title:

BIONIC SKIN THERAPY – A NEW METHOD OF TREATMENT OF SPIDER VEINS AND COUPEROSIS CLINICAL TRIAL

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introduction:

since some years it is possible to treat spider veins and couperosis with a new thermo- galvanic device which works with direct current and radio frequency produced by the bionic® corporation, hallein, austria

objects:

the study presented is a prospective clinical trial to evaluate the clinical practicability, handiness, effectiveness, safety and cost-efficiency of the therapy of spider veins with this new thermo- galvanic equipment;

material and methods:

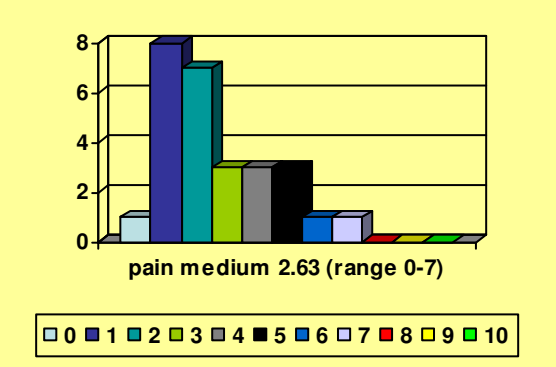
the treatment consists of the application of a very weak direct current followed by a high frequency current onto the skin vessel of interest with an extremely fine gold plated probe; the weak direct current (dc) interacts with the skin's natural moisture and salts creating a protective film (galvanic drop) around the gold probe; the immediately following high-frequency current (hf) causes the coagulation of the blood through thermolysis;
the study included 28 consecutive patients with spider veins of the legs seen at the ambulatory; non stratification was done, neither for the size of the spider veins nor its presumed cause;
inclusion criteria were: presence of spider veins of the legs, no effective treatment performed so far and ability and willingness to follow the protocol;
exclusion criteria were: arterial insufficiency or neuropathy of diabetic or other origin, acute dvt or varico-thrombosis requiring anticoagulant therapy, telangectasias of dermatologic cause (pyoderma gangraenosum, vasculitis, infection, neoplasia, …), primary lymphoedema, pregnancy, bad health conditions;
22 patients were treated two times and 5 patients were treated three times at the beginning of the study; the follow-up controls were made after the 1st, 3rd and 6th month; the controls consisted in a clinical valuation, control and documentation of side effects and a photographic documentation of each treated area;

all patients were female;
the medium age was 44.5 years (range from 27 to 61);
we treated 64 areas on 47 legs;
the treatment was performed by an experienced technician of the corporation in 1/3 of the cases; he instructed our staff consisting of two md's and three nurses;
the mean adjustment of the equipment was 20w dc/70w hf when we treated areas on the legs (range 15/70 to 45/90) and 20w dc/50w hf when we treated areas in the face (range 15/45 to 20/70);
three of the patients wore compression stockings for three weeks after the treatment

results:

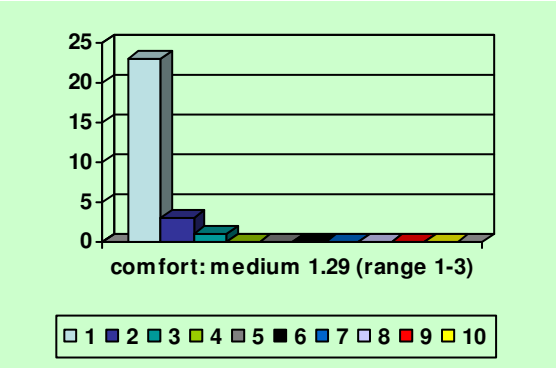
from the 28 patients at the beginning of the study one patient didn't present to the follow-up controls; so we had a follow-up for 6 months of 27 patients;
we treated a total number of 173 areas of this 27 patients in 69 meetings; the needed time for all treatments was 14h 15' (range 20'- 60'/pat.), that equals effectively 4'56" for each area
the costs of the probe, current and disinfectant were estimated to be about € 2.-, this is 0.8 € for each area;
at the last check up the patients were asked to evaluate pain, comfort/discomfort and quality of life during and after therapy;

concerning a pain scale from 0 to 10, medium value was 2.63 during treatment (range 0-7) ;
after therapy non of the patient had pain;



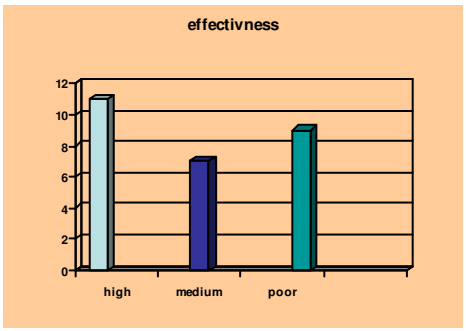
the intensity of pain was very individual and sometimes not to improve by reducing the adjustment of current;
those patients who had undergone laser therapy before, described thermo-galvanic therapy less painful and more comfortable after therapy;

medium value of comfort, in a scale from 1 to 10, was 1.11 (range 1-3);

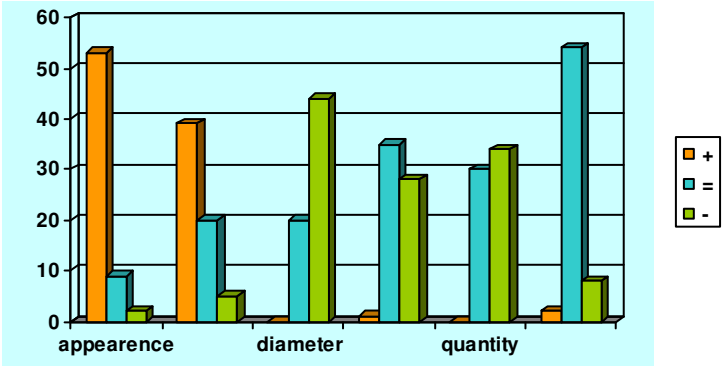


non of the treated patients reported a limitation in the quality of live (all patient declared the maximum of 10 at a scale from 1 to 10);
the only side effect we noticed was a temporary erythema at the treated areas witch passed in most of the cases after a few hours, in some cases it lasted a few days (2-3);

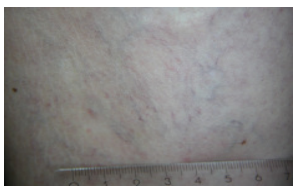
the patient's valutation of the effectivness of the therapy was very different from high to poor and a common comment was that there are needed more treatments to achieve a good result; major part of patients consider the bionic skin therapy a therapy to be recommended; only one of the patients would not undergo further therapy because of pain and poor result



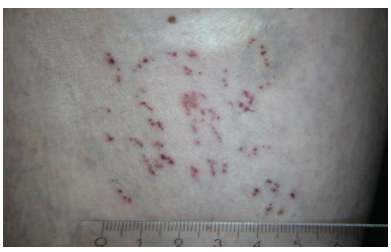
our own valuation , considering the photo before first therapy and the photo after 6 months, gave a better result than patients valuation as shown in the diagram below; the diagram shows to the left the valuation columns of an external control group and to the right the valuation columns of the study group witch had without doubt much more critical eyes; on the other hand it shows the difficulties to evaluate skin areas after 6 months often not photographed in an identical angle and with identical illumination;



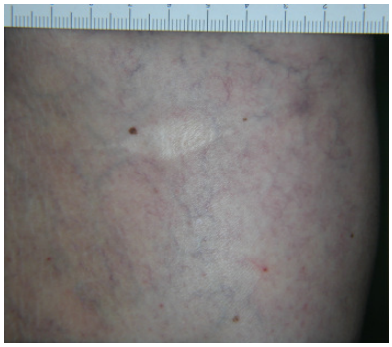
examples:
case 1: ok, female, 35aa



01 10 08 (before therapy)

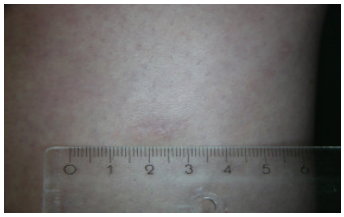


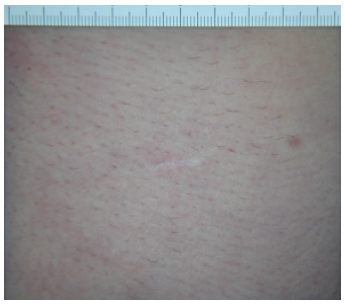
06 10 08 (before II° treatment)



15 04 09 (6 months, 2 treatments)

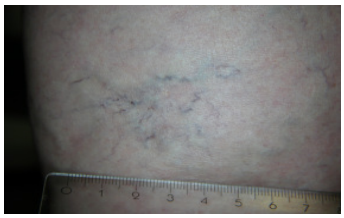
case 2: pe; female; 35 years

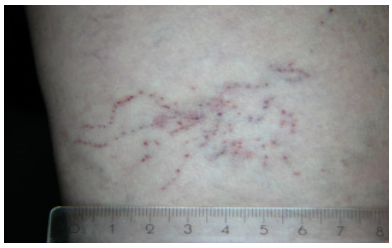


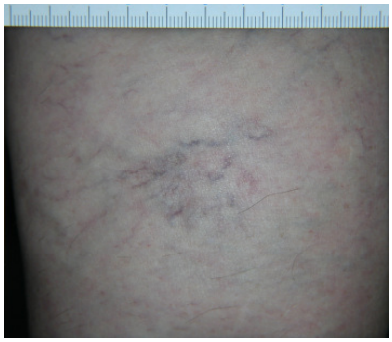


01 10 08 (before therapy) 15 04 09 (control after 6 months, 1 treatment)

case 3: lam; female, 57years

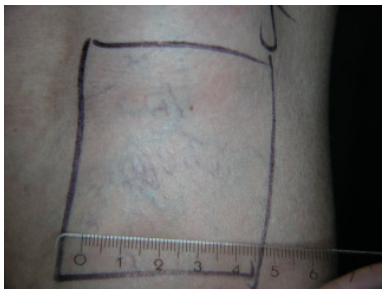


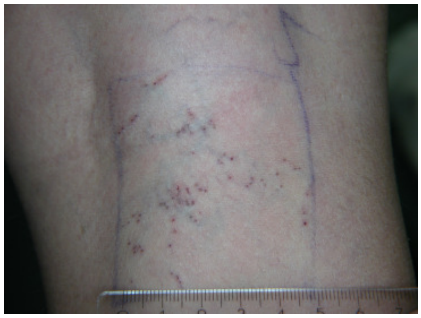


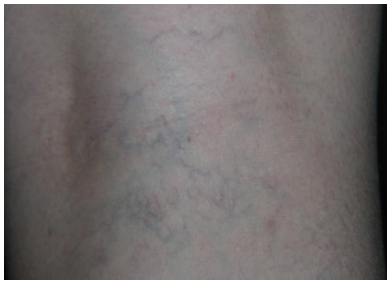


03 10 08 (before therapy) 06 10 08 (before II° treatment) 15 04 09 (6 months, 2 treatments)

case 4: ej, female, 35 years

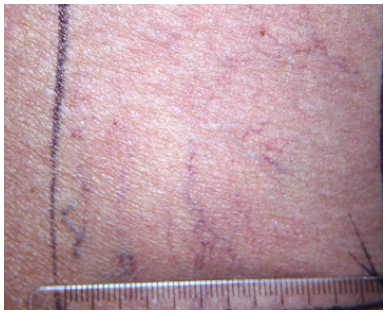


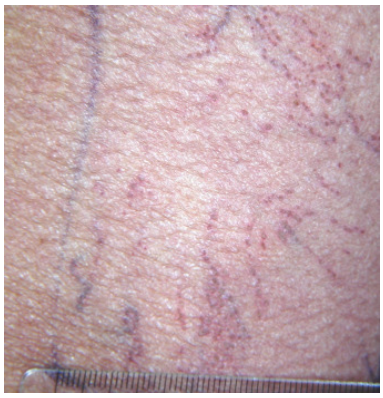


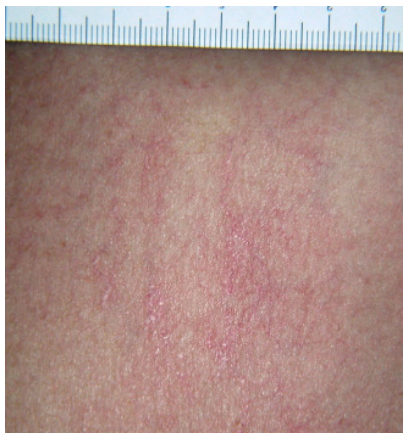


08 10 08 (before therapy) 10 10 08 (before II° treatment) 17 04 09 (6 months, 2 treatments)

case 5: das, female, 51years







08 10 08 (befor therapy) 10 10 08 (befor 2°treatment) 20 04 09 (6 months, 2 treatments)

conclusion:

since this is a new and totally innovative equipment we had to confront a learning curve by using it - although now we can say that it is a save and easy to use method; on the other side it is, noticed and confirmed also by the patients, a relatively time-consuming treatment; to achieve good results it is necessary to treat most of the areas more then twice; knowing this fact it was not possible for us to extend the study; we are now treating this patients until the follow up after one year after treatment;
an advantage of this new method is that it can be performed either by a doctor or by his assistant because it isn't an invasive therapy ;
this method could replace liquid- sclerotherapy of delicate, thin spider veins and couperosis; it is a very save and, with a little bit of patience, also successful therapy