Appendix

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IDE Master Graduation Project

Project team, procedural checks and Personal Project Brief

In this document the agreements made between student and supervisory team about the student's IDE Master Graduation Project are set out. This document may also include involvement of an external client, however does not cover any legal matters student and client (might) agree upon. Next to that, this document facilitates the required procedural checks:

- Student defines the team, what the student is going to do/deliver and how that will come about
- Chair of the supervisory team signs, to formally approve the project's setup / Project brief
- SSC E&SA (Shared Service Centre, Education & Student Affairs) report on the student's registration and study progress
- IDE's Board of Examiners confirms the proposed supervisory team on their eligibility, and whether the student is allowed to start the Graduation Project

STUDENT DATA & MASTER PROGRAMME

Complete all fields and indicate which master(s) you are in

Family name	[redacted]	IDE master(s)	IPD ✔ DfI ☐ SPD ☐
Initials		2nd non-IDE master	
Given name		Individual programme *(date of approval)*	
Student number		Medisign	☐
		HPM	☐

SUPERVISORY TEAM

Fill in he required information of supervisory team members. If applicable, company mentor is added as 2nd mentor

Chair	R.H.M. Goossens	dept./section	Human Centred Design
mentor	E.L. Doubrovski	dept./section	Sustainable Design Engineering
2nd mentor			
client:	J.J. Verlaan/ UMC Utrecht		
city:	Utrecht	country:	The Netherlands
optional comments			

! Ensure a heterogeneous team. In case you wish to include team members from the same section, explain why.

! Chair should request the IDE Board of Examiners for approval when a non-IDE mentor is proposed. Include CV and motivation letter.

! 2nd mentor only applies when a client is involved.

APPROVAL OF CHAIR on PROJECT PROPOSAL / PROJECT BRIEF -> to be filled in **by the Chair** of the supervisory team

Sign for approval (Chair)

Richard Goossens - IO — Digitally signed by Richard Goossens - IO Date: 2024.09.30 09:11:42 +02'00'

Name R.H.M. Goossens Date 4 sept 2024 Signature

CHECK ON STUDY PROGRESS

To be filled in **by SSC E&SA** (Shared Service Centre, Education & Student Affairs), after approval of the project brief by the chair. The study progress will be checked for a 2nd time just before the green light meeting.

Master electives no. of EC accumulated in total _____ EC

Of which, taking conditional requirements into account, can be part of the exam programme _____ EC

★	YES	all 1st year master courses passed
	NO	missing 1st year courses

Comments:

Sign for approval (SSC E&SA)

Robin den Braber — Digitaal ondertekend door Robin den Braber Datum: 2024.10.02 10:08:39 +02'00'

Name Robin den Braber Date 2 okt 2024 Signature

APPROVAL OF BOARD OF EXAMINERS IDE on SUPERVISORY TEAM -> to be checked and filled in by IDE's Board of Examiners

Does the composition of the Supervisory Team comply with regulations?

YES	★	Supervisory Team approved
NO		Supervisory Team not approved

Comments:

Based on study progress, students is ...

★	**ALLOWED** to start the graduation project
	NOT allowed to start the graduation project

Comments:

Sign for approval (BoEx)

Monique von Morgen — Digitally signed by Monique von Morgen Date: 2024.10.02 10:42:32 +02'00'

Name Monique von Morgen Date 2 Oct 2024 Signature

DESIGN FOR our future

TU Delft

Personal Project Brief – IDE Master Graduation Project

Name student Maxime Iserief **Student number** 4,868,749

PROJECT TITLE, INTRODUCTION, PROBLEM DEFINITION and ASSIGNMENT

Complete all fields, keep information clear, specific and concise

Project title Redesign of a Halo-Vest

Please state the title of your graduation project (above). Keep the title compact and simple. Do not use abbreviations. The remainder of this document allows you to define and clarify your graduation project.

Introduction

Describe the context of your project here; What is the domain in which your project takes place? Who are the main stakeholders and what interests are at stake? Describe the opportunities (and limitations) in this domain to better serve the stakeholder interests. (max 250 words)

The project aims to improve the experience of patients using a modern Halo Frame, as depicted in Figure 1. A Halo vest is a medical device used to externally stabilize the neck vertebrae, preventing movement following a cervical spine fracture or weakening due to disease. Typically, the vest is worn for about three months. It comprises three main components: a halo crown (a ring secured to the head with pins), a plastic vest with soft padding that rests against the skin, and four rods connecting the halo crown to the vest.

Despite its long-standing use, the halo vest's design has seen little change since the 1980s. Research from that era, see Figure 2, shows images of a halo vest nearly identical to those used today. This lack of development is mainly because, from a medical perspective, the device effectively stabilizes the neck. However, minimal attention has been given to the user experience, resulting in a design that prioritizes functionality over comfort. According to surgeons and plaster cast makers at UMC Utrecht, the current design is often poorly received by patients and doctors due to its lack of user-friendliness and intimidating appearance.

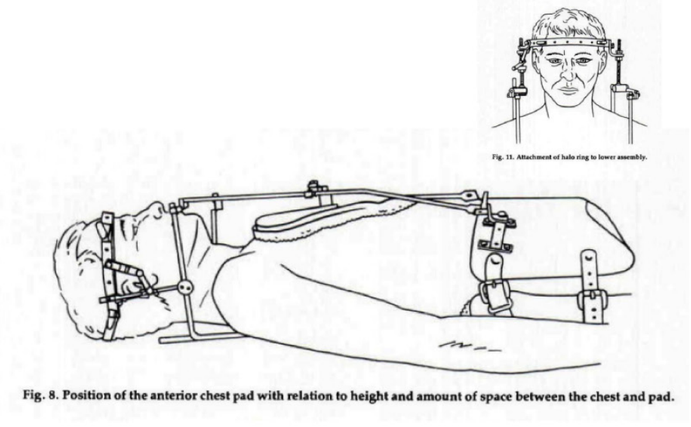
Patients and healthcare providers desire a less invasive, more comfortable, and reliable solution. Although the halo vest provides significant benefits, such as enhanced patient mobility compared to bed rest, it also presents challenges. These include ensuring complete stability of the neck vertebrae, addressing ethical and regulatory concerns, and conducting safe testing on vulnerable patients to meet safety and ethical standards.

➔ *space available for images / figures on next page*

introduction (continued): space for images

Halo Vest patient information brochure providing details on managing and caring for oneself while wearing a Halo Vest. (z.d.). [Pamflet]. In *Halo Vest* (p. 2). UZ Leuven. https://www.uzleuven.be/nl/media/20f68cca-4542-48df-847a-2fc1f81b39c7/700055_v122019_halo_jacket_EN_v01.pdf

image / figure 1 Modern Halo Frame (UZLeuven, n.d.)



Young, R., C. O., & Murphy, D. J., M. D. (1983). The Halo-Girdle Orthosis Application. Orthotics and Prosthetics, 37(2), 39–44. https://www.oandplibrary.org/op/pdf/1983_02_039.pdf

image / figure 2 Halo-Vest used in 1983 (Young & Murphy, 1983)

Personal Project Brief – IDE Master Graduation Project

Problem Definition

What problem do you want to solve in the context described in the introduction, and within the available time frame of 100 working days? (= Master Graduation Project of 30 EC). What opportunities do you see to create added value for the described stakeholders? Substantiate your choice.
(max 200 words)

The main challenge in developing an alternative Halo vest is improving user comfort. This requires addressing issues related to the fit and aesthetics of the device. Several issues can be addressed, including the intimidating appearance, discomfort while sleeping, movement restrictions beyond necessary limitations, compatibility with daily life and clothing, scalp infections, sizing, pressure sores, and chafing.

Conflicting requirements: It must provide strong cervical spine stabilization for safety while also enhancing comfort and reducing invasiveness. This includes managing discomfort during sleep, minimizing movement limitations, improving the device's appearance, and ensuring it integrates seamlessly with daily activities and clothing. However, these needs often conflict; increasing stability can decrease comfort and appearance, while improving comfort and appearance might compromise neck stability. Innovative materials and design strategies are essential to balance these demands.

Knowledge Gap: The current Halo vest works medically, but the design has drawbacks such as discomfort, maintenance challenges and overall low acceptance due to the look and feel of the product. The knowledge gap involves innovating the original design from the 1980's from a user perspective, as very little iterations have been done over time. It involves creating a design that provide necessary spinal stability while improving the patients experience. Acceptance and daily life integration is desired. New designs must be rigorously tested to meet safety standards without compromising stabilization. Addressing this gap is crucial for creating a better Halo vest for the patient.

Assignment

This is the most important part of the project brief because it will give a clear direction of what you are heading for. Formulate an assignment to yourself regarding what you expect to deliver as result at the end of your project. (1 sentence)
As you graduate as an industrial design engineer, your assignment will start with a verb (Design/Investigate/Validate/Create), and you may use the green text format:

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.

Then explain your project approach to carrying out your graduation project and what research and design methods you plan to use to generate your design solution (max 150 words)

Conducting literature research on halo vests, vertebrae constraints, personalized breast and backplates, additive manufacturing, personalization, and medical device development regulations is crucial. This includes analyzing existing stabilization solutions and aligning findings with stakeholders' insights. Interviews and observations with experts (surgeons, orthopedists, and `gipsverbandmeesters') and users will provide further understanding of their needs. Tools like SolidWorks and Grasshopper will aid in concept development.

The ideation phase will run concurrently, guided by a customized Double Diamond Model. This model allows for parallel work on prototyping and literature research, enabling comprehensive idea exploration through sketches, low-fidelity prototypes, and 3D renders. Periodic reviews with mentors, and user and field tests, will refine the design.

The project will culminate in functional prototypes, serving as proof of concept and tangible representations of the work, aimed at advancing neck vertebrae stabilization technology.

Project planning and key moments

*To make visible how you plan to spend your time, you must make a planning for the full project. You are advised to use a Gantt chart format to show the different phases of your project, deliverables you have in mind, meetings and in-between deadlines. Keep in mind that all activities should fit within the given run time of 100 working days. Your planning should include a **kick-off meeting**, **mid-term evaluation meeting**, **green light meeting** and **graduation ceremony**. Please indicate periods of part-time activities and/or periods of not spending time on your graduation project, if any (for instance because of holidays or parallel course activities).*

Make sure to attach the full plan to this project brief.
The four key moment dates must be filled in below

Kick off meeting	4 sept 2024
Mid-term evaluation	25 okt 2024
Green light meeting	20 dec 2024
Graduation ceremony	31 jan 2025

In exceptional cases (part of) the Graduation Project may need to be scheduled part-time. Indicate here if such applies to your project

Part of project scheduled part-time	
For how many project weeks	
Number of project days per week	

Comments:

Motivation and personal ambitions

Explain why you wish to start this project, what competencies you want to prove or develop (e.g. competencies acquired in your MSc programme, electives, extra-curricular activities or other).

Optionally, describe whether you have some personal learning ambitions which you explicitly want to address in this project, on top of the learning objectives of the Graduation Project itself. You might think of e.g. acquiring in depth knowledge on a specific subject, broadening your competencies or experimenting with a specific tool or methodology. Personal learning ambitions are limited to a maximum number of five.
(200 words max)

I wish to start this project to address the significant challenges faced by patients using the current Halo vest, aiming to enhance their comfort and quality of life. By developing a more personalized and less invasive alternative, I hope to make a meaningful impact on patient care and recovery.

Through this project, I aim to prove and develop several competencies. I seek to deepen my understanding of personalizing medical devices using additive manufacturing and to learn how to create digital prototypes that fit the human body accurately. Specifically, I want to gain proficiency in using SolidWorks and Grasshopper for these purposes.

Additionally, I have personal learning ambitions to expand my knowledge in medical product design. My interest in this field stems from a desire to merge engineering principles with healthcare needs, creating innovative solutions that directly benefit patients. By working on this project, I aim to contribute to advancements in medical technology, ultimately improving patient outcomes and healthcare experiences.

I also enjoy working with people and see this project as an opportunity to engage closely with patients. I look forward to collaborating with them to gain insights and feedback, which will be invaluable in developing a better solution. This hands-on interaction will not only help in creating a more effective device but also allow me to make a direct positive impact on the lives of those involved.

Appendix A: Analysis of the EU Medical Device Regulations for Halo Vests

The EU Medical Device Regulations (MDR), particularly the "Requirements for medical devices and medical electrical equipment," provide a comprehensive framework to ensure the safety, functionality, and usability of medical devices like the halo vest. The following sections of the MDR are especially relevant to the development and regulation of the halo vest.

1. Environmental Operating Conditions (Section 4.2):
Although the halo vest is not an electronic device, the materials and components must remain effective in a variety of environmental conditions. This includes exposure to changes in temperature, humidity, and potential contaminants to prevent skin irritation or material degradation.

2. Usability of Accompanying Documents (Section 7):
The accompanying documents, including user manuals and care instructions, must be clear and accessible to both healthcare professionals and caregivers. Detailed instructions are crucial to ensure proper fitting, maintenance, and cleaning of the halo vest, preventing misuse or injury.

3. Biocompatibility and Skin Safety (Section 10):
Given the prolonged contact of the halo vest with the skin, it is essential that the materials used are biocompatible and do not cause adverse reactions. Compliance with ISO 10993 standards on biological evaluation of medical devices should be ensured to avoid irritation or allergic responses.

4. Protection Against Excessive Pressure and Injury (Section 8):
The halo vest must be designed to prevent excessive pressure on the body, particularly the chest and neck, where the vest is anchored. The device must also safeguard against any risk of injury during fitting and prolonged wear, ensuring patient comfort and reducing complications like pressure sores.

5. Accuracy of Adjustment Mechanisms (Section 9):
The vest's mechanical components, such as screws and pins used to secure the head and neck, must allow for precise adjustments to ensure effective stabilization. Proper calibration and locking mechanisms are vital to avoid over-tightening or loosening, which could endanger the patient.

6. Structural Integrity and Durability (Section 10):
The construction of the halo vest must meet the mechanical strength requirements for long-term wear. The device should remain effective over extended periods without losing structural integrity, which is crucial to maintaining immobilization of the spine during recovery.

7. Protection Against Strangulation or Asphyxiation (Section 11):
Due to the vest's close proximity to the neck, it must be carefully designed to avoid any risk of strangulation or obstruction of airflow. Special attention must be given to the positioning and design of the components around the neck to ensure safe breathing at all times.

8. Sterility and Infection Control (Section 13):
The halo vest may have contact points that penetrate the skin, such as pins, which must be sterile and include instructions for maintaining cleanliness. Infection prevention measures should be highlighted, especially since improper care could lead to serious infections at the pin sites.

9. Alarms or Warning Systems (Section 13):
While a halo vest typically does not have an electrical system, any additional attachments or future modifications could include components (e.g., sensors for patient monitoring). If such devices are added, they must adhere to alarm and notification standards, providing clear warnings to users in case of failure.

10. Protection Against Electromagnetic Interference (EMI) (Section 12):
If the vest incorporates any electronic monitoring systems or sensors, it must comply with electromagnetic safety standards to ensure there is no interference with other medical devices or hospital equipment.

Under the EU Medical Device Regulations (MDR 2017/745), it is classified as a Class IIa device. This classification pertains to devices intended for managing serious conditions but not posing the highest level of risk. The following regulatory requirements are essential for the design, development, and clinical use of halo vests.

1. Conformity Assessment (MDR Article 52)
Class IIa devices require a conformity assessment conducted by a Notified Body—an independent organization designated by the EU. This body evaluates the device to ensure compliance with all relevant safety, quality, and performance standards before market approval.

2. General Safety and Performance Requirements (MDR Annex I, Chapter I)
The halo vest must meet strict safety and performance criteria, ensuring it does not jeopardize the patient's safety or clinical condition during use. This includes considerations such as material biocompatibility and overall effectiveness in stabilizing the spine.

3. Risk Management (MDR Annex I, Chapter I, Section 3)
Manufacturers must develop and implement a comprehensive risk management plan that identifies and mitigates potential risks, such as mechanical failures, infections, or improper fitting. These measures should encompass all stages of the device's lifecycle, from design and production to post-market use.

4. Clinical Evaluation and Performance (MDR Annex XIV)
A clinical evaluation must validate the safety and efficacy of the halo vest. This process involves collecting and analyzing clinical data, either through studies or literature reviews, to confirm that the device effectively stabilizes the cervical spine without causing undue harm or discomfort.

5. Technical Documentation (MDR Annex II)
Detailed technical documentation is a prerequisite. This includes design schematics,

mechanical testing results, material safety data, and manufacturing protocols. Such documentation is critical for the conformity assessment process and ensures transparency in the device's development and performance evaluation.

6. Post-Market Surveillance and Clinical Follow-up (MDR Annex III & Annex XIV, Part B)
Manufacturers are required to monitor the halo vest's performance after market introduction. Post-market surveillance involves collecting real-world data to identify potential issues, while Post-Market Clinical Follow-up (PMCF) assesses long-term safety, efficacy, and patient outcomes.

7. Quality Management System (QMS) (MDR Article 10, Section 9)
An effective Quality Management System must be implemented and maintained. The QMS ensures consistent production of the halo vest to meet required standards and controls all processes from design to post-market activities. This system is crucial for upholding high levels of quality and safety throughout the device's lifecycle.

8. Mechanical Testing (MDR Annex I, Section 10)
Rigorous mechanical testing is essential to verify that the halo vest meets strength and durability requirements. Testing should simulate real-world use by evaluating screws, pins, and the vest structure under various load conditions. This ensures the device can withstand mechanical stresses without failure during prolonged use.

9. Material Safety and Toxicity (MDR Annex I, Section 10.1)
Materials used must be evaluated for potential toxicity due to prolonged skin contact. They must not leach harmful substances or cause adverse reactions like skin irritation. Compliance with ISO 10993 standards for biological evaluation is critical to ensure material safety for patient use.

10. Protection Against Unintended Movement (MDR Annex I, Chapter II, Section 8.4)
The halo vest must provide sufficient rigidity to prevent unintended or excessive cervical spine movement. This includes robust vest construction, secure locking mechanisms, and reliable attachment of screws or pins to the skull. Minimizing movement is vital for patient recovery and preventing further injury.

11. Sterilization and Cleanliness Requirements (MDR Annex I, Chapter II, Section 13.3)
Components that penetrate the skin, such as screws or pins, must be sterile. Manufacturers should provide clear instructions on maintaining sterility during long-term use to prevent infection. Sterilization protocols also apply to non-invasive parts to ensure overall hygiene and patient safety.

12. Patient-Specific Adjustments (MDR Annex I, Chapter II, Section 10.4)
The device must allow for adjustments to accommodate different body sizes and shapes. Proper fit and comfort are essential to prevent discomfort, skin sores, or compromised immobilization. The halo vest should be adaptable to individual anatomical requirements while maintaining its primary stabilizing function.

13. Labelling and Instructions for Use (MDR Annex I, Chapter III, Section 23)
Clear, comprehensive labelling and user instructions are mandatory. This includes guidance on proper fitting, adjustment, maintenance, and warnings about potential risks. Instructions must be easily understood by healthcare professionals and caregivers to minimize the risk of misuse.

14. Protection Against Contamination (MDR Annex I, Section 11.2)
The halo vest must be designed to prevent contamination, especially for immunocompromised patients or during extended wear. Materials should not harbor bacteria, and all components must be easy to clean and disinfect. Emphasizing aseptic techniques is crucial when the device is used with surgical pins.

15. Monitoring and Maintenance Protocols (MDR Annex I, Section 13.6)
Manufacturers must provide protocols for regular monitoring and maintenance. Regular inspections should check the integrity of screws, pins, and other components to ensure they remain secure and functional. This helps prevent mechanical failures or deterioration over time.

16. Handling of Adverse Events (MDR Articles 87-89)
In the event of device-related adverse events, such as malfunctions or injuries, manufacturers are required to report these to relevant authorities. A system must be in place to identify, document, and resolve such events promptly, ensuring compliance with vigilance and corrective action requirements.

17. Unique Device Identification (UDI) (MDR Article 27)
The halo vest must be labeled with a Unique Device Identifier for tracking and traceability. The UDI facilitates monitoring throughout distribution and use, aiding in recalls if issues are identified, and ensures compliance with traceability requirements.

Appendix B: Stakeholder Analysis

Based on Ashby's Stakeholder Analysis (2015), stakeholders connected to the halo vest (or halo frame) can be categorized into core users, direct stakeholders, and indirect stakeholders. Each group has specific roles, objectives, and methods of involvement with the halo vest. Below is an organized overview addressing three key aspects for each stakeholder: A. Who they are, B. What they want, and C. How they might try to achieve their goals.

Core Users:

1. Patient

A. The individual wearing the halo vest due to severe spinal or cervical injuries.
B. They want effective immobilization, comfort, and a smooth recovery process.
C. They will cooperate with medical staff, follow prescribed care, and seek adjustments or alternative treatments if needed.

2. Orthopedic Surgeons

A. Specialists responsible for diagnosing spinal injuries and prescribing the halo vest.
B. They aim for successful recovery by ensuring proper stabilization of the spine and minimal complications during the recovery period.
C. Surgeons will oversee the application of the halo vest, monitor patient progress, and adjust treatment as necessary based on patient response and clinical outcomes.

3. Plastercast Makers (Orthopedic Technicians)

A. Medical technicians responsible for fitting and adjusting the halo vest.
B. They seek to ensure that the vest is properly fitted to support the patient's healing while preventing discomfort or pressure sores.
C. They achieve their goals by meticulously customizing the vest for individual patients and making adjustments as needed during follow-up appointments.

4. Social Circle of the Patient (Family/Friends)

A. The patient's immediate support system, including family and friends.
B. Their aim is to assist the patient during recovery, both emotionally and physically.
C. They will likely help the patient in daily activities, accompany them to follow-up appointments, and provide emotional encouragement during their recovery.

Direct Stakeholders:

5. Anjon Bremer Medical

A. A medical device manufacturer that supplies the halo vests or similar equipment.
B. Their goal is to deliver high-quality, reliable products while maintaining a strong market reputation.
C.They focus on product development, rigorous quality assurance, and effective marketing strategies targeting healthcare providers.

6. Zorginstituut Nederland (National Healthcare Institute)

A.Organizations such as the Dutch National Healthcare Institute, which evaluate treatments for inclusion in insurance plans.
B. Their primary objective is to ensure only safe, effective, and cost-efficient treatments are reimbursed.
C.They conduct thorough assessments of clinical efficacy and cost-effectiveness to decide whether treatments, including the halo vest, qualify for reimbursement.

7. Local Hospitals

A. Hospitals that provide care, including prescribing and fitting halo vests for patients with spinal injuries.
B. They want to ensure that patients receive high-quality care while managing costs and resources effectively.
C. They ensure compliance with healthcare guidelines, maintain relationships with medical device suppliers, and provide continuous training for staff to optimize patient care.

8. Medical Professional Groups

A. Associations or networks of healthcare professionals (e.g., orthopedic associations).
B. They aim to maintain high standards of practice for using the halo vest and ensure continuous education for members.
C. They issue clinical guidelines, host training sessions, and provide up-to-date research to improve patient care and device use.

9. 3D Lab at the Hospital

A. A hospital-based facility that produces custom components (such as 3D-printed adjustments) for medical devices like the halo vest.
B. They want to provide customized, patient-specific solutions that enhance the fit and comfort of the halo vest.
C. They achieve this by working closely with orthopedic teams and using advanced technologies like 3D printing to tailor components for individual needs.

10. Product Development Team at the Hospital

A. A team of researchers and engineers working on improving medical devices within the hospital.
B. They aim to refine the halo vest design to improve patient comfort, safety, and efficacy.
C. They collaborate with clinical teams to gather feedback from patients and healthcare professionals and test new design improvements.

11. UMC Utrecht (University Medical Center)

A. A leading academic hospital that may be involved in research, treatment, and clinical trials related to halo vests.
B. Their goal is to provide cutting-edge treatments and contribute to research on spinal injury recovery and the use of immobilization devices.
C. They collaborate with researchers, clinicians, and medical device companies to test and implement new technologies in patient care.

Indirect Stakeholders:

12. Medical Device Distributors

A. Companies responsible for distributing the halo vests from manufacturers to hospitals and healthcare providers.
B. They want to ensure a smooth supply chain and continuous sales of their devices.

C. They maintain relationships with healthcare providers, manage logistics, and ensure timely delivery of products.

13. Healthcare Administrators

A. Managers and administrators within healthcare institutions overseeing resource allocation, budget management, and policy compliance.
B. They aim to provide cost-effective care while ensuring compliance with healthcare regulations and quality standards.
C. They work with financial departments and insurance companies to manage costs and negotiate contracts for purchasing medical devices like the halo vest.

14. Insurance Companies

A. Private or public health insurers covering the costs of treatments under the basic healthcare package.
B. They want to provide necessary healthcare services while keeping costs manageable.
C. They assess claims, set reimbursement criteria, and work with healthcare providers to determine which treatments and devices, such as the halo vest, are covered.

15. Ministerie van Volksgezondheid, Welzijn en Sport (VWS)

A. The Dutch Ministry of Health, Welfare, and Sport, which oversees national healthcare policy.
B. They want to ensure that healthcare is accessible, affordable, and of high quality for all citizens.
C. The ministry works by regulating healthcare standards, ensuring that devices like the halo vest meet national guidelines for use and reimbursement.

16. Researchers

A. Academics and scientists studying spinal injuries and the efficacy of treatments like the halo vest.
B. They aim to gather evidence about the effectiveness and long-term outcomes of using the halo vest for spinal immobilization.
C. They conduct clinical studies, publish research, and collaborate with medical device companies and hospitals to improve patient outcomes.

17. Medical Information Resources

A. Providers of medical databases and educational tools that support healthcare professionals in decision-making.
B. They aim to disseminate accurate, evidence-based information regarding the use and outcomes of the halo vest.
C. They publish guidelines, host online resources, and collaborate with medical professional groups to ensure practitioners have access to the latest data.

18. Investors

A. Private investors or companies who fund the development and distribution of medical devices like the halo vest.
B. Their goal is to see a return on investment through successful product development and sales.
C. They invest in product innovation and collaborate with medical companies to market new or improved halo vests.

19. Consumer Stores

A. Medical supply stores that may sell components or accessories related to halo vests.
B. They aim to provide easy access to medical supplies for patients who may need replacements or additional products.
C. They achieve this through retail or online distribution of medical accessories.

Appendix C: DBC (Diagnosis Treatment Combination)

The DBC (Diagnosis Treatment Combination) for the use of a halo frame typically falls under the broader category of spinal trauma or injury treatments within the Dutch healthcare system. A DBC code covers the full treatment trajectory, from initial diagnosis and hospitalization to the application of the halo frame, follow-up care, and adjustments, which could include hospital stays, outpatient visits, and consultations with specialists.

An average DBC package for such spinal injuries may include:

1. Diagnostic Imaging: MRI or CT scans to assess the extent of spinal damage.
2. Surgical or Non-Surgical Treatment: In cases where the halo frame is used instead of surgery.
3. Hospitalization: Depending on the severity of the injury, the patient may need to stay in the hospital for monitoring during the application and initial adjustment of the frame.
4. Follow-up Consultations: Post-application monitoring, adjustments to the frame, and physiotherapy sessions.
5. Potential Physiotherapy: During recovery, to ensure that the patient regains mobility once the halo frame is removed.

Since the DBC pricing depends on the complexity of the care and resources used, the cost can vary. For instance, in 2019, spinal surgery DBC packages could range between €7,000 to €15,000 depending on the severity of the condition and the type of interventions required (Med Tech Reimbursement Consulting). The use of a halo frame, especially if non-surgical, might fall on the lower end of this range, but this can vary based on additional care needs like extended hospital stays or rehabilitation. (Med Tech Reimbursement Consulting)(https://www.hollandzorg.com/insured/reimbursements2023).

For an exact DBC and pricing, it would depend on the specific hospital or healthcare provider in the Netherlands, and their agreements with insurers.

Appendix D: List of Requirements

1. Movement

1.1. The patient should be able to perform daily tasks while remaining stable in the frame.
- 1.1.1. The patient should be able to sleep in the frame and remain stable.
- 1.1.2. The patient should be able to talk while in the frame.
- 1.1.3. The patient should be able to eat while in the frame.
- 1.1.4. The patient should be able to sit up, stand up, and lay down in the frame.
- 1.1.5. The patient should be able to walk in the frame.
- 1.1.6. The patient should be able to wash their hair and body while in the frame.

1.2. The patient should not be able to move their head in all 6 degrees of freedom (DOF) (Pitch, Roll, and Yaw).

1.3. The frame should allow the patient to perform some mobility tasks independently, such as washing hair or getting dressed, while maintaining spinal stability (related to patient independence)

2. After Care

2.1. The patient should be left with minimal scars after the procedure.

3. Engineering

3.1. The frame should not apply any pressure on the broken vertebrae.

3.2. The frame must support the weight of the head, with a safety factor of 2.5, lifting approximately 20 kg.

3.3. Pin pressure should remain constant to avoid injury and ensure even force distribution

3.4. The patient should not be able to move their head in all 6 DOFs:
- 3.4.1. On the Pitch, a maximum force of 177 N must be resisted.
- 3.4.2. On the Roll, a maximum force of 148 N must be resisted.
- 3.4.3. On the Yaw, a maximum force of 126 N must be resisted

3.5. The connection point of the frame to the halo-ring should be as close as possible to the center of mass of the head, minimizing strain during movement.

3.6. The frame must be MRI compatible to allow diagnostic imaging without removing the vest

3.7. The frame should resist dynamic forces experienced during activities such as sitting, standing, and bending.

4. Ergonomics

4.1. The frame should minimize pressure points to reduce the risk of irritation, particularly in sensitive areas such as:
- 4.1.1. The armpits, the area under the breast, the chest (below the collarbones), the shoulders, and the neck.
- 4.2. The frame should be adaptable to all body types, providing adequate fit for patients with different body sizes
- 4.3. The halo-ring should fit all head sizes, and customization options should be considered for unique anatomical requirements
- 4.4. The frame should allow for rapid production and application, especially in urgent medical situations
- 4.5. The frame should look less bulky, with reduced visual impact to alleviate psychological discomfort, encouraging patients to engage in social activities without self-consciousness
- 4.6. The frame should allow the patient to wear regular clothing comfortably, including

accommodating bras for wome.

5. Fit and Adjustability
5.1. The frame should offer modular components to ensure better adjustability and fit across a range of body types.
5.2. Custom-fit options for patients with unique anatomical needs should be integrated into the design.
5.3. Alignment and adjustability should be easy for healthcare providers to modify during and after the initial installation based on imaging results (CT or X-rays).
5.4. The frame should be designed to support a precise fit without the need for constant re-adjustments.]

6. Hygiene and Cleaning
6.1. The frame should be easy to clean without requiring full removal.
6.2. The materials should be selected to resist moisture buildup, improving skin health under the vest
6.3. Detachable padding for easier cleaning and hygiene maintenance should be included

7. Aesthetics and Psychological Impact
7.1. The frame design should reduce bulkiness and visual obtrusiveness to minimize the stigma associated with wearing it
7.2. Aesthetics should be a key consideration to ensure that patients feel comfortable in public and social situations while wearing the device

8. Modularity and Replaceability
8.1. The frame should include modular components to allow easy replacement of worn-out parts, such as padding or straps, without requiring full vest replacement
8.2. The vest should be designed for a competitive cost target to ensure affordability for hospitals and healthcare providers

9. Structural Integrity and Safety
9.1. The materials selected should be lightweight but durable, providing the necessary structural integrity for spinal immobilization.
9.2. The frame must meet MDR standards for medical devices, ensuring safe and effective immobilization
9.3. The frame should reduce the overall weight to improve long-term wearability
9.4. The frame's materials must be biocompatible to avoid adverse skin reactions or discomfort during long-term use
9.5. The pin interfaces should be redesigned to distribute forces evenly across the skull

10. Ease of Use and Maintenance
10.1. The frame must be easy for healthcare professionals to install quickly, with minimal reliance on specialized personnel
10.2. Caregivers should be able to make minor adjustments to the frame without compromising stability
10.3. Simplified maintenance should be included to reduce the need for frequent hospital visits
10.4. The frame should include visual markers or indicators to guide caregivers in maintaining proper fit and tension

11. Sustainability and Future Requirements
11.1. The design should incorporate recyclable and durable materials to support compliance with upcoming regulations like the ESPR
11.2. Future versions of the frame could include a Digital Product Passport that provides transparency about the materials used, environmental impact, and end-of-life instructions

12. Medical and Clinical Compatibility
12.1. The frame must integrate smoothly with in-hospital care settings, allowing for easy monitoring and adjustments
12.2. The design should minimize interference with diagnostic imaging procedures like X-rays, CT scans, and MRIs

Appendix E: Exploration - Design considerations individually sorted per scenario.

Scenario 1 (Emergency Situations):

- 1. Pressure Points: Reducing pressure points for better comfort during urgent use.
- 6. Sizing Variability: Important for quick application in emergencies, accommodating various body types.
- 8. Frame Alignment and Adjustability: Essential for proper spinal immobilization in emergency situations.
- 10. Mobility: Enhancing mobility without compromising spinal stabilization, crucial for emergency cases.
- 13. Force Magnitudes: The design must withstand vertical (177N), anterior-posterior (126N), and lateral (148N) forces.
- 14. Dynamic Forces: Must handle forces during movements such as sitting, standing, and bending.
- 15. Pin Force Distribution: Evenly distribute forces to reduce discomfort and improve patient outcomes.
- 16. Reliable Immobilization: Ensure safety and effectiveness in rapid stabilization situations.
- 20. Ease of Installation: Quick and secure installation is vital in emergency cases.
- 21. Ease of Maintenance: Simple adjustments for caregivers in high-stress situations.
- 27. Medical Professional Ease of Application: Fast and intuitive application is critical in emergencies.

Scenario 2 (Planned Long-Term Use):

- 2. Breathing and Comfort: Ensuring comfort during long-term wear by reducing restriction on breathing.
- 3. Patient Comfort and Mobility: Focus on comfort during daily activities like sleeping and dressing.
- 4. Sleeping Comfort: Support better sleep postures, especially for patients wearing the device for extended periods.
- 5. Clothing Compatibility: Design to allow for the easy wearing of normal clothing, particularly for long-term use.
- 7. Custom-Fit Options: Customizable components for a better fit during long-term rehabilitation.
- 9. Modular Design: Modular approach to enhance comfort and adjustability for prolonged use.
- 11. Patient Independence: Allow more independence for patients in daily activities during long-term treatment.
- 12. Enhanced Hygiene and Cleaning: Important for long-term wear, ensuring materials are easy to clean and maintain.
- 17. Material Safety: Biocompatibility for long-term wear to avoid adverse reactions.
- 18. Aesthetic Improvements: Aesthetic changes to reduce the psychological impact of long-term wear.
- 19. Psychological Considerations: Reduced visibility or bulkiness to make the device less stigmatizing during long use.
- 23. Reduction of Labor-Intensive Check-Ups: Simplify follow-ups and reduce the frequency of check-ups during long-term use.
- 25. Modularity and Replaceability: Replaceable components for long-term use without requiring full vest replacement.
- 30. Vest and Component Hygiene: Design for better ventilation and cleaning to maintain hygiene over extended periods.
- 34. Long-Term Wearability: Reduce the overall weight and improve durability for long-term patient comfort.
- 35. Use of Modern Materials: Leverage lightweight and biocompatible materials to improve comfort and long-term use.

Applicable to Both Scenarios:

- 16. Reliable Immobilization: Ensure safe spinal immobilization in both emergency and planned use.
- 13. Force Magnitudes: Must handle forces during both emergency interventions and daily activities.
- 17. Material Safety: Essential for both short-term emergency use and long-term rehabilitation.
- 20. Ease of Installation: Important for quick and efficient application in both scenarios.
- 27. Medical Professional Ease of Application: Fast and secure application for both immediate and scheduled use.
- 33. Post-Market Surveillance: Critical to monitor performance in both emergency and long-term cases.
- 35. Use of Modern Materials: Applicable to both scenarios for weight reduction and improved durability.

Appendix F: Exploration - Clusters with design considerations sorted per scenario.

1. Patient Comfort and Ergonomics
Scenario 2: Planned long-term support
For Scenario 2, this cluster focuses on reducing pressure points, allowing comfortable breathing, and enhancing daily activities like sleeping and dressing. Comfort is critical for patients wearing the frame for extended periods.

2. Fit and Adjustability
Both
For Scenario 1, the vest must be easily adjustable to ensure quick and proper fit in an emergency. For Scenario 2, modularity and fit customization ensure ongoing comfort and proper support over time.

3. Mobility and Independence
Scenario 2: Planned long-term support
For Scenario 2, this cluster emphasizes enhancing mobility and allowing patients to perform daily tasks independently. This is less important for emergency immobilization, where immediate stabilization is the focus.

4. Structural Integrity and Safety
Both
For Scenario 1, this cluster ensures that the frame withstands forces during sudden movements like standing or sitting. In Scenario 2, it ensures the frame maintains consistent stability over long-term use while reducing discomfort.

5. Aesthetics and Psychological Impact
Scenario 2: Planned long-term support
For Scenario 2, this cluster is relevant for improving the vest's appearance, reducing stigma, and making patients feel more comfortable in social situations. Aesthetics are less of a priority in emergency settings.

6. Ease of Use and Maintenance
Both
For Scenario 1, quick and efficient application is necessary to ensure rapid immobilization. For Scenario 2, ease of maintenance is essential to allow caregivers and patients to handle the device over extended periods with minimal effort.

7. Modularity and Replaceability
Scenario 2: Planned long-term support
For Scenario 2, modularity is crucial for long-term use to allow for easier repairs and replacements without needing a full vest change. This is not as relevant for emergency situations, where quick installation is more critical.

8. Medical and Clinical Compatibility
Both
For Scenario 1, the frame must be quickly applied and adjusted by medical professionals in a clinical setting. For Scenario 2, it should integrate seamlessly with hospital workflows and allow for ongoing adjustments and diagnostics like imaging.

9. Hygiene and Cleaning
Scenario 2: Planned long-term support
For Scenario 2, maintaining hygiene is essential for long-term wear, with materials that allow easy cleaning and prevent skin issues. This is less critical in urgent, short-term immobilization.

10. Sustainability and Future Requirements
Scenario 2: Planned long-term support
For Scenario 2, sustainability concerns such as durability, recyclability, and compliance with future regulations are important. These factors are less relevant for short-term emergency use.

11. Regulatory Compliance and Surveillance
Both
For Scenario 1, post-market surveillance ensures that the device meets safety standards even in emergency use. For Scenario 2, long-term wearability and safety are equally critical, with regulatory requirements ensuring patient safety over extended periods.

None of the clusters are exclusively applicable only to Scenario 1 (Urgent emergency immobilization). This is because the nature of the halo frame's design requirements typically applies to both urgent and long-term care, though with some differences in emphasis.

For example:
- Fit and Adjustability and Ease of Use and Maintenance are important in both scenarios, though the urgency and long-term needs differ.
- Structural Integrity and Safety must be ensured for both, but the critical need for immediate immobilization in an emergency applies equally to both cases.

In Scenario 1, the design focus is often on quick, secure, and effective stabilization, which is still aligned with several clusters designed to ensure safety, reliability, and ease of application.

Appendix G: HREC Application

Date 21-Jan-2025
Correspondence

Human Research Ethics
Committee TU Delft
(http://hrec.tudelft.nl)

Visiting address
Jaffalaan 5 (building 31)
2628 BX Delft

Postal address
P.O. Box 5015 2600 GA Delft
The Netherlands

Ethics Approval Application: Redesign of a Halo-Vest
Applicant: Iserief, Maxime

Dear Maxime Iserief,

It is a pleasure to inform you that your application mentioned above has been approved.

Thanks very much for your submission to the HREC which has been approved.

In addition to any specific conditions or notes, the HREC provides the following standard advice to all applicants:
• In light of recent tax changes, we advise that you confirm any proposed remuneration of research subjects with your faculty contract manager before going ahead.
• Please make sure when you carry out your research that you confirm contemporary covid protocols with your faculty HSE advisor, and that ongoing covid risks and precautions are flagged in the informed consent - with particular attention to this where there are physically vulnerable (eg: elderly or with underlying conditions) participants involved.
• Our default advice is not to publish transcripts or transcript summaries, but to retain these privately for specific purposes/checking; and if they are to be made public then only if fully anonymised and the transcript/summary itself approved by participants for specific purpose.
• Where there are collaborating (including funding) partners, appropriate formal agreements including clarity on responsibilities, including data ownership, responsibilities and access, should be in place and that relevant aspects of such agreements (such as access to raw or other data) are clear in the Informed Consent.

Good luck with your research!

Sincerely,

Dr. Ir. U. Pesch
Chair HREC
Faculty of Technology, Policy and Management

Appendix H: Ethics Checklist

Delft University of Technology
HUMAN RESEARCH ETHICS
CHECKLIST FOR HUMAN RESEARCH
(Version January 2022)

IMPORTANT NOTES ON PREPARING THIS CHECKLIST

1. An HREC application should be submitted for every research study that involves human participants (as Research Subjects) carried out by TU Delft researchers
2. Your HREC application should be submitted and approved **before** potential participants are approached to take part in your study
3. All submissions from Master's Students for their research thesis need approval from the relevant Responsible Researcher
4. The Responsible Researcher must indicate their approval of the completeness and quality of the submission by signing and dating this form OR by providing approval to the corresponding researcher via email (included as a PDF with the full HREC submission)
5. There are various aspects of human research compliance which fall outside of the remit of the HREC, but which must be in place to obtain HREC approval. These often require input from internal or external experts such as Faculty Data Stewards, Faculty HSE advisors, the TU Delft Privacy Team or external Medical research partners.
6. You can find detailed guidance on completing your HREC application here
7. Please note that incomplete submissions (whether in terms of documentation or the information provided therein) will be returned for completion **prior to any assessment**
8. If you have any feedback on any aspect of the HREC approval tools and/or process you can leave your comments here

I. Applicant Information

PROJECT TITLE:	**Redesign of a Halo Vest**
Research period: *Over what period of time will this specific part of the research take place*	**4 sept 2024 – 31 januari 2025**
Faculty:	**IDE**
Department:	**Human Centred Design**
Type of the research project: *(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)*	**Master Thesis**
Funder of research: *(EU, NWO, TUD, other – in which case please elaborate)*	**TUD, UMC Utrecht**
Name of Corresponding Researcher: *(If different from the Responsible Researcher)*	**Maxime Iserief**
E-mail Corresponding Researcher: *(If different from the Responsible Researcher)*	[redacted]
Position of Corresponding Researcher: *(Masters, DreamTeam, PhD, PostDoc, Assistant/ Associate/ Full Professor)*	**Masters**
Name of Responsible Researcher: ***Note**: all student work must have a named Responsible Researcher to approve, sign and submit this application*	**R.H.M. Goossens**
E-mail of Responsible Researcher: *Please ensure that an institutional email address (**no Gmail, Yahoo, etc.**) is used for all project documentation/ communications including Informed Consent materials*	[redacted]
Position of Responsible Researcher : *(PhD, PostDoc, Associate/ Assistant/ Full Professor)*	**Full Professor**

II. Research Overview

NOTE**: You can find more guidance on completing this checklist **here

a) Please summarise your research very briefly (100-200 words)

What are you looking into, who is involved, how many participants there will be, how they will be recruited and what are they expected to do?

Add your text here – (please avoid jargon and abbrevations)
The project aims to enhance user experience for users using a Halo Frame. It needs to provide robust cervical spine stabilization to ensure user safety while enhancing comfort and reducing invasiveness. The device should also appear less intimidating and fit right. There will be 5-10 patricipants, they will be recruited via a doctor at UMCU.They will be interviewed only. They are expected to answer a couple of questions, rating their discomfort on different aspects of the frame on a scale of 1-7. Also their general experiences are talked about. This to find out what issues the users deal with.

b) **If your application is an additional project** related to an existing approved HREC submission, please provide a brief explanation including the existing relevant HREC submission number/s.

Add your text here – (please avoid jargon and abbrevations)

c) **If your application is a simple extension of, or amendment to,** an existing approved HREC submission, you can simply submit an HREC Amendment Form as a submission through LabServant.

III. Risk Assessment and Mitigation Plan

NOTE: You can find more guidance on completing this checklist here

Please complete the following table in full for all points to which your answer is "yes". Bear in mind that the vast majority of projects involving human participants as Research Subjects also involve the collection of **Personally Identifiable Information (PII)** and/or **Personally Identifiable Research Data (PIRD)** which may pose potential risks to participants as detailed in Section G: Data Processing and Privacy below.

To ensure alighment between your risk assessment, data management and what you agree with your Research Subjects you can use the last two columns in the table below to refer to specific points in your Data Management Plan (DMP) and Informed Consent Form (ICF) – **but this is not compulsory**.

It's worth noting that **you're much more likely to need to resubmit your application if you neglect to identify potential risks**, than if you identify a potential risk and demonstrate how you will mitigate it. If necessary, the HREC will always work with you and colleagues in the Privacy Team and Data Management Services to see how, if at all possible, your research can be conducted.

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
A: Partners and collaboration						
1. Will the research be carried out in collaboration with additional organisational partners such as: • One or more collaborating research and/or commercial organisations • Either a research, or a work experience internship provider[1] [1] *If yes, please include the graduation agreement in this application*						
2. Is this research dependent on a Data Transfer or Processing Agreement with a collaborating partner or third party supplier? *If yes please provide a copy of the signed DTA/DPA*						
3. Has this research been approved by another (external) research ethics committee (e.g.: HREC and/or MREC/METC)? *If yes, please provide a copy of the approval (if possible) and summarise any key points in your Risk Management section below*						
B: Location						

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?						
5. Will the research take place in a country or countries outside the EU?						
6. Will the research take place in a place/region or of higher risk – including known dangerous locations (in any country) or locations with non-democratic regimes?						
C: Participants						
7. Will the study involve participants who **may** be vulnerable and possibly (legally) unable to give informed consent? (e.g., children below the legal age for giving consent, people with learning difficulties, people living in care or nursing homes,).			Users might have medical issues beyond the neck injury.	All users interviewed have been at least in the frame for a couple of weeks. This makes sure they're healthy beyond their neck injury. Before each interview a short consult will be done with the treating doctor to verify the patients abilities.		
8. Will the study involve participants who **may** be vulnerable under specific circumstances and in specific contexts, such as victims and witnesses of violence, including domestic violence; sex workers; members of minority groups, refugees, irregular migrants or dissidents?						
9. Are the participants, outside the context of the research, in a dependent or subordinate position to the investigator (such as own children, own students or employees of either TU Delft and/or a collaborating partner organisation)? *It is essential that you safeguard against possible adverse consequences of this situation (such as allowing a student's failure to participate to your satisfaction to affect your evaluation of their coursework).*						
10. Is there a high possibility of re-identification for your participants? (e.g., do they have a very specialist job of which there are only a small number in a given country, are they members of a small community, or employees from a partner company collaborating in the research? Or are they one of only a handful of (expert) participants in the study?						
D: Recruiting Participants						
11. Will your participants be recruited through your own, professional, channels such as conference attendance lists, or through specific network/s such as self-help groups						
12. Will the participants be recruited or accessed in the longer term by a (legal or customary) gatekeeper? (e.g., an adult professional working with children; a community leader or family member who has this customary role – within or outside the EU; the data producer of a long-term cohort study)						

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
13. Will you be recruiting your participants through a crowd-sourcing service and/or involve a third party data-gathering service, such as a survey platform?						
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?						
E: Subject Matter *Research related to medical questions/health may require special attention. See also the website of the CCMO before contacting the HREC.*						
15. Will your research involve any of the following: • Medical research and/or clinical trials • Invasive sampling and/or medical imaging • Medical and *In Vitro Diagnostic Medical* Devices Research				**The product might be in a hospital setting, but is not nessecairly a medical device. This research is aimed at aesthetics.**		
16. Will drugs, placebos, or other substances (e.g., drinks, foods, food or drink constituents, dietary supplements) be administered to the study participants? *If yes see here to determine whether medical ethical approval is required*						
17. Will blood or tissue samples be obtained from participants? *If yes see here to determine whether medical ethical approval is required*						
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?						
19. Will the study involve discussion of personal sensitive data which could put participants at increased legal, financial, reputational, security or other risk? (e.g., financial data, location data, data relating to children or other vulnerable groups) *Definitions of sensitive personal data, and special cases are provided on the TUD Privacy Team website.*						
20. Will the study involve disclosing commercially or professionally sensitive, or confidential information? (e.g., relating to decision-making processes or business strategies which might, for example, be of interest to competitors)						
21. Has your study been identified by the TU Delft Privacy Team as requiring a Data Processing Impact Assessment (DPIA)? *If yes please attach the advice/ approval from the Privacy Team to this application*						
22. Does your research investigate causes or areas of conflict? *If yes please confirm that your fieldwork has been discussed with the appropriate safety/security advisors and approved by your Department/Faculty.*						

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
23. Does your research involve observing illegal activities or data processed or provided by authorities responsible for preventing, investigating, detecting or prosecuting criminal offences *If so please confirm that your work has been discussed with the appropriate legal advisors and approved by your Department/Faculty.*						
F: Research Methods						
24. Will it be necessary for participants to take part in the study without their knowledge and consent at the time? (e.g., covert observation of people in non-public places).						
25. Will the study involve actively deceiving the participants? (For example, will participants be deliberately falsely informed, will information be withheld from them or will they be misled in such a way that they are likely to object or show unease when debriefed about the study).						
26. Is pain or more than mild discomfort likely to result from the study? And/or could your research activity cause an accident involving (non-) participants?						
27. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*						
• Was the device built in-house?						
• Was it inspected by a safety expert at TU Delft? *If yes, please provide a signed device report*						
• If it was not built in-house and not CE-certified, was it inspected by some other, qualified authority in safety and approved? *If yes, please provide records of the inspection*						
28. Will your research involve face-to-face encounters with your participants and if so how will you assess and address Covid considerations?				**Getting regularly tested. Tested each week before visiting the hospital.**		
29. Will your research involve **either:** a) "big data", combined datasets, new data-gathering or new data-merging techniques which might lead to re-identification of your participants **and/or** b) artificial intelligence or algorithm training where, for example biased datasets could lead to biased outcomes?						
G: Data Processing and Privacy						
30. Will the research involve collecting, processing and/or storing any directly identifiable PII (Personally Identifiable Information) including name or email address that will be used for administrative purposes only? (eg: obtaining Informed Consent or disbursing remuneration)			**Name, (contact info) and signature will be collected for informed consent and further research.**	**Informed consent will be stored safely with other physical confidential documents at Damen and remain untouched to prevent it from getting lost or accidentally spread. All interview notes will be on**		

			If YES please complete the Risk Assessment and Mitigation Plan columns below.		*Please provide the relevant reference #*	
ISSUE	**Yes**	**No**	**RISK ASSESSMENT – what risks could arise?** *Please ensure that you list ALL of the actual risks that could potentially arise – do not simply state whether you consider any such risks are important!*	**MITIGATION PLAN – what mitigating steps will you take?** *Please ensure that you summarise what actual mitigation measures you will take for each potential risk identified – do not simply state that you will e.g. comply with regulations.*	**DMP**	**ICF**
				paper. No names will be digitized. No names will be in the rapport or appendix.		
31. Will the research involve collecting, processing and/or storing any directly or indirectly identifiable PIRD (Personally Identifiable Research Data) including videos, pictures, IP address, gender, age etc and **what other Personal Research Data** (including personal or professional views) will you be collecting?			Age will be asked.	Only notes will be made. No users will be photographed. Making photos in the hospital is not allowed. All PIRD data will be processed anonymously unless the participant has consented otherwise. The researcher will ask consent for the collection of PIRD. The PIRD information will be stored confidentially together with the informed consent forms until the end of the project and are processed as un-identifiable as possible		
32. Will this research involve collecting data from the internet, social media and/or publicly available datasets which have been originally contributed by human participants						
33. Will your research findings be published in one or more forms in the public domain, as e.g., Masters thesis, journal publication, conference presentation or wider public dissemination?			The master thesis will include research results and will be published to the repository.	Data of participants who wish to stay anonymous will be processed in results as anonymous. Confidential appendices wil not be published to the repository and only read by those authorised to do so. Participants who are not comfortable with the risk of reidentification will be asked not to participate		
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?						

H: More on Informed Consent and Data Management

NOTE: You can find guidance and templates for preparing your Informed Consent materials) here

Your research involves human participants as Research Subjects if you are recruiting them or actively involving or influencing, manipulating or directing them in any way in your research activities. This means you must seek informed consent and agree/ implement appropriate safeguards regardless of whether you are collecting any PIRD.

Where you are also collecting PIRD, and using Informed Consent as the legal basis for your research, you need to also make sure that your IC materials are clear on any related risks and the mitigating measures you will take – including through responsible data management.

Got a comment on this checklist or the HREC process? You can leave your comments here

IV. Signature/s

Please note that by signing this checklist list as the sole, or Responsible, researcher you are providing approval of the completeness and quality of the submission, as well as confirming alignment between GDPR, Data Management and Informed Consent requirements.

Name of Corresponding Researcher (if different from the Responsible Researcher) (print)
Maxime Iserief

Signature of Corresponding Researcher:

Date: 30/09/24

Name of Responsible Researcher (print)

R.H.M. Goossens
Signature (or upload consent by mail) Responsible Researcher:

Date: 1 OCT 2024

V. Completing your HREC application

Please use the following list to check that you have provided all relevant documentation

Required:

- **Always:** This completed HREC checklist
- **Always:** A data management plan (reviewed, where necessary, by a data-steward)
- **Usually:** A complete Informed Consent form (including Participant Information) and/or Opening Statement (for online consent)

Please also attach any of the following, if relevant to your research:

Document or approval	Contact/s
Full Research Ethics Application	After the assessment of your initial application **HREC will let you know if and when you need to submit additional information**
Signed, valid Device Report	Your Faculty HSE advisor
Ethics approval from an external Medical Committee	TU Delft Policy Advisor, Medical (Devices) Research
Ethics approval from an external Research Ethics Committee	Please append, if possible, with your submission
Approved Data Transfer or Data Processing Agreement	Your Faculty Data Steward and/or TU Delft Privacy Team
Approved Graduation Agreement	Your Master's thesis supervisor
Data Processing Impact Assessment (DPIA)	TU Delft Privacy Team
Other specific requirement	Please reference/explain in your checklist and append with your submission

Appendix I: Data Management Plan

Plan Overview

A Data Management Plan created using DMPonline

Title: Re-Design of a Halo Frame

Creator: Maxime Iserief

Affiliation: Delft University of Technology

Template: TU Delft Data Management Plan template (2021)

Project abstract:

This project focuses on a re-design of a Halo Frame together with UMC Utrecht and consists of interviews, testing, surveys, and observations. The company aims to improve its product with the help of this research. The data gathered during this research will be used to design and develop a new Halo Frame. 5–10 users currently wearing the frame, will be recruited via the UMC Utrecht.

During the research, participants will be asked to answer some interview questions about their halo experience. Data gathered will consist of consent, interview/questionnaire answers, and observations.

ID: 160123

Start date: 04-09-2024

End date: 31-01-2025

Last modified: 30-09-2024

Re-Design of a Halo Frame

0. Administrative questions

1. Name of data management support staff consulted during the preparation of this plan.

My faculty data steward, Jeff Love, asks graduating students to fill out this online template for their HREC application.

2. Date of consultation with support staff.

2024-09-30

I. Data description and collection or re-use of existing data

3. Provide a general description of the type of data you will be working with, including any re-used data:

Type of data	File format(s)	How will data be collected (for re-used data: source and terms of use)?	Purpose of processing	Storage location	Who will have access to the data
Qualitative interview data	.docx	Collected through physical conversation as notes.	Understand the user and their needs and wishes and evaluate design solutions	Project storage drive	Graduation project team. (Client mentor: Jorrit-Jan Verlaan, Chair: Richard Goossens, Mentor: Zjenja Doubrovski and student: Maxime Iserief)
Interview data including consent forms with names.	Physical notes	Physical interview and questionnaire	Understand the user and their needs and wishes and evaluate design solutions	Confidential archive of physical documents at UMCU	Graduation project team

4. How much data storage will you require during the project lifetime?

- < 250 GB

II. Documentation and data quality

5. What documentation will accompany data?

- Other - explain below
- Methodology of data collection

The data will not be re-used by anyone outside the graduation project team. The members of the graduation project team are familiar with the methodology of data collection and the contents, therefore the graduation report will be sufficient as metadata.

III. Storage and backup during research process

6. Where will the data (and code, if applicable) be stored and backed-up during the project lifetime?

- Project Storage at TU Delft

IV. Legal and ethical requirements, codes of conduct

7. Does your research involve human subjects or 3rd party datasets collected from human participants?

- Yes

8A. Will you work with personal data? (information about an identified or identifiable natural person)

If you are not sure which option to select, first ask your Faculty Data Steward for advice. You can also check with the privacy website . If you would like to contact the privacy team: privacy-tud@tudelft.nl, please bring your DMP.

- Yes

Data including names, condition and age will be stored. Names are used solely for collecting consent, and scans will be anonymized according to the preference of the participants. A participant identification number will be used to store the data anonymously. Identification numbers are written in the physical consent form. The stored data is digital, separate from the physical consent forms, to prevent re-identification

8B. Will you work with any other types of confidential or classified data or code as listed below? (tick all that apply)

If you are not sure which option to select, ask your Faculty Data Steward for advice.

- No, I will not work with any confidential or classified data/code

9. How will ownership of the data and intellectual property rights to the data be managed?

For projects involving commercially-sensitive research or research involving third parties, seek advice of your Faculty Contract Manager when answering this question. If this is not the case, you can use the example below.

The dataset will not be publicly released. The rights to the confidential data will remain at UMC Utrecht. The confidential data will not be shared in the report and final presentation of the graduating student. A confidential appendix will be shared with the graduation team solely.

10. Which personal data will you process? Tick all that apply

- Gender, date of birth and/or age
- Signed consent forms
- Data collected in Informed Consent form (names and email addresses)

11. Please list the categories of data subjects

Users of a Halo Frame

12. Will you be sharing personal data with individuals/organisations outside of the EEA (European Economic Area)?

- No

15. What is the legal ground for personal data processing?

- Informed consent

16. Please describe the informed consent procedure you will follow:

All study participants will be asked for their verbal and written consent for taking part in the study and for data processing before the start of the interview or questionnaire.

17. Where will you store the signed consent forms?

- Same storage solutions as explained in question 6

The files will be stored physically with other confidential documents at UMCU.

18. Does the processing of the personal data result in a high risk to the data subjects?

If the processing of the personal data results in a high risk to the data subjects, it is required to perform a Data Protection Impact Assessment (DPIA). In order to determine if there is a high risk for the data subjects, please check if any of the options below that are applicable to the processing of the personal data during your research (check all that apply).
If two or more of the options listed below apply, you will have to complete the DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to receive support with DPIA.
If only one of the options listed below applies, your project might need a DPIA. Please get in touch with the privacy team: privacy-tud@tudelft.nl to get advice as to whether DPIA is necessary.
If you have any additional comments, please add them in the box below.

- None of the above applies

22. What will happen with personal research data after the end of the research project?

- Other - please explain below

The data will be processed into a graduation report. Bits of anonymised data may be shown in the research report. The report will be shared in the TU Delft repository. Participants will be asked for their consent with regards to the publicity of the graduation report.

23. How long will (pseudonymised) personal data be stored for?

- Other - please state the duration and explain the rationale below

The data will be deleted when the client chooses not to continue developing research results.
The data will be stored for 2 years maximum to give the company time to develop a product related to the research.

24. What is the purpose of sharing personal data?

- For research purposes, which are in-line with the original research purpose for which data have been collected

25. Will your study participants be asked for their consent for data sharing?

- Yes, in consent form - please explain below what you will do with data from participants who did not consent to data sharing

Study participants who do not consent for their data to be shared in the form of processed results in the graduation report will be asked not to participate.

V. Data sharing and long-term preservation

27. Apart from personal data mentioned in question 22, will any other data be publicly shared?

- All other non-personal data (and code) produced in the project

Results in the form of non-personal data (such as questionnaire results) will be shared anonymously in the graduation report.

29. How will you share research data (and code), including the one mentioned in question 22?

- My data will be shared in a different way - please explain below

Any data that is shared has been processed to become public in the graduation report, which is shared in the repository.

30. How much of your data will be shared in a research data repository?

- < 100 GB

31. When will the data (or code) be shared?

- At the end of the research project

32. Under what licence will be the data/code released?

- Other - Please explain

The raw data is not released.

VI. Data management responsibilities and resources

33. Is TU Delft the lead institution for this project?

- Yes, leading the collaboration - please provide details of the type of collaboration and the involved parties below

TU Delft is the lead institution for this graduation project. UMC Utrecht is involved as the client of the design project.

34. If you leave TU Delft (or are unavailable), who is going to be responsible for the data resulting from this project?

Richard Goossens) is the chair of the graduating student and Lecturer at the faculty of IDE at the TU Delft. Therefore, hewill be responsible for data left at the TU Delft after the student graduates.

35. What resources (for example financial and time) will be dedicated to data management and ensuring that data will be FAIR (Findable, Accessible, Interoperable, Re-usable)?

4TU.ResearchData is able to archive 1TB of data per researcher per year free of charge for all TU Delft researchers. We do not expect to exceed this and therefore there are no additional costs of long term preservation.

Appendix J: Informed Consent

Informed consent form

You are being invited to participate in a research study titled The redesign of a Halo-Vest. The purpose of this research study is to understand the flaw in the current design. This research is conducted as part of the MSc study Industrial Design Engineering at TU Delft. Student and contact person : Maxime Iserief, [redacted]

Informed consent participant
I participate in this research voluntarily. I acknowledge that I received sufficient information and explanation about the research and that all my questions have been answered satisfactorily. I was given sufficient time to consent my participation. I can ask questions for further clarification at any moment during the research.
I am aware that this research consists of the following activities:

1. **Interview**

I am aware that data will be collected during the research, such as **notes**, and possibly **photos and audio recordings**. I give permission for collecting this data and for making photos and audio recordings during the research. **Data will be processed and analysed anonymously** (without your name or other identifiable information). The data will only be accessible to the research team and my two TU Delft supervisors.

The photos, video and/or audio recordings will be used to support analysis of the collected data. The audio recordings and photos can also be used to illustrate research findings in publications and presentations about the project. I give permission for using photos and audio recordings of my participation: (circle what applies for you)

- ☐ in which I am recognisable in publications and presentations about the project.
- ☐ in which I am not recognisable in publications and presentations about the project.
- ☐ for data analysis only and not for publications and presentations about the project.

I give permission to store the data for a maximum of 5 years after completion of this research and using it for educational and research purposes. I acknowledge that no financial compensation will be provided for my participation in this research. With my signature I acknowledge that I have read the provided information about the research and understand the nature of my participation. I understand that I am free to withdraw and stop participation in the research at any given time. I understand that I am not obliged to answer questions which I prefer not to answer and I can indicate this to the research team.

Last name _____ First Name _____

Date (dd/mm/yyyy) ___ / ___ / 2022 Signature _____

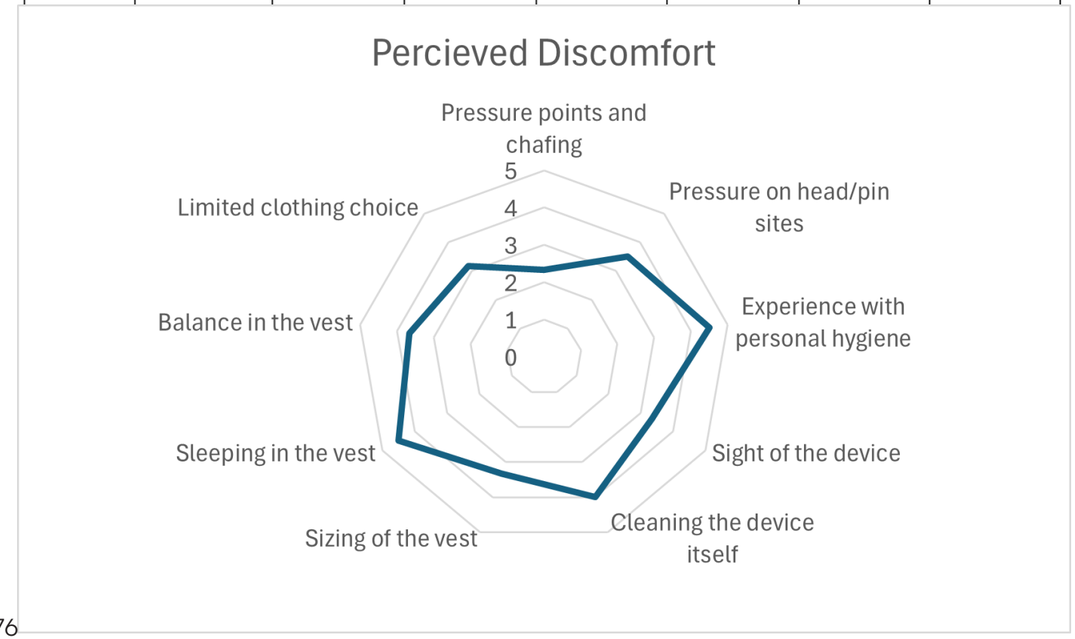
Appendix K: Interview Questions

Inerviews participants

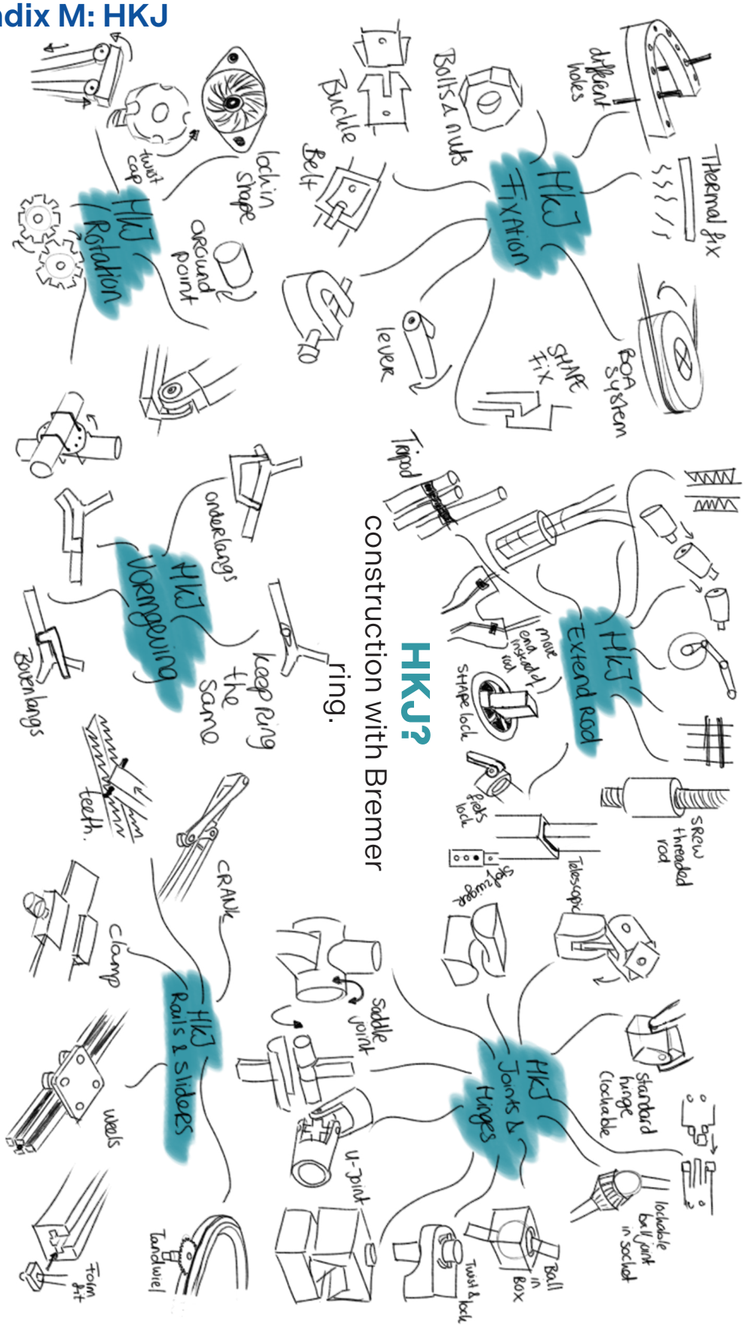
1. Wat is uw naam? – naam wordt **niet** vermeld in het onderzoek en is puur voor mijn admistratie.
2. Wat is uw leeftijd?
3. Wat is uw gewicht?
4. Wat is uw lengte?
5. Hoe zou u uw lichaamspostuur beschrijven?
6. Heeft u naast het Halo Vest ook nog andere medische bijzonderheden?
7. Hoe lang moet u het vest dragen?
8. Hoe lang draagt u het vest al?
9. Draagt u een normaal halo vest of een kyfose vest?
10. Welke klachten ervaart u met het Halo Vest?
    - Schaamte wat betreft het aanzicht
        - Wilt u dit beoordelen op een schaal van 1-7
    - Last van drukplekken
        - Wilt u dit beoordelen op een schaal van 1-7
    - Druk op het hoofd/rondom de pinnen
        - Wilt u dit beoordelen op een schaal van 1-7
    - Moeilijkheden met persoonlijke hygiëne (schoonmaken onder het vest/haren wassen)
        - Wilt u dit beoordelen op een schaal van 1-7
    - Moeilijkheden met schoonmaken en houden van het vest
        - Wilt u dit beoordelen op een schaal van 1-7
    - Maatvoering van het vest
        - Wilt u dit beoordelen op een schaal van 1-7
    - Moeilijkheden met slapen
        - Wilt u dit beoordelen op een schaal van 1-7
    - Moeilijkheden met balans
        - Wilt u dit beoordelen op een schaal van 1-7
    - Beperkte kleding keuze
        - Wilt u dit beoordelen op een schaal van 1-7
    - Anders namelijk:
        - Wilt u dit beoordelen op een schaal van 1-7
11. Ervaart u drukplekken? Zo ja, wilt u omcirkelen op het lichaam waar u deze plekken ervaart? Zo nee, kan u deze vraag overslaan.
12. Hoe voelt u zich tegenover het aanzien van het frame?
13. Welke dagelijkse taken heeft u voornamelijk problemen mee? Licht toe waarom.

Appendix L: Interview results

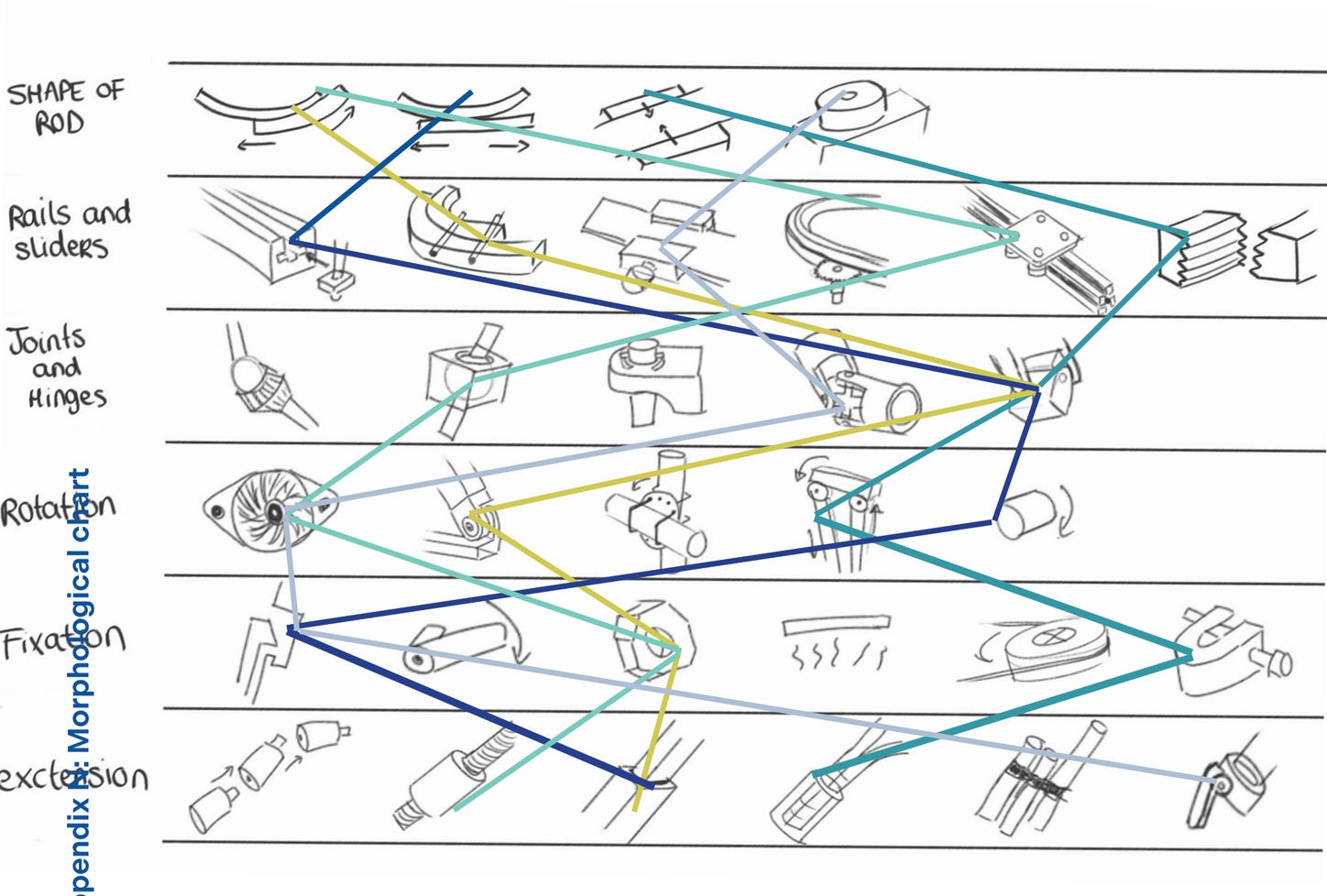
	Participant 1	Participant 2	Participant 3	Participant 4	Participant 5	Participant 6	Average
Pressure points and chafing	2	2	2	5-6	1	1	2,333333
Pressure on head/pin sites	5	1	3	5	1	6	3,5
Experience with personal hygiene	7	5	2	5	4	4	4,5
Sight of the device	3	6	3	4	3	1	3,333333
Cleaning the device itself	6	4	2	5	3	4	4
Sizing of the vest	4	4	4	3	3	2	3,333333
Sleeping in the vest	3	4	4	6	3	7	4,5
Balance in the vest	5	5	3	5	1	3	3,666667
Limited clothing choice	3	3	3	7	2	1	3,166667

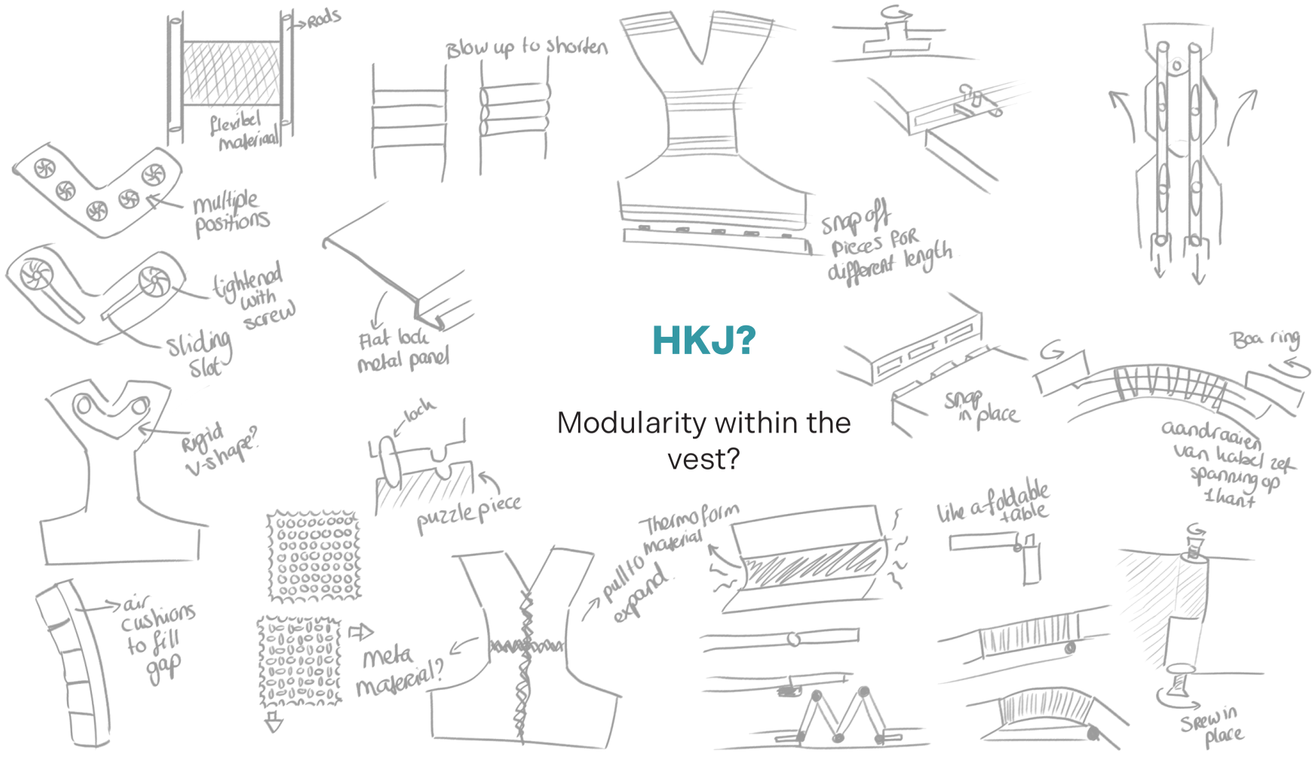


Appendix M: HKJ

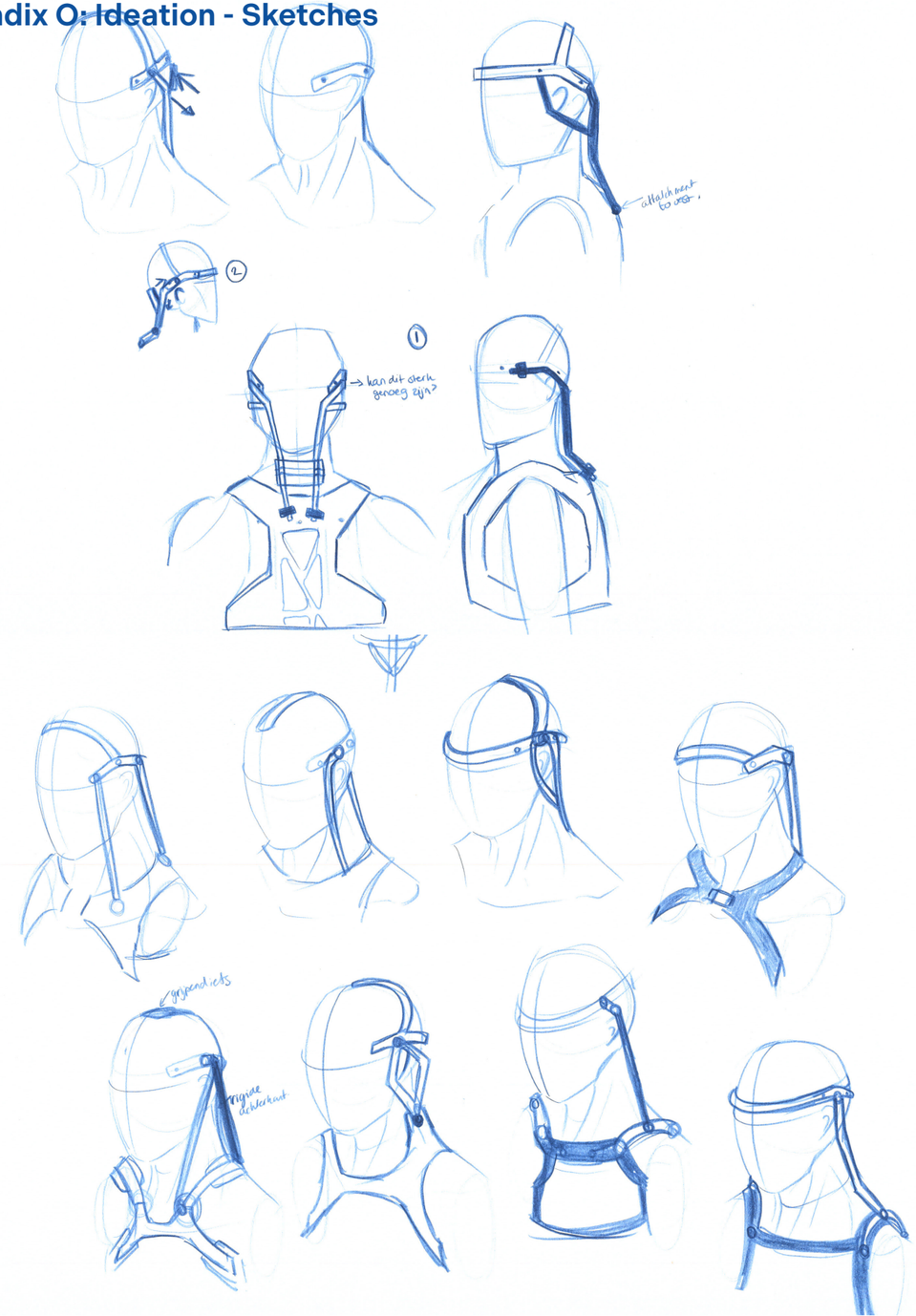


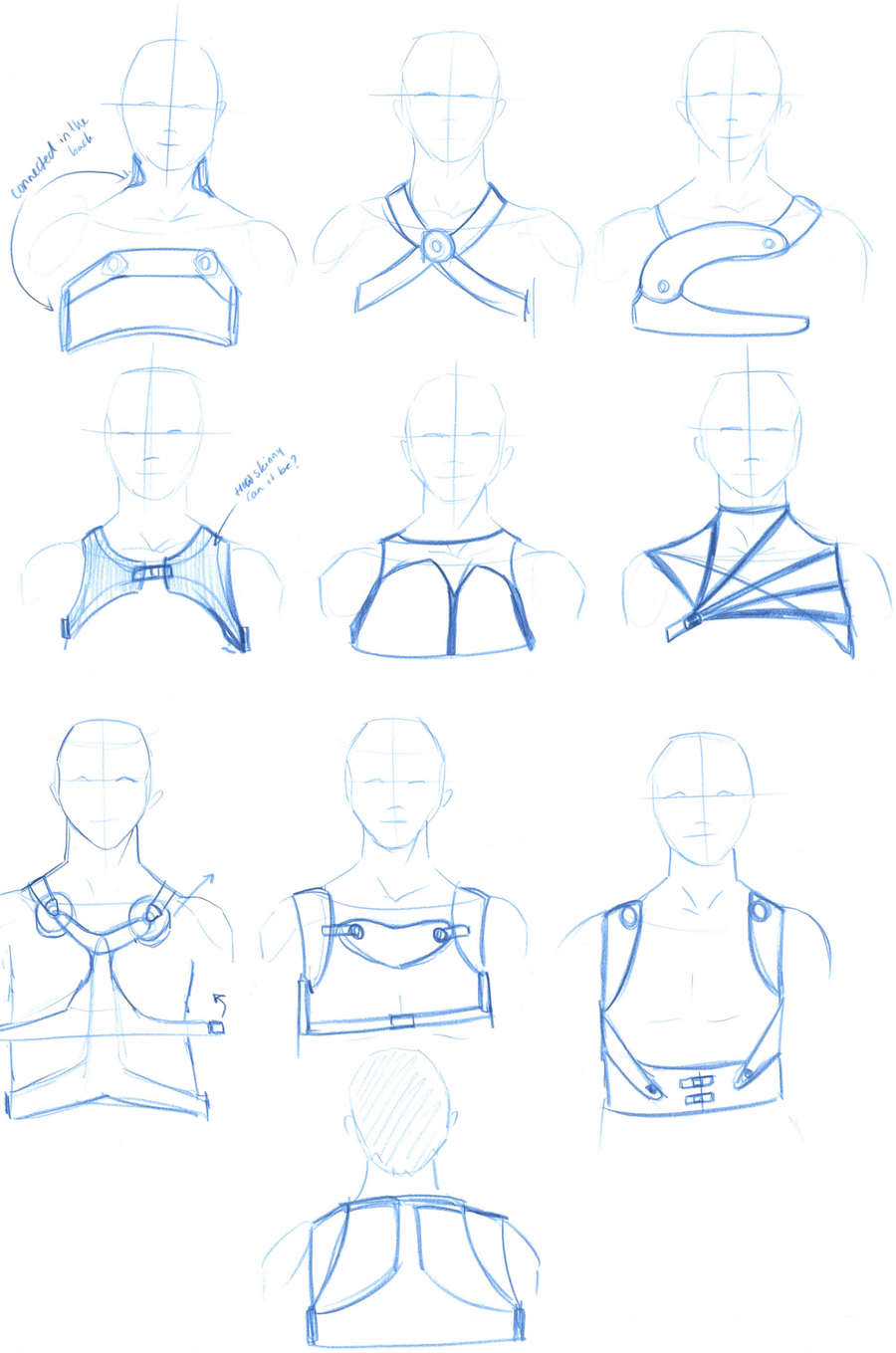
Appendix B: Morphological chart

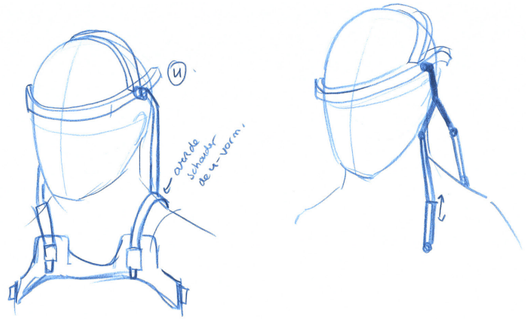


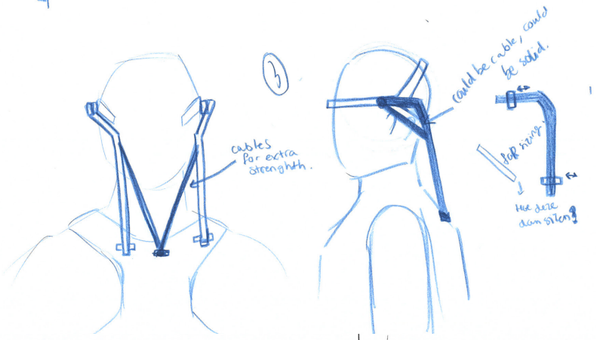


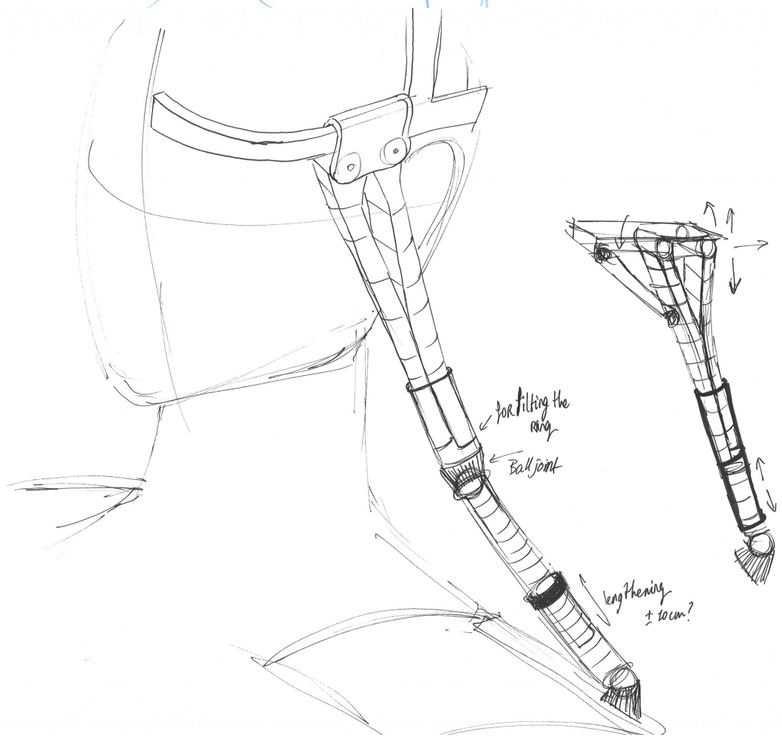
Appendix O: Ideation - Sketches

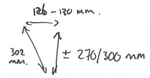


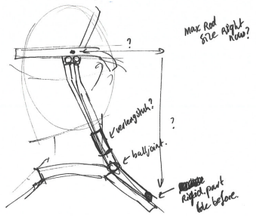


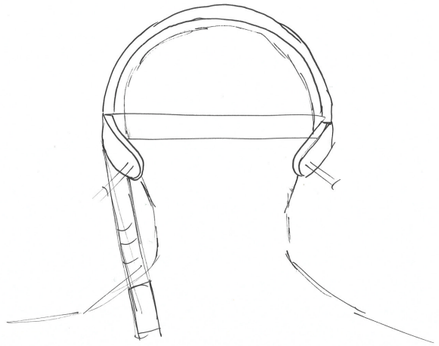


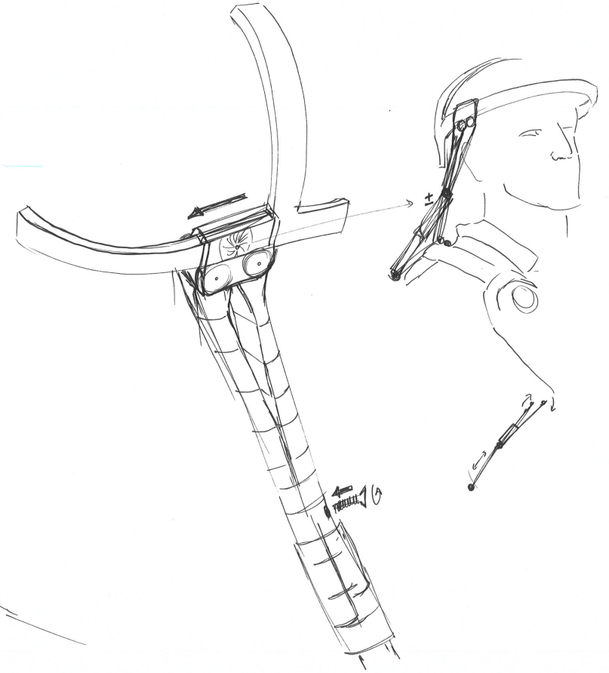




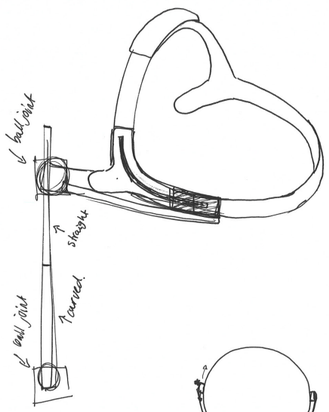


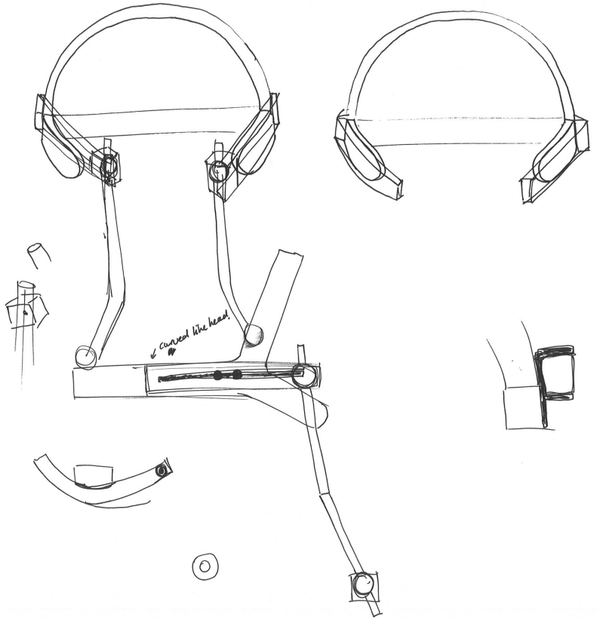


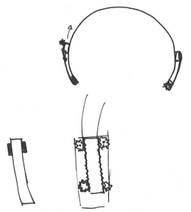


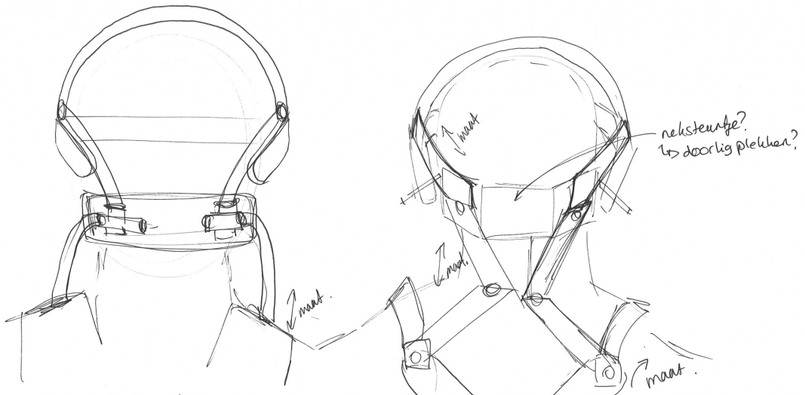


96.85 102.73 97.81

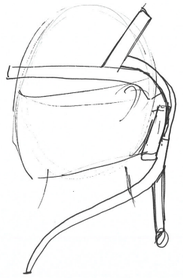


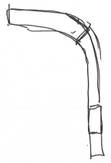


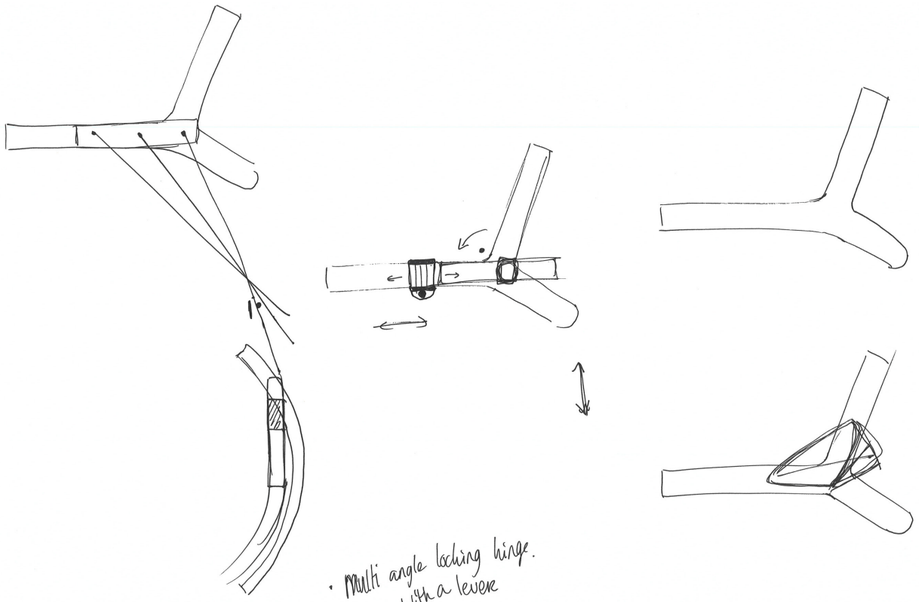


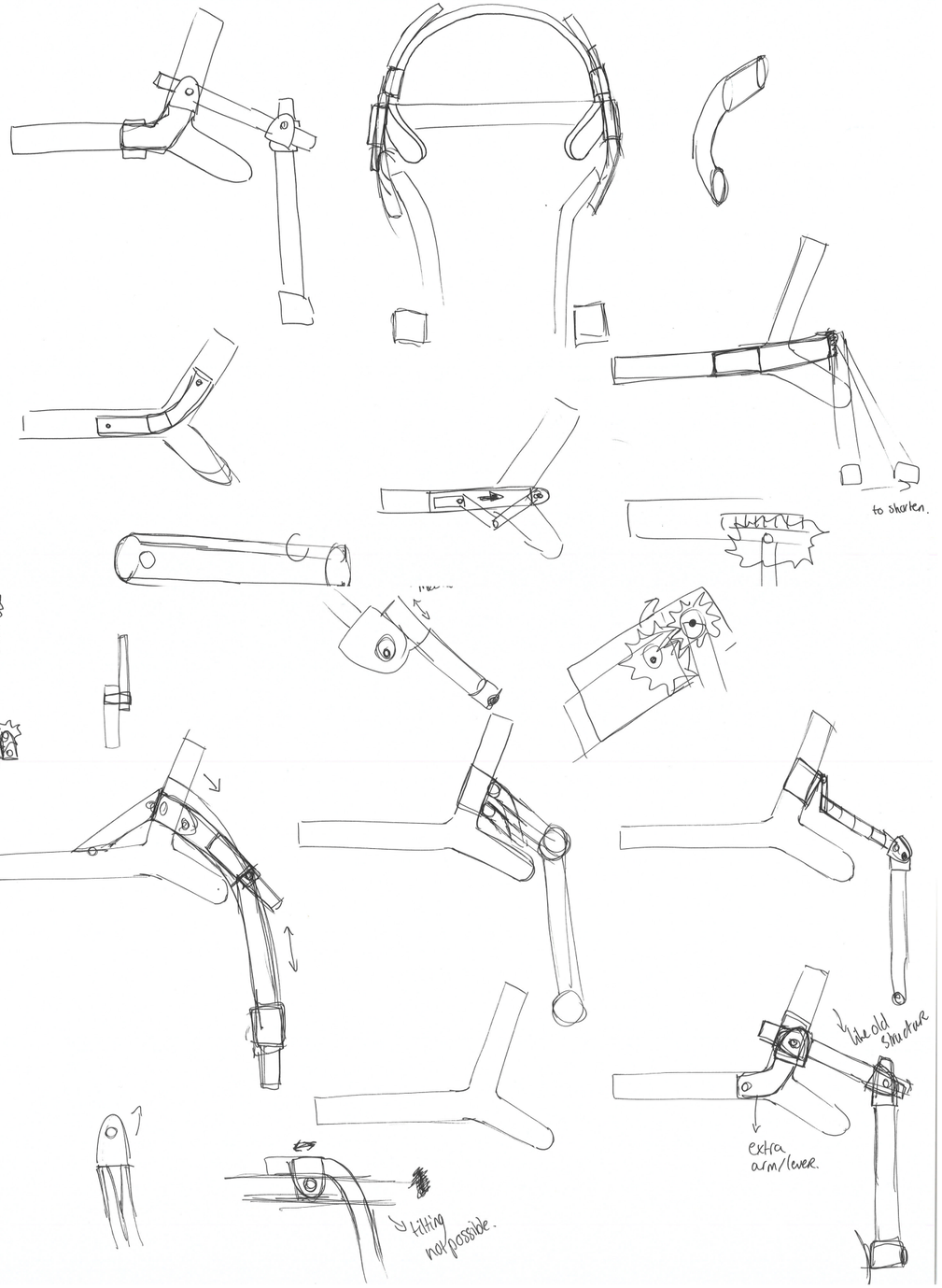

maat.

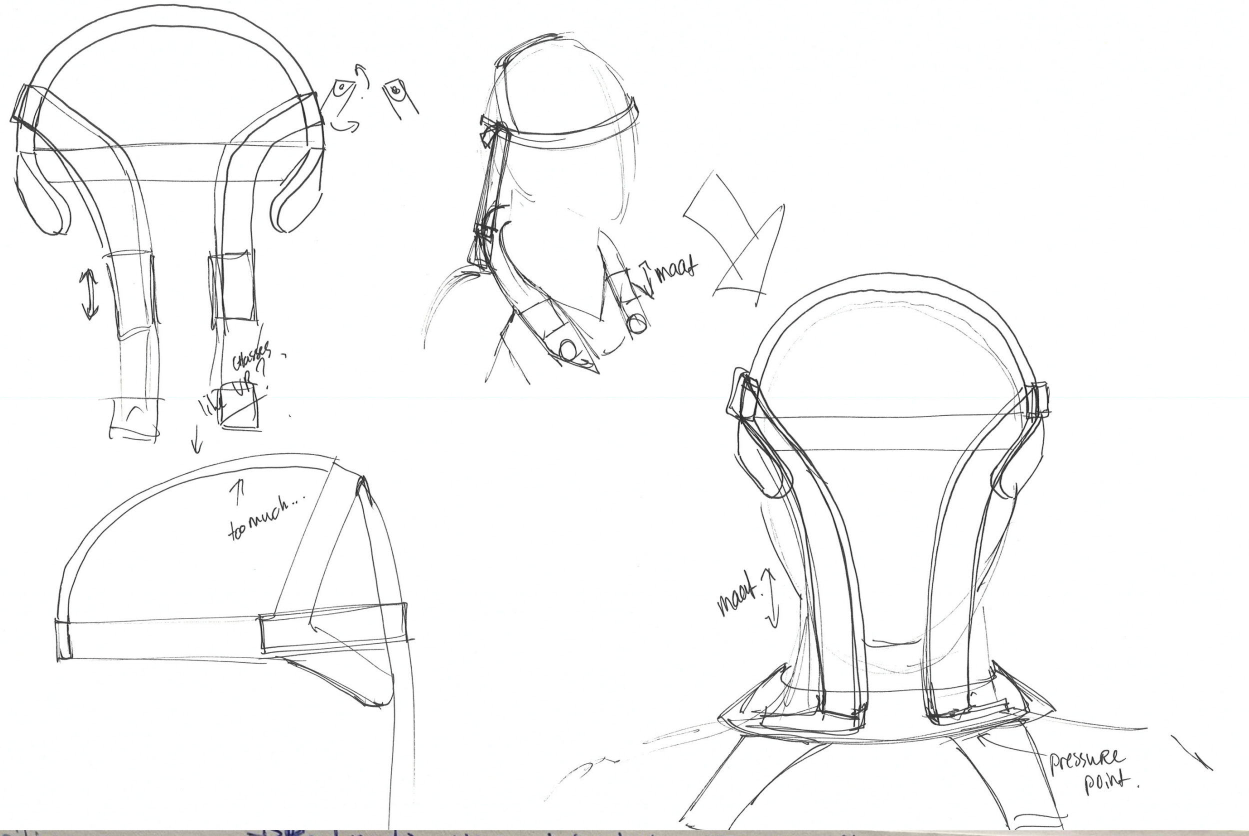
maat
neksteunje?
↳ doorlig plekken?
maat.
maat.

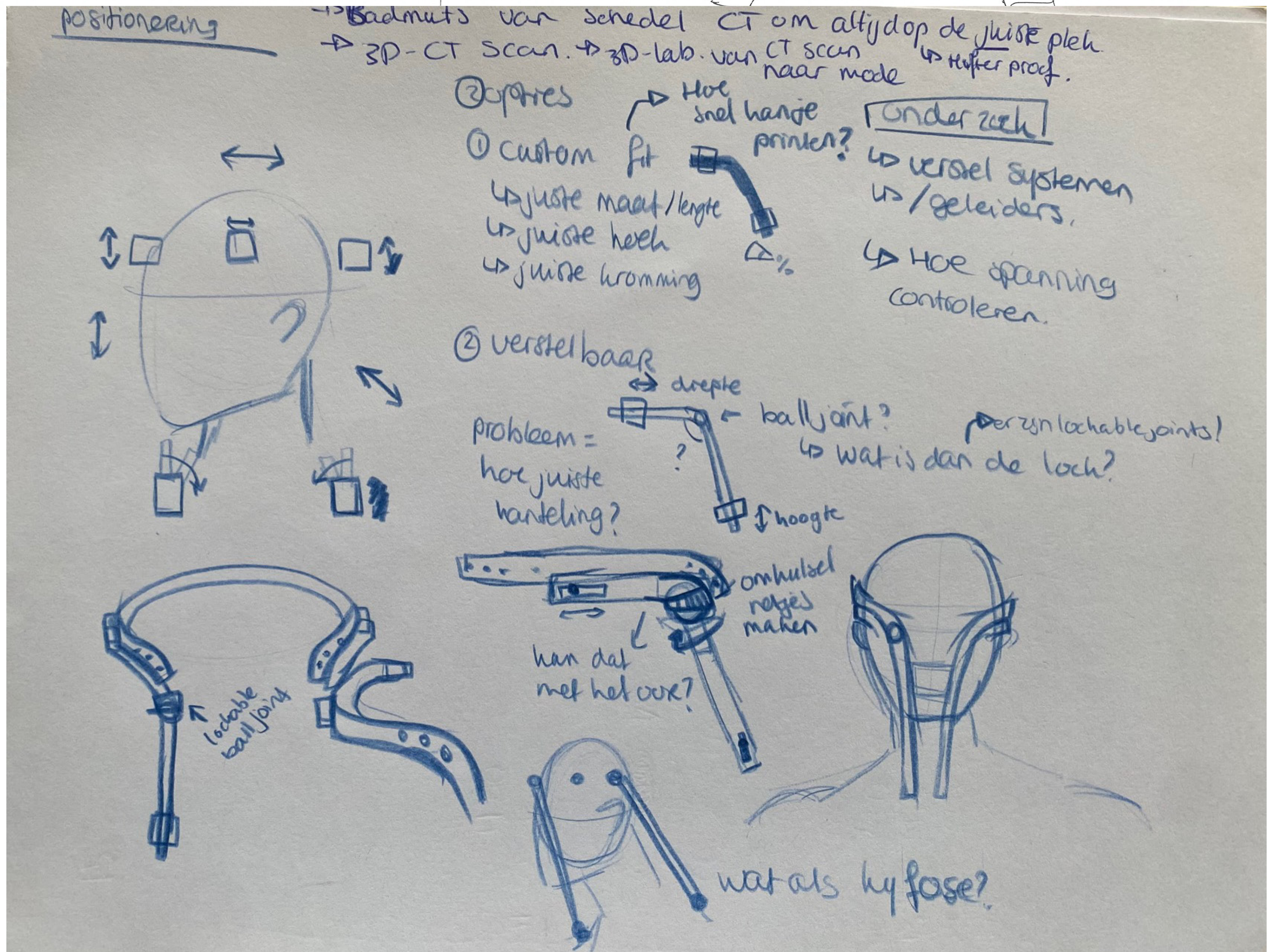


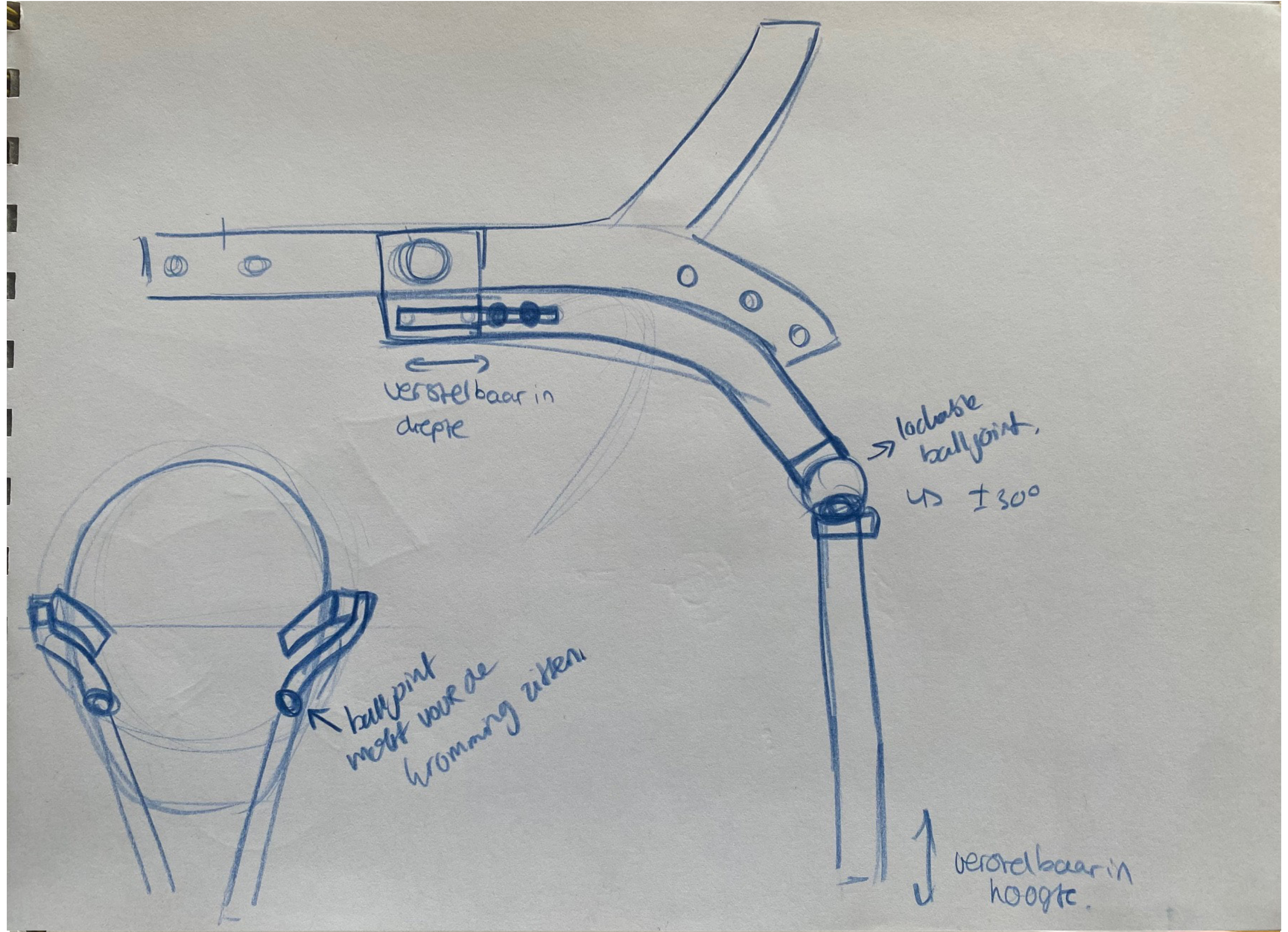


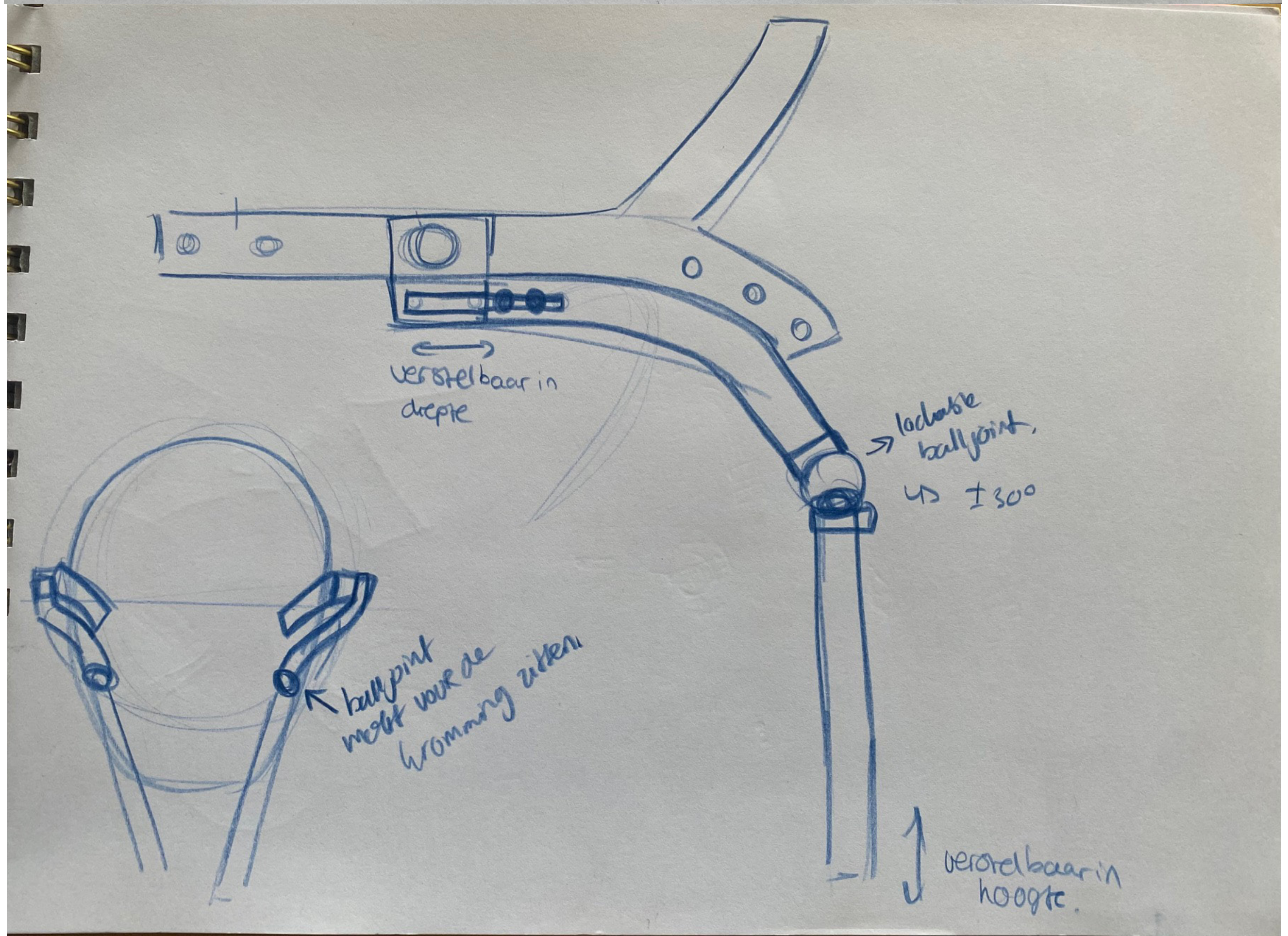

• Multi angle locking hinge.
With a levere

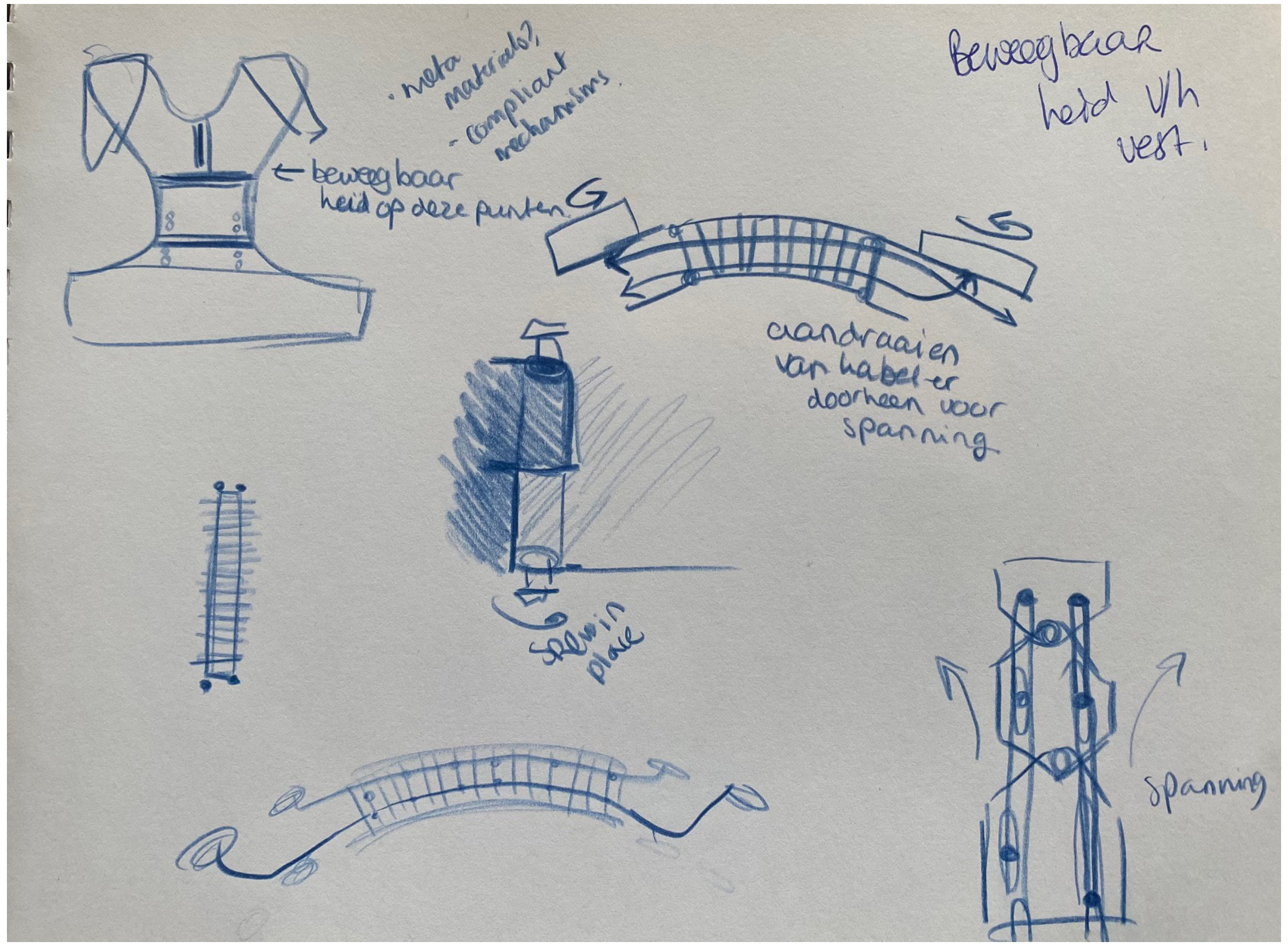

to shorten.
the old structure
extra arm/lever.
Fitting not possible.


maat
too much...
maat
pressure point.

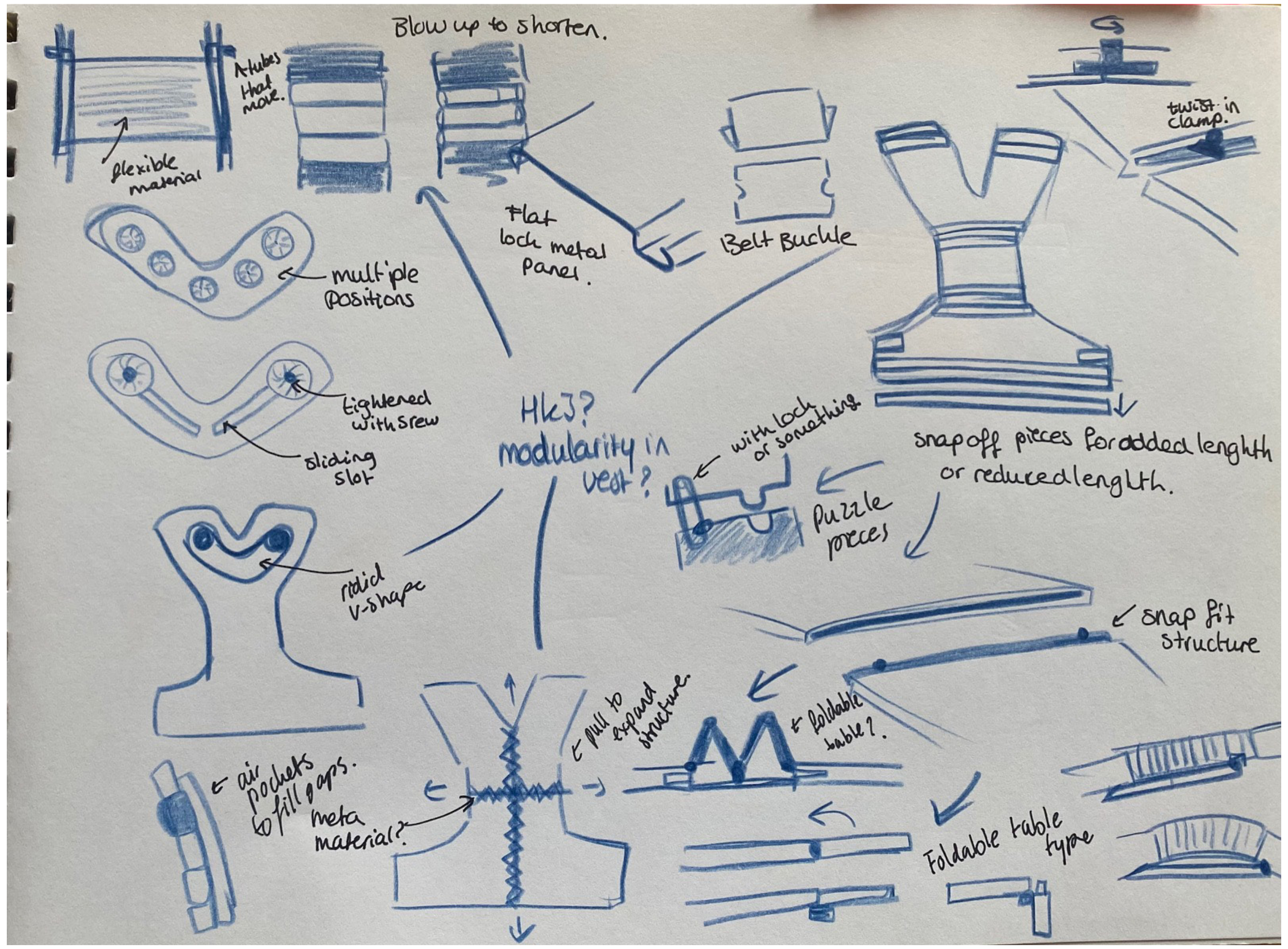

positionering
Badmuts van schedel CT om altijd op de juiste plek
3D-CT scan. 3D-lab. van CT scan naar mode
Hufter proof.
opties
Hoe snel kan je printen?
onderzoek
verstel systemen
/geleiders.
Hoe spanning controleren.
① custom fit
juiste maat/lengte
juiste hoek
juiste kromming
② verstelbaar
diepte
balljoint?
wat is dan de lock?
er zijn lockable joints!
probleem = hoe juiste handeling?
hoogte
omhulsel netjes maken
kan dat met het oor?
lockable balljoint
wat als hij fase?


verstelbaar in diepte
lockable balljoint.
± 30°
balljoint moet voor de kromming zitten
verstelbaar in hoogte.

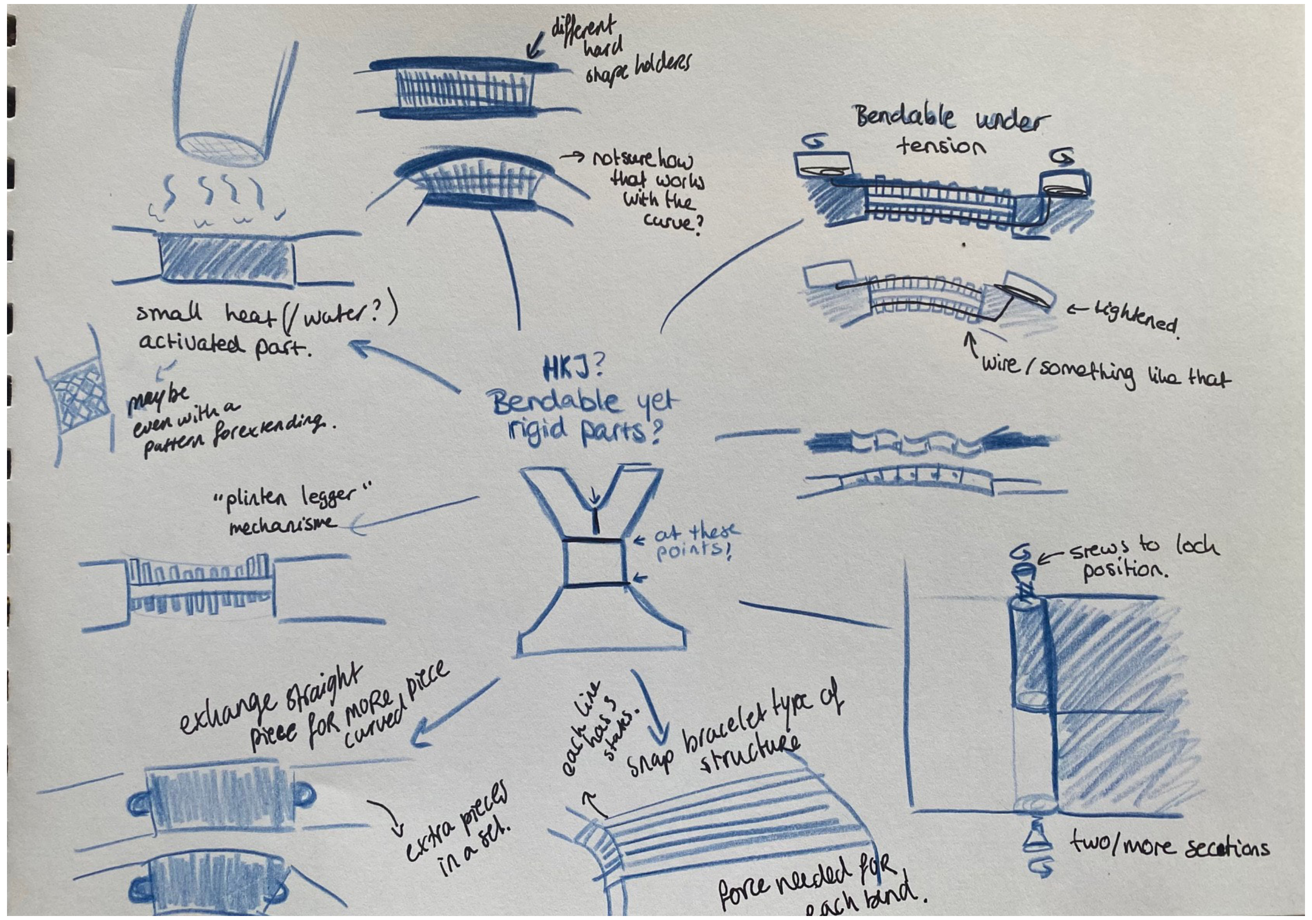

verstelbaar in diepte
lockable balljoint.
± 30°
balljoint moet voor de kromming zitten
verstelbaar in hoogte.



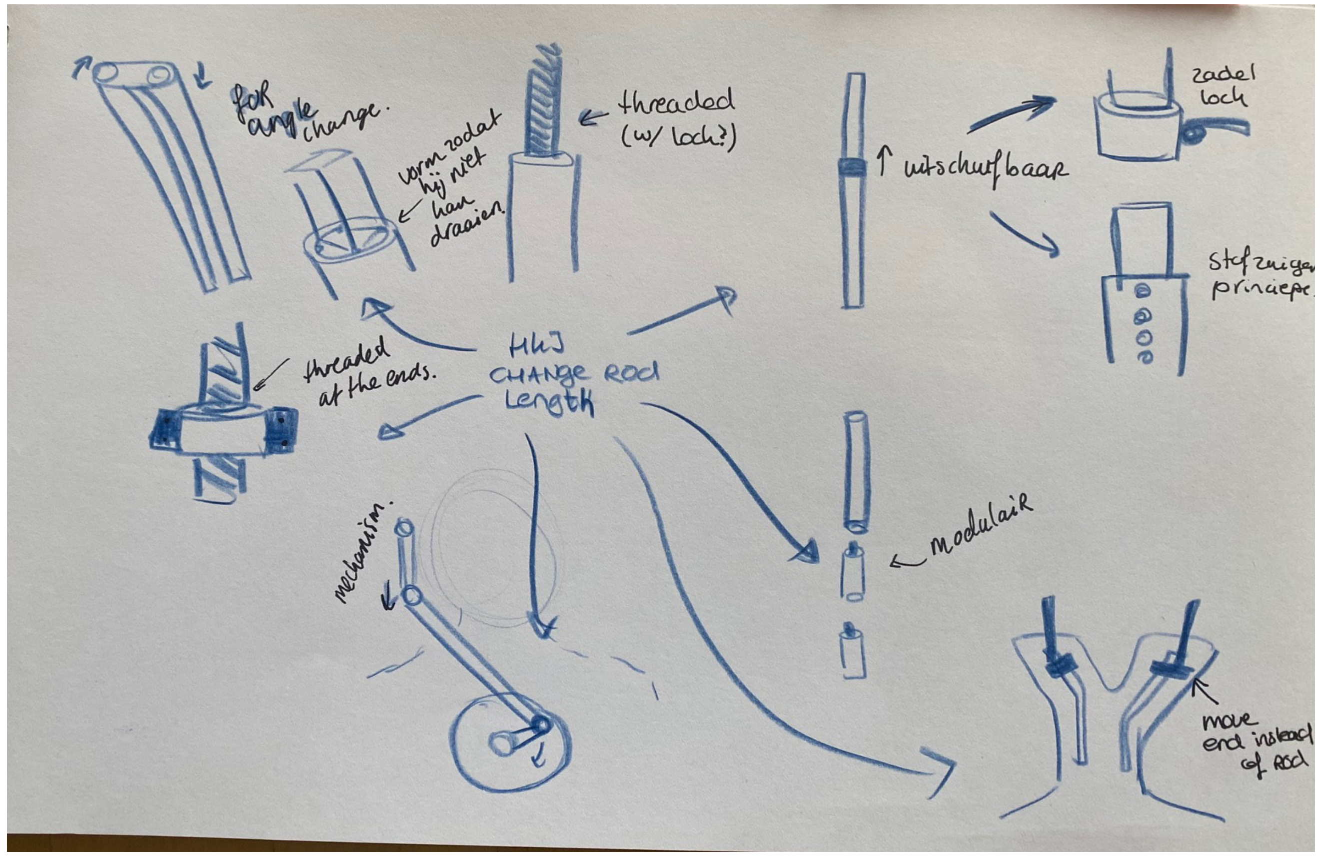
Beweegbaar
heid v/h
vest.
- meta materials?
- compliant mechanisms
beweegbaar
heid op deze punten.
aandraaien
van kabel er
doorheen voor
spanning
screw in
place
spanning



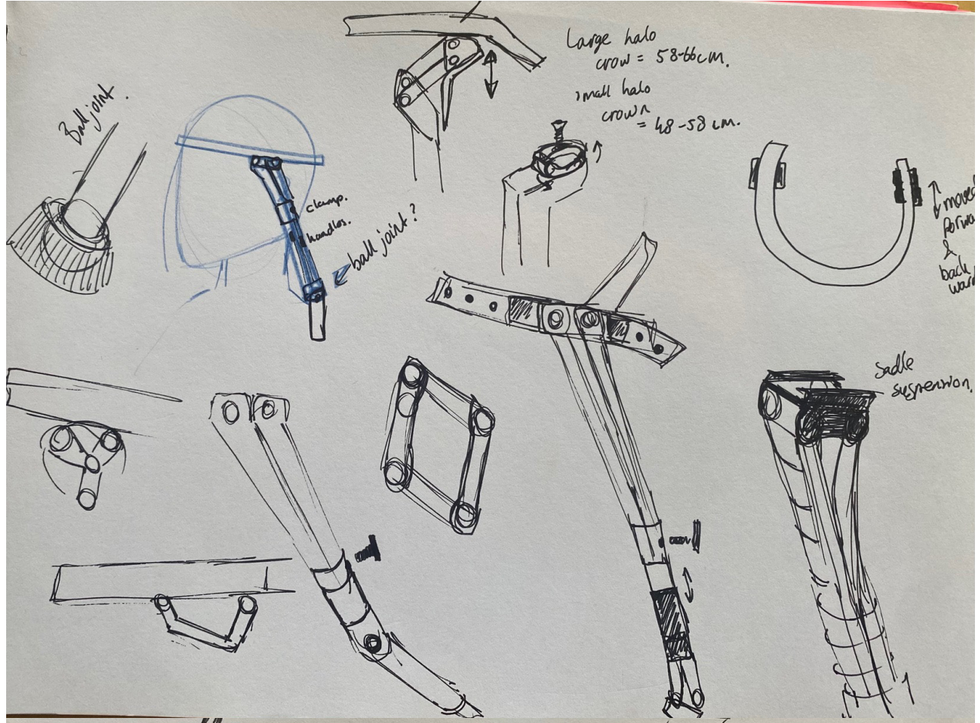
Blow up to shorten.
flexible
material
Flat
lock metal
Panel.
Belt Buckle
twist in
clamp.
multiple
positions
tightened
with srew
sliding
slot
HKJ?
modularity in
vest?
with lock
or something
snap off pieces for added length
or reduced length.
puzzle
pieces
rigid
V-shape
snap fit
structure
pull to
expand
structure
foldable
table?
air
pockets
to fill gaps.
meta
material?
Foldable table
type

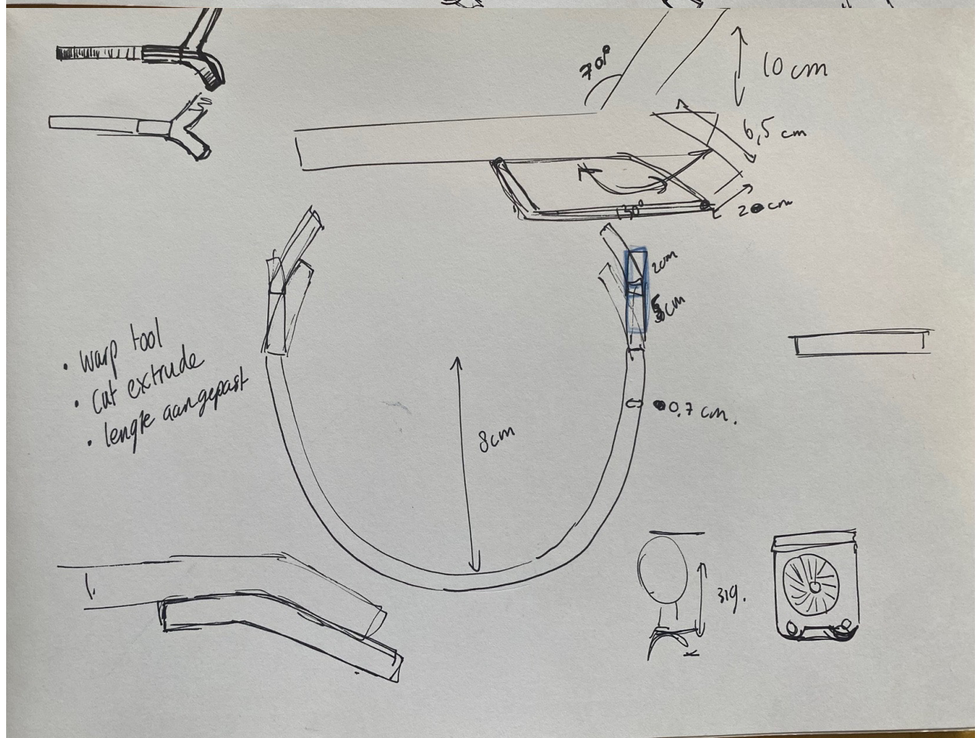


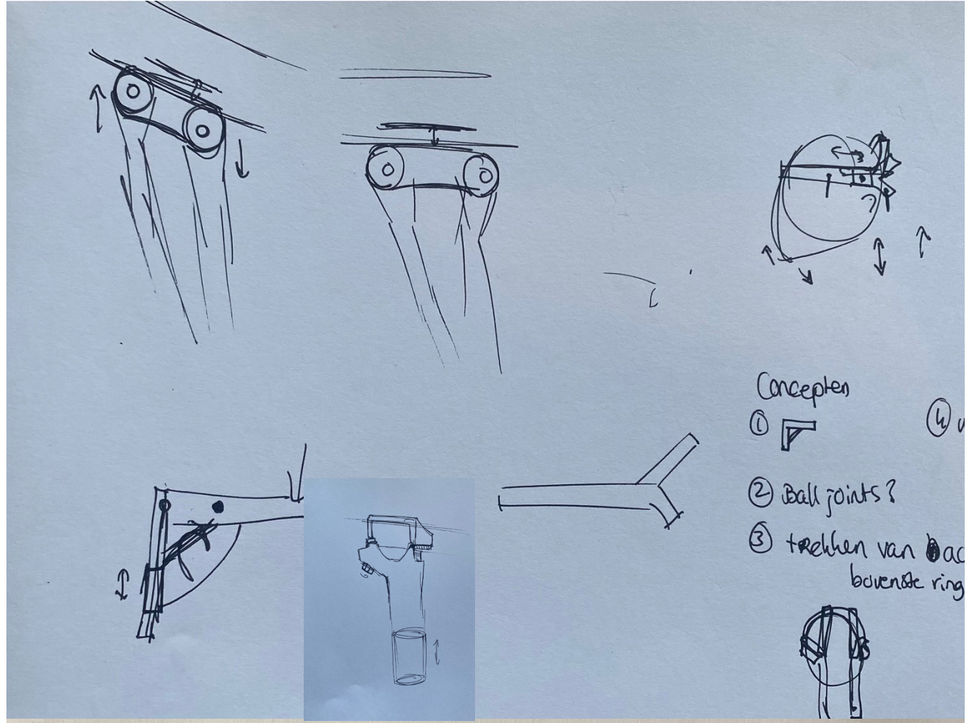
different
hard
shape holders
not sure how
that works
with the
curve?
Bendable under
tension
tightened.
wire / something like that
small heat (/water?)
activated part.
maybe
even with a
pattern for extending.
HKJ?
Bendable yet
rigid parts?
"plinten legger"
mechanisme
at these
points?
srews to lock
position.
exchange straight
piece for more curved piece
extra pieces
in a set.
snap bracelet type of
structure
force needed for
each band.
two/more secetions

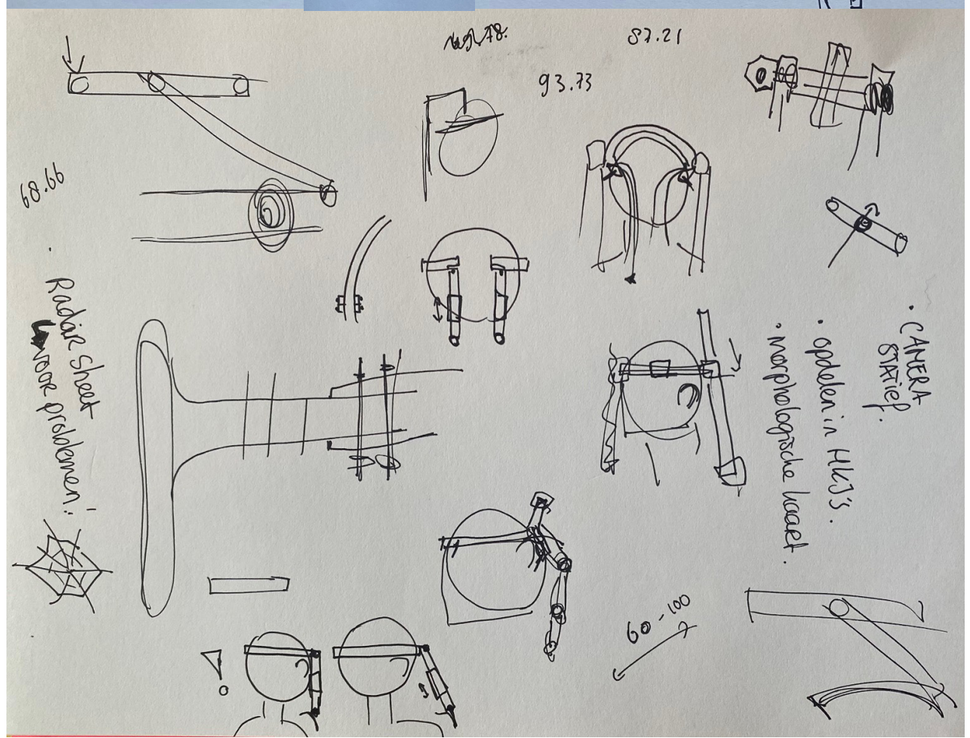


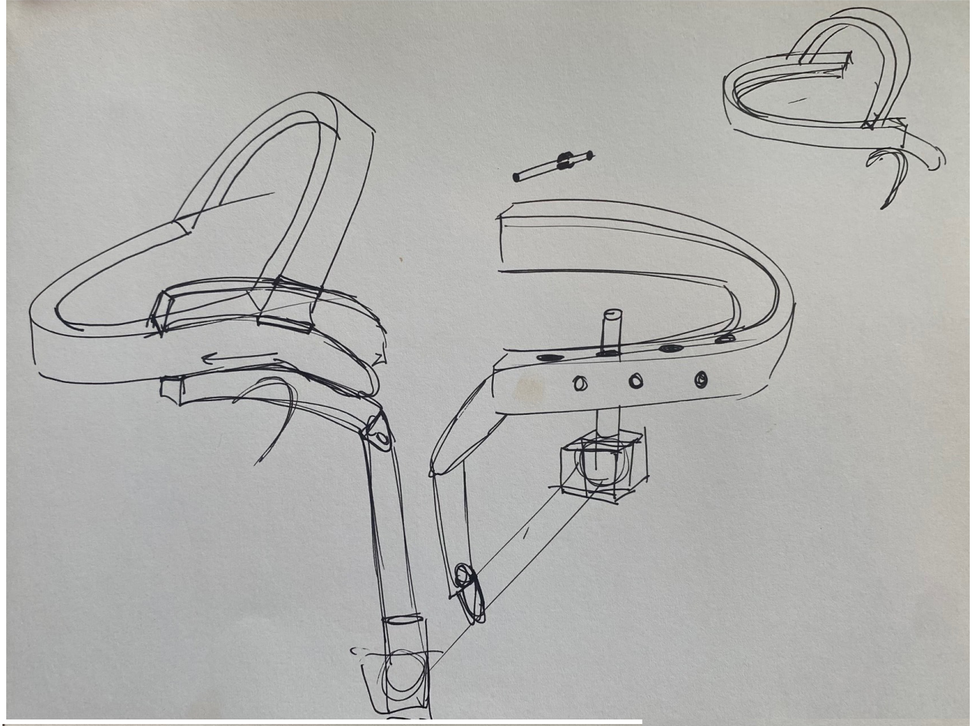
for
angle
change.
threaded
(w/ lock?)
vorm zodat
hij niet
kan
draaien
uitschuifbaar
zadel
lock
stofzuiger
principe
threaded
at the ends.
HKJ
CHANGE ROD
LENGTH
mechanism.
modulair
move
end instead
of rod

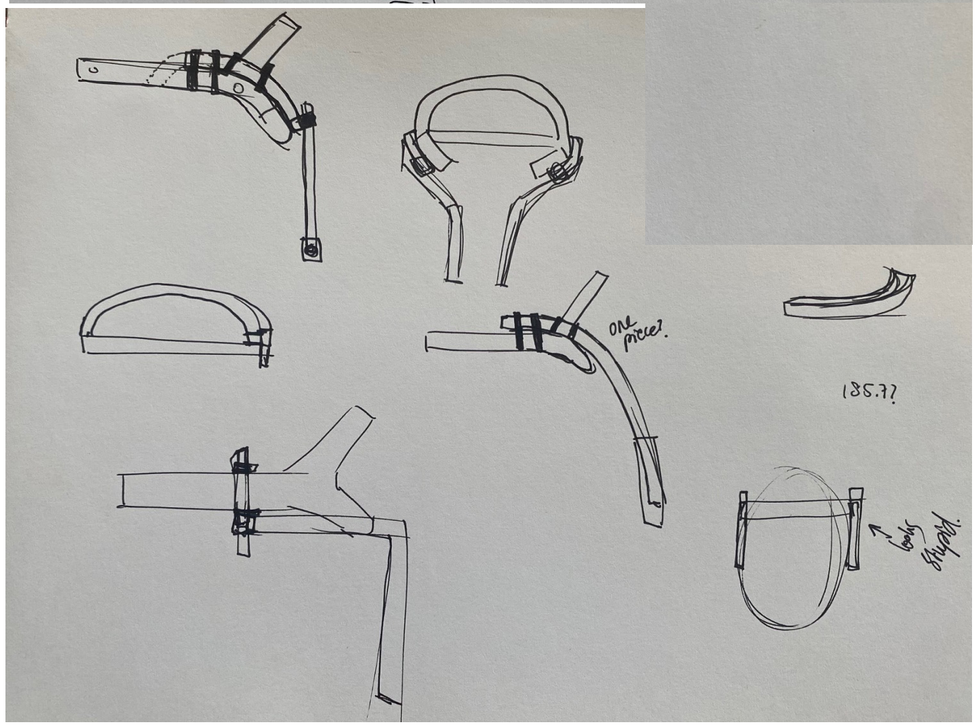

Ball joint.
clamp.
handle.
ball joint?
Large halo
crown = 58-66cm.
small halo
crown
= 48-58 cm.
saddle
suspension.

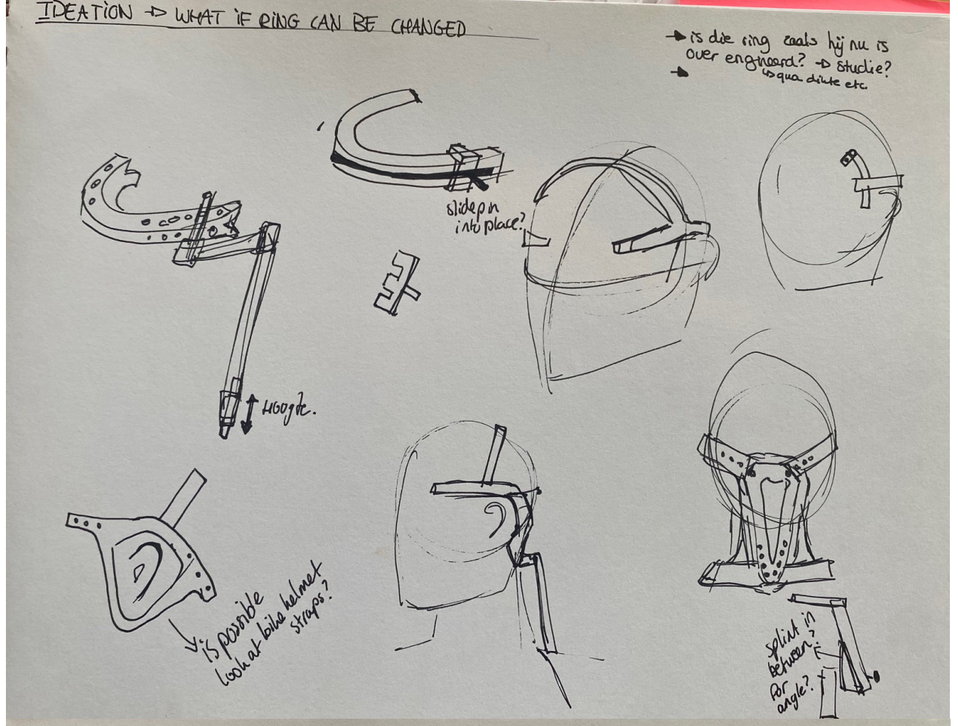

70°
10 cm
6,5 cm
20 cm
2cm
3cm
8cm
0,7 cm.
• warp tool
• cut extrude
• lengte aangepast
zig.

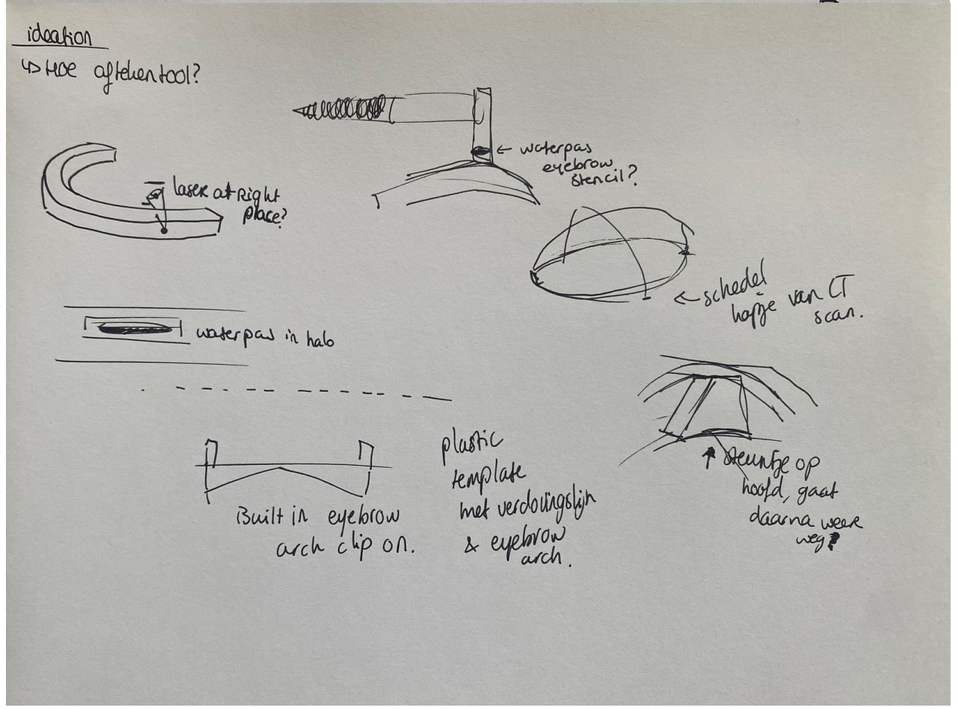

Concepten
① ④
② Ball joints?
③ trekken van
bovenste ring

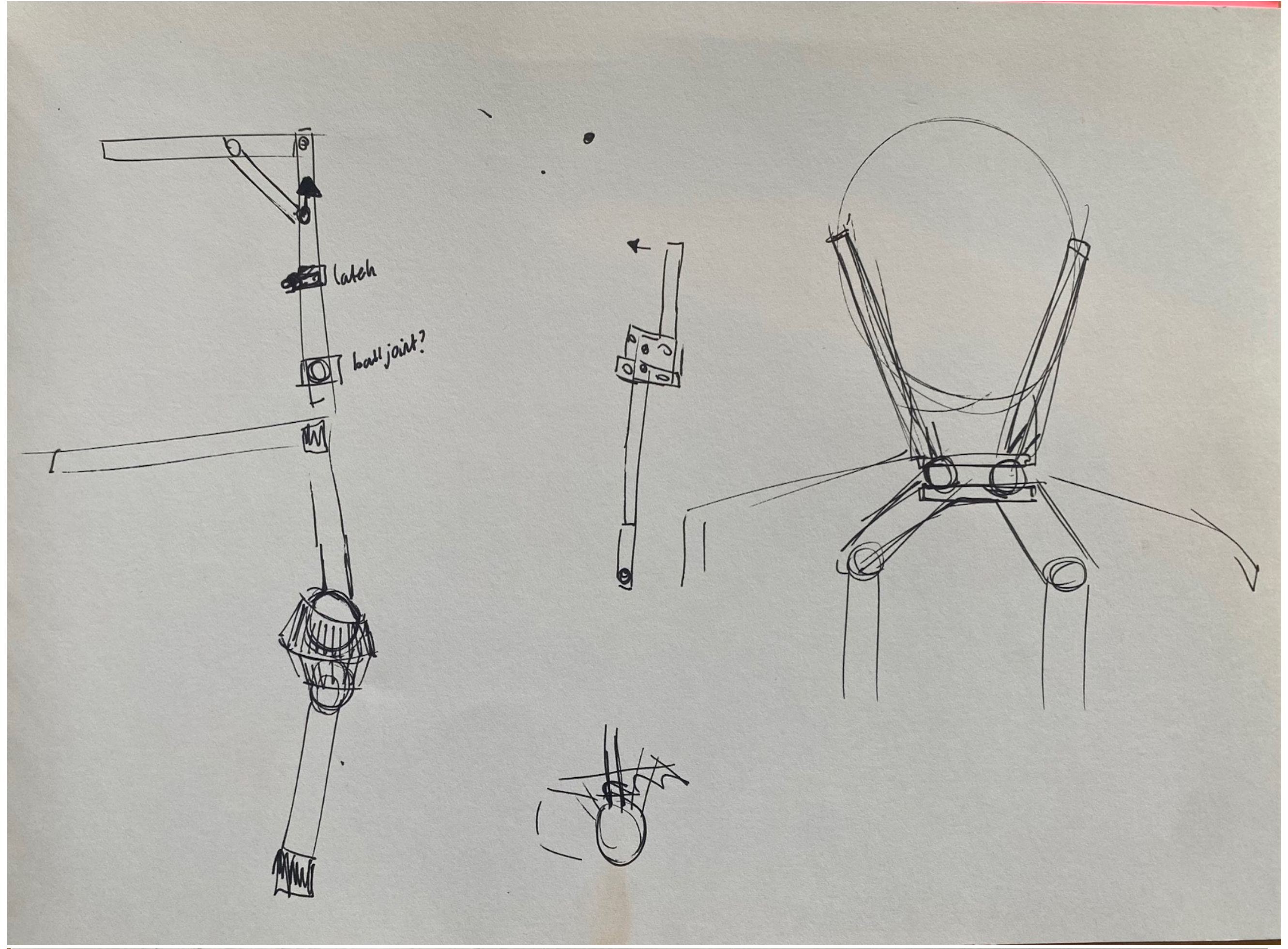

68.66
93.73
87.21
Radar Sheet
voor problemen:
• CAMERA
STATIEF.
• opdelen in HUIS's.
• morphologische waaier.
60 - 100

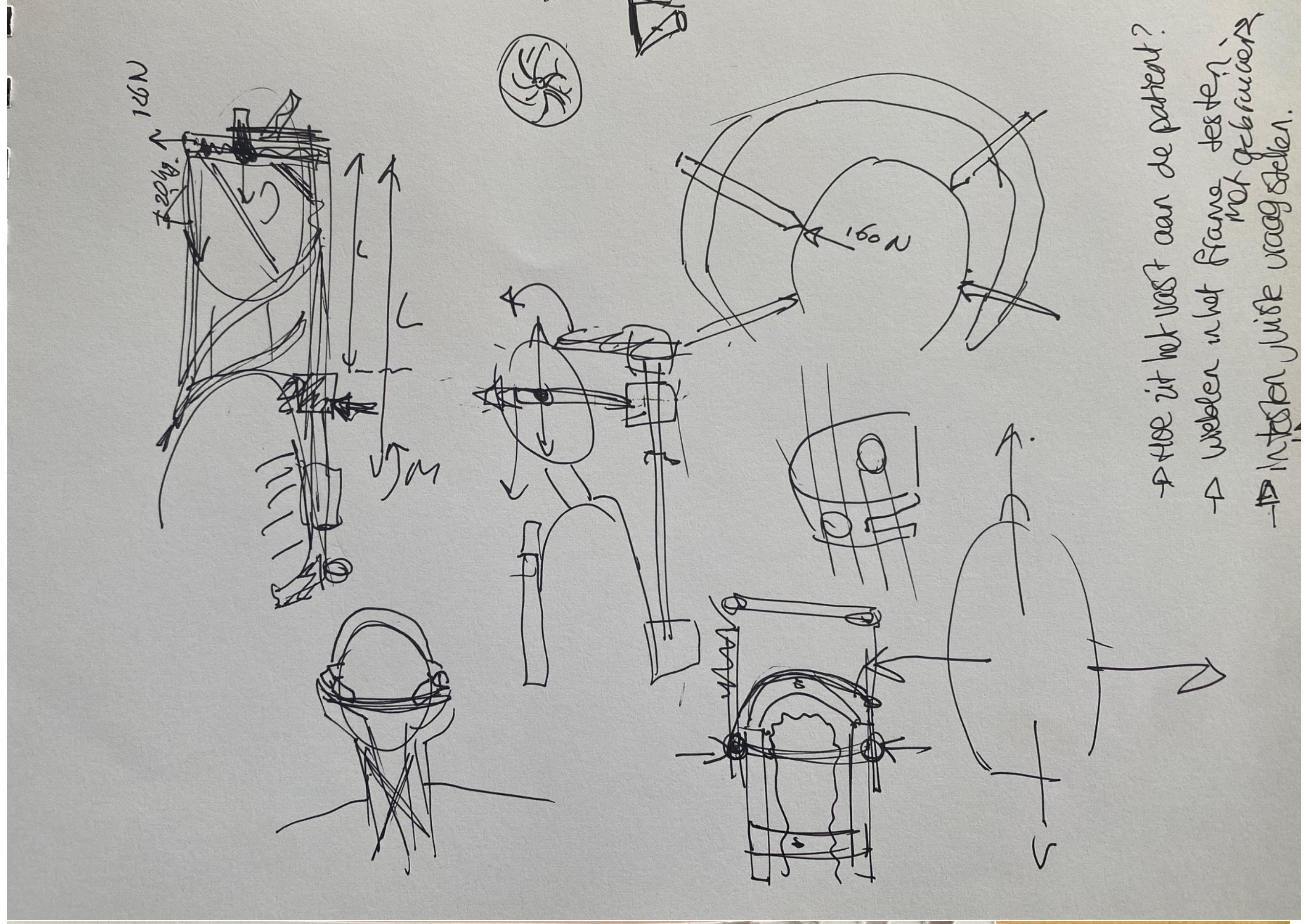


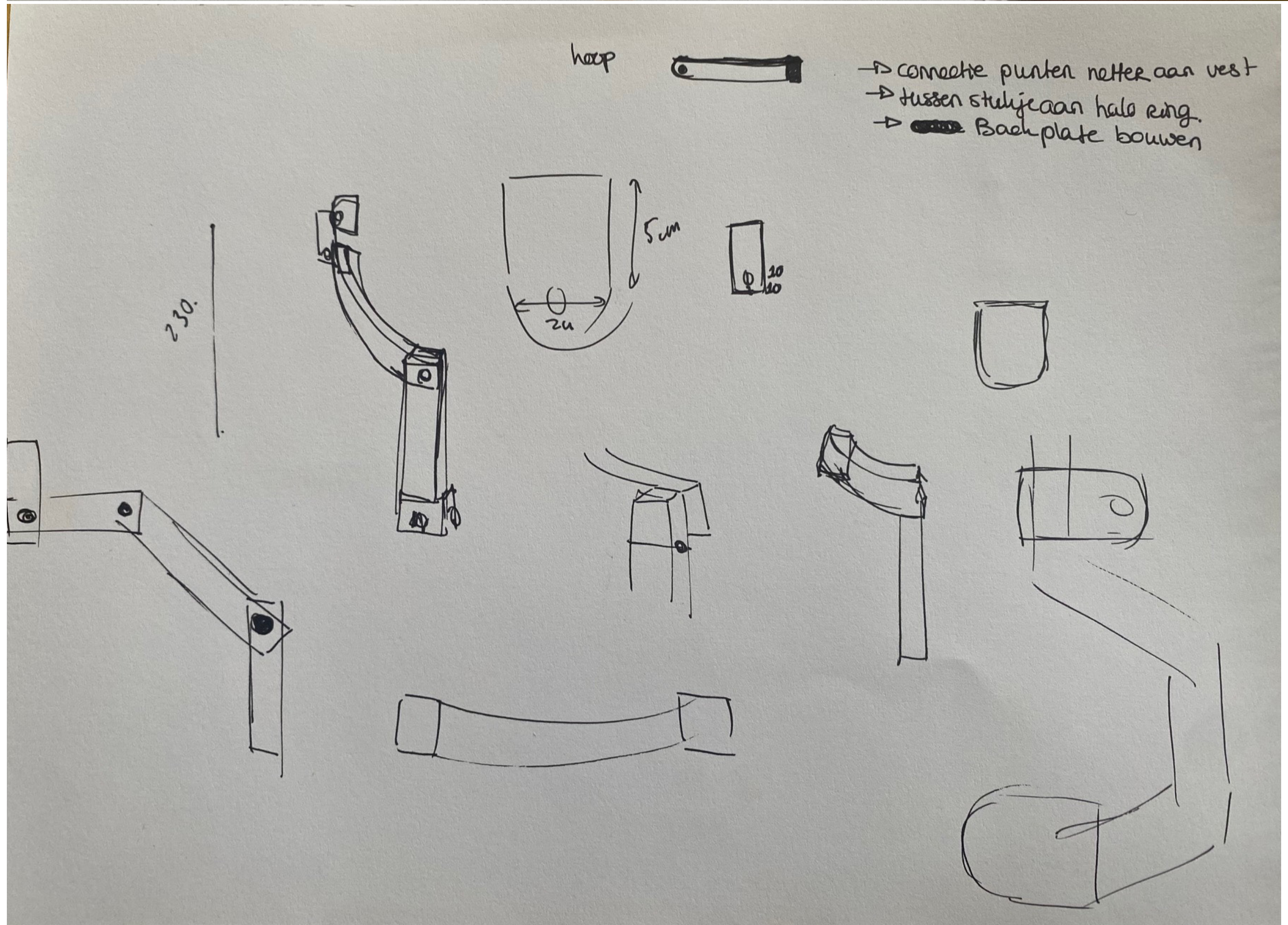

one piece?
185.77
body shape!

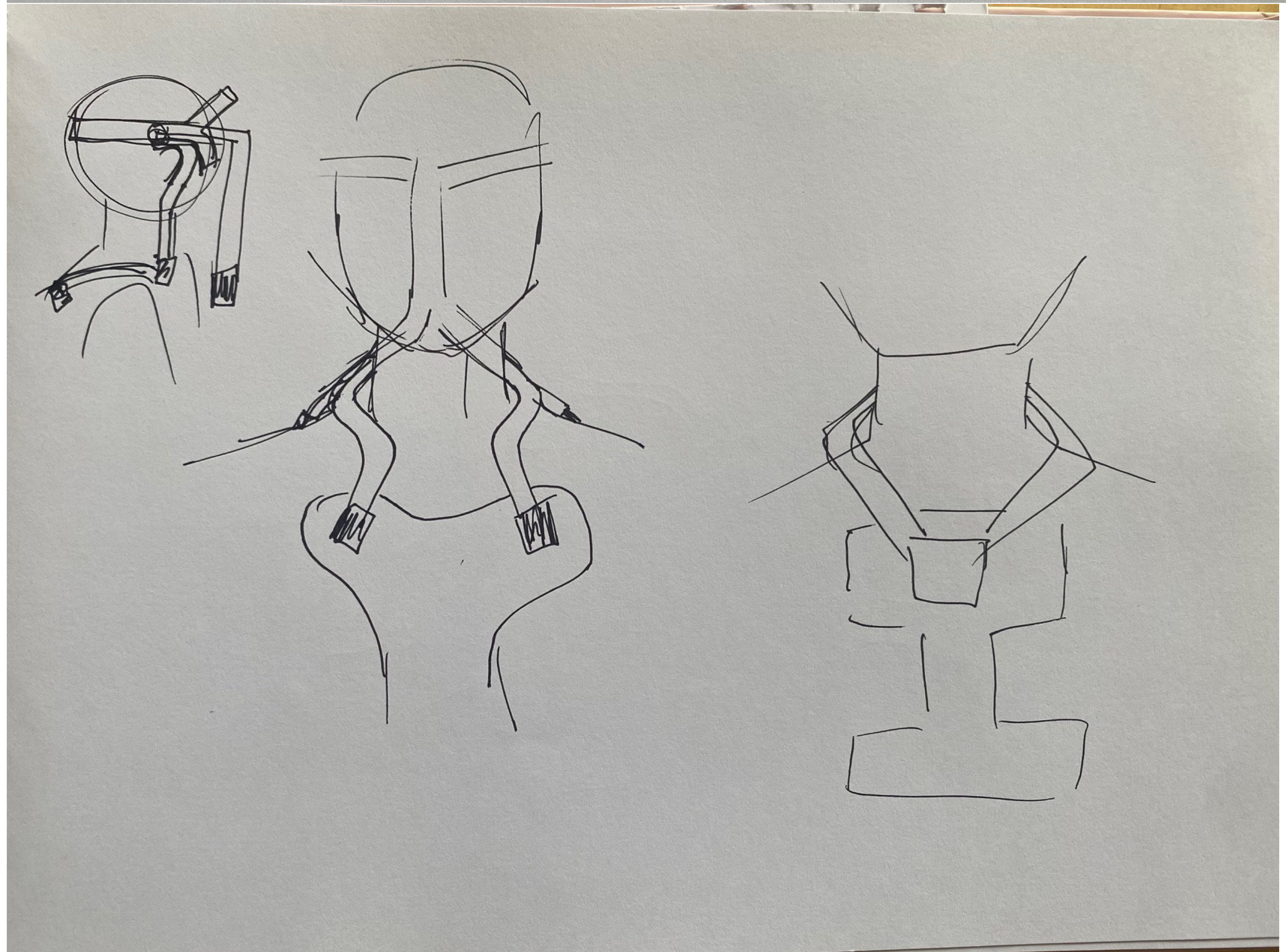

IDEATION ⇨ WHAT IF RING CAN BE CHANGED
→ is die ring zoals hij nu is over engineerd? ⇨ studie? ⇨ qua druk etc
slide in into place?
hoogte.
↳ is mogelijk kijk al bijv helmet straps?
splint in? tussen? for angle?

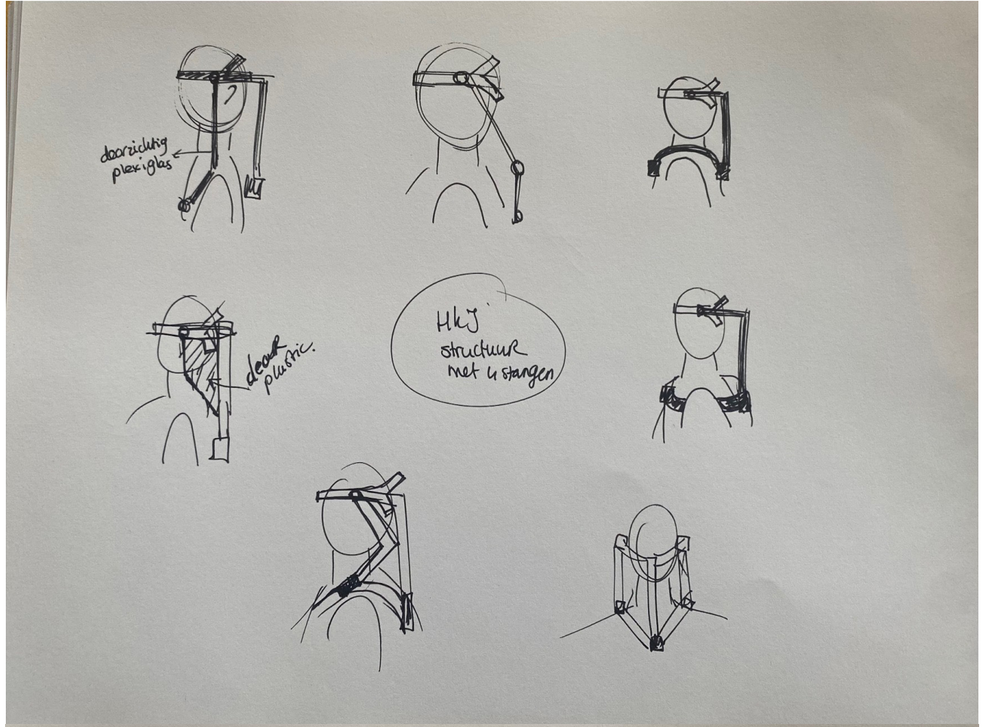

ideation
↳ hoe afdek tool?
laser at right place?
waterpas eyebrow stencil?
← schedel hoge van CT scan.
waterpas in halo
Built in eyebrow arch clip on.
plastic template met verdoezingslijn & eyebrow arch.
stencil op hoofd, gaat daarna weer weg?

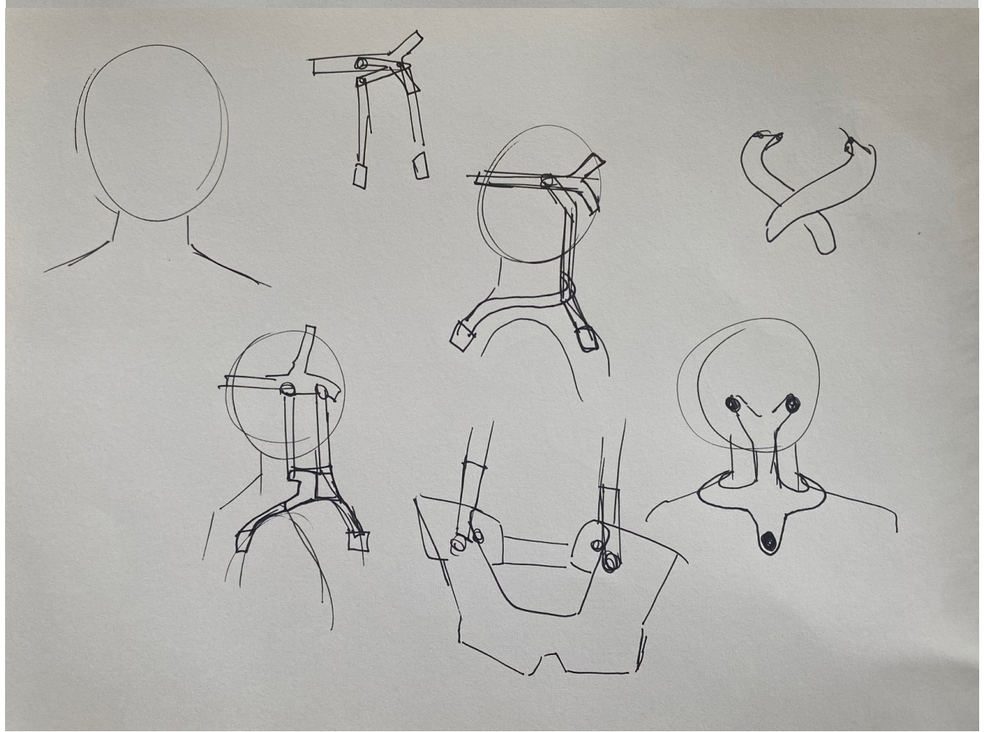

latch
ball joint?

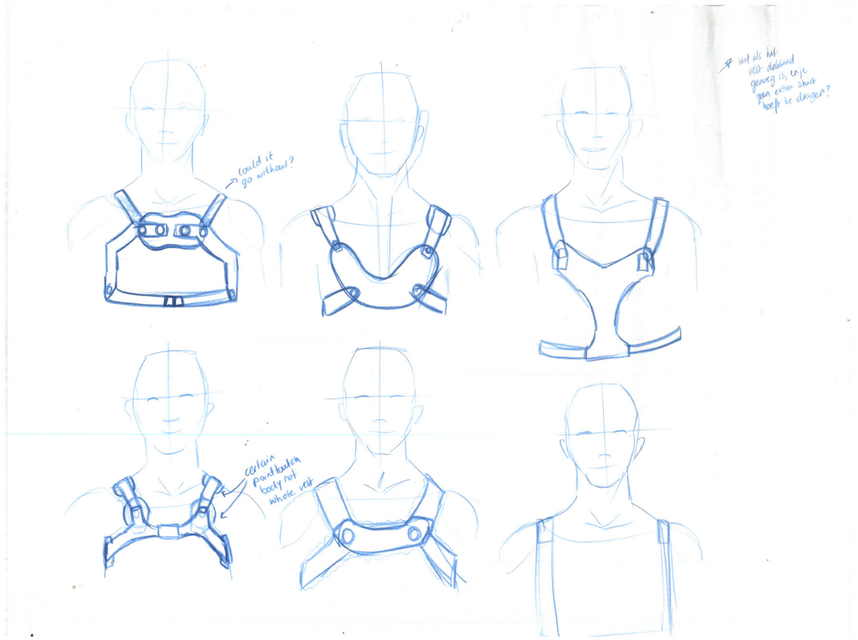

160N
160N
Hoe zit het vast aan de patient?
Wielden in het frame testen met gebruikers
Intesten juiste vraag stellen.


hoop
connectie punten netter aan vest
tussen stukje aan hele ring
Backplate bouwen
5cm
230.



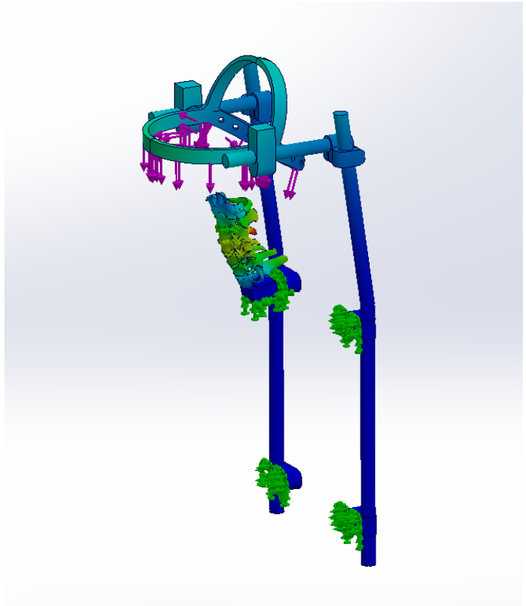


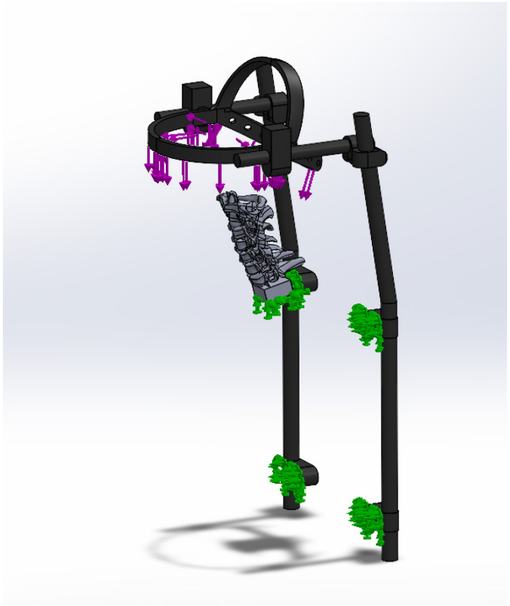




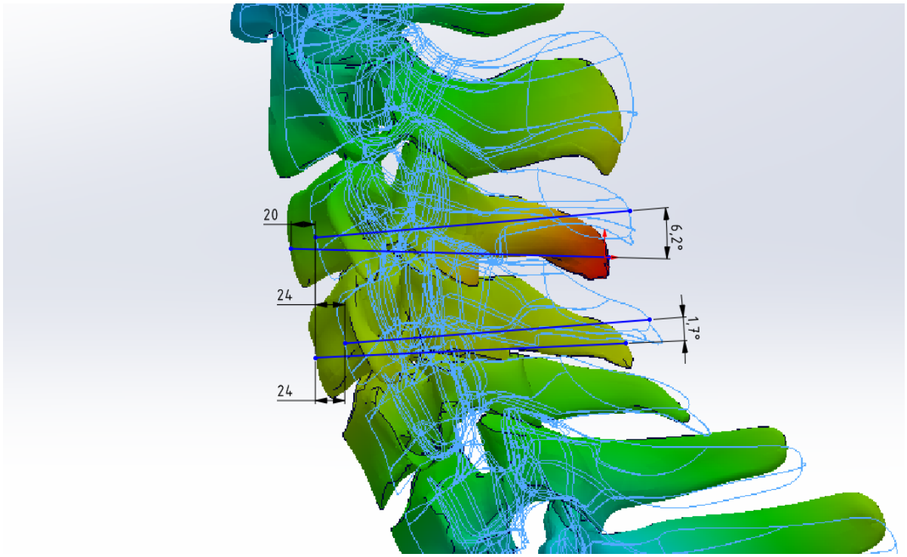
Appendix P: Ideation - Rapid CAD Prototypes

Appendix Q: Conceptualisation - Proof of Concept

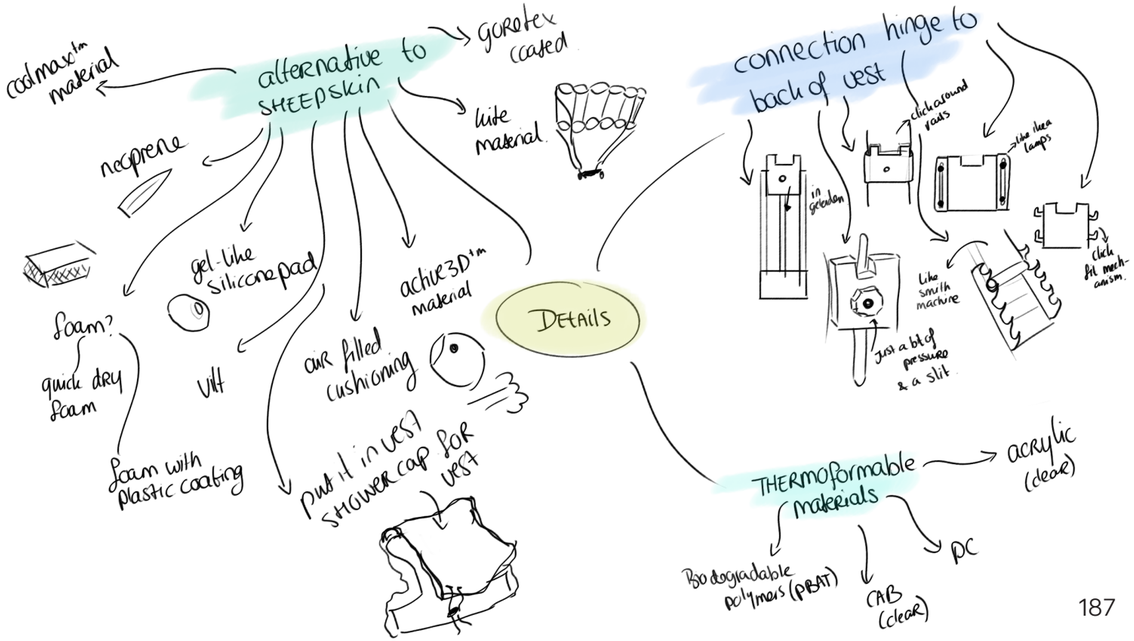




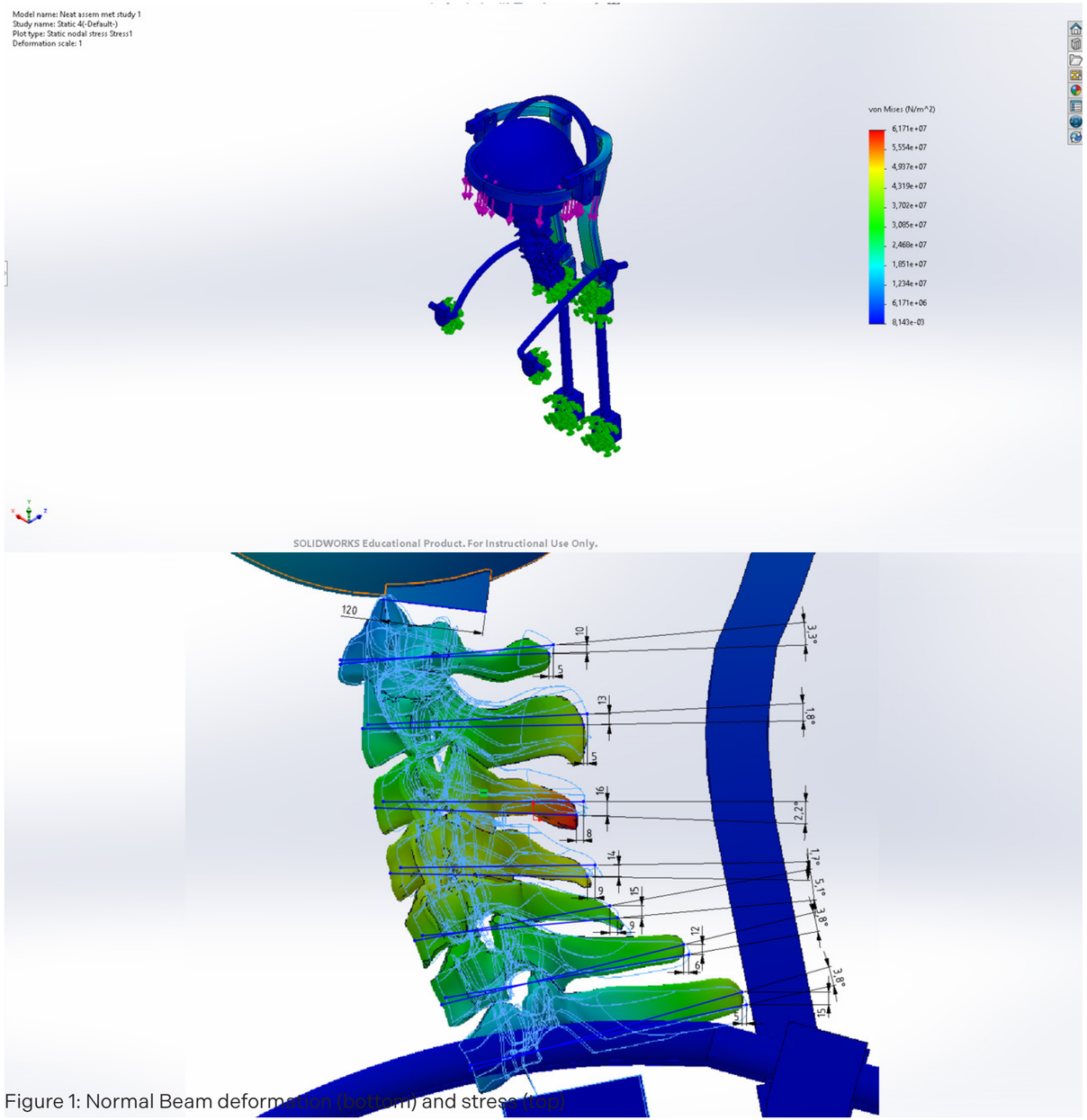
Beam thickness (in mm)	Horizontal displacement in the spine with safety margin (in mm)	Actual Horizontal dispacement in the spine (in mm)
10	10	3,2
12	8,7	2,7
15	7,4	1,8
17	6	1,3
18	4,5	0,8
20	4,2	0,5



Appendix R: Conceptualisation - Replacement Fur lining



Appendix S: Embodiment - Back Beam CAD Tests



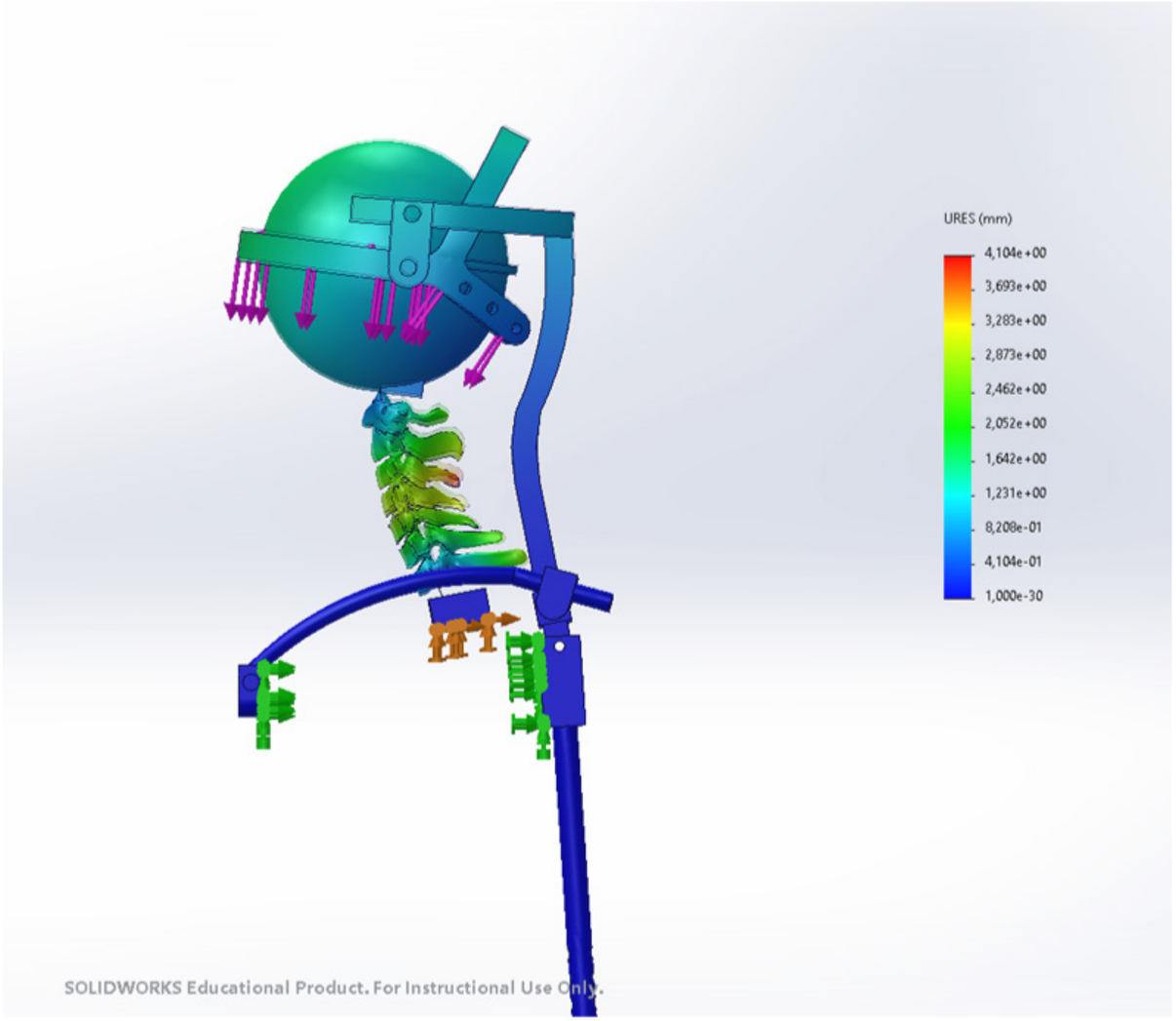


Figure 1: Normal Beam deformation (bottom) and stress (top)

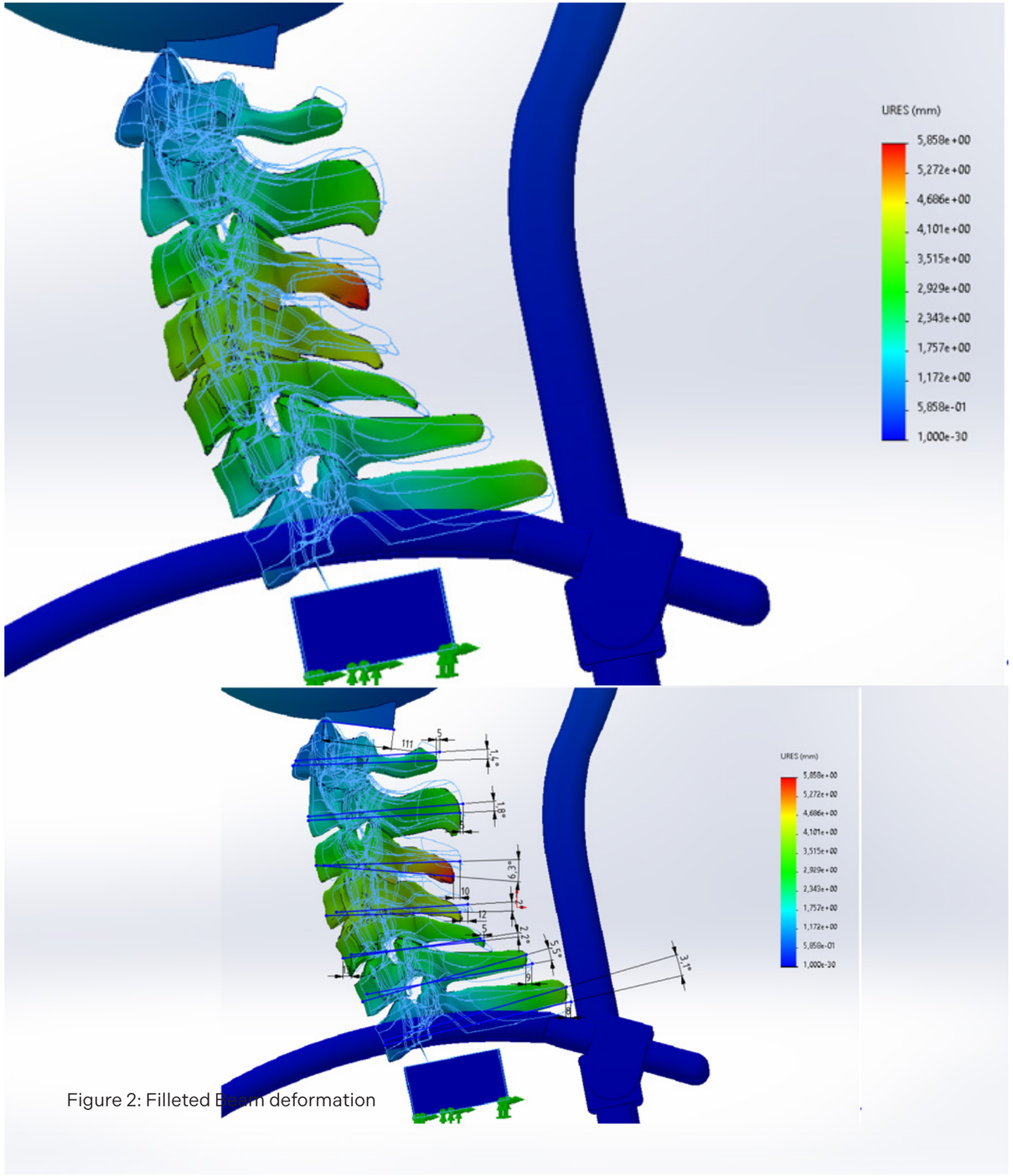


Figure 2: Filleted Beam deformation

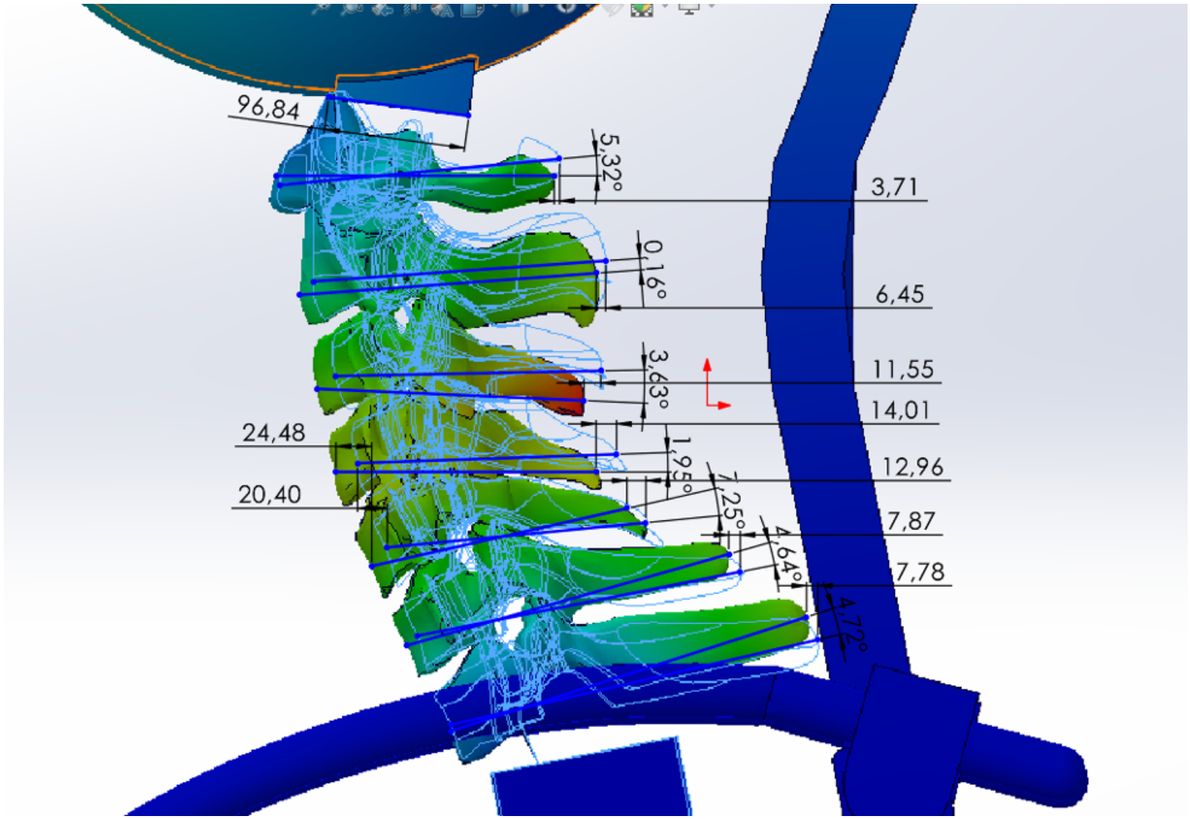


Figure 3: I-Beam deformation

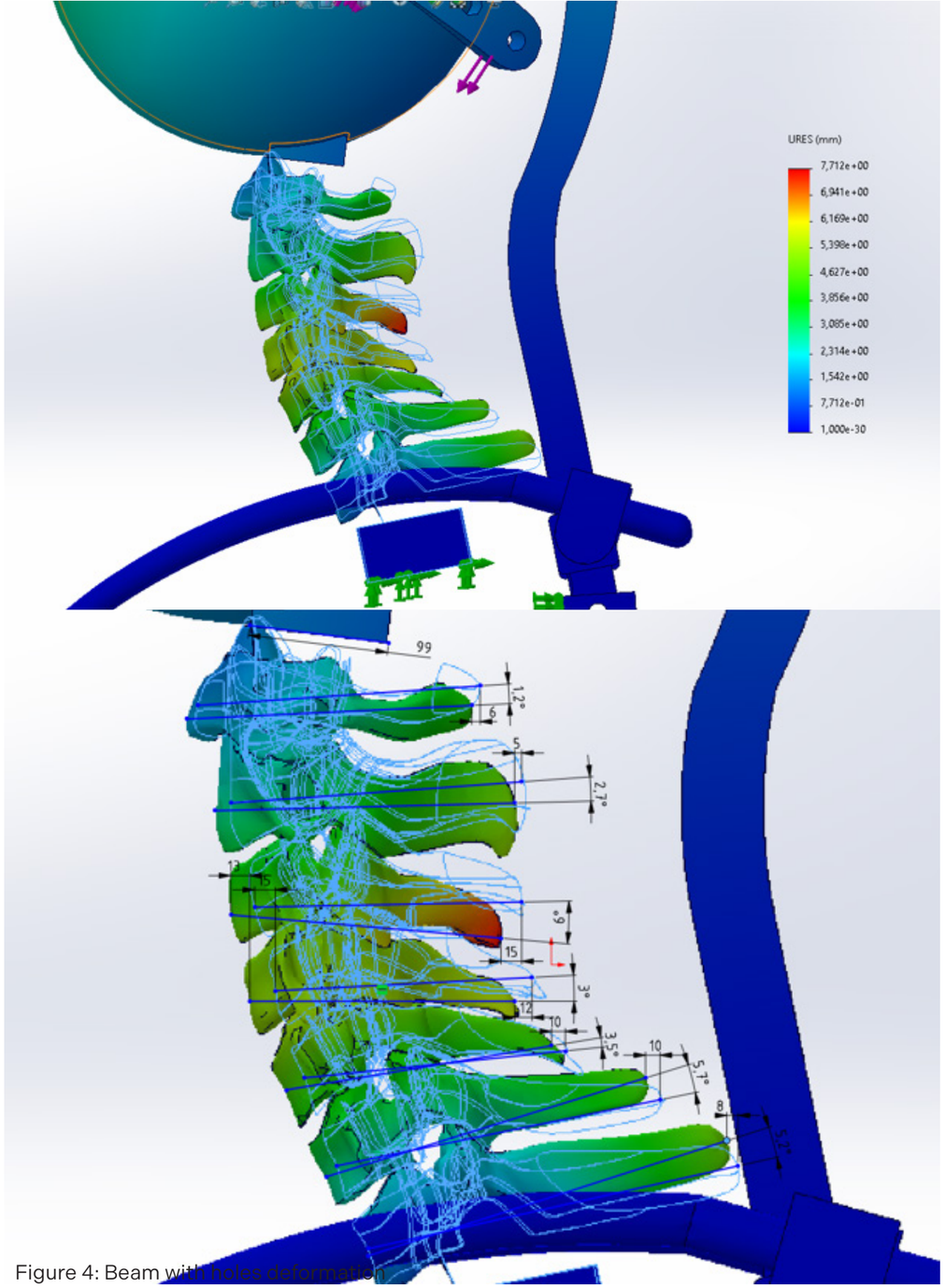


Figure 4: Beam with holes deformation

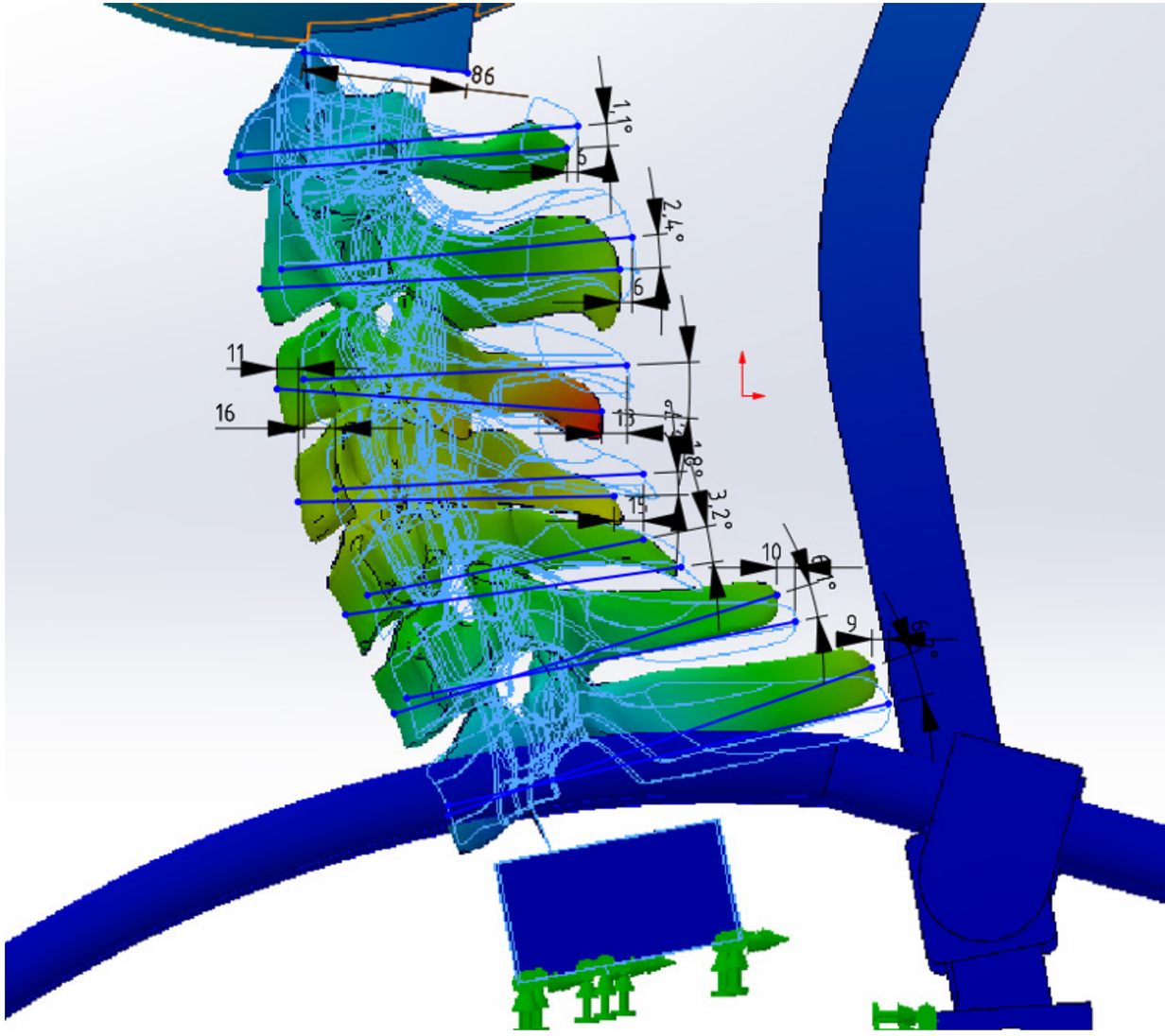


Figure 5: Curving/neck shaped beam deformation

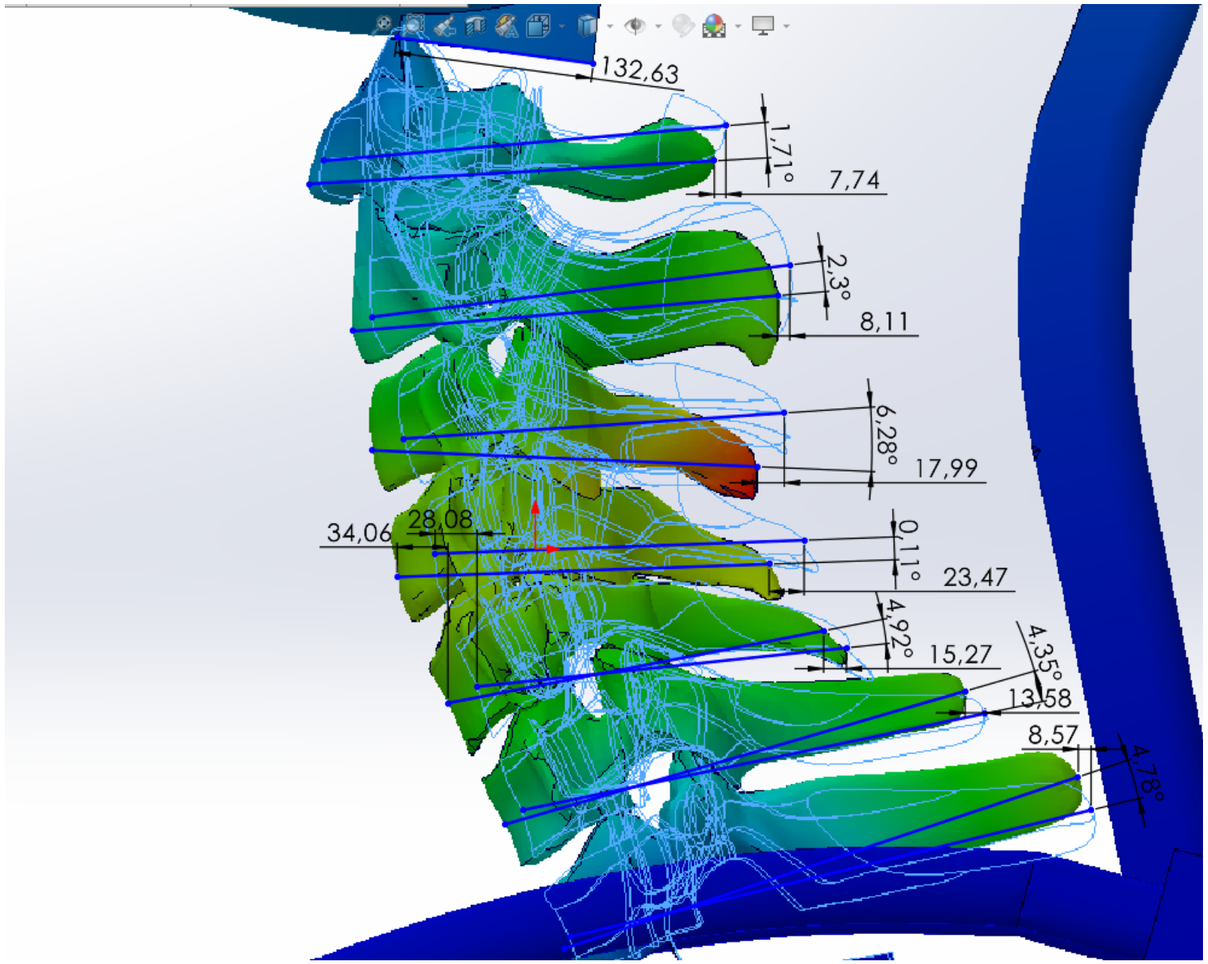


Figure 6: Deformation in titanium frame

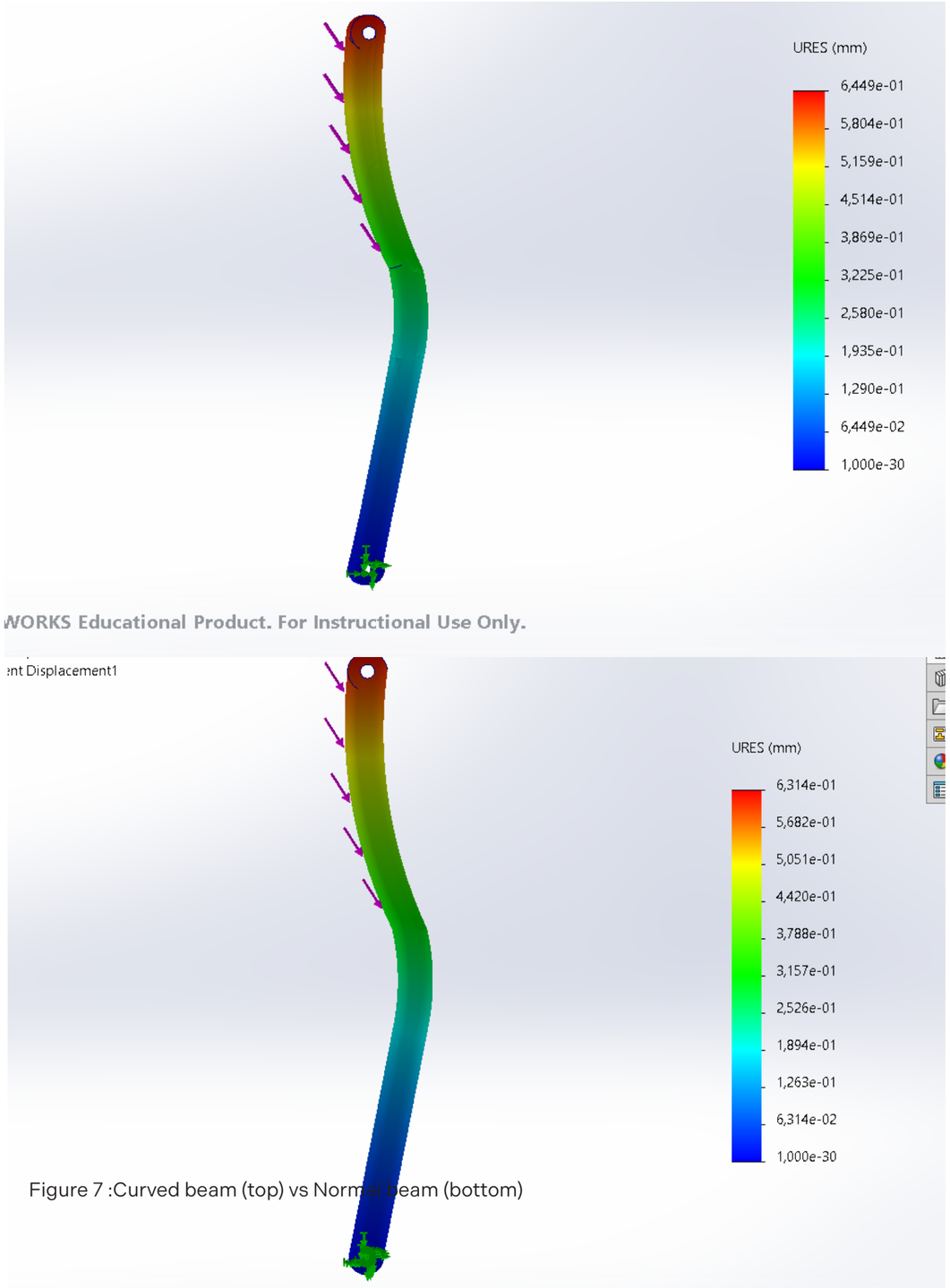


Figure 7 :Curved beam (top) vs Normal beam (bottom)

Appendix T: User Test 1 Questions

Re-Design of a Halo Frame

Thank you for
taking the time to contribute to this research. As part of my thesis, I am conducting a study to re-design the Halo Frame—a medical device used to stabilize the spine during recovery. Below, you will find an image of the original design.

The Halo Frame is
designed to keep the neck stable and provide a highly rigid structure, which is essential for its function. However, there is room to enhance the device by making changes that improve user comfort without compromising its primary purpose.

This re-design
aims to enhance the overall experience for both patients and healthcare professionals by focusing on key aspects such as appearance, usability, and comfort. Your input will be instrumental in shaping these improvements.

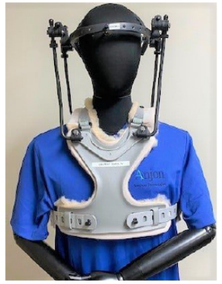
This survey
should take only a few minutes to complete, and your responses will remain confidential.

Thank you for
your valuable input!

* Verplichte vraag

Original Design
Below images and questions about the original design.

Halo Frame Original Design.



1. Aesthetics: How visually appealing is the concept? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very appealing

2. Look and Feel: How comfortable does it seem? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very comfortable

3. How intimidating or overwhelming does the concept feel? *

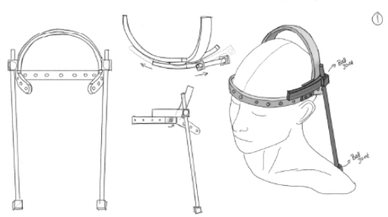
Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very intimidating

Concept 1:

Below images and questions about Concept 1

Concept 1



4. Aesthetics: How visually appealing is the concept? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very appealing

5. Look and Feel: How comfortable does it seem? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very comfortable

6. How intimidating or overwhelming does the concept feel? *

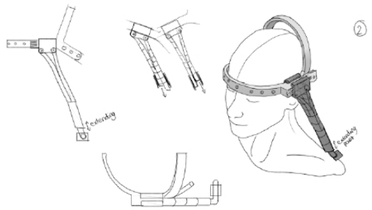
Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very intimidating

Concept 2:

Below images and questions about Concept 2

Concept 2



7. Aesthetics: How visually appealing is the concept? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very appealing

8. Look and Feel: How comfortable does it seem? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very comfortable

9. How intimidating or overwhelming does the concept feel? *

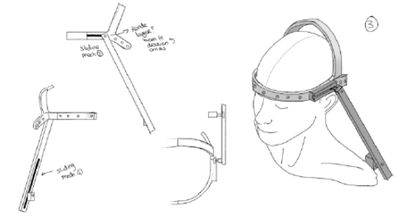
Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very intimidating

Concept 3:

Below images and questions about Concept 3

Concept 3



10. Aesthetics: How visually appealing is the concept? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very appealing

11. Look and Feel: How comfortable does it seem? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very comfortable

12. How intimidating or overwhelming does the concept feel? *

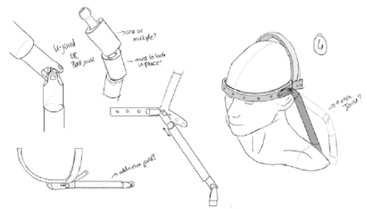
Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very intimidating

Concept 4:

Below images and questions about Concept 4

Concept 4



13. Aesthetics: How visually appealing is the concept? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very appealing

14. Look and Feel: How comfortable does it seem? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very comfortable

15. How intimidating or overwhelming does the concept feel? *

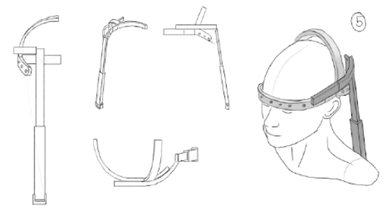
Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very intimidating

Concept 5:

Below images and questions about Concept 5

Concept 5



16. Aesthetics: How visually appealing is the concept? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very appealing

17. Look and Feel: How comfortable does it seem? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very comfortable

18. How intimidating or overwhelming does the concept feel? *

Markeer slechts één ovaal.

	1	2	3	4	5	6	7	
Not	◯	◯	◯	◯	◯	◯	◯	Very intimidating

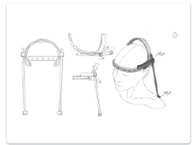
Concept Favourite

19. We are looking for a concept that is: *

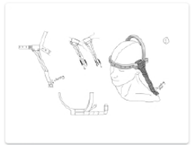
1. Visually appealing
2. Looks comfortable
3. Does not look intimidating or overwhelming.

Knowing this, which concept is your favourite?

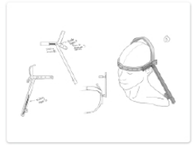
Markeer slechts één ovaal.



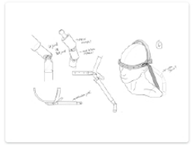
◯ Concept 1



◯ Concept 2



◯ Concept 3



◯ Concept 4

Re-Design of a Halo Frame

17 antwoorden

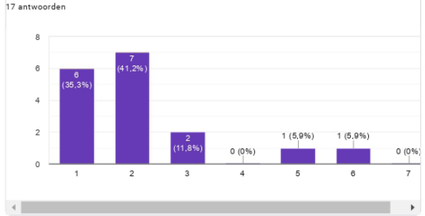
Analyse publiceren

Original Design

Kopiëren

Aesthetics: How visually appealing is the concept?

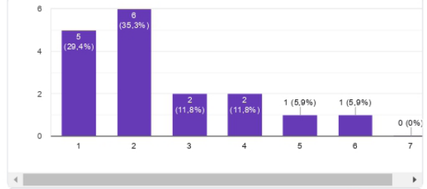
17 antwoorden



Kopiëren

Look and Feel: How comfortable does it seem?

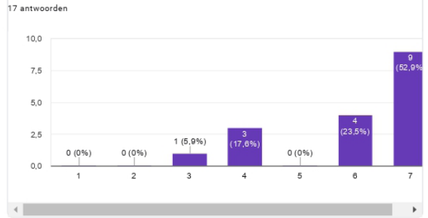
17 antwoorden



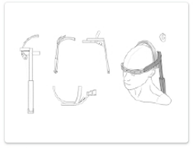
Kopiëren

How intimidating or overwhelming does the concept feel?

17 antwoorden



Concept 1:



◯ Concept 5

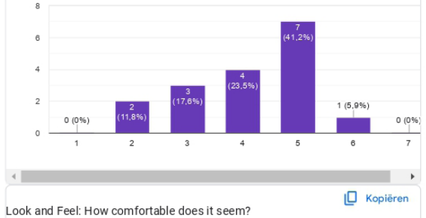
◯ I prefer the original design

20. What do you think can be improved in these concepts? Leave any suggestions here.

Kopiëren

Aesthetics: How visually appealing is the concept?

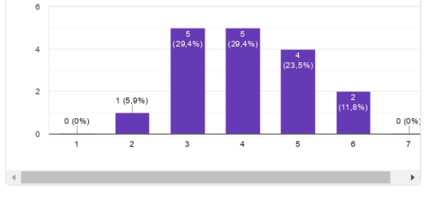
17 antwoorden



Kopiëren

Look and Feel: How comfortable does it seem?

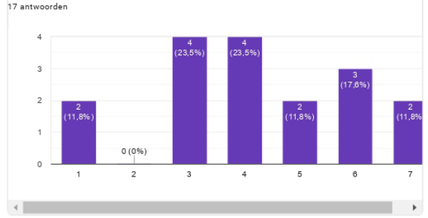
17 antwoorden



Kopiëren

How intimidating or overwhelming does the concept feel?

17 antwoorden

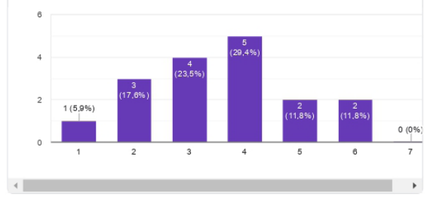


Concept 2:

Kopiëren

Aesthetics: How visually appealing is the concept?

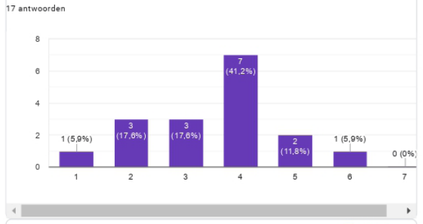
17 antwoorden



Appendix U: User Test 1 Results

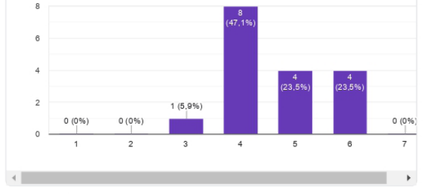
Look and Feel: How comfortable does it seem?

17 antwoorden



How intimidating or overwhelming does the concept feel?

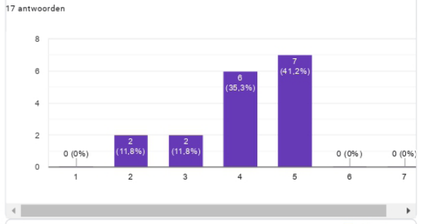
17 antwoorden



Concept 3:

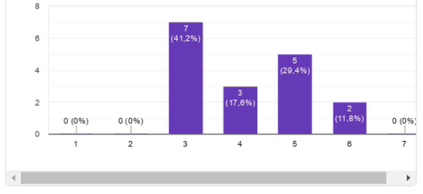
Aesthetics: How visually appealing is the concept?

17 antwoorden



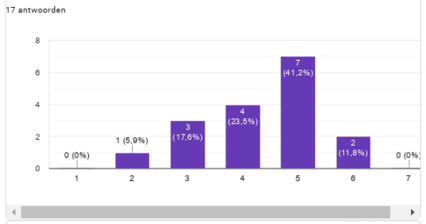
Look and Feel: How comfortable does it seem?

17 antwoorden



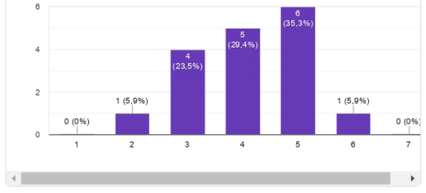
Aesthetics: How visually appealing is the concept?

17 antwoorden



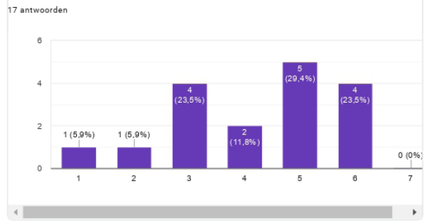
Look and Feel: How comfortable does it seem?

17 antwoorden



How intimidating or overwhelming does the concept feel?

17 antwoorden



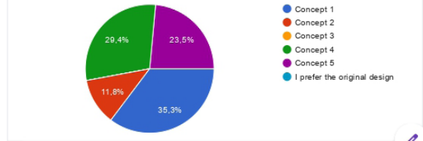
Concept Favourite

We are looking for a concept that is:

1. Visually appealing
2. Looks comfortable
3. Does not look intimidating or overwhelming.

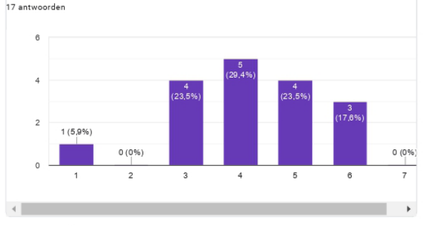
Knowing this, which concept is your favourite?

17 antwoorden



How intimidating or overwhelming does the concept feel?

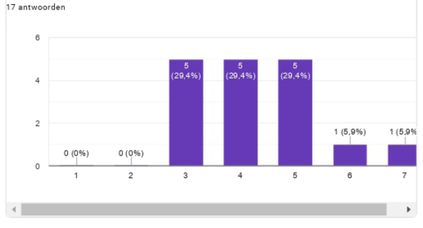
17 antwoorden



Concept 4:

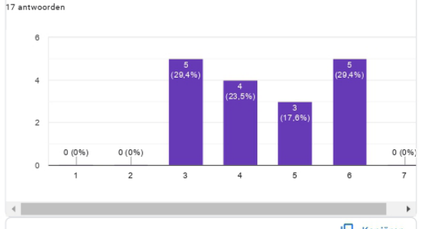
Aesthetics: How visually appealing is the concept?

17 antwoorden



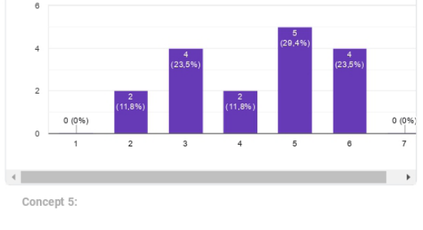
Look and Feel: How comfortable does it seem?

17 antwoorden



How intimidating or overwhelming does the concept feel?

17 antwoorden



Concept 5:

What do you think can be improved in these concepts? Leave any suggestions here.

4 antwoorden

Cool designs, if the structure allows it I would make everything as slim as possible

Misschien scheelt het al als het van kunststof is ipv van metaal. Maar ik weet niet of dit constructueel gezien mogelijk is?

Glitters

Maybe something softer around the head on the inside

Appendix V: User Test 2 aesthetics study - Questions

Re-design of a Halo Frame 2

Beschrijving (optioneel)

Thank you for taking the time to contribute to this research. As part of my thesis, I am conducting a study to re-design the Halo Frame—a medical device used to stabilize the spine during recovery. Below, you will find an image of the original design.

The Halo Frame is designed to keep the neck stable and provide a highly rigid structure, which is essential for its function. However, there is room to enhance the device by making changes that improve user comfort without compromising its primary purpose.

This
survey aims to compare two designs of a halo vest: the original design and a newly developed design. Your feedback will help evaluate how the new design is perceived in terms of appearance, comfort, and overall impact

This survey should take only a few minutes to complete, and your responses will remain confidential.

Thank you for your valuable input!

* Verplichte vraag

Design 1

All these questions are regarding Design 1.

Design 1

Design 1

1. **How visually intrusive do you find the design 1** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very intrusive

2. **How well does design 1 blend in with the user's body** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Very ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very well

3. **How visually appealing is design 1?** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very appealing

4. **How heavy does design 1 appear?** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very heavy

5. **How intimidating or overwhelming does design 1 appear?** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very intimidating

Design 2

All these questions are regarding Design 2.

Design 2

Design 2

6. **How visually intrusive do you find the design 2** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very intrusive

7. **How well does design 2 blend in with the user's body** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Very ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very well

8. **How visually appealing is design 2?** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very appealing

9. **How heavy does design 2 appear?** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very heavy

10. **How intimidating or overwhelming does design 2 appear?** *

Markeer slechts één ovaal.

1 2 3 4 5 6 7

Not ◯ ◯ ◯ ◯ ◯ ◯ ◯ Very intimidating

Preference

Concept 1&2

11. **Taking everything into account, which design do you prefer?** *

Markeer slechts één ovaal.

◯ Design 1 ◯ Design 2

◯ No preference

12. **What is the main reason for your choice?** *

Appendix W: User Test 2 Aesthetics study - Results

13. **Do you have any other suggestions or observations regarding the new design compared to the old one?**

20-12-2024, 10:30 Re-design of a Halo Frame 2

https://docs.google.com/forms/d/1UD19LJXBYWVfWqDNr5d-WS7_Jq_GlpD3TQzTEfJ1b_o/edit

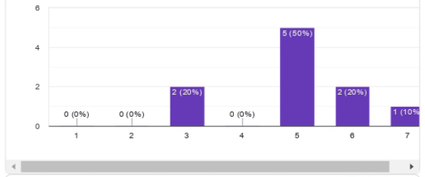
Re-design of a Halo Frame 2

10 antwoorden

Design 1

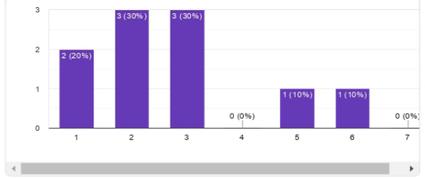
How visually intrusive do you find the design 1 Kopiëren

10 antwoorden



How well does design 1 blend in with the user's body Kopiëren

10 antwoorden



Which part does not blend in well?

10 antwoorden

The poles which run from the shoulder to the ears. The belt around the waist which is wider then the waist itself

The metal top-parts

Sticks

the black metal framework

Around the waist

The black head piece

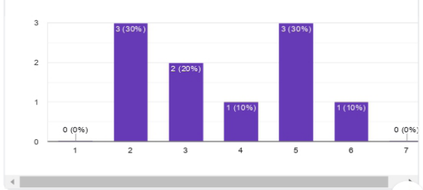
The metal part on the head

the pillars

Where the breasts are for women

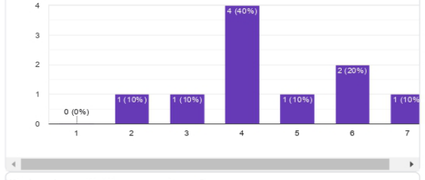
How visually appealing is design 1? Kopiëren

10 antwoorden



How heavy does design 1 appear? Kopiëren

10 antwoorden



What part specifically appears heavy?

10 antwoorden

The black colour around the head

the upper part around the head.

Top

Sticks and blocks next to head

the black parts

The head structure

The midbody part

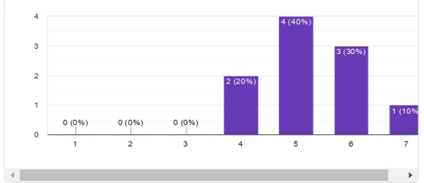
The metal part

the metal frame

Around the hips

How intimidating or overwhelming does design 1 appear? Kopiëren

10 antwoorden



What part specifically appears intimidating?

10 antwoorden

-

the upper part around the head in combination with the poles to the shoulders

Metal at the top

The head part connection to harnass

the black rods

More how to live your life with it

The part around the neck

The metal

the pillars in front of the face

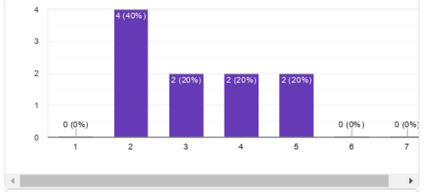
The broad party at the hips and body

Design 2

How visually intrusive do you find the design 2

Kopiëren

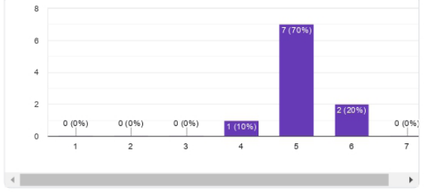
10 antwoorden



How well does design 2 blend in with the user's body

Kopiëren

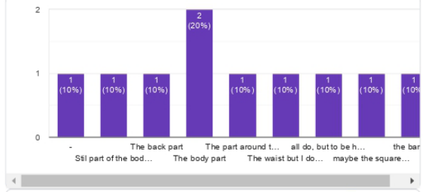
10 antwoorden



Which part does not blend in well?

Kopiëren

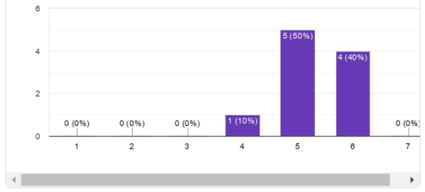
10 antwoorden



How visually appealing is design 2?

Kopiëren

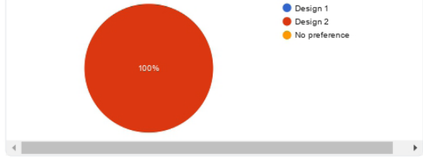
10 antwoorden



Taking everything into account, which design do you prefer?

Kopiëren

10 antwoorden



What is the main reason for your choice?

10 antwoorden

Less heavy

Less in your face. Placing the poles behind the head in stead of next to it, creates a more attractive look.

Less invasive

much more clean / less material / less extreme design

The design looks more comfortable because the structure seems to be attached better to the body, which likely makes it more stable and less prone to movements and gravity. Its also more pleasing for the eyes of people around you

How minimalist and easy to use in daily life that one will be. Also if you want look left and right there is more space

It looks less intimidating and more efficient with less parts

The metal part

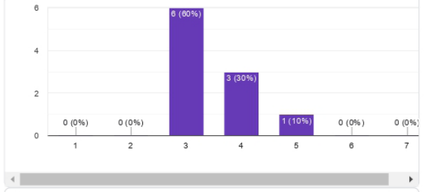
there is no barrier between the person and other people. first design looks like a prison

Visuele vrijheid, de stokken zie je zelf niet. Het ziet er daarnaast minder angstaanjagend uit doordat er minder schroeven bouten en ijzeren elementen aan zitten

How heavy does design 2 appear?

Kopiëren

10 antwoorden



What part specifically appears heavy?

10 antwoorden

-

The back, behind the head.

Top

the back part

Sstill the black parts, but it looks more stable now

Not thing feels heavy to be honest, it just looks like an extraspine

The body part

Head band

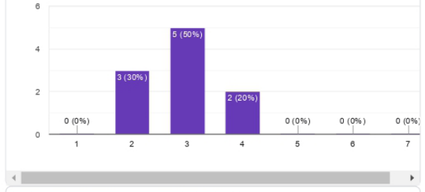
metal frame

Deel op het lichaam zit

How intimidating or overwhelming does design 2 appear?

Kopiëren

10 antwoorden



What part specifically appears intimidating?

10 antwoorden

-

The band around the head

Skull part

none

maybe the squares on the sides of the head

Just the concern of the problem not the design

The part around the body

The body

the band over the forehead

Het dikke volume rond borst en heup

Preference

Do you have any other suggestions or observations regarding the new design compared to the old one?

7 antwoorden

-

Do the band around the waist have to be bigger then the waist itself?

[redacted]

Maybe the part around the waist looks too massive

The body part smaller

Ik weet niet in hoeverre het mogelijk is. Maar mij lijkt het deel rond de buik ook niet top voor een vrouw :)

Appendix X: User Test 3: Assembly of frame - Questions

Test Plan: Evaluating the New Halo Vest Design

Objective

The primary goal of this user test is to evaluate the ease of assembly, fit, and adjustability of the newly designed halo vest. Orthopedic technicians will serve as users, and testing will involve a dummy or the designer as the patient.

Test Setup

- **Location:** Orthopedic workshop or controlled testing environment.
- **Participants:**
  - Orthopedic technicians (minimum of 3 participants for diverse feedback).
  - Dummy doll or designer (to simulate patient conditions).
- **Materials Required:**
  - Prototype of the redesigned halo vest.
  - Instructions for assembly.
  - Dummy doll or other simulated patient.
  - Feedback forms/questionnaires.
  - Measuring tools (e.g., calipers, measuring tape) for assessing fit.
  - Tools for making adjustments (if applicable).

Test Procedure

1. Ease of Assembly

1. Provide each participant with the halo vest prototype and assembly instructions.
2. Instruct participants to assemble the frame as per the instructions.
3. Record:
   - Time taken to assemble the frame.
   - Number and type of errors made during assembly.
   - Comments on clarity of the instructions and assembly process.

2. Fit Evaluation

1. Once assembled, ask the participant to fit the frame onto the dummy or patient (designer).
2. Assess:
   - Alignment with expected body contours.
   - Stability of the frame after fitting.
   - Observations regarding comfort (e.g., pressure points or misalignment).
3. Use measuring tools to compare the fit to expected dimensions.

3. Adjustability Check

1. Ask participants to simulate a real-world scenario requiring adjustments (e.g., loosening or tightening specific parts, changing the fit for a different body type).
2. Evaluate:
   - Ease of making adjustments.
   - Range of adjustability.
   - Time taken to complete adjustments.

Data Collection

1. **Quantitative Metrics:**
   - Time for assembly, fitting, and adjustment.
   - Number of errors during assembly.
   - Accuracy of fit measurements.
2. **Qualitative Feedback:**
   - Open-ended feedback on assembly instructions, ease of use, and design improvements.
   - Participants' perceived level of confidence in using the new design.
3. **Observational Notes:**
   - Issues encountered during assembly or fitting.
   - Non-verbal cues indicating frustration or ease.

Post-Test Survey

Provide each participant with a brief survey to collect feedback:

- **Ease of Assembly:** Rate from 1 (very difficult) to 5 (very easy).
- **Fit:** Rate the comfort and accuracy of the fit from 1 (poor) to 5 (excellent).
- **Adjustability:** Rate ease of adjustments from 1 (very difficult) to 5 (very easy).
- **Overall Feedback:** Open text box for comments on improvements.

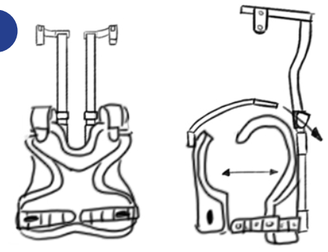
Analysis

1. Compile quantitative metrics into a table for comparison across participants.

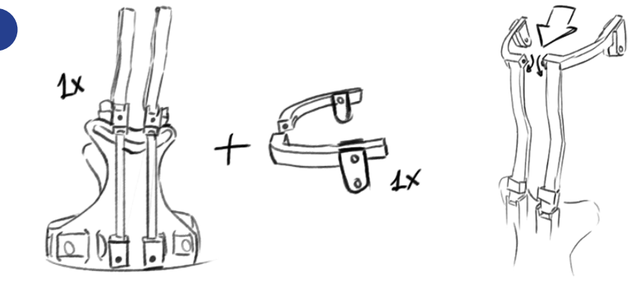
2. Analyze qualitative feedback for recurring themes or suggestions.
3. Identify key areas for improvement based on observed issues.

INSTRUCTIONS APPLICATION HALO VEST

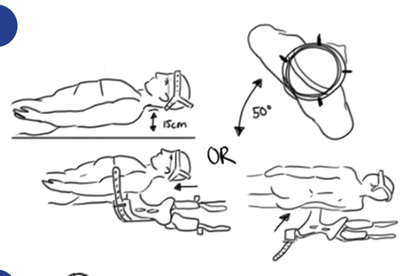
1. The halo ring needs to be placed at 1 cm distance of the head. The patient gets local ansthesia. The pins are tightened with a toque wrench.



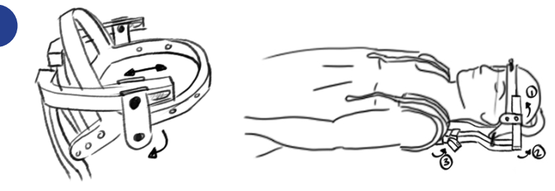
2. The vest consists of two parts. A front part of the vest, which has two rods attached, and the back part of the vest which has the rest. We first assemble the back parts of the vest.



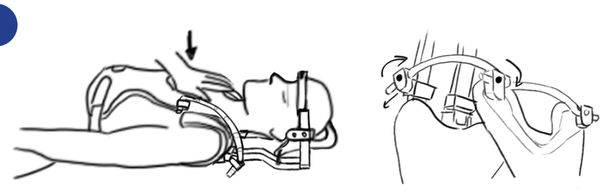
3. The backplate comes with the two back rods attached. You need to attach the curved rods to the back rods. Do this using the bolts in curved rods. Don't screw tight.



4. Tilt the person carefully to slide the backplate with attached rods under the patient. This can be done in two ways, as pictured.



5. Next attach the halo ring which the patient is wearing to the structure. Use the bolts in the curved rods. Screw the bolts tight. First around the head, then behind the head, and lastly the back.



6. Lastly place the front plate on the chest of the patient. Press firmly. Attach the front rods to the back rods and screw the bolts tight at this front to back connection and at the front of the vest.

Appendix Y: User Test 3: Assembly of frame - Results

Assembly Forms

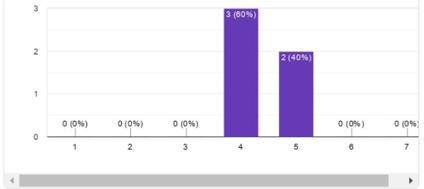
5 antwoorden

Analyse publiceren

Kopiëren

How clear were the assembly instructions?

5 antwoorden



Can you elaborate on the previous question?

5 antwoorden

Tekst aan de andere kant, duidelijker wat er al gedaan is en dat lekker bovenaan zetten
Intro van onderdelen waar je mee werkt. Kijk naar lego instructies.
Stap 5 moet eerder. Stoffen banden miste in de uitleg en die riem

Elk person is visueel ingericht, dus niemand gaat de tekst lezen. In het plaatje meer duidelijkheid en minder stappen per keer. Plaatjes heel erg versimpelen. Overview wat zit er in het pakket. Stap 5 en 6 meer inzoomen. Close up maken van onderverdeelde stappen

Maak bij het aandraaien stap 1,2 en 3 meer duidelijk. Misschien mogen de stappen iets uitgebreider. Als je het een keer voor had gedaan dan had ik het heel makkelijk kunnen volgen.

Ik keek eerst naar de plaatjes, daarna pas naar de tekst. Maak de afbeeldingen meer close up. Kijk naar lego pakketjes

6 stappen wat weinig, haal de stappen duidelijk uit elkaar. Binnen elke stap iets meer detaillering en highlights. gebruik close ups. Gebruik kleur. Ik denk dat ik het wel makkelijker zou kunnen herhalen nu ik weet hoe het moet.

Did you encounter any challenges while assembling the frame?

5 antwoorden

Achterkant op de juiste hoogte, om de front rods te connecten. Nek rods lopen te dicht langs de nek. Nek deel langs al die pinnen is moeilijk.

Weten of het vest hoog genoeg zit op de rug. Ik durfde niet aan de onderkant te zitten. Weten of hij goed zit op de patiënt. Misschien beginnen bij de schouders, want dan weet je waar hij op leunt.

De achterkant zijn wat moeilijk om aan te draaien

de achterkant is moeilijk bij te komen en aan te draaien.

De pinnen rond het hoofd erin stoppen. Lastig om onder zijn rug te komen. Zeker al: het zo bij de wervel zit. Ook wist ik even niet welke pin ik moest hebben van de ring.

What aspects could be improved?

5 antwoorden

Hendel anders op vest, ring en zijkanten meer laten blenden met het lichaam.

Meer fillets, zachter maken van look. Meer een assesoire maken. Material finish, Hoofd deel meer blenden met halo ring.

Sommige plekken zijn wat krampachtig om aan te draaien. Dit is vooral moeilijk. Ook vond ik dat er veel aandraaipunten bij elkaar zaten waardoor ik verward raakte welke ik nou moest aandraaien.

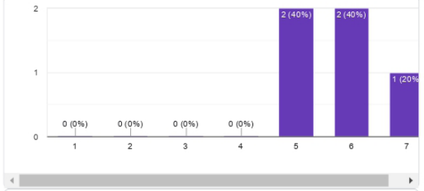
Misschien kan de afwerking wat zachter, wat ronder

Momentsleutel vs. wrench, range of motion is wat klein aan de achterkant. Patiënt ligt niet heel stabiel. Komt door die stangen aan de achterkant.

Was it straightforward to adjust the frame for a different body type or size?

Kopiëren

5 antwoorden



Can you elaborate on the previous question?

5 antwoorden

Best intuïtief maar kom er niet helemaal uit. Ik zou wel even moet wrikken, en ik denk dat dat net niet kan met een patiënt met een nekfractuur.

Ja, alle punten aangewezen die vertselbaar waren

Ja, om de gaten te vinden waar de front rods in moeten was heel makkelijk. Ook snapte ik de tekeningen. Ik merk dat ik voornamelijk keek naar de tekeningen en niet naar de tekst.

de middelste band zat nu wel al best strak, ik weet niet of die strakker kan.

it just was

How would you describe the range of adjustments available?

5 antwoorden

Prima, front rods mogen langer zijn,

ziet er prima uit

De front rods zouden wat langer kunnen zijn voor wat dikkere individuen. Ook zitten de front rods best dicht langs de nek.

zie hierboven

Voorkant vest aan de zijkanten is zwaar. En achter zn rug krijgen van die staven kostte wel moeite.

What aspects of the design work well?

5 antwoorden

Dat het gezicht vrij is. Lijnen zijn logisch vanuit het lichaam.

Vorm mee met lichaam

Hij ziet er echt minder heftig uit. Je kan er kleren over aan trekken.

Dat het visueel minder is, Het hoofd lijkt vrij.

Naar voren klappen spanbanden met pinnen, dat gelijktijdig doen.

Appendix Z: User Test 4: Fit of prototype - results

Fit Of Halo Vest

10 antwoorden

Analyse publiceren

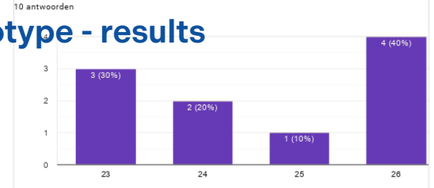
Participant data

[redacted]

Age

Kopiëren

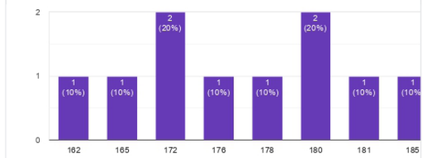
10 antwoorden



Length in cm

Kopiëren

10 antwoorden



Are there any areas where the vest feels too tight, loose, or restrictive?

10 antwoorden

I stand a bit forward with my neck from myself, so this is overall just a bit uncomfortable because you put me in quite straight up.

It is just a bit restrictive, but it is not as cage like as it seems when you first showed me.

It feels slightly tight around the neck, You almost poked me with the front rods when putting on the vest. It feels a bit too big around the back, I am slightly bent forward.

I have quite large boobs, it fit okay but it just looked very very ugly.

Not really, maybe if you had actual pins it would be worse. The vest pokes a bit in my stomach

not really

it fits right but overall it sucks if you have to wear this 3 months.

No! I thought it would be way worse. But it is actually fine. I feel it is very restrictive in the neck movements, but that is supposed to be so....

no! feels like a snug backpack

No actually, feels snug but not uncomfortable.

Pressure Points

Are there specific areas where the vest applies uncomfortable pressure?

10 antwoorden

no

Not really, just that i can't move my neck

on the boobs a bit and on my midriff.

my stomach

not really

not really, maybe my neck. The rods chafe a bit.

no really

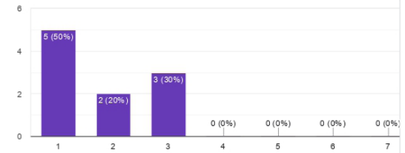
Not really, it feels more secure.

Not really. The ring is a bit small for me, I have a very large head, so normally i would get a bigger ring but other than that, it is fine.

Rate the severity of any pressure points felt during the test. (1-7)

Kopiëren

10 antwoorden

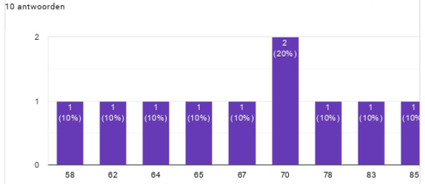


Perceived Size

Weigth in kg

Kopiëren

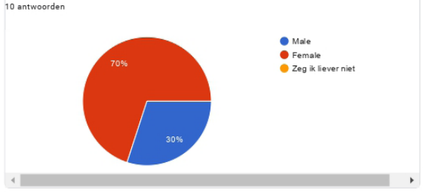
10 antwoorden



Gender

Kopiëren

10 antwoorden

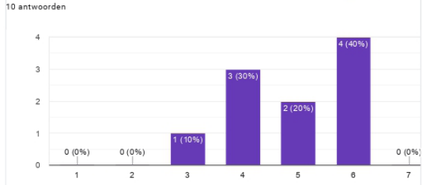


Comfort

How comfortable does the vest feel to wear? (1-7)

Kopiëren

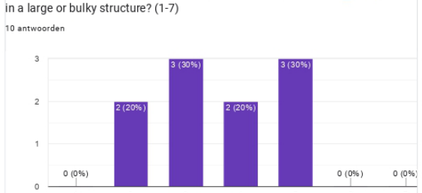
10 antwoorden



How much does wearing the vest make you feel like you are in a large or bulky structure? (1-7)

Kopiëren

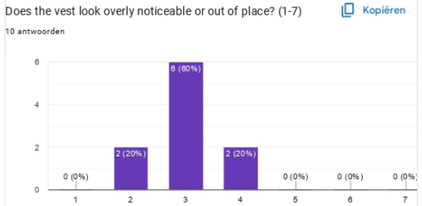
10 antwoorden



Does the vest look overly noticeable or out of place? (1-7)

Kopiëren

10 antwoorden

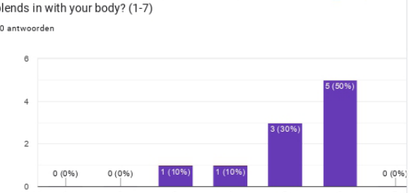


Visual Integration

After viewing yourself in the vest, how well do you feel it blends in with your body? (1-7)

Kopiëren

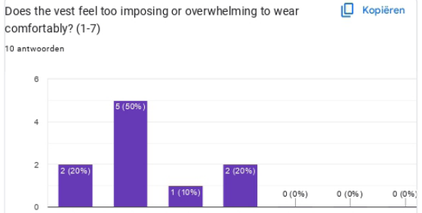
10 antwoorden



Does the vest feel too imposing or overwhelming to wear comfortably? (1-7)

Kopiëren

10 antwoorden



General Feedback

What did you like or dislike about the fit of the vest?

10 antwoorden

I liked the way it looks, it just looks high-tech and expensive. I don't like the lining. That looks cheap and a bit gross.

I did not like the bit around my head. The sides are a bit large. The way it connects to the back. It is also poking me a bit in the back of my head when I sit in a chair.

I liked that it was a lot less visible than what you showed me from the original design. I like that i do not see the structure while wearing it myself.

I disliked the chest part. I liked the top! It looks okay. I would go out like that if i can cover up the chest part.

Well it would suck if i had to wear this, still. However, it felt like a lot bigger than what it looked like on. Especially if i can wear my sweaters or tshirts over it. Then you only see the head piece.

I liked the look of it with a sweater over it. The back could be a bit more rounded, shofter shapes, It looks a bit stiff

I dislike the colour, i dislike the big middle part. I like the way my view is clear.

It looked way less in the mirror than I thought!

I felt hugged and secure. Felt safe. I dislike The way it gives me a hump. I would make the back less big.

I liked that the back looks designy, and shapes with my head. The feeling of not being able to move is just very weird. The lines are logical for me when i look at the body. I dislike the way the mid-part is so high for me.

Are there any improvements you would suggest to make the vest fit better?

10 antwoorden

Make the neck rods wider. They chafe a little bit

Maybe make a pillow or something soft between the rods and the back of the head.

I would make the neck rods wider

make it better for boobs

Maybe make the back even less. also, I can imagine this is not nice when laying down. I would hate that.

Make it blend even more in with the head.

Make the things in the back nice to lay on.

The neck tings are a bit tight.

not really

Maybe let it blend even more with the body at the top part.