Best Practices for Treatment of Axillary Hyperhidrosis and Bothersome Underarm Sweating

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Introduction

Hyperhidrosis is a relatively common disorder characterized by excessive sweating and reduced quality of life.[1] Primary hyperhidrosis results from over-activity of the sympathetic nerves and most often involves 1 or more body areas, such as the axillae.[1] In the US, a recent survey showed approximately 4.8% of the population, or about 15.3 million people, have been diagnosed with primary axillary hyperhidrosis.[2] In Europe, similar estimates have been reported, with even higher rates in some regions.[2-6] Of affected patients, 70% report severe sweating on one or more areas, most notably the axillae.[2]

However, the true number of people bothered by underarm sweat may be much larger and is not well understood. A recent U.S consumer survey estimates that 37.3 million consumers identify as being bothered by sweat.[7] Roughly 75% of those identifying as sweat-bothered, have never discussed concerns about sweat with a physician, and therefore unaware of treatment solutions other than over-the-counter products. Results of the survey also revealed nearly half of those who sweat excessively find this to be an issue at work (44%) and in typical social situations (46%).

The excessive sweating of hyperhidrosis has a range of impact. For some people, the ability to engage in routine activities is impaired, adversely affecting mood and mental health.[3,6,8] One study found significantly higher rates of anxiety (21.3%) and depression (27.2%) in patients with hyperhidrosis compared to dermatologic patients with other conditions ($P<0.001$).[8] In fact, quality of life deficits in hyperhidrosis are comparable to those in other debilitating chronic diseases, such as psoriasis.[9,10] Patients who excessively sweat make conscious choices to hide their condition on a daily basis, including avoiding colorful clothing, investing in sweat-controlling clothing, and bathing multiple times a day. Despite the impact of excessive sweating on daily life, more than half of affected people do not seek treatment for the condition, often because they are unaware of treatment options.[2,3]

miraDry® for the Treatment of Underarm Sweating

Several treatments for hyperhidrosis have been developed.[11,12] However, most of these therapies provide only short-term relief or require invasive surgical procedures. In contrast, miraDry (miraDry Inc.; Santa Clara, California) is a non-surgical device that delivers precisely controlled microwave energy (5800 MHz) to the dermal-fat interface at a depth of 2-5 mm, where eccrine (sweat) and apocrine (odor) glands and hair follicles reside. Unlike other non-surgical modalities, such as botulinum toxin, miraDry destroys targeted sweat glands, providing a permanent reduction in underarm sweat for both axillary hyperhidrosis patients and those who are seeking a reduction to their bothersome sweat. A reduction in odor glands as well as hair follicles has also been demonstrated.[14]

In clinical trials, >80% of patients treated with miraDry achieved significant reductions in sweating and >90% were satisfied with the results after an average of two treatments.[13,15,16] In follow-up studies, results were sustained through at least 2 years.[13] Reductions in sweating have been associated with substantial improvement to quality of life, including less embarrassment and fewer disruptions to work and social activities.[13,15]

The miraDry system is the only FDA-cleared and CE-marked non-surgical device proven to effectively and safely reduce axillary sweat, odor, and hair.

The miraDry Procedure

The miraDry procedure consists of identifying the target area in the axillae (typically the hair-bearing area), administering high volume tumescent anesthesia, and using a template to guide delivery of microwave energy via the miraDry Handpiece. Each placement of the Handpiece delivers microwave energy for approximately 20 seconds. A ceramic cooling plate simultaneously cools the epidermis, preventing damage to the skin and restricting heat to the narrow zone where target glands are located (see Figure 1).

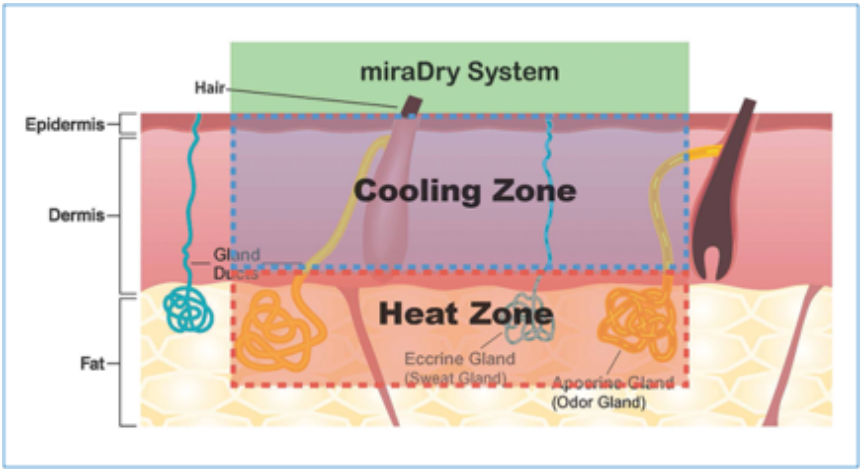

Figure 1: Microwave energy to dermal-fat interface with simultaneous cooling of the epidermis

The energy travels through the dermis in the form of heat. Once it contacts the fat layer, the heat "bounces" back to cause a focal heat zone. This focal heat zone is generally in the dermal-fat interface and those glands that reside in this region are destroyed. This treatment phase is then followed by an interim-cooling phase, the "post-cool period", during which the device continues to cool the skin without microwave heating for an additional 20 seconds, keeping the heat from rising to the epidermis.

Depending on the patient, there may be as many as 78 placements of the Handpiece bilaterally, each placement lasting approximately 40 seconds. The level of energy delivered can be adjusted from 1 (lowest) to 5 (highest) by the clinician; the higher the energy level, the longer the duration of energy delivery and the deeper the heat is penetrated into the skin to destroy glands. Energy levels can be chosen by the physician based on patient characteristics and level of sweat severity. During the clinical trial, an average energy level of 3 was used. Currently, most physicians use energy level 5.

Optimizing miraDry for Clinical Use

Dr. Wim Venema was the first European physician to utilize the miraDry System in 2014. Although previous clinical data demonstrated that an average of two treatments at energy level 3 was necessary to achieve optimal results,[13,15,16] the author identified a need to provide results with one treatment. During early adoption of the technology, the energy level was increased from 3 to 4 and observed that patients treated at energy level 4 often did not achieve the desired outcome after a single treatment. Histologic analysis of biopsy tissue following one treatment at level 4 showed destruction of eccrine glands in the lower dermis and fat but only partial damage to glands higher in the dermis. In addition, overall treatment time was noted to be lengthy (over 52 minutes) and added to clinician and patient fatigue. Total clinic room time can exceed 90 minutes to complete a single treatment due to preparation of the clinic room, administration of anesthesia, and number of placements for the given treatment area, etc.

Because the use of high volume tumescent anesthesia increases the distance between the epidermis and underlying structures, the author theorized that increasing energy delivery to level 5 for every patient during the treatment phase would provide greater destruction to the glands at a deeper depth. At the same time, by decreasing the post-cool period to less than 20 seconds, heat would rise to cause damage to sweat glands that may reside in the upper dermis and decrease overall procedure time. Therefore, by increasing the energy level and decreasing the post-cool period would enable the destruction of glands beyond the 2-5mm depth, thereby achieving optimal results with a single treatment.

A Study of Reduced Post-Cool Period

An informal evaluation of 182 patients using post-cool periods ranging from 0 to 20 seconds to reduce overall procedure time was performed. After energy delivery for a given placement, the Handpiece was purposely removed from the skin after the desired post-cool period was achieved. When evaluating 15, 10 and 5 second post-cool periods, the author noted side effects were as expected and similar to those evidenced in the clinical trial when utilizing energy level 3 with a 20 second post-cool. However, when evaluating 0 seconds of post-cool time, an increased incidence of minor superficial burns was noted.

Since overall side effects were similar when comparing the 15, 10 and 5 second post-cool periods within the first 79 patients, a continued series of 103 patients were treated using energy level 5 for the treatment phase followed by an average reduced post-cool period of 5 seconds to assess patient satisfaction and a reduction in procedure time. All patients were administered high volume tumescent anesthesia and no other aspects of the procedure were modified.

Results

One hundred and three patients were treated with energy level 5 and 5 second post-cool period during this informal evaluation. With the increased depth of delivery to the dermal-fat interface with the higher energy level and presence of heat in the upper dermis due to the shorter post-cool, over 80% of patients achieved satisfaction in only one treatment session. Two patients experienced minor burns and necrosis, which may have been due to damage to the epithelial layer. Some patients reported a slight burning sensation, similar to a mild sunburn, post procedure which was managed by normal post procedure protocol of icing and over-the-counter ibuprofen as needed. Other side effects of the treatment were similar to those reported during the previous clinical trial as well as the 15 and 10 second post-cool periods. Duration of post-procedural recovery (approximately 24 hours when returning to daily activities) was also unaffected. Patients reported high levels of satisfaction with their results of reduced sweating with the treatment.

Another improvement using this modified post-cool is the reduction in overall procedure time. Table 1 provides time savings for treatment sizes.

Template size	Time saved for each post-cool period (minutes) when compared with 20 seconds		
	15 sec	10 sec	5 sec*
50x100 60x100	3	7	10
50x120 60x120	4	8	12
60x140	5	9	14
70x100	4	8	13
70x120	5	10	15
70x140 80x120	6	12	18
80x140	7	13	20*

Table 1: Time saved (in minutes) with “post-cool” periods of 15, 10, and 5 seconds, compared to 20 seconds, based on template size.

The actual treatment time when using the 20 second post-cool can be over 52 minutes, with overall clinic time being 90 minutes or more. Since the post-cool period is decreased by 75% (from 20 seconds to 5 seconds), it decreases the overall treatment time, allowing clinicians to perform this entire treatment within 60 minutes. Even when utilizing the 10 second post-cool, the reduction to treatment time is still significant at a 13 minute time savings. Being able to administer the treatment in about 60 minutes is a significant improvement for the miraDry procedure.

Conclusion

There are a significant number of patients suffering from axillary hyperhidrosis and bothersome sweat. These patients often do not seek a solution nor are they aware that a permanent solution exists. Providing the miraDry procedure enables patients to no longer worry about their bothersome sweat. By utilizing the highest energy setting (level 5) and a 5 second post-cool, patients can expect significant sweat reduction in as little as one treatment, with a significant time savings for the clinician. Although the use of the 5 second post-cool is safe, the 10 second post-cool has less potential to cause epithelial damage and may be the optimal approach. The 10 second post-cool decreases the procedure time and still enables the clinician to administer miraDry to patients within an hour. The decrease in treatment time benefits both the patient and clinician, while still providing high patient satisfaction. Therefore, this treatment regimen is a significant improvement and is recommended when administering miraDry.

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