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Original Article

Empirical practical evaluation instrument for thermoplastic materials for orthoses[1]

Instrumento de avaliação prática empírica de materiais termoplásticos para órteses

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Abstract

Introduction: After the advent of low-temperature thermoplastics, their prevalence in the manufacture of orthoses for upper limbs has been identified by several authors. The understanding of their properties by occupational therapists and other professionals working in this field is important in the process of selecting the thermoplastic, which follows a logic to match the material's characteristics to the desired function for each orthosis. **Objectives**: Systematize the characteristics of low-temperature thermoplastics and, from that, develop an instrument for carrying out practical empirical tests with the materials, to establish criteria for their handling and evaluation. **Method:** Exploratory study consisting of the creation of testing procedures and, consequently, the development of a qualitative assessment instrument that values the practical experience of the professional who handles the material and evaluates each requirement. **Results:** The created instrument includes 14 material characteristics, accompanied by a definition, a procedure with recommendations for the practical testing, and a field for filling in response alternatives. **Conclusions**: The instrument considers important characteristics to be verified during the evaluation of materials and can direct the professional's observations and records, aiding in clinical decision-making. This will be important to improve the quality of orthoses and other assistive technology devices made with these thermoplastics. In addition, the systematization of the practical evaluation of thermoplastic materials can assist in the development of health studies and research involving materials for orthoses.

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Keywords: Occupational Therapy, Orthotic Devices, Polymers, Mechanics, Materials Testing.

Resumo

Introdução: Após o advento dos termoplásticos de baixa temperatura, sua prevalência na confecção de órteses para membros superiores é identificada por vários autores. A compreensão de suas propriedades, por parte do terapeuta ocupacional e de outros profissionais que atuam na área, é importante no processo de seleção do termoplástico, que segue uma lógica para combinar as características do material à função desejável para cada órtese. **Objetivos**: Sistematizar as características dos termoplásticos de baixa temperatura e, a partir disso, elaborar um instrumento para realizar testes práticos empíricos com os materiais a fim de estabelecer critérios para o seu manuseio e avaliação. **Método:** Pesquisa de caráter exploratório, constituindo a criação de procedimentos de teste e, consequentemente, a elaboração de um instrumento de avaliação de abordagem qualitativa e que valoriza a experiência prática do profissional, que manipula o material e avalia cada requisito. **Resultados:** O instrumento criado contempla 14 caraterísticas do material, acompanhadas de uma definição, um procedimento com recomendações para o teste prático e um campo destinado ao preenchimento das alternativas de resposta. **Conclusão:** O instrumento considera características importantes a serem verificadas durante a avaliação dos materiais e poderá direcionar o olhar e os registros do profissional, auxiliando o nas decisões clínicas. Isso será importante para melhorar a qualidade das órteses e de outros dispositivos de Tecnologia Assistiva confeccionados com esse grupo de materiais. Além disso, a sistematização da avaliação prática dos materiais termoplásticos poderá auxiliar no desenvolvimento de estudos da área da saúde e de pesquisas envolvendo materiais para órteses.

Palavras-chave: Terapia Ocupacional, Aparelhos Ortopédicos, Polímeros, Mecânica, Teste de Materiais.

Introduction

Orthoses are part of a range of resources that can be used in occupational therapy for therapeutic or assistive purposes, commonly applied in conjunction with other strategies to enhance occupational performance, either directly or indirectly. There is a wide variety of orthoses that can be categorized according to different criteria: anatomical location, functionality and therapeutic indication, manufacturing and crafting system, as well as structural components, including diversified materials (Agnelli Martinez, 2018).

Because polymeric materials are lightweight, flexible, exhibit good resistance to corrosion, and are made up of organic, synthetic, or natural macromolecules, they have been often used in the orthopedic market since the 1970s and 80s (Maitz, 2015; Mano, 1991; Ramakrishna et al., 2001). Among these materials, thermoplastics have been the most used since, as suggested by their definition, they deform when heated and harden when cooled, and can be molded and remolded when heated (Canevarolo, 2019; Malick, 1978; Meng et al., 2008).

After the advent of low-temperature thermoplastics, which have a working temperature range of 45-70 ºC (113-158 ºF) and can be applied directly to the body, their prevalence in the manufacturing of orthoses for upper limbs has been identified in several national and international studies (Agnelli & Toyoda, 2003; Agnelli Martinez, 2018; Almeida et al., 2016; Fess, 2011; Mckee & Morgan, 1998; Mckee & Rivard, 2011; Meng et al., 2008; Silva, 2001; Silva, 2014). In studies conducted in Brazil, where the samples were composed of professionals working in the crafting of orthoses for upper limbs, 90.9% of the participants mentioned the use of low-temperature thermoplastics in the study by Agnelli & Toyoda (2003), 83% of participants in the research conducted by Silva (2014), 83% in the work of Almeida et al. (2016), and 100% of the professionals who participated in the study by Agnelli Martinez (2018). These materials have potential for the fabrication of custom orthoses, favoring anatomical contours and enabling the individualization of the device to a specific need, also simplifying the manufacturing process.

In addition to orthoses, these materials are recommended for the manufacturing of other assistive technology (AT) devices, such as grasp substitutes for Activities of Daily Living (ADLs), adaptations for school materials, tips for computer use, among other resources aimed at optimizing function, and can be associated with some type of orthosis if necessary (Agnelli & Toyoda, 2003; Fess, 2002; Orfit Industries, 2023; Souza, 2014).

Regardless of the application, whenever possible, occupational therapists must design individualized devices that meet biological and occupational needs through a client-centered approach that considers physical, cognitive, and affective attributes, according to the context (Mckee & Rivard, 2011). Some authors assert that the prescription and crafting of orthoses constitute a complex process that involves determinant variables for people's health and quality of life (Assumpção, 2006; Callinan, 2013; Gradim & Paiva, 2018), as well as skills in activity analysis and knowledge in distinct areas, including anatomy, physiology, biomechanics, orthopedic materials, mechanical principles, manufacturing techniques, physical assessment with the application of corrective forces, and muscle testing (Macdonald et al., 2004; Mckee & Morgan, 1998; Mckee & Rivard, 2011).

According to Fess (2011), an understanding of hand conditions and realistic expected goals is needed to optimize the characteristics and possibilities that different materials can offer. Understanding the physical and mechanical properties improves the process of selecting the material to be used – a crucial factor in the routine of professionals who seek to match the material's characteristics with the desirable function for each orthosis (Canelón, 1995; Fess, 2011; Van Petten et al., 2014). To this end, it is important to be well acquainted with certain characteristics, such as conformability, adherence, memory, stiffness, resistance to stretching, surface finish, durability, hygiene conditions, user comfort, and cost (Lindemayer, 2004; Mckee & Rivard, 2011; Sauron, 2003). The specific working temperature and heating and cooling times also need to be considered (Meng et al., 2008).

For Lindemayer (2004), some strategies can be adopted to make this evaluation objective, and other methods can be associated, such as conducting tests to verify the properties of the materials. According to Garcia et al. (2000), material tests are important as they enable the development of new information about them and the creation and/or modification of manufacturing processes and treatments. There are national studies addressing heat moldable materials that present diverse and standardized laboratory analyses, satisfactory for evaluating some properties of these materials (Danckwardt, 2016; Leite, 2007; Lindemayer, 2004; Ramos, 2017; Rodrigues, 2007; Silva, 2001; Silva, 2014; Souza, 2014). However, no tests or assessment instruments were found to assist professionals in evaluating these materials in clinical practice, regarding the specific characteristics for application in orthoses, so that they can verify exactly what is expected of a material for this purpose. There are works describing initiatives of this standardization, such as the tests created by Breger-Lee & Buford Junior (1992) to assess different commercially available low-temperature thermoplastics at the time for moldability, durability, and stiffness. Another study, carried out by Souza (2014), characterized a polymeric material based on vegetable oil developed by Leite (2007) and compared it with some market thermoplastics adopting certain procedures to verify moldability, comparing advantages and disadvantages of different materials. Souza (2014) also developed two more tests: a "human skin contact temperature test" to verify the safe and comfortable temperature range for an individual during the molding of orthoses, and a "cooling test" in which the speed of its heat loss was monitored to determine the time needed for it to return to room temperature.

Other studies have developed practical tests to verify difficulties during the molding of orthoses, and some of them involve the perception of those who handle them. Lindemayer (2004) presented two qualitative tests involving the handling of materials: a stretch test and a memory test. This researcher found interesting results, relating, for example, the ability of the material to return to its original state to the amount of rubber present in its composition. Souza (2014) characterized the polymeric material based on vegetable oil developed Leite (2007) and compared it with some thermoplastic materials on the market. To this end, she developed empirical and comparative procedures aiming to standardize and evaluate the immersion time in water, memory, and the human skin contact temperature, as well as the safe and comfortable temperature range for an individual during the molding of orthoses. Another study, conducted by Francisco (2004), assessed three wrist orthoses made from three alternative materials. Although she did not use low-temperature thermoplastics, this author proposed empirical practical tests related to 10 characteristics of the evaluated materials, considered essential for the good performance and manufacture of an orthosis.

Despite advances involving materials and the development of standardized experiments, especially those in laboratory, the materials for upper limb orthoses are not commonly assessed objectively by healthcare professionals. Instead, they are evaluated based on the ease and difficulties during handling, in a subjective manner (Francisco, 2004; Lindemayer, 2004; Souza, 2014). Thus, there is a lack of consistency in the way low-temperature thermoplastics are evaluated, tested, and experimented with, as well as in interpreting the results.

There are many studies addressing orthoses; however, most of them discuss the effectiveness of the devices along with occupational performance components, such as strength, range of joint motion, and dexterity, or the functionality and application of the resource in different situations. Few works are specifically aimed at evaluating, defining, and testing the properties of the materials used for this application (Agnelli Martinez, 2018).

In this context, the aim of this study was to systematize the characteristics of the thermoplastics used in the manufacturing of orthoses and, from that, develop an instrument for carrying out empirical practical tests with these materials to establish criteria for their handling and evaluation by the professionals who work in the crafting of orthoses.

Method

Exploratory research that consists of the development of criteria and testing procedures for thermoplastic materials for orthoses, and consequently, the creation of an assessment tool for this application. Therefore, the methodological path followed here sought to develop something that does not yet exist and enables improvements in the evaluation process of a specific group of materials.

Procedures for planning the instrument

Initially, a review of the literature was conducted regarding low-temperature thermoplastics used to manufacture orthoses, as well as the instruments and strategies employed for their evaluation and the existing tests to examine their properties. Based on what is considered important in the specific literature of the area—as reported in the theoretical foundation—meetings were held between the occupational therapy team and materials engineering researchers to exchange experiences regarding the properties of this group of materials and to determine and select the most relevant characteristics for this clinical application. These initial procedures composed the first phase in the construction of the instrument, corresponding, according to Coluci et al. (2015), to the establishment of the conceptual structure and the definition of the objectives and target population.

Thus, the instrument is intended for occupational therapists, physical therapists, and other professionals who use low-temperature thermoplastics to craft orthoses and who work in this area, with the aim of establishing criteria and testing procedures for these materials. Each item of the instrument, therefore, relates to a characteristic/property to be verified during the handling of the material, but considering the specificities necessary for its application in the manufacturing of orthoses.

The instrument establishes its own language, standardizes the definition of each characteristic of the materials, and seeks to systematize the recording of information. However, it values the practical experience of the professional and maintains subjectivity during the evaluation. Therefore, a qualitative approach was chosen, maintaining the perception of the professional who handles the material and who will judge its behavior for each requirement previously established by the instrument.

Creation and format of the instrument

The next phase comprised the construction and organization of the items and response scales, aimed at structuring the instrument (Coluci et al., 2015), which was organized in the form of a script or checklist and named "Empirical Practical Evaluation Instrument for Thermoplastic Materials for Orthoses".

Fourteen items were determined, corresponding to the characteristics to be tested and observed in the materials, namely: ease of cutting the cooled material; ease of cutting the heated material; thermal perception; molding time; moldability (conformability); memory; ease of finishing; self-adhesion; susceptibility to fingerprints; comfort to the touch after molding; stiffness; esthetics; weight; Velcro fastening. All the items were determined based on what the national and international literature in the field of rehabilitation mentions and/or describes as relevant aspects and properties in thermoplastic materials for orthoses (Agnelli & Toyoda, 2003; Agnelli Martinez, 2018; Assumpção, 2006; Breger-Lee & Buford Junior, 1992; Callinan, 2013; Canelón, 1995; Ferrigno, 2007; Fess, 2011; Francisco, 2004; Leite, 2007; Lindemayer, 2004; Macdonald et al., 2004; Malick, 1978; Martinez et al., 2022; Mckee & Rivard, 2011; Meng et al., 2008; Sauron, 2003; Silva, 2014; Souza, 2014) in conjunction with the engineering literature concerning the thermal and mechanical properties of polymeric materials (Canevarolo, 2019; Nunes & Lopes, 2014).

The developed instrument proposes an interpretation and a description for each selected property. The aim is to provide a conceptual parameter and establish a line of reasoning to be followed during the assessment of a material. In this way, each of the characteristics/properties that compose the instrument has a definition (when applicable), followed by recommendations for the procedure(s) for testing the material. This explanation present in each item was planned to translate specific engineering terms related to material properties into a language accessible to professionals from other fields, including healthcare and rehabilitation professionals. The intent was to facilitate the evaluator's understanding of the material characteristics, and it proposes criteria to verify each of them, instructing the evaluator on how to handle and what to check for each item.

After the definition and "instructions" for the test, each item presents a field for completion where there are response options to be marked based on the behavior of the tested material. In several items corresponding to the characteristics to be assessed, it was not possible to establish linearity in the response alternatives, adopting three to six alternatives for each item. Although there is a gradation of the response alternatives, which facilitates completion by the professional, there was variation and differences between the items. Therefore, the instrument does not propose converting the collected data into a numerical scale, and some response options are descriptive about the ease and difficulties encountered in the handling performed with low-temperature thermoplastics.

Furthermore, a numerical scale could compromise the interpretation of the results, considering that more than one alternative per question may be suitable or correct, depending on the desired application for the material. In other words, the information described in one response alternative may be contraindicated for a particular situation (depending on, for example, the orthosis model, target population, clinical aspects, etc.) and suitable for another demand. Therefore, it would not be advisable to elect one of the options to assign a weight or a higher score.

Even though these are practical tests and, despite not producing numerical data, an attempt was made to systematize the assessment and recording with respect to the materials, lending objectivity to empirical perceptions. Following each item, the professional who is evaluating the material may detail their personal impressions if they deem it necessary, supplementing their response in designated spaces on the form. The evaluator may also record qualitative data that they believe is essential to connect the material's characteristics to the demands of their clinical practice, such as regarding the target population or information about other materials, which may facilitate decision-making and therapeutic approaches.

To consolidate the development process, the instrument was tested by researchers and applied to 20 different low-temperature thermoplastics, with adjustments made to the wording, especially in the response alternatives, aiming to obtain the final version presented here, available in Supplementary Material. To make the instrument more reliable, it is suggested to carry out future phases for content validity and assessment of psychometric properties, according to the steps described by Coluci et al. (2015).

Results

The present work has social relevance since it can impact and bring improvements to interventions involving orthoses for upper limbs and other AT resources crafted with low-temperature thermoplastics. Additionally, the results obtained involve innovation, as criteria and procedures for empirical practical testing have been developed for the materials most commonly used in the fabrication of orthoses for upper limbs. The evaluation instrument created consists of empirical practical tests of thermoplastic materials for orthoses and can aid the evaluation process and clinical practice procedures, as well as facilitate communication between professionals and researchers by establishing criteria and recommending specific terminology.

The instrument proposes specific fields at the beginning of the "Application Form" (presented at the end of this manuscript) for the evaluation date and details related to the material being assessed: commercial name (if any), brand/manufacturer, manufacturing date, expiration date, thickness (in millimeters), presentation/format of the material (among the options: smooth or perforated plate, granules, or strip), and a field for filling in "other specifications", if any. Information also included refers to the "shelf life", which corresponds to the difference between the manufacturing and evaluation dates, i.e., the period (in months) the product has been stored since manufacturing until its date of use/evaluation. The form further provides fields for recording whether there is control of the ambient temperature (air conditioning) and the water in which the material will be heated (if there is control, in both cases there is a field for filling in the temperature, in degrees).

The characteristics selected to compose the assessment tool are laid out and enumerated below, along with specific definitions and/or recommendations on how to evaluate each item (testing procedures), as well as the reasoning followed to establish the response alternatives to be marked after testing a particular material.

1 - Ease of cutting the cooled material: "Use multipurpose scissors, of the plier type, for rigid materials. Preferably, the scissors that are regularly used to cut a thermoplastic material plate before heating should be used". For this item, six graded response alternatives were determined, ranging from "*Extremely easy*" to "*It is not possible to cut the cooled material with multipurpose scissors*".

2 - *Ease of cutting the heated material:* "Cut the material after heating it, while it is still moldable, using very sharp scissors. Preferably, use scissors reserved only for thermoplastics". Following the same reasoning as the previous item, six graded response alternatives were established, ranging from "*Extremely easy*" to "*It is not possible to cut the heated material with the scissors*".

3 - *Thermal perception* "Test the heated material on the skin and assess the thermal sensation it provides while it is still at the molding point". For this item, four response alternatives were determined, in the following sequence: "*Pleasant sensation*", "*Hot*", "*Very hot*", and "*Intolerable*".

4 - *Molding time:* "Check the available time to mold the orthosis, that is, the time during which the material remains softened and moldable before it cools and hardens". Five graded response alternatives were established to evaluate this item: "*Excessively long*", "*Long*", "*Moderate*", "*Short*", and "*Insufficient*".

5 - *Moldability (conformability):* "Evaluate the force needed to mold the orthosis while the material is still softened. Considering its use in the crafting of orthoses, a material with excellent moldability is easy to handle and provides a satisfactory finish to the molded product (orthosis), fitting the body region intended to be immobilized and allowing accommodation to curves and anatomical contours". For this item, five alternatives were developed that describe the ease/difficulty encountered during handling to fit the material to a surface, considering the necessary force to be exerted by the professional molding it. The following response alternatives were established to assess this item: "*Material runs and deforms too much, hindering molding*", "*Material fits the body without needing to press it*", "*Material fits the body after slight pressure*", "*Material fits the body, but much pressure is needed*", and "*Material presents no moldability, requiring constant holding in the desired position until it cools*".

6 - *Memory:* "Check during molding if the material shows a tendency to return to its previous shape (with the material heated and softened, during molding time). One can, for example, stretch the material slightly and observe its return. Moreover, after being molded and cooled, the material can be placed back in hot water to check if it reverts to its original shape (partially or entirely). A material with 100% memory returns to its original size and curvature when heated". To asses this item, four graded response alternatives were determined that describe the return of the material to its natural state: "*Material does not mold to the desired surface as it presents high resistance to handling, constantly returning to its original shape, with much memory*", "*Material allows handling and partially returns to its original shape*", "*Material returns slightly to its original shape*", and "*After molding, the material deforms and does not return to its original shape, i.e., it has no memory*".

7 - *Ease of finishing:* "Check the material's ability for minor adjustments after molding by heating specific areas of it, such as the edges, and pressing them with the fingertips to round and/or smooth them. Additionally, evaluate the finish of the edges during cutting with scissors while the material is still heated and moldable". Four graded response alternatives were devised, describing the ease/difficulty with which the edges are rounded so that the evaluator can mark and select the one that best represents the material being tested: "*When cutting the material, its edges become rounded and well-finished*", "*The material's edges are easily adjusted with the* *professional's touch*", "*The material's edges are moderately adjusted*", and "*Material with difficult finishing*".

8 - Self-adhesion: "Check the material's adhesive ability by overlapping one surface over the other (while the material is still heated and moldable). If needed, press the two surfaces together. After adhesion and cooling of the material, try to separate the parts to verify the adhesive ability". From the proposed procedure, five response possibilities were established, grading the pressure needed for the adhesion of two surfaces of the same material: "*Material does not adhere even when pressed*", "*Material shows weak adhesion even when pressed*", "*Material adheres only with much pressure*", "*Material adheres with moderate pressure*", and "*Material adheres simply when the two parts touch, with no need to press*".

9 - Susceptibility to fingerprints: "During molding, check if fingerprint marks remain on the material". To evaluate this item, three response alternatives were developed: "*Material does not show marks after handling*", "*Material shows marks after moderate pressure*", and "*Material shows pronounced marks*".

10 - Comfort to the touch after molding: "After molding and cooling the material, check if it is pleasant to the skin and touch. 'Wear' the molded orthosis (if applicable) and evaluate the sensation caused by the material". For this item, five graded response alternatives were established, ranging from "*Very comfortable material*" to "*Very uncomfortable material*".

11 - Stiffness: "Verify if the material maintains the molded shape and resists deformations, even when constant force is applied". For this item, five response alternatives were developed, ranging from "*Very rigid material*" to "*Very flexible material*".

12 - Esthetics: "Visually inspect the quality of the molded product (evaluator's perception)". For this item, five graded response alternatives were determined, ranging from "*Excellent*" to "*Poor*".

13 - Weight: "Assess the weight of the material when placed on a body segment (evaluator's perception)". Three response alternatives were established for evaluating the material's weight: "*Light*", "*Moderate*", and "*Heavy*".

14 - Velcro fastening: "Attach a piece of Velcro that the professional is accustomed to using (whether self-adhesive or with contact glue) and verify the attachment". For this item, four graded response alternatives were determined, ranging from "*Good attachment*" to "*No attachment*".

Discussion

The devised instrument enables a qualitative analysis of the materials, according to the professional's perception and opinion, considering practical experience in the crafting of orthoses and other AT devices that involve this type of material. By offering staggered options regarding the characteristics of the materials so that the professional can record their perceptions, the developed tool can be used as a reference during the handling, assessment, and selection of materials for the manufacturing of orthoses.

The proposed instrument does not directly determine the model of the device to be fabricated, but it is capable of subsidizing professionals with specific and referenced information about a type of material widely used, which will certainly assist in decision-making and targeting of some interventions. It can be a tool for the work of occupational therapists and other professionals who use low-temperature thermoplastics in their clinical practice, whether in the construction of therapeutic resources, orthoses, or other AT devices.

It is worth emphasizing that there was no intention to assign or generate a score for the evaluated thermoplastics, as there is no one material suitable for all types of orthoses. Therefore, to achieve success in manufacturing, it is necessary to understand the material's characteristics and properties, as well as its advantages and disadvantages for each application.

Regardless of the application and specificities of each case – whether it is to alleviate pain, provide stabilization, increase the range of motion, protect vulnerable tissues, or prevent deformities, well-designed orthoses can make a difference in people's lives. Considering the principles of the International Classification of Functioning, Disability and Health (Organização Mundial da Saúde, 2003), the benefits generated in the body's structures and functions through the application of a well-indicated orthosis may impact the functionality of individuals and expand their participation in various activities, directly or indirectly, depending on the contexts. As part of the occupational therapist's practice, orthotic intervention may result in an individualized device that meets biological and occupational needs, including for use outside the clinical practice. Mckee & Rivard (2011) emphasize that this process should be client-centered. Therefore, the prescription and manufacturing of orthoses compose a process that involves many determining variables for a person's health and quality of life (Gradim & Paiva, 2018), as well as a thorough physical assessment and specific knowledge involving other areas.

According to Marcolino et al. (2015), custom-made devices, no matter how simple, require basic knowledge about principles of materials engineering and mechanical engineering to be correctly manufactured. Assumpção (2006) considers knowledge and understanding of these principles as a prerequisite to design and manufacture any type of orthosis. Specifically concerning the properties of low-temperature thermoplastics, it is worth mentioning that the definition and application of their properties are not always clear, as well as the most suitable terminology for each characteristic verified during their handling. It is important to understand what each property refers to and how to use it in the molding process of an orthosis and other AT devices, aiming to obtain anatomical resources that actually meet a specific need. Thus, before choosing the appropriate material for each situation and each model of orthosis to be crafted, the therapist must know and evaluate its properties, in addition to reviewing the manufacturer's technical information.

Many authors agree that success in choosing the material depends on knowledge of its characteristics, with emphasis on moldability (conformability), memory, molding time, adhesion, and stiffness (Agnelli & Toyoda, 2003; Assumpção, 2006; Breger-Lee & Buford Junior, 1992; Canelón, 1995; Ferrigno, 2007; Lindemayer, 2004; Mckee & Rivard, 2011; Sauron, 2003) – all considered in the devised instrument. Other characteristics described in the literature, such as surface finish, user comfort, weight, and esthetics (Agnelli & Toyoda, 2003; Lindemayer, 2004; Mckee & Rivard, 2011;

Sauron, 2003), are also present in the instrument proposed here. In this context, the instrument provides a parameter concerning 14 material characteristics mentioned in the literature, which facilitates each therapist's understanding of their own interventions and fosters communication between different professionals, as it standardizes language and evaluation criteria concerning the characteristics of thermoplastic materials.

Knowledge of the materials available in the market is important not only for the process of material selection but also for its better utilization during the handling and crafting of an orthosis (Lindemayer, 2004). Therefore, the therapist is challenged to select the most suitable material for each situation and to optimize its characteristics (Breger-Lee & Buford Junior, 1992; Fess, 2011). Well-prepared professionals optimize the material properties for orthosis manufacturing right from the selection process, aiming a customized production with the challenge of combining therapeutic functionality with users' expectations and needs, with good resolution of the products (Brasil, 2013).

Currently, there are materials with different chemical compositions and working properties, in addition to varied colors, thicknesses, textures, and perforations (Assumpção, 2006; Fess, 2002; North Coast Medical, 2023; Orfit Industries, 2023; Performance Health, 2023; Rodrigues et al., 2007). Given this variety and the diversity of characteristics to be analyzed, evaluating specifically without establishing parameters could compromise the interpretation of results and hinder the comparison between the features observed in clinical practice by different professionals, researchers, or companies in the field. Moreover, if there are no clearly defined criteria, the same professional may find it difficult to compare the materials they are using or intend to use, such as different brands and models that may exhibit different behaviors because they have different formulations both regarding their components and their quantity (Agnelli Martinez et al., 2017).

As in this work, other research addressing heat moldable materials for application in orthoses have also valued and opted for empirical practical tests to assess or complement the analysis of these materials (Breger-Lee & Buford Junior, 1992; Francisco, 2004; Lindemayer, 2004; Souza, 2014). Although these authors recognize the importance of making the assessment even more objective, they agree that the therapist's and/or researcher's experience in crafting orthoses and their opinions regarding the materials are important and should be considered.

The instrument developed can be easily used by occupational therapists, physical therapists, and other professionals who work with low-temperature thermoplastics, assisting, for example, in identifying the clinical application of each material evaluated aiming to guide some conduct, or even by researchers who intend to test/compare materials for orthoses and/or who are involved with the development of new materials. However, further studies can be carried out using the created guide and other measurement instruments, in association, with the possibility of improving existing instruments and/or creating other evaluation tools, as necessary. The quantification of properties and standardization of handling conducted on thermoplastics are important needs and point to new research possibilities that may contain, for instance, objective, numerical data, and/or scores concerning certain aspects verified in the materials. In this regard, Martinez et al. (2022) present an assay created specifically to measure the moldability of materials for orthoses through a testing system that simulates the handling performed during the manufacture of an orthosis and enables calculation of the thermoplastic material's deformation.

Through systematized health measures, professionals can establish a line of reasoning to base their decisions. Cruz et al. (2021) state that, in occupational therapy, assessment tools assist professional practice and are valuable for identifying and planning the objectives of the intervention, in addition to allowing the reassessment of results. In the case of this study, because of the specificity of the knowledge involved in the application and evaluation of low-temperature thermoplastics for orthoses, the importance of the partnership between researchers in the health and engineering fields is emphasized, aiming at the development of an easily accessible and fillable instrument that also presents appropriate terminology.

In this study, the approximation and joint work of occupational therapy and materials engineering were fundamental for communication, understanding, and alignment regarding the characteristics of the materials, especially given the specificity of parameters adopted in clinical practice involving the crafting of orthoses and other AT devices.

Conclusions

An assessment protocol with specific tests for low-temperature thermoplastics was developed, called the "Empirical Practical Assessment Instrument for Thermoplastic Materials for Orthoses", which includes relevant characteristics to be verified in these materials. In a concise and easy-to-understand manner, criteria are presented that enable the systematization of the handling to be performed with each material and assist in organizing the professional's impressions and records during the evaluation.

Therefore, the proposed objectives were realized, and the presented instrument identifies the main characteristics to be verified during the handling of materials, guiding the professionals' focus and possibly assisting them in clinical decisions regarding the selection of the commercial brand and the most suitable type for each situation. Despite the contributions presented here, it is recommended that the proposed instrument be validated with professionals experienced in the handling of low-temperature thermoplastics to verify if it is comprehensible and if all relevant characteristics are included.

There is a need to expand studies and strategies in occupational therapy in this area of practice, as well as evaluation methods and information collection tools. There is a recognized need to further refine the assessment process for thermoplastics so that they can be analyzed not only empirically and through the practical experience of therapists – as proposed by this study, but also in a standardized, accurate, and controlled manner. It is important that further studies addressing the evaluation of materials' properties for orthoses and the equipping of professionals and researchers be carried out, aiming for a realistic and objective comparison between different materials and also enabling the replication of test procedures.

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