New Science to Support 50 Years of Colloidal Oatmeal Use in Dermatological Practice

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Introduction

Oatmeal has been used for centuries in skin care as a soothing agent to relieve itch and irritation associated with various skin conditions, such as xerotic and inflammatory dermatoses. It contains a number of compounds with moisturizing, cleansing, buffering, anti-inflammatory, anti-pruritic and anti-oxidant properties. Products containing colloidal oatmeal are well tolerated with only rare reports of allergic contact dermatitis. Clinical studies support the adjunctive use of these products in the treatment of atopic dermatitis.

Background

- The oldest oat grains were found in Egypt about 2000 BC.¹
- The nutritional value of oatmeal and its benefits when used as a topical have been recognized since Roman times as shown in texts by Pliny, Columella and Theophrastus.¹,²
- Oats were introduced to North America at the beginning of the 17th century.¹
- Of the cultivated oats today, more than 75% belong to the Avena sativa (A. sativa) type.²
- In the 1930s, oatmeal started to be used for its cosmetic benefits in facial masks and bath oils and for cleansing, moisturizing and relieving itching.²
- In 1945, a ready to use colloidal oatmeal for skin care became available.²
- The colloidal oatmeal, which was made by finely milling dehulled oats to a powder, contained a concentrated starch-protein fraction of the oat grain.²,³
- In 2003, the US FDA approved colloidal oatmeal as a skin monograph ingredient which can temporarily protect and help relieve minor skin irritation and itching.²,³
- Today there are many formulations of colloidal oatmeal including cleansers, washes, bath products, creams, lotions, shampoos and shaving gels.²,³

Components of Colloidal Oatmeal and Their Therapeutic Effects

- Colloidal oatmeal contains starch (65-85%), proteins (15-20%), lipids (3-11%), fiber (5%), and beta-glucans (5%).³
- The lipid content is much higher than in other cereal grains, with unsaturated triglycerides rich in unsaturated fatty acids, being the most abundant lipids.²
- The phenolic compounds avenanthramides, ferulic and caffeic acids, glyceryl esters of hydroxycinnamic, and p-Coumaric in oat flour have antioxidant activity and protect the lipids from oxidation.²,³
- Avenanthramides also have anti-inflammatory and anti-pruritic properties. They have been shown to decrease activation of nuclear factor-kappa B (NF-κB) and production of proinflammatory cytokines, and reduce oxazolone-induced contact hypersensitivity, histamine-mediated itch and resiniferatoxin-induced neurogenic inflammation.³
- Flavonoids in oat absorb in the 320-370nm UVA range, while saponins with their large lipophilic region and short chain of sugar residues have a soap-like action.²
Beta-D-glucan is a hydrocolloid which binds water, forming a colloidal film holding moisture in the stratum corneum. Colloidal oatmeal can also act as a skin buffer, restoring the normal pH of the skin. Alpha-tocopherol, also present in oatmeal, has anti-inflammatory and anti-photodamage effects and can inhibit the synthesis of prostaglandin E2.

Safety and Colloidal Oatmeal Skin Care

Although more than 8 million oat-based cosmetics are sold yearly, there are very few reports of allergic contact dermatitis or contact urticaria. In the few patients with cutaneous adverse events to topical oat, the reactions were generally very mild and often did not recur with repeat applications.

In a double-blind, randomized, controlled study, colloidal oatmeal was applied for 15 minutes as an open patch test, and under a patch for 24-48 hours. No urticarial or contact allergic reactions occurred.

Transient low-level reactions have been reported in 1% of 2,291 men and women treated in 12 independent repeat insult patch test studies of 12 oatmeal-containing skin care products. No reactions occurred in 2 safety-in-use studies involving 80 adults and 30 children, of which one-third had atopic dermatitis.

In 302 children who underwent atopy patch tests, a 15% positive result was reported as was a 19% positive skin prick test.

Efficacy of Topical Colloidal Oatmeal

Colloidal oatmeal skin care can alleviate dry skin. In a 2-week, single-blinded study of subjects with Fitzpatrick skin types IV-VI, a significant improvement in moisturization and skin brightness was seen within the first day (p<0.05) and was maintained throughout the study period, when using the moisturizer containing colloidal oatmeal twice daily.

Moisturizers that soothe pruritus, hydrate, protect and restore the skin barrier are an essential part of the management of atopic dermatitis (AD). They may be first-line in mild AD or with more severe disease, or complementary to prescription medications for enhancement of treatment efficacy and for their steroid-sparing effects.

In a 6-week randomized, controlled study involving 173 infants with moderate to severe AD, the group treated with oat moisturizer demonstrated significant improvements in the Scoring Atopic Dermatitis Index (SCORAD) and quality of life scores (p<0.0001). Further, the quantity of moderate- and high-potency corticosteroids that were used decreased by 7.5% and 42% (p<0.05), respectively.

In an open-label, 12-week, multicenter study involving 99 patients aged 6 months to adulthood with mild-to-moderate AD, the efficacy and tolerability of an A. sativa extract based moisturizing cream used twice daily showed that by week 12, the SCORAD index improved by 48%. Skin hydration assessed in selected patients showed a 90% increase at week 8 and an increase of 100% at week 12. The results reported by patients indicated similar trends. The quality of life questionnaires showed significant improvement by week 4. Moreover the steroid sparing effect shown by Grimalt et al, was confirmed in this study.

A study conducted in Brazil, that evaluated colloidal oatmeal cream in an open trial in 75 AD patients aged 3-50 years showed significant improvements in SCORAD from baseline as early as week 4. At the end of the study, the SCORAD improvement was very similar to data reported by Nollent (2012).

Patients on chemotherapy with epidermal growth factor receptor inhibitors and tyrosine kinase inhibitors more often than not develop cutaneous adverse effects including acneiform eruptions which can preclude continuation of the treatment. In a study of 10 evaluable patients, treatment with an oatmeal-based lotion resulted in a complete clearing of the cutaneous adverse effects in 6 patients and a partial response in the remainder.

Conclusions

There are many different formulations of colloidal oatmeal including cleansers, washes, bath products, creams, lotions, shampoos and shaving gels. Colloidal oatmeal contains a number of components which contribute to its moisturizing, cleansing, buffering, anti-inflammatory, anti-pruritic and anti-oxidant properties.

Products containing colloidal oatmeal are well tolerated with only rare reports of allergic contact dermatitis. Studies have shown that A. sativa based products significantly decrease skin dryness, itch and irritation, improving quality of life in patients with mild to severe AD. Colloidal oatmeal use in patients with AD has been shown to significantly reduce topical corticosteroid consumption.

References

11. upcoming.
Advances in Acne Management and Patient Adherence

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Introduction

Acne vulgaris is a multifactorial disease characterized by different types of lesions at various stages of development. Treatment options must address a spectrum of disease from mild to severe; and encompasses topical to systemic agents, respectively. For all acne therapy however, adherence remains an issue. Advances in delivery mechanisms have been developed to improve patient compliance with both topical and systemic modalities. Most recently, the novel lipid technology (Lidose®) has been utilized in the administration of oral isotretinoin. CIP-Isotretinoin (Epuris™), approved by Health Canada in November 2012 and released commercially in June 2013, enhances drug absorption during fasted states and lessens the need for administration with a high-fat meal, thereby potentially improving bioavailability and patient adherence.

Topical Treatments for Mild to Moderate Acne

- Acne treatment selection is generally based on the severity and type of lesions, with the goal of treatment being to reduce sebum production, infundibular occlusion, inflammation and Propionibacterium acnes proliferation.
- Conventional topical therapies were originally composed of single agent preparations.
- Improved knowledge of acne pathogenesis and topical formulation chemistry led to development and clinical application of combination products (Table 1).
- Recent studies have demonstrated greater efficacy and tolerability with combination therapy compared to monotherapy.
- As a result, current consensus guidelines recommend the use of combination treatment as first-line therapy for most patients with mild to moderate acne.
- Notwithstanding efficacy, issues such as irritation and the emergence of bacterial resistance to both topical and oral antibiotics remain significant barriers to improved treatment outcomes.
- It is estimated that 30-40% of patients using topical formulations do not adhere to their prescribed regimen.

Improving Patient Adherence to Topical Therapy

- Treatment efficacy, local tolerance and adherence have all been improved through recent advances in vehicle technology.
- Additionally, delivery mechanisms such as pumps which provide convenience, are preferred by patients and may improve adherence.
- In a Patient Preferences in Acne: A Point-of-Care Educational Initiative, a national survey of 1709 Canadian patients showed that pump delivery systems are the preferred format (42% of patients).
- However, patient preferences have been shown to extend beyond treatment side-effects: variables such as vehicle composition, messiness, texture, aroma, difficulty of use, lack of early improvement, and staining, can all decrease compliance.
- Many new topical acne formulations have aqueous-based gel vehicle delivery systems that do not contain alcohol and are suitable for use in all skin types as they are less drying.
- Topical acne agents can cause cutaneous irritation related in part to impaired epidermal barrier function. Therefore:
  - the use of gentle cleansers and moisturizers has been shown to reduce this cutaneous irritation;
  - moisturizers containing ceramides can improve skin barrier function.

Table 1. Topical acne medications

<table>
<thead>
<tr>
<th>Class of Agents</th>
<th>Medications</th>
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<tr>
<td>Retinoids</td>
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<td>Tretinoin</td>
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<td>Tazarotene</td>
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<td>Antimicrobials</td>
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<td>Clindamycin</td>
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<td>Dapsone</td>
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<td>Sodium sulfacetamide</td>
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<td>Antiinflammatories</td>
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<td>Topical retinoids</td>
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<td>Combination products</td>
<td>Topical antibiotic + BPO</td>
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<td>• Clindamycin + BPO</td>
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<td>• Erythromycin + BPO</td>
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<td>• Topical retinoid + antibiotic</td>
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<td>• Tretinoin + clindamycin</td>
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<td>• Topical retinoid + BPO</td>
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<td>• Adapalene + BPO</td>
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• Additionally, vehicle advances, such as microsphere technology and solubilized crystalline formulations, reduce the potential of irritation from tretinoin.
• Photodegradation is not increased with microsphere tretinoin, tazarotene and adapalene, allowing for morning application.
• Clindamycin/BPO formulations with humectants and emollients may reduce the dry skin associated with BPO use.
• Clindamycin/BPO formulations without preservatives may reduce the irritation associated with these agents.7
• The addition of BPO to topical antibiotic agents and the use of BPO with long-term oral antibiotics can reduce the risk of cutaneous bacterial resistance.

Systemic Treatment for Severe Acne

Oral Isotretinoin
• Since US FDA approval of the oral isotretinoin agent Accutane™ in 1982, and its subsequent approval by Health Canada in 1983, it has remained the standard of treatment for severe nodular acne in Canada.
• Oral isotretinoin is a synthetic derivative of vitamin A, and is similar to the parent compound in being highly fat-soluble.
• As a result, ingestion of oral isotretinoin with food increases its bioavailability.6
• In the fasted state, ingestion of standard oral isotretinoin formulations leads to plasma levels that are approximately 60% lower compared to the fed state.8
• Accordingly, standard practice recommendations promote ingestion with food, particularly a high-fat meal, to enhance absorption.
• However, patient adherence and reliability in taking isotretinoin with high-fat meals may be inconsistent.9,11
• Irregular eating habits may result in irregular dosing and therefore variable drug absorption.

CIP-Isotretinoin (Epuris™)
• CIP-Isotretinoin (Epuris™) was approved by Health Canada in November 2012 and launched in June of 2013.
• It utilizes Lidose® technology to imbed isotretinoin in a lipid matrix, thereby increasing drug absorption during fasting.12
• CIP-Isotretinoin may lead to more consistent plasma levels of isotretinoin during variable dietary conditions, providing the potential for enhanced patient outcomes.
• Particularly for those with irregular eating times, treatment adherence may be improved as the absorption of the drug is better than the standard formulation in the absence of a high fat meal.
• This technology has already been successfully combined with a fenofibrate formulation (Lipofen™) to create a novel capsule used for treatment of hyperlipidemia.
• An application of this delivery platform encompassing oral CIP-Isotretinoin was approved by the US FDA in May 2012 (Absorica™) with indications for treatment of severe nodular and or inflammatory acne, acne conglobate, and recalcitrant acne.

Efficacy & Safety
• An open label, single dose randomized crossover study demonstrated pharmacokinetic bioequivalence of CIP-Isotretinoin to standard isotretinoin formulations during high fat fed states, with significantly greater absorption during fasting.13
• In the fasted state, the absorption of CIP-Isotretinoin, was approximately 83% greater than that of conventional isotretinoin.
• The products were bioequivalent when taken with a high fat meal.13
• In a double-blind, randomized, controlled trial comparing CIP-Isotretinoin under high fat fed conditions to a currently marketed formulation of oral isotretinoin (Accutane™), 925 subjects with severe recalcitrant nodular acne aged 12-54 years were recruited. Subjects had to have at least 10 acne nodules on the face and/or trunk.
• The number of responders, defined as those with ≥90% reduction in nodules at end of study compared to baseline, was similar in both treatment groups with overlapping 95% confidence intervals in per protocol (79% CIP-Isotretinoin versus 81% Accutane™) and intent-to-treat (70% versus 75%) analyses.
• Furthermore, the mean reduction in nodules in both groups was similar for both analyses (-17 versus -16, -16 versus -16, respectively), demonstrating clinical non-inferiority.
• Almost all patients experienced at least one adverse event in both groups at a similar rate (92% with CIP-Isotretinoin to 90% with Accutane™).14
• Reported adverse events were typical for oral isotretinoin use, with the majority related to dry skin and cheilitis.14
• Rates of serious adverse events occurring with the use of both CIP-Isotretinoin and standard oral isotretinoin were low (5/464 or 1.1% and 7/464 or 1.5%, respectively).14
• Adverse events leading to discontinuation of participation occurred in 4.1% (19/464) of patients with CIP-Isotretinoin, compared to 3.3% (15/460) of patients with standard oral isotretinoin.

Dosage & Administration
• Capsules of CIP-Isotretinoin are available in 10 mg (yellow), 20 mg (red), 30 mg (brown), and 40 mg (brown and red) doses in packages of 30 capsules (3 x 10 blister cards), which provides for flexible, individualized dosing according to the patient’s weight and disease severity.
• Inactive ingredients in this formulation include: stearoyl macrogolglycerides, soybean oil, sorbitan monooleate, and propyl gallocate.
• Accutane™ is currently available in Canada in 10 mg (pink), and 40 mg (orange) doses in blister packages of 30 capsules. Ingredients include beeswax, black iron oxide, gelatin, glycerol, soybean and peanut oils, parabens, shellac, and titanium dioxide.
• To prevent potential allergic reactions, Accutane™ should particularly be avoided in patients with sensitivities to peanut oil and parabens, in addition to the aforementioned contents.
As with standard isotretinoin formulations, the starting dose of CIP-Isotretinoin should be administered according to the patient’s weight and severity of the disease.

In general, patients should initially receive CIP-Isotretinoin 0.5 mg/kg body weight daily for 2-4 weeks while monitoring their responsiveness to the drug. Maintenance dose should be adjusted between 0.1 mg and 1 mg/kg body weight daily, depending on response and tolerance.

A complete course of therapy consists of 12-16 weeks of CIP-Isotretinoin administration. In view of differences in bioavailability, CIP-Isotretinoin is not interchangeable with standard oral isotretinoin formulations.

As with any oral retinoid treatment, the need for ongoing pregnancy prevention and safety monitoring is of paramount concern.

Generally, the side effects of oral isotretinoin have been well characterized, with the most common ones being mucocutaneous and mild.

It is recommended to initiate CIP-Isotretinoin treatment at a low dose of 0.5 mg/kg/day for 2-4 weeks to assess drug tolerance.

**Conclusion**

Advances in delivery technologies for mild, moderate and severe acne are improving treatment adherence. Additionally, in mild to moderate acne, a greater understanding of acne pathogenesis has led to the development of effective combination treatments. In severe nodular acne, the novel CIP-Isotretinoin formulation has been designed to reduce variation in bioavailability during fed and fasted states. In the context of clinical use, where patients may be unable to consistently take oral isotretinoin with a high-fat meal, this product enhances bioavailability and has the potential of improving clinical outcomes.

**References**

Clinical Management of External Genital Warts

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Introduction
External genital warts (EGW) is a common sexually transmitted infection (STI) affecting millions of individuals worldwide. It is likely the most frequent STI in both Canada and the US and is caused by infection with human papilloma virus (HPV) 6 and 11: importantly, these are non-oncogenic strains.¹ The lesions can be caused by HPV 6 (most commonly) or 11, both subtypes are rarely found together.¹ Patient and provider-applied therapies can be utilized concomitantly to effectively treat EGW. Recently, prophylactic strategies using HPV vaccines have been introduced with success, as has the introduction of a topical immunomodulator in a new formulation, all of which improve the therapeutic armamentarium, and ultimately, patient care.

Background
• The term EGW relates to the anatomic location of these lesions. The areas commonly involved include the penis, vulva, groin, perineum, perianal, suprapubic and even upper thighs and buttocks.²
• Most often EGW is painless and not bothersome. However, in certain individuals it can be quite symptomatic causing itching, pain during intercourse, stinging and burning. Larger lesions can cause obstruction of the meatus and the anus leading to restriction or complete blockage of normal excretory functions.
• Women are more frequently affected than men, with the most common age groups being 20-24 years and 25-29 years in men.³
• Reports indicate that lesions are only noticed in 65% of cases. Males notice the lesions 79% of the time likely due to the anatomic visibility.² Conversely, women only notice the lesions 52% of the time.⁵
• EGW are diagnosed by physicians in 16% of cases, more often in females and very infrequently in males.⁵ Likely, the clinician visit may have been regarding complaints of genital symptoms which lead to an unexpected diagnosis of EGW.⁵
• EGW carries a significant psychosocial impact. Often patients are embarrassed, angry and disgusted.⁵,⁶ Anxiety not only results in sexual tension but also raises concerns regarding recurrence, cancer, and the effectiveness of treatment.⁷,⁸
• EGW diagnosis can often result in a change in lifestyle.⁵ Therefore, patients may have higher expectations from their physician to properly diagnose, counsel, manage and treat these lesions.

Treatment Options
• Patients should expect a treatment that provides favourable efficacy, safety, tolerability, low recurrence rates, minimal scarring and that can be self-applied in the privacy of their own home.
• According to Canadian STI Guidelines, therapies are broadly grouped as patient-applied or office-based treatments.⁹ Often, combinations of treatments are used.
• Office-based cytodestructive therapies for EGW involve either chemical eradication or physical removal, specifically:
  • Cryotherapy (liquid nitrogen)
  • Surgical/ablative techniques (surgical excision, carbon dioxide laser, electocautery)
  • Trichloroacetic or bichloroacetic acid
  • Podophyllin resin
  • Podophylotoxin (0.5%) - standardized concentration of purified podophyllin
• Patient-applied treatments are usually preferred and include podophylotoxin and imiquimod.
  • Immunomodulatory therapy with topical imiquimod:
  • Classified as an immune response modifier, imiquimod has antiviral effects functioning through TLR-7 agonism.¹⁰
  • It induces TH-1 type immune responses resulting in the expression of cytokines such as interferon-alpha and tumour necrosis factor-alpha.¹⁰
  • Due to its favourable efficacy, safety and tolerability profiles, as well as lowest recurrence rate, Canadian Consensus Guidelines on HPV 14 recommends the use of imiquimod prior to initiating more invasive strategies, such as destructive/excision or laser therapies.⁹
  • Imiquimod 5% cream (Aldara™):
  • Approved by Health Canada in 1999.
  • Officially indicated for the treatment of external genital and perianal warts in immunocompetent adults.
  • Applied 3 times weekly for up to 16 weeks to a specific treatment area.
  • In a Phase 3 clinical trial, 72% of women and 33% of men had complete clearance of baseline target warts (analyses did not include non-target or new warts).¹¹
  • Side effects include erythema (67%), erosion (32%), excoriation/flaking (25%), edema (16%).¹¹
• Imiquimod 3.75% cream (Vyloma™):
  • Approved by Health Canada in March 2011 for the topical treatment of EGW and perianal warts (whether present at the start of therapy or emerging during therapy) in immunocompetent adults.
  • Developed from its predecessor, imiquimod 5%, with the goal of encouraging treatment adherence by shortening treatment length, simplifying the dosing regimen, and improving tolerability.
  • Applied once-a-day for up to 8 weeks to the external genital/perianal warts, but should not exceed 8 weeks even in the event of missed doses or rest periods.¹²
  • Treatment is generally well tolerated and common side effects included pain, irritation and pruritus at the treatment site.¹³

• Two randomized, placebo-controlled, double-blind studies of imiquimod 3.75% in 534 women (mean age 33.4 years) with 2-30 lesions (mean 7.9) in the vulvar (including mons), inguinal, perineum, and/or perianal areas, and with a minimum total wart area of 10 mm² demonstrated good efficacy and safety.¹³

• Imiquimod 3.75%, applied once daily for 8 weeks, achieved complete clearance in 36.6% of women versus 14.2% who applied placebo (p<0.001). A 63.5% decrease in wart count was seen in the imiquimod 3.75% group compared to a 10.7% decrease in the placebo arm (p<0.001). Discontinuation rates were 2.3% for the imiquimod 3.75% group versus 0.9% for placebo.

• Of the patients who completely cleared, 70% (71/102) remained clear of recurred EGW at the end of the 12-week follow-up.¹²

• Imiquimod 3.75% is pregnancy class C.

• It is available in 250 mcg single dose sachets and in a pump containing 7.5 g of cream.¹²

Vaccines for EGW

Currently, 2 vaccines are available for the prevention of HPV infection:

• Quadrivalent (HPV types 6, 11, 16, 18) vaccine (Gardasil®):¹⁴
  • Prevents EGW caused by HPV 6, 11 and cervical cancer and other cancers caused by HPV 16, 18 including vulva and vaginal cancers, cervical intraepithelial neoplasia, vulvar intraepithelial neoplasia, and vaginal intraepithelial neoplasia.
  • Indicated in females aged 9-45 years.
  • Indicated in males aged 9-26 years.

• Bivalent (HPV types 16, 18) vaccine (Cervarix®):¹⁵,¹⁶
  • Prevents cervical cancer and other cancers caused by HPV 16, 18.
  • Adjuvant results in very high serum antibody levels against HPV, excellent subtype cross-protection.
  • Does not protect against EGW acquisition.
  • Indicated in females aged 10-25 years.

Conclusion

EGW is a global problem. In addition to its physical symptoms, patients also suffer associated psychosocial sequelae. Therefore, the effective and safe treatment of this STI is important for a host of reasons. Therapeutic strategies for EGW include office-based cytodestructive therapies and patient administered topical therapy with imiquimod. Further, effective vaccines have been developed and are now widely available. All of these approaches are associated with good outcomes, and aid the clinician in helping their patients effectively manage EGW.

References

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