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# First Applications of Purified and Sterile Human Amniotic Fluid for the Successful Healing of Abrasion and Acne Lesions of the Face

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**Abstract**

The face and hands are among the most exposed areas of the human body. Maintaining healthy facial skin is particularly challenging due to its continuous exposure to environmental stressors. Factors such as ultraviolet (UV) radiation, air pollution, and adverse weather conditions, including humidity, wind, cold, and heat can all negatively impact the skin. UV radiation contributes to skin aging by inducing dermal thinning and hyperpigmentation, while pollution can lead to pore obstruction and the formation of comedones. Hormonal fluctuations, particularly in estrogen, testosterone, and cortisol play a significant role in modulating sebum production, comedogenesis, and cutaneous inflammation, all of which can contribute to the development of acne. Consequently, physiological stages such as puberty, menstruation, pregnancy, and menopause can markedly influence skin tone, texture, and overall clarity. Genetic predisposition plays a significant role in the susceptibility to dermatological conditions such as comedonal acne, inflammatory acne, rosacea, and hyperpigmentation. While topical and systemic acne therapies can be effective, their efficacy is often contingent upon appropriate selection based on individual skin type and acne phenotype. In some cases, treatments may be ineffective or associated with adverse effects, including irritation, scarring, or post-inflammatory hyperpigmentation. Additionally, mechanical trauma or incidental abrasions to the facial skin pose further challenges to maintaining cutaneous integrity and appearance. Here we provide evidence that a new therapeutic countermeasure, ViX001, can heal recalcitrant acne and sizeable abrasions.

**Keywords:** Purified Amniotic Fluid; Perinatal Products; Abrasion; Acne; Pain; Inflammation; Extracellular Vesicles; Exosomes; Healing; Tissue Repair; Regeneration; Immunity.

## Introduction

Skin health is closely influenced by lifestyle factors, including adequate sleep, regular physical activity incorporating both aerobic and resistance training, and adherence to an anti-inflammatory diet. Effective stress management practices, such as mindfulness and meditation also contribute to maintaining skin homeostasis. Conversely, detrimental behaviours such as tobacco use, excessive alcohol consumption, unprotected ultraviolet exposure, and the frequent use of occlusive or heavy cosmetics can compromise skin integrity and accelerate dermatologic aging. Given the critical role of the face in nonverbal communication and social interaction, visible facial skin conditions, such as acne and scarring can have a profound psychosocial impact. Acne commonly intensifies during adolescence and early adulthood, and in severe cases, can lead to disfigurement and long-term sequelae. These considerations underscore the need for therapeutic interventions that are both highly effective and demonstrate excellent safety profiles in reducing lesion burden and minimizing the risk of adverse effects.

Acne often manifests during adolescence and early adulthood, a developmental period when self-image and peer perception are closely tied to physical appearance. As a result, individuals with acne may experience diminished self-esteem and social confidence, leading to behavioural changes such as reduced eye contact, reluctance to initiate conversations, and avoidance of group interactions. Even in the absence of overt commentary from peers, affected individuals may experience feelings of embarrassment or shame. Anticipation of negative judgment or bullying can contribute to social withdrawal, avoidance of public or social events, including dating, parties, and school functions, and may ultimately result in heightened social anxiety or depressive symptoms [1]. Visible acne can significantly influence interpersonal communication, with affected individuals often exhibiting reduced verbal participation in group settings, avoidance of video calls or photographs, and heightened self-consciousness regarding others' perceptions. These behaviours may lead to a decline in spontaneous social engagement and contribute to broader impairments in social functioning.

Acne is frequently and inaccurately attributed to poor hygiene, stress, or dietary habits, contributing to persistent stigma, teasing, and misinformed assumptions. In both professional and social contexts, such as dating, visible acne can negatively influence first impressions, despite bearing no relation to an individual's character or overall health. Numerous studies have documented a strong association between acne and increased rates of anxiety, depression, and social withdrawal. Notably, the psychological burden of acne often does not correlate with clinical severity, as individuals with mild presentations may still experience significant emotional distress. These findings highlight the importance of early intervention, both to prevent physical scarring and to mitigate psychological harm. A comprehensive approach, including effective dermatologic treatment, access to mental health support, and promotion of inclusive environments can play a critical role in restoring self-confidence and improving social functioning.

Topical and systemic acne therapies can be highly effective when appropriately tailored to an individual's skin type and acne phenotype. However, in some cases, acne may be recalcitrant to standard treatments, necessitating professional dermatologic evaluation. Early consultation with a dermatologist is particularly important when acne is painful, associated with scarring, or exerting a negative impact on mental health. In such cases, a multidisciplinary approach that includes psychological support may be essential to address both the dermatologic and psychosocial dimensions of the condition.

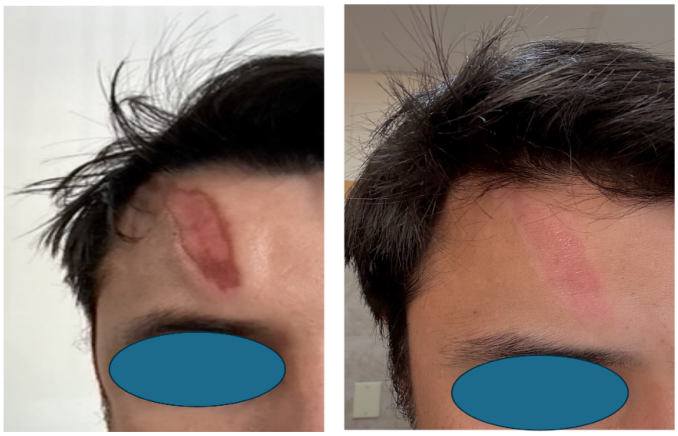
We have recently reported the remarkable protective properties of purified amniotic fluid in maintaining and supporting fetal skin integrity in utero, a function shaped by millions of years of evolutionary refinement. These findings led us to explore the potential therapeutic applications of amniotic fluid in postnatal skin repair. Specifically, we investigated its safety and efficacy in promoting wound healing in cases of severe burns, recalcitrant diabetic ulcers, and complex dermatoses such as pyoderma gangrenosum. Additionally, recent studies have demonstrated that facial micro needling procedures combined with amniotic fluid-derived mesenchymal signalling cell (MSC) products can reduce cystic scarring associated with severe acne. Building upon this evidence, we sought to evaluate the preventive cosmetic effects of a novel purified amniotic fluid fraction, ViX001, a proprietary amniotic fluid–based formulation, on acne and abrasion in otherwise healthy volunteers.

## Case Report #1: Accelerated Healing of Post-Traumatic Facial Abrasion Using a Sterile Fraction of Human Purified Amniotic Fluid (ViX001)

We report the first documented case of a substantial facial abrasion resulting from a motor vehicle accident that was successfully treated with daily topical applications of ViX001, a sterile, purified fraction of human amniotic fluid. ViX001 was derived from rigorously screened, term-pregnancy donors undergoing elective caesarean section, and processed via a proprietary method to yield a frozen 1 mL cryovial formulation containing approximately 1 mg/mL total protein. Each vial was thawed prior to first application and then kept refrigerated for no more than one week to ensure bioactivity and sterility [2].

The subject was a 27-year-old man who sustained a traumatic abrasion to the forehead, just above to the right eyebrow, upon impact with the steering wheel during a car accident. Following written informed consent, the volunteer received training by the Neobiosis clinical team for supervised, topical self-application of ViX001 to the affected area [3].

Notably, the patient reported immediate analgesic effects following the first application. Subsequent daily treatments led to a rapid reduction in local inflammation and edema, with visible signs of progressive epidermal regeneration. By day 14, the abrasion site demonstrated complete re-epithelialization, with restoration of normal skin texture and tone, and critically, no evidence of scarring, dyspigmentation, or textural irregularities (Figure 1).



**Case #1**: Day of injury 15 days later

**Figure 1**: The abrasion site demonstrated complete re-epithelialization, with restoration of normal skin texture.

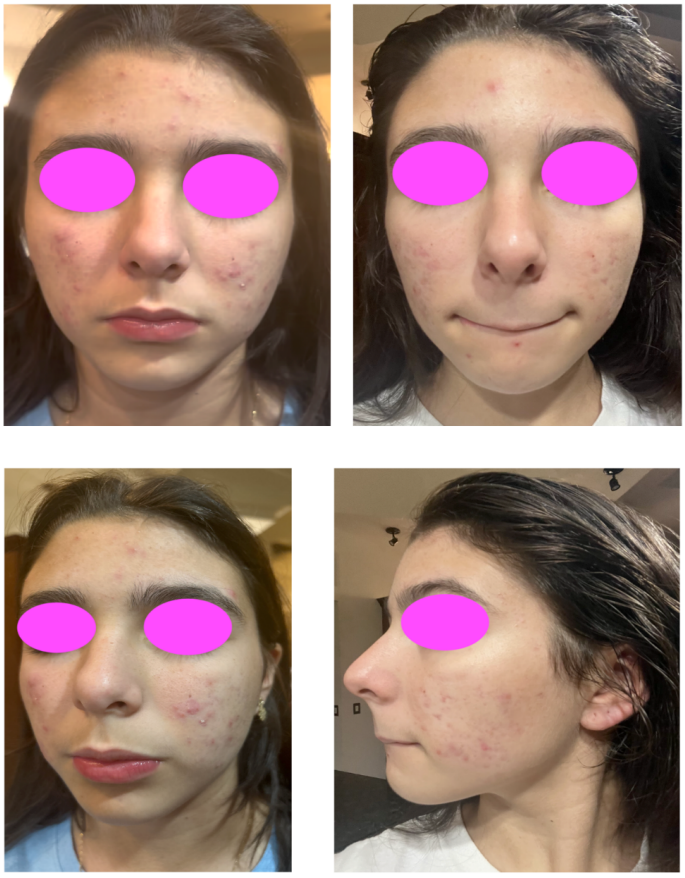
While these findings are preliminary and derived from a single-subject case, the observed outcomes suggest that ViX001 may have significant therapeutic potential for promoting scarless healing in acute dermal injuries. Further investigation in larger, controlled studies is warranted to validate these initial observations and to elucidate the underlying mechanisms of action.

## Case Report #2: Resolution of Recalcitrant Acne with Topical Application of Human Purified Amniotic Fluid (ViX001)

We report the first documented case of recalcitrant acne successfully treated with ViX001 [4], a sterile, purified fraction of human amniotic fluid (see Case Report #1 for product description and preparation). The patient, a 13-year-old girl with a history of treatment-resistant acne, underwent a three-week regimen consisting of twice-daily topical applications of ViX001. For the treatment period, the purified amniotic fluid was diluted 1:10 in physiological sodium chloride and kept refrigerated in three 3 mL vials. One week of applications consumed a total of 3 ml of 1:10 diluted ViX001.

The volunteer and both parents provided a written informed consent. Acne lesions were primarily distributed across the forehead and bilateral cheeks, with relative sparing of the nasal region. Despite previous use of various conventional therapies, her acne had remained unresponsive, significantly affecting her well-being and participation in school activities, including theatre and vocal performance that she enjoyed before the onset of her acne.

Under guidance and training provided by the Neobiosis clinical team, the patient self-administered diluted ViX001 topically to the affected areas. A rapid and progressive improvement in lesion count and skin appearance was observed. By the end of the three-week treatment period, the inflammatory and comedonal lesions had practically resolved, and the affected areas were fully re-epithelialized with restoration of normal skin texture and no evidence of scarring or post-inflammatory dyspigmentation [Figure 2].



**Case #2**: Day before treatment 21 days later

**Figure 2**: Restoration of normal skin texture and no evidence of scarring or post-inflammatory dyspigmentation.

While this case represents a single-subject observation, the results suggest that diluted ViX001 may offer a safe and effective topical therapeutic option for patients with acne unresponsive to conventional therapies. These findings warrant further investigation in controlled clinical studies to determine efficacy, optimal dosing protocols, and mechanisms of action [5-7].

## Discussion

Human skin relies on a delicate balance of sebum production to maintain hydration, barrier integrity, and immune defense. Sebum, produced by sebaceous glands within the dermis, plays a critical

role in protecting the epidermis from environmental insults, supporting the skin microbiome, and promoting wound healing [8]. Disruption in this balance, whether through diminished production following injury or overproduction associated with acne, can impair skin function and lead to inflammatory or degenerative skin conditions.

In this report, we present two distinct clinical scenarios: one involving a deep facial abrasion with presumed loss of sebaceous gland function, and the other characterized by excessive sebum production and treatment-resistant acne. In both cases, repeated topical application of ViX001, a sterile, purified fraction of human amniotic fluid, was associated with marked clinical improvement and complete restoration of the epidermis without scarring or dyspigmentation.

Facial abrasions, particularly those penetrating the upper dermis, may damage sebaceous structures, resulting in localized deficits in sebum production during the healing phase. Without the lipid-rich, antimicrobial layer provided by sebum, regenerating skin becomes vulnerable to desiccation, microbial invasion, UV damage, and inflammatory responses. In Case #1, application of ViX001 appeared to compensate for this loss, providing a bioactive scaffold enriched with extracellular vesicles (exosomes, ~100-150 nm) containing lipids, proteins, nucleic acids, glycoproteins and other cargo [2]. These components likely contributed to epithelial stabilization, immune modulation, anti-microbial activity and tissue regeneration. Early intervention with ViX001 may have preserved sebaceous gland function and prevented secondary scarring by modulating the wound microenvironment during the critical early stages of repair.

Conversely, in Case #2, the patient exhibited severe, treatment-resistant acne, an inflammatory condition closely linked to overactive sebaceous glands and microbiome dysbiosis. Excessive sebum fosters proliferation of pro-inflammatory Cutibacterium acnes (formerly Propionibacterium acnes) strains [9], which stimulate toll-like receptor 2 (TLR-2) pathways, triggering cytokine cascades including interleukin-1 (IL-1) and tumor necrosis factor-alpha (TNF-α) [10]. This inflammation not only contributes to lesion formation but also reduces host defenses, allowing further microbial imbalance, neutrophil recruitment, and eventual nodular or cystic scarring.

Recent research has shifted the acne paradigm from simply targeting bacterial load to modulating the microbial ecosystem. Interventions that restore microbial balance or selectively suppress inflammatory strains of C. acnes can yield significant clinical benefits. ViX001, derived from amniotic fluid, may contribute to such rebalancing. Although the intrauterine environment is generally considered sterile, the amniotic fluid is known to precondition fetal epithelial tissues, including skin, mucosa, and gut, potentially preparing them for colonization by commensal microbiota at birth. The bioactive milieu of amniotic fluid, along with the vernix caseosa, supports anti-inflammatory signalling, barrier maturation, and microbiome readiness [11].

We hypothesize that the therapeutic effects of ViX001 observed in both cases may stem from its ability to modulate inflammation, support tissue regeneration, and restore ecological balance within the skin's microenvironment. Our previous studies have demonstrated the potent anti-inflammatory and regenerative properties of amniotic fluid components, and the present findings are consistent with those observations.

While these are preliminary case reports and further validation in controlled trials is necessary, the clinical outcomes suggest that specific fractions of purified amniotic fluid, such as ViX001, holds promise as a topical biologic therapy for diverse dermatologic conditions characterized by disrupted sebum balance and barrier dysfunction. Whether through replacing lost protective factors in abraded skin or modulating microbial and immune dynamics in acne, ViX001 appears to facilitate restoration of intact, resilient, and scar-free skin.

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