Development of prosthetic device based on engineering design approach

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Abstract

Engineering design with innovative characteristics that offer additional benefits to the customer is a process consisting of complex activities that require research, planning, and systematic methods. A prominent product development process has been driven by technological innovations used to assist the disabled in acquiring greater autonomy and performing daily tasks. Assistive product development has ensured the disabled more excellent prospects, contributing to providing or expanding the functional abilities of people with disabilities, resulting in the promotion of independent living and inclusion. This paper aims to develop a prosthetic device to aid patients with hand agenesis in practicing swimming based on the engineering design approach. The assistive product development was made based on the four phases: (i) demand perception, (ii) product projection, (iii) product characterization, and (iv) optimization. In addition, it was used for Monte Carlo simulation, multivariate analysis, and tolerance interval analysis techniques in the product development phases. We developed this approach as an alternative to classical engineering design used in the additive manufacturing process for prosthetic devices. The assistive product set aims to significantly stimulate the hand agenesis patient in physical activity, representing one of the doors of entry for social inclusion, providing a better quality of physical and emotional life for the individual with a disability.

1. Introduction

The product development process is a complex activity involving several interests and skills to meet consumer expectations. Therefore, the product development process requires research, careful, precise, detailed control, and systematic methods with an interdisciplinary approach from different organization sectors. This multidisciplinary approach allows the strengthening of the flow of information between people from other areas of knowledge (Baxter 1995; Palmer 1990; Chen et al. 2015). Developing a product with new or different characteristics that offer additional benefits to the consumer is based on a collaborative procedure between design, production, and support, whose concept is the philosophy of simultaneous engineering. This systematic approach to product development seeks to induce the participation of several teams in an organization in activities constantly and simultaneously, starting from the initial phases, considering all elements of the product life cycle, including those found during the product development phase. manufacture, distribution, and use of the product (Ulrich 2016; Fernandes et al., 2017; Pessoa & Becker, 2020). Design For Six Sigma methodology allows the developing products with performance levels Six Sigma in production with predictable costs and risks and provides means to accelerate innovation (Tennant 2002; Dodziuk 2016). Design For Six Sigma methodology has presented several methods in the literature; however, all processes have common goals: to develop a robust product and meet the needs and consumer satisfaction.

Cudney and Furterer (2012) argued that the design for six sigma methodology is a compilation of several methods and an integrated set of tools to design and develop products and services that include three important aspects that must be balanced without compromising consumer satisfaction: (i) maximizing profit; (ii) minimize the development time and (iii) minimize the cost of product development. Hasenkamp and Olme (2008) asserted that design for six sigma directs efforts to the essential aspects in a systematic way from the beginning of the product. Antony (2002) mentions that design for six sigma allows the introduction of new products, processes, and services in a more efficient, reliable, and capable of meeting customer expectations and requirements, eliminating steps or functions that do not add value to the design of the product or service, with the application of statistical tools to predict and improve quality before the construction of prototypes. Francisco et al. (2020) present a systematic literature review about design for six sigma based method oriented to the product development process, highlighting that the application of engineering tools and effective statistical techniques is one of the pillars of the design for six sigma to improve performance in the development of new products, allowing the organization to meet consumer expectations. Some examples of engineering and statistical techniques applied to different phases of the Design for Six Sigma: Quality Function Deployment (QFD), Design of experiment (DOE), Failure mode and effect analysis (FMEA), Statistical Process Control (SPC), Simulation, Tolerance Design, among others. Figure 1 shows the systematic procedure based on the synergy of engineering design integrating the product development process and design for six sigma method,

The success of a for-profit organization is linked to its ability to identify the needs of the consumer market and develop products that can serve it. The growing competition in the business world and product complexity leads organizations to find new paths in the product development process, mainly to reduce the time involved in the development, increasing quality and competitiveness in the business market. Among the activities involved in the product development process, the use of a physical prototype has become an essential part of this process, as it helps to reduce the possibility of failures, improve the quality of the product, and facilitates the communication process between the people involved in the development of the product. The emergence of new technologies has contributed to this product development process, with additive manufacturing or 3D printing being a key element in the product design stage. Additive manufacturing is a process that is characterized by the addition of materials through successive layers from a Computer-Aided Design (CAD) model of the object to be manufactured, encompassing technologies of rapid prototyping, rapid tooling, and rapid manufacturing (Chua, 2003; Gremyr, 2005). The use of additive manufacturing is one of the pillars of industry 4.0, which integrates the recent technological inventions in Artificial Intelligence (AI), Communication, and Information technologies, among other domains, to increase the levels of automation, efficiency, and productivity of production, manufacturing and industrial processes. Several industrial segments have benefited from the improvement of additive manufacturing, such as automotive, aeronautics, and health. In the health segment, additive manufacturing has been applied in the production of assistive products, personalized implants and medical products (Thomas et al., 2022), and orthoses (Edelstein, 2006). Orthoses are an example of assistive products, which are devices external to the body that are available on the market or manufactured especially for the disabled, capable of offering support, preventing, compensating, controlling, mitigating, or neutralizing deficiencies and limitations in activities (Pudles 2014; Zhang & Thomson, 2019).

Several people around the world have a disability. About 6.7% of the population in Brazil has physical, visual, or intellectual disabilities (Heller 2004). Being disabled has a double challenge: the first to learn or relearn to live with the “abnormality,” the second to face the barriers imposed by society. Based on these two challenges for a person with a physical disability, assistive technology, and additive manufacturing have become great allies, helping disabled people to have new perspectives through the development of prosthetic devices suitable to the individual's characteristics and needs at a more affordable cost, contributing to providing accessibility and dignity to the disabled. Assistive technology is defined as a set of resources and services that provide or expand the functional abilities of the disabled with a wide range of equipment, services, strategies, and practices designed and applied to alleviate the problems encountered by the disabled by promoting independent living and inclusion (Schein 2021).

Foley (2017) asserts that the disabled person is more susceptible to secondary health problems such as depression, anxiety, obesity, pain, fatigue, contractures and deformities, urinary and respiratory tract infections, and physical activity is vital for their rehabilitation and prevention. Swimming is a versatile sport for this population, being recommended for treating an acute injury or promoting health and high-performance sports. However, the participation of the disabled person in swimming is limited by a multifactorial set that includes personal and environmental aspects. Vergeer et al. (2021) emphasize that inclusive sport is an efficient way of stimulating the practice of self-esteem, self-expression, and self-confidence, as it represents one of the doors of entry into society, improving the quality of life and the individual's physical and emotional health.

This paper proposes the development of a prosthetic device for patients with hand agenesis based on engineering design approach for swimming activities, integrating the product development process and design for six sigma. In addition, it was used for Monte Carlo simulation, multivariate analysis, and tolerance interval analysis techniques in the product development phases. We developed this approach as an alternative to classical engineering design used in the additive manufacturing process for prosthetic devices.

2. Background

Developing new products becomes real based on a need observed in the market. In this sense, this article applied the steps of product development to design an assistive product that aims to assist in learning a sport like swimming. This prosthetic device seeks to provide the apprentice with hand agenesis deficiency with more excellent safety and speed in learning to swim or to use the device for regular physical activity. Emphasizing that the prosthetic device developed is not intended for use in sports competitions. In this context, this section aims to present an understanding of the topic of hand agenesis and assistive technology.

2.1 Agenesis of the upper limb

People with physical disabilities can benefit physically from using prosthetic devices to develop daily tasks and obtain psychological benefits. However, most prosthetic devices are expensive, complex, and inaccessible to those who have few resources. A prosthetic device must be accessible and intuitive, and suitable for the daily tasks that a user must perform. Cases of agenesis of the upper limb can be traumatic due to traffic accidents and accidents at work - in the latter, there is an amputation of fingers, hand, and arm. In children, the most common causes are due to congenital malformation and tumors. In middle-aged adults, agenesis of the upper limb occurs due to direct trauma or accidents and chronic infections; in the elderly population, the significant causes of amputations occur due to diabetes with gangrene (Okumura and Canciglieri Junior 2017).

The physical disability of the upper limb is classified according to medicine through the level of amputation represented by the location (Loewenstein et al., 2021). Figure 2 shows the different levels of amputation. Regardless of the origin of the agenesis, the use of a prosthetic device allows greater autonomy in the performance of routine activities and improves the self-esteem of the individual with the disability. Specifically, this paper is directed at developing a prosthetic device for the sports activity of swimming for the hand agenesis deficiency in the level of wrist disarticulation, presented in Fig. 2.

2.2 Assistive technology versus social inclusion

Assistive technology emerged with rehabilitation engineering out of the need to improve the prostheses and orthoses of disabled military personnel in the 1940s. Assistive technology is an area of knowledge with an interdisciplinary characteristic, which encompasses products, resources, methodologies, strategies, practices, and services that aim to promote the functionality related to the activity and participation of the person with disabilities, disabilities or reduced mobility, aiming at their autonomy, independence, quality of life and social inclusion (Brazil 2009). Cook et al., 2020 assert that assistive technology can also be defined as the entire arsenal of resources and services that contribute to providing or expanding the functional skills of the disabled and consequently promoting independent living and inclusion. Assistive technology applies technological advances and technical knowledge from professionals from different areas who interact to restore human function or enhance the abilities of the disabled, which extends in the scope of manufacturing, use of equipment, resources, or strategies.

Thus, assistive technology assists disabled person who needs to perform tasks in different spaces in their daily life, both in self-care and professional activities. Assistive products are any products including devices, equipment, instruments, and software, specially produced or generally available, used by the disabled to compensate, protect, support, train, replace bodily functions / alleviate or neutralize the carrier's disability, disability, or handicap, allowing the achievement of their autonomy and more active participation in society. Therefore, the interaction of the user of the assistive device between people with and without disabilities becomes more frequent, favoring human diversity and social inclusion (ISO 2020; Okumura and Canciglieri Junior 2015).

2.3 Social inclusion versus Sport

Physical disability is a theme that has gained notoriety and importance in society in recent years. However, it still lacks understanding and acceptance because there is still prejudice and discrimination due to the easy use of the term. Several people contact the universe of disability when there is a direct or indirect approach to a carrier. The social inclusion of people with disabilities through sport allows individuals to understand their physical limits and seek motivation to overcome them. Sport provides development in the physical, psychological and social aspects of the individual, being empowered for the disabled, as it means an opportunity for change (Labronici et al., 2000; Levermore, 2008; Foley, 2017). The practice of physical activity provides significant improvements in the quality of life and health of the disabled, playing an important role in reducing the occurrence of health problems secondary to the disability, such as symptoms of anxiety and depression, as well as increasing general well-being of people with disabilities (Cooper et al., 1999; Durstine et al., 2000; Heller et al., 2004; Lui and Hui, 2009). According to Vieira (2018), the disabled person faces several obstacles to physical activity and a lower level of involvement than people without disabilities. The barriers to the practice of physical activity and sport by the disabled are multifactorial, covering personal, environmental, and psychological aspects. Loewenstein et al. (2021) and Vergeer et al. (2021) mention that the practice of physical activity allows people with disabilities to test their limits and potential, preventing secondary illnesses and promoting social integration.

Swimming is a physical activity composed of motor skills that seek to provide the individual with autonomous, independent, safe and pleasurable movement in the liquid environment. Learning to swim initially requires a familiarity with the liquid environment, development of the domain of balance, fluctuation, correct breathing, and propulsion. The practice of swimming can have a competitive purpose or improve physical conditioning as well as a form of relaxation (Gallahue 2005; Fernandes et al. 2017). The physical activity of swimming provides the disabled with benefits such as reduced spasticity, improved blood circulation, maintenance or increased range of motion of the joints, re-education, and stimulation of paralyzed muscles, development of motor coordination, improved balance and body posture (Skinner 1985; Lui and Hui 2009; Foley, 2017). In this context, developing a prosthetic device to assist in learning swimming seeks to break the obstacles faced by the hand agenesis handicap, providing the individual with an opportunity to integrate into physical activity.

3. Research Method

The methodological approach applied in developing the assistive product is described in Fig. 3. The development approach uses four stages: *i*) demand perception, which seeks to identify the opportunity to develop an assistive product for people with hand agenesis, following with the outline of ideas and feasibility analysis; *ii*) product scope, with acquisition and analysis of product requirements through a questionnaire and application of a product development tool; *iii*) product characterization, which seeks the conception of the assistive product to meet the characteristics identified in the previous step and finally; *iv*) optimization, seeks the application of statistical techniques to parameterize the sizes of the assistive product in small, medium and large.

In the development process of the prosthetic device, the application of statistical techniques stands out, which allowed the optimization of the product. For the optimization stage, the software Minitab® was used to apply the Monte Carlo simulation, Multivariate Analysis, and Tolerance Interval analysis techniques. Through Monte Carlo Simulation, data were generated for subsequent application of the multivariate analysis technique by the *K*-means algorithm, which is considered in the literature as the most popular and simplest among partitioned algorithms, in addition to converging with few iterations for a stable configuration. The *K*-means algorithm is a non-hierarchical grouping heuristic that seeks to minimize the distance of the elements to a set of *K* centers, given by $X = \{x_1, x_2, ..., x_k\}$ in an iterative way. The distance between a point p_i and a set of clusters is given by $d(p_i,$ □$)$, which is defined as the distance from the point to the nearest center. The function to be minimized is given by Eq. (1):

$$\boxed{d(P, X) = \frac{1}{n}\sum_{i=1}^{n} d(P, X)^2 \qquad (1)}$$

The *k*-means method consists of 3 steps: (i) arbitrary partitioning of items into *k* initial groups; (ii) relocation of each item in the group with an average distance from the nearest centroid; the Euclidean distance is generally used. The centroid recalculation occurs for the group that received the new observation and for the group that lost some observation; (iii) repetition of the step (ii) until there ithe the s no observation to be relocated. The mean distance is a Euclidean measure calculated by Eq. (2):

$$\boxed{d(x, y) = \sqrt{\sum_{i=1}^{p} \left(x| i - y_i\right)^2} \qquad (2)}$$

where: x_i, y_i are variables of the items and d is the Euclidean distance.

Following the multivariate analysis technique, an analysis of the tolerance intervals was applied to determine the lower and upper limits of the study variables for product parameterization.

4. Development Of The Prosthetic Device

The development of the prosthetic device for swimming used the development approach presented in Fig. 1, established by the stages: i) demand perception; ii) product scope; iii) product characterization; and iv) optimization, which will be detailed below.

4.1 Demand perception and Product scope

The development of the assistive product began with identifying the opportunity to develop an assistive product aimed at the practice of a sports activity by the hand agenesis sufferer in partnership with the Association *Dar a Mão*. This association was created with the main objective of giving support in the granting of prosthetic devices at no cost to children, adolescents, or individuals who were born with Limb Agenesis (physical disability), affected by Amniotic Band Syndrome, Simbraquidactilia, or other rare syndromes/diseases, or who suffered amputations (Okumura and Canciglieri Junior 2015). The proposal arose from the opportunity to serve this audience to develop a prosthetic device to assist patients with hand agenesis in learning the individual swimming sport. Figure 4 summarizes the activities carried out in the stages: demand perception and product scope.

Rese et al. (2015) cite that the exploration of the knowledge of the needs and problems of users and customers are the main sources for the generation of innovative ideas and that the instruments of the Voice-of-Customer (VOC) technique are generally easy to use and useful to bring together customer needs and expectations. Diverse VOC mechanisms are reported by authors (Cooper 2010; Creusen 2013; Rese et al., 2015; Goetz et al., 2020; Benabdellah et al., 2020) to understand and explore this knowledge. For the development of the prosthetic device for swimming, the instrument applied to understand the user's needs was a research questionnaire aimed at the product's end-user, such as patients with hand agenesis and swimming teachers with experience with apprentices with physical disabilities.

The brainstorming technique was also applied to agenesis specialists to understand better the user's needs for the ideal prosthetic device. From the knowledge exploration, it was possible to apply the Prioritization Matrix tool to assess the interviewees' important requirements. The prioritization matrix assists in decision-making by defining, with criteria, the level of importance of the product's characteristics (Canciglieri Junior et al. 2015). Figure 5 shows the prioritization matrix applied in this study. The characteristics, width, length, and thickness were based on the result obtained.

4.2 Product characterization

In the product design, the objective was to identify the product's main functions to be developed by analyzing similar existing products. During the research, it was possible to observe the existence of a prosthetic leg for adults to practice swimming. From identifying the relevant characteristics observed in the prosthetic leg that could be implemented in the design of the prosthetic device in this study, it was possible to create the concept of the prosthetic device for the upper limb.

After creating the product concept, 3DS Max™ and Solidworks™ software were used. The initial step consisted of creating the component coupled to the stump of the disabled with a simple fitting concept for later coupling to the hand paddle. In this step, a generic virtual model of a scanned arm was used to assist in modeling the stump geometry. In Figs. 6(a)-(c) the sequences of the steps performed to reach the final proposal for molding the stump coupling are presented.

For the development of the hand paddle, a manual drawing was first made with the configuration of the human hand in the shape of a shell (shape of the human hand during the stroke). Based on the manual drawing, it was possible to create a surface in the 3DSMax™ software. Figures 7(a) to (f) show the evolution process of modeling the hand paddle surface.

After completing modeling the non-parametric geometries of the device's stump and hand paddle component, the drawings were exported to the SolidworksTM software and edited. Following the product concept development, a locking mechanism was created to support the efforts to be applied to the product's hand paddle. In this way, a male-type fitting was designed on the stump coupling piece and a female-type fitting on the hand paddle. Figures 8(a)-(b) show the stump and hand paddle components developed for the prosthetic device for swimming, as well as the male and female fitting. In Fig. 7(c) a better understanding of the fitting mechanism of the prosthetic device is possible. The rectangular geometry of the fitting was chosen to prevent rotation between the coupling components of the stump and the hand paddle.

A third component was designed for coupling in the inner region of the hand paddle. This component aims to reproduce the concept of the thumb of a human hand, to allow the user to be able to hold a swimming board through the pressure mechanism. Figures 10(a)-(b) illustrate the thumb component and the attached hand paddle and thumb set, respectively. This set will allow the user to fix the swimming board to enable the process of learning and training the kick and breathing movements. Figure 10 shows the assembled prosthetic device in different positions with all components of the developed product.

4.3 Optimization of the product

At this stage, the specifications for dimensional parameterization of the prosthetic device were determined in the sizes, small (S), medium (M) and large (L). Initially, a range of measurements was established for the important characteristics for parameterization of the dimensional, S, M and L. The variables considered were: the height and width of the palm, the circumference of the wrist and the length of the forearm, based on the measurements of the human hand. In addition to these variables, a measurement interval was established for the thickness of the hand paddle of the prosthetic device, based on the thickness of the swimming hand paddles existing on the market, whose thickness is 0.3 cm.

Figure 11 illustrates the variables considered for analysis of the dimensional parameterization of the prosthetic device's hand paddle, representing the human arm and hand. Table 1 shows the measurement intervals established for the application of the simulation. Based on these intervals, the Monte Carlo Simulation technique was applied to generate 5,000 iterations of each study variable. In this analysis, the uniform continuous distribution for data iteration was selected, as it is a distribution that models an equally probable range of values.

Table 1
Reference dimensional parameters for prothetic device

Dimensional parameters (cm)						
Variables	**Small**		**Medium**		**Large**	
	lower	upper	lower	upper	lower	upper
Width_Palm	6,5	9,0	9,1	13,0	13,1	18,0
Height_Palm	11,0	15,0	15,1	18,0	18,1	21,0
Circumference_wrist	11,0	13,0	13,1	17,0	17,1	21,0
Length_forearm	14,0	17,0	17,1	22,0	22,1	26,0
Thickness_ hand paddle	0,3	0,5	0,3	0,5	0,3	0,5

Following the Multivariate Analysis technique, a cluster analysis was applied to group observations into subsets. This study selected a final partition with 8 clusters (cluster k = 8). Table 2 presents the cluster analysis results with the eight divisions obtained for the parameters' prosthetic device to Small size. Likewise, Tables 3 shows the results for Medium size, and Tables 4 presents the results for Large size.

Table 3 presents the results of the cluster analysis about size Medium size. Cluster number 6 was selected from the nonparametric statistical method to present the best dimensional measures for prosthetic devices in size S.

The information in Tables 2 (a), 3 (a) and 4 (a) show the cluster number in the first column, with each cluster associated with a combination of study variables that can be parameterized for the prosthetic device. The second column shows the number of observations in this data cluster. The following columns explain the sum of squares of each cluster, the average distance of the observations from the centroid, and finally, the maximum distance of a single observation to the centroid. The objective is to extract the centroid with greater homogeneity, observed by the variability of the mean centroid distance and the sum of squares of the clusters.

Thus, the most appropriate clusters were selected, following the following criteria: (i) homogeneity, (ii) number of observations, and (iii) the most appropriate centroid measure in terms of the parameter expected for the proposed objective. The results for the cluster centroid for the parameterization of measurements S, M, and L obtained by multivariate statistical analysis using the *K*-means method, are highlighted in Tables 2, 3 and 4.

Table 2
Results of Cluster analysis for dimensional parameters - Small Size

Cluster centroid analysis – Size S								
	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	**Cluster 6**	Cluster 7	Cluster 8
Final Partition (*n*)	622	689	618	669	541	**613**	593	656
Variables								
Width_Palm	8.3441	8,.562	8.4004	7.1338	7.1469	**8.3888**	7.1189	7.5182
Height Palm	14.0923	12.1709	13.8911	12.1068	11.7745	**11.8250**	14.1815	7.1003
Circumference_wrist	11.9820	12.0090	12.0248	12.0820	11.9681	**11.9831**	11.9483	0.3961
Length forearm	16.2740	16.3208	14.7192	14.7886	16.2614	**14.7754**	14.7938	12.0813
Thickness_hand paddle	0.4025	0.3988	0.3968	0.4044	0.3996	**0.4015**	0.3995	13.8081

Table 3
Results to Cluster analysis for dimensional parameters - Small Medium

Cluster centroid analysis – Size M								
	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	**Cluster 6**	Cluster 7	Cluster 8
Final Partition (*n*)	610	656	622	652	638	**656**	615	643
Variables								
Width_Palm	12.1036	10.0533	11.9356	11.9645	10.1672	**10.0094**	9.93a86	12.0244
Height Palm	16.4207	16.4984	16.7257	16.5405	16.6034	**16.4936**	16.5637	16.6146
Circumference_wrist	14.0671	16.0863	15.9720	14.0525	14.0636	**14.1455**	15.9957	16.0402
Length forearm	20.6898	18.1434	20.8191	18.2871	20.8681	**18.3497**	20.5590	18.3649
Thickness_hand paddle	0.4016	0.4016	0.4033	0.3997	0.3993	**0.4027**	0.4018	0.4009

Table 4
Results of Cluster analysis for dimensional parameters - Small Large

Cluster centroid analysis – Size L								
	Cluster 1	Cluster 2	Cluster 3	Cluster 4	Cluster 5	Cluster 6	Cluster 7	**Cluster 8**
Final Partition (*n*)	490	719	640	801	500	684	561	**605**
Variables								
Width_Palm	17.2126	16.6957	14.4944	16.8740	13.8446	14.4155	15.6808	**14,3014**
Height Palm	19.3054	19.3501	19.3212	19.3109	19.2825	19.2687	19.3302	**19,3471**
Circumference_wrist	18.1237	18.4016	20.1349	20.2423	18.2091	20.0087	18.4066	**18,0210**
Length forearm	24.9583	22.8846	25.0703	24.0701	25.0581	23.0335	24.9285	**23,0886**
Thickness_hand paddle	0.4001	0.4032	0.3955	0.4008	0.4009	0.4029	0.4018	**0,4057**

After selecting the dimensional parameterization clusters S, M, and L, the observations of each cluster were extracted for further analysis of the non-parametric tolerance interval. For the study of the tolerance interval, a percentage of the population was established in the interval and a 95% confidence interval. Table 5 presents the results of the tolerance intervals obtained for the parameterization in sizes S, M, L of the prosthetic device, where N represents the size of the sample extracted from the selected cluster.

Table 5
Tolerance intervals for dimensional parameters from Monte Carlo simulation

Size S (N = 613)		**Size M (N = 656)**		**Size L (N = 605)**		
Variable	**Mean (SD)**	**TI (95%)**	**Mean (SD)**	**TI (95%)**	**Mean (SD)**	**TI (95%)**
Width_Palm	8.389 (0.367)	(7.681; 8.986)	10,010 (0.533)	(9.087; 10.942)	14,301 (0.697)	(13.094; 15.530)
Height_Palm	11.826 (0.520)	(11,035;12,790)	16,495(0,827)	(15,158;17,943)	19,347(0,698)	(18,142;20,467)
Circumference_wrist	11.982 (0.572)	(11,020;12,947)	14,145(0,578)	(13,150;15,101)	18,021(0,552)	(17,147;18,987)
Length_forehand	14.777 (0.452)	(14,027;15,587)	18,348(0,714)	(17,147;19,546)	23,089(0,540)	(22,156;24,060)
Thickness_hand paddle	0.401 (0.058)	(0,306;0,498)	0,403(0,058)	(0,304;0,498)	0,406(0,058)	(0,305;0,497)
SD - standard deviation; TI -tolerance interval; N - number of observations extracted from the cluster						

5. Conclusion

The development of the assistive product presented in this study was carried out through the application of four stages derived from the engineering design approach oriented to the product development process, with the use of engineering tools and statistical techniques for the innovation of assistive product requirements. In the assistive technology area, the development of this product was conceived in partnership with the non-governmental organization *Give a Hand*, which assists in the granting of prosthetic devices at no cost to patients with agenesis of the limb. To develop the prosthetic device, different statistical techniques were implemented to ensure an understanding of the technical requirements required for the assistive product.

To identify the product's characteristics, a questionnaire for investigation was applied to the public of interest for further analysis, interpretation, and prioritization of the product's features, which allowed the design of the prosthetic device based on the CAD model. The Monte Carlo simulation and Multivariate Analysis statistical techniques were applied for the dimensional parameters from assistive product to three sizes (small, medium, and large) to meet the different profiles of the disabled person, whose prototype was obtained by 3D printing. In addition, it was possible to get the specification limits for the product control variables through the analysis of the tolerance interval. The prosthetic device consists of three independent components (stump, hand paddle, and thumb). The stump and hand paddle components have a fitting system that allows the user to select the size of the component that best adapts to the profile. The prosthetic device was patented by the Brazilian National Institute of Industrial Property (INPI) under process number 102020019058-0 and registration BR 10 2020 019058-0. The experience in the development of a non-existent product aimed at Assistive Technology has an essential meaning for recognizing sports activity as a channel for social inclusion, allowing the disabled person to reduce the barrier of accessibility in the physical activity of swimming.

Declarations

Disclosure statement

The authors declare that have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Figures

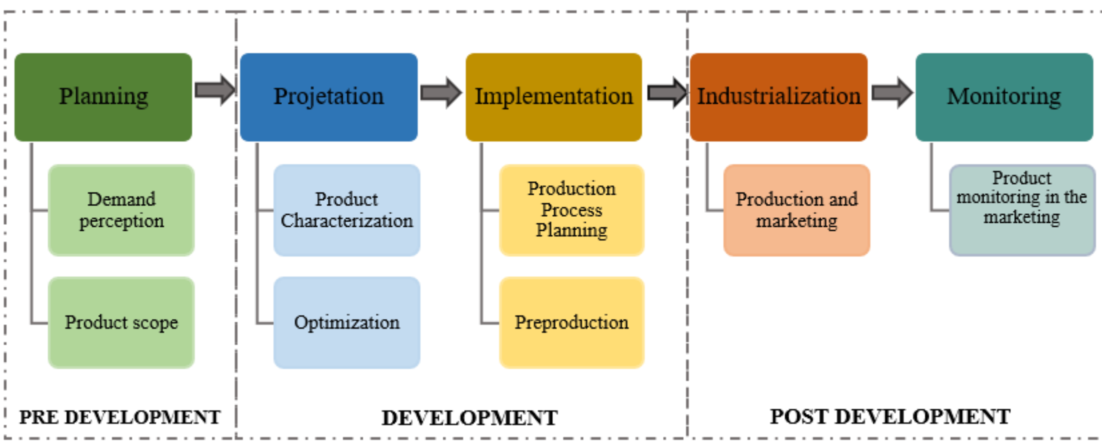

Figure 1

Steps for product development integrated with the design for six sigma

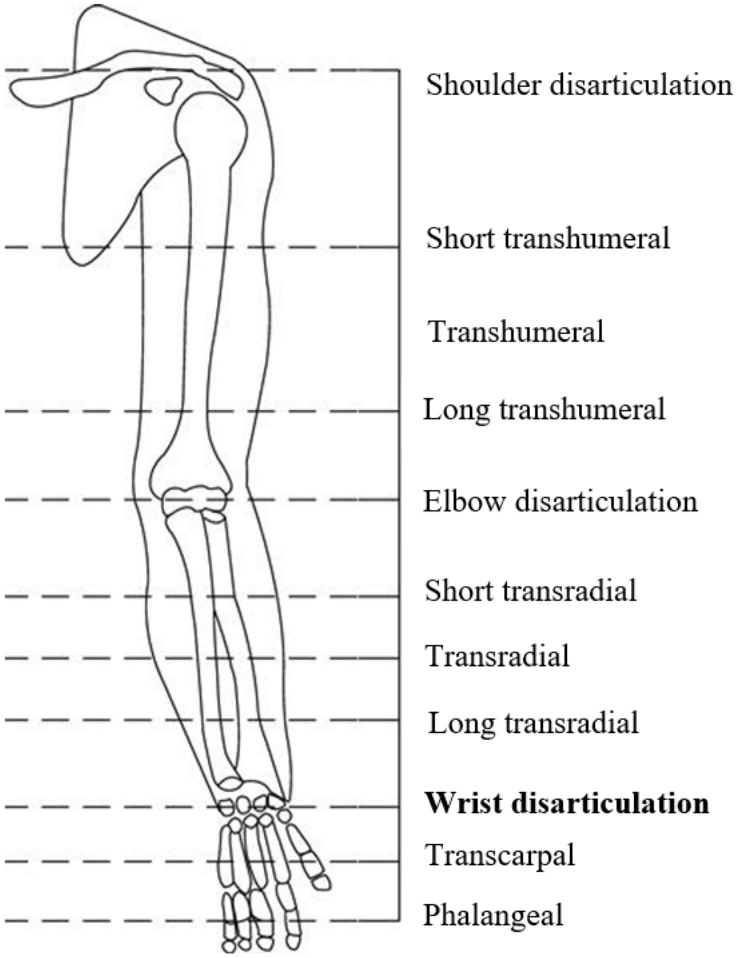

Figure 2

Illustration of upper limb amputation levels

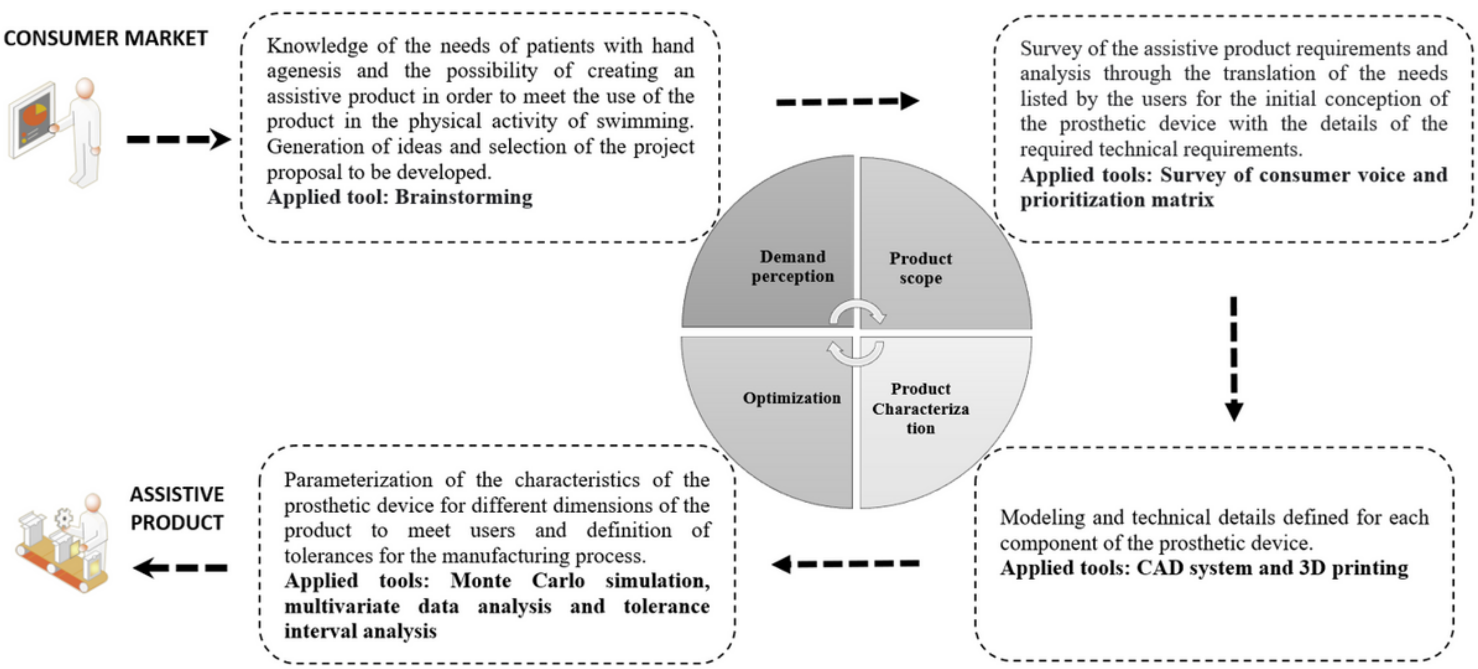

Figure 3

Phases of the assistive product development process

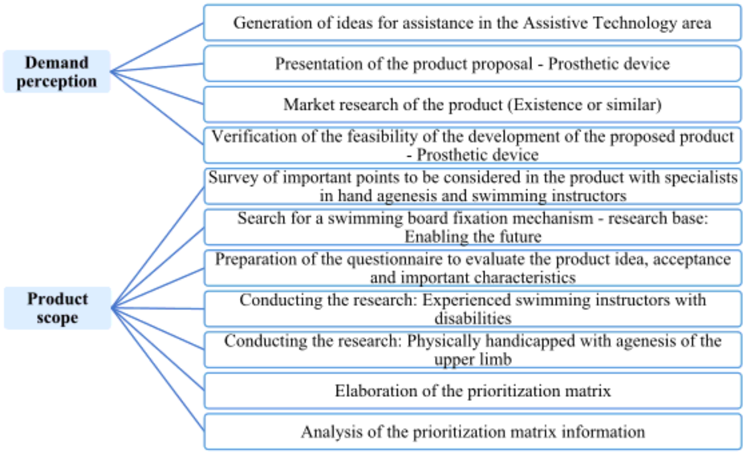

Figure 4

The sequence of activities developed in demand perception and product scope stages.

Quality Required		Functionality				Dimension			Planned Quality			
Customer Voice Items	Importance for the customer	Claw type	Cleat type	Type of material	Roughness	Wall thickness	Width	Length	Improvement index	Pitch	Absolute weight	Relative weight
Exposure to sunlight	5	0	0	9	3	1	0	0	1	1	5	0,09
Exposure to a saline water environment (sea water for example).	**3**	0	0	9	3	1	0	0	1	1	3	0,05
Roughness of the prosthetic device when in contact with another object.	**5**	0	0	9	9	3	0	0	1	1	5	0,09
Exposure of the prosthetic device to a chlorinated	5	0	0	9	3	1	0	0	1	1	5	0,09
Price	**4**	3	3	9	1	9	9	9	1	1	4	0,07
Weight	**4**	3	3	3	3	9	9	9	1	1	4	0,07
Hand paddle size	**5**	0	0	0	1	3	9	9	1	1	5	0,09
Learning agility	**5**	0	0	1	1	1	1	1	1	1	5	0,09
Safety and stability during use.	**5**	9	9	3	9	3	3	3	1	1	5	0,09
Durability	**5**	3	3	9	1	3	3	3	1	1	5	0,09
Inclusion in physical activity	**5**	1	1	1	1	1	1	1	1	1	5	0,09
Ease of placement and use	**5**	9	9	0	0	3	9	9	1	1	5	0,09
											56	
PLANNED QUALITY												
Absolute weight		2,39	2,39	5,00	2,95	3,04	3,61	3,61				
Relative weight		10,4%	10,4%	21,8%	12,8%	13,2%	15,7%	15,7%				

Characteristics of the prosthetic device for swimming	**%**
Type of material	21,8%
Width	15,7%
Length	15,7%
Wall thickness	13,2%
Roughness	12,8%
Claw type	10,4%
Cleat type	10,4%

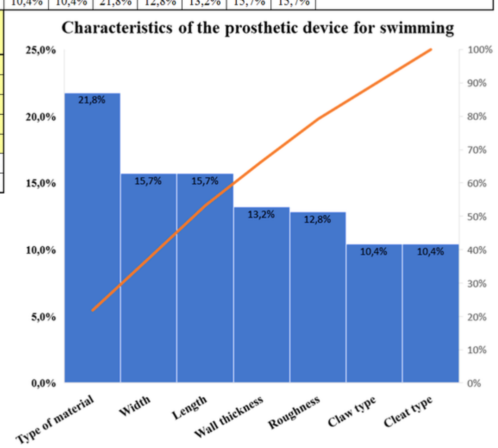

Figure 5

Prioritization matrix applied in the product planning phase

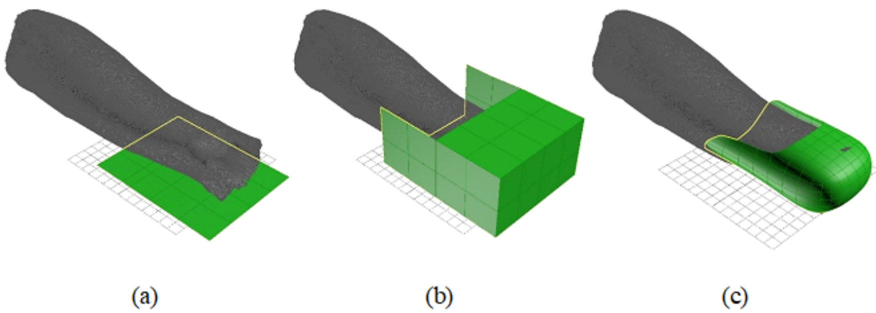

Figure 6

Modeling the stump coupling in the 3DS Max™ software

Figure 7

Conception created for the prosthesis for teaching swimming

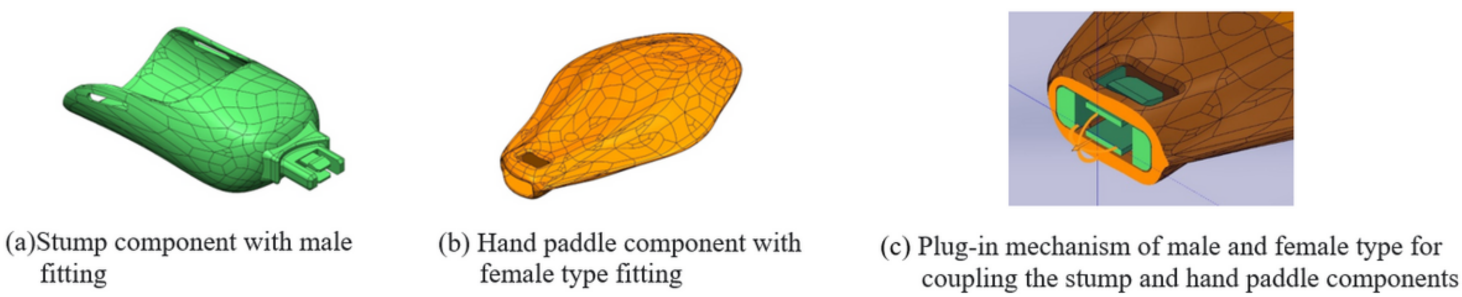

Figure 8

Fitting system of the developed prosthetic device.

Figure 9

Thumb (a) and (b) Hand paddle and thumb joint

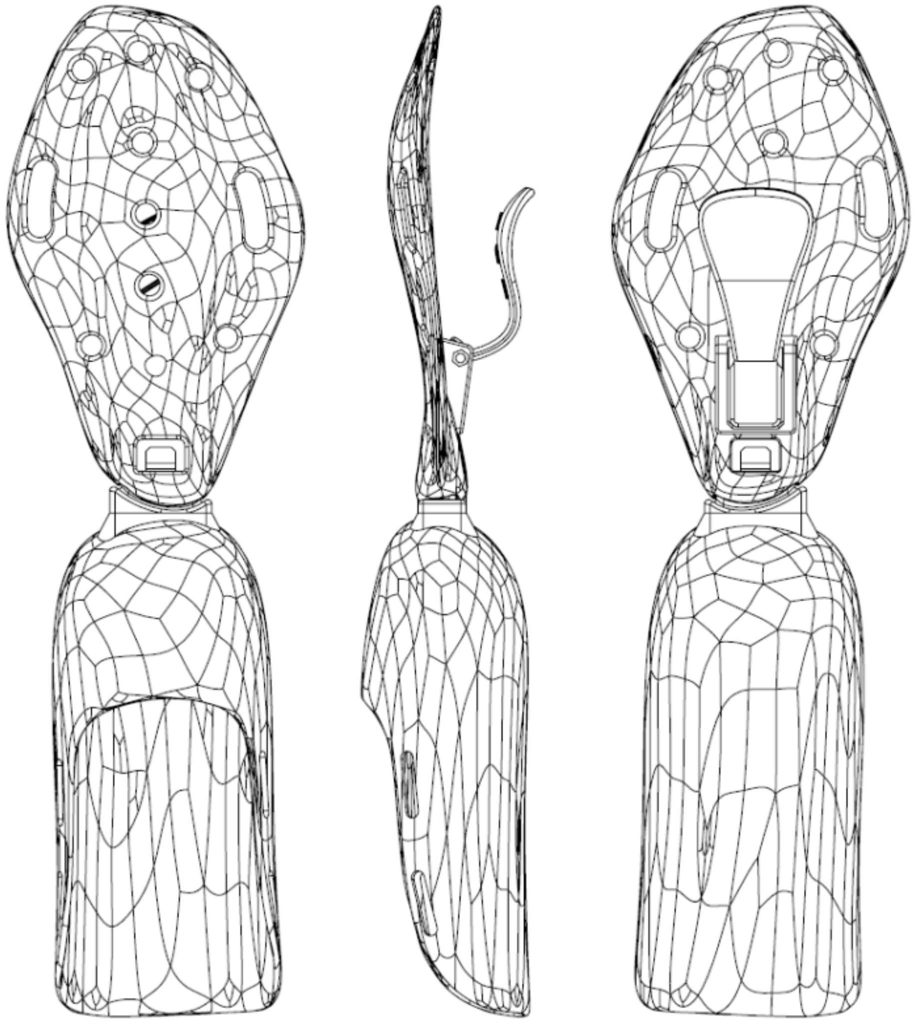

Figure 10

Assembled prosthetic device

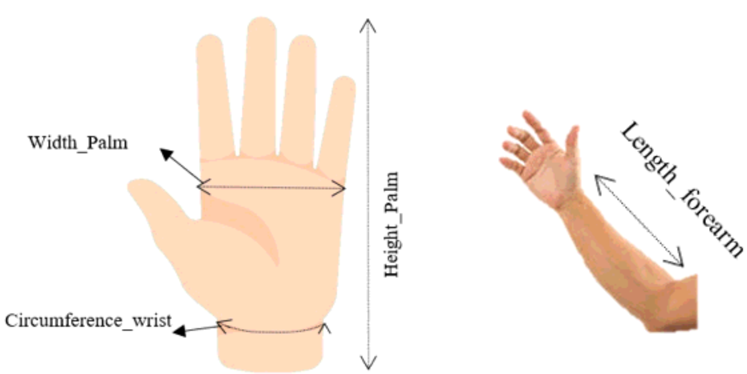

Figure 11

Illustration of the dimensional variables for the prosthetic device from the human body.