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## **Comparison of the Efficacy and Tolerance of Zeel<sup>®</sup> comp. and Diclofenac for the Oral Treatment of Gonarthrosis: Results of a Doubleblind Equivalence Study**

Summary by Anette Porcher-Spark from:  
Maronna U, Weiser M, Klein P. Orale Behandlung der  
Gonarthrose mit Zeel comp. - Ergebnisse einer  
doppelblinden Äquivalenzstudie versus Diclofenac.  
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Anette Porcher-Spark

## Comparison of the Efficacy and Tolerance of Zeel® comp. and Diclofenac for the Oral Treatment of Gonarthrosis: Results of a Double-blind Equivalence Study

For the treatment of gonarthrosis, the homeopathic complex preparation Zeel comp. (tablets) displays an efficacy comparable to that of the conventional antirheumatic agent diclofenac. This was demonstrated in a double-blind equivalence study carried out by the Institute for Antihomotoxic Medicine and Basic Regulatory Research in Baden-Baden, Germany.

Diclofenac is one of the non-steroidal antirheumatic agents (NSAR) most frequently used worldwide. The efficacy of this NSAR for gonarthrosis and other rheumatic conditions is considered as established. However, especially when diclofenac is taken for long periods, there is the risk of gastrointestinal side-effects such as nausea, diarrhea, occult gastrointestinal hemorrhages, and even the development of gastrointestinal ulcers. In view of these undesirable drug reactions, the period of therapy and the dosage for a

treatment with this medication is limited. This is why there is increased interest on the part of doctors and patients in a drug with superior tolerance and comparable efficacy for the treatment of rheumatic joint complaints that are often of a chronic nature.

### Homeopathic Remedies for Rheumatic Diseases

The homeopathic complex preparation Zeel comp. is a natural remedy available for this indication area. Its efficacy and tolerance with intra-articular injection has already been demonstrated in a clinical study and in a multi-center observation of application. To establish whether the homeopathic complex preparation was just as effective for gonarthrosis (of the knee), the most common form of joint arthrosis, as the allopathic NSAR diclofenac, 121 patients with gonarthrosis were investigated in a multi-center, random-

ized, double-blind and actively controlled parallel study.

### Study Design and Results

Men and women suffering from slight or medium-severe gonarthrosis for at least six months and from a total of 13 orthopedic practices took part in the study. The patients were treated for the 10-week period of the study with test preparations whose identity was concealed by the double-blind technique: 60 patients received one tablet of Zeel comp. and a diclofenac placebo 3 times per day, 61 patients took one tablet of diclofenac 25 and a Zeel comp. placebo tablet 3 times per day. The efficacy of the medication was measured by the WOMAC (Western Ontario and McMaster Colleges) arthrosis index by which the parameters pain, stiffness, and physical activity are assessed after 2, 4, 6, and 10 weeks.

According to the data obtained by the scientists, both Zeel comp. and diclofenac led to a statistically significant improvement in the gonarthrosis symptoms. After 2 and 4 weeks, a marked improvement in the parameters of pain, stiffness, and physical activity was first observed in the patients of the diclofenac group. After 6 weeks, however, there was no longer any difference between the groups and statistical analysis of the data showed the therapeutic equivalence of the two test medications (Fig. 1). In all, 47% of the patients of the Zeel comp. group assessed the efficacy of the treatment at the end of the study as "very good" or "good" (diclofenac group: 51%) (Fig. 2). The tolerance of the two test preparations was also assessed by the patients in both treatment

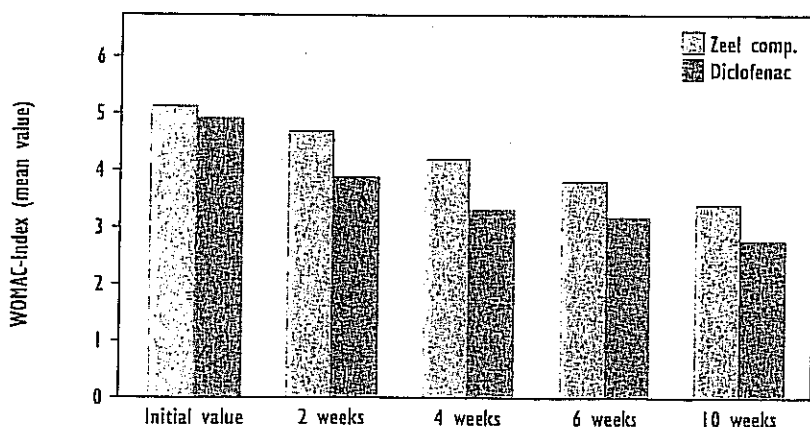


Fig. 1: Change in the WOMAC arthrosis index after 2, 4, 6, and 10 weeks' treatment.

COMPARISON OF THE EFFICACY AND TOLERANCE OF ZEEL® COMP. AND DICLOFENAC FOR THE ORAL TREATMENT OF GONARTHROSIS: RESULTS OF A DOUBLEBLIND EQUIVALENCE STUDY



Fig. 2: Overall assessment (opinion of patients) of the efficacy of the treatment after 10 weeks.

groups in more than 85% of the cases as "very good" or "good".

Possible Future Treatments

While the therapeutic efficacy of diclofenac, which is based on inhibition of

cyclooxygenase - a catalyst of the prostaglandin synthesis - has been well studied, the exact mechanism of action of Zeel comp. is still unknown. *In-vitro* investigations have shown that the antihomotoxic complex preparation inhibits activity of

the leukocyte elastase. This enzyme is released during inflammatory reactions and attacks the articular cartilage which is rich in proteoglycans.

From the study results available and the good experience obtained with Zeel comp. over many years in daily practice, researchers recommend that further studies be carried out to determine whether an agonist or an additive action exists between the homoeopathic medication and the NSAR. Interesting new treatments could emerge from the combination of the two preparations. For example, with severe forms of gonarthrosis, a combination treatment would be a very much more tolerable therapy option for the patient since the additional administration of the antihomotoxic complex preparation reduces the dose of diclofenac and, with efficacy maintained, the risk of severe side-effects could be substantially lowered.

## Zeel comp. vs. Diclofenac - Summary

### Aim:

The purpose of the study was the verification of the efficacy and patient tolerance of Zeel comp. (tablets) administered for osteoarthritis indications.

### Methodology:

The efficacy and patient tolerance of Zeel comp. was compared to that of Diclofenac in the context of a randomised, controlled, double-blind study. Both preparations were administered three times daily over a period of 10 weeks (concentration of Diclofenac per tablet = 25 mg) to 125 patients in total. The characterization (anamnesis) of the osteoarthritis was carried out at the beginning of the study by the physician.

The efficacy was determined by the following parameters:

- WOMAC (Western Ontario MacMaster) arthritis index, which is a widely accepted osteoarthritis questionnaire to be filled out by the patient. The scale ranges from 0 (no symptoms) to 10 (very severe symptoms)
- Global assessment (by physician and patient)

The tolerance was determined by the following parameters:

- Global assessment (by physician and patient)
- Undesired events
- Vital parameters
- Laboratory tests (haematology/clinical chemistry/urine)

### Results:

The study demonstrates that the efficacy of Zeel comp. (tablets) in treating mild to moderate gonarthrosis is equivalent to the efficacy of Diclofenac.

Furthermore, the study provided a parallel confirmation of the safety of Zeel comp. (tablets).