

TITLE

OBSERVATIONAL, ANECDOTIC, SPONTANEOUS STUDY IN PATIENTS WITH CHRONIC VENOUS INSUFFICIENCY (CVI), UNDERWENT TO SFALT TECHNIQUE PLUS NUTRACEUTICAL TREATMENT.

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1 - OBJECTIVE

CVI affects a great number of subjects in adult population. The aim study is to enhance the efficacy of sclerofoam assisted laser therapy (SFALT) technique, that connects the sclerofoam to low flow (5W/40J/cm) endothelium ablation with fiberoptic diodic 1470 wavelength laser, associated to nutraceutical protocol in a cohort of these patients.

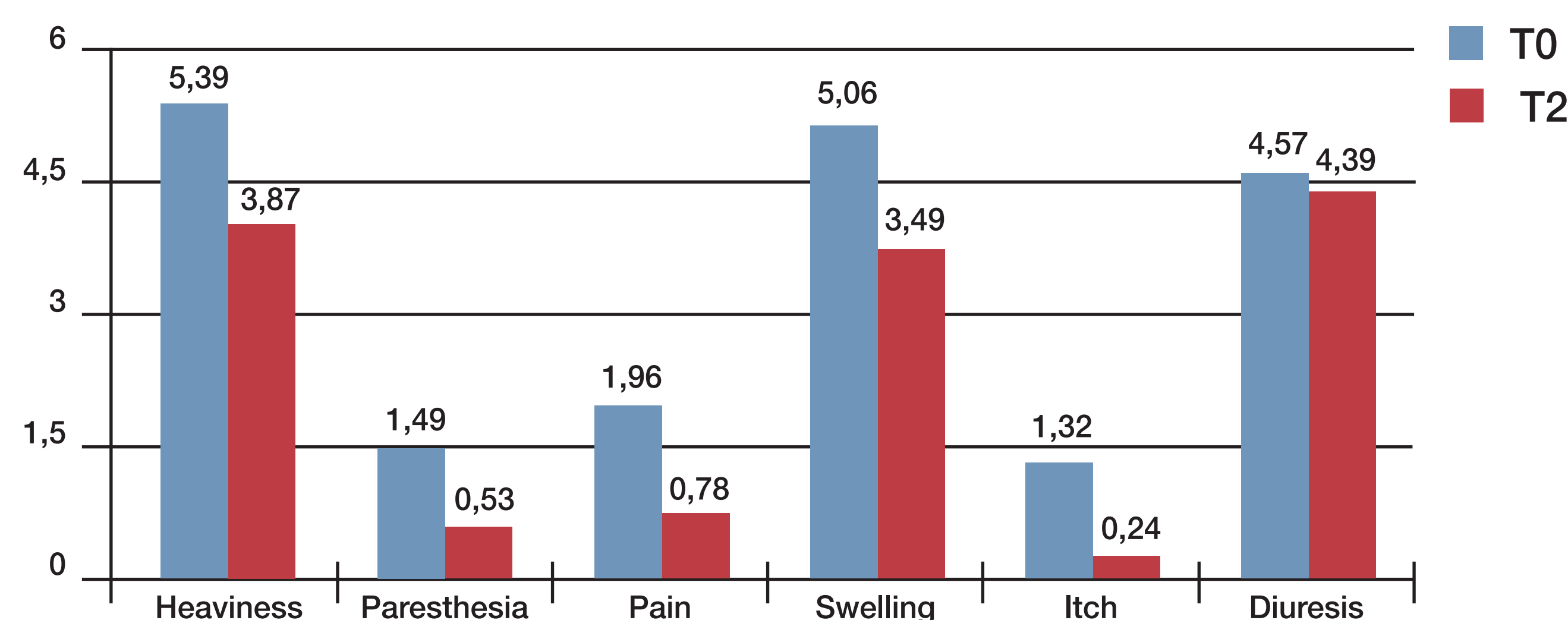
2 - METHODS

30 women spontaneously appealing to our Second Opinion Consulting Network (Modena), were recruited, based on definite CVI history proved by echo color doppler imaging. All the patients displayed thigh and leg varices due to major saphenous vein valve incontinence with saphenous trunk reflux causing flebo-lymphoedema (C2-C3). Since the first postoperative day, the patients have swallowed, for 3 months, 2 capsules/day containing each: Aesculus Hippocastanum (200 mg), Chondroitin sulphate (125 mg), Oligomeric proanthocyanidins (Opc) from Pinus pinaster (60 mg) and from Vitis vinifera (15 mg), Organic silicon stabilized on marine collagen (12 mg) and Carcinine dihydrochloride (10 mg).

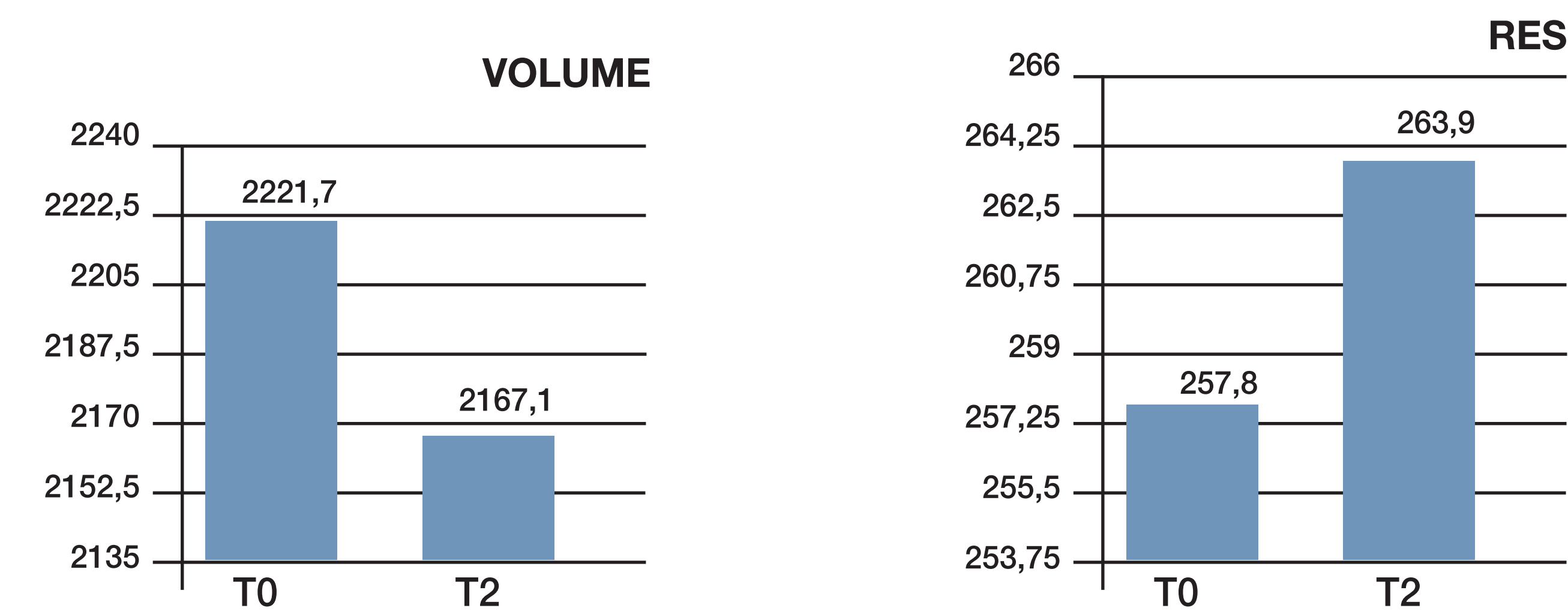
3 - RESULTS

All the patients fulfilled the nutraceutical schedule without showing any untoward effect related to the oral supplement or SFALT procedure.

The symptoms score confirmed a substantial satisfactory relief after 1 month of treatment, with significant ($p < 0.02$) lower distal leg volume reduction, particularly in the distal part of leg, measured with spectroscopic bioimpedentiometry. We observed also a reduction of the VAS symptoms.

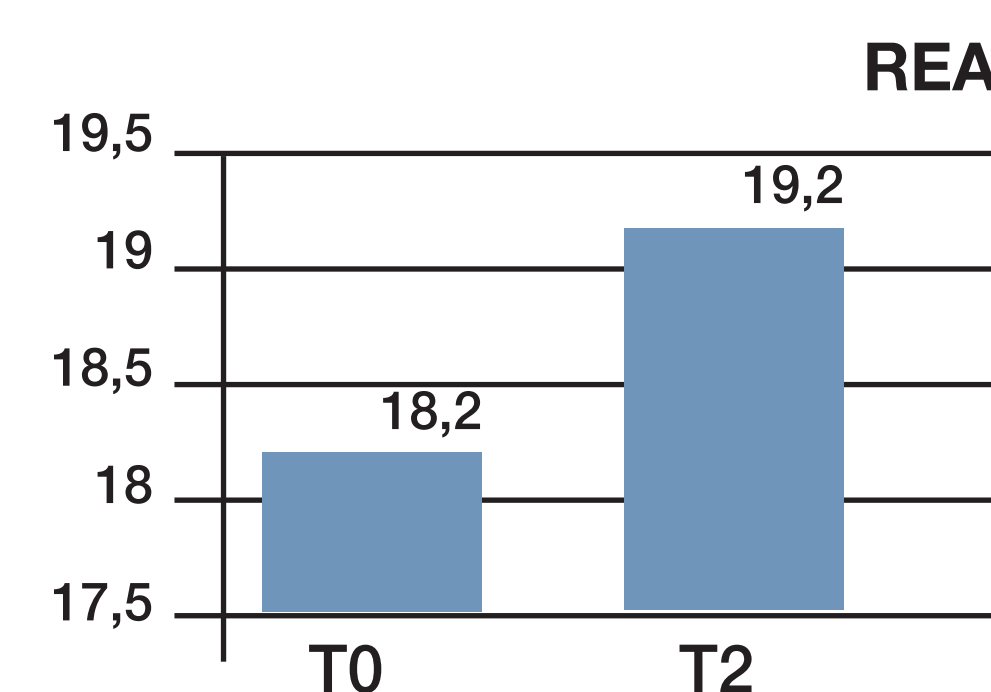


Graph 1
Values of VAS. The values were detected before taking the nutraceutical (T0) and 60 days after treatment (T2).



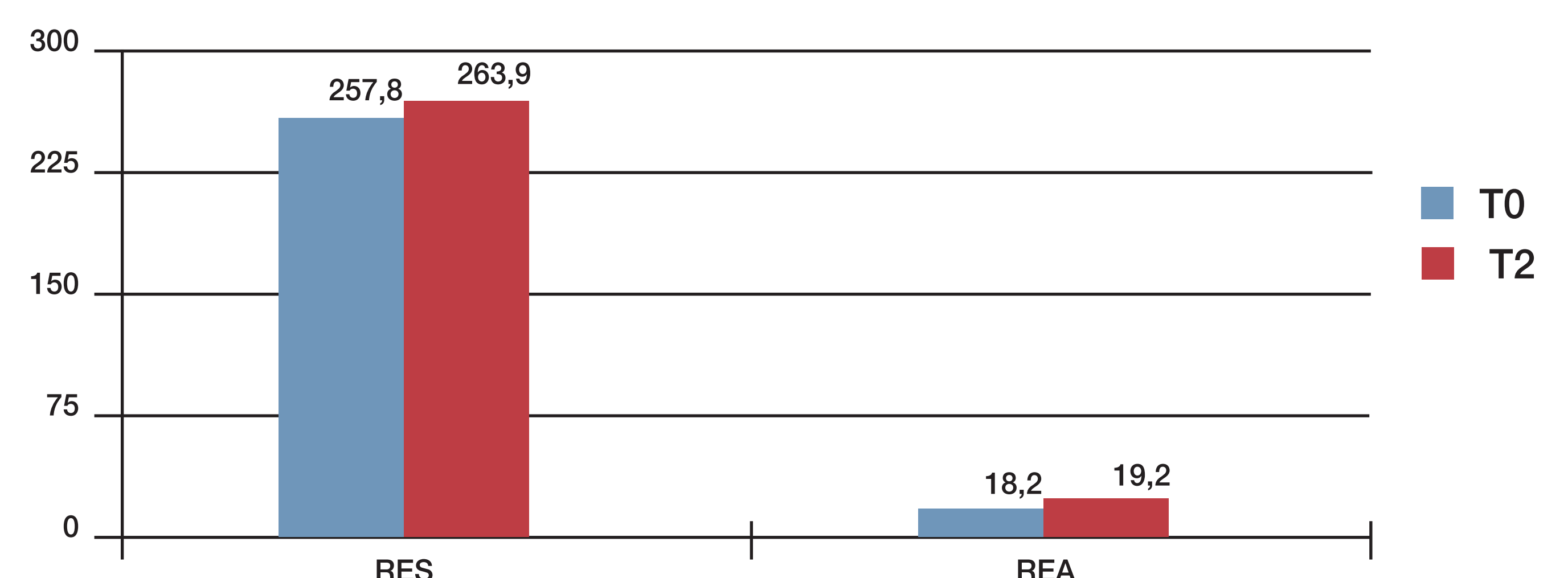
Graph 2
Calculation of the volume. Measurement of the circumference of the limb first (T0) and after (T2) the intake of the nutraceutical.

Graph 3
Average values of RES for single limb. The values were detected before (T0) and after (T2) the intake of the nutraceutical. Analysis performed on 10 patients with CEAP index equal to C3.



Graph 4
Average values of REA for single limb. The values were detected before (T0) and after (T2) the intake of the nutraceutical. Analysis performed on 10 patients with CEAP index equal to C3.

This variation demonstrates the effectiveness of the treatments adopted for the reduction of leg fluids and the best state of tissue health during the two months of the study (Graph 5).



Graph 5
Comparison of average RES and REA values for single limb. Analysis performed on 10 patients with CEAP index equal to C3.

4 - CONCLUSION

For an effective CVI treatment, it is mandatory to improve the life quality of patient, usually severely reduced by the impaired lymph flow, that worsens the standing and moving patient's conditions. In our preliminary trial, the combination of a low invasive saphenous vein endovascular treatment with a nutraceutical protocol targeting the microcirculation of lymphatic and venous capillaries reached statistical evidence of smart clinical benefit not only subjectively on the

skin quality and legs cosmetic improvement, but also objectively with imaging analysis and instrumental evaluation. The results evidenced a definite customers and phlebologists satisfaction compared with currently marketed nutraceuticals over the counter.