NON-ABLATIVE RADIOFREQUENCY FOR WRINKLE REDUCTION PILOT STUDY

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INTRODUCTION

The use of radiofrequency (RF) in antiaging treatments is well established, in order to optimise working parameters a pilot multicentre evaluation of INDIBA® Facial Treatment Methodology for wrinkle treatment with a 40°C application protocol has been undertaken.

MATERIALS AND METHODS

Volunteers received 6 treatment sessions over a 4-week treatment period. Results were evaluated after the treatment, at two and three months after the completion of the treatment.

Study Design

The study population has included 23 healthy volunteers (22 women and one man), suffering of wrinkles with ages ranging from 31 to 83 years old and skin photo type from II to IV (Fitzpatrick scale).

RF Device and accessories

As RF source, an INDIBA® device (INDIBA SA, Barcelona, Spain) was used. To assure that the desired temperature (40°C) was achieved an IR Thermometer (Fluke 62 MAX+) was used. Finally to measure wrinkles (total size, depth, width and maximum depth) a skin analyser was used (Antera 3D®).

Efficacy and safety evaluation

Effectiveness was assessed by standardized facial photographs. Images were taken before starting the treatment, at the end of the treatment and at one and two months as follow up pictures after the last session.

Treatment results were evaluated with subjective questionnaires for both, patients and professionals, to rate: improvement, effectiveness and friend recommendation. To assess in an objective manner, digital measure of wrinkles was done to get data of: total size, depth, width and maximum depth.

Statistical significance was determined by Paired student’s t-test. Safety was assessed by subjective questionnaires (pleasantness, tolerance and erythema) filled out by the professionals and the volunteers as well as a record of undesirable side effects. Questionnaires where about:

RESULTS

Study Population

All 23 subjects enrolled into the study completed all 6 RF sessions, although three cases where excluded for not fitting the inclusion criteria. Age ranged from 37 to 83 years old with an average age of 57 ±12 y.o. Skin Fitzpatrick photo types distribution was: 5% Type I, 40% Type II, 45% Type III and 10% Type IV. Fitzpatrick wrinkle score distribution of patients before the treatment is shown in Table 2.

Fitzpatrick Wrinkle Evaluation

Overall the mean basal wrinkle degree was Fitzpatrick 6.5 (±1.5), at the end of the treatment , the mean degree decreased to 5.8 (±1.6) and at three months follow up, after the end of treatment, it had decreased to 5.3 (±1.4), percentage distribution can be seen at Table 2. Paired student’s t-test showed statistical significance in Fitzpatrick Wrinkle degree reduction at the end of the treatment (p=0.002), at two months follow up (p=0.000) and at three months follow up (p=0.000).

Images showing the basal state (before treatment) and the outcome at three months of completing the treatment can be seen from Figure 1 to Figure 3.
Figure 1. 63-year old patient before and 3 months after the last tx.

Figure 2. 55-year old patient before and 3 months after the last tx.

Figure 3. 74-year old patient before and 3 months after the last tx.

Figure 4. Case 2, 45-year. Wrinkle measures: total size 15,4 / depth 0,0517 mm / Width 1,65 mm / Max. Depth 0,080
Total size 12,6 / depth 0,0356 mm / Width 1,83 mm / Max. Depth 0,059
Efficacy

Not all the patients that undertook INDIBA treatment were tested with the skin analyser, just the data of eleven patients could be collected after the end of treatment.

Paired student’s *t*-test showed a significant total size reduction (*p*=0.000) of wrinkles as depth reduction (*p*=0.001), maximum depth reduction was not significant as neither was the slight increase in width after the treatment was concluded (Table 3). Examples of the Skin analyser images are shown in Figure 4 and 7.

Subjective questionnaires say that Professionals saw no change in 11% of the patients, 58% improved, 21% showed much improvement and 11% improved very much (Table 4). Among patients answers, 26% didn’t see any improvement at all, 42% improved somewhat, 11% moderately and 21% strongly. The treatment was felt as moderately or strongly pleasant by 95% of the patients (Table 5).

There were no withdrawals.

**Table 3.** Wrinkle mean loss and percentage of loss one month after starting the treatment. After a Paired student’s *t*-test, total size reduction was statistically significant (*p*=0.000) as depth reduction (*p*=0.001).

<table>
<thead>
<tr>
<th></th>
<th>Total size</th>
<th>Depth mm</th>
<th>Width mm</th>
<th>Max. depth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean loss</td>
<td>4.93</td>
<td>0.02</td>
<td>0.01</td>
<td>0.03</td>
</tr>
<tr>
<td>% loss</td>
<td>16.10</td>
<td>15.48</td>
<td>0.57</td>
<td>18.23</td>
</tr>
</tbody>
</table>

**Table 4.** Results of the subjective therapist questioner to evaluate the efficiency of INDIBA® treatment on wrinkles per treated patient.

<table>
<thead>
<tr>
<th>THERAPIST EVAL</th>
<th>Worse</th>
<th>No change</th>
<th>Improved</th>
<th>Much improved</th>
<th>Very much improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement</td>
<td>0</td>
<td>2 (11%)</td>
<td>11 (58%)</td>
<td>4 (21%)</td>
<td>2 (11%)</td>
</tr>
</tbody>
</table>
Safety

The treatment proved to be safe, no undesirable side effects were reported. Regarding tolerability, therapist evaluation gave punctuation of 2 being 0 no pain and 10 worst possible pain. In general it has been a treatment well tolerated by most of the patients (Table 5). There were no withdrawals.

<table>
<thead>
<tr>
<th>SELF EVALUATION</th>
<th>Not at all</th>
<th>Somewhat</th>
<th>Moderately</th>
<th>Strongly</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improvement</td>
<td>5 (26%)</td>
<td>8 (42%)</td>
<td>2 (11%)</td>
<td>4 (21%)</td>
</tr>
<tr>
<td>Atractiveness</td>
<td>4 (21%)</td>
<td>8 (42%)</td>
<td>3 (16%)</td>
<td>4 (21%)</td>
</tr>
<tr>
<td>Pleasantness</td>
<td>1 (5%)</td>
<td>0 (0%)</td>
<td>8 (42%)</td>
<td>10 (53%)</td>
</tr>
<tr>
<td>Friend recommendation</td>
<td>1 (5%)</td>
<td>2 (11%)</td>
<td>5 (26%)</td>
<td>11 (58%)</td>
</tr>
</tbody>
</table>

Table 5. Results of the patients’ subjective perception questioner.

DISCUSSION

INDIBA® treatment for wrinkles has proven to be a safe technology, stated by all questionnaires to both professionals and patients. Although pictures in many patients do not show a relevant improvement, all evaluations showed an improvement of wrinkles appearance. Skin analysis showed a decrease of wrinkles total size by a 16%, decrease of depth by a 15% and decrease of maximum depth by 18%, only width showed an increase by 0.5%. Subjective assessment by therapist claim improvement of wrinkles in 89% of patients, as well as self-evaluation where 74% of patients said to have experience some degree of improvement.

What looks contradictory at first glance is the increase of the mean wrinkles width (0.57%) whilst the rest of measures showed a decrease (total size, depth and maximum depth). This could be a result of the relaxation of the depth, that would track the tissue and get both sides of the wrinkle closer, with this relaxation and its resurfacing would relax the sides and make them spread away from the centre of the wrinkle giving a false appearance of wrinkle widening.

Pictures do not seem to show the effect of the treatment. This can be deduced because there is no real correlation among what the pictures show and what the patient’s and doctor’s perceptions and values showed in the different questionnaires for different concepts.

CONCLUSIONS

The use of INDIBA® with Temperature Monitoring up to 40°C has shown to be safe and effective in the improvement of wrinkles appearance up to three months after the end of treatment. Further studies would help to evaluate the risks and benefits of different temperature limits as well as additional treatment sessions.

REFERENCES