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Establishment of BM-TRIZ Biomedical Inventive Principles and Design-thinking Methods for Innovative Design of Medical Devices Based on A New Polymeric Biomaterial Containing Polyvinyl Alcohol Foam via an Air-foaming Procedure

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Abstract

A new biomaterial containing polyvinyl alcohol foam with a fully open-cell microstructure would be designed and prepared via air-foaming procedure in this study. The resulting biomaterials might provide several functional properties for various clinic potential applications. Also, the resulting biomaterial containing polyvinyl alcohol foam could be employed to prepare a series of new medical device for the clinic potential applications. Further, a systematic design-thinking method for innovative design of medical device would be built up and provided. A series of new medical devices would be designed and obtained.

Keywords: Medical Device; Biomaterial; Open-cell microstructure; Design thinking Methods

Abbreviations: HPLC: High-performance Liquid Chromatography; DNPH: Dinitrophenylhydrazine.

Introduction

Medical innovation, designs and developments start with analyzing and identifying the market, the need of which is untapped or unmet or there is a more efficient way to address those clinic particular needs. The clinic needs would be anything that delivers a solution such as a new or better way of monitoring health, enhanced care delivery solutions, materials, devices or technologies to deliver better administration and treatments that supports health. For these reasons, numerous materials would be proposed, modified and used for clinic applications such as synthetic materials and natural materials [1-14]. In usual, the materials of medical dressings must provide water absorption, porosity, mechanical strength, water permeability, and/or breathability to satisfy clinic needs. In this study, a series of designed biomaterials containing polyvinyl alcohol foam were designed and prepared by using a clean air-foaming process without an addition of starch to build up a special fully open-cell microstructure. The process without any addition of starch could avoid fungi contaminations. A systematic method containing biomedcial TRIZ (BM-TRIZ) inventive principles and a new design-thinking method could be built up and applied in this study. The variables in TRIZ are tied up with engineering problems, although TRIZ is powerful enough to be a universal problem solving method [15-19]. However, development and design of medical devices was limited by using the TRIZ method. In order to design a new medical device with good potentials in clinic applications, a

systematic design-thinking method must be established.

In this study, methodology for innovative design of new medical derives based on guide information of TRIZ inventive principles and new design-thinking routines would be established. A new designed biomaterial containing polyvinyl alcohol foam with a fully open-cell microstructure would be prepared. A series of new medical devices based on the resulting biomaterial containing PVA foam could be designed by using the resulting systematic method combined BM-TRIZ inventive principles and new design-thinking routines.

Materials and Methods

Materials

Designed polyvinyl alcohol foam could be prepared in this work by using a designed super clean air-foaming process and the medical grade Cenefom materials (PARSD Pham. Tech. Co.).

Water Permeability

The water permeability of the resulting polyvinyl alcohol foam dressings could be determined by following ASTM D4491 (standard test methods for water permeability).

Residual Formaldehyde

The high-performance liquid chromatography (HPLC) analysis and 2,4-dinitrophenylhydrazine(DNPH) was employed for determination of residual formaldehyde which follows ISO17226-1 and ISO 10993-12:2012. While there are no standardized methods available at present for testing absorbents, the following is a suggested protocol. Determine the volume of extraction vehicle that each 0.1 g or 1.0 cm2 of material absorbs such as PVA foam as an additional corrected volume. Then, in performing the material extraction, add the additional corrected volume to each 0.1 g or 1.0 cm^2 in an extraction mixture as stated in ISO 10993-12:2012 for preparation of PVA foam samples.

Results and Discussion

Preparation of New Biomaterial Containing Polyvinyl Alcohol Foam

In this work, a new biomaterial containing polyvinyl alcohol foam was obtained, purified, and characterized. Low residual formaldehyde content (<10 ppm) was determined. SEM morphology of the resulting biomaterial containing polyvinyl alcohol foam was determined. The resulting biomaterial containing polyvinyl alcohol foam with a fully open-cell microstructure was observed as shown in Figure 1. The diameter of the open cell in the fully open-cell microstructure could be observed in a range between 100μm and 500μm. The fully open-cell microstructure would provide high water permeability and high water absorption. The resulting PVA foam with higher water permeability than 85% was obtained. The high water absorption of the resulting biomaterial could be obtained (>13 times).

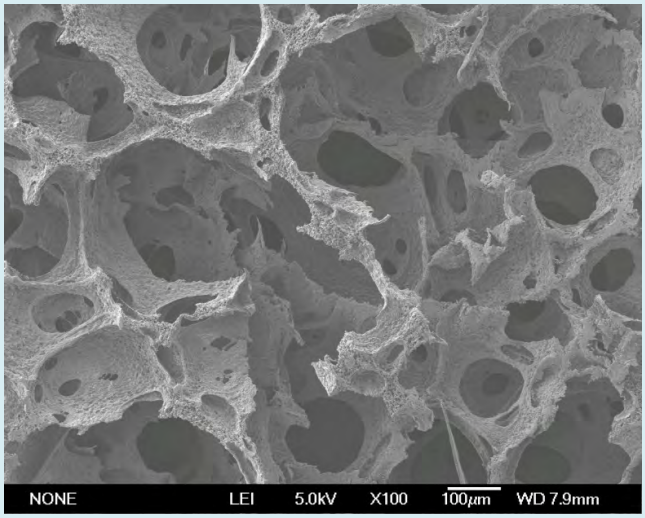


Figure 1: SEM morphology of the new polyvinyl alcohol foam material via air-foaming process(x100).

BM-TRIZ Biomedical Inventive Principles and Design-Thinking Methods for an Innovative Design of New Medical Devices

In this study, the 40 principles of TRIZ could be employed to build up BM-TRIZ biomedical inventive principles and design-thinking methods for an innovative design of new medical devices such as segmentation(1), extraction(2), local quality(3), asymmetry(4), merging(5), universality(6), Russian dolls(7), anti-weight(8), preliminary anti-action(9), preliminary action(10), beforehand cushioning(11), equipotentiality(12),The other way round(13),spheroidality/curvature(14),dynamics(15),partial or excessive actions(16), another dimension(17), mechanical vibration(18), Periodic action(19), continuity of useful action(20), skipping(21), blessing in disguise(22), feedback(23), intermediary(24), self-service(25), copying(26), cheap short-lived objects(27), mechanics substitution(28), pneumatics and hydraulics(29), flexible shells and thin films(30), porous materials(31), colour changes(32), homogeneity(33), discarding and recovering(34), parameter changes(35), phase transitions(36), thermal expansion(37), strong oxidants(38), inert atmosphere(39) and composite materials(40).

A series of new medical devices based on the resulting PVA foam materials were designed for new clinic potential

applications depending on some selected BM-TRIZ biomedical inventive principles as shown in Tables 1-6. The different features such as space conversion features, time conversion features, subject transformation features, force conversion features, material or form conversion features, and environmental conversion features were considered for inventive designs of new medical devices as design-thinking routines. Table 1 showed new designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles such as 1, 3, 4, 7, 14 and 17 with space conversion features. For example, the shape of nasal packing product with PVA foam was changed from a symmetrical membrane to an asymmetrical nasal packing product for anatomical reasons as shown in Table 1 (MD4, selected BM-TRIZ inventive principle 4).

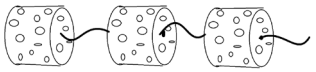
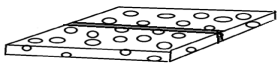
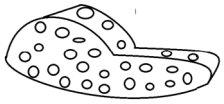
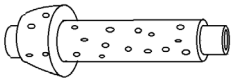
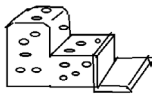
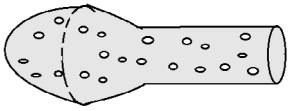
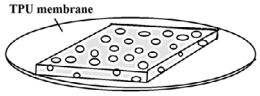
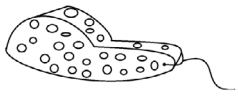
Space conversion			
New design number	**BM-TRIZ inventive principles**		**New Design for clinic application**
MD1	1	Segmentation	
MD3	3	Local Quality	
MD4	4	Asymmetry	
MD7	7	Russian dolls	
MD14	14	Spheroidality – Curvature	
MD17	17	Another dimension	

Table 1: New designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles with space conversion features.

Table 2 showed new designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles such as 9, 10, 11, 15, 19, 20, and 21 with time conversion features. Changing the continuous suction module to a periodic suction module, NPWT dressings with periodic suction could be obtained (MD11 in Table 2, selected BM-TRIZ inventive principle 11).

Time conversion			
New design number	**Selected BM-TRIZ inventive principles**		**New Design for clinic application**
MD9	9	Preliminary anti-action	
MD10	10	Preliminary action	
MD11	11	Beforehand cushioning	

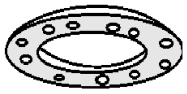
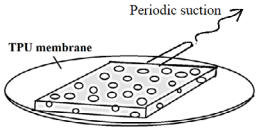
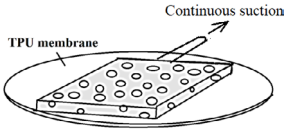
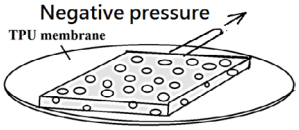
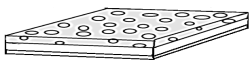
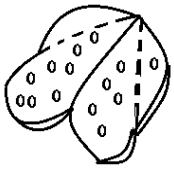
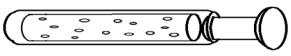
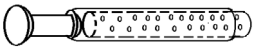
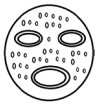
MD15	15	Dynamics	
MD19	19	Periodic action	
MD20	20	Continuity of Useful Action	
MD 21	21	Skipping	

Table 2: New designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles with Time conversion features

Table 3 showed new designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles such as 2, 5, 6, 13, 22, 23, 24, 25, 26, 27, 28, and 34 with subject transformation features. For example, the medical device of eye drain was obtained by singling out an only necessary part of a LASIK ring as shown in Table 3 (MD2). Low cross-linked PVA foam with a shape of nasal cavity was employed as a medical degradable ENT dressing (MD13 in Table 3, selected BM-TRIZ inventive principle 13).

Subject Transformation			
New design number	**Selected BM-TRIZ inventive principles**		**New Design for clinic application**
MD2	2	Extraction	
MD5	5	Merging	
MD6	6	Multiple functions	
MD13	13	The other way round	
MD22	22	Blessing in disguise	
MD23	23	Feedback	
MD24	24	Intermediary	
MD25	25	Self-service	

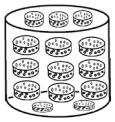
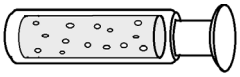
MD 26	26	Copying	
MD27	27	Cheap short-lived objects	
MD 28	28	Mechanics substitution	
MD34	34	Discarding and recovering	

Table 3: New designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles with subject transformation features

Table 4 showed new designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles such as 8, 12, 16, 18, and 29 with force conversion features. For example, the medical device of NPWT dressings was designed by introducing a continuous suction module, a suction tube, and a NPWT dressing based on the resulting biomaterial containing PVA foam as shown in Table 4(MD12, selected BM-TRIZ inventive principle 12).

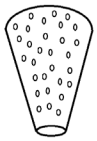
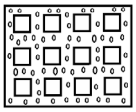
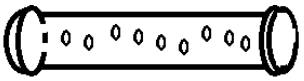
Force conversion			
New design number	**Selected BM-TRIZ inventive principles**		**New Design for clinic application**
MD8	8	Anti-weight	
MD12	12	Equipotentiality	
MD16	16	Partial or excessive actions	
MD18	18	Mechanical vibration	
MD29	29	Pneumatics and hydraulics	

Table 4: New designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles with force conversion features

Table 5 showed new designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles such as 31, 32, 33, 35, 36, 37, and 40 with material or form conversion features. For example, the chitosan oligosaccharide modified cross-linked polyvinyl alcohol complex foam (COS/ cPVACF) dressings was designed as a new medical device (MD40 in Table 5, selected BM-TRIZ inventive principle 40).

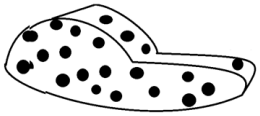
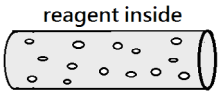
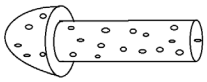
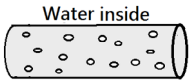
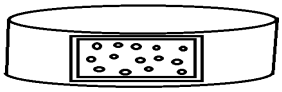
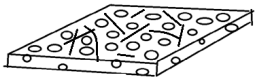
Material or form conversion			
New design number	**Selected BM-TRIZ inventive principles**		**New Design for clinic application**
MD31	31	Porous materials	
MD32	32	Colour changes	
MD33	33	Homogeneity	
MD35	35	Parameter changes	
MD36	36	Phase transitions	
MD37	37	Thermal expansion	
MD40	40	Composite materials	

Table 5: New designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles with material or form conversion features.

Table 6 showed new designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles such as 38 and 39 with environmental conversion features. For example, strong oxidant (HClO3)-containing PVA foam with a big size was considered as a new medical device of wet NPWT dressings (MD38 in Table 6, selected BM-TRIZ inventive principle 38).

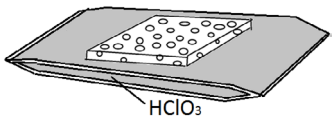
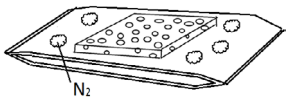
Environmental conversion			
New design number	**Selected BM-TRIZ inventive principles**		**New Design for clinic application**
MD38	38	Strong oxidants	
MD39	39	Inert atmosphere	

Table 6: New designs of medical devices based on PVA foam depending on selected BM-TRIZ inventive principles with environmental conversion features.

In this study, an innovative medical device design-thinking procedure was established as shown in Figure 2. First, all properties of new biomaterials must be characterized for clinic potential applications. The proposal design must focus on targeting clinic needs. The selected biomaterial-TRIZ (BM-TRIZ) inventive principles could be built up and considered for specific designs of new medical devices to satisfy targeting clinic needs. The targeting model devices could be obtained as listed in Tables 3~6. Finally, summary of technical documentation (STED) information could be employed for risk assessments. A series of novel medical devices could be obtained for clinic needs (Figure

2). Also market information and patent information could be further considered for market reasons.

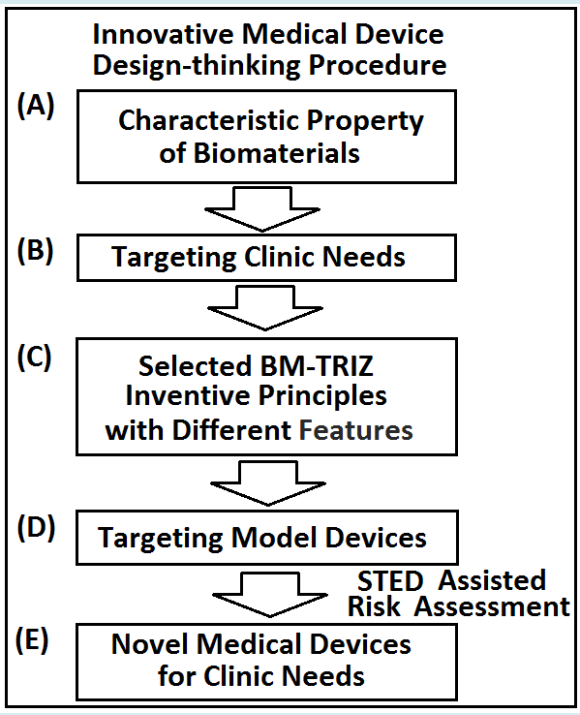


Figure 2: Innovative Medical device design-thinking procedure in this work.

Conclusion

A kind of new biomaterial containing polyvinyl alcohol foam was successfully designed and prepared via air-foaming procedure in this work. The resulting biomaterial containing polyvinyl alcohol foam could be employed to prepare a series of new medical device for various clinic applications. Establishment of BM-TRIZ biomedical inventive principles and a design-thinking method for innovative design of medical device was achieved. The systematic design method of PVA foam for the clinic applications of medical dressings could be used to demonstrate the capability of the proposed method. Importantly, summary of technical documentation (STED) information was suggested to be employed for references assisted risk assessments. A series of new medical devices were designed by using the resulting BM-TRIZ biomedical inventive principles and the design-thinking method to satisfy various clinic needs.

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