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Research Whitepaper

New NEM® Research: Helping "Man's Best Friend"

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Introduction

A *new* NEM® brand eggshell membrane study has published in the journal, *Veterinary Medicine: Research & Reports*, which is the first study demonstrating NEM's benefits in a **canine population**. This study, which was conducted in several canine breeds, adds to the growing portfolio of human and veterinary research demonstrating NEM's outstanding benefits for joint comfort and flexibility, as well as cartilage protection![1,*]

NEM® is a unique joint health ingredient that has been researched in multiple human clinical trials for its benefits to joint structure and function.[2,3,4,5,*] NEM® has also previously demonstrated effectiveness in several animal populations.[6,7,8]

Background

Poor joint function is a common malady affecting many dog breeds. Structural abnormalities and injury are the two principal causes; though, because of the increasing lifespan of companion animals, aging is also an important contributor. In some breeds, the prevalence is as high as 50% and is most common in the hip joints, manifest as pain, stiffness and loss of flexibility.[9] Joint laxity, misalignment of the hip joint, and the resulting uneven weight distribution frequently lead to the development of osteoarthritis (OA). Though there are few studies tracking the prevalence of osteoarthritis in dogs, it is estimated that 20% of adult dogs and 80% of geriatric dogs (over 8 years old) have OA, roughly mirroring the incidence in humans.[10,11,12]

1 Ruff KJ *et al.* "Effectiveness of NEM® brand eggshell membrane in the treatment of suboptimal joint function in dogs: a multicenter, randomized, double-blind, placebo-controlled study" *Vet Med Res Reports* (2016) 7:113-121

2 Ruff KJ *et al.* "Eggshell membrane: a possible new natural therapeutic for joint and connective tissue disorders. Results from two open-label human clinical studies" *Clin Interv Aging* (2009) 4:235-240

3 Ruff KJ *et al.* "Eggshell membrane in the treatment of pain and stiffness from osteoarthritis of the knee: a randomized, multicenter, double-blind, placebo-controlled clinical study" *Clin Rheumatol* (2009) 28:907-914

4 Danesch U *et al.* "NEM® brand eggshell membrane effective in the treatment of pain associated with knee and hip osteoarthritis: results from a six-center, open-label German clinical study" *J Arthritis* (2014) 3(3):136

5 Brunello E and Masini A "NEM® brand eggshell membrane effective in the treatment of pain and stiffness associated with osteoarthritis of the knee in an Italian study population" *Int J Clin Med* (2016) 7:169-175

6 Bauer KL *et al.* "Evaluation of a nutraceutical joint supplement in cranes" *Proc North Am Crane Workshop* (2014) 12:27-32

7 Dierenfeld ES *et al.* "Evaluation of a nutraceutical joint supplement in camels" *Amer Hol Vet Med Assoc J* (2014) 39:59-66

8 Wedekin KJ *et al.* "Efficacy of an equine joint supplement, and the synergistic effect of its active ingredients (chelated trace minerals and natural eggshell membrane), as demonstrated in equine, swine, and an osteoarthritis rat model" *Open Access Anim Physiol* (2015) 7:13-27

9 Simon S *et al.* "Incidence of canine hip dysplasia: A survey of 272 cases" *Vet World* (2010) 3(5):219-220

10 Marshall WG *et al* "A review of osteoarthritis and obesity: current understanding of the relationship and benefit of obesity treatment and prevention in the dog" *Vet Comp Orthop Traumatol* (2009) 22:339-345

11 Rialland P *et al.* "Clinical validity of outcome pain measures in naturally occurring canine osteoarthritis" *BMC Vet Res* (2012) 8:162

12 Helmick CG *et al.* "Estimates of the prevalence of arthritis and other rheumatic conditions in the United States. Part I" *Arthritis Rheum* (2008) 58(1):15-25

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Study Summary

This new prospective, randomized, double-blind, placebo-controlled study was conducted through eight veterinary clinics across the St. Louis, MO metropolitan area. The dogs in the trial were between the ages of 3 and 14 years and weighed 10-100 pounds. Their owners had all reported joint related issues of at least three months duration, including difficulty getting up from a lying position, a noticeable limp, impaired gait, and difficulty climbing stairs.

The study used an owner survey called the Canine Brief Pain Inventory (CBPI) questionnaire, in combination with a veterinary assessment called the Veterinary Canine Scoring Assessment (VCSA). CBPI is a validated questionnaire designed to evaluate chronic pain and how it impacts dogs' daily activities and overall quality of life. Through the VCSA, the veterinarians assessed joint pain and mobility, as well as lameness while walking and trotting. In addition, potential chondroprotective benefits were also analyzed by assessing levels of serum CTX-II – a biomarker directly indicating cartilage degradation.

Results

The NEM® treated dogs experienced a relatively rapid improvement in pain (average of 19.4% improvement for all dogs as reported by owners) in just 1 week! By the end of the 6-week follow-up period, veterinarians also reported significant improvement in the dogs' joint pain. In addition, by the end of the 6 week study period, nearly half (48%) of the NEM-treated dogs experienced a 33% improvement or greater in both VCSA pain and CBPI pain. As for joint function, treated dogs also experienced a relatively rapid (1 week) average improvement in CPBI function of 20.5%. This increased to 21.1% by the end of the 6-week period. The veterinarians' assessments for mobility and lameness also showed trends toward improvement.*

One of the most important factors for the ultimate success of a treatment is its effect on overall quality of life (QOL). Benefits of a joint treatment on QOL involve not only improvements in joint pain, immobility, and lameness, but also several intangible qualities as well. In the present study, dog owners reported a rapid (1 week) response in QOL with a mean improvement of 14.0%. This increased to 26.8% by the end of the 6-week follow-up period! This magnitude of improvement is considered very meaningful in the quality of life of dogs suffering from poor joint function.*

Relief from painful symptoms is certainly important for any joint treatment, however additional factors should be considered in assessing long-term benefits of a joint-support ingredient. Reducing inflammation in and around the joint and preserving the integrity of the joint cushioning cartilage, in addition to providing symptom relief, can contribute to better compliance and long-term success. Unfortunately, chondroprotection is an area where research has been lacking – *until now*. In the current study, chondroprotective effects were evidenced by a substantial reduction (47.9%) in serum CTX-II levels after 6 weeks of supplementation with NEM® versus the placebo.1 This chondroprotective effect from NEM® was previously documented in an arthritis-induced rat model[13] and can most likely be attributed to a reduction in joint inflammation,[14],[15] along with a reduction in various cartilage-degrading enzymes known as matrix metalloproteinases (MMPs).12,*

13 Sim BY *et al.* "Effects of natural eggshell membrane (NEM) on monosodium iodoacetate-induced arthritis in rats" *J Nutr Health* (2015) 48(4):310-318

14 Benson KF *et al.* "Effects of natural eggshell membrane (NEM) on cytokine production in cultures of peripheral blood monocuclear cells: increased suppression of tumor necrosis factor-α levels after in vitro digestion" *J Med Food* (2012) 15(4):360-368

15 Ruff KJ and DeVore DP. "Reduction of pro-inflammatory cytokines in rats following 7-day oral supplementation with a proprietary eggshell membrane-derived product" *Mod Res Inflamm* (2014) 3(1): 19-25

There were no reports of serious adverse events in the study, and no notable changes in the dogs' blood chemistry. The owners further reported that consuming NEM® was well tolerated by their pets. This exceptional level of safety is in agreement with what has been noted in prior human and animal studies.

Conclusions

This eight center randomized, double-blind, placebo-controlled study demonstrates that NEM® brand eggshell membrane is a viable therapeutic option for management of the pain and impaired quality of life associated with sub-optimal joint function in dogs. Supplementation with a once daily human equivalent dose of NEM® of 6 mg/lb (~13.5 mg/kg) quickly reduced joint pain (CBPI) with a lasting benefit through 6 weeks (VCSA). Moreover, a profound chondroprotective effect was demonstrated following 6 weeks of supplementation with NEM® which should slow loss of joint function over the dog's lifetime. A majority of pet owners concluded that a significant number of dogs could benefit substantially from NEM® supplementation.*