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Multimodal Radiofrequency Application for Lower Face and Neck Laxity: Subdermal Adipose Remodeling and Fibro Septal Network Contraction

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Abstract:	p.p1 {margin: 0.0px 0.0px 0.0px 0.0px; font: 9.0px Helvetica; color: #333666} Introduction: Non-excisional facial skin tightening has long been an elusive goal in aesthetic surgery. The 'treatment gap' includes patients who are not 'severe' enough for excisions surgery but not 'mild' enough for most traditional non-invasive aesthetic modalities. In this retrospective review, we present the largest evaluation to date of radiofrequency skin tightening technology combination including bipolar radiofrequency (Facetite, InMode) and fractional bipolar radiofrequency (Fractora modified to Morpheus8, InMode) Methods: A multicenter retrospective study was conducted between January 2013 - December 2018 using a combination of bipolar radiofrequency and fractional bipolar radiofrequency for the treatment of facial aging. Data collection included demographic information, Baker face/neck classification, amount of energy used, as well as adverse events and patient satisfaction. Four cadaver dissections were also conducted to correlated the underlaying neuromuscular anatomy to radiofrequency treatment of the lower face and neck. Results: 247 patients (224 Female, 23 Male) were included in the study. Average age was 55.1 (STD +/- 8), BMI 24.3 (+/- 2.4), 12% (23/247) of patients were active smokers at the time of treatment, Patients were an average 3.1 Baker Face Neck Classification (STD +/-1.4). 97.2% (240/247) of patients had procedure under tumescent local anesthesia. Patients objectively improved their Baker Face Neck Classification by 1.4 points (STD +/- 1.1). 93% of p.p1 {margin: 0.0px 0.0px 0.0px 0.0px; font: 9.0px Helvetica; color: #333666}

	patients indicated they were pleased with their results and would undergo the procedure again. Complications recorded for our cohort included prolonged swelling >6 weeks (4.8%, 12/247), hardened area >12 weeks (3.2%, 8/247), and marginal mandibular neuropraxia (1.2% 3/247) which all resolved without further intervention. When considering possible control variables, age seems to be a significant factor. That is, older patients were more likely to benefit from a larger magnitude of the treatment effect (as demonstrated by a decrease in the Baker rating from pre- to post-treatment) compared to younger patients. However, both groups did demonstrate significant improvements across time. Conclusion: While this combination RF treatment (FaceTite bipolar RF and fractional bipolar RF) does not aim to replace a facelift/necklift in appropriate candidates, it does broaden the plastic surgeons' armamentarium to potentially fill a treatment gap.
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Multimodal Radiofrequency Application for Lower Face and Neck Laxity: Subdermal Adipose Remodeling and Fibro Septal Network Contraction

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Introduction:

Non-excisional correction of facial soft tissue laxity has long been an elusive goal in aesthetic surgery. Improvements in skin texture, dyschromias, and deflation are achievable with chemical peels, lasers, microneedling, and fillers. Areas of neck adiposity may be treated using liposuction, deoxycholic acid (Kybella, Allergan, Dublin, IR) and cryolipolysis (CoolSculpting, Allergan, Dublin, IR) with limited improvements in properly selected patients. However, even in cases where these treatments appear successful, skin and- soft tissue laxity often remain uncorrected.

There are three groups of patients with facial skin laxity that we characterize as part of a 'treatment gap': (1) young patients whose skin redundancy is not 'severe' enough to justify a traditional excision procedure (i.e. facelift/necklift), but also not 'mild' enough to treat with liposuction or noninvasive procedures alone; (2) patients that have already undergone a facelift or necklift, who present with recurrent laxity, and (3) patients who may benefit from traditional face/necklift but want to avoid surgery and are willing to accept a more modest improvement.

Energy-assisted skin tightening procedures have rapidly evolved over the past decade. Multiple technologies including laser, high-intensity focused ultrasound (HIFU), and radiofrequency (RF) have been developed in an attempt to meet this rising demand.[1-8] Radiofrequency technology has steadily gained popularity since the early 2000s with consecutive increases annually of 10% or more.[9,10] These gains encompass aesthetic surgery as well as numerous non-aesthetic applications (tissue electrodissection, cardiac catheter ablation, ophthalmic surgery, etc).[7] Through impedance of electromagnetic current, RF waves lead to differential heating across distinct tissue types consistent with Ohm's law (energy=current^2 x impedance x time). For example, adipose tissue is less conductive than water (higher impedance), and leads to generation of higher temperatures than muscle. Once soft tissue temperatures reach 50C and skin surface reaches 40-42C there is a trigger to induce neocollagenesis, angiogenesis, and elastogenesis. Through different applications of RF energy (i.e. monopolar, bipolar, multipolar, microneedling), subdermal adipose remodeling (SAR) and long-term soft tissue contraction can be safely and consistently achieved.

An increasingly popular soft tissue tightening technique of the lower face and neck has been a combination procedure (Embrace Protocol, InMode, Lake Forest, CA) using bipolar radiofrequency (FaceTite, InMode, Lake Forest, CA) and fractional bipolar RF (Fractora modified to Morpheus8, InMode Aesthetics, Lake Forest, CA).[11] The purpose of this manuscript is to evaluate this combination therapy in the largest study to date.

Methods:

A multicenter retrospective study was conducted evaluating treatments from January 2013-December 2018 (New York, NY; Dallas, TX; Verona, Italy) using combination of bipolar radiofrequency (Facetite, InMode Aesthetics, Lake Forest, CA) and RF microneedling (Fractora modified to Morpheus8, InMode Aesthetics Lake Forest, CA) for the treatment of facial aging. Procedures were performed by all authors of this manuscript (E.D., S.T., P.R., R.J.R., C.T.C, S.A.).

Patients all voluntarily presented to respective plastic surgery practices with a desire to improve facial aesthetics. Patients included in the study were deemed to fit into one of the three aforementioned treatment gaps. Exclusion criteria included: active infection, collagen disorders, immunocompromised state, medications that mitigate inflammatory response, and propensity for keloids/hypertrophic scaring. Valcyclovir was given to patients with history of Herpes Simplex. All Fitzpatrick types were included in the study.

Patient were all marked in standardized fashion, first identifying the mandibular border and jowls bilaterally. The jowls were subdivided into Zone 1 (above mandibular border) and Zone 2 (below mandibular border). Areas of localized adiposity in the lower face and neck region were marked. Non-treatment zones were identified by carrying a line inferiorly perpendicular to the lip commissures (i.e. marionette lines). The area medial to these lines were avoided, to preserve marginal mandibular innervation to the depressor anguli oris, mentalis, and depressor labii inferioris. Five access points are identified: (1) the submental midline (2) 1-2cm inferior to the mandibular parasymphesial/body junction, (3) post auricular. (Video 1) (See Video 1 [online] which displays bipolar radiofrequency markings)

Depending on clinical circumstances and patient desires, cases were performed either under general or local anesthesia. In cases of local anesthesia, patients were pre-medicated with oxycodone (5mg) and/or benzodiazepam (5mg). Access sites were each injected with 2-4cc of 2% lidocaine with epinephrine. A 14-gauge needle was used to make access ports that were slightly dilated with Stevens scissors. A spinal needle was used to slowly infiltrate tumescent solution (1g lidocaine per liter of Lactate Ringers solution) from deep to superficial, starting in the pre-platysmal plane and moving to the subdermal plane (approx. 100-150cc of tumescent total). At the conclusion of tumescent infiltration, the cannula was passed through the subdermal plane to confirm adequate analgesia.

In all cases, bipolar radiofrequency was performed first. The RF settings included an internal temperature cutoff of 68C and external cutoff temperature of 38C. The RF cannula was used to pre-tunnel treatment areas for ease of treatment. The predetermined treatment areas were systematically heated to avoid heat loss when treating wide areas. RF application was applied on retrograde movement of the cannula and stopped within 1cm of the access port to prevent overheating this area. Audible and visual cues from the RF console were used to assess temperature of tissues and treatment was stopped after one minute of reaching target internal and external temperatures. (Video 2) (See Video 2 [online] which displays bipolar radiofrequency technique)

Fractional bipoar RF (Fractora modified to Morpheus8, InMode Aesthetics) was subsequently used at a depth of 2mm and energy of energy 30 with 50% overlap. The hand-piece was applied firmly and perpendicular to the treatment area prior to delivery of RF energy pulses. (Video 3)(See Video 3 [online] which displays RF microneedling technique.) In patients with thinner skin or darker Fitzpatrick types, energy settings were reduced by 20%. Patients were seen at 1 week, 1 month, 3 month, 6 month intervals.

Data evaluated included demographic information, prior procedural history, anesthesia, medications, Baker face/neck classification, amount of energy used, as well as adverse events. The Baker face/neck classification comparing pre- and postprocedure photos was the primary outcome evaluated. Three independent plastic surgeons graded the pre and post procedure photos and subsequently a t-test was used to determine statistical significance. Repeated measured ANOVA test was used to determine any impact of control variables.

Additionally, four cadaver dissections were conducted in order to correlate the underlying neurovascular anatomy to access points and application of RF energy. These cadaver specimens were treated with the combination procedure mentioned previously and dissections were subsequently performed to identify proximity and potential impact on underlying specific neurovascular structures (i.e. marginal mandibular nerve, facial vessels, etc).

Results:

247 patients (234 Female, 13 Male) were included in the study. Average age was 55.1 (STD +/- 8), BMI 24.3 (+/- 2.4), 12% (23/247) of patients were active smokers at the time of treatment, 2% (5/247) had prior neck liposuction and 8.5% (21/247) had prior facelift/necklift. Patients were an average 3.1 Baker Face Neck Classification (STD +/-1.4). 97.2% (240/247) of patients had procedure under tumescent local anesthesia (50cc 2% Lidocaine, 1.5mg epinephrine, 1.5cc bicarbonate, in 1L or Lactated Ringers solution) and 2.8% (7/247) had the procedure under general anesthesia or IV sedation. Average procedure time was 58 min (STD +/-23). All patients were given Valium and cephalosporin antibiotics prior to the procedure.

Average energy used per jowl was 3.2kJ (STD 1.1). Patients objectively improved their Baker Face Neck Classification by 1.4 points (STD +/- 1.1). 93% of patients indicated they were pleased with their results and would undergo the procedure again. Average follow-up time was 2.1 years (STD +/- 1.1).

In order to test the efficacy of the treatment, a one-way, repeated measured t-test was conducted. A decrease of pre-test to post-test Baker Face Neck Classification rating mean values would indicate a positive effect of the treatment. Indeed, the t-test demonstrated a favorable effect of the treatment of the 247 patients. The pre-test mean value was 2.66 (SD = 0.72) and the post-test mean value was 1.86 (SD = 0.64). This mean difference ($\mu = 0.81$, SD = 0.46) was statistically significant: $t(237) = 27.34$, $p < .001$, and the effect size was large ($D = 1.76$). In other words, the mean values of the patients' Baker Face Neck Classification decreased as a result of the treatment. (SDC1) (See figure, Supplemental Digital Content 1 which displays pre and post treatment Baker Face Neck Classification. INSERT LINK HERE)

However, it is also possible several control variables may have had an un-hypothesized effect on the relationship. Thus, a one-way, repeated measures ANOVA test was conducted, inclusive of control variables. These control variables were: 1) patient gender, 2) patient smoking habit, 3) patient liposuction history, 4) patient weight, 5) patient age (dichotomized at the median value – 55), 6) patient body mass index, 7) right jowl energy (in kJ), 8) left jowl energy (in kJ), and 9) neck energy (in KJ). While 247 valid cases were present, complete data were present for 238 patients; thus, data from 9 patients were excluded in these analyses. The following table presents the mean values or percentages of the control variables in the overall fitted model.

(SDC2) (See table, Supplemental Digital Content 2 which displays the descriptive statistics. INSERT LINK HERE)

When considering the overall model, it is clear from the analysis the treatment was effective in reducing the Baker Face Neck Classification rating: Pre-Treatment Baker Classification $\mu = 2.62$ (SE = .03), Pre-Treatment Baker Classification $\mu = 1.84$ (SE = .03); $F(1, 208) = 11.36$, $p = .001$. None of the control variables was statistically significant, except for age. A significant treatment by age interaction effect was present: $F(1, 208) = 17.53$, $p < .001$. Simply, this indicates that the Baker Neck Classification pre- and post-treatment rating is different at different age groups. Looking at the mean values demonstrates that while older patients seem to benefit from the treatment more than younger patients by a larger magnitude, both age groups still show marked and significant improvements in their Baker Neck Classification scores from pre-treatment to post-treatment, as evidenced by Supplemental Digital Content 3. (See figure, Supplemental Digital Content 3 which displays Baker Face Neck Classification by treatment age. INSERT LINK HERE)

Complications recorded for our cohort included prolonged swelling >6 weeks (4.8%, 12/247), hardened area >12 weeks (3.2%, 8/247), and marginal mandibular neuropraxia (1.2% 3/247) which all resolved without further intervention. There were no repeat treatments or cases requiring operative intervention following RF treatment.

Discussion:

While this combination RF treatment (FaceTite bipolar RF and fractional bipolar RF) does not aim to replace a facelift/necklift in appropriate candidates, it does broaden the plastic surgeons' armamentarium to potentially fill a treatment gap. Also, it provides patients with an option to improve facial soft tissue laxity without traditional surgery.

In recent years, RF has emerged as an effective treatment to achieve non-ablative skin tightening.[6,7,10,12,13] Heating the dermal tissue to 42C has been shown to trigger a healing cascade that leads to stimulation of new collagen and elastin formation.[9,14-16] In animal studies, after 10 minutes of exposure to temperatures of 39-43C the amount of collagen increased from average of 9% before therapy to 25.9% after 3 month follow up period compared with no change in untreated areas.[4,17] Clinical studies on RF assisted liposuction have shown up to 25% area contraction at 6 months and 35-40% achieved at 1 year.[10,18-20]Other studies have similarly shown through electron microscopy, that collagen fibrils had greater diameter post RF treatment. Additionally Northern blot analysis confirmed microinflammmatory stimulation of fibroblasts and other substances that enhance dermal structure.[21] RF has not only been proven effective for skin tightening but it has also been studied and proven effective in diminishing adipocytes.[14]

A number of RF applications are available to apply this energy in different ways (monopolar, bipolar, multipolar, microneedling). The two RF delivery methods (bipolar radiofrequency and fractional bipolar RF) in this study achieve different treatment goals. The

bipolar RF applicator employs a small 1.8mm in diameter, 13cm long, silicone coated RF-emitting probe. This directs electrical current flow from the internal to external electrodes connected by the handpiece. As current is applied, heat coagulates subcutaneous fat in close proximity to the internal probe and denatures the reticular dermis while preserving the papillary dermis. The controlled heating allows for immediate tightening of the collagen triple helix via breakdown of hydrogen bonds in collagen causing shrinkage of normal collagen structure; as well as induction of the healing cascade leading to neocollagenesis, elastin remodeling, and angiogenesis over the following 3-4 months.[9] Additionally, using a parachute analogy, application of heat tightens the overlaying fibroseptal networks (strings) and serves to uniformly contract the overlaying skin (parachute). Complications are minimized by internal and external temperature and impedance probes to rapidly detect (10X/msec) the soft tissue environment and automatically turn off RF energy if beyond preset safety parameters. (Fig1-2)

In bipolar RF, the penetration depth is half of the distance between the electrodes, meaning the energy does not reach beyond the epidermis. Many attempt to circumvent this limitation by combining RF with other technologies to penetrate deeper, such as application of a vacuum to thin skin, infrared light pretreatment to change impedance, or cooling procedures to increase penetration depth.[4] In this study, the effect of bipolar radiofrequency treatment was augmented by performing fractional bipolar RF in the same session. Fractional bipolar RF (Fractora modified to Morpheus8, InMode Aesthetics) deploys RF-emitting needles at variable programmable depths and energies depending on the region being treated. Unlike fractional CO_2 or erbium, the fractional bipolar RF resurfacing can induce three types of effects- minimal superficial ablation for dyschromias and rhytids, controlled dermal coagulation for tissue renewal, and overall volumetric heating for collagen stimulation.[4] Also, in contrast to fractional photothermolysis that creates thermal injury that tapers as it descends deeper, fractional bipolar RF creates zones of dermal injury narrowest at the epidermis with conical enlargement as the microneedles descend until the pattern is truncated by attenuation.[10] When the RF needles penetrate deep to the dermis there is a 'molding' component of the subdermal adipose tissue we term 'subdermal adipose remodeling'. Hruza et al showed that 90% of patients with skin types II to IV had improvement in smoothness and rhytids, 87% in skin tightness.[16]Seo et al compared facial soft tissue laxity improvement with RF versus surgical facelift using blinded grading of photographs. They demonstrated a 49% improvement in skin laxity relative to baseline for surgical facelift compared to 16% for fractional bipolar radiofrequency. Further, the mean laxity improvement from a single fractional bipolar radiofrequency treatment was 37% of the surgical facelift.[13] Peterson et al also studied objective measurements of mechanical skin properties and demonstrated a statistically significant improvement (5-12% decrease in Young's modulus and 10-16% decrease in retraction time) as well as 1.42 grade improvement on the Fitzpatrick scale for wrinkles, and 0.66 on the Alexiades scale for skin laxity, increasing to 1.57 and 0.70 improvement at 6 months. Patient satisfaction was noted to be 'very high' for >90% of patients.[22] A clinical study of the microneedle fractional bipolar RF handpiece (Intensif handpiece, EndyMed, Caesarea, Israel) demonstrated significant improvement after two sessions and after 4 and 12 weeks of follow-up. [6] A similar system (Scarlet, Korea) was studied in three consecutive sessions 4 weeks apart. Immunohistochemical staining (fibrillin-1) showed a significant increase in dermal collagen content at 4 weeks after three sessions compared to

baseline as well as significant increase in fibrillin-1 density from the dermal epidermal junction to the deep dermis compared to baseline.[23]

Other studies have demonstrated efficacy of combined multimodal RF application for facial aesthetic purposes. Kaplan et al. used three RF delivery methods together (nonablative skin tightening, RF fractional skin resurfacing, microneedling RF) on 14 subjects showing improvements (>50%) in skin texture, laxity, and rhytids in 43% of the cohort without adverse effects or significant downtime. Previous studies have shown efficacy of non-ablative multi-source RF as a single modality for face/body contouring.[15,20,24] Other studies have shown the efficacy of RF microneedling as a single modality[25] and the efficacy of a combination of non-ablative RF and fractional skin resurfacing.[26] Similar to our findings, Mulholland identified the benefit of combining bipolar RF and fractional RF; stating that combining these applications allows for thermal stimulation for an 'inside-outside dermal stimulation' which can induce both an ablative rejuvenation of dyschromia, fine lines, and rhytides as well as nonablative deeper dermal tightening. Our study findings were consistent with Mulholland's conclusion, that combination therapy can deliver safe and consistent soft tissue rejuvenation.

The anatomic dissections performed as part of this study demonstrated the important surgical anatomy relevant to this procedure. Specifically, the marginal mandibular nerve was found to always be above the inferior border of the mandible while anterior to the facial artery. The position was more variable posterior the facial artery, in which case it was above the inferior border of the mandible in majority of cases. Importantly, consistent with prior anatomic studies, at approximately 2cm from the oral commissure the marginal mandibular nerve divides and subdivides to enter the lip depressors. At this anatomic location, the skin and underlying muscle planes are closely adherent. It is for this anatomic reason that we elect to not treat areas medial to the marionette lines. Using this anatomic knowledge and aforementioned access ports, we found no nerve injuries (i.e. transection, neuropraxia) and no extension of the device heat signature to in proximity of the marginal mandibular nerve - consistent with the relatively low complication rate in the clinical arm of the study.

Conclusion:

Combination therapy of bipolar radiofrequency and fractional radiofrequency had a positive effect on reducing the Baker Face Neck Classification rating. When considering possible control variables older patients were more likely to benefit from a larger magnitude of the treatment effect (as demonstrated by a decrease in the Baker rating from pre- to post-treatment) compared to younger patients. However, both groups did demonstrate significant improvements across time.

Legend:

SDC 1. See figure, Supplemental Digital Content 1 which displays pre and post treatment Baker Face Neck Classification. INSERT LINK HERE

SDC 2. See table, Supplemental Digital Content 2 which displays the descriptive statistics. INSERT LINK HERE

SDC 3. See figure, Supplemental Digital Content 3 which displays Baker Face Neck Classification by treatment age. INSERT LINK HERE

Figure 1. 12 month postop result of radiofrequency assisted liposuction with fractional bipolar radiofrequency 12 months

Figure 2. 24 month postop result radiofrequency lower face and neck treatment with fractional bipolar radiofrequency

Video 1. This video displays bipolar radiofrequency markings

Video 2. This video displays bipolar radiofrequency technique

Video 3. This video displays RF microneedling technique

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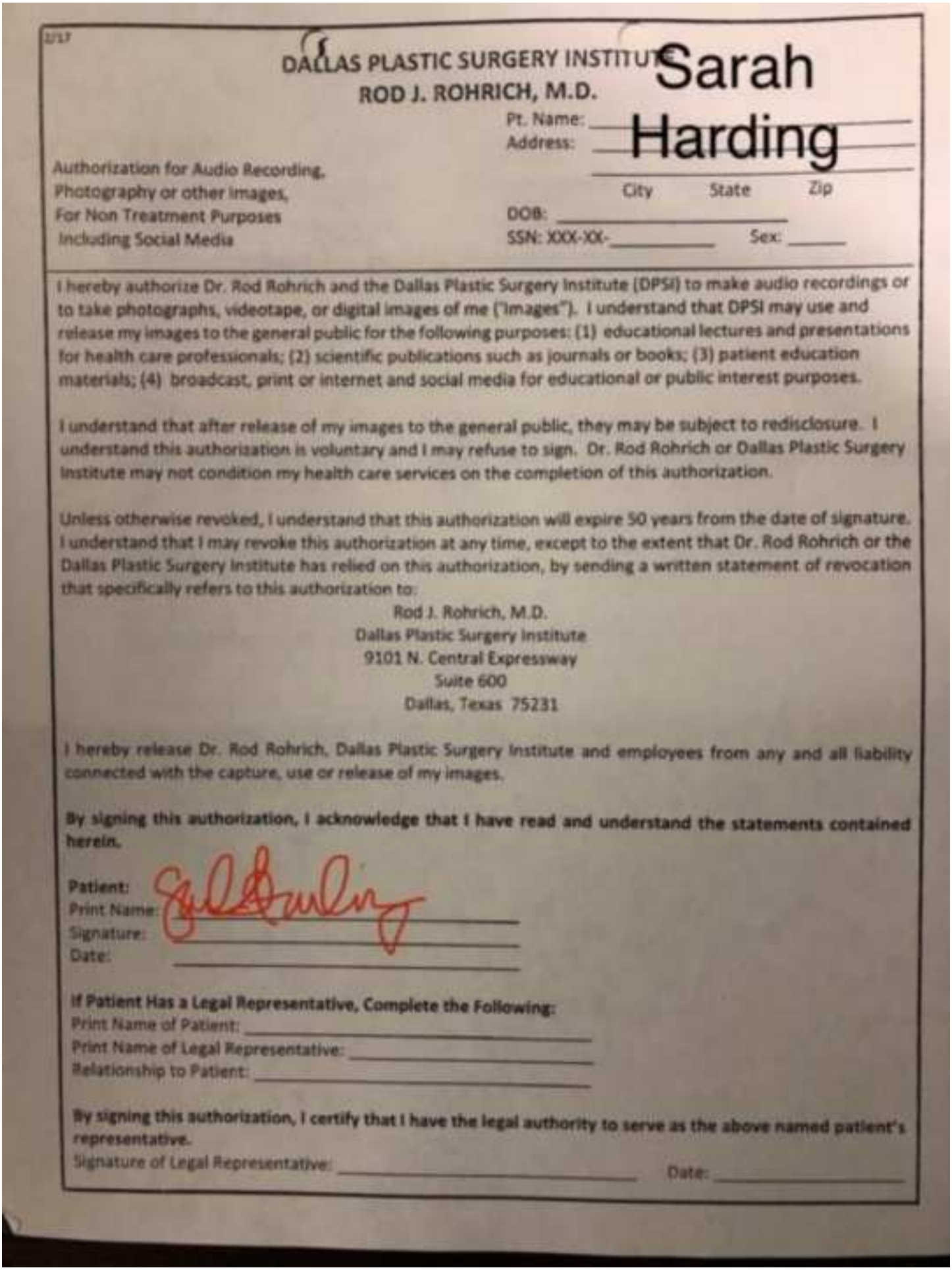

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Sarah Harding

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Signature: _____
Date: _____

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Date/Time: 11/8 3pm

Printed Name: X GABRIELLA SERANTES

Signature: X

I have read the above Release and Authorization. I am the parent, guardian, or conservatory of _____, a minor. I am authorized to sign this authorization on his/her behalf and I give this authorization in the interest of public education.

Date/Time: _____

Printed Name: _____

Signature: _____

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I voluntarily request **Dr. Rod J. Rohrich**, as my physician, and such associates, technical assistants and other health care providers as they may deem necessary, to perform the following operation upon me: BodyTite Neck

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I **(DO)** **(DO NOT)** consent to the use of blood and blood products as deemed necessary. (Circle one)
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I have been given an opportunity to ask questions about my condition, alternative forms of anesthesia and treatment, risks of non treatment, the procedures to be used, and the risks and hazards involved. and I believe that I have sufficient information to give this informed consent. I certify this information has been explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in, and that I understand the contents. Please DO NOT give your permission or sign this consent form if you have any questions regarding your procedure(s). Please advise Dr. Rohrich's office of your questions or concerns so that arrangements can be made for Dr. Rohrich to address them with you.)

DATE 11-8-18 Patient's Printed Name Gabriella Speranza

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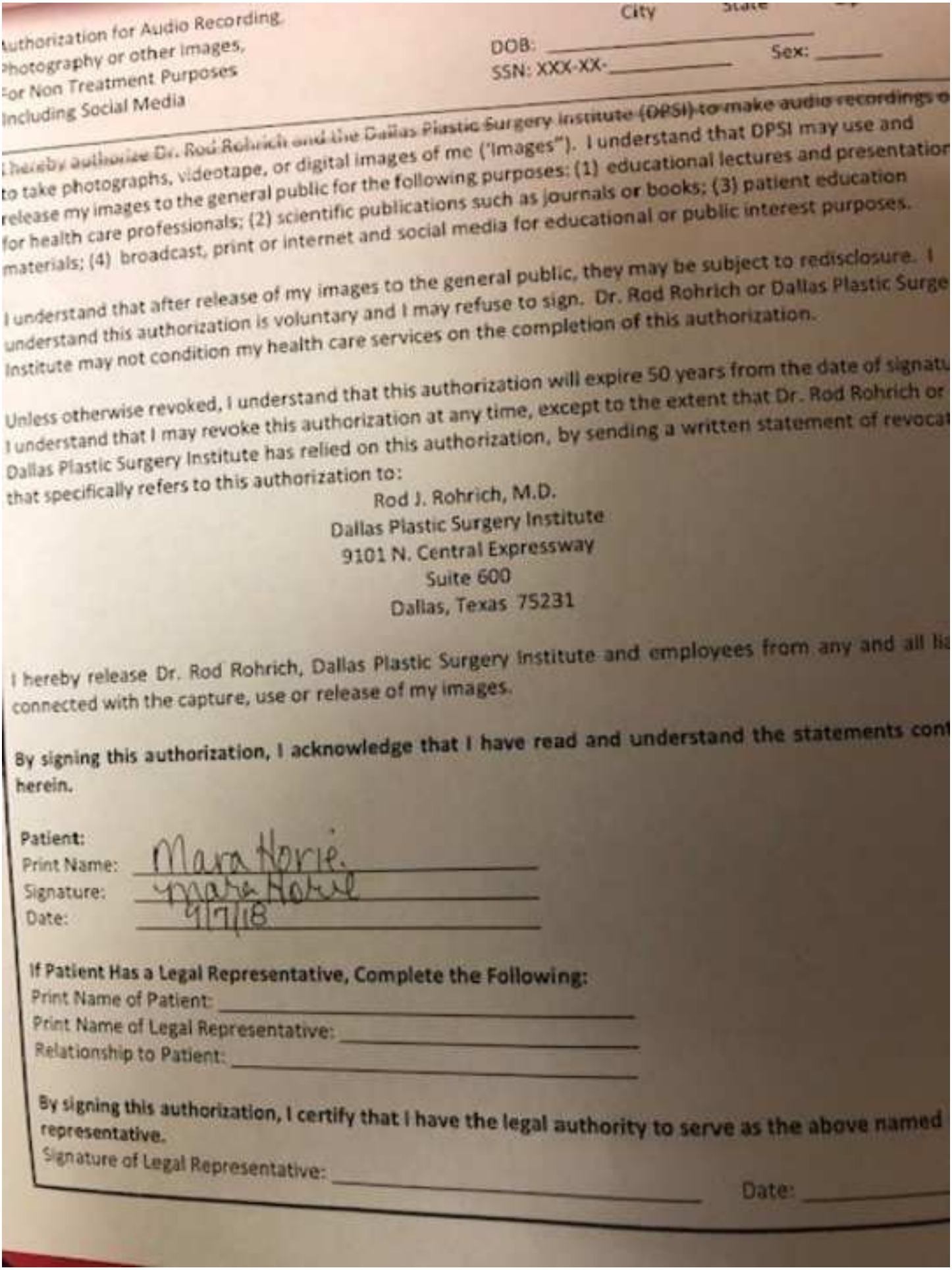

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Signature: Mara Horie
Date: 9/7/18

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