IJFAE International Journal of First Aid Education

Volume 2 | Issue 1 Article 4

September 2018

# Pressure Methods for Primary Hemorrhage Control: A Randomized Crossover Trial.

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Recommended Citation

Charlton, Nathan Phillip; Solberg, Robert; Rizer, Justin; Singletary, Nici; and Woods, William A. (2018) "Pressure Methods for Primary Hemorrhage Control: A Randomized Crossover Trial.," *International Journal of First Aid Education*: Vol. 2 : Iss. 1 , Article 4.
DOI: 10.21038/ijfa.2018.0011
Available at: https://digitalcommons.kent.edu/ijfae/vol2/iss1/4

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# Original Research

# Pressure Methods for Primary Hemorrhage Control: A Randomized Crossover Trial

Nathan Phillip Charlton, Robert Solberg, Justin Rizer, Nici Singletary, William A. Woods

**Abstract**

Background: The importance of hemorrhage control in traumatic injury has been highlighted by the 2015 Stop the Bleed federal campaign in the United States and subsequent development of modular bleeding control courses offered by organizations such as the American Red Cross (https://www.dhs.gov/stopthebleed). However, the scientific evidence regarding the best methods and mechanisms of applying direct manual pressure to stop hemorrhage is lacking to inform first aid education skill development.

Hypothesis: The purpose of this tri-phase study is to evaluate the pressure generated when adding increasing layers of gauze dressings and to compare the force generated using different techniques of force application. Additionally, we aimed to measure the pressure generated by a pressure wrap using two commonly used types of bandages in comparison to manual pressure.

Methods: In this tri-phase randomized crossover trial of medical personnel, a standardized bleeding simulator with a flat force sensitive resistor on the surface was used to measure force. Participants were randomized to order of pressure with gauze application (10, 20 & 30 layers of 4x4 inch cotton gauze, respectively) and subsequently to three different methods of pressure application: the finger pads of 3 digits of the right hand, 3 fingers of the dominant hand with the opposing hand applying counter pressure, or 3 digits of each of two hands on top of the other. Participants were asked to hold pressure continuously during each application for 10 seconds and all completed each method sequentially. Participants then applied a compression wrap using either an elastic wrap or self-adhesive wrap.

Results: Thirty-three participants were enrolled, and all had data available for analysis. Pressure applied with a stack of 10- 4x4 inch gauze pads generated a greater force than with 30 gauze pads [3.20 (95% CI: 2.80-3.59) lbs. of pressure vs 1.58 (95% CI: 1.39-1.77) lbs.]. Two hand pressure application generated a greater force than one hand application [3.75 (95% CI: 3.20-4.30) lbs vs. 3.00 (95% CI: 2.54-3.46) lbs]. Neither pressure wrap technique generated a comparable amount of force to that of manual force.

Conclusion: In this simulated model of bleeding, medical personnel generated the most force when a single stack of gauze and when two hands were used to apply pressure over the wound. This study also demonstrated direct manual pressure generated much higher pressures than a pressure dressing. First aid educators may apply results to lessons in describing the thickness of material and need to apply sufficient pressure to stop bleeding.

Traumatic injury is a major source of morbidity and mortality and in the United States is the leading cause of death in people under 45 years of age (Centers for Disease Control and Prevention, 2017). Hemorrhage is cited as the primary cause of death in 35% of traumatic mortalities and often contributes to death ultimately attributed to other causes (Kauvar, Lefering, & Wade, 2006). The launch of the White House's Stop the Bleed campaign in 2015 highlights the importance of hemorrhage control in traumatic civilian injury and mass casualty events (https://www.dhs.gov/stopthebleed) (Stop the Bleed, 2018). The importance of hemorrhage control is reflected by a movement to the "MARCH" (massive hemorrhage, airway, respirations, cardiac, head injury/hypothermia) approach to initial assessment and resuscitation by the U.S. Military (Hodgetts, Mahoney, Russell, & Byers, 2006).

Published first aid guidelines and texts generally suggest initial assessment following the airway, breathing, circulation (ABC) approach (The American Red Cross, 2017; International Federation of Red Cross and Red Crescent Societies, 2016). If life-threatening hemorrhage is identified on the primary survey, this guidance suggests direct pressure accompanied by the immediate application of a tourniquet or hemostatic dressing if available. Training organizations, such as the American Red Cross (ARC) and American Heart Association (AHA), teach direct pressure as the first line therapy to stop non-life-threatening external bleeding. But guidelines give little guidance regarding the best method of applying direct pressure, including hand or finger placement and mechanics of applying the pressure. Neither the European Resuscitation Council (ERC), nor the American Heart Association) and American Red Cross first aid guidelines comment on the method of applying pressure (Markenson et al., 2010; Zideman et al., 2015). The ERC notes "there is a paucity of literature comparing different bleeding control strategies commonly employed by first aiders (Zideman et al., 2015). The literature cited by the AHA/ARC and the ERC comparing methods of holding direct pressure comes primarily from in-hospital studies of holding pressure following artery catheterization for a medical procedure (Koreny, Riedmuller, Nikfardjam, Siostrzonek, & Mullner, 2004; Lehmann, Heath-Lange, & Ferris, 1999; Mlekusch et al., 2006; Naimer & Chemla, 2000; Naimer, Anat, Katif, & Rescue Team, 2004; Naimer, Nash, Niv, & Lapid, 2004; Simon, Bumgarner, Clark, & Israel, 1998; Upponi et al., 2007; Walker, Cleary, & Higgins, 2001; Yadav, Ziada, Almany, Davis, & Castaneda, 2003).

In the hospital environment, gauze is often used over the wound as a dressing to absorb blood while applying pressure, but recommendations on use of gauze are also variable. The ERC states that pressure can be applied "with or without a dressing" (Zideman et al., 2015). Several sources recommend that if the gauze becomes saturated with blood, to add additional layers of gauze and apply more pressure, but these recommendations are not evidence-based (The American Heart Association, 2015; The American Red Cross, 2017; National Highway Traffic Safety Administration, 2009). There has been no evaluation regarding the effect of applying gauze or increasing layers of gauze in combination with direct manual pressure on a wound. Theoretically, adding more gauze layers or wraps will dissipate the force applied to the wound requiring more pressure to compress the gauze and spreading the force over a larger area.

The purpose of this study was to evaluate the pressure generated when adding additional layers of gauze to a simulated wound in order to stop bleeding. Our hypothesis was that adding gauze will disperse the force and effectively decrease the pressure applied to a bleeding area. A secondary goal was to compare the force generated using different techniques of pressure application. Finally, we aimed to measure the force generated by a pressure wrap using two commonly used types of bandages (elastic wrap or self-adhesive wrap) in comparison to manual pressure. To our knowledge, this is the first study evaluating different techniques of application of direct manual pressure for control of bleeding used by first aiders, with the intent for providing evidence for curriculum development and teaching of this critical skill in first aid classes.


DOI: 10.21038/ijfa.2018.0011

## Methods

This study was a tri-phase crossover design with independent analysis of variance performed on each phase of the study, as approved by the University of Virginia Institutional Review Board. Participants were recruited as a convenience sample of emergency medical providers during a weekly medical conference at the University of Virginia. This population was chosen as they have significant experience in application of pressure for hemorrhage control and this study was not designed to be a measure of teaching outcomes, rather of appropriate content. Participants were recruited by verbal announcement at the beginning of the conference and participated when convenient for them during the course of the one-day conference. Participants were eligible if they were greater or equal to 18 years of age and self-selected to participate in the study. There was no incentive provided for participation in this study.

After obtaining verbal consent, participants were assigned a unique identifier and demographics were collected including gender, age, and level of training. A standardized bleeding simulator (Z-Medica Hemorrhage Control Trainer, Z-Medica, Wallingford, CT, USA) was used as a model. Force on the surface of the model was measured with a flat, 15mm diameter pre-calibrated force sensitive resistor (SingleTact PPS Los Angeles, CA, USA) with a range of 0 to 10 pounds (45N). An Arduino Uno microcontroller (https://www.arduino.cc/) was programmed with standardized SingleTact code and force measurements were recorded at an average of 50 data points per second. To standardize terminology, the word "pressure" describes the action of participants on the model, the word "force" describes the data output measured during this trial.

For each phase of the study a similar blinding method was used. To attempt to blind participants from seeing the sensor, a single 4x4 inch cotton gauze with red ink to simulate blood was placed directly over the measuring device to hide it from participants' view. The participants were verbally instructed that this red ink was the area of bleeding and that they should attempt to apply pressure over this area. Participants were not told the premise of this study, that force was being measured or allowed to see the force readings, but they could not otherwise be blinded. Researchers were not blinded during data collection, but researchers analyzing data were blinded to the groups.

Participants completed three separate phases of this tri-phase study: layers of gauze, pressure methods, and pressure wrap. Required sample size was calculated for the primary outcome of gauze application, based on pilot data, with a standard deviation of 0.8 pounds, a sample size of 18 participants were needed to have 80% power to detect a 0.6-pound difference between two variables, with a significance level (alpha) of 0.05 using a repeated measures ANOVA test with 3 repeated measures. During the first part of the study, participants applied pressure to the simulated wound with three different stacked layers of gauze: 10 layers of 4x4 inch cotton gauze, 20 layers of 4x4 inch cotton gauze, and 30 layers of 4x4 inch cotton gauze. A control of 10 4x4 inch gauze was used as it is the number of gauze pads in a commonly available sterile gauze package used by emergency medical providers. Participants were randomized (www.randomizer.org) to the order in which each of the gauze stacks were applied. The participants were verbally instructed by the enrolling researcher, who is a board-certified emergency medicine physician, to place the stack of 10 gauze over the simulated wound and apply pressure with the finger pads of 3 digits of the dominant hand as they would to stop bleeding. Participants were asked to hold pressure continuously for ten seconds and then release. For each phase of the study no feedback was given by the researchers on method of pressure administration or quality of pressure. Data were recorded after each event and automatic instrument calibration occurred after each event resulting in an approximately 20 second interval between each trial. Following recalibration and data recording, the participant applied the next stack for which they had been randomized, this was followed by the third in similar fashion. All participants completed application with each of the three stacks.

In the second phase of the study participants were verbally instructed by the enrolling researcher to apply pressure using three different techniques to determine which technique generated the most amount of pressure. The methods of pressure application were chosen based on a pilot study of commonly used methods for applying pressure to a simulated model of bleeding. Using a single stack of 10- 4x4 inch gauze, participants were instructed to apply pressure over the simulated wound using each of the following methods: the finger pads of 3 digits of the dominant hand placed flat on the simulated wound, 3 fingers of the dominant hand with the opposing hand applying counter pressure on the opposite side of the manikin, or using the finger pad of 3 digits of each of two hands on top of the other placed on the wound. The participants were instructed to apply pressure to the simulated wound as they customarily do to stop bleeding and to hold pressure at each application continuously for 10 seconds. Data was recorded after each event and automatic instrument calibration occurred after each event resulting in an approximately 20 second interval between each trial. Following recalibration and data recording, the participant applied the next method for which they had been randomized, this was followed by the third in similar fashion. Participants were randomized (www.randomizer.org) as to the order in which each type of technique was applied; all participants completed each technique.

In the third phase of this study, participants were verbally instructed by the enrolling researcher to apply a compression wrap using either an elastic wrap or self-adhesive wrap as the dressing. Participants were not randomized in this phase of the study, but the order of elastic wrap and self-adhesive wrap was alternated for each participant, with each participant only applying one type of wrap. As participants were medical providers they were not given instructions on how to apply the dressing. However, to allow for comparison to the control (which was selected as single hand direct manual pressure done in the second phase of this study) all participants applied the wrap over 10- 4x4 gauze. Participants took approximately 45 seconds to apply a pressure wrap; total time of participation in the study was approximately 5 minutes.

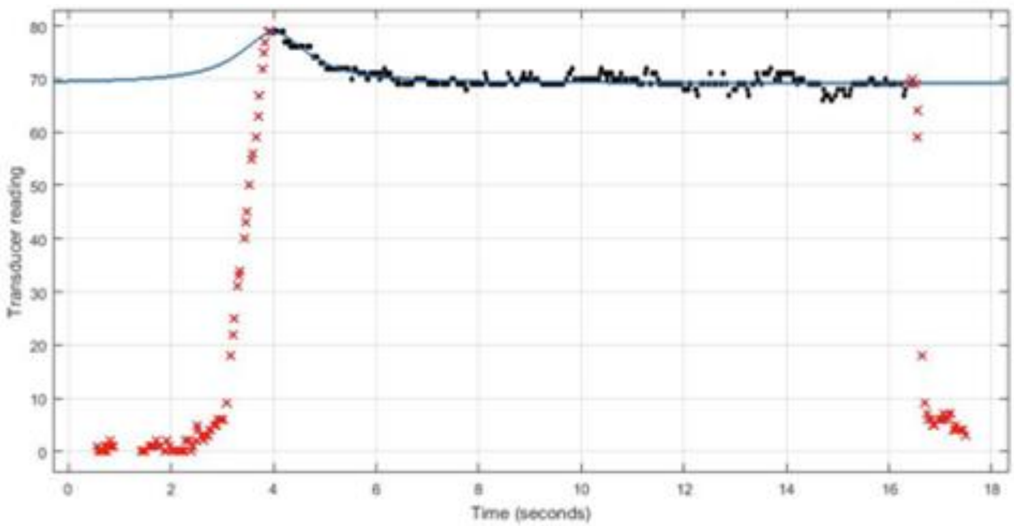
## Statistical Analysis

Data were exported into Microsoft Excel Version 2010 spreadsheet (Microsoft, Redmond, WA, USA) and data from each trial were merged in a column and row-fashion using a common unique identifier. Force readings typically fluctuated over a few second period following initial pressure application before reaching a more constant state. As these fluctuations were variable and typically lasted only a few seconds, we determined that they were a result of fatigue, the material properties of the gauze or test device, but rather an adjustment period until a steady state was reached. In addition, compression wraps had marked fluctuation during the active process of wrapping and did not achieve steady state until the participant completed application of the wrap. To help accommodate for this force fluctuation and only report the steady state, the data was analyzed using MATLAB R2015a (MathWorks, Natick, MA, USA) to fit curves to each trial in order to quantify the steady state value (value c in equation below), the peak force above steady state (value a in the equation below) and the time to decay from peak to steady state (value b in the equation below). See Figure 1 for example curve of force fluctuation and modeling.

$$\text{force} = a/[b*(\text{time from peak})^2+1] + c$$

As the steady state values were felt to better represent the true measured force, rather than just taking an average of all data points, the "c" values, referred to as force "constant" for the remainder of the manuscript, were used for all force calculations in this study. Descriptive statistics were used to describe demographics. This study employed the use of the two three-factor repeated measures analysis of variance with a Bonferroni multiple comparisons test to identify difference between the amount of gauze used, hand placement methodology. The levels used for each phase were as follows: Phase 1: 3 layers of gauze, Phase 2: 3 Methods of Pressure application. As participants applied either an elastic wrap or a self-adhesive wrap, but not both, statistical comparison between a pressure wrap and single hand manual compression was completed using an independent t-test. Mauchly's Test was used to determine sphericity. A Shapiro-Wilk test was used to determine normality. Data were analyzed using SAS 9.4 Software (SAS Institute Inc., Cary, NC, USA). Results are presented in mean and 95% confidence interval (CI) when presenting from a single data set and mean difference with 95% confidence interval when comparing data sets. Repeated measures ANOVA results are reported as F value with degrees of freedom and p value [F(df_num, df_den) = value, p = value]. Individual post hoc results were reported as a mean difference with related 95% confidence intervals.

*Figure 1. Example of data modeling for force decay over time.*




## Results

Thirty-three participants were enrolled. All completed each phase of this tri-phase study and all had data from each phase available for analysis. The sample included twenty-two resident physicians, 11 attending physicians, and 22 males. The average age of the participants was 34.2 years (range 26-63) (Table 1).

**Table 1. Participant Demographics (*n* = 33)**

| | (%,(range/count) |
|---|---|
| Age | 34.2% (26-63) |
| Gender | |
| Male | 66.7% (22) |
| Female | 33.3% (11) |
| Provider Type | |
| Resident Physician | 66.7% (22) |
| Attending Physician | 33.3% (11) |

Mauchly's Test of Sphericity for the layers of gauze indicated that the assumption of sphericity had been violated, $\chi2(2) = 7.417$, $p = 0.025$; therefore, degrees of Freedom (df) were adjusted using the Greenhouse-Geisser correction. Mauchly's Test of Sphericity regarding methods of pressure indicated that the assumption of sphericity had not been violated, $\chi2(2) = 2.685$, $p = 0.261$. Data was normally distributed by the Shapiro-Wilk method, except for the data set for 2 hand pressure application [Number of gauze used followed by significance (10 gauze = 0.205, 20 gauze = 0.811, 30 gauze = 0.498, Single Hand = 0.205, Opposing Hands = 0.104, Two Hands = 0.014, Elastic Wrap = 0.225, Self-Adhesive Wrap = 0.163)

### *Gauze Layers*

The adjusted repeated measures ANOVA of force for gauze layers reached statistical significance, $F(1.649,52.770) = 97.101$, $p <0.001$) thus indicating the presence of a main effect of method on the response. A steady decline in measured surface force with increasing layers of gauze was identified (Table 2). Pressure application using a single stack of 10 4x4 inch gauze pads generated the greatest amount of force, with an average force constant of 3.20 (95% CI: 2.80-3.59) lbs of force, whereas pressure application using a stack of 30 gauze pads generated an average constant of only 1.58 (95% CI: 1.39-1.77) lbs of force [Mean difference: -1.62 (95% CI: -1.27 - (-1.97); p<0.001].

### *Pressure Method*

The repeated measures ANOVA of pressure method on force reached statistical significance, $F(2,64) = 6.558$, $p = 0.003$) thus indicating the presence of a main effect of method on the response. Two hand pressure application generated the most amount of force averaging a constant of 3.75 (95% CI: 3.20-4.30) lbs (Table 2). This was

**Table 2. Pressure Constants by Modality**

| Intervention: Gauze | Int Avg* "c value" (95% CI) | Comparison | Mean Difference* (95% CI) | p value |
|---|---|---|---|---|
| 10- 4x4" gauze | 3.20 (2.80 - 3.59) | 20 | 0.95 (0.65-1.24) | <0.001 |
| 20- 4x4" gauze | 2.25 (1.98 - 2.53) | 30 | 0.67 (0.44-0.90) | <0.001 |
| 30- 4x4" gauze | 1.58 (1.39 - 1.77) | 10 | -1.62 (-1.27-(-1.97)) | <0.001 |
| Intervention: Pressure Method | | | | |
| Single Hand | 3.00 (2.54-3.46) | Opposing Hands | -0.27 (-0.73-0.19) | 0.441 |
| Opposing Hands | 3.27 (2.88-3.66) | Two Hands | -0.48 (-1.07-0.11) | 0.143 |
| Two Hands | 3.75 (3.20-4.30) | Single Hand | 0.75 (0.22-1.29) | 0.004 |
| Intervention: Pressure Wrap (n) | | | | |
| Elastic Bandage (17) | 0.88 (0.62-1.15)‡ | Single hand manual pressure | -2.12 (-1.46-(-2.78)) | <0.001† |
| Self-adhesive bandage (16) | 0.52 (0.30-0.73) | Single hand manual pressure | -2.48 (-1.81-(-3.15)) | <0.001† |
| Combined Compression Wrap (33) | 0.70 (0.53-0.88) | Single hand manual pressure | -2.3 (-1.82-(-2.78)) | <0.001† |

Table notes: *in lbs; † versus Single Hand manual pressure; ‡ Mean Difference vs Self-adhesive bandage 0.36 (0.03-0.69); p=0.03

statistically significant compared with one hand application which generated an average constant of 3.00 (95% CI: 2.54-3.46) lbs of force [Mean difference: 0.75 (95% CI: -0.22-(-1.29); p=0.004]. Comparison of opposing hands with single hand did not reach statistical significance, nor did two hands compared with opposing hands (Table 2).

*Pressure Wrap*

Neither pressure wrap technique generated a comparable amount of force to that of manual force, generating a combined average constant of 0.70 (95% CI 0.53-0.88) lbs of force [Mean difference compared with 1 hand with 10 4x4" gauze pads: -2.30 (95% CI: -2.78-(-1.82); p <0.001)]. A pressure wrap with an elastic bandage generated slight more force that a self-adhesive bandage (Table 2).

## Discussion

This tri-phase study gives further insight into the most effective techniques for pressure application to stop bleeding. In this study of a simulated model of bleeding, medical personnel generated the most force on a wound using a single stack of 10 4x4 inch gauze pads, and when two hands were used to apply digital pressure over the wound. We were not able to determine a significant difference between one hand compared with opposing hands or opposing hands compared with two hands. A larger sample size may have allowed us to determine statistical significance between these methods.

The evidence from this study, while indirect, has significant implications for first aid skills. In the hospital, gauze is often used to cover a wound to absorb blood while applying pressure, whereas, in the lay person first aid environment, clothing, towels or other materials may be substituted in the place of gauze. However, sometimes bleeding is profuse and not initially controlled by direct pressure and blood soaks through the gauze or clothing that is being used. In this case, traditional first aid recommendations include the application of additional layers of gauze or dressing material over the existing dressing and continued or increased pressure application. From this study, it is apparent that increasing the layers of gauze on top of a wound will decrease the pressure


DOI: 10.21038/ijfa.2018.0011

effectively generated onto the wound. This is expected when considering the Law of Laplace, which predicts that sub-bandage pressure is directly proportional to bandage tension, but inversely proportional to the radius of curvature of the limb to which it is applied. As layers of dressing material of bandages are added, the effective radius is theoretically increased and leads to lower sub-bandage or dressing pressure. Because pressure on the bleeding vessel is critical to stop bleeding, the practice of applying additional layers of gauze to a wound with uncontrolled bleeding is likely detrimental to hemorrhage control. While gauze was used in this study, it can be also inferred that an increasing amount of padding, whether it be gauze or clothing over the wound, will decrease the amount of pressure effectively applied to the source of bleeding.

We did not model blood-soaked gauze, which might alter transmission of the forces. However, a 2018 study by Hartka showed that wet gauze transmitted forces in a similar manner to that of dry gauze in a force transmission model (personal communication, unpublished data). In a wound with significant bleeding, it is expected that at least the bottom layer of gauze becomes saturated with blood. If a wound continues to bleed through a saturated gauze bandage or dressing, the results from the current study suggest that instead of applying additional layers of gauze, this should trigger recognition that the ongoing bleeding is potentially life-threatening and consideration of alternative methods of hemorrhage control such as a tourniquet or hemostatic dressing.

This study also confirms previous studies demonstrating that direct manual pressure generated much higher pressures than a pressure dressing either using an elastic bandage or self-adhesive bandage. In a study by Naimer, Anat, Katif, & Rescue Team (2004)., applying manual pressure generated higher pressures than either a commercial or improvised pressure dressing. While pressure dressings may be useful for maintaining hemostasis after control is obtained by direct pressure, based on the current study results we would not recommend elasticized or self-adherent pressure wraps such as Coban™ or roller gauze to attain initial hemostasis.

## Limitations

We recognize several limitations to this study. Because this study was a convenience sample in medical personnel, it is very important to note that it is not known if it can be generalized to lay providers. We also used a model in this study that has a pressure sensor on the surface. It is not known how this surface pressure translates to pressure transmission to deeper bleeding structures. The model used did not allow us to determine patient discomfort, which could hinder some methods of pressure application in some patients. In addition, the simulator model used in this study did not allow us to assess for actual control of bleeding with the various techniques tested. We did not use a standardized pressure to test either the gauze pads or the techniques used, we felt the method used in this study is more applicable in a real-world scenario. While the gauze was replaced every three applications, it is possible that compression of the gauze from repetitive use altered the data. We feel that randomization of application order helped to mitigate some of this confounding. Neither the participants nor the enrolling researchers were blinded, which could have introduced bias into this study. The order of compression wrap application was not randomized making this phase of the study observational in nature; this may have introduced bias to both participants and researchers. In addition, there was no direct control for this phase of the study, instead results were compared with phase two single hand manual pressure using a similar 10 gauze pads under the wrap. There was a limited sample size; increasing this sample size may have allowed detection of more subtle differences between techniques. Finally, the extrapolation of our findings to 'real world' conditions may not correlate with our findings.

## Conclusion

This study demonstrates that pressure application using a single stack of 10- 4x4 inch gauze pads provides more average force than with the use of either a 20 or 30 stack of 4x4 inch gauze pads. It additionally demonstrates that providing pressure with the digits of two overlapping hands provides more force on a simulated model of bleeding than a single hand force application. Finally, it demonstrates that a pressure dressing applied over 10- 4x4 inch gauze pads using either an elastic wrap or self-adhesive wrap generates significantly less force than manual pressure with a similar amount of gauze. Developers of first aid curriculum and instructors should consider these results when teaching or demonstrating techniques for control of bleeding with direct pressure. Instruction should emphasize avoiding application of thick layers or additional layers of gauze pads to a bleeding wound as this will lower the force applied and potentially contribute to ongoing bleeding.

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DOI: 10.21038/ijfa.2018.0011

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