

# An Open Labeled Multicentric Pilot Trial to Study the Safety and Efficacy of Colloidal Nano Silver Skin Cream in Patients with Various Skin Diseases

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**Keywords:** Colloidal Nano Silver Skin Cream; SilverSol®; post-aesthetic skin procedure; Tinea; Intertrigo; Vulvitis; Bullous pemphigoid

## ABSTRACT

**Introduction:** In this open labelled multicentric pilot clinical trial we studied the efficacy and safety of a Colloidal Nano Silver Skin Cream containing patented Colloidal nano silver (SilverSol®), coconut oil, vitamin E, and hyaluronic acid as the active ingredients. Various studies have been conducted using this patented nanosilver and it has proven effective against various bacteria, yeast, fungus, black mold, virus, and parasites. A pilot study was conducted to evaluate the efficacy of Colloidal Nano Silver Skin Cream in the prevention and management of the adverse effects of aesthetic skin procedures and investigated its role in the management of various fungal skin infections when given as an adjuvant to topical and/or oral antifungal agents.

### Material and Methods:

#### Study Design

This study was an open-labeled study and included patients who had fungal infections and patients who had undergone aesthetic skin procedures and had thus suffered from adverse side effects such as erythema, itching, burning sensations, skin scarring, and erosion post these procedures. The study was conducted at three centers viz. Sparsh Derma Centre, Dr. Pathak's Skin World Clinic, and Upasani Hospital, Mumbai, India after obtaining the approval from Inter System BioMedica Ethics Committee, Mumbai, and registration with the Clinical Trial Registry of India (CTRI/2021/01/030388).

#### Study Procedure

A total of 24 patients including 9 males (Age 22 to 60 years) and 15 females (Age 26 to 58 years) who met the inclusion criteria were selected for the study after a prop-

er history taking, examination, and investigations as per the criteria of choice mentioned in the protocol.

**Results:** Post aesthetic skin procedures: On application of Colloidal Nano Silver Skin Cream on the affected area for 7 days, a reduction in redness, red marks, and pigmented scars was observed with no burning and itching sensations.

**Tinea Infections:** Within 2 weeks, the symptoms of itching and burning sensations reduced significantly and much earlier in the affected sites to which the topical antifungal cream plus Colloidal Nano Silver Skin Cream was applied, when compared to the sites where only topical antifungals were applied. All the subjects received oral antifungals throughout their treatment period. The dryness, pigmentation, and erythema subsided on both sides. The superimposed bacterial infection was very well taken care of by Colloidal Nano Silver Skin Cream.

**Intertrigo:** Within 2 weeks, the erosion, and cracks healed much better in the affected site to which the topical antifungal cream plus Colloidal Nano Silver Skin Cream was applied, when compared to the sites where only topical antifungals were applied. All the patients received oral antifungals throughout their treatment period.

**Vulvitis:** Within 7 days, the symptoms of itching and burning improved. The scaly erythematous lesion was reduced. All the patients received oral antifungals throughout their treatment period.

**Bullous Pemphigoid:** Within a span of 15 days, the burning sensation reduced completely, and the erosions were healed effectively. The patient received an oral immunomodulator and steroids throughout the treatment period.

**Conclusion:** Colloidal Nano Silver Skin Cream appears to be one of the most innovative and cutting-edge solutions for skin rejuvenation according to the results of the current pilot clinical study. In addition to facilitating healing and repairing the skin's barrier function, it reduces inflammation and guards against any secondary infections following cosmetic skin procedures. As an adjuvant along with topical antifungal applications, it helps in fighting various fungal and bacterial infections.

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## Introduction

In addition to increasing incidence rates of lifestyle-related disorders such as obesity and type II diabetes among the young and aging population (especially in developing countries), new challenges to skin healing must be addressed. There is a scarcity of treatments that are both effective and cost-efficient. The use of advanced therapeutic healing methods to promote rapid and complete wound healing in various skin ailments is currently among the top research interests. The financial burden on every nation has led to a desire for novel strategies to achieve expeditious skin healing. In modern society, the desire to retain a youthful appearance has led to the development of minimally invasive dermatological procedures designed to rejuvenate the aging face. Aesthetic treatments, also known as cosmetic treatments, are non-invasive procedures designed to counteract the effects of aging

and restore the youthful appearance of the skin. To counteract the effects of aging on the face and recreate a youthful appearance, numerous aesthetic skin procedures have been developed. Aesthetic skin procedure can be performed on almost any part of the body, though it is mostly done on the face and neck. The commonest forms of such non-invasive procedures include TCA peel (trichloroacetic acid chemical reconstitution of skin scars), yellow peel, salicylic acid peel, glycolic peel, black peel (with or without comedone extraction), laser hair removal for hirsutism, microneedling radiofrequency (MnRF) for post-acne scarring, etc. After a procedure, the primary aim of the skincare regimen is to restore, soothe and rejuvenate the skin. This includes reducing erythema and irritation, protecting the skin from secondary infections, and keeping the skin hydrated.

Common cosmetic procedures that leave the skin intact but inflamed include microdermabrasion; nonablative laser resurfacing procedures; mild chemical peels and fillers or Botox. The procedures that leave the skin with open wounds or broken skin barriers include deep chemical peels; ablative laser resurfacing treatments and surgical procedures, such as eyelifts, rhinoplasty, and facelifts. These procedures bring about certain unwanted side effects such as redness, burning sensation, itching, dryness, etc. Such side effects persist for some time before any desired effects of the procedure done could be seen. At this point, topical agents are indispensable to take care of post-procedural skin damage. Fungal infection likewise called, mycosis, is a fungus-caused disease. Fungal infections are generally classified as superficial, subcutaneous, or systemic, depending on which body part is afflicted [1,2]. Fungal infections are widespread and prevalent, impacting over one billion individuals each year[3]. Annually, an estimated 1.7 million people die from fungal diseases [4]. Some superficial fungal infections comprise common tinea of the skin, such as tinea of the body, groin, hands, feet, and beard. The common yeast infections are pityriasis versicolor and candidal intertrigo [5]. Eumycetoma and chromoblastomycosis are two subcutaneous kinds that affect tissues in and underneath the skin[5,6]. Cryptococcosis, histoplasmosis, pneumocystis pneumonia, aspergillosis, and mucormycosis are examples of severe systemic fungal infections. Signs and symptoms, microscopy, culture, and sometimes a biopsy and medical imaging are used to make a diagnosis. Antifungal drugs, usually in the form of a cream, or by mouth or injection, are used to treat the infection, depending on the type and severity of the infection. Miconazole, terbinafine, luliconazole, eberconazole, ciclopirox olamine, oxiconazole creams are used to treat fungal infection[7]. Itraconazole and voriconazole, two newer antifungal agents are now available. These agents have a broad spectrum of action that includes dermatophytes, Candida species, and non-dermatophyte molds.

Effective management of skin infections and healing is often difficult due to the complexity of the healing process. In addition to the conventional healing practices, various novel agents are gaining increased importance in wound care [8]. For thousands of years in various countries, especially in countries like India, silver has been used for what was empirically known to be its bactericidal properties – to keep water, and often foods, safer [9]. Silver as a metal is nontoxic and no known adverse health effects have ever been recorded. The most common form of silver liquid is ionic silver. Another most commonly available form of ionic silver is Silver Bound with Proteins (Mild Silver Proteins). This form of silver is more stable and bioavailable than ionic silver. It is less functional and more useful than ionic silver. Higher levels of silver (ppm) are needed to obtain the desired effect. Metallic Nano Silver is Next Generation Colloidal Silver. Nanotechnology is an innovative

sector of applied science in which metal-based approaches have demonstrated promising results [10]. Silver nanoparticles are considered to be potentially useful in controlling various pathogens including viruses, bacteria, and fungi[11]. Colloidal Nano Silver Skin Cream is formulated with colloidal Nano Silver (SilverSol®) along with certain excipients for various indications. SilverSol® has broad-spectrum antimicrobial properties. Other active ingredients include coconut oil, vitamin E ( $\alpha$ -tocopherol), and hyaluronic acid. It is an advanced healing skin cream for physiologically dry, inflamed, and bruised skin caused by aging, climate, environmental conditions, chemical soaps & cosmetic use; pathological dry skin caused by eczema/dermatitis, psoriasis, topical fungal infections, bullous diseases, autoimmune diseases, etc; and intense skincare and repair post-cosmetic skin procedures (including exfoliating scrubs, chemical peels, laser resurfacing, and microdermabrasion). We, therefore, conducted a pilot study to evaluate the efficacy of Colloidal Nano Silver Skin Cream in fighting fungal skin infections when given as an adjuvant to oral/topical antifungals.

## Material and Methods

### Study Design

This study was an open-labeled study to evaluate the efficacy of a colloidal Nano Silver cream in patients who have undergone non-invasive cosmetic procedures and suffering from certain fungal infections like tinea, intertrigo, and pemphigus/ bullous pemphigoid. The study was conducted at three centers viz. Sparsh Derma Centre, Dr. Pathak's Skin World Clinic, and Upasani Hospital, Mumbai, India, after obtaining the approval from Inter System BioMedica Ethics Committee, Mumbai, and registration with the Clinical Trial Registry of India (CTRI/2021/01/030388).

### Study Procedure

A total of 24 patients, including 9 males (Age ranging from 22 to 60 years) and 15 females (Age ranging from 26 to 58 years), who met the inclusion criteria were selected for the study after proper history taking, clinical examination, and investigations as per the criteria of choice mentioned in the protocol. (Table 1) Colloidal Nano Silver Skin Cream was manufactured and supplied by Viridis BioPharma Pvt Ltd, Mumbai.

**Table 1:** Various dermatological conditions and the number of patients in each condition.

Dermatological conditions	Number of patients (N = 24)
Post aesthetic skin procedures	8 (Chemical peeling – 4; Laser hair removal -2 and Micro needling radiofrequency – 2)
Tinea infections	12
Intertrigo	2
Vulvitis	1
Bullous pemphigoid	1

## Post-Aesthetic Skin Procedures

A. **Chemical Peeling:** A chemical peel is a technique used to improve the appearance of the skin on the face, neck, or body. In this process, a chemical solution is applied to the skin, causing it to exfoliate and eventually peel off. As the skin regenerates, it usually becomes smoother and less wrinkled. This study included patients (n = 4) suffering from the adverse effects of commonly used chemical peel procedures such as TCA CROSS, yellow peel, black peel (with comedone extraction), and glycolic peel (30%). The side effects included redness, burning sensation, scabbing, and swelling in the treated area. Additionally, the patients also suffered excruciating pain, skin scarring, and infections post-procedure. The patients were treated with Colloidal Nano Silver Skin Cream. As a remedy for the post-procedure side effects, Colloidal Nano Silver Skin Cream was applied to the affected skin area for 7 days, i.e., twice a day.

B. **Laser Hair Removal:** Laser hair removal is a light-based technology to remove unwanted hair. In this process, a light-absorbing pigment in the follicles absorbs light and impairs hair growth. Some patients had received laser treatment for hair removal. Post-procedure, they experienced red spots and dark spots on the chin, upper lip, and cheeks. The side effects included a burning sensation and irritation in the affected area. In such situations, other potential side effects include swelling, redness, and skin scarring. Blisters are rare but are more likely in people with darker complexions. However, permanent scarring or changes in skin color is rare. In order to relieve the patients (n = 2) of the post-procedure side effects, Colloidal Nano Silver Skin Cream was applied to the affected skin, over a period of 7 days, twice a day. No other moisturizer or any anti-inflammatory cream was prescribed. The patients attended follow-up every two days. However, as per a standard protocol, an ice pack, sunscreen, moisturizer, or cold water was applied only after the completion of the 7-day period to ease any discomfort.

C. **Microneedling Radiofrequency (MnRF):** Atrophic acne scars are dermal depressions commonly caused by the degradation of collagen and inflammation. There are many treatments available to improve acne scarring. The most common therapies include chemical peeling, subcision, dermabrasion, fillers, and punching. However, many a time they have disappointing results in terms of certain side effects. Comparatively, MnRF is a simple, safe, effective, and minimally invasive therapeutic technique. Needles are introduced into the skin with a preselected depth. RF is delivered through these needles to heat the dermis. The benefits of RF are that it is color blind and can be used on all skin types. However, there are

certain common side effects which include erythema, crusting, pain, infections, post-inflammatory hyperpigmentation, scarring, needle track marks, a flare-up of acne, and milia-like eruptions. A post-procedure application of sunscreen and moisturizer is necessary to ensure that the skin is adequately cooled. MnRF treatment was performed on two subjects (n = 2) suffering from post-acne scarring all over their faces. Post-procedure, the skin appeared red, swollen, and tender. Erythema (all over the face) and a severe burning sensation in the affected area were also observed. During the next 7 days period, Colloidal Nano Silver Skin Cream was applied (twice a day) to the affected skin to alleviate the unwanted effects of the MnRF procedure.

## Tinea Infections

Patients with various types of tinea infections (n = 12) were also enrolled in this study (Table 2). Depending on the source of the etiologic agent, the clinical presentation varied and included scaly erythematous plaques, severe itching, and burning sensation in the affected areas. Patients in some cases had scratched extremely hard, resulting in pustular lesions and exudation, which further led to a bacterial infection. In cases of Tinea cruris (n = 4) and Tinea corporis (n = 7), both sides of the body were equally affected. Therefore, one affected side was treated with a topical antifungal agent only, while the other side was treated with a topical antifungal cream plus Colloidal Nano Silver Skin Cream. The rate of improvement on both sides was assessed. In the case of Tinea incognito, the topical antifungal cream plus Colloidal Nano Silver Skin Cream was applied on the back of the trunk, and a topical antifungal cream only was applied on the underarm.

**Table 2:** Clinically relevant tinea and the site of infection.

Type of Tinea infection	No. of Cases	Site of infection
Tinea cruris	4	Buttocks, inner thighs, genital areas
Tinea corporis	7	Feet, underarms, hip area, Back, abdomen, buttocks, inner thighs, lower legs
Tinea incognito	1	Underarms, buttocks

## Intertrigo

Two cases of intertrigo were reported. The first case had genital vitiligo with small erosion and thinning of vulval skin. The patient later developed intertrigo in both inguinal regions with more erosion on the right side compared to the left side. Erosion and cracks with an erythematous border were present on the right side. The left side had minimal erythema with no erosion. The other case presented with an erythematous scaly patch on both sides of the groin. Itching and burning sensations in the infected

site were evident in both cases. Both sides showed similar signs of infection. A topical antifungal cream only was applied on the right side, and on the left side, the topical antifungal cream plus Colloidal Nano Silver Skin Cream was applied. For the topical antifungal cream plus Colloidal Nano Silver Skin Cream treatment, the topical antifungal cream was applied in the morning while Colloidal Nano Silver Skin Cream was applied in the evening on the left side. On the right side, for the topical antifungal cream-only treatment, the same was applied at both times, i.e., in the morning and evening. All the patients received oral antifungals throughout their treatment period.

### **Vulvitis**

One patient presented with a scaly well defined erythematous lesion on the left vulval region. The patient had previously applied steroids locally and was on oral fluconazole but there was no improvement. The patient complained of a severe burning sensation and itching in the affected areas. Upon inclusion in this study, the patient received oral antifungal medication and Colloidal Nano Silver Skin Cream (once a day) along with Candid Gel (once a day) for local application. Additionally, a soap containing Ketoconazole (2% w/v) and Triclosan (0.3% w/v) was prescribed for washing the affected area.

### **Bullous Pemphigoid**

A 50-year-old female presented with vesiculobullous disorder. She had a few bullae on the back and breast folds. The patient had been on steroids and cyclosporine. She had intense pruritus and erosions on the back. She was prescribed azathioprine and steroids orally and Colloidal Nano Silver Skin Cream twice a day was given for topical application.

## **Results**

### **Post-Aesthetic Skin Procedures**

A. **Chemical Peeling:** Patients with acne scars, including deep ice pick acne scars, needed to have their damaged skin repaired. They experienced several side effects after the chemical peel procedure. The side effects included redness, burning sensation, itching, scabbing, and swelling in the treated area. Additionally, some patients also suffered excruciating pain, and infections post-procedure. Colloidal Nano Silver Skin Cream was applied to the affected area over a period of 7 days. A reduction in redness, red marks, and dark scars was observed within 7 days of the application. The patients showed improvements with no burning sensation or itching. Scabbing and swelling disappeared. The skin appeared healthier with a considerable reduction in acne scar marks.

B. **Laser Hair Removal:** As a result of laser treatment, patients reported redness, dark spots, and a burning sensation in the

treated area. The patients experienced tenderness around the lips. After 7 days of application of Colloidal Nano Silver Skin Cream, the affected site did not show redness, swelling, or dark spots. The burning sensation subsided, and the skin felt normal.

C. **Microneedling Radiofrequency (MnRF):** Patients with post-acne scarring all over their faces received MnRF treatment. Post-procedure, the skin appeared swollen and tender. The other side effects included erythema (all over the face) along with a severe burning sensation. Within 7 days of application of Colloidal Nano Silver Skin Cream, the skin appeared normal with no redness. Patients reported a considerable reduction in burning sensation and erythema.

### **Tinea Infections**

In cases of tinea infections, itching, burning sensation, and bacterial infection reduced significantly (within 2 weeks) in the affected areas to which the topical antifungal cream plus Colloidal Nano Silver Skin Cream was applied, in comparison to the areas where topical antifungal cream-only was applied. However, the dryness, pigmentation, and erythema subsided on both sites. The pustules in the topical antifungal cream plus Colloidal Nano Silver Skin Cream treated areas were much drier in comparison to the sites treated with topical antifungal cream only.

### **Intertrigo**

In the left inguinal region, intertrigo was treated with the topical antifungal cream plus Colloidal Nano Silver Skin Cream. The healing was faster in the left inguinal region when compared to the right inguinal region where the topical antifungal cream only was applied. Within 2 weeks of the application of the topical antifungal cream plus Colloidal Nano Silver Skin Cream, the erosion, and cracks healed significantly in the left inguinal region. There were no signs of rawness or burning sensation. The erythematous border was not visible. However, this was not true for the right inguinal region.

### **Vulvitis**

Within 7 days of the application of the Colloidal Nano Silver Skin Cream, the symptoms of itching and burning sensation eased. The scaly erythematous lesion was reduced. The patient continued the application of the Colloidal Nano Silver Skin Cream for 3 more weeks. By the end of the 4th week, the scaly erythematous lesions subsided significantly though minor traces were still present with no defined borders. The Colloidal Nano Silver Skin Cream was well accepted and tolerated by the patient.

### **Bullous Pemphigoid**

Within a span of 7 to 15 days, the burning sensation subsided completely, and the erosions healed effectively. Colloidal Nano Silver Skin Cream Skin had a cooling effect, improved the healing, and was found to be non-messy. In addition to not being sticky or

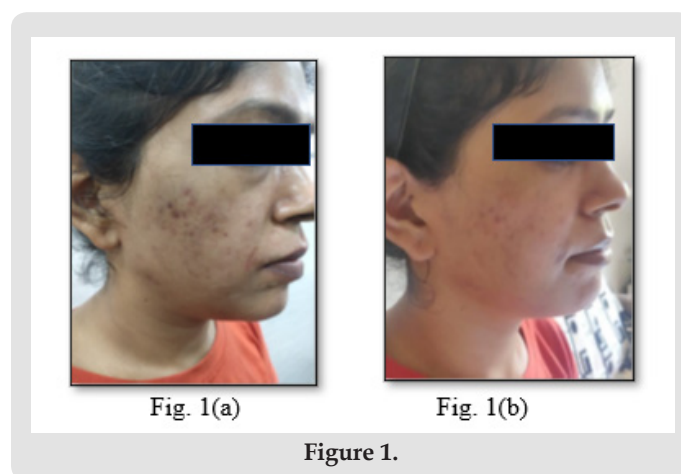
oily, it did not cause discomfort to the patient. The patient willingly continued the application of Colloidal Nano Silver Skin Cream till all the lesions healed.

## Discussion

In addition to providing protection against dehydration and external pathogens, the skin serves as a barrier between the body's internal organs and the outside environment [12]. Since the skin is constantly exposed to the outer atmosphere, it is very susceptible to various lesions, such as infections, burns, ulcers, and wounds. In the aftermath of an injury, the human body triggers a complex cascade of biological reactions to repair and regenerate damaged or lost tissue. Several mediators, including extracellular matrix (ECM) molecules, platelets, inflammatory cells, growth factors, cytokines, and chemokines, interact in a synchronized and integrated manner during various phases of hemostasis, inflammation, migration, proliferation, and tissue remodeling[13]. There are several wound care treatments and therapies available to speed up healing, prevent scarring, and improve the quality of regenerated skin [13]. Increasingly, cosmetic surgery and cosmetic procedures (laser, dermabrasion, fillers, microinjections, peeling, and micro-needling) are also a potential source of skin damage. Unlike most surgical procedures or traumatic damage that result in wounds, some cosmetic procedures involve causing an injury to the skin to stimulate the body's natural healing process and achieve the desired effect. In order to achieve optimal results from any type of exfoliation treatment, the skin must be protected. Facilitating a reduction in inflammation and guarding against any sort of secondary infection are all necessary for lasting skin rejuvenation. Basic skincare seems to have a key role during the remodelling phase of wound repair and skin regeneration. In this background, it is important to note that Colloidal Nano Silver Skin Cream provides a barrier and maintains a moist microenvironment required for optimal healing.

Colloidal Nano Silver Skin cream was studied in post aesthetic skin procedures and was found to be very effective in relieving symptoms such as erythema, burning sensation, swelling, pain and itching. A female patient with acne scars who underwent glycolic acid peel 50% applied Colloidal Nano Silver skin cream twice daily for 1 week post procedure (Figure1(a)). It was interesting to note that her symptoms resolved rapidly, scars reduced significantly and her skin was brighter after treatment with Colloidal Nano Silver skin cream (Figure1(b)). Tinea is the most common type of fungal infection. Depending on the affected site, these have been classified clinically as tinea corporis (body), tinea cruris (groin), tinea capitis (head), tinea incognito (steroid modified), tinea faciei (face), tinea barbae (beard), tinea manus (hand), tinea pedis (foot), and tinea unguium (nail), etc. Tinea corporis is a superficial fungal infection and it may occur on any part of the body. The common organisms

which cause fungal infections are Trichophyton mentagrophytes and Micosporum canis. Tinea cruris, also known as 'jock itch', is a dermatophyte fungal infection of the groin region, more often seen in males. It is more specifically located between intertriginous folds of adjacent skin, which can be present in the groin or scrotum, and be indistinguishable from fungal infections caused by other species of tinea. Tinea incognito is a fungal infection of the skin caused by the presence of a topical immunosuppressive agent. As a result of commonly used agents such as topical corticosteroids (topical steroids), the fungal infection in the skin often loses its characteristic features. Due to suppression of inflammation, it may have a poorly defined border, skin atrophy, telangiectasia, and florid growth. Tinea can often be diagnosed based on appearance, but a potassium hydroxide preparation or culture should be performed in cases of atypical appearance. Acceptable treatments for tinea include terbinafine and fluconazole. Oral antifungal agents may be prescribed in severe cases, failed topical treatment, and when the patients are immunocompromised. In cases of Tinea incognito, topical corticosteroids are discontinued. Attention should be given to the resolution of the lesions.



In the current study, the affected sites treated with a topical antifungal cream plus Colloidal Nano Silver Skin Cream showed better improvement in terms of skin appearance, symptoms of itching, burning sensation, and management of bacterial infection (in some cases) due to excessive scratching of the affected areas in comparison to the affected sites that were treated with topical antifungal cream only. It is of great interest to review the case of a 28-year male patient diagnosed with Tinea incognito, in the underarm and on the back of the trunk (Figure 2 (a)). Erythema with dark circled pigmentation in both the sites of infection was evident. In the underarms, a topical antifungal cream only was applied, whereas, in the back of the trunk, topical antifungal cream plus Colloidal Nano Silver Skin Cream was applied for 2 weeks. Within 2 weeks of the application of topical antifungal cream plus Colloidal Nano Silver Skin Cream, the symptoms such as itching, pigmentation, burning

sensation, and bacterial infection reduced significantly in the patch on the trunk. The reduction in bacterial infection was indicated by the dryness of pustules in the affected patch on the trunk. However, no such change was observed in the infected site at the underarms which was treated with topical antifungal cream only (Figure 2(b)). Intertrigo is inflammation of skinfolds caused by skin-on-skin friction. It is a common skin condition affecting opposing cutaneous or muco-cutaneous surfaces. The condition appears in natural and obesity-created body folds. The friction in these folds can lead to a variety of complications such as secondary bacterial or fungal infections. The usual approach to managing intertrigo is to minimize moisture and friction with absorptive powders or with barrier creams. Secondary bacterial and fungal infections are treated with antiseptics, antibiotics, or antifungals. In the current study, the intertrigo in the left inguinal region was treated with Colloidal Nano Silver Skin Cream in addition to the topical antifungal cream. The left inguinal region healed faster in comparison to the right inguinal region. The left side showed signs of reduction in erosion and cracks in the skin along with improvement in lesions (Figures 3(a) & 3(b)).

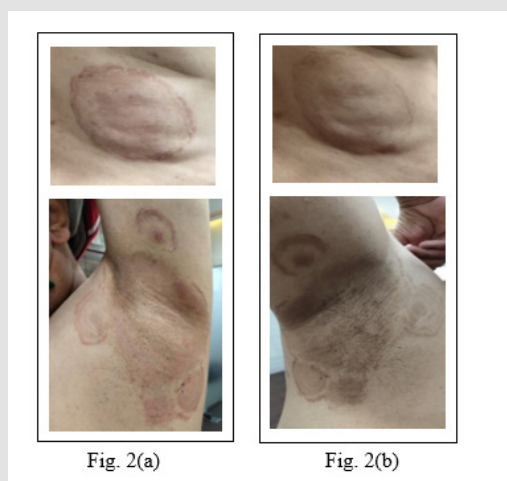


Figure 2.

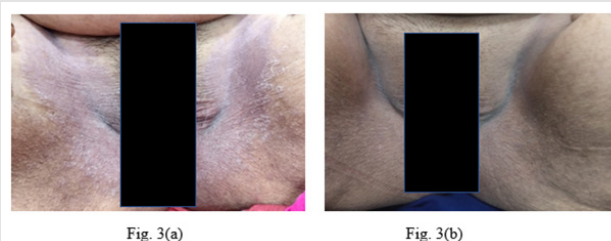


Figure 3.

The symptoms of rawness and burning sensations in the left side subsided much earlier when compared to the right side. Vulvitis is an inflammation of the vulva. The causal factor could be an infection, a change in hormones, or antibiotic use. Vaginal

infections resulting in vulvitis are commonly caused by yeast, bacterial vaginosis, and trichomoniasis. Symptoms of vulvitis include itching, irritation, burning sensation, redness, swelling, dryness, rashes, and blisters or bumps in the infected sites. Yeast infections are treated with antifungal medications. For both bacterial vaginosis and trichomoniasis, metronidazole clindamycin topical applications are used. In the current study, a 25-year-old female presented with a scaly well defined erythematous lesion on the left vulval region (Figures 4(a) & 4(b)). She was diagnosed with Vulvitis. As it turned out, the patient insisted on only applying Colloidal Nano Silver Skin Cream and not Candid Gel as part of the treatment. This is due to the fact that the application of Colloidal Nano Silver Skin Cream had a cooling and soothing effect, whereas the latter left a mild burning sensation. Colloidal Nano Silver Skin Cream was well accepted and tolerated by the patient. This effect can be attributed to its use as a moisturizer as well. A similar cooling effect was observed by another patient who was suffering from the vesiculobullous disorder. The patient had a few bullae on the back and breast fold (Figures 5(a) & 5(b)).

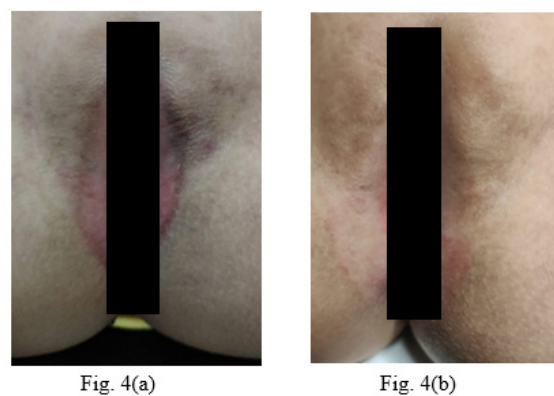


Figure 4.

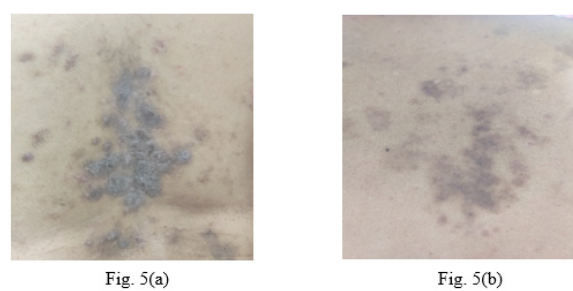


Figure 5.

SilverSol® from American Biotech Labs (ABL), USA is recognized as one of the newest and most innovative solutions for advanced skin healing and rejuvenation. The gel can be used to help soften, soothe, and rejuvenate the skin. It can also be used in combination with lotions or moisturizers. It is non-irritating,

non-greasy, and contains no alcohol. It can be applied all over the body, even underneath make-up and moisturizers, to help heal the skin naturally all day long. SilverSol<sup>®</sup> contains silver nanoparticles of size 5-15 nm with metallic silver in the interior and silver oxide in the exterior, i.e., multivalent silver (I, III) oxide, Ag<sub>4</sub>O<sub>4</sub>. SilverSol<sup>®</sup> combines the properties of ionic silver and Ag<sub>4</sub>O<sub>4</sub> to provide optimum results. Its multi-mode action ensures that microbes are relentlessly bombarded and annihilated. Various studies have been conducted using Nano Silver. It has proven to be effective against bacteria, yeast, fungus, black mold, virus, and parasites. It is well known that a silver cream is effective in providing immediate relief and sustained antimicrobial action against a broad spectrum of wound pathogens without inducing bacterial resistance. Various in vitro studies have reported antimicrobial activity of SilverSol<sup>®</sup> against Methicillin-resistant *Staphylococcus aureus* (MRSA) [14]; *Klebsiella pneumoniae*, *S. typhi*, *S. flexneri*, Vancomycin-resistant *E. faecalis* (VRE), drug-resistant *E. coli*, drug-resistant *P. aeruginosa*, Fungi - *C. albicans* [15]; Gram-negative bacteria. Reportedly, SilverSol<sup>®</sup> has a wide range of antimicrobial activity when compared to the antibiotics such as penicillin, macrolides, cephalosporins, fluorinated quinolones, and tetracyclines [16]. In a recently conducted in vitro study by Tran et al, a colloidal silver gel (Ag-gel) was found to be effective in inhibiting bacterial biofilm formation by the principal bacteria (*S. mutans*, *S. sanguis*, and *S. salivarius*) that cause plaque formation and tooth decay [17].

In this study, the Killing curve tests were performed as per CLSI (Clinical and Laboratory Standard Institute). The tests were carried out to determine the killing rate of SilverSol<sup>®</sup> and ionic silver. SilverSol<sup>®</sup> showed a superior killing rate against MRSA and *S. aureus* when compared to Ionic Silver [Data on file]. SilverSol<sup>®</sup> is a breakthrough among the currently available advanced wound-healing technologies as it offers a next generation therapy for the treatment and management of severe, chronic, and infectious wounds that are difficult to manage. The clinical efficacy of SilverSol<sup>®</sup> has been proven in wounds of varied etiology, such as acute and traumatic wounds, lacerations, diabetic-, pressure-, and venous- ulcers, infectious wounds, third-degree burns, MRSA, and Vancomycin-Resistant *Enterococcus* (VRE) infected wounds [18]. Colloidal silver gel wound dressing has shown complete inhibition of *S. aureus*, *P. aeruginosa*, and *Acinetobacter baumannii* in vivo and in vitro [19]. An in vitro study compared the efficacy of a combination of 5% Betadine solutions and silver colloidal gel with each individual treatment in inhibiting the growth of both Gram-negative and Gram-positive bacteria in wound infections. The study demonstrated that the combination of 5% Betadine solution and Ag-gel completely inhibits the growth of bacterial biofilms including those of *K. pneumoniae*. However, the individual treatments were not found to be effective in killing all the bacteria tested [20].

Skin Irritation Test conducted according to ISO 10993-10 showed

no signs of irritation. Maximization Test for Delayed Hypersensitivity was conducted according to the ISO 10993-10. SilverSol<sup>®</sup> did not show any signs of hypersensitivity. Intracutaneous (Intradermal) Reactivity Test was conducted according to the ISO 10993-10. The primary irritation responses to SilverSol<sup>®</sup> were negligible [Data on file]. SilverSol<sup>®</sup> gel has been rigorously tested in animals, humans, and laboratory agents with a delivery system consisting of ingested, injected, and cytotoxic experiments. A number of studies have shown that SilverSol<sup>®</sup> is absorbed, distributed, excreted, and passed through the body unchanged. SilverSol<sup>®</sup> nanoparticles produce no metabolites. The unique structure of SilverSol<sup>®</sup> prevents silver from falling out of the solution, which can otherwise accumulate in tissues causing argyria (a condition observed with ionic/colloidal silver). It is non-toxic to humans [21]. SilverSol<sup>®</sup> is thus a highly effective and safe antimicrobial product that leverages the latest nanotechnology. The other ingredients in Colloidal Nano Silver Skin Cream include coconut oil (natural skin protection & moisturizer), vitamin E (powerful antioxidant), and hyaluronic acid (natural skin moisturizer). Coconut oil contains saturated fats that protect the skin from moisture loss and provide excellent emollient properties, while the fatty acids present have strong antimicrobial properties. Because vitamin E is a powerful antioxidant, it prevents skin damage from free radicals and reactive oxygen species and reduces UV-induced skin inflammation. Hyaluronic acid hydrates the skin and reduces the appearance of fine lines and wrinkles. Hyaluronic acid also helps relieve inflammation and regulate tissue repair in damaged skin.

## Conclusion

Colloidal Nano Silver Skin Cream, which contains SilverSol<sup>®</sup>, in combination with other skin-protective ingredients, offers a new and innovative solution for skin rejuvenation in post-cosmetic skin procedures and ensures significantly better treatment of various fungal skin infections when used as an adjuvant to oral and/or topical antifungal agents. It was observed to have many benefits with no side effects. The results of this study demonstrate the efficacy of Colloidal Nano Silver Skin Cream in skin rejuvenation and fighting infections. Further studies with specific indications on a larger sample size followed by multicentric placebo-controlled trials can clearly establish the efficacy of SilverSol<sup>®</sup>.

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