



## THE EFFECTIVENESS OF USING A CHONDROPROTECTOR IN PATIENTS WITH STAGE 1–2 OSTEOARTHRITIS IN GENERAL MEDICAL PRACTICE

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The effectiveness of a new European chondroprotector in the combination therapy of stage I–II osteoarthritis (OA) of various localizations was assessed. The study included 98 patients with OA of the knee and hip joints, as well as polyosteoarthrosis. According to

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The effectiveness of the new European chondroprotector in combined therapy in the 1–2 stage of osteoarthritis (OA) of different localization was estimated. The study included 358 patients with knee and hip joint OA, as well as polyosteoarthrosis. According to the study, all patients experienced a decrease in the severity of pain, a decrease in need for analgesics, an increase in functional activity and improvement in the quality of life. The drug is well tolerated, and patients demonstrated high adherence to treatment.

Osteoarthritis (OA) is a heterogeneous group of diseases of various etiologies with similar biological, morphological, clinical manifestations and outcome [1]. Damage to cartilage, subchondral bone, synovial membrane, capsule, ligaments and periarticular muscles is the basis of this pathology [2]. In the English-language literature, the disease name “osteoarthritis” is usually used, which emphasizes the role of inflammation in the development of the disease [3].

OA is the most common joint disease. OA accounts for 60–70% of all joint diseases; arthrosis affects 10–20% of the population [4]. At the same time, the proportion of patients with OA is steadily growing; it is expected that by 2020 OA will become the fourth cause of disability [5]. OA represents a serious socio-economic problem, as it significantly worsens the quality of life of patients. OA is one of the main causes of premature disability, second only to coronary heart disease.

In OA, the resistance of articular cartilage to mechanical load is impaired. The balance of cartilage tissue metabolism shifts towards increased catabolic processes. Changes in articular

cartilage contribute to the deterioration of its biomechanical properties, which negatively affects the underlying bone tissue, causing metabolic disorders, increased intraosseous pressure, and the development of subchondral sclerosis and osteophytosis. Depolymerization of hyaluronic acid (HA) is associated with deterioration of the viscoelastic properties of synovial fluid in OA [6].

According to the modern classification of drugs used in the treatment of OA [7], they are divided into the following groups:

- 1) fast-acting symptom-modifying drugs (NSAIDs, acetaminophen, opioid analgesics, corticosteroids, muscle relaxants, etc.). These drugs relieve the main clinical symptoms, such as pain and inflammation;
- 2) structure-modifying slow-acting drugs, or chondroprotectors.

These drugs have a chondromodifying effect. They are able to influence inflammation and metabolic processes in cartilage tissue and, thus, prevent the degradation of articular cartilage.

Among the structure-modifying drugs used to treat OA, the largest evidence base is for chondroitin sulfate (CS) and glucosamine sulfate, level of evidence 1A [8].

Another substance with a proven chondroprotective effect is HA. It plays a number of key roles in the trophism of cartilage and, by improving the properties of synovial fluid, facilitates the sliding of articular surfaces [1, 9].

It is also known that taking type II collagen increases joint mobility and reduces the severity of pain in patients with osteoarthritis [10].

In this regard, it seems interesting to study the effectiveness of chondroprotective drugs containing collagen II, chondroitin, glucosamine and HA for OA of various localizations in the initial stages of the disease. Such a drug has recently appeared on the Russian pharmaceutical market and is called Flexinovo.

Flexinovo is a European-made chondroprotector that contains a combination of structure-modifying slow-acting components, whose effectiveness has been confirmed from the standpoint of evidence-based medicine. Active ingredients (mg): hydrolyzed collagen type II - 300.0; chondroitin sulfate (including 200 mg from shark) - 240.0; glucosamine sulfate from crustaceans (D- glucosamine sulfate 2 KCl) - 105.0; L-ascorbic acid (vitamin C) - 40.0; hyaluronic acid (Nutrihyl) - 24.0; ginger root extract (*Zingiber officinalis*) - 10.0.

### Research objectives

- 1) To evaluate the effectiveness of treatment of osteoarthritis of various localization stages I–II with a chondroprotector Flexinovo.
- 2) To evaluate the safety and tolerability of Flexinovo therapy in patients with stage I–II osteoarthritis of various localizations.

Chondroprotector therapy for patients suffering from stage I–II osteoarthritis of various localizations.

### Material and methods

The study included 98 patients with stage I–II OA of various locations.

### Inclusion criteria:

1) the presence of one of the following symptoms:

- *pain and crepitus in the knee joints;*
- *morning stiffness  $\leq 30$  min;*



2) the presence of pain requiring drug therapy (40 mm or more on the visual analogue scale (VAS));

3) the duration of the articular syndrome is no more than 10 years.

**Exclusion criteria:**

- *high inflammatory activity;*
- *reliable signs of another rheumatic disease;*
- *the presence of an ulcer of the gastric or duodenal mucosa in the acute stage;*
- *severe concomitant pathology.*

Taking into account the above criteria, 358 patients were included in the study. Of these, 210 (59%) patients had OA of the knee joints, 97 (27%) patients had polyosteoarthritis, and 51 (14%) patients had OA of the hip joints (Fig. 1).

The average age of the patients was  $54.5 \pm 2.02$  years. The duration of the disease was on average  $6.7 \pm 1.24$  years.

The diagnosis of OA was established according to the Altman criteria (2009). To determine the radiographic stage of arthrosis, the classification of Kellgren and Louhrsen (2005) was used.

All 98 patients received complex therapy, including immediate action -modifying drugs (paracetamol/NSAIDs). As a slow- acting structure-modifying drug, patients received Flexinovo 1 tablet per day for 3 months. The effectiveness of therapy was assessed by the dynamics of joint pain according to VAS, Lequesne functional severity index over 3 months. Additionally, the number of patients who completely stopped taking painkillers was assessed.

**Research results**

Starting from the 1st month of treatment, patients in all three groups began to notice a decrease in pain and other clinical signs of the disease, but significantly more significant changes in indicators were observed in group 1.

When analyzing the results of treatment in the group of patients with OA of the knee joints who received Flexinovo 1 tablet once a day for 3 months, there was a decrease in pain when moving according to VAS by the 3rd month of observation from  $7.44 \pm 1.51$  to  $3.3 \pm 0.96$ . In the same group, there was a significant decrease in pain at rest according to VAS from  $3.44 \pm 0.74$  to  $1.12 \pm 0.31$ . The Lequesne functional index in this group of patients decreased from  $6.6 \pm 1.19$  to  $4.35 \pm 0.49$ .

In the 2nd group of patients with polyosteoarthritis, positive dynamics were also noted: a decrease in pain when moving according to VAS from  $7.52 \pm 3.7$  to  $3.7 \pm 0.96$  by the 3rd month of observation. At rest, pain in group 2 decreased from  $3.37 \pm 0.81$  to  $1.41 \pm 0.54$ . The Lequesne functional index in this group of patients decreased from  $6.5 \pm 1.36$  to  $4.5 \pm 0.51$ .

In the 3rd group of patients with OA of the hip joints, the pain index during movement decreased from  $8.6 \pm 1.37$  to  $4.24 \pm 0.98$ , and the pain index at rest from  $3.44 \pm 0.72$  to  $2.5 \pm 0.81$  by the 3rd month of observation. At the same time, the Lequesne functional index also decreased from  $6.8 \pm 1.23$  to  $5.3 \pm 0.81$ .

Thus, in all three groups, after 3 months of treatment, there was a significant decrease in the VAS pain index during movement (Fig. 2) and at rest (Fig. 3).

After three weeks of taking Flexinovo, the Lequesne index decreased in all three groups, but the most significant decrease in this indicator was noted in the knee OA group (Fig. 4).

Flexinovo made it possible to reduce or completely eliminate the use of traditional analgesics in patients of all three groups.

Three months after the start of therapy, 23% of patients took analgesics on demand, and 77% of patients completely stopped taking pain medications (Fig. 5).

The drug was well tolerated. Patients demonstrated high adherence to therapy. No side effects were identified when taking Flexinovo .

#### conclusions

1. *The use of Flexinovo , 1 tablet once a day for 3 months, in complex therapy of patients with OA of the knee joints, OA of the hip joints and polyosteoartosis reduces the severity of pain and the need for painkillers. Increases functional activity and quality of life of patients.*
2. *Flexinovo is well tolerated. Using Flexinovo 1 tablet once a day for three months is safe in terms of side effects.*

Thus, the data obtained confirm the effectiveness of Flexinovo in the complex therapy of OA of large joints and the feasibility of its use in general medical practice.

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