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Development of a method of comparative analysis based on consumer properties of polymer compositions illustrated by adhesive plates

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Abstract

Introduction. Polymer compositions, which are the basis of most dosage forms intended for application to the skin, including transdermal patches, determine both the biopharmaceutical properties of the drug and the consumer properties of the dosage form. Consumer properties are important for the patient. They determine the patient's commitment not only to therapy, but also to a specific manufacturer. Adhesive plates of colostomy bags are used for fixing ostomy bags and protecting the skin of the peristomal area. They are characterized by a set of consumer properties that determine their quality and may be a good model for studying the influence of consumer properties on patient preferences.

Aim. Development of comparative analysis method of adhesive plates polymer compositions based on consumer properties.

Materials and methods. To achieve the research goal, a set of methods was used, including bibliographic, analytical, comparative, survey and structural-functional analysis. To determine the weighting coefficients of various consumer characteristics of adhesive plates, a survey of experts was conducted.

Results and discussion. The main consumer properties of adhesive plates of ostomy pouches have been determined, which include: no adhesive residue on the skin after removal, ease of removal, wearing time, flexibility, ease of use, resistance to moisture and secretions, comfort of use, adhesion, strength of adhesion to the skin, prevention of leakage and no peristomal complications. Based on expert evaluation, weighting coefficients for each consumer property were determined, and a methodology for comparative evaluation of adhesive plates of ostomy pouches was proposed. The methodology can be used for comparative analysis of adhesive plates from different manufacturers.

Conclusion. A methodology for the comparative evaluation of ostomy pouches was successfully developed. It can be used as a basis for developing a similar methodology for evaluating skin-applied dosage forms based on their consumer properties.

Keywords: polymer composition, adhesive plates; comparative analysis; consumer properties

Conflict of interest. The authors declare that they have no obvious and potential conflicts of interest related to the publication of this article.

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Разработка метода сравнительного анализа на основе потребительских свойств полимерных композиций на примере адгезивных пластин

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Резюме

Введение. Состав полимерных композиций, являющихся основой большинства лекарственных форм, предназначенных для аппликации на кожу, в том числе трансдермальных пластырей, помимо биофармацевтических свойств лекарственного препарата, определяет также потребительские свойства лекарственной формы. Потребительские свойства, в свою очередь, имеют важное значение для пациента, в том числе обуславливая его приверженность не только к терапии, но и конкретному производителю. Адгезивные пластины калоприемников (уроприемников), служащие для крепления стомных мешков и защиты кожи перистомальной области, характеризуются совокупностью потребительских свойств, определяющих их качество, являются хорошей моделью для изучения влияния потребительских свойств на предпочтения пациента.

Цель. Разработка методики сравнительного анализа полимерных композиций адгезивных пластин на основе их потребительских свойств.

Материалы и методы. Для достижения цели исследования применялся комплекс методов, включающий в себя библиографический, аналитический, сравнительный, опросный и структурно-функциональный анализы. Для определения весовых коэффициентов различных потребительских характеристик адгезивных пластин был проведен опрос экспертов.

Результаты и обсуждение. Определены основные потребительские свойства адгезивных пластин, к которым отнесены: отсутствие остатков адгезива на коже после удаления, легкость удаления, время ношения, гибкость, простота использования, устойчивость к влаге и выделениям, комфорт использования, прилипание, прочность сцепления с кожей, предотвращение подтеканий и отсутствие перистомальных осложнений. На основании экспертной оценки определены весовые коэффициенты для каждого потребительского свойства, предложена методика сравнительной оценки адгезивных пластин калоприемников (уроприемников), которая может быть использована для сравнительного анализа адгезивных пластин различных производителей.

Заключение. Разработанная методика сравнительной оценки адгезивных пластин может быть использована в качестве основы при разработке подобной методики оценки аппликируемых на кожу лекарственных форм на основе их потребительских свойств.

Ключевые слова: полимерные композиции, адгезивные пластины, сравнительный анализ, потребительские свойства

Конфликт интересов. Авторы декларируют отсутствие явных и потенциальных конфликтов интересов, связанных с публикацией настоящей статьи.

Вклад авторов. М. А. Мандрик – автор идеи, концепция работы, интерпретация результатов, написание текста статьи. С. А. Албагачиев – поиск и анализ литературы, интерпретация результатов, написание текста статьи. Л. А. Король, Е. А. Шеметова, И. И. Краснюк, Г. В. Раменская – дизайн исследования, консультирование, редактирование окончательной

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INTRODUCTION

The composition of polymer compositions – carriers of active pharmaceutical substances, as a rule, includes a wide range of excipients, including low-molecular ones, and determines not only the biopharmaceutical properties of the drug, but also its physicomechanical properties.

For example, in the case of patches, including transdermal patches, the polymer matrix and functional fillers determine such characteristics as mechanical strength, elasticity, adhesion to the skin, resistance to moisture, etc.

Ease of application, absence of traces after removal and pleasant tactile sensations, which are also consumer properties of transdermal patches, increase patient confidence in the selected drug and ensure a high level of treatment compliance.

Thus, the combination of consumer properties is directly related to patient satisfaction and determines the composition and technology for the production of polymer compositions intended for skin application. In addition, it can serve as a basis for comparing dosage forms from different manufacturers.

Adhesive plates intended to fix the ostomy pouches tightly and securely to the skin of the anterior abdominal wall, as well as to protect the peristomal skin from stoma secretions and preserve the physiological functions of the skin, are a key element in ensuring the proper functioning of the pouching system (urostomy pouch)[1] [1, 2].

At the same time, adhesive plates as a product have a number of quality-defining properties that are shown while used by the consumer[2], which is shared with drugs intended for skin application, since it is the correctly selected adhesive plates that ensure the comfortable and appropriate use of ostomy pouches (urostomy pouches) that are crucial for the health, well-being and general quality of life of ostomy patients.

This makes adhesive plates a good model for developing a method for comparative analysis of shapes intended for skin application based on their consumer properties.

The goal of this work is to develop a method for comparative analysis of polymer compositions of adhesive plates based on their consumer properties.

MATERIALS AND METHODS

To achieve this goal, a set of study methods was used: bibliographic, analytical, comparative, survey and structural functional analysis.

To determine the main consumer properties of adhesive plates, information search was carried out in the Russian Science Citation Index, PubMed, Scopus, Google Scholar databases.

The following keywords and phrases were searched: “adhesive plates for stoma/colostomy/urostomy/ileostomy”; “adhesive plates for stoma pouches/urostomy pouches”; “Comparative Analysis of Medical Devices”; ”Consumer properties of medical aids/stoma pouches/urostomy pouches”, as well as their analogues in English.

[1] GOST R ISO 12505-1-2019. Skin barrier for ostomy aids – Test methods – Part 1: Size, surface pH and water-absorbency. Available at https://docs.cntd.ru/document/1200166274. Accessed: 06.11.2024.

[2] GOST R 51303-2013. Trade. Terms and definitions. Available at: https://docs.cntd.ru/document/1200108793. Accessed: 06.11.2024.

To determine the weight coefficients of the consumer properties of adhesive plates, reflecting the importance of each value (property) for the consumer, a survey of experts was conducted in the form of an interview [3]. The survey was conducted in accordance with the Delphi method, as a result of which 11 specialists in the field of development, production and use of stoma pouches (urostomy pouches) in clinical practice were interviewed [4, 5]. The significance of the value was assessed using a 10-point scale (Table 1).

Table 1. Criteria for assessing the significance of consumer properties

Appraisal	Significance of the indicator (consumer property)
10	Significance of the indicator has a decisive influence on consumer preference
9	Significance of the indicator has a major impact on consumer preference
8	Significance of the indicator has a significant impact on consumer preference
7	Significance of the indicator has a great impact on consumer preference
6	Significance of the indicator has an above-average impact on consumer preference
5	Significance of the indicator has an average effect on consumer preference
4	Significance of the indicator has an impact on consumer preference below average
3	Significance of the indicator has a negligible effect on consumer preference
2	Significance of the indicator has little or no effect on consumer preference
1	Significance of the indicator does not affect consumer preference

RESULTS AND DISCUSSION

Main consumer properties of adhesive plates

Flexibility

Flexibility, which is one of the most important consumer characteristics of adhesive plates, which is of great importance for patients [6], means the ability of the plate to bend and stretch under the influence of external forces without breaking. So, with sufficient flexibility of the plate, the patient can go about everyday activities without experiencing discomfort, since in this case the plate adapts to body movements, maintaining close contact with the skin of the peristomal region in conditions of uneven relief and without causing discomfort. In turn, it is the provision of a tight fit to the skin that is one of the key conditions for both long-term wear and the prevention of leakage from the stoma under the plate [7].

The flexibility of the adhesive plate depends primarily on the structural and mechanical properties of the materials that make up the plate, as well as on the quantitative relationships between these materials, so it can be adjusted within a relatively wide range at the stage of developing the plate composition.

The thickness of the plate is another factor that affects flexibility: the lower is the thickness, the higher is the flexibility, usually due to which the thickness of the plates usually decreases from the center to the edges.

The main parameters that can characterize the flexibility of the insert include such structural and mechanical characteristics as elasticity [8, 9] and ductility[1] [10].

Adhesion

The ability of adhesive plates to adhesion, i.e. to form and maintain a bond in contact with the skin during the entire period of use, or, in other words, adhesion to the skin, is one of the key consumer requirements for adhesive plates [11]. In addition to its main function – holding the stoma pouch, this factor is directly related to the time of wearing the pouch and protecting the peristomal area from leaks. Adhesion is realized due to intermolecular interaction at the interfacial boundary between the hydrocolloid layer of the plate, which has sufficient intrinsic stickiness (or an additional adhesive layer in the absence of stickiness in the hydrocolloid base), on the one hand, and the substrate (skin), on the other [12]. At the same time, the formation of an adhesive bond, as well as the strength of an already formed bond, is provided by a complex

[1] GOST 18299-72. Paint and varnish materials. A method for determining tensile strength, elongation at break, and modulus of elasticity. Available at: https://docs.cntd.ru/document/1200019439. Accessed: 06.11.2024.

of factors, including mechanical, chemical, adsorption, electrical and diffusion properties of the adhesive and substrate, as well as environmental factors [13].

The adhesion properties of plates containing pressure-sensitive adhesives can be characterized by both the ability to form an adhesive bond (instant tack) and the ability to hold this bond under the influence of various types of deforming influences (adhesion and cohesive strength). However, if we consider the effect of the adhesion characteristics of the plates on the ability to adhere to the skin, then the main measurable value for the characteristics of the product by this parameter will be the instant stickiness, which characterizes the ability of the material to form a strong adhesive bond with the substrate when a small external pressure is applied to the adhesive for a short time (a few seconds). It is the instant stickiness of the adhesive that provides the very possibility of contact between the surface of the product and the skin or mucous membrane [12].

The study of instant tack is carried out both to assess the fundamental ability of the adhesive plate to form an adhesive bond, and to assess the change in adhesion characteristics during storage and operation (for example, in contact with water vapor). In addition, stickiness control is especially important to ensure that the product is non-traumatic, since if the value of this parameter is too high, the use of the product can be associated with damage to the skin.

In doing so, instant tack can be characterized not only by measuring the force required to break the joint and calculating a number of other adhesion characteristics, but also by predicting based on the rheological properties of the adhesive in the plate.

Skin adhesion strength

Unlike the ability to adhesion, the strong adhesion of the plate to the skin implies not only the ability to form an adhesive bond with the skin, but also to hold it during operation. As with adhesion, the adhesion properties of the plates play a key role in ensuring this. At the same time, in order to characterize how strong the adhesion of the adhesive to the skin is when the plate is worn, the key adhesion characteristics are such as the adhesive strength when peeling and the cohesive strength of the adhesive (static shear resistance), which characterize the ability to hold this joint under the influence of deforming forces.

In addition to the adhesion parameters that directly affect the adhesion strength of the plate to the skin, indirect factors related to the environmental conditions in which the plate is located can be used to characterize this property. As such, erosion resistance can be considered as a factor affecting the ability of the adhesive layer in contact with the skin to remain continuous and not reduce the contact area; In addition, factors related to the effect of moisture on the adhesion characteristics of the plate deserve attention. As such, water absorption value of the plate and vapor permeability can be considered.

No leakage

Leaks or leakage of secretions from the stoma beyond or under the adhesive plate is a serious problem for ostomy patients. Stoma leaks have a negative impact on patients' everyday activities. It has been shown that most patients with a stoma experience constant anxiety and fears that a leakage may occur, and the leakage that has occurred will cause negative emotions in others. In addition to psychological discomfort, leaks can cause the development of peristomal skin complications, such as contact dermatitis [14].

However, the appearance and structure of the plate that do not correspond to the stoma, the geometry of the stoma hole in the plate can affect the tightness of the reservoir system, and poor adhesion to the skin can lead to leakage of secretions and irritation [15].

To understand how well the plate is able to resist leaks, it is necessary to assess the frequency of leaks, the scale of leakage and the impact of leaks on quality of life. A method for assessing these parameters can be a retrospective analysis based on data from a survey of users and healthcare professionals, as was done in the Ostomy Life Study 2019 [16]. To assess the impact of leaks on quality of life, specially designed questionnaires can be used, for example, Ostomy Leak Impact (OLI) [17] or Ostomy-Q [18], developed to assess the impact of ostomy aids on quality of life.

Comfort of use

Comfort, as well as the ease of using something, is quite difficult to characterize by any objective parameters, since both of these concepts are very much dependent on the subjective perception of people. Speaking specifically about the comfort of using adhesive plates,

we can only assume that the feeling of comfort may be responsible for those parameters of the plates, owing to which the plate at least does not cause negative physical sensations and emotions in patients or helps to cope with them, allowing them to live a full life. However, to determine the exact parameters of the plates that provide this, a comprehensive sociological study among patients may be required, for which existing tools for assessing quality of life, such as the Stoma-QOL questionnaire, can be used [19].

Resistance to moisture and excretion (resistance to erosion)

Erosion resistance refers to the ability of an adhesive plate to retain its physical shape when exposed to moisture[1].

Resistance to moisture and stoma excretions directly affects the ability of the plate not to erode, not to lose adhesion to the skin, and thus to protect the peristomal area from the aggressive effects of discharge.

Resistance to moisture and excretions can be characterized by such parameters as resistance to erosion and the value of water absorption [20].

Wearing Time

The time (duration) of wearing an adhesive plate is one of the main consumer properties used for comparative evaluation of various ostomy systems [21, 22]. A long wearing time is considered preferable, since, according to the currently available data, frequent changes in the adhesive adjacent to the peristomal skin, also exfoliates epidermal cells, which is why frequent plate change may be associated with peristomal skin complications such as erythema, blisters, and bleeding [23].

The time of wearing the plate before it needs to be replaced strongly depends on most of the other consumer properties: strong adhesive contact with the skin, resistance to moisture and secretions (due to the high absorption capacity and resistance of the plate materials to aggressive intestinal secretions, which slow down the erosion of the plate), as well as vapor permeability. The socio-economic aspect also plays an important role: for example, according to the Canadian Society for Intestinal Research, in North America, due to the high financial burden and low degree of social support, patients often arbitrarily exceed the period of wearing ostomy aids, which is why plates with increased erosion resistance and improved adhesion values have become widespread there, thanks to which they last for a week or more[2].

At the same time, in Europe, where social support from the state is more developed, patients can afford to change plates much more often, on average once every 2–3 days, and the plates themselves are often not designed for long-term wear2. The wearing time can be characterized by the time required for the adhesive to completely peel off when the patient wears it loosely in a clinical trial [24].

As well, to assess this value, the survey method can be used, using questionnaires similar to the one used in the work of Richburg et al [25].

Ease of Use

Ease of use is an important requirement for ostomy care products, which quite a few patients note as an important property for themselves [26]. Ease of use means that the adhesive plate and pouch should be designed in such a way that patients do not have significant difficulties in replacing the plate or pouch, and the process itself does not take much time. This is especially important for certain groups of patients who may experience problems with self-care. Ease of use also increases the likelihood of faster patient education to self-use of stoma care products.

Easy removal of the plate

The ease of removing the plate is directly related to the absence of trauma and the possibility of quick replacement of the product, while non-compliance with this requirement can lead to psychological discomfort, pain and even damage to the skin of the peristomal region [27].

For easy and painless removal of the plate, it may be necessary to use additional accessories, such as special adhesive removers [23]. However, the main factor that ensures the ease of peeling is the optimal value of

[1] GOST R ISO 12505-2-2019. Adhesive plates of stoma pouches and urostomy pouches. Test methods. Part 2. Erosion resistance and adhesive strength. Available at: https://docs.cntd.ru/document/1200166275. Accessed 06.11.2024.

[2] Appliance wear times. Available at: https://badgut.org/information-centre/ostomies/appliance-wear-times/ Accessed: 06.11.2024.

the already mentioned adhesive strength: high enough to maintain the contact of the plate with the skin, even under the influence of external forces, without causing pain or significant damage to the skin. It is believed that the optimal values of the peeling force of the plate from the substrate (human skin) are in the range of 0.8–1.2 N [28].

No adhesive residue on the skin after plate removal

The absence of adhesive residues on the skin after the removal of the adhesive plate acts as one of the criteria for the selection of stoma aids by patients. This is an important factor allowing preventing contamination of clothes and linen with adhesive residues and, more importantly, appearance of additional irregularities on the skin surface, thereby preventing the worsening of adhesion of replaceable plate to the skin[1].

The attribute is characterized by adhesion values, namely the cohesive strength of the plate adhesive (low cohesive strength leads to the destruction of the continuous layer of adhesive and its incomplete removal from the skin surface).

No peristomal skin complications

In addition to contact dermatitis, which usually occurs due to leakage, there are other peristomal complications that are directly due to the negative effect of the plate on the skin. These include mechanical damage caused by excessive adhesion of the plate to the skin or too frequent peeling of the adhesive, and in the case of low cohesive strength of the adhesive, they can be caused by friction when cleaning the skin from adhesive residues. In the case of high sensitivity of the skin to any of the components included in the plate, an immunological complication may develop – an allergic reaction. Chemical damage to the skin may also occur, for example, if there is too much difference between the pH of the surface of the plate and the pH of the skin.

Finally, peristomal skin complications may occur as an infectious process, usually a fungal infection, for which the environment under the plate is extremely favorable due to the heat of the human body and high humidity, especially if the plate does not provide the proper level of absorption or does not allow water vapor to pass through poorly [15].

Thus, when considering the parameters that characterize the ability of the plate to prevent peristomal complications, it is necessary to pay attention to those that may be the cause of the phenomena described above. These are all the adhesion characteristics of the wafer: erosion resistance, water absorption value, vapor permeability, wafer irritant and sensitizing potential, microbial purity, and surface pH (Tables 2 and 3).

Table 2. The main consumer properties of adhesive baseplates

Main consumer properties of adhesive baseplates	Main parameters characterizing consumer properties of adhesive baseplates
Flexibility	Elasticity
	Plasticity
Adhesion	Tack
Skin adhesion strength	Adhesion strength
	Cohesive strength
	Resistance to erosion
	Water absorption value (absorption)
	Vapor permeability
No leakage	Leakage frequency
	Scale of leakage
	Impact of leakage on quality of life
Comfort of use	–
Resistant to moisture and excreta	Resistance to erosion
	Water absorption value (absorption)
Wearing time	Wear time without loss of functionality.

[1] It is difficult to make the adhesive stick to the skin when applying. Available at: https://www.coloplast.co.uk/global/ostomy/ostomy-self-assessment-tools/troubleshooter/application-and-removal/poor-adhesion-when-applying/ Accessed: 06.11.2024.

Main consumer properties of adhesive baseplates	Main parameters characterizing consumer properties of adhesive baseplates
Ease of use	–
Easy removal	Adhesion strength
No adhesive residue on the skin after removal	Cohesive strength
No peristomal complications	Tack
	Adhesion strength
	Cohesive strength
	Resistance to erosion
	Water absorption
	Vapor permeability
	Irritation potential of the baseplate
	Sensitizing potential of the baseplate
	Microbiological purity
	pH of the surface

Expert assessment of the significance of consumer properties

The results of the survey of 11 experts as interviews are given in Table 4. The significance of the value was evaluated by points from 1 to 10.

Statistical Processing of Expert Assessment Data

Calculated statistical values such as arithmetic mean ($\bar{x}$), sample standard deviation (S), variance (S^2), standard error of the mean ($S\bar{x}$), the error of the arithmetic mean or half-width of the confidence interval ($\Delta\bar{x}$), the range of the data (Δx), the relative standard deviation (RSD), as well as the values of the weighting coefficients, are presented in Table 5.

The degree of agreement of experts' opinions is determined by the coefficient of variation of answers: $V \leq 0.10$ – high consistency; $V = 0.11–0.15$ – above-average consistency; $V = 0.16–0.25$ – average consistency; $V = 0.26–0.35$ – below average consistency; $V > 0.35$ – the consistency is below the allowable limit. The variation coefficients in determining the consumer weights of adhesive plates were less than 0.25, which is statistically acceptable. It should also be noted that the agreement of expert opinions increases in relation to consumer properties with the highest weight coefficient, which additionally confirms the fundamental importance for the patient of such parameters as "No leakage" and "No peristomal complications".

Table 3. Some parameters of consumer properties and methods of their testing

Parametr	Test methods	Standards
Elasticity	Tensile testing	ASTM D882-18[1]
Plasticity		
Tack	Tensile testing	ASTM D2979-01[2]
	Rolling Ball test	ASTM D3121-17[3]
	Loop Tack test	ASTM D6195-22[4]
Adhesion strength	Peel testing at 180° or 90°	GOST R ISO 12505-2–2019 (identical to ISO 12505-2:2016)[5]
		ASTM D3330/D3330M-04 (2018)[6]
		ASTM D6252/D6252M-98 (2019)[7]
		ISO 29862:2018 8[36]

Окончание таблицы 3

Parametr	Test methods	Standards
Cohesive strength	Shear resistance test	ASTM D3654/D3654M-06(2019)[9]
		ISO 29863:2018[10]
Wet integrity	Wet integrity testing	GOST R ISO 12505-2–2019 (identical to ISO 12505-2:2016)[5]
Water-absorbency	Water-absorbency test	GOST R ISO 12505-1–2019 (identical to ISO 12505-1:2014)[11]
Vapor permeability	Cup method	ASTM E96/E96M-24[12]
Irritation potential of the baseplate	*In vivo* tests	GOST ISO 10993-10–2011 (identical to ISO 10993-10:2002)[13]
Sensitizing potential of the baseplate		
Microbiological purity	*In vitro* bioburden assessment	GOST ISO 11737-1-2012 (identical to ISO 11737-1:1995)[14]
pH of the surface	Potentiometric pH determination	GOST R ISO 12505-1–2019 (identical to ISO 12505-1:2014)[11]

Note. [1] ASTM D882-18. Standard Test Method for Tensile Properties of Thin Plastic Sheeting. Available at: https://store.astm.org/d0882-18.html. Accessed: 06.11.2024.

[2] ASTM D2979-01. Standard Test Method for Pressure-32. Sensitive Tack of Adhesives Using an Inverted Probe Machine. Available at: https://store.astm.org/d2979-01.html. Accessed: 06.11.2024.

[3] ASTM D3121-17. Standard Test Method for Tack of Pressure-Sensitive Adhesives by Rolling Ball. Available at: https://store.astm.org/d3121-17.html. Accessed: 06.11.2024.

[4] ASTM D6195-22. Standard Test Methods for Loop Tack. Available at: https://store.astm.org/d6195-22.html. Accessed: 06.11.2024.

[5] GOST R ISO 12505-2-2019. Adhesive plates of ostomy and urostomy bags. Test methods. Part 2. Erosion resistance and adhesive strength. Available at: https://docs.cntd.ru/document/1200166275. The link is active on 06.11.2024.

[6] ASTM D3330/D3330M-04. Standard Test Method for Peel Adhesion of Pressure-Sensitive Tape. Available at: https://store.astm.org/d3330_d3330m-04.html. Accessed: 06.11.2024.

[7] ASTM D6252/D6252M-98(2019). Standard Test Method for Peel Adhesion of Pressure-Sensitive Label Stocks at a 90° Angle. Available at: https://store.astm.org/d6252_d6252m-98r19.html. Accessed: 06.11.2024.

[8] ISO 29862:2018. Self-adhesive tapes – Determination of peel adhesion properties. 2018. Available at: https://www.iso.org/standard/70311.html. Accessed: 06.11.2024.

[9] ASTM D3654/D3654M-06(2019). Standard Test Methods for Shear Adhesion of Pressure-Sensitive Tapes. Available at: https://store.astm.org/d3654_d3654m-06r19.html. Accessed: 06.11.2024.

[10] ISO 29863:2018. Self adhesive tapes – Measurement of static shear adhesion. 2018. Available at: https://www.iso.org/standard/70312.html. Accessed: 06.11.2024.

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[12] ASTM E96/E96M-24. Standard Test Methods for Gravimetric Determination of Water Vapor Transmission Rate of Materials. Available at: https://store.astm.org/e0096_e0096m-24.html. Accessed: 06.11.2024.

[13] GOST ISO 10993-10–2011. Medical devices. Evaluation of the biological effects of medical devices. Part 10. Irritation and sensitization studies. Available at: https://docs.cntd.ru/document/1200097629. The link is active on 06.11.2024.

[14] GOST ISO 11737-1-2012. Sterilization of medical devices. Microbiological methods. Part 1. Evaluation of the microbial population on products. Available at: https://docs.cntd.ru/document/1200097807. The link is active on 06.11.2024.

Table 4. **Results of interviewing experts on the importance of consumer properties of adhesive plates**

Property \ Score	Experts										
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**
Flexibility	8	6	7	7	6	6	8	8	8	7	7
Adhesion	9	9	10	8	9	9	10	9	8	9	8
Skin adhesion strength	9	10	9	9	9	8	10	10	9	10	9
No leakage	10	10	10	10	10	10	10	10	10	10	10
Comfort of use	8	9	9	9	8	8	9	8	9	8	8
Resistant to moisture and excreta	9	7	8	8	9	8	9	8	8	8	8
Wearing time	7	7	8	7	6	7	8	6	8	7	6
Ease of use	7	8	8	6	8	7	6	8	7	7	6
Ease of removal	8	6	6	7	7	6	8	5	7	6	6
No adhesive residue on the skin after removal	5	4	5	6	3	7	4	5	3	5	5
No peristomal complications	10	10	10	10	10	10	10	10	10	10	10

Table 5. **Results of statistical data processing**

Consumer property	Metrological characteristics	Weight coefficient
Flexibility	$\bar{x}$ = 7,09; S = 0,83; S^2 = 0,69; $S\bar{x}$ = 0,25; $\Delta\bar{x}$ = 0,56; Δx = 2,00; RSD = 0,12	0,081
Adhesion	$\bar{x}$ = 8,91; S = 0,70; S^2 = 0,49; $S\bar{x}$ = 0,21; $\Delta\bar{x}$ = 0,47; Δx = 2,00; RSD = 0,08	0,102
Skin adhesion strength	$\bar{x}$ = 9,27; S = 0,65; S^2 = 0,42; $S\bar{x}$ = 0,20; $\Delta\bar{x}$ = 0,43; Δx = 2,00; RSD = 0,07	0,106
No leakage	$\bar{x}$ = 10,00; S = 0,00; S^2 = 0,00; $S\bar{x}$ = 0,00; $\Delta\bar{x}$ = 0,00; Δx = 0,00; RSD = 0,00	0,114
Comfort of use	$\bar{x}$ = 8,45; S = 0,52; S^2 = 0,27; $S\bar{x}$ = 0,16; $\Delta\bar{x}$ = 0,35; Δx = 1,00; RSD = 0,06	0,097
Resistant to moisture and excreta	$\bar{x}$ = 8,18; S = 0,60; S^2 = 0,36; $S\bar{x}$ = 0,18; $\Delta\bar{x}$ = 0,41; Δx = 2,00; RSD = 0,07	0,094

Consumer property	Metrological characteristics	Weight coefficient
Wearing time	$\bar{x}$ = 7,00; S = 0,77; S^2 = 0,60; $S\bar{x}$ = 0,23; $\Delta\bar{x}$ = 0,52; Δx = 2,00; RSD = 0,11	0,08
Ease of use	$\bar{x}$ = 7,09; S = 0,83; S^2 = 0,69; $S\bar{x}$ = 0,25; $\Delta\bar{x}$ = 0,56; Δx =2,00; RSD = 0,12	0,081
Ease of removal	$\bar{x}$ = 6,55; S = 0,93; S^2 = 0,87; $S\bar{x}$ = 0,28; $\Delta\bar{x}$ = 0,63; Δx = 3,00; RSD = 0,14	0,075
No adhesive residue on the skin after removal	$\bar{x}$ = 4,73; S = 1,19; S^2 = 1,42; $S\bar{x}$ = 0,36; $\Delta\bar{x}$ = 0,80; Δx = 4,00; RSD = 0,25	0,054
No peristomal complications	$\bar{x}$ = 10,00; S = 0,00; S^2 = 0,00; $S\bar{x}$ = 0,00; $\Delta\bar{x}$ = 0,00; Δx = 0,00; RSD = 0,00	0,114

Based on the data obtained, a petal diagram was built (Figure 1), demonstrating the impact of each consumer property on the customer's choice.

Based on the weights obtained during the expert evaluation for each of the specific consumer properties of adhesive plates, a comparative analysis of adhesive plates from different manufacturers can be carried out, which

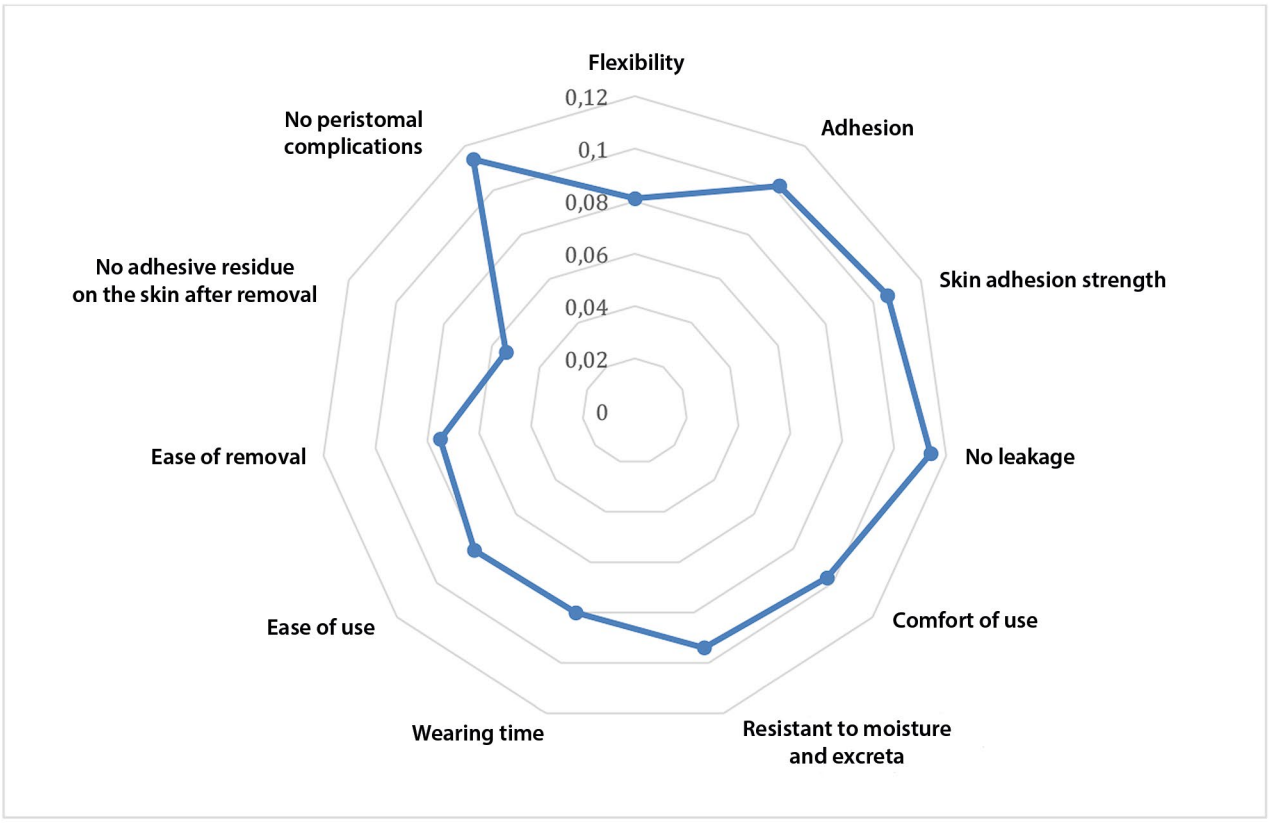

Figure 1. **Radar chart of consumer properties**

requires a survey of patients and/or nursing staff with experience in using these adhesive plates. At the same time, each consumer property of adhesive plates can be evaluated by respondents on a scale from 1 to 5, where 1 is "completely dissatisfied" and 5 is "completely satisfied".

For example, in the case of a comparison of two adhesive plates, the data calculation table can be presented as follows (Table 6).

Based on weighted estimates for adhesive plates from different manufacturers, a radar comparison chart can be plotted.

As well, based on the answers received during the survey, a correlation can be made between the parameters characterizing the consumer properties of adhesive plates, which can be obtained as a result of an experimental study, and consumer preferences.

CONCLUSION

As a result of the study, the main consumer properties of polymer compositions of adhesive plates were determined, which include: the absence of adhesive

Table 6. An example of an adhesive plate comparison table

Consumer properties of adhesive baseplates	Average score in points $i_{av.}$		Weighted coefficients (WC)	Weighted score	
	Product No. 1 ($i_{av.1}$)	Product No. 2 ($i_{av.2}$)		Product No. 1 $i_{av.1}$/WC	Product No. 2 $i_{av.2}$/WC
Flexibility	$i_{av.1} = (a_1 + a_2 + a_3 + a_n)/n$, where a – respondent's answer from 1 to 5; n – number of respondents	$i_{av.2}=(a_1 + a_2 + a_3 + a_n)/n$, where a – respondent's answer from 1 to 5; n – number of respondents	0.081	$i_{av.1}$/0.081	$i_{av.2}$/0.081
Adhesion	—"—	—"—	0.102	—"—	—"—
Skin adhesion strength	—"—	—"—	0.106	—"—	—"—
No leakage	—"—	—"—	0.115	—"—	—"—
Comfort of use	—"—	—"—	0.097	—"—	—"—
Resistant to moisture and excreta	—"—	—"—	0.094	—"—	—"—
Wearing time	—"—	—"—	0.080	—"—	—"—
Ease of use	—"—	—"—	0.081	—"—	—"—
Ease of removal	—"—	—"—	0.075	—"—	—"—
No adhesive residue on the skin after removal	—"—	—"—	0.054	—"—	—"—
No peristomal complications	—"—	—"—	0.115	—"—	—"—

residues on the skin after removal, easy removal, wearing time, flexibility, ease of use, resistance to moisture and secretions, comfort of use, adhesion, strength of skin adhesion, prevention of leakage and the absence of peristomal complications. Based on expert assessment, weight coefficients for each consumer property were determined, a method of comparative assessment of urostomy pouches and stoma pouches was proposed.

The developed technique can serve as a basis for the development of methods for comparative evaluation of analogue drugs intended for the skin application, including transdermal patches, based on their consumer properties.

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