

miraDry[®]fresh

CLINICAL STUDIES OVERVIEW

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Topics



- How did we measure sweat reduction?
- Two main clinical studies for underarm sweat
 - Randomized: FDA approval study, Gen 2 device
 - Commercial: Canada Study, Gen 3 device
- Clinical Study for hair reduction
- Common Questions

How did we measure sweat reduction?

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HDSS for Efficacy

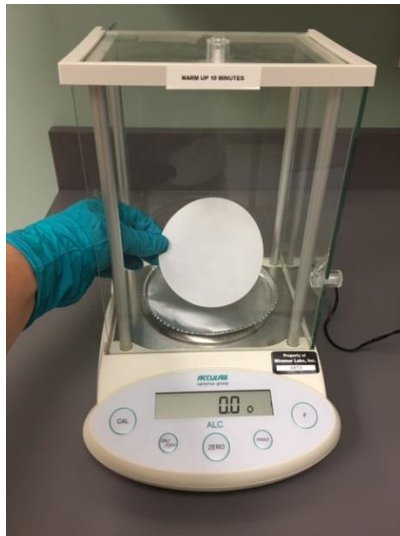
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Hyperhidrosis Disease Severity Scale (HDSS)

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

- Subjects enrolled had HDSS of 3 or 4
- At follow up visit, subjects must have had HDSS of 1 or 2 to be considered successful (or efficacious)

Gravimetric Assessment



- **“Objective” measure of sweat production**
- Pre-weighed filter paper is placed under each arm for 5 minutes
- Filter paper is weighed and difference in results give amount of sweat produced
- Subjects must produce 50mg of sweat to be enrolled in study

Starch-Iodine Test

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- Swab axilla with alcohol-based iodine solution
- Sprinkle corn starch on the area; gently brush away
- Areas of wetness (sweat) turn black
- Used in clinical studies, sometimes to locate particular areas of sweat for touch-up.

Dermatology Life Quality Index (DLQI)



DERMATOLOGY LIFE QUALITY INDEX			DLQI
Hospital No:	Date:	Score:	<input type="text"/>
Name:	Diagnosis:		
Address:			
<p>The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.</p>			
1.	Over the last week, how itchy, sore, painful or stinging has your skin been?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
2.	Over the last week, how embarrassed or self conscious have you been because of your skin?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
3.	Over the last week, how much has your skin interfered with you going shopping or looking after your home or garden ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
4.	Over the last week, how much has your skin influenced the clothes you wear?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
5.	Over the last week, how much has your skin affected any social or leisure activities?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
6.	Over the last week, how much has your skin made it difficult for you to do any sport ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
7.	Over the last week, has your skin prevented you from working or studying ?	yes no	<input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
	If "No", over the last week how much has your skin been a problem at work or studying ?	A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/>
8.	Over the last week, how much has your skin created problems with your partner or any of your close friends or relatives ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
9.	Over the last week, how much has your skin caused any sexual difficulties ?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>
10.	Over the last week, how much of a problem has the treatment for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all	<input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> Not relevant <input type="checkbox"/>

Please check you have answered EVERY question. Thank you.

- Highly validated
- Used for many dermatologic conditions. Psoriasis = 10.5, Severe acne vulgaris = 7.5
- 10 questions that cover all aspects of quality of life
- Scores range from 0 (no problem) to 30 (huge problem)

Evolution of miraDry Technology Used in Studies



Gen 1

Tx small areas



Gen 2

Tx full axillae

Randomized study



Gen 3

Tx full axillae; optimized procedure and device

Commercial study

Clinical Data



Peer-Reviewed Publications



- Glaser et al Derm Surg 2012 (Feb)
 - **Randomized** study for FDA clearance
- Hong et al Derm Surg 2012 (May)
 - **Commercial** device study for efficacy
- Lupin et al Derm Surg 2014 (July) –
 - **2 year data from Commercial** device study
- Brauer et al Derm Surg 2016 –
 - **1 year data** – Prospective multi center study

Sweat Reduction



Randomized Study

- Glaser et al – FDA Approval Study
- Conducted from May 2009 to Nov 2010
 - 120 subjects, 7 sites (all in US)
- Randomized
 - 81 subjects treated
 - 39 received sham treatment (everything but energy delivery)
- Used Investigational (Gen 2) system and ONE device setting (equivalent to EL 1 on current system)
- Data was key part of 510(k) FDA clearance K103014

Sweat Reduction



Randomized Study – 12 Months Results

HDSS Efficacy

69%

Gravimetric
Efficacy
>50% reduction

78%

DLQI
Satisfaction

71%

Sweat Reduction



Commercial Study

- Conducted from Feb 2010 to Nov 2010
 - 31 subjects, 2 sites (Dr. Mark Lupin and Dr. Chih-ho Hong)
- Non-Randomized (one to three treatment sessions)
- Used Gen 3 miraDry system
- All subjects completed 12 month visit in original study
- A separate follow-on study tracked 18 patients (via web survey for an additional year)

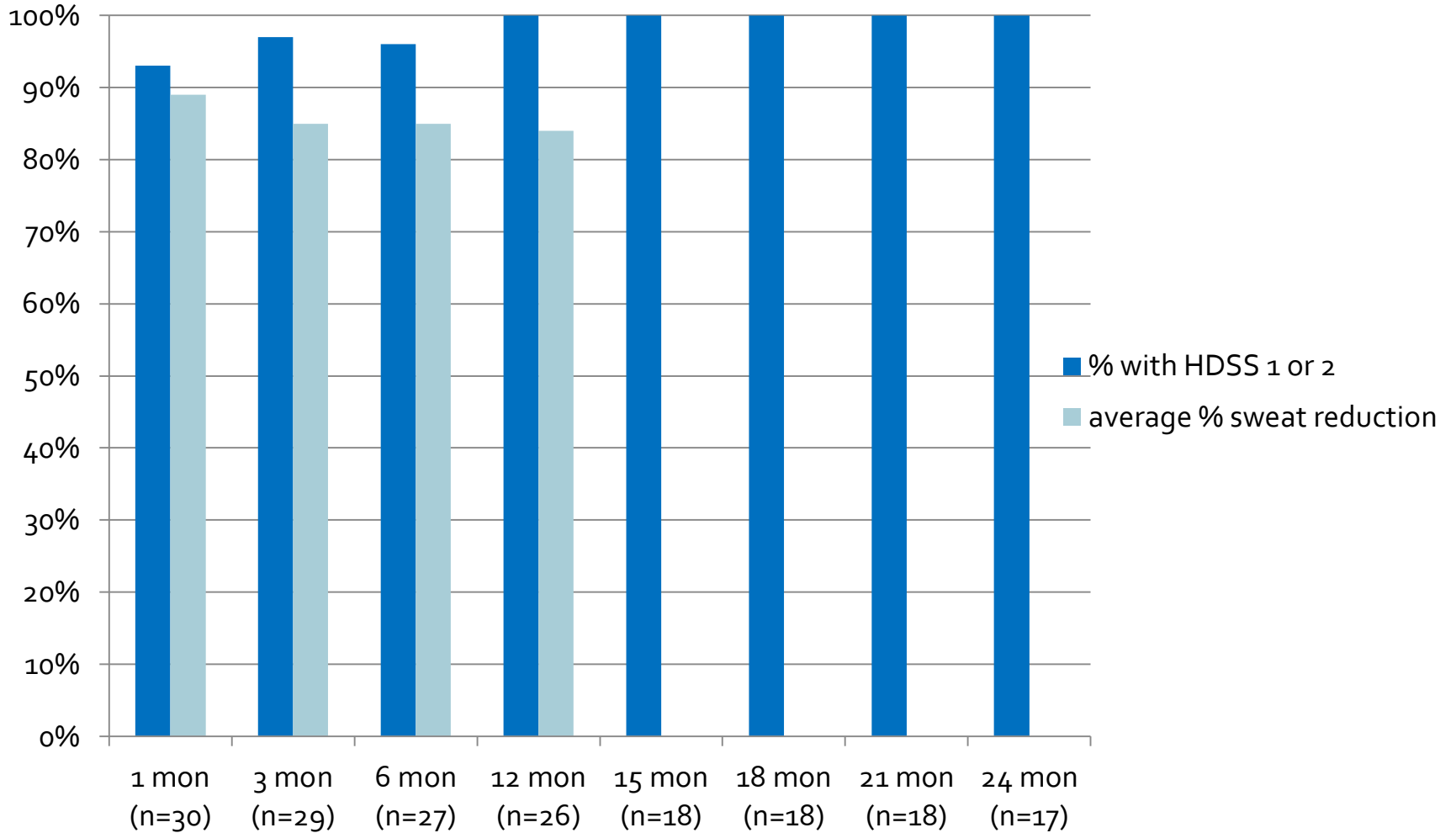
**12 month data
published May 2012**

**24 month data
published July 2014**

Sweat Reduction



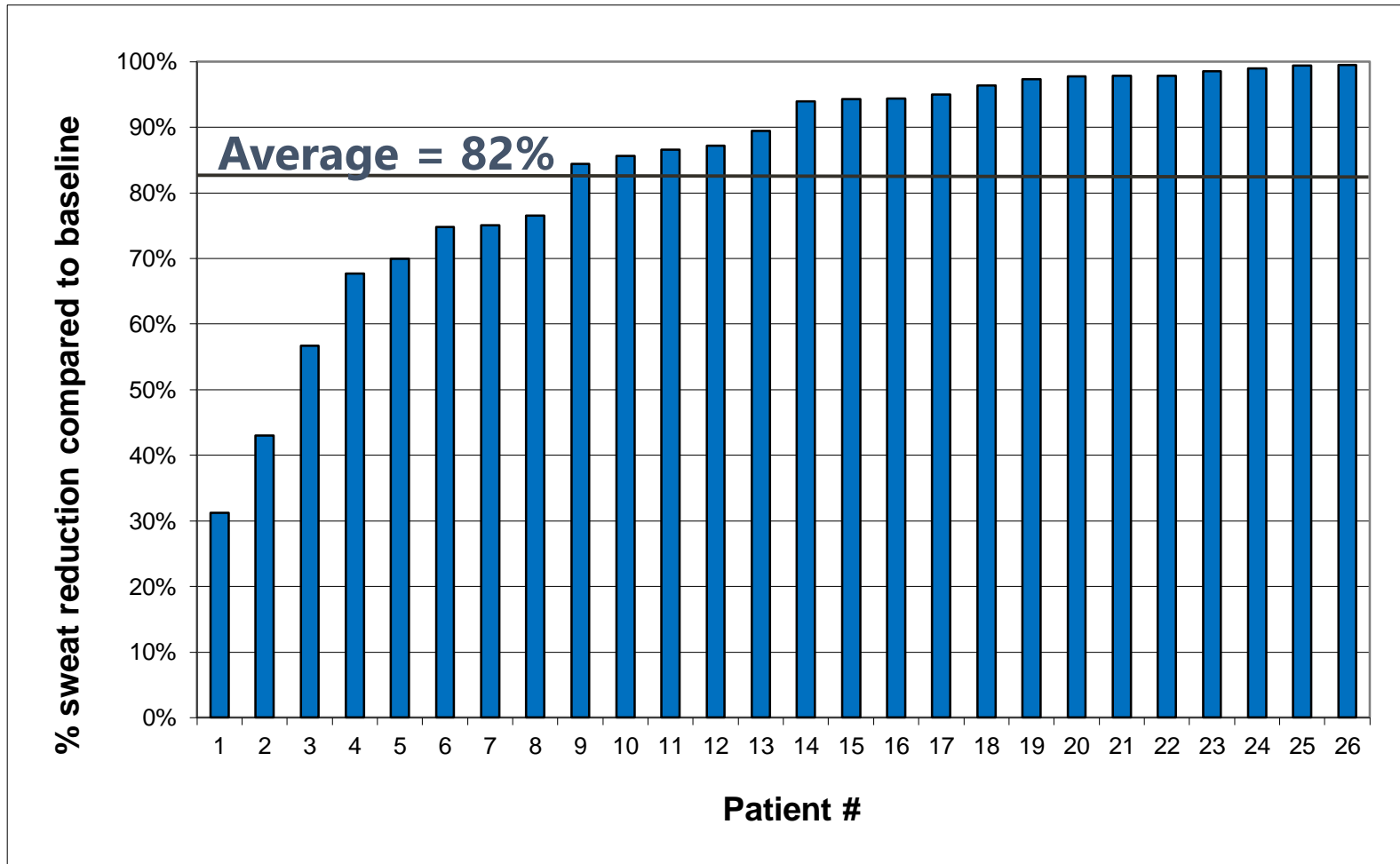
Commercial Study – Gravimetric and HDSS



Sweat Reduction



Commercial Study – More Detailed Gravimetric



Sweat Reduction



Commercial Study – 12 Months Results

HDSS Efficacy

90%

Gravimetric
Efficacy
>50% reduction

90%

*82% Average Sweat
Reduction*

DLQI
Satisfaction

90%

Hair Reduction

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A Prospective Study of Axillary Hair Reduction in Patients Treated with Microwave Technology

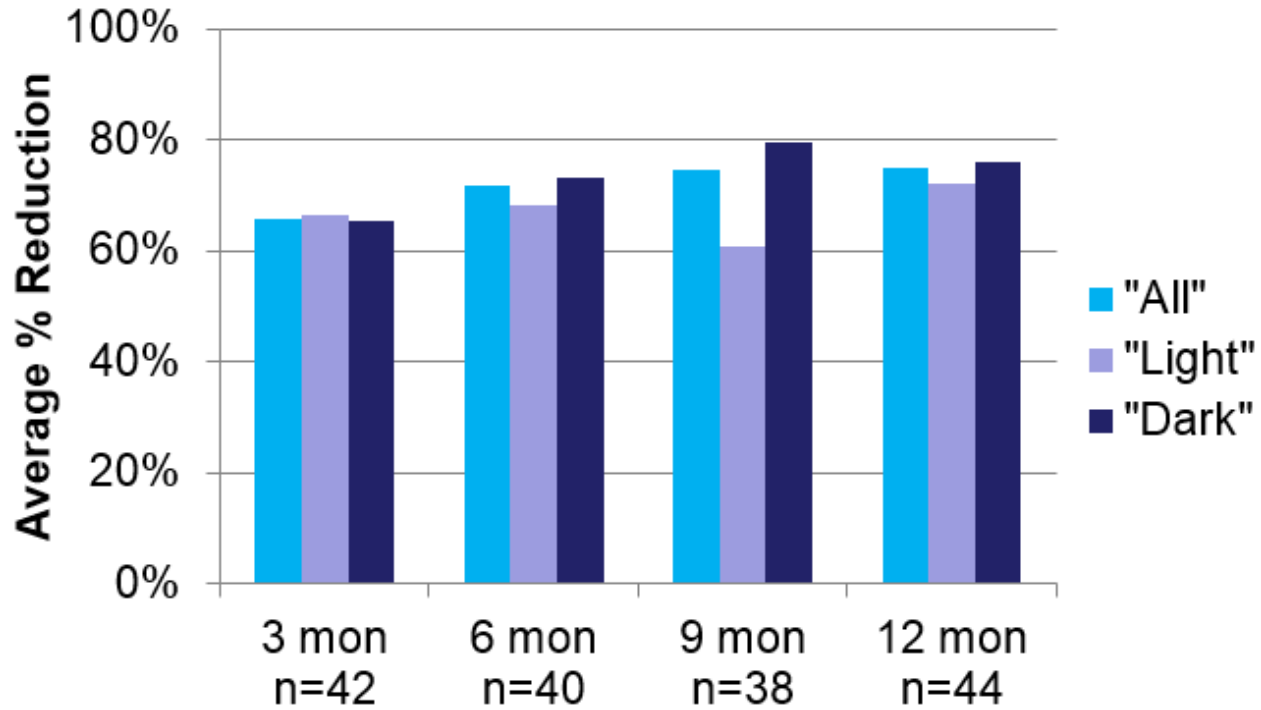
-Brauer et al

- Prospective multi-center study
- Population: 56 patients
 - 80% female
 - Average age 32.5
 - 62% darker hair color
- One or two treatment sessions at various energy levels
- Follow-up: Hair reduction at 3, 6, 9, 12 months post treatment follow-up visit
- Helped to acquire the FDA indication for hair reduction for miraDry device

Hair Reduction



Quantitative Assessment

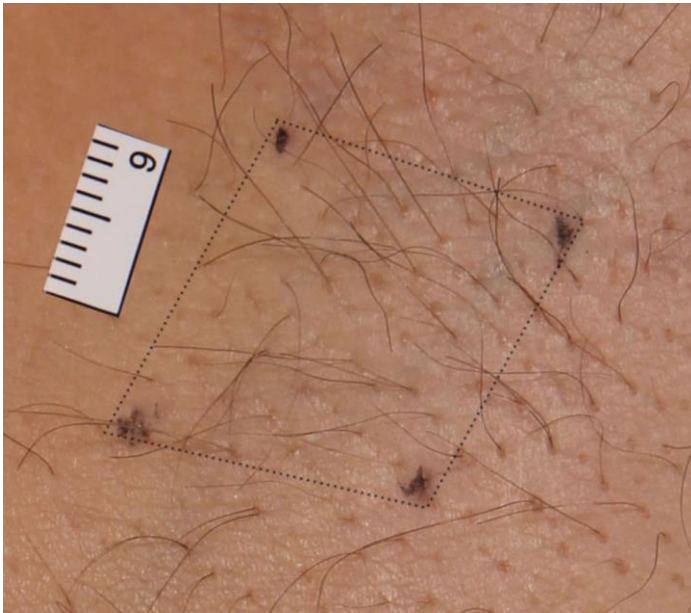


Average reduction was approx 70% independent of hair color

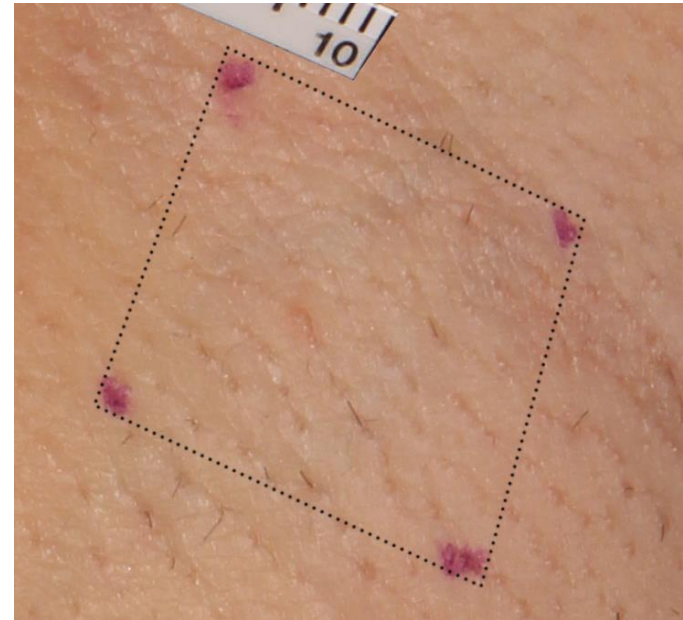
Hair Reduction



Quantitative Assessment



Baseline



12 month follow-up; 84%
reduction

Hair Reduction



Side-by-side Analysis



Baseline



1 year post Tx

Hair Reduction



Results Summary

Quantitative

Hair reduction
at 12 months

74.9%

Average

Qualitative

Side-by-side
analysis

70%

Approximately

Common Questions



Common Questions



- **How long does the effect last?**
 - Histology shows that the sweat glands are destroyed; sweat glands don't grow back. Our studies show stable efficacy results at 12 and 24 months.
- **How can you say “90% clinically effective”?**
 - Data presented (Hong + Lupin publications) from Canadian study shows 90% efficacy across multiple measures (HDSS, Gravimetric....). Patient satisfaction is also at 90% or better.
- **Does this work better on one group compared to another?**
 - The treatment seems effective across a wide variety of patients. We've tested men, women, older, young adults....We haven't seen a group where it clearly does not work.

Common Questions



- **Have you tested the device on men? Ethnicities besides Caucasian?**
 - In our clinical studies, about 40% of the patients treated were men. They seem to see the same high level of efficacy.
 - Our clinical study enrollment has typically been mostly (85%) Caucasian, but we have treated African American, Asian, and Hispanic patients.

- **How do your results compare with Botox?**
 - The primary Botox publication (Lowe et al) provides the data that 75% of treated subjects had a 2 or more point drop on the HDSS scale, compared to 25% in the placebo group – a difference of 50%.
 - For our randomized study, the numbers are 67% for the treated group and 13% for the sham treatment group – a difference of 54%.
 - More importantly, that publication showed that the mean duration of effect for Botox was 6.7 months; our randomized study data shows that we have a stable effect out to 12 months.
 - We might not get someone “bone dry” – but the effect we provide lasts.

Common Questions



- **What kind of safety data do you have?**
 - Over 100,000 treatments worldwide with an excellent safety record.
 - In our clinical studies, we have shown that almost all subjects experience mild side effects in and around the treatment area: edema, discomfort, tenderness, some bruising.
 - Canada study data:
 - Side effects were generally mild (88% of AEs)
 - Adverse events were seen in half (61%) of the patients
 - All resolved or were resolving when the subject left the study
 - Physician has some flexibility to tailor the treatment (energy setting or treatment area) to trade off side effects and efficacy; part of training and miraDry certification