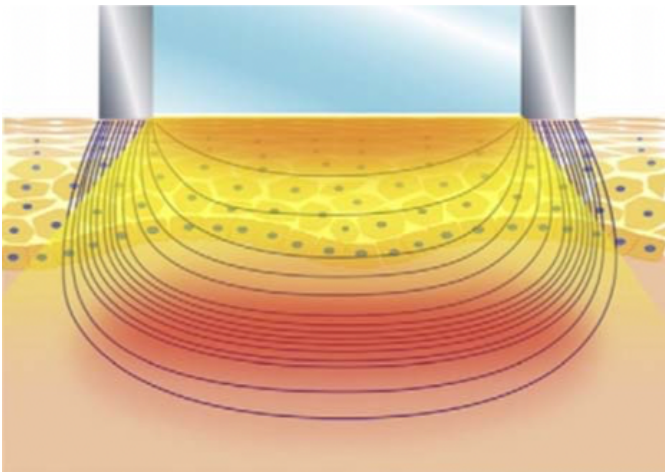


SMART-ST, a Bipolar micro pulsed RF technology by Formatk Systems

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Background: Radio frequencies have been commonly used in medicine since the beginning of the 20th century. In 1907 K.F Nagelschmidt, a German physician coined the term Diathermy to describe the heating process of a living tissue, which is accomplished by a conversion of high-frequency currents to heat while refraining from painful muscle contractions that occur while inducing low frequency currents.



The electromagnetic endogenous heating has some advantages over other forms of tissue heating (conduction, infrared radiation, etc.). In particular, long waves allow for the heating of deeper skin layers. Whereas during heating by conduction the temperature decays exponentially to the physiological value of 37°C in a few millimetres, electromagnetic heating allows a more homogenous distribution of temperature in a few centimetres depths, which cannot be reached with other external means. Radio frequency as applied to aesthetic medicine applications targets the reticular dermis matrix, aiming to increase the intra-dermal temperature in order to obtain two different physiological effects:

- A. A short-term effect, also known as the "BBQ Effect" or "Shrinking Effect": an immediate contraction of the existing collagen fibres and initial protein denaturation induced by heat, which reacts to a reorganisation of the tridimensional protein structure. This reaction generates a perceptible skin toning and a gradual but visible facial lift-up.
- B. A long lasting effect: due to the continuous denaturation process (5% - 30% of total collagen fibres in the treated area) and the formation of a damaged area with an inflammatory component that finally induce a reparative response resulting in a long lasting tightening effect.

Objective: The technology behind the ST applicator has been used in the field of medical aesthetic for more than two decades. The use of Forma™ ST bipolar RF applicator has become increasingly popular and demonstrated high levels of treatment effectiveness. However, despite the positive treatment results, many patients were avoiding the treatment due to the high levels of treatment discomfort. A new technological breakthrough by Forma-TK systems Ltd lead to the development of the SMART-ST applicator. The new SMART-ST applicator enables the deliverance of high amount of energy to the skin by using an advance micro pulses technology. The objective of this trail is to evaluate and compare clinical skin modification and pain levels during treatment in using the SMART-ST and ST applicators.

Method: Initially, patients' faces were photographed from different angles and skin temperatures were measured by an infrared scanner. Next, using Forma's diamond peeling, a light dermal – abrasion was performed prior to the

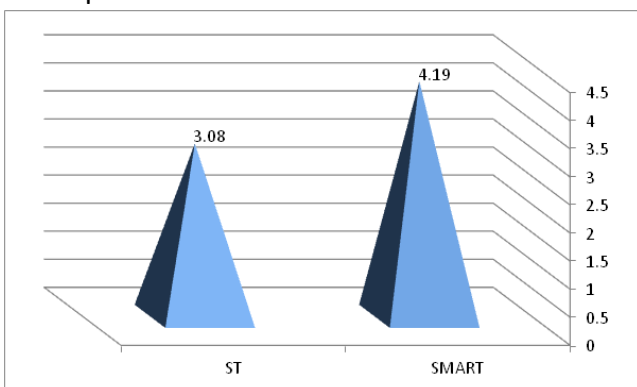
RF session in order to reduce the skin impedance and improve the ST/ SMART applicator – skin coupling. A generous layer of RF gel (type: Parker 03) was then applied along 1/2 of the treatment area. The appropriate mode of operation, either deep or shallow, was then selected depending on the treatment area, a shallow mode for boney areas and a deep mode for fleshy ones. Two double passages were performed before the energy increased up to the point that the patient couldn't stand the pain. The perception of pain was graded on a scale of 1-10, 1 standing for not painful at all and 10 for intolerable pain.

A skin temperature was measured again and the whole procedure was repeated on the other half of the face/neck with the other applicator (e.g. ST vs. SMART). Participants were treated 6 times in 3-week interval. The last follow up evaluation took place 4 weeks post last treatment. 4 weeks post last treatment; patients arrived for a follow up meeting where they were asked to fill up a questionnaire regarding the improvement levels in their skin appearance. The patients were asked to choose one of the 5 options below:

1. No improvement at all
2. 1%-25% improvement
3. 26%-50% improvement
4. 51%-75% improvement
5. 76%-100% improvement

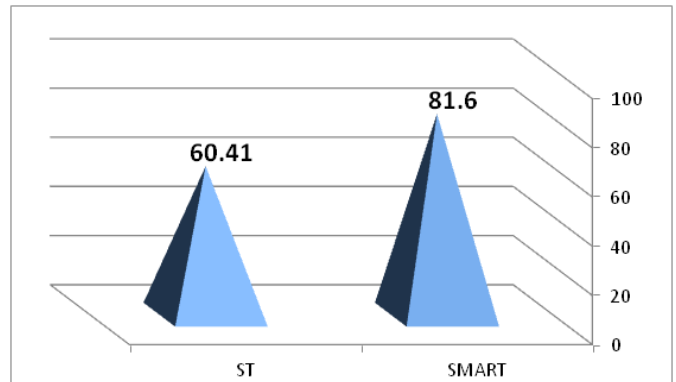
Cases: There were 23 participants in the clinical trial, ranging in ages 26 - 71, two of them males.

Results: Improvement scale per patients assumptions:



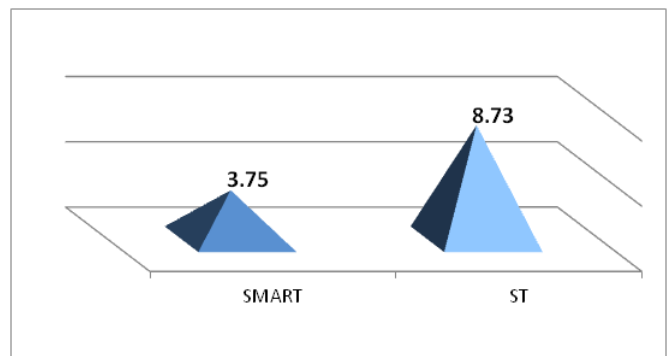
Graph no. 1 - Average improvement

Average maximum energy level that patients could have tolerate during ST treatment was 60.41 J/cm. Average maximum energy level that patients could have tolerate during SMART treatment was 81.66 J/cm³.



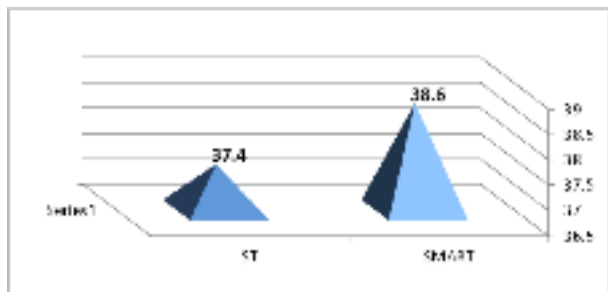
Graph no. 2 - Average energy level/J

Average pain level during ST applicator treatment, deep mode of operation (1.25 MHz), 60J/cm³: graded 8.73 Average pain level during SMART applicator treatment, deep mode of operation (1.25 MHz), 60J/cm³: graded 3.75.



Graph no. 3 - Average pain level

Average post treatment tissue temperature - ST applicator: 37.4°C. Average post treatment tissue temperature - SMART applicator: 38.6° C.



Graph no. 4 - Ave. maximal skin temperature - post treatment

Side effects: The treatment caused an immediate hyperemia and edema that lasted a few hours only.

Conclusion: Bi polar pulsed RF by Forma-TK is a safe and clinically proven way to tighten and contour skin. The treatment generated improvements in tone, contour, and texture occurring naturally through stimulation of the patients' own collagen. Forma-TK mission is to deliver innovative treatments with minimal inconvenience and pain. The trail demonstrated that the use of the new SMART-ST applicator provides practitioners with the ability to deliver more effective treatment at significantly lower patient discomfort.

The participants in the trail indicated a drastic decrease of more than 50% in pain levels during a treatment with the SMART- ST applicator. Up until now, pain levels induced by ST treatments constructed a major barrier for patients. The introduction of the new SMART-ST application dramatically reduces this main barrier for using the application. Moreover, the reduction in participants discomfort levels by using the SMART-ST application enabled practitioners to admit higher levels of energy during the treatment resulting in more effective treatment outcome.

