Redesign of a Halo-Frame

A more user centered alternative.

Graduation Rapport

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Faculty of Industrial Design Engineering
Delft University of Technology

Author
Maxime Iserief

Graduation committee
Prof. dr. ir. Richard Goossens | Chair
Department of Human Centred Design
Faculty of Industrial Design Engineering
Delft University of Technology

Prof. dr. ir. Zjenja Doubrovski | Mentor
Department of Sustainable Design Engineering
Faculty of Industrial Design Engineering
Delft University of Technology

In collaboration with
Dr. Prof. Jorrit-Jan Verlaan from UMCU

Table of Contents

Table of Contents

Table of Contents

Deliver

Table of Contents

Abstract

The Halo frame is a **medical device used to provide cranial and cervical immobilisation** for patients with severe spinal injuries. It ensures proper alignment of the spine during healing by stabilising the head and neck through a combination of a **halo ring attached to the skull and a vest worn on the torso**. While the device is effective, its acceptance among patients and healthcare professionals has been limited.

This **lack of acceptance** is largely due to the **unaesthetic appearance of the frame**, which can have a negative psychological impact on patients, along with issues related to **comfort, bulkiness**, and the **difficulty of assembly and adjustment**. These factors often discourage patients and doctors from opting for the device, despite its clinical benefits.

The redesigned Halo frame addresses these challenges with a focus on i**mproving aesthetic appeal, comfort, and usability**. The new design minimises visual intrusion by using only **two vertical rods** and an additional set of **horizontal rods extending over the shoulders**, moving much of the structure behind the head. Carbon fibre rods and a medical-grade plastic vest were incorporated to significantly reduce the weight while maintaining structural strength. Adjustability has been enhanced with a rack-and-pinion mechanism, allowing precise height adjustments even when the patient is lying down. The design also reduces the bulk of the frame and improves the fit, ensuring it accommodates a wide range of body types.

Allowing **controlled micromovements** in the redesigned Halo frame supports healing by promoting natural bone stimulation, which prevents weakening over time. Research shows complete immobilisation can inhibit recovery, as seen in other orthopaedic devices like knee braces. The frame balances stability and small movements to enhance the healing process while ensuring safety.

Finite Element Analysis (FEA) was conducted to evaluate how **deformation in the frame translates to deformation in the spine**. Boundary conditions from existing research were used to assess whether the design meets safety and performance requirements, confirming its viability as a medical device. In the re-design, it was determined that the **maximum angular displacement** in the vertebrae is **6.1 degrees**, and the **maximum horizontal displacement** between two vertibrae is **1.2 mm**, confirming the design's safety and performance.

User feedback played a significant role in refining the design. Orthopaedic technicians and design students provided valuable insights, leading to improvements such as **increased adjustability** of the horizontal rods and optimised **hinge placemen**t for greater accessibility. Additional considerations, such as developing reusable components and enhancing the frame's visual appeal, aim to increase patient acceptance and sustainability.

Finally, this report outlines key recommendations for further development, including **advanced performance testing** under dynamic loads, **prototyping** with actual materials, and f**ocused user studies** to refine aesthetic appeal. **Early collaboration with manufacturers** is emphasised to ensure the design is cost-effective and feasible for production. Finally, steps toward **MDR certification** are detailed to prepare the product for market introduction.

Introduction

Background

Spinal injuries often require immobilization of the cervical spine to promote healing, with the halo frame being a widely used device in both emergency and long-term treatment settings (Halo-Frame (Folder) - Catharina Ziekenhuis, 2021). While effective in stabilizing the spine, the traditional halo frame presents several challenges, including patient discomfort, limited mobility, and social stigma due to its bulky, visible structure (Misterska et al., 2018) These factors can hinder patient compliance and reduce quality of life, especially in long-term use cases (Cerillo et al., 2023). Additionally, the current design can restrict basic daily activities, requiring assistance from secondary users such as caregivers or family members (UMCU, 2024).

Recent advancements in medical technology, treatments and materials offer opportunities to re-evaluate and improve the design of the halo frame, focusing on enhancing patient experience without compromising its primary function of spinal stabilization. A redesign of the halo frame aims to address these issues by exploring lighter, more ergonomic materials, reducing the visibility of the device, and improving ease of movement while maintaining necessary immobilization.

This project seeks to develop a new concept for the halo frame that balances patient comfort, functionality, and aesthetics. The goal is to create a solution that not only aids in spinal recovery but also fosters greater acceptance among both patients and healthcare providers, ultimately improving long-term outcomes for individuals with cervical spine injuries.

FIgure 1: Halo Frame Re-Design

Project Goal

The University Medical Center Utrecht (UMCU) utilizes the halo frame approximately 50 to 70 times per year. Last year, an additional 20 frames were employed as part of a new trial that explored the use of halo frames as an alternative to long-construct spondylodesis in patients with multiple unstable cervical metastases. While halo vests are commonly used for spinal fractures, their application could be expanded to other medical conditions. However, realizing this potential requires significant development, which is the focus of this graduation project.

The design of the halo frame has seen minimal advancements over time. Though it remains effective from a medical standpoint, it presents challenges from the user's perspective. The frame is invasive, uncomfortable, and visually intimidating, leading to low acceptance among both patients and doctors.

Therefore, the objective of this project is to redesign and prototype a halo frame that enhances the user experience, improving acceptance by both patients and medical professionals.

It is important to note that this project will not address all aspects of the halo system—such as the frame, vest, rods, lining, ring, and ergonomics—due to time constraints. Instead, various potential directions will be explored, and the most

Project Structure

The project uses the the Double Diamond design framework (Design Council, n.d.) (see Figure 2) as the structure. This approach involves an initial phase of divergence, followed by convergence on more specific and relevant areas. This process is repeated twice, forming the "double diamond" structure. As a result, the framework consists of four phases, which are defined as follows:

Discover: The first phase focuses on thoroughly understanding the problem rather than making assumptions. It explores why acceptance is so low. This process includes collaborating with individuals directly impacted by the issues as well as consulting with experts in the field. In this project, the discovery phase will involve a comprehensive investigation into all aspects of the problem, identifying areas of interest for further exploration, and gaining a complete understanding of what is needed to redesign the Halo Vest.

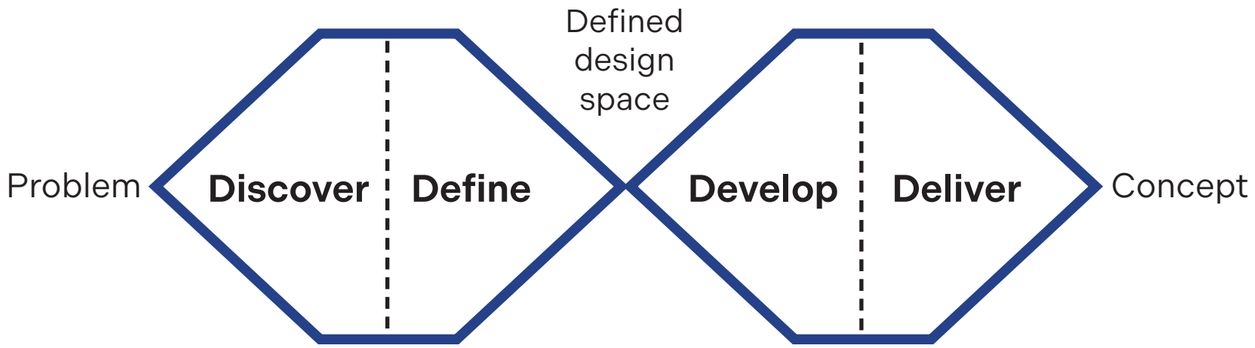


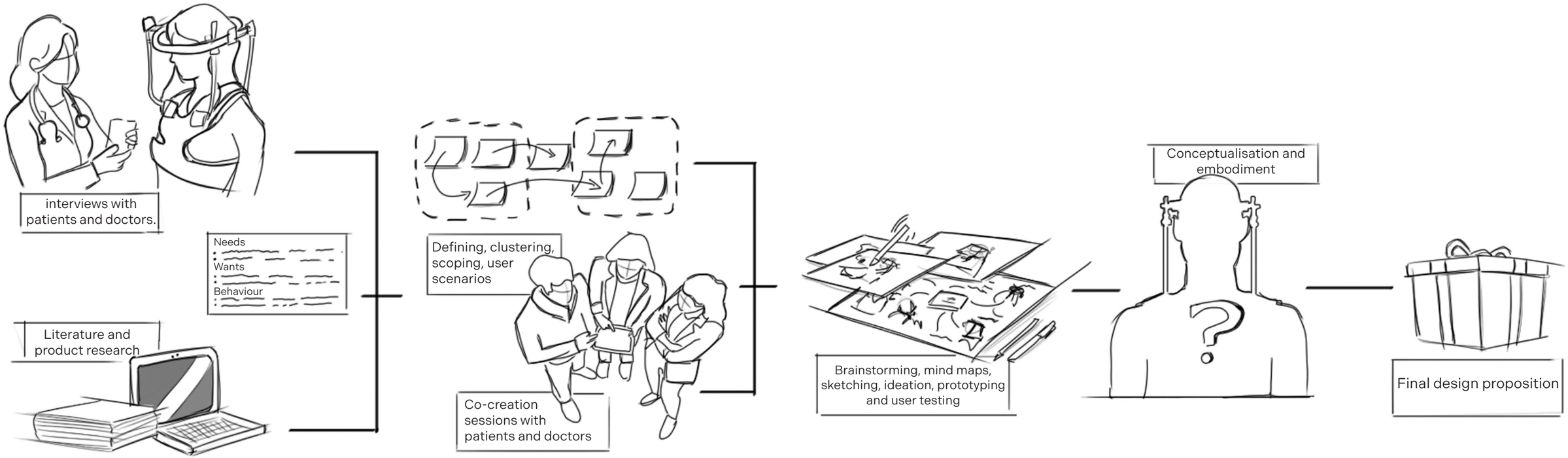
FIgure 2: Double Diamond Design Framework

Define: With the insights gathered from the discovery phase, the design challenge can be more clearly defined. This phase will involve specifying the target users, identifying when and where the product might be used, and determining how it should function. it focusses on how this acceptance can be improved? By narrowing down these aspects, the project will develop a clearer focus for the design process.

Develop: During the first half of the second diamond, the focus shifts to exploring different solutions to the defined scenario. Based on the knowledge and expertise gained in earlier phases, various design directions will be proposed. It focusses on what this could mean for the design of the frame. This phase is about creative exploration within the defined design space to generate potential approaches for improving the Halo Vest.

Deliver: In the final phase, the proposed directions will be tested on a small scale. Designs that are not viable will be discarded, while those with potential will be refined. The ultimate goal of this phase is to use these findings to guide future design improvements, culminating in the creation of an initial concept for a new Halo Vest

Problem



Discover | Define | Develop | Deliver

FIgure 3: Detailed overview of the project

Discover

Introduction

This section of the thesis explores various topics to outline the key requirements for developing a design that is viable, feasable and desirable. In the following chapters, different subjects will be examined, selected based on discussions with the project team during initial meetings and guided by areas of specific interest.

The first chapter examines the current Halo-Frame design, assessing its features and functionalities. The following chapter considers potential target groups for the Halo-Frame, accompanied by a review of relevant regulatory requirements. Subsequent chapters focus on the increasing trends in spinal stabilization, market strategies, potential distribution pathways, and options for insurance coverage. This is followed by an analysis of different users and concludes with an examination based on all teh stakeholders.

Each chapter includes a summary of design considerations, which are drawn from the analysis presented. These considerations are labeled “DC” and paired with their corresponding reference numbers, such as “(DC 1).” At the end of this phase, all considerations will be consolidated under 33 design considerations, all foun din teh conclusion of this chapter, contributing to an understanding of the broader context and identifying key factors to address in the development of a new Halo-Frame design.

In the next phase of the report – the “Define” phase – the focus will narrow to physical design aspects, limiting the scope of the study. This process will guide the development of a design that addresses the physical requirements, informed by the context discussed earlier.

This chapter provides an exploration of several aspects related to the context, creating a basis for informed design decisions.

FIgure 4: Halo Frame Re-Design

Current Design Analysis

As this project focuses on redesigning the Halo-Vest, it is crucial to begin with an analysis of the current design (figure 5). The analysis starts with an explanation of the vest's function, followed by a discussion of why a more user-centered design is necessary to enhance acceptance among both patients and healthcare providers. The fundamental mechanical principles underlying the current frame are then examined. Additionally, a timeline outlining the development of the Halo-Vest is presented. The analysis continues by addressing the sizing and ergonomic aspects of the existing products, along with a review of the specific halo-frames currently in use at UMCU. Finally, the manner in which patients interact with the frame is described, highlighting the key considerations users must keep in mind when using the device.

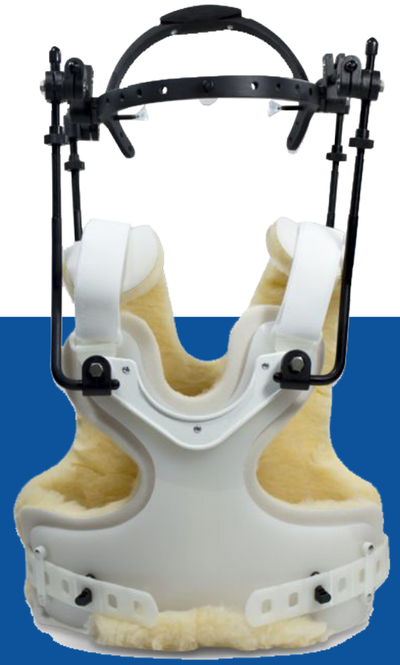


FIgure 5: Halo-Vest (Anjon Bremer, n.d.)

Target Use

A halo-brace, also known as a halo vest or halo-frame, is a medical device designed to immobilize the cervical spine following severe injuries or surgical procedures (see figure 5). This type of brace is typically prescribed for patients with cervical spine fractures, instability, or certain post-operative conditions where rigid immobilization is critical for recovery. One common reason for the use of a halo-brace is a cervical vertebrae fracture. These fractures occur in the bones that make up the neck region of the spine, known as the cervical vertebrae. (Koutsogiannis et al., 2024) Such fractures can result from trauma such as motor vehicle accidents, falls, or sports injuries. Depending on the location and severity of the injury, these fractures can be life-threatening due to the proximity of the spinal cord, which runs through the vertebral column. Common fractures or use cases are: (Whitney & Alastra, 2023)

1. Fracture of the odontoid process: Part of the second cervical vertebra (C2), is a serious condition often stabilized with a halo-brace. The odontoid process, or dens, helps provide pivot motion for the head and neck. When fractured, it can lead to instability and risk of spinal cord injury, making rigid immobilization necessary.
2. Cervical spondylolisthesis: Here one vertebra slips over another, potentially compressing the spinal cord or nerves. In more severe cases, surgical correction is needed, and post-operatively, a halo-brace can be used to ensure the cervical spine remains in the correct alignment during the healing process.
3. Burst fractures: a type of spinal fracture where a vertebra breaks into multiple pieces due to high-energy trauma may also require halo-brace treatment if the fracture involves the cervical spine. This type of injury often necessitates stabilization to prevent further damage to the spinal cord.
4. Atlantoaxial instability: This condition involves instability between the first cervical vertebra (C1) and the second cervical vertebra (C2), often due to trauma, congenital abnormalities, or rheumatoid arthritis. Halo immobilization can stabilize this joint and prevent spinal cord injury.
5. Post-operative stabilization: After certain types of cervical spine surgeries, such as those involving decompression or fusion, a halo vest may be used to ensure the spine

remains in proper alignment during the healing process.
6. Cervical dislocations: In cases of severe cervical dislocations, where the vertebrae become misaligned due to trauma, the halo vest can provide necessary support to reduce the dislocation and promote healing.
7. Complex or unstable cervical fractures: Beyond burst fractures and odontoid fractures, other types of complex or unstable fractures, including those affecting multiple vertebrae, may require immobilization with a halo vest to prevent further damage to the spinal cord.
8. Congenital cervical spine abnormalities: Certain congenital conditions, such as Klippel-Feil syndrome (a rare fusion of cervical vertebrae), may result in instability that necessitates the use of a halo vest for protection and alignment.
9. Cervical spine infections: In cases of infections like osteomyelitis (infection in the bone) affecting the cervical vertebrae, halo immobilization might be required to stabilize the spine during treatment.

In addition to trauma-related injuries, such as cervical vertebrae fractures or odontoid process fractures, recent research (Huele et al., 2024) has highlighted a new application for the halo-brace. It can also be used as a *temporary alternative to long-construct spondylodesis*—a surgical procedure that permanently fuses unstable vertebrae—in patients with multiple unstable cervical metastases. These metastases, which are secondary cancerous growths in the cervical spine, can compromise spinal stability. Halo fixation can offer temporary support while healing, reducing the need for extensive surgical intervention in certain cases.

This last bit is among one of the reasons to initiate this project. It is a new use case of a halo-frame which goes beyond the standard scope of fractures. The client - UMCU - has been leading in Halo-installment and progessive in the use of the frame in other spinal complications.

When initiateing these projects, doctors at UMCU realized how low the accpetance of the frame is among patients and doctors.

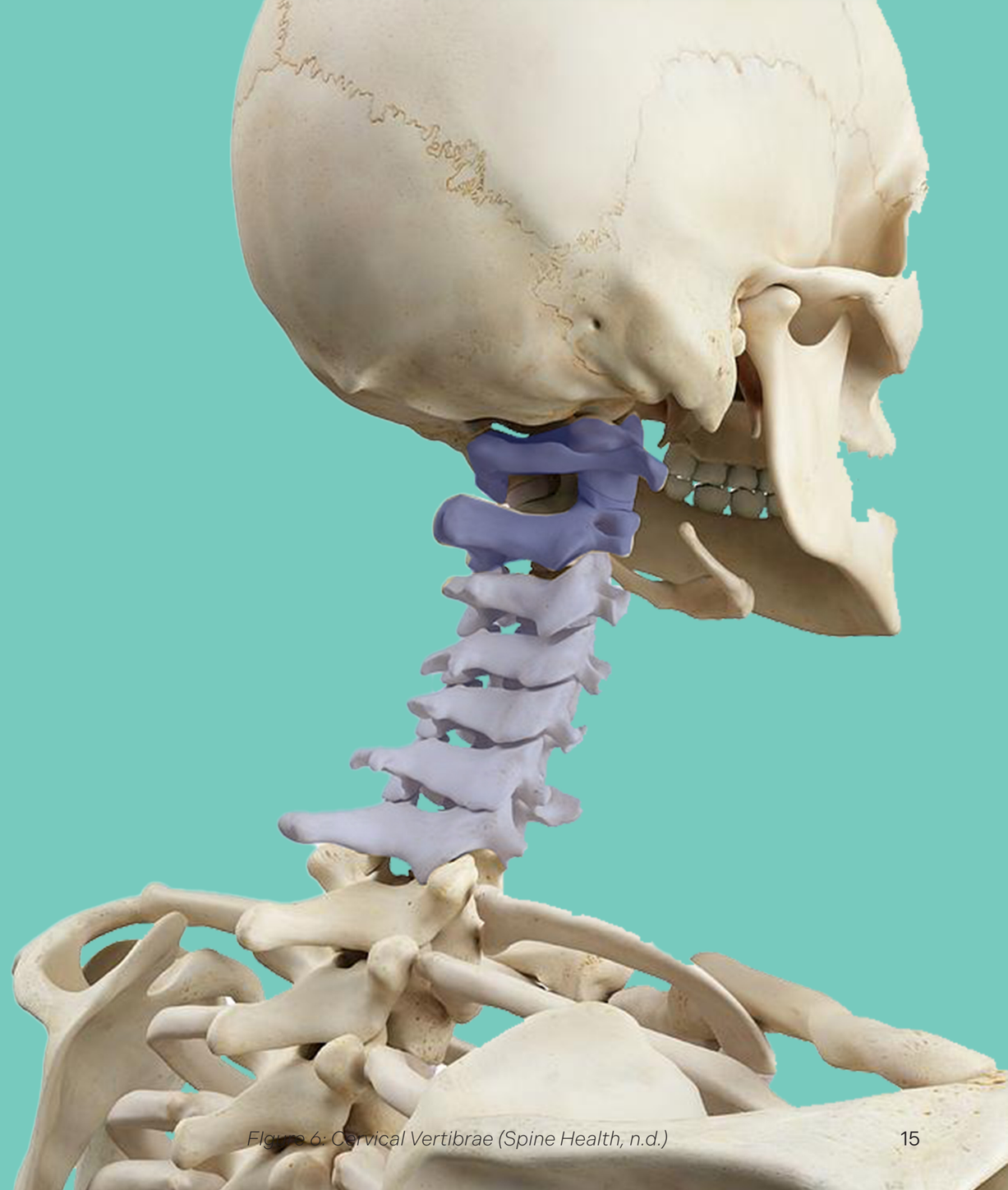


Figure 6: Cervical Vertibrae (Spine Health, n.d.)

Why a Halo Vest?

A doctor may choose a halo vest over spinal fixation or fusion surgery for several reasons, many of which relate to the Hippocratic Oath (Wikipedia, n.d.), particularly the principle of "first, do no harm." This guideline urges doctors to avoid treatments that could worsen a patient's condition or introduce unnecessary risks.

A halo vest is a non-invasive treatment typically used to stabilize the cervical spine after injury. It helps avoid the risks of surgery, such as infection, blood loss, nerve damage, or complications from anesthesia. These risks are particularly concerning for patients with other health issues, where surgery may increase the likelihood of further complications.

Spinal surgery, though necessary in some cases, often involves longer recovery times and possible long-term effects, including reduced mobility (especially with spinal fixation) or persistent pain. (Curtis, 2022) In contrast, a halo vest allows the spine to heal gradually without surgery. This method can be effective, especially when the fracture (or other complication) is expected to heal naturally. This approach consideres the patients long term health.

Why would we need a re-design of this product?

The current design of the halo vest has remained largely unchanged since its introduction in the 1970s. (see Figure 11) (Nickel et al., 1968) This can also be seen in the timeline presented later in this chapter, figure 11. While the principle of rigid immobilization remains effective from a medical perspective, the basic structure and functionality of the device have seen little innovation. This lack of progress, despite advances in technology, materials, and medical knowledge, highlights the urgent need for a redesign.

One of the primary reasons for this is patient comfort. Traditional halo vests can cause significant discomfort due to pressure points, leading to irritation and sores, especially during prolonged use (Hummelgard, 1982). Additionally, the mobility of patients is often severely restricted by the bulk and rigidity of the vest, making simple daily tasks challenging. (Babashahi et al., 2021) An updated design could focus on lighter materials and better ergonomics, offering the same level of spinal stabilization while allowing for greater mobility.

User acceptance is another critical factor. Both patients and healthcare providers often find the halo vest cumbersome and difficult to adjust (Verlaan, 2024) (Van Greithuysen, 2024). Enhancing ease of use through more intuitive adjustments and patient-friendly features would improve compliance and reduce complications.

However, the most compelling reason for a redesign lies in the aesthetic and psychological impact of the halo vest. The appearance of the traditional halo frame can negatively affect a patient's self-image and mental well-being (Misterska et al., 2018), especially during a prolonged recovery process. (Cerillo et al., 2023) (Fällström et al., 1986) An updated, more visually appealing design could help mitigate these psychological effects, making the experience of wearing a halo vest less stigmatizing and more manageable for patients.

In addition, according to surgeons at UMCU, the low acceptance of the halo vest has possibly led to doctors being more inclined to choose surgery over prescribing the frame. Recent research from 2024 indicates a decreasing trend in the use of the halo system, as advancements in surgical techniques have led many surgeons to favor operative interventions. Despite this shift, halo vest immobilization continues to play a vital role in the management of occipital-cervical injuries and has been associated with favorable patient outcomes (Rispoli et al., 2024). The inconvenience and discomfort associated with the device make both patients and doctors hesitant to rely on it. However, this trend has negative implications for patients in the long term. Surgery, while sometimes necessary, carries higher risks and longer recovery times. Relying on surgery instead of non-invasive options like the halo vest may increase the likelihood of complications, potentially affecting the patient's overall health and well-being (Bucholz & Cheung, 1989).

Given that the halo vest's fundamental design has changed little since the 1970s, it is clear that with today's advances in materials, technology, and medical knowledge, the device is overdue for an upgrade. A modernized design could address both the physical and psychological needs of patients, making the device more comfortable, functional, and acceptable, ultimately leading to better patient and doctor outcomes and experiences.

Therefore the goal of this project is:

Create a re-design and prototype of a Halo-Frame to improve patients' user experience and therefore acceptation of the Halo-Frame among patients and doctors.

Hardware

The halo vest consists of several key components that work together to provide stability and prevent movement in the neck and head. (UHN, n.d.) Each part has a specific function in maintaining the correct positioning of the spine and ensuring patient safety during the healing process. The main components of the halo vest include:

Halo ring: The halo ring is the circular metal frame that surrounds the patient's head. This is the central element of the halo system, and it is attached directly to the skull using halo pins. The halo ring is essential for maintaining the head in a fixed position, preventing any movement that could jeopardize the healing process.

a. Standard Halo Ring: The most common type, typically with four pins, used for general cervical spine immobilization.
b. Crown Halo Ring: Has a contoured shape and usually six pins for added stability, useful for more severe injuries.
c. Open-back Halo Ring: Allows access to the back of the head, often used post-surgery or for specific trauma cases.
d. Pediatric Halo Ring: A smaller, lighter version designed for children, with adjusted pin placement for smaller skulls.
e. Multi-pin Halo Ring: Includes more than four pins for extra stability, used in cases of severe fractures or instability.
f. Custom Halo Ring: Tailored to fit unique anatomical needs when standard designs are insufficient.

Halo pins (screws): These are small titanium or steel screws that secure the halo ring to the patient's skull. They penetrate the outer layer of the skin and are fastened into the bone at specific points on the forehead and back of the skull. Typically, there are four to six pins evenly distributed around the halo ring. These pins ensure the halo ring stays securely in place, effectively immobilizing the head. Most halo

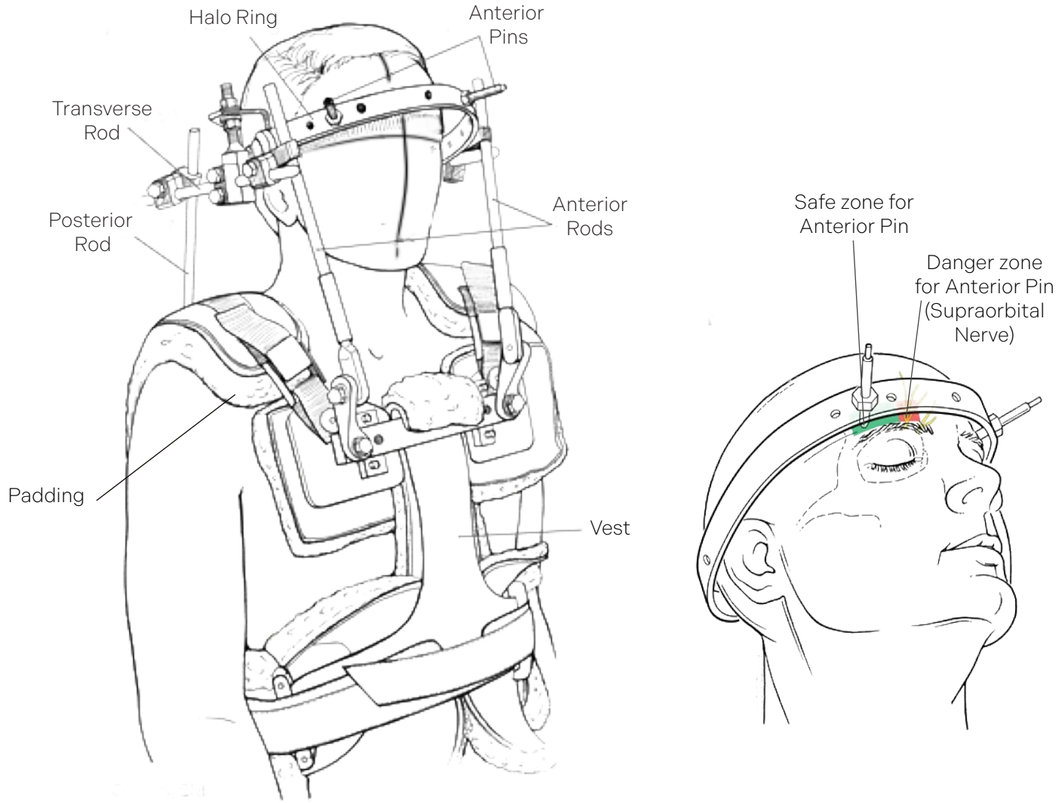


FIgure 7: Product Hardware (Lomed, n.d.)

pins are standardized and can be used with different types of halo rings, as long as they are designed to fit the pinholes in the ring. However, certain halo systems or manufacturers may have specific pin designs that are optimized for their particular halo frame, although the core functionality remains similar. Most halo pins are made from medical-grade materials like titanium or stainless steel, which ensures strength and biocompatibility, but there may be minor variations depending on the manufacturer.

Vest: The vest portion of the halo system is a rigid, thermoplastic or shell (Bremer Medical, n.d.) that fits snugly around the patient's chest and upper torso. The vest is padded inside for comfort and to prevent skin breakdown. Its primary role is to serve as a foundation for the support structure and to keep the spine in proper alignment.

Vertical support rods: These are metal rods that connect the halo ring to the vest. There are typically four rods, two on each side, that attach at the top of the vest and extend upwards to the halo ring. The rods provide a rigid structure that keeps the head fixed relative to the body, ensuring that the cervical spine remains immobilized.

Liners and padding: The vest is lined with soft padding to provide a more comfortable fit and reduce skin irritation. The padding helps to distribute pressure evenly across the torso, minimizing the risk of pressure sores. Patients often need to wear a snug-fitting shirt underneath the vest to further prevent friction between the skin and the device.

Straps and fasteners: Adjustable straps and fasteners are used to secure the vest tightly around the patient's torso. These allow for minor adjustments in fit and ensure that the vest stays in place as the patient moves or changes position.

Superstructure or crossbars (optional): Some halo vests may have additional crossbars or a superstructure that connects the vertical support rods for added rigidity. These crossbars further stabilize the system and provide extra support in maintaining head and neck immobilization.

The halo vest must be properly fitted and regularly checked to ensure it continues to provide the necessary support without causing additional complications such as skin irritation or pressure sores.

Mechanical Principle

The halo vest is a device designed to mechanically stabilize the cervical spine by limiting all degrees of head motion. The core mechanical function of the halo vest is to immobilize the head and neck by anchoring the skull to the torso, preventing harmful movement after spinal injuries such as fractures. The Walker et al. (1984) study gives detailed insight into the forces that are involved in this process, which is crucial for understanding how to re-design the device while maintaining its effectiveness.

Head Movements and Mechanical Control

The human head can move in three primary ways, (Jantunen et al., 2016) each of which the halo vest must restrict to ensure stability and healing:

1. Pitch (Flexion and Extension):

Pitch describes the forward (flexion) and backward (extension) tilt of the head. These movements are particularly dangerous for a patient with cervical spine injuries because flexion can place a high load on the vertebrae, while extension can destabilize fractures.
The halo vest restricts this movement through its vertical rods, which connect the rigid halo ring (where pins are inserted into the skull) to the vest worn on the torso. Forces generated by flexion or extension are transferred from the halo ring to the vest, which stabilizes the head and prevents excessive movement.

2. Yaw (Rotation):

Yaw is the left-to-right rotational movement of the head. For patients with cervical fractures, this type of motion is particularly dangerous because it can cause torsion on the spinal column. The rigid halo ring and the vertical rods act as a solid frame, preventing the head from rotating, which protects the spine from rotational forces.

3. Roll (Lateral Flexion):

Roll refers to the side-to-side tilting of the head (lateral flexion). This motion is controlled by the structure of the halo vest, which uses the lateral rods to prevent the head from moving sideways. Any tilt in the head generates mediolateral forces, which are absorbed by the structure of the vest.

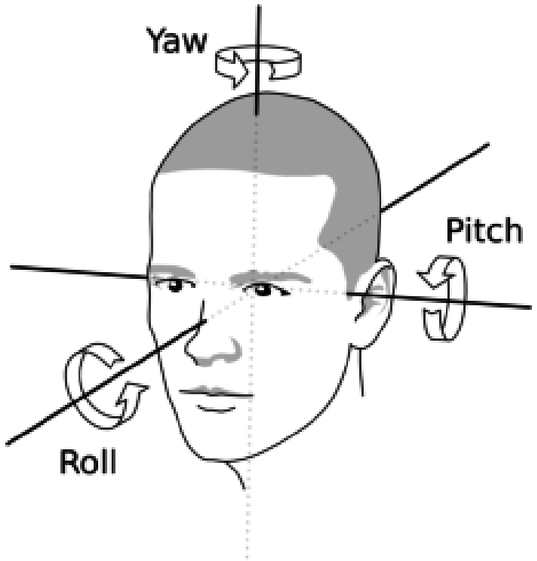


FIgure 8 : Head movements. (Jantunen et al, 2016)

Key Forces in the Halo Vest

In the Walker et al. (1984) study, forces acting on the halo vest during different activities were recorded using transducers placed on the vertical rods and pins. These forces vary significantly depending on the type of movement and the patient's activity: (DC14 &14)

1. Vertical (Axial) Forces:
   The average steady forces in the Fz direction were found to be 177N on the right side and 161N on the left side when patients were at rest. These forces represent the load of the head transmitted through the pins, halo ring, and vertical rods. When patients moved, such as during bending or standing up, these forces could increase dramatically, as the head's weight was borne more directly by the apparatus.

2. Anterior-Posterior (Forward and Backward) Forces:
   Forward bending produces forces as high as 126N in the anterior-posterior (Fx) direction. These forces are particularly dangerous for patients because they exert pressure on the spine during dynamic activities like sitting up, bending forward, or reaching out.

3. Lateral Forces:
   The mediolateral forces (Fy) (side-to-side) are generally lower than vertical and anterior-posterior forces, but they still play an important role in maintaining stability. Lateral tilting of the head during activities like reaching sideways or moving from lying to sitting can generate forces of up to 148N (measured during tests), indicating that lateral stabilization is crucial for proper spinal immobilization.

Mechanical Principles Applied in the Halo Vest

The mechanical principles that underlie the halo vest design ensure it functions effectively to limit head movement and protect the cervical spine: (Vernon et al., 1978) (Mirza et al., 1997)

1. Rigid Body Mechanics:
   The halo vest creates a rigid mechanical system between the head and torso, using the halo ring, vertical rods, and vest to stabilize the cervical spine. This rigid structure prevents motion in all directions, which is vital for ensuring spinal injuries do not worsen.

2. Force Distribution:
   Forces generated by the head's weight and patient movement are transferred from the skull (via the pins) to the halo ring and then through the vertical rods to the torso. The vest helps distribute these forces over a larger area, reducing localized pressure on the spine and preventing movement that could interfere with healing.

3. Lever Arm Principle:
   The length of the rods acts as a lever, increasing the mechanical advantage by distributing the force over a greater distance. This principle ensures that forces acting on the head are efficiently transferred to the vest, preventing excessive strain on the spine.

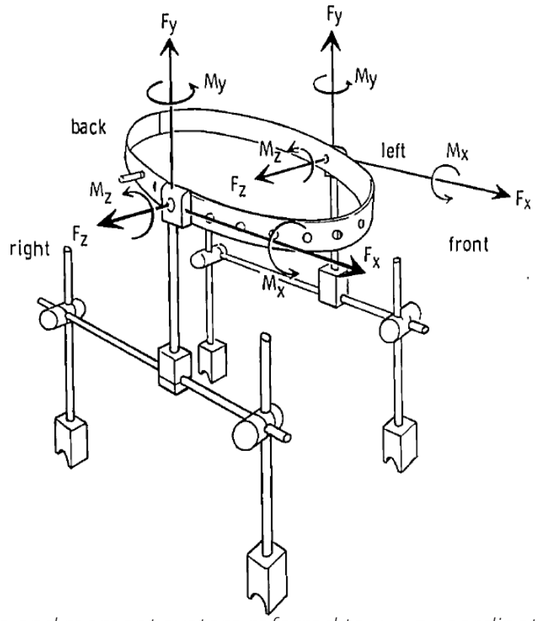


FIgure 9: The force and moment system referred to x-y-z coordinates at the vertical rod-halo connection connections. (Walker et al., 1984)

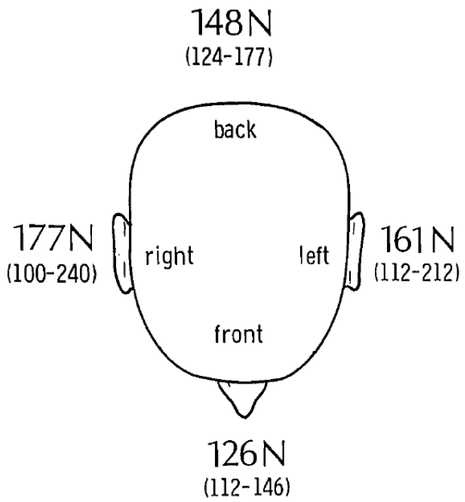


FIgure 10: The maximum force exerted by normal is four directions. The forces are in Newtons. The mean values and ranges are shown. (Walker et al., (1984)

Relevant Information for Redesign

1. Force magnitudes: The forces recorded in the study by Walker et al. (1984.) —177N vertical, 126N anterior-posterior, and 148N mediolateral—are essential thresholds that the new vest design must accommodate. Materials used for the vertical rods, pins, and vest must be strong enough to handle forces upwards of 177N in the vertical direction, while also being lightweight enough to improve patient comfort.

2. Pin forces: Managing the force applied to the skull through the pins is crucial for preventing complications. Redesigning the pin interfaces could help distribute the forces more evenly across the skull, improving patient comfort.

3. Movement impact: The halo vest must handle dynamic forces during patient movements like sitting, standing, or bending. Designing for these forces is critical to ensuring both the effectiveness of the device and patient safety.

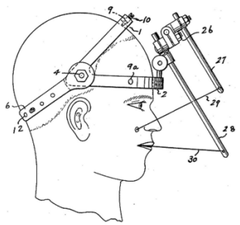
Timeline of Halo-Vest development

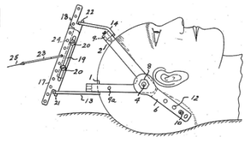
In the previous chapter, the lack of significant advancements in the design of the halo vest since its introduction in the 1970s was discussed. This chapter presents a timeline outlining key moments in the development of the halo vest, illustrating the minimal changes made over the years despite advances in medical technology and materials. This timeline provides context for understanding the current need for redesign and innovation.

FIgure 11: Timeline

1950's

Early concepts of externa fixation for spinal injuries are explored, primarily using traction. Designed by Frederick
A. Bloom and Submitted for
United States patent in March 1947 and approved in January 1950.

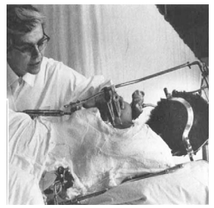


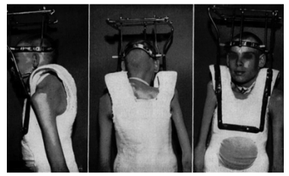


(Bloom, 1950)

1960's

The development of skeletal traction devices to stabilize the cervical spine starts. Basic versions of external frames are experimented with.



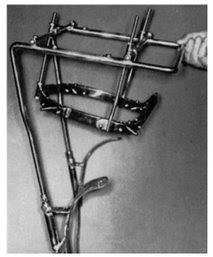


(Perry and Nickel, 1959 and 1963)

1970's

Dr. Vernon Nickel and his team develop the first modern halo vest system. This design uses a metal ring attached to the skull via pins, with a vest for spinal stabilization. The principle remains similar to today's halo vests.

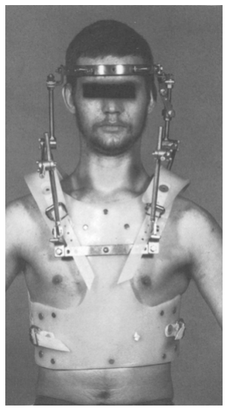
(Kyoshima et al., 2003)



(Nickel et al., 1968)

1980's

The halo vest system becomes standard for cervical spine injuries, offering an alternative to prolonged bed rest and traction. Materials improve during this period, with the use of lighter metals (titanium) for the halo ring and vest components.



(Cooper et al., 1979)

1990's

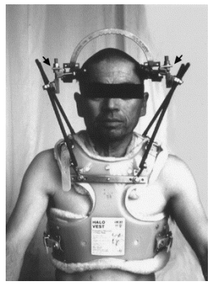
Advances in biomechanics and materials lead to better-fitting, more ergonomically designed vests. Introduction of carbon fiber materials for lighter and more durable vests, making them more comfortable for long-term use. and compatible with MR Imaging

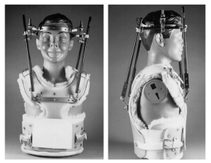
(Shellock & Slimp, 1990)

2000's

Improvements in pin technology, including more stable and safer pin designs, reduce complications like infections and loosening. Halo vests are adapted for pediatric use, with smaller versions designed for children.

(Kyoshima et al., 2003)





(Hunter et al., 2004)

2010's

Continued improvements in materials and manufacturing techniques lead to more personalized and lightweight halo vests. The introduction of semi-waterproof vests (Coolmax® liner PMT) for easier patient care and maintenance.

(PMT, nd.)

(Bremer, nd.)

TODAY

The basic design of the halo vest remains largely unchanged, though newer technologies and improved ergonomics make modern vests more comfortable and effective for longer durations. Custom-fit and specialized vests are now available for various patient needs, including post-operative care and complex spinal conditions.

1950 1960 1970 1980 1990 2000 2010 Today

Vests at UMC Utrecht

At UMCU, the halo vests used primarily come from Bremer Medical. The hospital utilizes two variants of this brand: the tall vest, designed for patients over 160 cm, and the small vest, for individuals under 160 cm. Additionally, UMCU employs the PMT Corporation Vest for larger patients, offering greater sizing flexibility. Previously, UMCU also used The ReSolve Halo System by Ossur, but they have since been discontinued, leading the hospital to focus on Bremer and PMT models to meet diverse patient needs.

Bremer Medical vests are known for their lightweight materials and ease of use, which makes them suitable for long-term immobilization, while PMT vests provide additional comfort for patients with larger body types due to their enhanced padding and larger sizing.

Bremer vests have been found by the UMCU as the most user firendly and most adjustable on the makert. Since Bremer vests are the standard at UMCU, this brand will be the main focus when looking at the sizing systems of a Halo-Frame.

FIgure 12: From left to right: The Bremer Vest (Bremer, n.d.), The PMT Vest (PMT, n.d.) and the Ossur vest. (Ossur, n.d.)

Sizing and Ergonomics

Sizing and ergonomics play a crucial role in the effectiveness and comfort of a halo vest. A well-fitted halo vest ensures proper immobilization of the cervical spine while minimizing discomfort for the patient. Poor sizing can lead to inadequate support, pressure sores, or restricted breathing.(DC 1 &2) Additionally, ergonomic considerations are essential for enhancing the user experience, as a halo vest is worn for extended periods. Factors such as adjustability, weight distribution, and padding must be optimized to ensure that the device is not only medically effective but also as comfortable and manageable as possible for the wearer.

Sizing of the Ring

At UMC Utrecht, the halo ring used most frequently is from the Bremer brand. The Bremer halo has a double C-shaped structure that provides the necessary rigidity to ensure proper support (See figure 13). The ring includes fifteen threaded holes that allow the placement of halo pins at various locations based on the patient's needs.

The current standard sizes of the Bremer ring are small (S) and large (L). If the small ring does not fit properly, a larger ring is used, which also requires the use of larger pins for stability. In the past, UMC Utrecht also utilized a halo ring from the Ossur brand (See Figure 13). This ring had a single C-shaped design and was produced in a one-size-fits-all model. It featured a slight indentation near the ears to enhance comfort for the patient. Regardless of the brand, for sizing it is important that there is a gap of 1 to 2 cm between the halo ring and the patient's head. This gap is essential for hygiene, as it allows for regular cleaning and checking of the pins, and helps to prevent chafing or irritation between the ring and the skin.

FIgure 13: From left to right: The Bremer Ring, The PMT Ring and the Ossur Ring.

Sizing of the Vest

Bremer offers a variety of vests, see figure 14 & 15. The light vests come in two main versions: the Short Light Vest and the Tall Light Vest. The Short Light Vest is intended for individuals with a chest circumference of 28 to 38 inches (72-98 cm) and is recommended for people who are 170 cm or shorter. For taller individuals, the Tall Light Vest is a better option, accommodating chest sizes from 30 to 44 inches (76-112 cm) and fitting those taller than 170 cm. Both vests are lightweight, ensuring proper spinal support while still being comfortable to wear. (Bremer, n.d.)(DC6)

In addition to these, Bremer offers a specialized vest, the Kyphosis Light Vest. This vest is specifically designed to provide support for patients dealing with kyphosis. Kyphosis is a condition where the upper spine curves excessively outward, leading to a hunched or rounded back. Bremer also produces Classic Vests, available in a range of sizes to ensure proper fit for different body types. The Petite Slim Classic Vest is designed for smaller individuals with a chest circumference between 26 and 34 inches (66-86 cm). For those who need a slightly larger fit, the Small Classic Vest accommodates chest sizes from 32 to 38 inches (82-98 cm). For even broader fits, the Large Classic Vest supports chest circumferences of 36 to 42 inches (92-108 cm). Finally, the X-Large Classic Vest is ideal for those with a chest circumference between 42 and 58 inches (108-148 cm), providing a comfortable fit for larger body frames. the Bremer classic vest does not differentiate based on height, but solely on circumference. The Ossur vest had roughly the same sizing as the Bremer Classic vest. (Ossur, n.d.). The PMT vests are only occupied at the UMCU in the larger sizes (XL/XXL).

		SHORT LIGHT VEST
AF101 / AF101W	100001	28-38 IN. (72-98 cm)
		(170 cm or Shorter)
		TALL LIGHT VEST
AF102 / AF102W	100002	30-44 IN. (76-112 cm)
		(170 cm or Taller)
		KYPHOSIS LIGHT VEST
AF103	100003	* Available on Special Order

FIgure 14: Sizing Light Vest (Bremer, n.d.)

CV100 / CV100W	100004	PETITE SLIM CLASSIC VEST 26-34 IN. (66-86 cm)
CV101 / CV101W	100005	SMALL CLASSIC VEST 32-38 IN. (82-98 cm)
CV102 / CV102W	100006	LARGE CLASSIC VEST 36-42 IN. (92-108 cm)
CV103XL / CV103XLW	100007	X-LARGE CLASSIC VEST 42-58 IN. (108-148 cm)

FIgure 15: Sizing Classic Vest (Bremer, n.d.)

Design Considerations 1

In conclusion, redesigning the Halo vest not only addresses the technical requirements of cervical spine stabilization but also takes into account the diverse needs of patients and healthcare providers. The analysis of the current design highlights several opportunities for improvement, from enhancing patient comfort and fit to integrating more modern materials and ergonomic features. These design considerations reflect the need for a more user-centered approach that prioritizes ease of use, psychological well-being, and adaptability, ensuring the new design is both functionally effective and more widely accepted by users. The following considerations, drawn from the detailed analysis of the current Halo vest, aim to guide the development of a more practical, comfortable, and patient-friendly device.

1. Pressure Points: Current halo vests often cause discomfort due to pressure points, leading to irritation and sores, especially during prolonged use. The redesign should focus on minimizing these pressure points, potentially through improved padding or more adaptable fit.

2. Mobility: The current design significantly restricts mobility, making everyday tasks difficult. A more ergonomic design with lighter materials could enhance patient movement while still ensuring proper stabilization.

3. Sizing Variability: A key issue is the limited sizing options, which can result in poor fit. The vest should be designed to accommodate a wider range of body types, and a modular or adjustable fit could be beneficial.

4. Breathing and Comfort: Ensuring that the vest allows for adequate chest expansion to prevent restricted breathing is critical. The design should also account for extended wear by optimizing weight distribution and reducing friction between the skin and the device.

5. Force Magnitudes: The forces acting on the vest during patient movements, such as vertical (177N), anterior-posterior (83N), and lateral (148N) forces, must be accounted for. Materials used for the vertical rods, pins, and vest need to withstand these forces while remaining lightweight to improve patient comfort.

6. Dynamic Forces: The vest must handle forces during activities like sitting, standing, and bending, ensuring stability without compromising patient safety.

7. Pin Force Distribution: The current pin interfaces could be redesigned to distribute forces more evenly across the skull, which would reduce discomfort and the risk of complications. Considerations for pin placement and biocompatibility of materials are essential.

8. Aesthetic and Psychological Impact: The appearance of the halo vest plays a significant role in user acceptance. A more visually appealing design could improve patient morale and reduce the stigma associated with wearing the device.

9. Ease of Use: Enhancing the ease of adjustments for both patients and healthcare providers could lead to better compliance and reduced complications. Features that simplify the fitting and maintenance of the vest would be beneficial.

10. Use of Modern Materials: Advances in materials, such as lightweight composites and biocompatible alloys, should be leveraged to reduce the overall weight of the vest while maintaining or improving its structural integrity.

11. Custom-Fit Options: The potential for customizable components, particularly for unique anatomical requirements, could improve the fit and performance of the vest across a diverse patient population.

Metro Map Treatment Plan

This metro map-style visualization outlines the entire treatment pathway for a halo vest user, from initial assessment through post-removal care. By mapping out each step in the care process—covering assessments, consultations, treatments, and follow-ups—this visual provides a structured overview of the journey a patient experiences with a halo vest. Each phase is broken down into specific actions, decisions, and consultations, showing recurring actions, key decision points, and areas where support or adjustments are needed.

Understanding the complete treatment plan is helpful for the halo vest redesign, as it shows the different requirements at each stage of use. For example, in the early stages, stability and ease of fitting are essential for immediate care, while later stages require more focus on comfort and adaptability for prolonged wear. Insights from each stage can guide design adjustments that support user needs throughout the process, such as making the device more wearable over time and simpler to manage during rehabilitation. A full view of the user's journey allows for a redesign that balances clinical requirements with patient experience, supporting comfort and usability across the entire recovery process.

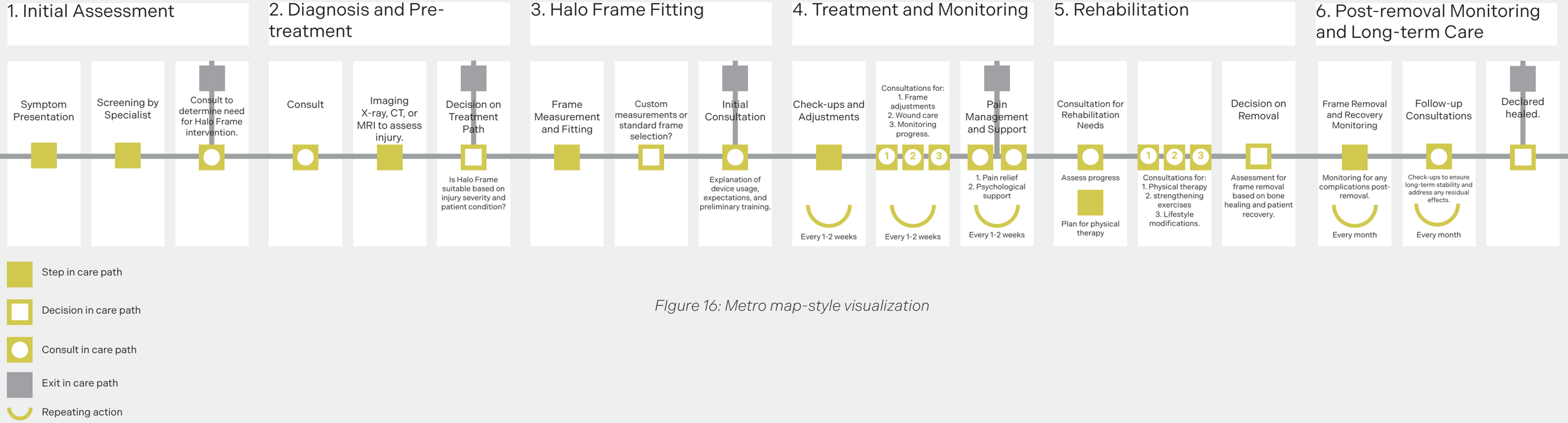


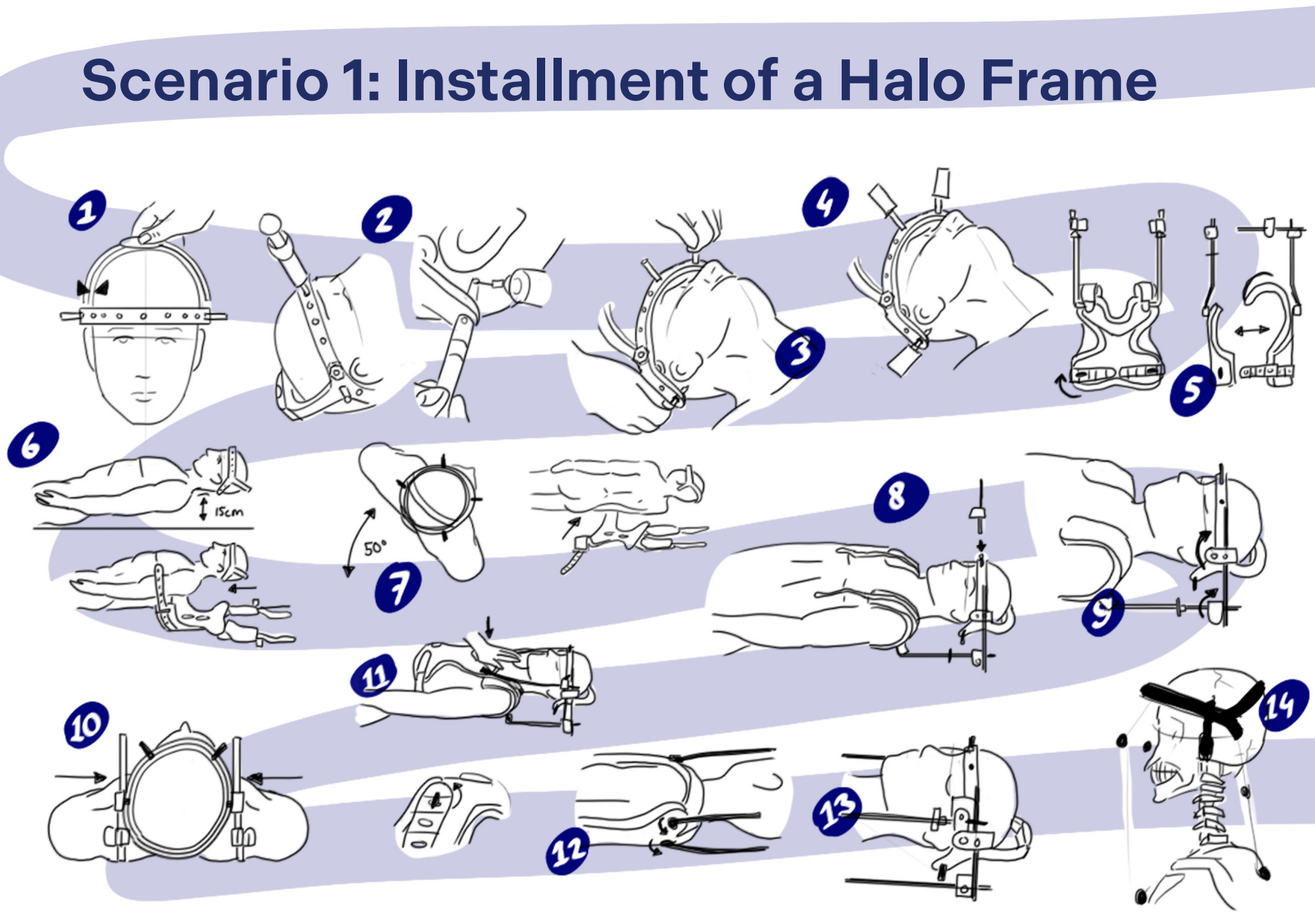
FIgure 16: Metro map-style visualization

User Scenario: Installment of a Halo Frame

Halo vest placement is a protocol that takes approximately one hour, however in practice the whole assembly of the frame usually takes up to 3-4 hours due to the personal approach for each patient. The patient gets briefed by the surgeon or the orthopaedic. Afte that the patient is completely in the hands of the plaster cast makers. The plaster cast makers will take the lead and install the halo with 2-3 people. One holding the head, and two putting on the vest. The patient will be awake and lie face up on a hospital bed or table throughout the procedure. Placement of a halo ring and vest generally follows these steps as mentioned in the brochure of (verywellhealth.com):

1. Halo is fitted around the patient head. The halo should have at least 1-2 cm distance between the ring and the head.
2. A local anaesthetic and antiseptic are applied to numb and sterilize the areas of the head where titanium pins will be placed.
3. Four pins are threaded through the halo ring and anchored to the skull—two above the eyebrows and one behind each ear. The pins help keep the halo ring in place and prevent neck movement.
4. The pins on the halo are tightened using a torque screwdriver, and bolts are applied to fully secure the ring. The pins have a toque of 0.7- 0.9 Nm.
5. The vest is separated to a front and back part.
6. The brace (vest) is placed on the chest and torso. This will fit snugly and can be worn under clothes. There are two options to place the vest. One is by lifting the patient and placing the vest underneath. This is at least a two man job.
7. The second option is a roll manoeuvre. Both are fine and depend on the doctors preference.
8. The vest is connected to the halo ring with adjustable metal rods. The back rods are connected to the middle beam and screw.
9. The head's pitch is aligned in the right position based on the CT scan of the fracture.
10. After that the heads'roll and yaw are aligned in the right position based on the CT scan of the fracture.
11. Furthermore the front part of the vest is placed on the patient. This has to be done quite firmly to secure a snug fit.
12. First the front rods are screwed tightly, then the back rods.
13. The front rods are connected to the halo ring and the frame is comepletly screwed tightly to secure the patient.
14. Following the procedure, X-rays or CT scans may be performed to verify proper alignment of the cervical spine. The tools used, such as specialized screwdrivers, are stored with the vest for potential adjustments or emergency removal. Regular follow-ups with healthcare providers are required to monitor recovery, adjust pin tension, and ensure the spine's alignment remains intact.

FIgure 17: Installment of a Halo Frame



User Scenario: Living with a Halo Frame

This visual maps the full journey of living with a halo vest, from fitting to removal, showing the daily challenges patients face, such as discomfort, maintenance, and limited mobility. This overview is crucial for the redesign, as it highlights specific needs and pain points, guiding improvements that better support patients in their daily routines(DC3).

1. Vest gets measured at the hospital, depending on the severity of your injuries the patient might need to stay there for one night to get accustomed to the vest in terms of balance and the pressure on the head and eyes.
2. When going home, the patient gets picked up. They can sit in a car but they can not drive one
3. Eating will go fairly normal, it is advised to take smaller bites. It might be a bit messy because the patient can't look down. It is important to stay the same weight, or otherwise the vest needs to be adjusted.
4. Clothing goes over the vest. The patient has to buy/find clothing with a larger than normal neck line. People get really creative. (DC5)
5. Sleeping happens on the back. A towel or small pillow can be placed under the neck for support. A wedge to elevate the head of the bed may increase the comfort.(DC4)
6. Getting in and out of bed is difficult. The patient can't sit up by bending at the waist. This will put stress on the front pins. The patient has to roll over on their side.
7. The patient should have a family member or visiting nurse check the pin sites every day for signs of infection. They can clean them as needed with hydrogen peroxide. It is best to let the skin heal naturally.
8. The patient can't shower. Instead, they can sponge bathe by sitting in a chair next to the sink. They need to keep the vest dry at all times. To clean the skin under the vest and vest liner the patient can slightly dampen a thin hand towel with rubbing alcohol. After that they can "Feed" the towel under vest. Lastly they can pull the ends of the towel back and forth in a drying motion.
9. They patient can't wash their hair until the physician tells them that they are allowed. They can wash their hair by slightly bending over at the sink. A family member or nurse will need to help them by using a hand-held pitcher or flexible hose to rinse the hair
10. If the vest does get wet, dry it with a blow-dryer on a cool setting.

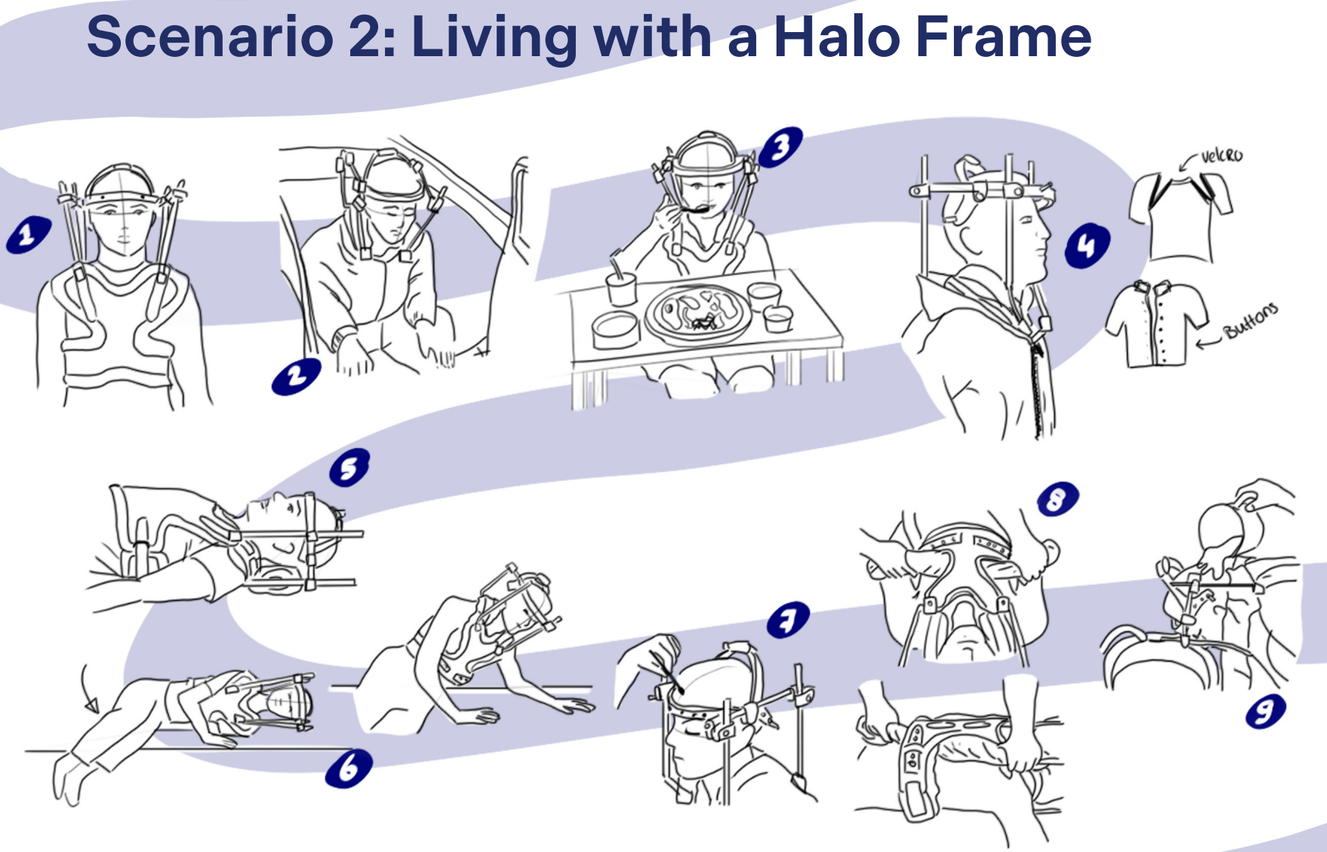


FIgure 18: Living with a Halo Frame

Key take aways from user scenarios's

Installation Process:
The process of installing the Halo vest is both intricate and personalized, typically involving 2-3 people, including plaster cast makers. A significant portion of the procedure relies on the expertise of these plaster cast makers, particularly in securing the frame and ensuring a proper fit. While the actual installment of the Halo vest is relatively fast, positioning the frame correctly takes up most of the time, as it requires precise alignment based on imaging like CT scans or X-rays to ensure optimal stabilization.(DC20)

Force Distribution:
The Halo frame must be installed securely with the pins applying the correct amount of torque (0.7-0.9 Nm) to ensure stabilization of the cervical spine. (Abbasi, n.d.) Proper force distribution is key to prevent movement of the head and neck, which could jeopardize recovery.(DC15)

Daily Living Challenges:
Patients face several daily challenges while wearing the Halo vest. Simple tasks like eating, sleeping, and getting dressed become difficult. Patients are encouraged to make adjustments such as wearing clothing with larger necklines and sleeping on their back with a slight elevation for comfort.(DC3,4&5)

Pin-Site Management:
Pin sites, where the Halo frame is attached to the skull, require careful daily cleaning to prevent infections. Patients or caregivers are advised to use hydrogen peroxide for cleaning, ensuring that the skin around the pins is kept dry and allowed to heal naturally.(DC22)

Physical Limitations:
Movement and certain activities are severely restricted. Patients cannot drive, and they must roll to their side to get in and out of bed to avoid putting stress on the pins. They also cannot shower, but can sponge bathe, and need assistance to wash their hair. (DC10)

Patient Support:
Due to the physical and mental challenges of wearing a Halo frame, patients require continuous support from family members or nurses. Assistance is necessary for tasks like hair washing, vest maintenance, and monitoring pin sites for infection.

Vest Maintenance:
The Halo vest must be kept dry at all times. If the vest gets wet, it must be dried immediately using a blow-dryer on a cool setting. Regular cleaning of the vest liner with rubbing alcohol is necessary to maintain hygiene and patient comfort.

Expertise in Halo Frame Installation:
A large part of the successful installment of the Halo frame depends on the expertise of the plaster cast makers, who play a critical role in ensuring the correct fit and stability of the device. Their experience is key in handling the complex procedure of securing the frame to the patient's body.

These points highlight both the technical complexity of the Halo frame installation process and the ongoing challenges patients face during their recovery.

Design Considerations 2

The current Halo vest design, while effective in stabilizing the cervical spine, presents several challenges for both patients and healthcare providers. From the complex installation process that relies heavily on specialized expertise to the discomfort patients experience during daily activities, there is a clear need for a more user-friendly and adaptable design. This section outlines key design considerations based on the user scenario's.

1. Ease of Installation: The Halo vest installation process relies heavily on the expertise of plaster cast makers, and while the installation itself is fast, positioning the frame correctly takes considerable time. The redesign should aim to simplify the positioning process, allowing for more efficient and accurate placement with less dependency on specialized personnel.

2. Frame Alignment and Adjustability: Proper alignment of the Halo frame is critical for spinal stabilization, and adjustments are often based on imaging scans (e.g., CT or X-rays). The design should include clear, user-friendly mechanisms that allow healthcare providers to make precise adjustments easily and securely during and after the initial installation.

3. Pin-Site Management: Pins are a crucial part of the Halo frame system, but they pose a risk for infections and skin irritation. The redesign should focus on improving pin placement interfaces, perhaps by integrating materials or mechanisms that evenly distribute pressure and reduce skin irritation while maintaining firm skull attachment.

4. Patient Comfort and Mobility: Living with a Halo vest can be uncomfortable, especially during daily activities like sleeping, eating, or dressing. The new design should focus on improving patient comfort by incorporating lighter materials, better padding, and ergonomic features. Additionally, ease of mobility should be considered, particularly in how the vest integrates with daily life (e.g., sleeping on the back or avoiding stress on pins during movements).

5. Vest and Component Hygiene: Maintaining hygiene is a challenge, as the vest cannot get wet, and cleaning under the vest and around the pin sites requires special care. The redesign should consider materials that are easier to clean and maintain, as well as features that provide better ventilation to avoid moisture buildup and improve skin health under the vest.

6. Modularity and Sizing: The current process involves choosing vest sizes based on the patient's body measurements, but a more modular design could allow for easier customization and better fit across a broader range of patients. Adjustable or interchangeable components that cater to different body types and specific medical needs (e.g., pediatric versus adult) could improve the overall fit and effectiveness.

7. Long-Term Wearability: Since patients often wear the Halo frame for extended periods, the redesign should prioritize long-term wearability. This includes reducing the overall weight of the frame and optimizing material selection to improve durability and comfort over time.

8. Simplified Maintenance and Follow-Up Care: Regular follow-up care is necessary to monitor pin tightness, adjust the frame, and ensure proper healing. The design should incorporate features that allow for easy adjustments and monitoring by both healthcare providers and patients, potentially reducing the need for frequent hospital visits.

9. Patient Independence: Given the difficulty patients face in managing basic tasks, such as washing hair or getting dressed, the design should consider elements that allow patients more independence in their daily routine. This could include features like easier access points for caregivers to assist with cleaning or maintenance.

Target Group Research

This chapter examines the various groups of people who will use the halo vest, focusing on their distinct needs, backgrounds, and expectations. It begins by defining the primary user groups and then discusses their health conditions, daily routines, and hospital experiences. Additionally, the chapter looks at the role of medical professionals, secondary users, such as family members, and possible other stakeholders in influencing how the vest is used, installed and experienced. A summary of all identified stakeholders is provided, followed by the introduction of three personas that will serve as a reference for testing and shaping future design decisions. Finally, the chapter concludes with a list of key design factors to be considered in the continued development of the halo vest

UMCU context of target users

Halo vests are crucial medical devices used to immobilize the cervical spine, aiding in the healing process of various neck and spinal conditions. Three primary patient groups benefit from the use of halo vests:

1. Patients with temporary or chronic neck Instability due to trauma
Trauma patients, such as those involved in car accidents or severe falls, often experience acute neck instability. For these individuals, the application of a halo vest is urgent. Immediate immobilization is essential to prevent further spinal damage and to protect the spinal cord and surrounding nerves. The halo vest provides the necessary support to stabilize the neck promptly, allowing the healing process to begin without delay. These patients typically require a robust and quickly deployable version of the halo vest to address the severity and immediacy of their injuries.

2. Patients recovering from neck or spinal injuries due to underlying conditions
Individuals with conditions like osteoporosis, degenerative spinal diseases, or unstable cervical metastases may develop spinal instability over time. While their need for a halo vest is critical, it is generally less urgent than that of trauma patients. The device supports the cervical spine during recovery from injuries exacerbated by their underlying conditions. These patients benefit from a halo vest designed for extended wear, emphasizing comfort and adjustability to accommodate prolonged use and the nuances of their specific conditions.

3. Post-surgical patients
After undergoing surgical procedures on the cervical spine, patients require immobilization to ensure proper healing and to prevent postoperative complications. The halo vest maintains spinal alignment during this critical recovery period. Unlike trauma cases, the application for post-surgical patients is planned and occurs in a controlled environment. The halo vest used in these instances needs to be compatible with the surgical site and allow for easy monitoring of the healing process.

The primary differences among these groups revolve around the urgency and duration of halo vest application. Trauma patients need immediate immobilization, necessitating a more rigid and swiftly applied device to prevent further injury. In contrast, patients with underlying conditions and post-surgical patients have scheduled applications, focusing on long-term stability and comfort. Their halo vests may feature adjustable components and enhanced comfort for extended wear. (DC7) Additionally, trauma patients often deal with unexpected injuries requiring rapid response, whereas the other groups have more predictable and manageable treatment timelines.

The existing design of the Halo Vest primarily targets the first group, trauma patients, as they represent the largest user base (Van gruyth, 2024). The design is also tailored to facilitate ease of use for medical professionals, particularly in terms of quick installation. However, the patient experience has received less attention in the design process.

During an interview, Dr Jorrit Jan Verlaan (Orthopaedic (spine) surgeon) highlighted the potential benefits of directing a Halo Brace towards individuals who did not get a Halo Brace due to trauma. The acceptance is low to implement other use cases. He highlighted that since the market is very niche, it is valuable to make a solution for the largest group (trauma), but optimize it so that additional changes can be made for the groups that need a less urgent and more planned application. Then it will be an over more inclusive device.

Exploring the target group

This section examines the key target audience by focusing on three main user groups: the patient, the secondary user, and the healthcare provider. Each of these groups plays a crucial role in interacting with the vest.

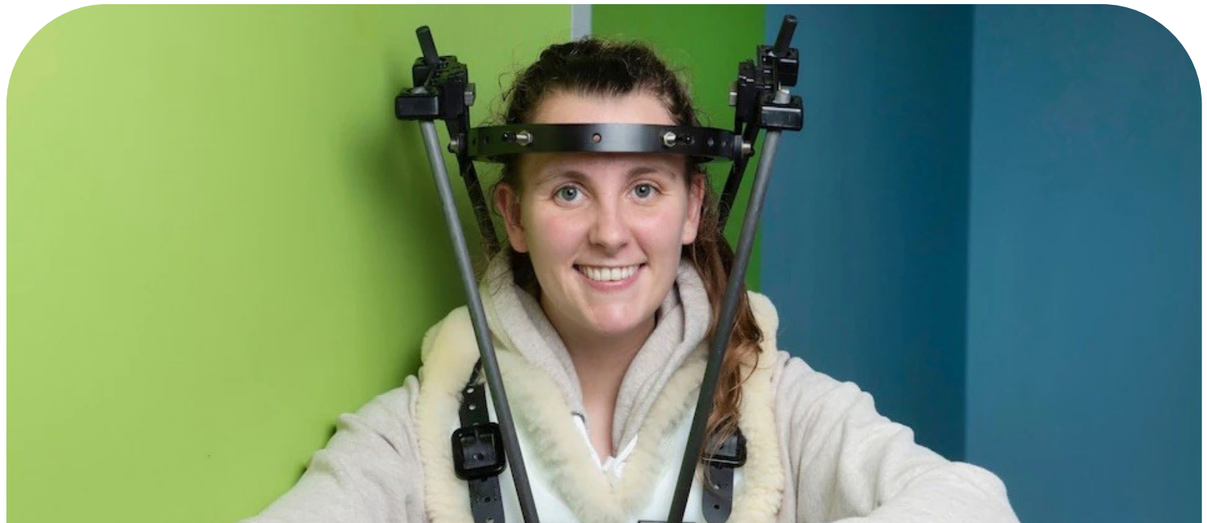
The Patient

This section looks at the experiences and needs of patients who wear the halo vest. Understanding their daily challenges, comfort needs, and emotional responses is important for guiding a redesign that improves usability and supports their quality of life during treatment.

Demographics

Since neck injuries can happen to anyone, regardless of age, gender, or physical condition, it is essential that the halo vest be adaptable for a wide range of patient groups. These injuries can occur due to various incidents, including falls, vehicle accidents, or sports injuries, affecting people from different demographics. As such, a well-designed halo vest must accommodate the diverse physical characteristics and medical needs of this broad patient population. This includes considerations for variations in body size, underlying health conditions, and the specific nature of each injury, ensuring that the device provides optimal support and promotes proper healing for all users.

FIgure 19: Person in Halo Frame (Lomed, n.d.)



Age groups

The use of a halo vest varies across different age groups, as the causes and management of neck injuries can differ based on a patient's stage of life. In adolescent patients, the vest is primarily used to manage traumatic injuries or provide stability after surgery, as younger individuals generally have stronger bones and a greater capacity for healing. For middle-aged patients, the need for a halo vest often arises from trauma or surgery, but degenerative spine conditions start to become a more significant factor, requiring careful management.

Older patients, however, face an increased risk of fractures due to weakening bones, which can occur even from minor falls or impacts. In this age group, halo vests are commonly used post-trauma or post-surgery, but special adjustments may be needed due to frailty. Extra care must be taken to prevent skin pressure injuries or discomfort, as older patients are more vulnerable to these complications.

Patient types

Recognizing that patients have diverse needs and preferences is essential. There are many types of patients. Although detailing every patient profile associated with a Halo Vest use is beyond our project's scope, reflecting on some identified profiles in literature can guide our development process of a future Halo Vest.

For instance, Warth (2011) identified 15 distinct patient profiles, ranging from those who are cooperative to those who are more emotionally withdrawn. A few notable profiles include:

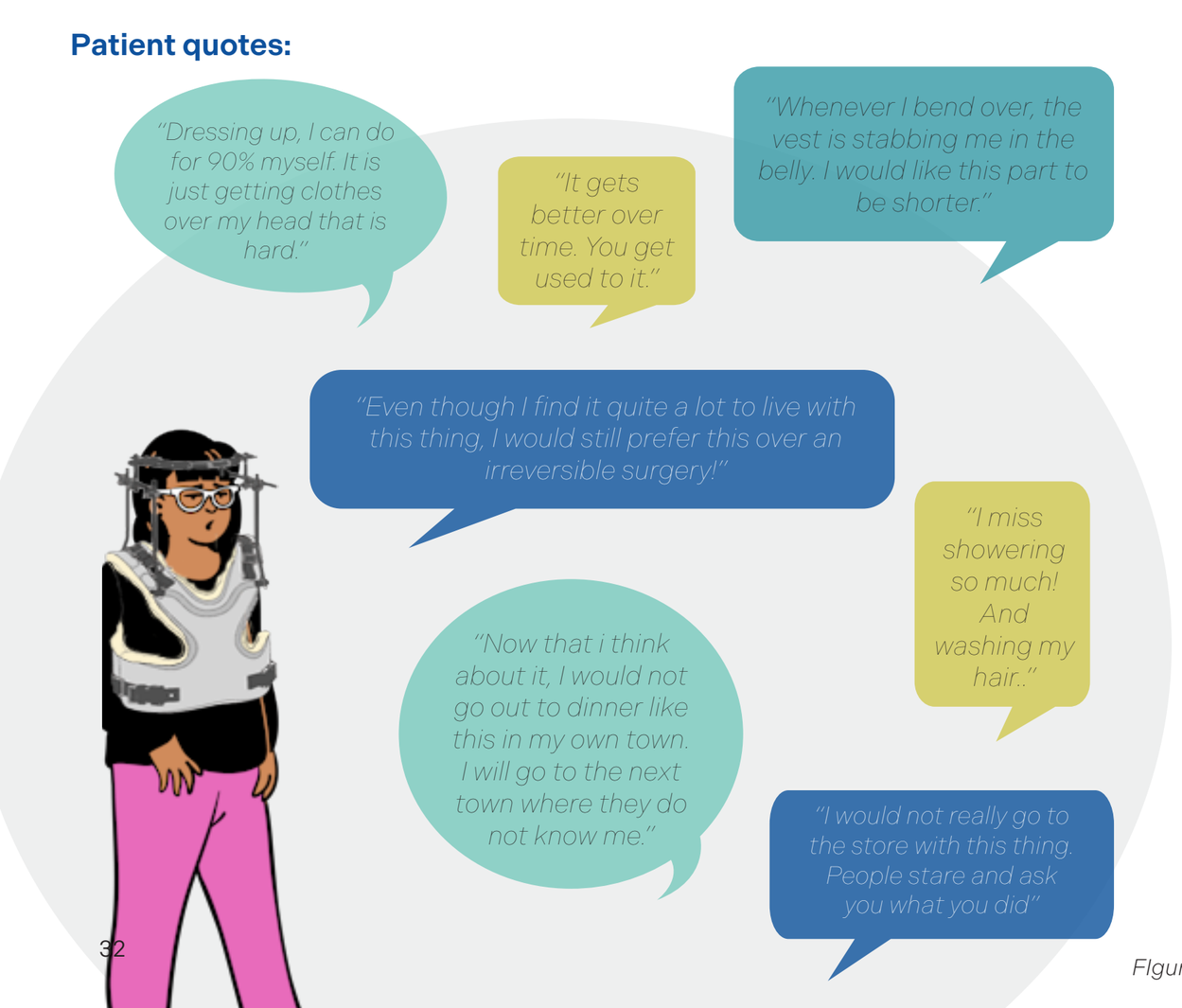
1. Patients who are highly demanding and require significant attention.
2. Patients who are non-compliant and tend to disregard medical advice or prescriptions.
3. Patients who experience anxiety and often need consistent reassurance.
4. Patients who perceive themselves as highly knowledgeable about medical topics and may challenge professional recommendations.
5. Patients who prefer to maintain a sense of control in their treatment process.

These profiles highlight the varied informational needs among patients and underscore the importance of a personalized patient journey.

Interviews

To better understand the challenges faced by both users and plaster cast makers, a series of interviews were conducted with several plaster cast makers. These individuals are responsible for fitting the vest onto the patient and performing regular check-ups. Through these appointments, they engage in frequent discussions with patients, gaining valuable insights into user experiences. The interviews were informal, focusing primarily on the difficulties they encountered while fitting the vest. Additionally, the procedure for placing a patient into a halo vest was observed to identify any potential issues during the process. Alongside these observations, semi-structured interviews were conducted with patients currently wearing a halo vest. These patients were at varying stages of their treatment—some had been wearing the vest for only three weeks, while others had been wearing it for up to eight weeks. This difference in duration was evident in how accustomed they had become to the vest and how they described their experiences. Below are some of the most noteworthy quotes from these interviews.

Patient quotes:



Orthopedic Technician quotes:

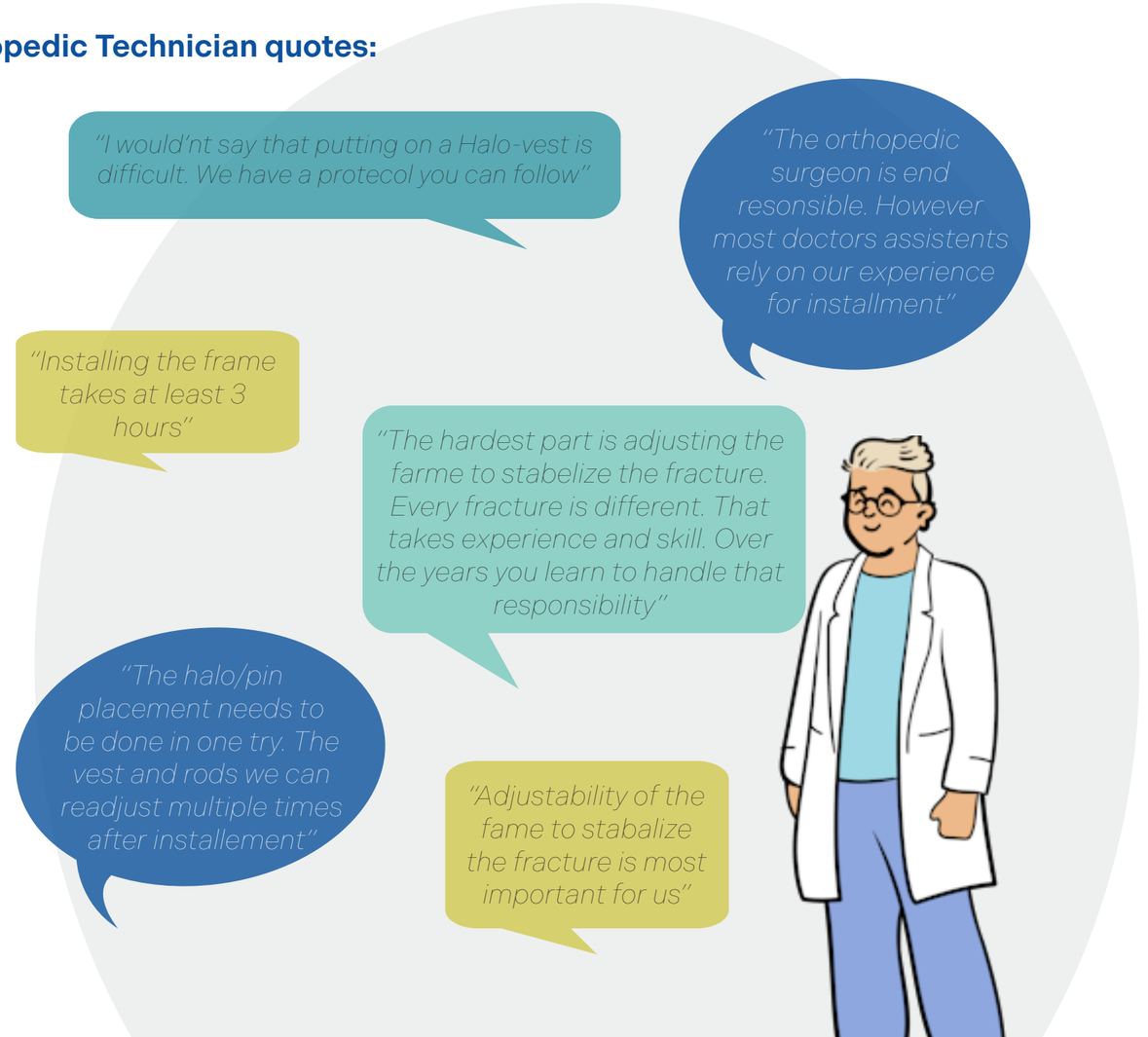


FIgure 20: Quotes

Interview key insights

The table in appendix L, provides valuable insights into the discomforts experienced by six participants who wore the halo frame. These participants rated several areas of discomfort on a scale of 1 to 7, where 1 indicates that the issue did not bother them at all, and 7 indicates significant discomfort. The purpose of this analysis is to better understand the challenges patients face and to inform the development of a more user-friendly halo frame design.

Among the highest-rated areas of discomfort are pressure on the head or pin sites (average score of 3.5), personal hygiene management (4.5), and sleeping in the vest (4.5). These results suggest that the current halo frame design may significantly interfere with basic daily activities, such as maintaining hygiene and getting restful sleep, both of which are essential for patient comfort and recovery.

It's also worth noting that some of the ratings change over the course of wearing the device. For example, pain at the pin sites and difficulty sleeping in the vest were rated very high by participants who had only recently started wearing the device. In contrast, patients who had been wearing the vest for more than three weeks rated these issues much lower. This suggests that discomfort in these areas tends to decrease over time, possibly as the body adjusts or as patients become more accustomed to the device. However, addressing the discomfort during the early stages remains crucial for improving the overall experience of halo frame wearers.

Interestingly, while the sight of the device itself was not rated as highly in terms of direct discomfort (average score of 3.33), this aspect still emerged as a key area of concern during the interviews. Many patients, even those who did not rate it particularly high, expressed sentiments like, "I am not going out of the door like this," indicating that the visual impact of the device may have been underestimated during initial ratings. Upon further discussion, it became clear that four out of six participants had strong negative feelings about how the device looked, especially when considering how they were perceived by others. (DC18 &19)This discrepancy suggests a potential flaw in the rating system, where participants may not have fully recognized the extent of their discomfort until prompted to reflect more deeply. The sight of the device, therefore, remains one of the key aspects to address in the redesign, as it significantly affects patients' willingness to engage in social activities.

Additionally, there was a noticeable gender difference in the emotional impact of wearing the halo frame. Female participants expressed a greater degree of shame compared to their male counterparts, indicating that the visual appearance of the device may disproportionately affect women. This aspect of patient experience is important to consider in the redesign, as creating a less obtrusive or more aesthetically pleasing device could help alleviate some of this gendered discomfort.

Furthermore, while the fit of the current device was generally rated as acceptable by both plaster cast makers and patients, there is room for improvement. The existing halo vest is designed for an "average" body shape, but this one-size-fits-all approach does not adequately serve most patients. (DC8) Both patients and the professionals who create the casts noted that the fit is "all right, but not the best." A more adaptable design, potentially incorporating some level of modularity or flexibility, would allow the vest to be better tailored to the unique shape of each individual. This would significantly enhance comfort by reducing unnecessary pressure points or movement restrictions. The goal is to create a vest that is not only functionally secure but also offers a more personalized fit for different body types, improving overall wearability and comfort.(DC9)

It's also crucial to consider the feedback bias present in this data. The interviews reflect the opinions of those willing to participate in the study, but two potential participants declined due to anxiety. It is unclear whether their anxiety was pre-existing or a result of wearing the halo frame. However, their treating doctors emphasized that these patients, who tend to feel more vulnerable to the shame and discomfort associated with the device, might benefit the most from a redesign. The absence of their input highlights a potential gap in understanding how the device impacts individuals who may be more emotionally or psychologically affected.

In conclusion, the results provide important insights into areas for improvement, particularly in terms of hygiene, sleep, appearance, and fit. While some aspects of discomfort may lessen over time, addressing these key issues early on can greatly enhance the patient experience and the effectiveness of the treatment. The redesign aims to improve the halo frame's fit and appearance to ensure it better aligns with both medical requirements and patient needs, ultimately leading to greater patient satisfaction and better outcomes.

Patient Needs

In addition to the various patient profiles, there is also a wide range of patient needs.These needs are clustered into four large needs that were derived from user interviews.

1. Patient want the vest to be less noticeable and more subtle.(DC 18) The psychological impact of wearing a halo vest can be significant. A design that looks less intimidating or bulky, while still being functional, could help reduce feelings of self-consciousness or anxiety in patients. Allowing patients some degree of personalization (e.g., color choices, additional comfort accessories) might improve their overall experience and reduce the emotional burden of wearing the vest.

Patients generally reported feeling little embarrassment while wearing the vest. However, when asked about daily activities, most noted that they avoid many tasks outside the home as they would typically do, often because they dislike being watched. Many patients mentioned being asked about their condition, particularly by children. While this is often uncomfortable, some approach it with humor, and responses vary greatly from person to person.

Regarding the design, the black halo ring and overall structure are seen as solid. Color and size influence this perception, with smaller individuals finding the rods positioned far to the side, while for larger individuals, the rods can sit close to the face. Most patients are not disturbed by the presence of the rods, even though they remain visible in their peripheral vision.

2. The vest should fit right and leave little pressure points.(DC3) The pressure point on the front of the vest (chest and collar bone area) (See figure 21) are the most present. Also chafing at the stomach. The bottom part of the vest irritated most when bending over and while sitting. On their backs, patient report much less issues. The people who have most issues are very the thinner, bony patients. They have naturally less cushioning. However, very large individual often also have trouble with the vest due to chafing due to an ill-fitting and the larger amount of soft tissue.

3. Normal clothes should be wearable over the vest.(DC5) The patients have difficulty with normal clothes. Right now, the neckline needs to be adjusted. Most

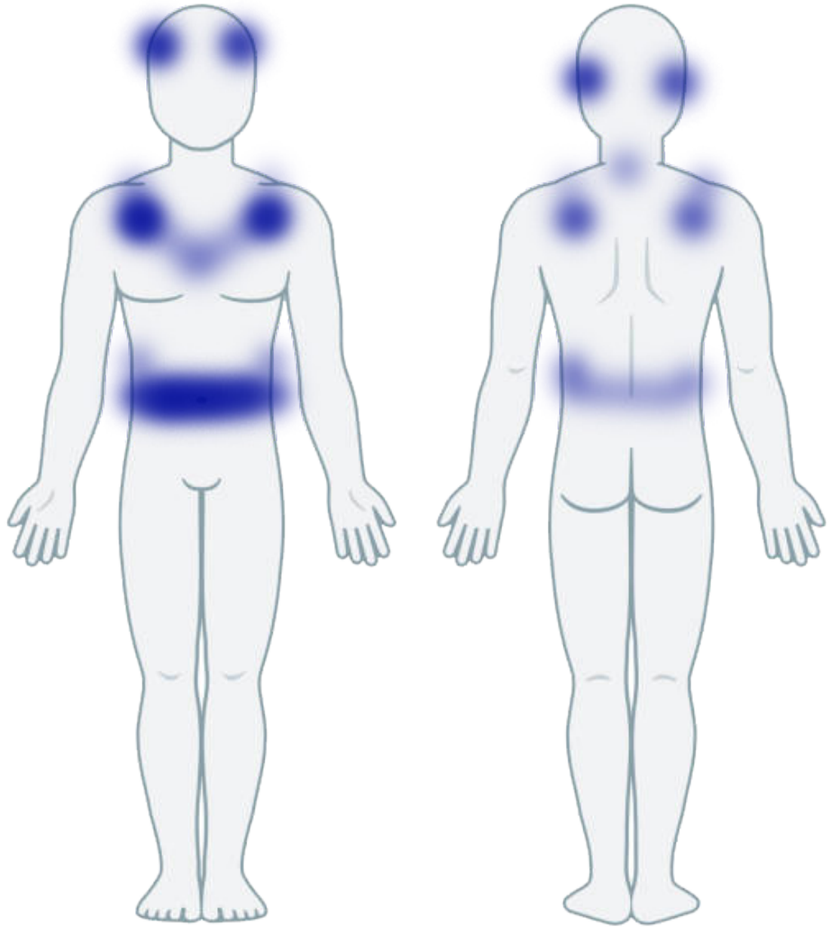


FIgure 21: Pressure Points

patients wear either button up shirts or custom made shirts and sweaters. The neck of patients gets cold easily because of this. Wearing a bra for women is a lot of hassle. They
either need to shuffle it under the vest or pull it over the back of the vest. Either way the participants are not pleased with it. The design should facilitate wearing regular clothing or special garments that fit over the vest, as patients may struggle with dressing themselves. This can improve patient autonomy and reduce the need for assistance.

4. Sleeping should be made more comfortable. (DC4) Sleeping is a big problem the first weeks. The pain and "hanging feeling", make sleeping uncomfortable.

5. Easy Cleaning: (DC12& 30**)** Patients must be able to maintain hygiene, so the vest should be designed with materials that are easy to clean or wipe down without needing to remove the entire structure. Detachable padding or components for cleaning would also be beneficial.

6. Safety and Stability: (DC16 &17))The primary purpose of the halo vest is to immobilize the cervical spine, so the design must ensure rigid and stable fixation of the head and neck. Any adjustments must be precise and secure to prevent unintended movement that could harm the patient's recovery. The fastening system should be simple to use but secure, ensuring that the vest remains stable without frequent re-tightening or adjustments. Patients are at risk of developing pressure sores, particularly where the halo frame and pins make contact with the skin. Pressure monitoring features, such as soft pressure sensors, could alert patients or caregivers if adjustments are needed to avoid injury.

7. Modular Components:(DC24 & 25) If certain parts of the halo vest wear out over time (e.g., padding or straps), the design should allow for easy replacement of individual components without requiring the entire vest to be changed.It might aslo be beneficial to add a modularity aspect to the vest in terms of sizing. One base plate which can be made larger or smaller according to the user.

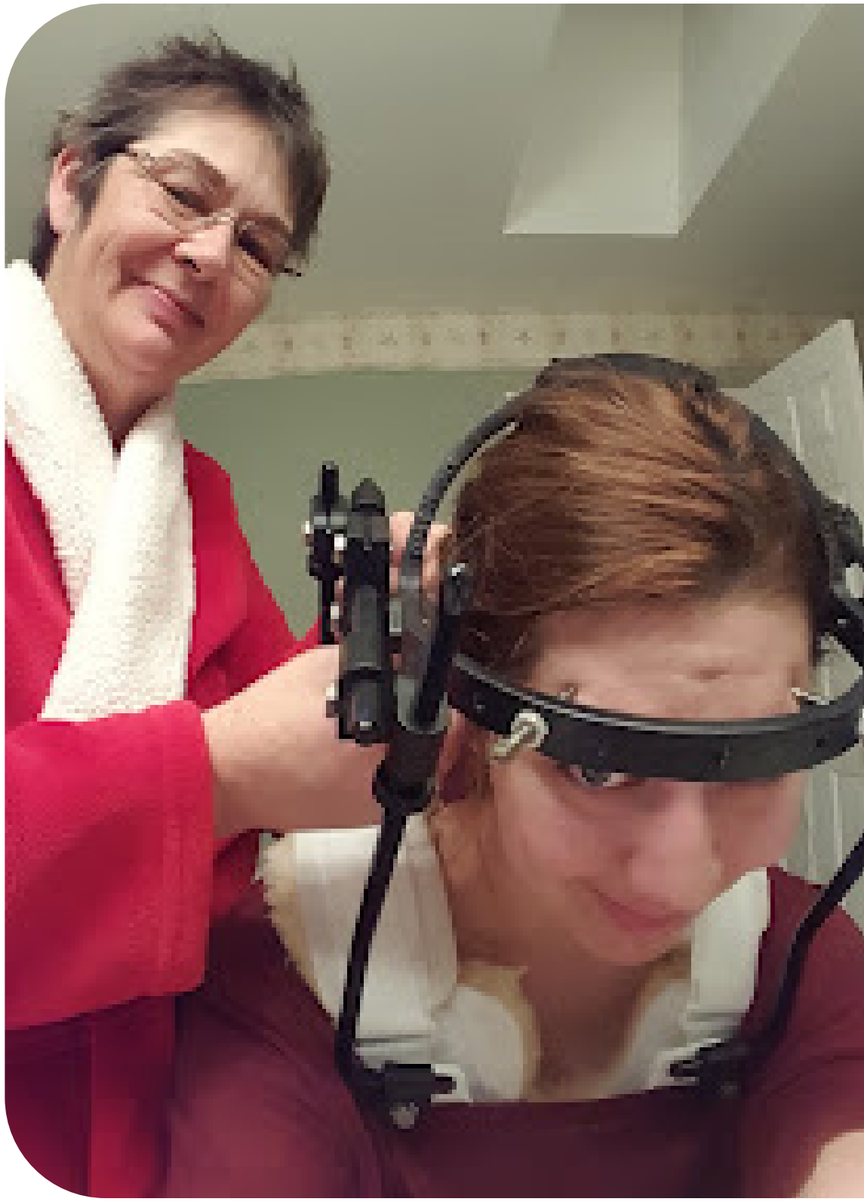


FIgure 22: Halo brace care (The halo diaries.com, 2016)

Secondary Users

Secondary users of the halo vest are individuals who assist spinal patients with their daily activities while the patient undergoes treatment. These individuals include family members, caregivers, healthcare providers, and friends who take on supportive roles in the patient's recovery process. Due to the rigid structure of the halo vest, patients often experience limited mobility and may require assistance with tasks such as personal hygiene, dressing, eating, and getting in and out of bed. Furthermore, they may need help navigating their surroundings and attending medical appointments, as the halo vest restricts head and neck movement, making even basic activities challenging.

The involvement of secondary users is crucial for the patient's well-being, as they often need to manage tasks related to the proper maintenance of the halo vest. This includes ensuring the device remains clean, securely fitted, and comfortable for the patient while minimizing the risk of complications such as skin sores. Secondary users may also be responsible for monitoring the patient's health, particularly by watching for signs of infection or improper healing. Their role in providing this support is essential for helping the patient focus on recovery while reducing the risk of further injury or discomfort.

Secondary Users Needs

When designing a new type of halo frame, it is important to consider the needs of secondary users, as they play a vital role in the patient's recovery process. The ease of use and functionality for these caregivers should be a priority to enable them to provide effective care without unnecessary strain.

1. Ease of Adjustment and Maintenance: (DC21)Currently, secondary users are unable to make any adjustments to the halo vest, as doing so could compromise the patient's stability. They are limited to assessing whether the vest fits properly, but adjustments must always be made by a medical professional, resulting in frequent visits to healthcare providers. A new design should allow for simple, intuitive adjustments to straps, pins, and other components, enabling non-medical caregivers to assist with daily maintenance without risking the stability of the device.

2. Clear Instructions and Indicators: (DC22) Secondary users would benefit from built-in visual indicators or clear instructions on the device, such as markings for proper tension or alignment. These features would allow caregivers to quickly assess the frame's security and positioning and seek timely assistance from medical professionals if needed. This could help prevent errors from going unnoticed between appointments.

3. Lightweight and Comfortable Design: A lighter, more ergonomic halo frame would improve the patient's comfort and make tasks such as lifting or repositioning the patient easier for secondary users. Reducing the physical strain on caregivers would make their responsibilities more manageable.

4. Durability and Easy Cleaning: (DC23) A halo frame designed with durability and ease of cleaning in mind would allow secondary users to maintain hygiene standards without difficulty. A frame that can be easily wiped down or sanitized would save time and effort, especially for those involved in long-term care.

5. Safety Features: Built-in safety mechanisms, such as features that prevent overtightening or sensors to detect skin irritation, would give secondary users confidence in handling the device. These safety features would help avoid complications due to improper handling and provide clear indicators of when medical attention is necessary.

6. Training and Support Materials: Accessible training materials, such as instructional videos or interactive guides, would help secondary users understand how to manage the halo vest effectively. These resources could reduce anxiety about managing the device and enable caregivers to provide better care for the patient.

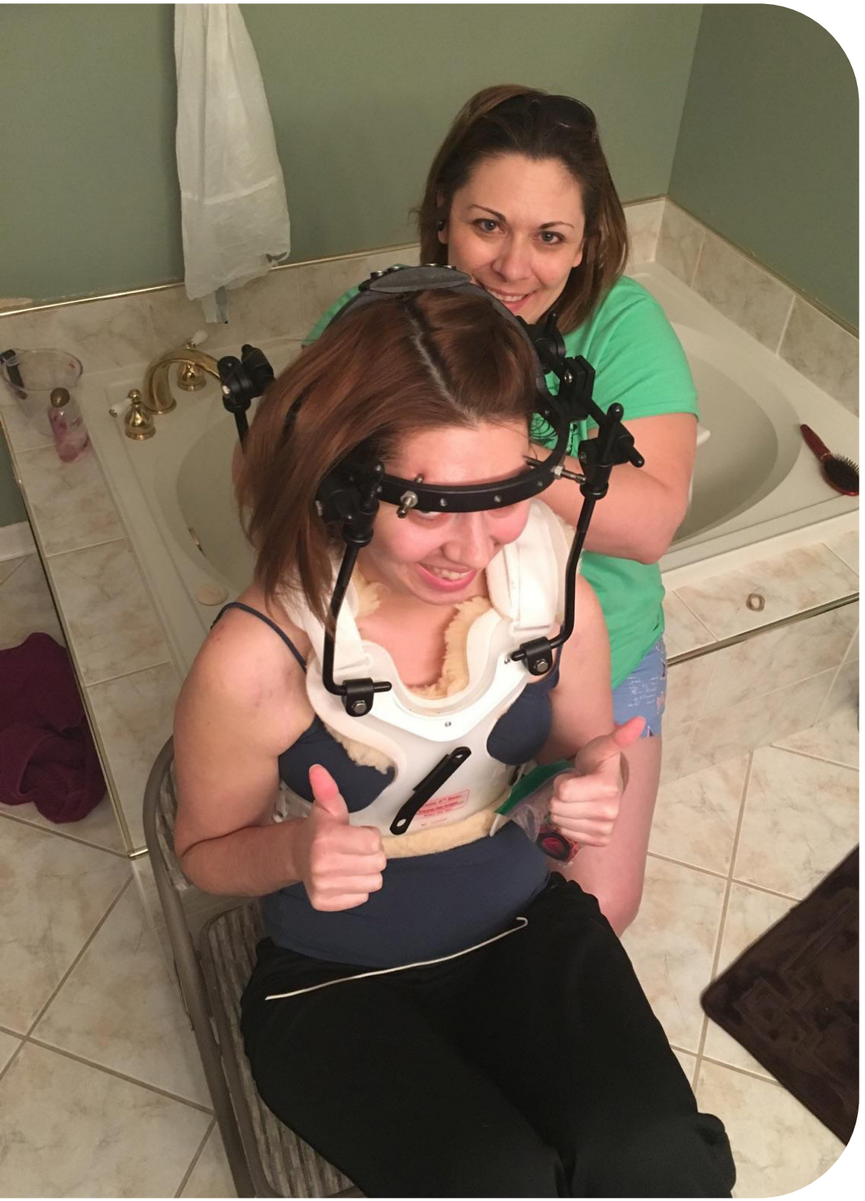


FIgure 23: Halo brace washing (The halo diaries.com, 2016)

FIgure 24: Halo brace adjustment (The halo diaries.com, 2016)

Medical Professionals

Medical professionals involved with the use of a halo vest play a crucial role in the patient's treatment and recovery. The process typically begins with the orthopedic surgeon, who diagnoses the spinal injury and determines that a halo vest is necessary to immobilize the cervical spine. The surgeon also oversees the overall treatment plan, ensuring that the spine heals correctly. Their expertise is critical in ensuring that the halo vest provides the right level of stability without compromising patient safety.

Once the decision is made, plaster cast makers, also known as orthotists or cast technicians, are responsible for installing the halo vest. They ensure that the frame is securely fitted to the patient and adjusted to provi-de the correct immobilization. Their role involves precise alignment and securing of the vest's components to support proper healing while also ensuring that the device is comfortable and safe for the patient.

It is important to take the needs of these stakeholders into account when designing a new halo vest, as their interactions with the device directly affect patient outcomes. A design that streamlines the surgeon's ability to make adjustments or simplifies the plaster cast maker's installation process can improve both the safety and comfort of the patient, as well as the overall efficiency of care

Medical Professional Needs

1. Reliable immobilization: (DC16) The halo frame must be designed to provide robust and reliable immobilization of the head and neck. Surgeons need to trust that the frame will maintain alignment without risk of unintentional movement or loosening. This is crucial for preventing complications during the healing process. It is important that the vest works just as good mechanically as the previous one, or acceptance will stay low.

2. Urgent immobilization: (DC 28)Most of the Halo braces are installed urgently. This leaves very little time for personalisation. The patient needs to be stabilized and fixated into the frame as soon as possible. Therefore the idea of custom printing parts per patient might not very viable.

3. Streamlined application process: (DC27) The new halo frame design should allow for quick and efficient application in both planned and emergency situations. Surgeons and plaster cast makers need a straightforward process to secure the frame to the patient with minimal complexity. This includes intuitive fastening systems, pre-set adjustable components, and clear instructions for proper fitting.

Halo installation takes up half a day. The installed itself is not the issue, that takes around one hour. Most of the extra time goes into adjusting the fame to stabilize the fracture, as well as checking the stabilization afterwards with a scan.

4. Adaptable Design for Different Anatomies:(DC7) Surgeons and plaster cast makers work with patients of different sizes and body types, from children to adults. A modular design that allows for easy adjustment or customization to fit individual patients would improve the ability to treat a wide variety of cases.

The rigidity on the vest, is mostly caused by a very hard V-shape that gives stabilisation to the rods. This V-shape has the connectors from rod to vest at the end of each tail. Shown in figure 25. The placement of these connectors is fixed. This does not fit well on each patient. Also there are a couple of places in the vest teh orthopedic technician wished he could "Break the vest" to fit to the patient. This to shape it to each person's chest, belly or circumference. An image of all the "Breaking points" can be found in figure 26.

FIgure 25: V-Shape (RehaCare, 2022)

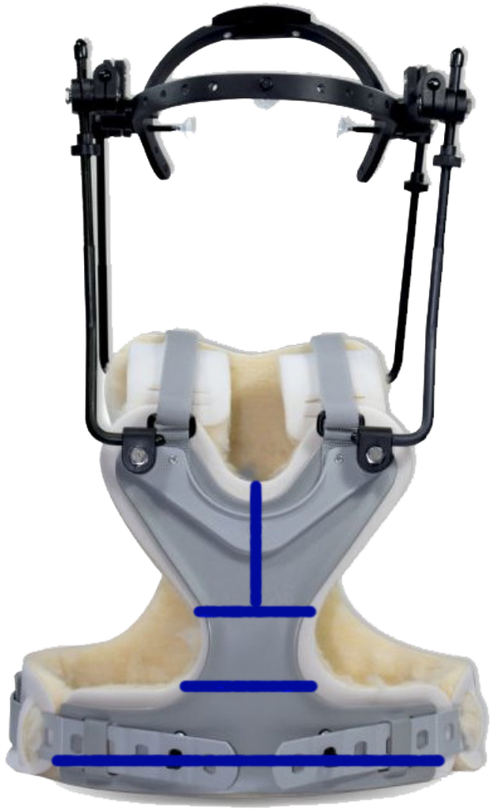


FIgure 26: Breaking points (Anjon Bremer, 2022)

5. Precise Adjustability:(DC8) Surgeons require precise control over adjustments to ensure the halo frame provides the correct amount of immobilization without compromising the patient's comfort. Adjustable features should offer accurate control, with clear markings to indicate proper tension and positioning. This ensures that the frame maintains the correct alignment of the cervical spine for optimal healing.
Placement of the ring is mostly expertise and guesswork. They know that the pin needs to be placed at one third and above the eyebrow. Preferably the ring is also placed just below the biggest part if the head. This way the halo will lock itself when carrying the head.

The rods can be adjusted in many positions. This is a very important requirement. Every patient is different and needs a different placement and stabilization of the head. One of the current downsides to the rod system is that if one of the sizes is not right, the rods and clips need to be completely disassembled, put in the right position and then reassembled. This takes a lot of time.

The pins are first placed on the back, then in the front. This to place the halo ring not too far from the skull but also not to close. This is most important in the front because the patient should not see the ring while wearing it, but also still needs to be able to care for the front pins.

6. Pre-formed Templates or Models: Having access to pre-formed templates or models for different sizes of patients (pediatric, adult, etc.) would reduce the time and difficulty in customizing the fit. This could improve efficiency and help ensure the frame is applied correctly on the first attempt.

The pin placement needs to be done in one go. The local anaesthesia needs to be placed accurately and do overs take a lot of time and unnecessary recourse. The marks on the forehead, the patient gets from the halo pins are also a reason to avoid do-overs. The vest and the rods however can be adjusted many times after instalment. They would prefer for this process to be faster, easier and more accurate. This personalization is in contrast with the urgency and speed of some halo applications.

7. Acceptation among doctors and hospital buyers: Plaster cast makers and surgeons at UMCU say that at UMCU they like the vest, at other hospitals they prefer fixation surgery. This very much depends on how the surgeon feels about the vest. The vest is not used optimally due to the shortcomings for the patient and the dated look. The surgeons at UMCU believe that for the patient the trade off on being in the vest for three months versus limited neck mobility for the rest of your life, is not beneficial on the long term.

8. Consistent pin tension: Pin tension loosens over time due to the skull bone. Bone is a living thing that changes shape under very long pressure (BRON). This causes the

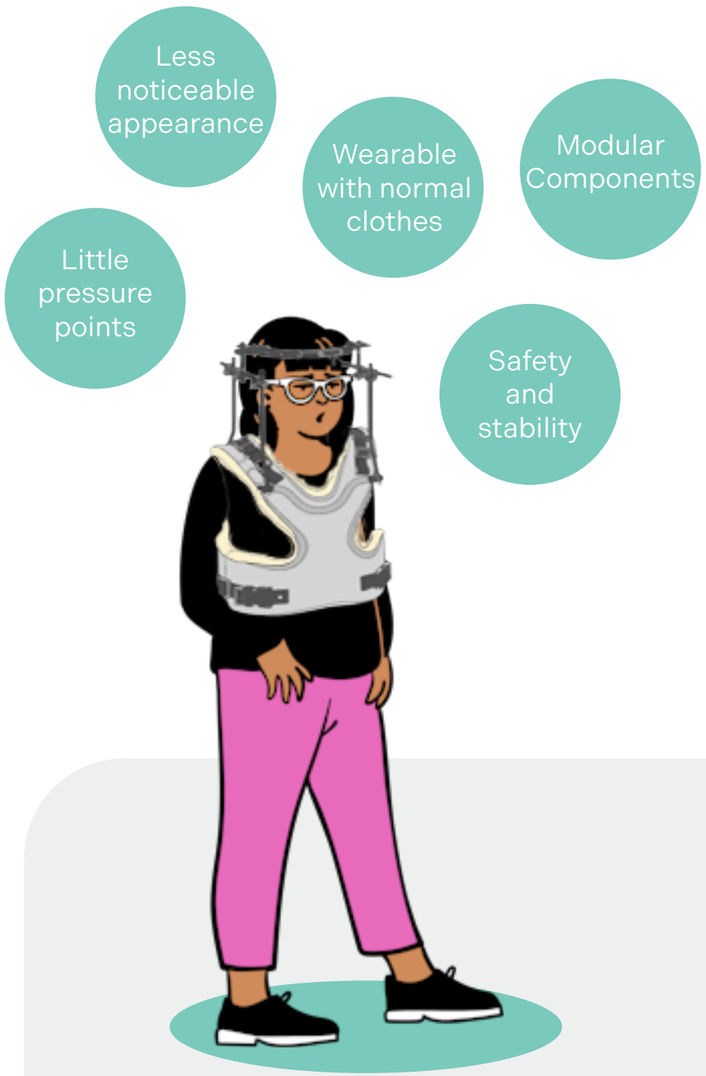
tension to loosen over time. Therefore the pins need to be checked every two weeks.

9. Imaging Compatibility: (DC 19)The halo frame should be designed to minimize interference with medical imaging procedures, such as X-rays, CT scans, and MRIs. Surgeons need to monitor the progress of spinal healing through these imaging techniques, so the frame should be constructed from radiolucent materials, or at least allow for sections that do not obscure key anatomical areas.

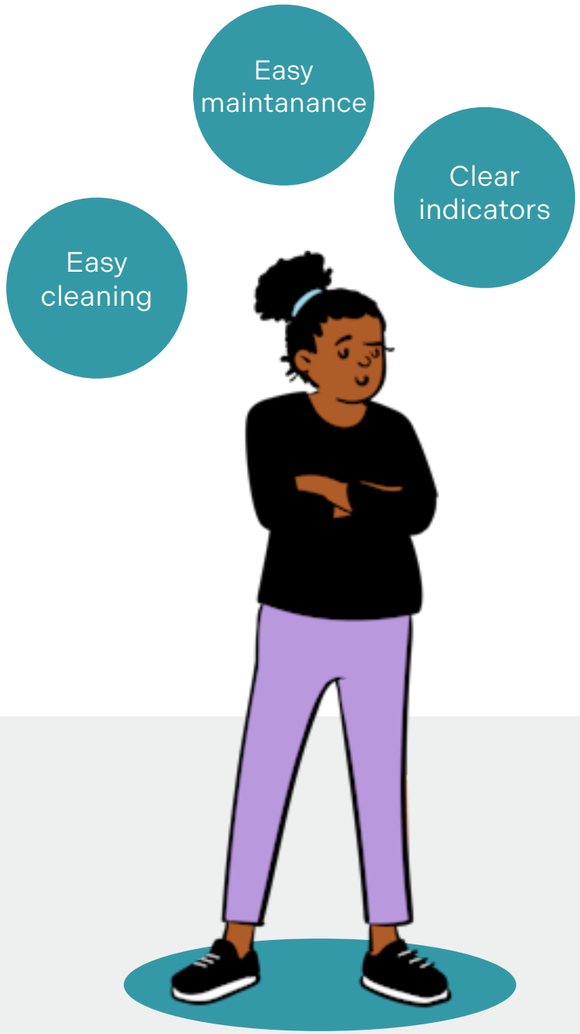
10. Affordability: (DC 26) The design should strike a balance between advanced features and cost-effectiveness. Surgeons and healthcare providers operate under budgetary constraints, so the halo frame should be designed with cost-efficiency in mind, while still providing the necessary functionality and safety.

In conclusion, creating a system that is straightforward and easy to use, reliable, and can be easily incorporated into the current practices of medical professionals is important for ensuring its appealable as a substitution of the current frame for this group.

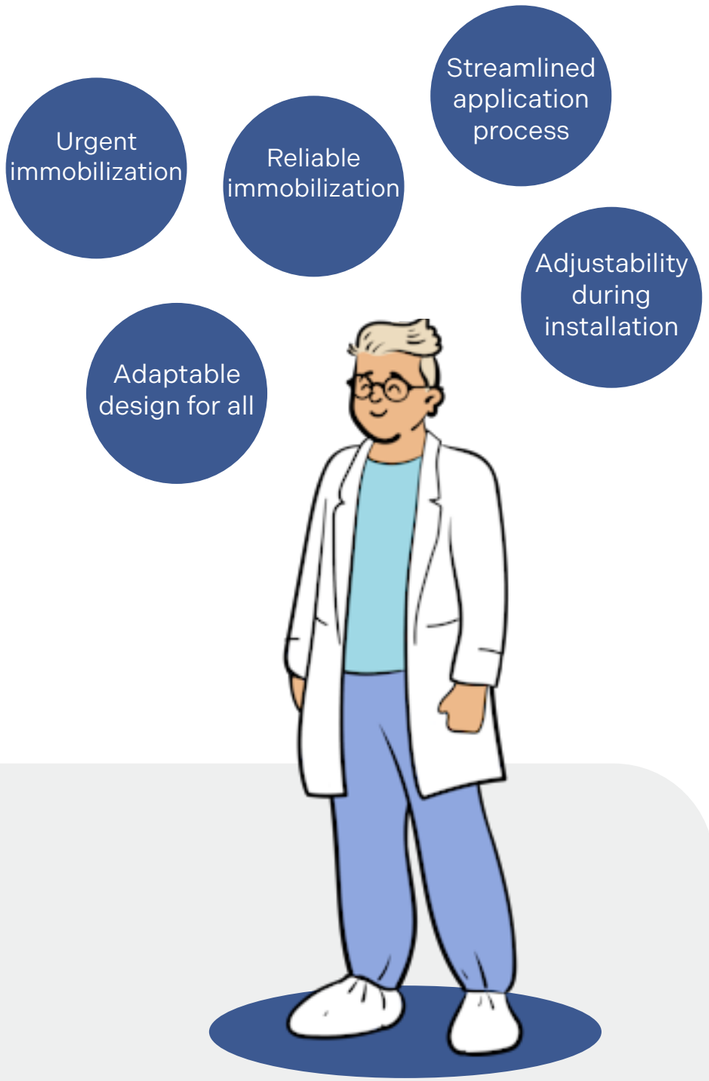
Needs per user



Patient



Secondary User



Medical Professional

FIgure 27: User Needs

User centred stakeholder analysis.

Stakeholder mapping is an essential step in the redesign of a new Halo Frame, as it helps identify and understand the various groups and individuals who have a vested interest in the device. By analyzing these stakeholders, the design process can account for their needs and how they influence the system.

A comprehensive stakeholder analysis was performed using the framework described by Ashby (2015). This method involves addressing three fundamental questions for each stakeholder: (A) Who are they? (B) What are their needs or interests? (C) How can their objectives be supported? The full results of this analysis are provided in Appendix B.

Based on this analysis, a stakeholder map was created to visually represent the stakeholders and their relationships, as shown in Figure 28. The stakeholders were categorized into three groups: primary, secondary, and tertiary. Primary stakeholders, such as patients and doctors, are those who interact directly with the device. Secondary stakeholders, including manufacturers and distributors, have a direct influence on the system but are not in direct contact with the device itself. Tertiary stakeholders, such as regulatory bodies, exert indirect influence on the system.

The connections between these stakeholders highlight the interactions and dependencies that form a complex network. Understanding these relationships is crucial for the successful development and implementation of a new Halo Frame. By mapping these connections, the analysis reveals the intricate web of interactions, which will serve as a foundation to ensure all stakeholders are considered throughout the project.

FIgure 26: User centred stakeholder map

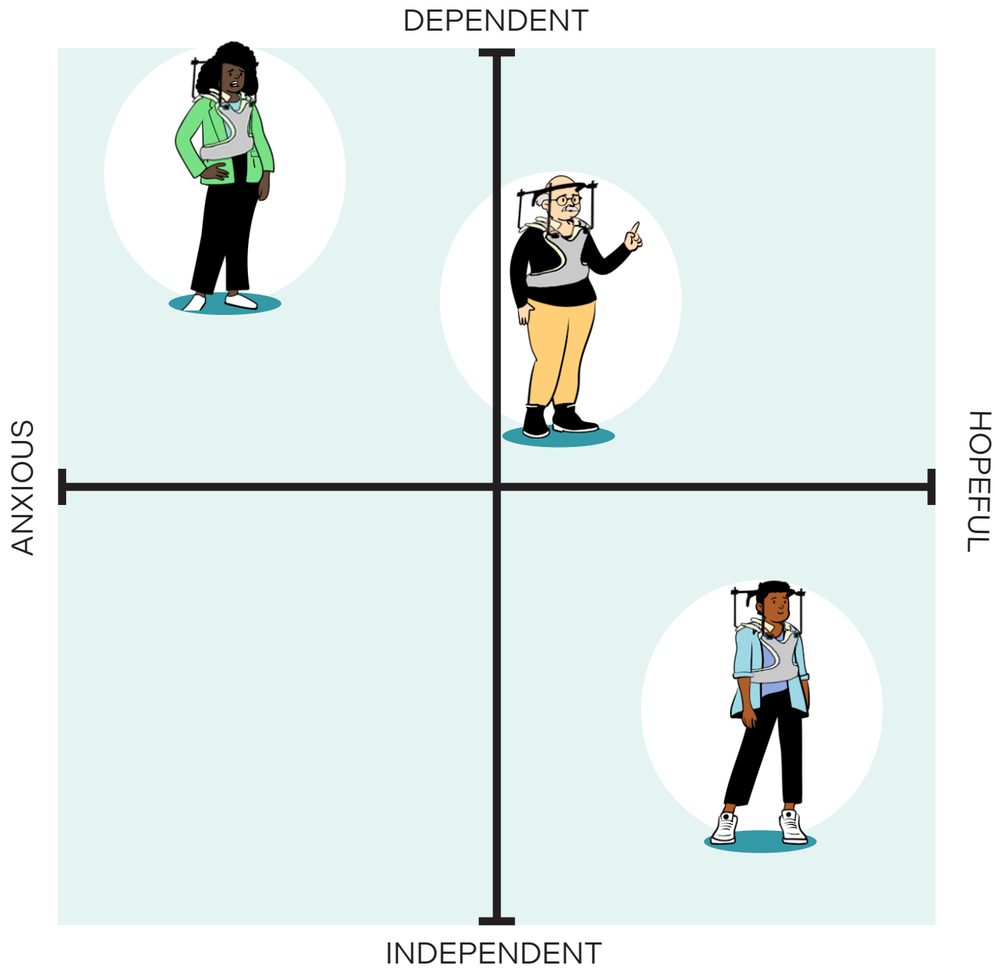
Persona’s

To better understand the intended audience for this project, three unique personas were created (refer to figure 29). According to Goodwin (2009), personas are notactual individuals but hypothetical representations of the intended users. In this project, these personas were created based on interviews with halo frame patients currently receiving treatment at UMCU, supplemented by insights from plaster cast makers and surgeons. While the embedded quotes are fictional, they reflect sentiments expressed by real patients. Developing these personas was essential to understanding the range of factors influencing how patients experience wearing a halo vest.

To further analyze the personas, they were plotted on two key axes representing common personality dimensions observed in halo vest patients. The first axis, anxious vs. hopeful, illustrates how individuals feel about their treatment. The second axis, independent vs. dependent, reflects how they navigate life with the halo vest and the extent to which they rely on others. (DC10 & 11). Plotting the personas in this way helps visualize where each user type falls in terms of their emotional response to the treatment and their level of self-reliance. This mapping is particularly useful as it highlights how different personalities and coping strategies affect their experience with the vest, showing that a one-size-fits-all solution would not address the unique needs of these diverse users (Cooper, 2004). As mentioned before Warth (2011) mentiones 15 different types of patients. However, these are the three ones most seen by the interviewd medical professionals and have a bit more depth. Oftentimes the patient has more than one characteristic, from the ones mentioned by Warth, combined.

These personas and their placement on the axis will guide the evaluation of design choices later in the project. The framework used follows Muzus & Lost Lemmon’s (2018) method, where eight critical questions are answered to capture the essence of each persona. This approach ensures that each persona reflects the unique combination of feelings and behaviors related to the treatment, enabling more personalized and effective design solutions.

FIgure 29: Persona’s and their personality dimensions.



The Faithful Experiencer

"It's tough, but I've accepted it. I focus on the fact that this vest is temporary and that every day in it is a step closer to getting my life back."

1. This is me.

While swimming with friends, I jumped into a shallow pool, it lead to my spinal injury. Not the way I imagined things to go. I'm optimistic about my recovery and place a lot of trust in the expertise of my doctors. Despite the challenges, I'm committed to finding ways to maintain as much independence as possible, I've embraced the challenge and adapted to my new routine. My mom brought me to the hospital, because I can't drive by myself right now, but she does not need to go in with me. I can go to the check-up appointments alone. My life now revolves around my healing process, and while it's far from perfect, I believe this treatment is a better option than undergoing surgery. Though my life looks different now, I'm confident that with time, I'll heal.

2. This is what holds me back.

The physical limitations of wearing the halo vest are my biggest constraint. I can't move as freely as before, and this affects my ability to do everyday activities. At times, I feel isolated because people treat me differently due to my condition. Like, I got free from school, but that gets boring after a while. Even though I strive to stay independent, there are tasks where I must rely on others, which can be frustrating. Despite this, I find ways to work around these obstacles. I try not to dwell on these limitations. I focus on what I can do, which keeps me moving forward.

3. This is how you seduce me.

Support my desire for independence while acknowledging my trust in the treatment process. Provide me with tools, strategies, or products that enhance my ability to take care of myself while accommodating the limitations of the halo vest. Empower me with knowledge about my condition and recovery so I can be proactive. The more I understand, the more in control I feel.

4. This is my goal

My ultimate goal is to recover fully from my injury and regain as much normalcy in my life as possible. I want to get to the point where I no longer need the halo vest and can move on without having to worry about long-term complications. Until then, I aim to live as independently and confidently as I can.

5. This is how I feel about it

I'm realistic about the situation—it's not easy, and it's not the life I would have chosen. But I accept that this is my path, and I'm grateful that there is a non-surgical option available. The healing process is a challenge, but I feel positive knowing that I'm on the right track and that my doctors are looking out for my best interests. I know it's temporary, and I trust the process. I've learned to adapt.

6. This is what motivates me

I'm motivated by the idea of getting better and regaining control of my life. Every milestone, no matter how small, reinforces my belief that I can heal. My optimism and faith in the treatment keep me going, as does the support from my doctors and loved ones. Being able to handle things on my own as much as possible also drives me forward—it's important to me to show that I can do this.

7. This is when I disengage

I start to disengage when I feel overly dependent or incapable of managing basic tasks on my own. Furthermore is also disengage when I feel like my independence is being unnecessarily taken away. If I sense a lack of progress in my healing or feel dismissed by healthcare providers, I might lose some of my optimism. Being treated as fragile or helpless, rather than as a capable person going through recovery, can also cause me to shut down.

8. These are my conditions

I need to feel informed about my treatment and progress. Respect my independence and give me space to manage as much as I can on my own, but also offer support when I ask for it. I need a recovery plan that balances caution with encouragement, allowing me to push myself while staying within safe boundaries. The environment around me should be accommodating without making me feel like I'm restricted to certain activities or spaces. Clear, honest communication from my doctors and caregivers is essential, as is a plan that respects both my physical and emotional well-being.

The Anxious Conscript

"I don't even recognize myself in the mirror with this thing on. I'm scared people will see me like this, so I just stay inside. I wish I could fast-forward through this."

1. This is me.

I got the halo vest prescribed for a spinal injury due to falling down the stairs, and to be honest, I really hate it. The thought of wearing this vest for three months feels unbearable—it's as if time is dragging on. I'm not comfortable being seen in public with the halo around my head, so I don't leave the house as often as I used to. The appearance of the vest makes me self-conscious and a little ashamed. I rely heavily on others for help, from getting groceries to handling daily tasks. I've become anxious about many things, and the vest constantly reminds me of what I'm going through.

2. This is what holds me back.

My anxiety and discomfort with the halo vest are the biggest barriers. I feel trapped in it, and I hate how it looks and feels. Usually I am really skinny, it makes me look huge! And the black structure is so black in my face. The thought of being seen by others while wearing it makes me withdraw and avoid social situations. I don't like depending on others, but I find it hard to manage even simple tasks without their help. This has made me feel powerless in my own life.

3. This is how you seduce me.

Appeal to my need for comfort and reassurance. Show me that you understand how overwhelming this experience is for me, and offer ways to make it more manageable. Solutions that help me feel less exposed in public—whether that's through physical aids, support, or social encouragement—would make me more likely to engage. Provide a sense of control, even if it's in small ways, and offer a safe space where I can voice my fears without judgment. I need gentle reminders that this phase won't last forever and that I'm not alone in feeling this way.

4. This is my goal

My immediate goal is to get through these three months and be free of the halo vest. I want to return to my life without feeling weighed down by the anxiety and discomfort this device causes me. In the meantime, I want to find a way to feel more comfortable in my own skin and gain some control over my day-to-day life. I'm not aiming for big milestones right now—just getting through each day without feeling completely overwhelmed is enough for me.

5. This is how I feel about it

I feel anxious, frustrated, and a little hopeless. Every day in this vest feels like an eternity, and I can't help but focus on how long I'll have to wear it. The thought of going out in public fills me with dread because I feel like everyone is staring at me. The kids are the worst, they bluntly ask what is wrong with me. I also feel a bit ashamed of relying on others so much, but I don't know how to manage everything on my own. This whole situation makes me feel anxious about things I never used to worry about.

6. This is what motivates me

What motivates me most is the thought that eventually, this will end. The idea of finally taking off the vest keeps me going. I also don't want to be a burden to others, so I try to manage where I can, even if it's small things. Knowing that every day brings me closer to the end of this experience helps, as do gentle reassurances from loved ones and healthcare professionals that I'm making progress.

7. This is when I disengage

I disengage when I feel like things are getting out of my control, or when the anxiety becomes too much to handle. If I feel overwhelmed by the way the vest looks or if someone makes a comment, I shut down and retreat further into isolation. I also lose motivation when it feels like I'm not making progress or when the physical discomfort becomes too hard to ignore.

8. These are my conditions

I need emotional support and understanding from those around me, without feeling rushed or pressured to "get over it." I need to be reassured that the discomfort and anxiety I'm feeling are valid but temporary. Any assistance that helps me manage the anxiety—whether that's through mental health resources, practical tools, or ways to make the vest feel less intrusive—would make a huge difference. Most of all, I need patience from those around me as I navigate this tough period, knowing that even small steps are still progress.

The Vulnerable Navigator

"I know I'm lucky to be here, but this thing digs into me, and at my age, that's hard to ignore. I just want to get through this as comfortably as I can. That's all I ask."

1. This is me.

I am recovering from a bike accident that left me with a spinal injury. I trust my doctors completely—they're doing their best, and I'm grateful for all the check-ups and attention I'm receiving. But, let's be honest, the halo vest is uncomfortable. At my age, I don't have the patience for unnecessary discomfort. I'm not the fittest anymore, so wearing this vest isn't easy, and it doesn't always feel like it fits right. I rely heavily on my wife and some home care for help, as I don't really get all the interactive online manuals and apps that are out there. My main priority is comfort—I've lived long enough to know I don't want to suffer unnecessarily. But, I realize this is just how it is. What can I say?

2. This is what holds me back.

The fit of the halo vest is a major issue for me. It's often uncomfortable. The fit of the vest isn't perfect, and I often wonder whether the discomfort I'm feeling is because of my age or if the vest itself just isn't right. I don't have the energy or the technical skills to navigate the online guides and resources, so I rely on others for most of the information. This makes me feel somewhat disconnected from my own treatment. The uncertainty around what's normal discomfort and what's not, combined with my body being more fragile, holds me back from feeling at ease. I get that the fit is standardized but honestly, my biggest concern is simply getting through this with as little pain as possible.

3. This is how you seduce me.

If you can make me more comfortable, I'm on board. I don't need fancy apps or online manuals; just talk to me clearly and help me feel better in this vest. Adjustments that reduce the pain or make daily life easier are what will win me over. Give me simple, direct answers to my questions, and I'll trust you—just like I trust my doctors. I appreciate when things are straightforward.

4. This is my goal

I want to heal and get back to living a more comfortable life. I know I'm lucky to be alive after the accident, and I'm not expecting miracles—just a bit less discomfort and a return to some normalcy. I don't need excitement; I just want to feel like myself again without the constant bother of this vest. My goal is to find a way to navigate

these next few months in the halo vest without feeling constantly sore or frustrated, and to get back to a life that doesn't feel burdened by discomfort.

5. This is how I feel about it

I feel hopeful, but I'm also realistic. I trust my doctors, and I know they have my best interests at heart. Still, the discomfort is always there, and that's what bothers me most. I know this isn't going to be easy, but what can I do? It is what it is. I'm just taking it one day at a time and hoping the fit gets better soon. I'm cautiously hopeful.

6. This is what motivates me

I'm motivated by the idea of eventually being free of this vest and returning to a life where I don't have to constantly think about comfort. The fact that my doctors are keeping an eye on things and checking up on me regularly reassures me. I don't want to cause any trouble—I just want to make it through this phase as smoothly as possible.

7. This is when I disengage

I lose interest when things get too complicated or when people expect me to manage things I don't understand, like all the online resources. If the discomfort doesn't improve or if people aren't listening to me about how I'm feeling, I pull back. I'm not looking for complexity; I just want practical solutions that work.

8. These are my conditions

I need simplicity and comfort above all else. The solutions offered to me must be straightforward, with as little reliance on technology as possible. I want to be heard when I express discomfort, and I need reassurances that the pain isn't just something I have to live with, but something that can be addressed. I also need patience from those around me—both from the medical team and my caregivers. Respect for my limitations, and clear, simple explanations of what to expect, are crucial. My age means I don't want to waste time on anything that makes life harder than it needs to be.

Design Considerations 3

In conclusion, the target group research does not only reveal the distinct needs of various users but also underscores the importance of addressing these differences in the design of the halo vest. By examining the experiences of primary users (patients), secondary users (caregivers and family members), and medical professionals, we can identify specific areas for improvement. This diversity offers valuable insights into potential modifications that could make the halo vest more effective, comfortable, and user-friendly for all involved. The following design considerations have been compiled from this research to guide future development.

1. Personalized Fit and Comfort: A one-size-fits-all approach is insufficient. A modular and adaptable design should be considered to improve the fit of the vest across different body types, reducing discomfort and pressure points, especially around the chest and stomach areas.

2. Minimizing Pressure Points: Areas such as the chest, collarbone, and stomach experience the most discomfort, particularly for thinner patients or those with larger body masses. Design improvements should focus on reducing chafing and discomfort in these areas.

3. Adaptability for Different Patient Types: The halo vest must cater to diverse patient groups, including trauma patients, those recovering from surgery, and individuals with chronic conditions. Each group has distinct needs, particularly in terms of comfort and duration of wear.

4. Aesthetic Improvements: The visual appearance of the vest significantly affects patients' willingness to engage in social activities. A more aesthetically pleasing, less bulky and less intrusive design, including options for personalization, could help reduce feelings of self-consciousness and improve the overall patient experience.

5. Ease of Maintenance: Caregivers play a significant role in maintaining the vest and assisting patients. The design should allow secondary users to make simple adjustments without compromising the device's stability. Clear indicators or visual markers could guide proper fit and tension

6. Clothing Compatibility: The vest should allow for the easy wearing of normal clothing. Adjustments in the neckline or creating a design that accommodates bras for women would improve user comfort

7. Enhanced Hygiene and Cleaning: Materials used in the vest should be easy to clean and maintain, enabling patients and caregivers to uphold hygiene standards without the need to remove the vest frequently. Detachable padding for easier cleaning should also be considered.

8. Sleeping Comfort: The design should support better sleep postures, addressing early discomfort experienced by patients, particularly in the first few weeks of wearing the vest.

9. Lightweight and Durable Structure: A lighter, more ergonomic vest would improve overall patient mobility and reduce the physical strain on both patients and caregivers. Durability is essential to ensure long-term use and minimize wear and tear.

10. Modularity and Replaceability: The vest should incorporate modular components that allow for easy replacement of worn-out parts, such as padding or straps, without requiring the entire vest to be replaced. Modular components would also help with sizing adjustments

11. Reliable Immobilization: The vest must provide robust and secure cervical immobilization, ensuring stability throughout the healing process. Adjustable features should allow for precise control, ensuring proper alignment and tension.

12. Medical Professional Ease of Application: The vest's design should enable quick and efficient application by medical professionals, with clear and intuitive fastening systems to simplify the process during both planned and emergency situations.

13. Precise Adjustability: Adjustable components should offer precise control, allowing medical professionals to fine-tune the vest's fit for individual patients to ensure optimal immobilization and patient comfort.

14. Imaging Compatibility: The design should minimize interference with diagnostic imaging procedures such as X-rays, CT scans, and MRIs, allowing doctors to monitor the healing process without needing to remove the vest.

15. Psychological Considerations: The design should take into account the psychological impact of wearing the vest, especially the stigma associated with its appearance. Reducing the vest's visibility or bulkiness could help patients feel more comfortable in public spaces.

16. Cost-Effectiveness: The design should balance advanced features with cost-efficiency to ensure that the vest is accessible to a broad range of users without significantly increasing healthcare costs.

Regulatory Requirements

This chapter provides an overview of the current regulatory landscape relevant to the development of the Halo Frame. Although testing a final concept against regulatory requirements is beyond the scope of this project, understanding these regulations is crucial for ensuring that conceptual designs align with key legal and safety standards.

The first section focuses on the most significant regulatory framework for the Halo Frame: the EU Medical Device Regulations (MDR). A detailed analysis of these regulations will inform the design process by highlighting the essential requirements for compliance. Following this, regulations specific to spinal immobilization devices are examined to further refine the design considerations, ensuring that the device meets industry-specific standards. In addition to current medical regulations, the chapter also considers the potential influence of future eco-design regulations. As sustainability becomes increasingly important, accounting for these emerging standards will help make the design more future-proof.

Finally, the regulatory research concludes with a set of key design considerations derived from the analyses, which will guide the subsequent phases of the project.

Medical device regulations

The EU Medical Device Regulations (MDR) are a set of rules that govern the design, production, and distribution of medical devices in the European Union. Introduced in 2017, the MDR replaced the previous Medical Device Directive (MDD) to create more consistent standards for medical devices, focusing on safety, performance, and traceability. For the development of a new Halo Vest, it is necessary to comply with these regulations to ensure that the device can be used safely and effectively.

A Halo Vest, designed for spinal immobilization and rehabilitation, falls under Class IIa in the MDR classification system. This category includes devices with a moderate level of risk, requiring specific attention to safety and clinical effectiveness. In this context, the Halo Vest must meet the requirements for clinical evidence, material safety, and product labeling as outlined in the MDR. A detailed analysis of the specific MDR sections relevant to the Halo Vest can be found in Appendix A.

The MDR requires that medical devices undergo a clinical evaluation to confirm their intended therapeutic benefit and safety. For a Halo Vest, this means providing evidence that the device helps immobilize the cervical spine effectively without posing unnecessary risks to the patient. The materials used in the vest must also meet safety standards, ensuring they are biocompatible and suitable for long-term use, given that patients often wear the device for extended periods.

Post-market surveillance is another important aspect of MDR compliance. Manufacturers must monitor how the device performs in real-world conditions and report any incidents or issues. This helps ensure the ongoing safety and reliability of the device after it has been introduced to the market.

The MDR also considers environmental factors, such as the use of sustainable materials, which could become more important in the future. Designing the Halo Vest with these aspects in mind may help future-proof the device in light of upcoming regulations.

In conclusion, the MDR plays an important role in guiding the development of a new Halo Vest. By addressing the applicable regulations and ensuring the device meets the necessary standards, the project can move forward with a focus on patient safety and regulatory compliance. (DC33)

FIgure 30: MDR logo (MDR, n.d.)

Eco-design regulations

In the European Union, regulations guiding the sustainable design of products, including medical devices like the Halo Frame, are informed by the Eco-design Directive (2009/125/EC) and the forthcoming Eco-design for Sustainable Products Regulation (ESPR) (Bakker et al., 2023). While sustainability is not the primary focus of this research, it remains essential to consider these aspects for future Halo Frame developments to ensure compliance with evolving standards.(DC31)

The 2009 Eco-design Directive established a framework for environmental performance standards, initially targeting energy efficiency in specific product groups (The European Parliament & The Council of the European Union, 2009). The ESPR, now under negotiation, broadens this scope to cover nearly all product categories, including medical devices.

This regulation introduces requirements for durability, repairability, resource efficiency, recyclability, and waste reduction, aiming to encourage a more circular design approach. Furthermore, the ESPR proposes a digital product passport, which would associate detailed sustainability information with each product, enhancing transparency and traceability (European Commission, 2020; Directorate-General for Environment, 2022). Once ratified, member states will have 24 months to incorporate the ESPR into national law (Balkenende et al., 2024). (DC32)

Incorporating the ESPR's sustainability goals into future designs of the Halo Frame presents a valuable opportunity to align with these standards without compromising its therapeutic function. Emphasizing durability, ease of repair, and recyclability will help the device meet upcoming regulations, extend its operational lifespan, and position it as a sustainable medical device design. This proactive approach will enable the Halo Frame to comply with new environmental regulations and remain adaptable to future regulatory changes.

Design Considerations 4

While direct testing against regulatory standards falls outside the scope of this project, a detailed review of the regulatory landscape for the Halo Frame has been completed. This review highlights that EU regulations, particularly the Medical Device Regulations (MDR) and the upcoming Eco-design for Sustainable Products Regulation (ESPR), set specific requirements that should be considered in the design process. Incorporating these requirements early on helps ensure the Halo Frame aligns with both current and future regulatory expectations. The following design considerations were identified from this analysis:

1. Patient Safety and Therapeutic Effectiveness: Meeting MDR standards requires that the Halo Frame demonstrate safety and effectiveness in immobilizing the cervical spine, with minimal risk to the patient. This focus on therapeutic benefit and patient safety is crucial to the design.

2. Material Safety: The materials selected for the Halo Frame need to be biocompatible and suitable for long-term wear, as specified by MDR. This consideration helps avoid adverse reactions and ensures comfort during extended use.

3. Sustainability for Future Requirements: Although sustainability is not the main focus, designing for durability, repairability, and recyclability will support compliance with the ESPR. This approach also aligns with a circular economy model, which can make the device more adaptable to future needs.

4. Post-Market Surveillance: MDR requires manufacturers to monitor device performance once it is in use. Incorporating features that allow for effective post-market surveillance will help ensure that the Halo Frame remains safe and reliable, enabling prompt responses to any issues that may emerge.

5. Digital Product Passport: In line with ESPR's potential requirement for a digital product passport, future Halo Frame designs could include information on environmental impact, material origins, and end-of-life instructions. This would enhance transparency, traceability, and support regulatory compliance.

Design Considerations 4

6. Risk Management and Device Classification: As a Class IIa device under MDR, the Halo Frame needs to be designed with moderate-risk management in mind, ensuring it adheres to the relevant safety and performance standards.

By taking these considerations into account, the Halo Frame design can address both current regulatory needs and anticipated sustainability requirements, helping ensure it remains compliant, safe, and environmentally conscious.

Market Considerations

The Halo Frame's introduction into the healthcare market involves various challenges and considerations related to reimbursement, distribution, and specific design factors. Given the complexities of deploying medical devices, examining these areas is essential to assess the market viability of the Halo Frame.

A New Market

As healthcare costs continue to rise, there is an increased focus on value-based care, encouraging providers to improve outcomes while minimizing costs (Porter, 2015). Technologies that reduce hospital stays, such as the Halo Frame, align with these goals. The current halo vest commonly used by hospitals, such as those provided by Bremer Medical, retails for approximately €3,000. (UMCU, n.d.) This cost is considerably lower than surgical alternatives for spinal stabilization. However, while the Halo Frame avoids the high upfront costs of surgery, it still incurs significant expenses due to labor-intensive follow-up and check-up visits, which are bundled under the Diagnosis Treatment Combination (DBC) system in the Netherlands (Appendix C).

In the DBC system, spinal injury treatments that utilize a Halo Frame fall under the same category as spinal trauma interventions. The DBC package encompasses diagnostic imaging, initial application, hospitalization if necessary, and regular follow-up care. Although this bundled approach offers a standardized pathway for reimbursement, the labor-intensive nature of frequent adjustments and patient monitoring contributes to a higher DBC cost. For the Halo Frame to achieve greater market adoption, solutions that streamline care without compromising quality may be necessary to reduce the overall cost burden.

Reimbursement by Insurance Companies

In the Netherlands, the Halo Frame is generally eligible for reimbursement under the basic health insurance package, provided it is prescribed for severe spinal or cervical injuries requiring immobilization. According to the Dutch healthcare authority (Nederlandse Zorgautoriteit, 2023) and the Federation of Medical Specialists (Federatie Medische Specialisten, 2022), the treatment must meet specific criteria for medical necessity, and the healthcare provider must adhere to established guidelines for spinal stabilization. The intervention is intended to provide a cost-effective, non-surgical alternative to stabilize the spine, aligning with the goals of cost-efficiency and improved patient outcomes.

Reimbursement agreements are established between healthcare providers, like UMCU, and insurers to cover treatments involving the Halo Frame. These agreements include structured billing codes and pricing protocols, allowing the Halo Frame to be declared under designated DBC codes for spinal injuries or trauma. However, due to the need for frequent monitoring and adjustments, the Halo Frame's DBC cost remains high, posing a challenge to long-term adoption unless operational efficiencies can be achieved in care delivery.

Distribution Channels

UMCU, as a major healthcare provider, manages the distribution and deployment of medical devices within its clinical network. The distribution model for the Halo Frame, therefore, relies on the existing infrastructure within UMCU, where device management is handled in-house. This approach supports close monitoring of device use, patient outcomes, and adjustments, which are essential for the safe and effective application of the Halo Frame. Additionally, utilizing UMCU's distribution channels ensures the necessary training for healthcare staff and seamless integration into the hospital's patient care processes.

Design Considerations 5

To improve market viability and address the operational challenges associated with the Halo Frame, the following design considerations are proposed:

1. Cost Target: Setting a competitive cost target is essential to ensure affordability for healthcare providers while meeting DBC reimbursement requirements. The total cost, including maintenance and follow-up care, should remain within market standards to prevent excessive financial strain on hospitals and insurers.

2. Reduction of Labor-Intensive Check-Ups: The current high DBC cost is partly due to frequent, labor-intensive check-ups required for patients with a Halo Frame. Innovations that allow for easier adjustments or that extend the intervals between necessary check-ups could help reduce these operational costs. Streamlined adjustment mechanisms or modular components could improve efficiency without compromising patient safety.

3. Alignment with In-Hospital Use: The design of the Halo Frame should prioritize compatibility with in-hospital care settings. Given the intensive nature of initial application and adjustments, the device should be tailored to support efficient handling by medical staff within a clinical setting, rather than a home environment. Ensuring that the Halo Frame integrates smoothly into UMCU's care pathways will improve both patient experience and operational efficiency.

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Conclusion Discover Phase

In summary, 44 design considerations were outlined for the re-design of a halo frame. These considerations are organized and clustered below by specific features related to the redesign, which will help clarify what is required for each area on the re-design of the frame. This clustering reduced the original list of 44 design considerations to 35 considerations by combining similar items. Important to note is that these considerations are not in order.

1. Patient Comfort and Ergonomics

1. Pressure Points: Current halo vests often cause discomfort due to pressure points, leading to irritation and sores, especially during prolonged use. Areas such as the chest, collarbone, and stomach experience the most discomfort, particularly for thinner patients or those with larger body masses. Design improvements should focus on reducing chafing and discomfort in these areas as well as minimizing these pressure points, potentially through improved padding or more adaptable fit.

2. Breathing and Comfort: Ensuring that the vest allows for adequate chest expansion to prevent restricted breathing is critical. The design should also account for extended wear by optimizing weight distribution and reducing friction between the skin and the device.

3. Patient Comfort and Mobility: Living with a Halo vest can be uncomfortable, especially during daily activities like sleeping, eating, or dressing. The new design should focus on improving patient comfort by incorporating lighter materials, better padding, and ergonomic features. Additionally, ease of mobility should be considered, particularly in how the vest integrates with daily life (e.g., sleeping on the back or avoiding stress on pins during movements).

4. Sleeping Comfort: The design should support better sleep postures, addressing early discomfort experienced by patients, particularly in the first few weeks of wearing the vest.

5. Clothing Compatibility: The vest should allow for the easy wearing of normal clothing. Adjustments in the neckline or creating a design that accommodates bras for women would improve user comfort

2. Fit and Adjustability

6. Sizing Variability: A key issue is the limited sizing options, which can result in poor fit. The vest should be designed to accommodate a wider range of body types, and a modular or adjustable fit could be beneficial.

7. Custom-Fit Options: The potential for customizable components, particularly for unique anatomical requirements, could improve the fit and performance of the vest across a diverse patient population.

8. Frame Alignment and Adjustability: Proper alignment of the Halo frame is critical for spinal stabilization, and adjustments are often based on imaging scans (e.g., CT or X-rays). The design should include clear, user-friendly mechanisms that allow healthcare providers to make precise adjustments easily and securely during and after the initial installation. Adjustable components should offer precise control, allowing medical professionals to fine-tune the vest's fit for individual patients to ensure optimal immobilization and patient comfort.

9. Modular Design: A one-size-fits-all approach is insufficient. A modular and adaptable design should be considered to improve the fit of the vest across different body types, reducing discomfort and pressure points, especially around the chest and stomach areas.

3. Mobility and Independence

10. Mobility: The current design significantly restricts mobility, making everyday tasks difficult. A more ergonomic design with lighter materials could enhance patient movement while still ensuring proper stabilization.

11. Patient Independence: Given the difficulty patients face in managing basic tasks, such as washing hair or getting dressed, the design should consider elements that allow patients more independence in their daily routine. This could include features like easier access points for caregivers to assist with leaning or maintenance.

12. Enhanced Hygiene and Cleaning: Materials used in the vest should be easy to clean and maintain, enabling patients and caregivers to uphold hygiene standards without the need to remove the vest frequently. Detachable padding for easier cleaning should also be considered.

4. Structural Integrity and Safety

13. Force Magnitudes: The forces acting on the vest during patient movements, such as vertical (177N), anterior-posterior (126N), and lateral (148N) forces, must be accounted for. Materials used for the vertical rods, pins, and vest need to withstand these forces while remaining lightweight to improve patient comfort.

14. Dynamic Forces: The vest must handle forces during activities like sitting, standing, and bending, ensuring stability without compromising patient safety.

15. Pin Force Distribution: The current pin interfaces could be redesigned to distribute forces more evenly across the skull, which would reduce discomfort and the risk of complications. Considerations for pin placement and biocompatibility of materials are essential.

16. Reliable Immobilization: Meeting MDR standards requires that the Halo Frame demonstrate safety and effectiveness in immobilizing the cervical spine, with minimal risk to the patient. The vest must provide robust and secure cervical immobilization, ensuring stability throughout the healing process. Adjustable features should allow for precise control, ensuring proper alignment and tension.

17. Material Safety: The materials selected for the Halo Frame need to be biocompatible and suitable for long-term wear, as specified by MDR. This consideration helps avoid adverse reactions and ensures comfort during extended use.

5. Aesthetics and Psychological Impact

18. Aesthetic Improvements: The visual appearance of the vest significantly affects patients' willingness to engage in social activities. A more aesthetically pleasing, less bulky and less intrusive design, including options for personalization, could help reduce feelings of self-consciousness and improve the overall patient experience

19. Psychological Considerations: The design should take into account the psychological impact of wearing the vest, especially the stigma associated with its appearance. Reducing the vest's visibility or bulkiness could help patients feel more comfortable in public spaces. This to improve patient morale and reduce the stigma associated with wearing the device.

6. Ease of Use and Maintenance

20. Ease of Installation: The Halo vest installation process relies heavily on the expertise of plaster cast makers, and while the installation itself is fast, positioning the frame correctly takes considerable time. The redesign should aim to simplify the positioning process, allowing for more efficient and accurate placement with less dependency on specialized personnel.

21. Ease of Maintenance: Caregivers play a significant role in maintaining the vest and assisting patients. The design should allow secondary users to make simple adjustments without compromising the device's stability. Clear indicators or visual markers could guide proper fit and tension.

22. Simplified Maintenance and Follow-Up Care: Regular follow-up care is necessary to monitor pin tightness, adjust the frame, and ensure proper healing. The design should incorporate features that allow for easy adjustments and monitoring by both healthcare providers and patients, potentially reducing the need for frequent hospital visits.

23. Reduction of Labor-Intensive Check-Ups: The current high DBC cost is partly due to frequent, labor-intensive check-ups required for patients with a Halo Frame. Innovations that allow for easier adjustments or that extend the intervals between necessary check-ups could help reduce these operational costs. Streamlined adjustment mechanisms or modular components could improve efficiency without compromising patient safety.

7. Modularity and Replaceability

24. Modularity and Sizing: The current process involves choosing vest sizes based on the patient's body measurements, but a more modular design could allow for easier customization and better fit across a broader range of patients. Adjustable or interchangeable components that cater to different body types and specific medical needs (e.g., pediatric versus adult) could improve the overall fit and effectiveness.

25. Modularity and Replaceability: The vest should incorporate modular components that allow for easy replacement of worn-out parts, such as padding or straps, without requiring the entire vest to be replaced.

26. Cost Target: Setting a competitive cost target is essential to ensure affordability for healthcare providers while meeting DBC reimbursement requirements. The total cost, including maintenance and follow-up care, should remain within market standards to prevent excessive financial strain on hospitals and insurers. The design should balance advanced features with cost-efficiency to ensure that the vest is accessible to a broad range of users without significantly increasing healthcare costs.

8. Medical and Clinical Compatibility

27. Medical Professional Ease of Application: The vest's design should enable quick and efficient application by medical professionals, with clear and intuitive fastening systems to simplify the process during both planned and emergency situations.

28. Alignment with In-Hospital Use: The design of the Halo Frame should prioritize compatibility with in-hospital care settings. Given the intensive nature of initial application and adjustments, the device should be tailored to support efficient handling by medical staff within a clinical setting, rather than a home environment. Ensuring that the Halo Frame integrates smoothly into UMCU's care pathways will improve both patient experience and operational efficiency.

29. Imaging Compatibility: The design should minimize interference with diagnostic imaging procedures such as X-rays, CT scans, and MRIs, allowing doctors to monitor the healing process without needing to remove the vest.

9. Hygiene and Cleaning

30. Vest and Component Hygiene: Maintaining hygiene is a challenge, as the vest cannot get wet, and cleaning under the vest and around the pin sites requires special care. The redesign should consider materials that are easier to clean and maintain, as well as features that provide better ventilation to avoid moisture buildup and improve skin health under the vest. Detachable padding for easier cleaning should also be considered. This to enable patients and caregivers to uphold hygiene standards without the need to remove the vest frequently.

10. Sustainability and Future Requirements

31. Sustainability for Future Requirements: Although sustainability is not the main focus, designing for durability, repairability, and recyclability will support compliance with the ESPR. This approach also aligns with a circular economy model, which can make the device more adaptable to future needs.

32. Digital Product Passport: In line with ESPR's potential requirement for a digital product passport, future Halo Frame designs could include information on environmental impact, material origins, and end-of-life instructions. This would enhance transparency, traceability, and support regulatory compliance.

11. Regulatory Compliance and Surveillance

33. Post-Market Surveillance: MDR requires manufacturers to monitor device performance once it is in use. Incorporating features that allow for effective post-market surveillance will help ensure that the Halo Frame remains safe and reliable,

enabling prompt responses to any issues that may emerge.

34. Long-Term Wearability: Since patients often wear the Halo frame for extended periods, the redesign should prioritize long-term wearability. This includes reducing the overall weight of the frame and optimizing material selection to improve durability and comfort over time.

35. Use of Modern Materials: Advances in materials, such as lightweight composites and biocompatible alloys, should be leveraged to reduce the overall weight of the vest while maintaining or improving its structural integrity.

Define

Introduction Define Phase

To advance the development of new concepts for the Halo Frame, it is important to first narrow the design scope by defining a specific use scenario. Without a clear scenario, the design space remains broad, which can make it difficult to focus on particular user needs and situational requirements. Establishing a defined context helps ensure that future design decisions address the specific needs of the end users and the conditions in which the device will be used.

At this stage, two potential use scenarios will be identified and evaluated to understand the advantages and limitations of each. The evaluation will consider key criteria such as feasibility, practicality, and relevance. Based on this analysis, one scenario will be selected in consultation with the project team. The selected scenario will then be refined to focus on specific design considerations and establish clear boundaries for the design process. These steps will provide a structured framework to guide development and support informed decision-making as the design progresses.

Defining the Scenario

To effectively define the scope of this project, it is essential to address both the primary clinical scenarios in which the halo frame is used and the perspectives that influence its design. The halo frame currently serves two main scenarios—urgent emergency immobilization and planned long-term support—each with distinct requirements in terms of application, comfort, and patient experience. Additionally, understanding the differing needs of both the orthopedic technician and the patient provides insight into the priorities for this redesign. Achieving a balanced focus on adjustability, stability, comfort, and appearance is central to developing a patient-oriented solution.

Scenario 1

In Scenario 1, the halo frame is used in emergencies where the patient has suffered a severe injury, such as a cervical fracture, requiring immediate immobilization. This scenario naturally holds a priority, given the critical nature of such injuries. The role of the halo frame here is to ensure rapid and secure stabilization, which is crucial to prevent further damage during initial treatment. A standardized, "one-size-fits-all" model is applied swiftly in these situations, providing the essential stability required without the need for individualized adjustments. The orthopedic technician's primary focus is on quickly securing the frame to protect the spine, emphasizing efficiency and stability over considerations like comfort or appearance. While this design is largely functional, addressing only the immediate medical needs, it is undeniably indispensable in urgent care settings where time is a critical factor.

Scenario 2

Scenario 2 presents a different set of priorities, focusing on patients requiring prolonged cervical support due to chronic or progressive conditions. These individuals rely on the halo frame not just as a temporary solution but as a part of their daily lives, often over several months. Unlike the emergency scenario, there is time to consider modifications and customization to make the frame more compatible with the patient's needs for comfort and overall wearability. The device in this context needs to be practical and comfortable, with features like additional padding, lighter materials, and a fit tailored to the patient's body to improve usability and reduce discomfort over extended wear. Also the appearance of the device is much more present in the design considerations. For patients, this scenario is not solely about physical stability; it also involves integrating the frame into their routines and adapting to its presence both physically and mentally.

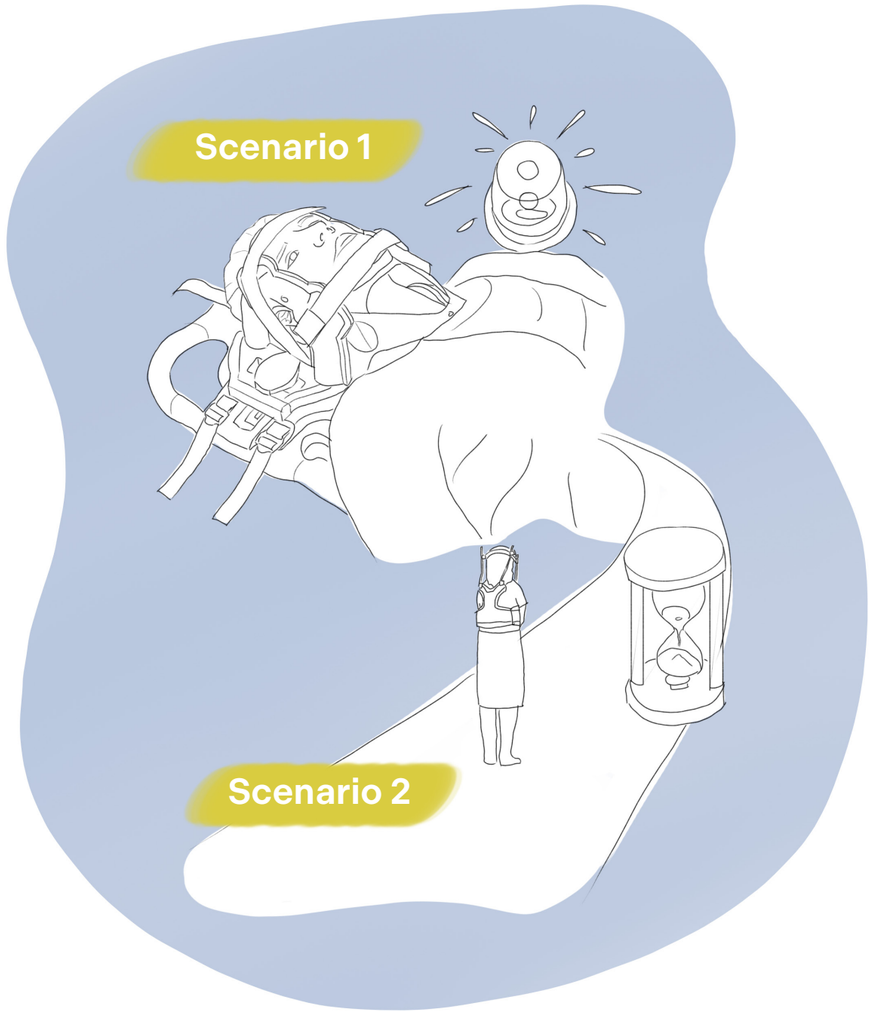


FIgure 31: Scenario 1 vs Scenario 2

Use scenario

While the priority of Scenario 1 is clear due to the inherent urgency of severe injuries, the focus of this project will be directed toward Scenario 2. This choice arises from the potential for design modifications in long-term use to significantly impact acceptance among both patients and doctors. The primary goal of this project is to enhance the experience of wearing the halo frame over time, which has a direct influence on compliance, comfort, and emotional well-being. Historically, the design approach has focused first on meeting medical-grade requirements, with only minimal attention given to appearance and comfort. By reversing this approach—starting with an aesthetic and patient-centered design that aligns with medical standards rather than conforming to them later—this project aims to address a need that has often been overlooked.

To clarify, this approach will still produce a medically graded, stable device. However, the focus at the initial stages will be to explore ideas beyond traditional limitations, embracing an "outside-the-box" ideation process to prioritize aesthetics, comfort, and usability. Once the concept has been developed, the design will be refined toward achieving full medical stability and compliance with clinical standards. This sequence aims to ensure a balance between clinical functionality and patient experience without compromising safety.

The decision to prioritize Scenario 2 sets the foundation for a redesigned halo frame that considers patients' long-term experiences and the practical needs of orthopedic technicians. Through this approach, the project aims to challenge the traditional design model, which has typically prioritized medical standards first and appearance second. This reorientation could yield markedly different results, creating a device that not only fulfills clinical requirements but also enhances patient comfort and overall acceptance of the device. In taking this approach, the goal is to produce a halo frame that supports stabilization and long-term wearability equally, aligning both patient and clinician needs in a cohesive design.

Selection Reasoning

To evaluate the feasibility, viability, and desirability of focusing on Scenario 2—the long-term use of the halo frame—considering technical and practical requirements is essential to align with patient and clinician needs.

Feasability

The project's feasibility relies on balancing a patient-centered design with the medical-grade stability required in a halo frame. Advances in medical materials, like lighter composites and modular components, allow adjustments in padding and structure, making a design suitable for long-term wear. Ensuring these modifications align with clinical standards while retaining stability shows that a more comfortable, adaptable design is feasible.

Viability

Viability considers market potential and long-term value. Traditional halo frames prioritize stabilization, often limiting their comfort for extended use. Addressing this gap by incorporating feedback on comfort and appearance aligns with the industry shift toward user-centered devices, enhancing long-term usability. Testing within medical settings may support adoption, and while initial development may require additional resources, the focus on patient compliance and improved experience supports long-term viability.

Desirability

Desirability is crucial, as comfort and appearance significantly impact patient compliance in long-term scenarios. Many users report discomfort and social unease with current designs. A frame that integrates into daily life with improved comfort and a less clinical appearance supports a more positive experience for patients. For clinicians, a customizable frame adds flexibility, enhancing patient satisfaction.

Scoping

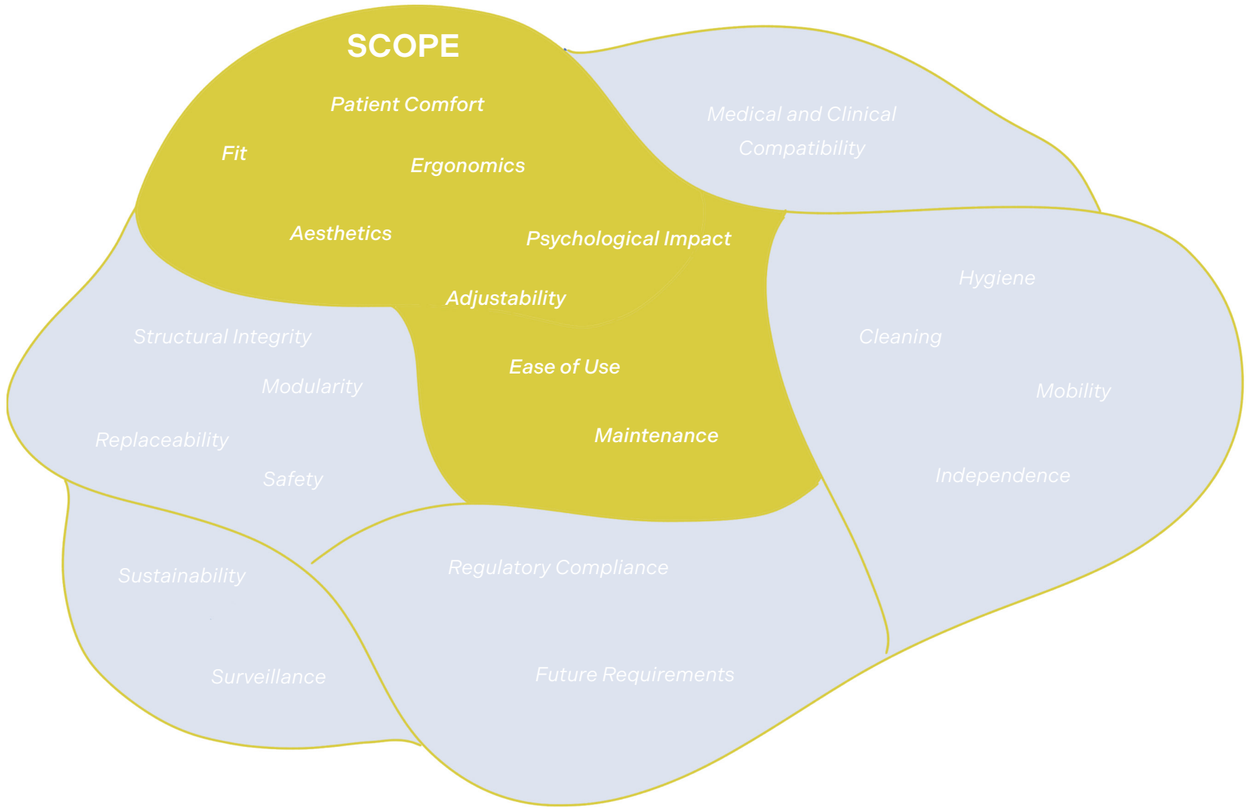
Scope of Project

After defining the primary scenario for the halo frame redesign, the remaining design space still covers a wide range of considerations. Given the project's time constraints, it was necessary to narrow the focus by selecting only specific design considerations from the discovery phase. This further scoping ensures that the project can concentrate on developing improvements with the most significant impact on patient experience and usability in the chosen scenario. In appendix E and F, two approaches can be found in deviding the considerations per scenario. Eventually it chosen to devide the clusters as a whole among teh scenario's, rather than all 35 design considerations on their own.

Based on the focus on long-term use, concentrating on the clusters related to Patient Comfort and Ergonomics, Fit and Adjustability, Ease of Use and Maintenance, and Aesthetics and Psychological Impact will be most effective. These clusters address key aspects for extended wear, including reducing discomfort from pressure points, enhancing fit for a diverse range of body types, and simplifying maintenance for patients and caregivers. Additionally, improving aesthetics and addressing the psychological impact of the halo frame can help alleviate social discomfort and stigma, which are often barriers to patient compliance and well-being. By focusing on these areas, the project aims to create a halo frame that better supports patients' physical and emotional needs throughout the recovery process while also addressing practical needs for healthcare providers.

The choice to focus on these particular design clusters does not diminish the relevance of other considerations; rather, it reflects a deliberate emphasis on enhancing the system's core functionality. By prioritizing these areas, the project seeks to develop a halo frame that meets the essential physical and emotional needs of long-term users, while also addressing practical requirements for caregivers and medical staff throughout the treatment process.

FIgure 32: visual of the selected design considerations



Boundaries

Boundaries within chosen design considerations

To refine the extensive possibilities within the design space, specific boundaries have been established. These boundaries serve to concentrate the project's scope, guiding it towards key improvements that can realistically be achieved within the project's timeframe and that align with the long-term use scenario identified.
In this context, a boundary defines the scope within which the project will be conducted, clarifying the aspects that will be prioritized and those that will be excluded. These boundaries provide structure for the design process and ensure that efforts are directed toward impactful areas. Below, each boundary is defined, along with explanations for inclusions and exclusions within the design space.

Cost Considerations

Included: Setting a general cost range ensures that design choices remain practical and accessible. The redesign will focus on cost-effective solutions to make the halo frame affordable for healthcare providers and patients alike.
Excluded: A comprehensive economic analysis or cost optimization study will not be part of the project. This boundary excludes financial aspects that would require significant resources and time, allowing the project to focus directly on patient-centered design improvements instead.

Comfort and Long-Term Wearability

Included: Given the scenario's emphasis on prolonged use, comfort is a primary focus. The design will address common issues such as pressure points, limited mobility, and discomfort during daily activities. Materials and ergonomic features that promote comfort over extended wear will be prioritized.
Excluded: Detailed biomechanical studies or specialized testing for wearability under various conditions are beyond the project's scope. Instead, the redesign will be based on existing user feedback and general ergonomic principles, ensuring feasible yet meaningful comfort improvements.

Fit and Adjustability

Included: To accommodate a wide range of body types, the design will incorporate modular and adjustable components, ensuring a better fit across diverse users. The project will emphasize versatility in fit to enhance comfort and functionality for as many users as possible.
Excluded: Customization on an individual level, such as highly personalized fittings or tailor-made components, will not be explored extensively. Such approaches are resource-intensive and may not be practical within the scope, so the focus will remain on flexible yet standardized solutions.

Aesthetics and Psychological Impact

Included: Aesthetic improvements will be considered to reduce the clinical appearance of the device, making it less obtrusive and more socially comfortable. This boundary allows for small design adjustments aimed at minimizing stigma and supporting the patient's emotional well-being.
Excluded: A full exploration of aesthetics, including options for personalization or a detailed study on the psychological impact, is excluded. While these elements are important, they fall outside the immediate scope, allowing the project to maintain a focus on physical functionality and comfort improvements.

Ease of Use and Maintenanc

Included: The design will focus on practical features that make daily maintenance simpler for patients caregivers and medical professionals, including easy-to-adjust components that require minimal upkeep. This will support flexibility and durability without overly complex design changes.
Excluded: An in-depth examination of maintenance processes, including specialized training for caregivers or robust maintenance testing, will not be conducted. Instead, the project will focus on straightforward design changes that are easier to integrate into the existing framework of care.

Excluded Design Considerations and Themes

While this project seeks to enhance the usability and comfort of the halo frame, certain design considerations and broader themes are excluded due to resource and time constraints. These exclusions do not imply a lack of importance; rather, they reflect a strategic focus on elements that directly impact patient experience during long-term wear. Excluded considerations include:

1. Structural Integrity and Safety: While essential for any medical device, extensive testing and redesigns related to complex force distribution, load-bearing capacity, and impact resistance are mostly beyond the scope of this project. There will be proof of concepts, but most of the structural tests will be on a smaller scale or in simulations.

2. Sustainability and Future Requirements: Considerations for sustainability, such as the use of recyclable materials, eco-friendly manufacturing processes, or a circular design approach, will not be actively explored. While these aspects align with long-term industry trends and environmental responsibility, they require dedicated research and testing to ensure compliance with regulations like the European Sustainability Product Regulation (ESPR). This project will concentrate on immediate usability improvements, though sustainable materials could be explored in future iterations of the device.

3. Regulatory Compliance and Post-Market Surveillance: Meeting Medical Device Regulation (MDR) requirements and establishing systems for long-term surveillance are critical for a device intended for prolonged use. However, detailed investigations into regulatory standards, documentation requirements, or post-market surveillance mechanisms will not be addressed. This project assumes compliance with existing regulations based on the current frame's established design, directing resources toward improvements in patient-centered features instead of regulatory considerations. A set up will be made into setting up teh right documentation (e.g. intended use, device specifications etc.)

4. Material Testing and Advanced Durability Studies: Although material choice is integral to comfort and functionality, extensive testing for material durability, wear resistance, and biocompatibility is excluded.

Conclusions Define Phase

This phase has been essential in focusing the redesign efforts for the halo vest on a scenario that addresses the needs of long-term patients and considers the practical requirements of caregivers and healthcare providers. In the define phase, we analyzed the primary scenario, emphasizing comfort, wearability, and usability of the halo vest over extended periods. The project's scope was then narrowed to concentrate on key design areas—such as patient comfort, fit, adjustability, aesthetics, and ease of maintenance—which have a direct impact on the patient experience.

Specific boundaries were also set to guide the design, including general cost guidelines, limited customization options, and exclusions of complex structural changes. These boundaries help keep the project focused on improvements that can realistically be achieved within the available resources, avoiding areas like regulatory compliance, advanced material testing, or sustainability that fall outside this project's scope.

In conclusion, this phase has distilled the project brief into its core elements, providing a clear direction. With these foundations, we are ready to move into the development phase, concentrating on a targeted redesign that supports the needs of long-term halo vest users.

Develop

Introduction Develop Phase

The upcoming chapter focuses on the develop phase of the design process. After the define phase, where the design brief was broken down into its key components, the next step is to begin exploring possible design directions based on these insights.

This phase starts with generating ideas by identifying and analysing the factors that influence the stability of the Halo frame. These factors are used as a basis for ideation, during which various methods are applied to explore and shape potential solutions. Basic calculations are also performed to test and validate some of the ideas as proof of concepts, ensuring they are practical and grounded in reality.

The goal of this phase is to gradually refine the ideas into a clear and focused concept direction, addressing the stability challenges in a structured and straightforward manner.

Creating idea’s

This chapter focuses on identifying and analysing the factors that play a role in the stability of the Halo frame. The process started by compiling a list of factors that influence the frame’s stability. These factors served as a basis for generating ideas through different methods. Afterward, the ideas were reviewed, and the most feasible options were chosen for further exploration. This approach ensures that the design process is both methodical and grounded in a clear understanding of stability-related considerations.

Design Directions

In the previous chapter, we outlined four key design directions to explore further. These directions, shown in Figure 35, were chosen to address specific aspects of the Halo frame, breaking the larger problem into smaller, more manageable components. This approach allows for a focused exploration of each direction while ensuring they align with the needs identified during earlier stages. The four design directions are as follows:

1. Adaptable Vest: Orthopedic technicians expressed the need for a vest that can adapt to the anatomy of individual patients. Creating an adaptable vest would allow for a better fit and improved patient comfort.
2. Structure Relocated to the Back: Feedback from users indicated a preference for removing the front rods and pulling the structure toward the back. This adjustment would provide a clearer view and make the frame less visually intrusive, with most of the structure positioned behind the head.
3. Maintaining Rigidity: Even with a simplified structure relying on two beams, the frame must remain rigid enough to stabilize the patient effectively.
4. Adjustable Size: Orthopedic technicians prefer a solution that reduces the need for multiple sizes. A one-size-fits-all or a minimal range of sizes would simplify fitting while maintaining functionality.

These design directions are heavily integrated with stability factors. For example, relocating the structure to the back aligns with user preferences but requires adjustments for force distribution and rigidity. Adaptable, size-adjustable vests accommodate diverse patient needs and simplify fitting.

The next section explains how these design directions were turned into concepts, combining insights from the stability analysis with the main design goals to meet user needs. The design directions form the basis of the following design exploration

Sizing variations

Our product needs to accommodate a wide range of users. To achieve this, it is important to identify the necessary sizing variations.
To determine these variations, we examined the dimensions of the existing frame. The current frame, which caters to a wide variety of sizes, provides adjustability of 5 cm in both directions along the X-axis and 10 cm in both directions along the Y-axis. This makes it a suitable benchmark for our design, which must offer similar flexibility. Figure 34 illustrates the basis for these measurements.

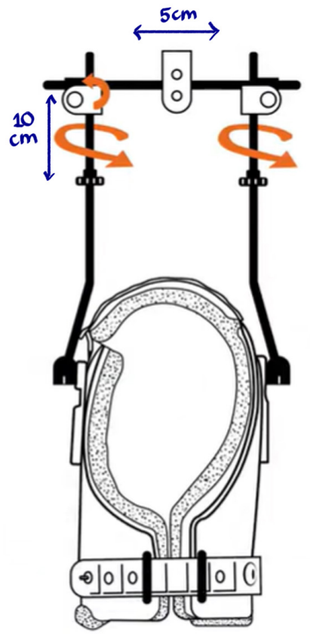
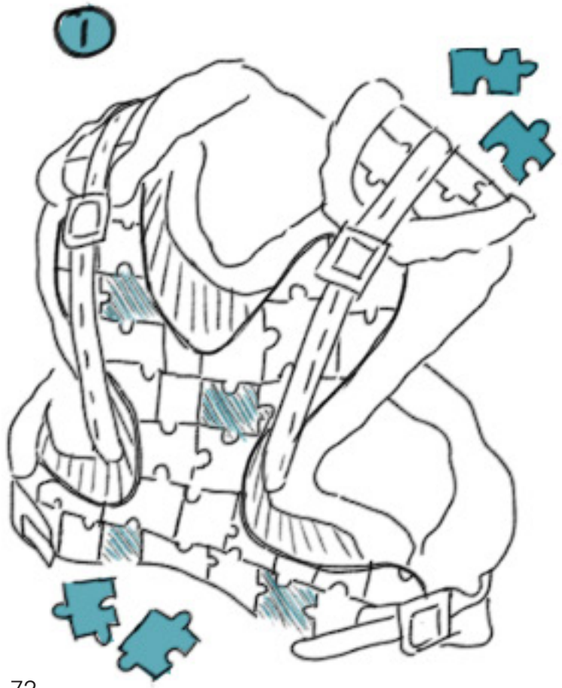


FIgure 34: Halo Frame size variations

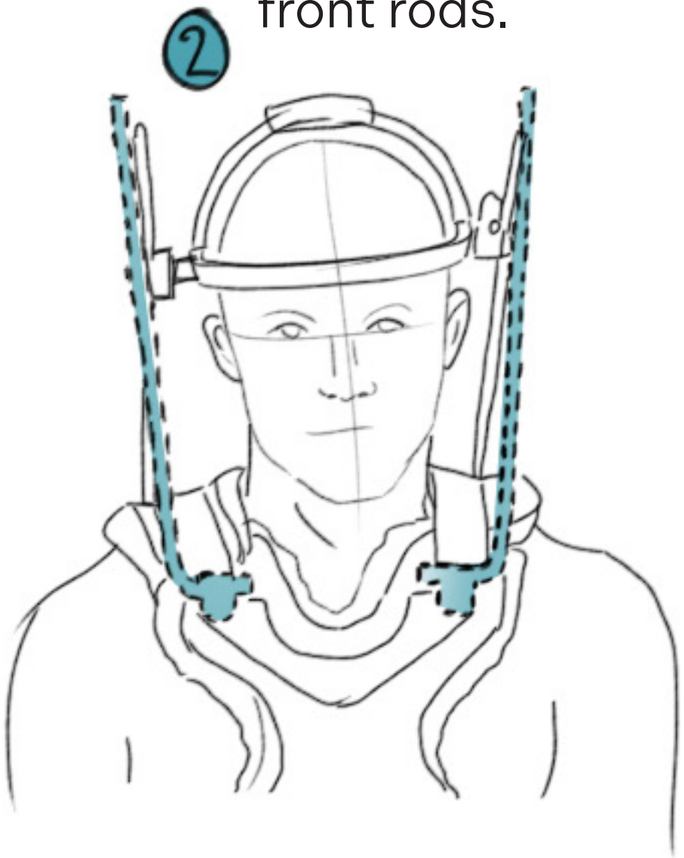
Design Directions

Figure 35: Design Directions

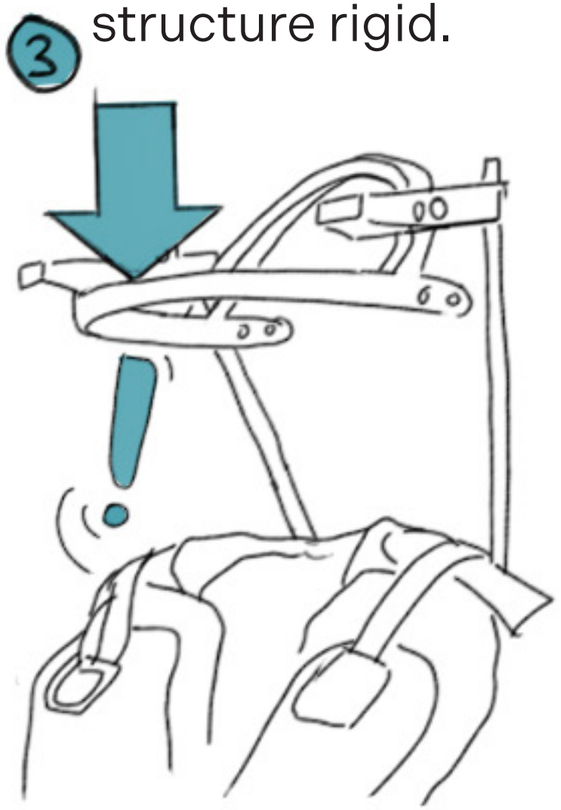
How to make vest adaptable at breaking points.



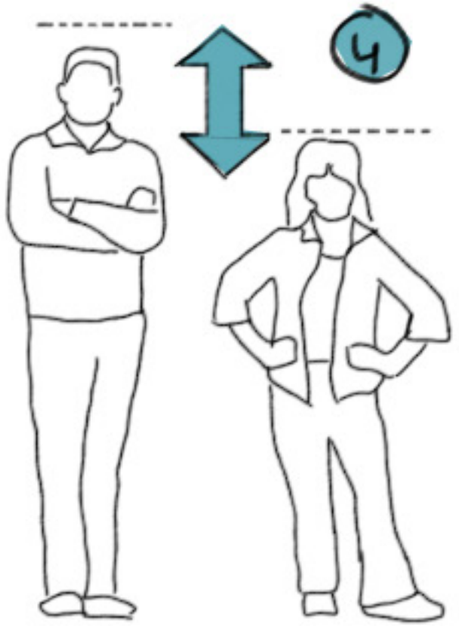
How to remove the front rods.



How to make the structure rigid.



How to make structure adaptable in size.



Ideation

To explore potential design interventions for the factors influencing the stability of the Halo frame, several methods were applied to generate and develop ideas. These methods included mind maps, HKJ (Hoe Kan Je..) frameworks, desk research, sketching, rapid prototyping, and quick CAD modelling. Each method contributed to the process by encouraging different perspectives and enabling the exploration of a wide range of possibilities. This variety of approaches helped identify promising ideas for further development.

Mindmaps

A mind map was created for each of the identified factors to investigate potential improvements through design modifications. These changes could include adjustments to the geometry, providing clear instructions for users, incorporating feedback, strengthening existing mechanisms, or adding or removing specific elements. The mind maps were created with a focus on answering the question, "How can I...". These mind maps are included in Appendix M.

Desk resreach

Desk research played an important role in the ideation process. It was used both to validate existing ideas and to generate new ones by drawing inspiration from a variety of sources. For example, exploring other braces on the market, modern head and neck wearables, and motorcycle body armour contributed to shaping the current design. This research offered useful insights into ways the Halo frame could be improved to enhance usability and comfort.

Sketching

Sketching was used alongside other methods to explore potential geometries for the device. Rather than being solely a way to represent ideas, it served as a tool for visually examining various form factors and combinations of components, guided by a morphological chart. One advantage of sketching was the ability to rapidly iterate on ideas and share them for discussion. Additionally, it played an important role in connecting the abstract concepts from the mind maps to the physical prototypes created with 3D printing. Figure 21 illustrates the use of mannequins as a foundation for creating quick and rough sketches of initial design ideas. The outcome of the morphological chart can be found in appendix O, alongside various other sketches.

Rapid Prototyping

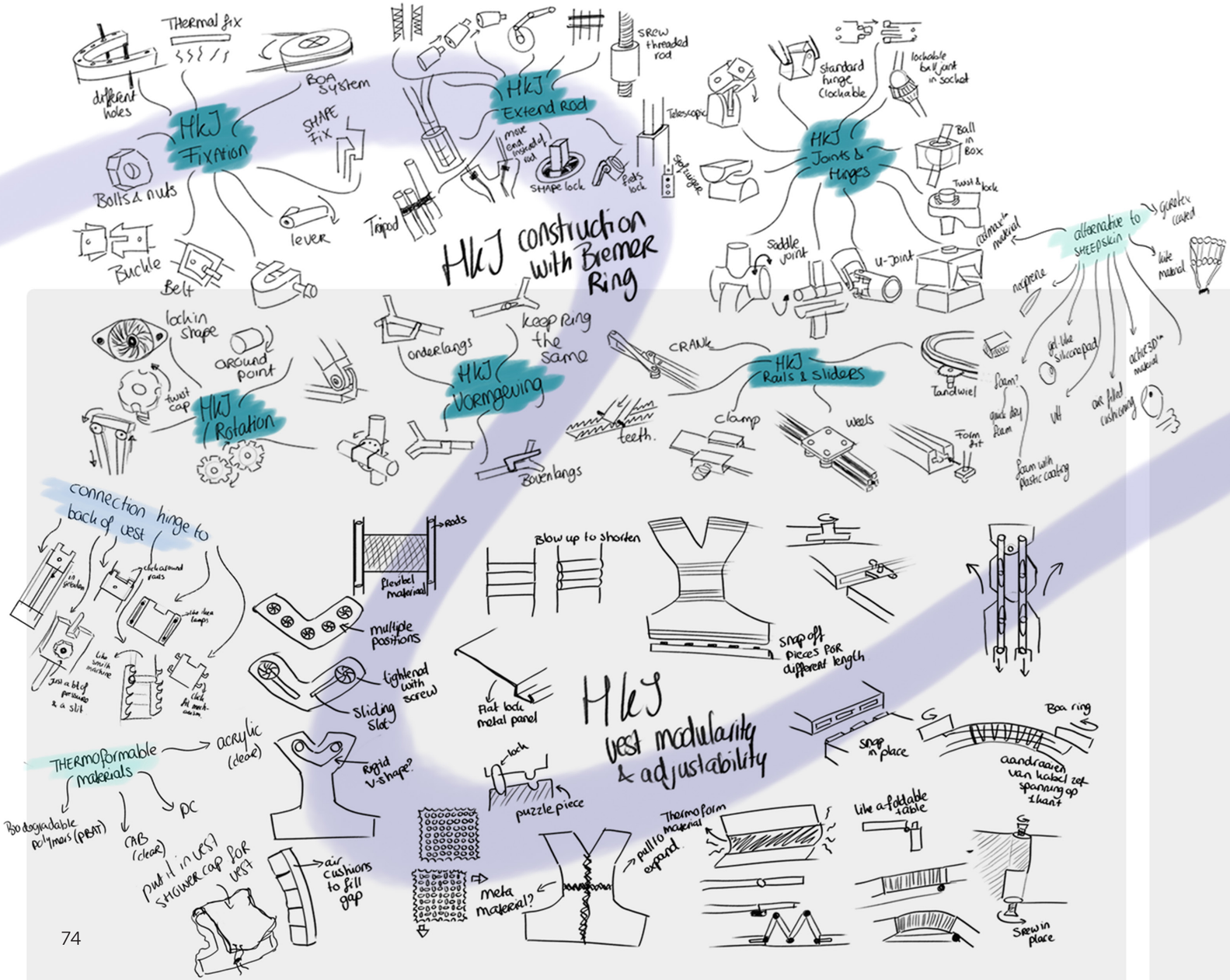
Throughout this process, various physical prototypes were developed using 3D printing, cardboard, and other crafting materials such as pipe cleaners. The figures on the following pages illustrate how pipe cleaners were utilized to explore the ergonomics of different shapes. 3D printing facilitated the creation of tangible representations of proposed design concepts, allowing them to be tested in real-world scenarios. This approach enabled rapid evaluation of what elements were effective and which required adjustments, supporting quick iterations. For instance, a more curved bar was added to the back and sides of the device to achieve a streamlined appearance.

Rapid CAD Models

Rapid CAD modeling was used to test mechanisms and check how components behaved under specific constraints. By creating simple digital models, it was possible to simulate movements, check alignments, and see if parts interacted as expected. This helped make small adjustments to the design and evaluate ideas before moving to physical prototyping.

This approach was useful because it helped identify potential issues early on, which reduced the need for unnecessary physical tests. It also provided a way to visualize and refine mechanisms to ensure they worked within the given constraints. Using CAD models made the design process more practical and allowed for better preparation before building prototypes.

Mindmaps



Sketches

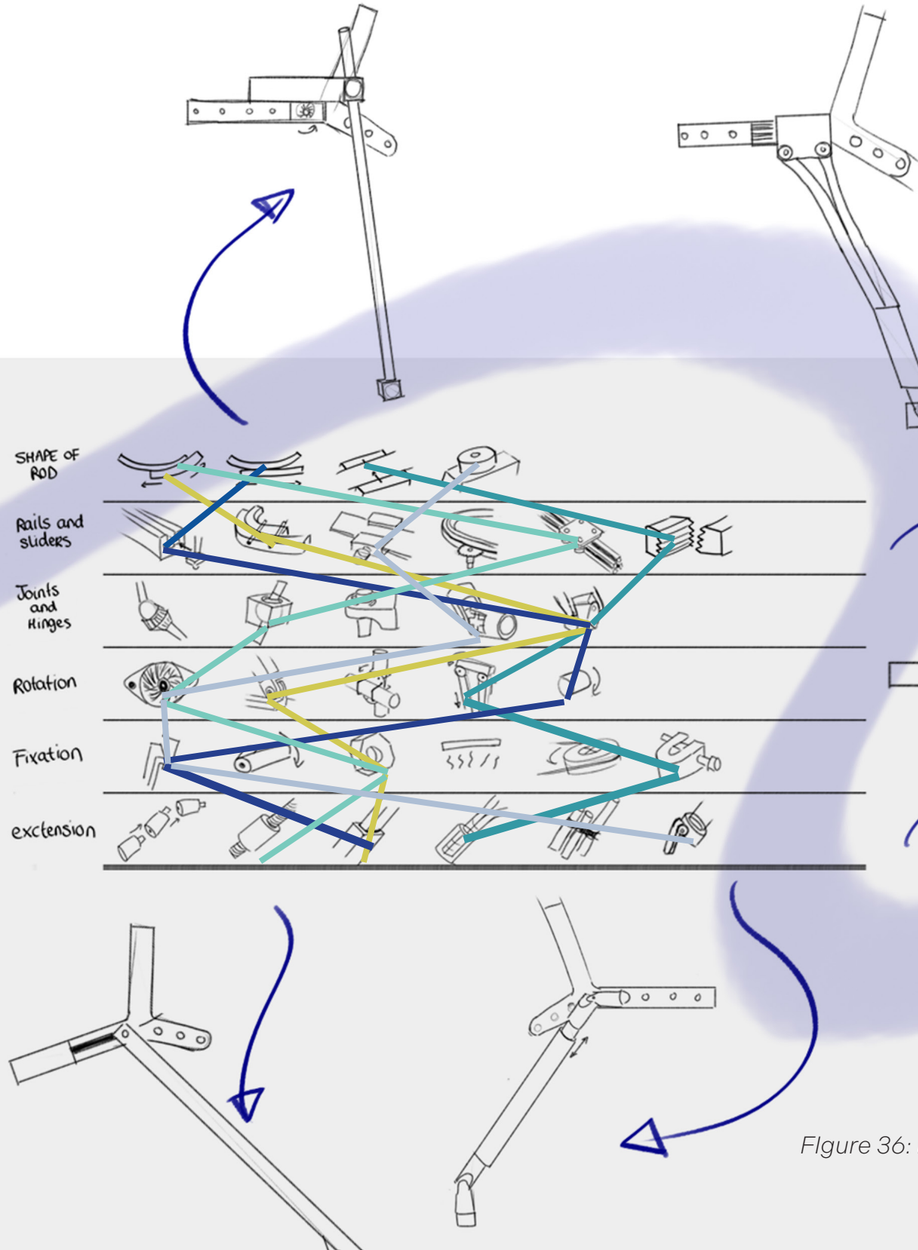
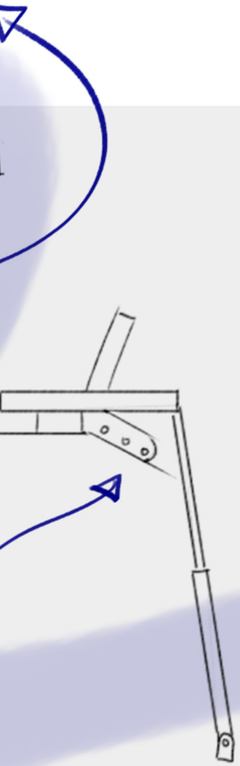
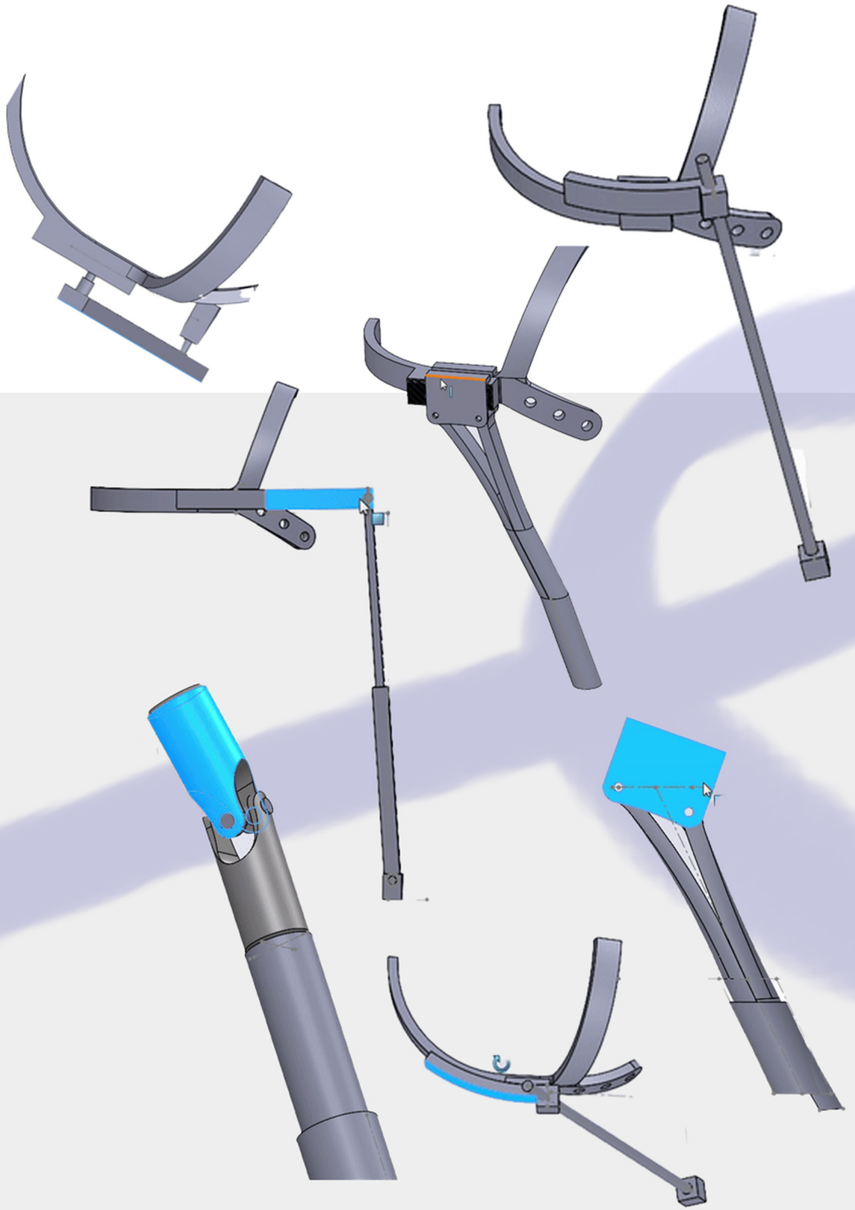


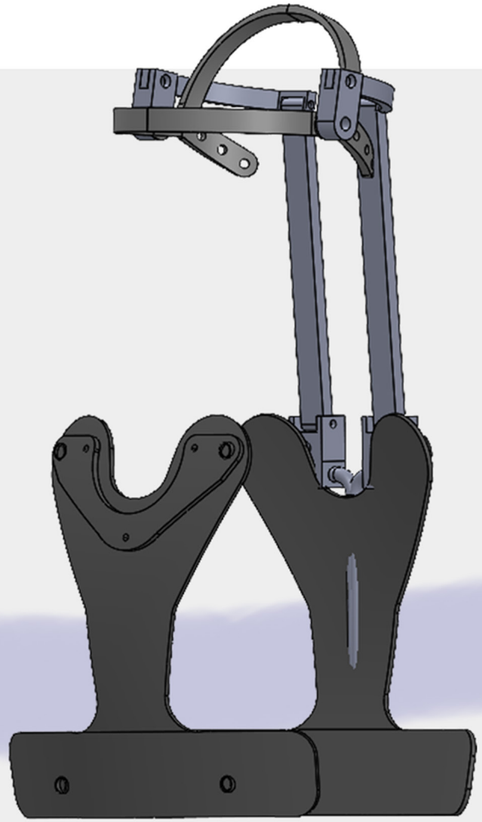
Figure 36: Id

Prototypes



eation Process





Conceptualisation

This chapter focuses on the conceptualization phase, which builds on the ideas developed during the ideation process. It begins with a summary of the main directions that came out of the ideation phase, highlighting the ideas selected for further exploration. One specific concept direction will be examined in more detail, with a proof of concept provided to explore its potential.

The chapter will also outline the process of designing a single concept device by combining elements from different concept directions. To ensure the concept can be evaluated effectively, a set of clear and measurable requirements will be defined. These requirements will guide the testing and refinement of the design in later stages.

Evaluation and Selection

Before starting the test, it was important to reduce the number of ideas to a smaller group, as it was not possible to test all ideas within this project. Several factors helped decide which ideas to keep:

- The feasibility, desirability, and viability of the idea.
- Alignment of the idea with the project's defined scope.
- Input from discussions held with the team at UMCU.

This process led to five concepts being chosen for testing. The next chapter will explain the user test in detail. These concepts address aspects such as look and feel, complexity, rigidity, and bulkiness. Figure 37-41 provides a summary of the selected ideas. The following sections will explore each idea in detail, explaining how it was developed during the ideation phase and the rationale behind it.

Concept directions

Each concept provides a different way of achieving the translations needed to make the structure size adjustable. These directions also focus on pulling the structure further back, meeting the need for a less intrusive design. Rigidity has not yet been fully addressed at this stage, but research into these specific mechanisms suggests that they can be made rigid with some adjustments. The basic structure remains consistent across all concepts.

Concept 1

Concept 1 uses ball joints and a slider mechanism to provide adjustability. The ball joints are placed at key points to allow movement in different directions, making it easier to fit various user anatomies. The slider mechanism enables linear adjustments to the structure, ensuring the size and positioning can be modified when needed.

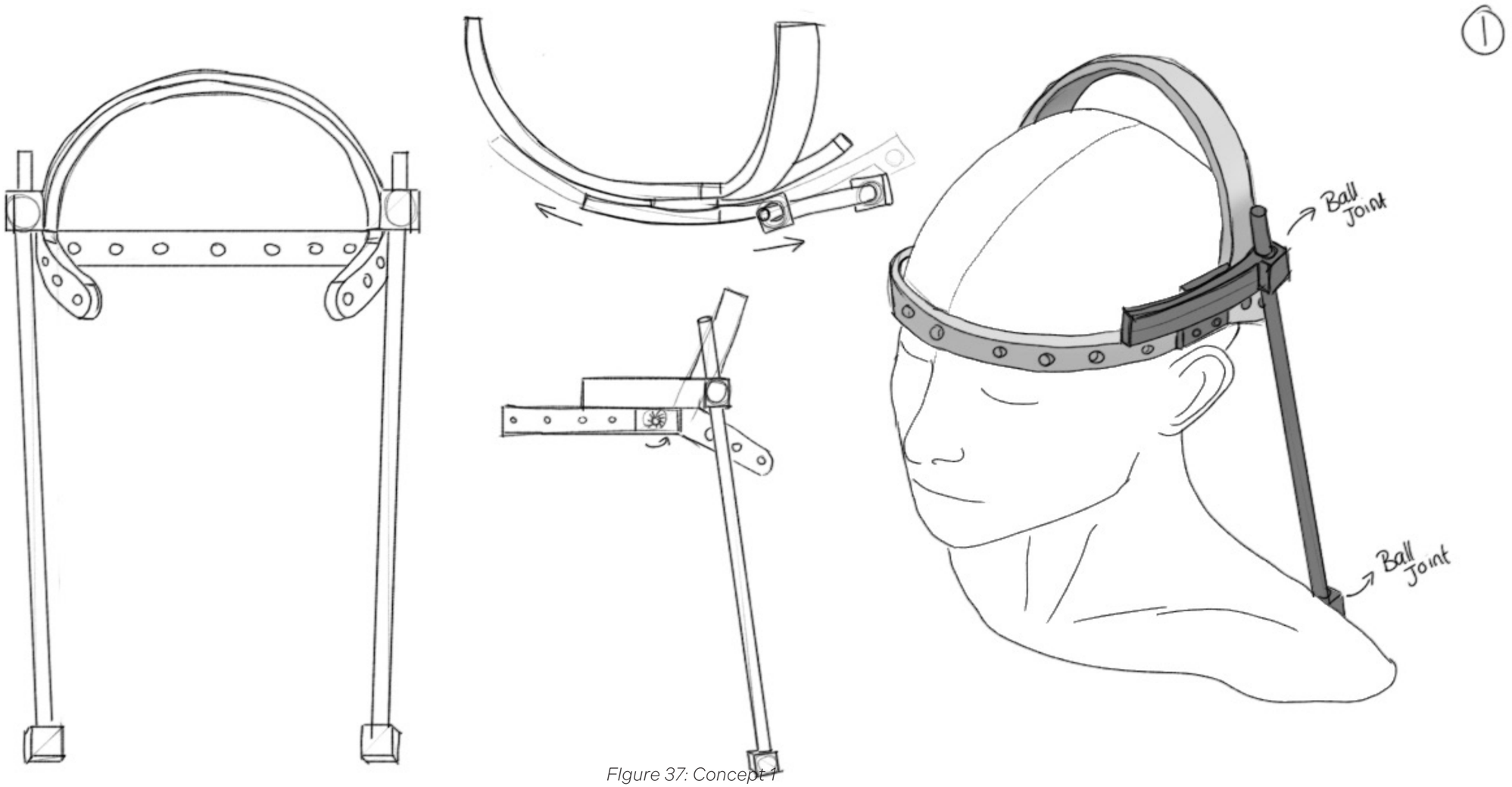


FIgure 37: Concept 1

Concept 2

Concept 2 is inspired by the design of a race bike saddle, using a clamping mechanism to hold the Halo ring by wrapping around its sides. This ensures a secure connection while keeping the structure compact. An extending part is included to allow for size adjustments, making it suitable for a range of users.

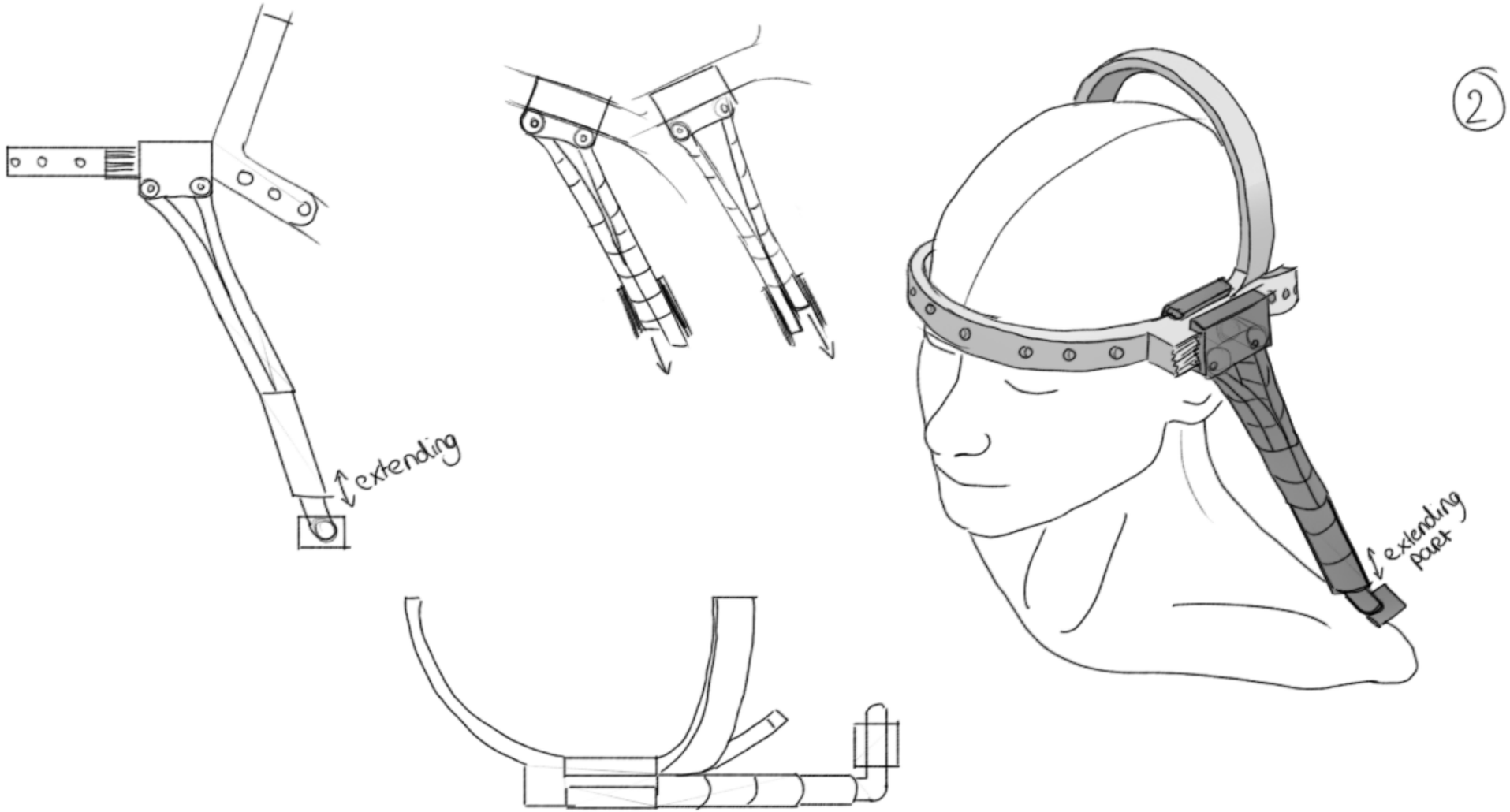


FIgure 38: Concept 2

Concept 3

Concept 3 uses two sliding mechanisms to allow for the necessary translations. One slider is positioned at the back and the other at the side, enabling adjustments in multiple directions.

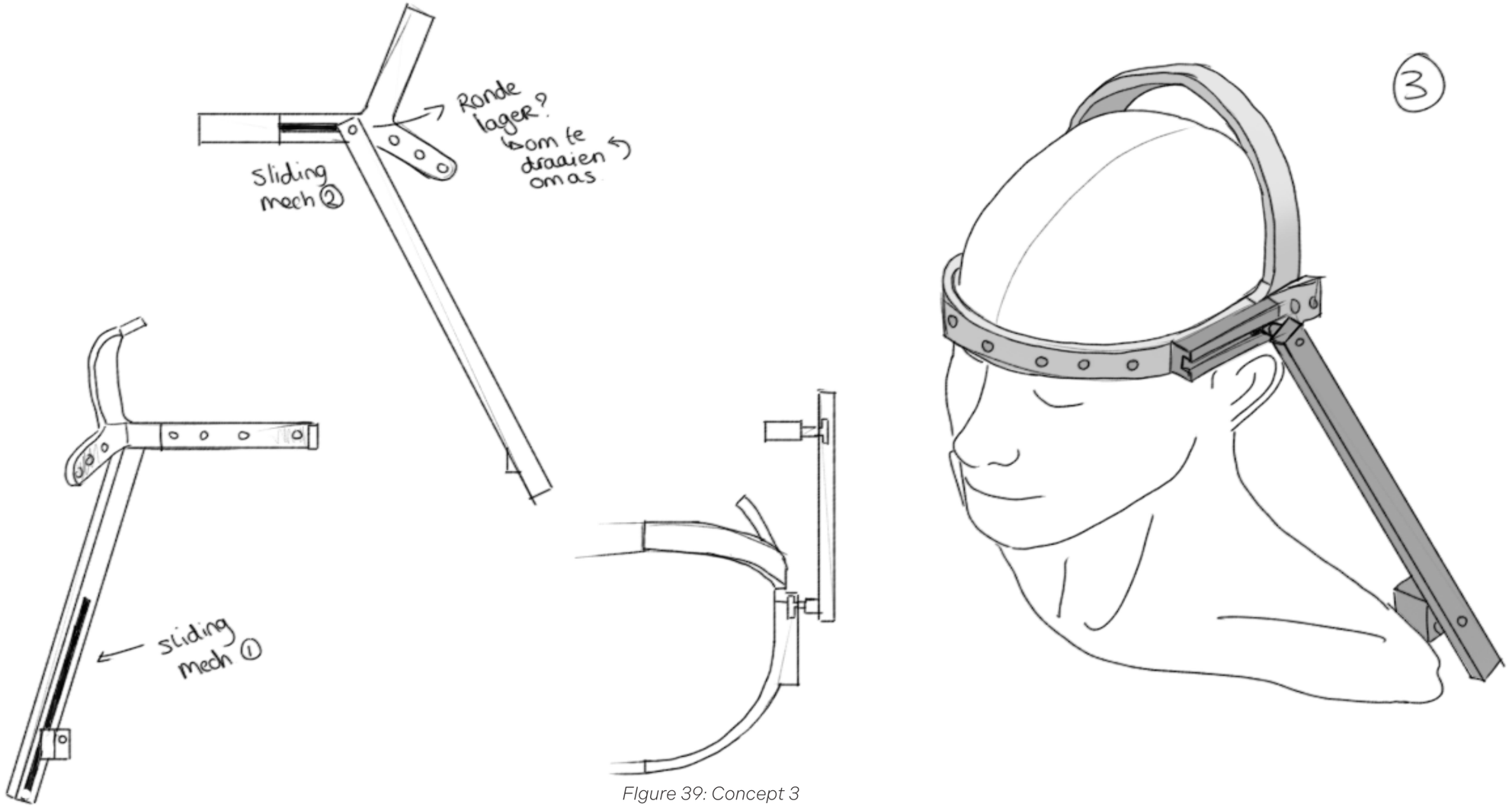


FIgure 39: Concept 3

Concept 4

Concept 4 uses either ball joints or U-joints to provide rotational adjustability. These joints allow for smooth alignment and flexibility in the structure. The concept also includes an extending part to make size adjustments possible. T

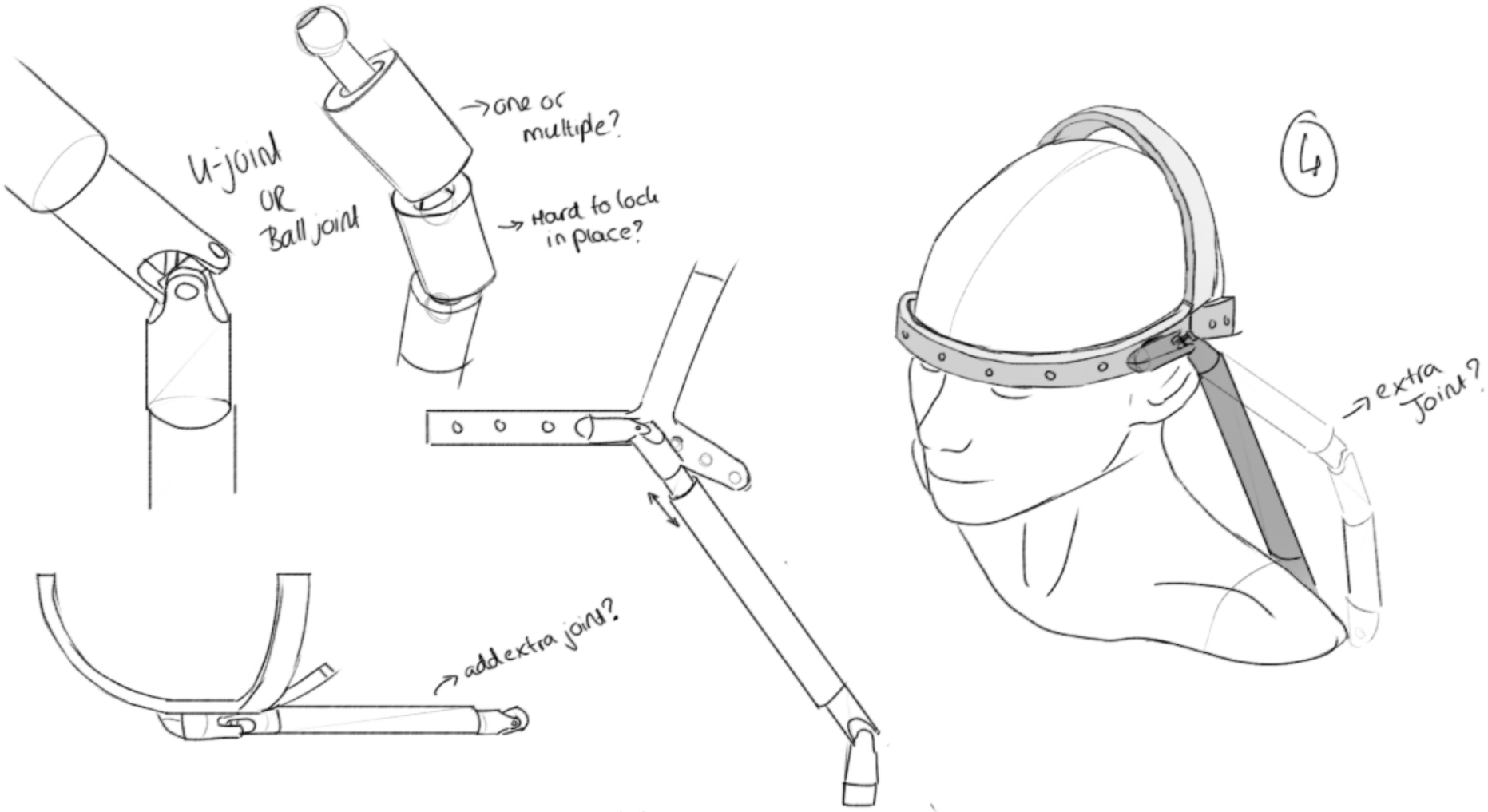


FIgure 40: Concept 4

Concept 5

Concept 5 is shaped to fit smoothly around the head, ensuring a comfortable fit. It uses a slider mechanism to achieve the required translations and regular friction hinges for controlled movement. These elements make it easier to adjust the frame while keeping it stable and straightforward to use

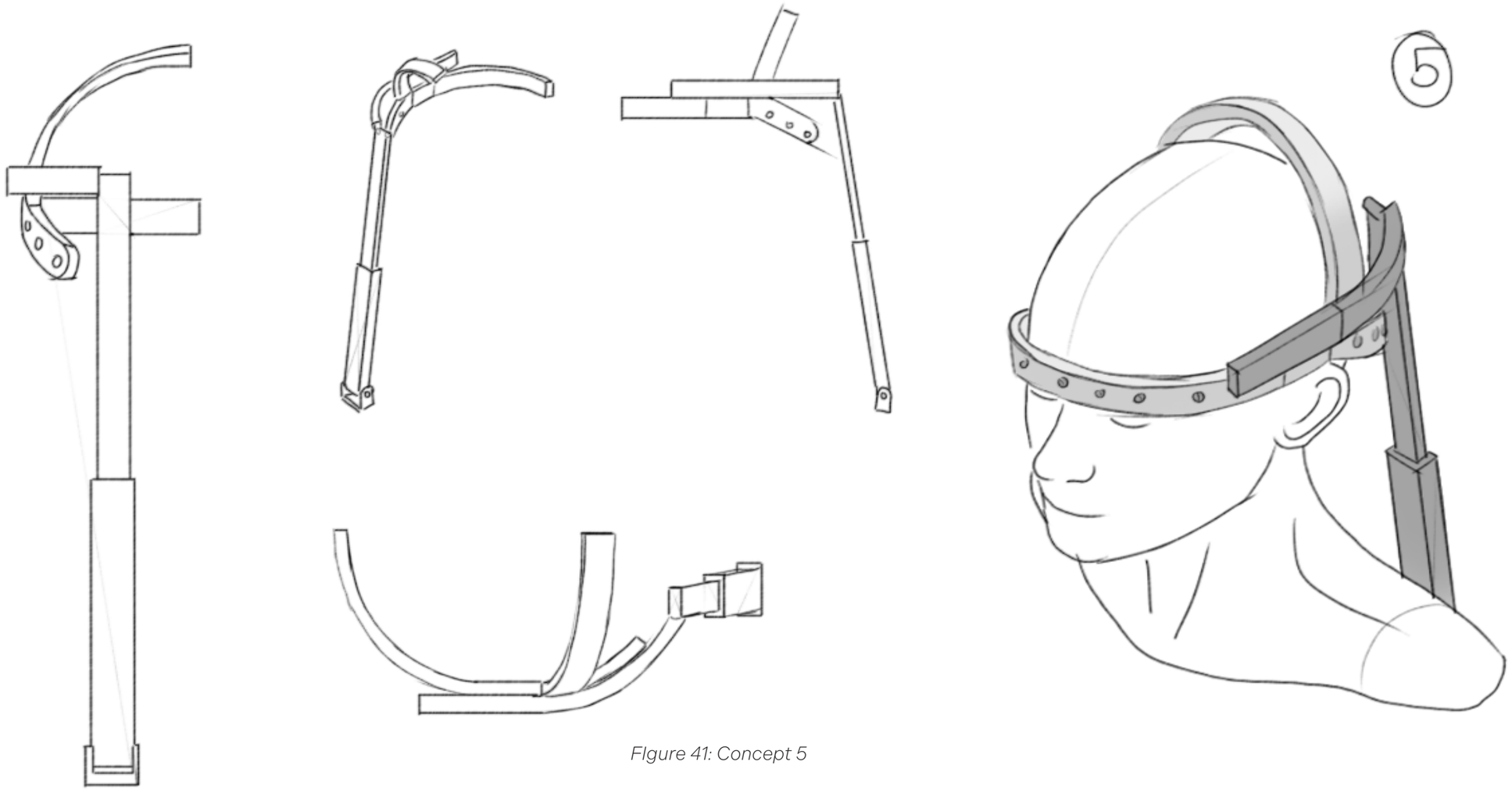


FIgure 41: Concept 5

User test: Appearance, comfort and usability

Testing design sketches with users.

To gather feedback on the proposed design concepts and compare them to the original Halo frame, a survey was conducted. Seventeen people participated, providing input on how the concepts were perceived in terms of appearance, comfort, and usability. Each respondent rated the following aspects for each concept, as well as the original design:

1. Aesthetics: How visually appealing is the concept?
(1 = Not appealing, 7 = Very appealing)
2. Look and Feel: How comfortable and intuitive does the concept seem?
(1 = Not comfortable, 7 = Very comfortable)
3. Dauntingness: How intimidating or overwhelming does the concept feel?
(1 = Not intimidating, 7 = Very intimidating)

These criteria were selected to evaluate the visual and practical aspects of each design. The original design was included to provide a baseline for comparison, giving context to the responses for the new concepts.

Participants were also asked for suggestions to improve the frame and to indicate which design they preferred. The results showed that Concept 2 was the most preferred, with Concepts 4 and 5 following as second and third..

Using this feedback and considering what is structurally possible, elements from all the concepts were combined into a final design. Features from Concepts 2, 4, and 5 were most prominent in the final design, as they reflected the preferences expressed in the survey while aligning with the design's practical needs. The full survey and the respones can be found in Appendix U. In figure 42 it is shown which design is preffered.

We are looking for a concept that is:
1. Visually appealing
2. Looks comfortable
3. Does not look intimidating or overwhelming.
Knowing this, which concept is your favourite?

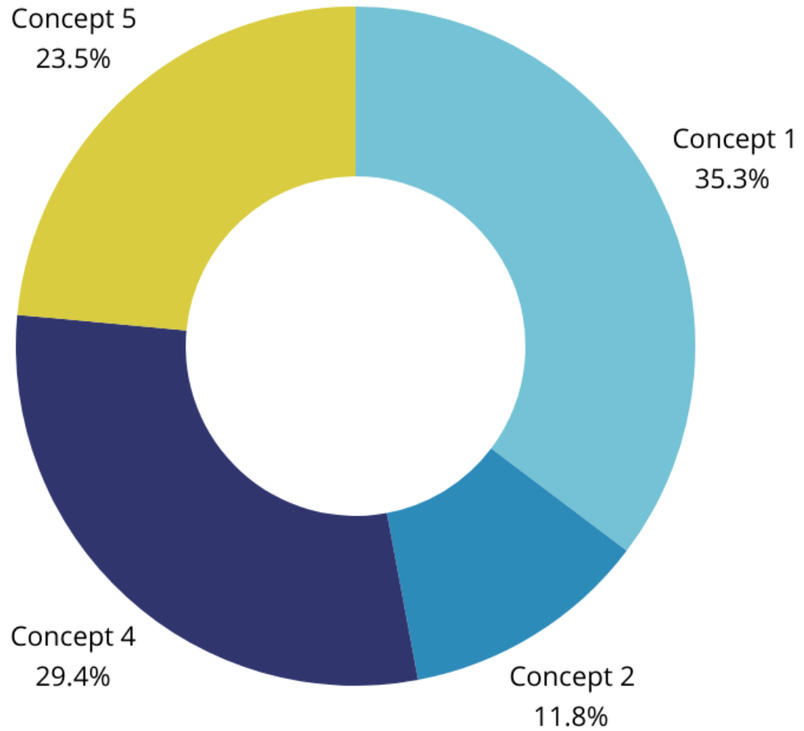


FIgure 42: Survey Responses

Proof of Concept

Mechanical strength – FBD

To assess the feasibility of the two-beam concept for the Halo frame, an overview of alle forces on the head was created as a first step. This image incorporates forces recorded in the study by Walker et al. (1984), which identified critical thresholds for stability: 177 N vertical, 126 N anterior-posterior, and 148 N mediolateral. These forces represent essential criteria that the new vest design must accommodate. Additionally, findings from Snijders et al. (2018) suggest that the neck muscles can generate a downward force up to three times the weight of the head. This value was included as an additional downward force, combined with the gravitational weight of the head, to represent realistic loading conditions for when the person tilts their head forward. The maximim angle a person can tilt their head, is 60 degrees.

The analysis focused primarily on the forces at the front of the Halo, as this scenario represents the least supported position in a two-rod structure. Such conditions would likely result in the largest deformations, providing critical insights into the limitations and challenges of the design.

In figure 43, an FBD can be found of this situation without the halo frame. The halo frame should be capable of counteracting the forces that are normally generated by the head during movement.

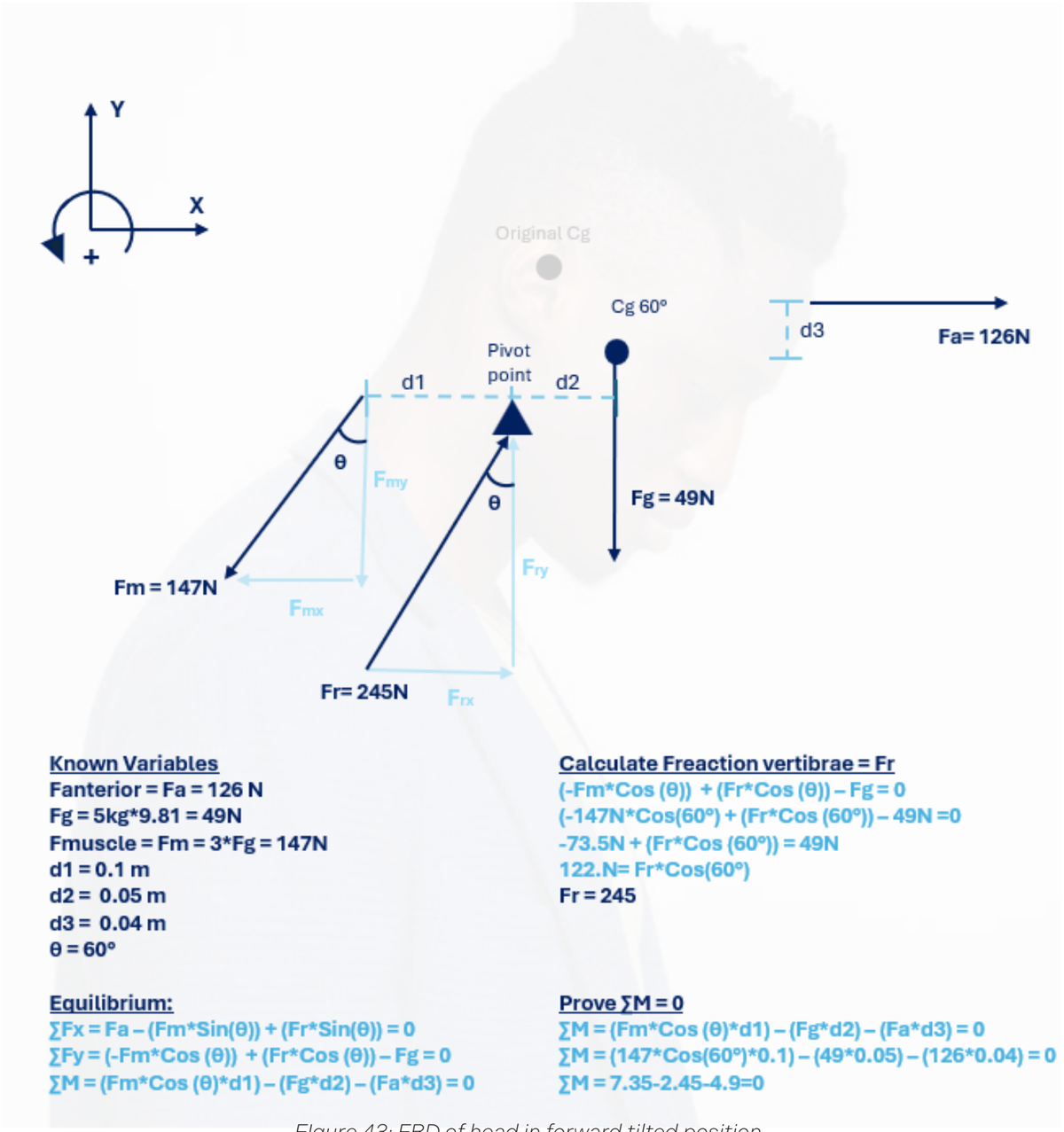


FIgure 43: FBD of head in forward tilted position

Movability in healing

In spine stabilization, allowing controlled micromovements rather than enforcing complete rigidity may support the healing process. According to Professor Verlaan (2024), controlled micromovements can promote the biological processes necessary for recovery. These movements provide mild mechanical stimulation to the bones, which helps maintain their strength and supports proper healing. Similar findings have been observed in knee orthoses, where controlled micromovements help prevent stiffness and encourage tissue regeneration (Janssen et al., 1996).

The case report on knee orthoses illustrates that low-intensity, consistent forces applied over time can promote gradual tissue elongation and improve mobility. This highlights how controlled mechanical stresses can aid in tissue adaptation and recovery.

Applying this principle to spine stabilization suggests that incorporating limited, controlled movement—within safe boundaries—could assist spinal tissue healing. This approach might help prevent stiffness, improve circulation, and support the recovery process in a way comparable to the benefits observed in knee orthoses. It is important to note that this assumption was made in consultation with Professor Verlaan.

Complete rigidity in stabilization can have unintended consequences. Without movement or loading, bones may weaken over time due to a lack of mechanical stimulation (Steinberg, 1980; Rolvien & Amling, 2021). This effect is seen in astronauts who experience bone density loss during extended periods in microgravity. Similarly, rigid immobilization of the spine could hinder healing by failing to provide the mechanical signals required for bone remodeling and maintaining strength.

By designing a stabilization structure that allows small, controlled movements, it is possible to balance stability with flexibility. This approach supports the spine while encouraging biological recovery. Controlled movement prevents bone weakening and aligns with the body's natural healing processes, creating a supportive environment for effective recovery.

Quantifiable deformations

The next step in the process was to quantify micromovements into measurable values that could be used to test the design concepts. Since there was no direct research or data available specifically for this application, some assumptions were made based on the study by White et al. (1975), which provides useful values related to cervical spine stability and movement.

The study outlines key thresholds for cervical spine instability:

- Horizontal displacement exceeding 3.5 mm between vertebrae, measured on lateral radiographs during flexion-extension, indicates instability.
- Angular displacement beyond 11° between adjacent vertebrae also suggests instability.
- Under normal physiological conditions, horizontal displacement is limited to 2.7 mm. Displacement beyond this is considered abnormal and requires external stabilization to prevent neurologic damage.

These findings align with data from Snijders et al. (2018), which provides additional insights into angular displacement. In Snijders' book, the angular displacement of individual vertebrae is detailed. The average of these values corresponds closely with the thresholds outlined in White et al.'s work, reinforcing the use of these thresholds for guiding the design process.

Using these values, the design must allow micromovements that stay within the normal physiological range while ensuring that the structure prevents displacements near the instability thresholds. Specifically:

- The design should limit horizontal displacement to 2.7 mm or less to allow natural movements without risking instability.
- Similarly, angular displacement must remain below 11°, restricting abnormal motion but still permitting small, controlled movements.

These values were translated into design criteria for testing the concepts. The goal is to ensure the designs provide enough flexibility for micromovements that support recovery, while also preventing excessive movement that could compromise spinal stability.

In Figure 44 is shown how angular and horizontal displacement is measured in the work of White et al. In their method, displacement is calculated by comparing the position of a vertebra relative to the one below it. In our approach, we will measure displacement by comparing the position of the same vertebra to its original state before movement. This method simplifies the measurement process while also providing a built-in safety margin.

Since we are not comparing vertebrae directly to one another, the actual displacement between vertebrae in our method will be smaller than what is recorded. However, if the values in our measurements remain below 2.7 mm for horizontal displacement and 11 degrees for angular displacement, the actual intervertebral displacements will fall well within these limits when calculated using White et al.'s approach. This ensures both simplicity in measurement and an added layer of conservatism in evaluating stability. If the designs do not match this threshold with safety margin, then we will look into the more complex measuring method as demonstrated in White et al. to get the exact horizontal displacement in the spine.

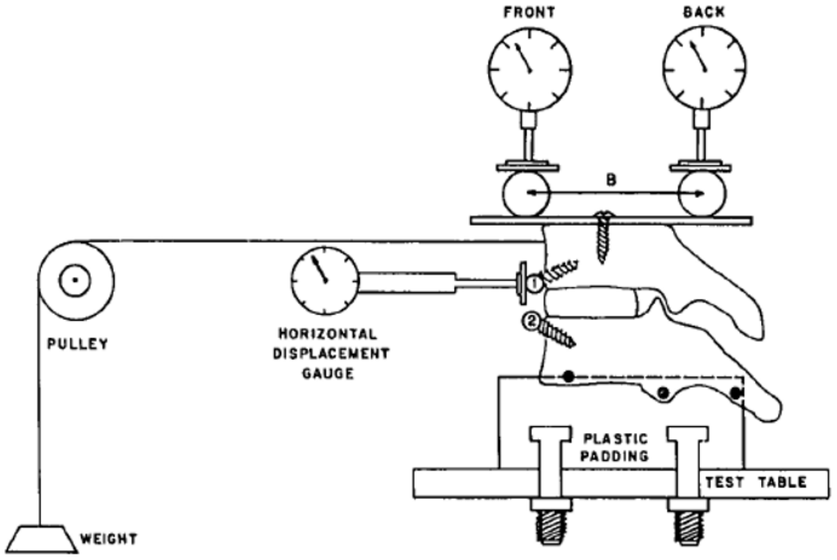


FIG. 1. Diagram of motion segment fixed on test stand.

FIgure 44: Testsetup in paper of White et al. (1975)

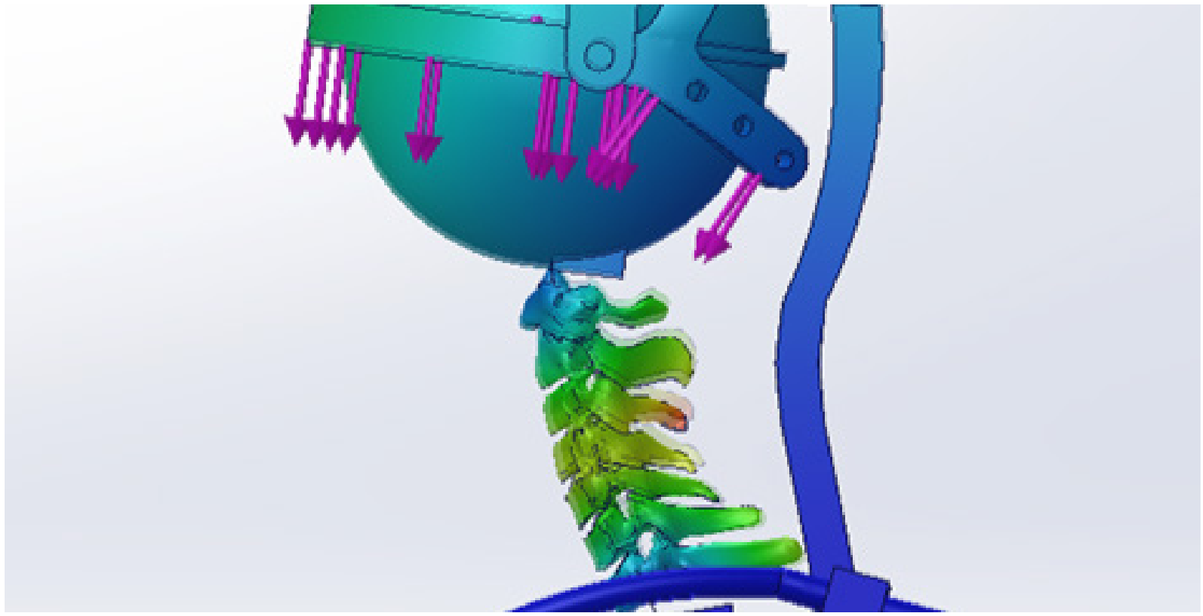


FIgure 45: Deformation in the spine

Mechanical strength – proof of concept using FEA Analysis

To assess the feasibility of the two-beam concept, it was important to quickly and efficiently evaluate whether the deformation would remain within a reasonable range before committing to building a detailed model. A simplified approach was taken by constructing a structure that represented half of the current frame. This method allowed for an initial assessment of the deformation and, more importantly, the relationship between the thickness of the back beams and the resulting deflection. The connection pieces currently available on the market were assumed to be sufficiently strong, as they have been proven reliable in the original design. This assumption allowed the focus to remain on the performance of the two-beam concept.

This simplified model, shown in Figure 46, provided a practical way to examine the concept without unnecessary complexity. With a back beam thickness of 20 mm, the deflection was found to fall within the range of the thresholds that are introduced in the next chapter. This alignment with the expected limits demonstrated that the concept was promising, and therefore the proof of concept was accepted and further explored. By taking this approach, it was possible to efficiently validate the idea and lay the groundwork for its development.

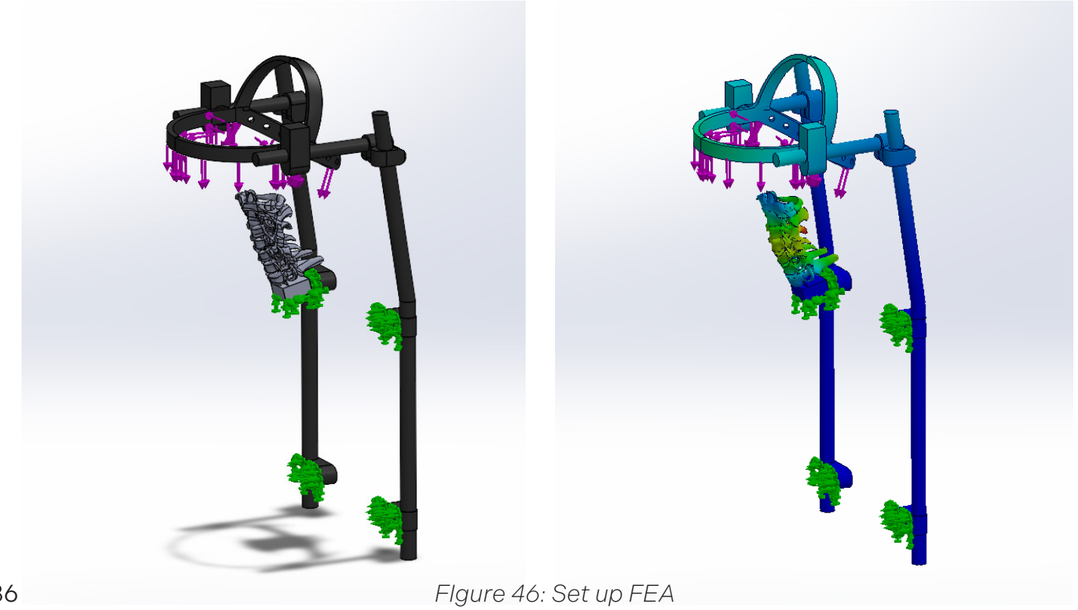
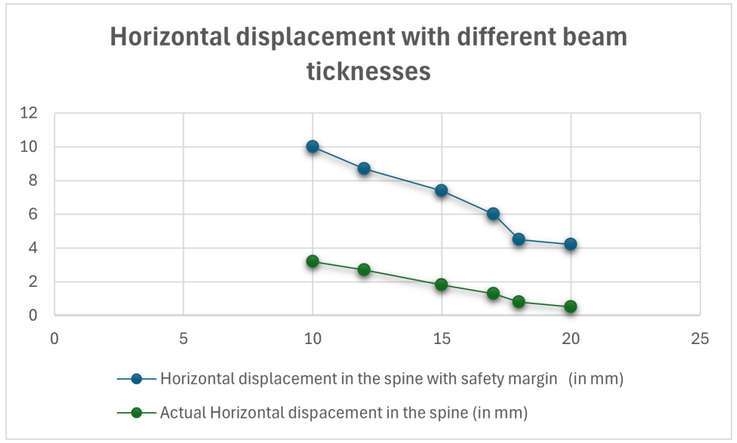


FIgure 46: Set up FEA



Beam thickness (in mm)	Horizontal displacement in the spine with safety margin (in mm)	Actual Horizontal dispacement in the spine (in mm)
10	10	3,2
12	8,7	2,7
15	7,4	1,8
17	6	1,3
18	4,5	0,8
20	4,2	0,5

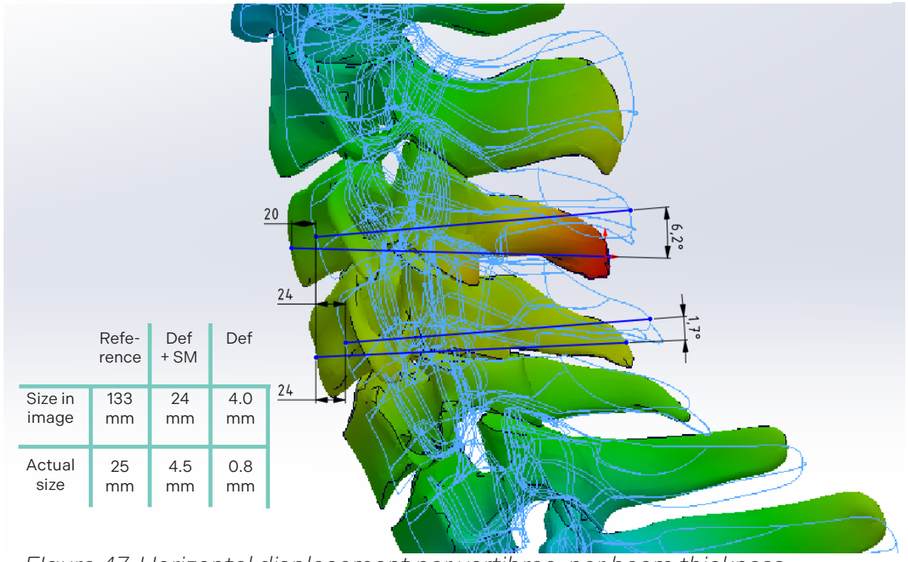


FIgure 47: Horizontal displacement per vertibrea, per beam thickness

Choosing concept: Decision Matrix

The final concept direction was not determined using one specific method. Instead, it was developed through an iterative process of adding and removing elements to find a solution that was simple to produce, not overly complex, provided reliable stability, and allowed for the necessary translations. The final design took inspiration from all five initial concepts, combining different features and ideas to create a balanced and effective solution.

This process was based on a series of assumptions informed by discussions with experts, including orthopedic specialists, engineers, and other involved parties. These conversations offered practical insights into the design requirements, such as manufacturability, usability, and safety. By drawing on this expertise, the adjustments made during the process were grounded in real-world considerations.

Aesthetics were also an important consideration during this process. The design was evaluated for how well the structure could be concealed, aiming to make it less intrusive and more visually acceptable for users. This added an additional layer of complexity to the process, as adjustments needed to maintain functionality while improving the overall appearance.

Several factors were considered during this process:

- Ease of Production: Ensuring the design could be manufactured efficiently without requiring overly complicated techniques.
- Simplicity: Avoiding unnecessary complexity to reduce potential issues during assembly or use.
- Stability: Ensuring the structure could provide consistent support under expected conditions.
- Translations: Verifying the structure could make the adjustments needed to fit different patient anatomies.
- Aesthetics: Exploring ways to conceal the structure, making it more visually appealing and less intrusive for users.

The final design reflects the strengths of all five concepts, integrating the most effective elements from each into a one structure.

Chosen Concept

The final concept brings together elements from all the initial sketches, resulting in a design that balances functionality, usability, and user comfort. The structure is primarily supported from the back, with the design focusing on minimizing the visual impact of the front elements while ensuring stability and adjustability.

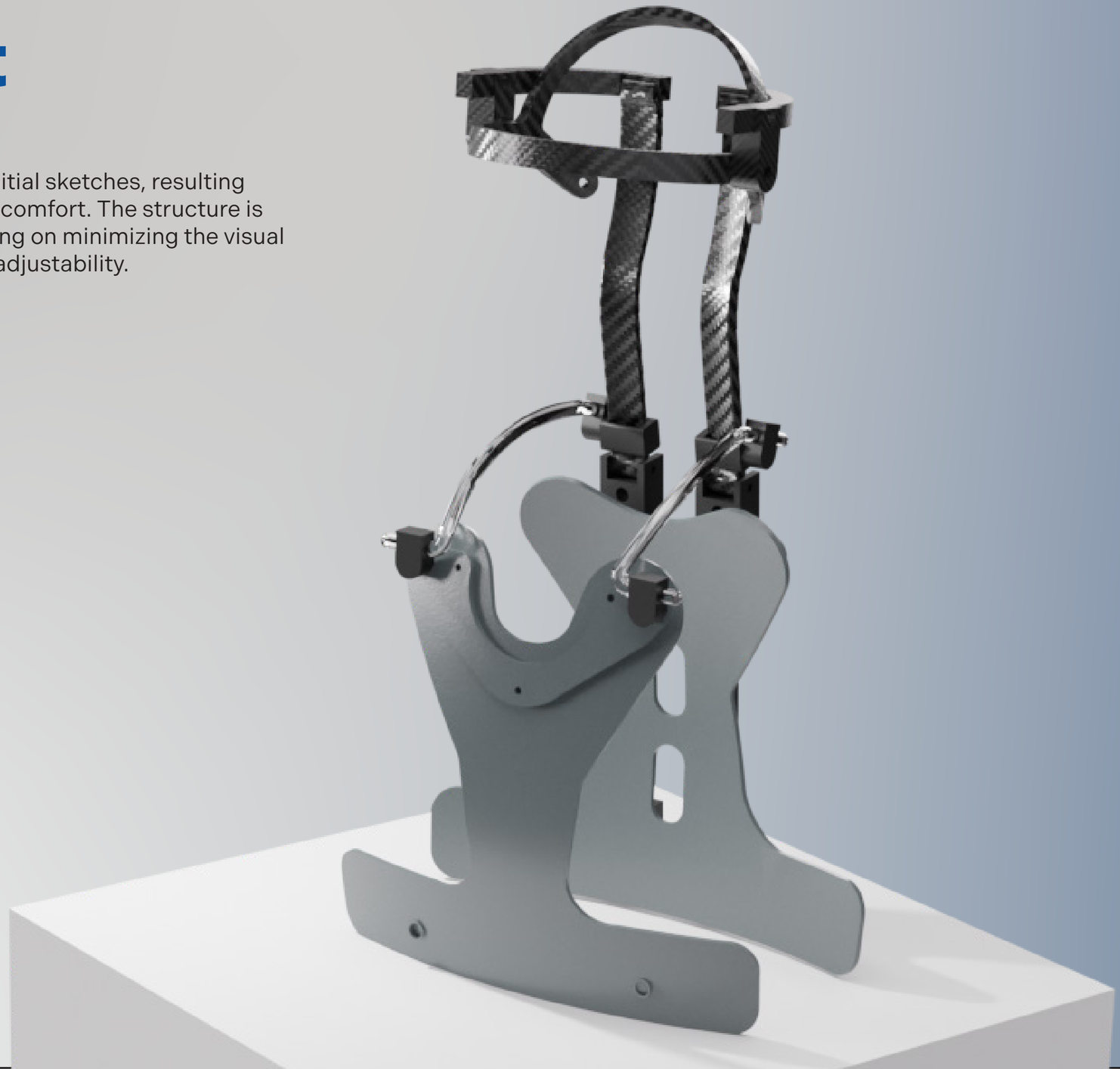


FIgure 48: Re-Design

Back Rod Design and Adjustments

The back rods are made slightly larger and constructed from carbon fiber, chosen for their strength and durability. These rods are curved to follow the shape of the head and neck but do not touch the patient to prevent pressure points or bedsores. To improve comfort during rest, a pillow can be strapped around these rods using Velcro, relieving some of the weight of the head while sleeping.

The back rods are adjustable in length, with an extension range of approximately 10 cm, reflecting the adjustability found in the original frame. They connect to the vest at two points using friction hinges. This dual connection helps counteract the moment created at the first hinge, ensuring better stability. The use of friction hinges simplifies the design, offering reliable movement without adding unnecessary complexity.

FIgure 49: Re-Design

Front Rod Design and Repositioning

Initially, the front rods were removed from the design. However, further discussions highlighted their importance in limiting the “wiggle space” for the user. Since the front rods no longer bear significant loads, they are made from transparent acrylic to reduce their visual presence.
The rods are repositioned closer to the shoulders instead of being placed alongside the head. This adjustment allows users to wear regular clothing, such as t-shirts, over their heads, making the rods less visible and more practical for daily use.

In the context of the Halo frame, the front rods play a crucial role in providing rigidity against the torsional forces generated during axial rotation. Without the front rods, the two back rods alone would lack sufficient lateral support to counteract this twisting motion. Positioned behind the head, the back rods would experience increased torsion and likely deform or twist under the load, reducing the frame’s overall stability. By including the front rods, the structure gains additional support in the anterior-posterior plane, effectively bracing against the rotational forces and reducing the risk of instability.

The inclusion of the front rods also changes the structural geometry of the frame. Together with the back rods and the vest, the front rods form a triangular configuration. This triangular shape is inherently stronger and more resistant to deformation compared to the U-shaped structure found in the original design. The triangle distributes forces more evenly, preventing twisting or flexing of the frame during axial rotation.

FIgure 50: Re-Design

FIgure 51: Re-Design

Horizontal Rods and Hinges

On the sides of the head, the concept uses two curved horizontal rods instead of straight ones. These rods are designed to follow the shape of the head and can be adjusted by sliding them along rails. Once positioned correctly, they are secured using screws. The horizontal rods have an extension range of approximately 5 cm, aligning with the adjustability of the original frame.

The horizontal rods are connected to the back rods with friction hinges. These hinges were chosen for their simplicity and ability to provide smooth adjustments. Friction hinges are available in configurations capable of supporting loads up to 30 kilograms, which ensures they meet the stability requirements of the design. This assumption is based on the performance of similar hinges in existing applications.

Comfort and Simplified Mechanisms

To keep the design straightforward, friction hinges were used throughout instead of more complex mechanisms like ball joints. While ball joints offer more degrees of freedom, they also introduce challenges in strength analysis and stabilization that are unnecessary for this application. By opting for friction hinges, the design ensures ease of use and reduces potential complications.

Stability and Aesthetic Considerations

The final design incorporates aesthetic considerations to make the structure less intrusive. Transparent acrylic rods and repositioned front rods contribute to a cleaner, less noticeable appearance. At the same time, the use of dual vest connections and carefully placed hinges ensures stability under normal use..

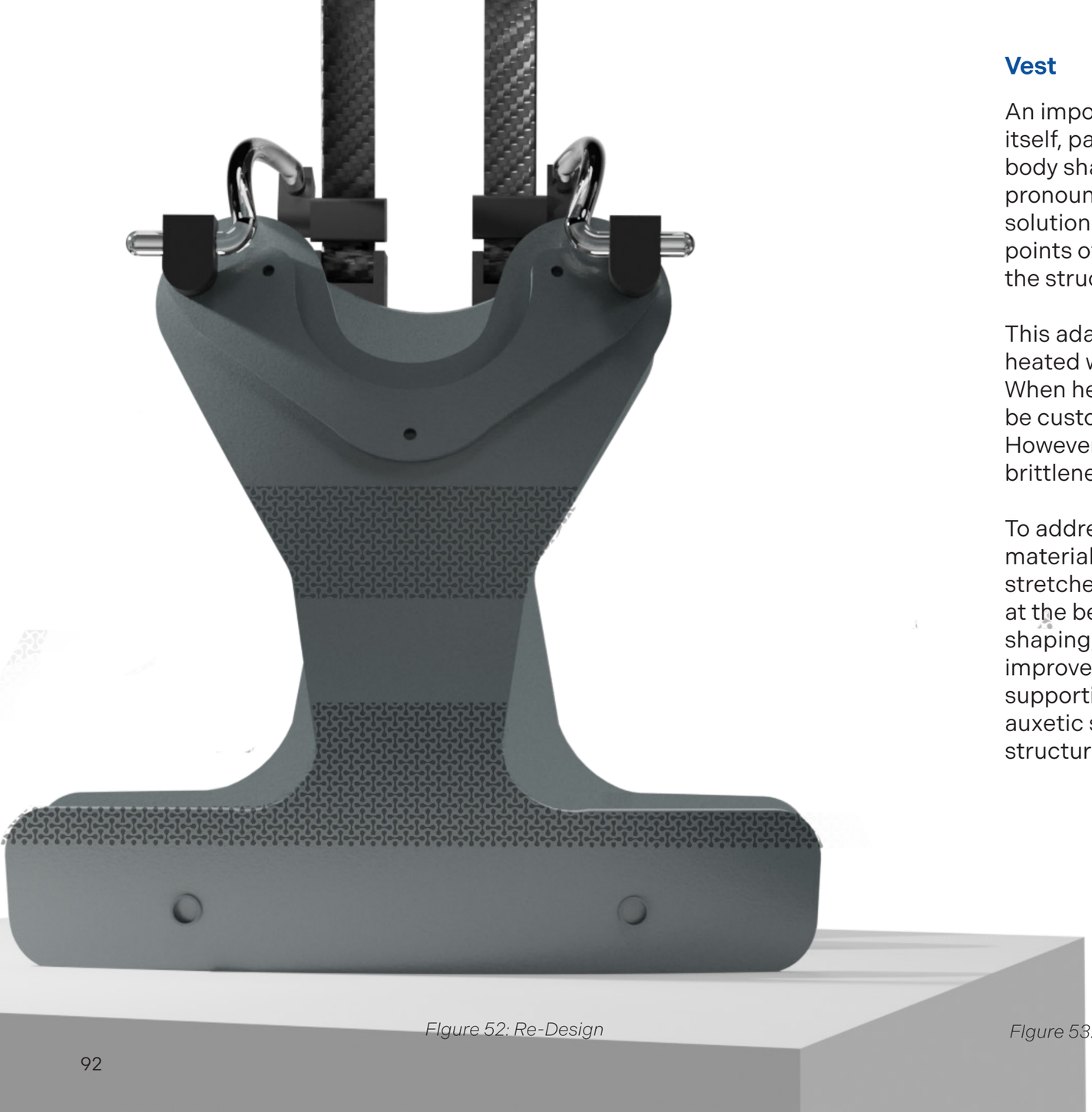


FIgure 52: Re-Design

Vest

An important request from the orthopaedic technicians was to make the vest itself, particularly the plastic structure, more adaptable to accommodate different body shapes. Some individuals have a higher sternum, while others have a more pronounced belly, requiring adjustments for a better fit. In the discover phase, a solution was proposed to address this by incorporating a bendable material at key points of the vest. After bending, the material should become rigid again to provide the structural support needed and hold its position.

This adaptability can be achieved by using a material at these points that can be heated with a heat gun, a tool already widely used by technicians in the plaster room. When heated, the material becomes flexible and easy to shape, allowing the vest to be customized to the patient's anatomy. Once cooled, the material regains its rigidity. However, a common downside of such materials is that repeated heating can cause brittleness, and stretching during shaping can lead to thinning in certain areas.

To address these issues, the use of auxetic structures can be beneficial. Auxetic materials, which have a negative Poisson's ratio, expand perpendicularly when stretched rather than thinning out. Incorporating a 3D-printed auxetic structure at the bending points ensures that the material maintains its thickness during shaping, avoiding weak spots and brittleness after cooling. This structure also improves durability and strength at these critical points, allowing the vest to remain supportive while still being adjustable. By combining heat-malleable materials with auxetic structures, the vest can be made more adaptable without compromising its structural integrity.

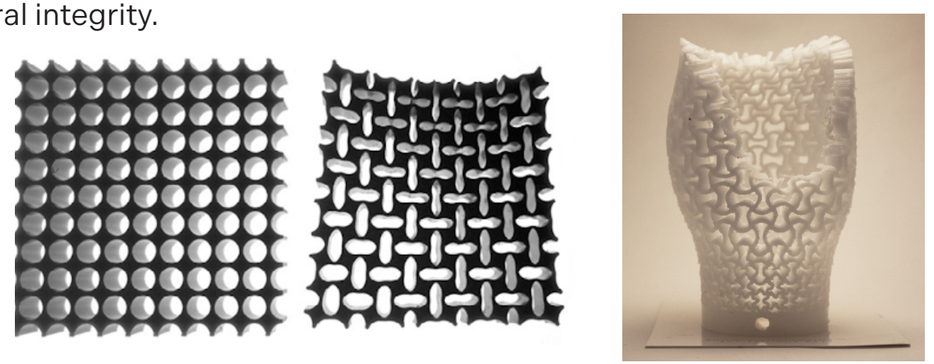


FIgure 53: Heat Actuated Auxetic Facades (Abdel rahman, 2015) and The use of Heat activated auxatic materials in a prosthetic socket (Snijder, 2017)

Lining

A gel-filled silicone material could be a choice for replacing the fur lining in the Halo vest, as it offers several benefits that align with the requirements. In appendix R, an overview of other possibilities can be found, however, gel-filled silicone pads are deemed most promising.

Benefits of Gel-Filled Silicone:

1. Cushioning and Pressure Distribution:
The gel provides a soft, conforming surface that distributes pressure evenly, significantly reducing the risk of pressure points. Furthermore, Silicone gel is known for its ability to mimic soft tissue, making it ideal for prolonged contact with the skin.
2. Waterproof and Easy to Clean:
Silicone is inherently waterproof and resists absorbing water. This ensures the lining remains functional and hygienic even if it gets wet. Gel-filled silicone can be wiped clean, making it easy to maintain in a clinical or home setting.
3. Skin-Friendliness:
Silicone is hypoallergenic and widely used in medical devices and prosthetics. It is gentle on the skin and unlikely to cause irritation or allergic reactions. Some gel-filled silicone products come with a protective skin-like layer that further enhances comfort and prevents abrasion.
4. Durability:
Silicone gel materials are robust and can withstand repeated use without significant wear. They retain their shape over time, maintaining consistent cushioning.
5. Flexibility:
The material can contour to different body shapes, ensuring a snug and comfortable fit for patients with different anatomies. Besides this, It adapts well to movement, maintaining comfort without compromising support.

There are also potential drawbacks:

1. Weight: Gel-filled materials can be heavier than foam alternatives. To minimize this, use thin layers of gel combined with a silicone shell.
2. Cost: Silicone gel tends to be more expensive. However, its long lifespan and performance benefits often justify the cost.
3. Heat Retention: Silicone can retain heat, which might cause discomfort in warm conditions. Adding small ventilation channels or perforations can address this issue.

A gel-filled silicone material could be a solution for replacing the fur lining. It meets the criteria for cushioning, waterproofing, and skin-friendliness while offering durability and flexibility. If cost and weight are manageable, this material could significantly improve the vest's functionality and user comfort.

FIgure 54: Gel Filled Silicone

Sizing Range in the New Halo Frame Design

The redesigned Halo Frame incorporates a structured sizing system to accommodate different patient body types while maintaining practicality in clinical use. The design achieves this balance by standardizing components into a limited number of adjustable and interchangeable sizes. Each package contains size-specific components as follows:
Components and Sizing
1. Vest:
    - Available in small or tall sizes to fit variations in torso length.
2. Rods:
    - Front Rods: Provided in small or tall sizes.
    - Back Rods: Provided in small or tall sizes.
    - Size Difference in Rods: The difference between small and tall rods is approximately ±5. This adjustment accommodates differences in patient height and overall body proportions.
3. Halo Ring:
    - Available in small or large sizes.
    - Size Difference in the Ring: The large ring has a greater width. To maintain proper alignment, the horizontal curved rods used with the large ring are proportionally longer. This ensures that the back rods stay correctly positioned, regardless of whether a small or tall vest is used.

While offering an extensive range of sizes may seem inclusive, it is not always practical. Hospitals face challenges with inventory management, including limited storage space and logistical complexities in stocking too many variations. A more streamlined approach ensures that patient needs are met effectively while reducing the burden on clinical resources.

Proposed Modular Packaging

To address both patient variability and hospital inventory concerns, the design introduces a modular packaging system comprising three distinct packages:
1. Vest Package:
    - Includes a small or tall vest.
2. Rod Package:
    - Includes all required rods, provided in either the small or tall size.
3.Halo Ring Package:
    - Includes either a small or large halo ring with appropriately sized horizontal curved rods.

This modular system simplifies storage and distribution while allowing hospitals to combine the appropriate components for each patient. The approach reduces unnecessary inventory while maintaining flexibility for diverse patient needs. By grouping components into these three packages, the system achieves a balance between adaptability, efficiency, and ease of use in clinical settings.

New Application Flow for the Updated Design

The new Halo frame design introduces an updated application process that keeps some steps from the original design while making changes to improve how it fits and is assembled. Clearly defining these steps is important to make sure the assembly is consistent and simple for both the patient and the medical team. Below is a description of the new flow and a comparison with the original process.

Updated Application Steps

1. Application of the Halo Ring

The way the Halo ring is applied remains the same as in the original design. All steps leading up to applying the vest are unchanged.

2. Positioning the Patient and Applying the Vest

The patient is placed lying down on a table with the Halo ring already on. One person holds the patient steady while another applies the vest.

3. Attaching the Back Rods and Horizontal Rod.

- The patient is tilted slightly so the back of the vest can be placed under their torso.
- The back rods are loosely attached to the vest to allow adjustments during assembly.
- With the patient lying flat, the horizontal rods are connected to the back rods and lightly screwed into place. The horizontal rods are then attached to the Halo ring.
- The horizontal rods are tightened first, followed by the back rods, to ensure everything is in the correct position.

4. Attaching the Front Rods

The front rods are attached last. The vest is pressed firmly against the patient's torso to ensure a snug fit. The front rods are then connected to the back rods and tightened securely.

The process of applying the Halo ring and positioning the patient remains the same, keeping things familiar for the medical team. The updated process includes a clear order for attaching and tightening the rods: horizontal rods first, back rods second, and front rods last. This order helps ensure the frame is stable and properly aligned.

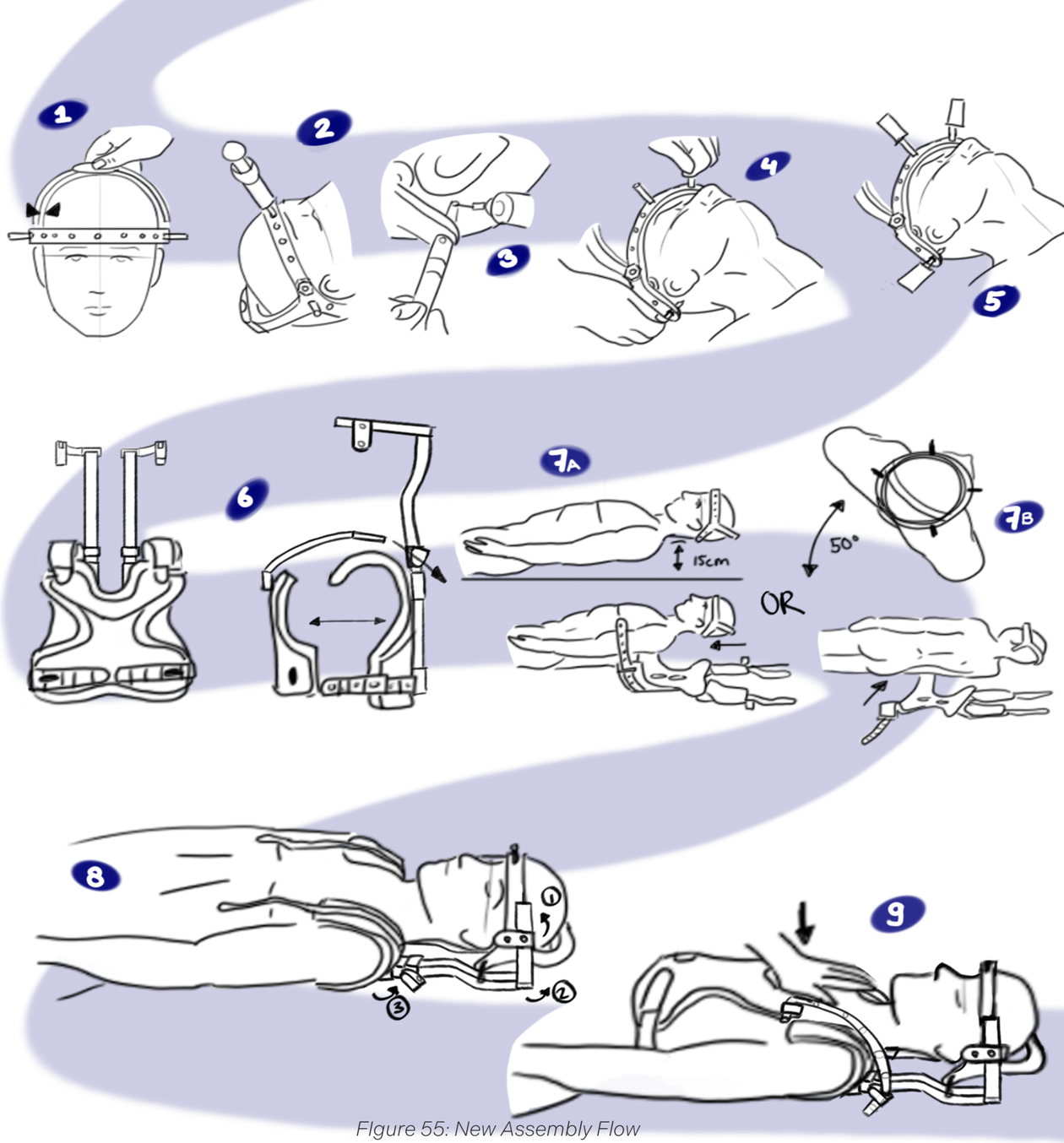


FIgure 55: New Assembly Flow

User Test: Aesthetics of New Frame.

Testing aesthetics of the new frame

A second user test was conducted to compare the original Halo vest (Design 1) with a newly developed alternative (Concept 2). The survey aimed to gather feedback on appearance, comfort, invasiveness, and overall preference. Participants reviewed rendered images of both designs from multiple angles and evaluated them based on the following factors:

1. Visual intrusiveness.
2. How well the design blends with the user's body.
3. Aesthetic appeal.
4. Perceived weight or bulkiness.
5. Whether the design appears intimidating or overwhelming.

The main question is: which design is more aesthetically pleasing and which factors contributing to this preference?

Participants rated each factor on a scale from 1 to 7, and the survey concluded with an open-ended question about their overall preference. The full list of questions can be found in Appendix V.

Results

Overall Perception: Concept 2 consistently received higher ratings than Design 1 across all categories. It scored an average of 5.4 for visual appeal compared to 4.0 for Design 1. In terms of how well the design blended with the user's body, Concept 2 achieved an average score of 5.1, while Design 1 scored 3.9. Concept 2 was also perceived as less visually intrusive, with a score of 4.9, compared to Design 1's 4.0.

Strengths of Concept 2: Participants highlighted Concept 2's cleaner and less intrusive design. The placement of the poles behind the head, rather than alongside the face, was seen as more practical and less obstructive. Many participants felt the design appeared lighter and better suited for daily use compared to the original.

Areas for Improvement: Despite its positive reception, Concept 2 still has aspects that could be improved. The body section, particularly around the waist, was described as bulky and visually disproportionate. The headband was also noted as appearing heavy, though it was rated as less intrusive than the corresponding structure in Design 1. These areas require further refinement to improve the design's overall balance and appearance.

Implications for the Design: The survey results indicate that Concept 2 is an improvement over Design 1, with better integration and reduced intrusiveness. However, addressing the bulkiness of the waist section and reworking the headband to appear lighter would further enhance the design. The placement of the poles behind the head should remain unchanged, as this feature was a key factor in the positive feedback.

Conclusion: Concept 2 was rated higher in most categories and preferred by the majority of participants. Its less intrusive and more practical design makes it a strong alternative to the original. Refining specific areas, such as the waist and headband, would help address remaining concerns while retaining the strengths of the design. These results provide clear guidance for further development of Concept 2.

Current concept vs Old Concept.

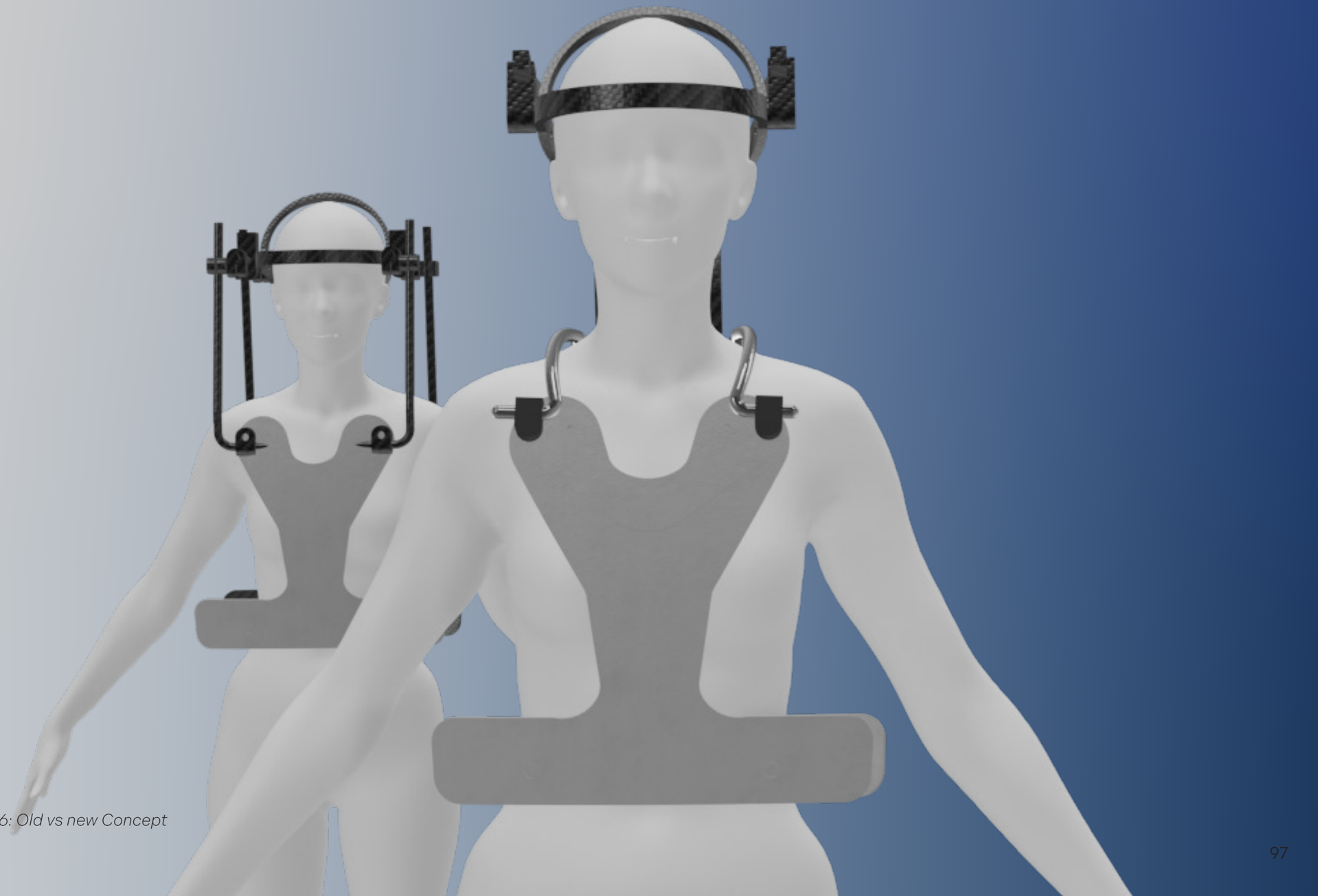


FIgure 56: Old vs new Concept

Deliver

Introduction deliver phase

The delivery phase focuses on testing and refining the proposed directions to create a feasible and improved Halo vest design. By evaluating which designs are viable and discarding those that are not, this phase answers the question: What would a re-design of the Halo vest look like?

This phase involves deepening the chosen concept to ensure it is practical, feasible, and meets the needs of users. CAD analyses will be conducted to help finalize certain details, while user testing will provide feedback for further refinement. An additional iteration round will be completed to address any remaining issues.

Research into the appearance and feel of medical devices will also guide decisions about the finish of the product, helping to improve its usability and acceptance. Considerations around manufacturability and cost will be included to provide an estimate for the new design. Finally, the chapter will conclude with a set of recommendations for further research, offering a path forward for continued improvement.

Embodiment

CAD prototype

The first step in this phase was to evaluate how the design would perform under extreme loads. This required refining the CAD model, moving from a basic structure to a more complete design that included connecting mechanisms, proper inserts, and other necessary features. This step was important to ensure the design was ready for testing.

Exploration of Design Features

Several features of the design were tested and refined during this phase. One of these was the idea of connecting the front rods as a neck ring. This approach aimed to make the structure look more streamlined and blend in better. However, the neck ring design reduced size adjustability, as the structure was less adaptable to different body shapes. Although the ring could be made extendable, this required the connection points to the back rods to include hinges, adding extra moving parts to an already complex structure. This made the design less stable, and the idea was replaced by using two separate front rods to connect the front and back.

FIgure 57: Exploration of different parts

Hinges

In our design, the hinges play a critical role in maintaining the structure's stability, especially given the removal of the front rods. The top hinges, which connect the curved horizontal beams to the back beam, experience a moment of approximately 159.3 inch-lbs. Additionally, the hinge at the bottom of the back beam, where it connects to the vest, must withstand a moment of approximately 156.36 inch-lbs When analyzing the forces and moments on the back beam system, we simplify the structure as a vertical and horizontal beam connected by hinges. The forces acting on these beams create rotational forces (moments) at the hinges, which are calculated as the force multiplied by the perpendicular distance to the pivot point (hinge). We remove the front rods to simplify the structure and make the scenario a worse case. Then we can get the highest moment that acts on the hinges. For this design, when leaning forward the vertical beam experiences a force of 126 N over a length of 0.3 m, while the horizontal beam experiences a force of 196 N over a length of 0.18 m. See figure 58.

Leaning forward

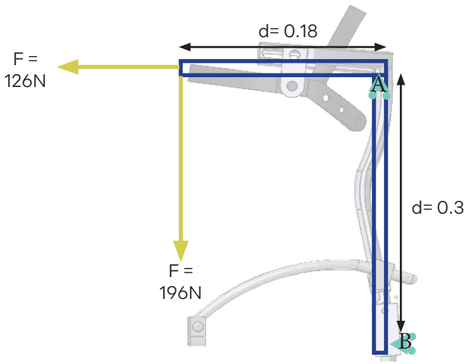


FIgure 58: FBD of Frame

At the upper hinge, the horizontal force produces a moment of:
Mupper = F*d = 196*0.18 = 35.28Nm
At the lower hin
ge, the vertical force creates a moment of:
Mlower = M1+M2 = F*d = (126*0.3) + (196*0.18) = 73,08Nm

To reduce these moments, the load can be distributed across the two back beams, effectively halving the force on each beam. With this configuration the reduced moments are:

- Upper hinge (per beam): Mupper per beam = 98*0.18 = 17.64Nm
- Lower hinge (per beam): Mlower beam = (61*0.3)+(98*0.18) = 36,54Nm

Converted to inch-lbs, the moments per beam are approximately **156.13 inch-lbs**, (upper hinge), **323.41 inch-lbs** (lower hinge).

To address these requirements, Variloc® Hinges - 360 and 180 Incremental Locking Hinges from 'Adjustable Locking Technologies" were identified as a potential solution. Specifically, their medium-duty aluminium locking hinges are capable of withstanding up to **500 inch-lbs of torque**, positive locking at any 10° increment. Once locked, the hinge becomes an absolutely rigid joint, making them more than sufficient for both the top and bottom hinge locations. These hinges are also compact enough to fit within the design constraints, providing confidence that hinges meeting the required specifications can be produced.

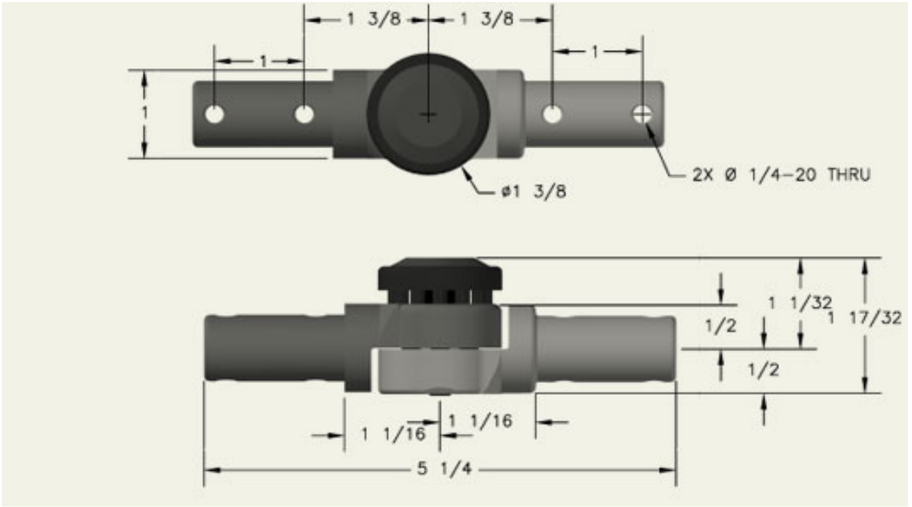


FIgure 59: Hinge dimensions in inches (Adjustable Locking Technologies, nd.)

While the hinges are critical to the structure, they represent one of the more vulnerable components of the design. With the updated configuration and the absence of the front rods, the hinges must bear significant moments to ensure the frame remains stable and functional. In addition, the back beam plays a key role in supporting the structure, as it must be rigid enough to prevent deformation under load and provide overall stability.

Due to time constraints, certain assumptions had to be made during the design process. While both the hinges and the back beam are important, more focus was placed on optimizing the back beam. This decision was based on evidence that suitable hinges, such as those identified from Adjustable Locking Technologies, already exist and can meet the required specifications. The hinges in the model shown are simplified a lot and will likely look different than modelled right now. However they will also be likely to be roughly the same size, thus not changing the appearance of the frame too much. The back beam, on the other hand, required more detailed analysis and testing to ensure it could provide the necessary rigidity and support.

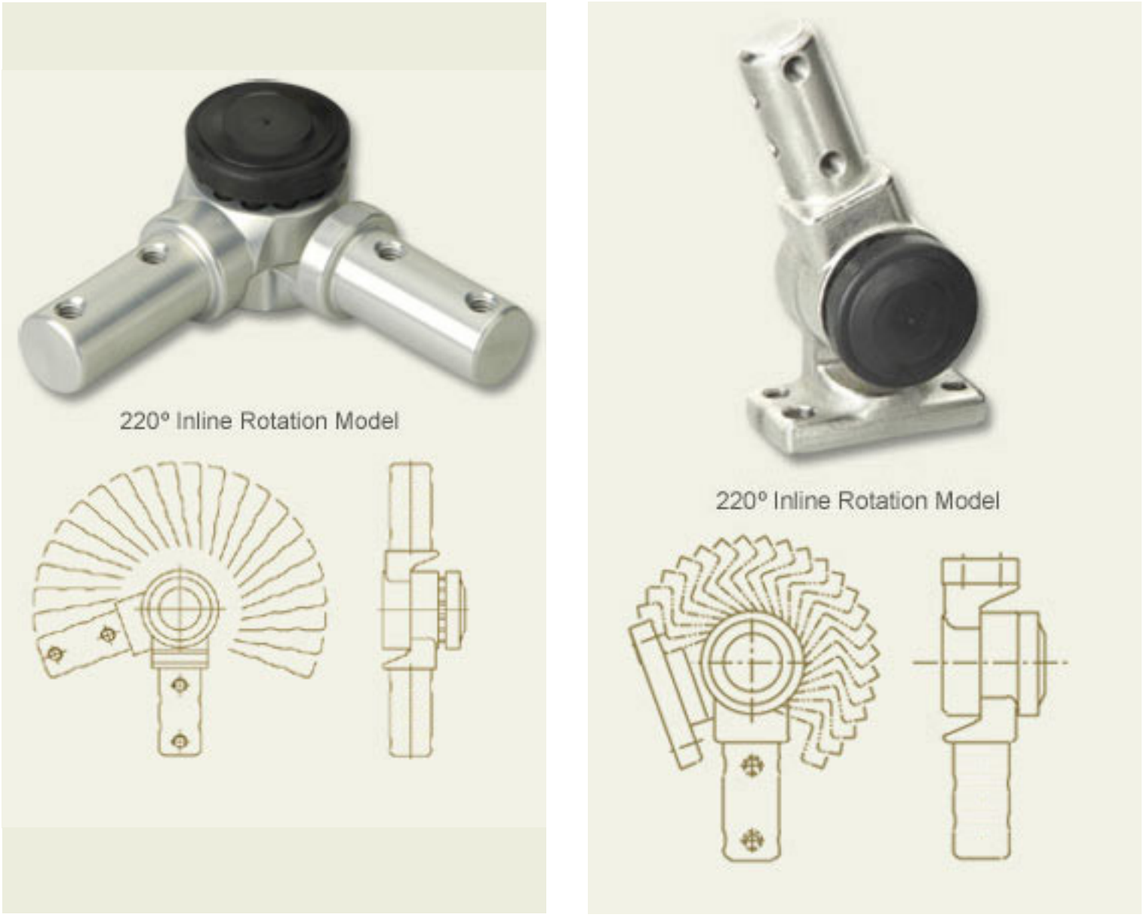


FIgure 60: Hinge types (Adjustable Locking Technologies, nd.)

Choosing Carbon Fibre for the Design

The decision to use carbon fibre instead of medical-grade titanium or aluminium is based on several key factors related to weight, performance, and user experience.

1. Weight: The carbon fibre frame weighs only 829 grams, compared to a titanium frame at 2265 grams. This significant reduction in weight makes the frame easier for users to handle, particularly during daily activities or prolonged use, reducing physical strain. See Appendix S for this comparison.

2. Deformation: Preliminary analysis indicates that the titanium frame results in greater deformation in the spine under load. The horizontal displacement in the spine for Carbon fibre is 2.7 mm with safety margin and 0,9 mm of actual displacement without safety margin and for titanium is a horizontal displacement of 4,4 mm with safety margin, and 1,2 mm actual displacement. The maximum angular displacement is in both cases 6,3° (see Figure 61), this suggests that carbon fibre offers better stability for the intended application, helping to maintain spinal alignment more effectively. See appendix S for this comparison and the SolidWorks setup.

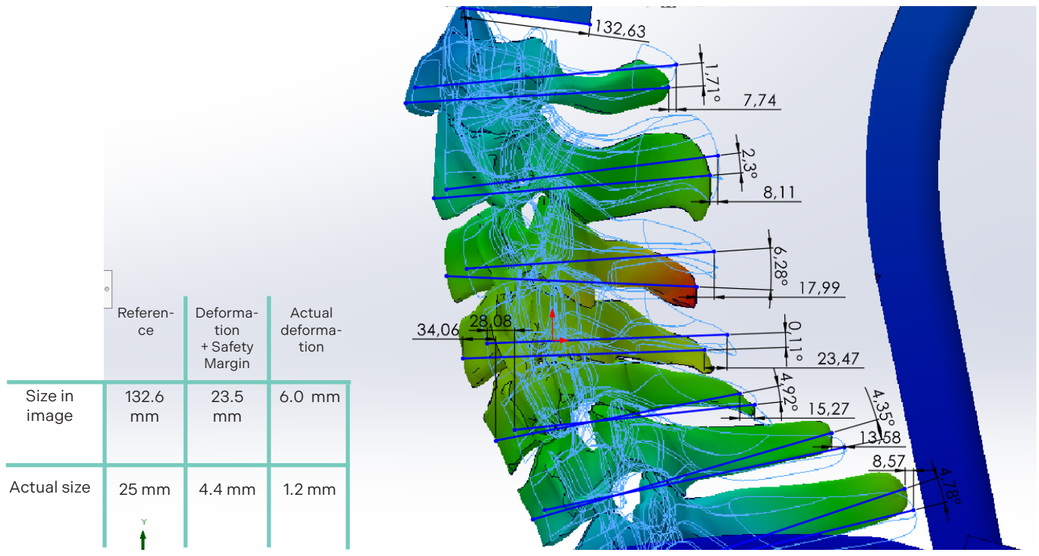


FIgure 61: Displacement in the spine in Titanium frame

3. Noise Transmission: Feedback from patients indicates that metal structures, like those made from titanium, act as a "tuning fork," amplifying noises that travel through the frame. These vibrations are transmitted to the pins in contact with the skull, making the check-ups and the tightening of the pins uncomfortably loud for patients. Carbon fibre, being less conductive to sound vibrations, significantly reduces this issue, improving patient comfort.

4. Imaging: A carbon fibre frame offers clear advantages for medical imaging over a titanium frame. Its radiolucency and non-magnetic properties allow for clearer and more precise imaging, making it a more suitable choice for patients requiring frequent monitoring or imaging-based interventions.

Simplifying Carbon Fiber Properties for Simulations

Modelling carbon fibre in SolidWorks is challenging because it is an anisotropic material, meaning its mechanical properties vary depending on the fibre direction. SolidWorks, however, is primarily designed to handle isotropic materials, which have uniform properties in all directions. This makes simulating anisotropic materials like carbon fibre more complicated and less straightforward.

To address this, a simplified approach was used. By approximating carbon fibre as an isotropic material and assigning a single value for each property, the material becomes much easier to input and analyse within SolidWorks. This method simplifies the simulation process and avoids the complexities of directional behaviour, especially for general-purpose analyses.

The simplification involves using representative or averaged values for key properties such as tensile strength, elastic modulus, and density. While this approach sacrifices some precision, it still provides a reasonable approximation of how carbon fibre performs in most scenarios. It allows for faster, more manageable simulations without compromising the overall usefulness of the results.

For the material data, MatWeb was used as a source. MatWeb provides detailed information on various materials, including carbon fibre composites. The data sheet referenced offers an overview of epoxy/carbon fibre composites, summarizing

properties such as density, tensile strength, and modulus of elasticity. These values are based on averages compiled from multiple data points, reflecting typical properties for this type of material. Using data from MatWeb (2024) ensures the input values are reliable and standardized, lending credibility to the simplified simulations.

In conclusion, simplifying carbon fibre properties by using single values for each parameter avoids the complexity of modelling directional behaviour. Although this method is less precise than full anisotropic modelling, it works well for most applications and is compatible with SolidWorks' standard simulation tools. This approach allows for practical, efficient simulations without requiring advanced composite modelling features.

Simplified Material Properties

As said before, when modelling carbon fibre, its anisotropic nature poses challenges. To simplify this, single representative values for each key property were chosen, focusing on the most critical direction (longitudinal) for structural loads.

• **Elastic Modulus:** A value of 101 GPa (1.01E11 Pa) was selected, reflecting stiffness primarily along the fibre direction (longitudinal direction), which is crucial for the design. This value avoids averaging with the much lower transverse modulus to better represent the material's primary load-bearing capacity.

• **Tensile Strength:** The higher longitudinal strength of 1085 MPa was used, as most forces act along the fibres. Carbon fibre is optimized for this direction, and using the transverse tensile strength (~50 MPa) or an average would underestimate its performance. By selecting the higher value, the simulation aligns with how the material is intended to function, ensures accuracy for the primary load-bearing direction.

• **Compressive Strength:** An average of longitudinal (700 MPa) and transverse (125 MPa) compressive strengths yielded 412.5 MPa, reflecting the material's ability to withstand compressive forces.

• **Shear Modulus:** A simplified value of 5 GPa was used, averaging in-plane and out-of-plane shear resistance, relevant for twisting and shear forces.

• **Density:** A consistent density of 1.6 g/cm^3 was applied, representing typical values for carbon fibre composites and aiding in weight calculations.

• **Poisson's Ratio:** An average value of 0.4 was chosen, accounting for both longitudinal (~0.3) and transverse (~0.5) behaviour when stretched.

Beam optimalisation

The back rod, being larger than other parts of the structure, was reviewed to see if weight and material could be reduced while keeping it stable. Five variations of the back rod were developed:

FIgure 62: From left to right: 1.Original Rod, 2.Rod with an I-Profile, 3.Rod with Cutouts, 4.Rod with Filleted Edges, 5.Rod with a Neck Shape

These variations were tested using Finite Element Analysis (FEA) to evaluate how each performed under load. The aim was to confirm that spinal deformation stayed within acceptable limits. Images of these tests can be found in Appendix S.

Selection of Back Rod for Prototyping

Based on the FEA results, the original rod and the rod with a neck shape were chosen for prototyping and testing. The neck-shaped rod offers a more compact appearance but may have sizing issues that need to be checked. The original beam is the strongest and therefore stable option. Testing both options helps balance appearance with functionality.

Analysis and Results

The FEA analysis is detailed in Appendix S, with figure 63 summarizing the findings for each configuration. The results include:

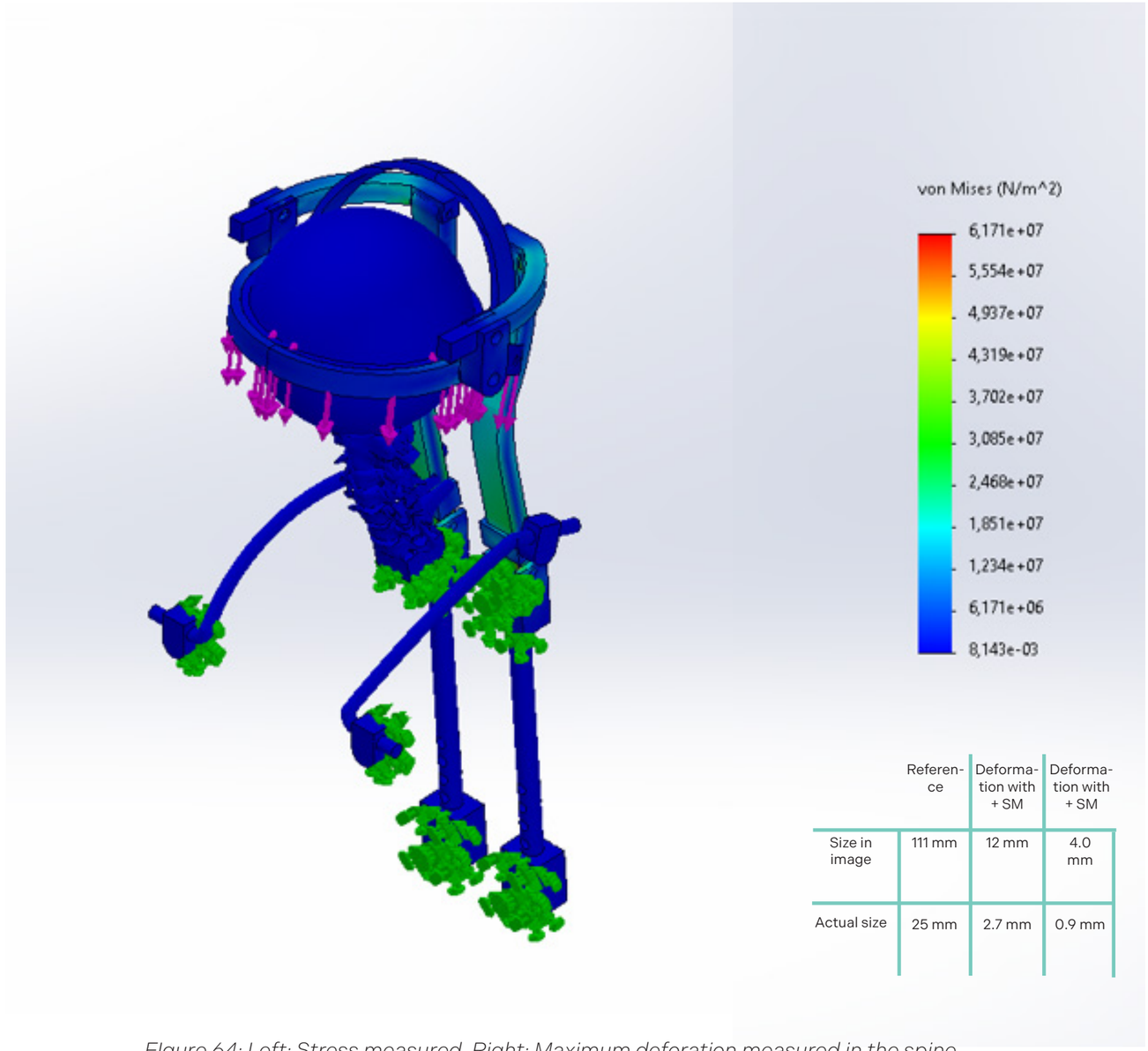
1. Maximum Angular Rotation: The total angular displacement recorded in the vertebrae.
2. Horizontal Displacement : Movement relative to the vertebrae itself, representing the micromovement with safety margin as mentioned earlier.
3. Horizontal Displacement (Actual micromovement): Movement relative to the vertebra below, representing actual micromovement like mentioned in White et al. (1975)

Beam type	Horizontal displacement in the spine with safety margin (in mm)	Actual Horizontal dispacement in the spine (in mm)	Maximum angular rotation (in degrees)
Normal rectabgle	1,9	0,6	3,8
Beam with fillets	2,7	0,9	6,3
Beam with holes	3,8	0,7	6
Beam with curved edge	4,3	1,5	6,7
Beam with I-Profile	3,6	1,1	7,3

FIgure 63: Tabel of Horizontal Displacement Per Beam

This process of refining the CAD model, testing design features, and analysing results helped move the final design closer to being ready for prototyping and further testing. This design was 3D printed to do some user test with.

Based on these values, the filleted beam was chosen. It has a softer appearance compared to the rectangular beam while remaining rigid enough to handle all the loads, including the safety margin.



	Referen-ce	Deforma-tion with + SM	Deforma-tion with + SM
Size in image	111 mm	12 mm	4.0 mm
Actual size	25 mm	2.7 mm	0.9 mm

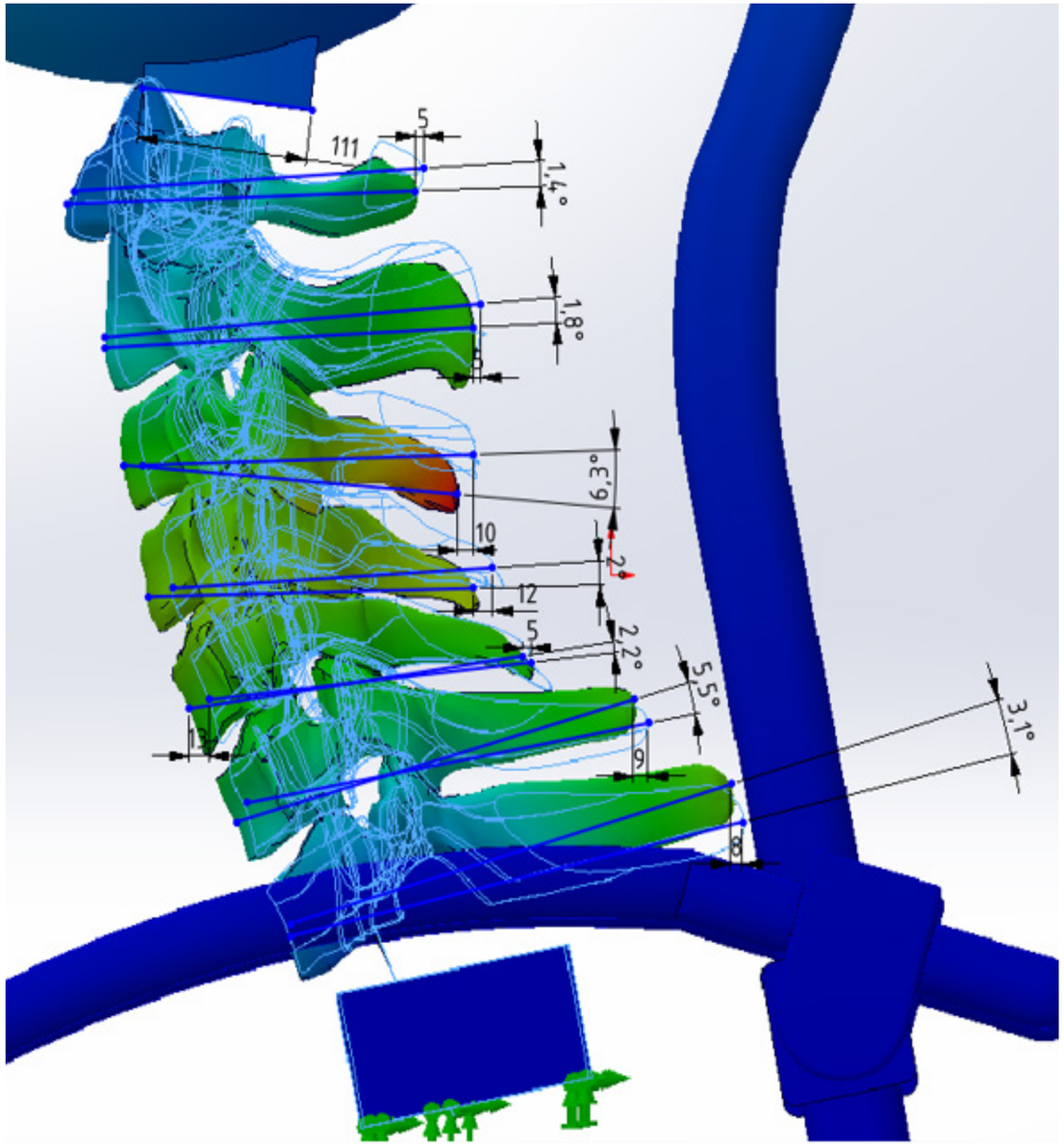


FIgure 64: Left: Stress measured. Right: Maximum deforation measured in the spine

Moment of Inertia and Deformation in the Back Beam

The structural behaviour of the back beam under load can be understood by simplifying it as a rectangular beam and analysing its moment of inertia. The moment of inertia, a measure of a beam's resistance to bending, depends on the beam's geometry, specifically its thickness (h) and width (b): I=b*h^3/12

Here, b represents the width (perpendicular to the bending forces), and h represents the thickness (parallel to the bending forces). Because h is cubed in the formula, it has a much greater influence on the moment of inertia compared to b, which is a linear factor.

For the back beam, the thickness (h) is oriented in the front-to-back direction, while the width (b) spans side-to-side. When forces act front-to-back, the beam resists bending primarily through its thickness. However, since the thickness is much smaller than the width, the moment of inertia is lower in this direction, leading to greater deformation. In contrast, when forces act side-to-side, the beam's larger width provides higher resistance to bending, resulting in less deformation.
This relationship highlights why increasing the thickness of the beam has a much larger impact on reducing deformation than increasing the width. For instance, doubling the thickness increases the moment of inertia by a factor of eight (2^3 = 8), whereas doubling the width only doubles the moment of inertia (2^1 = 2).

When I first analysed the back beam designs, I used a black box approach by creating various beam shapes and measuring their deformation under load. While this was a reasonable starting point, it lacked a deeper understanding of how the beam's geometry, particularly its thickness, directly affects its performance. With a clearer understanding of the relationship between thickness and deformation, I can now refine this process and explore the designs more effectively, focusing on the consequences of adding or reducing material in specific areas.

One of the designs I initially disregarded was the curved beam that followed the shape of the neck. This design was dismissed because its deformation under load was significantly larger compared to the standard straight beam. However, in hindsight, this increased deformation likely occurred because the curved design removed material in the thickness direction, which, as shown earlier, has the largest influence on the beam's rigidity. In contrast, the straight beam maintained its thickness, resulting in better performance in terms of resisting deformation.
With this new understanding, I re-evaluated the curved beam design by creating a version with the same thickness as the straight beam. A new comparison study has been conducted to analyse the deformation of the curved beam versus the straight beam under identical conditions. This study allows for a more accurate comparison and will help determine whether the curved beam, which better blends with the user's body, is a feasible option in terms of deformation. The results of this study will further guide the decision on whether the curved design can be implemented effectively.

Re-Evaluating the Curved Back Beam Design

The curved back beam design was revisited and modelled in SolidWorks to evaluate its feasibility. However, incorporating this design required significant changes to the overall structure, See image 65. The curved nature of the beam introduced challenges, particularly in the placement of hinges and the design of the rings at the top of the structure. These adjustments were necessary to accommodate the curved shape but had a noticeable impact on the overall design.

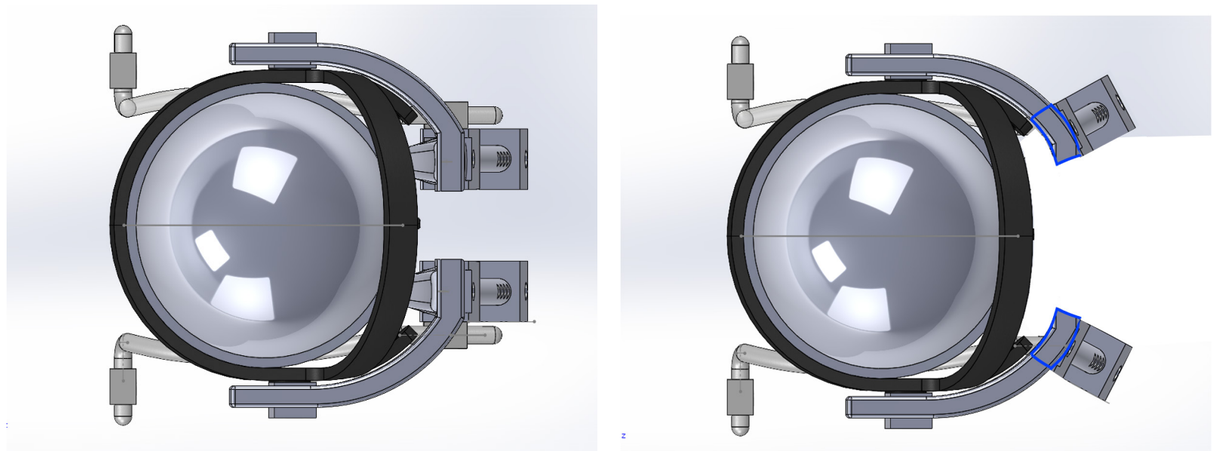


FIgure 65: Top view of old (left) configuration with straight beams vs. new (right) configuration with curved beams.

A simplified deformation analysis showed that the curved beam performed roughly similarly to the chosen filleted beam in terms of structural rigidity. (See Appendix S). However, the curved beam made the structure more visible, as it appeared to sit less behind the user's head and projected more into view. Additionally, the curved design altered the way the structure adjusted for sizing, which compromised its intended functionality.

Although the curved beam initially seemed to better match the contours of the user's body, these benefits were outweighed by the issues it introduced. The increased visibility, difficulties in hinge placement, and loss of proper sizing functionality made the design less practical. As a result, the curved beam design was ultimately abandoned.

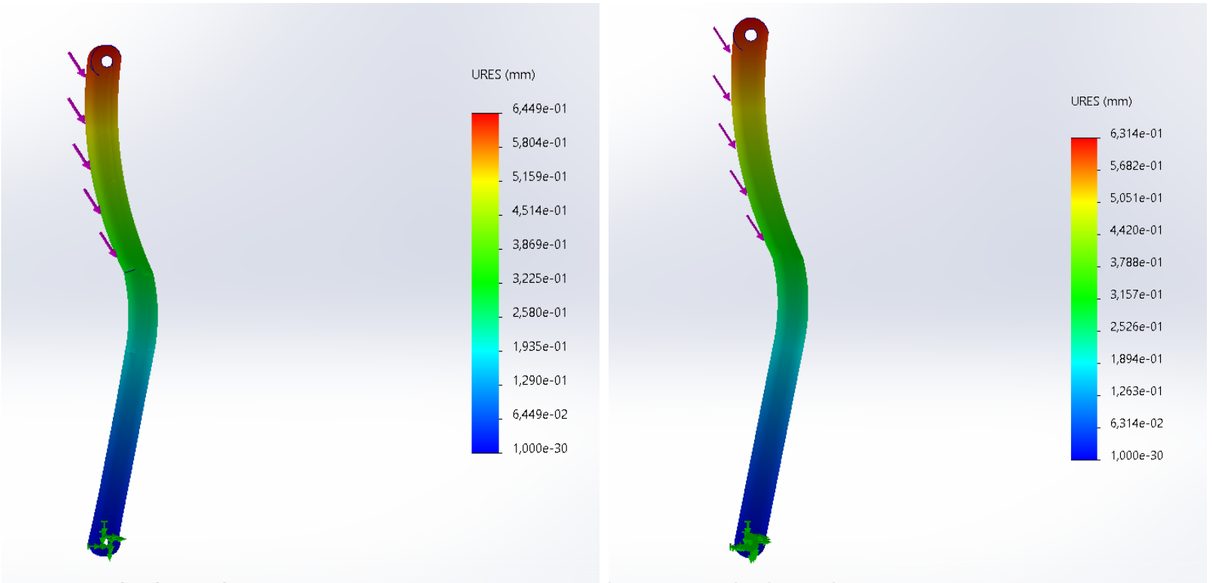


FIgure 66: Deformation on curved beam (left) vs. deformation on the straight beam (right)

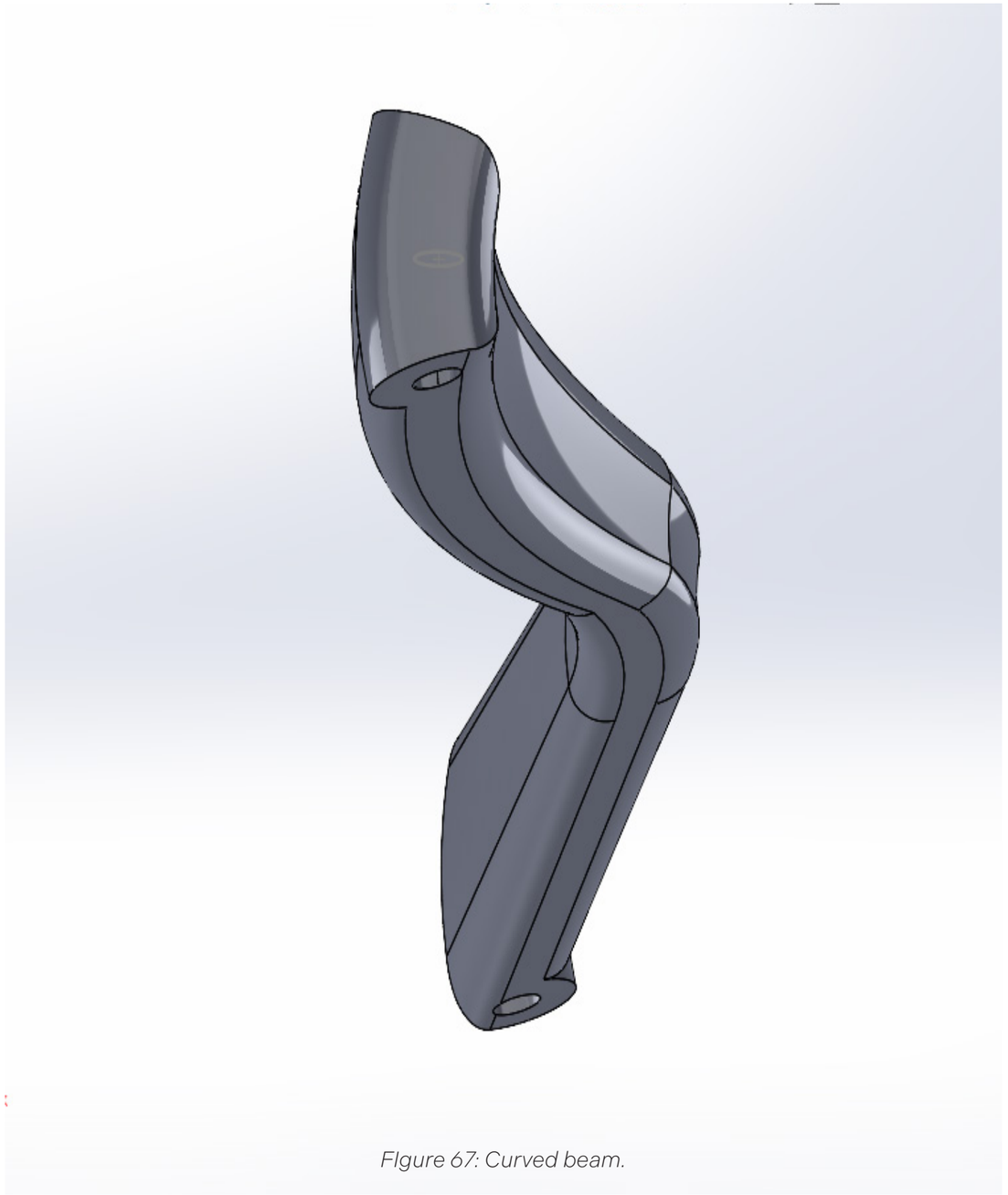


FIgure 67: Curved beam.

Prototype

Creating a Prototype for the Halo Vest

A prototype was made for the chosen Halo vest design to evaluate the assembly process and fit. Building a physical prototype allowed for testing to identify practical challenges that were not apparent during the design phase. It also provided an opportunity to check how the components and mechanisms worked together as a complete system.

The prototype was created for several reasons:
1. Testing Assembly: Assembling the prototype made it possible to check whether the process was straightforward and the instructions were clear. Any difficulties could then be addressed in the next design iteration.
2. Assessing Fit: The prototype was used to check how well the vest fit different body types and whether it provided enough comfort and adjustability. Observing the prototype in use helped identify areas for improvement.
3. Understanding Components: A physical model helped show how the individual parts worked together. This made it easier to refine the design and ensure the mechanisms functioned correctly.
4. Identifying Design Issues: The prototype revealed potential problems, such as parts that were hard to adjust or areas where the structure did not perform as expected.

Figure 68: Prototype

User test: Assembly of vest

Pilot Test on Assembly and Adjustability

A pilot test was conducted to evaluate the redesigned Halo Frame, focusing on three key aspects: ease of assembly, fit after assembly, and adjustability. Unlike a formal assembly test with orthopedic technicians, this initial study was carried out with five design students to gather general insights on usability and workflow. each asked the participants to think out loud while performing the actions. While orthopedic technicians previously stated in interviews that, aside from the halo ring, the frame can generally be assembled by anyone, this test provided an opportunity to observe how users with no prior experience interacted with the design.

The main question guiding this test was:
How effectively does the assembly flow perform, and what key insights can be gathered for potential improvements?

This test was essential to gain early feedback on whether the design changes improved usability compared to the current version. Assembly and adjustability are practical requirements to ensure the device can be used efficiently in clinical settings, and checking the fit ensures the frame provides proper support and comfort for the patient.

Test Structure & Observations

Since this was an exploratory session, the focus was on qualitative observations and participant feedback rather than strict performance metrics. However, in future studies, incorporating time measurements and error tracking would be beneficial to gain more structured insights into efficiency and potential pain points.

Participants were asked to assemble the frame, assess its fit, and explore its adjustability. Their feedback was gathered through structured questions and open-ended discussion.

Key Questions for Participants

Participants were asked specific questions to gather detailed feedback:

1. Ease of Assembly:
   - How clear were the assembly instructions?
   - Did you encounter any challenges while assembling the frame?
2. Fit Assessment:
   Does the assembled frame align well with the body?
   - Are there any noticeable pressure points or areas of discomfort?
3. Adjustability:
   - Was it straightforward to adjust the frame for a different body type or size?
   - How would you describe the range of adjustments available?
4. General Feedback:
   - What aspects of the design work well?
   - What aspects could be improved?

Future Considerations

While this pilot test provided useful initial insights, a more structured test with orthopedic technicians should be conducted in the future. Such a test could include:

- Time measurements to evaluate efficiency improvements.
- Error tracking to identify common mistakes during assembly.
- Comparative testing with the current frame to assess improvements more systematically.

This initial test demonstrates that the redesigned frame can be assembled by individuals without specialized training, supporting the claim that the device is more intuitive. However, further validation with professionals in a clinical setting will be essential to refine the design and ensure it meets practical requirements.

Key Takeaways from assembly test

Assembly Instructions
The instructions received an average rating of 5.6 out of 7, indicating they were generally clear but could benefit from improvements. Participants suggested:
• Adding clearer visuals, such as close-up images and colour-coded steps.
• Simplifying the steps into smaller, more detailed actions.
• Providing an overview of the components before starting, similar to how assembly kits like LEGO present their instructions.

Challenges During Assembly
Several issues were noted during the assembly process:
• Back Section Placement: Aligning the back section with the front rods was challenging, especially in terms of height.
• Tight Spaces: Adjusting and tightening components around the neck and back was difficult due to limited access.
• Fastening Confusion: Participants struggled to identify which screws or pins to adjust, as multiple adjustment points were located close together.
• Stabilisation Issues: Ensuring the dummy patient remained stable while attaching the back section was unintuitive and time-consuming.

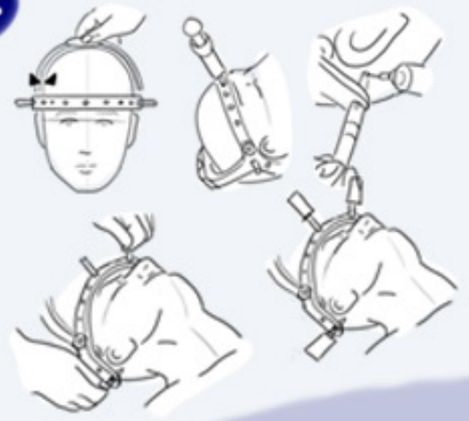
Adjustability
The ease of adjustment scored an average of 5.4 out of 7, reflecting a generally intuitive process with room for improvement:
• Front Rods: Participants noted these could be longer to accommodate larger body types.
• Middle Strap: The strap was described as tight and difficult to adjust effectively.
• Adjustment Points: While the range of adjustments was adequate, the proximity of screws around the back and neck made the process feel cramped and cumbersome.

Positive Aspects
Participants identified several strengths in the design:
• Face Visibility: The design kept the face unobstructed, creating a less overwhelming experience.
• Integration with Body: The lines of the vest followed the body’s shape, making it visually more appealing.
• Clothing Compatibility: The vest allowed for regular clothing to be worn over it, an improvement compared to traditional designs.

Areas for Improvement
Key areas for refinement include:
• Back Section: Simplify the alignment process and improve the tightening mechanism.
• Adjustment Points: Increase accessibility and reduce the number of screws in clustered areas.
• Visual Simplicity: Soften the mechanical appearance with fillets and rounded edges.
• Material Finish: Improve the finish to make the vest look less like a medical device and more like a wearable accessory.

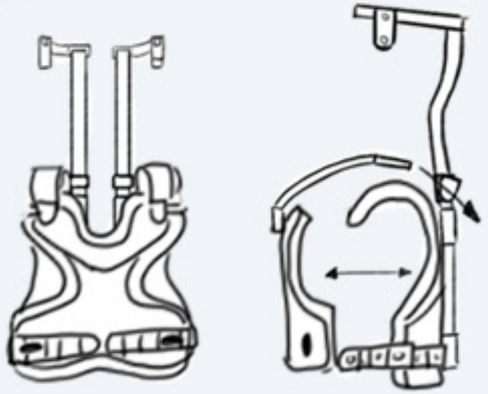
Conclusion
The assembly test highlighted both strengths and weaknesses of the redesigned Halo vest. Participants appreciated the improved aesthetics, better body integration, and compatibility with clothing. However, challenges with assembly and adjustability point to areas that require refinement. Addressing these issues will result in a more practical and user-friendly design for orthopaedic technicians.

1



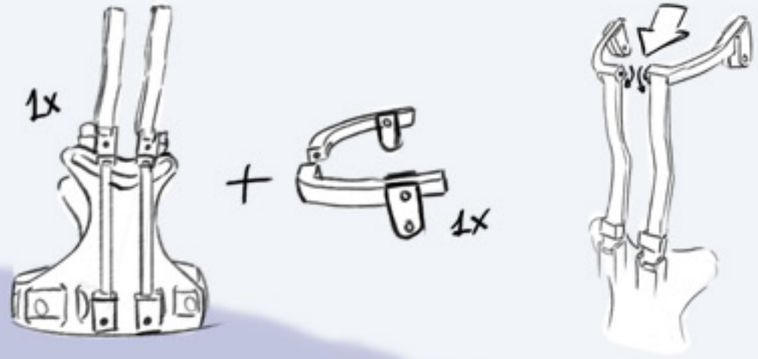
The halo ring was already placed on the dummy's head, as it remains unchanged. Participants were given time to review the vest, its components, and the manual.

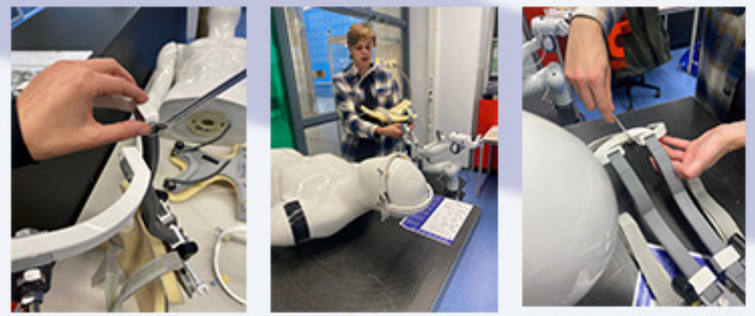
2



3

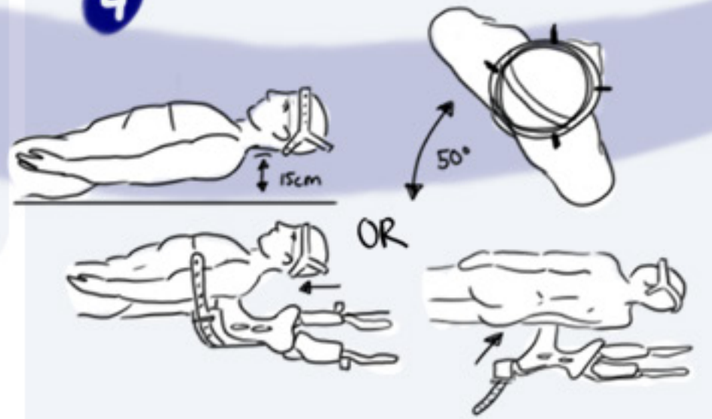
The backplate is preassembled with the two back rods attached, leaving the curved rods to be connected. Participants completed this step without any difficulty.





Participants carefully tilted the dummy to slide the backplate with the attached rods beneath it. The most challenging aspect for participants was positioning the vest correctly on the shoulder blades, with some placements ending up too far back.

4



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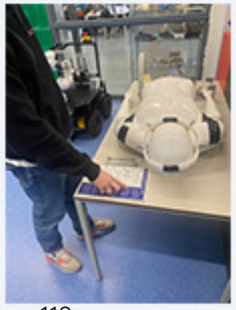
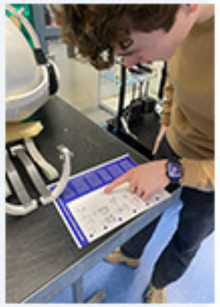




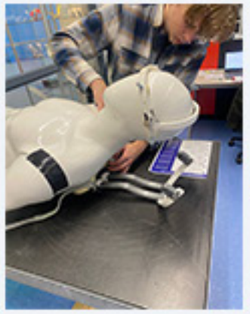
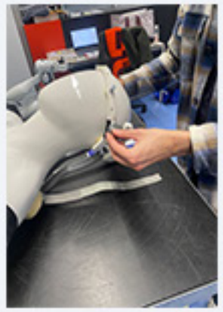
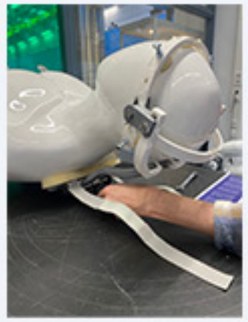


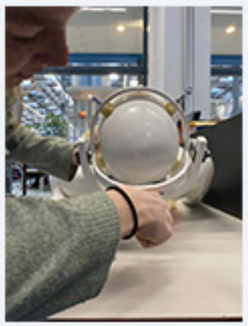
Figure 69: A

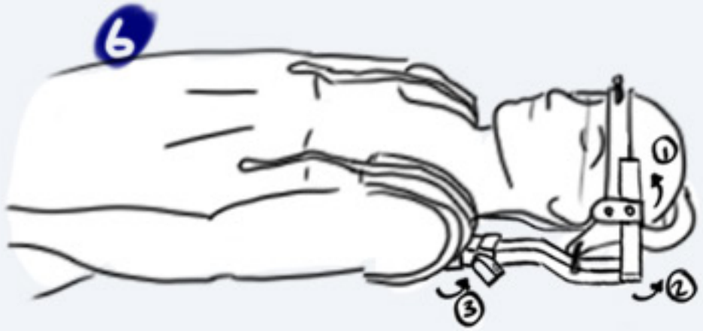



Next, participants attached the halo ring worn by the patient to the back structure, encountering the most difficulty in identifying the correct bolts for mounting the back structure.

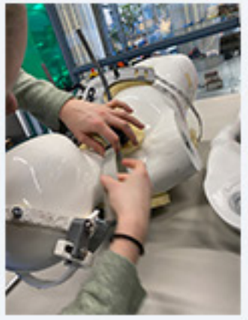




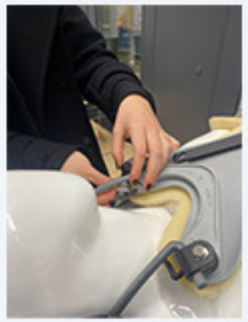




They tightened the bolts in sequence: first around the head, which they found very easy; then behind the head, which was also straightforward but limited in range of motion; and finally at the back, which was perceived as very difficult and would benefit from a different type of wrench to achieve the proper angle.


The participants closed the vest by applying pressure. Tightening the straps was difficult due to the front rods obstructing access, but once secure, the connection holes were easy to locate. Firmly pressing the front plate while tightening the bolt was percieved as straightforward.




User test: Fit of prototype

Test

A fit test was conducted with 10 participants to evaluate how well the prototype of the redesigned Halo vest accommodates different body types, heights, and genders. The primary goal of the test was to assess the overall fit of the vest and gather feedback on comfort and appearance. Participants were asked to wear the vest for 15 minutes and provide their thoughts through a combination of ratings and verbal feedback. They did not see themselves in the vest during the test, only at the end in a mirror.

The main question is: How well does the redesigned Halo vest fit users of various body types, and what aspects of its design contribute to or detract from comfort and visual integration?

Procedure: Participants were selected to represent a range of body types, heights, and genders. During the test, they were asked to evaluate their experience using a combination of Likert scales (1 = very poor, 7 = excellent) and think-aloud verbal feedback. This approach allowed participants to express their immediate thoughts while providing structured ratings. Below a figure of the distribution of height and weight of the participants. Also the division male-female. The age of the user group was between 20-30.

Purpose of the Test: This test aimed to determine whether the redesigned Halo vest provides a comfortable and secure fit across a diverse range of users. By focusing on aspects such as comfort, pressure distribution, and visual integration, the test provided insights into how well the vest meets user needs and highlighted areas for potential refinement.

Questions Asked: Participants were asked to provide feedback on the following aspects:

1. Comfort:
- How comfortable does the vest feel to wear? (1-7)
  - Are there any areas where the vest feels too tight, loose, or restrictive?

2. Pressure Points:
  - Are there specific areas where the vest applies uncomfortable pressure?
  - Rate the severity of any pressure points felt during the test. (1-7)

3. Perceived Size:
  - How much does wearing the vest make you feel like you are in a large or bulky structure? (1-7)
  - Does the vest feel too imposing or overwhelming to wear comfortably? (1-7)

4. Visual Integration:
  - After viewing yourself in the vest, how well do you feel it blends in with your body? (1-7)
  - Does the vest look overly noticeable or out of place? (1-7)

5. General Feedback:
  - What did you like or dislike about the fit of the vest?
  - Are there any improvements you would suggest to make the vest fit better?

The findings will be used to guide adjustments to the design for improved usability and comfort.

Participants in Vest

FIgure 70: Fit Test

Key Takeaways Fit Test

Overall Fit and Comfort

• Comfort Ratings: Participants rated the vest's overall comfort with an average score of 4.8 out of 7. Most comments suggested that the vest felt snug but not overly restrictive, with several describing it as "secure" or "like a backpack." However, some felt discomfort around specific areas, such as the neck and midriff.

• Pressure Points: The average rating for pressure points was 4.6 out of 7, indicating moderate discomfort in certain areas. Feedback highlighted the chest and neck as areas where the vest felt tight or chafed.

Perceived Bulkiness

• Before viewing themselves in the mirror, participants rated the vest's perceived bulkiness as 5.1 out of 7, indicating it felt somewhat large.

• After seeing themselves in the mirror, participants revised their perception, with an average score of 4.2 out of 7 for how bulky the vest looked. This suggests that the vest feels bulkier than it appears, particularly when worn under clothing.

Visual Integration

• The average score for how well the vest blended with the body was 4.9 out of 7. Positive comments focused on how the design was less intrusive than the original version and how it appeared less visible when paired with regular clothing.

Positive Aspects of the Design

• Less Intrusive: Many participants appreciated that the vest appeared less bulky than the original design and liked the placement of the structure behind the head.

• Secure Fit: The snugness of the vest gave participants a sense of stability and safety.

• Design Elements: Some praised the logical flow of the design lines and how the vest adapted to the body's shape.

Areas for Improvement

1. Chest and Midriff Fit: Participants with larger chests found the fit uncomfortable and visually unappealing. Adjusting the vest's shape or more room in these areas could improve comfort and appearance.
2. Neck and Head Support: The neck rods were noted as tight or chafing. Adding padding or adjusting the rod width could resolve this issue. Several participants suggested adding a pillow or softer material for the back of the head to improve comfort, especially when lying down.
3. Perceived Bulkiness: Although the vest looked less bulky in the mirror, participants felt it was large while wearing it. Reducing the size of the chest section could address this perception.
4. Visual Integration: Some participants suggested refining the top section to blend more seamlessly with the head and body.

Perception Change and Implications for the Design

The change in perceived bulkiness after participants saw themselves in the mirror suggests that the vest feels heavier and more imposing than it looks. This indicates a mismatch between the physical experience and visual perception of the vest. Addressing the areas where participants feel restricted, such as the chest and neck, while maintaining a sleek appearance, could balance this discrepancy.

Conclusion

Overall, the redesigned Halo vest was received positively, with participants noting improvements in visual integration and less bulkiness compared to the original design. However, there are clear areas for refinement, particularly in improving comfort around the chest and neck, reducing perceived bulkiness, and enhancing usability when lying down.

Design improvements based on user tests.

Introduction

Based on the feedback from both the fit and assembly tests, the following aspects should be prioritised in the next iteration of the design:

1. Assembly Improvements

• **Back Section Alignment:** Simplify the process of aligning and securing the back section with the front rods. Consider adding clearer markings or guide tracks to ensure proper placement.
• **Adjustment Screws:** Increase accessibility around the back and neck adjustment points by spacing out screws or using a more intuitive adjustment mechanism.
• **Instructions:** Enhance the assembly instructions with:
- Clear visuals, such as close-up images or diagrams.
- Colour-coded components and steps.
- An initial overview of all parts and tools needed.

2. Fit and Comfort

Key Takeaways from the Fitting Test:
• **Chest and Midriff Fit:** Some participants found the vest tight or uncomfortable around the chest and midriff, particularly those with larger body types. Adjusting the design to provide more flexibility in these areas would improve comfort and usability.
• **Neck and Pressure Points:** Tightness and chafing around the neck rods were commonly noted. Adding padding or adjusting the rod placement could alleviate this discomfort.
• **Snugness vs. Pressure:** While the snug fit was appreciated for its sense of security, certain areas, such as the chest, created noticeable pressure points that need to be addressed.

3. Perceived Bulkiness

• **Back Section Size:** Reduce the size and bulk of the back section to improve the overall balance and appearance of the vest.
• **Mirror Effect:** Participants initially perceived the vest as bulkier than it appeared when they saw themselves in the mirror. This suggests the design feels imposing, even though it may not look that way. Reducing weight and improving comfort could bridge this perception gap.

4. Visual Integration

• **Headband and Neck Design:** Rework the Halo ring attatchmets to make it appear lighter and more integrated with the body. A seamless transition between the neck and head sections could improve visual appeal.
• **Material Finish:** Use a softer, more polished material finish to make the vest look more like an accessory and less like a medical device.

5. Functional Refinements

• **Pressure Distribution:** Revisit the frame’s design to ensure pressure is distributed more evenly across the body, especially in the chest and neck areas.
• **Clothing Compatibility:** Maintain and enhance features that allow the vest to be worn under regular clothing without discomfort or visual intrusiveness.

Iteration based on user tests

Re-design of the halo vest

Several adjustments were made to the Halo vest to address feedback from previous tests, focusing on improving functionality, comfort, and appearance while maintaining structural integrity. The key changes are outlined below.

Wider rod placement

The rods were positioned further apart to prevent interference with the vest straps during assembly. This adjustment also reduces chafing around the neck, which was a common issue noted in earlier feedback.

Streamlining the headpiece

The curved rods around the head and the connection piece were redesigned to remove excess material. This was done carefully, as these rods and the connection piece play an important role in maintaining the frame's strength. Material was removed while keeping the structure within the allowable range of spine deformation. The revised headpiece has a reduced visual profile while maintaining its function. Visuals of this change can be seen in figures 71-73.

Figure 71: Re-Design

Streamlining the back

The back structure was redesigned to remove unnecessary bulkyness. By relying on the strength of the hinges at the back, the large supporting frame was removed. This change improves the appearance and makes the vest easier to lie on, addressing discomfort reported during extended use.

Material Finish and Rounded Fillets

A softer material finish was applied to the frame, making it lighter and more comfortable to wear. Rounded fillets were added to reduce sharp edges, giving the frame a smoother look and feel. These adjustments help reduce the mechanical appearance of the design.

Figure 72: Re-Design

FIgure 73: Re-Design

Impact on Structural Strength

Each design change affects the frame's structural performance. For example:
• Widening the rods and removing material from the back may alter how forces are distributed.
• Reducing material in the headpiece could affect how the structure handles loads.
To ensure safety, further testing is required to confirm that the new design remains within the safety margin for spine deformation. This step is necessary to validate the changes and ensure the frame performs as intended

With these changes, the spine deformed with a maximum angular rotation of 6.1 degrees, which remains below the limit of 11 degrees. The maximum horizontal displacement between two vertebrae was 1.2 mm, staying within the allowable limit of 2.7 mm. These results indicate that the structure meets the required strength criteria.

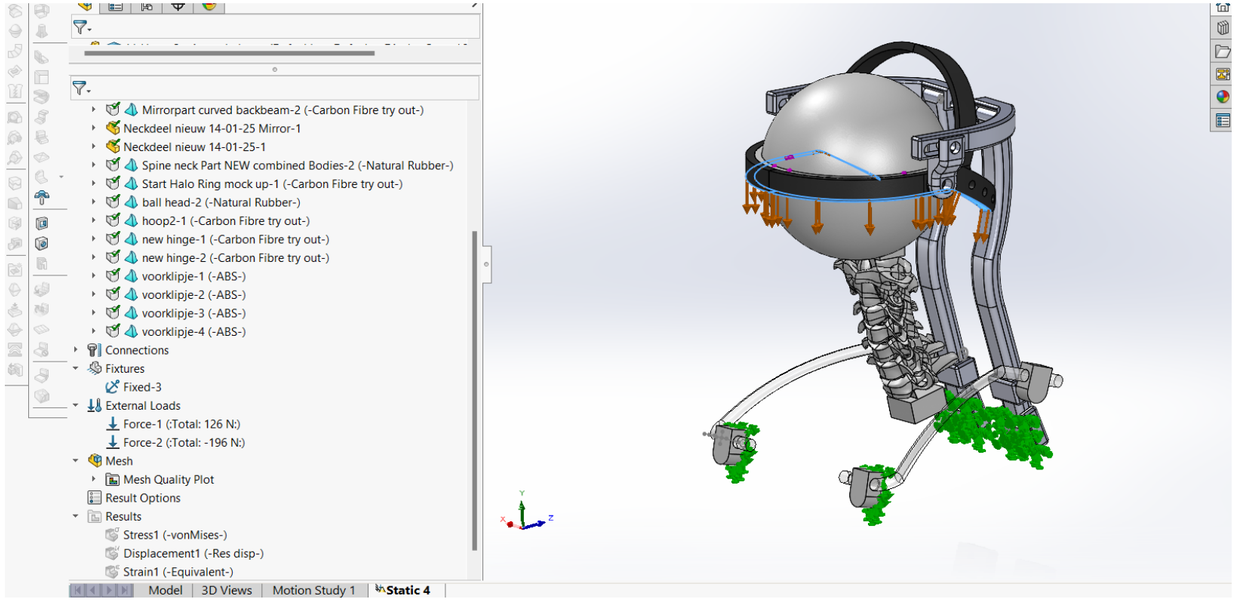


FIgure 74: FEA Set Up

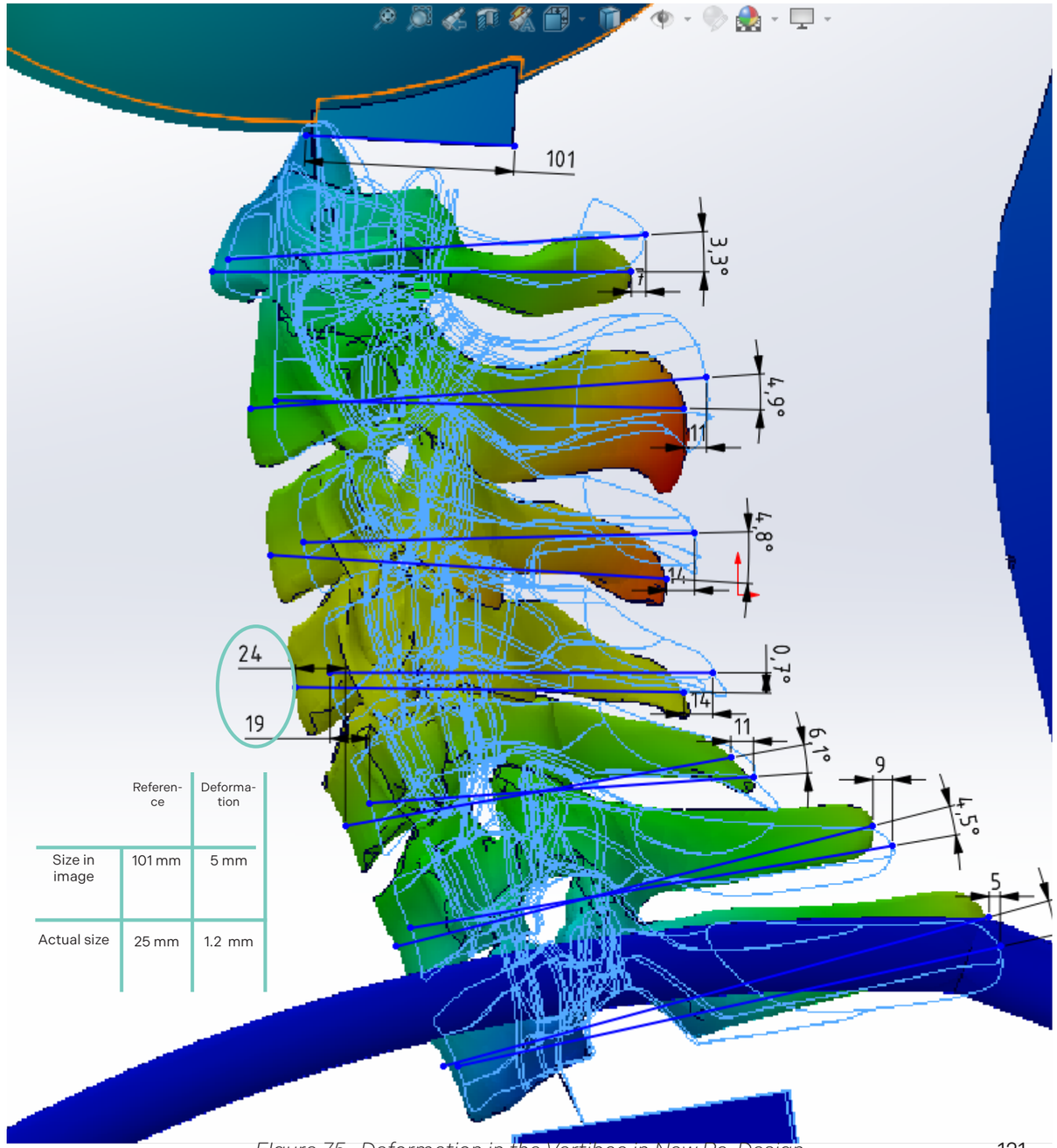


FIgure 75: Deformation in the Vertibae in New Re-Design

Feedback Session with an Orthopaedic Technician

Introduction

A feedback session was conducted with an orthopaedic technician to review the current Halo vest design and gather insights for potential improvements. The session focused on evaluating the visual aspects, adjustability, and overall functionality of the design.

Adjustability

The technician agreed that the visual appearance of the new design was an improvement compared to the previous version. However, concerns were raised regarding the adjustability of certain parts. In particular, the horizontal curved rods around the head required a longer range of adjustment in the front-to-back direction to accommodate a wider variety of patients. This was changed in the SolidWorks models.

Back adjustments

Another important aspect discussed was the accessibility of the hinges and their placement. The technician highlighted the need for careful positioning to ensure easy access, especially when adjusting the vest while the patient is lying down. This led to a brainstorming session on potential solutions for improving the adjustability of the back mechanism. The conclusion was that a rack and pinion system with a locking mechanism would be the most practical approach. It was suggested that the pinion should be designed in such a way that it can be adjusted from the side of the hinge, making it easier to operate in different patient positions. A similar system can be found in the PMT vest, which uses gearing to facilitate movement in the vertical direction. This was also changed in the SolidWorks model.

FIgure 76: Re-Design

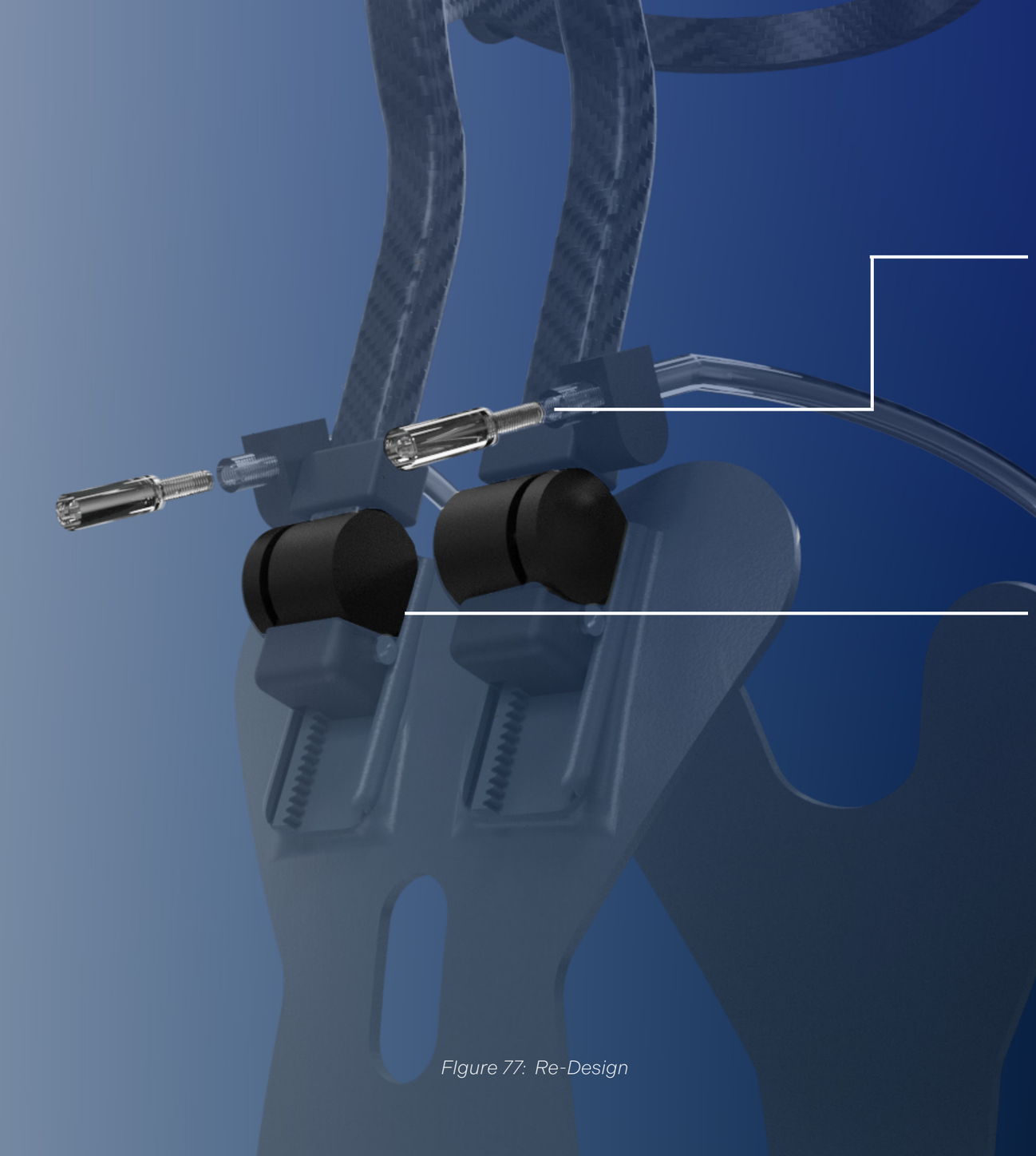


FIgure 77: Re-Design

Front rods

Another issue addressed was the front rods, which may protrude significantly at the back if the patient is small, or be too short for larger patients. Two possible solutions were proposed:
1. Offering different sizes of front rods to accommodate various patient body types.
2. Developing an adjustable extension that could be added to a standard-sized rod.
The second option, inspired by stackable children's pencils, was seen as more practical from a business perspective, as it would simplify inventory management and reduce the number of different parts needed. However, it was noted that this approach would require further testing to ensure it provides sufficient strength and stability for the patient. The front rods would just simply come with a set of extenders.

Hinges accuracy

During the feedback session, the importance of modelling the hinges to match the recommended size was discussed. The technician pointed out that accurately representing the hinge dimensions in the design is an important next step, as it provides a clearer understanding of the overall bulk of the frame and offers a realistic presentation of what the patient will be lying on. It was observed that the hinges appeared bulkier than desired, which could affect patient comfort and ease of use. This concern requires further investigation to explore potential alternatives or design modifications that could reduce bulk while maintaining the necessary functionality and strength of the frame.

Torsion in frame

During the feedback session, concerns were raised about torsion in the frame and the role of the front rods over the shoulders. The current analysis mainly considered front-to-back forces, but the two-beam structure may also be affected by bending and torsional forces, which could impact stability and comfort.

Torsion occurs when rotational forces cause the frame to twist, and without additional support, the two-beam design may allow unintended movement. Bending can also happen if side-to-side forces, such as patient movement, are not fully accounted for. Insufficient stiffness in this direction could lead to flexing and reduced support.

Adding front rods over the shoulders provides extra support and helps distribute forces more evenly across the frame. This can reduce the strain on the back beams and limit movement caused by rotational forces. However, the exact effectiveness of these rods needs further testing.

Testing should include simulations and physical trials to check how well the rods improve stiffness, distribute weight, and maintain comfort. Results from these tests will help decide if further changes are needed, such as adjusting the length, placement, or attachment points of the rods.

Overall, the session provided valuable insights into the necessary improvements for the Halo vest, with a focus on making adjustments more accessible and ensuring the design remains adaptable to different users.

FIgure 78: Re-Design

Torsion in frame

A small test was carried out to examine the torque and the resulting torsion in the device. The study is not yet finished, but it provides an estimate of the order of magnitude involved.

The torque generated by head rotation depends on several factors, including the mass of the head, the speed of rotation, and the resistance from the neck muscles and joints. There is no fixed value, but estimates can be made based on biomechanical studies.

For reference, the average mass of the head is between 4.5 and 5.5 kg. (Sijders, 2018) The speed of rotation varies depending on the movement. Slow movements, such as turning the head to the side, occur at around 30–50°/s, while rapid movements, such as a startle response, can exceed 300°/s. The moment of inertia of the head is estimated to be between 0.015 and 0.020 kg·m², depending on its size and shape. Based on these values, the torque can be estimated. For slow rotations (~40°/s² angular acceleration), the torque ranges from 0.2 to 0.6 Nm. For rapid movements, such as a startle response (~1000°/s² angular acceleration) (Sijders, 2018), the peak torque can reach 10 Nm or more.

In this test, a maximum torque of 10 Nm was chosen to simulate a fast movement, representing a worst-case scenario. Due to time constraints, the resulting torsion and angular displacement were not calculated. However, the simulation provided information about the maximum displacement and which parts of the structure were affected the most. It also gave an idea of the order of magnitude of the forces involved and how they translate to the spine. Further work is needed to determine the exact torsional effects, but this test gives a first indication of how the model behaves.

The maximum displacement was mostly seen on the sides of the frame, with a peak value of 1.6mm. While this is not a very large displacement, it is also not insignificant, as small deformations can still affect the function of the device. The top curved beam showed high stress levels, which suggests that this part may need additional attention in future tests.

The spine showed limited movement, both in terms of rotation and displacement. No literature values were available for comparison, but based on the images, an estimate was made to assess whether the deformation was meaningful. The spine primarily rotated in the XZ plane, with a maximum deformation of around 1.1 mm, though no specific direction was assigned to this measurement.

In summary, the frame shows some displacement, but the effect on the spine remains small. Future work should focus on adjusting the top beam design and further evaluating the displacement in the spine.

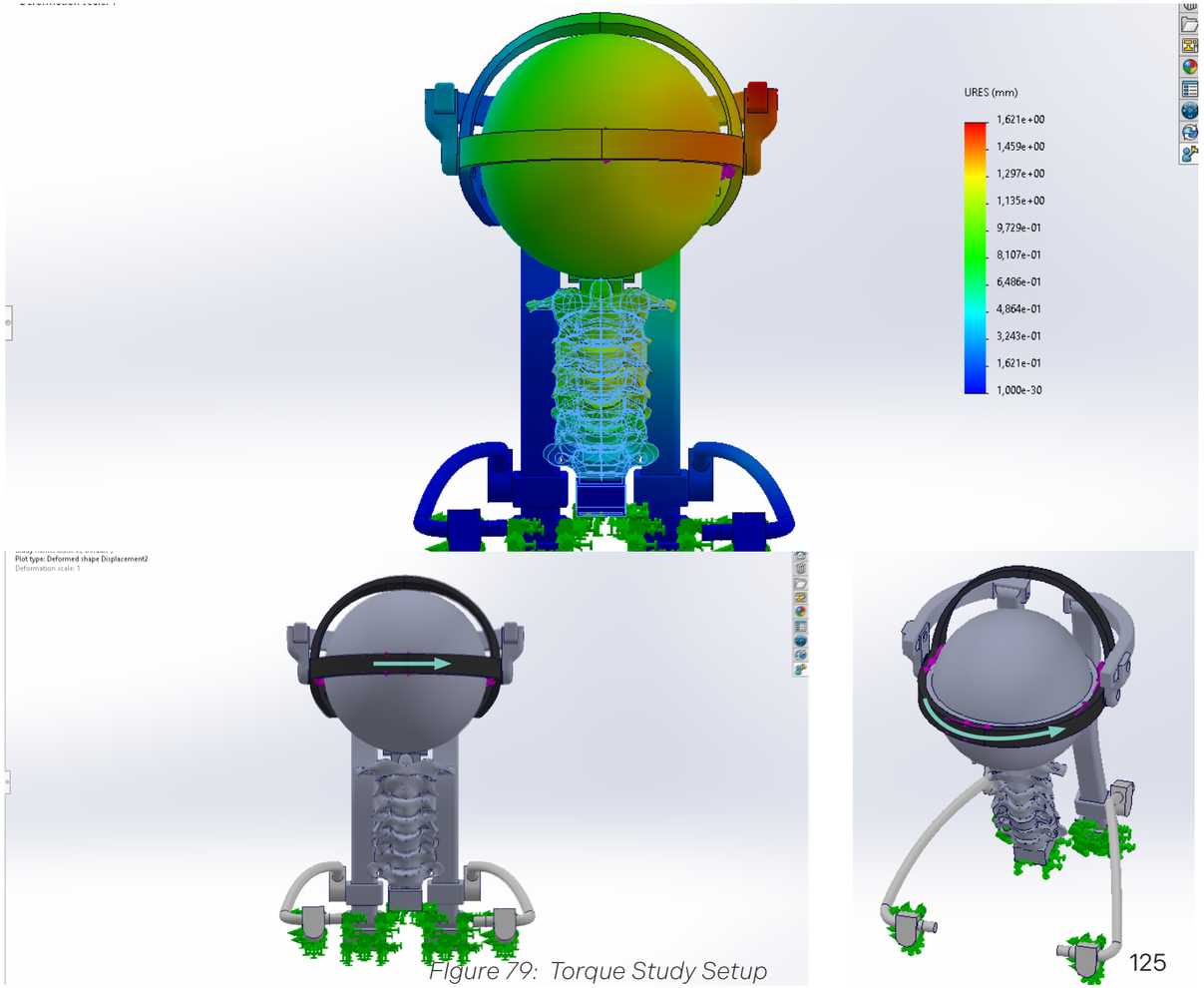


Figure 79: Torque Study Setup

FIgure 80: Re-Design

Manufacturing

Research into manufacturing.

The production of the redesigned Halo vest involves two primary manufacturing processes: carbon fibre composite production for the structural rods and injection moulding for the plastic vest. Since the new design uses some components of the old bremer vest, a collabpration with bremer medical is adviced.

Carbon Fibre Composite Manufacturing

Carbon fibre composites are widely used for their high strength-to-weight ratio and durability. Two factors that are very important in our design. The manufacturing process involves layering carbon fibres in a matrix, typically epoxy resin, and curing them under heat and pressure to achieve the desired mechanical properties.

Estimating Production Volume

To determine the most appropriate carbon fibre manufacturing process for the Halo vest, several assumptions need to be made. Since there is no available data on the estimated number of halo frame users in Europe, we base our calculations on figures from UMC Utrecht, one of the largest buyers of halo frames in the Netherlands. UMC Utrecht is a specialised centre focused on complex spinal injuries and treats patients referred from various hospitals. On average, they purchase around 70 halo frames per year, considering it a reliable solution for patient immobilisation.

In the Netherlands, there are approximately 120 hospitals, including 8 academic hospitals that generally handle more complex cases, such as halo frames. Most patients with severe spinal injuries are referred to these larger academic hospitals, as they have the necessary expertise and resources to manage such conditions. While these hospitals may not have the same level of specialisation as UMC Utrecht, it is reasonable to estimate that they manage about 50% of similar cases, leading to an estimated annual demand of: 7*35+70= **315 halo frames per year.**

Each halo frame consists of approximately 6 carbon fibre parts, resulting in a total production volume of: 315*6 = **1890 carbon fibre components per year**.
Given this production volume, Resin Transfer Moulding (RTM) is considered the most suitable manufacturing process. RTM offers the required balance of production efficiency, consistency, and cost-effectiveness, making it a practical choice for medium-scale production.

Key Considerations for the Halo Vest Design:

1. Manufacturing Process Selection
Resin Transfer Moulding (RTM) must be chosen for the production of the carbon fibre rods. RTM offers high precision and consistency, making it suitable for the estimated production volume of 1890 units per year. While it requires higher initial tooling costs, it ensures durable and lightweight components with minimal defects.

2. Fibre Orientation and Layup Design
Unidirectional lay-up must be selected to align the fibres with expected load paths, optimising the strength-to-weight ratio. FEA simulations need to be conducted to determine the specific required number of layers, ensuring structural integrity without adding unnecessary bulk.

3. Mould Design and Tooling
Aluminium moulds must be chosen due to their durability and ability to produce consistent parts over multiple production cycles. Shrinkage compensation needs to be factored into the design, and complex shapes must be simplified to enhance manufacturability.

4. Surface Finish and Aesthetic Considerations
A matte finish can be selected to reduce reflections and improve visual appeal. A clear protective coating must be applied to enhance durability and UV resistance. Post-processing includes light sanding and polishing to remove imperfections.

5. Joining and Assembly
Adhesive bonding must be chosen to connect the hinges to the carbon structure. This method provides a strong, lightweight solution while avoiding stress concentrations that mechanical fasteners might introduce.

6. Cost Considerations
The choice of RTM balances production efficiency with material costs. While carbon fibre components are expensive, their lightweight nature justifies the investment by improving usability and comfort for the patient.

Injection Moulding

Injection moulding is a manufacturing process that produces plastic components by injecting molten material into a mould cavity. It is widely used for creating complex parts with high precision and tight tolerances, typically in large production volumes. Although a production volume of 315*2 (front & backplate) units per year may be considered relatively low for this process, it is expected that the new design will be developed in collaboration with Bremer Medical. Since the new design closely resembles the existing vest, it is likely that a new mould will not be required, allowing the current moulds to be utilised.

Key Considerations for the Halo Vest Design

1. Material Selection
Medical-grade plastic must be chosen to ensure biocompatibility and durability.

2. Mould Design
An aluminium mould must be selected for its ability to produce consistent, high-quality parts while maintaining a long lifespan.

3. Surface Finish
The plastic vest must feature a smooth finish to enhance patient comfort and ease of cleaning.

Estimated Costs

Cost Estimation

When evaluating the cost of producing the redesigned Halo frame, it is important to consider the high expenses associated with carbon fibre manufacturing. Carbon fibre production involves specialised processes and materials that contribute to higher overall costs compared to traditional manufacturing methods.

The figures presented in this analysis are estimates and are not based on extensive research. They are intended to provide an initial illustration of a potential business case for the new design. A more detailed investigation is required to obtain accurate pricing and production costs. This can be achieved through discussions with manufacturers, suppliers, and industry experts.

1. Mould Investment Costs

The production of the Halo Frame requires significant upfront investment in moulds.

Two types of moulds are needed (Tempelman et al., 2014):
- Injection Moulding Moulds (2 units): ± €50,000 per mould, totaling €100,000.
- Carbon Fibre Moulds (4 units): €70,000 per mould, totaling €280,000.

Total Mould Investment:
€100,000 + €280,000 = €380,000

2. Production Costs per Unit

Each Halo Frame comprises several components, incurring the following estimated costs per unit. These estimations are made by checking suppliers, comparing with existing products, and estimating based on the price of raw materials.

- Plastic Vest: €200
- Titanium Screws: €100 (McMaster-Carr, n.d.)
- Carbon Fibre Material: €150
- Hinges (4 @ $30 each): €111.60 (McMaster-Carr, n.d.)
- Connection Pieces (4 @ €5): €20 (McMaster-Carr, n.d.)
- Labour and Assembly: €200
- Packaging and Logistics: €100

Total Production Cost per Unit:
€200 + €100 + €150 + €111.60 + €20 + €200 + €100 = €881.60

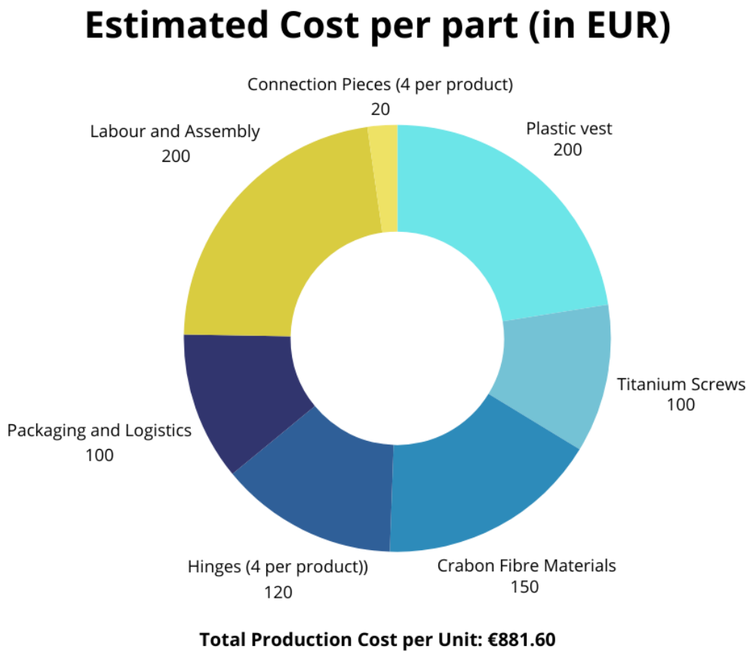


FIgure 81: Production Costs per Unit

3. Annual Production Costs

With an estimated production volume of 315 units per year, the production costs scale accordingly:

- Annual production cost: 315* €881,60 = €277.704
- Fixed operational costs per year: €50,000

Total Annual Costs:
€277.704 + €50,000 = €327.704

4. Compliance Costs for Class IIa Certification

Achieving regulatory compliance is critical, and the associated costs are estimated within the following ranges:

- Preclinical Testing: €30,000 – €60,000
- Clinical Evaluation: €50,000 – €120,000
- Documentation & Consultancy: €20,000 – €50,000
- Certification Fees (Notified Body): €40,000 – €100,000 (“Fees According to Regulation (EU) 2017/745 on Medical Devices,” 2023)
- Risk Management & Quality System: €20,000 – €50,000 (Peercode Regulatory Consultancy, n.d.)
- Usability Testing: €10,000 – €30,000
- Legal & Regulatory Consulting: €15,000 – €40,000 (BPT, 2024)

Total Estimated Compliance Cost: €185,000 – €450,000

Key Compliance Considerations:

- Clinical Evidence: Detailed clinical evaluation reports and patient trials.
- Ongoing Compliance: Regular audits by notified bodies.

5. Additional Investment Costs

Several other investment areas are critical to ensuring efficient production and market readiness:

- Assembly Equipment & Fixtures: €5,000 – €20,000
- Quality Control Equipment: €10,000 – €30,000
- Certifications & Compliance: €20,000 – €100,000
- Manufacturing Facility: €50,000

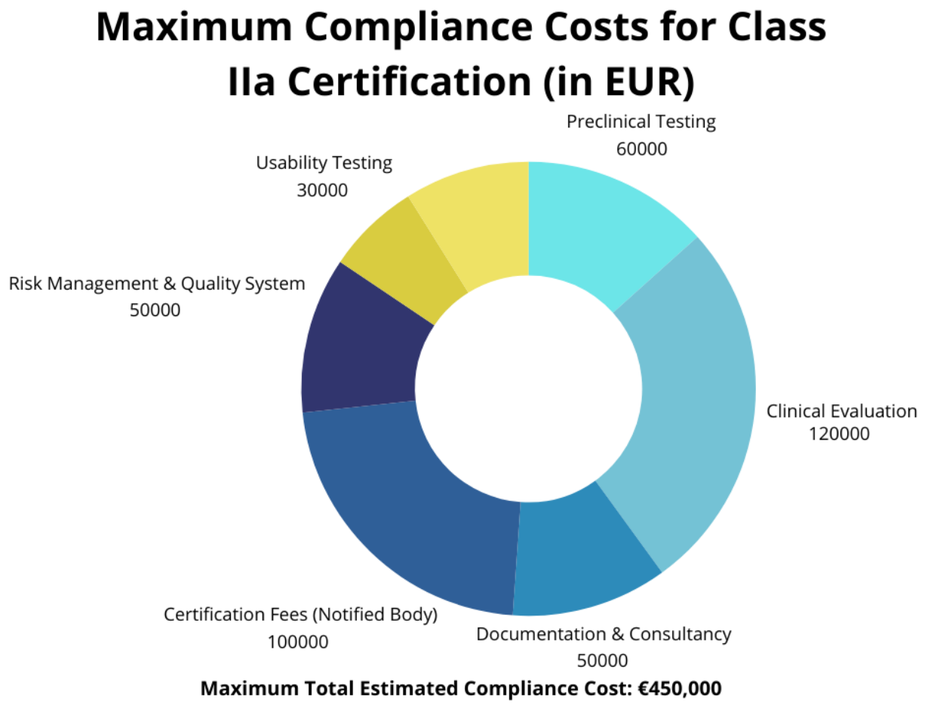


Figure 82: Compliance Costs for Class IIa Certification

- Personnel Training: €10,000 – €50,000
- Marketing & Distribution: €20,000 – €50,000

All of these estimates are made based on two business template for major startup expenses for medical device manufacturing and major startup expenses for equipment device manufacturing, both by BPT, 2024.

Key Considerations:

- Assembly Efficiency: Custom fixtures to ensure precision and repeatability.
- Quality Assurance: Load-bearing tests, fit checks, and non-destructive inspections.
- Facility Needs: Storage, utilities, and potential leasing options.
- Workforce Training: Specialized skills for handling composite materials.

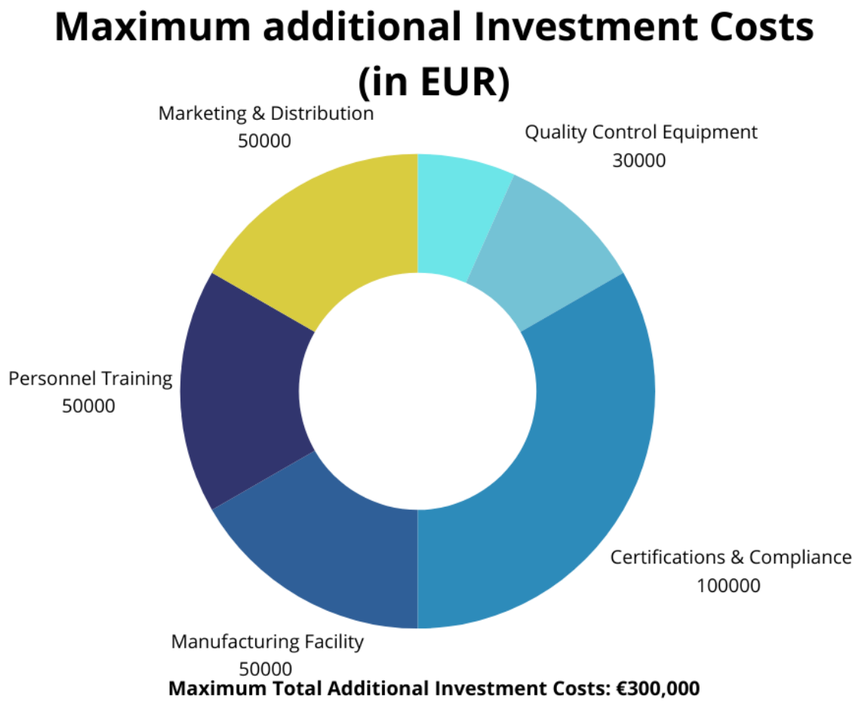


FIgure 83: Additional Investment Costs

6. Summary of Total Cost Structure

Combining all elements, the total investment needed encompasses:
1. Mould Investment: €380,000
2. Annual Production Costs: €327.704
3. Compliance Costs: €185,000 – €450,000
4. Additional Investments: €75,000 – €250,000 (excluding facility costs)

Grand Total Estimated Investment:
€1,439,360 – €1,879,360 (plus facility costs)

7. Determining Price Point

The price of a new halo frame could be set at €3,600. While the previous vest was sold for €3,000, the enhanced design of the new model offers significant improvements in aesthetics without compromising fit and adjustability—key factors identified as critical by both patients and healthcare providers.

Feedback from the orthopedic technician responsible for procurement at UMCU indicated that a **price point of €3,600–€4,000 could be acceptable,** if the benefits are substantial. The new vest delivers on this expectation by offering a modern, more visually appealing design that improves patient confidence and compliance, while maintaining the high standards required for comfort and functionality.

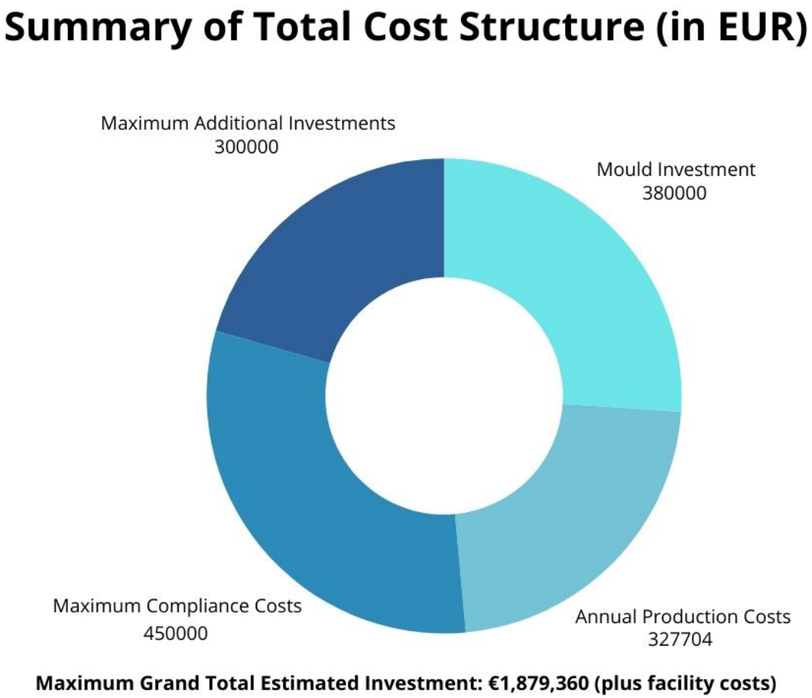


FIgure 84: Summary of Total Cost Structure

8. Revenue and Profit Calculation

The selling price per Halo Frame is set at €3,600. With an annual production of 315 units:

- Annual Revenue: 315 × €3600= €1,134,000
- Annual Profit (Revenue - Costs): €1,134,000 – €327,704= €806,296

9. Break-Even Analysis

1. Initial Investment:
- Mould Investment: €380,000
- Compliance Costs: €185,000 – €450,000
- Additional Investments: €75,000 – €250,000
- Total Investment Needed: €1,439,360 – €1,879,360 (excluding facility costs)

2. Annual Profit Calculation:
- Selling Price per Unit: €3,600 (up until €4,000)
- Annual Sales Volume: 315 units
- Annual Revenue: €1,134,000
- Annual Production Costs: €327,704
- Annual Profit: €806,296

3. Break-Even Point Calculation:
To calculate the payback period:
Break-Even Time=Total Investment/Annual Profit

Worst Case (Higher Investment Estimate):
1,879,360/806,296≈2.33 years

Thus, the company would reach break-even within 2.3 years, depending on final investment costs.

MDR Certification Process for the Halo Frame (Class IIa Device)

Introduction

The certification of the Halo frame under the Medical Device Regulation (MDR) (EU) 2017/745 is essential to ensure compliance with regulatory requirements and market access within the European Union. The Halo frame is classified as a Class IIa medical device, indicating a moderate risk level and requiring conformity assessment by a Notified Body. The following document outlines the necessary steps to achieve MDR compliance and provides a detailed overview of the design, risk management, and verification and validation processes.

Intended Purpose

The Halo frame is designed to provide cranial and cervical immobilization for patients with spinal fractures, neck injuries, or head trauma. Its primary function is to stabilize the head and neck, preventing movement and ensuring proper alignment during the healing process. It is intended for use by healthcare professionals in hospital or clinical settings and is suitable for both adult and pediatric patients.

- The Halo frame consists of the following components:
- A halo ring that encircles the patient's head, secured using pins attached to the skull.
- Adjustable back rods connecting the halo to a medical-grade plastic vest worn on the torso, ensuring the head and neck remain fixed in the correct position.
- The redesigned structure features carbon fibre rods and a medical-grade plastic base, providing enhanced durability and lightweight support.
- The frame is adjustable to fit patients of various sizes, covering height ranges of 155 cm to 175 cm and 175 cm to 200 cm.

Steps for MDR Compliance

While it is too early to begin the formal MDR documentation process, understanding the necessary steps is important for effective preparation. This chapter outlines the key requirements for obtaining certification, ensuring the Halo frame meets regulatory standards and is ready for MDR approval.

Step 1: Determine Device Classification

As a Class IIa medical device, the Halo frame requires involvement from a Notified Body for certification. Classification validation should be done using MDR Annex VIII guidelines.

Key Actions:
- Confirm classification according to MDR criteria.
- Consult with regulatory experts (like PONTES at UMCU) to ensure compliance.

Step 2: Quality Management System (ISO 13485)

Compliance with ISO 13485 is required to establish a Quality Management System (QMS) that covers all aspects of design, production, and distribution.
Key Actions:
- Develop procedures for design control, supplier management, and complaint handling.
- Maintain comprehensive records for audits.
- Train staff on QMS implementation.

Step 3: Technical Documentation (MDR Annex II & III)

A comprehensive Technical File must be compiled, covering the entire lifecycle of the device, including:
1. Device Description & Specifications – Purpose, design, materials, and performance

criteria.
2. Risk Management (ISO 14971) – Potential risks and mitigation strategies.
3. Clinical Evaluation Report (CER) – Safety and performance validation.
4. Preclinical Testing – Mechanical testing, fatigue analysis, biocompatibility reports.
5. Usability Testing – Ergonomic assessments.
6. Labeling & Instructions for Use (IFU) – Compliance with MDR requirements.

Step 4: Risk Management (ISO 14971)

Risk Management involves the systematic process of identifying, assessing, and controlling risks associated with the halo frame. The risk management process includes:

- Risk Assessment: Identifying potential hazards related to the device, such as mechanical failure, biocompatibility issues, and user errors. Each identified hazard is evaluated for its severity and probability of occurrence.
- Risk Control Measures: Implementing measures to mitigate identified risks, such as using high-strength materials, ensuring proper manufacturing processes, and providing detailed instructions for use.
- Residual Risks: Documenting any remaining risks after control measures are applied and evaluating their acceptability. Continuous monitoring and review are conducted to ensure ongoing safety.

Step 5: Selecting a Notified Body

A Notified Body will perform conformity assessments and approve the CE certification.
Verification and Validation activities ensure that the halo frame meets its intended purpose and specifications. The process includes:

- Verification: Conducting tests and inspections to confirm that the device design and manufacturing processes meet the specified requirements. This includes dimensional inspections, material testing, and performance tests.
- Validation: Demonstrating through clinical and laboratory testing that the final device performs as intended in real-world conditions. This includes user trials and simulated use scenarios to confirm device safety and efficacy.

Key Actions:

- Choose a Notified Body (e.g., TÜV SÜD, BSI, DEKRA).
- Submit applications and plan audits.

Step 6: Preclinical and Clinical Testing

Testing is required to validate the design and performance of the device.

Preclinical Testing

- Material Testing: All materials used in the halo frame must undergo rigorous testing for biocompatibility, mechanical strength, and durability.
- Dimensional Inspection: Each component must be inspected using precision measurement tools to verify that it meets the specified dimensions and tolerances.
- Performance Testing: Assembled halo frames must be subjected to dynamic performance tests, including more advanced stress tests, cyclic loading tests, impact tests, torsion tests, etc. to ensure they can withstand the forces encountered during use.
- Sterilization Validation: The sterilization methods must be validated to confirm that the materials and components can be effectively sterilized without compromising their integrity or performance.
- Final Inspection: A comprehensive final inspection must be conducted on each halo frame to ensure it meets all design and safety requirements before being approved for distribution.

Clinical Evaluation

Clinical Evaluation involves a comprehensive assessment of clinical data to demonstrate the safety and performance of the halo frame compliance with ISO 14155. This includes:

- Reviewing clinical studies and literature related to similar devices.
- Collecting clinical data from real user trials and real-world use cases.
- Analyzing the data to confirm that the device performs as intended and does not pose undue risks to patients.
- Preparing a clinical evaluation report that summarizes the findings and supports the device's safety and efficacy.

Step 7: Post-Market Surveillance (PMS)

Post-Market Surveillance Plan ensures ongoing monitoring of the halo frame's performance and safety after it is placed on the market. This includes:

- Collecting and analyzing data from users and healthcare professionals.
- Monitoring adverse events and device-related incidents.
- Implementing corrective actions if necessary to address identified issues.
- Regularly reviewing and updating the surveillance plan to ensure continued compliance and safety.

Step 8: Audit Preparation and Submission

Submit the Technical File to the Notified Body for review and prepare for the certification audit.

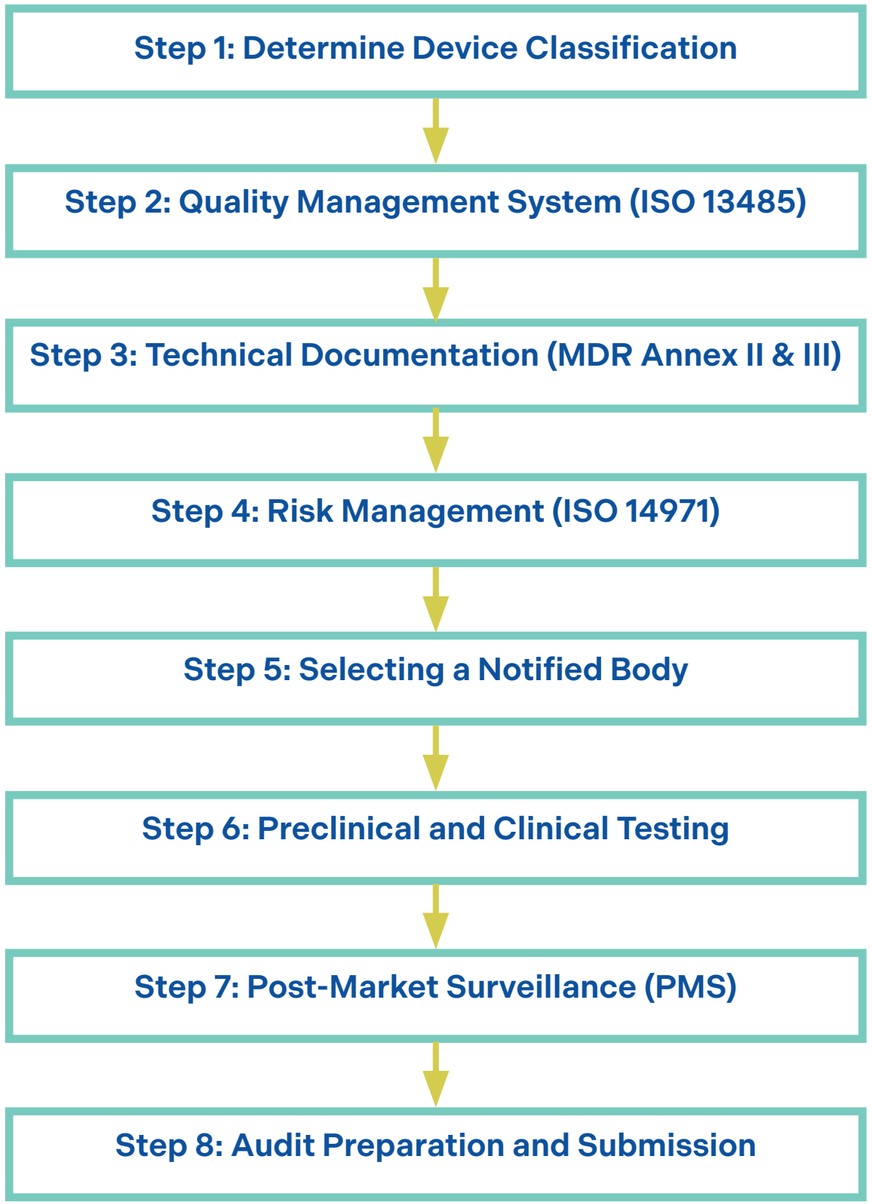


FIgure 85: MDR Flowchart

Material Finish

Exploration of Color Schemes for the Halo Framel

An initial exploration into the color scheme of the Halo Frame was conducted by sketching different combinations and divisions. The selected colors were based on those commonly used in other medical devices, ensuring familiarity and professional aesthetics. This chapter aimes to demonstrate that the traditionally black structure of the frame can be adapted to a variety of colors, significantly influencing its visual appeal.

While this project did not include a formal color analysis or user feedback on preferred colors, it is recommended that future research incorporates such evaluations. Understanding patient and healthcare provider preferences will be essential in selecting colors that enhance acceptance and usability.

Most of the explored color schemes consist of neutral and earth tones, as these are generally perceived as more discreet and calming. Colors that closely match a person's skin tone can help the frame blend with the user's features, making it less visually intrusive. However, lighter shades—though appearing less heavy—are more prone to staining, which is a crucial consideration for a device that restricts the ability to shower.

Despite these practical limitations, a variety of colors were tested to illustrate the potential impact of different tones. This exploration highlights the importance of further investigating color choices, as they can play a significant role in improving the overall aesthetics and user experience of the Halo Frame.

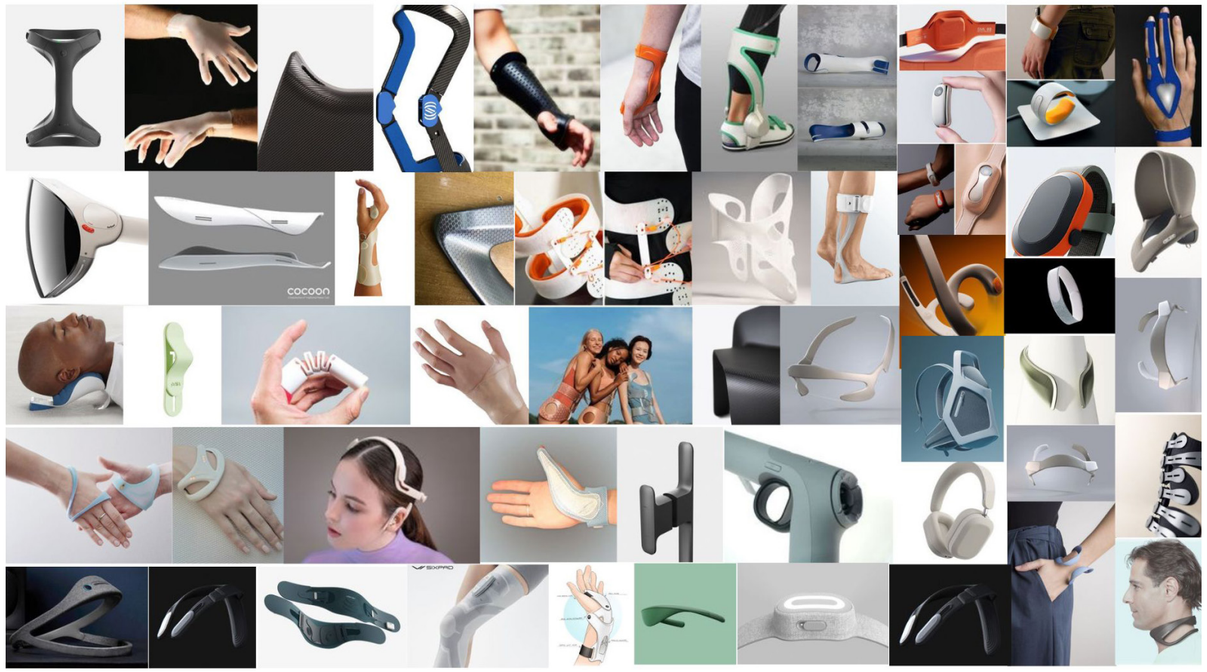


FIgure 87: Inspiration Board

FIgure 88: Different Look and Feel Options

Final Product

Curved Horizontal Rods

To make horzontal rods blend in with the head.

Two Curved Back Beams

To carry most of the load. The shape blends in with the neck and head

Adjustable and Lockable Hinges

To facilitate different physiques of various users. See the next slide for details of different hinges.

Clear Acrylic Front Rods

Shaped around the shoulder to minimize appearance

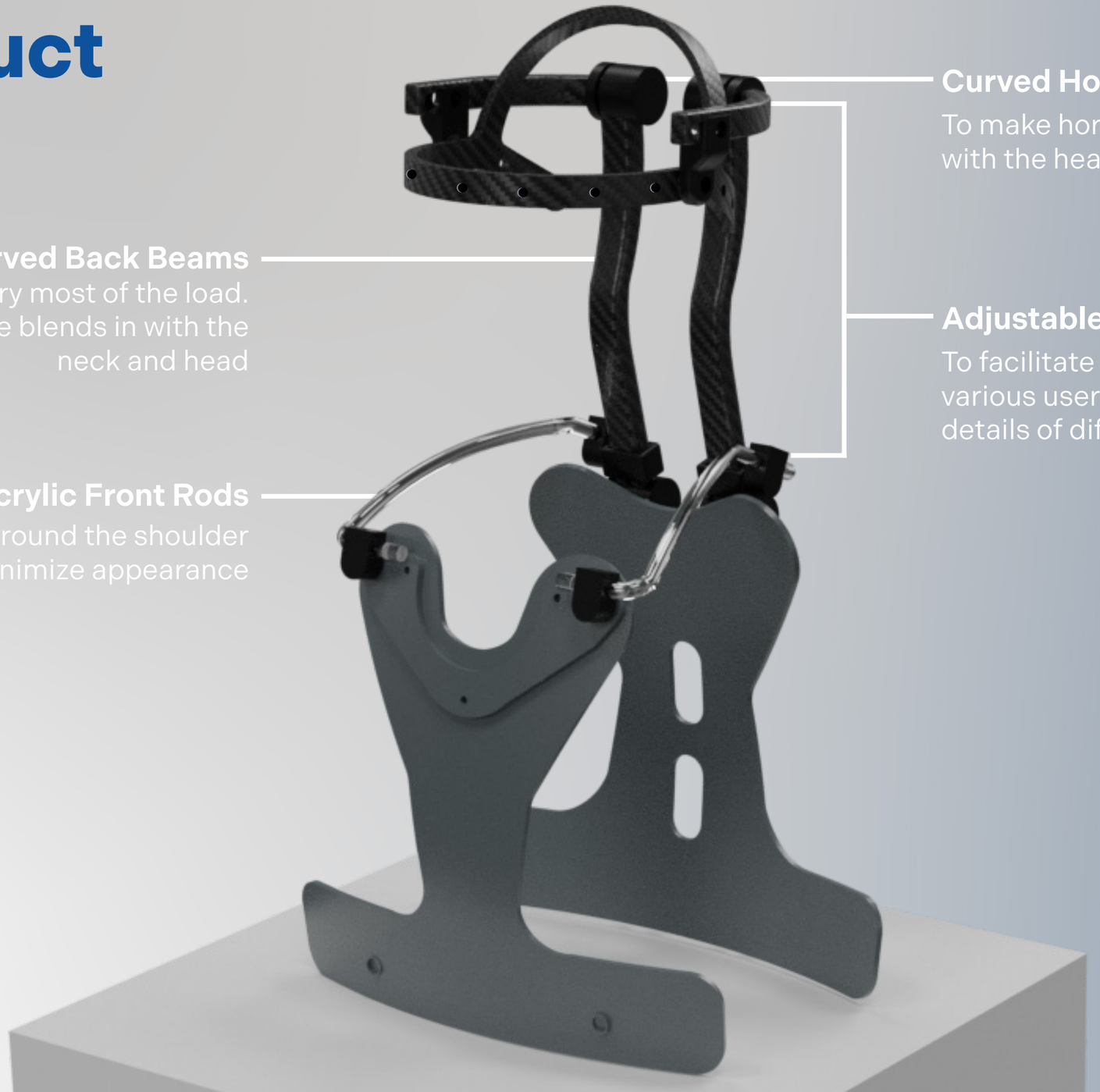
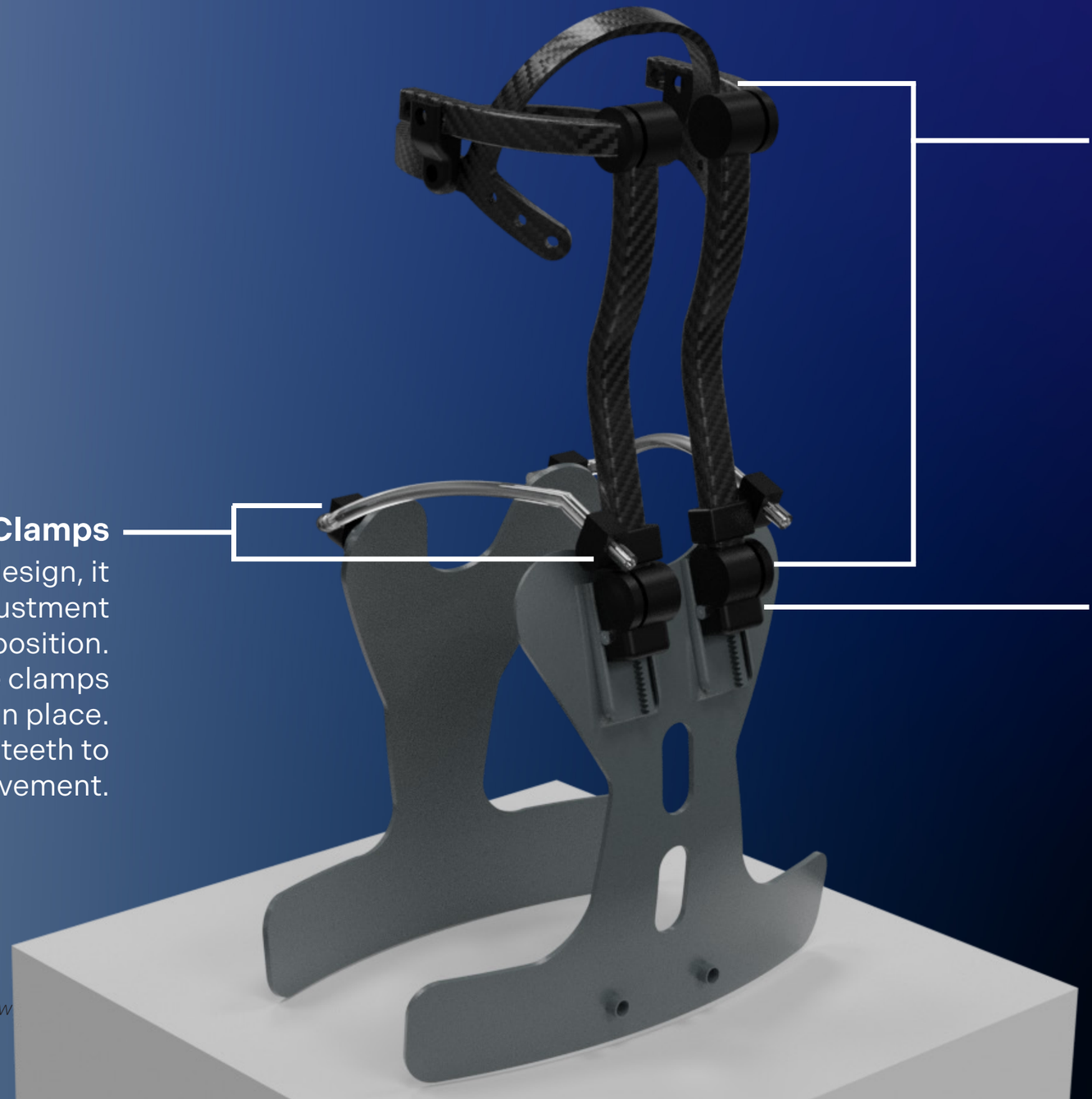


FIgure 89: Final Product - Front View



Rotational Hinges

Click the round sides to adjust rotation in 10-degree increments.

Rod Clamps

As in the original design, it allows for the adjustment of the front rods' position. After tightening, the clamps keep the rods in place. The clamps have teeth to prevent movement.

Sliding Hinges

A rack and pinion system gradually moves the hinge block up and down, allowing the back structure to extend to different heights

FIgure 90: Final Product - Back View

Project Wrap-up

Recommendations

1. Intellectual Property (IP) Application

Before moving forward, a novelty search should be conducted to ensure that the design does not infringe on existing patents. If the design is confirmed as unique, applying for a patent is recommended to protect the intellectual property and ensure exclusivity in the market.

2. Research and Prototype Development

Creating a prototype using the actual materials, such as carbon fibre rods and medical-grade plastic, is essential. This will allow for more realistic testing of the design's fit, performance, and usability. Testing with a physical prototype will also help identify potential design flaws and areas for refinement that cannot be fully captured in simulations or theoretical models.

3. Testing Aesthetic Appeal

While initial steps have been taken to improve the visual appeal of the Halo frame, further focused research is needed to refine the design's aesthetics. This includes identifying a style that best aligns with user preferences and improves the device's acceptance among patients and healthcare providers. Surveys, interviews, and visual prototypes can help determine the most effective style.

4. Performance Testing

The assembled Halo frames must undergo comprehensive performance testing to ensure their durability and safety. These tests should include:

- Dynamic Performance Tests: Simulating real-life forces and movements.
- Stress Tests: Evaluating the frame's resistance to extreme loads.
- Cyclic Loading Tests: Assessing long-term durability under repeated forces.
- Impact Tests: Ensuring the frame can handle sudden shocks or impacts.
- Torsion Tests: Measuring resistance to twisting forces.

While computer simulations can provide valuable insights, these tests must also be conducted on physical prototypes to validate the results and ensure the frame meets all safety requirements.

5. Design for Manufacturing (DfM)

To ensure the product can be efficiently produced at scale, it is essential to engage with manufacturers early in the design process. Collaboration with manufacturers can help:

- Optimise the design for ease of production.
- Reduce material waste and production costs.
- Ensure the design is compatible with the chosen manufacturing methods, such as injection moulding and resin transfer moulding.

6. Extensive Assembly Testing with Orthopaedic Technicians

Conducting extensive testing of the frame assembly process with orthopaedic technicians is crucial to ensure the design is intuitive and practical for real-world use. Using a high-quality prototype, the assembly process should be tested on a dummy or simulated patient to identify potential challenges and refine the design. Key areas to focus on include:

- • Ease of Assembly: Evaluate whether the assembly instructions and process are clear and straightforward.
- • Time Efficiency: Measure the time it takes to assemble the frame and identify steps that can be streamlined.
- • Accessibility of Components: Assess whether parts, such as hinges and adjustment points, are easily accessible during assembly, particularly in challenging scenarios (e.g., when the patient is lying down).
- • Feedback Collection: Gather input from orthopaedic technicians to understand their experiences and suggestions for improvement.

This testing will help optimise the design for ease of use in clinical settings and ensure the frame meets the needs of healthcare professionals.

8. MDR Process and Regulatory Compliance

The MDR certification process must be prioritised to ensure the device can be legally marketed in the EU. This includes:

- Establishing a Quality Management System (QMS) compliant with ISO 13485.
- Preparing the necessary technical documentation, including risk management and clinical evaluation.
- Engaging with a Notified Body to perform conformity assessments.
- Ensuring ongoing compliance through post-market surveillance and feedback collection.

7. Packaging and Distribution

An important but currently vaguely addressed aspect of the design is how the device will be packaged and distributed. Decisions need to be made regarding:

- Which parts are shipped pre-assembled and which require assembly on-site.
- Whether interchangeable parts (e.g., rods of varying sizes) are included or sold separately.
- Packaging design that ensures safe transport and efficient storage.

9. Research into Component Reuse

Currently, the Halo frame is designed for single use, which raises concerns about environmental sustainability and cost justification for a higher price point. To address these issues, research should be conducted into the potential for reusing certain components of the frame. This process would involve:

- Strength Testing for Reuse: Establishing procedures to test components, such as carbon fibre rods and hinges, to ensure they maintain their structural integrity after extended use.
- Sanitization and Sterilization: Developing methods to safely sanitize and sterilize reusable components without degrading material properties.
- Usage Guidelines: Creating clear guidelines on how long a frame or its components can remain in use, including maximum timeframes or patient cycles.
- Component Replacement: Identifying parts that can be easily replaced, such as screws or straps, while reusing the primary structure.
- Environmental Impact Assessment: Evaluating how reusability can reduce waste and the environmental footprint of the product.

By exploring reusability, the Halo frame can become a more sustainable solution while reducing long-term costs for healthcare providers. Clear procedures for reusing components can also increase the product's appeal to environmentally conscious stakeholders.

Conclusion

Based on the research and analysis of the current Halo Frame, areas for improvement have been identified and translated into a redesign that must be both practically feasible and commercially attractive. The three core aspects—Feasibility, Viability, and Desirability—serve as the guiding principles for the final assessment of this project.

Feasibility

The technical feasibility of the redesign has been evaluated through material analyses, production methods, and simulations such as Finite Element Analysis (FEA). The results show that the proposed design offers comparable structural integrity compared to the current frame.

- **Material selection:** The use of lightweight, strong materials such as carbon fiber epoxy composite provides a balance between strength and wearing comfort.
- **Regulations & certification:** The new design must comply with medical guidelines and certification requirements (e.g., MDR in Europe). The proposed materials and construction indicate that certification is feasible, but validation through clinical testing remains necessary.
- **Structural strength:** The vest meets safe spine deformation limits while maintaining structural performance as shown in the FEA analysis, ensuring that it provides adequate support without compromising patient safety.
- **Imaging compatibility:** Carbon fiber allows for clear medical imaging without interference, ensuring that X-rays, CT scans, and MRIs can be performed without obstruction. This benefits form the current frame, which is Titanium or Aluminium which does disrupt medical imaging.

In conclusion: The technical feasibility of the new Halo Frame is high, but implementation requires validation steps and possible production adjustments.

Viability

The economic and market feasibility analysis of the redesign shows that the product is commercially viable, provided that the added value is substantiated and effectively communicated.

- **Cost & pricing:** The estimated production costs of the new design remain within an acceptable margin compared to the current version. Since the old frame was sold for €3,000, and an increase to €3,600–€4,000 is considered acceptable if significant improvements are made, the redesign is financially feasible.
- **Market demand & competition:** User feedback supports the demand for a better-fitting and more aesthetically appealing frame. However, competition with existing suppliers and the willingness of healthcare institutions to pay more remain key considerations.
- **Market Fit:** The enhanced aesthetics make the Halo Frame more appealing to patients, reducing stigma and improving compliance. Healthcare providers may favor it as a more patient-friendly alternative without compromising medical effectiveness.

In conclusion: The redesign is economically viable within the expected price range, but further market validation and positioning are crucial to justify the investment.

Desirability

Research on the user experience of the Halo Frame has confirmed that both patients and healthcare professionals desire improvements, particularly in terms of comfort, fit, and aesthetics.

- **Patient experience:** Interviews and quantitative assessments indicate discomfort and negative perception, especially during prolonged use. A more ergonomic shape and aesthetic design can significantly improve the experience.
- **Psychological well-being:** A modern and less medical-looking design helps reduce the stigma of wearing a Halo Frame, contributing to an improved psychological well-being for the patient.
- **Acceptance by healthcare professionals:** Orthopedic technicians and physicians are open to innovation, but they emphasize that functional reliability must not be compromised by aesthetic improvements. Therefore, the new design is both practical and visually appealing.
- **Modularity and adaptability:** The design can easily be adjusted to different body

types and enhances usability.
- **Integration of patient feedback:** An iterative development process that directly incorporates patient feedback ensures that the final product aligns with actual needs and user preferences.

In conclusion: The demand for an improved Halo Frame is evident. The adjustments in comfort and appearance increase acceptance among users, provided that functional performance remains guaranteed.

Overall, this redesign of a Halo Frame can not only meet the functional requirements of healthcare professionals but also significantly improve the quality of life for patients.

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