

The Importance of Users in Prosthetics Design Process

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The medical device industry shifted from creating solely functional solutions to solutions focused on functionality and improving the quality of life for patients. This paper investigates the prosthetics industry and shows how the industry evolved to create new prosthetics that support people of varying lifestyles and ages via their methods of collecting user data and involving users in their design process. For example, Össur is a world leader in the prosthetic device industry. Össur claims to “focus its efforts and experience on helping people be confident, safe and mobile, regardless of injuries or conditions that could compromise their quality of life” (*Life Without Limitations*, n.d.). Prosthetic companies like Össur are very successful. They sought out user data to improve their products in order to improve the quality of life for their users. This thesis assesses how Össur and other prosthetic corporations became companies that develop cutting-edge prosthetic designs. It also evaluates how these companies understand, interpret, and collect data from their users in order to create these innovative approaches into their design process that focus on quality of life and functionality for their users.

Introduction to Prosthetics and User Influence on Design

Prosthetic companies like the Salem Leg Company during the Civil War took advantage of a rising market demanding for more durable and comfortable leg prosthetics. The rise in demand inspired Professor George B. Jewett to develop a new prosthetic leg. Being an amputee himself, Jewett knew from user experience that wooden fitted legs alone would not be sufficient to a lifelong use. The new prosthetic leg mimicked the shape and movement of a real leg and provided additional cushioning to the leg sockets for extra comfort (*The Salem Leg: Under the Patronage of the United States Government*, 1864). In this particular case, Professor Jewett was the user and the designer. He used his user experience from uncomfortable wooden

sockets to create a far superior design, suiting the user better. Around this point in time, the prosthetics industry boomed and took a turn focusing on user feedback to create new designs advancing to incorporate a variety of activities and lifestyles that the world sees today such as running, bicycling, swimming, or skiing.

Amputees: User Representation and Product Influencers

Hyysalo et al. in the chapter titled *User Representation* discusses the need and importance of incorporating users into the design process. This process of user representation can be exhibited in several fashions, whether it be from surveying or direct user design input. Users help to interpret how a product may be viewed prior to its release, which helps mature the design process to a point where it is maximally impacting the user group. Different sources of user representation can change how designers approach a project. In addition, the designers need to be mindful of users that are affected by the design but might not be directly using the product. There is a new focus on users being viewed not as subjects but as valuable members to the design process, now labeled as design participants (Hyysalo et al., 2016).

The ideas from Hyysalo et al. highlight the main framework throughout this paper. These ideas help show how the orthopedic companies are creating new dynamic designs for the prosthetic industry. They changed their focus on how to incorporate design input from their users. Companies incorporate user feedback and user data by reevaluating their current product designs and make adjustments accordingly. Companies also incorporate the user feedback and use data to directly inspire new design possibilities and products not originally on the market. Surveys, commentary, qualitative data, and user feedback are all used by the companies to develop the shift from merely functional and static prosthetics to adaptive devices suiting users with different lifestyles and activity aspirations (Hyysalo et al., 2016).

Schairer more specifically discusses the importance of users in the design process for prosthetics in her paper titled “Communities of Prosthetics Users and Possibilities for Personal Innovation.” Schairer argues that amputees have the best knowledge about how to operate and maintain prosthetics, and they share their knowledge and experiences with physical therapists and fellow amputees. The paper mentions scenarios where many amputees believe the best teachers for learning how to use an artificial hand or how to walk on a new prosthetic leg are actually the fellow amputees they meet at a clinic while attending a physical therapy session. Amputees share these tips amongst themselves such as how to walk differently to compensate for pivoting in one place (Schairer, 2011). This reinforces the idea of prosthetic users having the best experience and expertise of prosthetics. They know exactly what is wrong with the device and simple tricks on how to compensate for the problem, which is shown by several other interviews and examples in this work. Schairer also states, “groups of users play an important role in the innovation process” (Schairer, 2011). She continues to imply the power and influence amputees possess to change the prosthetic industry and the devices they produce depending on what they want and request. Amputees have built these communities of assistive technology that have collected and addressed many problems associated with current devices. Amputees own the best knowledge for how their devices can best improve. Their role is to share their knowledge with prosthetic device companies, which can be expressed through a variety of manners as discussed by Hyysalo et al.. These prosthetic companies take feedback and ideas from their target population, which are amputees, in order to develop the most optimal products that increase users’ functionality and enhance their everyday lives.

The ideas from Hyysalo et al. and Schairer are two separate sources for how users can be incorporated into the prosthetic design process. Hyysalo et al. focuses on the variety of ways

companies implement communication methods to gather user feedback or data. They then use this user data to innovate a current design based on a negative or positive result or to inspire a completely new product. Schairer expands on these ideas but specifically relates to the prosthetics industry itself. Amputees are product users who are experts on the devices they use daily. They possess the most up to date knowledge about how they want products to improve and what they want in a new device. Amputees influence the prosthetic market and new product design after a company gathers user feedback and data through one of the many forms of communication presented within Hyysalo et al.. The following thesis exemplifies the two literary works by incorporating both of their ideas and background into several case studies. The case studies focus on the different ways users are involved in the design process in order to develop optimal products and improve the quality of life for prosthetic users.

Össur Analysis: Integration of Users

Össur is a prosthetics manufacturing company that has developed some of the most diverse and effective prosthetic designs of the modern-day market. Össur is the second largest company operating in prosthetics in the world with a market share estimated at 23.5 percent (Össur, n.d.). Upon early research, Össur claims to “accumulate medical and biomechanical data during their development process” (*Össur 2019 Annual Report*, n.d.). This includes collecting data from users before the product is released and finalized. In fact, Össur “initiates and promotes clinical studies” in participation with scientists, users, and healthcare professionals (*Össur 2019 Annual Report*, n.d.). Often, a clinical trial is used to judge the safety and effectiveness of a design with the users’ feedbacks having a large effect on the reevaluation of the original design in order to improve usability (Bitkina et al., 2020).

An example of Össur involving users in the design process can be seen in the 2015 clinical test report for the RHEO KNEE, the mechanical knee component of Össur's lower limb prosthetics. Össur gathered user data from 13 participants and used a combination of four different questionnaires to evaluate the new device. They used a six-minute walk test to evaluate a faster walking performance and a PEQ questionnaire to determine the users' overall perceived quality of life and experience to support the new device being more advantageous, less exertive, and natural for the users (*RHEO KNEE XC Clinical Test Report*, 2016). These tests specifically focused on quality of life for each user and gained feedback about how the new device compared to the existing prosthetics. The RHEO KNEE clinical test conducted in 2015 allowed Össur to obtain user feedback and data in order to modify their design before its full product release that following year in 2016 (*RHEO KNEE XC Clinical Test Report*, 2016). Össur uses data to confirm the usability of its devices and improves them based off user data before they are released into the market. The prosthetics users indirectly modified the design of the product based on their user feedback presented over questionnaires and physical tests.

Traditionally, most prosthetics devices are “designed and hand-crafted by orthopedists,” which leads to a product varying in quality due to the “specialists’ skills and experience” (Barrios-Muriel et al., 2020). More advanced companies use more elaborate methods of measuring amputees’ morphology such as CT scans and 3D anatomical data acquisition technologies in order to gather user data for precise fitting. They also incorporate computer assisted manufacturing techniques for rapid prototyping such as powder bed 3D printing and selective laser sintering (Barrios-Muriel et al., 2020). Össur is able to differentiate its self from other prosthetics companies because it can afford to incorporate these advanced techniques allowing for a focus on product precision for each individual user. Additionally, Össur listens to

amputees demands and needs in order to develop new devices improving their quality of life and functionality.

Markus Rehm is a competitive Paralympian long jumper fondly nicknamed “The Blade Jumper.” Markus set the world record long jump for amputees in 2018 and won two consecutive gold medals in 2012 and 2016. At the time, Markus used an Össur prosthetic leg specifically designed for sprinting. Össur wanted to create a better product. The company knew the incorporation of a user into the design process would help create an even better product. Therefore, in 2018, Össur reached out to Markus Rehm. They asked him to collaborate with the design team at Össur to help construct a new product specific to long jumping. With the assistance and advice from Markus Rehm, Össur released a new product in early 2019 called the Cheetah Xpanse. Markus collaborated by requesting for a blade “specially designed for jumping” while also being a test subject for the new product throughout development in order to provide more feedback to the developer team (*Paralympics*, 2019; *Science of Paralympic Long Jump*, n.d.). This example is one of many where Össur has incorporated an amputee directly into the design process. While the incorporation of users is not unique within the prosthetic design process among varying companies, Össur stands out in this particular case where they sought out a prosthetic user with specialized knowledge about the type of product they strived to create. With Markus’s specialized user experience and specific needs, Össur used his advice and feedback to develop an optimal new product for their company. For Markus and other fellow amputee long jumper enthusiasts, the Cheetah Xpanse will help them pursue an activity that gives them enjoyment to their lives by further improving their functionality for the sport they love.

Hanger Analysis: Custom Products and User Influence

Össur is not the only prosthetic company to take advantage of prosthetic users to create new products or innovate existing devices. Multiple companies experienced the shift to involve amputees in the design process such as Hanger, which is a leading prosthetic care company in the United States in terms of its size and profits earned from its two million patient encounters per year at its approximately 800 locations (*HANGER - Investor Relations*, n.d.). Hanger takes the incorporation of amputees into the design process farther than the generic prosthetic company. They personally customize all of their products for each of their users to ensure the most optimal fit using 3D scanning technologies and CT scans, similar to Össur's modern prosthetic design techniques (*Limb Loss Above the Knee*, n.d.). Many of Hanger's competitors only have sizing charts and premade devices for their customers. Hanger "custom-makes all sockets, knees, and feet to be specific to each users' limb and activity level," thus suiting all patients' needs (*Limb Loss Above the Knee*, n.d.). At Hanger, every product involves the user in the design process. Amputees can share how active they are to receive more flexible and durable joints on their prosthetics. Also, the designers take 3D scanned measurements from the users' body, which is then directly incorporated into the exact shape and contour of their socket, the fabrication of their artificial foot, and other components of their new prosthetic (*Limb Loss Above the Knee*, n.d.). At Hanger, the users are directly involved in the creation of their own crafted prosthetic ensuring comfort, durability, and optimal functionality. Hanger is successful in the United States' market because amputees know they produce superior products that involve their own feedback, personal requests, and personalized care.

Much like Össur, Hanger also developed new products directly inspired by and created for an individual user. Hanger specifically shares a story about the development of a new prosthetic arm designed for a young girl named Giovanna Dubuc who was born with a partial

right arm. When Giovanna was seven, she strived to become a violinist. However, this goal required functionality she previously could not perform with or without her original prosthetic arm design. With 800 service locations in the United States, a Hanger fabrication clinic is near most urban centers. Due to its convenient proximity and nationwide reputation for creating quality customized products, Giovanna's parents reached out to the Hanger Clinic in Charlotte, NC. The engineers worked with Giovanna to develop their company's very first, custom-made prosthetic arm enabling her to play the violin (*Giovanna Dubuc, 2019*). Giovanna was the direct inspiration for this product design. It is now used for all amputees reaching out to Hanger and desire to play the violin. She was directly involved in the design process while they "worked and tweaked" the design to her requests such as "making the prosthetic slightly longer than her real arm to help the bow move better" (*Giovanna Dubuc, 2019*). Giovanna is a prime example of a prosthetic user seeking to develop a new prosthetic for her wants and needs. The company's reputation for incorporating users into the custom design process and its convenient accessibility throughout the United States reeled the Dubuc family in as new client. Her collaboration on the design of this product contributed to developing a device that enhances her functionality by enabling her to enjoy an activity she pursued. The users of prosthetics continue to incorporate their feedback into the design of new devices that improve the quality of their own lives.

Novel Prosthetic Technologies and User Personalized Design

The prosthetic industry continues to develop new and exciting devices that seem to enhance user functionality. Most importantly, the most successful businesses are those developing innovative devices which incorporate amputees into the design process. Open Bionics is a biotech startup company based in the UK who develops bionic arms for users with below the elbow amputations. Open Bionics was created by Joel Gibbard and Samantha Payne

with the vision to create a more affordable and functional bionic arm for their users. With this vision of affordability for all users, they developed the first prototype Hero Arm which was 3D printed using PLA as the main material. The Hero Arm continues to be the world's top selling myoelectric prosthetic arm and won the company multiple new startup awards such as The Europa Award in 2018 (*Our Story*, n.d.). This inexpensive design drastically brought down the pricing to \$3,000 from around \$50,000 of the next level competitor with the same functionality (Inglis, n.d.). It was a successful design because it took users heavily into consideration for cost as well as construction time and functionality.

In an interview, Samantha Payne commented about the user involvement for the Hero Arm design. She stated, “we’re working really closely with the amputees not just designing a solution for them, they’re helping us design the solution” (Shamo, n.d.). Each Hero Arm is uniquely crafted for each user. A 3D scan allows the engineers to develop a custom fitted arm aligned with EMG electrodes specific to each users’ muscles on their upper arm. The user’s software is then calibrated specifically to incorporate the patient’s “strongest muscle sites” for these electrode locations (*How Does a Bionic Arm Work?*, n.d.). The Hero Arm product incorporates the users into the design process by using their personalized data to fabricate an optimal prosthetic which enhances their functionality. This design itself gives users the ability to control grip strength with high precision via the myoelectric sensors and allows users to personalized their own control software via an app to create specific grips and movement speeds (*How Does a Bionic Arm Work?*, n.d.). The Hero Arm also comes with the ability to swap out the outer casing for a more stylistic design. The company comments that they took this aspect into consideration for adults and children who might feel self-conscious about their disability and device, thus giving them the ability to express their personality by building their own unique

style (*Meet the Hero Arm*, n.d.). The fabrication of the Hero Arm focuses on the importance of the user and incorporates them into the design process via customized fitting, control, grips, and style which is then associated with a lower construction cost. As the modern-day prosthetic industry continues to advance, more devices are personally customized in order to fabricate a device that improves their everyday lives in ways only the association of individual users in the design process produces.

The user population inspired other customizable prosthetic technologies. As mentioned in the Hero Arm section, many amputees, but not all, feel self-conscious about their assistive technology and physical limitations. Because of this, a new market population formed and companies began to design cosmetic accessories for prosthetic limbs that would conceal the user's prosthetic with artificial skin. For example, Touch Bionics developed an attachable skin sleeve called i-LIMB Skin. This technology can be customized to fit around any prosthetic limb such as a myoelectric arm like the Hero Arm. I-LIMB "flexes like human skin" and has options to include hairs, skin pores, freckles, and change the skin tone while also incorporating life-like nails and wrinkles (Connolly, 2008). Amputee communities expressed their desire to conceal their disability. The users drove the prosthetic industry to create a new cosmetic product which suited their social and emotional needs. In addition, the development of such technology involves the participation of the user. The users choose what additions they want to include into their skin sleeves, and their measurements are directly used to sculpt the shape and size of the prosthetic skin covering.

Discussion: Users in Design and the Future of Prosthetics

Prosthetic designs were originally developed to temporarily provide function back to patients who were unlikely to survive for very long. Due to modern technology and medicine,

amputees and humans in general are living longer and require more durable and comfortable prosthetics. The prosthetics industry continues to enter a new business era focused around the creation of products that not only provide functionality but also improve the comfort and quality of life for amputees. To create the best designs for these new products, these companies have found new ways to involve amputees into the development of their new products. Amputees are no longer just users. They are valuable “design participants” who can contribute to the development of new products in a variety of manners (Hyysalo et al., 2016). Amputees have the best understanding of their own impairments and can provide valuable feedback for medical device companies to develop new products, thus suiting their new needs and desires (Schairer, 2011).

At Össur, users provide feedback for new devices through a variety of means such as study trial questionnaires and in some cases the users even provide design parameters such as Markus Rehm. Hanger similarly follows this trend by incorporating clients into the custom design process and development of their new devices such as the prosthetic arm requested by Giovanna for playing the violin. Össur and Hanger both produce novel devices and innovations that improve the quality of life for amputees by allowing them to participate in life activities that they enjoy or enhance their functionality even further. Other technologies like the Hero Arm are influencing the prosthetics industry to turn towards a more personalized approach using modern, computer-assisted manufacturing and design techniques. Users are shifting to assist in the design of their own devices via their own requests and through the collection of their personal data. Each prosthetic is catered for one user alone. Lastly, new innovations such as the i-LIMB skin were directly created and inspired by users due to various amputee groups expressing their

emotional and social desire to conceal their disability beyond a functional prosthetic. Innovations such as these life-like, skin sleeves give foresight to where the prosthetic industry is headed next.

The next generation of prosthetics will involve more specifications that are personally tailored for each user and will incorporate more bionic technology. In addition, the prosthetic industry will continue to bring in users to assist in the design process. For example, there are already products in development to incorporate amputees' own muscles and nerves into prosthetic designs, thus improving functionality even further (Aman et al., 2020). The innovations of the future aim to bring back even more control and normalcy for their users which continues to build a better quality of life for amputees through their involvement in the creation of new products.

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