

HEMOSTASIS PADS: A COMPARISON

Blind Comparison of Three Topical Hemostasis Pads

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Hemostasis is a mechanism that restricts loss of blood from damaged blood vessels via the formation of clot. This mechanism is essential to maintain the closed blood-circulatory system. There are numerous hemostatic devices and agents in use today to help control bleeding following percutaneous catheterization procedures. The efficacy of these agents may vary significantly. Using a topical hemostatic pad is an inexpensive and efficient way to control bleeding. There are already studies on several hemostatic pads that have been conducted in order to evaluate the outcomes relating to clinical effectiveness, complication rates, patient comfort and operational efficiencies. The purpose of the testing reported in this article was to evaluate comparatively the blood coagulation performance, in an *in vitro* setting, of three different topical hemostatic pads:

- Clo-Sur P.A.D.[™] (Scion Cardio-Vascular Inc., distributed by Medtronic Vascular)
- SyvekPatch[®] (Marine Polymer Technologies, Inc.)
- Chito-Seal[™] (Abbott Laboratories, Inc.)

Materials and Methods

A blinded test was conducted with a total number of 15 sample pads, (5 for each type of pad), with the product name and manufacturer identification blacked out. Prior to the test, all pads were cut into the same dimension of 3 cm x 3 cm (width x length). Pad thickness was not altered, so that all the products were tested in their original thickness. Each hemostatic pad was prepared in accordance with the manufacturer's instruction for use. The

blood used in the test was heparinized blood from ovine source. The ACT level of the blood was measured before testing each pad by using a Hemochron[®] 401 ACT Blood Analyzer (ITC Corp., itcmed.com). To perform the test in an *in vitro* setting, a circulating water bath with temperature control was used to maintain the temperature of blood at 37±3 degrees Centigrade.

The performance of the hemostatic pads was evaluated by measuring the weight amount of thrombus that formed around the test sample for an incubation time of 10 minutes at room temperature. In addition, visual inspections of the thrombus were performed at 2, 5 and 10 minutes, with photographs taken to record the inspections.

Results and Conclusions

Visual Inspection for Clot Formation

For Pad A, a clot was noted to have formed wherever the blood was in contact with the pad. Figure 1 clearly shows clot formation along the edges of Pad A. A majority of the thrombus was noted to have formed within the first 2 minutes of the Pad A contacting the blood. The coverage of the thrombus was approximately 10–25%. For Pads B and C, no visible clots were found to form throughout the testing. Figure 1 shows typical photographs of Pads A, B and C during testing.

Performance Testing

Compare the weight data of the pads before and after the test, it could be seen that type A pads gain significantly more weight during the test than type B and C pads. The mean difference between type A and type B is 3.43 g (P=0.004). The mean difference between type A and type C is 3.086 g (P=0.006). Relating these data with visual inspection, the extra weight gain may be the result of more clot. However, it could also be because the different nature of the pads absorbing the blood. The ACT level of the blood remained stable during the test.



Figure 1. Visual inspection of the hemostatic pads in blood after an incubation time of 2 minutes. Type A pad (left) visible clots can be seen at the edge of the pads; type B pad (center) — pad sinks into blood, no visible clots were found on the pad; type C pad (right) — pad floats in blood, no visible clots were found on the pad.

Pad	Prior	After	Weight Gain (g)
A* (sets 1-5)			
A1	0.19	4.25	4.06
A2	0.18	5.05	4.87
A3	0.2	4.63	4.43
A4	0.18	3.49	3.31
A5	0.19	1.79	1.6
* Pad A: the Clo-Sur P.A.D. [™] , Scion Cardio-Vascular Inc., distributed by Medtronic Vascular.			
B** (sets 1-5)			
B1	0.12	0.34	0.22
B2	0.09	0.38	0.29
B3	0.1	0.31	0.21
B4	0.14	0.29	0.15
B5	0.1	0.35	0.25
** Pad B: the SyvekPatch [®] , Marine Polymer Technologies, Inc.			
C*** (sets 1-5)			
C1	0.12	0.63	0.51
C2	0.12	0.75	0.63
C3	0.09	0.66	0.57
C4	0.12	0.7	0.58
C5	0.1	0.65	0.55
*** Pad C: Chito-Seal [™] , Abbott Laboratories, Inc.			

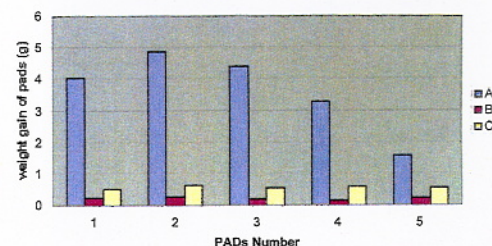


Figure 2. Comparison of weight gain on the three types of pads after an incubation time of 10 minutes.

Conclusion

Based on the visual inspection and performance testing for these 15 pads, we concluded that type A pads are more effective in blood coagulation performance than types B and C. However, this sample pool is small and further study is needed. In addition, this study did not test the pads in a "real world" cath lab situation, elements of which may have unknown effects on the results.

Unblinding of test samples

Upon completion of the testing, the identities of the test samples were unblinded:

- Pad A: Clo-Sur P.A.D.[™], Scion Cardio-Vascular Inc., distributed by Medtronic Vascular.
- Pad B: SyvekPatch[®], Marine Polymer Technologies, Inc.
- Pad C: Chito-Seal[™], Abbott Laboratories, Inc.