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Biomaterials Characterization for Orthopedic Orthoses: a Systematic Review

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Abstract

The term biomaterial is used for materials used in medical implants, extracorporeal and disposable devices, and must have compatible biological, physical, chemical and mechanical characteristics for use in humans. Objective: to identify and characterize the biomaterials used for the preparation of orthopedic orthoses. Methods: Systematic review, conducted through the following databases: Google Scholar, PubMed, Bireme, Lilacs, Embase, CINAHL and Science Direct. Results: We selected 8 studies that indicated a variety of biomaterials used for the manufacture of orthopedic orthoses, in addition to characterizing the respective materials regarding their physical and chemical qualities. It was observed that the polymers were the most used biomaterials for the preparation of orthopedic orthoses, with a wide variation in their physical and chemical characteristics. Conclusion: Orthotics made from biomaterials has been shown to be effective for orthopedic treatment, often reducing cost and favoring new biomedical technologies.

Keywords: Orthotic; Orthopedic; Materials

Introduction

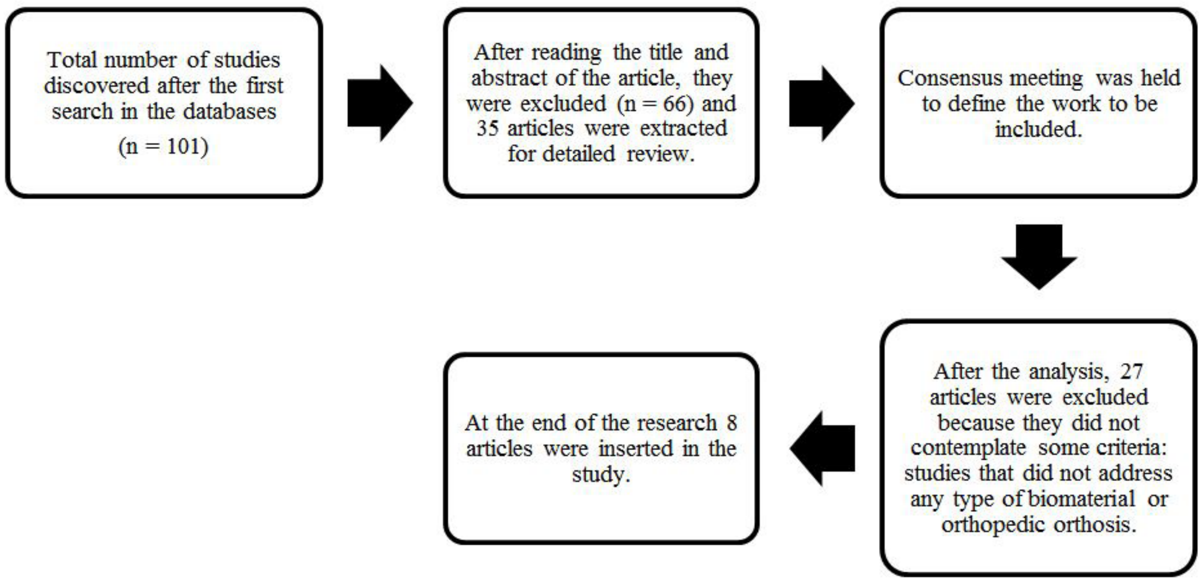
Osteoarticular diseases are causes of a serious clinical and public health problem with an evident social and economic impacts, to such an extent that the World Health Organization declares the last years as the "Bone and Joint Decade". Reconstruction and restoration of locomotor injuries and function restoration assume an unequaled magnitude in a society in the midst of globalization and, therefore, more demanding, desirous of making the most of the social labor potential of a population with an increasing life expectancy [1]. In the 1990s, in Brazil, the area of biomaterials development became relevant in scientific and technological research activities. In recent years it has been a priority in development policies in all spheres of government, as well as protagonist in national and international industrial technological innovation [2]. Biomaterials are generally differentiated from medicinal products because they do not achieve their main therapeutic objective through a chemical effect within the organism, wich means, without the need for metabolism in the organism1. The term biomaterial is used for materials used in medical implants, extracorporeal and disposable devices, and must have biological, physical, chemical and mechanical characteristics compatible with the use in humans [3,4]. As for the type, they are classified in metals, ceramics, polymers and natural materials. Its application is in the areas of orthopedics, dentistry, cardiovascular, neurology, rheumatology, among others [5]. Within orthopedic rehabilitation, prostheses and orthotics are great examples of the application of these materials. A prosthesis is defined as a device that substitutes the limb partially or totally [6]. Orthoses have as function the biomechanical support of the segment, correction of deformities, seeking as well, the comfort for the individual who is wearing the device [7]. In the field of rheumatology orthotics are widely used to aid in the treatment of diseases, especially those involving lower limbs. Commonly indicated dysfunctions for the use of orthoses are: Rheumatoid Arthritis, Plantar Fasciitis, Hallux Valgus, Posterior Tibial Tendon Dysfunction, among others [8]. Therefore, the objective of this work is to identify and characterize the biomaterials used for the preparation of orthopedic orthoses through a systematic review.

Methodology

Two independent reviewers conducted research and selected eligible studies in the databases: Google Scholar, PubMed, Bireme, Lilacs, Embase, CINAHL and Science Direct between June and July 2016, with the following descriptors: "Órtese Ortopédica", “Biomateriais”, “Palmilhas”, “Características químicas” e/ou “características físicas polímeros ou fibra de palmeira”, “biomaterials” AND “orthopedic orthosis” AND “insole”, “chemical characteristics” AND/OR “physical characteristics” AND “polymers”, “chemical characteristics” AND/OR “physical characteristics” AND “palm fiber”. Orthopedic Orthopedic studies containing at least one biomaterial were considered eligible. Studies involving other types of orthosis were excluded. There was no language restriction. The two reviewers performed a pre-selection of studies by title and summary using eligibility criteria. Subsequently, a complete reading of potentially eligible articles was carried out to confirm their inclusion. It was pre-defined that disagreements between the two reviewers were refereed by a third reviewer at a consensus meeting. The data extraction was performed in a standardized way, through a pre-established data extraction form. Data extracted were: title, authors, year of publication, database, study objective, methodology, biomaterial type and conclusion. After the article table was constructed, a new search was made for the physical and chemical characterization of the biomaterials found in the selected studies and, afterwards, a consultation was made for the analysis of the patents of insoles existing in national collection. The search was conducted at the patent office Instituto Nacional da Propriedade Nacional (INPI). INPI is a Brazilian federal authority responsible for stimulating innovation and competitiveness in the service of technological and economic development in Brazil, linked to the Ministry of Development, Industry and Foreign Trade. As a search strategy we used the keyword "insole" with the Índice de Desenvolvimento de Patentes (IPD) "A43B" and included only those that had their manufacturing material properly described.

Results

A total of 101 studies were found, of which only 8 were included through the eligibility criteria (Flowchart 1).



Of the 8 selected studies, 9 types of biomaterials were identified. The characterization of the included studies is presented in (Table 1), as well as the characterization of the biomaterials in (Table 2).

Author/ Year	Database	Purpose	Methodology	Biomaterial	Conclusion
Chen *et al.*, (2016) [9]	Science Direct	To discuss about some exoskeletons for lower limbs that are being developed around the world.	Sistematic review	Polymer (Carbon Fyber)	Several typical exoskeletons for lower limbs (Lees) were analysed in three applications (gait, assistance to human locomotion, and force gain). The review discusses exoskeletons made today and discusses strategies for future research
Reis; Fleury; Rocha, (2010)[10]	PubMed/ Google Scholar/ LILACS	Development of a prototype of an insole derived from the natural latex of rubber tree (Hevea brasiliensis) with pressure control and tissue capacity to target people with diabetic foot.	The insole, which is the object of research and development, was developed through four macro-steps: i) mold making; ii) treatment of the biomaterial; iii) confection of the product and iv) instrumentation amplifier.	Polymer (natural latex)	A "smart", preventive, high-quality, low-cost insole was made, opening a new approach in trying to solve the problem of diabetic foot.

Author/ Year	Database	Purpose	Methodology	Biomaterial	Conclusion
Brodsky *et al.*, (2012)[11]	PubMed/ LILACS	To test individualy 4 materials used to make insoles worn in four different clinic conditions, before and after being heated.	Four materials used to produce insoles were tested individually and in combination, analyzing their mechanical properties before and after heating	Polymer (Polyethylene, Ethylene Vinyl Acetate (EVA), Acetate (EVA) and polyethylene, Urethane foam	The heating of the materials resulted in an increase in the load transmission when compared to the unheated material.
Tonga; Ng, (2010)[12]	PubMed	To investigate the materials capacity used to produce insoles with the purpose to reduce the plantar pressure.	The plantar pressure of 5 individuals was measured in the following situations: with common sports footwear, using the insoles and with a padding (SCF) with a cut in the first MCP joint.	Polymer (SRP – Slow Recovery Poron® , P – Poron®, PPF – Poron® +Plastazote (firm) and PPS – Poron® +Plastazote (soft)	All 4 materials used were able to reduce plantar pressure, but the PPF achieved greater significance. Pressure reduction in the 1st metacarpophalangeal joint would still be better achieved with a plantar metatarsal pad (SCF) with the opening design.
Ossami; Miosso; Fleury, (2014)[13]	Google Scholar	It proposes the development and evaluation of a system of automatic classification of foot alterations in children from 6 to 10 years old, in arch maturation phase, in order to this system be able to detect and classify possible changes of the foot in this population.	Latex insoles with pressure sensors and coupled accelerometers were used. The latex used to produce the insoles is centrifuged at 60% concentration and stabilized with ammonia, standard procedure with industrial latex.	Latex	The system is able to classify the signals as proposed.
Mulinar; Vidali, (2014)[14]	Google Scholar	To develop a biocomposite obtained from polyurethane (PU) derived from castor oil reinforced with palm fibers for application in insoles providing comfort and reduction of environmental impact and compare it to the material currently used.	Divided into 5 phases: material; obtaining biocomposite; mechanical testing of the biomaterial; determination of specific mass; morphological analysis.	Polymer (Polyurethane - Palm fiber)	It presented lower density and interconnected and open pores in its microstructures, but with smaller cells. It also presented less rigidity when compared to the commercialized material. It is lighter and has lower cost.
Seligman; Dawson, (2003)[15]	Lilacs	To develop a cost-effective and comfortable orthosis to treat heel pain associated with plantar fasciitis through (?)	Orthoses were made for 10 patients with uni or bilateral heel pain associated with plantar fasciitis.	Sorbothane Visco-Elastic Polymer (Sinthetic polyurethane), Plastozone (Polyethylane Foam)	The orthosis ceased or significantly decreased the pain of the patients. In addition to being comfortable, inexpensive and quick to make.
Meng, Zhu (2008)[16]	Lilacs	Analyze the shape memory of polyurethane used as a low-temperature biomaterial for thermoplastic orthoses.	A series of PCL-based polyurethane shape memory were synthesized via bulk prepolymerization. Its thermal, mechanical, shape memory and softening and hardening processes were investigated and compared with the commercialized orthoses. A cytotoxicity test was also performed.	Polymer	The results suggest a possible application of PCL-based shape memory polyurethane as an excellent low temperature thermoplastic material, but the hard material content may not exceed 22% by weight. The material is not cytotoxic.

Table 1: Study Qualities

Biomaterial	Structure Characteristics	Chemical characteristics
Polymer (Carbon fiber)	Lightweight, low-cost, fatigue-resistant and heat-resistant material[17]	Resulting from the carbonization process of organic polymers such as polyacrylonitrile, among others [18]
Polymer (Natural Latex (*Hevea brasiliensis*)	Lightweight, impermeable to micro- organisms, permeability to oxygen and water vapor, ease of processing, biodegradability and biocompatibility[19]	It is a polydisperse containing 30-45% of its rubber weight (cis-polyisopropene), 4-5% non-rubber constituents such as proteins, lipids, carbohydrates and sugar and 50% water [20,21]

Biomaterial	Structure Characteristics	Chemical characteristics
Polymer (Poliurethane Termo-plastic)	Good flexibility, moldable, resistant. For dynamic applications, it must be reinforced [22]. They are fusible and soluble polymers, that is, they melt when heated and solidify when cooled. If heated again, they become plastics again and can be molded into new shapes[23]	It is a class of random block copolymers containing two organic segments: a rigid segment and a malleable segment, connected to each other by a urethane bond [24]
Polymer (Polyethyene)	Effective impact damping and low coefficient of friction and, on the other hand, has a relatively significant wear rate characterized by being non-antigenic, non-allergenic, non-absorbable and having a low rate of wear [25,26]	High density and high molar mass is highly stable. It has a chain with linear structure and is the base polymer for other materials, such as polypropylene and polytetrafluoroethylene [27]
Polymer EVA (Ethylene Vinyl Acetate)	Lightweight, moldable, antifungal, good thermal and acoustic properties [28,29]	Thermoplastic having ethylene segments that are semi-crystal-line [30]
Polymer (Acetate)	Not found	Also known as ethanoate, acetate is a chemical compound expressed by the formula CH3COO-, which may be an ion of an organic salt, ester or conjugate base of acetic acid [31]
Polymer (Polyurethene foam)	Foam insulation, anticorrosive coatings [32]	Resulting from the reaction between isocyanate and hydroxyl [33]
Polymer (SRP – Slow recovery) Poron®, P - Poron®, PPF - Poron® + plastazote and PPS - Poron® + plastazote)	Poron: Resilience, antimicrobial, resistance to bases and organic acids. Plastazode: temperature resistance, moldable, lightweight, low flame conduction [34]	Plastazode: closed-cell cross-linked polyethylene foam [34]
Polymer (Palm fiber)	Low density, high porosity value and aeration space and low water retention [35]	Not found.
Polymer (Polyethylene foam)	Low cost, rigid, good flexibility, chemical and abrasion resistant [36]	Generally its production consists of two phases, a solid and a gas phase where the material is transformed into foam [36]

Table 2: Material Characteristcs

After the identification of the physical and chemical characteristics of the biomaterials identified, the search of patents in INPI database using the term "insole" presente in (Table 3).

Title	Order/Publication	Proposal	Material
Absorbing Insole A43B 17/10 2010.1	MU 8700301-5 U2 04/05/2010	3-layer insole with embellishment function, shock absorption and moisture maintenance functions	Surface: absorbs moisture and gases. Intermediate: perforated to allow moisture to pass down. Bottom: retains all moisture and removes it when removing the shoe insole
Gel Insole A43B 17/02	PI 0715344-9 A2 26/11/2013	Insoles with cushioning support in regions of greater foot pressure	Viscoelastic material or foam
Damping Insole A43B 7/32 2008.4	MU 8702617-1 U2 15/07/2008	Insole for high heel shoes with cushioning areas that evenly distribute the corporal load cable	Uninformed
Palmilha Bimaterial para Absorção de suor A43B 17/00 2006.1	PI 0904866-9 A2 02/08/2011	Sweat absorption, greater adherence to walking, flexibility and softness without derforming	Top layer: microfiber based on polyester or synthetic polyurethane Lower layer: EVA
Cicatrizant Insole for diabetic feet A43B 13/38	PI 1103690-7 A2 16/07/2013	Low emission laser insole that promotes tissue regeneration for diabetic foot	Electrical circuit and polymeric and / or silicone materials, specialy latex
Vibrating Insoles for Shoes in General A43B 17/00	BR 10 2012 021304 4 A2 10/06/2014	Through vibration promoting comfort and comfort of the feet, combined with ergonomic and orthopedic benefits	Traditional insole connected to an electric vibrator
Thermal Insole for footwear A43B 17/02	BR 20 2013 015272 8 U2 23/06/2015	Through a circuit in a conductive material, the insoles keep the feet warm with their use	Insole made of EVA or any other material that conducts heat
Insole Of Mineralised Or Biosynthetic Residues A43B 17/00	BR 10 2013 024289 6 A2 17/11/2015	It offers a product of high structural strength and low cost of production	Composed of the association of mineralized solid waste from the shoe industry, resins and binders

Title	Order/Publication	Proposal	Material
ltifunction Orthopedic Insoles With Adjustable Accessories A43B 17/00	BR 20 2014 011571 0 U2 15/12/2015	Adjustable insoles by the application of polymeric compounds to specific plantar surfaces	Polyurethane compound with density from 30 to 60 Shore and with four different colors
Insole with Accident Prevention A43B 13/38 2006.1 A43B 17/04 2006.1 A43B 13/12 2006.1 A43B 7/36 2006.1 A43B 7/32 2006.1	PI 0617706-9 A2 02/08/2011	Insole that does not allow to be penetraded by sharp materials through a force and diameter (?)	Composed of a multilayer fabric (polyester, polyamide, polyamide, polypropylene and artificial filaments) coated with a resin bed
Corrective Insole for Orthopedic Relief and Treatment of "Hallux Valgus" (Bunion) A43B 17/00 2008.1	PI 0602950-7 A2 26/02/2008	Innovative insole with anatomical shape and support for the hallux that avoids incorrect angulations that give rise to bunions	Made of resistant materials and coated with silicone materials or with rubber, elastic and malleable materials
Kinetic Insole A43B 17/00	PI 0405280-3 A2 01/08/2006	Device indicated for specific cases of pain and deformation of the feet that uses kinetic energy for areas of hypertension	Composed of two sheets of polyvinyl chloride (PVC) and communicating vessels with gel inside
Sport Insole A43B 17/00	MU 7400750-5 U2 28/11/1995	Provides better performance (running, jumping, etc.) through transversal furrows and elastic bands	Insole: latex, EVA, etc. Strips: polyester and cotton, silk, polyamide and polyamide, etc.

Table 3: Patents from Instituto Nacional da Propriedade Industrial

Discussion

Studies indicate that for the preparation of orthoses the chosen biomaterial is, primarily, the polymer. The origin of the polymers used for the manufacture of the orthoses was from its synthetic form until the extraction of the organic material. The advantages of this material are its great price-quality ratio, lightness, strength and diversity as to its physical and chemical characteristics. Its application to the production of orthopedic orthoses was from foams to structures with higher stiffness contente [10,12,23]. Insole were developed with the objective of reducing foot pressure and reducing pain and all achieved significant results [10,13,25]. Reis, Fleury, Rocha (2010) produced a "smart" preventive insole with pressure sensors for diabetic patients. The result was the creation of a natural latex insole of high quality and low cost [10]. When performing an experiment with patients with Rheumatoid Arthritis with foot involvement using an EVA brace, it was possible to assume that there was a significant decrease in plantar pressure points and consequently pain [36]. The practice of heating insoles to improve their contact with the foot has reduced the pressure leading to a decrease in the properties of the materials, which may decrease their clinical effectiveness [11]. The use of closed cell reticulated polyethylene foam is able to reduce pressure throughout the foot without losing the properties of the materials used [11]. Corroborating with the findings of the studies, the main biomaterial used to make the patented insoles was the polymer. The most frequent proposals of these orthoses are the promotion of impact cushioning, sweat absorption and decrease of pressure peaks in the plantar region.

Conclusion

The evidences show that the polymers were the most used biomaterials for the preparation of orthopedic orthoses, with a wide variation in their physical and chemical characteristics. Orthotics made with biomaterials have been shown to be effective within the proposed objectives, in addition to often reducing the cost and enabling new technologies for the studied groups.

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