Case Report

Histologic Assessment of Biopsy Samples Taken Before and After the miraDry Procedure Performed on a Patient with Axillary Hyperhidrosis

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Introduction

Hyperhidrosis is defined as excessive sweating beyond what is physiologically required to regulate body temperature[1]. Although not life-threatening, hyperhidrosis has a significant impact on peoples' lives and is a condition which affects millions of people worldwide[2]. The negative impact on people's quality of life is comparable to many of the commonly recognized dermatologic disorders such as psoriasis, acne, and vitiligo[3].

Hyperhidrosis occurs in a number of different locations on the body, but the main areas of concern are the armpits (axillary), hands (palmar), and feet (plantar).

A new non-invasive, microwave-based device received FDA clearance in early 2011 for treating patients with primary axillary hyperhidrosis [miraDry System, Miramar Labs, Sunnyvale, CA]. This case study reviews the histologic findings of a patient who was treated with the miraDry system. The patient volunteered to allow biopsy samples to be taken at various timepoints before and after treatment.

Device Description

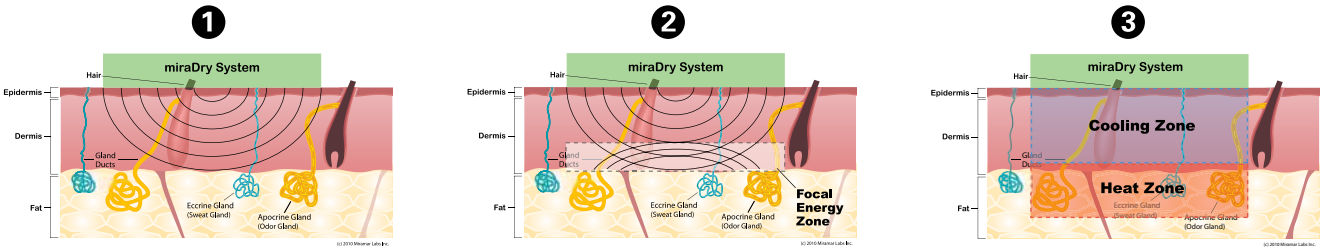
The miraDry system (Figure 1) utilizes microwave energy at 5.8 GHz to specifically heat the region of skin containing sweat glands to the point of causing thermolysis of the glands.

The miraDry system has an integrated hydro-ceramic cooling system which protects the superficial skin from thermal damage and a vacuum acquisition system to stabilize the target tissue during energy delivery.

The miraDry system automatically targets the dermal-hypodermal interface (Figure 2), where the majority of sweat glands reside in the axilla[4]. The eccrine glands are responsible for the wetness-producing sweat; the apocrine glands produce the substance that leads to odor. The system is designed to take advantage of the difference in microwave-related tissue properties of the dermis and subcutaneous tissue. Since the majority of the sweat glands reside at that interface, automatic targeting of that region, regardless of skin thickness, is a key feature of the miraDry system.

Figure 1.
miraDry System

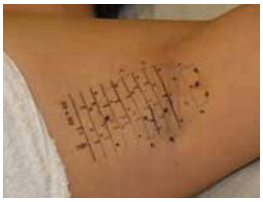
Figure 2.
miraDry System and mechanism of targeting the region where the sweat glands reside.



1 – Electromagnetic energy is delivered down into the skin from the external Handpiece.

2 – The energy reflects off of the dermal-hypodermal interface due to the abrupt change in microwave-related properties of the tissues.

3 – Surface cooling protects the dermis from thermal damage while allowing the thermal energy to spread within the target region.



Procedure Description

The miraDry procedure is performed in 3 steps.

Figure 3. Step 1 – Apply guidance template

The first step involves sizing the area to be treated and marking that area with the template system (Figure 3). The markings guide the user for anesthesia injection locations and placement of the Handpiece.

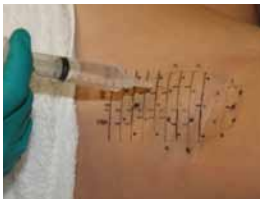


Figure 4. Step 2 – Deliver local anesthesia

The second step is the injection of local anesthesia (lidocaine) for pain management (Figure 4). Recommendations are provided for anesthesia delivery including injection site spacing, volume of anesthesia per injection site, and the depth of injection.

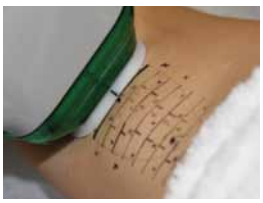


Figure 5. Step 3 – Place Handpiece on designated areas to deliver the therapy.

The third step is to apply the therapeutic energy by placing the Handpiece on the locations in each axilla (Figure 5). Multiple placements with the Handpiece are required to deliver therapy to the entire axilla. Typically, 2 procedures separated by a minimum of 3 months are necessary to get the optimal benefit. In the case reported here, the patient only received one procedure.

Case Description

The 37 year old male patient was enrolled in a study conducted by one of the authors (NK). The study was to evaluate the utility of the miraDry procedure in Japanese patients with axillary hyperhidrosis and/or osmidrosis. This patient presented with axillary hyperhidrosis as evidenced by both subjective patient evaluations and objective sweat measurements.

4mm cylindrical punch biopsies were taken from the left axilla before the procedure and at multiple timepoints after the procedure (nominally 10 days, 30 days, 60 days, 90 days, and 180 days ± 2 days). The samples were taken in a central location near each other, but not directly adjacent or overlapping (Figure 6). Residual hyper-pigmentation from the previous biopsies allowed accurate targeting of subsequent biopsies.

Biopsy samples were fixed in 10% neutral buffered formalin. Tissues were routinely processed in graded alcohols, cleared in xylene, embedded in paraffin, microtome sectioned at 5 microns, mounted on glass slides and stained with hematoxylin and eosin (H&E) for light microscopic evaluation. The histologic assessment was carried out by one of the authors (JK), who is a dermatopathologist.

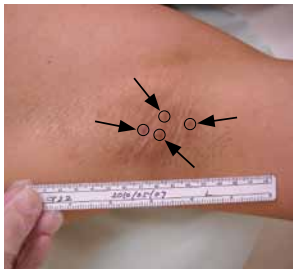


Figure 6. Arrows show the locations where biopsies were taken. The photo was taken before the 90 day follow-up.

Histologic Assessment

The pre-treatment "baseline" sample (Figure 7) demonstrated basketweave orthokeratosis overlying a normal appearing papillary and reticular dermis. The subcutis is abundant with normal appearing obulated apocrine glands, eccrine glands, and adipose tissue.

The biopsy sample taken at 10 days post-treatment is shown in Figure 8. Necrotic sweat glands and ducts are identified within the reticular dermis and subcutis. The necrotic glands and ducts are devoid of nuclei. A mild perivascular lymphohistiocytic infiltrate is present within the subcutis, which may be suggestive of inflammation and subsequent healing.

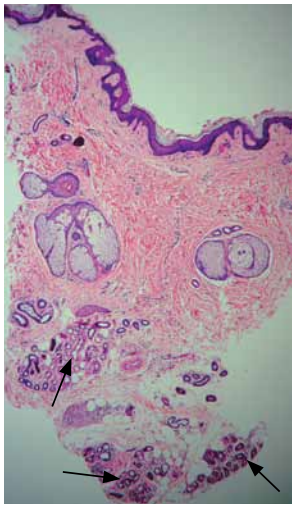


Figure 7. "Baseline" sample. Normal-appearing apocrine and eccrine glands are present in the subcutaneous tissue. Arrows point to some of the sweat gland lobules.

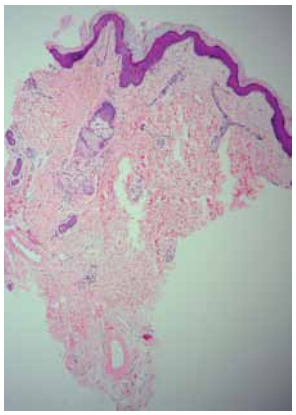


Figure 8. 10 days post-treatment sample.

The biopsy sample taken at 30 days post-treatment is shown in Figure 9. Unfortunately, the subcutis is not well-represented due to sampling. However, the sample is devoid of normal appearing sweat glands. The lower reticular dermis does show mildly atrophic eccrine gland with perieccrine fibrosis.

Figure 10 shows the biopsy sample taken at 60 days post-treatment. The reticular dermis and subcutaneous tissue is devoid of normal appearing sweat glands. Mild lymphohistiocytic infiltrate, periglandular fibrosis, and neovascularization are identified surrounding atrophic glands, suggestive of post-traumatic reactive changes.

Biopsy sample taken at 90 days post treatment is shown in Figure 11. This sample demonstrates similar findings to the prior time point (60 days). There are small foci of atrophic glandular lobules present within the subcutaneous tissue. An associated mild lymphohistiocytic infiltrate, periglandular fibrosis, and neovascularization are identified and surround the atrophic glands, suggestive of post-traumatic reactive changes.

The final biopsy sample, taken at 180 days post-treatment, is shown in Figure 12. In this specimen, a single well-formed sweat gland lobule is present in the subcutis. There is associated neovascularization and mild inflammatory infiltrate. The subcutaneous tissue contains minimal reactive changes associated with prior fat necrosis.

Discussion

The miraDry treatment uses microwave energy to non-invasively heat the region of the skin where sweat glands reside. The heat generated is enough to cause thermal necrosis of the sweat glands. This case study demonstrated that thermal injury that is sufficient to cause necrosis of sweat glands are indeed delivered by the miraDry system. There is a clear reduction of viable sweat gland structures when comparing the before treatment ("baseline") sample to any of the follow-up time point samples from this one patient. There was no significant histopathologic evidence of adverse effect on other cutaneous structures in this study.

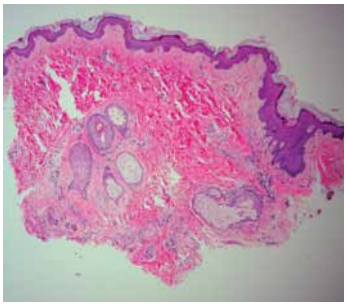


Figure 9.
30 days post-treatment sample.

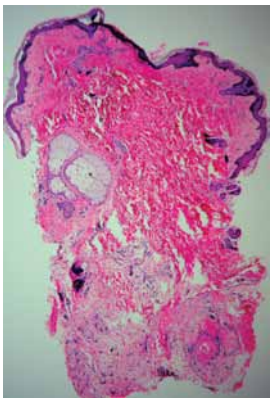


Figure 10.
60 days post-treatment sample.

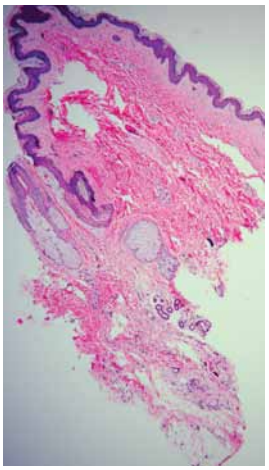


Figure 11.
90 days post-treatment sample.

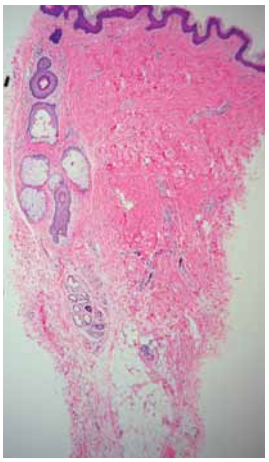


Figure 12.
180 days post-treatment sample.

References

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