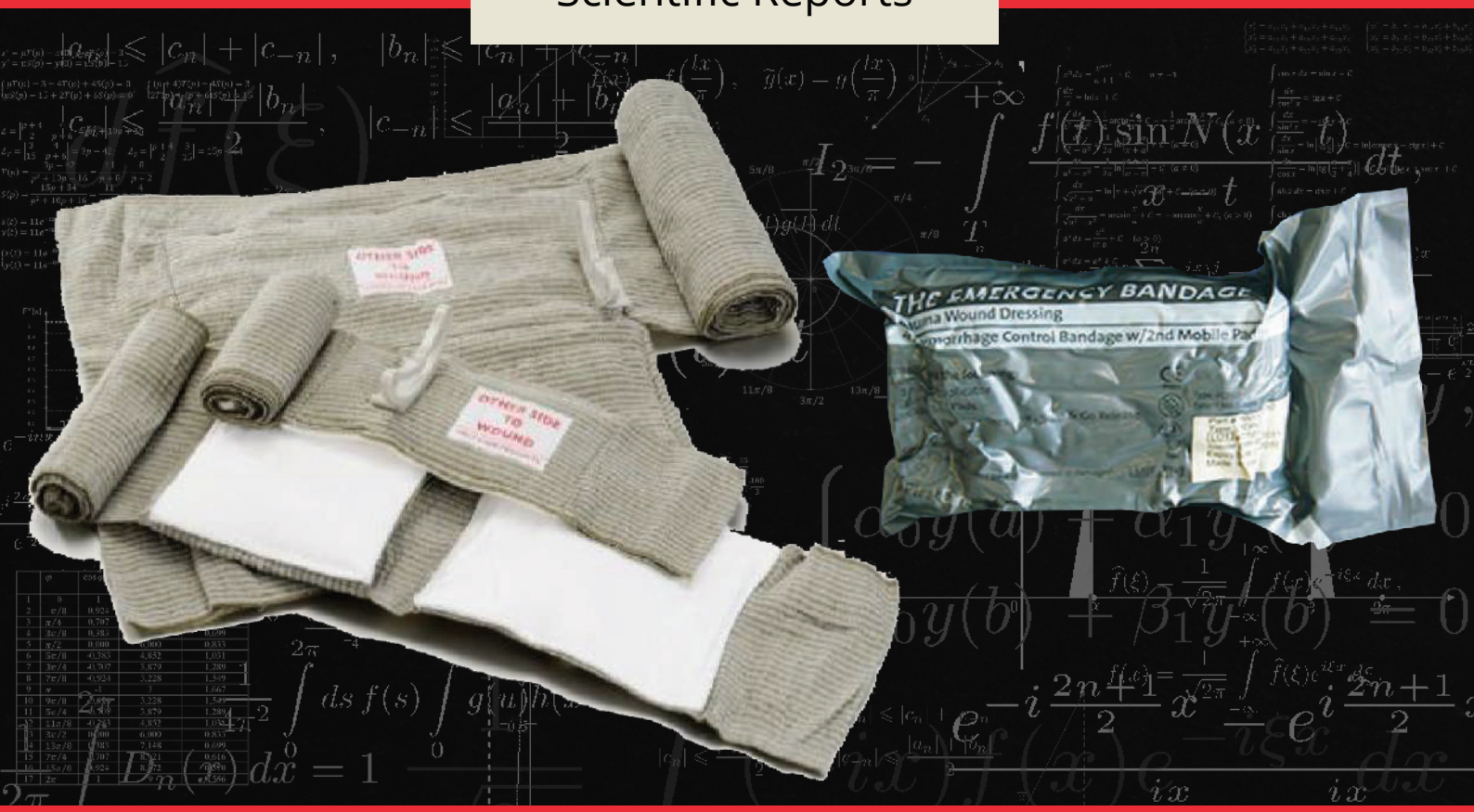
Emergency Compression Bandage

Scientific Reports



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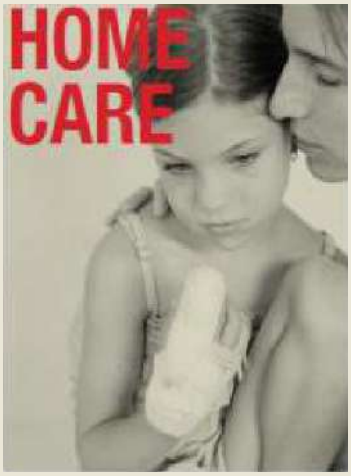

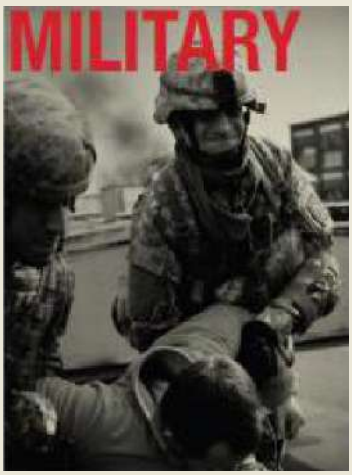

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Medihelp Healthcare Pvt. Ltd. 6052/1, D-6, Vasant Kunj, New Delhi-110070, India
Phone No. : 011-41055048, +91-9810005136 Email: medihelpindia@gmail.com



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Pressured Applied by the Emergency/Israeli Bandage

By
Charles S. Lessard, Ph.D.
Nolan Shipman, M.D.
Amanda Bickham
Jasper Butler

9 December 2007

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 90o, 180o, and 270o), 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

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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^{o}, 180^{o} and 270^{o} 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.

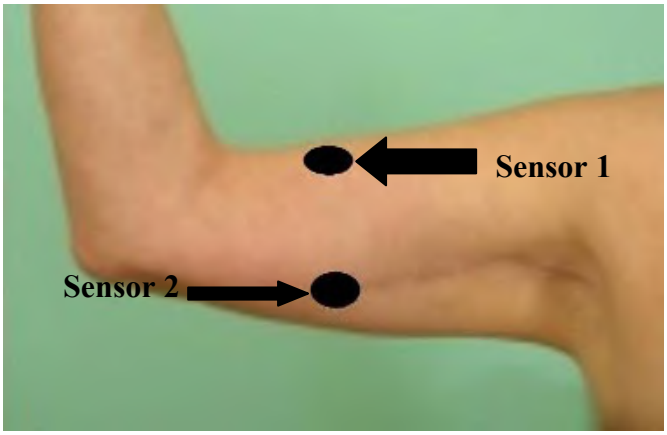

Figure 1. Major Superficial Muscles of the Upper Arm.

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 None-compliant tests without the pressure applicator (pressure bar),
2. Static None-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.

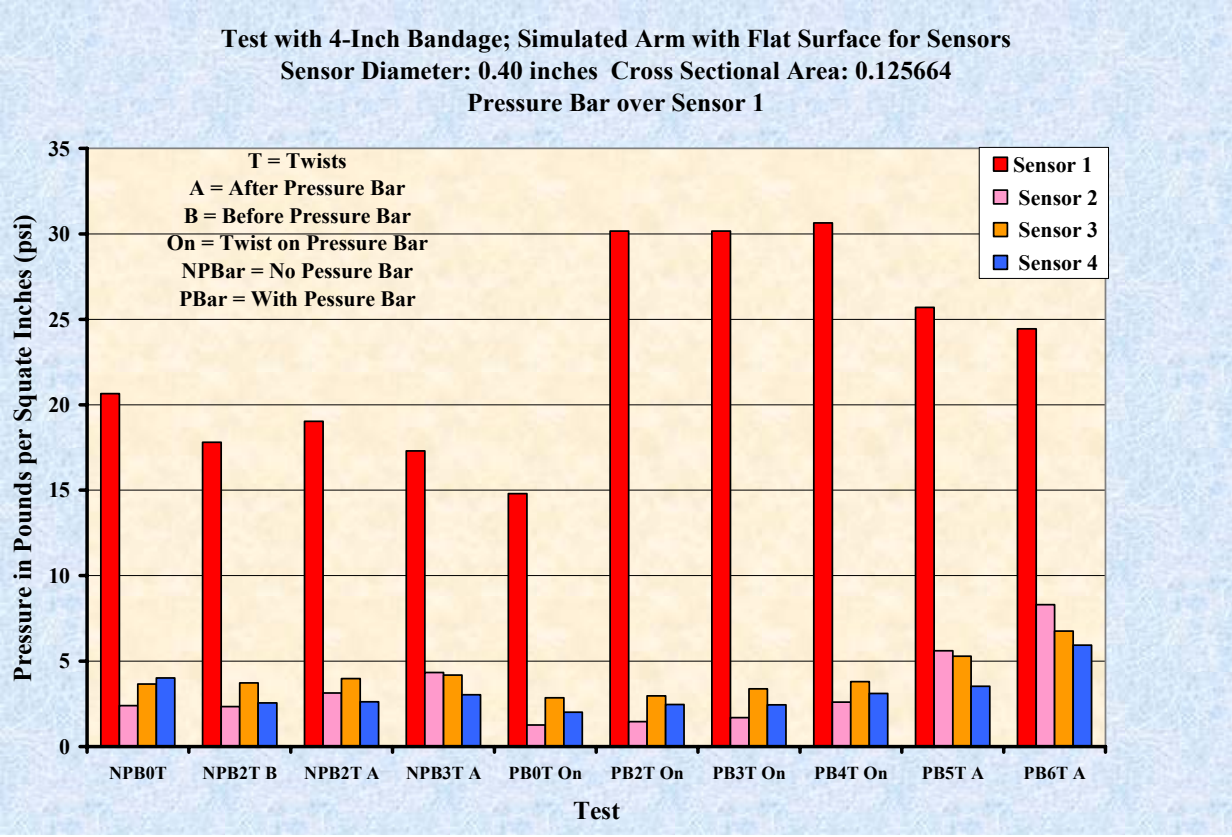

Figure 3. Bar chart showing the average (mean) pressures of the static test runs conducted with the 4-inch Emergency Bandage.

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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 form 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)

	Pressure in pounds per square inches			
Tests	**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 taunt 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.

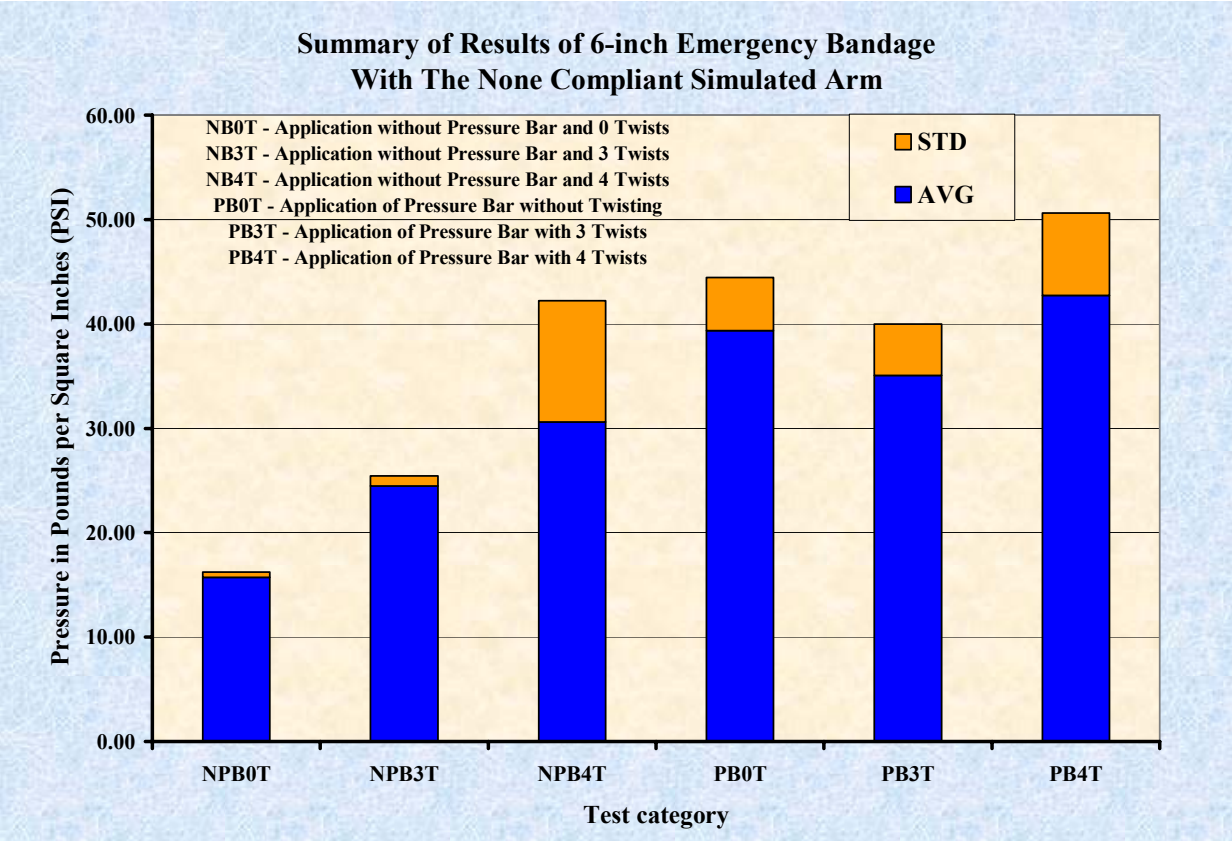

Figure 4. Bar graph of the averages (mean) and standard deviation of the static tests conducted with the 6-inch emergency bandage.

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

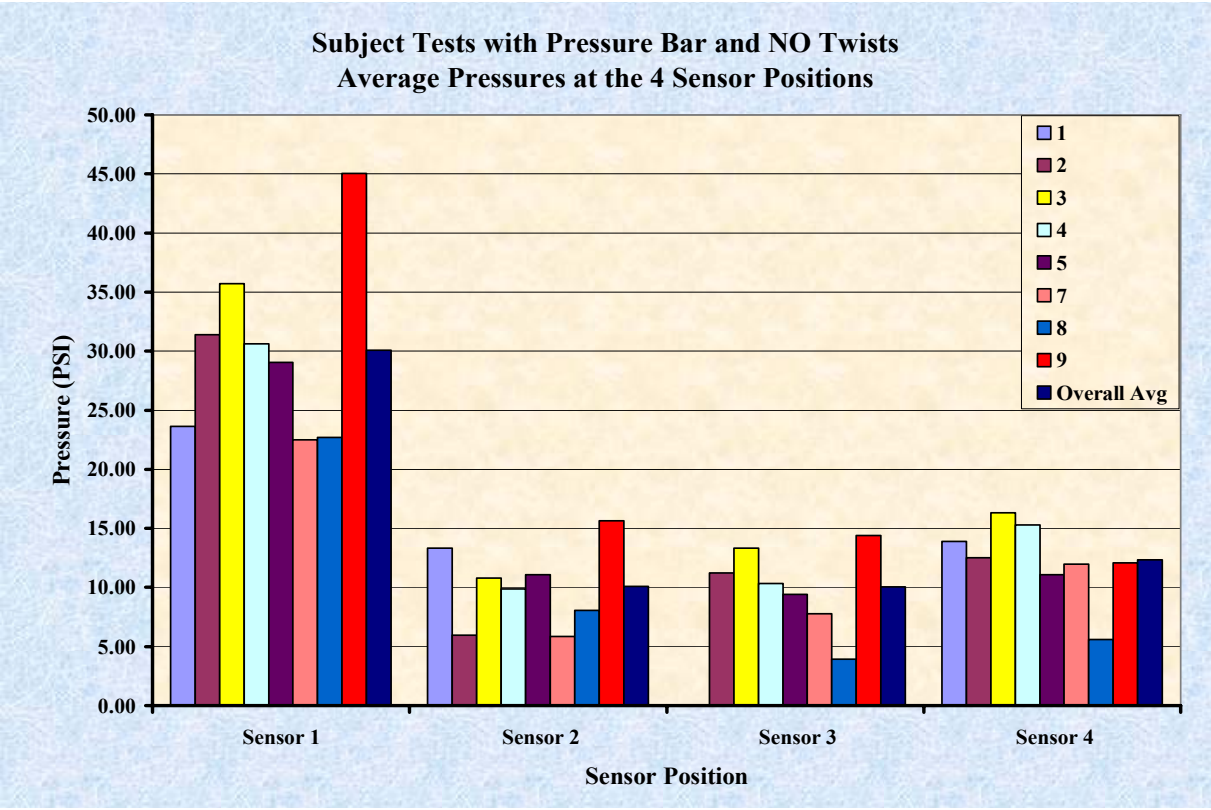

Figure 5. Subject Tests with Pressure Bar. Average Pressures at the 4 Sensor Positions.

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

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

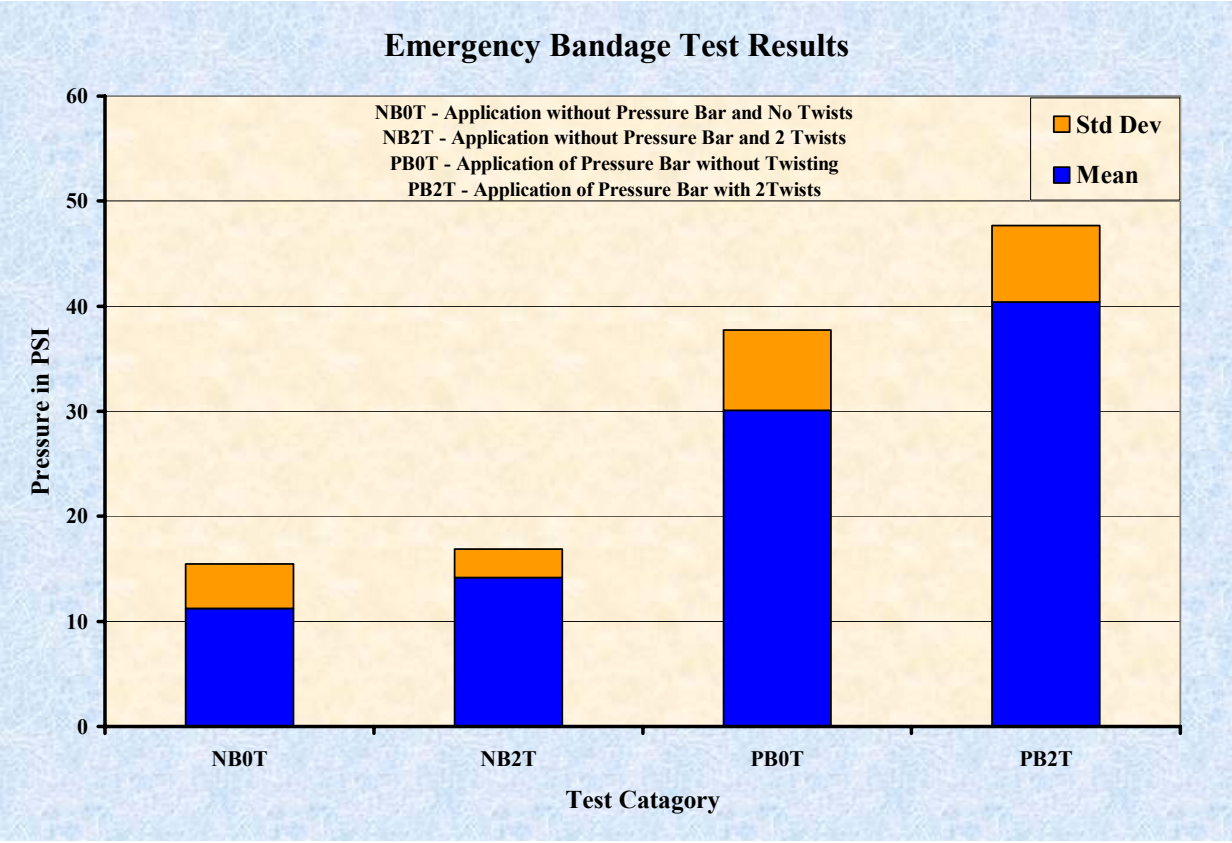

Figure 6. Summary of applied pressure (averages and standard deviation) for the subject tests runs conducted with the 6-inch Emergency Bandage.

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 rums 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 rums 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 α = 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 α = 0.05				
Test Variables	**Test #**	**By**	***P-value***	**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						
	Groups	***Count***	***Sum***	***Average***	***Variance***	
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**	
Source of Variation	***SS***	***df***	***MS***	***F***	***P-value***	***F crit***
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-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.

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GOOD STORY

Mass Casualty Incidents: The Pima County, Arizona, Sheriff's Department's Development and Use of Individual First Aid Kits

SUMMARY
The Pima County, Arizona, Sheriff's Department developed and distributes Individual First Aid Kits (IFAKs) to all deputies. These kits provide deputies with the necessary equipment to perform life-saving procedures in the minutes before emergency medical services personnel arrive on scene. Pima County Sheriff's deputies used the IFAKs after the January 8, 2011, mass shootings to treat the wounded. The IFAKs saved at least three lives on that day.

BACKGROUND
The Pima County Sheriff's Department purchased and distributed basic first-aid kits to all deputies. The kits contained supplies, such as bandages, from bulk packages that deputies could use to treat injuries to themselves or members of the public. However, the first-aid kits did not contain the materials necessary to treat serious injuries, such as gunshot or stab wounds.

Pima County is located in south central Arizona. The county had a population of 980,000 people in 2010, and it encompasses over 9,000 square miles. Tucson is the largest city in the county.

A Pima County Sheriff's Department Special Weapons and Tactics (SWAT) medic recognized that deputies needed advanced first-aid equipment and supplies. The SWAT medic observed that better first-aid kits could help reduce fatalities suffered by the Department and the public. These kits would be particularly valuable during incidents in areas of the county that are not near hospitals, some of which require a 35-minute air medical flight. The SWAT medic realized that deputies could employ some of the same supplies as combat medics to treat the injured in the "golden hour" and, thus, save lives in Pima County.

An IFAK's Contents

GOALS
IFAKs provide Pima County Sheriff's deputies with advanced first-aid equipment in a convenient, easy-to-access package, which enables them to treat injured individuals.

DESCRIPTION
The Pima County Sheriff's Department developed IFAKs and the training to augment the basic first-aid kits used by deputies. By the end of July 2010, all Pima County Sheriff's deputies had received IFAKs and the necessary training.

IFAK Development Process

The Pima County SWAT medic began development of the IFAK by evaluating off-the-shelf first-aid kits available through vendors. None of the vendor kits proved comparable to the kits used by combat medics in Afghanistan or Iraq. Consequently, the Pima County Sheriff's Department decided to develop its own IFAK. The SWAT medic consulted other jurisdictions throughout the U.S. to determine if any had undertaken a similar initiative, but none had. The medic collaborated with other SWAT-trained paramedics, emergency physicians, and a Pima County Sheriff's Department deputy who had been deployed to Afghanistan to determine the standard supplies and equipment that would be included in every IFAK.

IFAK Contents

The IFAK is designed to enable deputies to treat blunt force and penetrating trauma usually associated with traumatic gunshot and stab wounds. Every IFAK contains the following standard equipment and supplies:

- One tactical black nylon tourniquet;
- Two six-inch emergency military bandages pioneered by the Israeli Army;
- One Asherman chest seal that fits over a wound and has a valve that allows fluid to escape;
- One strip of Quick Clot combat gauze that coagulates blood on contact; and
- One pair of emergency medical technician shears that can slice victims' clothing.

The Sheriff's Department explored and sampled other types of medical equipment for inclusion in the IFAKs. However, it determined that the above combination of materials would achieve the goal of the program: namely, enabling deputies to treat gunshot and stab wounds successfully. Each IFAK includes $99.00 worth of supplies, 4 times the cost of the basic first-aid kits.

IFAK Training and Deployment

The Pima County Sheriff's Department developed a training program, entitled "The First Five Minutes," for deputies on the use of IFAKs. This training familiarizes deputies with the medical equipment and supplies in each IFAK and how to use them. The Department also provides annual IFAK refresher training for deputies. Further, the State of Arizona's Good Samaritan Law (32-1471) protects deputies from legal liability when using IFAKs or the basic first-aid kits to assist injured persons.

By July 2010, the Pima County Sheriff's Department had assembled 550 IFAKs, trained all personnel on their use, and deployed them in every departmental vehicle. The Department mandated that every IFAK be placed on the passenger headrest; this standard location was intended to ensure that deputies could access the IFAKs quickly and easily in an emergency.

January 8, 2011, Mass Shootings

On Saturday, January 8, 2011, at 10:10 a.m. Mountain Standard Time, a gunman opened fire on Representative Gabrielle Giffords and a group of citizens attending her "Congress on Your Corner" event in front of a Safeway supermarket in Tucson, Arizona. The gunman fired 31 rounds, killing 6 people and wounding Representative Giffords and 12 others. U.S. District Judge John M. Roll and Gabriel M. Zimmerman, a staff member for Representative Giffords, were among those killed. Citizens acted immediately to detain the gunman while Congressional staff and two doctors, who were shopping at the Safeway, provided first aid to the victims.

Pima County 9-1-1 operators received the first call from the incident scene at 10:11 a.m. A Pima County Sheriff's Department deputy arrived on site at 10:15 a.m. and detained the suspect; a second deputy arrived soon after and secured the shooter's weapon. As the incident site was being secured, Sheriff's Department deputies used IFAKs to administer first aid to survivors of the shooting in the six minutes before emergency medical services personnel entered the incident scene. Deputies used tourniquets and gauze in the IFAKs to stop bleeding, chest seals to close wounds, and shears to cut victims' clothes. The standard location of IFAKs in departmental vehicles enabled an Oro Valley police officer to quickly and easily locate a kit to provide first aid. An attending physician at University Medical Center examined the survivors and stated that the use of the IFAK chest seals saved the lives of at least three people.

Future Plans

After the Tucson shootings, the Pima County Sheriff's Department reviewed the use of IFAKs and assessed whether additional equipment or supplies should be included in the kits. The Department determined that the current composition of the kits is appropriate. However, the Department observed that some departmental personnel who responded to the incident were off-duty and arrived at the incident scene in their personal vehicles. Consequently, the Department has decided to provide each officer with an IFAK that can be placed in his or her personal vehicle. This will require the purchase of an additional 700 IFAKs.

Many departments and other organizations have considered adopting IFAKs and have contacted the Pima County Sheriff's Department. The Metropolitan Medical Response System in Tucson has adopted the IFAKs, and the Oro Valley Police Department has considered developing them as well.

Resources

Each IFAK's medical equipment and supplies cost $99.00. The Pima County Sheriff's Department developed 550 IFAKs for departmental vehicles and is in the process of developing an additional 700 kits for personal vehicles. The Department has funded the IFAK program through its general operating funds.

REQUIREMENTS

Keys to Success

IFAK Contents

The use of IFAKs after the Tucson mass shooting confirmed the Pima County Sheriff's Department's decisions regarding which medical equipment and supplies to include in each IFAK.

Standardization

The standardized IFAK contents and location in vehicles promotes familiarity and ease of use.

Training

"The First Five Minutes" training program helps to ensure that deputies are able to employ the IFAK equipment and supplies to save lives.

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FirstCare

First Care Products – Emergency Trauma Dressing –

Clinical Evaluation (Literature)

Written by: Amnon Hamdani – COO, First Care Product
Tali Hazan – R.A Independent Consultant.

Date: March 31, 2010

1. Purpose of the review

This document purpose is to demonstrate that ***First Care Products Emergency Trauma Dressing*** (also can be called: *"Bandage"* or *"Emergency Bandage"*) device, intended purposes and claims made in relation to safety and performance are achieved, as referred to in *First Care Products* technical documentation and that the device is clinically appropriate for its intended use.
This clinical evaluation was conducted according to the literature route and all clinical data was obtained from the published literature as well as *Firs t Care Products* long experience with these bandages.
This clinical evaluation was written with accordance to the Council Directive 93/42/EEC (2007/47/EEC amendment) Annex X and with accordance to MEDDEV 2.7.1 *Guidance document for Clinical Evaluation*, Rev 3, December 2009.

2. Device Description

First Care Products' Emergency Trauma Dressing is a line of products providing an optimal solution when emergency dressing is required in order to avoid unnecessary blood loss. It improves field hemorrhage control in both military combat casualties and civilians casualties.

According to US military statistics, more than half of all military combat deaths results from blood loss. According to US government statistics, blood loss resulting from trauma leads directly to the deaths of 50,000 civilians in the United States alone. By enabling focused pressure on the wound and maximal flexibility in manipulating the bandage *'Pressure Bar'* and *'Wrapping Leader'* it provides an easy to use solution when, naturally, used under extremely hard conditions. The *'closure system'* which is a built-in closure enables closing and stabilizing the bandage position only by sticking it into one of the bandage layers like a pen. There are two ends to secure the closure system but in most cases one end is sufficient to close and stabilize the bandage, protecting the wound until the casualty is evacuated. The built-in *closure system* save the need of using pins, clips, tape, Velcro or knots.
The bandage can be easily use with any type of traumatic wound injury in the body. Including amputation dressing, neck, head, entry/exit wounds, abdominal wounds and even for self application using the *'handle'* exists in the end of the wrapping leader.

The bandage is already commercially available in the market ever since 2004 and already became a standard of care in many of the military forces worldwide.

The bandage is provided sterile (SAL 10^{-6}) and packed individually in double sealed bags. The internal bag is vacuumed and in addition, packed in an outer sealed bag. This bag can also be used as **waterproof** when protecting the wound from water is required. It can be open up from any of the sealed sides, spread-out between one of the first dressing layers, and protect the wound from water. Both bags have **notches** for easy opening. The notches are designed to enable opening with one hand (when the notch is being held with the medic teeth), in case one hand of the medic is pressing the bleeding blood vessel.
The bandage is made of medical grade cotton and elastic wrapping leader which keeps its widths even if it is strongly pulled when tightening the bandage.
In some cases when blood vessel is damaged, due to the stability of the bandage and the pressure holding, casualty may continue walking after the wound was properly dressed and hemorrhage is controlled (see section 3.1.1 in more details).

According to the Medical Device Directive 93/42/EEC (and 2007/47/EEC amendment) classification rules, the device is classified as Class I, sterile.

First Care Products' Emergency Trauma Dressing **Intended Use** –
The device is a direct pressure Emergency Bandage intended to provide an innovative first-response in emergency combat injuries by enabling the improvement of serious hemorrhage control.

The device is therefore, provides a convenient, sterile and safe solution in emergency situations when blood loss is crucial.

3. **SELECTION CRITERIA FOR LITERATURE ARTICLES (issues to be discussed within this document) -**

   3.1 Scientific publication of similar products; including literature review, references sources and websites search key words.

   3.2 Clinical and Non-Clinical studies performed by *First Care Products* and another similar device.

   3.3 *First Care Products' Emergency Trauma Dressing* device and similar devices intended use and performances.

   3.4 *First Care Products' Emergency Trauma Dressing* Market feedback.

   3.5 Adverse events related to Emergency Trauma Dressing

Following is a specific reference for paragraphs 3.1 – 3.5 described above:

3.1) Scientific publication of similar products; including literature review, references sources and websites search key words – The ***Emergency Trauma Dressing*** bandages are commonly needed in battle fields or other sites when immediate medical assistance is required once critical injuries occur and require an immediate hemorrhage control in order to save the casualties lives. The use of a tourniquet is required when hemorrhage cannot be stopped by applying pressure on the wound. The Tourniquet may stop the bleeding beyond the injured site but many times the limb beneath the tourniquet tie will be damaged or lost due to the lack of blood flow. The dressing solutions which are based on activating local pressure on the bleeding area and thus stop the bleeding and in the same time allow blood flow along the injured body site, are available in the market ever since 1942. Yet, there are only few types of bandages which are utilizing old and non-modern techniques.
Other device recently placed in the market (see sub-section 3.1b below) provides some improvements comparing to the old 1942 bandage but still, share some of the old non-state-of-the-art elements.

First Care Products' has developed the *Emergency Trauma Dressing* which provides a state of the art solution based on the same old techniques, of constant pressure on the wound, yet it is much more usable, modern and not requiring improvisations during treatment. The product contains all accessories required for the dressing procedure as built-in instruments and keeping the bandage as clean as possible when opened for use. It is already acknowledged as current **'standard of care'** within the US, UK, NATO (Germany, Netherland, France, etc) and Israeli military forces (see reference 6.2 of this document).

The most common similar products currently available in the market, except for ***First Care Products' Emergency Trauma Dressing*** and that are being used for the same intended purpose are hereby identified:

a) First Field Dressing (old 1942 bandage and earlier).
b) OLAES Modular Bandage made by Tactical Medical solutions, USA.

These already existing devices were used as the base for the scientific publications search to support our device.

The ***"First Field Dressing"*** bandage which exist ever since 1942 and even earlier (as could be traced in the written literature) is the oldest dressing solution. It was the standard care for many years and it provides a limited solution when used.

According to the *Science Museum* *in London, exploring the history of medicine (see ref number 6.1); "Back on 1916, soldiers of nearly all the nations involved in the First World War would be expected to carry a so-called First Field Dressing or an equivalent. This was a basic emergency first aid kit consisting of a length of gauze, a small bandage pad, a safety pin and an ampoule of iodine (later replaced by a mild antiseptic). The kit was carried in a waterproof cover...."*

We shall address each similar device in relation to our ***Emergency Bandage***.

a) ***First Field Dressing*** **(old 1942 bandage)** – This bandage is almost the oldest bandage available. It uses elementary features to perform wound dressing. It can create some level of pressure but it is not always sufficient and controlled. In addition, if the bandage is pulled strongly as sometimes necessary to create the required pressure on the wound, it can turn into an unwanted tourniquet. It has some accessories which are provided with the device but are not 'built-in' the device. Therefore, under the intense treatment in battle field, components might be hard to find or manipulate. Metal components such as clips and staples might be problematic when casualty is being evacuated and required an urgent MRI screening.

First Care Products has conducted a **comparison** evaluation between the old ***first field dressing*** (from 1942) and our ***Emergency Bandage.***
The comparison showed that our product provides many advantages especially with regards to the **wrapping leader** length together with the flexible cloth type. While the ***First Field Dressing*** cloth type (gauze or muslin), might create a tourniquet when pulled and pressured, ***First Care Emergency Bandage*** is made by a non-woven non-adherent 70% cotton and 30% polyamide which provides a flexible wrapping leader which gets stretched when pulled but does not get thinner (rope like) and keeps covering the wound surface leaving additional margins above and under the wound for additional protection without acting as a tourniquet. If the pressure applied would not sufficiently stopped the bleeding, blood signs will be shown on the bandage margins and make the sign to increase the pressure using the **pressure bar**. The wrapping leader is rounded and hold in a way that if falls from the medic hand, it will not open out on the ground but will stay round.
First Field Dressing still requires looking for a stick to be used as a pressure bar, and if the rolled wrapping leader shall fall from the medic hand, it shall open on the ground and get contaminated. The ***First Care Emergency Bandage*** **non-adherent cloth** provides a bandage with no loose threads, gauze and cotton fibers to become involved in the wound. It prevents the wound from being re-opened upon removal of the bandage and thus expedites wound healing and avoids additional unnecessary pain. ***First Field Dressing*** is made of gauze or muslin, and thus may be involved in the wound and will cause pain and reopening of the wound when bandage is removed.
The **pressure** activated directly and homogeneously on the wound helps to control the hemorrhage and will not result in an unwanted tourniquet if pulled too tight.
The pad surface of the *Emergency Bandage* is available in variety of sizes and can be used on any site of the body, covering any type of wound.
Unlike ***First Field Dressing, First Care Products' Emergency Bandage*** has a built-in **pressure bar** which saves the time of finding and fixing a stick or an alternative bar to increase the pressure on the wound. It also has a built-in **closure system** which saves the time of finding a clip or staple for closing and stabilizing the bandage in place.
The **double waterproofing** of ***First Care Products' Emergency Bandage*** is achieved from both sides of the package while the ***First Field Dressing*** product is waterproof only from the external side.

Unlike the old *First Field Dressing* bandage, *First Care Products' Emergency Bandage* has an internal and external **vacuum packed** according to current military specifications. It has **4 opening notches** for easier opening instead of only one in the comparative product.
***First Care Products* has also conducted a comparison between the**

b) ***OLAES Modular Bandage* made by Tactical Medical solutions -** This bandage is newer in the market and still it has some elements which are similar to ***First Care Products'*** *Emergency Bandage* but other useful elements are not included.
The *OLAES Modular Bandage* has two **fixed pads** to wrap an entry/exit wound from its both sides, while in *First Care Products' Emergency Bandage* one **pad can be maneuvered** along the wrapping leader so in case of an entry/exit wound, the fixed pad can be placed on the entry wound and the maneuverable pad can be adjusted and placed exactly on the other side of the wound (depends on the body site and the wrapping leader length required), cover and protect it entirely. The additional maneuverable pad can also be removed from the wrapping leader and used as a "**packing**" (pushing the pad into the wound) for open and deep wound is treated.
Behind the pad, the ***OLAES Modular Bandage*** is made of a three meters of gauze fibers that may become involved in the wound causing pain and reopening the wound when the gauze is removed. ***First Care Products' Emergency Bandage*** pads made of medical grade cotton and are firmly stitched to the bandage on all four sides. No interference of loose fibers in the wound is possible.
While ***First Care Products' Emergency Bandage*** is designed to create an immediate and **direct pressure** exerted on the wound through the pad by the pressure bar (until it functions as a tourniquet if bleeding doesn't stop), the ***OLAES Modular Bandage*** has a limited 4cm*4cm pressure on the wound and no additional pressure can be achieved.
The **closure system/bar** in *OLAES Bandage* is not a built in component like in *First Care products Emergency Bandage.* Therefore, it can be lost during treatment. *OLAES* has also a Velcro used for closure. Yet, Velcro when get wet - may not work well since the fluid softens it. *OLAES Bandage* is vacuumed only in the inner package while *First Care Products* provides a double vacuumed package sealed to water and gas and serves as waterproofing.
All *First Care Products Emergency Bandage* accessories are made of plastic and therefore, no limitation if an immediate **X-Ray** is required. There is no need to spend time on removing pins and staples.

The length and flexibility provided by *First Care Products Emergency Bandage* enables to perform an effective banding on every site of the body. It can be therefore, shown from every functional aspect that the device is superior over the existing similar most common devices.

3.1.1 Published Literature - Many articles and published literature has been described the pressured emergency bandages. These articles naturally are

focused on military experience from battle fields where these kinds of bandages are most commonly supplied and being actually used.
More published information also found in professional websites and in the manufacturers publications.

Some of the articles and publications discussing our *Emergency Bandages* and similar devices are hereby described:

3.1.1.1 The ***US Army Medical Department Center*** has published the *"Tactical Combat Casualty Care and Wound Treatment"* sub course. Section '***e.***' in page 2-5 of this document, specifically refers to the Emergency Trauma Dressing, saying:

> *"The emergency trauma dressing, sometimes called the "Israeli Dressing", is a combination dressing and compression bandage that incorporates a pressure applying locking bar and elastic bandage.... This allows a great deal of pressure to be applied directly to the wound. .... The emergency trauma dressing is part of the improved first aid kit ... that is replacing the first aid kit...."*

The First Care Products emergency bandage was adopted by the US army as a 'standard of care'. The referenced document can be found in section 6.2.

3.1.1.2 ***NATO organization*** has published a research comparing compression bandages against tourniquet with 68 patients injured with traumatic amputation after mine injuries. The highest priority was to stop the external hemorrhage and the method of measuring this was by measuring the mortality level among these casualties and measuring the hemoglobin levels and number of transfusions required during treatment.
It was shown that in all parameters the casualties that were treated with compression bandages had lower mortality numbers, less transfusions were required to stabilize them and hemoglobin levels were higher. These data are presented tables number 1, 2 and 3 in the research. See paragraph 6.3 of this document.
The conclusion of this research was therefore that:

> *"Tourniquet has no place in the treatment of hemorrhaging in traumatic amputations after mine injuries. A tight compressing bandage should be applied from distal end and in proximal direction."*

3.1.1.3 ***Homeland Security Europe*** has published an interview with Bernard Bar-Natan who is the founder and ECO of First Care Products and the developer of the Emergency Trauma Dressing. Mr. Bar-Natan was served in the Israeli Defense Forces (IDF) as a Combat Infantry Medic himself. Afterwards he was in reserved servise for another 20 years. He used his wide experience to develope the pressure bandage that would be the most effective and that will provide solutions wherever they were missed.
In an answer to a question Mr. Bar-Natan was asked about: *"what sort of research goes into developing and producing your bandage products?"*
The answer was: *"The Emergency Bandage is the result of my training and experiences as a combat infantry medic in the IDF Reservers for more than 20 years and the product of extensive research. Each country where the Emergency Bandage is used received detailed and extensive training and then conducted trials and evaluations of the product. In each case, the test results were always positive".*
According to Mr. Bar-Natan, the *Emergency Bandage* is being provided to the Belgian and Frence Special Forces served in Bosnia in 1998, to the US Special forces serving in Afganistan and Iraq, also UK forces in Afganistan uses *FirstCare Products Emergency Bandages* as well as, German, Italian, Duch, Baltic States and many other forces in their international activities. The *FirstCare Prodcts Emergency Bandages* are the default bandages for every active duty soldier in the IDF.

The article is referenced in section 6.4 and the full version can be found in **Appendix A** of this Document.

3.1.1.4 The Tactical Edge Magazine has published an article presenting the *Tactical casualty care innovations; news from Iraq*.
The article describes the innovative method developed in time in battle casualties' treatment. It specifically refers to First Care products ***emergency bandage*** advantages in the battle field:

• **The Emergency Bandage ("Israeli Combat Dressing").** This is an improved version of the individual military field dressing that is in common use with the U.S. military. It consists of a thick absorbent gauze pad that is applied next to the wound and an elastic bandage that holds the dressing in place. In addition, there is a flattened D-shaped plastic bar into which the elastic bandage can be placed to allow the dressing to be tightened, making it a very effective pressure dressing (Figures 9 and 10). The remaining length of the elastic dressing is then applied over the plastic bar.

The dressing stays in place much better than the old military combat dressing, which would often loosen as the fabric stretched. The elastic portion of The Emergency Bandage is similar to what many of us have used for combat dressings: kerlex gauze and an ace wrap, but in a flat self-contained package. It is much easier to apply to head wounds and other awkward anatomical locations than the traditional combat dressing.

Red underline was added by the clinical evaluation writer.

The article is referenced in section 6.5 and the full version can be found in **Appendix B** of this Document.

3.1.1.5 One of the main daily newspapers in Israel (Ma'ariv) has published pictures if injured IDF soldiers evacuated in real time, back on December 2008, from a battle zone.
One of the highest advantages of First Care Products emergency bandage is hereby demonstrated in real clinical situation where the soldiers can be showed walking when their wounds are being dressed with the Emergency Bandage.

Enlarged focus on First Care Products Emergency Bandage

3.1.1.6 The *Tactical Medicine Magazine* has also published an article about the most crucial aspects of emergency casualties' treatment. In the article *"Stop the Bleeding!"* - In this article, the writer (Lawrence E. Heiskell, MD) refers to the emergency bandage:

> *"The Emergency Bandage, Trauma Wound Dressing is an improved version of the time-honored battlefield dressing. This sterile, non-adherent bandage applies pressure to any site, is easily wrapped, secured and can act as a tourniquet in cases of severe bleeding. The beauty of this product is that the bandage can be applied to the head, armpit or groin for control of hemorrhage in these difficult areas."*

The writer also screens some other innovative solutions involving with drugs or blood clotting agents in order to expedite blood homeostasis. He raised some questions claiming that not always sufficient information is available in the literature and that there are conflicting reports about these emergency dressing solutions.

Discussion - Being *First Care Products' Emergency Bandage* acknowledged as a "standard of care" within active military forces such as Nato, US, UK, IDF etc,

in many combat zones, may provide sufficient assurance that *First Care Products Emergency Bandage* is clinically effective not only according to its developer and producer claims but mainly based on wide practical experience in the field.
As can be shown in the above scientific published literature by NATO, US Army, Tactical Medicine and Homeland Security Europe magazines, the direct pressure method for hemorrhage control is the most effective and the *Emergency Bandage* functional advantages make it the first choice of medics in the field.

We believe that the information provided within the above articles and publication provides sufficient data regarding the Emergency Bandage clinically effective for its intended use.

The **websites** we looked at, during these published information searches are: *PubMed (no findings), Medline (no findings), Medscape (webMD/CDC) (no findings), FDA, CDRH (no findings), US Army website, NATO website, Tactical-Life website and Firstcare-Products website.*

Keywords searched are as follows: *Pressure, Bandage"* (each word separately and the sentence as a whole), *"Hemorrhage", "Trauma injury/injuries", "Bleeding", "Dressing", "First Aid/Response/Field".*

Other informative publications from newspapers (such as the newspaper pictures) were collected and provided by *First Care Products.*

3.2 Clinical and Non-Clinical studies – Non-Clinical studies have been performed by ***First Care Products*** as well as comparison analysis performed by ***First Care Products*** (as described in section 3.1 above).
A formal clinical study of the bandage was not performed yet, **clinical experience** is widely known. Being the bandage recognized as 'standard of care' in many highly active military forces worldwide ever since 2004, when it was launched, and the positive market feedbacks (see also section 3.4 of this document) may teach that this emergency bandage is solidly clinically proved for its intended purpose.
The fact that army medicine centers that actually have the widest experience in field with other emergency pressure bandages and with variety of injuries, practically chose to replace old bandages with *First Care Products* Emergency Bandage, teaches the most about the significant advantages this bandage has in the clinical practice for both the medic and the casualty.

It should be emphasized that *First Care Products Emergency Bandage* has a long clinical use as it is already in the market for about 6 years with increasing orders of both military forces and civilian Emergency Medical Service (EMS).

<u>Tests and Technical data to support safe use of the device</u> –

3.2.1 Material used - The material selected to be used for our *Emergency Bandage* is 70% cotton and 30% Polyimide. The bandage's material was

evaluated under ISO 10993-1 standard referring to *Biological evaluation of medical devices*. It was evaluated for *Cytotoxicity*, *Sensitization* and *Skin Irritation*.
All results met the tests' acceptance criteria and passed successfully.

Material mechanical strength - All plastic components are made of medical grade plastics (PC 122) which demonstrated stability and the required strength when manipulated in the field.
The bandage itself showed that even if strongly pulled, it shall not be torn or unstitched, the pad shall remain hold firmly and will not deform and the wrapping leader shall not change its wideness and will not become "rope-like".

The information concerning product's materials' biocompatibility and mechanical performances was provided in the device's technical documentation.

3.2.2 Sterilization - The *Emergency Bandage* is provided sterile by Gamma Irradiation. The bandage is going through ETO sterilization as a pre-sterilization treatment in order to reduce bioburden, naturally exist in high levels on cotton products. Only after this pre-sterilization treatment, final Gamma Irradiation sterilization, under VDmax 25kGy, is taking place assuring SAL 10^{-6}.
The single unit double bag pouch is sealed against penetration of bacterium and water.

The information concerning sterilization and bacterial/water barrier package also provided in the device's technical documentation.

3.2.3 Dimensions – The *Emergency Bandages* are available in a variety of dimensions which were all identified, adjusted to the different types of injuries and are in-process inspected.

The information about available dimensions was provided in the device's technical documentation. The information is also available in **Appendix C** of this clinical evaluation.

3.2.4 Pressure level – The *Emergency Bandage* can apply minimum 30 PSI pressure on the opened wound.

The performances information about pressure application was provided within the technical documentation.

3.2.5 Environmental conditions – The *Emergency Bandage* performances were evaluated under extreme conditions. It was exposed temperature between -40°C to +60°C and tested according to its specification and intended use.

The bandage was performed according to its specifications under these conditions. The performances information was provided within the technical file.

As described above and as demonstrated in *First Care Products* technical documentation, all V&V (Verification and Validation) activities were performed in order to establish the safe use of the device and its performances according to its specifications and clinical intended use/purpose.

3.3 *First Care Products Emergency Bandage* and similar devices intended use and performances – *First Care Products Emergency Bandage* is basically similar to number of existing similar products already available in the market as identified in paragraph 3.1 above. The table below summarizes the similarities and differences as follows:

Criteria	Grading	Explanation
Same or similar product?	Similar device	Use the principle of wound dressing using direct pressure for hemorrhage control.
Same indication?	Same indications	Better performances and ease of use.
Intended for the same subject population?	Same population	--

As can be shown above, the *Emergency Bandage* developed and produced by *First Care Products* is providing an innovative first-response solution which save lives by improving field hemorrhage control and also yield significant saving in time and resources.
This unique mechanism of direct pressure is, clinically proven and has been successfully adopted by military and civilian organizations worldwide.

3.4 Market feedback to *First Care Products Emergency Bandage* – Along the years the device is used in the market, post marketing activities yielded satisfactory results related to its quality, performances and meeting customers' requirements and expectations.

Between the years of 2005 to the end of 2009 almost 8,000,000 units were sold worldwide.

Market feedbacks from territories were the device is being sold was received whether in the formal professional medic route by the organizations and many times as letters from injured casualties and even from their family members.

Some of these feedbacks can be found section 6.8 of this document.

Additional "market feedbacks" are hereby presented in the next pages:

3.4.1 A feedback letter received from a police Sergeant and high-risk patrol tactics trainer from Nebraska, USA on September 2007, stated:

"I am a police Sergeant and high-risk patrol tactics trainer. In all courses I teach, and especially during Rapid Deployment to the School House Shooter, I strongly recommend that officers carry at least one Israeli bandage with them for treating their own wounds and wounds of others. We simulate an injured officer so students in the course can fully realize what they are up against and how best to control trauma in rapid time. I am writing to see if First Care would consider gifting any amount of bandages to the training. I will put them into the officer's hands so that they can use them during the course. Many of the attendees are in a position to make purchasing recommendations to their agencies so I would be glad to distribute any marketing materials you would care to include.

I might mention that I am also an advanced life support-Paramedic and find this bandage one of the best pieces of equipment I have seen lately in emergency care of trauma patients.

Matthew Jarvis
3212 Rahn Blvd
Bellevue, NE 68123-2640
Phone 402-630-1600"

3.4.2 Following next page, a feedback letter sent from Borough of North Arlington, Department of Police to Chief of Belleville Police Department, after using the Emergency Bandage in one of their casualties by "applying a Israeli Combat Bandage"**:**

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BOROUGH OF NORTH ARLINGTON
Department of Police
214 Ridge Road
North Arlington, NJ 07031
Phone (201) 991-4400 Fax (201) 991-4068

May 15, 2007

Chief Joseph P. Rotonda
Belleville Police Department
152 Washington Avenue
Belleville N.J. 07109-2541

Dear Sir:

I am writing to thank you and Police Officer John Shaw for his outstanding performance that proved to be critical in saving the life of a local resident. On May 12, 2007 North Arlington Police Officers responded to a report of a male with a severe arm laceration. Upon arriving at the call location, North Arlington Officers were informed that the patent ran from the scene. A subsequent call from the Arlington Diner reported the male was in the parking lot.

Officer Shaw was in the parking lot and immediately administered first aid. I'm told the doctors at University Hospital along with Emergency Medical Technicians credit Officer Shaw with saving the life of the patent by applying a Israeli Combat Bandage.

Please thank Police Officer Shaw in behalf of North Arlington. The young adult's family and he are deeply indebted to your department.

Sincerely,

Louis M. Ghione
Chief of Police

3.4.3 Following is a feedback email sent from a police tactical officer experiencing First Care Products Emergency Bandage:

From: *Eric Armstrong [mailto:earmstrong@auburnwa.gov]*
Sent: *Thursday, November 15, 2007 8:31 PM*
To: *info@firstcareproducts.com*
Subject: *VIA FCP WEBSITE: REQUEST FOR INFORMATION*

Good Morning,

I'm Eric Armstrong with the Auburn Police Department. I am a tactical officer with the agency. I recently used you bandages is some foreign distant land in South East Asia. I brought back all the wonderful experience back to my agency and requested we get these bandages for our operators.

I'm looking to purchase "The Emergency Bandage" Can you give me an approximate cost for 30?

Eric Armstrong
Auburn Police Department

3.4.4 Feedback email received in First Care Products website by an accident casualty who managed to treat himself:

Full Name: Richard Fullmer
Email: fullmer49@msn.com
Company Name:
Phone: 540-869-6395
Country: United States
Comments: A couple of years ago I was sent to Afghanistan to do some hospital construction. One of the items I was given in my first aid kit was one of your compression bandages (part # FCP-01 stock # 6510-01-460-0849). Yesterday I had a chance to see how well the worked. I was doing some wood carving and somehow managed to push one of my chisels into my wrist. In the process I punctured a vein. Lots of blood coming out real fast. I manage to loose about a pint before I got your bandage on. When I finally applied the bandage I was able to accomplish it with one hand. The bleeding slowed immediately and stopped completely before I could get to medical help. Later in ER when they removed the bandage the wound was clean and sealed while the bandage was removed without sticking. I can compare your bandage to the one I was given in the 1970's and 1980's when I was on active duty. I have now used both in trauma situations and while I would prefer not to have the occasion to use either, yours is so much better the the original. I don't know how many lives your bandages have saved but I want to thank you for each one, especially mine.

RAF

3.4.5 Feedback email received in *First Care Products* website by a Norway trainee:

From: *Bård Erik Nilsson [mailto:bard.erik@mac.com]*
Sent: *Friday, October 31, 2008 8:15 AM*
To: *info@ps-med.com*
Subject: *how do i order?*

Hi! Greetings form Norway!
I have trained with your combat/ or as we call it; "Israeli Combat dressing", I actually don't know why? Did the Israeli Defense forces develop the concept?
My experience so far; I would never go out in the field without the "Israeli Combat dressing"
Do you have any distributors in Norway?

Is there a web shop for ordering? Or is there enough with a mail?

Mvh

Bård Erik Nilsson
Hoffsveien 6A
0275 OSLO

(0047)992 64 247
bard.erik@mac.com

3.4.6 Acknowledgment letter received from the United Rescue (Hatzala) of Israel:

From: United Hatzalah [mailto:daniel@israelife.org]
Sent: Thursday, July 31, 2008 6:05 PM
To: Bernard Bar-Natan
Subject: United Hatzalah of Israel- July 31 2008

Dear Friends and Supporters,

This week we get a report from Jerusalem of a lifesaving hero from the fire department who was treated by the United Hatzalah volunteers from Neve Yaakov and Pisgat Zeev. We also look behind the headlines and behind the scenes at some volunteers and the work they do when they don the uniforms in the IDF.

Additionally, I want to point out some of the prevention and safety issues our teams are working on with various government agencies. I hope to share with you samples of the campaigns after they hit the street. Lastly, we focus on a lifesaving pressure bandage developed by a former IDF combat infantry medic now being supplied to special forces units around the globe.

Have a great week,

Eli Beer
Chief Coordinator
United Hatzalah

3.4.7 Medics Personnel wrote to First Care Products:

a) *"During the war the bandage performed spectacularly... Every medic in my unit had them in his aid bag... After seeing it in action, my chain of command is sold on your dressing, as I knew they would be. We will continue to use it as my unit's primary trauma dressing, replacing the standard field dressing." (M. N.)*

b) *"We used your bandages in IRAQ and it proved to be a life saver. We are looking to incorporate this into our disaster plan, and possible into our search and rescue units." (J. C.)*

c) *"To those I have exposed the bandage too this past week, they have been overwhelmingly amazed and interested in its ease of use and function. I found it interesting in just how quickly 'non medical' personnel were able to adapt to the new bandage and use it properly." (W. M.)*

d) *"We just de briefed from Seal Team 3, it seems your dressing was a big hit in Afghanistan... All our Seal platoons will now deploy with your dressing!" (C. B.)*

e) *"As of 10 December 2002 the Emergency Trauma Dressing is the official primary battle dressing for the 75th Ranger Regiment, United States Special Operations Command. The Emergency Trauma Dressing was selected by our staff as the "Best in Class" based on manufacturing, effectiveness, ease of use and price." (R. M.)*

f) *"Dep. L. spent only four days in the hospital ..., but your bandage was a god's sent for me on that night. I am now working on issuing the SWAT team one each of these bandages as standard equipment for their first aid kit they are required to carry." (P. R.)*

g) *"I carried your products when I was deployed to Afghanistan. When a friend of mine who is on our department's SWAT Team asked me for my opinion on the best trauma bandage I pulled out one of your bandages that I still carry with me and showed him how they worked. He said 'Great, get me 100 of them.'" (S. M.)*

3.5 Adverse events related to Emergency Trauma Dressing –

We have reviewed the FDA, DCRH database for adverse events or/or recalls related to similar products identified in this document and others, sharing the same intended use, in order to seek for potential safety or quality issues might be relevant to our *Emergency Bandage*, and mitigating them.

There were no complaints or adverse events reported to *First Care Products* in the last 5 years.

No relevant adverse events were detected with regards to Emergency wound dressing available in the market, either of *First Care Products* or others'.

5. **Data analysis and Conclusions** – As can be shown in the above data and information presented, *First Care Products* has undergo a wide and thorough evaluation and testing in order to establish its suitability to perform under its clinical use as intended.

   It is clear from the information presented in this clinical evaluation that *First Care Products Emergency Bandage* is as good and even better in comparison to other similar products currently available in the market.

   According all evidences; written literature, publications, field experience and market feedbacks, it can be shown that the *Emergency Bandage* developed and manufactured by *First Care Products* is the most beneficial product in its category.

   The product, developed by *Bernard Bar-Natan* based on his practical experience of more than 20 years as a combat medic. This *Emergency Bandage* provides a comprehensive solution helps to control hemorrhage which is the most crucial situation in traumatic injuries, causing more than 50% of deaths after such injuries.

   The *Emergency Bandage* was found highly effective as a first response to casualties. It performs well in every aspect other bandages do-not such as; applying highest effective direct pressure on the wound without the need to improvise solutions in the field and without using tourniquet when unnecessary. The bandage contains built-in pressure bar and closure system all made of plastic, so easy manipulation and closure are possible and whenever immediate MRI is required, it can be performed without any delay. Pad and wrapping leader materials are made of medical grade non-woven and non-adherent that can not be involved in the wound and cause unnecessary pain or reopening of the wound when bandage is removed. Flexibility of the bandage during use enables dressing every injured part of the body.

   First Care Products Emergency Bandage was acknowledged as a 'standard of care' in the majority of military forces and civilian Emergency Medical Services worldwide. As such, it is exposed to high numbers of clinical situations required hemorrhage control after traumatic injuries. Many of the market feedbacks actually acknowledge this bandage a 'lifesaving product'.

   In the light of the above, we believe that we have presented sufficient clinical data, medics professionals' inputs and market feedbacks to conclude that *First Care Products Emergency Bandage* is safe for human use according to its intended use.

6. References:

6.1 *Science Museum London, Exploring the History of Medicine* (link can be found at: http://www.sciencemuseum.org.uk/broughttolife/objects/display.aspx?id=5575.

6.2 *Tactical Combat Casualty care and Wound Treatment,* Sub course MD0554, Edition 200 by the *U.S army Medical Department Center* and *School Fort Sam Houston, Texas.* (link can be found at: http://www.scribd.com/doc/3193263/MD0554-TACTICAL-COMBAT-CASUALTY-CARE-AND-WOUND-TREATMENT)

6.3 *Compression Bandage, not Tourniquet. Experience in 68 Patients with Traumatic Amputation after Mine Injuries,* by *LtCol Johan Pillgram-Larsen, MD, Chief Consultant in Surgery, Ulleval University Hospital, Oslo, Norway. (link can be found at:* http://ftp.rta.nato.int/public/Pubfulltext/RTO/MP/RTO-MP-HFM-109///MP-HFM-109-02.pdf).

6.4 *Emergency Care article (HSE speaks with Bernard Bar-Natan... about the company's Emergency Bandage product, a unique innovation in battlefield care),* by *HSE (Homeland Security Europe) Magazine. August 2007.*

6.5 *Tactical casualty care innovations: News from Iraq*, by *Michael Madsen from the Tactical Edge Magazine* (winter 2006).

6.6 *Casualties' evacuation after wound dressing, Ma'ariv (Israeli daily Newspaper), December* 2008.

6.7 Stop The Bleeding!, by Lawrence E. Heiskell, MD from the *Tactical Medicine* Magazine (link can be found at: http://www.tactical-life.com/online/tactical-weapons/stop-the-bleeding/)

6.8 Market Feedback - Testimonials (link can be found at: http://www.firstcareproducts.com/apage/2128.php)

First Care Products' Approvals and Signatures:

Name	*Job Title*	*Signature*	*Date*
Bernard Bar-Natan	*Founder and CEO*		7/Jan/2010
Amnon Hamdani	*COO*		7/1/2010

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APPENDIX A

First Care Products' Clinical Evaluation

Emergency Care Article
(referenced in Sec. 6.4)

Emergency care

HSE speaks with **Bernard Bar-Natan**, Founder and CEO of First Care Products, about the company's Emergency Bandage product, a unique innovation in battlefield care.

HSE. What makes the Emergency Bandage unique?

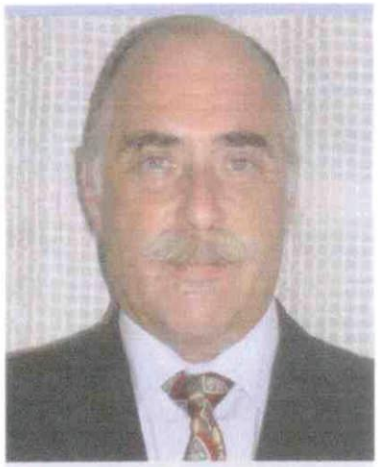
BBN. The two main goals of the Emergency Bandage are the stopping of blood loss and the consolidation of numerous, separate functions into a single, easy to use unit. Within seconds of application, immediate direct pressure is exerted through the sterile, non-adherent pad onto the wound site by the wrapping of the specially woven elasticized wrapping leader over the top side of the Emergency Bandage. The wrapping leader provides a sterile secondary cover keeping the wound area clean and more importantly, maintains the pad and pressure firmly over the wound site without causing a tourniquet and without slipping from the wound. The leader can also be used to immobilise the limb or body part to prevent further injury. Situated at the end of the leader is the closure bar enabling the fastening of the dressing at any point in the same way that a pen is inserted into a shirt pocket. In cases of very severe bleeding, the closure bar is used to exert additional direct pressure to the wound to arrest the blood loss.

HSE. How do you strive to keep the product as simple to use as possible but highly effective, especially during the panic of an emergency situation?

BBN. The Emergency Bandage supplies the functionality of numerous pieces of equipment providing the caregiver with a full treatment device. The bandaging procedure is quick, simple and familiar. If you've tied a box with string, or a birthday present with ribbon, you know how to apply the Emergency Bandage.

HSE. What sort of research goes into developing and producing your bandage products?

BBN. The Emergency Bandage is the result of my training and experiences as a combat infantry medic in the IDF Reserves for more than 20 years and the product of extensive research. Each country where the Emergency Bandage is used received detailed and extensive training, and then conducted trials and evaluations of the product. In each case, the test results were always positive.



Bernard Bar-Natan is the founder and CEO of First Care Products, and the inventor of the Emergency Bandage. Born and raised in New York, he has lived in Israel since 1979 and served as a Combat Infantry Medic in the Israel Defense Forces (IDF) Reserves for 20 years.
Bar-Natan established First Care Products in 1995. Prior to this he had been a successful photojournalist, served with the Israel Police, held field and then managerial positions with local pharmaceutical companies, and served as the European Sales Manager for an international medical simulation training device developer. For more information contact **bernard@firstcareproducts.com** or call + 972 8 9152721.

HSE. What has been the feedback from clients and where in the world have your products been put to good use? Iraq perhaps?

BBN. We started supplying Belgian and French Special Forces serving in Bosnia in 1998, and US Special Forces prior to the US involvement in Afghanistan. Subsequently the Emergency Bandage has been carried by every US combatant in Afghanistan and Iraq. Our products are used to satisfaction as well by UK Forces in Afghanistan and Iraq, by German, Italian, Dutch, Baltic States and many other forces in their international activities, and is the default bandage for every active duty soldier in the IDF. The feedback we receive from our clients is continued, and our success is attested to by the ever increasing volume of orders we recieve.

HSE. After seeing your products put to good use and saving lives what future ideas or developments do you have planned to drive the business forward?

BBN. First and foremost we are gratified that our products have been put to good use and have saved lives. First Care Products is very pleased to have made a better bandage and not a better bullet.

I am also pleased to report that within the next six to eighteen months, First Care Products will be launching a number of new products. These include an even more effective and user friendly Emergency Bandage, Emergency Bandages combined with haemostatic and/or medicinal agents, and a 'smart' first-aid kit for the untrained civilian. In addition, during this period, we will begin clinical testing of a pressure device/bandage for in-hospital applications.

In five years we hope the Emergency Bandage will be the standard for all soldiers, in every army. We also want a wider presence in the area of Homeland Security and the preparedness for a natural or 'man-made' disaster/mass casualty incident with a significant increase in the use by police and emergency services worldwide. The Emergency Bandage should also be available either as a stand-alone, off-the-shelf item, or in a first-aid kit to the general public. ■

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APPENDIX B

First Care Products' Clinical Evaluation

Tactical Casualty Care Innovations Article
(referenced in Sec. 6.5)

First Care PRODUCTS LTD.

Excerpt from Article appearing in: **THE TACTICAL EDGE**• WINTER 2006

TEMS - INSIDE THE PERIMETER

Tactical casualty care innovations: News from Iraq

By Michael Madsen

At the battle of Mogadishu, Somalia in 1993, U.S. Special Operations forces sustained the most U.S. casualties from a single battle since the Vietnam War. The lessons learned from that conflict resulted in a critical reexamination of the way in which we train Special Operations combat medics and identified several potential areas for improvement in tactical combat casualty care in general. Ongoing operations in support of the current global war on terrorism have resulted in a far greater number of combat casualties and validated a number of the recommendations from the Somalia panel. Many of the tools and techniques presently being used to save lives on the battlefields are directly applicable to the domestic tactical law enforcement medical environment.

The intent of this article is to review some of the current military medical devices that may be useful for law enforcement tactical operators and their supporting TEMS team. The descriptions, techniques and cost estimates are for basic familiarization only. The reader is referred to the manufacturers for current pricing, training and instructions regarding the safe and appropriate use of their medical material before using any of these products.

Patterns of injury

Despite advances in weaponry and different types of warfare, the location of injuries has stayed remarkably consistent over the years. From World War I to Operation Iraqi Freedom, most combat wounds involved the extremities, averaging 60 to 70 percent of the total. The use of modern Kevlar vests with Small Arms Protective Insert plates, rated to protect against rifle-velocity bullets, may have contributed to the reduction in the incidence of chest wounds from 12 percent in the first Gulf War to 6 percent in OIF. Head and neck injuries ranged from 14 percent in Vietnam to around 30 percent in the present conflict. Comparable data from domestic law enforcement tactical teams is sparse: training accidents may account for up to a quarter of the injuries documented and the mechanism of injury is less likely to involve penetrating trauma. With those limitations in mind, one reliable database of law enforcement tactical team injuries documenting 612 incidents with casualties from 1990-1997 revealed a similar injury distribution: 57 percent involved extremity injuries, 12 percent trunk and 30 percent head/face/eye.

The primary mechanism of injury in the present military conflict is an improvised explosive device. These devices account for about one third of the casualties transported from the point of injury by our air ambulances in Iraq. Injuries are quite similar to those produced by mortar and artillery fire during the World Wars and Korea. This is not surprising as many of the IEDs rely on military ordinance, such as a shell or bomb, for the explosive force. Multiple fragmentation wounds, blast injury and amputations are common. Civilian police stations and vehicles are specifically targeted by the insurgents. Most of the remaining cases of battle injuries involve small arms fire and non-battle accidents, which are more typical of the injuries that might be sustained by U.S. law enforcement personnel.

• **The Emergency Bandage ("Israeli Combat Dressing").** This is an improved version of the individual military field dressing that is in common use with the U.S. military. It consists of a thick absorbent gauze pad that is applied next to the wound and an elastic bandage that holds the dressing in place. In addition, there is a flattened D-shaped plastic bar into which the elastic bandage can be placed to allow the dressing to be tightened, making it a very effective pressure dressing (Figures 9 and 10). The remaining length of the elastic dressing is then applied over the plastic bar.

The dressing stays in place much better than the old military combat dressing, which would often loosen as the fabric stretched. The elastic portion of The Emergency Bandage is similar to what many of us have used for combat dressings: kerlex gauze and an ace wrap, but in a flat self-contained package. It is much easier to apply to head wounds and other awkward anatomical locations than the traditional combat dressing.

For wounds that are not bleeding as severely, the dressing can be simply applied around the wound without using the clip. The instructions state that the dressing can also be used as a tourniquet "by medical professionals." By using the straight plastic clip on the tail end of the dressing as a windlass, this is indeed possible, although the inherent stretch in the elastic bandage makes this less effective than the tourniquets detailed above.

The dressing comes in four- and six-inch sizes that will be useful for most wounds.

Fig. 9: The Emergency Bandage (Israeli Dressing)

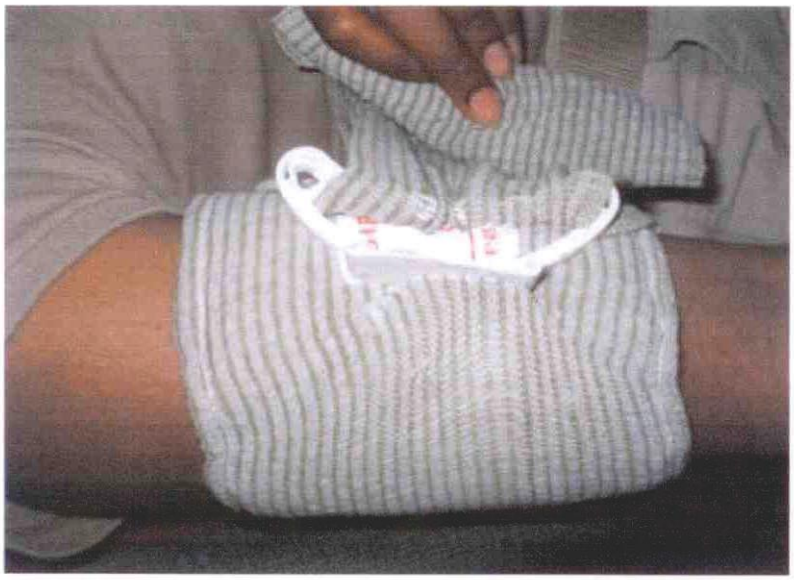

Fig. 10: Using the plastic clip to provide tension for a pressure dressing

Conclusion

A very effective personal medical kit for the police tactical operator can be assembled by placing an Emergency Bandage and one of the improved tourniquets in a ziplock bag that can all be carried in a cargo pocket. A few bandaids could be added for the more frequent minor cuts and scrapes. An Asherman Chest Seal could be added, although the wrapper from the Emergency Bandage or the ziplock bag itself can be used to seal an open chest wound in conjunction with the Emergency Bandage.

TEMS medics may want to consider adding one of the newer tourniquets, a couple of hemostatic dressings and a FAST-1, contingent upon local EMS system rules and medical director approval, to their tactical medical sets.

As with all new gadgets, the most important tool in tactical medicine is the individual medic's training, experience, sound reasoning and adaptability. The medical innovations detailed are no substitute for these abilities but may provide the extra edge in helping to reduce unnecessary deaths from otherwise survivable wounds.

About the author

Michael Madsen is a board-certified emergency medicine physician presently serving as the Medical Director/Flight Surgeon for the unit providing MedEvac for all U.S. and Coalition Forces in Iraq. He has served in the Army since 1977 in a variety of active duty and reserve medical, operational and SOF assignments, with major deployments to Bosnia, the Philippines, Afghanistan and Iraq. Madsen also served as the team physician and tactical medic for the Washington County (OR) Tactical Negotiations Team (SWAT) from 1995-2000 and the Tripler Army Medical Center Special Operations Team from 2000 to 2004. Col. Madsen is a CONTOMS graduate and has completed numerous civilian and military tactical team courses.

The opinions and assertions in this article are those of the author alone and do not represent those of the Department of Defense, United States Army or the Army Medical Command. The author has no financial interest in any of the companies or products mentioned in this article and does not provide official endorsement for any products.