Mass Customization in Medical Devices for Quality of Life

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January 21, 2016

Abstract

Healthcare is an inherently risky sector for innovation. In particular, breakthrough innovations pose an even greater risk for investment and potential consequences for the end user. These factors make the healthcare sector inherently risk averse, resulting in medical devices that become outdated.

This research highlights the maker movement as an opportunity to reevaluate how medical devices are perceived, and presents Quality of Life as a factor to focus on in order to encourage breakthrough innovation. By employing tools of the maker movement, and designing a new business model using a lean approach, this research assess new technologies as a way of empowering medical device users to take ownership of their devices.

The final design project for this thesis involves a custom sit-ski, which would disrupt the traditional methods for building and distributing custom sit-skis and athletic wheelchairs.

Preface

My early education was a Bachelor of Commerce degree from the University of Alberta, and I have also been studying as an industrial designer since 2012. Since 2011 my professional interests have gravitated toward the healthcare sector.

I have focused on the areas of: philanthropic design, medical product design, and emotional design. My research centers on three related areas: innovation in healthcare, sustainable business models, and mass customization. Healthcare research focuses on guality of life as an area for optimization, through the economic lens of balancing infinite needs with finite resources. Taking a critical look at how healthcare is deployed has driven much of my research, examining how design thinking can shift traditional practices within the healthcare industry. Business model exploration examines how scalable design can serve as a catalyst for innovation in industries with traditionally high barriers to entry, while critically challenging regulatory policies. My research in mass customization explores tools that can transform medical devices and healthcare services to be tailored to individuals, and encourage the reconciliation between patients' identity and their condition.

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BACKGROUND

Intro

My research explores how I can combine my business and design expertise to make a meaningful impact in medical devices. Specifically, I discuss the current business and economic context for medical devices, how that context impacts innovation, and how shifting that perspective can have a positive impact on breakthrough innovation. Furthermore, my research explores deinstitutionalized medical devices, and how they can be combined with mass-customization to improve users' quality of life.

Many variables influence Quality of Life, but the WHO defines Quality of Life as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment (WHO)."

My goal is to better understand the tools and methods we can use to include user feedback in medical product design, empower consumers to improve their Quality of Life, and shorten the time it takes for innovative ideas to make it into the hands of consumers.

Economics of Healthcare

My interest in this area began while I was studying the economics of healthcare. I learned that Quality of Life was rarely employed in the decision making process within healthcare, often leading to sub-optimal healthcare decisions. I then learned that there are ways that Quality of Life can be integrated to create value for users in healthcare. This has inspired my research to explore ways that entrepreneurial design could benefit healthcare users.

One of the most common tools for assessing the effectiveness and value of a healthcare system is through economics: There is an almost infinite demand on healthcare, wanting it faster and better, and yet only a finite amount of resources to serve our healthcare needs. We therefore must optimize our costs in relation to the benefits. This is not the same as reducing costs; but rather, achieving the greatest value with a given sum of resources.

Healthcare economics uses quantitative data in order to serve decision making. However; one of the problems facing this field is the lack of objective methods for evaluating a treatment's value. Measurement of the number of bed-days, treatment period, and the number of patients seen all provide quantitative data, but fail to consider health in terms of quality of life. The QALY, quality-adjusted life years (NICE), takes into account both length of life and quality of life that are added by a given medical treatment, but evaluating the quality of life is still such a subjective assessment; one that can vary from patient to patient, and often leads to high variability in valuing various medical interventions (Schlander 214).

Quality of life may be difficult to measure, but its value is still an important design consideration. Understanding the factors that contribute to Quality of Life will be useful as I discover where I create the most impact as a designer and entrepreneur.

Quality of Life

There are many ways to improve one's quality of life. The factors that contribute to Quality of Life can also be a subjective measurement, and guite diverse. However, in addition to the WHO's definition for Quality of Life, the University of Toronto breaks Quality of Life into this conceptual framework, which can be useful for designers, see Figure 3.

BELONGING

1. Physical belonging

+ Community

2. Social belonging

· Co-workers

· Employment

· Friends

. Intimate others + Family

3. Community belonging

Adequate income

· Educational programs

Recreational programs

· Workplace/school

· Home

(connections with one's environments)

Neighborhood and community

Health and social services

· Community events and activities

BEING

(who one is)

- 1. Physical being
- Physical health
 - · Personal hygiene + Nutrition
- Exercise
- · Grooming and clothing
- General physical appearance
- 2. Psychological being
- Psychological health and
- adjustment Cognitions
- · Feelings
- · Self-esteem, self-concept and self-
- control
- 3. Spiritual being
 - · Personal values Personal standards of conduct
 - + Spiritual beliefs

BECOMING

(achieving personal goals, hopes, and aspirations)

- 1. Practical becoming Domestic activities
 Paid work

 - School or volunteer activities · Seeing to health or social needs
- 2. Leisure becoming · Activities that promote relaxation and stress reduction
- 3. Growth becoming · Activities that promote the maintenance or improvement of knowledge and skills · Adapting to change

Figure 3 - Quality of Life Factors - University of Toronto

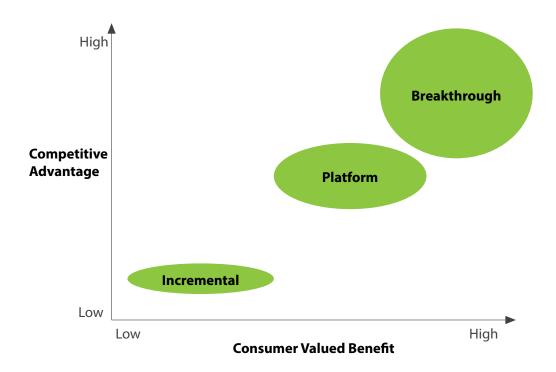
The points outlined by the University of Toronto are factors that can influence Quality of Life, but do not necessarily require healthcare intervention. Many of the factors in this frame work can be influenced by designers, without the need for FDA regulated devices.

In order to test a design intervention's effectiveness on Quality of Life, guestionnaires are commonly used to evaluate the gualitative impact of a design intervention (WHO)(Juniper)(Hootman). Participants will generally be asked to answer a series of questions on a scale of qualitative responses, to which statistical correlations can be applied.

Quality of Life incorporates many gualitative benefits that can be designed for, and explores how the user's satisfaction goes beyond the practical or functional benefits of a product. Designing with this area in mind can be very valuable when designing for disabilities - "a difficulty encountered by an individual in executing a task or action" (WHO).

The University of Toronto's framework highlights a huge opportunity for designers that wish to improve the Quality of Life in relation to medical devices. Additionally, questionnaires serve as a value tool allowing us to assess the effectiveness of design interventions targeting these qualities.

Innovation in Healthcare



Size represents market impact

Figure 1 - Competitive innovation matrix – Accenture

Innovation is a term with many definitions and various levels of risk and reward. One can make the argument that health care is moving forward, but I would argue that progress in this industry is disproportionately unbalanced to bias a conservative form of innovation.

Accenture describes innovations as falling into one of these three categorical definitions (Accenture):

- Incremental innovation Often viewed as the next logical step in a product's development or "a form of maintenance," this type of innovation offers the least amount of consumer valued benefit, and only serves to maintain market share for a company.
- Platform innovation Focused on "superior customer benefits" over competitors, this type of innovation is primarily used to grow market share.
- 3. Breakthrough innovation the largest

advancement of innovation characterized as "market-changing by delivering new benefits" and creates the most consumer valued benefit. "Often use existing technology in novel business models." This level of innovation creates new markets that did not exist before.

Throughout healthcare, we primarily see incremental innovation, but we very rarely see breakthrough innovation, despite the fact that it holds the greatest consumer benefit, and offers companies strong competitive advantages, see Figure 1.

The abundance of incremental innovation is not by accident though. There are many factors that contribute to this lack of innovation, but this counter intuitive choice medical companies are making to invest in incremental innovations can partially be attributed to the health care sector's risk for liability, and the regulatory atmosphere that controls it. From an investment perspective, new ideas may put the company at risk for lawsuit. Management may also see the extensive regulatory process as barriers to the company ever realizing a profit. Furthermore, the lawsuit risks and regulations are expensive hurdles that need to be overcome before you can even test the question 'does our customer actually want the product we are trying to sell them?'

Dixon-Woods explains that there are additional problems with breakthrough innovations in the healthcare context. Breakthrough innovations can be so disruptive, that it can be hard for healthcare professionals to keep pace with new innovations, and still provide quality care. Keeping medical professionals up to date is yet another risk factor to consider (Dixon-Woods). These risks can lead to medical device companies acting conservative in their perspective on innovation, and may lead to advancements that stop short of breakthrough innovation.

These risks are valid concerns, but that does not mean that breakthrough innovations should be passed on completely to settle exclusively on incremental innovations. These risks can be overcome with a thoughtful approach.

Breakthrough innovation in Healthcare

From an investment perspective, understanding risk is still only half of the equation when assessing an investment. The other half of the equation relies upon the return on investment. How much reward is gained from a given level of risk?

Breakthrough innovations not only require risk, they also require time and sizable resources to be locked in for long periods of time. These circumstances demand a large return on investment, as is the economical trade-off for higher risk and longer-term investments. This expectation for a higher rate of return presents problems, as some areas of healthcare just do not economically justify the risk and expense necessary for research and development. See Figure 2.

	Market Cap	Net Profit	
Industry	(\$ Billion)	Margin %	
Drug Manufacturers - Major	72,481	21.6	
Biotechnology	16,685	19,3	
Drug Manufacturers - Other	255	17.6	

High Performers

Low Performers		

	Market Cap	Net Profit	
Industry	(\$ Billion)	Margin %	
Home Health Care	9	-0,5	
Long-Term Care Facilities	47	-2	
Medical Practitioners	3	-11.5	

Figure 2 – Industry Net Profit margin as of Sept 28, 2015

Figure 2 compares some of the largest and smallest healthcare industries (in Market Cap) and also shows those industries' performance (in Net Profit margin). It can be seen that pharmaceuticals and biotech companies are among the largest markets, they are also amongst the most profitable. The lower performing industries suffer not only from thin (or sometimes negative) profit margins, but they also suffer from a low market cap. As a result, the risk of investing in breakthrough innovations in this sector is not worth the investment of resources, since their market does not have enough profit margin to make up for the risk. Even if higher profit margins were available in these sectors, their market size is still relatively small, which limits the room for growth.

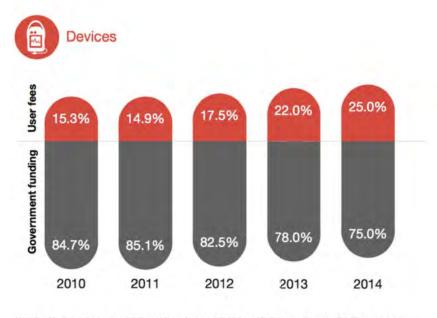
Given this positive relationship between risk and reward, it is

understood in business that if you want to explore novel business ideas you'll need to position yourself in a way that allows for a high rate of return on investment.

Many of the devices that I am interested in designing serve activity limitations, and these devices fall into categories like 'Home Health Care.' These are industries that are typically characterized by low profitability, and low market cap. Therefore, if I am going to start my own business to serve these needs, it is in my best interests to find ways of increasing the profitability in order to compensate for the high level of risk I will be taking.

Participatory design

Though the lean methodology struggles to fit in with the health care sector, there are signs that show the sector may be shifting and revealing new opportunities. One such opportunity is called "participatory medicine," a system where more responsibility falls upon the end consumer (SMP). This new trend may be influenced by a number of factors; one such factor is a recent trend that PwC highlighted, indicating an increase in the fees users are charged for their medical devices, as seen in Figure 4.



Note: Total budget authority appropriations and user fees are collected specifically for the Center for Drug Evaluation and the Center for Devices and Radiological Health at the FDA

Source: Health and Human Services Justification of Estimates for Appropriations Committees

Figure 4 - PwC

In correlation to the increased user fees, PwC found that 49% of consumers said they would pay more for personalized therapies and treatments (PwC), suggesting that some users are comfortable paying more, in return for higher quality. In addition, they also observed patients taking more responsibility for their health care decisions, and using the Internet to evaluate products based on price, side effects and patient testimonials (PwC). PwC's research also emphasizes the need to understand the value in the eyes of the consumer - this perspective will be critical in the future, and health companies will need to learn to utilize user feedback, especially in the early stages of their product development (PwC). This sentiment in method echoes the lean methodology mentioned earlier.

These trends suggest that as patients become increasingly responsible for the cost of their devices, they become more involved in understanding the value their devices are offering, suggesting that there is an opportunity to bring the consumer into the development of medical products and services, and embrace this trend of participatory medicine.

The inclusion of user feedback early in the product development cycle comes with many benefits such as; increased transparency for consumers, faster access to innovative medical products, and also increased product success (PwC). Participatory medicine also complements this practice by testing how the consumers' respond to the additional responsibility, and iterating through designs to find something that compliments the consumer's behavior. Quality of life issues are simultaneously addressed when you include user feedback as well. In the case of athletic wheelchair development, users will be able to directly impact factors that will allow them to participate in activities for recreation - an environmental factor contributing to Quality of Life (WHO). Furthermore; an approach that combines user participation with collaboration would also lead to better informed decisions, encourage more sustainable outcomes, increase the potential for innovation, and improve people's willingness to accept change (Dixon-Woods).

This new trend towards participatory design creates value for the end users in the form of greater transparency, faster access to innovative products, and also greater influence in the final design of the product. Depending on how extensive a designer wishes to apply participatory design, the user may be able to influence some of the final design details of their device by combining participatory design with technologies from the maker movement, discussed next chapter. This approach could enable emotional durability between the user and their device. One of the ways that emotional durability can be formed is by involving the user in the final design of the product. Maker-movement technology could allow the user to tailor the product to their own specific needs and desires, strengthening the user's internal sense of ownership for the device (Chapman).

Background Summary

So far in my research, I have discussed how healthcare economics and the University of Toronto's Quality of Life framework have inspired me to explore ways that I can create value as an entrepreneurial designer. I have also expressed my interest in designing devices that can impact activity limitations, which for the remainder of this paper I will refer to as disabilities.

Due to the high risk level required for breakthrough innovation, and the corresponding return on investment, there is very little breakthrough innovation going on in the healthcare products that I am interested in developing.

The conclusion that I draw from all of these summaries is that it would be best for me, as an entrepreneurial designer, to focus on de-institutionalized medical devices. By this, I am referring to devices not bound to regulatory guidelines, but still in response to disabilities. By focusing on these types of devices, I would be in a better position to serve users with the skills and resources at my disposal.

Furthermore, by focusing on de-institutionalized medical devices, I can increase the user's involvement during the participatory design process, potentially even giving the user control of the final design details of the device - a process which may be enabled by the maker movement.

RAPID PROTOTYPING

The Maker Movement

It has been suggested that product development is at a pivotal point with technology, where democratized production methods have created new opportunities in trans-disciplinary collaboration, and lowered the walls to innovation - this opportunity is called the Maker Movement. The Maker Movement is a subculture of do-ityourself (DIY) 'tinkerers' that often combine the making of physical products and software.

This movement has gained momentum from the advance of affordable rapid prototyping technologies such as 3D printers, and programmable micro controllers like arduinios (Deloitte). The maker can facilitate the Quality of Life devices mentioned in the previous chapter, as the maker products break free from the regulation of healthcare products, and bring in an aura of 'use at your own risk.' Built by a community of trans-disciplinary collaborators, these products can blur the lines of what we call a 'medical device.'

What makes this era of makers different from previous generations of DIY-ers is the "incredible power afforded them by modern technologies and globalized economy, both to connect and learn and as a means of production and distribution" (Deloitte). With this power, makers are now able target incredibly specific niches, or as Chris Anderson calls it the "long tail" (Anderson). The long tail is the sum of demand for niche products, and prior to the Internet, the long tail of demand was impossible to meet with physical stores (Anderson). Now, with the Internet as a distribution system, niche demand has an opportunity to be satisfied.

"The long tail of supply can now meet the long tail of demand, and the long tail of demand itself is changing as individuals change their own consumption... The maker movement is an important manifestation of the economic landscape to come. Companies would be well served to find ways to participate, learn, and perhaps shape the movement." (Deloitte)

Putting the power of production into the hands of consumers changes their patterns for consumption. When you combine this with the maker-culture; a movement that is inherently interdisciplinary and collaborative, the result is a community where new ideas can grow fast and make their way to the consumer in record time. Makers not only produce new ideas, but they also help to satisfy the long-tail of demand that would not have had the economies of scale to be profitable in the past. The maker movement is having a huge impact on consumption, especially for niche products. The technologies of the maker-movement can be valuable in the realm of disability related devices. Not only are they well suited for satisfying the long-tail of supply, but also for democratizing production in such a way that allows users to have very specific control over some of the product's final details. This could result in emotionally durable connections between the user and their device, in addition to satisfying demand for a niche product. Furthermore, these technologies allow for greater market access through digital distribution, allowing for greater accessibility.

Precedent

The maker movement has already led to various trends within health care devices. 3D printed prosthetics are just one of these recent trends that have emerged from this technology. Organizations such as E-nabling the future have been successful in making a global impact with very few resources, but their approach is not perfect. There are many lessons that can be learned from this organization about what to do, and what not to do.

E-Nabling the Future, a non-profit from the US, released the 3D model files for a 3D printed upper-limb prosthetic in 2013 (E-Nable). By making these models available for free Online, E-Nabling the Future has been able to deliver over 1,500 prosthetics in 37 countries. Achieving this breath of impact over such a short period of time is largely the result of the Online community of designers, makers, and volunteers that act as a distribution system. With every 3D printer owner that joins E-Nabling the Future, their distribution system also grows.

What's interesting is that E-nable's products are technologically equivalent to traditional body powered prosthetics that have been around for 100 years (Dorrance). If you were to observe the evolution of body-powered prosthetics over the 100 years prior to E-Nabling the Future, you will see that little has changed from Dorrance's 1913 patent (Figure 5). Products that look almost identical to Dorrance's design are still commonplace amongst upper-limb prosthetic users. E-Nabling the Future's design is no more technologically complex than Dorrance's design, using extension and flexion of a joint to operate, but by introducing 3D printing a substantial growth in the product's evolution rate can be observed.

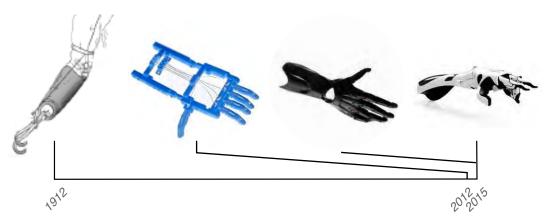


Figure 5 - Product Evolution Time-line

By observing the time line in figure 5, one will observe that most of

the evolution of body powered prosthetics happened over the past 3 years, with the previous 100 years remaining stagnant. Some of these changes have been functional, while others aesthetic. Since E-Nabling the future began in 2013, they have released 10 different body-powered prosthetics, and have spawned an entire community of collaborators and co-designers that have added countless modifications, improvements, accessories, and breadth to the product line. This product evolution has also resulted in the creation of myo-electric 3D printed prosthetics (E-Nable). Some designers have even been inspired to use 3D printing to make their prosthetic in the likeness of an octopus tentacle (Kau). All of these examples illustrate how new technologies can open up opportunities for democratizing production. Additionally, by allowing the user to customize the appearance of their device, their Quality of Life can benefit from a psychological perspective by putting them in control of their disability.

From a cost perspective, 3D printing is as a manufacturing method is well suited for bespoke products like prosthetics. Compared to traditional prosthetics that cost about \$5,500 dollars (Martin), a 3D printed product could be printed and assembled by a consumer for only a few hundred dollars. For example, the myo-electric Exii is only \$300, and most of E-Nabling the Future's body powered prosthetics cost less than \$60 to produce. However, Jon Schull has also expressed concerns about the limitations of E-nabling the Future's business model. At present E-Nabling the Future relies heavily on volunteers, donations, sponsors, and grant funding (Schull), which has presented unique challenges for E-Nabling the Future. This issue of funding is an important consideration for designers offering an open source product in the maker movement space.

Overall, the maker movement and 3D printing have the ability to dramatically change the way that we see medical devices, and open up a wide number of opportunities for de-institutionalized devices. The reduced expense that comes by using 3D printed products make 3D printing and the maker movement very important, and give the maker movement the power to be very disruptive. Additionally, these new areas of de-institutionalized devices have the opportunity to give the user greater control of their disability and outward appearance, both of which contribute to Quality of Life. As such, these are important developments for designers to be aware of. Specifically, it is important for us designers to understand our role and the opportunities within this movement.

Empowerment

Empowerment as mentioned in the previous chapter, is a factor of high importance when considering an audience with disabilities, and deserves special attention. 3D printed medical devices empower the user to take control of their disability's identity, giving users access to the tools necessary to modify and customize their prosthetic to suit their own unique needs and aesthetic desires (3D print)(Scott Summit), see Figure 6.

Figure 6



3D printed hand prosthetic with a tactical mounting system for military amputees

3D printed Prosthetic Fairing for Sports

Both of the examples in Figure 6 illustrate how empowering users can change the conversation we have about these devices. No longer do they need to be seen as 'medical devices,' rather, we can begin to look at these devices through the lens of ability, augmentation, and empowerment. This method of production best compliments Amy Mullen's vision to shift the conversation about prosthetics. It doesn't need to be a conversation about replacing loss anymore, "It can stand as a symbol that the wearer has the power to create whatever they want in that space. People can be architects of their own identities" (Mullens).

By turning people into their own 'identity architects,' several benefits begin to emerge. Firstly, there are many practical benefits, as a product can be designed for a person's exact needs. But more importantly, these products also become more emotionally durable to the user, their emotional connection is strengthened out of the fact that they've designed it, or made it, for themselves (Chapman). This emotional durability can also be continued as some products can be custom designed to mimic their body's own form, or be sculpted to echo their identity (Summit). This trend of making products to a user's specifications, mass customization, is becoming popular across a variety of sectors (Indochino) (NikeID) (Swatch). But, particularly in the case of medical devices, mass customization has the ability to shift the function and aesthetic of designs, giving users unprecedented control of how the world perceives them, and how they perceive themselves. No longer does a user's identity have to be decided for them; rather, the user can decide for themselves.

Allowing consumers to decide the outward aesthetics of prosthetics has become widely popular in recent years, and work like Scott Summit's suggests that this trend will continue to spread over to other medical devices in order to impact Quality of Life. The trends of mass-customization are already being employed on a modular level (Swatch), but we're starting to see other companies evolve mass-customization to be the result of user-driven data (Indochino)(Nike). This level of customization will be an important consideration when envisioning future products and services.

Regulation

Regulation is a concern for any medical product. Some of the products that have truly been innovative in the maker space have been exempt from regulation, while changing only a few qualities of those same products can suddenly make them regulated. New technology is always ahead of regulation, and designers should be cognizant of this when considering innovative designs.

The 3D printed prosthetics released by E-Nabling the Future are not regulated by the FDA. 3D printed prosthetics can exist without regulation for a few reasons: "The prosthetics are body powered, they are giving them away for free, and they are upperlimb prosthetics. If you were to change any of these factors, your business becomes a lot more complicated" (Schull).

E-Nabling the Future's model as a non-profit has served the 3D printed prosthetic industry well by highlighting the potential for this technology, but the fact that 3D printed prosthetics are currently limited to upper-limb prosthetics is problematic, since lower-limb amputations account for 80% of all limb amputations (Dillingham). If this technology is so valuable, it needs to start exploring how 3D printing will navigate the regulatory landscape.

While changing these factors may make it more complicated, I concede that these limitations should not prevent these areas from being explored. The limiting factor here is acquiring further resources, and a sustainable business model to support this exploration.

In summary, the regulatory environment is one to be aware of as a designer, but it is also full of nuance, and is a moving target for new technologies. Designers need to understand how their innovations fit into the regulatory climate, and approach that fit strategically. Viewing my own situation, as an entrepreneurial designer, I recognize that I am not skilled in the areas of fundraising, and regulatory management, and it is becoming clear that the regulatory environment is not the ideal area for me to focus my design efforts. Given that 3D printed prosthetics have demonstrated that designers can impact disabilities and aesthetic factors without having to enter into the regulatory realm, I will instead focus my research efforts on devices outside of regulations, on what I call 'de-institutionalized' devices.

Bringing the Maker to Market

Considering the maker movement is well positioned to serve the long-tail (niche) areas of demand, it is worth exploring ways that the maker movement's technologies and methods can be connected to meet the needs of consumers. Currently, there is a significant gap between the 'Maker' space and general consumers. By combining mass customization with maker tools designers can deliver better products to their users.

There is a large portion of the world that could benefit from the maker movement, but have no interest in the process of 'making.' In order to extend the benefits of the maker-movement to these consumers, a gap needs to be bridged. As Deloitte describes, we need to bring the maker to market (Deloitte).

One of the ways that this can be accomplished is to develop a Mass-Customization process that empowers users. Mass customization, as a tool, is an opportunity for users to be in control of their own device, while operating within predefined design constraints. For users with disabilities, mass-customization could allow them to change their medical device, and align it to their own vision of function and personal identity. In this respect, designers would effectively be curators of an experience, facilitating the design process by which the user can be the "architect of their identity" (Mullens).

Mass-customization often uses web interfaces to interact with the customer, but these interfaces do not need to be elaborate. A mass-customization interface can be achieved by having the user submit various design details into an Online form; dimensions, color, frame configuration, etc. For more elaborate customization elements, I as the designer, can offer my design services at a premium, specifically targeting higher-end clients.

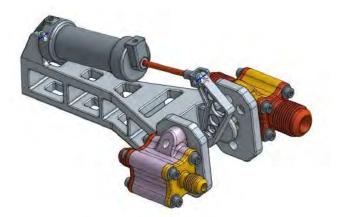
Mass customization is just one of the ways that I as the designer can help bring the maker and the market together. This approach would provide users with the ability to influence the design of their medical devices, allowing for greater empowerment and control over the function and aesthetics of their device. This process can be employed differently at various price points, potentially allowing all users to have at least some control over the customization of their device, regardless of price point.

Parametric Modeling

As mentioned in the previous chapter, my research will be exploring ways that designers can be curators of the design process for medical products, allowing users control over their medical product's design. Part of this curatorial process requires the design of the consumer's buying process, and evaluating tools that might improve that process. Both the process and tools involved in the manufacture of bespoke medical devices need to be adaptive to the user's unique specifications. Parametric modeling is one back-end tool that may streamline these design problems.

Parametric Modeling can be described as a method of 3D modeling that generates a form from a set of input data (parameters). If the parameters for that model change, all of the entities affected by those parameters will respond, and the model will update. Because of the flexibility of these parameters, this method of modeling allows for quick and easy customization. This means that parametric modeling allows the designer to build a 'generic' 3D model, and then adjust it for custom fit depending on the individual user's needs or specifications. This could employ various software programs like SolidWorks or OnShape, which would streamline the design of parts that rely on multiple parameters, and where the relationships may be complex, such as in Figure 7.

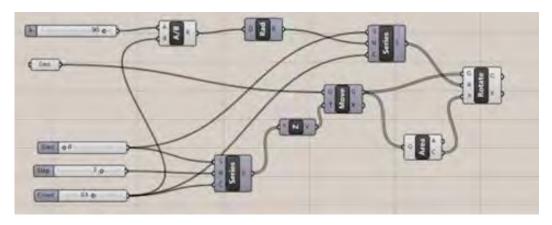
Figure 7



A Parametric Model in OnShape, illustrating a number of interconnected parts working together harmoniously. If a modification is made, the parameters automatically update to ensure that the parts still fit together as designed.

Parametric Modeling can also be used for much more organic models as well. Generative Design works by incorporating algorithms into the parametric method, allowing for the creation of very complex geometry that can fulfill a variety of structural and pattern parameters. However, this method does not give the user very much control over the technical details of the model, and therefore is best suited to macro-level design. Because of this, generative design works well as an iteration tool, but can be limiting as a one-shop-stop modeling tool for mass customization.

Figure 8



Above: Grasshopper Algorithm in lieu of traditional 'modeling.' The data that comes out of this algorithm is output as a 3D model.

Right: The model generated from the algorithm above.

Parametric Modeling and Generative Modeling both have huge potential for designing bespoke medical products since a 'generic' model can be adjusted to suit almost any consumer with just a few parameter changes.

This flexibility in parametric 3D modeling combined with 3D printing is in line with the mass customization business model, and removes much of the labor that would go into design time - making the customization of these products a scalable service.



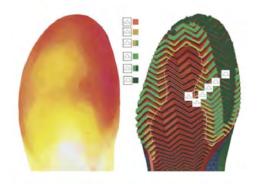
Precedent

Nike has been using participatory design for decades. Collaborating with professional athletes, Nike's been able to improve the design of their athletic equipment for both professional athletes and for everyday consumers. The NikeCourt Flare, a collaboration between Nike and Serena Williams, is one recent example of industry using generative design. For the Flare, Nike used pressure data that was gathered by recording Williams' on court performance. This data was recorded as a pressure map, which was then translated into the durability map (Figure 9) for the outer soul of the shoe.

Furthermore, Nike has also been incorporating 3D printing into their prototyping process, and printing functional prototypes from which to iterate. Shane Kohatsu of Nike explains that "(3D printing) allowed us to test, iterate and create shapes not possible with traditional manufacturing processes, which in turn allowed us to push the limits of innovation faster." (Nike Football)

The Football cleat (Figure 9), was designed using motion capture dots to generate movement data. This data in turn inspired a series of cleat designs that used an iterative process in order to build off of one another. The use of modern technologies, such as 3D printing, motion capture, and parametric modeling allow the designer to respond to the user's feedback, and incorporate important ergonomic data that is unique to the user.

Figure 9



The foot's Pressure – Map influenced the design of the sole's Durability-Map.



Nike Using 3D printing in the prototyping and testing of shoe design

Both of the examples in Figure 9 show how industry is beginning to use parametric modeling and 3D printing to make custom products, and how elite athletes are already demanding a high level of control in the customization of their products. Part of my research will be exploring the advantages and disadvantages of various customization tools in order to promote the scalability.

Rapid Prototyping Conclusion

The maker movement has made the technology necessary for customization much more accessible. Combined with the possibility of digital distribution for physical products, businesses are now in a better position to reach the long-tail of demand.

Organizations like enabling the future are already doing this. They can have a significant impact on Quality of Life, and have succeeded in establishing a global digital distribution system. However, as mentioned earlier, their effectiveness is limited by their not-for-profit business model.

Regulations are typically behind technology, and they are also evolving. I have recognized that I am not an expert in managing regulations, and so I have decided to focus primarily on deinstitutionalized devices.

By focusing on de-institutionalized devices, I can place much more emphasis on applying the user's requests into my designs. I can even include mass-customization, allowing the user to have a high level of influence in the product's functional and aesthetic properties. Mass-customization helps to reinforce QoL factors, and also begins to bridge the gap between the maker and the market. Various levels of customization can be offered at various price brackets.

Parametric modeling can be a valuable tool in facilitating this mass customization, by reducing the time it takes to adjust a 3D model for production.

Companies like Nike are already started using parametric client data to drive the design of their products, and have paired this with rapid-prototyping technology to build one-off final products. Nike's designs illustrate a demand for this level of control at an elite performance level, and also suggest a possible trend for future manufacturing.

PRELIMINARY RESEARCH

Walker Research

One of my earlier Quality of Life research projects included the design of a mobility walker – a purely utilitarian device whose innovation had stalled. Aware of the discussions I mentioned earlier in this paper from Amy Mullens and Scott Summit, I began my design work by including the individual as a component of the design process.

The problem I was trying to solve for that project was not can they use it, but will they use it? The device has to serve practical needs, but there is a level of user empathy and input that are missing from the current product offerings. By addressing this area, my hope was to facilitate a reconciliation between the users' identity and their limited mobility. Users deserve the opportunity to influence how they see themselves in the mirror, and also influence how the world perceives them. Walkers are predominantly perceived negatively by their users, my goal was to change that. After seeing the work being done in 3D printed prosthetic covers and custom prosthetics, I began considering the impact that a redesigned walker may have for their users.

Idea Reception

In the summer of 2014, I had the opportunity to submit an idea at Calgary's Hacking Health competition - For this presentation I decided to present my early thoughts on walker re-design. The problems facing mobility walkers resonated with the audience of marketers, engineers, and medical professionals, and soon I had seven researchers join my team. By the end of the weekend, we had won an award for our walker proposal that was both functionally and aesthetically customizable. Throughout the competition, we had met multiple walker users, their health care professionals, and their loved ones. We understood very clearly that there was a need for work to be done in this space. At this stage; however, the exact 'solution' was still unclear.

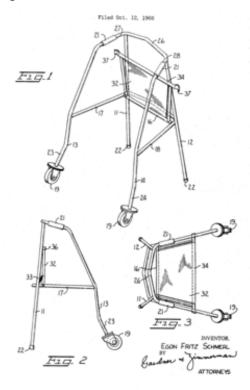
Walkers - the Quantitative & Qualitative Impact

The problems facing walkers are both quantitative and qualitative. Mobility walkers, like so many other medical devices, have seen very few improvements or design changes over the past several decades. This is problematic from a functional perspective, since walkers face several challenges related to weight, ergonomics, and posture. But this outdated product also faces another problem, the heavy stigma that walkers bring with them. When people think of walkers, they think of: old age, disability, slow movement, and helplessness. The device's visual language also speaks to the cold and sterile environment of a hospital. Though these are qualitative metrics, they have quantitative consequences.

Research shows that aesthetics can be responsible for device abandonment (Li, CIHI, Bates), this correlates with 30-50% of users abandoning their mobility device (Bates). Walkers are primarily prescribed to prevent falls, and yet falls are still the leading cause of deaths among older adults (Li). Furthermore, 10% of falls result in serious injury for users 65 years and older. Statistically, seniors already use a disproportionate amount of healthcare services; in fact, they account for 40% of all hospital stays, despite only being 14% of the population (CIHI). Seniors are at the greatest risk of falling, dying or being stuck in a hospital for extended periods, and yet almost half of users still abandon their walking device. These are troubling statistics, and these figures are only expected to grow with the arrival of the aging baby boomers, the "Silver Tsunami" (Shepard).

Economically, this is one of the many justifications for investing in preventative measures, as they cost the system far less than the consequential medical expenses. And yet, the innovations and improvements in rehab medical devices, such as walkers, are incremental at best - as illustrated in Figure 10.

Figure 10





Initial Walker Patent - 1966

Contemporary Walker Design - 2015

Since the earliest walkers of the 1960's until today, almost 50 years later, the design has hardly changed.

Strategy

As mentioned earlier, research showed that aesthetics are responsible for device abandonment (Li, CIHI, Bates), from the beginning, our team made our main priority clear; "we want to do to walkers what fashion did for eye-wear." As the designer, I also needed to be careful not to design a device that "panders" to a specific age group, as this can be insulting and demeaning.

Though the walker needed to be aesthetically pleasing, it also needed to be a proven load-bearing device. We theorized the best way to a make this possible was to make it safe first, and then customizable by the user. We knew that this would be a qualitative hypothesis that would need to be tested. First we wanted to explore a new ergonomic form for the entire walker frame. To keep our hypothesis testing simple, we decided to proceed with evolving the form and ergonomics first, and reserve our 'customization' tests for later.

Ergonomic Design

By exploring the walker design from a utilitarian perspective, and keeping aesthetics in mind, our team was aiming for a walker redesign that would encourage an increase in the adoption rate. Per the recommendations from my supervisor, I began the design of an ergonomic prototype to address the functional problems facing mobility walkers. This was accomplished by building a plywood mock-up of one of my proposed walker concepts - Figure 12.

The ergonomic prototype was designed in order to address three observed problems in walker designs:

- 1. The walker has a large footprint, and often bumps into furniture
- 2. The walker feels unnatural to control
- 3. When users rely on the walker for load bearing, the device encourages a 'hunched' posture, creating a spinal position that leads to back discomfort and a load distribution that travels through the wrists

Figure 11



Ergonomic Prototype - Rendering



Ergonomic Prototype - Plywood

The ergonomic prototype design in Figure 12 addresses three problems:

- 1. Enclosing the user within, rather than sitting in front. This minimizes the combined footprint of the user and walker.
- 2. This 'enclosed' design also allows the device to pivot with the user as they rotate, making for more intuitive control.
- 3. The arm rests are raised to sit at forearm height, allowing the user to apply their body weight through their elbows and forearms, encouraging an upright posture and neutral spine position. This configuration also removes the wrists from the force transfer, as most of the load is transferred through the elbows and forearms.

Aesthetics

At this stage, the aesthetic considerations were to avoid the 'aesthetics of disability' as much as possible. We were exploring new materials and production methods that would make sense for the product's structural and functional requirements. Visually, we wanted the device to compliment the individual, and avoid boxing them in. Our design was aiming for the user to be 'wearing' the device as much as possible. By breaking free from the original form of the device, we believe that we were at least partially successful in moving toward the goal of a Quality of Life focused mobility device that was considerate of aesthetics. However, we began to run into concerns about the viability of a product like this becoming commercially successful.

The Concerns

Taking this product further ran into various hurdles, including regulatory, funding and social perception (on behalf of both the users and the public). I showed my design to a professional in Rehab Medicine and Occupational Therapy, and their comments were encouraging. However, we still faced several challenges moving forward. There was some uncertainty about the regulatory process for FDA approval. Officially, a walker manufacturer just has to be registered through the FDA, but some professionals were concerned that the walker would have to pass through a thorough testing regime. Class 1 devices only need to be FDA registered if they are viewed as "substantially equivalent" (FDA).

It was also becoming clear that this product would require significant capital for manufacturing. Though the number of people expected to live past 85 is expected to increase four fold by 2050 (Shepard), we have to keep in mind that this is a product that historically does not have very generous profit margins. This is also a product that people typically do not want. The social stigma is a very real challenge, and one that is not easily reversed. Not only would we be shaping the internal feelings users have toward the device, we would also need to influence some of the external opinions the public have of walkers, and of the people who use them. Changing society's opinion of walkers and aging is a social problem outside of my scope of expertise. Even though I still believe that there is a need for a new mobility walker to address various practical and aesthetic problems, given my limited resources and skill set, I believe that other projects would be more achievable at this time.

Lessons Learned

Business

The need for a scalable product.

After several months of working with a team to develop the mobility walker, we came to the realization that we did not have a strategic advantage to address the concerns facing this product. We were working with products that require lots of resources and large amounts of capital funding in order to build. And yet, we were still working within a market traditionally faced with thin profit margins, and high regulations. We needed a new product that would allow us to innovate outside of the regulatory atmosphere, and present more opportunities for us to pivot and grow our business.

Consider the resources at my own disposal, now and in the future

The most significant resources we were lacking were those necessary for manufacturing the product. This made it a challenge to build Minimum Viable Products (MVP), and test hypotheses. This lack of equipment is also a strategic short-fall. Our team needed to step back, and understand that our value was not in manufacturing the device, but in our design focused skill-set.

Explore new ways that physical products can be tested as lean as possible.

If our team was going to focus on disabilities related to activity limitations, then the lack of a MVP highlighted an opportunity to explore new rapid prototyped structures. New technologies needed to be explored to identify the most efficient means for building a MVP for activity limitations.

Quality of Life is important, and often neglected.

Anecdotally speaking, many of the users and Occupational Therapists we contacted about our proposal were very excited about the product that we were designing. Nobody would agree about a given aesthetic, or ergonomic position, but every single person we talked to agreed that the current product offering was sub-optimal. It is important to help users to reconcile their disability with their identity. This involves addressing the aesthetics of the device in such a way that the user can choose how it speaks to the world, and how it speaks to themselves. These aesthetic considerations can have a significant ripple effect in the realms of Independence Levels, Psychological Health, Social Relationships, and their Environment. According to the WHO, these are all factors that contribute to Quality of Life (WHO).

There is an opportunity for non-institutionalized devices.

Again, anecdotally speaking, the impact of 3D printed prosthetics has suggested that there are potential gains to be made by designing bespoke prosthetics, or disability devices. By focusing on the de-institutionalized realm, users can have greater control over the identity of their device, and potentially, over other Quality of Life factors that would benefit from improved aesthetics.

Framework

Following research, I have developed this frame work of concepts which allow me to focus my attention on the value I am creating for users as a designer and entrepreneur.

Quality of Life Products

Quality of Life can be defined as "an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept affected in a complex way by the person's physical health, psychological state, personal beliefs, social relationships and their relationship to salient features of their environment" (WHO). I as a designer am in a valuable position to address these factors.

Makers as Participants

The tools of the Maker Movement will be valuable when factoring QoL design factors into disability devices. But designers will need to explore how we will bring the flexibility offered by these tools to the average consumer.

Users as designers

With Maker Movement tools, users can now be in control of the QoL factors that are built into disability devices. However; as mentioned in the previous paragraph, designers will need to explore how we will bring the flexibility offered by these tools to the average consumer.

Designers as Facilitators

Deloitte highlighted the opportunity that exists for bringing the Maker to Market (Deloitte). The maker movement has the potential to make mass-customization feasible; however, it will still require designers middle-men, to facilitate this process. We as designers are part of the force that will decide what future buying processes will look like.

Design

Know what pain point /problem you are trying to solve for your consumer.

While working on our mobility walker, we became very distracted with the infinite number of directions a product like this could go into the future. We also had a rudimentary understanding of the problem we were solving. If we had been more focused on the principle pain point, we would have been much more streamlined.

Does your consumer know that this is a problem?

Convincing your customer they have a problem can be an uphill battle. The same can be said for convincing your customer that there is nuance to their problem. Our hypothesis was that, in addition to ergonomics, aesthetics were a problem facing mobility walker abandonment. Anecdotally speaking, many users said that their mobility walker was terrible, but they could not say for sure if improve aesthetics would result in greater walker use.

Architect for their own identity

Putting people in control of their own device's design helps to empower them. The user can be in charge of how their device speaks to them, and to themselves.

Focus the discussion on "feeling empowered," not about "feeling less disabled" (Chin).

Designing devices they want to use, like athletic wheelchairs, results in more user feedback than designing devices the user does not want to use, like mobility walkers. As a designer trying to change the status quo, I should focus first on products people actually want.

Pillars to design

From the lessons I learned above, I've compiled these pillars of design for myself. These pillars, inspired by Eloy van Hal, may evolve over time, but can serve me as a micro-manifesto of what I believe in as a designer.

- 1. User driven input (the user needs to have a say in the product's design)
- 2. Lifestyle (Everyone leads a different lifestyle, design should be considerate of this)
- 3. Life's pleasures (should enhance the little things we take for granted)
- 4. Health (physical & emotional)
- 5. Safety (not a hazard)
- 6. Business Plan(a pathway to market)

Summary of Previous Research

So far in this report, I have discussed various topics that could impact the way that we view medical devices in the future. Not all of these topics will be applicable to the same extent in every scenario; however, for designers they will be important considerations as new technology redefines medical devices.

Mass Customization will evolve beyond the selection of premanufactured modules that merely need to be assembled together. Rather, users will be able to select from particular aesthetics and functions and have an entire device built to suit their functional and emotional needs.

Innovation in Healthcare is very important; and yet the nature of the industry makes it averse to embracing new ideas. Not only are new ideas economically valuable, they are valuable to the people whose lives are impacted by innovation. While there are many clinical pursuits of innovation to improve health care, those pursuits are often incremental. Breakthrough innovations are inherently risky, and must overcome a costly and time-consuming regulatory process. However, there is an apparent opportunity to emphasize innovation outside of a clinical setting, by focusing on Quality of Life (QoL). Innovations improving QoL would be lower cost, and more affective as they would be able to reach the market faster, and result in more breakthrough innovations.

The Maker Movement is the term used to describe the combined collaborative communities of 'makers' and their ability to produce products with 3D printers, microcontollers, CNC machines, and laser cutters. This movement is particularly well suited for targeting niche products, and empowering consumers.

The Lean approach is a business model prototyping strategy whereby you test your consumer hypotheses as quickly as possible. The approach involves making a rough prototype, and giving it to your consumer to assess whether they behaved as you expected them to. The goal is to get your consumer to test your idea as quickly, and cost-efficiently as possible, in order to create validated learning.

Overall, I believe that these topics all compliment each other. By taking a mass customization approach, we can innovate in healthcare by using tools and communities from the maker movement. These tools allow for the opportunity to use the lean approach for medical innovation, and also improve patient's quality of life. Not all of these topics will always be applicable for every medical design scenario; but, it is important for designers to be considerate of the opportunities within these new technologies, and how they might apply to medical device design.

NEW ENTREPRENEURIAL DIRECTION

Nordic Sit Skis

My next project came after I was exposed to some of the more subtle issues in wheelchair design, and how those issues challenged wheelchair users on a regular basis.

Wheelchairs need to properly fit their user in order to reduce the likelihood of chronic muscle and joint pain. However, there are many variables that go into building a custom wheelchair, such as; numerous measurements, expensive / challenging materials for construction, and costly fabrication just to name a few. Many of the processes and methods used date back over half a century, and do not take advantage of new technology. As a result, most wheelchairs, though simple, can still be relatively expensive. As these antiquated approaches for manufacturing are not ideal for custom or one-off products, it is not surprising to see a wheelchair cost more than \$5,000.

This high cost can be very problematic for a variety of reasons; but the main problem facing users is that despite the expensive cost of a custom wheelchair, a user might still end up with a wheelchair that does not fit them properly. If a user finds that their chair does not suite them, their options to resolve this issue are extremely limited - Manufacturers do not warranty their products for fit, the construction of the frames do not promote modification, and the cost is too prohibitive to order a replacement. As a result, users are forced to use a device that can cause them chronic pain, and may result in them no longer able to use a manual wheelchair – both of which are health issues, but are also Quality of Life issues.

The purpose of my research is to explore how new technology might improve the wheelchair buying process for users, so that they are less likely to be stuck with a wheelchair that is leading to chronic pain, resulting in permanent damage.

Wheelchair fit

The ergonomic issue of wheelchair fit is an important concern for daily wheelchair users because the user's arms are replacing the function of their legs. Because of this, efficient ergonomics are important to ensure that chronic pain does not result. There are many factors that go into wheelchair ergonomics, and efficiency, hence the need for wheelchairs that are customized for their users. Not all of the factors that impact the ergonomics are related to the wheelchair's design, but it is important for a designer to be aware of how important ergonomic factors and design relate to one another.

Legs handle a lot of repetitive force, and as a result, the hip joint is designed to be sturdy, with large muscles, and have a relatively low range of movement. Conversely, the shoulder joint is designed for a high range of movement, and as a result the joint is not nearly as sturdy, the muscles are smaller. The shoulder is simply not designed for the large repetitive forces of locomotion, but that is the task they need to take over for wheelchair users. Long-term use leads to high risk of upper extremity injury, between 42% (Curtis) and 73% (Dalyan) of patients report pain in their shoulders. Therefore, it is important to ensure that the ergonomics of the wheelchair are as efficient as possible, in order to reduce the likelihood of chronic pain developing.

Some of the main design variables that impact the ergonomic efficiency of a wheelchair include; structure (Boninger 2000), interaction / kinematics (Guo), and propulsion method (Boninger 2002).

Figure 12 - Wheelchair Axel Relation to Shoulder

o push angle • push angle • frequency • rate of rise of F • push angle • push angle

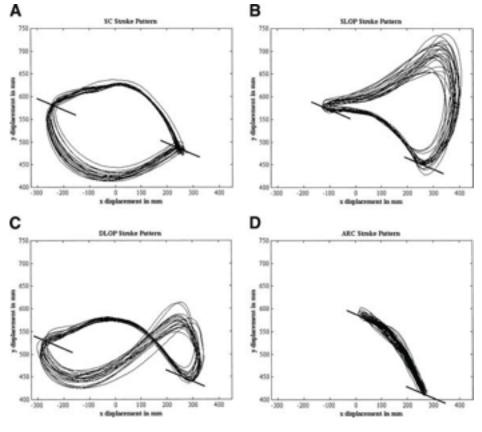
Figure 13

Structure is very important, as you change the shoulder's position relative to the axle of the wheelchair, you can impact efficiency (Boninger 2000).

The shoulder generates the majority of force during wheelchair propulsion, as seen in figure 14 (Lan-Yuen).

It is important for designers to be aware that the method of propulsion can also have an impact on wheelchair efficiency (Boninger 2002).





Newtons of Force Required (N)

- Single-Loop Over 60.5
- Double-Loop Over 70.8
- Semi-Circular Loop 86.2
- Arcing 68.7 (Boninger 2002)

Ergonomic efficiency can be impacted by the frame structure, kinematics, and propulsion method. The wheelchair frame is the focus of this research, but it is important for the designer to take into account an understanding of how all of these variables connect together.

Wheelchair Assessment & Fitting

Currently there appears to be multiple standardized methods, depending on the organization, for measuring users for custom fit wheelchairs. None of these methods take into account the user actually testing the product out in person, and all are very rudimentary from a data-driven design perspective - sometimes classifying certain dimensions into a range, rather than one precise value. The Alberta Aids to Daily Living (AADL) Wheelchair Assessment Tool (Alberta Health), and the WCB's Wheelchair Assessment Tool (WCB) measure the following variables for fitting a wheelchair:

- Seat width
- Seat depth
- Armrest height
- Seat height
- Footrest length
- Back height
- Hip, Knee and Ankle angles
- Overall width

TiLite, a higher-end custom wheelchair manufacturer boasts about a trademarked process called "TiFit," where "every frame is made to measure" (Ti-Lite, Ti-Lite Product), but their process does not use any different measurements from AADL or WCB; in fact, Ti-Lite's order form breaks measurements up into 'ranges', not specific numbers (Ti-Lite, Order Forms). Currently, there is no single standardized method for measuring wheelchairs, but most processes tend to rely on the same eight variables. These measurements provide valuable data to inform a design direction; however, they still are incomplete. Even though there are eight variables, it would appear that despite precise manufacturing methods, manufacturers still cannot guarantee a perfect fit with measurements and engineering alone. Instead, I believe that we need to assess other method for getting the perfect fit.

After conducting a focus group, it seems that trial-and-error seems to be the preferred method for assessing fit. Though this route lacks a degree of elegance, most injuries are the result of highcadence, repetitive movements, therefore physically testing the product is the only way to confirm whether the device is compatible with the user for long-term use.

I also believe there may be a complimentary opportunity for datadriven design. Later in my research I explore 3D printed seat/ bucket methods, and how the seat can be more adaptive to a specific user's anatomy.

Manufacturing Method

The wheelchair fitting process also needs to be viewed from a manufacturing perspective. Current production methods are expensive, and therefore not well suited for a wheelchair fitting procedure that relies on trial-and-error.

In order to produce wheelchairs that are both strong and lightweight, they are often built from aluminum or titanium tubing. The most sophisticated of manufacturers use CNC tube cutting and bending machines to ensure a proper fit, but still require highly skilled labor to weld this metal, which is inherently costly and difficult to work with (Ti-Lite, Overview).

In my research, I will assess whether other materials and production methods would be better suited for this trial-and-error approach, and propose a new buying process for wheelchair users to get a custom chair.

Problem Resolution

In order to address the aforementioned problems, I have decided to pursue the lean approach to design, and focus on a product whose design considerations parallel wheelchairs, sit-skis. This method is less risky than developing wheelchairs exclusively, and can allow for a diversified revenue portfolio.

Nordic sit-skis are a specialized piece of sports equipment, often used by wheelchair users, for cross-country skiing. Sit-skis are very simple in design; however, many of their design issues parallel those for wheelchair design - Both require a strong, lightweight, and durable frame that is custom fit to the user.

There are two advantages of designing a Sit-Ski instead of a Wheelchair: The first advantage is that a Sit-Ski is simpler in configuration than a Wheelchair, allowing for simpler prototyping, testing, and faster validated learning. The second advantage is that sports equipment for spinal cord injuries are an un-regulated industry, whereas daily use wheelchairs are regulated medical devices. Since sit-skis are un-regulated, this makes the process of prototyping, testing, and iteration much faster and cost effective.

This approach does not eliminate the need for a regulated product; rather, it reduces the risk of taking an unproven product through the regulated process. Instead, all of the risky testing can be incubated in a relatively low-risk environment, and then brought to the highrisk medical environment once all of the major issues have been addressed.

Furthermore, this method also has the fortunate advantage of building non-medical revenue streams, from the sale of sit-skis, which could help in the funding of its regulated counterpart – wheelchairs.

In summary, by designing a sit-ski, a product who's design problems echo those of a wheelchair, I can take a lean approach to a medical device problem.

Focus Group

In order to drive my design direction, I employed the use of a focus group. I put out a call specifically for Sit-Ski users, choosing to focus my work on this niche product; rather than being distracted by the design issues facing both wheelchairs and sit-skis. The group consisted of three people, which was smaller than expected, but their backgrounds were very diverse and provided a broad knowledge base of the sport. The group's size meant that their comments cannot be conclusive, but I believe that their comments are valuable for establishing an initial design direction. The following are the main conclusions drawn from the focus group:

Focus Group Insights

Frame Design

Fit:	The user's height, and angle are important. Their Center of Gravity on the skis is also important	
Strength:	A chair has to be able to withstand a crash. The frame needs to have rigidity, and feel like you are connected to it.	
Weight:	7 pounds frames are typical, 20 pound frames are too heavy.	
Bucket Design		
Shape:	Bespoke / Can accommodate for different body types, disabilities	
Seat Position:	Accommodates different seating positions: Sitting, Kneeling, Tilted, etc.	
Fitting		
Coarse Adjust: Can generally be fixed, once you know what position is best for you		
Fine Adjust:	Users need to still make small adjustments, usually with spacers	
Price		
Entry Level:	\$2,000 for a one size fits all sit-ski is typical, and fair	
Advanced:	\$5-6k for a custom sit-ski is typical, and can go as high as \$8-10k.	
Quality	Peace of Mind in quality and performance are very important, much more important than price. People can sometimes spend \$5-6k on custom chairs that don't work.	

The focus group concluded that paramount sit-skier considerations were fit, weight, and strength. Factored into those qualities were the shape of the bucket, its ability to accommodate various body types, and also its position in consideration with the frame. Additionally, as a group, we discussed ways to improve the process of making coarse and fine adjustments as well. This began to highlight that there were in fact multiple customer segments that could be designed for; novice, advanced, and expert skiers. These different customer segments would probably have very different expectations for the buying process, and final product design. These various market segments will require special attention during the business model canvas stage.

Lastly, implicitly in the focus group comments I realized that there was a concern for the risk of buying a new sit-ski, without having tested it first. There are many stories of users spending large amounts of money on their sit-ski, only to find that it is not optimized for their skiing style, or is not built properly. These considerations will also require attention during the business model canvas stage.

Market Segmentation

There appear to be many different sit-ski users, but their preferences are largely based around how long they have been in the sport and how competitive they are. Finding a target audience of innovators (Rogers), and creating product-market fit will be important for developing this new product and service.

Entry Level:

It is quite common for wheelchair users to have to invest thousands of dollars for even the most basic of sports wheelchairs. Therefore, most of the users entering the sport use borrowed equipment, and then decide if it is worth it to invest in the sport later. The equipment quality and performance can vary considerably in these scenarios, that's assuming the equipment is even available to borrow. These challenges may lead to new users leaving the sport.

In this scenario, it is less likely to see users buying the chairs, and more likely to see a local foundation buying various styles of low cost chairs. Customization does not play a factor here, rather it is all about a strong, and lightweight frame that accommodates the majority of user's disabilities.

Intermediate Level:

These users are enjoying the sport of sit-skiing, and are wiling to make the investment to find better fitting equipment to improve their performance. They demand that their chair is strong, lightweight, has a good position set. They may not know exactly what seating position is ideal for them, and so they will need to try out a variety of positions in order to find good fit. This market segment is probably the most under-served, since they are looking for a somewhat custom product, but cost still plays a significant factor in their buying decision.

Advanced Level:

These are the most competitive users, and they spend a lot of time training for their sport. Cost is less of a factor for these users. Performance is key for advanced athletes, but they do not want to take a chance on an untested product. Rather, they want to know it works before they buy, and so they have probably already seen another competitor using the product they are interested in before they make their switch. Similar to users at the intermediate level, advanced athletes demand that their chair is strong, and lightweight. They also want the chair to have the perfect sitting angle. Though users sometimes require coarse adjustment in their sit-ski, once that angle is identified, they will only need fine adjustment for the long-term.

The market segments within sit-skiing are quite diverse, and are largely driven by how experienced and competitive the user is. The early adopters in this sector are somewhere within the intermediate level, and the advanced level. The key difference between these two groups is that 'innovative' users need to be willing to take a chance on a new product, ruling out many of the advanced users, since they need to know it performs well before they buy. However, a handful of well respected athlete endorsements may be able to influence this. SIT-SKI PROOF OF CONCEPT

Materials / Construction:

Now that I have identified a target market, I need to assess a production method that best suits this target market. I encountered heavy skepticism from designers and engineers when I spoke to them about 3D printed structures. The common perception is that typical 3D printed objects are too brittle and weak to be structural components.

However, 3D printing companies are rapidly bringing new materials and new production methods to the market. There are several types of materials and building methods that use 3D printing and laser cutting for structural components, proving that many options are available for low-cost custom-made structural components. The question is not can we 3D print structural components; rather, the question is what method works best for our target audience?

Potential Materials & Methods

3D Printing Plastic

This method has been done before, but lacks the strength demanded by users

Strength Fit Weight Cost Aesthetics

Poor Good Average Very Poor Good



Figure 15: Aplha 3-D

3D printing with carbon fiber wrap

By using a soluble core that dissolves after being wrapped in carbon fiber, composite frames are slightly more affordable than they used to be.

Strength Fit Weight Cost Aesthetics

Poor Good Average Very Poor Very Good



Figure 16: Stratasys

3D printing with hand wrapped carbon fiber reinforcement

Using a normal 3D printer and plastic, and hand-wrapping carbon fiber for reinforcement

Strength	Very Good
Fit	Excellent
Weight	Excellent
Cost	Excellent
Aesthetics	Poor



Figure 17: Thingiverse

3D printing titanium

Laser sintering of an object in titanium. The same technology can be used in aluminum

Strength Fit Weight Cost Aesthetics Very Good Excellent Very Good Poor Excellent



Figure 18: Ralf Holleis

3D printing continuous carbon fiber

A dual extrusion printer where one nozzle extrudes carbon filament, and the other extrudes nylon

StrengthExcellentFitExcellentWeightExcellentCostPoor - AverageAestheticsPoor



Figure 19: MarkForged

3D printing stainless steel

Direct laser sintering of an object in stainless steel. It is cheaper than titanium and aluminum, but heavier

Strength Fit Weight Cost Aesthetics Very Good Excellent Good Average - Good Excellent



Figure 20: Shapeways

3D printing carbon fiber filament

Using a normal 3D printer with a filament that contains ${\sim}20\%$ carbon fiber

Strength Fit Weight Cost Aesthetics

Good Excellent Good - Excellent Good Very Good



Figure 21: ColorFabb

3D printing with coaxial extrusion

Uses a printing pattern atypical of normal 3D printers, and extrudes continuous carbon filament while vertically wrapping it in nylon (not yet mainstream).

Strength	Excellent
Fit	Excellent
Weight	Good - Excellent
Cost	Good - Excellent
Aesthetics	Good - Excellent



Figure 22: Orbital Composites

Laser Cutting sheet metal

Cut from sheet metal using a laser, parts can be assembled together with only a rivet gun

Strength	Excellent
Fit	Good
Weight	Good - Excellent
Cost	Excellent
Aesthetics	Poor - Good



Figure 23: Industrial Origami

Potential Materials and Methods Conclusion

There are many different technologies for rapidly generating custom structural components, and new technologies are entering the market on a regular basis. At this stage in rapid prototyping, the question is not can we built it; rather, what method works best for our purposes.

Optimizing 3D printed material choice would be a continual process; requiring customer involvement and in-situ performance tests. My goal for this project then is not to prototype in a final material, but instead to develop work-flows that compliment 3D printing and laser cutting so that both methods of production are at my disposal and can be considered in the design process.

Modeling Methods - 3D Printing

Rhino Nurbs - 3D Printing

By developing a series of pre-modeled modules as an inventory, I was able to develop a work-flow that allowed me to assemble nodes / lugs for a sit-ski in under 20 minutes. This process was very flexible, and allows me to design a lot of different frames within a short period of time

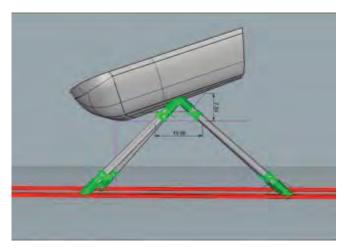


Figure 24 - Assembly with modules allows for fast 3D modeling

- **Pros:** Good for building new frames from scratch, with some potential for aesthetics
- Cons: Slow for adjusting frames

T-Splines - 3D Printing

Similar to the Rhino Nurbs method, this process involved building a pre-modeled inventory of shapes, but finishing their exterior with a t-splines surface that was more organic. This process requires one more step per node, adding approximately 5-10 minutes.



Figure 25: T-Splines Allow for more organic geometry

- **Pros:** Good for building new frames from scratch, with some potential for aesthetics
- Cons: Slow for adjusting frames

Grasshopper - 3D Printing

This work-flow required a great deal of setup time, but once setup, it sped up my ability to adjust frames. Each node currently requires its own algorithm; hopefully, by working with plug-ins like kangaroo, topologizer, and exoskeleton, and weavebird, I will be able to streamline this algorithm, making it more adaptable to new frame designs therefore reducing the initial setup time.

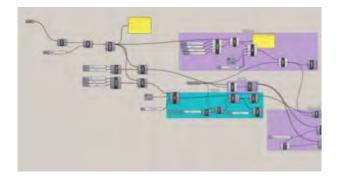


Figure 26 - Grasshopper modeling requires algorithms



Figure 27 - The resulting geometry that can update with inputs

Pros:

Great for adjusting frames, with a strong potential for aesthetics.

Cons:

Slow setup time, approximately an hour for each node, meaning several hours for a frame. Will require more experimentation with algorithm to prove its long-term effectiveness.

OnShape - 3D Printing

Much like grasshopper, this work-flow requires setup time, approximately 2 hours. This is significantly lower than grasshopper's setup time, but the resulting model is not as robust. This can lead to glitches in the 3D model if extreme adjustments are made.

Pros:

Good for adjusting frames, might be good for open source development.

Cons:

Requires significant setup time. Not a medium many people are familiar with. May require tutorials to be effective.

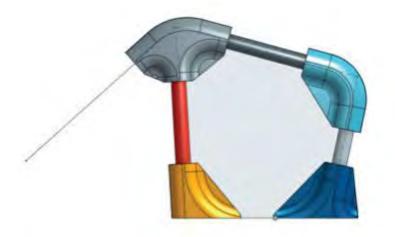


Figure 28 - OnShape is also parametric, in that the geometry updates with inputs

3D Modeling for 3D printing Conclusion:

Parametric modeling options offer the fastest work-flow, but require the most setup. In the future, this may be worth streamlining; however, given that nurb modeling can be done with pre-modeled modules in less than 30 minutes, 3D modeling is unlikely to be a bottleneck in the foreseeable future. This method also allows for the most flexibility in adapting to new frame styles, helping to keep this entire operation as lean as possible.

Modeling Methods - Laser Cutting

Rhino Nurbs

Creating the basic paneled shape for a laser cut frame takes minimal time, less than 15 minutes. Adding the perforated fold lines and tabs for assembly takes considerably longer. Rhino is not optimized for this; but SOLIDWORKS is. If I continued this route, I would need to invest in the SOLIDWORKS software and learn the work-flow.

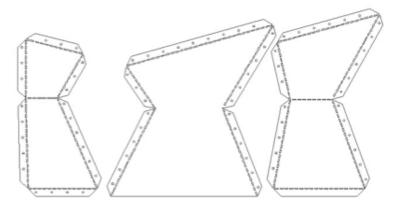


Figure 29 - The laser cut frame could be cut out of flat sheet metal

Pros:

Final product can be flat-packed. There is a greater standardization of sheet metal materials than 3D printed materials, and would require less experimentation in open source applications.

Cons:

Reduced flexibility in the way of aesthetics. Requires new software and accompanying skills.

Laser Cutting Conclusion

Laser cutting is a viable direction for moving forward. This method has its challenges, such as complex geometry for 3D modeling, and also material waste. But this method also has some strengths, such as end-consumer assembly, and flat-packing. Overall, this method is worth exploring further.

Bucket Experiments

In order to develop a process to cost effectively make one-off sit-ski buckets, I explored a different method of construction. As a proof of concept, I experimented with forming a flat 3D printed part into a contoured form by boiling the part. I then scaled up a similar process, where modules of a bucket could be printed in succession, and assembled, and contoured to fit an individual.

Proof of Concept

After 3D printing this part in PLA plastic, I put it in boiling water, which is close to the melting temperature of PLA. Ten minutes in boiling water softens the plastic enough to the point that it is malleable. Though the part is not too hot to touch, a towel is recommended as insulation to protect sensitive skin.

The part can then be applied and molded to conform to a surface. After about a minute, the part cools, becomes rigid, and locked into its new shape.

Figure 30



The part starts off flat



It is then heated to soften the



Then molded to a surface

3D printed Bucket



Once cooled off, the part will permanently hold a form

Having done a proof of concept, I moved on to build a mock-up of a full-scale 3D printed bucket. This had to be broken into 10

pieces in order to accommodate our facility's 3D printer, but would work using a similar procedure as the proof of concept. The only difference would be that this bucket would use a large heating element, rather than boiling water to heat the material.

Figure 31 - Screenshot of Rhino Bucket Model

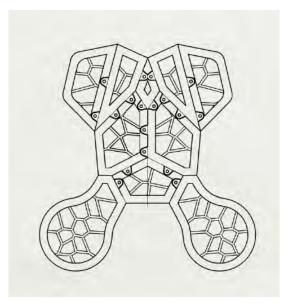
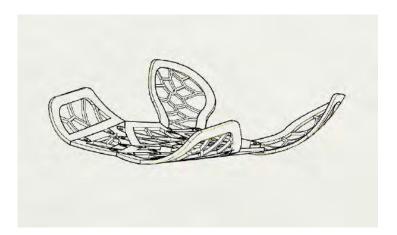


Figure 32 - Screenshot of 3D Formed Rhino Bucket Model



This design was successfully 3D printed in PLA to prove a concept for a modular bucket system that is adaptable to various disabilities. For a more generic bucket, this same design can be quickly adapted for CNC work, reducing the overall cost and time required for production.

Fitting Process

During my focus group, I learned that in most of the cases where a user is ordering a custom-made sit-ski, they are open to spending time to identify their optimal seating position. This relates to their torso position, seat height, leg angle, and range of movement. During my focus group, I showed participants a proposal for an adjustable sit-ski jig. The proposal for this jig was that it would be included as part of the service for purchasing a custom sit-ski, allowing the user to try before they buy.

The Focus Group was very positive about the idea of introducing a jig like this into the process. Though this example would not work well for users with higher level injuries, it would work well for users with lower level injuries, those that still have abdominal control. By changing the bucket to include a backrest, the jig can account for a greater number of disabilities. The jig will also need to adjust along the length of the ski.

Overall, by introducing this jig, it gives the user the flexibility to identify their optimal performance position, without the need to access and test multiple sit-skis. This sit-ski rig can be offered as service as part of the sit-sky buying process for an improved retail experience.

Figure 33:



Screenshot of Sit-Ski Jig in OnShape. Jig Allows for vertical and angular bucket adjustment.

Business Models

Open source ideas and free 3D models generally characterize the maker movement. Though this is good for the democratization and accessibility of new ideas, one question that designers face is how do they flourish in this environment? How can a designer make a sustainable business here? There are some startups that have begun to address this concern.

Open Bionics

Open Bionics, and their sister organization The Open Hand Project, have released open source plans for their prosthetics Online (Open Hand Project). However, this has not stopped them from building a sustainable business though. In 2013, they raised capital by crowd-funding, enabling their lab to push their research further (Indiegogo). This has allowed them to continue developing their product, which has in turn lead to the addition of a revenue generating branch in their business. Recently, Open Bionics has partnered with the Disney Corporation, and are now selling themed prosthetics inspired by Disney (Inhabitat).

This has allowed Open Bionics to strike a balance between making the product accessible, and furthering its development through a sustainable business model. To further develop products, customers can choose to pay extra for the service that Open Bionics provides, instead of opting for the DIY open source method.

43 Layers

43 Layers is another company that is finding a profitable business model within the maker movement space. Realizing that many 3D printed products are outside of the technical ability of the average consumer, they are presenting themselves as design facilitators. Clients present a sketch or idea, and 43 Layer's designers collaborate with that person to 3D print or Laser-Cut the product. In this example, the designers at 43 Layers act as design facilitators for the user, helping them turn their idea into reality (43 Layers).

Hero Forge

Hero Forge, a startup that was also crowd-funded (Kickstarter), has a business model that is centered around their Online customizer engine. Users can go onto their website, and construct 3D character models by selecting from a library of features and settings (Hero Forge), then the miniature figurines are 3D printed (Shapeways). Hero Forge has gone one step further than 43 Layers by giving the user full customization control, but within predefined constraints.

The Maker movement has generated a lot of free ideas and content on the Internet. Ethically speaking, I also believe that innovative medical products should strive to be accessible to everyone who needs them. Fortunately, as seen with 43 Layers, Open Bionics, and Hero Forge, being in the maker movement does not mean that one cannot also have a sustainable business model. These businesses are proof that a variety of business models have found niches throughout the maker movement, and are also proves that the democratization of making still includes designers in the picture.

As they relate to my own business model, these companies can provide inspiration, but ultimately, I will need to develop business model canvasses of my own in order to build a business that effectively caters to my desired niche.

The process of designing the business model canvasses (Appendix C) was valuable for providing insight into the various market segments identified by the focus group (Novice, Advanced, and Expert Sit-Skiers). Each target demographic has a unique value proposition, and possibly, they will even have their own unique revenue streams. For example, coaches and ski-clubs may be more interested in renting sit-skis, rather than buying them. These distinctions amongst revenue streams will require actual testing with customers for validation though.

Additionally, designing the business model canvasses also revealed a strategic opportunity for collaboration with local bike and sports goods stores. Stores' could have incentive to become retailers, since the sit-ski's take up zero space and capital for inventory, only ship when ordered, provide acceptable profit margins, and also generate a positive public relations impact.

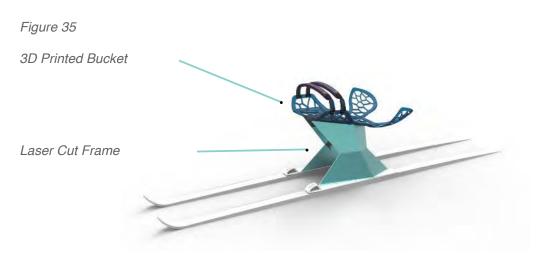
Though the business model canvas is a continual process that will have to be revisited throughout the life of my business; Initially, I will focus on developing the expert / elite sit-ski athlete market first. As a designer at this stage, this is the group that I am best positioned to design for. I can cater to their specific requests for a custom sit-ski design, and I can focus on close client relationships. This strategy will also be important for branding and networking. By catering to professional athletes, the brand will be perceived as a premium brand from the beginning. Additionally, this target market will also lead to more networking opportunities for clients through athlete communities, coaches, and competitive events.

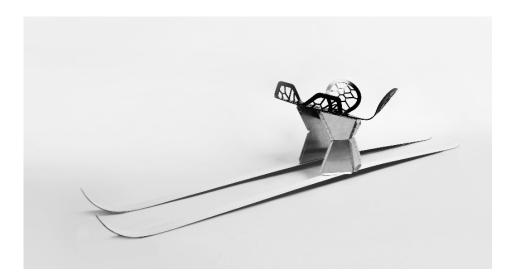
Final Proof of Concept

In order to test the economic and functional feasibility of using rapid prototyping methods as a means of production, I sought to build a proof of concept prototype using these methods. The key points of consideration were the cost, as well as the availability of the technology. Laser cutting, 3D printers, and CNC machines are relatively common, and were therefore chosen for this prototype.

Figure 34







Proof of Concept Built

The frame for the proof of concept shown in Figures 34, 35 and 36 were laser-cut in aluminum by an outside vendor. Total expenses for the materials and cutting were \$130. After a discussion with the vendor, this cost could be brought down further by using different cutting methods. The current cost of goods to produce the design in Figure 36 was only \$368.00 (see Appendix D).

The bucket was test 3D printed with PLA plastic. Depending on the material properties; specifically, the material's resistance to fatigue and cold temperatures, the final material the bucket is printed in could range from \$50 (CNC) to \$400 (Shapeways).

This proof of concept also allowed me to experiment and test the custom bucket fitting process. The bucket could be 3D printed to already be form fitting; however, it could also be milled flat with a CNC, and then thermoformed to the user, or a mold after. This has given me a greater insights into some of the possible challenges and the time requirements for this stage of the customization process.

Conclusion

BACKGROUND

My early research helped to point me in a direction that would allow me to best serve the needs of those living with ability limitations. My design skill set is well suited for dealing with Quality of Life concerns, specifically concerns relating to ability limitations, aesthetics, and empowering the user to have more influence over their device. Initially, I believed that my research would be able to influence wheelchair design, but then realized that I am currently not in the position to effectively impact this area. In order to innovate freely within these areas, and generate what could be breakthrough innovations, I will need to focus on deinstitutionalized medical devices. These de-institutionalized devices generally face less regulation, and are much more compatible with innovative business development strategies. Furthermore, deinstitutionalized devices allow us to focus proportionately more time and energy on the end user, allowing them to have more control and influence over the device's final design.

RAPID PROTOTYPING

The Maker Movement has made the technology necessary for customization much more accessible than it was previously. This has also allowed for the possibility of digitally distributing physical products, allowing businesses to reach the long-tail of demand easier than before.

The maker movement has already been serving the area of deinstitutionalized devices, such as 3D printed prosthetics for over three years. 3D printed prosthetics illustrate the power of a digital distribution network, and highlight the opportunity for users to customize their device in order to suit their own identity. However, the not-for-profit model of E-nabling the Future presents growth challenges, and financial bottlenecks, relying heavily on donations and volunteer labor to stay in service.

If I am going to pursue entrepreneurial endeavors of my own, I will need to design a business model that is responsive to market demands, and can generate a sustainable cash flow on its own.

Additionally, the maker movement also presents new opportunities related to mass-customization. By using production tools that are well adapted at building one-off products, a design can be easily manipulated with parametric 3D modeling, allowing each new product to be custom designed and fit to its unique user. This design flexibility presents unique opportunities for the designer to facilitate the 'making' process, bringing the "Maker to Market" (Deloitte).

This level of mass-customization also allows for users to become "architects of their own identities" (Mullens), and facilitates a greater level of emotional durability in the design (Chapman). All of these are factors that reinforce positive independence, environmental, and psychological factors that contribute to a user's Quality of Life (WHO).

ENTREPRENEURIAL APPROACH

My research then explored new ways that physical products could be tested using the lean method. This required me to analyze what resources were at my disposal, now and in the future, in order to build Minimum Viable Products (MVP), and to test hypotheses about my consumers.

After my work on the mobility walker, I decided that athletic wheelchairs, specifically sit-skis, would be the product that I would focus on developing an MVP for. The Nordic sit-ski fit had fewer constraints than the mobility walker project, making it an easier design to innovate with. The sit-ski is a non-regulated device, allowing me to be more flexible during my business model design, while not being restricted by FDA or Health Canada regulations.

Furthermore, the sit ski, as a product, is more aspirational of a product than a mobility walker. By this, I mean that the sit ski is a product that people actually want to use, rather than have to use. This makes getting feedback on the design more productive and efficient. Users do not want to user their mobility walker, at all. The users recognize that they have a problem with mobility walkers, but are not very helpful in addressing them. The sit-ski has an audience of dedicated, elite athletes. These athletes are excited to use the product. They already have ideas about how to make the product better, and also give feedback for improving the sit-ski buying experience.

Lastly, sit-skis are a technically simple device. This technical simplicity allows me to efficiently iterate the device in response to user design critiques. Designing a sit-ski, instead of a more complicated device, such as a basketball wheelchair, allows me to focus on the specific niche's needs of the user without being distracted by precedent, and without being restricted by other complicated mechanisms that the device needs in order to function properly. All of this flexibility in the design process is important in order to remaining agile, and responsive to user feedback. These characteristics are extremely valuable to the lean startup methodology.

FOCUS GROUP

In order to gain deeper insight into my target demographic, para-Nordic sit-skiers, I decided to conduct a focus group. Though this focus group was small, it was comprised of a very diverse selection of participants that had deep insights into the sport, and decades of combined experience.

The focus group concluded that the most important sit-skier considerations are fit, weight, and strength. Factored into those qualities were the shape of the bucket, its ability to accommodate various body types, and also its position in respect to the frame.

Additionally, the group discussed various methods for making coarse and fine adjustments, which highlighted various customer segment strata. Lastly, focus group members expressed concern for the risk that comes when buying new products, like athletic wheelchairs, without testing them first. These are all factors to be accounted for during the business model canvas stage of the design process.

MATERIALS AND METHODS

Having established the design scope of my project, a Nordic sit-ski that was strong, lightweight, and could be rapid-prototyped for fit, I then conducted extensive research into new and experimental technologies in 3D printing and Laser Cutting. This allowed me to compile a thorough list of technologies that included various Price Points, Strengths, Weights, Accuracy, and Aesthetics. Through this research, I also experimented with various parametric and surface modeling software applications, in order to assess the relative strengths and weaknesses of each. The result of this research was a survey of various materials, production methods and design tools that would be necessary for this sit-ski, and future products.

BUSINESS MODEL DESIGN

Having a thorough understanding of the flexibility of my design skill-set in the realm of 3D modeling, and also understanding various production methods that are at my disposal, I chose to revisit my business model canvasses in order to assess the possible business models that would be viable for this project.

43 Layers, Open Bionics, and Hero Forge all demonstrate diverse and unique ways that companies have been successful within the maker-movement. 43 Layers is acting as a direct design facilitator, largely appealing to users that need a short-term design consultant (43-Layers). This is one possible revenue stream for my business in the future. Meanwhile Open Bionics has successfully made their design opensource, while still being able to monetize a portion of their value proposition (Open Hand Project). Currently, I am still assessing whether or not this option would be a good fit for my company. Releasing my plans as open source material could be done in conjunction with a crowd-funding campaign to further my research. Currently, I do not believe I require resources for further research, but I may consider this option when it comes time to develop a customizer engine.

Lastly, Hero Forge presents a customization engine for masscustomization (Hero Forge). The use of a customization engine might be worth considering as a value-added feature in the future.

Designing the business model canvasses gave me insight into the various ways that my business would be impacted by the multiple market segments I am trying to serve (Novice, Advanced and Expert). Each target market segment requires a unique value proposition, and potentially their own unique revenue stream. Currently though, some of my conclusions are only faith-based hypotheses, and will require several more business model canvasses, and customer inquiries, before they become fact based decisions that are validated.

SIT-SKI PROOF OF CONCEPT

Building the physical proof of concept was important to validate that my resources and skill set were enough to produce a MVP. Not only was I able to design a prototype where the custom components could be outsourced, this prototype also came in at a reasonable cost and assembly time for my target price point.

This proof of concept also allowed me to experiment and test the custom bucket fitting process, giving me a greater insight into some of the possible challenges and the time requirements for this portion of the customization process.

MOVING FORWARD

With my proof of concept built, I have validated that a MVP is within reach. I would still like to produce one more prototype before I begin selling to clients. Once the final prototype has been built and tested, I will begin selling sit-skis and trying to build a customer base.

Initially, I am planning to focus on elite athletes as a target market. This demographic will likely be the user group for whom I can offer the most value. I can work closely with athletes to custom build a sit-ski for them, creating added value by facilitating a custom design process. Working in this target demographic will also serve to build my brand identity, and help me to connect with a diverse group of clients through events, clubs, and sit-ski coaches / trainers.

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Appendix A - Ethics



RESEARCH ETHICS OFFICE

308 Campus Tower Edmonton, AB, Canada T6G 1K8 Tel: 780.492.0459 Fax: 780.492.9429 www.reo.ualberta.ca

Notification of Approval

Date: October 1, 2015

Study ID: Pro00059456

Principal Investigator: Adam McKertcher

Study Supervisor: Robert Lederer

Study Title: Identifying significant factors in sports wheelchair performance.

Approval Expiry Date: Friday, September 30, 2016

Approved Consent Approval Date Form: 10/1/2015

Approved Document Informed Consent Letter.pdf

Thank you for submitting the above study to the Research Ethics Board 1. Your application has been reviewed and approved on behalf of the committee.

A renewal report must be submitted next year prior to the expiry of this approval if your study still requires ethics approval. If you do not renew on or before the renewal expiry date, you will have to re-submit an ethics application.

Approval by the Research Ethics Board does not encompass authorization to access the staff, students, facilities or resources of local institutions for the purposes of the research.

Sincerely,

Anne Malena, PhD Chair, Research Ethics Board 1

Note: This correspondence includes an electronic signature (validation and approval via an online system).

Appendix B - Focus Group Transcript

Time In	Participant	
	Me	How long have you guys been using your sit-skies? Or been in the sport?
	Two	Two Years.
	Three	I've been in para for close to ten.
	One	Fifteen, since 2002
	Me	Did you buy your own sit-ski, or did you buy it from a company? Is it custom made?
	One	All of the above
	Three	Pretty much, yeah.
	One	Some skiers make their own
	Two	I've just borrowed, and I've just borrowed out of his flock of sit-skis
	Three	It's called a fleet
	All	Laughter
	Three	Well we spent years developing that initial part, back in the beginning, if you go back 10 years ago we'd get calls, there was always that generic question of "If there's interest, then we would find some equipment." And people would say "is there any para-programs?" and they'd say "well we'd like to but" So I spent a few years building these, and getting some equipment and grant money so we could start "learn to ski" programs. So at this point we have three distinct styles, from very recreational to some that could be used for competitive pieces. THey're certainly not custom, but you can't do that for the general public. Yeah I have approximately a dozen or so. Three different types of a dozen, now we're just working from one consistency, the general square little frame there that attaches to the bindings there, but everything else is different for people. And then we also had sit skis that we would loan, well one to their (One's) organization, the **Strathcona Centre**, and there's one in Canmore, we just loan out a few
	Two Me Three	So can 3d printers print out in aluminum? Yup! Aluminum is actually one of themore relatively affordable materials, they can 3d print in titanium, which is the strongest, and the most expensive. One of the parts I had built up, about this size, and that thick for a sit-ski because that's the shortest distance between your butt and the skis themselves, and I thought "how much could this cost?" The low range was \$5,000 and the high range was \$12 (thousand), for the 1 part in titanium. That cut down to about \$1,100 in aluminum. And the way that I am proposing doing this is that it wouldn't necessarily be the entire thing that's 3D printed, one of the ideas that That's the thing, we always joke that if you've got a template, then you could make it out of balsa wood, titanium, carbon fiber,
	Me	Well one of the ideas that I'm kinda floating with, and we can bring this to the discussion now, but we've got this idea here (showing them proof of concept 2), that you would have these joints that are 3D printed, and then you'd just connect it with carbon fiber tubes in the middle.

	Three	Or Aluminum
	Me	Or Aluminum, or whatever, depending on
	Three	Yeah.
	Me	Yeah. And so if we can 3D print these, we could 3d print all of those pieces for \$80 in plastic, or \$200 in stainless steel, or for maybe a few hundred dollars more in aluminum.
5:15:00		
	Two	When you say these joints here, the four joints
	Me	Yeah, the corners themselves. These spanning would be
	One	Joints and tubes
	Me	Any kind of tubes that you'd find cost effective, and lightweight enough, and these joints would be 3D printed themselves.
	Three	Which would then be 8 for those pieces there, p
	Two	Well the cross bars would have to be separate too
	Three	Well the bars would be separate, but you've got 8
	Me	Exactly. Exactly. Eight joints, and I've even been kicking around the idea of cutting that down. I don't want to say "screw this already" (the printed questions)
	All	Laughter
	Three	We can get your questions, you can ask those too
	Me	Here, I'll show you guys something that's been kind of interesting me
	Three	That' is intriguing because there's always your strong parts, but say there's Martin down in down in Stettler who just wanted a recreational sit-ski just to go ski with his children, sio he purchased the same one derrick had who went on to the world champs last year, but you could have just straight aluminum, or carbon fiber, or
	Me	I did see something very recently that assumption that I've been making this whole time that it needs to have that boxy frame, four post design
	Three	It definitely does not need to be a square frame, but the wheel of the ski track creates a limitation to how wide it could be, and that's why it kind of attaches to the ski the general box frame is why it does it so So that's the cross bar, how would the tubing be held in? Just free held in, or would there be some sort of
	Two	Glue?
	One	Press fitting?
	Me	We were talking about that earlier and we think that's something worth discussing because let's say if they were just screwed in
	Two	What's a cross-fit?
	One	Well press-fit
	Two	Oh press-fit
	One	would just be pressed in there with a force so it'll never move, they build bikes, bonding different materials together for bikes for 25 years and they hold together.
	Me	And so I wanted to show you guys this, this is a guy named Martyn Ashton. He used to do competitive downhill biking until he had his accident. And then he got his buddies to take a sit-ski bucket
	Two	Basically, yup. That's a sledge bucket
	One	Additional back on it

	Me	It's from a sit-ski company in Europe, Fessier or something like that. And they attached it to a seat mount pole, so it's got a bracket right there, and I found that really interesting because what that allows you to do, if you've got just a bucket, and this is the side view, and you've got one pole coming down and then these poles just splay outward to the skies, you can eliminate a lot of this bulky frame here, just keeping it to the one pole, and this is your adjusting angle, and theoretically we don't need to stick to that boxy frame. There are a lot of other options out there provided that you're smart with the material choices, they're strong enough, things like that. This guy goes down mountains on that bike, and all of his weight's on that bucket,
	Two	Yeah, there's gotta be a lot of torque on that
	Me	Yeah, but they just have a reinforced seat post, and that's it
9:15:00		
	Two	Wow
	Three	Sorry, I always bad with names, haven't seen him in two years but there was a black fella from the US he just had the straight post, the straight carbon fiber posts with his own bucket, and it was \$2000 per post. He just had one. Very upright position with his spine, but a similar idea to that (pointing), there's just one big post to attach to
	Me	Obviously weight is not as much of a concern, becauase he's just using gravity (the biker), but I believe it's a reinforced bike post
	Three	It would have to be
	Me	And it works, the only thing that's not a bike component on that entire bike is the seat. And his whole thing is that he wanted it to look as much like a downhill bike as possible
	Two	And strapping the feet down would give him the stability
	Me	Yeah, they use electrical tape
	Two	Haha
	One	We have athletes with their hands taped to the poles
	Me	And this is all just to act as a primer to say, there are a lot of different directions that we can go with this. And I don't by any means assume that we need to stick to one design, and so we can be pretty flexible on a lot of this stuff.
	Me	How much did your sit ski cost?
	One	For commercially available ones, around \$1,000 - \$1,200
	Three	No, the commercially available ones are around \$1,700 - \$1,800. Chris's were \$1,500- \$1,700, the toby's were 18, your american guy is about 18 US. That's just the general frame, because that included all of it, the straps parts and buckets.
	Me	Those are just the one-size-fits all kind of thing?
	Three	Basically. The guy in spokes-in-motion talks about a custom seat or a general seat, and a custom seat is that one (points to the bike), which is not really custom, and the other one
	One	He's got a glove seat and the scoop bucket
	Three	But the ballpark range is about \$2,000
	One	The OX sled from japan is about \$2,000
	Chie	The ON SIEU HOITI Japan is about \$3,000

	Three	The norweigan ones that Tony had were probably about \$2,000-\$3,000. And if you get
		a custom one, which is what Tony did, getting a carbon fiber custom seat, that was
		\$3,000 or whatever it costs for that, the frame was \$700, so it could be the range of
		\$5,000 plus for a custom piece
	Me	So really as much as a custom wheelchair then, or getting close to that range
	Three	It's more the labor but it's approximately about \$1,600-1,700
	One	Collet's had a sled made for her by the russians out of their excess military grade
		titanium, another skier wanted one, and they said it would probably cost around
		\$8,000
	Three	That was a long time ago, wasn't it?
	One	Well they asked in Sochii
	Three	And she still uses it, it's close to 20 years old is it?
	One	Somewhere between '02 and 05'
	Three	So 15 years, I'm trying to say she's had it for a long time, and still used it. It's quite
		light, and functional and durable too. But anything custom is gonna be more so.
	Me	And like you said, the labour in my perception as well seems to be the thing that
		drives up the custom direction, and that's why I've been going the 3D printed direction
		because your added cust for going custom is non-existent almost.
	One	Right
	Three	That makes sense.
	Me	Whereas if you have skilled trade labour welding it all otgether, all of those custom
		joints, titanium is a difficult metal to work with, so
	One	We've been picking on modifications for Collet's sled we've picked someone who
		welds titanium bikes from Vancouver. A good welder with a Jig and a welder, they
		won't charge that much, but then if you give them a lot of work it becomes a job instead of
	Three	It's the components again, if its aluminum, carbon fiber, titanium, it's the same
	mee	process (referring to mine). For these guys it drives the labour up, the ones I have are
		just aluminum tubing.
	One	Yeah, the buys building Derrick's sleds are just aluminum tubes.
	Three	Chris, who's an athlete in the National team, and olympic world champion it was a
		large tube the first ones I had, then the next ones are just a smaller diameter tubing. It
		made it lighter, and he hasn't been able to break it yet, just bent it. Just like how
		carbon fiber bikes came out, and that was all the rage, the initial ones had some flaws,
		because of strength, integrity, torque, but they fixed all of that. If you're a mountain
		bike racer, you want it to be light, especially if you're going up. Not sure if they worry
		too much about the down, gravity probably helps, or they probably have a maximum
		weight I'm assuming.
	All	Yeah
	Me	I just came across this this week (still talking about the bike), and it's the same bucket
		as a sit-ski
14:45:00		
	Three	It is with a back added onto it, and that's why I love the sledge bucket they're used for
	_	multiple purposes it seems
	Two	Can you get me a sit-ski that also works as a downhill bike?

All	Laughter
Me	So what do you guys think are the most important design factors of a sit ski?
Me	What are your top list items?
One	Fit, weight, strength
Three	Yeah, it's gotta fit properly
One	And by fitted, I don't just mean the bucket, I mean its gotta be the right angle, and for the wearer's functionality
Three	Where he's full abdominal (two), whereas Anna is a spinal injury, so she needs a different fit, and there has been some, the saskatchewan ones years ago, were heavy, lowrider ones, were probably 20ish plus pounds, so if you're recreational and you're trying to go up a little incline, the ones you're using (two) are about 7-8 lbs
Me	(to Two) do you have anything else to add to that?
Тwo	This is where the 3D printer would work, because every disability requires something different. And I'm more disabled sit skiing as I am riding my bike here, or walking to the store, because I don't wear my legs, I don't want to carry the weight, and my positioning is much better because I can go forward. And my new ski I'm getting built now I have it leaning forward a bit, and I'll play with getting it forward as much as I can without feeling like I'm sliding forward
Three	There are spacers
Two	YouTubing and watching races, you see people who are sitting on their stumps, and they're vertical, they are quite high up. For my that would be quite uncomfortable, my stumps wouldn't take it
Three	I think it's uncomfortable for them too
Me	And so correct me if I am wrong, but the amount of figuring out what that comfortable / optimal angle is pretty limited because you're limited to the spacers, and what you can bump up the bucket
Three	It's just the shape of the frame
One	Well we've used wedges and spacers to angle it a bit you look at the femur angle and the femur angle is relative to how much abdominal control you have. Most double amputees sit flat, it gives them the most freedom for maneuverability because they can support themselves in a full range of motion with support whereas if you go to a spinal inuury you have less abdominals so you have to start looking at flat to negative on the femur angle so you start to create stability in the hip pocket
Two	This is the shape of the bucket that nordic ski alberta loaned me, and I just filled it with foam, and played with cutting it down and raising it,
Me	And so if I understand this correctly, you're filling in this area (draws on board)
Two	The one that Ana, and everyone starts with has a dip, so I went and foamed it flat
Three	Trying to make it fit your form better, whereas the custom carbon fiber buckets can be molded to your body.
Two	And what I was using was quite tight. My legs could not go through the front of it
Me	I think I've sat in that bucket before, and I remember it's a pretty tight squeeze in the front

	Three	we were once asked by the Alberta Parapelegic Association "what's the max weight?" because they had a guy that was 375 lbs, he wasn't very mobile. Talking to Toby, we figured it could hold 250 +, maybe more, but if he ever fell over They're quite strong, your bike is strong. But if you crash, you'd help yourself back up, but at 375 lbs, and he's not mobile, whoa. And even getting myself up, I still have to put myself in the position.
20:47:00	Me	What are some of your biggest concerns / complaints abou the sit skis you have to use right now?
	Two	Wasn't designed for my disability, it's not a complaint, it's a reality. If I was wealthy, and I decided to get a sit-ski, I'd still be in the same position (physically), I don't know enough about it to say let's do this, or let's do that. I may be a guinea pig for testing strength, but using sit skis I don't know what position is best
	Three	Well there's not a lot of options to try, of the three I have, that's the best one I have for him. Ultimately if he was in a better position for his conditiom, then he'd have a little better stability and better balance so he'd feel more confortable in the corners, as opposed to he feels a little bit off because he's a little further back
	Two	Yeah, my weight is back, and because of the bucket I don't feel as attached as I should. Popping out of tracks, I'm lifting my front end up.
	Three	If you're attached to it, like if this guy (bike guy), has to move with it, but if he started coming out of his seat, gravity would pull one way
	Me	Do you feel like an improved bucket design is in order?
	Three	Well just shaped to the individual, again recreational ones people can try, but what's cool is that more people are getting one made for themselves, which makes us the progression
	Two	And chances are that its our tax dollars that have supplied some of this
	Three	The Canadian parapelegic association is probably funded by the government That's just the thing, the custom in anything, like in a mountain bike, if you're gonna get competitive, you'll get a lighter one, as opposed to a super-cycle
	Me	The question I have here is what a bucket and a frame looks like for someone like **Ana** and someone like Two. It sounds like those are two different frames, and two different buckets as well.
	Two	I think the frames are similar, aren't they?
	Three	The bottom attachment that connects to the ski, that piece is similar
	Me	Where yours (two) is sitting high on the front right now, but could be sitting lower.
	Two	We're aspiring to come out of it starting with flat
	Me	And then, how would the bucket look different for you?
	Two	It would be shorter
	Three	He doesn't need the back support
	Two	And the back support up til now has been a disadvantage for me, because when you stay forward, you start to lean back, and I'm starting to lean against my back and I don't need it.

	One	Depends what you want it for too, sitskiing for performance vs. fitness are slightly different. With a few exceptions, most of the double amps are on a totally flat seat with no back support whatsoever, they just strapped in once
	Three	Well you just get rid of all of this and sit on canvas. But (two) can control, where as for Ana if she went too far back she can't control, Collet's the same way, she's even a higher spinal injury than Ana
	One	Collet's tucked right in, her knees are in
	Three	Everything's in the frame, she needs that support
25:05:00	Me	Have you ever broken sit-skis?
	Three	An actual sit ski, no, he (one) has
	One	I've seen many broken, the guys who are racing hard, and pushng hard and they crash hard. Well Chris has one he made from an air-core wood panel, balsa wood almost, impregneted with resin and fibers, but when he crashes it it falls apart. He's changed it so it has more integrity, I've seen metal ones break, I've seen metal ones disentegrate, I've seen a guy with a bucket on top of milk crate once, that broke.
	Three	Just saw that guy, Kevin in vancouver, coming down a hill on one he built himself
	One	Hockey sticks
	Three	He separated from the botton, he's like a luge
	One	The tubes were made from graphite hocket sticks
	Three	So it does matter what kind of material you're using and all that stuff
	Two	Money aside, you 3D printed an entire sit ski no joints and tubes going in, I assume that it would be the lightest and the strongest,
	Three	Depends on material
	One	(aside)< maxiim, the three big boys are all on the exact same kind of sled, it'll be flat
	Three	You'll see how the base is a little wider (than the sle)d, and it tapers in for the width of the track
	One	This is the classic double amp sled right now, flat top, all three of them on the exact same sled. This guy behind here, Maxiin, he's got his hips probably at a 25 degree angle, because he's only got (control) from his pectorals up.
	Three	The width of the ski part has to be equal, but the rest of it
27:40:00		
	Me	This is a sit that's been entirely 3D printed by another university.
	One	That's Martin Fleig, he trains at Freiburg. The guys in Frieburg have a sports science lab there
	Me	This was probably a \$6,000 print
	One	Germans have money
	Three	Was this guy a racer?
	One	He was in the world cup, top 10 last year in the circuit
		· · · · · · · · · · · · · · · · · · ·

Me	Sure, its custom, but I don't know how much stronger it would be, it would be a higher grade plastic than this (PLA), but if you're doing lots of crashes or biathlon, I don't know how robust it would be. This was kind of a proof of concept for them, and I dont think it's gone much further. I think there are parts of this that are good, in terms of 3D printing parts of the bucket, I think that's good, but when you're talking about putting all of the weight on a purely plastic frame, I am a little bit skeptical. I'm not an engineer, but I think that you might as well take advantage of stock components where they're good for that. You can get stock aluminum, stock carbon fiber, they're not that expensive,
One	Especially then, it allows you for more ability to play around. If you're doing a layup for carbon fiber you're kind of stuck with the design
Me	Wheras if you have a carbon fiber tube, you can cut it to length
One	layup vs. modular, way more
Me	The advantage of modular designs, whereas this is one piece, and you're stuck with it. And for \$6,000 in my opinion this isnt taking full advantage of what 3D printing can do. And you have to think about 3D printing in concert with all of these other methods of production.
Three	Yeah, just pushing the limits for making it maximum lightness.
Me	Do you have any ideas about how we might set up the angles for a seating position?
One	The research project we're doing right now is looking at that. It's kind of a process. There are two parts when you are developign a sit ski and a sit skier. They first get into the sled, it's partly sled , partly athlete. As they train, especially spinal injuries, don't do a lot of core work, they only work on upper body, so as they train more you can then start pushing the angles. Take Chris Couple for example. He's been doing this for almost 20 years. He's gone from negative 15 (degrees) or more all the way up to zero, and even tried going positive a bit. That took not just sled designs, but every percent he went up took a year of training to accomadate, especially when you get to that point where they are at their functional capacity for power vs. control, he could chnage the angle about 1 degree and go on the mountain board and be fubar'd for weeks. It took him hundreds of hours for him to retrain his body to adapt to that extra little.
Me	It gave him a performance advantage by
One	Yeah, so finding the angle we have starting points, again for spinal injuries there's much variation in how much innervation they have. It's a bit of training v. feel. V. analysis. And it's a matter of putting in a small spacer.
Three	Two, double amputee, has abdominal usage, you'd start with a flat seat, and then adjust with spacers. We've had a few differences with Ana, the engineers here at the university have used different foams and angles.
One	Typically your double amps are flat, single amps are kneeling, some of your high functioning spinals are going to kneeling now
Two	So when you say kneeling, are they actually kneeling, or tilted forward?

Three	Martin Fleig, the guy he's talking about, he had spina bifda or something like that, so he's probably got impaired lower limbs, he's actually sitting with his shins almost 90, almost 100 degrees parallel to the ground, Trib larson, he's actually like this. And there's variations on the kneeling as well. There was a recent skier who's got more less function than him tried kneeling she broke both patellas because she was just pounding her kneecaps in. In sit skiing right now there are 5 categories, based on functional ability. Each of those categories will have a distinct style of sled, that's generally homogenous for that class, with exceptions on each end. Based on individual preferences, training technique, and individual functional capacity. Most LW12's, double amps, are in the flat one. Most. Most LW10's, like Collet and Ana are like that (tucked in). People have tried, they've tried all kinds of differnt things and they generally tend to float back to whats been working.
Me	In terms of adjustability, how much room do we need to design for coarse adjustability, like huge magnitudes in figuring out where initially your most comfortable position is, and then fine adjustability to hone in that exact angle? Does a design need to account for coarse adjustability?
One	According to the rules, the sled cannot have any adjustable plates or slide. Before 2010 we had a wack of money from On-the-podium, we had a sled project from the university of lavall, you can talk to the office in Canmore, they have all the contacts, they basically built two mules. One for the knees up, negative femur angle, one for the flat angle. The mules had every angle adjustable, they weighed a ton but you could lengthen, shorten, raise lower, that just let them figure out instead of building 10 prototypes, you could put them in the mule, and figure out what they liked and weld up your prototype.
Me	That as a process, do you think that's effective in figuring out the course angles, and then switching to a lighter one?
One	For fine tuning, absolutely.
Three	Then you can at least get the template for what might work best for him, and start to build one, as opposed to having 10 - 20 different prototypes.
Me	I was thinking along the same lines, so here's one I whipped up this morning, and you can see in the bottom there you've got these areas for that coarse adjustmen, big angle changes. With this you might have a binding mount that would allow you to slide the bucket, so you can keep your center of gravity in the center of the ski. This is just to see, would something like this be of value as a step 1 phase?
One	Yes
Three	Oh it is, it's huge.
Me	Then lean it forward a bit, say this is the angle I like, this is the height I like, and figure out the position on the skis, then print out the lightest thing that can fulfill
One	Without the articulation
Me	Exactly, get rid of all that excess weight
One	With this design here, this is going to work well with your higher function abilities
Me	This is just something I whipped this together
One	Fair enough
Three	In theory you could have a different attaching seat or bucket
One	Seats, legholders, slings
	שבמנש, ובפווטועבוש, שוווצש

Three	Ana wouldn't really work in that one where Two would, that kind of stuff.
Me	I don't have a lot invested in this
One	But if you're building them, you're going to need to start that way, otherwise you would need 10 different
Three	You need a jig that gives you a direction of where to go.
Me	Do you have any ideas of how we could make transitioning in and out of the jig an easier process?
One	For wheelchair athletes? Transferring is part of their life.
Me	Is it something that they just have to deal with?
Three	Pretty much, they use other wheelchairs
One	we did some work with the guys in 2009 in Quebec and same thing we were in and out of that sled probably 100 times a day, adjust adjust adjust. Theirs was nowhere as refined as this one, theirs was all just little pins and and a tube with little holes in it
Me	That's all this is, just plates instead of tubes, the point is just that by adding pneumatics or stuff like that so that it could bump up by itself would add unnecessary weight, so I wasn't sure about the transfers, if that's just something they get used to. I know that the guy with the bike I just showed you, transfers for that are very difficult because he's up high, on a bike. So he needs two guys to lift him up. And I've seen Ana, her husband helps her get into it.
Two	Yeah, if it was reversed it would be a difficulty if Ana were doing it another way.
Three	She'd possibly do it for a longer timeframe
One	With my coaches toque on, if the athlete's end goal is to have a better sled, then that's part of the process. If the end result is to be a better skier, then you train for 100 hours on the ski erg, that's the deal.
Me	It wouldn't be impossible to design a modified car jack to put on the front and back end where they could use it to prop up the whole thing, take the weight off of the skis, let the ski drop when you pull out the pins,
One	Yeah, like jack stands.
Me	Yeah, is it worth designing something like that?
Three	It's a fitting process, so
Me	I'm wondering if we need to address this fitting process
One	It'll depend person to person, some will say not a problem, others.
Three	An athlete wil just say its part of the process. Recreational skier who just wants to say "where do I buy something?"
One	For the training plan today, 100 dips
Three	This guy last year, Martin, he used a some of our stuff, the one that Ana used, he's got the same similar injury. He ordered one from Spoke in motion, we were back and fourth, I gave them the specs, and they built one for him. He's quite happy for it, but might have been easier for him if he could have done some jerry rigging, but he just basically wanted to get a similar design he was using, but his own and feel better. He wouldn't have minded too much, but he's not in the lab part of the process.
Two	No matter what, if you jig it up and make an adjustment, I would never be able to tell unless I went out to ski for a while

	One	That's what we did back in Quebec, wein the lab back in Canmore, put them on the erg to get the position right, they'd say "well I think it feels right but I cant tell," so they'd throw them out on the mountain board.
42:10:00	Me	3D printed hand, this whole product came out from a carpenter who was missing a few fingers, and a guy who designed puppets, and they just came together, the carpenter explained that he just needed some fingers, and the puppeteer said, I could probably do that for you. So they came together and made a rough idea of this, and made the plans available online for free, and now 1,500 people around the world have received one of these hands. It's had a wider reach because you can make the plans available online, and you assemble it yourself. Do you think that there would be room in the marketplace for people who would download something online, 3D print it, and assemble it themselves? Or if the pieces came printed, and they assembled it themselves?
	One	The latter, I don't think (the latter sounding more favourable)
	Three	I think it depends on the handiability of the person, something like ikea furniture some people don't mind doing it, some people would hire someone to do it.
	Me	I'm curious about how that one guy you mentioned with the hockey sticks, who built his own, he's obviously pretty handy
	One	We're talking about building for two different levels here, if you're talking about people who just want to go skiing, probably CCA could buy a wack of them, and there's way less cost, absolutely, I would put it together myself. You go to the athletes, with the high performance model, and your athletes psyche is one of, well I wont categorize into ??carb longe 2??, some love to do their own things, Chris club is a prime example. He's thinking all the time, he's constantly designing. Some dont want to think they want someone to build it for them, and they want to trust that its rock solid. Some they can't handle that, that's out of their realm of capacity. So it would depend on the athlete.
43:50:00		
	Three	Chris is the guy that I mentioned, he has a company that builds stuff, he actually doesn't use one from his company, all the technology out there, he still tinkers in his garage with epoxy, wood and resin. And he's won world championships on it. He likes to tinker, but his company went through designing general recreational stuff. It's really great stuff.
	One	So the building part for clubs and divisions, I think that would be brilliant, but for the athletes in, they probably want to see it first and come check out the ones that someone else built because that's how athletes are, they are gonna wait see how it looks, how it feels.
	Two	If I were racing and I had a sit ski with all of the joints, I don't know if I would trust the joints with epoxy or
	One	(steps out of the room for a phone call)

He's going for the maximum lightness he can do, 5 lbs is too heavy if he can make it 4 lbs, that's the difference between an olympic vs.... I mean you do competitions in the sense of local stuff, but you're not winning champs. So there is a different market that way

45:45:00 How much do the recreational models weigh compared to the competitive models?

Two	The ones I have from Chris, they are about 6-7 lbs, they are quite light and strong. They are don't fit perfect but it's a very good alternative until someone gets their own. But I have seen recreational ones where they are just building with so much metal it's 20 lbs, Like I said, that's just too much. The world elite are not much less than 5 lbs, so there's not much difference. Even the one we purchased from the states, Chris has commented that company stole all of his designs, and then he said they made it wrong because the center of gravity is all off. I said its true, but its a compliment to you that they took your stuff. But we purchased it (the american one), and instantly last winter built one off of the same identical design, locally and knocked 2.5 lbs off of it. So it was just the construction tubing. (re enters the room)
Me	Price range. To me it seems the prices are still really high here to make the sport
IVIE	accessible for anyone to go out and just pick one up
Three	Well ignore the guys who say they had a dozen in their basement and could sell one for \$100 a piece, I'd like to see a \$100 a piece unit, but they were heavy
One	They were heavy, I think a lot of them were from the old alpine ski team where they were pulled them along, or they took the lift to the top of the hill.
Three	I heard that price and I thought, that seems too good to be true, because I'm going back to that one person a few years ago that built a similar frame to what we have but half the cost, so if they're \$1,500-\$1,600 but the first girl that tried a prototype the welding joint crimped, the tubing bent on her 110 pounds. And I thought well cool, it's half the price but it doesnt work so whats the point? I had no problem with the \$1,500 range, it would be cool if we could get less than that but
One	I think you could build two separate things, you could build a sit ski for clubs to get as you can, and then if you wanted to build the best sit ski possible for a performance athlete, then it's different. Then you're looking at more custom fit, way more lightweight, and then because there's more at stake, you're willing to pay for it. Like buying a bike
Three	you can get a \$150 bike, you can get a \$10,000 bike
Me	I agree, I think there are people out there that just want the \$150 bike and the \$10,000 bike, there are probably people that want the \$100 sit ski and the \$10,000 sit ski
Three	There's probably more interest than we think its just the availability of the product. Lets use that facility that rents equipment, and now they have grants to have some of their own in house
One	And we have a lot of family groups come through, and a lot of schools have kids with mobility issues

	Me	
		And for me, I don't see this stopping at sit skis, I don't see it stopping at one product, I see it as a methodolgoy of howe we start viewing the manufacturing and the process of how we customize things to unique individuals because everybody has a different injury and so everybody needs a different product, and how do we get that to people
	One	and you're not mass producing them
	Me	Exactly, we're not mass producing them but we've got 3D printing and unique distribution systems, fitting is a bit of a concern when you're talking about digital stuff, but what are some of the ways we can work around this stuff.
	Two	So how would you print the seat with a 3D printer? How would you get Ana's butt My experience with prosthetics
	Me	They do some interesting things with prosthetics where they do scanning and stuff like that
	Two	But ultimately the ones that work for me are where they haven't taken the scanning. That's why I wonder
	Me	So which process works best for you?
	Two	Where they actually cast my leg
	Me	with a mold
	Two	Not just a mold, but a mold that's made in several positions, a fairly bit of hands on contact with the muscles, and I'm not sure if that's based on technology, the people that build my legs are old school.
	Me	Oldschool, but there's a reason why it still works. MIT is doing an interesting thing. (shows the residual limb measure)
52:30:00		
	Me	This is probably one of the only methods I've seen that's been getting close to the plaster
	Two	Hugh Herr has a youtube video on this from MIT, and its quite neat, but my foot is \$60,000 right there and they've still got the rest to do
	Me	\$60,000 is a lot of money, tehre's a lot you can do with \$60,000. And if it's driven by a labor we can try to get technology to substitute that, but we shouldn't try to substitute it in for a lower quality product, it should be the same or better
	One	Absolutely
	Me	And I think a lot of the problems that we can sort out with sit-skis can also help wheelchair users one day because if we develop a new process for that we could develop a new process for wheelchairs. You know Ana tells me about how she got a wheelchair custom
	Three	"custom" (sarcastically), wasn't as good as her other one
	Me	Exactly, wasn't as good as her 10 year old one which is breaking, but her custom one which cost a lot of money
	Three	Derick tells me the same thing
	Me	To me how much wheelchairs cost is just ridiculous

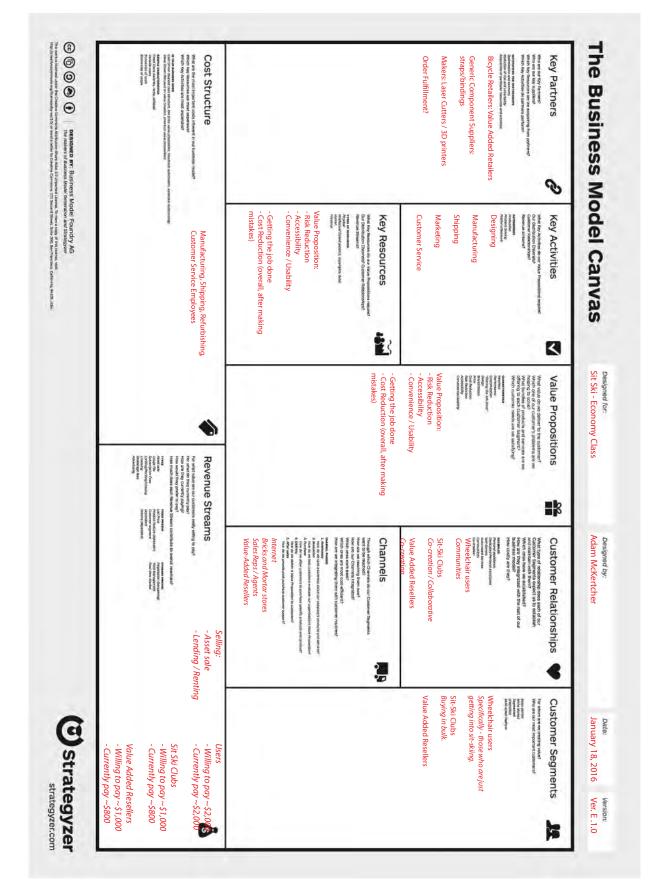
Two	But all this stuff is based on, I mean this little pump here gets billed out to ADL at \$3,000. I've got a sump pump in my basement in my basement for \$140 that's been working longer than this. And it's part of the research, you're paying for the future, past and there's no company that's just building sit skis.
Three	There's a few, but a very few. That's the question, people used to call me and say they didn't know where to go. There's a guy in vancouver who's owns a bike store, he does a great job, he says he'll build any design if they gave him one, but he's got, it's very recreational which is great for the general masses. And supposedly there's a guy in Quebec, there's a guy in Norway, there's a guy in France, but in the end there is a guy, but we don't know really where.
All	Laughter
Three	
	We hooked up with the prosthetic alpine guys a few years ago, but their mindset is that with alpine weight isnt a concern. He's an awesome person, a great designer, but then he got terminal cancer. But there's no Canadian Tire you can go to and pick one up. The spokes in motion in the united states is as good as any for availability, but we're starting to see more locally. You don't want to wait three years to get into this. Whereas with you (Two) you've skied your entire life and you call me up, and I can say I've got SOMETHING for you. And for two years he's been "this is pretty good."
Me	My vision for this is that if you're an athlete around the world, and say I want to get into this sport, what's the equipment out there, I know there's a website I can go to and see what's already made, and get it to my door in a week or two
Three	For the elite of the world, they will find it somehow
One	This all based on know-a-guy You know a guy who Who's this know-a-guy? I would love to Noah?
Three	And you go by experience, Tony the first one he bought, it was from Norway, and thought it's a skiing nation, it must be awesome, he jumped into the damn thing and he hated it and that's \$4,000-\$5,000 a pop and now he's getting another one built
Me	I think we need to bring down the cost, we need to make the products a lot better, it shouldn't be as difficult to get into these sports
two	or see if you want to get into it.
Me	Exactly.
Three	\$1,500 is a lot of money, but compared to his foot, compared to hand-bikes, compared to most of the affordable sports.
One	An apline sled, they're \$20,000 for a fully equipped world cup, GSTH sled
Three	So \$1,500 isn't tragic. So as an organization we've been able to get grants and purchase a dozen or more, but when he calls me and said "buy one for \$1,500" and next day I hate it, that sucks. But overall, most of the wheelchairs are crazy (for price). So you can keep the cost down, but most of all it has to be durable
Me	So cost is less of a driver
Three	It can't be ridiculous
One	Even if you were an athlete at a development level, \$3,000 for a sled, that's a big consideration, but you know you need something better to get you
Me	You need a sled for introductory level, you need a sled for intermediate, all of those are going to look different for how customizable they are will look different

One From my perspective, from the athlete development side, where everyone's challenge from the national team is, is recruitment. For para athletes, how do you sell a sport? It's cold, it's hard, it's 600 hours of training, it's not an easy sport to get into. Then you tell them you need a sit ski, and this and that, so if you can take any one of those steps, you can get more people into it. And from the athlete development side that can only do good things.

Three The recreational stuff was always twice as heavy, and they're the ones with generally low ability. So their first impressions are, oh my god this is too hard, I quit.

Continuous discussion about how heavy frames play a role in getting new people into the sport, and specialized bindings (One talks about bindings a bit more).

Appendix C - Business Model Canvasses



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Appendix D - Cost of Goods Sold

Cost o	f Goo	ds So	bld	

Cost of Goods Sold		
	\$	% of total
Aluminum Frame	140.00	38%
Plastic Buckles	75.00	20%
Labour	50.00	14%
Design Time	50.00	14%
CNC Time	33.00	9%
Plastic Bucket	20.00	5%
Total	368.00	

Appendix E - Photos of Prototype

See following page



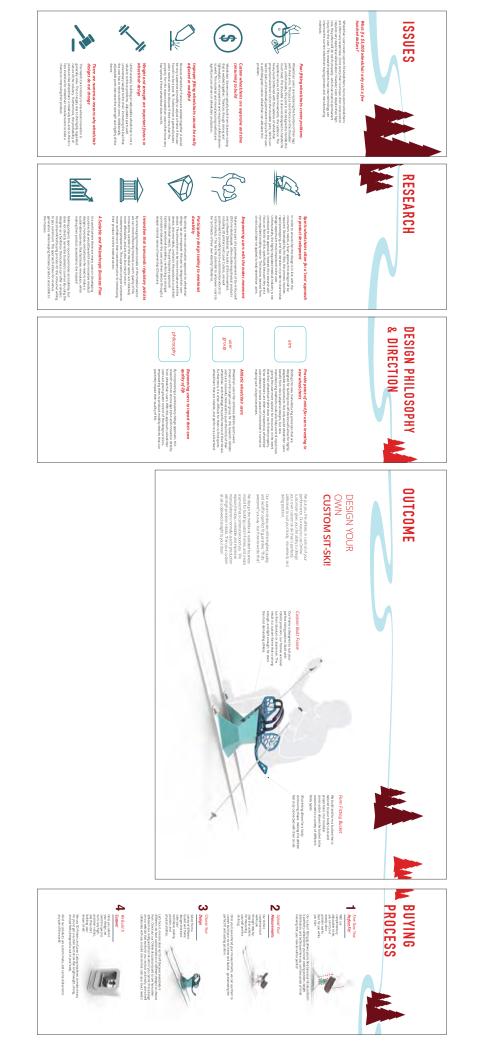






Appendix F - Exhibition Panels

See following page



Appendix G - Exhibition Photos

See following page

