

LETTER to the EDITOR REPLY

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We thank Dr Schwartz and colleagues, The Journal, and the operational medicine community for the opportunity to increase awareness of junctional hemorrhage control in replying to a letter of Dr Schwartz and colleagues about our publication in the Fall 2014 issue titled, “Testing of Junctional Tourniquets by Military Medics to Control Simulated Groin Hemorrhage.”¹ The letter tries to make the following points about our study: methods were not followed, previous works were not cited, and the tourniquet was approved for groin placement at the time of the study.

The methods were followed. The tourniquet in question was tested as applied to the umbilicus. As we understand the relevant public documents, the tourniquet when tested was not approved for placement on the groin. The tourniquet was approved for an indication of inguinal (i.e., groin, hemorrhage), but its instructions for use (IFU) only instructed application to the umbilicus, the surface landmark of aortic compression. IFU, also known as a product insert, is regulated as part of the labeling of a medical device. The first way umbilical application was expressed was in the listed steps of use. The second step of use was “2. Position bladder over umbilicus.” Nothing in the IFU mentioned the groin, inguinal, or any other site as a place of application. The second way umbilical application was described in the IFU was by the mechanism of aortic compression. The IFU stated in part to begin the second paragraph of the indication section: “Proximal compression of vessels is still the most effective way of hemorrhage control. The abdominal aortic tourniquet does this by compressing the descending aorta at or near its bifurcation.” No other mechanism is mentioned in the IFU. The original publication again repeated the restricted application to the umbilicus with elaboration of: “The AAJT was applied to the umbilicus; other models were applied to the groin.” Methods and findings of the original publication were similar to those of another study we published.²

Directly relevant references were cited. One reference mentioned by Dr Schwartz and colleagues as not cited by

us was their reference 3, which is nearly identical to our reference 11, which we cited correctly. We acknowledge and remain aware of the studies Dr Schwartz and colleagues cited, two of which were associated with more tolerance of discomfort than as we reported. One of the references we did not cite had a different design, different methods, and different placement, so it was only tangentially related to points made. We selected only references that were directly relevant to points we made.

By its design, testing was to compare tourniquets in a head-to-head manner at a time when there was only one way to do so. That way was executed and reported. The ethical oversight body mentioned in the original publication could not, and cannot, permit testing other than in accordance with the IFU. To assess a medical device contrary to its IFU would be a research experiment, not a customer assessment of user preference. The IFU for a medical device is the responsibility of the device’s sponsor, which in this case was a company. The company holds its regulatory filings as does the regulatory administration. Portions of filings may be made public if or when the sponsor so discloses. We are aware of no disclosure of why the IFU was limited to umbilicus placement. The letter of Dr Schwartz and colleagues is opaque on this matter. A review article on the medical device may provide a platform to clarify the potential of this tourniquet to the operational medicine community. In the past, we asked the sponsor to consider such a clarification. We look forward to learning more about the potential risk and benefit of the junctional tourniquet.

References

1. Kragh JF Jr, Parsons DL, Kotwal RS, et al. Testing of junctional tourniquets by military medics to control simulated groin hemorrhage. *J Spec Oper Med.* 2014;14:58–63.
2. Kragh JE, Kotwal RS, Cap AP, et al. Performance of junctional tourniquets in normal human volunteers. *Prehosp Emerg Care.* 2014 Dec 12. [Epub ahead of print]