

Operating Room Patient Positioning Pressure Distribution of Foam and Gel Devices

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Morris V. Shelanski, M.D., C.M. and Steven Holley, R&D Engineer, Covidien

INTRODUCTION:

An independent study, conducted by Product Investigations, Inc. in Conshohocken, PA was performed to evaluate pressure distribution exerted by patients in the supine position, using several types of foam and gel positioning aids. The study was approved by an Institutional Review Board and subjects were consented prior to enrollment. The principal investigator conducting this study was Morris V. Shelanski, M.D., C.M.

METHOD:

Twelve subjects were tested to compare the pressure distribution between foam positioning products, gel positioning products and a standard Operating Room Table Pad. A Steris[®]/Amsco[®] 2" polyurethane pad was used as the control (no additional positioning devices) and also in conjunction with all of the trial products. Trulife[™]* reusable gel positioners, Action[®]* reusable gel positioners (Action Products Inc.) and Devon[™] disposable foam positioners (Covidien) were all separately tested with each subject involved in this study.

Subjects were chosen to represent a cross section of the patient population by having two subsets composed of different weight classes as measured by Body Mass Index (BMI). Six of the subjects were normal weight (BMI = 18.5-24.9) and six were overweight (BMI = 25.0-29.9) as defined by the Centers for Disease Control.¹ Each of the BMI subsets was composed equally of 3 males and 3 females.

The study was designed to record the pressure distribution of each subject on four different surfaces (Control, Trulife, Action, and Devon). The subjects were asked to remain motionless in a supine position for 20 minutes. At the end of

the 20 minute period, a digital pressure map was recorded using the same pressure scale for each subject and product tested.

Per the 2008 Perioperative Standards and Recommended Practices published by AORN "Pressure against the skin above 32 mm Hg interferes with tissue perfusion."² An analysis of the resulting pressure maps was conducted to determine the percentage of pressure distribution for each subject at levels above 32 mm Hg. Further analysis was conducted to determine the amount of patient surface area that exceeded 32 mm Hg.

RESULTS

Pressure maps for each subject provided specific pressure readings in mm Hg. There was an average of 1,476 different measurements taken per individual pressure map. These digital maps classified the individual pressure points of each subject into distinct pressure categories.

The table below denotes the average pressure distribution of all 12 subjects with each test product. The percentage of pressure exerted in each specific pressure category is also listed. Highlighted at the bottom of this table is the average percentage of the 12 test subjects' pressure distribution recorded at levels greater than 32 mm Hg.

Average Pressure Distribution

Pressure (mm Hg)	Control	Trulife	Action	Devon
46.0	1.3%	1.4%	1.1%	0.2%
43.2	1.0%	1.3%	1.2%	0.5%
40.4	2.1%	2.3%	2.4%	1.0%
37.6	4.1%	3.6%	3.6%	1.9%
34.8	6.2%	5.8%	6.4%	3.3%
32.0	7.9%	8.1%	8.0%	4.9%
29.2	9.4%	9.2%	9.5%	6.2%
26.4	10.2%	9.7%	9.1%	7.9%
23.6	9.7%	9.3%	9.5%	8.8%
20.8	9.7%	9.0%	9.1%	9.9%
18.0	9.0%	8.9%	9.0%	11.0%
15.2	8.7%	9.0%	8.8%	12.1%
12.4	8.9%	9.9%	9.9%	14.9%
9.6	11.3%	12.5%	12.2%	17.4%
6.8	0.2%	0.0%	0.0%	0.0%
4.0	0.1%	0.0%	0.0%	0.0%
Percentage of Pressure Distribution over 32 mm Hg	22.7%	22.5%	22.7%	11.7%

There is 48% less pressure distribution at levels above 32 mm Hg when using the Devon™ foam positioning devices compared to other products tested.

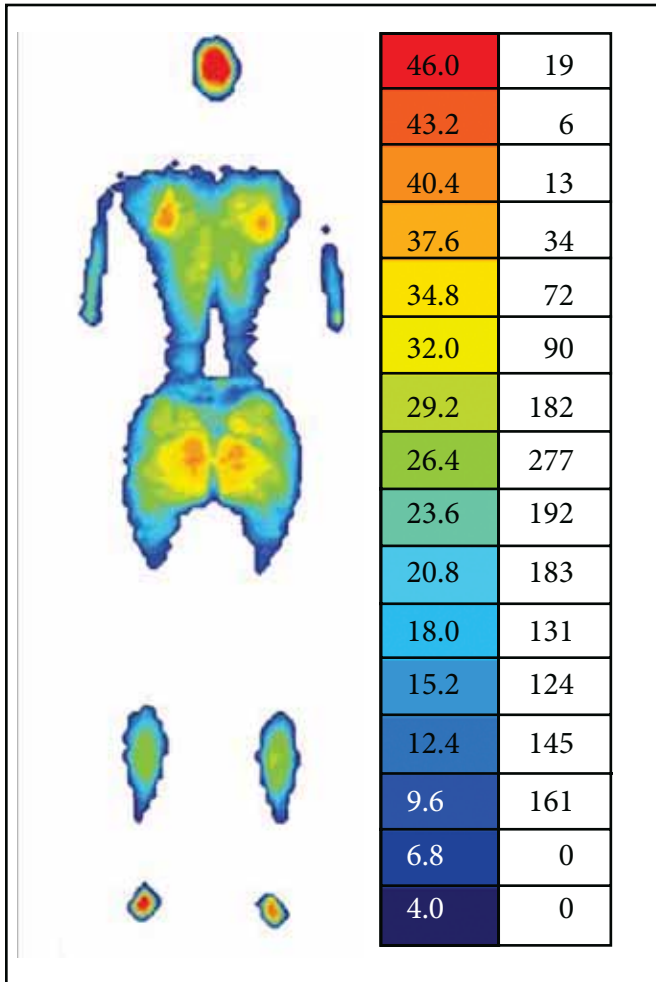
Percentage of Pressure >32 mm Hg per Subject

Age	Sex	BMI	Control	Trulife	Action	Devon
21	F	19.6	16.9%	23.9%	18.3%	11.8%
26	F	19.8	9.1%	12.8%	15.1%	5.3%
57	F	22.7	13.0%	11.2%	9.2%	4.3%
24	M	20.4	30.4%	33.2%	33.0%	14.3%
29	M	20.4	27.8%	25.8%	24.6%	12.5%
21	M	22.5	14.4%	20.2%	24.3%	10.5%
44	F	25.1	20.6%	15.3%	16.8%	11.1%
59	F	25.8	18.1%	16.9%	24.4%	7.4%
52	F	29.4	21.4%	22.0%	24.1%	12.9%
63	M	25.8	27.7%	27.2%	23.8%	17.5%
44	M	26.6	32.2%	28.2%	24.6%	12.5%
49	M	28.9	32.4%	29.3%	29.2%	15.3%

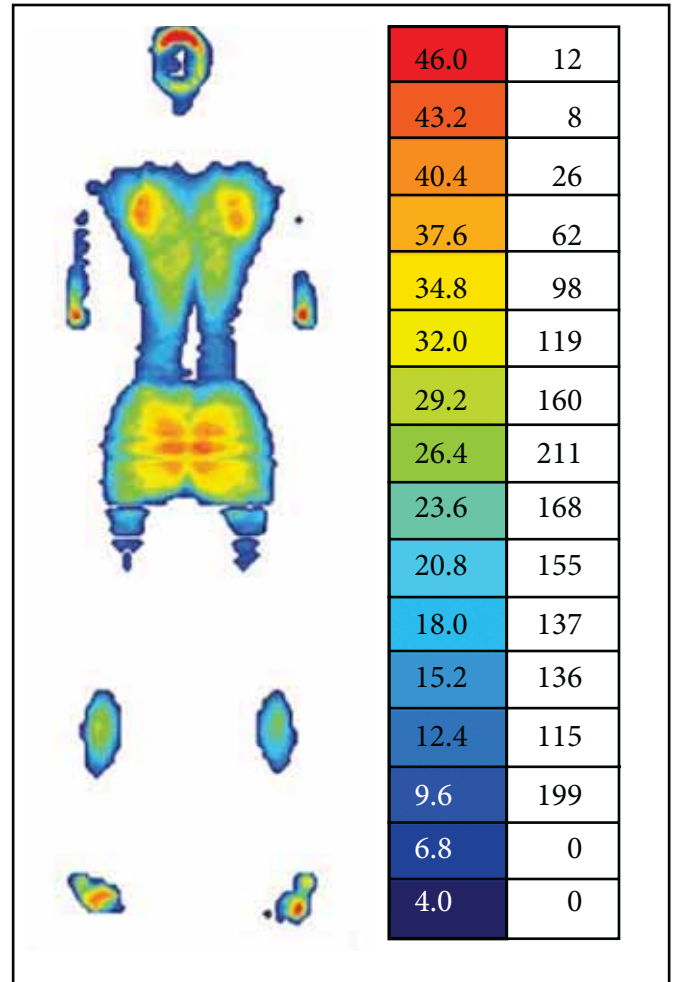
Additionally, the data for each individual subject also demonstrates that the Devon foam product has a lower percentage of pressure distribution at levels above 32 mm Hg. In all cases, regardless of age, sex or BMI, the Devon product has a significantly lower amount of pressure distribution above 32 mm Hg compared to the other products tested. Conducting a 2-sample t-test on the data proves that the percentage of pressure above 32 mm Hg is statistically lower ($p < 0.05$) for the Devon products when compared to all of the other products. There was no difference between gel positioners and the control.

Four pressure maps for one subject (Male – BMI = 22.5) tested in this study are compared side by side below. Color coding is used to indicate the specific pressures exhibited by the subject after 20 minutes of lying in a supine position. Each pressure map uses the same pressure scale where red indicates the highest pressure and blue the lowest (see Pressure Scale on the right). The number to the right of the pressure scale provides the amount of individual pressure map sensors recording that specific level of pressure.

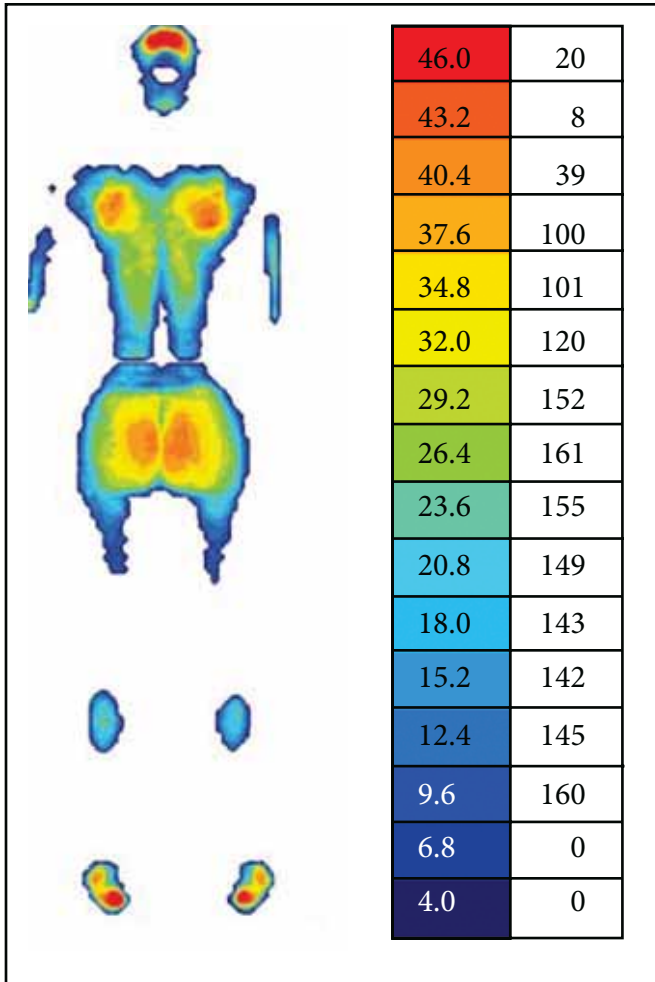
OR Table Pad (Control)



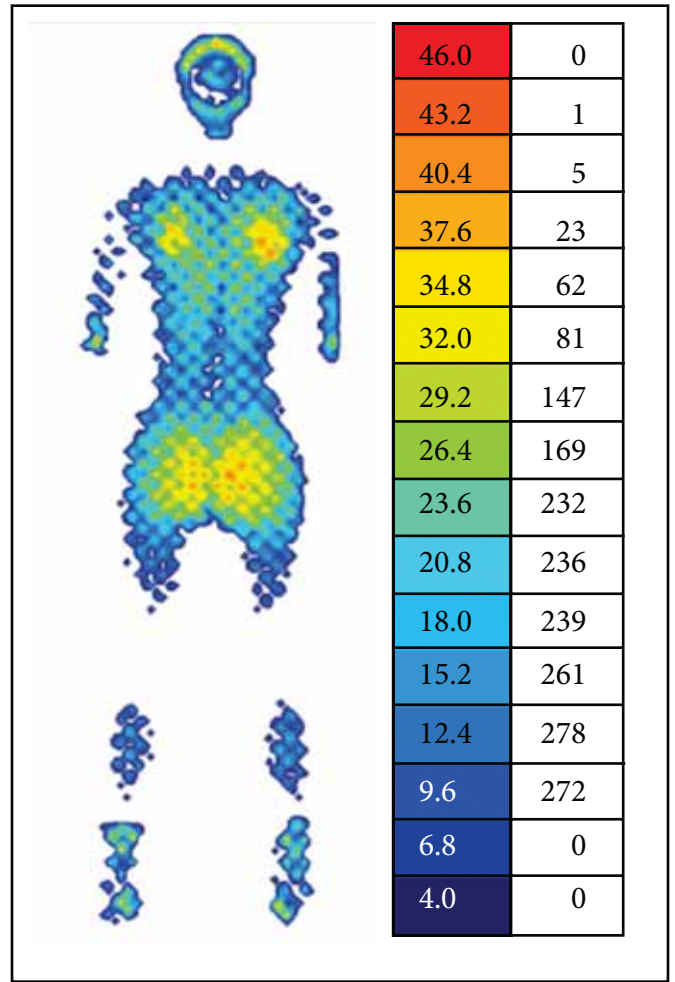
Trulife™* Gel Positioners



Action™* Gel Positioners



Devon™ Foam Positioners

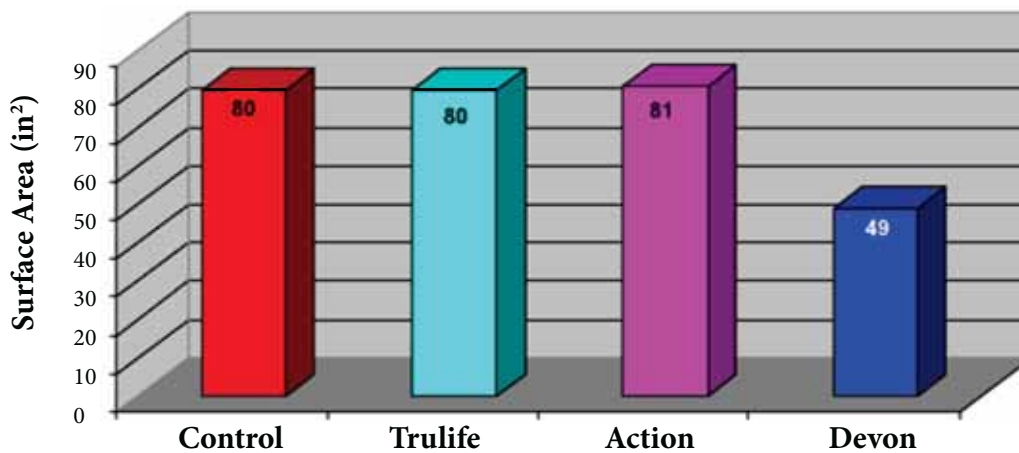


The following table indicates the total surface area with readings above 32 mm Hg for each patient with each product (measured in inch²). According to this data, there is 38% less surface area at levels exceeding the recommended risk tolerance of 32 mm Hg when using the Devon™ foam as compared to the other products tested. The average of all of the subjects is depicted in the graph below.

Surface Area above 32 mm Hg (in²)

Age	Sex	BMI	Control	Trulife	Action	Devon
21	F	19.6	50.00	68.00	54.75	39.50
26	F	19.8	21.00	31.50	37.00	14.50
57	F	22.7	37.50	33.75	27.25	14.25
24	M	20.4	86.75	94.25	93.50	55.75
29	M	20.4	84.75	91.50	83.50	49.25
21	M	22.5	58.50	81.25	97.00	48.50
44	F	25.1	68.25	52.25	59.25	40.75
59	F	25.8	66.75	61.25	86.75	29.50
52	F	29.4	98.50	104.00	109.00	71.00
63	M	25.8	108.25	107.25	88.75	82.00
44	M	26.6	139.50	118.50	107.00	63.50
49	M	28.9	137.75	113.25	122.75	79.00
AVERAGE			79.79	79.73	80.54	48.96

Surface Area with Pressure >32 mm Hg



Conducting a 2-sample t-test on the data proves that the surface area of concern (>32 mm Hg) is statistically lower ($p < 0.05$) for the Devon products when compared to all of the other products. There was no difference between gel positioners and the control

CONCLUSION:

The Devon™ foam positioning devices provided superior results with respect to both total pressure distribution and patient surface area exposed to pressure levels that may interfere with tissue perfusion. A 48% reduction in pressure distribution at levels above 32 mm Hg was achieved using Devon foam positioning devices as compared to commonly used gel positioning aids. Likewise, a 38% reduction in surface area measured at levels above 32 mm Hg was realized using Devon foam as compared with gel devices.

¹http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html

²Perioperative Standards and Recommended Practices, 2008 edition



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15 HAMPSHIRE STREET
MANSFIELD, MA
02048

508-261-8000
1-800-962-9888

WWW.COVIDIEN.COM