

WHITE PAPER

Treatment of Hyperhidrosis and Axillary Glands with Unique Targeted Laser Energy Through SideLaze800™ Delivery System

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BACKGROUND

Hyperhidrosis, commonly known to as excessive underarm sweating, causes significant impairment of an individual's daily activities and emotional well-being. Multiple studies have established the psychosocial burden of excessive sweating and its negative impact on quality of life.¹⁻⁵ In addition; the risk of cutaneous infections caused by bacterial, fungal and viral pathogens is substantially increased at affected body sites.²

Hyperhidrosis 2.8% of the world's population (7.8 million individuals) and it is estimated that this condition effects over 1.4% of the U.S. population, representing more than four million individuals, a prevalence comparable to that of psoriasis.^{3, 4}

Affected people are constantly aware of their condition and try to modify their lifestyle to accommodate this problem. This can be disabling in professional, academic and social settings, causing profound embarrassment. Many routine tasks become impossible chores, which can psychologically drain the individual. It is found slightly more frequently in females than in males and most often occurs before the age of 25.

First-line medical therapy employs the use of topical agents such as aluminum chloride (AC). However the effectiveness of topical AC is quite variable, long-term application is required and local irritation (erythema, stinging, burning) can be a limiting factor (compliance) for many patients, due to the highly acidic nature of AC.⁴

Botox injections are effective with results lasting six months.⁶ However, pain associated with the

injection, repeated treatments and cost are major limitations. Other treatments include curettage⁸, liposuction, and open or endoscopic thoracic sympathectomy.⁹ Each treatment presents advantages and limitations that include both compensatory sweating and recurrence.¹¹

Only a few instances of laser therapy used for the treatment of Hyperhidrosis have been published. Goldman and colleagues reported in their study that 82% of patients were assessed as experiencing good to excellent results by the physicians' global assessment scale, using Minor's Iodine Starch Test. Seventeen patients between the ages of 17 and 54 were treated utilizing a 1064nm Nd:YAG laser with subdermal laser irradiation. Postoperative histologic examination showed a mild to more pronounced alteration of the eccrine glands, from microvesiculation and decapitation to complete vaporization.⁵

The following case report discusses a new minimally invasive approach and proof of concept for the treatment of Hyperhidrosis that utilizes a unique and focused delivery method to target and ablate the function of the eccrine glands within the axillae. This concept is now being validated in a fifteen patient IRB controlled study in which treatments have been completed and follow-up assessments are being made at three, six, nine, and twelve months. The results of this study will be presented at industry meetings and submitted for peer review publication.

PATHOGENESIS

The primary function of the eccrine unit is thermoregulation, which is accomplished through the cooling effects of the evaporation of sweat on the skin's surface. In the case of Hyperhidrosis and excessive sweating, the condition occurs in amounts greater than physiologically needed for thermoregulation. Eccrine glands begin to form in the fourth month of gestation, as a down growth of the epidermis, and are responsible for the generation of sweat. They are distributed throughout the body, and the highest density of eccrine glands is seen on the palms and soles in addition to in the axillae.⁷

Patients with excessive sweating do not demonstrate any changes in size of the sweat glands or changes in their numbers. Up to two thirds of patients report a family history of the disorder, suggesting that a genetic predisposition may exist.

The eccrine glands are innervated by the cholinergic fibers of the sympathetic nervous system. A complex dysfunction in the sympathetic system which hyperstimulates the eccrine glands likely contributes to the cause.³

The eccrine duct extends upward and opens directly onto the skin. Eccrine sweat is composed primarily of (hypotonic saline) water, sodium, potassium, urea and ammonia.

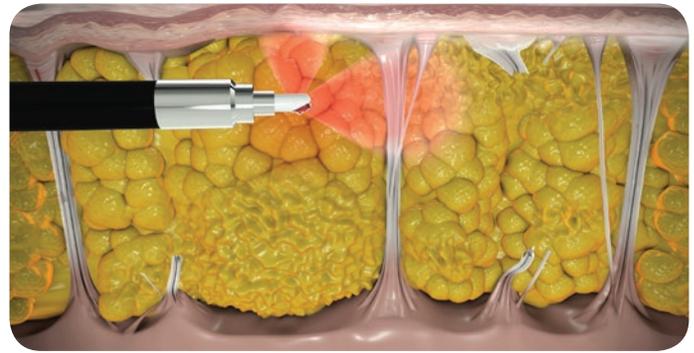


Figure 1.

METHODOLOGY

Previous studies have demonstrated the effects of delivering thermally controlled laser-assisted energy subcutaneously as being safer and more effective for the treatment of the sweat glands associated with Hyperhidrosis.¹ The purpose of this study was to evaluate the efficacy and safety of the pulsed, Nd:YAG 1440nm wavelength, with a unique delivery system (SideLaze800™, Cynosure, Inc., Westford, MA). The specific wavelength (1440nm) and its high affinity for absorption in water, as well as the specially designed directional fiber tip, allow the laser energy to be directed in a targeted and specific direction to the eccrine gland. Refer to Figure 1. The ThermaGuide™ integrated temperature monitoring system was utilized for more effective distribution of laser energy and safety. The ThermaGuide system will immediately stop distribution of laser energy when target subdermal skin temperatures are reached.

The SideLaze800 side-firing fiber has been cleared for the surgical vaporization and ablation of soft tissue, including subcutaneous tissue and glands.

Before treatment, the patient was asked a series of questions regarding prior treatment for axillary sweating and their personal estimation of the severity of this condition using a scale associated with Hyperhidrosis, the

Question: How would you rate the severity of your sweating?	Score
My underarm sweating is never noticeable and never interferes with my daily activities.	1
My underarm sweating is tolerable but sometimes interferes with my daily activities.	2
My underarm sweating is barely tolerable and frequently interferes with my daily activities.	3
My underarm sweating is intolerable and always interferes with my daily activities.	4

Table 1. Hyperhidrosis Disease Severity Scale (HDSS)

Hyperhidrosis Disease Severity Scale. The *Hyperhidrosis Disease Severity Scale* (HDSS) is a diagnostic tool that provides a qualitative measure of the severity of the patient's excessive sweating based on how it affects daily activities.

The patient is asked to select a statement that best reflects his or her experience with sweating in the specific body area. Next to each statement is a number (see Table 1). These numbers indicate how responses should be scored. A score of 3 or 4 indicates severe excessive sweating. A score of 1 or 2 indicates mild or moderate excessive sweating. A 1-point improvement in HDSS score has been associated with a 50% reduction in sweat production and a 2-point improvement with an 80% reduction.³ The validity and reliability of the HDSS has been analyzed using three studies which showed a strong to moderate correlation with the *Hyperhidrosis Impact Questionnaire* (HHIQ), *Dermatology Quality of Life Index* (DLQI), and gravimetric sweat production measurements.³

Secondly, a Minor's Starch Iodine Test was performed prior to treatment. All tests were performed by a single examiner in the same room at a constant temperature of 75° F. A 10% povidone iodine antiseptic solution was applied to both axillae and allowed to dry for five minutes. Cornstarch powder was then brushed onto this area and any excess starch was brushed away. After 15 minutes, the regions were photographed.

The test was noted to be positive if the light brown color turned dark purple when the iodine starch complex formed in the liquid medium, as the eccrine sweat came to the surface of the skin. High-resolution digital photographs were taken as a pre-operative record of the affected area and again at three, six, nine and twelve months post-treatment to gauge the response to the treatment. The photographs were taken using the same camera, same background and same lighting and exposure conditions to provide maximum test detail and minimize the potential for bias in evaluating results. A ruler was placed adjacent to the treatment area in each photograph.

A centimeter scale was then used to calibrate the images. All photos were cropped to remove the scale for analysis purposes. All photos representing the area to be analyzed were cropped to 7½ cm by 7½ cm and maintained similar pixel dimensions. In order to determine quantitative improvement, image processing and analysis software (Image J Software, <http://imagej.nih.gov/ij>) was used to estimate the surface area of the dark iodine stain both before and after surgery. This was calculated using an intensity threshold of the calibrated image and the post-operative reduction in the surface-area was then calculated.

In addition, the photographs were assessed by the physician and graded from poor to excellent as outlined in Table 2, and the patient was provided with a patient diary to monitor postoperative side effects.

PHOTOS –MINOR'S STARCH IODINE TESTS

- Dark areas: Area of excessive sweating and location of sweat glands
- Red areas: Digital marking of excessive sweating area used for quantitative calculation of sweat reduction through imaging software

Left Axilla

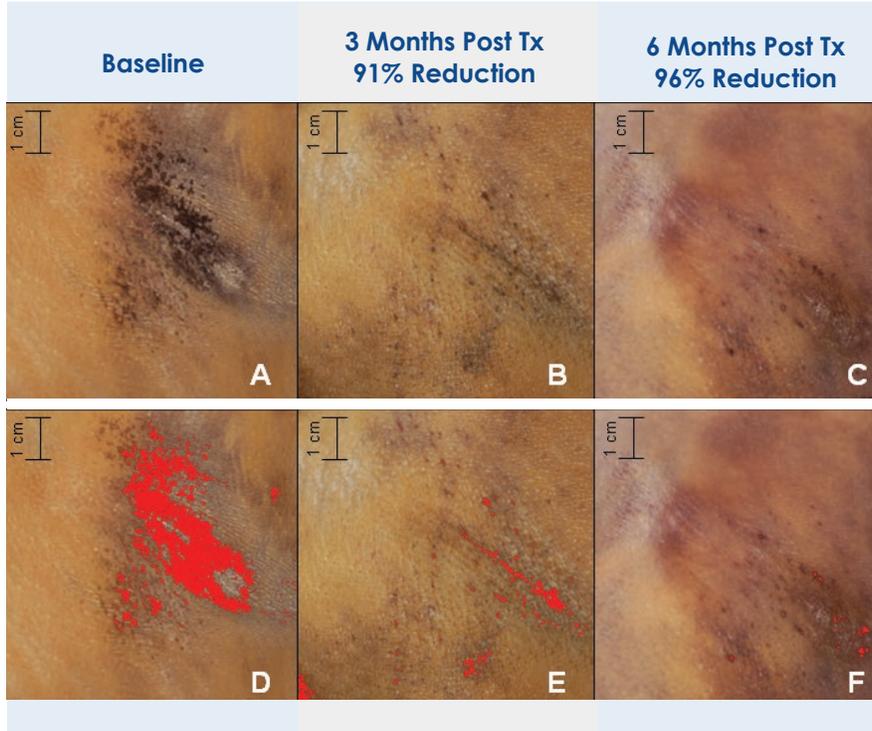


Figure 2

Right Axilla

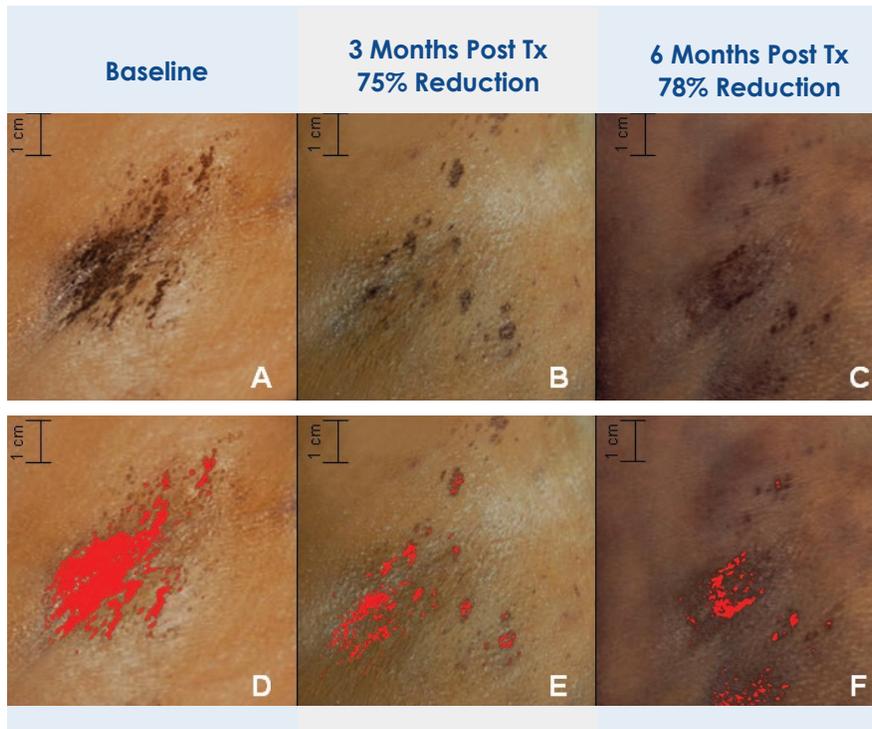


Figure 3

Improvement	% of Sweat Elimination
Poor	0% to 25%
Fair	26% to 50%
Good	51% to 75%
Excellent	More than 75%

Table 2. Physician Assessment Scale

CASE REPORT

Subject # 1

A 31-year-old Caucasian female presented with a history of Hyperhidrosis, first noted at the age of 18. Her self-assessed HDSS score was rated as a 4, which indicated her underarm sweating was intolerable and always interfered with her daily activities. She had been treated during the past eight years with 100 units per axilla of Botox at each visit with moderate success. She expressed frustration at the need for repeated Botox treatments and the associated cost. We suggested the ablation of sweat glands associated with Hyperhidrosis using the SideLaze800 delivery system. The patient's last Botox treatment was more than six months previous to undergoing this procedure.

Prior to the procedure, the Minor's starch iodine test was once again performed to reconfirm the degree of sweating and outline the location of the eccrine glands. Starch was applied followed by 10% iodine solution and left for 15 minutes at a room temperature of 75°. After 15 minutes, photos were taken (see Figure 2 and 3).

The area was then cleansed with saline solution and re-prepped with Betadine. The treatment area had been marked based on the results of the starch-iodine test. The patient was given 10 mg of valium orally as a pre-operative sedative with a sip of water. A total of 300 cc's of tumescent anesthesia was then administered to the right axilla area and 350 cc's to the left axilla.

The laser was set to 5 watts of 1440nm wavelength at 25hz, with a ThermaGuide endpoint temperature set at 43° C. The starting internal temperature, as indicated by the ThermaGuide, was 29° C. The energy delivery system utilized a unique SideLaze800, side-firing fiber, designed to target laser energy to the deep surface of the dermis. The cannula was introduced through two stab incisions to allow crisscrossing of the surface area being treated.

Each axilla within the marked area received 2000 joules of energy delivered superficially. The endpoint was a lack of tissue resistance and clear cavitation separating the subdermal tissues from the dermis. The endpoint internal temperature, as measured by the ThermaGuide, was 37-38° C. The patient did not experience any discomfort.

When the laser treatment was completed, any remaining fluid was manually rolled out through the incision sites. To allow for drainage, incision sites were not sutured. A light dressing was then applied to the treated area. The procedure, including tumescent administration, lasted approximately one hour. Lasing time for both axilla totaled twenty minutes. The patient was instructed not to use deodorant or to shave the area until the incision sites were healed and closed, which normally occurred within a few days.

RESULTS

To date, the patient has been seen at one week, three months, and six months. The patient felt that the procedure was easily tolerated with minimal postoperative discomfort, as indicated in the one-week patient diary. At the one-week follow-up, the surgical site showed no sign of infection and minimal edema. Physician assessment of the treatment was rated excellent.

At three months, the patient has reported a 90% reduction of sweat in the axillary areas. Her HDSS score went from a 4 (My underarm sweating is

intolerable and always interferes with my daily activities) to a score of 1 (My underarm sweating is never noticeable and never interferes with my daily activities). Patient reports her quality of life has significantly improved.

The image processing analysis of the Starch iodine tests confirmed the patient's assessment of improvement. The right axilla showed a 75% sweat reduction and the left axilla showed a 91% reduction at month three (see Figures 2 and 3).

At six months post-treatment, the patient continued to report a reduction in axillary sweating, with no recurrence. Quantitative calculation of the digital imaging showed a slight improvement from month three, increasing to a 78% improvement of the right axilla and 96% for the left. Patient is now able to control axilla perspiration through standard OTC antiperspirant. The patient will return for follow-up assessments at the ninth and twelfth months.

DISCUSSION

Hyperhidrosis can be a disabling condition for many. Treatment options vary from conservative approaches, which are limited by duration of effect (Botox), to surgical measures: curettage and thoracic sympathectomy, with considerable side-effects and variable efficacy (recurrence and compensatory sweating respectively). The goal of this case study was to develop a minimally invasive approach to thermally target the

eccrine glands using a highly specific delivery method. This proof of concept case study demonstrates the success of our approach to date. This case study is now being followed by an IRB-approved 15 patient study to treat patients with a HDSS score of 3 or 4 in order to further validate this minimally invasive technique. All patients have completed the procedure and are being followed for a twelve month period.

Today the treatment options for Hyperhidrosis are (1) non-invasive methods such as topical antiperspirants containing aluminum chloride, which require repeat treatments and limited efficacy; (2) Botox, which requires repeat treatments every six to eight months and is costly when considering a lifetime of treatments; and (3) surgical options such as curettage, which reports a recurrence rate up to 23.8% by six months, and endoscopic thoracic sympathectomy, which reports a 63% satisfaction or control rate with a 52.3% incidence of compensatory sweating—and require a significant and invasive surgical procedure.¹⁰

As discussed by Larson “The ideal procedure should permanently relieve the problem, be minimally invasive, simple, and predictable: and have minimal morbidity and scarring.”¹⁰ Precise and targeted delivery of subcutaneous laser energy to the subdermal layer of the axilla appears to meet these criteria and represents a viable option for the treatment of sweat glands associated with Hyperhidrosis.

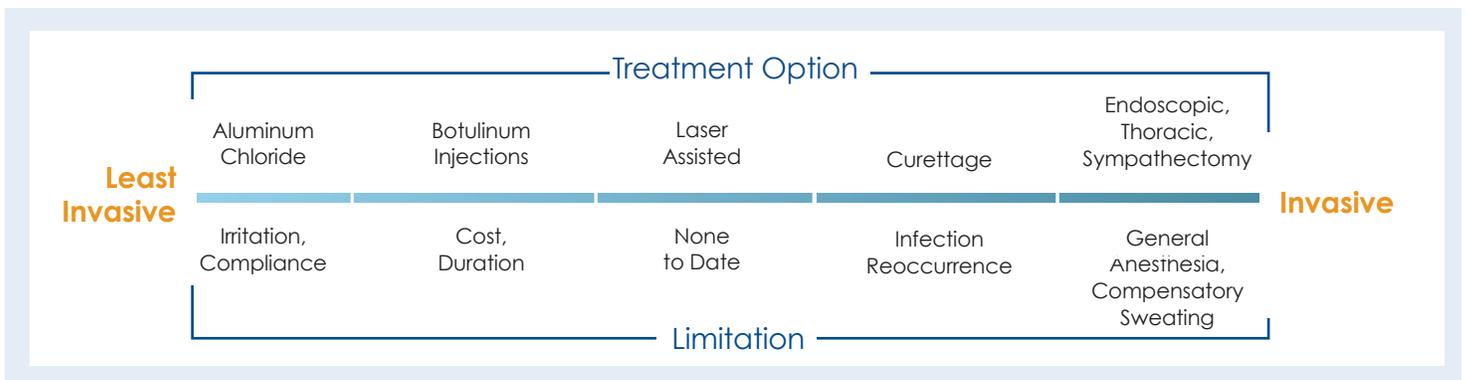


Figure 4 Treatment Approaches for Excessive Sweating

CONCLUSION

Early results indicate that the pulsed, side-firing, Nd:YAG 1440 wavelength, delivered through the SideLaze800 delivery system, is an effective tool in the treatment of sweat glands associated with Hyperhidrosis. Additional studies are recommended and in process.

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