

Efficacy of VETIGEL® as a Novel Hemostatic Gel in Canine Mass Removals

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Abstract:

Objective

To compare use of VETIGEL®, a novel plant- and fungi-based hemostatic device, versus conventional hemostatic techniques in dogs undergoing surgical mass removals.

Design

Retrospective cohort study.

Animals

16 client-owned dogs undergoing surgical mass removals at 19 sites in various anatomical locations and a range of sizes.

Procedures

Surgical mass removals were performed on 19 sites across the 16 client-owned dogs, utilizing conventional mass excision techniques. Bleed severity of post-removal bleeding was evaluated based on clinical assessment. VETIGEL® and a control/standard of care (compression with gauze) were compared in their time to hemostasis and blood volume loss.

Results

VETIGEL® had a statistically significant improvement in time to hemostasis across all bleed severities and in high bleeds specifically as compared to the control/standard of care. Similarly, VETIGEL® had a much lower measured average blood volume loss across all bleed severities. The variance in both time to hemostasis and blood volume loss was notably lower in VETIGEL(R), indicating variability was lower as compared to the control.

Conclusions and Clinical Relevance

Time to hemostasis and blood volume loss are critical metrics when assessing impact to patient outcomes from a surgery. VETIGEL® represents a notable improvement to standard of care and introduces a more effective and consistent alternative to compression with gauze for hemostasis. With faster times to hemostasis, reduced blood volume loss, and greater consistency in performance per procedure, veterinarians performing surgical mass removals are more likely to ensure more favorable patient outcomes.

Introduction: Hemorrhage control during surgical procedures is of paramount importance to ensure the safety and well-being of veterinary patients. In the practice of veterinary medicine, there are few devices designed specifically to stop all levels of surgical bleeding and that easily conform to a variety of wound geometries. VETIGEL[®], a novel plant- and fungi-derived hemostatic gel, has been used by veterinarians in a wide array of surgical cases [1]. Prior to this clinical evaluation, use of VETIGEL[®] in canine mass removals had not been comprehensively studied. This investigation aimed to assess the effectiveness of VETIGEL[®] across a spectrum of bleed severities in a series of canine surgical mass removals.

Materials & Methods: A total of 16 dogs undergoing elective mass removal surgery were included in this series of clinical evaluations, with a total of 19 masses removed.

All subjects were treated at the Virginia Beach Society for the Prevention of Cruelty to Animals (VBSPCA) under the supervision of Medical Director Dr. Ann Marie Woyma. The subject ages ranged between 1 and 13 years old, across both male and female groups. Sites of mass removals included but were not limited to mammary, oral, thoracic, rectal, dermal (i.e., shoulder, skull, tail), and paw pad regions. Dr. Woyma administered all test and control treatments to ensure consistency of application. Two licensed veterinary technicians assisted in data collection over the duration of the study.

Masses removed varied in size from 1cm x 1cm x 1cm to 7cm x 5cm x 5cm. Most masses were removed by a 15-blade scalpel via elliptical incision, and Metzenbaum scissors were used to access the masses sub-dermally. For ear and oral masses, a 15-blade scalpel was sufficient for full mass removal. Bleeding severity was classified as low, moderate, or high, based on clinical assessment. Patients were allocated into two groups: VETIGEL[®]-treated (6 patients, n=9 sites) and control-treated (10 patients, n=10 sites).

VETIGEL[®] is provided as a sterile, pre-filled 5mL syringe with a wide bore, for easy material deployment directly to a wound. The gel acts as a hemostatic wound covering and plug to stop bleeding. Once gel contacts the wound, it maintains local pressure and adhesion to aid in the quickening of clot formation. The material stiffens and forms a strong barrier that maintains durable and long-term hemostasis. In the VETIGEL[®] group, the gel was applied to the surgical site immediately after mass excision.

The control group sites underwent compression with standard woven surgical gauze. Compression was sustained until hemostasis was observed. In cases where the gauze became fully saturated with blood, the gauze was replaced with a new piece.

In both groups, intraoperative time to hemostasis, bleeding severity, blood loss, and postoperative assessments were recorded. Some patients had more than a single mass removal site; all sites were assessed and treated individually across all patients. Subjects were assessed for any comorbidities or complications that could lead to a confounding or more challenging clinical scenario for a mass removal, although none were deemed influential to the outcome of this study.

Results:

Data for VETIGEL[®] and control treated groups is summarized below:

Table 1: VETIGEL[®] Treated Group

Patient	Site	Size of Mass	Bleed Level (Low, Moderate, High)	Time to Hemostasis (min)	Blood Volume Loss (mL)
Patient 1	1	2cm x 3cm x 2cm	High	2	15
Patient 2	2	15cm x 4cm x 2cm	High	2	10
Patient 3	3	1.5cm x 2cm x 1cm	High	1	5
Patient 4	4	2cm x 1cm x 1cm	Moderate	0.5	5
	5	3cm x 2cm x 1cm	Moderate	0.5	10
Patient 5	6	3cm x 3cm x 2cm	Moderate	1	5
	7	1cm x 1cm x 1cm	Moderate	1.5	5
	8	2.5cm x 2cm x 1cm	Low	1.5	1
Patient 6	9	1.5cm x 1.5cm x 1cm	Low	1	5
Average Time to Hemostasis (min)				1.1	
Average Blood Volume Loss (mL)				6.7	

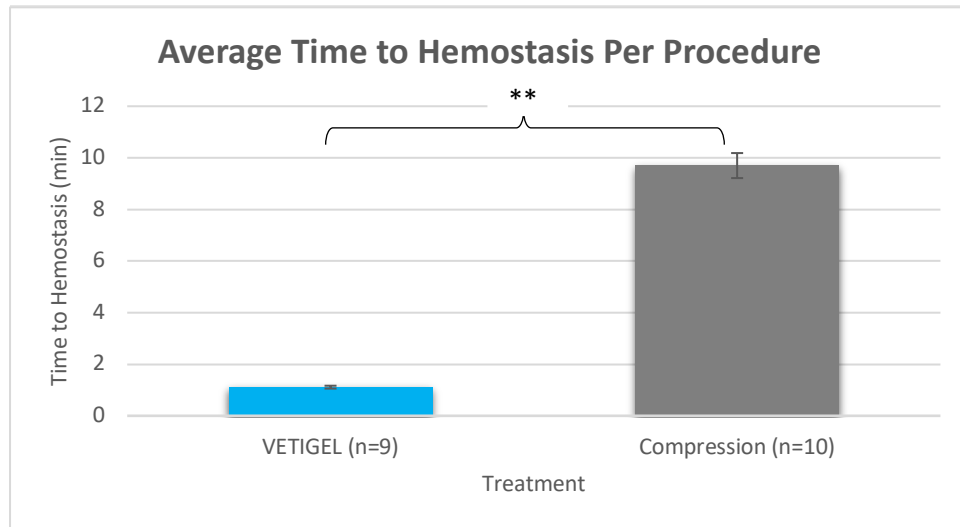
Table 2: Control Treated Group

	Site	Size of Mass	Bleed Level (Low, Moderate, High)	Time to Hemostasis (min)	Blood Volume Loss (mL)
Patient 1	1	4cm x 3cm x 2cm	High	20	100
Patient 2	2	7cm x 5cm x 5cm	High	15	40
Patient 3	3	10cm x 10cm x 3cm	High	25	300
Patient 4	4	3cm x 5cm x 2cm	High	9	20
Patient 5	5	2cm x 2cm x 1cm	Moderate	4	10
Patient 6	6	3cm x 2.5cm x 3cm	Moderate	4	35
Patient 7	7	4cm x 3cm x 2.5cm	Moderate	6	30
Patient 8	8	2.5cm x 3cm x 1cm	Low	5	10
Patient 9	9	1.5cm x 1cm x 1cm	Low	6	20
Patient 10	10	2cm x 1cm x 2cm	Low	3	15
Average Time to Hemostasis (min)				9.7	
Average Blood Volume Loss (mL)				78	

Time to Hemostasis

The use of VETIGEL[®] demonstrated superiority in achieving hemostasis across all bleed severities. For average time to hemostasis, VETIGEL significantly reduced time to hemostasis ($p < 0.004$) compared to the control group. Time to hemostasis was recorded to the nearest 30s for this study.

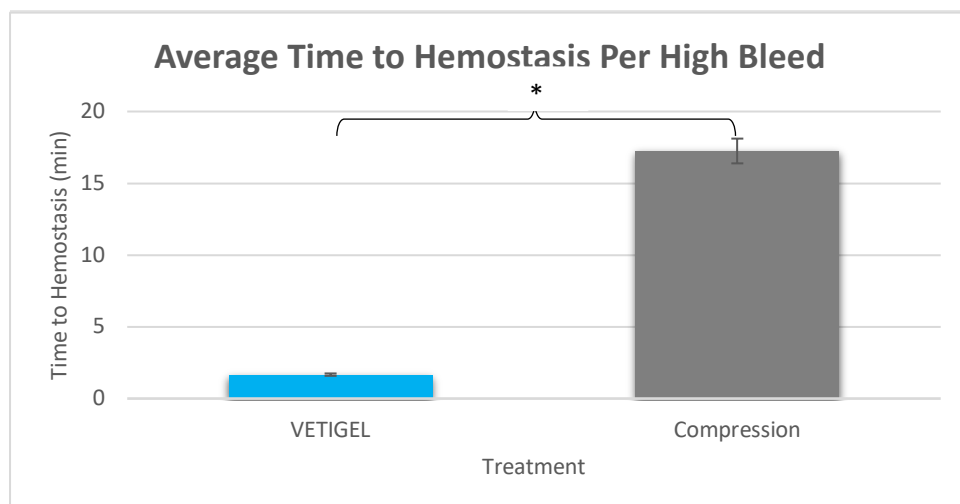
Figure 1. Average Time to Hemostasis Per Procedure



For the VETIGEL[®] group, the average time to hemostasis was 1.1 minutes as compared to the control, which was 9.7 minutes. The VETIGEL[®] treated wounds had times to hemostasis ranging between 30 seconds and 2 minutes, with both 2-minute bleeds being of a high severity. In contrast, the control group time to hemostasis ranged from 3 to 25 minutes, where the two longest (20 and 25 minutes) were also of high bleed severity.

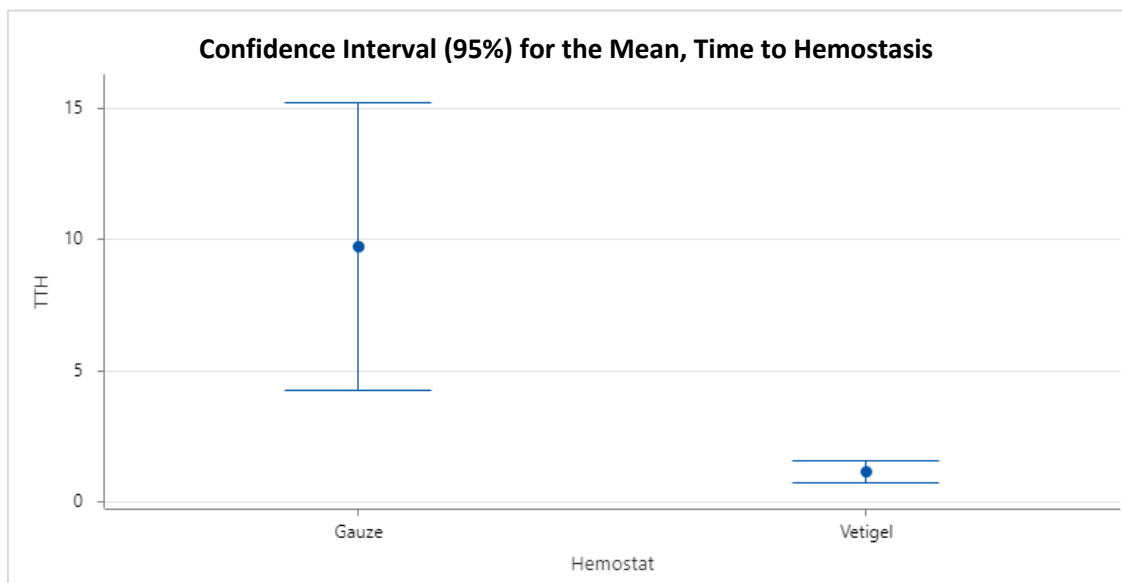
In the high bleed severity groups, time to hemostasis VETIGEL[®] outperformed compression methods in terms of bleeding time ($p < 0.02$). This group is of particular importance due to its clinical relevance relative to potential downstream complications due to blood loss [2].

Figure 2. Average Time to Hemostasis Per High Bleed



It is worth noting that not only was the average time to hemostasis lower for VETIGEL[®], but the data also shows that VETIGEL[®] time to hemostasis is more consistent across bleed levels, with a tight Confidence Interval (CI) for the mean, as shown below:

Figure 3. Confidence Interval (95%) for the Mean, Time to Hemostasis

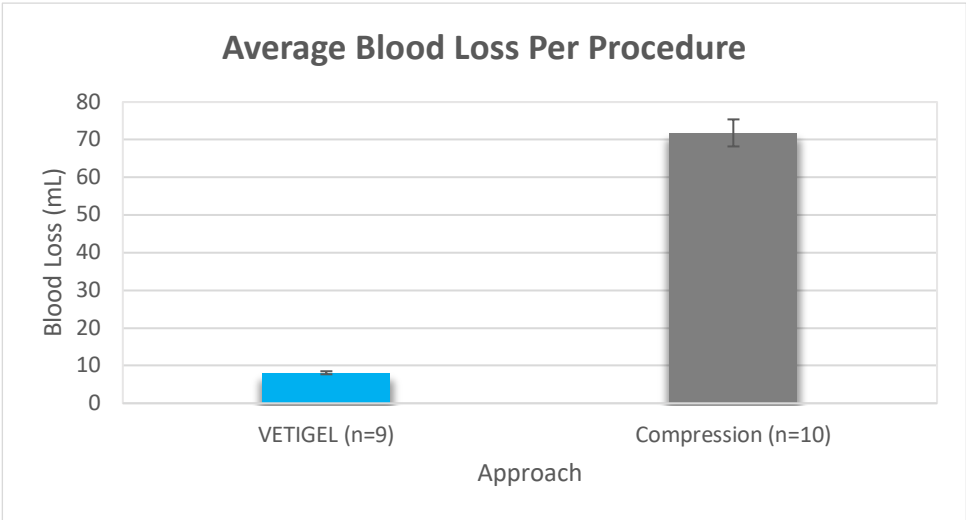


This is important clinically, as confidence in addressing all bleed types is a key factor in selecting an approach for hemostasis. Surgical bleed levels are highly variable, and the control demonstrated poor consistency, with a strong favoring of lower bleed levels. Masses requiring removal are often heavily vascularized, which further increases the need for confidence in an approach [3].

Blood Loss

The use of VETIGEL[®] as a measure to reduce average blood loss was evaluated during this study. The resulting average blood loss for VETIGEL[®]-treated wounds was 6.7mL while that of the control group was 78mL. Blood loss was measured to the nearest milliliter over the duration of the study.

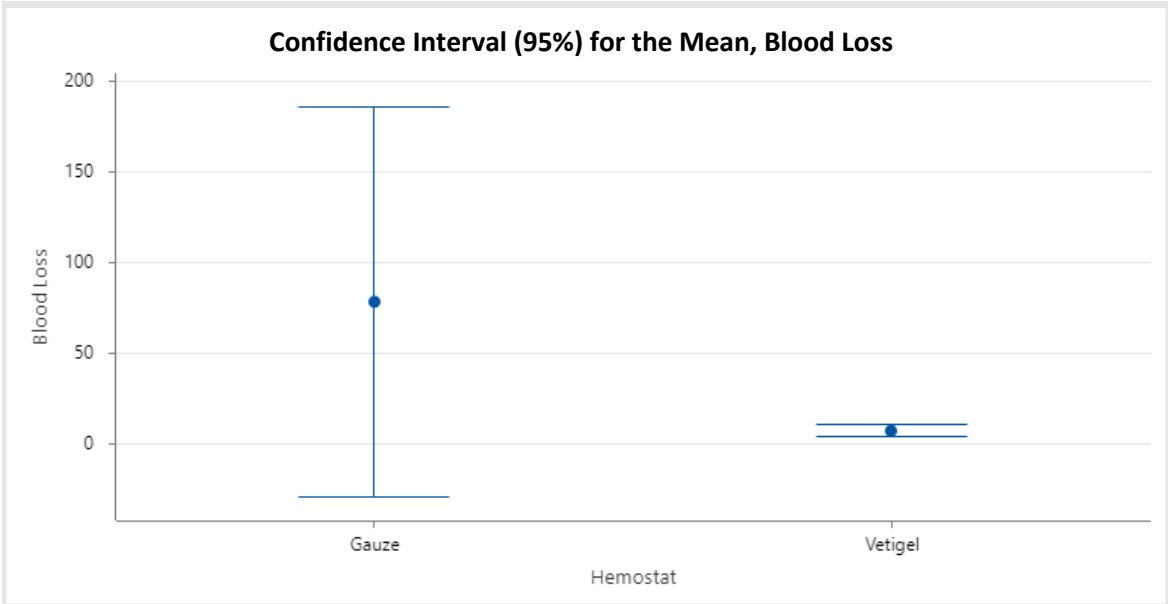
Figure 4. Average Blood Loss Per Procedure



While the difference between the two values is large, the data set does not represent a statistically significant difference due to the inherently high nature of two extreme data points in the control group (100 and 500mL). Additional data will be collected over time to assess its significance in subsequent iterations of this study.

As calculated in the case of time to hemostasis, the 95% CI for the mean was calculated across the blood volume loss data as shown below:

Figure 5. Confidence Interval (95%) for the Mean, Blood Loss



This data suggests that there is high variability in blood volume loss in patients treated with the control, which is important due to its inherent ties to lethality and risk to the patient overall. VETIGEL® proved to have a tighter CI, indicating that blood volume loss across all sites was not especially variable. Between time to hemostasis and blood volume loss across a variety of bleeding severities, VETIGEL® presented a notably more consistent performance than the control.

Discussion:

In the surgical theatre, it is of paramount importance to reduce operation time and minimize blood loss. As bleeding introduces some of the more unpredictable and variable circumstances in surgery, solutions to address bleeding across all severities is a priority. The sooner a patient can be stabilized, the more likely there is to be a favorable outcome of a surgery. While this study did not assess quantities of anesthesia used per procedure, it is important to acknowledge that a reduced time to hemostasis may also reduce the amount of time a patient is under anesthesia. Said time under anesthesia also may be correlated to longer recovery times.

Given the high propensity for veterinary practitioners to use gauze with compression and its suboptimal results in terms of average time to hemostasis and blood volume loss, innovations in the hemostatic space such as VETIGEL® offer a compelling alternative. Likewise, in a field where every second counts, being able to utilize a device where bleeding can stop quickly allows a practitioner the ability to continue performing surgery in other areas, given compression-based approaches require compression until bleeding stops.

In future evaluations, there may be value in assessing use of VETIGEL® vs other hemostatic products, its potential benefits in reducing amount of anesthesia needed per procedure, and expedited recovery times. There are also several other wound types that would be useful to assess to characterize the full benefits of its use in animal surgery.

Conclusion:

This study demonstrates that VETIGEL® is a highly effective hemostatic gel in canine mass removal surgery, surpassing conventional techniques across a broad range of bleed severities. VETIGEL® demonstrated a statistically significant reduction in time to hemostasis and a lower measured blood loss per procedure. These findings suggest that VETIGEL® holds notable promise as a valuable tool on the surgical table of veterinary surgeons, improving the outcomes of canine surgical mass removals. In addition to superior performance, the consistency and robustness of applications of VETIGEL® exceeded those of standard of care, which affords practitioners a higher degree of confidence and consistency in its application regardless of bleed severity. Further research is warranted to explore its long-term effects and broader applications in veterinary medicine.

References

- 1- VETIGEL® Video Library. www.vetigel.com/pages/library. Accessed on 2023 Dec 6.
- 2- Taghavi S, Nassar Ak, Askari R. Hypovolemic Shock. [Updated 2023 Jun 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan.
- 3- Giese RA, Valero C, Shah JP. Surgical management of vascular tumors and malformations of the head and neck in adults. *J Oral Pathol Med*. 2022 Nov;51(10):854-859. doi: 10.1111/jop.13302. Epub 2022 Jun 3.

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Disclosures

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The data was analyzed and drafted by Omar Ahmad and Dr. Irene Dris who are employees of Cresilon Inc., in conjunction with Dr. Ann Marie Woyma.