

Article Identifying Users' Needs to Design and Manufacture 3D-Printed Upper Limb Sockets: A Survey-Based Study

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Abstract: The development of prosthetic arms has increased in recent years, particularly with the growth of 3D printing technologies. However, one of the main weaknesses of 3D-printed prosthetics is the prosthetic socket, which commonly presents a generic adjustable design that may produce discomfort. In fact, the socket has always been a part that has frequently caused discomfort in traditionally manufactured prosthetics and, consequently, high rejection rates. Studies about improving the socket component in traditional and 3D-printed upper limb prostheses are scarce. Advancements in 3D printing and 3D scanning will offer a high potential to improve the design and manufacturing of 3D-printed sockets. Thus, to propose better designs and manufacturing protocols, this paper presents a questionnaire to assess the needs of upper limb prosthetics users or potential users, as well as a survey-based study with 18 respondents. The results reveal that users prioritize breathability and low cost, a stable fixing system, products without the need for shape adjustments, a light weight and comfort regarding the products they require. The results of this study provide insights into the key characteristics that sockets should accomplish according to users' needs that are applicable to 3D-printed sockets and traditionally manufactured sockets, and they contribute to improving their design and manufacturing.

Keywords: 3D printing; 3D scanning; prosthetics; questionnaire; socket; upper limb



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1. Introduction

1.1. Prosthetic Arms

Prosthetic arms are generally classified into two main groups depending on their motion type: passive and active. Although passive prostheses do not allow any active motion to be performed, they are crucial for stabilizing grasps, ensuring body symmetry, or providing cosmetic resemblance to users' limbs [1]. On the contrary, active prostheses allow active motion control. They employ several control types, including body-powered (cables attached to a harness), electrical (switches or other control devices), myoelectric (residual limb muscular activation through electromyography sensors) and hybrid (by combining many of the aforementioned control types) control types [1]. Active prosthetic arms consist of several essential components. One of them is the prosthetic socket, which is directly attached to users' residual limbs. Another key component is the terminal device, which is attached to the socket via a connecting module that replicates users' forearm lengths and shapes. In some cases, however, this module is already integrated with the socket. There are different types of terminal devices, such as hands, hooks and grippers, among others. Finally, the connecting module links both components together and often contains all of the control systems in myoelectric and electric prostheses. Of these types of prostheses and terminal devices, the most suitable one for each user will depend on individual needs, including tasks to perform and work conditions, which are key aspects to consider in the prosthetic fitting stage [2].

1.2. Fit Problems of Traditional Sockets

The socket is a component that must provide stable fixation and maximize user comfort because it comes in direct contact with skin (or is separated from it by liners or socks). It has to provide the arm stump, shoulder, or upper body with a good anatomical fit, but this is not always accomplished and impacts the device's acceptance [2–4]. In this regard, methods like studying the pressure between the residual limb and the socket may help to improve fit. However, contact pressures do not directly correlate with users' perceived discomfort [5].

The abandonment rates for prosthetic arms are high [3,4], with reported mean rejection rates of 45% and 35% in pediatric populations for electrical and mechanical body-powered prostheses, respectively [4]. These percentages are significantly lower in adult populations, with 26% for mechanical devices and 23% for electrical ones [4]. Users commonly report problems, such as high temperatures and excess sweating [6]. These problems have been identified by users as the main prosthetic arm usage difficulties [7], and even as primary factors for use abandonment [8]. Poor socket fit may also cause skin problems, such as irritation, ulcers, or even cysts [9]. Thus, adjustable prosthetic socket designs [10,11] aim to address fitting issues and minimize the effect of slight residual limb volume loss that may occur during prosthetic use. Nevertheless, most lack appropriate safety features to limit over- or undertightening, which imply either a tissue damage risk or inadequate fixation [12].

1.3. 3D-Printed Sockets

Three-dimensionally printed prosthetics provide an alternative for users who cannot afford conventional prosthetics or their associated costs [13]. Many initiatives, such as the e-NABLE project [14], embrace open-source principles to conceive low-cost 3D-printed upper limb prostheses. Three-dimensionally printed prosthetics allow for a high degree of customization, fast and efficient manufacturing, design flexibility and a wide quantity of materials with different properties. Regarding materials, organizations dedicated to making 3D-printed prosthetics explicitly state that their designs should not be considered fully functional prosthetic devices [15]. Instead, they should be considered as tools that assist in simple tasks to prevent prosthetic uses that could lead to material failure. Catastrophic failures of 3D-printed lower-limb sockets have been documented [16], and standardized safety and durability tests are available [17]. In contrast, no such standard exists for upper limb sockets [18], which makes it difficult to introduce new materials for these prosthetics.

Another challenge of 3D-printed upper limb prosthetics is the design of the socket part, which is typically conceived as a modular design of an adjustable socket using straps or a BOA[®] dial tensiometer (BOA Technology Inc., Denver, CO, USA) to fit all users. However, traditional adjustable sockets do not allow the applied tension to be controlled.

In order to overcome this situation, recent studies have proposed and assessed the manufacturing of personalized upper limb sockets using 3D printing and 3D scanning techniques [19–22]. These works aim to improve stump morphology measurements to propose 3D-printed socket designs that fit users' anatomies and converge full 3D designs and manufacturing. Three-dimensional scanners allow the volume and geometry of users' residual limbs to be accurately measured [23] toward a more reproducible and less invasive customization process than the traditional casting process. Nevertheless, as the tissue of an amputation-generated stump may undergo a loss of compactness compared to a stump that results from hand agenesis, it may be necessary to apply a certain compression to the stump before performing 3D scanning.

Traditional socket manufacturing mainly involves molding, shaping and lamination, which require a lot of materials, time and manual labor. Moreover, the obtained socket fit commonly requires several modifications [13]. This entire manufacturing and adjustment process might not be affordable, particularly in low-income countries or in pediatric prosthetics, where frequent adjustments may be required. In this regard, 3D scanning offers a high potential for accurate morphology measurements, and it is especially interesting in

the 3D-printed prosthetics realm as it facilitates a full 3D process with a very high potential for traditional manufacturing methods.

1.4. Importance of User Perception and Context

During product design, the user-centered design concept is essential because it prioritizes users' needs, preferences and experiences [24]. Users associate different significances with products like assistive technologies, which can have a stigmatizing effect [25,26]. The stigma that a product's appearance can generate for users is one of the reasons for product rejection [27], as it can cause anxiety and depression [28]. Users' perceptions and emotions are indispensable in the product design field [29], and several works in the literature have studied stigma factors in prosthetics through both interviews [30] and questionnaires [31]. Recent studies [32] have compared 3D-printed prostheses and standard prostheses as regards functionality indicators and users' perceptions by employing specific questionnaires, such as the Quebec User Evaluation of Satisfaction with assistive Technology (QUEST 2.0) [33] or the Modified Orthotics Prosthetics Users Survey (OPUS) [34]. They highlight the importance of users' perceptions and identify it as a key factor in prosthetics rejection. Thus, 3D printing techniques would allow for the customization of the socket appearance by attending to users' preferences [35]. Nevertheless, one of the weaknesses of the esthetics of 3D-printed parts is perceived quality [36]. In fact, an assessment method with the Esthetic Quality Index (EQI) has already been proposed in the literature [36] and has been validated [37]. Hence, this aspect should not be underestimated and should be studied when proposing prototypes.

1.5. Hypotheses, Aim and Contribution

Three-dimensionally printed prosthetics is an emerging field that would benefit from improved socket designs to fit users' anatomies because the current adjustable designs lack features to control tightening [12]. Socket fit has always been a problem in traditionally manufactured sockets, and it is a key factor for the acceptance of prosthetic devices [2–4]. Advances in 3D printing and 3D scanning allow for new personalized socket designs to be proposed that very accurately fit users' stump morphologies [23]. These personalized sockets present several advantages compared to 3D-printed adjustable sockets, such as more comfort, a lower risk of skin problems, no need for shape modifications, and more stability. Nevertheless, it is key to listen to users' experiences and perceptions to propose new socket designs because personal and contextual factors are critical determinants of prosthesis acceptance [38]. However, there is a gap in the studies that analyze functional [12] and esthetics-related aspects of upper limb sockets. In fact, no agreement between professionals and prosthesis users has been reached [39].

Therefore, the aim of this work is to define and apply a specific questionnaire to study prosthetic arm users' and potential users' perceptions by focusing on the socket part. To achieve this, this work presents and provides a specific questionnaire (SOCKET-BIOEMO survey) as supplementary data and reports the results obtained from respondents with upper limb amputations or congenital disorders. The questionnaire also comprises an analysis of aspects related to the socket manufacturing process, perceived comfort, functionality, esthetics and durability by integrating questions adapted from standardized questionnaires, such as QUEST 2.0 [33] or OPUS [34]. Finally, the results and their implications are discussed, and the main lines of action using current 3D printing technologies are outlined to meet the reported user preferences.

The results reported in this work may help to detect the problems faced by current traditional socket users, which would contribute to creating 3D-printed socket designs that meet final users' needs. Furthermore, it may provide the prosthetics field with insightful data about aspects to reconsider or improve in current socket designs that are applicable to both 3D-printed and traditionally manufactured sockets. Apart from this, the results of this study may contribute to understanding the aspects that lie behind prosthetic arm rejection and may help move toward user-centered designs and increase users' quality of life.

2. Methods

2.1. Participants

Upper limb prosthetic users and potential users were asked to voluntarily answer an anonymous online questionnaire. The inclusion criteria for the study were having an upper limb amputation or upper limb congenital disorder and being over 18 years old (or having the questionnaire answered by parents or legal guardians). A total of 18 participants (7 males and 11 females aged 32.9 ± 11.8 years; 15 Spanish, 1 Mexican, 1 American and 1 Japanese) answered the questionnaire. The experiment was approved by the Ethics Committee of the Universitat Jaume I (protocol code CEISH/82/2023 and date of approval 14 July 2023). All the respondents gave their written consent to participate.

2.2. Questionnaire Design

The questionnaire, which was made available in English and Spanish, was tailored to encompass several aspects detected in previous survey-based studies in the prosthetics field: user context and prosthetics usage; manufacturing process; comfort; functionality and esthetics. It comprised 105 questions or aspects to assess, which were distributed across 10 different sections. The complete questionnaire is available in the Supplementary Materials.

The questions about both context and usage were prepared to obtain data about participants' conditions, the devices used (if applicable), use type, use frequency, nationality and economic difficulties faced to afford prosthetic costs. The other sections were prepared with questions to assess the participants' satisfaction with specific aspects of their socket manufacturing processes, comfort, functionality and esthetics. Some of these sections also presented an open-answer question to allow participants to provide additional comments that they considered insightful. Finally, there was a final section in which participants were asked to rate the importance they attach to some of the previously assessed aspects.

Several questions were specifically developed for this survey, while others were adapted from standardized questionnaires, such as "OPUS: Satisfaction With Device and Services" (OPUS-S henceforth), "OPUS Upper Extremity Functional Status" (OPUS-F henceforth) or QUEST 2.0 (QUEST henceforth), by either selecting the questions that directly correlated with upper limb prosthetic usage or adapting their wording. In the Results Section, specific details of the questions are provided along with the results obtained from 18 respondents. It is noted whether a question was adapted from a specific question or a set of questions in the previously mentioned standardized questionnaires.

The questionnaire was digitized using the Google Forms platform and distributed via social media and through several specific associations.

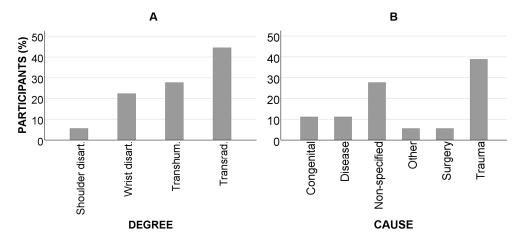
2.3. Data Analysis

All of the data collected after acquiring 18 responses were revised and processed using the IBM SPSS Statistics 29 software. Open-answer questions were separately annotated. Descriptive statistics (mean and standard deviation) and/or plots were performed with both categorical and numerical variables. The most suitable plot types were selected to better present the information for each variable type, and they varied from bar plots to box-and-whisker plots and a semantic differential scale plot. All of the descriptive statistics and plots are presented in the Results Section.

3. Results

3.1. Sample Data

The participants were asked about general data, such as their gender, age, country, degree of amputation or congenital disorder and cause of amputation (if applicable). They were also asked about the dominant hand before amputation (if applicable), the dominant hand after amputation (if applicable) and affected hand(s). A total of 18 participants (7 males and 11 females, aged 32.9 ± 11.8 years; 15 Spanish, 1 Mexican, 1 American, 1 Japanese) completed the questionnaire. Figure 1 displays bar plots. They illustrate



the responses to specific questions, including (A) the reported degree of amputation or congenital disorder and (B) the cause of amputation.

Figure 1. Bar plots illustrating the responses to the following: (**A**) the degree of amputation or congenital disorder and (**B**) the cause of amputation.

All of the participants reported a change in their handedness after amputation. The participants who were right-handed and had right hand amputations became left-handed, and vice versa. In a case with amputations of both hands, the participant did not change their handedness and remained right-handed.

The participants were also asked about their current and past prosthetic use statuses. Of the 18 participants, 12 were currently using prosthetics (one for both hands), 4 had discontinued using them and 2 had never used them. The individuals who never used prosthetics or abandoned them were requested to specify their reasons. The reported reasons are listed in Table 1 after distinguishing between the participants who never used prosthetics and those who had discontinued their use.

 Table 1. Reported reasons for prostheses abandonment.

Never Used Prosthetics (2 Participants)	Abandoned Prosthetics (4 Participants)	
	The prosthesis appeared non-functional with shoulder disarticulation; it merely served a cosmetic purpose.	
Learned to perform *ADLs without prosthesis	The prosthesis appeared non-functional with a damaged brachial plexus; it merely served a cosmetic purpose and hindered the performance of ADLs rather than helping them.	
Rejection in childhood; learned to	The prosthesis was rejected after a period of use in childhood. The individual felt that the prosthesis restricted elbow movement. They learned to perform ADLs without the prosthesis.	
perform ADLs without prosthesis	It was abandoned after a challenging adaption period because the individual was capable of performing all ADLs without the need for a prosthesis.	

*ADLs = activities of daily living.

Additional data were obtained from current users: the prosthesis type, the manufacturing method and the duration required to achieve comfort in controlling their prosthesis. Of the current users, 15.38% reported employing mechanical prostheses, while 84.62% reported using electrical/myoelectrical ones. In terms of the average period of familiarization with prostheses, most participants reported a period of only a few days. However, the individual with a double amputation reported still being in the learning process. The current users were also asked about socket materials, those in contact with a limb, the socket fixing system, socket sensorization, the manufacturing method and the anthropometric measurement system.

All of the prostheses used by the participants were commercially available. Their socket materials included rigid polymers (52.94%), soft polymers (29.41%), fabrics (11.76%) and metal (5.88%). The materials in contact with the residual limb were rigid polymers (50%), soft polymers (42.86%) and fabrics (7.14%). The socket fixing systems were rigid structures (46.1%), Velcro[®] straps (15.4%), silicone/suspension structures (15.4%), elastic straps (7.7%), harnesses (7.7%) and mechanical fixing systems (7.7%). The locations of the fixing systems were the forearm (33.33%), elbow (27.8%), shoulder (22.22%), torso (11.1%) and biceps (5.55%). The only socket manufacturing process reported was molding, and the anthropometric measurement processes were molding (50%), molding combined with manual anthropometric measurements (41.67%) and 3D scanning (8.33%).

3.2. Prosthetic Use

Current users and those who abandoned prosthetics (past users) were queried about their prosthetic use frequency. Past users were asked to respond by considering their experience in the past in the whole section. The obtained responses are detailed in Figure 2 as a bar plot.

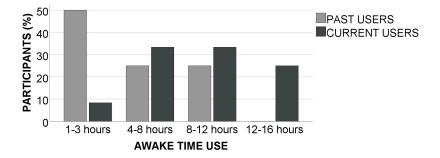


Figure 2. A bar plot depicting the prosthetic use frequency reported by past and current users.

They were also asked about the use type and use frequency in specific environments. The obtained responses are detailed in Figure 3 as a bar plot.

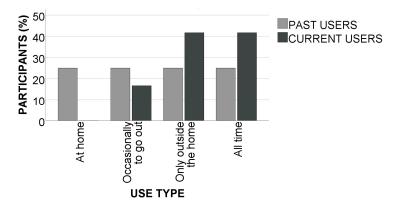


Figure 3. A bar plot detailing the use type reported by past and current users.

Finally, they were queried about prosthetic use frequency in specific environments using a Likert scale with a range of 1-5 (1 = never; 5 = always). The obtained responses are shown in Figure 4 as a box-and-whisker plot.

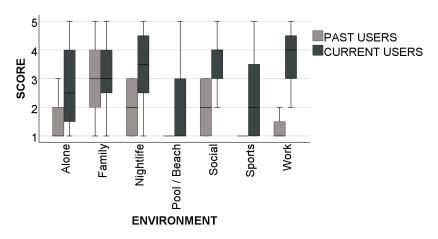


Figure 4. Box-and-whisker plot detailing prosthetic use frequency reported by past and current users in certain environments, where 1 = never and 5 = always.

3.3. Manufacturing Aspects

Current users were asked to rate certain aspects related to the manufacturing processes of their sockets on a 1–5 Likert scale (1 = strongly disagree; 5 = strongly agree). Table 2 presents the aspects and specifies whether they were derived from a question or a set of questions from the OPUS and QUEST questionnaires. The rating obtained for each statement is presented as a box-and-whisker plot in Figure 5.

Table 2. Aspects related to manufacturing processes of their sockets.

ID	Aspect
M1	The socket was ready in a short period of time (OPUS-S-14)
M2	The residual limb morphology measurement was comfortable
M3	The residual limb morphology measurement was not invasive
M4	Almost no fit adjustments were required after the final shape
M5	In general, I am satisfied with the socket manufacturing process

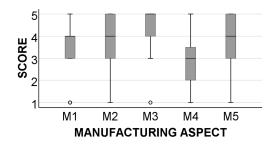


Figure 5. A box-and-whisker plot illustrating the score obtained for each aspect related to the socket manufacturing process, where 1 = strongly disagree and 5 = strongly agree. The statements are labeled as detailed in Table 2.

3.4. Comfort Aspects

Current users were asked to rate certain aspects related to the comfort of their sockets on a 1-5 Likert scale (where 1 = strongly disagree and 5 = strongly agree). Table 3 presents the aspects and specifies whether they were derived from a question or a set of questions from the OPUS and QUEST questionnaires. The rating obtained for each statement is presented as a box-and-whisker plot in Figure 6.

ID	Aspect
C1	The socket is comfortable and does not cause any skin wound (OPUS-S-3, OPUS-S-8)
C2	The socket has an appropriate weight given its characteristics (QUEST-2)
C3	The socket is breathable and does not cause excess sweating
C4	The socket has a good fixing system and there are no unexpected displacements. (QUEST-4)
C5	The socket has a good fixing system and the motion control is not lost 1 (QUEST-4)
C6	The socket does not cause pain (OPUS-S-9)
C7	The process of fixing and removing the socket is comfortable (OPUS-S-4, QUEST-3)
C8	In general, I am satisfied with socket comfort (QUEST-7)

Table 3. The aspects related to the comfort of their sockets.

¹ Only for the prosthetics with mechanical, electrical or myoelectrical control.

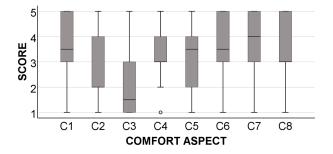


Figure 6. A box-and-whisker plot representing the score obtained for each aspect related to socket comfort, where 1 = strongly disagree and 5 = strongly agree. The statements are labeled as detailed in Table 3.

3.5. Functionality Aspects

Current users were asked to rate certain aspects related to the functionality of their sockets on a 1-5 Likert scale (1 = strongly disagree; 5 = strongly agree). Table 4 presents the aspects and specifies whether they were derived from a question or a set of questions from the OPUS and QUEST questionnaires. The rating obtained for each statement is presented as a box-and-whisker plot in Figure 7.

Table 4. The aspects related to the functionality of their sockets.

	ID	Aspect
F3 The socket has enough rigidity and does not deform while performing high-stress tag	F1	The socket allows me to perform all the ADLs I need (OPUS-F)
	F2	The socket allows me to perform ADLs with all the products I need (OPUS-F)
F4 In general I am satisfied with socket functionality (OPLIS-F)	F3	The socket has enough rigidity and does not deform while performing high-stress tasks
in general, i ani sausned with socket functionality (Of 0.5-1)	F4	In general, I am satisfied with socket functionality (OPUS-F)

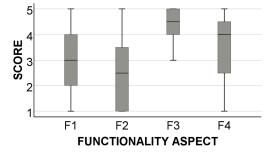


Figure 7. A box-and-whisker plot representing the score obtained for each assessed functionality aspect, where 1 = strongly disagree and 5 = strongly agree. The statements are labeled as detailed in Table 4.

The participants were also requested to assess their usual degree of fulfilling a set of ADLs on a 1-5 Likert scale (1 = with considerable difficulty; 5 = very easily). These

questions were based on those presented in OPUS-F, but they were grouped by fields of key tasks for personal autonomy. They were also asked to rate their performance when employing specific products that require different grasp types.

Figure 8 depicts the degree of fulfillment of ADL performance as reported by users. Figure 9 illustrates the reported level of fulfilling the use of products that require specific grasp types.

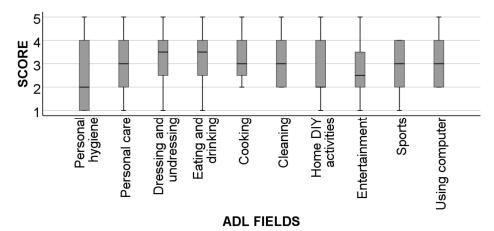


Figure 8. A box-and-whisker plot detailing the degree of difficulty of performing tasks from the different fields of ADLs. Ratings: 1 = with considerable difficulty and 5 = very easily.

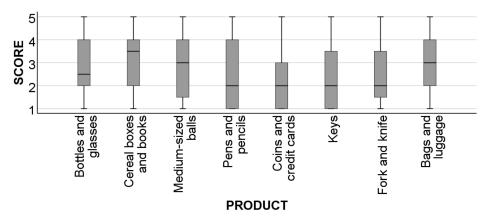


Figure 9. A box-and-whisker plot depicting the level of task fulfillment using specific products requiring certain grasp types. Ratings: 1 = with considerable difficulty and 5 = very easily.

The participants were also asked to estimate the maximum weight they could grasp using the prosthesis, which was reported to be 9.8 (\pm 8.8) kg. In the open-answer section, the participants mentioned difficulties when performing tasks involving water, combing their hair and using tactile screens. They also identified tactile screens as products that involve difficulties.

3.6. Esthetic Aspects

Current users were asked about certain aspects related to the esthetics of their sockets on a 1–5 Likert scale (1 = strongly disagree; 5 = strongly agree). Table 5 presents the aspects and specifies whether they were derived from a question or a set of questions from the OPUS and QUEST questionnaires. The ratings for each assessed statement are presented as a box-and-whisker plot in Figure 10.

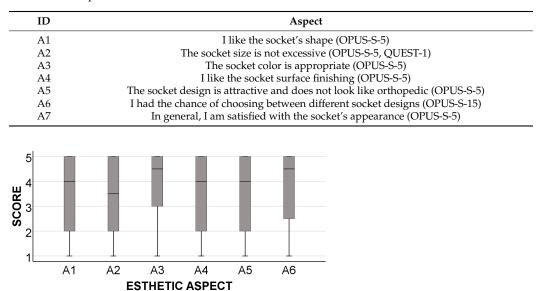


Table 5. The aspects related to the esthetics of their sockets.

Figure 10. A box-and-whisker plot illustrating the score obtained for each assessed aspect related to socket esthetics. Ratings: 1 = strongly disagree and 5 = strongly agree. The statements are labeled as detailed in Table 5.

They were also asked to use a semantic differential scale to evaluate the following design characteristics: stylish/sportive, modern/classic, colorful/neutral, eye-catching/discreet and patterned/plain. The obtained results are presented in Figure 11 after distinguishing them based on degree of amputation (A) and gender (B).

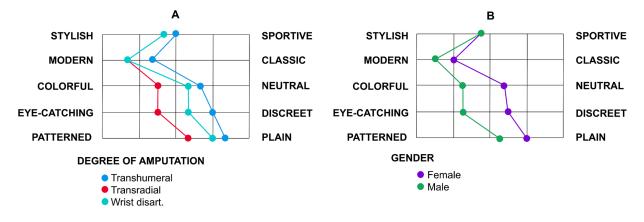


Figure 11. A summary of the results obtained from the semantic differential scale after distinguishing by the degree of amputation (**A**) and gender (**B**).

3.7. Durability and Cost

Current users were inquired about various aspects, including the average life span of their sockets (question D1), the frequency of maintenance required (question D2) and, for the electrical prostheses only, how long the battery charge lasted (question D3). These questions were based on questions OPUS-S-6 and QUEST-5. The reported average life span of current users' sockets was 2.30 (\pm 1.72) years (question D1), and the mean reported frequency of required maintenance was 1.39 (\pm 1.77) years (question D2). The mean reported charge duration (for the electrical prostheses only) was 43.94 (\pm 26.21) hours (question D3).

Subsequently, the participants were asked to rate their possibility of being able to afford the costs of acquiring and maintaining their sockets (question D4) and their prostheses (question D5) on a Likert scale ranging from 1 (with considerable difficulty) to 5 (very easily). These questions were based on question OPUS-S-10. In terms of difficulty affording

the economical costs of acquisition and maintenance, the participants reported a mean difficulty of 2.00 ± 0.94 for affording the overall socket cost (question D4) and 1.80 ± 0.79 for affording the overall prosthesis costs (question D5) on a 1–5 Likert scale (1 = with considerable difficulty; 5 = very easily).

3.8. Importance of Specific Socket Properties

All of the participants in the questionnaire (both prosthetic users and non-prosthetic users) were requested to assess the importance they attached to 19 socket properties listed in Table 6 on a 1–5 Likert scale (1 = not important at all; 5 = very important).

Table 6. Aspects	that were assessed	about their importance.
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ID	Properties
P1	Fast manufacturing
P2	Easy anthropometric measurement process
P3	No need for shape adjustments
P4	Comfort (not causing skin wounds)
P5	Breathability
P6	Easy fixing system
P7	Stable fixing system
P8	Lightweight
P9	Allows me to perform the ADLs I need
P10	Allows me to use the products I need
P11	Allows me to carry the weight I need
P12	Has enough rigidity and does not deform while performing high-stress tasks
P13	Attractive shape
P14	Small size
P15	Appropriate color
P16	Appropriate surface finishing
P17	Attractive design
P18	Low maintenance required
P19	Low cost

The importance that the participants attached to the 19 socket properties is detailed in the box-and-whisker plot in Figure 12. Figure 13 presents a satisfaction–importance plot, which is tailored by correlating the answers to the first survey sections with the obtained importance of specific socket properties in this section.

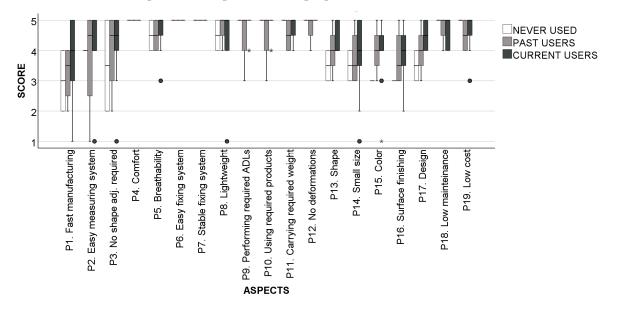


Figure 12. A box-and-whisker plot detailing the score obtained for each assessed socket property, where the ratings range from 1 (not important at all) to 5 (very important). Outliers (dots) are the cases with values between 1.5- and 3 times the interquartile range (beyond whiskers). Extreme outliers (asterisks) are the cases with values bigger than 3 times the interquartile range.

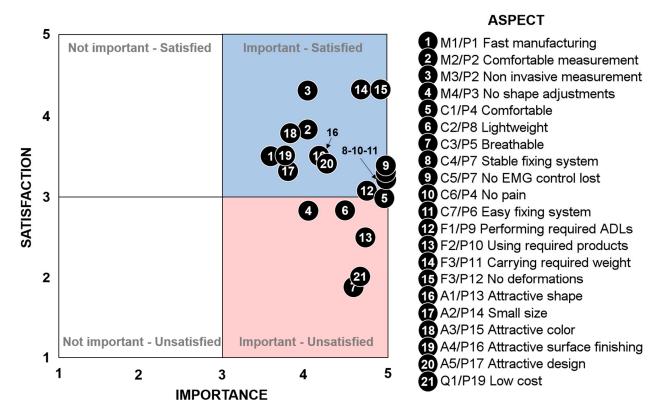


Figure 13. A satisfaction–importance plot tailored to correlate answers to the first survey sections with the obtained importance of the specific socket properties in this section. The correlated questions are specified in the plot legend. The questions are labeled as detailed in the entire manuscript.

4. Discussion

4.1. Sample Data

In relation to the sample data, one of the most remarkable results was the high rejection rate, which was 33.3%. This result aligns with other studies in the literature [3,4,40]. The participants who rejected prosthetics mainly indicated that they were accustomed to performing ADLs without using a prosthesis, or they believed that a prosthesis would not confer them additional personal autonomy given their degree of amputation (as reported by the individual with shoulder disarticulation and a damaged brachial plexus). Although the lack of need is a recurring justification for prosthesis rejection [38,40,41], personal and contextual factors are critical determinants of prosthesis acceptance [39]. However, in this case, the degree of amputation did not seem to have an apparent effect on the rejection rates, except when explicitly mentioned by the user, as in the individual with shoulder disarticulation. This may be interpreted as a need for prosthetic devices that are easier to use by individuals who are unable to activate their arm muscles, who commonly perform myoelectric prosthesis control via their torso muscles, which is complex and involves a hard adaptation period. Another significant observation is the used prosthesis type, with 84.62% of individuals using electrical/myoelectrical prosthetics. This aligns with recent studies and denotes a rising use in such prostheses over the past decade, which was reported in previous studies to be 34.2% by the participants in a study in 2012 [42] and 92.86% in 2022 [43]. Furthermore, the study of 2012 reports that 19.9% of users use cosmetic prostheses, which were reported neither in the present study nor in that of 2022 [43]. These results denote the current trend of moving toward the use of functional and active prostheses and highlight the importance of considering 3D-printed upper limb socket prototypes that accommodate myoelectrical sensors.

4.2. Prosthetic Use

Prosthetic use frequency seems to be correlated with the user group (see Figure 2). Twenty-five percent of current users wear prosthetics all day long (12–16 h), while no past users reported wearing it for this duration. The reported mean usage time was 8.95 h, which aligns with previous studies [43]. Prosthetic use frequency for past users was generally lower, with 50% of them wearing prosthetics for only 1–3 h per day.

The reported use type also appears to be associated with the user group (see Figure 3). Approximately 41.67% of current users reported using their prosthesis for almost everything, while this rate was only 25% for past users. Similarly, 25% of past users reported only using the prostheses at home, which is a pattern that was not reported by any current users.

Regarding the environment, the most common environment for current users is at work (see Figure 4), followed by social interactions and nightlife. Less frequent usage occurred at the pool/beach and during sports activities, which is coherent because most prosthetic arms cannot be wetted. Past users reported lower use frequency in all of these environments. The only environment in which both user groups reported nearly equal use frequencies was "only in the family environment". This high prosthetic use rate at home for past users may indicate that past users could have experienced social stigma associated with their use. These users might have preferred only using their prostheses in the family setting because it is sometimes more discreet to conceal stumps than to wear a body-powered prosthesis that requires wearing a harness over clothing. Other explanations may be related to prolonging the prosthesis's life span for cost-related reasons or to functional considerations like wearing it to perform household tasks.

Although our findings in this section suggest an association between usage patterns and user group (current user or past user), it is important to acknowledge the potential influence of other factors. For instance, factors like the possibility of receiving the appropriate training for prosthetic use could influence both use type and the compositions of user groups. Therefore, alternative explanations may be considered before interpreting the reasons that lie behind the observed patterns.

4.3. Manufacturing

The only reported socket manufacturing process was molding, and the anthropometric measurement processes were molding (50%), molding combined with manual anthropometric measurements (41.67%) and 3D scanning (8.33%). These results evidence that, although 3D-printed prosthetics have emerged in recent years, the method of applying 3D scanning to take morphology measurements is still in its early implementation and development stages for upper limb prosthetics. The observed low 3D scanning rates could be correlated with the reported manufacturing processes, which were only molding-based. The importance of 3D scanning techniques is particularly evident when conceiving 3D-printed prosthetics because the data that are derived from scanning are integrated into the CAD/CAM design and manufacturing workflow.

Of all the materials in contact with the residual limb, 50% were reported to be rigid polymers. This is a very high rate given all the dermatologic problems caused by sockets [6,44–46]. Apart from this, it is worth noting the low score obtained when assessing aspect M4 (almost no fit adjustments required after the final shape; Figure 5) and the considerable importance that the participants attached to it (Figures 12 and 13). These results are consistent with other works in the literature, in which users reported multiple adjustments regarding their sockets' fit [13].

All of these results reinforce the novelty that introducing new manufacturing methods based on 3D scanning and 3D printing would imply by not only allowing for a fast, precise and non-invasive anthropometric measurement system, but also a low-cost manufacturing method for individuals who cannot afford conventional prosthetics and their derived costs by offering them an alternative tool to improve their personal independence. Moreover, given the problems that rigid materials which come into contact with residual limbs can generate, it should be noted that one of the advantages of the latest advances in 3D printing is the possibility of employing flexible and rigid materials. The popularity of soft materials is growing in 3D-printed prosthetics thanks to their flexibility and shock absorption. They better adapt to the body's contours, which lowers the risk of irritation and pressure sores. However, rigid materials play a crucial role in prosthetic design by serving as mechanical supports and providing structural integrity. Therefore, a suitable solution for a 3D-printed

4.4. Comfort

The results from the assessment of comfort aspects reveal that participants' sockets are too heavy (C2) and are not breathable enough (C3) (Figure 6), which are extremely important aspects for participants (P5 and P8 in Figures 12 and 13). This reported breathability problem is in accordance with previous observations made by several authors [6,47], who claimed that more attention must be paid by researchers, clinicians and manufacturers of prosthetic components to the heat-related biomechanics of soft tissues, a proper fabrication technique, better material selection and the introduction of efficient thermoregulatory systems [6]. Nevertheless, it must be taken into account that wetness may sometimes be altered by phantom pain, which has a high prevalence in adult upper limb amputees and implies sensations like an altered sense of touch, altered temperature and even the sense of wetness [48].

socket design may consist of a rigid shell with an inner layer of soft material.

The aforementioned results clearly indicate that future socket prototypes should strike a balance between a low weight and mechanical strength to minimize the weight while preserving the mechanical properties Their breathability should be tested to move toward designs that are as breathable as technically possible, bearing in mind that designs that involve socket structures with perforations or meshes may produce small edemas on users' limbs and should be avoided.

The overall socket comfort satisfaction rate was 3.08 ± 1.44 , with the least satisfaction being reported among all of the other assessed sections, including 3.92 ± 1.24 for manufacturing, 3.58 ± 1.31 for functionality and 3.75 ± 1.60 for esthetics, despite the latter being one of the aspects that participants attributed the most importance to (P4). These results align with those of previous studies in which users identified comfort as the area that needed the most improvement, while esthetics were deemed less necessary [43].

4.5. Functionality

The functionality aspects with the lowest scores were F1 (the socked allowed the individual to perform the ADLs they needed) and F2 (the socked allowed the person to perform ADLs with the products they needed) (Figure 7), and both were extremely important to the participants (see Figures 12 and 13). The most challenging area of ADLs was found to be personal hygiene, which is a key field in anyone's personal autonomy. The products that posed the most serious difficulties in task performance were those that required precision grasps (keys, credit cards, coins, pens/pencils, forks and knives, keyboards and mobile phones) because these grasp types are harder to perform with prosthetics. These results point out the need to test the whole prosthesis during tasks requiring both power and precision grasps to ensure that a wide range of products and ADLs is covered despite the fact that the capability of performing precision tasks relies on the prosthetic hand itself rather than the socket part. Moreover, the participants' answers to the open-answer questions highlight the need for better solutions to employ tactile screens. Current commercial prostheses allow for fingertips to be equipped with conductive materials to enable interactions with tactile screens, but the achieved touch precision is not optimal.

4.6. Esthetics

Regarding esthetics, the aspect with the lowest score was A2 (appropriate size). However, it is important to note that when comparing esthetic aspects to manufacturing, comfort or functionality, the esthetics ratings were higher (Figure 10), but it was not considered the most important requirement for the participants (Figure 12).

The semantic differential scale results (Figure 11) provide a glimpse of the main design styles preferred by participants: modern and plain. There is no consensus about colors, style (sportive or stylish) or visibility (eye-catching or discreet). This evidences that a certain degree of personalization would be well received. No evident preferences were detected when comparing results among the users with different degrees of amputation. Nevertheless, preferences between males and females were observed: females prefer plain, discreet and neutral designs, while males prefer patterned, eye-catching and colorful ones. The obtained general guidelines for esthetics should be considered when proposing prototypes by noting that the 3D printing manufacturing process allows for a high degree of personalization regarding colors, patterns or surface finish. Nonetheless, the perceived quality of printed parts should be studied when proposing prototypes on scales like the EQI [36] because it could cause the products to be rejected by final users [36].

4.7. Durability and Cost

The average reported socket durability was 2.30 (\pm 1.72) years, which is relatively short, particularly when considering the high expenses associated with socket renovation. In fact, the participants reported a limited ability to afford the economic costs of sockets, with an average rating of 2.00 (\pm 0.94) out of 5. The capacity to afford prosthetic costs was even lower, with an average rating of 1.80 (\pm 0.79) out of 5. When assessing the importance of various aspects, the participants identified cost as a highly significant factor (see Figure 12). There is a clear need to develop cost-effective solutions that can facilitate the necessary fit modifications and adjustments at a lower cost.

4.8. Importance of Specific Socket Properties

When assessing the relevance of specific socket properties, it is essential to note the differences observed depending on the user group. Current users attached more importance to almost all of the assessed aspects (P1–P17). The only aspects for which they did not attach more importance compared to non-users were those related to low maintenance (P18) and low cost (P19), which might be contributing factors for non-users.

The aspects that were generally rated as the most important ones included (P4) comfort, (P5) breathability, (P6) an easy fixing system, (P7) a stable fixing system, (P8) a light weight, (P9) "Allows me to perform the ADLs I need", (P10) "Allows me to use the products I need", (P11) "Allows me to carry the weight I need", (P12) "Has enough rigidity and does not deform while performing high-stress tasks", (P18) low maintenance required and (P19) low cost. Conversely, aspects related to the manufacturing process and esthetics were considered less important. These results align with the pyramid hierarchy of product needs proposed by Jordan [49], with functionality at the base, usability in the middle and pleasure (esthetics and use experience) at the top.

Finally, the importance–satisfaction plot (see Figure 13) depicts that the aspects with which participants are unsatisfied and consider to be extremely important are breathability, low cost, using required products, a stable fixing system, no shape adjustments required, a light weight and comfort, which should be considered to improve upper limb prosthetics.

5. Conclusions

The findings of this study highlight the importance of prioritizing comfort and functionality in prosthetic designs by emphasizing the demand for lightweight, breathable and adaptable socket solutions. Although esthetic preferences were generally less prominent among users, there was a discernible trend toward modern and plain designs. Nevertheless, challenges regarding durability and cost persist, which highlights the urgent need for costeffective strategies to improve affordability and mitigate abandonment rates. Overall, users prioritize comfort, functionality and affordability, which align closely with the product needs hierarchy outlined by Jordan [49]. All of the obtained results provide an outline of cover to meet final users' needs, lower the rejection rate and improve users' quality of life. Our future work will involve conceiving prototypes of prosthetic upper limb sockets by following 3D scanning and 3D printing methodologies, which will allow for non-invasive anthropometric measurements of users' residual limbs to be taken, as well as a fast, low-cost manufacturing process. This will provide individuals who cannot afford conventional prosthetics with access to alternative tools to improve their personal independence. When creating the proposed prototypes, one should bear in mind that myoelectric sensor allocation may be necessary, and several fixing solutions should be studied. Socket designs should be as breathable as technically possible, lightweight and conceived using soft/mixed polymeric material in the areas that come into contact with residual limbs to avoid causing skin wounds and skin problems, and to reduce the required shape adjustments. Socket functionality should be tested with different products, grasp types and product weights to find stabler fixing systems. Finally, design customization may be performed to meet users' preferences, and the perceived quality of 3D-printed sockets should be assessed.

One of the main limitations of this study is our relatively small sample size (18 participants) owing to the difficulties in recruiting participants that meet the requirements to take part in this study. This sample size may be considered small for drawing generalized conclusions, but it is important to note that similar sample sizes have been utilized in comparable studies in the literature, with a respondent ratio of 25 [43] or even 12 [50]. However, our small sample size may restrict the generalizability of the findings and the robustness of the possible statistical analyses to perform. In order to corroborate the results and allow for an in-depth study of the data, our future work will also include collecting additional responses. Therefore, the results in this study must only be seen as general guidelines to follow to propose new socket designs.

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