

# THE INFLUENCE OF THE WATER BATHS WITH OR WITHOUT OZONE ASSOCIATED WITH KINESITHERAPY ON LOWER LIMBS MUSCLES PERFUSION IN PATIENTS WITH GONARTHROSIS

Jolanta Kujawa<sup>1(A,D,E,F)</sup>, Joanna Szmagaj<sup>1(B,D,E,F)</sup>, Kamila Gworys<sup>1(D,E,F)</sup>, Katarzyna Dudek<sup>1(B)</sup>, Marta Chrzanowska<sup>1(B)</sup>, Adrian Woźny<sup>1(B)</sup>, Ireneusz Pieszyński<sup>2(C)</sup>, Przemysław Gworys<sup>3(C,E)</sup>, Zbigniew Maziarz<sup>4(A,D,E,F)</sup>, Mariusz Gadzicki<sup>4(B,C,D,E,F)</sup>, Wiesław Tryniszewski<sup>4(A,B,C,D,E,F)</sup>.

<sup>1</sup> Lodz Medical University Rehabilitation Clinic, Adult Rehabilitation Unit of the Provincial Orthopedy and Rehabilitation Centre in Lodz

<sup>2</sup> Physical Education and Sport College of Lodz Medical University

<sup>3</sup> Cardiology and Internal Diseases Unit of the Provincial Specialist Copernicus Hospital in Lodz

<sup>4</sup> Diagnostics and Radiological and Isotopic Therapy Institute of Lodz Medical University

## Abstract

**Background and objectives:** Ozone therapy is a frequently applied physiotherapy method. There are reports that ozone has a wide spectrum of possible effects.

The aim of the study was to examine a possible influence of the water baths with ozone on lower limbs muscles perfusion in patients with gonarthrosis.

**Materials and methods:** 30 patients (mean age 62,3±11,0 years) with gonarthrosis (II-III degree according to Seyfried's scale) were included in the study. The patients were assigned to three groups:

- Group A (10pts) – water massages with ozone + exercises (kinesitherapy) were applied in this group
- Group B (9pts) - water massages without ozone + exercises (kinesitherapy) were applied
- Group C (11pts) – kinesitherapy alone was applied.

All the patients realized the same kinesitherapy program. Radioisotopic examinations of the lower limbs muscles perfusion in rest were performed before and after the treatment.

**Results:** the study revealed a significant lower limbs muscles perfusion increase in the group A (water massages with ozone were applied in this group). A slight perfusion increase was also observed in other groups (B and C) but the differences were not statistically significant. No patient had any adverse reaction after the applied treatment.

**Conclusions:** The study revealed a significant lower limbs muscles perfusion increase after hydrotherapy with ozone procedures. The results confirm that ozone has a positive influence on microcirculation. Ozonotherapy can be recognized as a safe method as no adverse reactions during and after the treatment were observed in the study.

**Key words:** ozone therapy, water massages, perfusion, gonarthrosis

## Introduction

Ozone is an allotrope of oxygen. It is located in the stratosphere where it filters ultraviolet radiation. Ozone is also known as a disinfectant (e.g. in the water enrichment processes). Ozone is used in medicine extra- or intracorporeally as a oxygen-ozone mixture (injections, autohemotransfusion).

The effects of the lower limbs muscles perfusion decrease give various symptoms in patients and sportsmen (1-4). Circulation disturbances and vascular injury in sportsmen are caused by high physical activity. They are difficult to diagnose. Sportsmen are susceptible to many kinds of injuries which can be asymptomatic or poorly symptomatic. Discreet circulation disturbances often cause muscle efficiency decrease and worse sport competition results. Lower limbs muscle perfusion improvement is an essential condition to recover physical

efficiency. Various treatment forms and biological renovation procedures may improve muscle blood perfusion and accelerate its regeneration.

Gonarthrosis is one of the most common locomotor system diseases. It has a progressive course and leads to locomotor system impairment. The disease is accompanied by the pain which makes up not only medical but also social problem. To limit the disease progression, to stop the pain and to improve the knee joint physical condition are the main goals of the gonarthrosis' treatment.

The methods that improve physical efficiency and decrease lower limbs functional disturbances are applied in the treatment and biological renovation. Water massages and exercises have a positive trophic influence on the lower limbs. Ozone therapy could play a significant role as a non-invasive treatment in the

cases where routine methods are not effective. Ozone produced during whirlpool baths has the following characteristics: it is 15 times more soluble in water than oxygen, improves microcirculation and tissue oxygenation, increases erythrocyte metabolism, inhibits acute-phase proteins production and improves the delivery of medicines and nutrients to the tissues. Hydromassage with ozone causes capillaries to dilate what improves ozone diffusion into the blood and organs' oxygenation. Blood stickiness decreases, metabolic rate increases and tissue regeneration accelerates (5,6). The ozone therapy efficacy was confirmed in many diseases e.g. of locomotor system (soft tissue and bones' diseases of various origin) (7).

### Objective

The aim of the study was to examine a possible influence of hydromassages with ozone, hydromassages without ozone and kinesitherapy on lower limbs muscles perfusion in patients with gonarthrosis.

### Materials and methods

The study protocol was accepted by the Lodz University Bioethical Board (consent number RNN/243/07/KB).

30 patients (mean age  $62.3 \pm 11.0$  years) were included in the study. The patients were assigned to three groups:

- Group A (10pts, mean age  $67.9 \pm 9.7$  years) – water massages with ozone + exercises (kinesitherapy) were applied in this group
- Group B (9pts, mean age  $61.4 \pm 6.6$  years) - water massages without ozone + exercises (kinesitherapy) were applied
- Group C (11pts, mean age  $58.3 \pm 12.6$  years) – kinesitherapy alone was applied.

All the patients from the A, B and C groups realized the same kinesitherapy program during 10 days. The patients were randomly included in the groups just after gonarthrosis (II-III degree according to Seyfried's scale) was recognized. Whirlpool massages of both knee joints were performed simultaneously.

Water massages with ozone were performed by means of pearl bath device Balsan Futura delivered by K. H. Leader. It is a medical device of IIa class rule 9 according to MDD 93/42 EEC, safety class IIB according to EN 60601/1:1999, IP 44. It has the medical certificate CE 0494 number 103990N5 and is protected by the patent law (patent number 196060). The device produced ozone concentration  $64 \mu\text{g}/\text{m}^3$  (0.032 ppm) in ozone bath. It is consistent with EG European Union guidelines (92/72/EWG). According to these guidelines the maximal acceptable ozone concentration is  $120\text{-}200 \mu\text{g}/\text{m}^3$  (0.05-0.1 ppm) of the air.

The first procedure lasted 10 minutes and the other 9–20 minutes. The temperature of water was  $37^\circ\text{C}$ . The

hydromassages program was set on the program with alternately increasing and decreasing intensity.

Water massages without ozone were performed in the same way using the same procedure programs and the same pearl bath device (Balsan Futura) but the function of ozone production was switched off.

Every patient performed exercises after each water massage (with or without ozone).

Knee joints kinesitherapy consisted of the following exercises: active without load, active free, active with 1.5kg load, isometric of quadriceps and gluteus muscles and the exercises on stationary ergometer THERA VITAL. An intensity and resistance of the exercises were adjusted to individual patient's abilities. Every exercise lasted 20 minutes.

Radioisotopic examinations of the lower limbs muscles perfusion in rest were performed by means of gamma-camera ELSCINT SP6-HR. An original method and ALLP program were applied (8). Radiopharmaceutical Tc99mMIBI (activity  $11.11 \text{ MBq}/\text{kg}$  of body weight) was administered to a patient. The whole body scintigram was performed 5 minutes after radiopharmaceutical injection. Then static scintigrams of thighs and shins were performed. Acquisitions were made in posterior projection, on  $256 \times 256$  matrix, during 300 s. The examinations were performed twice – before and after the treatment.

The received data allowed to calculate the thighs and shins muscles perfusion index (PI) according to the following equation:

$$\text{PI} = \left(1 - \frac{A}{B}\right) \times 100$$

Where:

A – mean number of detections per one matrix pixel (density of detections) in the tested muscle

B – density of detections in the whole body

The reference range of PI values for thighs and shins are presented in table 1. They were received on the basis of many control healthy patients examinations performed in Diagnostics and Radiological and Isotopic Therapy Institute of Lodz Medical University (8) (table 1).

Table 1. *The reference range of PI (perfusion index) values for thighs and shins (PI has no units)*

	perfusion index in rest	
	shin	thigh
upper limit of reference values	8.02	7.08
lower limit of reference values	5.28	4.54

Statistical analysis of PI before and after the treatment was performed by means of the Wilcoxon signed-rank test. Significance level of  $\alpha = 0.05$  was assumed. Mean, median and standard deviation were also calculated for each group. Calculations were made by means of Statistica v. 8.0.

**Results**

Statistical analysis of the lower limbs perfusion indexes revealed a significant PI decrease in the group A (water massages with ozone) – see table 2. A significant PI decrease was observed in shins (from  $10.50 \pm 2.24$  to  $8.65 \pm 1.49$ ) (fig.1) and thighs (from  $8.34 \pm 0.81$  to  $7.46 \pm 0.69$ ) (fig.2). PI of thighs and shins were not significantly decreased in the groups B and C (table 2, fig. 1 and 2).

None of the patients suffered from any adverse reactions of applied treatment.

Shins and thighs perfusion indexes (PI) changes in relation to the reference range of PI values were analyzed in the group A (10pts, water massages with ozone + exercises), B (9pts, water massages without ozone + exercises) and C (11pts, exercises alone). The increased value of perfusion index indicates that lower limb muscle perfusion is decreased. The results are presented in the table 3.

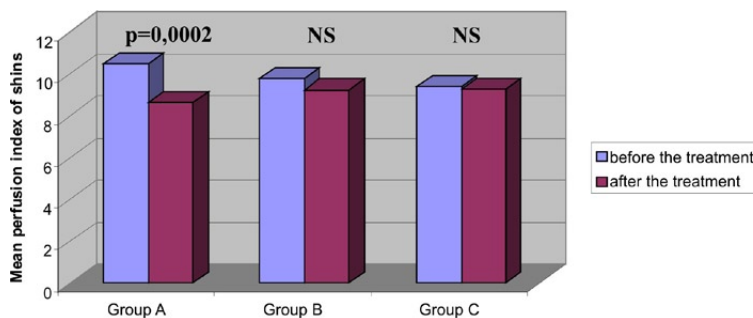


Fig. 1. Mean perfusion indexes of shins in the groups A, B and C before and after the treatment (NS – not significant)

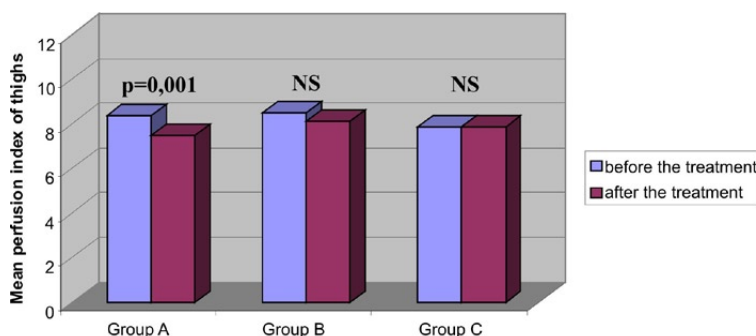


Fig. 2. Mean perfusion indexes of thighs in the groups A, B and C before and after the treatment (NS – not significant)

Table 2. Radioisotopic tests results – perfusion indexes (PI) of shins and thighs before and after the treatment (NS – not significant)

	PI of shins before the treatment	PI of shins after the treatment	P	PI of thighs before the treatment	PI of thighs after the treatment	P
Group A	10.50±2.24	8.65± 1.49	0.0002	8.34± 0.81	7.46±0.69	0.001
Group B	9.79± 1.20	9.24±1.58	NS	8.52±0.84	8.10±1.30	NS
Group C	9.39±2.03	9.26±1.94	NS	7.82±0.92	7.82±0.94	NS

Table 3. Shins and thighs perfusion indexes (PI) changes in relation to the reference range of PI values

	before the treatment		after the treatment	
	number of shins within the reference range of PI values	number of shins with increased values of PI	number of shins within the reference range of PI values	number of shins with increased values of PI
Group A (n=20)	3	17	9	11
Group B (n=18)	2	16	5	13
Group C (n=22)	8	14	9	13
	before the treatment		after the treatment	
	number of thighs within the reference range of PI values	number of thighs with increased values of PI	number of thighs within the reference range of PI values	number of thighs with increased values of PI
Group A (n=20)	1	19	5	15
Group B (n=18)	2	16	5	13
Group C (n=22)	3	19	5	17

## Discussion

Most of the former studies concerned the effects of the oxygen and ozone mixture applied intracorporeally (injections or ozone autohemotherapy) (9,10).

The use of ozone therapy, especially intracorporeally, arouses fears of possible toxic influence on the tissues. But Tylicki's et al. (11) researches do not confirm that. The aim of their studies was to investigate the influence of ozone autohemotherapy on the oxidative stress. The therapy caused neither an increase of protein and lipid peroxidation nor erythrocytes damage. The significant decrease in glutathione level probably reflects anti-oxidative processes stimulated by ozone.

Bocci (12,13) also emphasizes in his studies that properly and adequately applied ozone can be clinically very useful. A brief oxidative stress (especially during intracorporeal ozone therapy) proved to be safe. Ozone improves the diffusion of oxygen to the blood and oxygen uptake in the cells.

Ozone is useful in ischemic or infectious diseases and difficult wounds healing where traditional methods have failed (14).

Ozone may influence on the rheology properties of the blood and improve microcirculation. Ozone therapy leads to hypocoagulatory changes by platelet aggregation inhibition, lowering of fibrinogen concentration, prolongation of activated partial thromboplastin time and enhancing fibrinolytic activity (15).

Some studies suggest that intracorporeal ozone therapy has a positive influence on microcirculation (16). Romero Valdés et al. (17) applied ozone in patients with arteriosclerosis obliterans (stage II). The ozone was administered by three different ways: intravenously, intramuscularly and per rectum in the three different groups of patients. The patients in the fourth (control) group were treated conventionally. There were a significant improvement expressed as an increase of the claudication distance in the treadmill in all three ozone-groups.

Valacchi et al. (18) tried to explain a phenomenon of vasodilatation after ozone autohemotherapy in patients with chronic limb ischemia. They noticed that ozone therapy increases the release of nitric oxide (NO) that is recognized as the most important vasodilator in the human body. It may explain the mechanism of vasodilatation and reduction of hypoxia after ozone therapy.

Clavo et al. (19) observed similar vasodilating effect in cerebral arteries. Seven patients were treated by transfusing ozone-enriched autologous blood. Three autohemotransfusion procedures caused about 75% increase of the common carotid artery blood flow, about 22% increase of the systolic velocity and about 33% increase of the diastolic velocity in the middle cerebral artery.

In the studies on animals Schelegle et al. (20) noticed the bronchial vasculature vasodilatation after exposition to ozone-enriched air. There was a significant bronchial artery flow increase without affecting mean aortic pressure, pulmonary artery pressure, cardiac output, arterial blood gases and core temperature.

The perfusion of lower limb muscles improvement after ozone hydrotherapy noticed in the current study proves that extracorporeal ozone therapy has the influence on the blood vessels properties and microcirculation.

The similar observations were made by Kulikov et al. (21). The patients with diabetes mellitus type 2 were treated with ozone-oxygen therapy in external („ozone boot” method) and/or systemic (intravenous or rectal) administration. The external and combined methods (external and systemic at the same time) proved to be effective in trophic disorders in the region of distal parts of the lower limbs.

Hydrotherapy found the application in athletes' biological renovation (22). The use of ozone hydrotherapy in sport medicine should be taken into consideration. The muscle perfusion improvement after ozone therapy in patients with gonarthrosis was confirmed in the study. It can be assumed that this positive effect could be also visible in patients with other locomotor system diseases and in sportsmen. The microcirculation improvement may be important during regeneration and treatment of injured athletes. Further investigations in larger groups of patients with many other locomotor system dysfunctions and in sportsmen representing various sport disciplines should be performed.

Contemporary nuclear medicine applies radiopharmaceuticals, methods and programs enabling to estimate even small changes in lower limb muscle perfusion indexes evaluating by perfusion scintigraphy (23,24). The introduction of Tc<sup>99m</sup> MIBI complex enabled researchers to study perfusion of the muscles (25-28).

On the basis of Maziarz et al. (8,29,30) investigations, the reference value of the lower limb muscle perfusion index was established – separately to the shin and to the thigh. The higher values of perfusion index indicate the worse perfusion and muscle ischemia. Long-lasting experiences allowed to include radioisotope methods in evaluation of muscle perfusion in different pathologies. It convinced the authors to use this method in evaluation the effects of ozone hydrotherapy associated with kinesitherapy on the lower limb perfusion.

We observed perfusion index improvement in 15 shins (75% of tested shins) and 16 thighs (80% of tested thighs) after ozone hydrotherapy (group A). Ozone hydrotherapy improved muscle perfusion in 76%

tested shins and thighs (counted altogether). There were patients in which perfusion index returned to the reference range as well as the patients in which index improved but did not achieve the reference range. The differences of perfusion indexes measured before and after the treatment were statistically significant in this group.

The improvement was lower and not significant after hydrotherapy without ozone (group B). We observed perfusion index improvement in 9 shins (50% of tested shins) and 6 thighs (33% of tested thighs). Hydrotherapy without ozone improved muscle perfusion in 41% tested shins and thighs (counted altogether). There were patients in which perfusion index returned to the reference range as well as the patients in which index improved but did not achieve the reference range. The differences of perfusion indexes measured before and after the treatment were not statistically significant in this group.

The improvement was also not significant after kinesitherapy alone (group C). We observed perfusion index improvement in 6 shins (27% of tested shins) and 4 thighs (18% of tested thighs). Kinesitherapy without hydrotherapy improved muscle perfusion in 22% tested shins and thighs (counted altogether). The differences of perfusion indexes measured before and after the treatment were not statistically significant in this group.

The perfusion scintigraphy is very valuable test that estimates lower limb muscle blood flow intensity. Due to its high sensitivity it precisely evaluates muscle perfusion and microcirculation changes. It is not possible to achieve such precise estimation when standard methods are used.

The results of our study revealed that the most significant perfusion improvement occurred in patients with combined therapy treatment – ozone hydrotherapy and exercises. We did not observe any significant improvement in patients who were applied hydrotherapy without ozone + kinesitherapy and kinesitherapy alone.

There is a possibility that ozone could play more important role in rehabilitation. The studies on its influence on the tissues should be continued – after extracorporeal application too.

## Conclusions

1. the study confirmed the positive influence of ozone on lower limbs muscle microcirculation
2. when three methods are compared (hydrotherapy with ozone, hydrotherapy without ozone and kinesitherapy) the first one gives the most significant lower limbs muscle perfusion improvement in patients with gonarthrosis
3. no patient had any adverse reaction after the applied treatment – ozone therapy can be recognized as a safe method of treatment.

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Proffesor Jolanta Kujawa

Lodz Medical University Rehabilitation Clinic, Adult Rehabilitation Unit of the Provincial Orthopedy and Rehabilitation Centre in Lodz

75 Drewnowska St., 91-002 Lodz

tel./fax: +(48) 42 6540119

e-mail: jolantakujawa@gmail.com