



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

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## Introduction

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 skin laxity.

## Methods

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. All subjects received one treatment with the ThermiRF device 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).

**Table 1. Quantitative and Qualitative Evaluation of Effectiveness**

Evaluations	Day 90	Day 180
<b>Improvement ≥ 20 mm<sup>2</sup></b>	N = 67	
% (95% CI)	72.1 (62.2-84.0)	
P value <sup>b</sup>	<b>P &lt; 0.001</b>	
<b>Change from baseline in mm<sup>2</sup></b>	N = 67	
Absolute change, mean ± SD (mm <sup>2</sup> )	-71.7 ± 79.0	
% change, mean ± SD	-21.3 ± 22.7	
<b>Qualitative blinded reader analysis</b>	N= 66	N = 56
Much improved, %	28.8	32.1
Minimally improved, %	45.5	39.3
No change, %	25.8	26.8
Minimally Worse, %	0	1.8
Much Worse, %	0	0
Improvement, % (95% CI)	74.2 (62.0-84.2)	71.4 (57.8-82.7)
P value <sup>s</sup>	<b>P &lt; 0.001</b>	<b>P &lt; 0.001</b>

**Figure 1. 60 year-old Female Before and Six Months After Treatment**



**Figure 2. 43 year-old Female Before and Six Months After Treatment**

