High Frequency Treatment for Non-Invasive Non-Surgical Labia Remodeling

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I. Background and objectives

The main purpose of this study was to evaluate the use of a novel high frequency device for the indication of labia remodeling.

The basic principle of the device is to emit oscillating electrical current with forced collisions between charged molecules and ions. These collisions are transformed into heat. The main heat effect is to temporarily change helical structure of the collagen, change structure of elastin and stimulate ground substances. The result is micro-inflammatory stimulation of fibroblasts which produces new collagen and new elastin, as well as other substances to enhance dermal structure.

II. Introduction

There are many women who suffer from skin laxity around and on their labia minora and labia majora. Many are complaing about low sexual satisfaction and low self-confidence. Until now they have only had a choice of removing the unwanted skin by a surgical procedure (labioplasty). This procedure is usually expensive, the healing can take three weeks. The procedure can also be painful and has been associated with risks typical of invasive procedures.

While a few laser devices have been known to treat vagina, consumers increasingly demand non-invasive methods to treat vulva, particularly labia majora and labia minora.

III. Protégé Intima

The Protégé Intima is a new device designed to address labia remodeling. The system combines focused monopolar high frequency with built-in safety features engineered for this indication.

The device can reach temperature on the skin surface at around 40 to 42°C. A patient typically feels pleasant warming sensation at this temperature. One treatment takes around 12 minutes, 6 minutes per one side of vulva. The device has embedded safety system to prevent burns, sparking and arcing, and uses the proprietary Energy Flow Control safety system (EFC Elite). The EFC Elite includes visual contact confirmation (should the applicator loose contact with the skin), dual ground contact monitoring (to eliminate the burns), and the Impedance Intelligence system (to guarantee energy uniformity).

IV. Materials and methods

This preliminary study is a study on 10 female patients treated with the device for labia remodeling. The age of the patients was between 21 to 55 years. The patients were photographed before and after the 4th

treatment. The change in the labia appearance was recorded after the 4th treatment by the physician, based on the photographs. The patients also filled a questionnaire about the change in their sexual satisfaction. The improvement in the appearance was assessed by the physician as none [0], significant - mild [1], significant - moderate [2], and significant - excellent [3]. The changes in sexual satisfaction were evaluated on the same 4-point scale (none [0], significant - mild [1], significant -moderate [2], and significant - excellent [3]). Further, the comfort of the treatment was evaluated by the patients on the 4-point scale (intolerable [0], uncomfortable [1], comfortable [2], very comfortable [3]).

Each patient was administered four (4) treatment sessions, with a period of 5 to 8 days between each session. The initial treatment parameters were set at the power of 50 units and 80% duty cycle. A water based gel was applied to the skin. The initial power was adjusted according to a patient's subjective level of temperature tolerance or until mild erythema appeared. A special hygienic cover was applied to the tip of the applicator. The applicator was moved in a slow linear fashion around the labia major and labia minor region. One side of the vulva was treated approximately 6 minutes. The surface temperature was in the range of 40 to 42°C.

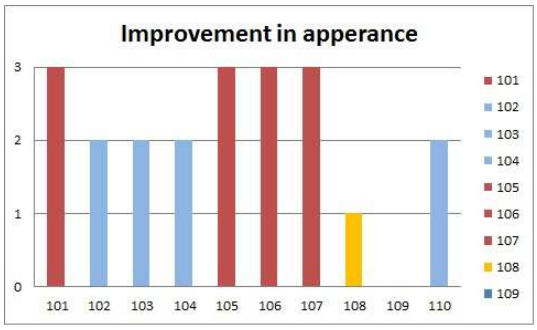

Figure 1: *Improvement in appearance, subjects 101 to 110*

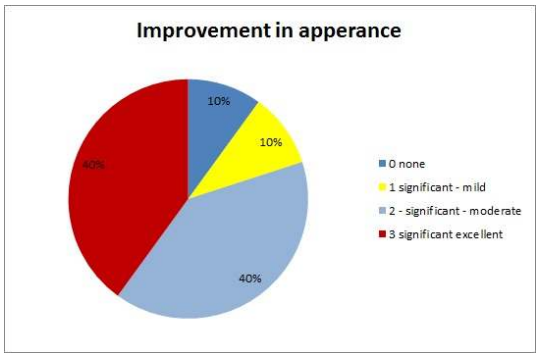

Figure 2: *Percetange of improvement in appearance*

V. Results

All patients finished 4 labia remodeling treatments in this preliminary study. The results were divided into 3 groups: An improvement in the appearance, an improvement in perceived sexual satisfaction, and rating of the treatment comfort.

The primary endpoint is an improvement of the shape and skin laxity of the vulva. The graphs show that 40% of the patients had significant - excellent improvement of vulva appearance, 40% of the patients had significant - moderate improvement of vulva appearance.

The secondary endpoint of the labia remodeling treatment is an improvement in sexual satisfaction. Fourty percent of the patients reported the improvement in sexual satisfaction as significant - moderate and 40% reported their sexual satisfaction improvement as significant - mild.

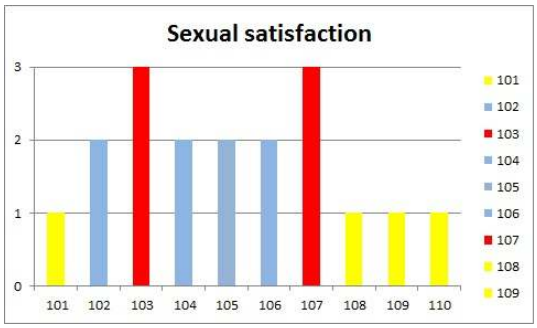

Figure 3: *Sexual satisfaction, subjects 101 to 110*

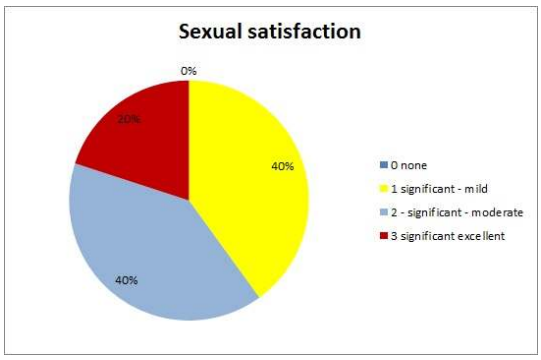

Figure 4: *Percentage of sexual satisfaction*

Fifty percent of the patients reported the treatment with the device to be comfortable. Fourty percent of the patients reported the treatment to be very comfortable.

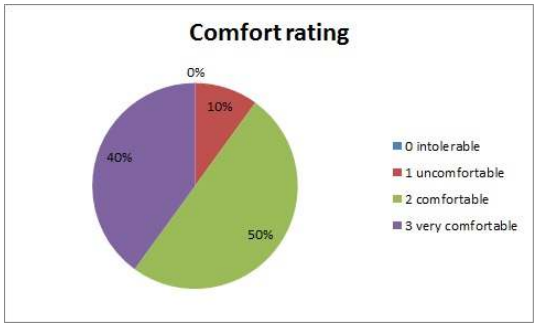

Figure 5: *Percentage of comfort rating*

VI. Conclusions

The results of this study show that the Protégé Intima is a safe and effective device with indications for non-invasive non-surgical labia remodeling. The use of the device leads to the improvement of the appearance of the vulva and to the improvement of sexual satisfaction. Eighty percent of the patients had significant improvement in the appearance of the labia and in the improvement of sexual satisfaction. Ninety percent of the patients reported the treatment to be comfortable or very comfortable.

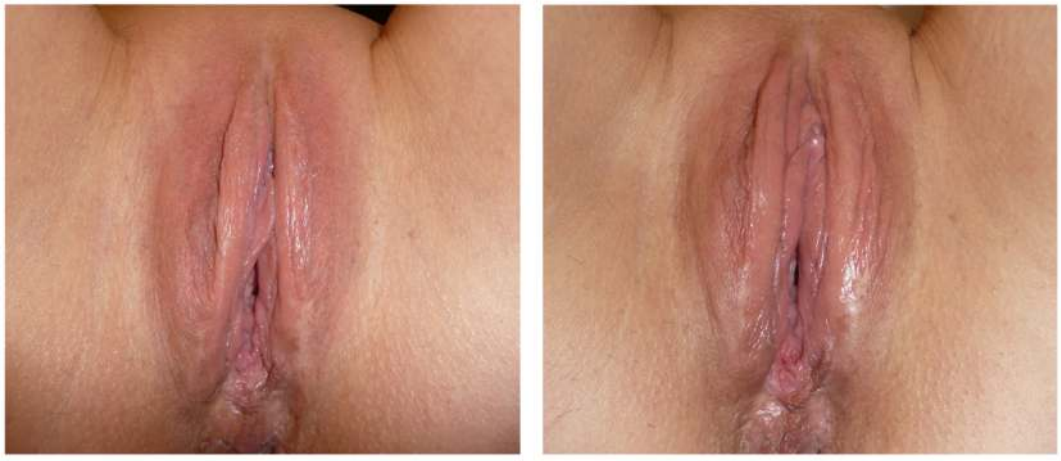

Figure 6: *Remodeling of labias. Labias are more firm*

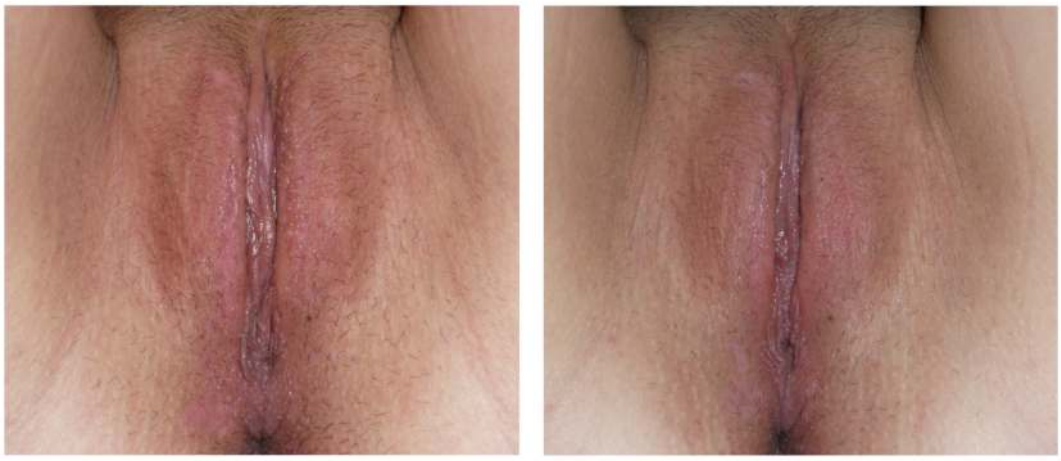

Figure 7: *Labia shrinkage*