P8633

Robotically assisted follicular unit extraction in surgical hair restoration

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Thousands of surgical hair restoration procedures are performed across the world every year. Transplantation of individual follicular units (FU) from the donor region to the recipient region is considered the criterion standard in terms of creating natural looking hair restorations. The 2 most common procedures used to extract FUs from the donor region are strip/linear extraction and manual follicular unit extraction (FUE). Both of these methods provide natural looking hair transplantations and hold their own individual merits; however, both methods are also associated with their own limitations. The introduction of robotic surgical assistive devices that operate under the supervision of a physician may circumvent many of the limitations associated with the traditional strip/linear and FUE extraction methods. FUE surgery performed with robotic-assistance offers a novel, effective, timely, and relatively painless procedure for harvesting healthy FUs grafts with a low transection rate directly from the donor site. Thus far, robotically assisted FUE surgeries have demonstrated hair restoration outcomes comparable to that of traditional manual FUE; however, additional independent scientific evaluation is required before a final determination of efficacy and long-term results can be established. At this time, robotic assistive FUE devices have FDA approval in the United States and have a medical device license for use in Canada for use on men with dark colored hair, although they are being successfully used in more diverse populations including women and people ranging in hair colors, textures, and densities. Overall, robotically assisted FUE appears to be an innovative means for performing safe, effective, and replicable FUE procedures with low transection rates, thereby ensuring full and natural looking hair growth on the recipient scalp.

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P8723

Safety and efficacy of tavaborole (AN2690), a novel boron-based molecule, in 3 phase II trials for the topical treatment of toenail onychomycosis

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Purpose: Three phase II trials were conducted to determine the safety and efficacy of tavaborole topical solution for topical treatment of toenail onychomycosis.

Methods: The 3 phase II studies (200, 201, and 203) enrolled adults with distal subungual onychomycosis involving 20% to 60% of the targeted great toenail. Study 200 was a double-blind, vehicle-controlled, dose-ranging trial; studies 201 and 203 were open-label. Across the 3 trials, vehicle or tavaborole solution at concentrations of 1%, 2.5%, 5%, or 7.5% was topically administered for 180 or 360 days. Mycologic assessments (KOH wet mounts and fungal cultures) and clinical assessments (Investigator Static Global Assessment [ISGA] and clear nail growth) were performed in all studies. For studies 200, 203, and for study 201 cohorts 1 and 2, the primary endpoint was treatment response at day 180, defined as negative culture $\geq$ 2 mm clear nail growth or ISGA score of clear or almost clear after 6 months. For study 201 cohort 3, the primary endpoint was treatment response at day 360, defined as clear nail plus negative fungal culture. Safety assessments included collection of adverse events (AEs), application site reactions, laboratory tests, physical examinations, and vital signs.

Results: The studies enrolled a total of 336 patients. In the studies with treatment duration of 180 days, efficacy was observed across tavaborole concentrations of 2.5%, 5%, and 7.5%; the proportion of patients achieving a treatment response with tavaborole of any concentration ranged from 26% to 53% across the 3 trials. In the randomized, vehicle-controlled, dose-ranging study (study 200), all concentrations of tavaborole (2.5%, 5.0%, or 7.5%) demonstrated superiority versus vehicle, with 5% tavaborole showing the best balance between efficacy and safety at the day 360 follow-up. In most treatment cohorts, a negative mycology culture was obtained in >90% of subjects within the first 2 weeks of treatment. In all 3 phase II trials, tavaborole topical solution was well tolerated. Most AEs were mild and most were considered not related to study drug. All 13 serious AEs were considered unrelated to study drug. Application site reactions were generally mild and reversible.

Conclusion: In 3 phase II trials of adult patients with onychomycosis, tavaborole topical solution showed a good safety profile as well as a therapeutic effect at all concentrations tested; the 5% solution exhibited the best balance of efficacy and tolerability.

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P7547

Telogen effluvium and associated incidence of abnormal serum ferritin, zinc, 25-hydroxy vitamin D, and thyroid-stimulating hormone

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Introduction: Telogen effluvium (TE) is a diffuse, nonscarring alopecia after an abrupt and predominant shift of hair follicles from anagen to telogen phase. Proposed cofactors include, but are not limited to, endocrine and nutritional abnormalities, drug reactions, and physical and psychological stress. In addition, possible triggers that can be objectively measured include abnormalities of iron, vitamin D, zinc, and thyroid hormone. The primary objective was to determine the reported incidence of abnormal serum ferritin, zinc, 25-hydroxy vitamin D, thyroid-stimulating hormone (TSH), and free thyroxine (fT4) in a population of patients with TE, and to identify possible trigger events in this TE population.

Methods: A diagnostic code search was performed to identify patients clinically diagnosed by a dermatologist as TE over a 24-month period in a large, urban, single site, academic-based dermatology practice in Chicago. Data collected from medical records included age, race, sex (all females), suspected hair loss trigger factor(s), and serum ferritin, zinc, 25-hydroxy vitamin D, TSH, and fT4. Trigger events were categorized as endocrine, nutritional, drug-related, physical, or psychological stressors.

Results: Nintey-nine females with TE were included in our analysis. The incidence of abnormal laboratory results was as follows: low serum ferritin 9/93 (9.7%), low serum zinc 4/61 (6.6%), low serum 25-hydroxy vitamin D 34/79 (43%), low TSH 2/58 (3.4%), and high TSH 4/58 (6.9%). The proportions of patient and/or physician suspected trigger factors were: endocrine 21/99 (21.2%), nutritional 15/99 (15.2%), drug-related 7/99 (7.0%), physical stressor 7/99 (7.0%), and psychological stressor 31/99 (31.3%). Multiple triggering factors were suspected in 15/99 (15.2%) patients. In 32/99 (32.3%) patients, no triggering factor was identifiable. There was no statistically significant correlation between category of trigger factor and age, race, or serology.

Conclusion: In our patient population, vitamin D deficiency was the most frequent laboratory abnormality identified (43% of 79 tested patients). Psychological stressors were the most common patient and/or physician-suspected triggering events, yet in 32% of patients, no triggering factor was identifiable. Recently, low vitamin D in a controlled study has been associated with TE. Additional investigation is needed to understand the mental and physical stressors that precipitate TE.

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P7666

The features of onychomatrimas on in vivo reflectance confocal microscopy

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Onychomatricoma is a benign nail matrix tumor that often presents as yellow onychodystrophy with overcurvature and splinter hemorrhages. The involved nail plate characteristically shows multiple holes in the free edge. On histology, it is a fibroepithelial nail matrix tumor infiltrating the nail plate, with multiple tunneled cavities filled with serum and lined with matrix epithelium. RCM is a noninvasive diagnostic tool with cellular resolution that correlates well with histology. RCM VivaStack (Z-axis) mode can reach structures deeper than 300 μm. RCM has been extensively used to evaluate melanocytic lesions, with only a few reports on RCM in nail assessment. There has not been any publication of using in vivo RCM in the evaluation of onychomatricoma. We used RCM to assess 4 patients with onychomatricoma before surgical excision. We evaluated the affected nail and unaffected nail of each patient with VivaScope 1500 (Lucid Inc, Rochester). VivaStack mode was used to take series of images at increasing depths from the dorsal nail plate to the nail bed. We noticed in all 4 patients that the lesional nail plates demonstrated longitudinal dark areas and white/grey lines, forming channel structures within the nail plate at a depth of 186 to 505 μm. The channels were outlined by bright circular lines with a grey dot in the center. The unaffected nails showed homogenous, white/grey structureless areas, corresponding to healthy nail plates. All 4 patients had surgical excision with histopathologic confirmation. We were able to correlate the tunneled cavities found in histology with the channel structures observed on RCM. The channels are dark, likely corresponding to serum and blood which have low refraction of light on RCM. In addition, the matrix epithelium cells outlining the cavities appeared as circular bright lines with dark dot in the center (nuclei) on RCM. These RCM features seen in onychomatricoma can be easily differentiated from onychomycosis (bright linear elements corresponding to the hyphae). In conclusion, RCM evaluation of onychomatricomas prior to surgical excision provided important RCM—pathologic correlation, and can be used as a noninvasive diagnostic tool for onychomatricomas.

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