

## **Temperature-Controlled Monopolar Radiofrequency in the Treatment of Submental Skin Laxity: A Prospective Study**

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**Background/Objective:** Laxity of the submental area is a common cosmetic complaint of the aging population. The objective of this study was to determine the safety and effectiveness of a temperature-controlled minimally invasive percutaneous monopolar radiofrequency device to improve dermal laxity.

**Method:** A total of 72 subjects (35–65 years old) with mild to moderate skin laxity in the submental area were included in this single-center prospective study (New Jersey, USA). All subjects received one treatment at baseline with an average subdermal temperature of 63°C. The primary endpoint was the proportion of subjects with at least a 20 mm<sup>2</sup> decrease in submental surface area at day 90 based on 3D imaging. Secondary endpoints included skin elasticity measured by a cutometer, assessment by a blinded physician panel using 2D photographs, and physician and subject-reported outcomes.

**Results:** At Day 90, 72.1% (95% confidence interval: 62.2-84.0%,  $P < 0.001$ ) of subjects achieved at least a 20 mm<sup>2</sup> lift of the submental area. All values for skin elasticity (R2, R5, R7) showed significant improvement by 180 days as measured by cutometer. 74.2% of subjects were graded by the independent panel as “Improved” at 90 days. (62.0-84.2%,  $P < 0.001$ ). The treatment was well tolerated, and only one possibly related serious adverse event was reported (pharyngeal inflammation).

**Conclusions:** Treatment with temperature-controlled monopolar radiofrequency alone is a safe and effective treatment to improve submental laxity for at least six months.