft and formable.

Moulding and machining are therefore the available alternatives for making a prototype out of POM. However, making a mould is both time-consuming and expensive. As the shrinkage of POM in the mould is 2%, the mould design will be complicated, also, I have little knowledge about mould design, and therefore a moulded prototype will give little insight relative to the effort needed. The handover between 3D-models and injection moulding is a known problem as the moulds are expensive. Considerable effort is

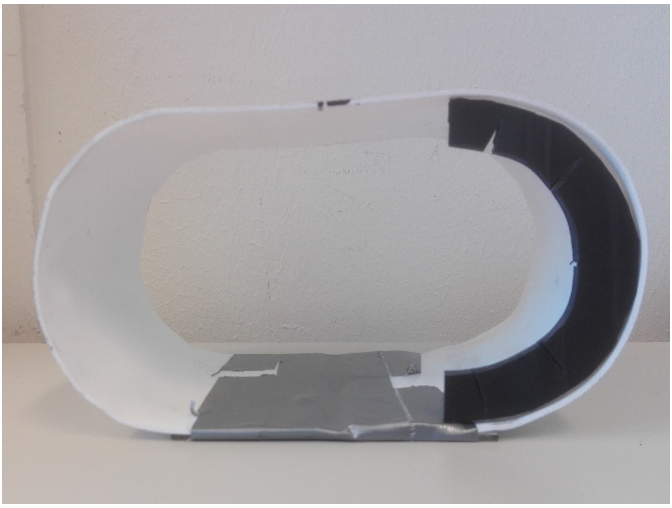


Figure 5.21

made to improve the handover from 3D-models to injection moulding at NTNU. The master thesis of Oystein Bjelland investigated techniques for low-volume injection moulding production. Primarily results showed limited similarity in terms of mechanical properties between parts produced by low-volume injection moulding techniques and parts produced by high-volume injection moulding techniques [32].

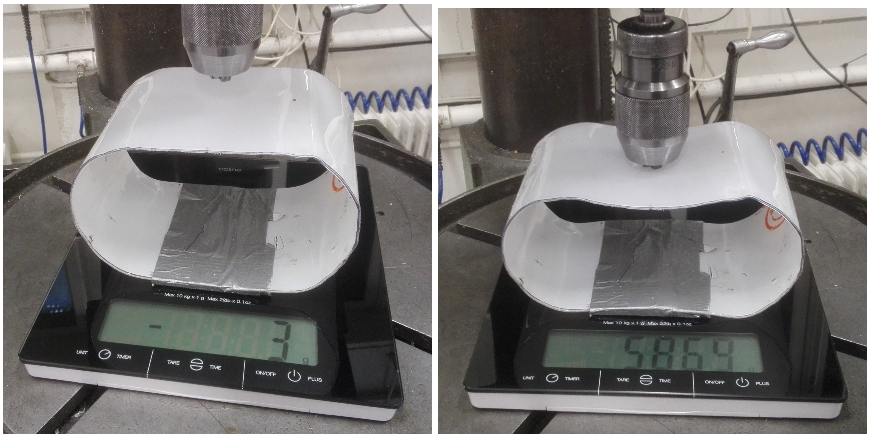
I also considered processing by milling. The smallest POM plate, with a thickness at a minimum of 100 mm, available to order in Norway, was a 100 mm x 1000 mm x 2000 mm plate [33]. With a price of 30NOK/kg [1], and a weight of $1,49 * 10^3$kg/m^3 $*$ 0.1m*1m*2m=298kg, the total price for such a plate would be about 9000 NOK [1]. The wall thickness of a POM model will resemble the model made in PMMA as both have a Youngs Modulus in the range 2.5 - 3.5 MPa [1]. The wall thickness of the PMMA model is 2 mm. Machining of such thin walls with a height of up to 120 mm, involves risking much vibration and the walls will be prone to fracture. Making a prototype of POM by machining was considered not be worth the effort, due to high costs both in effort and money, combined with a considerable chance of failure. POM could be the correct material for a serial production, but at this stage there was not enough knowledge base to defend such an investment required for physical testing. To gain more insight of the behaviour of POM, I later performed structural analysis of the geometry by the Finite Element Method (FEM). Also, the materials provided by Unica AS, has rather similar mechanical behaviour as POM. Therefore, the initial testing was done by the four materials provided so far : HIPS, PC, ABS and PETG.

As Unica uses the provided material for vacuum-forming, they are also easily thermoformable with a heat gun. One model of each material was made. So far, the evaluation of the models has been based on appearance, as the flaws have been obvious. Now, while evaluating different materials, the differences between each model were not that obvious anymore and I needed to evaluate the models quantitatively. A very simple and coarse test

(a) **(b)**

Figure 5.22

was performed for each model. The test investigated the relationship between deflection and force applied. This was done by placing the model to be tested on a scale and applying a certain deflection at the centre of the model. Raw data can be found in appendix B.



(a) **(b)**

Figure 5.23

The tested models are 10 cm. Thus, $\frac{1}{3}$ of the chest depth is 33mm. According to the requirements, the force required to compress at that depth should require a force in the range of 6kg to 10kg. As seen in Figure 5.24, PC and PETG are the materials that satisfy the requirements. Therefore, these materials were studied further. After much testing, the HIPS model seemed to have got a plastic deflection. As none of the other materials had got any plastic deformation with similar testing, HIPS is considered to be an unsuitable material. The ABS model did not satisfy the stiffness requirement, but could be applicable if the dimensions of the model is adjusted to increase the stiffness.

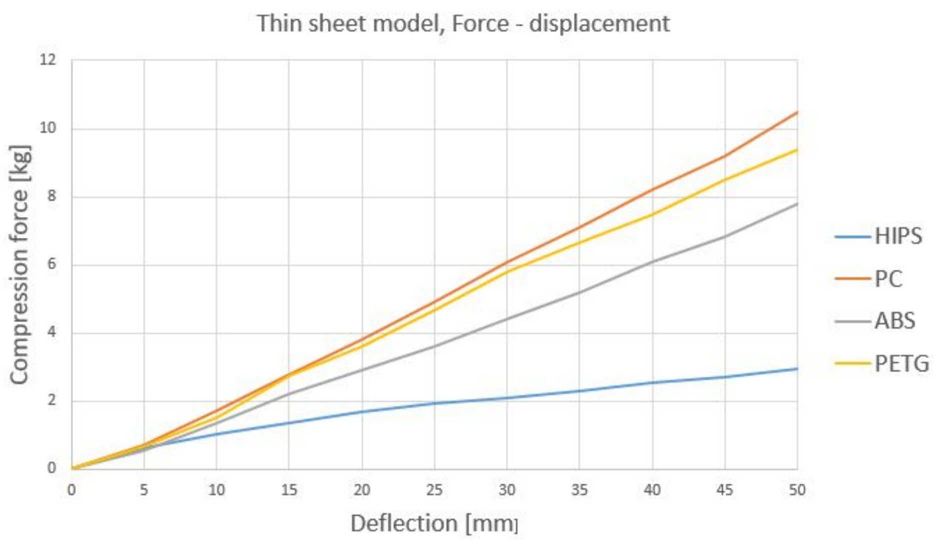


Figure 5.24: Test results from thin sheet model with various materials

5.4 Knowledge based material choosing

Continuing, as a promising geometry was designed, I could look more into material knowledge and take more knowledge based material choices. The spring material is required to deflect a minimum of $\frac{1}{3}$ of the chest depth, handle compressions at a rate of $100\frac{repetitions}{minute}$ and have a lifetime of at least 100 000 compressions. So far, tests have showed that ABS, PC and PETG can satisfy the requirement of deflecting $\frac{1}{3}$ of the chest depth. POM, which has similar stiffness as the provided test materials, is also considered as an applicable material. The following section provides more detailed knowledge of each of the tested materials. The main concern about using polymers as spring elements is its fatigue-resistance. Therefore, literature about the polymer materials' fatigue properties will be presented after presenting definitions of material terms.

Definitions of material terms

Impact resistance - the ability of a material to absorb energy in case of an impact

Thoughness - the ability of a material to absorb energy and plastically deform without fracturing

Isochronous - Stress- strain curves which the test is performed at a certain time. This is relevant for polymers as the behaviour is time dependent.

Maximum stress - σ_{max} Maximum stress during cyclic fatigue testing

Minimum stress - σ_{min} Minimum stress during cyclic fatigue testing

Stress ratio - $R = \sigma_{min}/\sigma_{max}$ Relationship between maximum and minimum stress

Mean stress - $\sigma_m = (\sigma_{max} + \sigma_{min})/2$

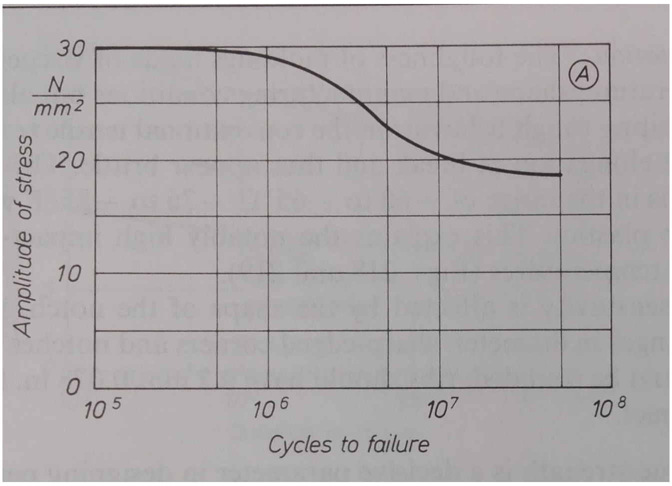
Stress range - $\Delta\sigma = \sigma_{max} - \sigma_{min}$

Stress amplitude - $\sigma_a = \Delta\sigma/2$

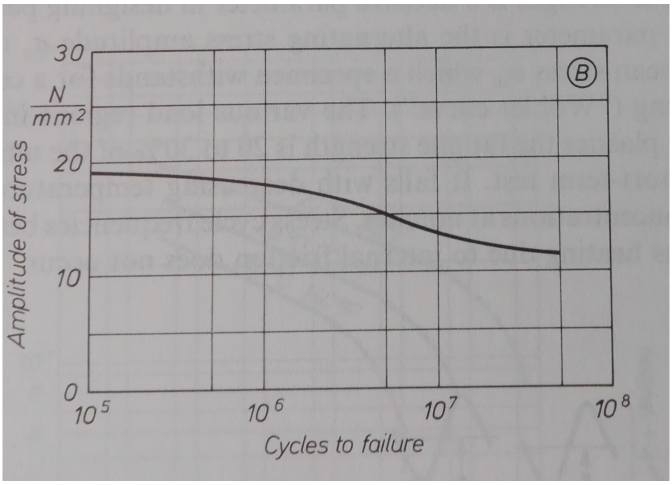
Fatigue limit, σ_{fat} - The stress amplitude of cyclic stress that can be applied to the material without causing fatigue failure. For materials without a distinct fatigue limit, 10^7 cycles are used to represent the fatigue limit.

POM

POM is one of the classic engineering thermoplastics with improved properties compared to commodity plastics as PE, PP and PS, and is competing with nylon (PA6 and PA66). POM is listed as one of the materials with good fatigue resistance [1]. SN curves for an injection moulded grade of acetal copolymer is provided in Figure 5.25. As there exist numerous variations of each polymer, a definite choice of finding the right one, is a huge challenge. Using literature to provide information about material properties can be confusing, as the properties a polymer can have a huge range. The variations of the properties depended on production method, and the parameters used with that particular production method. Furthermore, there is a range of different grades of each polymer and other polymers are commonly mixed with the base polymer, making a copolymer. Also, many polymers are reinforced with various fibres. The literature reviewed often tends to provide imprecise information of exactly composition of the polymer discussed, and different sources provide different material property ranges. Consequently, the information on material properties is approximate. However, literature review can be used to see differences among materials, and exclude the materials which obviously are not applicable.



(a)



(b)

Figure 5.25: Fatigue curves for an injection moulding grade of acetal copolymer. A, alternating compression/tension (R=-1). B, pulsating tensile stress , (R=0) [13]

A consideration about using POM is its poor UV resistance, but this can be stabilised with carbon black- meaning that black parts are necessary for outdoor usage [1]. The typical usage of the manikin will be indoor, and the compression mechanism will be covered by a skin, so this is not a relevant concern for this product.

Acrylonitrile Butadiene Styrene (ABS)

ABS is a thermoplastic with high impact resistance. It means that the material can absorb much energy and deform considerably, without fracturing. Unfortunately, the fatigue resistance of the material is relatively low. The fatigue curve of various ABS grades are provided in Figure 5.26 [13].

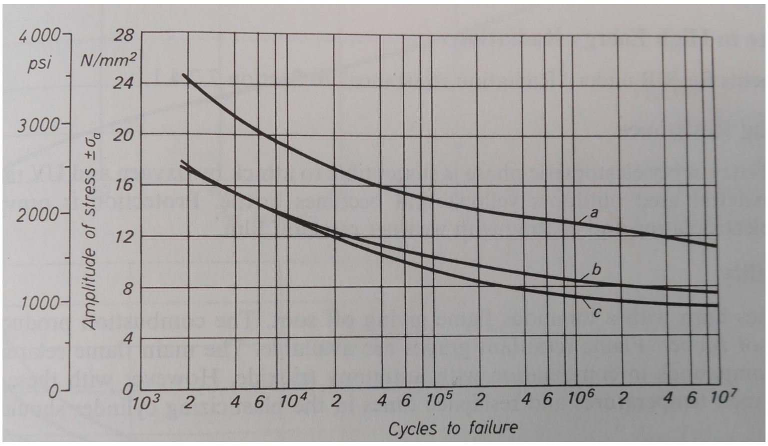


Figure 5.26: Fatigue limit of various ABS grades subject to tensile fatigue stress. a-Novodur PH-GV $\sigma_{fat} = 11.2N/mm^2$, b-Novadur PH-AT $\sigma_{fat} = 7.5N/mm^2$, c-Novadur PMT $\sigma_{fat} = 6.7N/mm^2$ [13]

The stress-strain relationship at various temperatures is described in Figure 5.27 and the temperature dependence of the E-modulus is shown in Figure 5.28. If other material properties are desired, many variations of ABS have been developed to achieve certain engineering properties. Blends of ABS and other thermoplastics, such as polyamide, polycarbonate and polyvinyl chloride, are some examples. These blends improve engineering properties such as toughness and heat-resistance. To increase the stiffness, ABS can be reinforced with fibres. Common reinforcement materials are aluminium flake, carbon fibres, stainless steel fibres and glass fibres. Reinforcing ABS increases the stiffness, but the strain at fracture decreases [1]. For the application of using the material as a spring, I am not interested in using reinforced materials, as the preliminary results indicated a sufficient stiffness and I am interested in obtaining the largest elastic strain possible.

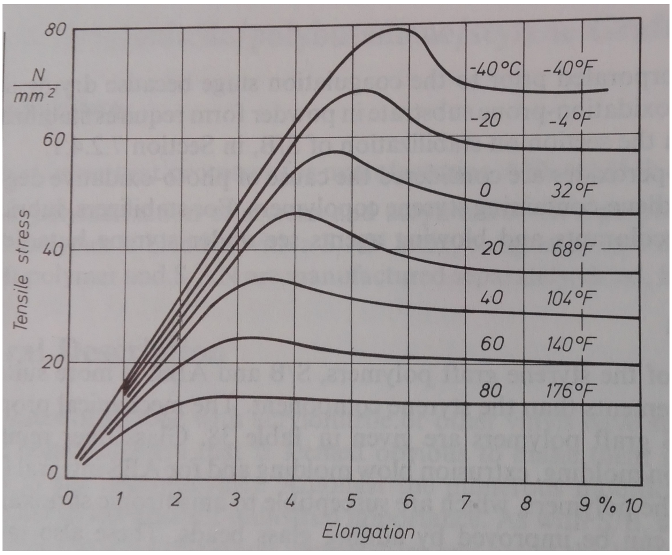


Figure 5.27: Stress/strain curves of a standard injection molded grade of ABS at various temperatures [13]

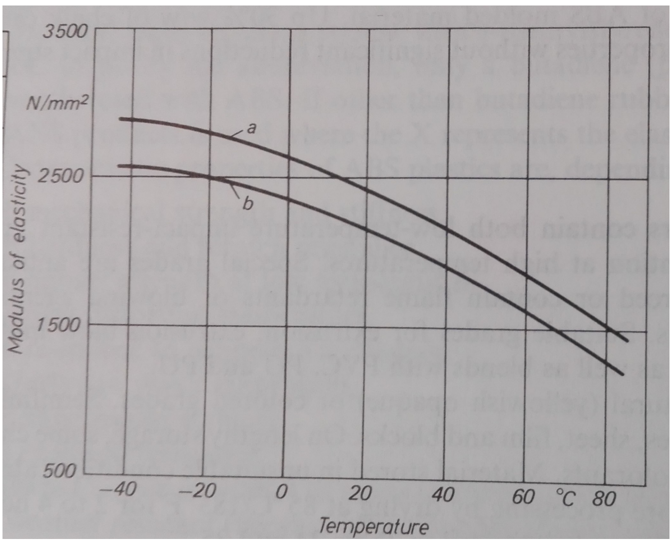


Figure 5.28: Modulus of elasticity in tension of two medium flow ABS grades as a function of temperature, a- Lerluran 877 T, b Terluran 967 K [13]

Regarding processing, ABS in a superior material. Due to the content of styrene, the material is easy to machine. ABS is also suitable for most thermoforming processes: injection molding, rotational molding, vacuum-forming and extrusion [1].

Polycarbonate PC

PC is also a tough thermoplastic. The material has a high impact resistance, stiffness and strength across a temperature range from $-150°C$ to $+135°C$. The impact resistance of PC is higher than ABS at temperatures above $-40°C$. PC is also stiffer than ABS, as seen in the stress strain curve in Figure 5.29. It is also possible to reinforce PC with for instance glass fibre. Regarding fatigue, PC has relatively low resistance against fatigue. The fatigue limit increases significantly if PC is reinforced with glass fibre, as illustrated in Figure 5.30. However, glass fibre reinforced PC is just half as elastic as unfilled PC. The elongation at yield of 30% glass fibre reinforced PC is 3%, in comparison, elongation at yield of unfilled PC is 6% [13].

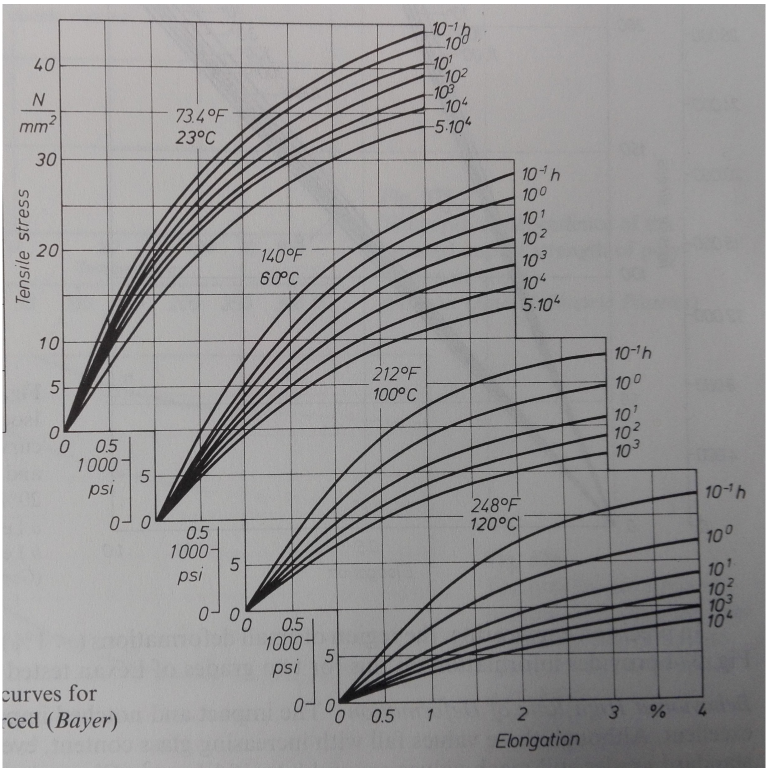


Figure 5.29: Isochronous stress/strain curves for unreinforced PC (Makrolon 2800)

Polyethylene terephthalate, glycol copolyester (PETG)

PETG is a copolymer of terephthalic acid with ethylene glycol (more than 50%) and cyclohexanedimethanol (less than 50%). It is permanently amorphous, having the benefits of full transparency, toughness and dimensional stability in moulding. The preliminary testing revealed that the stiffness when bending is similar to PC. An overview of properties of the materials considered is shown in Table 5.2.

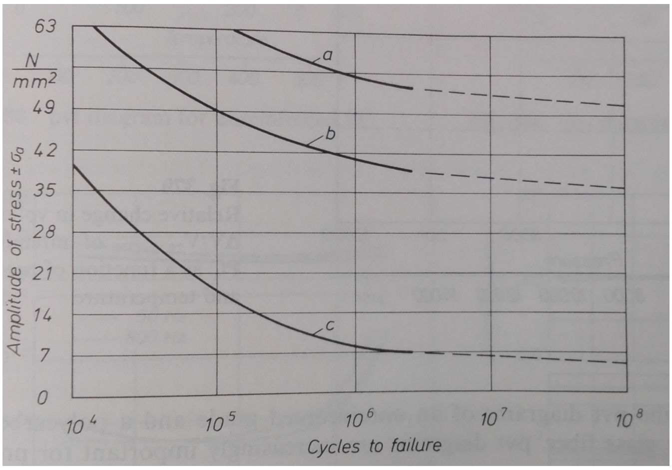


Figure 5.30: Flexural fatigue stress of unreinforced and glass fiber reinforced PC. a - PC-40GF, b - PC-20GF, c - PC (unreinforced)

Table 5.2: Material properties of considered materials [1]

Property	ABS (injection molding, platable)	POM, unfilled	PC, unfilled (high viscosity, molding and extrusion)	PC, 30% glass fiber reinforced	PETG, unfilled
Mechanical					
Yield stress [MPa]	42 - 46	65.5 - 69	59 - 65	105- 110	47.9 - 52.9
Elongation at yield [%]	n/a	n/a	6	3	n/a
Ultimate tensile strength [MPa]	42 - 46	66.9 - 69	62 - 72	131 - 138	60 - 66
Elongation at break [%]	15 - 20	10 - 75	110 - 120	2-5	102 - 118
Tensile modulus of elasticity [GPa]	2.2 - 2.6	2.7 - 3.6	2.3 - 2.44	8.6 - 9.16	2.0 - 2.1
Fatigue limit at 10^7 cycles. $\pm\sigma_{amplitude}$ fully reversed cycle [MPa]	7- 9	11.9 - 15.5	11.9 - 15.4	17 - 20	12 - 13
Thermal					
Glass transition temperature [°C]	100- 110	n/a	142- 158	142-158	81-91

5.4.1 Summary of material review

The materials considered have similar tensile modulus of elasticity (Young's modulus). The literature review tells that all the amorphous, thermoformable materials; ABS, PC and PETG, have poor fatigue resistance. This is also illustrated in the SN curves provided. Also, no distinct fatigue limit exists for any of the thermoformable polymers. Consequently, one can be certain that a compression mechanism will fracture at some point if is made out of one of the considered thermoplastics. On the other hand, POM, which is a crystalline polymer, has good fatigue resistance. This is also reflected in the fatigue curves. By comparing the fatigue curves, illustrated by Domminghaus [13], we see that ABS and PC have a fatigue limit of approximately σ_a =7 MPa, while POM has a significantly higher fatigue limit of σ_a =20 MPa of a fully reversed stress cycle,$R = \sigma_{min}/\sigma_{max} = -1$. (Note that the values given in Table 5.2 are from the material database Granta CES Edupack [1] and state other values than Dominghaus [13]). Regardless, it should be considered that POM is more brittle than the other materials. For the further design, some stopping mechanism should be made. This to ensure that the stress in the material will not exceed the fatigue limit. Such a material review can only provide indications of which materials will work as there exists very many varieties of each main type of polymer.

5.5 Deflection theory

As all the provided materials have similar Youngs' modulus, the stiffness will be similar for all the materials of the same geometry. The wall thickness is one parameter which really changes the stiffness of the overall structure. To prove this, I have explored some basic mechanics. The compression mechanism is a bent plastic plate with a cross section of 2 mm x 120 mm. A straight part of this plastic plate can be seen as a beam. Hence, beam theory can be applied to the plastic plate. Bending is the the main cause of deflection of the compression mechanism. The bending is the visible result of moment. Here, I refer to moment described as $Moment = Force * distance$. In the manikin's compression mechanism, the force is caused when a person presses at the middle of the chest. There is a linear relationship between the moment, M and the force applied, F. The deflection, u, is linearly proportional to the curvature of the beam, which is $\frac{1}{\rho}$. ρ is the radius of the curvature. To apply beam theory, I assume that the material is homogeneous and behaves in a linear elastic manner. This is a reasonable assumption as the materials used are amorphous. The compression mechanism must be able to handle at a minimum 100 000 compressions. Thus, the material must during all parts of a compression be linear elastic to avoid fatigue failure. Beam theory provides, given these assumptions, the relationship between a given moment and the curvature of the beam to be [34]:

$$\frac{1}{\rho} = \frac{M}{EI} \tag{5.11}$$

where

ρ - is the radius of curvature at the point on the elastic curve ($\frac{1}{\rho}$ is referred to as the curvature)

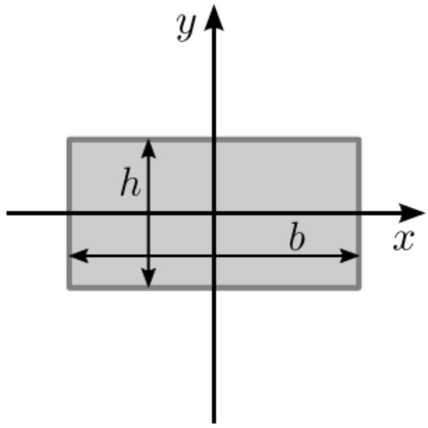


Figure 5.31: Cross-section

M - is the internal moment at the beam at that point

E - is the Youngs' modulus

I - is the beam's 2nd moment of area about the neutral axis

As mentioned, the force applied to the manikin's chest, F, the deflection at that point, u, is linearly proportional to the moment, M, and the curvature, $\frac{1}{\rho}$, respectively. Consequently, equation 5.11 can be rewritten and seen as a spring relationship, where the flexural rigidity, EI, is the spring constant:

$$M = EI\frac{1}{\rho} \tag{5.12}$$

Thus, the flexural rigidity, EI, must be tuned to achieve a desired relationship between force applied and deflection. Now, it is time to understand the factors of the flexural rigidity.

The first factor to address is the E. E is the elastic modulus of a material, also known as Young's modulus. It is a material constant for linear -elastic materials, which relates the stress of a material to its strain. This relationship is described by Hooke's law [35]:

$$\sigma = E\epsilon \tag{5.13}$$

σ - is the stress

ϵ - is the strain

This expression shows that there is a linear relationship between the Youngs' modulus and the flexural rigidity EI. Now, I will look into the other factor of the flexural rigidity, the 2nd moment of area. This is a geometrical property of the cross section of a beam. The

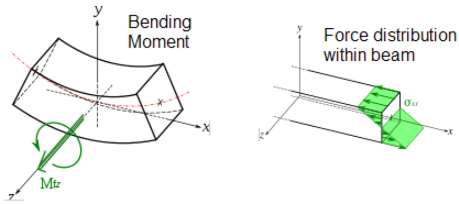


Figure 5.32: Stress-distribution in a beam prone to bending [14]

2nd area of moment reflects how the points of the cross section are distributed with regards to the neutral axis, x. The 2nd moment of area is a multiple integral over the particular cross section. For bending about the x-axis (see Figure 5.31), the 2nd area of moment of a rectangular cross section is:

$$I_x = \int\int y^2 dA = \int_{-\frac{h}{2}}^{\frac{h}{2}} \int_{-\frac{b}{2}}^{\frac{b}{2}} y^2 dxdy = \frac{1}{12} * bh^3 \tag{5.14}$$

where:

h - is the height of the beam

w - is the width of the beam

The 2nd area of moment is proportional to the cube of the height of the cross-section, as described in equation 5.14. Thus, the relationship between the flexural rigidity , EI, and the height of the cross section ,h, is cubic. In other words, for optimisation of the force-displacement-relationship in the compression mechanism, the height of the cross section, will play a considerable role.

It should also be noted that by adjusting the height of the cross- section, the max stress will also change, while keeping the curvature the same. The stress in a beam, prone to bending is distributed as follows [36] (also shown in Figure 5.32):

$$\sigma = \frac{M_x}{I_x} y \tag{5.15}$$

where

y - is the distance from the neutral axis, x

We can rewrite equation 5.11 to be:

$$M = \frac{1}{\rho} EI \tag{5.16}$$

Inserting the expression for M, into equation 5.15 and setting $y = \frac{h}{2}$ to give max stress:

$$\sigma_{max} = \frac{M}{I_x} y = \frac{\frac{1}{\rho} EI}{I} \frac{h}{2} = \frac{1}{\rho} E \frac{h}{2} \tag{5.17}$$

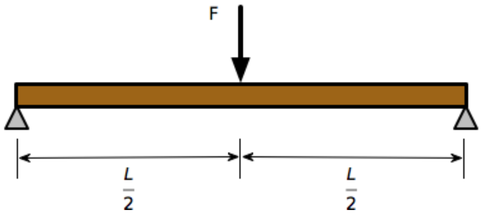


Figure 5.33: Simply supported beam [15]

Equation 5.17 proves that an increase in height of the cross-section, the wall thickness, leads to a proportional increase of max stress for a constant curvature $\frac{1}{\rho}$. Therefore, it is important to be aware that the max stress can exceed the yield strength if the wall thickness is increased too much.

5.5.1 Scaling effects

As the current concept looks promising, I looked into how well the concept is scalable to larger manikins. The compression mechanism is comparable to a simply supported beam, with a force at the centre, as shown in Figure 5.33.

The vertical deflection of a simply supported beam at the centre is expressed as [37]:

$$u_{max,initial} = \frac{FL^3}{48EI} = \frac{FL^3}{48E\frac{1}{12}bh^3} \tag{5.18}$$

where:

$u_{max,initial}$ - is the maximum vertical displacement of the beam at the centre

F - is the force applied to the centre of the beam

L - is the length of the beam

E - is the Youngs' modulus of the material

I - is the second moment of area

By scaling the length of the beam, L, with a factor C_1, the base of the cross-section, b, with a factor C_2 and the height of the cross-section, h, with a factor C_3, we get:

$$u_{max} = \frac{F(L * C_1)^3}{48E\frac{1}{12}(b * C_2)(h * C_3)^3} = u_{max,initial}\frac{C_1^3}{C_2(C_3)^3} \tag{5.19}$$

For the manikin case, the scaling factor C_1, will be determined by the manikin's chest size. For a given value of C_1, it is possible to modify C_2 and C_3 to match a required stiffness. For a value of C_1, representing the size of an adult, C_2 and C_3 can be used to match the data obtained by Tomlinson [7], as shown in Figure 3.4.

The critical part of scaling a mechanism, supposed to be exposed for large forces and deformations, is the stress. I, will now consider how the scaling factors, C_1, C_2, and

C_3, affect the max stress due to bending. The max stress due to bending has earlier been described in equation 5.17. With basis in the same structure, a simply supported beam, the moment at the centre is [37]:

$$M_x = \frac{FL}{4} \tag{5.20}$$

Thus, the stress can be expressed as:

$$\sigma_{max,initial} = \frac{M_x}{I_x} y = \frac{\frac{FL}{4}}{I_x} * \frac{h}{2} = \frac{\frac{FL}{4}}{\frac{1}{12}bh^3} * \frac{h}{2} = \frac{3}{2}\frac{FL}{bh^2} \tag{5.21}$$

By introducing the same scaling constants C_1, C_2 and C_3, the stress is affected by the scaling as follows:

$$\sigma_{max} = \frac{3}{2}\frac{F(L * C_1)}{(b * C_2)(h * C_3)^2} = \sigma_{max,initial}\frac{C_1}{C_2 * C_3^2} \tag{5.22}$$

The guidelines for Resuscitation 2015 state that the compression depth shall be $\frac{1}{3}$ of the chest depth. Consequently, as the size of the manikin, L, is scaled, the deflection u_{max} should be scaled at the same rate. In mathematical terms, we can set the scaling factor of the length , C_1, to be the same as the scaling factor of the deflection, lets give that factor the variable name C_4:

$$u_{max} = u_{max,initial}\frac{C_1^3}{C_2(C_3)^3} = u_{max,initial}C_4 \tag{5.23}$$

$$C_1 = C_4 = \sqrt{C_2(C_3)^3} \tag{5.24}$$

Furthermore, as the manikins are scaled up, the force required to do chest compressions should increase. This is due to an increase of bone size and stiffness of bones as humans grow and age. Lets name this scaling factor C_5. The stress accordingly be:

$$\sigma_{max} = \frac{3}{2}\frac{(F * C_5)(L * C_1)}{(b * C_2)(h * C_3)^2} = \sigma_{max,initial}\frac{C_5 C_1}{C_2 * C_3^2} \tag{5.25}$$

By requiring the scaling of length and deflection to be the same, the stress is expressed as:

$$\sigma_{max} = \sigma_{max,initial}\frac{C_5\sqrt{C_2(C_3)^3}}{C_2 * C_3^2} = \sigma_{max,initial}\frac{C_5}{\sqrt{C_2 * C_3}} \tag{5.26}$$

We can see from equation 5.26 that the stress will increase as the size of the manikin increases. To avoid high stresses, the area of the cross section must be increased.

5.6 Finite element analysis (FEA)

To investigate the stresses in the mechanism when being compressed, I performed finite element analysis. This was mainly useful to reveal stress concentrations in the design when performing compressions. The actual value of the stresses from the simulations, is treated with considerable caution as there are significant uncertainties of the material model chosen. Regardless, the deformation mode obtained from the simulations are very similar to the deformation mode seen from model testing.

5.6.1 FEA theory

I have earlier looked into analytic methods of determining deflection of the structure by doing major simplifications to the design. These calculations were performed by applying mechanics of materials theory. The usage of mechanics of materials theory is limited to simple geometries such as beams, shafts and columns. This limitation is eliminated by using the finite element method. Finite element analysis is a common way of obtaining knowledge about components' mechanical behaviour. It is a method by solving systems of differential equations. The usage of finite element analysis will always be an approximation, and the results will always be prone to error. The error can be minimised by adjusting the computational model.

Finite element analysis divides any geometrical shape into a finite number of elements, associated with some given material properties. Each element consists of several nodes; the contact point between the different elements. Each node is associated with an equation, which is solved. The solution to the equation can be used to obtain data such as load, deformation, stress and strain. The equations used are determined by the material model chosen. There exists both linear models and nonlinear models applicable to finite element analysis. The different material models have been developed to suit different materials with different properties.

Meshes and elements

As mentioned, small elements are used to represent the geometry to be analysed. Both shell elements (2D) and volume (3D) elements are used to represent three dimensional geometry. Shell elements are divided into membrane elements, and plate elements. The difference between the two is that plane element, can be subjected to moment and resist bending, while membrane elements is only applicable to represent materials which do not have significant bending stiffness. Both types of elements can create triangle and quadrilateral meshes. The volume elements can be divided into tetrahedral, bricks, prism and pyramids. For each geometrical shape of the element, there exists variations of the number of nodes in the element as illustrated in Figure 5.34. The element with the most nodes is expected to give more accurate results, but computational time will increase significantly.

A major concern when performing finite element analysis is the computational time. By representing 3D geometry using 2D elements, the number of nodes are reduced. Consequently, the number of equations required to solve is reduced, and the computational time is reduced. Simplifying geometry with 2D elements is applicable when working with thin structures. Therefore, when I performed a finite element analysis on the compression model, I used shell elements. To increase accuracy, I used shell elements with 8 nodes. The computational time of the analysis varied from 10 to 30 seconds. In comparison, the same structure was analysed with tetrahedron elements, and the computational time was in the range of half an hour to an hour. I used a linear elastic material model. This is a

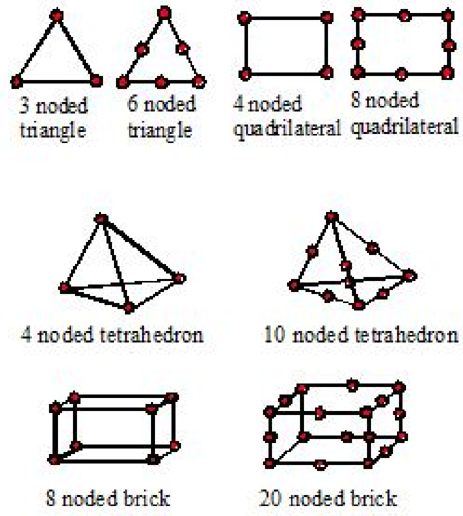


Figure 5.34: Mesh types [16]

good approach as long as the stress does not exceed the yield stress. Hopefully, this is the case for my compression mechanism. Further, I used ab isotropic material with Young's modulus of 2000 MPa, Poisson's ratio of 0.4 and yield strength of 40 MPa. To simulate a compression, the centre line of the mechanism was enforced to a motion up to 40 mm. An arbitrary block underneath the mechanism was modelled to represent the ground the mechanism lies upon. To establish contact between the two parts, glue elements were used. The finite element model is shown in Figure 5.35.

The simulation was performed in four steps: 10 mm, 20 mm , 30 mm, and 40 mm enforced motion of the centre line. It is a common practice for using finite element analysis, to compare your model with a physical model. This is to ensure that the finite element model is acceptable. To do this, I obtained the same parameters from the simulation which I already have from the physical testing. The results are shown in Figure 5.36.

The physical model and the initial simulation model have a wall thickness of 2 mm. To verify that the earlier analytic calculations is applicable in the simulation, I adjusted the wall thickness to be 1 mm. The analytic calculations assume that the flexural stiffness is described as follows:

$$\text{Flexural stiffness} = EI = E\frac{1}{12}bh^3 \tag{5.27}$$

By dividing the wall thickness, h, by 2, the force required to deflect the mechanism decreased approximately by a factor of 2^3 (see figure Figure 5.36). (Force required to deflect mechanism of 40 mm decreased from 16.58 kg to 2.15 kg.) Decreasing the Young's modulus from 2000 MPa to 1000 MPa, resulted in decreasing the force required by a factor 2, which also corresponds with equation 5.27. Figure 5.36 shows that the initial model is too stiff compared to the physical testing. The force required to deflect the model 40 mm

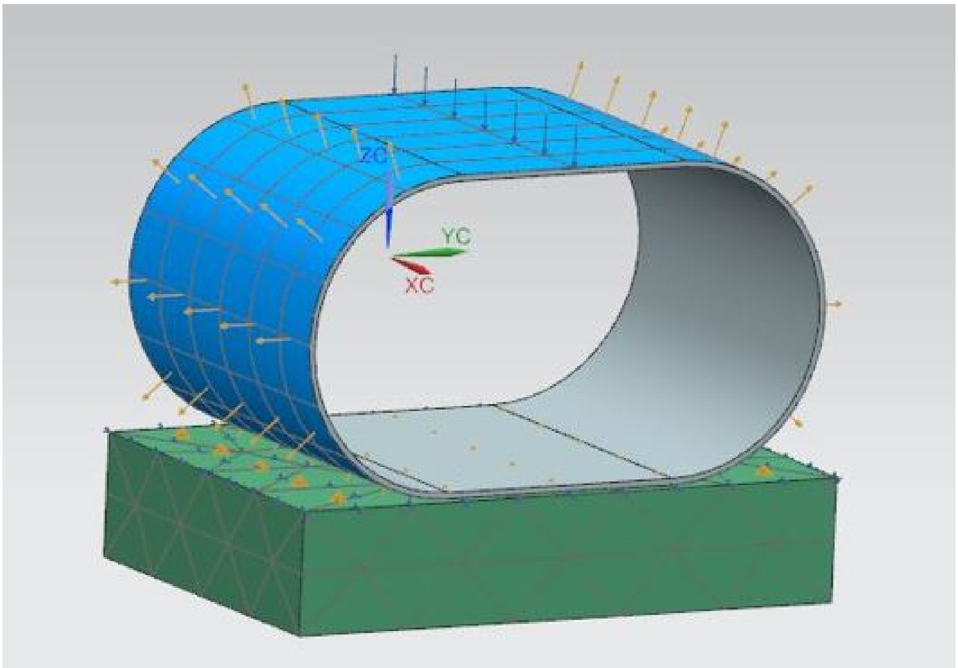


Figure 5.35: Setup od 2D shell element simulation

is 16.58 kg, and for the physical testing of the ABS model it was 6.1 kg. This means that the initial simulation model's flexural stiffness must be reduced with a factor of $6.1/16.58$. By checking the wall thickness of the physical model once more, I revealed that it was 1.8 mm. The following calculations show what the Young's modulus of the simulation model must be to represent the physical model.

$$\text{Flexural stiffness} = E_i I_i * \frac{6.1}{16.58} = (E_i * C_1) I_i * \frac{(1.8\text{mm})^3}{(2\text{mm})^3} \tag{5.28}$$

Consequently, C_1 must be:

$$C_1 = \frac{6.1}{16.58} \frac{(2\text{mm})^3}{(1.8\text{mm})^3} = 0.50468 \tag{5.29}$$

Thus,

$$E_{ABS} = E_i * C_1 = 2000MPa * 0.50468 = 1009MPa \tag{5.30}$$

A Young's modulus of 1009 MPa for ABS, seems to be fairly low. From the literature, the softest ABS is high- impact injection molded ABS, which is stated to have a Young's modulus in the range of 1.1 MPa to 2.41 MPa. Furthermore, we can calculate the Young's modulus of the other materials provided:

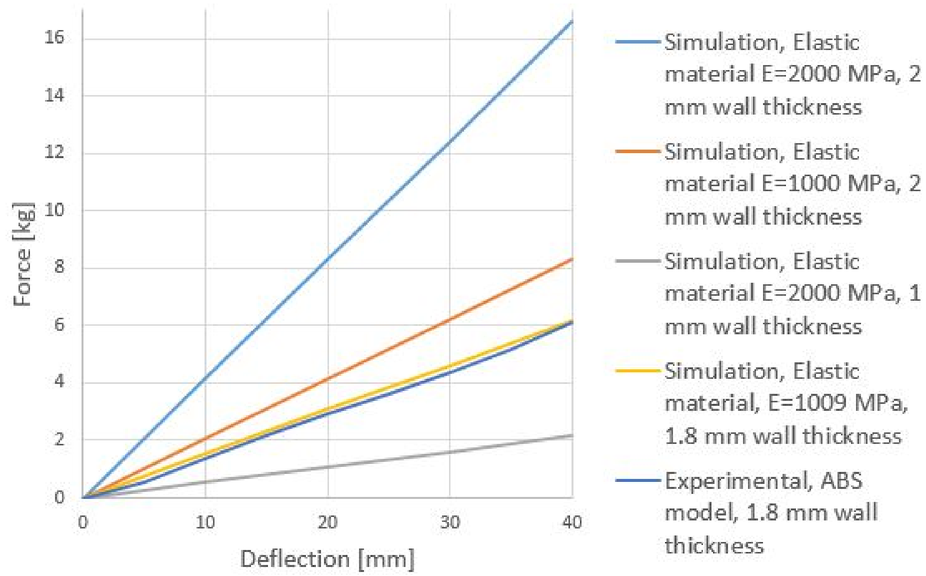


Figure 5.36: Results of linear 2D shell element simulation compared to experimental results

$$E_{HIPS} = E_i * C_2 = 2000MPa\frac{2.54}{16.58}\frac{(2\text{mm})^3}{(1.8\text{mm})^3} = 420MPa \tag{5.31}$$

$$E_{PC} = E_i * C_2 = 2000MPa\frac{8.2}{16.58}\frac{(2\text{mm})^3}{(1.8\text{mm})^3} = 1356MPa \tag{5.32}$$

$$E_{PETG} = E_i * C_2 = 2000MPa\frac{7.5}{16.58}\frac{(2\text{mm})^3}{(1.8\text{mm})^3} = 1241MPa \tag{5.33}$$

All of these values for the Young's modulus are fairly low for the material they should represent according to literature [1], [13]. This could imply that the linear elastic approach is a fairly conservative model. Another explanation is that the material tests provided by Unica AS are considerably softer than other producers of the same materials. However, I wanted to find out what values of the stresses the simulation would calculate. I obtained stress values from three material models;

Model 1 - E=2000 MPa, Poisson's ratio=0.4, wall thickness= 2 mm

Model 2 - E=2000 MPa, Poisson's ratio=0.4, wall thickness= 1 mm

Model 3 - E=1009 MPa, Poisson's ratio=0.4, wall thickness= 1.8 mm

The interesting stress, is the max stress, as this must be the design criterion. The stress obtained is Von-Mises stress. The Von-Mises stress is a commonly used yield criterion which is defined as [37]:

$$\sigma_{Von-Mises} = \sqrt{\sigma_1^2 + \sigma_2^2 + \sigma_3^2 - \sigma_1\sigma_2 - \sigma_2\sigma_3 - \sigma_3\sigma_1} \tag{5.34}$$

The Von-Mises stress is calculated for each node and averaged over each element to avoid artificial high stresses at stress concentrations. The Von-Mises stress is showed in Figure 5.37.

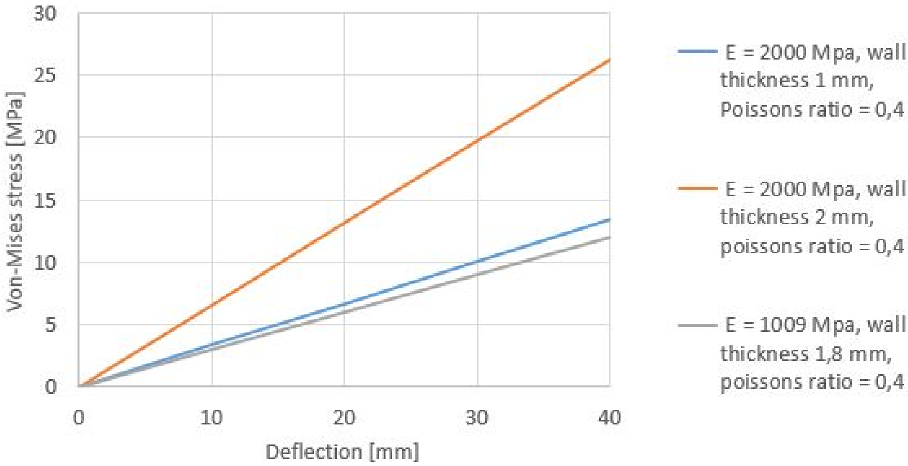


Figure 5.37: Elemental average Von-Mises stress [MPa] for three material models

This shows that there is a proportional relationship between the max stress and the wall thickness. Again, the analytic calculations done earlier seem to correlate with the material model of the finite element analysis which stated this relationship in Equation 5.35. The equation is again represented below.

$$\sigma_{max} = \frac{M}{I_x}y = \frac{\frac{1}{\rho}EI}{I}\frac{h}{2} = \frac{1}{\rho}E\frac{h}{2} \tag{5.35}$$

I can evaluate the stresses calculated by assuming that the simulation model, representing the ABS model with wall thickness of 1,8 mm is correct. Figure 5.37 shows that the stresses in the model will be approximately 12.5 MPa at a 40 mm deflection. The ABS type with the Young's modulus most similar to the one simulated is high impact injection molding ABS. This type of ABS has a Yield stress in the range 18.5 MPa to 40.7 MPa [1] and a fatigue strength at 10^7MPa cycles of 12 MPa to 17 MPa. This means, that the stress calculated is close to the fatigue limit. The fatigue limit of injection molded, platable ABS is in the range 7 MPa to 9 MPa as listed in Table 5.2 and will certainly not be applicable to the application.

A stiffer material such as PC or PETG will increase the stress linearly as the Young's modulus increases. Typical Yield stress values for these materials are in the range of 50 to 60 MPa. As Figure 5.37 shows, these materials will be prone to stress in the range of

20 to 25 MPa for the desired compression depths. Hence, yielding or fracture will not occur for the first compressions. The next step is to be aware of the fatigue failure. The listed fatigue limit at 10^7 cycles listed in Table 5.2 for PC and PETG are in the range 12 MPa to 15 MPa. Consequently, such a mechanism will have a finite lifetime. To get an approximation of the expected lifetime, I must examine the SN curves for the materials. The stress ranges from 0 MPa to 20 MPa. Thus, $\delta\sigma$= 20 MPa. The SN curves obtained are obtained for alternating stress, a stress ratio R=-1. To use these curves, I need to correct the stress range. A stress amplitude, σ_a, with a mean stress, σ_m, different than zero can be corrected to a stress amplitude with mean stress of zero, σ_W, by using the Goodman approach [38]:

$$\frac{\sigma_a}{\sigma_W} + \frac{\sigma_m}{R_m} = 1 \tag{5.36}$$

σ_a - stress amplitude of stress cycle with mean stress different than zero

σ_W - stress amplitude of stress cycle with mean stress equals zero

σ_m - mean stress of cycle

R_m - tensile strength

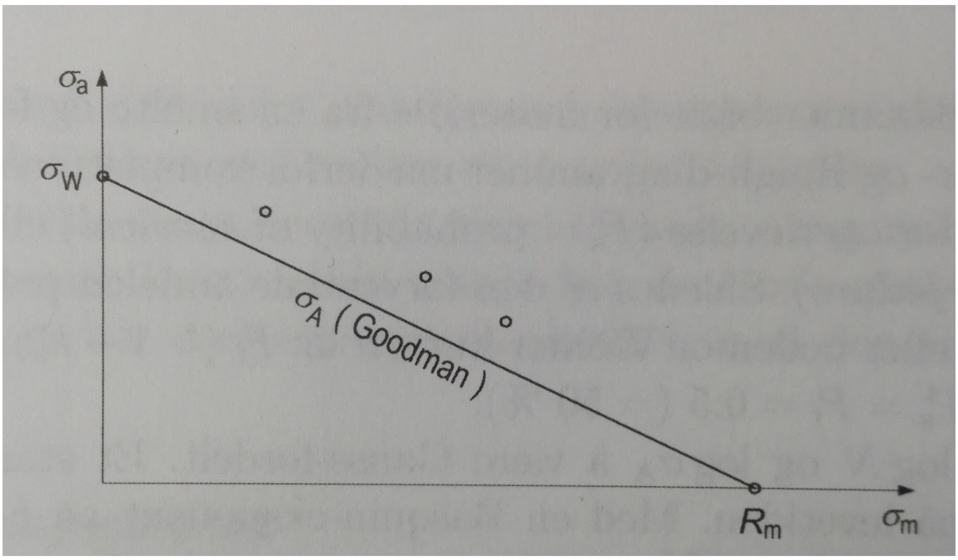


Figure 5.38: The Goodman line in a Haigh diagram compared to test data

For σ_m=σ_a=10MPa, and $R_m = 60MPa$, σ_W becomes:

$$\sigma_W = \frac{\sigma_a R_m}{R_m - \sigma_m} = 12MPa \tag{5.37}$$

By using the S-N diagram in Figure 5.30, I find the cycle lifetime of the component. An amplitude of 12 MPa correlates to a lifetime between 10^5 and 10^6 for unreinforced PC.

In the literature, POM was as a material with higher fatigue resistance. Therefore, I wanted to investigate how POM would perform over the lifetime of the mechanism. I assume that the stress alternate from 0 MPa to 20 MPa. As 20 MPa is the stress range, Δ_σ , the stress amplitude, σ_a is 10 MPa. The stress ratio is

$$R = \frac{\sigma_{min}}{\sigma_{max}} = \frac{0 \text{ MPa}}{20 \text{ MPa}} = 0 \tag{5.38}$$

Thus, we can use Figure 5.25b to determine the lifetime of the mechanism. I can see that the stress is below the fatigue limit. Hence, a compression mechanism of POM will not be prone to fatigue failure with the desired usage.

Chapter 6

Discussion

An improved CPR manikin requires changes to satisfy the user's needs. The relevant anatomy, CPR procedures and the usage of training manikins were thoroughly studied to get insight into the improvements needed. This resulted in three new target specifications in addition to the requirements already fulfilled by the current manikin.

- A compression mechanism which allows room for implementation of advanced airway management
- Progressive chest stiffness, which is more realistic
- Simulate breaking of ribs

Further, I analysed technologies that could solve these new target specifications. As the new target specifications are added to the existing, it has been challenging to find technologies which solve all the target specifications.

6.1 Project status

6.1.1 Air spring concept

Air springs were promising in terms of reducing the diameter, relative to the current coil spring mechanism. This could enable the implementation of an advanced airway. Also, the characteristics of an air spring is more similar to force- deflection curves obtained by patient measurements. On the other hand, this solution does not solve the target specification of simulating rib breakage.

6.1.2 Linear force sensitive linear actuator

The linear force sensitive actuator is the concept evaluated which enables most new functionalities of the compression mechanism. It makes it possible to simulate different chest stiffness characteristics on the same manikin. Consequently, it will be possible to adjust the stiffness characteristic to match any chest stiffness obtained by patient measurements. Also, this technology will allow for changing stiffness during the simulation, representing broken ribs, which normally happens during a chest compression. At this point in the development process, this technology does not indicate that it will be less space consuming.

6.1.3 Thin plastic sheet

The thin plastic sheet is less space consuming as it used the geometry of the outer chest as the stiffness. Allowing room for advanced airway is the most important target specification. Therefore, this concept was developed the most. The biggest uncertainty about using a polymer as a spring are the stresses obtained in the material. Therefore, considerable effort was done to gain knowledge about what stresses that will occur in such a mechanism, and what material is most suitable. The most difficult specification to meet is the large compression depth, equivalent to 1/3 of the chest depth. To obtain stresses at such a compression depth, a finite element analysis was performed, by using a linear- elastic material model. However, linear- elastic material models often provide artificially stiff structures. Consequently, to fit the finite element analysis to the physical tests, the material stiffness, Young's modulus had to be set lower than what is stated in literature (the supplier of the polymer plates could not provide material data of the materials tested). As the material model was fitted to physical testing, the finite element analysis results could be used to obtain stresses occurring in the mechanism at compression depths expected to occur during practice. None of the considered materials exceeded the elastic limit at a single compression. Another concern was the fatigue behaviour of polymers. Polymers do not have a distinct fatigue limit such as spring steel. Therefore, when a polymer structure is subjected to deflection, it will likely suffer from fatigue failure some time during its lifetime. Thus, fatigue curves were used to estimate the expected lifetime of the concept solution. The two most promising material are PC and POM. PC was estimated to have a lifetime of minimum 10^5 cycles of 3 deflection in a 10 cm chest. In comparison, POM is expected to have a lifetime of more than 10^7 cycles with the same deflection. This is in accordance with the literature which states that POM has a high fatigue resistance. To verify these results, it is advised to build a model of POM and actually perform a fatigue test. For any final concept, a stopper mechanism of the deflection is needed, so that it is impossible to break the thin plate mechanism if compressing it to deep. The calculations of Section 5.5 describe how different parameters of the geometry affect the stiffness and max stress. The idea is to use these calculations to optimise stiffness of a physical model. For scaling the mechanism to other manikin sizes, stiffness and stress effects of scaling geometry is also presented in Section 5.5.

The function of the chest was divided in two sub-functions; to function as a spring and to imitate the outer anatomy of the chest. How the thin plastic sheet concept can be combined with imitation anatomy such as ribs, sternum and xiphisternum is still considered an unsolved problem. An idea could be to cover the mechanism with a softer material to imitate the structure of these bones.

6.2 Further work

The main properties of several technologies are obtained and evaluated in this thesis. Different technologies enable different target specifications. However, Laerdal must evaluate what kind of specification they find most important to obtain, meaning, to decide which technologies to develop further.

There are several other aspects of an improved training manikin which is not covered in this thesis. Features of giving digital feedback is not considered in this master project as the current feedback systems provide sufficient feedback. If Laerdal chooses to further develop one of the proposed concepts, it is necessary to address how sensors shall obtain compression depth. Furthermore, the ventilation system with advanced airway must be addressed. There may be several aspects of the ventilation system that could be improved with new technologies.

6.3 Assessment of working method

From the very start of this project, Laerdal's goal was to improve an existing manikins by implementing an advanced airway. However, this challenge proved to be difficult to solve due to the limited space inside the manikin. The pre-master did not involve a good enough technology analysis to solve the problem. Moreover, the pre-master was based on generating concepts by searching internally in Laerdal and already gained knowledge. The master project involved a more diverse technology analysis, including searching externally for solutions and technologies. This eabled me to come up with better concepts for solving some target specifications. The working method was inspired by Ulrich and Eppinger's approach in "Product design and development" [3], but not followed in detail. In the concept generating phase, I used prototypes to learn about various methods. These prototypes have been used to quickly iterate and incrementally improve a concept. Regardless, some of the concepts considered require considerable effort if one wants to build them. The knowledge gaps in these problems have been solved by applying theoretical analysis, and finite element analysis. Retrospectively, I see that these analyses required considerable effort in terms of time invested. Regardless, I hope that the usage of the finite element analysis and its limitations will be captured by employees at Laerdal, as it can reduce the number of iterations required when a concept solution is chosen. By selecting a linear-elastic material model, the results will be conservative and might not represent the strength correctly, but it is useful to reveal stress concentrations and obtain knowledge about deformation shape.

Chapter 7

Conclusion

Through this semester, this master project has been my main area of focus. Consequently, I have gained considerable knowledge about CPR manikins and the available technologies to solve issues regarding their usage. The work has also given me valuable insight and experience in working with various product development methods. Ullrich and Eppinger's "Product design and development" has guiding me with the required activities for taking the project one step further. By using prototyping and a hands-on approach, I have gained considerable knowledge fast. It has also been highly motivating to apply mechanics of material and finite element theory to a project. This has provided me with knowledge about the value of using the theory in practice.

I hope that the results presented in project will be valuable for Laerdal Medical. I have addressed some areas of possible improvements they they could take a to the next level. The main benefits and drawbacks of the technological analyses are highlighted. Also, some possibilities of new technologies are revealed. Finite element analysis is, as far as I know, not widely used at Laerdal. I hope that information in this thesis will give insight of how such analysis can be applied there. It has been motivating to work for a company like Laerdal Medical which has such an encouraging mission: "Helping save lives"

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Appendix A

Arduino Code for Progressive Linear Actuator

```
#define potPin    A0
#define enA       9
#define in1       3
#define in2       4

void setup() {
  // put your setup code here, to run once:
Serial.begin(9600);
pinMode(potPin,INPUT);
pinMode(enA,OUTPUT);
pinMode(in1,OUTPUT);
pinMode(in2,OUTPUT);
}
void loop() {
  //Serial.println(analogRead(potPin));
    long val = analogRead(potPin);
    long springval= val*val;
    if(val > 10){
      Serial.print("\t");
      Serial.print(val);
      Serial.print("\t");
      Serial.print("");
      Serial.println(springval);
        digitalWrite(in1, HIGH);
        digitalWrite(in2, LOW);
        analogWrite(enA, map(springval, 100, 1046529, 100, 255));
        // The value of val is in the range 0 -1023.
```

```
        // Consequently, the max value of val*val= 1046529.
    }else{
        analogWrite(enA, LOW);
    }
}
```

Appendix B

Raw data from thin sheet model testing

Table B.1: Raw data force- deflection of thin sheet model in four different materials

Deflection [mm]	HIPS Force [kg]	PC Kraft [kg]	ABS Kraft [kg]	PETG Kraft [kg]
0	0	0	0	0
5	0.63	0.717	0.53	0.68
10	1.02	1.71	1.35	1.5
15	1.37	2.78	2.2	2.75
20	1.68	3.8	2.9	3.6
25	1.91	4.9	3.6	4.67
30	2.1	6.1	4.4	5.8
35	2.31	7.1	5.2	6.65
40	2.54	8.2	6.1	7.48
45	2.72	9.2	6.8	8.5
50	2.95	10.5	7.8	9.4
55	3.14			
60	3.32			

Appendix C

Risk assessment

Enhet: Institutt for produktutvikling og materialer **Dato: 18.05.2017**

Linjeleder: Torgeir Welo

Deltakere ved kartleggingen (m/ funksjon): Knut Aasland,veileder./ Henrik Aasheim, student
(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Kort beskrivelse av hovedaktivitet/hovedprosess: Masteroppgave av Henrik Aasheim «New Technology for Muscles, Springs and other Elements in Resuscitation Manikins»

Er oppgaven rent teoretisk? (JA/NEI): **Nei** *«JA» betyr at veileder innestår for at oppgaven ikke inneholder noen aktiviteter som krever risikovurdering. Dersom «JA»: Beskriv kort aktiviteteten i kartleggingskjemaet under. Risikovurdering trenger ikke å fylles ut.*

Signaturer: *Ansvarlig veileder:Knut Aasland* [signature] *Student:Henrik Aasheim* Henrik Aasheim

ID nr.	Aktivitet/prosess	Ansvarlig	Eksisterende dokumentasjon	Eksisterende sikringstiltak	Lov, forskrift o.l.	Kommentar
1	Bruk av Trolllabs workshop.	HAa	Romkort	Romkort		
1a	Bruk av roterende maskineri	HAa	Maskinens brukermanual	Ukjent	Ukjent	
1b	Bruk av laserkutter	HAa	Maskinens brukermanual	Ukjent	Ukjent	
1c	Bruk av 3D printer	HAa	Maskinens brukermanual	Ukjent	Ukjent	
1d	Bruk av skjæreverktøy	HAa	Ukjent			
1e	Bruk av samenføynigsmidler (lim og lignende.)	HAa	Produktets brukermanual og datablad	Datablad	Ukjent	

1f	Bruk av loddebolt	HAa	Ukjent	Ukjent	Ukjent	
2	Tilstedeværelse ved arbeid utført av andre.	Andre	Andres HMSRV2601	Andres HMSRV2601	Prosessavhengig	

Enhet: Institutt for produktutvikling og materialer **Dato: 15.09.2016**

Linjeleder: Torgeir Welo

Deltakere ved kartleggingen (m/ funksjon): Knut Aasland,veileder./ Carlo Kriesi, Stud ass./ Henrik Aasheim, student
(Ansv. Veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Risikovurderingen gjelder hovedaktivitet: Prosjektoppgave av Henrik Aasheim «Advanced airway for baby mannequin that can be used in medical teaching»

Signaturer: *Ansvarlig veileder:Knut Einar Aasland* *Student:Henrik Aasheim*

ID nr	Aktivitet fra kartleggings-skjemaet	Mulig uønsket hendelse/ belastning	Vurdering av sannsyn-lighet (1-5)	Vurdering av konsekvens: Menneske (A-E)	Ytre miljø (A-E)	Øk/ materiell (A-E)	Om-dømme (A-E)	Risiko-Verdi (menn-eske)	Kommentarer/status Forslag til tiltak
1	Bruk av Trolllabs workshop.								
1a-i	Bruk av roterende maskineri	Stor kuttskade	2	D	A	A	D	2D	Sørg for at roterende deler tilstrekkelig sikret/dekket. Vær nøye med opplæring i bruk av maskineri.
1a-ii		Liten kuttskade	3	B	A	A	A	3B	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iii		Klemskade	2	D	A	A	C	2D	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iv		Flygende spon/gjenstander	3	C	A	A	B	3C	Bruk øyevern og tildekk hurtig roterende deler (Fres og lignende.)
1a-v		Feil bruk-> ødelagt utstyr	3	A	A	C	A	3C	Vær nøye med opplæring i bruk av maskineri

1b-i	Bruk av laserkutter	Klemskade	2	D	A	A	C	2D	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1b-ii		Brannskade	3	B	A	A	A	3B	Vær nøye med opplæring i bruk av maskineri. Bruk hansker ved håndtering av varme materialer.
1b-iii		Øyeskade-laser	2	D	A	A	C	2D	Bruk øyevern! Skru av laser når maskinen ved oppsett.
1b-iv		Brann	2	B	A	D	C	2B	Vær nøye med opplæring i bruk av maskin. Ha slukkeutstur tilgjengelig
1c-i	Bruk av 3D-printer	Brannskade	3	B	A	A	A	3B	Vær nøye med opplæring i bruk av maskin.
1c-ii		Innhalering av plast/ printemateriale	5	A	A	A	A	5A	Bruk åndedretsvern/ vernebriller
1c-iii		Feil bruk-> ødelagt maskineri	3	A	A	C	A	3A	Vær nøye med opplæring i bruk av maskin.
1d-i	Bruk av skjæreverktøy	Stor kuttskade	2	D	A	A	D	2D	Bruk skapre verktøy og riktig skjæreunderlag
1d-ii		Liten kuttskade	3	B	A	A	A	3B	Bruk skapre verktøy og riktig skjæreunderlag
1e-i	Bruk av samenføynigsmidler (lim og lignende.)	Eksponering på øyet	2	D	A	A	B	2D	Bruk øyevern, ha datablad tilgjengelig

1e-ii		Eksponering hud	4	A	A	A	A	4A	Bruk hansker, ha datablad tilgjengelig
1e-iii		Eksponering åndedrett	4	A	A	A	A	4A	Bruk åndedretsvært/ god ventilasjon. Ha datablad tilgjengelig.
1e-iv		Søl	4	A	B	A	A	4A	Ha papir/ rengjøringsmateriell tilgjengelig. Ha datablad tilgjengelig.
1f-i	Bruk av loddebolt	Brannskade	4	A	A	A	A	4A	Være påpasselig ved håndtering av loddebolt
2	Tilstedeværelse ved arbeid utført av andre.	Se andres risikovurdering om sikkerhet betviles.	3	C	C	C	C	3C	Hold et øye med hva som foregår rundt deg.

Sannsynlighet vurderes etter følgende kriterier:

Svært liten 1	Liten 2	Middels 3	Stor 4	Svært stor 5
1 gang pr 50 år eller sjeldnere	1 gang pr 10 år eller sjeldnere	1 gang pr år eller sjeldnere	1 gang pr måned eller sjeldnere	Skjer ukentlig

Konsekvens vurderes etter følgende kriterier:

Gradering	Menneske	Ytre miljø Vann, jord og luft	Øk/materiell	Omdømme
E Svært Alvorlig	Død	Svært langvarig og ikke reversibel skade	Drifts- eller aktivitetsstans >1 år.	Troverdighet og respekt betydelig og varig svekket
D Alvorlig	Alvorlig personskade. Mulig uførhet.	Langvarig skade. Lang restitusjonstid	Driftsstans > ½ år Aktivitetsstans i opp til 1 år	Troverdighet og respekt betydelig svekket
C Moderat	Alvorlig personskade.	Mindre skade og lang restitusjonstid	Drifts- eller aktivitetsstans < 1 mnd	Troverdighet og respekt svekket
B Liten	Skade som krever medisinsk behandling	Mindre skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1uke	Negativ påvirkning på troverdighet og respekt
A Svært liten	Skade som krever førstehjelp	Ubetydelig skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1dag	Liten påvirkning på troverdighet og respekt

Risikoverdi = Sannsynlighet x Konsekvens
Beregn risikoverdi for Menneske. Enheten vurderer selv om de i tillegg vil beregne risikoverdi for Ytre miljø, Økonomi/materiell og Omdømme. I så fall beregnes disse hver for seg.

Til kolonnen "Kommentarer/status, forslag til forebyggende og korrigerende tiltak":
Tiltak kan påvirke både sannsynlighet og konsekvens. Prioriter tiltak som kan forhindre at hendelsen inntreffer, dvs. sannsynlighetsreduserende tiltak foran skjerpet beredskap, dvs. konsekvensreduserende tiltak.

MATRISE FOR RISIKOVURDERINGER ved NTNU

KONSEKVENS	Svært alvorlig	E1	E2	E3	E4	E5
	Alvorlig	D1	D2	D3	D4	D5
	Moderat	C1	C2	C3	C4	C5
	Liten	B1	B2	B3	B4	B5
	Svært liten	A1	A2	A3	A4	A5
		Svært liten	Liten	Middels	Stor	Svært stor
		SANNSYNLIGHET				

Prinsipp over akseptkriterium. Forklaring av fargene som er brukt i risikomatrisen.

Farge		Beskrivelse
Rød		Uakseptabel risiko. Tiltak skal gjennomføres for å redusere risikoen.
Gul		Vurderingsområde. Tiltak skal vurderes.
Grønn		Akseptabel risiko. Tiltak kan vurderes ut fra andre hensyn.

Appendix D

Pre-master project

Project task 2016

Needs and technologies for infant CPR and airway management training manikins

Written by: Henrik Aasheim

December 2016

Supervised by: Knut Aasland

NTNU

Abstract

This project task is a pre-master work which gives an overview of the practices regarding CPR and advanced airways for infants, which enables developing a training manikin for these practices. Technologies which can simulate the needed functionality are explored and concept solutions are suggested. Choosing promising concepts, designing, building and testing prototypes remains to be done. By doing user empathizing some of the core values of using training manikins are identified. The values of using training manikins is to practice collaboration between medical personnel in emergency situations and practicing life saving procedures without any patient at risk. The importance of having reliable manikins became clear. It also became clear to me that the manikins should be so simple to use that the students should not need specific training to handle the manikin. The only focus during training should be giving the right treatment, as for a real patient.

Definitions

New born Age from birth to the child has left the hospital

Infant Age from leaving the hospital until 1 year old

Child Age from 1 year until puberty

Oesophagus Food pipe

Trachea Windpipe

Tidal volume Lung volume representing the normal volume of air displaced between normal inhalation and exhalation

CPR Cardiopulmonary resuscitation

Preface

This project thesis describes the exploration of solutions for a infant manikin used to train medical personnel in CPR and advanced airway management.The task was requested by Laerdal Medical, represented by Arild Eikefjord. It was written to fulfill the requirements of the Product Development and Materials specialization at NTNUs Department of Engineering Design and Materials.

The task have been assisted by my supervisors Knut Aasland, Martin Steinert, representatives from Laerdal Medical, Arild Eikefjord and Helge Anglevik. Medisinsk SimulatorSenter at St. Olav's Hospital have assisted me in getting insight of how patient manikins are used in medical training.

Signed: Henrik Aasheim

Date: 22.12.2016, Stavanger

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1 Introduction

1.1 Motivation

It is estimated that there were more than 400 000 incidents of cardiac arrest in the US in 2014 (Go et al., 2014). To maximise the chance of survival there are several time-sensitive interventions that must be optimised (Nolan et al., 2006). This article will concern CPR and advanced airway management training for infants. CPR is an emergency procedure that combines chest compressions with artificial ventilation to circulate blood and supply oxygen to a patient who is in cardiac arrest. This procedure combined with defibrillation are the central elements to restore spontaneous blood circulation and breathing. The chain of survival poster illustrates these elements.

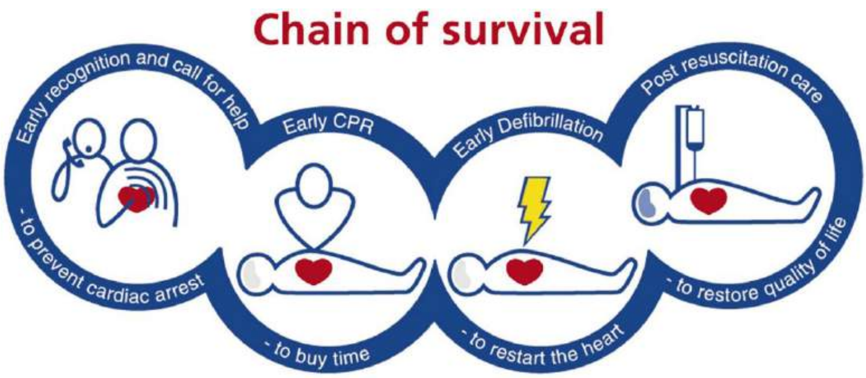


Figure 1: Chain of survival (Nolan et al., 2006)

Regularly CPR practice has showed improved quality of CPR performance in terms of adequate ventilation volume and compression depth (Oermann et al., 2011). Consequently, it is important to provide equipment that enables practice and feedback to both medical personnel and laymen. Advanced airway management is conducted during CPR, resuscitation and transportation (Eivind Bjerkelund et al., 2010).

1.2 About Laerdal

Laerdal is a world leading company in terms of developing, manufacturing and selling medical equipment for training and clinical usage. The company started of as a toy manufacturer in the 1940s. Laerdal transitioned towards first aid and emergency medicine products in the 1960. At that time, pre-hospital emergency medicine began to be seen as an extension of advanced hospital treatment. To teach students mouth-to-mouth resuscitation, a training manikin called Resusci Anne was introduced. Today, Laerdal provides a diversity of products and training programs for emergency care, such as advanced patient simulators for training and various medical equipment for patient treatment. The patient simulators enables training of handling medical conditions that are life threatening without putting patients at risk. The operation unit in Stavanger contains both a manufacturing facility, sales office and a R&D department, which makes cooperation between the departments easy. The core values of Laerdal have remained unchanged since they changed focus to emergency care. These are:

Mission ”Helping save lives”

Vision ”No one should die or be disabled unnecessarily during birth or from sudden illness or trauma”

2 Theory and method

2.1 Agile and set-based

Agile product development is a methodology with its origin from software development. This approach to product development is a very flexible approach where working prototypes and customer satisfaction is highly valued. Some of the main outcomes from a conference in 2001 about Agile software development the following four manifesto are:

- Individuals and interactions over processes and tools
- Working software over comprehensive documentation
- Customer collaboration over contract negotiation
- Respond to change over following a plan

Lately, some models made for agile **product** development have been proposed. These approaches focus on iterative development as an important aspect of the methodologies. Prototypes will be built in each iteration, and based on a close collaboration with customers and users, each prototype will become closer to the final product. The purpose of building functional prototypes at an early stage is to unveil hidden knowledge gaps as early as possible. Physical prototypes also make communication with customers and users clear and tangible. Too refined prototypes can make the feedback too detailed at an early stage. Furthermore, we might miss out on some of the diversity in possible solutions. The purpose of the prototypes is not to present a final product, but to have a physical representation of an idea. The prototypes should be very coarse at the start of the project, and be refined after more and more as specifications are set.

Each iteration could typically last for 3-4 weeks. It should be clear for everyone in the team what questions are to be addressed in each iteration and what the expected outcome of the iteration should be. The voice of the customer should be included in each iteration. Either, by giving direct input to the design, building testing or in the review of the prototype. An iteration should bring new knowledge to the project.

Front loading of a project is also an aspect of the agile methodology. This means that much effort is put into the start of a project to explore and experiment. A diversity of concept solutions, and testing of these from the very start of the project reduces putting to much effort into a concept that eventually will never work.

As the requirements can change quite a lot during such a development project, it can be useful to have some fixed points that don't change. Such fixed points can be:

- Product vision
- Personas
- Use cases
- User stories

Moreover, anticipate customers needs can be useful. This could be done by emphasizing with customers and by establishing a collaboration with some lead users.

Deferring decisions is also a way of handling requirement changes. This means that we will keep multiple alternatives available as long as possible. A good starting point could be to draw out architectural schematics and recognize different modules. Changes on one module must affect the other modules as little as possible to make the product more robust to requirement changes (Leitão and Restivo, 2006). The set-based approach also supports deferring decisions.

2.1.1 Set-based design

One of the main goals of set-based design is to reduce rework. The main causes of rework in product development is late learning, premature design decisions and poor cross functional coordination. Set-based design explores larger number of possible concepts, which provides more knowledge early. When a knowledge gap is identified, you try to decouple the area of uncertainty. By building several prototypes of a subsystem, you will get specific knowledge about that subsystem, and how it affects the rest of the system. Systematic testing should be done and each prototype will give a datapoint of what works or doesn't work. Only prototyping the areas of knowledge gaps, saves a lot of building time. An example of set based decoupling is what the Wright brothers did when they developed the first plane. They recognized that there was a knowledge gap concerning the construction of the sustaining wings. Therefore, they built a wind tunnel to test out over 200 wing designs. They also studied the lift versus angle of the wing. Based on this knowledge, they could build an accurate wing design on the first try. The main focus was to design minimal tests which could provide sufficient data to close the knowledge gap. When it is impossible to decouple the knowledge gaps, it could be wise to approach the problem with set based prototypes. Different from set-based designing, where several prototypes are built, the set based prototypes have flexibility in one prototype. This means that we can get several data-points of what works and what doesn't work from one single prototype.

.

3 Background

The background of this work was a need to reduce the number of manikins needed to held complete courses in resuscitation for newborns and infants. The basis is from the "Resuscitation Quality Improvement®"course (later referred to RQI) which is developed and held by the American Heart Association ®. Figure 2 shows an overview of Laerdal manikins which are used in RQI courses. The conclusion was to combine the ALS Baby and the Resusci Baby QCPR. This will reduce the number of manikins the operators and simulation participants have to deal with. Reducing the numbers of manikins produced is also expected to save production costs. The goal for this work have been to identify functionality that are required for such a manikin, generate concept solutions and identify knowledge gaps.

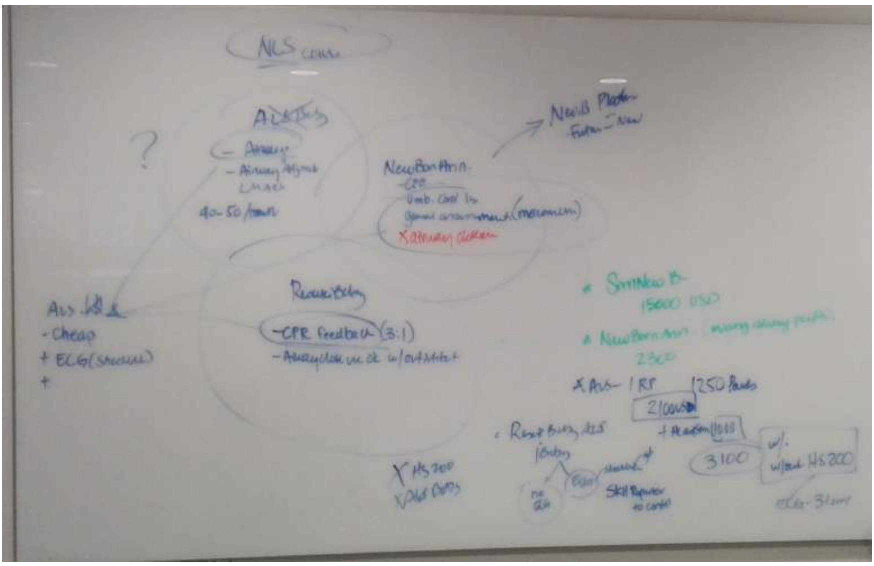


Figure 2: Overview of Laerdal baby manikins and functions

4 Development

4.1 User empathizing

To get some first hand observation about how the manikins are used simulation observation and interviews were done at the simulator center at St. Olav's hospital. A simulation of emergency care of an infant arriving in ambulance, conducted in the emergency room was observed. Three user groups were identified. A main user group is the simulation participants (later called participants), which can be a doctor, medical student or other. A other main user group is the manikin operator, which are able to control the response of the manikin. A third, minor, user group is the actors of which plays the role as dependents of the patient. The simulation room were very similar to the operational emergency rooms at the hospital in terms of equipment available and overall structure. An important aspect of the simulation was the interaction between the simulation participants, and how leadership were performed. The participants needed to extract information about the medical condition of the manikin to be able to make reasonable actions of treatment. The information about the manikin was given through mechanical feedback, sounds and medical equipment connected to the manikin. The participants task was to diagnosticate the manikin and give the right treatment. The participants often do not know the full capabilities of the manikin, and therefore often misinterpret a lack of response of the manikin. This makes an artificial environment where the participant approaches the operator to get information about the medical condition of the manikin. This interrupts the simulation and the participants becomes very aware of that it is just a simulation. After this observation, some of the overall needs of such a manikin was identified. For the operators, the main needs are that the manikin with all of its functions are operational at all time. That means that the manikin adapts to the treatment it gets without any delays, and if necessary the operators can decide the response of the manikin remotely. For the participants it is important that the manikin is realistic enough to understand the symptoms of the manikin. Also it is realistic enough to do the desired treatment. For the manikin being developed the main focus will be to make it possible to the right treatment, rather than to identify symptoms. Therefore we will much focus on the anatomy of the patient and about the procedures that are done during CPR and advanced airway management.

4.2 CPR and advanced airway practices of infants

To develop manikins which can provide valuable training it is important to have a good understanding of the anatomy and what procedures that are commonly used medically. From this knowledge we can make reasonable simplifications of the anatomy and choose which procedures which shall be possible to practice. In the next sections we will take a deeper look into common practices.

Airway management is a key skill in anesthesiology and emergency care. Failure to manage the airway correctly is associated with high risk of mortality. Specially for infants that have a high oxygen consumption, and relatively small oxygen reservoir. For a healthy adult of 70 kg, the oxyhemoglobin saturation drops to 85 % after no breathing for 84 seconds. In comparison, a child of 10 kg will get the same oxyhemoglobin saturation drop just after 41 seconds. This means that the time span is even more critical for small children than adults (Østgaard and Ulvik, 2010) . The focus on the need for more oxygen for children is also rooted in the guidelines for CPR performance from Norwegian Resuscitation council (later referred to as NRR) (NorskResuscitasjonsråd, 2015).For adults the algorithm is to start of with 30 cardiac compression and two ventilations. For children, the guidelines states that you shall start of with giving five ventilations and then proceed with 15 cardiac compressions (NorskResuscitasjonsråd, 2015). The guidelines are divided into two algorithms. The basic CPR algorithms is advised for non-medical personnel, see Figure 3, and the advanced CPR algorithm is meant for medical personnel which require more medical equipment. (The guidelines from Norwegian Resucitation council are based on guidelines from the European Resuscitation Council.)

These guidelines are compiled for emergency care. Airway management are also important for anesthesia. Being able to maintain an open airway is essential to perform safe anesthesia (Eivind Bjerkelund et al., 2010). The airway can be blocked by foreign objects, infections or by forward tilted neck. For infants under a year, some medical personnel states that a hyperextension of the neck could also block the airway. Therefore the guidelines from the Norwegian Resuscitation Council states that you should keep the head in a natural position while ventilating infants (NorskResuscitasjonsråd, 2015). To get rid of foreign objects, the Heimlichs maneuver should be performed. Trained personnel should also be able to use a laryngoscope and pull out the object with a plier (Eivind Bjerkelund et al., 2010). Despite great emphasis on maintaining an open airway, critical low oxygen levels due to blocked

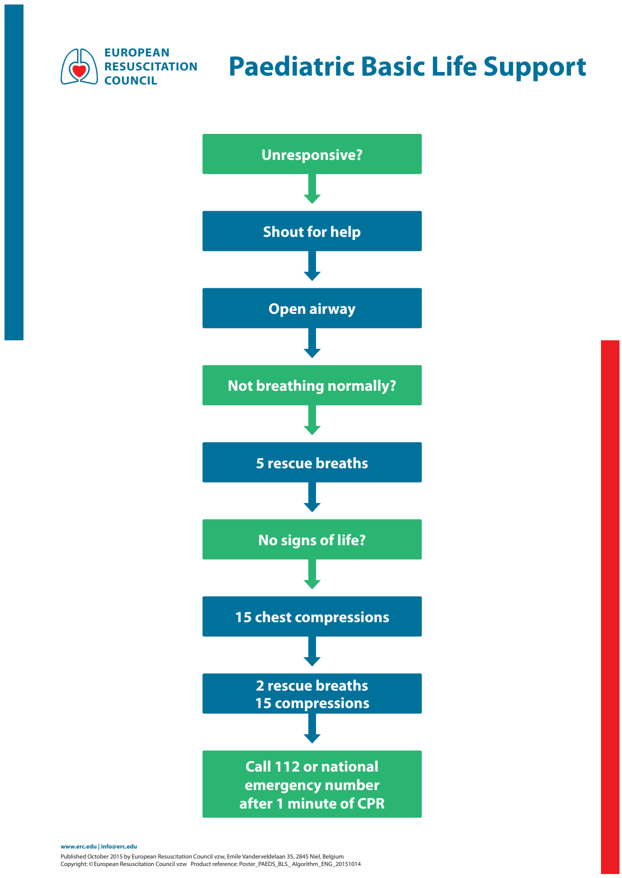


Figure 3: Paediatric Basic Life Support poster from European Resuscitation Council

airway are still the cause for anesthesia related deaths and injuries. There are several methods and tools to achieve oxygen supplies to the blood of a patient that don't breathe spontaneously. I will now present the most used methods and tools. For all the methods it is important to open the airway. For infants, that means holding the head in a natural position (mark: no hyperextension as for adults) and lift the chin forward. For children older than 1 year, it is advised to hyper-extend the neck and lift the chin forward to open the airway. Each ventilation shall last for one second and stop once thorax starts to move (NorskResuscitasjonsråd, 2015).

4.2.1 Mouth to mouth

Mouth to mouth means that you use your own exhaust air to ventilate the patient. For infants you should cover both the nose and the mouth of the patient with your mouth and start to ventilate. This is a method advised to use for non-medical persons because it is simple and requires no medical equipment.

Figure 4: Mouth to mouth (U.S.ArmyMedicalDepartmentCenterAndSchool, 2008)

4.2.2 Pocket mask

This is a simple device that you easily place over the patients mouth and nose, and blow your exhaust air into the mouthpiece. It can sometimes be hard to get a good sealing between the mask and the patient. Therefore it is advised to use both hands to hold the pocket mask.

Figure 5: Pocket mask (Eivind Bjerkelund et al., 2010)

4.2.3 Mask and bag

This is device works similarly to the pocket mask, but it ventilates from the room or extra oxygen can be used. It takes some more practice to get a good sealing with this device, as one hand is used to press air from the bag and one hand is used for sealing.

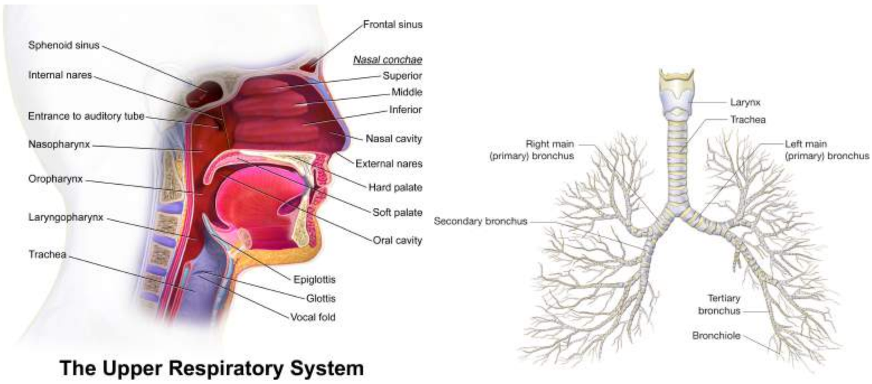
Figure 6: Laerdal Silicone Resuscitators, (Laerdal, 2016)

4.2.4 Intubation

Intubating is the placement of a flexible plastic tube into trachea to maintain an open airway (Eivind Bjerkelund et al., 2010). It is done during resuscitation, respiratory treatment, anesthesia, and transportation. A non-recognized incorrect intubation easily leads to death. Pulmonary aspiration of stomach content, and placement of the tube in oesophagus (food pipe) instead of trachea can both be fatal complications. It is also possible to place the tube to deep in the trachea which leads it down to the right main bronchus. This placement will result in only ventilating the right lung. Because of the high patient risk, it is very important for medical personnel to get sufficient training in placing the tube correctly. It should be possible to experience the most common complications in a training situation.

4.2.4.1 Endotracheal tube

The endotracheal tube (later referred to as ET) is the oldest used form of intubation tool. After the introduction on supraglottic airway devices in the 1980s, which are easier to place, intubation with ET have been reduced and are now done almost only performed by anesthesia personnel (Eivind Bjerkelund et al., 2010). Regardless, it is still considered the safest

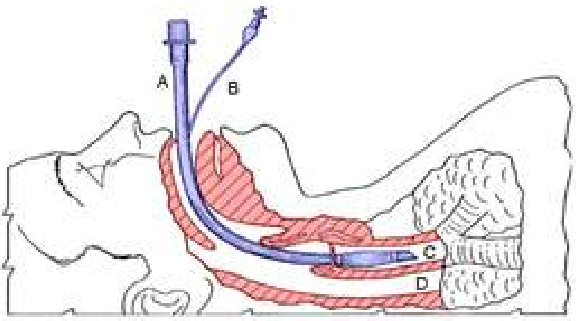


(a) (Blausen, 2014) (b) (Unknown, 2012)

Figure 7: Airway anatomy

way of intubating considering pulmonary aspiration, which means getting stomach content from the oesophagus (food pipe) into the larynx, trachea and lungs. The reduced risk of pulmonary aspiration is because the tube is placed below the larynx in the trachea and blocks the oesophagus (food pipe). It is a common practice to use a laryngoscope when placing the tube. To get a better sealing, some endotracheal tubes comes with a inflatable cuff that is inflated after correct placement (see fig. 8a). The ET comes in diameters from 2.5 mm to 7 mm which will suit different airway diameters (Klingenberg et al., 2013). There is no single method for confirming correct endotracheal tube placement, but a combination of several methods is the common practice (Stone and Gal, 2000). Direct visualization is the simplest method, which means that you visually sees that the tube goes into the larynx. It is often hard to get a direct view of the larynx with a laryngoscope, so a bronchosope is also used to get a visual confirmation. If the ET is placed correctly there will be a visual bilateral chest rise during ventilation. According to the Norwegian guidelines, ventilation shall stop once the chest starts to rise (NorskResuscitasjonsråd, 2015). This makes bilateral chest rise a bad method of detecting correct tube placement. Therefore it is common to use a stethoscope to listen for breath sounds at both lungs. If the tube is placed to deep in trachea and is lead into the right main bronchus only the right lung will be able to ventilate. This can be detected visually and by hearing after breath sounds in a stethoscope. A breath sound over the stomach can indicate that the tube is placed in the food pipe. A small amount of water vapor will also be evident within the lumen of the tube with each exhalation. A more reliable confirmation procedure is to use a capnometer. This is a device which monitors the partial pressure of CO_2 of exhaled air. This can be coupled between the end of the ET and the ventilation bag (Mazimo, 2016).

(a) Endoctrial tube with (upper) and without cuff (lower)



(b) Illustration of placement of endoctrial tube (Christopher, 2000)

Figure 8: Endotrachial tube

4.2.4.2 Supraglottic Airway Devices

Supraglottic airway devices (later referred to as SAD), also called larynx-mask, refers to airway devices that is placed in the airway above the vocal cords. The "Laryngeal Mask Airway" was introduced to the market in 1983. It became the first of many supraglottic airway devices used in modern anesthesiology. The advantage with these devices is the ease of use, speed of insertion and less post-operative discomfort compared to the earlier much used endotracheal tube. Therefore it have became standard equipment for airway management in several ambulances. A disadvantage with these devices is lower seal pressure and higher incidence of gastric insufflation. Also, it have not been proved that supraglottic airway devices can provide the same safety against pulmonary aspiration as the Endotracheal tube. Therefore some SADs have a oesophagus tube which allows placement of suction catheter through the SAD. Some of the different SADs are shown in figure 9. The main advantages with both SADs and endotracheal tube in relation to face masks is more reliable ventilation and hands-free operation (Almeida et al., 2016).

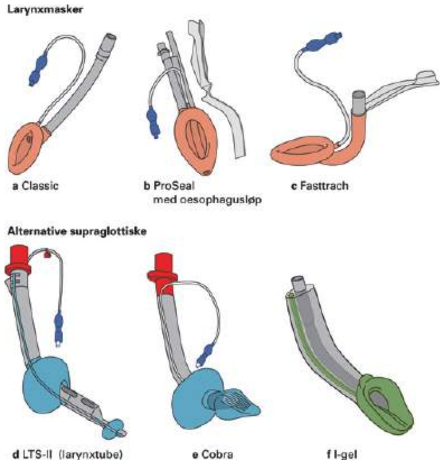


Figure 9: Different types of larynxmasks

4.2.5 Other airway tools

When it is expected difficult airway management, bronchoscopy is the gold standard to assist intubation (Eivind Bjerkelund et al., 2010). A bronchoscope is a flexible tube with a camera at the end which allows the medical personell to see inside the airway. This is then used to get better view of where the tube is in the airway, and can verify correct placement of the intubation tool. Training of bronchoscopy does not require anything other than a realistic airway. When it is impossible to ventilate or intubate the patient through orally and nasally, surgical methods like cricothyrotomy and tracheotomy is useful. Cricothyrotomy is the last resort solution in critical situations which is done very fast, but not the preferred solution when there is a prolonged need for airway support. The method consist of accessing the trachea through the skin and cricothyroid membrane in the neck with a needle. The access point is below the larynx and vocal cords (Katos and Goldenberg, 2007). Tracheotomy is a method which also access the trachea directly through the skin below the larynx and vocal cords. This method is the preferred option when it is expected a prolonged need for airway support (Ferlito et al., 2003). The need for such surgeries are needed when the airway is either blocked higher up or facial trauma makes it hard to access the airway through the nose or mouth.

4.2.6 Training of airway management

Regarding training on airway management, there have been some discussion if training, education and research using the manikins should be reconsidered due to significant dimension differences between manikins and those of humans. The differences was found by computed tomography scans of humans and comparing it to several high- and low-fidelity manikins, including manikins from Laerdal Medical. (Schebesta et al., 2012). Regardless, there are several large organizations like American Heart Association which acknowledge that the training on manikins provides better learning than no training (AmericanHeartAssociation, 2016). There also exist manikins that are based on true CT data to improve the realism of the training (TruCorp, 2016).

4.3 Temporary functionality requirements

Based on medical practices and input from Laerdal Medical we have agreed on the functional requirements for the manikin shown in Table 1.

Airway Features	Airway occlusion (head tilt/chin lift, jaw thrust)
	Bilateral Realistic chest rise and fall
	Realistic visible upper airway
	Oral and nasal intubation
	Detection of correct, right main stem intubation and esophagus intubation
	Realistic airway / lung resistance & compliance
Blood pressure / pulses	Brachial pulses (pulse bulb)
CPR	Mouth-to-mouth ventilations
	Ventilations with face-shield
	Ventilations with pocket mask
	Ventilation with bag-valve-mask
	Ventilation with bag-tube
QCPR feedback (Measurements)	Ventilation measurement and feedback
	Compression measurement and feedback
	Intubation
	Head tilt

Table 1: Functionality requirements of the manikin

4.4 Technology review and suggested solutions

As most of the functionality which are desired for the manikin that are to be developed already exist, it is very interesting to look at existing manikins. The most relevant manikins are of course the Resusci Baby QCPR and ALS baby from Laerdal medical. The main challenge about the new manikin are if it is possible to combine the technology from existing manikins into a new manikin.

4.4.1 Making room for bronchial tree

The development process started off with basis in the already existing manikin, Resusci Baby with QCPR. An airway from the Laerdal ALS baby was attached to this manikin. The bronchial tree of the ALS baby then hits the chest compression spring as seen in Figure 10. There is a need for some alternatives to solve this space issue.

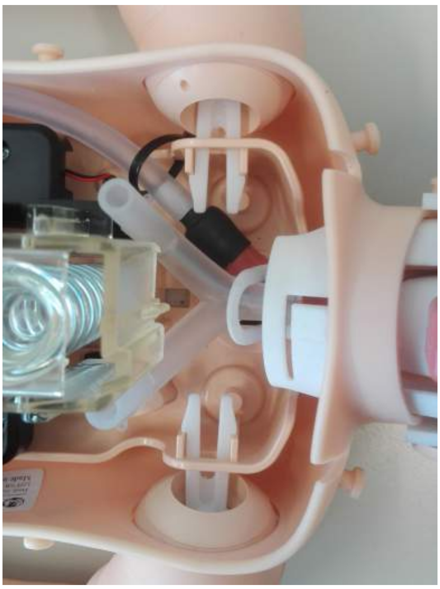


Figure 10: Resusci Baby with ALS baby head. Bronchial tree colliding with slidehouse

4.4.1.1 Alternative 1

Keep the overall structure of the resusci Baby QCPR manikin. Move the slide house and compression spring about 20 mm downwards. As the spring will be placed closer to the hinge, the spring needs to be stiffer, and the chest plate will might need strengthening as it will be subjected to bending for each compression. To save some space, it will might be possible to measure the compression depth inside the compression spring with proximity sensor.

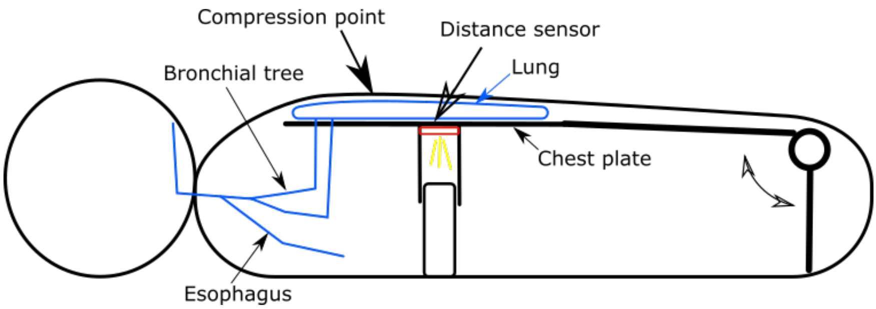


Figure 11: Alternative 1

4.4.1.2 Alternative 2

Keep the head from ALS baby. Remove the slidehouse and compression spring. Add a torsional helical spring attached at the very bottom of the manikin. This solution will require a very stiff chest plate as it will work as a torque arm. This alternative will also require another new way of measuring the compression depth. A suggestion is to have a proximity sensor at the bottom of the manikin which detects the movement of the chest plate.

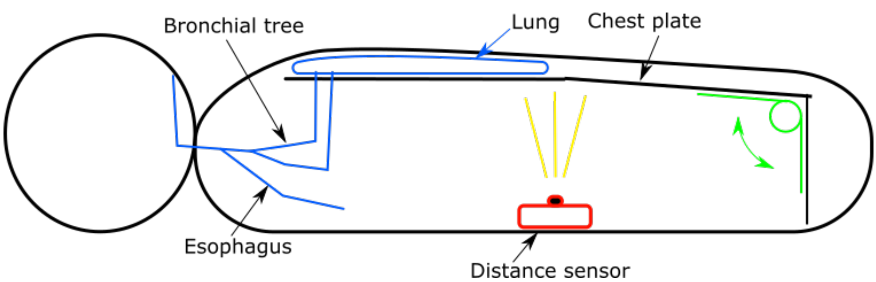


Figure 12: Alternative 2

4.4.1.3 Alternative 3

Use the existing head from ALS baby. Remove slidehouse and spring. Replace it with a compressible foam material. This foam material could be used to support the airway. The existing solution with an slide house and compression spring makes some noise. By using a foam, it will might be possible to reduce the noise. Also, it will might be possible to achieve a more realistic compression with more internal damping. Unfortunately, there is not much data about the damping of the chest. But there exist some measurements about the force-depth relationship. The measurement was done during out-of-hospital CPR and showed a strong non-linear relationship between compression force and depth (Tomlinson et al., 2007). As most CPR manikins today have a compression spring with a linear relationship between force and depth, there is a potential to improve this aspect of the manikins. There have already been some testing at Laerdal of foam. The result was initially promising, but the mechanical properties of the foam changed while doing lifetime testing. The testing was done up to 500 000 compressions. It will might be possible to use other types of foams that don't change mechanical properties over time. Another possibility would be to replace the foam during the lifetime of the manikins.

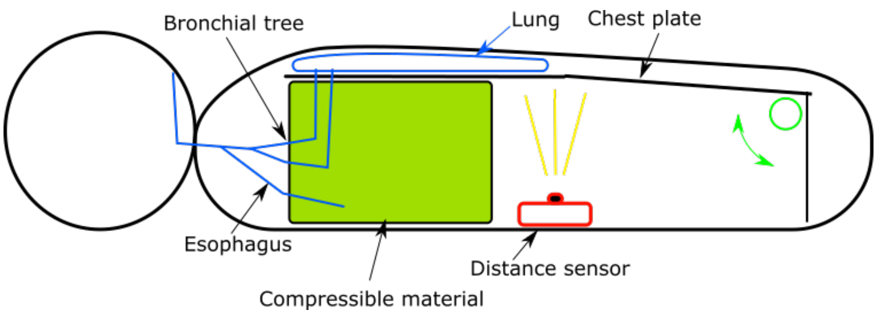


Figure 13: Alternative 3

4.4.1.4 Alternative 4

Use the head from ALS baby. Remove slidehouse, replace it with leaf spring at the bottom of the manikin.

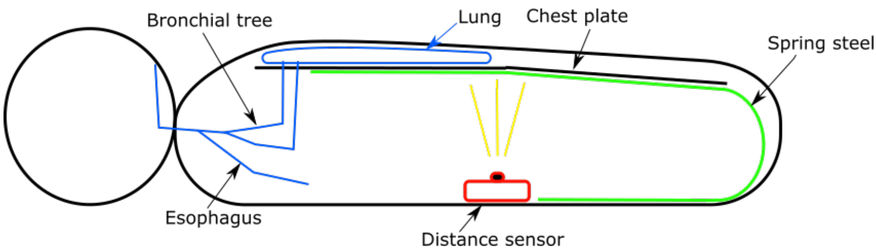


Figure 14: Alternative 4

4.5 Realistic airway

What does it mean that the airway must be realistic? It must be that realistic that it is possible to do the desired functions as described in the requirements. That means, we need to include the basic elements of an airway made with a material with similar mechanical properties as the human airway. As it should be possible to perform tracheal intubation the airway must be similar to the human airway all the way down to the right main bronchus. To get the shape of the airway as similar as to a real patient it would be a good idea to base the design on real CT data, as the company "TruCorp" have done with their airway simulator "Airsim child" (TruCorp, 2016). To make the airway even more realistic it could be possible to control the shape of the airway, replicating infections, tumors, tongue edema and gag reflex. These changes is shape of the airway could make the training more realistic and the students better prepared for patient treatment.

To make such a flexible material that could do these movements several concepts could be used. An interesting technology is artificial muscles that can generate large strains. One of the promising artificial muscles are conducting -polymers. The cross section of the actuator is seen in Figure 15. Baughman (2005) describes the artificial muscle in Figure 15 as following:

A highly twisted nanofiber yarn electrode (black) is filled with a conducting polymer or gel electrolyte (red). The conducting polymer or electrolyte does the actuation. The nanofibers provide nanometer-scale electronic connections and giant surface area for electrochemical charge injection. A counterelectrode and a porous electrode separator are also included. A liquid electrolyte (yellow) provides the electrochemically inserted solvated ions that cause actuation when a voltage is applied between the electrodes (Baughman, 2005).

Conducting-polymer artificial muscles operates at a few volts, and can gen-

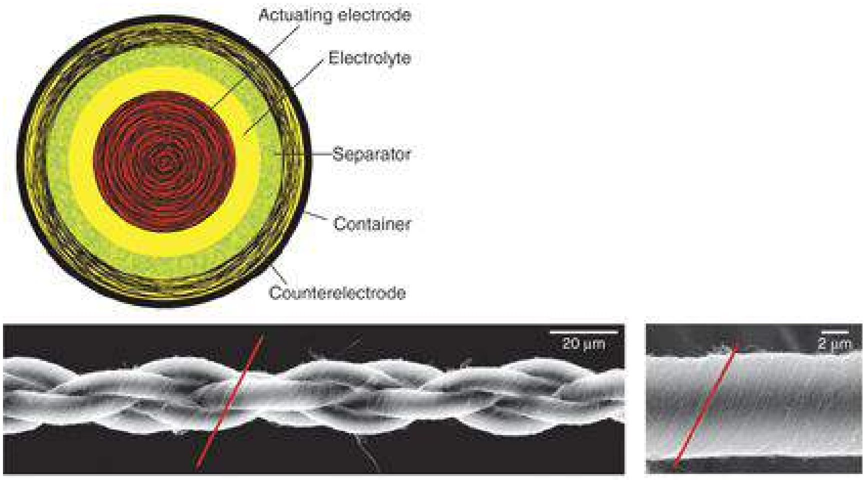


Figure 15: A proposed artificial muscle (Baughman, 2005)

erate strains up to 26%. For comparison, human muscles typically generate 20% strain (Madden et al., 2004). The technology is not fully commercialized yet, but it will be interesting to see what happens in this area in the future (Baughman, 2005).

Another way of make movement of the airway is to use mechanical objects pushing toward the airway. The electromagnets which are used as pulses in SimMan (see Figure 16) could be tested. An advantage for using these is that they are not mechanically fixed. When activated, they could minimize the airway opening, but the airway tissue will still be flexible enough to allow an intubation.

(a)

(b)

Figure 16: Electromagnetic controlled pulse

A third solution for airway movement is using air pressure to control movement of the airway. TruCorp (2016) have done this to simulate tongue edema. The edema is simply controlled by inflating the tongue.

4.6 Ventilation

4.6.1 Bilateral chest rise depending on tube placement

The concept solution which is used on ALS baby seems sufficient. It is possible to insert the tube too deep in trachea, as it ends up in right main bronchus. That gives ventilation of the right lung only, which is what happens at a patient. It is also possible to place the tube in esophagus, which makes it impossible to ventilate. That means that there is sufficient mechanical feedback. Further work can lead to digital feedback to a control unit, but there are no detected need for this.

4.6.2 Ventilation measurements

There are several conceptual possibilities to measure the volume ventilated. When considering what measurements technology to be used it is important to be aware of what kind of ventilation we shall measure. A ventilation in CPR is a transient flow of air. That means e.g. turbine flow meters which require steady state flow to have a proportional relationship between flow and rotation speed is expected to give inaccurate results. We also need to take into account that the ventilated fluid is air or oxygen, which is compressible. . Also, the tidal volume ventilated at infants is very small. A typical volume related to the weight of an infant is 9 ml/kg (Scalfaro et al., 2001).

To deal with the transient, compressible flow and low volume, pressure based measurements are suggested. The pressure based measurements rely on Bernoulli's principle which states that an increase in the speed of a fluid occurs simultaneously as a decrease in pressure or a decrease in the fluids potential energy (Bernoulli, 1738). For low pressure differences and low Mach number, compressible fluids, can be assumed to have a constant density. Then Bernoullis equation can be written as:

$$\frac{v^2}{2} + gz + \frac{p}{\rho} = constant \tag{1}$$

where:

v - is the fluid flow speed at a point on a streamline

g - is the acceleration due to gravity

z - is the elevation of the point above a reference plane

p - is the pressure at the chosen point

ρ - is the density of the fluid

Based on this knowledge several measurement system have been developed like the venturimeter, orifice plate and pitot-tube. A orifice plate version is placed in the Resusci Baby QCPR (see Figure 17a). To measure the ventilation volume based on flow data requires numerical integration which might cause some errors. There is also some uncertainty about the assumption of air having the same density at all places. The Bernoulli equation also only apply at a specific streamline. What if the flow becomes turbulent? A possibility of turbulent flow is checked by calculating Reynolds number (Re).

$$Re = \frac{\rho v L}{\mu} \tag{2}$$

where:

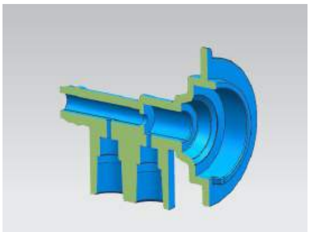
ρ - is the density of the fluid $[kg/m^3]$

v - is the fluid flow speed $[m/s]$

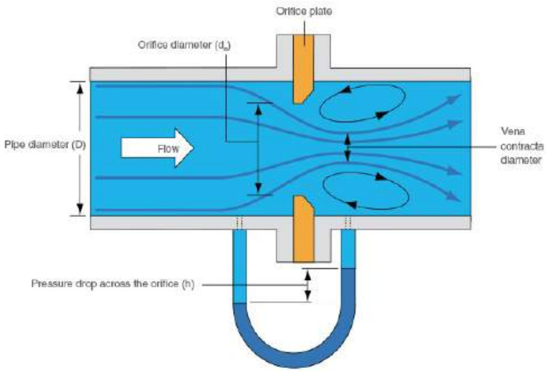
L - is a characteristic linear dimension $[m]$

μ - is the dynamic viscosity of the fluid $[kg/(m * s)]$

Inserting $\rho = 1,22kg/m^3$, $v = 1m/s$, $L = 0.002m$ and $\mu = 1,846*10^-5kg/(m*s)$ gives $Re = 132$. For flow in a pipe it is observed that for $Re < 2300$ the flow is laminar. The diameter in the calculations are taken from the hole in the orifice plate. If the flow actually is laminar around the orifice plate are unknown becuase the calculations are not considering that the sudden restriction can cause a pressure drop right behind the plate. At least considering alternatives can be wise.



(a) Cross section of existing orifice plate measurement in Resusci Baby QCPR



(b)

Figure 17: Orifice plate

So far we have only considered measurement systems that detects the flow and not measuring the volume directly. It could be possible to measure the expansion of the lung directly given the right measurement tools. By measuring the expansion of the lung it could be possible to detect the volume ventilated at all times. An alternative to test would be strain gauges. They are mainly used to measure strain in metals, but could might me possible to attach to a lung foil. The strain of the foil is expected to have a relationship to the volume ventilated. A main advantage about strain gauges is their ability to measure small strains accurately.

Another proposal is to measure the chest rise. That can be done by proximity sensors measuring the distance from the back of the manikin to the top of the chest. By applying a metal sheet on top of the lung, an inductive proximity sensor could measure the chest rise, without being affected by the non-metal parts in between. A IR proximity sensor would require a open passage between the sensor and the top of the lung/chest skin which could reflect the light back to the sensor.

The system should also determine which of the lungs that are being ventilated, so splitting the lung in two will be necessary, and connecting measurement systems to both lungs are needed.

5 Further work

Further work includes choosing promising concepts, which are described in section 4.4. Promising concepts needs to be designed, built and tested. Involving medical personnel for user testing will be interesting to get valuable feedback. For functionality testing of concepts, prototypes will be made and iterated.

5.1 Measuring ventilations

It seems like there is a potential of improving the measurement system of the ventilated air. By somehow measure expansion/strain of the lungs seems like a promising path to explore more of. Also using an induction proximity sensor will be interesting to do more testing of.

5.2 Realistic compressions

We discovered that the relationship between compression depth and force applied did not have a linear relationship on patients. Today, most manikins use a linear spring. Therefore, it will be interesting to see how we can make a progressive spring which are applicable to use in training manikins. Different types of foam and metal springs could be tested.

5.3 Realistic airway

As for today's solution there it is not possible to simulate tongue edema and infections. Developing a prototype which can change shape caused by artificial muscles, moving electromagnets and simple inflatable bulbs could be explored.

6 Conclusion

This project task should give insight to be able to develop a training manikin for infant CPR and airway management. The common practices of CPR and airway management have been found and user emphasizing have given valuable insight of what the values of practicing with training manikins are. Technologies of how to simulate CPR and airway management have been explored. It was also expected to build prototypes, build test setups, test and compare alternatives and judge concepts. In this project, the work is limited to generating concepts and evaluating them based on literature. Prototypes and testing are postponed to the master work.

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THE NORWEGIAN UNIVERSITY
OF SCIENCE AND TECHNOLOGY
DEPARTMENT OF ENGINEERING DESIGN
AND MATERIALS

PROJECT WORK FALL 2016
FOR
STUD.TECHN. Henrik Aasheim

Lærdal Medical advanced airway for baby mannequin that can be used in medical teaching

Identify, collect judge and conceptualize technologies to simulate human physiology – e.g. airway, to be able to perform nasal and oral intubation, insertion of gastric tube.

- generate concepts,
- build prototypes
- build test setups
- test and compare alternatives
- judge concept

Also, it is expected to contribute to one or more scientific publications during the project/master thesis.
The supporting coach Carlo Kriesi, the contact at Lærdal Medical is Helge Anglevik. Also the student shall collaborate with Truls Hjertnes Nygaard and Martin Steinert who are conducting the second Lærdal challenge.

Formal requirements:

Students are required to submit an A3 page describing the planned work three weeks after the project start as a pdf-file via “IPM DropIT” (http://129.241.88.67:8080/Default.aspx). A template can be found on IPM’s web-page (https://www.ntnu.edu/ipm/project-and-specialization).

Performing a risk assessment is mandatory for any experimental work. Known main activities must be risk assessed before they start, and the form must be handed in within 3 weeks after you receive the problem text. The form must be signed by your supervisor. Risk assessment is an ongoing activity, and must be carried out before starting any activity that might cause injuries or damage materials/equipment or the external environment. Copies of the signed risk assessments have to be put in the appendix of the project report.

No later than 1 week before the deadline of the final project report, you are required to submit an updated A3 page summarizing and illustrating the results obtained in the project work.

Official deadline for the delivery of the report is 13 December 2016 at 2 p.m. The final report has to be delivered at the Department’s reception (1 paper version) and via "IPM DropIT".

When evaluating the project, we take into consideration how clearly the problem is presented, the thoroughness of the report, and to which extent the student gives an independent presentation of the topic using his/her own assessments.

The report must include the signed problem text, and be written as a scientific report with summary of important findings, conclusion, literature references, table of contents, etc. Specific problems to be addressed in the project are to be stated in the beginning of the report and briefly discussed. Generally the report should not exceed thirty pages including illustrations and sketches.

Additional tables, drawings, detailed sketches, photographs, etc. can be included in an appendix at the end of the thirty page report. References to the appendix must be specified. The report should be presented so that it can be fully understood without referencing the Appendix. Figures and tables must be presented with explanations. Literature references should be indicated by means of a number in brackets in the text, and each reference should be further specified at the end of the report in a reference list. References should be specified with name of author(s) and book, title and year of publication, and page number.

Contact persons:

At the department	Knut Aasland, Carlo Kriesi
From the industry	Helge Anglevik

Knut Aasland
Supervisor

NTNU
Norges teknisk-naturvitenskapelige universitet
Institutt for produktutvikling og materialer

NTNU	Kartlegging av risikofylt aktivitet	Utarbeidet av	Nummer	Dato
HMS		HMS-avd.	HMSRV2601	22.03.2011
		Godkjent av		Erstatter
		Rektor		01.12.2006

Enhet: Institutt for produktutvikling og materialer **Dato: 15.09.2016**

Linjeleder: Torgeir Welo

Deltakere ved kartleggingen (m/ funksjon)**:** Knut Aasland,veileder./ Carlo Kriesi, Stud ass./ Henrik Aasheim, student

(Ansv. veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Kort beskrivelse av hovedaktivitet/hovedprosess: Prosjektoppgave av Henrik Aasheim «Advanced airway for baby mannequin that can be used in medical teaching»

Er oppgaven rent teoretisk? (JA/NEI)**: Nei** *«JA» betyr at veileder innestår for at oppgaven ikke inneholder noen aktiviteter som krever risikovurdering. Dersom «JA»: Beskriv kort aktiviteteten i kartleggingskjemaet under. Risikovurdering trenger ikke å fylles ut.*

Signaturer: *Ansvarlig veileder:Knut Aasland* *Student:Henrik Aasheim*

ID nr.	Aktivitet/prosess	Ansvarlig	Eksisterende dokumentasjon	Eksisterende sikringstiltak	Lov, forskrift o.l.	Kommentar
1	Bruk av Trolllabs workshop.	HAa	Romkort	Romkort		
1a	Bruk av roterende maskineri	HAa	Maskinens brukermanual	Ukjent	Ukjent	
1b	Bruk av laserkutter	HAa	Maskinens brukermanual	Ukjent	Ukjent	
1c	Bruk av 3D printer	HAa	Maskinens brukermanual	Ukjent	Ukjent	
1d	Bruk av skjæreverktøy	HAa	Ukjent			
1e	Bruk av samenføynigsmidler (lim og lignende.)	HAa	Produktets brukermanual og datablad	Datablad	Ukjent	

1f	Bruk av loddebolt	HAa	Ukjent	Ukjent	Ukjent	
2	Tilstedeværelse ved arbeid utført av andre.	Andre	Andres HMSRV2601	Andres HMSRV2601	Prosessavhengig	

NTNU	Risikovurdering	Utarbeidet av	Nummer	Dato
HMS		HMS-avd.	HMSRV2601	22.03.2011
		Godkjent av		Erstatter
		Rektor		01.12.2006

Enhet: Institutt for produktutvikling og materialer **Dato: 15.09.2016**

Linjeleder: Torgeir Welo

Deltakere ved kartleggingen (m/ funksjon): Knut Aasland,veileder./ Carlo Kriesi, Stud ass./ Henrik Aasheim, student

(Ansv. Veileder, student, evt. medveiledere, evt. andre m. kompetanse)

Risikovurderingen gjelder hovedaktivitet: Prosjektoppgave av Henrik Aasheim «Advanced airway for baby mannequin that can be used in medical teaching»

Signaturer: *Ansvarlig veileder:Knut Einar Aasland* *Student:Henrik Aasheim*

ID nr	Aktivitet fra kartleggings-skjemaet	Mulig uønsket hendelse/ belastning	Vurdering av sannsyn-lighet	Vurdering av konsekvens:				Risiko-Verdi (menn-eske)	Kommentarer/status Forslag til tiltak
			(1-5)	Menneske (A-E)	Ytre miljø (A-E)	Øk/ materiell (A-E)	Om-dømme (A-E)		
1	Bruk av Trolllabs workshop.								
1a-i	Bruk av roterende maskineri	Stor kuttskade	2	D	A	A	D	2D	Sørg for at roterende deler tilstrekkelig sikret/dekket. Vær nøye med opplæring i bruk av maskineri.
1a-ii		Liten kuttskade	3	B	A	A	A	3B	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iii		Klemskade	2	D	A	A	C	2D	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1a-iv		Flygende spon/gjenstander	3	C	A	A	B	3C	Bruk øyevern og tildekk hurtig roterende deler (Fres og lignende.)
1a-v		Feil bruk-> ødelagt utstyr	3	A	A	C	A	3C	Vær nøye med opplæring i bruk av maskineri

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1b-i	Bruk av laserkutter	Klemskade	2	D	A	A	C	2D	Vær nøye med opplæring i bruk av maskineri. Ikke ha løse klær/tilbehør på kroppen.
1b-ii		Brannskade	3	B	A	A	A	3B	Vær nøye med opplæring i bruk av maskineri. Bruk hansker ved håndtering av varme materialer.
1b-iii		Øyeskade-laser	2	D	A	A	C	2D	Bruk øyevern! Skru av laser når maskinen ved oppsett.
1b-iv		Brann	2	B	A	D	C	2B	Vær nøye med opplæring i bruk av maskin. Ha slukkeutstur tilgjengelig
1c-i	Bruk av 3D-printer	Brannskade	3	B	A	A	A	3B	Vær nøye med opplæring i bruk av maskin.
1c-ii		Innhalering av plast/ printemateriale	5	A	A	A	A	5A	Bruk åndedretsvern/ vernebriller
1c-iii		Feil bruk-> ødelagt maskineri	3	A	A	C	A	3A	Vær nøye med opplæring i bruk av maskin.
1d-i	Bruk av skjæreverktøy	Stor kuttskade	2	D	A	A	D	2D	Bruk skapre verktøy og riktig skjæreunderlag
1d-ii		Liten kuttskade	3	B	A	A	A	3B	Bruk skapre verktøy og riktig skjæreunderlag
1e-i	Bruk av samenføynigsmidler (lim og lignende.)	Eksponering på øyet	2	D	A	A	B	2D	Bruk øyevern, ha datablad tilgjengelig

1e-ii		Eksponering hud	4	A	A	A	A	4A	Bruk hansker, ha datablad tilgjengelig
1e-iii		Eksponering åndedrett	4	A	A	A	A	4A	Bruk åndedretsvært/ god ventilasjon. Ha datablad tilgjengelig.
1e-iv		Søl	4	A	B	A	A	4A	Ha papir/ rengjøringsmateriell tilgjengelig. Ha datablad tilgjengelig.
1f-i	Bruk av loddebolt	Brannskade	4	A	A	A	A	4A	Være påpasselig ved håndtering av loddebolt
2	Tilstedeværelse ved arbeid utført av andre.	Se andres risikovurdering om sikkerhet betviles.	3	C	C	C	C	3C	Hold et øye med hva som foregår rundt deg.

Sannsynlighet vurderes etter følgende kriterier:

Svært liten 1	Liten 2	Middels 3	Stor 4	Svært stor 5
1 gang pr 50 år eller sjeldnere	1 gang pr 10 år eller sjeldnere	1 gang pr år eller sjeldnere	1 gang pr måned eller sjeldnere	Skjer ukentlig

Konsekvens vurderes etter følgende kriterier:

Gradering	Menneske	Ytre miljø Vann, jord og luft	Øk/materiell	Omdømme
E **Svært Alvorlig**	Død	Svært langvarig og ikke reversibel skade	Drifts- eller aktivitetsstans >1 år.	Troverdighet og respekt betydelig og varig svekket
D **Alvorlig**	Alvorlig personskade. Mulig uførhet.	Langvarig skade. Lang restitusjonstid	Driftsstans > ½ år Aktivitetsstans i opp til 1 år	Troverdighet og respekt betydelig svekket
C **Moderat**	Alvorlig personskade.	Mindre skade og lang restitusjonstid	Drifts- eller aktivitetsstans < 1 mnd	Troverdighet og respekt svekket
B **Liten**	Skade som krever medisinsk behandling	Mindre skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1uke	Negativ påvirkning på troverdighet og respekt
A **Svært liten**	Skade som krever førstehjelp	Ubetydelig skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1dag	Liten påvirkning på troverdighet og respekt

Risikoverdi = Sannsynlighet x Konsekvens
Beregn risikoverdi for Menneske. Enheten vurderer selv om de i tillegg vil beregne risikoverdi for Ytre miljø, Økonomi/materiell og Omdømme. I så fall beregnes disse hver for seg.

Til kolonnen "Kommentarer/status, forslag til forebyggende og korrigerende tiltak":
Tiltak kan påvirke både sannsynlighet og konsekvens. Prioriter tiltak som kan forhindre at hendelsen inntreffer, dvs. sannsynlighetsreduserende tiltak foran skjerpet beredskap, dvs. konsekvensreduserende tiltak.

MATRISE FOR RISIKOVURDERINGER ved NTNU

KONSEKVENS						
KONSEKVENS	Svært alvorlig	E1	E2	E3	E4	E5
	Alvorlig	D1	D2	D3	D4	D5
	Moderat	C1	C2	C3	C4	C5
	Liten	B1	B2	B3	B4	B5
	Svært liten	A1	A2	A3	A4	A5
		Svært liten	Liten	Middels	Stor	Svært stor
		SANNSYNLIGHET				

Prinsipp over akseptkriterium. Forklaring av fargene som er brukt i risikomatrisen.

Farge	Beskrivelse
Rød	Uakseptabel risiko. Tiltak skal gjennomføres for å redusere risikoen.
Gul	Vurderingsområde. Tiltak skal vurderes.
Grønn	Akseptabel risiko. Tiltak kan vurderes ut fra andre hensyn.