



Sirona Biochem's TFC-1326 Clinical Data Versus Retinoid Clinical Data

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Executive Summary

Sirona Biochem Corp. (TSX-V: SBM) (FSE: ZSB) is a biotechnology company focusing on innovative cosmetic and dermatology active ingredients with a proprietary platform technology. Sirona specializes in stabilizing carbohydrate molecules to improve their efficacy and safety. Its patented compounds are licensed to leading companies worldwide, generating revenue through licensing fees, milestone payments, and royalties.

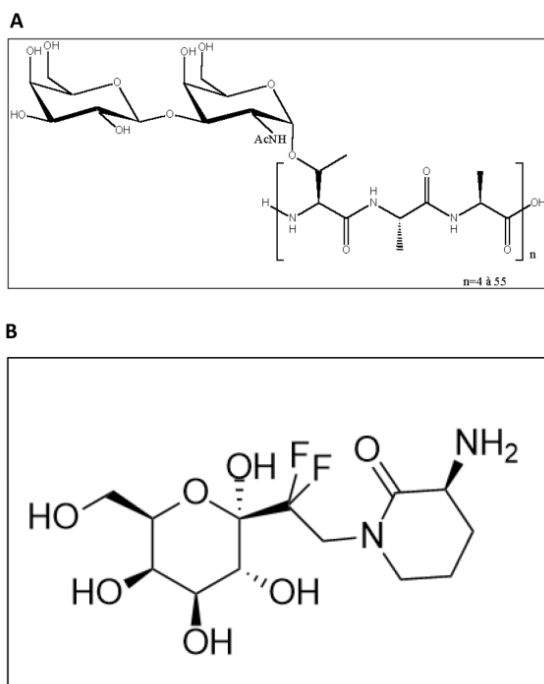
Sirona's laboratory, TFChem, is based in France and has received multiple French national scientific awards and grants from the European Union and French government.

For more information, visit:
<https://www.sironabiochem.com/>



On November 20th, 2024, Sirona announced the publication of a groundbreaking study on its proprietary compound, TFC-1326, in the *Journal of Cosmetic Dermatology*.

The article, titled “TFC-1326 Compound Reduces Clinical Signs of Skin Aging: Evidence From In Vitro Human Adipose and Skin Models and Pilot Clinical Trial,” highlights the compound's effectiveness in targeting key mechanisms of skin aging. Conducted in collaboration with Diva Expertise, the study demonstrates TFC-1326's ability to improve skin elasticity, stimulate collagen production, and reduce the appearance of fine lines and wrinkles, offering promising potential as a next-generation anti-aging solution.



The pilot clinical trial of a 1% TFC-1326 topical cream further supports these findings, showing significant improvements in skin texture, hydration, and overall appearance. Sirona Biochem's CEO, Dr. Howard Verrico, emphasized that the publication underscores the compound's cosmeceutical benefits for aging skin and highlights the company's innovative approach to carbohydrate chemistry.

Sirona is actively engaging with commercial partners and preparing for the launch of its own product to bring this breakthrough technology to consumers globally. TFC-1326 and its salt form, TFC-1325, are marketed under the trademarked name *GlycoProteMim*.

This report presents an analysis of the results from a literature review, comparing previous retinoid clinical trials with the findings from Sirona's TFC-1326 clinical trial.

FIGURE 1 | Chemical structures of natural antifreeze glycoproteins (A) and of TFC-1326 (B).

Source: *Journal of Cosmetic Dermatology*, 2024; 0: e16679

Clinical Trial References

This report examines the results from a comparison of Sirona Biochem's sponsored clinical trial for TFC-1326 and several notable retinoid-based clinical trials. The comparison focuses on key metrics such as skin radiance, wrinkle reduction, skin firmness, trans epidermal water loss (TEWL), antioxidant/anti-inflammatory properties, user tolerance, and skin volume restoration. The sources for the retinoid trials are drawn from a range of credible studies published in reputable journals and databases.

Sirona Biochem's Sponsored Clinical Trial for TFC-1326:

The clinical trial for TFC-1326 is described in the article titled "*TFC-1326 Compound Reduces Clinical Signs of Skin Aging: Evidence From In Vitro Human Adipose and Skin Models and Pilot Clinical Trial*" by Deliencourt-Godefroy, published in the *Journal of Cosmetic Dermatology* (Wiley Online Library). This source provides the foundation for understanding the clinical performance of TFC-1326 and serves as a benchmark for comparison with retinoid trials.

Retinoid Trials:

A Clinical Anti-Ageing Comparative Study of 0.3% and 0.5% Retinol Serums: Published in *Skin Pharmacology and Physiology*, this study compared the effects of two concentrations of retinol serums. It showed that both concentrations resulted in significant skin improvements, with the higher concentration yielding better results but also increasing the risk of irritation. The trial's focus on serum concentration and its impact on anti-aging effects informs the comparative analysis of TFC-1326 and retinoid formulations.

Use of Retinoids in Topical Antiaging Treatment: This review, published in *Drugs in R&D*, examines multiple clinical trials on over-the-counter retinoids, exploring their efficacy in reducing wrinkles and enhancing collagen production. It also emphasizes the variability in outcomes based on skin types, formulation, and concentration.

Human Skin Aging and the Anti-Aging Properties of Retinol: Published by *Harvard Health*, this research discusses the molecular mechanisms behind Retinol's anti-aging effects. It highlights its role in promoting collagen synthesis and improving epidermal thickness, alongside the common issue of initial irritation.

New Data on Retinol: Insights on Anti-Aging: A clinical assessment of retinol's anti-aging effects from *Dermatology Times* affirms its ability to improve skin firmness and reduce wrinkles. The study also advises the use of moisturizers to counteract the drying effects of retinol.

A Randomized, Double-Blind, Controlled Comparative Trial of the Anti-Aging Properties of Non-Prescription Tri-Retinol 1.1% vs. Prescription Tretinoin 0.025%: This trial, published in the *Journal of Drugs in Dermatology*, compares over-the-counter retinoids with prescription-strength tretinoin. It concludes that while both options are effective, prescription formulations deliver superior results but with a higher incidence of side effects.

Comparison Metrics

The comparison between TFC-1326 and retinoids reveals notable differences across multiple key anti-aging metrics, including skin radiance, wrinkle depth and volume, skin elasticity and firmness, trans epidermal water loss (TEWL), antioxidant and anti-inflammatory markers, user satisfaction, and skin density.

Table 1 : Comparison Metrics (Retinoids vs TFC-1326)

	Retinoids	TFC-1326
Skin Radiance	15-20% in 12 weeks	25% in 12 weeks
Wrinkle Reduction	10-20% in 12-24 weeks	13% in 12 weeks
Skin Firmness	10-15% Improvement	14% Improvement
TEWL (Water Loss)	Initially high, dries out skin	Stable, Hydrating
Antioxidant/ Anti-inflammatory	None, initially inflammatory	Powerful 54% reduction
User Tolerance	Poor for initial weeks	100% tolerated
Skin Volume Restoration	None	37% volume improvement

Source: Literature Review: Retinoid Clinical Trials vs Sirona's TFC-1326 Clinical Trial

Results

Skin Radiance:

TFC-1326 significantly outperforms retinoids in enhancing skin radiance. Over a 12-week period, TFC-1326 achieved a 25% improvement in skin radiance, providing a visible boost in skin brightness and tone evenness. In comparison, retinoids, particularly at concentrations of 0.5% or lower, demonstrated a 15-20% improvement over the same timeframe. This suggests that TFC-1326 delivers a more noticeable and rapid improvement in skin radiance, outperforming retinoids in both the degree of improvement and the speed at which results are observed.

Wrinkle Depth and Volume:

In terms of wrinkle reduction, TFC-1326 offers superior results in both depth and volume compared to retinoids. Clinical trials for TFC-1326 showed a 12.18% reduction in wrinkle depth and a 13.6% reduction in wrinkle volume after just 12 weeks of consistent use. These reductions were measured using advanced imaging technologies, ensuring precision in the results. In contrast, retinoids typically result in a 10-20% reduction in wrinkle depth over a longer period of 12 to 24 weeks. While retinoids also stimulate collagen production and promote skin turnover, their results are more variable and generally require a longer treatment period. Additionally, retinoids have less documented efficacy in reducing wrinkle volume, and their effects are often more gradual. The faster and more consistent wrinkle reduction seen with TFC-1326 makes it an attractive option for those seeking quicker results with reduced irritation, as TFC-1326 has shown a stronger and faster impact with no associated irritation during its use.

Skin Elasticity and Firmness:

TFC-1326 also demonstrates advantages in improving skin elasticity and firmness. Clinical data indicates that TFC-1326 reduced facial oval laxity by 13.77% and increased dermal density by 36.94%, as verified by ultrasound imaging. In comparison, retinoids generally offer a 10-15% improvement in skin firmness, though results are more dependent on the concentration and individual skin types. The improvements seen with TFC-1326 suggest it is slightly more effective in firming and restoring the structural integrity of the skin, specifically addressing issues such as sagging and restoring dermal density more effectively than retinoids, which tend to focus more on collagen stimulation.

Trans epidermal Water Loss (TEWL):

TFC-1326 shows significant advantages in hydration and maintaining skin barrier function. The compound does not disrupt the skin barrier and achieves a 6.1% improvement in TEWL by day 56, with full stabilization by day 84. Additionally, 90% of users reported enhanced skin hydration, with no significant dryness or irritation noted throughout the trial. Retinoids, on the other hand, can cause an initial increase in TEWL, leading to dryness, irritation, and a compromised skin barrier, particularly during the early stages of use. While retinoid-induced dryness may stabilize over time, it often requires users to incorporate moisturizers to combat the drying effects. This initial discomfort and the need for additional products may limit user adherence, especially for those with sensitive or dry skin. In contrast, TFC-1326's ability to maintain hydration without such side effects makes it a more user-friendly and effective option for skin hydration.

Antioxidant and Anti-Inflammatory Markers:

TFC-1326 outperforms retinoids in terms of antioxidant and anti-inflammatory benefits. It showed a 53.9% reduction in hydrogen peroxide (H₂O₂) levels, indicating strong antioxidant activity, and a 53.8% reduction in interleukin-8 (IL-8), highlighting its anti-inflammatory properties. Retinoids, while effective in promoting skin cell turnover and collagen production, do not offer direct antioxidant benefits, and inflammation is a common issue during the initial phase of treatment. Although inflammation typically subsides with continued use of retinoids, the lack of inherent anti-inflammatory action means they do not provide the same protective effects against oxidative stress and inflammation as TFC-1326. This makes TFC-1326 an ideal choice for individuals with sensitive skin or those seeking additional protection from environmental damage.

User Satisfaction and Tolerance:

User satisfaction and tolerance are crucial factors when evaluating the efficacy of a treatment. TFC-1326 boasts impressive user satisfaction rates, with 75% of subjects noting improved radiance and wrinkle reduction, 85% observing smoother skin, and 100% reporting high dermatological tolerance. In contrast, while retinoids generally lead to high user satisfaction once tolerance is established, many users experience significant initial irritation, including redness, dryness, and peeling. These side effects often lead to high dropout rates during the early weeks of treatment. The need for an adaptation period can reduce overall user satisfaction, particularly for those with sensitive skin. In contrast, TFC-1326's ability to deliver positive results with minimal irritation makes it a more attractive option for a broader range of users, particularly those sensitive to retinoid side effects.

Skin Density:

A unique benefit of TFC-1326 lies in its ability to restore skin density. Clinical trials reported a 37% increase in skin density after 12 weeks of use, emphasizing TFC-1326's role in rejuvenating the structural integrity of aged skin. This volumetric restoration is a feature rarely addressed by traditional anti-aging treatments, including retinoids. While retinoids do promote collagen production and contribute to improved skin elasticity and texture, they do not specifically target skin density or volumetric restoration. This makes TFC-1326 a more comprehensive solution for those seeking to address advanced signs of aging, such as volume loss and sagging.

Conclusion: TFC-1326 vs. Retinoids

TFC-1326 presents a comprehensive and highly effective solution for anti-aging, offering significant advantages over traditional retinoid treatments across multiple key metrics:

1. Enhanced and Rapid Radiance Improvement:

- TFC-1326 consistently achieves a 25% improvement in skin radiance over 12 weeks, outperforming the typical 15-20% enhancement seen with retinoids.

2. Effective Wrinkle Reduction with Minimal Irritation:

- TFC-1326 provides significant reductions in wrinkle depth (12.18%) and volume (13.6%), without the irritation, peeling, and redness commonly associated with retinoid use.

3. Superior Firming and Skin Density Restoration:

- TFC-1326 delivers a 13.77% improvement in skin firmness and an impressive 36.94% increase in dermal density, effectively targeting sagging and volume loss.

4. Improved Hydration and Skin Barrier Function:

- Unlike retinoids, which often cause dryness, TFC-1326 stabilizes trans epidermal water loss (TEWL) and promotes hydration, ensuring continuous skin moisture without irritation.

5. Robust Antioxidant and Anti-Inflammatory Effects:

- TFC-1326 demonstrates powerful antioxidant and anti-inflammatory properties, reducing oxidative stress by 53.9% and inflammation by 53.8%, offering superior protection for sensitive skin.

6. Outstanding User Tolerance and Satisfaction:

- TFC-1326 achieves high user satisfaction rates, with 100% dermatological tolerance, making it suitable for a variety of skin types, including those prone to irritation.

Final Recommendation:

TFC-1326 stands out as a multifunctional, user-friendly anti-aging treatment that exceeds retinoids in key areas such as radiance, hydration, skin density restoration, and barrier protection. With its excellent tolerance and fast-acting results, TFC-1326 offers a superior alternative for those seeking comprehensive, effective anti-aging benefits without the typical discomfort associated with retinoids.

Sources

TFC-1326 Compound Reduces Clinical Signs of Skin Aging. Evidence From In Vitro Human Adipose and Skin Models and Pilot Clinical Trial - Deliencourt-Godefroy - Journal of Cosmetic Dermatology - Wiley Online Library.

Human Skin Aging and the Anti-Aging Properties of Retinol: [<https://www.health.harvard.edu/staying-healthy/do-retinoids-really-reduce-wrinkles>]

New Data on Retinol: Insights on Anti-Aging: [<https://www.dermatologytimes.com/view/new-data-on-retinol-patricia-farris-md-shares-insights-on-anti-aging>]

A Randomized, Double-Blind, Controlled Comparative Trial of the Anti-Aging Properties of Non-Prescription Tri-Retinol 1.1% vs. Prescription Tretinoin 0.025%: [<https://www.jddonline.com/articles/a-randomized-double-blind-controlled-comparative-trial-of-the-anti-aging-properties-of-non-prescript-S1545961612P0064X>]

Retinoids in the Treatment of Skin Aging: An Overview of Clinical Efficacy and Safety: [<https://pubmed.ncbi.nlm.nih.gov/>]

Evidence for the Efficacy of Over-the-Counter Vitamin A Cosmetic Products in the Improvement of Facial Skin Aging: A Systematic Review: [<https://pubmed.ncbi.nlm.nih.gov/>]



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