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Research Article

Competitor analysis of high-temperature and low-temperature thermoplastic, 3d-filament and polyvinyl chloride wrist orthoses

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Abstract

Physical therapy makes use of several types of devices in the rehabilitation process, such as the use of orthoses or prostheses, considered Assistive Technology (AT). The use of this type of device is old, being the first one dated in 2,300 B.C., and various materials have been used in its manufacture throughout history. There is a range of AT artifacts that help treat patients with reduced mobility, such as devices applied to any part of the body, especially on upper limbs, to increase range of motion. The State, which should guarantee its concession through the Unified Health System, is limited by the high cost and delay in the supply of products. Therefore, this work presents analysis based on the technical procedures of a descriptive study on the difference of orthosis materials of the high temperature, low temperature, 3D filament, and polyvinyl chloride (PVC) thermoforming market. The analysis is performed according to weight variation, supported force for material deformation, local temperature before and after the use of the orthosis, device temperature, fabrication time, and values. After analysis, it was found that the high temperature orthosis is the heaviest and responds better under the applied load, besides supporting greater daily strength and less oscillation over temperature. The low temperature orthosis is lighter compared to the high temperature one, responds minimally to the load cell, and provides low temperature oscillation. The literature reports that 3D orthosis is the lightest of all evaluated, the third most resistant under the load cell, and exhibits low temperature rise. And the PVC orthosis has a similar weight to a low temperature orthosis and occupies a second placement in the load cell holder and temperature oscillation after use.

Keywords: Assistive Technology; Orthosis; Prosthesis.

Abbreviations: BC: Before Christ; CM: Centimeter; EVA: Ethylene Vinyl Acetate; FDM: Fused Deposition Modelling; G: Grams; HG: Kilogram; KGF: Kilogram- force; MM: millimeter; UL: Upper Limbs; PLA: Polylactic acid; PVC: Polyvinyl Chloride; AT: Assistive Technology; 3D: Three-dimensional; °C: Degree Celsius

Introduction

The most visible and recurrent symptoms in individuals with neurological disorders are tone and

spasticity. According to Sanvito [1], muscle tone is the state of contraction existent normally in the muscles. It is characterized by the degree of resistance to passive stretching. Since muscle fibers do not contract without a nerve impulse at rest, muscle tone is maintained through impulses from the spinal cord. The main cause of tone change would be a disharmony of alpha and gamma motor neurons. This tone may change depending on whether the muscle is active or at rest. Tone changes are known to interfere with functions such as motor control, balance, muscle strength, deformities and pain process [2].

Changes in tone may be increased hypertonia, decreased hypotonia or complete absence atony. Hypotonia can be produced immediately if the ventral roots containing the motor nerves innervating the limb are cut. Hypertonia is accompanied by the resistance in the clasp knife and the contraction reflexes are exaggerated, i.e., there is an increase of responsiveness of the alpha motor neurons to the type Ia sensory stimulus. The clasp knife phenomenon refers to the relatively higher resistance to passive manipulation during a given movement angle and can be classified according to this angle. And the rapid decline of the resistance as the range of limb movement is increased. The resistance of the initial clasp knife response results from the hyperactivity of the stretch reflex, while Golgi tendon organ is probably involved in the sudden triggering of the stretch reflex [3].

Spasticity is the reduction in the amount of active movement by the expansion of muscle tone as a result of injury to central command effector systems, which will cause changes in postural and motor function due to the mechanical disadvantage of some antagonist and antigravity muscles. The fall in movement selection and reciprocal inhibition, also known as co-contraction, occurs jointly and is characterized by the parallel contraction of agonist muscles that are spastic and antagonistic, interceding in the speed of automatic movements, such as wrist changes, incapacitating the individual in basic activities of daily living [4].

Thus, the physiotherapy makes use of several devices for the rehabilitation process, among these

devices are orthoses and prostheses, considered assistive technologies. The earliest record dates from 2300 B.C. when Russian archaeologists discovered the skeleton of a woman with an artificial left foot. The prosthesis was composed of a goat's foot adapted to the stump by a fitting made by the animal's own dissected skin. This news was published on January 26, 1971 in an article by France Presse that reported Fajal's thesis (Figure 1).

Figure 1: The wooden finger found in a three thousand year old mummy

Figure 2: Metal, leather and wood orthoses.

Source: SHIMITHSONIA [5] n.d. Three-thousand-year-old wooden toe shows the early art of prosthetics.

In the first half of the twentieth century, orthoses were mainly made of metal, leather, fabric, and wood (Figure 2).

A: Metal orthosis (Source: PAUL COLLECTION [6] n.d. Prosthetic hand made for a knight from sixteenth century); B: Leather and wood (Source: PASSO FIRME [7] n.d. Wood and iron leg, nineteenth century).

In the trajectory of these materials, it is worth mentioning that practically wood is no longer so used

in the production of orthoses; plaster began to be used in medicine, more specifically in orthopedics, in the tenth century and remains so far in the twenty-first century, although less frequently due to products with new technologies. Fabric, metal and thermoplastic are certainly the most commonly used materials for orthoses fabrication, but this position is only due to the fact that fibers have a higher cost; the use of plastic (thermoplastic or thermo-rigid) in orthoses fabrication began in 1960 (Figure 3A). When some authors mention rubber as one of the materials for orthosis fabrication, they include elastics, neoprene (Figure 3B), silicone, polyurethane (Figure 3C) and foams in this material [8].

Figure 3: Thermoplastic, Neoprene and Polyurethane.

A: Thermoplastic (Source: ORFIT [9] n.d. Dynasyst - dynamic splinting); B: Neoprene (Source: MERCUR [10] n.d. Orthosis for Wrist with Bilateral Split); C: Polyurethane (Source: MAGAZINE MÉDICA [11] n.d. Dynamic foot in polyurethane).

Assistive Technology (AT) is a term used to identify the full arsenal of resources and services that contribute to provide or amplify functional skills of people with disabilities and, consequently, promote independent living and inclusion [12].

The AT artifacts are the full range of devices designed to enable greater functionality to older people

or other individuals with disabilities or reduced mobility, assisting them in their domestic or occupational activities of daily life. Among these are the orthoses that are mechanical devices placed externally to the body segment aiming greater independence, functionality and biomechanical performance of users [13].

According to Teixeira [14] also Cavalcanti and Galvão [15], orthosis is defined as the device applied to any part of the body in order to protect repaired structures, maintain or increase the range of motion, to contribute to movement when there is not enough muscle strength, perform the action of muscle strength or to be the basis for insertion in self-help devices.

Based on the phases of upper limb (UL) functional recovery and that patients with spasticity present postural pattern in the flexion of wrist, finger, and thumb adducted or flattened, the orthosis is considered an essential resource in hand rehabilitation, which acts by preventing or correcting existing deformities. Moreover, the devices keep the tissues in a single position for correct joint alignment, avoiding deformities and preventing the development of contractures by the positioning [16].

Brazil's public health system has principles that guarantee the user a universal and integral care. Before that, it is the state's responsibility to guarantee the concession of orthoses, prostheses and mobility aids. However, it is known that the practice of this state's responsibility to guarantee to its users is not effective in most cases [17].

The limiting factors for orthosis acquisition is the high cost and the delay of the public service to

provide it, so the market is seeking to adapt products and treatments to people with neurological disorders. All of these factors add value to draw the attention of industries, so they create low-cost specific equipment for the fabrication of these orthoses, both for therapy and to assist their lives and their quality of life.

Materials and Methods

This research is a proposal to perform a competitor evaluation of orthoses made in high temperature and low temperature thermoplastic, 3D filament printing, and PVC pipe for changes in wrist angulation. This was based on the technical procedures of a descriptive study, through the fabrication of orthoses.

The research location was physiotherapy Clinic of Centro Universitário Barão de Mauá.

To produce the high temperature thermoplastic orthosis, the following materials were used: Plaster bandage, silicone protection, scalpel, electric heating element, water, plastic container, liquid plaster, sander, 4mm high temperature thermoplastic plate, industrial oven, vacuum, hook and loop clasp, 3mm EVA, rivets, hammer, 2.0mm pilot permanent marker, drill and wood glue.

To produce the low temperature thermoplastic orthosis, the following materials were used: Alcohol 70%, A4 bond paper, ballpoint pen, scissors, 1.6mm thick Ezeform low temperature thermoplastic plate, 75°C high temperature water container, Fiskars scissors, super shears scissors, towel and hook clasp and self-adhesive loop.

To produce the mold for the 3D orthosis, the following materials were used: Scissors, 15cm plaster bandage, measuring tape, plastic container with water, ballpoint pen, A4 bond paper.

And to print the 3D printing filament orthosis the following equipment and parameters were used:Low cost Fused Deposition Modeling (FDM) 3D Printer; 1.75 mm Easy Fill polylactic acid filament (PLA) from 3D Fila.To produce the PVC orthosis, the following materials were used: A4 bond paper, ballpoint pen, scissors, 5-inch PVC pipe, grinder, high temperature water container, ethylene vinyl acetate (EVA) sheet, instant glue, transparent strong fixed double-sided tape and hook and loop clasp (Velcro).

For the beginning of the process of the high-temperature orthosis fabrication, the employee places

the plaster bandage in a plastic container with heated water, then a silicone shield is placed on the volunteer researcher's arm and this bandage is molded; after drying the mold is removed from the arm of the individual above the protection using a scalpel, so we have a negative plaster mold, this mold is taken to production where the filling is done with liquid plaster.

After the complete drying of this mold, now called positive plaster, it is sent to the matrix, where it is sanded and adjustments are made, such as bone projections, pressure distribution for the customization of the orthosis.

Then a piece of the 4mm high temperature thermoplastic plate is baked at 300 ° C and a vacuum thermoforming is made using a vacuum on the positive plaster mold, after the material has cooled it is cut out and the orthosis is removed from the mold starting the finishing step, where the irregular edges are sanded with different thicknesses of sandpaper giving the proper finish.

Next, five hook Velcro stitches are attached with rivets to the back of the orthosis, and after that the 3mm EVA is taken to the oven and molded on the positive plaster, which facilitates the adhering within the orthosis, so it is glued inside of the orthosis, which is in contact with the skin of the individual, thus protecting from the exposure of rivets and promoting comfort, finally the Velcro rings are placed with an EVA finishing (Figure 4).

In the low temperature thermoplastic orthosis, initially, the volunteer researcher's forearm and hand area was cleaned with alcohol 70% and under this region an A4 bond paper was placed and the forearm was traced with a pen to the phalanges, after that it was cut out and used as a template for tracing the individual's measurements on the low-temperature thermoplastic plate, later this tracing was cut with Fiskars scissors and taken to be heated in a container with water at a temperature of 65 ° C to 75 ° C, until the plate is malleable, the cut completed with the super shears scissors so the necessary finishes are made on the edge so that it does not have points; then, the material was dried with a towel and modeled directly on the individual's hand, allowing a good fit and making the necessary adjustments, after cooling the material recovers the stiffness, and was finished fixing the hook and loop self-adhesive clasp in five positions (Figure 4).

In the confection of the 3D orthosis, the volunteer researcher remained seated, with elbow flexion at 90 degrees, forearm in pronation position and supported by a table, the forearm region was cleaned with alcohol 70%.

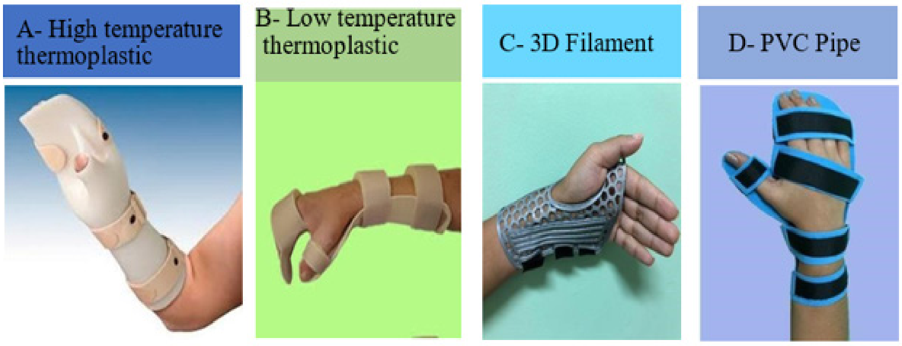

Figure 4: Hand and wrist orthoses.

Under his forearm an A4 bond paper was placed and the upper limb (from the wrist to the phalanges) was traced, shortly after it was cut, which later served as a template for the plaster.

A plastered bandage of 15cm folded seven times and the mold of the bond paper that was reserved were used, the last one serving to make the outline on the bandage, soon after that the plastered bandage was cut and dipped in potable water inside a plastic container being squeezed to remove excess water (three individuals were placed in a supination position and the plaster bandage was applied on the affected limb of the individual being molded under his forearm, remaining for five to ten minutes to dry. After the plaster dried, it was removed, and the individual's forearm was cleaned so that no residue remains.

After the plaster mold process was completed, it was sent to the place where the 3D printing took place (Figure 4).

For confection the PVC orthosis, the mold was carried out of the phalanges outline to the forearm was made on an A4 bond paper, which was cut with scissors, and then transferred to the PVC pipe. With the aid of a grinder, the excess material was removed around the marking to facilitate the next step, which is to cut the exact demarcation. After cutting it, the same disc was used to sand the edges and remove any irregularities that may have been remained, this process was immersed in a container with boiling water to shape it in the appropriate position to the type of orthosis developed.

For the EVA coating a cut in it that covers the entire surface of the PVC orthosis was made, on the side that will be in contact with the skin of the individual. Using the instant glue, the EVA was glued, and the finishing was done to remove all the burrs.

The double-sided adhesive tape was glued to the back of the rough side of Velcro and then fixed to the back of the orthosis. Five attachment points were also inserted using the Velcro process. After attaching the straps that will hold the individual's hand and forearm to the orthosis, it was necessary to make an EVA protection on the top of the Velcro straps to avoid friction with the individual's skin (Figure 4).

A: High temperature thermoplastic (Source: EXCLUSIVAS IGLESIAS [18] n.d. Hand immobilization splint in functional position); B: Low temperature thermoplastic (Source: ADPOSTURAL [19] n.d. Upper Limb Orthoses: Hand e Wrist); C: 3D Filament (Source: own authors); D: PVC Pipe (Source: own authors).

The evaluation process occurred through the application of photothermography, weighing, dynamometry, time to confection and estimated values.

Photothermography: For the analysis of the orthosis through infrared temperature a photothermography FLIRC2 (Serial No.: 720103682 – FLIR Systems OÜ, Estônia was used.

The analyzes were performed using the FLIR TOOLS software, which gives a reliable result of the thermographic evaluation, with predetermined temperatures between 26ºC and 37ºC, using the Sp tool which, when positioned, indicates the local temperature.

With the 3D printed filament, PVC orthoses and those available on the market at hand, they were positioned on a table where the thermographic recording occurred in a specific room with closed windows and doors with ambient local temperature ranged from 21ºC to 25,1ºC. The literature informs us that the temperature must be constant 23ºC [20].

Weight: The orthoses were weighed using the SF-400 high precision digital electronic scale with a maximum capacity of 10kg.

Dynamometry: A fastening belt was used to stabilize the orthoses attached to the table and with the lafayette instrument 01165-manual muscle tester, also known as manual dynamometer, a force was applied until the orthosis deformed.

Production time and cost: There was a budget and fabrication time request by telephone to orthoses companies in the city of Ribeirão Preto.

Results

The results that will be presented below demonstrate the data obtained by the researchers regarding weight, strength, material temperature analysis, as well as time and average values for making the orthoses.

(Table 1) presents the weight of each evaluated orthosis in this research. In a comparison it is noted that the high-temperature thermoformed orthosis is the heaviest one being 175 grams and the 3D is the lightest one weighing 19 grams. Low temperature thermoformed and PVC orthoses have similar weights, being 108 grams and 105 grams, respectively.

Table 1: Values regarding the weight of the evaluated orthoses.

	High temperature thermoformed	Low temperature thermoformed	3D	PVC
Weight	175g	108g	19g	105g

(Table 2) shows the values related to the resistance of each orthosis evaluated in the present work, and the high temperature thermoformed supports the highest load, being 17.7kgf. In second place is the PVC orthosis with 11.4kgf, followed by the 3D orthosis with 7.2 kgf and the least resistant of those evaluated is the low temperature thermoforming.

Table 2: Values regarding the resistance applied with manual load cells over the evaluated orthoses.

	High temperature thermoformed	Low temperature thermoformed	3D	PVC
Manual load cell	17,7kgf	1,1kgf	7,20kgf	11,4kgf

Table 3: Values regarding the photothermography analysis.

	High temperature thermoformed	Low temperature thermoformed	3D	PVC				
Orthosis temperature before and after use	Before	After	Before	After	Before	After	Before	After
Point 1- Higher temperature	24,8° C	27,9° C	24,2° C	30,7° C	24,4° C	29,1° C	24,4° C	29,0° C
Point 2- Lower temperature	24,0° C	22,8° C	23,9° C	24,5° C	23,4° C	25,7° C	24,0° C	24,9° C

In (Table 3) the temperature, without use and after five minutes of use, of the evaluated orthoses were analyzed by photothermography: high-temperature thermoformed, low-temperature thermoformed, 3D filament printing and PVC.

As shown in (Table 3), it is possible to state that the low temperature thermoplastic orthosis is the one that warms most in contact with the body with a difference of 23.9°C to 24.2°C before use and 24.5°C to 30.7°C after five minutes of use (Figure 5), followed respectively by the 3D orthosis, with a temperature of 23.4°C to 24.4°C before use and 25.7°C to 29.1°C after five minutes of use (Figure 6), subsequently the PVC orthosis with 24.0°C to 24.4°C before use and 24.9 to 29.0°C after use (Figure 7), the one with the lowest temperature compared to the studied materials was the high temperature thermoplastic orthosis with a temperature of 24.0°C to 24.8°C without use, after five minutes of use 22.8°C to 27.9°C (Figure 8), considering these results we can say regarding the temperature in contact with the body, the material with the best performance is the high temperature thermoplastic.

Thermographic evaluation was performed with the environment at 25.1° C and 50% humidity and ended with 24.1° C and 57% humidity. ° C: degrees Celsius

(Table 4) shows the average values (in reais) and fabrication time of orthoses according to research conducted by the authors with three companies specialized in the area.

In case of delivery in 30 days, the cost of orthosis in company 1 is R$900.00, this amount being increased by R$50 if delivery is anticipated by 15 days.

Table 4: Information regarding the time and average values for making orthoses.

	High temperature thermoformed	Low temperature thermoformed	3D	PVC
Fabrication time	Average of 30 days	Average of 15 days	Average of 10 days	Average of 02 days
Value company 1	R$ 900,00	R$ 95,00	-	-
Value company 2	-	R$ 780,00	-	-
Value company 3	-	-	-	-
Third parties	-	-	R$ 30,00	R$ 15,00

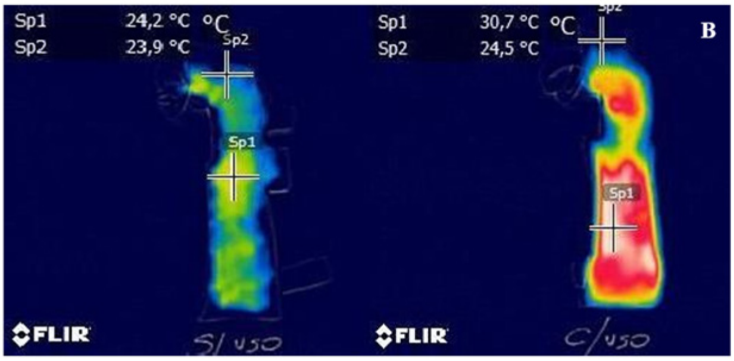

Figure 5: Photothermography of the low temperature thermoformed orthosis before and after the use.

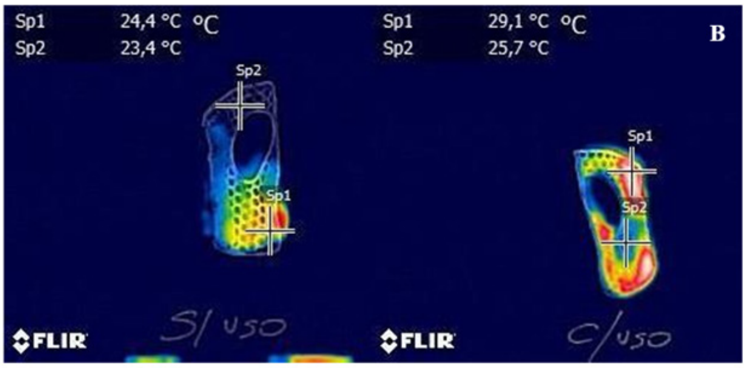

Figure 6: Photothermography of the 3D printing orthosis before and after the use.

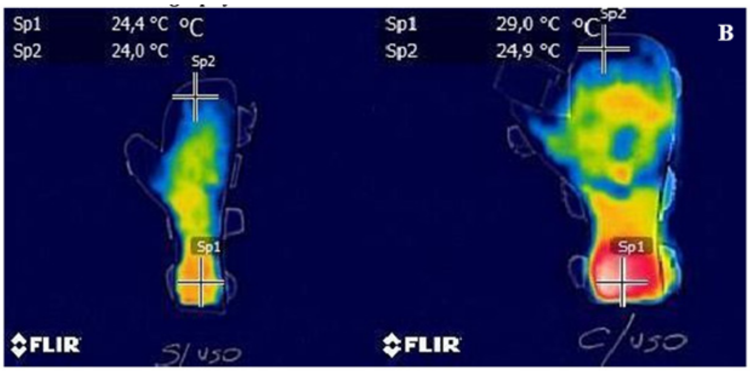

Figure 7: Photothermography of the PVC orthosis before and after the use.

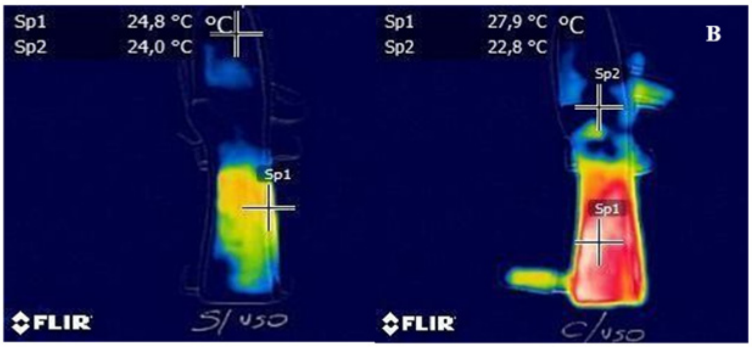

Figure 8: Photothermography of the high temperature thermoformed orthosis before and after the use.

The cost presented by company 2 is lower, being R$780.00, with estimated delivery in 15 days.

The third company did not provide the values and fabrication time of the orthoses.

3D and PVC filament printing orthoses are not commercialized, yet the values and the average fabrication time are R$30,00 and R$15,00, ten days and one day respectively.

Company 3 declined to report by phone the values and average time of fabrication.

Discussion

Through the results obtained by the researchers, the importance of the study was verified, given

the large number of individuals who make use of this Assisted Technology and the difficulty of access.

In the last decades there have been several advances in the areas related to orthoses, however some requirements such as low weight and high efficiency remain a challenge in relation to the research [21].

We emphasize the difficulty in finding information on orthoses in national bibliographies,

especially when it comes to the weight of orthoses in different types of materials. Although this is a resource commonly prescribed by professionals such as physiotherapists, occupational therapists, doctors and others, there is a lack of research and publications on this theme, which leaves the information restricted and some gaps still unanswered.

It is interesting to consider the importance of the subject, since the number of people who use these devices is relatively large considering that it will be used for several hours and weight becomes a key characteristic to be analyzed [22].

Research on this study is necessary due to the lack of literature on the application of load cells in

orthoses.

According to Maud and Foster [23], Load cell is a brief device that can measure the tension

force or compression force applied on the object. It allows to estimate the enormity, modification of the structure, pressures, forces, weights, among others.

The force that acts on a target causes its deformation. This deformation can be measured

electrically. It has been quite differentiated through the use of load cells, which are force transducers for electrical magnificence [24].

The property of stiffness is the material's ability to withstand daily aggression, and for that, the

material needs a combination of flexibility and stiffness. These aggressions are associated with the spasticity expressed by the individual, force generated in the lever arm that is created between the forearm and hand and that can transfer the fragmentation of the orthosis [25].

The Ezeform material shows in the tension evaluation its stiffness to flexibility relation which had

already been written by the catalog, and in the evaluation of elongation, but the load and tension stands out from these descriptions in the unit of resistance, because it shows little resistance among the other materials [25].

According to Lindemayer [25]"[...] Elongation at break: represents the percentage increase in

the length of the piece under tension at the moment of break, causing a deformation of the material".

The author Lindemayer [25] presents the low temperature thermoformed material with a small resistance compared to other materials contained in the orthosis comparison. In our present study, we also note the lower resistance of low temperature thermoformed orthoses, thus the high temperature thermoformed is the most resistant.

It is notorious the literary scarcity regarding the subject of the present study, so the researchers made a thorough investigation, among others, about the values and time for making orthoses. There are several factors that guide the choice of an orthosis, the main factor highlighted [26] is the price of the material. Of the forty-four professionals in the area of physical rehabilitation interviewed by the authors, 89% presented the price of the material as the main difficulty found "in the production of really effective orthoses".

The Ministry of Health's Manual for Confecção e Manutenção de Órteses, Próteses e Meios Auxiliares de Locomoção (Making and Maintaining Orthotics, Prosthetics and Assistive Means) (2013), on the concept of Conceito de Gestão e Controle de Qualidade (Quality Management and Control), warns that "products are custom-made, i.e. personalized and customized". Quality control aims to ensure the satisfaction and need of the client/patient, meeting the therapeutic proposal.

"It is necessary to remember that the products are custom made, that is, personalized and customized, and the quality requirements of the products are described by their need for functionality, respecting the prescriptions of the medical team and therapists. Thus, the great challenge is to combine the therapeutic functionality with the expectations of customers (patients), regarding the needs of comfort and esthetic, without prejudicing the functionality and resoluteness of products and services. This challenge requires workshops to establish well-defined manufacturing processes with description pf responsibilities and to adopt partnerships with suppliers to acquire quality inputs, ensure the traceability of products and their inputs/components, train technical staff and implement quality control based on product quality requirements, aiming to provide reliable, durable and high-resolution products to provide quality of life to users/customers" [27].

Agnelli and Toyoda [26] point out that the benefits outweigh the expenses, since "few people

fail to make a satisfactory orthosis because of the price, when it is needed".

Also, according to the authors, there is not much variety of materials in the Brazilian market, due to economic and distribution issues. Thus, part of the population uses plaster-based materials, despite having a lower quality (according to the authors' opinion), but is more accessible than imported materials, due to socioeconomic conditions.

According to Agnelli and Toyoda [26], currently an analogy to search for these materials is their comparison to the characteristics of the human body, that is, the study of the mechanical and chemical properties of the skin, bones and muscles indicate the class of materials to be used.

Regarding the study as for the temperature with and without the use by means of photothermography, no data were found in the literature and no specific publication on the subject, therefore we will discuss the data obtained in our analysis in order to collaborate with future research. Given the data obtained it was possible to state that the low temperature thermoplastic orthosis is the one with the lowest performance in terms of body contact temperature, followed by the 3D orthosis, subsequently the PVC orthosis and the high temperature thermoplastic orthosis with a difference after five minutes of use of 2.8° C compared to the highest performing material (low temperature thermoplastic), however we can say that in body contact temperature analysis, the best performing material is the high temperature thermoplastic, considering that the highest temperature peaks are at pressure points, caused by the positioning of the orthosis.

Orthoses as assistive therapy should be used according to the characteristics of each person and

their respective clinical case and their use is widely indicated by professionals. The studied authors point out the scarcity of materials in Brazil, as well as high prices and delay in the fabrication as important factors, which emphasize the importance of the research of the present work.

Conclusion

Regarding the analysis of the difference of orthosis materials available on the market, it can be concluded that the high temperature orthosis is the heaviest; however, it responds better on the applied load, tolerating more the force in daily life and showing less oscillation on temperature during use. About the low temperature orthosis, it was verified that it is lighter compared to the high temperature one, responding minimally to the load cell and providing greater oscillation over the temperature. In relation to the 3D orthoses, the literature reports that it is the lightest among all the evaluated orthoses, being the third most resistant, and intermediate in relation to the temperature changes. And, regarding the PVC orthosis, it is concluded that its weight is similar to the low temperature orthosis, and according to this study, it is the second in the load cell support and presents greater temperature oscillation. Nevertheless, it must be observed that despite this observation, there are no evidences in the scientific literature that can corroborate or disagree with the results obtained in this research; shows the need for further studies in order to improve the scientific literature related to the theme.

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