# Outcomes from the SAHARA Clinical Study on the TAT Patch for Excessive Axillary Sweating or Primary Axillary Hyperhidrosis.

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## Background

One-third of U.S. adults are bothered by excessive sweating and ~5% have hyperhidrosis. However, data shows that 58% of adults who have this condition have never spoken to a healthcare provider about it and ultimately only 18% are actually diagnosed[2]. Thus, the majority of cases (82%) are undiagnosed and there is a lack of recognition of hyperhidrosis as a medical condition and an inadequate realization that treatment options exist[2]. Awareness and innovation in this field are therefore warranted. To this end, the technology of Targeted Alkali Thermolysis (TAT) technology has been developed as a novel approach for sweat reduction.

The Sahara Study was a randomized, double-blind, sham-controlled pivotal study to evaluate an investigational TAT patch for treatment of excessive axillary sweating or primary axillary hyperhidrosis.

## Methods

110 adults with Hyperhidrosis Disease Severity Scale (HDSS) scores of 3 or 4 and Gravimetric Sweat Production (GSP) greater than 50mg/5minutes were treated bilaterally with either an active (TAT) or sham patch for up to 3 minutes.

HDSS, GSP, and Quality of Life Assessments (QoL) for Degree of Bother from sweating and Level of Impact of Sweating on daily activities and were measured through 12-weeks and responders were followed for up to 24 weeks.

## Results

No serious or severe adverse events (AEs) were reported at any time for any subject. All reported AEs for subjects treated with the TAT Patch were mild to moderate and most resolved within 2 weeks.

All endpoints were assessed at 4-weeks. 64% of active (n=44) vs 44% of sham (n=43) subjects improved to HDSS 1 or 2 (p=0.0332), and 43.2% of active vs 16.3% of sham (p=0.0107) subjects achieved a 2-point HDSS improvement.

60.5% of treated subjects showed a ≥50% reduction in GSP with a mean GSP reduction of 46% for active and 17% for sham subjects.

Finally, treatment success is measured not only by objective means, but ultimately by the improvement the treatment makes in a person's quality of life. Therefore, we also evaluated (on a scale of 1-5) how much the patients' sweat bothered them and the impact that their sweating had on daily activities. The results showed that the Degree of Bother was reduced by 1.52 points for active subjects vs. 0.61 points for sham subjects (p=0.0005). Level of Impact was reduced by 1.44 points vs. 0.57 points (p=0.0004) in the active and sham groups respectively.

All subjects were followed for 12 weeks and responders were followed for up to 24 weeks after treatment. The follow-up data showed that the sweat reduction lasts for approximately 3 months, with some patients lasting longer. **Specifically, 48% of subjects treated with the TAT Patch were still responding at 14 weeks and 43% were still responding at 16 weeks.**

## Conclusion

The SAHARA clinical study establishes the safety and efficacy of the novel TAT patch in offering an innovative treatment option for sweat reduction after one treatment that last approximately 3 months.

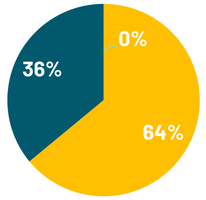
## Hyperhidrosis Disease Severity Scale (HDSS)

**How Would You Rate the Severity of Your Hyperhidrosis?**

| Score | Patient Response | Clinical Interpretation |
|---|---|---|
| 1 | My sweating is never noticeable and never interferes with my daily activities | Mild |
| 2 | My sweating is tolerable but sometimes interferes with my daily activities | Moderate |
| 3 | My sweating is barely tolerable and frequently interferes with my daily activities | Severe |
| 4 | My sweating is intolerable and always interferes with my daily activities | Very severe |

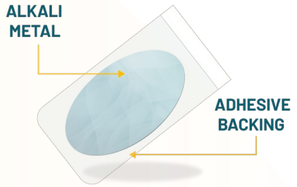
**Brella™ Duration of Effect is 3 to 4 months**

## Adverse Event Severity




■ Mild ■ Moderate ■ Severe

## Brella™ SweatControl Patch™




## Adverse Event Summary

| | % Subjects |
|---|---|
| **NO ADVERSE EVENT** | |
| All Subjects | 83% |
| TAT Patch Subjects | 75% |
| **SERIOUS ADVERSE EVENT** | |
| All Subjects | 0% |
| TAT Patch Subjects | 0% |

## DURABLE RESULTS: Subjects Maintained HDSS 1 or 2

**Percentage of Subjects Still Responding to N-SWEAT Treatment**

| Week Since Treatment | N-SWEAT Treated (N=44) |
|---|---|
| 12 | 47.7% (32.5, 61.5) |
| **14** | **47.7% (32.5, 61.5)** |
| **16** | **43.0% (26.9, 58.0)** |

## References

[1] Glaser DA, Hebert A, Pieretti L, Pariser D. Understanding Patient Experience With Hyperhidrosis: A National Survey of 1,985 Patients. J Drugs Dermatol. 2018;17(4):392-396.

[2] Doolittle J, Walker P, Mills T, et al. Hyperhidrosis: an update on prevalence and severity in the United States. Arch Dermatol Res 308, 743–749 (2016). https://doi.org/10.1007/s00403-016-1697-9.

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