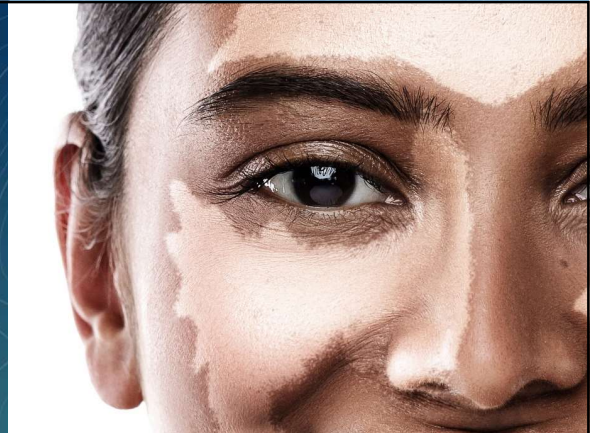


# Navigating Novel Terrain in Vitiligo Management:



## A Practical, Patient-Centric Review



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## Faculty Information & Disclosures



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#### Disclosures:

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## Learning Objectives

- Appraise the clinical presentation and diagnosis of vitiligo including the fundamental role of autoimmune response and potential triggers
- Describe the significant, multifaceted impact of vitiligo on patient quality of life, with emphasis on both cosmetic and non-cosmetic manifestations
- Evaluate the pathophysiologic autoimmune mechanisms driving vitiligo pathogenesis and progression with a focus on the functional loss of melanocytes
- Explore and characterize the JAK signaling pathway as a prominent therapeutic target in the treatment of vitiligo
- Review historical vitiligo treatment approaches and identify clinical gaps and unmet patient needs
- Examine the expanding treatment armamentarium for patients with vitiligo, with an expert deep dive into a newly approved topical treatment and recent advancements in understanding the potential impact of lifestyle modification as a management strategy
- Design individualized treatment strategies for patients with vitiligo, highlighting clinical trial findings of newer, emerging therapeutics and their placement in the evolving treatment calculus

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## Establishing Context

Vitiligo Presentation, Prevalence, and Patient Burden

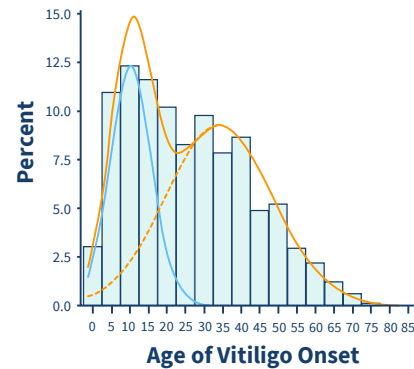
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# Vitiligo

- 1% prevalence in US and Europe; up to 8.8% in India
- ½ of all patients have onset of disease prior to age 20
  - 70-80% before age 30
- Equal incidence in men and women but females experience peak in onset in first decade of life and for males it is in the fifth decade of life
- Unpredictable disease course
- Itch associated in up to 20% of patients
- Treatment has historically been difficult
- Spontaneous repigmentation is possible but uncommon (about 10% of patients)



Vitiligo Onset is Bimodal



AL-smadi K, et al. *Cosmetics*. 2023; Gandhi K, et al. *JAMA Dermatology*. 2022; <https://www.aad.org/public/diseases/a-z/vitiligo-causes>; Varma K, et al. *IP Indian J Clin Exp Dermatol*. 2022; Alikhan A, et al. *J Am Acad Dermatol*. 2011; Jin Y, et al. *Nat Commun*. 2019.

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# Disease Presentation

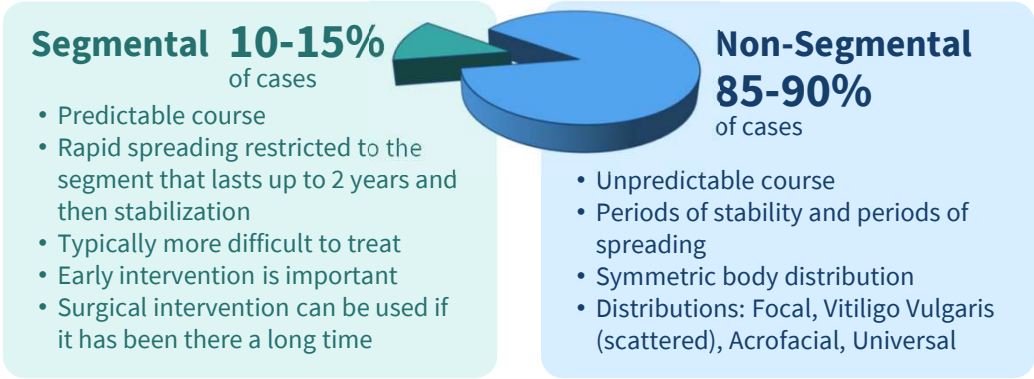
- Well demarcated, patchy, depigmented macules and patches
- Accentuates with wood's lamp
- Signs of Disease Activity
  - **Confetti-like depigmentation:** 1-5 mm depigmented macules in clusters, often at edges of existing lesions
  - **Trichrome lesions:** Hypopigmented zone between normal and depigmented skin
  - **Koebner phenomenon**



Aboul-Fettouh N, et al. *J Am Acad Dermatol*. 2017.

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# Segmental vs Non-Segmental Vitiligo

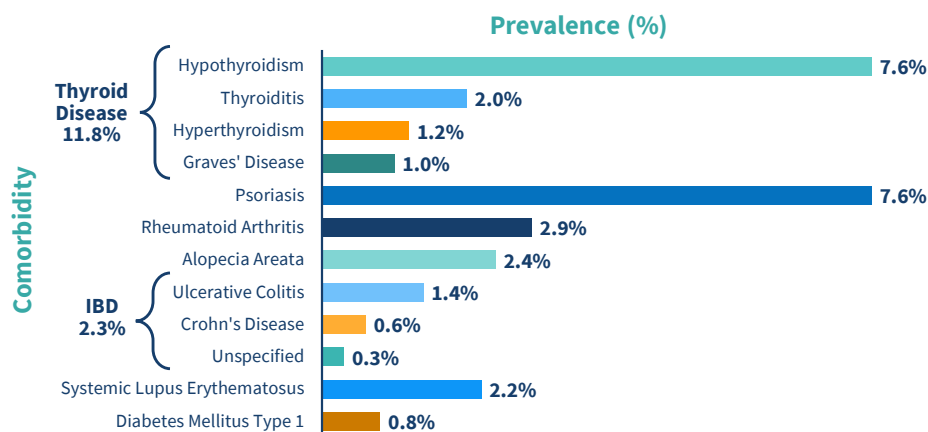


**Unclassified:** Focal or mucosal (1 site in isolation)

Ezzedine K, et al. *Pigment Cell Melanoma Res.* 2012; Bergqvist C, et al. *Dermatology.* 2020; Ezzedine K, et al. *J Am Acad Dermatol.* 2023.

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# Prevalence of Comorbidities in Vitiligo



Sheth VM, et al. *Dermatology.* 2013.

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“Because **skin color plays a major role in an individual’s perception of health, wealth, worth and desirability**, pigmentary disfigurements may influence social interactions. Vitiligo may even lead to social exclusion in certain societies.

Therefore, vitiligo is considered to be one of the **major medical disorders** ...vitiligo is **often considered as a harmless, cosmetic skin disorder**, whereby **the importance of treating patients with vitiligo is often underestimated.**”

Linthorst Homan MW, et al. *J Am Acad Dermatol.* 2009.

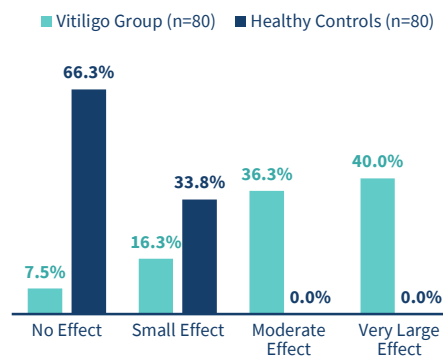
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## Psychological Burden of Vitiligo

- In QOL studies, impact of vitiligo is similar to atopic dermatitis, psoriasis, and acne
- Patients can feel stressed and stigmatized by the depigmentation
- Major impact on self-esteem and confidence
- Given that **most patients have onset before age 20**, these patients are facing this burden at a time that is crucial for their personal, psychological, and professional development

Effect of Vitiligo on Quality of Life, Assessed via DLQI Score



Vallerand IA. *J Am Acad Dermatol.* 2018; Baidya S, et al. *Ind Psychiatry J.* 2021.

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## Psychological Burden of Vitiligo

- Vitiligo patients can experience a variety of psychological problems like depression, anxiety, sleep disturbance, adjustment disorder and dysthymia
- Risk of depression is higher in patients that were diagnosed prior to age 30
- Risk of depression diminishes as diagnostic age increases
- There are even studies showing that patients with depression could be at increased risk for subsequent development of vitiligo
  - Treatment with an anti-depressant is protective

Vallerand IA. *J Am Acad Dermatol.* 2018.

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## Psychological Burden of Vitiligo

- In some countries, **vitiligo can be mistaken for leprosy or STI** which adds to stigma
  - Women in these countries can have difficulty getting married
  - In some religions, vitiligo can affect **“expectations for the destiny of the soul after death”**
- In some cultures, patients will be ostracized and unable to work, marry, or participate in social life



Vallerand IA. *J Am Acad Dermatol.* 2018; Ezzedine K, et al. *J Am Acad Dermatol.* 2019; Alikhan A. *J Am Acad Dermatol.* 2011.

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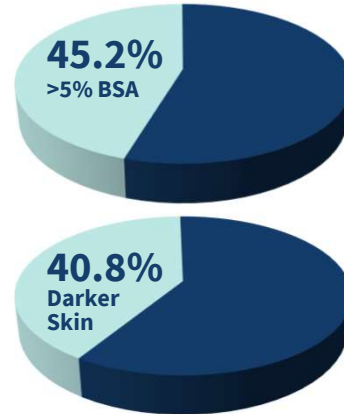


# The Global VALIANT Study (Vitiligo And Life Impact Among International Communities)



- Qualitative, cross-sectional population-based study
- May 6, 2021 – June 21, 2021
- 3541 adults with vitiligo asked questions about their emotional well-being, including QoL and mental health
  - Range: 18-95 years, median 38 years
  - 54.6% were male
- Vitiligo Impact Patient scale (VIPs) scores
  - Range 0-60
  - Higher scores = more psychological burden

## Key Patient Characteristics



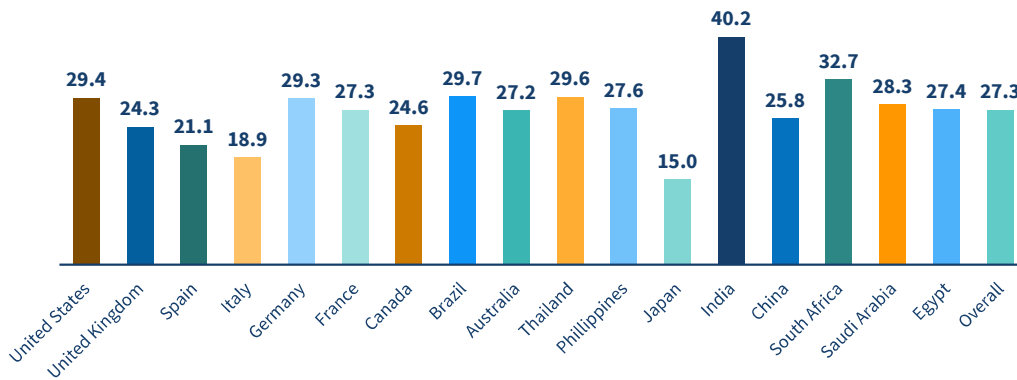
Bibeau K, et al. *JAMA Dermatol.* 2023.

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# The Global VALIANT Study (Vitiligo And Life Impact Among International Communities)



## VIPs Scores, by Geographical Area



Bibeau K, et al. *JAMA Dermatol.* 2023.

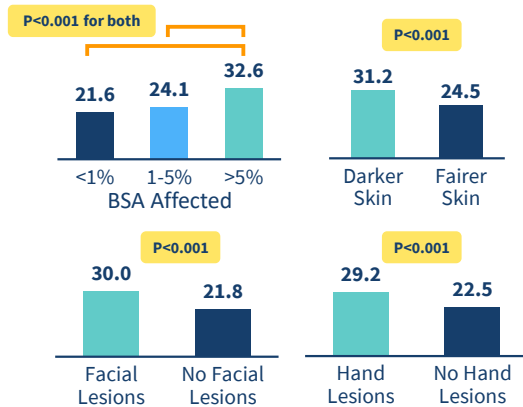
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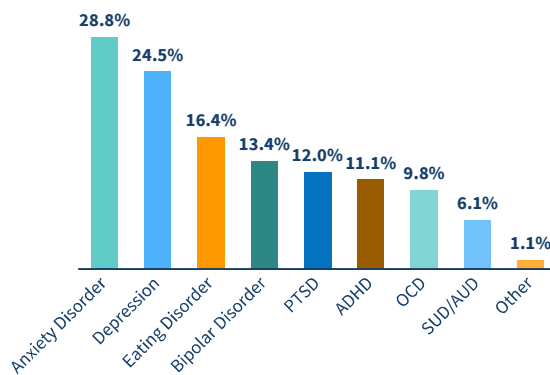
# The Global VALIANT Study (Vitiligo And Life Impact Among International Communities)



**VIPs Scores, by BSA, Fitzpatrick Skin Type, and Facial or Hand Lesions**



**Percentage of Individuals with Formal Mental Health Diagnoses**



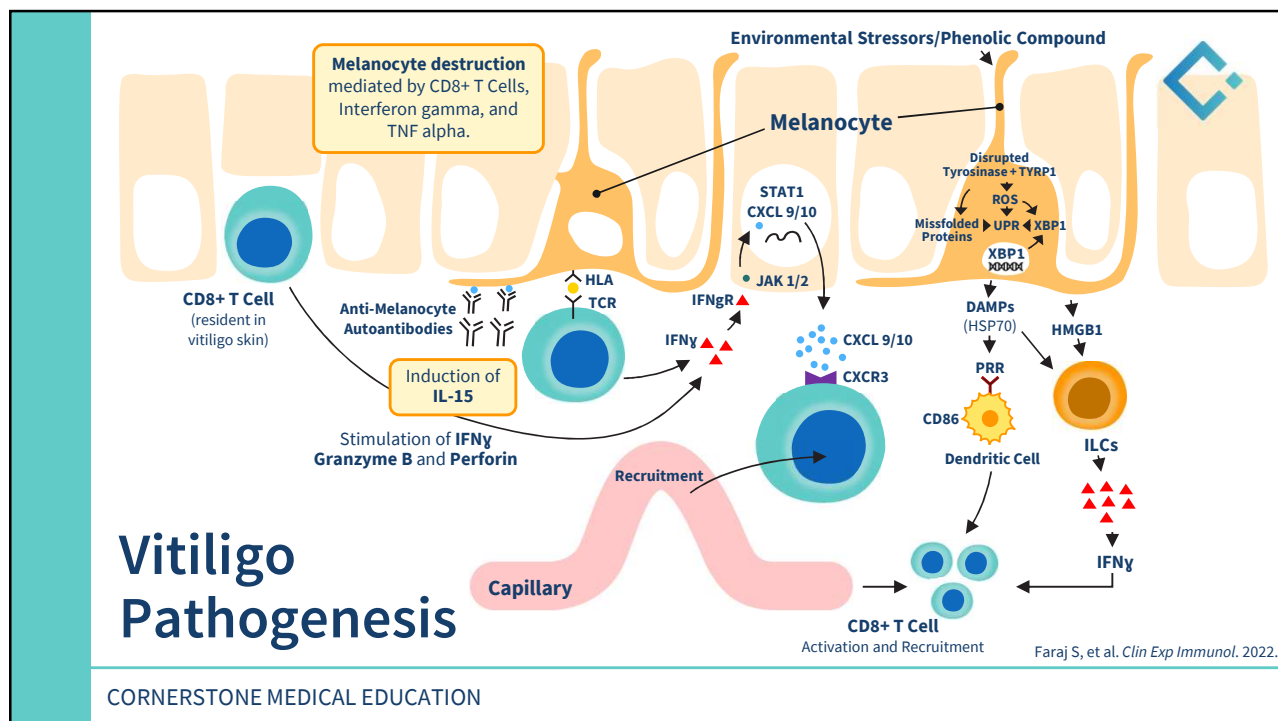
Bibeau K, et al. *JAMA Dermatol.* 2023.

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## State of the Science

Understanding Vitiligo Pathogenesis and Therapeutic Targets

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## Vitiligo Triggers

- **Genetic Propensity** → often family history of vitiligo (25-50% of patients; 6% will have affected sibling) or other autoimmune diseases
- **Psychological Stress**
- **Drugs**
  - Imiquimod, Interferons, Nivolumab, Pembrolizumab, Ipilimumab, and Adalimumab
  - Induction of melanoma-associated vitiligo with Nivo, Pembro and Ipi is actually a positive indicator of therapeutic response
- **Oxidative Stress**
  - Exposure to environmental toxins, chemical agents and UV radiation
  - Overproduction of reactive oxygen species
- **Viral Infections/Vaccinations**
  - Could trigger activation of autoreactive CD8+/CD4+ T and B cells that can trigger autoimmune disease
  - Could also just be dysregulation of the CD8+ T cells amidst the storm of viral illness
  - CMV, EBV, HIV, and COVID-19 have all been reported to trigger vitiligo

Buckhair A, et al. *JAAD Case Rep.* 2022; Schmidt A, et al. *JAAD Case Rep.* 2022.

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# Novel Approaches to Vitiligo Treatment

Moving Beyond Traditional Therapeutic Options

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## Treatment Goals

Halt Progression

Repigment Skin

Maintain  
Repigmentation

Make Your Patient  
Happy

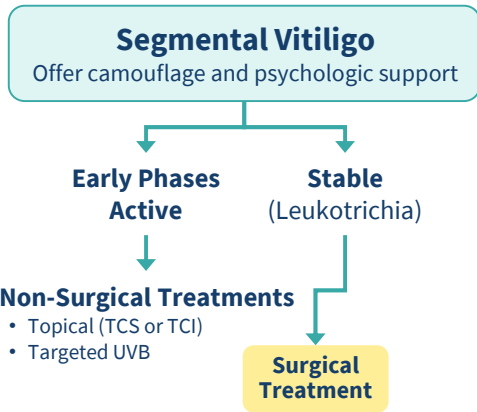
*“Clinicians should be aware that vitiligo is **not merely a cosmetic disease** and that there are **safe and effective treatments available** for vitiligo.”*

Rodrigues M, et al. *J Am Acad Dermatol*. 2017.

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# Treatment Algorithm for Vitiligo



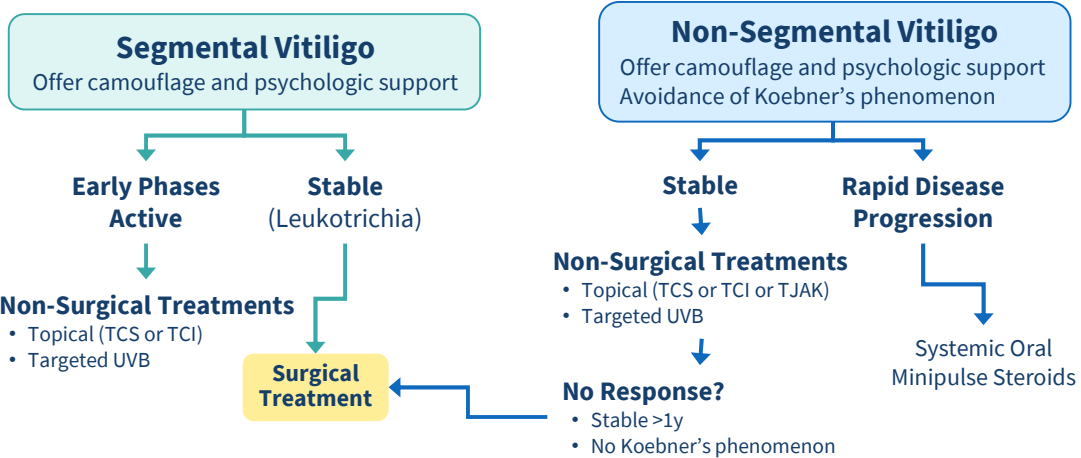
TCI, topical calcineurin inhibitor; TCS, topical corticosteroid; UVB, ultraviolet B

Bergqvist C, et al. *Dermatology*. 2020.

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# Treatment Algorithm for Vitiligo



TCI, topical calcineurin inhibitor; TCS, topical corticosteroid; UVB, ultraviolet B

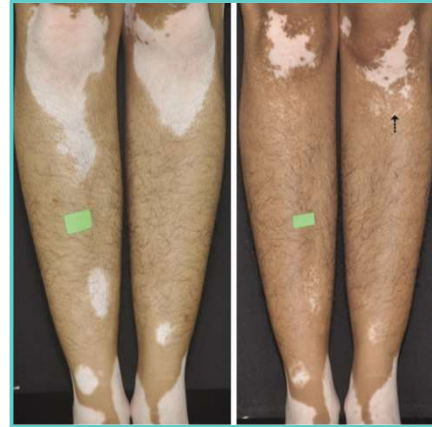
Bergqvist C, et al. *Dermatology*. 2020.

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## How Does Repigmentation Happen?

- Perifollicular- 55%
- Marginal- 5%
- Diffuse- 28%
- Combined
- Most Stable Repigmentation Pattern:
  - Marginal> Perifollicular> Combined> Diffuse
- Speed of Repigmentation:
  - Diffuse> Perifollicular



Parsad D, et al. *J Am Acad Dermatol.* 2004; Image from Narahari SR, Aggithaya MG. *Current Science.* 2016.

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## Prognostic Indicators

### Favorable Prognosis

- Younger patients
- Recent onset of disease
- Darker skin types
- Areas of involvement on face, neck, and trunk

### Poor Prognosis

- Mucosal involvement
- Family h/o vitiligo
- Koebnerization
- Distal extremity involvement

Delbaere L, et al. *Dermatological Reviews.* 2022; Zhang L, et al. *JAMA Dermatol.* 2020; Sosa JJ, et al. *J Am Acad Dermatol.* 2015.

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## Treatments

- Numerous treatment options exist but there is **no cure**
- **Early treatment is always more effective**

- Topical corticosteroids (TCS)
- Topical calcineurin inhibitors (TCI)
- Topical calcipotriene
- Topical JAK inhibitor
- Light therapy
- Pulsed dose oral corticosteroids
- Surgical modalities
- Depigmentation

**+ New Treatments on the Horizon**

Thawabteh AM, et al. *Molecules*. 2023; Diotallevi F, et al. *Int J Mol Sci*. 2023; Cunningham KN, et al. *Am J Clin Dermatol*. 2023.

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## TCS (Topical Corticosteroids)

- Commonly used **first line**
- Can halt progression and induce repigmentation
  - **Complete repigmentation rates as high as 49%**
- Patients need to be followed and monitored for signs of atrophy
- More effective in kids compared to adults
- Head and neck areas have best response
- Work better if **combined with light therapy**
  - **Enhances repigmentation rate threefold** when combined
- Most commonly used:
  - Clobetasol once daily for body
  - Fluticasone once daily for face and folds

Patra S, et al. *J Am Acad Dermatol*. 2021; Radakovic-Fijan S, et al. *J Am Acad Dermatol*. 2001; Thawabteh AM, et al. *Molecules*. 2023; Diotallevi F, et al. *Int J Mol Sci*. 2023; Cunningham KN, et al. *Am J Clin Dermatol*. 2023.

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## TCI (Topical Calcineurin Inhibitors)

- Tacrolimus (0.03, 0.1) and pimecrolimus
- Similar to slightly inferior results to topical steroids
- **Seemingly safer long term** than topical steroids
- Best results on head and neck
- **Mean repigmentation rates range from 26-73%**
- Works better when **combined with light**
  - Studies combining topical tacrolimus and excimer laser showed great efficacy

Lee JH, et al. *JAMA Dermatol.* 2019; Thawabteh AM, et al. *Molecules.* 2023; Diotallevi F, et al. *Int J Mol Sci.* 2023; Cunningham KN, et al. *Am J Clin Dermatol.* 2023; Bertolani M, et al. *Dermatol Reports.* 2021.

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## TCS vs TCI

- One study (randomized, double-blind, comparative trial) looked at clobetasol 0.05% cream once daily vs tacrolimus 0.1% ointment twice daily in kids with vitiligo
- Clobetasol- 49% repigmentation
- Tacrolimus- 41% repigmentation
- But the difference was **not** statistically significant

Lepe V, et al. *Arch Dermatol.* 2003.

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## Topical Calcipotriene

- **Inferior** to topical steroids and TCIs
- Can be used **adjunctively for steroid holidays**, etc.
- **No benefit** when combined with light therapy

*“When combined with topical corticosteroids, repigmentation rates increase, the delay in the onset of repigmentation shortens, and there is a greater stability of repigmentation compared with either as monotherapy.”*

Felsten K, et al. *J Am Acad Dermatol.* 2011.

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## Topical Ruxolitinib

- Approved for patients age 12 and up to treat nonsegmental vitiligo
  - **First and only FDA approved topical treatment for repigmentation**
- Applied twice daily to up to 10% BSA
- Binds to JAK1/2 and inhibits Interferon Gamma signaling which reduces the CD8+ T Cell destruction of melanocytes
- TRuE-V1 and TRuE-V2 (phase 3 studies) showed efficacy in producing repigmentation, especially on the face
- **50% of patients achieved F-VASI75** over a year; **30% F-VASI90**
- Very tolerable

FDA Prescribing Information.

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## Topical Ruxolitinib

- Note: <20% BSA for atopic dermatitis, <10% BSA for vitiligo
- **Black Box Warning:**
  - **Serious Infections:** Avoid use if active infection, including local infection
  - **Mortality:** Patients  $\geq 50$ y with  $\geq 1$  CV risk factor had higher rate of all-cause mortality vs TNFi
  - **Malignancy:** Lymphoma and other malignancies observed, with smokers at higher risk
  - **MACE:** Smokers at higher risk; D/C in patients with history of MI or stroke
  - **Thrombosis:** PE/DVT/arterial thrombosis
    - Patients  $\geq 50$ y with  $\geq 1$  CV risk factor had higher rate of thrombosis vs TNFi

FDA Prescribing Information.

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## TRuE-V1 and TRuE-V2 Trials (Topical Ruxolitinib Evaluation in Vitiligo Study 1 and 2)

- Two phase 3, double-blind, vehicle-controlled trials
  - North America and Europe
- Age  $\geq 12$ y with non-segmental vitiligo
  - Depigmentation <10% BSA
- 2:1 ratio
  - 1.5% ruxolitinib cream
  - Vehicle

Apply twice daily x 24 weeks

Option for all to apply ruxolitinib cream through week 52
- Primary Endpoint: F-VASI75 at week 24
  - F-VASI: range 0 to 3, with higher scores indicating a greater area of facial depigmentation

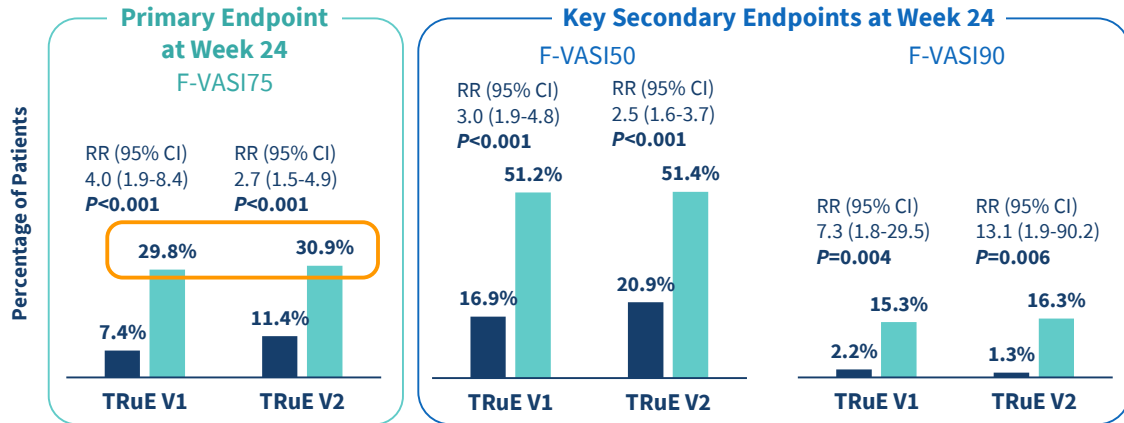
Rosmarin D, et al. *N Engl J Med*. 2022.

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# TRuE-V1 and TRuE-V2 Trials (Topical Ruxolitinib Evaluation in Vitiligo Study 1 and 2)



■ Vehicle ■ Ruxolitinib 1.5%



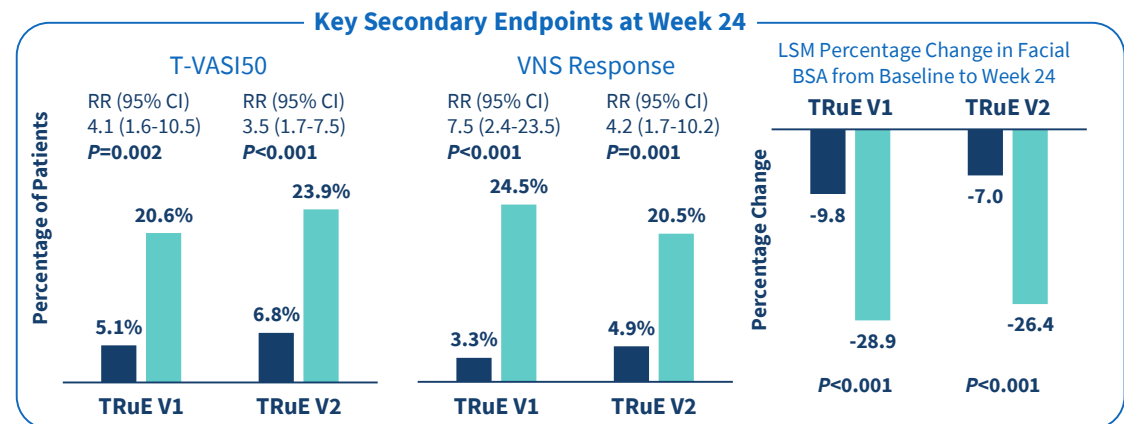
Rosmarin D, et al. *N Engl J Med.* 2022.

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■ Vehicle ■ Ruxolitinib 1.5%



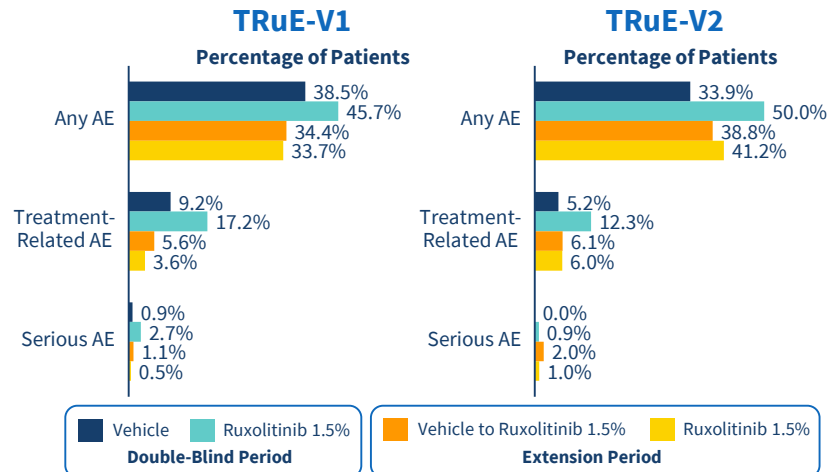
Rosmarin D, et al. *N Engl J Med.* 2022.

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## TRuE-V1 and TRuE-V2 Trials (Topical Ruxolitinib Evaluation in Vitiligo Study 1 and 2)



- Ruxolitinib was well-tolerated
- Most common adverse events (AEs) over 52 weeks:
  - Application-site acne (6.3% and 6.6% in V1 and V2, respectively)
  - Nasopharyngitis (5.4% and 6.1%)
  - Application-site pruritus (5.4% and 5.3%)



Rosmarin D, et al. *N Engl J Med*. 2022.

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## On the Horizon: Tapinarof




- Tapinarof is an aryl hydrocarbon receptor agonist
- MOA capable of suppressing immune response and inhibiting oxidative stress → seems like a good candidate to treat vitiligo
- Capable of inducing remission in psoriasis by reducing formation of memory T cells, it could possibly induce long lasting remission of vitiligo too
- Case reports of its benefit have been in the literature

Liu L, et al. *J Am Acad Dermatol Case Reports*. 2023.

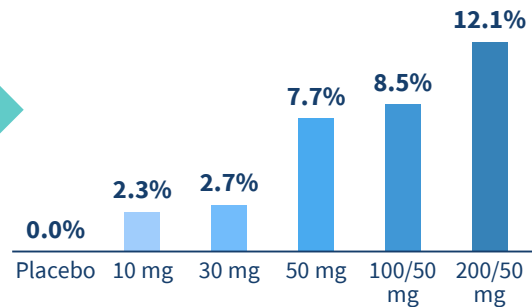
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## On the Horizon: Oral JAK Inhibitors



- Case reports have been published showing benefit with oral tofacitinib and oral ruxolitinib
- Phase 2 b study of **oral ritlecitinib** 
- Other oral JAK Inhibitors are in the process of being evaluated to treat vitiligo

Percentage of Patients Achieving F-VASI75 by Week 24, by Placebo or Dose of Oral Ritlecitinib Administered



Ezzedine K, et al. *J Am Acad Dermatol.* 2023.

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## Light Therapy



- Narrowband UVB (311 nm) > PUVA and broad band UVB
  - **PUVA really increases risk of NMSC and melanoma (as high as fivefold increase in melanoma)**
- Probably works by immunosuppressive and melanocyte stimulatory effects
- Narrowband UVB also induces tyrosinase (an enzyme essential for production of melanin)
- A good fit for extensive disease and rapidly spreading disease
- Can be difficult logistically (2-3 times/wk, often in office setting)
- **If it hasn't worked within 6 months, it won't work**

Mohammad T, et al. *J Am Acad Dermatol.* 2017; Garza-Mayers AC, et al. *J Am Acad Dermatol.* 2023.

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# Narrowband UVB Therapy for Vitiligo



4 Months

6 Months

14 Months



[https://www.umassmed.edu/globalassets/vitiligo/compare/before\\_10.jpg](https://www.umassmed.edu/globalassets/vitiligo/compare/before_10.jpg)

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# Light Therapy: Excimer Laser



- Xenon Chloride Monochromatic Laser that emits at 308 nm
- More focused on the spots
- Doesn't create increased tanning on the normal skin
- Works better in combination with topicals (steroids or TCIs)
- Can be particularly nice for segmental vitiligo (best when done early in the course)



<https://images.squarespace-cdn.com/content/v1/5ac6c106a2772c5ffa1b584c/1591120459687-6M13FM196UJYGSQ56E/excimer-before-after.jpg>

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## Heliocare (Polypodium Leucotomos)

- OTC supplement
- Derived from a fern leaf extract from south/central America
- 1 pill PO daily in the morning before sun exposure
- Used to protect the skin from the sun but also, interestingly, makes light therapy work better
  - Fewer treatments required, repigmentation occurs faster

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## Oral Pulsed Dosed Steroids

- Most effective at stopping rapidly spreading vitiligo
  - **Can halt disease progression in 88-92% of patients with active disease**
- Dexamethasone 4 mg or Betamethasone 5 mg 2 consecutive days a week x 12-24 weeks
- **Stops progression in about 90% of patients**
- *Does not tend to provide benefit in repigmentation*
- Well tolerated, no evidence of suppression of endogenous cortisol production
- Tends to work well with light therapy

Patra S, et al. *J Am Acad Dermatol*. 2021.

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## Surgical Modalities

- Avoid in patients with features of the Koebner phenomenon
- **Patients must have STABLE, NON-RESPONSIVE vitiligo**
  - Stable for **at least 12 months**
- Face and neck lesions do the best
- Sometimes people will treat after the surgery with light therapy and/or tacrolimus 0.1% ointment to potentially improve benefit

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## Surgical Modalities

- **Suction Blister Grafting**
  - Flexor arm is great source site
  - Induce a blister with pencil eraser and then unroof the blister and transplant to the affected areas (which you also suction blister to prepare it for adherence and uptake)
  - Tang et al has a great article on how it's done
- **Punch Grafting**
  - Multiple teeny PGs are harvested and placed on the affected site
  - Boersma et al has great article on how it's done
- **Split-Thickness Skin Graft**
  - Can cover larger areas
  - Requires anesthesia (requires a dermatome to harvest tissue)

Kim J, et al. *J Am Acad Dermatol*. 2023.

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## Maintenance of Repigmentation

- After repigmentation, there is a 30-40% chance of recurrence
- Using topical tacrolimus 0.1% can reduce that chance to around 5-10%
  - Apply bid 2 days a week

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## Depigmentation

- Patients with recalcitrant and widespread vitiligo might choose this option
- Monobenzylether of hydroquinone (MBEH) 20%- FDA approved for depigmentation
- Applied twice daily x 4-12 months
- Strict sun avoidance
- Permanent

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# Practical Considerations for Managing Vitiligo

Combining the Latest Data and Shared Decision-Making Strategies to Determine Treatment

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## Case Discussion

- 13 year old female presents for evaluation of some “light skin spots”
- They started to appear about a year ago, and was told it was "fungus"
- Upon exam, you see depigmented macules and patches that accentuate with wood's lamp on her face, neck, back, arms, and legs
- You also notice that there is “confetti-like” depigmentation on her knees and forearms
- What diagnosis and treatment options should we discuss with the patient and her family?



[www.dreamstime.com/portrait-beautiful-woman-vitiligo-profile-portrait-beautiful-woman-vitiligo-isolated-white-background-image110996204](http://www.dreamstime.com/portrait-beautiful-woman-vitiligo-profile-portrait-beautiful-woman-vitiligo-isolated-white-background-image110996204)



## Case Discussion

- 6 year old boy presents with a 6 month history of depigmented macules and patches on his face
- Upon exam, the depigmentation is limited to one segment on the left side of his face
- What should we tell this patient and his family about this type of vitiligo?
- What treatment options could we consider?



## Case Discussion

- 22 year old female presents with a several year history of vitiligo
- In the past, she has tried topical steroids and a topical calcineurin inhibitor with minimal success
- She saw a commercial for a new topical cream for vitiligo and she wants to try it
- What should we tell her about topical ruxolitinib?



Vitiligo is a photograph by Peakstock/Science Photo Library which was uploaded on March 20, 2024.

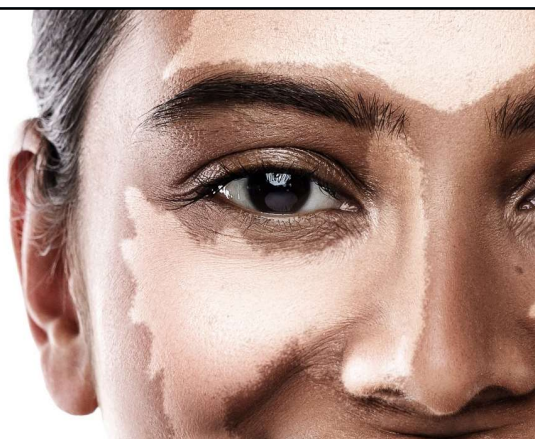


## Summary

- Vitiligo is thought to affect more than 2 million Americans
- Vitiligo affects all skin tones and ethnicities
- Can be associated with other autoimmune conditions:
  - Thyroid disease, Psoriasis, RA, IBD
- Treatment has historically been difficult
- First/only FDA approved treatment = Ruxolitinib Cream 1.5%
- More potential treatment options on the horizon

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# Navigating Novel Terrain in Vitiligo Management:



## A Practical, Patient-Centric Review



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