A shin guard to boost my confidence and protect your legs

Appendix

Positive design for child amputees' sports performance

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Master Thesis Report

Msc Integrated Product Design

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A

Benchmarking Process

Feature Selection Process

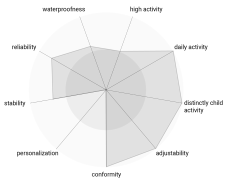
In order to approach the products on the market from a wellbeing lens, it is important to select investigation (criteria that are rooted in the fundamental psychological needs of children.

Fundamental needs theory dictates that we have certain needs (Maslow) and meeting these needs will contribute to our wellbeing. The approach was revisited by Desmet and a comprehensive list of these have been made, containing 13 fundamental psychological needs. As this collection of needs is made with a design focus, and is more comprehensive than previous topologies, Desmet's list was selected to be used in this study.

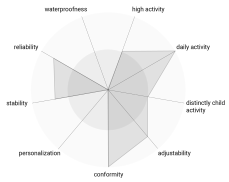
As needs manifest differently for people of different ages (Beyond Maslow), the most relevant needs for children of this age group were selected to be studied based on literature on children's development by Bee & Boyd (2010), Sharman (1995) and Acuff & Reiher. (1997) Different products and different features can help address these needs. Looking at the current portfolio of children's prosthetics and their features, toys and other children's products as well as solutions available for adults living with limb difference, I identified ways in which fundamental psychological needs in question could be embodied through products in proximity(WC) to children's prostheses. From this smaller list of core needs and examples of embodiment, I expanded to a list of features that meet, contribute to, or answer to these needs.

need	Significance to preteens	Can it meet this need?	Physical embodiment of how the product can answer to a need	
autonomy	y (preteens)	y	**physical abilities** (active and daily), freedom to choose **(time)**	opportunity is a cool one, individuality, self reliance
beauty	n	y	forms and colors, fairings, accessories	communal understanding of beauty
comfort	y (all kids)	y	comfort in socket, gait, **adjustability**	already addressed, mechanical problem
community	y (preteens)	y	**mimic natural look** or be represented in social groups (role models)	about conforming
competence	y (5+)	y	physical abilities (active and daily), **waterproof**, environment-proof	play spontaneity is a challenge
fitness	n	y	physical ability (active), social participation in play(recognition)	already addressed by ossur
impact	n	n	-	has not been identified as a priority for children
morality	y (preteens)	n	eco-friendliness	out of scope
purpose	y (preteens)	n	-	out of scope (too large)
recognition	y (preteens)	y	**identity:** reflecting preferences & interests of child in colors, characters, forms, accessories...	expressing identity and being accepted for it
relatedness	y (all kids)	n	-	out of scope. important for the child, but not through a product
security	y (all kids)	y	**reliability** of product and **stability** of movement it provides	already addressed, mechanical problem
stimulation	y (all kids)	y	indirectly, through enabling participation (physical, social)	allow for play

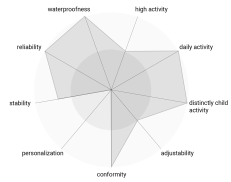
			switching between high and low activity in same foot, high articualtion at ankle, allows for a specific activity						
foot/features	**high activity (run, jump)**	**daily activity (walk, stand)**	**distinctly child activity**	**adjustability**	**conformity**	**personalization**	**stability**	**reliability**	**waterproofness**
Scout - College park	medium	high	high?	very high (19.5mm)	high high (light medium dark covers)	none	high	high	fresh water (medium)
Truper - College Park	medium	high	medium	high (?)	high (light medium dark covers)	none	high	high	no
Rush kid	medium	high	high ("most dynamic foot") & all terrain	medium	high (light/dark foot covers)	none	high	very high	very high (all terrain, including salt water)
Pediatric formula - Fillauer	high	high	medium	high ("grows with child")	medium (has foot, but long blade)	none	high	high	medium (up to 1 meter)
Mini Blade XT - Blatchford	medium/high	medium (no ankle dof)	medium (cycling)	medium	low	medium (2 colors)	high (traction foot)	high	fresh water splash
Runner junior - Ottobock	high (very high)	low	medium	medium	low	none	high	high	fresh water (and dust)
Dynamic Foot - Ottobock	low	high	medium	medium	high	none	high	high	none
SACH foot - Ottobock	none	low	low	medium	high	none	high	high	none
Flex Foot jr	medium	high	high	medium	high (light, dark)	none	high	high	medium/low (fresh water splash)
Vari-flex jr	medium/high	high	high (both run and walk)	medium	high (light, dark)	none	high	high	medium/low (fresh water splash)
Flex run jr	high/extreme	medium/low most flexible of running feet	medium/high (most flexible of running feet)	medium	low	medium (nike sole)	high	high	medium waterproof (submerge)
Cheetah jr	high/extreme	low	medium	medium	low	medium (nike sole)	high	high	medium waterproof (submerge)
Cheetah xplore jr	high/extreme	high	high (walk and run well)	medium	high (light, dark)	none	high	high	medium waterproof (submerge)



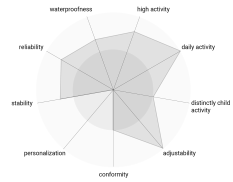
Scout - College park



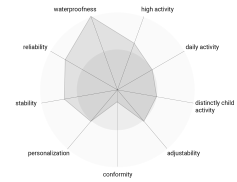
Truper - College Park



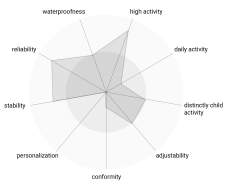
Rush kid



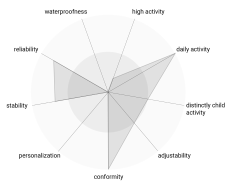
Pediatric formula - Fillauer



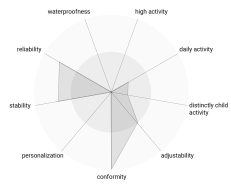
Mini Blade XT - Blatchford



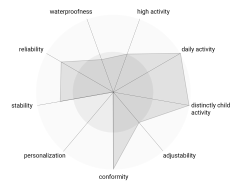
Runner junior - Ottobock



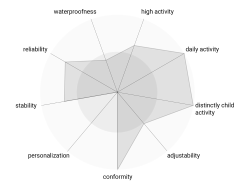
Dynamic Foot - Ottobock



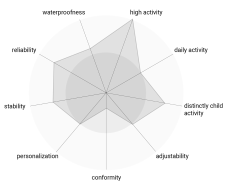
SACH foot - Ottobock



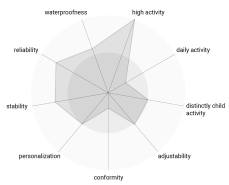
Flex Foot jr



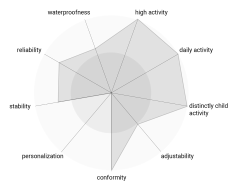
Vari-flex jr



Flex run jr



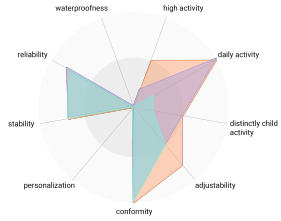
Cheetah jr



Cheetah xplore jr

Lower Impact

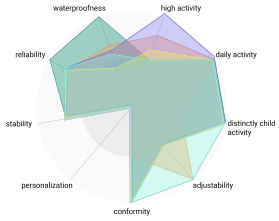
For daily wear



Truper - College Park
SACH foot - Ottobock
Dynamic Foot - Ottobock

Medium Impact

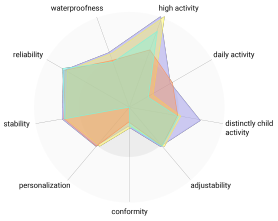
For daily wear and play



Rush kid
Scout - College park
Pediatric formula - Fillauer
Flex Foot jr
Vari-flex jr
Cheetah xplore jr

High Impact

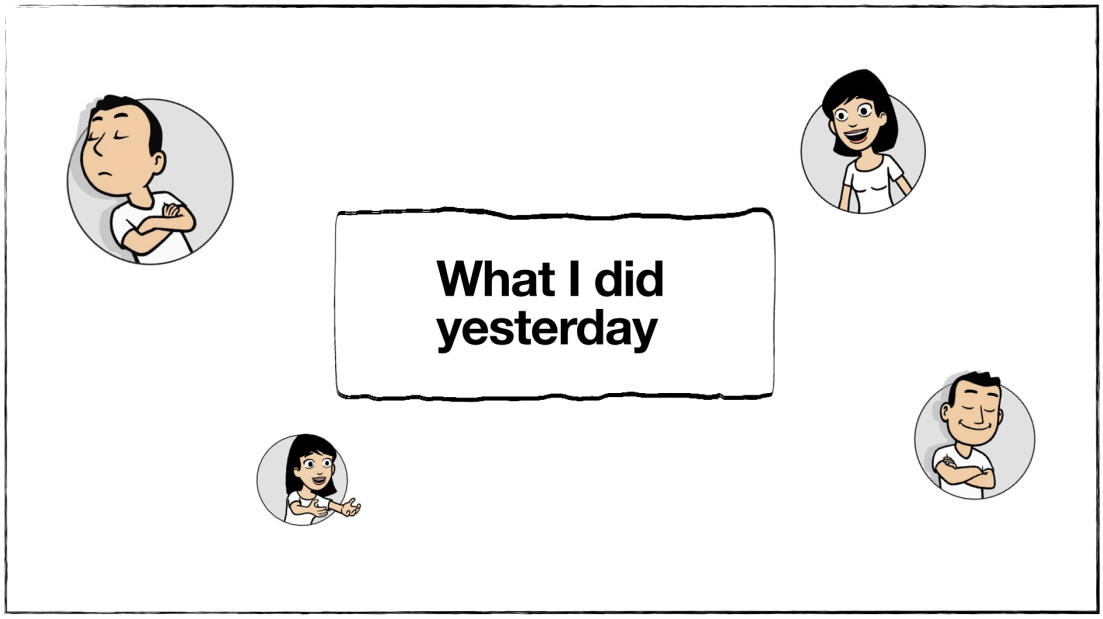
For specific exercise activities



Mini Blade XT - Blatchford
Runner junior - Ottobock
Flex run jr
Cheetah jr

B

Interview Materials



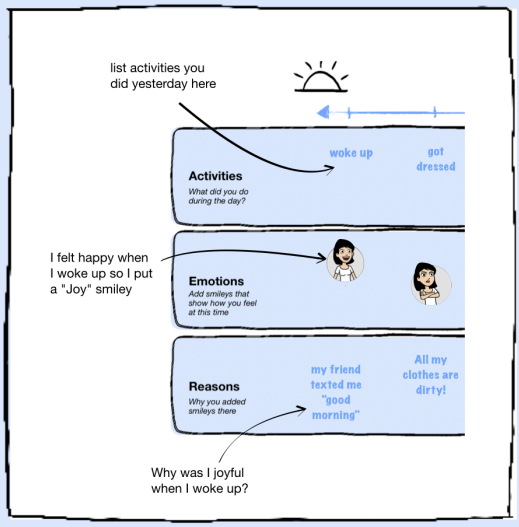
What I did yesterday

Assignment

We go through a lot of emotions in one day. In the first box labeled "Activities" list what you did yesterday, starting from the moment you wake up to going to sleep.

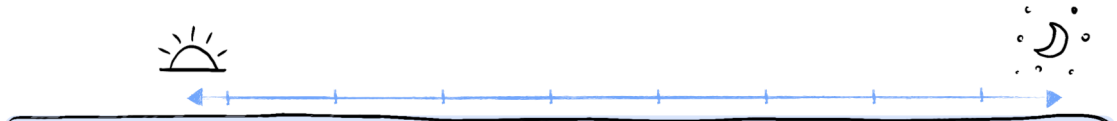
While playing with friends can be exciting, having an exam can be scary. In the middle box, add smiley stickers under the activity to show how you were feeling. In the bottom box, write why you felt this way.

If you did not remember, or did not feel anything, you can leave it empty!



What I did yesterday

Playing with friends can be fun, having an exam can be scary. In this exercise, first list all the activities you did yesterday. Later, add smiley stickers to show how you felt at the time. If you do not remember, you can leave spaces empty.



woke up

Activities
What did you do during the day?

Emotions
Add smileys that show how you feel at this time

Reasons
Why you added smileys there

Smileys

Sticker pack for "What I did yesterday"

TU Delft · Delft Institute of Positive Design · emotion studio

Shame

The feeling when someone knows something bad about you. You believe this to be true, so you also feel bad about yourself.

Satisfaction

The feeling when something meets or exceeds your expectations.

Admiration

The feeling when you look up to someone who has excellent abilities or impressive accomplishments.

Fear

The feeling when something can harm you or someone you care about, and you are not sure whether you can do anything about it.

Joy

The feeling when something good happens to you. You fulfil a need, achieve something, or make progress towards achieving a goal.

Desire

The feeling when you anticipate that something will be beneficial once acquired or consumed.

Contempt

The feeling when someone is inferior or unworthy in your eyes; they have done something blameworthy.

Anger

The feeling when someone does something bad that harms or offends you, and you blame that other person.

Hope

The feeling when you believe (but are not certain) that something good or desirable may happen in the future.

Disgust

The feeling when you find something repulsive and want to avoid having contact with it in any way.

Boredom

The feeling when there is nothing interesting or engaging to door expereince.

Fascination

The feeling when you encounter something new and interesting that you do not immediately understand.

Pride

The feeling when you possess (or have accomplished) something that exceeds your own expectations, or that others find praiseworthy.

Sadness

The feeling when you have lost something that was important to you, and believe it cannot be undone.

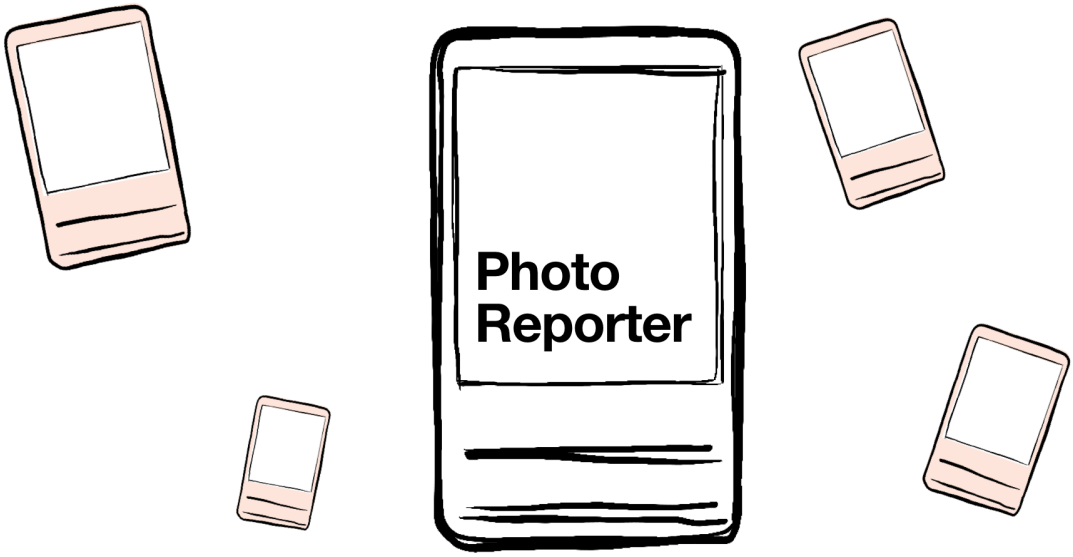
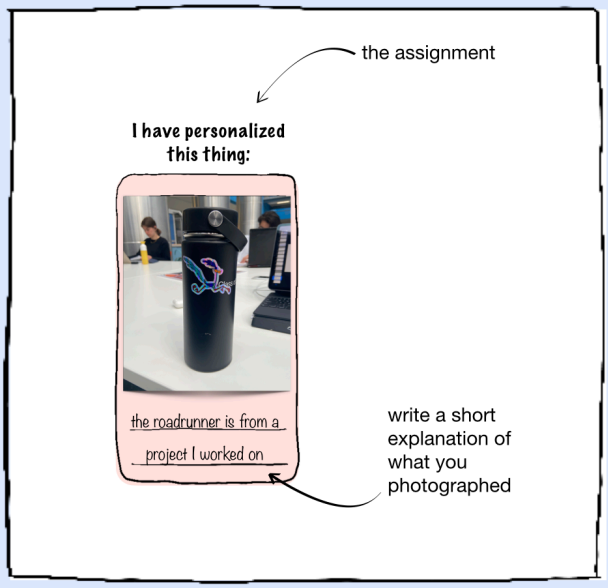


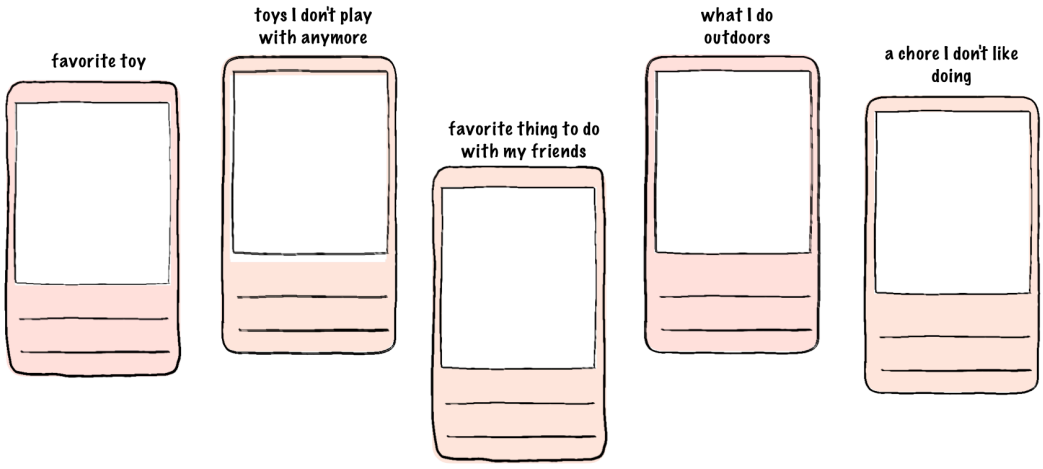
Photo Reporter

Assignment

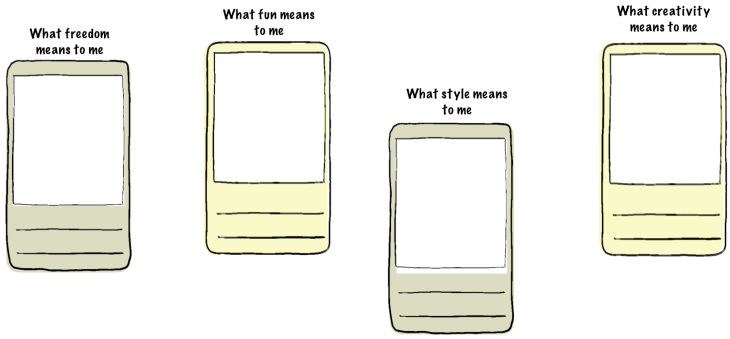
Photographers take pictures that help tell a story or record an event. For this activity, you are a photographer studying your own life. Take photos of objects, people and places that you think fit each assignment. While some assignments are very specific, other are more open ended, so use your creativity to capture the scene you think is the most fitting!



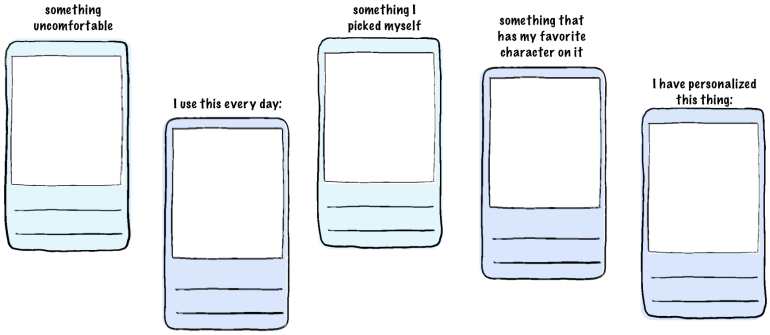
Activities



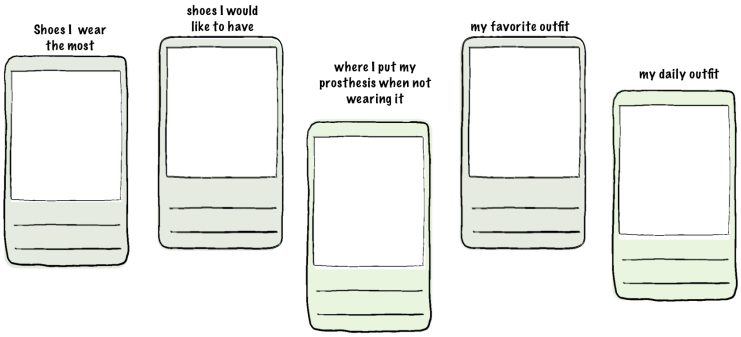
What ... means to me



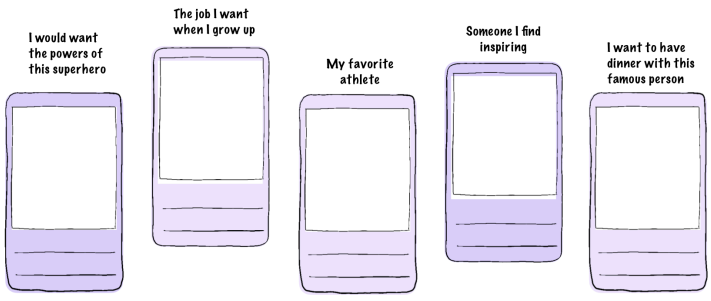
Preferences



Clothes



Role Models

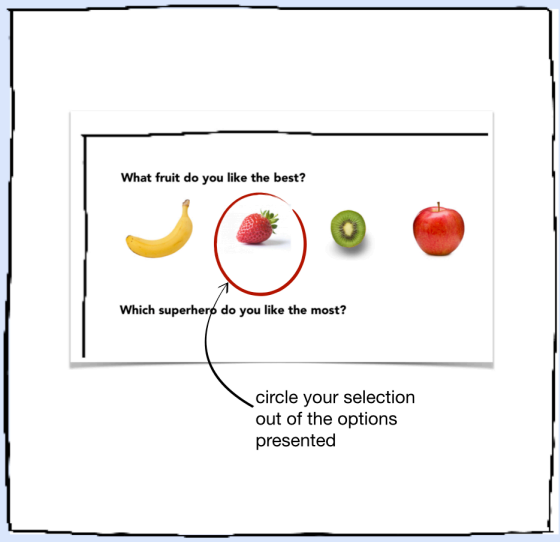


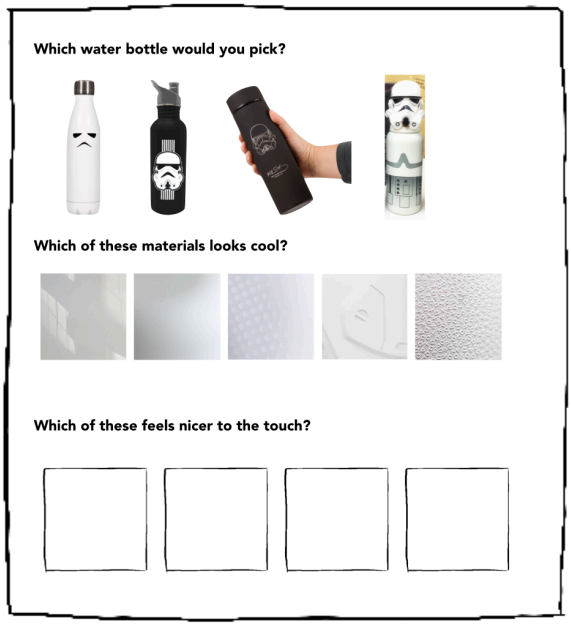
This or That

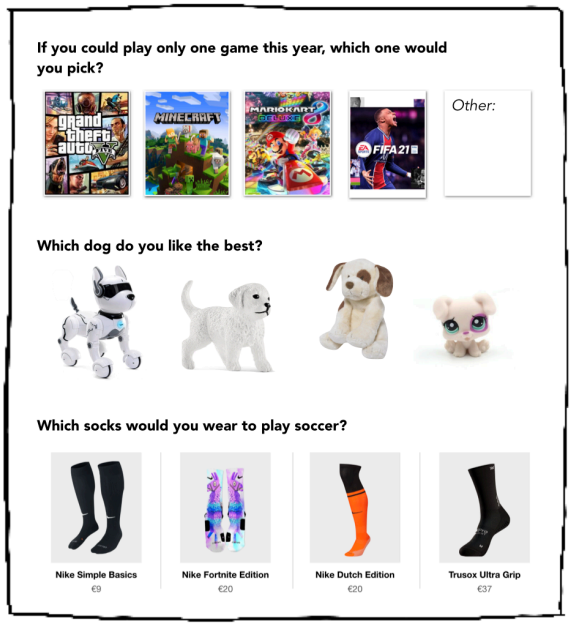
Assignment

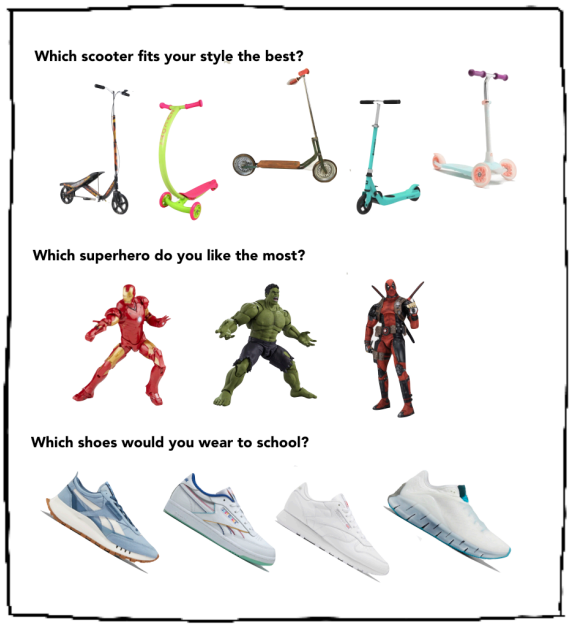
To design something especially for you, we want to get to know you. In this activity, select between options presented based on which one you like better.

We tried to select the items that would be the best for you, but we understand that you actually might like something else. If this is the case, please try to still select an option from what is presented. You can still write your actual choice next to the question.









Session 1

Goals

- Establish a friendly relation without viewing the interviewer as an authority figure
- Get base information regarding activities, places, characteristics to build on with the parent & in later activities
- Direct their attention to their relationship with the prosthesis and their emotional responses towards various stimuli

Schedule

Before the session: “What I did yesterday” Worksheet.
Introduction - Icebreaker - Daily Routine Discussion. Tour of the house if time permitting

Introduction

The introduction is a conversation with the child to get basic information they offer and give them an opportunity to ask questions to the interviewer. Some questions to ask at this time are:

Name, age, where you live (a chance for them to talk about their neighborhood)
People around me: Friends, family

Hobbies and interests

What sports do you like? Why do you like this sport? (Spending time with friends, have fun, winning as a motivator) What does a good player do differently? What skills should they have?

Information about your prosthesis: Can you tell me a little bit about this foot? I have never seen one before, can you help me understand? Where did you get it from? For how long have you had it? Do you have other ones?

What do they categorize it as? (An accessory, clothing item, part of body, actual leg, vehicle...)

Icebreaker

The icebreaker shifts the tone of the session to a friendly, creative and conversational one. Here it is important to continuously show that the interviewer appreciates any input the child has and that there are no right or wrong answers in these sessions.

The icebreaker selected is the Winnicott squiggle game. On a piece of paper, one person draws a squiggle. The other person turns the squiggle into something by drawing on it. The two people take turns squiggling and drawing on top of it. The goal is to make the squiggle into something meaningful. (Winnicott et al., 2010)

Figure 35: Examples results of the squiggle game

Daily Routine Discussion

Look out for: Is it clear where in the day the interactions with prostheses take place? Are there any emotional responses to it? Interesting emotional reactions the child has to understand their origin

Can you tell me about a time you felt X? (X: pride, admiration, shame, fear, worry)

How do you get to school?

Product related- touchpoints with the prosthesis throughout the day, other product cycles (maintenance frequency, cleaning, getting a new one)

Have they adapted any school activities to play/work with friends?

(If they have more than one kind of prosthesis) How do you decide which foot to wear that day? (Are they thinking about their plan for the day or not)

Emotions can be an entry point into concerns

Shift away from a right or wrong mindset

Keep questions concrete

Session 2

Goals

- Explore the product language child is familiar with and prefers in terms of aesthetics and interaction
- Gain a broad understanding of the participant in terms of their personality and preferences and how these color their concerns
- Build upon the knowledge on how the lower limb difference has been affecting their participation and social activities and the effect of the prosthesis in these

Schedule

Before the session: This or that

This or That discussion

This or That

A discussion on the choices children have made. What makes something preferable? Ask questions about the qualities of the chosen item. If stuck, ask them to explain why their choice is better than another option in that category.

Why did you choose X for this question? What makes X the best in Y? How is it better than Z in Y?

Your mother/father told me you also might like Z, what do you think about it? Do their preferences change based on the situation?

Is this your favorite game for playing alone or with friends?

Do you like custom things or things that are similar to those your friends have?

Keep questions concrete by asking children to compare

Laddering can help uncover motive hierarchies

Diversify expression opportunities

Session 3

Goals

- Get an idea of the personal qualities the participant is familiar with and find relations between these and their aspirations, goals. personality traits and motives
- Understand their motives and concerns at different situations, using the results of past activities as a starting point

Schedule

Photo Reporter

Reporting discussion - Role Models discussion

Reporting

The reporting activity has a small booklet that has various prompts. Assuming the role of a reporter, the child must take photographs that reflect the prompts in the booklet. The interviewer and the child together follow prompts, brainstorms possible photos that can capture the statement and discuss their ideas. After the photo is taken it is glued to the booklet and a short caption is written to explain the reasoning.

The interviewer and the participant go over the photos and discuss the selection of scenes/items selected to depict statements, focusing on the justification process of the participant. The following questions can be used in this session.

Why did you select X to picture this statement?

How does this image reflect ?

What makes X the best in Y?

Role Models

This activity brings together all past findings and relates them to the personal preferences, motives and concerns of the participant. The first part of the discussion brings out the personal qualities the participant is familiar with. The following questions are used to discuss role models and their motives.

What would you want to be in the future? Can you tell me about this job? Who do they interact with, what responsibilities do they have? What do you like about this job?

Is there anyone you look up to? Tell me about them, what do you like about them? Do you think you are like this person? Why/why not? In X situation/activity, how do you think they would feel/act? IF you were more like them in terms of X, how would you behave?

What do you most like about your best friend? Can you tell me about a time you had a lot of fun with them?

These questions can be used to start conversations on personal values. If the result of a discussion is not fruitful, another one can be used. The goal is to get to statements of motives(needs, goals, impulses, values) that can be expanded on using the laddering technique to reach more generalized personal values of the participant through uncovering motive hierarchies. The full list of questions do not need to be followed.

The interviewer refers to the complaints, worries and negative experiences previously mentioned with the goal of understanding why this experience has been undesirable for them and what psychological needs or expectations have gone unsatisfied. These are brought up and discussed one by one, and as they relate to the personal qualities that are being discussed with respect to the role models.

Do you think X has similar grievances?

How do you think X would feel in a situation like this?

Keep questions concrete

Diversify expression opportunities

Allow children to experience first

Assign roles

Session 4

Goals

- Conduct follow up discussions in any activity that needs room to expand on
- Confirm initial conclusions and understandings regarding research questions
- Inform direction on initial product ideas through discussion with the participant.

The specific content of this last session is planned after the three sessions, and varies for each participant. As interests, cognitive level and attention span of each participant differs, this session is primarily an opportunity to follow up and expand on any previous activities determined to be elaborated on.

Topics of significance that should be discussed if they have not been so far:

Are they secure about their looks regarding the prosthesis? Has their attitude towards the product changed?

How do they want to present themselves?

As a preteen, are they self conscious about their appearance?

Are there activities they do not need their prosthesis for or prefer not wearing it?

Are they aware of different prostheses on the market? Do they have any preferences regarding models?

Do you get worried that you might damage your prosthesis while playing/exercising?

Questions specific to the design of prostheses.

What features do they value on a prosthesis?

If someone could make them their dream prosthesis, what should it look like? What should it do?

need/motive hierarchies regarding the product

Sessions with other stakeholders

Parents

Following every session with the participating child, a conversation with a parent takes place. The goals of these sessions are:

Confirm/expand on results of sessions with the child (e.g. Identify the effect of peer perception through concealment of “childish” interests)

Their categorization of and their view on the prosthesis

Information the child does not have into the prosthesis selection, (e.g., lower limb difference or amputation rehabilitation process)

Medical Professionals

In the selection of the appropriate prosthesis and the following adaptation process, physical therapists and other medical professionals are instrumental.

Prescriptive perspective on the prosthesis selection and rehabilitation process. Their priorities and concerns.

How familiar are they with the concerns/motives of the child, being in a decisionmaking position on their prosthesis & rehabilitation

Questions for initial session

Goal identification process. How does it inform the prosthesis selection? Is it a personal process or standardized?

What happens to the product EOL?

Who are the people in contact with the child from the moment of intake to prosthesis delivery?

Do children reject lower limb prosthesis? What are their reasons, and what does the process look like from then on?

What are the most common physical complaints? Are there any psychological/emotional complaints you come across?

Peers

Preteens are increasingly susceptible to their peers’ opinions, therefore it is possible to discover the interests of children in this age group through interviewing their classmates.

Which concerns/motives are shared amongst the friend group, which ones are particular to the student, which ones are due to lower limb difference?
Aesthetic preferences and trends of the demographic the participant belongs in.

Teachers

Gain an understanding of the class social dynamics and the role of the child
Observations on topics discussed with the child, peers or parents that can deepen understanding of motives

C

First Level Insights

data analysis

cpo observation day

blades for small children are not effective, they are too stiff

I dont use Ossur junior products, the carbon blades are too stiff for them.

Ossur Pro Flex is the best, but not for children. (weight lower limit) There are children who use this one, for example recently I gave one to an 11 year old child, but it really comes down to the size.

I have been asking Ossur to make Pro Flex in small sizes for years

children get a soft dynamic foot and a hard cover combination

So when children are small, he will start them on a soft (dynamic foot) or sach foot and switch them to pro fex when they are old enough.

“Cover-type” prosthesis for children. (endoskeletal with the foot, attaches to socket). Versus adults get the traditional setup with pylon and a cover or stocking to go over it.

Not having an ankle joint in their opinion is not a problem as the foot already has some affordance in movement.

he prefers the scooter that stands out the most

M: [smiles] Yes they all don't fit me very much, so I just chose the most beautiful one, I think.
J: What makes this one the most beautiful?
M: In a special way, on a bend and then like this [follows the bend front part of the scooter with his finger]. But I prefer a stunt scooter.

he prefers trendy, futuristic designs in sneakers

Here in This or That shoe, he is detailing the aesthetic motivations he has towards having a preference. He is refering to the looks - the stripe shapes on the sole, the colors and how the colors of the whole shoe fit together in general to make it beautiful. Nothing about one looking more comfortable than the other.
“M: Which shoes would you wear to school? A: yes, I like these the best.
J: What makes the shoe so beautiful?
M: Yes the bottom, those stripes, tiger stripes. And yes the color.
J: So the color of the sole? Or in general?
M: Yes I think those are just beautiful in general. And it fits well together those colors.

tension between saying he values function and preferring beautiful designs

But when asked what he looks for in a shoe, he only lists functional reasons. He deliberately says that the looks are not important, which contradicts his initial statement in This or That.
“J: What do you think is important about a shoe?
M: Not much, that they fit nice. And a good size.
J: And how they look?
M: That doesn’t matter to me very much.”

“I’d rather hope that they break a little quickly [talking about his own shoes] because then I can pick out new shoes. Shoes I would like”

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he trusts his CPO to make him the best prosthesis

A: Would you like Nike to design it? [the prosthesis]
M: No [explaining he wants Bert, cause he knows him for 11 years already. Nicer than Nike making it]

falling is a part of the process to getting better

M: Yesterday I fell really hard, I wanted to go on a high one. And my foot went wrong so it went like this, and then I fell on my stomach but it didn't hurt that much.
J: Do you continue immediately afterwards?
M: Yes

does not want too many expectations on him

“And what makes Ronaldo your favorite player?
M: uhh, I don’t really know. [Pauses] Yes he plays the same position as me. That's a bit nicer.
J: And do you find Ronaldo, do you find only that he can shoot hard good about him?
M: No he can also do other things, his tricks, yes his tricks especially.
J: Would you like to be him maybe?
M: No, much too busy
J: So you would not like to be a professional football player because there is too much pressure.
M: No not that
J: OK so you would like to be a professional footballer?
M: Yes
J: Just not Ronaldo
M: No, rather one who is a little less pressured”

worst chore is better when you can make it like a video game

“J: I have a question for you, what would make vacuuming fun?
M: That you get money for it [big smile].
J: And the activity itself, are there any things you would change to make it fun?
M: Yes maybe one of those little electric things, then you just have to press the button and it cleans up by itself. Or that you can control it with one of those game controllers.
J: Yes then you make it more of a game.
M: Yes Mario Kart.”

He prefers not having his prosthesis on, he takes it off whenever he is sitting, and uses crutches at home.

M: Where I put my prosthesis when I'm not using it. Yes, where I take it off I put it, so anything. But most of the time it's against the couch. When I play games I put it in front of that. So yes.

A: And when you are sleeping?
M: Downstairs, then there's a... If I've played [soccer] before then because then I take it off here.
J: And downstairs where do you put it then?
M: Yes against the couch.
J: And then you continue on your crutches.
M: Yes then I continue on my crutches.

hulk is the preferred character because he is smart and strong

M: Which superhero do you like best? [Very decisive] Yes the Hulk.
J: What makes him better than the others?
M: That he is very strong, and also very smart. As a Hulk he's not but as a human he is. As Hulk he is very stupid, but as the Derk the gentleman he is very smart.
J: What do you think is less of Iron Man?
M: Just not a very fun superhero.

Even when not asked about, he feels like he must explain/justify what is going on with his leg if unordinary

Going up and down the stairs, there is a bit of a squeezing sound

M: Sound is what comes out of my leg, is still a little water that is in my leg from swimming. J: Yes

he loves gaming, especially FIFA

M: What is freedom for me?
M: Gaming! If one day I can't play games, I won't be happy. Then you have an angry “me”.

cosmesis is a choice they make for other people

And most of the time, the environment makes a problem of it, not the , its ,, the environment i think is the biggest problem for most of the amputees, not only the children. That's the reason why I think go for a covering, “dutch word” (6:15) and not for shocking. We have to make sure its not a problem, that you have a leg, what's the problem?! I don't see the problem, but that's also my job For him, if you have a leg, you have a leg, he does not see it as different.

young children cannot make use of a blade properly, dont need one

Yeah I see in America from CAS foundation there are young ones, i don't see what the results are getting started that young. I understand that giving young children the experience to run, but when you have a good socket and you have a good knee, for an above knee amputation, they can also run with a daily prosthetic. I don't see the use of getting a daily prosthesis that young.

parents want the best product available for their children, compare their progress to others

The question is, who wants the blade, the parents or the patient? 9:05 most of the time the parents. So they can run and they can play. But with the right running technique or the right walking technique, they can also do that with the daily prosthetic. Cheaper too, that is my opinion

The problem is that parents want the best for their children. I understand that one, but not every child is good enough to run. Because they dont have the right qualities or they don't have the interest or other possibilities. Amputation is good enough to run, we sometimes have that problem, but parents will not always listen to that. 10:00 This guy is running, so why can't my son run? I don't see the value of starting young in the blade, perhaps even if there is no, less experience, there are no medical results.

children should get a sport prosthesis at 11, when they exercise, not only play

I think they have to start with the blade at around 11. Because they can, they also have choice, they know what running means, they know what track and field means, they know what tennis means. When you are 4 or 5, 6, 7 they are always playing, it's not sports, it's playtime. That's the reason, that's the hard, the last two years of primary school, perhaps the last year. Depending on how good the person is physically, and mentally.

frank interview

children get a soft dynamic foot and a hard cover combination

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Not having an ankle joint in their opinion is not a problem as the foot already has some affordance in movement.

sports prosthesis gives them a chance to be a kid again

I see, do they have any first reactions when they get a sports blade?

Girl with a Extension Prosthesis wanted to try a blade so we put on a different knee and the a blade and she was thrilled about it. So two weeks after that de came back to try it again. This is something you see a lot with children because they suddenly can run around and therefore be a kid again.

hiding prosthesis less important when exercising, becomes important in daily scenarios

I think that if people start sporting they care less about covering their prothesis. If you sport with a blade, everybody can see that you have a prosthetic leg. With a daily prothesis it is not visible or they don't want it to be visible.

proud of my little brother/son

T: Are you proud of your little brother?

B: Very proud

T: Tell me about it?

B: Well he is not bothered by it, and he is already doing so well.

T: And dad how proud are you?

D: very proud, he is my example (rolemodel). You know when sometimes you have to go to the dentist you are nervous (as an example). But now i am never nervous cause if you see what M has been through last year and how fast he is upn and running again.

wearing a prosthesis is normal for me

T: But this is really special, did it become normal for you already?

M: Yeah very normal, just put it on every morning, becomes easier every time. Just have to put it, then I can walk and bike to school.

T: And did you think of how other kids would react?

M: Yeah they dont see it, only if i sit down there is this bump. But for the rest it very normal, cause I now have it a few months but i play football with it every day with all the children

positive attitude of family on child's recovery

Mom: Well M is handling his condition SO well, he is a great guy

B: I Am very proud of M, I think it is badass how he pushed through all this

D: M is doing really well at the moment. And I expect it to only improve, and that he will stay as diligent (in a positive way) as he is now.

assist is just as important as the goal

Mama did you see the assist?
Yeah I saw it.
He always says, mom an assist is just as important as scoring a goal. Maybe more important

he loves soccer, both as an activity and following (entertainment)

"M: What is fun for me? Soccer! Downstairs!
A: downstairs?
M: Yes, with soccer I have the most fun. "
M: Football, know the same picture, a little boring though but that doesn't matter.

touzani video

bullying 'would not bother him'

T: Haha you couldnt see me through the gap?

M: No I did see your large nose.

T: Hahahaa

[then Touzani explaines that he always mentions this himself in his video's because he knows a lot of children get bullied, but i you joke about it yourself nobody can bully you)

T: But i read they also called you something right?

M: Yeah, little foot

T: But it wasn't meant as bullying right?

M: No

T: And what if this was the case, would it bother you then?

M: No

if you have a driver's license, you start with a car that is close to 2000 euros, instead of 200000, don't start in a ferrari.

Yeah. but i think that everyone with a blade has to go to a regular track and field club. They have to train 2-3 times a week. Depends on the age, but they have to. Otherwise, the blade has no use. You have to make sure that the blade has been used for running, and not standing around. I have the blade. I put it in the closet. So that's my idea.

The way you speak about it sounds like a sports car, like a ferrari. They should be able to drive it and they should use it.

Yeah! Yeah! I said that several years ago to a guy who said, I want the best for my patient. And I said the same thing, if you have a driver's license, you start with a car that is close to 2000 euros, instead of 200 tho, don't start in a ferrari.

the responsibility of owning a blade encourages them to use it more often

And the blade gives some response [responsibility] because they know they have to use it. The foot, the daily prosthesis also gives a response if they have the right one, but they don't use it, they don't push. They slide they "taps lightly on the table" versus they should "smacks table loudly" [demonstrating how much force should be put on the foot] with the blade you do this "smack table loudly" with the daily prosthesis you don't put any pressure on it. With the blade you have to put pressure on it, otherwise you won't get a response.

children are adaptive and get used to their situation

they are really adaptive, so you don't see the problem on the healthy side. Because they are…adaptive. They don't feel the prosthesis is 2 inches too short. Slowly, they are growing, and ofc then the prosthesis is too short, but they don't really feel it. They feel it when they come to change it and then say that, but it doesn't walk like before. Because they are getting more one with the first one. I think that's what goes for most of the young ones. Because they are growing, they are getting stronger, they get more energy. They don't really see that problem. It also depends on what's the reason for the amputation. If it's cancer, then you have to work hard to get some strength in. because of chemo or whatever. At a younger age, they just go because they don't know any better, and that's the difference.

the outlook of the parent affects the child's outlook

Yeah, because most of the time parents are afraid that their child will fall or break something. The child is a child.

The child never feels like they will break it, they don't care?

Yeah, parents are scared. He is running on grass and parents are, shit might fall. We start walking by falling. You stand up and walk again. That's how you learn it, I learned it, and for younger ones with an amputation its still the same. Fall down, stand up, walk again. Most of the parents are really scared. Because when parents are scared then the child doesn't develop and that's the problem.

stability and springiness tradeoff in feet.

For all prosthetic feet, alignment is very important. (alignment of knee and foot) there is a tradeoff between more springiness and stability. If you are more on your toes, it is better for running, but further back for stability. Plus, alignment also determines the reaction loads you see in the stump. If they are too concentrated that also causes blisters so it is important that the foot is aligned correctly. This is the CPOs job and every foot is different, so they must pay attention.

important to address comorbidities for long term health

Comorbidities - the impact of the prosthetic foot on the sound side. According to Peter, this is a really important thing to consider. They will only stand on their sound foot, and start only leaning on this foot for daily activities.

Standing is not a passive activity. The foot is actively working, balancing the person, so standing on a prosthesis for a long time is challenging. This causes spine, back and neck problems in the future.

"In short term, it is about acceptance", children need to see what is the benefit for me. Long term, its about instilling the healthy and preferable practices that will keep them painless for life.

"in short term, its about acceptance"

"in short term, its about acceptance"

clicking sound when the leg is securely attached giving confidence

Liner lock and pin - this is a ratchet system that makes clicking sounds and snaps when it is locked. The locking sound gives the user confidence, knowing it will not come off. "Nice, audible click. Talk about confidence"

clicking sound when the leg is securely attached giving confidence

Liner lock and pin - this is a ratchet system that makes clicking sounds and snaps when it is locked. The locking sound gives the user confidence, knowing it will not come off. "Nice, audible click. Talk about confidence" The liner is what the leg is attached to.

acceptance by peers is important

Social relationships present the child with a unique set of demands, both cognitive and interactive, and have unique consequences for the child's social and emotional functioning"

Acceptance: need to feel approved of by the important people in this life. Formational conclusions about their identity in relation to people around them.

Success. Focus on finding out what the rules are and how they will deal with them. good/bad and right/wrong. Emulation of role models

Desire to be "old enough" for cooler things that are for older kids

ossur/peter slijkhuis

k level is lifestyle, impact level is max force

K level is about the person and their lifestyle. Eg a truck driver who sits all day and comes home to watch TV is K2 level, but will need a high impact prosthesis as they might need to jump out of their truck a couple times a year.

Impact level is about the load/force the prosthesis will see.

12 is a treshold age for children to use a sports prosthesis

12 as a threshold age for using a sports prosthesis. Children younger than 12 have no problem with a non-cosmetic (natural looking) prosthesis, so if they get used to a sports prosthesis before then, they will continue on with them. It is much harder for a child older than 12 to switch to a sports prosthesis if they had no experience with it before. They will prefer a natural looking prosthesis even over increased functionality.

This can be a Dutch thing, because children 8-12 are the older kids in primary school, they have no problem standing out in this way, but 12-18 they are the younger kids in high school, they want to disappear and not stand out.

D

Interview Summaries

DeHoogstraat Rehabilitation Center

Initial Chat with Bert

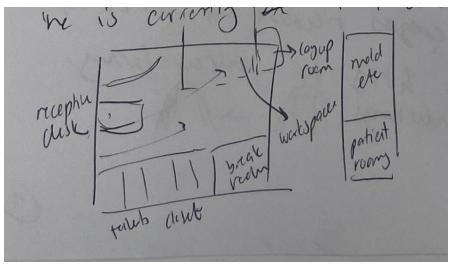
Bert works with Koen, who he is training to take over his job when he retires in 3 years.
Their legs are small, carbon blades are too stiff for them. Insurance does not cover sports blades easily either.
Ossur Pro Flex is the best, but not for children. (weight lower limit) There are children who use this one, for example recently I gave one to an 11 year old child, but it really comes down to the size.
I have been asking Ossur to make Pro Flex in small sizes for years, but they don't.

So when children are small, he will start them on a soft (dynamic foot) or sach foot and switch them to pro fex when they are old enough.
"Cover-type" prosthesis for children. (endoskeletal with the foot, attaches to socket). Versus adults get the traditional setup with pylon and a cover or stocking to go over it. Not having an ankle joint in their opinion is not a problem as the foot already has some affordance in movement.

Most children have congenital differences, with a big proportion having a shorter leg. In this case, they stack a prosthetic foot right under their natural one.

Bert also validated this assumption on the take of amputees versus congenital difference. **"Relearning how to walk" with something not as good as their first leg is frustrating. Children with congenital differences are more tolerant of the prosthetic as it gives them a new skill.**

Children get 1 foot, and it is hard to make the argument to get a sports foot in addition.



Tour

Layup Room

There is someone making a leg prosthesis cover from carbon fiber. It is on the mold, he is slowly wrapping the carbon fiber sheet around the mold. On the other side, there is a leg mold covered with pink patterns.

Chatted with the person working on this prosthetic cover. The cover needs a knee and a foot prosthesis to attach on.

They use many resins, and prefer acrylic as it is more flexible. Epoxy while there, is not used as it is more brittle. (cannot absorb shocks etc)

I asked him, how crazy can you go with the mold/layup? He said that as long as you can pay attention to the following, you can make whatever you like:

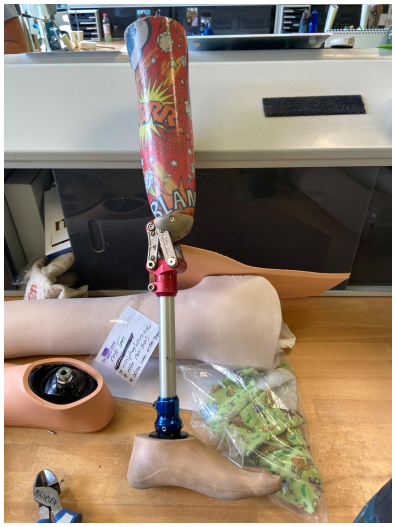
- **Socket fit: the socket must make the maximum contact possible (in surface area)**
- **Can 3D print whatever you want as a cosmetic cover, there are no limitations**
- **All edges must be soft. Especially with carbon fiber, the splinters can be a problem, so all edges of the design must be properly finished/covered with tape or something soft**
- **The layup process is done in vacuum. The shapes made should be fitting for vacuumforming. Overhangs etc cannot be formed and some spaces will remain. Especially important if it creates spaces between skin and socket.**

They can add whatever pattern the wearer desires, they have about 30 patterns on hand and the person can always send them a new pattern.**The pattern/color is added to the cover as a fabric during the layup.**

There are many pattern options in the layup room, but children do not choose them often, they go for more natural designs, especially girls, especially starting at 15-16 years old. The layup person says he wishes more children chose the patterned designs as they are more fun to work with.

Cosmetic color options available at DeHoogstraat.

Elbow prostheses or braces are silicone, and they can cast these in a lot of crazier designs. These are soft and flexible for children as well. This contrasts with the leg prostheses, because while adults get a soft foam cover, they specifically refrain from giving these to children.



“When I give these foam covers or stockings to children, they get dirty or ripped apart within days” Adults & older kids get foam covers, but younger children (including 12 year olds) hard covers are preferred for damage they will take in play.

Prosthesis products for children should be ready to endure relatively high wear and damage (activities, lack of care)

The feet they have from people (the ones they are currently being used or returned to be sized up) are dirty. I expected them to be clean, that people would want to protect this product by wearing socks/shoes but if it is dirty, it must be that they walk around “barefoot” a significant

amount. I also observed this in my second session with the participant, **he was barefoot (with prosthesis) when we were in the garden.**

The Mold Casting Room
This is where they cast molds of the residual limb to design a prosthesis around. They directly use these to do a cover layup. They are plaster casts with a thick metal rod going through. This metal rod is used to fix the mold in a clamp, to be sanded, finished, or various other activities.

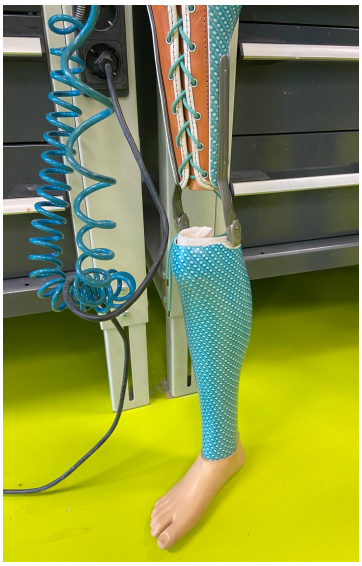
As he was working on this limb, Bert informed me that this is the stump of my participant. He visited DeHoogstraat recently for a fitting because he went swimming recently, and his dad put his prosthesis on the heater to dry. This caused the liner to warp, so they must make him a new one. As it had been a long time since his last visit and he grew quite a bit (he was due for a new one in June anyways) they took a new cast of his stump to make a prosthesis that fits him well. He is using a wheelchair in the meantime.
The worry here might have been that he had to go to school the next day with the prosthesis , and the liner took too long to dry. They wanted to speed up the process. This speaks to how necessary he/the parents believe the prosthesis to be in public spaces. The way he takes it off as soon as he gets home/sits down makes me think it is uncomfortable, so not preferable to wear if not needed. (like a bra)

Here Bert is smoothing over the parting line and shaping the mold. Here **he is feeling the mold to match the stump better. Where his bones end, where there is scar tissue, he must feel these things by hand to accommodate these in the prosthesis making process.**
Bert said that he prefers doing this by hand as it is important for him to get a feel for the anatomy and different textures. I asked him about the 3D scanners, he said he is both hesitant to use these new technologies because he feels too old, and that there is information that cannot be captured in this process, ie. what he is getting a feel for.

The workshop
Everyone has their own workbench. Tools, various materials everywhere. There is a scissor lift stand(like a portable welding station to me) on which is a tricycle with two people having a discussion around. About 10-15 people are walking around, working on different things. Walking around and chatting with Bert. He mentioned that for one patient with severe deviation in the direction of foot, he tried to make a prosthesis for this child 3 times, but it never took. In these cases, he recommends amputation as it provides more options and a better fit for a good prosthesis. **Here while the dad agreed with him, they had to wait years for the mom to come around, she was hesitant to agree on a surgery.**
Difference in parents' opinions. How does this impact the child? Will they be less secure in the decision going into the surgery, or will they look forward to their surgery and prosthesis more, considering they have tried every other option?

I asked him if there are any common complaints amongst children. He said that **"children have no complaints until they are about 15, and these are usually girls, they want to look more normal"**

To be able to conform with their peers, the girls get more vocal about their wishes. In the same day I also observed children have bruises or marks on their legs, not be able to walk properly due to muscle growth, but he did not mention these mechanical complaints here.
Maybe complaints = wishes/needs he thinks are not vital, therefore he does not agree with.
Mechanical problems are functional, therefore "valid concerns"



Bin of various dynamic/daily feet on Bert's workbench. (left) Ossur vari flex (middle) Prosthesis recently returned by a girl who is 15 years old. She now would like a cosmetic design. (right)
The workshop is visible to patients through a glass partition.
Bert displays the thank you cards and notes he gets next to his workbench.

The storage room

The storage room is not small. Every person from the workspace has 1 or 2 shelves there filled with old prosthetics. Frank has many Ossur blades for people to try them on. There are shelves of boxes of liners. Bert says they keep several feet in stock for children to try.

He was excited to see the new junior liner from Ossur. I asked him if it is because it is much softer and flexible, easier to roll on, make better contact with the limb but no, it was because of the color. **“Parents always ask for a liner that is not white, it shows dirt” he was relieved that the new one was not white, but black.**
I asked about the liner about my participant, and he said that he has no liner because of the stump shape. His residual limb has the ball of the heel in the end, so the end point is larger than the middle, making it impossible to get full contact in an ossur liner. So he has a foam liner made for him instead. He has a congenital difference, his foot was curved and did not develop properly. (missing toes) they had to amputate it for him to use a prosthetic foot.

Patient Visits
First Patient (Bert)

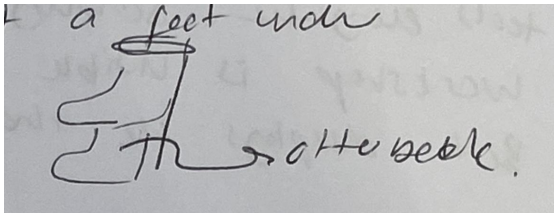
- Very young girl, toddler (2-4 year old). She is limping, with her upper body heavily leaning to the other side. She uses her upper body strength to move her prosthesis.
- The mother tells Bert about pain in her leg and knee. Bert sits on the floor, gestures for the child to come over to him. She walks over and he checks the alignment of her legs. He is explaining to the child what he needs from her, and they are talking. The physical therapist also comes in. (Iris)
- **The environment is very comfortable. Bert is sitting on the floor, mom seems relaxed (laughing, asking tons of questions)The child is walking around, not shy at all (looking out the door)**
- There also is a nurse assisting. (more serious)
- The jeans look tight, how did she get it around the leg? (later note) put the leg in the pants from the other side and connect inside with liner.
- The kid sits on mom's lap, the mom yanks off the prosthesis. The child was not in a bad mood until mom took off her prosthesis. Does she feel naked? She can no longer walk around, her freedom is taken. This is a contrast from the reaction of the second child, who was highly active after taking off her prosthesis.

From hip/upper leg vs a short leg length. One of them has mobility without prosthesis.

- She is curious, an explorer (children do not feel the difference between working and not, could this be a problem or can the professionals always see through it? Children work with whatever they have)
- **Her leg muscles are not enough, needs a brace. But she walks around constantly, wiggling and whole body compensating.**

Second Patient (Coen)

- Coen already went in first to have a chat and modify her prosthesis. He told me that she came in with bruising, so he modified the prosthesis to take off the pressure at



these points. He took out the velcro bands and eyelets, warmed up the prosthesis with a heat gun and formed it by hand. He later put on new eyelets and new velcro straps. **He rounded off the cut end of the velcro to be softer, swiped his finger around to check.** (also toddler) care for the patient/child at every part of the making process. product made for this application should be made to be safe and comfortable.

- She was sliding around on the stool with wheels when we came in. was upset that she would have to stop. She has a short leg so she got a foot under her real one to balance it The way she was moving around with such loud and constant laughter, and her high activity made me think she is trying to show how well she is doing without the prosthesis
- We go to a casting room. She then starts dancing around, no prosthesis. (i think she dances as a hobby, she seems practiced)
- I can see how for her it is harder to understand/justify why she needs it [the prosthesis], to her she is doing just fine.
- Coen brought in a stack of laminated sheets to select prints, as he is doing the casting, they are talking about the prints and animals.
- Casting: plastic sheet on the bed, he wraps her short leg in plastic wrap, puts a 90 degree bent stick and wraps that with the wrap too, then wets the whole roll of plaster cast, wrap it around her leg starting from the knee. It takes two rolls. In a minute, it is dry enough and he cuts it out.
- As Coen and mom are talking, the girl is a stream of songs and sounds. **She does not seem to like the prosthesis** (she does not want to put it back on in the beginning, did not want to get a cast, now she is refusing to pick a print for a new one. She is saying “no” every time they ask her what print she wants)

Third patient

- 11 year old boy, first fitting of new prosthesis.
- Coen goes back to shave the bottom off. Prosthesis making looks a lot like feeling and eyeballing, in making of the thing and checking alignment.
- Old foot is superhero exclamations, the one he came in wearing is green with graffiti styling.
  The designs he got were a lot louder than my participant, who is also a 11 year old boy, even though he personally seems more shy.

Open observation

- They are open to making whatever you like within the constraints of the production process. (vacuum forming cf with acrylic resin)
- Bert (or CPOs in general) have been working with the same children since their birth. They trust him to make them the best prosthesis available.

Ossur Pro Flex

- Enhanced range of motion and energy return
- LP = low profile,
- Pro-Flex XC prosthetic foot is designed for active users who enjoy hiking and jogging, as well as walking on level ground.
- Pro-Flex XC is fully resistant to both chlorine and salt water submersion.

- Starting at 45 kg (around 12 years old)

Frank Dik is a track and field trainer who trains children and adults on using their sports feet.
He seconded 11-12 being the best age for children to start with blades (the last two years of primary school)

A: So you work with children when they get sports prosthesis?
F: Yes, ummm… *dutch* (0:15 - 1:50) Soms werk ik met Bert op het moment dat ze een dagelijkse prothese krijgen, dan vraag Bert of het qua lopen allemaal goed is, of de knieën gesteld staat en daarnaast ben ik bezig met kinderen die sportvoorziening krijgen en geef ik daarnaast ook nog een keer, zegmaar een speltraining 1 keer in de maand op vrijdag. Voor jongeren tot een jaar of 16. Dus dat wisselt heel erg dus de ene keer heb ik het ADL verhaal en de andere keer doe ik kinderen die een prothese willen of bijvoorbeeld een blade willen proberen, dat is mijn rol een beetje in het hele verhaal.
Sometimes I work with Bert once they get a daily prosthesis, then I'll ask Bert if everything is good in terms of walking, if the knees are well placed and configured. In addition I am working on children getting a sports facility and am giving a training game one once a month on Friday. For young people under the age of 16. So that changes a lot so sometimes I've the ADL thing and other times I work with children who want a prothesis or try an for example a blade, so that's my role in this.

A: can you talk about the transition from a daily prothesis to a sports one, is there any training you do?
F: Yeah, it's always about how good the person is physically and mentally. If it's okay we can decide to try the running blades or an another sporty facility, but it's always starting with the physical capacity of the person otherwise its no use.

Ok, I see, what are some important skills they should learn first when they are getting a prosthesis?
Do you mean the blade or do you mean the daily?
Either way
For the daily one most of the kids get rehab from the PT and then they get a daily prosthetic, and sometimes they go because they are getting regular check ups until they are 18 over here. After that, they go to the adult rehab doctor. So most of the time in that first part i am not involved bc i am not a pt, i am not looking as a pt.. For safety i am looking for what do i see and what do I have do to get a better result
So a pt goes for safety, and I go for result, thats the difference
I see, do they have any first reactions when they get a sports blade?
Most of them like it, I, three weeks ago, girl with *dutch* (3:50 - 4:20)

Verlengingsprothese wilde graag een keer een blade proberen dus we hebben een andere knie eronder gezet en een blade eronder gezet en ze vond het helemaal te gek. Dus twee weken later was ze er weer om het nog een keer te proberen. En dat zie je wel vaak terug bij kinderen, ze in eens weer heen en weer hardlopen en ze kunnen weer kind zijn.
Girl with a Extension Prosthesis wanted to try a blade so we put on a different knee and the a blade and she was thrilled about it. So two weeks after that de came back to try it again. This is something you see a lot with children because they suddenly can run around and therefore be a kid again.

I am asking because regular prosthesis looks a little bit different from the blade, so maybe they get a bit scared, or overwhelmed..
No, no no, they just wanna try it. And what you see in a daily prosthetic is that they are all covered up like a normal leg but when the blade is going, they don't care. And that's also transition to getting more one with your prosthetic leg. *dutch* (4:50- 5:25)

Ik denk echt op het moment dat mensen sporten met een blade dat de covering van hun dagelijkse prothese minder een ding is. Op het moment dat je sport met een blade ziet iedereen dat je een kunstbeen hebt en met een dagelijkse prothese zien ze dat niet of willen ze dat niet zien.
I think that if people start sporting they care less about covering their prothesis. If you sport with a blade, everybody can see that you have a prosthetic leg. With a daily prothesis it is not visible or they don't want it to be visible.

And most of the time, the environment makes a problem of it, not the , its ,, the environment i think is the biggest problem for most of the amputees, not only the children. That's the reason why I think go for a covering, “dutch word”

(6:15) and not for shocking. We have to make sure its not a problem, that you have a leg, what's the problem?! I don't see the problem, but that's also my job For him, if you have a leg, you have a leg, he does not see it as different.
Do they get the sports prosthesis as an additional one, so they have a daily one and a sports one?
Yes
So they can switch
Yes, sometimes, we only switch the blade, so you only get, the parents are instructed, they get a socket for their daily prosthetic, they change the knee or the blade or the foot. But it's not always possible, it's also depending on how much coverage it is, that is also possibility and a cheaper one, because you only have one socket
Is there an age that is best for tying sport prosthesis for first time
Yeah I see in America from CAS foundation there are young ones, i don't see what the results are getting started that young. I understand that giving young children the experience to run, but when you have a good socket and you have a good knee, for an above knee amputation, they can also run with a daily prosthetic. I don't see the use of getting a daily prosthesis that young. The question is, who wants the blade, the parents or the patient? 9:05 most of the time the parents. So they can run and they can play. But with the right running technique or the right walking technique, they can also do that with the daily prosthetic. Cheaper too, that is my opinion
The problem is that parents want the best for their children. I understand that one, but not every child is good enough to run. Because they dont have the right qualities or they don't have the interest or other possibilities. Amputation is good enough to run, we sometimes have that problem, but parents will not always listen to that. 10:00 This guy is running, so why can't my son run? I don't see the value of starting young in the blade, perhaps even if there is no, less experience, there are no medical results.
By young what age do you mean
I think they have to start with the blade at around 11. Because they can, they also have choice, they know what running means, they know what track and field means, they know what tennis means. When you are 4 or 5, 6, 7 they are always playing, it's not sports, it's playtime. That's the reason, that's the hard, the last two years of primary school, perhaps the last year. Depending on how good the person is physically, and mentally.
Do you think having this goal of doing track and field or tennis also helps, a goal they are working towards, and play is more free?
Yeah. but i think that everyone with a blade has to go to a regular track and field club. They have to train 2-3 times a week. Depends on the age, but they have to. Otherwise, the blade has no use. You have to make sure that the blade has been used for running, and not standing around. I have the blade. I put it in the closet. So that's my idea.
The way you speak about it sounds like a sports car, like a ferrari. They should be able to drive it and they should use it.
Yeah! Yeah! I said that several years ago to a guy who said, I want the best for my patient. And I said the same thing, if you have a driver's license, you start with a car that is close to 2000 euros, instead of 200 tho, don't start in a ferrari. But that is what lives by parents, but also the environment. Why does he have a running prosthesis and why doesn't he?
Do you think it would help if the daily prosthesis looked a little more sporty?maybe they won't ask for the blade as much
Yeah but, it would help but the problem is the foot from the daily prosthesis is not as good as the blade, so that's the other problem. And the blade gives some response [responsibility] because they know they have to use it. The foot, the daily prosthesis also gives a response if they have the right one, but they don't use it, they don't push. They slide they *taps lightly on the table* versus they should *smacks table loudly* [demonstrating how much force should be put on the foot] with the blade you do this *smack table loudly* with the daily prosthesis you don't put any pressure on it. With the blade you have to put pressure on it, otherwise you won't get a response.
If you put energy in, you will get a response back. Most of the young ones, they don't put any pressure so ‘
They are not heavy enough to put pressure on?
yeah , then you have a problem because walking is getting more heavy than running. Daily prosthesis also gives some response, but they don't know how to use it.
I heard that comorbidities, the good leg, have some problems…
No, it's not really common I think, they are really adaptive, so you don't see the problem on the healthy side. Because they are…adaptive. They don't feel the prosthesis is 2 inches too short. Slowly, they are growing, and ofc then the prosthesis is too short, but they don't really feel it. They feel it when they come to change it and then say that, but it doesn't walk like before. Because they are getting more one with the first one. I think that's what goes for most of the

young ones. Because they are growing, they are getting stronger, they get more energy. They don't really see that problem. It also depends on what's the reason for the amputation. If it's cancer, then you have to work hard to get some strength in. because of chemo or whatever. At a younger age, they just go because they don't know any better, and that's the difference.
If the parents are not too scared, then there is no problem.
Can you tell me more about that
Yeah, because most of the time parents are afraid that their child will fall or break something. The child is a child.
The child never feels like they will break it, they don't care?
Yeah, parents are scared. He is running on grass and parents are, shit might fall. We start walking by falling. You stand up and walk again. That's how you learn it, I learned it, and for younger ones with an amputation its still the same. Fall down, stand up, walk again. Most of the parents are really scared. Because when parents are scared then the child doesn't develop and that's the problem.
How do you work with that?
Send them away, hahaa. No, not always but you have to explain what will happen, and why it will happen and then if your explanation is good enough, they understand. Several years ago I had a small girl. 10 years ago when she started with the blade, she lived a few miles from the track and field club so parents came. When she came out of the car she walked to the club and the parents brought her her running leg and daily prosthesis and we try one time two times, and i said, she wont run, that's her problem, give it to her. Yeah but we like to do it, if you don't like it, she expected that she do it. If she expected to go to track and field club, her problem. That's the way it has to be, a bit stronger to also the parents but also to child, if you fall, stand up, cry, wipe your hands and go, thats the way. In my training i am not afraid that people will fall. If they fall they fall. I dont like it, but it happens.
In 3 years time, 1 elder person has fallen. So dont be scared. But you have to know that's the walking technique, whats the running technique, thats no problem. You can explain it to a parent, to run with the child.
Can you tell more about that? What are the proper techniques?
How do you run? Running is quite easy, if you run you stand up, you bring your leg up and bring it down. Stand on it and raise it again. Running with a prosthesis leg is exactly the same, bring it up, bring it down, stand on it. And Because you are bringing it down, with people who are above the knee, with mechanical knee, because you are bringing it down you get a knee extension. You bring the knee in extension than you put it on your hips, then thats no problem, then you can run. You can stand on it.
Ive also seen in the videos they run sometimes… (cut me off)
Yeah no thats not running. That has nothing to do with running.
Really! I think one of the paralympic athletes…
Naaah, nah, this guy, with Whitehead , but that has nothing to do with running,
What do you mean?
You dont run with circumduction. Thats *dutch* lopen met bilateral been..?? (24:11 - 25:00) Lopen met een bilateraal bovenbeen, zonder de knieën maar met veel circumductie heb ik met hardlopen te maken. Dat heeft te maken met een blade en het optimale gebruik ervan. Als jij als [name athlete] die je dan bedoelt, wordt je paralympisch kampioene op de 200 meter maar loopt ook de marathon in 2 uur en een beetje, gaat niet. In de invalide atletiek kan een 100 meter sprinter nooit een marathon lopen of andersom. En hij kan dat wel dus heeft niks met lopen te maken, gewoon zo hard mogelijk neerzetten.
Walking with a bilateral upperleg, without the knees but with a lot of circumduction i am working with running. If you take [name athlete] who you meant, you become paralympic champion on the 200 meter sprint but also run a marathon in 2 hours and some minutes, that won't work. In the paralympic sports a 100 meter sprinter can't do a marathon or vice versa. And he can do it so it has nothing to do with walking, [don't know what he means]

They only use the blade, nothing else, no muscles. Whitehead can mabye run the marathon in 2 hours and 35 minutes I believe. So thats the reason why I said, I dont like it, If you look at at Vanessa Low, thats an australian girls that bilateral but above knee, she runs with knees. Thats what running is, not with stiff legs, because we have, if you run with stiff legs, its not running.
Whats bad about it?
For me its the visual. I dont like it. I hate it when people run like that, even with one leg.
Is it the easier way to do it?
Yeah, yeah its easier.

Then you are not teaching that either?
No i dont, i dont. Haha. i have one guy now, he is on holiday, bilateral, knee legs amputation. Young one, 22, w etry to start, he is now walking with c legs, and he is paralympic ski (?) about sports and what he has to do for it. Perhaps with him we can start with walking and running with knees. It has to be with knees otherwise i cant, i wont start, i hate it. it has nothing to do with, what we want to do with paralympic or with sport or walking. We start to walk as close to an able body. We start to run, to sport as an able body as much as possible. You dont see an able body run like that, thats why for me its a no go.
And i understand, bc it gives results, but for me its a bad result.
Have you tried running like that before?
No, no i dont do it.
Cause thats my second question, if you are working with people who have a different kind of foot than you, do you know how they feel, like that kind of springiness, how to you empathize?
If i have never driven this ferrari before, and have only read the manual, how do you teach someone who has a ferrari but you drive a different car?
I dont know, i also dont know why i started it with people with an amputation, i get this question 25 years ago, and I said yes, and i still dont know why. On the other hand, i dont see a problem, just by, if i see a problem as a coach for teaching someone, then im not a good coach. then I try to get some information how to start with something, develop something by myself, to get a person to a higher level, i think thats the way to start coaching. Training is, dont be scared if its not looking as good as you want to be, try to figure whats going wrong. When i started 25 years ago.
I started training 2 people with below knee amputees so that was an easy start for me, with running. But every training was taken on film, every training. We discussed it with the guys. What do you want to see? Bc 25 years ago the internet was a bit there, so with the guys we had to figure out what training was good, what training was bad, what results did we have. Get it to a several times with exercises and sometimes it doesnt work, sometimes it does work perfect. And thats the difference. You have to see and learn from the guys and from yourself. I am a track and field coach from able-bodied person and thats how I looked to walking and running and I use my track and field skills to get someone better. Thats really different form a PT bc we discussed, PT is used to getting safe and not used to seeing, and making connection with what they are seeing and what exercise. And by track and field you learn you see an able body long jump, he comes to you, you have to tell him whats going wrong, you have to for example say the high knee is an attention point. You have to see that in less that 5 seconds. depending on how far he jumps, but you have to see that really quick, in a blink of an eye. To see and inform the jumper whats going wrong and whats going right, the PT, thats no use there.
I have a group in … where I live, and I have a track and field club, there are last week two girls with blade, 2 guys with a blade, several people with amputation with above knee with c legs and rio (?) (34:20) A new guy with mechanical knee and a lady with 73 with rolleys(?) in the same hour. Thats what I am used to. PT always 1-1. Pt, a patient, I am from of track and field group of 30 and I have to check every one. I have to see almost every one in a split second, and give them the right information.
Do you still train able bodied people?
No
Because maybe children want to train with their friends?
Yeah, when I started with the amputee group in …, we always trained together with able bodied, always. In the last 1.5 years we dont bc when you start its most of the guys live nearby, and now they have to travel 2 hours for 1.5-2 hours one way. So they only come on saturday, so we only train amputees. And if there are. Tomorrow I train with a girl in amsterdam, there is 4 in amsterdam, so I go to them. It depends always, how far and how much time. Some people want to start 3 times a week, on the evening, they are training with able bodies for sure.
Children train at their school teams and come to learn the right techniques here. And the shame is that PT doesnt know that, I can explain it several times and they dont understand. I dont know why they are working as a PT. we have pt s specializing in child with an amputation, then I expect them to know what they have to do to get a child running or waling better and they dont understand, they dont see it, and thats a shame. And this is everywhere, because they are going for safety.
How is it different? Is it the same as a parent then who want a safe child if sitting at home.
No, no they want the child to run, but they dont get the child to move because they dont give them the right information. If you learn to run, i quickly showed you about the right running technique and the right walking technique. You can explain that, there is no problem.
Is your job common, or unique to here?

Haha, jesus, i know lisanne from Ossur, I think benefit for me is that I can do whatever I want, lisanne has other skills about the knee and foot, but she has to more in the relation to the boss, the ossur company, and i dont. So i can have guys on an ossur blade or ossur foot, i have guys with bock foot or whatever, i dont care, I think for me thats whats quite nice, because it gives me some independence.
So thats for me its nice, i think lisanne is a PT. she knows an awful lot about running and walking but I think my part is that I can, i have more freedom. For me thats a perfect job. I like track and field, for me its the ideal combination track and field running with blade.
Do you think, should children in the US for example, join their track and field club at school or try to learn running with their PT?
I think, if you say to a child, above knee amputee, with a good socket, good knee, good foot, with not a lot of information, if you say to the guy or girl, run, they will run. They dont need a PT, they run. Because they are not scared. They are not scared of falling, they are not scared of breaking something. And parents should be behind the screen, then its no problem. In most of the cases with good fitting, good material, young one, runs within 10 minutes.
Is is also same for football?
The problem is soccer is not allowed after 14-15 years with prosthetic leg. Because of if you kick the prosthesis leg with your healthy leg, they you have a problem. The problem of injury by your opponent is quite high. Thats another problem for children who wants to sport. Most sports must be individual, because team sports are not allowed.
By who, the insurance?
The governing board of the sport, the foundations, so thats the other problem. If they want to go to a team sport, only sitting sports are allowed. If they want to go to a contact sport, Most of the time it is forbidden by the soccer government, UEFA, FIFA, KVB. they dont allow people with amputation to play,
why?
Because of possibility of injury to the other guy., opponent. Harming the prosthesis leg is not an issue. The problem is when an opponent kicks it, and kicks hard, he breaks his leg. So most team sports are out of the question for the amputees. Only the sitting
Sitting?
The wheelchair, sitting volleyball, so that kind of sports are the ones allowed. As a team, otherwise I dont see, there are no team sports with an amputation.
Maybe the leg needs to change to protect the opponent from injury?
Its quite a risk for the opponent, kicking a prosthetic leg. The insurance companies don't matter. Sometimes the prosthesis maker makes a problem, but otherwise it doesn't matter
My research is about increasing the child's confidence. Making them feel proud of, …
I think its important that people are proud to wear a prosthetic leg, you can make them proud by making them special. Make it their own. Something special, I try to figure out if i can, put the blade a special color, make it special, and make it proud to wear.

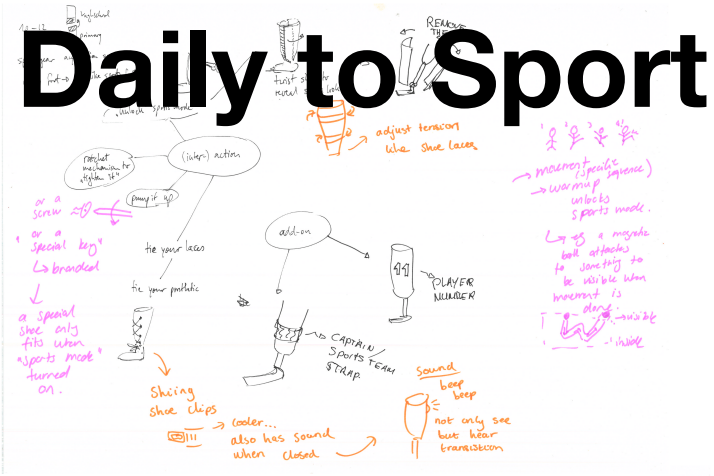
Open observation

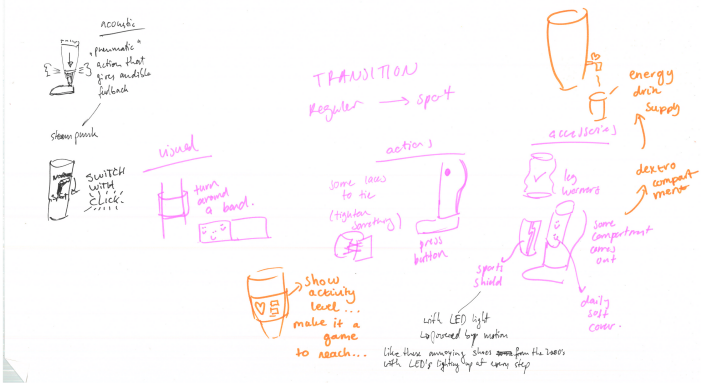
- Function of the product must be visually communicated.
- Frank is a lot about feeling, instincts and trying and failing. He is a coach. The were getting a sense of the foot by using it is important for them to want to use if frequently, be open to trying new things
- Age limit to contact sports. People with prosthetics cannot pursue team sports professionally due to regulations of the sports boards.
    - what does this do to the child’s motivation? Do they even know this? When do they find out?
    - emotional/concern level fallout of this situation. anger/frustration/stigma
    - Effect on socializing behavior of children? Especially the socialization of boys seem to be centered around team sports at this age

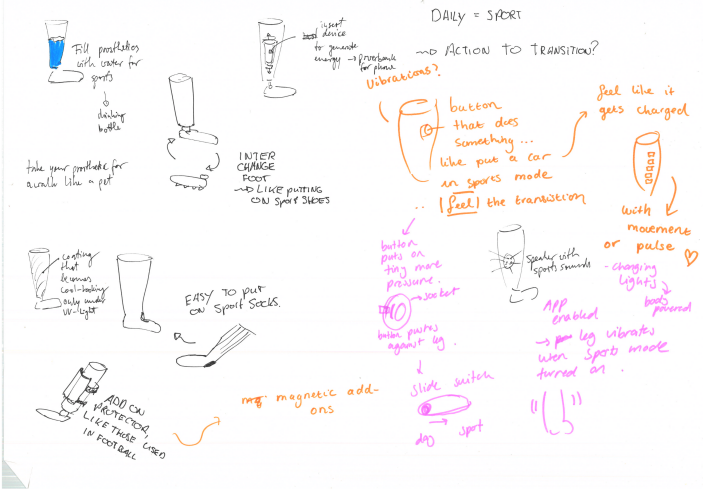
E

Brainwriting Results

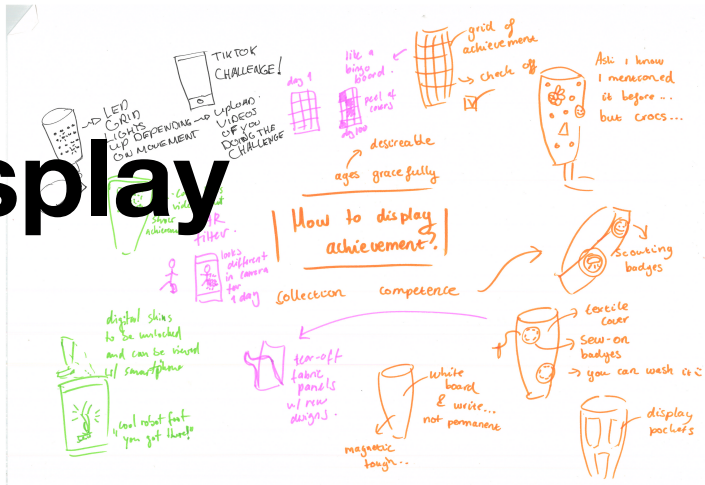
Daily to Sport

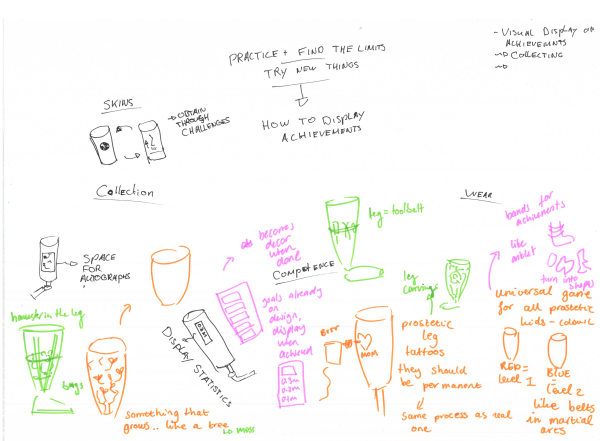




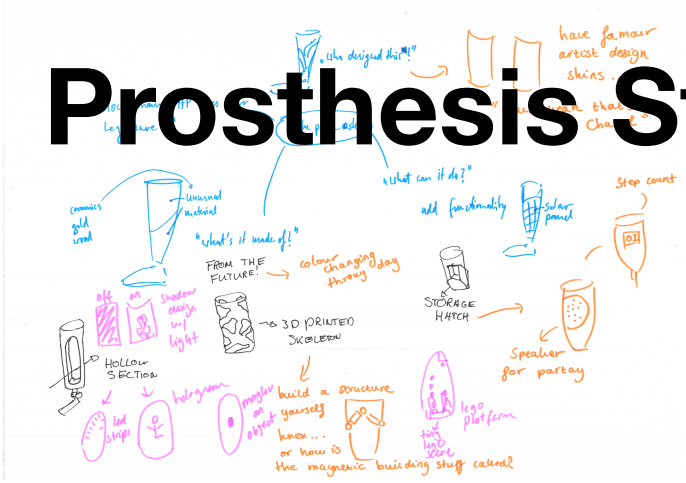


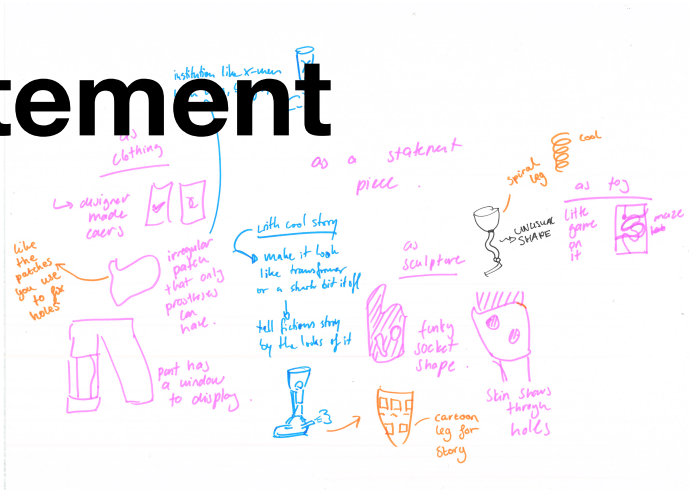
Collect and Display

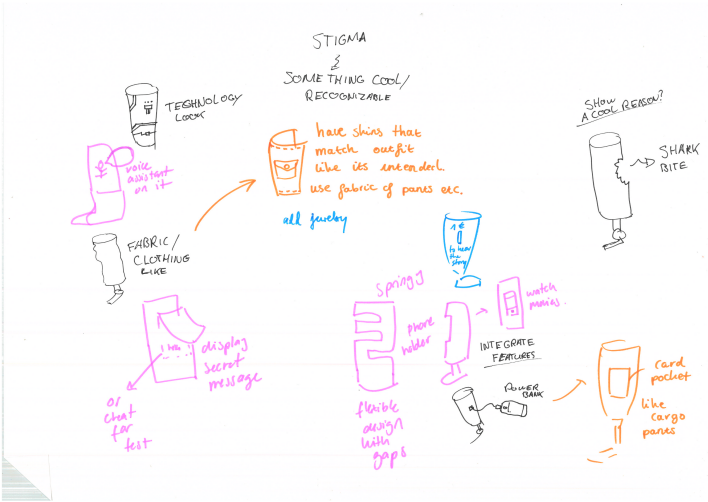


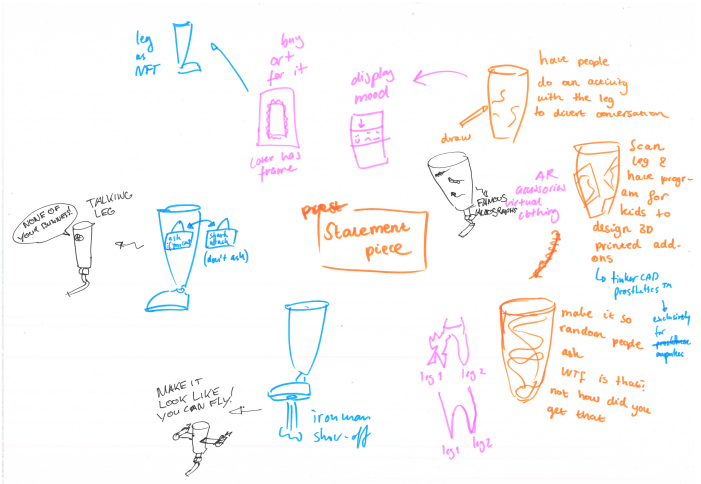


Prosthesis Statement

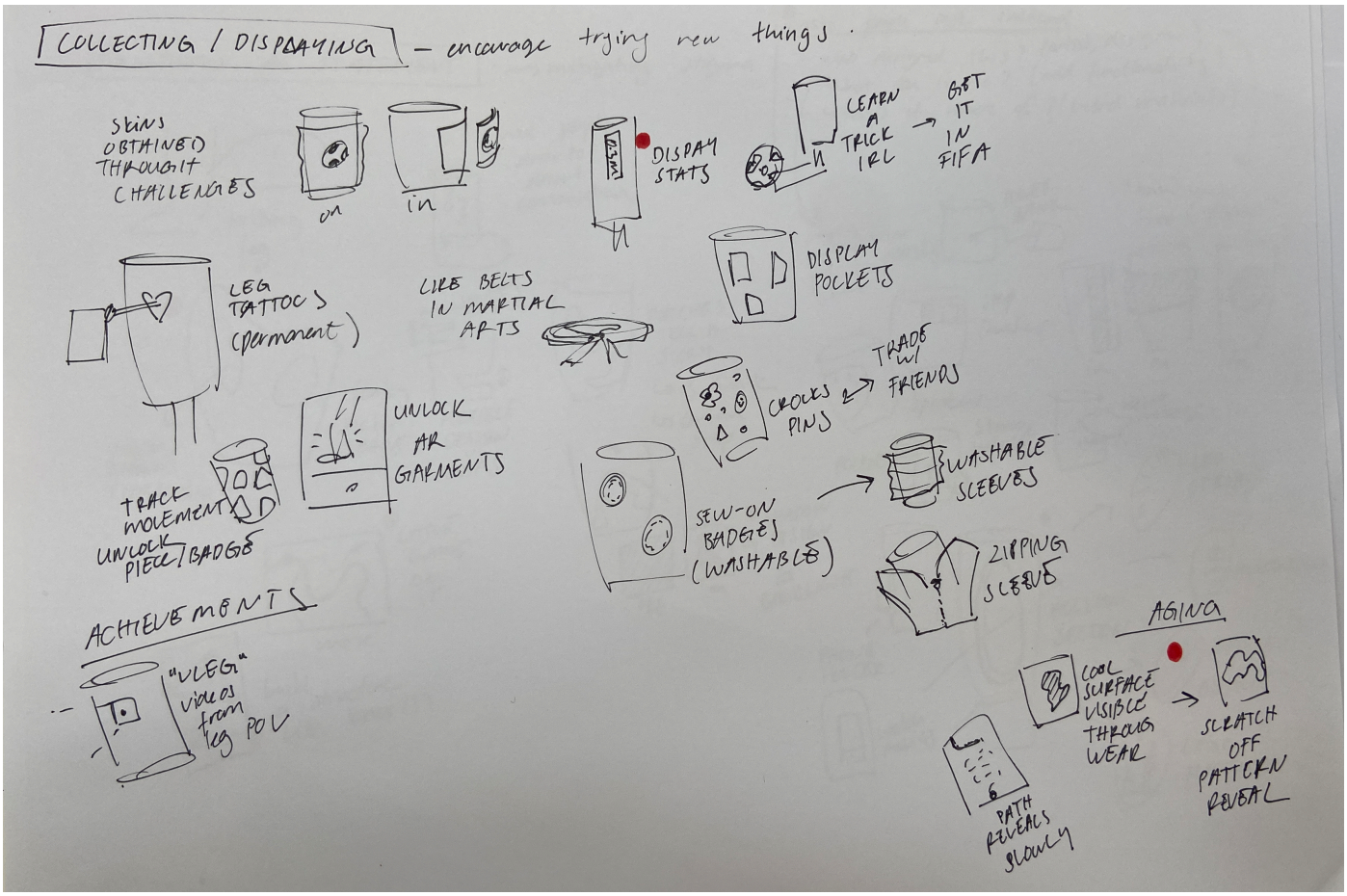




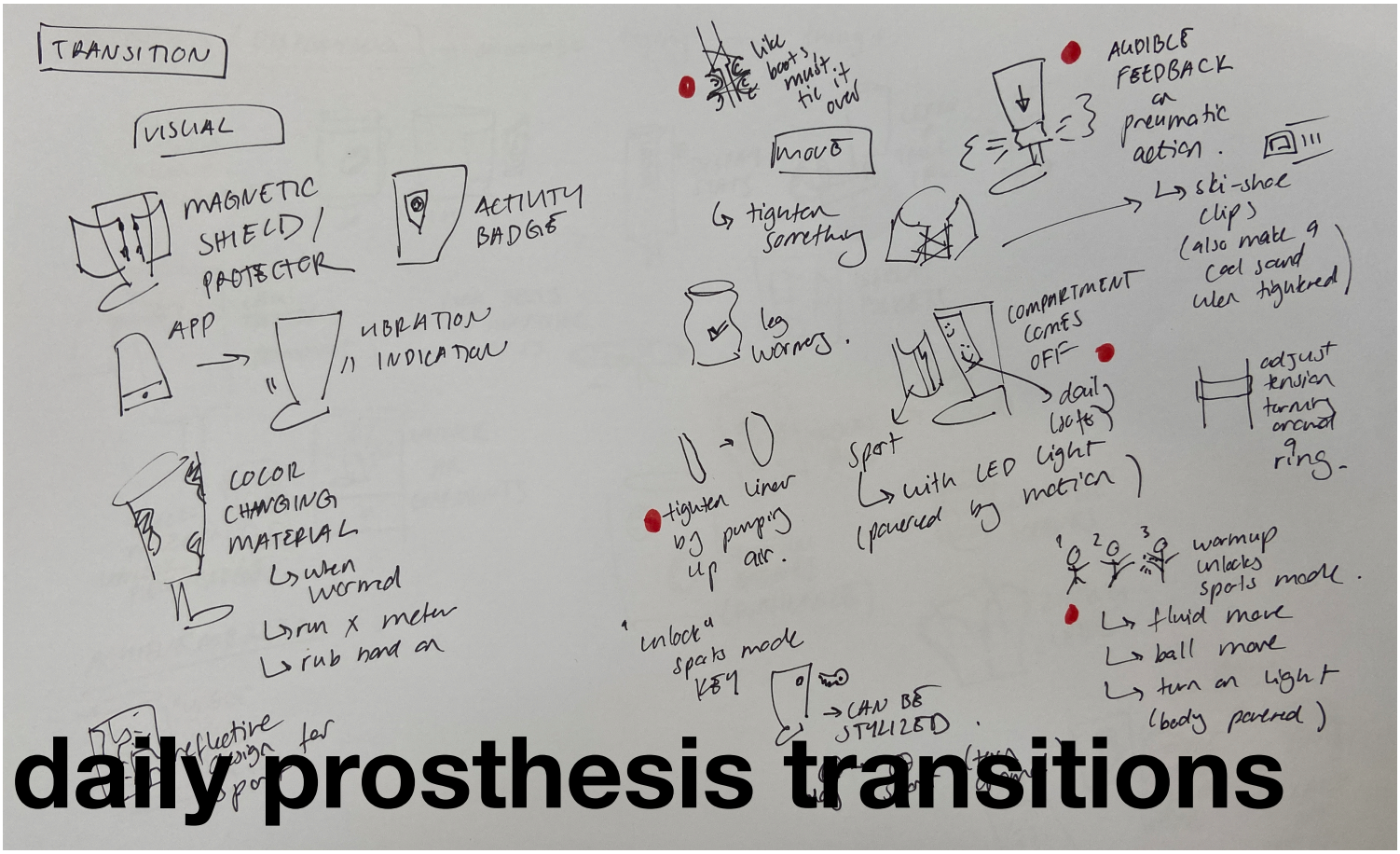




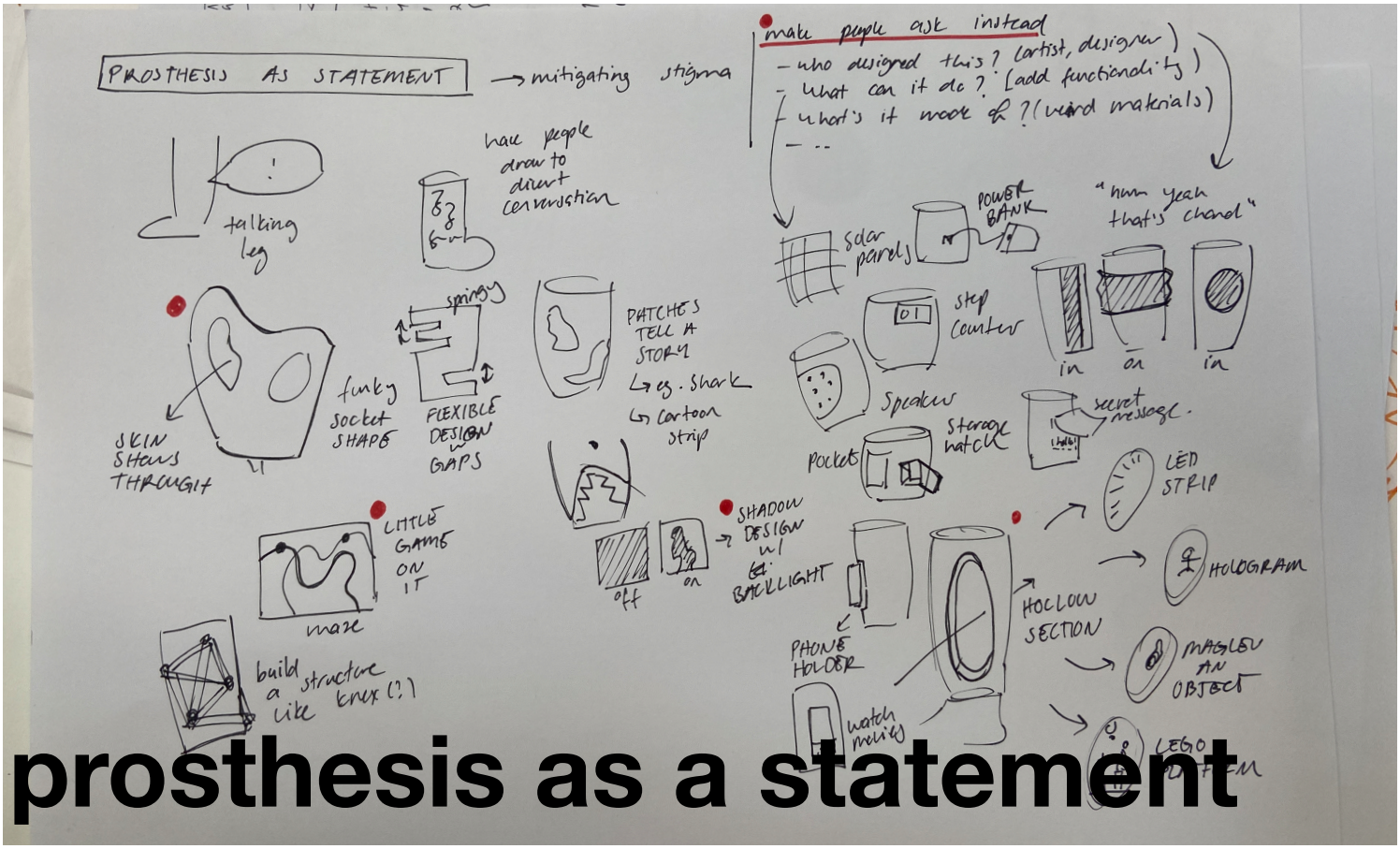
Brainwriting Summary



a visual display of lived experience



daily prosthesis transitions into sports context



prosthesis as a statement

F

Brainstorming with Ossur Design Team

Brainstorm & idea prioritization

Asli Graduation

15 minutes to prepare
45 min to collaborate
2-8 people recommended

Scope

Ideate on product directions based on identified contexts and proposed concepts.

1-2 minutes

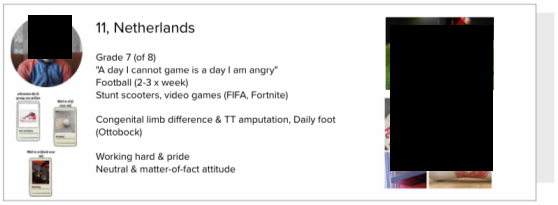
A **Brief presentation**
Explain the user persona, 3 story case scenes and what ideas have you generated so far. Keep it clear and straight to the point :)

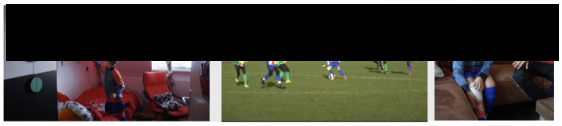
B **Ideas all over**
Based on the insights you've shown and your ideas, the Team will ask questions and fulfill the sticky notes on the stage 5.

C **Conclude**
Before prioritize the ideas (based on your feasibility or real life product development), gather the ideas with the Team of what will be good to you to develop or really no go.

1

User Research





2

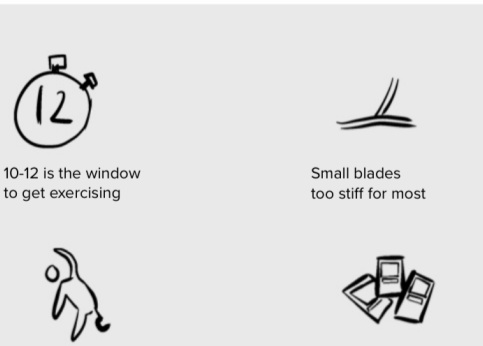
Insights

3

Brief Interview Insights

Fill up with key words, sticky notes or images what's been collected so far

5 minutes

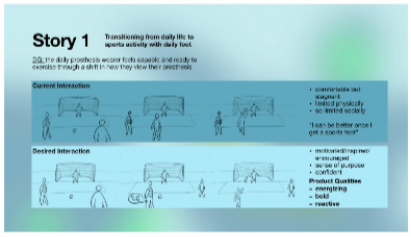


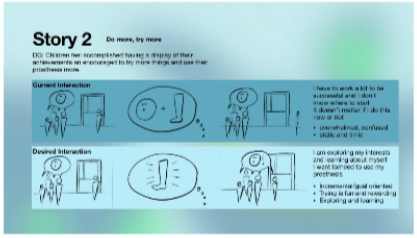
4

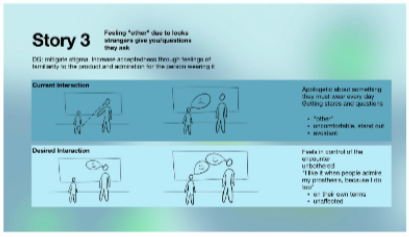
Case Scenarios (x3)

What problem are you trying to solve? Frame your problem as a How Might We statement. This will be the focus of your brainstorm.

5 minutes







4

IDEATION PHASE

Fill up with key words, sticky notes or images what's been collected so far

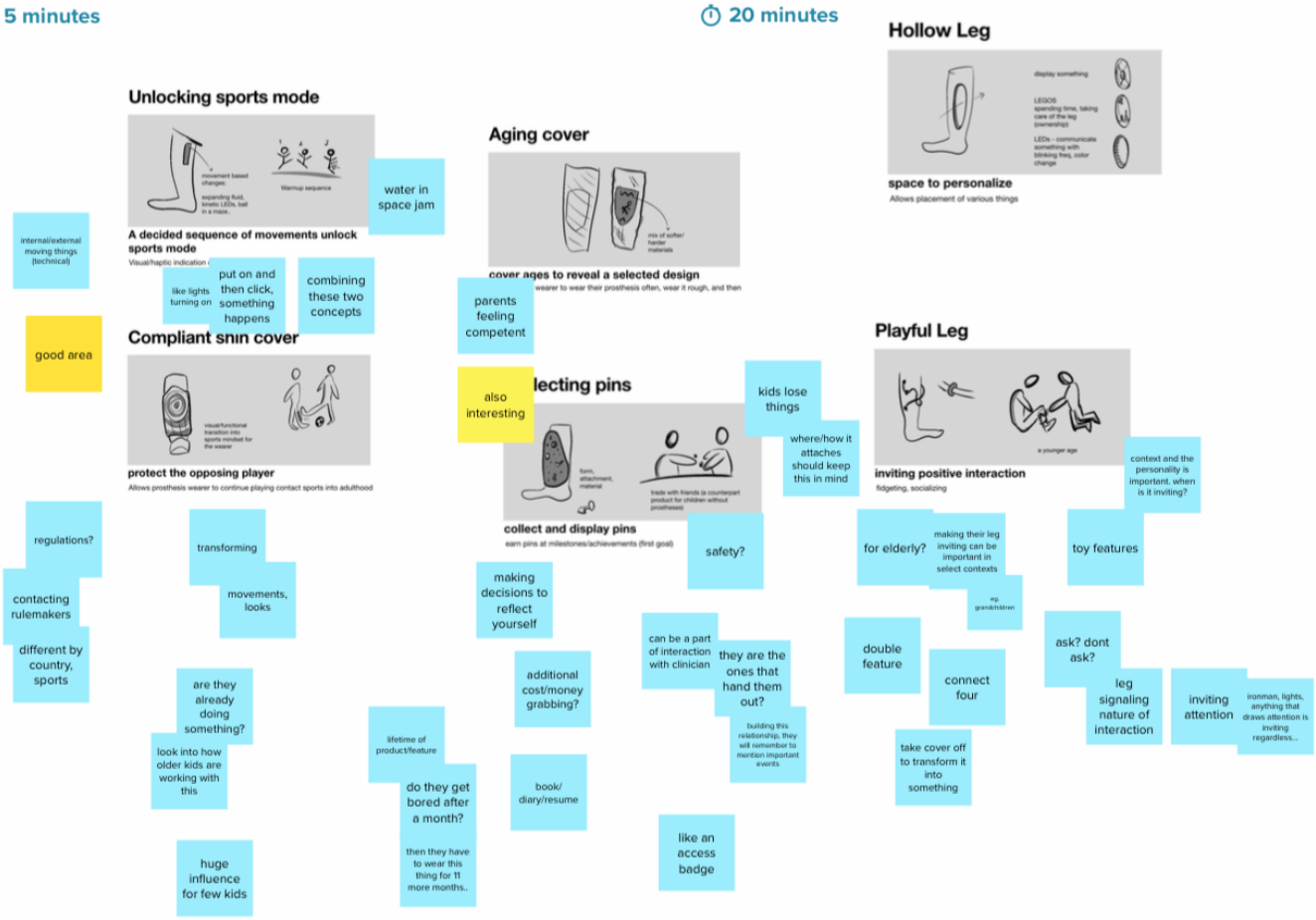
5 minutes

5

Brainstorm

Write down any ideas that come to mind that address your problem statement.

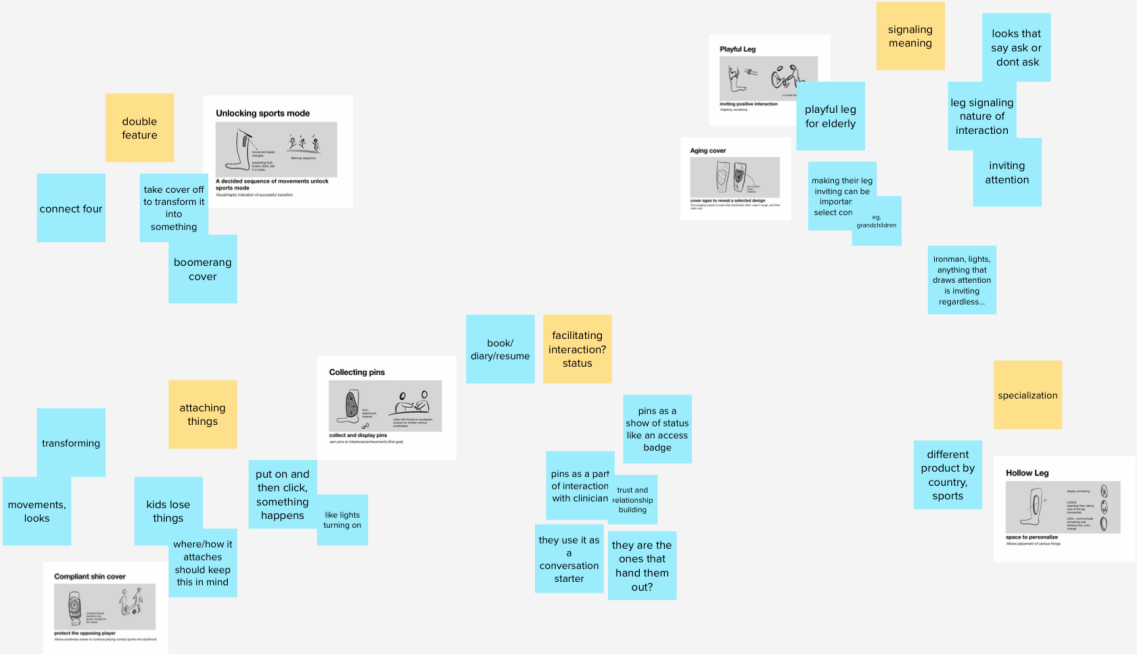
20 minutes



6

Group ideas summary

10 minutes

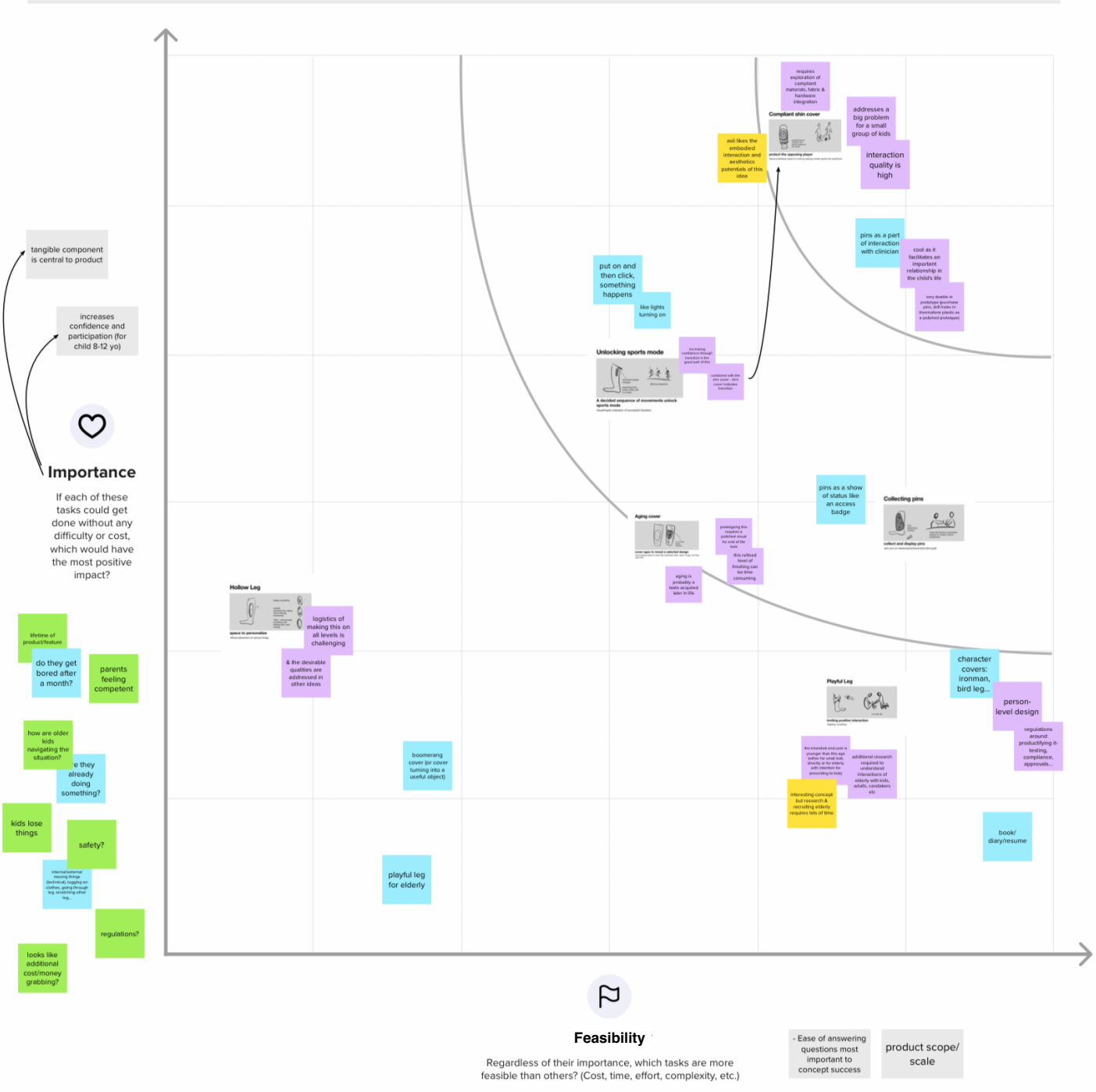


7

Prioritize

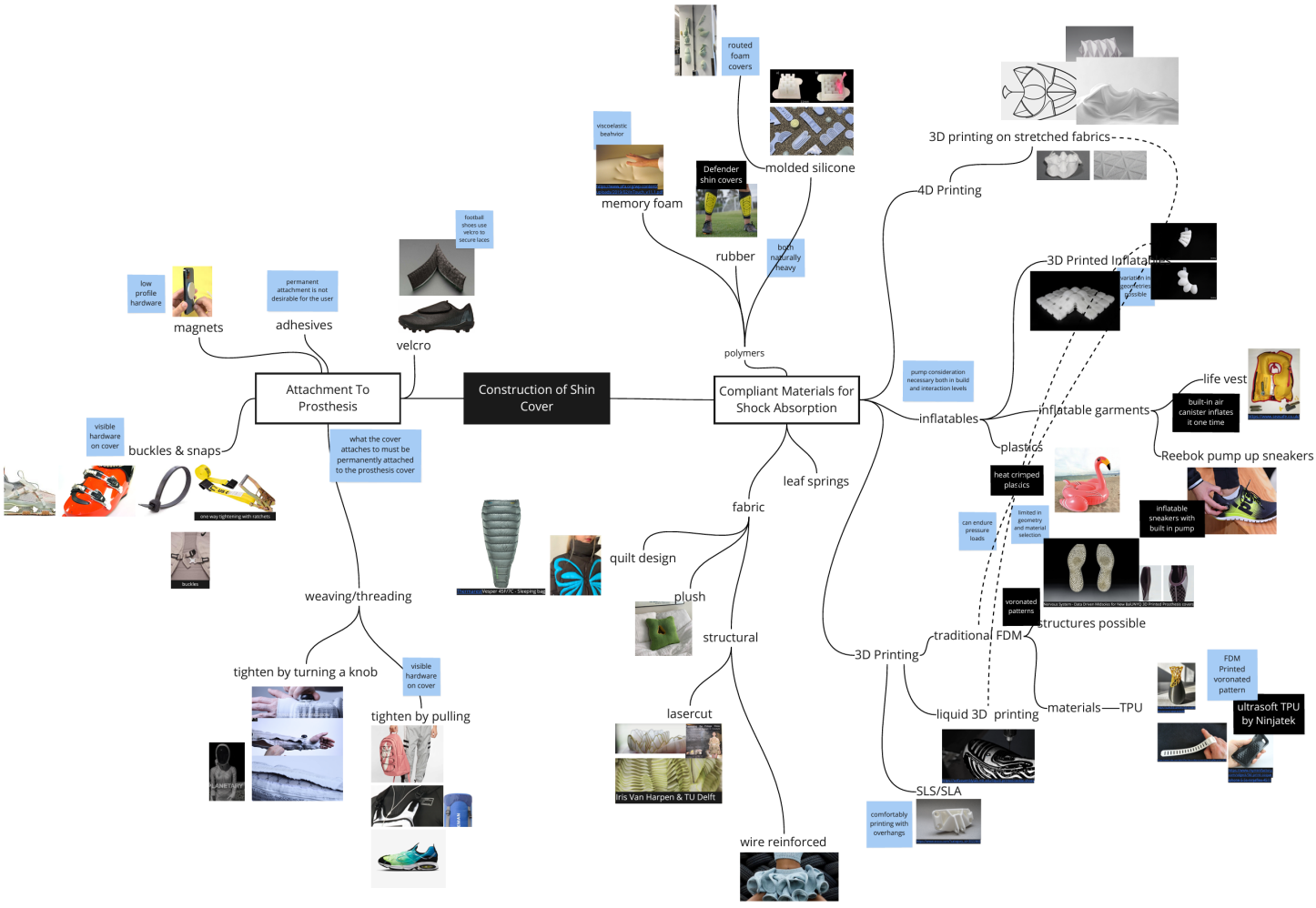
Your team should all be on the same page about what's important moving forward. Place your ideas on this grid to determine which ideas are important and which are feasible.

10 minutes



G

Technology Exploration



H

Stiffness Range for Adequate Leg Protection

Appendix H

Stiffness Range for Adequate Leg Protection

Mechanics of kicking
Impacts involving contact due to one player kicking another reach velocities of 18 to 24 m/s.[2] (Barfield, WR : The biomechanics of kicking in soccer. Clin Sports Med17: 711–728, 1998)

A youth player will be able to deliver a speed of 14.9 meters per second which amounts to about 600 pounds of force, (2670 Newtons) https://mmachannel.com/how-hard-can-an-average-person-kick/

Mechanics of bone breaking
An experimental study of effectiveness of shin guards on the market
(https://journals.sagepub.com/doi/full/10.1177/03635465000280021401)
The average peak force at fracture was 2927 ± 403 N
For male leg: 2980N for fracture
For female leg: 2873N for fracture
Contact time is 5.5 and 6.1[ms] (considering the bone elasticity) but even harder shin guards increase this to 20ms on average

Forensic science paper experimentally determining break loads for tibia
https://reader.elsevier.com/reader/sd/pii/0379073896020099?token=A1A2B20724B2FA3E67187FC7E333AFB51AD72AB850E500527850C31CACF559023201F08482ACBA52CBED837746492F94&originRegion=eu-west-1&originCreation=20220714085140
https://www.sciencedirect.com/science/article/pii/0379073896020099
Ventral & dorsal loads to break the tibia are the lowest
2508N is the lowest recorded value, and average for ventral and dorsal in low weight adults (40-50kg) is 3000N

Other variables
Weight of legs of males as a percentage of total body weight: 20%
https://www.medicalnewstoday.com/articles/what-is-the-average-weight-of-a-12-year-old#averages (their data is from CDC)
For 12 year old male it is 40 kg, with 95th percentile being 59kg. And 5th is 30kg. which makes leg mass 6.8kg on average and 10.03kg max.

Given x (the compliant layer thickness) is 5mm or 10mm

For a steel spring K, the stiffness is about 500N/m (between 100 and 1000 N/m) (for reference)

known parameters		units [SI]						
child				**kick**				
max avg kick force	2670	N		max velocity	14.9	m/s		
12 yo male child weight (average)	40	kg		Fbreak	2500	N		
12 yo male child weight (95 perc)	59	kg						
leg to body weight ratio (male)	0.17			**geometry**				
average leg mass	6.8	kg		x1	0.005	m		
max leg mass	10.03	kg		x2	0.01	m		
--LOWER BOUND FOR K--								
conservation of energy				**force balance**				
for an average child				assuming half the break force is the acceptable force				
k_avg (x=5mm)	**7770.889267**	N/m		F_spring (safe)	1420	N		
k_avg (x= 10 mm)	3885.444634			k(x=5mm)	**284000**	N/m		
k_max (x=5mm)	9437.712223	N/m		k(x=10mm)	142000	N/m		
--UPPER BOUND FOR K--								
It is the pressure that breaks the bone (not force alone, the area it is applied to plays a role)						--UPPER BOUND FOR K--		
In the experiment						F allowed	20000	
force break	3000	N				t_collison	0.005066	
contact area of force	2	cm2	(line contact)			acceleration	2941.176471	
Pbreak	1500					x	0.0377417	
In my case						k	529917.8362	
Ac	20	cm2	The load is distributed to a wider area					
Fexp	30000							
STIFFNESS VALUES								
kmin (from energy)	3885.444634	N/m		If I were to compress it with a 10kg load, this is how much they should move:				
kmin (from force)	**284000**	**N/m**		**0.3454225352**	**mm**			
kmax(from impact)	**529917.8362**	**N/m**		**0.1851230385**	**mm**			

Style Questionnaire

Shin Guard for Football

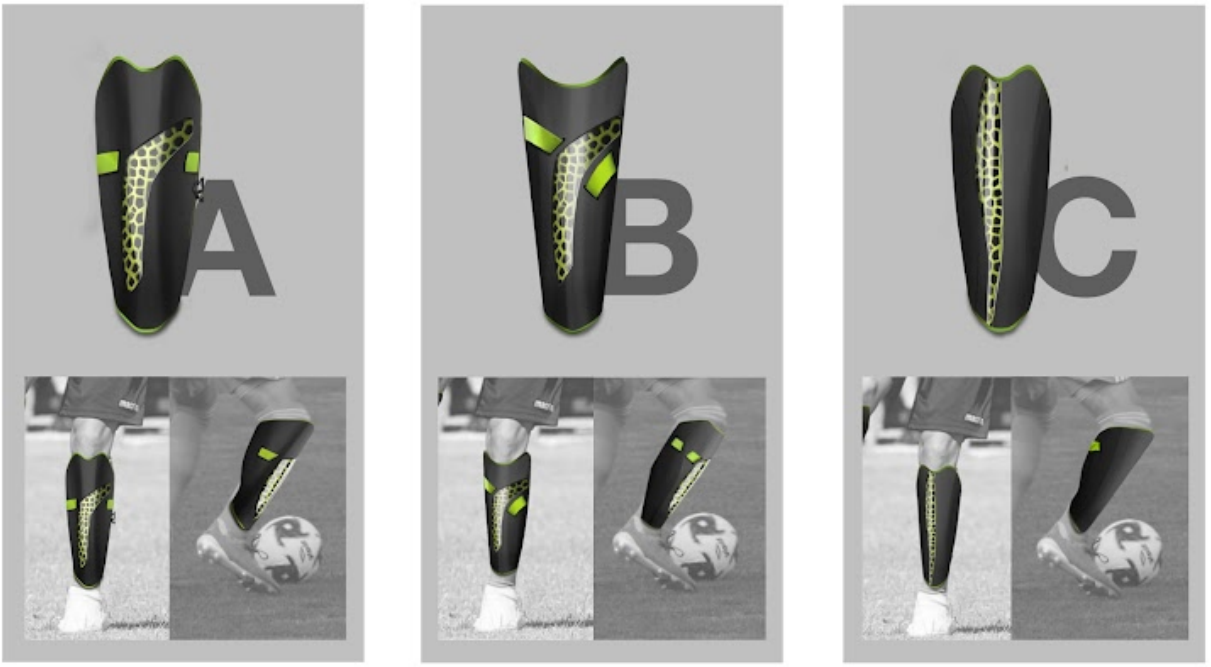
Hello! Thank you for taking the time to complete this short survey. I am designing a shin guard for young football players that need a little more protection and coverage and I would like for it to fit your style.
(This survey will take less than 2 minutes)

1. I am a...

   Markeer slechts één ovaal.

   - ◯ Boy
   - ◯ Girl
   - ◯ Anders: _____

2. Which shin guard do you prefer?



Markeer slechts één ovaal.

- A *Ga naar vraag 11*
- B *Ga naar vraag 7*
- C *Ga naar vraag 9*

3. What about it do you like?

Vink alle toepasselijke opties aan.

- [ ] The straps
- [ ] The window in the middle
- [ ] The general shape
- [ ] Anders: _____

4. What do you not like?

Vink alle toepasselijke opties aan.

- [ ] The straps
- [ ] The window in the middle
- [ ] The general shape
- [ ] Anders: _____

Least Liked Design

5. Which one do you like the least?

Markeer slechts één ovaal per rij.

	A	B	C
I don't like:	⬭	⬭	⬭

6. Would you wear any of these shin guards when playing soccer? Please explain your reasons.

_____

B.

7. Which color option best suits you?

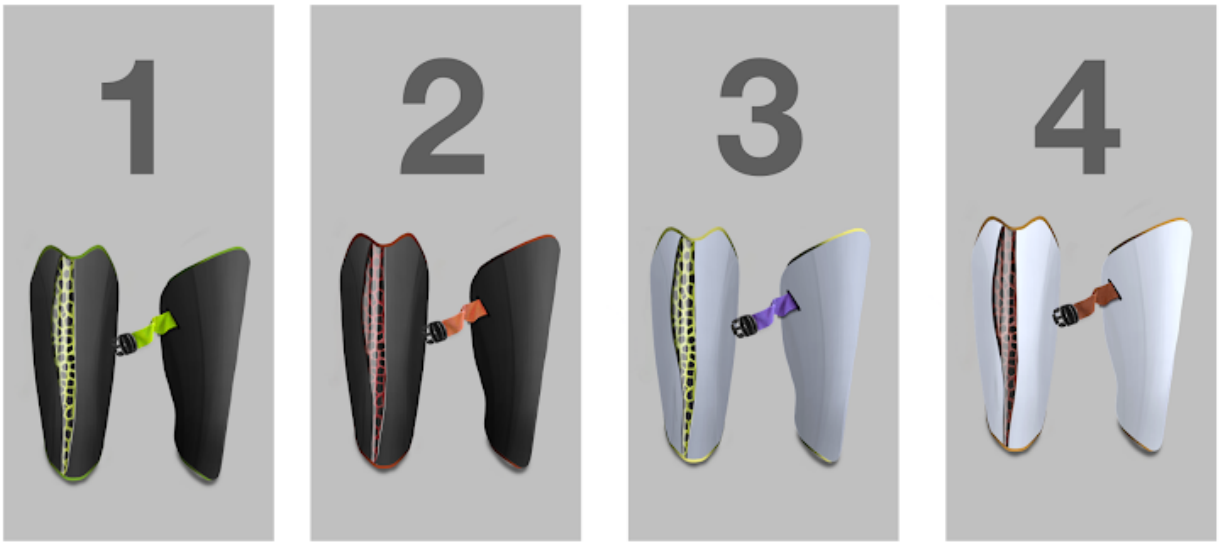
Markeer slechts één ovaal per rij.

	1	2	3	4
I like:	◯	◯	◯	◯

8. Why do you prefer this one?

C.

9. Which color option best suits you?



Markeer slechts één ovaal per rij.

	1	2	3	4
I like:	◯	◯	◯	◯

10. Why do you prefer this one?

_____

_____

_____

_____

_____

A.

11. Which color option best suits you?

Markeer slechts één ovaal per rij.

	1	2	3	4
I like:	◯	◯	◯	◯

12. Why do you prefer this one?

J

Project Brief

Emotion Driven Redesign of Children's Lower Limb Prosthetics — project title

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

start date 28 - 02 - 2022 — 22 - 07 - 2022 end date

INTRODUCTION **

Please describe, the context of your project, and address the main stakeholders (interests) within this context in a concise yet complete manner. Who are involved, what do they value and how do they currently operate within the given context? What are the main opportunities and limitations you are currently aware of (cultural- and social norms, resources (time, money,...), technology, ...).

An estimated 230 children with lower leg difference live in the Netherlands. About 70% of them have a congenital deficiency, meaning a partial or total absence of skeletal elements of limbs at birth, and the rest have undergone amputations. The reasons for amputations vary from malignancies (37%), trauma (29%), infections or other pathology. (Rjinders et. al, 2001) In the United States, it is estimated that 25000 children live with limb loss. (Hall et. al, 2021)
Children with these kinds of significant limb differences wear prosthetics to participate in daily activities like walking, running and playing with peers. In order to find the correct solution for the child, they must undergo pediatric rehabilitation, which encompasses the selection and fitting of the suitable prosthetic device and the following treatment. A multidisciplinary team is instrumental in this process, including physical therapists, device makers, technicians and teachers. The social environment of the child like parents, siblings and friends can play an important role as well. (De Hoogstraat)
The proportion of children with limb differences is very small compared to adults. For example, in the US, children account for 1.6% of the persons living with the loss of a limb. While there is a lot of innovation in prosthetics, this smaller market results in a smaller number of solutions available to children. In addition to this, children grow quickly, resulting in a need for rapid limb changes. Another factor hindering the variety of products suitable for children is the restrictions in weight and need for different activities. For example, microprocessor powered knees improve stability and safety, but it is very difficult to produce smaller versions of these. (Hall et. al, 2021)
Ossur provides the leading technological solutions for prosthetics, bracing and supports. Ossur's junior line is suitable for children between the ages 5 and 12, and focuses on movements specific to children and their anatomy. (Ossur, 2021) Prosthetics such as feet are made from silicone and carbon fiber for lightweight construction and shock absorption. Most of their offerings are suitable for high and extreme impact, suitable for walking and jogging as well as sprinting and long distance running. The Junior line is unisex and comes in four sizes. They currently offer two liners, one knee and five feet products for juniors. Products in this line are highly sophisticated and innovative in technology, but the personal relationship the wearer constructs with the prosthetic has not been investigated in detail. The wearer of the prosthetics has a close relationship with it as they must interact with it daily. Their own opinions on the form and interactions they have with the product, as well as the opinions of others around them color how they feel towards the prosthetic limb. The complex and multi faceted emotional response and attachment the wearer has with the product presents a new opportunity space in its design. As it is previously uninvestigated, solutions stemming in this field can provide a significant increase in quality of life for the wearer.

Rijnders, L. J. M., Boonstra, A. M., Groothoff, J. W., Cornel, M. C., & Eisma, W. H. (2000). Lower limb deficient children in the Netherlands: epidemiological aspects. Prosthetics and Orthotics International, 24(1), 13-18.
Kind & ouder. De Hoogstraat Revalidatie. (n.d.). Retrieved February 24, 2022, from https://www.dehoogstraat.nl/kind-en-ouder/
Ossur. (2021). Prosthetic Solutions 2021 Catalogue. Ossur.
Hall, M. J., Wustrack, R. L., & Cummings, D. R. (n.d.). Innovations in Pediatric Prosthetics.

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introduction (continued): space for images

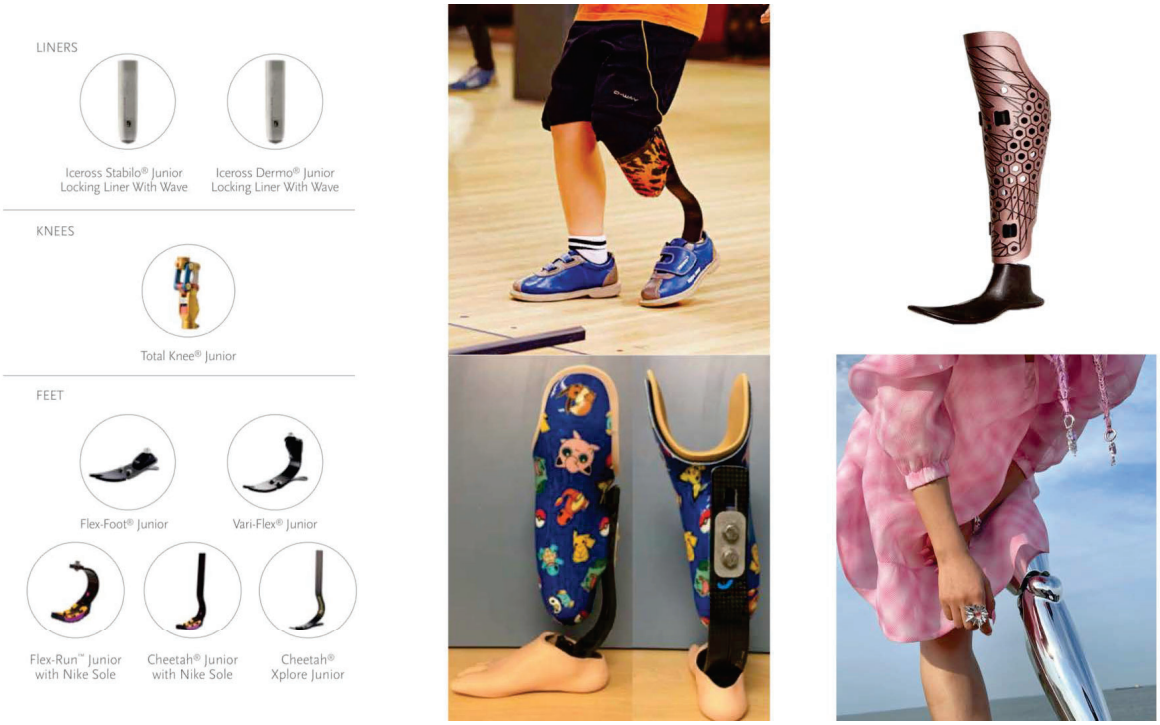


image / figure 1: Ossur Junior Products (Left) Varying prosthetic lower limb solutions

TO PLACE YOUR IMAGE IN THIS AREA:

- **SAVE THIS DOCUMENT TO YOUR COMPUTER AND OPEN IT IN ADOBE READER**
- **CLICK AREA TO PLACE IMAGE / FIGURE**

PLEASE NOTE:

- **IMAGE WILL SCALE TO FIT AUTOMATICALLY**
- **NATIVE IMAGE RATIO IS 16:10**
- **IF YOU EXPERIENCE PROBLEMS IN UPLOADING, COVERT IMAGE TO PDF AND TRY AGAIN**

image / figure 2:

PROBLEM DEFINITION **

Limit and define the scope and solution space of your project to one that is manageable within one Master Graduation Project of 30 EC (= 20 full time weeks or 100 working days) and clearly indicate what issue(s) should be addressed in this project.

The impact of prosthetics in providing mobility to children with limb differences is immense. This impact can overshadow smaller feelings of discomfort or dissatisfaction in the evaluation of the product. Micro-level emotions children experience when interacting with the product might hinder their comfort and satisfaction day to day. On a larger scale, these interactions affect the confidence and wellbeing of the children. It becomes crucial to understand how they view their prosthetics and ensure that it can be a source of pride and can facilitate their socialization with peers.

In order to serve the emotional needs of the wearer, technological innovations in the current Junior prosthetics need to be bridged with the priorities and values of the target group. Informing the design processes with the motives, values and expectations of the wearer enables Ossur to meet the psychological needs alongside physical ones. The embodiment of this ideal entails decisions in material choice, ergonomics, forms and how these shape the interactions the user has with the prosthetics.

Therefore, the scope of the project is defined by the following research questions: What are the typical daily scenarios children with limb differences go through in relation to their prosthetic devices? What are the primary concerns and motivations of child prosthetics wearers when interacting with the prosthetics? How do their concerns and motivations change in different daily scenarios (e.g., when alone and in social situations)?

ASSIGNMENT **

State in 2 or 3 sentences what you are going to research, design, create and / or generate, that will solve (part of) the issue(s) pointed out in "problem definition". Then illustrate this assignment by indicating what kind of solution you expect and / or aim to deliver, for instance: a product, a product-service combination, a strategy illustrated through product or product-service combination ideas, ... In case of a Specialisation and/or Annotation, make sure the assignment reflects this/these.

I am going to research the relationships of children with a lower limb difference to their prosthetic limb. I will utilize insights obtained to design a product that illustrates a strategy for pursuing an emotion based design approach that meets fundamental psychological needs of the children. The result will be a design of a physical product feasible to adopt in the near future and a product development strategy that increases the desirability of the product.

The project consists of three main phases: research, synthesis and design. In the research phase, I will investigate associations, values and priorities of children wearing prosthetics through an in depth interview process with a small number of users. In the synthesis phase, these qualities are abstracted away and generalized into guidelines for design that focus on the fundamental psychological needs of children. In the design phase I plan to generate storyboards that reflect how the interaction of the wearer and the prosthetics is envisioned to change and form a design vision. From here I will redesign the product per the guidelines. The redesign also encompasses validation, where I study the extent to which the product can embody personal and emotional qualities it targets through interviews with initial participants and further target group members.

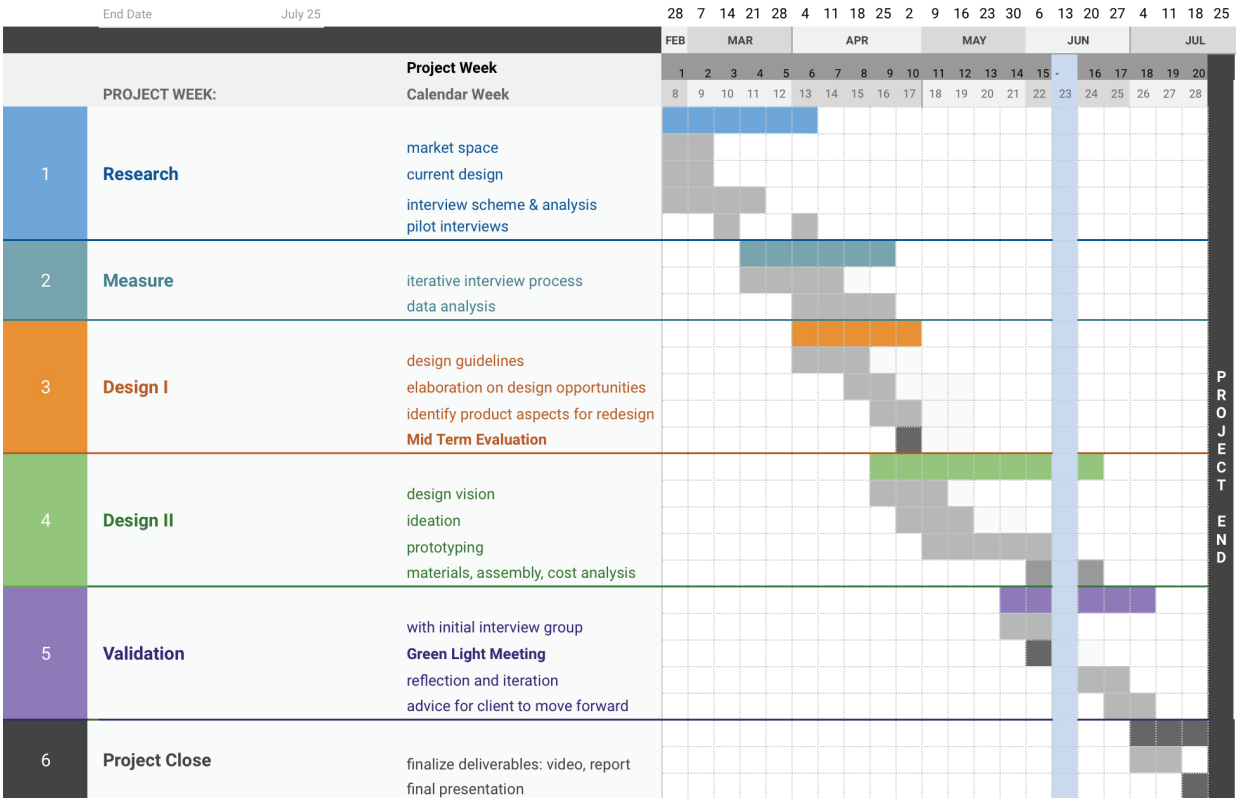
Initials & Name Demir Student number 5046718

Title of Project Emotion Driven Redesign of Children's Lower Limb Prosthetics

PLANNING AND APPROACH **

Include a Gantt Chart (replace the example below - more examples can be found in Manual 2) that shows the different phases of your project, deliverables you have in mind, meetings, and how you plan to spend your time. Please note that all activities should fit within the given net time of 30 EC = 20 full time weeks or 100 working days, and your planning should include a kick-off meeting, mid-term meeting, green light meeting and graduation ceremony. Illustrate your Gantt Chart by, for instance, explaining your approach, and 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 activities.

start date 28 - 2 - 2022 22 - 7 - 2022 end date



Project is scheduled to be pursued for 20 weeks. One week holiday is planned strategically in the middle of the design phase, where an initial prototype can be sent to the company abroad for them to conduct their own validation and provide feedback in direction.

A large part of this project is in depth, personal data collection from selected participants. Their in depth and personal accounts accompanied with market and literature research will form the general guidelines. This is a design method that the research of my supervisor focuses on. The method will require significant time in developing the right interview questions and experience sampling methods, which is why it consumes a lengthy period in the project timeline. In addition, the research participants are children, which means specialized rules apply in terms of Human Research Ethics. In the initial research phase, it is of utmost importance to prepare the HREC application and obtain approval before the "Measure" phase of the project.

Initials & Name Demir Student number 5046718

Title of Project Emotion Driven Redesign of Children's Lower Limb Prosthetics

MOTIVATION AND PERSONAL AMBITIONS

Explain why you set up this project, what competences you want to prove and learn. For example: acquired competences from your MSc programme, the elective semester, extra-curricular activities (etc.) and point out the competences you have yet developed. Optionally, describe which personal learning ambitions you explicitly want to address in this project, on top of the learning objectives of the Graduation Project, such as: in depth knowledge a on specific subject, broadening your competences or experimenting with a specific tool and/or methodology, ... Stick to no more than five ambitions.

The IPD programme in my experience focuses on thinking about products with a feasibility and viability perspective. In design classes I struggle with forming design visions and brainstorming when taking these as a starting point. I get stuck on practical considerations and cannot come up with creative solutions that can actually be more efficient or stronger, which points to a rigidity in my thinking.
My program made me realize that I want to approach design from an individual, highly personal perspective in initial development, then navigating the embodiment with the added challenge of preserving these qualities in a practical setting. I hope to be able to expand my thinking processes. In the elective space I had some classes that helped me with this. For example, Design for Emotion sensitized me to how design can be informed by emotions, psychological needs and motives. Lifestyle focused on design requirements as formed by the cultural customs, rituals and values of groups. Introspective design taught me how to rely on my own intuition as a tool to guide the design process.
I would like to practice theories I find compelling in these spaces and experiment with creating my own processes and methodologies as a designer. As a practicing design engineer, I observed these parts are often the first to be dropped in practical restrictions such as cost and time. This high level ambition translates itself to my graduation project, redesigning lower limb prosthetics for children with limb differences, taking the emotional reactions of the child as a starting point for design. Specific ambitions I have in relation to this are:
Visualization. Graphical representation of stories, context and product and person behavior. Realistic product rendering in relation to the user. CAD work in surface based programs in a dynamic way rather than parametrically.
Communication. Let go of waiting to achieve the perfect result and present ideas in earlier phases and use this input to steer my work. In addition, learn to be organized in leading meetings and communicate requirements, expectations and updates in a clear and timely manner.
Formgiving. Practice translating abstract concepts of emotions and personal motives into physical design features and requirements.

FINAL COMMENTS

In case your project brief needs final comments, please add any information you think is relevant.

Initials & Name Demir Student number 5046718

Title of Project Emotion Driven Redesign of Children's Lower Limb Prosthetics

K

Human Research Ethics Application Materials

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.

I. Applicant Information

PROJECT TITLE:	**Emotion Driven Redesign of Children's Lower Limb Prosthetics**
Research period: *Over what period of time will this specific part of the research take place*	**28 March - 1 July 2022**
Faculty:	**Industrial Design Engineering**
Department:	**Design Aesthetics**
Type of the research project: *(Bachelor's, Master's, DreamTeam, PhD, PostDoc, Senior Researcher, Organisational etc.)*	**Master's**
Funder of research: *(EU, NWO, TUD, other – in which case please elaborate)*	**Ossur**
Name of Corresponding Researcher: *(If different from the Responsible Researcher)*	**Asli Demir**
E-mail Corresponding Researcher: *(If different from the Responsible Researcher)*	**a.demor@student.tudelft.nl**
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*	**Dr. Haian Xue**
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*	**h.xue@tudelft.nl**
Position of Responsible Researcher : *(PhD, PostDoc, Associate/ Assistant/ Full Professor)*	**Assistant 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)
Children with lower limb differences sometimes use prosthetic devices for cosmetic reasons and to increase their mobility. As the market is very small, design development in this area has been limited. For identifying future directions for product development in children's prosthetics, 2-3 children with lower limb prosthetics will be observed in a classroom or home setting with the caregiver present. If in a classroom setting, other children who are in the class will be observed as well. Later, semi structured interviews with children, parents, teachers and other caregivers will be conducted to collect information on their daily activities and their view of the prosthetic device. The research is funded by Ossur but they only will have access to information submitted in the Graduation Project, no raw data.

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)
n/a

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 alignment 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*	**X**		**Ossur, the client in this graduation project, is a company that produces prosthetic limbs. The company could request access to all data collected as a part of this research. This would put the children at risk of being identified as raw data contains video and photos of children collected as a part of the observation and interview processes.**	**The graduation agreement ensures that Ossur is only entitled to the material in the final graduation report and advice on design work. This agreement ensures that Ossur will not have access to raw data collected that contains any identifiable information.** **The participants and parents will be informed that this research is in collaboration with Ossur in the ICF. To ensure privacy of children, any data regarding the children is anonymized by the corresponding researcher: names are changed and faces blurred within one week of collecting the data and the originals deleted.**	I.3 IV.9 IV.10	A3 B7 B9
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*		**X**				

			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**
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*		**X**				
B: Location						
4. Will the research take place in a country or countries, other than the Netherlands, within the EU?		**X**				
5. Will the research take place in a country or countries outside the EU?		**X**				
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?		**X**				
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,).	**X**		Children are not able to legally give consent. Data collected could potentially put the children at risk of being identified.	**The primary participants are children with limb differences. Informed consent of the parent is collected digitally at least one week before any research activity can be conducted. The parents will always be present in home sessions and teachers when in school and physicians if in the rehabilitation center. All caretakers are informed of the research activity to be conducted in advance.**	IV.8A IV.8B IV.16	Parental ICF (Section A, B9)
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?		**X**				
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).*		**X**				
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		**X**				

			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**
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	**X**		**Children living with limb differences and their parents could feel stigmatized, or that their information is used in ways they did not consent to if the researchers directly reach out to participants found in online support groups. It is of utmost importance that participants feel that their participation in research is voluntary, and that information they share with the intention to connect with others in similar situations is not misused.**	The participants are contacted through a gatekeeper. The network of Ossur, as well as online search is utilized to identify potential hospitals and rehabilitation centers. The centers found online will only be contacted if they provide contact information on their websites for informative purposes. The personnel of these centers will identify potential participants, and contact their parents to inform them of this voluntary study. Only if parents volunteer to participate, their information can be shared with researchers. The initial contact document is used to inform the parents and personnel.	I.3	A1, A2 & See Practical Information Document
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)		**X**				
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?		**X**				
14. Will you be offering any financial, or other, remuneration to participants, and might this induce or bias participation?		**X**				
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		**X**				
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*		**X**				
17. Will blood or tissue samples be obtained from participants? *If yes see here to determine whether medical ethical approval is required*		**X**				

			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**
18. Does the study risk causing psychological stress or anxiety beyond that normally encountered by the participants in their life outside research?		**X**	**There is no intention of causing stress or anxiety but the effect of the presence of an observer in a classroom, or of questions asked in interviews to different individuals is hard to predict. The questions asked to children, parents, teachers or other caretakers will only be about the daily activities of the children and how they might be emotionally responding to daily situations. Because the researcher is strongly motivated to ensure the wellbeing of the participants, a mitigation plan is put in place even if this risk is not probable.**	**Research activities are determined in collaboration with the supervisory team. Any research activity first needs to be approved by the legal and liability teams in Ossur. Afterwards, they are presented to teachers and parents, and their approval of the research activity is necessary before it can be conducted. The parents will be informed of the activity 1 week in advance by the corresponding researcher, and her contact information will be available in the case that the parent would like to modify or give feedback on certain questions, research material used or activities conducted.**	**III.8B III.10 III.11 III.16**	**B6**
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)	**X**		Data relating to children is considered personal sensitive data. The risks involved as well as how the data is handled is covered in sections A1 and D11 of this document.	The risks involved as well as how the data is handled is covered in sections A1 and D11 of this document. If video recording is found appropriate, it will only be recorded in the presence of the caretaker (parent at home and teacher at school). These parties will be invited to review the footage immediately after it is taken and can choose for it to be kept for processing and anonymization or ask for it to be deleted immediately.	**III.6 III.8B III.10 III.11 III.16 III.18-20**	A3, B6, B9
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)		**X**				
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*	**X**		Data relating to children is considered personal sensitive data so the Privacy team saw fit that DPIA was conducted.	DPIA advice has been attached.		
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.*		**X**				
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.*		**X**				

			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**
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).		**X**				
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).		**X**				
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?		**X**				
27. Will the experiment involve the use of devices that are not 'CE' certified? *Only, if 'yes': continue with the following questions:*		**X**				
• 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?	**X**		**Covid could be spread from the researcher to the participants, which is a significant health risk.**	**Before an in-person meeting, the corresponding researcher will inform the parents of the precautions they will be taking in the informed consent form, and make their contact information available to parents for follow up questions. For in person research, the researcher will take all precautions advised by the RIVM including vaccination, ventilation, 1.5m social distancing and wearing masks when indoors. Any materials the participant will come in contact with in the scope of the researches to be disinfected and left in its package for 7 days before it comes into contact with participants. Each participant will get their own packages and no material will be reused between participants to prevent cross-contamination.**		**Opening Statement**
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**		**X**				

			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**
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)	**X**		**Having this data publicly accessible poses significant safety risks for the children, and emotional stress and anxiety for adults.**	**This data will only be stored in the Project Storage Drive set up by the TU Delft and only be accessible to Asli Demir.**		**A10, A11**
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?	**X**		Demographic information such as age and gender of children will be collected. In addition to this, some observation sessions will be recorded and participants are asked to submit photos and videos of daily tasks. Information regarding children's emotions is also collected from parents and other caretakers.	**Data will only be collected directly in research activities with the participants and their caretaker. Only data with informed consent of the parents will be collected. The anonymization of raw data is covered in sections A1 and D11 of this document. Handling of personal data in public documents is covered in section G33 of this document.**	**III.6 III.8B III.10 III.11 III.16 III .18-20**	Opening Statement, A9
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		**X**				
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?	**X**		The research is to be published in the TU Delft Repository in compliance with TU Delft graduation requirements. This poses the risk of identification to children who cannot legally give informed consent. As this is the most significant risk in the research, the handling of raw data and any information to be included in the graduation project documentation is covered in this document.	The anonymization of raw data is covered in sections A1 and D11. Before submitting materials to the TU Delft Repository, the researchers will send all materials to be made public to the parents of the children whose information is used in the graduation project documentation. **Parents need to submit a written approval, such as an email to the researcher, of data used pertaining to the participant included in publicly accessible documents such as masters thesis and any literature prepared for the company.**	VI	D15, D16
34. Will your research data be archived for re-use and/or teaching in an open, private or semi-open archive?		**X**				

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)
Asli Demir

Signature of Corresponding Researcher: 

Date: March 9th, 2022

Name of Responsible Researcher (print)

Signature (or upload consent by mail) Responsible Researcher:

Date:

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

Emotion Driven Design of Lower Limb Prosthetics

0. Administrative questions

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

My faculty data steward, Jeff Love, has reviewed this DMP on March 4th, 2022.

2. Date of consultation with support staff.

2022-03-04

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
Handwritten Notes	.docx, .pdf. .txt	recording during interviews and observation sessions	Keep an account of findings relevant to the research & orient the video and audio records	Project storage drive and design notebook	Asli Demir. The notes will be transcribed or otherwise digitized (in photos or digital drawings) and any personal information (names, ages of participants) will be psudeonymized

Contact list of participants	.csv	through gatekeeper organization after participants agree to participate in the reseach	Documentation of contact information to reach out for research activities	project storage drive	Asli Demir
Photos	.png, .jpeg	recording during interviews and observation sessions, asked from participants to be collected after filling out Informed Consent Form	Used in developing insights and expressing daily problems the user encounters	personal device for interim storage prior to anonymization (1 week max), later Project Storage Drive	only Asli Demir will have access to raw data as it might contain confidential and private information. Photos with personal information will be psudeonymized (faces blurred) within 1 week and originals will be deleted.
Video	.mp4, .mov	recording during interviews and observation sessions, asked from participants to be collected after filling out Informed Consent Form. Video recorded will focus on a detail and not have faces in it.	used in developing insights and expressing daily problems the user encounters. some video will be used in the final video deliverable required by the faculty for the submission of the graduation report.	personal device for interim storage prior to anonymization (1 week max), later Project Storage Drive	only Asli Demir will have access to raw data as it might contain confidential and private information. Photos with personal information will be psudonymized (faces blurred) within 1 week and originals will be deleted. Dr. Haian Xue and Maurizio Filippi will have access to some the anonymized data included in documentation. Video recording will be used conservatively, only when the researcher finds an audio recording not sufficient.

Audio	.mp3	recording during interviews and observation sessions, asked from participants to be collected after filling out Informed Consent Form	used in developing insights and expressing daily problems the user encounters. some video will be used in the final video deliverable required by the faculty for the submission of the graduation report.	personal device for interim storage prior to anonymization (1 week max), later Project Storage Drive	only Asli Demir will have access to raw data as it might contain confidential and private information. Photos with personal information will be psudonymized (faces blurred) within 1 week and originals will be deleted. Dr. Haian Xue and Maurizio Filippi will have access to some the anonymized data included in documentation.

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

- < 250 GB

As this project requires the collection of sensitive information (photos of children with the consent of the parent), the researcher must first fully anonymize the data (blur faces and remove names) before it can be put in the Project Storage Drive. I intend to mitigate the risk of this information to be accessed by others by putting a time constraint on for how long this data prior to anonymization can be saved for before it is permanently deleted, which is 7 days from recording.

II. Documentation and data quality

5. What documentation will accompany data?

- Other - explain below
- README file or other documentation explaining how data is organised
- Methodology of data collection

Data will be organized by location and date of data collection. Documentation that arises in the process of graduation work (reports, visuals) will also be stored here.

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, ask your Faculty Data Steward for advice. You can also check with the privacy website or contact the privacy team: privacy-tud@tudelft.nl

- Yes

The HREC application is in progress for the study!

8B. Will you work with any 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.

- Yes, data which could lead to reputation/brand damage (e.g. animal research, climate change, personal data)

I will be working with children and collecting visual documentation on their daily activities, which is considered personal sensitive data as they are not able to legally give consent. This will only be done with the consent of the parent though the Informed Parental Consent Form. Related risk mitigation and data storage concerns are being covered either here or in the HREC checklist.

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.

IP rights are managed though an NDA and a student-company agreement. The participant hold the copyrights to any photos/videos they might be taking and give consent for them to be used in the graduation project through ICFs.

I, as the graduation student am considered the owner of the data and can choose to provide access to relevant stakeholders previously specified. Only data selected to be in the graduation report, which I am obligated to publish in the TU Delft Repository will be shared publicly, and with the approval of the participants and company Ossur.

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

- Data collected in Informed Consent form (names and email addresses)
- Signed consent forms
- Photographs, video materials, performance appraisals or student results
- Gender, date of birth and/or age
- Email addresses and/or other addresses for digital communication
- Telephone numbers
- Names and addresses

11. Please list the categories of data subjects

Children living with limb differences making use of a prosthetic device. Peers, parents, healthcare professionals and teachers in contact with the children mentioned.

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 participants, or parents/legal guardians of the participants, must sign an Informed Consent Form written by me and approved by Dr. Haian Xue and the legal team of company Ossur. They will be informed that their involvement in this study is on a voluntary basis.

17. Where will you store the signed consent forms?

- Same storage solutions as explained in question 6

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.

- Data concerning vulnerable data subjects

DPIA has been completed and Privacy Team advice has been reported in question 20 of this section.

19. Did the privacy team advise you to perform a DPIA?

- Yes

20. Please include below the outcome of the DPIA, what measures did you take?

Additional measures taken:

- data will be encrypted in the Project Storage Drive and secured with a password
- all instances of anonymized have been changed to psudonymized as even though no names of the participants are recorded in the data and no reseachID/code is assigned, considering the participant pool is very small, is could be relatively easy to trace the data back to the individual persons and therefore cannot be considered anonymized.
- Specified how parents will send photos to be included in the research. They will upload their images to Sharepoint, to a file only they and I(Asli Demir) have access to.
- Specified that all children participating children, including the peers of participants are considered a part of the research and their parents need to sign an Informed Parental Consent Form to be able to participate in any interviews or observation sessions, and for any photo to be made that includes their children.
- Specified that employees of Ossur do not have access to any research data of the participants that is not included in the graduation report. Even in this case, the parents need to approve the section of the report that might contain information regarding their children (i.e the Research or Validation sections) before it can be shared with Ossur before it can be shared.

21. Where will you store the DPIA documents (document on data processing features and document on risk assessment)?

- Same storage solutions as explained in question 6

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

- Personal research data will be destroyed after the end of the research project

I have no intention to keep or share any data regarding this project. I am required to put my Graduation Report on the TU Delft repository. No data beyond what is included in the report is shared with anyone else. All data on the report is psudonymized and needs to be approved by the parents of the participants before it can be submitted to the repository.

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) underlying published articles / reports /

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

Only data that might be stored will be in the TU Delft Repository as a part of the graduation report. No other data will be stored.

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

- No data can be publicly shared - please explain below

Only data that might be stored will be in the TU Delft Repository as a part of the graduation report. No other data will be stored or shared.

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

The graduation topic is given by Ossur. Ossur will be a part of the midterm and green light meetings, and receive project updates on findings and give some feedback. All data that can be shared will be in accordance with the processes and regulations outlined in the Informed Consent Forms signed by the participants or their parents.

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

Only data that might be stored will be in the TU Delft Repository as a part of the graduation report. No other data will be stored therefore will need to be managed in the long term.

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)?

The data is considered sensitive so the data collected will not be accessible as a dataset. Some data might be used in the graduation report that will be in the TU Delft Repository. In this case, the approval of the participants or their parents (when applicable) will be sought before it can be put on this public platform.

I have a responsibility towards the vulnerable group to protect their information and

ensure their safety so any data I collect is not intended to be reused.

Participant Informed Consent Form

You are being invited to participate in a research study titled Emotion Based Redesign of Children's Lower Limb Prosthetics. This study is being done by Asli Demir from the TU Delft in collaboration with Ossur as a part of a graduation project at the TU Delft Faculty of Industrial Design Engineering. Ossur is a company producing non-invasive orthopedic solutions and will potentially use the insights gathered in this research project to guide future product development.

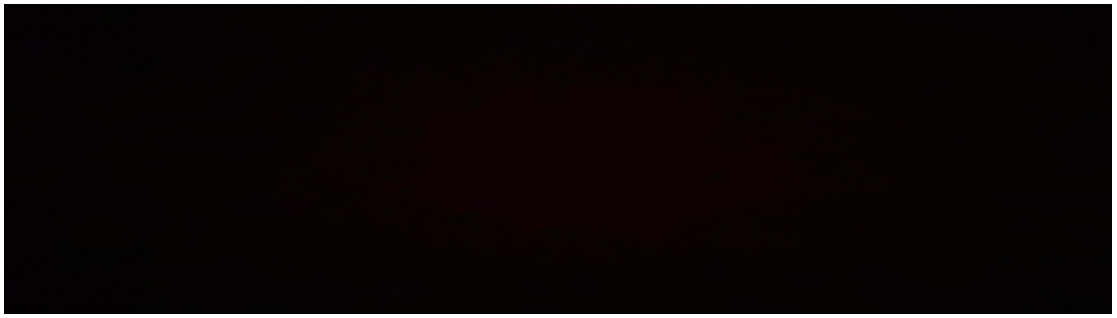
Description
The purpose of this research study is to understand the daily life and routines of children with lower limb differences, and emotions they experience in relation to their prosthetic devices. The research will span 4 weeks and include observation sessions as well as 30 minute interviews each week with the children, their primary caretakers as well as teachers and healthcare professionals. The data will be used to form guidelines and design concepts for guiding future directions for product development in the field of children's lower limb prosthetics. We will be asking you to:

- Participate in semi-structured interviews about your daily life
- Participate in observation sessions where a researcher will be taking notes regarding your daily activities
- Receive some assignment to work on at home, such as take photos and short videos of daily activities and products used day to day

Confidentiality
As with any online data storage activity the risk of a breach is always possible. To the best of our ability your answers in this study will remain confidential. We will minimize any risks by anonymizing participants' data by covering their faces in photos and video and not including their names in any documentation to be made public.

Your participation in this study is entirely voluntary and you can withdraw at any time. You are free to omit any questions. You can ask for data to be removed at any time before the final document is submitted for approval at the end of the study on July 1st.

You can reach out to the researchers with any questions or reservations regarding the research.



Explicit Consent points

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
A: GENERAL AGREEMENT – RESEARCH GOALS, PARTICIPANT TASKS AND VOLUNTARY PARTICIPATION		
1. I have read and understood the study information dated [*DD/MM/YYYY*], or it has been read to me. I have been able to ask questions about the study and my questions have been answered to my satisfaction.	☐	☐
2. I consent voluntarily to be a participant in this study and understand that I can refuse to answer questions and I can withdraw from the study at any time, without having to give a reason.	☐	☐
3. I understand that taking part in the study involves: [*see points below*]	☐	☐
• *Observation sessions with written notes* • *Observation sessions with audio and video recording* • *Video recorded interviews* • *Photographs and video captured by research participants themselves* *Audio and video recordings made during interviews and observation sessions will be transcribed as text and the recording will be destroyed at the end of the study. In the case that the researcher would like to use a video still or a clip in public documentation, the personal data (face and name) of the participant will be anonymized.*		
4. I understand that I will not be compensated for my participation	☐	☐
5. I understand that the study will end July 15th, 2022.		
B: POTENTIAL RISKS OF PARTICIPATING (INCLUDING DATA PROTECTION)		
6. I understand that taking part in the study involves the following risks […]. I understand that these will be mitigated by […]	☐	☐
• *Psychological stress or anxiety. You can ask for the interview or observation to stop at any point. Prior to the activity, the observation and interview activities will be reviewed by Ossur's internal legal team as well as personnel in the team who recruited you for this study. You will be informed of the research activity to be conducted 1 week before it can take place, in the contact method of your choosing.*		
7. I understand that taking part in the study also involves collecting specific personally identifiable information (PII) [name and contact information] and associated personally identifiable research data (PIRD) [written accounts of daily activities] with the potential risk of my identity being revealed	☐	☐
8. I understand that some of this PIRD is considered as sensitive data within GDPR legislation, specifically [*see points below*]	☐	☐
List the relevant issues: eg: • *religion, political views* • *Data concerning criminal activities will/may be collected and processed* • *Research has a Data Processing Impact Assessment (DPIA) in place*		
9. I understand that the following steps will be taken to minimize the threat of a data breach, and protect my identity in the event of such a breach […]	☐	☐
• *Data collected regarding children will be anonymized within 1 week of collection and raw data will be deleted. Faces of children will be blurred and audio recordings will be transcribed. All research data will be stored in a secure storage with access limited to Asli Demir.*		
10. I understand that personal information collected about me that can identify me, such as *my name or where I live*, will not be shared beyond the study team.	☐	☐
11. I understand that the (identifiable) personal data I provide will be destroyed within 6 months of collection	☐	☐
C: RESEARCH PUBLICATION, DISSEMINATION AND APPLICATION		

PLEASE TICK THE APPROPRIATE BOXES	Yes	No
12. I understand that after the research study the de-identified information I provide will be used for reports and publications.	☐	☐
13. I agree that my responses, views or other input can be quoted anonymously in research outputs	☐	☐
14. *Copyright of the works I provide such as images, videos and written works belong to me, and I give permission for them to be used for the purposes of this research.*	☐	☐
D: (LONGTERM) DATA STORAGE, ACCESS AND REUSE		
15. I give permission for the de-identified *images and quotes* that I provide to be archived in the TU Delft Graduation Project repository so it can be used for future research and learning.	☐	☐
16. I understand that access to this repository is open.	☐	☐
If different from Explicit Consent points 8 and 9 above: • • *Specify in which form the data to be stored will be deposited, e.g. anonymised transcripts, audio recording, survey database, etc.; and if needed repeat the statement for each form of data you plan to deposit.* • *Specify whether deposited data will be anonymised, and how. Make sure to describe this in detail in your Opening Statement* • *Specify whether use or access restrictions will apply to the data in future, e.g. exclude commercial use, apply safeguarded access, etc.; and discuss these restrictions with the repository in advance.* • *Include when the data will be deleted – or provide criteria for when and how that decision will be made*		

Signatures

_____ _____ _____

Name of participant [printed] Signature Date

I, as legal representative, have witnessed the accurate reading of the consent form with the potential participant and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

_____ _____ _____

Name of witness [printed] Signature Date

I, as researcher, have accurately read out the information sheet to the potential participant and, to the best of my ability, ensured that the participant understands to what they are freely consenting.

_____	_____	_____
Asli Demir	Signature	Date

[redacted]on:

Practical Information for Parents, Schools and Medical Professionals about the project "Emotion Based Redesign of Children's Lower Limb Prosthetics"

Project Description

Children differ from adults in anatomy, activities they partake in as well as their view of themselves, and children with limb differences are no exception. This design project aims to explore how children with living lower limb differences view their prosthetic devices, and how their expectations change in different daily scenarios. The project is supported by Ossur, a non-invasive orthopedics company based in Iceland.

The purpose of this research study conducted in the context of the design project is to understand the daily life and routines of children with lower limb differences, and emotions they experience in relation to their prosthetic devices.

For the period March - July I am looking for children between the ages of 8-12 who have lower limb differences and are using prosthetic devices to participate in this research activity. Their parents, peers, teachers and medical professionals working with them are also invited to join this research.

Research Activities

The main part of the research will span 4 weeks in April 2022 and include observation sessions as well as 30 minute interviews each week with various caretakers as well as the children. The participants might be contacted later on to express their opinions regarding the concepts developed in May and June 2022 on a volunteer basis. The data collected in the study will be used to generate product design guidelines and concepts to guide future directions for product development in the field of children's lower limb prosthetics.

The research will include the following activities:

- Observation of children and their peers in social environments such as the classroom with the permission of their teacher.
- Semi-structured interviews with children regarding their daily activities.
- Semi-structured interviews with parents, teachers and healthcare professionals regarding the daily activities, behavior and the emotional reactions of the children.
- Short, at-home activities such as taking photos and videos of products used, activities done, and written reflections for everyone involved
- For parents, short phone calls or emails for them to approve the interview activities to be conducted with their children each week.

If any of the participants wish, they can participate in the following product development process. In this process, they can exchange experiences and ideas to develop the guidelines to design for children with limb differences.

Project Outcomes

With this project, I hope to gain some understanding of how children view their prosthetic devices and how they can be designed to meet their psychological needs and serve their wellbeing better. End products of this project are:

- Toolbox for Ossur to conduct emotion based design research to design products that could better reflect the psychological needs of children
- Design concepts
- Documentation of the design process in a Master's thesis

During the observation sessions and the interviews, the researcher might ask to record video, audio or take photos. Any of the recordings collected will be treated with utmost respect for privacy and security of the children. None of this documentation could be published in publicly accessible channels without the consent of the parents.