Double-Blind Study of the Effects of Cortaflex in Horses with Asymmetric Movement of the Tarsal Joint.

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Study outcome:
Horses showed a significant reduction in gait asymmetry after receiving Cortaflex (an oral supplement intended to support joint health) for 2 weeks, compared with a placebo supplement.

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This paper has been amended in the U.K. to comply with guidelines provided by the Veterinary Medicines Directorate, but properly represents the original content of the study.

Key points in the study:

- **Study was designed and performed by one of the leading independent veterinary research groups and lead by Dr. Hilary Clayton BVMS, PhD, MRCVS - world renowned veterinary research scientist.**

- **Study was double blind – neither the researchers nor the horse owners knew which solution was Cortaflex and which was the placebo until the study had been completed. Both test groups were assessed on the placebo and on Cortaflex.**

- **Subjective scoring of mild-to-moderate asymmetry is not very repeatable in comparison with kinematic analysis. Therefore, the accurate and objective gait analysis was the preferred technique used, with measurements obtained from video and force plates.**

- **The subjects had naturally occurring asymmetry. This was representative of the condition encountered in most mature equine athletes.**

- **All the measured variables showed a trend toward greater symmetry after receiving Cortaflex compared with the placebo.**

- **Peak vertical ground reaction force and vertical impulse, which represent the weight-bearing function of the limbs, were improved by being made significantly more symmetrical after receiving Cortaflex.**

- **Hock joint range of motion during stance was improved by being made significantly more symmetrical after receiving Cortaflex.**

- **Energy generation at the hock joint, which represents propulsive force, was improved by being made significantly more symmetrical after Cortaflex.**

Introduction.

In recent years, the use of oral supplements that are intended to support joint health has become very popular for decreasing asymmetry and increasing joint mobility in people and animals. There is considerable anecdotal evidence to support the use of natural chondroprotective dietary supplements, which is supported by experimental evidence of their efficacy in supporting joint health in horses.

Therapy for horses with extreme asymmetry, reflecting reduced joint motion, is usually based on non-steroidal anti-inflammatory drugs. Unfortunately, their long-term use may suppress chondrocyte metabolism and inhibit normal collagen and proteoglycan synthesis, resulting in further degradation of the cartilage matrix.

Traditionally, soundness has been evaluated subjectively and graded on a five-point scale. More recently however, gait analysis has enabled researchers to assess this factor objectively. Gait analysis uses kinematic variables to describe the movements of the segments and joints, and to describe the forces associated with locomotion. Ground reaction forces, which are usually resolved into vertical and horizontal (shear) components, measure the forces between the hoof and the ground. Summation of the ground reaction force throughout the stance phase is the impulse. Kinematic and force variables are used to calculate the torque (turning force) around each joint and the burst of mechanical energy absorption and generation. Energy absorption is indicative of the function of the joint in absorbing concussion; energy generation is indicative of the provision of propulsion.

Even for experienced clinicians, subjective scoring of soundness is not very repeatable in comparison with kinematic analysis. Therefore, objective gait analysis is the preferred technique for evaluating changes in the degree of gait symmetry over time. However, it is important to select a set of variables that are consistent with the objectives of quantifying soundness. Vertical ground reaction force (GRF) represents the weight-bearing function of the limb, with peak vertical force and vertical impulse being the most useful measurements. Redistribution of the vertical GRF between the limbs is indicative of changes in the ability to bear weight on different limbs, which is a relevant consideration in limb soundness. Net joint torques and mechanical energy profiles across a joint have received less attention to date, but may prove more sensitive to changes in the degree of symmetry than the kinematic or GRF variables.

Velocity affects the gait variables, and asymmetric horses tend to move more slowly thus decreasing GRF's. Therefore, it is important to ensure that horses move at the same velocity if the objective is to compare signs of soundness and symmetry at different times. In this study, trials were saved in which the horse moved at a pre-selected velocity that was scaled to the horse's height and weight. It might be argued that a voluntary increase in velocity is a sign of reducing asymmetric movement however, this is a subjective evaluation rather than an objective measurement. It is unlikely that horses will show significant changes in stride length while being constrained to move at constant velocity.

The goal of this study was to assess changes in gait variables objectively in horses with asymmetrical tarsal movement after supplementation of a joint nutraceutical in a double-blind placebo-controlled trial.

Materials and Methods.

The study was a double-blind placebo-controlled study designed to test the effects of Cortaflex on enhancing gait symmetry of mature equine athletes displaying degrees of stiffness and asymmetric movement. The eight subjects were riding horses that were in regular use, being ridden 4 to 6 days per week.
The active Cortaflex solution and a placebo were supplied in bottles identified only by numbers 1 through 16. The placebo solution was indistinguishable from the active solution in taste, smell, colour and consistency. Horses were admitted into the study in pairs and were numbered sequentially so there was an odd and an even-numbered horse in each pair. Horses #1, 3, 5 and 7 received the odd-numbered solution first, and horses #2, 4, 6 and 8 received the even-numbered solution first.

The owners were instructed to withhold all dietary supplements and medications, commencing two weeks before the start of the study, and continuing until after the study was completed. After the initial 2 week stabilization period, horses received the first solution orally for 2 weeks, followed by 2 weeks without the solution and then the alternative solution was given orally for a further 2 weeks. During each period with the solution, the horses received a loading serving of 60ml/day for 5 days, followed by a maintenance serving of 30ml/day for 9 day.

Gait analysis was performed using standard methods as the horses trotted in hand along a rubberised runway. Briefly, reflective spheres were attached over the centres of rotation of the hip, stifle, tarsal, fetlock and coffin joints and the distal hoof wall at the toe and heel. These markers were tracked automatically by a six-camera infrared system recording at a frame rate of 120 frames/s. The marker locations were used to determine joint angles during the stance phase of the stride.

Ground reaction forces were collected synchronously with the kinematic data using a 60 x 120 cm2 force plate that was embedded in the rubberised runway. Gait analysis was performed at the completion of each 2-week period with each solution. The horses moved at the same velocity during each evaluation, with the appropriate velocity for each horse being determined according to its height and weight.

Variables for analysis were selected based on the researchers experience and published literature indicating which variables are sensitive to changes within tarsal joint movement. The following variables were measured for the left and right fore and hind limbs during the stance phase of the trot.

- Peak vertical GRF
- Vertical impulse
- Range of tarsal joint motion
- Peak torque around the tarsal joint
- Mechanical energy absorption and mechanical energy generation across the tarsus

A symmetry index was constructed for each variable using the values measured for the left and right limbs: the lower value was divided by the higher value, so the index is always less than one. This index provided an indication of contra lateral limb symmetry without differentiating between the left and right limbs. The higher the value (closer to unity) the greater the left-right symmetry for the variable under study.

Comparisons between the symmetry indices for each variable after supplementation with the two solutions were made using paired samples t-tests with a probability level of $P<0.05$.

In addition, the total vertical impulse for the two hind limbs was determined as an indication of the total weight bearing by the hind limbs. It was calculated by summation of left hind limb vertical impulse and right hind limb vertical impulse. Paired t-test was used to compare the weight bearing by the hind limbs following supplementation with Cortaflex and the placebo. If the total amount of weight borne by the hind limbs did not change, but the symmetry index for peak vertical force or vertical impulse increased, it was indicative of a more symmetrical weight distribution. A reduction in total vertical impulse would indicate an overall weight shift to the forelimbs.

Results.

The velocities did not differ between groups (placebo solution: 3.26 = 0.16 m/s; active solution: 3.27=0/16m/s) The total vertical impulse summed over the left and right hind limbs was the same for the two evaluations.

Compared with the placebo, supplementation with Cortaflex resulted in significant increases in left-right symmetry of vertical GRF (P = 0.023), tarsal joint range of motion (p = 0.005) and tarsal joint energy generation during stance (P = 0.043). The other variables did not change significantly, but the vertical impulse (P = 0.080) showed a trend toward greater symmetry after supplementation with Cortaflex. In horse 2, symmetry of tarsal joint energy absorption was markedly lowered following supplementation with Cortaflex, which had a marked effect on the statistical analysis. This was the result of an inconsistent kinematic pattern in the left hind limb, which may have been related to the presence of a bone chip in the fetlock joint of that limb.

Discussion

Visual assessment of soundness is based on observation of a complex array of clinical signs that are indicative of asymmetrical movement patterns.

Gait analysis of asymmetric horses offers a means of quantifying the movements and associated forces in a repeatable and quantitative manner.

Symmetry indices have been applied in analysis of kinematic variables and ground reaction forces.

In the study reported here, every effort was made to ensure an objective and quantitative evaluation by using a placebo control, blinding the researchers and the owners to the order of supplementation, and using objective measurements of gait analysis. Subjects were selected that were typical of the type of horses that are supplemented with Cortaflex in the field. They were mature horses that were in regular work and that had stiffness in many regions.

Shortened stride length and stiffness is a common aspect of the older working horse and the majority of these horses show these changes in more than one region. The fact that the horses used in this study were recognised as being restricted in multiple areas produced complex patterns of gait differences and compensations, which are typical of the older working horse. However, the presence of multiple gait changes complicates the clinical evaluation and the gait analysis. However, the use of symmetry indices provided a better method of assessing gait changes.

The gait variables chosen for analysis represented the weight-bearing function of the hind limbs and the movements and functions of the tarsal joint. The results clearly indicated that Cortaflex produced a more symmetrical gait pattern at the tarsal joint in older horses that have worked hard on their joints for a length of time, which was interpreted as being indicative of an improvement in locomotor function. It is unrealistic to expect that a feed supplement will result in complete symmetry, but an

effective product might be expected to improve the motion, so that the horses gait pattern more closely approaches left-right symmetry.

The supplementation period of 2 weeks was quite short, but there is evidence of a rapid improvement in clinical signs following the supplementation of Cortaflex. A previous study of the effects of this product in horses with reduced joint motion showed that flexion test grade and stride length improve rapidly during the first 2 weeks of supplementation, and then more slowly during the following 2 weeks.

It is concluded that the gait pattern at the trot became more symmetrical in horses with tarsal stiffness after they received Cortaflex compared with supplementation of a placebo.