

Pressured Applied by the Emergency/Israeli Bandage



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Introduction

At the request of Performance Systems, this study was undertaken to quantify the pressure that the Emergency Bandage applies around a cylindrical object; i.e., a simulated arm (4" inner diameter with 4.5" outer diameter PVC pipe), an arm, or a thigh. Pressure tests were performed on a simulated arm and were followed by tests on 10 subjects (males and females) about the arm. The primary objective of the study was to determine the amount of pressure exerted by the bandage with a modification called the "Pressure Bar". The data were collected using emergency bandages with and without the pressure bar. In addition to measuring the pressure under the pressure bar, other pressure sensors were used to measure the amount of pressure being exerted to other areas under the elastic emergency bandage (at 90°, 180°, and 270°), but not directly under the pressure bar. The secondary objective of the study was to quantify the distribution of pressure that the emergency bandage applied at 90, 180, 270 degrees to the pressure bar in order to determine the effective ability of the emergency bandage to apply localized pressure with the pressure bar over a wound without applying unnecessary pressure over the other areas.

Background

The Emergency Bandage is designed to increase the pressure under the pressure applicator (pressure bar) with support for the closure bar to maintain the pressure to a wound (under the pressure bar) while securing the bandage. The bandage is similar to any elastic bandage used for wrapping sprained ankles, knees, elbows, or wrists except for three special purpose components that have been added to the elastic wrap. These special purpose components include: 1) the dressing, 2) the pressure applicator (pressure bar), and 3) the closure bar as shown in Table 1.

Pictures of the three special purpose components with their descriptions are shown in Table 1.

The bandages are provided in various sizes: 4-inches wide, 6-inches wide and 8-inches wide. Only the 6-inch wide Emergency Bandages (FCP-02 Military [NSN #6510-01-492-2275]) were used on volunteer subjects. The 6" wide, all-in-one device consolidates multiple first-aid devices such as a primary dressing, pressure applicator, secondary dressing, and a foolproof closure apparatus to secure the bandage in place. The internationally patented and FDA approved emergency bandage is especially ideal for emergency treatment. The Emergency Bandage's sterile, non-adherent pad applies pressure to any site, can be easily wrapped and secured, and has an additional application, similar to a tourniquet, to further constrict blood-flow. All of the emergency bandages used for testing arrived in individual sealed vacuum sterile packages. One side of the emergency bandage has a 4 x 4 or a 6 x 6 dressing

TABLE 1
Three Special Purpose Components

Dressing



non-adhering - allows the bandage to be removed without reopening the wound.

sterile – by using vacuum packaging, the dressing remains entirely stable for use.

Pressure applicator



improves tightness – by allowing the bandage to change directions in application, the pressure applicator provides better pressure around the wound.

localized pressure – when the bandage wrapping direction is changed to create additional traction on the site of the wound, tightening isolates pressure under the pressure applicator to stop bleeding.

Closure Bar



one handed application – by making closure and fixation of the bandage a simple sliding motion, the bandage makes self-application simple

additional pressure – by sliding the closure bar under a surfaced dressing layer and twisting, the bar allows the user to add a variable pressure to the area to help stop bleeding.

Method

This section describes the test equipment used in the tests, subject procedures, and the statistical procedures. All tests were conducted at the Physician’s Centre Hospital in Bryan, TX.

Equipment and Setup

Four LoadStar “iLoad Mini-10 Lbs” (P/N FP-C-010-050), 0.5% accuracy miniature load cells were placed equally spaced around the arms. The load cells are specified to handle up to a maximum load of 50 Lbs. The pressure sensing head on the load cell sensor had a diameter of 0.40 inches, which equates to a cross-sectional area of 0.125664 square inches. The load cell was connected to a LoadStar “Freq to USB Convertor” (P/N DQ-1000), through a mini-USB cable to a Dell Inspiron Notebook computer. All the load cells were calibrated by the company and are NIST traceable. The LoadStar program, “LoadVUE Software” (P/N LV-2000), was used to acquire and download the data from the 4 load cells (sensors) in a spreadsheet format for subsequent analyses.

Subjects

Ten healthy male and female volunteers were selected for the bandage's compliant surface tests (soft tissue). Four (4) load cells (sensors) purchased from LoadStar, Inc., California were placed equally spaced around the subject's right upper arm as shown in Figure 1. Sensor #1 was placed midway between the shoulder and the elbow anteriorly, with sensor #2 midway between the shoulder and elbow medially, sensor #3 was placed midway between the shoulder and elbow posteriorly (Triceps), and sensor #4 midway between the shoulder and elbow laterally.

The pressure bar was placed above load cell (Sensor #1) on the bicep so that the pressure exerted by the wrapped pressure bar would be measured independently of other areas under the bandage which were not under the pressure bar. The other three load cells (Sensors #2, #3, and #4) were placed about the circumference of the arm or pipe at 90°, 180° and 270° from the sensor #1. During each run, the subject's fingers and pulse at the wrist (radial artery) were observed to check for the hand capillary bed perfusion.

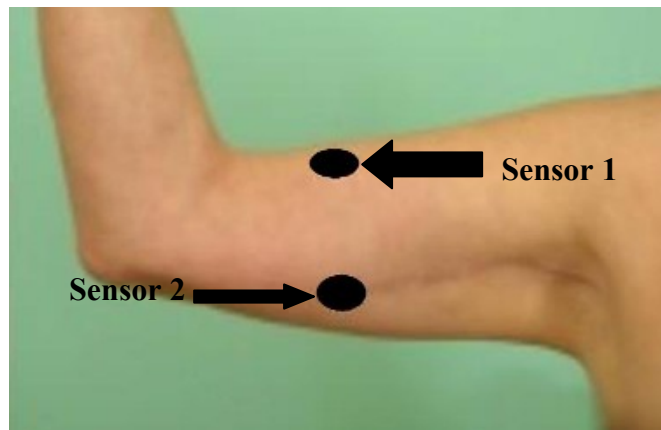


Figure 1. Major Superficial Muscles of the Upper Arm.

Figure 2 portrays how the emergency bandage was wrapped around the upper arm of the volunteer subjects. Note the closure bar (Figure 2) that is used to allow closure of the emergency bandage at any point without have to use pins, clips, tape, knots, or hooks.



Figure 2. Emergency Bandage applied to the upper arm.

Test Runs

The first set of tests run were the “Static” tests on a 4” inner diameter with 4.5” outer diameter PVC tube that was mounted on a rigid stand, simulating an upper arm. The static tests were followed by the subject testing at the hospital. The general category of test runs are:

1. Static Non-compliant tests without the pressure applicator (pressure bar),
2. Static Non-compliant tests with the pressure applicator (pressure bar),
3. Compliant (Subject) tests without the pressure applicator (pressure bar), and
4. Compliant (Subject) tests with the pressure applicator (pressure bar).

Tests without the Pressure Applicator (Pressure Bar).

The first set of test involved the application of an emergency bandage without the pressure bar (to apply additional pressure) and using only the closure bar. Additional test runs were conducted by applying twists to a previous wrap with the closure bar. Different pressures result depending on how many times the bandage is twisted with the closure bar and fastened.

The various test runs with both the static non-compliant PVC and the subject (compliance) tests are summarized in Table 2.

TABLE 2
Various Test Runs

Case Number	Compliant (Human subject):	Non-Compliant (PVC tube):
	Without Pressure Bar Closure Bar Only	Without Pressure Bar Closure Bar Only
1	Without twisting with closure bar	Without twisting with closure bar
2	1 full Twist with closure bar	1 full Twist with closure bar
3	2 full Twist with closure bar	2 full Twist with closure bar
4	3 full Twist with closure bar	3 full Twist with closure bar

	With Pressure Bar and Closure Bar	With Pressure Bar and Closure Bar
5	Without twisting with closure bar	Without twisting with closure bar
6	1 full Twist with closure bar	1 full Twist with closure bar
7	2 full Twist with closure bar	2 full Twist with closure bar
9	3 full Twist with closure bar	3 full Twist with closure bar

Tests with the Pressure Applicator (Pressure Bar).

The second set of tests involved the application of an emergency bandage with a pressure bar and by tightening the bandage after changing directions over the pressure applicator. At the same time the pressure applied by the elasticity of the dressing to other parts of the arm were measured in order to make sure that the major application of pressure is isolated to the pressure bar applicator. The closure bar can be fastened wherever possible without twisting. Additional tests were conducted by applying twists to a previous wrap with the closure bar. The increase of pressure resulting from twisting the emergency bandage with the closure bar were recorded and a presented in the results section.

Analysis

The pressure results from all four sensor positions will be placed in a data table for each case as shown in Table 2. The results from the compliant and non-compliant tests will be compared statistically and graphically. The Statistical analysis will be composed of a standard deviation, mean value, and pressure distribution values compared between test cases.

Statistical Tests and Null Hypothesis

Tests of the means (t-tests assuming uneven variances) were conducted between averages of pressure under the pressure bar when the bar is applied and pressures when the bar is not applied. The null hypothesis for this case is stated as follows: “There is no statistical difference between pressure readings when the pressure bar is applied and pressure readings when the pressure bar is not applied.”

Analysis of Variance (ANOVA) will be used in the pressures distributions tests of pressure under the pressure bar when the bar is applied and the pressures not under the pressure bar when the bar is applied. The null hypothesis for this case is stated as follows: “There is no difference between the pressure at the site under the pressure bar when the bar is applied and the pressures at site not under the pressure bar when the bar is applied.”

Results

Results of the tests are presented in the following order:

1. Static tests with 4-inch Emergency Bandage applied to simulated arm.
2. Static tests with 6-inch Emergency Bandage applied to simulated arm.
3. Subject tests with 6-inch Emergency Bandage applied to right arm.

The following test runs were conducted with the 4-inch emergency bandage:

1. 4-inch emergency bandage without the Pressure Bar and no twisting with closure bar.
2. 4-inch emergency bandage without the Pressure Bar and 2 twists with closure bar.
3. 4-inch emergency bandage without the Pressure Bar and 3 twists with closure bar.
4. 4-inch emergency bandage with the Pressure Bar and no twisting with closure bar.
5. 4-inch emergency bandage with the Pressure Bar and 2 twists with closure bar.
6. 4-inch emergency bandage with the Pressure Bar and 3 twists with closure bar.
7. 4-inch emergency bandage with the Pressure Bar and 4 twists with closure bar.
8. 4-inch emergency bandage with the Pressure Bar and 5 twists with closure bar.
9. 4-inch emergency bandage with the Pressure Bar and 6 twists with closure bar.

A summary of the average (mean) pressures of the static test runs conducted with the 4-inch emergency bandage are displayed in a graphical bar chart (Figure 3). The primary Sensor 1, shown as the red bar on the graph, was located under the pressure bar and/or twisted knot.

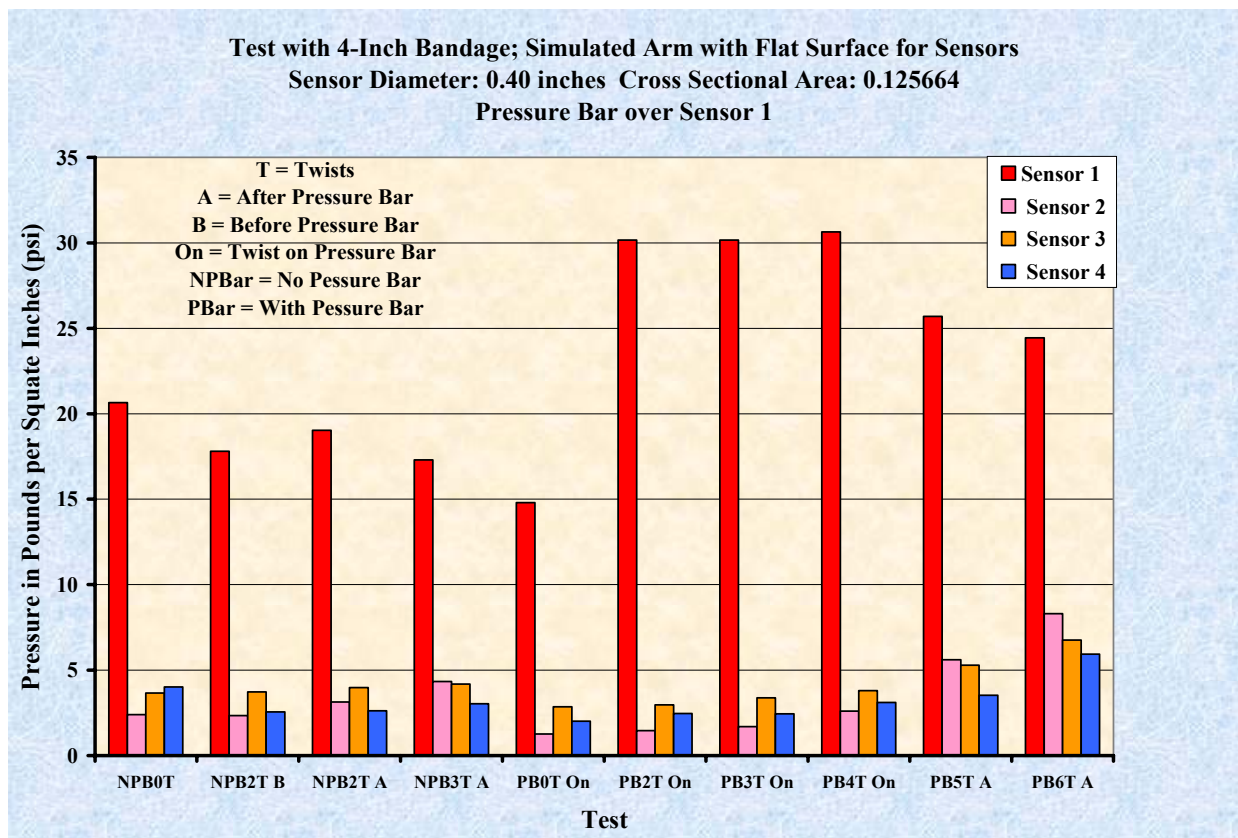


Figure 3. Bar chart showing the average (mean) pressures of the static test runs conducted with the 4-inch Emergency Bandage.

The tests with the 4-inch emergency bandage provided a valuable insight on the effects of the twisted knot not being directly over the sensor or wound (the desired location). This effect is noted with the decrease in the applied average pressure if the twist knot and closure bar are before or after the area of interest (directly over Sensor 1). If the twisted knot is not directly over the sensor or wound (the desired location), less pressure is applied at the desired location. The 4-inch bandage with the pressure bar showed that twisting the bandage with the closure bar approximately doubled the applied pressure on Sensor 1. It should be noted from Figure 3 that the pressures applied to others areas (Sensor 2, Sensor 3, and Sensor 4) are generally less than 5 PSI, indicating that the Emergency Bandage exerts its major pressure under the pressure bar and/or the twisted knot.

The static tests runs conducted with the 6-inch emergency bandage are as follows:

1. 6-inch emergency bandage without the Pressure Bar and no twisting with closure bar.
2. 6-inch emergency bandage without the Pressure Bar and 3 twists with closure bar.
3. 6-inch emergency bandage without the Pressure Bar and 4 twists with closure bar.
4. 6-inch emergency bandage with the Pressure Bar and no twisting with closure bar.
5. 6-inch emergency bandage with the Pressure Bar and 3 twists with closure bar.
6. 6-inch emergency bandage with the Pressure Bar and 4 twists with closure bar.

A summary of the averages (mean) and standard deviation of the static tests runs conducted with the 6-inch emergency bandage are given in Tables 3 and 4, and are displayed in a graphical bar chart (Figure 4). Table 3 shows the results of application without the pressure bar.

TABLE 3
Summary Results of
The 6-inch emergency bandage without the Pressure Bar
(Means and Standard Deviations in PSI)

Tests	Pressure in pounds per square inches			
	Sensor 1	Sensor 2	Sensor 3	Sensor 4
AVG 0 T	15.71	6.03	6.74	8.78
STD 0 T	0.52	2.60	1.16	3.32
AVG 3 T	24.49	4.35	6.68	7.39
STD 3 T	0.97	6.15	1.28	3.38
AVG 4 T	30.62	8.00	7.02	9.45
STD 4 T	11.61	4.01	1.27	1.90

Table 4 shows the results of application with the pressure bar.

TABLE 4
Summary Results of
The 6-inch emergency bandage with the Pressure Bar
(Means and Standard Deviations in PSI)

Pressure in pounds per square inches

Tests	Sensor 1	Sensor 2	Sensor 3	Sensor 4
AVG 0 T	39.36	8.05	5.86	7.25
STD 0 T	5.08	0.90	0.32	2.89
AVG 3 T	35.05	5.15	5.61	3.71
STD 3 T	4.93	2.78	0.64	1.11
AVG 4 T	42.70	8.01	6.29	5.48
STD 4 T	7.93	3.33	0.67	2.22

From Figure 4 the increase in applied pressure appears to be almost linear. To insure at least 30 PSI of pressure requires at least 4 twists of the emergency bandage directly above the wound area. The large variation in the pressure measurement can be explained partly on the individual applying the emergency bandage and partly on the location of the twisted knot and the closure bar. The nurses that applied the bandage appeared not to pull the elastic stretch bandage as taut as their male counterparts. If the twisted knot is not directly over the sensor or wound (the desired location), less pressure is applied at the desired location.

With the pressure bar the measured pressures at the desired location (sensor 1 or wound) did not change significantly. The effects of the timid nurses and the twisted knot not being directly over the sensor or wound (the desired location) is noted with the decrease in the average pressure being applied at the desired location with 3-twists. Never the less, all test cases with the pressure bar exceeded 30 PSI. The application of 4 twists over the pressure bar would appear to be excessive.

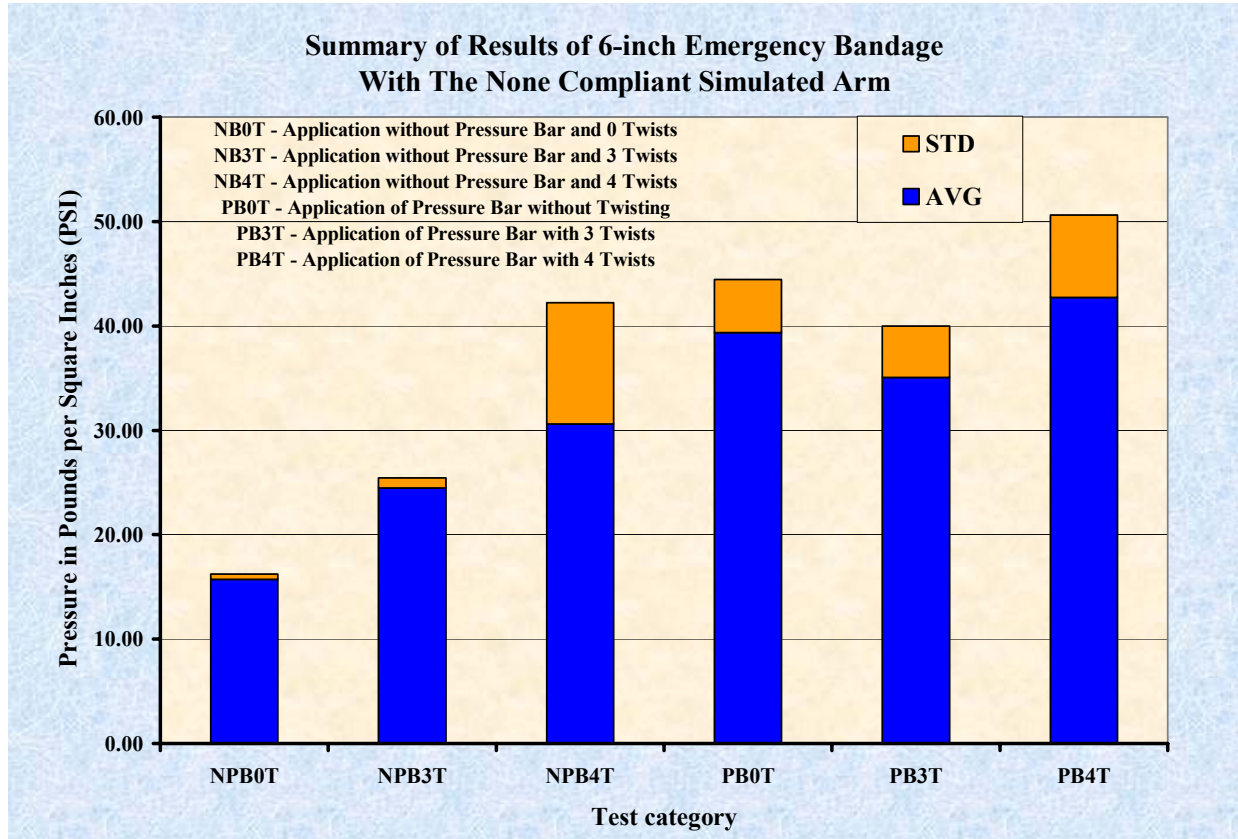


Figure 4. Bar graph of the averages (mean) and standard deviation of the static tests conducted with the 6-inch emergency bandage.

The single factor analysis of variance (ANOVA) test of the 6-inch emergency bandage without the Pressure Bar indicated statistical significant differences (P -value = 0.00166) between the mean pressure applied at the site of interest (Sensor 1) and the adjacent areas (Sensor 2, Sensor 3, and Sensor 4). Additionally, the single factor analysis of variance (ANOVA) test of the 6-inch emergency bandage with the Pressure Bar indicated statistical significant differences (P -value = 1.9E-07; much less than 0.0001) between the mean pressure applied at the site of interest (Sensor 1) and the adjacent areas (Sensor 2, Sensor 3, and Sensor 4). From these results it is concluded that the emergency bandage when applied to produce sufficient pressure to stop the bleeding of a penetration wound does not act like a tourniquet.

Results from Subject Tests

The following Subject test runs were conducted with the 6-inch emergency bandage applied to the subject's right arm.

1. 6-inch emergency bandage without the Pressure Bar and no twisting with closure bar.
2. 6-inch emergency bandage without the Pressure Bar and 2 twists with closure bar.
3. 6-inch emergency bandage with the Pressure Bar and no twisting with closure bar.
4. 6-inch emergency bandage with the Pressure Bar and 2 twists with closure bar.

Table 5 presents the pressures (PSI) recorded at each sensor when the 6-inch emergency bandage is applied without the Pressure Bar and not twisting the bandage over Sensor 1 with the closure bar. Even though it appears as if all the pressure readings are almost the same, the one factor analysis of variance indicated significant statistical differences with a *P-value* = 0.0137.

TABLE 5
Average Results within Subjects

No Pressure Bar Bandage without Twisting (NB0T)				
Average in: Pressure in Pounds per Square Inches (PSI)				
Subject	Sensor 1	Sensor 2	Sensor 3	Sensor 4
1	14.24	7.96	-	14.31
2	13.16	5.69	8.83	9.49
3	18.93	7.75	10.92	16.67
4	15.30	7.62	10.13	15.87
5	9.80	4.34	5.67	9.63
6	12.28	5.24	11.02	11.26
7	6.22	3.74	4.34	4.70
8	6.21	6.95	4.45	2.04
9	8.39	5.31	4.53	6.70
10	8.06	7.17	3.53	6.96
Overall Average	11.26	6.18	7.05	9.76
Overall Std Dev	4.22	1.51	3.13	4.84

Table 6 presents the pressures (PSI) recorded at each sensor when the 6-inch emergency bandage is applied without the Pressure Bar and not twisting the bandage over Sensor 1 with the closure bar, , and are displayed in a graphical bar chart (Figure 5).

TABLE 6
Average Results within Subjects

Pressure Bar Bandage without Twisting (PB0T)				
Average in: Pressure in Pounds per Square Inches (PSI)				
Subject	Sensor 1	Sensor 2	Sensor 3	Sensor 4
1	23.63	13.34	-	13.89
2	31.41	5.96	11.22	12.52
3	35.71	10.80	13.31	16.31
4	30.61	9.88	10.32	15.29
5	29.03	11.08	9.40	11.07
7	22.48	5.85	7.77	11.98
8	22.70	8.04	3.91	5.60
9	45.03	15.64	14.38	12.09
Overall Avg	30.08	10.07	10.05	12.35
Overall Std	7.67	3.43	3.51	3.26

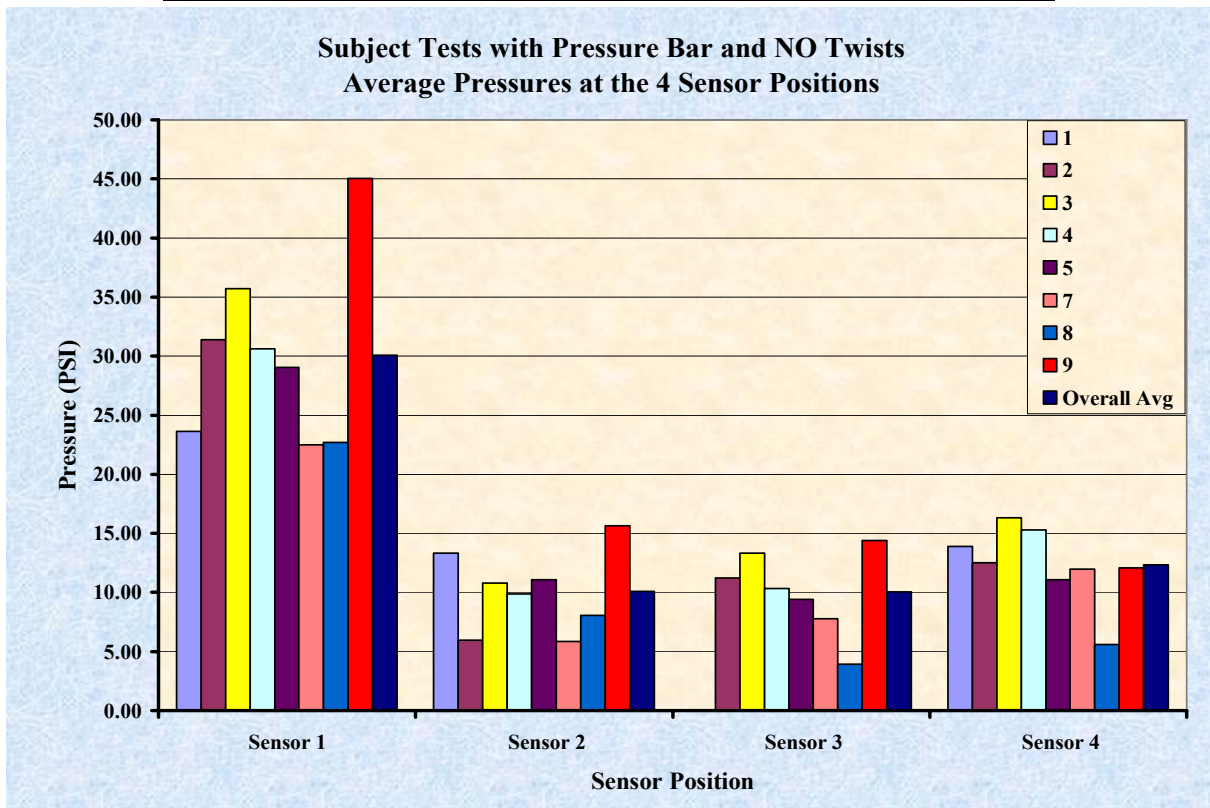


Figure 5. Subject Tests with Pressure Bar. Average Pressures at the 4 Sensor Positions.

From Figure 5, it is noted that the pressures in the areas not under the pressure bar are about one third of the pressure under the pressure bar (Sensor 1: AVG = 30.08 and STD = 7.67). The mean and standard deviation for Sensors 2, 3, and 4 are AVG = 10.82 and STD = 3.40.

The summary of the averages (mean) and standard deviation of the applied pressure at the site of interest (Sensor 1) for the subject tests runs conducted with the 6-inch emergency bandage are given in Table 7, and are displayed in a graphical bar chart (Figure 6).

TABLE 7
Averages and standard Deviation of Subject Tests

Test	Sensor 1	
	Mean	Std Dev
NB0T	11.2582742	4.21917234
NB2T	14.181599	2.68106317
PB0T	30.0752801	7.6737861
PB2T	40.3853057	7.28907335

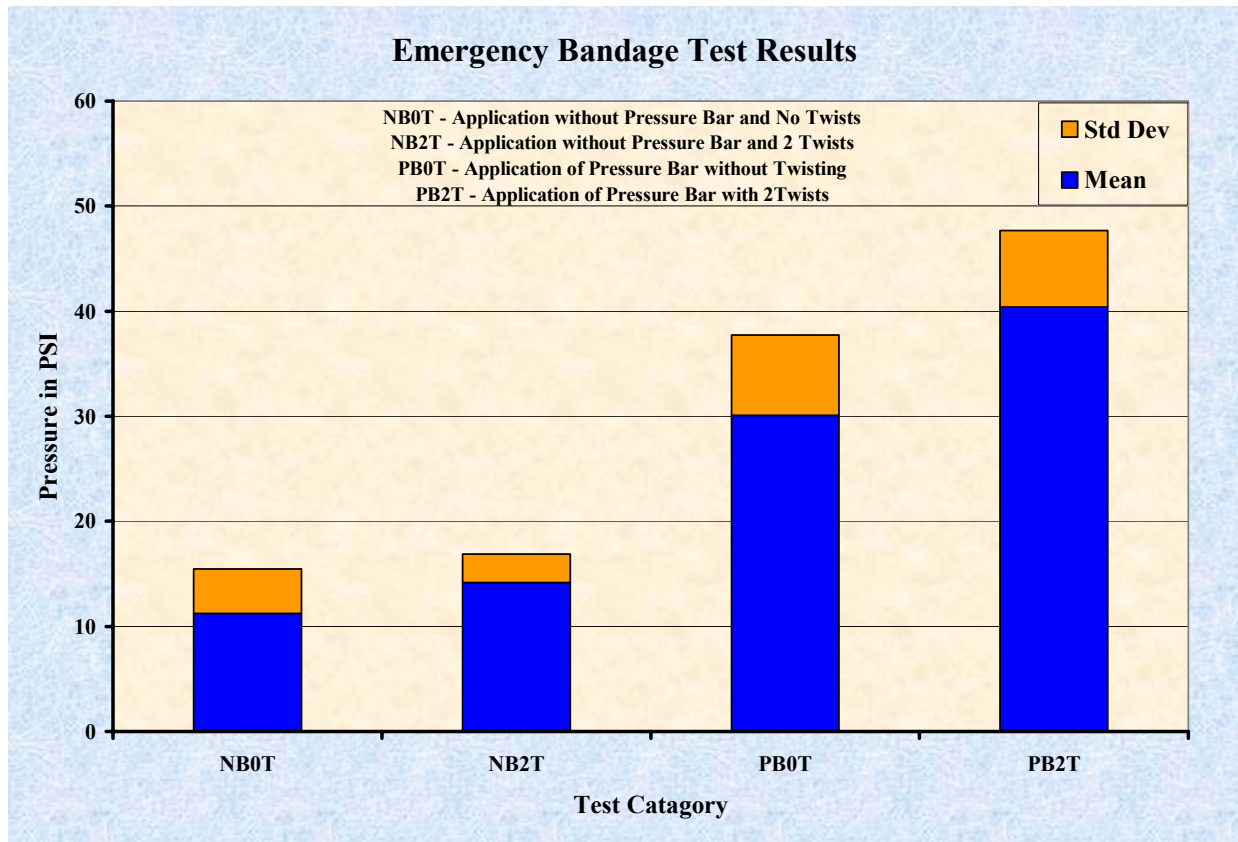


Figure 6. Summary of applied pressure (averages and standard deviation) for the subject tests runs conducted with the 6-inch Emergency Bandage.

Statistical Analysis

Two sets of statistic tests were use on the subject data shown in Tables 5 and 6, as well as similar data sets for the runs with 2 Twists. From Figure 6, it was noted that 2 twists over the pressure bar were sufficient to exceed the target applied pressure of 30 psi; hence it was decided not to continue with higher twist runs.

The first statistical tests conducted were “t-tests” assuming unequal variances from two-samples. The second set of statistical tests conducted were the “Analysis of Variance”, Single Factor ANOVA.

Summary of results from the t-Tests for two-sample assuming unequal variances are given in Table 8. No that there is no significant statistical difference in subject runs without the pressure bar between the “No Twist” and the “2 Twists” condition” (1st row of test variables). Significant statistical difference was found in subject runs between conditions “Without the Pressure Bar and No Twist” and the “Pressure Bar with No Twist” (3rd row of test variables).

TABLE 8
Summary of t-Tests Results

t-Test: Two-Sample Assuming Unequal Variances					
Significance level $\alpha = 0.05$					
Test Variables	Degrees f	P(T<=t) One-tail		P(T<=t) Two-tail	
NB0T vs. NB2T	14	0.0562	No Sig Dif	0.1124	No Sig Dif
NB2T vs. PB2T	5	0.0003	Sig Dif	0.0006	Sig Dif
NB0T vs. PB0T	10	> 0.0001	Sig Dif	0.0001	Sig Dif
PB0T vs. PB2T	9	0.0190	Sig Dif	0.0379	Sig Dif
NB2T vs. PB0T	9	0.0002	Sig Dif	0.0004	Sig Dif

Single-Factor ANOVA Tests

Single-factor ANOVA tests were conducted to test the two null hypotheses:

1. There is no statistical difference between pressure readings when the pressure bar is applied and pressure readings when the pressure bar is not applied.
2. There is no difference between the pressure at the site under the pressure bar when the bar is applied and the pressures at sites not under the pressure bar when the bar is applied.

The tests were conducted with the average pressures shown in Table 9. The pressure in rows 1 and 3 are the overall averages that are shown in the next to last row of Tables 5 and 6, respectively.

TABLE 9
Average Pressures Applied at the Sensors
for the Four Subject Test Conditions

		COL 1	COL 2	COL 3	COL 4
		Sensor 1	Sensor 2	Sensor 3	Sensor 4
ROW 1	NB0T	11.258274	6.17732377	7.04616833	9.76301858
ROW 2	NB2T	14.181599	6.6047429	7.26602089	11.4158619
ROW 3	PB0T	30.07528	10.0730715	10.0462602	12.345414
ROW 4	PB2T	40.385306	15.0467532	12.0348325	13.5092895

The results of the ANOVA tests are shown in Table 10. The results indicate that the pooled row pressures are not statistically significant for the conditions without a pressure bar. However, since the primary interest is in determining if the pressure applied by the by the pressure bar (above Sensor 1) is greater than the bandage without the pressure bar, analysis by column sum (sensors) is the better approach. Test 4 (Table 10), the test between Pressure Bar and No Pressure Bar with any twisting show that there is a significant statistical difference. Hence, the first null hypothesis that there is no statistical difference between pressure readings when the pressure bar is applied and pressure readings when the pressure bar is not applied is rejected in favor of the alternate hypothesis that there is a significant statistical difference.

Table 10
Summary of Subject Results
Single-factor ANOVA

ANOVA: Single Factor				
Significance level $\alpha = 0.05$				
Test Variables	Test #	By	<i>P-value</i>	Results
NB0T vs. NB2T	Test 1	By Rows	0.565	No SDif
NB0T vs. NB2T vs. PB0T vs. PB2T	Test 2	By Rows	0.244	No SDif
NB0T vs. NB2T	Test 3	By Cols	0.0175	Sig Dif
PB0T vs. NB0T	Test 4	By Cols	< 0.0001	Sig Dif
NB0T vs. NB2T vs. PB0T vs. PB2T	Test 5	By Cols	0.0425	Sig Dif

ANOVA Test 5 results are shown in Table 11, indicate that there are significant statistical differences between the pressures applied under Sensor 1 and the other adjacent sensors (Sensor 2, 3, and 4. Hence, the second null hypothesis that there is no difference between the pressure at the site under the pressure bar when the bar is applied and the pressures at sites not under the pressure bar when the bar is applied is rejected in favor of the alternate hypothesis that there is a significant statistical difference.

TABLE 11
TEST 4 ANOVA SUMMARY

ANOVA: Single Factor 4 Columns - All 4 Rows						
NB0T vs. NB2T vs. PB0T vs. PB2T						
	<i>Groups</i>	<i>Count</i>	<i>Sum</i>	<i>Average</i>	<i>Variance</i>	
Sensor 1	Column 1	4	95.901	23.975	188.046	
Sensor 2	Column 2	4	37.902	9.475	16.838	
Sensor 3	Column 3	4	36.393	9.098	5.697	
Sensor 4	Column 4	4	47.034	11.758	2.503	
<i>Source of Variation</i>	<i>SS</i>	<i>df</i>	<i>MS</i>	<i>F</i>	<i>P-value</i>	<i>F crit</i>
Between Groups	593.237	3	197.746	3.712	0.042	3.490
Within Groups	639.252	12	53.271		Sig Dif	
Total	1232.489	15				

To verify that the emergency bandage applied about the same amount of pressure to areas not under the pressure bar (adjacent secondary sensors 2, 3, and 4), a separate ANOVA test of only the pressure under the three secondary sensors was conducted. The ANOVA results indicated no significant statistical difference ($P\text{-value} = 0.408$) in the pressures applied by the emergency bandage to the areas under sensors 2, 3, and 4.

Conclusion

The primary objective of the study was to determine the amount of pressure exerted by the bandage with a modification called the “Pressure Bar”. The data were collected using emergency bandages with and without the pressure bar. In addition to measuring the pressure under the pressure bar, other pressure sensors were used to measure the amount of pressure being exerted to other areas under the elastic emergency bandage, but not directly under the pressure bar. A secondary objective of the study was to quantify the distribution of pressure that the emergency bandage applied in order to determine the effective ability of the emergency bandage to apply localized pressure with the pressure bar over a wound without applying unnecessary pressure over other areas.

From the results, it is concluded that the Emergency Bandage pressure bar is very effective in elevation the applied pressure directly over the pressure bar while at the same time not applying unnecessary pressure over other areas covered by the bandage. Perfusion of the capillaries of the hand and fingers were found to be adequate by observation of the fingers tips (finger nail quick) and subjective pulse measurement at the wrist (radial artery).

Recommendation

It is recommended that further testing be done to see how much restriction of blood flow occurs distal to the area of application of the Performance Systems Emergency Bandage. The reason for this is that if a semi conscious or unconscious patient has this applied the patient will not be able to communicate numbness or pain in the extremity that would indicate a possible tourniquet effect of the emergency bandage and damage or loss of limb may occur.