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Review Paper

Traumagel, A Revolutionary FDA- Approved Newly Introduced Hemostatic Agent

Anjali Rawat*, Juhi Joglekar

Smt. B.N.B. Swaminarayan Pharmacy College, Salvav, Vapi-396191, Gujarat, India.

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ABSTRACT

TRAUMAGEL is a groundbreaking, plant-based hemostatic gel designed to help EMS teams, first responders, and trauma centres quickly manage moderate to severe bleeding. Made from a proprietary polysaccharide blend, it forms a thick hydrogel that bonds to wounds, creating an immediate mechanical barrier — without the need for manual pressure. This means faster bleeding control, improved patient comfort, and greater efficiency in emergency settings. Packaged in a sterile, single-use syringe, TRAUMAGEL is easy to apply even in chaotic environments. FDA-approved in 2024 and rolling out nationally in 2025, it's already being adopted by emergency care providers across the U.S. TRAUMAGEL offers an effective alternative to traditional methods like tourniquets and gauze, especially for complex injuries. Early clinical results show rapid bleeding control and better patient outcomes, making it a major advancement in hemorrhage management for trauma care.

INTRODUCTION

Traumatic injury is the leading cause of death among children and adults under 45, surpassing cancer and cardiovascular disease in many parts of the world. Injury and hemorrhage account for 40% of trauma-related deaths. According to the World Health Organization (WHO), injuries, both intentional and unintentional, result in 4.4 million deaths worldwide as of June 19, 2024. Cresilon reports that 40% of gunshot or mass injury deaths are caused by substantial bleeding, whereas 91% of battlefield deaths are due to preventable hemorrhage. Post-traumatic bleeding causes approximately 1.5 million deaths worldwide each year. (1)

Many technologies have thought to control bleeding better, focusing on better effectiveness, ease of use, and lower complications. New treatments in emergency trauma care are modulatory tested first on animals and then, if proven effective, moved to civilian practice, especially in the military. Common hemostatic gauzes such as QuikClot Combat Gauze, Celox

***Corresponding Author:** Anjali Rawat
Address: *Smt. B.N.B. Swaminarayan Pharmacy College, Salvav, Vapi-396191, Gujarat, India*
Email ✉: anjalirawat4820@gmail.com
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Gauze, and ChitoGauze have special clotting agents that help enhance clotting and therefore help stop bleeding more quickly. However, they require that firm pressure is maintained for at least three minutes; they can take time to work and do not always achieve hemostasis. This has warranted additional investments for innovative and improved technologies toward increasing survival rates for seriously traumatic injuries. (2)

Robust Interdisciplinary research efforts are being directed on developing biomaterials-based Technologies that can be administered intravenously and can mimic, amplify and leverage Various mechanistic components of hemostasis to rapidly staunch bleeding. (2)

The Food and Drug Administration has given its approval to Traumagel, a drug-loaded hemostatic device developed to stop severe bleeding through applying it directly within seconds. A 30-milliliter syringe filled with a gel made of algae and fungi with the texture of hummus. The application of such bleeding control is comparatively easy for an operator, hence a great development for emergency use. (3)

UNDERSTANDING HEMOSTASIS AND ITS IMPORTANCE

1. The body's natural clotting mechanism

Healthy endothelial cells prevent clotting by secreting anticoagulants such as heparin-like proteins, thrombomodulin, nitric oxide (NO), and prostacyclin (PGI2), while the endothelial glycocalyx acts as a physical barrier. Upon injury, vasoconstriction reduces blood loss, and the exposure of von Willebrand Factor (VWF), sub-endothelial collagen, and Tissue Factor (Coagulation Factor III) triggers primary hemostasis, where platelets adhere, activate, and aggregate to form a temporary platelet plug. Simultaneously, secondary hemostasis occurs, in which the coagulation cascade amplifies thrombin production, converting fibrinogen into fibrin to stabilize the clot. Platelet-secreted molecules such as adenosine diphosphate (ADP) and platelet factor 4 (PF4) further regulate clot formation. (4,5)

After healing, the fibrinolysis process dissolves the clot through plasmin, which is generated from plasminogen by tissue plasminogen activator (tPA) from endothelial cells and urokinase plasminogen activator (uPA) from immune cells. Fibrin degradation products (FDPs) released during this process aid in wound healing, while inhibitors such as plasminogen activator inhibitor-1 (PAI-1), plasminogen activator inhibitor-2 (PAI-2), alpha-2 antiplasmin (α-2 AP), and thrombin-activated fibrinolysis inhibitor (TAFI) regulate fibrinolysis to maintain hemostatic balance. Disruptions in this system can lead to excessive bleeding (poor clot formation) or thrombosis (excessive clotting), affecting vascular health. (4,5)

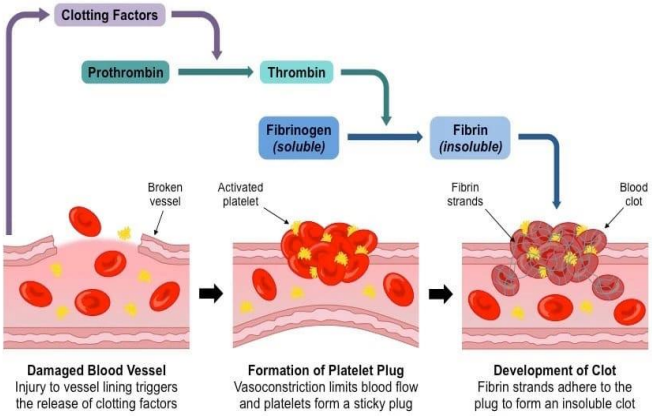

Fig.1. Hemostasis of clotting (6)

2. Challenges in managing excessive bleeding

Managing excessive surgical bleeding presents several challenges, including early recognition of postoperative hemorrhage, maintaining surgical hemostasis in patients with coagulopathies, and the need for rapid intervention to prevent complications.

1. Early Recognition of Postoperative Hemorrhage:

- One of the most difficult aspects is the early detection of ongoing bleeding postoperatively. Subtle clinical signs may be missed or attributed to postoperative fluid shifts. [7,9]
- Vigilance is essential to recognize signs of hemorrhage promptly and decide on reoperation if necessary. [7]

2. Coagulopathy and Hemostasis:
   - Patients with coagulopathies, such as those with renal failure or hepatic dysfunction, pose significant challenges. Conditions like uremia can lead to platelet dysfunction, requiring preoperative interventions like DDAVP or cryoprecipitate.[8]
   - Tissue friability in patients with conditions like Ehlers-Danlos syndrome or prior radiation treatment complicates surgical hemostasis. [7]
3. Damage Control Surgery:
   - In cases of severe, diffuse intraoperative bleeding, damage control surgery is employed to temporize bleeding in critically ill patients. This involves rapid closure and stabilization, followed by intensive care unit management to correct coagulopathy. [7,8]
4. Pharmacologic Interventions:
   - The use of antifibrinolytic agents like tranexamic acid can reduce blood loss but requires careful consideration of patient antithrombotic therapy status. [8]
   - Reversal of antithrombotic agents may be necessary to manage unexpected bleeding during surgery. [8]
5. Intraoperative Assessment and Monitoring:
   - Techniques such as thromboelastography are valuable for assessing global hemostasis and guiding transfusion strategies to minimize blood loss. [8,9]

2.3 Role of hemostatic agent in emergency and surgical care

Hemostatic agents play a crucial role in both emergency and surgical care by facilitating rapid blood clotting and controlling hemorrhage.

1. Emergency Care:
   - Prehospital Hemostasis: Hemostatic agents are used in prehospital settings to control severe bleeding from traumatic injuries. They are essential for preventing hemorrhagic shock and reducing mortality in trauma cases. [10]
   - Rapid Clot Formation: Agents like chitosan-based dressings can form clots quickly, even in patients on anticoagulants or in wet environments. [11]
2. Surgical Care:
   - Surgical Hemostasis: Hemostatic agents are used during surgeries to promote hemostasis, especially in procedures with high bleeding risks such as cardiac or liver surgeries.
   - Topical Application: Topical hemostats are applied directly to the surgical site to enhance clotting and reduce blood loss. [12]

3. WHAT IS TRAUMAGEL?

TRAUMAGEL a plant-based hemostatic gel. It is intended for brief external use and, when applied immediately to a cut, quickly reduces moderate to severe bleeding. The gel comes in a sterile, prefilled 30 mL syringe, which requires no preparation and allows for rapid administration and removal. When applied, TRAUMAGEL establishes a mechanical barrier at the wound site, effectively preventing blood flow and promoting natural clotting. This novel technique has been used in a variety of applications, including non-compressible junctional injuries, extremities injuries, penetrating wounds such as gunshot

wounds, deep lacerations, scalp injuries, amputations, road rash, and huge skin tears. [13]

TRAUMAGEL is the first syringe-applied hemostatic gel approved for moderate-to-severe hemorrhage control. Present hemostatic devices and gauze-based solutions may require preparation or be difficult to use, particularly in cases of severe hemorrhage. Cresilon's gel is intended for instant use, with no preparation necessary. The prefilled syringe style is adaptable to a variety of wound types and geometries. [14]

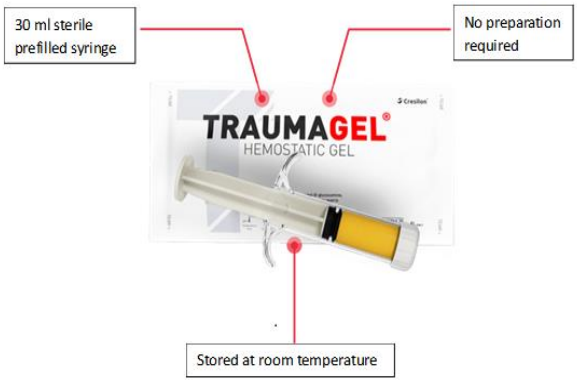

Fig 2 Traumagel [13]

3.1 Composition of Traumagel

Traumagel, a hemostatic agent, is composed of a proprietary blend of polyanionic and polycationic polysaccharides. The primary components include:

1. Sodium Alginate: A polyanionic polymer that forms a hydrogel matrix when exposed to bodily fluids.
2. Poly (N-acetyl-D-glucosamine, D-glucosamine): A polycationic polymer derived from chitosan, which is uniformly dispersed within the sodium alginate hydrogel.[15,16]

These components work together to create a mechanical barrier that stops bleeding and facilitates natural clot formation. [15,16] All components of Traumagel are non-animal derived, making it suitable for use in various medical settings.

3.2 Mechanism of action in stopping bleeding [16]

When mixed with water, it transforms into a gel that can be incredibly effective in stopping bleeding. This gel contains tiny particles of poly (N-acetyl-D-glucosamine and D-glucosamine) that are evenly spread throughout, enhancing its ability to work.

When you apply this hemostatic gel to a bleeding wound, it quickly sticks to the area, creating a protective barrier. This barrier is essential because it helps to stop the blood flow, giving your body the chance to start healing and form a natural clot. In simple terms, this gel not only prevents further blood loss but also supports your body's own healing process. It's a valuable tool in various medical situations, whether you're dealing with a minor cut or a more serious injury. [16]

Steps:

- **Rapid Adhesion and Mechanical Barrier Formation:** When applied directly into a bleeding wound via syringe, Traumagel rapidly adheres to the wound site and forms a mechanical barrier that physically blocks the flow of blood. This barrier effectively stops bleeding almost immediately, without the need for external pressure or packing.
- **Facilitation of Natural Clot Formation:** The gel's hydrogel matrix allows the patient's own blood to form a natural clot underneath it. The gel concentrates blood components at the wound surface, promoting the body's intrinsic hemostatic processes (platelet aggregation and fibrin clot formation) to stabilize the clot.
- **Nonporous, Non-fibrous Structure:** Unlike traditional gauze, which is porous and fibrous and can adhere to the clot, Traumagel is nonporous and lacks fibrous material. This

means the clot forms beneath or adjacent to the gel but does not become incorporated into it. As a result, the gel can be removed cleanly without disturbing the clot, reducing the risk of re-bleeding during subsequent wound care.

- **Polysaccharide Interaction:** The polyanionic and polycationic polysaccharides interact through electrostatic forces, creating a "Lego block" effect that enhances adhesion to tissue and the wound site, strengthening the mechanical barrier against bleeding.
- **Hydrogel Properties:** Being mostly water by weight, the hydrogel gradually loses adhesion over time, facilitating easy removal within 24 hours after application using saline lavage and gauze, without harming the underlying clot.

3.3 Advantages Over Traditional Hemostatic Agents

- **Speed**: Works within seconds, unlike gauze or tourniquets that may take minutes. [17]
- **Ease of Use**: Pre-filled syringe allows direct application without preparation. [16]
- **Safety**:
  - Reduces exposure to bloodborne pathogens by minimizing direct wound contact. [18]
  - Easily removable with saline and gauze, avoiding residue issues seen with powders. [17]
- **Versatility**: Effective for complex wounds (e.g., gunshots, amputations) where tourniquets or packing are impractical.

4. FDA APPROVAL OF TRAUMAGEL

TRAUMAGEL received FDA clearance through the 510(k) premarket notification process, which is used for moderate-risk (Class II) medical devices. Cresilon, the manufacturer, demonstrated that TRAUMAGEL is substantially equivalent in safety and effectiveness to legally marketed predicate hemostatic devices. The submission included data showing that TRAUMAGEL's plant-based hydrogel technology rapidly controls moderate to severe bleeding when applied externally at the point of care, without requiring manual pressure or wound packing. This clearance, granted in August 2024, allows TRAUMAGEL to be marketed and used by EMS, military, and healthcare professionals for temporary external hemorrhage control. The FDA's 510(k) clearance confirms that TRAUMAGEL meets regulatory standards for safety, efficacy, and manufacturing quality, enabling its commercial launch in the U.S. in late 2024 as a novel, easy-to-use hemostatic gel for trauma and emergency medicine. [1,19,20]

4.1 Regulatory standards met by TRAUMAGEL [21]

TRAUMAGEL has received U.S. Food and Drug Administration (FDA) 510(k) clearance as a Class II medical device for temporary external use to control moderate to severe bleeding. This clearance confirms that TRAUMAGEL is substantially equivalent in safety and effectiveness to legally marketed predicate devices. The FDA clearance process for TRAUMAGEL involved demonstrating that its plant-based hydrogel technology can rapidly stop life-threatening hemorrhage when applied at the point of care, without requiring manual pressure or direct contact with the wound. This regulatory approval enables TRAUMAGEL's commercial distribution and use by emergency medical services, military, and healthcare professionals in trauma and emergency settings. Thus, TRAUMAGEL meets stringent FDA regulatory standards for safety, efficacy, and manufacturing quality as a hemostatic medical device.

5. KEY BENEFITS OF TRAUMAGEL

Trauma gel offers numerous benefits for injury management:

1. Pain Relief: Trauma gel provides effective localized pain relief by numbing the affected area, making it particularly useful for managing pain from cuts, burns, or abrasions.
2. Accelerated Healing: The gel promotes faster wound healing by creating a protective barrier that reduces exposure to external contaminants and helps prevent infection due to its antimicrobial properties. [22]
3. Soothing & Cooling Effect: It cools and calms the skin, making it particularly effective for burns by alleviating irritation and inflammation.
4. Protection: Trauma gel creates a protective barrier over wounds, shielding them from environmental contaminants. [23]
5. User-Friendly: The gel forms a protective layer over wounds, guarding against dirt, bacteria, and other environmental factors that could impede healing. It is simple to apply, making it ideal for quick first-aid treatment in emergency situations.
6. Ease of Application: Trauma gel is convenient and straightforward to apply, making it an ideal option for quick first-aid treatment in emergencies or everyday injuries.
7. Versatility: It can be used for a variety of minor to moderate injuries, including abrasions, minor cuts, burns, insect bites, and more, making it a versatile addition to any first aid kit. [24]
8. Non-Sticky and Transparent: Many trauma gels are designed to be non-sticky and transparent, which allows for easy monitoring of the wound while keeping it protected.

6. APPLICATION AND USAGE GUIDELINES [12]

Step 1. Locate the source of the bleeding and remove excess blood from the wound site before applying treatment.

Step 2. Open the pouch and remove the cap. Insert the syringe deep into the wound, aiming for the bleeding source. Rapidly and firmly dispense the entire contents into the wound. Keep the empty package for reference.

Step 3. Place gauze over the wound opening, ensuring it covers the applied gel.

Step 4. Apply firm palm compression over the wound, covering as much surface area as possible. Maintain pressure for three minutes or until bleeding stops, ensuring the gel remains in place. If necessary, apply additional gauze. Retain the empty package and present it to medical personnel.

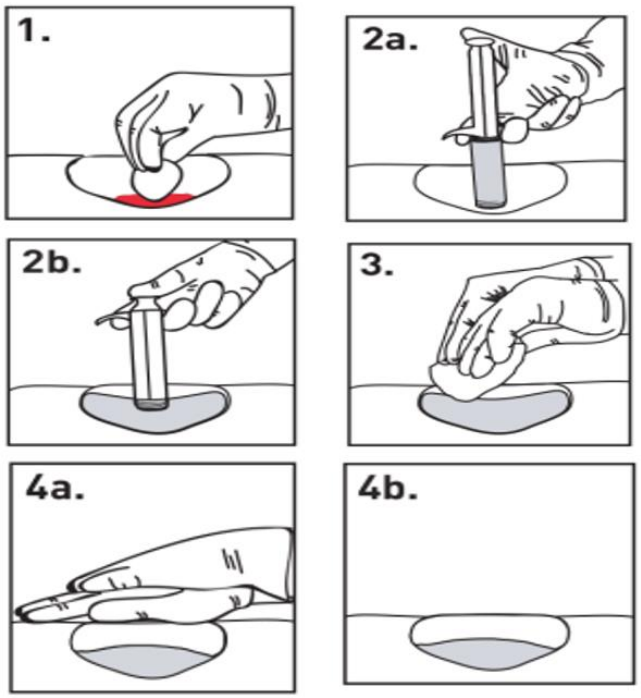

Fig. 3 Steps for application of Traumagel [12]

Trauma gel is a versatile first-aid product designed to manage minor injuries. Its proper application is essential to maximize its benefits during treatment.

1. Preparation Before Application

-Assess the Injury: Before applying trauma gel, examine the injury to determine its severity. Trauma gel is suitable for minor cuts, abrasions, burns, insect bites, and similar injuries. For deeper wounds or significant injuries, seek medical attention.

- Clean the Area: Gently clean the affected area with mild soap and water to remove dirt and debris. Pat the skin dry with a clean towel. Proper cleaning helps to minimize the risk of infection.
- Wash Hands: Before handling the trauma gel, ensure your hands are clean. Wash them thoroughly with soap and water or use hand sanitizer to prevent introducing bacteria into the wound.

2. Application of Trauma Gel

- Shake the Container (if applicable): If the trauma gel is in a container that requires shaking (like a spray), do so according to the manufacturer's instructions.
- Dispense the Gel: Squeeze or spray a small amount of trauma gel onto your clean fingers or directly onto the wound. Use enough gel to adequately cover the affected area.
- Even Distribution: Gently spread the gel over the injury, ensuring uniform coverage. Take care not to rub too hard, as this may cause further irritation to the wound.
- Avoid Inhalation or Contact with Eyes: While applying the gel, avoid inhaling any aerosolized particles (if applicable) and ensure that the gel does not come into contact with the eyes or mucous membranes.

3. Post-Application Care

- Allow to Dry: Let the gel dry naturally on the wound before covering it with a bandage or dressing. This helps form a protective barrier.
- Cover the Area (if necessary): Depending on the size and location of the injury, you may choose to cover the area with a sterile bandage or dressing to provide additional protection while keeping the gel intact.
- Monitor for Reactions: After application, keep an eye on the wound for any signs of an adverse reaction, such as increased redness, swelling, or pus. If any unusual symptoms occur, discontinue use and consult a healthcare professional.

4. Frequency of Reapplication

- Reapply as Needed: Depending on the severity of the injury and the manufacturer's guidelines, reapply the gel every few hours or as needed, especially if the wound is still exposed, dirty, or has been washed.
- Duration of Use: Use trauma gel for the duration recommended by the manufacturer or until the wound shows signs of healing. If the injury does not improve within a reasonable timeframe, seek medical advice.

5. Storage and **Shelf** Life

- Store Properly: Keep trauma gel in a cool, dry place away from direct sunlight and high temperatures. Follow any specific storage instructions provided by the manufacturer.
- Check Expiration Date: Regularly check the expiration date and do not use expired products.

7. HANDLING AND STORAGE CONDITIONS [4,15,16]

Handling:

- TRAUMAGEL is supplied as a sterile, single-use syringe containing 30 mL of hemostatic gel and must only be used by medical professionals.
- The syringe should not be used if the packaging is opened, damaged, or the seal is broken, as sterility may be compromised.
- It is recommended to use TRAUMAGEL immediately after opening the package; any unused contents must be discarded.
- The gel is for temporary external use only and must not be reused or re-sterilized.
- TRAUMAGEL should not be injected intravascularly due to embolization risk and is contraindicated for use in thoracic or abdominal cavity wounds.

- The gel must be removed within 24 hours of application to avoid complications.
- If irritation occurs, the site should be flushed with saline or water until all residue is removed; persistent irritation requires medical attention.

Storage:

- TRAUMAGEL should be stored dry at ambient temperature, specifically between 20-25°C (68-77°F).
- The product is terminally sterilized by gamma irradiation and has a shelf life of 12 months from manufacture.
- It must be kept in its protective pouch until use to maintain sterility.

These conditions ensure the product maintains its efficacy and safety for controlling moderate to severe bleeding in temporary external applications.

8. GLOBAL DEMAND OF ADVANCED HEMOSTATIC SOLUTIONS

The global demand for advanced hemostatic solutions is experiencing strong growth driven by several key factors:

8.1 Market Size and Growth Projections:

- The global hemostasis products market is projected to reach approximately USD 2.65 billion by 2033, growing steadily due to rising surgical demand and trauma care needs.[25]
- Another estimate places the hemostats market at around USD 4.93 billion by 2032, reflecting rapid adoption of advanced surgical procedures and hemostatic technologies.[26]
- The hemostasis product market is expected to grow at a CAGR of about 5.0% from 2025 to 2035, with the market size rising from USD 1.75 billion in 2025 to nearly USD 2.85 billion by 2035. [27]
- The hemostatic agents market specifically was valued at USD 5.2 billion in 2023 and is forecasted to reach USD 8.9 billion by 2032, highlighting robust expansion in this segment. [28]

8.2 Key Demand Drivers s[25,27]

- Increasing number of surgical procedures globally, including minimally invasive and robotic surgeries, which require effective bleeding control.
- Rising incidence of chronic diseases such as cardiovascular diseases, cancer, and liver disorders that often necessitate complex surgeries and trauma interventions
- Growing trauma cases worldwide, including accidents and injuries, which create urgent demand for rapid and reliable hemostatic solutions in emergency care.
- Aging global population with higher prevalence of bleeding disorders and coagulopathies, increasing the need for both therapeutic and diagnostic hemostatic products.
- Technological advancements in biomaterials, including bioengineered, biodegradable, and synthetic agents, as well as AI-driven diagnostics and smart hemostatic dressings, are expanding product efficacy and adoption.

8.3 Regional Insights[27]

- North America, led by the U.S., dominates the market due to advanced healthcare infrastructure, high surgical volumes, and strong R&D investment.
- Europe shows steady growth driven by supportive regulatory policies, increasing healthcare infrastructure, and emphasis on patient safety.
- Emerging markets in Asia, including South Korea, are rapidly expanding due to

government initiatives to improve emergency medical care and surgical treatments.

8.4 Product Segmentation:

- Topical hemostatic products hold the largest market share (around 47.8% in 2025) due to their ease of use and effectiveness in surgical and trauma settings.[27]
- Surgical applications constitute the majority of demand (over 54% market share) as bleeding control is critical for patient outcomes in diverse surgical disciplines.

9. FUTURE DEVELOPMENTS AND INNOVATION IN WOUND CARE

9.1 Technological Advancements

- Artificial intelligence (AI) is transforming wound assessment and treatment planning by analyzing wound images to predict healing, identify complications, and recommend personalized therapies. This enhances decision-making, optimizes resource use, and improves outcomes. [29, 32]
- Smart wound dressings equipped with sensors can monitor parameters like temperature, pH, and moisture in real time, alerting clinicians to infection risks or delayed healing and enabling timely interventions. [29, 30]
- Non-invasive imaging technologies, such as optical coherence tomography and near-infrared spectroscopy, are providing detailed insights into wound health without the need for biopsies, supporting early detection of complications. [29]

9.2 Regenerative Medicine and Bioengineering

- Stem cell therapy and tissue engineering are at the forefront, with stem cells being used to regenerate damaged tissue and bioengineered skin grafts offering more effective and personalized wound coverage. [30,31]
- Bioengineered skin substitutes that mimic natural skin structure are improving healing outcomes for complex and chronic wounds. [29, 31]
- Nanotechnology is enabling the development of dressings that deliver drugs directly to the wound site, increasing therapeutic effectiveness and reducing side effects. [30]

9.3 Personalized and Remote Care

- Personalized medicine is gaining traction, with care plans increasingly tailored to individual genetic profiles, comorbidities, and wound characteristics for more effective healing. [29,32]
- Telehealth and remote wound monitoring are expanding access to expert care, especially for patients in remote areas or with mobility challenges. Virtual consultations and wearable devices facilitate ongoing assessment and education without frequent clinic visits. [29, 30]

CONCLUSION

TRAUMAGEL represents a significant advancement in hemostatic technology, offering rapid, effective, and user-friendly bleeding control for emergency and trauma care. Its plant-based hydrogel formulation provides a safe alternative to traditional methods, enhancing patient outcomes and supporting healthcare providers in critical situations. With growing adoption and ongoing innovation, TRAUMAGEL is poised to play a vital role in the future of hemorrhage management worldwide. It holds significant importance in modern medicine as a rapid, effective, and easy-to-use hemostatic agent that can control severe bleeding within seconds. Originally developed for military use, its recent FDA approval and civilian availability mark a breakthrough in emergency and trauma care, enabling first responders and

healthcare professionals to save lives by preventing potentially fatal hemorrhage quickly and safely. Its plant-based hydrogel technology offers a practical solution that bridges advanced research with real-world applications, transforming bleeding management in both battlefield and civilian medical settings.

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