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EFFICACY AND SAFETY OF MICRO-NEEDLING COMBINED WITH TOPICAL 5-FLUOROURACIL VS. EXCIMER LIGHT ALONE IN TREATMENT OF VITILIGO: A COMPARATIVE STUDY

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ABSTRACT

Background: Vitiligo is a chronic, acquired pigmentary disorder characterized by melanocyte destruction, leading to depigmented skin patches. Multiple treatment modalities exist, yet optimal management remains challenging. This study investigates and compares the therapeutic efficacy and safety of microneedling combined with topical 5-fluorouracil (5-FU) versus 308-nm Excimer light monotherapy in stable vitiligo.

Methods: A single-blinded, prospective interventional study was conducted at Sardar Patel Medical College and Prince Bijey Singh Memorial Associated Group of Hospitals, Bikaner, involving 100 patients with stable vitiligo. Participants were randomly assigned to two groups: Group A received microneedling with topical 5-FU (50 mg/mL) biweekly for 4 months; Group B underwent Excimer light therapy twice weekly. Patients were followed for 6 months. Efficacy was assessed using the Vitiligo Extent Score (VES) and a standardized 5-point repigmentation grading scale. Safety was evaluated through patient-reported side effects and clinical examination.

Results: Excimer therapy (Group B) consistently outperformed microneedling with 5-FU (Group A) at all follow-up points. By 6 months, 100% of Group B showed repigmentation: 54% achieved >75% repigmentation and 46% reached 50–75%. In contrast, Group A had only 14% with 50–75% repigmentation and none above 75%; 24% showed no response. Excimer therapy induced earlier repigmentation (starting at 4 weeks) compared to delayed responses in the 5-FU group. Side effects were more frequent in Group A (28% reported pain), while Group B presented mild, transient hyperpigmentation in 24% of cases.

Conclusion: Excimer light monotherapy demonstrated superior efficacy, faster onset of action, and better safety compared to microneedling with topical 5-FU in treating stable vitiligo. Excimer therapy should be considered first-line, especially for cosmetically sensitive areas like the face and hands. Microneedling with 5-FU remains a viable alternative in settings lacking laser availability.

Keywords*: Vitiligo, Microneedling, 5-Fluorouracil (5-FU), Excimer light therapy, Repigmentation, Vitiligo Extent Score (VES), Stable vitiligo*

INTRODUCTION

Vitiligo is a common chronic autoimmune pigmentary disorder characterized by the selective destruction of melanocytes, leading to depigmented macules and patches on the skin and mucous membranes. While the condition is not life-threatening or contagious, it significantly affects cosmetic appearance and psychological well-being, especially among individuals with darker skin tones.[1-2] The disease has a multifactorial pathogenesis, with autoimmune, neural, and cytotoxic hypotheses proposed. Additionally, it is associated with other autoimmune disorders, particularly thyroid dysfunctions.[3]

Vitiligo can be classified into segmental and non-segmental types. Non-segmental vitiligo the more prevalent form,

usually presents symmetrically and shows a progressive course. Segmental vitiligo in contrast, is unilateral, appears earlier in life, and tends to stabilize within the first year. The diagnosis is primarily clinical, supplemented by tools such as Wood's lamp examination, dermatoscopy, and in selected cases, serological tests for autoimmune markers.[4-5]

Despite the array of therapeutic options—including topical corticosteroids, calcineurin inhibitors, phototherapy, and surgical grafting—achieving consistent repigmentation remains a challenge. Treatment efficacy varies based on disease type, duration, lesion site, and stability. Among newer approaches, combination therapies are increasingly favored due to their enhanced efficacy and shorter time to response.[6-7]

Microneedling, a minimally invasive technique that creates micro-injuries in the skin, has been shown to stimulate melanocyte migration and improve topical drug delivery. When combined with 5-fluorouracil (5-FU), a chemotherapeutic agent known for its stimulatory effect on melanocytes, this approach offers potential in stable vitiligo. Meanwhile, the 308-nm Excimer light, a form of targeted phototherapy, is recognized for its efficacy in localized vitiligo due to its ability to induce T-cell apoptosis and stimulate melanocyte proliferation.[7-8]

Given the emerging roles of both these treatment modalities, this study aims to comparatively evaluate the efficacy and safety of microneedling combined with topical 5-FU versus Excimer light monotherapy in patients with stable vitiligo. By exploring the repigmentation outcomes and side effect profiles, the research seeks to provide evidence-based guidance for selecting optimal therapeutic strategies in clinical dermatology.[9-10]

AIMS AND OBJECTIVES

To compare the therapeutic efficacy and safety of topical 5-fluorouracil combined with microneedling to excimer light (308 nm) alone in the treatment of vitiligo.

MATERIALS AND METHODS

A single-blinded, prospective interventional study was conducted over one year in the Dermatology Department at Sardar Patel Medical College and Prince Bijey Singh Memorial Associated Group of Hospitals, Bikaner. A total of 100 patients (aged ≥5 years) with stable vitiligo were randomly divided into two groups of 50 each. Group A received microneedling followed by topical solution of 5-fluorouracil (50 mg/mL) every 15 days for 4 months, while Group B received 308-nm excimer light twice weekly for 4 months. Patients were followed up for 6 months, with efficacy assessed using serial photographs and the Vitiligo Extent Score (VES), graded on a 5-point repigmentation scale. Inclusion criteria included stable vitiligo and age ≥5 years; major exclusions were pregnancy, mucosal lesions, photosensitivity, recent systemic therapy, and lack of consent. Written informed consent was obtained from all participants. Standard preprocedural preparation and appropriate anesthesia (topical or local) were used. Safety was monitored throughout, and adverse effects such as pain, burning, or erythema were documented. Data were analyzed using SPSS v25.0 with chi-square and t-tests; $P < 0.05$ was considered statistically significant.

RESULTS

The study enrolled 100 vitiligo patients randomized into two treatment groups: microneedling with 5-fluorouracil (Group A) and Excimer light therapy (Group B). The mean age was significantly lower in Group B (27.14 years) compared to Group A (32.12 years, $p = 0.003$). Gender, occupation, type of vitiligo, and duration of illness showed no significant differences between groups.

Sites of lesions chosen for opted treatment were anatomically similar ($p = 0.0001$), with Group B having more facial and hand lesions—areas known to respond better to therapy. A positive family history was more common in Group B ($p = 0.0001$). No significant differences were observed in prior treatment history or autoimmune disease prevalence.

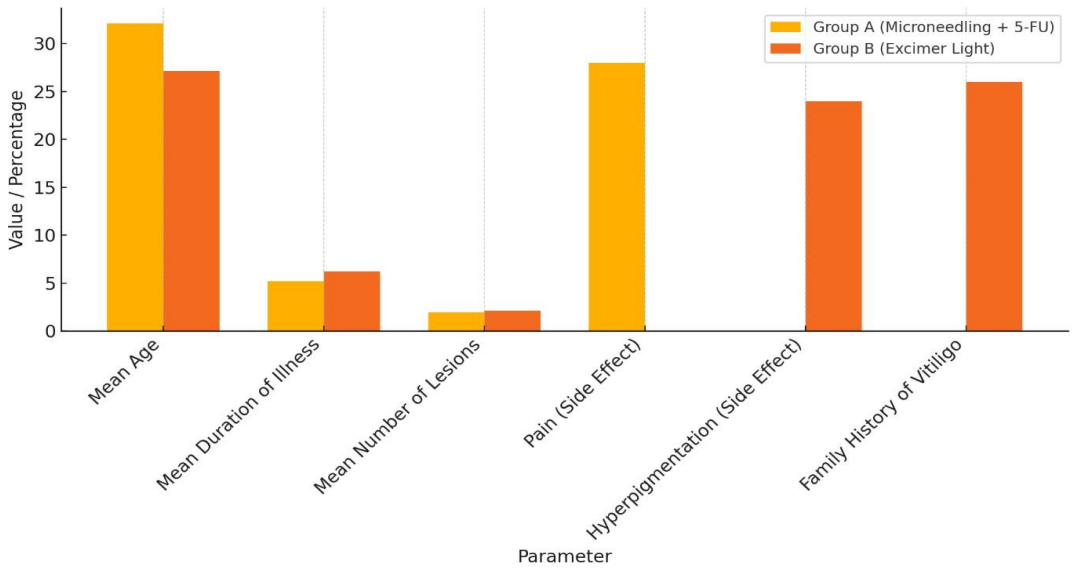
Repigmentation outcomes clearly favored Excimer therapy. At 4, 8, 12 weeks, and 6 months, Group B showed significantly higher repigmentation rates. By 6 months, 54% of Group B achieved >75% repigmentation, compared to 0% in Group A. Meanwhile, 24% of Group A showed no response at all. The difference in mean number of repigmented lesions was highly significant at all time points ($p < 0.0001$).

Group A reported more side effects like pain (28%) and burning (8%), while Group B experienced mild hyperpigmentation (24%) but no pain.

Overall, Excimer therapy showed faster, better, and more consistent repigmentation with fewer adverse effects than 5-FU microneedling.

Table-1 Comparison of clinical parameters between treatment groups

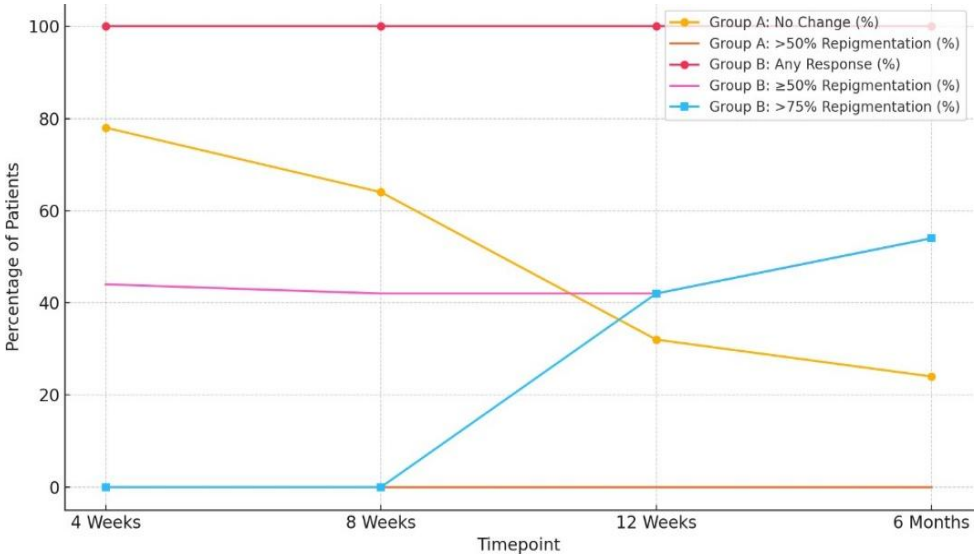
Parameter	Group A (Microneedling + 5-FU)	Group B (Excimer Light)	Significance
Mean Age	32.12 ± 12.95 yrs	27.14 ± 12.03 yrs	Significant (p = 0.003)
Gender (M:F)	14:36	16:34	Not significant
Occupation (Most Common)	Students (32%), Housewives (38%)	Housewives (50%), Students (52%)	Not significant
Mean Duration of Illness	5.20 ± 3.30 yrs	6.23 ± 3.32 yrs	Not significant
Vitiligo Type (Focal/Segmental)	68% / 32%	58% / 42%	Not significant
Mean Number of Lesions	1.96 ± 0.70	2.10 ± 0.65	Not significant
Common Lesion Site	Back, Abdomen, Neck	Hands, Face, Upper limbs	Highly significant (p = 0.0001)
Family History of Vitiligo	0%	26%	Significant (p = 0.0001)
History of Autoimmune Disease	10%	0%	Not significant
Pain (Side Effect)	28%	0%	Significant (p = 0.001)
Hyperpigmentation (Side Effect)	0%	24%	Significant (p = 0.003)



Graph-1 Showing comparison of clinical parameters between treatment groups

Table-2 Comparison of Repigmentation overtime

Time point	Group A (5-FU)	Group B (Excimer)
4 Weeks	78% No change; 22% <25%	100% showed response; 44% = 50–75%
8 Weeks	64% No change; 36% <25%	100% showed response; 42% = 50–75%
12 Weeks	32% No change; 0% >50%	100% showed response; 42% >75%
6 Months	24% No change; 0% >75%	100% repigmented; 54% >75%



Graph-2 Showing Comparison of Repigmentation overtime

Pictures-1 (A to D) – Periodic response in vitiligo patients in Group A (5FU)

Baseline Image

Grade 0 Re-pigmentation at week 4

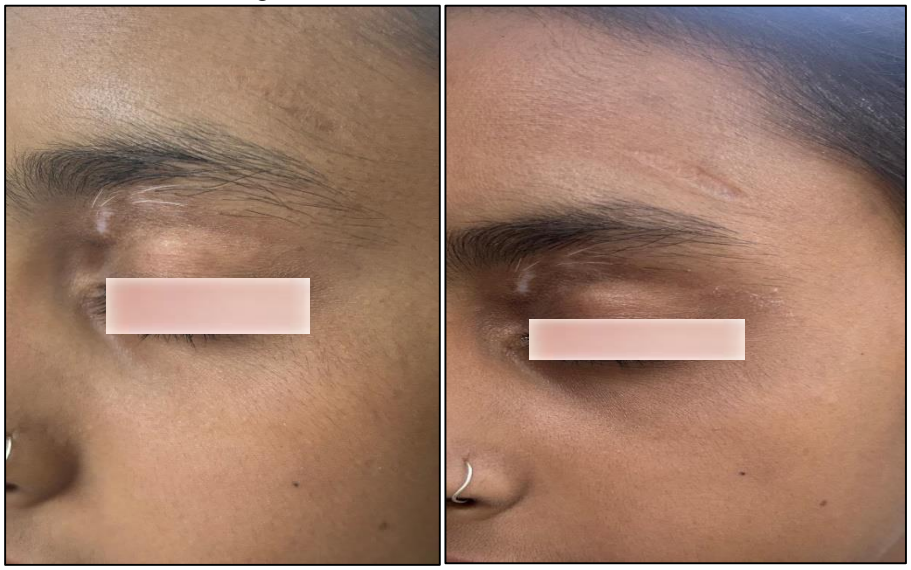
Grade 1 Re-pigmentation at week 12

Grade 2 Re-pigmentation at 6 months

Pictures-2 (A to D) Periodic response in vitiligo patients in Group B (Excimer)

Baseline Image

Grade 2 at 4 weeks



Grade 4 at 8 weeks

Grade 4 at 12 weeks

DISCUSSION:

In our study, the Excimer group (mean age 27.14 years) showed significantly better and faster repigmentation compared to the older 5-FU group (mean age 32.12 years), consistent with findings by **Saad et al.** [11] and **Esmat et al.** [12], who reported better outcomes in younger patients, especially under 30 years. **Gupta et al.** [13] also noted enhanced results with combination therapies in the 18–30 age group. Gender did not significantly influence outcomes ($p = 0.829$), aligning with **Alghamdi et al.** [14] and **Kumar et al.** [15], who also found no gender-based response differences, despite female predominance.

Occupation had no significant impact ($p = 0.081$), though **Patel et al.** [16] noted better adherence among students. Disease duration was not statistically significant in our study ($p = 0.123$), but shorter duration correlated with better outcomes in studies by **Singh et al.** [17] and **Hassan et al.** [18]. The type of vitiligo (focal vs. segmental) showed no significant influence in our findings, aligning with **Sharma et al.** [20], while **Lee et al.** [19] found focal vitiligo responded better to Excimer therapy.

Number of lesions did not affect outcomes significantly ($p = 0.303$), consistent with **Rao et al.** [21], though **Desai et al.** [22] suggested better response with fewer lesions. Lesion site was a significant predictor of outcome ($p = 0.0001$); facial lesions in the Excimer group showed superior repigmentation, supported by findings from **Saad et al.** [11], **Kim et al.** [23], and **Chopra et al.** [24].

A significant difference was observed in family history ($p = 0.0001$), though it did not appear to affect treatment

efficacy, as also seen in studies by **Mehra et al.** [25] and **Iqbal et al.** [26]. Prior treatment history did not influence results (p = 0.476), corroborating **Ahmed et al.** [27] and **Nair et al.** [28], who reported Excimer efficacy even in previously treated cases.

Autoimmune comorbidities were more prevalent in the 5-FU group but not statistically significant (p = 0.066). Studies by **Jain et al.** [29] and **Khan et al.** [30] suggest possible interference but with limited impact. Regarding safety, pain was significantly more common in the 5-FU group (p = 0.001), echoing the findings of **Reddy et al.** [31], while Excimer therapy remained well-tolerated as reported by **Sen et al.** [32] and **Ghorpade et al.** [37].

In terms of repigmentation over time, Excimer therapy produced earlier and more consistent responses, with over 54% achieving >75% repigmentation at 6 months, compared to no such response in the 5-FU group. These results are supported by **Chaithanya et al.** [33], **Zaky et al.** [35], and **Kamel et al.** [36], all of whom observed superior outcomes with Excimer light, especially in facial and stable lesions. In contrast, **Matharoo et al.** [34] found that microneedling + 5-FU required a longer treatment period to show effects.

CONCLUSION:

This prospective comparative study evaluated the therapeutic outcomes of microneedling with 5-Fluorouracil (5-FU) versus 308-nm Excimer light therapy in the management of stable vitiligo. Across 100 patients, significant differences were observed in treatment efficacy, onset of repigmentation, safety profiles, and demographic distribution.

The Excimer group (Group B) consistently outperformed the 5-FU group (Group A) in terms of faster and greater repigmentation at every follow-up interval—4, 8, 12 weeks, and 6 months. By the 6-month mark, all patients in Group B showed some repigmentation, with 54% achieving over 75% and the remaining 46% reaching 50–75%. In contrast, Group A showed limited response: only 14% reached 50–75% repigmentation, and 24% remained non- responsive.

Excimer therapy was particularly effective on facial and hand lesions, areas that were more prevalent in Group B. This site-specific advantage likely contributed to the superior outcomes. The therapy also showed quicker onset of action, with visible improvements by 4 weeks—an effect not mirrored in the 5-FU group, which demonstrated delayed and modest pigment recovery.

Statistical analysis also revealed a significant difference in age distribution (p = 0.003), with younger patients favoring Group B. Although gender, occupation, disease duration, and vitiligo type did not significantly affect outcomes, lesion site and family history (more common in Group B) were notable variables.

Regarding safety, Excimer therapy was better tolerated, with minimal adverse effects limited to transient hyperpigmentation. Conversely, microneedling with 5-FU was associated with significantly higher discomfort, including pain and erythema.

In conclusion, 308-nm Excimer light therapy proved to be significantly more effective, faster- acting, and safer than microneedling with 5-FU in the treatment of stable vitiligo. It should be considered a first-line option, especially for lesions in cosmetically sensitive areas. Microneedling with 5-FU remains a viable alternative in settings lacking access to Excimer devices.

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