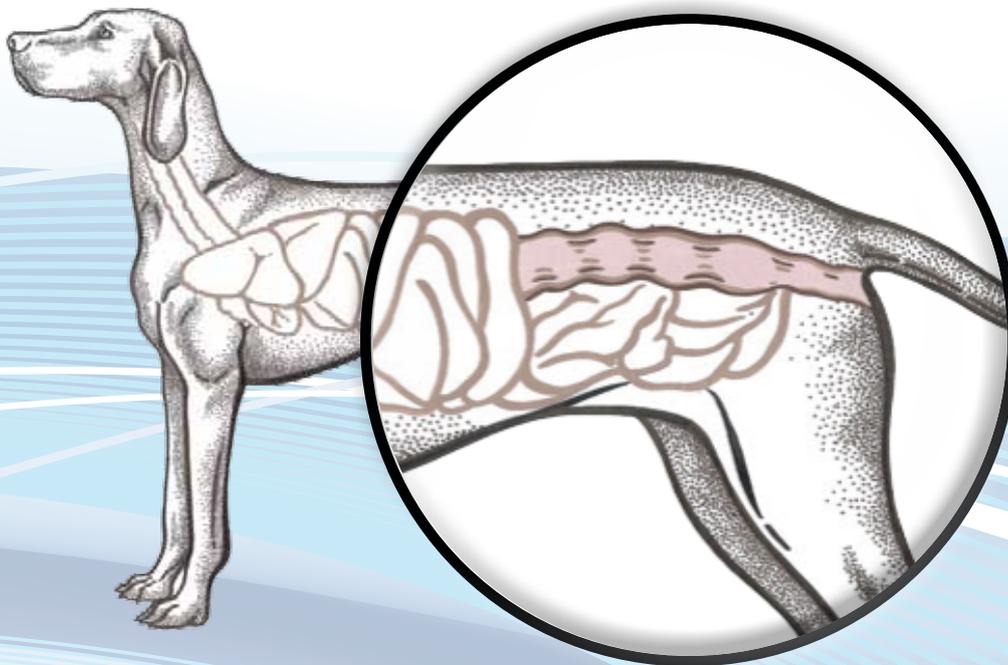


MULTICENTRIC STUDY ON

INTESTINAL COLITIS

Phase 1 - Dr. Graziano Pengo

nutritional instrument for intestinal problems



FORZA10
by **SANYpet** SpA

INTRODUCTION

Chronic intestinal inflammatory diseases are gaining increasing importance in small animal clinical medicine. A suitable diet seems to be the best complement to new therapeutic approaches, as it promotes restoration of optimum physiological conditions in the digestive tract. Specifically, it has become very clear that **dietary fibre** plays an important role in a healthy balanced diet, as it helps to normalize intestinal activity and balance bacterial flora. The purpose of increasing the amount of fibre in the diet is to rebalance the relationship between fibre and the other food components.

It is well known that, under natural conditions, dogs have a diet that is composed of a variety of unprocessed foods that includes both muscle tissue and lesser parts of the animal (bones, tendons, skin, feathers, intestinal contents of herbivore prey, etc.). Food that has a low nutritional value, but a high content of fibre and roughage, therefore represents a significant portion of the meal. Although these components are low in nutrients, they play an important role since they contribute to:

- ➔ maintaining proper functioning of all parts of the gastrointestinal tract;
- ➔ maintaining a proper balance in the intestinal bacterial population;
- ➔ efficient peristalsis, both segmental and linear;
- ➔ proper faeces formation;
- ➔ proper distribution of absorption of the various nutrients along the intestinal tract;
- ➔ maintaining appropriate intestinal microclimate conditions, including proper pH and moisture levels.

Dietary fibre is generally divided into two main categories – soluble and insoluble.

Soluble dietary fibre is composed of various components of plant origin, including pectins, gums and mucilages. When combined with water, soluble fibre forms a gelatinous mass that has a high satiating effect, as it distends the gastric walls and thus activates the mechanoreceptors that transmit a feeling of fullness to the brain. In addition, it has chelating properties and, due to the jellifying effect within the intestinal lumen, it increases the viscosity of the intestinal contents and consequently slows intestinal evacuation. A portion of the soluble dietary fibre is composed of oligosaccharides. Due to their composition and make-up, oligosaccharides are resistant to hydrolysis by the digestive enzymes of non-herbivore monogastric animals and therefore resistant to subsequent absorption. Since the fibre is not absorbed by the animal's intestinal tract, it is available for fermentation by bacterial flora, which transforms it

into methane, carbon dioxide, water and volatile fatty acids (VFA). In non-herbivore monogastric animals, including dogs, the fermentation processes take place exclusively in the colon, which contains “resident microbiota” composed of a large number of bacterial species. This bacterial flora has important functions in the host organism that include: stimulating the mucosal immune system, producing growth factors for proper development of intestinal mucosa, synthesizing approximately a quarter of all of the folates present in the body as well as other vitamins, modulating cholesterol absorption and replenishing bile acids.

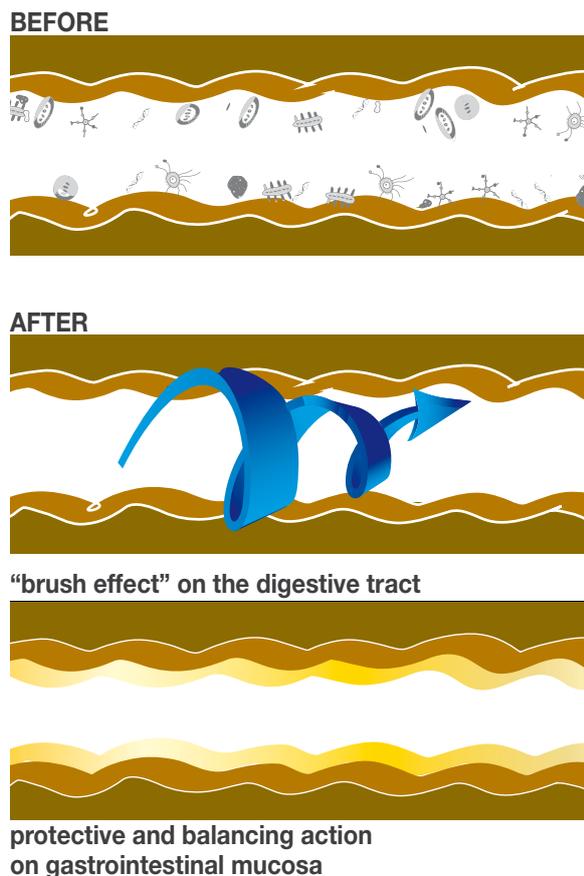
Insoluble fibre, on the other hand, is composed primarily of polysaccharides, like cellulose and lignin, and has the ability to absorb a considerable amount of water. Due to this characteristic, it increases the size of the faecal mass, thereby increasing motility and accelerating intestinal transit. As a result of its hygroscopic nature, insoluble fibre prevents constipation and diverticulitis by making the faeces larger, softer and more pultaceous. It has been demonstrated in humans that insoluble fibre can prevent certain types of tumours in the colon-rectal tract. This occurs because the water in the fibre dilutes toxic substances present in the intestinal lumen and increases the transit velocity, thereby reducing the time that toxins are in contact with the intestinal wall.

Due to the various important positive effects of dietary fibre, it can easily be assumed that the low dietary fibre content of most commercial dog foods could have a negative impact on several of these mechanisms and equilibriums, resulting in numerous chronic inflammatory diseases in the gastrointestinal tract over time.

Increasing the amount of fibre in the diet, while providing the proper ratio of soluble to insoluble fibre, therefore has the specific function of facilitating a return to normal conditions, particularly in subjects with chronic intestinal inflammation. The fibre selected for this purpose is provided by ***Ascophyllum nodosum***, a brown algae found in coastal Northern Europe that contains the optimum percentages of soluble (80%) and insoluble (20%) fibre.

The beneficial effects provided by the well-proportioned amount of fibre are synergistically combined with hydrolysed fish protein. Thanks to the low molecular weight and almost complete absence of contamination for pharmacological residues, this protein offers important non-allergenic properties. As a result, it does not stimulate the immune system in subjects with chronic inflammation, which can be prone to food intolerances due to an alteration in the mucosal barrier.

Pic.1 Combined effects of the seaweed *Ascophyllum nodosum* on the gastrointestinal tract



THE PRODUCT

Intestinal Colitis formula by Graziano Pengo is a diet created by Dr. Graziano Pengo, in collaboration with the SANYpet Research and Development Centre, with the objective of providing a nutritional tool to help treat chronic colitis, enteritis and enterocolitis. The formula synergistically combines a high-quality protein that has recognized biological value with a high content of fibre and electrolytes, making the product extremely effective in restoring normal intestinal absorption capacity and countering the loss of essential macro- and micronutrients. The innovative composition of Intestinal Colitis formula by Graziano Pengo also contributes to improving the physiological defence mechanisms of the lower digestive tract and the general condition of the dog.

OBJECTIVES OF THE STUDY

The purpose of this study is to demonstrate the role of Intestinal Colitis formula by Graziano Pengo in resolving symptoms in dogs with inflammatory disorders of the intestinal tract. The product, classified as a “Dietetic Food”, was formulated based on the fundamental points outlined above:

- ➔ Hydrolysed fish protein is the only protein source. This provides the subject with a protein having a high biological value that does not contain any of the main pharmacological residues that cause food intolerances. The hydrolysis process “pre-digests” the proteins by forming peptides and amino acids, which are directly absorbed by the intestines. This treatment promotes absorption of the components and significantly reduces allergic reactions.
- ➔ Rice, a highly digestible, low-allergy grain, is the only carbohydrate source.

- ➔ The high fibre content is provided primarily by *Ascophyllum nodosum*, a brown algae found in the Atlantic. This algae is also very rich in fucoidan, a complex polysaccharide that has been shown to have an important protective effect on the gastrointestinal tract. The two types of fibre have a combined action – insoluble fibre has a “scrub-brush effect” on the digestive tract and helps clean the intestines, while gelatinous soluble fibre creates a protective layer on the gastrointestinal mucosa and re-establishes its functionality.

The efficacy of the diet was tested through a 30-day dietary trial. The results were evaluated by means of clinical and instrumental protocols.

MATERIALS AND METHODS

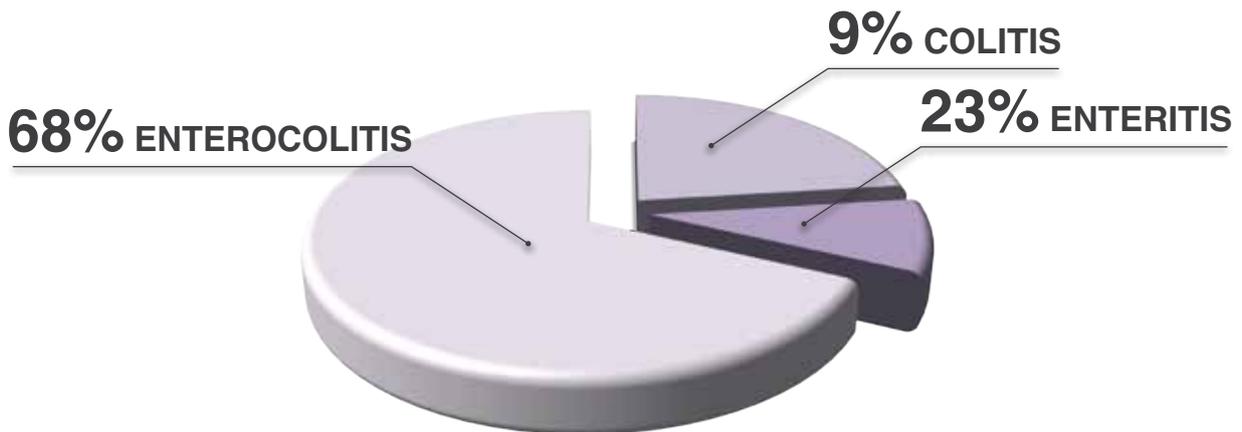
The clinical trial was conducted on 206 dogs of different breeds, sizes and ages. The subjects involved in the study suffered from chronic enterocolitis, enteritis or colitis, in the percentages shown in the chart below.

Clinical and symptomological evaluation was used to assess the state of health of each of the subjects involved in the study. Endoscopic diagnostic procedures were used as part of the clinical evaluation only in the most serious cases. Before administering Intestinal Colitis formula by Graziano Pengo, an evaluation of the symptoms of each subject was performed. These symptoms were then monitored during the entire period in which the product was administered.

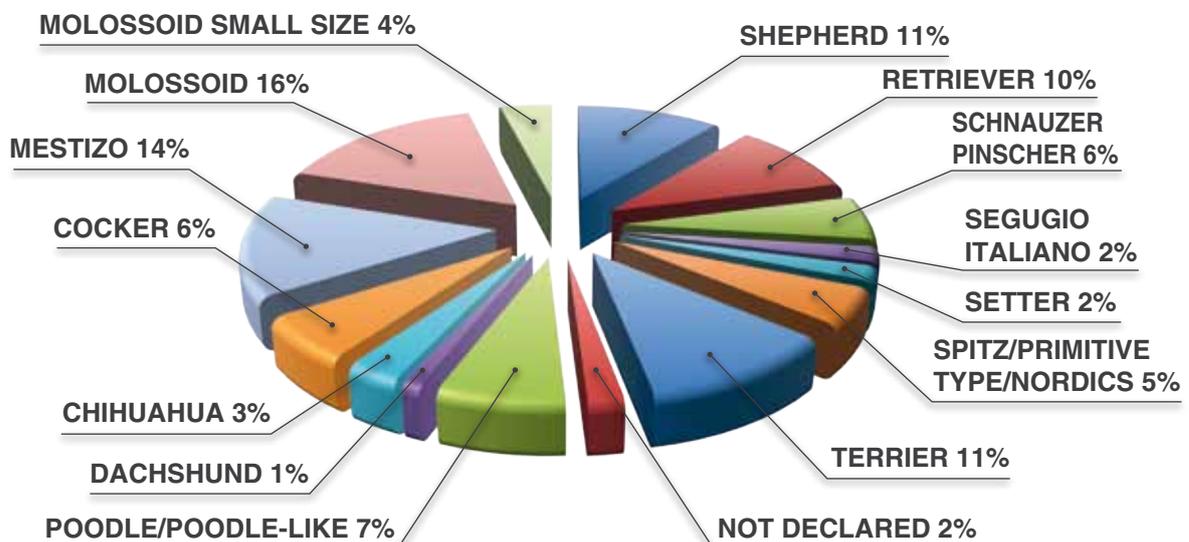
The disorders were considered to be resolved if the original symptoms disappeared.

More specifically, the subjects involved in the dietary trial were fed exclusively Intestinal Colitis formula by Graziano Pengo. The subjects were divided into three groups based on the predominant disease:

- ➔ The first group consisted of 19 dogs suffering from colitis. At the beginning of the dietary trial, the subjects displayed one or more of the following classic symptoms of colitis: diarrhoea (liquid or nearly liquid) more than once per day, faecal urgency, presence of mucus and/or blood in the faeces, vomiting, dysorexia or anorexia, abdominal pain, lethargy, flatulence and, rarely, weight loss.
- ➔ The second group consisted of 139 dogs suffering from enterocolitis. The subjects recruited for the trial displayed one or more of the symptoms associated with enterocolitis, including weight loss, dysorexia, and faeces of various colours and having a pultaceous consistency, in addition to the symptoms typical of colitis listed above.
- ➔ The third group consisted of 48 dogs suffering from enteritis. The subjects displayed increased borborygm, anaemia and leucopenia, in addition to the symptoms typical of enterocolitis listed above.



Pic.2a A subdivision of all dogs into 3 groups according to the predominant disease



Pic.2b A subdivision of all dogs into the breeds

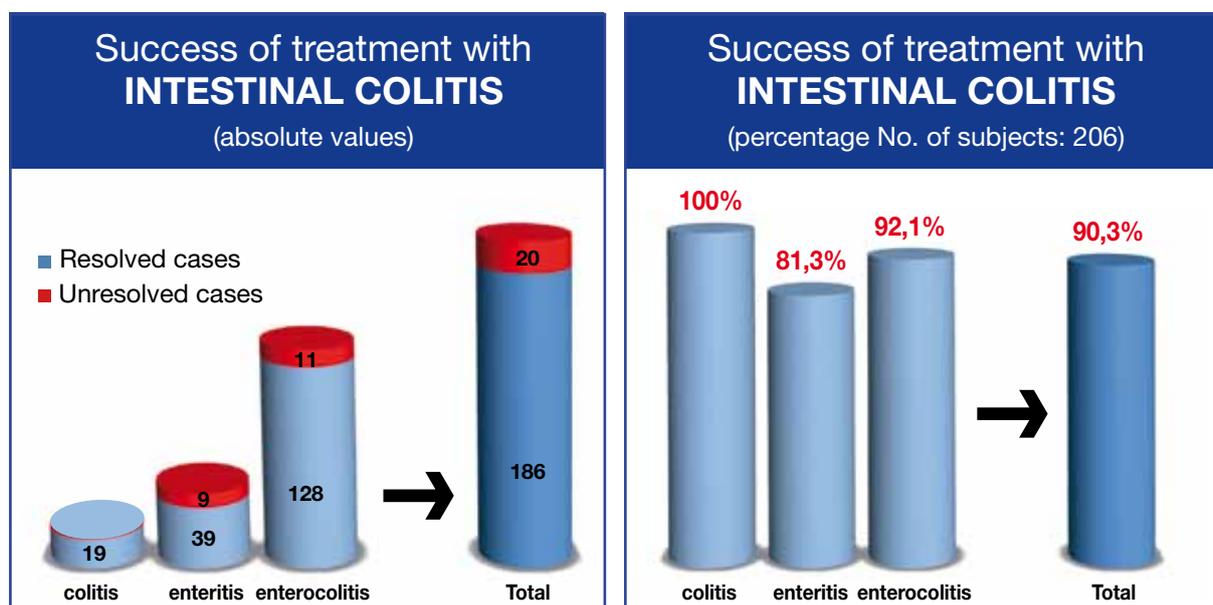
RESULTS

The symptoms had been resolved in 186 of the 206 subjects (90.3%) within 15 days of beginning the dietary treatment.

- ➔ In all of the subjects from the first group, which suffered from chronic colitis, the diarrhoea disappeared and normal intestinal transit, associated with defecation of compact faeces no more than 2-3 times per day, was restored. In addition, the symptom of faecal urgency disappeared. Mucus and blood were no longer present in the faeces, abdominal pain disappeared, appetite improved, which resulted in weight gain, and, in general, the subjects returned to normal daily activity. The tests conducted on subjects suffering from colitis demonstrated that exclusive administration of this product resolved 100% of the cases.
- ➔ In subjects belonging to the second group, which suffered from enterocolitis, the symptoms were resolved in 128 of 139 cases, or rather 92.1% of the subjects, within 20 days of beginning the dietary treatment. Specifically, in the subjects in which the enterocolitis was considered resolved, vomiting ceased and body weight increased.
- ➔ In the subjects recruited for the third group, which suffered from enteritis, the original symptoms

disappeared in 39 of the 48 subjects. The tests conducted demonstrated that exclusive administration of this product resolved 81.3% of the cases, with diarrhoea decreasing significantly and solid, compact faeces appearing, along with an increase in appetite and an increase in body weight. Overall, the disease was resolved in 90.3% of the subjects that received the dietary treatment.

More than 70% of the subjects suffered from a relapse of colitic symptoms, particularly soft or liquid faeces, as soon as a different food was introduced. Such relapses were resolved by reintroducing Intestinal Colitis formula by Graziano Pengo, which contains hydrolysed protein as a source of protein and has a high content of fibre. The remaining 30% of the subjects responded to the reintroduction of a conventional food in various ways, without significant reappearance of symptoms and without evident worsening of the consistency of the faeces that would cause it to be considered diarrhoeic or abnormal. It is believed that these particular subjects had already passed the acute inflammatory phase, in which the intestines are particularly sensitive and more inclined to develop an immune system response that could lead to a recurrence of the inflammation.



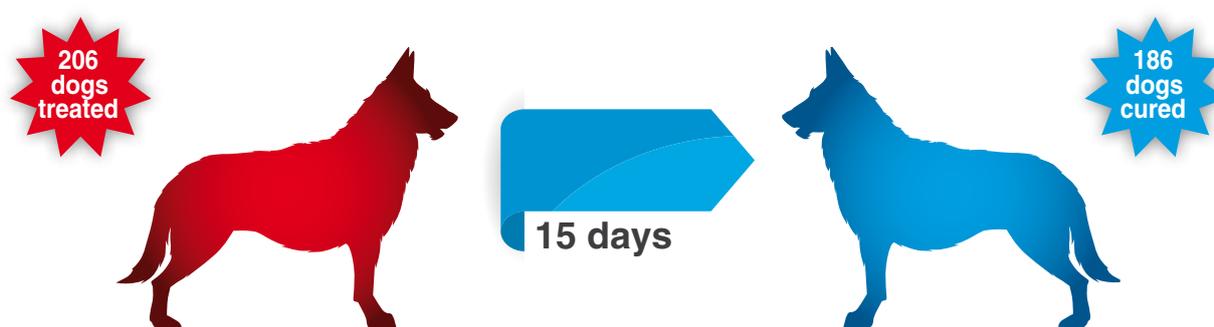
Pic.3 The results after 15 days treatment with Intestinal Colitis on 206 animals

DISCUSSION

The results of the present clinical study clearly demonstrate that the dietetic product Intestinal Colitis formula by Graziano Pengo can significantly reduce the symptoms associated with colitis, enterocolitis and enteritis. In fact, in a period ranging from 15 to 20 days from the start of the administration of the product being tested, the primary symptoms associated with these diseases disappeared or significantly decreased in a very high percentage of cases.

The best and most remarkable results were obtained in the group of subjects suffering from colitis, in which the

symptoms were resolved in 100% of the animals treated, an occurrence that is quite rare in biology. This data confirms the primary importance of a balanced high-fibre diet in promoting the recovery of the physiological environment of the colon and the re-establishment of the proper composition of bacterial flora, which make up the “resident microbiota” in the colon. Despite being less dramatic, the results obtained for the other groups, suffering from enteritis and enterocolitis, confirm therapeutic success in a very high number of subjects, 81.3% and 92.1% respectively.



Pic.4 The results of a clinical study with Intestinal Colitis after 15 days

CONCLUSIONS

Intestinal Colitis formula by Graziano Pengo, the formulation created specifically as a nutritional therapeutic support to resolve inflammatory intestinal diseases that is the subject of this clinical study, is a

targeted and effective, as well as palatable and easy to administer, “dietetic therapy” that promotes the resolution of the symptoms of enteritis, enterocolitis and colitis in dogs.

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