OBJECTIVE: Severe hemorrhage is a leading cause of death and difficult to control even by trained medical personnel. Current interventions have significant limitations in the prehospital setting; therefore, a need exists for a new and effective treatment. iTraumaCare has designed a temporary wound closure device, the iTClamp, which controls external hemorrhage from open wounds within compressible zones. The device approximates the wound edges, sealing the skin within a pressure bar, enabling creation of a hematoma and subsequent clot formation. The objective of this study is to test the effectiveness of the iTClamp to control external bleeding due to a major vascular injury to the groin in an in vivo swine model.

METHODS: Twenty Yorkshire-cross male swine were enrolled in this study. A complex groin injury was created by complete excision of the femoral artery and vein along with some surrounding muscle. The animals were divided into four treatment groups: control (no treatment), early iTClamp treatment, late iTClamp treatment, and standard gauze treatment. Survival rate, survival time, and blood loss were the primary endpoints. Physiologic parameters (heart rate, blood pressure, oxygen saturation) were monitored throughout the experiment and blood samples were collected to analyze partial thromboplastin time and fibrinogen.

RESULTS: All (100%) of the animals treated with the iTClamp lived through the end of the experiment, compared to 60% in standard gauze treated and 0% of untreated control animals (early and late iTClamp vs. control and standard gauze, Fisher's exact, p = 0.003). Both the early iTClamp and late iTClamp treatment groups survived significantly longer than the untreated control pigs (Mann-Whitney U-test, p < 0.009). External blood loss was significantly lower in animals treated with the iTClamp (early) compared to no treatment (Mann-Whitney U-test, p < 0.008). There was no significant change in physiologic or hematologic parameters between treatment groups.

CONCLUSIONS: The iTClamp showed statistically significant improvement in survival, survival time, and estimated blood loss when compared to no treatment. This proof-of-concept study demonstrates the potential of the iTClamp to control severe bleeding and prevent blood loss.