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Case Report

Evolutions in Diagnosis and Treatment of Vaginal Laxity

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Abstract

Introduction: The use of Dynamic Quadripolar Radiofrequency (DQRF) is a new therapy for the treatment of vulvovaginal conditions such as laxity and sexual dysfunctions, while Vaginal tactile imaging allows biomechanical assessment of vaginal tissues and pelvic floor muscles.

Purpose: The purpose of this study is to explore changes in vaginal tissue elasticity, pelvic floor support and muscle strength after applied vaginal radiofrequency treatments.

Case Report: In January 2017, a 42-year-old Caucasian Patient was treated for vaginal laxity. She had given birth to three children, the most recent being six years before vaginal rejuvenation was performed. She had experienced no previous non-surgical vaginal rejuvenation treatments and no past medical history that would be significant to this procedure such as recent surgical labiaplasty, etc. no known drug allergies, no sexual health history until the procedure, and cervical smears has never shown any abnormalities. DQRF procedures were performed at 2 week intervals for 4 consecutive treatments. The Vaginal Tactile Imager (VTI) was used to assess the vaginal walls, pelvic floor support structures and pelvic floor muscle (PFM) contractions before and two weeks after the final DQRF treatment. The VTI probe allows for an estimation of: a) vaginal tissue elasticity as a pressure gradient under vaginal wall deformation, b) pelvic floor support conditions as a pressure gradient under deformation of the posterior compartment, and c) PFM strength as a pressure feedback under voluntary and involuntary (cough) contractions.

Conclusion: Dynamic Quadripolar Radiofrequency treatment is a promising novel technology with clinical results improving tissue elasticity, pelvic floor support and PFM strength upon assessment with tactile imaging. VTI allows monitoring of biomechanical transformation of tissues before and after the radiofrequency treatment and may predict the effectiveness of therapy for individual patients.

Keywords: *Vaginal Tactile Imaging; Radiofrequency; Vaginal Laxity; Vaginal Rejuvenation*

Introduction

The use of Dynamic Quadripolar Radiofrequency (DQRF) is a new therapy [1,2]. for the treatment of vulvovaginal conditions, while Vaginal tactile imaging (VTI) allows biomechanical assessment of vaginal tissues and pelvic floor muscles [3-5].

The purpose of this study is to explore changes in vaginal tissue elasticity, pelvic floor support and muscle strength after vaginal DQRF treatments upon assessment with tactile imaging.

Standardized instruments for assessing biomechanical conditions of the pelvic floor and all urogynecologic aspects of female sexual dysfunction are lacking. In the last decade, a new modality for tissue characterization termed Elasticity Imaging (EI) or Elastography has emerged. EI allows visualization and assessment of mechanical properties of soft tissue. Mechanical properties of tissues (elastic modulus, viscosity), are highly sensitive to tissue structural changes in several physiological and pathological processes. Evaluating the biomechanical properties of the vaginal wall and its immediate surrounding connective tissue has been particularly difficult. The specific goal of VTI is to provide a reproducible and quantifiable means to visualize and measure vaginal tissue elasticity. VTI most closely mimics manual palpation because the TI probe, with a pressure sensor array, acts like human fingers during a clinical examination. The probe slightly compresses soft tissue and detects changes in the pressure pattern ("stress imaging," "computerized palpation," or "mechanical imaging").

Case Report

Methods

In January 2017, a 42-year-old Caucasian Patient was treated for vaginal laxity. She had given birth to three children, the most recent being six years before vaginal rejuvenation was performed. She had no previous non-surgical vaginal rejuvenation treatments and no past medical history that would be significant to this procedure such as recent surgical labiaplasty, etc., no known drug allergies, no sexual health history, until the procedure, and cervical smears has never shown any abnormalities. DQRF procedures were performed at 2 week intervals for 4 consecutive treatments.

The Vaginal Tactile Imager (VTI) developed by Egorov., *et al*. [3] was used to assess the vaginal walls, pelvic floor support structures and pelvic floor muscle (PFM) contractions before and two weeks after the final DQRF treatment.

VTI is performed on a patient the dorsal lithotomy position with empty bladder and rectum. The full VTI examination takes 2 to 3 minutes to complete. The VTI probe is calibrated before every clinical application. The VTI procedure consists of 3 independent parts: (i) probe insertion, (ii) probe rotation, and (iii) muscle contractions, with 8 different tests listed below.

VTI allows the acquisition of pressures applied to the vaginal walls and the acquisition of probe location to visualize vaginal and pelvic floor support structures and to record pelvic floor muscle contractions. The VTI software provides visualization, analysis, information, and reporting tools. The acquired data and analysis information can be used for quantitative assessment of the vaginal and pelvic floor conditions. The VTI device is associated with a movable computer display cart. The VTI probe is equipped with 96 pressure sensors along both sides of the probe, an orientation sensor, and temperature sensors with micro-heaters. During the patient examination procedure, data are sampled from the probe sensors and displayed on the VTI computer display in real time. The probe surfaces that contact the vaginal walls are preheated to human body temperature. A lubricating jelly is used for patient comfort and to provide reproducible boundary-contact conditions with deformed vaginal tissue.

The VTI probe allows for an estimation of: a) vaginal tissue elasticity as a pressure gradient under vaginal wall deformation, (test 1 and 2), b) pelvic floor support conditions as pressure gradient under a deformation of the posterior compartment (test 3), and c) PFM strength as a pressure feedback under voluntary and involuntary (cough) contractions (tests 4 to 8). Orthogonal cross-sections of the 3-D tactile image allow visualization of anatomy and elasticity distributions. Tactile imaging reveals not only the elasticity conditions of vaginal wall itself, but the elasticity distribution of underlying tissue structures. These images may be considered as documentation of the current elasticity state of the vaginal walls and surrounding support tissues. 8 VTI parameters were proposed to characterize vaginal conditions (2): Test 1 allows the calculation of: 1. Maximum resistance force to insertion (Flmax in newtons, N); 2. Insertion work (Wl in millijoules, mJ); 3. Maximum stress-to-strain ratio, i.e. gradient, elasticity (Glmax kilopascals per millimeter, kPa/mm). Test 2 allows the calculation of: 1.Maximum intravaginal pressure at rest (kilopascals, kPa); 2. Anterior vs posterior force at rest (newtons, N); 3. Left vs right force at rest (newtons, N). Test 3 allows the calculation of: 1. Maximum intravaginal pressure at pelvic muscle contraction (kilopascals, kPa); 2. Muscle contraction force (newtons, N).

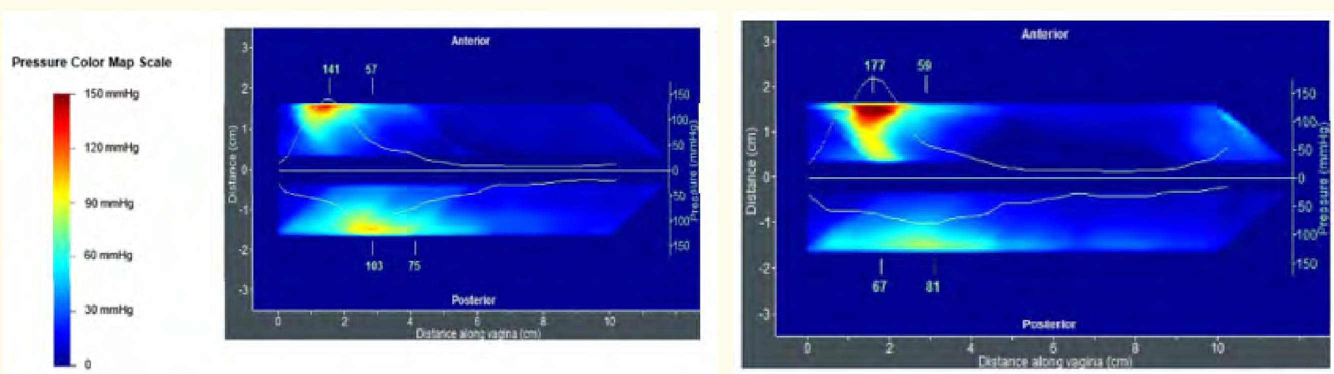
A Standard Vaginal Laxity Questionnaire (VLQ) translated in French was also used. It obtains perceptions on level of vaginal laxity/tightness assessed with 7-level ordered responses (very loose, moderately loose, slightly loose, neither loose nor tight, slightly tight, moderately tight, or very tight).

The patient was successfully treated with 4 consecutive DQRF treatments with 15 days interval.

The non-parametric Wilcoxon Signed Rank Test for repeated measurements on single populations was applied to both repeated measures in Improvement in Elasticity and Pelvic Floor Muscles Strength after treatment, and average calculation of vaginal elasticity. Two-sided levels were used for all statistical tests with $p < 0.01$ as cut-off for significance.

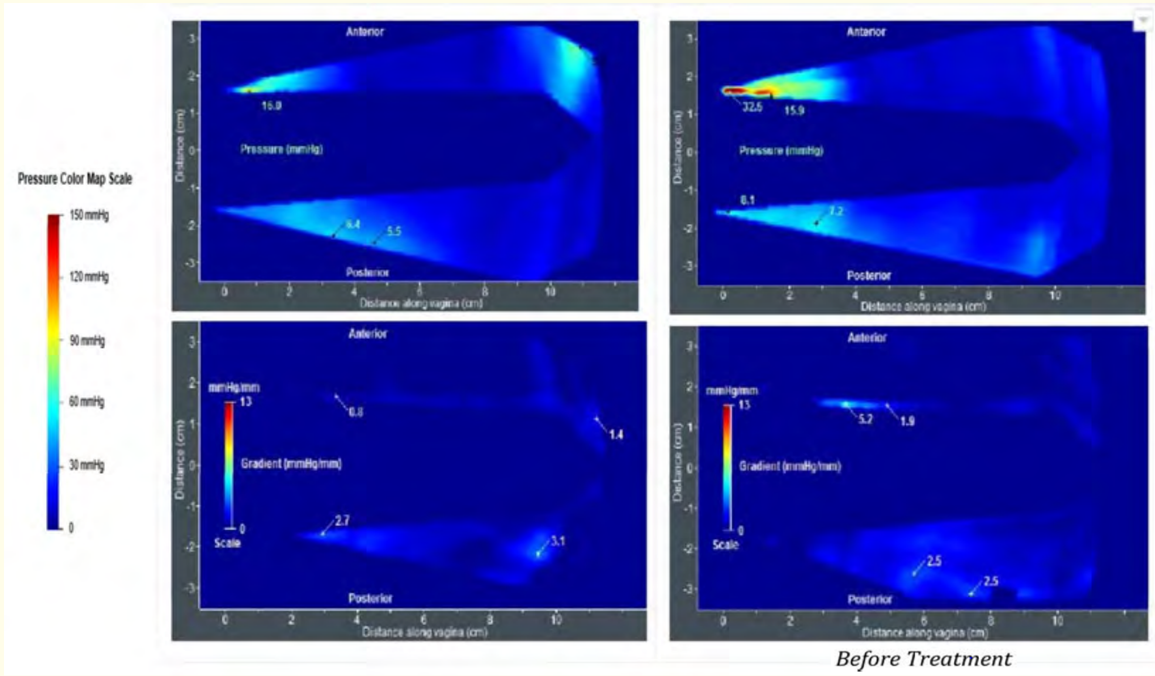
Results

The vaginal tissues elasticity improved from a VLQ score of 1 (very lose) to 6 (moderately tight), and improved in pressure and calculated pressure gradients with color map going wider in yellow and red colours for pressure in test 1 (Figure 1), gradient and pressure in test 2 (Figure 2) and pressure in test 3 (Figure 3). There are statistically significant improvements in pressure at test 1 by 100%, from 20% to 500% in gradient in test 2, and 60% in test 3 (Table 1). The PFM strength for voluntary muscle contractions (Figure 4) and PFM strength for involuntary contractions (contraction with a cough, figure 5) showed higher peak pressures after treatment. PFM increased respectively by 242% and 172% (Table 1).



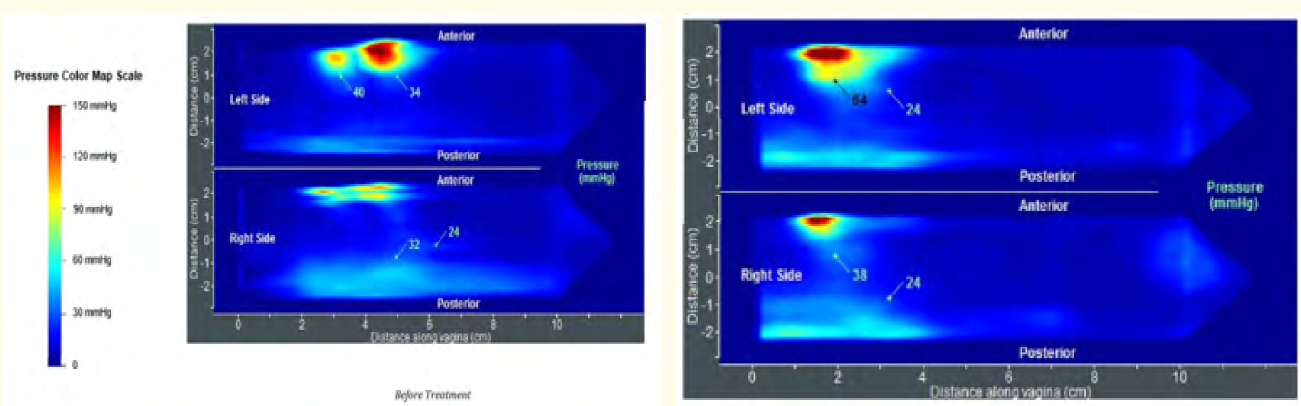
Before Treatment *After 4 sessions of treatment*

Figure 1: *Pressure patterns for vaginal tactile imaging probe elevation (test 1) and calculated pressure along the anterior and posterior compartments before and after radiofrequency treatment.*



After 4 sessions of treatment

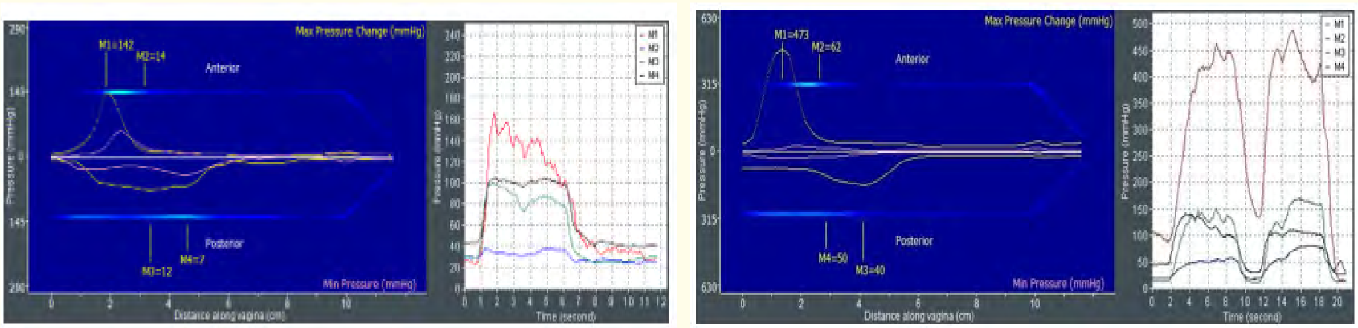
***Figure 2:** Pressure patterns for vaginal tactile imaging probe elevation (test 2) and calculated pressure and pressure gradients along the anterior and posterior compartments before and after radiofrequency treatment*



Before Treatment

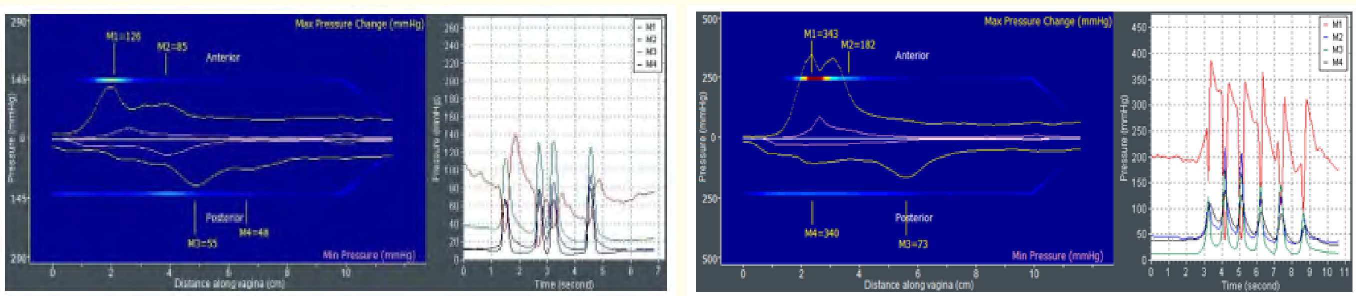
After 4 sessions of treatment

***Figure 3:** Pressure patterns for vaginal tactile imaging probe rotation (test 3) and calculated pressure along the vaginal walls before and after radiofrequency treatment.*



Before Treatment *After 4 sessions of treatment*

Figure 4: *Pelvic Floor muscles strength for voluntary contraction (test 5).*



Before Treatment *After 4 sessions of treatment*

Figure 5: *Pelvic Floor muscles strength for involuntary contraction (test 5).*

	Before treatment	After 4 sessions of treatment
Pressure at VTI Test 1	141	177
Pressure at VTI Test 2	16	32.5
Gradient at VTI Test 2	0.8	5.2
Pressure at VTI Test 3	40	64
PFM strength voluntary contraction	142	473
PFM strength involuntary contraction	126	343

Table 1: *Improvement in Elasticity and Pelvic Floor Muscles Strength after treatment Numbers in red shows statistical significance (p < 0.01).*

The measurement of elasticity (Gradient in kPa/mm in test 1) of the underlying tissues surrounding the vagina, significantly improved by 88%. Maximum intravaginal pressure at pelvic muscle contraction (kPa) increased by 10.5% and muscle contraction force (N) increased by 8.3% (Table 2).

	F_{max} (N)		**W (mJ)**		**Gradient (kPa/mm)**	
	Before	**After**	**Before**	**After**	**Before**	**After**
Test 1	0.665	0.928	32.9	39.9	098	1.84

	P_{max} at rest (N)		**F (N) at rest vert**		**F (N) at rest horiz**	
	Before	**After**	**Before**	**After**	**Before**	**After**
Test 3	23.76	26.24	1.56	1.69	0.69	0.68

Table 2: *Average calculation of Vaginal Tissue Elasticity Numbers in red show statistical significance (p < 0.01).*

Comfort level of the VTI examination procedure was classified as more comfortable as manual palpation; No report for the VTI exam as painful.

Discussion

Increasingly, thermal non-invasive treatments are used for vaginal modification. However, objective assessment of vaginal conditions before and after the applied treatment does not exist yet. Objective anatomic measures, biomechanical, and functional characterization are essential to understand the difference between normal and abnormal conditions. The VTI approach resembles soft tissue palpation, which has been the most prevalent medical diagnostic technique for accessible human organs and the musculoskeletal system. but clinical examination cannot be translated into objective and comprehensive information for a medical report for other clinicians. And that's where tactile imaging acquisition with stored data has a great interest in translating the sense of touch into a digital image [4].

Tactile imaging displays tissue anatomy and elasticity distribution by keeping the stress-strain relation for deformed tissue. The 3-dimensional tactile image can be transformed into an elasticity image with the use of a linear transformation for a region of interest. Functional tactile imaging is a translation of muscle activity into a dynamic pressure pattern. VTI allowed in our report better comprehension of vaginal walls and pelvic floor muscle changes, when Vagina Laxity Questionnaire (or other questionnaires) is not enough accurate for detailed analysis. It is always useful to have reproductible, stored DATA for comparison and further studies [5].

Vaginal laxity is common symptom in urogynecology everyday practice. It is often associated with younger age, vaginal parity, symptoms of prolapse. Vaginal laxity occurs in all women in the weeks after vaginal childbirth and after menopause. The stretching of the dense connective tissue of the vaginal walls and introitus during delivery varies in degrees of laxity and can worsen with successive deliveries. Although it may be considered physiological vulvovaginal laxity may deeply affect self-esteem and quality of life, due to discomfort in everyday life, and to negative impact on sexual relationships [6]. Then, loss of sensation is common in women with vaginal laxity. and vaginal laxity is described my practitioners as the most important change of body integrity experienced by women after vaginal childbirth.

Radiofrequency (RF) used for medical treatments [7] is an advanced technology based on converting the energy of an electromagnetic wave into heat: radiofrequency waves interact with the tissues, generating controlled thermal change. Unlike lasers, which produce heat by selectively targeting a specific chromophore, non-ablative radiofrequency generates heat as a result of the tissue's resistance to movement of the electrons subject to the RF field.

As also suggested for other thermal therapy technologies, DQRF vaginal rejuvenation in introital and vaginal laxity implies re- activation of fibroblast and connective tissue function and development of new networks of collagen and elastin fibers in the subepithelial layers of introitus and vagina [2].

One of the current gold standard treatments for after childbirth abnormal conditions are daily sessions of pelvic floor training (PFT). Significant improvement are mostly noticed after 2 months. However, the cost-effectiveness of is not well known. Population approaches (recruiting antenatal women regardless of continence status) may have a smaller effect on urinary incontinence, although the reasons for this are unclear. It is uncertain whether a population-based approach for delivering postnatal PFT is effective in reducing urinary incontinence. The new DQRF technique can bring valuable clinical outcomes for patients because of less discomfort for women and less disruption of their daily life and routine. This may require further investigations to compare both methods.

DQRF seems to hold advantage regarding its non-ablative characteristics compared to CO2 lasers, and deeper effects in the dermis compared to Erbium Lasers. Comparative studies could be interesting to conduct to assess these differences [8].

Conclusion

Dynamic Quadripolar Radiofrequency treatment seems promising to improve tissue elasticity, pelvic floor support and PFM strength upon assessment with tactile imaging. VTI allows monitoring of biomechanical transformation of tissues before and after the radiofrequency treatment and may predict the effectiveness the therapy for individual patients.

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