Prototyping a device for keloid compression

Felipe Isoldi[1], Fabio Isoldi[1], Antônio Aloise[1], and Lydia Ferreira[1]

[1]Universidade Federal de São Paulo

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Abstract

Introduction: Compression therapy for keloid is an important adjuvant treatment of this pathological scar, especially to reduce its elevation, improve scar features (e.g. pliability and plasticity) and ease symptoms. However, this therapy is unpleasant and uncomfortable for patients, due to the need to combine elastic bands or garments, foams (Ethylene Vinyl Acetate) and silicone sheets, for at least 8 to 12 hours a day. **Objective:** To create a device to apply compression on keloid, which would facilitate and simplify the scar compression therapy. **Material and Methods:** A review of existing devices was carried out through the main databases of patents, as well as on common research platforms (desk research). Design Thinking was used for the elaboration of the prototypes to validate the concepts and the functionality of the device. The component parts were 3D printed and assembled to form a single device. **Results:** Eleven documents were found in the main search and none found in desk research. The device for keloid compression was developed using a spring mechanism, comprised by three structural units, which were attached as a single piece and it was adhesive to the skin. **Conclusion:** A device for keloid pressure therapy was developed using the Design Thinking.

1. Introduction

Keloid is a pathological fibroproliferative scar and represents a challenge in wound care (Jumper, Paus, & Bayat, 2015; Ogawa, 2011; Ogawa, Akaishi, Kuribayashi, & Miyashita, 2016). In clinical practice, it is mainly characterized by intense pruritus, pain and scar hyperemia (Berman, Maderal, & Raphael, 2017). Also, it has an exuberant progressive vertical (elevation in relation to the skin plane) and horizontal growths (expansion on the skin) beyond the original wound boundaries, similar to a benign neoplasia (Ferreira, Gragnani, Furtado, & Hochman, 2009). It does not regress spontaneously and it is exclusive of healing in humans (Ramos, Gragnani, & Ferreira, 2008). It has been associated with increased psychology morbidity and anxiety (Furtado et al., 2011), resulting in low self-esteem and body image disorder, especially if it is present in socially exposed areas.

It does not have a definitive treatment due to the incomplete knowledge of its etiology. On the other hand, some therapeutics directed at its known risk factors alleviates clinical symptoms and remodel macro and microscopic aspects of the pathological scar mainly by reducing the local inflammatory intensity (Chang, Deng, Yeong, Wu, & Yeh, 2008). One of these therapeutics is the compression therapy on the scar tissue (Stella, Castagnoli, & Gangemi, 2008).

Currently, the literature is not yet conclusive in determining the value or range of values for safe and effective compressive therapy (Atiyeh, El Khatib, & Dibo, 2013; Macintyre & Baird, 2006), as well as the period and routine of use. The pressure exerted on the tissue should not exceed the limit of 28 to 32 mmHg, referring to the arterial capillary pressure of the skin, avoiding local ischemia (Sharp, Pan, Yakuboff, & Rothchild, 2016). The compression is then indicated to be used continuously for at least 12 to 23 hours a day, removing it only for hygiene and laundry purposes (compression garments), for the period followed from 06 to 12 months (Macintyre & Baird, 2006; Stella et al., 2008). The compression therapy can be associated with silicone sheets (BERMAN et al., 2007; Van den Kerckhove et al., 2001). This association aims to complement the

mechanical action of compression, contemplating the physical and chemical characteristics of the scar tissue and skin (Hassel, Löser, Koenen, Kreuter, & Hassel, 2011; Sharp et al., 2016). Although the mechanism of action of silicone on healing is still unclear, a number of explanations are proposed, notably increased local temperature (Musgrave, Umraw, Fish, Gomez, & Cartotto, n.d.), improved tissue hydration (Branagan, Chenery, & Nicholson, 2000; Suetake, Sasai, Zhen, & Tagami, 2000), increased oxygen tension and the polarization of the scar tissue caused by the negative static electric charge generated by the movement of the silicone (Hirshowitz et al., 1998; O'Brien & Jones, 2013).

Compression therapy is expensive because the garment is usually tailor-made and must be replaced as it is worn by the patient's growth, loss or weight gain (Macintyre & Baird, 2006). Moreover, clothing is uncomfortable, added to daily and continuous use, which diminishes its adhesion in the medium and long terms (Macintyre & Baird, 2006).

Innovation is a perceived and considerable value in the task of creating relevant solutions focused on the needs of others. These solutions are developed based on the difficulties and problems exhibited by patients in outpatient clinical practice. Design Thinking is a methodological tool capable of addressing the needs observed in patients during clinical practice, under a human-centered thinking model. Design Thinking is based on three main pillars, Empathy, Collaboration and Experimentation (Ferreira, Song, Gomes, Garcia, & Ferreira, 2015).

Several devices exist and are marketed exclusively for the purpose of compressing scars on the ears, especially for the ear lobes (Chamaria, De Sousa, Aras, & Mascarenhas, 2016; Rathee, Kundu, & Tamrakar, 2014). However, keloid at other high prevalent topographies such as the anterior thoracic, the back, deltoid regions, face, abdomen and limbs, could also benefit from compressive therapy. To date, a specific device for keloid compression, similar to those for the ear, is unknown without the use of compressive garment and other associated products.

2. Objective

To develop and prototype a device to apply compression on keloid using design thinking methodology.

3. Materials and Methods

3.1. Anteriority Search

A search in Medline database was performed using descriptors and terms defined in the Medical Subject Headings (MeSH). The keywords used, including their derivatives (singular and plural) were:

Device; medical device; compression bandage; scar; hypertrophic scar; healing; wound healing; wound healing; high scar; pathological scar; hypertrophic scar; fibroproliferative scar; keloid; rehabilitation; compression; pressotherapy; compression therapy; spring compression; silicone; adhesive; and, elastic mesh

In parallel, the same keywords and the International Patent Classification (A61B-17/00, A61B-17/03 and A61F-13/00) were carried out to track patents and registered utility models. The websites searched were the INPI database (Brazilian National Institute of Industrial Property): http://www.inpi.gov.br/, Google patents: https://patents.google.com/, of the Latin American Espacenet: http://lp.espacenet.com, from Espacenet: https://worldwide.espacenet.com/, the United States Patent and Trademark Office (USPTO): https://www.uspto.gov/, and the World Intellectual Property Organization (WIPO)): http://www.wipo.int/portal/en/index.html, State Intellectual Property Office (SIPO): http://english.sipo.gov.cn, and the Japan Patent Office (JPO): http //www.jpo.go.jp.

3.2 Design Thinking

To elaborate the prototype, it was used the Design Thinking methodology (Ferreira et al., 2015). The clinical observation and the conviviality with the patients with keloid and in use of compressive therapy contribute to the innovation in the medical practice. Then, the experimentation took place in prototyping and its gradual improvement, defined in other four phases: Discover, Define, Develop and Deliver (Ferreira et al., 2015).

3.2.1 The Discover phase

It consisted of *Interviews* with six patients with keloid, who were using conventional pressure therapy (elastic bands or garments, foams and silicone sheets). The patients were from the Outpatient Clinic of Pathological Scars of the Unifesp, Plastic Surgery Division. They were questioned in order to identify the main problems, needs and suggestions to improve the compression therapy. They were asked: a) Regarding the individual understanding of the use of pressure therapy for their treatment; b) The acquisition of products and materials (stores and values) to carry out the therapy; c) As for the routine of use (hours per day), comfort and practicality of the therapy. The conversations were individual, lasting about 15 to 20 minutes.

A *Desk Research* was also carried out on the acquisition of information about devices and garment available on the market used for compression therapy in scars. The databases used were Google and Medline. The keywords used were similar to those referred to in the main search. Finally, a scenario was elaborated to simulate the step-by-step performed by the patient with keloid in the adequate accomplishment of the therapy. It was sought to understand and experience all the process involved, from the purchase of the products, materials and garments used until the application of the compressive therapy. In addition, it was used to verify the routine of use and its practicality.

3.2.2 The Define and Develop phases

The main criteria and characteristics for the development of the device were determined based on the results of the interviews, Research Desk and the Scenario. After that, in the Develop phase, based on the two previous phases, a mechanical engineer was contacted and, after brainstorming meetings, the main characteristics of the device were stated.

3.2.3 The Deliver phase

A prototype with 8.5 x 5.5 cm was developed, which would resemble a dressing or bandage, containing a mechanical system of springs capable of exerting compression on the scar, associated with a silicone sheet in contact with the skin and scar. Around it, a synthetic mesh of adhesive resin stuffed the entire device attached to the patient and kept the system compressed. The device was divided into three parts for a better understanding of its characteristics and functionality: the first part in contact with the scar; the second, containing the compressor mechanism; and the third, joining the other parts into a single device and adhering it to the patient's skin.

3.3 Prototyping

The first part of the prototype was determined by the use of medical silicone elastomer sheet. The second part was defined by the mechanical compression system and was arranged on the first part. This mechanism was composed by a spring between two rigid bulkheads. The first one was positioned under the spring and was affixed over the first part. The second was movable on the spring, which slid vertically downwards, deforming and exerting force on the first part. The therapeutic range of pressure was safely between 28 and 35 mmHg or 0.038 to 0.048 kg/cm^2 (Ghassemi et al., 2015; Keller, Krenzer-Scheidemantel, & Meyer, 2011; Sharp et al., 2016; Tejiram et al., 2016). The modulus of elasticity (E) of the spring material was considered, and the higher its value, the greater its rigidity or the ability to withstand deformations, and consequently the greater the force for the complete deformation of the spring (deflection -). The third part was composed by the containment system of the other two parts, so as to unite them in a single device. In addition, it integrated a fixation system on the patient's skin. The containment system was designed in synthetic mesh material, involving the entire second part, on the movable bulkhead. Around this synthetic mesh, bypassing it, a synthetic resin was installed flexible and adherent for the attachment to the skin. In this way, the dimensions of the device were added approximately 1.5 cm, determining it in its final configuration, approximately 10.0 x 7.0 cm.

4. Results

4.1. Anteriority Search

The Anterior Search found 11 documents evidencing patented devices that would act in a similar manner to that proposed by the present study. Each technical report was read in full and compared regarding: material in contact with the scar; compression mechanism; device containment system; skin fixation; and, type of therapy performed (Table 1).

4.2 The Discover phase

The information collected in the *Interviews* revealed that the patients with keloid and in use of the compression therapy understood the necessity of this therapy in association with other therapeutics for the completeness of their treatment. The acquisition of the garments (compression mesh, foam and silicone sheet) is not difficult. Although the initial purchase cost is relatively high, maintenance costs have been contested for long-term use. The compression therapy application routine was disapproved for the inconvenience, discomfort, mobility restriction, lack of practicality, heat and sweating.

Thus, the criteria for the creation of the device were based on the results of the *Interviews* , *Research Desk* and the*Scenario* : a) To ensure that the patient performs the therapy daily according to the therapeutic orientation; b) A single device, bypassing the need to acquire different materials and combine them to perform the compression; c) Direct application of the device on the scar with practicality and convenience.

4.3 Delivery phase and Prototyping

The first part was delivered consisting of a medical silicone sheet, with dimensions of 8.5 x 5.5 cm, and thickness of 3 to 4 mm (Figure 1). It was affixed underneath the fixed bulkhead of the second part. The spring was made of *Eastman Tritan* (modulus of elasticity of $1.55x10^9$ Pa) (Figure 2 and Table 2).

The final parameters of the spring (and of the entire compression system) to obey the therapeutic limits were the thickness of 14mm, diameter of 76.2mm, width of 20mm and length of 60mm, in which the spring 6b (highlighted in table 2) has been chosen.

The third part was delivered composed of synthetic material in elastic mesh, with an adhesive resin plate in all its surroundings (Figure 3). Thus, as the mesh was stretched over the second part, force was exerted on the compressor mechanism, generating pressure on the skin and scarring. When the maximum deflection of the spring was reached, the surrounding peripheral region was attached to the patient's skin.

5. Discussion

The proposal of the present study originated from a need observed in clinical practice for the treatment of fibroproliferative scars, with emphasis on the keloid. The treatment of this scar is currently with multifactorial therapies, aiming to deal with its various morphophysiological aspects. In this sense, the literature corroborates the association of therapeutics (Berman et al., 2017; Ogawa, 2010).

Keloid compression is an indispensable tactic in the therapeutic arsenal. There are several options of devices for this purpose, but, only for keloids located in the ear. The use of these devices, as an adjuvant therapy, have been associated with decreasing the rate of relapse after surgical resection (Ogawa et al., 2013; Rathee et al., 2014; Tanaydin et al., 2016; Thierauf et al., 2017). Unfortunately, for other topographies, especially in the anterior thorax, a high prevalence site, there are no particular devices for compression therapy (Atiyeh et al., 2013; Macintyre & Baird, 2006).

Friedstat and Hultman (Friedstat & Hultman, 2014) published a systematic review, which included four articles with 234 patients regarding the use of compressive garment, and three articles with 226 patients with the association of the same clothing and silicone sheets. The authors reported conflicting results in isolated and polymer-associated compression therapy. They concluded that, although fibroproliferative scars are a common occurrence in burn patients, both the number of studies and their therapeutic consensus are limited. Better quality studies are therefore needed, specifically for the use of compression, silicone alone and in combination. Thus, the standardization of a clinical trial, using a standard compressor device could, in theory, minimize bias and elucidate many questions of this therapy.

The meta-analysis published by Anzarut (Anzarut, Olson, Singh, Rowe, & Tredget, 2009) concluded that compression therapy with compression garments did not alter the general characteristics of burn scars. It improved its height, although this result was of questionable clinical importance. The effects of compression therapy remained unproven, while the potential morbidity and cost were relevant points. The authors concluded that the current evidence lacks additional research to examine the efficacy compression therapy. In clinical practice, physical improvements are also observed and also reported by patients. For these reasons, the use of a proper keloid compression device would standardize therapy and improve the quality of scientific evidence.

The magnitude of the pressure on the scar is crucial in compression therapy (Friedstat & Hultman, 2014). Firstly, too much pressure on the keloid could cause tissue ischemia and, consequently, necrosis and a critical wound (Atiyeh et al., 2013). A wound in a pathological scar is a disastrous complication. Moreover, this lesion could evolve unfavorably with infection, healed by second intention and, consequently, present recurrence and aggravate the local tissue inflammation (Berman et al., 2017). On the other hand, low pressure is inefficient (Atiyeh et al., 2013). Second, the maintenance time of the compression is also relevant. There is preference for long periods, between 08 to 12 hours, uninterrupted, daily, for months in a row (Macintyre & Baird, 2006). These characteristics were relevant in the decisions taken during the brainstorming for the standardization and prototyping of the device developed.

Thus, the present device is an alternative for pressure therapy on keloid scars, with the exception of the ear. Similar to devices used in the ear, which have a mechanism to exert the scar compression; and, unlike those for the treatment of burn scars that uses compressive garments; the device presented showed the benefits of both situations. It is easy to apply, simple, lightweight and discreet. The design thinking methodology helped to understand patients' needs to address the long-term treatment of their scars, allowing after various brainstorming, experimentation, and prototyping to validate the final device.

Finally, the developed device has the potential to increase access and improve the treatment of patients with keloid. There is simplification of the therapeutic procedure, associating the necessary materials to its integral practice. This could help to reduce costs and the adoption of new technologies brings better quality to the patient.

6. Conclusion

A device for keloid pressure therapy was developed and prototyped using the Design Thinking methodology.

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Tables

Table 1: Characteristics of the devices found in the Anteriority Search (n=11).

PATENT DOCUMENT	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS
	Material in contact with the scar	**Compression mechanism**	**Device containment system**	**Skin Fixation**	**Therapy performed**
BR202013013590	Silicone sheet	Compression mechanism made by rods and a screw.	No containment system	Fixation on the skin by the proper compression mechanism.	Scar compression therapy, exclusive to ear.
CN203354864	Sponge for medical use	Inflatable device for the application of negative pressure	Plastic film, like a bandage	Plastic film	Negative pressure therapy
JP2004223087	Silicone sheet	Positive pressure directly on the scar	None	Silicone sheet adhesion	Positive pressure on the scar tissue
US5895656	Smooth or textured elastomer or silicone pad	Positive pressure directly on the scar after filling the pad	The silicone elastomer pad is filled by a fluid (gaseous or gel).	Elastomer pad adhesion	Positive pressure on the scar tissue
US8168850	Silicone elastomer, or other polymer, on tape	There is no compression. The device promotes reduction of tension in the scar.	None	Silicone elastomer adhesive tape	Therapy to reduce tension in the skin and scar
PATENTE *US2011/0004168*	Flexible and waterproof material	Negative pressure	Mounting the entire device in contact with the skin and wound to create negative pressure	Adhesion to the skin by the device chamber after the application of negative pressure	Negative pressure wound therapy
US2014/0350494	Porous material, polyester fabric or other materials	Negative pressure	Plastic film, like a bandage	Polyurethane adhesive film	Negative pressure wound therapy
US2015/0032035	Silicone, gel or elastomer, polyurethane foam, hydrogel and / or hydrocolloid	Monitored positive pressure	Flexible material	Medical adhesive tape or external support	Positive pressure on the scar tissue

PATENT DOCUMENT	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS	COMPARED CHARACTERISTICS
CN2448351Y	Cylinder composed of wood, stone, rubber, plastic, porcelain, iron, magnets, stainless steel or other materials.	Positive pressure achieved by applying the device directly over the scar	None	None	Positive pressure on the scar tissue
CN201110095000	Magnetic sheet	Positive pressure achieved by applying the device directly over the scar (magnetic)	None	Magnetic field	Positive pressure on the scar tissue
US20130331757	Material that can be attached to the skin, non-distensible (stretch-resistant or inelastic)	Dressing in adhesive tape to reduce traction on the wound. It can be added with a balloon or a spring, for different surfaces and compression modalities.	None	Adhesive tape	Mechanical restraint on wounds to reduce tension and traction

Table 2: Final parameters of the prototyping of the springs.

Spring	Thickness (H) (mm)	Arrow () (mm)	Value read in Balance (kgf)	Theoretical expected value (P) (kgf)	The
06	1,8	11,21	4,4	3,826	37,5
06a	1,6	11,21	3,65	2,687	26,4
06b	1,4	11,21	2,2	1,8	17,7
06c	1,2	11,21	1,44	1,134	11,1

Legend: The compressive force of the device (P) necessary to cause a deformation "" is obtained by isolating "P" in formula:$P = \frac{4d\mathrm{EBH}^3}{L^3}$, which "E" is the modulus of elasticity, "B" is the width of the spring, "H" is the thickness of the spring and "L" is its length. In order to obtain the value of the compression exerted by the system, the value of the compressive force (P) must be divided by the area of the bulkhead (A).

Figure Legends

Figure 1: In "A", side of the silicone sheet in contact with the skin and scar. In "B", the

other side in contact with the second part of the prototype.

Figure 2: In "A", movable bulkhead arranged on the arced spring (B). In "C", the fixed bulkhead arranged on the first part (silicone sheet).

Figure 3: Synthetic mesh for holding the other parts of the prototype, and adhesive resin around it to stick on the patient's skin.