

# **Efficacy and Tolerability of a Novel Fluorescent Therapeutic Material in the Treatment of Acne Vulgaris of the Back**

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## **Introduction**

Acne vulgaris is a common skin disorder affecting both adolescents and adults. This condition is characterized by comedones and inflammatory lesions manifesting as papules and pustules. In severe cases, nodules and cysts may develop, ultimately resulting in cutaneous scarring. Acne presents a source of tremendous psychosocial distress to millions of patients worldwide.

Of the various anatomic sites of involvement, acne of the back is particularly challenging to treat. The skin of the back is much thicker than that of the face, making it difficult for traditional topical medicaments to penetrate and reach their pilosebaceous target, thereby necessitating systemic medications with more potential side effects. Also, as the back is not readily visible, patients often neglect this area, allowing acne lesions to persist and develop into scars. Moreover, the large, difficult-to-reach surface area on which to apply topical agents coupled with the rigid schedule of oral medication therapy both serve to dramatically reduce patient compliance. Therefore, new therapies are needed to improve patient compliance to achieve better clinical outcomes in a safe and effective manner.

In this study, a novel fluorescent therapeutic material (FTM) was evaluated for efficacy and tolerability when used as monotherapy for moderate-to-severe inflammatory acne vulgaris of the back.

## **Materials and Methods:**

### **Subjects:**

Ten healthy male and female adolescent subjects with moderate-to-severe inflammatory acne of the back were selected for this study (see *Table 1* for subject demographics). Subjects were recruited from a tertiary care dermatology centre to which they were referred by primary care physicians for treatment of acne. Those with systemic medical conditions including endocrine or metabolic disorders, malignant or pre-malignant skin lesions, mental illness, currently pregnant or nursing women were excluded. Medication exclusions included the use of oral isotretinoin or oral contraceptives within 6 months, other systemic acne medications (including oral antibiotics) within 1 month, and topical agents applied to the back within 2 weeks. Subjects were excluded if they had received any form of light therapy or laser treatment of the

back within 12 months prior to enrollment.

*Table 1. Subject demographics*

Subject Number	Age (years)	Gender	Diagnosis	Fitzpatrick Phototype
1	14	M	Back acne	II
2	18	M	Back acne	II
3	16	F	Back acne	II
4	17	M	Back acne	II
5	17	M	Back acne	II
6	15	M	Back acne	II
7	14	F	Back acne	II
8	19	M	Back acne	II
9	18	M	Back acne	II
10	17	F	Back acne	II

### **Technology:**

In the current study, we used fluorescent therapeutic material (FTM), developed by SunSoul Inc., of Canada, which converts the broad solar spectrum to the specific spectrum providing benefits for the treatment of acne. The matrix of the fabric was treated with a fluorescent blue pigment which amplifies blue light transmission in the spectral range of 400-500 nm as well as light in the near infrared spectrum.

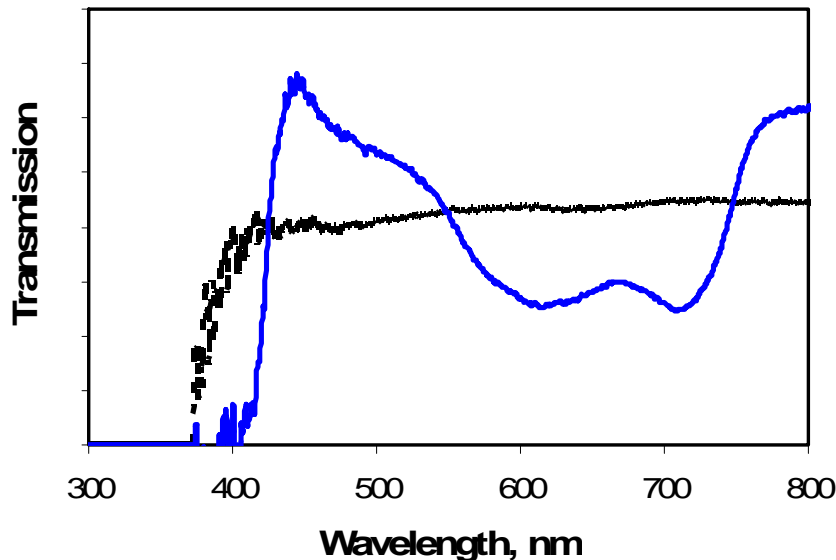
The transmission spectrum of the fluorescent therapeutic material (FTM) is shown in figure 1.

The transmission spectrum shows that FTM almost doubles the delivery of light in the range 400-450nm. Fluorescent pigments, applied to the polymer matrix, absorb the UV part of the sun's radiation and convert it into blue light and amplify this blue light to the skin's surface. The specific dye composition also increases light transmission in the near infrared spectrum above 700nm.

Light transmission in the UV range of spectrum is negligible. Microscopic analysis shows the material exhibits a high density of micro-fibers to a level of about 99%. Strong absorption of

the UV light, by the polymer matrix and the fluorescent pigment, provides UV protection factor (UPF) of 45.

This selective spectrum delivered to the patient's skin looks optimal for the treatment of acne.



*Figure 1. Black curve - light transmission by non-dyed material, Blue curve light transmission by FTM*

### **Study Protocol, Efficacy and Tolerability Parameters:**

The entire surface area of the back of each subject was irradiated by the light transmitted through the blue FTM by sitting at a distance of 18 inches from the fabric. Subjects received 2 treatment sessions per week over 4 weeks, for a total number of 8 treatments. The exposure time for each session was 40 minutes. Subject perceptions and adverse effects were noted after each treatment session. A final two-week follow-up visit was also conducted. Subjects were prohibited from using any topical medicaments on the back during the study and for two weeks after completion. The use of gentle, non-medicated moisturizers and cleansers were permitted.

The backs of all subjects were photographed at baseline and at every visit using high-quality digital photography with standardized lighting and positioning (entire treatment field in view and subjects standing with arms crossed and parallel to the ground).

Subjects were examined by two independent observers on four occasions: at baseline, at the fourth treatment, at the eighth treatment, and at 2 weeks follow-up. Each examination consisted of: i) a count of all inflammatory acne lesions (papules and pustules) on the back, and ii) an evaluation of the size of these lesions as per a range of lesion diameter (ie. a range encompassing the smallest and largest diameter lesion).

Subjects were also required to give a subjective evaluation of their tolerance of the treatment at every visit, and their perceived improvement from baseline to the 2 week follow-up visit.

## **Results:**

A total of 10 subjects completed the study. No adverse events were reported during the study for all subjects.

All subjects perceived that their back acne had improved minimally to moderately from baseline to the end of their treatment (See *Table 2*). All subjects expressed that they were pleased with the product to the point that they would recommend the treatment to others and if commercially available would purchase the product.

*Table 2. Subject perception of improvement in their inflammatory back acne*

Subject Number	Perceived improvement from Baseline to 2 Week F/U
1	1
2	2
3	2
4	1
5	2
6	1
7	1
8	1
9	1
10	1

\* -1 = Worsening, 0 = no improvement, 1 = mild improvement, 2 = moderate improvement, 3 = clearance

Seven out of 10 subjects demonstrated a slight increase in lesion inflammation and perilesional erythema during the treatment period and improvement at follow-up visits. Immediate post-treatment erythema was noted to last less than 4 hours (See *Figure 2b*).

All subjects found the treatments to be very tolerable with mild to no discomfort (See *Table 3*). Of note, those subjects who experienced mild discomfort also demonstrated the highest degree of inflammatory acne. For these patients, the degree of discomfort decreased over the treatment regimen.



Figures 2A, 2B and 2C show baseline, immediate response and 2 week follow-up photos of the same subject.

Table 3. Subject tolerability of treatment sessions

Subject Number	Tolerability of Tx #1	Tolerability of Tx #4	Tolerability of Tx #8
1	1	1	0
2	0	0	0
3	0	0	0
4	0	0	0
5	1	0	0
6	0	0	0
7	0	0	0
8	0	0	0
9	0	0	0
10	1	1	1

- 0 = no discomfort, 1 = mild discomfort, 2 = moderate discomfort, 3 = severe discomfort

Tables 4 and 5 show the results of the two independent evaluations for inflammatory lesion count and inflammatory lesion size respectively. The trend is towards decreased lesion size and lesion count with more treatments.

*Table 4. Average inflammatory lesion count at Baseline, After Treatment #4, After Treatment #8, and at Two Weeks Follow-Up (Based on two independent evaluations)*

Patient Number	Lesion Count (Baseline)	Lesion Count (After Tx #4)	Lesion Count (After Tx #8)	Lesion Count (2 weeks F/U)
1	168	172	164	160
2	98	89	59	48
3	82	86	70	55
4	112	106	101	88
5	140	130	114	96
6	106	100	108	98
7	77	75	72	68
8	109	105	99	92
9	87	88	85	86
10	153	156	148	144

Table 5. Average inflammatory lesion size at Baseline, After Treatment #4, After Treatment #8, and at Two Weeks Follow-Up (Based on two independent evaluations)

Patient Number	Lesion Size (Baseline)	Lesion Size (After Tx #4)	Lesion Size (After Tx #8)	Lesion Size (2 weeks F/U)
1	1 – 5 mm*	2 – 5 mm	2 – 5 mm	2 – 4 mm
2	1 – 4 mm	1 – 4 mm	1 – 3 mm	1 – 3 mm
3	1 – 3 mm	1 – 3 mm	1 – 3 mm	1 – 3 mm
4	1 – 5 mm	1 – 4 mm	1 – 4 mm	1 – 3 mm
5	1 – 5 mm	2 – 5 mm	2 – 4 mm	1 – 4 mm
6	1 – 4 mm	1 – 4 mm	1 – 4 mm	1 – 4 mm
7	1 – 3 mm	1 – 3 mm	1 – 3 mm	1 – 3 mm
8	1 – 4 mm	1 – 4 mm	1 – 3 mm	1 – 3 mm
9	1 – 3 mm	1 – 3 mm	1 – 3 mm	1 – 3 mm
10	1 – 6 mm	2 – 5 mm	1 – 5 mm	1 – 5 mm

\* This is a range encompassing the smallest inflammatory lesion and the largest inflammatory lesion seen

### **Discussion:**

Clinical efficacy through the antimicrobial action of various light based therapies such as blue light treatment has been demonstrated.<sup>1</sup> One study found that 24 hour cultures of *Propionibacterium acnes* bacteria after illumination with intense blue light with an emission spectrum of 407 – 420 nm had viability diminished by two orders of magnitude compared with non-illuminated cultures.<sup>2</sup> Various investigators have used high-intensity, narrow-band 420 nm UV-free blue light systems, and other more targeted blue light phototherapy systems with comparable success.<sup>3</sup> It is believed that the efficacy of blue light therapy in the treatment of acne vulgaris is due to the accumulation of *P. acnes* synthesized porphyrins, which are subsequently activated by the light to release reactive oxygenation species (ROS). These ROS are thought to impede bacterial population and function, and perhaps lower sebaceous secretion as well; two pathophysiological factors in the development of acne. A study by Tzung et al. found that patients without nodulocystic acne are better candidates for blue light therapy while factors such as gender, scar type and fluorescent intensity could not predict therapeutic effectiveness.<sup>4</sup>

Fabrics and dressings have also been previously studied for the treatment of acne. Chao et al found that the product Acne Dressing decreased acne severity scale and improved redness, oiliness, dark pigmentation, and sebum casual level in 20 patients studied.<sup>5</sup>

The mechanism of action of the fabric is based on delivering specific wavelengths to the surface of the skin. This range of light, 400-500nm, is currently used as a therapeutic modality for acne and other cutaneous conditions.

#### Specific Discussion of the Current Study

The primary goal of this study was to investigate the clinical response of lesions of back acne to fluorescent therapeutic blue fabrics. The results are very promising for this new therapeutic modality, both in terms of efficacy and tolerability.

*Figure 1* demonstrates mild erythema of perilesional skin post-treatment. It was noted that the degree of erythema was correlated to the degree of inflammatory acne present. That is, more perilesional erythema was noted with those subjects with higher lesion counts and lesion size. It therefore appears that the FTM treatments demonstrate specificity towards active acne lesions, slightly increasing the inflammation before ultimately reducing it.

This “excitation” phenomenon of active acne lesions by the FTM treatment may explain how those subjects who experienced mild discomfort were also those who had the highest lesion counts and the largest average lesion size.

*Table 3* shows that of those subjects who experienced mild discomfort, the discomfort improved over the course of the treatment regimen. This may due to decreased inflammatory acne over time or less likely, the subjects had grown tolerant of the discomfort over time.

*Tables 4* and *5* demonstrate a trend towards decreased lesion size and lesion count with more treatments. Of interest is the fact that this trend seems to continue for 2 weeks follow-up post treatment. Further study will be necessary to demonstrate how long this trend lasts and when, if at all, lesions demonstrate increased number and size back to baseline. These future studies will assist in determining the appropriate regimen necessary to achieve adequate lesion reduction and for suggesting maintenance treatments.

Limitations to this study include the fact that photography is limited in documenting inflammatory acne lesions. These lesions often have a three-dimensional morphology which is difficult to capture with photography, necessitating physical examination by an evaluator. Also, the efficacy of the FTM may theoretically be decreased over time due to loss of fluorescence in the fabric by chronic illumination by the light source.

### **Conclusions**

Inflammatory acne of the back is an often difficult condition to treat due to anatomic factors and patient compliance. FTM represents a novel therapeutic modality that may serve as monotherapy or adjunctive therapy to improve lesion count and number in a safe and tolerable manner. This pilot study demonstrates the potential benefits of such treatment. Future studies will determine the best regimen of treatment and maintenance. It is also likely that FTM technology when used in combination with traditional medications for inflammatory back acne may have synergistic effects and yield faster and greater improvement.

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