ALOPECIA AREATA RESEARCH SUMMIT
Forging the Future

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HF IP collapse, AA most likely does not represents a single disease entity. Rather, AA is best understood as a stereotypic response pattern that every healthy anagen HF will show, independent of genetic predisposition and the establishment of true anti-HF autoimmunity, if and when the pathobiology triad of 1) IP collapse, 2) premature catagen induction and 3) HF dystrophy coincide.

Thus, we must distinguish between purely symptomatic AA treatment that target(s) one, two, or all three members of this triad, and therapeutic strategies that tackle the pathways leading up to it. To be maximally effective, future AA therapy needs be personalized - e.g., tailored to whether or not the AA response pattern in a given AA patient is likely to represent an antigen-specific autoimmune pathology, and/or whether complicating factors (e.g., atopy, stress-induced neurogenic skin inflammation, HF dysbiosis) are present. Also, causal AA therapy, which may become achievable one day by eliminating autoreactive CD8+ T cells or by tolerizing against as yet unknown HF-associated autoantigens, may neither be necessary nor attainable in all patients that show the AA response pattern.

**Pre-Clinical Research in Vivo: Pros and Cons of the C3H/HeJ versus the Humanized Mouse Model**

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Currently, one can choose mainly between two models: inbred C3H/HeJ mice that develop an AA-like hair phenotype spontaneously upon aging or after experimental induction whereby alopecia areata (AA) is one of the most prevalent in humans; and healthy human scalp skin xenotransplanted onto SCID mice in which a phenocopy of human AA is induced by intradermal injection of IL-2-stimulated PBMCs enriched for NKG2D+ cells. The C3H/HeJ model has long dominated basic AA in vivo research, produced many novel results with important implications for human AA by accessing the powerful tools of mouse genetics, and also provided insight into the role that could be played by psycho-emotional stressors in AA pathogenesis, confirming a crucial role of IFN-γ. However, the histological feature is not typical of human AA and cannot serve as a valid model for evaluating therapeutic effects of selected immunoinhibitory agents of interest in AA, such as Kv1.3 blocker. The humanized AA model can easily be applied for testing new candidate therapeutic agents for human AA. However, many biopsies from each human volunteer are required and this involves a complicated model. The C3H/HeJ mouse model was used to identify key immune cell and molecular principles in murine AA and proof-of-principle that Janus kinase (JAK) inhibitors are suitable agents for AA management in vivo, since both IFN-γ and IL-15 signal via the JAK pathway. Instead, the humanized mouse model of AA has been used to demonstrate the previously hypothesized key role of CD8+ T cells and NKG2D+ cells in AA pathogenesis, to

**SETTING THE STAGE**

**Current Treatment of Alopecia Areata**

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BACKGROUND: Patients and families who experience alopecia areata (AA) are eager for more information about this disease, its treatment, psychosocial related issues, and whether AA is inherited. Treatment of a patient with AA needs to take into consideration the patient’s and if a child, the parents’ goals and expectations. During the course of history taking, ascertaining what bothers the patient most is very important. For example, some patients may want to focus primarily on their scalp hair loss; others just on their eyebrow or eyelash loss. Male patients may want to focus on their beard AA. Those with active hair shedding may be treated differently than those with long standing extensive AA.

PURPOSE: To illustrate four clinic scenarios and the art of treating patients with AA in the absence of an approved treatment by the Federal Drug Administration. Representative cases will include pediatric and adult AA patients with active or long standing extensive stable disease.

RESULTS: Choosing a treatment for AA in children and adults should take into consideration several factors including not only the location of the hair loss but also the age of the patient, disease extent and activity, presence of other medical conditions and if available, the results of a biopsy which may include information about the hair cycle and the location and degree of inflammation present.

CONCLUSIONS: A number of treatments can induce hair growth in AA but few have been tested in randomized controlled trials and there are few published data on long-term outcomes; most focus on hair regrowth. Patients and families have heard the “buzz” about potential new treatments for AA and the current treatment of AA should include a conversation about ongoing and future clinical research opportunities as well as off label use of oral or topical Janus kinase (JAK) inhibitors.

**Alopecia Areata: Autoimmune Disease or Hair Follicle Response Pattern to Immunological Damage?**

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Collapse of the immune privilege (IP) of the anagen hair bulb is a necessary key element of AA pathogenesis without which AA does not develop and whose restoration is a prerequisite for hair re-growth. Thus, hair bulb IP restoration lies at the heart of successful AA therapy, while IP protection of neighboring hair follicles (HFs) represents the most effective strategy to prevent AA progression. Yet, how to achieve this most efficiently and predictably as well as the direct impact of both classical and novel AA therapeutics (incl. JAK inhibitors) on HF IP remain insufficiently examined.

Here, the essentials of hair bulb IP are briefly reviewed, and it is argued that, given the very distinct pathways that can induce
Alopecia areata (AA) often presents in childhood and is associated with a negative impact on health-related quality of life for both patients and their caregivers. Janus kinase (JAK) inhibitors have recently emerged as a pathogenesis-based therapy for AA. While the majority of data regarding their use in AA has involved adult patients, there have been several case reports and series of children treated with both topical and systemic JAK inhibitors. Three articles including 18 patients ages 4-17 have reported the use of topical tofacitinib and ruxolitinib in 1-2% concentrations, with partial response in 13 patients. Use of oral tofacitinib has been reported in 25 patients ages 4-17, with 18 patients achieving at least 50% improvement in SALT score, 12 of whom achieved near complete regrowth. Multiple ongoing clinical trials evaluating JAK inhibitors for AA are now enrolling patients ages 12-17. While more data will be important to further explore the safety and efficacy of JAK inhibitors in the pediatric age group, their use may be considered for children with AA who are experiencing significant psychosocial impairment.

Response to Tofacitinib Therapy of Eyebrows and Eyelashes in Alopecia Areata
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Alopecia areata (AA) can affect any hair-bearing site. There is involvement of the eyebrows and/or eyelashes in 76% of patients with AA. While Janus kinase (JAK) inhibitors have emerged as targeted treatment of AA, studies have focused on scalp hair growth. In this study, we evaluated the response of eyebrows and eyelashes in patients with AA treated with the JAK inhibitor, tofacitinib. Records of all patients treated with tofacitinib and evaluated by BAK between January 2014 and April 2018 were identified. Inclusion criteria for this study are: diagnosis of AA with scalp involvement in addition to eyebrows or eyelashes involvement, and ≥6 months of tofacitinib therapy. Treatment responses were documented (absent, partial, or complete).

Of 98 patients with total scalp hair loss, 86 had involvement of both eyebrows and eyelashes. Complete growth of all sites was achieved in 16% (19/119) of patients, and complete growth of eyebrows and eyelashes and partial growth of scalp hair in 16% (19/119) of patients. Complete growth of eyebrows was achieved in 34% (41/119) of patients. Complete growth of eyelashes was achieved in 39% (46/119) of patients.

The clinical course of severe AA is unpredictable and there is little data to guide expectations of disease course, with or without treatment. The results of this study of tofacitinib treatment of AA show that:

- Severe scalp hair loss often predicts eyebrows and/or eyelashes involvement.
- When there is more than one hair-bearing site involved, all of the hair-bearing sites do not necessarily respond similarly to treatment, i.e. scalp hair may grow without growth of eyebrows and/or eyelashes and vice versa.
- Although growth of scalp hair is uncommon in alopecia totalis/aloepecia universalis of >10 years duration, eyebrows and eyelashes in these patients may respond (completely) to treatment.

Our results not only highlight differences in hair follicle biology across different hair-bearing sites but also should help to both guide discussions with patients and manage expectations of therapy with oral JAK inhibitors.

Long-Term Treatment for Severe Alopecia Areata with Oral Tofacitinib Citrate
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A retrospective cohort of twenty patients treated with tofacitinib was reviewed. Seventy percent of patients had a diagnosis of alopecia universalis and 20% had alopecia totalis with the mean baseline SALT score of 88 percent. The average length of current episode of alopecia was 2.4 years (range 1 to 7 years).

Twelve of our 20 patients (60%) received tofacitinib for at least 12 months. Patients were treated for an average of 13 months (range 0.5 months to 28 months). Tofacitinib holding doses ranged from 10 mg to 25 mg, with the majority of patients taking 20 mg in split daily doses.

The average time to regrowth was 3.85 months with 70% of patients showing regrowth after 3 months. At 12 months, 94% of patients showed regrowth. SALT scores decreased over time and scores at 3, 9 and 12 months were significantly lower than baseline. In addition, the mean score at 12 months was lower than 6 months (p=0.015). Regrowth ranged widely, from 1 to 100% with a mean percent regrowth of 42.6% and a median of 55%. Eleven patients (55%) achieved an improvement of SALT score greater than 50 percent. Twenty-five percent of patients achieved full regrowth, or 90% or greater improvement in SALT score, during the period of time reviewed. Among those patients who took tofacitinib for longer than 12 months, 91.7%
had regrowth at the end of the study period. Three patients were non-responders with 5% or less change in SALT score.

Seven patients (35%) developed lab abnormalities. Four patients (20%) experienced a dose-dependent elevation of lipids, which resolved with decrease in dose or continued treatment, though one patient was placed on a statin by her primary care provider. There were six clinical adverse events (e.g. chest palpitations, herpes zoster, upper respiratory infection).

In summary, in our experience, tofacitinib appears to be a viable long-term treatment option for patients with severe alopecia areata with variable efficacy. Larger clinical trials and continued research are needed to elucidate the reason behind such variation in regrowth. Nevertheless, JAK-inhibition may be an invaluable tool in the treatment of alopecia areata.

**Platelet-Rich Plasma in the Treatment of Alopecia Areata**

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Platelet-rich plasma (PRP) is an autologous preparation of plasma with concentrated platelets containing various growth factors (GFs) and cytokines that enhance the body’s inherent capacity to repair and regenerate.

**METHODS:** A broad literature search was performed using PubMed and Google Scholar to compile published articles on PRP and alopecia areata

**RESULTS:** Up to now, five studies and a few case reports have been published, including a randomized double-blind study comparing PRP with placebo and intralesional steroids. The results of this study revealed that intralesional TAC and PRP resulted in significant hair regrowth in AA lesions compared to placebo. Another randomized controlled study comparing PRP versus 5% topical minoxidil and panthenol showed that PPR was effective in patchy alopecia areata but significantly less useful in alopecia totalis or universalis.

**CONCLUSIONS:** There is initial supporting evidence that PRP can be utilized for the treatment of alopecia areata. Further large-scale studies are needed to evaluate the efficacy of PRP procedure as monotherapy or in association with other therapeutic modalities for AA. Although PRP is relatively safe and potentially effective, we have no standardized protocols or recommendations for number of PRP sessions required to treat and maintain hair regrowth.

**Feature Characterization of Scarring and Non-Scarring Types of Alopecia by Multiphoton Microscopy**

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In vivo imaging studies using devices like the confocal microscopy (CM) and ultrasound (US) are becoming increasingly common among physicians because of their noninvasive nature and minimal risks. Our study explores the utility of multiphoton microscopy (MPM), which has greater resolution than both CM and US, as an adjunct to histological studies and a diagnostic tool for alopecia areata (AA). AA is a nonscarring type of hair loss that commonly presents as well-circumscribed patches on the scalp. This autoimmune disease causes a lymphocytic infiltration of the follicular bulb, predominantly catagen or telogen hairs, fibrous tracts, and intact sebaceous glands seen on histology. With the MPM, cellular details of the epidermal portion of the follicular unit can be visualized using autofluorophores and infrared wavelengths of light. Using MPM, differentiation of follicular structures can be visualized in real time without using any stains or contrast material. MPM also allows the clinician to examine multiple sites during the same imaging sessions without having to perform any incisions. The most impactful improvement of using MPM is that the same area can be followed through time to track disease progression, which is not possible with biopsy techniques. Many hallmark features of AA can be confirmed using MPM like exclamation point and vellus hairs. This pilot study using MPM to study AA bridges laser-based technological advances with modern clinical practice. In our results, histological features of AA were found on MPM images. MPM was able to visualize disease-related changes of the hair follicle.

**Cytokine Targeted Treatments for Alopecia Areata**

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Alopecia areata (AA) is a common, T-cell mediated, hair-centered skin disease that lacks efficacious, long-term therapies for extensive disease. Although, the Th1 pathway was suggested as pivotal in the disease, recent studies suggest that other axes and particularly Th2, and IL-23 might contribute to AA pathogenesis.

AA was shown to share some phenotypic similarities with atopic dermatitis (AD), a highly prevalent inflammatory skin disease. In line with clinical associations between the conditions, personal or familial history of atopy, and AD in particular, is the highest risk factor of AA development, and AA patients with concomitant AD have a higher risk for severe AA.

The therapeutic revolution for AA is beginning, with multiple possible therapeutic targets being explored, both broad and specific. These include small molecules with more broad cellular effects (JAK inhibitors), and specific IL-23, and Th2 (IL-4R) antagonists that are currently tested in clinical trials. Despite their reported efficacy, JAK inhibitors are relatively broad-targeting and cannot elucidate the pathogenic axes involved in AA. Similar to psoriasis and AD, targeting specific immune pathways will help elucidate primary disease pathogenesis for AA. Such approach will eventually help the therapeutic development in AA. We are now beginning a new treatment paradigm for AA, with introduction of possibly safer, and/or more efficacious drugs, in contrast to the limited treatment options that have been previously available. Ongoing and future clinical trials utilizing narrow- targeted therapeutics

3| PRE-READING BOOK
Adult tissue stem cells have the ability to self-renew long term and differentiate into one or more tissues. Many stem cells are used sparingly to replenish cells during normal homeostasis. However, even stem cells like the hair follicle that are quiescent must be able to respond quickly to injury in order to fuel rapid tissue regeneration. How stem cells balance self-renewal and differentiation is of fundamental importance to our understanding of normal tissue maintenance and wound repair. The regulatory circuitry governing this normal balancing act is must be intricately regulated in normal homeostasis, and then transiently altered to cope with injury responses. Increasing evidence suggests that the mechanism goes awry in inflammation and becomes hijacked in cancers.

Skin epithelium is an excellent model system to understand how stem cells remain quiescent during times of minimal wear and tear, how these cells become mobilized during the cyclical bouts of hair growth and wound-repair, and how the normal process of stem cell activation goes awry in inflammatory disorders such as Alopecia Areata. We’ve identified and characterized at a molecular level the skin’s stem cells and shown that they reside in distinct niches that impart to the stem cells their behavior both in task and in the molecular properties they display. We use high throughput genetic and genomic approaches to dissect at a molecular level how stem cell interactions with their niches differ in homeostasis, wound repair and inflammation. Our recent studies reveal that skin stem cells retain memories of their encounters with inflammatory cells, adding new insights into why the skin epithelium almost invariably responds more rapidly to secondary and tertiary inflammatory encounters than to the initial exposure. Our global objective is to dig into the underlying mechanisms involved and to apply our knowledge of stem cell memory to unfold new avenues for therapeutics.

**Coping with Stress: Stem Cells in Injury and Inflammation**

**E Fuchs | Howard Hughes Medical Institute, The Rockefeller University, New York, NY, USA**

Eyebrows Are Important in the Treatment of Alopecia Areata

**LY Liu1, BA King1, JM Ko2 | Yale School of Medicine, New Haven, CT, USA; Stanford University School of Medicine, Stanford, CA, USA**

**BACKGROUND:** Alopecia areata (AA) affects not only scalp hair but also other sites of body hair, including eyebrows.

**OBJECTIVE:** To investigate the importance of eyebrows in the treatment goals of AA patients.

**METHODS:** Through an online questionnaire, subjects were asked to assess satisfaction with the visually depicted level of response to treatment, using edited photos depicting a range of eyebrows and scalp hair growth.

**RESULTS:** The questionnaire was completed by 1741 adults. Absent or partial growth of eyebrows and scalp elicited ≤25% satisfaction. Images depicting either complete eyebrows or complete scalp hair achieved satisfaction in >50% of participants. More participants were satisfied with complete eyebrows and no scalp hair (69%) than complete eyebrows and partial scalp hair (51%). Female participants expressed significantly lower satisfaction than male participants when shown images with no scalp hair (p<0.001 each), regardless of level of eyebrows growth.
LIMITATIONS: Limitations include the online nature of the survey, lack of control group, and self-reported severity of AA in participants.

CONCLUSION: These results suggest that eyebrows may be just as or even more important than scalp hair. Future clinical studies should consider eyebrows growth as an outcome measure on par with scalp hair growth.

International Dermatology Outcomes Measures (IDEOM): Don’t Get Mad, Get Data
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IDEOM is a 501c3 non-profit organization whose mission is to establish patient-centered measurements to enhance research and treatment for those with dermatologic disease. Perspectives of patients, health economists, payers, physicians and regulatory agencies have been included from the onset. IDEOM’s goal is to establish validated standardized outcome measures that satisfy the needs of all stakeholders and can be applied to clinical research and clinical practice.

In this talk we will present the core domains for psoriasis and hidradenitis that have been published as a result of IDEOM’s research. We will also present the work to date on the development of global health care provider- and patient-reported outcome measures for clinical practice across multiple dermatologic disorders. This work is the result of an IDEOM-initiated, ongoing collaboration with the American Academy of Dermatology and patients.

SCIENTIFIC POSTERS

01 | Monitoring Response to Platelet Rich Plasma in AA Patients with Optical Coherence Tomography: A Case Series
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Alopecia areata afflicts people of all subtypes, is often difficult to treat, and is frequently disruptive to the psychological wellbeing of patients. Platelet rich plasma is a treatment option based on regenerative medicine principles of providing concentrated growth factors at sites of inflammation or degeneration. Platelet rich plasma is thought to benefit patients with alopecia areata by initiating proliferation of dermal papilla cells and imparting anti-inflammatory effects in active scalp locations. Optical coherence tomography is a non-invasive imaging modality with potential for providing quantitative endpoints in monitoring alopecia. This case series aims to share informative experiences with non-conventional treatments of alopecia areata with the aid of non-invasive optical imaging.

Three patients with alopecia areata, two with patchy and one with total scalp hair loss were treated with platelet rich plasma three times at six-week intervals. Patients had baseline and 3-month follow up imaging, analysis of which showed varying results. Both patients with patchy hair loss experienced improvement in inflammation and hair growth over the course of three months. Improvement ranged from 1-27 new hairs, or 12%-44%, depending on scalp location assessed. One of these patients also treated her scalp with daily application of ice and demonstrated the most significant regrowth. Alternatively, the patient with alopecia universalis did not experience any change in follicular activity throughout treatment.

This case series exemplifies the potential of platelet rich plasma in inflammatory regulation as well as hair regrowth. These cases elucidate the possibility of disease duration effecting treatment response as the patient with the most active lesions exhibited the best response. Additionally, this case series adds to the growing body of knowledge surrounding the possible value of cooling measures as part of routine treatment of alopecia, such as liquid nitrogen. Documenting additional cases of alopecia areata response to non-conventional treatments may allow further deliberation and prioritizing of treatment guidelines.

02 | Prevalence of Infectious Disease History in Patients with Alopecia Areata
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Alopecia areata (AA) is an autoimmune condition that causes patchy or diffuse non-scarring hair loss. The cause of AA is not well understood although studies reveal an autoimmune process to be likely. Environmental triggers such as infection have been hypothesized to play a role in the onset of this condition in predisposed individuals. This data analysis seeks to highlight potential areas for further research in understanding a potential environmental trigger for AA.

We reviewed hair loss clinic intake forms of 75 patients with AA and compared these to 75 age and sex matched controls with other forms of nonscarring alopecia (i.e. androgenic alopecia “AGA”, telogen effluvium “TE”, and female pattern hair loss “FPHL”). Patients confirmed or denied personal history of the following infections on the intake forms: Epstein Barr Virus (EBV), Hepatitis C, human immunodeficiency virus (HIV), cytomegalovirus, syphilis or other sexually transmitted disease, fungal infection of skin or hair, or bacterial infection of the blood.

The average age of patients with AA was 40 years old and 73.3% of patients were female. The average age of patients with AGA was 40 years old and 70.8% of patients were female.

Notably, 10.7% of AA patients reported a history of exposure to fungal infections of the skin or hair versus 1.33% in AGA/TE/FPHL controls (p=0.0166).

There was no other significant difference between groups. 13.3% of patients with AA reported a history of EBV compared to 8.0% in controls. 2.7% of AA patients reported a history of syphilis or other STDs compared to 4.0% of controls. Exposure to bacterial infections of the blood was equal in both groups at 2.7%.
These findings suggest that exposure to a fungal infection of the skin may be more likely in patients with alopecia areata. Larger studies are needed to confirm this possible association and to determine if immune processes involved in fungal infections may be involved in alopecia areata pathogenesis.

03 | Quality of Life Predictors Among Individuals Living with Alopecia Areata

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Many individuals living with alopecia areata (AA) experience decreased psychosocial functioning and quality of life, secondary to the onset of their hair loss. This issue is often exacerbated by the unpredictable and inconsistent nature of this condition. First line treatments for AA typically focus on hair regrowth; however, efficacy rates are low, and in many cases, gains made during treatment are lost upon conclusion of treatment. As such, many individuals continue to experience a detrimental impact to their psyche as a consequence of this frustrating health condition.

In the current study, the researchers sought to explore the psychological impact of AA with a focus on factors influencing the relationship between the condition and quality of life. The intention of this research was to identify strategies for assisting individuals with living a high quality of life, despite the presence of AA-related symptoms. A primary focus was given to Seligman’s five pillars of well-being, otherwise known as PERMA (i.e., positive emotion, engagement, relationships, meaning, and accomplishment), specifically, the relationship between an individual’s experience of PERMA and their overall quality of life. A secondary focus was on various styles of coping and their correlation with individual experiences of quality of life.

Preliminary results highlight that factors described by the PERMA framework account for a statistically significant amount of the variance in (a) one’s subjective experience of AA, and (2) the degree to which AA impacts an individual’s relationships. Furthermore, significant correlations between adaptive coping strategies and quality of life were identified. These results hold promise for improving the quality of life of this vulnerable population, as both the PERMA framework and the various coping styles evaluated represent modifiable factors that can be targeted by individuals and health practitioners. In turn, these findings hold promise for increasing the likelihood that people living with this condition will experience a satisfactory quality of life, regardless of the ongoing presence and severity of one’s symptoms.

04 | The Prevalence of Allergies in Patients with AA

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Alopecia areata is an autoimmune disease that results in nonscarring patchy or diffuse hair loss. Studies suggest increased rates of allergic diseases, such as asthma and atopic dermatitis, in patients with alopecia areata. The aim of this study was to determine the prevalence of allergies, including but not limited to environmental, food, and medication allergies, in patients with alopecia areata compared to age-and sex-matched controls with other forms of nonscarring alopecia, such as androgenetic alopecia, female pattern hair loss, and telogen effluvium.

A retrospective chart review of 124 patients was performed, including 62 patients with alopecia areata and 62 age-and sex-matched controls. The average age of patients was 38 years old and approximately 70% of patients in each group were female. Patients with alopecia areata and other forms of nonscarring alopecia were noted to have similar rates of allergies, with 53.2% of patients having at least one known allergy documented in their chart. Of those with allergies, the average number of allergies in both groups was 2.4 per person. Rates of documented drug allergies were also similar between alopecia areata patients and controls at 57.6% and 60.6%, respectively. Alopecia areata patients had higher rates of food allergies compared to controls (12.1% versus 6.1%) as well as environmental allergies (15.2% versus 3%).

The findings of this study support the previously reported association between an atopic diathesis and alopecia areata. Specifically, this study suggests that patients with alopecia areata may be more likely to have a history of environmental and food allergies when compared to controls, but not drug allergies. Limitations of this study include its retrospective nature and small sample size.

05 | Microneedling for the Treatment of Recalcitrant Alopecia Areata: A Systematic Review

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BACKGROUND: Microneedling represents a minimally invasive and low cost treatment for several dermatologic conditions including atrophic and hypertrophic scars, pigmentary disorders, actinic keratosis, and androgenetic alopecia. Utilizing a dualistic mechanism of action by (1) facilitating transdermal drug delivery and (2) inducing innate wound healing pathways with activation of platelet-derived growth factor, vascular endothelial growth factors, TGF-alpha, TFG-beta, and Wnt3a/Wnt3b, this technique may also serve as an efficacious treatment for alopecia areata (AA).

OBJECTIVE: To assess the efficacy and safety of microneedling in patients with AA.

METHODS: The PubMed®, Discovery of Medicine®, and Embase® databases were reviewed in September 2018 using keywords: alopecia areata, microneedling, and microwounding. Primary clinical studies detailing use of microneedling in patients with AA were included in the analysis.
RESULTS: The studies meeting inclusion criteria consisted of 6 case series with a total of 42 patients. All patients had failed previous treatment but displayed various AA subtypes including patchy (50%), totalis (24%), ophiasis (12%), universalis (7%), unspecified (5%), and diffuse (2%). Several microneedling devices were used including a standard dermaroller or scalp roller, electronic microneedling device, and three-microneedling device. A minority of studies (33%) described the microneedling technique in the methods sections, detailing its use in horizontal, vertical, and diagonal directions until petechiae or pinpoint bleeding developed. No study investigated microneedling use alone but rather reported 3-12 sessions of microneedling with topical triamcinolone acetonide (TAC: 0.1-2ml of 5-10mg/ml); compounded topical solution of 1 ml of TAC 10mg/ml, 0.5ml minoxidil 2-5%, and variety of multivitamins and minerals; or 5-aminolevulinate acid (MAL) cream with red light photodynamic therapy. Self-controls were provided in 33% of included studies, using microneedling on one-half of the scalp. When used in combination with TAC, microneedling was associated with “significant” or “excellent” improvements in hair regrowth in 5 out of 5 (100%) relevant studies. Mild pain and erythema were the only adverse events reported.

CONCLUSION: Microneedling is a safe and potentially efficacious intervention when used in combination with topical TAC for recalcitrant AA. Future randomized control trials are necessary to establish standardized techniques of microneedling and objective measures of hair regrowth with SALT scores.

06 | A Phase 2a Randomized, Placebo-Controlled Study to Evaluate Efficacy and Safety of Janus Kinase Inhibitors PF-06651600 and PF-06700841 in AA: 24-Week Results
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The study objective was to evaluate efficacy, safety, and tolerability of PF-06651600, a JAK3 inhibitor, and PF-06700841, a TYK2/JAK1 inhibitor, in patients with moderate-severe alopecia areata (AA). In this ongoing phase 2a, randomized, double-blind, multicenter study (NCT02974868), patients 18-75 years-old with chronic (≥6 months) moderate-severe (≥50% of their scalp) AA were randomized 1:1:1 to: PF-06651600 (200 mg once daily [QD] for 4 weeks, then 50 mg QD for 20 weeks), or PF-06700841 (60 mg QD for 4 weeks, then 30 mg QD for 20 weeks), or placebo. Primary efficacy endpoint: mean change from baseline (CFB) in Severity of Alopecia Tool (SALT) score at Week 24. Secondary endpoints: proportion of patients achieving 30%, 50%, 75%, 90% and 100% SALT improvement from baseline, eyelash/eyebrow responders (1 grade improvement on 0-3 scale among patients affected at baseline), adverse events (AEs), laboratory measurements.

Primary endpoint was analyzed using mixed-effects model with repeated measures; binary endpoints as two-sample proportions using Chan and Zhang’s exact unconditional method for confidence intervals (CI), treating missing values as non-responders. The study enrolled 142 patients (women: 98 [69%]): placebo, n=47; PF-06651600, n=48; PF-06700841, n=47; 62 (44%) patients had alopecia totalis (AT), 42 (30%) had alopecia universalis (AU). Mean (standard deviation [SD]) age: 36 (13) years, median (range) duration of current disease: 2 (0.2–30) years, mean (SD) SALT total score: 88.1 (17.3). At Week 24, both JAK inhibitors demonstrated a significant placebo-adjusted mean CFB (95% CI) in SALT score (PF-06651600: 33.6 [21.4, 45.7], P<0.001; PF-06700841: 49.5 [37.1, 61.8], P<0.001), with statistically significant separation from placebo at 6 and 4 weeks, respectively. Compared with placebo, both JAK inhibitors demonstrated significantly greater proportions (90% CI) of patients achieving SALT30 (PF-06651600: 48% [34%, 61%], P<0.001; PF-06700841: 60% [46%, 72%], P<0.001), SALT50, 75, 90, 100, and patients experiencing eyelash/eyebrow improvement. Significant improvements versus placebo occurred in those with AT and AU. The most common AE categories were infections, gastrointestinal, and skin/subcutaneous tissue; there were no cases of herpes zoster reactivation. These phase 2 data indicated that 24-week treatment with PF-06651600 or PF-06700841 was efficacious and well-tolerated in patients with moderate-severe AA, including AT and AU.

07 | A Series of Scalp Allergic Contact Dermatitis Cases Secondary to Nickel-Containing Products in Patients with AA
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INTRODUCTION: Allergic contact dermatitis (ACD) is a T-cell mediated, delayed, type IV hypersensitivity reaction. Nickel is a widespread allergen found in multiple consumer products and may cause ACD of the scalp resulting in hair loss.

PURPOSE: This case series aims to raise awareness of scalp allergic contact dermatitis (SACD) with nickel-containing products and subsequent alopecia exacerbation.

CASE PRESENTATION: Three female patients with alopecia areata present with worsening hair loss, scalp erythema and pruritus. The patients reported recent use of nickel-containing hair accessories. Dermatologic examination of all patients demonstrated erythematous plaques, with overlying fine scale and areas of excoriation, as well as hair thinning localized to areas of allergen contact. Patients were treated with high-potency topical corticosteroid and recommended to discontinue the use of clips or employ protective barriers against offending agents such as clear nail varnish. All patients experienced improvement of SACD over the course of days to weeks.

CONCLUSION: Many patients with alopecia use extensions to cover hair loss. The possibility that clips used in conjunction
with extensions may induce SACD and exacerbate underlying alopecia is concerning. Early clinical recognition of SACD is important to prevent scalp irritation and further hair loss in patients diagnosed with alopecia.

08 | The Relationship between Physical Activity Levels, Quality of Life and Symptoms of Depression, Anxiety and Stress in Individuals with Alopecia Areata

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BACKGROUND/OBJECTIVES: Alopecia areata (AA) is an autoimmune condition that is characterized by non-scarring hair loss. Its aesthetic repercussions can lead to profound changes in psychological well-being and Quality of Life (QoL). Physical activity (PA) has been associated with better mental health status and QoL in diverse populations, but the association in individuals with AA has not been established. The aim of this study was to examine the associations between physical activity, mental health and QoL in individuals with AA.

METHODS: A total of 148 individuals with AA completed the International Physical Activity Questionnaire-Short Form (IPAQ-SF), Depression and Anxiety Stress Scale (DASS-21) and SF-36 Questionnaire. A binomial logistic regression was performed to ascertain the effects QoL’s domain and mental health symptoms on the likelihood that participants on not meeting PA guideline.

RESULTS: The majority of participants (91; 61.5%) did not meet minimal physical activity levels according to Australia’s 2014 PA and Sedentary Behavior Guidelines. The logistic regression model was statistically significant, $\chi^2(4) = 28.363, p < .0005$. The model explained 23.7% (Nagelkerke R$^2$) of the variance in not meeting PA guidelines and correctly classified 73.0% of cases. Sensitivity was 85.7%, specificity was 52.6%, positive predictive value was 74.3% and negative predictive value was 69.8%. Out of the 8 QoL domains, physical functioning (p=.007), bodily pain (p=.025), vitality (p=.004) and social functioning (p=.006) were statistically significant. However, the analysis did not show any association with mental health status.

CONCLUSION: Increasing PA levels in these individuals may lead to reduced levels of symptoms of depression, anxiety and stress and improve mental well-being.

09 | The Role of Patients in the Development of the Alopecia Areata Investigator Global Assessment (AA-IGA™), a Clinician-Reported Measure Evaluating Clinically Meaningful Success in Clinical Trials

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To evaluate new alopecia areata (AA) treatments, AA outcome measures must incorporate input from both experienced clinicians and patients with AA to understand clinically meaningful success. Through in-depth interviews of these two key informant groups and thematic data analyses, we developed an investigator global assessment (IGA) to measure treatment response in AA studies for patients with ≥ 50% scalp hair loss. US dermatologists expert in the treatment of AA (n=10) judged AA treatment success by amount of scalp hair regrowth; most considered 80% (n=5) or 75% (n=3) scalp hair coverage as a treatment success threshold. Thirty patients (Patient Group 1; 5 adolescents and 25 adults) with AA who experienced ≥ 50% scalp hair loss participated in face-to-face interviews. In addition, full transcripts from patient interviews (Patient Group 2; n=40) conducted for the National Alopecia Areata Foundation (NAAF) Patient-Reported Outcomes (PRO) Consortium Partnership were reviewed to: confirm alignment with the key concepts for patients and gain further understanding of the patient voice. All patients in Group 1 identified scalp hair loss as a key AA sign/symptom, and scalp hair loss was the most bothersome AA sign/symptom for 23 (77%) of these patients. Patient-perceived treatment success—short of 100% scalp coverage—was ~70-90% scalp coverage (median 80%) in Group 1. Using additional clinician and Group 1 patient insights into scalp hair loss levels, the AA-IGA™ was developed as an ordinal, static measure comprising five distinct clinical gradations of the Severity of Alopecia Tool (SALT) 0-100% scores. When reviewed with patients and clinicians, the AA-IGA™ was supported as a meaningful clinician-reported measure of scalp hair loss, and patient informants confirmed that achieving 0-20% scalp affected was an appropriate treatment success threshold for patients with ≥ 50% scalp hair loss at baseline. Review of the Patient Group 2 interviews confirmed the AA-IGA™ key concept of scalp hair loss, and provided insights on patients’ aspirations for an ideal AA treatment. In summary, the ordinal, static AA-IGA™ for evaluating AA treatments measures clinically meaningful gradations of AA scalp involvement and reflects patients’ perspectives and expectations of treatment success for patients with ≥ 50% scalp hair loss.

10 | Integrated Behavioral Health in Alopecia Areata Dermatology Care: Pilot Study Purpose and Methodology

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The literature is replete with findings of increased psychosocial distress and lowered Quality of Life (QOL) in Alopecia Areata (AA) patients. Yet identifying, addressing and treating this psychosocial distress during routine dermatological clinical care is not routinely done. To begin addressing this assumed unmet need of AA patients for psychosocial care, a co-located behavioral healthcare pilot program was developed for implementation with AA patients. From the perspective of this study, behavioral healthcare refers to addressing and improving the QOL of persons with chronic
Alopecia Areata (AA) is a leading model system for studying cyclic tissue regeneration. While, in principle, each HF is able to undergo autonomous hair cycling, many thousands of HFs exist on the skin and they coordinate their collective regenerative behavior at the population level. To study mechanisms of collective HF regeneration, we developed a multi-scale mathematical model that accounts for the realistic HF morphology, and where hair-to-hair growth coordination emerges based on shared signaling. This model naturally produces stable periodicity and excitability of HF regeneration and predicts BMP and WNT as signaling. This model naturally produces stable periodicity and excitability of HF regeneration and predicts BMP and WNT as.

**The Prospect of Regulatory T cell Augmentation to Treat AA**

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Alopecia Areata (AA) is associated with polymorphisms in genes associated with regulatory T cell (Treg) function and Treg augmentation in a small cohort of AA patients resulted in hair regrowth. We have shown that Tregs in skin preferentially localize to hair follicles (HFs), which house a major subset of skin stem cells (HFSCs). We mechanistically dissected the role of Tregs in HF and HFSC biology. Lineage-specific cell depletion revealed that Tregs promote HF regeneration by augmenting HFSC proliferation and differentiation. Thus, our work demonstrates that Tregs in skin play a major role in HF biology by promoting the function of HFSCs. Currently, there is an impressive armamentarium of IL-2-based therapeutics that are currently being developed to treat chronic inflammatory diseases. Our data, taken together with current clinical and genetic data, suggest that augmenting Tregs using IL-2 based approaches may be efficacious in treating AA.

**SSEA-Positive Myeloid are Involved in Hair Loss in the AA Mouse Model**

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Alopecia Areata (AA) is an autoimmune disease with the clinical features of hair loss and skin inflammation. The mechanism by which inflammation persists in AA affected skin is not known. To study the problem of AA, induction of AA in C3H/HeJ mice have extensively been used by either grafting a piece of AA skin lesion or by injecting a large number of non-cultured lymphocytes or cultured IL-2 activated T cells isolated from AA mice. Here we hypothesized that dermal injection of a mixture of cells from AA lesion induces AA in healthy mice and the presence of high number of stage-specific embryonic antigen (SSEA-1 and 3) expressing cells are involved in persistency of inflammatory cells at the AA affected lesions. To generate AA in C3H/HeJ mice, a new approach without need for any skin transplantation or a cocktail of expansive cytokine treated T cells was used. To achieve this, cells from the AA affected skin were isolated and a mixture of them were intra-dermally injected in non-affected C3H/HeJ mice. Upon establishing this model, the presence of SSEA cells were...
evaluated in AA affected and control skin. To evaluate the inflammatory role of SSEA expressing cells in AA, we isolated and co-cultured them with splenocytes and examine the proliferation of T and B cells. We also examined AA induction by dermal injection of splenocyte-derived SSEA expressing cells in healthy mice. The result showed that dermal injection of a mixture of cells isolated from AA affected skin of a single mouse is sufficient in generating AA in more than 70 recipient mice. Interestingly dermal injection of suspension and adherent cells in recipient mice induced alopecia universalis and alopecia patchy, respectively. The result related to the role of SSEA in persistency of inflammatory revealed a significant increase in proliferation of both T and B cells co-cultured with SSEA cells. Further, dermal injection of splenocyte-derived SSEA cells induced AA not only in C3H/HeJ but also in B6 mice. This study showed a novel way in induction of AA in C3H/HeJ mice and the presence of SSEA-1 and -3 expressing cells in AA lesions likely to be involved in persistency of inflammation in AA.

**Rare Genetic Mutations Contribute to Alopecia Areata**

Etiology

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Research into the genetic architecture of chronic disease has unequivocally demonstrated etiological contributions from both common (polymorphisms; SNPs) and rare (mutations) genetic variants. For alopecia areata, genome-wide association studies (GWAS) have been successful in identifying SNPs that increase disease risk. However, mutations have yet to be identified. While exome sequencing permits genome-wide investigation of disease mutations, challenges arise because human genomes are riddled with mutations, most of which exert no effect on health, and because low allele frequencies limit power to detect associations. Therefore, new methods are needed to identify causal mutations in chronic disease. Here, we have developed a novel analytic pipeline to identify mutations that contribute to alopecia areata etiology. First, we performed genome-wide genotyping in 38 families and used tagSNPs to identify genomic regions that are co-segregating with AA and to perform family-based association tests. Together these analyses identified 20 co-segregating regions (4>LOD>1) containing 373 associated tagSNPs that capture variation in 6,688 SNPs and implicate 178 genes. Next, we performed exome sequencing on a subset of probands (N=29) and extracted co-segregating mutations that alter protein sequence in these 178 genes, reducing the number of candidate genes to 58. Pathway analysis of these 58 genes indicates that 12 genes from five genomic regions contribute to extracellular matrix structure, organization and signaling (0.016<p<9x10-4). We are currently performing replication analyses in a set of 124 patients with family history and 651 patients who don't report family history. Because it has been shown that the physical and biochemical properties of extracellular matrix can regulate CD4+ and CD8+ T-cell responses in the context of cancer, our preliminary results may suggest the identification of a new biological point of intervention for inhibiting aberrant immune-mediated destruction of the hair follicle.

**EPIEMIOLOGY AND BURDEN OF DISEASE**

**Using Big Data to Unravel Uncommon Diseases**

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BACKGROUND: Observations in uncommon diseases are limited by small cohorts and selected samples which restrict the ability to make important observations on disease burden, disease course, co-morbid associations, disease outcomes, and treatment outcomes.

PURPOSE: The purpose of this talk is to describe the application of big data in overcoming such limitations.

RESULTS: An overview of observations from big data analyses in hidradenitis suppurativa, as an example, will be shared.

CONCLUSIONS: Big data harnesses both power and granularity to advance knowledge of uncommon diseases.

**Prevalence of Alopecia Areata in the United States from a Large Cross-Sectional Survey**

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BACKGROUND: The prevalence of alopecia areata (AA) in the United States (US) is not well known. A commonly cited self-reported period prevalence of 0.16%1 is outdated and sourced from the National Health and Nutrition Examination Survey (NHANES) almost 50 years ago (1971-1974). Other smaller studies have focused on the prevalence of alopecia totalis (AT; 100% scalp hair loss) and alopecia universalis (AU; complete facial and body hair loss).

STUDY TYPE: Online cross-sectional survey targeting 45,016 participants.

METHODS: To obtain a 2017 prevalence estimate, we administered an online cross-sectional survey to a representative sample of the US population (aged ≥11 years) with respect to age (adolescents 11-17 represented by parent proxy), gender, race, income, and region. Participants screening positive for AA using the Alopecia Assessment Tool completed the Severity of Alopecia Tool (SALT)3 to determine severity (mild=50%, moderate-to-severe>50% hair loss). Participants with self-reported AA were invited to upload photographs for adjudication by three clinicians.

RESULTS: Self-reported AA point prevalence was 1.14% [95% CI:1.04%-1.24%] overall (mild=1.03%, moderate-to-severe=0.11%; AT/AU=0.04%), 1.24% (95% CI: 1.13%-1.35%)
In the United States, it is estimated that AA affects 0.1%-0.2% of the population, with a lifetime risk of 2.1%. Willingness to pay (WTP) is a monetary, preference-based measure designed to gauge patients' willingness to pay out of pocket (in US$) for a cure or control of their condition.

PURPOSE: We sought to measure willingness to pay in patients with alopecia areata.

RESULTS: Patients indicated they were willing to pay a median of $500-$1000, or approximately 13%-22% of their monthly income for a permanent cure for AA; 33% of patients (n=13) were willing to pay $5000 for a permanent cure, and 15% (n=6) were willing to pay $5000 to control the disease.

Patients with higher AASIS scores were more willing to pay ≥$1000 (mean AASIS score 47.8 vs 26.0, P=.012) and >$5000 (mean AASIS score 53.2 vs 25.8, P=.003) for a cure. Similarly, patients with higher AASIS scores were more willing to pay >$1000 (mean AASIS score 53.7 vs 30.4, P=.012) and >$5000 (mean AASIS score 66.3 vs 30.9, P=.003) to control disease. Furthermore, patients with higher SALT scores (≥25%) had significantly higher AASIS scores compared with those with lower SALT scores (<25%) (mean AASIS 59.1 vs 20.1, P<.0001). The average SALT score for all 40 patients was 28.3%.

Our results indicate that 33% of patients with AA were willing to pay ≥ $5000 for a permanent cure, comparable with the WTP of patients with vitiligo (32.9%). For a permanent cure, our patients were willing to pay a median of $500-$1000, compared with atopic dermatitis patients who were willing to pay a median of 1000 € (~US $1132) and rosacea patients who were willing to pay 500 € (~US $566). The median WTP as a percentage of monthly income was 10%-20%, which is comparable with the percentage found with atopic dermatitis and psoriasis patients and slightly more than that found with rosacea patients.

CONCLUSIONS: Severity of disease was associated with quality of life, a finding also noted in psoriasis. Quality of life was associated with WTP for both control and cure of disease. Our patients reported a WTP at levels similar to patients with vitiligo, atopic dermatitis, and psoriasis, demonstrating the need for ongoing research toward a potential cure for AA. One limitation of our study was the small sample size; thus, further large-scale studies are warranted to validate our findings.

Broadening Diversity in AA Clinical Trial Participants
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The FDA has taken the initiative to set expectations for sponsors and investigators to enroll study participants from diverse backgrounds. This plan is grounded in the knowledge that different groups within the US population have varying morbidity rates for diseases and that medications will act differently on patients of different ages, races, ethnic origin, and genders. To move forward with this initiative, there are a number of important factors that must be considered. These factors include: study site location, study staff diversification, cultural competency training, and patient recruitment materials. Hindrances to recruiting a more diverse subject panel include: linguistic translation issues with face to face communication as well as in study materials, few incentives for patients and study staff for diverse recruitment, low site commitment to recruiting diverse populations, and lack of sponsor reinforcement of diversity requirements. For alopecia areata, specifically, there must be a recognition that the younger ages of the affected individuals will almost certainly mean that school and/or work can interfere with study visits, often with those of lower socioeconomic levels shouldering more of this burden. Strengthening ties to the community of affected patients at individual sites through increased cultural competency and commitment can overcome other barriers that potential study participants may consider. Identifying and prioritizing our research gaps for underrepresented groups in alopecia areata can redefine a successful approach to more diverse studies.

The NAAF Patient Registry: Driving Towards a New Understanding of Alopecia Areata
MA Collins | Helomics Corporation, Pittsburgh, PA, USA

High quality, highly annotated specimens from patients or clinical trial subjects are key to advancing the search for new treatments for disease. Recognizing this, NAAF has an established registry which it is expanding, with help from its partners, to provide a new advanced bio-repository capability that will enable researchers to access high quality annotated specimens for research from this registry. We will discuss how housing the entire specimen storage, processing and analysis lifecycle under one-roof will deliver lower costs and higher quality specimens for research as well as allowing researchers to take advantage of the latest genomic analyses, such as next generation sequencing to look more deeply into the molecular mechanisms underlying Alopecia Areata. In addition, we will demonstrate how researchers will be able to perform in silico research using the registry data coupled to state-of-the-art information systems in order to learn more about Alopecia Areata patients before ordering precious samples for further research. Finally, we will give a future prospective for the evolution of the registry to be one-of-a-kind resource for advancing the treatment of alopecia areata.