

Evaluation of the enhancement of efficacy with injection of a hypo-osmolar solution prior to localized non-invasive ultrasound treatment for the reduction of localized fat deposits.

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Body contouring and fat reduction treatments are highly requested by patients. Invasive methods carry high risks for side effects and complications. The development of non-invasive technologies for body contouring has opened numerous doors in this field of medicine. Non-invasive ultrasound devices offer patients safe and effective results for reducing localized fat deposits.

The device used for this case study is the NovaShape by Ultramed. The selection of the NovaShape is based on the supposedly advanced technology which, unlike the focused beam and fixed frequency and heat generation of other known devices, has a seemingly variable frequency, non-focused beam and chilled transmitter with no-heat generation and a mechanical cell wall destruction mechanism. This device was also selected for its efficacy and safety that has been confirmed with a number of research studies already. Efficacy studies was written up as scientific papers and showed superior efficacy over other similar ultrasound devices.

Safety has been well researched with studies evaluating urinary and blood levels before, during and after treatment showed the normalizing of triglycerides, liver transaminases and urinary density within 48 hours after the treatment. After treatment, LaPente found significant reduction in circumferential measurement of abdomen (12cm), lower limbs (5cm). Abdominal volume reduced to 9.27 % and lower limbs 11.2 %. Shortly after treatment blood triglycerides rose by 77.7 %. Liver transaminase rose by 11.3 %. Total cholesterol, mean gammaglutamyl transpeptidase, ketonic bodies in urine showed slight changes. Mean urinary density was also slightly raised.

Studies published on the use of the technique of adiposytolysis using hypo-osmolar solutions combined with the weakening of cellular membrane using specific ultrasound energy designed for the destruction of adipocytes has shown the efficacy of the combination therapy. These studies will be briefly outlined in the case study report.

The purpose of this case study was to evaluate the efficacy of adding an injectable solution prior to treatment with the focused ultrasound.

Case Study Group

- 1 male and 4 females
- Age between 20 – 50 years

Exclusion criteria

- Diabetes
- Other weight loss medication or treatments
- Use of corticosteroids
- BMI > 35 or < 20
- Liver or kidney disease or abnormality

Area of treatment: Thighs or abdomen

Treatment:

- 1 side of treatment area only focused ultrasound with NovaShape
- Other side injection solution A plus focused ultrasound with Novashape

Areas of 80cm² was marked out in a standing position.

Solution A: hypo-osmolar solution containing injectable water, lidocaine and ascorbic acid.

10 ml of the solution per treatment area was injected with 27G 13mm needles in a multipuncture technique. 0.5ml solution is injected in points 1cm apart from each other over the marked area.

The patients were evaluated before and 3 weeks after the treatment by means of the following measures:

- Weight
- Bio-electrical impedance
- Measurements of the areas treated
- Photographs
- Sonar evaluation for measuring subcutaneous fat

Results:

Sonar evaluation showed an average of 11.2mm reduction of subcutaneous fat per patient after one session of treatment with NovaShape alone.

The contra lateral areas treated with the hypo-osmolar injection solution combined with NovaShape showed an average reduction of 14.2mm measured subcutaneous fat per patient. The patient's weight remained stable, the bio-electrical impedance remained the same and centimeter loss over the treated area (including obviously both treatment groups) averaged 4.6cm reduction.

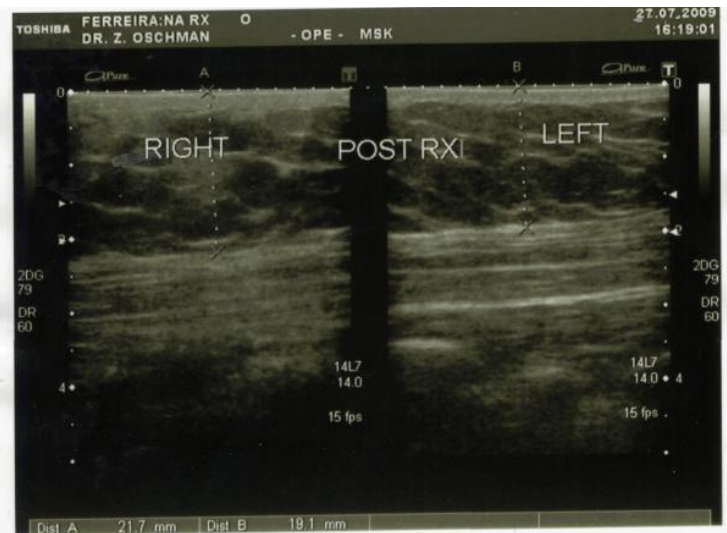
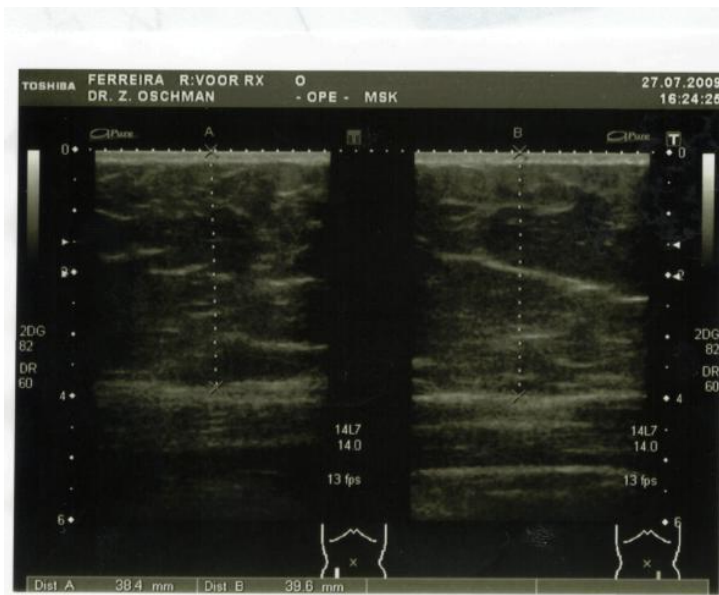
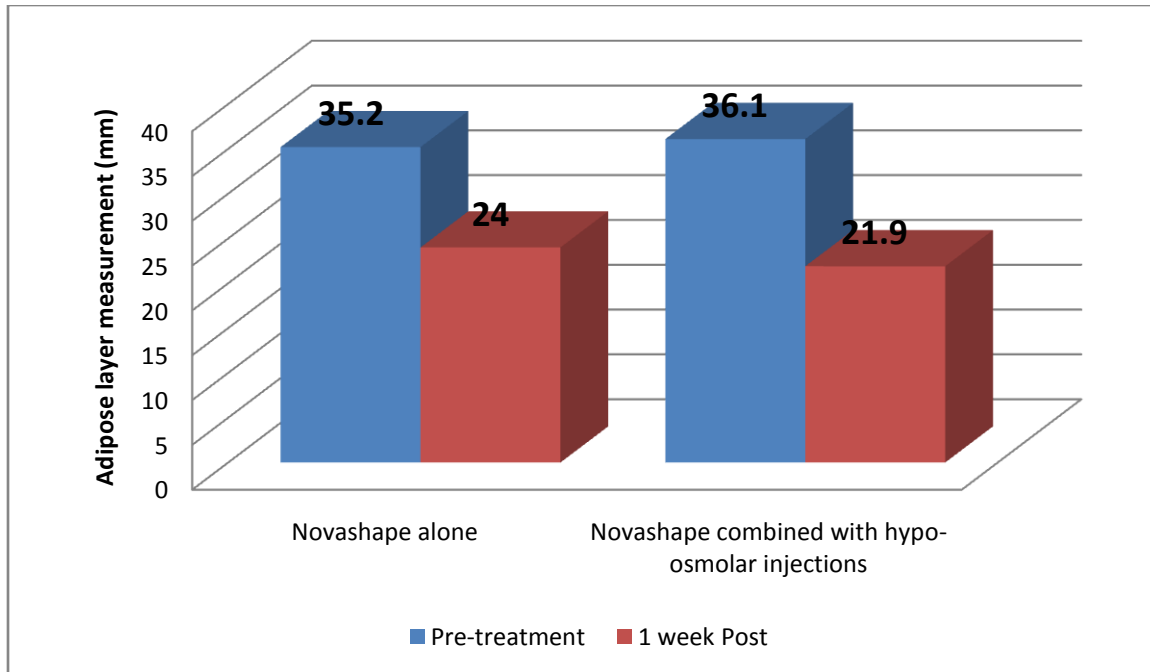


Figure 1. This first case shows the sonar evaluation of both treatment areas before (image on the left) and 1 week after (image on the right) of a patient that has been treated with the Novashape device. The treatment was performed over the abdominal area. The right side of the abdominal area was treated with the Novashape only and the left side with the Hypo-osmolar solution as well as with the Novashape. The measurements of the adipose layer was Right side

38.4 mm before treatment and 21.7mm after treatment. The lefts side was 39.6mm before treatment and 19.1mm after treatment.

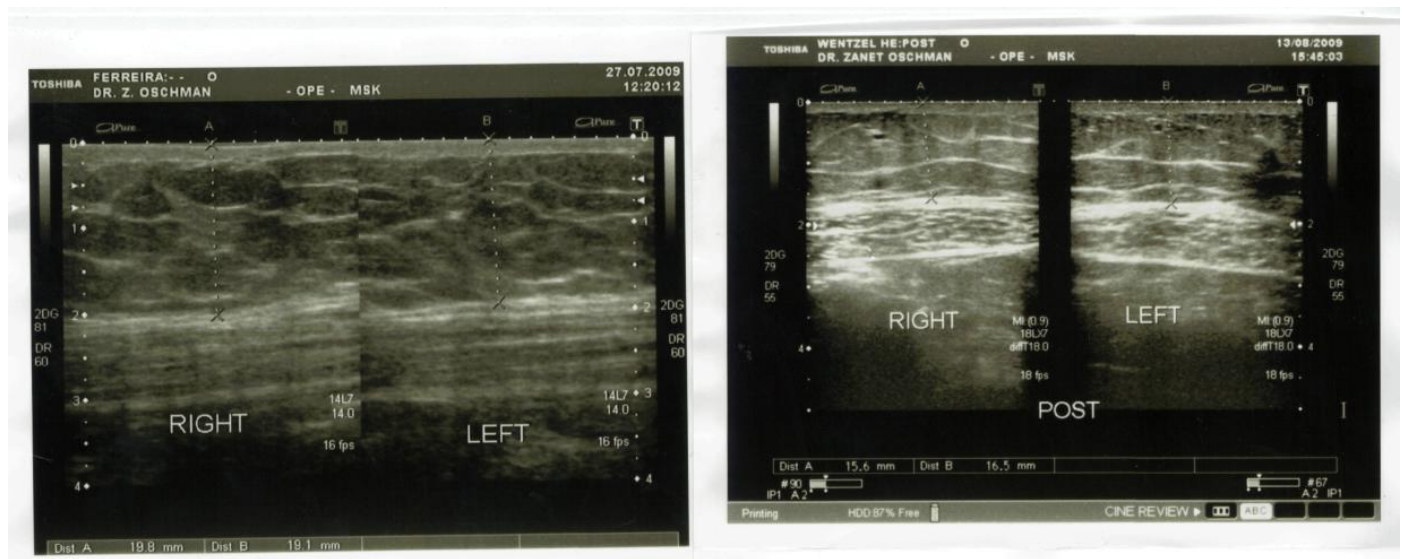


Figure 2. This sonar evaluation was performed on a patient receiving treatment over her waist area. The patient received Novashape alone on the left side and Novashape combined with the hypo-osmolar solution on the right side. Sonar measurement of the adipose layer showed the right side to be 19.8mm before treatment and 15.6mm after treatment. The left side measured 19.1mm before and 16.5mm after the treatment.

The sonar evaluations (figure 1 and 2) showed clear resolving of fat cells and reduction of the subcutaneous fat layer in all the treated areas. The measurements showed the improved efficacy of combining the Novashape with prior treatment with a hypo-osmolar injection solution over the area to be treated.

Discussion

Lipolysis by means of focused resonant ultrasound through ultracavitation is an effective new non-invasive method to reduce localized fat deposits. Efficacy and safety of this treatment has been confirmed by previous studies. The treatment on its own is very effective and deserves a significant place in treating fat deposits, though this study has shown that the results can be enhanced by combining the treatment with a prior hypo-osmolar injection solution in the area. This would be an excellent indication for the small amount of resistant cases and in patients wanting faster results. Though, not all patients will feel comfortable with the addition of an injectable procedure. Sufficient scientific support shows that the Novashape device treatment alone will be effective enough also. This specific study also showed the efficacy of the treatment on the side that received ultrasound treatment alone.

Therefore, the study demonstrates not only the visible efficacy of treatment of localized fat pads utilizing the NovaShape device, but also demonstrates the enhancements of results with prior injection of a hypo-osmolar solution into the area to be treated.

It would therefore be a good indication to include prior injection of hypo-osmolar solution over an area to be treated with the Novashape should the patient be comfortable with this.

References:

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