Thomas Eidhamar McAllister

Development of equipment to help understand and treat whiplash injuries

Master's thesis in Mechanical engineering
Supervisor: Bjørg Margrethe Granly
Co-supervisor: Christer Westum Elverum
June 2023

Master's thesis

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MIPROD - Mechanical Engineering

Development of Equipment to Help Understand and Treat Whiplash Injuries

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Abstract

This Master's thesis project will focus on developing equipment to help understand and treat whiplash injuries. The work will be based on concepts developed in a specialization project done as a precursor to this thesis, and earlier theses done in collaboration with FPMC. The aim of the project is, to mature the concepts and reduce uncertainty pertaining to their viability.

June, 2023

Table of Contents

List of Figures

List of Tables

Glossary

Acronyms

BLDC	Brushless Direct Current
CAD	Computer Aided Design
CR	Centre of Rotation
DC	Direct Current
FDM	Fused Deposition Modeling
FPMC	Firda Physical Medical Centre
ICR	Instantaneous Centre of Rotation
MCU	Multi Cervical Unit[1]
NTNU	Norwegian university of science and technology
STL	Standard Triangle Language

Terms

Motion platform	A mechanical system that can actively or passively move through space

Units

N m	Newton Meters - Unit for Torque
N	Newtons - Unit for Force

1 Introduction

1.1 Background

Whiplash injuries are a large problem and with them comes large costs. Not only for the directly afflicted but also for society at large. A major contributing factor is that whiplash injuries can lead to full or partial work disability. In a 2021 report for the Norwegian Labour and Welfare Administration, Eirik Lamøy and Andreas Myre estimate that Norway, on average, would save 4.7 million krones per person if they are able to work rather than go into early retirement due to injury.[2] More specifically for whiplash injuries, a study from Sweden found that a whiplash injury leads to societal costs in the form of lost income and direct health sector costs. The study estimates that these costs for Sweden in 2001 totaled 500 million euros. In addition, it was found that half of those in the study who missed work due to whiplash injuries did not return to the same income level they had prior to the injury.[3]

The patient stories found on the FPMC website give some anecdotes that speak to the personal costs that can come from a whiplash injury, as well as the large benefits that can come from regained function. One patient suffered severe pain and struggled to do tasks that had been non-problematic prior to injury and was not able to work. After a few years of rehabilitation with FPMC the patient was able to return to work full-time, with pain reduced and function increased. Another patient had been reduced to working only forty percent due to consistent struggles with neck pain and headaches. After working with FPMC the patient is now almost pain-free and is able to perform work without issues.[4]

1.2 The Problem

Firda Physical Medical Center is a company that specializes in the rehabilitation of whiplash injuries. Their process includes a range of different manual therapies, but also diagnosis and training exercises aided by specialized equipment. At present, this is done using the Multi Cervical Rehabilitation System, more specifically a device known as the Multi Cervical Unit or MCU.[1]

The MCU fills most of the requirements at the moment, however, there are some limitations that are not ideal. In order to address these limitations the FPMC initiated a project with the Department of Mechanical and Industrial Engineering at NTNU, to develop a product that better fulfills their requirements. The project was first initiated back in 2014 and there have been many different proposed solutions, yet none have reached a satisfactory level of functionality, hence the continuation of the project.

In a project done as a precursor to this thesis, hereafter referred to as the specialization project (A), the solutions proposed in earlier master projects done with FPMC were looked at and evaluated. This was done in an effort to determine what worked, what didn't, and to what degree a potential implementation could be possible. Based on this information, some new concepts were generated in addition to two more promising existing concepts. The set of concepts was then evaluated based on their fulfillment of performance criteria weighted to relevant stakeholder interests. There were two concepts that rose above the rest, and seemed to be most promising. These two concepts will be further explored in this master's thesis project.

1.3 Agenda

In this Master's thesis project, the most promising concepts from the specialization project, included in appendix A, will be further explored. The intention is to gain a better understanding of the concepts and the design challenges relating to them, reducing uncertainty pertaining to the viability of a final product.

In section 2, the theory applied in the Master's thesis projects is presented. Section 3 describes the method used and section 4 summarizes the work done in the specialization project (Appendix A) and discusses relevant conclusions. In section 5.2, the Masnak concept is described and explored. Here, an emphasis is put on the math behind Masnak's movement and force control, as well as initial considerations for actuators. Further, in section 5.3, the Gyro concept is described and explored. Here, an emphasis is put on the possibility of cable loading and the implications of minimal resistance CR axis movement. In section 6, both concepts are re-evaluated using the same criteria from the specialization project before the question of their viability is revisited in sections 7 and 8.

2 Theory

2.1 Law of Cosines

The Law of Cosines, also known as the cosine rule, is a trigonometric formula used to solve triangles that do not have a right angle. It relates the lengths of the sides of a triangle to the cosine of one of its angles. The formula for the law of cosines is given in equation 1.

$$a^2 = b^2 + c^2 - 2bc \cdot \cos(A) \tag{1}$$

In equation 1, a, b, and c are the lengths of the sides of a triangle, and A is the angle opposite to side a. The law of cosines can be used to find the length of any side of a triangle, or the measure of any angle in a triangle, given that the side lengths are known, or the measure of any side, given the two other sides and the angle between them is known.

The cosine rule is derived from the Pythagorean theorem, which only applies to right triangles. The law of cosines extends the Pythagorean theorem to any triangle, including those that do not have a right angle. [5]

2.2 Change of Basis

Changing the basis of a vector involves expressing the vector's components in terms of a different set of basis vectors. In other words, it is a way of transforming the vector from one coordinate system to another.

Suppose a vector $\mathbf{v}$ in the standard basis of $\mathbb{R}^2$ with coordinates $\begin{pmatrix}3 & 4\end{pmatrix}$. This vector can be expressed in terms of a different basis, say $\mathbf{b}_1, \mathbf{b}_2$, by finding the coefficients x_1 and x_2 such that the vector v is equal to the sum of the new basis vector scaled by coefficients x_1 and x_2 as in equation 2.

$$\mathbf{v} = x_1\mathbf{b}_1 + x_2\mathbf{b}_2 \tag{2}$$

These coefficients are simply the coordinates of $\mathbf{v}$ with respect to the new basis vectors. To find them, one can use the fact that relation in equation3 where the matrix on the left is the inverse of the matrix whose columns are the new basis vectors.

$$\begin{pmatrix}x_1 & x_2\end{pmatrix} = \begin{pmatrix}\mathbf{b}_1 & \mathbf{b}_2\end{pmatrix}^{-1} \begin{pmatrix}3 & 4\end{pmatrix} \tag{3}$$

Once one has the coefficients x_1 and x_2, the vector $\mathbf{v}$ can be expressed in terms of the new basis as in equation 2. [6]

2.3 Estimating the ICR from Point Path Coordinates

To estimate the instantaneous center of rotation (ICR) throughout the movement of a point, a technique called the Instantaneous Center of Rotation Method can be used. This method involves analyzing the motion of the point and identifying the center of rotation at each instant.

To estimate the coordinates of the instantaneous center of rotation of a point, a technique which involves analyzing the change in position from point to point and identifying the center of rotation at each instant can be utilized. The technique requires at least three separate points which are not collinear. Given this the process of estimation is as follows.

1. Collect the x and y coordinates of the points representing the trajectory.
2. Choose three consecutive points from the trajectory that are not collinear. They will be referred to as P1, P2, and P3.
3. Calculate the slopes of the lines formed by $P_1 - P_2$ and $P_2 - P_3$. Let's call them m_1 and m_2.
4. Calculate the coordinates of the midpoint between P_1 and P_2. Let's call them mP_{12}.
5. Calculate the coordinates of the midpoint between P_2 and P_3. Let's call them mP_{23}.
6. Calculate the slopes of the perpendicular bisectors of the line segments $P_1 - P_2$ and $P_2 - P_3$. Let's call them pS_{12} and pS_{23}.
7. Calculate the y-intercepts of the perpendicular bisectors. Let's call them yI_{12} and yI_{23}.
8. Solve the equations of the perpendicular bisectors to find the x and y coordinates of the ICR:
9. The estimated coordinates of the ICR at that particular instant are given by (icr_x, icr_y).
10. Repeat steps 2-9 for subsequent sets of three consecutive points along the trajectory to estimate the ICR coordinates at different instants.

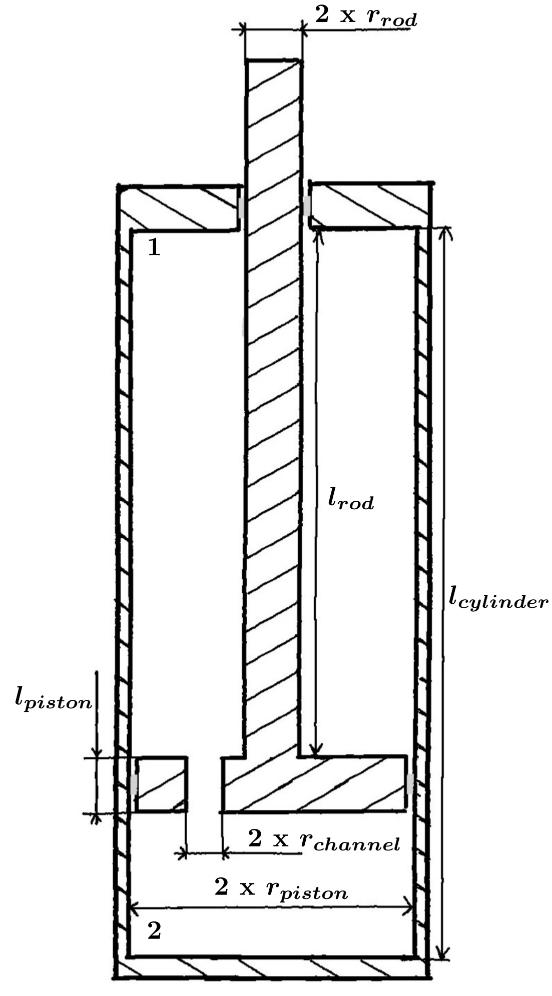
$$
\begin{gathered}
m_1 = \frac{y_2 - y_1}{x_2 - x_1} \qquad m_2 = \frac{y_3 - y_2}{x_3 - x_2} \\
mP_{12} = \left(\frac{x_1 + x_2}{2}, \frac{y_1 + y_2}{2}\right) \qquad mP_{23} = \left(\frac{x_2 + x_3}{2}, \frac{y_2 + y_3}{2}\right) \\
pS_{12} = -\frac{1}{m_1} \qquad pS_{23} = -\frac{1}{m_2} \\
yI_{12} = mP_{12} - pS_{12} \cdot mP_{12} \qquad yI_{23} = mP_{23} - pS_{23} \cdot mP_{23} \\
ICR_x = \frac{yI_{23} - yI_{12}}{pS_{12} - pS_{23}} \qquad ICR_y = pS_{12} \cdot ICR_x + yI_{12}
\end{gathered} \tag{4}
$$

The accuracy of the estimated ICR coordinates will depend on the quality and density of the data points in the trajectory. It will also work better with smooth regular movements as jitter in the data could cause the estimate to fluctuate wildly. It is also vital to ensure that the chosen points are not collinear as this would result in no ICR.

2.4 Approximate Constant Force Mechanisms

2.4.1 Gas Springs

Gas springs are used in office chairs, car doors, medical and fitness equipment, electric blinds and canopies. In its simplest form, a gas spring consists of a cylinder, a rod, and a piston, which moves between contraction and extension. The piston is sealed against the inner wall of the cylinder and the rod is sealed against a hole in the end of the cylinder. The cylinder usually contains nitrogen gas under pressure. During the compression phase, the nitrogen passes from the chamber below the piston (2) to the upper chamber (1) through one or more channels in the piston. The piston is biased towards extension as the area of the piston on the upper side of the chamber (Equation 5) is smaller than the area on the lower side of the chamber (Equation 6). When the piston is stationary, the pressure is equal in both chambers causing a force imbalance due to the different areas on either side. This force is defined in equation 7. When moving dynamically the piston will also experience friction in the seals, and resistance to the flow of gas through the channels meaning there will be some extra force resisting the motion.[7]



$$A_1 = \pi({r_{piston}}^2 - {r_{rod}}^2 - {r_{chanel}}^2) \quad (5)$$

$$A_2 = \pi({r_{piston}}^2 - {r_{chanel}}^2) \quad (6)$$

$$F_{static} = p(A_B - A_A) = p\pi {r_{rod}}^2 \quad (7)$$

Figure 1: Gas Spring

The advantage of gas springs over coil springs is that they have a more consistent resistance force regardless of deflection. They do, however, not provide an entirely consistent force as the volume changes, the piston rod fills more or less of the cylinder volume. Equation 8 shows how the cylinder volume changes depending on the length of the rod that is within the cylinder. Assuming an ideal gas, the pressure of the gas enclosed within the cylinder is given by equation 9, where n is the molar amount of substance, in this case, nitrogen, R is the ideal gas constant and T is the gas temperature in Kelvin. This results in the static force exerted by the gas spring being given by equation 10.

$$V = \pi {r_{piston}}^2 l_{cylinder} - \pi({r_{piston}}^2 - {r_{chamber}}^2) l_{piston} - \pi {r_{rod}}^2 l_{rod} \tag{8}$$

$$p = \frac{nRT}{V} \tag{9}$$

[8]

$$F_{static} = \frac{nRT\pi {r_{rod}}^2}{\pi {r_{piston}}^2 l_{cylinder} - \pi({r_{piston}}^2 - {r_{chamber}}^2) l_{piston} - \pi {r_{rod}}^2 l_{rod}} \tag{10}$$

2.4.2 Two Spring Mechanism

In the paper *Compliant constant-force mechanism with a variable output for micro/macro applications* [9] by Nahar and Sugar, it is described a constant force mechanism with one degree of freedom using two sliders connected by a rigid link. The sliders are constrained such that they slide perpendicular to each other at all times. The rigid link is connected to the sliders by rotary joints. Assuming no friction, that the stiffness and uncompressed length of the two springs is equal, and that the sliders are placed such that they are in line when the springs are uncompressed as in figure 2, the force output should be constant regardless of deflection.

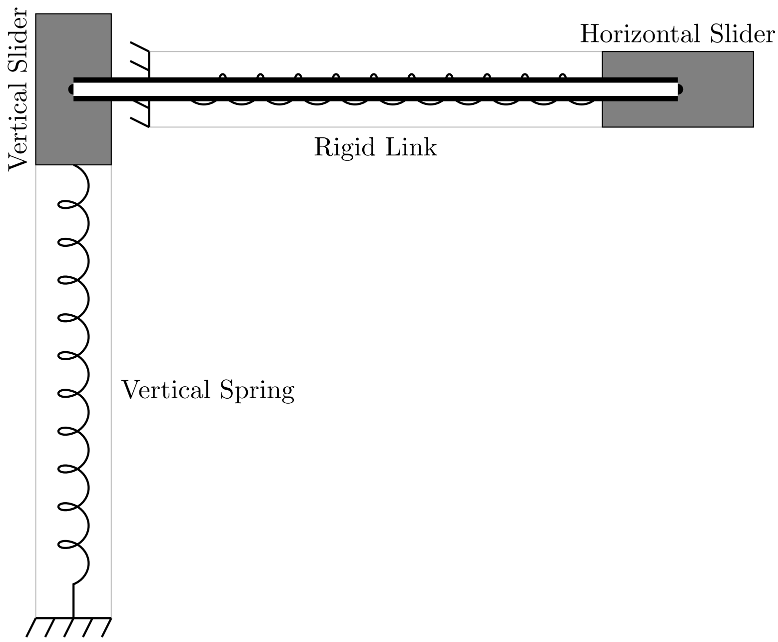
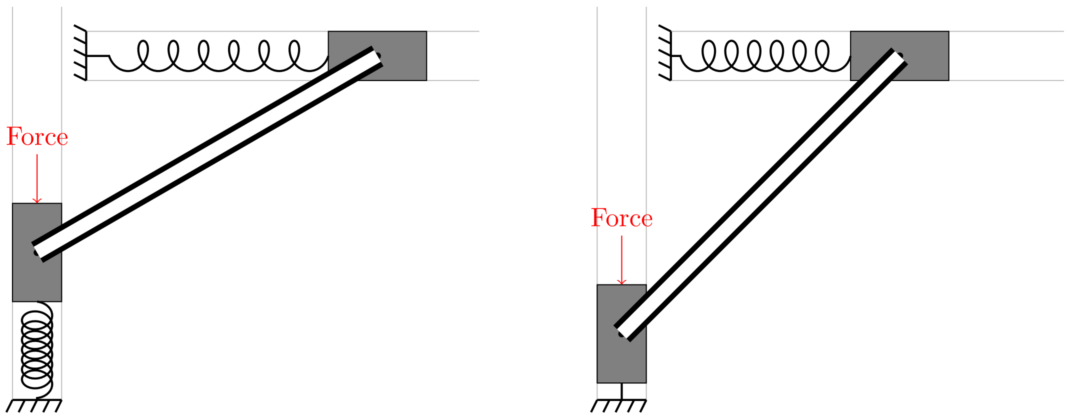


Figure 2: The constant force mechanism in the initial stable position

In practice, Nahar and Sugar did not achieve perfectly flat force curves as friction and the components' inertia diminished the output force below the theoretical value, especially at the beginning of the stroke. Despite this, the force was not far off from the desired value when the mechanism was around the middle of its stroke.



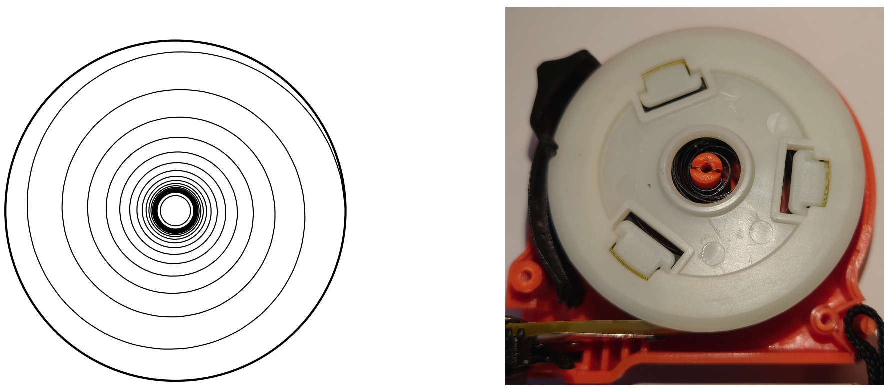
(a) Rigid link deflected 30°

(b) Rigid link defelcted 45°

Figure 3: Constant force Mechanism at two different deflections

2.4.3 Constant Force Helical Springs

Constant force helical springs, or just constant force springs, do not actually provide a constant force, but have a force output that does not change all that much throughout a portion of the angular scope of the spring. There are many types of constant force springs, but most of them consist of a spring steel strip that is coiled up. One end, typically the inner end of the coil, is then fixed to a shaft. The outer end is then either pulled out tangentially to the coil providing a "constant" resistance as the strip wants to retain its shape, or the outer end of the coil is fixed to a drum (Figure 4) providing a "constant" torque. The drum can then be attached to a pulley that then can provide a "constant" force to a cord. The force provided is in practice not constant, and is the least consistent as the coil approaches its equilibrium state and most consistent while it is maximally coiled. [10] Although these constant force springs fail to deliver on the promise of their name, they can provide something close enough for many applications as long as they are kept within the more consistent region of their full stroke. Such applications include tape measures, blinds, height-adjustable appliances, door closers, cable retractors, and toys.



(a) Sketch of helical spring within a drum

(b) Drum containing a constant force spring from a tape measure

Figure 4: Constant force spring

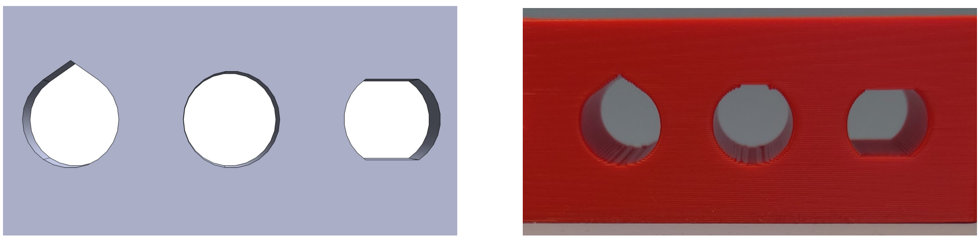
2.5 Design for FDM 3D Printing

Fused Deposition Modeling (FDM) is an additive manufacturing technology that utilizes a thermoplastic filament as a raw material. [11] In this process, the filament is heated and melted through a nozzle and deposited in a precise pattern, layer by layer, to create a three-dimensional object. FDM 3D printing offers many advantages in rapid prototyping, including the ability to produce functional prototypes quickly and cost-effectively with intricate geometries. FDM technology allows for the fabrication of complex parts with high accuracy, and with the ability to make rapid design changes, thus making it easier for engineers to optimize their designs for manufacturing. Additionally, the use of a variety of thermoplastic materials with different mechanical and physical properties allows for the creation of parts with specific attributes suited for a wide range of applications.

Despite its many benefits, FDM 3D printing has certain limitations when it comes to geometries that can be printed. The technology's layer-by-layer approach can result in visible layer lines and other surface imperfections, which may limit the types of geometries that can be printed with a high degree of accuracy and surface quality. Overhanging and bridging features, in particular, can pose challenges due to the need for support structures or other strategies to ensure proper adhesion and stability during the printing process. Overhang angles are particularly important to consider, as steep overhangs may require more support structures, or may even be impossible to print without distortion or collapse. To address these limitations, slicers – the software that generates the G-code that controls the 3D printer – can use various strategies such as generating support structures, adjusting the orientation of the part, optimizing the print settings, and other methods to improve the print quality of complex geometries with overhangs. Despite these limitations, FDM 3D printing remains a valuable technology for rapid prototyping and small-scale production of parts with complex geometries.

2.5.1 Minimal Supports

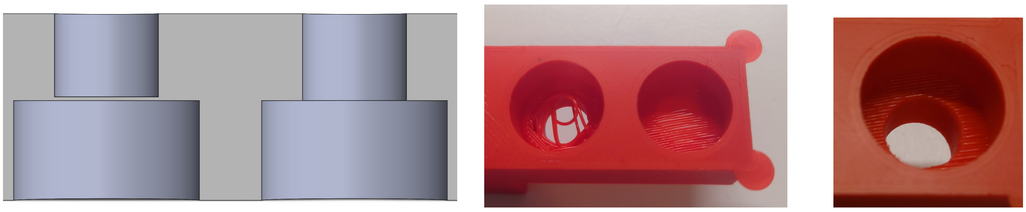
One type of feature that often is necessary, are horizontally printed holes. These can cause issues near the top edge of the hole when the overhang angle approaches zero. To resolve this without the use of supports one can alter the hole geometry. In figure 5a, a couple of options are shown. In the center, there is a regular circular hole. To the left, the upper edge of the hole is altered to allow for a printable overhang. To the right, the upper and lower edges of the hole are bridged for easy printing. This solution, however, requires an axle that is adjusted accordingly. In figure 5b the results of the implementation of these techniques can be seen. The center hole with no adjustments is slightly squared on the upper edge which would not allow a circular shaft with the correct nominal diameter to slide in easily.



(a) Modeled (b) Printed

Figure 5: Hole alterations for easier horizontal printing.

If unsupported overhangs are required, bridging can be a great option. However, the finished part geometry does not always lend itself to this. This can often easily be altered by the implementation of a sacrificial surface. This can be a thin strip that allows for the machine to bridge where it previously couldn't, while being quicker to remove and leaving a better surface finish than standard slicer generated supports. An example of this can be seen in figures 6a and 6b. The first shows a cross-section of a shoulder hole with and without a sacrificial surface, and the second shows the printing results. Figure 6c shows the printed result after a few seconds of post processing to remove the sacrificial surface.



(a) Modeled (b) Printed (c) Post processed

Figure 6: Holes for Shoulder bolts with unsupported surface

2.5.2 Bed Adhesion and Warping

Bed adhesion is vital for a successful print. A factor that can affect adhesion and warping in FDM 3D printing is the presence of sharp corners in the printed part that touch the build plate. When a sharp corner is printed directly onto the build plate, it can cause stress concentration, thus increasing the risk of warping or detachment during printing. To address this issue, designers can incorporate fillets or chamfers into the model to reduce stress concentration at corners and improve adhesion. Additionally, increasing the build plate temperature and using a suitable adhesive or surface treatment can also help to promote adhesion and reduce warping. Proper calibration and adjustment of the print settings, including the nozzle height and print speed, can also help to improve the adhesion and stability of the printed part. If sharp corners are a necessity, one can model some small circles at the corners, as can be seen in the figure 6b. These circles are one or two layers thick which allows for easy removal, while still avoiding the stress concentrations that occur around sharp corners. By taking these factors into consideration and incorporating appropriate features into the model and printing process, designers and engineers can achieve better adhesion and minimize warping, resulting in higher quality FDM 3D prints.

2.5.3 An-isotropic Strength Properties

Parts produced by FDM 3D printing tend to be stronger within the slice plane, as adhesion between the layers is weaker than the strength of the material strands. The proportional strength varies with different parameters such as print speed, extrusion temperature, material, and cooling fan speeds. If one is conscious of this phenomenon during design, print design, and orientation can be chosen to optimize the strength where it is needed the most.

2.5.4 Accuracy and Tolerances

STL files lack precision when defining curves. When an STL file is generated from a 3D model, it is done by lines between adjacent points on the object surface creating many triangles. The spacing of these points is dependent on the software settings. It is usually defined to keep error below a certain threshold, meaning tighter curves will require more points, thus more numerous and smaller triangles. This is still, however, an approximation, resulting in the effective diameter of a circular profile will be off. For internal curves, the clearance will be less than on the original model, while some material will be missing in places on external curves. Figure 7 illustrates how a circular profile may be approximated.

Figure 7: STL approximation of circular geometry

Printed part tolerances are also limited by the physical consequences of the printing process itself. Missing extruder calibration, inconsistent filament diameter, flex in belt drives, play in the axes, the squareness of axes, bed leveling and vibrations in the machine can all play a role in altering the dimensions of the final part. All of this means FDM 3D printing accuracy is not great. This requires clearance to be larger for parts that need to fit together and prevents the manufacturing of parts that require tight tolerances, at least without post-processing.

2.6 DC Motor Torque Control

Some applications call for DC motor torque to be controlled independently of speed. In these cases, one can control the motor torque by regulating the current draw. This is a result of the fact that the torque output of DC motors is roughly proportional to the current draw, assuming constant voltage, meaning a current control circuit is effectively a torque control circuit. [12] In the paper *Constant Current Models of Brushless DC Motor* by Krzysztof Krykowski and Janusz Hetmańczyk [13], it was investigated whether this torque current relationship could be modeled accurately. It was concluded that this was indeed the case, meaning that a torque control drive regardless of speed and direction should be an achievable goal.

2.7 BLDC Motors VS Stepper motors

Stepper motors and BLDC motors are two common types of electric motors. They both work through the interaction of a generated magnetic field with permanent magnets on the rotor. They also both require drive circuits and can change rotation direction by altering the order of drive circuit excitation phases. They do, however, have quite a few differences.

Stepper motors have better torque capabilities at lower speeds but tend to be limited in speed capabilities. They also tend to be more noisy, on the other hand, they are very precise in their movements. DC motors tend to be smaller and lighter, and can also have comparable precision to a stepper motor if the correct control circuitry or an encoder is used. They can also vastly improve their low-torque capabilities with gearing, which is essentially what a servo motor is. DC motors also tend to handle running continuously better, as stepper motors can get quite hot. [12]

2.8 Linear Actuators

Linear actuators come in many forms but can be roughly categorized into three different groups, namely electromechanical actuators, pneumatic actuators, and hydraulic actuators. Hydraulic actuators tend to be the most powerful and offer great precision, as the fluid used, generally, oil is pretty much incompressible. They do, however, require a tank, pump and return lines, which can get expensive and loud making it a poor fit for this application. Pneumatic actuators are generally smaller and lighter than hydraulic actuators and do not require return lines as they run on air. However, air is a compressible fluid, which means that they are not as precise in their movements as hydraulics. The final common type of linear actuator to be addressed is the electromechanical linear actuator. One common actuator that falls into this category is the ball screw-driven actuator. The ball screw converts the rotational motion of the electric motor into the linear motion of the ball nut. This is not dissimilar to a lead screw mechanism, although, they have much less frictional losses. Both types, however, can move with high precision and repeatability. They can also be quite fast when paired with a motor that has adequate power.

3 Method

The work done in the specialization project yielded two concepts that merited further investigation. This was the Masnak concept from a previous Master's thesis [14] and the Gyro concept generated during the specialization project (Appendix A). The aim of this Master's thesis project is thus to develop the concepts further and identify design challenges and propose solutions. The goal is to reduce uncertainty as to whether the concepts can become viable candidates to replace the current equipment used by FPMC in whiplash injury treatment, namely the MCU from BTE technologies[1].

3.1 Simple Prototypes to Better Understand Concepts

Initially, simple prototypes were made in order to not only get an understanding of the simple mechanisms and how they would move, but also to help communicate ideas in a meeting that was held with the Firda representative. At this stage, the ideas behind the concepts and their functions were presented, and feedback was given on whether the functions aligned with their requirements.

3.2 Exploring Possible Solutions to Accomplish Concept Goals

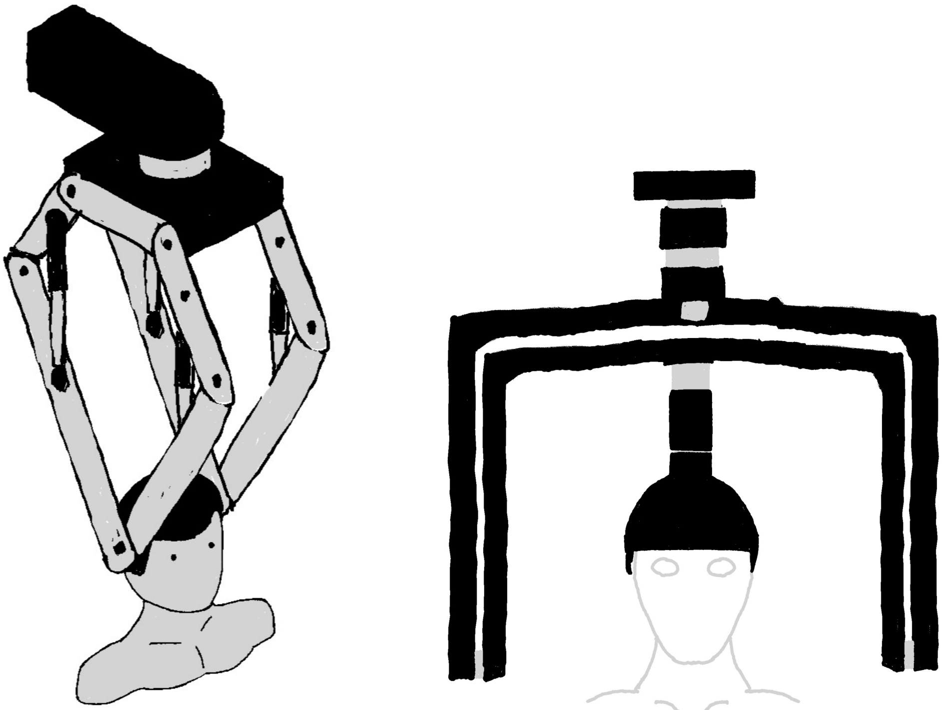
The next step was to take a proper deep dive into the concepts. The Masnak concept was more flushed out to begin with, as it was proposed in an earlier project. However, the specifics around reactive movement and force control were not properly defined, so this was a priority. The gyro concept required specificity around how the mechanisms could potentially work together. In addition, potential solutions for mechanical loading and free axis mechanisms were provided and analyzed.

3.3 Re-evaluating Concepts

Based on the information gained in previous steps, the concepts were then re-evaluated on the criteria identified in the specialization project. This was done in order to see if they still held promise when compared against the MCU from BTE technologies[1].

4 Specialization Project

During the specialization project (Appendix A), many concepts were explored. Among the concepts explored, there were two that seemed to be the most promising. The first was the concept named the Masnak in the previous Master's thesis *Utvikling av apparat for behandling av nakkeskadde* [14]. The second was the Gyro concept that was developed in the specialization project. It was designed to retain many of the features of the MCU, that is used today while aiming to solve some of the machine's shortcomings that were brought up during correspondence with Firda [15]. Some of the earliest sketches of the two concepts created for the specialization project are shown in figure 8.



(a) Masnak (b) Gyro-base

Figure 8: Concepts

Figure 8a shows the Masnak concept consisting of two five-bar trusses. Each truss is joined together in a pentagon, where two corners are fixed to a main hub that can rotate. The two corners adjacent to the two fixed ones are free, while the final corner is connected to a head fixture. This final corner is moved through space by altering the angle between the two linkages on either side. Here, this angle change is visualized to be controlled by linear actuators connected to the links, changing the angle by changing their length. Although, this could alternatively be accomplished by a motor and gearbox in the linkage points themselves.

The reason the Masnak was found to be one of the most promising in the specialization project is that it strikes a good balance of retaining a lot of possible functionality while avoiding being overly complex. Increased complexity often introduces a bunch of new potential issues that need to be resolved, so is best avoided if possible.

Figure 8b shows the most promising concept developed within the specialization project. Like the MCU used currently, it has two major rotational axes that facilitate the macro movements of the Human head. One of them is placed in line with the neck allowing for rotation, while the other is placed perpendicular to the neck allowing tilt in any direction, depending on the orientation of the other axis. What separates it from the MCU is the inclusion of additional linear axes that allow for the movement of the rotational axes, and thus the center of rotation, to travel as the head moves. This means it can avoid constraining the freedom to move more naturally, as is the issue with the current equipment.

One of the main reasons the Gyro concept was judged to be so promising is that it shares many key aspects with the tried and tested MCU. This gives some indication that the concept could work. Also, the added components had no obvious issues that would hinder their effective implementation. In addition, it added some key functionality FPMC had requested. This balance of familiarity and increased capability pushed the Gyro concept to the top of the heap.

The conclusion of the specialization project, was that both concepts had potential. There was, however, still some uncertainty as to their ultimate viability. The goal of this Master's thesis project is to address this by exploring and, hopefully, answering lingering questions to reduce the uncertainty surrounding the viability of the concepts.

5 Development

5.1 Flushing Out Concepts

To systematically evaluate the concepts, a methodology to better establish their individual feasibility was required. n the specialization project, concepts were evaluated by looking at different applications of similar technologies and considering the external requirements along with their implications for the engineering process. This was a useful strategy as it allowed for the narrowing down of possible solutions, forgoing the huge time investment that would be required to thoroughly test every single concept. However, now that the set of solutions is narrowed, time is no longer as constraining. Therefore, more time can be allocated to exploration with higher efficacy, which is necessary for development to continue. First though, the uncertainties regarding the concepts that require addressing need to be identified. Further, the uncertainty regarding the aspects identified needs to be addressed.

5.2 Masnak Concept

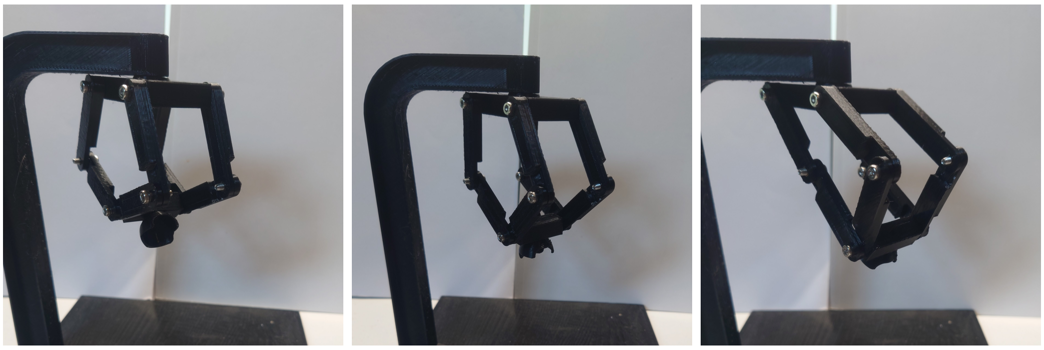


Figure 9: Masnak demo model

The Masnak has one movement axis that corresponds well with that of the neck, namely the rotational axis. The rest of the neck's degrees of freedom are facilitated by a mechanism that allows for planar movement. As long as the movement space envelopes the arch of a mounting point on the head during tilt, the Masnak should be able to cover the entire head movement space.

In table 1, the combined scores given to the Masnak Solution in the specialization project(A), as well as the weighting of the performance categories, are shown. The scores achieved do, however, have a high degree of uncertainty to them. To progress the design, this uncertainty needs to be reduced. Different performance criteria scores have different levels of uncertainty and require different types of tests to explore.

Masnak Evaluation Scores

Acronym	Criteria	Score	Weight
ROM	Range of motion	5	4.7
DOF	Degrees of freedom	4	10.0
RSA	Resistance Specificity and Adaptability	4	7.7
MCC	Movement Constraint and Control	3	7.0
SFT	Spacial and Force Tracking	5	4.7
PBI	Portability and Installation	1	7.3
UI	User Interface	3	5.7
CMPD	Complexity of Design	3	2.7
DUNC	Design Uncertainty	4	2.7
PS	Patient Safety	4	13.3
PSS	Patient's Perceived Safety	4	10.0
EE	Efficacy and Efficiency	4	10.0
DCC	Design Challenge Compatibility	4	6.0
	Cost	1	8.3
Total		347	100.0

Table 1: Masnak evaluation scores from the specialization project included in appendix A

One potential question relates to whether the mechanism can cover the full range of motion of the neck for most or all patients, and whether the movement could be actively controlled. Ole Jakob Berg and Øystein Kalve Sunde explored this question during their Master's thesis project [14]Section 5.6.3. What they did not address, however, was whether actuator force/torque could be applied and regulated to give consistent resistance in response to the movement of the head. A result of the mechanism's construction is that the force or torque of the actuators creating resistance must be dynamically adjusted if the tilting torque experienced by the patient's neck is to be consistent, even if moving in a straight line or a perfectly radial arc. This problem is one that requires further inquiry.

5.2.1 Masnak - Term Definitions

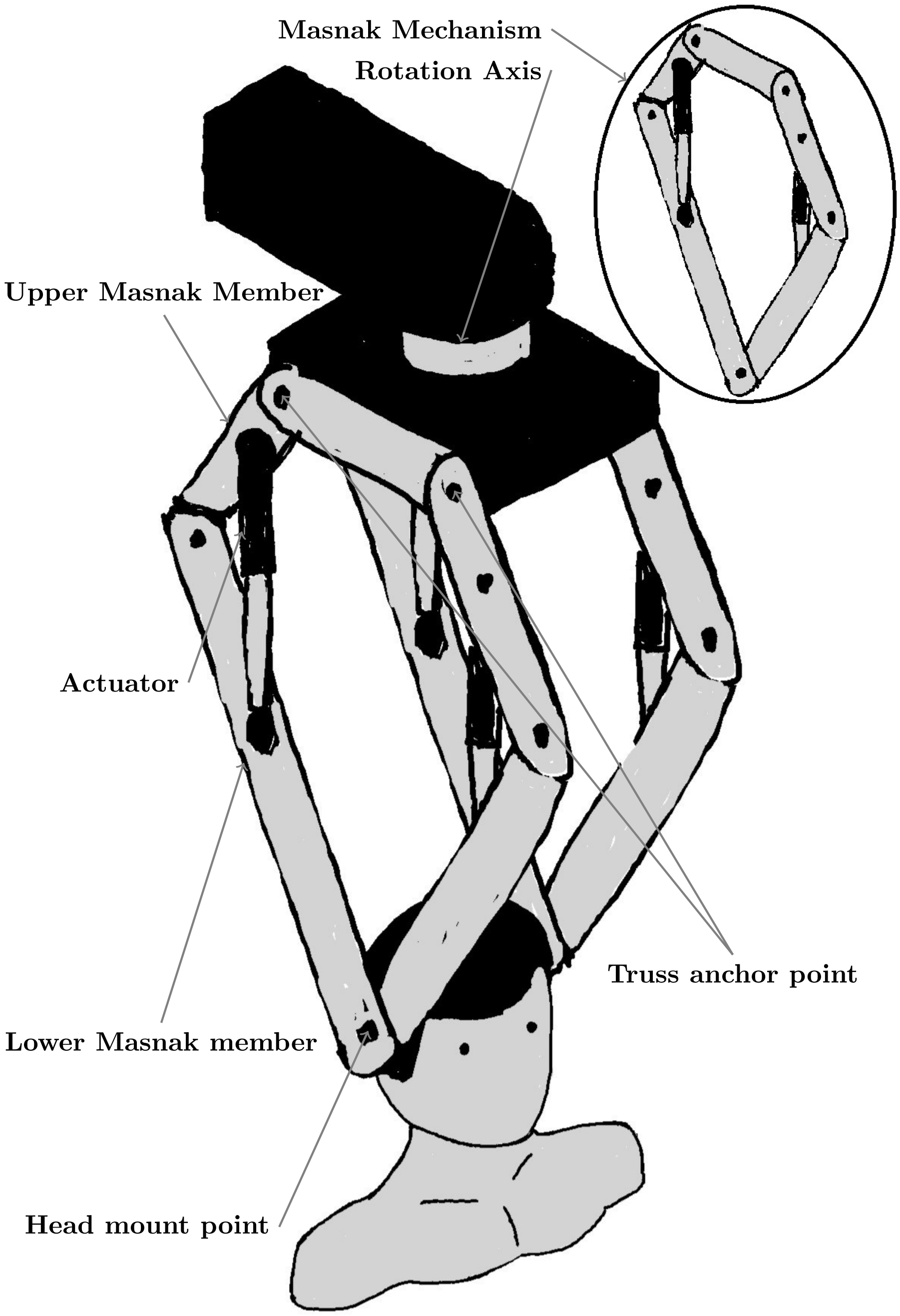
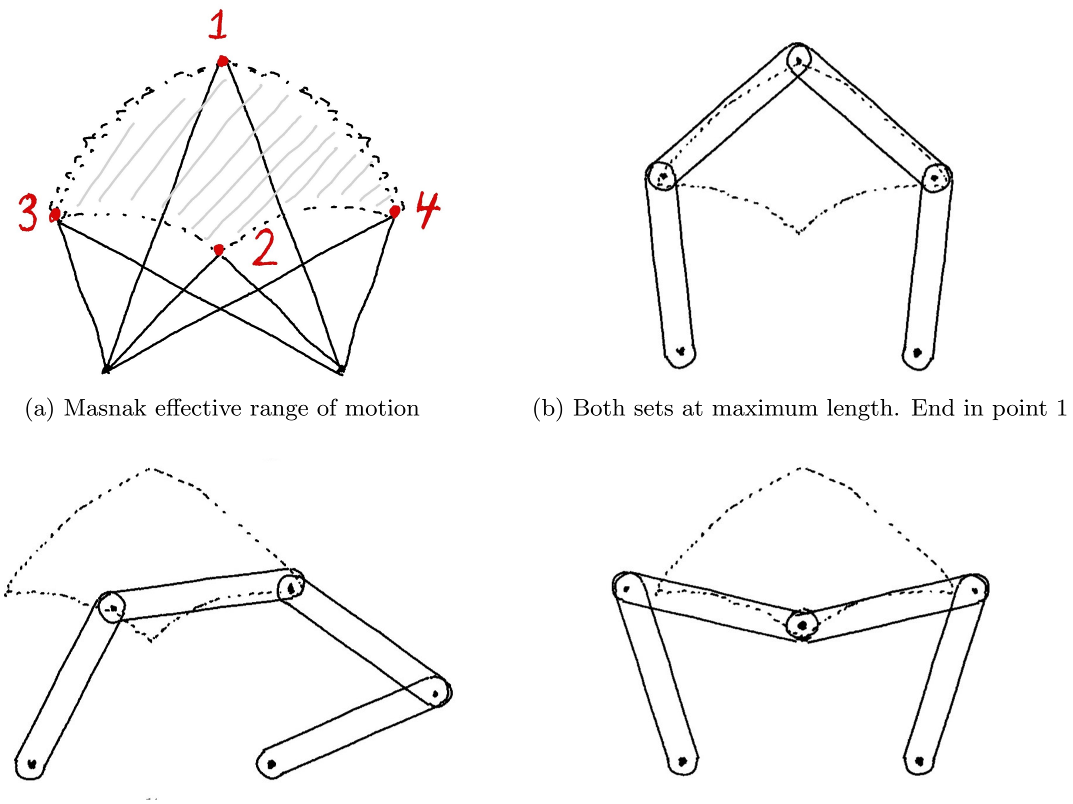


Figure 10: Masnak component terms

The Masnak mechanism refers to the motion platform of the Masnak concept that allows for planar movement. The rotation axis is the term used for the main rotational axis that allows for the loaded rotation of the occupant's head. This axis is able to be selectively decoupled and fixed to the loading mechanism, to allow for adjustment of tilt direction. Upper Masnak member refers to the four links in the Masnak mechanism that are connected directly to the truss anchors. Lower Masnak member is used for linkages that connect the head mount point to the upper Masnak members. An actuator is a mechanical component that can produce a movement with a given force in response to an input. Finally, the head mount point refers to the point at which the Masnak mechanism is connected to the module which secures the head of the occupant.

5.2.2 Positional Control

Although the question of positional control was tested previously, it is required to touch upon it again in order to gain the insight required to explore force regulation properly. Force regulation is covered in section 5.2.3. The Masnak concept accomplishes planar movement with the five-link Masnak mechanism. It consists of two pairs of links changing their combined length by altering the angle between them. The eventual movement space is constrained by the maximum and minimum effective combined lengths. In figure 11a this is visualized with the arc segments from points 1 to 3 and points 1 to 4, having a radius equal to the maximum combined length. The arc segments from points 2 to 3 and points 2 to 4, have a radius equal to the minimum combined length. In this case, the two sides are assumed to have an equal span of lengths. Figures 11b, 11c, and 11d show three positions at the boundary of the total movement space, those being a state with both sides at their maximum length, a state with one side at it's maximum length and the other at it's minimum length, and finally a state with both sides at minimum length.



(a) Masnak effective range of motion

(b) Both sets at maximum length. End in point 1

(c) One at max and one at min. End in point 4

(d) Both sets at minimum length. End in point 2

Figure 11: Masnak movement space

The two anchoring points and the endpoint create a triangle. If the variable side lengths and the distance between the anchoring points are known, then the coordinates of the endpoint can be calculated using the law of cosines [5]. Figure 12 shows the relevant lengths and angles, and the symbols used will be used throughout the section to refer to them.

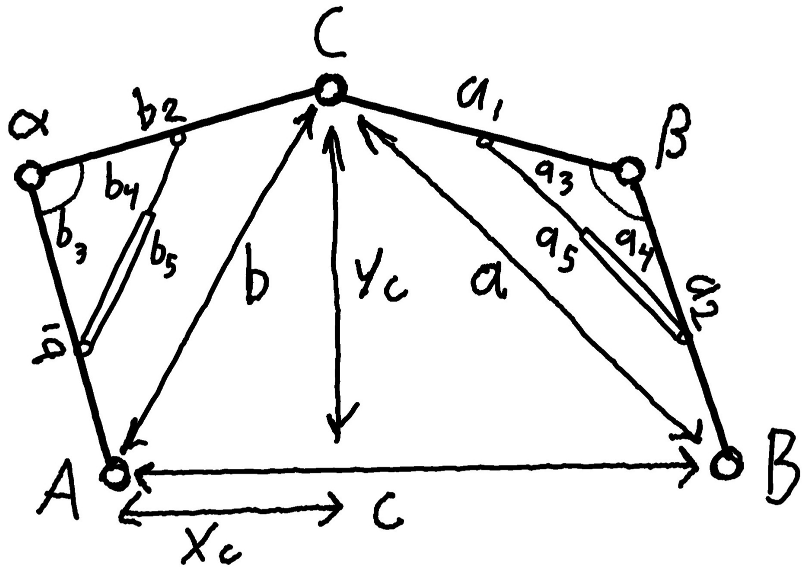


Figure 12: Triangle created by Masnak anchor points A and B and actuating point C. The triangles created by the links on the two sides are also included.

$$
\begin{gathered}
a^2 = b^2 + c^2 - 2bc \cdot \cos(A) \\
\frac{b^2 + c^2 - a^2}{2bc} = cos(A) \\
A = \arccos\left(\frac{b^2 + c^2 - a^2}{2bc}\right)
\end{gathered}
\tag{11}
$$

In equation 11, a relation between the length a and the angle A, between line b and line c, is shown. This is then used in equation 12 to calculate the Cartesian coordinates of point C, given that the origin is placed at point A and the y-axis co-linear with line c.

$$
\begin{gathered}
x_C = \cos(A) \cdot b = \frac{b^2 + c^2 - a^2}{2c} \\
y_C = \sin(A) \cdot b = \sin\left(\arccos\left(\frac{b^2 + c^2 - a^2}{2bc}\right)\right) \cdot b
\end{gathered}
\tag{12}
$$

As seen in figure 12, the lengths $a_{1,2}$ and $b_{1,2}$ are fixed and represent the lengths of the links. The lengths a and b are variable and are known through the length of the individual linkages $a_{1,2}$ and $b_{1,2}$, and the angles between them, α and β. Similar to the inscribed triangle ABC, the inscribed triangles of the two sides' linkages can be solved using the law of cosines as well. This is shown in equations 13 and 14, where expressions are given for the angles α and β as well as the lengths of the sides a and b, given that the angles are known.

$$
\begin{gathered}
b = \sqrt{{b_1}^2 + {b_2}^2 - 2b_1b_2 \cdot \cos(\alpha)} \\
a = \sqrt{{a_1}^2 + {a_2}^2 - 2a_1a_2 \cdot \cos(\beta)}
\end{gathered}
\tag{13}
$$

$$\alpha = \arccos\left(\frac{{b_1}^2 + {b_2}^2 - b^2}{2b_1b_2}\right)$$

$$\beta = \arccos\left(\frac{{a_1}^2 + {a_2}^2 - a^2}{2a_1a_2}\right) \tag{14}$$

If linear actuators are used, there will be two additional, even smaller, inscribed triangles that require solving. These are solved in equations 15 and 16, where lengths of potential linear actuators a_5 and b_5 are related to the angles α and β through the distances from the pivot point to the actuator ends, $a_{3,4}$ and $b_{3,4}$.

$$b_5 = \sqrt{{b_3}^2 + {b_4}^2 - 2b_3b_4 \cdot \cos(\alpha)}$$

$$a_5 = \sqrt{{a_3}^2 + {a_4}^2 - 2a_3a_4 \cdot \cos(\beta)} \tag{15}$$

$$\alpha = \arccos\left(\frac{{b_3}^2 + {b_4}^2 - {b_5}^2}{2b_3b_4}\right)$$

$$\beta = \arccos\left(\frac{{a_3}^2 + {a_4}^2 - a_5}{2{a_3}^2a_4}\right) \tag{16}$$

5.2.3 Force Control

To get the desired resistance tangential to the movement path, one must split the tangential force vector into two components, each in line with the lines a and b respectively. These lines connect point C to the anchor points A and B, which can be seen in figure 12 or in figure 13. This split can be done by changing the basis of the vector from the global Cartesian coordinate system into a coordinate system that uses unit vectors in the direction from the head to the anchor points with a length of one. This results in the required extension/contraction force of the individual members being equal to the vector components in the new coordinate system. The process for this is described in equation 17. Here, a vector T in form $[T_X\,T_Y]^T$, where T_x and T_y are the scaling values for the unit vectors $\hat{\imath}$ and $\hat{\jmath}$. These vectors are converted into a form $[T_A\,T_B]^T$ where T_A and T_B are the scaling values for unit vectors of A and B which have a length of one and that face towards the anchors A and B from the point C.

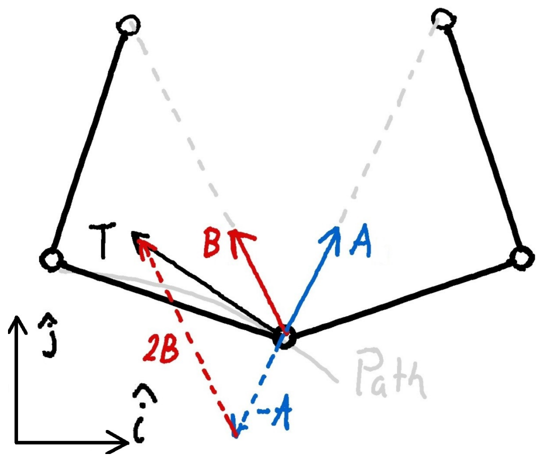


Figure 13: A and B Components of Force tangent to movement path

$$\begin{bmatrix} T_x \\ T_y \end{bmatrix} = \begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix} \begin{bmatrix} T_A \\ T_B \end{bmatrix}$$

$$\begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix}^{-1} \begin{bmatrix} T_x \\ T_y \end{bmatrix} = \begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix}^{-1} \begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix} \begin{bmatrix} T_A \\ T_B \end{bmatrix} = \begin{bmatrix} T_A \\ T_B \end{bmatrix} \tag{17}$$

$$\begin{bmatrix} T_A \\ T_B \end{bmatrix} = \begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix}^{-1} \begin{bmatrix} T_x \\ T_y \end{bmatrix} = \frac{1}{A_x B_y - B_x A_y} \begin{bmatrix} B_y & -B_x \\ -A_y & A_x \end{bmatrix} \begin{bmatrix} T_x \\ T_y \end{bmatrix}$$

In figure 13, the vectors A and B form the basis for a coordinate system that directly expresses the magnitudes of extending forces required from the two sides, through the scaling values T_A and T_B. In this example, the force tangent to a movement path works out so that $[T_A\, T_B]^T = [-1\, 2]^T$. This means that the B truss must contract with a force double the force A truss must extend with.

The extension forces, on the other hand, are not created directly, but rather as a consequence of motors at the joints or by linear actuators. To figure out the relationship between these forces, a set of equations is needed. Figure 14 shows the forces acting on the two sides of the truss.

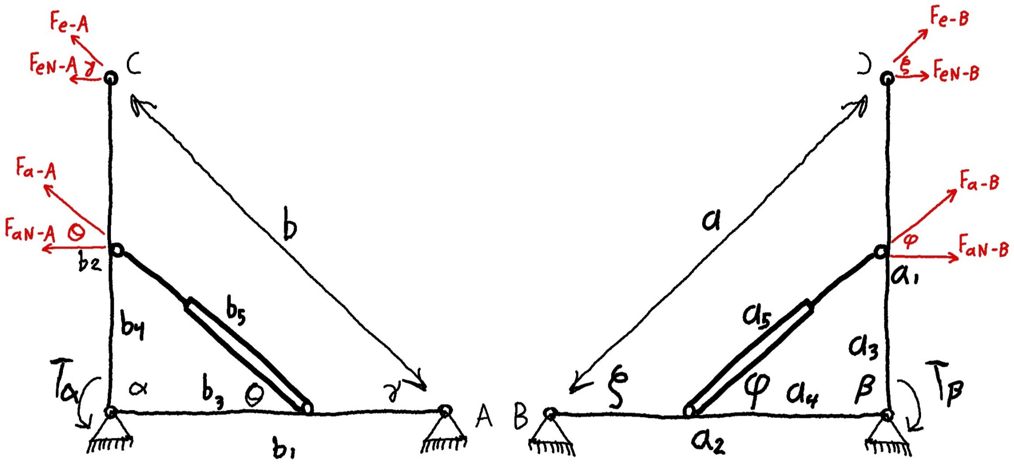


Figure 14: Extension Forces and Torque

Equation 18 shows expressions for the cosines of the angles θ, γ, ϕ and ζ formulated using the law of cosines. These are further used to convert from the actuator forces to the torques, and finally to the extending forces and vice versa.

$$\begin{aligned} \cos(\Theta) &= \frac{{b_5}^2 + {b_3}^2 - {b_4}^2}{2 b_5 b_3} & \cos(\gamma) &= \frac{b^2 + {b_1}^2 - {b_2}^2}{2 b b_1} \\ \cos(\phi) &= \frac{{a_5}^2 + {a_4}^2 - {a_3}^2}{2 {a_5}^2 {a_4}^2} & \cos(\zeta) &= \frac{a^2 + {a_2}^2 - {a_1}^2}{2 a a_2} \end{aligned} \tag{18}$$

Equation 19 shows the conversion from the actuator force on the A side to the extending force via the torque about point α.

$$
\begin{aligned}
F_{aN-A} &= F_{a-A} \cdot \cos(\Theta) \\
\tau_\alpha &= F_{aN-A} \cdot b_4 = F_{a-A} \cdot \cos(\Theta) \cdot b_4 \\
F_{eN-A} &= \frac{\tau_\alpha}{b_2} = F_{a-A} \cdot \cos(\Theta) \cdot \frac{b_4}{b_2} \\
F_{e-A} &= \frac{F_{eN}}{\cos(\gamma)} = F_{a-A} \cdot \frac{\cos(\Theta)}{\cos(\gamma)} \cdot \frac{b_4}{b_2}
\end{aligned}
\tag{19}
$$

Equation 20 shows the conversion from the actuator force on the B side to the extending force via the torque about point β.

$$
\begin{aligned}
F_{aN_B} &= F_{a-B} \cdot \cos(\phi) \\
\tau_\beta &= F_{aN_B} \cdot a_3 = F_{a-B} \cdot \cos(\phi) \cdot a_3 \\
F_{eN-B} &= \frac{\tau_\beta}{a_1} = F_{a-B} \cdot \cos(\phi) \cdot \frac{a_3}{a_1} \\
F_{e-B} &= \frac{F_{eN-B}}{\cos(\zeta)} = F_{a-B} \cdot \frac{\cos(\phi)}{\cos(\zeta)} \cdot \frac{a_3}{a_1}
\end{aligned}
\tag{20}
$$

Equation 21 shows the conversion from the extending force on the A side to the actuator force via the torque about point α.

$$
\begin{aligned}
F_{eN-A} &= F_{e-A} \cdot \cos(\gamma) \\
\tau_\alpha &= F_{eN-A} \cdot b_2 = F_{e-A} \cdot \cos(\gamma) \cdot b_2 \\
F_{aN-A} &= \frac{\tau_\alpha}{b_4} = F_{e-A} \cdot \cos(\gamma) \cdot \frac{b_2}{b_4} \\
F_{a-A} &= \frac{F_{aN}}{\cos(\theta)} = F_{e-A} \cdot \frac{\cos(\gamma)}{\cos(\theta)} \cdot \frac{b_2}{b_4}
\end{aligned}
\tag{21}
$$

Equation 22 shows the conversion from the extending force on the B side to the actuator force via the torque about point β.

$$
\begin{aligned}
F_{eN-B} &= F_{e-B} \cdot \cos(\zeta) \\
\tau_\beta &= F_{eN-B} \cdot a_1 = F_{e-B} \cdot \cos(\zeta) \cdot a_1 \\
F_{aN-B} &= \frac{\tau_{beta}}{a_3} = F_{e-B} \cdot \cos(\zeta) \cdot \frac{a_1}{a_3} \\
F_{a-B} &= \frac{F_{aN-B}}{\cos(\phi)} = F_{e-B} \cdot \frac{\cos(\zeta)}{\cos(\phi)} \cdot \frac{a_1}{a_3}
\end{aligned}
\tag{22}
$$

It is worth noting that these force calculations do not take into account resistance in the joints. They also do not account for the weights of the components.

5.2.4 Estimating Force Direction

A vital use case that the Masnak must be capable of handling, is when the path is not known and one must therefore somehow extrapolate movement direction. One simple way of doing this, barring any external positional tracking, is by sampling the lengths of the actuators continuously and using this data to calculate the coordinates of point C at different points in time. Firstly truss angle α and β are found using equation 16, which are then further used to find the lengths a and b using equation 13. Equation 11 is then used to find the angle A.

$$
\begin{aligned}
\alpha &= \arccos\left(\frac{{b_3}^2 + {b_4}^2 - {b_5}^2}{2b_3b_4}\right) \\
\beta &= \arccos\left(\frac{{a_3}^2 + {a_4}^2 - a_5}{2{a_3}^2a_4}\right)
\end{aligned} \tag{16}
$$

$$
\begin{aligned}
b &= \sqrt{{b_1}^2 + {b_2}^2 - 2b_1b_2 \cdot \cos(\alpha)} \\
a &= \sqrt{{a_1}^2 + {a_2}^2 - 2a_1a_2 \cdot \cos(\beta)}
\end{aligned} \tag{13}
$$

$$
A = \arccos\left(\frac{b^2 + c^2 - a^2}{2bc}\right) \tag{11}
$$

Given the same coordinate system and anchor placement as in section 5.2.6, which are listed in table 3, the coordinates of point C can be expressed as shown in equation 23.

$$
\begin{aligned}
x_C &= x_A - \cos(A) \\
y_C &= y_A - \sin(A))
\end{aligned} \tag{23}
$$

If the position is sampled many times, the direction can be approximated as the direction traveled between the current and the former sample coordinates. This can then easily be converted to the coordinates of a vector of length 1 by dividing each component by the length of the distance traveled. This is expressed in equation 24, leaving the direction vector $[T_{x_n}\, T_{y_n}]^T$. With frequent samples, the approximate direction would approach the real direction. This also applies to the required actuator force, as it depends on the accuracy of the movement direction, and can be calculated as in section 5.2.6.

$$
\begin{aligned}
T_{x_n} &\approx (x_{C_n} - x_{C_{n-1}})/\sqrt{((x_{C_n} - x_{C_{n-1}})^2 + (y_{C_n} - y_{C_{n-1}})^2)} \\
T_{y_n} &\approx (y_{C_n} - y_{C_{n-1}})/\sqrt{((x_{C_n} - x_{C_{n-1}})^2 + (y_{C_n} - y_{C_{n-1}})^2)} \\
Ang_{Tan} &\approx \arctan\left(\frac{T_{y_n}}{T_{x_n}}\right)
\end{aligned} \tag{24}
$$

This can be verified by taking two sets of $a5$ and $b5$ lengths that correspond to points along the path in section 5.2.6 as inputs. The estimated direction vectors can then be compared to the known ones. In table 2 it is shown that the accuracy improves as the sampling rate is increased.

$Sample_0$°	$Sample_1$°	Ang_{Tan} estimated°	Ang_{Tan}°	Error°
85.0	90.0	177.500	180.000	2.500
86.0	90.0	178.000	180.000	2.000
87.0	90.0	178.500	180.000	1.500
88.0	90.0	179.000	180.000	1.000
89.0	90.0	179.500	180.000	0.500
89.5	90.0	179.746	180.000	0.254

Table 2: How error decreases as sample 0 approaches sample 1

5.2.5 Influence of Component Weights

In practice, the weight of components would influence the requested actuator force. This must therefore be modeled. The links having rotational freedom at the anchors and having a non-zero mass would cause a torque, which in turn would cause it to swing if not constrained by the tension/compression of the b and a truss segments. This tension/compression will impose additional force requirements on the actuators to produce the desired resistance. As the truss segment moves the centers of mass of the individual segments parts $b_1, b_2 and B_5$ need to be tracked in order to dynamically determine the swing torque induced by gravity. Equation 25 shows expressions of the x distances of the centers of mass m_{a1}, m_{a2}, m_{a5}, m_{b1}, m_{b2} and m_{b5} for given Masnak positions determined by angles A, B, α, β, γ and ζ.

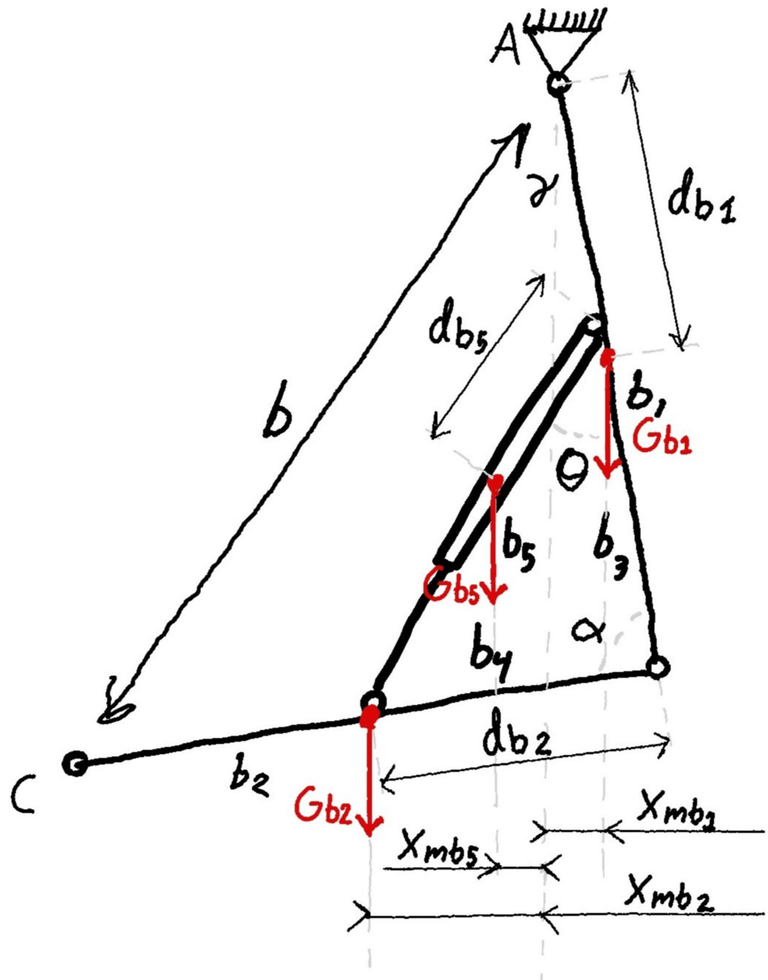


Figure 15: Weights of the linkages acting on their centres of mass

$$
\begin{aligned}
x_{m_{b1}} &= \cos{(A + \gamma - \pi)} \cdot d_{b_1} \\
x_{m_{b2}} &= \cos{(A + \gamma - \pi)} \cdot b_1 + \cos{A + \gamma + \alpha} \cdot d_{b_2} \\
x_{m_{b5}} &= \cos{(A + \gamma - \pi)} \cdot (b_1 - b_3) + \cos{(A + \gamma - \pi - \theta)} \cdot d_{b_5} \\
x_{m_{a2}} &= \cos{(-B - \zeta)} \cdot d_{a_2} \\
x_{m_{a1}} &= \cos{(-B - \zeta)} \cdot a_2 + \cos{(\pi - B - \zeta - \beta)} \cdot d_{a_1} \\
x_{m_{a5}} &= \cos{(-B - \zeta)} \cdot (a_2 - a_4) + \cos{(-B - \zeta + \phi)} \cdot d_{a_5}
\end{aligned} \tag{25}
$$

The center of mass of the actuators would vary with their length. This is expressed in equation 26, which expresses the distance to the center of mass of the actuators, d_{b_5} and d_{a_5}, to their fastening point on the upper Masnak member. This is done using the minimum length of the actuators $b_{5_{min}}$ and $a_{5_{min}}$, the current length of the actuators b_5 and a_5, and factors k_{b_5} and k_{a_5} which specify how much the center of mass moves given a change in length of the actuator.

$$
\begin{aligned}
d_{b_5} &= d_{b_{5_{min}}} + k_{b_5}(b_5 - b_{5_{min}}) \\
d_{a_5} &= d_{a_{5_{min}}} + k_{a_5}(a_5 - a_{5_{min}})
\end{aligned} \tag{26}
$$

When the x distances are known, the torque around the anchor points and the resultant forces at point C from these torques, can be calculated as shown in equation 27.

$$
\begin{aligned}
\tau_A &= (m_{b_1} \cdot x_{m_{b_1}} + m_{b_2} \cdot x_{m_{b_2}} + m_{b_5} \cdot x_{m_{b_5}}) \cdot g \\
W_{T_A} &= \tau_A / b \\
\tau_B &= (m_{a_2} \cdot x_{m_{a_2}} + m_{a_1} \cdot x_{m_{a_1}} + m_{a_5} \cdot x_{m_{a_5}}) \cdot g \\
W_{T_B} &= \tau_B / a
\end{aligned} \tag{27}
$$

Equation 28 calculates the components of the total force contributed by the weight of the two sides in the global Cartesian coordinate system.

$$
\begin{aligned}
W_x &= W_{T_A} \cdot \cos{(CA + \frac{\pi}{2})} + W_{T_B} \cdot \cos{(CB + \frac{\pi}{2})} \\
W_y &= W_{T_A} \cdot \sin{(CA + \frac{\pi}{2})} + W_{T_B} \cdot \sin{(CB + \frac{\pi}{2})}
\end{aligned} \tag{28}
$$

We can then borrow equation 35 to translate this to the AB coordinate system. This is shown in equation 29, and results in the forces W_A and W_B, which are the additional extending forces needed to be overcome in order to have the truss remain static.

$$
\begin{bmatrix} W_A \\ W_B \end{bmatrix} = \frac{1}{A_x B_y - B_x A_y} \begin{bmatrix} B_y & -B_x \\ -A_y & A_x \end{bmatrix} \begin{bmatrix} W_x \\ W_y \end{bmatrix} \tag{29}
$$

The addition of weights causes the necessity to alter equation 37, which calculates the required actuator forces to compensate for the additional load. This is done by including the components W_A and W_B, producing equation 30.

$$\begin{aligned} F_{a-A} &= (F_{e-A} - W_A)\frac{b^2 + {b_1}^2 - {b_2}^2}{2bb_1}\frac{b_2}{b_4}\frac{2b_5b_3}{{b_5}^2 + b_3^2 - b_4^2} \\ F_{a-B} &= (F_{e-B} - W_B)\frac{a^2 + {a_2}^2 - {a_1}^2}{2aa_2}\frac{a_1}{a_3}\frac{2a_5a_4}{{a_5}^2 + a_4^2 - a_3^2} \end{aligned} \quad (30)$$

5.2.6 Example Calculation 1 - Moving Through Known Path

The range of motion for the neck joint, specifically the movement from maximum extension of 84° to maximum flexion of 46°, is based on data collected by Dr. William Thornton and John Jackson in 1979 and 1980. [16] This range reflects the fifth percentile of the data collected during their study. For more information regarding the specifics of the data collection, please refer to the specialization project included as Appendix A.

For demonstration, the head movement is represented as a simple arch with a radius of 150, keeping the point of rotation constant as can be seen in figure 16. Here, the input is given as a head angle μ, where 90° or $\pi/2$ would be the neutral position.

Name	Symbol	Value	Unit
AC and BC max	b_{max}, a_{max}	0.6	m
AC and BC min	b_m, a_{min}	0.4	m
Head arch radius	r_{arc}	0.12	m
Starting angle	μ start	6	°
end angle	μ end	131	°
Arch centre x-coordinate	$x_{arc-cen}$	0	m
Arch centre y-coordinate	$y_{arc-cen}$	-120	m
Anchor distance	c	0.4	m
Length anchor links	b_1, a_2	0.4	m
Length end links	b_2, a_1	0.4	m
Actuator placement anchor side	b_3, a_4	0.22	m
Actuator placement head side	b_4, a_3	0.18	m
Force magnitude	F_{Mag}	10	N
Anchor A x-coordinate	x_A	0.2	m
Anchor A y-coordinate	y_A	0.38	m
Anchor B x-coordinate	x_B	-0.2	m
Anchor B y-coordinate	y_B	0.38	m

Table 3: Masnak parameters - Example 1

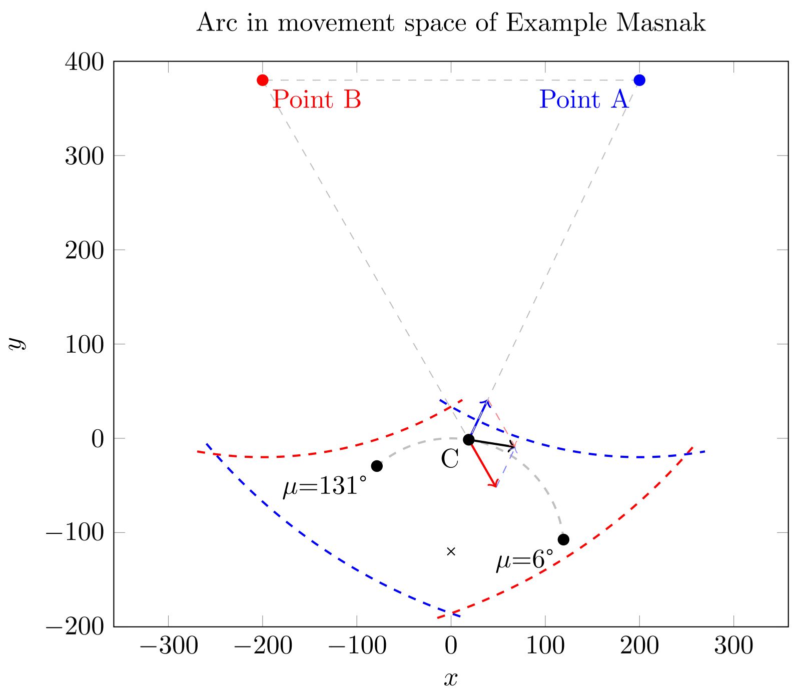


Figure 16: Movement path 1 within the working area of the Masnak

The position is converted to desired actuator lengths b and a using equation 31. The distances are found by combining the x and y distances from the anchor points and combining them using the Pythagorean theorem.

$$
\begin{aligned}
b &= \sqrt{(x_A - r_{arc} \cdot \cos\mu + x_{arc-cen})^2 + (y_A - r_{arc} \cdot \sin\mu + y_{arc-cen})^2} \\
a &= \sqrt{(x_B - r_{arc} \cdot \cos\mu + x_{arc-cen})^2 + (y_B - r_{arc} \cdot \sin\mu + y_{arc-cen})^2}
\end{aligned}
\tag{31}
$$

The angles α and β are then calculated using equation 14. Further, these angles are used to calculate the lengths of the actuators a_5 and b_5 using equation 15.

$$
\begin{aligned}
\alpha &= \arccos\left(\frac{{b_1}^2 + {b_2}^2 - b^2}{2b_1b_2}\right) \\
\beta &= \arccos\left(\frac{{a_1}^2 + {a_2}^2 - a^2}{2a_1a_2}\right)
\end{aligned}
\tag{14}
$$

$$
\begin{aligned}
b_5 &= \sqrt{{b_3}^2 + {b_4}^2 - 2b_3b_4 \cdot \cos(\alpha)} \\
a_5 &= \sqrt{{a_3}^2 + {a_4}^2 - 2a_3a_4 \cdot \cos(\beta)}
\end{aligned}
\tag{15}
$$

Now that expressions for the relevant distances have been established, the required actuator forces can be calculated. To do this, a basis to calculate the angles of lines a and b, as well as the tangent of the path, are required. This means that expressions for the absolute angles of the lines a and b in a global coordinate system are required. The global system in this case being that the x-axis is horizontal and the y-axis being vertical, with the positive directions being to the right and upwards.

$$
\begin{aligned}
CA = A &= \arccos\left(\frac{b^2 + c^2 - a^2}{2bc}\right) \\
CB = \pi - B &= \pi - \arccos\left(\frac{a^2 + c^2 - b^2}{2ac}\right) \\
Ang_{Tan} &= \mu + \frac{\pi}{2}
\end{aligned}
\tag{32}
$$

CA is the angle of the line from the head point to the Anchor point A, also known as b, while CB is the angle of the line from the same point to the Anchor point B, also known as a. Ang_{Tan} is the angle of the direction of travel at any given point in the arch. These angles are used to find the coordinates of the unit vectors A and B, as well as a vector for the travel direction expressed in the global Cartesian coordinate system. In equation 33 it is shown that the X coordinates are found by taking the cosines of the angles, while the y coordinates are found by taking the sines of the angles. All the resulting vectors $[T_x\, T_Y]^T$, $[A_x\, A_Y]^T$ and $[B_x\, B_Y]^T$ have a length of 1 due to the fact that $\sin^2 + \cos^2 = 1$. This is important for later when they are to be used to find the magnitude of the forces F_{e-A} and F_{e-B}.

$$
\begin{aligned}
T_x &= \cos Ang_{Tan} \\
T_y &= \sin Ang_{Tan} \\
A_x &= \cos CA \\
A_y &= \sin CA \\
B_x &= \cos CB \\
B_y &= \sin CB
\end{aligned}
\tag{33}
$$

Now, everything is in place to apply equation 17 and determine the transformation matrix that translates the travel direction vector from the global coordinate system to the AB coordinate system.

$$
\begin{aligned}
TransformABtoXY &= \begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix} \\
TransformXYtoAB &= \begin{bmatrix} A_x & B_x \\ A_y & B_y \end{bmatrix}^{-1} = \frac{1}{A_x B_y - B_x A_y} \begin{bmatrix} B_y & -B_x \\ -A_y & A_x \end{bmatrix}
\end{aligned} \tag{34}
$$

In equation 34, the translation matrix from the Cartesian to the AB coordinate system is generated by taking the inverse of the translation matrix from the AB to the Cartesian coordinate system. This Translation matrix is a 4x4 matrix that has coordinates for vectors A and B as the columns.

$$
\begin{bmatrix} T_A \\ T_B \end{bmatrix} = \frac{1}{A_x B_y - B_x A_y} \begin{bmatrix} B_y & -B_x \\ -A_y & A_x \end{bmatrix} \begin{bmatrix} T_x \\ T_y \end{bmatrix} \tag{35}
$$

The vector $[T_A \, T_B]^T$ is then found in equation 35, where the components T_A and T_B are the scaling magnitudes for the A and B components of the resistance force. The actual extending forces, F_{e-A} and F_{e-B}, are then simply calculated in equation 36 by multiplying the force magnitude F_{Mag} by the scaling values.

$$
\begin{aligned}
F_{e-A} &= T_A \cdot F_{Mag} \\
F_{e-B} &= T_B \cdot F_{Mag}
\end{aligned} \tag{36}
$$

Finally, equations 18, 21 and 22 are combined to calculate the actuator force required to facilitate the tangential resistance in equation 37.

$$
\begin{aligned}
F_{a-A} &= F_{e-A} \frac{b^2 + {b_1}^2 - {b_2}^2}{2bb_1} \frac{b_2}{b_4} \frac{2b_5 b_3}{{b_5}^2 + b_3^2 - b_4^2} \\
F_{a-B} &= F_{e-B} \frac{a^2 + {a_2}^2 - {a_1}^2}{2aa_2} \frac{a_1}{a_3} \frac{2a_5 a_4}{{a_5}^2 + a_4^2 - a_3^2}
\end{aligned} \tag{37}
$$

In Table 4, lengths of the actuators a_5 and b_5, as well as the forces F_{a-A} and F_{a-B}, are shown at a range of different points along the path. At maximum extension when, μ is 6°, both actuators are pushing. As the angle increases, the A side actuator's push force decreases before it eventually starts pulling harder and harder, until it tails off slightly at the end. The B sides actuator pushes throughout the entirety of the movement, initially increasing before decreasing again.

Angle°	$a_5(m)$	$b_5(m)$	$F_{a-A}(N)$	$F_{a-B}(N)$
6	0.293	0.249	24.302	14.972
31	0.268	0.227	2.992	34.777
56	0.243	0.214	-16.069	43.439
81	0.222	0.214	-31.675	39.824
106	0.212	0.227	-41.912	27.709
131	0.216	0.250	-42.311	11.052

Table 4: Actuator forces and lengths at different points along the arch, with weight ignored

The results in table 4 have ignored the effect the weight of components would have on the required actuator force. Using the equations in section 5.2.5, the effects of having components with mass can be explored.

Name	**Symbol**	**Value**	**Unit**
Upper link mass	m_{b_1}, m_{a_2}	2	Kg
Lower link mass	m_{b_2}, m_{a_1}	2	Kg
Actuator mass	m_{b_5}, m_{a_5}	2	Kg
Upper link centre of mass from anchor	d_{b_1}, d_{a_2}	0.2	m
Lower link centre of mass from α/β	d_{b_2}, d_{a_1}	0.2	m
Actuator centre of mass moving factor	k_{b_5}, k_{a_5}	0.5	m
Minimum actuator length	$d_{b_{5_{min}}}, d_{a_{5_{min}}}$	0.243	m
Minimum actuator centre of mass upper link	$b_{5_{min}}, a_{5_{min}}$	0.121	m

Table 5: Aditional Masnak parameters

Angle°	$\boldsymbol{a_5(m)}$	$\boldsymbol{b_5(m)}$	$\boldsymbol{F_{a-A}(N)}$	$\boldsymbol{F_{a-B}(N)}$
6	0.293	0.249	62.567	-32.721
31	0.268	0.227	33.645	-7.911
56	0.243	0.214	0.945	13.526
81	0.222	0.214	-31.454	27.135
106	0.212	0.227	-59.623	32.820
131	0.216	0.250	-76.430	32.316

Table 6: Actuator forces and lengths at different points along the arch, with weight included

The actuator force values vary considerably from table 4 to table 6. This difference shows up with a relatively modest weight of 1 kg for the linkages and actuators and the added weight makes a big difference when providing a resistance force of 10N. This resistance is in the middle of the required range defined in the specialization project (Appendix A). Unless the weight of the linkages can be reduced to values much smaller than 1 kg, they will dominate the requested actuator force in almost all cases. This also means that active actuator engagement would be required continuously to avoid the occupant feeling the weight of the Masnak unit's linkages. This could potentially be mitigated by having a spring or other source of passive force/torque biasing the linkages slightly towards a position corresponding to a neutral head position.

The known angle of the head in this example would require an encoder, or another angle monitoring component, to be placed in point C, monitoring the angle between the head mount and one of the linkages if the calculations are to be done as shown.

5.2.7 Example Calculation 2 - Tracker Data

This example takes data gathered with a video analysis and modeling tool called tracker [17]. It was used to track a high contrast point fixed to the head through space to generate pixel coordinates for every given frame. A known distance in the video is used to scale the coordinate data. The dot used to track, as well as the two lines placed 200 mm apart used for scaling, can be seen in figure 17.

Figure 17: Frame from video analyzed in tracker

The raw data gathered were smoothed using a 5-point rolling average to remove some of the fluctuations. Then, the ICR was estimated using equation 4. Further, the estimated ICR's that deviated a lot from the previous estimate, usually due to the three consecutive points used to calculate it, being close to col linear, were removed from the set. Finally, points where the individual ICR's moved more than 10 mm in a single step were replaced with a linear estimation between the last point and the next within 10mm. The resulting data was still rather messy, but it was sufficient to give an idea of the area the ICR is constrained to, and thus a basis to calculate an approximate head angle.

In order to fully enclose the gathered data points within the Masnak working area, the measurements had to be altered from those given in table 3. The new dimensions are given in table 7.

Name	**Symbol**	**Value**	**Unit**
AC and BC max	b_{max}, a_{max}	0.65	m
AC and BC min	b_m, a_{min}	0.4	m
Anchor distance	c	0.4	m
Length anchor links	b_1, a_2	0.4	m
Length end links	b_2, a_1	0.4	m
Actuator placement anchor side	b_3, a_4	0.2	m
Actuator placement head side	b_4, a_3	0.2	m
Force magnitude	F_{Mag}	10	N
Anchor A x-coordinate	x_A	0.2	m
Anchor A y-coordinate	y_A	0.4	m
Anchor B x-coordinate	x_B	-0.2	m
Anchor B y-coordinate	y_B	0.4	m

Table 7: Masnak parameter - Example 2

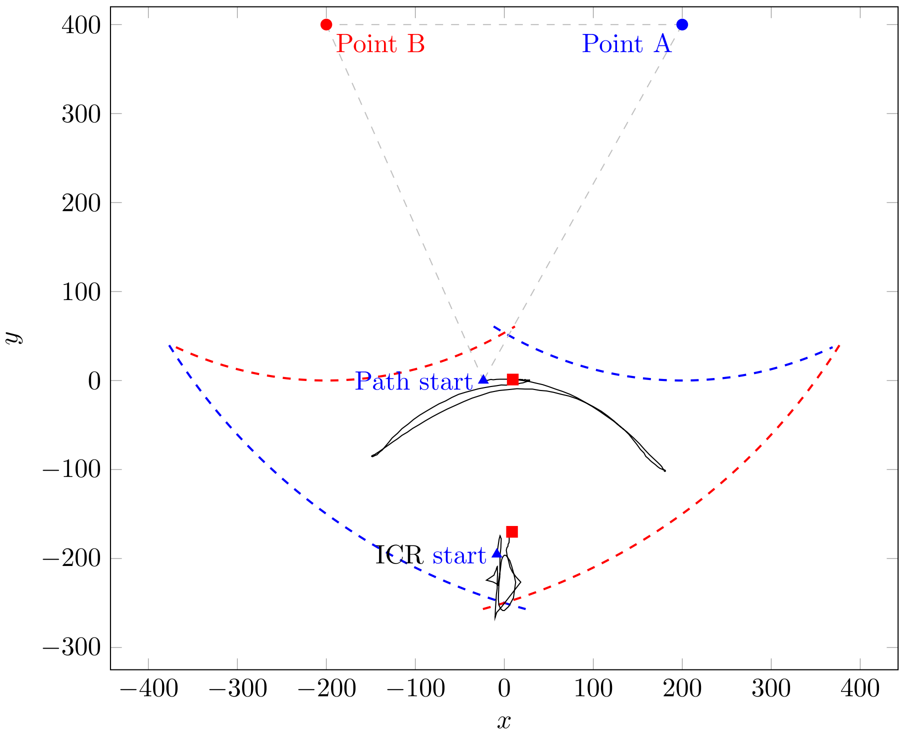


Figure 18: Movement path 2 within the working area of the Masnak

As can be seen by the lack of estimates of ICR at certain points in the data shown in table 8, the method of estimation struggles at full extension/flexion when the movement direction shifts, and at other points where the movement path is irregular. These points are marked red. When the head is relatively still, micro-movements and noise from inconsistent tracking cause the estimated center of rotation, and therefore the angle estimate, to vary considerably. This would need to be addressed with a more sophisticated estimation method or by gathering extra data, perhaps with an encoder on the head mount that could give an angle of the head mount in relation to one of the links.

$\mathbf{Angle_{ICR,C}}^{\circ}$	$\mathbf{x_{path}}$	$\mathbf{y_{path}}$	$a_5(m)$	$b_5(m)$	$F_{a-A}(N)$	$F_{a-B}(N)$	$\mathbf{x_{ICR}}$	$\mathbf{y_{ICR}}$
-97.0	-0.019	0.000	0.219	0.228	32.743	-40.776	0.833	6.904
82.3	0.021	0.000	0.229	0.219	42.682	-62.857	-0.005	-0.200
57.4	0.099	-0.029	0.262	0.221	56.596	-96.373	-0.003	-0.188
41.7	0.167	-0.087	0.305	0.244	70.601	-115.452	-0.008	-0.244
67.3	0.179	-0.101	0.314	0.251	43.326	-18.396	0.081	-0.335
50.1	0.162	-0.087	0.303	0.244	52.232	-21.721	0.026	-0.250
54.2	0.115	-0.040	0.271	0.224	25.058	-2.022	0.000	-0.200
82.6	0.031	-0.010	0.235	0.222	-35.130	30.240	-0.075	-0.837
121.6	-0.064	-0.032	0.227	0.253	-83.257	49.408	-0.011	-0.117
126.2	-0.130	-0.072	0.239	0.288	-107.608	67.682	-0.005	-0.243
-23.5	-0.149	-0.085	0.244	0.299	-20.833	-4.606	-0.660	0.137
135.6	-0.129	-0.069	0.237	0.287	-10.534	40.071	0.006	-0.201
114.9	-0.066	-0.023	0.222	0.250	19.636	-5.753	0.009	-0.185

Table 8: Output data from Step 25 to Step 145

5.2.8 Actuator Choice

The Masnak concept requires some active actuators in order to work. There are many different types of actuators, however, that may lend themselves to the application. They can be largely grouped into two different groups, namely joint and linear actuators. Joint actuators control the Masnak by directly controlling the angle between the upper and lower Masnak members, while linear actuators indirectly control the angle by altering the distance between two points on the upper and lower Masnak member.

When it comes to joint actuator selection, there are two main options. Those being stepper motors and BLDC motors which were discussed in section 2.7. Linear actuators come in many forms but can be roughly categorized into three different groups, namely electromechanical actuators, pneumatic actuators, and hydraulic actuators. all of which are discussed in section 2.8.

The actuator for this project needs to at least be able to keep up with the natural movement of the occupant. In order to determine this speed properly, a study would need to be done to check what speed is the highest likely to occur. Then, an analysis would be done to determine what actuator speeds this translates to. This should be no issue using the relations established in section 5.2.2. Then the required extension forces at these speeds, and by extension the actuator force, torque and/or power to achieve these speeds, would need to be established using the relations in section 5.2.3 specific to the actuators in question. Other considerations, like extra peripherals required for operation, noise generation, thermal management under operation and so on, must also be taken into consideration. This work is yet to be done, and the actuator type that is right for this application is not clear as things stand. Nevertheless, if it is the case that quiet operation with minimal extra components is desirable, the preferred actuators seem to be a ball screw-based linear actuator or a geared BLDC motor joint actuator at this stage of design. These only require a power source and a small controller in order to work, components that can be placed relatively freely which improves layout options. They will also likely be quieter than both the hydraulic and pneumatic actuators, and also lighter than hydraulic actuators. This is especially the case if the weight and sound contributed by pumps, compressors and other required peripherals that come with using pneumatic or hydraulics are included.

5.3 Gyro Concept

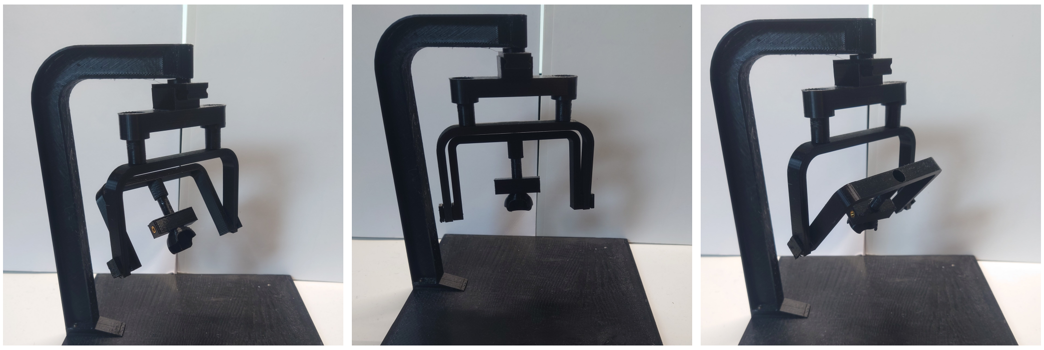


Figure 19: Gyro demo model

The gyro concept is designed so that the movement axes of the machine correspond, well with the movements of the neck to simplify loading. This is done all while allowing for slight movements of the CR, in order to not hinder the neck's natural movement. This goal, however, does lead to extra complexity over the MCU as some extra components are required to facilitate a moving center of rotation as the neck tilts and rotates. Nonetheless, the main movement component that is addressed during rehabilitation is two rotational degrees of freedom, while the remaining two serve to adjust automatically with minimal resistance to allow the neck to move naturally.

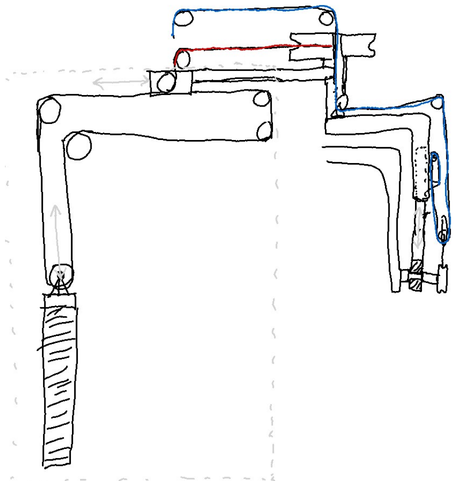


Figure 20: Potential pulley loading setup

In table 9, the scores given to the Gyro concept during the specialization project (A) are displayed. There is a large degree of uncertainty with these results as they are based on a minimally developed concept and projections of possible functionality, but they did give some insight into the potential of the concept. Now, however, the concept will be evaluated with more precision.

	Gyro Evaluation Scores		
Acronym	Criteria	Score	Weight
ROM	Range of motion	5	4.7
DOF	Degrees of freedom	4	10.0
RSA	Resistance Specificity and Adaptability	4	7.7
MCC	Movement Constraint and Control	3	7.0
SFT	Spacial and Force Tracking	5	4.7
PBI	Portability and Installation	1	7.3
UI	User Interface	3	5.7
CMPD	Complexity of Design	3	2.7
DUNC	Design Uncertainty	4	2.7
PS	Patient Safety	5	13.3
PSS	Patient's Perceived Safety	5	10.0
EE	Efficacy and Efficiency	4	10.0
DCC	Design Challenge Compatibility	4	6.0
	Cost	370	100.0

Table 9: Gyro evaluation Scores from the specialization project included in appendix A

The gyro concept has many similarities with the current MCU, so there is a lower degree of uncertainty relating to aspects they share. The main questions that arise are related to the addition of extra movement axes and the implications they have.

A crucial question, if the movement arc is to be natural, is if the passive joints can be moved in response to patient movements with minimal resistance. To achieve these additional degrees of freedom, either the entire gyro mechanism or the patient needs to be moved. Either way, there is a significant mass that has to be moved, and therefore significant force is required for acceleration. In addition, the weight of the components and/or occupant will either directly resist or indirectly resist movement through friction.

The question of whether friction can be reduced so that it contributes negligibly to free axis resistance needs exploring. So does the question of whether weight on the vertical axis can be balanced out through constant force mechanisms. The question of whether the accelerations involved are small enough that inertia's impact is negligible also needs to be answered. If this is not the case, solutions to deal with this issue, like active help of movement, akin to power steering should also be explored.

One additional impact of the extra movement axis is how it impacts the actively loaded rotational axis of the gyro mechanism. If the mechanism itself is to move, it makes using a passively loaded cable solution more difficult as the cable length is impacted, not only by the tilt in a desired direction, but also by the placement of the passive axes. This problem is widely dealt with in more complex cable machines with an adjustable height, however, in these applications, the height is always fixed when the cable is under tension.

If instead, motors are to be used to create resistance, the ability to create a consistent resistance regardless of movement speed or direction needs to be explored.

5.3.1 Gyro - Term Definitions

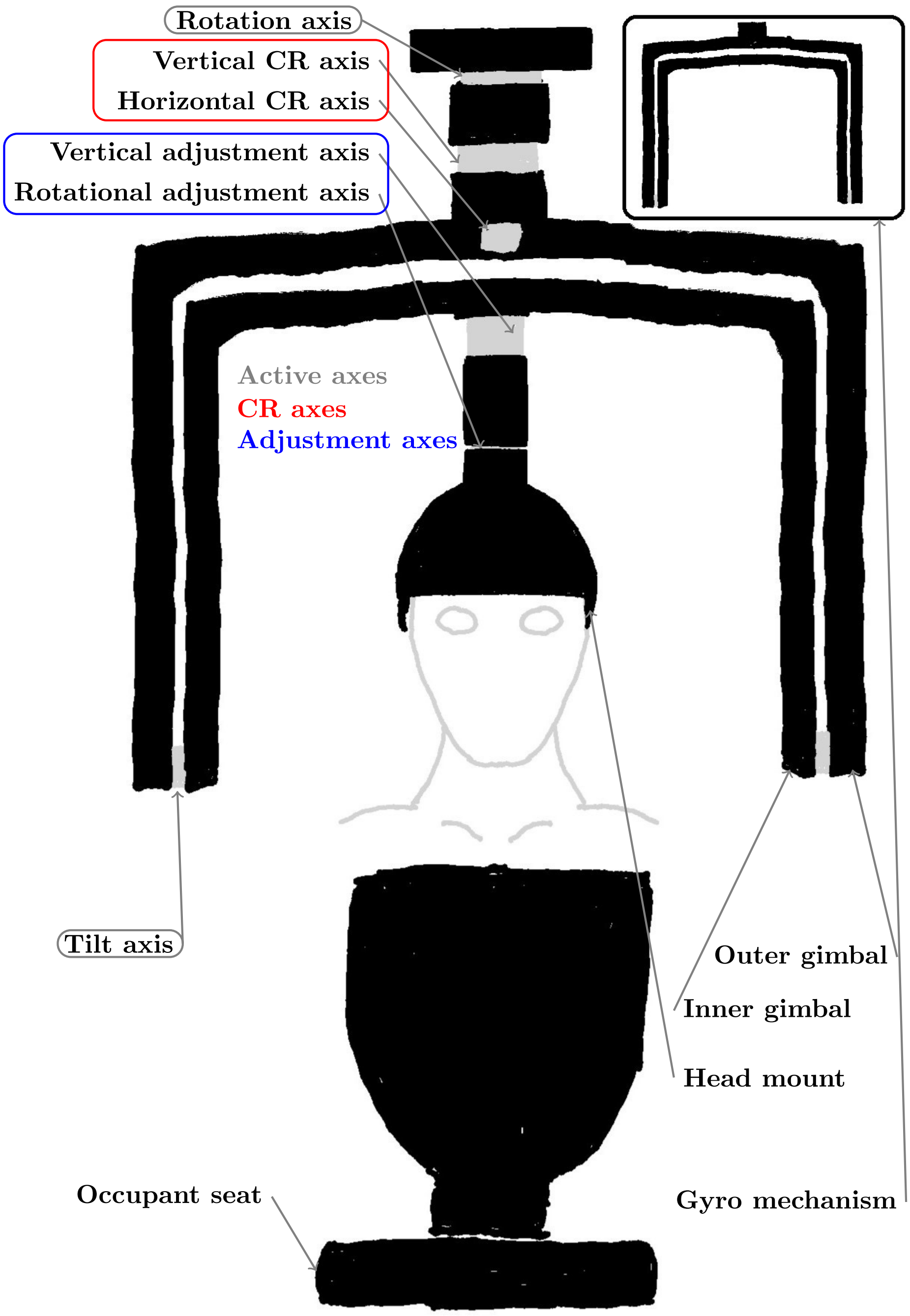
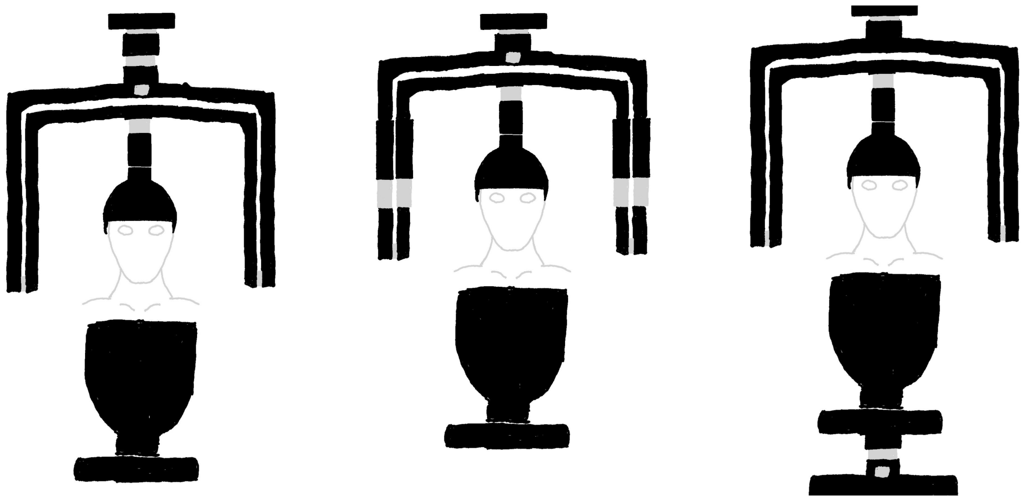


Figure 21: Gyro component terms

The rotation axis refers to the main rotational axis that allows for the loaded rotation of the occupant's head. This axis can be decoupled from the loading mechanism to facilitate adjustment of the tilt direction, for example from forwards/backwards tilt to right/left tilt. The tilt axis is the axis that facilitates the loaded tilting of the occupant's head. The vertical CR axis, is the axis that allows for free vertical movement of the Gyro concept's tilt axis' center of rotation. similarly, the horizontal CR axis facilitates free horizontal movement of the Gyro concept's tilt axis' center of rotation. The vertical adjustment axis is an adjustable axis that allows for the occupant's head position within the inner gimbal to be adapted to best fit individual patients. The rotational adjustment axis refers to an axis, that in conjunction with the rotation axis, facilitates the adjustment of tilt direction, and on its own can adjust the head's fixed rotation within the inner gimbal. This can allow for the movement of the neutral rotation, and facilitate different loading scenarios. An example might be forward tilt, but with the head facing to the side for more targeted training of specific muscles. Gyro mechanism refers to the outer and inner gimbal that makes up the portion of the concept that resembles a gyroscope and allows for tilting movement by supporting the tilt axis. Occupant seat simply refers to where the occupant sits within the machine. This is incidentally a module where the work done by Marius Kirkeeide in his Master's thesis project [18], could also be relevant for this project. The thesis explored the design of a seat for neck training equipment, albeit for a different machine design.

5.3.2 Alternative Layouts

The gyro concept can have many potential layouts for the axes. Different layouts will play a large role in the type of design challenges faced.



(a) Free axes above Gyro mechanism

(b) Vertical free axis in Gyro Mechanism, Horizontal free axis above

(c) Free axes in the occupant seat

Figure 22: Gyro Layouts

Figure 22a shows a layout that has the free axes above the Gyro mechanism, moving the entirety of the mechanism in order to move the CR. This means that the CR axes will have a large mass moving with them, in the form of the entire gyro mechanism, increasing momentum and also likely also the frictional forces. This is the case for both axes.

Figure 22b shows a layout where the vertical CR axis is placed within the Gyro mechanism. This is consistent with the layout sketched in figure 20. Potentially, this could reduce the mass moving with the vertical axis, though, it may end up increasing the weight moving with the horizontal axis due to the more complex gimbals.

Figure 22c shows a layout that moves the CR axes to the occupant seat. This allows for a potential pulley system to be vastly simplified. However, the CR axes would need to move the mass of the occupant. This would mean consistency in the moving mass would be absent, removing constant compensation as an option. This would therefore require some active control. On the other hand, the system to deal with this fluctuating weight would likely not interfere as much with the active axes as they are placed in a separate mechanism, which could simplify the design.

5.3.3 Cable Loading with CR Axes

To get an idea of the implications of cable loading, a simple model is made to represent the general shape and functions of a possible cable loading setup. This setup is shown in figure 23 and corresponds to a setup where the horizontal CR axis moves the Gyro mechanism.

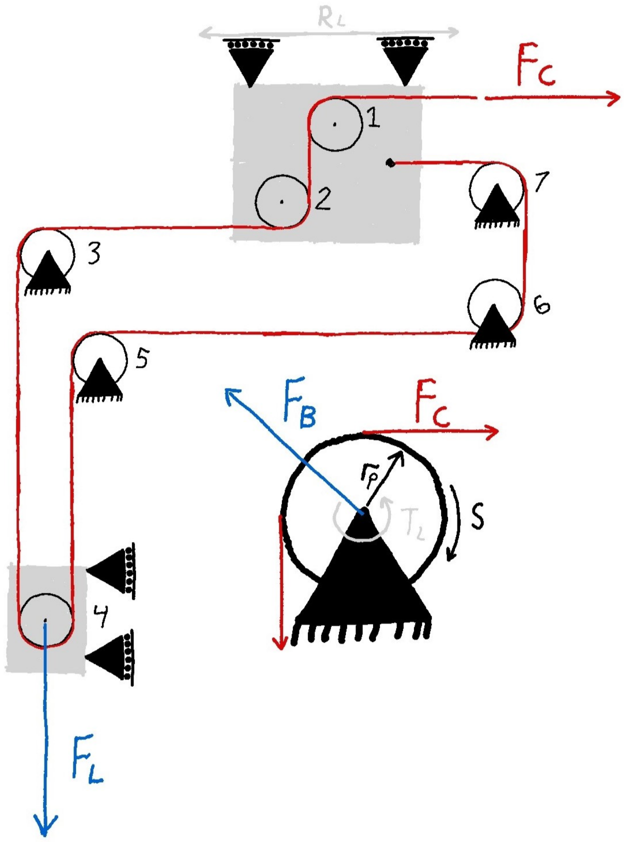


Figure 23: Pulley setup to deal with Horizontal CR movement

$$
\begin{aligned}
R_{Linearbearing} &= R_L = \mu_{LB} \cdot G \\
R_{Rotationalbearing} = R_{1,12} = \frac{T_{RB}}{r_P} &= \frac{\mu_{RB} \cdot F \cdot d_B}{2} \cdot \frac{1}{r_P} = \frac{\mu_{RB} \cdot F \cdot d_B}{2 \cdot r_P}
\end{aligned} \tag{38}
$$

Equation 38 defines the expressions for the resistance in generic bearings as a function of the bearing loads. For the linear bearings, their resistance is a function of the weight G, and the frictional coefficient mu_{LB}. As for the rotational bearings, the resistance is a function of the bearing load F, the bearing outer diameter d_b, the frictional coefficient mu_{RB}, and the pulley radius r_p. The frictional values and the equation to determine the resistance based on the force can be found on a technical sheet from the bearing manufacturer NSK. [19]

$$
\begin{aligned}
F_{Bearing} = F_B &= \sqrt{2F_{Cable}^2} = \sqrt{2}F_C \\
F_{Load} = F_L &= 2F_C \\
F_{Output} = F_{Out} &= \frac{1}{2}F_C
\end{aligned} \tag{39}
$$

Equation 39 shows the different sizes of bearing load, F_L and F_B, depending on how much the cable wraps around the pulley. These forces are then used in equations 40 and 41 to work out the resistance for the individual pulleys, which then are put into equation 42 to provide an expression for the total static friction in the system.

$$\begin{aligned} R_{1,3} \ \& \ R_{5,7} &= \frac{\mu_{RB} \cdot F_B \cdot d_B}{2 \cdot r_P} = \frac{\mu_{RB} \cdot F_C \cdot d_B}{\sqrt{2} \cdot r_P} \\ R_4 &= \frac{\mu_{rb} \cdot F_L \cdot d_B}{2 \cdot r_P} = \frac{\mu_{RB} \cdot F_C \cdot d_B}{r_P} \end{aligned} \tag{40}$$

$$\begin{aligned} R_{8,9} \ \& \ R_{11} &= \frac{\mu_{RB} \cdot F_B \cdot d_B}{2 \cdot r_P} = \frac{\mu_{RB} \cdot F_C \cdot d_B}{\sqrt{2} \cdot r_P} \\ R_{10} \ \& \ R_{12} &= \frac{\mu_{rb} \cdot F_L \cdot d_B}{2 \cdot r_P} = \frac{\mu_{RB} \cdot F_C \cdot d_B}{r_P} \end{aligned} \tag{41}$$

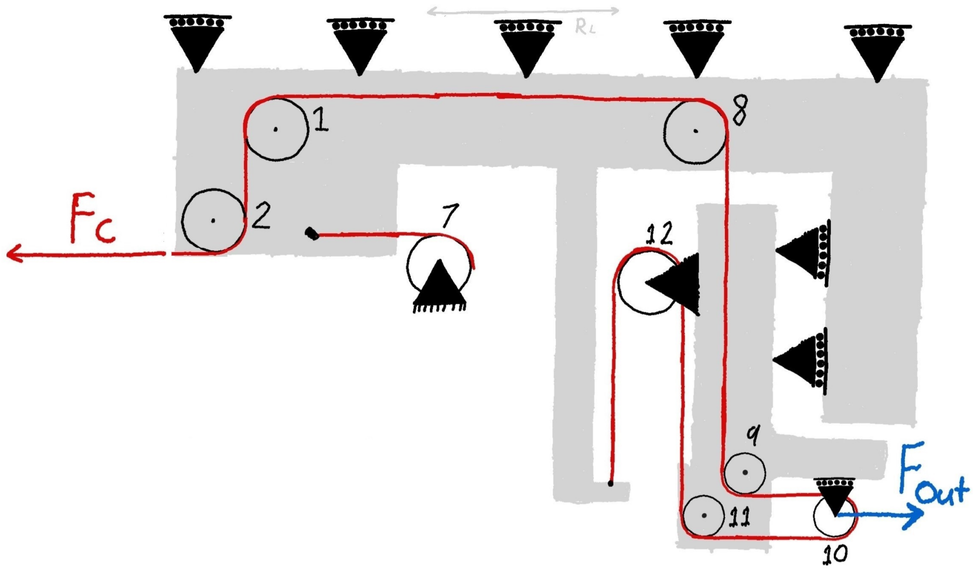


Figure 24: Pulley set up to deal with Vertical CR movement

$$R_{Total} = R_T = R_1 + R_2 + R_3 + R_4 + R_5 + R_6 + R_7 + R_8 + R_9 + R_{10} + R_{11} + R_{12} + R_L$$

$$R_T = 9\frac{\mu_{RB} \cdot F_c \cdot d_B}{\sqrt{2} \cdot r_P} + 3\frac{\mu_{RB} \cdot F_C \cdot d_B}{\cdot r_P} + \mu_{LB} \cdot G \tag{42}$$

$$R_T = \frac{9 + 3\sqrt{2}}{\sqrt{2}} \frac{\mu_{RB} \cdot F_C \cdot d_B}{\cdot r_P} + \mu_{LB} \cdot G$$

Assuming the Gyro mechanism weighs 600 N and the output force is 10 N, the overall force to overcome on the horizontal CR axis is 4.9 N, the majority of which is contributed by the linear bearings. Unless the assembly can be made considerably lighter, some actively actuated assistance would be needed in order to secure functionally free movement. This is of course presuming that there is a constant force acting on the part of the Gyro mechanism that moves vertically to counteract its weight. This could be done with gas springs, other constant force mechanisms, or through active motor control.

$$\mu_{RB} = 0.0013 \qquad \mu_{LB} = 0.008$$
$$d_B = 0.022m \qquad r_P = 0.05m$$
$$F_C = 20N \qquad G = 600N$$

$$R_{1,12} = \frac{9+3\sqrt{2}}{\sqrt{2}} \frac{0.0013 \cdot 20N \cdot 0.022m}{0.05m} = 0.107N \qquad R_L = 0.008 \cdot 600N = 4.800N \tag{43}$$

$$R_T = \frac{9+3\sqrt{2}}{\sqrt{2}} \frac{0.0013 \cdot 20N \cdot 0.022m}{0.05m} + 0.008 \cdot 600N = 4.907N$$

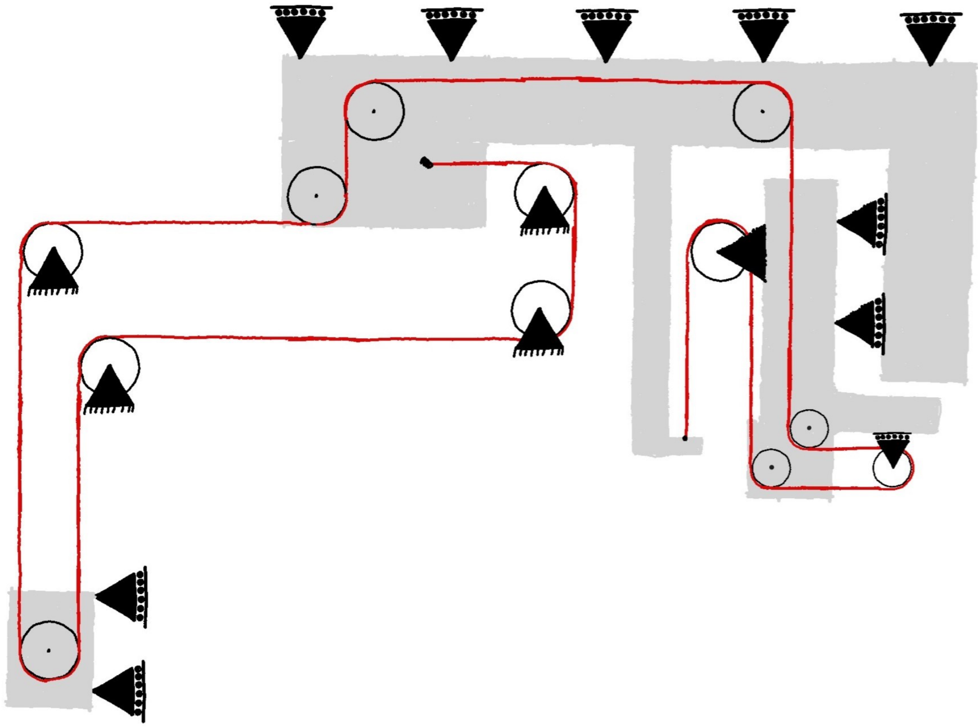


Figure 25: Pulley setup to deal with horizontal and vertical CR movement

If the CR axes are placed in the seat, a potential cable loading system becomes vastly less complex. This potential setup is shown in figure 26. Note that there are two weights required to load both tilt and rotation. This also means that two instances of the setup in figure 25 would need to be included in order to load both active axes simultaneously if the layout in figure 22b or 22a is to be chosen. If the layout in figure 22c is to be chosen though, a cable loading setup could simply focus on the active axes. Again, a potential setup for this layout is shown in figure 26, where one cable is connected to a weight that goes up around a pulley, and then goes between two pulleys meant to support the cable up against a larger pulley fixed to the gyro concepts rotational axis. As the occupant turns their head away from the neutral position pointing straight ahead, the cable would wrap around the pulley causing a constant torque pulling them towards the neutral position. The tilt axis is loaded similarly by a cable that is routed through a hole in the rotation pulley. This allows for both pulleys to be loaded simultaneously.

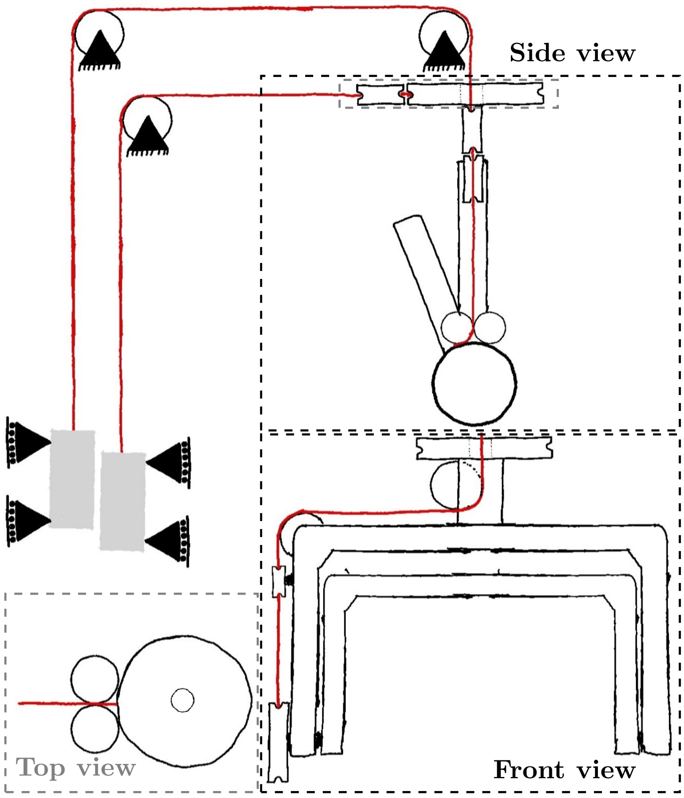


Figure 26: Cable load setup

5.3.4 Motor Resistance

One alternative way of creating resistance is the use of electric motors. They have the advantage that they can be mounted on moving joints, only requiring wires to be run which could significantly reduce the mechanical complexity of the design. There is also an advantage as torque and speed can quickly be adjusted. However, this requires a control mechanism, that needs to reliably produce a specific force in order to be implemented without introducing unacceptable risks to the patient. Nevertheless, as discussed in section 2.6, DC motor torque is roughly proportional to the current draw, meaning one could easily limit torque by limiting current.

5.3.5 Passive Support

Regardless of the axis layout on the Gyro concept, there will be some weight that requires constant support to allow for the CR to move freely. If the CR axes are placed in or above the Gyro mechanism, part of or the full gyro weight will need to be supported. If the CR axes are placed below the occupant seat the seat itself as well as the occupant weight would need to be supported. It would be advantageous to deal with this passively if possible.

If the CR axes are placed in or above the gyro mechanism, the required supported weight would be consistent. This means that adjustment of the support would not be necessary. Therefore, any mechanism that could reliably produce a constant force could be an option. However, as discussed in section 2.4, there aren't really any good passive mechanical options that can hold a perfectly consistent force. This may not be necessary though. The force from a constant force spring increases consistently as they are coiled. This could conceivably be tuned so that the axes would rest at a desired spot, as the sum of forces would push increasingly towards the neutral position when the CR increasingly strayed from a neutral position. This would be due to the spring force being larger than the gravitational force when the CR is below a neutral position, and vice versa when the CR is above a neutral position. The same could be accomplished with gas springs as they have a similar force curve.

Things get slightly more complicated if the CR axes are to be placed below the seat, because the support would then need the ability to adjust to varying patient weights. This should, however, not be too much of an issue. Constant force springs could be adjusted by adjusting the winding to reduce or increase the force output. Similarly, gas springs could be adjusted by regulating the internal pressure of the cylinders. One could argue there may be little benefit to having the passive supports at all if they need to be adjusted anyways. However, they wouldn't need adjusting once they were set for a specific patient, saving not only the need for constant active support, which could save on the complexity of the control mechanism required, but it could also save on energy use.

6 Evaluation

6.1 Masnak

The investigation into positional tracking and possible control algorithms for the Masnak showed that it should be possible to develop control software that could provide a desired force at the head mount point, depending on the position. There were some difficulties when trying to specify the center of rotation, with collected head movement data as the noise in conjunction with movement irregularity, caused wild variations in the direction from point to point. To get more accurate estimates, a better tracking algorithm is required, or alternatively, an encoder or some other method of tracking the exact angle of the head mount would need to be implemented. If the latter is chosen, the ICR estimation would be simpler, as the angle of the perpendicular bisectors could be known directly for every point, rather than having to be estimated from two consecutive points[2.3]. Angle tracking of the head would also simplify force direction control as the tangent angle could be calculated directly as in equation 32.

More work is still required in terms of choosing the actuator type and layout, as well as rigorous testing, as there still are potential safety concerns with regard to the use of actuators that are capable of providing large forces. This risk could potentially be reduced by limiting the strength requirements of the actuators. This could be done by using springs to help balance out the effect of component weights so that the position of the Masnak with the actuators providing no force would be a safe one. This would also reduce the risk of a patient suddenly having to bear the weight of the free-hanging Masnak components in the case of sudden power loss.

Vitally, there was a lot of new information gained that altered the perception of the concept, from what it was after the completion of the specialization project (Table 1). Considering how difficult it was to track the position and path of the head mount point, even in an idealized situation where most mechanical factors were controlled, reduced the optimism about the concepts' force tracking capabilities. This caused the score from the one received in the specialization project to be reduced. Similarly, the required force from the actuators contributed to an increased perceived risk of overstressing the fragile necks of patients. This caused a decrease in the safety score as well. On the other hand, the fact that these exact problems are now known is positive. The reduced uncertainty may warrant an improvement in the design uncertainty score, however, a perfect score would be excessive for a concept in the early stages of development. The design challenge compatibility score was increased as the problems faced proved to be very interesting.

Masnak Evaluation Scores

Acronym	Criteria	Score	Weight
ROM	Range of motion	5	4.7
DOF	Degrees of freedom	4	10.0
RSA	Resistance Specificity and Adaptability	4	7.7
MCC	Movement Constraint and Control	3	7.0
SFT	Spacial and Force Tracking	4	4.7
PBI	Portability and Installation	1	7.3
UI	User Interface	3	5.7
CMPD	Complexity of Design	3	2.7
DUNC	Design Uncertainty	4	2.7
PS	Patient Safety	3	13.3
PSS	Patient's Perceived Safety	4	10.0
EE	Efficacy and Efficiency	4	10.0
DCC	Design Challenge Compatibility	5	6.0
	Cost	1	8.3
Total		335	100.0

Table 10: Masnak evaluation scores altered from specialization project included in appendix A

Further information about the score categories and the previous thoughts on the Masnak concept can be found in the evaluation section of the specialization project (Appendix A).

6.2 Gyro

The investigation into possible cable loading setups did provide increased confidence that this was a feasible option, even if the CR axes' movement needed to be accommodated. The movement of the axes themselves proved to be a challenge as well. For the horizontal CR axis, some sort of powered assistance is likely required to overcome bearing friction, unless the weight of the moving Gyro mechanism parts can be brought down significantly, or bearing friction can be reduced below standard industry levels. Nevertheless, if this cannot be achieved, compensating for this force should not be an issue as powered movement assistance has been a mainstay in vital applications such as automobile power steering for decades. As for the vertical CR axis, some mechanism is needed to balance the force induced on the vertically moving parts by gravitational acceleration. Many mechanical mechanisms that produce an approximately constant force have been looked at. None quite accomplish this goal of constant force, though a slowly increasing force as the vertical axis moves down away from a neutral position may actually be desirable. This variation could help stabilize the mechanism to a safe equilibrium state. The final conclusion on this matter remains to be determined with more extensive testing, preferably done with a physiotherapist or another relevant professional involved in the process.

The investigations into the movement of the CR axes did result in the evaluations of the spacial force and tracking capabilities performed in the specialization project (Table 9) to be called into question. The increased uncertainty merited a score reduction. Similarly, the required complexity for a potential pulley system, especially if the CR axes are to be placed above the gyro mechanism, resulted in the design complexity score being reduced as well. This was not helped by the necessity of the support for CR axes being required, in order to operate with minimal resistance. An issue that seems to be a more difficult challenge than originally anticipated. The required support also raised some concerns with regard to the safety of the user. If the axes can't be moved passively then safety measures must be implemented to ensure that the users' necks are not stressed excessively. This caused the safety score to be reduced. The increase in required mechanical components might also make a patient more hesitant to use the machine, causing a drop in the perceived safety score as well. As in the case with the Masnak, the decreased uncertainty from the information gained during the project may have warranted a change in the design uncertainty score. However, this was deemed to be excessive as it would have resulted in a perfect score, which was judged to be unrealistic for a concept this early in development. Looking back, the scoring in the specialization project may have been a bit too high. That being said the challenges faced were interesting ones so the design challenge compatibility score was increased for the gyro as well.

Gyro Evaluation Scores

Acronym	Criteria	Score	Weight
ROM	Range of motion	5	4.7
DOF	Degrees of freedom	4	10.0
RSA	Resistance Specificity and Adaptability	4	7.7
MCC	Movement Constraint and Control	3	7.0
SFT	Spacial and Force Tracking	4	4.7
PBI	Portability and Installation	1	7.3
UI	User Interface	3	5.7
CMPD	Complexity of Design	2	2.7
DUNC	Design Uncertainty	4	2.7
PS	Patient Safety	4	13.3
PSS	Patient's Perceived Safety	4	10.0
EE	Efficacy and Efficiency	4	10.0
DCC	Design Challenge Compatibility	5	6.0
	Cost	1	8.3
Total		346	100.0

Table 11: Gyro evaluation scores altered from specialization project included in appendix A

Further information about the score categories and the previous thoughts on the Gyro concept can be found in the evaluation section of the specialization project (Appendix A).

6.3 Compared with the MCU

When comparing the concepts with the MCU it was decided this time around to remove design uncertainty and design challenge compatibility from consideration. This is probably something that should have been done in the specialization project as well, in order to give a more fair comparison between the finished product and the concepts. To get comparable values, the end scores were divided by the full hundred percent minus the weight of the two categories to bring the total back up to a combined weight of one hundred. This brought the Gyro score down to 334 and the Masnak score down to 322. As can be seen in table 12 the MCU comes in with a score of 342, outperforming both the concepts. This may put their capabilities to challenge the MCU into question, yet, the margins are not that wide with the Masnak scoring 94% of the MCU score and the Gyro scoring 98%. Given the uncertainty and subjectivity involved in such an analysis, they both still should be considered promising concepts.

MCU Evaluation Scores

Acronym	Criteria	Score	Weight
ROM	Range of motion	5	5.1
DOF	Degrees of freedom	2	11.0
RSA	Resistance Specificity and Adaptability	4	8.4
MCC	Movement Constraint and Control	3	7.7
SFT	Spacial and Force Tracking	4	5.1
PBI	Portability and Installation	1	8.0
UI	User Interface	1	6.2
CMPD	Complexity of Design	4	2.9
DUNC	Design Uncertainty	N/A	N/A
PS	Patient Safety	5	14.6
PSS	Patient's Perceived Safety	5	11.0
EE	Efficacy and Efficiency	3	11.0
DCC	Design Challenge Compatibility	N/A	N/A
	Cost	2	9.1
Total		342	100.0

Table 12: MCU evaluation scores altered from specialization project included in appendix A

7 Discussion

7.1 Work Process

The goal for this Master project was, as stated in section 1.3, to explore the most promising concepts from the specialization project A, with the intention of getting a more comprehensive design proposal and reducing uncertainty pertaining to the viability of a final product. This was achieved to some degree, however, the development did not get as far along as was initially planned. This was partially due to a lack of resources, limiting the ability to build a more functional prototype for conclusive testing. In hindsight, this may have been a good thing as it forced the capabilities of theoretical analysis to be explored. This eventual workflow adheres well to the principle of front loading, which should help reduce costs by pushing design choices earlier in a project before production. Although no major misconceptions was discovered about the concepts, a deeper understanding of the requirements from the mechanisms was gained, which might have had a positive outcome on future test efficacy. Another reason for the lack of progression was that the work required in the analysis phase was underestimated. Properly analyzing the concepts and building out the base to make design decisions took longer than expected. This means that even if the resources required for prototyping and testing had been available, the amount of work required may have hindered progress regardless. More extensive virtual prototyping and simulation may have been an option, yet, it was judged to be a less productive use of time than working on analysis, less dependent on a specific design.

Ultimately, the lack of CAD work, simulation, and physical prototyping was missed. On the other hand, the work done in kinematic analysis, analyzing functional requirements of systems and matching with capabilities of potential components was not only educational, but also more useful, given the stage of the project and the imposed constraints. Rushing forward with development just for the sake of it, would have been inadvisable as this could easily have led to costly rework down the line. Rework that could have been avoided if the proper due diligence had been applied earlier. No conclusive physical testing was performed during this project, but the work done should form a great basis for further development and hopefully contribute to a successful product down the line.

7.2 Demo Models

The demo models worked well to help visualize how the different axes in the gyro concept would move. This gave vital insight when it came to analyzing the movement of the axes, most notably relating to the movement of the CR axes on the Gyro concept. It also was very helpful when visualizing how cable loading could possibly work with a free-moving Gyro mechanism. The model was not as useful for the Masnak concept as the mechanism itself was easier to understand intuitively.

7.3 Mathematical Analyses

The kinematic analysis of the Masnak concept was very helpful to understand how it would move, and how the loading and movement tracking would need to work. The specifics of how the different sub-mechanisms interacted, which factors constrained movement space, and how the weight of different components would influence actuator requirements were all very useful. For the Masnak concept, the understanding of how bearing friction in the pulleys would not contribute significantly to the total ICR axes resistance, as it was small and proportional to the cable load, was eye-opening. Also, the fact that the linear bearings would contribute far more, even with a fairly conservative weight estimate, was surprising. Yet, it should be noted that in this case there will likely be some sources of friction in practice that do not show up on a fairly simplified model. Nevertheless, it still is valuable information and a good place to start off an analysis.

7.4 Functional Requirements and Component Consideration

The demo models and the mathematical analysis of the concepts yielded information on which to base system requirements. For the Masnak concept, things were more clear from the beginning as more work had been done on it previously. An idea was already established for the actuation, which is presented in the Master's thesis by Berg and Sunde [14]. The precise control of force in response to movement, however, had not been, hence being a subject in this project. This was explored in section 5.2.4 and 5.2.3, thus giving a basis on which to begin to consider actuator requirements. Although no conclusion for the final actuator was made, some initial considerations to narrow down the most likely candidates were able to be established.

Similarly, when exploring the Gyro concept, more information was gathered with respect to the required support for the vertical CR axis and for the presumably necessary powered assistance to ensure minimal resistance on the horizontal CR axis. Some research was done on constant force mechanisms, which lead to the discovery of multiple potential solutions for a largely, or perhaps even entirely, passive support for the vertical CR axis. This is better for safety as there are fewer potential points of failure.

7.5 Concept Evaluation

The renewed evaluation of the concepts, with respect to the same categories as was previously done in the specialization project (Appendix A), was useful to give perspective on how the evaluation and interpretation of the concepts changed with increased understanding. Many of the initial intuitions proved to be correct, however, some of the specifics pertaining to the design challenges were underestimated, which resulted in a lowering of the scores for both concepts. However, the scores were not lowered enough to change the ranking from the specialization project , where the Gyro concept came out on top and the Masnak second. The new evaluation did, however, reduce the difference, making the question of which concept is the most promising less clear.

8 Conclusions

In the large scheme of things, this project is only a leg of the journey, and there are many questions that remain to be fully addressed. Including but not limited to which concept is the most viable? Are any of the concepts a better alternative than the Multi cervical unit used today[1]? Should actuators be placed in the joints of the Masnak or between members? Which layout is the best choice for the gyro concept? There are many more questions where the final conclusion remains elusive, however, there is still much valuable insight to be gained from the project.

8.1 Work Process

In terms of efficiency, the project could have benefited from a more overarching structure. Much time was initially spent planning possible physical testing and prototyping which ended up exceeding the constraints. Having an organized list of available materials, components, and budget from the beginning could have gone a long way to avoid work that ultimately lead to a dead-end. However, the loss in project efficiency may still lead to increased efficiency if the project is to be continued. The more theoretical approach necessitated by the external constraints yielded many an insight that could potentially be beneficial for future development, by highlighting potentially unnecessary work and avoidable mistakes in early prototype construction. All in all, what was accomplished is satisfactory, although the result is more modest than what was initially envisioned.

8.2 Concept Viability

One conclusion that can be drawn from the information gathered is that obtaining the desired function from the concepts should be possible. There were issues discovered, however, none of them lacked a possible workaround after some thinking. It remains to be seen if the concepts can be cost-competitive, or meet the safety requirements imposed by specialists and regulatory bodies, however, at this stage in the development process, this is not a big surprise. Although the evaluation is decidedly less positive than the one from the specialization project(Appendix A), the concepts still show promise and should be seriously considered as contenders. The problems that remain should be solvable with sufficient time and effort, and the hope is that this project, along with the specialization project, might contribute to such efforts in the future.

9 Further Work

This section will outline the elements specific to the two concepts that will require further work. However, there are many surrounding elements necessary for a fully functional product that will also need to be looked at. These include the head attachment mechanism, the interface between the attachment mechanism and the movement platform (Explored previously in previous Master's thesis[20]), the occupant seat/fastening mechanism (Explored previously in previous Master's thesis [18]), the control software, the user interface and so on. These have not been explored sufficiently for informed suggestions on development strategies to be made, so this project will have to content itself with the above contributions and insights necessary for future work.

9.1 Masnak

Some further work will need to be done on the positional and force calculations provided to develop a program that can be properly simulated. In addition, the integration of some sort of a positional sensor, like an encoder in the head mounting point, could be looked at to avoid having to estimate head angle from path data. A study should also be done into the pros and cons of linear vs joint actuators, as well as a study into which types would ultimately be the best choice for the application. Work should be done in order to figure out what lengths of Masnak members are required to have a large enough working area to cover the movement space of a satisfactory range of patients. This would in turn help inform the choice of the actuators. Once general dimensions are nailed down, the strength requirements of the members should be worked out to assess how light they can be made, which in turn will influence the actuator requirements. Once these design choices are mostly finalized these ideas should be tested on a proper functional prototype.

9.2 Gyro

Further work should be done to explore cable loading and motor loading to weigh the pros and cons of both, and to choose the best solution. Similarly, an informed choice needs to be made regarding the placement of CR axes. Once this is established, work can be put into determining the required dimensions for the outer and inner gimbal in order to be able to fit most patients, as well as the required adjustable range for the vertical adjustment axis. Once this is in place, one can start to explore how light the design could be made and if it is possible to remove the need for assisted movement of the horizontal ICR axis if placed above the gyro mechanism. If motor loading is ultimately chosen, the possibility of implementing a motor in the rotational adjustment axis could also be explored. In addition, potential functionality improvements of the concept resulting from this addition could be explored allowing for rotational loading while tilting, which was a wish communicated by FPMC [21]. Finally, the mechanism for passive support of the vertical CR axis must be analyzed and determined, along with the movement assistance of the horizontal CR axis if this is deemed necessary.

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Appendix

A Development and evaluation of concepts for equipment to help understand and treat whiplash injuries

NTNU
Kunnskap for en bedre verden

Department of Mechanical and Industrial Engineering

MIPROD - Mechanical Engineering

Development and evaluation of concepts for equipment to help understand and treat whiplash injuries

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Abstract

Whiplash injuries impose large costs. Large sums are spent every year on treatment and sick leave, while the afflicted individuals suffer large reductions in their quality of life. Through rehabilitation patients can potentially improve symptoms and allow for functionality previously unattainable, improving quality of life. In addition, the improved functionality achieved can allow individuals to return to the workforce in a full or partial capacity improving productivity and reducing government spending on disability benefit payouts.

Firda Physical Medical Center is a company that specializes in this rehabilitation process. To improve their capabilities they have made an inquiry to the Department of Mechanical and Industrial Engineering at the Norwegian Institute of Science and Technology to conduct research into equipment to help diagnose specifics of an injury and help train the movements and muscles required to improve functionality.

This specialization project is conducted in relation to the 8th master thesis project that will be done with Firda Physical Medical Center, and will focus on establishing the needs of the relevant stakeholders to a potential product, mapping a design space of possible solutions for a motion support system, and establishing the feasibility of different design directions. The scope of possible solutions will be narrowed, giving direction for the master project that will be conducted the spring semester of 2023.

December, 2022

Table of Contents

List of Figures

List of Tables

Glossary

Acronyms

CT	Computed Tomography
DOF	Degree/Degrees of freedom
FPMC	Firda Physical Medical Centre
MCU	Multi Cervical Unit
MRI	Magnetic resonance imaging
MTP	Department of Mechanical and Industrial Engineering
NTNU	Norwegian university of science and technology
ROM	Range of Motion
SBCE	Set Based Concurrent Engineering
SBD	Set Based Design

Terms

Stakeholder	An individual, or group of individuals with mostly aligned interests, that have an interest in the production and or use of a product, that are salient enough to warrant consideration.
Motion platform	A mechanical system that can actively or passively move through space

Units

euro	Euros also known as €is the shared currency in most of European union
kr	Norwegian kroner also known as NOK is the Norwegian currency
N m	Newton Meters - Unit for Torque
N	Newtons - Unit for Force

1 Introduction

1.1 Background

Whiplash injuries are a large problem and bring with them large costs not only for those directly affected but also for society at large. Whiplash injuries can lead to full or partial work disability. In a 2021 report for the Norwegian Labour and Welfare Administration Eirik Lamøy and Andreas Myre estimate that Norway on average would save 4.7 million dollars per person if they are able to work rather than go into early retirement due to injury.[1] More specifically for whiplash injuries, a study from Sweden found that a whiplash injury leads to societal costs in the form of lost income and direct health sector costs. They estimate that the total cost for Sweden in 2001 was 500 million euros. In addition, they found that half of those in the study who missed work due to whiplash injuries did not return to the same income level they had prior to the injury.[2]

The patient stories found on the FPMC website give some anecdotes that speak to the personal costs that can come from a whiplash injury as well as the large benefits that can come from regained function. One patient suffered severe pain and struggled to do tasks that had been non problematic prior to injury and was not able to work. After a few years of rehabilitation with FPMC the patient was able to return to work full-time, with pain reduced and function increased. Another patient had been being reduced to working only forty percent due to consistent struggles with neck pain and headaches. After working with FPMC the patient is now almost pain-free and is able to perform work without issues.[3]

1.2 The problem

Firda Physical Medical Center is a company that specializes in the rehabilitation of whiplash injuries. Their process includes a range of different manual therapies but also diagnosis and training exercises aided by specialized equipment. At present this is done using the Multi Cervical Rehabilitation System, more specifically a device known as the Multi Cervical Unit OR MCU.[4]

The MCU fills most of the requirements at the moment however there are some limitations that are not ideal. These limitations leave a lot to be desired and due to this desire, FPMC initiated an ongoing project with the Department of Mechanical and Industrial Engineering at NTNU, to develop a product that better fulfills their requirements. The project was first initiated back in 2014 and there have been many different proposed solutions yet none have reached a satisfactory level of functionality, hence the continuation of the project. Some of the solutions may be viable, only requiring further development, and some may be hindered by present technological constraints or fundamental issues.

1.3 Agenda

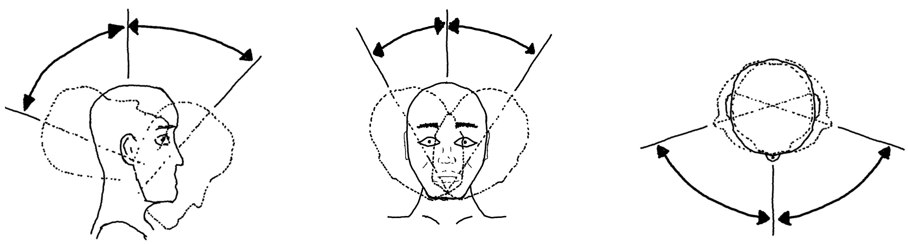
This specialization project will focus on laying the groundwork for developing a product that can successfully be implemented, satisfying the needs of FPMC. Interviews have been held with a representative from FPMC throughout the process where a focus has been on getting an understanding of the processes involved in rehabilitation, to parse out what product functions are essential for the product to fulfill. In addition, to avoid developing a product in a direction that fails to satisfy the requirements of the relevant stakeholders involved and to avoid redoing prior work, an analysis of prior project concepts will be performed. Based on knowledge gained about product requirement ranges, the design space will be mapped. Finally, the feasibility of possible solutions will be evaluated to narrow the design space down to the most promising designs.

2 Theory

2.1 Cervical spine Kinematics

The cervical spine is made up of two segments that contain a total of seven vertebrae that are numbered from one to seven from the one connecting to the scull to the one that connects to the rest of the spine. The sections differ both functionally and anatomically and work together with muscles and ligaments to produce the neck's total range of motion.

The lower section, called the subaxial spine, consists of vertebrae C3 through C7. The five vertebrae in this section are more or less identical when it comes to both mythological and functional features. They also share most features with the rest of the vertebral anatomy. The upper section, called the craniocervical junction, consists of the C1 and C2 vertebrae, more commonly referred to as the atlas and the axis, respectively. These vertebrae are the ones closest to the head and differ from the rest of the cervical vertebrae. Their unique morphology helps the joint between them, the scull and the joint connecting them to the subaxial spine, to contribute most of the total range of motion of the spine. Approximately half of the flexion/extension, meaning the forward/backward tilt, is facilitated by the joint between the skull and the atlas. This dominance is more prominent during extension resulting in the center of rotation of the head moving less and being higher during extension, the latter of which is apparent in figure 1a. Approximately half of the rotational range of motion is facilitated by the joint between the atlas and the axis. The sideways tilt of the neck is facilitated more evenly across the vertebrae of the neck causing the instantaneous center of rotation to move a lot more throughout a movement than it does during flexion or extension, particularly extension.[5][6][7]



(a) Extension and Flexion (b) Right and Left Tilt (c) Right and Left Rotation

Figure 1: Neck Movement

The particular range of motion varies widely on individual bases. [8] In table 1 the range of motion of individuals in the fifth and ninetieth percentile is shown. The table is based on data collected in 1979 and 1980 by Dr. William Thornton and John Jackson. The sample size was relatively small using only 192 males and 22 females, all astronaut candidates. The limited sample size and demographic range mean results may not apply fully to a general population so should not be taken as absolute fact. [8]

Movement	**Males**		**Females**	
	5th percentile	**95th percentile**	**5th percentile**	**95th percentile**
Tilt Right	34.9°	63.5°	37.0°	63.2°
Tilt Left	35.5°	63.5°	29.1°	77.2°
Flexion	34.5°	71.0°	46.0°	84.4°
Extension	65.4°	103.0°	4.9°	103.0°
Rotation Right	73.3°	99.6°	74.9°	108.8°
Rotation Left	74.3°	99.1°	72.2°	109.0°

Table 1: Range of Motion of the neck [8]

2.2 Whiplash injuries

Whiplash injuries are as the name suggests injuries that result from whiplash. Whiplash is a term used to describe a movement where the neck is exposed to a quick bending movement in one direction followed by a quick bending movement in the opposite direction, in other words, a whipping motion, hence the name. The term refers to a mode of injury and not any specific injury. One of the most common causes of whiplash is when one is rear-ended. Rear-ended refers to an automobile accident when the rear end of the vehicle an individual is seated in is impacted by something, typically another vehicle. This causes a forward acceleration of the body as it is pushed forward. The head's inertia results in its center of mass moving backward relative to the body causing the neck to go into sudden extension. This extension may be limited by the presence of a headrest. As the vehicle stops the body's inertia carries it forward until it is decelerated by the seat belts in the vehicle. The head's inertia carries its center of mass forward causing the neck to go into sudden flexion.

Rear-end collisions or other episodes resulting in acceleration followed by acceleration in the opposite direction in quick succession can dependent on the magnitude of these accelerations, impart large forces to the vertebrae, ligaments, and muscles of the neck. The resulting damage from these large forces can result in a wide range of symptoms, including but not limited to neck pain, shoulder pain, arm pain, headaches, tinnitus, visual symptoms, dizziness, low back pain, and concentration and memory disturbances. [9] This wide range of possible symptoms can make identifying whiplash injuries and the underlying causes difficult. [10]

2.3 Stakeholder Categorization

A unifying definition of what constitutes a stakeholder is hard to come by in the literature. There are a number of different narrow definitions that come up that attempt to specify Which categories or types of stakeholders require attention because the reality is that it infeasible for managers to consider every single actor that could potentially have some stake in the outcome of their decisions. To avoid getting bogged down in unending pursuits of the full picture, any useful framework must narrow down the full set of actors that could be argued to be stakeholders to an amount that is manageable, and identify the salience of their interests so that it can be used to inform a firms strategy. This could be done by ignoring those whose claims, by some measure, are determined to be negligible, or by grouping individuals with aligned interests. In this paper, the working definition of a stakeholder will be an individual, or group of individuals with mostly aligned interests, that have an interest in the production and or use of a product, that are salient enough to warrant some consideration. How these groups are categorized, and the salience of their claims is informed by a framework proposed in "Toward a Theory of Stakeholder Identification and Salience: Defining the Principle of Who and What Really Counts".[11]

One framework for categorizing stakeholders into groups was proposed by Ronald K. Mitchell, Bradley R. Agle, and Donna J. Wood. They suggest a system for identification and salience based on stakeholders possessing one or more of three relationship attributes. These attributes are power, legitimacy, and urgency. Looking at their status with respect to these attributes can help establish the salience of a given stakeholder and the implications they may have for decision-makers within a firm allowing them to make decisions on how to relate to their claims.[11]

This results in eight stakeholder classes, as can be seen in figure (2) where three classes possess one of the aforementioned attributes, three classes possess two of the aforementioned attributes and the final two classes possess all of them and none of them. The classes identified to be relevant to this project are the classes titled Dependent, Discretionary, Dominant and Definitive stakeholders.

Discretionary stakeholders are those who possess legitimacy but lack any of the other attributes. This means that they lack the power to affect the firm in question, but also do not have any urgency to their claims. Dependent stakeholders are those who have legitimate and urgent claims but lack the power to directly influence the firm in question. They are therefore dependent on other stakeholders, or decision-makers within the firm to get their needs met. Dominant stakeholders have power, and legitimacy but do not have urgency to their claims. Definitive stakeholders are those who have legitimate urgent claims, as well as the power to influence proceedings to get their needs met. The frame work does not give any explicit instructions on how to relate to the different categories of stakeholders however, it is meant to help highlight how a given stakeholder can effect or may need help affecting the firms proceedings.

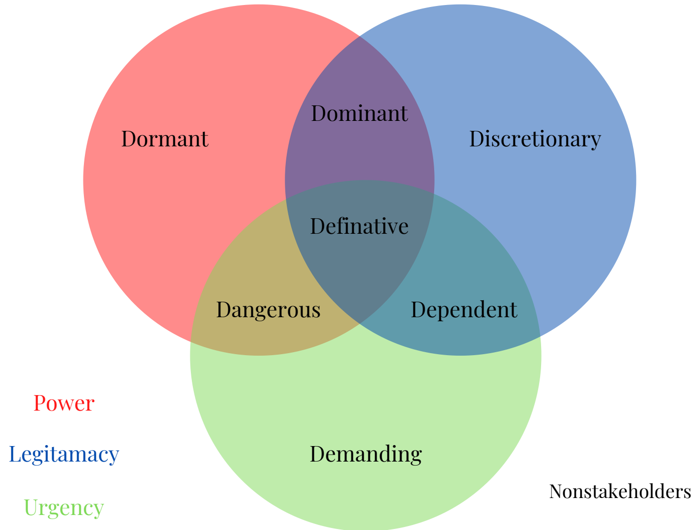


Figure 2: Stakeholder groups

2.4 Set based design theory

Set-based design (SBD) or set-based concurrent engineering (SBCE) are terms referring to a design philosophy. The goal of SBD is to design better products faster by designing multiple systems concurrently and delaying design decisions to a point when trade-offs are better understood. This decision delay is meant to reduce the chance of premature narrowing of design possibilities causing an optimal solution to be missed. There has been extensive research into SBD as applied to the design of products into already established categories. One of the first papers on the topic looked at how Toyota designed new automobiles [12]. There is however limited research done on the topic of applying SBD principles to early development stages of entirely new products, where there is little knowledge of the end design beforehand. As part of the course, Advanced product development [13] I wrote a paper titled Working with uncertainty: Adapting set-based design to early new product development phases. In this paper which is included as appendix A, an amendment was made to principles of SBD proposed by Allen C Ward and Durward K Sobek II and Jeffrey K Liker. [14] This resulted in the following principles.

1. Map the design space.
    - **Identify stakeholders and their interests.**
    - **Identify possible product functions to fulfill demands.**
    - **Establish feasibility based on existing technology from other products or research fields.**
    - Define feasible regions.
    - Explore trade-offs by designing multiple alternatives.
    - Communicate sets of possibilities.
2. Integrate by intersection.
    - Look for intersections of feasible sets.
    - Impose minimum constraint.
    - Seek conceptual robustness.
3. Establish feasibility before commitment.
    - Narrow sets gradually while increasing detail.
    - Stay within sets once committed.
    - Control by managing uncertainty at process gates.

Added principles and Original principles. Additions are explained in appendix A.

3 Method

Due to the fact that previously proposed solutions have failed to be implemented, great emphasis was placed on understanding the requirements of the process of rehabilitation as well as possible, to help ensure that the functionality required by FPMC is well understood, and therefore minimize the risk that the concept chosen fails to be successfully implemented after development.

3.1 Interviews and Discussions

Throughout the project, interviews and discussions with the FPMC representative played a major role. Firstly in the initial phases, they helped establish an understanding of the scope of the issues whiplash injuries caused to the individuals afflicted, and how FPMC works to help mitigate these issues. Later they played a large role in establishing an understanding of the rehabilitation process in general, and more specifically what exercises are currently done with the MCU and the desired functionality missing from the current equipment.

The interviews were generally conducted in an unstructured manner. Before the interview, questions were written down about specific things that I required answers two. This could be about specific practices or injury risks associated with certain types of loading or equipment at the disposal at a typical physio office. These questions would serve as a jumping-off point for discussion, where the representative would talk freely with me asking questions where the need would arise all the while taking note of details that seemed relevant to the question at hand.

3.2 Stakeholder mapping

To bring structure to how different stakeholders can affect and be affected by the product, stakeholders were classified according to their possession of different attributes outlined in the Theory section.(2.3) Then the relevant needs of the stakeholders were identified to inform the requirement ranges of the product.

3.3 Rehabilitation process mapping

An overview of the rehabilitation process from initial patient contact and assessment, before a personalized rehabilitation program is developed and executed was established. The specifics may vary widely, depending on the needs of the specific patient but some commonly occurring steps could be established. The focus was mainly on the parts of the process where the MCU is utilized today however some note was taken on other parts of the process where the functionality of the new product could potentially be helpful in improving the accuracy and efficiency of the process. This mapping was done to get an understanding of not only the tests and exercises done, but the reason behind them so that requirement ranges could be established without being too constrained by existing solutions. (5.1)

3.4 Concept generation

Based on the process requirement ranges established in the interviews concepts for possible movement platforms were generated. These were later compared and evaluated along with concepts described in earlier theses.(3.6)

3.5 Existing Solution mapping

In addition to descriptions of the use of the MCU in current rehabilitation practices provided by the FPMC representative, an analysis was done of the MCU based on available information about it, from the seller's website as well as conclusions drawn from available photos. Unfortunately, a unit was not available for an in-person inspection. Shortcomings of the product uncovered during interviews were looked at to try and find the design reasons behind them.

3.6 Previous Concept mapping

After an understanding of the problem was established and the design space had been partially mapped, a literature study was done on the theses relating to the previous projects. The goal of this study was to establish why these solutions failed to be successfully implemented.

3.7 Viability Analyses and Concept evaluation

Establishing the viability of design directions depends on many factors. The ease of manufacture, cost, and capability of the implemented technology. Available expertise, and hurdles for safety clearance could also play a role. These factors were weighted with respect to different interests before the concepts were scored for individual categories. These scores were then aggregated to get a more objective measure of concept performance, to help inform selection.

4 Summary of Previous Work

As mentioned earlier this specialization project is part of an ongoing collaboration between FPMC and NTNU. The related master thesis will be the eight written related to the collaboration. Promising solutions have been proposed and developed, yet there is at present no solution that has left FPMC fully convinced of its promise. This could, of course, be that some or all of the proposed solutions only need more work to be turned into viable products however to avoid further development on solutions that may turn out to be severely limited by technological constraints the solutions in the previous works were read and analyzed. The analysis was constrained to the development of the system for providing resistance. This has shown itself to be the hardest problem to solve.

The first master's thesis was submitted in 2015 under the title First Development of new Machine for Rehabilitation of Whiplash Patients [15]. It focused mainly on the development of a head and or neck attachment module and the development of a motion support platform. The authors put forward three different concepts deeming a concept based on a Stewart platform to be the most interesting.

The second thesis titled Development of Seat for New Machine for Rehabilitation of Whiplash Patients [16], built upon its predecessor but focused on the development of a seating module to hold the user in place and is, therefore, less relevant to the main analysis.

The third thesis titled "Utvikling av apparat for behandling av nakkeskadde" [17], looks at a head and or neck attachment mechanism, a motion support mechanism, and the interface between them however the largest chunk of the thesis relates to the motion support system. The authors go through the Stewart platform solution proposed by the preceding thesis is not suitable for the application. They acknowledge that the platform has strengths such as its stability and precision however they conclude that the platform's range of motion, was too limited to suit the application, given their minimum constraints. They also doubted the platform could meet the safety standards required for the application. They propose instead a solution combining a gyroscope-inspired solution and a planer movement actuator consisting of five trusses. They dubbed the solution Masnak and concluded that although it lacked the six degrees of freedom of the Stewart platform, it could still sufficiently fulfill the needs of the application as it accommodated neck bend movements better than the MCU used by FPMC today. They finally propose that the next step would be to investigate possibilities for loading.

The fourth thesis published was one called "Utvikling av maskin for opptrening av nakkeslengskadde" [18]. It again focused on developing a potion support platform. They investigated the possibility of a cable robot solution. However, discarded this solution as it looked to be more expensive and complicated than anticipated to develop a new robot from scratch and therefore opted for a solution utilizing an off-the-shelf robot. The robotic arm would interface with a head attachment contraption and provide variable resistance and motion guidance. They concluded that a robotic arm solution had a good chance of meeting necessary safety requirements and therefore chose to go forward with the concept.

The fifth thesis titled Development of Rehabilitation Apparatus for Whiplash Patients [19] looked into the feasibility of using a robotic arm continuing the work from the fourth thesis. They also quickly looked into the previous movement platform concepts and the reasons for their dismissal. They dismissed the Stewart platform concept proposed in the first thesis for the same reasons as those cited in the third thesis, plus concerns regarding singularities that often occur for closed chain kinematics. They also dismissed the Masnak from the third thesis deeming it to be simple and similar to the MCU currently in use. They also addressed the cost issues with the cable robot design cited in the fourth thesis. The scope of the fifth thesis was constrained to analyze the workspace and load capacity of a robotic arm called Panda. They concluded that their chosen placement of the robot arm meant that the Panda was not able to accommodate the training space required. They speculate that a change in position may resolve this issue though. They conclude that the torque capacities of the motors of the panda are sufficient.

The sixth thesis is titled Development of Robot Based Rehabilitation Apparatus for Whiplash

Injured Patients [20] and mainly focuses on the development of a control system for the Panda robotic arm. They also developed a user interface and a magnetic connection mechanism that would disconnect given a reasonable force improving safety. They developed a compliant control system that was able to allow a user to guide the robot through space with minimal resistance using a force controller. However, they had some issues with the stability of the system and the accuracy of the internal force estimations and rotational control. It was concluded that the system was still far from being ready for safe use.

The seventh master thesis is titled Development of a Robot Based Rehabilitation Apparatus for Whiplash Injured Patients [21] and focuses mainly on the development of a graphical interface and an improved magnetic head fastening mechanism.

In the seven previous theses, there have been proposed three different concepts concluded to be the most promising motion support mechanism. The Stewart platform, the Masnak, and the robotic arm. In all one project (project 1) goes with the Stewart platform, one project (project 3) goes for the Masnak solution and one project (project 4) goes for a robotic arm solution with three projects building upon the concept (projects 5, 6 and 7).

5 Communication with Firda Physical Medicine Centre

At the upstart of the project, a meeting was set up with the contact form FPMC. This meeting was centered was meant to give an initial understanding of whiplash injuries, how they can affect patients and how FPMC services can help improve symptoms, functionality, and quality of life.

5.1 The patient journey

When a patient first comes to FPMC, an extensive patient history is established. This is done to try to identify the moment of injury, in cases where this is unclear. The mode of injury can hint at where the issues may lie. In addition, the patient history includes symptoms that can also help point to where and what type of injury the patient has. This step could potentially be aided by some sort of AI algorithm that would take the inputs and output suggestions for where the patients issues may be. This will not be an aim of this paper as the specialization does not lend itself all that well to the application it will however be included as possible avenues for future work. (Section 9.2)

This is then followed up with a full body checkup, done by one of FPMC's specialists. Here potential limits in the range of motion, movements that cause pain, and other criteria are identified. The main focus of the checkup is the neck. The neck is typically done under slight tensile stress applied by the specialist. The range of movement of the individual vertebrae is checked. This gives a further indication as to where the issue is and what type of issue it is. This process could potentially be aided by a product if it had either the ability to manipulate individual vertebrae like a therapist or just track individual vertebrae somehow getting more precise measures than are possible currently. Aiding in any manipulation would likely require immense complexity, especially if a system was to be able to fit patients in many different sizes and shapes. These immediately apparent challenges lead to it not being a priority for this project. Some forms of tracking may be more doable with some sort of camera-based solution and is also a candidate for future work. (Section 9.2)

This is followed up with testing in the MCU. This is based on established standard methods as a person with a missing active range of motion in general, will also have a reduced range of motion in the MCU. In addition to the active range of motion, the passive range of motion is established. This can give information that allows a specialist to estimate if the range of motion is restricted by the vertebrae themselves, due to weakness in the surrounding muscles, damaged ligaments, or other issues, as these different issues typically correlate differently with obstructions to active and passive ROM. This step is somewhere a product could obviously be beneficial, proved by the current use of the MCU. For a product to be useful in this application DOF, ROM, and spacial tracking accuracy are particularly important.

The final diagnosis step is a CT and or MRI scan that is performed if it is deemed necessary to get a good image of the skeletal and muscular structure, to help determine the cause of a patients symptoms. This could conceivably be improved upon if a product could help get sufficient data to make a secure diagnosis without the use of a CT and or MRI. This could potentially save time and money.

After a diagnosis is made a training plan is made to fit the needs of the specific patient. This program will typically be a mix of many different types of exercises. This includes manual therapy, specialized MCU training, and an individual training program that can include, stability, mobility strength, and conditioning exercises.[22][10] This again is a sage in the process where a product could be of tremendous help. For this application, the possibility of variable combined loading would be a very useful attribute for a product to have. Portability, affordability, and ease of use would also be tremendously beneficial if a product should be widely available.

5.2 MCU limitations

Throughout the meetings with the FPMC representative inquiries were made in an attempt to understand where improvements can be made to the functionality of the MCU. The main issue brought up with the representative was the lack of correspondence between the Movement in the MCU and the natural movement of the head. This is especially an issue during sideways bending. This is due to the MCU having a static pivot point somewhere around the Adam's apple with a perfect radial arc of movement. During natural movement, the center of rotation moves as the head tilts.(Section 2.1)

Another limitation of the MCU is the limited ability to tailor loading in different planes of motion. A specific example brought up was a case of bending with the head twisted. The possibility of being able to perform a forward bend while being able to add an individually adjusted twisting resistance would open up more possibilities when designing training programs. This is illustrated in figure 3.

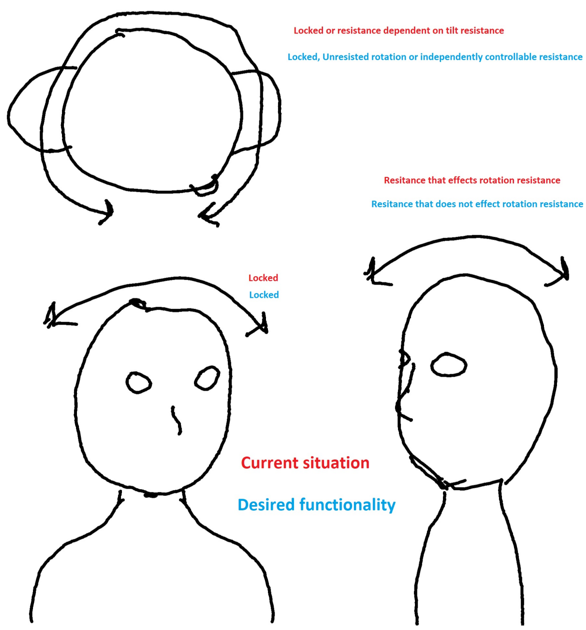


Figure 3: Twist and tilt Resistance

The MCU does produce a report on the range of movement of the patient. However, on the part of the representative, there was some desire to improve this with a more intuitive detailed presentation of the data, that gives a better representation of the actual neck movement, and not the movement of the machine. If possible there was also a wish for the product to make exercise suggestions based on the movement pattern of the patient, as well as give active feedback where a patient could compare their movement represented graphically to an ideal movement to help guide exercise.

The main areas for improvement identified in these meetings could now help provide potential focuses for product development. The focus would be to match the functionality to a large degree if the desire is to replace the MCU as the main diagnostic and training tool, or perhaps the focus could be to complement the MCU by being strong in the areas the MCU is week. These areas for improvement in functionality can be summarized as follows.

- Facilitation of more natural movement where the center of rotation can move as the head tilts or rotates.

- Ability to selectively load neck planes of motion without locking other planes.
- Possibility of consistent adjustable loading throughout the entire movement space of the patient.
- Facilitation of better documentation and active feedback to patients and experts.

[10][23]

5.3 Previous Project Feedback

Throughout the correspondence with the FPMC representative,[10][23][24] the ongoing project was also addressed. The representative shared thoughts on some of the previous concepts. (Section 4)

When it comes to the robotic arm the main challenge is with the control system that has to be able to facilitate free movement in all directions without any resistance. Some progress was made on this front by Baardsgaard and Brekke in their thesis [20] where they were able to get a decent level of quasi-compliant behavior, excluding rotation. However, they like the representative from FPMC conclude there is still a ways to go before this is anywhere near ready. The required precision and stability for safe and effective use in training are still far from being achieved. The nature of the robotic arm also makes it difficult to get a repeatable neutral position of the head. There are also some difficulties that arise from the fact that there is an infinite number of joint angle combinations that can correspond with a given head position.

The Stewart Platform has some clear disadvantages in terms of a range of motion but the representative believes it to have the highest potential as it has less of an issue with interminably in the inverse kinematic solving of in this case actuator lengths than the robotic arm. The Stewart platform also has the potential for movement with six degrees of freedom.

The Masnak solution proposed by Brattgjerd and Festøy in their thesis [17] does have some limitations when it comes to full movement freedom but should have fewer difficulties with implementing some minimal resistance motion.

In summary FPMC expressed some positivity towards the potential versatility of a robot arm solution, but had large concerns around safety and reliability. They liked the Stewart platform although the limits in ROM, especially in rotation were not ideal. FPMC were positive towards the Masnak and thought the solution may offer a good compromise.

6 Development

6.1 Stakeholders

Establishing the stakeholders relating to this product development process requires specificity. In this case, it could be unclear as to where a given stakeholder falls as they can relate differently to the project than they do to the product itself although the two are heavily linked, the project stakeholders are less urgently linked to the resulting product. Therefore these entities that could be categorized as stakeholders, being NTNU my project supervisor, and myself will be excluded as external stakeholders and rather categorized as internal parts of the firm.

There are many stakeholders that have their interests connected primarily to the potential use of the product itself. These are FPMC, the state, competitors in the specialty treatment market, hospitals and other institutions that treat whiplash victims, general physiotherapists, whiplash patients, and other potential product beneficiaries. In addition, a patient's friends and family have an interest, but as it is tied to the patient well being, they will be excluded from individual analyses.

FPMC proposed the project due to an unfulfilled need and therefore could improve the efficiency and efficacy of their practice if a successful product results from the project. They also have the ability to influence decisions through contact. However, it could still be argued whether or not this constitutes decision-making power. Nevertheless, they are categorized as definitive stakeholders.

The state could potentially save millions if a product could improve rehabilitation (Section 1.1) but lacks direct influence in development. They could however influence requirements through regulatory guidelines for the certification of training equipment. They are therefore categorized as definitive stakeholders although, their power won't influence the project until later stages.

Hospitals and other medical professionals that may have contact with and treat whiplash patients also have an interest in the functionality of a potential product. If they could more effectively and easily treat patients it could improve their outcomes and reduce workloads. Individual hospitals however are not specifically focused on whiplash injuries so their claims would not be as urgent as that of FPMC. They also lack power but due have legitimate claims so they fall into the category of Discretionary stakeholders.

General Physiotherapists will also have an interest in a product. Like hospitals, they and their patients could benefit from them being better equipped for treating whiplash injuries. No direct power and less urgent claims however put them in the class of discretionary stakeholders.

Competing specialty clinics also have some interest. Depending on the availability of a developed product other clinics may have their interests aligned with FPMC. If the product is available at the same price for competitors and made in a volume that allows them to acquire it, their interest will align well with FPMC. If this is not the case and the product provides a competitive advantage the competition could potentially be harmful. This may not have that much of an effect though as specialty clinics are limited and geography could lock one into their closest provider even if service quality is somewhat lower.

Competitors in the market like BTE technologies [4] are also categorized as a stakeholder. Their main interest comes in the form of how a potential new product would affect their sales. Similarly, their power comes in the form of their ability to influence the commercial viability of a developed product, by out-competing it in terms of price, function, reliability, or even just established trust or brand loyalty that may make potential customers apprehensive about trying something new. Depending on if the functionality of the final product is conducive to use alongside, or aims to replace a competitor's product, the passivity of a competitor's interests will vary. Competitors will possess power and legitimacy as they could potentially gain or lose market share, and therefore profits, based on the success or failure of a product. There may also be some influence in effect from the start as they set the benchmark for functionality and price that the product will inevitably be measured against if it aims to compete. However, as their interests and power are mostly linked to the market, they are less relevant initially during development, and therefore less urgent. This puts them firmly in the category of dominant stakeholders.

Whiplash patients have perhaps the most legitimate and urgent stake in a product that can improve their rehabilitation. Although they have no vested interest in it being any specific product that ends up full filling their needs. They fit well as dependent stakeholders.

Finally, there are users who may benefit from the product, but not for the intended use. There are others than those with injuries that may benefit from neck training. Practitioners of certain combat sports and other people who wish to do preventative training to avoid injury could conceivably benefit from a product designed for the rehabilitation of whiplash injuries. They do however have less urgency than someone currently suffering and therefore fall into the category of Discretionary stakeholders.

Stakeholders	
Discretionary	Unintended Beneficiaries, Hospitals, general physiotherapists
Dominant	Competing Producers, Competing Clinics
Dependent	Whiplash patients
Definitive	FPMC, State

Table 2: Stakeholders categorized

Patients and their needs are the most pressing, and the ultimate success of a product is largely dependent on a patient's user experience and they can therefore not be ignored. The same goes for FPMC as they initiated the project and are the facilitators for the potential patient benefit. Other potential beneficiaries are less important with their needs being less urgent however, they could prove useful in bringing the cost of the product down. The state's needs should be tied to the fulfillment of the needs of the patients.

6.1.1 Stakeholder needs

In a paper titled The fear-avoidance model in whiplash injuries, researchers look into the effect of a patient's fear of movement on disability and depression after whiplash injuries. [25] Their results show evidence that fear of movement and pain catastrophizing contribute to a patient's levels of functionality and depression. Therefore it is important for adoption that the product at the very least does not exacerbate these existing fears, and ideally helps mitigate them. In addition to perceived safety so that they can feel safe, patients also have a need for the use of the product to actually be safe. This means that the product ever applying force in a way that may cause harm should at least be exceedingly unlikely and ideally impossible. Another thing patients may benefit greatly from is accessibility, particularly if perpetual use is required to sustain benefits. If a patient can conveniently and safely benefit from the product where they are, without the need to have a professional present to help them, it could conceivably speed up or even improve the results of the rehabilitation process. Portability could be a factor as the ability to take the product with them while traveling could improve the adherence to and enjoyment of a rehabilitation routine. Accessibility also is tightly linked to cost as it would not matter much if the product was portable if it was prohibitively expensive to acquire. The possibility of personalization would also be useful as a patient's personal product could be adjusted to suit their specific needs better. Lastly, the patients have a clear need for efficacy, as there is little point in the product if it provides no benefits in terms of reduced pain or improved function, by either ongoing treatment or a confined treatment period.

Smaller private physiotherapists offices would like patients to be more dependent on lower costs as the 500 000 kr reference price of the MCU [24] (Section 6.1.3) would be a lot to spend on equipment that is only useful in a small percentage of a limited number of cases.

The needs of FPMC are heavily tied to the fulfillment of most of the patient needs as they are their customers and are dependent on their satisfaction. They will likely have a higher maximum acceptable price point than the typical patient though. Unlike patients, they may benefit more from generalization than personalization as the product would have to suit multiple different patients.

Quick and easy adjustability would also be a huge asset in this case. The potential efficacy and or efficiency improvements a product may provide to FPMC's process, and their patient's experience of these improvements, is hugely important for FPMC as it provides the basis for the reason to adopt the product in the first place. The same would likely go for a competing specialty clinic. A hospital would like FPMC, typically have a larger budget to play with than individual patients or smaller private practices and could therefore afford a more expensive product with more functionality. Being able to cater to a wide range of patients would also be crucial for a hospital.

6.1.2 Firm and Product developer needs

As internal actors in the firm go, the one with the most salient interests regarding the specifics of the product is me. My main priority is to do the initial development that allows for the best possible product to be produced. However in order to satisfy the requirements of my master's thesis, the contribution made should ideally allow for the use of as much of my specific expertise as possible. As My expertise primarily lies within the design and development of mechanical products, there is an interest that a proposed solution will require enough mechanical functionality to justify my writing a thesis within my field.

6.1.3 Markets

There is a lot of uncertainty pertaining to the market in which the product will be competing. Based on the asking price for a MCU being around 500 000 kr [24] the assumption is made that a specialty whiplash clinic would be willing to spend something in the same region for a product but is fair to assume that this is out of budget for the average patient. If the price is to be brought down to a more affordable level there would likely be some need for compromise on functionality, or perhaps through scaling up by expanding the user market beyond whiplash sufferers with some functionality conceivably carrying over well to training equipment for training for injury prevention in sports. If this strategy is to be chosen, early adopters would likely be specialty clinics anyway. It is also possible that the state would be open to subsidizing costs as the prevented loss from the utility of the machines could outweigh the costs, making it a worthwhile investment.

6.2 Product function ranges

According to SBD theory product requirements should initially be communicated as a set of wide ranges that later can be narrowed towards as more information is gained about the trade-offs between different design aspects. Based on potential product functions derived from the problem description given in the initial interview with FPMC [10] categories of product functions were derived. As mentioned in section 5.2 FPMC's main gripes with the MCU was the lack of degrees of freedom, lack of loading specificity and the lack of active patient feedback. The patients require safety, the perception of safety, and efficacy above all else(Section 6.1.1), while portability, affordability, and ease of use also could bring significant benefits.

6.2.1 DOF - Degrees of Freedom

The DOF referred to in this case is that of the Movement platform. At a minimum, the motion platform must correspond well enough with natural neck movement, that a patient can comfortably move within the portion of their ROM the product covers. Ideally, the patient should be able to move unencumbered by the product in any way unless the training application calls for it.

6.2.2 ROM - Range of Motion

The ROM referred to in this instance is that of the head. The requirements for any useful training application are the freedom to tilt 45 degrees forwards, backward, and to either side, and the freedom to rotate at least 70 degrees to either side. The maximum necessary range would logically be a range that allows for the full range of motion of a healthy individual.1 This being 75+ degrees of forward tilt, 100+ degrees of backward tilt, 70+ degrees of sideways tilt and 80+ degrees of rotation.

6.2.3 RSA - Resistance Specificity and Adaptability

To evoke a training stimulus the some resistance must be in place toward the motion of the head. At a minimum, this should be enough to evoke enough training stimulus to have a sizable benefit to the patient. This may even be attainable without any external resistance relying simply on gravity. FPMC would like resistance adjustable in discrete steps down to close to no resistance and up to 20 N in the case of tilt and 10 Nm in the case of rotation.[23] This allows for the product to exert stimulus that is required for the exercises currently done in the MCU. In addition, there should be no resistance in a neutral head position and the resistance should be mostly consistent throughout the ROM once set. The resistance should be stable for at least one movement direction at a time, meaning a given tilt or rotation direction. Ideally, the Resistance should be continuously adjustable up to the limit of human strength potential. Ideally one would also have the option to apply an axial force.

6.2.4 MCC - Movement Constraint and Control

Some exercises call for the ability to lock a patient into a path, or set of paths. without this capability, the exercise possibilities are reduced. For the full functionality FPMC want, a product should be able to constrain tilt to one plane. Ideally, a product would be able to rigidly or softly lock a patient to any path, plane, or space of movement, depending on the requirements of the exercise in question. At a minimum, the movement should be able to be controlled by the patient or a therapist regardless of whether the movement is constrained to a plain or not. This is required if the product is to fulfill diagnostic purposes, this of course is predicated on some level of motion tracking being present. Ideally, the product would be able to safely take soft, compliant control and guide a patient through a set of movements, taking feedback in form of patient resistance and or verbal or nonverbal communication of pain, doing much or all of what a therapist can do today during manual therapy sessions only with perfect repeatability and data collection for later comparison with prior sessions.

6.2.5 SFT - Spacial and Force Tracking

At minimum a solution would collect and record information about the position of the head of the patient, to obtain information about the patient's ROM that could be quantitatively correlated with actual neck placement to aid in diagnosis and training progress tracking. In addition, this data could be connected to the resistance level applied. Ideally, the product would have a way of either directly measuring or indirectly modeling the placement of the vertebrae of the neck with a high degree of precision. The force would be measured or modeled accurately giving information on the load applied to the individual vertebrae either by the product or by the neck musculature.

6.2.6 Cost

The product should at minimum be affordable for a specialty clinic such as FPMC and ideally be affordable for individuals to purchase. A per unit price of 500 000 kr will be used as a guiding figure unless further information is given.

6.2.7 PBI - Portability and Installation

The product should at minimum be small enough, and light enough that it could be installed in a standard building, without issues. This would mean entail that the force exerted at floor contact points or surfaces should not exceed the force specified in building codes. This means that force on the contact points should not exceed 1,5 kN and if distributed uniformly, not exceed 1,5 kN per square meter.[26] These values would be including patient weight if applicable. The product should also fit through typical doorways, without a degree of disassembly that would be infeasible for movers to perform with instructions. Ideally, though the product would be light enough and small enough easily portable between locations if required. This could range from fitting in a pocket or backpack, or being transportable in the storage space of most automobiles.

6.2.8 UI - User Interface

At a minimum the machine should be easy enough to use that it matches or exceeds the utility of the MCU, giving reports after the fact that allow for comparison towards a standard or to other sessions with the same patient. Ideally, the product would have real-time feedback allowing the patient to use it on their own with minimal therapist input. Training programs should be easy to generate and execute with detailed rapports and real-time feedback to help the patient perform the exercises as intended.

6.2.9 CMPD - Complexity of Design

The design should be simple enough to have the number of points of failure at a level that allows for reliable operation and maintenance intervals that don't hinder effective operation. Ideally, the design should be simple enough that it needs minimal maintenance and that the maintenance that is required can be done by anyone.

6.2.10 DUNC - Design Uncertainty

The design should be consisting of as many known and reliable mechanisms as possible to reduce the risk of unforeseen problems down the line in the design process. Ideally, every part of the system should be constructed with tried and true mechanisms to allow for not only the use of standard parts but also have minimal, and known risks relating to the design process.

6.2.11 PS - Patient Safety

At a minimum, the patients' expected value of using the product should be higher than the expected value of refraining to do so. If not there would be no point in using it. For the product to be viable though the risk of any serious lasting harm should be exceedingly low and the risk of minor harm should be very low as any harm incurred during use could severely erode patients' trust. Ideally, there should be no risk of injury and the product should look and feel safe for optimal patient comfort.

6.2.12 PSS - Patients Perceived Safety

The product should at the very least be constructed in a way that makes the patient minimally nervous to use it after reassurance from the specialist operating it. Ideally, the product should be constructed so that a patient would be as comfortable using it as any other form of treatment.

6.2.13 EE - Efficacy and Efficiency

The product should contribute to the rehabilitation process at minimum matching the performance of the MCU within a reasonable time frame. Ideally, the product would outperform the current improvement in patient outcomes, while additionally reducing the rehabilitation time.

6.2.14 DCC - Design Challenge Compatibility

The design process should preferably lead to challenges where some of the skills I possess can be applied, and that leads to enough interesting academic quandaries applicable to the field the master is written within. Ideally, the design process should include a wide range of interesting and relevant challenges that leave me spoiled for choice when it comes to master focus.

6.3 Design space

To narrow the scope of the product development project a decision was made to focus on aiding certain steps in the patient journey described in section 5.1. These steps are primarily the testing of active and passive ROM and/or rehabilitation exercises. This is partially due to the likely solutions requiring some mechanical application, which fits my expertise better than one without, although there always is room for mechanical application in the development of any product that must interact or respond to the physical world. There will be some elaboration on the potential for modularity in a final product where a computer vision system could be implemented to complement the functionality of the product and/or expand its use, as software could potentially be used on any camera opening up for home applications without the need for a specialized physical product. This will be elaborated on in section 9.

To help structure the range of possible design concepts, the design aspect can be split into three main aspects. The first of these is the system that facilitates the application of resistance to head movement as well as constraining movement to intended spaces. This would also be the system that would facilitate active movement if the solution is capable. The second is the system that tracks position for real-time and or post-session feedback. The last system is the one that either in real-time or after the fact, provides feedback to the patient and or therapist to aid in diagnosis or training. Most concepts will be connected to more than one of these aspects. The concept resulting from an early brainstorming session is categorized in a diagram that shows how they fulfill different design aspects in figure 4. The concepts that fulfilled the resistance creation were the ones taken forward for evaluation.

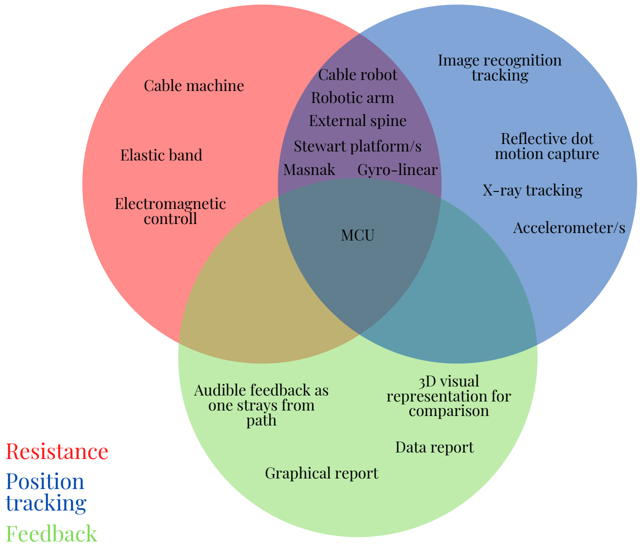


Figure 4: Design space

a The Stewart solution platform (SP) consists of 6 linear actuators arranged in a manner that allows for six DOF movements. This is the motion platform proposed in the first thesis in collaboration with FPMC.[15] This is also the platform favored by the FPMC contact.(Figure 5a)

b The Masnak (MN) is the solution proposed in the third thesis.[17] It consists of a rotating joint connected to two pentagon linkages that allow for movement in a flat plane. (Figure 5b)

c The gyro concept (GY) has a similar motion platform to that of the MCU. It consists of three rotating joints and two linear joints. The linear joints allow for the center of rotation for the curved track to move, better accommodating the natural movement of the neck. Gas cylinders like the ones in office chairs or another similar mechanism could be used to support the weight of the machine connected to the vertical linear joints leaving little resistance and allowing the neck to move naturally. Alternatively, this could be supplemented or replaced by a more active actuator that could actively move as the patient tilt or put tension on the neck throughout if this is favorable.(Figure 5c)

d The cable robot concept (CR) was considered in the fourth thesis but the concept was rejected it opting for a ready-made robot arm instead.[18](Figure 5d)

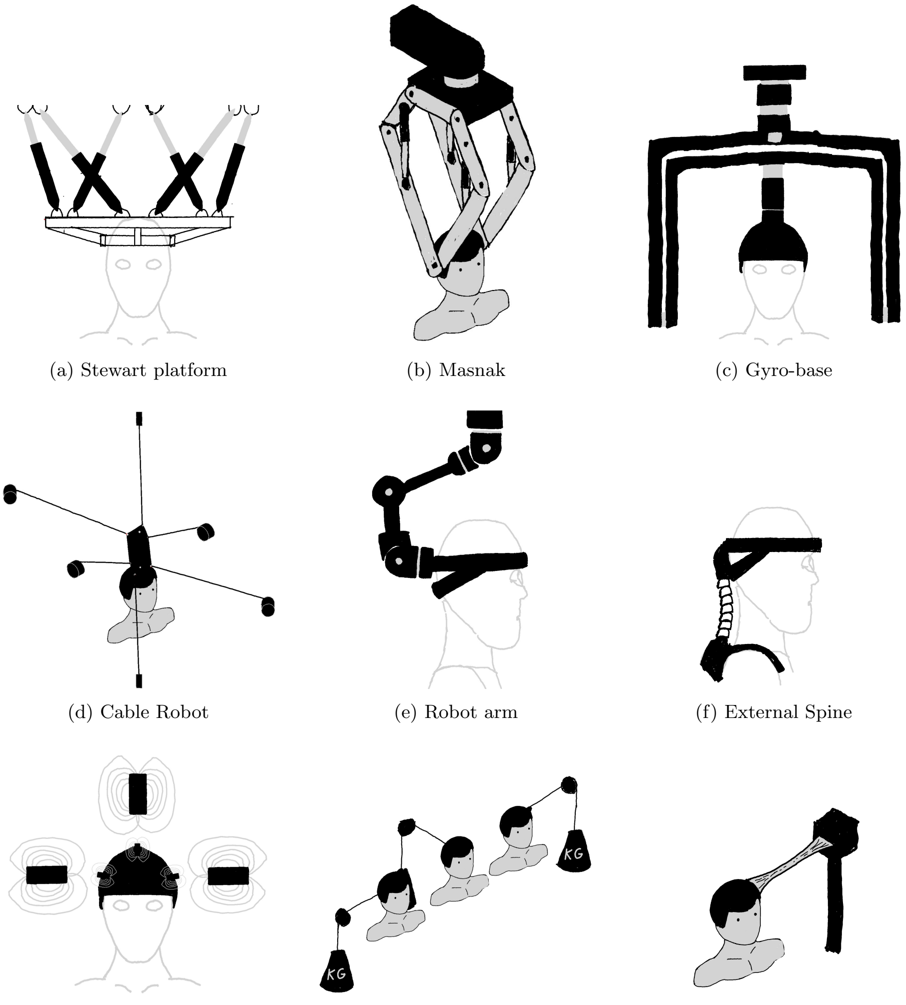
e A robot arm (RA) solution has been covered extensively in the previous masters. [18][19][20][21] It allows for free movement that is desirable but brings challenges when it comes to the complexity of both the mechanical system and the control system. (Figure 5e)

f An external spine concept (ES) proposes mimicking the movement platform of the neck itself. The idea is to control it with three or more internal wires, placed around a central core of universal joints or similar. By selectively shortening tendons one could control the bending of the external spine. There would have to be some axial play between the end of the spine and the head interface to make the solution work. (Figure 5f)

g The electromagnetic field concept (EM) proposes permanent magnets placed on the head mount and electromagnets being placed around. Manipulation of these fields would then provide resistance to head movement. (Figure 5g)

h The cable machine (CM) concept differs from the others as it does not directly have any form of stabilization but has the advantage that it could conceivably be constructed as an attachment to any cable machine making it more accessible. The solution could conceivably be combined with a simple movement guidance concept to provide a low-cost, low-complexity alternative.(Figure 5h)

i Similar to the cable machine concept this band concept (BA) does not provide support. However it is very simple, and if placed correctly, it could provide no resistance when in a neutral position. (Figure 5i)



(a) Stewart platform (b) Masnak (c) Gyro-base

(d) Cable Robot (e) Robot arm (f) External Spine

(g) Electromagnetic (h) Cable Machine (i) Band

Figure 5: Concepts

6.4 Evaluation

6.4.1 Previously developed concepts

The Stewart platform solution was visited and explored in the first thesis. It was later deemed unsuitable in the third thesis due to its limited range of motion. The limited range of motion could limit the efficacy of the training possible with a product based on the Stewart platform. The range of motion could be improved by connecting another Stewart platform in series with the first, however, this would give an infinite amount of actuator lengths and forces that could produce a given end position and force/torque, increasing the complexity required from a control system. This would also decrease the stability of the motion platform. Cost and safety concerns would also increase.

The Masnak solution was proposed in the third thesis. It compromises slightly on the degrees of freedom, to reduce complexity and simplify control. The solution still allows for a full range of motion but, similar to the MCU only allows for tilt in a single direction at a time, and rotation only while in a upright position. However, unlike the MCU it allows for a movement path that isn't a circular curve, better accommodating the natural movement of the neck.

The cable robot solution was rejected in the fourth thesis due to the difficulties that arise from developing a robot from scratch, opting instead for an off-the-shelf solution. A cable robot could produce the full range of motion with six degrees of freedom. For the simplest possible control, the cables would be assumed to be perfectly straight however this would in reality require infinite tension, which obviously is not an option. With very high tension the difference could be made negligible, however, the stiffness and power requirements would increase with an increase in force increasing cost as well as increasing safety concerns. Therefore any cable solution would need either a control algorithm that accounts for all of this or some external form of positional tracking, for instance, optical with a camera and recognition algorithms or reflective dot tracking. These forms of tracking are common and relatively inexpensive but the control algorithm would still need to adjust the cable tensions and lengths based on this data in real time. The cable robot would also have to simulate compliance. This would be difficult to do based on measurements of force at the cable connection points as the force applied by the patient would likely be negligible compared to the base tension from the other cables. An alternative would be some form of force sensing in a head mount which again would have to be fed into the control system and be compensated for in real time.

A robotic arm solution has been extensively covered in previous theses. The solution can potentially fulfill every requirement to a high degree, however, there are many caveats. The system is rigid and therefore has little issue with positional tracking to a high degree of precision as shown by the broad application of robotic arm solutions in many industrial settings. There could however arise issues as there are multiple joint angle combinations that could produce a given endpoint position, complicating controll algorithms when paths are not set from the get go. There are also huge challenges linked to mimicking a compliant system. For the head to be moved with minimal resistance with no external sensors the control system would first have to compensate for the weight of the robotic arms moving parts, the weight, and the center of gravity of the head mount. It would then have to calculate the expected torque load on all of the individual motors to a high degree of precision and compare this to the actual torque to work out which way the head is pushing and adjust the angle of the joints accordingly. This system could be bolstered by force and torque sensors at the head mount as a secondary source of data, making control more precise and reliable. The system would also be secured in the case of power loss so the fragile necks of patients would not have to carry the weight of the arm. Making the system reliable enough for safe use could be very difficult.

6.4.2 Undeveloped/New concepts

An electromagnetic control solution should cover the range of motion and the degrees of freedom of all patients. Researchers from the Beijing Advanced Innovation Center for Biomedical Engineering at Beihang University and Beijing University of Technology demonstrated the fast response control of a capsule robot with 5-DOF for the intended use of gastroscopy.[27] If this technology can be feasibly scaled up to provide the force required for this application however is not clear. The precision in the application of force could prove challenging and the power required to apply sufficient force as well as dynamic control of the electromagnetic field in response to patient movement are all challenges that would need to be addressed.

A spine robot could potentially fill the full range of motion and degrees of freedom required. A similar movement concept is found in the Survival Research Labs Spine robot. [28] It has considerably more linkages than would be suitable for this situation though and obviously has more power than would be safe or applicable, demonstrated at one of their presentations.[29] However, it does demonstrate that this sort of mechanism can produce complex movement. Researchers at the university of Craivo have also looked into the construction and control of what they call tentacle robots. [30] On the surface trying to facilitate natural neck movement by mimicking the neck's construction seems appealing however there may be some issues. The neck has numerous muscles that attach to different points on the vertebrae of the neck, the function of which could prove difficult to replicate. A combination of bending and rotation would be a challenge, as the former would require alignment of the holes for the tendon wires, while the latter calls for rotation between them. This could be addressed by an actuated rotating joint at the base or by a bearing that allows for rotation at the head interface. The head interface would require some linear play as the distance between the head and the base would vary in different positions. The spine robot is an interesting, novel concept but there is loads of uncertainty that comes with pursuing a complex and little-studied concept.

The Simple cable and band machines forgo any complex mechanical guidance in place of a simple, and cheap solution. This does give markedly less functionality provided by the mechanical system but motion tracking and force tracking could be fulfilled by some form of photo tracking. If this is software based a potential solution could retain a lot of benefits at a much lower marginal cost than what some of the other concepts with more substantial mechanical components can achieve, opening up the potential for a much wider reach, and therefore a larger total benefit although the individual efficacy of another solution may be higher.

A gyro-based solution retains a lot of the features of the existing MCU. The main difference is that in addition to the rotating joints some linear joints would be added to allow for the movement of the center of rotation throughout a neck tilt addressing one of FPMC's main qualms with the MCU. The system is not able to facilitate full six DOF movement but does, beat the MCU in terms of freedom of movement.

6.4.3 Trade-offs

By looking over the analysis of the concepts it became apparent that there were some trade-offs that tended to accompany concepts. There seems to be a clear trade-off between cost and portability and the functionality accommodated by the concept. The concepts with more functionality tended to be more complex, which tends to accompany higher costs holding all else equal. It also meant more and larger components decreasing portability. This is not necessarily the case for all functionality, as with the band and cable machine solutions you get a high DOF and high ROM with low complexity, but here positional control is sacrificed almost entirely. There is also an apparent trade-off between the safety metrics and the range of motion and degrees of freedom. If the platform can facilitate a head position that could cause injury it does make it a possible outcome. Little conclusive evidence can be taken from the trade-off analysis, as it is largely based on conjecture however, it does illuminate the possible conflict between different consumer focuses. The end goal of the product ultimately hinges on helping patients however the strategy to achieve this can vary. A trade-off involving cost and functionality, and stakeholders with different cost tolerances and functionality requirements means that choosing functionality over cost or vice versa could control the market segment the product fulfills. The specifics of these different considerations are explored in section 6.4.4.

6.4.4 Evaluation matrices

The evaluation categories are the product function ranges specified in section 6.2. These categories are given a weight based on a multitude of factors that differ depending on which stakeholder needs are valued. Evaluation matrices were made focused on patient needs, FPMC needs, and product developer needs. There was also an evaluation made where concepts were evaluated with the total needs combined. This was then verified against an average of the three single-stakeholder matrices.

For the patient-focused evaluation patients were not seen only as beneficiaries but as potential direct consumers that might wish to purchase a product for use outside of a medical institution. Patients have tighter budgetary constraints than any other stakeholders and high prices are therefore a big issue, in addition, they would require more guidance than a trained professional. The patient's perception of safety is also weighted higher than in the other matrices, as they would have less external reassurance without a professional on hand. With the chosen weighting the band concept came out on top with the Gyro concept and cable machine concept trailing in second and third. The band and cable machine concepts score highly due to much lower cost and better portability than the other solutions, whereas the gyro concept comes through due to high safety scores and a decent possibility for a user interface. The results are shown in table 3.

When FPMC needs are in focus ROM and DOF weighed heavily along with resistance specificity, adaptability, movement control, and spacial/force tracking. These aspects are important for the advanced more advanced diagnosis and training they require. Patient safety and efficacy also score highly. With the chosen weighting the gyro concept comes out on top, trailed closely by the Masnak and the robot arm concepts. The Masnak and gyro concepts balanced decent DOF scores with good safety and efficacy scores, whereas the Robot arm concept dominated DOF, movement control and efficacy. The results are shown in table 4.

When putting developer needs in focus three categories that were irrelevant to the patients and FPMC received weighting. The design complexity, the design uncertainty, and the design challenge compatibility. For the users of the product, these do not matter leaving all else equal while they have huge implications for the design process. Patient safety is weighed lower here than anywhere else, not due to the lack of importance but, due to more factors requiring consideration. With the chosen weighting, the gyro concept came out on top with the Masnak coming in second and the cable machine concept taking third place. The results are shown in full in table 5.

When estimating a combination of the stakeholder needs patients' health and safety play a big role for everyone as their outcomes are the driving force behind not only their own benefit, but also for the state, hospitals, clinics, and the firm and therefore categories such as Patient Safety, Perceived Patient Safety, and Efficacy and Efficiency are weighted heavily. FPMC's wants are also valued as they initiated the project and their input is the basis for most of the knowledge of the requirements for the exercises necessary for an effective diagnosis and rehabilitation of a whiplash injury. Therefore categories such as Degrees of freedom, Resistance specificity and adaptability, and Movement Constraint and Control also receive quite a high weighting. The results from the estimated weightings are shown in table 6.

When taking the average of the patient, FPMC and developer-centered matrices, all of them are given equal weighting the results are similar to those from the estimated weighting, however it is slightly different. In cases where the mathematical weighting is higher than the estimate, cells are colored green, while they are colored red if the mathematical weighting is lower. The darker the color the more of a proportional gap. Most of the estimates were very close however portability and installation was heavily underweight while design uncertainty was heavily overweighted. Otherwise, design challenge compatibility was quite underweighted and complexity of design was slightly overweighted. This can be seen in table 7.

The difference in weighting does not affect the top three highest-scoring concepts as they were the Gyro concept, the Masnak, and the MCU for both the estimated and mathematically combined matrices. The MCU scores highly mainly due to its substantial range of motion and the low degree of design uncertainty as well as perceived safety and safety benefits that follow from the product being proven effective in use. It is narrowly beaten by the Masnak solution that gains points over the MCU mainly through scoring better in degrees of freedom. The winner however is the Gyro concept that has a similar design to the MCU only that it adds the possibility for the translation of the pivot point within the plane of tilting. This allows a higher score in DOF while retaining some of the certainty that the design can work given it has a similar layout to the MCU with the linear joints the main unproven design aspect. In addition, the similar layout should be familiar to patients used to the MCU leaving them with slightly higher confidence than one would expect from an entirely novel experience.

Patient centred		Solution Scores										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	2	2	5	5	5	5	5	2	5	5	5	5
DOF	7	5	5	4	4	5	5	5	5	5	5	2
RSA	5	3	4	4	4	4	4	4	4	2	1	4
MCC	3	5	2	3	3	4	5	2	2	2	1	3
SFT	2	3	2	5	5	4	4	4	3	2	1	4
Cost	16	2	1	1	1	1	2	3	1	4	5	2
PBI	15	2	2	1	1	1	2	4	1	4	5	1
UI	10	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	3	5
PPS	14	3	2	4	5	1	2	2	3	5	5	5
EE	12	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
SUM	100	297	265	298	326	232	292	307	234	323	344	314

Table 3: Patient centred Evaluation

FPMC centred		Solution Scores										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	10	2	5	5	5	5	5	2	5	5	5	5
DOF	15	5	5	4	4	5	5	5	5	5	5	2
RSA	10	3	4	4	4	4	4	4	4	2	1	4
MCC	10	5	2	3	3	4	5	2	2	2	1	3
SFT	10	3	2	5	5	4	4	4	3	2	1	4
Cost	5	2	1	1	1	1	2	3	1	4	5	2
PBI	3	2	2	1	1	1	2	4	1	4	5	5
UI	5	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	3	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	10	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
SUM	100	337	320	381	403	335	371	320	315	314	292	358

Table 4: FPMC centred Evaluation

Developer centred		Solutions										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	2	2	5	5	5	5	5	2	5	5	5	5
DOF	8	5	5	4	4	5	5	5	5	5	5	2
RSA	8	3	4	4	4	4	4	4	4	2	1	4
MCC	8	5	2	3	3	4	5	2	2	2	1	3
SFT	2	3	2	5	5	4	4	4	3	2	1	4
Cost	4	2	1	1	1	1	2	3	1	4	5	2
PBI	4	2	2	1	1	1	2	4	1	4	5	1
UI	2	4	4	3	3	4	4	2	2	1	1	3
CMPD	8	2	1	3	3	2	1	1	4	5	5	4
DUNC	8	3	2	4	4	2	3	1	1	5	5	5
PS	12	3	2	4	5	1	1	3	2	3	3	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	8	3	4	4	4	4	5	3	3	1	1	3
DCC	18	3	3	4	4	3	3	3	2	3	2	0
	100	316	272	362	382	276	308	278	264	338	310	304

Table 5: Firm/Developer needs

Combined Estimate		Solution Scores										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	5	2	5	5	5	5	5	2	5	5	5	5
DOF	11	5	5	4	4	5	5	5	5	5	5	2
RSA	8	3	4	4	4	4	4	4	4	2	1	4
MCC	8	5	2	3	3	4	5	2	2	2	1	3
SFT	5	3	2	5	5	4	4	4	3	2	1	4
Cost	8	2	1	1	1	1	2	3	1	4	5	2
PBI	4	2	2	1	1	1	2	4	1	4	5	5
UI	5	4	4	3	3	4	4	2	2	1	1	3
CMPD	4	2	1	3	3	2	1	1	4	5	5	4
DUNC	5	3	2	4	4	2	3	1	1	5	5	5
PS	13	3	2	4	5	1	1	3	2	3	3	5
PPS	10	3	2	4	5	1	2	2	3	5	5	5
EE	10	3	4	4	4	4	5	3	3	1	1	3
DCC	4	3	3	4	4	3	3	3	1	3	3	0
SUM	100	322	286	357	380	289	330	293	280	331	318	344

Table 6: Estimated Combined Evaluation

Combined Estimate		Solution Scores										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	4.7	2	5	5	5	5	5	2	5	5	5	5
DOF	10.0	5	5	4	4	5	5	5	5	5	5	2
RSA	7.7	3	4	4	4	4	4	4	4	2	1	4
MCC	7.0	5	2	3	3	4	5	2	2	2	1	3
SFT	4.7	3	2	5	5	4	4	4	3	2	1	4
Cost	8.3	2	1	1	1	1	2	3	1	4	5	2
PBI	7.3	2	2	1	1	1	2	4	1	4	5	5
UI	5.7	4	4	3	3	4	4	2	2	1	1	3
CMPD	2.7	2	1	3	3	2	1	1	4	5	5	4
DUNC	2.7	3	2	4	4	2	3	1	1	5	5	5
PS	13.3	3	2	4	5	1	1	3	2	3	3	5
PPS	10.0	3	2	4	5	1	2	2	3	5	5	5
EE	10.0	3	4	4	4	4	5	3	3	1	1	3
DCC	6.0	3	3	4	4	3	3	3	1	3	3	0
SUM	100.0	317	286	347	370	281	324	302	271	325	315	325

Table 7: Mathematically combined evaluation

In addition to evaluating from different stakeholder perspectives, an evaluation was done based on what the design focus was to be. For these evaluations, stakeholder interests were combined as in table 6 and held constant to attempt to isolate the effects from a shift in problem focus. Firstly it was considered whether the product is meant to replace the MCU or complement it, which was evaluated in two different matrices. In the compliment-centered matrix, aspects, where the MCU scores well, were not weighted heavily, while in replace matrix these aspects were weighted much more heavily. Secondly, if the product aims to benefit mostly the process of diagnosis or training was evaluated in separate matrices. Finally combined training and diagnosis matrix was made as well, where weights were averaged for each category. Whether aiming to complement or replace the MCU the gyro concept scored highest with the robot arm concept getting third place. When aiming to complement the MCU the external spine concept came in a close second with the robot arm and Stewart platform tying in third.(Table 8) When aiming to replace the MCU the Masnak clinched second place with the robot arm tying the MCU in third.

Compliment centered		Solutions										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	1	2	5	5	5	5	5	2	5	5	5	5
DOF	12	5	5	4	4	5	5	5	5	5	5	2
RSA	10	3	4	4	4	4	4	4	4	2	1	4
MCC	7	5	2	3	3	4	5	2	2	2	1	3
SFT	3	3	2	5	5	4	4	4	3	2	1	4
Cost	13	2	1	1	1	1	2	3	1	4	5	2
PRI	14	2	2	1	1	1	2	4	1	4	5	1
UI	8	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	2	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	10	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
	100	318	282	308	330	266	318	327	253	313	306	306

Table 8: Complimenting MCU centered evaluation

Replace centered		Solutions										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	10	2	5	5	5	5	5	2	5	5	5	5
DOF	10	5	5	4	4	5	5	5	5	5	5	2
RSA	8	3	4	4	4	4	4	4	4	2	1	4
MCC	5	5	2	3	3	4	5	2	2	2	1	3
SFT	15	3	2	5	5	4	4	4	3	2	1	4
Cost	5	2	1	1	1	1	2	3	1	4	5	2
PRI	2	2	2	1	1	1	2	4	1	4	5	1
UI	8	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	3	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	15	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
	100	321	317	391	413	333	368	314	307	289	268	368

Table 9: Replace MCU centered evaluation

A diagnosis-centered approach ended up having equal weighting to a replace MCU approach. This was unintentional as these were weighted separately. The diagnosis centered results were therefore equivalent with gyro concept in first followed by the Masnak in second place and the robot arm tying the MCU in third.(Table 10) When taking a training centered approach patient use was more heavily weighed so cost and portability were prioritized. This led to the band and cable machine concepts taking first and third respectively, while the gyro concept again slipped into the top three with a second place.(Table 11) It was therefore not surprising that when combining training and diagnosis, the gyro concept came out on top followed by the Masnak in second.

Diagnosis centered		Solutions										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	10	2	5	5	5	5	5	2	5	5	5	5
DOF	10	5	5	4	4	5	5	5	5	5	5	2
RSA	8	3	4	4	4	4	4	4	4	2	1	4
MCC	5	5	2	3	3	4	5	2	2	2	1	3
SFT	15	3	2	5	5	4	4	4	3	2	1	4
Cost	5	2	1	1	1	1	2	3	1	4	5	2
PRI	2	2	2	1	1	1	2	4	1	4	5	1
UI	8	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	3	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	15	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
	100	321	317	391	413	333	368	314	307	289	268	368

Table 10: Diagnosis centered evaluation

Training centered		Solutions										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	5	2	5	5	5	5	5	2	5	5	5	5
DOF	5	5	5	4	4	5	5	5	5	5	5	2
RSA	8	3	4	4	4	4	4	4	4	2	1	4
MCC	8	5	2	3	3	4	5	2	2	2	1	3
SFT	2	3	2	5	5	4	4	4	3	2	1	4
Cost	16	2	1	1	1	1	2	3	1	4	5	2
PRI	16	2	2	1	1	1	2	4	1	4	5	1
UI	8	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	3	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	10	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
	100	297	266	295	317	248	306	307	234	314	328	311

Table 11: Training centered evaluation

Training and diagnisis		Solutions										
Criteria	Weight	SP	DSP	MN	GY	CR	RA	ES	EM	CM	BA	MCU
ROM	7.5	2	5	5	5	5	5	2	5	5	5	5
DOF	7.5	5	5	4	4	5	5	5	5	5	5	2
RSA	8	3	4	4	4	4	4	4	4	2	1	4
MCC	6.5	5	2	3	3	4	5	2	2	2	1	3
SFT	8.5	3	2	5	5	4	4	4	3	2	1	4
Cost	10.5	2	1	1	1	1	2	3	1	4	5	2
PRI	9	2	2	1	1	1	2	4	1	4	5	1
UI	8	4	4	3	3	4	4	2	2	1	1	3
CMPD	0	2	1	3	3	2	1	1	4	5	5	4
DUNC	0	3	2	4	4	2	3	1	1	5	5	5
PS	14	3	2	4	5	1	1	3	2	3	3	5
PPS	8	3	2	4	5	1	2	2	3	5	5	5
EE	12.5	3	4	4	4	4	5	3	3	1	1	3
DCC	0	3	3	4	4	3	3	3	1	3	3	0
	100	309	292	343	365	291	337	311	271	302	298	340

Table 12: Combined training and diagnosis centered evaluation

7 Discussion

7.1 Work Process

The goal of the pre-master project was, as stated in the introduction (Section 1.3) to lay the groundwork for developing a product that can successfully be implemented and satisfy FPMC's needs. This did change somewhat throughout the project as the process was later opened up to consider other possible beneficiaries like other physical healthcare providers. Still, the needs of FPMC and patients stayed central to the process throughout. If the goal of avoiding product development in an unproductive direction is achieved is yet to be seen however, I am confident that this project has made me familiar with some of the pitfalls earlier solutions encountered, most notably the difficulties with control inhereant to the robot arm. The full design space did not end up being mapped as the focus was shifted to the resistance creation set. This set though was narrowed a great deal by the end of the evaluation process. The risk assessment done at the outset of the project did not end up being all as relevant as the work done in the specialization project was largely theoretical, and did not require lab work. It will however likely be more relevant to the master thesis work itself. The document is included in appendix B.

7.2 Information gathering and stakeholder

Information gathering was quite a challenge for this project. The FPMC representative was open two questions and helpful when establishing the current process and some specifics around what activities specifically are important for proper diagnosis and training. However, there are limits to the amount of information that can be gathered through interviews, and the limited breadth of subjects, only gives the situation from FPMC's perspective. Ideally, this information would be supplemented by interviews with patients, and information gathering by sitting in on the diagnosis and treatment process as they may have other key insights or concerns. If starting over again I may have put effort into organizing a visit to FPMC's facilities, and perhaps patient contact or digital surveys if allowed within the limits of patient privacy. The framework for categorization and evaluation of different stakeholders and their needs forced a broader perspective on the possible effects of a product. It did help identify the less obvious stakeholders and get a better sense of their individual needs and where they may conflict with other stakeholders or firm needs, and where this could lead to constraints due to design trade-offs.

7.3 Design methodology

The application of set-based design principles was difficult when making decisions on early concepts. The design method calls for looking at a multitude of sub-system solutions and then searching for overlapping sets of design aspects that can work together. This process was somewhat useful when looking at the concept's potential to fulfill multiple functions in the brainstorming phase, for example when determining whether a moving platform could facilitate positional tracking built into the design, as is the case for the MCU itself. However, the application was limited later as the focus shifted to evaluating the resistance-creating subsystems. When these subsystems are further developed however SBD practices will be very useful. Here concerns related to manufacturing and different mechanical sub systems will be very relevant as concepts mature into detailed more designs. The SBD practice of exploring trade-offs of design solutions was very useful and vital when it came to weighting during evaluation.

If you follow SBD philosophy to a tee, the choice to narrow the design space early on, may have been premature. Ideally, a more objective understanding of the required ranges, of a potential product should have been established, and the exploration of possible resistance creation methods would have been done concurrently with other avenues for accomplishing improved diagnosis and or rehabilitation training outcomes. There are however issues with the application of this idealized plan. Firstly an understanding of the essential components of whiplash diagnosis and rehabilitation training, and the reasons behind the current processes in place was very limited. This could have been mitigated with improved research scope as mentioned in section 7.2 however, the time constraint of the process made this difficult so the compromise chosen was to rely on the information available. This was mainly from FPMC. The information being their current process and capabilities of motion constraint as well as resistances used for their current functionality testing, rehabilitation training programs, and the shortcoming in functionality specifically mentioned in interviews. [23] Perhaps there would have been a way to produce sufficient training stimulus without a source of external resistance, perhaps utilizing the body's own weight and inertia, but designing around these parameters would require a level of understanding of rehabilitation training I did not possess and was infeasible for me to require within the time frame of the project. These factors lead to the decision to do as the experts suggested, and design around a requirement of resistance.

In addition to knowledge and time constraints, related to diagnosis and rehabilitation, a similar issue arose around the subsystems for user interface and positional tracking. Again, an ideal SBD workflow would be to develop these ideas concurrently however, the effort and specific expertise required to do this would be slightly outside my capabilities given the time frame. The concurrent development ideas behind the SBD literature tend to be applied to organizations and teams with not only more resources and a higher total work capacity than an individual, but also a typically wider array of knowledge. I believe attempting in-depth concurrent development of all aspects simultaneously would ultimately take away from the quality, reduce productivity and increase inefficient time usage. Therefore the choice ended up being to limit the scope however, while keeping the other aspect in mind, and where applicable facilitating later integration.

A side effect of relying on information from current practices was that the intended use case of the product was pushed toward a clinical setting and to replace the MCU. A more open design process may have led to more concepts possessing functionality more different from those of that of the MCU. This could have led to concepts better suited to a wider market, where perhaps some compromises made on functionality could make it affordable for a typical household, or some innovative solution could have found a totally new way of attaining rehabilitation results. It is an interesting quandary and perhaps the agenda for the project established in the beginning limited the potential of developing a more innovative solution. After all, it was stated to be, the design of a product that met FPMC's requirements. When trying to push the market through radical innovation the potential returns are higher than when responding to market pulls however, there is an accompanying risk. Attempting to push the market with already limited knowledge within the field would have more risk of failure than responding to the market pulls, in this case from FPMC, and the potential returns, however large they are, may not be worth the risk.

7.4 Trade-offs

Like with much of the work in this project, trying to find trade offs was an exercise in working with limited information. Trade off analysis was done after quick theoretical analysis of the individual concepts. The accuracy of these analyses likely vary as some concepts incorporate more unproven technologies, or just technologies i am unfamiliar with. The process then was pretty straight forward. I did it by looking at the concepts individually, and taking note of how scores in different categories tended to correlate. If a consistent negative relationship between two performance categories or sets of performance categories became apparent, they were noted as trade-offs. This worked fine as there were not to many performance categories and concepts. A higher number of concepts and or performance categories would likely have necessitated a more structured approach perhaps by using creating a array and using software like STATA, or writing a python script to do a correlation analysis. Such an analysis would give a number value representing how to categories correlate. Once correlated categories were found it could inform a targeted search for potential reason behind them. This technique could have been useful for this project, and i might have invested time in this given the opportunity again.

7.5 Concept generation and evaluation

Most of the concept generation was done at a stage where design possibilities may have been artificially limited to a more MCU like set of capabilities. If done over, more time should probably have been invested early on to further explore more alternative solutions. Although this would have likely led to more infeasible designs, and perhaps nothing usable, the generation of alternatives would still have brought a new perspective, and a new set of design possibilities.

Evaluating generated concepts without any concrete data, necessitated reliance on information that was rather speculative in some cases. This uncertainty does limit the accuracy of feasibility predictions. In some cases like with robot arms and gyroscopic designs, this was easier as there are examples of similar mechanisms being used in similar or other applications however for some concepts like the external spine and electromagnetic concepts, examples of applications that were few and far between. The problem of uncertainty also crept in when having to give the concepts scores for evaluation purposes. Range of motion and degrees of freedom were relatively simple to estimate but it was much more difficult for some of the more complex aspects like cost, safety, and efficacy, that were all affected by multiple different design aspects. This was especially difficult for the novel designs that had not been explored in earlier masters or lacked any similar real-world application. There are some more risks of bias, in the weighting of the categories themselves. The weighting of design goals, the choice of evaluation categories, as well as the weighting of the stakeholder interest also does risk introducing bias. However, regardless of the limitations imposed by uncertainty, the process of systematic evaluation does remove some of the risks of personal bias or blind spots coloring the results, as rating concepts in specific and consistent categories gives less room for interpretation than when evaluating as a whole. The input from FPMC did give another perspective and helped, however ideally an external observer should have independently evaluated as well. Polling patients on the weighting of different categories could also have been very useful to further reduce uncertainty.

8 Conclusions

The path chosen was to go for replacing the MCU. Partially due to that I could not figure out a solution that had the desired missing functionality without a platform that had most of or all of existing functionality. This meant that it could replace the MCU, and if you can do everything with the new product it might as well replace the old. Unfortunately the goal of increased functionality also seems to require enough complexity that the price might make it infeasible to purchase for private individuals. In addition, the concepts that scored well for complimenting the MCU usually scored well for replacing the MCU as well. Although this me be due to the properties of the developed concepts rather than a general rule. When weighing whether to focus on diagnosis or training, there was a similar phenomenon as some concepts that scored high in diagnosis also did pretty well for training. In addition, the concepts that scored the best with simply a training focus were the band and cable machine concepts. Many competitors exist in this space as both bands and cable machines, as well as different types of head harnessing contraptions for the purpose of training the neck already exist. Therefore it was concluded that focusing on diagnosis or both had a higher potential for value creation. However, ideas on how existing, cheap home training solutions could be implemented into a regime more effectively are discussed in section 9.2.

There is still some uncertainty but from the information I have managed to gather and or produce, the gyro concept seems to be the most promising. It shares enough with the MCU that uncertainty around efficacy is reduced however still should manage to address some of its shortcomings. It consistently scored at the top or near the top regardless of the weighting of the evaluation categories. The Masnak concept also did well in most of the evaluations, and could potentially be a promising solution. The fact that it has already been explored is also an advantage.

9 Further work

9.1 Master Thesis Progression

For the master thesis work, the goal will be to have a well-developed concept and hopefully a semi-functional prototype by the end. However before one concept is chosen, some further exploration will be done into the top performers, this being the Masnak and the gyro concept. The aim will be to have an early meeting with the FPMC representative to get some feedback. In addition, a goal will be to make one or multiple small-scale prototypes of each to explore the specifics of the designs. Further, once the most promising concept or combination of concepts is chosen, the goal will be to build out a more comprehensive design. This will include plans for the integration of real-time and report-style fact feedback, choice of loading method, the integration of external systems to solve tracking and feedback challenges, part manufacturing, and other design considerations. In addition, exploring the application of modularity to extend some of the product functions for home use. Maybe in the form of training computer vision in congruence with the moving platform so that neck positions at home could be compared with those at FPMC, to track training progress through video data. In addition, it may be useful to look into laws and regulations around the certification of training equipment meant for medical treatment as there may be some hurdles down the road that could be avoided. An other goal would be to investigate the possibility of taking a trip to FPMC's facilities. Alternatively the possibility of inviting them up to Trondheim in the case that a relatively functional prototype is developed. This of course is dependent on scheduling factors and even a new flair up of COVID. This can be taken into account however when the time comes.

9.2 Future deveopment

If any form of camera tracking is to be incorporated into the product the software and or specific hardware for this purpose must be developed. If this is to be done through machine learning or through other methods I do not know. This video-tracking technology could then be implemented as a software module, that could be widely available for patients potentially increasing the efficacy of home exercise without requiring a dedicated physical product. This could also give the professionals in charge of treatment better information, allowing for remote follow-up or saving time during follow-up visits, allowing more time for focus exercises that may require the full product.

If the product is able to generate precise data about unencumbered neck movement and collect data about the issues patients are eventually diagnosed with there is potential for some form of machine learning algorithm to aid in diagnostics reducing or perhaps even eliminating the need for CT and or MRI scans in some cases. This could not only improve efficiency eliminating a step from the process but also limit radiation exposure.

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Appendix

A Adapting set-based design to early new product development phases

Department of Mechanical and Industrial Engineering

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Working with uncertainty: Adapting set-based design to early new product development phases

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Abstract

Set-based design (SBD) is in short, a design method that provides a strategy to reduce rework late in a design process by delaying final decisions until later in the process when different solutions' trade-offs of specialized solutions are better understood. This allows for the adaptation of goals and requirements throughout the design process resulting in high flexibility to design discoveries[1]. It can however be easier said than done to define the design space in the early phases of new product design where the base requirements are unclear. This paper discusses adaptations that can be done to typical SBD to better adapt it to cases where the product requirements are fuzzy in the earliest phases of a project.

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Table of Contents

1 Introduction

SBD is a term used to describe design practices that were observed at Toyota although similar principles of concurrent engineering had been discussed. previously [2]. Toyotas process involves the engineering of multiple design steps concurrently so that they can inform each other so that decisions can be made with a better understanding of trade-offs. This approach seemingly creates a paradox, where efficiency is decreased with more designs developed and more prototypes produced in the short term, while overall efficiency and product quality is increased over the course of the project. This is discussed in the groundbreaking paper "The second Toyota paradox: How delaying decisions can make cars faster"[3]. At Toyota however, these design principles are applied to a mature industry where although there is marginal innovation going on, general design requirements are well understood. The question to be discussed in this paper however is if these principles can be applied to early phases of new product development or NPD, where requirements are not well understood.

One major challenge in the development of new products is that stakeholder needs are not necessarily well understood and there are potentially huge benefits to be had if one can use a set-based approach to delay decisions and allow developers to get a better idea of what is needed before designs are finalized.

There has been much written about SBD. Even before the term "set-based" was coined by Allan C Ward and collaborates in the paper "The second Toyota paradox: How delaying decisions can make cars faster"[3] there had been papers with similar methodologies as in Ward's on Doctoral thesis [4]. Ward and some collaborators later contributed with a revised look in the paper "Toyota's Principles of Set-Based Concurrent Engineering"[5]. They don't however describe much when it comes to a guideline for the implementation of the principles put forth.

There have been papers that have looked at how it relates to specific applications like a paper by David J Singer on how SBD can be applied to naval ship design [1]. There were also papers found that suggested frameworks for transitioning to SBD [2] and papers on how one can reduce costs of rework by implementing changeability in the system architecture [6].

There have also been papers on how to easily introduce SBD to a design team and help them implement it. The researchers named the method Instant SBD or ISBD and found that the method could help a team implement SBD within a workday [7] however this method presumes some idea of required product functionality from the get-go.

One of the papers found during a literature search that was the closest to the goal of this paper was a paper by Brian M Kennedy[8] that discusses the implementation of SBD in early phases to reduce rework, however, it takes a more organizational focus rather than specific product development steps. This is what this paper aims to address.

The paper will first cover the general principles of SBD gathered from the literature above in section [2]. The following section [3] will identify the challenges that occur when trying to implement SBD principles in early phases where product requirements are fuzzy or unknown. Section [4] will then put forward suggestions for how to adapt principles to suit early-phase product development better, And outline an overall strategy. The paper is concluded in Section [5] where results are discussed and future research is proposed.

The challenges and implementation suggestions will be based on a qualitative case study of a development process related to a Master Thesis that aims to develop new training equipment for Whiplash injuries that improves functionality over existing options.

2 Principles of SBD

The main advantage of SBD over classic point-based approaches to design comes with the broad exploration of the design space and the discovery of information throughout the process that prevents premature narrowing of the design space of discrete areas that may limit potential innovation

[2].

Set-based design or set-based concurrent engineering as it was coined by [3] was first defined as a description of design practices observed at Toyota. These practices were later analyzed [5] to put forward the following principles of Toyota's concurrent engineering approach.

1. Map the design space.
    - Define feasible regions.
    - Explore trade-offs by designing multiple alternatives.
    - Communicate sets of possibilities.
2. Integrate by intersection.
    - Look for intersections of feasible sets.
    - Impose minimum constraint.
    - Seek conceptual robustness.
3. Establish feasibility before commitment.
    - Narrow sets gradually while increasing detail.
    - Stay within sets once committed.
    - Control by managing uncertainty at process gates.

These principles give an overview of how Toyota's teams work both on individual projects and also on a wider company scale and have been the basis for much of the discussion around SBD[9]. It consists of 3 main points.

The first point is to map the design space. In Toyota's case, this means outlining a set of possible solutions for the individual vehicle systems based on prior knowledge from the design and production of previous models, as well as newly developed technology.

The second point describes the integration phase where individual system sets are analyzed as to how they may work in conjunction with each other. In Toyota's case, this may be what chassis designs fit with different engine designs and what suspension designs can handle this weight, and so on.

The last point references the process of narrowing the developed sets down to a single solution based on the information learned throughout the process, which according to Toyota, and Ward leads to a better end product.

In their paper titled "Instant Set-Based Design, an Easy Path to Set-Based Design" Mikael Ströma, Dag Raudberget and Göran Gustafsson propose a set of steps to introduce SBD to a product development team and implement the principles laid forth by Sobek and his collaborators. [7].Their method does give a detailed recipe for the implementation of SBD, but in step two knowledge of the required functionality of the possible solutions is presupposed, knowledge that often is limited in cases of NPD.

3 Challenges with early phase SBD adoption

The main component not found in the current literature is how to actually start up a product creation process using SBD principles. Everything after the step of a general idea of product functionality is covered, but information on the generation of this knowledge was not found.

To explore the challenges of applying SBD in the early phases of NPD a case study will be employed. The specific case is the design of rehabilitation training equipment for patients that have suffered whiplash injuries. Current equipment lacks the degrees of freedom or DOF for some training applications and there is a demand for equipment that allows for more natural movement. In addition, there is a demand for a capability to more adaptable capability of selectively locking, resisting, or freeing specific head DOF to allow for targeted exercises.

The main challenges when implementing SBD in the earliest stages of NPD come when trying to implement the first step as defined in "Toyota's Principles of Set-Based Concurrent Engineering" [5] which is Mapping the design space, specifically when establishing feasible regions. At Toyota, they have a large knowledge base within the field of car design, if not for the specific vehicle they are designing. This means that they have a solid basis on which to make judgments on what is feasible to produce, what is affordable, what consumers won't accept design wise and so on. When designing a new product within a less mature field, the task of mapping a possible design space can be more difficult.

With a less defined design goal, establishing an idea of feasible design space is a less obvious task. When Toyota designs a car, they have a lot of decisions to make, however, they do have a few constraints they are working within. They know they need some sort of drive train, a chassis, a body, breaks, suspension, and so on. Through their manufacturing department, they also have a lot of information about their ability to realize certain types of designs and the expenses related to these processes.

When designing a new product in a new space knowledge about the product is implicitly limited so if SBD is to be implemented using the general framework some form of information gathering is necessary to be able to define feasible regions. This includes information about product needs but also about relevant technology and manufacturing capabilities.

An issue with doing the mapping step with less information as far as feasibility goes is that it can give you less to go on while designing alternatives and increases the likelihood of spending time designing alternatives that are impossible to realize for one reason or another. An issue with seeking to gather information at this stage is that with little to go on it could lead to hours wasted on unproductive paths. Both these issues can lead to significant rework. This is not a good thing however it is better to have this occur early in the process rather than accruing rework later as the ability to influence life cycle cost decreases throughout the development process.[10]

Mainly it seems that SBD in most representations is well-established in product development given a rough idea of the product already exists while being less suited to the very earliest phases of a process where little prior knowledge exists.

4 SBD adjustments for improved early phase integration

4.1 Strategies

In reviewing the current literature there was little found in terms of the start-up of a product creation process. As SBD is a product development strategy it seems that the cases studied tended to have a general idea of functionality that was intended for the final product.

In many cases as in the case of the development of the rehabilitation equipment, some editions are required to the initial principles of SBD to help establish the main product goals and production capabilities, before the standard set-based design process becomes more applicable. In this step, some idea of the final product functionality should be established, as well as some idea of the limits of applicable technology.

Based on these shortcomings changes to Wards SBD guiding principles were proposed.

1. Map the design space.
    - **Identify stakeholders and their interests.**
    - **Identify possible product functions to fulfill demands.**

- **Establish feasibility based on existing technology from other products or research fields.**
- Define feasible regions.
- Explore trade-offs by designing multiple alternatives.
- Communicate sets of possibilities.

2. Integrate by intersection.
   - Look for intersections of feasible sets.
   - Impose minimum constraint.
   - Seek conceptual robustness.
3. Establish feasibility before commitment.
   - Narrow sets gradually while increasing detail.
   - Stay within sets once committed.
   - Control by managing uncertainty at process gates.

The first additional point puts forth a prompt to study potential markets for a new product and what needs are currently not met. This is meant to partially address the knowledge deficit towards what needs are the most relevant to be addressed by the potential new product. This is meant to help establish a framework that can provide context on which to build requirement ranges for the product.

The Second additional point puts forth a prompt to use the knowledge gained from the first to help identify a range of functions that the product could have to satisfy the unfulfilled demand of the stakeholders. This is meant to build help designers get an idea of what performance ranges to aim for during the development of an entirely new product.

The last addition is a prompt to establish set feasibility through leveraging knowledge about technologically similar solutions. This specifically can mean doing a study of research done into new technology or studying existing commercial products that have components functioning under similar constraints as a sort of proof of concept for product functionality. This can also give an idea of product expense. This addition is meant to help bring context to the original SBD principle of defining feasible regions. In essence, the new prompt aims to give a place to start as it is not immediately obvious how to establish feasibility in a field one lacks experience in or a new field altogether.

In addition to these additional prompts, there are other potential strategies to adapt SBD to the uncertainty which is inherent to NPD. One of these is to implement design changeability as one of the parameters on which to judge alternatives. This is an idea that is explored as a strategy to reduce rework in a paper by Ernst Fricke and collaborators on how to reduce rework [6]. This strategy accepts that late changes to a design may be inevitable in some cases and that one therefore should design products with changeability in mind. This can as an example make a product module based so that functions can be added, removed, or altered without having to make major changes to the general design structure.

4.2 Implementation

To gain knowledge of the problem a conversation was held with a professional in the field of whip lash injury rehabilitation. The discussion included information about the nature of whip lash injuries, common symptoms and complications, the process for diagnosis and finally the process of treatment and the importance of different aspects. How current equipment is used and what it cannot be used for were also discussed. The knowledge gained helped build a base of knowledge on which to start to build a picture of the possible functions the product could/should fulfill.

Further a study was done of excising technology that could possibly fulfill functions. An example of this was looking into a dynamic control of robotic motion in response to environmental stimuli.

One example of research into the subject was found was the BESMAN project headed by the German Research Center for Artificial Intelligence GmbH and University of Bremen. Although still a complicated expensive and not fully commercialized technology it does give an indication that a robotic solution may be feasible.

5 Discussion

In the case study done, the initial steps were found to be helpful thus far. They made the process of beginning to implement the principles of SBD laid out by ward and collaborators easier than it seemed initially when there was quite a bit of uncertainty as to where to start.[5].

The limited sample size of one does limit the ability to make any confident conclusions on whether or not the proposed additions are applicable in a broader range of NPD cases. There is the possibility that the utility of the steps is specific to the case study as they were developed while working on the project, which could lead to it coloring the view of the effectiveness.

An acknowledgment should also be made, that pointing out the limitations of the SBD principles may be somewhat pedantic as one could argue that information gathering may be an implicit part of the first principle. However, if this is the case it still may be helpful to ease implementation to state it explicitly.

It can also be said that the fact that one must start the design process with little to no knowledge of product requirements (4.1) is a feature not a bug of NPD and that the perceived information gained may be incorrect or insufficient leading to multiple iterations being necessary. Although this may be the case it may still be helpful to have some specific steps to get someplace to start even though it may not end up being fully correct.

Creating a defined set of rules for an inherently unpredictable process like NPD tends to be is difficult. This means that any set rules will likely never perfectly match any given application. Nevertheless, a framework of principles may still give some utility to a designer as a starting point to base the development work. The Additional principles proposed were used fully in the case of the development of Whiplash injury equipment and may be helpful in the early phases of design for other new products although further testing is required to confirm the effectiveness of the adaptions.

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B Risk Assesment

Sannsynlighet vurderes etter følgende kriterier:

1 – Svært liten	2 – Liten	3 – Middels	4 – Stor	5- Svært stor
1 gang pr. 50 år eller sjeldnere Ergonomi/psykososialt: Ingen tilfeller	1 gang pr. 10 år eller sjeldnere Ergonomi/psykososialt: Ett enkelt tilfelle	1 gang pr. år eller sjeldnere Ergonomi/psykososialt: Enkelttilfeller	1 gang pr. måned eller sjeldnere Ergonomi/psykososialt: Periodevis	Daglig – hver uke Ergonomi/psykososialt: Kontinuerlig

Konsekvens vurderes etter følgende kriterier:

Gradering	Menneske	Ytre miljø	Økonomi/materiell	Omdømme
5 – Svært alvorlig	Død eller uførhet/ varig nedsatt funksjonsevne	Svært langvarig og ikke reversibel skade	Drifts- eller aktivitetsstans > 1 år	Troverdighet og respekt betydelig og varig svekket
4 – Alvorlig	Alvorlig skade/ belastning som krever medisinsk behandling. Mulig uførhet/ varig nedsatt funksjonsevne.	Langvarig skade Lang restitusjonstid	Driftsstans > ½ år Aktivitetsstans opptil 1 år	Troverdighet og respekt betydelig svekket
3 – Moderat	Alvorlig skade/ belastning som krever medisinsk behandling. Lang restitusjonstid.	Mindre skade og lang restitusjonstid	Drifts- eller aktivitetsstans < 1 måned	Troverdighet og respekt svekket
2 – Liten	Skade/ belastning som krever medisinsk behandling. Reversibel skade. Kort restitusjonstid.	Mindre skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1 uke	Negativ påvirkning på troverdighet og respekt
1 – Svært liten	Mindre skade/ belastning som krever enkel behandling. Reversibel skade/ belastning. Kort restitusjonstid.	Ubetydelig skade og kort restitusjonstid	Drifts- eller aktivitetsstans < 1 dag	Liten påvirkning på troverdighet og respekt

Risikoverdi = Sannsynlighet x Konsekvens:

KONSEKVENS	5 – Svært alvorlig	5	10	15	20	25
	4 – Alvorlig	4	8	12	16	20
	3 – Moderat	3	6	9	12	15
	2 – Liten	2	4	6	8	10
	1 – Svært liten	1	2	3	4	5
		1 - Svært liten	2 - Liten	3 - Middels	4 - Stor	5 - Svært stor
		SANNSYNLIGHET				

Fargene angir grad av risiko:

Rød		Uakseptabel risiko. Tiltak skal gjennomføres.
Gul		Middels risiko. Tiltak skal vurderes.
Grønn		Akseptabel risiko. Tiltak kan vurderes

Google translate

How to conduct risk assessments (do not use the digital assessment at present, use this form)

RISK ANALYSIS (alternative to using RiskManager)

Unit / Department:	Department of Mechanical and Industrial Engineering	**Date created:**	09/09/2022
Responsible manager (name):	Bjørg Margrete Granly	**Last revised:**	N/A
Responsible for the activity that is risk assessed (name):	Thomas McAllister		
Participants (name):	Thomas McAllister		

Description of the relevant activity, area, etc .:
The likely area for work will be TrollLabs and perhaps other labs if required. This project will likely be lighter on the LAB work as the main fokus is to get an idea of what solutions are likely to be good. Still the plan is to create some simple, partially functional prototypes that will help explore the feasabillity of a design. Given the this their will not liekly be parts manufactored in metal as it is likely not required for functionality. Wood and PLA FDM-3D printed parts should therefor be sufficient.

Activity / task	Possible unwanted event	Existing risk reduction measures	Assessment of probability (S)	Impact assessment (K) Evaluate one consensus category at a time. Human beings should always be considered.				Risk value (S x K)	Proposals for preventive and / or corrective measures Prioritize measures that can prevent the event from occurring (probability-reducing measures) before intensified preparedness (consequence-reducing measures)	Assesment of Probability after Measures(S)	Assesment of Impact after measures (K)	Residual risk after measures (S x K)
			(1-5)	Human (1-5)	Material (1-5)	Environmental (1-5)	Reputation (1-5)					
Use of angle grinder	*Eye damage due to splashes of abrasive dust / particles*	*Safety goggles are always available in the workshop*	*3*	*3*				*9*	*Before start-up: Carry out documented HSE training with the students (use of hand tools and required protective equipment)*	*1*	*3*	*3*
	Cuts to flesh and bone due to contakt with cutting disk	*Precausion is taken to always have a stable stance, and apropriatly fixed work peace when using tool. In Addition hands are kept away from the disk.*	*1*	*4*				*4*	*Before start-up: Carry out documented HSE training with the students (use of hand tools and required protective equipment)*	*1*	*4*	*4*
	Abrasions to the skin due to contakt with grinding disk	*Precausion is taken to always have a stable stance, and apropriatly fixed work peace when using tool. In Addition hands are kept away from the disk.*	*1*	*3*				*3*	*Before start-up: Carry out documented HSE training with the students (use of hand tools and required protective equipment)*	*1*	*3*	*3*
3D printing in PLA	*Burning of fingers from contact with Nozzle*	*Hands in general are kept clear of the nozzle when printer is on.*	*3*	*2*				*6*	*Before start-up: Make sure to check the nozzle temperature before handeling in case of nozzle change as it could be hot from previous use.*	*1*	*2*	*2*
	Damage of printer during use							*0*				*0*
	Inhalation of harmfull fuems	*Avoid breathing close to nozzle during melting. No gass mask required as PLA does not let off to many fumes unlike som other 3D printing materials.*	*2*	*1*				*2*	*During work: Leave the room after initial layers are printed to avoid potential prolonged exposure.*	*1*	*1*	*1*
Use of Jigsaw	*Laceration on fingers*	*Make sure that both hands are clear of the tool during all operation*	*1*	*4*				*4*				*0*
	Damage of worbench	*Make sure that cutting path does not intersect with workmench.*	*1*		*2*			*2*				*0*
	Eye damage due to splashes of abrasive dust / particles	*Safety goggles are always available in the workshop*	*2*	*3*				*6*	*Before start-up: Carry out documented HSE training with the students (use of hand tools and required protective equipment)*	*1*	*3*	*3*
Use of Bandsaw	*Laceration on fingers*							*0*				*0*
	Laceration on limbs							*0*				*0*
	Eye damage due to splashes of abrasive dust / particles	*Safety goggles are always available in the workshop*	*2*	*3*				*6*	*Before start-up: Carry out documented HSE training with the students (use of hand tools and required protective equipment)*	*1*	*3*	*3*
Use of dremel	*Eye damage due to splashes of abrasive dust / particles*	*Safety goggles are always available in the workshop*	*3*	*3*				*9*	*Before start-up: Carry out documented HSE training with the students (use of hand tools and required protective equipment)*	*1*	*3*	*3*
	Abrasive injury to hands due to contact with body.	*Safety gloves are always avialable in workshop*	*2*	*2*				*4*				*0*
Use of drill press	*Lacerations to fingers and hands from contact with drill bits.*	*Required spesific training before access to machines is granted*	*2*	*2*				*4*				*0*
Use of drill	*Lacerations to fingers and hands from contact with drill bits.*		*2*	*2*				*4*				*0*
	Wrist injury after jerk due to bit catchin on material.		*3*	*2*				*6*				*0*
Use of CNC-mill	*Damage to machine and cutting tools due to foreign objects in the cutting volume. Ore Impropper tool path planning.*	*Required spesific training before access to machines is granted*	*3*		*3*			*9*	*Before start-up: Carry out checklist where one of the points is to check the cutting volume.*	*2*	*3*	*6*
	Lacerations to fingers and hands from contact with cutting tools.	*Required spesific training before access to machines is granted*	*1*	*4*				*4*				*0*
	Crushing to fingers and hands in Machinery	*Required spesific training before access to machines is granted*	*2*	*4*				*8*				*0*
Use of Laser Cutting	*Have not had trainig but I assume the machine is constructed so that one can not run the machine unless the cover is closed so risk is minimal.*	*Required spesific training before access to machines is granted*	*1*		*3*			*3*				*0*
		Required spesific training before access to machines is granted	*1*	*3*				*3*				*0*
Desk work	*Back sourness from prolonged sitting*		*3*	*1*				*3*	*Make sure to get up and stand for at least 5 minuites every hour*	*2*	*1*	*2*
	Eye sourness from staring at a monitor for too long		*3*	*1*				*3*	*Make sure to take a break and change enviroment, prefribly outside 5 minutes every hour.*	*2*	*1*	*2*
	Back injury from prolonged sitting		*2*	*2*				*4*	*Make sure to get up and stand for at least 5 minuites every hour*	*1*	*2*	*2*

B Risk Assesment

NTNU

Date created	Last Revision
14.3.2023	14.3.2023

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

RISK ASSESSMENT

ONLY VALID FOR DETAILED ACTIVITIES LISTED IN SECTION 5

1. Identification

Laboratory name: Ubåten	**Room number:** M43
User's name: Thomas McAllister	☒Master ☐PhD ☐Post-Doc ☐SINTEF ☐Other:
User's e-mail: thomaemc@stud.ntnu.no	**User's Phone:** 0047 98400017
Supervisor: Bjørg Margrethe Granly	**Supervisor's phone:** 0047 95929739
Project number: 985489128	
Period: January 15, 2023 to June 11, 2023	

Description of the project and needs:
The project goal is to design training equipment for whiplash injury rehabilitation. The plan is initially to create some simple, partially functional prototypes that will help explore the feasibility of a design. Use of wood and PLA FDM-3D printed parts should be sufficient.

2. Signatures

The user and the supervisor are aware of all the risks involved in the lab activities that are going to be performed. Additionally, the user confirms that they will follow the preventive measures described in this form to minimize all the risks that have been identified.

User's signature	**Supervisor's signature**
Signature:	Signature:
Name: Thomas McAllister	Name: Bjørg M. Granly
Date: 14.03.2023	Date: 15.03.23

Approved by:

	Signature:	Name:	Date:
Room responsible:		Håvard Vestad	16.03.23
Lab manager:			

NTNU

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Date created	Last Revision
14.3.2023	14.3.2023

Note: a pdf copy with all signatures shall be sent to everyone who has signed above.

3. Team (write "NR" if not relevant)

Project manager and organization (Student)	Thomas E. McAllister	Responsible for instrumentation	NR
Laboratory responsible	Håvard Vestad	Operator	Thomas E. McAllister
Auditor for safety check	NR	Responsible for running the experiment	NR
Responsible for experimental and scientific content (Advisor)	NR	Responsible for logging and storing experimental data	NR
Responsible for dimensioning load bearing and pressurized components	NR	Responsible for building the rig	NR

4. Administration

Answer: Yes, No or NR (Not relevant)

Is the work order signed? (only for external work)	NR
Has the operator the required courses/training on the equipment?	Arranged
Has the operator followed the safety courses? **(Mandatory)**	Yes
Can the work be done alone?	Yes
- If not, the work may have to be done under special conditions (evaluated in section **5**)	NR
Does an expert have to check the start of the experiment?	No
- If yes, who?	NR

5. Description of the Activity

The use of 3D printers to make custom parts in PLA.

For each activity performed in the lab, health risks affecting the user or others need to be identified. For each risk identified, a preventive measure must be performed, and the final risk value calculated with the "risk matrix". Explanation of the "risk matrix" can be found in the last page of this form.

This page must be replicated for each different activity performed in the lab. Activities involving the use of chemicals must be filled out in the page titled "Chemical Risk Assessment" in section 5.2.

NTNU

Date created 14.3.2023 Last Revision 14.3.2023

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Activity: Upload g-code to printer and inspect that the initial layers are printed well. Returning at the end of print cycle to collect the printed result.

Risk overview: (mark with X the risk that applies for the activity)

Big loads		Danger of fire	X
Heavy lifting		Working at heights	
Hanging load		Hydraulic pressure	
Gas pressure		Water pressure	
High temperature	X	Low temperature	
Parts at high velocity		Chemicals, if yes; fill in sect. 5.2	
Sudden acceleration at fracture/failure		Pre-tensioned components	
Dangerous dust		Severe noise	
Danger of pinching	X	Rotating parts	

Detailed risk evaluation:

Risks
1. During printing of PLA the nozzle may reach temperatures of 200 degrees Celsius. If direct contact is made minor burns could occur.
2. During printing the axes could move fast and unpredictably and one could easily pinch fingers if not kept clear of moving parts.
3. If flammable material has prolonged contact with nozzle or shorts happen within the machine electronics a fire could occur.

Risk matrix of the activity <u>before</u> any safety measures has been applied (Include corresponding color):

Risk	**Probability (P) (1-5)**	**Consequence (C)**				**Risk value (P x C)**
		Health (1-5)	**Material values (1-5)**	**Environment (1-5)**	**Reputation (1-5)**	
1	2	1	0	0	0	2
2	3	1	1	0	0	3
3	1	2	2	0	1	2

Required safety equipment (mark with X the risk that applies for the activity)**:**

Glasses		Safety shoes	
Helmet		Gloves	
Screen		Lifting equipment	

Ear protection		Hazard suit	
Harness ropes, other measures to prevent falling		Fume hood	
Lab coat			

Description of other safety measurements: Eg. Safety cap on the instrument prevents the risk of… and/ or the probability of…

Risk after preventative and corrective measures:

Risks	Preventative and corrective measures
1. During printing of PLA the nozzle may reach temperatures of 200 degrees Celsius. If direct contact is made minor burns could occur.	1. Avoid touching the nozzle and make sure it is at an acceptable temperature if touching is necessary. If accidents occur, make sure to quickly cool affected area and access if further treatment is required.
2. During printing the axes could move fast and unpredictably and one could easily pinch fingers if not kept clear of moving parts.	2. Keep hands well clear during printer operation.
3. If flammable material has prolonged contact with nozzle or shorts happen within the machine electronics a fire could occur.	3. Make sure to keep any flammable clear of printer. Make sure to stop operation, and disconnect power if sparks, smoke or burnt components are detected. Also make sure to check that you are aware of the location of extinguishers and other measures in case of fire.

Risk matrix of the activity <u>after</u> safety measures has been applied:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	1	1	0	0	0	1
2	1	1	1	0	0	1
3	1	1	1	0	0	1

For each activity performed in the lab, health risks affecting the user or others need to be identified. For each risk identified, a preventive measure must be performed, and the final risk value calculated with the “risk matrix”. Explanation of the “risk matrix” can be found in the last page of this form.

NTNU

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Date created	Last Revision
14.3.2023	14.3.2023

This page must be replicated for each different activity performed in the lab. Activities involving the use of chemicals must be filled out in the page titled "Chemical Risk Assessment" in section 5.2.

Use of Jigsaw

For each activity performed in the lab, health risks affecting the user or others need to be identified. For each risk identified, a preventive measure must be performed, and the final risk value calculated with the "risk matrix". Explanation of the "risk matrix" can be found in the last page of this form.

This page must be replicated for each different activity performed in the lab. Activities involving the use of chemicals must be filled out in the page titled "Chemical Risk Assessment" in section 5.2.

Activity: Cutting out a desired shape from bords using jigsaw.

Risk overview: (mark with X the risk that applies for the activity)

Big loads		Danger of fire	
Heavy lifting	X	Working at heights	
Hanging load		Hydraulic pressure	
Gas pressure		Water pressure	
High temperature		Low temperature	
Parts at high velocity		Chemicals, if yes; fill in sect. 5.2	
Sudden acceleration at fracture/failure	X	Pre-tensioned components	
Dangerous dust		Severe noise	X
Danger of pinching		Rotating parts	
Sharp tools/parts	X		

Detailed risk evaluation:

Risks
1. Uncut bords could be quite large, heavy and difficult to maneuver.
2. The sharp teeth on the jigsaw blade can cause serious harm. Both when the saw is active and when inactive.
3. Remainder or main board could snap away from the rest as the carrying area decreases towards the end of a cut.
4. Cutting action creates dust that could cause irritation to eyes or lungs.
5. Cutting action creates noise.

Risk	Probability (P) (1-5)	Consequence (C)	Risk value (P x C)

NTNU

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Date created 14.3.2023 Last Revision 14.3.2023

		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	5	1	1	0	0	5
2	2	3	1	0	0	6
3	3	3	1	0	0	9
4	3	3	0	0	0	9
5	2	4	0	0	0	8

Risk matrix of the activity before any safety measures has been applied (Include corresponding color):

Required safety equipment (mark with X the risk that applies for the activity)**:**

Glasses	X	Safety shoes	
Helmet		Gloves	X
Screen		Lifting equipment	
Ear protection	X	Hazard suit	
Harness ropes, other measures to prevent falling		Fume hood	
Lab coat			

Description of other safety measurements: Eg. Safety cap on the instrument prevents the risk of… and/ or the probability of…

Risk after preventative and corrective measures:

Risks	Preventative and corrective measures
1. Uncut bords could be quite large, heavy and difficult to maneuver.	Make sure to ask for help if board is on the larger side. Make sure of a clear path to avoid collisions with people or material.
2. The sharp teeth on the jigsaw blade can cause serious harm. Both when the saw is active and when inactive.	Make sure to have limbs, workbench or other things that are not planned to be cut are not in the cutting path. Make sure to never work alone and be aware of where first aid equipment is. Also make sure to not handle the blade even when the saw is not active. If necessary to

	handle, during blade change or other operations, make sure to use gloves.
3. If not supported remainder or main board could snap away from the rest as the carrying area decreases at the end of cut.	Avoid large overhangs. If not possible be aware and weary when nearing end of cut. Recruit help from other students if necessary.
4. Cutting action creates dust that could cause irritation to eyes or lungs.	Always use eye protection. Make sure others nearby move or use as well. If prolonged use is required, make sure to use a mask to avoid breathing in dust. Be aware of placement of eye wash equipment.
5. Cutting action creates noise.	Always use ear protection. Make sure others nearby move or use as well.

Risk matrix of the activity after safety measures has been applied:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	1	1	1	0	0	1
2	1	4	1	0	0	4
3	2	1	1	0	0	2
4	2	1	0	0	0	2
5	2	1	0	0	0	2

Use of Dremel tool

For each activity performed in the lab, health risks affecting the user or others need to be identified. For each risk identified, a preventive measure must be performed, and the final risk value calculated with the “risk matrix”. Explanation of the “risk matrix” can be found in the last page of this form.

This page must be replicated for each different activity performed in the lab. Activities involving the use of chemicals must be filled out in the page titled “Chemical Risk Assessment” in section 5.2.

Activity: Sanding, grinding edges of wood board and post processing of 3D prints

Risk overview: (mark with X the risk that applies for the activity)

Big loads		Danger of fire	
Heavy lifting		Working at heights	
Hanging load		Hydraulic pressure	

NTNU

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Gas pressure		Water pressure	
High temperature		Low temperature	
Parts at high velocity		Chemicals, if yes; fill in sect. 5.2	
Sudden acceleration at fracture/failure		Pre-tensioned components	
Dangerous dust	X	Severe noise	X
Danger of pinching		Rotating parts	X

Detailed risk evaluation:

Risks
1. Dust created while sanding could irritate eyes or lungs.
2. Sanding certain parts could create resonance that amplifies the sounds created by the tool.
3. The Dremel tool head rotates at a high speed, often with abrasive tools that could cause damage if contacted.

Risk matrix of the activity before any safety measures has been applied (Include corresponding color):

Risk	**Probability (P) (1-5)**	**Consequence (C)**				**Risk value (P x C)**
		Health (1-5)	**Material values (1-5)**	**Environment (1-5)**	**Reputation (1-5)**	
1	2	4	0	0	0	8
2	2	4	0	0	0	8
3	2	4	1	0	1	8

Required safety equipment (mark with X the risk that applies for the activity)**:**

Glasses	X	Safety shoes	
Helmet		Gloves	
Screen		Lifting equipment	
Ear protection	X	Hazard suit	
Harness ropes, other measures to prevent falling		Fume hood	
Lab coat			

Description of other safety measurements: Eg. Safety cap on the instrument prevents the risk of… and/ or the probability of…

Risk after preventative and corrective measures:

Risks	Preventative and corrective measures
1. Dust created while sanding could irritate eyes of lungs.	Always use eye protection. Make sure others nearby move or use as well. If prolonged use is required, make sure to use a mask to avoid breathing in dust. Be aware of placement of eye wash equipment.
2. Sanding certain parts could create resonance that amplifies the sounds created by the tool.	Always use ear protection. Make sure others nearby move or use as well.
3. The Dremel tool head rotates at a high speed, often with abrasive tools that could cause damage if contacted.	When working with small or difficult to hold parts use appropriate clamping or gloves to minimize risk of slips causing direct contact with tool.

Risk matrix of the activity after safety measures has been applied:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	2	1	0	0	0	2
2	3	1	0	0	0	3
3	2	1	1	0	1	2

Use of drill

For each activity performed in the lab, health risks affecting the user or others need to be identified. For each risk identified, a preventive measure must be performed, and the final risk value calculated with the "risk matrix". Explanation of the "risk matrix" can be found in the last page of this form.

This page must be replicated for each different activity performed in the lab. Activities involving the use of chemicals must be filled out in the page titled "Chemical Risk Assessment" in section 5.2.

Activity: Use of drill to create or tap holes in boards or post process holes in 3D prints.

Risk overview: (mark with X the risk that applies for the activity)

Big loads		Danger of fire	

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Date created	Last Revision
14.3.2023	14.3.2023

Heavy lifting		Working at heights	
Hanging load		Hydraulic pressure	
Gas pressure		Water pressure	
High temperature		Low temperature	
Parts at high velocity		Chemicals, if yes; fill in sect. 5.2	
Sudden acceleration at fracture/failure		Pre-tensioned components	
Dangerous dust	X	Severe noise	X
Danger of pinching		Rotating parts	X
Sharp tools/parts	X		

Detailed risk evaluation:

Risks
1. Shavings created while drilling could irritate eyes.
2. Drilling in certain materials with incorrect or dull bits could cause squeaking.
3. The drill rotates at a high speed, often with sharp that could cause damage if contacted. In addition, seizing could cause jerks that could cause damage.
4. The cutting edges of drill bits could cause damage to people ore facilities.

Risk matrix of the activity <u>before</u> any safety measures has been applied (Include corresponding color):

Risk	**Probability (P) (1-5)**	**Consequence (C)**				**Risk value (P x C)**
		Health (1-5)	**Material values (1-5)**	**Environment (1-5)**	**Reputation (1-5)**	
1	2	3	0	0	0	6
2	3	3	0	0	0	9
3	2	4	1	0	0	8
4	2	3	0	0	1	6

Required safety equipment (mark with X the risk that applies for the activity)**:**

Glasses	X	Safety shoes	
Helmet		Gloves	
Screen		Lifting equipment	
Ear protection	X	Hazard suit	
Harness ropes, other measures to prevent falling		Fume hood	

Lab coat			

Description of other safety measurements: Eg. Safety cap on the instrument prevents the risk of… and/ or the probability of…

Risk after preventative and corrective measures:

Risks	Preventative and corrective measures
1. Shavings created while drilling could irritate eyes.	Always use eye protection. Make sure others nearby move or use as well. Be aware of placement of eye wash equipment.
2. Drilling in certain materials with incorrect or dull bits could cause squeaking.	Always use ear protection. Make sure others nearby move or use as well.
3. The drill rotates at a high speed, often with sharp that could cause damage if contacted. In addition, seizing could cause jerks that could cause damage.	When working with small or difficult to hold parts use appropriate clamping or gloves to minimize risk of slips causing direct contact with tool. Clamping is also useful to allow use of both hands minimizing risk of wrist injuries.
4. The cutting edges of drill bits could cause damage to people ore facilities.	Make sure to clamp parts with clearance or a sacrificial piece of material behind when drilling through holes, to avoid damage to facilities. Also make sure to keep hands away from cutting edges when inserting and fastening drill bits in the chucks.

Risk matrix of the activity after safety measures has been applied:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	1	3	0	0	0	3
2	1	1	0	0	0	1
3	1	2	1	0	0	2

4	1	2	0	0	1	2

Laser cutting

For each activity performed in the lab, health risks affecting the user or others need to be identified. For each risk identified, a preventive measure must be performed, and the final risk value calculated with the "risk matrix". Explanation of the "risk matrix" can be found in the last page of this form.

This page must be replicated for each different activity performed in the lab. Activities involving the use of chemicals must be filled out in the page titled "Chemical Risk Assessment" in section 5.2.

Activity: Use of laser cutter to create two dimensional parts in plywood

Risk overview: (mark with X the risk that applies for the activity)

Big loads		Danger of fire	X
Heavy lifting		Working at heights	
Hanging load		Hydraulic pressure	
Gas pressure		Water pressure	
High temperature		Low temperature	
Parts at high velocity		Chemicals, if yes; fill in sect. 5.2	
Sudden acceleration at fracture/failure		Pre-tensioned components	
Dangerous dust		Severe noise	
Danger of pinching	X	Rotating parts	

Detailed risk evaluation:

Risks
1. The laser creates high temperatures that can cause fires whilst cutting parts.
2. The moving toolhead could conceivably pinch limbs during calibration.
3. Materials could give off fumes during operation. The glue present in MDF is one of these materials. Inhalation could cause harm

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	2	4	4	1	3	8
2	2	4	2	0	0	8

NTNU
Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Date created 14.3.2023 Last Revision 14.3.2023

3	2	4	0	0	3	8

Risk matrix of the activity before any safety measures has been applied (Include corresponding color):

Required safety equipment (mark with X the risk that applies for the activity)**:**

Glasses		Safety shoes	
Helmet		Gloves	
Screen		Lifting equipment	
Ear protection		Hazard suit	
Harness ropes, other measures to prevent falling		Fume hood	X
Lab coat			

Description of other safety measurements: Eg. Safety cap on the instrument prevents the risk of… and/ or the probability of…

Risk after preventative and corrective measures:

Risks	Preventative and corrective measures
1. The laser creates high temperatures that can cause fires whilst cutting parts.	Be present during cutting and be ready to stop the machine if errors are detected. Make sure to clear any material with lab room responsible. When in doubt consult checklists or lab attendees. Never use machine without permission of lab attendees.
2. The moving toolhead could conceivably pinch limbs during calibration.	Keep hands clear of machinery during jogging. Keep lid shut during cutting operation. When in doubt consult checklists or lab attendees. Never use machine without permission of lab attendees.

3. Materials could give off fumes during operation. The glue present in MDF is one of these materials.	Make sure to clear any material with lab room responsible. Make sure to have fume extractor turned on during operation. Keep lid closed during operation and for a couple minutes after laser is turned off to allow extraction of fumes in chamber. When in doubt consult checklists or lab attendees. Never use machine without permission of lab attendees.

Risk matrix of the activity after safety measures has been applied:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1	2	1	1	1	0	2
2	1	3	2	0	0	3
3	1	3	0	0	0	3

5.2. Chemical Risk Assessment:

Only for activities involving the use of chemicals (except ethanol and acetone for cleaning).

This page **must be replicated** for each different chemical activity performed in the lab. Include all H-sentence and numbers for chemicals used. This can be found in the Safety Data Sheet og the specific chemical(SDS).

Activity: Include specification of **your** work, name of chemicals, composition of alloy, concentration, max volume etc.

Chemicals used:	Full name – Include concentration etc.	
Mixture:	If yes, include amount and/or concentration – if known. Otherwise, state roughly max amount	
Will the mixture be stored in the cabinet for several uses?		

NTNU

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Risk	Prevention Measures
1.	
2.	
3.	
4.	

Note: All H-sentences must be included as a risk, together with "general" risks when using the specific chemical.

Chemical disposal procedure:
Dangerous waste or not? If not, why? Etc. How are you going to store the waste?

Risk matrix of the chemical activity before safety measures:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1						
2						
3						

Required safety equipment: (mark with X the risk that applies for the activity)

Glasses		Safety shoes	
Helmet		Gloves	
Screen		Lifting equipment	
Ear protection		Hazard suit	
Harness ropes, other measures to prevent falling		Fume hood	
Lab coat			

Description of other safety measurements: Eg. Safety cap on the instrument prevents the risk of… and/ or the probability of…

Risk after preventative and corrective measures:

Risks	Preventative and corrective measures
1.	
2.	
3.	

Risk matrix of the activity after safety measures has been applied:

Risk	Probability (P) (1-5)	Consequence (C)				Risk value (P x C)
		Health (1-5)	Material values (1-5)	Environment (1-5)	Reputation (1-5)	
1						
2						
3						

Comments: Supplementary comments regarding the risk matrixes

6. Sources for mistakes/errors

Is the following considered? Answer: Yes, No or NR (Not relevant)

Loss of electricity	NR	Voltage surge	No
Electrical earth failure	No	Insufficient power of the machine	No
Climate control in the room (temperature, humidity, etc…)	No	Water jet	NR

Unstable pressure or hydraulic force	NR	Unintended interruption of power supply	No
Are load and displacement limits established?	NR	Leakage of pipes, hoses, joints, etc…	NR
Possible interference from other activities	Yes	Possible interference towards other activities	Yes
Troubles in acquisition and storage	No	Fire in the laboratory	Yes

7. Calibration of equipment

If a calibration of the equipment is performed during the activity, please indicate the date:

Equipment	Date (dd.mm.yy)

8. Traceability

Answer: Yes, No or NR (Not relevant)

Are all experimental materials known and traceable?	NR
Is there a plan for marking all specimens?	NR
Is the data acquisition equipment identified?	NR
Are the original data stored safely without modification?	NR
Is there a back-up procedure for the data (hard disk crash)?	NR
Is there a plan for storing samples after testing?	NR
Is there a plan for disposing of old samples?	NR

9. Conclusion

If proper safety precautions are taken the risk associated with the work should be at an acceptable level. Great care should still be taken to be present and engaged when performing some of the more risky operations.

Faculty of Engineering (IV)
Department of Mechanical and Industrial Engineering (MTP)

Risk matrix explanation

		Health	Material values	Reputation	Environment
Grade	1	Minor injury/strain that requires simple treatment. Reversible injury. Short recovery time.	Operational shutdown, or shutdown of activities <1 day.	Little effect on credibility and respect.	Negligible injury and short recovery time.
	2	Injury/strain that requires medical treatment. Reversible injury/strain. Short recovery time.	Operational shutdown, or shutdown of activities <1 week.	Negative effect on credibility and respect.	Minor injury and short recovery time.
	3	Serious injury/strain that requires medical treatment. Lengthy recovery time.	Operational shutdown, or shutdown of activities <1 month.	Reduced credibility and respect.	Minor injury and lengthy recovery time.
	4	Serious injury/strain that requires medical treatment. Possible disability /permanent disability.	Operational shutdown > 1/2 year. Shutdown of activities up to 1 year.	Credibility and respect considerably reduced.	Long-lasting injury. Lengthy recovery time.
	5	Death or disability / permanent disability.	Operational shutdown, or shutdown of activities >1 year.	Credibility and respect considerably and permanently reduced.	Very long-lasting and irreversible injury.

Consequence (C)						
	Very serious	5	10	15	20	25
	Serious	4	8	12	16	20
	Moderate	3	6	9	12	15
	Little	2	4	6	8	10
	Very little	1	2	3	4	5
		Very little	**Little**	**Medium**	**Big**	**Very big**
		Probability (P)				

Red	Unacceptable risk. Measures need to be implemented.
Yellow	Medium risk. Measures need to be considered.
Green	Acceptable risk. Measures can be considered.

Add the color of the risk matrix that corresponds with the value you have placed in your personal risk matrix.

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