

## PRELIMINARY STUDIES ON THE USABLE PROPERTIES OF INNOVATIVE WOUND DRESSINGS

**Magdalena Kucharska, Marcin H. Struszczyk<sup>1)</sup>,  
Magdalena Cichecka<sup>1)</sup>, Kinga Brzoza-Malczewska**

*Institute of Biopolymers and Chemicals Fibres,  
ul. M. Skłodowskiej-Curie 19/27, 90-570 Lodz, Poland  
e-mail: biomater@ibwch.lodz.pl*

*Institute of Security Technologies "MORATEX"  
Skłodowskiej-Curie 3, 90-965 Lodz, Poland  
e-mail: mstruszczyk@moratex.eu*

### **Abstract**

*There is endless and growing demand on a novel and innovative wound dressings, which except basic protective performance accelerate the process of wounds healing and/or replace the patient skin function. The studies on the new wound dressings result from the need of the quick and effective treatment of wounds, such as: having no tendency to heal, posttraumatic wounds, scalding wounds, ulcerations or bedsores. Chitosan is a biopolymer originated from chitin by N-acetylation. Due to the special behavior, such as: biological activity, it is linked to polymers having several and multifunctional applications, especially for designing of medical devices. The aim of the research was to evaluate the comprehensive performance of several kinds of chitosan prototypes of innovative wound dressings made of various usable form of chitosan. The evaluation of mentioned prototypes of wound dressing was carried out using the guidelines from series of PN-EN 13726 Standards harmonized with UE Directive 93/42/EEC and 2007/47/WE for medical devices.*

**Key words:** *wound dressings, microcrystalline chitosan sponges, preclinical studies, medical devices.*

## **1. Introduction**

There is endless and growing demand on an innovative wound dressings, which except basic protective performance accelerate the process of wounds healing and/or replace the patient skin function. The studies on the new wound dressings result from the need of the quick and effective treatment of wounds, such as: having no tendency to heal, posttraumatic wounds, scalding wounds, ulcerations or bedsores. Chitosan is a biopolymer originated from chitin by N-acetylation. Due to the special behavior, such as: biological activity, it is linked to polymers having several and multifunctional applications, especially for designing of medical devices.

Physical and mechanical properties, comfort usage and safety of novel wound dressings are assessed in laboratory tests according to suitable standards. During the research the following wound dressing will be evaluated:

- sponge made of microcrystalline chitosan for acceleration of wound healing;
- sponge made of chitosan or chitosan/alginate fibrids for primary wound treatments;
- sponge made of chitosan/carboxymethylcellulose for wounds treatments in first phase of healing;
- sponge made of chitosan gel as an artificial skin replacement;
- gel for wet treatment of wounds;
- films for directs treatment of wounds.

The more appropriate standards are used the closer to clinical application. Aforementioned methods are described in series of harmonized EN 13726 Standards [1 - 4] enabling to test:

- aspects of absorbency;
- moisture vapor transmission rate;
- water-proofness;
- conformability;
- antibacterial behavior;
- odour control.

This work shows selected aspects of functionality assessment and safety of primary wound dressings according to [1 - 4] in the context of possibility their usage in a risk assessment process according to PN-EN ISO 14971:2009 Standard [5] that leads to determining usability of a dressing and its application.

All parts of PN-EN 13726 Standards [1 - 4] specify test methods and do not contain performance requirements and are harmonized with EU Directive for medical devices 93/42/EEC and 2007/47/WE as well as polish act from 20<sup>th</sup> May 2010 about medical devices (Dz. U. No. 107, poz. 679) as well. Moreover the fifth part of EN 13726 is currently on project stage.

The aim of the research is:

- to estimate of selected physico-mechanical parameters of an innovative wound dressings made of various usable form of chitosan taking into the account the clinical usage;
- to elaborate of optimal requirements for the risk analysis of novel wounds dressings.

The evaluation of above-mentioned prototypes of a wound dressings was carried out using the guidelines from series of PN-EN 13726 Standards [1 - 4] harmonized with UE Directive 93/42/EEC and 2007/47/WE for medical devices.

## **2. Materials and methods**

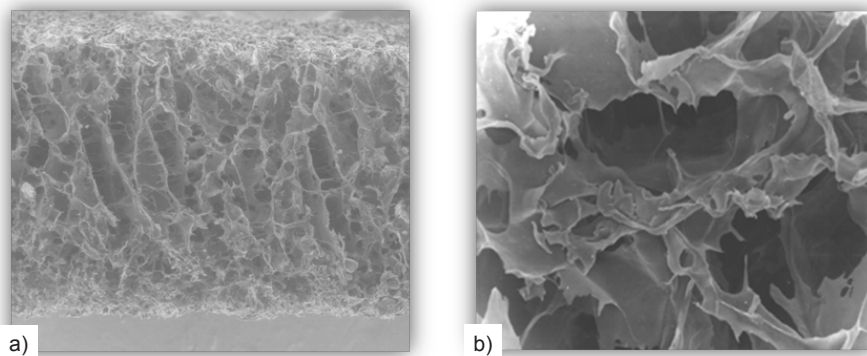
### **2.1. Materials**

The sponges made of microcrystalline chitosan or acceleration of wound healing before and after sterilization using accelerated electron beams (28 kGy) were applied for this study. The novel wound dressings were designed by the lyophilization procedure elaborated by IBWCh. The SEM microphotographs of wound dressings are shown in **Figure 1**.

### **2.2. Methods**

Physical and mechanical properties of chitosan, innovative wound dressing were assessed in the accredited Metrology Laboratory of Institute of Security Technologies „MORATEX” according to PN-EN 13726 Standards in range described in **Table 1**.

The range of studies was selected based aspects of the safety and performance aspects of the risk analysis according to [5].



**Figure 1.** SEM microphotographs of: a) – cross-section of microcrystalline chitosan sponge (mag.  $\times 100$ ); b) – surface of the microcrystalline chitosan sponge (mag.  $\times 200$ )

**Table 1.** Range of study [1-4].

| Title of standard  | Standard               | Determined parameters   |
|--|------------------------|---|
| „Test methods for primary wound dressings - Part 1: Aspects of absorbency”   | PN-EN 13726-1:2005 [1] | <ul style="list-style-type: none"> <li>■ free swell absorptive capacity;</li> <li>■ fluid handling capacity;</li> <li>■ gelling properties;</li> <li>■ dispersion characteristics.</li> </ul> |
| „Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings” | PN-EN 13726-2:2005 [2] | Moisture vapour transmission rate (MVTR) of a wound dressing when in contact with: <ul style="list-style-type: none"> <li>■ water vapour;</li> <li>■ liquid.</li> </ul>                       |
| „Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness”                   | PN-EN 13726-3:2005 [3] | <ul style="list-style-type: none"> <li>■ waterproofness.</li> </ul>   |
| „Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability”                   | PN-EN 13726-4:2005 [4] | <ul style="list-style-type: none"> <li>■ extensibility;</li> <li>■ permanent set.</li> </ul>  |

### 3. Results and discussion

#### 3.1. Aspects of absorbency

Both variants of microcrystalline chitosan sponges (unsterile and sterile) were tested according to [1] in range of:

- free swell absorptive capacity;
- fluid handling capacity;
- gelling properties;
- dispersion characteristics.

**Figure 2** shows the results of free swell absorptive capacity for sterile and unsterile microcrystalline chitosan sponges.

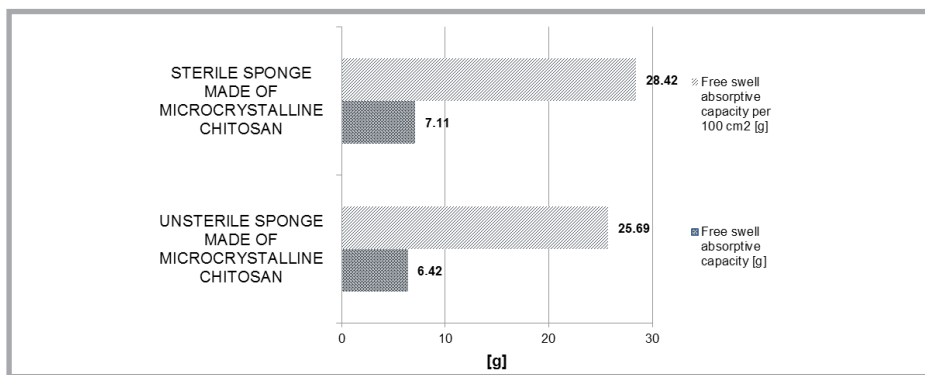
The sterilization process using accelerated electron beam yielded in the increase in free absorption capacity of sterile microcrystalline chitosan sponge by approx. 11% as compared with the unsterile sponge. Above-mentioned phenomenon may be connected with the change in the internal structure of the novel wound dressing affected by the radiation. The sterilization process resulted in enhance of the internal structure of the sponge influenced by the significantly higher absorption capacity.

The fluid capacity of sponges increases if time of contact with the tested fluid is prolonged: for unsterile sponges by 9.1%, whereas for sterile only by 7.8% (**Figure 3**). The higher value of the parameter of total fluid handling capacity was found for the unsterile wound dressings, especially after 48 h.

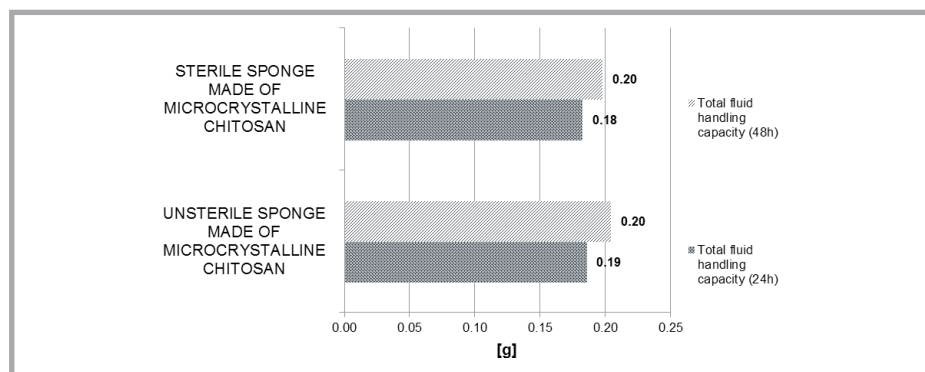
Both samples tested according to [1] did not show any dispersion or gelling behavior allowing pre-select the tested microcrystalline chitosan sponges as a resorbable wound dressing with high capacity for body fluid uptake.

#### 3.2. Aspects of moisture vapour transmission

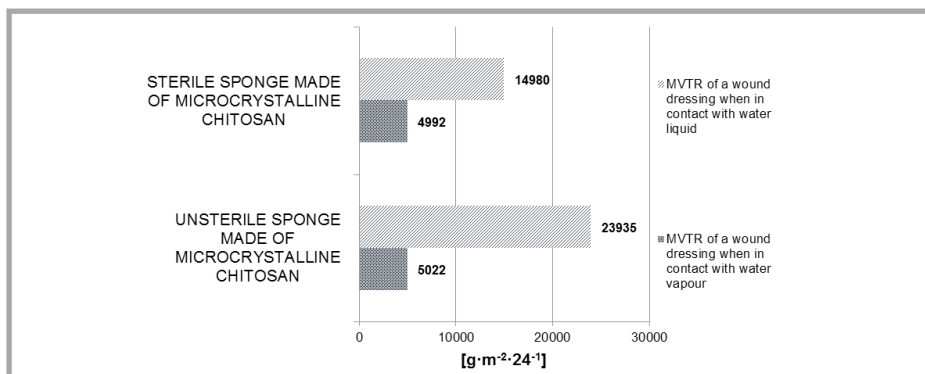
**Figure 4** shows the moisture vapour transmission of microcrystalline chitosan sponges, both unsterile or sterile, when contact with water liquid or water vapour.



**Figure 2.** Free swell absorptive capacity in g/100 cm<sup>2</sup> or in g for sterile and unsterile microcrystalline chitosan sponges.



**Figure 3.** Total fluid handling capacity for 24 h or 48 h for sterile and unsterile microcrystalline chitosan sponges.



**Figure 4.** MVTR (contacting with water liquid or water vapour) of sterile and unsterile microcrystalline chitosan sponges.

Unsterile sample of tested sponge shows significantly higher MVTR when contact with water liquid as compared with sterile sample. MVTR of either unsterile or sterile sponges when contact with water vapour are approximately comparable. Above-mentioned results confirm the changes in internal structure of microcrystalline chitosan sponges affected by the radiation sterilization. The process of sterilization may in some aspects totally change the usable properties of wound dressing. Taking into the account above it is strongly recommended to prepare whole characteristic of wound dressing after the sterilization process.

### **3.3. Aspect of waterproofness**

Both samples (sterile and unsterile) failed test of waterproofness and are not durable application of the hydrostatic head of 500 mm of water for 300 s to the circular area.

### **3.4. Aspects of conformability**

All variants of microcrystalline chitosan sponges show break before they reach 20% extension. Parameters describing the conformability were not possible to determine.

## **4. Conclusions**

PN-EN 13726 Standards [1-4] allow estimating the level of hazards connected with several aspects of:

- absorbency;
- moisture vapour transmission rate;
- dispersion characteristic and gelling properties;
- waterproofness;
- conformability;

It is the most important to screen optimal design of novel wound dressings during preclinical studies and before clinical study.

The next stages of research will be to evaluate the changes in the physical and metrological (usable) parameters for accelerated aged samples of innovative wound dressings according to ASTM 1980F:2002 Standard [6].

## **5. Acknowledgments**

*The work was carried out within research project No. N 508 389 137 „STUDY ON THE EVALUATION OF THE PROTOTYPES OF INNOVATIVE WOUND DRESSINGS” funded by the Ministry of Science and High Education.*

## **References**

1. PN-EN 13726-1:2005 „Test methods for primary wound dressings - Part 1: Aspects of absorbency”.
2. PN-EN 13726-2:2005 „Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings”.

3. *PN-EN 13726-3:2005 „Non-active medical devices - Test methods for primary wound dressings - Part 3: Waterproofness”*
4. *PN-EN 13726-4:2005 „Non-active medical devices - Test methods for primary wound dressings - Part 4: Conformability”.*
5. *PN-EN ISO 14971:2009 “Medical devices -- Application of risk management to medical devices”.*
6. *ASTM 1980F:2002 “Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices”.*

