Studies Characterizing the Novel FlexSure™ Hands-Free Applicator

Introduction to FlexSure Radiofrequency Technology

Used as an accessory to the one-of-a-kind TempSure® radiofrequency device, the FlexSure applicator delivers hands-free, non-invasive, deep-tissue RF treatments in only 15 minutes. As the world's first wrappable radiofrequency (RF) applicator, the flexible, peel-and-stick FlexSure applicator curves and conforms to multiple body parts, including the abdomen, flanks, back, arms, thighs, and above the knees. The technology treats any skin type and is customizable, to include multiple sizes and 6 treatment zones within the applicator. Standard mode sets temperature equally across applicator zones, while the advanced mode customizes temperature within each zone. This provides standardized customization. The FlexSure applicators provide heating for the purpose of elevating tissue temperature for select medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.

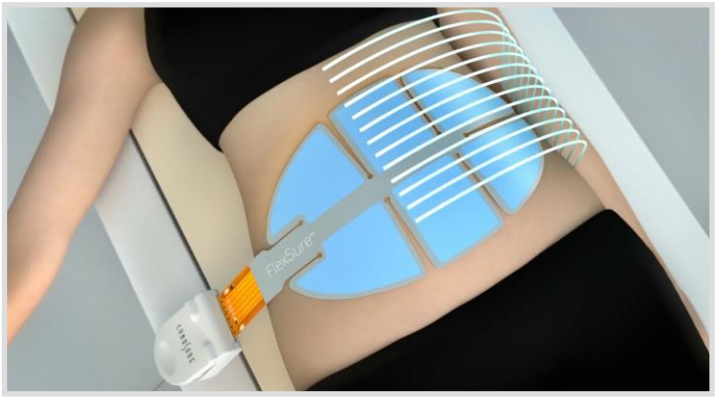
Characterization of a Novel Flexible Radiofrequency Applicator for Body Treatments

As part of an effort to address a larger market need for a radiofrequency (RF) device that is both effective and easily customizable to be applied to different treatment areas, doctors Ayala, Doherty and nurse Whitney characterized key heating capabilities and patient tolerability for this novel RF applicator (for use in tissue heating various parts of the body). After applying the associated large-sized neutral electrode monitoring (NEM) pad (for grounding in monopolar RF mode), the flexible hands-free RF applicator was connected to both the RF platform and study participant treatment area according to manufacturer directions (to deliver a 4 MHz RF treatment). 5 out of 5 study participants received treatment to the abdomen, while 3 participants underwent additional treatment to the thigh area (for a total of 8 areas treated and evaluated).

Multiple assessments were conducted, to include participant tolerability and temperature studies. Infrared thermal imaging was performed by using a FLIR thermal camera to evaluate skin surface temperature prior to and immediately post-treatment. As part of treatment safety protocol, participant feedback was assessed throughout the procedures.

Results were positive. Treatment regulation was reached for treatment areas (for abdomen and thigh), maintaining ≥ 40 °C for a 10 minute period (based upon the thermistor measurements on the applicator). To validate results, measurement of skin surface temperature, immediately post-treatment, revealed temperature results comparable with thermistor-based measurements on the applicator.

As anticipated, temperature-at-depth within the hypodermis increased with treatment time (while the target-skin surface temperature was maintained). The FLIR thermal images revealed a consistent heating profile. This study was built upon previous temperature characterization, which also demonstrated the ability to reach target temperatures.



Development of a Flexible Radiofrequency Applicator for 300 W Radiofrequency Device Intended for Tissue Heating

In an early study to characterize temperature, Dr. Sean Doherty demonstrated the ability of the FlexSure applicator to heat tissues uniformly and to reach target temperature. Treatments were conducted using 4 MHz in monopolar mode (with the flexible applicator powered by
TempSure RF device). Thermal imaging was utilized to assess temperature, specifically the ability to reach a target tissue temperature of 44 °C. Results were positive.

As part of routine safety protocol, participant sensation feedback was assessed throughout the treatments. Two tests were conducted. In Test 1, the largest temperature change recorded on thermal images was from 35.4 °C to 44 °C (which took approximately 65 s; adjacent zones took 41 s and 58 s). The same participant and treatment areas reached approximate target temperature as quickly as 25 s (from 37 °C to 43 °C) during Test 2. These tests demonstrated the ability of the device to safely and quickly reach the approximate target tissue temperature (of 44 °C, with pre-defined zones).

Conclusion

As with all FlexSure applicator studies, study participants tolerated all treatments. What is more, researchdemonstrated that the FlexSure RF treatment reached the necessary target tissue temperatures making it the ideal applicator to elevate tissue temperature for larger treatment areas.