Elastic suture thread

Fio de sutura elástico

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■ **ABSTRACT**

Introduction: Closing large and medium wounds is challenging for surgeons and often leads to the use of graft or flap surgical techniques. These procedures can leave sequelae and even mutilations. An "elastic suture" technique was developed to promote wound healing in a short time span with minor sequelae; however, improvised materials have been used in this procedure. **Objective:** To develop a surgical elastic suture thread that can be manufactured and sterilized following the standards of surgical medical products. **Methods:** We conducted a patent search, compared the findings with the study device, and researched materials with necessary characteristics such as elasticity and tension. Testing these characteristics in specialized laboratories. **Results:** The developed device is a double-needled elastic suture made of silicone that presents tensile strength. **Conclusion:** Here, we developed a double-needled elastic suture for medium and large wounds.

Keywords: Sutures; Wound closure techniques; Healing; Wounds and injuries; Suture techniques; Plastic surgery.

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■ RESUMO

Introdução: O tratamento de grandes e médias feridas é um desafio para os cirurgiões quando precisam fechá-las e, normalmente, são utilizadas técnicas cirúrgicas de enxertias ou retalhos, que podem deixar sequelas e até mesmo mutilações. Ao longo do tempo desenvolveu-se a técnica de "sutura elástica" que promove a cicatrização em curto espaço de tempo com sequelas menores, entretanto o procedimento tem sido realizado com material improvisado. **Objetivo:** Desenvolver um fio de sutura elástico cirúrgico que possa ser esterilizado e confeccionado nos moldes dos produtos médicos cirúrgicos. **Métodos:** Revisão das patentes existentes por meio da busca de anterioridade e comparação com o dispositivo do estudo. Pesquisa de materiais com as características necessárias como elasticidade e tensão. Teste destas características em laboratórios especializados. **Resultados:** O produto desenvolvido é um fio elástico com duplo agulhamento para suturas, com matéria prima de silicone que apresenta elasticidade e resistência a tensão. **Conclusão:** O fio de sutura elástico, com duplo agulhamento, para feridas de médio e grande porte foi desenvolvido.

Descritores: Suturas; Técnicas de fechamento de ferimentos; Cicatrização; Ferimentos e lesões; Técnicas de sutura; Cirurgia plástica.

INTRODUCTION

A wound is defined as a loss of skin coverage including skin, subcutaneous tissues, muscle, and bones. Wounds can be conceptualized as a "break in the continuity of a body structure" or a "rupture of normal tissue structures and functions." They can be caused by internal or external trauma to the affected tissue, ranging from an acute and controlled injury to extensive aggression[1]. Wounds are classified according to how they were produced and the degrees of contamination and tissue involvement[2]. Wounds are classified as medium or large when primary closure is not possible. However, despite the lack of a single universally accepted definition, the term complex wound usually describes wounds that can anatomically involve multiple tissues, which often develop after devastating lesions and do not heal in a timely manner or at all. Trauma, the leading preventable cause of death, mainly affects economically active adults, creating a major social impact[3].

Treating medium and large wounds is challenging because, without proper cleaning and care, they can lead to complications such as infections and poor healing. Optimal wound healing requires the removal of debris and necrotic tissue, bacterial load control, and appropriate closure. The ideal wound closure device should be easy and fast to use, be economical, cause no pain, and provide the best aesthetic result.

Preparation, the first step in medium and large wound resolution, involves cleaning and debridement for subsequent flap creation or grafting. However, surgical techniques using flaps or grafts have some disadvantages. Flaps can be cutaneous, fasciocutaneous, muscular, or myocutaneous, use tissues from adjacent or microsurgical/distant areas, and leave large scars and aesthetic deformities. On the other hand, skin grafts require donor areas and usually leave hypertrophic, retracted, and/or unaesthetic scars in the donor and recipient areas[4].

Reconstructive plastic surgery is an important tool in the surgical treatment of complex wounds. It is based on two theories regarding its planning and execution: the reconstructive ladder and the reconstructive triangle. The ladder theory prioritizes the simplest solution for case resolution, such as grafting. If wound resolution does not occur, one proceeds to a more complex option, such as the use of local, expander, and free flaps. Modern reconstructive surgery techniques and the availability of more sophisticated equipment and materials have made the reconstructive triangle the most used model today. In

this model, the chosen surgical technique is based on anticipating the quality of the final outcome. The chosen technique should preserve the shape and function of the area to be rebuilt regardless of complexity, provided that the patient is safe[5].

Skin properties are extremely important in wound treatment. Elasticity is the quality that underlies the use of "elastic sutures" to close wounds over a short time span. This type of suture has been successfully used to close medium and large wounds[6].

The elastic suture technique consists of stitching a rubber band on the wound margins. Tensioning the elastic band using an x-cross approximates the edges of the wound. This permanent and continuous tension approximates the edges, and total closure is achieved much faster than other closing techniques[7] (Figures 1–3). To date, the material used as a rubber band is improvised by cutting surgical glove cuffs or using a rubber band for cash sterilized in ethylene oxide[8].

Figure 1. Preoperative period.

Figure 2. Immediate postoperative period.

Figure 3. Result at 15 days postoperatively.

This study aimed to develop a sterile needled surgical elastic suture according to the standards required by regulatory agencies. To achieve the desired objective, the elastic suture should have the strength and elasticity of the elastic material currently used in surgeries.

OBJECTIVE

To develop a double-needled elastic suture thread for the surgical closure of medium and large wounds.

METHODS

The study was analyzed and approved by the Research Ethics Committee of the Federal University of São Paulo (UNIFESP) under CAAE number 6291011217.

The elastic suture described in this study was filed at the Technological Innovation Center of the UNIFESP and evaluated for registration as a utility model at the National Institute of Industrial Property (Instituto Nacional de Propriedade Industrial [INPI]).

Patent search

The present search was conducted by the patent office Clarke, Modet & C°, a NIT-UNIFESP-accredited company, to locate possible invention patent (IP) or utility model (UM) documents. PatBase® patent search software was also used.

The following international databases were used in the patent search: European Patent Office (www.epo.org); United States Patent and Trademark Office (www.uspto.gov); World Intellectual Property Organization (www.wipo.int); State Intellectual Property Office of China (english.sipo.gov.cn); and Japan Patent Office (www.jpo.go.jp). The INPI database (www.inpi.gov.br) was searched.

The following keywords were used for the search, including their derivatives (singular and plural) and the combinations of these words with their synonyms in English and Portuguese: *surgery, suture thread, suture line, surgery seam, elastic, flexible, and stretch*.

The International Patent Classification was also used for a more specific search. The classification related to the present invention was:

Section: *A - Human needs.*

Class: *A61 - Medical or veterinary science; hygiene.*

Subclass: *A61B - Diagnostic methods, surgery, identification.*

A61B 17/03 – Wound suturing instruments.

A61B 17/04 - Wound closure instruments.

Prototype development

Material search

Internet search tools (Google) were used to find laboratories that produced elastic materials, mainly silicone and rubber, and could potentially make an elastic tensile cylindrical cord similar to the elastic material used in elastic sutures. After a few visits, we found a company in the silicone industry called *Silicoflex*, the most technologically prepared to develop the product. The main silicone component is silicon, the most abundant element on the Earth's surface after oxygen[9] (Figure 5).

Suture prototype

The prototype begins with the production of a silicone rubber blanket that goes through several mixtures from which the operator collects samples to determine color and hardness using the shore durometer device[9]. This sample is placed in an extruder machine and the material gets the desired shape according to the matrix, in this case, a cylindrical cord[10]. The material passes through a heating tunnel with temperatures of 150–200 °C, where the silicone is vulcanized. Finally, the material is placed in a post-curing oven (200 °C/2 hours) to eliminate odors; after being treated with a catalyst, it becomes nontoxic. Subsequently, the cords are evaluated for size, hardness, and appearance[11].

The produced prototypes had diameters of 2.8 and 2.5 mm, similarly to the elastic materials, and 40, 50, and 60 shore density (Figure 4A). Manual, tactile, and visual tests favored the 50-shore density prototype, whose samples were sent to the Falcão Bauer Laboratory – Quality Control Technology Center – for elasticity, strength, and tension evaluations.

The laboratory tested five specimens (200-mm length) that were fixed one at a time to the test machine hooks and pulled at a constant speed of 50 mm/min until rupture. Maximum strength and elongation at rupture were recorded (Table 1).

A comparison with the elastic material normally used for elastic sutures showed that the length of the thread could be 45 cm, meeting the parameters already standardized by surgical suture companies. The double-needled elastic thread was produced with needle length, diameter, and type similar to those of standard suture threads (Figure 4B).

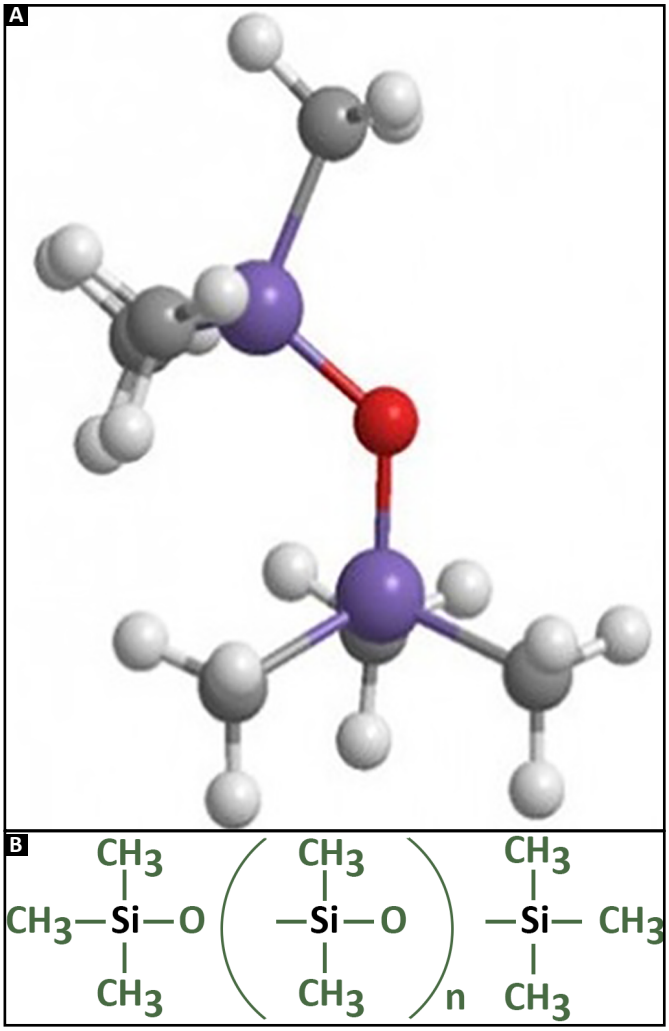


Figure 4. A: Silicone molecule; **B:** Molecular formula of silicone.

Table 1. Results of tests performed by Falcão Bauer laboratory evaluating elasticity, resistance and tension.

Test	Value found					
	TB1	TB2	TB3	TB4	TB5	Mean
Maximum strength, kgf	5.05	4.95	4.55	4.60	4.40	4.71
Elongation at rupture, %	10001.33	816.52	705.16	773.99	891.51	837.70

TB: Test Body.

RESULTS

The Clarke, Modet & C° office selected five documents that matched the research objective to identify products that were similar to the elastic suture developed in this study. The identified products were classified by relevance according to the following scale: low (2), medium (2), and high (1).

Tables 1–5 summarize the information presented in the technical patent reports and compare the patented devices with the device developed in the present study in terms of applicability, material used, and usage.

Table 1. Comparative 1.

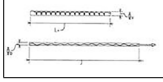
Study device			
Characteristics compared to patents			
Study device	**Applicability**	**Material**	**Usage**
	Large wound closure	Silicone	Elastic sutures
Patent 1 FR2926452A1			
	Ligament replacement or hernias	Braided polyurethane	Internal surgery

Table 2. Comparative 2.

Study device			
Characteristics compared to patents			
Study device	**Applicability**	**Material**	**Usage**
	Large wound closure	Silicone	Elastic sutures
Patent 2 us4621638			
No image	Corneal suture 1 mm diameter	Polymers	Corneal suture (edema)

The results of the tests at Falcão Bauer Laboratory evaluating the device's elasticity, resistance, and tension are presented in Table 1. The data show that the elastic suture prototype presented in this study has a mean elastic capacity 8.3 times its original length, greater tensile strength than the elastic material currently used, and great elastic capacity (1001.33%) and tensile strength (Falcão Bauer Laboratory).

The analysis of the data presented in Table 1 comparing the prototype to currently used elastic materials show that, despite some similarities, the elasticity properties along the entire thread, diameter of 2.5 mm (increasing strength), and double needles make the prototype a useful model. The device developed in this study is called *ElasticLine* (Figures 6 and 7).

Table 3. Comparative 3.

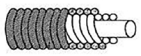
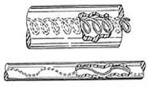
Study device			
Characteristics compared to patent			
Study device	**Applicability**	**Material**	**Usage**
	Large wound closure	Silicone	Elastic sutures
Patent 3 us2006121274			
	Wound suture	Non-elastic thread with elastic core	Sutures requiring low thread elasticity

Table 4. Comparative 4.

Study device			
Characteristics compared to patents			
Study device	**Applicability**	**Material**	**Usage**
	Large wound closure	Silicone	Elastic sutures
Patent 4 US5102419A			
No image	Suture in an area with edema	Various polymers	Suture in an area with edema

Table 5. Comparative 5.

Study device			
Characteristics compared to patents			
Study device	**Applicability**	**Material**	**Usage**
	Large wound closure	Silicone	Elastic sutures
Patent 5 W00112073AL			
	Vascular suture (anastomoses)	Isoplastic (polymer): A mixture of polyurethane, silicone, rubber, and others	Vascular sutures

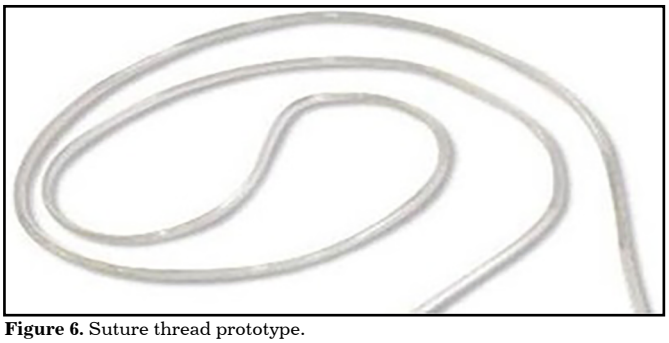


Figure 6. Suture thread prototype.

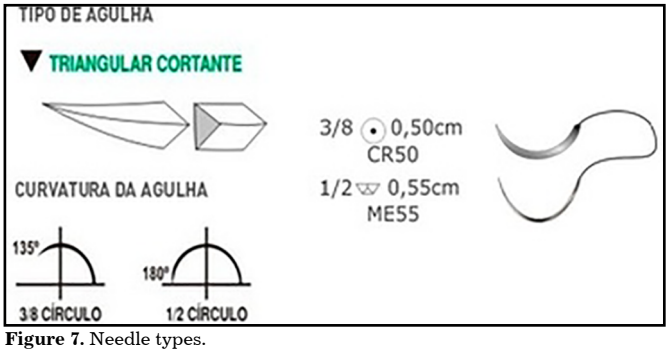


Figure 7. Needle types.

DISCUSSION

The present study describes the development of *ElasticLine*, a sterilizable elastic cylindrical monofilament thread prototype 2.5 mm in diameter when not tensioned created for elastic sutures. The *ElasticLine* is expected to be used in simple and fast elastic sutures using a product manufactured for this purpose that meets the requirements and standards outlined for medical products by the supervising bodies. The development of the *ElasticLine* is timely because, to date, plastic surgeons have improvised elastic sutures with cuffs cut out from surgical gloves or elastic rubber bands[7].

The viscoelastic properties of the skin allow the use of devices that stretch it through constant traction and maintain the edges of large wounds in contact to enable closure without exacerbated tension. Several types of skin stretching devices have already been described, such as the four pins inserted by Kirschner around a wound in 1987. In addition, in 1995, Armstrong developed a mechanical device for attaching wound edges, while Narayanan used a metal cylinder fixed inside the wound for suture traction in 1995. These devices are uncomfortable and costly. In 2011, Ismavel[16] sutured the edges of large wounds using glove cuffs. This technique was the inspiration for the present study of the development of a specific elastic suture thread called the *ElasticLine*.

The development of an elastic suture thread is necessary given the rigorous health surveillance of the use of appropriate products for each function and the need for a product like the currently used sutures. The *ElasticLine* enhances the elastic properties of the skin without causing dehiscence, which is very common with the use of inelastic sutures that promote high skin tension[12].

Silicone was the raw material chosen to produce the *ElasticLine* due to being easily available, being of low cost (approximately BRL 5.00/m), having high elastic capacity (1001.33%), and having high tensile strength. It is also nontoxic and sterilizable, recommended for surgical procedures according to the rules of regulatory agencies such as the National Health Surveillance Agency.

The inclusion of double needles will facilitate elastic suturing by x-crossing the thread. The other devices found in the patent search have different diameters and elasticity levels and do not have double needles, thereby establishing important differences between this utility model and the other devices.

It is increasingly important to search for practical and inexpensive solutions for medical treatments. The development of modern surgical devices is of paramount importance since easier procedures benefit surgeons and patients.

Social impact

Traffic accidents are the leading cause of injuries requiring surgical intervention. Causing 1.2 million deaths per year worldwide and approximately 40,000 deaths in Brazil, they represent a major health problem[13].

In 2013, Sistema Único de Saúde spent approximately BRL 231,000,000.00[14] on traffic accident victims alone.

The *ElasticLine* is expected to provide low-cost healing for patients with medium and large wounds in a short time span, thereby reducing long-term hospitalization costs. The Brazilian health surveillance agency does not allow the use of rubber bands for hair, and the high cost of the current wound closure devices represents a limitation for their use, especially in the public health system, where a large number of patients require wound treatment[15].

The applicability of the *ElasticLine* using the elastic suture technique should be tested in a prospective experimental study in rats and subsequently in humans to prove that its tensile strength is sufficient for use in animal or human wounds without damaging the tissues. The *ElasticLine* has the potential for use in other types of surgical procedures besides skin wound closure, such as tumor resection and large dehiscence closures. However, new uses will depend on further specific study findings.

CONCLUSION

The *ElasticLine* is a double-needled elastic suture that was developed for the surgical closure of medium and large wounds.

COLLABORATIONS

ELNS Project Administration, Realization of operations and/or trials, Writing - Original Draft Preparation, Writing - Review & Editing

EBG Supervision

LMF Final manuscript approval

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