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## INFLUENCE OF SYSADOA GROUP CHEMICALS ON GONARTHROSIS, RHEOLOGICAL PROPERTIES MEASUREMENT *IN VIVO*

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### SUMMARY

This study seeks to demonstrate the influence of pharmacological substances from the SYSADOA group on the progression of osteoarthritis in the human knee. The quantification methods were direct measurement of the rheological properties of the knee joints *in vivo* and standard WOMAC index questionnaires. The drugs were administered orally to 34 probands with second degree gonarthrosis for 13 weeks. The untreated control group consisted of 10 probands. The rheological properties of the joints were determined by a biorheometer, and subjective assessment of the knees by patients (WOMAC) before and after medication, and for a further 13 weeks. Changes in the calculated parameters over time were compared.

During the audited period slight deterioration in all of the parameters was observed in the untreated group. The treated group, however, improved in all the parameters and some indicators showed statistically significant differences. The positive effects of the SYSADOA persisted for 3 months after the end of treatments. Partial correlation was found between the results of the WOMAC questionnaire and the rheological measurements. The study shows the positive effects of the preparation on arthritic changes in the knee joint, but due to the large variance of the collected data, this conclusion is on the borderline of statistical significance. The method of measuring the rheological properties of the joints is suitable for evaluating the progression of OA.

### INTRODUCTION

Many professional studies have attempted to show the influence of pharmacological substances from the SYSADOA group on the progression of osteoarthritis (OA), but usually with not entirely convincing results. The main contribution of our study to a solution of this problem is the use of a unique objectification method of measurement of the rheological properties of the knee joint.

### METHODS

The study was attended in its entirety by a total of 44 probands, divided into two groups. The first group (34 probands), the "treated" group, used the manufacturer's recommended dosage of the formulation - 3 tablets orally per day (morning, noon, evening) for 13 weeks. The total daily dose was therefore 1500 mg of GS and 1200 mg of CHS. The group consisted of a series of patients who were

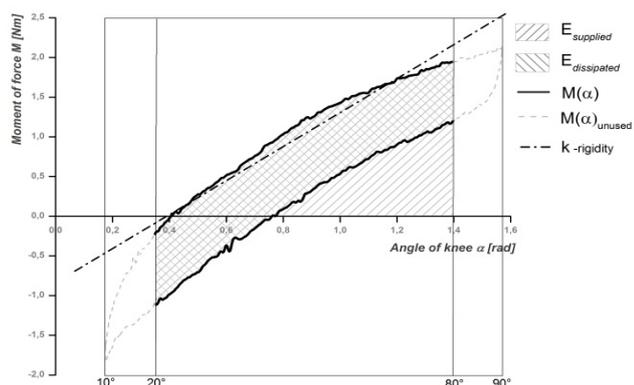
diagnosed with second degree gonarthrosis using X-rays and examination by a physician. The "control" group consisted of 10 probands with clinical findings of first degree gonarthrosis. This group did not receive any treatment or placebo, and there was therefore only measurement. The rheological properties of the joints were determined by a biorheometer, and subjective assessment of the knees by patients (WOMAC) before and after medication, and for a further 13 weeks. Changes in the calculated parameters over time were compared. Data obtained from WOMAC questionnaires and measured on the biorheometer were subjected to statistical analysis. Position and variability rates of individual parameters were calculated - means, medians and standard deviations and distribution normality (Kolmogorov-Smirnov) were checked. Absolute and percentage differences in the sizes of parameters were calculated, intra-individual to individual limbs in order to identify progression between the measurements. The weight of these differences was determined using the level of significance of a parametric paired t-test.

The questionnaires covered basic anamnestic data (past illnesses, injuries, medication) and physical activities (sports, work, daily activities), in both the controlled period and over the course of life. Furthermore, some physiological information was measured (weight, height, dimensions of selected segments of the body) and the current device settings and data from clinical examination of the knee joints by a physiotherapist were recorded.

The WOMAC (Western Ontario and McMaster Osteoarthritis Index) clinical questionnaire test was used by patients for subjective evaluation of changes in functional disability of the knee. The questionnaire included 24 questions divided into three thematic areas - knee pain (5 questions), knee stiffness (2 questions) and everyday activities (17 questions). Completion of data by patients was performed by checking values on a five-point scale. The questionnaires were evaluated according to the N. Bellamy method (American College of Rheumatology 2011).

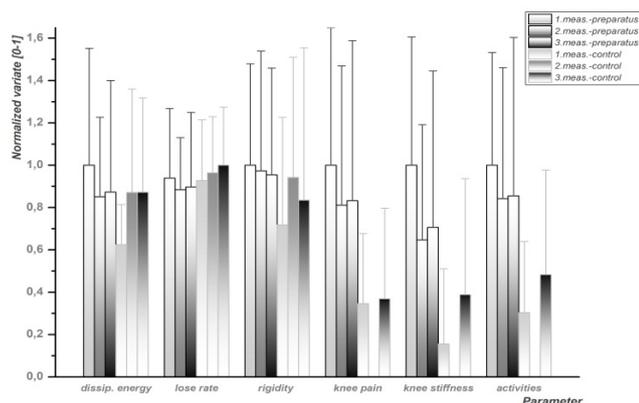
For quantification of the positive impact of the preparation on knee joint arthritis we started from the basic assumption that gonarthrosis causes a detectable change in the

rheological properties of the joint and the preparation is capable of detectably affecting the progression of this change. Our unique laboratory device, a biorheometer, served as detector. The principle behind this measuring method is in sensing the mechanical resistance (torque) in passive (forced) movement of the knee (flexion, extension) when the muscle system of the patient is fully relaxed. Changes in the rheological properties of the joint as a whole are then evaluated, i.e. parameter changes of a "hysteresis" loop. 3 parameters worked best for us - dissipated energy, loss rate and dynamic stiffness, which provide an understanding of the mechanical properties of the knee as a whole - its tribology, energy efficiency and viscoelastic characteristics. The method of determination of these parameters is shown in the graph (Figure 1).

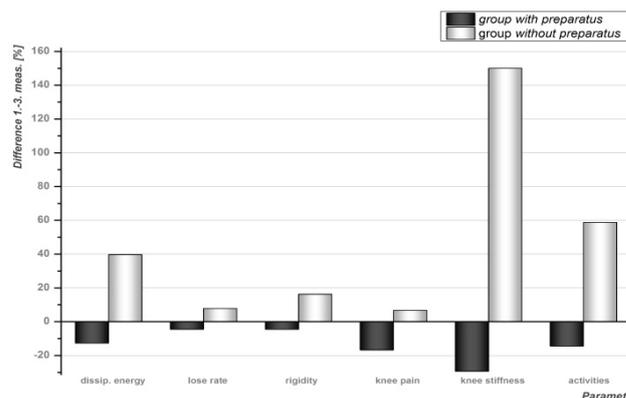


**Figure 1:** Hysteresis loop of dependence of bending moment  $M$  on the angle of knee flexion  $\alpha$  measured by a biorheometer. Only the interval  $\alpha$  between  $20^\circ$  and  $80^\circ$  was used to calculate the parameters. The areas are indicated in the graph corresponding to the dissipated energy ( $E_{\text{dissipated}}$ ) and supplied energy ( $E_{\text{supplied}}$ ) for loss rate calculation and the average directive  $k$  for the calculation of stiffness.

## RESULTS AND DISCUSSION



**Figure 2:** Normalized graph of mean values and standard deviations of monitored parameters sorted chronologically for the 1st, 2nd and 3rd measurement ( $0 = 0$ ,  $1 = \text{max}$  achieved average parameter value). Light tops of columns are the results of the treated group, dark of the untreated.



**Figure 3:** Graph of percentage differences of evaluation parameters between 1st and 3rd measurement. Positive values of the light control group indicate deterioration in the knee status in all aspects, as opposed to the dark treated group.

## CONCLUSIONS

The study demonstrated the positive effects of the preparation on arthritic changes in the knee joint, but due to the large scattering of measured and collected data, this conclusion is on the borderline of statistical significance. The results further show that there was a significant difference in the progression of the disease symptoms between treated and control groups in the monitored six-month period. A clear correlation between objective biorheometer measurements and the subjective WOMAC questionnaire method only showed itself in the progression of the individual parameters. A significant correlation of the original data was only found between the parameters of the hysteresis curves and the knee pain index of the WOMAC questionnaires. An important finding of the study is the evidence of the biorheometer measurements' appropriateness for the determination of the progression of osteoarthritis. However, to confirm the validity of the results it is necessary to increase the number of probands, especially the control group, as the variability among living creatures is always very high.

## ACKNOWLEDGEMENTS

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