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Biomechanical changes with intraarticular injections of the Hyapro synovial fluid prosthesis in patients with gonarthrosis

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Abstract

Introduction Deforming osteoarthritis is the most common articular disease, with gonarthrosis accounting for a quarter of the patients aged 50 years and over. The disease is associated with impaired function, pain, disability, reduced quality of life and requires total joint replacement in severe cases. There is no clear understanding of the causes of the disease, however, the pathogenesis is well studied. Intra-articular injection of synovial fluid prostheses including hyaluronic acid is one of the approaches to restore the properties of synovial fluid. Stabilometry that is a rare use in orthopaedics, and no use in this aspect was added to the traditional treatment effectiveness assessment. **The objective** was to explore biomechanical changes in patients with Kellgren-Lawrence grade II-III gonarthrosis who underwent a series of three knee injections of synovial fluid prosthesis over a period of 6 months. **Material and methods** An open prospective non-comparative study was performed for 30 patients with unilateral gonarthrosis at a mean age of 60 (56; 63) years. The effect of intra-articular injections of a sterile mannitol heat-stabilized biopolymer synovial fluid prosthesis on the biomechanics was evaluated in two samples using WOMAC score (overall and ⩾ 30). Biomechanics was assessed in the form of stabilometry. Standardized stabilography and questionnaires were used at 3 follow-up visits: at 0 month (before administration), at 3 and 6 months. **Results** General sample showed no cases of true drift of the stabilogram parameters, decreased area of the statokinesiogram, and the WOMAC ⩾ 30 sample demonstrated an additional improvement in the speed parameters of vertical oscillation at 6 months, a decreased area of the statokinesiogram at 3 months and at 6 months, decreased energy costs at 6 months ($p < 0.05$). **Discussion** Positive changes in stabilometry indicated a decreased pain and fatigue reactions in a vertical static position in gonarthrosis during the treatment. Most effects were statistically significant in moderate and severe dysfunction and pain. Intra-articular injection of synovial fluid prosthesis objectively improved the physiometric parameters of the support reaction. **Conclusion** Three intra-articular injections of a synovial fluid prosthesis based on mannitol-stabilized hyaluronic acid used in gonarthrosis Kellgren-Lawrence grade II-III showed improved body posture parameters of maintaining upright posture and reduced energy consumption in moderate and severe knee pain according to dynamic stabilometry for at least 6 months.

Keywords: stabilometry, gonarthrosis, synovial fluid prosthesis, hyaluronic acid

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INTRODUCTION

Deforming osteoarthritis (OA) is the most common arthropathy worldwide that occurs in 15 % of the general population projecting 30-35 % of symptomatic cases over the next 10 years [1]. The incidence of OA increases with age, with 25 % of the over 50s population having OA of the knee [2]. Gonarthrosis is the leading cause of pain, disability, poor quality of life and often leads to the need for joint replacement [3, 4]. The main pathogenetic aspects of osteoarthritis of the knee joint include anatomical and functional discrepancy, degeneration of the articular cartilage [5], subchondral bone, circulatory disorders leading to changes in intraosseous and intraarticular pressure, tone-strength muscle imbalance [6], metabolic factors [7-10]. Clinical management of OA typically entails a limited combination of pharmacological, non-pharmacological treatment options, surgical interventions [11-13]. Intra-articular injections of hyaluronic acid (HA) is widely used for over three decades in the treatment of OA [7, 14, 15]. It typically develops slowly over time and instrumentation methods including magnetic resonance imaging and radiography are impractical in evaluation articular changes at a short term, and various patient-reported outcome measures can be partially subjective. Stabilometry was used for a quick and productive analysis of a possible effect of intra-articular injections of HA on the functionality of the locomotor system considering changes in biomechanics that accompany degeneration of the joints [16, 17] and the existing experience [18, 19]. The methodology of stabilometry has been standardized [20, 21] and has been rarely used to explore the knee joint [22], and there is a paucity of publications on the problem [23].

The **objective** was to explore biomechanical changes in patients with Kellgren-Lawrence grade 2-3 knee treated with three injections of synovial fluid prosthesis into the articular cavity over a period of 6 months.

MATERIAL AND METHODS

An open, prospective, non-comparative study was conducted to explore a biomechanical effect of a medical device consisting of a sterile mannitol thermo-stabilized biopolymer prosthesis of synovial fluid in a disposable syringe for intra-articular injection between 2020 and 2022. Non-sulfated glycosaminoglycan, hyaluronic acid and mannitol (supporting production technology) [1] was the active substance of the drug.

The inclusion criteria included: 1. Age of 45 to 75 years. 2. Gonarthrosis Kellgren-Lawrence grade 2-3, 1963 (confirmed by radiographs at least 6 months ago). 3. Consent to sign the informed consent form for participation in the study. 4. The desire and ability of the patient to comply with the requirements of the protocol throughout the study. 5. Consent to use adequate methods of contraception during the entire study period.

Exclusion criteria included:

1) aggravated allergic history;

2) hypersensitivity to any component of the medical product;

3) gonarthrosis Kellgren-Lawrence radiological grades 1 or 4;

4) the presence of metabolic, infectious-inflammatory, autoimmune diseases of the knee, degenerative lesions of the knee joint in addition to deforming osteoarthrosis at the time of inclusion or in the history of the patient;

5) skin injuries and diseases at the knee joint;

6) reactive synovitis with clinically significant effusion into the cavity of the knee joint at the time of inclusion;

7) intra-articular injection of glucocorticoids into the knee within 3 months prior to inclusion in the study;

8) physiotherapy in the last month preceding inclusion in the study;

9) previous surgery on the target knee within a period < 1 year prior to the Screening Visit;

10) clinically significant consequences of injuries, operations, diseases of the hip and ankle joints that can dynamically affect the knee joint;

11) previous treatment with drugs that could affect the metabolism of cartilage and bone tissue: oral or intravenous bisphosphonates < 3 months; teriparatide or raloxifene < 7 days; diacerein, glucosamine (sulfate or other forms, ≥ 1500 mg/day), chondroitin sulfate, or avocado and soy unsaponifiables < 2 mo; intra-articular injections of hyaluronic acid for 6 months; drugs with properties of matrix metalloproteinase inhibitors (e.g., tetracycline or other structurally related components) in the 6 months prior to the Screening Visit;

12) body mass index > 35 kg/m^2;

13) positive test for HIV, hepatitis B and C, syphilis;

14) information about the patient's non-compliance with the prescribed therapy regimen or protocol requirements (when participating in other clinical trials) earlier;

15) participation in other clinical trials for the scheduled period of the current trial;

16) concomitant somatic diseases or conditions that can interfere with interpretation of the results of treatment, be an obstacle to the implementation of the protocol of this clinical trial or pose a danger to the patient when participating in this study.

Exclusion criteria included:

1) serious (acute or chronic) pathological conditions developed during treatment, including mental illness, which, in the opinion of the investigator, may increase the risk associated with participation in the study or affect the interpretation of the efficacy and safety data obtained in this study;

2) pregnancy and breastfeeding.

The full protocol study included 30 patients (34 at inclusion with four dropped out due to non-compliance and the use of treatment, which was the exclusion criterion) with Kellgren-Lawrence grade 2-3 gonathrosis at a mean age of 60 (56; 63) years; of these, 27 were females and three were males. There was left-sided (n = 15) and right-sided (n = 15) involvement grade 2 (n = 22) and grade 3 (n = 8). The biomechanical study was produced using stabilometry exploring the dynamics of a static vertical posture with a stable support represented by a tensometric platform. Stabilometry as a method for diagnosing postural disorders is a standard study and is included in the orders, protocols and standards of medical care in the Russian Federation (Order of the Ministry of Health of the Russian Federation of July 31, 2020 No. 788n "On Approval of the Procedure for Organizing Medical Rehabilitation of Adults"; order of the Ministry of Health of the Russian Federation of December 29 2012 No. 1705n "On the procedure for organizing medical rehabilitation").

Stabilometry was performed immediately after inclusion in the study (Visit 1), and then three intra-articular injections of the medical device was produced into the knee of the patients with an interval of 7 days. Subsequently, stabilometry was performed at 3 months (Visit 2) and at 6 months (Visit 3). The Western Ontario and McMaster University Osteoarthritis Index (WOMAC) was used at the time points, and stabilometry with digital and graphic (stabilography) registration of parameters was employed using Biokinect® serial stabilometric complex ("Nevrokor" company, Russia)

[1] In the study, a biopolymer joint fluid prosthesis "Hyapro" 1.5 % – 2 ml was used.

to assess the postural function. Stabilography does not allow establishing or ruling out the diagnosis of gonarthrosis. Nevertheless, the assessment of the ability to maintain body balance with stable support under standardized conditions and in the absence of other significant pathology of the musculoskeletal, nervous and other systems (in accordance with the inclusion criteria) provides significant information about the functionality of the body, body reserves and energy consumption in real time mode. The knee joint is a weight-bearing complex biocomponent involved in the body's counteraction to the gravity force maintaining a vertical posture, and changes in the anatomy and function of the knee joint have a potential impact on the ankle in normal condition and the hip in pathology to maintain body balance [16]. A list of conditions for a stabilometric test was formulated to explore this cohort of patients. Firstly, considering the average age of patients (60 years) and the associated vertical posture pattern, and optional foot placement on the diagnostic platform was allowed for the patients to avoid discomfort and pain in the presence of gonarthrosis. Standard options (an angle between the feet being open anteriorly in accordance with the reference lines) with parallel orientation of the feet in the anteroposterior direction were offered for the patients, or the patient could choose an intermediate option between the two offered to achieve a comfortable posture. As the methodology suggested, linear dimensions of the feet and the bipedal distance corresponding to the linear distance between the clavicular midpoints were measured. The examination lasted at least 60 seconds. With time-dependent changes (true parameter drift) detected the time increased to a maximum of 180 seconds. The refusal of a fixed study time for all patients including long-term registration options was associated with possible functional limitations in gonarthrosis. The variables that reflected projection, dynamic and vector characteristics were used for statistical analysis of the stabilography. The presence of a true drift of the general center of ressure (GCP) was additionally measured and regarded as a pathological sign with a steady shift in the projection of the GCP in one direction by an interquartile interval calculated with the variance method [16]. Clinical data collection, analysis of radiographs and stabilometry were used in the work. The data were analyzed using non-parametric statistical tools (median; Wilcoxon's T-test, McNemar's test for proportional features) using the Medcalc® software product.

RESULTS

Overall population (n = 30)

The major stabilometry parameters in the general sample showed (Table 1): a statistically significant decrease in the frequency of the true drift of the general center of pressure (GCP) ($p = 0.008$) in Visits 1/2; statistically significant differences in the area of the statokinesiogram ($p = 0.019$) comparing the Visit 1/2 groups, and there was also a tendency ($p = 0.05$) to normalize the position of the GCP on the Y scale with displacement in the sagittal plane (Table 2).

Table 1

Statistical analysis of the frequency of true GCP drift in the total sample (n = 30)

n = 30	Shares of answers "0" and "1"			The presence of a statistically significant difference in the proportions according to the McNemar test		
	Visit 1	Visit 2	Visit 3	Visit 1/2	Visit 1/3	Visit 2/3
True GCP drift	«0»: 60 % (18) «1»: 40 % (12)	«0»: 86.7 % (26) «1»: 13.3 % (4)	«0»: 83.3 % (25) «1»: 16.7 % (5)	**There is** (p = 0.008)	None (p = 0.065)	None (p = 1.000)

Table 2

Results of statistical processing of stabilometry parameters for the total sample (n = 30)

Stabilometry parameter	Descriptive statistics (lower quartile – median – upper quartile)			The presence of a statistically significant difference between groups according to the Wilcoxon T-test		
	Visit 1	Visit 2	Visit 3	Visit 1/2	Visit 1/3	Visit 2/3
Statokinesiogram area S95, mm^2	66.2725 – 109.0550 – 200.2450	52.4225 – 88.0100 – 139.3025	50.7155 – 88.4150 – 161.0625	**There is** (p = 0.019)	None (p = 0.199)	None (p = 0.530)
The average position of the GCP in the sagittal plane Y, mm	(-49.4) – (-1.4) – (+4.3)	(-7.0) – (+0.1) – (+7.4)	(-13.5) – (+0.9) – (-2.8)	None (p = 0.493)	None (p = 0.097)	None (p = 0.050)

WOMAC subsample ≥ 30 (n = 18)

A subgroup of patients with a total WOMAC score of 30 or greater was selected from the general sample with significant changes in the variables in patients with moderate and severe dysfunction and pain. The WOMAC score shows functional limitations in various actions and body positions, various conditions for the manifestation of pain (Table 3). The Wilcoxon T-test for paired samples showed statistically significant difference ($p = 0.0001$) in comparison of Visit 1/2 with decreasing WOMAC score (improvement), statistically significant difference ($p = 0.0003$) in comparison of Visit 1/3 with decreasing WOMAC score (improvement), and the difference in the total score was statistically insignificant ($p = 0.8317$) in comparison of Visit 2/3 (Fig. 1).

Table 3

Sample of patients with a total score of C ≥ 30 at Visit 1, Visit 2 and Visit 3, median, upper and lower quartile values for each sample

Observation	Total WOMAC score		
	Visit 1	Visit 2	Visit 3
1	47	30	41
3	37	9	31
4	37	17	13
6	49	22	40
7	55	16	6
9	44	17	15
10	45	21	24
11	49	54	40
12	45	10	0
13	45	25	41
14	30	5	0
15	37	16	13
22	30	13	6
23	48	15	24
24	36	49	58
25	41	10	8
26	40	22	19
29	59	47	44
Median (lower and upper quartile)	44.50 (37.0; 48.0)	17.0 (13.0; 25.0)	21.5 (8.0; 40.0)

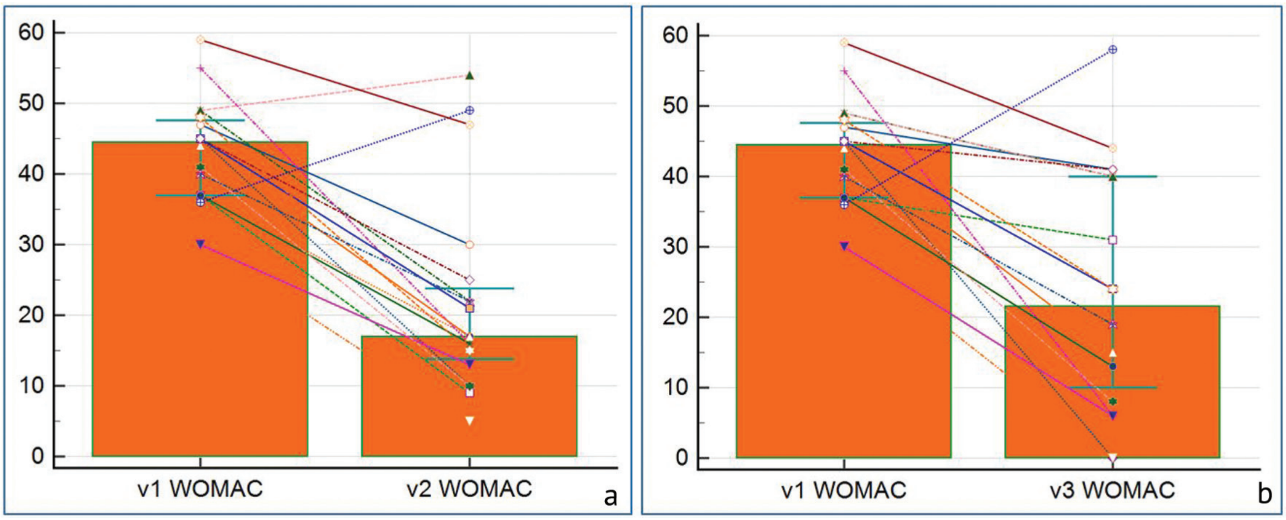

Fig. 1 Statistically significant differences in WOMAC score ≥ 30 in the groups: (a) Visit 1/2; (b) Visit 1/3

Statistically significant changes in biomechanics in the subgroup (n = 18) included:

1) decreased velocity of GCP (mm/sec) in Visits 1/3 (p = 0.0268) (Fig. 2). There was no statistically significant difference in the parameter in the samples of Visits 1/2 (p = 0.2837) and Visits 2/3 (p = 0.2288);

2) decreased velocity of GCP in the sagittal plane (mm/sec) in Visit 1/3 (p = 0.0077) and Visit 2/3 (p = 0.0483). There were no differences in Visit 1/2 (p = 0.2288);

3) decreased area of the statokinesiogram S95, mm^2, in Visit 1/2 (p = 0.0432) and Visit 1/3 (p = 0.0268). No differences were found in Visit 2/3 (p = 0.2121);

4) decrease in the kinetic energy E, J/min in Visit 1/3 (p = 0.0001), Visit 2/3 (p = 0.0208). The difference in Visit 1/2 was not statistically significant (p = 0.1297);

5) disappearance of true GCP drift (nominative trait) in Visit 1/2 (p = 0.016) and Visit 1/3 (p = 0.008), but not in Visit 2/3 (p = 1.000).

Table 4

Statistical analysis of the frequency of true GCP drift in the subsample WOMAC ≥ 30 (n = 18)

Stabilometry parameter and evaluation criterion		Shares of answers "yes" and "no"						The presence of a statistically significant difference in the proportions according to the McNemar test		
		Visit 1		Visit 2		Visit 3				
		abs.	%	abs.	%	abs.	%	Visit 1/2	Visit 1/3	Visit 2/3
True GCP drift	yes	11	57.9	4	21.1	3	15.8	**There is** (p = 0.016)	**There is** (p = 0.008)	None (p = 1.000)
	no	8	42,1	15	78,9	16	84,2			

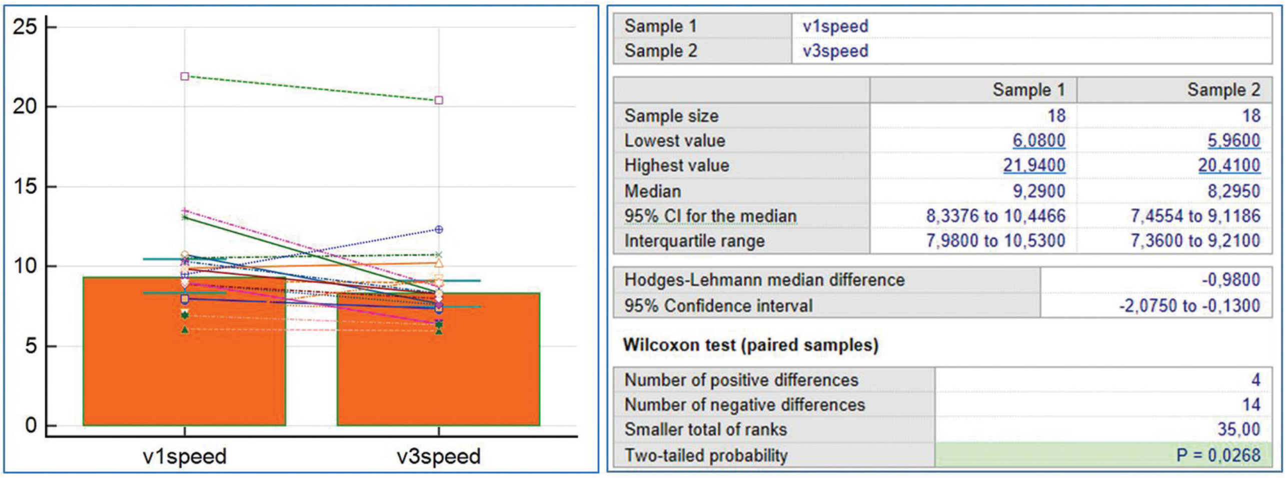

Fig. 2 Statistically significant decrease in the velocity of the GCP (mm/sec) in Visit 1/3

DISCUSSION

The total sample (n = 30) showed a decrease in the detection of true drift of the curves indicating a decrease in pain and fatigue response to static position, no need to "unload" painful structures through changing the body position [24]. A decreased area of the statokinesiogram (total GCP pattern on the supporting plane) at 3 months (2 months and 1 week from third final injection) indicated an improved stability of the vertical posture. The tendency towards normalization of the GCP position in the Y plane (anteroposterior oscillations and position) requires further study in a larger cohort of patients. Two-thirds of the weight is known to be borne by the hindfoot and one-third of the weight falls on the forefoot [16]. Improvement in muscle function and endurance is accompanied by increased loading on the forefoot and a forward shift in the GCP, and the result obtained potentially indicated a positive change in static biomechanics, although did not reach the level of statistical significance in this sample. The subpopulation WOMAC ≥ 30 (n = 18) of Visit 3 showed more stable upright posture at 6 months with lower velocity of physiological oscillatory movements tending to the normal values (7.4 mm/sec) [19]. The supporting area decreased indicating improved proprioception (joint position sense) and/or improved muscle coordination [25]. Improved control of the vertical posture entailed a reduced energy consumption and, consequently, a more comfortable and longer stay "on the legs" and improved exercise tolerance.

CONCLUSION

Dynamic stabilometry showed improved parameters of maintaining an upright body posture and reduced energy consumption for at least 6 months in patients with gonarthrosis grade 2-3 and moderate and severe knee pain following three intra-articular injections of a prosthesis of synovial fluid based on hyaluronic acid, thermally-stabilized by mannitol administered for.

***Conflict of interest**: no.*

***Financing** The study was sponsored by Infarm LLC (Russia). The sponsor was not involved in scientific research and did not make decisions independently of the researchers.*

***Ethical expertise** The study was approved by the LEC of the Ryazan State Medical University of the Ministry of Health of Russia (protocol No. 4 dated December 09, 2020).*

***Informed consent** All patients signed informed consent for treatment and inclusion in the study.*

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Fokin I.A. - methodology.
Antonovich M.N. – writing – reviewing and editing.
Rondaleva N.A. – visualization.
Vesnov I.G. – formal analysis, validation.