Novel medical device treatment for onychomycosis

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The problem — Please define the dermatologic clinical problem worth solving, the current solutions, and the strengths and weaknesses of the current solutions.

Fungal nail (onychomycosis) is a chronic infection that can be painful and have psychosocial effects that damage a patient's quality of life. Onychomycosis is common, affecting an estimated 38 million people in the US; 50% of people over the age of 70 and 30% of all diabetics. Diabetics with infected nails are 4x more likely to have a limb amputated. Current onychomycosis treatment options cover a broad range of remedies. Oral drugs have the highest cure rates and are the preferred treatment for most doctors, as a prescription fits in a typical 15-min visit time; however, liver toxicity risks and blood tests needed to monitor patient response have limited their use. Prescription topical drugs are easy to apply and eliminate the systemic drug route of orals but have a 15% or less chance of success despite laborious daily treatments over the course of a year that cause patient compliance problems. Lasers are unproven, costly and can cause pain. There are many ineffective over-the-counter products. Both patients and dermatologists express widespread dissatisfaction with the limited success, side effects, high cost and treatment time course for onychomycosis.

Your solution — Describe how your solution is it different and why is it valuable.

DeviceFarm's medical device utilizes room temperature plasma gas as the antifungal agent as gas better penetrates the nail structure than creams (you do not fumigate a house by putting cream on the door sill, you fill it with gas). Gas penetration and antimicrobial activity is augmented with an FDA cleared nail penetration enhancer. Our treatment will kill the fungus under and within the nail (mycological cure) during 1 to 3 outpatient visits to a dermatologist. Our product's primary value proposition is the topical delivery of a safe and highly effective therapy that offers simpler, shorter treatment times directly at the site of...
infection. The short treatment duration (one week) will improve patient compliance. A treatment with no pain or side effects that is easy for both patients and doctors will contribute to more people receiving treatment. Our product will also have device / drug combination synergies with current topical therapies. Our treatment will achieve mycological cure within a week but to protect the nail after treatment, a topical drug acting as a barrier to onychomycosis re-infection could be recommended as the treated nail grows out free of infection.

Clinical hypothesis Summarize the scientific or technical basis of the drug/device/diagnostic/other technology you are developing, and briefly provide evidence that support its approach as useful and feasible.

DeviceFarm's medical device turns electricity and air into a room temperature plasma gas. In a plasma, various reactive oxygen and nitrogen species form a cauldron of redox gases such as NO, NO2, H2O2, and ozone that kill pathogens. This chemistry mimics the oxidative burst of macrophages the body uses to attack microbial infections. We are substantially harnessing nature's innate immune system and its healing mechanism to provide an immune system-like response to the nail structure that lacks its own blood supply. DeviceFarm's treatment shows compelling results in both pre-clinical and first-in-man tests. We built a novel plasma system and demonstrated its effectiveness in eliminating the primary causes of onychomycosis (T. rubrum and T. mentagrophytes fungi) through both bovine keratin barriers and human cadaver nails. We demonstrated that nonthermal plasma achieves 100% mycological cure through a keratin barrier with three 45 minute treatments. In addition, self-treatment of one of our founders who suffers from onychomycosis cleared the infection and resulted in healthy nail growth on all 9 of his infected nails. This provides our first in vivo proof of concept.

Product profile and development plan- Describe the product (i.e. some information of what it is) and what stage it is in (e.g. concept, preclinical, prototyped, closed beta, etc. as applicable). Also please include the next major milestone (and costs to that milestone) in the product’s development.

DeviceFarm's medical device will combine a small-footprint instrument that works in conjunction with a disposable patient interface tray and a consumable nail penetration enhancer fluid. It will be like a beauty salon hair dryer: you insert the infected foot into the treatment device and the therapy is performed automatically while the patient reads a magazine and the doctor can see other patients. Our product stage is currently a preclinical prototype. We have 2 patent applications submitted on the technology. The next major milestone is to create a clinical-ready device capable of use in our first clinical trial. Alpha prototype development combined with safety, verification and validation studies is expected to cost $1.6M. A 20 person feasibility clinical trial to test the Alpha prototype is estimated to be $0.6M. We are currently performing in vitro studies on a human nail model to establish a viable clinical treatment protocol. We are seeking dermatologists and partners interested in participating in our clinical trials.

Value of your solution – What is your rough estimate of the yearly market revenue potential (and what are some for the basic assumptions underlying that estimate, e.g. this product could be used by X individuals per year, etc.).

The US prescription drug market for onychomycosis is $1.26B (2010) annually according to IMS Health data. Thomson Reuters estimated the size of the onychomycosis worldwide market at about $2.8B (2012)
where the overall market growth is estimated at 7%. We are not trying to create a new market; we are supplying a better tool to help physicians and patients with a medical problem that they are struggling with today. We estimate annual US revenue in Y2021 of $265M. Revenues will come from instrument, consumable, and service sales to physicians. The average selling price to doctors is $4K/instrument, $320/consumable kit, and service revenues at 12% of sales. We estimate 100 patients treated per year per doctor. The patient cost is targeted at $1500-$2000 for three treatments. This compares well to the much less effective treatments: $1000-$1800 laser treatments and the 12-month, $360 treatment with topical medications. Our yearly sales estimate represents 11% of US-based dermatologists and podiatrists using our product on only 0.6% of the onychomycosis patient population. The estimated annual revenue is 10% of the available US prescription market after 7% market growth projections.