CLINICAL EVALUATION OF PRESSURE THERAPY IN CONJUNCTION WITH AESTHETIC AND RECONSTRUCTIVE SURGERY

(Body Sculpturing by Lipoplasty, Yves-Gerard Illouz, 1989.)

There is a variety of compressive garments that have been marketed since Dr. Illous technique has been adopted.

However, because garments are circular, they may be excessively compressive if the size is too small. Their standardized size prohibits a perfect fit in all cases, and they are often too tight in one area and too loose in another. They may have to be ripped out at the seam to avoid distal edema. They, also, may roll at the ends or bind at the joints. They are not capable of molding a region. The incidence of phlebitis and pulmonary embolism seems to have risen dramatically since the adoption of inadequate pressure garments.

To be acceptable and beneficial, these pressure garments have to fulfill the following requirements: the applied pressure must be in the range of 17 to 20 mm Hg, that is, lower than the venous pressure (normally is 22 to 24 mm Hg). This should avoid or reduce venous stasis and the risk of phlebitis, and still allow the undermined tissues to glue together with seroma collection and limit somewhat the postoperative edema. These garments must be scientifically studied with control of multiple pressure monitors. The fabric must be hypoallergenic and repeatedly tested for strength and durability. Garments are better if they are double knit, giving elasticity in two directions, and allowing a drain to go through if necessary. They should come in many lengths and sizes and be able to be custom made from preoperative measurements to fit different areas of the body (face, chest, knees, ankles) without curling, creasing, or having a tourniquet effect. The Lipo-panty from Medical Z seems to have all these characteristics.

When we worked with Dr. Illous on his study to find the perfect pressure, there were Four questions that needed to be asked inorder to calculate the pressure necessary to bring the results that Dr. Illous was looking for.

Does the patient need pressure?

For many years pressure therapy has been proven beneficial in a wide variety of applications such as the treatment of edema, seroma, ecchymosis and hematoma.

Prior experience in the treatment of hypertrophic scars following burn injuries contributed to the study and development of special medical devices for use in conjunction with aesthetic and reconstructive procedures.

Development of these devices required an extensive scientific and clinical study which enabled Medical Z to evaluate their efficiency.

How much pressure is needed?

We started with 6mm Hg of pressure and tested the garments with a full range of pressure. The following is the gradiance of pressure that were studied on to come up with the correct pressure that was needed.

0-17 mm Hg We found that there were no results due to lack of sufficient pressure. The patients would develop skin waves.

Over 20 mmHg

This was very good for edema, but we saw problems with waves. Also with too much pressure it would flatten the skin on the muscle and it would not be effective. As a matter of fact, even when the results provided by a pressure range of 21-24 mm Hq seemed good, the appearance and texture of the skin did not meet aesthetic expectations.

17-20 mm Hg

This is the effective pressure that is needed to bring the optimal results without skin waves, which causes flattening of the skin and eliminates edema. So the patients wearing the Lipo-Panty with a Pressure range of 17-20 mmHg for an extended period of time beyond eight weeks did not experience any circulation problems.

Pressure therapy appears to be of utmost importance to achieve predictable aesthetic results. It considerably reduces edema and acts as a guide to control skin shrinkage in a desired manner, as well as distributing scar tissue to minimize the potential for "Bulges".

The study also revealed the necessity of applying an equalized pressure on all parts of the body affected by the surgical procedure. Thus, different designs were tested and developed.

Medical research and development of this medical device was developed in conjunction with the lipectomy technique pioneered by Dr. Yves-Gerard Illouz, MD and four other Doctors took part in this study.

- Yves-Gerard Illouz, MD., Paris, France.
- J. Greco, M. Prof., Tours, France.
- Charles L. Masson, MD., Lyon, France.
- Louise Valerie Forli, MD., Marseille, France.

Patient follow-up was performed to evaluate variations in volume after lipectomy.

Patients were measured:

- Prior to the Lipectomy;
- *Immediately following the Lipectomy;*
- Every two (2) weeks during the next six (6) weeks.

Facts verified were as follows:

- *Volume reduces immediately after the lipectomy;*
- Volume increases as a result of edema;
- Volume progressively reduces for 4 to 6 weeks, depending on specific case.

Following these results, another study involving 189 patients was conducted over a period of two years

The tests were conducted in order to determine the calculated pressure necessary to minimize the potential for edema and "skin waves".

The four doctors mentioned above fitted their patients immediately after the lipectomy with a Lipo-Panty providing a equalized pressure for a 3 to 8 week period.

37 PATIENTS WERE FITTED WITH A LIPO-PANTY PROVIDING BETWEEN 8-11 MMHG OF PRESSURE.

40 PATIENTS WERE FITTED WITH A LIPO-PANTY PROVIDING BETWEEN 12-16 MMHG OF PRESSURE.

47 PATIENTS WERE FITTED WITH A LIPO-PANTY PROVIDING BETWEEN 17-20 MMHG OF PRESSURE.

65 PATIENTS WERE FITTED WITH A LIPO-PANTY PROVIDING BETWEEN 21-24 MMHG OF PRESSURE

TEST NO. 1

PATIENTS	MMHG PRESSURE	DEVELOPED EDEMA	SKIN RESULTS
10	8-11	10	POOR
10	12-16	9	POOR
10	17-20	1	GOOD
TEST NO. 2			
PATIENTS	MMHG PRESSURE	DEVELOPED EDEMA	SKIN RESULTS
10	8-11	10	POOR
10	12-16	10	POOR
10	17-20	0	GOOD
10	21-24	1	GOOD
TEST NO. 3 PATIENTS MMHG PRESSURE DEVELOPED EDEMA SKIN RESULTS			
10	8-11	7	POOR
10	12-16	10	POOR
10	17-20	0	GOOD
10	21-24	1	GOOD
TEST NO. 4			
PATIENTS	MMHG PRESSURE	DEVELOPED EDEMA	SKIN RESULTS
10	8-11	10	POOR
10	12-16	10	POOR
10	17-20	1	GOOD

The conclusion of this test done by the four doctors was that optimal final results were obtained with a range of 17-20 mmHq of pressure.

1

GOOD

10

21-24

As a matter of fact, even when the results provided by a pressure range of 21-24 mmHq seemed good, the appearance and texture of the skin did not meet aesthetic expectations. However, the patients wearing the Lipo-Panty with a pressure range of 17-20 mmHq for an extended period of time beyond eight weeks did not experience any circulation problems.

• How long will this pressure be necessary for the patients?

Both objective and subjective factors must be taken into consideration. Objectively, if edema or skin excess is noted or expected at this time, it is preferable for the patient to wear the garment intermittently during the day or at night for an additional two weeks.

Subjectively, if the patient feels better wearing the garment, as is often the case, then they may be allowed to do so intermittently. If, on the contrary, they feel relieved with it off, then they may discontinue wearing it.

In any case, it is useless to continue with a garment after four weeks-and may even be dangerous.

Garments will be worn for as long as 6 to 8 weeks.

• How does pressure work on the patient?

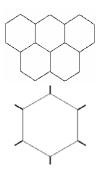
When you have the correct pressure this will cause a reaction-A Massage. That is every time that the patient's muscle makes a movement, the pressure garment will cause the outer layer of skin to move and massage the inner layer of muscle.

This is what Dr. Illous was looking for in garments. Pressure garments would massage the skin which would eliminate the risk of skin waves. The Garment acts as an external splint until scar formation is able to serve its purpose of internal splitting.

Medical Z calculated the pressure that was needed and designed a garment that has been tested with a full range of pressure. The garment and it's pressure were designed for this procedure to bring the positive results that Dr. Illous was looking for.

Medical Z garments have been tested with a full range of pressure. The choosing of the fabric is a combination of 70% polyamide and 30% lycra. The textile is the result of an exhaustive analysis of 107 different materials. This provides between 17 and 20 mmhq of pressure and supplies optimal elasticity in vertical and horizontal direction. Medical Z's

hexagonal weaving design provides controlled pressure in all directions. Making it more comfortable and effective for the patients.



MEDICAL Z'S EXCLUSIVE HEXAGONAL WEAVING DESIGN PROVIDES CONTROLLED PRESSURE IN ALL DIRECTION.

Our main concern will always be the patient's safety and that the patient receives the positive results for which the garments were designed.

• Medical Z Custom shapes and designs.

In order to provide an equalized pressure and prevent looseness, it was necessary to dart the Lipo-Panty in the groin area. A double row of hook and eye fasteners allows adjustment of the pressure in the abdominal area with consideration for weight loss or gain.

Velcro and zippers were tested in an attempt to make the application of the Lipo-Panty easier. The final results were negative because of the limited vertical elasticity and the danger of promoting circular pressure. This verified the preference for the hook and eye design.

We listen closely and respond quickly to doctor's technical needs. We are always working on new techniques in garment design with surgeons around the world. By doing so we have developed an extensive line of garments.

Garment edges provide 40% less pressure to avoid constriction and circulation problems such as phlebitis. It also appeared that the application of the Lipo-Panty required only slightly greater effort over the use of Velcro or Zippers and provided predictable aesthetic results.

• Sizing of the Garments.

Garments are designed circular. They may be excessively compressive if the size is too small. Many companies garments that are standardized in size will prohibit a perfect fit. They are often too tight in one area and too loose in another. The garment

may have to be ripped out at the seams (for example at the cuffs) to distal edema. They also may roll at the ends or bind at the joints.

Garments should come in many lengths and sizes and be able to be custom made for preoperative measurement to fit different areas of the body without curling, creasing, or having a tourniquet effect.

Medical Z fabric is hypoallergenic and has been repeatedly tested for strength and durability.

Medical Z is the innovator of plastic surgery garments for lipo-suction. At Medical Z we have scientifically studied our garments and the fabrics we use on monitors that control and measure multiple levels of pressure to assure that our garments deliver the control of pressure that is needed to be beneficial and effective. Medical Z pressure is 17 to 20mmHq.

When you are sizing the garments, always remember that a patient is always measured before the surgery at the widest part of the buttocks. When you have a staff person who wants to try the garment out on herself you must go to the next size up. For example if you are a size 3 then you would be a size 4. The reason for this is that the garments are designed and calculated for after the surgery.

NOTE: Because people come in all shapes and sizes, the proper size should be determined by the physician to insure that all desired areas are receiving the proper compression.