

Magnetic device for closing skin wounds

Dispositivo magnético para fechamento de feridas cutâneas

Dispositivo magnético para el cierre de heridas em la piel

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Gleyse Karina Lopes de Oliveira Pinheiro

ORCID: <https://orcid.org/0000-0003-0461-2517>

Universidade Potiguar, Brasil

E-mail: gleysekarina@msn.com

André Lima Batista

ORCID: <https://orcid.org/0000-0001-5264-3620>

Universidade Potiguar, Brasil

E-mail: batista.nchir@gmail.com

Ricardo Ney Cobucci

ORCID: <https://orcid.org/0000-0002-8958-1344>

Universidade Potiguar, Brasil

E-mail: drcobucci@ufrn.edu.br

Amália Cinthia Meneses Rêgo

ORCID: <https://orcid.org/0000-0002-0575-3752>

Universidade Potiguar, Brasil

E-mail: amaliarego@unp.br

Irami Araújo-Filho

ORCID: <https://orcid.org/0000-0003-2471-7447>

Universidade Potiguar, Brasil

E-mail: irami.filho@uol.com.br

Fausto Pierdoná Guzen

ORCID: <https://orcid.org/0000-0002-5458-7236>

Universidade Potiguar, Brasil

E-mail: faustoguzen@uern.br

Francisco Irochima Pinheiro

ORCID: <https://orcid.org/0000-0001-8879-3997>

Universidade Potiguar, Brasil

E-mail: irochima@gmail.com

Abstract

The attempt to repair skin wounds dates back many years. We have observed bone fragments for making needles, hair, fibers, and animal tissues as sutures and even applying sensors to accelerate the healing process throughout history. Despite all the developments, the need for a qualified professional and prior local anesthesia to perform the suture still represent obstacles. The present study aimed to create 3D printing pieces containing N42 neodymium magnets to be fixed to the skin with adhesive tape to promote skin wounds' closure without the need for anesthesia. A descriptive, experimental study was carried out, divided into the Patent search, Ideation and creation, 3D Modeling, 3D printing of structural parts, Assembly, and Testing on artificial skin. ABSplus® plastic parts were created through 3D printing that received N42 neodymium magnets and the application of a double-sided adhesive to attach to the skin. A perilesional arrangement was simulated with the pieces created using an artificial skin model (EasySuture® Standart) after making the incision. After applying the pieces containing N42 neodymium, there was a perfect coaptation of the lesion's edges without detecting interspersed spaces in the longitudinal axis of the incision. The research resulted in creating a prototype that needs improvements and industrial adaptations for viable use in surgical practice.

Keywords: Sutures; Wound healing; Magnetic field; Medical device; Plastic surgery.

Resumo

A tentativa de reparar os ferimentos cutâneos remonta há milhares de anos. Ao longo da história observamos desde a utilização de fragmentos de ossos para a confecção de agulhas, o uso de cabelos, fibras e tecidos de animais como fios de sutura até a aplicação de sensores para acelerar o processo de cicatrização. Apesar de toda a evolução, a necessidade de profissional habilitado e anestesia local prévia para a realização de sutura ainda representam obstáculos. O presente estudo teve como objetivo a criação de peças em impressão 3D contendo ímãs de neodímio N42 para serem fixados na pele com fita adesiva no intuito de promover o fechamento de ferimentos cutâneos sem a necessidade de anestesia. Realizou-se estudo descritivo, experimental, dividido em: Busca patentária, Ideação e criação, Modelagem 3D, Impressão 3D das peças estruturais, Montagem e Teste em pele artificial. Criou-se peças em plástico ABSplus® por meio da impressão 3D que receberam ímãs de neodímio N42 e a aplicação de um adesivo dupla face para fixação na pele. Simulou-se um arranjo perilesional com as peças criadas utilizando um modelo de pele artificial (EasySuture® Standart) após a confecção de incisão. Após aplicação das peças contendo neodímio N42, houve a perfeita

coaptação das bordas da lesão sem detecção de espaços intercalares no eixo longitudinal da incisão. A pesquisa resultou na criação de um protótipo que necessita de aperfeiçoamentos e adaptações industriais para uso viável na prática cirúrgica.

Palavras-chave: Suturas; Cicatrização de feridas; Campo magnético; Dispositivo médico; Cirurgia plástica.

Resumen

El intento de reparar las heridas de la piel se remonta a miles de años. A lo largo de la historia, hemos observado desde el uso de fragmentos óseos para la fabricación de agujas, el uso de pelo, fibras y tejidos animales como suturas hasta la aplicación de sensores para acelerar el proceso de cicatrización. A pesar de todos los avances, la necesidad de un profesional calificado y anestesia local previa para realizar la sutura aún representan obstáculos. El presente estudio tuvo como objetivo crear piezas de impresión 3D que contengan imanes de neodimio N42 para ser fijados a la piel con cinta adhesiva con el fin de promover el cierre de heridas en la piel sin necesidad de anestesia. Se realizó un estudio descriptivo, experimental, dividido en: Búsqueda de patentes, Ideación y creación, Modelado 3D, Impresión 3D de piezas estructurales, Ensamblaje y Ensayos sobre piel artificial. Las piezas de plástico ABSplus® se crearon mediante impresión 3D que recibieron imanes de neodimio N42 y la aplicación de un adhesivo de doble cara para adherirse a la piel. Se simuló una disposición perilesional con las piezas creadas utilizando un modelo de piel artificial (EasySuture® Standart) después de realizar la incisión. Tras la aplicación de las piezas que contienen neodimio N42, se produjo una perfecta coaptación de los bordes de la lesión sin detectar espacios intercalados en el eje longitudinal de la incisión. La investigación resultó en la creación de un prototipo que necesita mejoras y adaptaciones industriales para un uso viable en la práctica quirúrgica.

Palabras clave: Suturas; Cicatrización de la herida; Campo magnético; Dispositivo médico; Cirugía plástica.

1. Introduction

The search for alternatives to repair injuries by affixing their edges goes back more than 50,000 years B.C. To be able to close the wounds, it was necessary to have a perforating instrument that transfixed the skin from side to side of the lesion. Primitive needles were made of bone fragments and had an orifice to anchor the first suture threads made of hair, fibers, tendons, and animal skin (Gierek et al., 2018).

Over time, the needles and threads have undergone improvements to promote rapid healing, less risk of dehiscence, and wound infection (Dennis et al., 2016). Easy handling, adequate resistance, reduced tissue reaction, low risk of infection, and adequate degradation were characteristics that guided the process of developing the arsenal currently available for suturing injuries (Medeiros, Araújo-Filho, & Carvalho, 2017). Curved needles, straight, cutting or not, absorbable and non-absorbable sutures, natural or synthetic, mono, or multifilament are examples of the diversity of options currently available (Dennis et al., 2016).

Despite all the developments in material properties, the act of suturing the skin still involves two important obstacles that make it difficult for anyone to perform, especially in remote areas lacking trained professionals to perform the surgical synthesis. The first consists of the need for local anesthesia on the skin to perform the suture since transfixion with a needle implies a painful sensation to be abolished. The second represents the need for a trained professional to perform both the procedure and remove the suture fixation points after the wound heals.

To solve these obstacles, several alternatives were created in an attempt to eliminate the need for local infiltrative anesthesia and that the procedure could be performed, in selected cases, by the patient himself. The state of the art of the alternatives that aim at the closing of blunt and linear wounds of the skin demonstrates a high number of patented products that range from tissue adhesives, known as biological glues, to a variety of devices and traction adhesives attached to the skin and adjacent to injury (Dennis et al., 2016; Petroianu, Silva, Melo, & Vasconcellos, 2001).

However, the use of magnetism as a property to act as a traction force to approach the wound edges has been very little explored. In this context, the present study aimed to demonstrate the creation and development of devices that, coupled around linear wounds, will act as traction points to keep them closed until complete healing, using the magnetic properties of neodymium magnets. A prospective study was also carried out in offices

specialized in relevant patents to assess both the state of the art of creation as well as the feasibility of improvements and adaptations, as highlighted by Quintella, Meira, Guimarães, Tanajura and da Silva (2011), in addition to Borschiver, Almeida and Roitman (2008).

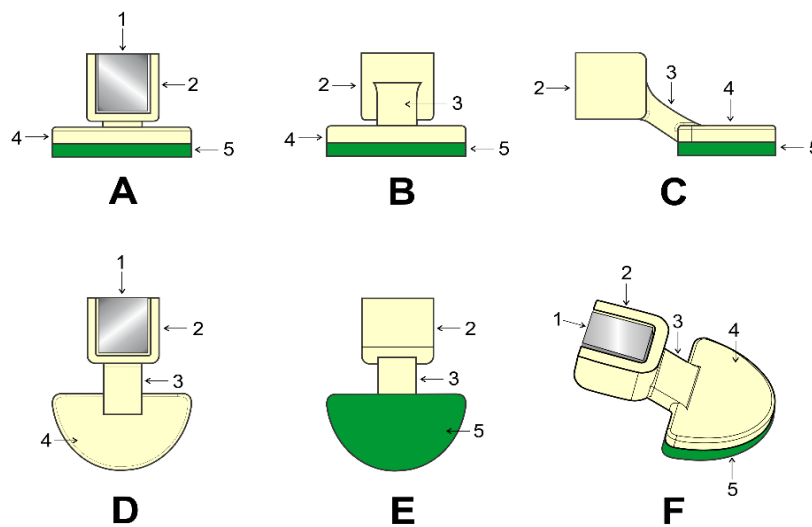
2. Methodology

The project was a descriptive, qualitative and inventive study that consisted of the ideation, creation, and development of a device that uses magnetism to promote skin wounds (Pereira, Shitsuka, Pereira, & Shitsuka, 2018). The research project was developed in the Postgraduate Program in Biotechnology at Universidade Potiguar (UnP) / Laureate International Universities with the support of two startups, one already graduated (Ciência Ilustrada Studio®) and the other incubated (Natal Makers®) at INOVA Metr pole from Instituto Metr pole Digital (IMD-UFRN). The device's prototype was developed over six months, covering six phases: Patent search, Ideation, and creation, 3D Modeling, 3D printing of structural parts, Assembly, Artificial skin testing.

The search for pre-existing patents related to state of the art was carried out at the European Patent Office - EPO in April 2020, using the practical guide of the National Institute of Industrial Property - INPI (INPI, 2020a). In the search, the terms in English "adhesive strip suture" were used; "Adhesive wound closures"; "Adjustable non-invasive wound closure system"; "Interlocking suture"; "Medical treatment method" and "device utilizing magnetic"; "Skin closure"; "Skin closure device"; "Surgical skin closure"; "Systems and methods for closing a tissue opening"; "Wound closure device" and "wound closing strip" in combination with the Cooperative Patent Classification (CPC) codes: A61B - "Diagnosis"; "Surgery"; "Identification", A61B17 / 00 - "Surgical instruments"; "Devices or methods"; e.g. "tourniquets", A61B17 / 04 - for "suturing wounds"; "Holders or packages for needles or suture materials", A61B17 / 08 - "wound clamps" {or clips, i.e. not or only partly penetrating the tissue (suture bridges); devices for bringing together the edges of a wound}, A61D1 / 00 - "surgical instruments for veterinary" use, A61F13 / 00 - "bandages or dressings" (suspensory bandages; {contact-avoiding wound protectors; bandages or dressings with incorporated medicaments; radioactive dressings}); "Absorbent pads" (chemical aspects of, or use of materials for, bandages, dressings or absorbent pads; {absorbent pads for tracheostomy}) and A61N2 / 00 - Magnetotherapy (INPI, 2020b). After the initial search, the selected patents were analyzed for the content of their abstracts and used to support the state of the art of the new device developed.

The ideation method was based on the Theory of Inventive Problem Solving, acronym TRIZ, (proposed by Genrich Altshuller (Vincent & Mann, 2002)). After the initial search, the selected patents were analyzed for the content of their abstracts and used to support the state of the art of the new device developed. In this phase, the team was composed of a dermatologist, a general surgeon, two pharmacists, and two biotechnology specialists. A materials engineer and a physicist participated as consultants to resolve technical questions. At the end of the ideation phase, it was decided to use magnetism to propose a new way to provide the apposition of the edges of blunt wounds involving skin and subcutaneous tissue. The final idea was based on devices modeled on a suitable material that housed an N42 neodymium magnet. These devices could be affixed on each side of the skin wounds' edges employing self-adhesive adhesive in an arrangement that ensured an adequate and continuous affixing of the edges of the skin wounds. (Figures 1 and 2).

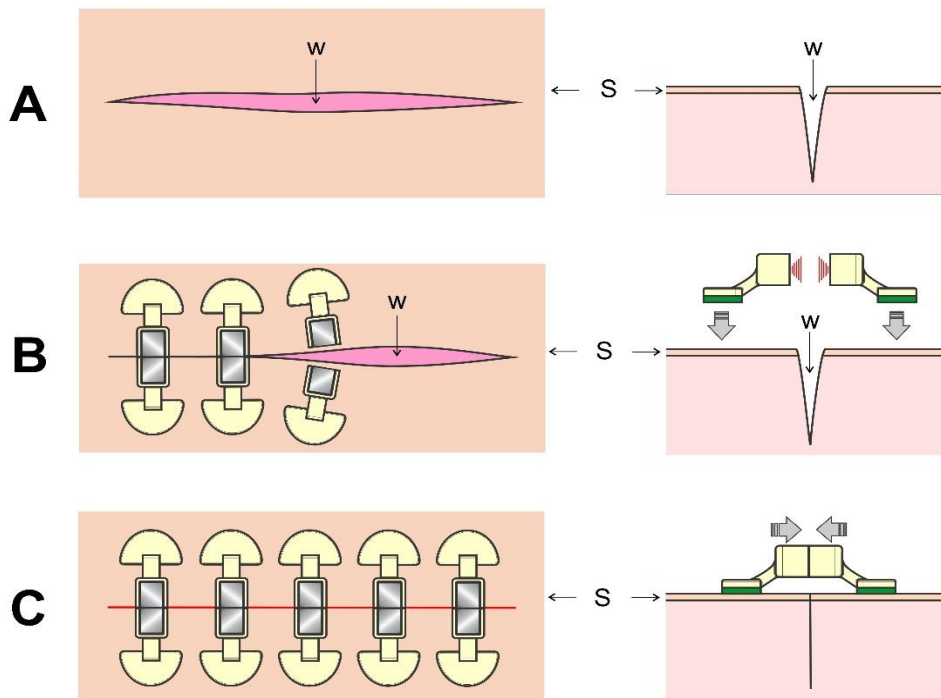
Figure 1. Design of the magnetic device for closing skin wounds (A- anterior view, B- posterior view, C- lateral view, D- superior view, E- inferior view, F- oblique view, 1- magnet, 2- magnet box, 3 - support bridge, 4- base support and 5- double-sided tape).



Source: Illustrations made by the authors themselves (2020).

Figure 1 shows several views (A, B, C, D, E, and F) of a piece that serves as an anchor for the wound closure. In each piece, we can observe a neodymium magnet (1), a box that receives the magnet (2), a support base (4) that is adhered on its underside to one of the adhesive sides of the double-sided tape (5). The support bridge (3) joins the magnet box (2) with the support base (4) at an angle of 45 ° to leave the magnet box (2) at three millimeters.

Figure 2. Arrangement of magnetic pieces equipped with N42 neodymium magnet for closing skin wounds (W-wound, S - skin). A - Open cutaneous wound (top view on the left and transverse view on the right), B - Partial closure with magnetic parts (top view on the left and transverse view on the right), and C - Total closure (top view on the left and transverse view on the right).



Source: Illustrations made by the authors themselves (2020).

Figure 2 shows an open skin lesion in A. In B, the gradual fixation of the magnetic pieces on each side of the wound is demonstrated utilizing the double-sided tape promoting the lesion's closure by the interaction of the magnetic fields of the magnets present in each piece. Finally, in item C, the wound's total closure is observed after the bilateral insertion of the pieces at the edges of the lesion, promoting the juxtaposition of its edges and consequent closure.

To create the drawings of the parts that support the magnets and are attached to the skin, the CorelDRAW X8® vector drawing program (Corel Corporation, Ottawa, Canada) was used. At the same time, the 3D modeling was performed using the Inventor Professional 3D CAD program (Autodesk, Inc 111 McInnis Parkway San Rafael®, CA 94903) and printed using the Sethi 3D AiP® printer (Sethi 3D Ind Com Prod Eletrônico, Campinas, SP) in ABSplus® plastic.

Parts were made to support the magnets and fix the skin. A 5x5x5mm N42 neodymium magnet with a tractive force of approximately 5.0kg and a magnetic flux density of 5,700Gauss was affixed to a strategically designed compartment on each piece to harbor it. A 3M Scotch® Fixed Strong Foam Double Sided Self Adhesive Adhesive 19mm wide adhered to each piece's fixing plate keeping the other self-adhesive side with its protector.

After manufacturing the structural parts and assembling the components, a linear wedge incision 7cm long x 0.5cm deep and 0.5cm in its largest central width was performed with a disposable scalpel blade number 15 in a suture simulator, skin model, in silicone with 3 layers (epidermis, subcutaneous and muscle) with 10x7x1.2cm of the EasySuture® Standart brand. With the incision made, 3 pieces containing the magnets were positioned 0.5cm on each side of the edges. There is 1cm of the distance between them, fixed after removing the second protector from the double-sided tape and brought together by its magnetic power.

3. Results and Discussion

The search at the European Patent Office - EPO using the terms and codes of the Cooperative Patent Classification (CPC) specified in the methodology resulted in 513 patents, the vast majority, 465, belonging to the A61B classification, 35 related to the A61B17 / 08 code, 10 with code A61B17 / 04 and codes A61B17 / 00, A61F13 / 00 and A61N2 / 00 each with 01 patents. At the end of the search, a total of 513 patents were found. After analyzing the abstracts' contents, the authors selected 27 patents as an investigation of the methods already existing in state of the art (Table 1).

Table 1. Result of the number of patents after searching the European Patent Office - EPO using Keywords and codes from the Cooperative Patent Classification - CPC.

	CODES (Cooperative Patent Classification - CPC)						
	A61B	A61B17/00	A61B17/04	A61B17/08	A61D1/00	A61F13/00	A61N2/00
KEYWORDS							
Adhesive strip suture	2	-	-	-	-	-	-
Adhesive wound closures	1	-	-	-	-	-	-
Adjustable non-invasive wound closure system	1	-	-	-	-	-	-
Interlocking suture	3	-	-	-	-	-	-
Medical treatment method and device utilizing magnetic	1	-	-	-	-	-	1
Skin closure	69	-	3	11	-	-	-
Skin closure device	18	-	1	5	-	-	-
Surgical skin closure	8	1	1	-	-	-	-
Systems and methods for closing a tissue opening	2	-	-	-	-	-	-
Wound closure device	359		5	19		1	
Wound closing strip	1						

Subtotal	465	1	10	35	1	1
TOTAL	513					

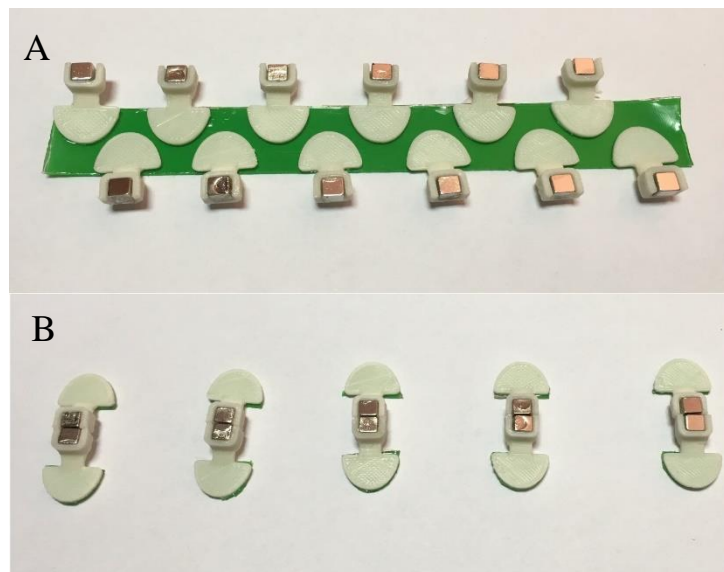
Source: Illustrations made by the authors themselves (2020).

Table 1 shows the search for patents carried out at the European Patent Office - EPO using related Keywords and codes from the Cooperative Patent Classification - CPC. It is possible to observe the highest concentration of patents when the keyword Wound closure device was crossed with the code A61B.

The ideation process based on TRIZ pointed to the making of a device that used magnetism as a force to affix the edges of the wounds, avoiding the need for a needle, prior local anesthesia, and as little material as possible. The idea was to make a piece of plastic material that would act as a traction bridge between the skin on each incision side. The support piece matrix was modeled to house the N42 neodymium magnet and receive the double-sided adhesive tape. Each piece was made with a square box (magnet box) with dimensions of 9x9x6mm. There was a 6x6x7mm cavity in its center where the magnet was fixed, a semicircular support base measuring 10x10x1.5mm to fix a double-sided tape keeping the protector of the side that attaches to the skin. A support bridge measuring 6x3x 1.5mm joins the fixing plate to the magnet box at a 45 ° inclination.

After the ideation and modeling process, the pieces were printed on ABSplus® plastic. A magnet was bonded with cyanoacrylate adhesive (Loctite®, Henkel Ltda., São Paulo) in its own compartment. The double-sided adhesive tape was cut using the skin fixation plate as a template (Figure 3).

Figure 3. Assembly of parts with a magnet on the double-sided tape.



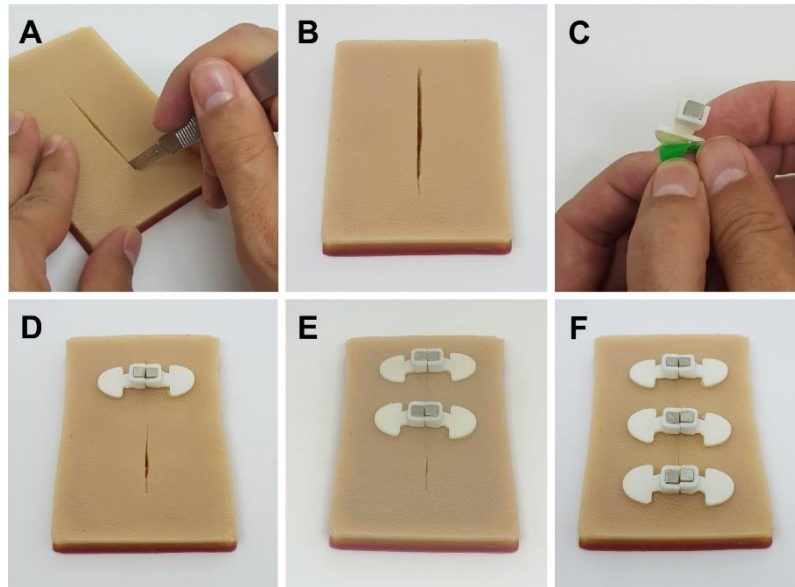
Source: Illustrations made by the authors themselves (2020).

The upper part of Figure 3 (A) shows the pieces' fixation on one of the self-adhesive faces of the double-sided tape with the support base as a template. The lower part of the figure (B) shows the parts assembled and joined by their magnetic poles.

Subsequently, the protector was removed from only one side of the tape, which was attached by this self-adhesive surface to the skin fixation plate's underside. Parts were made using the same assembly method to be used in tests with artificial skin, half of them containing magnets with the north pole (N) facing the incision and the other half with the south pole (S) directed towards the incision. This allowed the attraction between the opposite poles (N and S) on each side of the incision, avoiding repulsion between the pieces.

After identifying the pieces in type N (with the north pole facing the incision) and type S (with the south pole facing the incision), one by one was fixed on each side of the incision made in artificial skin in an arrangement where each piece it was spaced 10mm from each other and 10mm from the edge of the incision. After the pieces' placement, there was a magnetic interaction and attraction between the opposite poles (N and S) of each magnet aligned on each side of the incision, promoting its closure. It was observed a perfect apposition of the lesion's edges in a satisfactory way and the absence of visible opening spaces in the longitudinal axis of the simulated wound (Figure 4).

Figure 4. Carrying out the incision in artificial skin (EasySuture® Standart) and inserting the magnetic parts (A- Carrying out the linear wedge incision; B- Carrying out; C- Removing the double-sided tape protector; D- Fixing the first set of magnetic parts; E - Fixation of the second set of magnetic pieces and F- Complete closure of the incision).



Source: Illustrations made by the authors themselves (2020).

Figure 4 demonstrates the step of making the linear wedge incision (A), the incision after making the space between the edges (B), the removal of the double-sided tape protector for fixing the piece on the artificial skin (C), and the fixation of 3 sets of pieces promoting the closing of the incision (D, E, and F).

Despite the wide variety of adhesives, devices, and arrangements designed to promote wound closure, searches for patent registrations or scientific articles that use magnetism have shown that few studies on the use of this mechanism as a viable alternative for this purpose. The explanation for the largest number of records is concentrated in the A61B - Diagnosis category; surgery (465 patents) is in the fact that this code is more comprehensive and less specific than the others.

Analyzing the selected patents, we noticed a predominance of an inventive pattern observed by Altshuller when establishing TRIZ after analyzing thousands of inventive records (Vincent & Mann, 2002). Most of the proposals that had the objective of not using a needle or suture to close the wounds and, therefore, without the need for prior local anesthesia, adopted as a basic mechanism the use of adhesives fixed on each side of the lesion edge. The anchorage and approximation points provided by the adhesion tapes basically used the mechanical traction transmitted in the most diverse ways at the wounds' edges. Taking this

principle as a basis, it should be noted that the inventive line of the present study distanced itself from the simple use of mechanical traction, replaced by the traction provided by the magnetism produced by the neodymium magnets present in the manufactured pieces, giving more adhesion strength in the closing complete injury.

The record deposited by Brower (1987) consists of bandages with adhesive capacity where one of its extremities is fixed on one side of the wound and pulled until the perfect apposition of the edges. Only after this stage, the other end of the adhesive is fixed on the opposite side (Brower, 1987). Other variations that use adhesive tapes crossing the wound only change the arrangement and the way of traction, as observed in the records of Lebner, 2005. This solution line has many advantages due to its simplicity, low cost, and practical application. However, the small tensile strength and low adhesiveness of the type of tape used to increase detachment risk from exposure to water and other products.

Authors such as Haverstock (1975) and Will (1990), among others, developed systems where the adhesive tapes fixed on each side of the wound are joined by a pressure mechanism or by a zipper system that longitudinally promotes the closure of the wound (Haverstock, 1976; Haverstock, 1978; Haack, 1995; Luchetti, 2007). Although it can be made of plastic, the presence of recesses and excess material in the zipper case can cause the accumulation of residues in the wound and increase the risk of infection, an undesirable fact as reported by Medeiros et al. (2017). The prototype proposed in the present study also has plastic material and some recesses. However, as it remains distanced from the wound, the risk of infection would be lower than the zipper systems.

In an attempt to solve the reduced traction and risk of wound dehiscence in some systems that use only adhesive tape fixation, in some patents, the authors adapted gradual traction systems that can be manipulated to increase the traction between the wound edges to maintain them together until healing is consolidated. These arrangements range from adjustable rails to bandages for upper and lower limbs where a kind of brace is encircled on the limb, and a mooring is performed using anchor points placed above an adhesive bandage (Haverstock, 1990; Hasson, 1975; Hasson, 1976). Like the others, these solutions present an excess of material with little practicality and a higher risk of infection due to the accumulation of residues and microorganisms (Kawchitch, 1976; Riskin, 2006).

Analyzing the various records, we observed some systems that differ from the vast majority of the proposed alternatives. Some proposed the wound edges' diagonal compression with complex and poorly reproducible systems to keep them together (Detour, 2001). Others have suggested, in addition to the use of adhesives, the invasive fixation of the skin by pins to

accelerate healing by stimulating the dermis (Sheehan, 1985). Other than that, other patents showed a very complex character with deficient levels of practicality and replication and several negative points for a new and promising skin wound closure system (Cory & Levine, 2008; Anvar, 2005).

The patent registered under the number US6730014B2 refers to registering several systems that use magnetism as a force for traction and closure of wounds. In this document, the author suggests introducing material with magnetism to close anastomoses in the tissues and introducing pins into the skin so that the magnetic attraction promotes the closing of the skin wound. In another item of the same document, the authors demonstrate the fixation by longitudinal adhesive tapes to the largest axis of the wound employing magnetic plates that approximate the edges of the lesion (Wilk, 2004). This proposal is the one that most resembles what the authors propose in the current research. However, as it is a continuous plate, the patent's idea presents a limitation for injuries that are minimally arched. Other negative points of the patent would be introducing foreign material into the tissues and the need for prior anesthesia.

Contrary to the above, the present inventive proposal has several individual parts, so the system has the ability to adapt to arched injuries, with more than one branch or different angles, which represents an evolutionary advantage concerning the previous proposal.

Comparing with the various options available for the synthesis of wounds, the proposal of a tissue adhesive or biological glue is an up-and-coming and reproducible alternative. Adding easy application, low toxicity, and good tensile strength, biological adhesives today represent a difficult possibility to be overcome. However, the cost can still be a major obstacle for its use in more remote regions and less purchasing power. Another limiting factor is the limited validity of the product, which can be compared with the option presented here that does not present a limited use (Bruns & Worthington, 2000).

It is noteworthy that the proposal suggested here did not pass a traction and resistance test, as highlighted by Horeman et al. (2013), because it is an experiment carried out on artificial skin. In the literature, these tests are carried out in the post-healing of tissues after the sacrifice of guinea pigs; therefore, they cannot be performed on artificial skin. Thus, the authors suggest that further improvements be made so that the prototype presented here can be used in compliance with all requirements in an appropriate manner. Reducing the size of the parts and, consequently, the amount of material may lower the manufacturing cost and risk of infection due to waste accumulation. Improvements such as the incorporation of drugs that are designed to reduce the risk of infection, shortening the healing time, and absorbing

exudation from the wound may represent a greater added value to the proposal, as already observed in studies by Padula et al. (2007), Shukla, Fuller and Hammond (2011) and Chen et al. (2012).

4. Final Considerations

The inventive process resulted in creating a new proposal for the affixing of superficial blunt wounds using magnetism. The prototyping of the system exposed here is far from being used in daily surgical practice. However, it opens a new perspective for developing new systems and devices that can use magnetism in wound healing.

In future works, the authors suggest searching for more suitable materials that can be used without causing allergies or increased risk of infection but without losing the ability to stabilize the skin lesion's edges with as little material as possible. This proposal envisages an alternative in which the need for local anesthesia for minor injuries is dispensed with, especially in locations that do not have available medical assistance.

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Percentage of contribution of each author in the manuscript

Gleyse Karina Lopes de Oliveira Pinheiro – 40%

André Lima Batista – 10%

Ricardo Ney Cobucci – 10%

Amália Cinthia Meneses Rêgo – 10%

Irami Araújo Filho – 10%

Fausto Pierdoná Guzen – 10%

Francisco Irochima Pinheiro – 10%