Original Article

Stop bleeding armband for venipuncture at antecubital fossa for blood donor

Supaporn Maneewan[1], Wilaivan Nachatree[1], Pimpilalai Choothanorm[1], Suparat Burananayok[1], Chaninporn Yodsawad[1], Praopim Limsakul[2] and Krit Charupanit[3]

[1]Blood Bank and Transfusion Medicine Unit, Department of Pathology, Faculty of Medicine; [2]Division of Physical Science, Faculty of Science; [3]Department of Biomedical Sciences and Biomedical Engineering, Faculty of Medicine, Prince of Songkla University

Abstract:

Introduction: *Blood donation is a common and important practice to provide blood for the saving of lives in medicine. Although several measures have been used to ensure the safety of both blood donors and recipients, there is still a small proportion of blood donors encountering unwanted post-donation complications, including, delayed bleeding, bruising, and hematomas. One of the causes for these unwanted complications is due to an incomplete or incorrect stop bleeding procedure.* ***Objective:*** *To reduce the possibility of complications, we designed equipment that produces an appropriate force to prevent bleeding of the venipuncture at the antecubital fossa from blood donations in the form of an adjustable armband.* ***Materials and Methods:*** *The armband was designed using the actual pressing force for stop bleeding of the venipuncture from a group of 63 experienced donors and evaluated the reliability with 424 practices in real practices.* ***Results:*** *The armband creates 1.6 N/cm^2, which was measured from experienced donors. The armband is adjustable for different arm sizes, providing an appropriate generated force. Use of proper force can reduce the chances of adverse complications to 1.2% comparing to the prior study of the conventional stop bleeding method at 3.4%. Surprisingly, the armband can prevent all cases of delayed bleeding (0.8% found in the conventional stop bleeding method). In addition, the average deterioration of the armband was 1.6%, after 250 times of usage in real practice.* ***Conclusion****: The stop bleeding armband is effective in preventing bleeding of a venipuncture from the blood donation process, and it can reduce the number of occurred complications by generating an appropriate force.*

Keywords : ● *Bleeding prevention* ● *Blood donations* ● *Blood donation complications* ● *Venipuncture*

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Correspondence should be addressed to Krit Charupanit, Affiliation: Department of Biomedical Sciences and Biomedical Engineering, Faculty of Medicine, Prince of Songkla University, Hat Yai, Songkhla, 90110, E-mail: krit.ch@psu.ac.th

นิพนธ์ต้นฉบับ

สายรัดกดห้ามเลือดจากการเจาะหลอดเลือดดำบริเวณข้อพับแขนสำหรับผู้บริจาคโลหิต

สุภาภรณ์ มานีวัน[1] วิไลวรรณ นะชาตรี[1] พิมภิลาลัย ชูถนอม[1] ศุภรัตน์ บูรณะนายก[1] ชนินพร ยอดสวัสดิ์[1]
เพราพิมพ์ ลิ่มสกุล[2] และ กฤต จารุพานิช[3]

[1]คลังเลือดและเวชศาสตร์บริการโลหิต ภาควิชาพยาธิวิทยา คณะแพทยศาสตร์ [2]สาขาวิทยาศาสตร์กายภาพ คณะวิทยาศาสตร์ [3]สาขาชีวเวชศาสตร์และวิศวกรรมชีวการแพทย์ คณะแพทยศาสตร์ มหาวิทยาลัยสงขลานครินทร์

บทคัดย่อ

บทนำ *แม้ว่าการบริจาคเลือดจะมีหลายกระบวนการที่สำคัญเพื่อความปลอดภัยของผู้บริจาคโลหิตและผู้รับโลหิต แต่ก็ยังมีเหตุการณ์ไม่พึงประสงค์เกิดขึ้นกับผู้บริจาคโลหิต เช่น รอยฟกช้ำ หรือ เลือดไหลหยุดช้า ซึ่งหนึ่งในสาเหตุคือการหยุดเลือดที่ไม่สมบูรณ์ หรือไม่เหมาะสม* ***วัตถุประสงค์*** *เพื่อลดการเกิดเหตุการณ์เหล่านี้ จึงมีการออกแบบสายรัดห้ามเลือดให้สายรัดสามารถปรับเปลี่ยนความยาวได้และสร้างแรงกดที่เหมาะสมในการกดห้ามเลือดในแผลที่เกิดจากการเจาะเลือด* ***วัสดุและวิธีการ*** *สายรัดถูกออกแบบให้สร้างแรงกดได้ใกล้เคียงกับแรงกดเฉลี่ยที่วัดมาจากผู้บริจาคเลือดจำนวน 63 คน จากนั้นสายรัดได้ทดสอบในการใช้งานจริงจำนวน 424 ครั้ง* ***ผลการศึกษา*** *สายรัดห้ามเลือดถูกออกแบบให้สามารถสร้างแรงกดที่ 1.6 N/cm^2 (ค่าที่วัดจากผู้บริจาคเลือด) โดยสายรัดสามารถปรับเปลี่ยนความยาวเพื่อสร้างแรงกดให้คงที่และสอดคล้องกับผู้ใช้ที่มีขนาดเส้นรอบวงแขนแตกต่างกัน ทั้งนี้การหยุดเลือดด้วยแรงกดที่เหมาะสมสามารถลดการเกิดเหตุการณ์ที่ไม่พึงประสงค์ได้ ในสถานการณ์จริงที่ใช้สายรัดห้ามเลือด มีผู้บริจาคโลหิตร้อยละ 1.2 ที่เกิดรอยช้ำและไม่พบอาการที่เลือดไหลหยุดช้า ซึ่งพบร้อยละ 3.4 และ 0.8 ตามลำดับในการศึกษาก่อนหน้า จากการทดสอบความทนทานของสายรัดหลังการใช้งาน 250 ครั้ง พบว่าสายรัดเกิดการยืดถาวรร้อยละ 1.6 ของความยาวสายรัด* ***สรุป*** *สายรัดห้ามเลือดที่ถูกออกแบบให้มีแรงกดที่เหมาะสมสามารถห้ามเลือดจากการบริจาคเลือดได้อย่างมีประสิทธิภาพ และลดการเกิดเหตุการณ์ไม่พึงประสงค์ได้*

คำสำคัญ : ● *การหยุดเลือด* ● *การบริจาคโลหิต* ● *การเกิดภาวะไม่พึงประสงค์จากการบริจาคโลหิต* ● *การเจาะหลอดเลือดดำ*

วารสารโลหิตวิทยาและเวชศาสตร์บริการโลหิต. 2565;32:111-9.

Introduction

Blood is a vital component of the human body that plays a crucial role in maintaining homeostasis and regulating the body's systems. Currently, there is no substitute for real blood replacement; hence, human blood donations remain the most important resupply resource for preserving life. The process of blood donation starts with screening including blood testing, filling in a questionnaire, and oral interviews to ensure the safety of both donors and blood. The most common type of blood donation is in the form of whole blood, using a large needle (16-18 gauge) to puncture, and draw the blood from the vein at the antecubital fossa.[1] Usually, approximately 350-450 mL of blood is collected from volunteers, which takes around 10 to 15 minutes for the donation procedure. Apheresis for plasma and platelets donation is less frequently used, as it requires an apheresis system.[2] This process draws blood from the donor's body and separates various components; such as, plasma, platelets, white blood cells and red blood cells. Depending on the reason for apheresis, one of these components is isolated and collected by the instrument. After this, the remaining components will be returned to the donor.

Adverse complications related to common blood donations are generally local symptoms (including hematoma, arterial puncture, delayed bleeding, and localized infection) and generalized symptoms (e.g., loss of consciousness), whereas those related to apheresis include; air embolisms, citrate reactions, allergy and others.[3] At Blood Bank and Transfusion Medicine Unit, Songklanagarind Hospital, Faculty of Medicine, Prince of Songkla University, approximately 23,000 whole blood donations and 1,000 platelet donations are undertaken each year. In a recent study of 3,194 donors,[4] there were 0.8% of donors encountering unwanted delayed bleeding and more than 3.4% local adverse effects of bruising and hematomas in the post donation recovery period. However, these values are varied between studies (0.4-3.4%), wherein, whole blood donations tend to have a higher chance of adverse complications occurring.[5-11] The sources of adverse complications occurred from an ineffective stop bleeding process, violating the control bleeding suggestion, donor fainting, improper pressing force on the venipuncture, and so forth.[12] In apheresis, some cases happened due to hyperhydration of the donor from receiving 300-500 mL of saline through the platelet extraction machine during the donation causing the urgency of donor urination. Therefore, during or immediately after the donation process ended, the donors' sudden movements, or an incomplete preventive bleeding procedure leading to undesirable bleeding through venipuncture. Although these complications are non-fatal, they increase the workload of staff, waste resources, cause dissatisfaction with donors, and carry the risk of infection; thereby, reducing the likelihood of any subsequent donation.[4,13]

Bandages and tourniquets are the two most common tools to control bleeding; however, they are unsuitable for venipuncture from blood donations. This is because bandage is too weak against blood pressure, and a tourniquet is designed for the stoppage of bleeding in an emergency, which can later leave both marks and bruises. Although there is also a strap for stop bleeding available, it is costly and, mostly, for one-time-use. Currently, there is no cost-effective stop bleeding tool available in the marketplace; therefore, an effective control bleeding tool is necessary.

For this reason, we designed this stop bleeding equipment for venipuncture at the antecubital fossa from blood donations as an adjustable armband to effectively stop bleeding and to reduce the possibility of complications in practice. The armband was designed to generate the proper pressing force to stop bleeding, which was measured from a group of experienced donors. Furthermore, the band length was adjustable to ensure suitable force for different arm circumferences. The armband was designed to prevent delayed bleeding of venipuncture received from the blood donation process, to minimize other complications due to improper applied force, and to reduce the workload of the medical staff.

Materials and Methods

Subject selection

At Blood Bank and Transfusion Medicine Unit, Songklanagarind Hospital, two voluntary groups were recruited between January and September 2021. In the first group, the information from 63 experienced blood donors (34 males and 29 females), who had completed blood donations at least twice without any complications, were utilized for designing and fine tuning of the armband. The collected variables consisted of the arm circumferences at the antecubital fossa, donor body weight, and stop bleeding force by imitating the stop bleeding process without actual skin puncturing. The second voluntary group was for evaluating the performance of the armband in practice, which involved 140 blood donors (98 males and 42 females). Note that, several participants repeated the blood donation more than once over the data collection period; therefore, in total, the armband was tested 424 times (317 and 107 times from males and females, respectively). All subjects gave consent to participate in this study, and the study was approved by the local ethics committee.

Measuring the pressing force

The actual force required to control bleeding was essential information for the armband design. The force was measured using Interlink Electronics Force Sensitive Resistor (FSR) model 402, which converted the pressed force against the sensor active area to the electrical resistance. To measure the force, first, we determined the force-resistance relationship of each individual FSR, by the All-Electric Dynamic system (ElectroPuls E1000). The regression of force-resistance relationship followed the exponential model. The force was then converted to pressure, force per area of the active surface of the FSR sensor (N/cm^2), using the predetermined force-resistance relationship. However, to avoid any confusion later on, we referred to pressure as being force.

The stop bleeding force was measured by the donor imitating the post-donation stop bleeding procedure without any puncturing of the skin. The procedure can be summarized as placing the gauze on top of the skin at the antecubital fossa with the FSR on top of the gauze. After this, the subject was asked to press the active area of the FSR using their index finger or thumb for 5 seconds, which is the force generally used to prevent bleeding. The recording process was repeated three times for each individual. During the whole procedure, the resistance was continuously recorded, and the median value was used as the representative resistance for further analysis.

Armband design and materials

The armband is intended to be wrapped around the arm of the donor at the antecubital fossa, and to generate the appropriate pressing force against the venipuncture to prevent bleeding. The armband is designed to have two pads attached to the elastic fabric band, which act as the backbone of the armband: one pad is a small cushioning pillow, and the other is a small silicone pad with a short-protruding cylinder (Figure 1). The cushion (12.0x9.0x2.5 cm^3) is made of polyurethane filled with synthetic fibers, which is positioned at the middle of the elastic band to support the elbow of the user. The smaller silicone pad is to directly transfer the generated force to the gauze placed upon the wound (Figure 1). The silicone pad size is 4.5x4.0x1.0 cm^3, and the protruding cylinder part is 2.5 and 0.5 cm in diameter and height, respectively. The surface of the protruding part is concaved, for retaining the gauze above the venipuncture. Both ends of the elastic fabric (50.0x3.75 cm^2 with 1.2 mm thickness) are stitched with Velcro (15.0x1.5 cm^2), which is used to connect the ends of the armband together.

As the armband will be used in medical related services, safety has been prioritized. Hence, the skin-contacting materials were carefully selected to avoid any skin allergies of the user. The components that contact

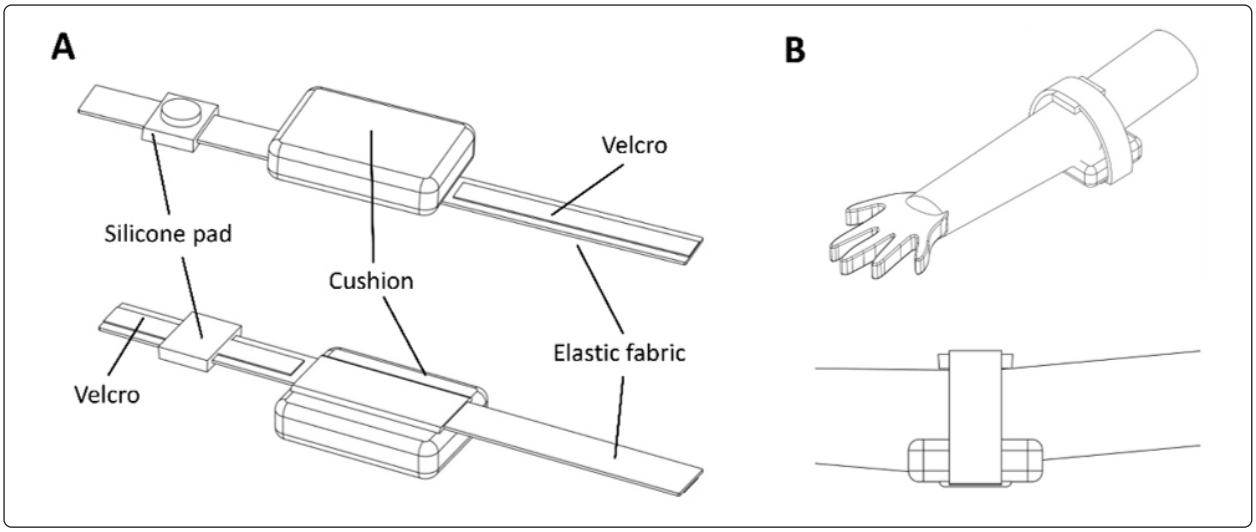

Figure 1 A) Sketch of the armband and components, and B) armband usage wrapping around the arm at the antecubital fossa

the skin are only the elastic band and the cushioning pillow (the molded silicone pad is pressed against the gauze, not the skin). The designated elastic band is made of 70% polyester and 30% rubber knit elastic fabric, as used in the clothing industry. The cushion case is made of polyurethane (synthetic leather), found in daily life accessories and furniture. Both are everyday materials; therefore, the chance of causing an allergic reaction is low.

The main functions of the armband are to hold to the gauze and generate a proper force, preventing the bleeding of venipuncture in additional to reduce the possibility of any adverse events. The generated force is controlled by the armband tightening, which directly relates to the band length and arm circumference of the donor. Therefore, the proportion of the band length to the arm size is a crucial factor to ensure adequate pressing force for individuals. However, in practice, measuring the arm circumference of every donor would increase the work burden of medical staff. We hypothesized that body weight is proportional to arm circumference. Thereby, instead of determining the band length based on arm circumference, the donor's body weight was used instead as it is mandatory information in the blood donation screening procedure.[2] To validate this statement, we studied the relationship between both variables from the first subject group, using a measuring tape and digital scale to record arm circumference at the antecubital fossa, and the body weight of the donor, respectively.

To determine the proper band length, it is crucial to evaluate the influence of how the tightening armband affects the generated force; therefore, the relationship between the tightening band length and generated force was studied. We varied the band length for different arm circumferences, and recorded the generated force according to band length of approximately 5-20% shorter than the arm circumference at 24, 26, and 28 cm. The procedure was then repeated as the stop bleeding except for puncturing the skin. Then, the band length was adjusted to four to five different lengths to investigate the effect of tightening the arm band to the generated force. Three armband prototypes were tested, with three repetitions for each condition. On the band of the final product, the appropriate band length for different arm circumferences has been labeled.

Prevent bleeding procedure

The procedure starts after the blood donation, once the medical staff have removed the needle, and the gauze is taped on top of the venipuncture site with adhesive tape. Concurrently, the armband is wrapped around the arm at the antecubital fossa with the silicone pad positioned on top of the taped gauze. The length of the armband is then adjusted to the pre-determined

length (S, M, or L) according to the body weight of the donor, which was recorded in the screening process. The armband is wrapped until the bleeding stops, or approximately 10-15 minutes before being removed.

Armband performance evaluation

The armband performance was determined by the successful rate of the armband in preventing adverse complications. There were two stages of evaluations: primary complications (within 15-20 minutes after blood donation has finished) and delayed complications (within 48 hours after blood donation). Any complications occurring, either in the primary or secondary time frames, were considered as armband failure. The performance was reported in terms of failure rate, which was defined as the percentage of complications found.

Deterioration of the armband

The main component of the armband is made of elastic fabric; therefore, deterioration is unavoidable. To evaluate this, the elongation of the band length after 100, 150, 200 and 250 times of normal usage were measured. Three prototypes were employed to estimate the deterioration rate.

Results

Donor pressing force

The actual force to prevent the venipuncture from bleeding was not directly measured. We only gathered the practical pressing forces used from the experienced donors. The collected forces varied among the subjects, especially males (Table 1 and Figure 2). Here, the

Table 1 Pressing force, arm circumference, and body weight of 63 experienced donors used for designing armband (IQR: interquartile range, S.D.: standard deviation)

	Male		Female		Overall	
	Median (IQR)	Mean (S.D.)	Median (IQR)	Mean (S.D.)	Median (IQR)	Mean (S.D.)
Pressing force (N/cm^2)	1.48 (1.33)	2.01 (1.60)	1.62 (1.00)	1.69 (0.72)	1.51 (1.21)	1.86 (1.27)
Arm circumference (cm)	27.0 (3.5)	27.2 (2.5)	23.0 (2.1)	23.4 (2.5)	25.5 (4.7)	25.4 (3.1)
Body weight (kg)	72.0 (22.0)	76.3 (16.8)	54.0 (11.0)	57.4 (12.9)	64.0 (22.8)	67.3 (17.7)

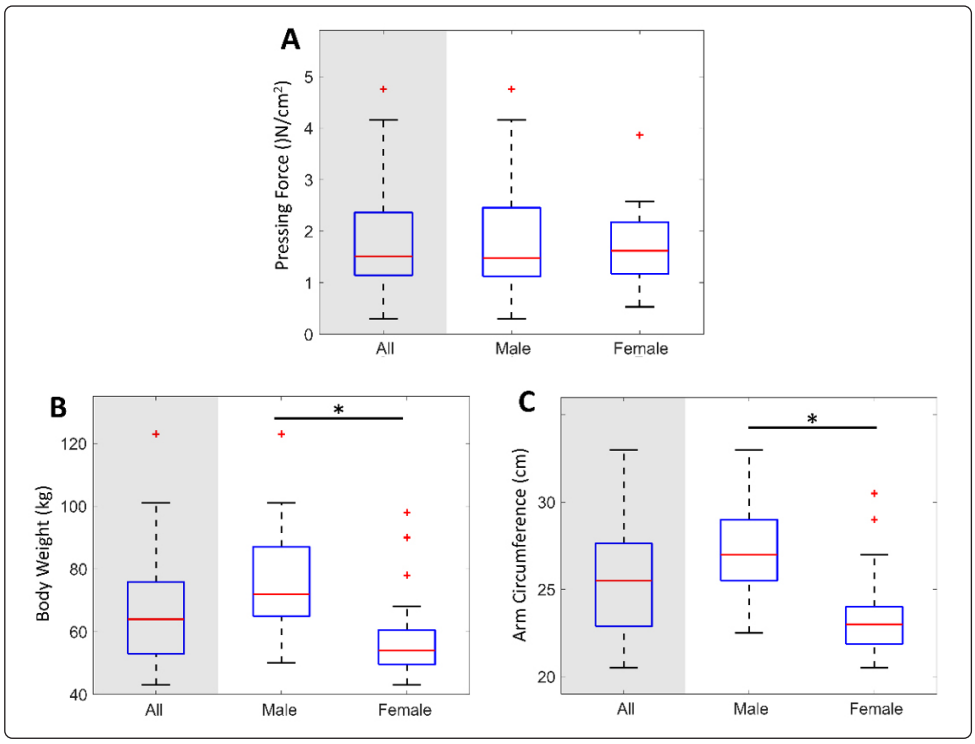

Figure 2 Boxplots of A) pressing force, B) body weight and C) arm circumference of 63 experienced donors. All features are shown separately, for all males and females. *p-value < 0.001, Wilcoxon rank sum test between male and female donors

median was 1.48 N/cm^2 (IQR 1.33 N/cm^2) and 1.62 N/cm^2 (IQR 1.00 N/cm^2), for males and females, respectively. Therefore, we employed a force of 1.6 N/cm^2 as the standard force for designing the armband.

Relation of arm circumference and weight

We hypothesized that the weight of the donor is proportional to the arm circumference. Although, the measured arm circumference and the body weight of males was significantly higher than that of females (27.0 cm and 23.0 cm - 72.0 kg and 54.0 kg; Table 1 and Figure 2), we found the same trend of linearly relationship between arm circumference and weight of the volunteers for both genders (Figure 3). A linear regression equation was calculated to predict the relationship of arm circumference and body weight (arm circumference = 0.1575 x (weight) + 14.804, R^2 = 0.802).

Relation of band length and generated force

The arm circumferences of 24, 26, and 28 cm were selected for evaluating the effect of tightening the armband. The increasing force and the percentage of the shortened band length were linearly proportional (Figure 4). The results showed that all three prototypes created similar trends for all arm sizes. To ensure a proper force of at least 1.6 N/cm^2, a band length of at least 7.7% shorter than the arm circumference was the minimum requirement (Figure 4). However, due to the possibility of armband deterioration, and precautions regarding safety, a 10% margin was added to the designated standard force of 1.6 N/cm^2. Finally, a 10% shorter band length was selected (according to the generated force of 1.76 N/cm^2).

The arm circumferences were divided according to the body weight at 60 and 85 kg (this can be converted to arm circumference of 24 and 28 cm). Therefore, the proper band lengths for each arm size ranges are S: < 21.8 cm, M: 21.8-26.2 cm, and L: > 26.2 cm (for body weight < 60, 60-85, and > 85 kg, respectively).

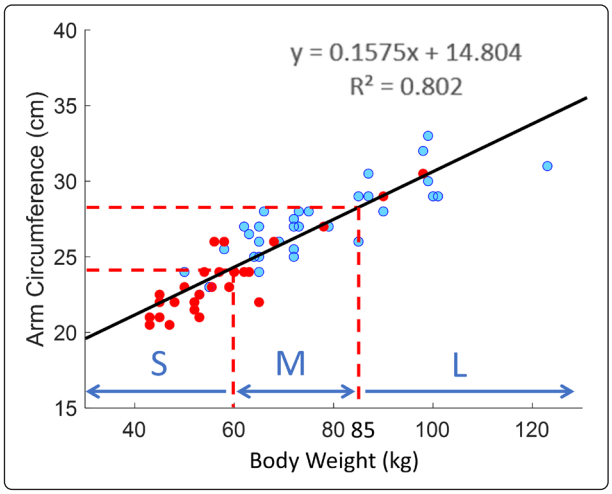

Figure 3 Scatter plot of body weight vs arm circumference of males (blue) and females (red). The arm circumference is divided into three ranges (S: < 24 cm, M: 24-28 cm, and L: > 28 cm); according to the body weight of < 60, 60-85, and > 85 kg. The equation for the regression line is y = 0.01575 x + 14.804

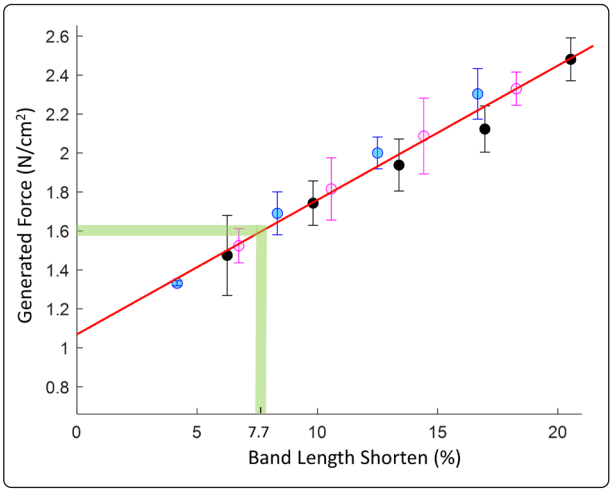

Figure 4 Scatter plot of the percentage of shortened band length, respective to the arm circumferences of 24, 26, and 28 cm versus the average generated force. Three prototypes were tested (blue, black, and pink). All prototypes showed a similar trend, as shown in the red linear line. The green band illustrates the expected standard force of 1.6 N/cm^2 (recorded from 63 experienced blood donors) required to prevent bleeding as used in the armband adjustment

Armband evaluation in practice

The armband was tested 424 times. Five (1.2%) complications were reported (2 males and 3 females) consisting of only bruises. There were no other recorded complications, such as hematoma or delayed bleeding. All bruise cases were delayed complications found within 48 hours after blood donation; without any complications occurring during the period of resting at Blood Bank and Transfusion Medicine Unit. The recorded size of bruises from the donors were all under a centimeter in diameter, which faded after a couple of days without effecting their movement or daily life activity. In addition, we found no relation between the occurred bruise cases and the size of the armband used.

Deterioration of the armband

The armband showed signs of deterioration after extensive use. Using three prototypes, we found that the armband length extended by 0.3±0.2%, 0.6±0.3%, 1.1±0.3%, and 1.6±0.3% compared to the original length after 100, 150, 200, and 250 times, respectively. Although the generated force decreases accordingly, we found that the generated force still exceeds the minimum requirement at 1.6 N/cm^2, without any alteration of the designated band length for different arm circumferences.

Discussion

The armband used to prevent bleeding from venipuncture worked as designed. The reported, undesired complications from using the armband consisted of five cases, which were reported as only bruises. There were no cases of delayed bleeding, hematoma or other complications from its usage. Although, the adverse complication rate of 1.2% was drastically reduced, the rate is within the report range of other studies.[5–11] However, using the armband can reduce the possibility of complications when comparing to the traditional procedures of the previous study (3.4% of bruises and hematomas combined) from Blood Bank and Transfusion Medicine Unit, of Songklanagarind Hospital.[4] This suggests that using the armband could possibly help decrease the chance of complication occurrence with a suitable generated force.

Bruising, also known as ecchymosis, normally happens when capillaries under the skin are damaged, causing bleeding underneath the skin. The definition of a bruise is discoloration, due to the blood being trapped underneath. Although, we consider bruising as an adverse complication, it is unavoidable as the inserted needle may damage a few capillaries leading to the formation of a bruise. Another reason is the inadequate force placed on the venipuncture site after removal of the needle. This allows blood to leak into the surrounding tissues; thereby, causing a bruise in the post-blood donation period. The results from the pressing force measuring showed that most donors tended to exert more force to the wound than required; subsequently, the percentage of undesired bruising is not found to be that high in standard situations.

Prolong and delay bleeding from venipuncture are common complications found in both blood donation and blood collection. Here, our armband was designed to directly tackle these concerns. Apart from improper stop bleeding action, bleeding is caused by several factors, including thrombocytopenia, which is the low platelet count condition, and hemophilia, which is a rare genetic disorder causing impairment of the body to properly make blood clot. Moreover, other factors, such as high blood pressure, taking anticoagulant medicine, state of weakness, and vitamin K deficiency, can affect the coagulation. Fortunately, the screening procedure can filter out the majority of mentioned cases.

Other advantages of the armband over the traditional stop bleeding procedure, apart from complication reduction, are the lessening of the medical staff workload, standardizing the stop bleeding procedure, and allowing the donor to be able to use both hands in such needed cases, such as urination. On the contrary, one drawback is the additional cost, which is inevitable. Although, the armband can be used multiple times, up to more than 250 times according to the deterioration study,

the aforementioned cost comes from the manufacturing cost $10 per prototype for materials and manufacturing, and additional costs incurred from the requirement of cleaning the armband.

Degradation of the materials is also an important concern, as this not only increases of the cost, but also effects the performance of the armband. We found that the armband can be used at least 250 times, with only less than 2% extension of the elastic band. Howbeit, to ensure sufficient generated force, and as a precautionary safety measure, we recommend adjusting the proper band length according to the extended band after every 150-200 times of use. Hence, the maximum reusability of the armband has not been reported, as the conditions for usage can be varied. For example, we found that a couple of prototypes used in the mobile blood donation unit outside the hospital deteriorated faster than the ones used within the hospital, due to heat and other environmental factors. Replacing the elastic fabric of the armband after it has been used 500-600 times is suggested, because of deterioration of its elasticity as well as its unappealing appearance.

Conclusion

The stop bleeding armband is an ordinary device that is effective in preventing bleeding of a venipuncture from the blood donation process. The armband can reduce the number of occurred complications to 1.2%, by generating an appropriate force that is sufficiently strong enough to stop bleeding, without causing excessive harm to the donor or causing any other adverse complications. Although, it can decrease the workload of the medical staff, and standardizing the stop bleeding procedure at the same time, there is an additional cost incurred from manufacturing and cleaning of the armband compared to the conventional procedure. However, this existing stop bleeding armband would benefit both the donors, as it allows the donor to freely use both hands if necessary, and the blood donation unit, because of the standardizing stop bleeding practice in addition to reducing the staff workload.

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