The industrial design of a robotic device for upper-limb stroke rehabilitation.

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Abstract

Over 16.9 million people worldwide suffer a stroke annually (Feigin et al., 2014, p. 2). Up to 80% of stroke survivors suffer weakness or paralysis in one half of their body, frequently compromising their ability to lead an independent life (Alankus, Lazar, May, & Kelleher, 2010; Buma, Lindeman, Ramsey, & Kwakkel, 2010, p. 589). In order to promote recovery, stroke survivors are recommended to participate in rehabilitation through intensive and repetitive training (McLaren et al., 2020). Robotic rehabilitative devices are a promising tool in assisting stroke rehabilitation, increasing the ability for clinicians to treat more individuals, and facilitating the ability for rehabilitation to be completed at home. However, robotic rehabilitative devices are poorly accepted by users, and experience high levels of rejection and abandonment (Cruz, Emmel, Manzini, & Braga Mendes, 2016). Based on current models of acceptability, it is suggested that this low acceptability is derived from poor user perceptions of ease of use, usefulness, enjoyment, adaptivity, around robotic rehabilitative devices, as well as product-related stigma (Heerink, Kröse, Evers, & Wielinga, 2010; Vaes, 2014a). Instigated by this, this study adopted an empathic, user-centred design model that aimed to implement industrial design to improve the acceptability of these devices. This comprised of the extensive iterative redesign of an existing robotic rehabilitative device, with frequent engagement from stakeholders. This device, alongside the original device, was then tested through trials, questionnaires, and interviews. Results from our study indicate industrial design strategies facilitated meaningful improvements to many dimensions of acceptability. Furthermore, our research identified several novel connections between dimensions of acceptability, and that design may strongly influence them.

Dedication

To my Grandfather Captain Huáng Zhāng Sēn

I wish we could have spent more time together. I wish you had gotten to use this device when it was finished. I hope you're happy wherever you are now, and that this family continues to make you proud. Only in death does duty end, and we shall know no fear.

To my mother Diana

Words cannot describe the endless love, generosity, support, and patience you have shown me. I am everything I am today because of your nurturing and guidance. This thesis is the current capstone of your labours, and its achievements are as much yours as mine.

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Contents

Introduction

Stroke is the leading cause of disability in industrialized nations (Alankus et al., 2010, p. 2113). Up to 80% of stroke survivors suffer weakness or paralysis in one half of their body, compromising their ability to lead independent lives (Alankus et al., 2010; Buma et al., 2010, p. 589). Successful stroke rehabilitation depends on early, intensive, and repetitive treatment (Carr & Shepherd, 2011; McLaren et al., 2020), however with the the global stroke population outgrowing healthcare infrastructures (Feigin et al., 2014, p. 9), many stroke survivors are unable to access the resources required to facilitate recovery (Carr & Shepherd, 2011, pp. 1–2; Kimberly, Samargia, Moore, Shakya, & Lang, 2010; Lang, MacDonald, & Gnip, 2007; Xie, 2016, p. 2).

Robotic rehabilitative devices have been extensively described as a promising tool in addressing this issue. Their ability to function remotely and tirelessly significantly increases the number of PWS a clinician can treat simultaneously, and it has also been proposed that they could increase rehabilitation efficacy (Signal, Scott, Taylor, & Kayes, 2019; Xie, 2016, p. 4). However, these devices experience poor acceptance by users. Models of acceptability outline that acceptability of technology is determined by perceptive dimensions, such as ease of use, and usefulness (Heerink et al., 2010).

Industrial design is a practice which excels at shaping user perceptions (Shapiro, 2016; Tjalve, 2015). To date, few studies have investigated how industrial design can address the acceptability of robotic rehabilitative devices, illustrating an opportunity for investigation.

Chapter 1:
Background Research

Chapter Summary

This chapter outlines our investigation into stroke, and how robotic devices may benefit stroke rehabilitation. Our findings conclude that robotic devices are poorly accepted by users, which instigated further research on models of acceptability, and how industrial design may improve the user acceptance of these devices. Stroke

Stroke

Stroke is a neurological disorder that occurs when a blood clot or bleeding prevents blood flow to the brain, resulting in oxygen deprivation. This deprivation damages the brain's neurons, often resulting in cognitive, perceptual, sensory, and motor (movement) impairment (Alankus et al., 2010, p. 2113)

Stroke affects over 16.9 million people worldwide each year (Feigin et al., 2014, p. 2); and is the largest cause of disability among adults in industrialized nations (Alankus et al., 2010, p. 2113). Over 80% of stroke survivors suffer weakness or paralysis on one half of the body; known as hemiparesis or hemiplegia (Buma et al., 2010, p. 589; Levin, Kleim, & Wolf, 2009, p. 314; McLaren et al., 2020, p. 3237). Hemiparesis and hemiplegia often compromise a person with stroke's (PWS) capacity to lead an independent life, and complete activities of daily living (ADL) such as eating, bathing, and dressing (Alankus et al., 2010, pp. 2113–2114; Burke et al., 2009, p. 1085; Carr & Shepherd, 2011, p. 1). Beyond physical impairments, stroke often also leads to adverse effects on a PWS's emotional wellbeing, social participation, and their capacity to self-regulate (Rashid, Clarke, & Rogish, 2013; Sun et al., 2014).

Stroke Rehabilitation

In order to promote recovery after stroke, it is recommended that PWS participate in rehabilitation through intensive and repetitive training (Carr & Shepherd, 2011, p. 1; Kimberly et al., 2010, p. 851; McLaren et al., 2020). Rehabilitation facilitates restructuring of the neural pathways damaged by stroke through a process known as neural plasticity (Carr & Shepherd, 2011, p. 1; Kleim, 2011; Levin et al., 2009, p. 316; Luster et al., 2013, p. 1).

To facilitate effective stroke rehabilitation, previous literature has recommended between 160-2000 exercise or task repetitions be undertaken per session, and for regimes to include several sessions per week (French et al., 2016, pp. 35, 48; Kimberly et al., 2010, pp. 851–852, 857; Lang et al., 2007, p. 3). Rehabilitation regimes with fewer repetitions have been shown to output little to no improvement (Kimberly et al., 2010, p. 852).

Rehabilitation is most effective when implemented in the early stages of stroke recovery, known as the acute and sub-acute stages (Burke et al., 2009, pp. 1085–1086; McLaren et al., 2020, p. 3237). Previous literature has outlined that neural plasticity and recovery from motor impairment is greatest in the four-week period immediately following a stroke (McLaren et al., 2020, p. 3237; Timmermans, Seelen, Willmann, & Kingma, 2009, p. 2). Correspondingly, delaying rehabilitation has significant adverse effects. PWS treated later (21-150 days after stroke) have been found to have less functional independence in ADL (Salter et al., 2006); require longer stays in hospital (Salter et al., 2006); and experience more motor weakness than those treated earlier (Paolucci et al., 2000).

Significant motor weakness following stroke often leads to a variety of complications such as spasticity and disuse; which in turn lead to accelerated muscle atrophy and learned non-use (Ballester et al., 2016, p. 1; Carr & Shepherd, 2011, p. 1; Luster et al., 2013, p. 1; Ng & Shepherd, 2000, p. 228; Shaughnessy, Resnick, & Macko, 2006, p. 15). Learned non-use is a common phenomenon among PWS which manifests as artificial disability of the affected limb. Learned non-use occurs due to poor experiences using the affected limb, and dependence on the unaffected limb (Ballester et al., 2016, p. 1; Luster et al., 2013, p. 1; Taub & Uswatte, 2003, p. 35). If left untreated, learned non-use leads to further exacerbation of motor impairment even after motor neuron depression ends, often resulting in chronic disability (Luster et al., 2013, p. 1; Taub & Uswatte, 2003, p. 35). To counteract this, it is widely agreed that use of the affected limb must be initiated and sustained (Taub & Uswatte, 2003); emphasizing the need for PWS to rehabilitate early, intensively, and continuously.

Traditional stroke rehabilitation involves PWS performing exercise regimes with the assistance of a clinician often in a hospital or rehabilitation clinic (Xie, 2016, pp. 1–2). This process is expensive, time-consuming, and labour intensive; and is frequently needed for the majority of a PWS's life (Xie, 2016, p. 2). Consequently, PWS often do not receive sufficient time with clinicians to facilitate recovery (Carr & Shepherd, 2011, pp. 1–2; Kimberly et al., 2010; Lang et al., 2007; Xie, 2016, p. 2). This situation has been exacerbated by the global aging crisis, with the international population of PWS increasing many times faster than the growth of healthcare infrastructure (Duncan, 2017, p. 7; Scopelliti, Giuliani, & Fornara, 2005, p. 146; Ziefle & Wilkowska, 2010, p. 1).

In an effort to address the aforementioned issues, home-based rehabilitation has become increasingly popular, with early discharge and self-moderated rehabilitation being

promoted (Holmqvist et al., 1998; Lang et al., 2007, p. 8). In addition to reducing strain on healthcare resources, home-based rehabilitation has also been argued to be more effective than conventional rehabilitation (Holmqvist et al., 1998, p. 1). Outpatient Service Trialists (2003), in their review of over 1600 PWS, reported that those undergoing home-based rehabilitation, either from a therapist or self-moderated, experienced improved and sustained independence in ADL.

Despite these benefits, research has found engagement with self-moderated rehabilitation is often not sufficient to induce recovery. As few as 31% of PWS independently undertake exercises regularly (Shaughnessy et al., 2006); and 69% of PWS do not perform "as much exercise as they would like to" (Shaughnessy et al., 2006, p. 17). Other literature highlights that "little to no adherence to therapist-prescribed home exercises creates an impediment to stroke recovery" (Luster et al., 2013, p. 1). Consequently, PWS are unlikely to realise the full potential of their home-based rehabilitation.

To combat this, medical industries have developed assistive technology in the form of robotic devices for rehabilitation. Robotic devices for rehabilitation – when implemented appropriately – are an effective tool in rehabilitation regimes (Mazzoleni, Turchetti, Palla, Posteraro, & Dario, 2014; Wu et al., 2014; Xie, 2016). These devices significantly improve motor recovery in PWS by promoting improved and accelerated restoration of biomechanical capabilities; supplementing absent motor function; isolating joinery to generate complex and targeted rehabilitation movements; and enforcing quantity of movement (Dellon & Matsuoka, 2007, p. 30; Masiero, Celia, Rosati, & Armani, 2007; Xie, 2016). These devices range in complexity from motorized armskates designed for domestic tabletops to powered exoskeletons designed to complement the 650 muscles in the human body. The accelerated rehabilitation provided by these devices and their ability to function remotely and tirelessly significantly increases the number of PWS a clinician can treat simultaneously (Xie, 2016, p. 4).

Despite these potential benefits of rehabilitation robotics to PWS, clinicians, and healthcare systems, robotic rehabilitative devices have not been a 'silver bullet' solution. Questions have been raised regarding the acceptability of these devices, with many experiencing high rates of abandonment and rejection – especially by older adults, the devices' primary user demographic (Cruz et al., 2016; Gitlin, 1995; Jacobson, 2010; Scopelliti et al., 2005; Wu et al., 2014). "The lack of user's acceptance represents a critical obstacle to the success of innovative technologies" (Mazzoleni et al., 2014, p. 117), instigating the need to investigate the acceptability of robotic devices for stroke rehabilitation.

Acceptability

To elucidate semantics - medical technology is defined as technology utilized for medical purposes. Healthcare design is the process of designing healthcare items and systems; including medical technology (Ulrich et al., 2008). Medical technologies are further distinguished between "assistive (enabling), rehabilitative (promoting recovery), and administrative (supporting efficient work) (Signal et al., 2019, p. 266). Robotic rehabilitative devices are a form of rehabilitative technology, and are distinguished from other robots such as social robots (Wu et al., 2014).

Acceptability is defined as "the demonstratable availability to use technology, and the way people perceive, accept, and adopt technology use" (Mazzoleni et al., 2014, p. 117).

Several health and technology models outline determinants of acceptability. These include the Technology Acceptance Model (TAM) (Davis & Venkatesh, 1996), the Unified Theory of Acceptance and Usage of Technology Model (UTAUT) (Venkatesh, Morris, Davis, & Davis, 2003), and the Health Belief Model (HBM) (Champion & Skinner, 2008). Between these models, it is widely agreed that acceptability of medical robotic devices is primarily determined by perceived ease of use and perceived usefulness (Gitlin, 1995; Mazzoleni et al., 2014, p. 117; Smarr et al., 2012, p. 154; Wu et al., 2014, p. 802; Ziefle & Wilkowska, 2010, pp. 1–2). Furthermore, these models frequently define overall device acceptance as device use or intention to use (Heerink et al., 2010, p. 363).

The main differences between the aforementioned models are in their dimensional complexity in how acceptability is assessed. As models of acceptability have evolved, the determinants of user acceptance have become more refined. The Almere Model builds upon the UTAUT, which in turn is built off the TAM, reporting that:

- Perceived ease of use is influenced by perceived enjoyment and anxiety;
- Perceived usefulness is influenced by perceived ease of use, perceived adaptivity, and anxiety;
- Attitude and perceived enjoyment influenced intention to use;
- Anxiety and social influence influenced attitude and;
- Facilitating conditions also promoted use. (Heerink et al., 2010).

Based on this model, it can be inferred that in the context of evaluating rehabilitative devices, social presence and sociability were not applicable, and instead perceived

enjoyment was determined by how pleasurable device usage was perceived to be (Heerink et al., 2010, pp. 364–365). This suggests that perceived positive user-experience (UX) directly influences intention to use and device acceptability.

Barriers to the acceptability of medical technology are classed as technological, behavioural, organizational, and economic (Mazzoleni et al., 2014, p. 118). Examples respectively consist of unwillingness to learn new skills, fear and distrust towards innovation, resistance to change, and poor perception of cost to benefit ratios (Mazzoleni et al., 2014, p. 118). Furthermore, stigma experienced by PWS resultant of device use, has also been suggested to be a significant barrier to the acceptability of medical technology (Gitlin, Schemm, Landsberg, & Burgh, 1996; Jacobson, 2010; Skogsrød, 2014; Vaes, 2014b; Wu et al., 2014).

Influencing Acceptability

User acceptance is a critical factor in the adoption of medical technology (Mazzoleni et al., 2014; Wu et al., 2014; Ziefle & Wilkowska, 2010). Currently, robotic rehabilitative devices experience a high rate of abandonment, mistrust, and user dissatisfaction by PWS (Cruz et al., 2016; Gitlin, 1995; Jacobson, 2010; Scopelliti et al., 2005; Wu et al., 2014); suggesting poor acceptance.

It has been suggested that acceptability motivators and barriers are concurrent forces and to increase the acceptability of a device, both motivators must be increased, and barriers palliated or eliminated (Liu et al., 2015; Ziefle & Wilkowska, 2010). It can therefore be extrapolated that motivators and barriers are holistically interlinked. For example, improving the usability of a device also increases user perceptions of ease of use and simultaneously decreases learning barriers. Similarly, educating users on technological capabilities increases perceived usefulness, whilst simultaneously reducing uncertainties of cost-effectiveness (Wolff, Parker, Borisoff, Mortenson, & Mattie, 2014, p. 177). Thus, it can be argued that facilitating motivators should also simultaneously reduce barriers, and vice versa.

Previous literature outlines how the primary manifestations of acceptability barriers to rehabilitative devices are usability issues, stigma, and a lack of user consideration (Huang, Lee, Hsieh, & Chen, 2013; Liu et al., 2015; Skogsrød, 2014).

Usability

"Device usability refers to the aspects of a product that make a consumer prefer, select, and use one product instead of another" (Lane, Usiak, Stone, & Scherer, 1997, p. 131), and is a significant influencer of perceived ease of use, one of the primary determinants of acceptability (Story, 2012; Venkatesh, 2000; Wu et al., 2014). High levels of usability facilitate conditions where users experience greater control, reduced anxiety, increased openness of environment, and a positive user-interaction (Huang et al., 2013; Venkatesh et al., 2003).

Brooke (2006) defines usability as the appropriateness to a purpose. The United States Food and Drug Administration (FDA) breaks down usability into:

- Device set-up (installation, calibration, deployment);
- Use (primary functions) and;
- Cleaning (maintenance and use after primary function) (Story, 2012, p. 23).

It can therefore be inferred that the usability of a robotic device for rehabilitation is defined by the appropriateness of its features in achieving a quality rehabilitative experience, and that this appropriateness influences the user's perceptions of how easy the device is to use.

Key usability issues experienced during rehabilitative device use include instability of both devices and user securing mechanisms; difficulty of installation of both the device and the user into the device; a lack of adjustability of both device ergonomics and difficulty, and an uninteresting user interaction (Huang et al., 2013).

Other studies investigating the usability of robotic devices support these findings; reporting training barriers, safety concerns, and cumbersome design as the primary barriers to device usability (Scopelliti et al., 2005; Wolff et al., 2014). Detailed usability issues on device interfaces included "too small buttons, containers hard to open, printed instructions hard to read, etc" (Scopelliti et al., 2005, p. 147).

Stigma

One of the greatest barriers to the use and acceptability of medical technology is stigma (Gitlin et al., 1996; Jacobson, 2010; Skogsrød, 2014; Vaes, 2014b; Wu et al., 2014). Stigma is defined as "a mark of disgrace or infamy" (Oxford English Dictionary, n.d.).

Product-related stigma is defined as social rejection caused by a product (Vaes, 2014b, p. 4). Product-related stigma can be further distinguished as 'visible' (as opposed to hidden stigmas common to internal illnesses) and 'existential' (where the individual has little to no control over the stigma) (Vaes, Stappers, Standaert, & Desager, 2012, p. 2). Therefore, stigma experienced by users of robotic devices for stroke rehabilitation can be described as visible, existential, product-related stigma; as the stigma has manifested due to device usage for the rehabilitation of an involuntary and visible disability. This stigma is derived from the highlighting of negative associations such as disability and decline of autonomy, and can have an adverse effect on a PWS's identity, self-esteem, and cause conflict between a PWS and their device (Jacobson, 2010; Skogsrød, 2014; Vaes, 2014b; Wu et al., 2014).

This stigma is experienced so long as the PWS characterizes their rehabilitative device by their disability, and thus is a significant and prevalent barrier to device acceptability.

User Subgroups

Technology rarely has a singular user, but rather a user community (Shah, Amirabdollahian, & Basteris, 2014, p. 132). A rehabilitative device's user community includes PWS, clinicians, and often the PWS's friends and family, caregivers, and design and maintenance engineers. Whilst extensive research has been conducted on the acceptance of medical technology by PWS, few studies have investigated the perceptions of other user subgroups (Liu et al., 2015; Signal et al., 2019, p. 448; Wolff et al., 2014).

In current clinical contexts, clinicians are the primary advocators, mediators, and facilitators of robotic devices (Wolff et al., 2014, p. 177). Without clinicians, it is impossible for PWS to access or use devices. To date, it is still unclear the extent clinicians are adopting and accepting novel rehabilitation technologies (Liu et al., 2015, p. 448). This lack of user consideration and understanding for a primary user subgroup poses a significant barrier to the overall acceptance of robotic rehabilitative devices. Therefore, if the development and subsequent implementation of robotic rehabilitative devices is to be meaningful, its acceptability must be considered for both PWS and clinicians.

Clinicians and People with Stroke

User perceptions between PWS and clinicians have subtle but significant differences (Wolff et al., 2014, p. 177). Inherently, the concept of device ease of use and usefulness are different between PWS and clinicians, with attributions to self and client respectively. Whilst it can be surmised that as both user subgroups have the same intention of effective rehabilitation, their pragmatic nuances lead to differences in value attribution. For instance, a PWS may denotate ease of use as how functionally easy it is to set up and use the device, whilst clinicians will also consider the ease and practicality of implementing a fleet of devices in their clinic (Signal et al., 2019, p. 267). These differences cause clinicians to view functional capabilities and usability as more important than their clients (Wolff et al., 2014, p. 177).

Signal et al. (2019) expands upon this, describing how implementation of technology by a clinician in a clinical environment is dependent on the value clinicians attribute to it (Signal et al., 2019, p. 267). 'Value' was determined by three factors:

1. The degree a clinical need was addressed by the technology;
2. Effectiveness of the technology and supporting knowledge base and;
3. Ease and practicality of implementation (Signal et al., 2019, p. 267).

Other literature supports this, reporting that belief in the technology's potential to improve the clinician's job performance or the PWS's rehabilitation outcome, as well as facilitating appropriate supporting facilities and infrastructure, were the greatest predictors of technology use and acceptance for clinicians (Liu et al., 2015, pp. 452–453). Interestingly, ease of use, and social expectations from colleagues were found to not influence technology acceptance (Liu et al., 2015, p. 453). The former suggested clinicians would overcome personal hurdles of learning barriers so long as performance expectations were present (Liu et al., 2015, p. 453), reiterating the subtle differences between ease of device use and ease of device implementation. The latter was attributed to the idea that "physicians generally work more autonomously compared to others" and "value their own assessments more than the opinions and suggestions of others" (Liu et al., 2015, p. 454), further cementing the notion of personal beliefs denoting what is 'valid' professional rehabilitation and the validity of technology thereof (Signal et al., 2019, p. 267).

These subtle differences between PWS and clinicians suggest differences in internal processes in evaluating medical technology between the two subgroups, despite similar acceptability motivators and barriers. The absence of literature investigating these differences illustrates a void in knowledge and a significant barrier to the acceptance of robotic rehabilitative devices, instigating the need for further research and user-considered design.

Design as a Solution

This study proposes industrial design as a research solution to the aforementioned barriers of acceptability.

Industrial design – also known as product design – is the process of designing products fit for purpose functionally, aesthetically, and commercially (Industrial Design, Competition and Globalization, 2010; Shapiro, 2016; Tjalve, 2015). The practice has been responsible for many iconic products ranging from the iPhone by Jonathan Ive, to the Airblade by James Dyson.

Industrial design is a holistic process, which is described as manipulating five interlinked variables:

- Structure;
- Form;
- Material:
- Dimension and;
- Surface (Tjalve, 2015, p. 7)

These variables, when crafted with function in mind, allow the designer to alter user perceptions (Shapiro, 2016; Tjalve, 2015). For example, distribution of weight can suggest stability, increasing support structures can suggest durability, and increasing geometric order can suggest accuracy (Tjalve, 2015).

Few studies have investigated how industrial design can influence the acceptability of robotic devices, despite the apparent suitability. The following sections will detail promising areas of research regarding how industrial design can influence the acceptability of robotic devices for upper-limb stroke rehabilitation.

Perception and Categorization

As determinants of acceptability are all perception based, a product's ability to communicate desirable qualities is critical in initial adoption (Lane et al., 1997, p. 131). Perceptions that influence acceptability comprise of "complex relationships between the cognitive, affective and emotional components of people's images of robot"(Cesta et al., 2007, p. 229).

Categorization is the mental action of categorizing objects (Goldstein, 2010). Each category is distinguished from another by attributable descriptions or qualities, such as 'robot' and 'effective' respectively. The exemplar approach to categorization outlines membership within a category is determined by resemblance to previous examples (exemplars) displayed by the object being categorized (Goldstein, 2010, p. 246). For example, smartphones may be categorized with screened electronics.

Categorization also generates information on the object being categorized (Goldstein, 2010, p. 241). Goldstein (2010) illustrates how the category of 'cat' encompasses attributes such as having whiskers and being largely inactive during the day. Resultantly, when new members are added to that category, those attributes are automatically assigned to the new member without further learning.

Categorization presents a unique avenue of research in relation to industrial design. It facilitates the ability for objects to be perceived a certain way (such as useful), by simply being categorized with other related useful objects. Similarly, the attribution of categorical information to newly categorized objects could potentially decrease training barriers. For example, designing devices to be strategically categorized as high-tech electronics should theoretically impart information such as 'this device has a battery, needs to be charged, and should avoid water'.

Capitalizing on desirable thematic traits identified through categorization is used across the design industry (Skogsrød, 2014, p. 3). The colour red being categorized as fast and invoking feelings of hunger has been adopted by many fast-food giants such as McDonalds and Kentucky Fried Chicken. Similarly, major technology brands in recent years have shifted their design style towards a sleek, curvaceous, and sports car reminiscent aesthetic in an effort to acquire some attributes of the luxury automotive industry such as speed, precision, and prestige (McQuarrie, 2020).

This research avenue therefore holds the potential to function as a lateral approach to directly manipulating the determinants of acceptability through industrial design. Identifying traits of desirable categories could yield tangible design goals that directly allow design interventions to increase specific determinants of acceptability or mitigate design shortcomings.

Addressing Usability

Many of the aforementioned shortcomings regarding usability are derived from poor UX

consideration. A poor UX results in a poor user impression, possibly confusing or frustrating them, and causing negative associations to be imparted (Goldstein, 2010; Heerink et al., 2010; Scopelliti et al., 2005). This in turn, would reduce perceived enjoyment, ease of use, and adaptivity; consequently, decreasing acceptability.

Industrial design can holistically remedy usability issues two-fold. Firstly, the inherent function of industrial design is to manipulate design elements to make the design suitable for function. This is done through addressing usability features such as ergonomics, user interaction, and product performance (Industrial Design, Competition and Globalization, 2010, p. 5), increasing device ease of use, enjoyability, and adaptivity for all users. Secondly, decreasing training barriers and increasing adjustability to accommodate for a wider range of clientele increases both the usefulness and ease of implementation for clinicians.

Addressing Stigma

Extensive research has been conducted on how industrial design can address the stigma of medical devices (Jacobson, 2010; Skogsrød, 2014; Vaes, 2014b).

Product-related stigma is primarily experienced when interacting with bystanders (Vaes, 2014b). Principle issues which contribute to product-related stigma include poor usability, a lack of comfort, and poor aesthetics; all of which contribute to highlighting the user's disability and/or decline of autonomy (Jacobson, 2010; Skogsrød, 2014; Vaes, 2014b; Wu et al., 2014). This further illustrates that usability is not only essential to consider regarding the functionality of a device, but also in how it impacts the way users look and feel during device use.

Jacobson (2010) investigated how stigma could be challenged by industrial design, outlining three strategies for overcoming stigma in medical devices:

1. Disguising stigmatizing features;
2. Incorporating distracting features to prevent attention on stigmatizing features and;
3. Turning stigmatizing features into symbols of status or prestige.

The first two of these strategies are disputed by other literature, who argue suggesting impairment should be hidden or distracted from inherently builds more stigma as it reinforces the notion it should not be looked at (Pullin, 2007). Attempts to camouflage devices, such as imitating human skin, also frequently fall short, alienating users with their unnatural and tacky materials (Pullin, 2007, p. 8).

However, the third of these strategies, is strongly supported by Skogsrød (2014) and Pullin (2007). Elevating stigmatizing elements of medical products to become prestigious and fashionable, such as in the case of designer eyewear, "challenges the notion that discretion is the best policy" (Pullin, 2007, p. 10). Attractive products - such as glasses - are viewed more favourably by users, and allow them to communicate the active intention of making their healthcare products visible, palliating stigma (Skogsrød, 2014, pp. 3–4).

Jacobson's (2010) third strategy, having been formulated from a designer's perspective, capitalizes on industrial design's capacity to shape user perception, and the practice's ability to make products luxurious and fashionable. This, in line with aforementioned literature, illustrates the validity of implementing industrial design to reduce the product-related stigma of robotic rehabilitative devices, and consequently decrease the barriers to their acceptance.

Addressing User Consideration

The healthcare design industry differs from other commercial industries in a major manner: end-users – PWS and clinicians – are frequently excluded from the design and development process of their products (Ferris, Sawicki, & Daley, 2007; Lane et al., 1997, p. 130; Shah et al., 2014, p. 133).

Not involving end-users in development often results in significant usability and safety issues, and will likely result in end-user rejection (Shah et al., 2014, p. 133). Correspondingly, codesign between users and designers significantly improves design quality, function, usability, effectiveness, commercial value and user acceptance; as well as reduces subsequent development costs, and time over run (Hill, Holloway, Morgado Ramirez, Smitham, & Pappas, 2017, p. 164; Shah et al., 2014).

The poor acceptability of current robotic rehabilitative devices, and absence of literature investigating stakeholder perspectives illustrates the tangible consequences of this practice (Liu et al., 2015; Signal et al., 2019, p. 448; Wolff et al., 2014).

Industrial design practices have been traditionally formulated to address user-needs. Methodologies such as user-centred design (UCD) and empathic design are common approaches recommended for healthcare design (Hill et al., 2017; ISO, 2019; Postma, Zwartkruis-Pelgrim, Daemen, & Du, 2012; Skogsrød, 2014). These methodologies advocate for the inclusion and investigation of end-users during the design process so

authentic user-needs can be generated and satisfied, and the aforementioned benefits may be capitalized upon. Their presence and validated effectiveness in other design industries – such as the hospitality, transport, and information technology sectors – (McQuarrie, 2020; Skogsrød, 2014) further illustrate the validity of industrial design as a research solution to the acceptability of robotic rehabilitative devices.

These methodologies are further detailed in chapter 2: methodology.

Industry Paradigm

It might now be asked, if industrial design is such a panacea to the poor acceptability of rehabilitation robotics, why hasn't it been widely implemented?

Research and design of medical technology has predominantly been driven by the engineering, medical, and commercial industries (Ferris et al., 2007, pp. 507–508; Jacobson, 2010, p. 3; Skogsrød, 2014, p. 4; Ziefle & Wilkowska, 2010, p. 1), guided by "medical necessity, technical feasibility, and economic interest" (Skogsrød, 2014, p. 4; Ziefle & Wilkowska, 2010, p. 1). It has been proposed that the current industry culture is very self-contained, and believes outside contribution to be of less value than that of a researcher (Shah et al., 2014, p. 134). Others have suggested that a focus on commercial viability restricts the transparency of research (Ferris et al., 2007, p. 508), which would incapacitate the interdisciplinary dependency of industrial design. In either case, the current industry does not believe in the value of industrial designers, and their integration within healthcare design remains rare (Jacobson, 2010, p. 3; Skogsrød, 2014, p. 10). Unsurprisingly, few studies have investigated how industrial design can influence the acceptability of robotic rehabilitation devices.

This failure to consult end-users on their needs, or appropriate experts on matters of design has resulted in a lack of consideration of user acceptance outside of commercial viability (Hill et al., 2017; Lane et al., 1997, p. 130; Shah et al., 2014; Skogsrød, 2014, p. 4; Ziefle & Wilkowska, 2010, p. 1). This dangerous dynamic where devices intended for healthcare – a fundamental human necessity – are designed without proper process or goal in mind is likely to be one of the underlying causes to the poor acceptability of robotic rehabilitative devices, instigating the need for further research and a shift in practice.

Conclusion

Stroke is a serious neurological disorder, and is the leading cause of disability in the industrialized world (Alankus et al., 2010, p. 2113). The growing population of PWS is rapidly outpacing healthcare services and resources (Ziefle & Wilkowska, 2010, p. 1), instigating the need for healthcare innovation. Robotic devices for rehabilitation are a promising tool with the ability to supplement clinician time, and potentially improve rehabilitation efficacy (Xie, 2016). However, they are poorly accepted by end-users (Wu et al., 2014), and their acceptability to clinicians is unclear (Liu et al., 2015).

The primary determinants of acceptability are perceived ease of use and perceived usefulness (Mazzoleni et al., 2014, p. 117; Wu et al., 2014, p. 802; Ziefle & Wilkowska, 2010, pp. 1–2). The Almere Model further reports perceived enjoyment, perceived adaptivity, social influence and user anxiety as facilitators of perceived ease of use and usefulness, as well as determinants of acceptability themselves (Heerink et al., 2010). As these determinants are all perception based, a product's ability to communicate desirable qualities is critical in ensuring its acceptance by the user (Lane et al., 1997).

Industrial design is the process of designing products fit for purpose functionally, aesthetically, and commercially, and allows the designer to manipulate user perception through inducing desirable product communication (Shapiro, 2016; Tjalve, 2015). This manipulation can be strategically used to alter cognitive processes such as categorization, improve device usability, reduce product-related stigma, and satisfy user-needs; ultimately increasing motivators and decreasing barriers to device acceptability.

Furthermore, the current healthcare design industry possesses a unique culture where neither designer nor end-users are involved in the design process (Jacobson, 2010; Lane et al., 1997; Shah et al., 2014). Exclusion of both design professionals and end-users exhibits both arrogance and disregard for research integrity. This dangerous practice will at best, result in mediocre medical hardware, and at worst, result in significant usability and safety issues and end-user rejection (Shah et al., 2014, p. 133). The absence of appropriate design expertise also brings into question the validity of the 'design improvements' proposed by previous literature.

Instigated by these shortcomings in the research, design, and commercialization of potentially life-changing technology, and absence of previous literature on the subject, it is both imperative and appropriate to investigate how industrial design can influence acceptability of robotic devices for upper-limb stroke rehabilitation.

Criteria from Background Research

	Criteria	Rationale
1.0	Investigate user perceptions of acceptability determinants with respect to user sub-groups	Understanding how users measure, value, and conclude on determinants will allow more precise manipulation of them in an effort to improve device acceptability. Similarly, understanding the difference between device acceptance by PWS and clinicians will allow design criteria to be established which can satisfy both subgroups.
1.1	Utilize industrial design to manipulate acceptability determinants	To investigate the validity of industrial design as a design research tool in the manipulation of acceptability
1.2	Introduce end-user (PWS and clinicians) into design process	Exclusion of end-users causes usability and safety issues, and user rejection (Shah et al., 2014, p. 133).

Table 1.0. Initial criteria from literature review

Chapter 2:
Methodology

Constraints of Covid-19

The Covid-19 pandemic began during the course of this study. Prior to the outbreak, this study had gathered formal ethics approvals from both affiliated university ethics committees, and the New Zealand Government's Health and Disabilities Ethics Committee (HDEC). Unfortunately, due to nature of the pandemic, and the requirements for social distancing, recruitment and data collection were curtailed until October 2020. This resulted in a reduced scope of research than that detailed here, particularly with regards to physical consultation and testing.

Research Question

How can industrial design address user acceptance of a robotic device for upper-limb stroke rehabilitation?

Intention

This study aims to use a criteria-based, empathic, and user-centred design approach to redesign a robotic device for upper-limb stroke rehabilitation to improve its acceptability.

Situating the Research

Several studies have been undertaken on the acceptability of medical robotic devices, human computer interfaces, and other technology systems, yielding many measures and determinants of acceptability. However, few studies have examined how these measures can be manipulated to influence acceptability. In particular, within the area of designing robotic devices for upper-limb stroke rehabilitation, little has been reported about how industrial design can influence acceptability.

This study aims to redesign a robotic device for upper-limb stroke rehabilitation to improve its acceptability. A refined measure evaluating determinants of acceptability, as well as overall device acceptability, will be implemented on the Roborover – an evidence-based medical platform – both before and after design intervention. The use of a controlled medical platform with consistent efficacy reduces extraneous variables; whilst the implementation of partitioned acceptability measures will allow for more explicit and categorized analysis of design interventions and how they individually influenced acceptability.

The Researcher

This researcher is a Master of Design Innovation student from Victoria University of Wellington, with a background in industrial design and psychology. I have a particular interest in designing in collaboration with other disciplines as I believe design is a language that translates between disciplines, and brings out the best parts of each.

The Team

The team consists of several clinicians from Auckland University of Technology's (AUT) Health and Rehabilitation Research Institute (HRRI), and engineers from Exsurgo Rehabilitation and Callaghan Innovation. The majority of the team have over 10 years of experience researching stroke rehabilitation. The most recent additions to the team are industrial designers from Victoria University of Wellington (VUW), which include my supervisor, Dr Edgar Rodríguez, and myself. A full list of the expanded team can be found at the start of this study.

Theoretical Framework

The aim of this research is a practical one: to design a device that improves acceptability. This brings along a particular challenge: to use the researcher's subjective creativity to design, while at the same time use as objective as possible data to inform the design and test it for acceptability. This means neither Objectivist or Subjectivist theoretical frameworks are appropriate for this research.

The pragmatist epistemology allows for a research question to be addressed through research-through-design. Pragmatism offers a freedom of choice regarding the methods that can be used and it is based on the foundation that objects and events need to be evaluated in the context of the given situation (Dalsgaard, 2014)

User-Centred Design, as later defined, can be situated within a Pragmatist epistemology as both seek to find practical solutions to human problems.

Criteria-Based Design Research Model

The backbone of this study comprises of the industrial design of a complex piece of medical hardware. To facilitate an effective and iterative design process, with evolving design goals, Rodríguez Ramírez's (2017) Criteria-Based Design Research Model (CBDRM) was adopted.

The model comprises of the following steps:

1. Situating the Research within the Body of Knowledge of the Discipline
2. Experimental Discovery through Making
3. Designing as Systematic Enquiry
4. Assessing the Designs Based on the Final Criteria (Rodríguez Ramírez, 2017, pp. 13 14)

The model aims to establish questions, opportunities, and criteria for researchers to design towards, creating a grounding framework comprised of evolving qualitative measures. This adaptive structure aligns with the scope of this study, and will help in reducing the dissonance between its quantitative medical, and qualitative design halves. Furthermore, the model's implementation of systematically assessed iterative design will bring cohesion to the otherwise unfocused explorative design process, allowing causality to be more easily attributable rather than designs having to be holistically appraised, thus refining the explicitness of how design interventions contribute to acceptability.

User-Centred Design

User-centred design (UCD) is a research methodology which generates user-needs through the integration of end-users, and designs to meet these needs (Friess, 2010; ISO, 2019; Skogsrød, 2014; Steen, 2012)

Previous literature, as well as major international authorities such as the International Organization for Standardization (ISO), and the United States Food and Drug Administration (FDA), suggest a UCD approach for medical devices (Hill et al., 2017; Skogsrød, 2014; Ziefle & Wilkowska, 2010).

The ISO (2019) outlines the main themes of UCD as:

1. Involving users to better understand their practices, needs, and preferences.
2. Searching for an appropriate allocation of functions between people and technology.
3. Organising project iterations in conducting the research and generating and evaluating
4. Organizing multi-disciplinary teamwork.

This is in line with the FDA, who further details the need to analyse users, user risks, use environments, and use scenarios as a means to better understand users (Story, 2012).

UCD's ability to generate authentic user-needs, and develop designs with high usability, usefulness, and user satisfaction makes it highly suitable to tackle the issues identified in chapter 1 (Friess, 2010, p. 41; Skogsrød, 2014; Steen, 2012, p. 72).

Empathic Design

Empathic design is a qualitative research methodology which allows designers to design with insights of their user, rely on their intuition, and values 'unorthodox solutions' over empirical data (McDonagh & Thomas, 2010; Postma et al., 2012; Skogsrød, 2014). Because a user's experience is often very different to the designer, such as in the case of designing for disability (McDonagh & Thomas, 2010, pp. 183–184) empathic design encourages designers to develop an intimate working relationship in an effort to facilitate codesigning and mutual insight; generating appropriate design solutions rather than 'correct' solutions (McDonagh & Thomas, 2010, p. 194; Skogsrød, 2014, p. 7).

Empathic design shares many similarities to UCD, but deviates in its reduced reliance on empirical data, and greater emphasis on the role of designers (McDonagh & Thomas, 2010; Postma et al., 2012; Skogsrød, 2014). Empathic design argues that designers initially lack an understanding of their user demographic and intended use environment (McDonagh & Thomas, 2010, p. 182; Skogsrød, 2014, p. 8); and resultantly fail to collect the right information in design research (Steen, 2012, p. 72). A similar view is shared on users; whilst users often know what they need, expressing it as part of a codesign process can be difficult – especially for those experiencing disabilities (McDonagh & Thomas, 2010, p. 182; Skogsrød, 2014, p. 8). Consequently, empathic design argues empirical data is ineffective in many respects of healthcare design, as research scope can easily overlook relevant design opportunities (Steen, 2012, p. 72); and self-reporting is equally unreliable (Skogsrød, 2014, p. 6). Correspondingly, empathic design places a greater emphasis on the designer's intuition and expertise (Postma et al., 2012, p. 66; Skogsrød, 2014, p. 7); aiming for them to develop "a feel for the user" (Postma et al., 2012, p. 59). By eliminating the restraints of utilizing empirical data for all design decisions, empathic design facilitates designers to interpret and recognize a user's perspective through their own empathized experience, envisioning intuitive solutions through insight, creativity, and simulating future use (McDonagh & Thomas, 2010; Postma et al., 2012).

Empathic design's ability to improve the designer's understanding of the user, coupled with its emphasis on out-of-the-box thinking, makes it highly suitable for creatively enhancing the design opportunities of this study, whilst also circumventing the logistical limitations of large-scale data collection.

Our Methodology

Skogsrød (2014) discusses how adherence to a single methodology causes research to become overly rigid, suggesting a flexible, hybrid approach should be adopted instead.

The CBRDM greatly aligns with the scope of this current study, and serves as a framework to design within. The implementation of evolving sets of design criteria, and iterative refinement also facilitates focused explorative design research. However, the CBRDM is an overarching framework, and to explore meaningful design opportunities through granular user insights, more detailed user-orientated methodologies must also be amalgamated.

UCD is highly applicable to this current study as it integrates end-users in the design process to produce and validate genuine user needs. Similarly, its iterative and parallel prototyping methods are very compatible with industrial design practice. However, UCD's strict reliance on empirical data conflicts with explorative design methods (Friess, 2010; Skogsrød, 2014); as well as the logistical limitations of this current study. Recruiting a large statistically significant sample group (>30) is frequently beyond the resources available to student research (Skogsrød, 2014, p. 6). Consequently, whilst the underlying themes of UCD should be adhered to, the methods of execution need amending to fit the scope of this study.

As previously outlined, empathic design shares many similarities, but deviates from UCD in its reduced reliance on empirical data, increased degree of user integration, and greater emphasis on designer intuition and understanding (McDonagh & Thomas, 2010; Postma et al., 2012; Skogsrød, 2014).

A hybrid of UCD and empathic design structured within an adapted CBRDM is an appropriate approach, which literature reports to create more inspired and relevant design outcomes when approached with a balance of the rational and the empathic (McDonagh & Thomas, 2010, p. 184; Postma et al., 2012, pp. 60, 69).

Concludingly, this study will adopt the following hybrid approach adapted from Ziefle & Wilkowska's (2010) UCD methodology:

1. Explore and weigh the contributing factors of device acceptability by:
    - Reviewing previous literature (Martin & Hanington, 2012, p. 112);
    - Researching users, user risks, use environments, and use scenarios (Story, 2012);
    - Allowing users to shape fundamental research questions and design trajectories (McDonagh & Thomas, 2010, p. 185);
    - Allowing users to create priority of design to ensure important needs are least affected by resource limitations (Hill et al., 2017, p. 164; Wolff et al., 2014, p. 170);
    - Codesigning with users to better understand their practices, needs, and preferences (ISO, 2019) and;
    - Considering the needs of a highly heterogeneous user community and comprising user subgroups (Shah et al., 2014, p. 132)
2. Identify how acceptability determinants are influenced.
3. Search for an appropriate allocation of technology to achieve user needs (ISO, 2019).
4. Derive practical interventions from aforementioned research aiming to promote greater user acceptance of robotic devices for upper-limb stroke rehabilitation by:
    - Exploring provocative concept ideation through envisioned alternative futures (Postma et al., 2012, pp. 66–67);
    - Reviewing different design alternatives and evaluate the trade-offs between them (Story, 2012);
    - Developing device iterations to iteratively improve solutions and criteria (ISO, 2019; Rodríguez Ramírez, 2017);
    - Regularly consulting with users to involve them in the generation and evaluation of concepts against research established criteria (Friess, 2010, p. 42; Rodríguez Ramírez, 2017) and;
    - Facilitating multi-disciplinary teamwork (Hill et al., 2017; ISO, 2019; Wolff et al., 2014)

Emphasis will be placed on consulting both end-user subgroups of clinicians and PWS, to ensure needs of all users are universally recognized. User input will be sought as early and frequently as possible to facilitate an iterative dialogue and maximize its value (Shah et al., 2014, p. 132). This is intended to bolster research value two-fold: firstly, to build rapport between researcher and user to illicit responses of greater detail and authenticity, and secondly, to exponentially improve design quality through iterative feedback and improvement (Hill et al., 2017; Shah et al., 2014)

Our primary design methods will include design workshops, questionnaires, and semi-structured interviews, and are extensively used in previous literature (Huang et al., 2013; Scopelliti et al., 2005; Smarr et al., 2012; Wu et al., 2014).

As the scope of this research involves several smaller studies, the detailed methods for each study will be reported in the corresponding chapter.

Aims	Objectives	Methods
Aim 1: To define requirements for improving user acceptance of devices.	**Objective 1a:** To identify variables which influence user acceptance.	**Method 1a:** Conduct Literature review (Martin & Hanington, 2012, p. 112) of determinants of user acceptance and validated methods of assessing it.
		Method 1a ii: Facilitate design workshop (Martin & Hanington, 2012, p. 62) to define user journeys and perspectives for all user subgroups.
		Method 1a iii: Conduct evaluative research (Martin & Hanington, 2012, p. 74) of precedents to identify existing design issues and trends.
	Objective 1b: To produce design criteria for designing during Aim 2.	**Method 1b:** Utilize findings from Objective 1a to construct criteria for designing (Rodríguez Ramírez, 2017)
		Method 1b ii: Assess criteria from Method 1b through a stakeholder walkthrough (Martin & Hanington, 2012, p. 168) with PWS, clinicians, and engineers.
Aim 2: To produce a robotic device that addresses user acceptance based on design criteria from Aim 1	**Objective 2a:** Iteratively design and manufacture prototypes that satisfy the developed criteria.	**Method 2a:** Research-through-design through sketching, computer aided-design (CAD), rapid low fidelity prototyping (Martin & Hanington, 2012, p. 139), and high fidelity prototyping through 3D printing.
		Method 2a ii: Conduct stakeholder walkthrough (Martin & Hanington, 2012, p. 168) with PWS, clinicians, and engineers to assess concepts through an interdisciplinary lens.
	Objective 2b: Iteratively test prototypes against developed criteria.	**Method 2b:** Conduct rapid iterative testing & evaluation (RITE) (Martin & Hanington, 2012, p. 142) and stakeholder walkthrough (Martin & Hanington, 2012, p. 168) of concepts with participants to refine design solutions.
	Objective 2c: Measure changes in acceptability of the device before and after design intervention.	**Method 2c:** Measure the acceptability of the original device (control) through validated questionnaire.
		Method 2c ii: Measure the acceptability of the final device (control) through validated questionnaire.
		Method 2c iii: Construct semi-structured interviews (Martin & Hanington, 2012, p. 102) for participants to facilitate thematic analysis (Braun & Clarke, 2006) of the acceptability influence of design interventions.

Table 2.0. Aims and objectives of the study.

Chapter 3:
Design Research 1

Chapter Summary

To achieve Objective 1a of this study, variables which influence determinants of acceptability must be understood. The literature review in Chapter 1 outlined determinants of acceptability, and how industrial design can be used to manipulate user perceptions of them. However, the specificality of features to manipulate to cause desirable outcomes is still unclear. User perspectives on medical technology is poorly documented (Wolff et al., 2014, p. 170), instigating the need to research the criteria industrial designers should strive to meet to facilitate user perceptions that increase acceptability. A 2-day design workshop was conducted to achieve this, and included evaluative research on the existing Roborover prototype. This workshop was formally documented as an FDA design file for the device's regulatory approval processes.

Background

The design workshop was a collaboration between Victoria University of Wellington, Auckland University of Technology, Exsurgo Rehabilitation, Callaghan Innovation, and various subsidiaries and affiliated organizations. To justify the significant material, travel, and time costs of organizing the design workshop, research outcomes were expected for multiple research projects, as well as for the Roborover's commercialization. Information not directly related to this current study has therefore been omitted from the following report.

Design

The design workshop comprises of 6 activities. A descriptive research design was adopted for all 6 activities.

Participants

Participants included 4 people with stroke, 5 clinicians (4 neuro-physiotherapists, 1 occupational therapist), 4 engineers, 1 design lecturer, 1 engineering student, and 2 master's students.

All PWS experienced chronic stroke for more than 6 months, and experienced their last stroke no less than 12 months prior to this study. 7 out of the 17 participants (41.2%) were female. No other demographics were collected.

Procedure

Participants completed the study during a design workshop at Auckland University of Technology's Health and Rehabilitation Research Institute. The workshop comprised of 210-minute sessions, with PWS participating for no more than 90 minutes of each. Each session consisted of up to 16 participants. Participants were grouped into 3 groups consisting of at least 1 PWS, 1 neuro-physiotherapist, 1 engineer, and 1 design lecturer or master's student.

Instructions of each activity were read aloud prior to their start. Each participant was allocated their marker(s), blue-tack, and post-it notes.

Detailed instructions are described in each activity.

Informed consent was obtained from participants; participants were debriefed with the purposes of the study. The entire workshop was audio recorded.

Activity 1 – User Journey Map

Materials: A0 user journey map templates, user journey cards comprising of 'leisure/free time' cards, 'activities enjoyed' cards, and 'rehabilitation exercise' cards; each card included 2 variants, 1 for PWS and 1 for all other participants.

4 of each PWS variants were administered to PWS, and 7 of each of the non-PWS variants were administered to all other participants. 1 template was administered to each group.

Instructions: Participants were instructed to fill out cards to describe their day. The cards focused documentation on when the participant had free/leisure time during the day, when the participant enjoyed an activity, and when the participant did rehabilitative exercises. Each response required an indication of the duration of time spent, location, and variables which helped initiate/motivate or stop/inhibit the activity.

PWS were instructed to answer with respect to their own experiences, whilst all other participants were instructed for each card to assume either a motivated or demotivated stroke survivor persona. Other participants were also instructed on the card to indicate if they were a clinician or engineer.

Participants were then instructed to adhere the card on the template using blue-tack respective to what time of the day it was and which persona they were responding with.

Rationale: Activity 1 aimed to capture the everyday user journey of a PWS. Evaluating rehabilitation as a whole allowed a broader viewpoint on user perspective on robotic rehabilitation device acceptance, identifying potential barriers outside of clinical measures, and facilitating empathic design. We hypothesized that there would be correlations between motivators, barriers, location, and time, which would provide us with a deeper understanding of user perspectives, as well as highlight potential design opportunities that clinical trials would fail to identify, such as if rehabilitating in the garden was preferrable to the living room.

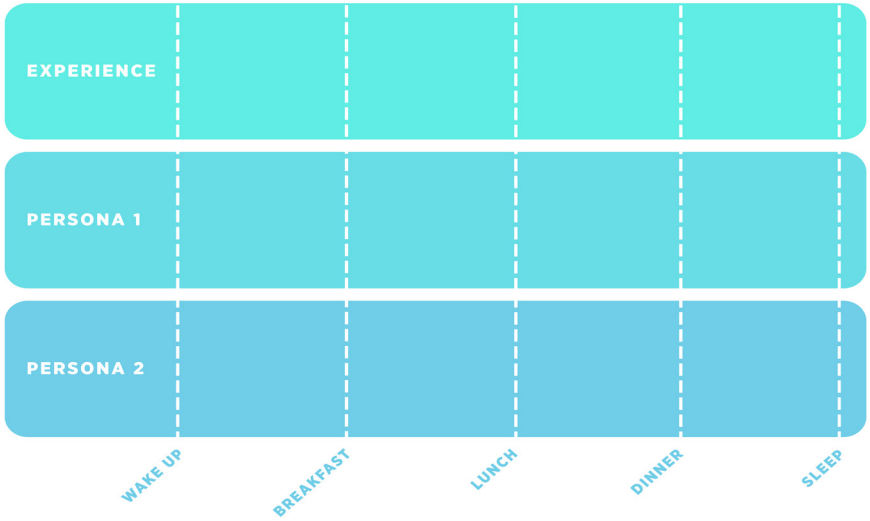


Figure 3.0. A0 user journey map template.

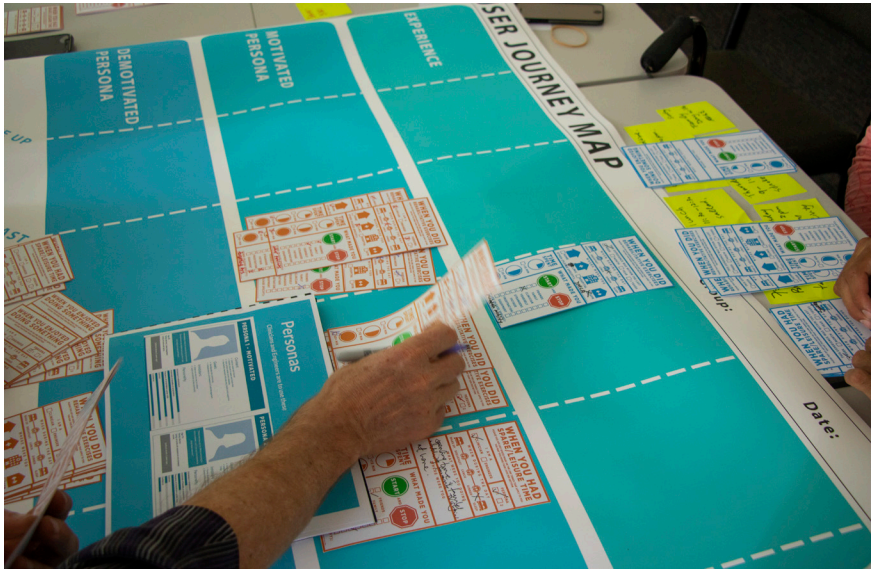


Figure 3.2. User journey map being completed by participants.

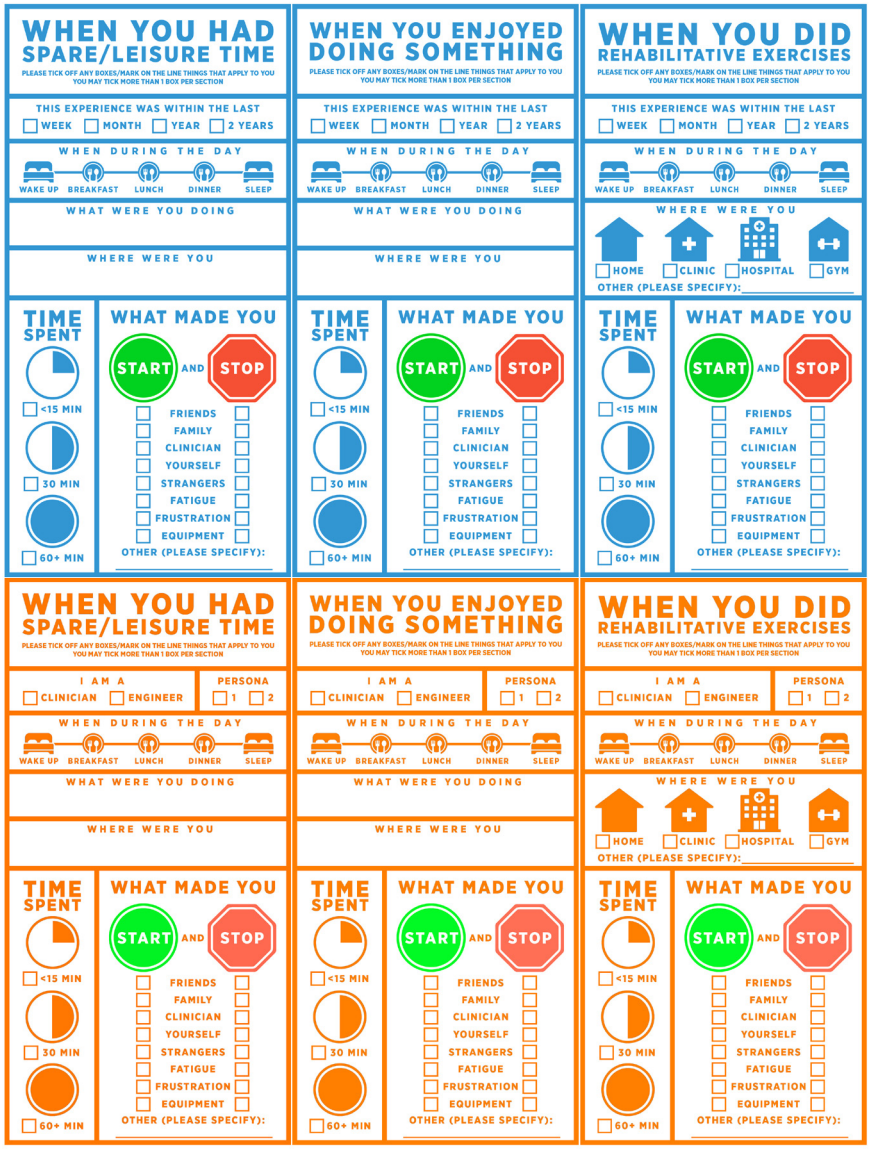
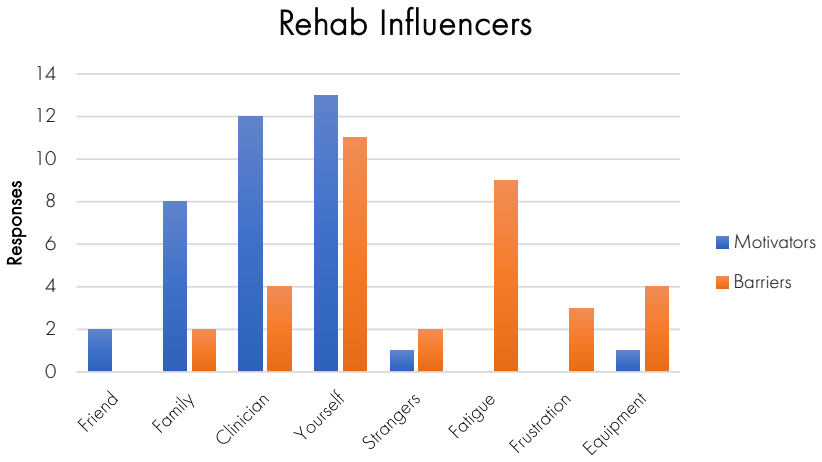


Figure 3.2. User journey map response cards for PWS (blue) and Clinicians (orange)



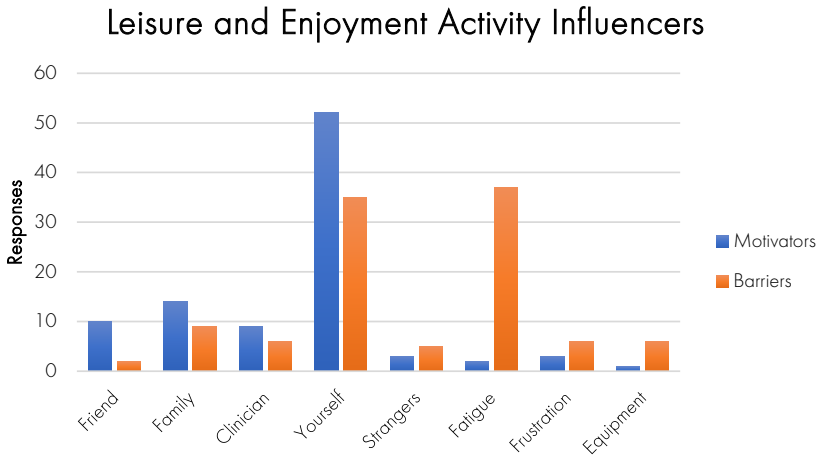
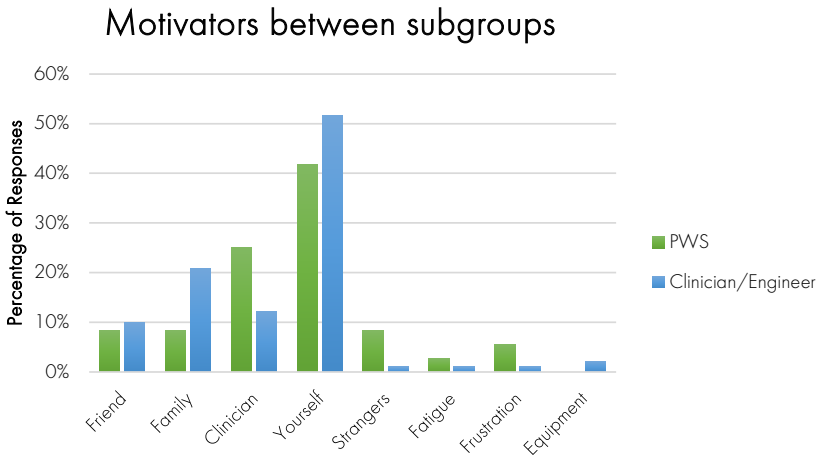


Figure 3.3. Cumulative responses for activity variables.

Results: Family, clinicians, and self, were reported as significant motivators for rehabilitation, whilst fatigue and self were reported as significant inhibitors. Similar results were shown for motivators and inhibitors for free time and enjoyed time, although clinician and family were significantly lesser motivators.



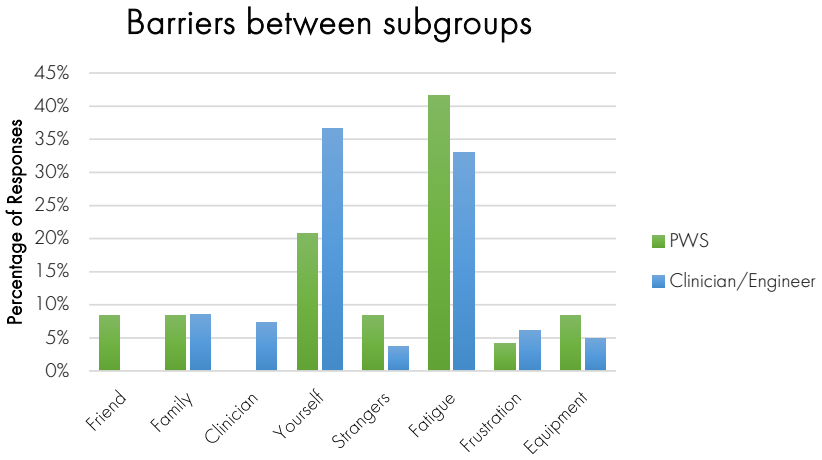


Figure 3.4. Response proportions between different subgroups.

PWS reported clinicians as a greater motivator to all activities than clinicians and engineers, whilst clinicians and engineers reported self as a greater motivator than PWS. Similarly, PWS reported fatigue as a greater inhibitor to activity, whilst clinicians and engineers reported self as a greater inhibitor.

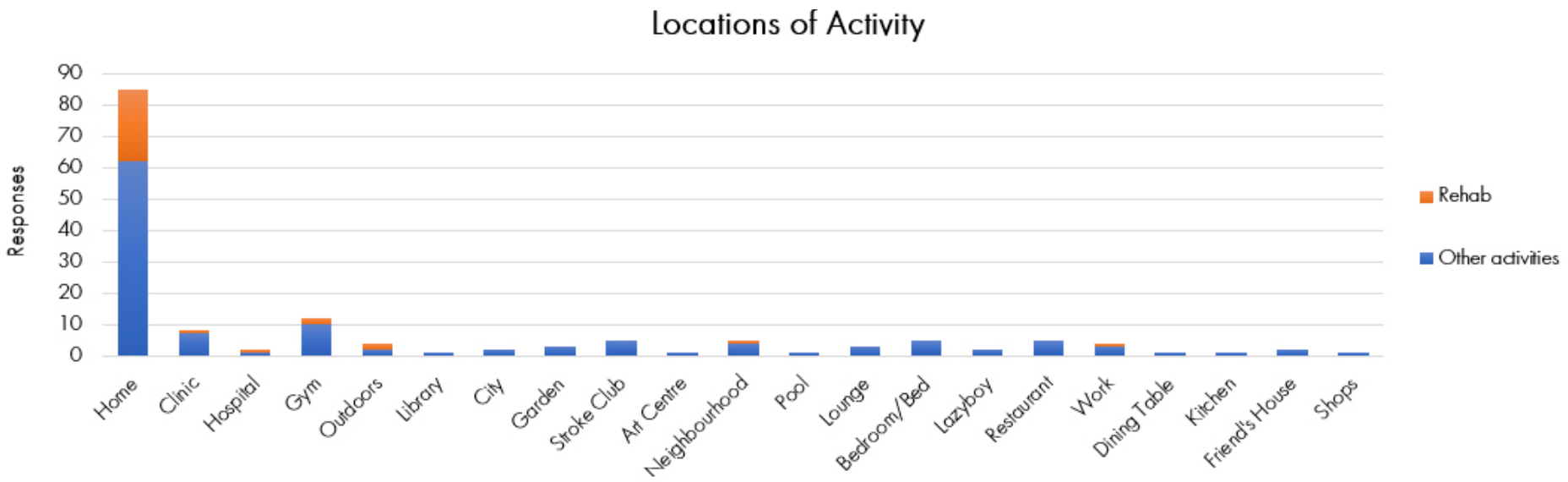


Figure 3.6. Geographic locations of activities.

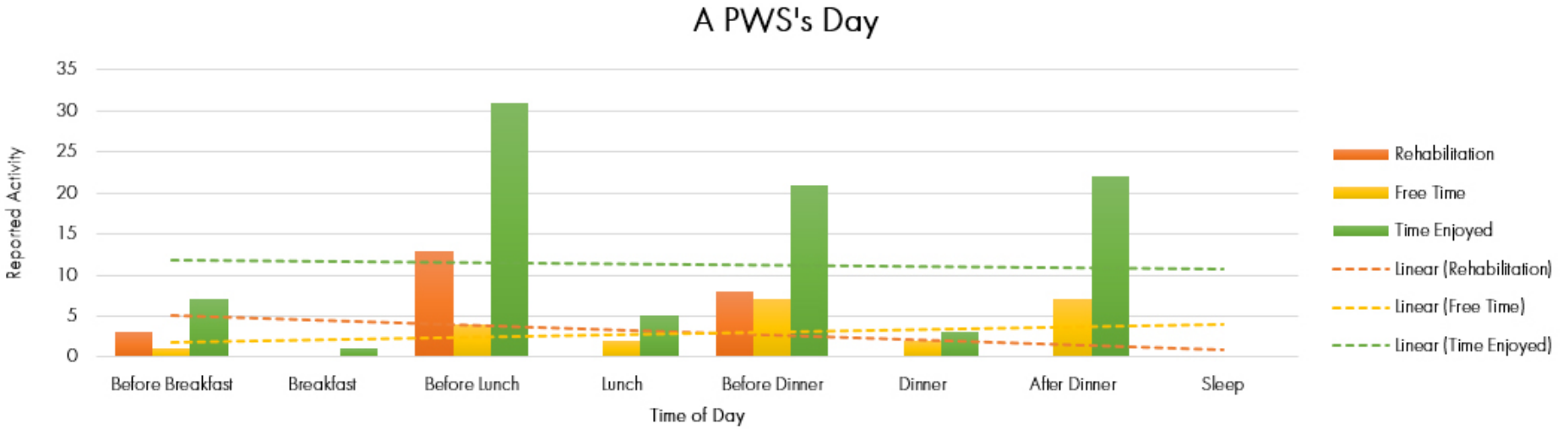


Figure 3.7. Response rate by time of day.

A majority of reported activities (70.4%) occurred within or near the home. Over half of rehabilitation (54.3%) occurred within or near the home. Rehabilitation was reported more frequently earlier in the day, before lunch, whilst free time was reported more frequently near the end of the day, before and after dinner. Enjoyment was stable across the day. Few responses were recorded at meal times.

Activity 2 – Empathy Map

Materials: A3 empathy map templates, 1 administered to each participant.

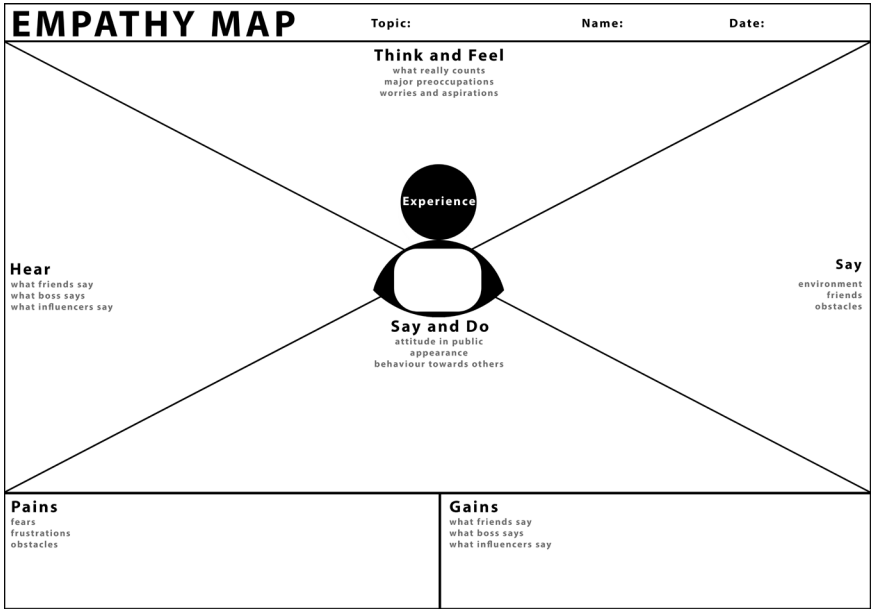


Figure 3.8. Empathy map template.

Instructions: Participants were instructed to write down on post-it notes experiences related to the following statement:

Think of a time when you had a positive experience in a medical or rehabilitation setting

Participants were then instructed to organize experiences into categories by adhering the post-it note within one of the six corresponding sections of the template. Categories included what participants saw, heard, thought and felt, said and did, and challenges (pains), and improvements (gains) they experienced.

Rationale: Activity 2 aimed to evaluate constructs which comprise a positive healthcare experience. Deriving data from personal experience rather than roleplaying scenarios, facilitated the documentation of nuanced emotions and detail making this activity highly suitable for thematic analysis (Braun & Clarke, 2014).

Results: Audio recordings were transcribed. These, alongside physical results were collated and thematically analysed to identify themes within the data (Braun & Clarke, 2006). Themes identified included communication and feedback, social connection and wellbeing, engagement, accessibility, and progress. Themes were used as value cards in the next activity.

Figure 3.9. Participants discussing experiences to distinguish experiential categories.

Activity 3 – Card Sort

Materials: 1 A1 card sort template, and 1 deck of 32 cards were administer to each group. Each card had a value or theme of rehabilitation technology written on it such as 'engagement' or 'accessibility'. Themes were collated from brand values of popular consumer technology, healthcare, and sports enterprises, or were sourced from the results of Activity 2.

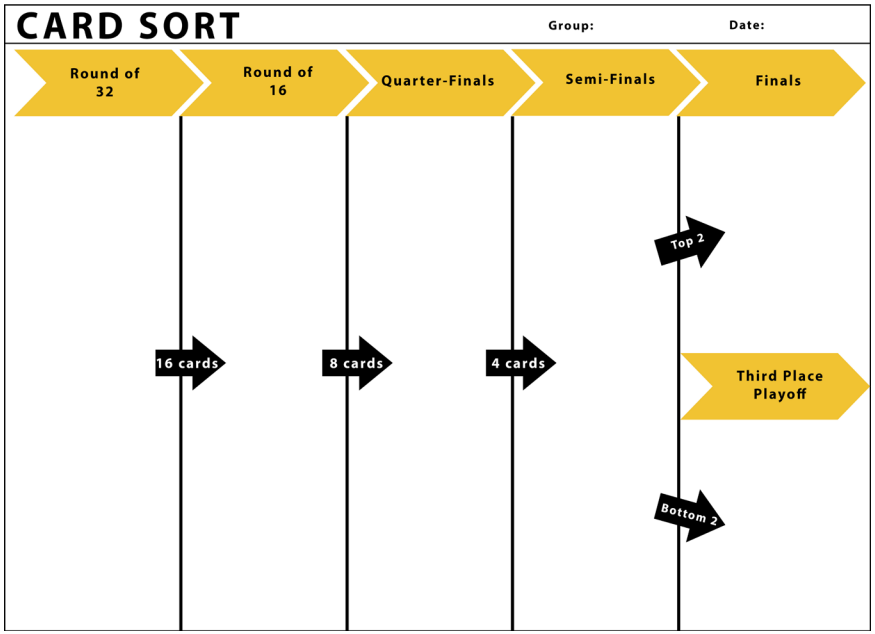


Figure 3.10. Card sort template.

Instructions: Cards were initially placed at the left most section of the template titled 'round of 32'. Participants were instructed to discuss and select half of the values they believed were more critical to the successful design of a robotic device for stroke rehabilitation than the other half and move those cards one section towards the right. This process was repeated with each subsequently halved group until only 2 value cards remained. Cards that were not chosen to move forward were left in their sections.

Each group was instructed to present to all participants their top 2 value cards for 1 minute. A non-blind vote was then conducted to indicate the top 3 values all participants agreed were most important for a successful rehabilitation enterprise. Participants were permitted to vote 3 times amongst the 6 values.

Rationale: Activity 3 aimed to identify the order users prioritized attributes of a robotic device for stroke rehabilitation. The sourcing of values from both industry and Activity 2 was intended to identify any dissonance between what end-users valued and what the industry thinks end-users value.

Results: Each item was scored points corresponding its final category, with higher category items scoring more points. Cumulative totals were made of each item.

The top 10 items included:

Engagement, customization & flexibility, independence & autonomy, simplicity, respect & trust, quality, progress, social connection, accessibility, and motivation.

The top 3 items were used to title the three areas of Activity 4.

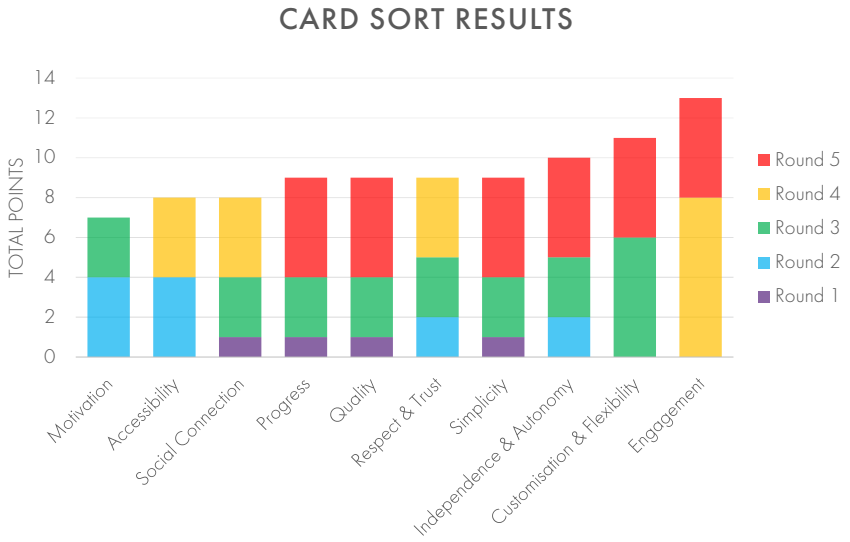


Figure 3.11. Card sort results.

Figure 3.12. Participants discussing which card to take forward.

Activity 4 – Mood Board 1

Materials: 1 A0 mood board 1 template, and 1 decks of image cards, comprising of 60 different images, was administered to each group. The top three values from Activity 3 were used to title the three areas of the template.

Instructions: Cards were administered face down. Participants were instructed for mood board 1 accordingly:

As a group, draw a card from the deck and discuss what qualities it aligns with from those listed on Mood Board 1.

Place the card within circles of qualities your group it feels aligned with.

If the card aligns with more than one quality, place it in the overlap.

If the card aligns with no qualities, place it in either the liked or disliked circle based on how much your group likes the card.

Continue with each card until you run out. Feel free to reshuffle cards as you place more cards on and feel their qualities have changed in comparison to new cards.

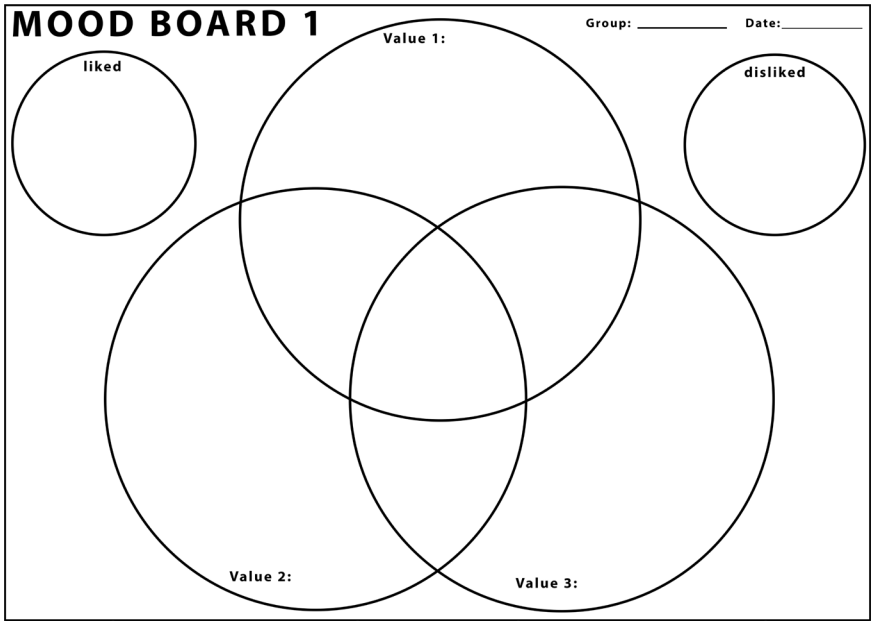


Figure 3.13. Moodboard 1 template.

Rationale: Activity 4 aimed to identify how users physically categorized designs in relation to values they perceived as important for rehabilitation. Visual analysis of this physical categorization was expected to yield patterns which could provide a deeper understanding as to which design features resemble exemplars that facilitate desirable cognitive categorization.

Results: Results were collated and visually analysed. Several trends were identified:

- Games were frequently categorized as engaging or simple, with digital and traditional games aligning closer to the former and latter respectively.
- High-tech designs (machines, electronics, and robots) were categorized as progressive, with those of fewer functions – such as automatic vacuum cleaners -

also being categorized as simple, and those more affiliated with gaming – such as controllers – also being categorized as engaging.

- Designs with clear and limited functions – such as armskates and dustpans - were categorized as simple.
- Of the designs not categorized with a value, high-tech designs were liked.
- Disliked designs were less cohesive than other categories, and included lower-fidelity armskates, designs of bright saturated colours, and games which required extensive dexterity.

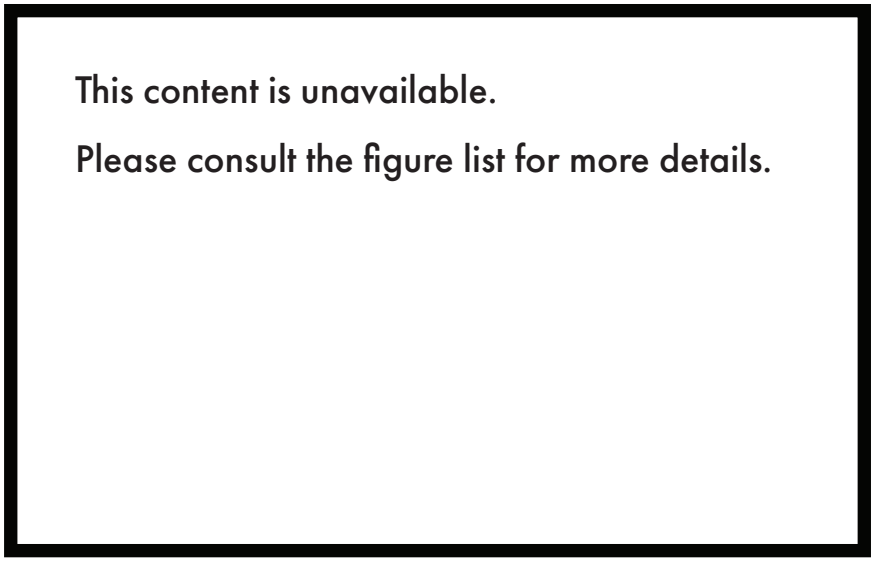


Figure 3.14. Participants assessing a card before assigning it a category.

Activity 5 – Mood Board 2

Materials: 1 A0 mood board 2 template, and 1 deck of image cards, comprising of 60 different images, 30 of which are identical to mood board 1, was administered to each group.

Instructions Cards were administered face down. Participants were instructed for mood board 2 accordingly:

As a group, draw a card from Deck 2 and discuss what qualities it aligns with from those listed on Mood Board 2.

Place the card in the centre of the Board. If it aligns with a certain quality, move it down that axis. The more aligned it is with that quality, the closer it should be to the arrow.

Continue with each card until you run out. Feel free to reshuffle cards as you place more cards on and feel their qualities have changed in comparison to new cards.

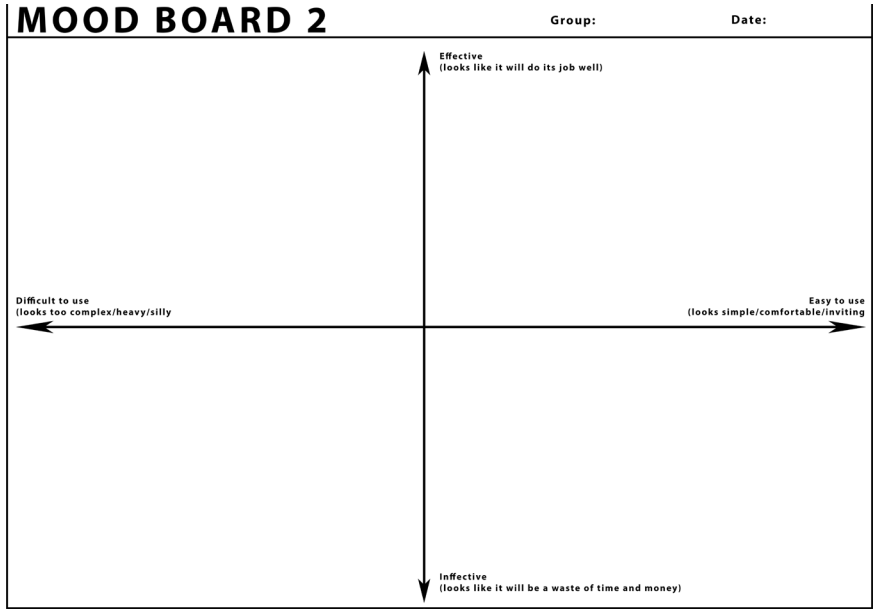


Figure 3.15. Moodboard 2 template.

Rationale: Activity 5 aimed to identify how users physically categorized designs in relation to determinants of acceptability. Usefulness was substituted with effectiveness due to prior expert consultation suggesting that usefulness would be subjectively confusing for participants.

Visual analysis of this physical categorization was expected to yield patterns which could provide a deeper understanding as to which holistically embodied determinants of

acceptability, as well as to see if these were in line to results from Activity 4.

Results: Results were collated and visually analysed. The location of each card was mapped out on a grid and averaged to determine the 'average location' the card had between all groups. These average locations are detailed on Figure 3.17.

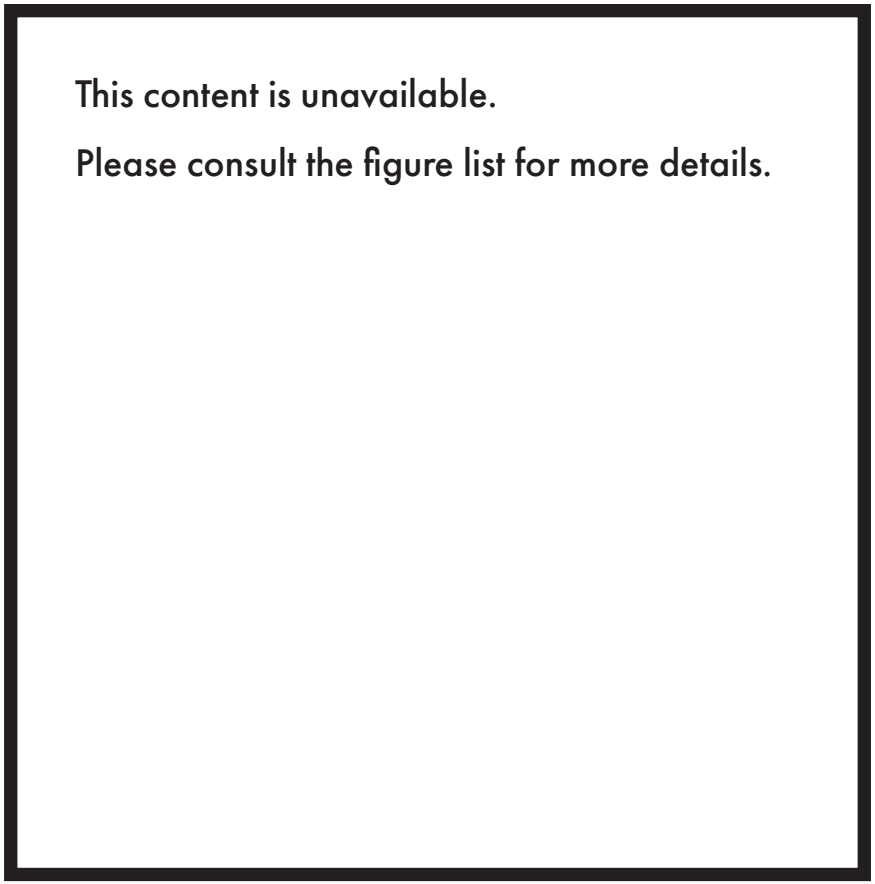


Figure 3.16. Average locations of cards between all groups.

Several trends were identified:

- Low-fidelity armskates were rated as easy to use, but somewhat ineffective.
- Consumer electronics with a complex interface (game controllers, cameras) were rated as hard to use and somewhat effective.
- Effective, but neither easy or hard to use designs tended to have clear functions, but required dexterity, strength, or training to operate.
- Effective and easy to use designs tended to have a simple interface, comprising of few forms, and had a limited colour palette.
- Ineffective and hard to use designs tended to be mechanically complex, and had unclear functions.

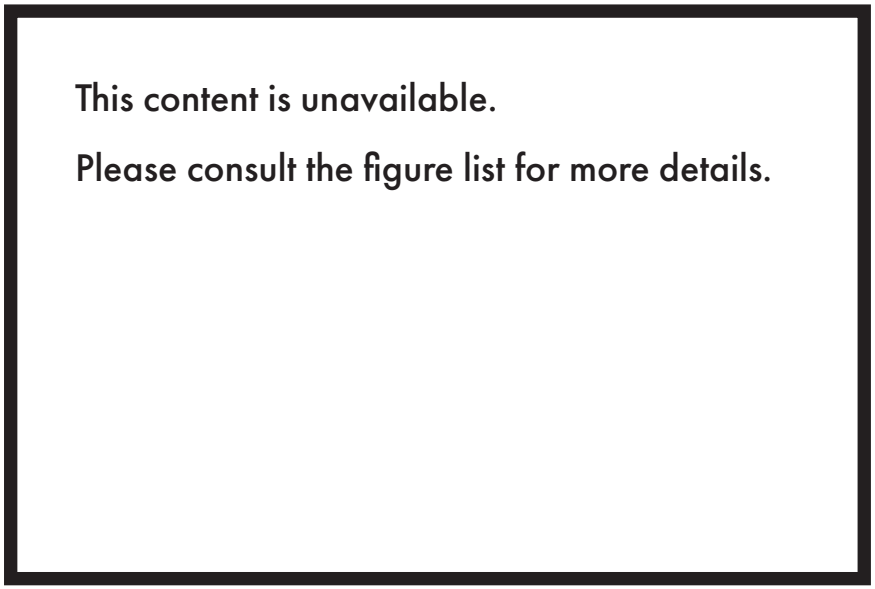


Figure 3.17. Participants assessing a card before assigning it values.

Activity 6 – Design Requirements and Precedent Analysis

Materials: 1 A0 design requirement template, and a pack of red dot stickers.

Instructions: All participants completed this activity as a singular group. The existing prototype was deployed and demonstrated to the crowd. The design requirements template was then presented, and participants were instructed to discuss the prompts indicated by the template, record ideas on post-it notes, and adhere these notes onto the respective prompt area discussed. Once completed, participants were instructed to place a red dot sticker on the line between two images and their respective qualities, with stickers closer to the image/quality proportionate to how important they think that quality is to the final design. This process was repeated for each of the 6 lines. The prototype remained active and demonstrated throughout the activity, with users prompted to try it out themselves and roleplay scenarios.

Rationale: Activity 6 aimed for stakeholders to co-evaluate the existing design, and codesign design goals and solutions. This was to both formulate a developmental roadmap of the Roborover for this study, as well as formally document the current feature set, expert evaluation, and intended design trajectory as an FDA design file. The activity felt appropriate as a capstone to the workshop, prompting participants to answer key design questions with accumulated insight after two days of critical inquiry. The live demonstration of the prototype was intended to function both as evaluative analysis of the precedent, as well as prompt potential design solutions and opportunities for the remainder of the activity through self-inquiry (Martin & Hanington, 2012, p. 74).

Results: Audio recordings were transcribed. These, alongside physical results were collated and thematically analysed. Themes were then compiled in the Table 3.0 as a stand-alone FDA design file.

Users tended to prefer medical, performance, functional, affordable, homely, and modern devices.

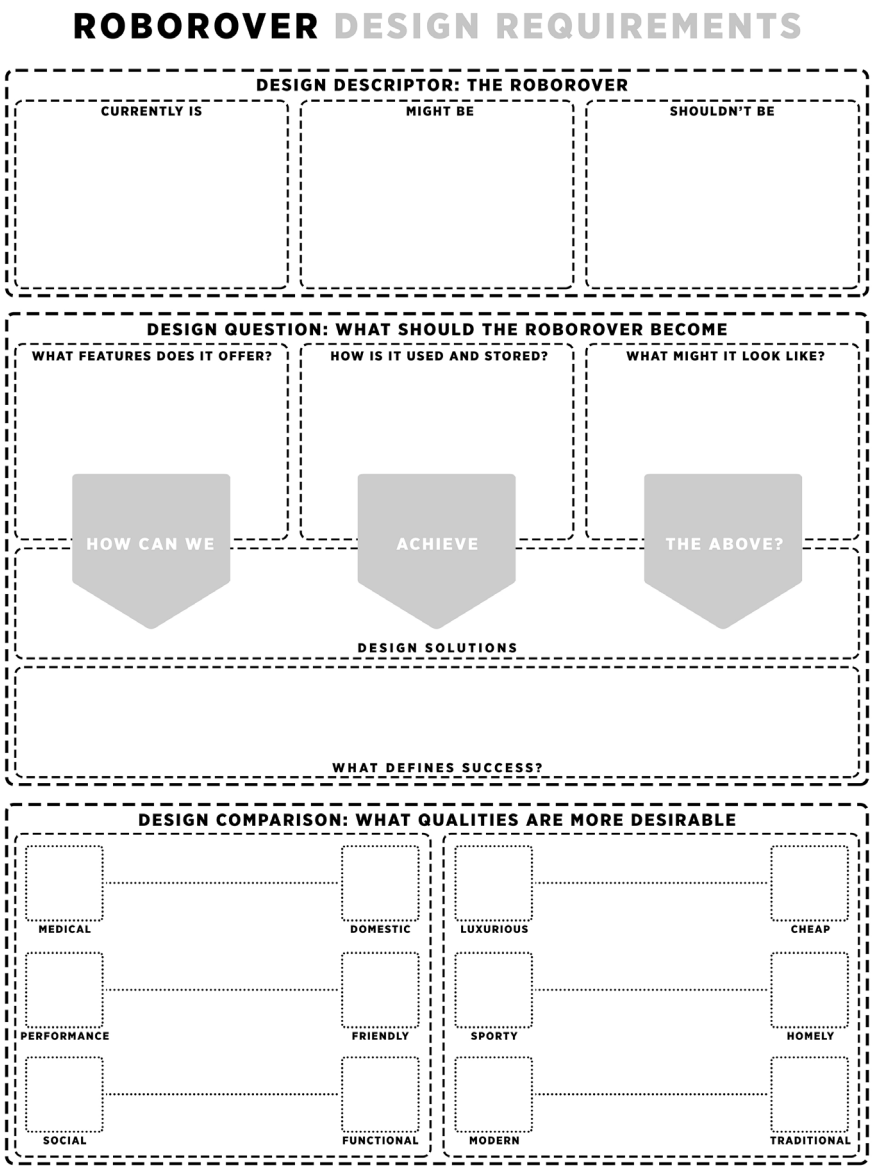


Figure 3.18. Design requirements template.

Currently	Should	Might/Opportunities	Shouldn't

• Is 2-3 kg
• Has detachable handles
• Has forward and side movement capacity
• Is stable, but still skids, especially if driven too far forward. It is therefore safe but not ideal for circuit accuracy
• Measures and controls travel distance by rotation of wheels rather than absolute location
• Requires two hands to deploy/store
• Has no ergonomics or shaping
• Has poor forearm stabilization
• Fits long elbows
• Can fall off table
• Has a hard-to-reach interface
• Has Bluetooth indicator
• Has battery charge level indicator
• Has battery charging indicator
• Has charging Port
• Has on off
• Uses a battery
	• Have tablet attachment on front
	• Be usable in hospital, clinic and at home
	• Integrate games which appropriately represent the movements of the arm
	• Be portable (carry-on luggage safe)
	• Be usable on multiple surfaces (relatively coarse to relatively smooth table surfaces).
	• Look effective
	• Be driven via patients and/or clinicians
	• Have an emergency stop accessible from both sides for patient and clinician
	• Be easily learnt and relearnt
	• Have low risk for low-level supervision in a multiple patient to clinician circumstance
	• Be prescribed by clinicians
	• Be ergonomic, particularly having a place for the arm to rest in/on
	• Secure/strap the forearm in position required to facilitate rehabilitative exercise
	• Support the forearm and elbow, and its weight/pressure at different angles
	• Be adjustable for all arms including:
	  • "big men" (95th percentile men)
	  • "little old ladies" (5th percentile women)
	• Be hygienic and easily cleaned
	• Comply with regulations including:
	  • MedSafe
	  • TGA
	  • FDA
	  • CE
	• Be user-aware, addressing sizes of obese populations
	• Have absolute position tracking and edge detection for preventing falling off the table
	• Be usable within rehabilitation groups
	• Aesthetically fit within a domestic environment
	• Be reminiscent of non-medical consumer products
	• Reduce fatigue experienced from device use
	• Reduce equipment frustration/improve ease of use of the design
	• Utilize few elements comprised of simple continuous forms (2-3 forms)
	• Utilize a selective colour palette (1-3 colours)
	• Have an obvious, easy to use, and reduced interface (1-5 buttons/indicators)
		• Incorporate physical targets patients can 'drive/reach' towards
		• Incorporate physical obstacles for navigation-based exercises
		• Elbow weight sensor as failsafe against too much forward drive
		• Custom table/platform with opportunities for height adjustment, markers, whiteboard, digital interface, physical objects, and lipped edges
		• Be used as a mouse substitute/supplement
		• Be used as a TV remote substitute/supplement
		• Be stored with one arm
		• Torque sensors to prevent arm pulling with/in lieu of distance calibration
		• Gamified interface/experience
		• Force sensitive joystick
		• Be waterproof
			• Risk damaging the user by:
			  • Dragging arm/moving too far forward
			  • Twisting arm
			• Be too heavy
			• Be able to drive itself off the table
			• Be uncomfortable
			• Be used whilst connected to the mains
			• Use Velcro for sanitary reasons

Table 3.0. Design requirements generated from Activity 6.

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Please consult the figure list for more details.

Figure 3.19. User responses to Activity 6.

Discussion

The results from **Activity 1** are subjective to the participants' definition of self. Audio transcripts suggested that participants defined self primarily as user perceptions and intrinsic motivation.

Results from **Activity 1** showed self and fatigue were the most significant motivator and inhibitor respectively of all activities. When evaluating rehabilitation activities independently, family and clinicians became significant tertiary and secondary motivators respectively. These findings are in line with the Almere Model Heerink et al., (2010) regarding intention of use being influenced by user perceptions; and further extends it by introducing family and clinicians as motivators. In particular, clinicians being a significant influence for rehabilitation, but not for leisure and enjoyment activities, challenges the social influence dimension of the Almere Model. The implications of this finding are intriguing when it is noted that PWS reported clinicians as a significantly higher motivator than clinicians and engineers did, suggesting either clinicians are unaware of the significance they hold over motivating rehabilitation, or confirms the ramifications of the current shortage of healthcare professionals.

PWS reporting fatigue as a significant inhibitor to rehabilitation is in line with expert consultation. Poor device usability results in greater levels of user effort being exerted than necessary during usage, inducing fatigue (M. King, personal communication, December 2, 2019). The fact that clinicians and engineers reported fatigue as less of an inhibitor and self as more of an inhibitor than PWS suggests clinicians and engineers may view fatigue as less serious of an issue due to lack of personal experience. Whilst speculative, this could simply mean usability issues are not as prioritized by clinicians and engineers, and have therefore been underdeveloped, which would explain some of the shortcomings of current device design identified in the literature review and validates the current research trajectory.

The high proportion of activities being reported within or near the home (70.4%), as well as over half of rehabilitation (54.3%) suggests the home is an ideal location to explore rehabilitation opportunities, supporting the increasing popularity of home-based rehabilitation (Holmqvist et al., 1998; Lang et al., 2007, p. 8).

Rehabilitation patterns and free time exhibiting inverse patterns with the former being more frequent early in the day, suggested an opportunity where rehabilitation can be facilitated near the end of the day to capitalize on the free time there. However, expert consultation argued that these correlations might just be biproducts of a PWS's schedule,

and disrupting it might lead to adverse effects.

Interestingly, personas did not noticeably affect responses. Participants answered 38 and 32 motivated and demotivated response cards respectively, and no concentration of responses based on persona could be witnessed. Instead, many participants commented on how a PWS would fluctuate between a motivated and demotivated mindset, which resulted in some response cards being recorded as both personas. Little has been reported on the implications of user motivation on their acceptance of robotic intervention, and these results suggest motivation of PWS itself may be a more nuanced and dynamic concept. Future studies are recommended to investigate the findings from **Activity 1** further to elucidate the behaviour and motivation patterns of PWS.

The results of **Activity 2** indicated communication and feedback, social connection and wellbeing, engagement, accessibility, and progress were key themes to a positive healthcare experience.

Participants extensively discussed **Communication and feedback,** communicating sub-themes such as empathy, feedback, respect/trust, and uncertainty. Emphasis was placed on not only empathy from healthcare professionals, but also a degree of equality in status. This was mirrored by the clinicians who participated in the activity, who explicitly commented PWS are 'people first'.

"Felt like my opinion was heard and valued. It felt like we were equals rather than clinician and patient."

This increases the validity of the notion that a positive experience is one where the individual is valued and respected, suggesting perceived respect as an influencer of perceived enjoyment. Participants furthered this by explaining how uncertainty was prominent, even in a positive experience where they were respected, and appropriate feedback helped mitigate this. Appropriate feedback was described as information with complexity appropriate to the user, delivered at intervals desired by the user, suggesting efficient communication and user consideration should be acknowledged when designing interfaces for rehabilitation devices.

"Getting the information when you want, at the level you want at the time you want"

The identification of **social connections and wellbeing** as a theme mirrored findings from literature, as well as **Activity 1,** where clinicians and family were found to hold significant influence over rehabilitation (Wolff et al., 2014). Sub-themes identified comprised of relationships, family, attitudes and emotions. Participants commented extensively on how they formed deep connections with their therapist/client and other stroke survivors, and that that relationship would be difficult to replace with a robotic device.

"what you're trying to do with this technology is to replace the relationship that I have had with this person I have been working with for months"

Discussions around family and emotions outlined that family presence was desirable, as they invoked supportive emotions, which contrasted assumptions that PWS would want as few bystanders as possible to reduce stigma experienced during rehabilitation (Vaes, 2014). This suggests those closest to PWS may be exempt from 'bystanders' that would cause stigma, and integrating family and clinicians as motivators through digital interfaces may be a design opportunity for future studies.

Engagement was identified as a theme for a positive healthcare experience, with sub-themes of focus and concentration, enjoyment, and comparing to others. Participants described how actively engaging and stimulating the mind invoked a positive response during rehabilitation. Similarly, the involvement of other PWS promoted friendly competition and the ability to compare with others undergoing rehabilitation. This both increased user engagement, as well as facilitate the ability to measure progress with friends.

"It made her happy because she was doing something about her rehabilitation and said that it made her feel good when she was engaging in it"

It can therefore be suggested the promotion of user enjoyment will facilitate intention to use and, validating the approach of increasing perceived enjoyment to improve acceptability.

Accessibility of healthcare was a prominent theme among participants, derived from sub-themes of simplicity of use, setup time, and customization. Participants described how the simplification of design, reduction of setup time, and introduction of user customization made the rehabilitation intervention more suitable for independent use. These desired design features are all common improvements implemented during an industrial design process, validating its potential as a design research tool. Extrapolating from this, the sub-themes also align closely to acceptability determinants such as perceived ease of use and adaptivity. It can therefore be argued that accessibility encompasses the product usability dimension of a positive healthcare experience.

"People wanted device to be accessible so they could use it themselves"

Participants consistently described **progress** as a theme for positive healthcare experiences, comprising of the sub-themes: progression in rehabilitation, recovery time and managing expectations, and pressure/lack of empathy. Participants elucidated that a positive medical experience revolves around the ability to visibly see recovery and milestones thereof. Despite describing positive experiences, participants outlined juxtapositions with a lack of empathy from bystanders, and subsequent social pressures to recover faster.

"friends/boss don't see pain ... they don't get it"

The inability for bystanders to see the pain of users builds upon the findings of the literature review, suggesting product-related stigma can also be invisible. This would undoubtably cause frustrations for PWS when bystanders fail to see the effort and discomfort experienced during rehabilitation, and appropriate support is not given. The ability for stigma to discredit an individual is linked to the highlighting of their disability (Vaes, 2014), emphasizing the need to reduce stigma so disability is emphasized, whilst also increasing usability so users experience less discomfort during device use.

Results from **Activity 3** indicated Engagement, Simplicity, and Progress were the most important values to users for a robotic device for stroke rehabilitation to embody. These findings validated findings from **Activity 2** as all three values were themes identified in a positive healthcare experience. From audio transcripts, it was observed that the decision making behind card selection at each stage was primarily influenced by how many other card values were encompassed by the assessed card.

"performance and efficiency is not the same as reliable, it certainly is the same as quality isn't it?"

Participants expressed that they felt a majority of values were important for a robotic device for stroke rehabilitation to have, and that this encompassing assessment was merely a means to ensure as much value could be captured holistically with as few words as possible (R. Little, personal communication, December 3, 2019). This suggested values independently did not hold more 'value' over one another, but rather a hierarchy could be established where certain values embodied numerically more subsidiary values, i.e., quality embodying performance, efficiency, and reliability.

Interestingly, respect & trust was not allocated to the final section by any group, yet scored enough cumulative points to rival some of the top values. This suggests that whilst it was no group's top contender, it had universally high importance. As a sub-theme of **Activity 2**, a construct within the Almere model, and a basic human courtesy; this was not surprising, and reiterates the need for the device to make the user feel respected and valued.

Overall, as values were not more important than one another individually, **Activity 3** provided little value in terms of identifying a priority of qualities to address through design. Instead, **Activity 3** provided a reference list for how design objectives could be broken down into more tangible goals. For instance, if accessibility embodied simplicity and adjustability, reducing design complexity, and increasing adjustability ranges could be measurable ways to improving accessibility.

The results of **Activity 4** showed that gamification of medical devices could improve user engagement. This could be implemented through the direct introduction of digital games into the design, or through the categorization of the device within game-associated categories. The latter is within the scope of this study, and proposes that the Roborover could be categorized as engaging when visual semantics resemblance to gaming technology is present in the device's aesthetic. However, designs that were rated as embodying progress in **Activity 4** were classed as hard to use and somewhat effective in **Activity 5.** This suggests current designs that exemplify the values users desire are not easily used by users. Similarly, designs that were effective, and neither easy nor hard to use had less functions than those rated hard, but required dexterity, strength, or training to operate. Furthermore, **Activity 5** indicated current armskate technology is considered ineffective by all users, validating a need for redesign.

This suggests overall, ease of use correlates with not only usability, but is subjective to the user's ability, and the suitability of the design thereof. Designs that are easily used by an able-bodied person are often hard to use for a PWS, but differences can be subtle, such as a twist knob being harder to use than a push button for PWS. Consequently, many of the commonplace consumer products which embodied positive attributes in **Activity 4** were suddenly unacceptable when the ease of use for PWS was considered. It can be argued that this dissonance between devices embodying user ideals, and devices being practical for PWS, is a causal factor for poor device usability and acceptability in current practice, as the differences is easily overlooked during development.

Effective and easy to use designs conversely, had simple interfaces, comprised of few forms, and a cohesive colour palette. These are all hallmark features of a well designed product that is fit for purpose, and is validated by embodying several of the key themes to successful rehabilitation design identified in prior activities, as well as literature (Scopelliti et al., 2005)

Results from both **Activity 4 and 5** suggested complex designs with fiddly interactions were disliked and perceived as ineffective and hard to use. This can be extrapolated from findings from the literature review, where complexity decreased usability and increased learning barriers, and client suitability greatly influenced acceptability. The latter illustrates the need for medical technology, particularly robotic devices for upper-limb stroke rehabilitation to be purpose built, with end-users in mind. The use of a device for a person with low-dexterity should not be fiddly or complex, but rather easily accessible and operatable. This finding confirms results from the other activities, and validates the need for a user consideration in design.

Activity 6 yielded a significant number of design requirements for the Roborover as a whole, detailed in Table 3.0. This served as the basis for formulating the design criteria detailed in Table 3.1.

The precedent analysis conducted as part of **Activity 6** contributed significantly to the design requirements yielded. Having stakeholders witness and experience device use first hand elicited extensive self-discovery of usability issues, and potential solutions amongst participants; whilst roleplaying facilitated several lines of elucidating discussion. Sanitation concerns with Velcro were extensively explained with respect to regulations, whilst biomechanics and anthropometrics were elaborated upon for designers and engineers to better understand comfort and safety from a medical perspective.

The design workshop was this study's first large scale research undertaking to validate and expand upon the rudimentary knowledge built from the literature review. Overall, several constructs which influence acceptability were validated, including usability, perceived ease of use, perceived enjoyment, perceived adaptivity, and stigma. Results from activities revealed opportunities to design towards in an effort to increase these constructs and resultantly improve device acceptability. In particular, **Activities 4, 5, and 6** yielded specific functions and aesthetics the design should strive towards in this endeavour, whilst **Activity 3** yielded a reference to how qualities can be systematically broken down into more tangible design elements.

The design workshop also identified new areas of research interest, such as the enhanced integration of clinicians and family through gamification, and the complex dynamics behind the suitability robotic devices for upper-limb rehabilitation in the domestic environment. Whilst the aesthetic considerations of the latter will be investigated, the former is a complex area of research that is outside the scope of this current study, and consequently will not be investigated further.

Limitations

It is recognized that several limitations were present in this design workshop. PWS who volunteered for this workshop are likely to be highly motivated individuals within their cohort. Consequently, their responses are likely to not be representative of the average PWS. Design limitations included a relatively small sample size. Over the course of 2-days, only 4 PWS participated in the workshop. This limitation was noticeable in data analysis as the number of non-PWS responses frequently outnumbered the PWS responses. Using persona-based responses from clinicians and engineers, despite their expertise, can be considered expert consultation at best, and does not guarantee data collection of nuanced user-experience. Future studies are recommended to recruit more participants, facilitating statistical significance and inferential analysis.

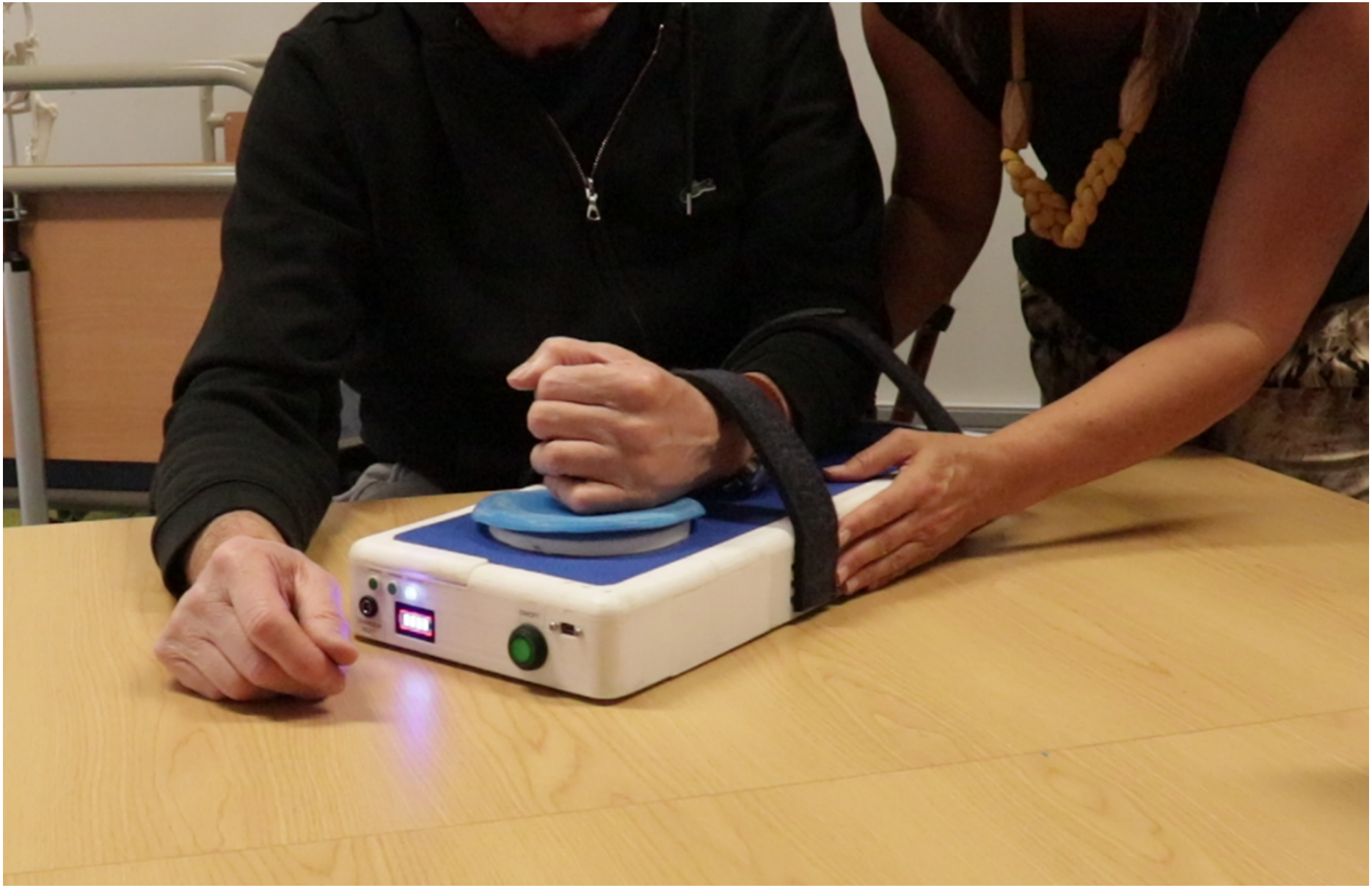


Figure 3.20. Current prototype in use.

Review of Existing Design Criteria

	Criteria	Rationale	Achievement Status	Comments
1.0	Investigate user perceptions of acceptability determinants with respect to user sub-groups	Understanding how users measure, value, and conclude on determinants will allow more precise manipulation of them in an effort to improve device acceptability. Similarly, understanding the difference between device acceptance by PWS and clinicians will allow design criteria to be established which can satisfy both subgroups.	Partially achieved, Updated	Has been initiated through design workshop. New criteria in Table 3.2, supersedes this criterion with more refined exploration.
1.1	Utilize industrial design to manipulate acceptability determinants	To investigate the validity of industrial design as a design research tool in the manipulation of acceptability	Updated	Has not been attempted. New criteria in Table 3.2, supersedes this criterion with more refined exploration.
1.2	Introduce end-user (PWS and clinicians) into design process	Exclusion of end-users causes usability and safety issues, and user rejection (Shah et al., 2014, p. 133).	Achieved	Has been achieved, but needs to be sustained. Has been updated to criteria 1.0 in Table 3.2

Table 3.1. Review of existing design criteria.

Revised Design Criteria

Criteria			Approach	Rationale
1.0	Maintain end-user involvement (PWS and clinicians) in design process		Maintain regular communication and consultation, and frequently conduct stakeholder walkthroughs (Martin & Hanington, 2012, p. 168)	Exclusion of end-users causes usability and safety issues, and user rejection (Shah et al., 2014, p. 133).
2.0	The device must:	Have a detachable handle	Design and engineering	Facilitates different handle models as per requirement from Table 3.0
2.1		Be a portable weight suitable for carry-on luggage (<7kg)	Minimize weight during design	Facilitates portability of device, as well as transportability of lithium-ion batteries as they cannot be checked-in
3.0	The device's form must:	Not interfere with device function	Keep designed elements clear of mechanical components	Compromising the medical function of the device is unacceptable
3.1		Be stable enough not to tip over	Appropriate distribution of size and weight	Increases device safety
3.2		Be introduced to ergonomic improvements	Introduce contouring	Increases comfort and usability of device, particularly for PWS who have brittle skin
3.3		Be adjustable to fit a majority of users	Introduce adjustment mechanism	Current device is too long for some. Device should be universally usable by people of different sizes, as well as facilitate high perceivable adaptivity
3.4		Integrate digital devices	Introduce device securing mechanism	The software device currently does not physically integrate with the device
4.0	The device's interface must:	Be easily understood	Reduce interface features, increase readability	Reduces user confusion and learning cost
4.1		Be accessible with respect to a PWS	Reduce effort required to interact with the device	Ensures features are suitable for the functional capabilities of a PWS
4.2		Have a battery level indicator	Integrate component within design	Increases usability and satisfies requirements from Table 3.0
4.3		Have a bluetooth indicator		
4.4		Have a charging indicator		
4.5		Have a charging port		
4.6		Have a USB port		
4.7		Have 2 easily accessed emergency stops		
5.0	Aesthetically, the device should:	Be suitable for hospital and clinic	Conduct rapid prototyping and conduct stakeholder walkthrough (Martin & Hanington, 2012, p. 168) to assess concept aesthetics	Facilitates clinical viability to promote clinician acceptance
5.1		Be suitable for domestic environment		Over half of rehabilitation is done at home. This facilitates integration within the home without looking out of place.
5.2		Be desirable and/or prestigious		Reduces product-related stigma (Jacobson, 2010)
5.3		Look effective	Look professional and fit for purpose	Facilitates user acceptance
5.4		Look easy to use	Reduce design complexity	
5.5		Comprise of few forms		
5.6		Utilize a succinct colour palette		
6.0	Device usage should:	Be easily learnt and relearnt	Have usage be simple to understand, and congruent with interface	Increases usability and reduces learning cost
6.1		Require low supervision and not cause harm to the user	Reduce safety risks and increase emergency countermeasures	Increases device safety and ability to be used independently at home
6.2		Secure the elbow and forearm	Explore securing mechanisms	Enforces correct biomechanical movements for rehabilitation
6.3		Be hygienic	Replace Velcro, and use non-porous materials	Facilitates clinical viability to promote clinician acceptance
6.4		Not be physically taxing to use	Explore design interactions and reduce points of effort expenditure	Improves usability and decreases visibility of stigma
6.5		Be quick to set up and pack down	Explore deployment options	Improves usability

Table 3.2. Revised design criteria after Design Research Phase 1.

Chapter 4:
Design Research 2

Chapter Summary

This chapter details the design process undertaken to implement industrial design strategies identified through background research, in an effort to improve the acceptability of the Roborover.

Design Process

Figure 4.0 illustrates my process of translating research findings into design concepts. Concepts are assessed with respect to the criteria of the current stage in design. Opportunities, areas of interest, and impracticalities are equally documented to iteratively refine a design concept. Concepts are then collated and developed by taking the most promising ideas forward. As concepts mature in feasibility, they are also displayed in equally escalating fidelity with the intention of final designs to be presented in styles suitable to be developed for manufacturing.

Due to the volume of design work, only higher fidelity concepts are documented in this chapter.

Mediums used include sketching, computer aided-design (CAD), and 3D printing.

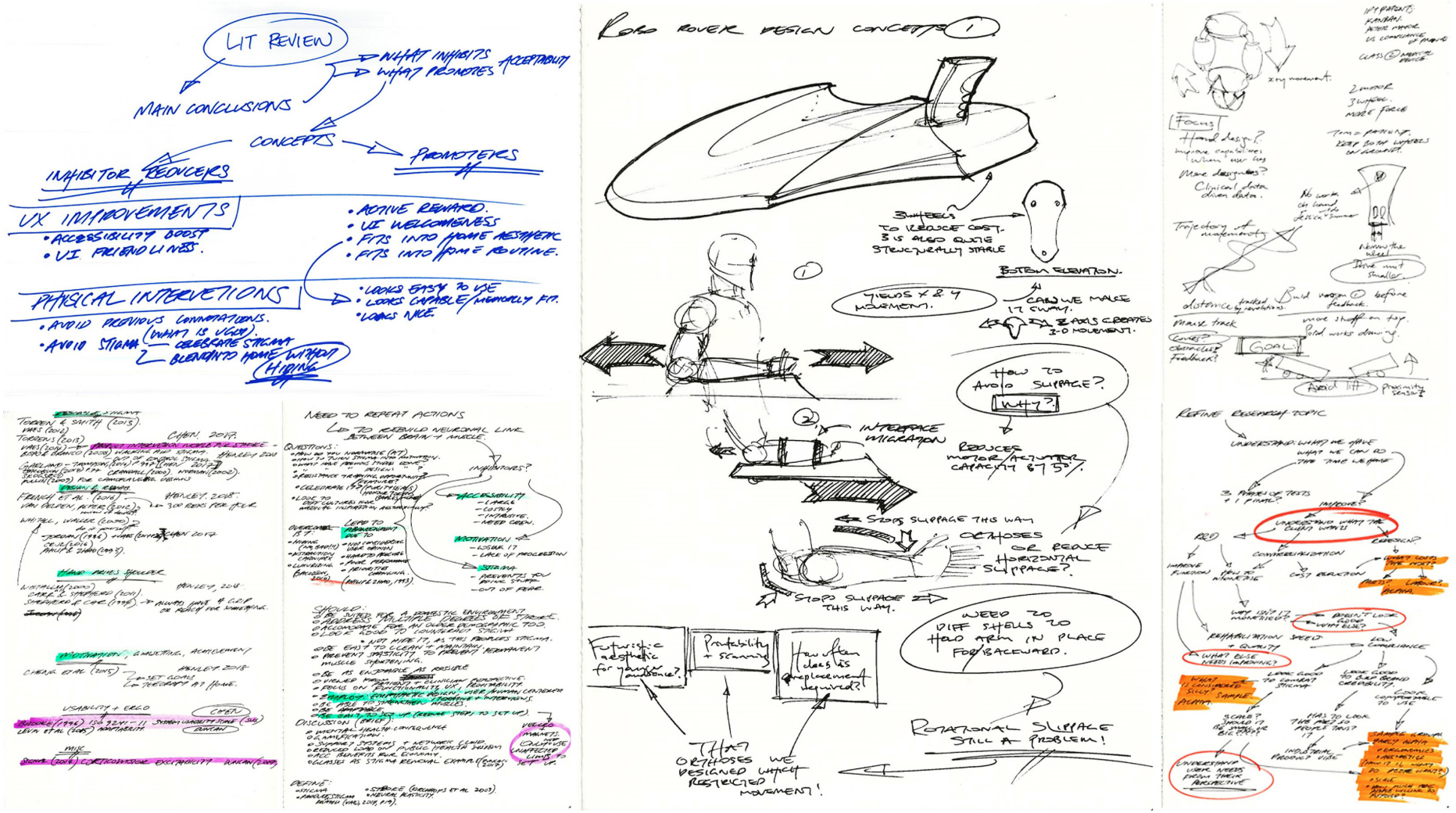


Figure 4.0. Design Process.

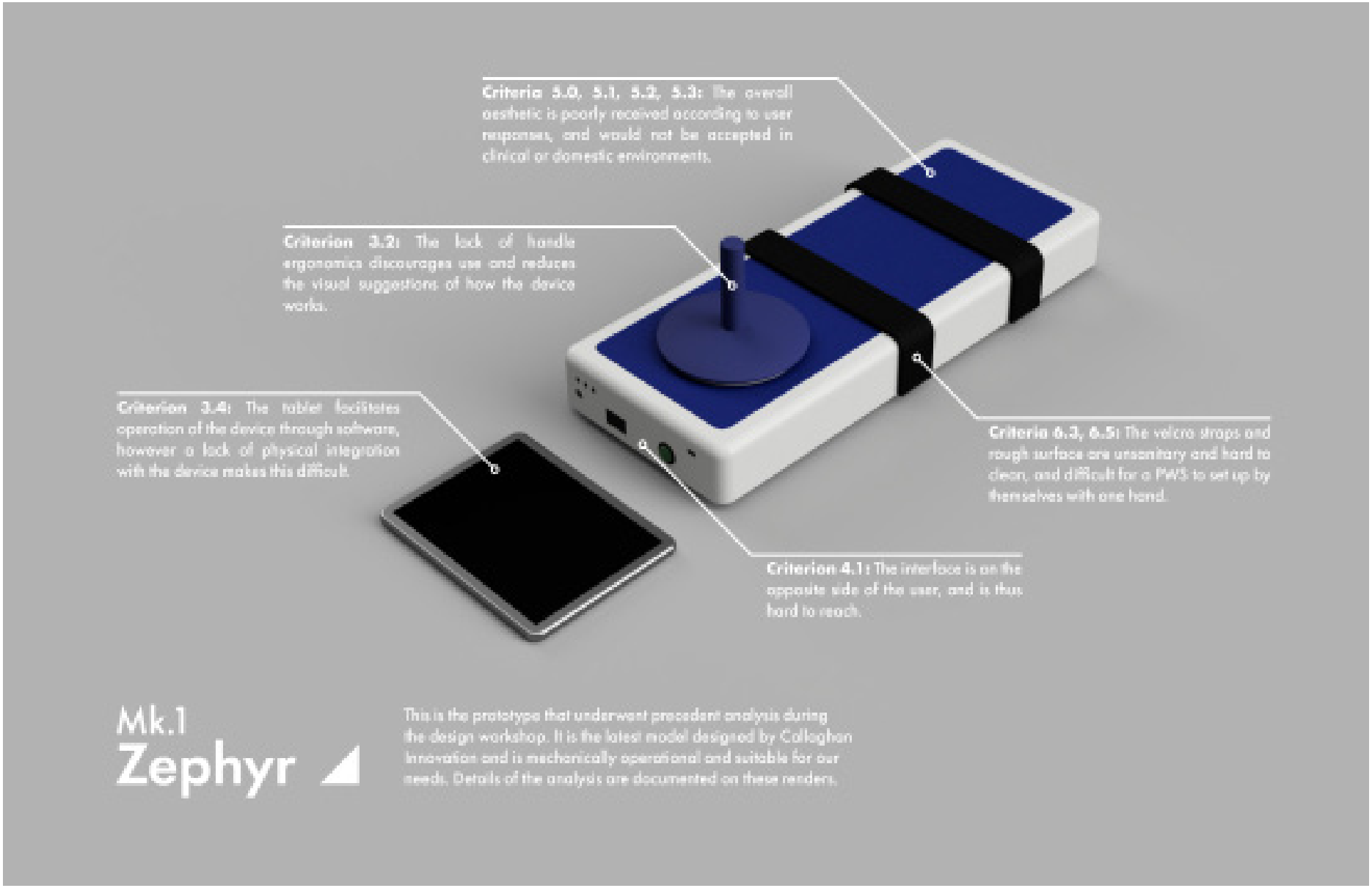


Figure 4.1. Findings from Precedent Analysis.

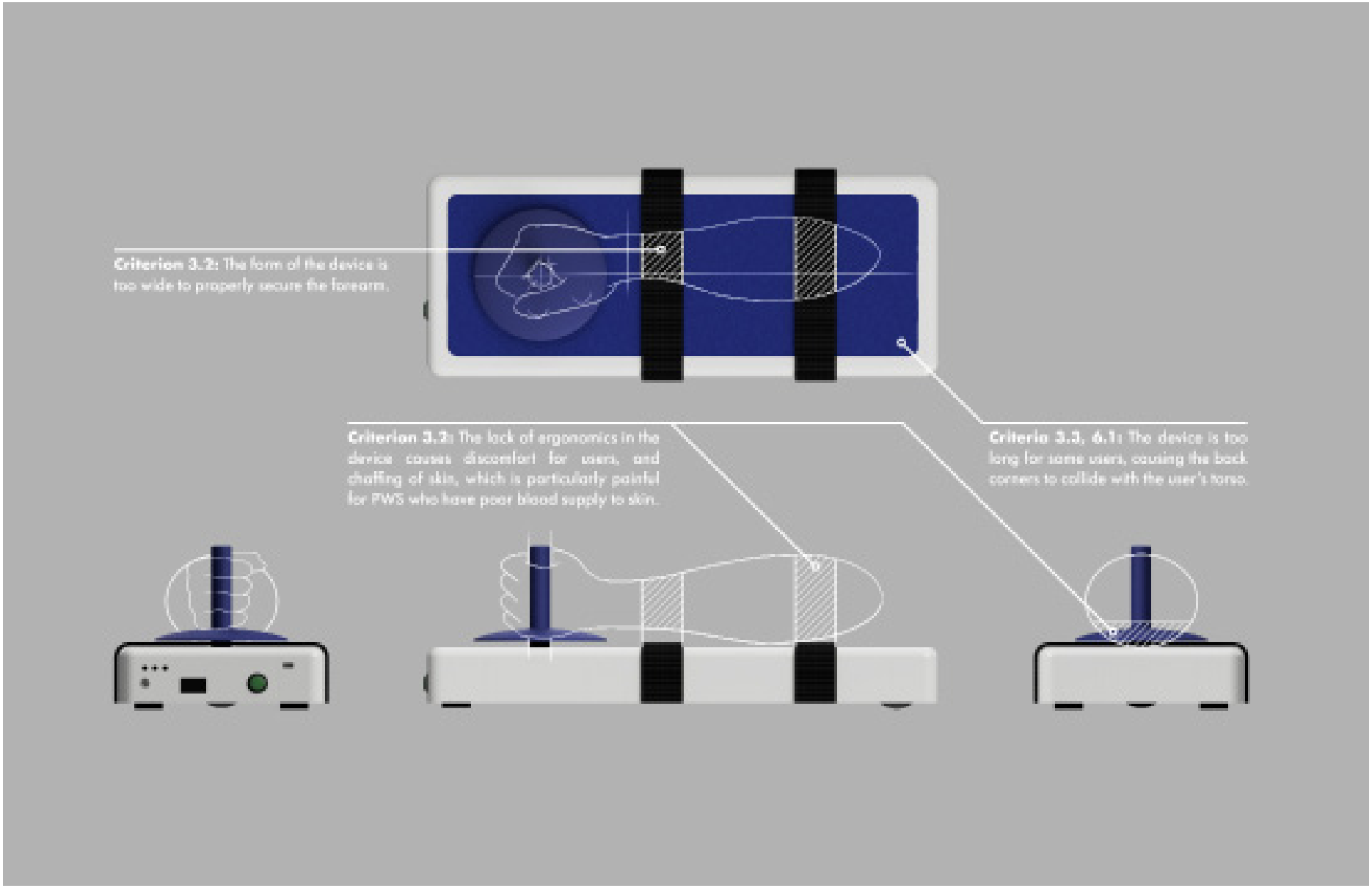


Figure 4.1 (continued).

Form and Ergonomics

As much of the criteria outlined in table 3.1 revolves around the form of the device, an exploration of form was appropriate to initiate the conceptualization process. Form and structure are inseparable in industrial design, and considerations needed to be made of how these features would influence components, assembly and use. Consequently, to focus the exploration, ergonomics and integration of the arm and hand were prompts used to guide design. Observation studies were also conducted on how users interact with other objects, as seen in Figure 4.3, giving insight into natural hand behaviours, as well as pave some opportunities for cognitive categorization in the future.

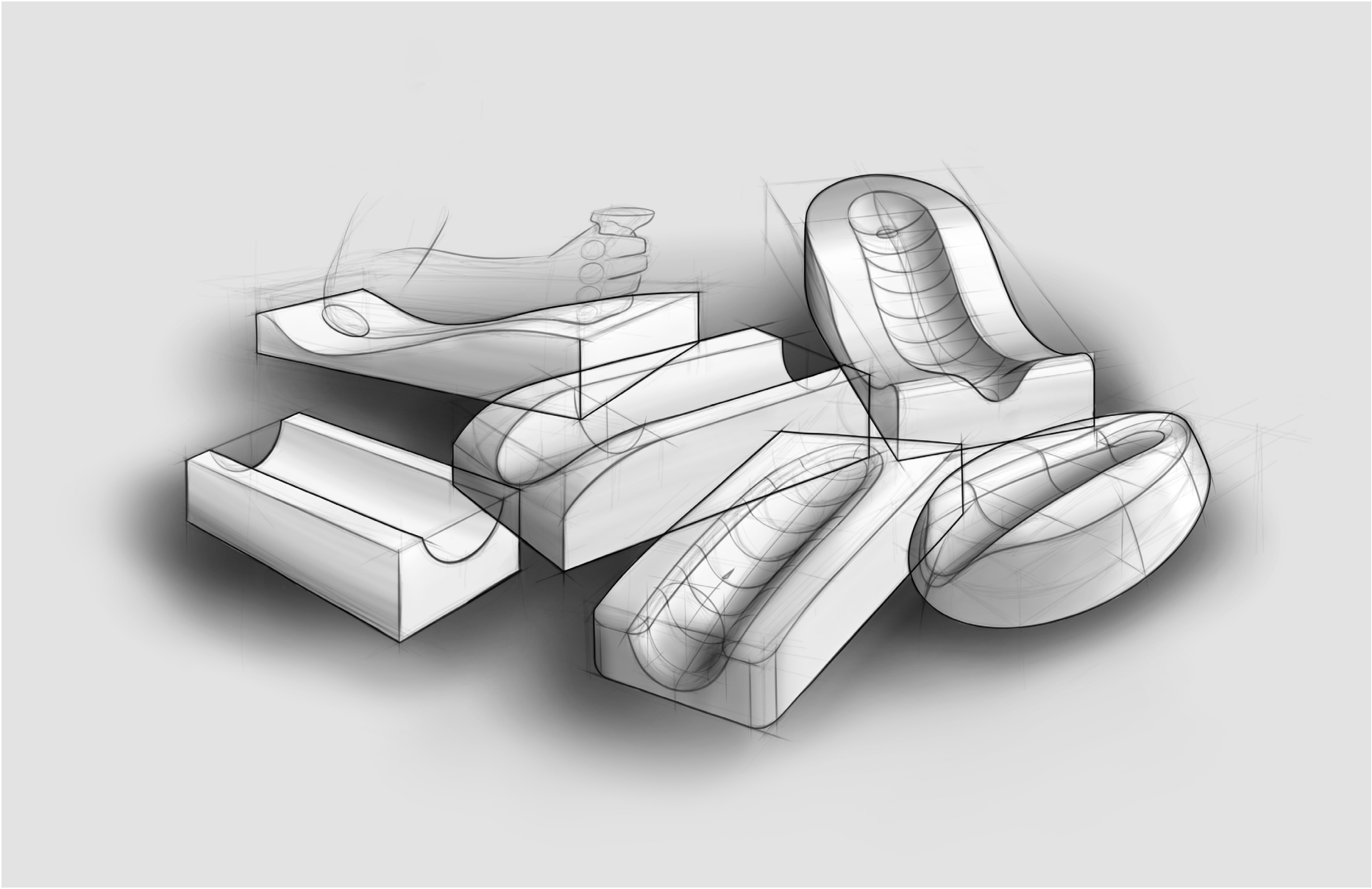


Figure 4.2. Exploration of arm integrating forms.

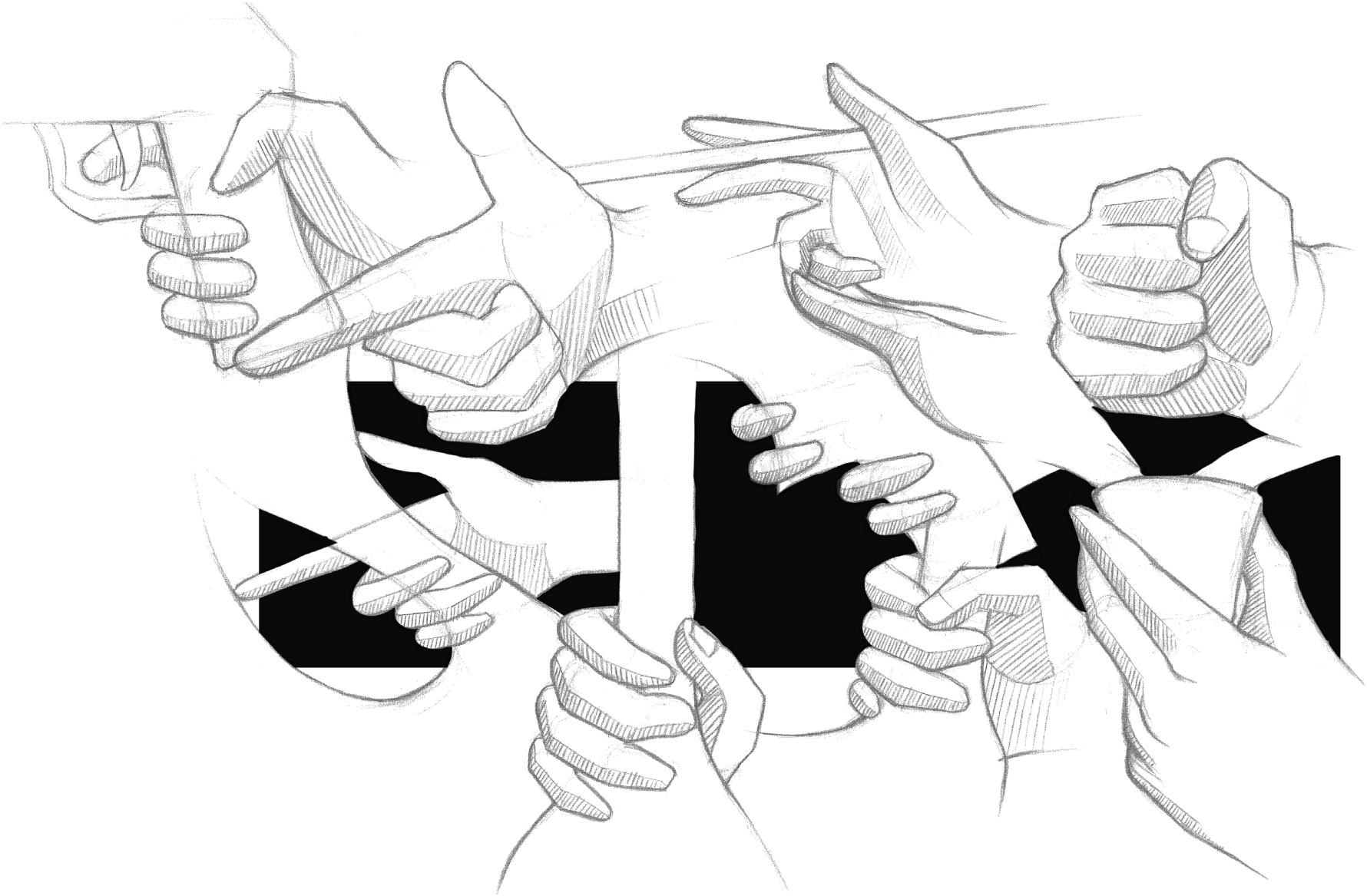


Figure 4.3. Hand ergonomic studies.

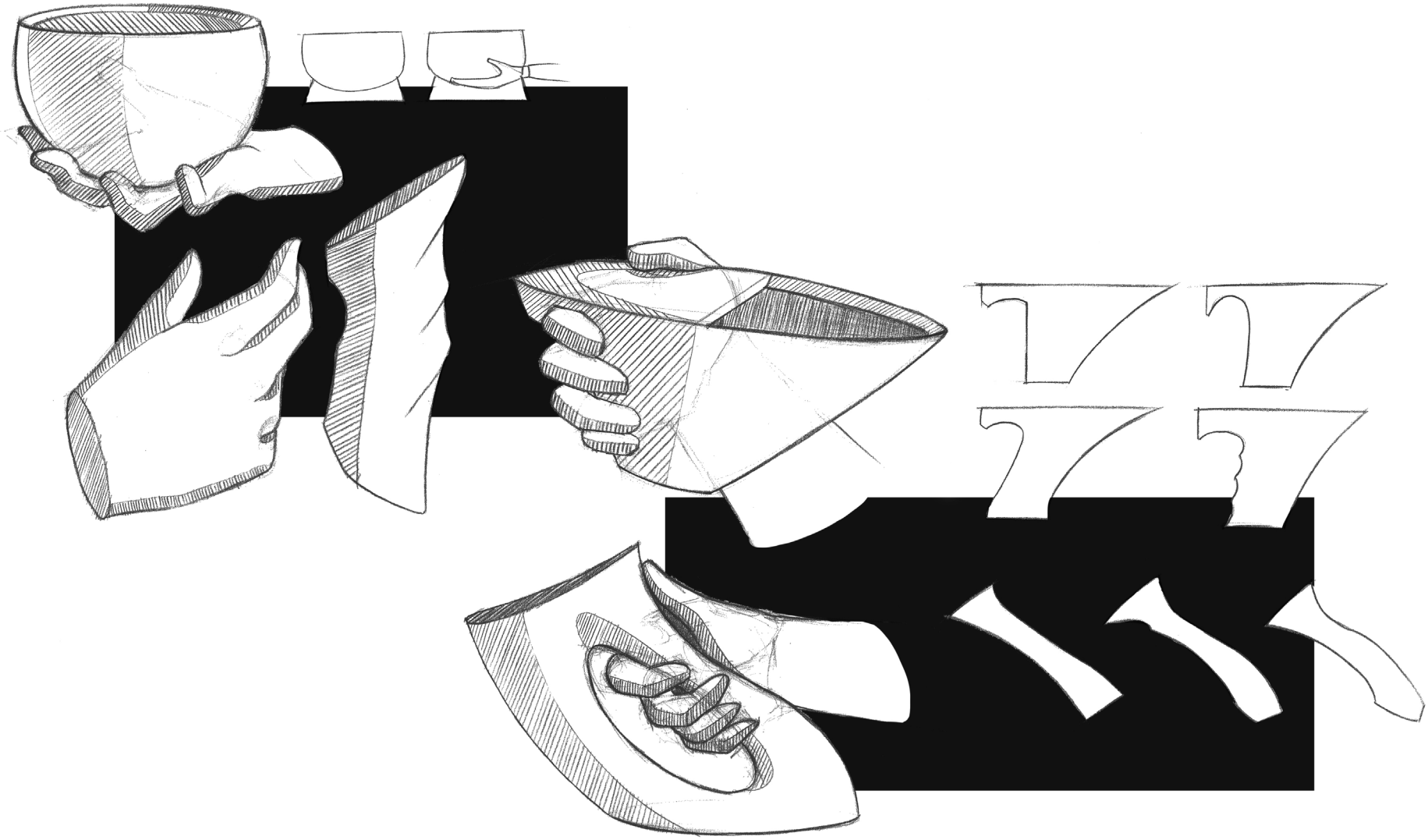


Figure 4.3 (continued).

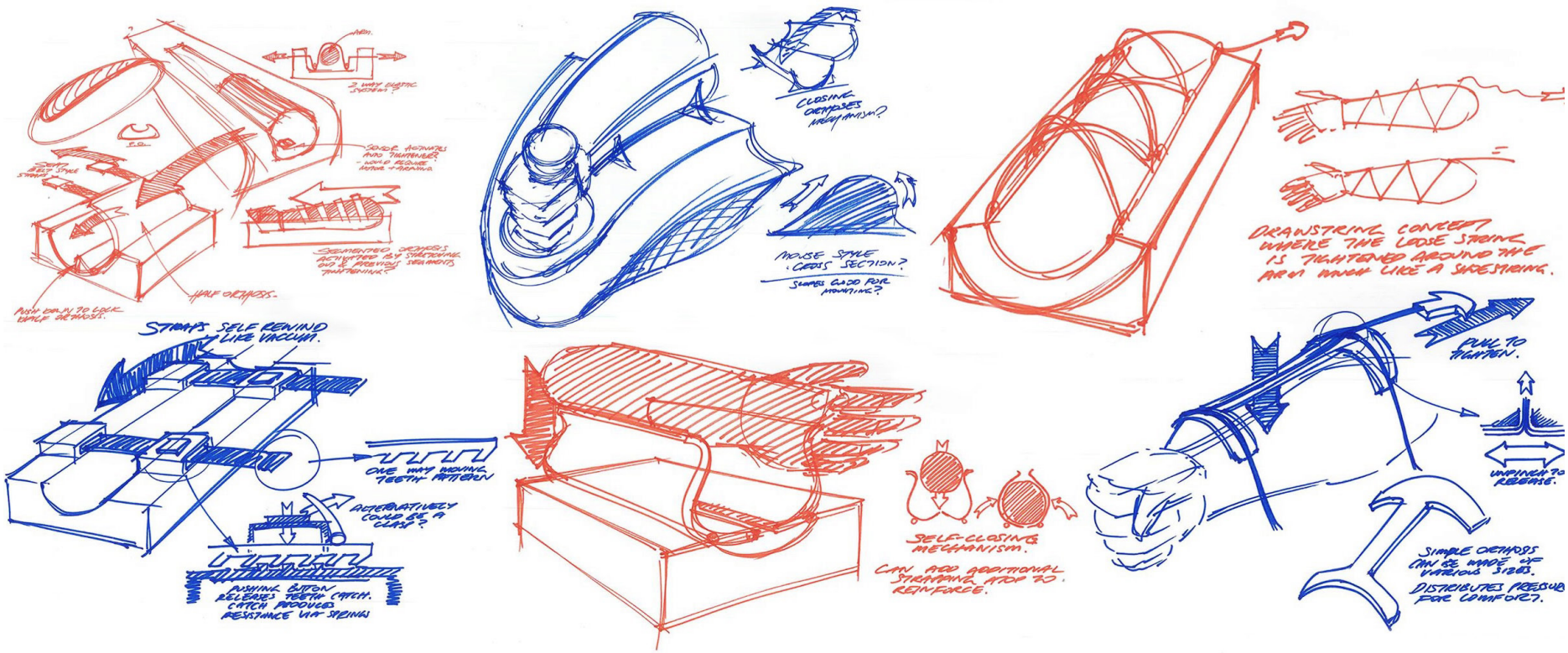


Figure 4.4. Arm securing concepts.

Securing the Arm

As ergonomic options were developed, the securing of the arm became a key area needing design exploration. Not only does the securing mechanism apply to Criterion 6.2, it also had major UX implications on Criteria 3.2, 3.3, 5.4, 5.5, 6.1, 6.3, 6.4, and 6.5. Focus was given on creating a system that could be entered and tightened with one hand and with as few steps as possible. Due to the need for sanitation and replacement, several elastic materials were ruled out, whilst wet cleaning processes also reduced the feasibility of using electronic actuators. Similarly, the need for safety also meant emergency release and suitability for a PWS's skin and muscles had to be considered in each design.

Adjustability

The mk.1 device was designed by Callaghan for relatively large users. Whilst it is desirable for the device to have a large surface area for increasing stability and drive torque, the mk.1 device was too large for a significant proportion of smaller users. To satisfy criterion 3.3, it was decided from expert consultation that 90% of the population needed to be able to use the device. An investigation into these measurements was undertaken, with gender as well as race considered, as Caucasian anthropometrics are relatively larger than Asian equivalents. The dimensions of the anthropometrics are detailed in table 4.0. To satisfy this large range of dimensions, the form and ergonomics of the device

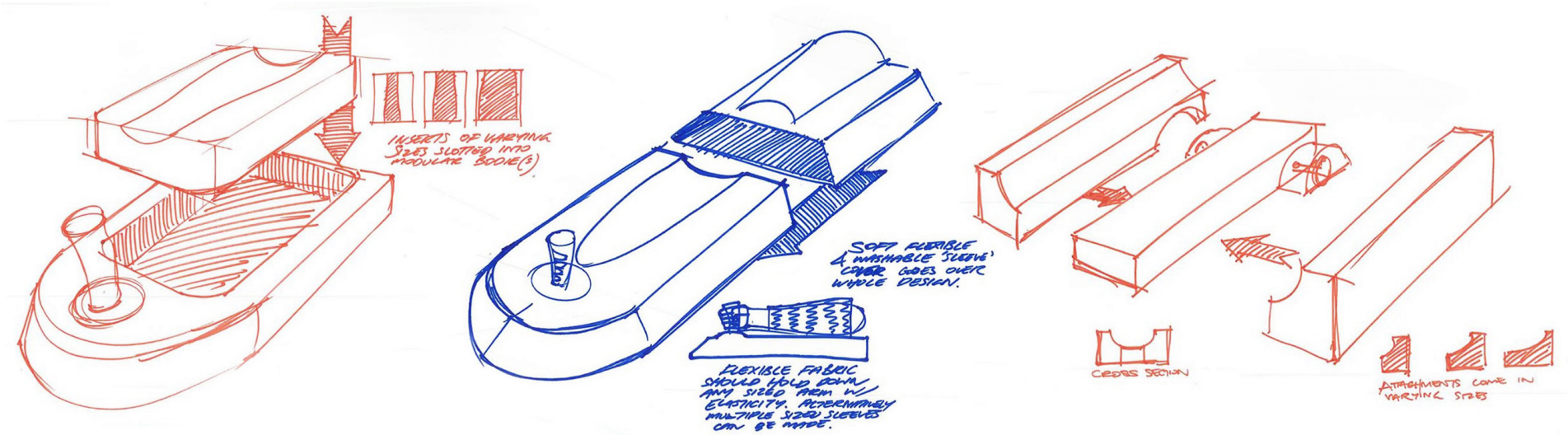


Figure 4.5. *Size adjustment concepts.*

needed to be adjustable in both length and width. This had several implications on the mechanical chassis of the design, and several concepts were presented and discussed. Expert consultation ruled that creating multiple sizes of the device was impractical in terms of cost and storage. Designs that had multiple 'inserts' instead were favoured, alongside extendable 'orthosis' sections, as the former was easy to detach and clean, whilst the latter was suitable for being wiped down, and did not risk having extra parts that could be lost.

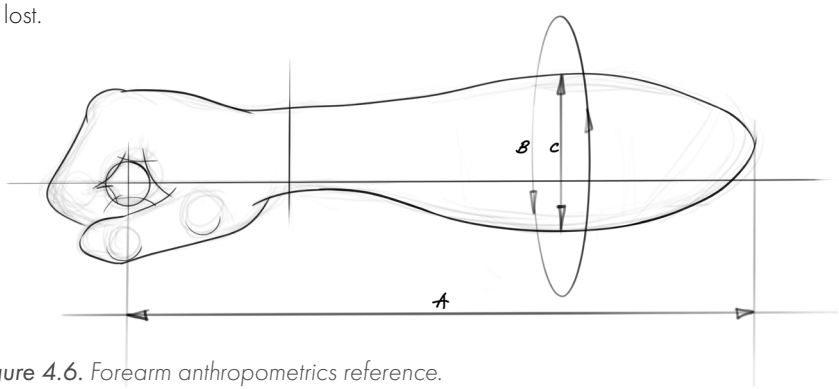


Figure 4.6. *Forearm anthropometrics reference.*

Dimension	Length (mm)		
	5th Percentile Asian Woman	95th Percentile Caucasian Male	Difference
(a) Elbow to Center of Grip*	278	391	113
(b) Forearm Circumference (relaxed)	199	327	128
(c) Forearm Diameter (relaxed) **	63	104	41

Table 4.0. *Anthropometric data of the forearm.*

(Christensen et al., n.d.; Gordon et al., 1989)

**Derived from subtracting hand length from elbow to tip of hand.*
***Derived from dividing circumference by π.*

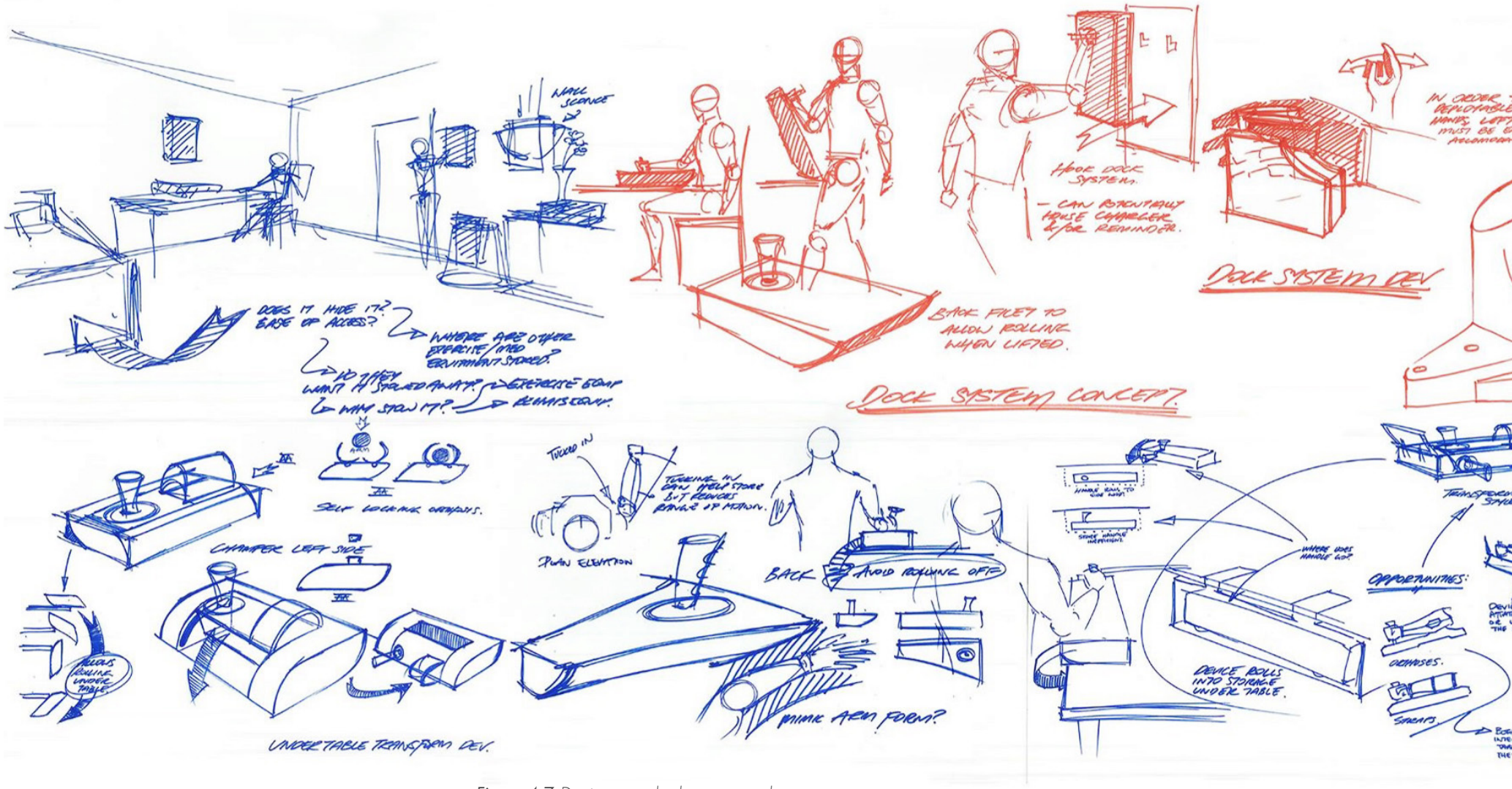


Figure 4.7. Device use, deployment, and storage concepts.

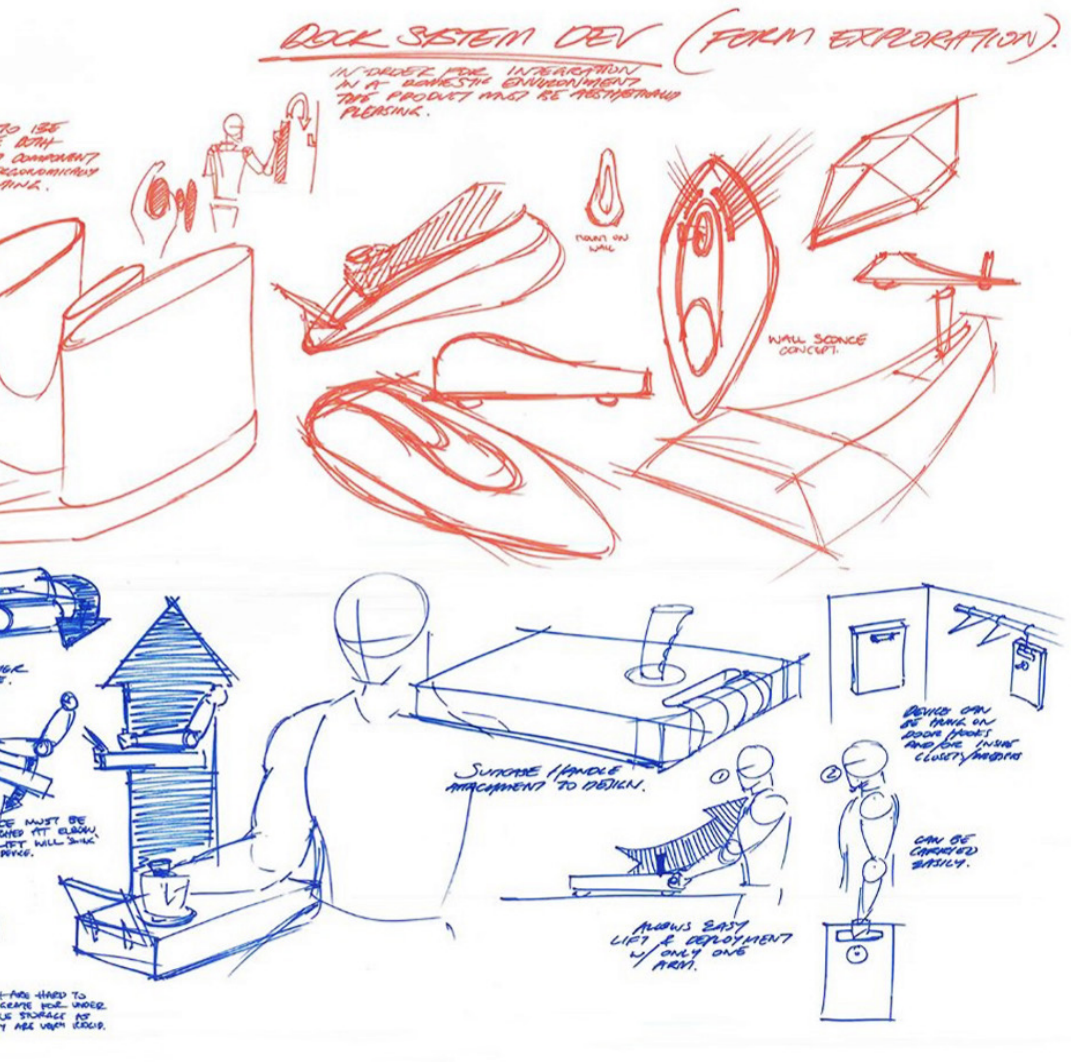


Figure 4.7 (continued).

Designed for Use

Extensive conceptualization was explored for how and where the device could be used. Concepts investigated areas within the home that could facilitate appropriate storage and convenient setup and pack down of the device. Some concepts explored the idea of designing housing for the device to 'park in', which could also serve as a charging booth; whilst others aimed at integrating the device as pseudo-furniture in an effort to satisfy criterion 5.2 with respect to Jacobson (2010). Major counterarguments to concepts revolved around the suitability of housing systems when the device was needed to be transported between the home and the clinic, and the suitability of complex deployment mechanisms with respect to mechanical limitations of the chassis.

Challenging Anthropometrics

Through iterative consultations with PWS, clinicians, and engineers, the wide range of design concepts began to converge into trends. One of the trends noticed was that the anthropometrics strongly influenced the form of the design, and that it had not been challenged in previous iterations. Concepts began to revolve around changing the anthropometric manner the user interacted with the device, for instance, literature suggested a pronated hand position was more natural (Christensen et al., n.d.), instigating the design of pronated and partially pronated joystick configurations. Concurrently, the most desirable design trends found through user review were also introduced into new concepts so they could simultaneously be presented during subsequent stakeholder walkthroughs. One of the major counterarguments to designing form ergonomics to angles not perpendicular or parallel to the table surface was that logistically a left- and right-handed version would need to be made, doubling resources and logistics for manufacture and clinical implementation.

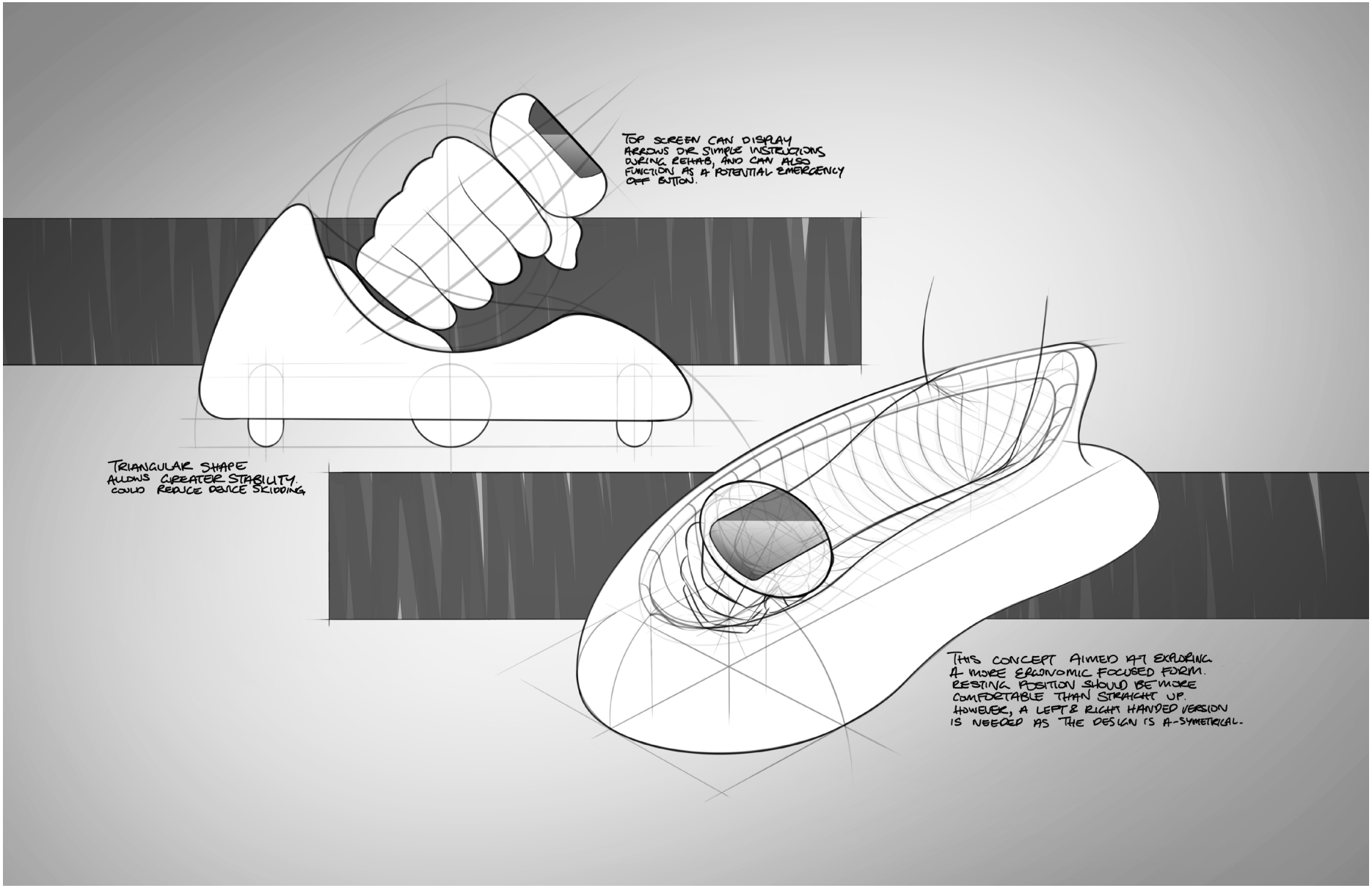


Figure 4.8. Concept with 45-degree joystick configuration.

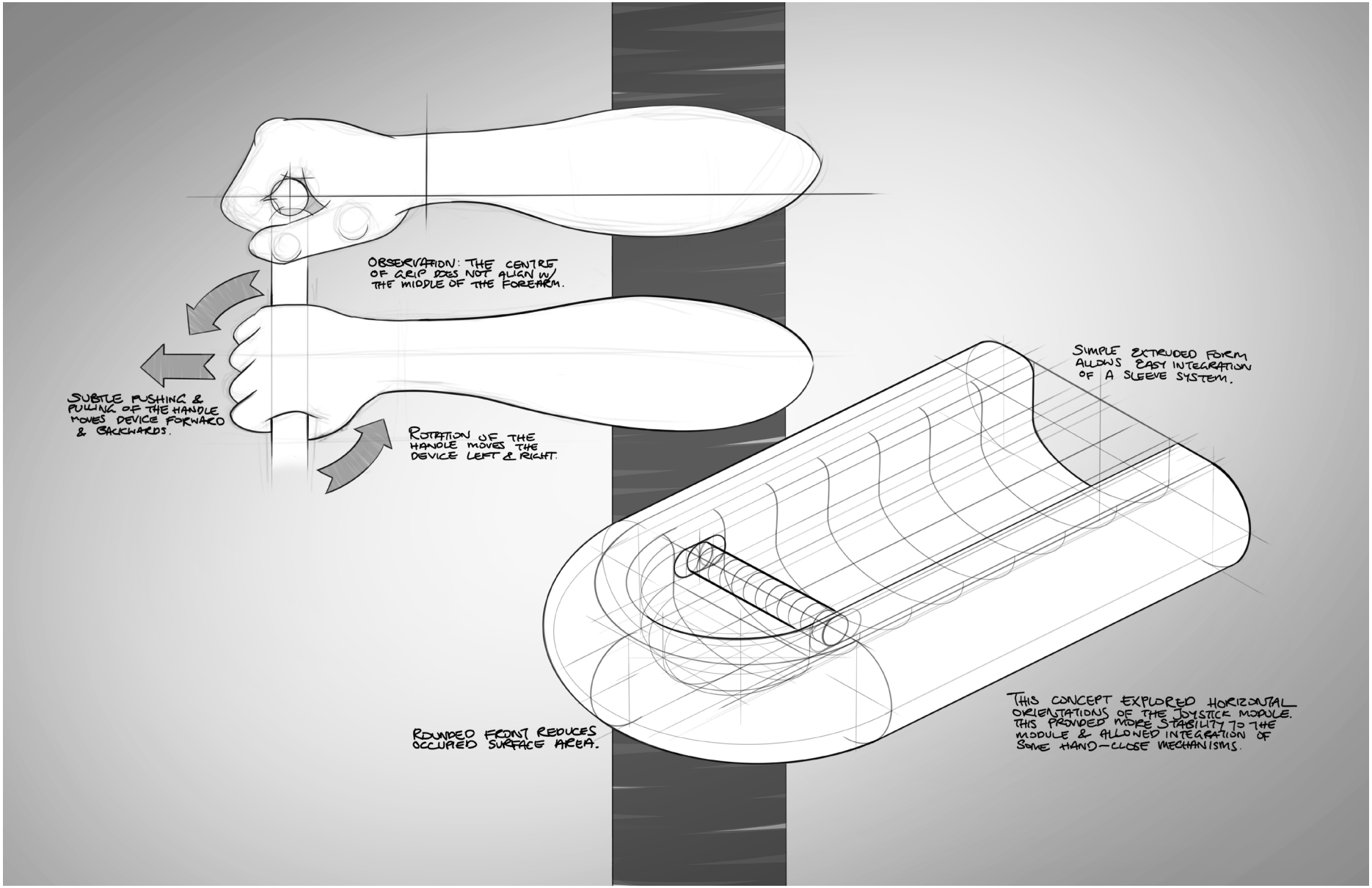


Figure 4.9. Concept with pronated joystick configuration.

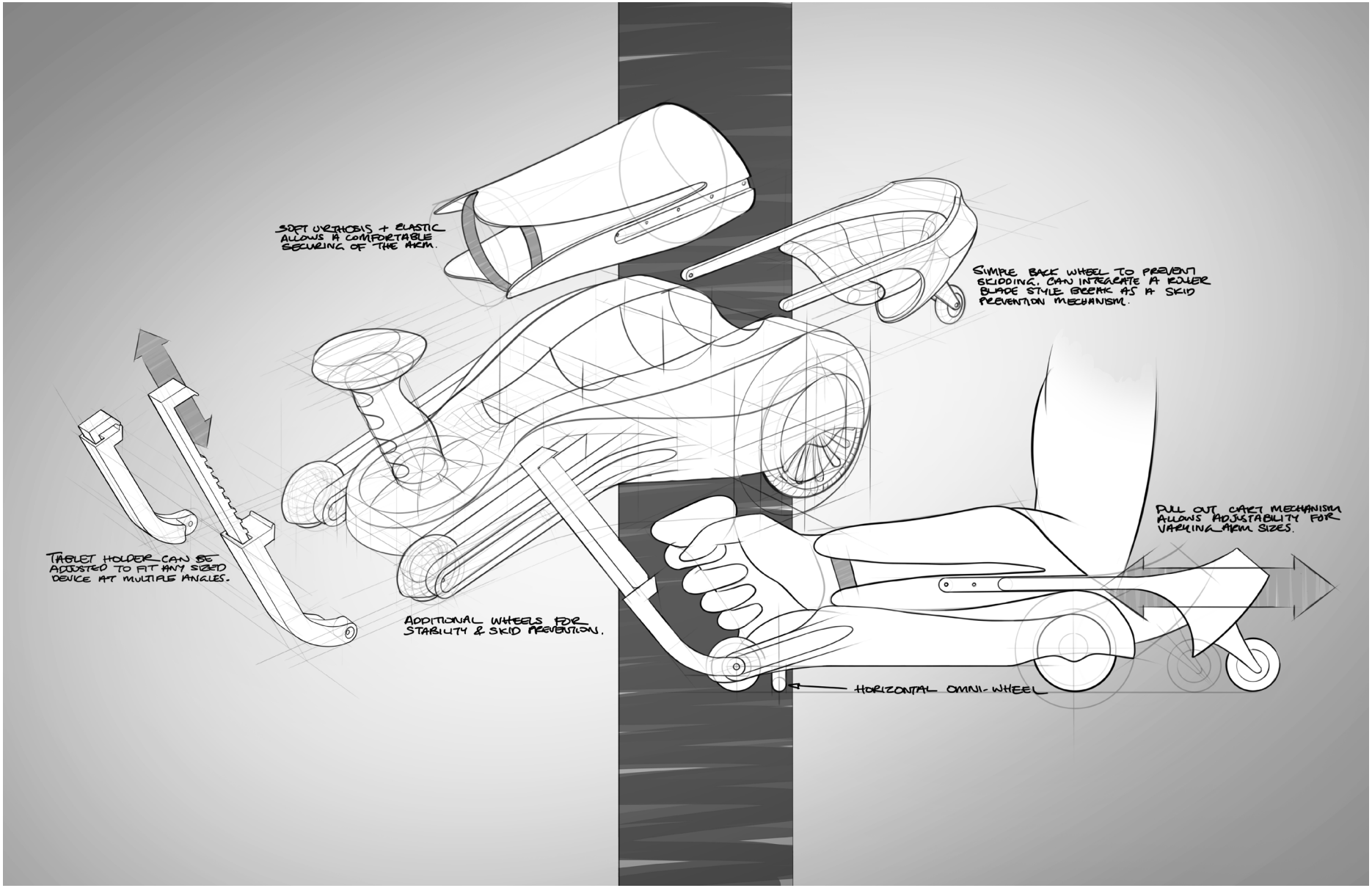


Figure 4.10. Concept with forward leaning joystick configuration.

A New Mechanic

Expert consultation after a stakeholder walkthrough recommended expanding the investigation of anthropometrics to full body dimensions to facilitate detailed analysis of deployment concepts in relation to the environment. These investigations uncovered an interesting fact: the average table was taller than the average elbow height of a seated person. When the thickness of the device is added, this props the elbow upward and forces the arm forward or the shoulder joint upward. This significantly compromised the fundamental principle of an armskate, and explained much of the discomfort and unusual placement of the scapula observed during use, as the arm was too high up to facilitate meaningful elbow extension. Therapists traditionally palliate these types of issues by adjusting furniture, such as by finding a taller chair or adding cushions, but this is not always possible and is a significant usability barrier regardless (N. Signal, personal communication, March 5, 2020). A new design criterion was generated due to this issue as it distinguishable from both criteria 3.2 and 3.3:

6.6 – *The device's usage should not be physically uncomfortable for the user.*

Consequently, this instigated the need to explore a new mechanism that could lower the elbow or facilitate elbow extension with a partially raised bicep.

Figure 4.11 illustrates some of the proposed solutions to this issue. Due to the mechanical implications the introduction of a system like this would have, form exploration was concurrently executed for assembly options. The concept aimed to add an axel to the device so the elbow could be lowered whilst the hand was raised, facilitating a lower resting position for the elbow, and increasing the range of elbow extension. The mechanism has since earned the moniker the 'see-saw' mechanism.

The novelty of such a mechanism meant physical prototyping was necessary. Expert consultation of the device suggested of all the configurations, an axel placed directly beneath the middle of the arm was the most beneficial configuration. The balance afforded by this produced the least counterweight effect, meaning users felt most comfortable raising and lowering their elbow with forward motion.

This new see-saw mechanism ended up not only solving the anthropometric issue, but also increased flexion and extension range of the rehabilitation movement, increasing medical value, and satisfying criteria 3.2, 3.3, and furthering 3.0.

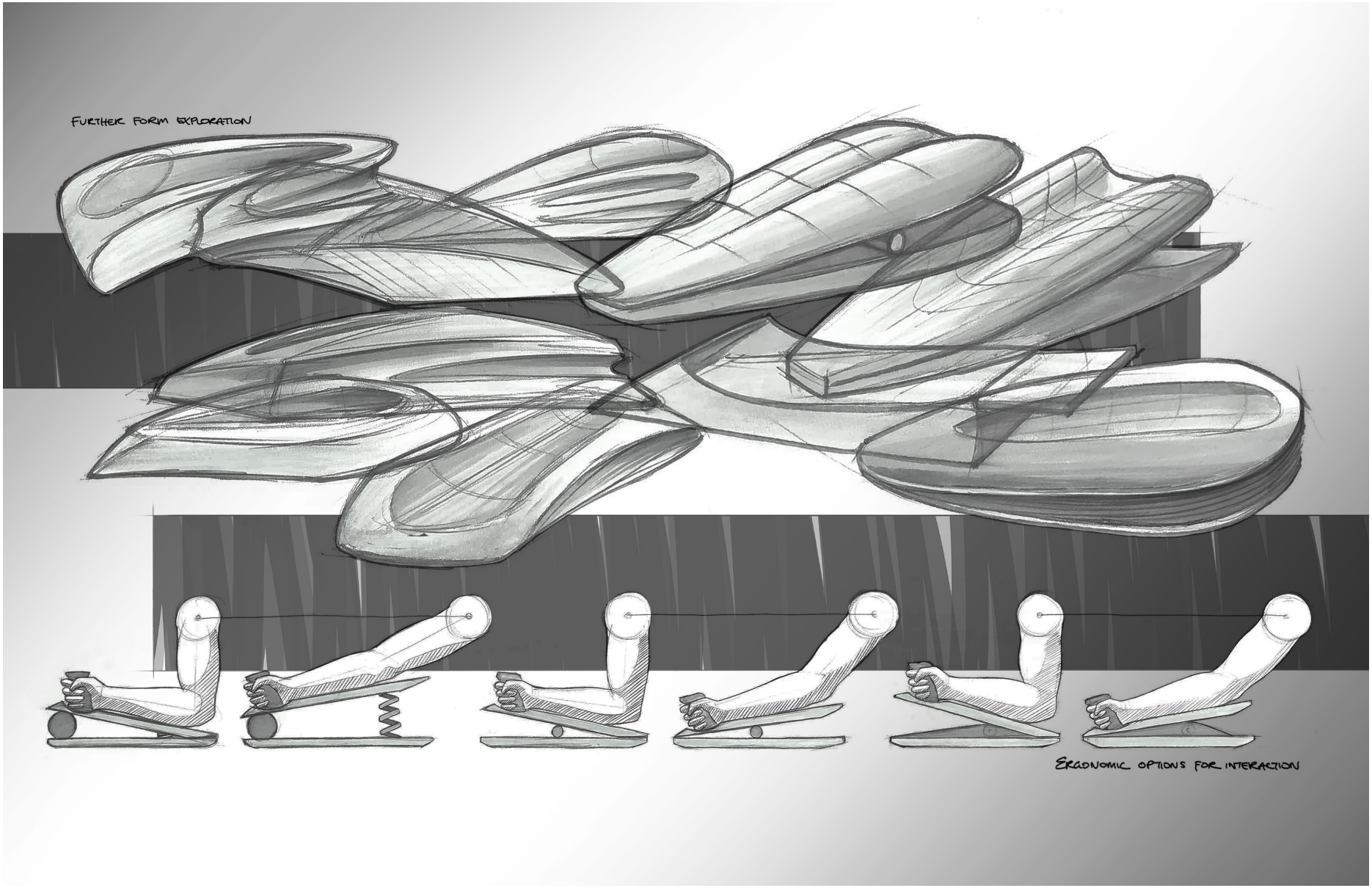


Figure 4.11. Novel mechanic concepts and accompanying form exploration.

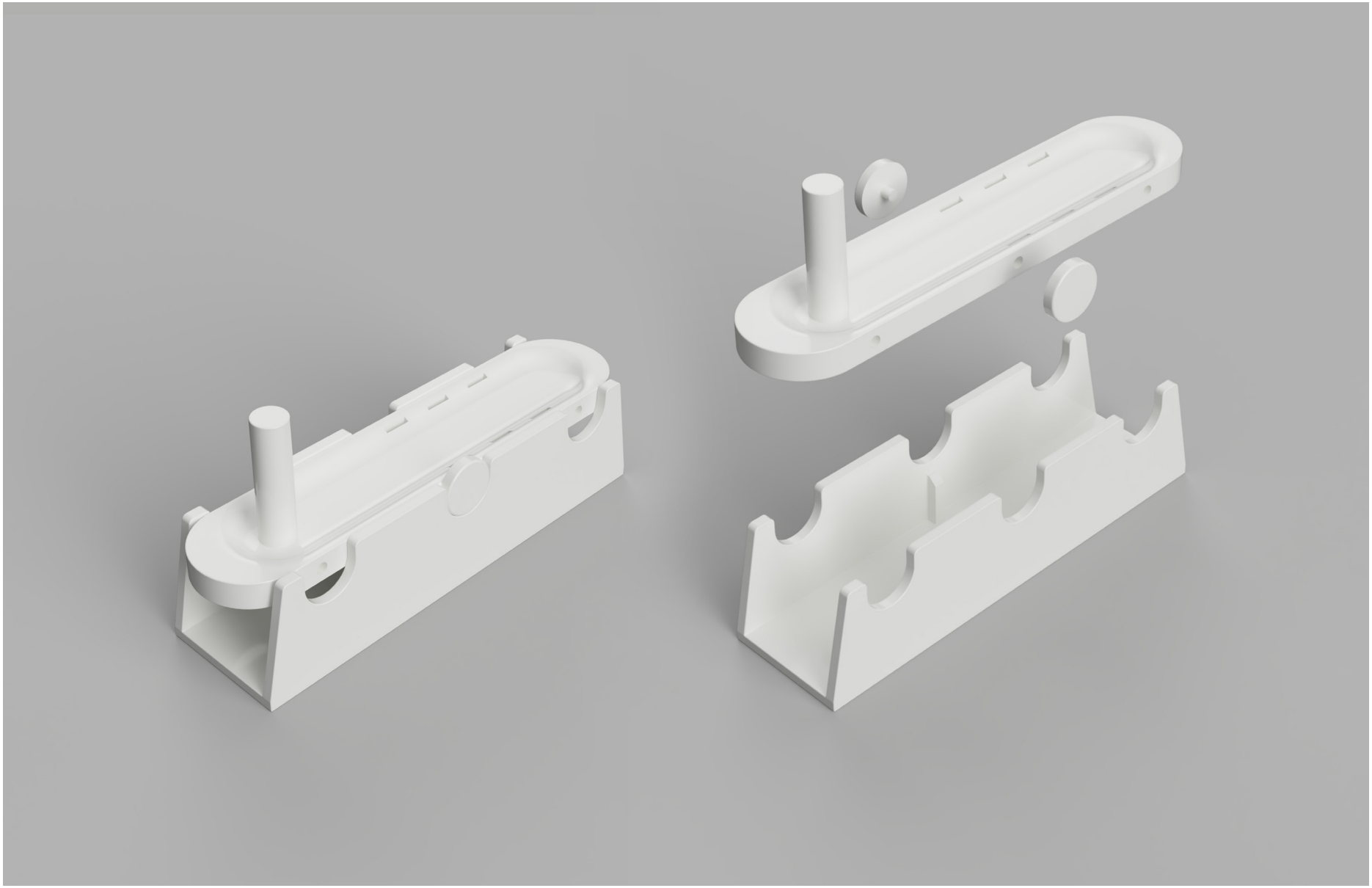
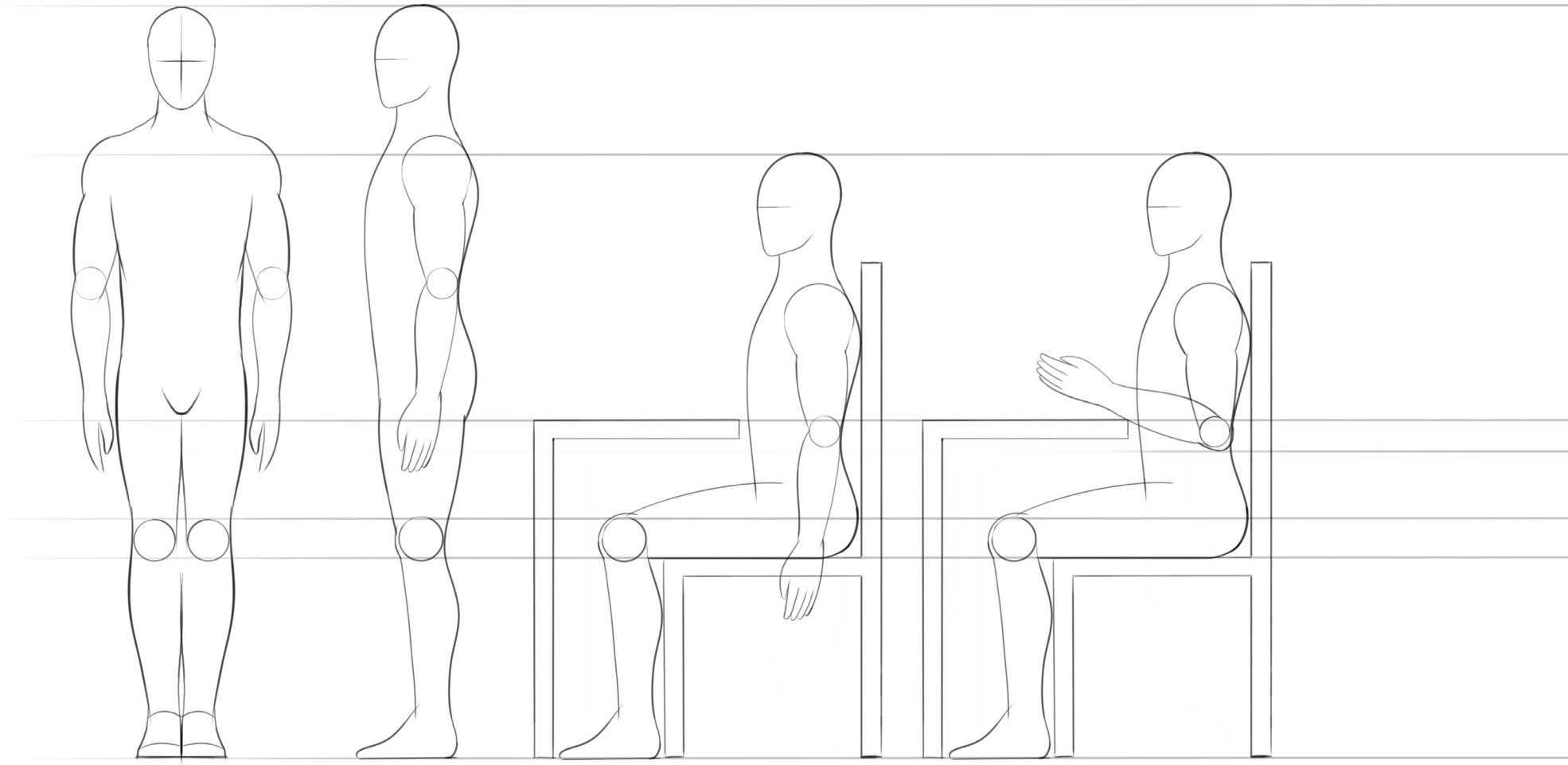


Figure 4.12. Low-fidelity test rig of new mechanic.

Figure 4.13. Expert review of new mechanic by neuro-physiotherapists.



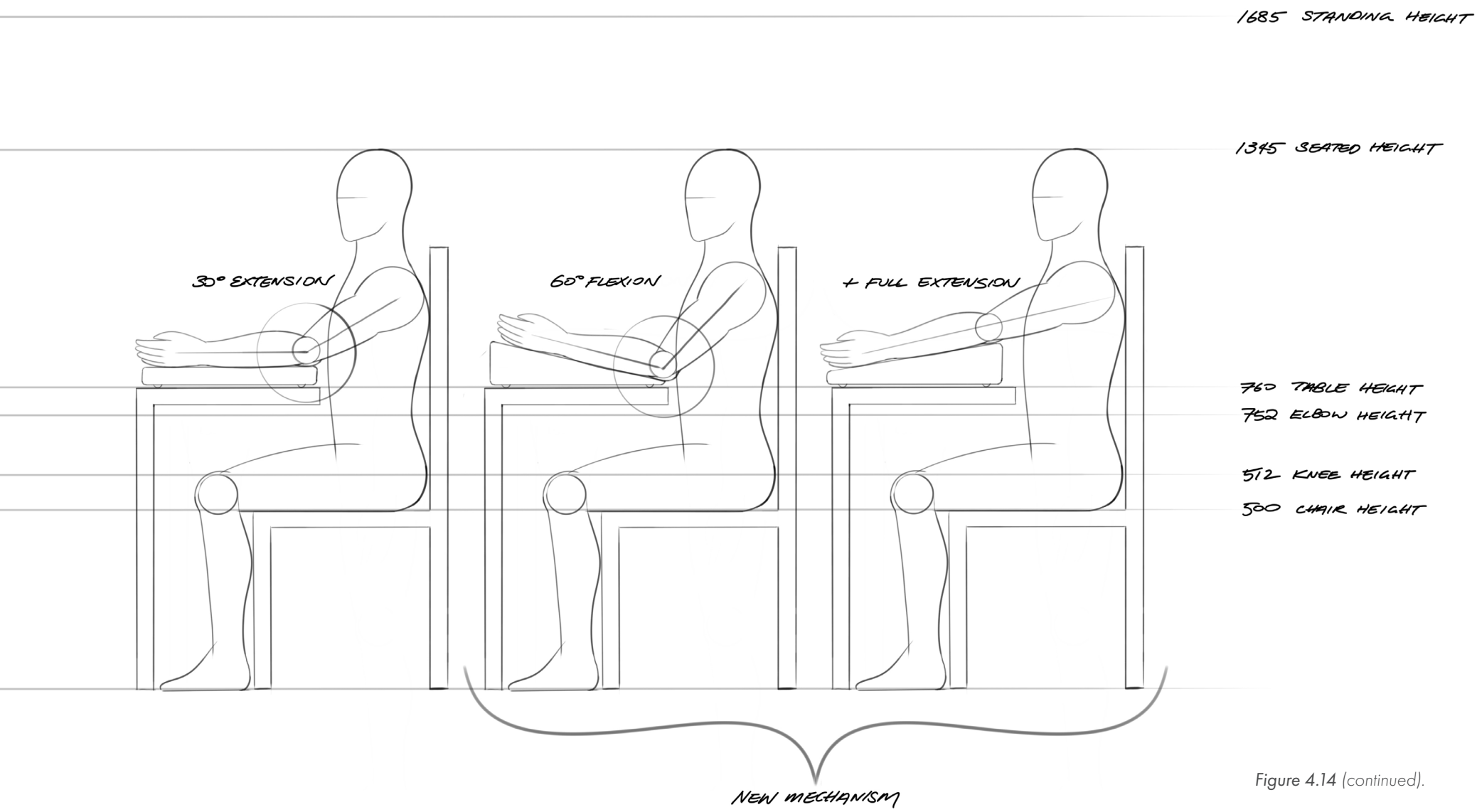


Figure 4.14 (continued).

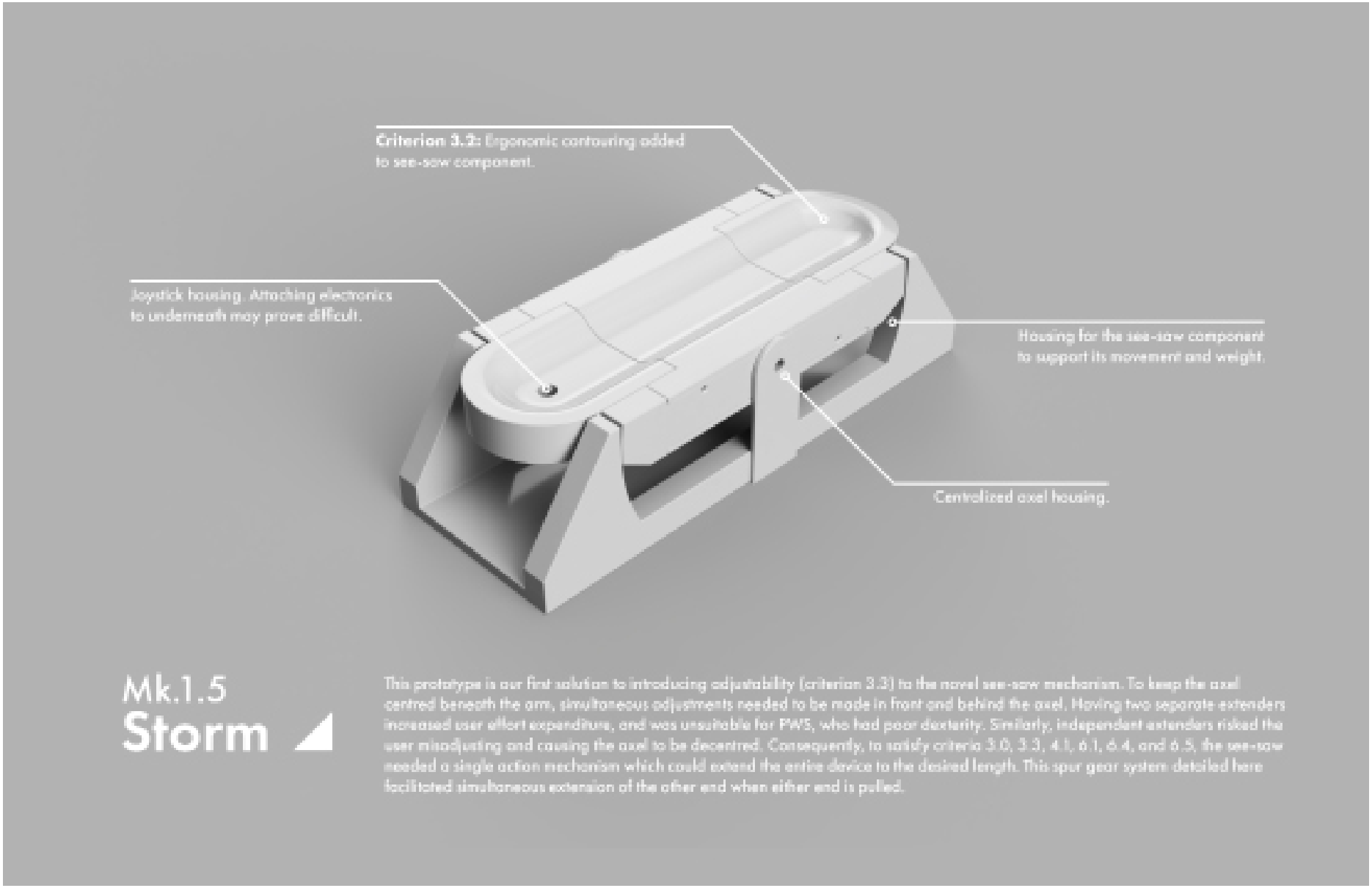


Figure 4.15. Developed see-saw mechanic concept with adjustability.

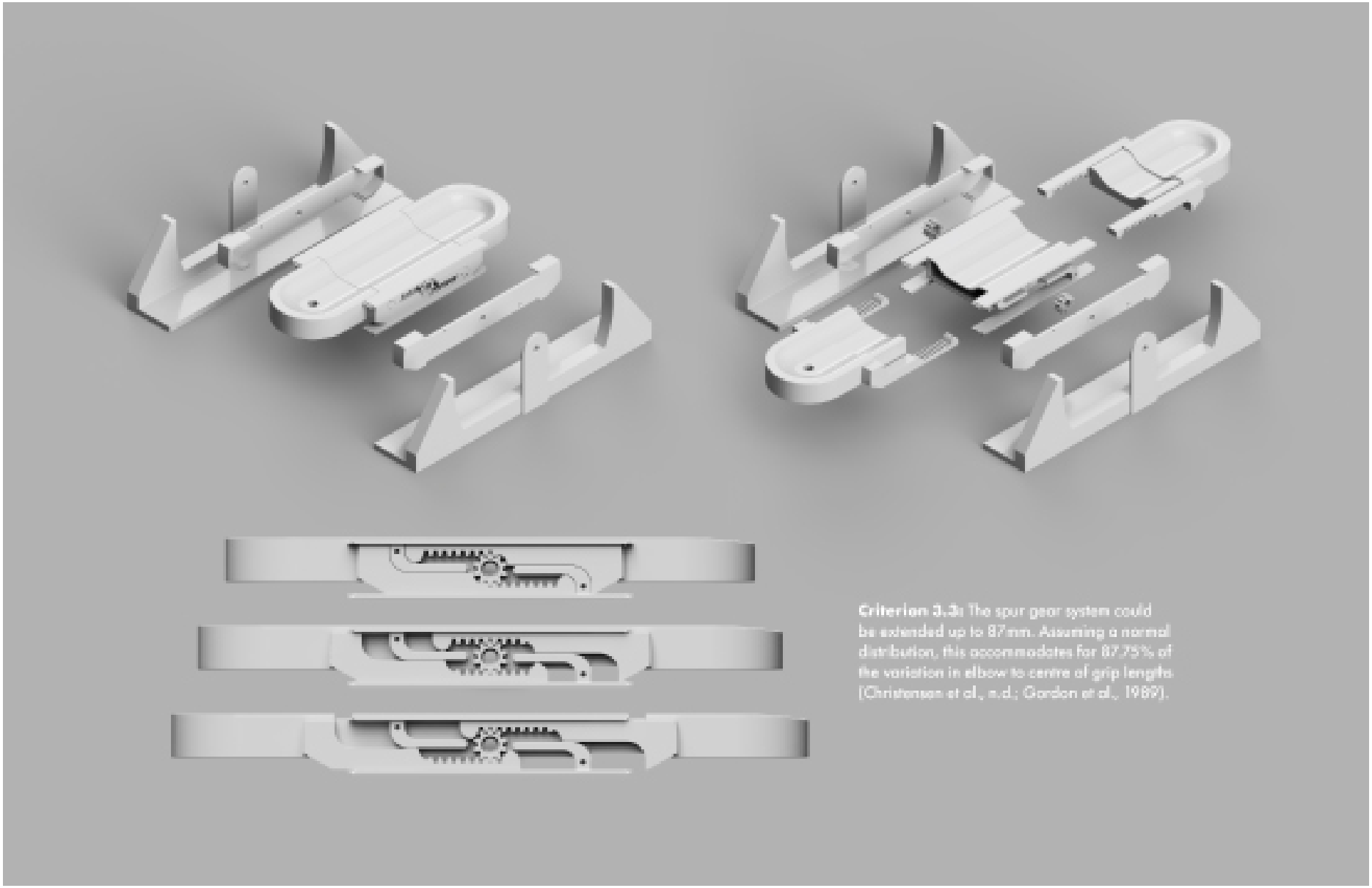


Figure 4.15 (continued).

Design Development

The see-saw mechanism was well received by all stakeholders, but also sparked new difficulties in design. Ensuring the axel was directly beneath the middle of the forearm meant the adjusting of the device to fit different arms needed to be multi-directional, with the axel as the centre point. The housing of the see-saw also required redesign to ensure ample room for both the see-saw orthosis, as well as mechanical componentry. Simultaneously, three-dimensional forms were explored to ensure suitable aesthetics to match the mechanical developments were available. Figure 4.16 details this 3D design process.

Figure 4.16. CAD Development of structure and form.

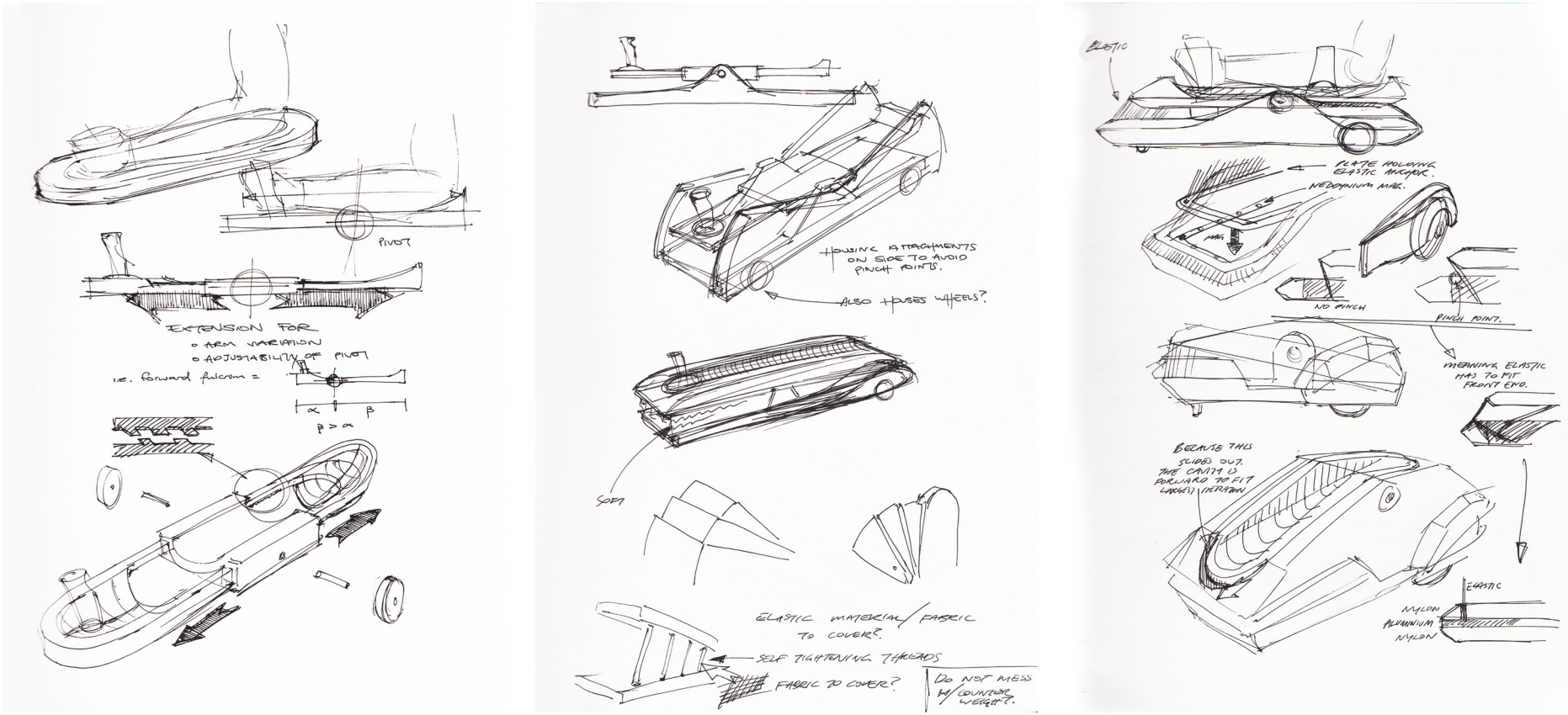


Figure 4.17. Development of structure, form, and function..

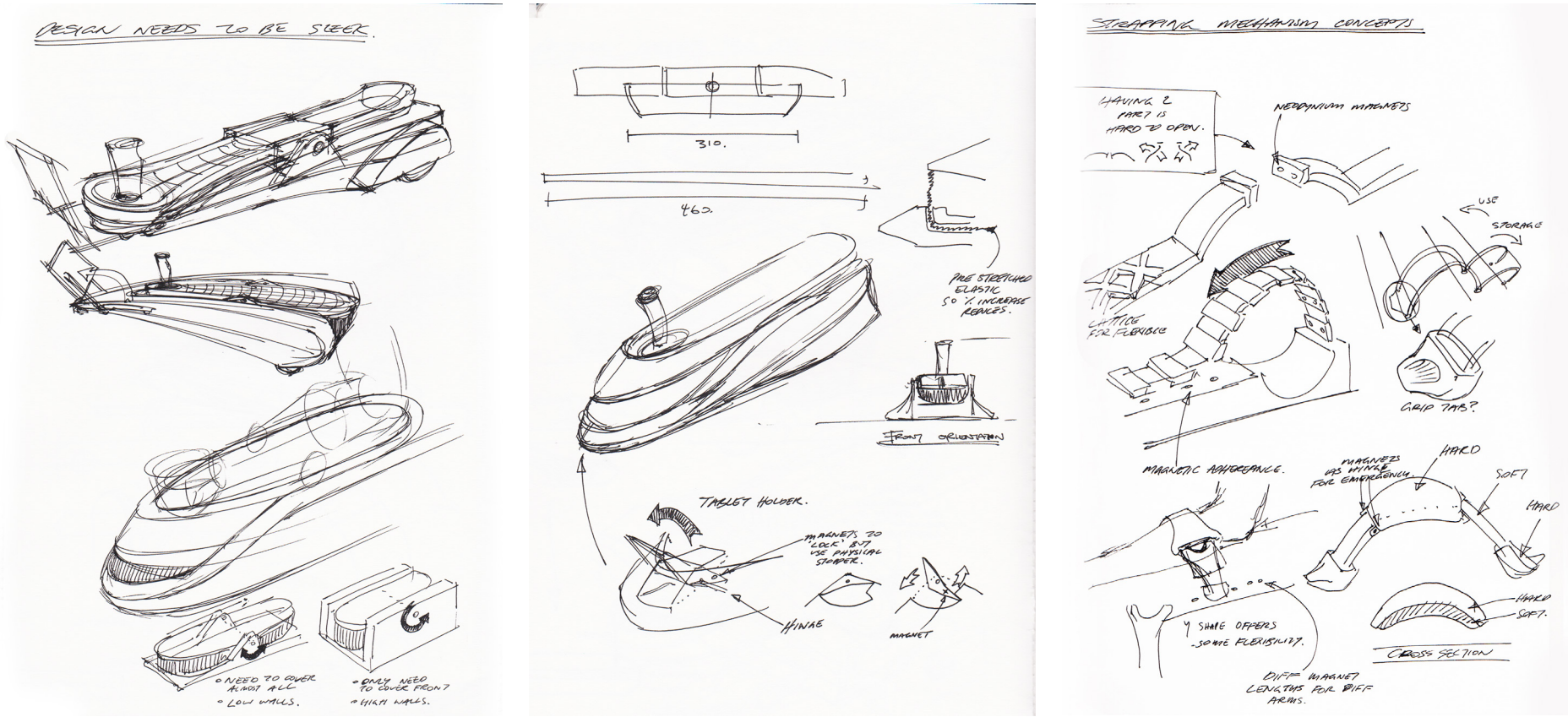


Figure 4.17 (continued).

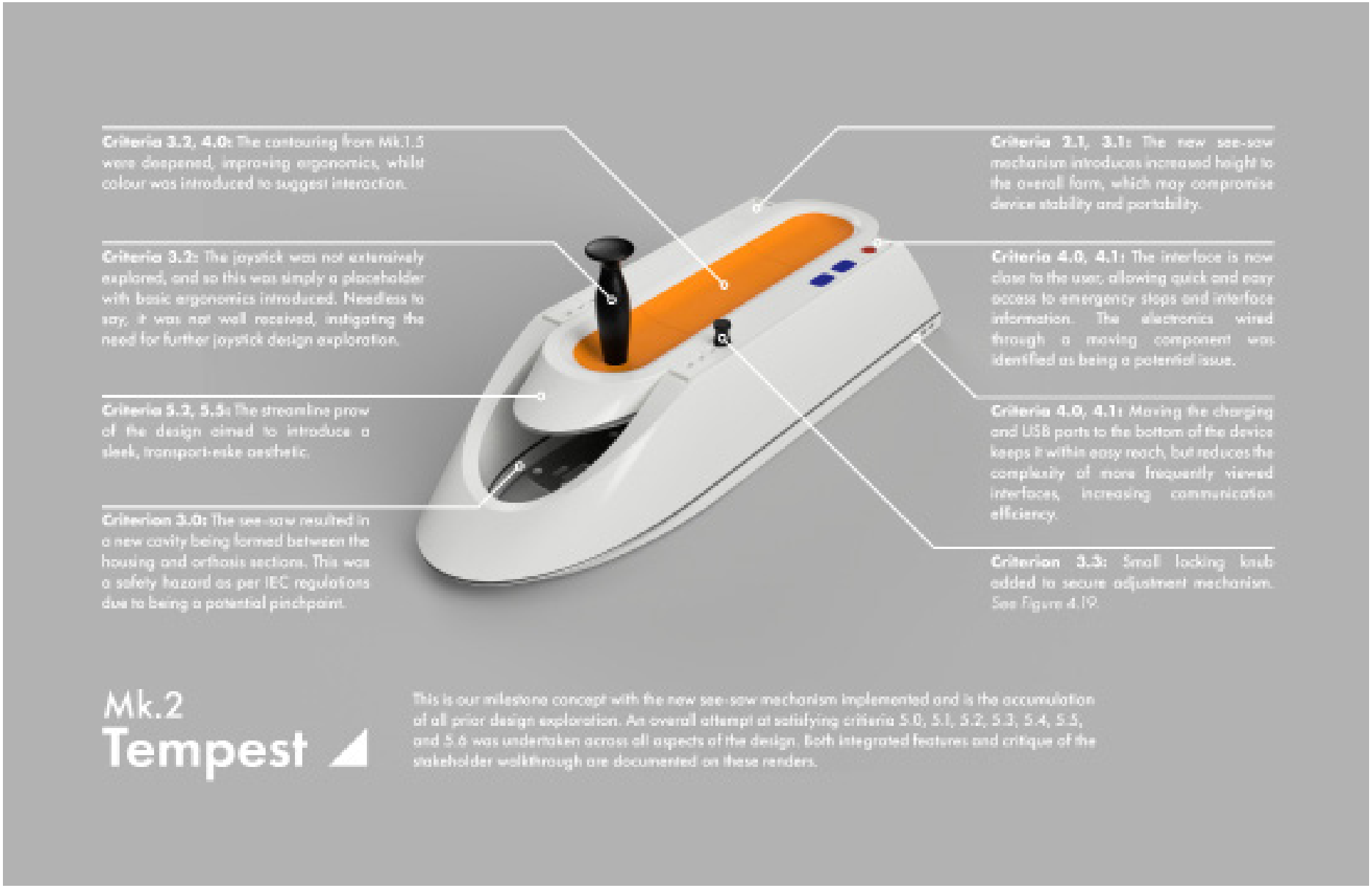


Figure 4.18. Mk.2 concept with features and critique.

Figure 4.18 (continued).

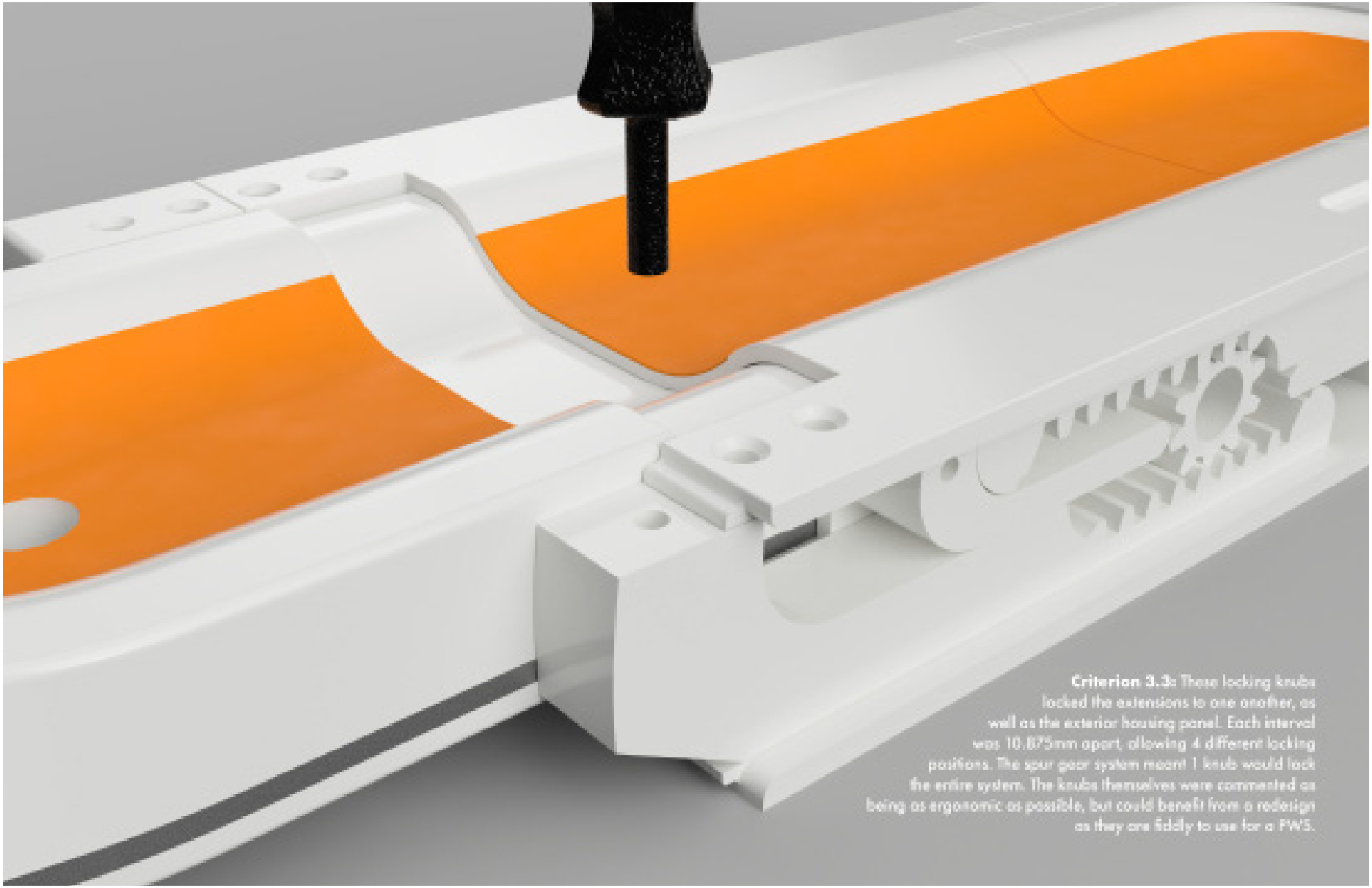


Figure 4.19. Locking knub.

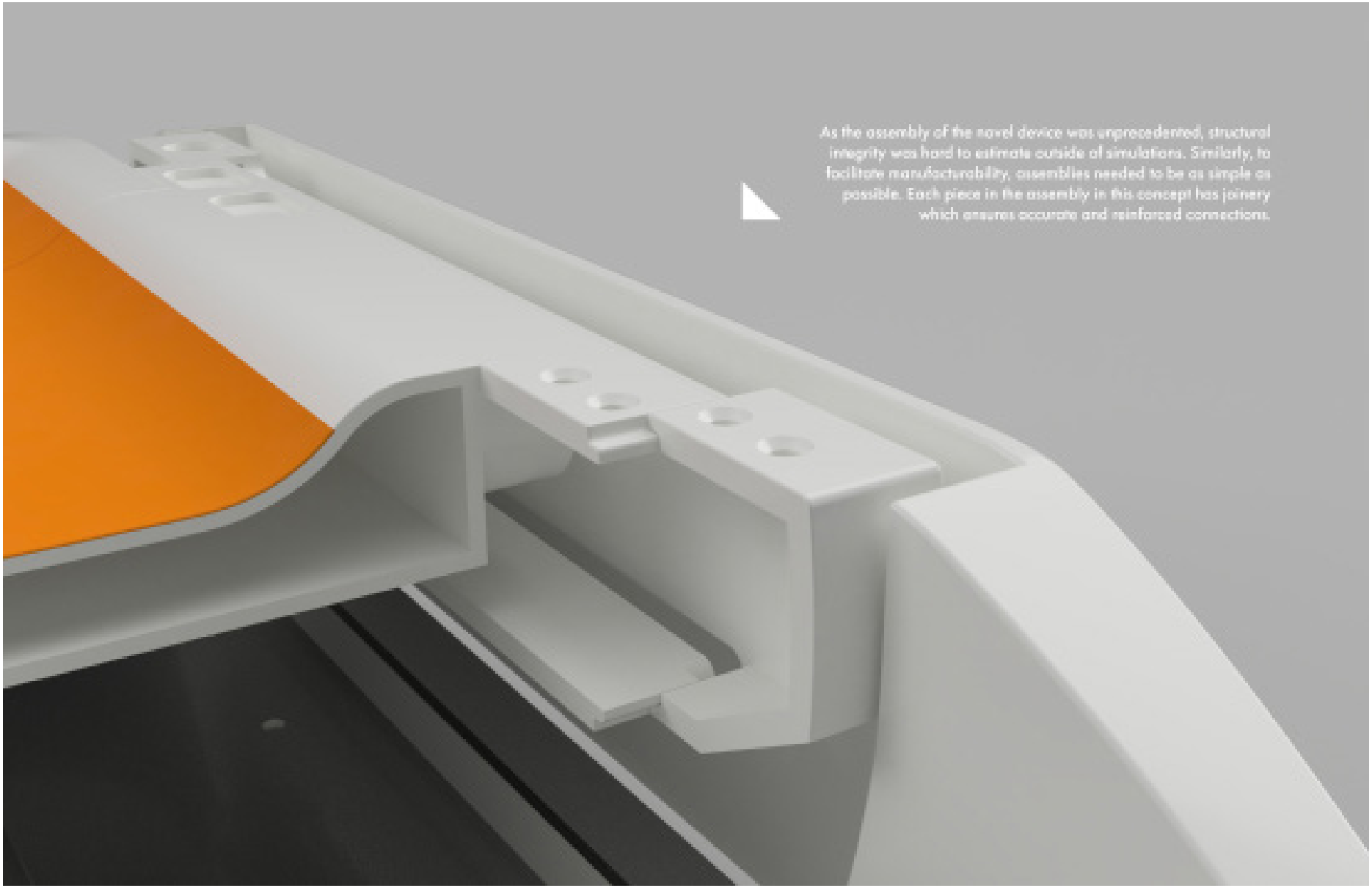


Figure 4.20. Structural joinery.

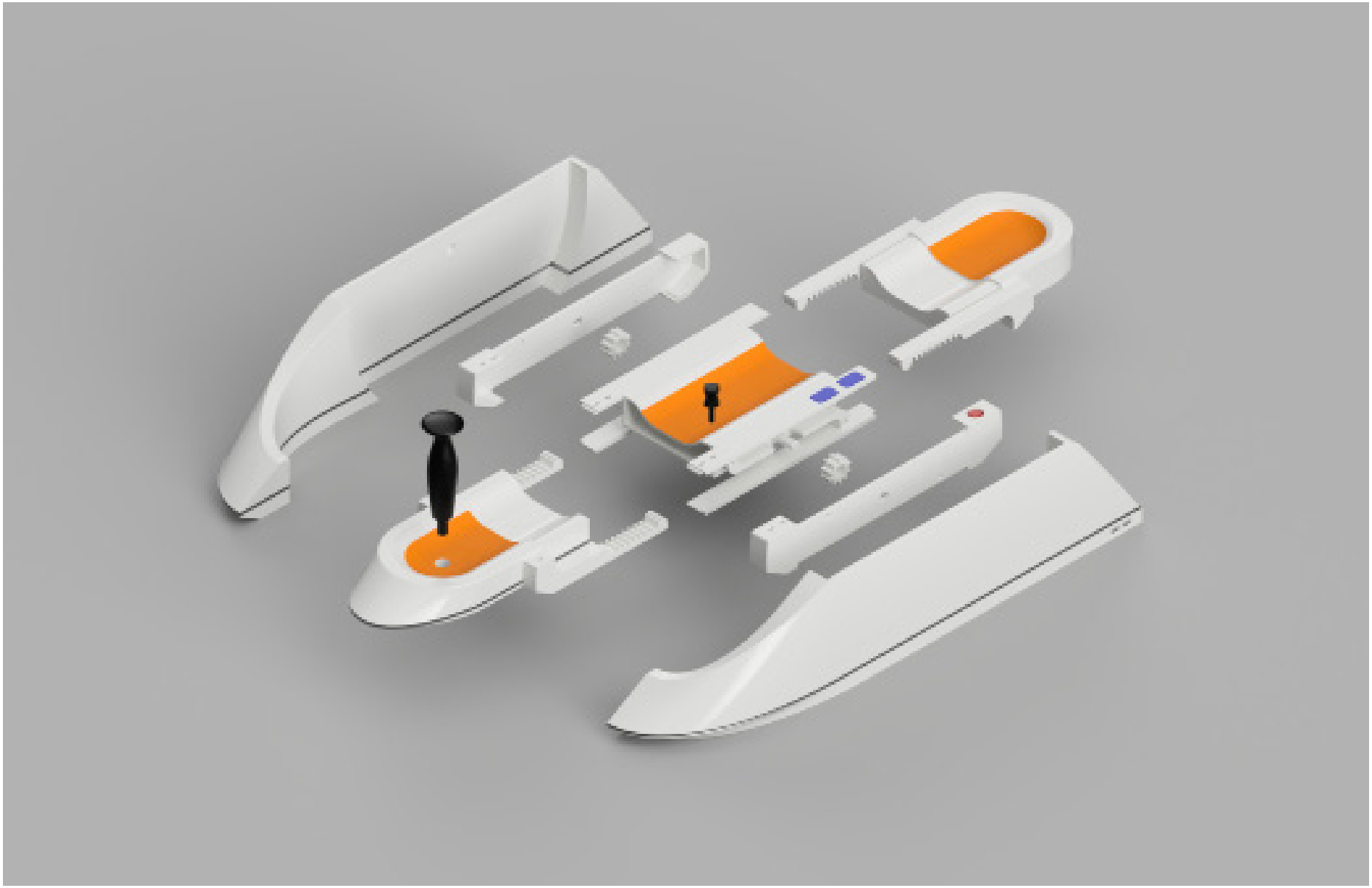


Figure 4.21. Exploded view of Mk.2.

Figure 4.22. Physical prototype of see-saw extension mechanism.

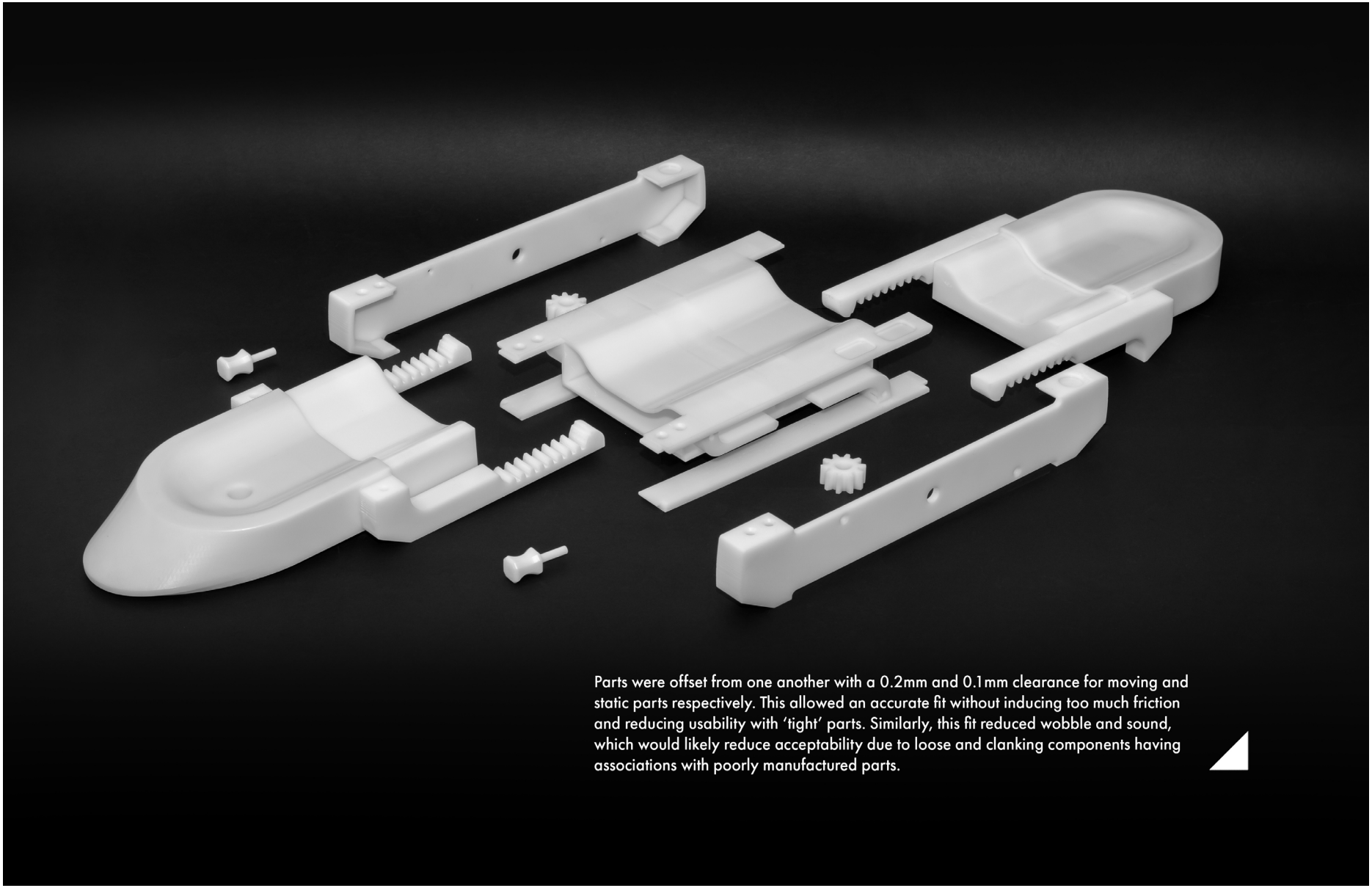


Figure 4.23. Exploded view of see-saw extension prototype.

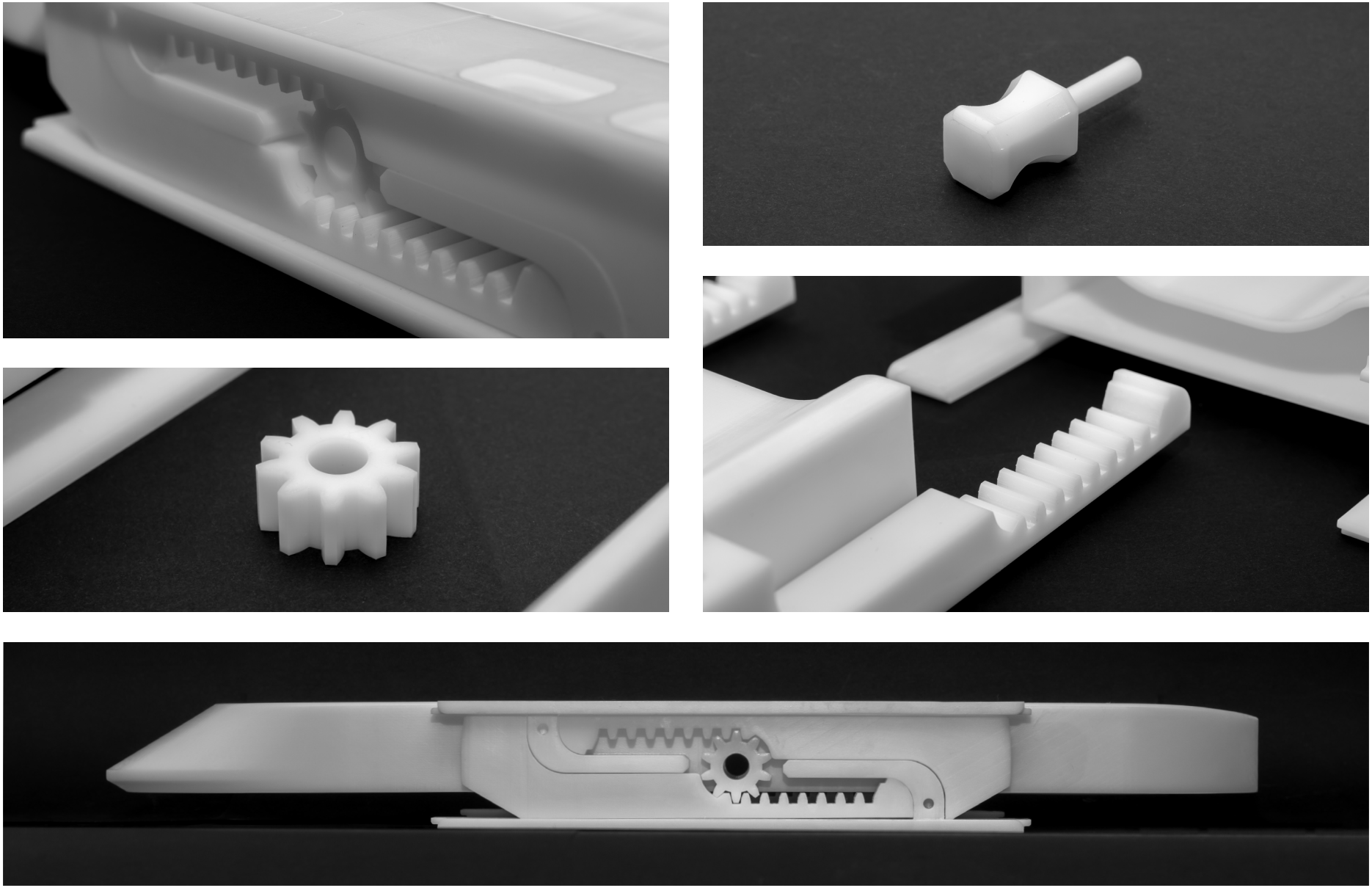


Figure 4.24. Close-up shots of prototype.

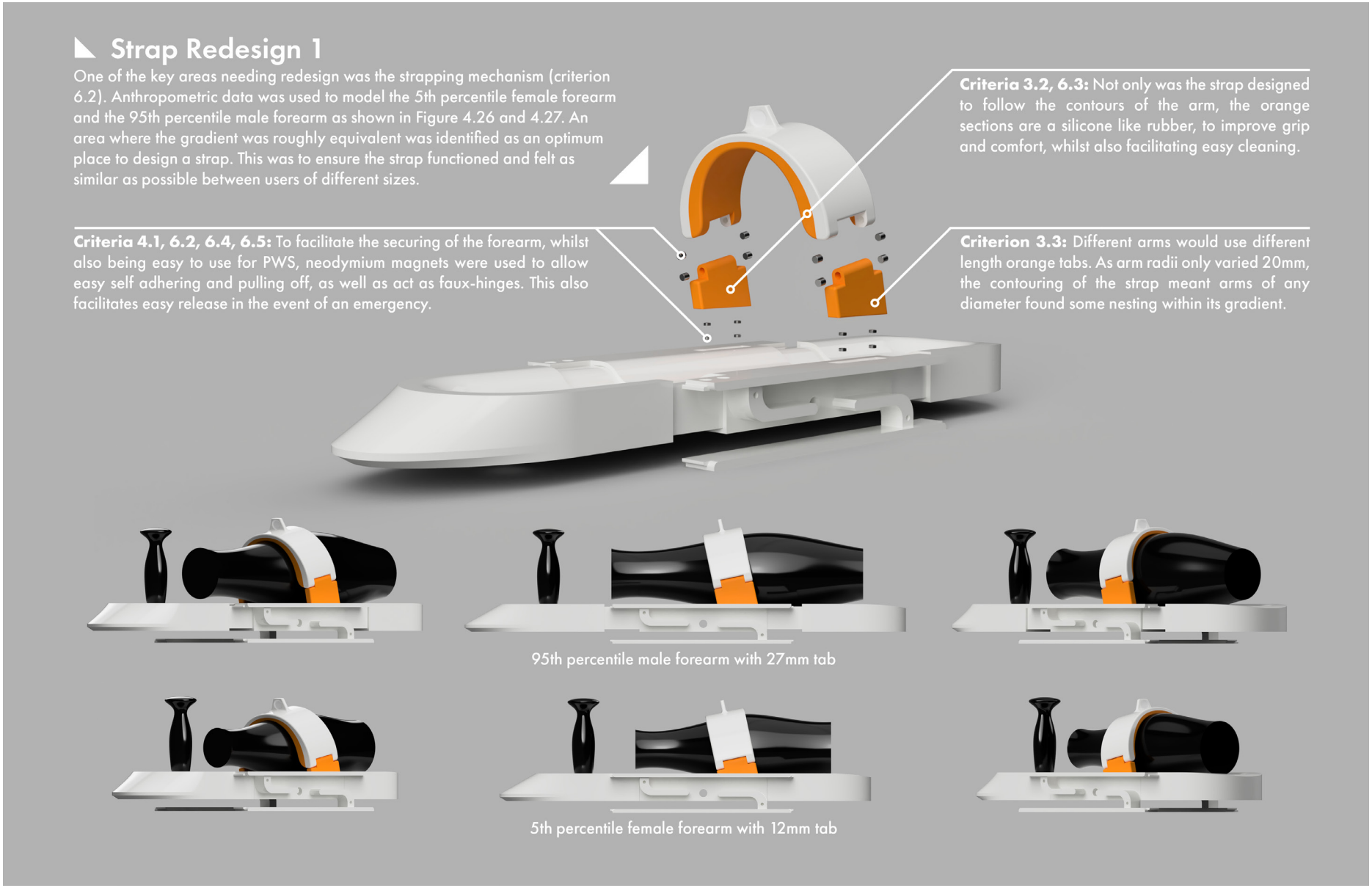


Figure 4.25. Strap redesign 1.

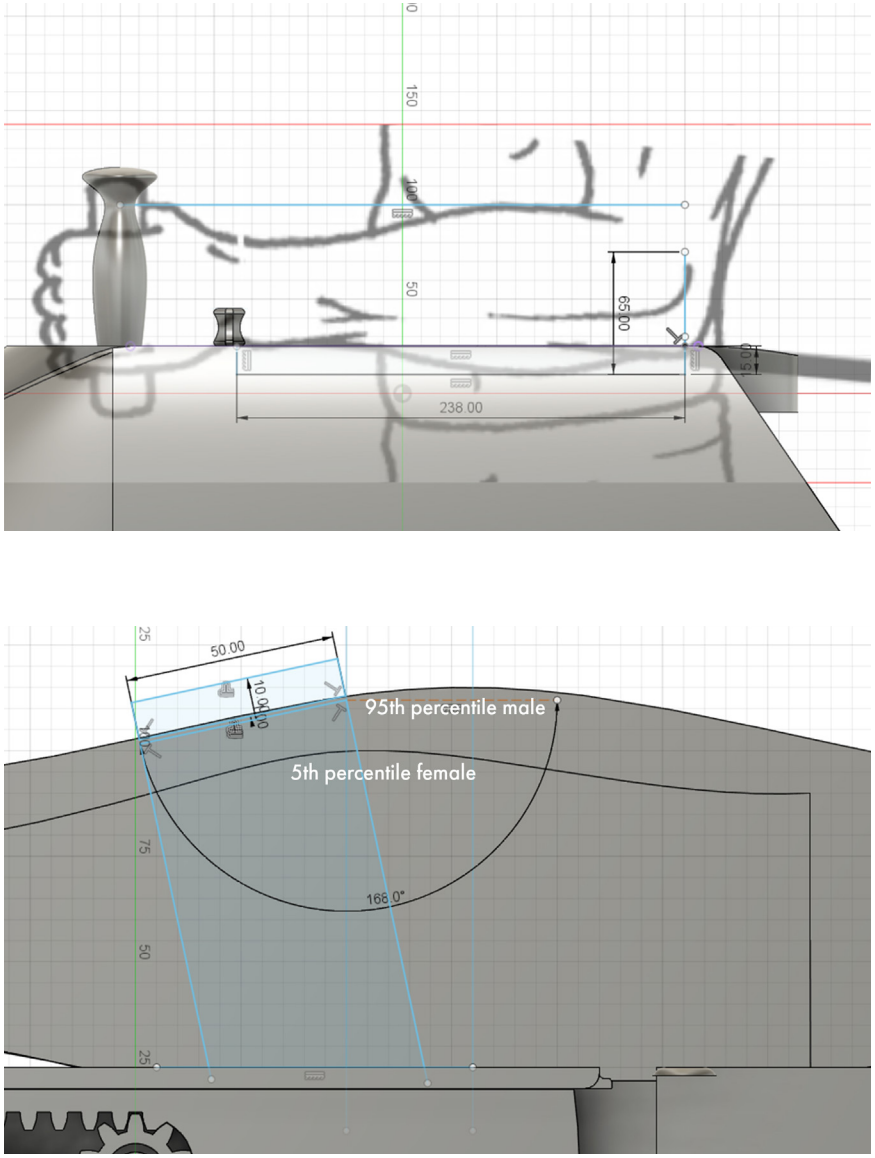


Figure 4.26. 5th percentile female and 95th percentile male forearm modelled to determine strap gradient.

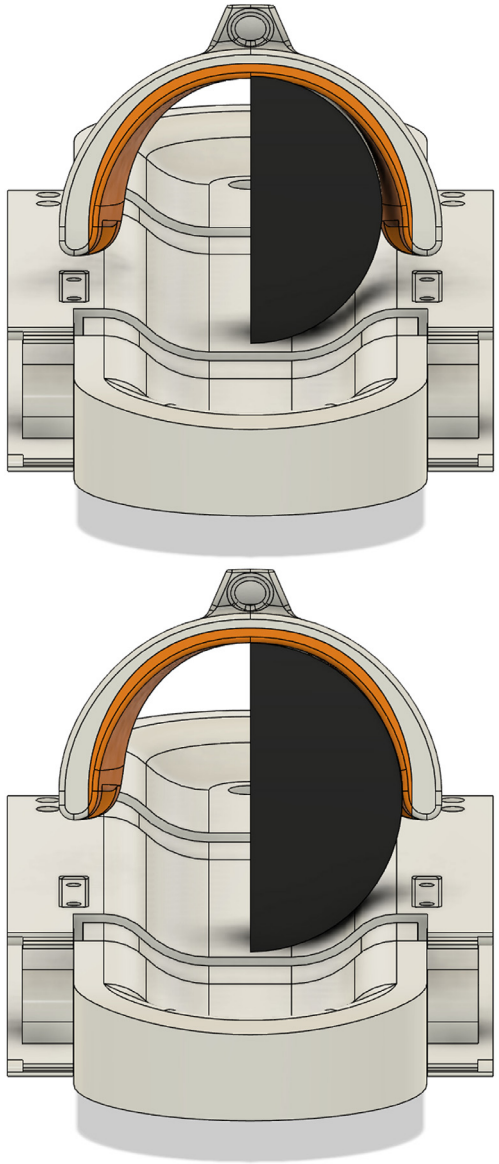


Figure 4.27. 5th percentile female and 95th percentile male forearm cross-sections modelled to determine strap contour.

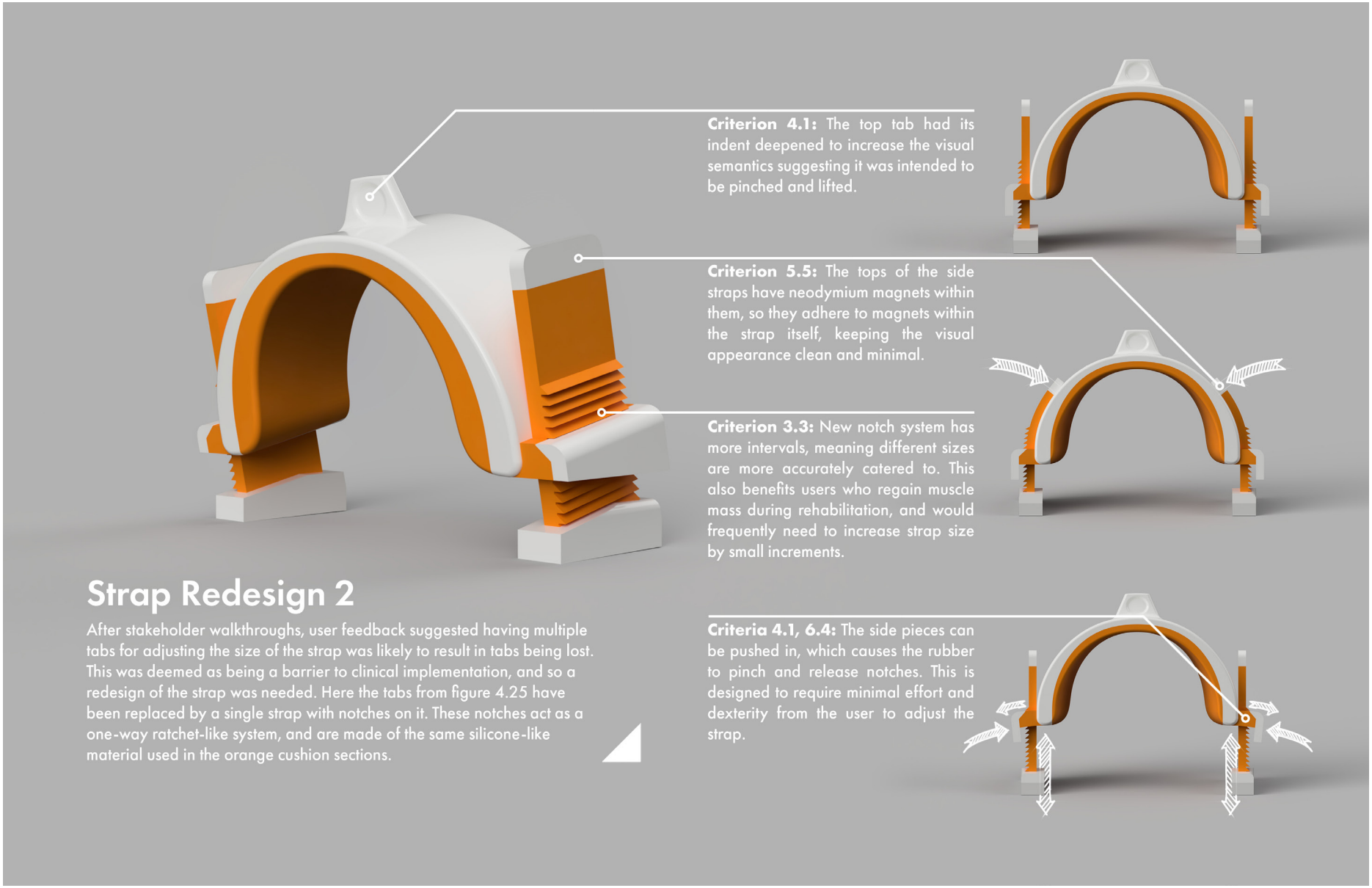


Figure 4.28. Strap redesign 2.

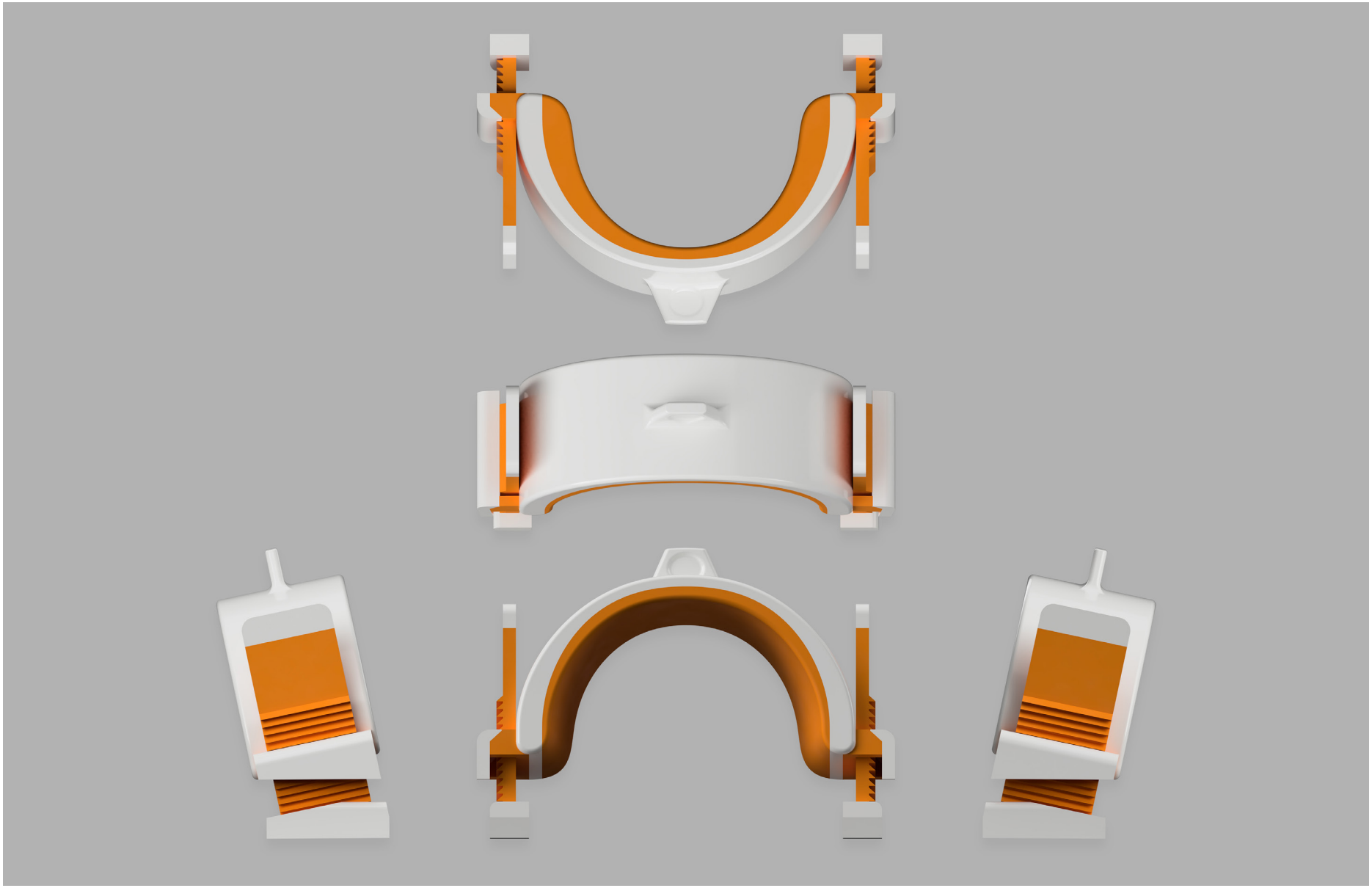


Figure 4.28 (continued).

Figure 4.29. Physical prototype of strapping system.

Regulations Compliance

As the design became more refined, it became critical to its success to not only consider manufacturability but also viability as a commercial product. Safety regulations such as those from the United States Food and Drug Association (FDA), International Organization for Standardization (ISO), and the International Electrotechnical Commission (IEC) enforce detailed assessments of safety before a product is deemed commercially acceptable.

Under the FDA, the Roborover is classed as a class IIb device – a device of medium to high risk designed to be attached to the human body for extensive periods. This meant user safety needed to be extensively considered during the design process, especially leading up to the design for manufacturing process.

The novel see-saw mechanism saw the introduction of trapping hazards (known frequently as 'pinch points') that would not be acceptable by these regulations (International Electrotechnical Commission, 2005, pp. 48–49, 131–134). These hazards had to be closed up to less than 4mm or opened up to more than 25mm so appendages cannot be jammed in them (International Electrotechnical Commission, 2005, p. 133). Alternatively, guards and other protective measures could be installed to limit access to hazardous areas of the device (International Electrotechnical Commission, 2005, p. 132). Concepts at this point focused on reducing safety issues, and the redesign of mechanical hardware configurations to accommodate for the novel mechanism's relatively large operational area.

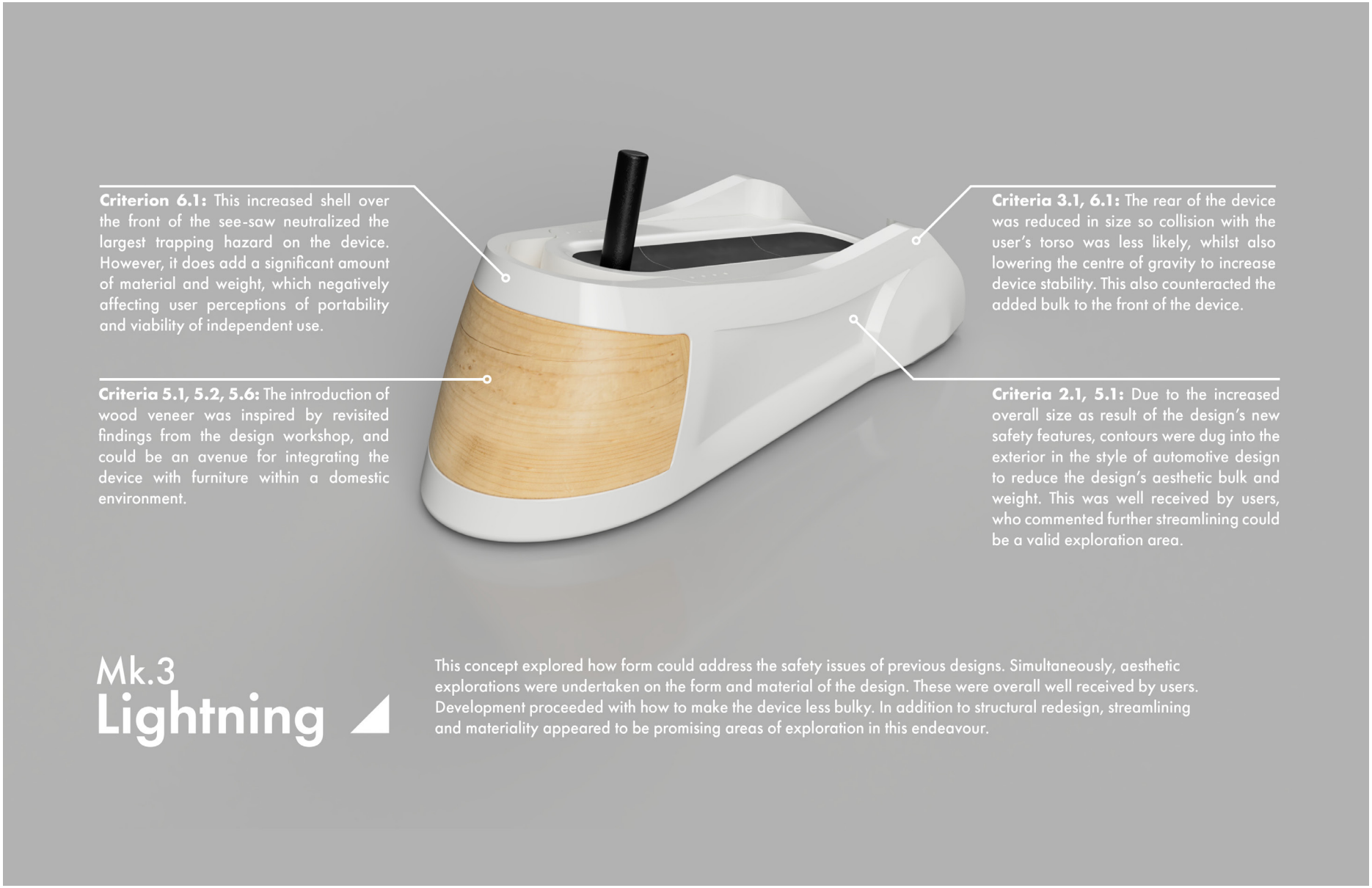


Figure 4.30. Mk.3 concept with features and critique.

Figure 4.30. (continued).

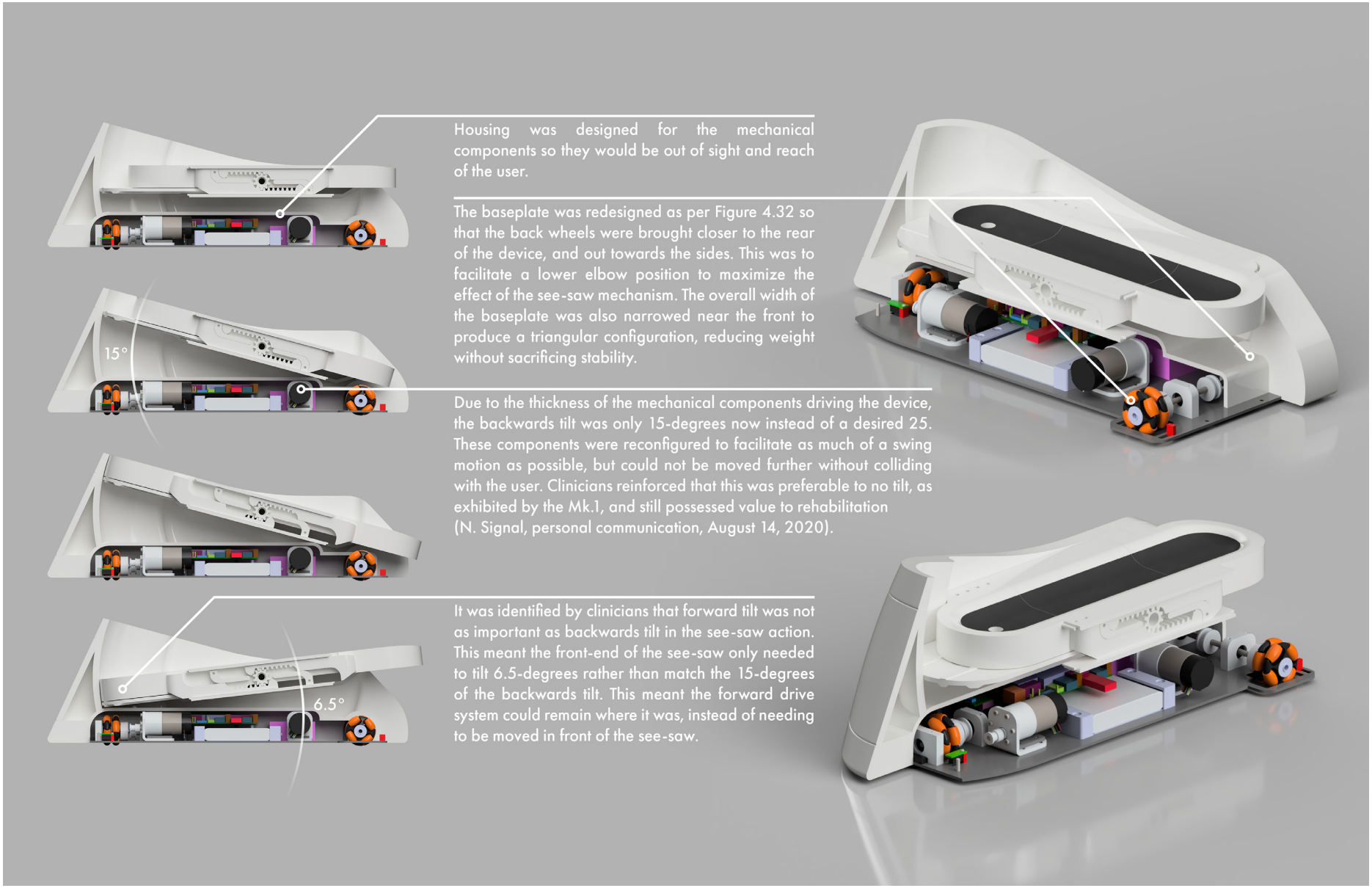


Figure 4.31. Mk.3 cross-section illustrating new degrees of movement and mechanical assembly.

Figure 4.32. Baseplate and configuration of mechatronic components of the Mk.2 (left) and Mk.3 (right).

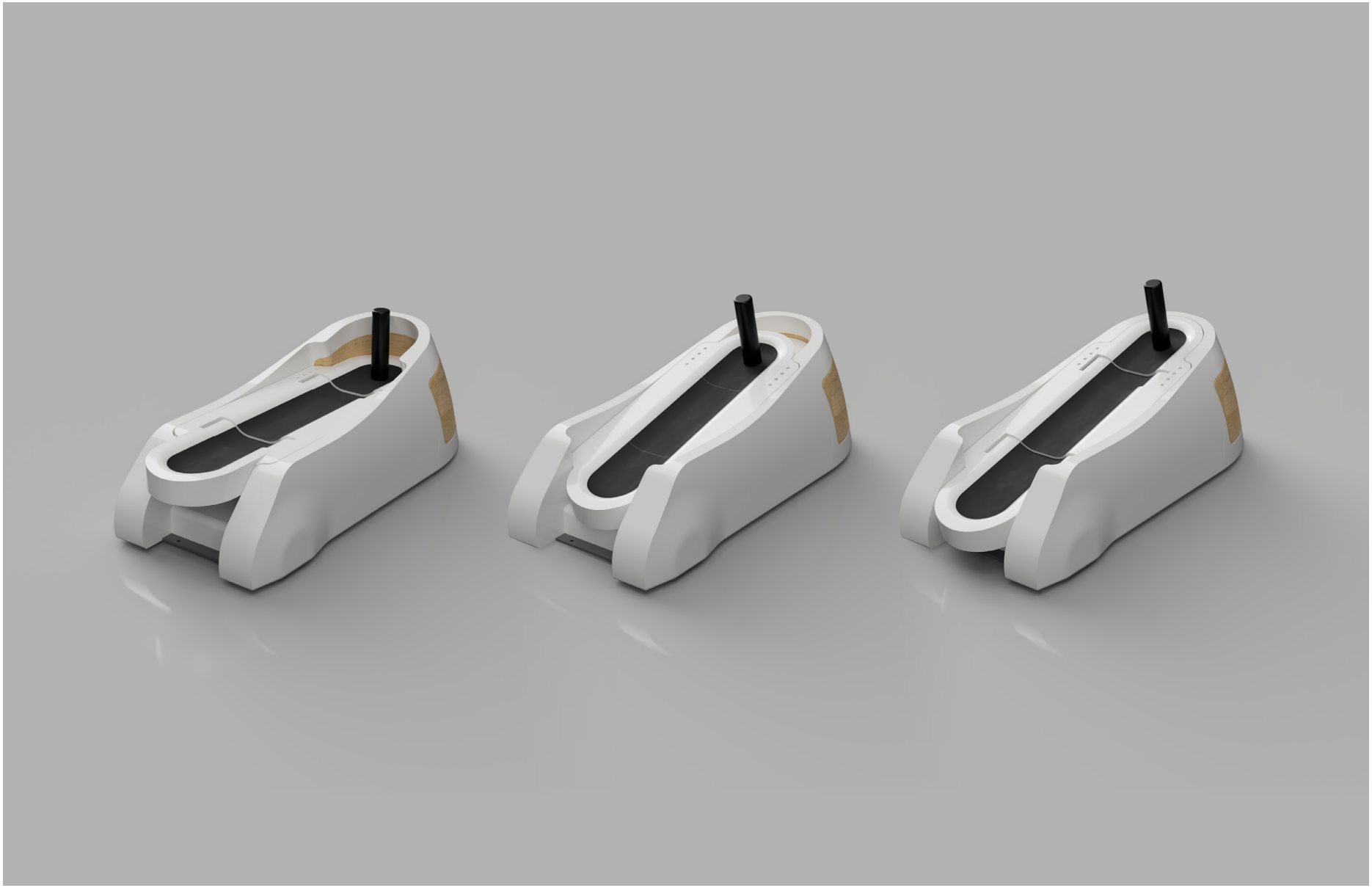


Figure 4.33. Rear view of see-saw movement afforded by the Mk.3.

Figure 4.34. Close-up of the shell mechanism acting as a safety guard to trapping hazards.

Form and Aesthetics

The major shortcoming of the Mk.3 was the bulkiness of the design, instigating an overall redesign of the device's front. As structure, form, material, and surface are interlinked (Tjalve, 2015, p. 7), this also was a prime opportunity to explore aesthetic options for the Roborover.

Structural Redesign

It was quickly identified that the front prow of the device did not need to be as tall as the top of the see-saw during full tilt. Instead, it could at the very least be lowered to become level with the top of the section highlighted in blue. After some low fidelity concepts, it was found the front prow could be further lowered if the front of the see-saw was lowered (highlighted in blue). This produced a three layered 'armadillo' style shell covering as seen in the bottom image, and allowed the entire red section to be removed, as well as the sides above the dotted red line.

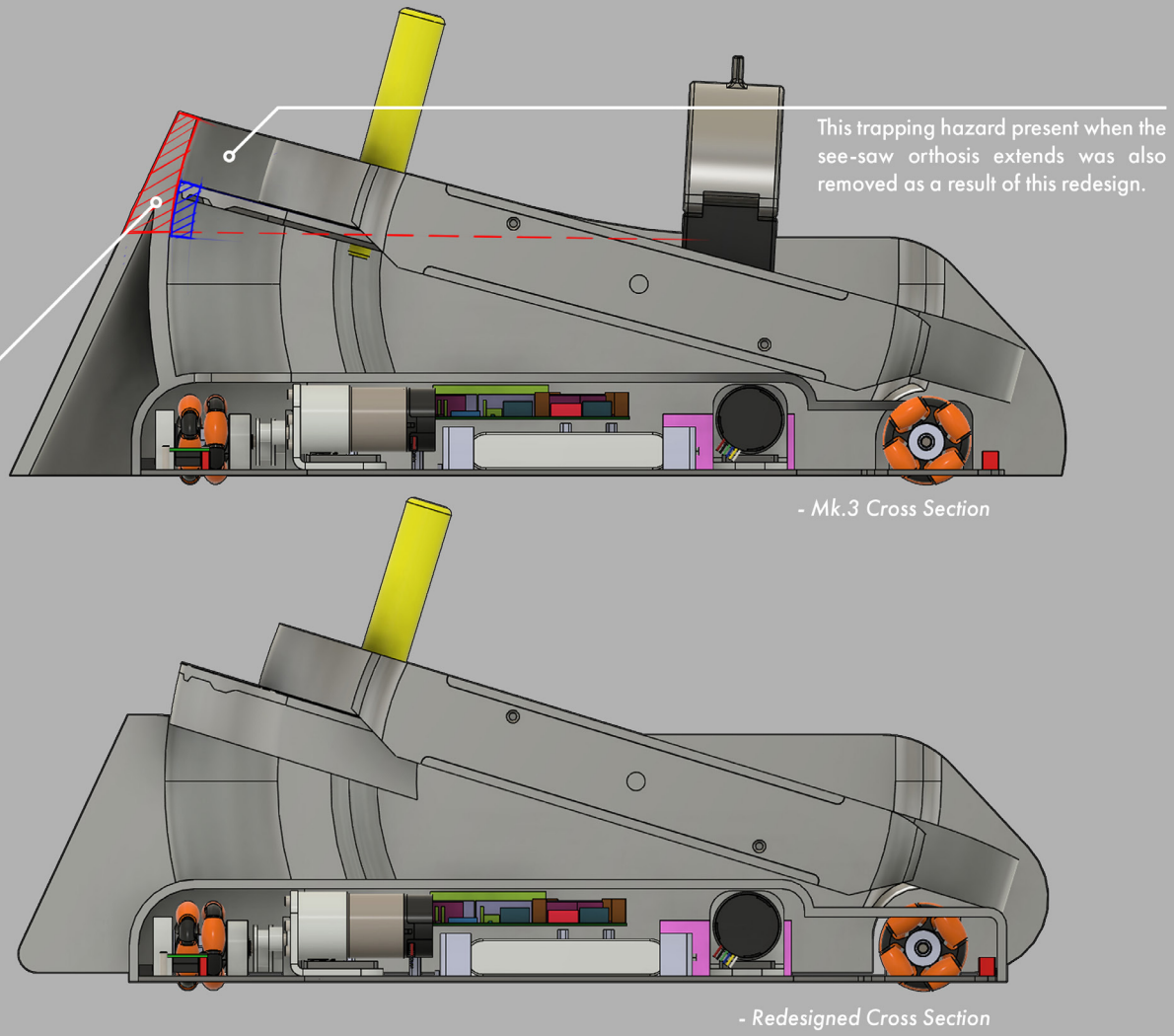


Figure 4.35. Cross-section of the structural redesign between the Mk.3 and the Mk.4.

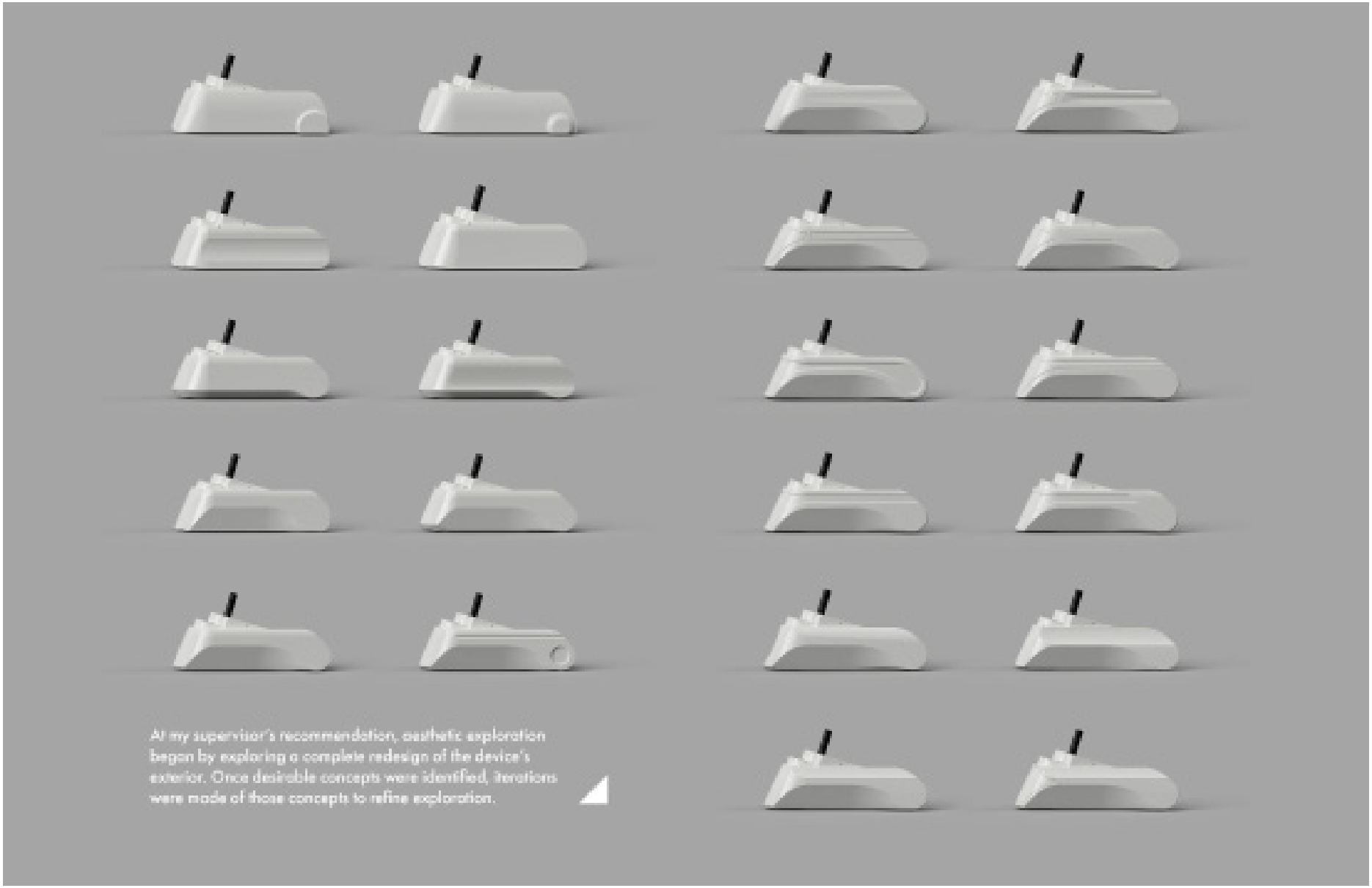


Figure 4.36. Initial form exploration.

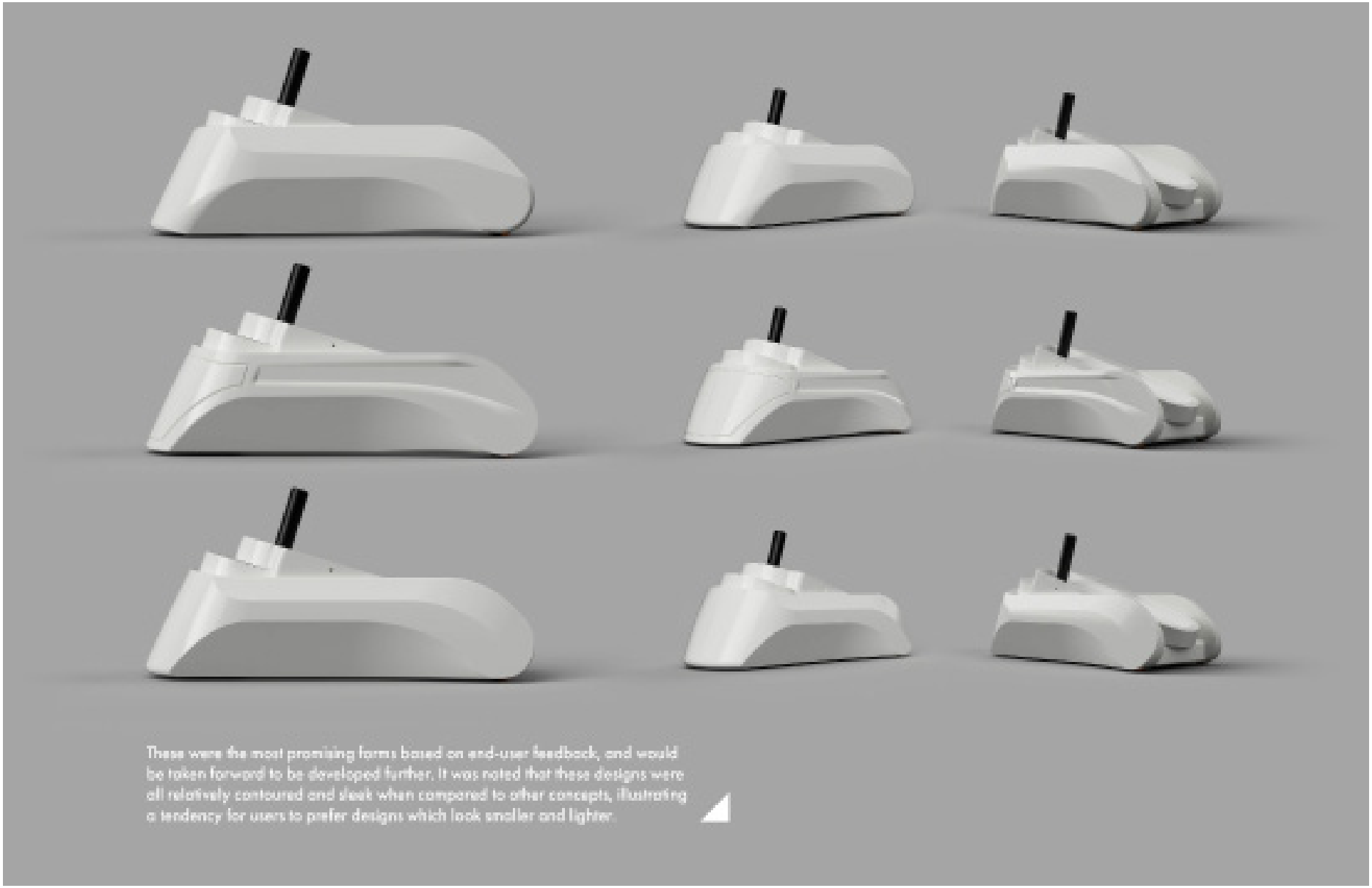


Figure 4.37. Promising form concepts.

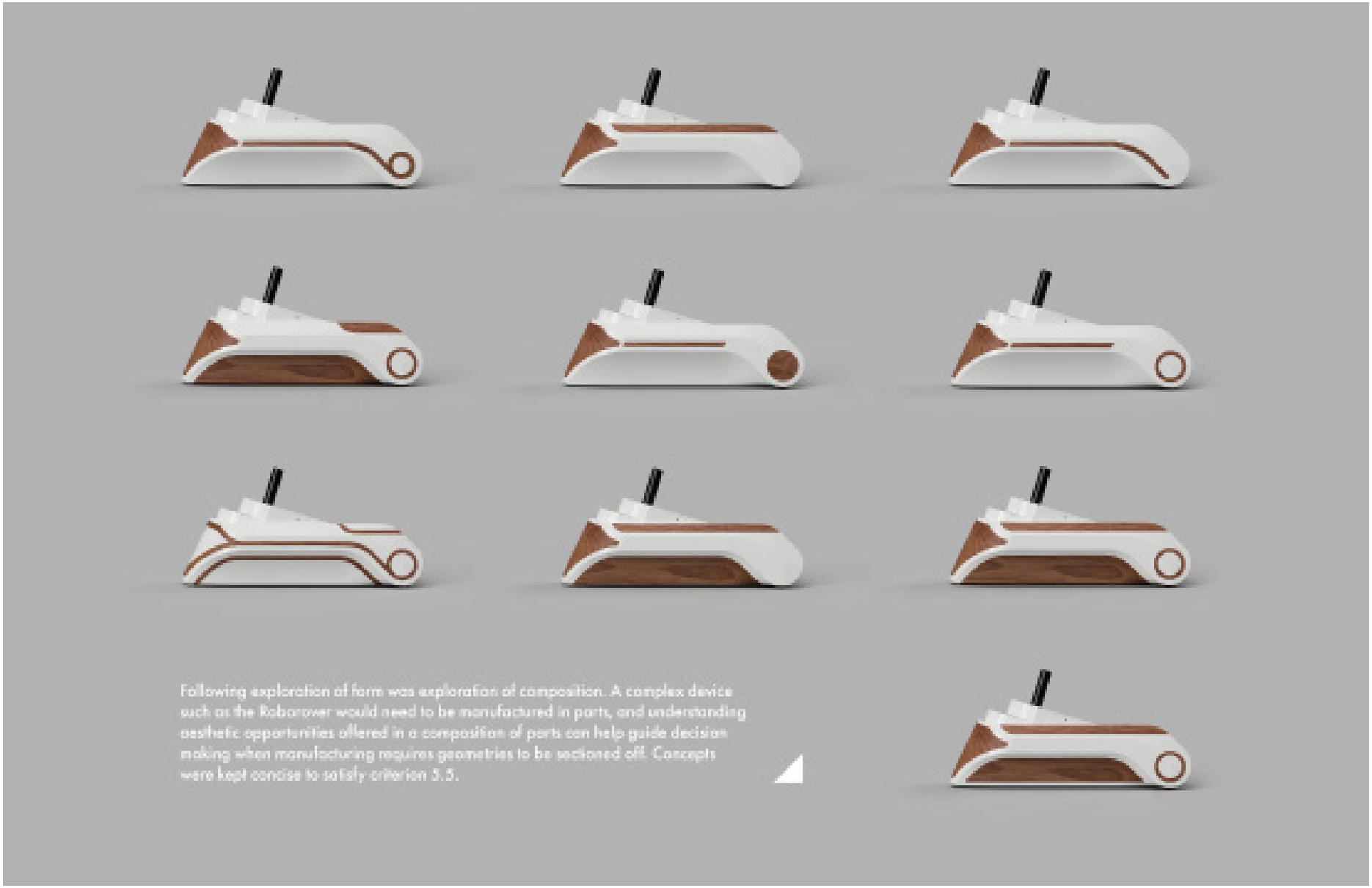


Figure 4.38. Form composition exploration.

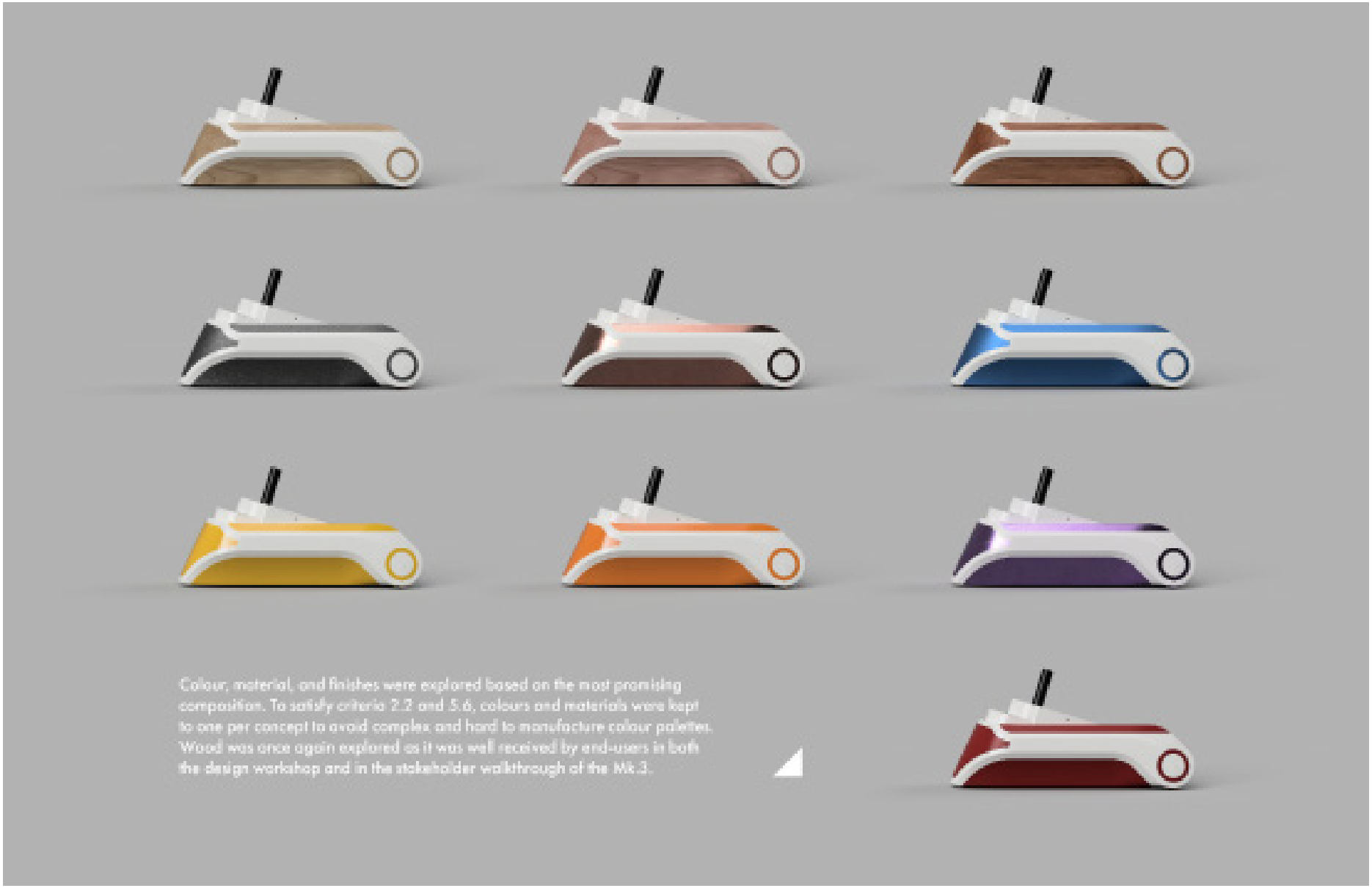


Figure 4.39. Colour, material, and finish exploration.

Figure 4.40. Frontal configuration exploration.

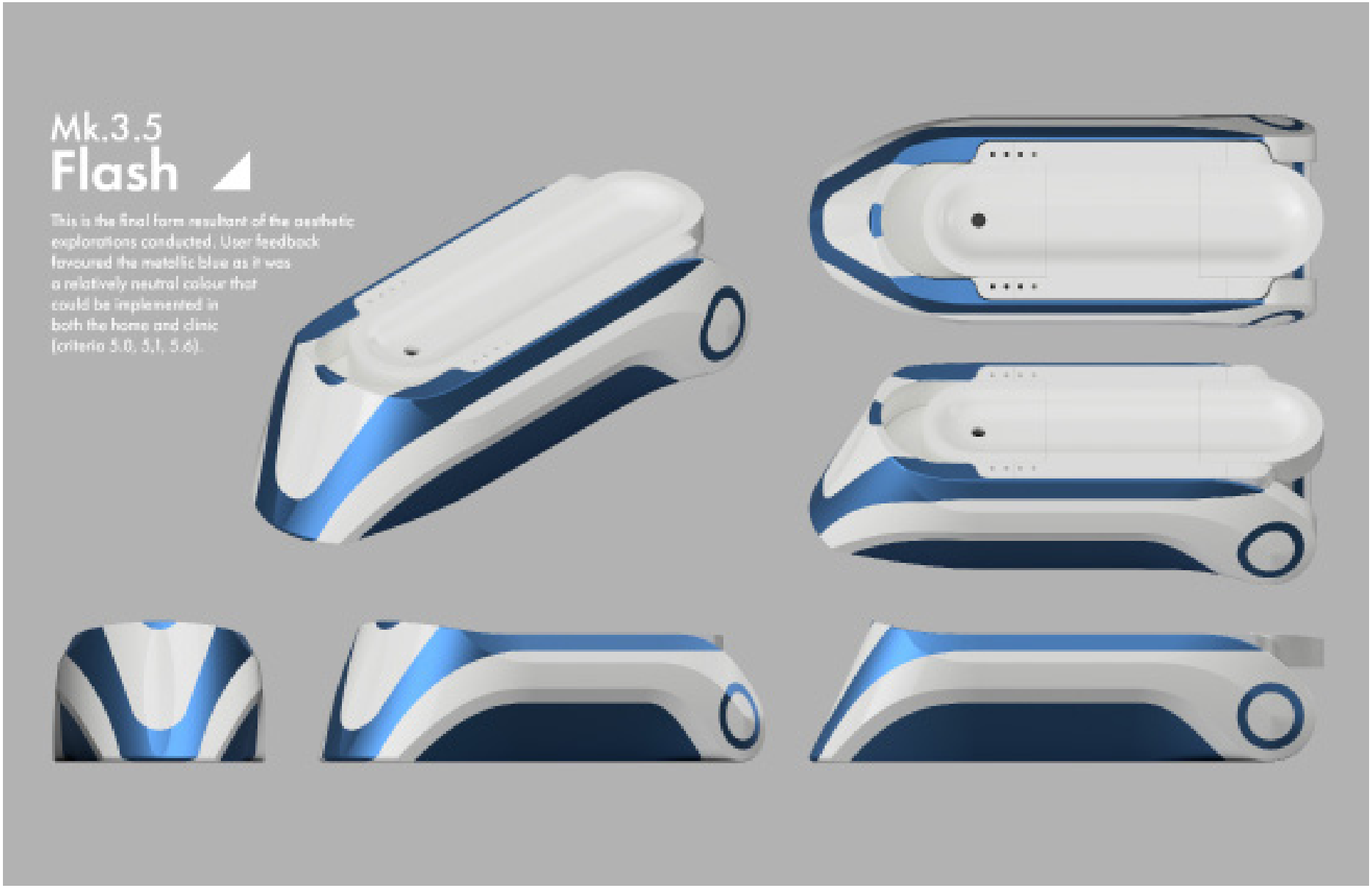


Figure 4.41. Final form resultant of aesthetic exploration.


ML4
Thunder

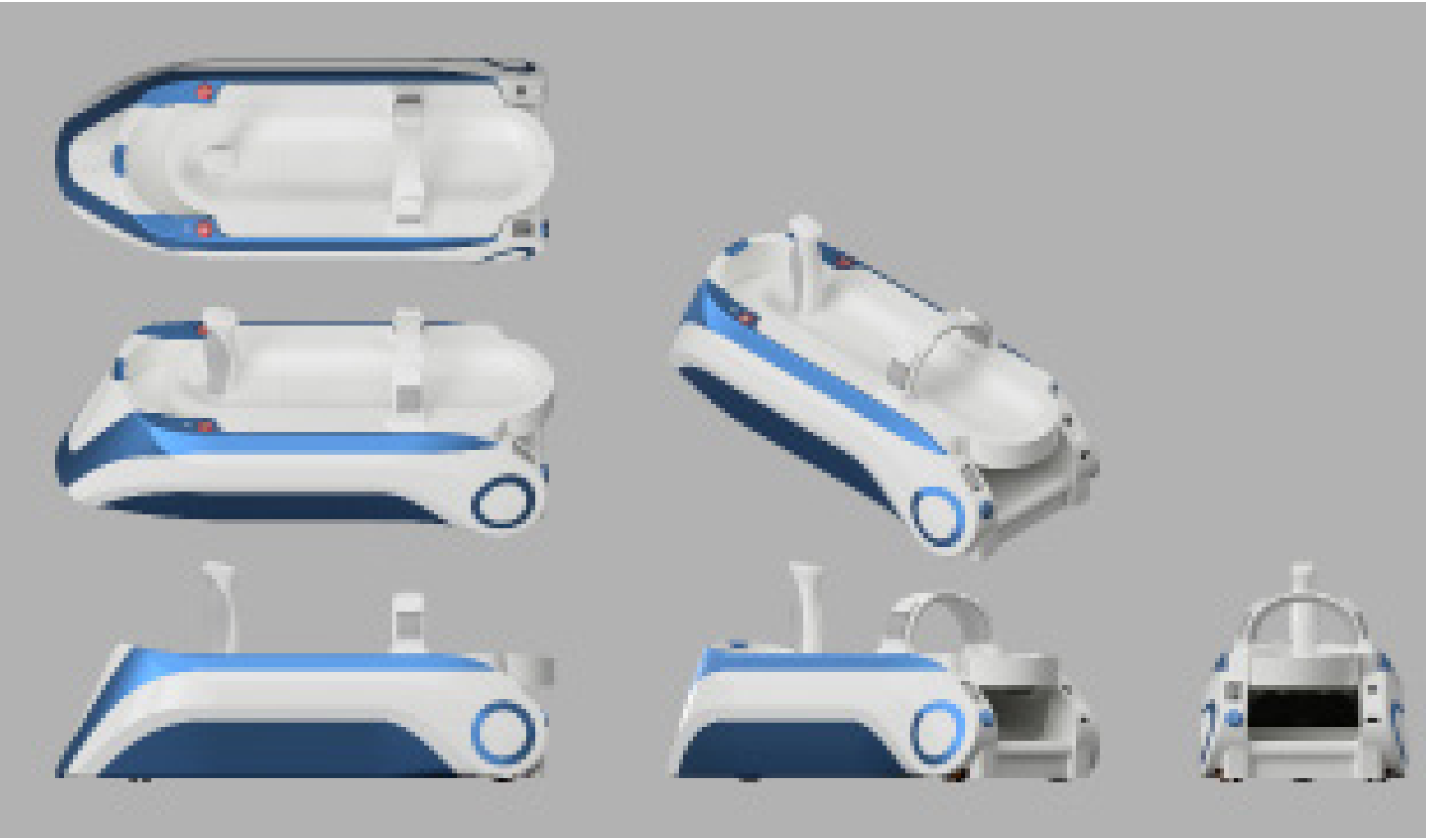


Figure 4.42. Mk.4 concept with feature reference.

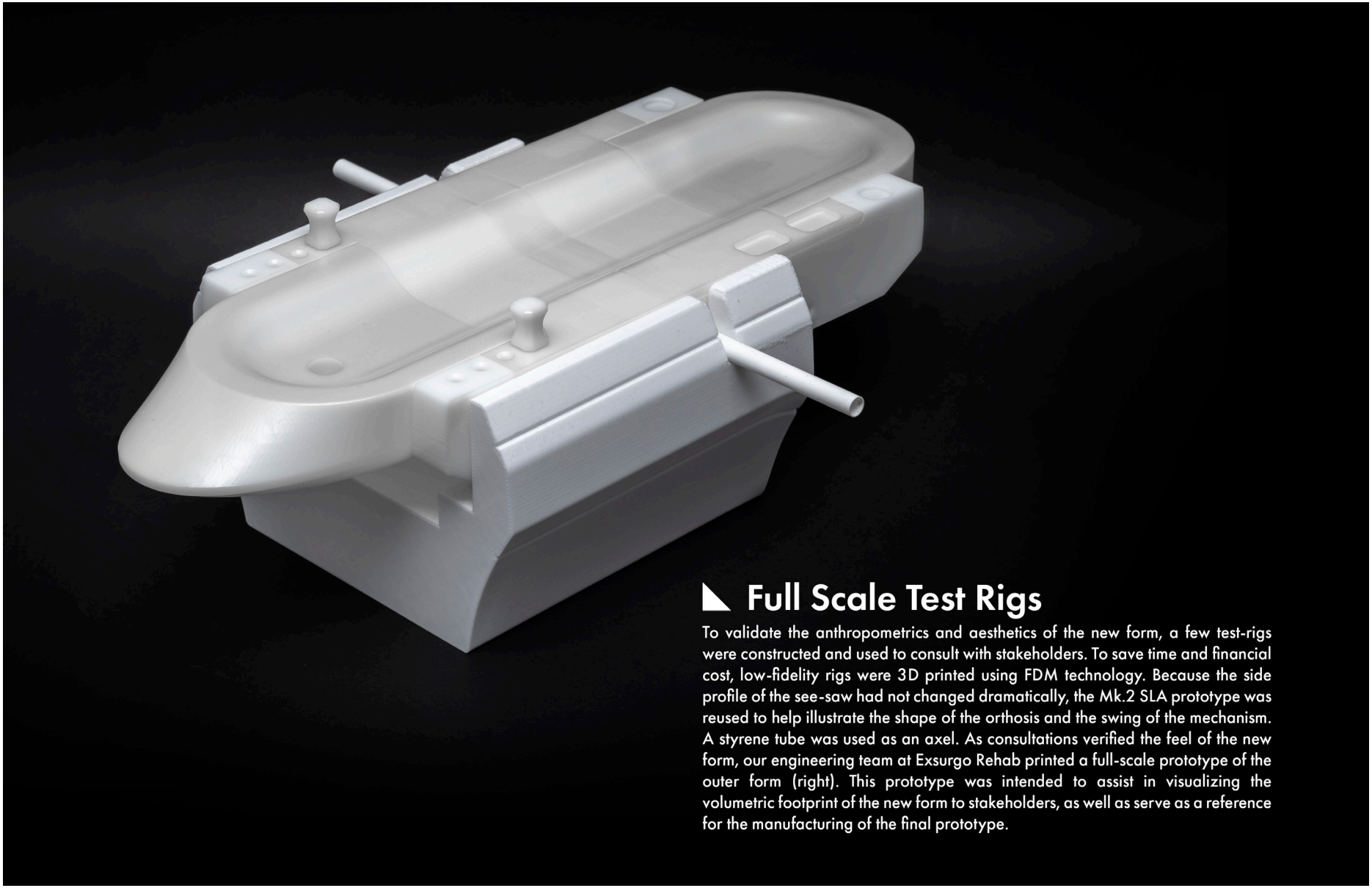


Figure 4.23. Low-fidelity test rig of the Mk.4 form.

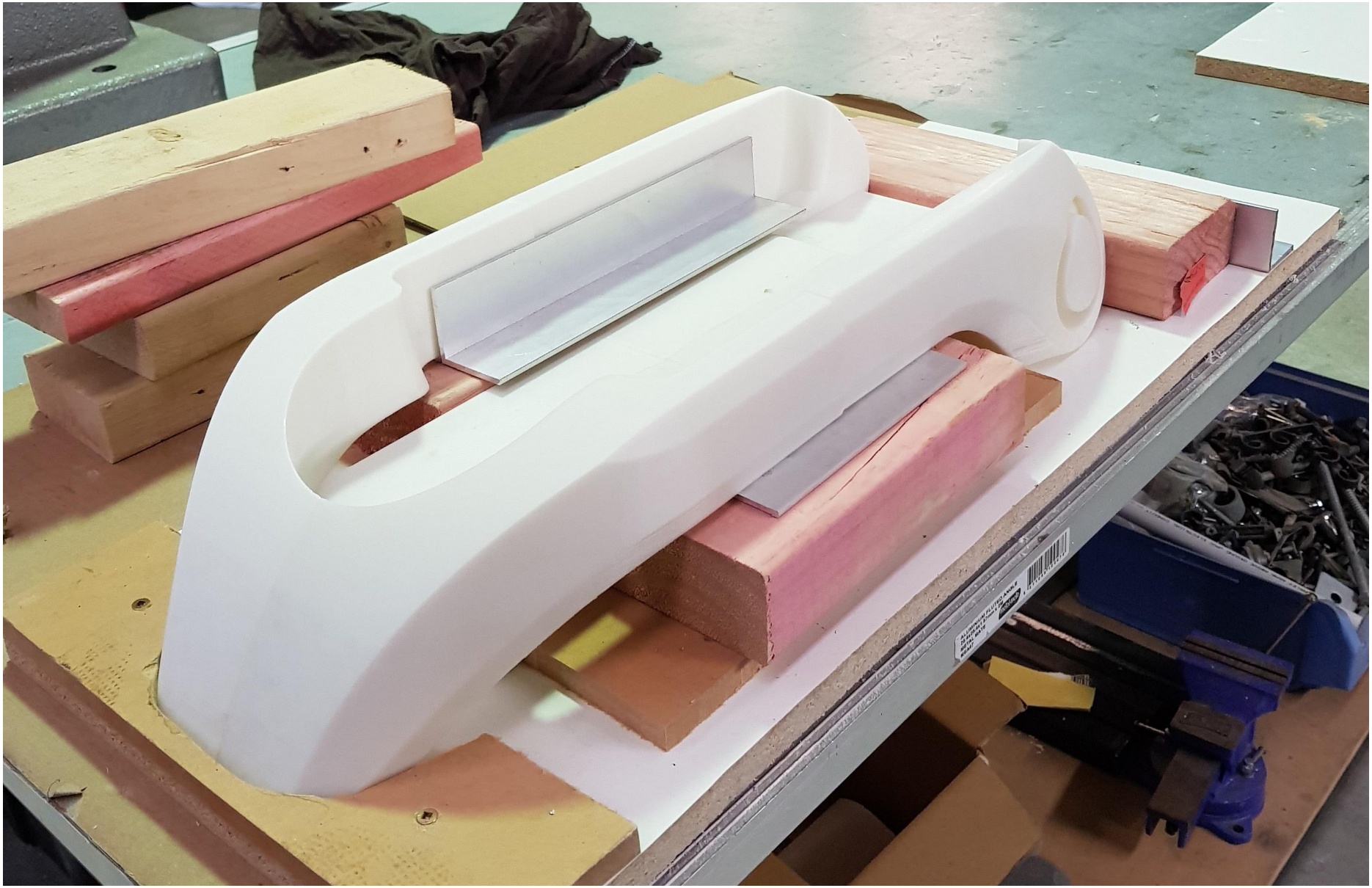


Figure 4.24. Medium-fidelity test rig of the Mk.4 form.

Designing for Purpose

One of the major efforts undertaken in the design of the Mk.4 prototype was the redesign of the joystick module. Feedback on the Mk.3 indicated end-users desired for the device to be smaller. To accommodate this, the Mk.4 was designed to be shorter vertically and narrower horizontally. However, this meant the joystick module no longer fit in the space available. Our first resolution to this was to reconfigure the force sensors beneath the joystick as detailed in Figure 4.45. However, this was still too large to fit in the space available. Consequently, a completely new module was designed with our team at Callaghan. This module functions using the same principles as the old module; by detecting force exhibited on the joystick in the x and y axes, the module sends corresponding direction data to control the motors.

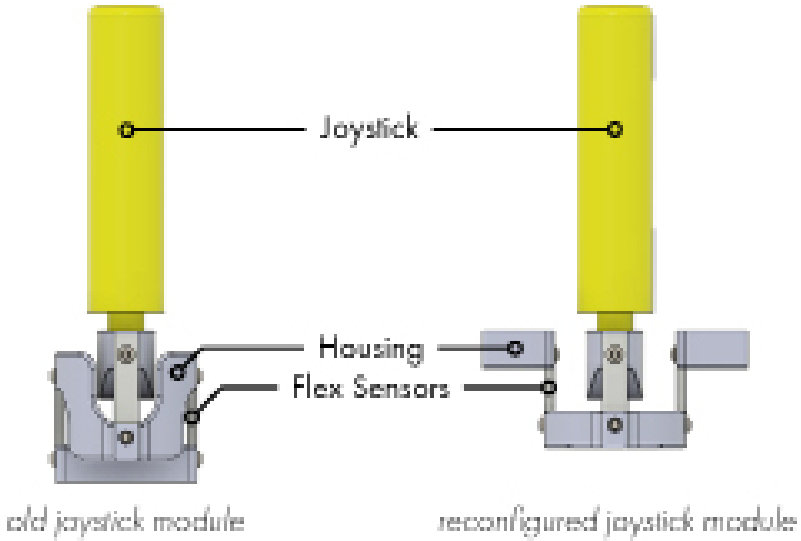
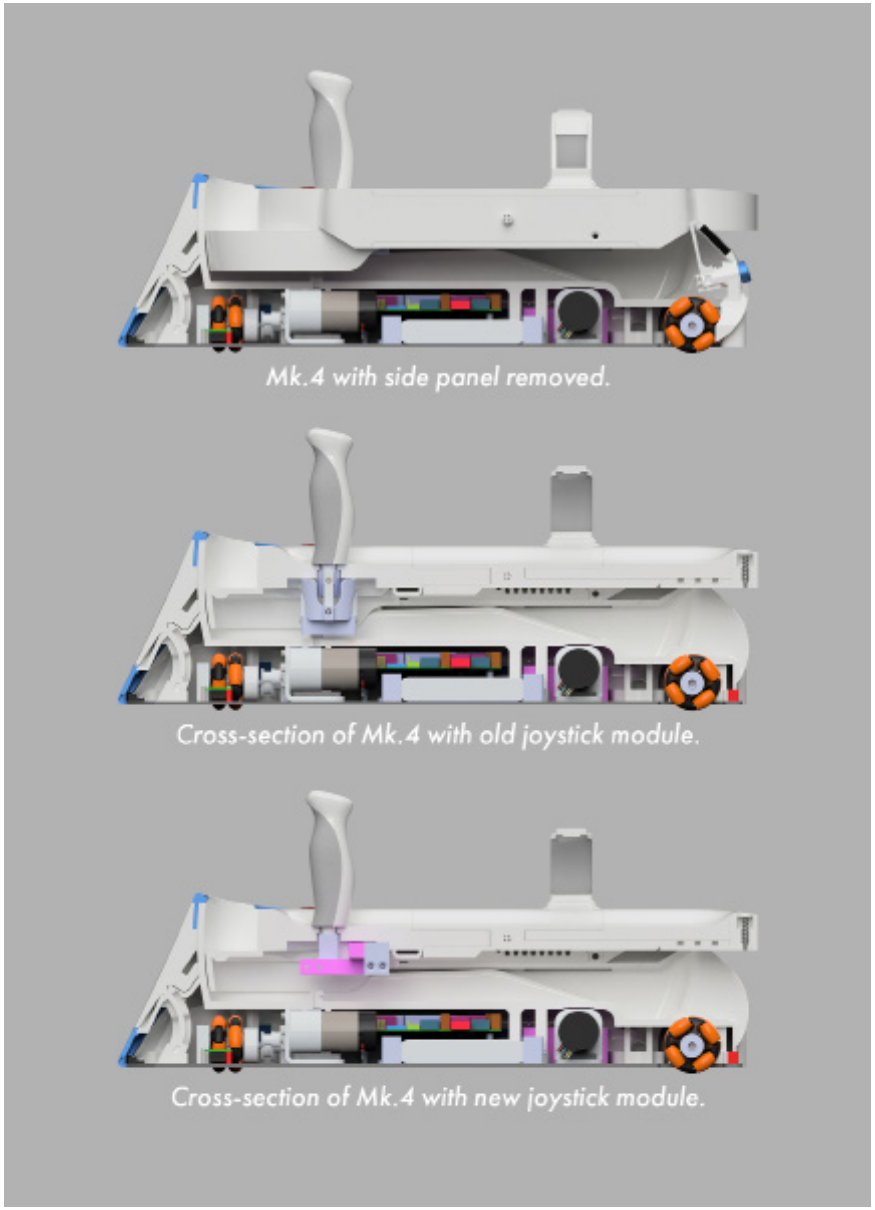


Figure 4.45. (above) Joystick module reconfiguration concept.

Figure 4.46. (right) Joystick module in relation to space afforded by structure.



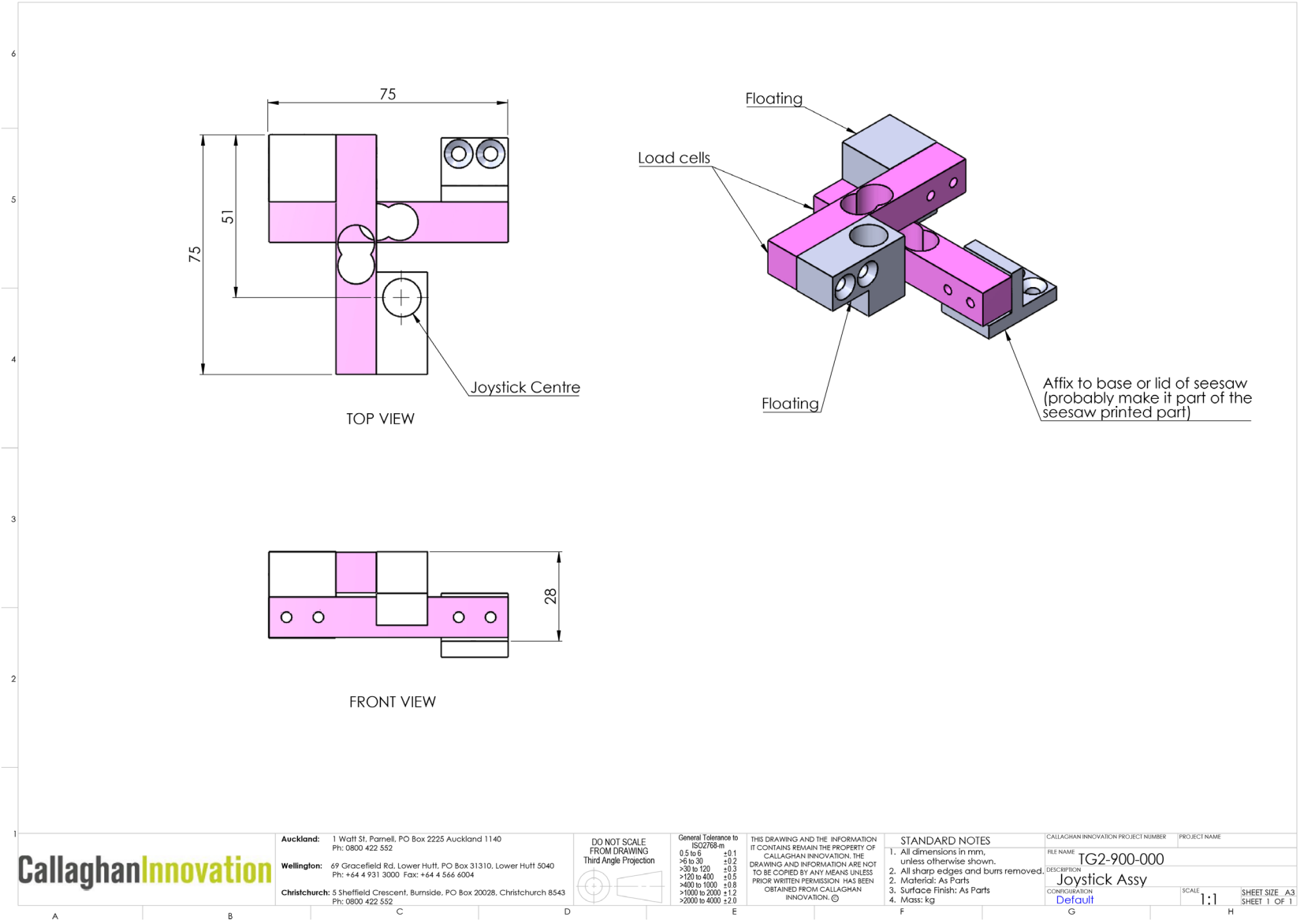


Figure 4.47. Novel joystick module designed by Callaghan Innovation.

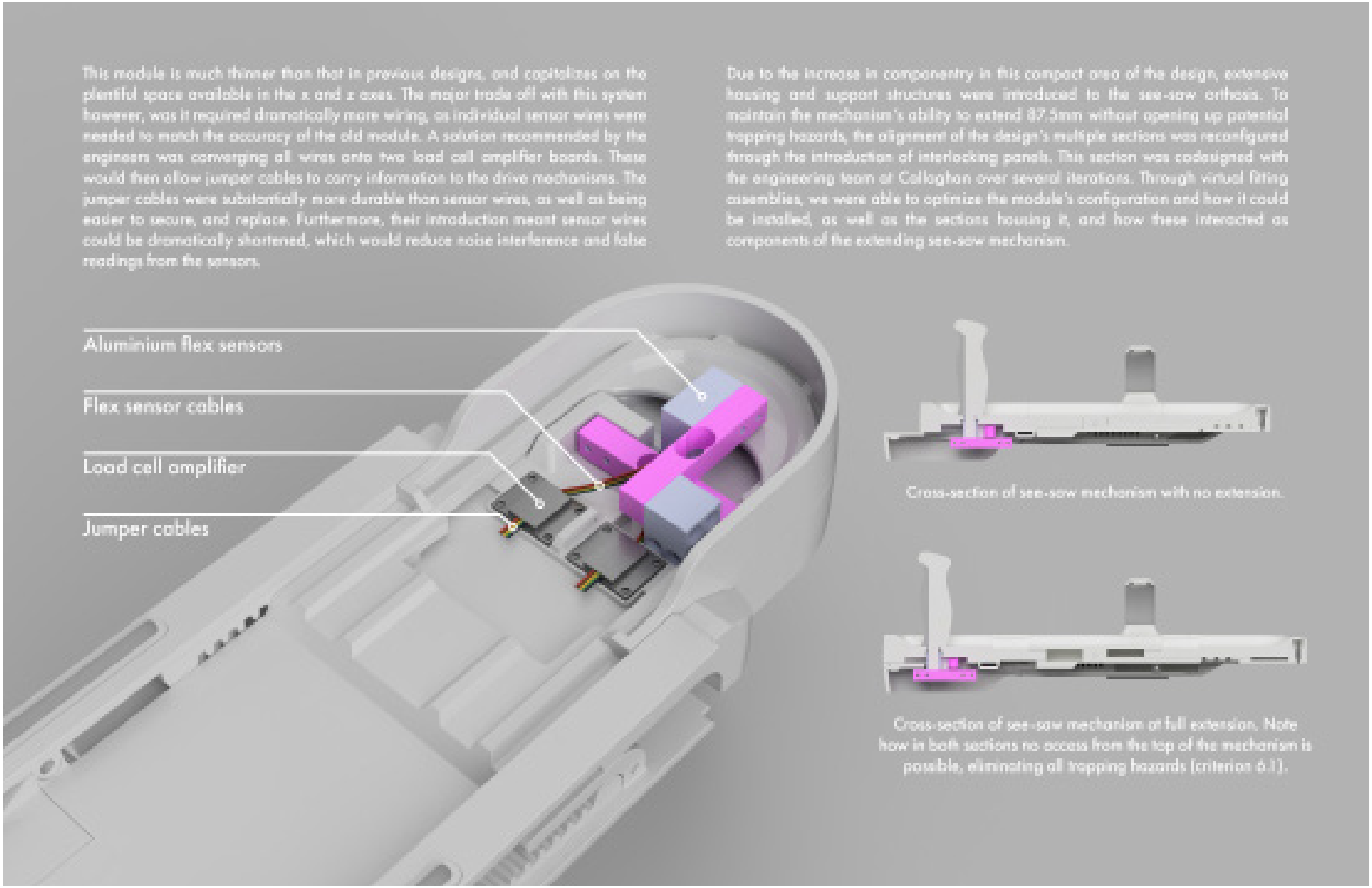


Figure 4.48. Novel joystick module and corresponding see-saw housing.

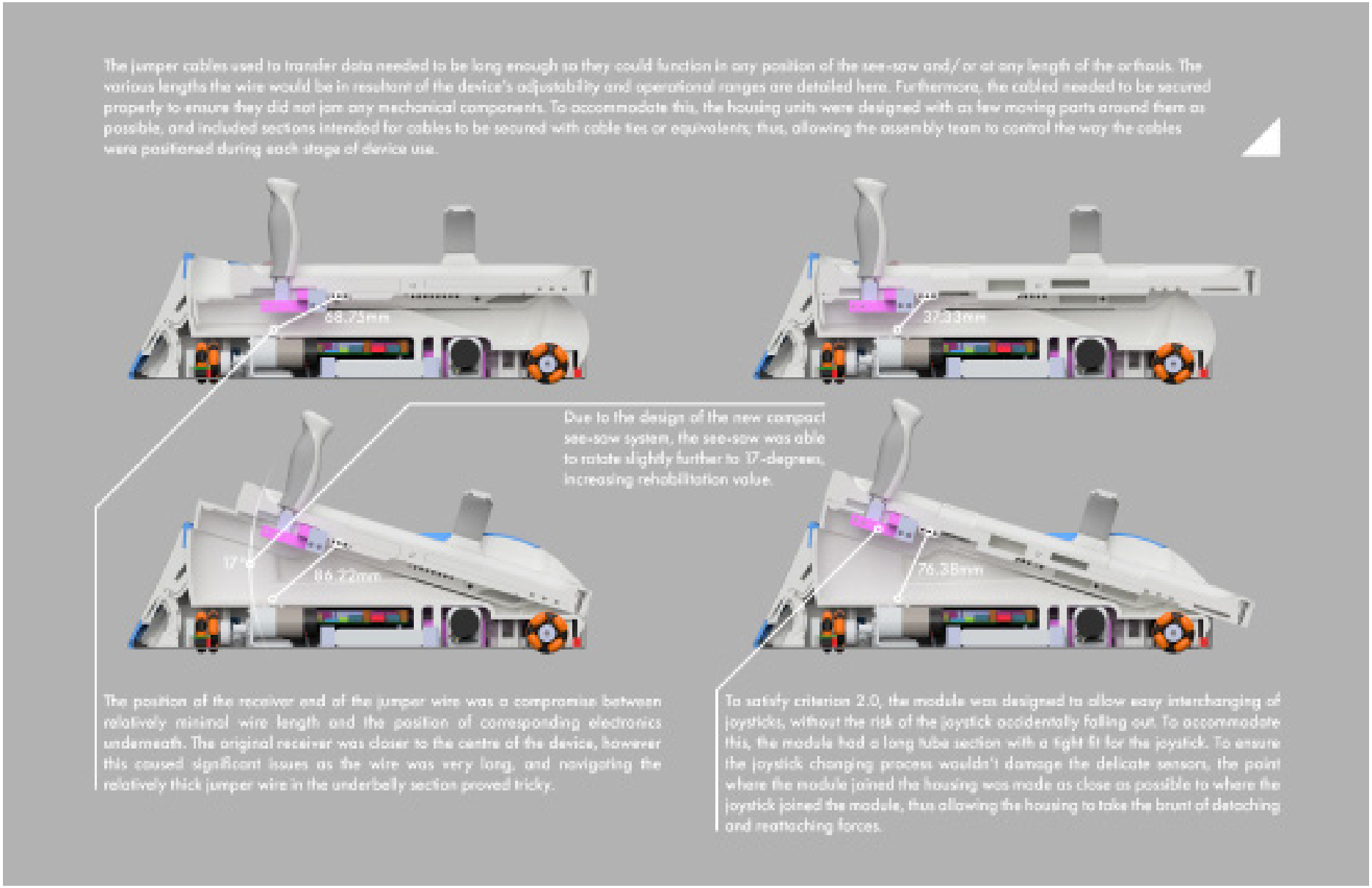


Figure 4.49. Cross-sections of the device's range of extension and tilt, in relation to joystick module and wire length.

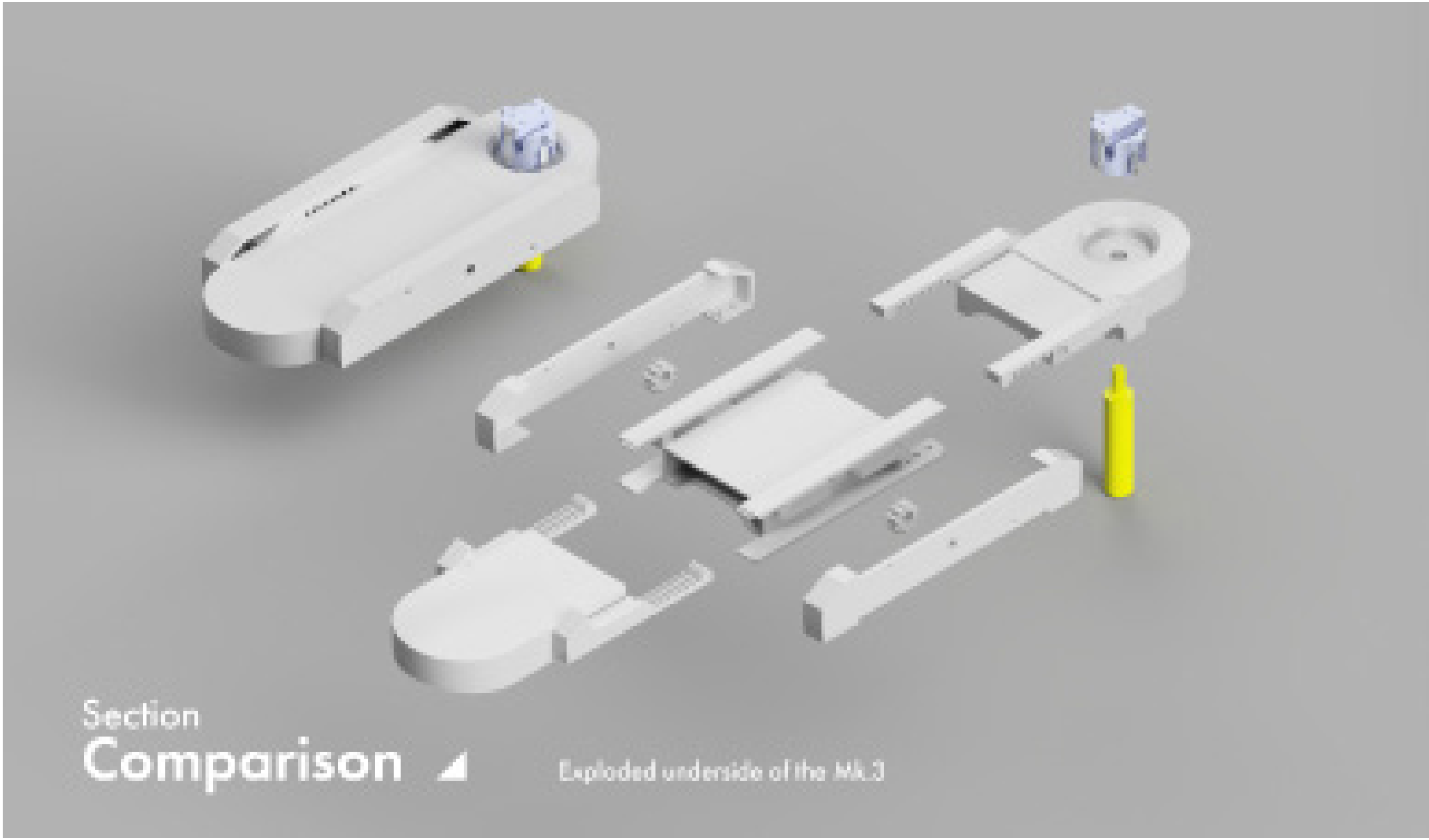


Figure 4.50. Comparison of underside assemblies between the Mk.3 and Mk.4.

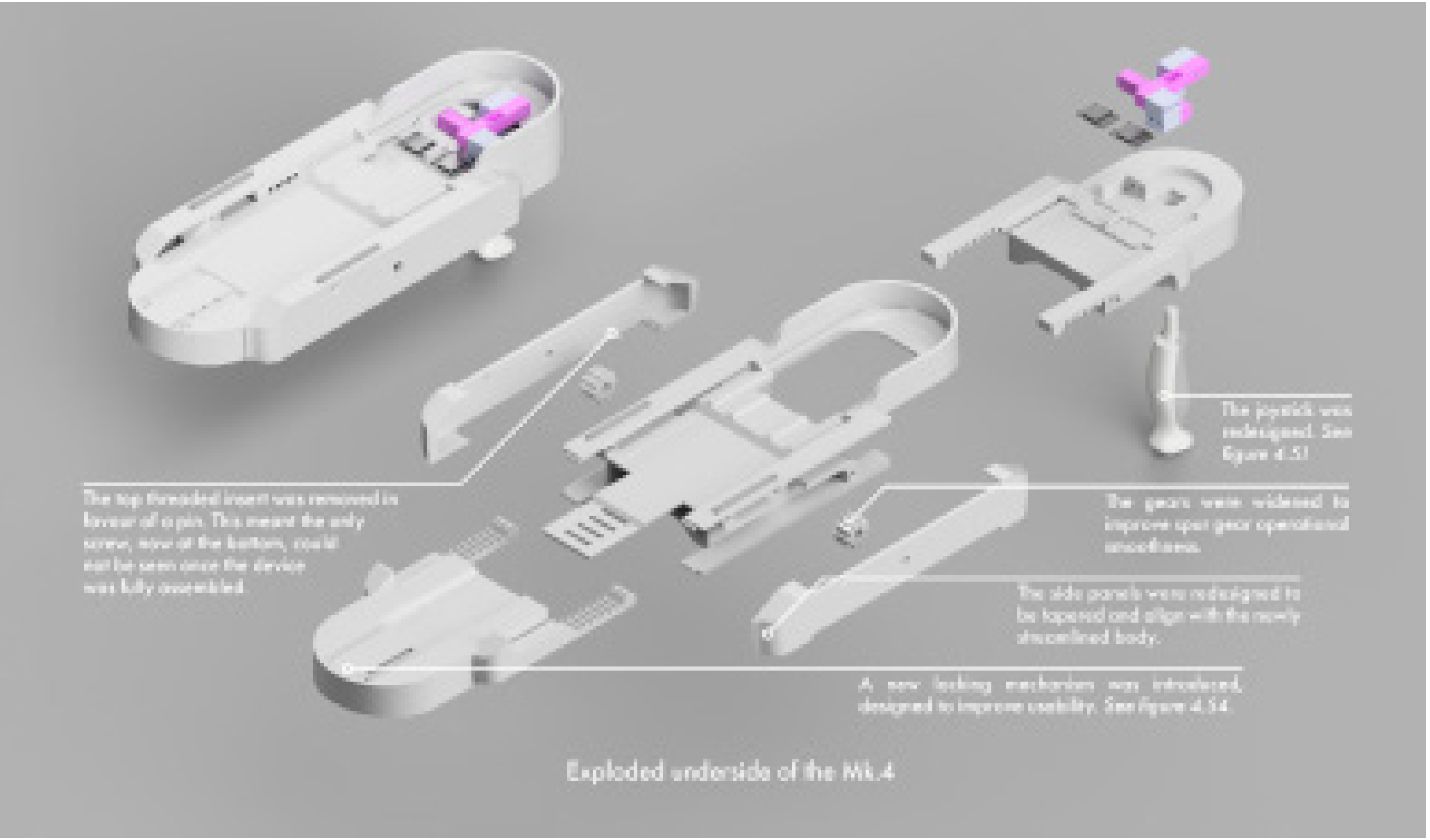


Figure 4.50 (continued).

Joystick

Alongside the joystick module, the joystick itself was also redesigned. To refine ergonomics, our earlier observation studies (figures 4.3, 4.13) were re-examined and iterated upon. Concept development followed a similar process to that of the design exterior (figures 4.36-4.41), with exploration of form, composition, and materiality. To achieve criteria 4.0 and 6.0, the joystick was made a different colour to the body. This visual distinguishment, combined with connotations of a joystick, gave visual semantic cues to the user of its function. To satisfy criteria 2.2, 5.5 and 5.6, the joystick was designed to comprise of two pieces, allowing easy manufacturing and coating (painting, metalizing, electroplating, etc), and was made a neutral white and grey to remain cohesive with the rest of the aesthetic. The grey used a subtle rough texture to improve both usability through enhanced grip, as well as visually suggest effectiveness (criterion 5.3).

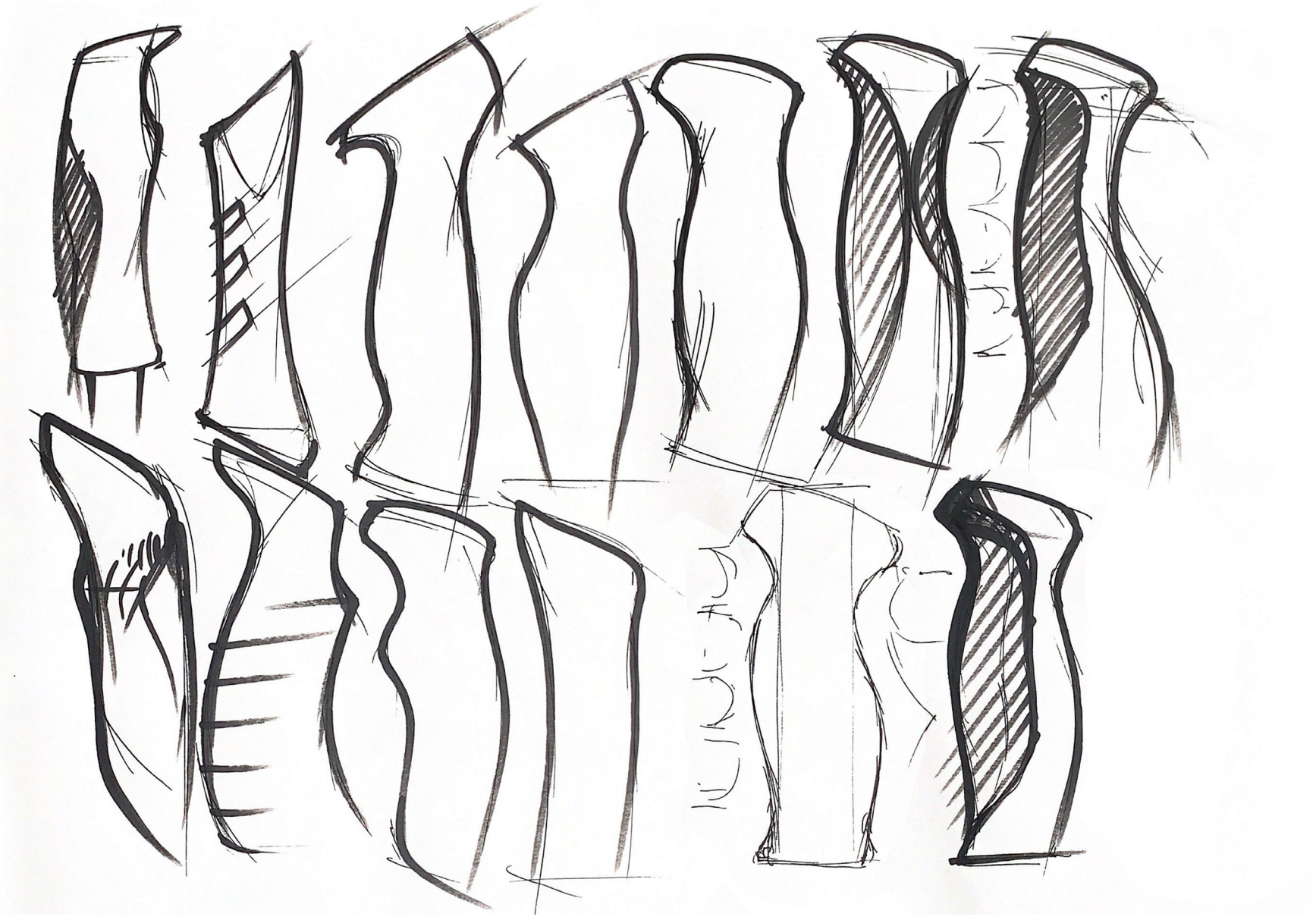


Figure 4.51. Initial joystick concepts.

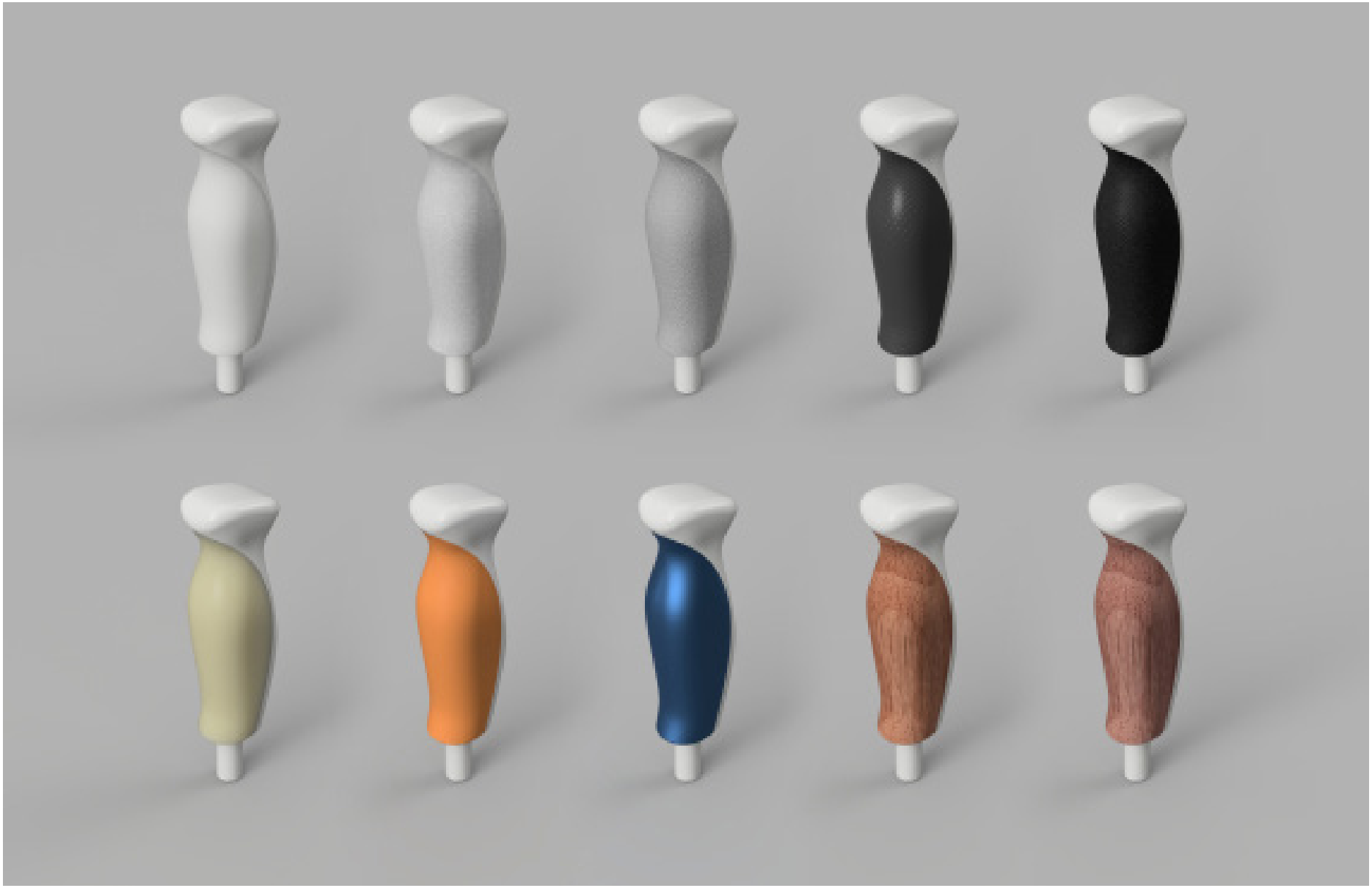


Figure 4.52. Joystick materiality exploration.

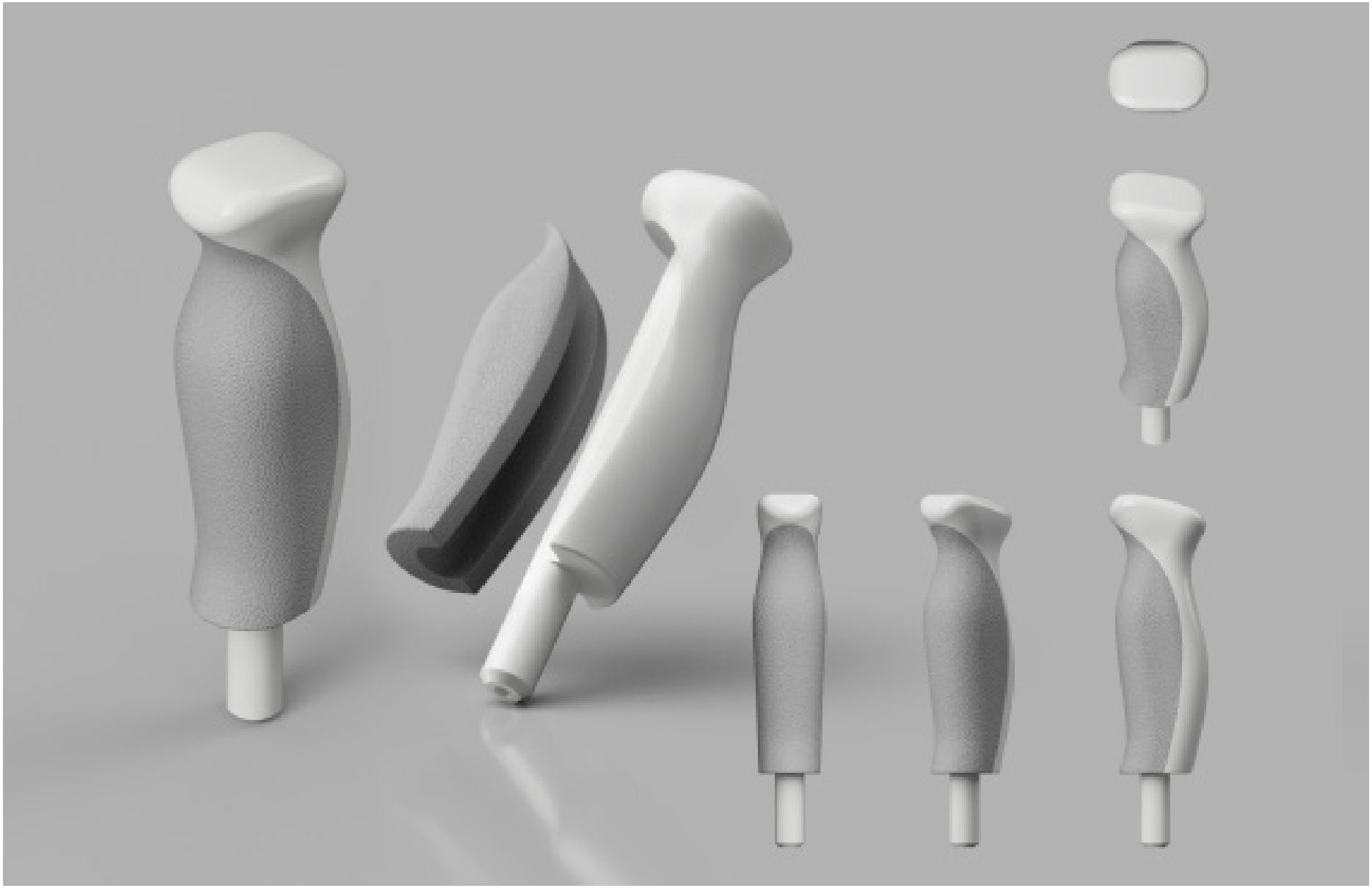


Figure 4.53. Final joystick design.

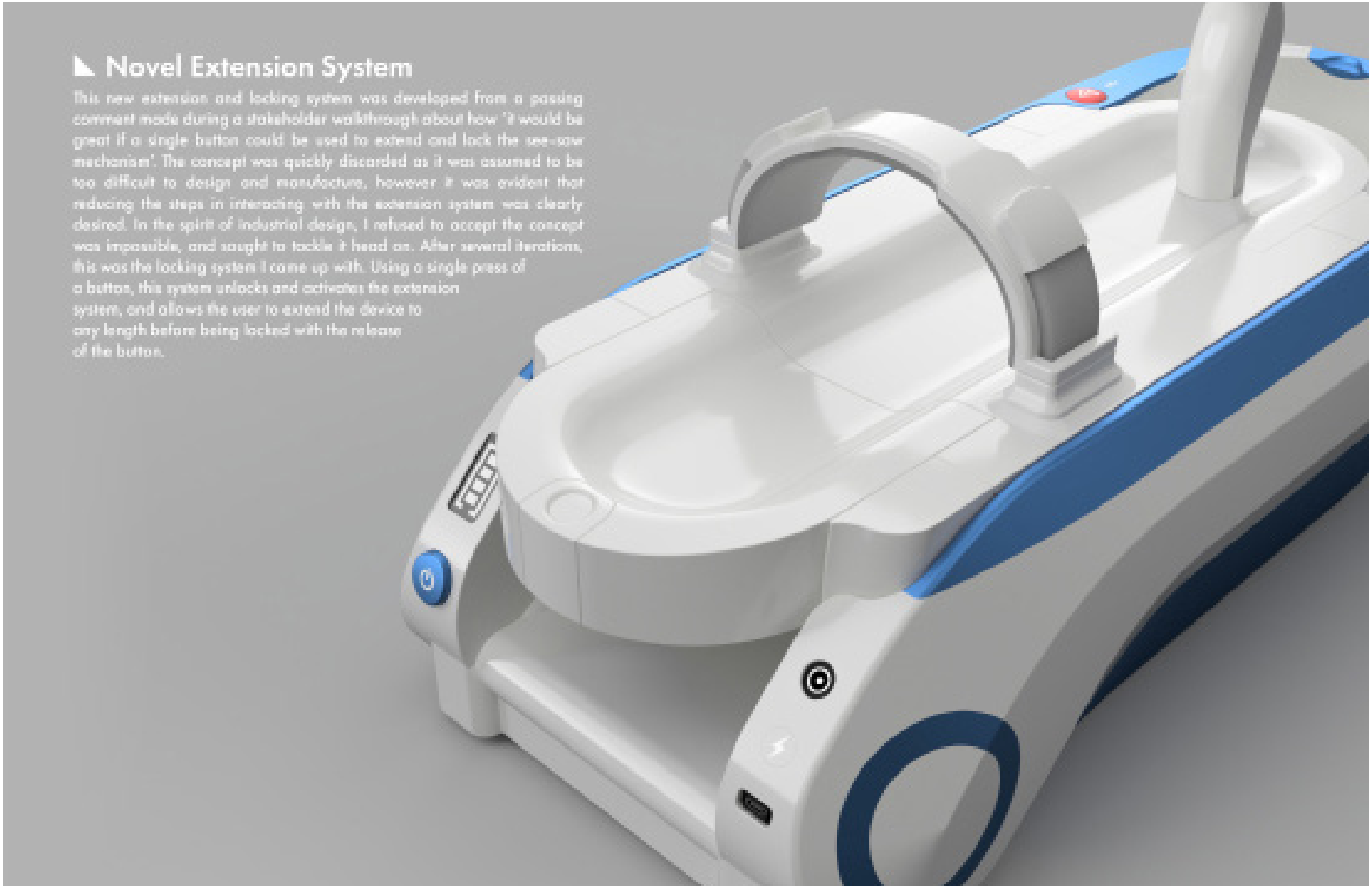


Figure 4.54. Novel extension and locking system.

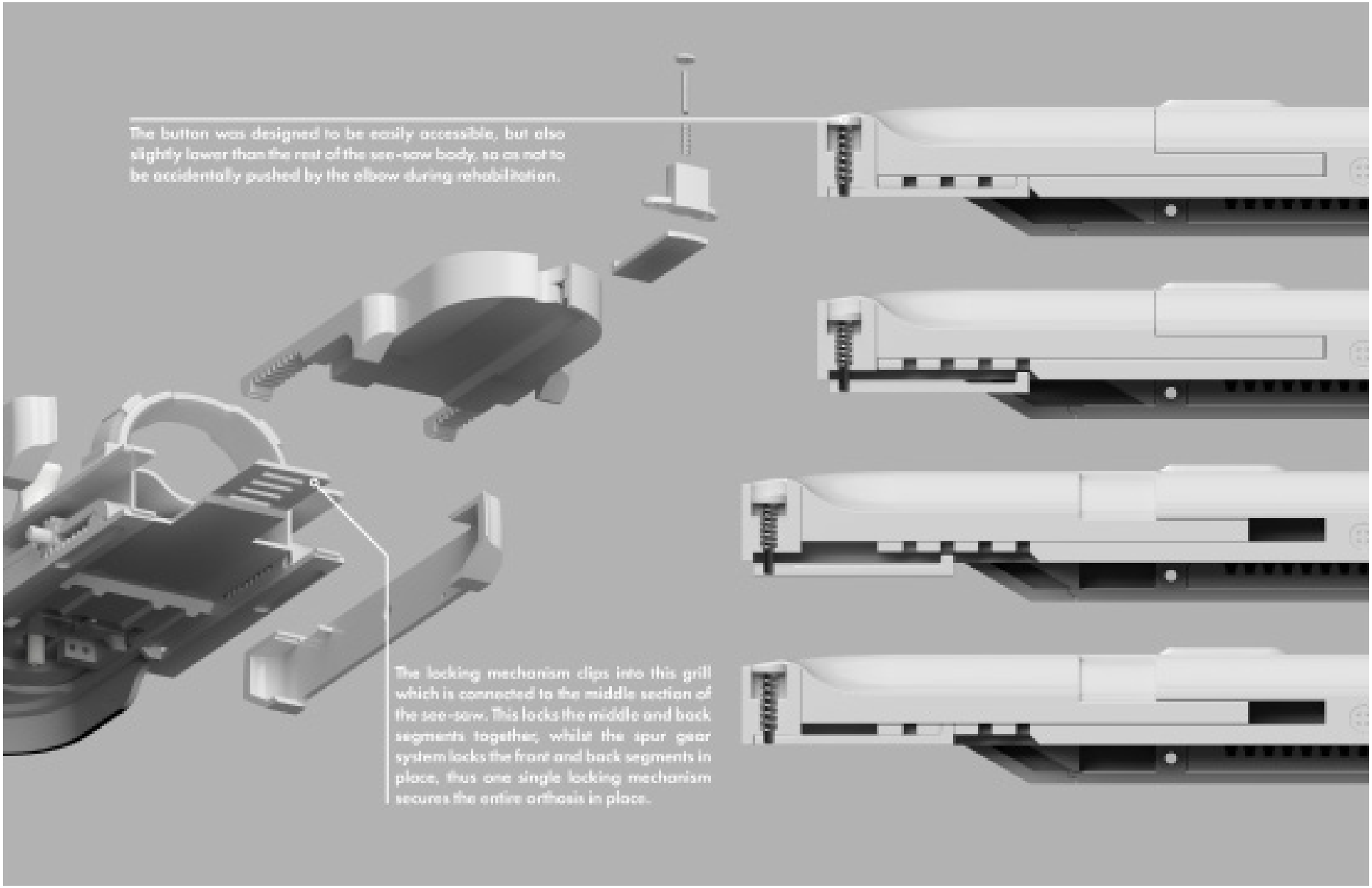


Figure 4.54 (continued).

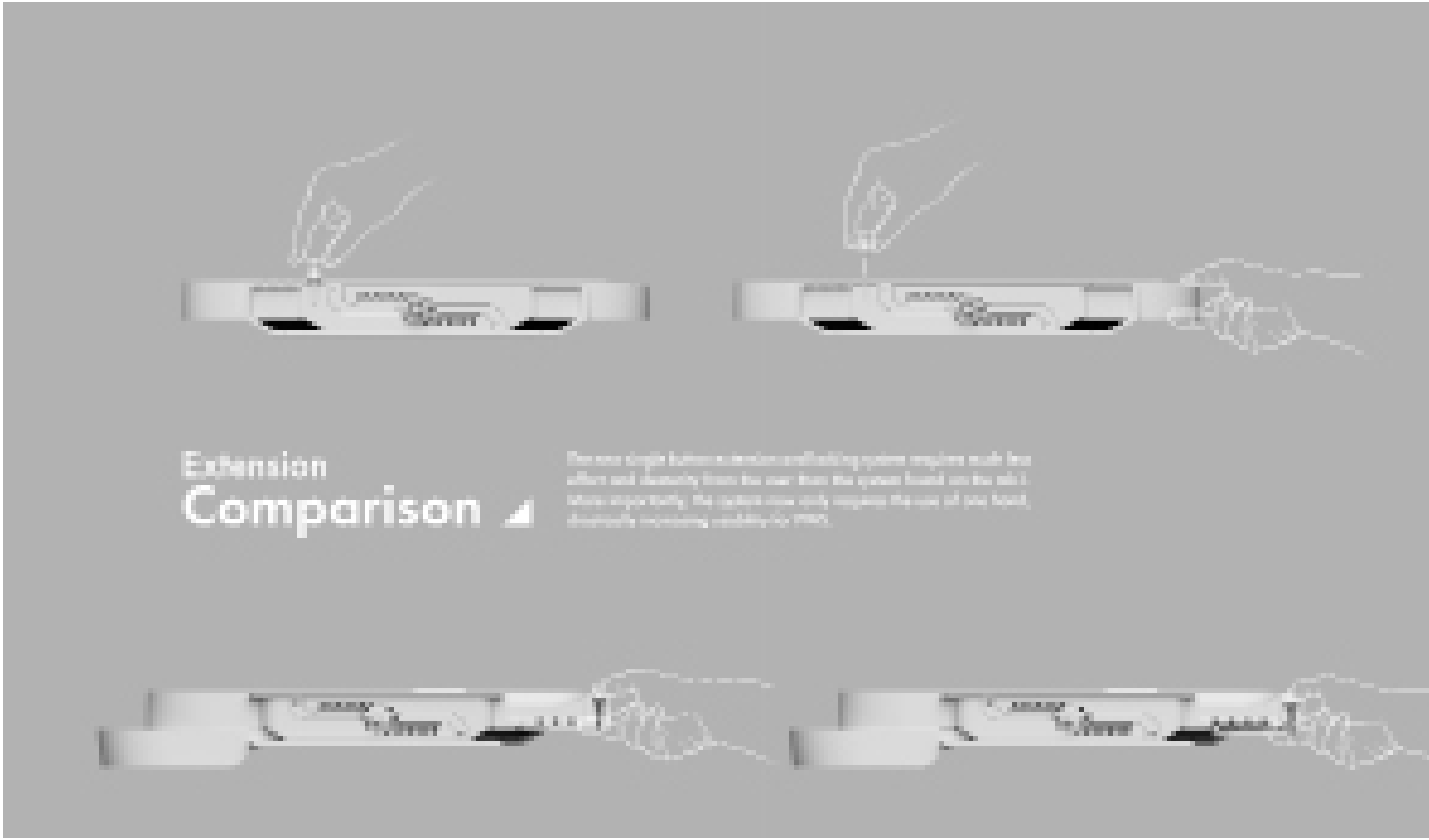


Figure 4.55. Comparison of extension systems between the Mk.3 and Mk.4.

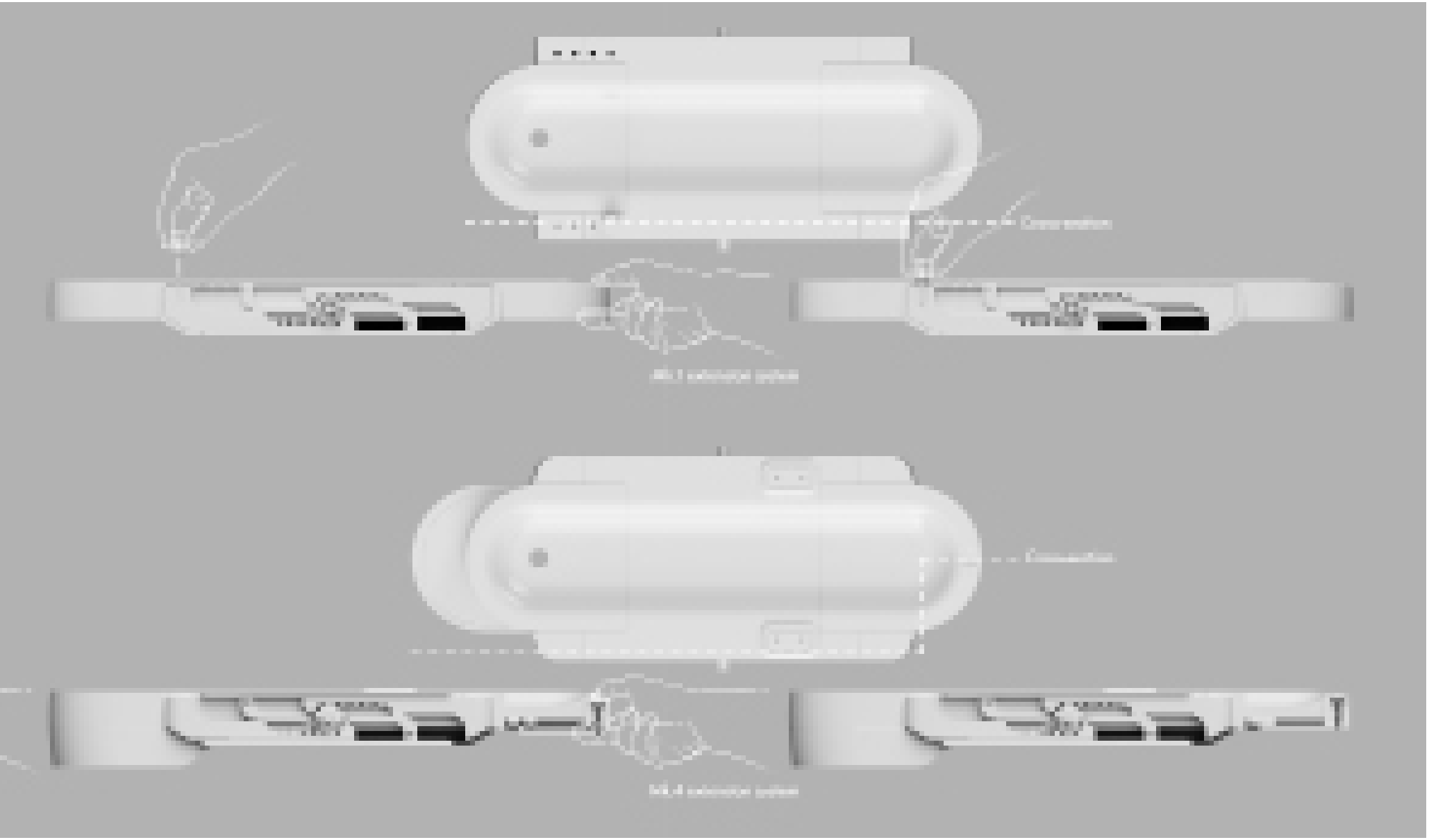


Figure 4.55 (continued).

Figure 4.56. Strap redesign 3.

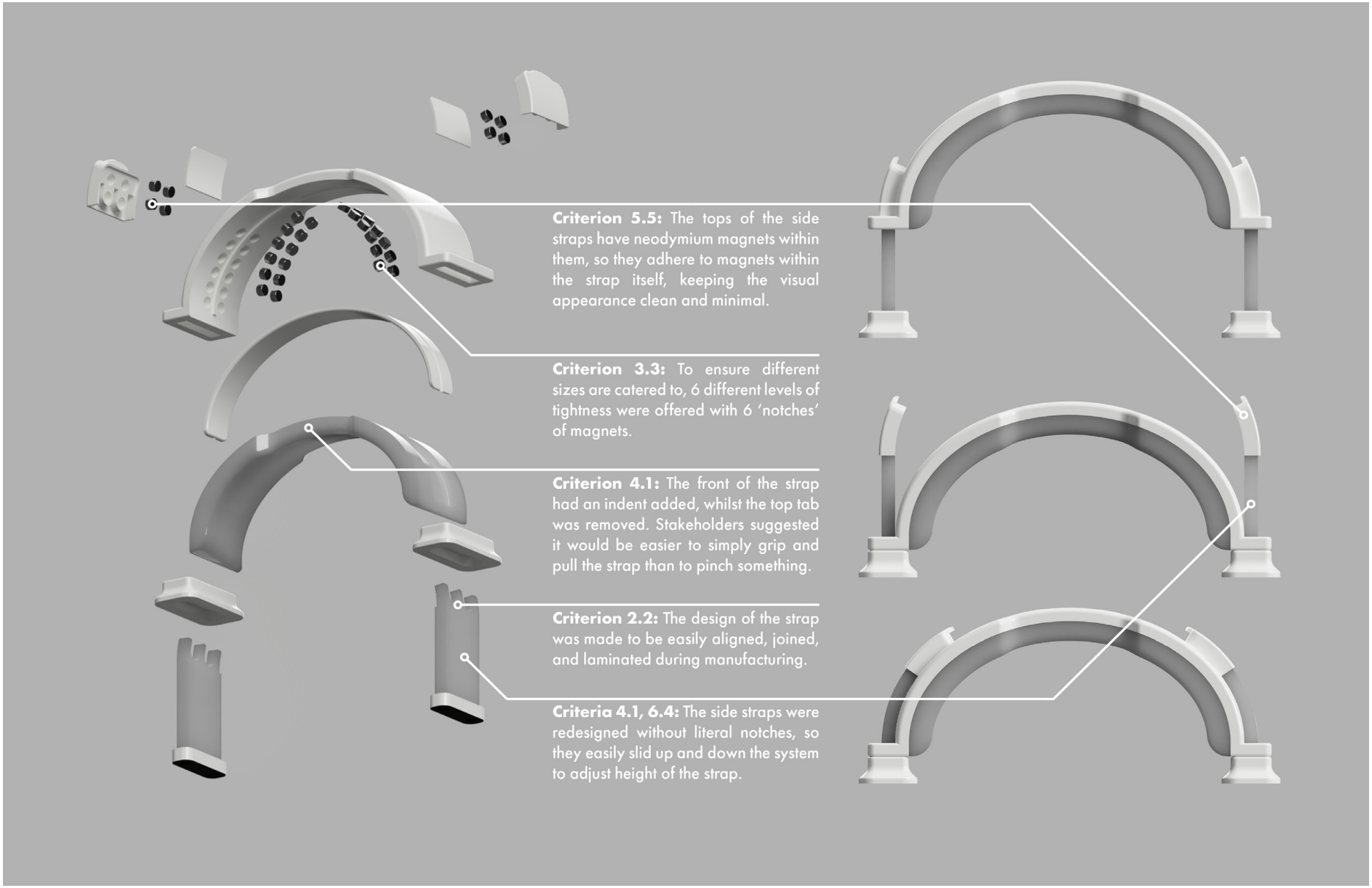


Figure 4.56 (continued).

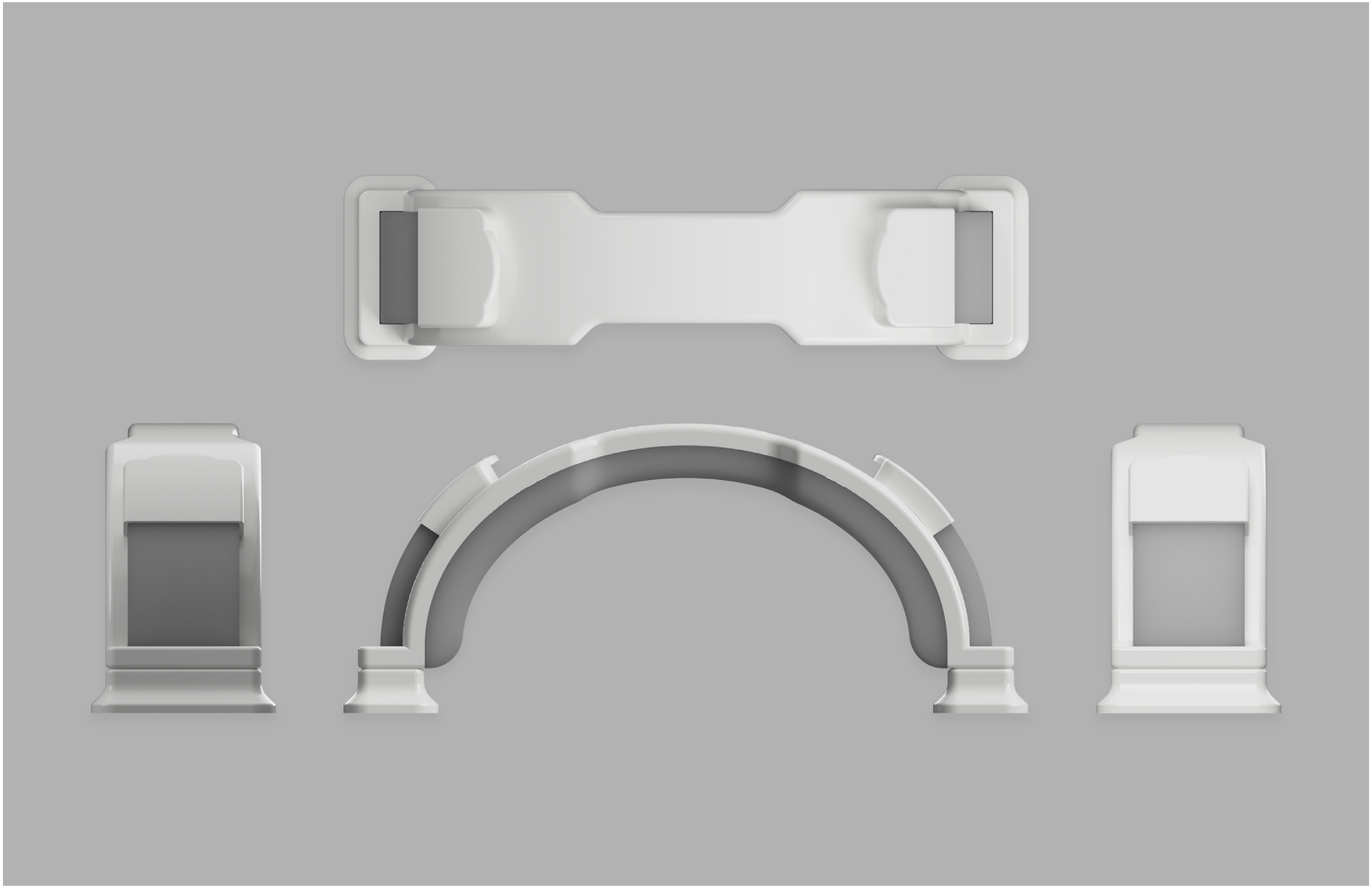


Figure 4.56 (continued).

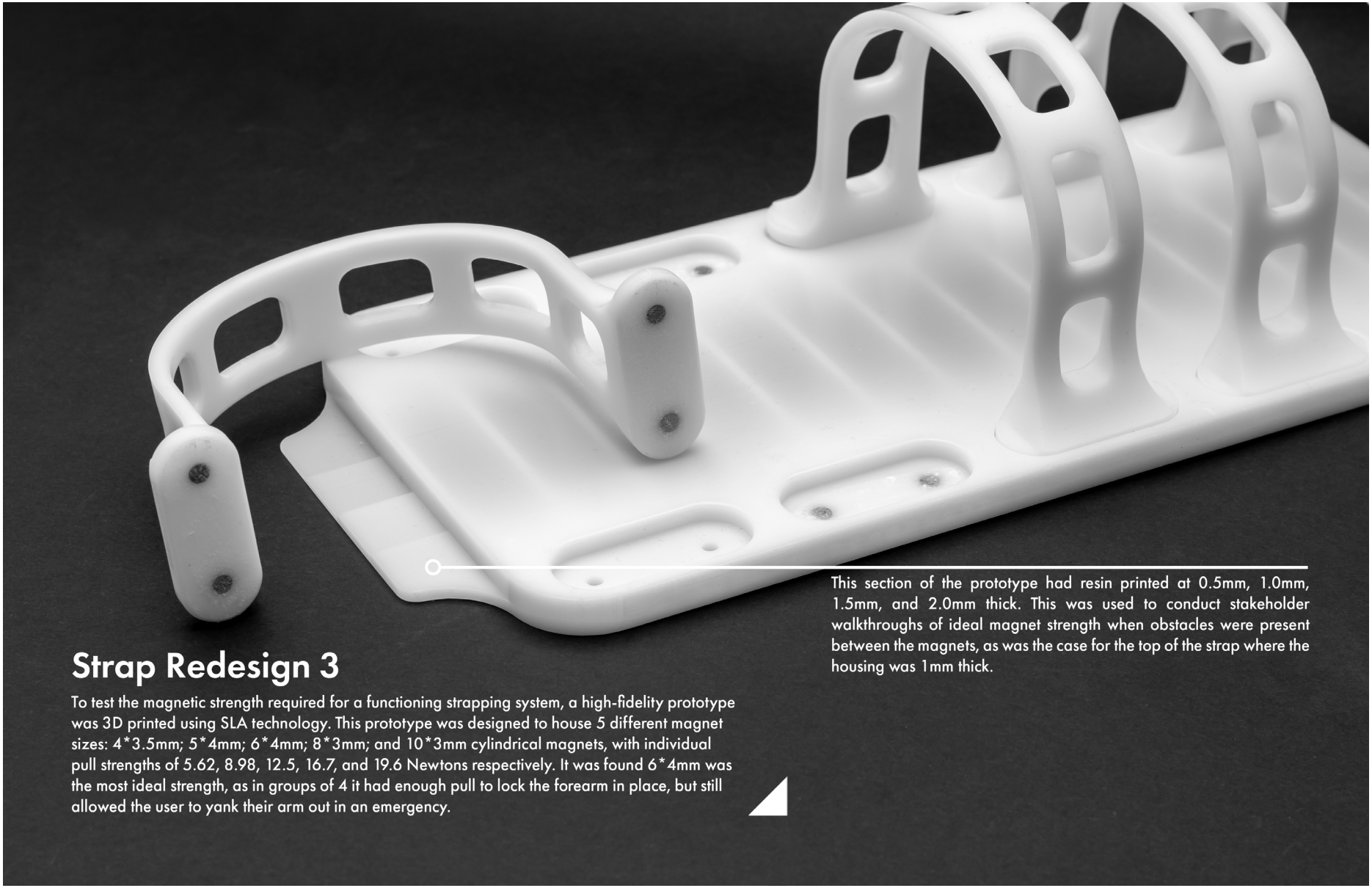


Figure 4.57. Magnet strength test-rig.

Figure 4.58. Initial tablet holder concept.

Figure 4.59. Final tablet holder concept.

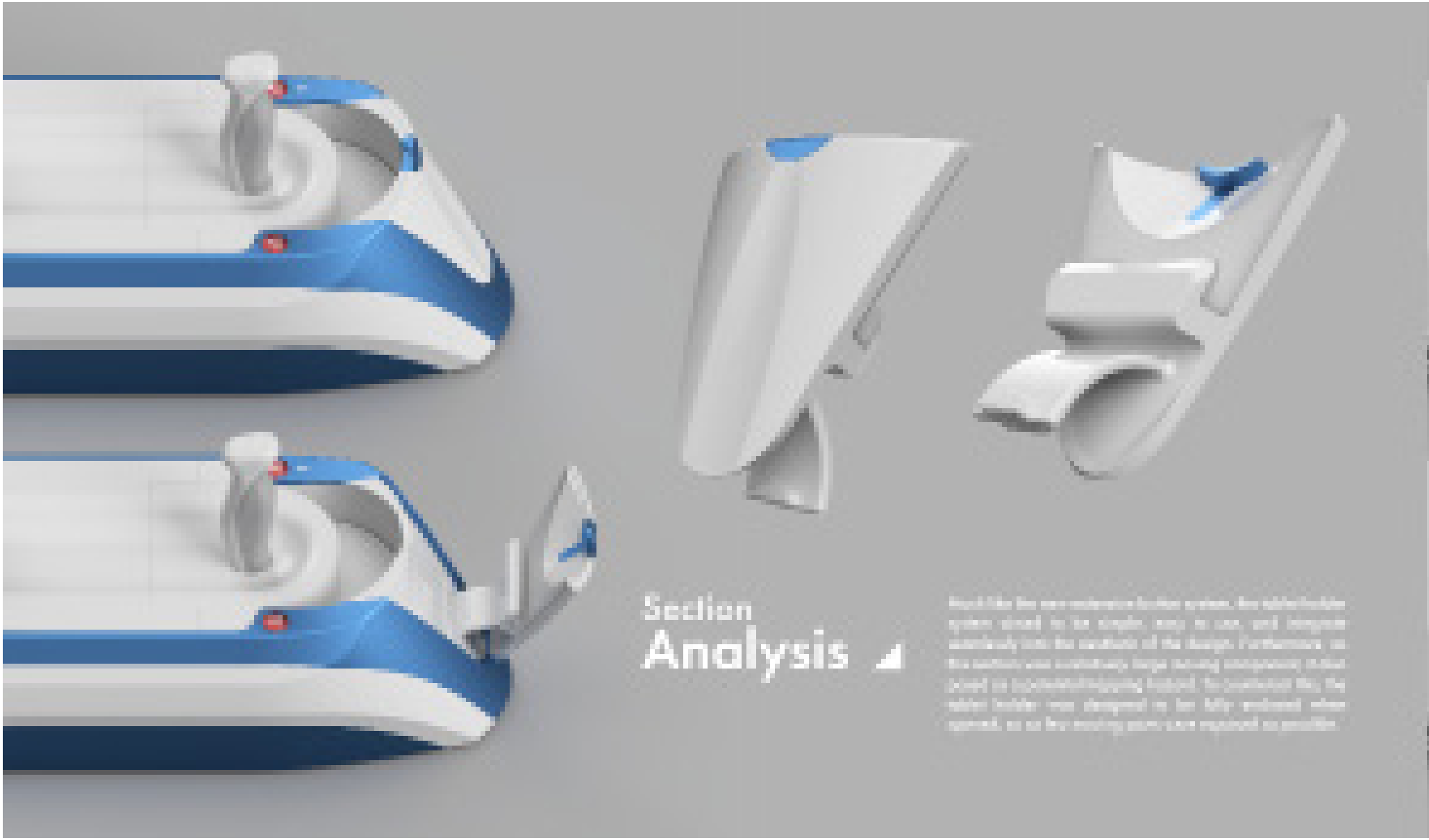


Figure 4.60. Section analysis of tablet holder.

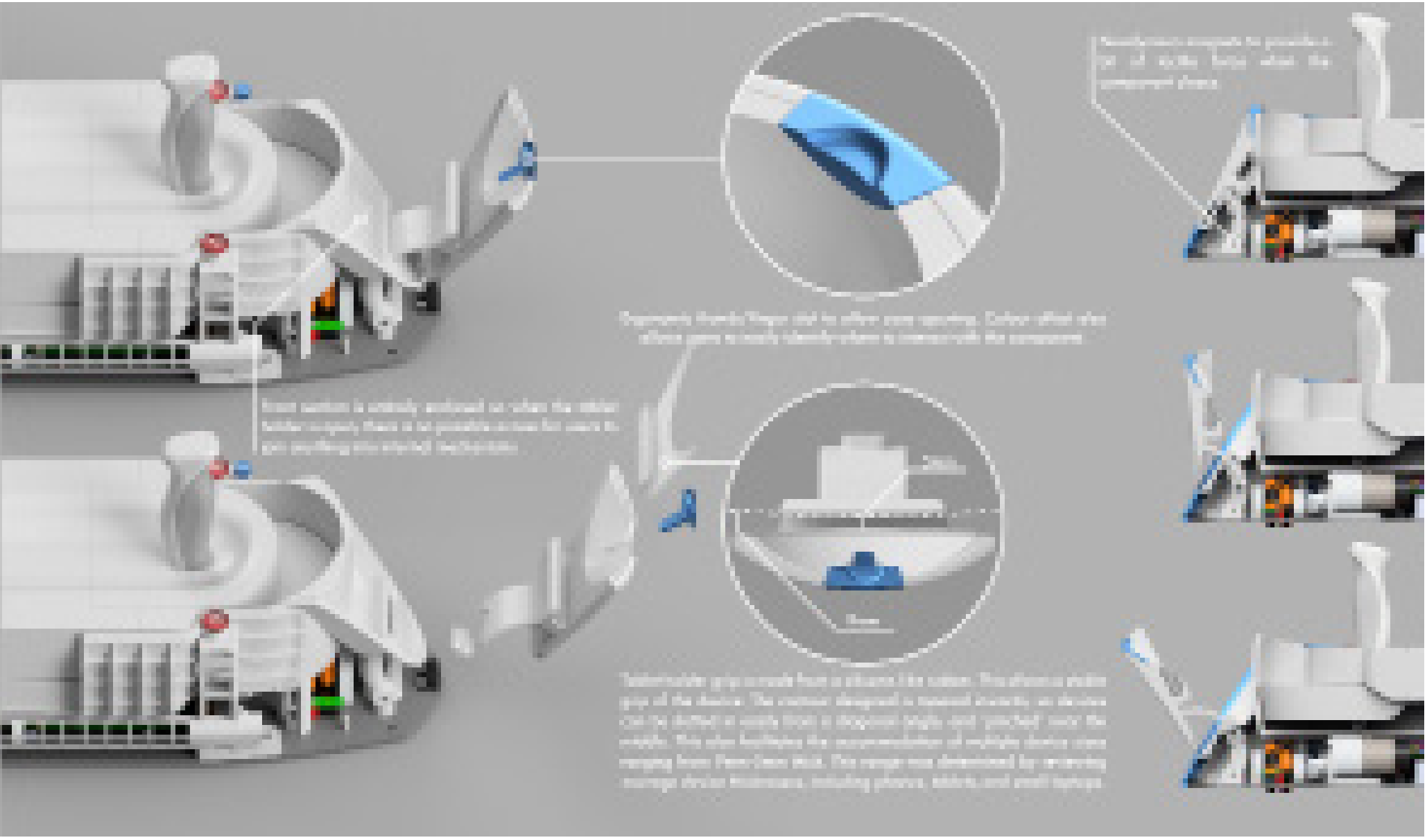


Figure 4.60 (continued).

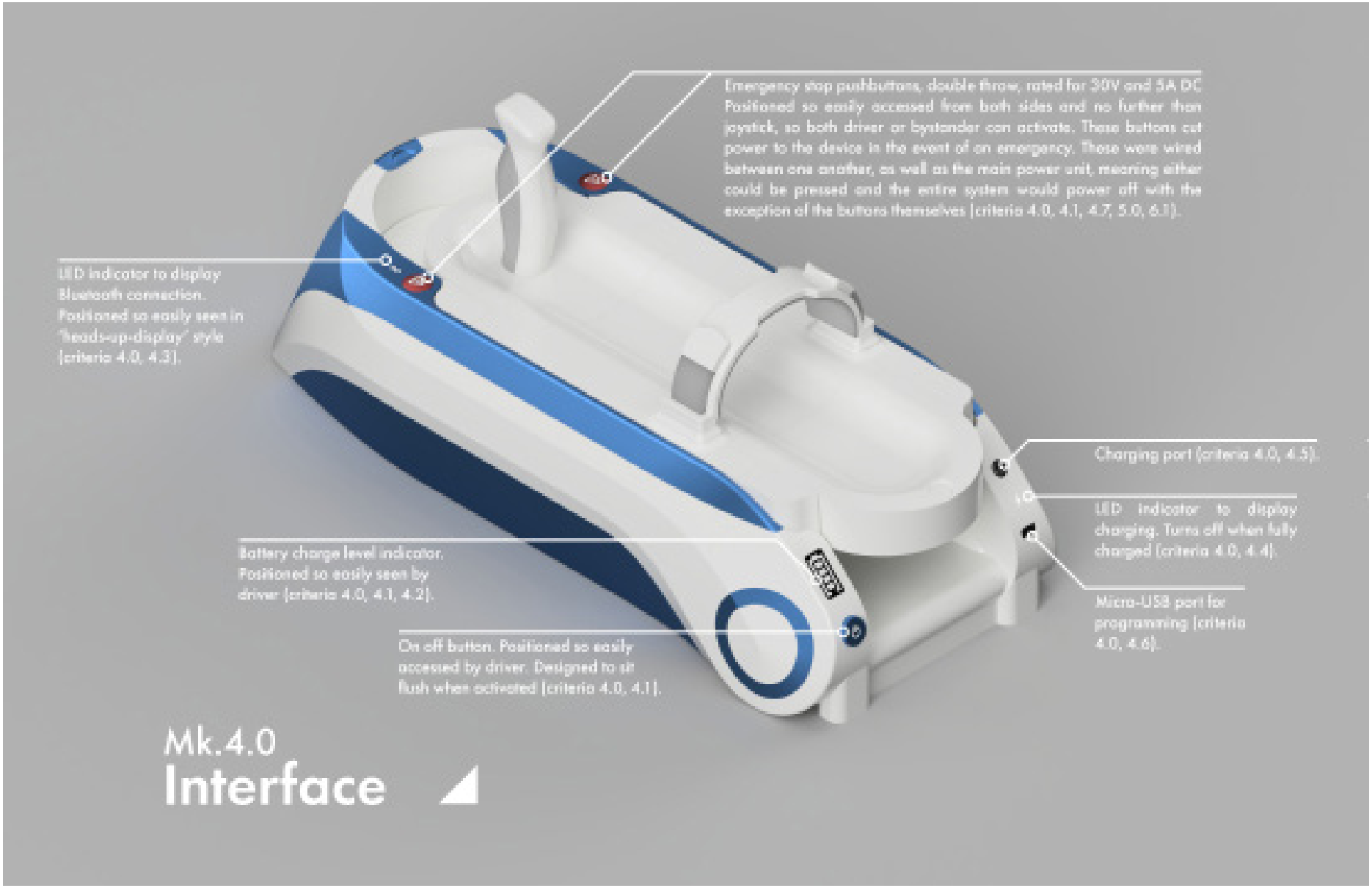


Figure 4.61. Final interface design.

The device's interface was redesigned to satisfy criteria 4.0-4.7. This design is built off the interface concept on the mk.2, aiming to present features in a convenient manner to the driver of the device. This allowed the user to quickly view the status of the device, and control its many features. In addition to usability and convenience, this was an important step in ensuring the safety of the device. The mk.1, as outlined in figure 4.1, had an interface which was opposite where the driver was, meaning the driver could not actually see if battery levels were low, nor could they easily access the on-off switch. Thus the mk.4 aimed to mitigate these shortcomings in prior prototypes.

Extensive consultation with the engineering team was undertaken during the development of the interface, as the device is powered by a lithium-ion battery, and consequently ports needed to be configured and rated to withstand high voltages and currents, whilst still being compliant to safety regulations.

All button components, including emergency stop buttons, were chosen to be maintained push-buttons with LED backing. This ensured when they were on, they stayed pushed in, and had a bright light emitting behind it. This meant it was obvious to the user when a button was activated, and the pushed in position meant it was hard to be accidentally unriggered.

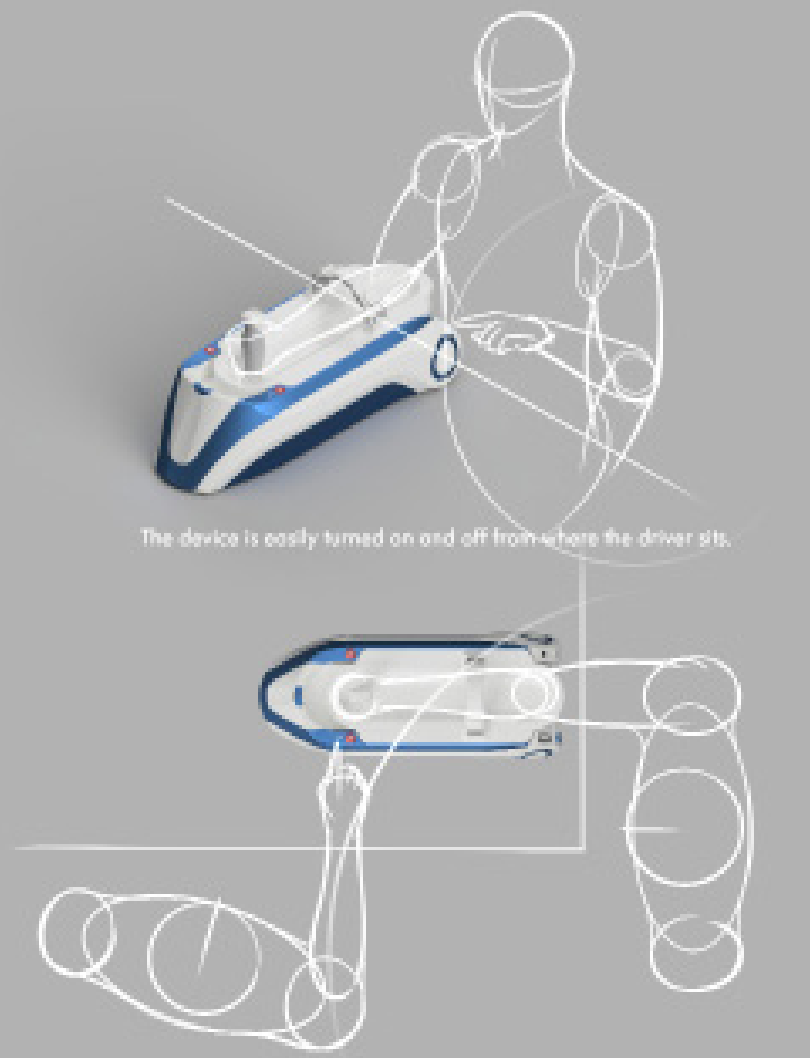
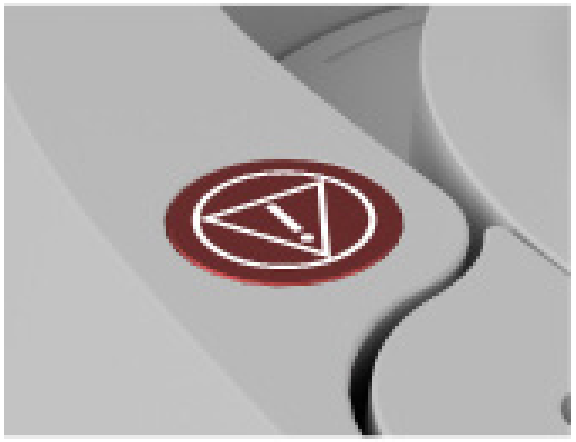


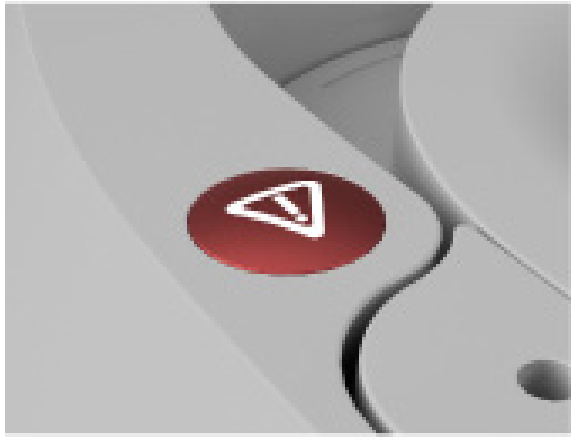
Figure 4.62. Positioning rationale of final interface.

Mk.4.0
Button Variations

A variety of button forms and icons were conceptualized so users had a selection to critique and choose from during stakeholder walkthroughs. Overall, this exploration process identified that users preferred easier to access buttons (protruding/convex), and simplified graphics. This was not surprising as these preferences were very much in line with prior research and criteria 4.0 and 4.1.



This concept was a flat button using the IEC emergency symbol 60417-5638 (International Electrotechnical Commission, 2005, p. 136). Users commented that this flush design looked relatively aesthetically pleasing.



This convex concept used a revised version of the IEC symbol 60417-5638. This new symbol was made more bold and thus easier to identify from a distance. Users commented this convex design facilitated an easier interaction.

This concave concept aimed to make a button that was more concealed. Users commented there would be few instances where reducing the accessibility of a button would be beneficial for a PWS.

Figure 4.63. Variations of interface form and iconography.

Figure 4.64. Close-ups of interface.

Figure 4.65. Exploded view of interface assembly.

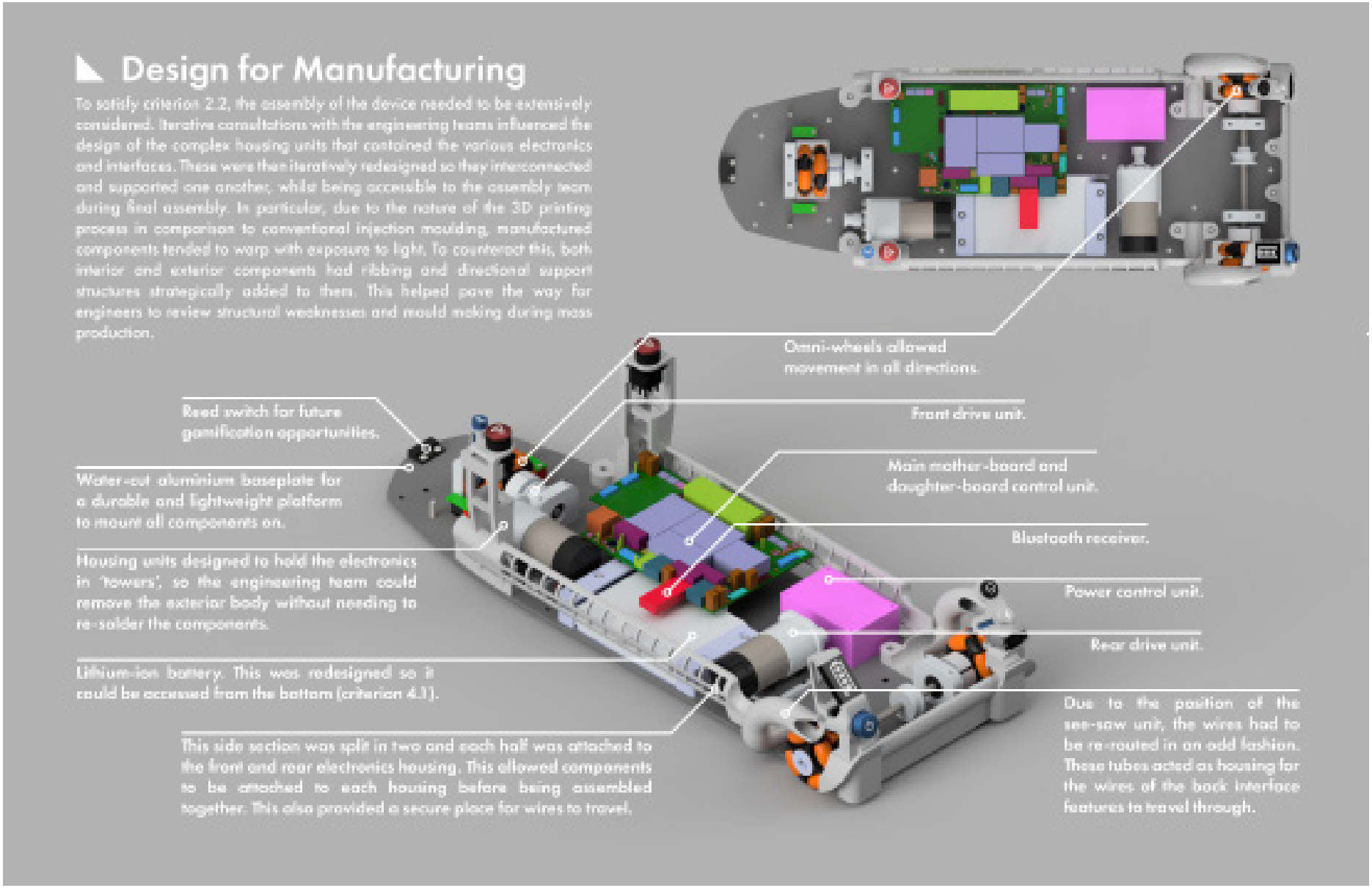


Figure 4.66. Final baseplate assembly with all mechatronic components.

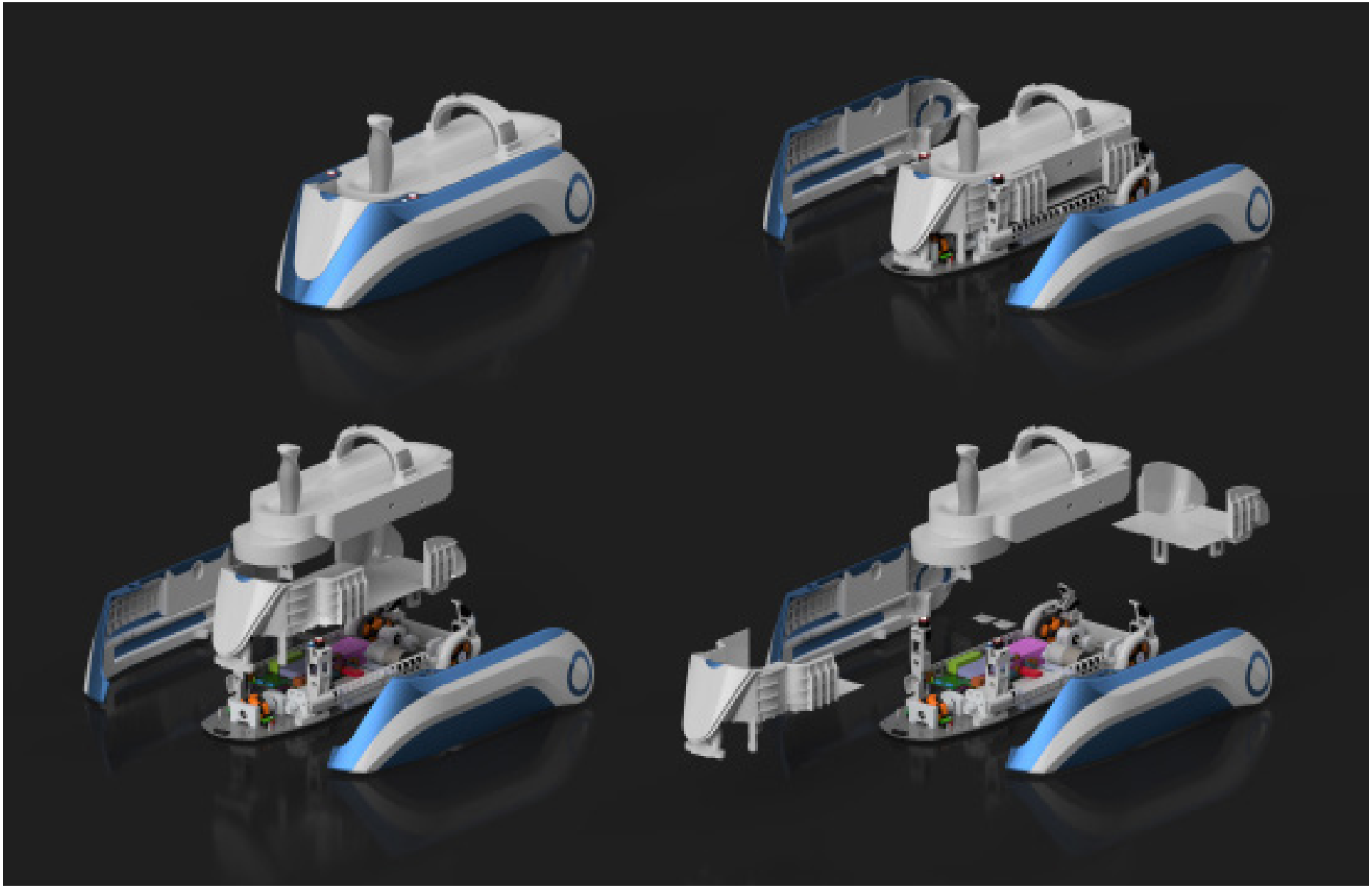


Figure 4.67. Final assembly of the Mk.4.

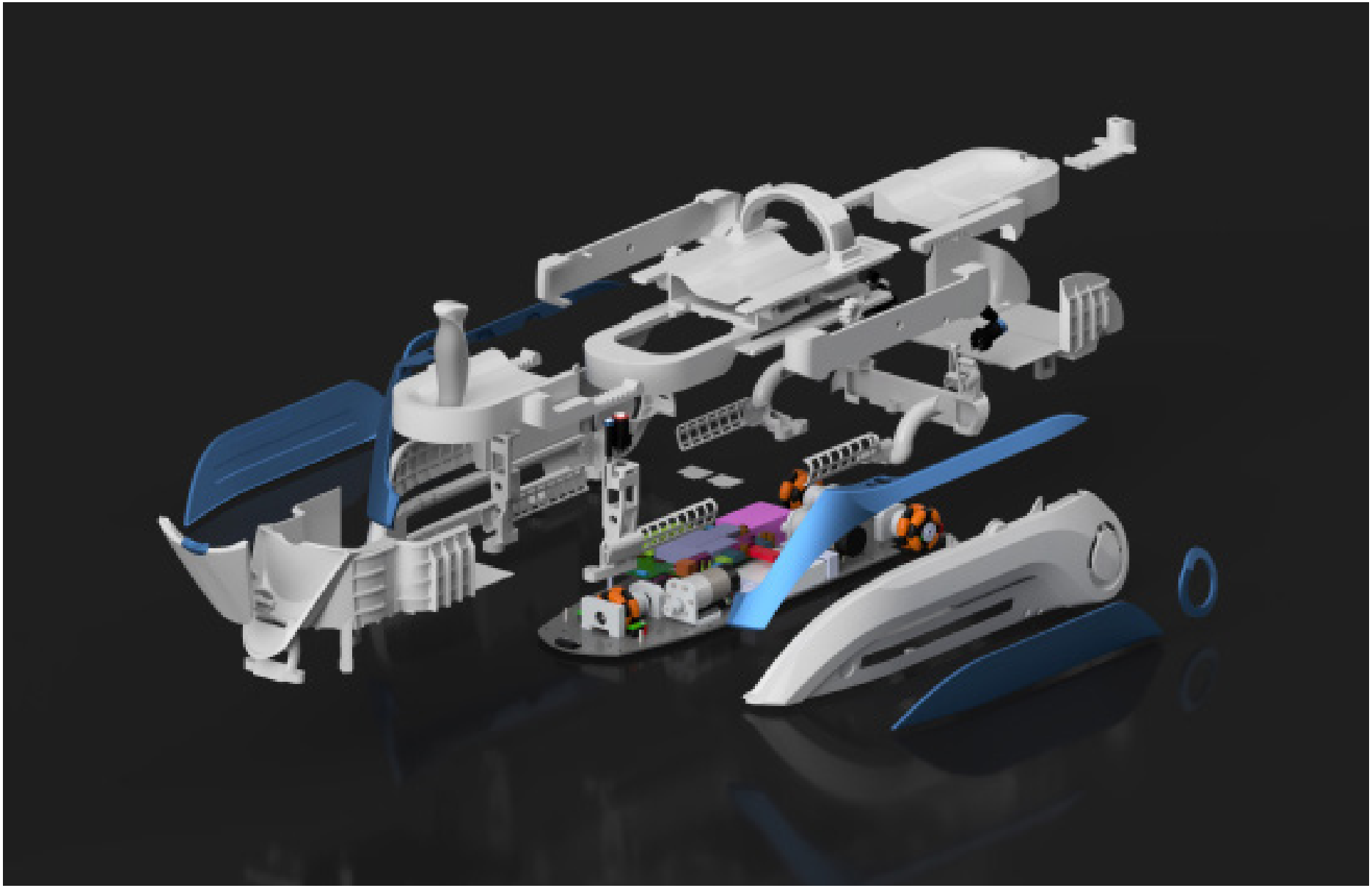


Figure 4.67 (continued).

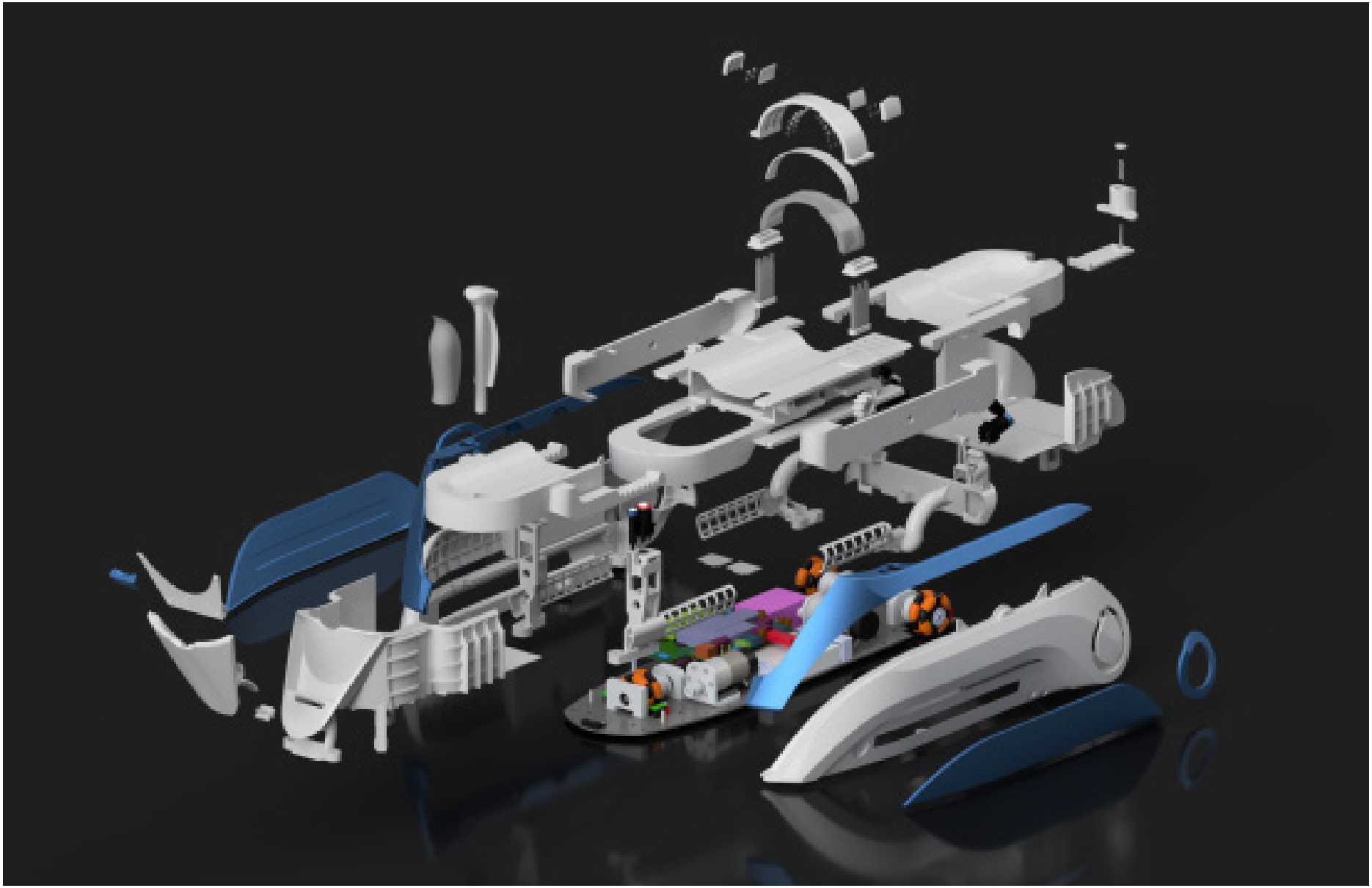


Figure 4.68. Full exploded view of the Mk.4.

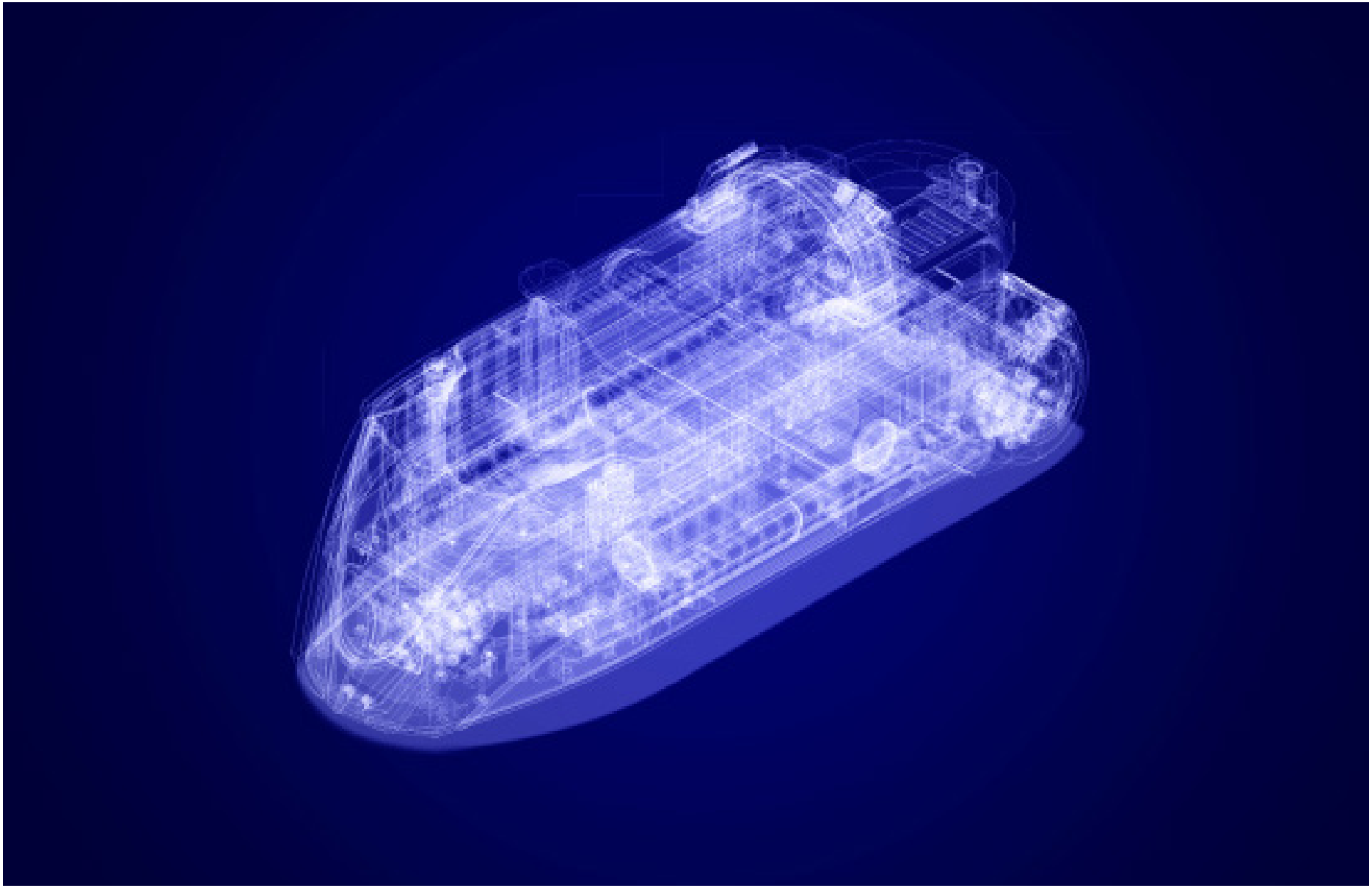


Figure 4.69. Blueprint stylized schematic of the Mk.4.

Tolerance Tool

To prepare for the production of the final prototype, as well as improve the knowledge base for future mass manufacturing, this basic tolerance tool was 3D printed using SLA technology. The function of this tool was to understand how much clearance was needed between moving parts to ensure paint does not chip. The tool was designed to be painted and have parts interlock with escalating clearance intervals of 0.1mm. It was found that a 0.2mm clearance was sufficient between two moving parts. Furthermore, it was found that through-holes required a 0.1mm clearance to avoid being scratched by screws.

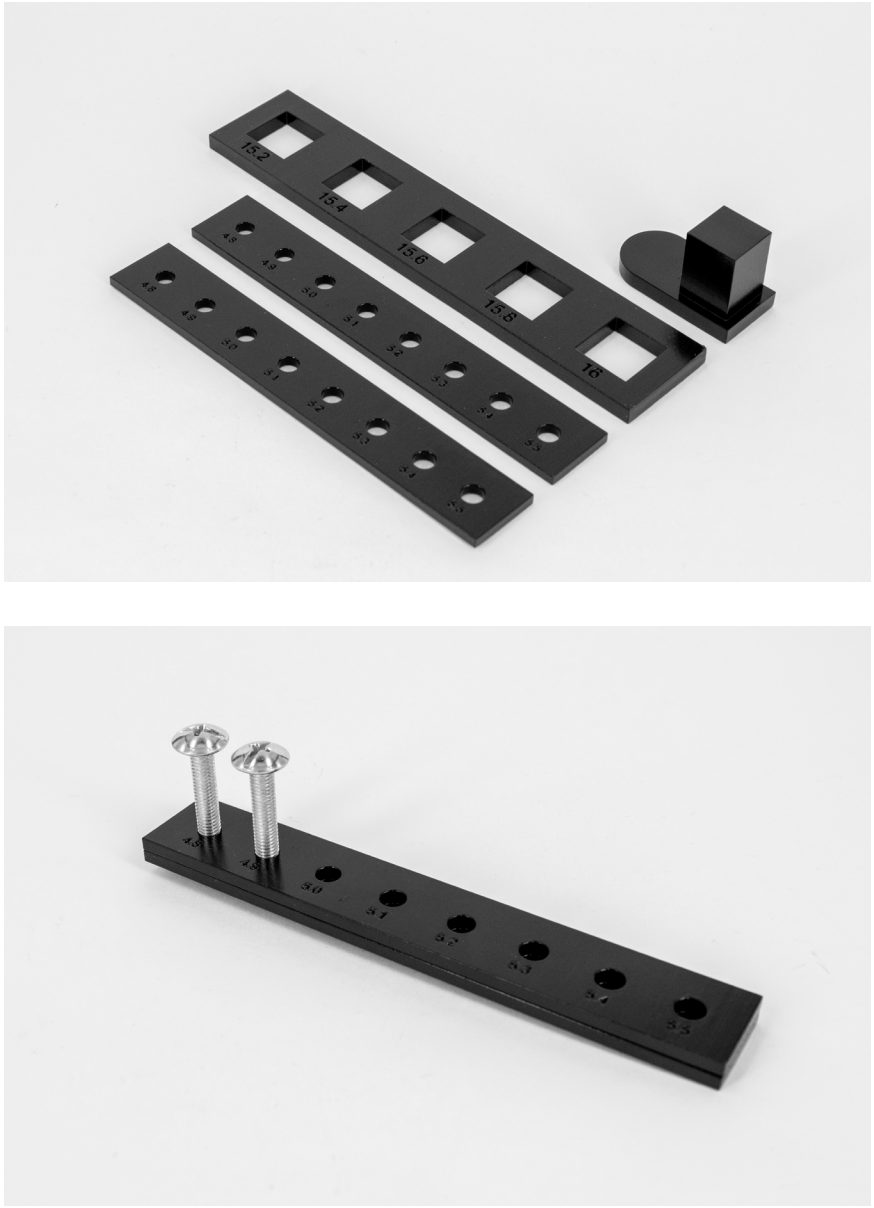


Figure 4.70. SLA tolerance tools.

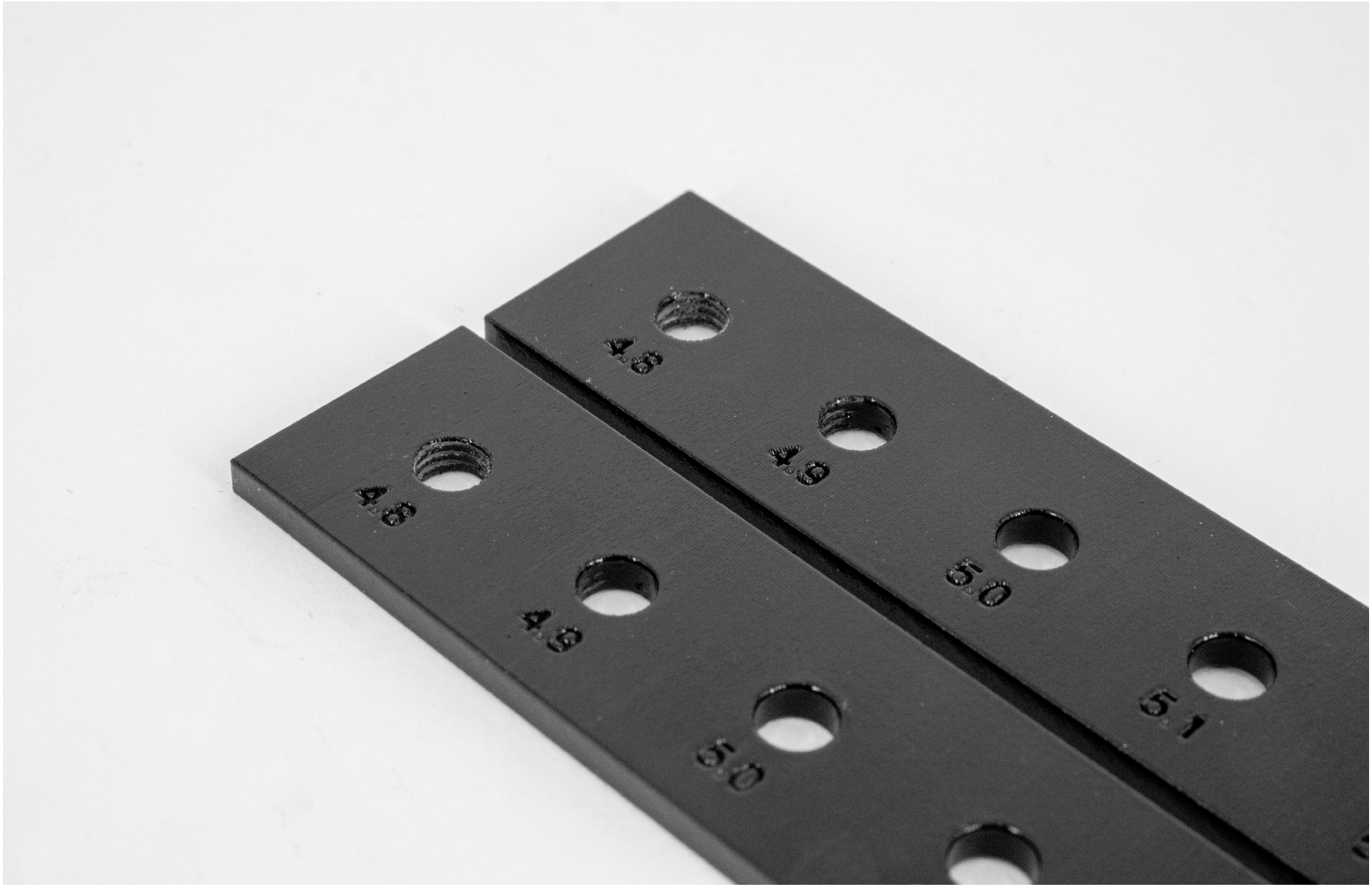


Figure 4.71. Through-hole tolerance tool after m5 screws were passed through.

Final Prototype

The final design was 3D printed using SLA technology. The parts were hand finished with sandpaper and then painted using a mixture of acrylic and enamel-based paints. Textured undercoats were used on the parts with non-gloss finishes, whilst painting masks were used to maintain the clarity of the clear resin in the interface components. Due to manufacturing limitations and some genuine mistakes on our part, some of the design elements were not as refined as originally intended.

Figure 4.72. Final prototype.

Figure 4.73. Final prototype with see-saw tilted.

Figure 4.74. Front of final prototype.

Figure 4.75. Final prototype with tablet holder deployed.

Figure 4.75 (continued).

Figure 4.76. Strapping mechanism of final prototype.

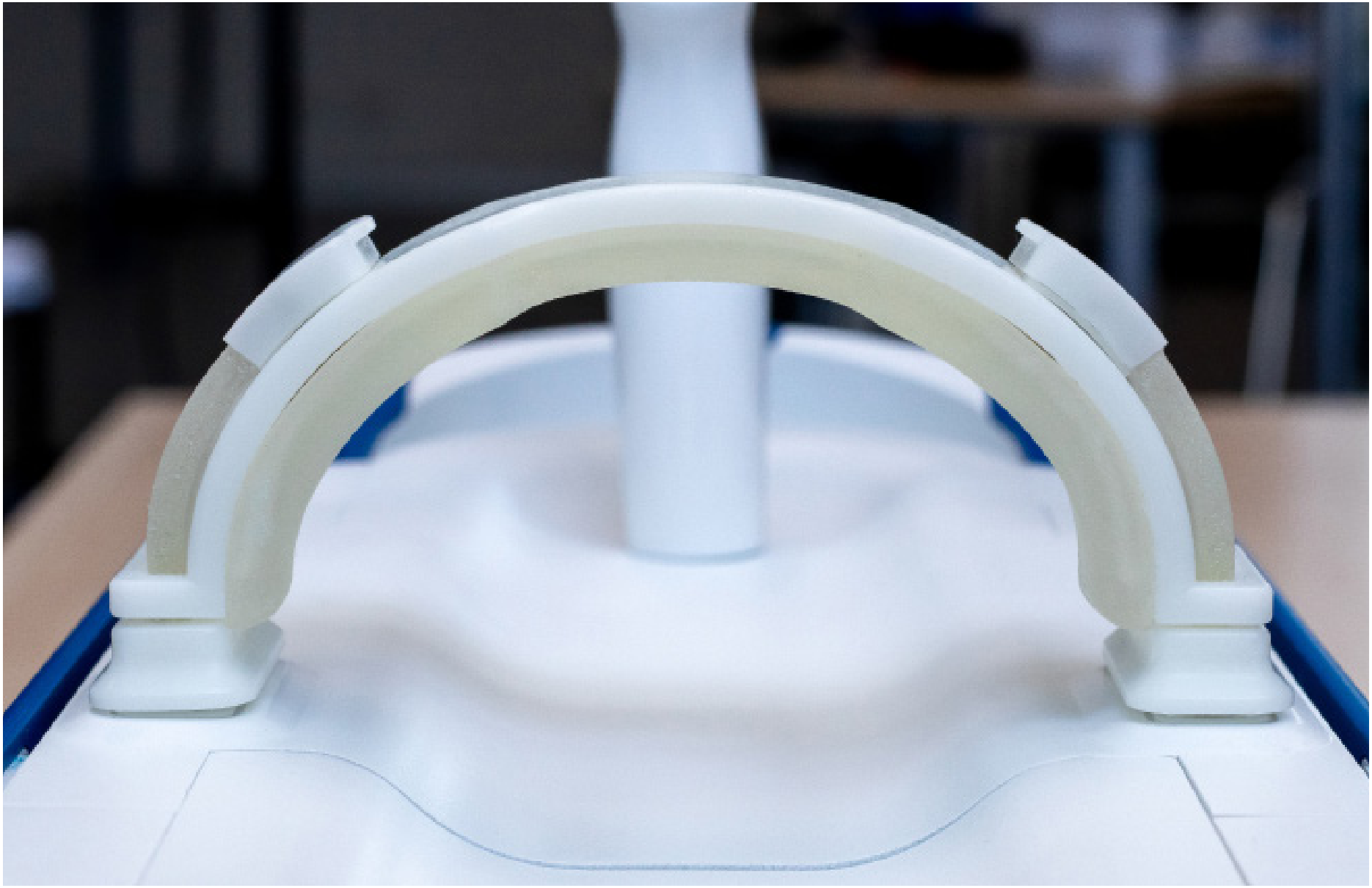


Figure 4.76 (continued).

Figure 4.77. Back interface of final prototype.

Figure 4.78. Final joystick prototype.

Figure 4.79. Final prototype.

Chapter 5:
Testing the Device

Chapter Summary

To achieve **Objective 2c**, a formal assessment of the acceptability of the device before and after design intervention was conducted. This chapter details the testing and assessment process undertaken in this endeavour.

Objective

To evaluate if and how the design interventions detailed in chapter 4 on influenced the acceptability of the Roborover.

Design

A within-subjects descriptive research design was adopted utilizing questionnaires and semi-structured interviews. Ethics approval for the study was received from the New Zealand Ministry of Health's Health and Disability Ethics Committee to test with PWS, the VUW Human Ethics Committee (HEC) to test with experts and clinicians, and locality approval by the Auckland University of Technology Ethics Committee.

Protocol was designed to capitalize on the within-subjects so participants could compare the two devices. This also provided participants a baseline for assessing device acceptability, as previous literature suggested many users do not have a clear impression of robotic devices (Scopelliti et al., 2005). The adoption of a questionnaire allowed a quantitative measure of acceptability to complement the qualitative interview, whilst the semi-structured interview offered greater flexibility in responses to interviewees and facilitated deeper probing of user perspectives.

The Questionnaire

As few studies have investigated how industrial design can influence the acceptability of robotic devices, it was difficult to predict how this study's design interventions would specifically affect acceptability. To test our research, a large questionnaire was implemented to capture a wide scope of data. This questionnaire drew upon multiple measures from different studies. This requisition process aimed to use validated measures where they were most appropriate, to measure determinants of acceptability, rather than acceptability as a whole. The rationale behind this was individual measures excel at assessing their original intended value, such as Brooke's (2006) System Usability Scale at measuring usability, whilst overall acceptability measures in other studies often were too generalized to yield tangible design opportunities. Only measures using Likert scales were included.

The questionnaire comprised of 66-items scored using a 7-point Likert scale. Items were adapted from multiple studies to investigate usability from a clinical perspective (Huang et al., 2013); usability from an end-user perspective (Brooke, 2006); perceived ease of use, usefulness, and enjoyment (Wu et al., 2014); user-experience (Mazzoleni et al., 2014); and stigma (Vaes, 2014). A full questionnaire can be found in appendix 2.

Participants

Six participants were recruited through professional networks.

Participants included three healthcare professionals with at least five years in rehabilitation, including stroke rehabilitation, and three PWS.

Four out of the six participants (67%) were female. No other demographics were collected.

Inclusion and Exclusion Criteria

Participants were included if they were aged 18 years or old, had experienced a stroke within the last 12 months which impacted upper-limb function or were a healthcare professional with five years or more rehabilitation experience, including experience in stroke rehabilitation.

PWS were excluded if that had any pre-existing neurological, neuro-muscular or skeletal conditions affecting joint mobility and control of the upper limb or had a significant cognitive or communicative deficit that in the opinion of the screening physiotherapist would have impacted their ability to participate in the research.

Protocol and Rationale

Participants completed the study during 60-minute testing sessions at Auckland University of Technology's Health and Rehabilitation Research Institute. A neuro-physiotherapist presided over the sessions with PWS to assist in strapping them into the device and ensuring safe testing practice.

Participants were emailed information sheets and consent forms. These were signed and collected prior to the testing sessions. Each session began with participants being informed of the study protocol. Two devices were presented to the participant during data collection, the devices before and after the design intervention described in chapter 4, the mk.1 and mk.4 respectively. The devices were referred to as device 1 and device

2 and presented in a randomised order to reduce bias. To keep conditions consistent between the two devices, only basic functionality that the mk.1 was capable of executing was used.

For each device, the participant was strapped into the device, then the researcher used the tablet software to drive the device in passive mode. This included driving the participant forward and back, and then left and right. Each functionality began on a low speed (20%) and low distance travelled per repetition (10cm) for 5 repetitions. Then speed and distance were increased by 40% and 10cm and another 5 repetitions completed. Finally, 5 repetitions at 100% speed and 30cm distance was undertaken. Participants were then asked to complete the questionnaire based on the experience they had just had. The questionnaire instructed participants with the following:

'The following statements are regarding the robotic device you just used. Please indicate how much you personally agree or disagree with the statement by circling a number between 1-7 (with 1 indicating that you strongly disagree with the statement, and 7 indicating that you strongly agree with the statement)'

After both devices' passive mode and accompanying questionnaires were completed, participants were then given 10 minutes to explore each of the devices further to prompt self-discovery of features and design elements. Participants were then given the opportunity to use the joystick mode on device 2. In joystick mode the researcher activated the device on the tablet and then enabled the participant to take control of the device through the joystick. Participants were informed that the joystick mode was a work in progress, and it engineering shortcomings were responsible for the joystick's poor functionality.

Finally, a 20-minute semi-structured interview was conducted. Questions included items such as:

'What were the main differences you found in your experience between using the two devices?'

'What barriers can you foresee stopping adoption of the device?'

'How would you improve the user experience of the device?'

Prompts were used to encourage participants to further elaborate experiences and opinions. Interviews were audio-recorded and transcribed.

Protocol Amendment

The joystick did not operate properly prior to testing. When pushed, it would occasionally drive in the opposite direction. The original protocol had 5 minutes allocated to passive mode and immediately after, 10 minutes to active mode per device, prior to questionnaires. However, due to this engineering limitation, the joystick mode was rescheduled to after questionnaires, as it was assumed that poor joystick functionality would have lowered user acceptance and cause questionnaire responses to be more reflective of the engineering shortcomings rather than the device's design. The last engineering iteration was very close to the date of testing, and so a fix was not found in time to remedy this. The safety of the joystick mode was approved by clinicians prior to testing.

Data Collection and Analysis

The results of the questionnaires were collated and analysed using descriptive statistical analysis. Items were adjusted so negatively framed statements had their scores inversed and scores became positively correlative with acceptability. Scores were averaged for each device, as well as by subgroups of participants (clinicians and PWS), determinants of acceptability, and individual measures. Scores were then compared between one another to determine differences between devices and participant subgroups.

Audio from interviews were transcribed and iteratively thematically analysed to identify themes within the data (Braun & Clarke, 2006). For the purposes of data representation, illustrative quotes were selected.

Data did not undergo batched statistical analysis due to the small sample size.

Bias

The researcher was also the designer of one of the devices being tested. This had the risk of the designer biasing the responses to obtain the desired results. In order to reduce bias, a neuro-physiotherapist with experience working with PWS led the testing sessions with PWS. Furthermore, the order of which the devices were presented to participants was randomized to reduce bias. The analysis of the data was performed by the researcher and checked by the two supervisors, one a designer and the other a neuro-physiotherapist

with a specialisation in stroke rehabilitation.

Materials

Materials comprised of a printed questionnaire and pen per participant, 1 audio recorder, and the mk.1 and mk.4 devices.

Questionnaire Results

Results of the questionnaire are detailed in table 5.0.

Results from the questionnaire indicated higher scores of acceptability for the mk.4 than mk.1, with respective mean scores of 5.19 and 4.66. This was reflected across all measures and subgroups bar one, with an average increase in acceptability of 13.96% for the mk.4 . PWS found both devices on average more acceptable than clinicians, rating the mk.1 24.82% and mk.4 14.13% more acceptable than clinicians . Clinicians on the other hand, exhibited significantly higher increases in scores between the mk.1 and mk.4 than PWS. This latter trend was most notable on usability measures, where clinicians reported an increase more than four times that of PWS between the two devices, with a 34% increase in the usability scale by Huang et al., (2013), compared to a 7% increase for PWS. Similar results were observed on the measure by Wu et al., (2014), as well as the PAMS measure of consequences, with clinician increases of 15% and 19% respectively, and PWS increases of 3% and 5% respectively.

Items were categorized into acceptability determinants and dimensions as per table 5.1. Since stigma was entirely encompassed by the PAMS, it was not included in table 5.1. Results of acceptability determinants and dimensions are detailed in table 5.2. Trends in acceptability determinants were similar to the overall questionnaire results, with significantly higher increases from clinicians than PWS, and higher overall scores from PWS than clinicians. Clinicians indicated the greatest increases between the mk.1 and mk.4 in dimensions of enjoyment and adaptivity, with increases of 47 and 59% respectively. Overall, acceptability determinants and dimensions increased by 16.5%, with a mean score of 4.29 and 4.94 for the mk.1 and mk.4 respectively. Breaking aforementioned trends, ease of use was witnessed to drop by 1% for PWS between the two devices, despite a 9% increase for clinicians.

Interview Results

Thematic analysis of the interviews identified user consideration, usefulness, gamification, uncertainty, user-experience, and visual semantics as themes. An excerpt of the thematic analysis can be found in appendix 2.

User Consideration

Participants described how they perceived the mk.4 as having undertaken greater levels of user consideration during design and development than the mk.1. This consideration enhanced participant perceptions of usability and engagement when compared to the mk.1, and consequently made the mk.4 more enjoyable to use.

"It's more ergonomic...I enjoyed this one far more [the mk.4]."

Participants outlined positive user considerations of the mk.4 as the device's ability to fit each user comfortably, and facilitate the user's sense of autonomy, relatedness, and competence. When prompted, participants explained that these considerations both facilitated rehabilitation, as well as user motivation. Further questioning around what user considerations are important led to participants detailing how user considerations should be user-sensitive (with respect to subgroups), aware of variation between user subgroups, and adaptable to individual user needs and preferences.

Clinicians and PWS varied significantly on perceptions of preference and practicality. For instance, clinicians held significant reservations about the clinical value of the device's passive mode, whilst PWS perceived it very favourable.

"If you want to use it as a passive motion machine literally, and it think it would be a waste of time."

"When you were operating that was, I was in heaven."

User preferences within the same subgroup also differed notably. Several clinicians commented that professionals in their industry treating PWS in the acute or sub-acute stage would likely find more use in the Roborover than those treating patients who had their last stroke 5 years ago, due to the increased value of repetitive movement on neural plasticity during those stages. PWS also exhibited similar variations, with preferences

between active and passive rehabilitation seemingly dependent on their individual ability post-stroke.

Usefulness

Participants described how their perceptions of device usefulness was defined by the number of use cases they could foresee for the device in question. PWS defined this as how widely and frequently they could use the device, with respect to environment and bystanders (family, friends, etc), whilst clinicians defined this as how applicable the device was in assisting their specific clinical environment.

Between both subgroups, participants explained that the mk.4's see-saw mechanism improved their perceptions of device usefulness, albeit to varying degrees. Both subgroups explained that the see-saw facilitated new movements in the y-axis, increased extension and flexion, and enhanced the organic nature of movements. In particular, participants commented that this made the movements more comfortable for upper-limbs with significant tone.

"I like the tilt of the arm. I find that that was really, really easy, because it just about feels unnatural to do it in that slant, so to have that arm slightly, um, so the hand's higher than the elbow, I found that really made it a lot easier to manoeuvre with that one."

Clinicians reiterated the suitability of the device in question with respect to their specific occupational circumstance strongly influenced their acceptance. Some clinicians found the mk.4 very useful, whilst others did not. The former was identified to be clinicians working in early recovery clinics, whilst the latter worked in later recovery facilities. This judgement of usefulness was described to be an internal evaluation of cost-effectiveness.

"So, if I, however, worked in a clinic where people were in week 1 or 2 of rehab. I might say "yeah the 90% of my clients will use that" so the cost wouldn't matter so much."

PWS all perceived the mk.4 as extremely useful, although their reasoning varied between maintaining mobility and autonomy, to facilitating active recovery.

Gamification

Both user subgroups described how gamification had the potential to increase and sustain engagement of PWS in rehabilitative regimes. Some participants described how gamification could also act as a means to reduce learning barriers, by integrating instructions, goals, and progress within the game itself. One participant expressed how gamification could distract PWS from the fact they were completing rehabilitation, and would allow them to perform exercises for longer without being entirely aware of it.

"Playing a game is usually far more motivational and interesting and makes you work longer than doing an exercise."

Participant responses to games themselves were less positive than the potential games afforded rehabilitation. Gamification was described as being subject to personal preference, with some participants commenting that mainstream video games may be too 'silly' for certain demographics, and that mentally stimulating puzzles such as crosswords and sudoku, may be more preferable.

Uncertainty

Throughout all interviews, participants exhibited uncertainty regarding the technology behind robotic rehabilitative devices. When prompted, participants clarified this uncertainty comprised of a lack of education on technology trends in rehabilitate robotics, affordances offered by technology, and their relative availability. Resultantly, participants exhibited complacence with shortcomings in design functionality. PWS in particular, tended to 'settle' for both devices, and struggled to communicate desired improvements.

"I think it's marvellous, it would suit me fine."

"I don't really know the technology in it."

Similarly, clinicians also exhibited a tendency to 'settle' for sub-par device functionality – describing how they would find different furniture to accommodate for devices that were too small or big for users. When prompted for design improves to remedy this, clinicians frequently stated their unfamiliarity with the technology involved was a barrier to their contribution to design development.

"if there was a short person they could be sat at a lower table"

All user subgroups described relatively uniform uncertainty regarding the technological capabilities between the mk.1 and mk.4, however, participants outlined that they perceived the mk.4 to have incorporated a greater quantity of uncertain technology than the mk.1

User-Experience

Participants described how the device's user-experience extended beyond its rehabilitation function, and that storing the device, setting it up, packing it down, and having it suitably integrated within the environment – both at home and in the clinic – were critical aspects to their acceptance of the device.

"If my wife was involved, she would be putting it away because it um, because it doesn't fit in, ah not being critical of my wife, but doesn't fit in with the décor of the house."

Both user subgroups outlined how they perceived the mk.4 to better integrate within the environment, but that its size made it perceptively harder to transport. Clinicians in particular commented that the device looked clinical and suitable for a clinical environment.

Visual Semantics

Throughout all interviews, participants described the mk.4 as visually more appealing and preferable than the mk.1. Detailed descriptions of the mk.4 included perceptions of being "easy to use" and "simple". Several participants outlined that perceptions of professionalism and refinement in the execution of the mk.4 imparted associations of modernity, which induced a sense of control and trust in the device. Participants went on to detail how this made them feel valued and could potentially facilitate user motivation in the short-term.

"That would excite me more just by looking at it, and I think that would, clients would also look at this...they would think and this would be modern and special."

"Very user friendly...I have this subconscious belief that I could identify that I was controlling the, controlling the movement and the direction."

"I think that the look of something might make the person a bit more trusting in its ability and its functionality."

Both user subgroups outlined how the aesthetic of the mk.4 suggested aspects of the device's functionality. Several participants described how the shape of the joystick on the mk.4 communicated where a user should put their arm, the position of grip, and direction of device travel. One participant commented that it was difficult to separate the aesthetics "from the function and the sound", and that the overall user-experience of the device was reminiscent of vacuuming, but the components visually reminded them of gaming consoles.

Clinicians commented extensively on the materiality of the devices, describing the mk.4 as sterile and easily cleaned when compared to the mk.1, and how this increased feasibility of clinical implementation. This sterile image was elucidated to stem from the smooth white finish of the mk.4, as well as the non-porous nature of the device's finish. Conversely, the unfinished surface of the mk.1 juxtaposed with Velcro was described as unsanitary and untrustworthy.

"And it looks like it would wipe down easy. Do you know what I mean?"

Visual semantics were not entirely positive, however as some participants described how the mk.4 looked bulkier than the mk.1, and were concerned with the weight and safety of the device. Conversely, the mk.1 was described as being too light, and participants expressed that they felt they had less control of the device during usage. Participants also explained how the greater volume of the mk.4 increased their perceptions of how much stigma device use would attract. When prompted, this was elucidated to stem from the anxiety caused by the size of the device and possible safety issues. Participants went on to detail how the safety features implemented in the mk.4, as well as the sleekness of the aesthetic did somewhat palliate these negative perceptions of safety and stigma.

"My concern it's good to have that mechanism where it stops if it goes over the edge it's really important because this device looks quite heavy and I'm very concerned what if it lands on person's lap or on their foot."

One participant commented that increasing the aesthetic appeal of the device, such as making it more refined or "sporty", made it more viable to show to bystanders, such as family members. Conversely, some participants described that they felt no stigma whilst using the device, and expected others to share their mindset.

Participants also commented that the more refined the device looked, the more delicate it was perceived as. Participants described greater concern with damaging the mk.4 than the mk.1, despite little evidence to verify the comparative durability of the two devices. Several participants even went on to describe how they prioritized the device's integrity over their own wellbeing, and that the safety features would 'get in the way' of them trying to prevent damage to the device in an emergency. When clarified, it was explained that device delicateness stemmed from its visual complexity.

"And it's got lots of little bits of it, and that it's feels like I've pushed it too hard, that it might break, and I'm worried by that."

Extensive commentary was made around how the mk.1 was visual unappealing. Participants described the device as functional, but lacklustre, and that a lack of aesthetic refinement suggested poor functionality and a lack of user consideration.

			Usability			Acceptability			Stigma			
		Overall Average	Huang et al., (2013)	Brooke (2006),	Average	Wu et al., (2014)	Mazzoleni et al., (2014),	Average	Vaes (2014) Perception	Vaes (2014) Use	Vaes (2014) Consequence	Average
All Participants	Mk.1	4.62	3.89	4.72	4.30	4.90	4.79	4.84	4.93	4.78	4.59	4.77
	Mk.4	5.15	4.61	5.05	4.83	5.32	5.55	5.43	5.26	5.48	5.07	5.27
	Increase (%)	**12%**	**19%**	7%	12%	9%	**16%**	12%	7%	**15%**	10%	11%
PWS	Mk.1	5.13	4.56	5.00	4.78	5.27	5.43	5.35	5.15	5.22	5.56	5.31
	Mk.4	5.49	4.89	5.13	5.01	5.43	6.19	5.81	5.44	5.96	5.81	5.74
	Increase (%)	**7%**	7%	3%	5%	3%	14%	9%	6%	14%	5%	8%
Clinicians	Mk.1	4.11	3.22	4.43	3.83	4.53	4.14	4.34	4.70	4.33	3.63	4.22
	Mk.4	4.81	4.33	4.97	4.65	5.20	4.90	5.05	5.07	5.00	4.33	4.80
	Increase (%)	**17%**	**34%**	12%	21%	15%	18%	16%	8%	15%	19%	14%

Table 5.0. Questionnaire response means.

	Ease of Use	Usefulness	Enjoyment	Adaptivity	Attitude	Anxiety
Items	4, 5, 6, 7, 8, 9, 10, 14, 15, 16, 17, 18, 19, 20, 22, 25, 26, 27, 28, 29	23, 24, 37	1, 4, 8, 9, 10, 12, 13, 20, 21, 30, 31, 32, 33, 36, 38	3, 4, 11	1, 3, 4, 12, 14, 15, 16, 19, 20, 21, 22, 25, 27, 29, 31, 32, 33, 37	2, 5, 6, 7, 10, 12, 16, 20, 21, 22, 28, 33

Table 5.1. Questionnaire items used to calculate acceptability determinants and dimensions.

		Ease of Use	Usefulness	Enjoyment	Adaptivity	Attitude	Anxiety
All Participants	**Mk.1**	4.79	4.50	3.94	3.39	4.71	4.38
	Mk.4	4.96	5.11	5.16	4.56	5.11	4.76
	Increase (%)	3%	14%	**31%**	**34%**	8%	9%
PWS	**Mk.1**	4.95	5.44	4.67	4.33	4.98	4.58
	Mk.4	4.88	6.11	5.58	5.22	5.14	4.89
	Increase (%)	-1%	12%	20%	21%	3%	7%
Clinicians	**Mk.1**	4.63	3.56	3.22	2.44	4.44	4.17
	Mk.4	5.03	4.11	4.73	3.89	5.07	4.64
	Increase (%)	9%	16%	**47%**	**59%**	14%	11%

Table 5.2. Questionnaire means of acceptability determinants and dimensions.

Chapter 6: Discussion

Discussion of the Questionnaire

Results from the questionnaire suggest the mk.4 was more acceptable to users than the mk.1. The higher scores indicated by PWS than clinicians suggested that PWS are generally more accepting of devices than clinicians. This could be attributed to PWS being less aware of technological capabilities, expectations, and availability of devices than clinicians, and thus are more open to trying devices, whereas clinicians may be less accepting due to pre-existing professional opinions regarding medical technology (Liu et al., 2015; Signal et al., 2019).

The increase of scores between the mk.1 and mk.4 was significantly greater in clinicians than PWS. This suggests clinicians found the design interventions of the mk.4 more impactful on acceptability than the PWS did. In line with findings from our background research, this greater increase can be attributed to how the clinicians may have interpreted the questionnaire items differently to the PWS. Items from measures by Huang et al.,(2013), Wu et al., (2014), and Vaes (2014b) included statements such as "The device is hard to set up", "I think the robot is useful for me today", and "The device conflicts with the cultural values, beliefs, and expectations of stroke rehabilitation". The interpretation of these items would differentiate significantly between clinicians and PWS. The former was likely to construe items from a perspective of clinical implementation - with respect to the logistical nuances of purchasing, deploying, and maintaining a fleet of devices - whilst the latter was likely to perceive the items in terms of personal usage. This suggests that the design interventions applied to the mk.4 increased the device's acceptability to clinicians more than the increase in acceptability to PWS, as interventions were perceived as enhancing clinical viability more than device suitable for individual use.

This is was an unexpected conclusion, as we anticipated improving usability aspects of the device would benefit users experiencing greater difficulty with device use, such as PWS with poor dexterity and motor control.

The overall increase of measures and acceptability determinants – with the exception of ease of use – indicated the industrial design process that yielded the mk.4 was successful in increasing the acceptability of the Roborover. The ease-of-use dimension, whilst having an overall increase of 3% between the mk.1 and the mk.4, exhibited a decrease of 1% for PWS between the two devices. This was inconsistent with later findings from our interviews, suggesting an anomaly in the data, or a shortcoming in the categorization of items into acceptability dimensions.

Implications of these findings suggest industrial design is a suitable strategy for improving

the acceptability of robotic devices for stroke rehabilitation, particularly for appealing to the acceptance of clinicians. These findings illustrate that design improvements are significant in influencing user perceptions of enjoyment, adaptivity, and usefulness, but may not be significant in affecting ease of use. It is acknowledged that inferential conclusions made from such a small sample size are speculative at best, and so these results are merely indicative of possible trends. Future studies are recommended to investigate this further to clarify the specific influence industrial design improvements can have on device acceptability.

Discussion of Themes

These results outlined how user consideration, usefulness, gamification, uncertainty, user-experience, and visual semantics are major themes in the acceptability of a robotic device for upper-limb stroke rehabilitation.

User Consideration

Results from the interviews outline that user consideration enhances perceptions of usability, engagement, and enjoyment. This is in line with previous literature, which outlines usability as a determinant of perceived ease of use, engagement as synonymous with intention to use, and enjoyment as a determinant of overall acceptability (Heerink et al., 2010). The results also suggest design interventions implemented on the mk.4 that aimed to improve usability communicated to users that their needs were considered. This was identified to be both perceptual and experiential, as users commented on both visual and ergonomic improvements. This illustrates industrial design strategies were successful in increasing the acceptability of the device. Furthermore, this identifies that user perceptions of acceptability are influenced not only by visually perceptive dimensions, but experiential aspects as well. This finding was not surprising, as conventionally 'good' products have to both look and feel great during use. Future studies are recommended to investigate this further to properly determine the disposition of this dynamic, and if either visual or experiential dimension takes precedent in influencing user acceptance.

Participant responses around the need for devices to facilitate the user's sense of autonomy, relatedness, and competence, identified a user expectation for rehabilitative devices to facilitate self-moderated rehabilitation. This is in line with previous literature, which outlines a restitution of autonomy is a major dimension of stroke rehabilitation, and a frequent goal of PWS. Autonomy, relatedness, and competence are also fundamental dimensions of the Self-Determination Theory (Deci & Ryan, 2000), which directly influences intrinsic motivation. This suggests that user autonomy, relatedness, and competence may be sub-determinants of perceived enjoyment, and robotic rehabilitative devices should aim to facilitate these in an effort to increase user acceptance.

Identification of variation of user preferences within sub-groups illustrated that distinguishing users into subgroups may not be sufficiently granular when determining user-needs. The significant dissonance between some user responses from within sub-groups illustrates detailed user research and involvement in the design process is necessary. Designers and researchers cannot foresee nuances in sub-groups such as those witnessed in the interview. Instead, allowing end-users to communicate their own variations and preferences prior to the deployment of rehabilitative devices may be the only means to appropriately ensure user needs are catered for. Future studies are recommended to implement methodologies which promote end-user involvement, such as those found in chapter 2.

Usefulness

Our results showed perceived usefulness was defined by number of use cases. This is in line with previous literature, which illustrates perceived usefulness as determined by perceived adaptivity. Our results build upon prior knowledge, by identifying these use cases are dependent on personal circumstance, and mirror the findings of the theme of user consideration. This suggests perceived adaptivity may not be a simple construct regarding the adjustability of the device itself, but rather its breadth of applicability. Despite being classified as the same subgroup, users were found to vary in perceptions of device usefulness and meaningful number of devices use cases. These variations are once again entirely dependent on individual user circumstances, and thus are hard to predict. Furthermore, these variations appear to be dealbreakers in the acceptance of devices, particularly with respect to clinicians. Participant responses elucidate that clinicians who treat later stage PWS are unlikely to ever find use in an armskate. Without fundamentally redesigning the technology, this means under no circumstance can armskates be made acceptable to certain users. Future studies are recommended to investigate the validity of this argument, and if these users' perceptions can be changed.

Outside of this disposition, these results suggest increasing the usability of a rehabilitative device with respect to increasing its ability to be used frequently and in as many places

as possible may be a viable strategy to increasing the perceived usefulness and thus acceptability of the device. This appears to be especially true to PWS, where it is much easier to improve a device's usability on a tabletop than it would be to improve the device's clinical applicability to clinicians. Identifying that user judgements of usefulness are internal evaluations of cost-effectiveness builds on questions posed by previous literature, which outline that a lack of understanding of how users assess the cost-effectiveness of devices is a major barrier to acceptability (Wolff et al., 2014).

Gamification

Results indicated participants viewed gamification as having significant potential benefits for rehabilitation. However, participants also exhibited relatively poor perception of current games available, suggesting current game options are not entirely appropriate for the rehabilitation demographic. This illustrates gamification may simply be viewed as a tool by clinicians and PWS as a way to enhance rehabilitation, and reduce the barriers thereof; and that this tool requires further development before it is palatable to these users. The potential benefits of gamification identified can be classified as increasing usability, and decreasing learning barriers, reiterating that acceptability is a by-product of satisfying user needs.

Whilst gamification is out of the scope of this current study, these results illustrate game design is a significant design opportunity with regards to the acceptability of robotic rehabilitative devices. Participant responses around the implementation of mentally stimulating games such as puzzles, crosswords, and sudoku identifies a potential avenue of exploration for rehabilitation game designers. This finding also reiterates the variation of user preference and how designers must be equipped to tackle this.

Uncertainty

Results from the interview suggest users are poorly educated on robotic rehabilitative devices, and that this lack of education reduces their capacity to effectively evaluate, and contribute to the development of these devices. This is in line with previous literature, which outlines that most users do not have a realistic perception of robotic devices (Scopelliti et al., 2005). The implications of this are that end-users will struggle to determine their needs regarding these devices, compromising the effectiveness of user involvement in the design and development of these devices. This is especially significant with respects to the acceptability of these devices, as users may generate unrealistic criteria, such as those inspired by science fiction (Scopelliti et al., 2005). The observed tendency for end-users to 'settle' for sub-par devices due to a lack of awareness of better opportunities illustrates a barrier to innovation and acceptability.

These results validate the use of empathic design in the design of robotic rehabilitative devices as empirical data struggles to accurately capture user-needs when end users struggle to self-report. Rather, empathic design facilitates the designer to familiarize themselves with the end-user, and deduce user-needs through a combination empathy and design intuition.

With respect to the design of the mk.4, the fact that users perceived it to be just as technologically foreign as the mk.1 outlines that industrial design may have very little effect on perceptions of technology uncertainty. Future studies are recommended to investigate this further to determine alternative strategies to improving user uncertainty.

User-Experience

These results outline that user perceptions of acceptability extend beyond the rehabilitation function of devices. This suggests perceived ease of use and enjoyment are also evaluated by the experience of deployment and environmental suitability of a device. This is in line with previous literature (Davis & Venkatesh, 1996; Heerink et al., 2010), which outlines that facilitating conditions influences acceptability, and further builds upon this by elucidating that facilitating conditions not only involves providing suitable environments and circumstances for rehabilitation, but also ensuring the end-user can easily access those environments and circumstances. The deployment of devices in particular, identifies key implications for researchers, as many robotic rehabilitative devices on the market are large, heavy, and difficult to access (Xie, 2016).

It is known that device abandonment can frequently manifest in being simply left in storage (Cruz et al., 2016). Consequently, developing a lightweight, easy to pack down device may not be a viable solution to barriers of acceptability stemming from device deployment. Future studies are thus recommended to investigate how deployment directly influences acceptability.

Identification of environmental suitability again illustrates the prevalence of varying user preferences in user needs. In particular, discussions around how the device must be suitable for both the home and clinic, so it may be transported between the two interlinks

deployment and aesthetic barriers. Given the findings regarding user preference variation, even within subgroups, it can be speculated that there may be no panacea to every user-experience barrier to acceptability, and instead future studies should investigate user customization as a potential strategy to combat this.

Visual Semantics

Results outlined that the mk.4 exhibited higher levels of perceived ease of use, enjoyment, and usefulness than the mk.1. This suggests the design interventions implemented on the mk.4 were successful in increasing the acceptability of the device. Overwhelming preference for the mk.4 over the mk.1 indicates the magnitude of this increase was significant. This finding validates the ability of industrial design to shape user perceptions and influence acceptability.

Furthermore, results suggest design refinement promotes user perceptions of high functionality and user consideration. Correspondingly, a lack of design refinement is suggested to impart perceptions of poor functionality and lack of user consideration. This influence is speculated to function in one of three ways. This suggests not only is industrial design able to influence acceptability by directly enhancing perceptions of ease of use, enjoyment, and usefulness, the very practice of improving design refinement induces user acceptance. It is speculated that this could be resultant of users categorizing the mk.4 with refined designs, which traditionally have high functionality and extensive user consideration. However, given other findings from this study outline that categorization is influenced by more than just visual cues, this is an unlikely explanation. Consequently, an underlying ability for design refinement to influence acceptability may be present. Future studies are recommended to investigate the influence design refinement has on acceptability to elucidate exactly how this influence functions.

Results also suggest categorization was at least partially successful. With respect to reducing training, barriers participants were able to deduce aspects of device functionality without training. Similarly, categorization with sanitary environments was achieved through the use of a smooth white finish on the mk.4, which increased clinical viability and user perceptions of usability when compared to the mk.1. Inconsistent experiential and visual categorization by participants between vacuuming and gaming respectively illustrates categorization may be dependent on more than visual cues. Much like findings from the theme of user consideration, this suggests communication through design may be a complex process executed through both visual and experiential mediums. Future studies are recommended to investigate this concept further, so that categorization can be better utilized as a design tool for improving device acceptability.

The impact of design interventions made on the mk.4 were found to be somewhat inconclusive regarding stigma. Our findings also suggested stigma is dependent on individuals, as some participants simply did not experience stigma during device use, sparking inconsistencies with previous literature (Skogsrød, 2014; Vaes, 2014b). Furthermore, results suggested perceptions of stigma were reduced through aesthetics and safety features, elucidating that size, function, aesthetics, and stigma are interlinked. Whilst there is some evidence that industrial design strategies could be useful in the reduction of stigma, these irregularities indicate this dynamic of size, function aesthetics, and stigma should be further examined.

Overall, these findings suggest the design interventions implemented through industrial design strategies were successful in increasing the determinants of acceptability, and the overall acceptability of the Roborover. These findings are in line with previous literature, validating measures of acceptability, and further builds upon prior research by identifying that perceptions of acceptability are influenced not only by visual dimensions, but experiential aspects as well. Furthermore, these results suggest user autonomy, relatedness, competence, and motivation may be influencers of acceptability.

Of particular note, it was identified that perceptions of user consideration and usability stemmed from not only visual first impressions, but impressions generated during use of the device, and from facilitating the device, suggesting that acceptability may be a dynamic value, and that an overall well-considered user-experience is required to fully facilitate and maintain it. These findings both validate the effectiveness of industrial design to satisfy user needs, as well as the need for consulting with end-users. Identification of variations between user preferences illustrates the clear and key need for researchers to involve end users, as variations make universal needs difficult to generate in many cases. This need is heightened when considering our findings that detail an absence of user knowledge bases of technology affordances regarding robotic rehabilitative devices.

In terms of industrial design strategies, designing for usability and manipulating visual semantics were found to be the most effective. Usability played a significant role in influencing several facets of acceptability, whilst visual design refinement appeared to increase acceptability overall. Building upon previous literature, it can now be argued that usability influences perceived usefulness and perceived adaptivity, with respect to breadth of applicability. It is inconclusive if categorization played any meaningful role in increasing the acceptability of the mk.4, however some evidence suggests it may

underpin much of the aforementioned. Our findings suggest categorization may be a more dynamic process than previously assumed, as user response indicates it is difficult to separate the aesthetics of the device from the rest of the experience. Future studies are recommended to investigate categorization further to elucidate its role in user perceptions of acceptability.

Several themes identified extend beyond the scope of this study. The gamification and the extended user-experience of the device outside of rehabilitation fall into the realms of game design and UX design respectively. Whilst the entire suite of the Roborover experience should be considered to facilitate the most acceptable device for end-user(s), these areas of design are independent industries in their own right. Respecting the appropriate experts in their own fields is crucial in ensuring every aspect of a design is properly executed. Consequently, this study calls upon further investigation into these fields of study in collaboration with these experts.

Limitations

This study acknowledges several limitations were present throughout its design. Firstly, the sample size of this study was relatively small, quantitative data derived from results are not statistically significant, and inferential analysis was not possible as a result. Secondly, PWS who volunteered for this study are likely to be highly motivated individuals within their demographic, consequently their responses are likely to not be representative of the average PWS. Thirdly, due to recruitment processes, some participants were not entirely unaware of the Roborover project, and resultantly could have been primed to the affordances of the motorized armskate.

Finally, extraneous variables resultant of study limitations must be acknowledged. Due to engineering shortcomings in joystick functionality, protocol amendment resulted in participants answering the questionnaire before being made aware of the full range of use cases of the mk.4. Participants expressed in the subsequent interviews how if they were aware of the joystick feature, they would have responded more positively towards the mk.4 in the questionnaire. Furthermore, some participants were noted to have cognitive impairment due to their stroke. Some commented they experienced difficulty answering positively and negatively framed questions in quick succession, and that some of their responses may not have been entirely representative of their opinion. Similarly, some participants answered the questionnaire in a very polarizing manner, with a majority of responses being either 'strongly agree' or 'strongly disagree', indicating a possible inability to accurately reflect their opinion on a Likert scale. These aforementioned complications may have influenced responses in unforeseen ways. Future studies are recommended to recruit more participants to facilitate statistical significance and inferential analysis, as well as mitigate biases and extraneous variables within the sample group.

Final Design Criteria Assessment

Criteria			Achievement Status	Comments
1.0	Maintain end-user involvement (PWS and clinicians) in design process		Achieved	End-users were consulted throughout the design research process.
2.0	The device must:	Have a detachable handle	Achieved	This feature was integrated in the mk.4.
2.1		Be a portable weight suitable for carry-on luggage (<7kg)	Partially Achieved	The device is approximately 7kg, however many components were overengineered to ensure durability. Future iterations should easily be reduced in weight.
2.2		Be affordably manufacturable	Achieved	Generated during design. The device was assembled relatively successfully, however as it is still a prototype, future design for manufacturing considerations – such as those for injection moulding – should be made to optimize the device's production affordability.
3.0	The device's form must:	Not interfere with device function	Achieved	The form of the mk.4 does not interfere with the device's function, rather it collides less with the user than the mk.1, making it more successful.
3.1		Be stable enough not to tip over	Achieved	The mk.4 does not exhibit tendencies to tip over, however like the mk.1, it can lose traction and skid if pulled very tightly or lifted.
3.2		Be introduced to ergonomic improvements	Achieved	The mk.4 has several ergonomic improvements over the mk.1 that were favourably received by users.
3.3		Be adjustable to fit a majority of users	Achieved	The mk.4 is able to adjust 87mm in length, accommodating 87.5% of forearm lengths. The strapping system was also able to adjust 40mm, accommodating 97.5% of forearm diameters.
3.4		Integrate digital devices	Achieved	The mk.4 can integrate a digital device on its front up to 9mm thick.
4.0	The device's interface must:	Be easily understood	Achieved	User responses indicate the interface of the mk.4 was easily understood.
4.1		Be accessible with respect to a PWS	Achieved	User responses indicate the interface of the mk.4 was easily accessible for PWS.
4.2		Have a battery level indicator	Achieved	These features were integrated in the mk.4.
4.3		Have a bluetooth indicator		
4.4		Have a charging indicator		
4.5		Have a charging port		
4.6		Have a USB port		
4.7		Have 2 easily accessed emergency stops		
5.0	Aesthetically, the device should:	Be suitable for hospital and clinic	Partially Achieved	User responses indicate the mk.4 is suitable for both environments, however customization may yield to even greater acceptance as individual users had unique preferences on aesthetics.
5.1		Be suitable for domestic environment		
5.2		Be desirable and/or prestigious	Partially Achieved	User response indicate the mk.4 appeared 'fancy', 'professional', and 'pretty'. This was successful in increasing user acceptance, and reducing bystander stigma, although the extent to which this was successful is unclear.
5.3		Look effective	Achieved	User responses indicate the mk.4 appeared effective.
5.4		Look easy to use	Achieved	User responses indicate the mk.4 appeared easy to use.
5.5		Comprise of few forms	Possibly Achieved	User responses indicate the mk.4 was not overly cluttered or complex visually. However, users also suggested the increased complexity of the mk.4 compared to the mk.1, albeit little, introduced a perception of fragility, rendering the assessment of this criterion unclear.
5.6		Utilize a succinct colour palette	Achieved	User responses indicate the colour palette of the mk.4 was successful in increasing acceptability. In particular, the white aesthetic increased perceptions of cleanliness and clinical viability.

Table 6.0. Assessment of design against final design criteria.

Criteria			Achievement Status	Comments
6.0	Device usage should:	Be easily learnt and relearnt	Achieved	User responses indicate the mk.4 was relatively easy to learn.
6.1		Require low supervision and not cause harm to the user	Achieved	User response indicate the mk.4 was relatively safe for independent use thanks to safety features and emergency countermeasures.
6.2		Secure the elbow and forearm	Partially Achieved	User response indicates the strapping system was partially successful, however was not tight enough in certain conditions, particularly when used on PWS with significant tone. Ways to increase the tightness of the strap needs to be explored.
6.3		Be hygienic	Achieved	User responses indicate the mk.4 was perceived as very hygienic and clinically viable.
6.4		Not be physically taxing to use	Partially Achieved	User responses indicate the mk.4 was not taxing to use during rehabilitation, however transporting the device might prove difficult and taxing.
6.5		Be quick to set up and pack down		
6.6		Not be uncomfortable	Partially Achieved	Generated during design. User responses indicate the mk.4 was overall quite comfortable, and significantly more comfortable than the mk.1. However, in a few instances, the mk.4 would have benefited from additional design improvements around comfort, such as added cushions, or rounding off edges on moving parts.

Table 6.0 (continued).

Assessment of final design criteria indicates that most criteria were achieved, with shortcomings in weight, strapping, deployment, and visual aspects around user preference. Reflection on these shortcomings identifies that further user consultation and design iteration would likely remedy them, validating the methodology of this study. Overall, this assessment suggests the objective of this study was successfully achieved.

Chapter 7:
Conclusion

This study aimed to investigate how industrial design can address the acceptability of a robotic device for upper-limb stroke rehabilitation. The acceptability of this device was influenced by a number of interlinked determinants including perceived ease of use, usefulness, adaptivity, enjoyment, anxiety, and stigma. The findings of this study showed that by involving end-users (PWS and clinicians) in generating authentic design criteria, and utilizing industrial design to strategically satisfy these criteria, the determinants of device acceptability could be manipulated. In particular, industrial design strategies of increasing usability, manipulating categorization, and enhancing visual semantics were found to be viable design solutions to increasing the determinants of acceptability; although the extent to which these individual strategies were effective is still of question.

The findings of this study build upon previous literature by demonstrating that improving the individual determinants and dimensions of acceptability, overall user acceptance could be enhanced. The implications of this study on the current medical industry are that end-user engagement and meaningful design consultation must be instigated during the design process to ensure end products are acceptable. Furthermore, validating the breakdown of acceptability dimensions as part of a design strategy increases the tools available to designers in the design of medical technology. Based on the findings of this study, designers can now assess what aspects of a design are unacceptable, allowing for refined improvements rather than needing to rely on blanket strategies.

Future studies are recommended to investigate industrial design strategies for healthcare design in greater detail to understand the complex dynamics within them, such as the relationship between device size, aesthetics, and stigma, and the extent to which categorization influences acceptability. Greater understanding of these dynamics could further refine the tools available to designers in their endeavour to develop acceptable medical products such as robotic devices for stroke rehabilitation.

Overall, this study believes that implementing industrial design, and integrating users as part of the design of robotic devices for upper-limb stroke rehabilitation, or any medical technology, should be a universal given. It is evident that generating authentic user needs and designing correspondingly to satisfy them is an effective means of developing successful products, as seen across the world in the commercial sector. Design for healthcare should be no different, especially given that it is a cornerstone of human wellbeing. The meagre results of this current study begin to expose the potential of user-inclusive industrial design for healthcare.

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List of Figures

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Figures made unavailable were redacted for copyright reasons.

List of Tables

All tables made by author.

Appendix 1

Human ethics application approval 0000023011. Automated Email, Do Not Reply

researchmaster-help@vuw.ac.nz <researchmaster-help@vuw.ac.nz>
Thu 11/14/2019 3:05 PM

To: Edgar Rodriguez-Ramirez <edgar.rodriguez-ramirez@vuw.ac.nz>; Brian Robinson <brian.robinson@vuw.ac.nz>; kah.chan@flickelectric.co.nz <kah.chan@flickelectric.co.nz>; Kah Chan <kah.chan@vuw.ac.nz>
Cc: Isobel Cairns <isobel.cairns@vuw.ac.nz>; HEC <hec@vuw.ac.nz>

Dear Edgar,

Thank you for your application for ethical approval (Designing a System for Stroke Rehabilitation, reference 0000023011), which has now been considered by the Standing Committee of the Human Ethics Committee.

Your application is approved as of today. Your approval applies for three years from the date of this email.

If you would like to receive a formal letter please contact the HEC Administrator (ethicsadmin@vuw.ac.nz).

Best wishes with the research.

Judith Loveridge, Convenor
Human Ethics Committee

*****This is an automated email. Do not reply to this email address*******

Queries for the central Human Ethics Committee can be sent to ethicsadmin@vuw.ac.nz

Amendment/extensions to Human Ethics Application approved 0000023011 Vs 1

researchmaster-help@vuw.ac.nz <researchmaster-help@vuw.ac.nz>
Tue 5/19/2020 11:38 AM

To: Edgar Rodriguez-Ramirez <edgar.rodriguez-ramirez@vuw.ac.nz>; brebnescot@myvuw.ac.nz <brebnescot@myvuw.ac.nz>; Dena Fridman <dena.fridman@vuw.ac.nz>; e.henley11@gmail.com <e.henley11@gmail.com>; jessicajsaul@gmail.com <jessicajsaul@gmail.com>; Nick Wellwood <NickWellwood@hotmail.co.nz>; senai.m.lk@gmail.com <senai.m.lk@gmail.com>; Tiger Guo <tiger.guo@vuw.ac.nz>; tomcreagh@outlook.com <tomcreagh@outlook.com>; William Duncan <willduncannz@gmail.com>; yeo.ruifeng@gmail.com <yeo.ruifeng@gmail.com>; Brian Robinson <brian.robinson@vuw.ac.nz>

Kia ora Edgar,

Thank you for your application to amend/extend your human ethics approval.

The amendment/extension is approved as of today. In the case of an amendment, this approval is valid until the end date of your original ethics approval; in the case of an extension, this approval applies until the new end date that you have nominated.

Application ID: 0000023011 Vs 1
Title: Designing a System for Stroke Rehabilitation
Primary investigator: Edgar Rodriguez-Ramirez

If you would like to receive a formal letter, please contact the Research Office. If you need to make further changes to your project, you will need to apply for another amendment to this application.

Best wishes with the research.

Ngā mihi,
the Research Office

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@health.govt.nz

07 January 2020

Dr Edgar Rodriguez
139 Vivian St
Wellington 6011

Dear Dr Rodriguez,

Re:	**Ethics ref:**	**19/NTB/171**
	Study title:	Design requirements and usability of a desk-based robotic device for upper-limb stroke rehabilitation

I am pleased to advise that this application has been ***approved*** by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 7 January 2021.

Participant access to ACC

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Kate O'Connor
Chairperson
Northern B Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
PIS/CF: PIS/CF for usability testing	02	19 December 2019
PIS/CF: PIS/CF for online survey	01	18 September 2019
PIS/CF: PIS/CF for focus groups	02	19 December 2019
Protocol: Focus group schedule	01	18 September 2019
Protocol: Research protocol	02	19 December 2019
Survey/questionnaire: Robotic acceptance survey to be applied online	01	18 September 2019
CV for CI: CV for principal investigator	01	18 September 2019
Covering Letter: Covering letter: Responses to comments	02	19 December 2019
Evidence of scientific review: Evidence of scientific review on template	02	19 September 2019
Application		19 September 2019
PIS/CF: PIS/CF for usability testing, clean file	02	19 December 2019
PIS/CF: PIS/CF for focus group, clean file	02	19 December 2019
Survey/questionnaire: Robotic Acceptability survey to be applied in person, printed	02	19 December 2019
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2022
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018
Ms Susan Sherrard	Lay (consumer/community perspectives)	19/03/2019	19/03/2022
Mrs Jane Wylie	Non-lay (intervention studies)	20/05/2017	20/05/2020

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

http://www.ethics.health.govt.nz

Participant Information Sheet

Study title:	**Designing a Physiotherapeutic Exoskeletal Rehabilitative Device for People with Stroke**		
Locality:	**Auckland**	Ethics committee ref.:	**16/CEN/5**
Lead investigator:	**Brian Robinson**	Contact phone number:	**(04) 463 6155**

You are invited to take part in a study on a device designed for hand, arm, and shoulder rehabilitation in stroke survivors. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 6 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

This study is to develop a device that can be used by people who are recovering from stroke. This device aims to facilitate rehabilitation of the upper limbs, which can be carried out independently by users at home.
We are wanting to know your experience using this device; ranging from how easy it is to use, down to how you think it looks. Our aim is that the device will be easy to use and understand;challenging and rewarding for you in function; and looks appealing enough that you would want one in your home. Similarly, we want to evaluate the effectiveness of the therapeutic aspects behind the device, to ensure a high level of rehabilitation quality.
These devices are developed by a student as a requirement for a Masters degree. This research is funded by the School of Design at Victoria University of Wellington.
Any other questions you have can be answered by Dr. Brian Robinson (463 6155)

This research has been approved by the Health and Disability Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

We asked you to take part in this research because you have had a stroke in the past 12 months and may have limited use of one of your legs or arms.
The research study will take place either at a Stroke Club, rehabilitation unit, or research facility
We will ask some questions about you such as how old you are, your ethnic background, how long ago you had the stroke and how the stroke affects you now.
We will show you a table-mounted arm support device. The device will fully support your forearm and hand, and provide you with a joystick for moving the device; and a small screen to display instructions and accompanying applications. Your upper arm and shoulder will be free to move whilst using the device, however the device is designed to fully support them.
You will be asked to use the device following instructions presented on screen or by the researchers.
You can use this device for as long as you like and can tell us when you want to stop.
We will take a video and photographs of you using this device. This is to make sure that using the controls and the device in ways that will be useful for stroke recovery and not cause harm. Stroke rehabilitation physiotherapists will review these recordings. We will keep the video and photographs securely in the University. Because other researchers will be interested in our research we may show the photographs or a video of you. Your involvement in the study will only be known by the researchers. All photographs and videos will be taken using cameras belonging to the School of Design. The images and videos will be taken off these cameras and immediately after this session and then kept secure in the University computer system."
If we do use photographs or videos of you for presenting our research we will not show any part of you, such as your face, that can tell other people that you have taken part. We will do this by blurring parts of the images and videos
We will ask you for your thoughts on using the device. We will record what you say. If you tell us something useful that we quote, we will not use your name with what you say".
Your participation requires your concentration using the device. We realize that this can be tiring for you so we ask you can tell that you are wanting to rest or to stop the session. You may be invited to take part again if you would like to help us test changes.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

We know that people who have had stroke cannot access stroke rehabilitation therapy regularly. They have to travel to clinics or hospital. We also know that rehabilitation is more effective when it is carried out for several hours throughout day, every day.
This study is to support people who have had a stroke to provide stroke rehabilitation therapy in their home. This can be by themselves or with the help of carer support or family members.
While there is evidence suggesting the device may be useful in stroke rehabilitation, we are wanting to find ways to improve its efficiency, efficacy, and appearance. This research is finding out whether you can use it and what you think of it.
This does not replace any other therapy you may be receiving.
While you are using the device you will be sitting in a chair, by a table. Your forearm and hand will be placed on and supported by the device. The screen will display some instructions and the device will automatically move your arm. After a while, the device will

allow you to move the device freely using the joystick. Your shoulder will stay in the same place, whilst the rest of your arm will be moving on the table. We will want you to stay sitting.

WHO PAYS FOR THE STUDY?

This study is funded by Victoria University of Wellington and the School of Design through medical technology research grants from the Centre of Research Excellence of Medical Technologies.
You will not incur any costs by taking part and we will travel to you, or reimburse you for travel costs.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

WHAT ARE MY RIGHTS?

You are volunteering to take part. You do not have to take part in this study and you can withdraw at anytime.
We can show you the video recording and photographs of you we have collected. We can also give you a copy of what we have recorded you saying to us about using the computer device and game.
It is unlikely that participating will affect your health but if it does, we will contact you immediately.
We will not identify you in any of the students work or presentations of the work.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

After you have taken part and change your mind about being involved, please contact the researcher (the design student) or the lead investigators (Brian Robinson, in the first instance, or Edgar Rodriguez) and any data, information and images associated with your participation will be destroyed.
We will securely store the information and data you have provided for five (5) years and it will then be destroyed.
We can present the findings of this study at stroke clubs within a year of conducting the study.
We can also send you a summary of the student's thesis describing the outcome of the study.
We may also present this study with other similar studies we are conducting at conferences or in books or journals.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Dr Brian Robinson, Senior Lecturer, School of Nursing, Midwifery and Health Practice, Victoria University of Wellington.
Work phone: (04) 934 9321
brian.robinson@vuw.ac.nz

24 Hour contact numbers:
Dr Robinson: 029 776 9321
If you cannot contact Dr Robinson, please contact
Associate Professor Edgar Rodriguez:

If you have other questions, concerns or complaints and wish to contact a Māori support person, you can contact:

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

For Maori health support please contact your health provider and they will refer you to the representative Maori health support group.

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

If you need an INTERPRETER, please tell us.
If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.	Yes ☐	
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.	Yes ☐	
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.	Yes ☐	
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.	Yes ☐	No ☐
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	Yes ☐	
I understand the compensation provisions in case of injury during the study.	Yes ☐	
I know who to contact if I have any questions about the study in general.	Yes ☐	
I understand my responsibilities as a study participant.	Yes ☐	
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by participant:
I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: ChongSheng Guo(Tiger Guo)

Signature: Date:

Appendix 2

Name: _____ Date: _____

Device: Device 1 / Device 2 *(please circle one)*

The following statements are regarding the robotic devices you just used. Please indicate how much you personally agree or disagree with the statement by circling a number between 1-7 (with 1 indicating that you strongly disagree with the statement, and 7 indicating that you strongly agree with the statement).

		STRONGLY DISAGREE						*STRONGLY AGREE*
1.	The device is uninteresting	**1**	**2**	**3**	**4**	**5**	**6**	**7**
2.	The device is easily damaged	**1**	**2**	**3**	**4**	**5**	**6**	**7**
3.	The device is not easily adjustable	**1**	**2**	**3**	**4**	**5**	**6**	**7**
4.	The device does not fit me well	**1**	**2**	**3**	**4**	**5**	**6**	**7**
5.	The device is unstable	**1**	**2**	**3**	**4**	**5**	**6**	**7**
6.	The device is too heavy	**1**	**2**	**3**	**4**	**5**	**6**	**7**
7.	The device is too light	**1**	**2**	**3**	**4**	**5**	**6**	**7**
8.	The device is hard to set up	**1**	**2**	**3**	**4**	**5**	**6**	**7**
9.	The device is hard to put away	**1**	**2**	**3**	**4**	**5**	**6**	**7**
10.	The device easily loosens	**1**	**2**	**3**	**4**	**5**	**6**	**7**
11.	The device lacks difficulty adjustment	**1**	**2**	**3**	**4**	**5**	**6**	**7**
12.	The device felt unhygienic	**1**	**2**	**3**	**4**	**5**	**6**	**7**
13.	I think that I would like to use this device frequently	**1**	**2**	**3**	**4**	**5**	**6**	**7**
14.	I found the device unnecessarily complex	**1**	**2**	**3**	**4**	**5**	**6**	**7**
15.	I thought the device was easy to use	**1**	**2**	**3**	**4**	**5**	**6**	**7**
16.	I think that I would need the support of a technical person to be able to use this device	**1**	**2**	**3**	**4**	**5**	**6**	**7**
17.	I found the various functions in this device were well integrated	**1**	**2**	**3**	**4**	**5**	**6**	**7**
18.	I thought there was too much inconsistency in this device	**1**	**2**	**3**	**4**	**5**	**6**	**7**
19.	I would imagine that most people would learn to use this device very quickly	**1**	**2**	**3**	**4**	**5**	**6**	**7**
20.	I found the device very cumbersome to use	**1**	**2**	**3**	**4**	**5**	**6**	**7**
21.	I felt very confident using the device	**1**	**2**	**3**	**4**	**5**	**6**	**7**
22.	I needed to learn a lot of things before I could get going with this device	**1**	**2**	**3**	**4**	**5**	**6**	**7**
23.	I think the robot is useful for me today	**1**	**2**	**3**	**4**	**5**	**6**	**7**
24.	I think the robot will be useful for me in the future	**1**	**2**	**3**	**4**	**5**	**6**	**7**
25.	I think I will know quickly how to use the robot	**1**	**2**	**3**	**4**	**5**	**6**	**7**
26.	I find the robot easy to use	**1**	**2**	**3**	**4**	**5**	**6**	**7**
27.	I can use the robot without any help	**1**	**2**	**3**	**4**	**5**	**6**	**7**
28.	I can use the robot when there is someone around to help me	**1**	**2**	**3**	**4**	**5**	**6**	**7**

		STRONGLY DISAGREE						*STRONGLY AGREE*
29.	I can use the robot when I have a good manual	**1**	**2**	**3**	**4**	**5**	**6**	**7**
30.	I find the robot enjoyable	**1**	**2**	**3**	**4**	**5**	**6**	**7**
31.	I find the robot fascinating	**1**	**2**	**3**	**4**	**5**	**6**	**7**
32.	I do not find the robot boring	**1**	**2**	**3**	**4**	**5**	**6**	**7**
33.	Did you feel comfortable with the device?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
34.	Do you agree with the statement that you did not experience pain during the use of the device?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
35.	Did you get tired during the use of the device?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
36.	Did you enjoy using the device?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
37.	Do you believe the usage of the device is beneficial for your rehabilitation?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
38.	Would you like to use the device more?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
39.	Would you suggest the device to anyone else who has suffered from stroke?	**1**	**2**	**3**	**4**	**5**	**6**	**7**
40.	The device exhibits features that are discomforting for me	**1**	**2**	**3**	**4**	**5**	**6**	**7**
41.	The device exhibits features that are discomforting for bystanders	**1**	**2**	**3**	**4**	**5**	**6**	**7**
42.	The device violates social or cultural taste	**1**	**2**	**3**	**4**	**5**	**6**	**7**

		STRONGLY DISAGREE						*STRONGLY AGREE*
43.	The appearance of the device stops me performing exercises	**1**	**2**	**3**	**4**	**5**	**6**	**7**
44.	The appearance of the device stops bystanders from obtaining their goals	**1**	**2**	**3**	**4**	**5**	**6**	**7**
45.	The appearance of the device obstructs a culture from obtaining its goals	**1**	**2**	**3**	**4**	**5**	**6**	**7**
46.	The associations elicited by the device are unacceptable	**1**	**2**	**3**	**4**	**5**	**6**	**7**
47.	The associations elicited by the device are unacceptable to bystanders	**1**	**2**	**3**	**4**	**5**	**6**	**7**
48.	The associations elicited by the device will change positively over time	**1**	**2**	**3**	**4**	**5**	**6**	**7**
49.	The device is discomforting or repelling during its use	**1**	**2**	**3**	**4**	**5**	**6**	**7**
50.	The device causes unease or is a threat to others	**1**	**2**	**3**	**4**	**5**	**6**	**7**
51.	The device conflicts with cultural habits, rules or laws	**1**	**2**	**3**	**4**	**5**	**6**	**7**
52.	The device fails its purpose of use, physically, functionally, ergonomically, morally	**1**	**2**	**3**	**4**	**5**	**6**	**7**
53.	The device interferes negatively with the behaviour of bystanders	**1**	**2**	**3**	**4**	**5**	**6**	**7**

		STRONGLY DISAGREE						*STRONGLY AGREE*
54.	The device indicates inappropriate cultural or societal behaviour	**1**	**2**	**3**	**4**	**5**	**6**	**7**
55.	The device causes dissonant experiences during use (unbalances between thinking/feeling and acting)	**1**	**2**	**3**	**4**	**5**	**6**	**7**
56.	The device challenges the tolerance of bystanders	**1**	**2**	**3**	**4**	**5**	**6**	**7**
57.	The introduction of the device still needs to overcome thresholds in view of cultural or social acceptability	**1**	**2**	**3**	**4**	**5**	**6**	**7**
58.	The look and feel of the device conflicts with my personality and lifestyle	**1**	**2**	**3**	**4**	**5**	**6**	**7**
59.	The look and feel of the device conflicts with the attitudes of bystanders	**1**	**2**	**3**	**4**	**5**	**6**	**7**
60.	The look and feel of the device and its user conflicts with cultural preferences	**1**	**2**	**3**	**4**	**5**	**6**	**7**
61.	The device is tolerated purely out of necessity or physical dependency	**1**	**2**	**3**	**4**	**5**	**6**	**7**
62.	The consequences of using the device cause harm to the physical or psychological integrity of bystanders	**1**	**2**	**3**	**4**	**5**	**6**	**7**

		STRONGLY DISAGREE						*STRONGLY AGREE*
63.	The device fails to comply with cultural and society goals and regulations	**1**	**2**	**3**	**4**	**5**	**6**	**7**
64.	The device conflicts with my beliefs and expectations	**1**	**2**	**3**	**4**	**5**	**6**	**7**
65.	The device conflicts with the bystander's beliefs and expectations	**1**	**2**	**3**	**4**	**5**	**6**	**7**
66.	The device conflicts with the cultural values, beliefs, and expectations of stroke rehabilitation	**1**	**2**	**3**	**4**	**5**	**6**	**7**

Thematic Analysis Excerpt			
Quotes	**Codes**	**Code 2**	**Sub-Themes**
• "It's more um ergonomic…more shaped to the arm" • "So that's, so that's quite hard on the elbow…it was a little bit a little bit painful" • "I was pleased um when it stopped" • "underneath – yeh yeh, just with the bone, just where the bone meets the hard surface just a slight cushion" • "I quite like the joystick the shape and the handle of the joystick and it give um a very good grip again"	• Ergonomic improvements • Increased usability • Reduced discomfort • Discomfort barrier to rehabilitation • Material too hard for stroke affected limbs	• Improving ergonomics reduce usability barriers • Materiality of current engineering practice is not optimised for PwS	• User Consideration improves usability and engagement
• "And if someone's got, you know, spasticity in their hand and their stuck on it, or they've got a subluxed shoulder I feel like there is a bit of a safety risk with that if it, if the change in distance feels quite large" • "I think that the speed differences were problematic for me. Medium and hard didn't really feel any different and distance going back and forth from a medium to a high"	• Movement variation not user sensitive • Potential movement hazard	• Lack of human calibration causes potential user risks	
• "But I also think that I, I feel like that I'd also love to see someone using it, and seeing their reaction, and how, how integrated they felt, and how it felt for them to use that device." • "I enjoyed this one far more, than this one here" • "Enjoyability?. Um 7.5, and this one, 2."	• User integration facilitates positive UX • Design intervention improves user experience	• User consideration improves user experience	
• "I'm somebody who's quite short, and I've got quite short arms, and actually the distance from here, was quite problematic for me so I already felt like even where this was placed I felt like I'm already quite forward so…this, this kind of ability to, to change the length of that might, might be relevant" • "With the stroke population we want, we want our participants to release and not the grasp all the time because that is um at times that is increased tone in the hands and fingers and we want the opposite to it so if there is a possibility of changing the the size of it [joystick] over the time" • "When someone else is helping you to get it into position…my skin got caught in this bit"	• Importance of adjustability • Users differ in size and condition • Pinchpoint	• User customization important for function • User customization important for aesthetic preference • User customization important for environmental integration	• User customization improves usability
• "but for an older lady, you may want to have flowers on it…sporting motifs on the side" • [once it matches the environment] "then it would have a fixed place" • "It looks quite clinical? um but for me that's the blue and white thing?"	• Personalization • Custom aesthetic facilitates integration • Default aesthetic is clinical		

Sub-Themes	Themes and Implication
User consideration improves usability and engagement	User Consideration *Increasing user consideration improves device usability and engagement*
User customization improves usability	
User subgroups vary in value attribution	
The device should facilitate a user's sense of autonomy, relatedness, and competence (Self-determination theory)	
Optimization and adjustability of the device's mechanical movement is needed to match medical - rather than engineering - models of movement	
Facilitating multi-dimensional movement improves value and usability of device	Usefulness *Increasing device use cases improves value and usability of device*
Gamification complements rehabilitation engagement, direction, and intensity	Gamification *Gamification of rehabilitation increases utilitarian value for users.*
Data collection should focus on providing inferential value for users.	
Users are uncertain of devices, device opportunities, and lack the education required to gauge device suitability in respect to their needs.	Uncertainty *Users require education on devices.*
Device has an operational and perceptive square footage beyond itself, and can be used in multiple environments: thus, it should be environmentally sensitive and flexible.	User-Experience *Device user experience extends beyond use during rehabilitation*
Setup of the device is a barrier to acceptability that could be reduced through design intervention.	
Visual semantics, such as perceived modernity and aesthetic consideration of the device, strongly influence user acceptance, categorization, perceived usability, and engagement.	Visual Semantics *Strategically improving visual semantics increases device acceptability*
Changing the size of the device influences visual semantics and product-related stigma	
The weight of the device poses a safety risk to users which may be addressed through the strategic design of visual semantics	
The device exhibits product-related stigma, which may be reduced by increased aesthetic consideration with emphasis on the visual semantics regarding safety.	
Succinct and accessible design features are easy to use	
Increasing degree of design refinement also increases certain negative attributions to the device	