EFFICACY OF A FATTY ACID SUPPLEMENT TO REDUCE CLINICAL SIGNS OF ATOPIC DERMATITIS IN DOGS AND CHANGE SERUM FATTY ACID LEVELS: A DOUBLE-BLINDED PLACEBO-CONTROLLED CROSS-OVER STUDY

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BACKGROUND

Megaderm®* (US: Omegaderm®) oral emulsion is a dietary supplement designed to help control skin allergies in dogs. The product contains 450 mg/ml of omega-6 and omega-3 fatty acids (EFA) in a ratio of 5:1, together with vitamin A and E co-factors. It aims at restoring skin integrity and regulating the metabolic pathways responsible for the inflammatory response observed in atopy.

* Other brand names: Complederm® (UK), EFA-Z® (Germany)

MATERIALS & METHODS

Study format: randomized, double-blinded, placebo-controlled, cross-over, clinical response trial.

Animals: 23 dogs, of various breed and age, diagnosed with canine atopic dermatitis (CAD) according to revised Willemse criteria, after exclusion of other skin diseases and treatment of previous infections.

Treatments:

Allocation	Sequence	8 weeks	4 weeks	8 weeks
10 dogs	**1**	Megaderm® SID	Wash-out	Placebo SID
13 dogs	**2**	Placebo SID	Wash-out	Megaderm® SID

- Dose for both products: 5-20 ml / weight (**label test product dose**).
- Megaderm®: calculated mean daily EFA intake > eicosapentaenoic acid (EPA 28 mg/kg), Docosahexaenoic acid (DHA 19 mg/kg), linoleic acid (LA 229 mg/kg), gammalinolenic acid (GLA 5 mg/kg).
- Placebo: generic olive oil (75% oleic acid, 7% linoleic acid).
- All dogs concomitantly bathed once every other week with Hexadene® (3% chlorhexidine shampoo).

Concurrent medications:

- 1/3 of dogs also exhibited flea hypersensitivity and thus were maintained on continuous flea medication, other occasional treatments were cephalexin (3 cases), ketoconazole (1 case) and immunotherapy (3 cases).
- None of the dog received any corticosteroid, antihistamine, other EFA supplement or EFA-enriched diet, thyroid supplementation or anti-pruritic shampoo.

Clinical evaluation:

- Lesions: erythema, excoriation, lichenification graded at 12 different dermal sites, according to a 10-point extent-severity scale, to calculate the aggregate lesional index (LICAD: 0 to 360).
- Pruritus: scratching or rubbing or licking graded on 6 body areas, according to a 10-point frequency-intensity scale, to calculate the aggregate pruritus index (PICAD: 0 to 60).

Determination of serum FA levels:

- 10 ml of whole blood collected following overnight fast.
- Lipids extracted in a 2:1 mixture of chloroform:methanol and methylated using 4% sulfuric acid in methanol.
- Sequential extractions after alkalinization and acidification.
- Gas liquid chromatography.
- Results as mg individual EFA/100mg total C14-22 fatty acids (% weight).

OBJECTIVES

Evaluate the efficacy of Megaderm® in reducing pruritus and improving skin and coat condition in atopic dogs.
Determine the change in serum fatty acid levels following supplementation.

RESULTS

- Most frequent **major CAD features**: pruritus (100% of dogs), facial and/or digital involvement (96%), chronic/relapsing dermatitis (91%).
- Most frequent **minor CAD features**: onset of signs <3 years of age (96%), recurrent superficial pyoderma or otitis externa (65%), facial erythema/cheilitis (52%).
- No treatment carryover effects were detected in this study (RM ANOVA, P>0.05, SAS), thus results of both periods could be evaluated.
- **Megaderm® significantly reduced the PICAD** (40%) **as compared to the placebo** (14.7%) over the 8-week period (RM ANOVA, P<0.05, SAS). Fig 1.
- The LICAD was significantly reduced at week-8 in both Megaderm® (55.2%) and placebo group (28.8%). Fig 2.
- **The serum concentrations of anti-inflammatory omega-3 fatty acids, EPA and DHA, were significantly increased in the EFA** treated dogs as compared to the placebo as from week-4 of supplementation onward. Fig 3.
- By week 8, **the serum concentration of LA, a major component of the epidermal intercellular lipid cement, was increased in the EFA group versus the placebo**.
- **Megaderm® supplementation decreased the percent of pro-inflammatory omega-6 fatty acids**, dihomogammalinolenic acid (DGLA) and adrenic acid (precursors of arachidonic acid, AA), in the blood of treated dogs as compared to placebo controls. Fig 4.

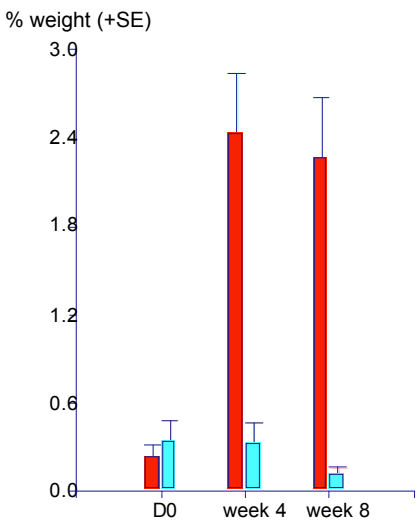

Fig 3. EPA serum levels

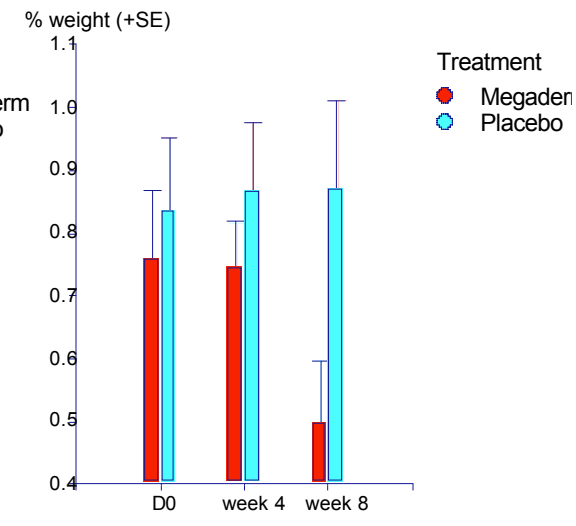

Fig 4. DGLA serum levels

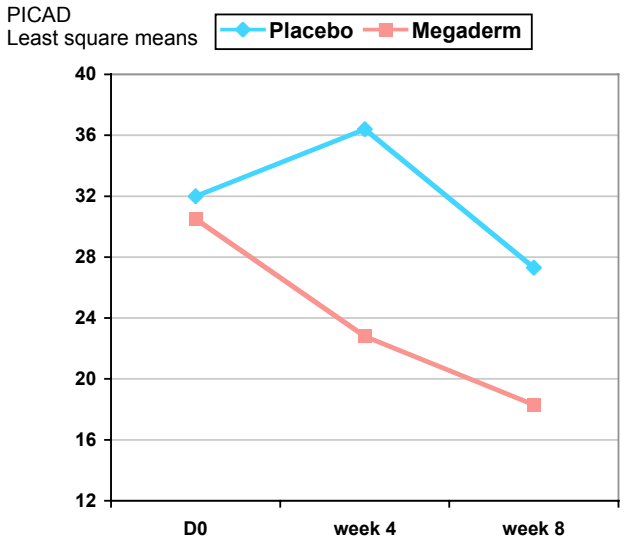

Fig 1. Pruritus index over the study period

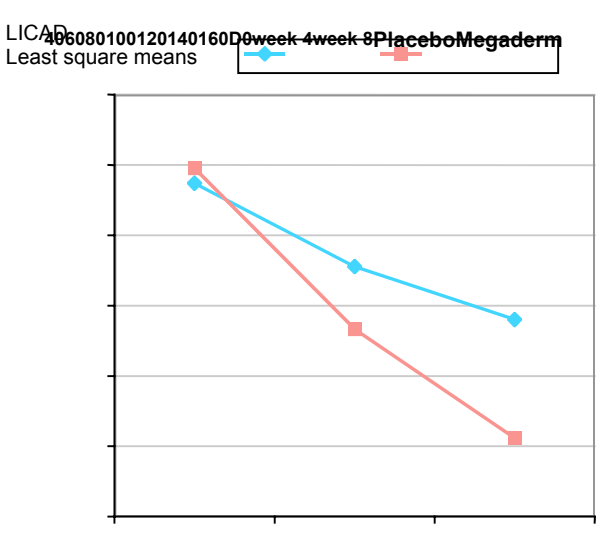

Fig 2. Lesional index over the study period

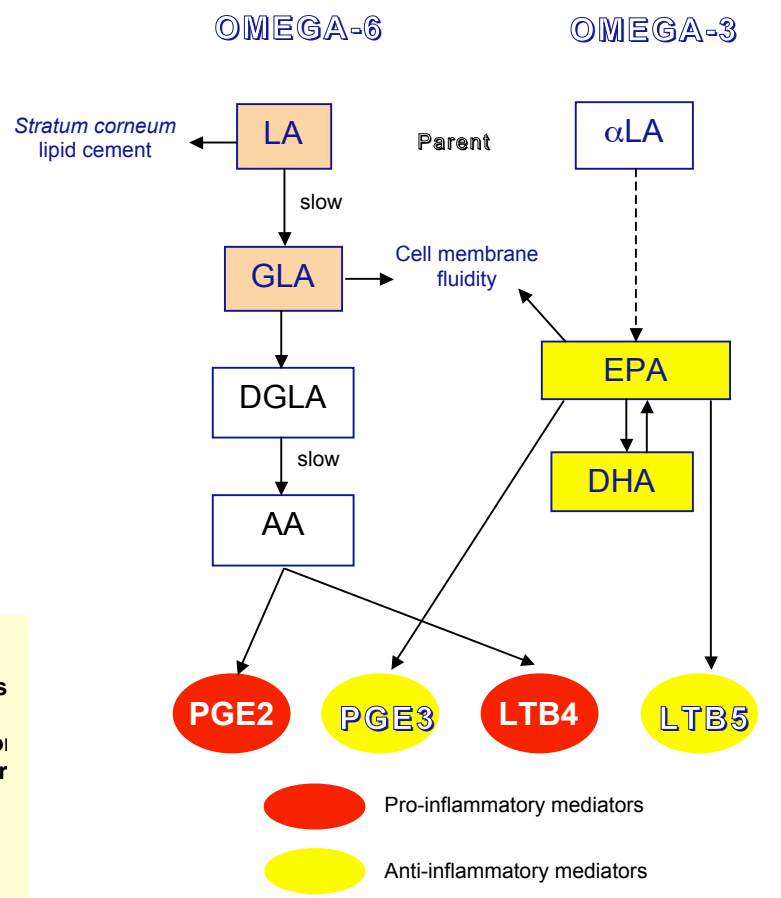

Fig 5. Structural and functional roles of EFAs

CONCLUSIONS AND CLINICAL RELEVANCE

- **Megaderm® supplementation at label dose proved more effective than placebo to decrease pruritus in dogs with atopic dermatitis.**
- Despite dogs in this study were fed differing basal diets **, the supplement was successful in altering the compositio of their serum fatty acids, increasing the concentrations of EFAs that play key roles in epidermal barrier restructuring and inflammation attenuation.** Fig 5
- Beneficial effects of a supplement containing preserved EFAs can therefore be obtained without the need to change the basal diet itself. Significant reduction of the lesions in the placebo group may be attributed to so-called placebo effect, slight beneficial effect of olive oil, intermittent bathing with the chlorhexidine shampoo or the few concurrent medications given to individuals. This **underlines the need for controlled studies in assessing the impact of therapeutic measures**. A trend for clinically significant better score reduction was nevertheless apparent with Megaderm ® by week 8. A longer period of EFA supplementation, or a higher number of test animals, may be required to detect statistically significant differences.

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