

«26» November 2020 No. 60

REPORT

on results of performed clinical test of innovational devices “Medical tubular bandages containing camelid hair LEONARDA” in athletes

Moscow

«26» November 2020

1. List of persons who participated in the assessment of clinical test results:

- Parastayev S.A., Professor, MD, Professor of the Chair of Rehabilitation and Physical Culture of Federal State Autonomous Educational Institution of Higher Education Pirogov Russian National Research Medical University of the Ministry of Health of the Russian Federation (FGAOU VO Pirogov RNIMU of the Ministry of Health of the Russian Federation)
- Anisimov E.A., sport medicine doctor of Federal State Budgetary Institution Sport Medicine and Rehabilitation Center of Federal Medical-Biological Agency of Russia (FGBU TsSM FMBA of Russia)
- Karmazin V.V., sport medicine doctor of Federal State Budgetary Institution Sport Medicine and Rehabilitation Center of Federal Medical-Biological Agency of Russia (FGBU TsSM FMBA of Russia)

2. General:

2.1. Information on clinical test of medical devices in athletes:

Medical tubular semi-wool bandages containing camelid hair, LEONARDA trademark, manufactured by LLC LEONARDA-SERVIS, Moscow.

Clinical test object description:

Medical tubular semi-wool bandages LEONARDA according to TU 9396-005-75606424-2010, Roszdravnadzor Registration Certificate No. FSR 2010/08307, containing camel hair (belts, knee bandages, elbow bandages and sural bandages), Patent No. 2319800, Patent No. 2657996, manufactured by LLC LEONARDA-SERVIS, are the sewed non-detachable contour devices, including those of cone form.

Medical tubular semi-wool bandages LEONARDA are designed to produce warming, heating and massage effect on skin and muscular tissues, which provides the increase of muscular power at the stages of circannian cycle of athletes' training.

Description of components of the innovational solution “Medical tubular semi-wool bandages LEONARDA”:

Elastic warp-knit fabric (Patent No. 2319800, 2657996) with set performance and curative properties, of which the medical bandages LEONARDA are sewed.

2.2. *Clinical test center:*

– The clinical test was performed on the site of clinical centers of the Chair of Rehabilitation, Sport Medicine and Physical Culture of Federal State Autonomous Educational Institution of Higher Education Pirogov Russian National Research Medical University of the Ministry of Health of the Russian Federation (FGAOU VO Pirogov RNIMU of the Ministry of Health of the Russian Federation).

2.3. *Clinical test period:* 15 January 2020 – 15 July 2020.

3. **Clinical test objective:**

- Assessment of thermostabilizing effects and muscular power during the use of innovational medical bandages LEONARDA at the stages of circannian cycle of athletes' training;
- Analysis of the prospects of the use of innovational medical bandages LEONARDA in Russian sport.

4. **Clinical test results:**

4.1. *Report on conformity with the stated purpose of medical bandages LEONARDA manufactured by LLC LEONARDA-SERVIS.*

To assess the efficacy of the use of medical bandages LEONARDA manufactured by LLC LEONARDA-SERVIS (Knee bandage containing camelid hair (Medical tubular semi-wool bandage (according to TU 9396-005-75606424-2010, RU No. FSR 2010/08307) at the stages of circannian cycle, a study of intensity and duration of the changes of the local temperature of the knee joint region (according to remote thermometry data) was performed with the medical knee bandage LEONARDA worn (region A) and the similar region of the contralateral knee joint (region B).

Besides, the isometric and isokinetic study of the muscles providing knee joints motion was performed to determine the muscular torque of hip flexor and hip extensor using Isomove Tecnobody software (Italy) (hardware-software complex Isomove) in the subjects.

10 athletes – representatives of various sports – participated in the study:

1. Basketball – 2 persons
2. Football – 2 persons
3. Volleyball – 3 persons
4. Track-and-field athletics – 3 persons

A medical knee bandage LEONARDA manufactured by LLC LEONARDA-SERVIS was put on a less used and strong leg (according to the athlete's opinion).

The test method was the symmetrical registration of the readings of thermal imager NEC and the data of isometric and isokinetic studies using hardware-software complex Isomove:

- A) before the use of knee bandage LEONARDA
- B) after intensive squats and running in place for 3 minutes
- C) after 30 minutes of wearing the knee bandage LEONARDA
- D) 20 minutes after removal of knee bandage LEONARDA.

The results are presented in the Tables No. 1, No. 2, No. 3.

Table No.1 Thermography results

Study stages.	Temperature of the leg in the knee bandage LEONARDA (degrees Celsius)	Temperature of the contra-lateral leg (degrees Celsius)	P
before the use of knee bandage LEONARDA	34.1±0.1 $\sigma=0.23$	34.3±0.2 $\sigma=0.28$	0.05
after intensive exercises	36.5±0.2 $\sigma=0.31$	36.2±0.1 $\sigma=0.23$	0.04
after 30 minutes of wearing the knee bandage LEONARDA	38.4±0.4 $\sigma=0.17$	35.1±0.4 $\sigma=0.21$	0.04
20 minutes after removal of knee bandage LEONARDA	38.2±0.2 $\sigma=0.11$	34.2±0.3 $\sigma=0.25$	0.03

P- statistical significance of variations in the group

σ - mean square deviation

Figure 1. Temperature readings dynamics

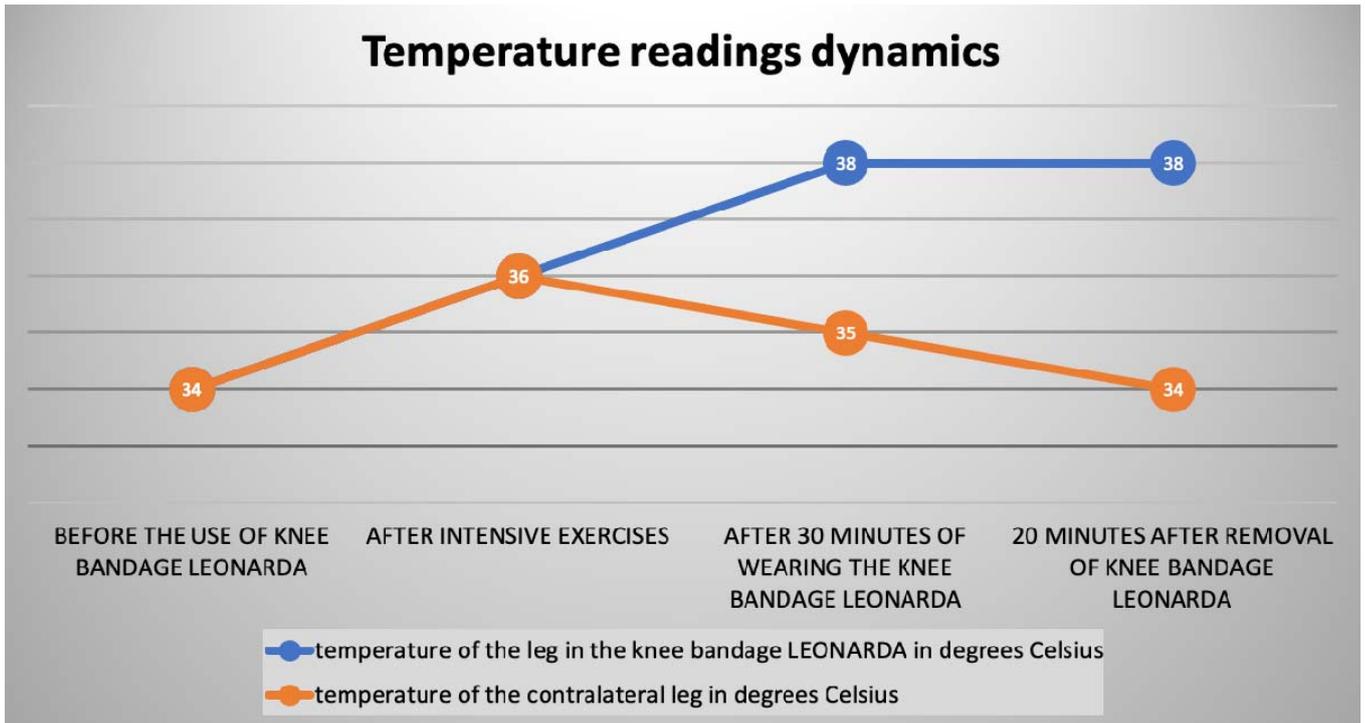


Figure 2. Comparative results of the knee joint local temperature

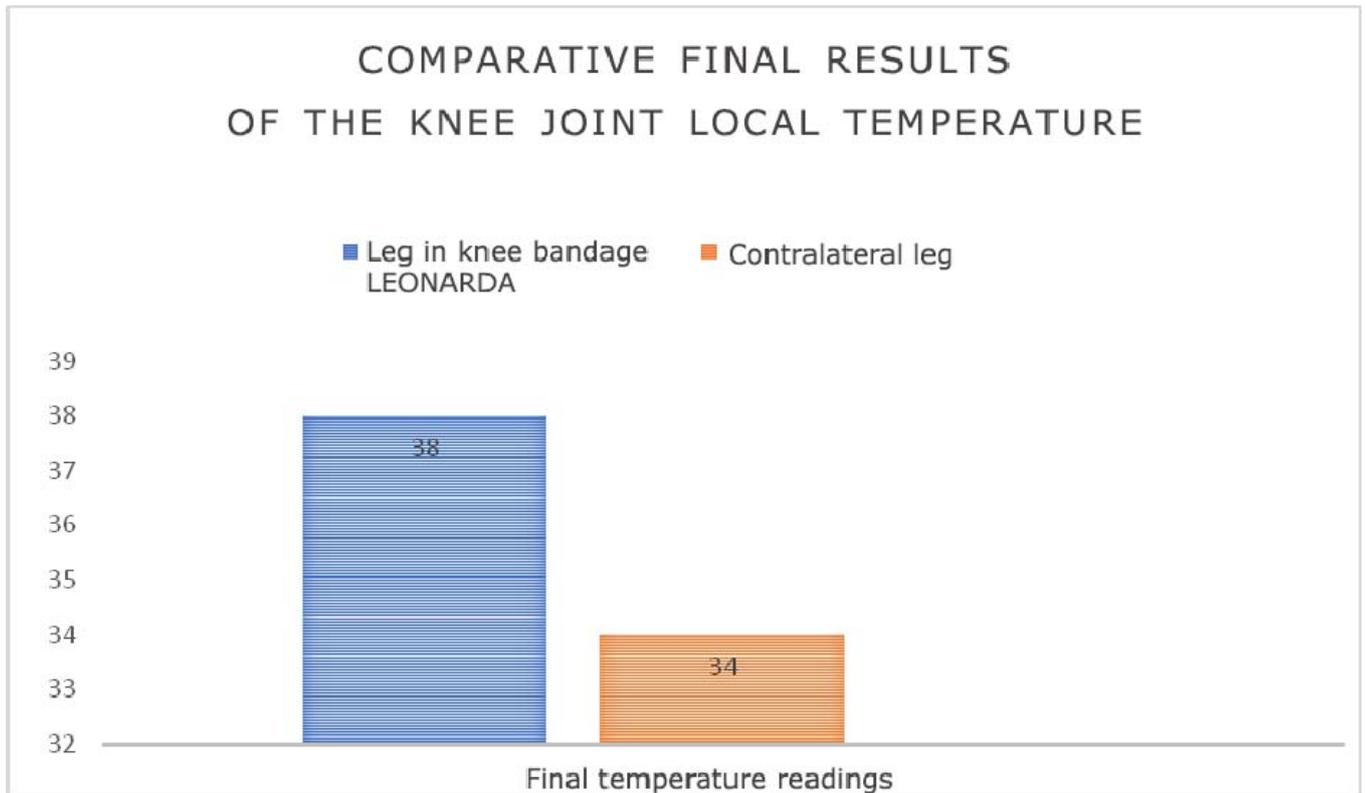


Table No.2 Results of isokinetic and isometric knee joint examinations (hip flexors)

Study stages.	Isokinetic study. Torque (Nm)		Isometric study (10 degrees flexion). Torque (Nm)		P
	Leg in knee bandage LEONARDA	Contralateral leg	Leg in knee bandage LEONARDA	Contralateral leg	
before the use of knee bandage LEONARDA	74.2±2.1 $\sigma=0.16$	78±1.9 $\sigma=0.18$	85±2.2 $\sigma=0.12$	88.4±2.3 $\sigma=0.08$	0.05
after intensive exercises	82.4±1.3 $\sigma=0.21$	85±2.8 $\sigma=0.18$	96±1.3 $\sigma=0.24$	100.3±1.5 $\sigma=0.13$	0.04
after 30 minutes of wearing the knee bandage LEONARDA	110.7±2.4 $\sigma=0.06$	84.6±2.3 $\sigma=0.09$	122.3±2.3 $\sigma=0.15$	101.4±2.6 $\sigma=0.27$	0.05
20 minutes after removal of knee bandage LEONARDA	112.2±1.3 $\sigma=0.26$	81.4±1.7 $\sigma=0.22$	125.1±2.2 $\sigma=0.14$	92.4±1.8 $\sigma=0.18$	0.04

P- statistical significance of variations in the group

σ - mean square deviation

Figure 3. Hip flexor torque (Nm) in isokinetic mode

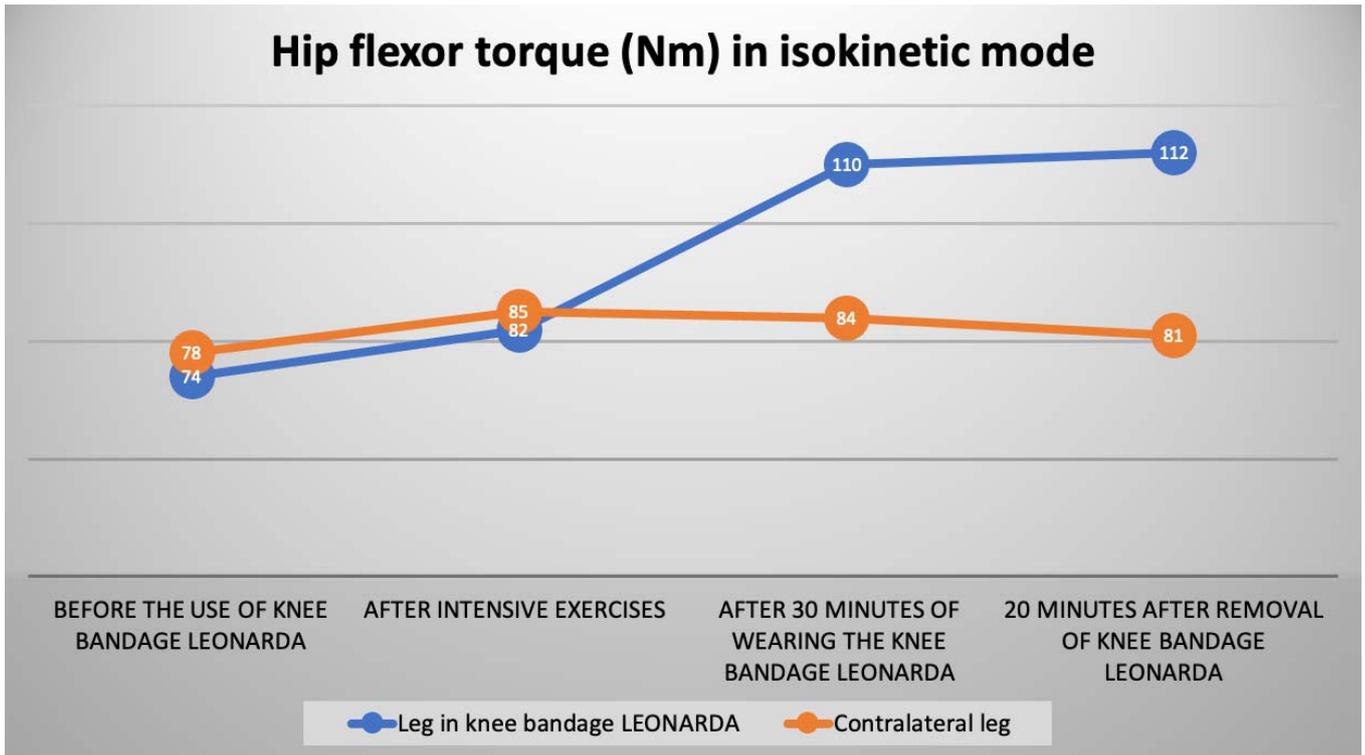


Figure 4. Hip flexor torque (Nm) in isometric mode

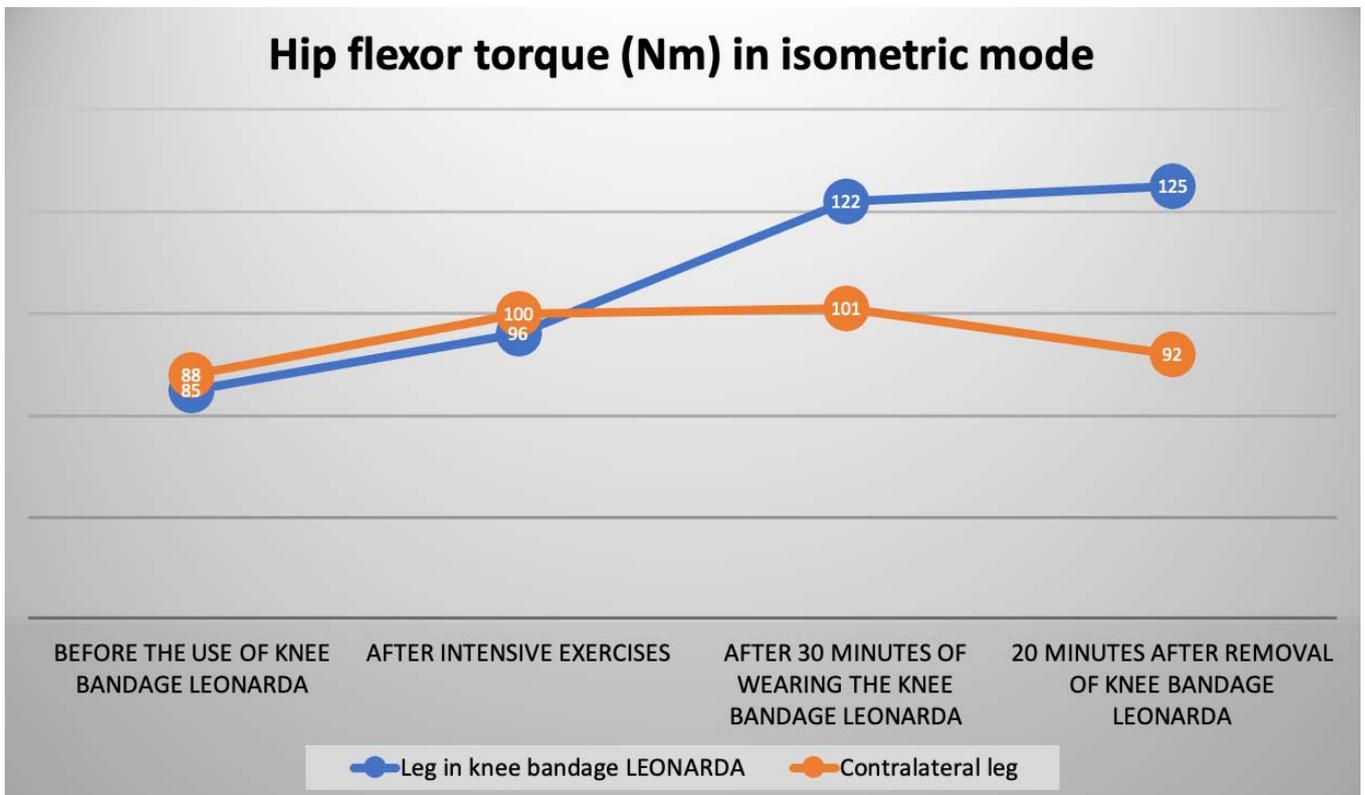


Table No.3 Results of isokinetic and isometric knee joint examinations (hip extensors)

Study stages	Isokinetic study. Torque (Nm)		Isometric study (10 degrees flexion). Torque (Nm)		P
	Leg in knee bandage LEONARDA	Contralateral leg	Leg in knee bandage LEONARDA	Contralateral leg	
before the use of knee bandage LEONARD A	125.3±2.2 $\sigma=0.24$	131.2±2.1 $\sigma=0.21$	140.8±1.4 $\sigma=0.16$	156.2±1.4 $\sigma=0.06$	0.04
after intensive exercises	148.1±1.4 $\sigma=0.25$	157.6±1.1 $\sigma=0.08$	164.5±1.3 $\sigma=0.15$	172.8±0.8 $\sigma=0.28$	0.03
after 30 minutes of wearing the knee bandage LEONARD A	178.8±2.3 $\sigma=0.11$	150.1±1.4 $\sigma=0.17$	195.3±2.1 $\sigma=0.29$	163.6±1.8 $\sigma=0.07$	0.04
20 minutes after removal of knee bandage LEONARD A	191.2±1.2 $\sigma=0.11$	143.4±1.3 $\sigma=0.22$	207.3±1.7 $\sigma=0.15$	158.8±1.4 $\sigma=0.14$	0.04

P- statistical significance of variations in the group

σ - mean square deviation

Figure 5. Hip extensors torque (Nm) in isokinetic mode

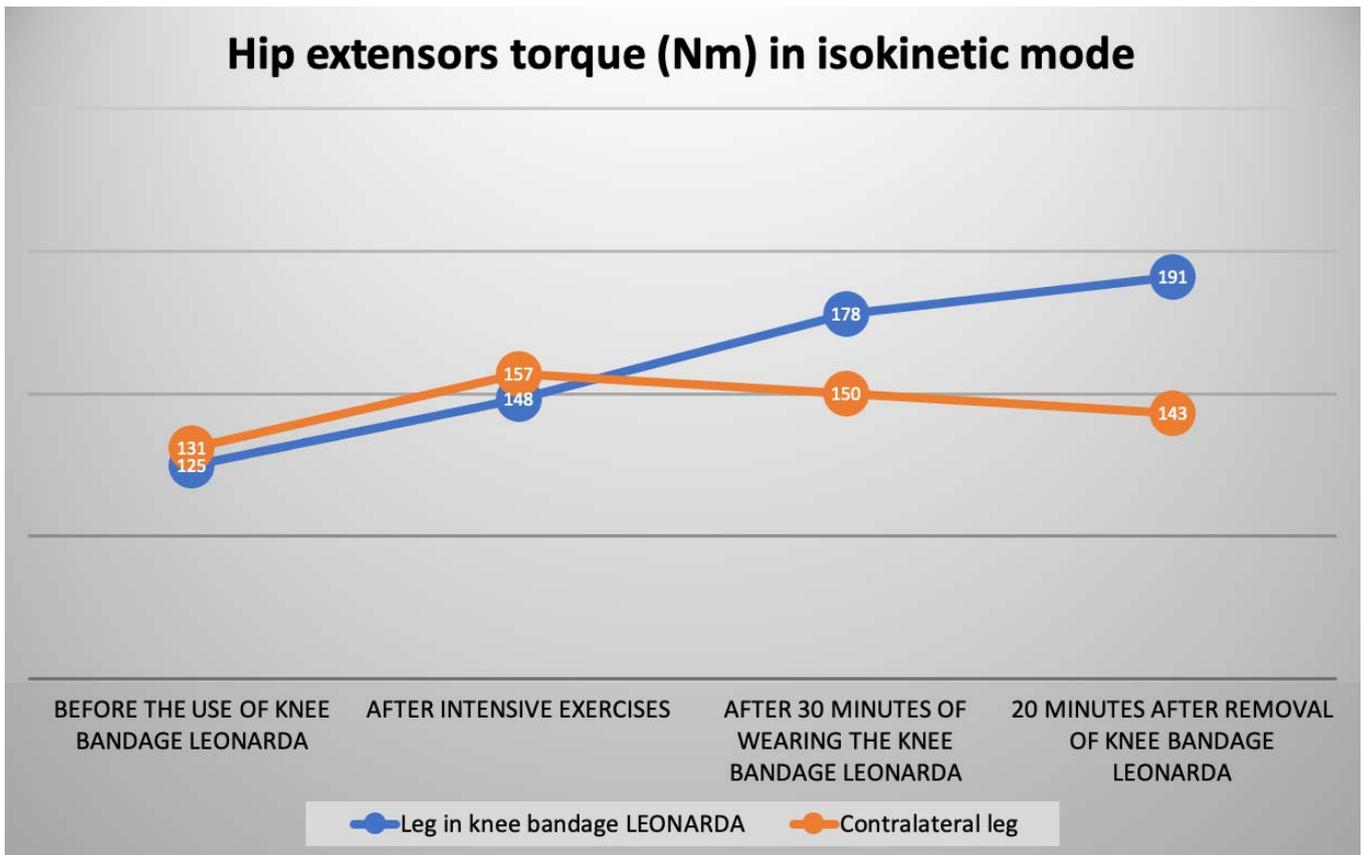


Figure 6. Hip extensors torque (Nm) in isometric mode

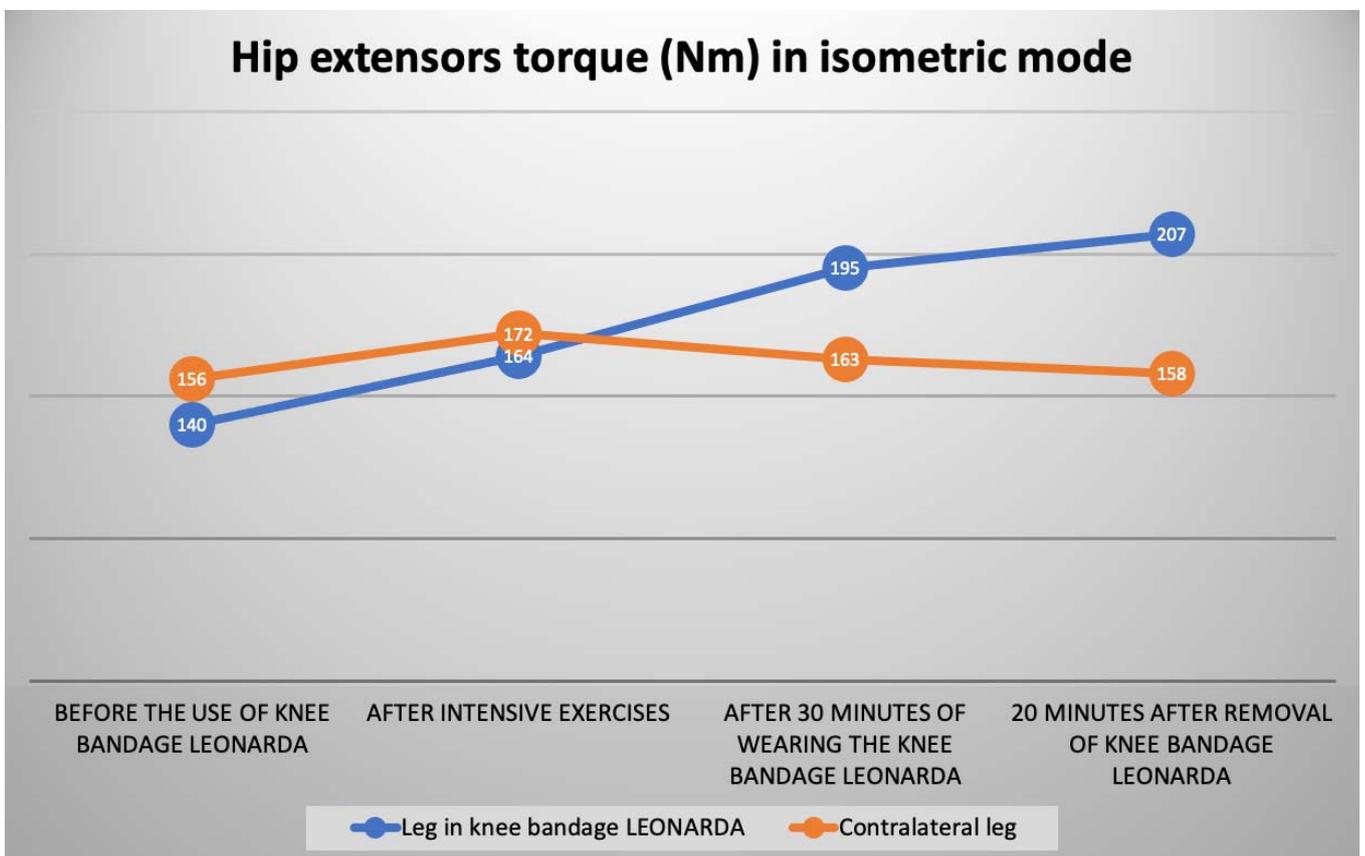
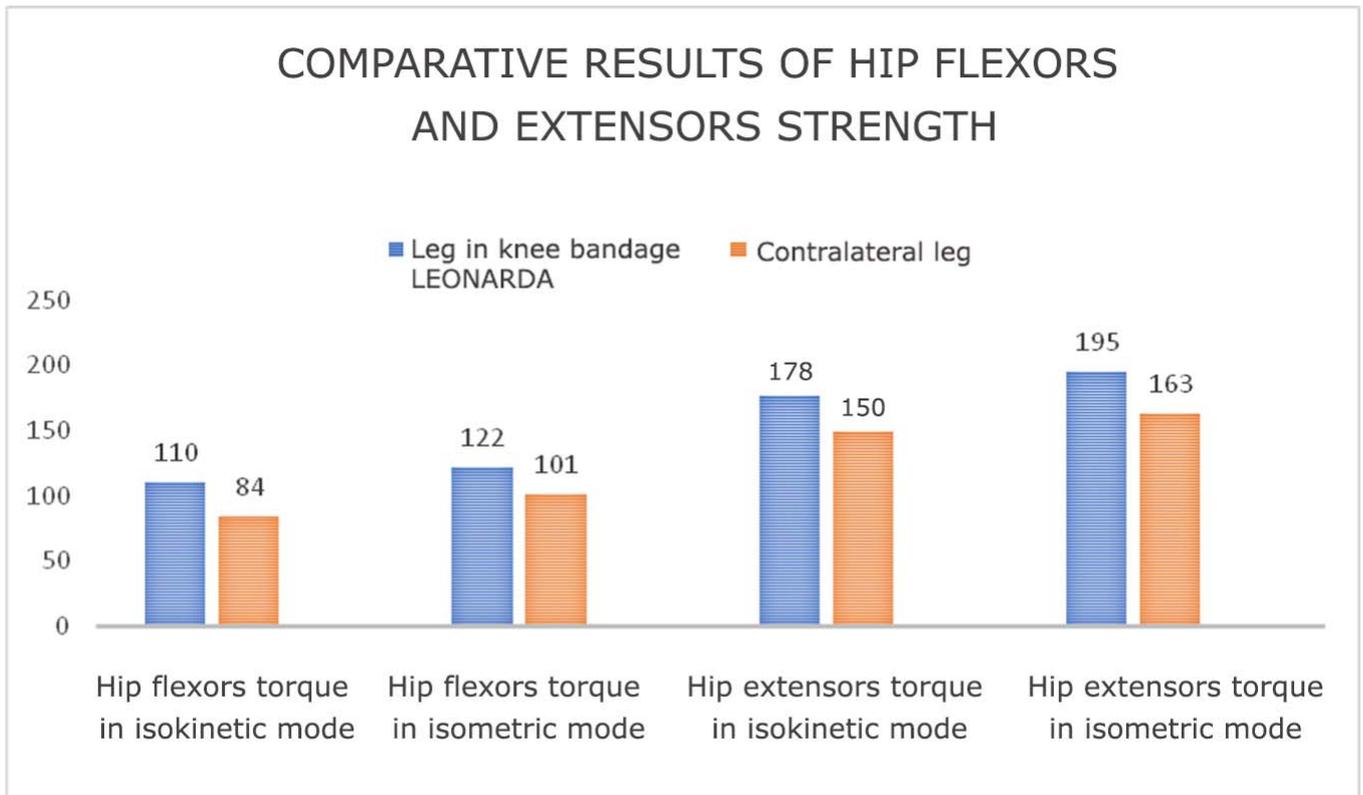


Figure 7. Comparative results of hip flexors and extensors strength



Taking into account the active load during the intensive exercises, both symmetrical rise of the local temperature and the muscular power increase were found based on all tests results using hardware-software complex Isomove. However, after 30 minutes of wearing the medical knee-bandage LEONARDA, a stable difference in temperature and considerable reliable increase of the muscular power was observed in this leg in comparison with the contralateral one:

1) A homogeneous temperature rise of 3 degrees Celsius was observed at side A compared to the region B.

2) A considerable increase of muscular power of this leg compared to the contralateral one – no less than 10 %.

20 minutes after removal of knee bandage LEONARDA from A region the following was observed:

3) Maintaining the temperature readings at side A and the increase of the temperature difference compared to the region B up to 4 degrees Celsius.

4) Further reliable increase of the leg muscular power (region A) compared to the contralateral one (region B). The difference between the muscular power of the region A and region B increased by no less than 20 %, because by that moment the power of the contralateral leg (region B) approximated the initial one.

This phenomenon was revealed based on the results of all tests using Prokin hardware-software complex for hip flexors and extensors.

4.2. The prospects of further use of the medical devices LEONARDA in Russian sport.

We recommend using innovational solution “Medical tubular semi-wool bandages LEONARDA” in Russian sport at the stages of circannian cycle of athletes’ training for rising and further prolongation of warming effect of limbering up and the increase of muscular power.

Comments and offers:

No comments. The item parameters stated by the manufacturer have been completely confirmed.

5. Conclusion:

From the clinical test results, it is possible to conclude about the real efficacy of the use of innovational bandages LEONARDA manufactured by LLC LEONARDA-SERVIS, during preparatory and contest period in athletes to increase the intensity and duration of warming-up effect not only during the limbering up, but at any stage of training, because hyperthermia at the side of wearing the medical knee-bandage did not decrease but even increased 20 minutes after removal of the medical knee-bandage LEONARDA. Besides, the increase of the muscular power by no less than 20% was observed after the medical knee bandage removal which confirms the thermostabilizing effect of the medical knee bandages LEONARDA and gives strong evidence for stimulation of trophic and exchange processes in the muscular tissue under the effect of wearing medical bandages with camelid hair LEONARDA.

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