

OTO ACTIVE

MULTICENTRIC STUDY

The nutritional solution of recurring chronic otitis in dogs



INTRODUCTION

Symptoms linked with adverse reactions to food are very common in cats and dogs and may affect different organs. Like in human beings, symptoms linked with adverse reactions to food may also affect various apparatus of small animals: the gastroenteric, cutaneous, otologic, nervous, urinary and respiratory apparatus^{1,2,3,4,5}. Recurring otitis externa and/or otitis media are observed in more than 80% of dogs with adverse reactions to food^{13,14}. It may actually manifest as a single symptom in more than 20% of cases^{14,15}. This pathology is particularly frustrating for various reasons: little response to drug treatment, continuous recurrences, unsatisfied owners and the clear difficulties that owners have when curing with topical treatment or even systemic drug treatment.

Based on these considerations, the FORZA10 R&D center sets its goal to develop a concept of curing through nutrition, creating the FORZA10 Nutraceutical a Line, of products, formulated specifically for each organ. The term "Nutraceutical" is a neologism, which indicates a concept of "food-medicine" or a healthy food that combines nutritional components selected for characteristics of high digestibility and high hypoallergenicity with curative properties of natural active principles extracted from plants with proven effectiveness. Nutraceutical food also resolves the obvious difficulties of owners in treating with drugs whether the administration is topical, oral or parenteral.

ADVANTAGES

- Does not require direct treatment on the animal
- A single nutritional treatment for otitis
- Excellent results just after 10 days
- Innovative bi-component formula
- Highly appetizing

AIM OF THE STUDY

The purpose of this study is to assess the role performed by this special diet with **FORZA10 Oto Active** on dogs with chronic or recurring otitis; this product is based on fish and is supplemented with standardized, titrated phytotherapeutic active principles.

The effectiveness of the diet was tested by means of a 30-day dietary trial. The results were based on specific clinical protocols developed and completed by 96 veterinary surgeons in Italy.

MATERIALS AND METHODS

The study was conducted on 107 dogs and 96 veterinarians participated to the realization of this project; the clinical trial lasted 30 days and dogs with clinical manifestations in otitis were examined as having one or more of the following: excessive earwax, itching, red auricle, presence of pus, edema, pain, blood, shaking, unpleasant odor, presence of parasites and alterations of the tympanic membrane. The dogs examined were administered a 30 day diet of **FORZA10 Oto Active**, a mono protein product based on fish and supplemented with standardized, titrated phytotherapeutic active principles (*Tea Tree, Linden, Garlic, Rose hip* and Zinc chelate). The Nutraceutical food was administered proportionally based on 15 grams per kilo live weight; four visits were conducted during the dietary trial: a first visit and then three health check-ups after 10, 20 and 30 days.

On each health check-up the veterinarian filled out a special section on the protocol we provided. A minimum period of 30 days was planned and deemed necessary in order to have significant modifications on the case history.

The breeds most commonly involved were cross-breed (32%), German shepherd (6.5%), Cocker (5.6%) and Labrador (5.6%) (others 50.3%). A recent publication has actually revealed that the breeds Cocker Spaniel and Labrador are more prone to Otitis externa as single symptom of food hypersensitivity^{1,12}.

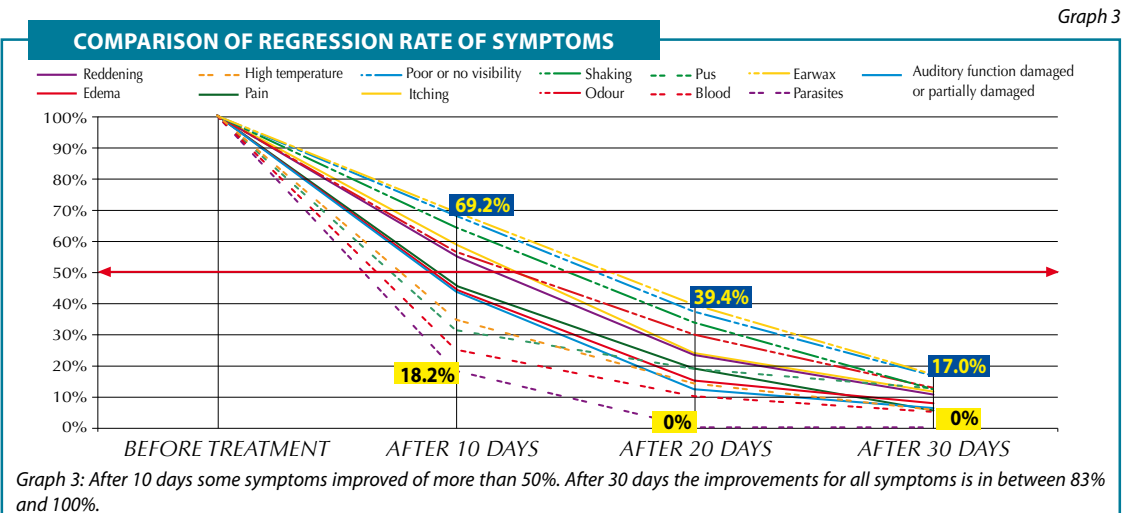
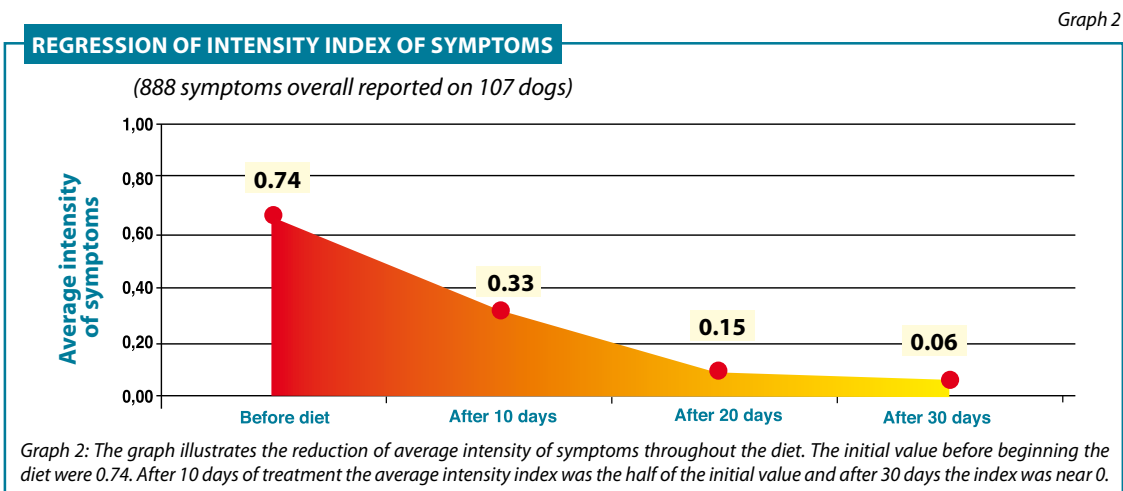
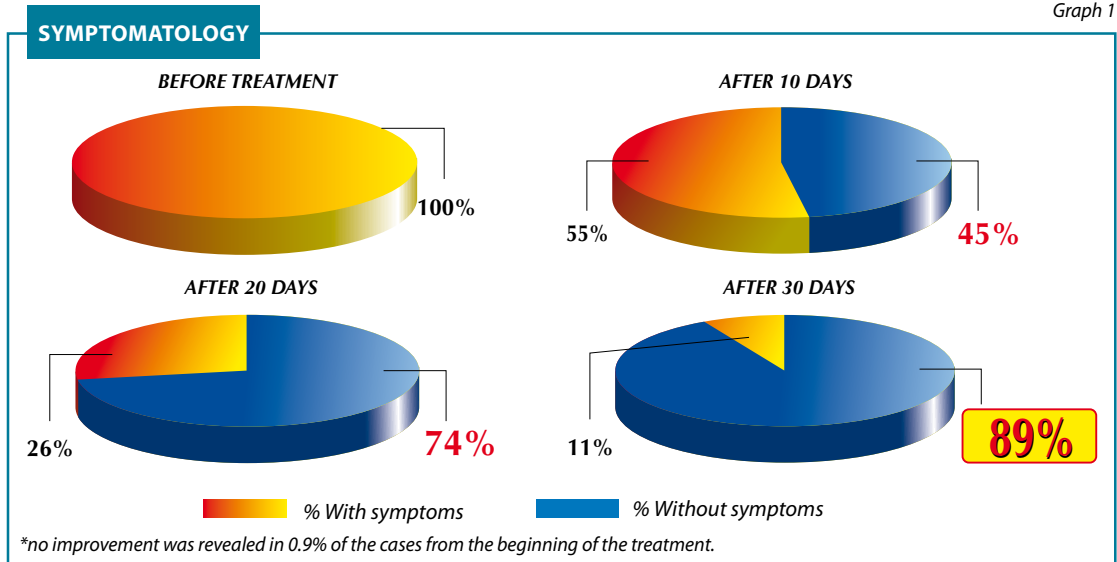
Female dogs were 49 (45.8%) and male dogs 58 (54.2%). The average age of dogs was 6 years. On 60% of cases (64 dogs), the previously used diet was industrial; 32% (35 dogs) were fed with a mixed diet (homemade and industrial) and 8% (9 dogs) were fed with a homemade diet.

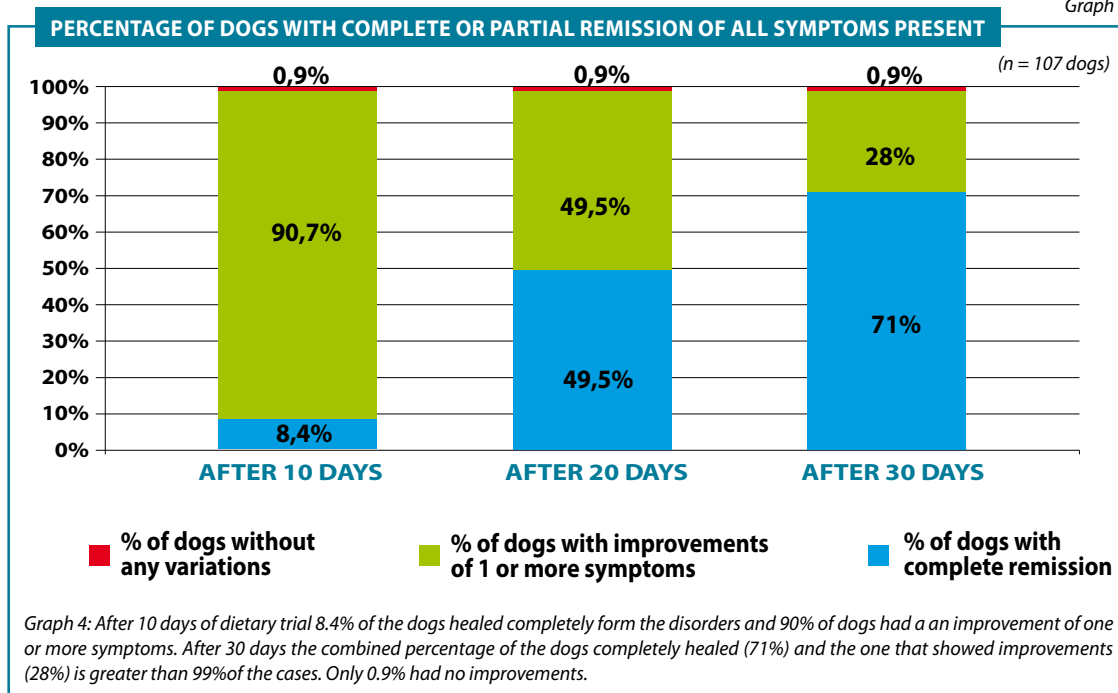
RESULTS

The results of this study clearly reveal that **FORZA10 Oto Active** is capable of drastically reducing symptomatology linked with otitis in a brief period of time: 45% of the symptoms reported before the treatment disappeared just after 10 days following the diet; this percentage increased to 74% after 20 days; and lastly after 30 days 89% of the initial symptoms were vanished. In fact this clinical trial reveals that the intensity of the symptoms that were still present after 30 days of treatment did, however improve,

going from pronounced down to moderate. Only one case showed no improvement on symptomatology during the dietary trial (see Graph 1).

The overall regression of symptoms during treatment is shown in Graph 2 from the average INTENSITY INDEX with values that vary on a scale of 0 (no symptoms) to 1 (display of a severe degree of symptoms) (see Graph 2).





DISCUSSION

The dietary trial was based on the direct collaboration of Italian Veterinary who offered their clinical experience to help conduct this study.

Veterinarians found that already in the first check-up after using **FORZA10 Oto** results were the complete remission of symptoms in the 45% of the subjects. Otitis externa has a greater impact on cats and dogs; in fact the eardrum is quite resistant to inflammatory processes⁶. Otitis externa is a widespread condition in dogs, nevertheless only 15% come for a specialized health check-up^{7,8,9,10}.

The most evident results were revealed in reddening, edema, odor, itching and pain.

Dogs with ear infection are often aggressive because of **ear pain**, so that local treatment of otitis is almost impossible. **FORZA10 Oto Active** is a highly efficient and useful tool for these cases.

This study revealed that 55% of dogs with **ear infections** healed already just after 10 days from the beginning of the diet treatment.

In 56% of 68 dogs, a clear improvement of **edema** was seen in terms of the auricular organ and external auditory duct also 10 days after the trial.

Reddening vanished on 77% of 103 dogs after 20 days of administering the specific diet and on the following health check-up, 90% of dogs were completely healed. On 65% of the 86 cases, the **temperature of the ear** went back to normal just 10 days after the diet. Only 5% of dogs manifested a slight rise in temperature of the ear on the thirtieth day.

Unpleasant ear odor is linked to an infection and excessive quantity of **earwax** in the external auditory duct. The study actually revealed that the unpleasant odor and the excessive earwax disappeared 20 days after the trial, on 70% and on 61% of the 94 cases, respectively.

The results obtained from this study were very promising even for the 11 cases of **otoacariasis**, as the study revealed 100% healing on dogs that manifested ear parasites. The anti-parasitological activities of garlic, in synergy with the rest of the active principles of this formula seem to be the key elements for this treatment. Dogs that manifest food hypersensitivity associated with non-seasonal itching are not very sensible to glucocorticoid and cyclosporine¹³. The FORZA10 R&D Center considers **FORZA10 Oto Active to be the only nutritional treatment also capable of efficiently treating cases of otitis that are more resistant to conventional therapies**. The fact is that this study reveals that in 77% of the 97 dogs which manifested itching initially, the symptom vanished just after 20 days and **89% healed from the disorder after 30 days** from beginning of the diet treatment.



CONCLUSIONS

FORZA10 Oto Active, covered by this study, is the only product so far studied and formulated for treating food related inflammatory processes or multifactorial etiology that target the hearing organ. The use of **FORZA10 Oto Active** has helped to improve symptoms and/or help vanish over 89% of symptoms present in dogs.

This innovative diet is the most practical and effective therapy formulated against chronic and/or recurring otitis. Creamy substances, paste and powders are difficult to apply down the external auditory duct and are expensive and complicated to use in aching and/or aggressive dogs. This is why these formulations are rarely

suitable for treating Otitis externa in dogs¹⁶.

FORZA10 Oto Active is the result of selected antioxidant agents and other precious natural principles combined with the proven effectiveness of FORZA10 mono-protein formulas to fight against food intolerances.

It is reasonable to believe that once the acute phase is resolved, a daily use of Nutraceutical foods formulated specifically to purify the organism and free it from harmful radicals and environmental pollutants may allow it to maintain homeostasis and help prevent relapse of such complex pathologies.

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FORZA10 Oto Active, covered by this study, is the only product studied and formulated for treating food related inflammatory processes or multifactorial etiology that target the hearing organ. These conditions are among the most common and most frustrating issues in clinical practice¹⁶. Often, recurring otitis may be the only clinical manifestation of these pathologies¹¹.

Just like other FORZA10 NUTRACEUTIC products, **FORZA10 Oto Active** consists of marine fish as the mono-protein in kibbles, mixed with 7% of special tablets (SANYpet AFS European patent n. EP 2526781) made up of added natural principles, whose total effectiveness is preserved thanks to the use of this new innovative Active Fresh System (AFS) technique. The special cold-processed AFS tablets consisting of pure fish hydrolysates give great advantages because they are: absent of pharmaceutical excipients, highly palatable, hypoallergenic, have a desirable kibble density for standard parameters, and are easily eaten by dogs.

FORZA10 Oto Active, a strictly mono protein product (marine fish) contains specific antioxidant and phytotherapeutic properties including *Melaleuca alternifolia* (Tea Tree), *Echinacea purpurea*, *Tilia platyphyllos scapoli et cordata*, *Allium sativum L.*, *Rosa canina* and Zinc chelate.

Tea Tree (*Melaleuca alternifolia*). It is also known as tea tree. The essential oil obtained from its leaves has antiseptic and bacteriostatic properties

Linden (*Tilia cordata*). The natural principles contained in the inflorescence and sapwood have healthy emollient and soothing properties.

Garlic (*Allium sativum*). Since ancient times, Garlic has been known for its antiparasitic benefits.

Rose hip (*Rosa canina L.*). The extract of its fruits is a precious natural source of vitamin C and flavonoids.

Zinc chelate. It is a trace element that has anti-oxidant properties and supports the immune system.



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Active Fresh System

European patent n. EP 2526781
International patents pending



Tea Tree
Linden
Garlic
Rose hip
Zinc chelate

Omega3-Omega6 ratio 1:4

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Veterinary Formulation