Clinical Parameters for Predicting Efficacy and Safety With Nonablative Monopolar Radiofrequency Treatments to the Forehead, Face, and Neck

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Background: Patient selection is key to obtaining a successful outcome after nonablative monopolar radiofrequency (NMRF) treatments to the forehead, face, and neck.

Objective: The purpose of this study was to discover at baseline from patient demographics, skin and fat characteristics, measurable degrees of tissue mobility and photoaging, any predictors of a positive result under a standardized treatment algorithm.

Methods: Twenty-five patients (22 females, 3 males; average age 52.3 years) were selected randomly for NMRF treatments (2 nonoverlapping passes, additional passes for vectored contraction and contouring) between 350 and 450 firings with 1.5-cm tips to the forehead, periorbitum, face, and upper neck. Patients were evaluated at baseline and monitored for outcomes beyond 1 year by a number of quantitative assessments.

Results: At baseline and 3, 6, and 12 months, measurements of skin thickness, subcutaneous fat depth, tissue mobility, and wrinkle and fold depth were obtained at 9 different reference sites on each patient. Nineteen patients (76%) who progressively responded to NMRF energy over 12 months were observed at baseline to have a global mobility score (mean ± SD) of 3.4 ± 0.27 mm; 6 patients who were assessed to be nonresponders over 1 year of evaluation began with more tissue laxity and exhibited at baseline a larger global mobility score (mean ± SD) of 4.4 ± 0.60 mm. Other factors that were more likely to be associated with a positive response to NMRF treatment included minimal degrees of photoaging and shallower wrinkle/fold development. The variables of skin thickness and fat depth did not play significant roles in predicting positive responses to treatment. Side effects and complications were minimal throughout the study.

Conclusions: This study represents one of the first investigations that attempts to identify systematically objective baseline parameters that are more likely to be associated with positive responses to NMRF treatments to the forehead, face, and neck. Longer follow-up of our patients and further studies will be required to verify our preliminary findings. (Aesthetic Surg J 2007;27:376–387.)

Appropriate patient selection remains one of the keys to obtaining a successful clinical outcome of skin tightening and contouring of the forehead, periorbitum, face, and upper neck by nonablative monopolar radiofrequency (NMRF) energy (ThermaCool; Thermage, Hayward, CA). Most publications to date have reported modest to moderate subjective\textsuperscript{1-13} and objective\textsuperscript{14,15} elevation of the brow, periorbitum, and malar mounds, softening of the nasolabial and marionette folds, and sharpening of the mandibular margins and cervicomenal angles. However, consistent, predictable, and timely results have varied widely even when standardized treatment algorithms were applied with minimal adverse effects. The purpose of this study was to determine any patient demographics, skin and subcutaneous fat characteristics, degree of tissue mobility, and photoaging that could serve as predictors for a positive outcome when a uniform standardized treatment algorithm is used and assessed after at least 1-year follow-up.

Patients

The study population consisted of 22 women and 3 men (18 white, 6 Hispanic, and 1 Asian), with ages rang-
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Methods

Preparation

Patients were instructed to remove all make-up and jewelry and thoroughly cleanse their faces with a mild soap and water. After application of the grounding return pad on the low back, light microdermabrasion removed the superficial epidermis in order to improve the effectiveness of the topical triple anesthetic gel (20% benzocaine, 6% lidocaine, and 4% tetracaine) under occlusion for 30 to 45 minutes. After the anesthetic gel was completely removed with water-soaked gauzes, the facial skin was dried.

Treatments were outlined with a 1.5-cm² ink grid, which extended across the entire forehead from the frontal hairline to the brow, from the temporal hairline to the orbital rim in the periorbital region, from the nasolabial and marionette folds to the preauricular and mental branches), and other susceptible tissue (mid platysma, temporal fat). Usually only half of the forehead, face, and neck were first treated to assess visual endpoints of tightening to estimate the treatment technique and settings that would be used for the opposite side. Immediately after treatment, the grid markings and conductive gel were removed, and cool compresses were applied up to 1 hour.

Objective assessments

An objective measurement of skin thickness, subcutaneous fat depth, and tissue mobility was performed, and VISIA (Canfield Imaging Systems, Fairfield, NJ) Computerized Complexion Analysis of the largest and deepest rhytid or fold within each of the nine reference sites was recorded as follows: (1) vertical glabellar fold; (2) superior level of brow; (2) midforehead horizontal rhytid; 3 cm above brow in line with pupil; (3) lateral forehead rhytid; 1 cm above tail of brow; (4) brow’s feet rhytid; 2.5 cm lateral to commissure; (5) pretragal fold, 1 cm anterior to tragus; (6) nasolabial fold, midway between nasal sill and lip commissure; (7) upper lip vertical rhytid, midway between lip commissure and cupid’s bow; (8) marionette fold, midway between lip commissure and mandibular margin; and (9) upper horizontal neck rhytid, midway between the anterior sternocleidomastoid border and superior thyroid notch. An average

Energy set-
of 3 measurements from each of these sites provided the final determination of skin/fat depths and tissue mobility. Tissue mobility measurements could not be obtained from the upper lip because of the absence of a fixed reference point. A score (mean ± SD), derived from the averages obtained at each of the measured sites, was calculated for each patient’s face. Independent Samples t test and Mann-Whitney test were used to compare the mean scores in the clinically responsive and nonresponsive groups. In this manner the number, timing, and efficacy of treatment in responders were compared with the same variables as obtained from patients who did not demonstrate any meaningful responses.

**Measurement of skin thickness.** Measurements of skin thickness (in millimeters) at each of the nine reference sites were obtained initially both by the Longport High Resolution Digital Ultrasound Imaging Scanner (Longport, Inc., Glen Mills, PA) and by a mini-caliper. Each method produced almost identical measurements of skin thickness. Since a mini-caliper device is available to all clinicians, this method became the most practical means of assessment. For this study, the Longport Digital Ultrasound Scanner spot-checked the measurements obtained by the mini-caliper device throughout the entire evaluation period to ensure the latter’s validity.

The mini-caliper measured the distance in millimeters between pinched skin at each of the nine reference sites on the face in order to estimate the double layers of skin thickness. This value was then divided by 2 to estimate the actual thickness of the skin. The average of three measurements provided the final depth at each site. From an average of all nine measured sites, a grading of “thin,” “medium,” or “thick” skin was assigned to each patient at each evaluation period (Table 1). The mean score from the averages of all responders was compared to the mean score from averages of all nonresponders at each posttreatment period to assess whether skin thickness influences final outcome.

**Measurement of subcutaneous fat depth.** Measurements of subcutaneous fat depth (in millimeters) at each of the nine reference sites were obtained in a similar fashion as those recorded for skin thickness. The Longport Digital Ultrasound Scanner device was able to determine depths down to 2.5 cm from the hypodermal border. Because the use of the mini-caliper closely matched the depths of subcutaneous fat obtained by the Longport Ultrasound Scanner, caliper measurements became the most practical method for recording fat levels.

The mini-caliper measured the millimeter distance between a larger grasp of pinched subcutaneous fat and skin at each of the 9 referenced sites on the face to estimate double layers of these tissues. This value was divided by 2 to obtain the thickness of the skin and subcutaneous fat. The isolated fat depth was derived from subtracting the skin thickness from the combined tissue depth. The average of 3 measurements provided the final depth at each site. From an average of all 9 measured sites, a grading of “thin,” “medium,” or “full” subcutaneous fat was assigned to each patient (Table 2). A mean score from the averages of all responders was compared with the mean score from the averages of all nonresponders at each posttreatment evaluation time to assess the importance of subcutaneous fat to final outcome.

**Measurement of tissue mobility.** Tissue mobility was determined at each of the eight reference sites by maximally transposing the tissue from a reference point in the desired direction of lift or contraction. The vectors of movement were vertical at the midforehead rhytids and crow’s feet rhytids, superolateral at the lateral forehead rhytids and the nasolabial folds, and horizontal at the glabellar folds, marionette fold, and midneck rhytids. Mobility at the upper lip could not be reliably measured because of the lack of a fixed reference site. The distance of transposition was measured with a mini-caliper from its initial starting position to its final point of forced translocation. The average of 3 measurements provided the final determination of tissue mobility at each site. From the average of all 8 measured sites, a grading of “small,” “moderate,” or “large” was assigned to each patient (Table 3). A mean score from the averages of all responders was compared with the mean score from

<table>
<thead>
<tr>
<th>Table 1. Skin thickness grading by mini-caliper measurements at 9 sites</th>
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<tbody>
<tr>
<td>Thin = ( \leq 1.0 ) mm</td>
</tr>
<tr>
<td>Medium = 1.1-2.0 mm</td>
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<td>Thick = ( \geq 2.1 ) mm</td>
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<table>
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<tr>
<th>Table 2. Subcutaneous fat grading by mini-caliper measurements at 9 sites</th>
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averages of all nonresponders at each posttreatment period to evaluate the importance of skin mobility to final outcome.

**Measurement of wrinkle or fold depth.** Determination of the maximal depth of the deepest portion of a wrinkle or fold at each of 9 sites was obtained either by laying into the depression a BD Precision Glide Hypodermic Needle (Becton Dickinson & Co., Franklin Lakes, NJ) of known outer diameter that “best-fits” the groove (Table 4). The average of 3 measurements provided the final depth at each site. From the average of all 9 sites, a grading of “thin,” “moderate,” or “large” was assigned to each patient (Table 5). A mean score from the averages of all responders was compared with the mean score from the averages of all nonresponders at each posttreatment evaluation period to assess whether these aging findings contribute to the final outcomes.

### Results

Typical results are illustrated in Figures 1 to 4. Skin thickness was measured at each of the 9 reference sites in 25 patients (Figure 5). At baseline, the mean score of 1.6 ± 0.2 mm in the 19 responders demonstrated no statistical significance from the mean score of 1.8 ± 0.2 mm in the 6 nonresponders. Both of these baseline scores represented a “medium” thickness of skin (1.1 to 2.0 mm, Table 1). At each posttreatment period of 3, 6, and 12 months, there were negligible differences between the mean scores in the responder group of 1.6 ± 0.2 mm, 1.5 ± 0.2 mm, and 1.5 ± 0.2 mm compared with the mean scores in the nonresponder group of 1.6 ± 0.2 mm, 1.6 ± 0.2 mm and 1.5 ± 0.2 mm, respectively. These results suggested that “medium” skin thickness played a minimal role in predicting a clinical response to NMRF energy. The influence that “thin” skin (≤1.0 mm) or “thick” skin (≥2.1 mm) brings to bear on Thermage treatment could not be evaluated in this study.

Subcutaneous fat depths were obtained at the 9 reference sites in 25 patients (Figure 6). At baseline, the mean score of 3.3 ± 0.2 mm in 19 responders was equal to the mean score of 3.3 ± 0.2 mm in the 6 nonresponders. Both of these scores represent a “medium” thickness of subcutaneous fat. Although certain zones of the face, such as the nasolabial fold, marionette fold, and jowl, may be thicker than others, the thickness of subcutaneous fat over the 9 measured sites averaged a “medium” thickness score. At each posttreatment interval of 3, 6, and 12 months, there were no significant differences in the responsive patients’ scores of 3.1 ± 0.2 mm, 3.2 ± 0.2 mm, and 3.1 ± 0.2 mm compared with nonresponders’ scores of 3.2 ± 0.1 mm, 3.3 ± 0.2 mm, and 3.2 ± 0.1 mm, respectively. These results indicated that the depths of subcutaneous fat did not influence the outcomes to NMRF energy in patients with a “medium” subcutaneous fat depth. Because there were no significant reductions of fat depth in the treated areas over time, the beneficial effects of NMRF in the responsive group may not involve fat loss from thermal injury. The effect of Thermage treatment in patients designated to have either “thin” or “full” subcutaneous fat could not be evaluated in this study.

Tissue mobility was measured at 8 reference points in 25 patients (Figure 7). At baseline, the mean score of 3.4 ± 0.3 mm in 19 responders was statistically significantly lower than the mean score of 4.4 ± 0.6 mm in the 6 nonresponsive patients (P < .001). Both scores represented a “medium” degree of tissue mobility. Although

### Table 3. Tissue mobility grading by mini-caliper measurements at eight sites

<table>
<thead>
<tr>
<th>Grade</th>
<th>Range (mm)</th>
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<tr>
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<tr>
<td>Moderate</td>
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<tr>
<td>Large</td>
<td>≥6.1</td>
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### Table 4. Outer diameter of BD Precision Glide Hypodermic Needles

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<th>Gauge</th>
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<td>18</td>
<td>1.250</td>
</tr>
<tr>
<td>16</td>
<td>1.625</td>
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</tbody>
</table>

### Table 5. Wrinkle depth grading by “best-fit” outer diameter of BD Precision Glide Hypodermic Needles

<table>
<thead>
<tr>
<th>Grade</th>
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<tbody>
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<tr>
<td>Moderate</td>
<td>0.51-1.0</td>
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<tr>
<td>Large</td>
<td>≥1.0</td>
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certain facial areas, such as the marionette fold and midneck sites, demonstrated greater displacement, the overall mobility of 8 sites averaged a “medium” score. At each posttreatment evaluation period of 3, 6, and 12 months, the mean scores of 3.2 ± 0.4 mm, 2.9 ± 0.2 mm, and 2.5 ± 0.3 mm in the responsive group were statistically significantly lower than the scores of 4.7 ± 0.4 mm, 4.3 ± 0.4 mm, and 3.9 ± 0.5 mm, respectively, in the nonresponsive group (\( P < .001 \)). These results suggested that patients who presented with smaller amounts of tissue mobility were more likely to respond to NMRF energy than patients who exhibited greater tissue displacement.

The maximum depth of a wrinkle or fold from the 9 reference sites was obtained in 25 patients (Figure 8). At baseline, the mean score of 0.3 ± .05 mm in 19 responders was statistically significantly smaller than the mean score of 0.5 ± .01 mm in 6 nonresponders (\( P < .001 \)). Both values represented a “moderate” degree of wrinkle or fold depth. Although folds exhibited a deeper line than wrinkles, their overall depth at 9 sites in a patient averaged a moderate score. At each posttreatment period of 3, 6, and 12 months, the mean scores of 0.3 ± .05 mm, 0.3 ± .07 mm, and 0.2 ± .06 mm in the responsive group was statistically significantly smaller than the mean scores of 0.4 ± .05 mm, 0.4 ± .07 mm, and 0.4 ± .05 mm in the nonresponder group (\( P < .002 \)). These results suggest that patients with shallower wrinkles and folds are more apt to respond to NMRF energy over time than patients with deeper rhytids and folds.

**VISIA Computerized Complexion Analysis**

VISIA Computerized Complexion Analysis was obtained on both sides of the midface in 25 patients at baseline and 3, 6, and 12 months after a single NMRF treatment. The standardized analysis consisted of 6 parameters that included percentages of pigmented spots,
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pores, wrinkles, and evenness (100% = the optimum level), as well as numerical counts of bacterial porphyrins and ultraviolet damaged spots. At baseline in the responsive group, the average percentage of spots, pores, wrinkles, and evenness ranged between 77% and 92%, whereas bacterial porphyrin and ultraviolet counts were each less than 100 in number. On the other hand, the average percentage of spots, pores, wrinkles, and evenness in the nonresponsive group was distributed between 35% and 75%, whereas bacterial porphyrin and ultraviolet spots ranged between 150 and 320 counts. At the 12-month evaluation period, the responder group recorded a 38.8% improvement of the 6 parameters from their respective baseline average measurements in contrast to a 27.2% change in the nonresponder group.

Relationship of age and gender to NMRF energy

The ages and genders of the responsive and nonresponsive patients are tabulated in Table 6. Sixteen of the 19 patients in the responsive group were below the age of 60, whereas 3 were older than 61 years of age. Five of the 6 patients in the nonresponsive group were under the age of 60, except for one patient who was older than 61 years of age. There were 2 men in the responsive group and 1 man in the nonresponsive group. The data suggested that a candidate’s age and gender were not significant factors in predicting a favorable outcome to NMRF energy treatment.

At the 12-month evaluation period, the responders in general demonstrated an increase of 36.8% improvement from baseline measurements of photoaging, in contrast to a 25% improvement over baseline measurements in patients in the nonresponder group. These findings suggest that an expected beneficial effect may be predicted in younger patients with lower tissue mobility and less photoaging than in older candidates who possessed increased tissue laxity and increased photoaging.
Side effects and complications

In 25 patients, there were no major early or late complications such as blistering, scarring, prolonged dyschromia, fat atrophy, or permanent sensory and motor nerve injuries. These patients were evaluated during the 12-month study but were followed up for another year off-study. Minor and transitory side effects, such as erythema, edema, and numbness, resolved themselves spontaneously within a week and required no interventional treatment. The use of the patient’s pain threshold level of 2.0 to 2.5 provided not only a guide to safe and effective energy treatment levels but also a thermal level acceptable for patient compliance.

Figure 3. A, C, A 45-year-old white woman with baseline mean scores of tissue mobility (3.5 ± .25 mm) and wrinkle and fold depth (0.31 ± .03 mm). B, D, Clinical improvement was observed at 6 months with brow elevation, effacement of orbital hooding to the upper lid, periorbital lifting, tightening of lower lid skin creping and folds, elevation of the malar fat pad, and improvement of the nasolabial and marionette folds, including perioral rhytids. These clinical benefits continued up to her last evaluation period at 23 months, posttreatment. In addition, a positive 50% change over baseline in the VISIA Analysis was observed at the 12-month evaluation period.
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Discussion

Successful clinical responses to photodamaged and lax skin, rhytids, folds, and contours by NMRF energy has been difficult to predict, evaluate, and measure with objective criteria. This dilemma is in part due to the wide intrinsic variations of skin and soft tissue characteristics of the candidate population base, including the differing degrees of skin aging, laxity, wrinkle formation, and amount of subcutaneous fat within the treated areas. Although recent studies1-13 have attempted to assess clinical facial improvements with NMRF by subjective scoring systems, fewer reports14,15 have been published that more accurately quantify the effectiveness of volumetric and tightening changes.

Although the objective clinical efficacy of nonablative cutaneous radiofrequency to the brow and periorbital complex has been documented by height measurements from standardized photography and measuring tools from computer imaging systems,1-6,17 the development of similar objective criteria for measuring improvements in the midface and neck has been more difficult. In this area, most successful results have been assessed by subjective clinical grading systems,1-11 such as softening of the nasolabial folds; tightening of the cheek contours, jowls, and marionette lines; sharpening of the mandibular line; and cervicomental angle with improvements to skin parameters (laxity, wrinkles, texture, clarity, pore size). A few publications objectively document beneficial changes in the nasolabial folds and jowls by Primos microtopography imaging15 and morphologic analysis with computer imaging software14 after radiofrequency treatment.

The theoretical framework for understanding the mechanisms of action after NMRF treatment is hypothesized to be a selective immediate contraction injury to collagen fibers within the dermis and septal connective network between the subcutaneous fat lobules, followed thereafter by secondary neocollagenesis and elastinogenesis, remodeling, and contraction.19 These salutary colla-

Figure 4. A, A 66-year-old white woman presented with baseline mean scores of tissue mobility (3.0 ± .15 mm) and wrinkle and fold depth (0.3 ± .07 mm). B, Progressive clinical responses were observed at 12 months after treatment with brow elevation, effacement of the hooded area to the upper lid, tightening of the crepey lower lid skin, elevation of the midface, and softening of the nasolabial and marionette folds. In addition, a positive 25% change over baseline in the VISIA Analysis was observed at the 12-month evaluation period.
gen effects are believed to account for the duration of clinical response up to a year and a half. On the basis of these observations and findings, the “ideal” candidate for NMRF energy treatment (or for that matter any nonablative techniques, such as laser, intense pulsed light, light emission diode, and ultrasonography) by inference should be one whose collagen and elastic fibers are abundant and of optimal size and orientation to allow maximal and selective thermal absorptive injury. Typically, this describes candidates whose skin and underlying supportive structures demonstrate not only a mild to moderate degree of chronologic or photoactinic aging, but also minimal to moderate signs of skin laxity and tissue ptosis (primary aging or after rhytidectomy), as emphasized in

Figure 5. Skin thickness scores in 19 responders and 6 nonresponders over 1 year after Thermage treatment. There were no statistically significant differences in the scores of skin thickness between the responder and nonresponder groups.

Figure 6. Fat thickness scores in 19 responders and 6 nonresponders over 1 year after Thermage treatment. There were no statistically significant differences in the scores of fat thickness between the responder and nonresponder groups.
A recent publication states that there are minimal clinical means to predict responders from nonresponders. This study represents one of the first attempts to develop quantifiable baseline parameters for the forehead, face, and neck that may predict either a more favorable or minimal outcome to this novel NMRF treatment modality. First, the baseline mean scores for both skin depth and subcutaneous fat thickness in the responder group were not statistically significant from corresponding mean scores in the nonresponder group. Moreover, the baseline mean scores of skin depth and subcutaneous fat thickness in each of the 25 patients were assessed to be of “medium” grade. These findings
suggest their minimal importance in predicting a positive response to treatment. Although isolated sites (nasolabial and marionette folds) were graded at baseline to be either “thin” or “thick” by our grading criteria for skin and fat depth, they were of limited prognostic value for a beneficial response. Second, the mean score for tissue mobility at baseline was observed to be a consistent and reliable prognosticator for response to NMRF energy treatment. Those patients with lower tissue mobility scores at baseline demonstrated both progressive clinical improvements and reductions in tissue displacement, (ie, tissue tightening) months after treatment. The presence of less tissue mobility may be dependent not only on a favorable genetic background but also on the amount of photoaging and ptosis, rather than depending strictly on the chronological age of the patient at the time of treatment. Lastly, the baseline mean score for depth of wrinkle and fold in the responder group was significantly lower than the mean score in the nonresponder group, suggesting that the least amount of photoaging and ptosis was more favorable to obtaining a positive result.

The 19 patients in our responsive group, whose ages ranged from 43 to 68 years (average age 52.6), presented with lesser degrees of tissue mobility, higher percentages of photoaging values, and lower number of ultraviolet spots from the VISIA Computerized Complexion Analysis, and shallower depths to wrinkles and folds than those observed in the nonresponsive group. A younger versus older age may be of some importance to response in that younger patients are more apt to present with less skin laxity, photoaging, and wrinkles/folds. Because all of our patients globally presented with “medium” skin and subcutaneous fat thicknesses, the importance of “thin” and “thick” skin and fat could not be evaluated and may be a contributory predictive factor for NMRF treatments. This limited study provides preliminary subjective and objective observations that may be relevant for the clinician involved in this novel technology. Realistic expectations and selection of the patient by the practitioner remain cornerstones of accepted outcomes.

**Conclusion**

This study demonstrated the safety and effectiveness of a single standardized NMRF treatment-algorithm to the forehead, face and neck in 25 patients who presented with varied ranges of chronologic and photoactinic aging to the skin and deeper structures. A clinical assessment scale of measuring skin thickness, fat depth, tissue mobility, wrinkles and fold depths, and photoaging by VISIA Computer Analysis was obtained to determine their baseline value as predictors for a positive outcome. Tissue mobility proved to be the most consistent and principle factor for predicting outcome. Another influential variable was the stage of photoactinic aging of the skin. One of the challenges of NMRF technology will be the development of treatment tips that can precisely account for tissue resistance, mobility, and quantity of collagen and elastic fibers at each treatment site in order to deliver a therapeutic amount of energy to obtain a predictable outcome in a timely manner with minimal side effects.

Dr. Sasaki received a Thermage unit for use in this study only, which was returned to the manufacturer after completion of the study. He received no other financial support other than disposable tips and has no financial interest in the manufacturers of other products mentioned in this article.

**References**


**Table 6. Relationship of age and gender to NMRF outcomes**

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<tr>
<th>Gender</th>
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<th>51-60 Years</th>
<th>≥61 Years</th>
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<td>3</td>
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<tr>
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<td>3</td>
<td>1</td>
<td>5</td>
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