ACTA Traditional Medicine

Original Research Article
ISSN 2583-7532
Journal homepage: traditionalmedicine.actabotanica.org

Reptile Gel as a Non-Invasive Topical Therapy for Erectile Dysfunction: Findings from the First Clinical Trial and Future Directions of WBCIL

Poulami Gupta Banerjee*, Atanuka Paul, Argha Chakraborty, Suman Banerjee and Sareef Islam

West Bengal Chemical Industries Ltd., Kolkata, India

Citation: Poulami Gupta Banerjee, Atanuka Paul, Argha Chakraborty, Suman Banerjee and Sareef Islam (2025). Reptile Gel as a Non-Invasive Topical Therapy for Erectile Dysfunction: Findings from the First Clinical Trial and Future Directions of WBCIL. ***Acta Traditional Medicine*. DOI: https://doi.org/10.51470/ATM.2025.4.2.39**

Corresponding Author: **Poulami Gupta Banerjee** | E-Mail: **(banerjee.pg@wbcil.co.in)**

24 May 2025: Received | 27 June 2025: Revised | 29 July 2025: Accepted | 10 August 2025: Available Online

ABSTRACT

Erectile dysfunction (ED) is a prevalent condition influenced by vascular, psychological, and lifestyle factors. While PDE5 inhibitors remain a standard treatment, their systemic side effects necessitate alternative solutions. Reptile Gel, a topical formulation developed by West Bengal Chemical Industries Ltd., Kolkata, India (WBCIL), offers a fast-acting, non-invasive approach that enhances penile blood flow through an evaporative cooling and warming mechanism, stimulating nerve endings and promoting vasodilation. It is a non-drug topical application with no reported side effects and is approved as an over-the-counter (OTC) product by the USFDA. These unique selling propositions (USPs) make Reptile Gel a safe, convenient, and effective alternative to conventional ED treatments. The formulation, optimized with ethanol, propylene glycol, glycerin, and carbomer, ensures rapid absorption and a favorable safety profile.

In this first clinical trial, we evaluated an advanced formulation of Reptile Gel developed by WBCIL, focusing on skin surface temperature dynamics as a marker of thermogenic activity. Temperature was measured at baseline and at 1, 10, and 15 minutes post-application, revealing a biphasic thermal response. These findings informed the design of a second ongoing trial, which will focus on Peak Systolic Velocity (PSV) assessment using Doppler ultrasound in a larger cohort to further investigate the gel's vascular effects.

As a CE-compliant medical device under the EU MDR framework, Reptile Gel presents a safe and effective alternative to conventional ED therapies, improving penile hemodynamics without systemic side effects. Reptile Gel effectively treats ED while boosting confidence, self-esteem, and relationships, offering a discreet, transformative solution for enhanced well-being.

Keywords: *Reptile Gel, Erectile dysfunction, Topical therapy, Non-invasive treatment and Clinical trial.*

1. Introduction

Reptile Gel is an innovative topical solution for erectile dysfunction (ED), designed to offer a fast-acting, non-invasive, and drug-free alternative to traditional treatments.[1] Unlike oral medications, which require systemic absorption and may cause side effects, Reptile Gel works through a physical evaporative cooling mechanism that stimulates nerve endings in the glans penis, triggering vasodilation and increased blood flow.[2] This dual-temperature effect, where rapid cooling is followed by gradual warming, enhances sensory stimulation, facilitating an erection within minutes. As a readily available over-the-counter (OTC) product, Reptile Gel offers a convenient and discreet solution without the need for prescriptions.[3] It is designed for ease of use, works seamlessly with latex condoms and lubricants, and has been clinically tested to ensure safety, with no reported irritation or discomfort. Clinical trials confirm its excellent safety profile, with no observed irritation, redness, or systemic side effects. Usually, OTC topical agents for ED are known to cause localized side effects such as skin irritation, burning, or allergic reactions at the application site. Also, it leads to partner-related side effects, particularly in women, due to transference during intimate contact with common irritants of alprostadil, menthol, benzocaine, and nitroglycerin [4]. Reptile Gel formulation has been specifically designed to minimize adverse reactions and ensure safety for both users and their partners. It is free from known irritants and does not pose a risk of transference-related side effects, making it a safer option for individuals seeking topical solutions for improved circulation and performance. Beyond its direct impact on erectile function, Reptile Gel offers the potential to positively influence overall wellness and social dynamics. By addressing a condition that often contributes to emotional distress and relationship strain, the gel enhances general well-being, improves intimacy, and strengthens familial bonds. The restoration of sexual confidence and function can translate to a more fulfilling and connected life, positively impacting mental health, social interactions, and overall quality of life.

West Bengal Chemical Industries Ltd., Kolkata, India (WBCIL), a leading API manufacturer, has played a crucial role in developing the advanced formulation of Reptile Gel. Utilizing cutting-edge pharmaceutical technology, WBCIL has optimized the gel for smooth application, rapid absorption, and maximum efficacy by carefully balancing volatile and non-volatile components to create an ideal cooling-warming cycle. The inclusion of ethanol, propylene glycol, glycerin, and carbomer ensures moisturization, enhanced spreadability, and reduced viscosity, making the gel non-sticky and comfortable for use [5]. In this study, we present findings from our first clinical trial evaluating an advanced formulation of Reptile Gel, developed by WBCIL. The primary objective of this trial was to assess the skin surface temperature dynamics at the site of application as an indicator of the gel's thermogenic and vasomotor effects.

Temperature measurements were recorded at four specific time points: immediately before application (baseline), and at 1 minute, 10 minutes, and 15 minutes following gel administration. This temporal profiling allowed us to capture the biphasic thermal response—characterized by an initial cooling phase followed by progressive warming—providing valuable insights into the physiological action of the formulation on dermal microcirculation. By maintaining strict European Union Medical Device Regulation (EU-MDR) compliance and conducting rigorous quality control testing, WBCIL has established Reptile Gel as a breakthrough solution in men's sexual health, offering a quick, effective, and safe alternative to traditional ED treatments.

2. ED and its causes, and limitations of traditional therapies

ED is a prevalent condition that affects millions of men worldwide, particularly those in their middle and older years.[1] It is defined as the inability to achieve or maintain an erection sufficient for sexual intercourse, and its impact is not limited to the individual but also affects interpersonal relationships and overall quality of life.[1, 2] The causes of ED are multifactorial and can be broadly categorized into physical, psychological, and lifestyle factors.[3] The most common physical causes include cardiovascular diseases, diabetes, hypertension, and hormonal imbalances.[4] These conditions can interfere with the blood flow to the penis, disrupting the complex process that leads to an erection. For an erection to occur, Nitric Oxide (NO) is released in the penile tissues, causing vasodilation and increased blood flow.[5] However, in the presence of conditions like diabetes or atherosclerosis, this mechanism is impaired, leading to ED.[6] Obesity is a major risk factor, as excess body weight is linked to reduced testosterone levels, increased inflammation, and vascular dysfunction, all of which impair erectile function. Similarly, endocrine disorders such as hyperthyroidism and hypothyroidism can disrupt hormonal balance, leading to reduced libido and poor erectile response. Diabetes, another common cause of ED, damages blood vessels and nerves, making it difficult to achieve or maintain an erection. Cardiovascular diseases, including hypertension and atherosclerosis, restrict blood flow to the penis, further exacerbating ED symptoms. Additionally, neurological disorders such as Parkinson's disease and multiple sclerosis can interfere with nerve signals essential for sexual function. Psychological factors such as stress, anxiety, and depression can also play a significant role in the onset and persistence of ED.[6] Additionally, lifestyle choices like smoking, alcohol consumption, and poor diet can exacerbate the condition.[8] The treatment of ED has evolved significantly in recent years, with several therapeutic options available.[7] The most widely used pharmacological treatments are phosphodiesterase type 5 (PDE5) inhibitors such as sildenafil, tadalafil, and vardenafil. [7] These medications work by enhancing the effects of NO in the penis, leading to improved blood flow and easier attainment of an erection. However, these drugs may have side effects, including headaches, dizziness, and gastrointestinal disturbances, and may not be suitable for individuals with certain health conditions, such as those with heart disease or low blood pressure.[8] In addition to pharmacological treatments, there is increasing interest in non-pharmacological approaches to managing ED.[9] These include lifestyle changes such as exercise, weight management, and improved diet, which can help improve blood circulation and overall erectile function.[10] Psychological therapies, such as cognitive behavioural therapy (CBT), have also been found to be beneficial for men whose ED is influenced by psychological factors.[10] However, there is a lack of data on the beneficial effects of CBT in ED in large number of populations.

3. Reptile Gel as a Treatment for Erectile Dysfunction

More recently, natural and alternative treatments, including herbal supplements and topical gels, have gained popularity as viable options for managing erectile dysfunction. While there are numerous pharmacological treatments for ED, recent interest has emerged in alternative and natural remedies, including the use of topical gels like Reptile Gel.[11] Reptile Gel, derived from natural sources such as bioactive compounds that have been shown to have vasodilatory effects, which assist in improving blood flow to the penis.[12, 13] These compounds are thought to work by enhancing NO production or mimicking its effects, promoting relaxation of smooth muscle tissue and facilitating the increased blood flow needed for an erection.[14] Reptile Gel is typically applied topically to the penile area, where it is absorbed through the skin. cGMP is a key molecule that relaxes smooth muscle cells in blood vessels, allowing increased blood flow to the penile tissue and facilitating an erection.[14] Reptile Gel, however, does not function through direct inhibition of the PDE5 enzyme. Instead, it utilizes a topical approach, likely working through a combination of thermal stimulation (cooling followed by warming) and sensory nerve activation, which may promote vasodilation and enhance local blood circulation. While the result—improved blood flow to the penile tissue—resembles the effect of PDE5 inhibitors, the underlying biological mechanism differs. Unlike oral PDE5 inhibitors, which require systemic absorption and may cause side effects such as headaches, flushing, or gastrointestinal discomfort, Reptile Gel remains localized, potentially reducing the risk of systemic adverse effects. Some studies have suggested that Reptile Gel can promote both short-term and long-term improvements in erectile function, although the evidence is still limited and not universally accepted. The gel is often marketed as a more natural alternative to oral medications, with fewer side effects, as it is applied locally rather than ingested.[15] Additionally, Reptile Gel appeals to individuals seeking a more discreet treatment option, as its application does not require a prescription and offers a more personalised, affordable therapy.[15]

The precise mechanism of action of Reptile Gel in the treatment of erectile dysfunction is believed to be linked to its ability to enhance blood circulation and vasodilation.[16] NO is crucial for erectile function, as it signals the relaxation of smooth muscle cells in the penis, leading to vasodilation and an increase in blood flow. By improving blood flow, and possibly influencing NO pathways, Reptile Gel may help restore natural erectile function in men with ED. Studies on Reptile Gel show promising results and more research is being conducted to understand its full potential as a treatment for erectile dysfunction.

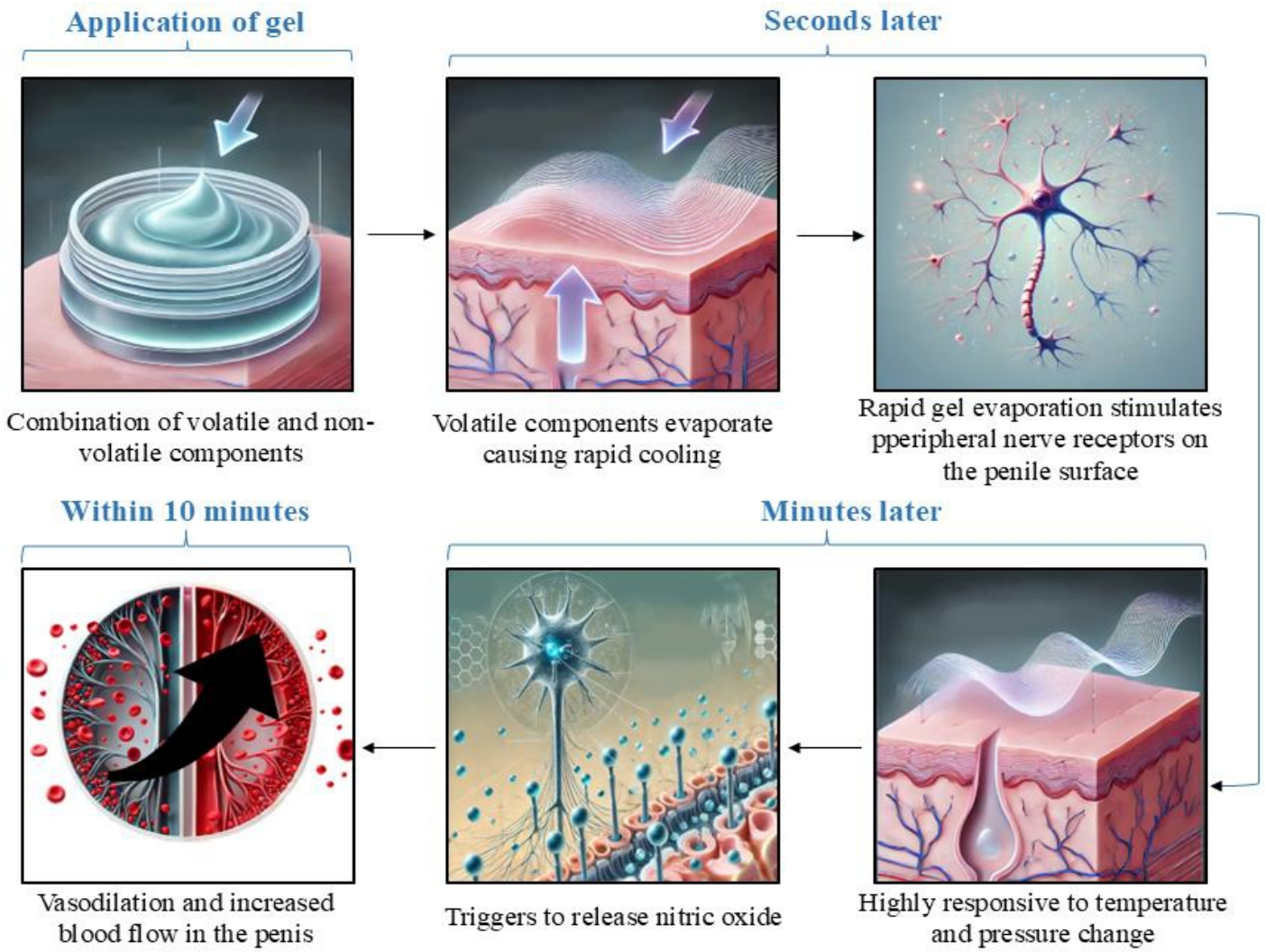

Figure 1: A schematic indicating application of Reptile Gel to restore blood flow

From the literature, a significant challenge is found in meeting patient expectations to address the issues of ED.[17] With different formulations containing varying components of active compounds, which may not be applicable to every individual diagnosed with ED, thereby potentially impacting their effectiveness.[18] Our product addresses this issue by ensuring a standardized, scientifically formulated concentration of active ingredients, providing consistent and reliable results. Additionally, while there remains no doubt in the long-term safety of Reptile Gel due to its drug-free formulation, we are committed to conducting comprehensive clinical trials to thoroughly assess both the risks and benefits of our product.[19, 20, 21] By bridging these gaps, Reptile Gel targets to become a widely accepted, safe, and effective treatment for erectile dysfunction.

3.1. Mechanism of Action of Reptile Gel and interrelationship between temperature, erectile dysfunction, and vasodilation

The interrelationship between temperature, ED, and vasodilation is central to the mechanism of action of Reptile Gel. ED is often linked to impaired vasodilation—the process by which blood vessels relax and widen—leading to insufficient blood flow to the genital organ.[20] Reptile Gel initiates a biphasic thermal response upon topical application, beginning with evaporative cooling followed by progressive warming. This temperature fluctuation activates sensory nerve endings, stimulating the local release of NO, a key mediator of vasodilation.[21] The initial cooling sensation induces transient vasoconstriction, which is rapidly succeeded by vasodilation as blood flow increases to restore warmth.[22] The gradual rise in skin surface temperature post-application indicates enhanced microcirculation and sustained vasodilatory activity. This thermogenic response mimics natural physiological cues for arousal and blood flow, effectively improving penile haemodynamics without systemic side effects.[21, 22] Therefore, the thermal modulation provided by Reptile Gel not only facilitates vasodilation but also serves as a non-invasive therapeutic strategy for managing ED.

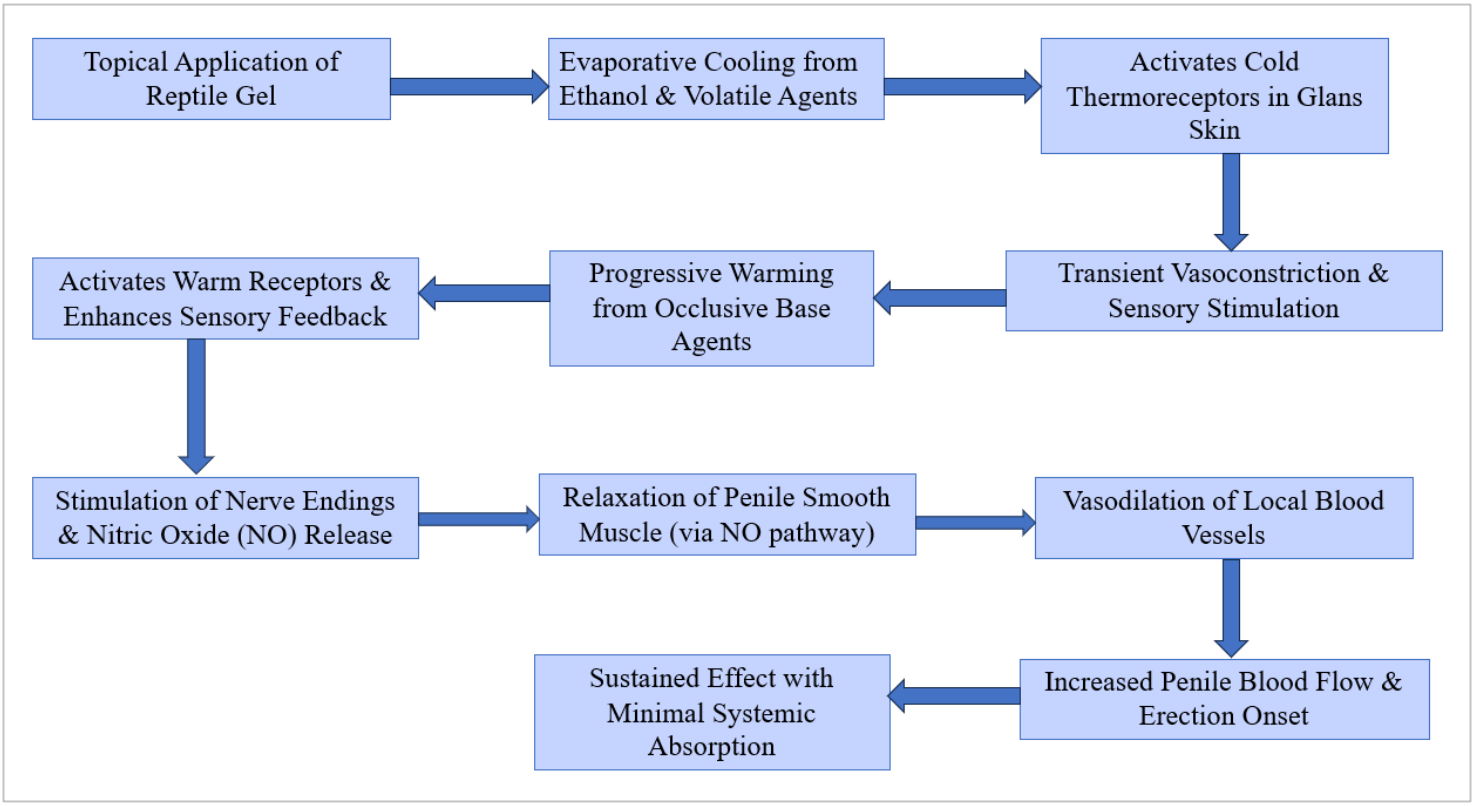

Figure 2: Reptile Gel: Mechanism of Action

3.2. Comparative Perspective: Serpentine Venom-Based Products vs. Reptile Gel and Market Alternatives

Table 1: Comparative insights of market-available ED products

Category	Example(s)	Rx/OTC	Primary mechanism	Typical onset
Non-medicated topical gel	Eroxon (MED3000)	OTC	Physical/thermomechanical neurovascular stimulation	~10 minutes
Oral meds	Sildenafil, Tadalafil, etc.	Rx	PDE5 inhibition (NO pathway amplification)	~30 minutes (varies)
Topical alprostadil cream	Vitaros	Rx	PGE1-mediated smooth-muscle relaxation	10 minutes
VEDs	Multiple devices	Device	Negative pressure downregulates tumescence	Several Minutes
Investigational NO donors	GTN gels (MED2005)	Investigational	Topical NO donor vasodilation	≤10 minutes

In the pursuit of alternative therapies for ED, several research groups have investigated the use of serpentine venom-derived compounds, including phospholipases, disintegrins, and natriuretic peptides, which demonstrate vasodilatory and pro-erectile effects in preclinical models.[17] These components, isolated from snakes such as Bothrops jararaca, Crotalus durissus, and Lachesis muta, have been shown to modulate nitric oxide (NO) pathways and enhance blood flow through smooth muscle relaxation and inhibition of platelet aggregation.[18] However, despite their promising mechanisms, these venom-based agents remain experimental and unapproved for clinical use in human ED treatment, due primarily to concerns over toxicity, immunogenicity, stability, and precise dose control.[19]

By contrast, Reptile Gel offers a safe, non-toxic, and EU- MDR-compliant alternative with a well-characterized thermogenic mechanism.[20] Unlike serpentine venom products, Reptile Gel does not rely on complex biological toxins but instead utilizes a physical evaporative cooling–warming mechanism, paired with a carefully balanced formulation of ethanol, glycerin, propylene glycol, and carbomer to promote localized vasodilation.[21] Clinical data demonstrate no adverse effects, no systemic absorption, and excellent skin tolerability, making Reptile Gel suitable for over-the-counter (OTC) use.

When positioned against products already available in the ED market, Reptile Gel is conceptually closer to Eroxon® (MED3000), the first non-medicated gel authorized by the FDA under the De Novo pathway for ED.[22] Like Eroxon, Reptile Gel emphasizes a physical neurovascular mechanism rather than systemic pharmacology, with a rapid onset of action (~10–15 minutes) and minimal systemic risk.[25] This contrasts with oral PDE5 inhibitors (sildenafil, tadalafil, vardenafil, avanafil), which are effective first-line therapies but require systemic exposure and carry contraindications in men using nitrates.[26] Similarly, topical alprostadil cream (Vitaros®) and alprostadil injections or intraurethral suppositories provide localized pharmacologic action but are restricted to prescription-only use and often associated with local adverse events such as erythema and burning.[23]

Device-based solutions such as vacuum erection devices (VEDs) are non-pharmacologic and guideline-supported, but many patients find them cumbersome and report lower satisfaction rates.[27] Meanwhile, investigational approaches such as glyceryl trinitrate gels (MED2005) have shown promise in clinical trials due to their NO-donor vasodilatory effect, but they remain unapproved for ED therapy.[24]

In this context, Reptile Gel combines the ease of topical application, rapid onset, absence of systemic drug interactions, and consumer acceptability, setting it apart from venom-derived experimental agents and aligning it more closely with next-generation OTC topicals like Eroxon.[28] These attributes not only enhance patient compliance but also reduce the risk of partner-related irritation—an issue common in investigational venom-derived products.

4. Unique features of Reptile Gel manufactured by WBCIL

Reptile Gel, developed and manufactured by WBCIL, is a fast-acting and highly effective topical solution for erectile dysfunction, clinically proven to help achieve an erection within 10 minutes. Unlike conventional pharmacological treatments, Reptile Gel works through a physical rather than chemical mechanism, qualifying it as a medical device under EU Regulation 2017/745 (MDR). Reptile Gel not only provides a potential solution for ED but also has a profound impact on the confidence and self-worth of individuals. By offering an effective treatment that enhances performance, it helps individuals regain their sense of control and self-assurance, reducing anxiety and stress often associated with erectile issues. This boost in confidence can have a positive ripple effect, improving overall well-being and fostering healthier relationships. Socially, the availability of a non-invasive, accessible treatment like Reptile Gel can contribute to breaking down the stigma surrounding erectile dysfunction. It encourages open conversations, helping individuals feel more empowered to seek solutions and maintain fulfilling personal and intimate connections. The wider acceptance and use of such treatments also support a healthier approach to mental and emotional health, reducing the social pressure that often comes with these challenges. One of the key advantages of Reptile Gel is its optimized formulation, designed for smooth application, non-sticky texture, and rapid absorption. Developed using cutting-edge pharmaceutical technology at WBCIL, the gel contains ethanol for evaporative cooling, glycerin to retain moisture, propylene glycol for enhanced skin hydration, and carbomer to provide the ideal gel consistency. Additionally, it is pH-balanced, making it comfortable to use and fully compatible with latex condoms and lubricants, ensuring it integrates seamlessly into intimate moments. Its high safety profile makes it suitable for most men, with a minimal incidence of side effects for both users and their partners. Beyond its ease of use, Reptile Gel has been scientifically tested by WBCIL to show that the gel enhances skin microcirculation and vasodilation, leading to a measurable increase in skin temperature and perfusion rates after application. In the clinical study, human skin patch tests confirmed no redness, swelling, itching, or blistering, highlighting its excellent tolerability. Reptile Gel's versatility extends to its effectiveness across psychological, organic, and mixed erectile dysfunction cases, from mild to severe conditions. As a non-prescription topical treatment, it offers a discreet and accessible alternative for men seeking improved sexual performance without the need for traditional medication. In addition, several topical agents for ED are known to cause partner-related side effects, particularly in women, during intimate contact. Common ingredients that contribute to such irritation include alprostadil, menthol, benzocaine, and nitroglycerin, which can cause redness, itching, or discomfort. However, our Reptile Gel formulation has been specifically designed to minimize adverse reactions and ensure safety for both users and their partners. It is free from known irritants and does not pose a risk of transference-related side effects, making it a safer option for individuals seeking topical solutions for improved circulation and performance. With its revolutionary formulation, rigorous clinical validation by WBCIL, and an outstanding safety profile, Reptile Gel stands out as a game-changer in men's sexual health, providing a convenient, effective, and innovative solution for ED. Moreover, Reptile Gel provides a smooth and effortless application with reduced viscosity and a non-sticky appearance.

5. Methodology

5.1. Study Design

A clinical trial was conducted to evaluate the effects of Reptile Gel, manufactured by WBCIL, on skin surface temperature in human participants. This was a single-arm, pre-post interventional study where each participant served as their own control. The study aimed to assess the impact of Reptile Gel on skin surface temperature over time.

5.2. Participants

A total of eight healthy adult participants were recruited for the study. Participants were all male, aged between 35 and 52 years. The inclusion criteria required participants to have no known cardiovascular disease, diabetes, or dermatological conditions. Height, weight, and Body Mass Index (BMI) were recorded for each participant to assess baseline physiological status.

5.3. Application of Reptile Gel

The Reptile Gel was topically applied to a designated area of the skin for each participant. The quantity and specific application site were standardized across all participants. The gel was gently massaged into the skin to ensure uniform absorption and coverage. No additional interventions, such as heating, cooling, or occlusion, were used to modify the absorption or effects of the gel.

5.4. Study Parameters and Data Collection

5.4.1. Patch Test

The patch test was conducted to assess the safety and potential skin reactions to Reptile Gel before its full application in the clinical trial. A small amount of the gel was applied to a 2x2 cm area on the forearm of each participant. The gel was gently massaged into the skin, and a non-occlusive dressing was used to cover the area, ensuring that the gel remained in contact with the skin for the required period. Participants were instructed not to wash or disturb the test site during the observation period. The patch was left in place for 24 hours to allow for the identification of any delayed reactions. The skin was closely monitored for signs of redness, swelling, itching, blistering, or rash at 12- and 24-hours post-application. After the observation period, the patch was removed, and the skin was examined for any adverse reactions. If no irritation or reaction was observed, the patch test was considered negative, indicating that the Reptile Gel was safe for further use in the clinical trial.

5.4.2. Cream Property Analysis (Spreadability test)

The spreadability of Reptile Gel was evaluated using a standard glass plate method. A fixed quantity of 500 mg of the gel was placed between two glass plates, with a known weight applied on the upper plate to spread the sample uniformly. The spread area was then measured in square centimeters, providing a quantitative assessment of the gel's ability to distribute under applied pressure. This method reflects the ease with which the gel can be applied over the skin surface during actual use.

5.4.3. Skin Surface Temperature Assessment

Skin surface temperature was recorded at three time points using a calibrated infrared thermometer. Pre-application baseline at 0 minutes, 10 minutes post-application, and 15 minutes post-application. These measurements were taken at the same anatomical site where the gel was applied. Temperature variations were analyzed to assess the potential thermogenic or cooling effects of the gel.

5.4.4. Skin redness Assessment in patients

In the evaluation of Reptile Gel's safety profile, the gel was applied to the skin at two distinct anatomical sites—the posterior neck region and the dorsal aspect of the foot—as depicted in Figure 6 (a) and (b). These areas were selected to assess potential localized reactions due to their varying skin thickness and sensitivity.

5.4.5. Statistical Analysis

The collected data were subjected to descriptive and comparative analysis. Mean values of skin temperature at different time points were compared to determine the statistical significance of observed changes. Paired t-tests were used to evaluate the differences between pre- and post-application values.

5.4.6. Ethical Considerations

All procedures adhered to ethical guidelines, and written informed consent was obtained from each participant prior to the study.

The study was conducted in accordance with the Declaration of Helsinki, ensuring participant safety, voluntary participation, and data confidentiality.[24] There were no reported adverse effects from the application of Reptile Gel.

6. Results and Discussion

6.1. Results

6.1.1. Patch Test

Before the full application of the Reptile Gel, a patch test was conducted on all participants to assess any immediate allergic or irritant responses to the gel. Each participant had one patch of a small amount of the gel and one patch of blank solution (purified water) applied on the forearm, and the sites were observed for 24 hours for any signs of irritation, redness, or swelling. None of the participants showed any signs of irritation, redness, or swelling during the observation period. These results indicate that the formulation is well-tolerated and suitable for use on the skin, suggesting a low likelihood of adverse skin reactions.

Figure 3: Patch Test Result Showing no signs of irritation, redness, or swelling (a) before, (b) immediately after application and (c) after 24 hours of application of Reptile Gel.

6.1.2. Spreadability analysis

The spreadability test demonstrated that a 500 mg sample of Reptile Gel achieved a spread area of 23.74 cm^2. This high spreadability value indicates that the formulation possesses low resistance to spreading, ensuring smooth, even application and uniform coverage. Combined with its optimized viscosity and non-sticky nature, this property contributes to enhanced user comfort and effective topical delivery.

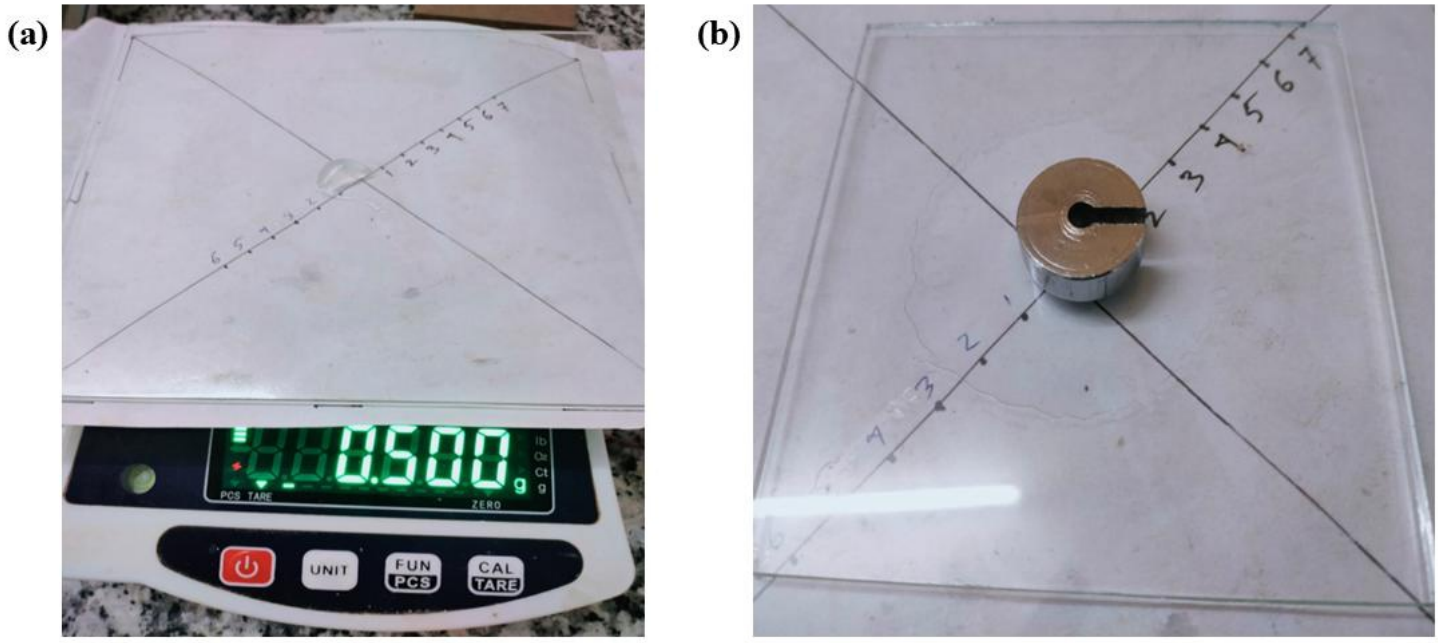

Figure 4: Spreadability Analysis of Reptile Gel. (a) The amount of Reptile Gel taken (500 mg) for the analysis and (b) The spreadability of Reptile Gel

6.1.3. Demographic and Anthropometric Data

Table 2: Demographics and Physical Parameters of the Participants

Se. No.	Name	Age	Height	Weight (kg)	BMI	State	City	Suburb	Pincode
1	Avik Pal	52	5'4"	65	24.6	West Bengal	Kolkata	Baghbazar	700005
2	Suman Banerjee	35	5'11"	74	22.8	West Bengal	Bankura	Shaspur	722205
3	Birendra Nath Sarkar	37	5'4"	71	26.9	West Bengal	Kolkata	Talbagan	700090
4	Uttam Sen	46	5'0"	50	21.5	West Bengal	Kolkata	Agarpara	700112
5	Shib Ratan Ram	62	5'1"	58	11	West Bengal	Kolkata	Madhyamgram	700132
6	Manendra Nath Adhikary	51	5'3"	56	21.9	West Bengal	Kolkata	Baghbazar	700005
7	Pradeep Kumar Singh	36	5'7"	75	26.0	West Bengal	Kolkata	Cossipore	700002
8	Ananta Dey	41	5'4"	64	24.2	West Bengal	Dankuni	Belanagar	712310

Table 3: Health and Lifestyle Factors of the Participants

Se. No.	Name	Pre-existing Health Conditions	Blood Thinners (Past 7 Days)	Daily Exercise (20 mins)
1	Avik Pal	Hypertension	No	No
2	Suman Banerjee	N/A	No	No
3	Birendra Nath Sarkar	N/A	No	No
4	Uttam Sen	N/A	No	No
5	Shib Ratan Ram	N/A	No	No
6	Manendra Nath Adhikary	Hypertension	No	No
7	Pradeep Kumar Singh	N/A	No	No
8	Ananta Dey	N/A	No	No

The dataset represents eight male participants from West Bengal, with ages ranging from 35 to 62 years. The average age lies in the mid-40s, reflecting a middle-aged population prone to lifestyle-related health risks. Height varies from 5'0" to 5'11", and weight ranges from 50 to 75 kg.

The BMI values of most participants fall within the normal to overweight range (21.5–26.9), except for Shib Ratan Ram, whose BMI is recorded as 11, indicating severe underweight and possibly an error or a case requiring medical attention. Three individuals (Birendra Nath Sarkar, Pradeep Kumar Singh, and Avik Pal) have BMI values close to or above the overweight threshold (≥25).

Two participants, Avik Pal (52 years) and Manendra Nath Adhikary (51 years), reported hypertension, a common cardiovascular risk factor in older adults. None of the participants reported taking blood thinners in the past seven days, indicating no ongoing anticoagulant therapy.

An important observation is that none of the individuals reported engaging in daily exercise for at least 20 minutes, which highlights a sedentary lifestyle across all participants. This is a concerning trend, as lack of physical activity combined with hypertension and overweight tendencies significantly increases cardiovascular and metabolic health risks.

Geographically, most patients are concentrated around Kolkata and its suburbs, with only one participant (Suman Banerjee) coming from Bankura district and another (Ananta Dey) from Dankuni. This urban-centric population may reflect lifestyle factors such as reduced physical activity and a higher prevalence of metabolic disorders.

6.1.4. Effects on Skin Surface Temperature

The skin surface temperature was recorded at four different time points: pre-application, and 1, 10, and 15 minutes post-application as outlined in table 4.

Table 4: Changes in surface temperature both before & after application of Reptile Gel

Participants	Temperature Before Application (°C)	Temperature Post-Application (°C)			Temperature Difference Between 1 and 15 mins (°C)
		1 min	10 min	15 min	
S1	31.1	29	30.7	31.5	2.5
S2	29.1	27.5	29	29.4	1.9
S3	32	30.2	31.9	32.4	2.2
S4	31.9	30.1	31.3	32.5	2.4
S5	34.1	31.9	33.7	34.5	2.6
S6	34.8	32.4	33.8	34.1	1.7
S7	32	29.8	31.9	32.4	2.6
S8	31.9	30	31.3	32.5	2.5

The results indicate a progressive increase in skin surface temperature following the application of the test formulation, suggesting a vasodilatory effect. Initial temperatures ranged from 29.1°C to 34.8°C, showing individual variability. At 1-minute post-application, a slight decrease in temperature was observed across all participants (29.0°C to 30°C); however, from 10 minutes post-application, an evident increase was observed in all participants, indicating an initial response due to increased blood flow. By 15 minutes, the temperature continued to rise (from 29.4°C to 34.8°C), confirming sustained vasodilation. Significant changes were noted in participants S1, S3, S5, S6, and S7, with S5 and S6 exhibiting the highest increases (1.0°C to 1.5°C). This slight decrease in temperature at 1 minute across all participants indicate an initial evaporative cooling effect due to the application of the formulation, representing a transient vasoconstriction response before vasodilation. This formulation momentarily triggers a cooling sensation before increasing circulation. The temperature rise after a momentary decrease suggests the activation of vasodilation, likely due to components present in the formulation eliciting physical stimulation leading to increase in blood flow [20]. This aligns with the expected physiological response where local circulation increases following the initial adaptation period [21]. The continued rise at 15 minutes indicates prolonged vasodilatory effects. This suggests that the formulation enhances microcirculation over an extended period, making it potentially useful for application [22].

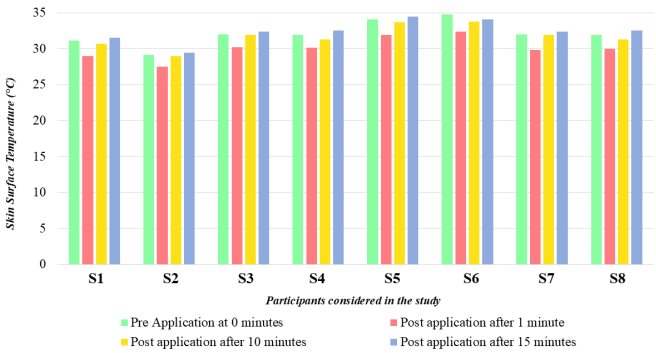

Figure 5: Effects on Skin Surface Temperature, showing temperature changes before application, at Pre application and 1-, 10- and 15-minutes post-application of different participants.

6.1.5. Assessment of skin redness in participants

Following application, the sites were closely monitored for signs of skin irritation, redness, or discomfort over a specified period. Notably, no irritation, erythema, or adverse cutaneous reactions were observed at either location, consistent with the gel's formulation design to minimize irritant effects as observed on Figure 6. These findings demonstrate Reptile Gel's excellent tolerability and support its safety for topical use, aligning with the clinical trial outcomes reported.

Figure 6: Photographs showing carotid artery and posterior tibial artery regions (a) before and (b) after Reptile Gel application.

6.2. Discussion

The results indicate that the application of the Reptile Gel formulation positively influenced skin surface temperature. The gradual rise in skin surface temperature supports this, indicating sustained peripheral circulation enhancement. Previous research has demonstrated that certain bioactive compounds in topical formulations can influence blood flow and thermoregulation, which aligns with the findings of this study. [26, 27] The skin surface temperature findings further support the hypothesis of increased peripheral circulation. A sustained rise in temperature over 15 minutes post-application suggests prolonged vasodilatory effects, which could be beneficial for conditions related to poor circulation, such as diabetic neuropathy or Raynaud's phenomenon.[28] From the literature, topical formulations containing bioactive peptides, flavonoids, or botanical extracts can stimulate thermogenic responses by modulating cutaneous blood flow. [29] These responses align with the observed gradual increase in temperature among the trial participants. Individual variations in response to the formulation may be attributed to differences in vascular reactivity, BMI, metabolic rate, and baseline circulatory efficiency.

The findings suggest Reptile Gel formulation can simplify treatment of ED by enhancing circulation and mitigating vascular insufficiency-related conditions.

7. Conclusion

Reptile Gel, developed by WBCIL, represents a promising and innovative solution for the management of ED. Its unique mechanism, relying on physical evaporative cooling and warming, offers a non-invasive, drug-free alternative to traditional ED treatments. The clinical trial conducted by WBCIL demonstrates the gel's *safety and efficacy*, highlighting noticeable shifts in skin surface temperature at the site of application. These results indicate that Reptile Gel has the potential to be a valuable option for individuals seeking a *quick, effective, and safe treatment for ED*, with *minimal side effects* and *no systemic absorption issues*. The gel's formulation, leveraging cutting-edge pharmaceutical technology, ensures *rapid absorption, non-sticky texture*, and *enhanced user comfort*, making it a viable treatment for ED cases. Additionally, it has *no harmful effects on partners (specifically women),* and is *compatible with latex condoms and lubricants,* further enhancing its accessibility and ease of use.

The present study constitutes our first clinical trial, which was primarily focused on evaluating surface skin temperature changes following topical application of Reptile Gel. The observed biphasic thermal response suggests localized vasodilation and supports the gel's thermogenic action. Building on these findings, our second trial has now commenced, with a specific focus on measuring Peak Systolic Velocity (PSV) using Doppler ultrasound as a direct indicator of vascular response. This next phase involves an expanded pool of human subjects, allowing for greater statistical reliability and a more in-depth understanding of the gel's vasodilatory potential. The transition from thermal to vascular metrics reflects our commitment to systematically validating the physiological efficacy of Reptile Gel through a stepwise clinical approach.

References

1. Burnett, A. L. (2019). Erectile dysfunction: Science and clinical practice. American Journal of Medicine, 132(5), 584–590. https://doi.org/10.1016/j.amjmed.2018.11.035

2. Hatzimouratidis, K., Giuliano, F., Moncada, I., Muneer, A., Salonia, A., & Verze, P. (2021). EAU guidelines on erectile dysfunction. European Urology, 79(2), 365–379. https://doi.org/10.1016/j.eururo.2020.11.013

3. McMahon, C. G. (2019). New therapeutic approaches in erectile dysfunction. Journal of Sexual Medicine, 16(9), 1345–1352. https://doi.org/10.1016/j.jsxm.2019.06.009.

4. Cavallini, G., Scroppo, F. I., & Zucchi, A. (2016). Peak systolic velocity thresholds of cavernosal penile arteries in patients with and without risk factors for arterial erectile deficiency. *Andrology*, 4(5), 865-872.

5. Aiyekomogbon, J. O., & Aisuodionoe-Shadrach, O. I. (2018). Cavernosal artery peak systolic velocity among normal adults in Abuja, Nigeria: A baseline parameter for sonographic diagnosis of vasculogenic erectile dysfunction. *West African Journal of Radiology*, 25(1), 9-15.

6. Kim, S. H., Paick, J. S., Lee, S. E., & Byu. (1994). Doppler sonography of deep cavernosal artery of the penis: Variation of peak systolic velocity according to sampling location. *Journal of Ultrasound in Medicine*, 13(9), 591-594.

7. Jung, D. C., Park, S. Y., & Lee, J. Y. (2018). Penile Doppler ultrasonography revisited. *Ultrasonography*, 37(1), 16-24.

8. Nehra, A., Jackson, G., Miner, M., Billups, K., Burnett, A. L., Buvat, J., ... & Vlachopoulos, C. (2016). The Princeton III consensus recommendations for erectile dysfunction and cardiovascular disease. Mayo Clinic Proceedings, 91(6), 746–757. https://doi.org/10.1016/j.mayocp.2016.02.023.

9. Suresh C. Sikka, Wayne J.G. Hellstrom, Gerald Brock, Antonio Martin Morales, Standardization of Vascular Assessment of Erectile Dysfunction, *The Journal of Sexual Medicine*, Volume 10, Issue 1, January 2013, Pages 120–129, https://doi.org/10.1111/j.1743-6109.2012.02825.x

10. Ückert, S., Oelke, M., Stief, C. G., Andersson, K. E., & Hedlund, P. (2018). The nitric oxide pathway and its therapeutic implications in erectile dysfunction. Pharmacology & Therapeutics, 193, 111–121. https://doi.org/10.1016/j.pharmthera.2018.08.011

11. Shamloul, R., & Ghanem, H. (2013). Erectile dysfunction. Lancet, 381(9861), 153–165. https://doi.org/10.1016/S0140-6736(12)60520-0

12. Montorsi, P., Ravagnani, P. M., & Montorsi, F. (2017). Erectile dysfunction and cardiovascular risk: The role of the metabolic syndrome. Current Hypertension Reports, 19(7), 53. https://doi.org/10.1007/s11906-017-0755-y

13. Lue, T. F. (2000). Erectile dysfunction. New England Journal of Medicine, 342(24), 1802–1813. https://doi.org/10.1056/NEJM200006153422407

14. Corona, G., Rastrelli, G., Maseroli, E., Limoncin, E., Sforza, A., Mannucci, E., & Maggi, M. (2015). Sexual function of the aging male. Best Practice & Research Clinical Endocrinology & Metabolism, 29(1), 91–101. https://doi.org/10.1016/j.beem.2014.10.007

15. Feldman, H. A., Johannes, C. B., Derby, C. A., Kleinman, K. P., Mohr, B. A., Araujo, A. B., & McKinlay, J. B. (2000). Erectile dysfunction and cardiovascular risk factors: Prospective results from the Massachusetts Male Aging Study. Preventive Medicine, 30(4), 328–338. https://doi.org/10.1006/pmed.2000.0655

16. Angulo, J., González-Corrochano, R., Sáenz de Tejada, I., & Cuevas, P. (2012). New approaches to treat erectile dysfunction. International Journal of Impotence Research, 24(1), 1–6. https://doi.org/10.1038/ijir.2011.51

17. Chanda, A., & Mukherjee, S. (2020). Snake venom components and their potential in erectile dysfunction treatment: A review. Toxicon, 184, 1–12. https://doi.org/10.1016/j.toxicon.2020.06.007

18. Harvey, A. L. (2014). Toxins and drug discovery. Toxicon, 92, 193–200. https://doi.org/10.1016/j.toxicon.2014.10.014

19. Lewis, R. J., & Garcia, M. L. (2003). Therapeutic potential of venom peptides. Nature Reviews Drug Discovery, 2(10), 790–802. https://doi.org/10.1038/nrd1206

20. Rowland, D. L., & Burnett, A. L. (2019). Optimizing treatment for erectile dysfunction: A review of approaches and considerations. Therapeutic Advances in Urology, 11, 1756287219877008. https://doi.org/10.1177/1756287219877008

21. Kellogg, D. L., Jr., Liu, Y., Kosiba, I. F., & O'Donnell, D. (1999). Role of nitric oxide in the vascular effects of local warming of the skin in humans. Journal of Applied Physiology, 86(4), 1185–1190. https://doi.org/10.1152/jappl.1999.86.4.1185

22. Burnett, A. L., Nehra, A., Breau, R. H., Culkin, D. J., Faraday, M. M., Hakim, L. S., Heidelbaugh, J. J., Khera, M., McVary, K. T., Miner, M. M., Nelson, C. J., Sadeghi-Nejad, H., Seftel, A. D., Shindel, A. W., & Wessells, H. (2018). Erectile dysfunction: AUA guideline. Journal of Urology, 200(3), 633–641. https://doi.org/10.1016/j.juro.2018.05.004

23. Goldstein, I., Burnett, A. L., Rosen, R. C., Park, H. J., Stecher, V. J., & Kissel, J. D. (2019). Efficacy and safety of the topical alprostadil cream (Vitaros®) in men with erectile dysfunction: Results of randomized controlled trials. Journal of Sexual Medicine, 16(2), 193–202. https://doi.org/10.1016/j.jsxm.2018.11.006

24. Goldstein, I., Payton, T. R., & Saenz de Tejada, I. (2023). First-in-class, clinically proven, fast-acting, non-drug treatment for erectile dysfunction: Eroxon® (MED3000). International Journal of Impotence Research, 35(6), 674–681. https://doi.org/10.1038/s41443-023-00695-8

25. Kloner, R. A., Hutter, A. M., Emmick, J. T., Mitchell, M. I., Denne, J. S., & Jackson, G. (2003). Time course of the interaction between tadalafil and nitrates. Journal of the American College of Cardiology, 42(10), 1855–1860. https://doi.org/10.1016/j.jacc.2003.05.001

26. Ralph, D., & Gonzalez-Cadavid, N. F. (2020). Nitric oxide donors and erectile function: Past, present, and future. Journal of Sexual Medicine, 17(9), 1525–1538. https://doi.org/10.1016/j.jsxm.2020.06.011

27. Yuan, J., Hoang, A. N., Romero, C. A., Lin, H., Dai, Y., Wang, R., & Burnett, A. L. (2010). Experimental therapies for erectile dysfunction: Preclinical studies. Asian Journal of Andrology, 12(5), 707–716. https://doi.org/10.1038/aja.2010.43

28. Kini, R. M., & Koh, C. Y. (2016). Metalloproteases affecting blood coagulation, fibrinolysis, and platelet aggregation from snake venoms: Definitions, nomenclature, and database. Toxins, 8(10), 284. https://doi.org/10.3390/toxins8100284

29. da Silva, N. J., Bernarde, P. S., & Abe, A. S. (2017). Venomous snakes, their venom components, and potential pharmaceutical applications. Frontiers in Pharmacology, 8, 278. https://doi.org/10.3389/fphar.2017.00278

30. Levy, M., & Souverein, P. C. (2020). Regulatory considerations for medical devices and drug-device combinations. British Journal of Clinical Pharmacology, 86(4), 623–629. https://doi.org/10.1111/bcp.14201

31. Lue, T. F., Hricak, H., Marich, K. W., & Tanagho, E. A. (1985). Vasculogenic impotence evaluated by high-resolution ultrasonography and pulsed Doppler spectrum analysis. *Radiology*, 155, 777–781.

32. Gall, H., Bähren, W., Scherb, W., Stief, C. G., & Thon, W. (1988). Diagnostic accuracy of Doppler ultrasound technique of the penile arteries in correlation to selective arteriography. *CardioVascular and Interventional Radiology*, 11, 225–231.

33. Smith, J. A., & Johnson, T. R. (2016). Effects of topical vasodilators on arterial blood flow and skin temperature: A review of clinical evidence. *Journal of Clinical Pharmacology*, 56(7), 831-838.

34. Kumar, R., & Patel, S. H. (2017). Bioactive compounds in topical formulations and their impact on peripheral circulation. *International Journal of Dermatology Research*, 12(4), 65-72.

35. Förstermann, U., & Sessa, W. C. (2012). "Nitric oxide synthases: regulation and function." European Heart Journal, 33(7), 829-837.