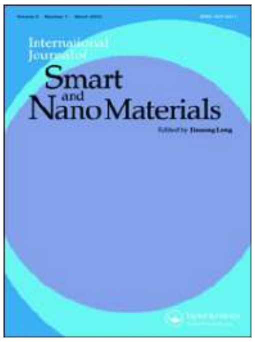

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Design of 4D printed shape-changing tracheal stent and remote controlling actuation

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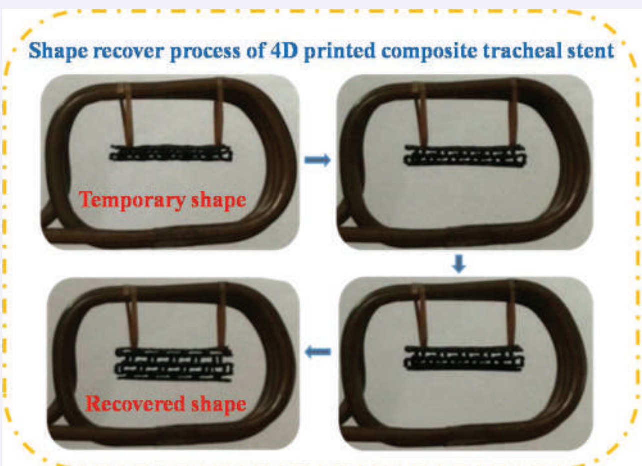
ABSTRACT

As a kind of medical treatment device, shape memory tracheal stent has a good application prospect. The biodegradable stent can effectively reduce the damage to patients and improve the therapeutic performance of stents. In this work, a series of shape memory polylactic acid (Fe_3O_4) composite tracheal stents were manufactured by 4D printing. The composite tracheal stents with different structures were designed. Moreover, with the addition of magnetic particles Fe_3O_4, the shape memory PLA/Fe_3O_4 composite tracheal stent has a magnetic driving effect. Under the magnetic field, the shape recovery process is completed within 40 s, and the shape recovery rate is more than 99%. Moreover, the 4D printed tracheal stent was also triggered by the irradiation of infrared lamp to realize the remote controlling recovery. The research on the structure design and driving method of 4D printing tracheal stent expands the application scope of shape memory polymer composites in biomedical field, provides a new way for personalized implantable medical devices and minimally invasive surgery. It is of great significance for better precision medical treatment.



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KEYWORDS
Shape memory polymer composite; 4D printing; shape-changing tracheal stent; magnetic field actuation; infrared light actuation

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1. Introduction

Shape memory polymers (SMPs) and their composites (SMPCs) can recover from the preset temporary shape to the initial shape under the external stimuli including heat, light, electricity and magnetism. Due to the advantages of large deformation and strong recovery ability, SMPs and SMPCs have attracted much attention in biomedicine, aerospace, flexible electronics and other fields. Polylactic acid (PLA) with good biocompatibility has been widely used in biomedical field [1–4]. The shape memory epoxy-acrylate hybrid photopolymer was synthesized by Yu [5], and the complex structure was prepared by stereolithography. Sonawane, V.C [6]. et al. prepared tacrolimus-eluting scaffolds with shape memory PLA and poly-L-glycolic acid (PLGA) by solvent casting. The mixed hydroxyapatite of PLA was used to repair the bone defect. However, the traditional manufacturing process cannot provide accurate complex structures for SMPs, and it is difficult to further meet the requirements of high-tech fields such as minimally invasive medicine and precision medicine for the complexity of smart structures.

4D printing is a novel concept proposed in recent years. The 3D printing technology and smart materials were integrated in 4D printing process to realize the accuracy fabrication of smart materials [7–10]. The printed structures can change shape, physical properties or function autonomously with the change of time and under the conditions of external excitation such as temperature, electric field, magnetic field and solution [11–13]. 4D printing has the characteristics of complex structure forming, fast processing, high utilization efficiency of raw materials [14,15]. It has been widely used in many fields, such as flexible electronic devices [16–18], biomedical field [19–24], robot [25,26]. 4D printing completely breaks through the limitations of traditional manufacturing methods in material, complex structure and error accumulation. Without the need of mold, we can produce very complex, highly personalized, topological complex structural parts to meet various needs, and realize the complex, programmable, customized and personalized manufacturing of smart structures and devices. According to the different characteristics of raw materials, there are many 4D printing methods can be selected such as fused deposition modeling (FDM), direct ink writing printing, digital light processing and stereolithography printing, in which all can provide accurate structure and convenient fabrication process compared with traditional methods [27,28]. Wei Zhang et al. [29] prepare 4D textile structure composites with PLA as raw material by 3D printing technology, and further studied their shape memory performance. Combined with the integrated design of bionic structure, the application of 4D printing in biomedical field is expanded, and the vascular stent, tracheal stent and bone tissue scaffold with smart bionic structure which can be actively deformed under the stimulation are manufactured, so as to realize the combination of smart materials and personalized complex structures in biomedical field. Fenghua Zhang et al. [30] introduced Fe_3O_4 particles into shape memory PLA matrix to prepare shape memory composites which can be driven under magnetic field, and tested the temperature range of the composites during the shape recovery process. Cheng Lin et al. [31] prepared a shape memory cardiac occluder based on shape memory PLA/Fe_3O_4 composites, and completed the preliminary experiment in mice. In addition to the above structures, SMPs and SMPCs have been developed for manufacturing various implantable medical devices including tracheal stents.

The trachea can keep the respiratory tract unobstructed [32], but the trachea is very fragile and vulnerable to various diseases [33–35]. As a common critical disease, airway stenosis is the main airway restriction caused by airway obstruction, which can cause dyspnea and even endanger the life of patients. However, due to the fragility and special structure of the trachea, it is difficult to repair the injured trachea [36–39]. Till now, endotracheal stent intervention is the most common and effective treatment of tracheal stenosis. In this process, the stent is implanted into the narrow trachea to reshape the diameter of the trachea, quickly relieve the airway stenosis and relieve the symptoms of dyspnea. NiTi shape memory alloy tracheal stent are commonly used in clinic. The main disadvantages of NiTi stents are difficult reduction, easy to cause tracheal obstruction if collapse occurs. In addition, it is difficult to remove after implantation. Moreover, tumor or granulation growth is easy to pass through the mesh. In view of the shortcomings of the above shape memory alloy tracheal stent, the shape memory PLA composite tracheal stent was designed with SMP as material, and the collapse of the stent was repaired with SMP of the stent. The degradability of SMP makes it unnecessary to remove the stent. Combined with 4D printing, the shape memory tracheal stent with complex and optimized structure can be customized.

In this work, 4D printing of shape memory PLA composite tracheal stent was prepared. By doping Fe_3O_4 particles into shape memory PLA, the composite has a magnetic driving effect. The complex 3D structure of the composite was prepared by fused deposition modeling (FDM) printer. The properties of the composite were characterized by Fourier infrared spectroscopy, thermogravimetric analysis and differential scanning calorimetry. The structure of shape memory tracheal stent was optimized, and the shape recovery performances of 1D filament, 2D printing plane and 3D shape memory tracheal stent were investigated. The infrared thermal imager was used to monitor the temperature distribution during shape recovery process of 4D printing shape memory tracheal stent.

2. Experimental section

2.1 Fabrication of 4D printing composite filaments

The shape memory PLA/Fe_3O_4 composite filament used in this experiment was prepared by Harbin Institute of Technology (HIT) [29]. Fe_3O_4 was purchased from Aladdin Chemistry Co., Ltd., Shanghai, China. 10 g shape memory PLA was mixed with certain proportion of Fe_3O_4 particles (8 wt%, 12 wt%, and 18 wt%) and dichloromethane was added. After stirring for 6 h at the speed of 250–300 r/s, the mixed solution was poured into the mold and placed at room temperature for a period of time until the solvent evaporated to form a shape memory PLA/Fe_3O_4 composite film. The shape memory PLA/Fe_3O_4 composite filament was extruded by twin-screw extruder, and the composite was optimized by six temperature controllers. The filament diameter was controlled at 1.75 ± 0.5 mm.

2.2 4D printing of composite structures

According to the size parameters of shape memory alloy stent in clinical application, the basic parameters of SMP tracheal stents were designed. The 3D model of tracheal stent was established by Unigraphics NX. On the basis of 3D model, the shape memory PLA/Fe_3

O_4 composite trachea stent was printed by FDM printer. The printing parameters were set as follows: nozzle temperature 205°C, hot bed temperature 70°C, printing speed 33 mm/s, and layer thickness 0.2 mm. The printing process adopted PLA printing mode with no filler. The printer used in this process was Tianwei 3D printer Print-Rite 1.0 plus. In order to clearly describe the different performances of shape memory PLA/Fe_3O_4 composite trachea stents with different parameters, we design and print six different ones according different center angle and stent aperture. The basic printing parameters all follow the data mentioned above, and every sample with different parameters was printed at least three times to ensure the accuracy of test.

2.3 Characterization

In order to understand the chemical structure of the composite, FTIR analysis was carried out. The thermal properties of shape memory PLA/Fe_3O_4 composite were characterized by thermogravimetric analysis (TGA) and differential scanning calorimetry (DSC). The thermogravimetric analyzer is the model sta7300 produced by Hitachi Company. The temperature range is from room temperature to 700°C at the heating rate of 10°C/min and the protective gas is nitrogen. The differential scanning calorimeter is the sf1942 instrument of METTLER TOLEDO Company produced in Switzerland. The temperature range is from room temperature to 200°C at the heating rate of 10°C/min. The sample was 2 mm × 2 mm film. Three samples were tested for each test to ensure the accuracy of the experiment. The temperature distribution of 4D printing complex structures in the process of shape recovery was photographed by using an infrared camera (JENOPTIK InfraTec).

2.4 Magnetic field induced shape memory behaviors

The shape memory properties of 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent were characterized by magnetic field. The size of the alternating magnetic coil is 65 × 17 × 45 mm. The shape memory performance of 1D filament, 2D printing plane and 3D printing bracket under magnetic field was investigated. Firstly, the printed stent is heated above the transition temperature and the external force is applied to deform the stent into a temporary shape. When the temperature drops to room temperature and the external force is maintained, the temporary shape is fixed. Finally, the magnetic field is used to trigger the deformed stent to make it recover the original shape. It is a shape memory cycle process, showing one-way shape memory effect. The shape recovery process of the composite was recorded by camera. In addition, infrared camera was used to recorded the shape recovery process of 4D printing shape memory PLA/Fe_3O_4 composite tracheal stent, and the temperature distribution during the recovery process were observed. The shape memory behaviors of 4D printed structures were studied in 27.5 to 47.5 kHz magnetic field. Shape recovery rate (R_r) is an important parameter to characterize the shape recovery performance of SMPs. In this work, a 4D printed film is deformed as a 'U' shape and placed in the magnetic field to trigger the shape recovery process. The prepared three-layer printing film was put in a water bath at 90°C, bending it at a certain angle and recording the angle θ_0. The calculation of R_r according to the following Figure 1 and equations:

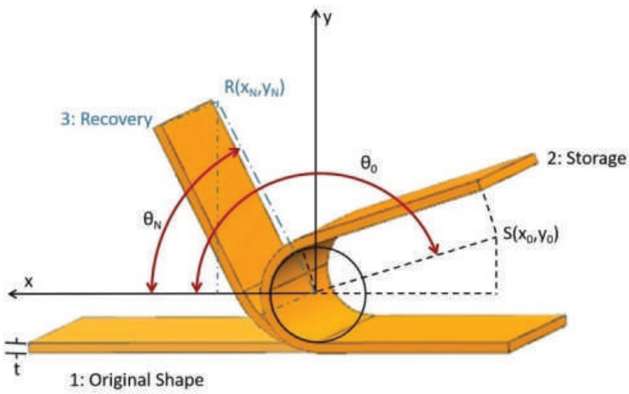

Figure 1. The principle diagram of shape recovery rate test.

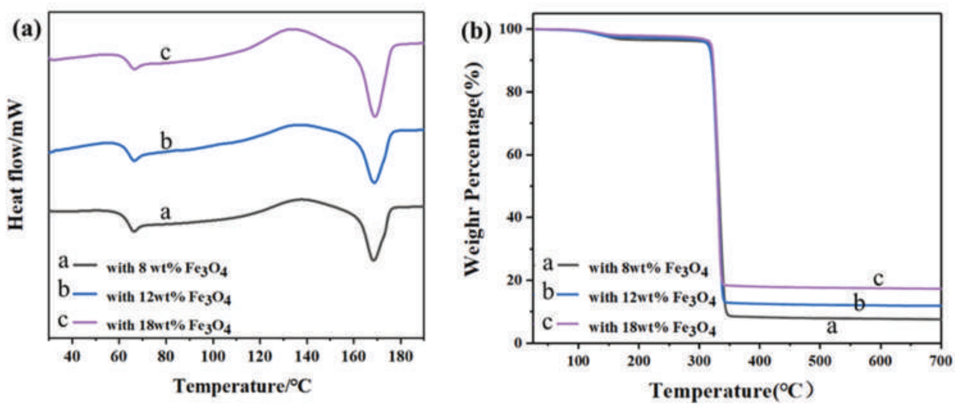

Figure 2. (a) DSC and (b) TGA curves of shape memory PLA/Fe_3O_4 composite with different contents of Fe_3O_4.

$$\theta_N = ArcCot\left(\frac{x_N}{y_N}\right)(N = 1, 2, 3 \ldots\ldots, 0 \le \theta_N \le 180^\circ) \quad (1)$$

$$R_N = \frac{\theta_0 - \theta_N}{\theta_0} \times 100\%(N = 1, 2, 3 \ldots\ldots) \quad (2)$$

Where R_N is the shape recovery rate of the Nth second unfolding, θ_0 is the initial bending angle, and θ_N is the Nth second bending angle.

3. Results and discussion

The thermal properties of 4D printed shape memory PLA/Fe_3O_4 composite were characterize by DSC and TGA. According to the DSC curves of Figure 2(a), the glass transition temperature, the crystallization temperature and the melting temperature of PLA/Fe_3O_4 composite are 66°C, 135°C and 170°C, respectively. Around 66°C, there is a significant drop

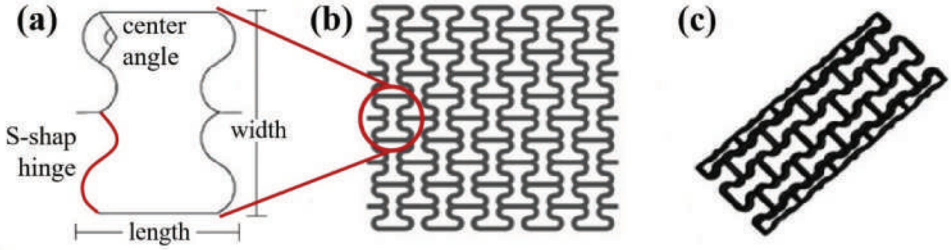

Figure 3. (a) Basic structural unit of shape memory tracheal stent, (b) Structural expansion diagram of tracheal stent, (c) 3D model of tubular tracheal stent.

in the curve, showing this temperature is the transition temperature of shape memory PLA/Fe_3O_4 composite polymer. When the temperature rises to about 110°C, the slope of the curve begins to increase, proving that the temperature at this time is the crystallization temperature of shape memory PLA/Fe_3O_4 composite polymer. At about 170°C, the curve shows a cliff drop, confirming that 170°C is the melting temperature of the shape memory PLA/Fe_3O_4 composite polymer. It is proved that the melting temperature is suitable for printing. The glass transition temperature and melting temperature were not affected by Fe_3O_4 content. Figure 2(b) shows the TGA curves of PLA/Fe_3O_4 composites with five different contents of Fe_3O_4. The composites began to degrade at 313°C, and the content of Fe_3O_4 had no obvious effect on it. Based on the thermal properties of PLA/Fe_3O_4 composite obtained from the above experiments, the nozzle temperature was set at 205°C in 4D printing process. And the deformation temperature was set at 90°C to obtain the temporary shape.

The basic structural unit of 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent is curved rectangle, as shown in Figure 3(a). The curved edge of S-shaped hinge was adopted to replace the right-angle edge of ordinary rectangle. Through the dispersion of stress and strain, the elastic S-shaped hinge structure can minimize the stress concentration and maintain the stability of the structure. By changing the arc of S-shaped hinge and adjusting the Poisson's ratio of structural elements, the designed shape memory tracheal stent can be changed according to the actual situation of patients, which has better pertinence. The deformation behavior of the shape memory tracheal stent is mainly completed by the deformation of the S-shaped hinge. The shape memory tracheal stents with different arc parameters have different deformation behaviors. According to the accuracy of 3D printer in printing the smooth structure, the connection between S-shaped hinge and straight edge was smoothed, which was conducive to more complete shape memory tracheal support in the forming process.

The tracheal stent structures with different parameters were designed based on the aperture (length × width), center angle and diameter of tracheal stent. As shown in Figure 3(a), the stent aperture is controlled by the length and width of basic structure unit. According to the aperture, the tracheal stents were divided into 5mm × 10mm, 3mm × 6mm and 2mm × 4mm of stent, respectively. According to the center angles of S-shaped hinge, it can be divided into 60°, 120° and 180°, respectively. The center angles of S-shape hinge refer to the center angle of marked arc in Figure 3(a). Based on the structural parameters of the commercial shape memory alloy stent, the stent diameter

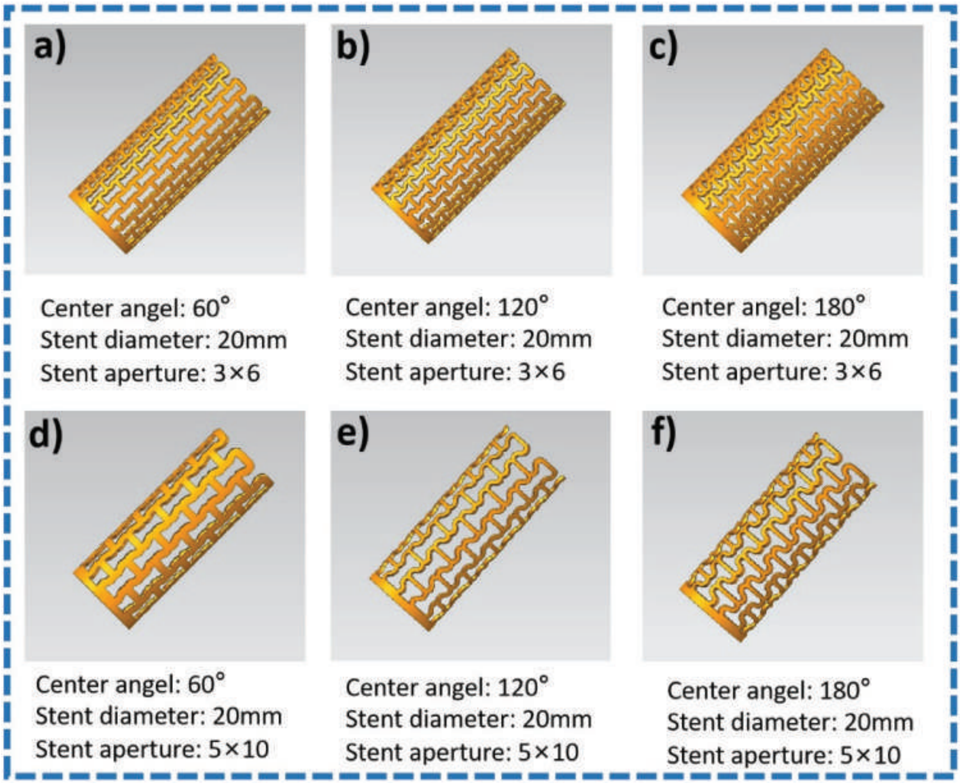

Figure 4. 3D model of shape memory tracheal stent with different structural parameters.

was 20 mm and 10 mm. The wall thickness was 1.5 mm and the length was 30 mm. The diameter of tracheal stents was designed in 10mm and 20mm, respectively. The tracheal stent designed with curved rectangle can improve the mechanical properties of the stent. Figure 3(b) shows the structural expansion of the tracheal stent. The basic structural units are arranged repeatedly to form a network structure. Figure 3(c) is a 3D model of the complete tracheal stent. The angle in the figure is the center angle of the variable curved rectangle.

In order to analyze the shape recovery performances of tracheal stents with different structures, the models were established with the center angle of curved rectangle (60°, 120° and 180°), stent diameter (10 mm and 20 mm) and stent aperture (3mm × 6mm and 5mm × 10mm) as variables. Six kinds of shape memory tracheal stent models with different structural parameters are designed, as shown in Figure 4.

Based on the 3D model of tracheal stent and PLA/Fe_3O_4 composite filaments, the shape memory PLA/Fe_3O_4 composite tracheal stents were printed by FDM. The 3D model of tracheal stent designed in Figure 4 was imported into the 3D slicing software to slice the 3D model. The printing route was preset and there were no supporting parts. In the printing mode, the formed stent did not need to cut the supporting part, which is conducive to the direct use of the stent. The process is shown in Figure 5. The shape memory PLA/Fe_3O_4 composite filament (Figure 5a) was fed into commercial FDM printer

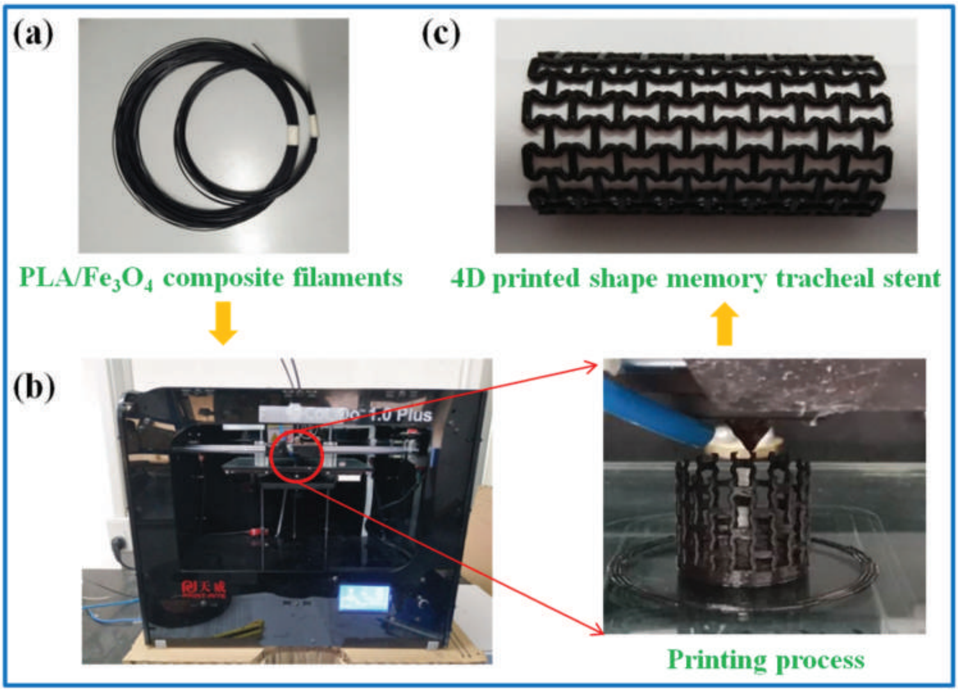

Figure 5. (a) Shape memory PLA/Fe_3O_4 composite filaments, (b) Commercial FDM printer and printing process, (c) 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent.

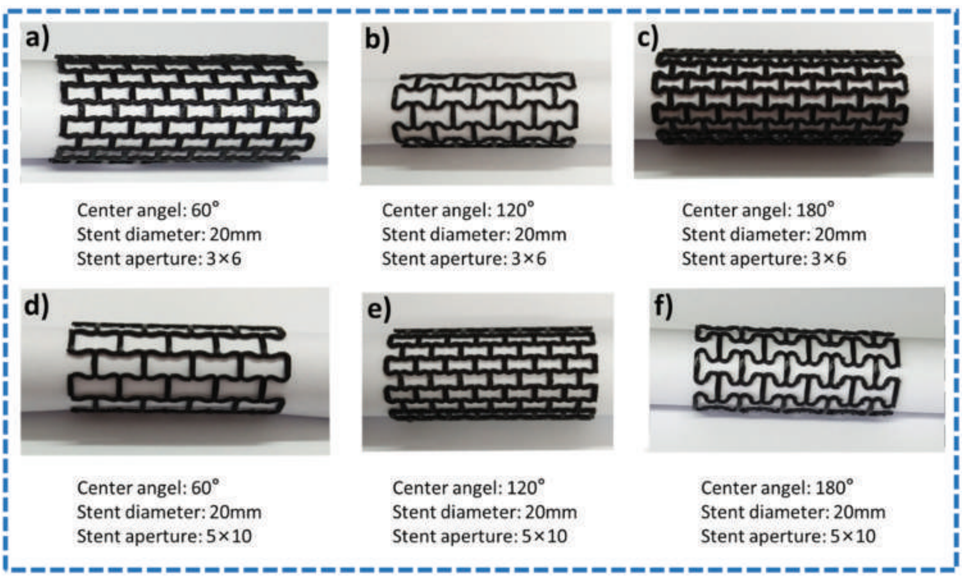

Figure 6. 4D printed shape memory PLA/Fe_3O_4 composite tracheal stents.

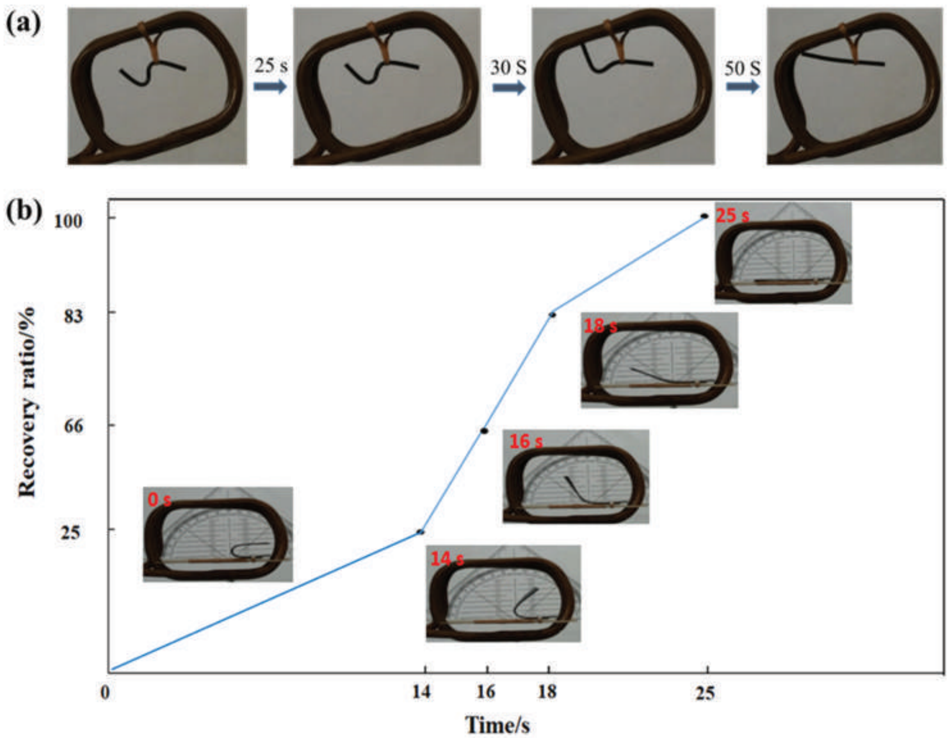

Figure 7. Shape recovery process under magnetic field: (a) 1D shape memory PLA/Fe_3O_4 composite filament, (b) 2D SMP film printed by FDM.

Table 1. Shape recovery performances of PLA/Fe_3O_4 filaments and 4D printed structures.

Sample	Shape recovery time	Shape recovery rate (R_r)
PLA/Fe_3O_4 filament	50 s	100%
4D printed film (1.5 mm)	25 s	100%
4D printed tracheal stent (2 × 4 mm)	40 s	100%
4D printed tracheal stent (3 × 6 mm)	21 s	100%

(Figure 5b). The filament melted in the nozzle and was extruded gradually with the movement of the nozzle. The printer prints layer by layer according to the preset program to obtain the shape memory PLA/Fe_3O_4 composite tracheal stent as shown in Figure 5(c).

Figure 6 shows the printed shape memory PLA/Fe_3O_4 composite tracheal stents with different structures. The outer diameter of the stent is 20 mm and the wall thickness is 1.5 mm. The shape memory tracheal stents are printed with three angles (60°, 120° and 180°), two apertures (3 × 6 mm and 5 × 10 mm) and two diameters (20 mm and 10 mm).

The shape memory behaviors of PLA/Fe_3O_4 composite filaments and printed PLA/Fe_3O_4 composite polymer structures were investigated. The shape memory behaviors of PLA/Fe_3O_4 composite filaments and printed structures were investigated. The shape recovery process of 1D PLA/Fe_3O_4 composite filaments is shown in Figure 7(a), which proves that the PLA/Fe_3O_4 composite filament has excellent shape memory property. In this test, the testing sample is 1.75mm diameter filament prepared by twin-screw extruder

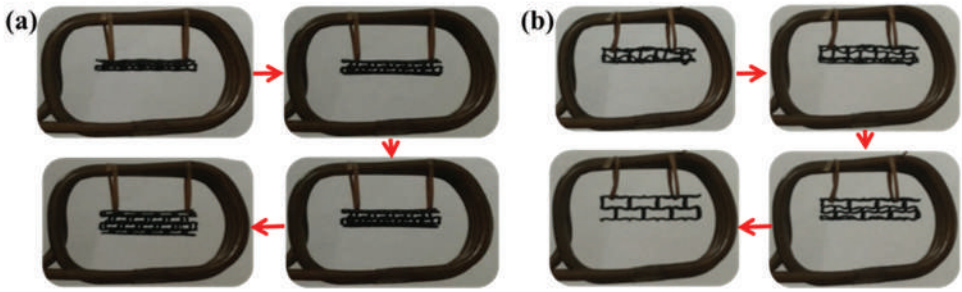

Figure 8. Recovery process of 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent: (a) tracheal stent 2mm × 4mm, (b) tracheal stent 3mm × 6m.

with shape memory PLA/Fe_3O_4 composite film as raw material. The deformed PLA/Fe_3O_4 composite filament was placed in the magnetic field, and it started to recover after 25 s. The shape recovery process was completed after 50 s, and the shape was returned to the original shape. The 2D printing PLA/Fe_3O_4 composite film was also test to describe the shape recovery performance of printing PLA/Fe_3O_4 composite polymers. In this test, the testing sample was printed by FDM with the thickness of 1.5mm, the width of 30mm and the length of 50 mm. The shape recovery process of the printed composite film is shown in Figure 7(b). Within 14 s, 16 s and 18 s, R_r was 25%, 66% and 83%, according to shape recovery rate (Figure 1 & equation 1, 2), respectively. The shape recovery process was completed in 25 s, showing excellent shape memory performance. It is proved that the design of the wall thickness of tracheal stent is feasible. Table 1 shows the shape recovery performances of PLA/Fe_3O_4 composite filaments and 4D printed film.

We investigated the shape memory behavior of 4D printed PLA/Fe_3O_4 composite tracheal stent. The printed shape memory PLA/Fe_3O_4 composite tracheal stent was heated in hot water to form a temporary shape. Compared with the original shape of tracheal stent, the volume of shape memory PLA/Fe_3O_4 composite tracheal stent was reduced, and it was easy to be implanted into human body in surgical treatment. Figure 8(a,b) show the shape recovery process of tracheal stent with different parameters (2mm × 4mm and 3mm × 6m). Under the magnetic field, shape recovery can start in 10 s to 20 s, and can be completed in 40 s. R_r was 100%, showing excellent shape memory performance. Table 1 shows the shape recovery performances of 4D printed tracheal stent with different units.

Shape memory tracheal stent can be divided into internal stent and external stent. The shape recovery process of the expandable tracheal stent is that the shape recovery of the shape memory tracheal stent with reduced volume occurs under the magnetic field, and the stent expands into the original tubular structure. The shape recovery process of the external tracheal stent is that the shape memory tracheal stent after molding is the unfolding plane, and the inner deformation of the unfolding plane after magnetic field actuation is the original tubular structure. In this experiment, the shape memory performance of tracheal stent was tested by two different expansion forms. It was shown that the 4D printed composite tracheal stent in this experiment has two deployment modes including internal deployment and external support, as shown in Figure 9. Figure 9(a) shows the shape recovery process of the internal expansion of 4D printing shape memory

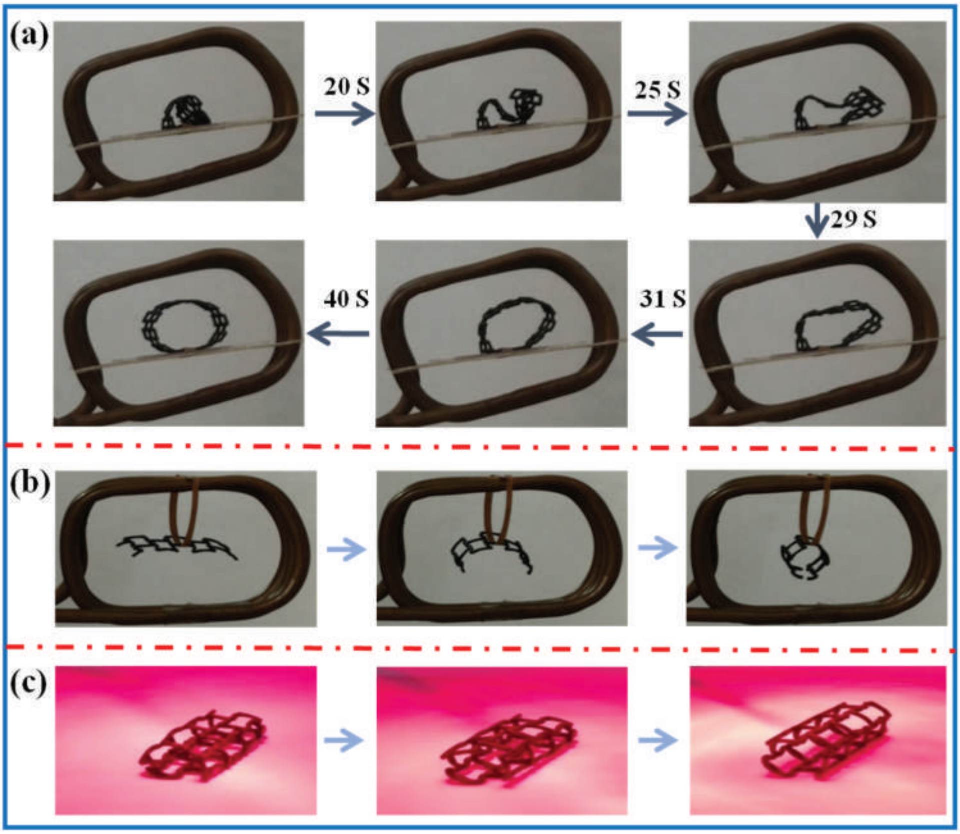

Figure 9. Recovery process of 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent: (a) tracheal stent 2 m × 4 mm, (b) tracheal stent 3 m × 6 m.

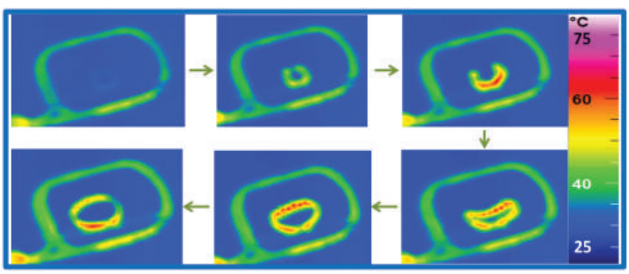

Figure 10. Shape recovery process of PLA/Fe_3O_4 composite tracheal stent under infrared thermal imaging.

tracheal stent. The volume of tracheal stent was greatly reduced by molding, which was conducive to the implantation in patients in clinical application. The shape memory tracheal stent was placed in the magnetic field. The shape recovery of 4D printed tracheal stent begins to recover after 20s and expanded outward. After 40s, the deformed shape recovered the original shape. When the diameter of the stent was compressed to 50%, the stent still had good shape memory performance, and can complete shape recovery in

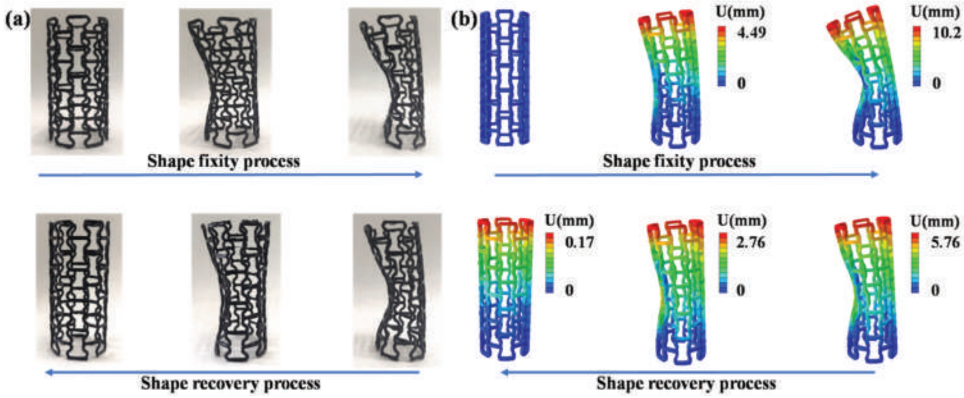

Figure 11. Shape recovery process of the tracheal stent bent in 30 º: (a) recorded pictures, and (b) simulation.

a short time. Figure 9(b) shows the shape recovery process of external 4D printed tracheal stent and the unfolded plane structure almost returns to the original cylinder structure. Moreover, the 4D printed shape memory tracheal stent can also be trigged by infrared light and the shape recovery process is shown in Figure 9(c). Infrared light heating mainly depends on the absorption degree of the heated sample. The higher the absorption rate, the better the infrared radiation effect. The transmittance of infrared light varies with the properties and thickness of the material. The molecular structure of the material is not very dense, and the material has characteristic vibration frequency at room temperature. Therefore, when the incident electromagnetic wave reaches the interface, the electromagnetic wave is rarely reflected, which is easier to pass through the interface and enter the surface layer, arousing resonance and turning into heat. Because the PLA/Fe_3O_4 composite tracheal stents are not simple substances with a single structure, some radiation waves that are not absorbed by the surface will be absorbed in varying degrees by the resonance of other substances in the process of deepening. After a period of time, the shape recovery of 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent began to occur, and the original shape was completely recovered. It can be used to give the tracheal stent smaller shape by the method of endowing before the tracheal stent implantation, which is convenient for implantation, alleviating the sufferings of patients and improving the success rate of the implantation.

According to the above experiments, 4D printed tracheal stent has excellent shape memory performance, and can complete the shape recovery process in a short time triggered by magnetic field. As a kind of medical treatment device that needs to be implanted into the human body, tracheal stent needs to ensure that the shape recovery process could not cause harm to the human body. A certain amount of heat is generated in magnetic field. The temperature range and distribution of the tracheal stent during the shape recovery process are characterized by infrared thermal imager. The temperature distribution of 4D printing tracheal stent during shape recovery process is shown in Figure 10. The maximum temperature of tracheal stent was 58.7°C, which was acceptable to human body.

Furthermore, in order to verify the functional application of tracheal stent in vivo, the stent was bent at an angle of 30 °, and the stent gradually returned to its original shape under the action of magnetic field, as shown in Figure 11(a). Combined with WLF time-temperature equivalent equation, the generalized Maxwell model was used to simulate the deformation process of 4D printed tracheal stent. The model of tracheal stent as shown in Figure 11(b) is established by using SolidWorks software package, and then imported into the commercial software ABAQUS (version 2016) for simulation. 42,088 secondary tetrahedral elements (C3D10) and 668 solid 8-node quadrilateral brick elements (C3D8R) were used to mesh the support. Neo Hooke model was used to describe the deformation behavior at high temperature. The time domain viscoelasticity defined by Prony series was combined with WLF equation to describe the deformation behavior in viscoelastic state. The relevant parameters are from the previous work [15]. The stress relaxation data was input into ABAQUS viscoelastic material module as shear test data. The relaxation data are fitted with KWW function. Apply 30 to the bracket. The simulation schematic diagram of angular displacement, bracket shaping stage and recovery stage is shown in the figure. The simulation results are consistent with the experimental results.

4. Conclusions

In summary, taking the curved rectangle of S-shaped hinge structure as the basic structural unit, the shape memory tracheal stents were designed. Combined with 3D printing technology, 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent was manufactured, which proved that it had excellent shape memory performance under magnetic field. The shape recovery behavior of 1D filament, 2D printing plane and 3D tracheal stent were investigated, and the temperature distribution during the shape recovery process was measured. The shape memory function of tracheal stent can reduce the volume of 4D printed stent and reduce the injury to the patients. Excellent shape memory performance, reduced volume and suitable medical temperature provide a good prospect for the application of 4D printed shape memory PLA/Fe_3O_4 composite tracheal stent.

Disclosure statement

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