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**Overview of  
Pure Omental Lipids  
P.O.L.**

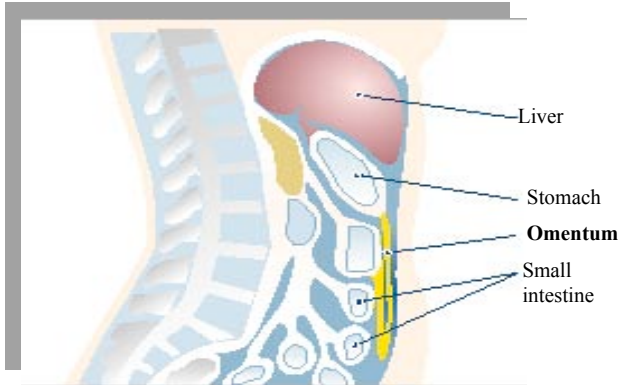
## P.O.L. - History

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- Porcine Omental Extract developed in the 1980s by a group of researchers at Boston University (Angio-Medical).
- 1990 - 11 U.S. patents, 4 others had been allowed, and 12 pending.
- "Omental Lipids" entered the CTFA Dictionary in 1989.
- Angio-Medical licenses Difa Cooper for production in Europe.
- 1992 Difa Cooper launched P.O.L. Cream in Italy; positioned for the prevention of decubitus ulcers.
- 2002 P.O.L. relaunched to extend indications (diabetic ulcers, burns).
- 2005 Cooperlabs (retained US distribution rights) begins testing US market possibilities for P.O.L. Cream.
- 2007 Cooperlabs establishes new business enterprise for CABOT P.O.L. Cream to be marketed as a non-prescription product.

## The Omentum

Large peritoneal fold begins at the stomach and extends downwards to cover the abdominal organs.



- Defensive / Protective capabilities due to mobility and structure
- Defends against infections
- Adheres to infected area
- Surgical grafting tool
- Angiogenic factors stimulate growth of new blood vessels
- Evidence suggests omental tissue contains stem cells
- Rich in lipids, neutral glycerides, phospholipids, glycolipids and gangliosides
- Polypeptide growth factors with angiogenic activity present in omentum is the VEGF (vascular endothelial growth factor)
- In the omentum, the VEGF is produced primarily by adipocytes

# P.O.L. - The Science

## Pharmacological properties of omentum

- In the early 1900s omentum was being used to revascularization ischemic tissues
- Vascularization observed during the study was significantly higher in the presence of omental lipids.

### Effects observed during experiments carried out using lipids extracted from omentum

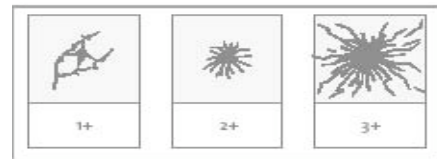
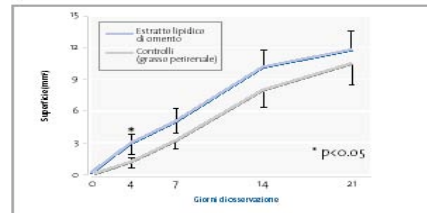
angiogenic activity on rabbit cornea

increase in proliferation and migration of culture endotheliocytes and keratinocytes

increase in skin flap survival in experimental animals

increased turnover of basal keratinocytes

acceleration of wound healing



## **The properties of purified omental lipids have provided effective prevention against pressure ulcers (decubitus ulcers)**

Bertoli et al. (1999), 210 patients confined to a bed or: 22 presented decubitus ulcers, 45 local dystrophy, and 143 apparently unaffected skin where the medication was applied for prevention.

Period of application lasted 2-6 weeks (average 3.5 weeks). After treatment, 144 patients presented unaffected skin, two patients with ulcers went into remission and 63 patients showed marked improvement in ulcers and local dystrophy (erythema, edema, de-epithelisation, maceration and pain). The overall improvement obtained was statistically significant ( $p < 0.01$ ).

Lisi et al. (1993), 20 bed-ridden patients at risk of developing decubitus ulcers. Evaluation of clinical effectiveness: excellent (disappearance of erythematic area) 25%; good (considerable preventative action) 60%; satisfactory (slight preventative action) 15%.

## **Effectiveness and tolerability was evaluated in patients suffering from chronic venous insufficiency**

Lisi et al. (1993), 20 patients suffering from chronic venous insufficiency of the lower limbs. Evaluation of clinical effectiveness: excellent (disappearance of erythematic areas) 25%; good (considerable preventative action) 60%; satisfactory (slight preventative action) 15%.

# P.O.L. - Studies

## **Faster healing was observed in patients treated with purified omental lipids ...**

Data on file (1990), 15 patients each of which underwent four biopsies with 4mm diameter punches, two on the right parasacral area and two on the left parasacral area. One of the wounds made by the biopsies on each side was treated with a cream containing heterologous purified omental lipids (25%) while the other on each side was used as control. The cream was applied once daily for 28 days even after the wounds had healed.

Measurements were made of the wounds' external and internal diameters (with a micrometer and planimeter respectively) and of their depth (with an ultrasound technique). The results showed that the wounds treated with the cream healed more quickly: 21.2 days as opposed to 25.1 days for the control wounds ( $p=0.001$ ).

## **Significant improvement in skin conditions and a 20% increase in microcirculation was observed in diabetic patients with polyneuropathic ulcers and skin dystrophy...**

Rinaldi et al. (1993), 25 patients all suffering from polyneuropathic ulcers and widespread skin dystrophy caused by diabetes. On one of the legs, the skin areas surrounding the necrotic tissues were treated with POL; on the other, used as a control, a product containing hyaluronic acid was applied. Application of both topical products were made twice daily for thirty days.

At the end of the follow-up period, the measurements of TEWL, corneometry, sebometry and pH values all showed significant improvement on the limbs treated with omentum, while the control limbs underwent varying evolution with some slight improvements but also a few cases of worsened conditions. Monitoring of microcirculation with the laser-doppler velocimeter showed no changes in limbs where only hyaluronic acid had been applied, but 13 of the limbs treated with the cream containing omentum derivative experienced significant improvement with an increase of 20% with respect to baseline values.

# P.O.L. - Studies

## **Favorable results in 81% of burn pruritis patients. . .**

### **53 Patients Treated with POL topically for chronic itching.**

Burn Impression (2005) 53 patients recovering from deep partial and full thickness burns with skin damaged to point of destruction of sweat glands leaving prone to chronic itching and dry skin due to a decreased or elimination of sweat gland activity. 43 (81%) reported favorable results, 6 (11%) reported results equal to other interventions, while 4 (8%) reported unfavorable results. Itching in a burn wound begins at the time of wound closure then peaks in two to six months. Typically, the itching persists for months. Optional treatments are antihistamines, corticosteroid gels, ointments creams and lotions, etc. all associated with potentially severe side effects and pharmaceutical treatment options are costly and not overly effective.

## **P.O.L. increases the quantity of oxidised haemoglobin in dystrophic skin ...**

Derming Institute (2003), 13 subjects. P.O.L. was applied twice daily to the inside of the forearms, the other was left untreated as a control. The quantity of oxidised hemaglobin in the skin was measured using a spectrophotometer: there was a statistically significant growth ( $p < 0.001$ ) in treated arm after 2 and 4 weeks treatment, while no significant difference was observed in the untreated arms.

# P.O.L. - The Product

## CABOT P.O.L. Cream

### Protect Skin At Risk

- Diabetic Skin & Foot Care
- Severely Dry Skin
- Minor Burns
- Irritation
- Itch
- Dry, Cracked, Fragile Skin
- Pressure Ulcers



# P.O.L. - The Product

## CABOT P.O.L. Cream

### Protect Skin At Risk

- **25% Pure Omental Lipids**
- **Vitamin E** - Tocopheral Acetate
- **Vitamin A** - Retinyl Palmitate
- **Allantoin**
- **Stearoxy Dimethicone**
- **Hyaluronic Acid** - Sodium Hyaluronate
- **Glycerin**
- **Propylene Glycol**
- **Phenoxyethanol**



# P.O.L. - The Product

## CABOT P.O.L. Cream

### Protect Skin At Risk

- Super Moisturizer
- Softens Rough, Dry Skin
- Promotes Healing
- Soothes Irritated Skin
- Gentle on Fragile Skin
- Non-Prescription
- Relieves Itch
- Protective Barrier
- Will Not Stain Clothing or Bedding
- Non-Prescription

