

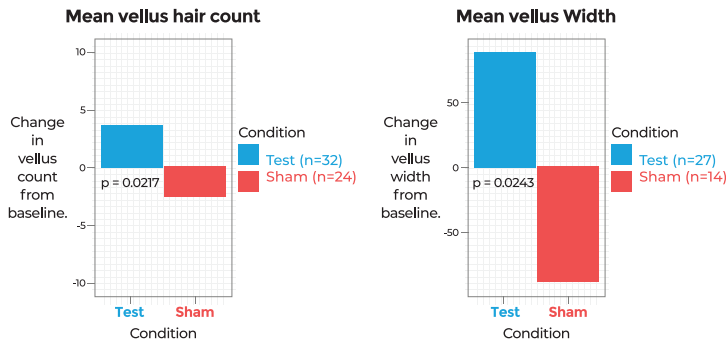
Theradome LH80 PRO Clinical Study Hair Growth Results

Study Overview

A multicenter, randomized, double-blind, sham-controlled clinical trial was conducted to evaluate the efficacy and safety of the Theradome® LH80 PRO for men experiencing androgenetic alopecia (male pattern hair loss).

The study was conducted across four independent U.S. research centers and was approved by an Institutional Review Board (IRB). Participants used either the Theradome laser device or a visually identical sham device containing red LEDs.

All Subjects (Norwood II-IV)



Trial Design

- **Participants:** 49 men randomized
 - 27 received Theradome LH80 PRO
 - 22 received Sham (LED-based placebo) device
- **Duration:** 26 weeks
- **Usage:** Participants used their assigned device twice per week for 20 minutes per session.
- **Measurements:** Changes in hair count and thickness were evaluated using HairCheck® assays and standardized global photographic assessments.

Key Findings

- All Theradome (Laser) users experienced significant improvements, while the sham (LED) group continued to lose hair:
 - **Total hair count:** Significantly increased by an average of 10.4 hairs (Theradome) compared to a loss of 14.0 hairs (sham), $p < 0.001$.
 - **Terminal hair count:** Improved by an average of 4.8 hairs compared to a decline of 9.7 hairs in the sham group, $p = 0.04$.
 - **Vellus hair count:** Increased by an average of 5.6 hairs versus a decrease of 4.3 hairs (sham), $p = 0.04$.
- **No adverse effects** were reported demonstrating excellent tolerability and safety.
- Benefits were most evident in participants with active hair loss and early to moderate thinning, though improvements were seen across multiple hair loss stages.
- Post-study survey results indicated a significant reduction in hair loss among Theradome users, while no reduction was reported in the sham group.

Study Strengths

- IRB approval, ensuring adherence to strict ethical and scientific standards.
- Multicenter trial, providing diverse and broadly applicable data.
- Randomized and double-blind design, minimizing bias.
- Sham-controlled methodology, confirming that improvements were due to laser therapy and not placebo effects.

Conclusion

This clinical trial confirmed that the Theradome LH80 PRO is a safe, effective, and scientifically validated solution for hair restoration. Within just 26 weeks, men using Theradome twice weekly achieved measurable increases in hair count, density, and thickness, while participants using LED sham devices continued to lose hair.

This clinical study was independently conducted by a third-party research organization, funded by Theradome, and solely used to support FDA clearance of the device. The results have not been published in a peer-reviewed medical journal.