

MiraDry:

A Notable Advance in Treating Primary Axillary Hyperhidrosis

Harnessing the power of microwaves, a new device offers a patient-friendly option for the treatment of hyperhidrosis.

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In a technological tour de force, microwave energy has been harnessed to provide the latest breakthrough for the treatment of primary axillary hyperhidrosis. The miraDry (MiraMar Labs) system represents the first use of this 5800 MHz wavelength energy in dermatology.

The proprietary system focuses microwave energy delivery directly to the dermal-fat interface for targeted thermal destruction of sweat glands. Microwaves create heat by causing physical vibration of dipole molecules. Microwave energy has good absorption in tissues with significant water content, such as the dermis and sweat glands, because of their high dipole moments; however, there is poor absorption in the subcutaneous layer because of its low dipole moment.

THE CHALLENGE OF HYPERHIDROSIS

Axillary hyperhidrosis is a difficult quality of life problem for many individuals. A mail survey in 2002 found 2.8 percent of respondents felt they had excessive or abnormal/

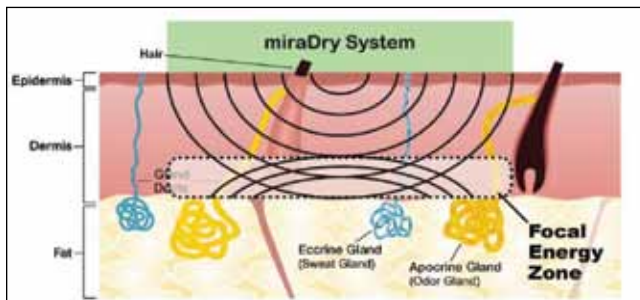


Fig. 1. MiraDry concentrates microwave energy at the dermal-fat border. Energy becomes concentrated along this interface and creates a Focal Energy Zone.

TAKE HOME TIPS

The miraDry system represents the first use of 5800 MHz wavelength energy in dermatology. The proprietary system focuses microwave energy delivery directly to the dermal-fat interface for targeted thermal destruction of sweat glands.

unusual sweating (approximately 1.4 percent complained of axillary hyperhidrosis).¹ An online survey in 2008 found that 33 percent of adults felt that they have too much underarm sweat but only five percent sought help.² The impact of axillary hyperhidrosis on the Dermatology Life Quality Index (DLQI) has been calculated to be similar to the effects of psoriasis and acne.³ Sufferers complain of social embarrassment, ruined clothes, and an increased tendency to develop skin irritation and infections.

TREATMENT OPTIONS

Previous medical and surgical approaches used for this

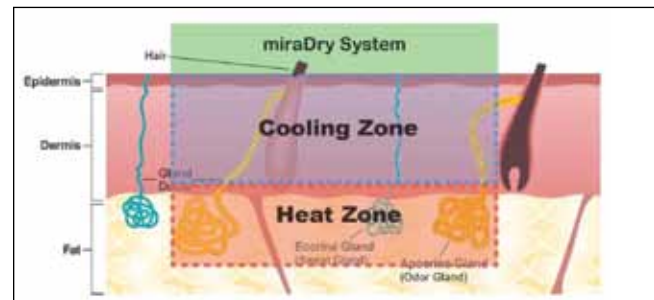


Fig. 2. Continuous hydroceramic cooling prevents thermal conduction of heat superficially and creates a heat zone at the level of sweat glands, resulting in thermolysis.

common problem have all had drawbacks. Prescription topical antiperspirants, like aluminum chloride hexahydrate 25%, can stain clothes, irritate skin, and have no lasting benefit; yet, these topical therapies often fail to suppress sweating sufficiently. Oral anticholinergic medications may cause xerostomia, cycloplegia, mydriasis, as well as bowel and bladder dysfunction. Botulinum toxins, while highly successful, require significant doses every six to eight months, which can be prohibitively expensive.⁴ Surgical excision of the axilla and dermal curettage leave unsightly scars and may restrict range of motion. Liposuction of sweat glands has been shown to work well but is invasive. Endoscopic thoracic sympathectomy is also invasive and may lead to Horner's syndrome, pneumothorax, hemothorax, gustatory sweating, and compensatory hyperhidrosis. An effective non-invasive technique is attractive to patients and is a welcome addition to dermatologists.

MiraDry (microwave thermolysis) is a non-invasive office procedure that received US Food and Drug Administration (FDA) 510(k) clearance in January 2011 for treatment of excessive underarm sweat. This novel device delivers microwave energy to the dermal-fat interface to destroy sweat glands (Figure 1). Continuous hydroceramic cooling prevents thermal conduction of heat superficially and creates a heat zone at the level of sweat glands, resulting in targeted thermolysis (Figure 2). The device consists of three components:



Fig. 3. The miraDry console contains a chiller, vacuum pump, and custom software that controls energy delivery.



Fig. 4. The miraDry handpiece delivers a 1cm x 3cm zone of therapy and contains four antennas and active cooling to protect the dermis. **Fig. 5.** (Inset): A sterile and disposable BioTip lifts skin from the underlying structures and stabilizes tissue during the cycle.

1) a console (Figure 3), composed of a chiller, vacuum pump, and custom software that controls energy delivery; 2) a handpiece (Figure 4), which delivers a 1cm x 3cm zone of therapy and contains four antennas as well as active cooling to protect the dermis; and 3) a sterile and disposable BioTip (Figure 5) that lifts skin from the underlying structures and stabilizes tissue during the therapy cycle.

THE MIRADRY PROCEDURE

The miraDry procedure is straightforward. The dermatologist identifies the areas of excessive sweating (usually the entire hair bearing area) and then a proper-sized template is used to mark out a treatment grid (Figure 6). After administering local anesthesia, the operator moves the handpiece from zone to zone in a specified pattern until the entire hyperhidrotic area is treated. Software on the console guides the user through the treatment session so that each zone is treated, but only once (Figure 7).



Fig. 6. Proper-sized templates help mark out a treatment grid.

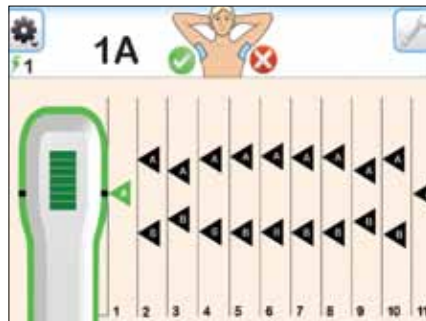


Fig. 7. Software guides the user so that zones are treated correctly.

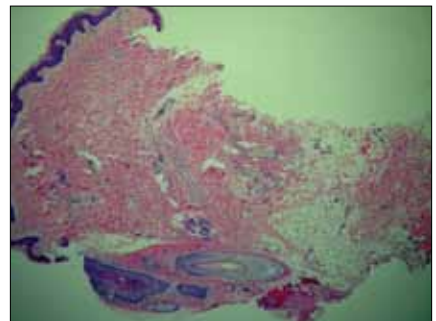


Fig. 8. Six months after miraDry treatment, no viable sweat glands are visible.

(Photograph courtesy of Dr. Nishuharu Kishikawa.)

TABLE 1: THE HYPERHIDROSIS DISEASE SEVERITY SCALE (HDSS)

 1.	My sweating is never noticeable and never interferes with my daily activities
 2.	My sweating is tolerable but sometimes interferes with my daily activities
 3.	My sweating is barely tolerable and frequently interferes with my daily activities
 4.	My sweating is intolerable and always interferes with my daily activities

Swelling and bruising are common immediately after treatment and may persist for several days. The procedure typically lasts 60-75 minutes, depending on the size of treatment area. Two procedures (spaced three months apart) are required for optimal results.

The miraDry device is highly effective in destroying sweat glands. Axillary biopsies as early as 11 days post-treatment demonstrate eccrine and apocrine gland cells devoid of nuclei as well as complete cellular necrosis. At six months, histology confirms a complete absence of sweat glands in the treated area (Figure 8).

Studies of the effectiveness and safety of miraDry have been encouraging. A randomized, blinded, sham-controlled, investigational device exemption (IDE) study utilizing an investigational device on 120 patients at seven sites resulted in 89 percent of severely hyperhidrotic subjects reaching a level of 1 or 2 on the Hyperhidrosis Disease Severity Scale (HDSS; Table 1) at one month. Sixty-nine percent maintained this effect at one year.⁵ Treatment side effects were mild and transitory. The most common complaint was temporary altered sensation in the skin. One subject exited the study with complaint of altered sweating on the face. The commercial version of miraDry was studied in an open label trial of 31 hyperhidrotic subjects followed for 12 months.⁶ Efficacy of sweat reduction was measured using HDSS, gravimetric assessment, and DLQI, as well as gravimetric changes. Over 90 percent of subjects demonstrated a reduction of HDSS to level 1 or 2 at 12 months. The average gravimetric reduction in sweat was 81.7 percent at one year post treatment, and 85.2 percent reported a greater than five-point reduction in the DLQI. There was also a statistically significant reduction in underarm odor based on patient surveys. Interestingly, many patients reported hair loss in the axilla, which the female subjects actually appreciated. The side effect profile was similar to that seen in the IDE study, although one

patient reported a treatment-related triceps neuropathy, which was resolving at six months when she was lost to follow up. Clinical experience gathered since commercial release of miraDry confirms the results of these two published studies.

Most patients are quite satisfied with the treatment. It is clear that two treatments three months apart are required to obtain a lasting result. A small number of patients may benefit from a third procedure targeting resistant areas of persistent sweating. Although transient, altered sensation in the skin seen in some patients is the most significant potential side effect of treatment and appears to be related to the amount of energy delivered as well as to the thickness of the patient's skin. Very slender patients have a smaller tissue buffer between the treated dermal-fat interface and the underlying sensory nerves and may have a higher chance of experiencing altered sensation. Experienced users recommend decreasing the energy dose on the most peripheral portions of the axilla (especially on the arm side) in individuals with low body fat.

MiraDry is a fascinating new technology that promises to radically change dermatologists' approach to treating hyperhidrosis. ■

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