**Original article / Оригинальная статья**
https://doi.org/10.47093/2218-7332.2025.16.4.20-30

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# Validation of a test setup for measuring compression load under elements of multilayer bandages: an *in vitro* study

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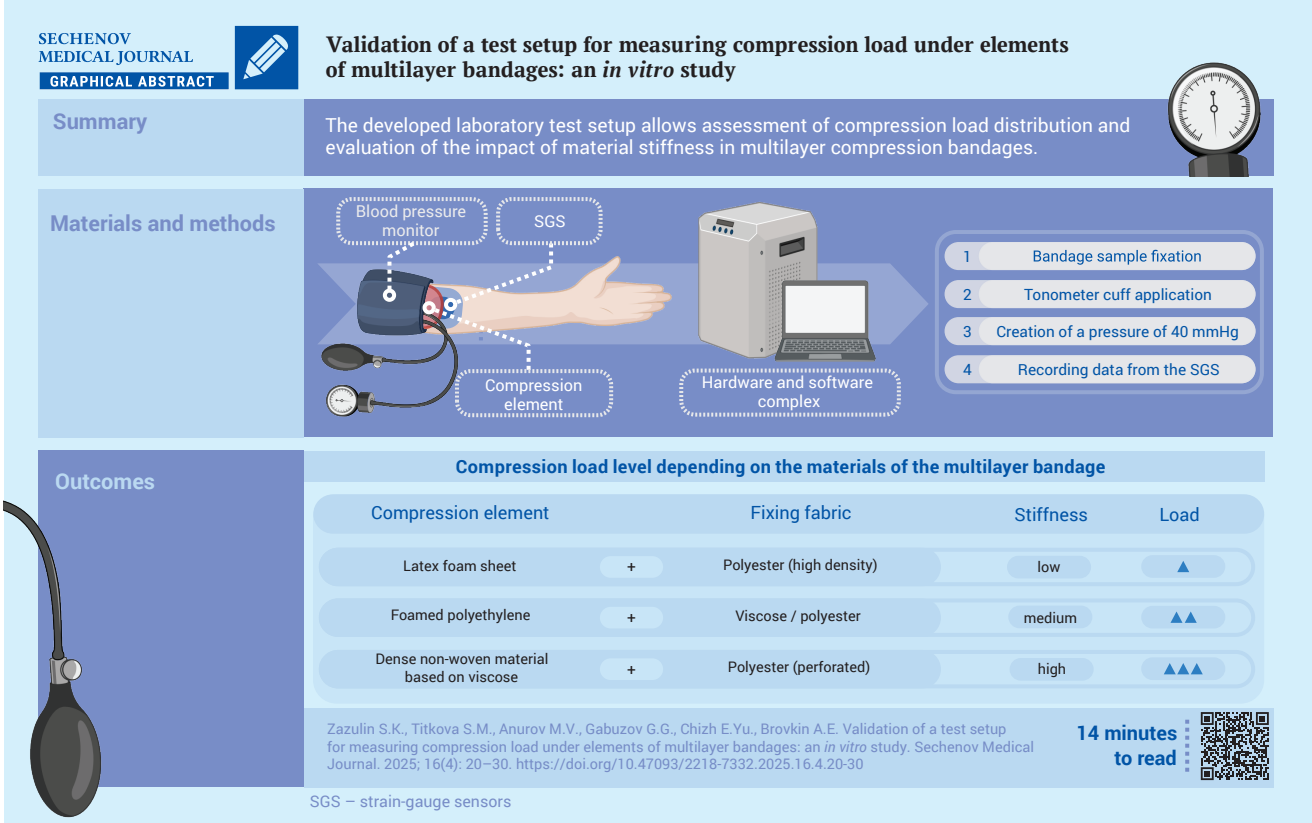


## Abstract

**Aim.** To develop and validate a test setup for measuring the load under compression elements (CE) of multilayer bandages composed of materials with different stiffness.

**Materials and methods.** Prototypes of multilayer bandages were fabricated in the laboratory by combining three types of CEs (foam polymer and dense nonwoven viscose material) with three types of fixing fabrics (FF) based on polyester and viscose/polyester. The test setup consisted of an upper-limb model made of rigid plastic covered with artificial skin and a block with two strain-gauge sensors that recorded the load in gram-force (gf) under the CE area and in a control zone without a CE at an external pressure of 40 mmHg. For each CE–FF combination, 10 repeated

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measurements were performed in two regions of the sample (60 values per sensor per group), and the data were analysed using nonparametric statistical tests.
**Results.** The load under the CE differed significantly between groups ($p < 0.001$) and depended on the type and stiffness of the material: the median load under type 3 CE with the highest stiffness was 259.4 (252.6; 263.3) gf, whereas under type 1 CE with the lowest stiffness it was 149.9 (145.1; 171.9) gf. Type 2 CE produced intermediate values of 241.7 (206.4; 259.3) gf. Testing of the FFs also showed statistically significant differences in pressure in the absence of a CE ($p < 0.001$): the highest load was recorded under type 2 FF (viscose/polyester) at 141.0 (140.2; 142.1) gf, and the lowest under type 1 FF made of polyester with higher surface density at 14.5 (14.3; 15.6) gf; type 3 FF provided an intermediate level of 65.7 (64.9; 69.3) gf.
**Conclusion.** The developed *in vitro* setup shows high sensitivity to differences in CE stiffness and FF properties and can be used as a screening tool for quantitative comparative assessment of multilayer bandage prototypes with locally differentiated compression areas prior to *in vivo* studies.

**Keywords:** peripheral edema; lymphedema; compression therapy; complex decongestant therapy, short-stretch bandage; differentiated compression
**MeSH terms:**
EDEMA – THERAPY
COMPRESSION BANDAGES
LYMPHEDEMA – THERAPY
**For citation:** Zazulin S.K., Titkova S.M., Anurov M.V., Gabuzov G.G., Chizh E.Yu., Brovkin A.E. Validation of a test setup for measuring compression load under elements of multilayer bandages: an *in vitro* study. Sechenov Medical Journal. 2025; 16(4): 20–30. https://doi.org/10.47093/2218-7332.2025.16.4.20-30

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**Ethics statements.** The study involved the development and in vitro testing of the experimental setup and did not include any experiments involving human participants or animals; therefore, approval by an ethics committee was not required.
**Data availability.** The data confirming the findings of this study are available from the authors upon reasonable request. Data and statistical methods used in the article were examined by a professional biostatistician on the Sechenov Medical Journal editorial staff.
**Conflict of interest.** The authors declare that there is no conflict of interest.
**Financing.** This study was supported by grant No. 89526 from the Foundation for Assistance to Small Innovative Enterprises (FASIE) dated December 11, 2023[1].

**Received:** 13.09.2025
**Accepted:** 25.11.2025
**Date of publication:** 30.12.2025

[1] https://online.fasie.ru/m/user-projects/registry (access date: 25.09.2025).

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УДК 616-005.98-085.468.2

# Валидация испытательного стенда для измерения компрессионной нагрузки под элементами многослойных повязок: исследование *in vitro*

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**Аннотация**

**Цель.** Разработать и валидировать испытательный стенд для измерения нагрузки под компрессионными элементами (КЭ) многослойных повязок, состоящих из различных по жесткости типов материала.

**Материалы и методы.** Лабораторно изготовлены прототипы многослойных повязок путем сочетания трех типов КЭ (из пенополимера и плотного нетканого материала из вискозы) и трех типов фиксирующих полотен (ФП) на основе полиэфира и вискозы/полиэфира. Испытательный стенд представлял собой макет верхней конечности из твердого пластика с искусственной кожей и блоком из двух тензорезистивных датчиков, регистрирующих нагрузку в граммах силы (гс) под участком с КЭ и контрольной зоной без КЭ при внешнем давлении 40 мм рт. ст. Для каждой комбинации КЭ–ФП выполняли по 10 повторных измерений в двух зонах образца (60 значений с датчика в группе); анализ проводили с использованием непараметрических критериев.

**Результаты.** Нагрузка под КЭ статистически значимо различалась между группами ($p < 0{,}001$) и зависела от типа и жесткости материала: медиана нагрузки под КЭ 3-го типа с максимальной жесткостью составила 259,4 (252,6; 263,3) гс, тогда как под КЭ 1-го типа с минимальной жесткостью – 149,9 (145,1; 171,9) гс. КЭ 2-го типа формировал промежуточные значения – 241,7 (206,4; 259,3) гс. Испытания ФП показали статистически значимые различия давления в отсутствие КЭ ($p < 0{,}001$): максимальная нагрузка зарегистрирована под ФП 2-го типа (вискоза/полиэфир) – 141,0 (140,2; 142,1) гс, минимальная – под ФП 1-го типа из полиэфира с большей поверхностной плотностью – 14,5 (14,3; 15,6) гс; ФП 3-го типа обеспечивало промежуточный уровень – 65,7 (64,9; 69,3) гс.

**Заключение.** Разработанный *in vitro* стенд демонстрирует высокую чувствительность к различиям жесткости КЭ и свойств ФП и может использоваться как скрининговый инструмент для количественной сравнительной оценки прототипов многослойных повязок с участками дифференцированной компрессии до проведения исследований *in vivo*.

**Ключевые слова:** периферические отеки; лимфедема; компрессионная терапия; комплексная деконгестивная терапия, бинт короткой растяжимости; дифференцированная компрессия

**Рубрики MeSH:**
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КОМПРЕССИОННЫЕ ПОВЯЗКИ
ЛИМФЕДЕМА – ТЕРАПИЯ

**Для цитирования:** Зазулин С.К., Титкова С.М., Ануров М.В., Габузов Г.Г., Чиж Е.Ю., Бровкин А.Е. Валидация испытательного стенда для измерения компрессионной нагрузки под элементами многослойных повязок: исследование *in vitro*. Сеченовский вестник. 2025; 16(4): 20–30. https://doi.org/10.47093/2218-7332.2025.16.4.20-30

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**Соответствие принципам этики.** Исследование было посвящено разработке и *in vitro* испытаниям экспериментального стенда и не включало эксперименты с участием людей или животных, поэтому одобрение этического комитета не требовалось.
**Доступ к данным исследования.** Данные, подтверждающие выводы этого исследования, можно получить у авторов по обоснованному запросу. Данные и статистические методы, представленные в статье, прошли статистическое рецензирование редактором журнала – сертифицированным специалистом по биостатистике.
**Конфликт интересов.** Авторы заявляют об отсутствии конфликта интересов.
**Финансирование.** Исследование выполнено за счет гранта Фонда содействия инновациям № 89526 от 11.12.2023[2].

**Поступила:** 13.09.2025
**Принята:** 25.11.2025
**Дата печати:** 30.12.2025

## Abbreviations:

CE – compression element
DC – differentiated compression
FF – fixing fabric
gf – gram-force
HSC – hardware and software complex
SGS – strain-gauge sensor

## HIGHLIGHTS

Placement of two strain-gauge force sensors on the test bench enables simultaneous measurement of the applied load under standardized external pressure beneath distinct components of a multilayer bandage, including a compression element and a fixation nonwoven fabric.

The load distribution across bandage components is significantly influenced by both the stiffness of the compression elements and the type of the fixation nonwoven fabric. These factors should be taken into account in prototype design and material selection.

The proposed model represents a reproducible screening tool for the comparative assessment and optimization of multilayer bandage prototypes with differential compression zones during in vitro development.

Peripheral edema is a general clinical term used to describe chronic edema persisting for more than three months and characterized by complex, multivariate pathogenesis [1]. The prevalence of this condition reaches 20% among the working-age population, resulting in significant medical, social, and economic burden [2], including a significant reduction in patients' quality of life [3]. In clinical practice, peripheral edema often develops as a complication of anticancer treatment [4] and may be accompanied by the development of panniculitis [5] and progressive tissue fibrosis [6].

One of the leading clinically significant forms of peripheral edema is lymphedema, characterized by the accumulation of protein-rich interstitial fluid in the skin and subcutaneous tissue due to primary or secondary lymphatic drainage impairment [7]. According to literature data, over the past 10–15 years, the prevalence of lymphedema worldwide has been estimated at 140–250 million people [8–10]. In the Russian Federation, official statistics on lymphedema are not maintained. However, according to estimates by the Russian Association of Lymphologists, based on data from the World Health Organization, the number of patients with lymphedema in the country may could be as high as 10 million [11]. Over the past decade, there has been an increase in the incidence of lymphedema which is associated with an ageing population and the increase in the number of patients with cancer [4].

Due to its chronic nature, lymphedema requires long-term, step-by-step treatment based on the anatomical and functional characteristics of the lymphatic system [12]. Modern approaches to lymphedema therapy are based on the principles of Complex Decongestive Therapy, developed by M. Földi [13], which includes compression bandaging as a key component. Compression therapy determines the effectiveness of reducing the volume of limb edema [14].

To improve patient self-care and prevent recurrence of edema, multilayer compression bandaging techniques are widely used. In recent years, new materials and design solutions have been developed for the formation of

[2] Фонд содействия инновациям. https://online.fasie.ru/m/user-projects/registry (дата обращения: 25.09.2025).

multilayer compression bandages, including mobilizing systems with volumetric elements that perform a compressive function and generate locally differentiated pressure; hereinafter referred to as compression elements (CE). Examples of such systems that implement the principle of locally differentiated pressure through the use of foam polymer elements placed between layers of nonwoven materials are described in the literature. When exposed to external compression, areas of increased pressure are formed in the area of the volumetric elements, which facilitates the redistribution of edema fluid to surrounding areas with lower pressure and improves its reabsorption into venules and lymphatic capillaries [15, 16].

Currently, there are no registered mobilizing multilayer compression systems of this design on the Russian market, limiting the potential for comprehensive anti-edema therapy for lymphedema and edema of other etiologies. The development and commercialization of domestically produced alternatives is hampered, in part due to the lack of standardized testing methods and test setups for objectively evaluating the effectiveness of prototypes under development.

**Aim**. To develop and validate a test model for measuring the load beneath CE of multilayer bandages composed of materials with different stiffness.

## MATERIALS AND METHODS

The study was conducted in two stages: the first stage (June 24, 2024–October 18, 2024) involved the production of multilayer compression bandage prototypes and the development of a test setup; the second stage (November 8, 2024–November 22, 2024) involved testing the developed model.

### Stage 1
### Manufacturing multilayer compression bandage prototypes

Nine multilayer bandage samples were laboratory-fabricated to replicate the differentiated compression (DC) achieved by similar compression bandages from foreign manufacturers. Each multilayer bandage consisted of a CE placed between two layers of fixing fabric (FF). Three types of CE and three types of FF were used in the study (Table).

Each multilayer bandage consisted of CE placed between two layers of FF. Nine types of multilayer bandages were studied: each of the three types of CE was married with each type of FF. The analysis used aggregated data separately by CE type or by FF type.

### Development of a test setup

To simultaneously record pressure under various components of a multilayer bandages with DC areas, a test setup simulating a human limb was developed. The model is made of hard plastic covered with artificial skin. The setup has a rigid platform (mounting socket) for a block with two strain-gauge sensors (SGSs) and contact pads above them (Fig. 1). This block is placed inside the mounting socket. Herewith the SGSs are at the level of artificial leather and record in grams-force (gf) the applied load of the test object (compression bandages), placed under the cuff of a tonometer that generates external pressure.

To convert signals coming from the SGSs, a hardware and software complex (HSC) recorder was developed and manufactured. The HSC includes an ESP32 microcontroller (Espressif Systems, China), two analog-to-digital conversion modules based on the HX711 microcircuit (integrated circuit: Avia Semiconductor (Xiamen), China; module manufacturer: Shanghai Ruichi Industry Co., China), with a built-in programmable amplifier with a gain of up to 128 and 24-bit operation, as well as two MLC616C SGSs (Manyyear Technology Company Limited, China) with a permissible measurement range from 0 to 5 kg. The developed HSC is connected to a personal computer via a USB cable to receive power and transmit the recorded signals. A load recording system consisting of two SGSs and two contact pads above them, supports, and a unit with recording electronic devices was manufactured and mounted.

The developed microcontroller program code the initial initialization of the two SGSs and the amplifier

***Table.*** **Characteristics of the components used in compression bandages**

| Components compression bandages | Material | Density | Load at 40% sample deformation, kg/cm$^2$ | Production |
|---|---|---|---|---|
| CE-1 | Latex foam sheet | 0.177 kg/cm$^3$ | 0.082 | Experimental sample made by the authors |
| CE-2 | Foamed polyethylene | 0.225 kg/cm$^3$ | 0.123 | Experimental sample made by the authors |
| CE-3 | Dense non-woven material based on viscose | 0.225 kg/cm$^3$ | 0.147 | Experimental sample made by the authors |
| FF-1 | Non-woven fabric – polyester 100% | 45 g/m$^2$ | | Avangard LLC, Russia |
| FF-2 | Non-woven fabric – viscose/ polyester 30/70% | 40 g/m$^2$ | | Avangard LLC, Russia |
| FF-3 | Non-woven perforated fabric – polyester 100% | 40 g/m$^2$ | | Medline LLC, China |

Note: CE – compression element of type 1, 2 or 3; FF – fixing fabric of type 1, 2 or 3.


**FIG. 1.** Test setup simulating a human limb.

Note: 1 and 2 – strain-gauge sensors, 3 – mounting socket.

chips with analog-to-digital converters. Then, readings are taken sequentially from the two SGSs, first from the first, then from the second, with a one-second interval between readings. The following data is transmitted to the PC via a USB cable and COM port every second: the measurement time elapsed since the HSC was turned on (in seconds), and the load values recorded on the first and second SGS (in gf). The accuracy of the SGSs readings is 0.01 gf. The data received from the HSC is written to a text file on the personal computer for subsequent processing and analysis.

### Stage 2
### Calibration of the developed model

The developed model was calibrated under experimental conditions before each series of tests. The load on the first SGS was recorded without a load and with a load equivalent to 5g. Before testing each of the three types of CE, five calibration tests were performed without the CE on the SGS I and with the CE secured on the SGS II without fixing bandage. For all tests, the CE size indicated the size of the sensor contact pad. The load was recorded during the first five seconds (Supplementary materials on the journal's website https://doi.org/10.47093/2218-7332.2025.16.4.20-30-annex).

### Testing multilayer bandages prototypes

In three groups of samples, each grouped based on the type of CE material and the type of FF used, 10 repeated load measurements were taken in two randomly selected areas of each Prototype (a total of 60 readings from each sensor for each group). The Prototype size for the measurements was determined by assuming a clinically significant difference in load under the different CE types of 25% at a significance level of 0.05 and a power of 80% ($\beta = 0.20$).

During the study, the load values recorded on the first and second SGSs (in gs) were recorded every second for 10 minutes after applying the cuff of a mechanical tonometer and creating a pressure of 40 mmHg in it.

The strain gauge test protocol included the following steps:

1. Fixing the multilayer bandage sample to the test stand (Fig. 2A).
2. Mechanically removing the CE in the SGS I projection.
3. Fixing the sample to the test stand using a Peha-haft® cohesive self-adhesive bandage (Paul Hartmann AG, Germany).
4. Applying the mechanical tonometer cuff (Fig. 2B).
5. Inducing a predetermined pressure level in the cuff, simulating the pressure generated by a compression bandage on the specimen under a multilayer bandage.

This protocol allowed for simultaneous recording of the load under the area with CE and the control area without CE, allowing for a comparison of the contribution of the multilayer bandage construction and the applied FF to local pressure formation. This allowed for the evaluation of the effectiveness of different CE types under simulated imitation of local pression load. This allowed for the evaluation of the effectiveness of different CE types under simulated compression load.

### Statistical analysis

Quantitative indicators were assessed for normal distribution using the Kolmogorov-Smirnov test. Descriptive statistics were presented as medians and interquartile ranges (25th and 75th percentiles) for

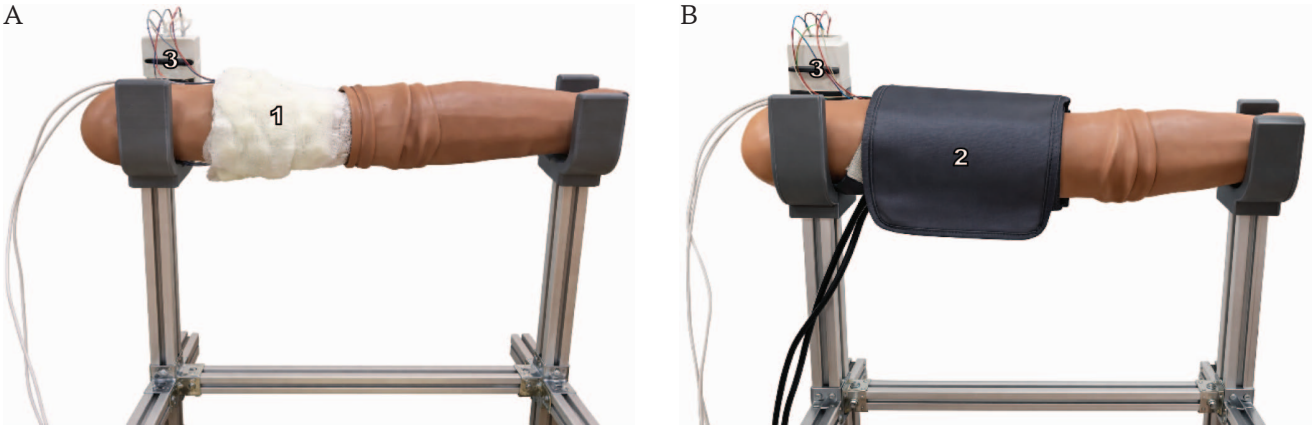


**FIG. 2.** Stages of strain gauge tests on the developed test setup.
A. Fixing the multilayer bandage sample to the simulator of a human upper limb.
B. Applying the cuff of a mechanical tonometer to the upper bandage to create an external pressure of 40 mm Hg.

Note: 1 – multilayer bandage; 2 – cuff of a mechanical tonometer; 3 – a hardware and software complex that records signals from strain-gauge sensors and transmits data to a personal computer.

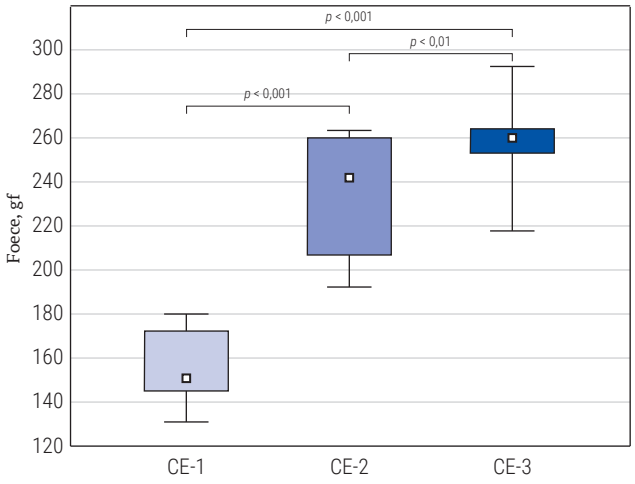


**FIG. 3.** Load recorded during the study of compression element sample.

Note: CE – compression element type 1, 2 or 3; gf – gram-force.

continuous variables with a non-normal distribution. Since the data were non-normally distributed, the Kruskal–Wallis test was used to compare results between groups. If statistically significant differences were detected between groups, paired comparisons were additionally performed using Dunn's *post-hoc* test. Differences in indicators were considered statistically significant at a significance level of $p < 0.05$. Statistical analysis was performed using Statistica 13.3 (StatSoft. Inc., USA).

## RESULTS

The load recorded on the SGS II under the CE differed statistically significantly between groups and depended on the type and stiffness material of the CE ($p < 0.001$). The maximum load was recorded under the type 3 FF, characterized by the highest stiffness, and amounted to 259.4 (252.6; 263.3) gf. The minimum load was observed under the type 1 FF with the minimum stiffness – 149.9 (145.1; 171.9) gf (Fig. 3).

The type 2 FF occupied an intermediate position: the recorded load was 241.7 (206.4; 259.3) gf and statistically significantly differed from both the values obtained for the type 1 and type 3 FF. The data obtained showed that an increase in the CE stiffness was accompanied by an increase in the local load recorded beneath it, all other conditions being equal. The load recorded beneath the blended nonwoven viscose-polyester FF (FF-2) combined with CE 2 made of polyethylene foam was 1.6 times greater than the load recorded beneath the sample with FF-1 made of polyester nonwoven fabric combined with CE-1 made of latex foam.

The test setup also allowed us to record statistically significant differences in the load on the TSG I generated by different types of FF ($p < 0.001$). The highest load was recorded under FF type 2, made of a blended nonwoven material (viscose/polyester), and amounted to 141.0 (140.2; 142.1) gf.

The minimum load was recorded under FF type 1, made of polyester with the highest surface density – 14.5 (14.3; 15.6) gf. FF type 3, also made of polyester but with a lower density, generated an intermediate load level – 65.7 (64.9; 69.3) gf, which was statistically significantly different from the values for FF types 1 and 2 (Fig. 4).

## DISCUSSION

One of the modern methods for treating peripheral edema, in whose pathogenesis lymphedema plays a significant role, is Complex Decongestive Therapy, and its effective component is compression bandaging

[15] using a multilayer bandage with areas of DC [16]. The development and production of such a product is associated with difficulties. It is necessary to select a material for each component (CE and FF), and also to study its compressive properties. While determining the mechanical properties of each component individually is not difficult, evaluating the effectiveness of a finished prototype of a multilayer bandage with areas of DC is currently practically impossible due to the lack of model setups and standard requirements for testing such products.

We developed a test setup consisting of simulating a human upper limb (a hard plastic covered with artificial skin) with a rigid platform for a block with two SGSs capable of simultaneously recording the load under various components of a multilayer bandage. The setup's design enables synchronous load recording in two zones: in the CE projection and in the zone under the FF in the absence of the CE. This measurement scheme is aimed at comparing the local CE impact with the "background" pressure of the multilayer structure, thereby enabling a more practical selection of prototypes.

*In vitro* pressure and stiffness measurement is a well-known method used to classify medical elastic compression devices. This relatively simple approach allows for easy reproducibility and recording of results [17–20]. There are models that measure pressure using a strain gauge and a pressure gauge. However, the sensors in these models record the overall pressure, not the selective pressure of the CE, while the external pressure gauge records the pressure on the surface of the limb [21, 22]. At the same time, it is the ratio of the pressure under the CE to the pressure under other zones of the multilayer bandage that can become a determining indicator for assessing the potential effectiveness of the product and selecting prototypes for further testing. Since it is assumed that multiple CEs, which are placed in a certain order in the bandages, create a significant pressure difference between the area in the projection of the CE and the area surrounding it, which improves lymph flow in the affected limb [23].

The developed test setup proved to be a sensitive instrument, allowing us to record statistically significant differences in the load under CEs with different stiffnesses, both when the stiffness difference reached 1.8 times (between CE types 1 and 3) and when the stiffness difference did not exceed 1.1 times (between FE types 2 and 3). Statistically significant differences were also recorded between the loads exerted by different types of FFs. The maximum load in the absence of FEs (141.0 gf) was demonstrated by a blended viscose/polyester nonwoven fabric.

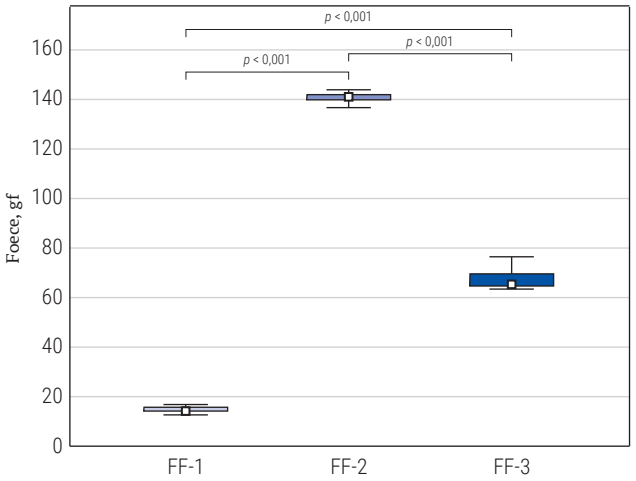


**FIG. 4.** Load recorded during the study of fixing fabric sample.

Note: FF – fixing fabric type 1, 2 or 3; gf – gram-force.

In the trials, a pressure of 40 mmHg was chosen to simulate the pressure generated by a multilayer compression bandage. The literature notes that lower pressure may be preferable for upper limb lymphedema, while the range of 40–60 mmHg appears to be more effective for lower limb lymphedema or when targeting specific areas of the upper limb (forearm, back of hand) [24, 25].

An original experimental model for recording pressure under the components of a multilayer bandage for *in vitro* studies has been developed. Comparison with existing international developments is difficult: despite the widespread use of SGS for assessing the functional characteristics of compression devises in preclinical and clinical studies [26, 27], no systems capable of recording selective pressure generated by individual layers of CE have been identified in the available literature.

An additional element of novelty is the choice of the limb model. Rigid limb mannequins are traditionally used to reproduce the conical shape of the limb [28]. However, even when using polyurethane foam pads, such systems do not consider natural skin turgor which can lead to significant discrepancies between the results and *in vivo* data. According to existing publications, similar approaches to experimental modeling have not been described; standardized data on protocols, device design, measurement methods, software, as well as the accuracy and permissible errors of pressure recording are also lacking [24].

Taken together, this allows us to consider the proposed model as an important intermediate link between the assessment of the properties of individual materials and subsequent studies of the functionality of multilayer compression bandages under conditions as close as possible to clinical ones.

### Study limitations and directions for further research

The tests performed using the developed setup were conducted under experimental conditions and were static tests. This approach ensures standardization of external influences and comparability of results between samples but does not reflect the dynamic characteristics of compression textiles during limb movement and position changes.

This protocol did not evaluate changes in load with limb volume fluctuations, nor the possible evolution of the texture and mechanical properties of the materials over time. Furthermore, an *in vitro* model cannot fully reproduce the influence of physiological factors, including variability in soft tissue properties, skin turgor, and limb contour heterogeneity, which can alter load distribution under the bandage components.

A promising direction for further work could be to conduct a series of tests at different levels of external pressure to evaluate the load generated by individual components of a multilayer bandages with DC areas. It is also advisable to develop protocols that simulate dynamic conditions (movement, change in position and change in limb volume) and evaluate the stability of the load during long-term use of the bandage.

## CONCLUSION

A test setup was developed and tested in vitro. It allows for the simultaneous recording of the load generated by different components of multilayer bandages with DC areas under a given external pressure (40 mmHg). The obtained data allow us to draw conclusions about the functional properties of the materials used (polymer foams and nonwoven fabrics) and use them as a basis for comparative evaluation when designing multilayer compression bandages.

Under experimental conditions, it was shown that the magnitude of the recorded load statistically significantly depends on both the stiffness of the CE material and the type of nonwoven FF. The highest load values were recorded under the CE with the highest stiffness. When developing prototypes, it is necessary to consider not only the density but also the composition of the material. For example, the maximum pressure on the simulation model was recorded under a blended nonwoven FF made of viscose and polyester combined with a CE in the form of foamed polyethylene. The obtained data justify the use of the developed setup as a screening tool for comparative evaluation and selection of samples of multilayer dressings with DC areas at the development stage.

## AUTHORS CONTRIBUTION

Alexey E. Brovkin and Sergey K. Zazulin formulated the idea. Sergey K. Zazulin, Ekaterina Yu. Chizh, and Svetlana M. Titkova developed the study design. Gregory G. Gabuzov created and described the experimental setup. Ekaterina Yu. Chizh, Svetlana M. Titkova, and Gregory G. Gabuzov conducted the experiments and performed statistical processing of the results. Alexey E. Brovkin studied the literature and wrote the text of the article. Ekaterina Yu. Chizh and Svetlana M. Titkova designed the illustrations. Sergey K. Zazulin, Mikhail V. Anurov, and Svetlana M. Titkova performed scientific editing of the article. All authors of the article approved the final version of the article.

## ВКЛАД АВТОРОВ

А.Е. Бровкин и С.К. Зазулин сформулировали идею. С.К. Зазулин, Е.Ю. Чиж и С.М. Титкова разработали дизайн исследования. Г.Г. Габузов создал и описал экспериментальный стенд. Е.Ю. Чиж, С.М. Титкова и Г.Г. Габузов провели эксперименты и выполнили статистическую обработку результатов. А.Е. Бровкин изучил литературные источники и написал текст статьи. Е.Ю. Чиж и С.М. Титкова оформили иллюстрации. С.К. Зазулин, М.В. Ануров и С.М. Титкова провели научную редактуру статьи. Все авторы статьи утвердили окончательную версию статьи

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