CASE REPORT

3D print orthesis for shoulder: case report

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ABSTRACT

Subluxation of the shoulder is the most common musculoskeletal complication of Central and Peripheral Nervous System disorders, which leads to decreased movement, function, and increased pain. **Objective:** Orthosis is one of the assistive devices used in the treatment of this pathology and it focuses in correcting deformity, decreasing pain and providing function to the affected member. This study proposes a new methodology for designing and manufacturing customized shoulder stabilization orthoses with 3D scan image acquisition and 3D printing technologies, for ensuring better adaptability and comfort for the user. **Method:** The methodology used in this study was divided into five phases: case study, scanning, modeling and 3D printing; and finishing. The case study included a user with brachial plexus injury that motivated the original design of hybrid orthosis, personalized and manufactured in 3D, with rigid structure and traction straps, for stabilizing the shoulder, reduce pain and allowing function. **Results:** After 3D scanning, we used specialized software to process the three-dimensional STL image. Optimization of the project with generation of models and prototyped parts in FDM based on the user evaluations was performed. The developed concept was: personalized orthosis, easy to clean and wear, resistant, articulated, for wearing in both arms with traction straps in rigid fabric coupled to the waist. **Conclusion:** The user test corroborated with the designed concept and showed a preliminary prototype with good trunk coupling, satisfactory traction and possibility of performing a greater number of ADLs with less pain and/or tiredness.

Keywords: Upper Extremity, Orthotic Devices, Technological Development, Printing, Three-Dimensional

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INTRODUCTION

According to the International Standards Organization, orthoses is a device external to the body which is used to modify functional and/or structural characteristics of the neuromusculoskeletal system. Depending on the specificity of each individual, this device may have several objectives, such as stabilizing or immobilizing, preventing or correcting deformity, protecting against injury or assisting function.[1]

According to the classification system of orthosis elaborated by Fess,[2] currently in use, orthoses are classified by three criteria: (1) the forces applied according to the spatial planes in which they occur; (2) the anatomical site they are placed; and (3) the main kinematic objective of the orthosis.

As for its manufacturing, orthoses can be classified in two types: pre-fabricated, which has a definite size and is manufactured in series and generally made in specialized orthopedic workshops with thermomoldable material at high temperature and other materials; and tailor-made that is usually made by the therapist directly on the patient's skin respecting their individualities and always evaluating anatomical principles and applied forces to determine their effectiveness, comfort and adequate protection to the joint.[3,4]

There are several models of orthoses for stabilizing the shoulder on the market, such as arm slings with one or two straps, which also immobilize the elbow. Of the models that do not immobilize the elbow, the most commonly used for the treatment of shoulder subluxation is the humerus holder produced by Mercur®, which is made of neoprene. In the clinical experience, patients have reported that its tissue is very flexible, not being resistant enough to maintain the correction, since with frequent use, the tissue wears off and does not perform the necessary traction to position the humerus in the glenoid fossa.

In addition, shoulder stability is of extreme importance for adequate movement of the most distal joints and consequently allow the necessary movements for the performance of the upper limb functions in daily activities. The shoulder is also important in the balance function during gait, as well as it is an active component in wheelchair locomotion and transfers.[5]

Therefore, considering the importance of maintaining the functionality of individuals with shoulder impairment due to the reduction of strength, studies are needed to find new alternatives that minimize pain and the consequent loss of functionality of these individuals.

3D printing (or Additive Manufacturing) is a technology increasingly employed in product development, given its potential for multiple applications. The process, in general, consists in the deposition of successive layers of material on top of each other, starting from a geometry modeled in a 3D CAD (Computer Aided Design) system. Assistive Technology devices are also manufactured with additive manufacturing. In the case of orthoses, as it is an emerging technology, there is still little published scientific research concerning the shoulder, and there are strong indications that this technology may aid the development process of these devices. One of the indicative factors is the speed of production of single pieces.[6,7]

Therefore, 3D printing is a very appropriate technology to advance the manufacture of customized orthoses, since it can minimize the time of manufacture, despite the problems with imprecision and discomfort.

OBJECTIVE

The objective of this study is to present a new methodology for the development of customized stabilizing shoulder orthoses with the use of technologies such as scanning and 3D printing to ensure better adaptability and greater comfort for the user.

METHODS

The application of 3D printing in the development of health products follows the following steps: a) Case study, b) 3D scanning, c) 3D modeling, d) 3D printing and e) finishing.[8] These are followed by a process of evaluation of the product by the user and by the occupational therapist.

The concept of the orthosis we developed was based on bibliographic, patent and market research that resulted in the sketch presented in Figure 1. The rigid parts have the function of better distributing the tensions in order to direct the loads to the bony prominences, and the personalization focuses on the distribution of tension by better coupling with the body, also by clinical knowledge the concentration of tension in sites that are susceptible to skin lesions and pain is avoided. The colored part in orange shows the structural rigid part, prototyped in ABS and the blue parts are traction straps (automotive safety belt) attached by Velcro and fixed at the waist. The traction will be controlled by the transverse straps in the arm, and the cross straps in the back have the objective of better positioning the scapula so that it does not become winged.

CASE STUDY

G.O. is 26 years old, married, right-handed, professional in the area of Accounting Sciences, and signed the Free and Informed Consent Form, in accordance with the HCRP Process no. 15916/2014 and the Resolution 466/12 of the National Health Council, which authorizes all stages of the development of this study. He suffered a motorcycle accident two years prior to the study and presents, as sequelae, left brachial plexus injury.

After 1 month of the lesion, he was referred to the rehabilitation once a week (60 min) and began using a static hand wrist positioning brace and sling with one strap for approximately 6 months, when the occupational therapist indicated the neoprene stabilizing orthosis.

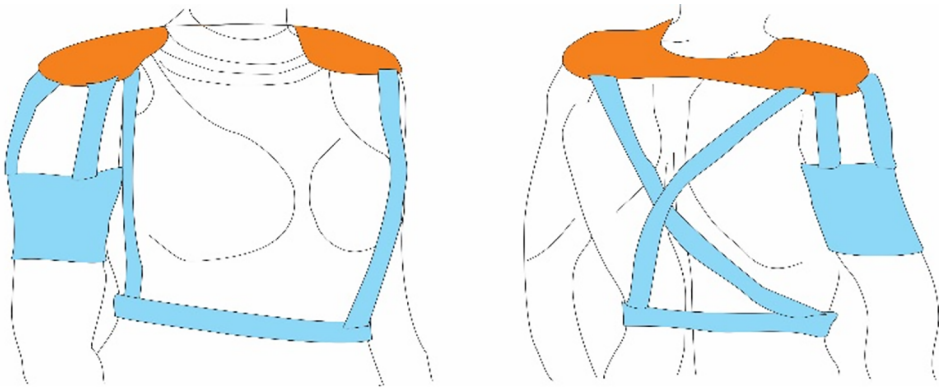

Figure 1. Sketch of the orthosis prototype. (A) Anterior view; (B) posterior view.

3D SCANNING

For digital acquisition of the anatomy and biomechanical study of the user's shoulder, the 3D scan of the user was performed with the Sensue® Scanner by 3D System, with the occupational therapist positioning the affected limb in order to place the humeral head in the glenoid cavity, correcting the subluxation of the shoulder.

The figure 2 (A-C) shows the anterior, lateral and posterior views of the user without the orthosis and the 3D drawing of the user stored in STL (Stereo Lithography) as shown in Figure 2 (D-F). The image was segmented into the volume of interest and an external surface was generated and was converted into CAD.

3D MODELING

The model generation methods were developed from the vest model of CAD (Solid Edge ST9) with the superior dimensions of the individual and conversion to the STL format. In the Magics® software 18.03 the model was overlaid with the individual's scanned model followed by a Boolean subtraction operation. A selection of the region of interest of the scanned 3D image was performed, the upper trunk and head were removed (Figure 3A) and the trunk remained (Figure 3B); considering that between the vest and the individual body there must be a distance of 5 mm for cushioning. Then, the following options were made:

Option 1: A surface was generated on the trunk (Tools-Making-Mark Surface) and with the Off Set Part operation a thickness of 5mm (Outside) is selected (Figure 3C). The Figure 3D shows the new volume and Figure 3E illustrates dimensional superiority with respect to the head. The model of the STL-converted CAD jacket was placed on the trunk with an exceeding thickness of 5 mm (Figure 3F) and after a Boolean subtraction operation was performed, the result is shown in Figures 3G and 3H.

Option 2: The converted CAD vest model transformed into STL format and positioned on the thickened trunk, followed by Boolean subtraction operation with the clearance option of 5 mm.

Option 3: An alternative was developed directly on the upper trunk with double thickness of 5 mm each. The intermediate thickening was removed to be filled with cushioning and the upper one was shaped according to Boolean subtraction operations directly in the Magics® software with areas for support of the shoulder and the scapula as well as clearance for degrees of freedom. Certainly, the degrees of freedom of the affected side was different from the contralateral side, that required greater movement, according to Figure 3 (J-N):

Option 4: The model was developed directly on the upper trunk and shaped according to Boolean subtraction operations directly in the Magics® software.

3D PRINTING

In order to verify if the process used for 3D printing led to good coupling, the model was reduced and fragmented to the dimensions of the reduced size prototype machine. A general spacing of 5 mm was provided for cushioning, with the rectangular holes for the passage of the stripes.

After the 3D impression of the reduced size model of the orthosis was concluded, it was possible to notice the complete coupling of the orthosis in the reduced size prototype.

The orthosis was then printed in a full-size 3D with the Dimension Elite Stratasys®. The thermoplastic Stratasys® ABS plus was used for the manufacture of the parts. According to the manufacturer of the thermoplastic, this material is up to 40% more resistant than a conventional ABS and its mechanical properties make it ideal for the production of prototypes and final prodocts, as it offers greater mechanical resistance and dimensional stability.

The Fused Deposition Modeling (FDM) technology uses supporting structures and materials during the printing, as to provide greater dimensional and shape stability. The material used for the supporting structures is different from the material used to make the parts, which in this case was the polymer SR30L, also from Stratasys®.

To perform the communication between the PC and the AM machine, the specific software CatalystEX was used. This software allows STL files from CAD softwares to be converted into 3D printing paths, including the support structures.

FINISHING

Traction belts (automotive belt) were made as to allow the straps to cross the user's trunk in the posterior view and to run parallel in the anterior view. Neoprene was the material for the abdominal and arm strap, specifically in the region of the biceps

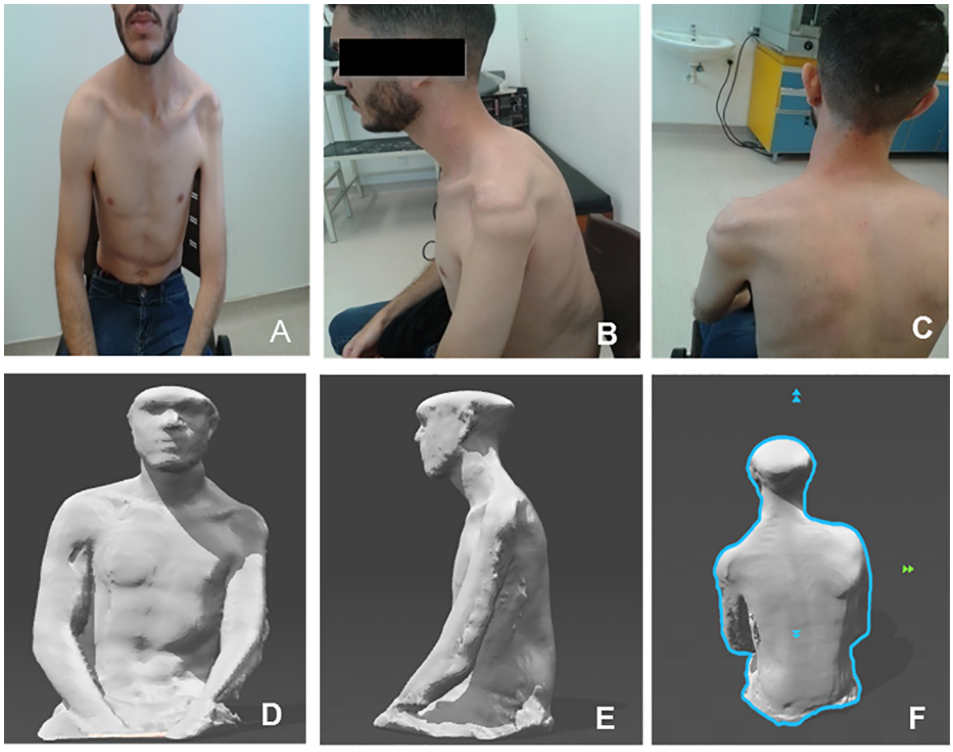

Figure 2. Patient G.O. (A) anterior view; (B) lateral view; (C) posterior view. 3D digitalization of the user potential of the orthosis to be developed: (D) anterior view; (E) lateral view; (F) posterior view.

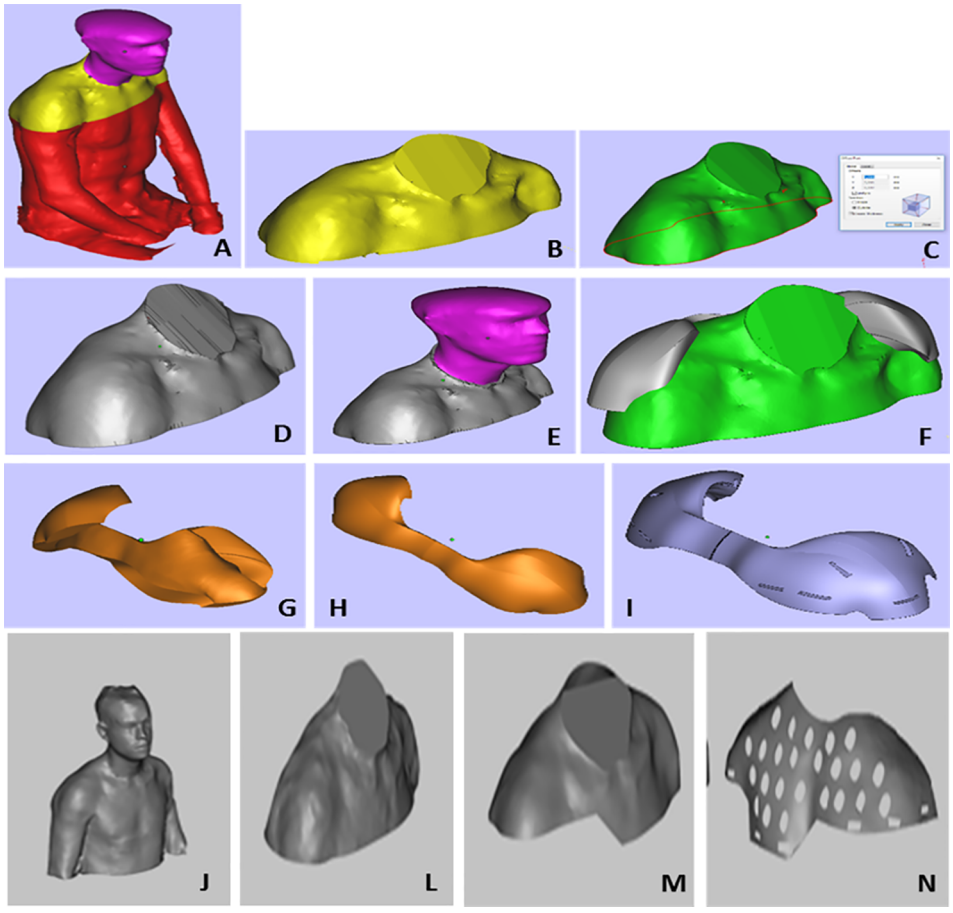

Figure 3. (A-I) 3D image of the user and the cuts for the option 1. (J-N) 3D image of the user with the cuts for the option 3.

muscle. In this strap, three parallel straps were made to intensify the superior traction based on the three portions of the deltoid muscle that covers the shoulder: the anterior (clavicular) portion is fixed to the lateral third of the clavicle; the middle part (acromial) attaches to the lateral margin of the acromion of the scapula, and the posterior part (spinal) originates in the inferior part of the posterior margin of the spine of the scapula.

RESULTS

To date, 3 versions of the orthosis was manufactured, and the patient G.O. answered the questionnaire on the satisfaction of each orthosis version. The answers guided the modifications made combined with the researchers' expertise.

The questions approached aspects such as: pain, positioning, safety, comfort of the fabric, thermal comfort, hygiene, dressing, impact on daily activities and walking, durability, tissue resistance and design (type of orthosis model). The response options were categorized (from 0 to 10) based on the Likert Scale, allowing scores from the worst to the best for each aspect of the questionnaire.

The researchers defined that the scores below 5 (50%) should be taken into account to guide the design modifications.

The patient G.O. answered the questionnaire regarding neoprene orthosis he already used and reported that it did not help the pain and the stabilization of the shoulder, and that he felt considerable weight and fatigue which made it difficult to perform daily activities. He referred scores below 5 (50%) the following items of his neoprene orthosis: pain, positioning, gait, ADLs and fabric.

EVALUATION

After the 3D print, the patient G.O. performed the test with the first version of the orthosis, which was prototyped in two pieces according to the concept presented previously, that were screwed together in the center, with a thickness of 10 mm.

Firstly, the orthosis was used without the cushioning, to facilitate the visualization of the structures and their coupling, which ended up generating discomfort and pain due to the excessive friction in the region of the neck against the plexus injury, since it was manufactured with 5 mm of extra space. This issue evidenced the necessity to adequate the design and the preparation of cushioning. The cushioning was made for all the vest (region of the bilateral trapezius muscle) and after 60 minutes using the orthosis, the patient G.O. answered the evaluation questionnaire. Within the 60 minutes, the patient was encouraged to simulate movements of reach objects, and training of ADLs (reaching objects in cabinets, computer use, etc.).

The patient G.O. rated the first version of the 3D with scores below 5 points: pain (4); thermal comfort (3); dressing (2); daily activities (4). Based on these scores, the design of the prototype of the orthosis was modified.

The second version of orthosis was printed in two parts and a guiding part was added for fixing the screws in the center, and the thickness was decreased.

Based on the necessary improvements, the following modifications were made to the prototype:

Pain: a new scan with high resolution was performed, the orthosis was printed again with smaller thickness (5mm) to reduce the weight of the piece and increase user comfort. Also, one more trap was inserted on the posterior contralateral side and the design of the orthosis was modified with an extension in the region of the scapula;

Thermal comfort: the orthosis was made with more spaces (holes) to decrease the area of contact with the skin (10mm), therefore it allowed breathing expansion and temperature decrease during use. The cushioning lining used was also reduced to fit only the contact areas of the orthosis;

Dressing: the bracing of the orthosis was made in the "T-shirt" format allowing the user to wear it without the assistance from another person, and the steps to dressing the orthosis pieces were reduced;

Activities of Daily Life: to allow the free and active movement of the contralateral healthy side, other modifications were necessary in the design of the orthosis, because still in this second prototype there was limitation of the movement of the upper limb causing the sliding of the orthosis towards the injured side.

The user tested the second version of the prototype and performed the same tests and steps of the first version and reported some items with a scores below 5 of the first test had improved. The second prototype largely met the needs for improvement and maintenance with a high degree of user satisfaction regarding the requirements: positioning, safety, comfort of the fabric, locomotion and design (type of orthosis model). Regarding the "Performance of ADL", we observed, a limitation of the movement of the healthy arm, and therefore the design of the orthosis was modified with the placement of a hinge in the posterior portion of the shoulder.

The patient tested the orthosis with the third version of the shoulder orthosis in a therapeutic setting, performing the same activities that he performed with the first prototype and reported improvements in the satisfaction with the performance of the activities of daily life, since the hinge allowed the full movement of the shoulder of the healthy arm (Figure 4).

Some issues were pointed out for improvement, such as changing the waist belt to a belt on the pants or using straps as in mountain climbing safety equipment. Also another issue that needed improvement was the extension of the of the rigid orthosis towards the contralateral shoulder region (deltoid region) and the insertion of another hinge in the region of the acromium for better coupling when under traction, to avoid possible displacement of the orthosis in the direction of the traction.

Comparing the patient's evaluation of the first version with the second version and after the third version, we have a significant improvement in the requirements: design, activities of daily life, walking, dressing, hygiene and positioning (Figure 5).

In order to verify the correction of the deformity, an X-ray examination with and without the orthosis was performed, in anterior and lateral view, as shown in Figure 6.

When analyzing the X-ray images we observe that the patient does not present static subluxation, as the lateral view seen in the X-ray does not present alteration with and without the orthosis, but dynamic subluxation, as it has the subluxation symptoms are present when there is movement, that is, during the daily activities and when he walks. From the user's report, the orthosis minimized the symptoms of the subluxation and promoted improvement in functionality. In relation to the X-ray with anterior view, it is observed that the orthosis performs traction, since there is modification of the posture of the humerus in the glenoid cavity.

DISCUSSION

The most commonly used model to describe Assistive Technology, including orthoses, currently known as the Human Activity Assistive Technology Model (HAAT Model), defines that the integration between the user, the activity to be performed and the equipment must be in harmony, so that the activity is facilitated. Another very important point is to contemplate the "client-centered approach", that is, an approach designed to the client.[9]

Based on this model, the Assistive Technology products developed without considering of human contextual needs and their influences are easily liable to not meet user needs. For this reason, preparatory studies are advocated to investigate these needs before a product is designed. Therefore, the experiences of individuals with disabilities are critical parts of AT research and development, and this process is necessary to support the identification of the real requirements for a product and to evaluate the success of each design intended to meet these requirements.[10]

Fisk et al. distinguish the utility and usability of the device. Since utility describes

Figure 4. Test with the third version of the prototype. (A) anterior view; (B) posterior view; (C) reach above 90°; (D) Object grasping; (E) and (F) reach below 90°; and (G) and (H) computer use.

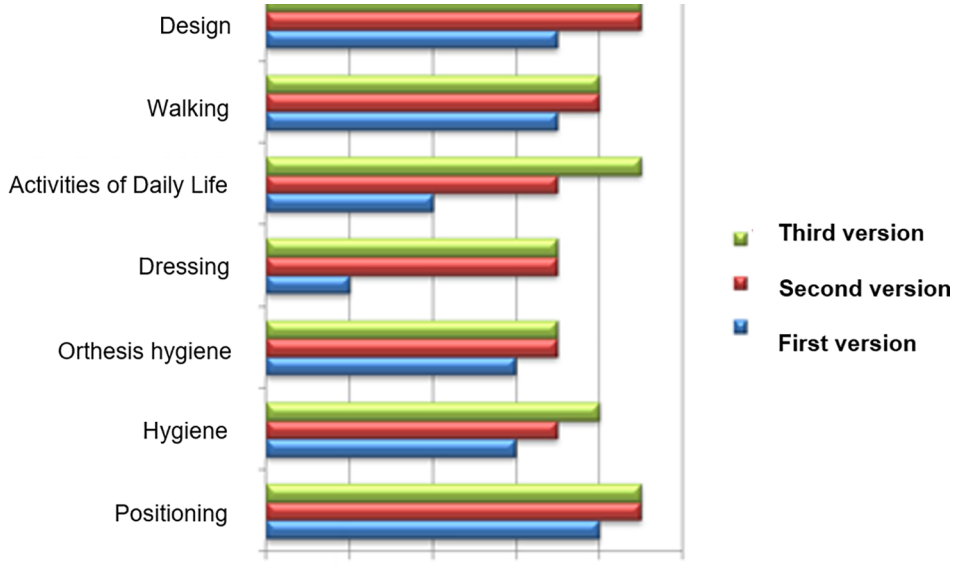

Figure 5. Comparison of the prototypes evaluation by the patient.

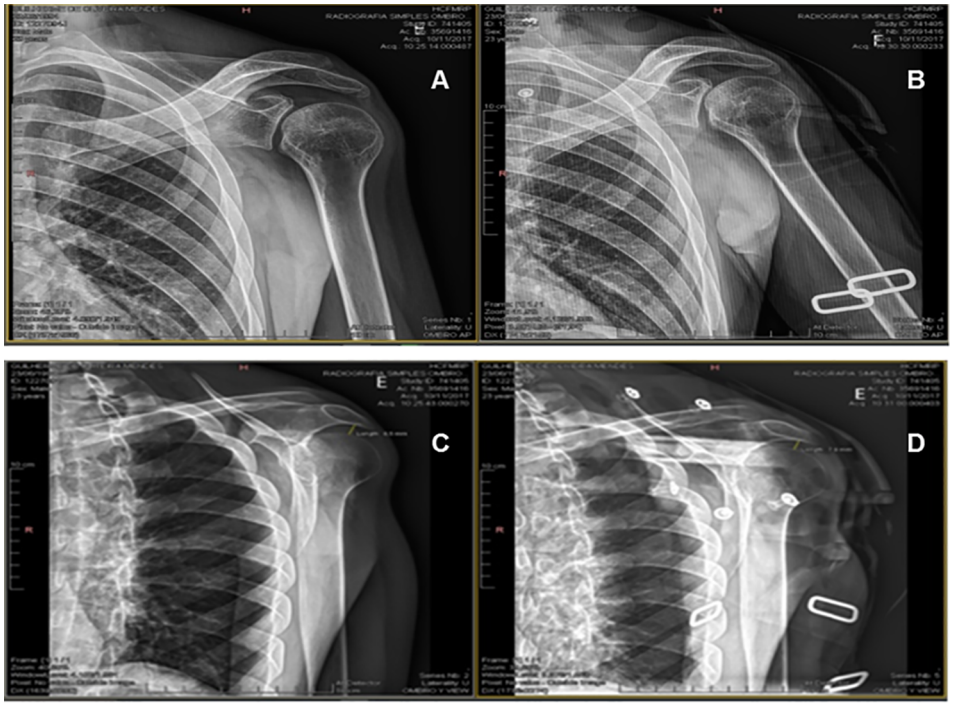

Figure 6. X-ray: (A) anterior view without the orthosis; (B) anterior view with the orthosis (C) lateral view without the orthosis; (D) lateral view with the orthosis.

how well the device meets its intended function, usability describes how well the user can access the functionality of the device.[11]

The process of developing the prototype of the shoulder orthosis followed the two main perspectives of usability analysis. First, the goal was to identify and correct problems the users have while using the device, and the second involves performing various tasks with the device and analyzing the user performance. Although both provide useful information about problems with using the device, the second type of analysis provides details on the steps necessary to use the device, as well as cognitive, communicative, sensory and physical requirements.[11]

Thus, the development of the prototype and the user test enabled researchers and users to exchange important information about the use, the needs for improvements, the adequacy of the positioning and necessary modifications to maintain the functionality of the user and, therefore, it was possible to design modifications to the project that make the public acceptance.

CONCLUSION

The orthosis was positive evaluation by the user, since it showed effectiveness regarding to positioning and safety, allowing the user to perform activities of daily life and instrumental activities of daily life and to walk independently. The design of the orthosis was approved by the user, however with the need for improvements regarding issues of comfort of the fabric and thermal comfort of the waist belt.

Thus, the concern to generate a product that meets all the physical requirements of users that also meets the needs and desires of users guided the development of the final prototype, which focused primarily on functionality aspects, as aesthetic aspects were considered secondary.

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