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Review Article

Fabrication of biodegradable nano medical patches incorporating a sustained-release pharmacological agent using electro-spinning technique

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ABSTRACT

Nano-polymer (self-disappearing) medical patches loaded with a long-acting drug (each substance separately) were created by electro-spinning synthetic polymers PVA and PVP at a rate of 10%W for each polymer and adding various medicinal substances, such as diclofenac de ethylamine and gentamicin, in concentrations of 5%w each. The morphological structure of the produced samples was further studied using a scanning electron microscope (SEM) and X-ray diffraction (XRD) before they were turned into a medical adhesive and tested directly on a human hand. This approach has already proven to be effective in delivering the medicine to the affected area without the use of any intermediaries. It is relatively simple to use, safe for medical usage, and inexpensive due to the lack of expensive industrial apparatus required for production.

1. Introduction

Instruments based on electro-spinning technology to generate nano-fibers are beginning to pique the interest of scientific researchers worldwide due to their ability to treat the majority of medical problems swiftly, efficiently, and affordably. As a result, global demand for nanomaterials is rapidly increasing. The nanomaterials market is estimated to have cost $2.6 trillion in 2015. Medical diagnosis, immunization, therapy, and even healthcare items have all been transformed by various nanotechnology applications. Loading materials can be attached to NPs in a variety of ways, including chemically (coupling), physically (encapsulation), or through adsorption. The selection of acceptable nano-materials for loading is determined by the application's purpose. Cell fusion allows the transfer of numerous chemicals (drugs, imaging aids, or chemotherapeutic agents) as well as biological materials (antigens or antibodies). They can also be used to provide heat and light to specific cells as needed.[1,2]

Electro-spinning is a technology for fabricating fibers with extremely small diameters because of its ability to manufacture nano-materials and structures of extraordinary quality in terms of their properties. Bioactive materials and drugs can be encapsulated in polymeric nano-fibers as a drug delivery system,[3] where nano-fiber networks have a high percentage of porosity and surface area, through coaxial or uncoaxial Electro-spinning or through some other method that includes adding medicinal materials and linking them as nano-particles to the nano-fiber network, of antimicrobial/antioxidant substances.[4,5] The only method for manufacturing nano-fibers from polymer solutions or melts using electrostatic force is electro-spinning. Because it relies on manufacturing nano-fibers from a polymeric solution at low temperatures, electro-spinning is unique and unusual.

It has found widespread application in a variety of fields due to the ease with which the diameters of the nano-

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fibers produced when changing certain working conditions, such as controlling the rate of flow of the solution over time, controlling the amount of electrical tension applied, or controlling the chemical composition of the spun solution. This is because any change in one of the operating conditions alters the composition of the resultant fiber.Figure 1 depicts the operation of the Electro-spinning machine and the creation of nano-fibers.[5]

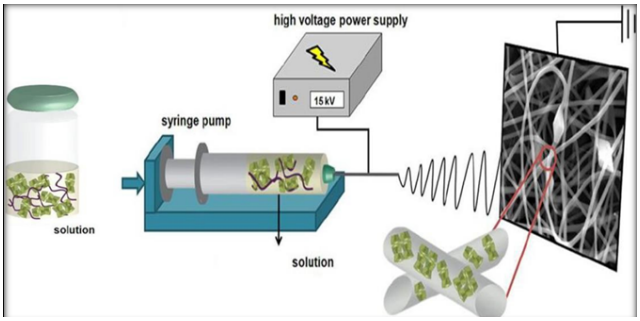

Figure 1: The electro-spinning Machen and the resulted nano-fibers.[6]

The skin, the largest organ in the body, functions as a defense and barrier against bacteria and other living things. However, multiple incidents, specific operations, or certain conditions (including diabetes) may cause the skin to be ripped or torn. Because wound healing is a complex process that strives to restore the natural anatomical structure and function of the skin, it is divided into three stages: inflammatory, proliferative, and granulation. It is expected that the wound's condition and spread will worsen, especially in the elderly and diabetics (including protein production and wound contraction). Furthermore, in order to prevent infections, a strict antibiotic regimen is utilized to cure wounds throughout the reconstruction phase, inflicting a significant financial burden on the patient. As a result, there is an urgent need to halt the spread of microbes and reduce the likelihood that they will do so by using antibiotics that are safe for human use or herbal extracts to accelerate wound healing and reduce the need for pharmaceutical chemicals like antibiotics, which will help prevent side effects from their use. Wound dressings were one example. The majority of its basic composition is composed of plants, plant fibers, and animal fats. Because of technological innovation, it now contains therapeutic compounds that expedite the healing process.[6,7] Because of its specific properties, electro-spinning is an effective process for producing nano-fibers, a type of nanostructure structural that can be used in medical plasters and wound dressings. Electrically spun nano-fiber wound dressings have a high surface area to volume ratio, high wound exudate absorption, high air permeability, mimic extracellular matrix (ECM) morphology for tissue damage, and the potential for slow drug release from nano-fiber-containing materials.[8–10]

It is becoming increasingly popular to employ medications in combination with natural and synthetic medical polymers to generate nano-fibers in order to combine the physical qualities of the nano-fiber structure with the chemical and antibacterial capabilities of drugs. This is done to prevent harmful side effects and the spread of antibiotic resistance. In recent years, plant-based antibiotics have included active extracts, essential oils, and pure oils. These compounds were mixed with a few medical polymers to create therapeutic nano-fibers using electro-spinning.[11,12]

Because some drugs taken orally have undesirable side effects, researchers devised a drug delivery system by electro-spinning of various polymeric solutions with different pharmaceuticals depending on the application to be produced.[13–15] This method employs drug-loaded nano-fibers with long-term release. This improves the body's ability to repair wounds and treats the burn area on the skin by utilizing a range of components such as proteins, lipids, amino acids, vitamins, and enzymes.[16] There hasn't been much research in this area, and what there is is scattered.[17,18]

Diclofenac is one of the most effective NSAIDs for treating both acute and chronic pain and inflammation. It is a nonsteroidal anti-inflammatory medication (NSAID) derived from acetic acid and benzene. Encapsulating drugs in polymeric nano-fibers can make them more clinically efficacious and selective. Tolerance, therapeutic indication, and polymer nano-fibers can protect drugs and reduce toxicity or side effects. Despite the fact that diclofenac is a potent anti-inflammatory, analgesic, and antipyretic, it has been suggested to add diclofenac to polymeric nano-fibers for local postoperative pain relief, and a 10-day continuous release of diclofenac has been recorded while maintaining the mechanical strength of the wound closure. It does, however, have negative toxicological effects.[8–20]

Furthermore, gentamicin, an antibiotic[17] used to treat severe or critical bacterial infections, aids in the removal of acne-causing germs and is utilized to treat bacterial skin dissections and eczema.[10,21,22]Figure 2 shows the chemical structures of Diclofenac sodium DS and Gentamicin GM.

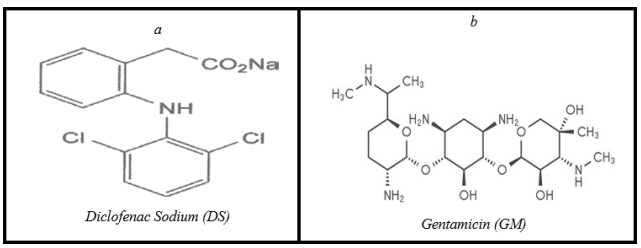

Figure 2: Chemical structure of **(a)** Diclofenac Sodium DS and (**b**) Gentamicin GM

A range of polymers, including natural and synthetic polymers and polymer blends, have been used to manufacture drug-filled polymeric nano-fibers utilizing the electro-spinning technique. Polyvinyl alcohol and polyvinyl pyrrolidone are two of the most important polymers used in the medical business to make nano-fibers (medical plasters).[23]

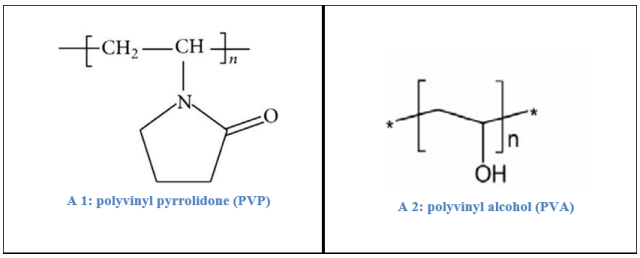

Figure 3: Chemical structure of (A 1) polyvinyl pyrrolidone (PVP) and (A 2) polyvinyl alcohol (PVA)[23]

2. Materials and Methods

2.1. Materials

We acquired polyvinyl alcohol (PVA), polyvinyl pyrrolidone (PVP) (Mw 360,000), Gentamicin (GM) 80, which was added to the liquid component in drug-loaded samples, and Sigma- the diclofenac sodium salt (DS). The cement liquid was made up of 50:50 pure ethanol and distilled water.

2.2. Sample preparation

1. 20 g of PVA powder was dissolved in 45 mL of distilled water and 45 mL of Absolute Ethanol (20% w/v). To obtain a homogeneous and crystal-clear solution, the solution was agitated for 3 hours at 80oC using an electromagnetic stirrer.
2. 20 g of PVP powder was dissolved in 45 ml of distilled water and 45 ml of Absolute Ethanol (20% w/v). To obtain a homogeneous and crystal-clear solution, the solution was agitated for 3 hours at 60oC using an electromagnetic stirrer. Then combine the two solutions, yielding a polymeric solution containing PVA/PVP 10%w/v of each polymer separately.
3. Meanwhile, Diclofenac 5% powder was combined with PVA/PVP at a 10%v/w ratio. Gentamicin 5% was combined with PVA/PVP at 10%v/w. Before electro-spinning, all solutions were allowed to cool to ambient temperature for several hours.

2.3. Electro-spinning process

The electro-spinning apparatus used by the work team was used throughout the project. The three basic sections that comprise the intended device are the voltage booster, injection pump, and rotating cylindrical collector.[15] Two 5-ml syringes with 0.5 mm needles were loaded with 0.5 mm Electro-spinning fluid, resulting in a twofold yield of nano-fibers in half the time. A high voltage of 20 kV was applied across the needle with the collector covered in aluminum foil to make it easier to remove the fibers from the collection and revolving at a speed of 100 rpm. The injector head was separated from the collector by 100 mm, and the flow rate was set to 0.5 ml/hr. All samples were spun for ten hours to achieve uniformly thick nano-fibers. Figure 4 depicts the work team's apparatus and its three primary elements.

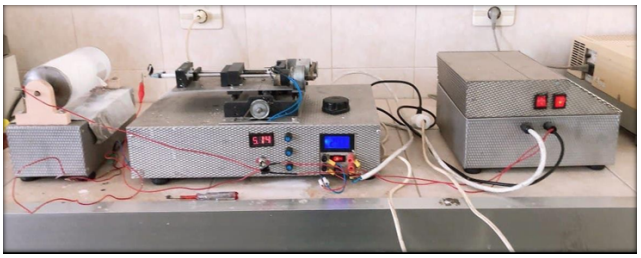

Figure 4: The device designed by the work team

Figure 5 also depicts the process of droplet extrusion and the formation of the Taylor cone, which is required for electro-spinning., leads to the accumulation of charges on top of the formed droplet and it stretches at an angle of 49.3^{o}, and this called Taylor Cone is formed where tangential electrical stress causes the polymeric solution to move and it helps for creating hydro-dynamic pressure on the droplet's surface and the reciprocal effects between electrical.[24]

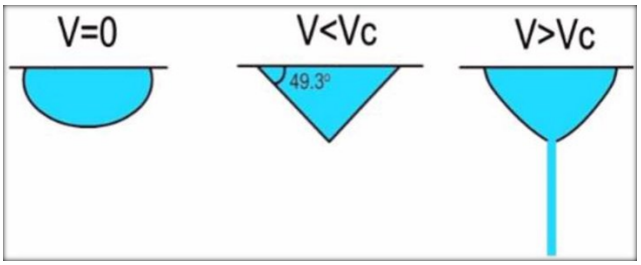

Figure 5: Taylor cone

Figure 6 shows the placement of the extruded fibers on the revolving cylindrical collector, with the injector head linked to the positive electrode and the collection connected to the negative electrode. Figure 6 (a) also shows the fibers being extruded and assembled on the rotating cylindrical collector, where the injector head is connected to the positive electrode and the collector to the negative electrode, and Figure 6 (b) shows the shape of the finished fibers on an aluminum sheet after the electro-spinning process is complete.

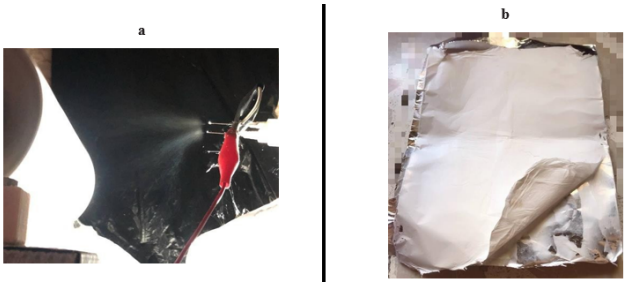

Figure 6: (a) The extrusion of the fibers, **(b)** the shape of the resulting fiber

2.4. Surface morphology characterizations (SEM)

The surface morphology of Nano-fibers was studied using SEM (Scanning Electron Microscopy), an American-made Tuscan Veca 2 model with a 12 kV accelerating voltage. The average diameter distribution of nano-fibers was determined using image analysis software (Image, version 1.49). The nano-fiber specimen was platinum sputtered prior to SEM imaging.

2.5. Physicochemical characterizations

FTIR spectroscopy (FT/IR-4100, Jasco, Japan) was used to determine the chemical composition of the nano-fibers. FTIR spectra in the wavelength range of 4000-600 cm-1 were scanned at a temperature of 25°C.

3. Result and Discussions

3.1. Nano fiber characterization

SEM micrographs (Figure 7) were utilized to analyze any surface variations between the PVP/PVA loaded DS, GM nano-fibers and the original nano-fibers. According to SEM micrographs, continuous is uniform and bead-free, and nano-fibers were formed in all instances. Figure 7 (P1) demonstrates the production of fine, homogeneous fibers and continuous fibers of pure PVP nano-fibers with an average diameter of 85 nm and no bead formation inside the fibers. There is no bead formation within the PVA nano-fibers, and their average diameter is 110 nm, according to Figure 7 (P2), which demonstrates the production of fine, homogeneous, and continuous PVA nano-fibers.[25,26] The average diameter of the nano-fibers formed when PVA and PVP are mixed (at a 50:50 ratio) is illustrated in Figure 7 (P3). The forces of attraction between the molecules of one type of polymer induce the rise in average diameter, but the overall diameter of the fibers remains unaltered. The PVA/PVP nano-fibers had an average diameter of 190 nm, a smooth surface, and fine, continuous fibers without beads.[2] The addition of diclofenac sodium salt DS, which is highly soluble in water, to the polymeric mixture of polyvinyl alcohol PVA and polyvinyl pyrrolidene PVP preserved the smooth, fine-structured matting while slightly increasing the average diameter of the resulting nano-fibers. The average diameter of the PVA/PVP/DS nanofibers was 225 nm.[16]

Gentamicin, a highly water-soluble antibiotic, was introduced to a polymeric blend of polyvinyl alcohol and polyvinyl pyrrolidene, resulting in nano-fibers with a small increase in average diameter while maintaining mats with a smooth and fine structure. The average diameter of the PVA, PVP, and GM nano-fibers was 265 nm.[20]

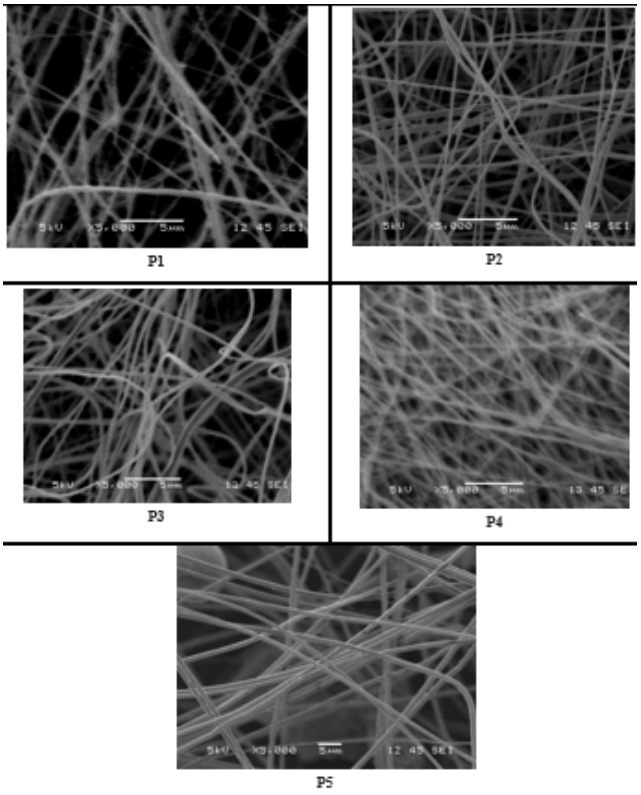

Figure 7: SEM micrographs showing the fibers morphology Electro-spinning from (**P1**) PVP; (**P2**) PVA; (**P3**) PVP/PVA; (**P4**) PVP/PVA/DS; (**P5**) PVP/PVA/GM

The Table 1 also shows the average diameter of the nano-fibers for each sample.

Table 1: The average diameter of the nano-fibers for each sample.

Samples	Composition	Diameter (nm)
P1	PVP	180
P2	PVA	194
P3	PVP+PVA	200
P4	PVP+PVA+ Diclofenac	220
P5	PVP+PVA+ Gentamicin	250

3.2. Infrared spectrophotometer (FT/IR)

By comparing the single and previously prepared virgin polymers, FTIR spectroscopy was used to confirm the

interaction between the two PVA/PVP manufactured polymers. Figure 8 depicts the FTIR spectra of (1) PVA nano-fibers, (2) PVP nano-fibers, PVA/PVP nano-fibers, (4) Gentamicin GM, (5) Diclofenac Sodium DS, (6) PVA/PVP/GM, and (6) PVA/PVP/DS.

FT-IR spectral range Figure 8(1) of PVA electro spun nano-fibers demonstrated the characteristic PVA absorption bands: broad(C-H) alkyl stretching band (2950 cm1) and stretching hydroxyl bands (O-H) 3370 cm1, 1045 cm1 (C-C), 1260 cm1 (C-O), 1480 cm1 (CH2 bend).[27]

Figure 8 (2) depicts the FT-IR spectra of the PVP electro spun fibers. PVP has notable peaks at 3450 (O-H stretching), 2900 (aliphatic C-H), 1640 (amide C=O), and 1284 cm1 linked to (C-N).[28]

Figure 8 (3) depicts the FT-IR spectrum of PVA/PVP nanofibers. The vibrations of C-N, C-O, C-O-C, amide C=O, acetate C=O, (aliphatic C-H), and OH were ascribed to the peaks at 1050, 1250, 1365, 1590, 1650, 2900, and 3400 cm1.[29]

The FT-IR spectrum of PVA/PVP nano-fibers with PVA and PVP nano-fibers, the existence of both PVA and PVP structure in blend nano-fibers was analyzed, as shown in Figure 8,[3] the distinctive absorption bands of PVA/PVP.

FT-IR spectrumFigure 8 (4) of Gentamycin Sulfate (GM) depicted the typical absorption bands of (GM): 3490 and 1250 cm1 were assigned to the vibrations of -O-H Stretch and -C-O-C Stretch, respectively.

FT-IR spectrum Figure 8 (5) of Diclofenac Sodium (DS) demonstrated the typical absorption bands of (DS): 3480, 2950, 1550, and 700 cm11 were ascribed to the vibrations of -N-H Stretch, -C-H alkyl, -C=C Aromatic, and -C-Cl, respectively.

FT-IR spectral range Figure 8 (6) of PVA/PVP/GM depicted the typical absorption bands of PVA/PVP/GM: 3500, 3050, 1650, 1590, 1550, 1250, and 1050 were attributed to the vibrations of -O-H Stretch, -C-H Stretch, -C=O acetate, -C=O amide, -CH2 Bend, -C-O-C Stretch, and -C-N.

FT-IR spectral range Figure 8 (7) PVA/PVP/DS exhibited the distinctive absorption bands of PVA/PVP/DS: 3500, 3050, 1650, 1590, 1550, 1500, 1050, and 700 were attributed to the vibrations of -N-H Stretch, -C-H Stretch, -C=O acetate, -C=O amide, -C=C Aromatic, -CH2 Bend, -C-N, and -C-Cl correspondingly[30–33].

The FTIR spectroscopy for each bent of material is shown in Table 2.[2]

3.3. Test of self-disappearing for produced patches

To test the self-disappearing capacity of the medical patches developed, the patches were directly put to human skin, as shown in Figure 9.

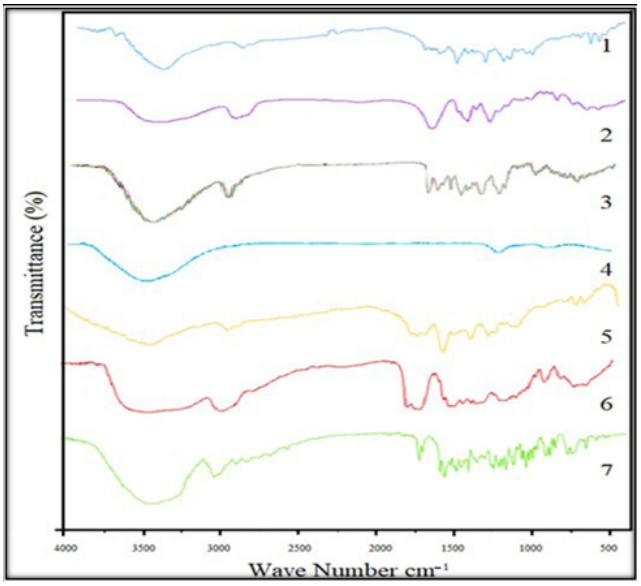

Figure 8: (FT-IR) spectra of (1) PVA nano-fibers, (2) PVP nano-fibers, (3) PVA/PVP nano-fibers, Gentamicin GM, (5) Diclofenac Sodium DS, (6) PVA/ PVP/GM, (6) PVA/PVP/DS.

Figure 9: Self-disappearing ability of prepared medical patches.

4. Conclusion

Self-disappearing medical labels (dissolved in live tissue) were created by co-electro-spinning polymers (PVP/PVA) at a rate of 10%W for each polymer and in the presence of two medicinal substances independently, diclofenac sodium DS and gentamicin sulphate GM.

When gentamicin and diclofenac were combined, the average diameter of the Nano-fibers increased slightly compared to their previous state. SEM pictures showed a homogeneous, fragile, and porous structure in all samples, with no adhesion or entanglement. In addition, the IR

Table 2: FTIR spectroscopy for each bend of material.

No.	Effective Material	Wave Number (cm^{-1})	Functional Group
1	PVA	3370	O–H Stretch
		2950	-C-H alkyl
		1480	–CH2 Bend C–O
		1260	Stretch C-C
		1045	
2	PVP	3450	O–H Stretch
		2900	-C-H alkyl
		1480	–CH2 Bend
		1640	–C=O
		1284	-C-N
3	PVA/PVP	3400	O–H Stretch
		2900	-C–H Stretch
		1650	–C=O acetate
		1590	–C=O amide
		1365	-C-O-C
		1250	-C-O
		1050	-C-N
4	Gentamycin Sulfate (GM)	3490	-O-H Stretch
		1250	-C-O-C Stretch
		3480	-N-H Stretch
5	Diclofenac Sodium (DS)	2950 1550	-C-H alkyl -C=C Aromatic
		700	-C-Cl
6	PVA/PVP/GM	3500	-O-H Stretch
		3050	-C–H Stretch
		1650	-C=O acetate
		1590	–C=O amide
		1550	–CH2 Bend
		1250	-C-O-C Stretch
		1050	-C-N
7	PVA/PVP/DS	3500	-N-H Stretch
		3050	-C–H Stretch
		1650	–C=O acetate
		1590	–C=O amide
		1550	-C=C Aromatic
		1500	–CH2 Bend
		1050	-C-N
		700	-C-Cl

spectra revealed strong interactions between the two copolymers (PVP/PVA) and the two additives (DS, GM), resulting in separate and potent functional peaks.

When evaluating the ability of the medical patches to absorb medications when loaded with them, we discovered a good capacity for the patches to self-disappear.

5. Source of Funding

None.

6. Conflict of Interest

None.

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