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A Novel Tourniquet with an Alarm System, Replaceable Components, and The Ability to Adjust Pressure and Detect Body Temperature for Medical Applications

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ABSTRACT A tourniquet is a practical device in the medical field that is employed to collect blood and prevent bleeding in medical centers. The need for a durable tourniquet with leveled pressure adjustment capabilities, which indicates the time, can be used for both blood collection and control of intense bleeding, and has replaceable components in case of damage is strongly felt. Thus, developing a tourniquet with the aforementioned features is highly beneficial. The designed tourniquet includes four main parts (end hook, strap, main clip, and pin), and the other three parts are mounted on the strap. This tourniquet has a unique strap design and a sturdy lock and fastener, a body temperature detection sensor, a pressure adjustment section at four levels, a timer with an alarm, buttons (pins) to open the strap, a linen pad, and a special end hook (with an end clamp). The proposed time warning tourniquet with replaceable components can adjust the pressure, detect the temperature, and create local pressure, and therefore, can boost the performance of the medical staff during blood sampling and bleeding control procedures.

INDEX TERMS Tourniquet, Temperature, Alarm, Bleeding, Blood Pressure.

I. INTRODUCTION

The origins of the tourniquet can be traced back to ancient times, particularly the Neolithic period, coinciding with the earliest instances of limb amputation procedures. Throughout its evolution, the tourniquet has seen diverse applications, notably in wartime settings. Over time, modifications have predominantly centered on alterations in structure and materials, while its core functionality and intended purpose have remained unchanged up to the present era [1]. In medical centers, such as diagnostic laboratories and hospitals, an instrument known as a tourniquet is used to collect blood and prevent bleeding. The type of instrument that is used for blood collection enables the medical staff to more accurately locate the veins and arteries of the hands and feet. The tourniquet that is used to prevent bleeding has a very strong cuff and more durable clamps, and the medical staff uses this type of tourniquet for bleeding patients and to prevent severe bleeding during surgeries such as arthroplasty and knee replacement. Although there are two types of tourniquets in terms of application, which have similar general structures, any type of tourniquet can be utilized for either application when necessary [1–3].

The existing tourniquets are each assigned to one of the applications of blood collection or prevention of bleeding, and the lack of a tourniquet that is applied in both fields is felt. Moreover, most of the existing devices have a simple plastic locking and fastening mechanism, adhesive elastic, or clips that lose their functionality after several uses, rendering the tourniquet ineffective. Additionally, in most types of tourniquets, it is not possible to adjust the pressure in a precise and leveled manner, which is crucial in surgeries. In the production of tourniquets, either an inflatable cuff or a strap is used, which both have certain disadvantages; for example, the type with an inflatable cuff has lower carrying capacities [4]. The utilization of this apparatus is associated with potential complications. These include possible harm to limb tissues, encompassing skin, muscles, blood vessels, and nerves. Additionally, a pertinent complication linked to its usage is the potential hazard of cross-contamination due to tourniquet exposure. Several investigations have indicated that these devices can harbor an array of potentially harmful bacteria. The subsequent and shared use of a tourniquet on multiple patients escalates the risk of healthcare-associated infections, which can transfer from one patient to another through the hands of healthcare practitioners. Infections stemming from care represent a substantial peril to patient well-being, leading to heightened morbidity, mortality, prolonged hospitalization, and increased healthcare expenditures [5,6].

Due to the COVID-19 outbreak and the fact that the measurement of body temperature is a fundamental part of the diagnosis of COVID-19 patients, having a tourniquet in laboratories and medical centers that can be used for both blood collection and body temperature detection is essential. Although there are devices such as electronic thermometers that can be used to detect the body temperature of COVID-19 patients, in medical facilities owing to the increase of different patients in the laboratory setting and the lack of initial screening in these settings, the patient's body temperature index can be used to notify the medical staff of the patient's condition [7–9].

Hence, the development of a tourniquet that can be applied for both blood collection and the prevention of bleeding, with a unique and durable locking mechanism, replaceable components, the ability to measure body temperature, the ability to adjust leveled pressure, and a greater ability to produce local pressure is necessary. Therefore, our tourniquet was designed with the aforementioned capabilities.

II. MARITAL AND METHOD

Currently, tourniquets available in the market can be categorized based on the following factors:

a) Form: cylindrical or planar;
b) Composition: latex, nitrile, silicone, Velcro, textile;
c) Stretchability: elastic or adaptable;
d) Closure mechanism: manual, Velcro, clip-on/Snap-on;
e) Application: arterial and venous;
f) Utilization frequency: single-use or reusable [1].

The optimized tourniquet with a timer designed in this study, which has replaceable components as well as the ability to adjust pressure and detect body temperature (FIGURE 1), consists of four main parts: the strap (FIGURE 1, part 1) on which other parts are mounted and has the most critical role in producing pressure, the buckle (FIGURE 2, part 4), the main clamp (FIGURE 3B), and the end hook (FIGURE 3A).

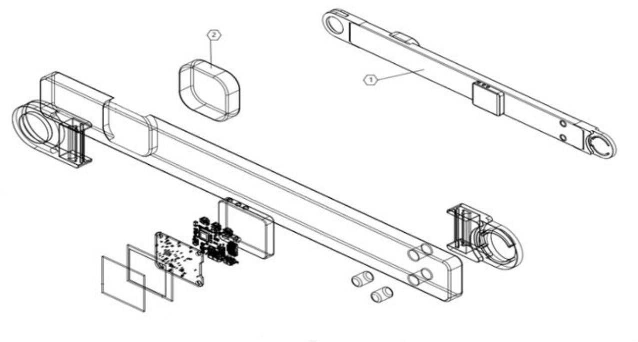

FIGURE 1. The 3D view of the designed device along with the exploded view

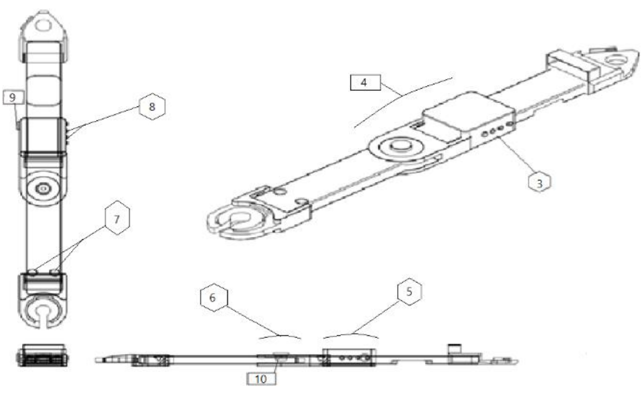

FIGURE 2. The 3D structure with three main viewpoints (front, side, top)

Using its flexible and elastic band, the tourniquet is fastened around the radial or femoral arteries in the hand or thigh, and the closing action occurs by locking the main clip inside the lock part of the buckle (FIGURE 2). The buckle has a timer with an alarm, which is located in the display section (FIGURE 2, part 5) and gives the medical staff the ability to control the closing time of the tourniquet. The display screen has four numbers: the two digits on the left side denote the minutes and the two digits on the right side denote the seconds. There are also two buttons in this section, one is the reset button and the other is the mute button (FIGURE 2, part 7). The pressure control and adjustment part (FIGURE 2, part 3) is the most important part of the buckle of the tourniquet, which allows the medical staff to adjust the pressure level according to the age of the patients at four levels. In this section, L indicates the low level, M indicates the middle level, H indicates the high level, and S indicates the severe level. These letters show the pressure level on the display screen (FIGURE 2), and under the display screen, there is a pressure-sensitive sensor (FIGURE 3C) that detects alterations in the pressure level.

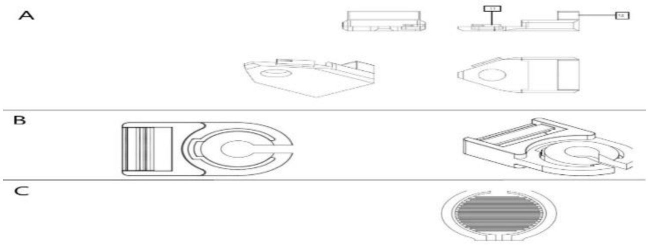

FIGURE 3. (A) End hook, (B) main clip, (C) pressure-sensitive sensor

On the side wall of the mechanical section, there is a button pressure control part (FIGURE 2, part 9) that allows lowering the pressure to the previous level. Moreover, in the buckle section and underneath the control and pressure adjustment section, there is a body temperature detection sensor that is positioned such that it contacts the skin surface while closing. The buckle's lock section (FIGURE 2, part 6) has a pin with varying elastic thicknesses attached to an iron button (Figure 2, part 10). On the strap next to the main clip, there are two plastic or iron buttons (in FIGURE 2, part 7). If the main components, including the buckle, strap, hook, and clip are damaged, they can be replaced by opening the strap.

The end hook (FIGURE 3A) limits the path for the buckle. Moreover, this part features an end spike (FIGURE 3A, part 11) that connects the hook to a portion of the strap when the tourniquet is folded. There is also a clamp located next to this hook (FIGURE 3A, Part 12), which allows the tourniquet to control external bleeding. During external bleeding, the strap should be placed above the bleeding area and the main clip should pass through the end clip close to the hook. Then the clip must be inserted into the lock in the buckle to secure it. Additionally, a linen pad (FIGURE 1, part 2) is placed on the strap, which is put on the cotton after blood collection, in order to lessen the risk of venous thrombosis and trauma, or it is placed on the bleeding site during bleeding.

III. RESULT and DISCUSSION

For numerous centuries, surgeons have utilized tourniquets to create a bloodless surgical environment during extremity surgeries. The primary purpose of employing a tourniquet is to minimize blood loss and enhance visibility within the surgical area. The decision to utilize a tourniquet is influenced by various factors such as the technical intricacies of the procedure, the location and duration of the surgical intervention, and the anticipated amount of blood loss. Attempts to reduce blood loss through pharmacological or alternative means (e.g., tranexamic acid, controlled hypotensive anesthesia, intraoperative blood salvage) may impact this decision. However, in all cases, the advantages of using a tourniquet must be carefully considered about the associated risks. The adverse effects of prolonged tourniquet application are well documented. Numerous published guidelines and anecdotal suggestions exist concerning appropriate pressure, design, duration of inflation, and the permissible amount of reinflation for a given patient during a single surgical session. The heightened focus on healthcare quality and cost management has led to the establishment of standardized practice protocols, encompassing guidelines for the proper use of tourniquets [10].

Our tourniquet features a robust and durable lock with a unique mechanism, which is not observed in most of the previous devices. With this mechanism, the possibility of the lock breaking is lowered, thereby preventing untimely openings during blood collection and bleeding control.

In diagnostic laboratories and other medical centers where blood collection is carried out, since the duration of tourniquet usage affects the results of biochemical tests, e.g., in the prolactin test, which is an important hormone in men and women, the absence of a mechanism that indicates time is a disadvantage of the available tourniquets. This hormone is crucial for women during puberty, pregnancy, and breastfeeding. The level of this hormone in men is 3–13 ng/mL in normal conditions, while in women who are not pregnant, this level is 3–27 ng/mL in normal conditions and 20–400 ng/mL during pregnancy. Due to the pulsating nature of this hormone, the presence of physiological stimuli for its release, and its half-life of 26 to 47 min, it is recommended to take three samples in the lab at intervals of 20 to 30 min. This hormone is highly sensitive to environmental stressors, and therefore, excessive pressure on the veins and arteries causes the body to experience tension and stress, as a result of which the concentration of this hormone in the blood increases by 88% in men and 86% in women compared to baseline. In such cases, hyperprolactinemia might be diagnosed by mistake, even though this increase is only due to temporary stress at that time. Although frequent stress and the resulting pressure in high-risk jobs can be one of the causes of hyperprolactinemia, the most common cause is macroprolactinemia, especially in women. In the tests conducted, about 55% of patients with hyperprolactinemia had macroprolactinemia [11–13].

By utilizing a warning display with a timer, the time to fasten the tourniquet can be controlled during blood sampling, which reduces inaccuracies in the results of biochemical and hormone assays. It also helps the medical staff to take into account the duration of bleeding while carrying a bleeding patient, which is a feature not offered by other tourniquets. According to medical references, the tourniquet should not be fastened at the site of blood collection for longer than one minute during the blood collection procedure because it causes hemolysis of blood cells and alteration in biochemical factors at that site, thus causing false results in laboratory tests [14]. In tourniquets that can be used for blood collection, the band is so elastic and soft that it snaps under maximum tension and excessive use. Moreover, in tourniquets that are employed to prevent bleeding, strong and flexible bands with low elasticity are used. Unlike other tourniquets, this tourniquet can be used for both blood collection and bleeding control due to the presence of the end clamp as well as the strong flexible band. The ability to be multi-functional is crucial in medical equipment, and one of the criteria for product selection in some medical fields is their multi-functionality [15].

Research indicates a shift towards utilizing reusable tourniquets constructed from diverse materials, primarily rubber, but also encompassing plastic and fabric. Notably, in Georgiana's study, none of the participants in the study reported the utilization of single-use tourniquets in their clinical practice, although this could present a viable solution. This is particularly relevant in numerous settings where reusable tourniquets are consecutively applied to a large number of individuals, aligning with the findings of Costa. Opting for single-use tourniquets would mitigate the issue of medical device sharing, a practice often observed among students in their care-related activities, who frequently overlook the necessity of sanitizing the tourniquets between uses. The data analysis suggests that healthcare professionals acknowledge the potential infectious risks associated with tourniquets. However, this awareness does not consistently translate into the systematic adoption of preventive hygiene and health practices, which are imperative for all healthcare practitioners. Less than one-fifth of the surveyed individuals consistently clean their tourniquets following a procedure, and an equivalent proportion reported never cleaning or disinfecting the tourniquets after use. The majority of the sample indicated sporadic cleaning or disinfection of the tourniquet post-use, rendering this practice largely ineffective [6,16,17].

The unique design of the strap as well as the two buttons on the strap allows the replacement of damaged main components, while other devices become unusable when one of the main components is damaged. In addition, another criterion for choosing medical equipment is their repairability, which is more common in semi-consumable equipment and devices.

This tourniquet, unlike other tourniquets, has a unique pressure control and regulation section, which can be important in blood collection and bleeding control by adjusting the pressure in four levels. The ability to adjust the pressure at four levels can be useful in laboratory tests that are sensitive to environmental stress, such as pressure; for example, the prolactin hormone test is sensitive to stress, pressure, and environmental stress and excessive local pressure during sampling can result in false test results [18]. The linen pad also offers the possibility of adequate local pressure during bleeding control and after blood collection, which was not available in other tourniquets.

In tourniquets, the cuffs are found in various forms, or they are in the form of ventilated cuffs that function as pressure gauge devices. These cuffs work using a manual or electronic pump or are made of a (fabric, plastic, or leather) strap. In this tourniquet, due to the importance of controlling the pressure at four different levels, a fabric strap is used, which is not only easy to use and carry but also more affordable and easier to replace in case of damage. Another issue with inflatable cuffs is that if they are not in the correct size, they are difficult to fasten in obese individuals, and therefore, they cannot serve their function effectively [19].

The introduction of novel tourniquets has sparked discussions regarding the safety and effectiveness of various tourniquet types. These deliberations primarily focus on the impact of tourniquet width on the pressure needed to achieve a bloodless surgical field and the development of soft-tissue injuries. Ochoa and colleagues conducted a study using a baboon model, revealing nerve damage directly beneath the cuff. They proposed that this damage is a result of the pressure gradient at the cuff's edge. While the width of the tourniquet itself wasn't investigated, the notion that using a narrower cuff could potentially reduce nerve damage has, in part, supported the recent design of a narrow no pneumatic silicone ring tourniquet. In a recent research endeavor, it was observed that the median nerve conduction was more significantly impacted with a 14-cm tourniquet compared to a 7-cm tourniquet after 15 minutes of inflation. However, nerve conduction normalized within 30 minutes after deflation for both tourniquet sizes. Some studies have proposed that a wider cuff might be safer, as it permits blood flow occlusion at a lower pressure. Nevertheless, no studies have demonstrated clinical advantages concerning neurological alterations or functional outcomes associated with a specific tourniquet design [10,20–23].

This tourniquet features an infrared sensor to measure the body temperature, which comes into contact with the skin by closing the tourniquet around the hand. This sensor can help the medical staff, particularly the laboratory technicians, in identifying individuals suspected of having COVID-19 [7,8]. In certain strains of the coronavirus, detection of body temperature is important for the initial screening of patients, and thus, at the beginning of the pandemic, infrared temperature detection devices were one of the most crucial tools [24].

Various systems are accessible for temperature screenings, with the widely utilized ones being contactless infrared cameras and point thermometers. These systems gauge the infrared radiation emitted by diverse bodies. Infrared cameras utilize an array of thermal detectors to construct a 2D temperature map. Conversely, contactless infrared point thermometers employ a singular thermal detector per device and provide a singular temperature value as output. Any physical body with a temperature exceeding absolute zero (i.e., –273.15 °C; 0 Kelvin) emits electromagnetic radiation that is proportionate to its intrinsic body temperature. Infrared radiation constitutes a component of this intrinsic temperature.

Technically, infrared radiation encompasses a section of the complete electromagnetic spectrum, commencing in the visible range at approximately 0.78 μm and concluding at wavelengths of about 1 mm. Typically, thermal detectors are broadband, encompassing the collection of all infrared radiation from the source. However, the wavelengths within the range of 3 to 14 μm are conventionally utilized for body temperature measurements. Recently, Chen and colleagues elucidated the mathematical principles behind measuring body temperature using a contactless infrared point thermometer. In essence, infrared radiation emanates from the body's surface and traverses the atmosphere. Employing a lens (referred to as input optics), the radiation beam is focused onto a detector, which produces an electrical signal commensurate with the input radiation. This phenomenon enables contactless infrared point thermometers to be frequently employed for swift, non-destructive, non-interactive, and non-intrusive body temperature measurements. Typically, contactless infrared point thermometers comprise a lens, a detector, a signal amplifier, digital signal processing components, and a display. The current market offers a wide array of contactless infrared point thermometers, often referred to as infrared contactless thermal guns. Most commonly, the relevant datasheets indicate an accuracy of approximately 2 °C within the range of 36–39 °C. Moreover, these devices can measure body temperature at different anatomical sites [25–32].

IV. CONCLUSION

In summary, it is concluded that this tourniquet can be used for both blood collection and bleeding control, and this dual functionality, which has been created by increasing the quality of the strap, clamps, and hook, has decreased costs and improved the performance of this device. Moreover, due to its strong and durable lock and its ability to adjust the pressure at four levels, this tourniquet is suitable for different individuals and varying situations. In addition, the timer and the linen local pad promote efficiency and minimize human errors, and most importantly, the replaceability of the components in this tourniquet makes it possible to use the device again even if the parts are damaged.

APPENDIX

None.

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None.

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I am Shadi Shafaghi, MD, MPH and PhD in the field of biotechnology. After graduating in medicine from Shahid Beheshti University of medical sciences in 2005, I continued my professional research activity by studying PhD by research. As my PhD thesis, I established a new method of lung transplantation as named Ex-vivo lung perfusion (EVLP) for the first time in the Middle East. I am active in various research projects, from design to implementation, data analysis, writing the various research projects and articles. I am familiar with statistical soft wares including SPSS, STATA. Also, I have good knowledge for systematic review and meta-analysis, randomized controlled trial, modern version of case control study (case cohort and nested case control), and cross-sectional study. Moreover, I teach many courses for medical students and researchers in regard of advanced scientific article writing.
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I'm Fariba Ghorbani, MD, PHD in the field of tissue engineering. I've been working as a director of researche and development in organ procuremegt unit in the reseach institute of Tuberculosis and lung diseases. I am interested in the both basic science and clinical researches and have conducted many studies regarding organ donation, transplantation, innovation, tissue engineering and pulmonary diseases.
I've some experiences to make people more innovative and I've had many training courses to improve student's ability for generation different ideas.
I am expert in conducting a systematic review process and clinical trials and also I am active in providing training courses of the research including methodology, statistics, scientific writing, advance search, reference management tools and peer review.

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Masoud Shafaghi, Strategic Planning and Executive Office Manager at International Federation of Inventors Association- IFIA Office in Geneva- Switzerland, holding the position of Strategic Planning and Coordination Manager at International Federation of Inventors' Association- IFIA for more than six years.
IFIA is a global organization founded in 1968 in Geneva, Switzerland, having more than 100 organizations and countries participating in this NGO. Masoud has been awarded honorary diplomas from Germany, Kuwait, Switzerland, Croatia, Romania, Russia, and Belgium since 2008. He has also won awards and medals at many top world competitions and exhibitions worldwide, including Germany, Belgium, Russia, Malaysia, South Korea, International Federation of Inventors Association - IFIA, Iran, Malaysia, Czech Republic, Romania, Croatia, West Asia.
Masoud has published many articles about his inventions and research in various journals around the world.
He is currently a consultant on personal branding, marketing, and trade. In addition to lecturing at the TED talk series, he was also invited to speak at several world-renowned universities in Canada. Masoud has served as a mental advisor to many inventions operating both in their own countries and internationally that they have done a lot to achieve international success today.
He is a highly-skilled international speaker who raises awareness among the audience in several areas such as inventions, personal branding, strategic management, entrepreneurship, sustainable integration of people with disabilities.
Masoud is also coaching many exceptional innovators around the world.