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Design and Fabrication of NiTi Frame Utilizing for Endobronchial Valve

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Abstract. This study aims to design and fabricate the NiTi frame for Endobronchial valve (EBV) utilizing shape memory alloy wires. In order to evaluate the transformation and mechanical properties, heat-treatment at 450 °C, 500 °C and 550 °C respectively for 10 minutes are carried out. Results from differential scanning calorimeter (DSC) and load-unloading test by universal tensile testing machine were used to select the heat-treatment condition for NiTi frame fabrication. Moreover, NiTi frames were fabricated by braiding 12 wires together by braiding machine with take up speed of 10, 15, 20 and 25 mm/sec respectively and constant carrier speed at 25 rad/sec. It is confirmed that all specimens show superior superelasticity at body temperature. Radial force of frame was measured by Mylar test at 37 °C. Heat-treatment temperature at 500 °C was selected since the highest stress for induce Martensite and recovery stress was obtained. The highest radial force was obtained in NiTi frame fabricated with taking up speed of 15 mm/sec. It is able to be concluded that NiTi frame can be illustrated for Endobronchial valve frame in future work.

1. Introduction

Chronic Obstructive Pulmonary Disease (COPD) is currently the fourth leading cause of death in the world and projecting to be the 3rd leading cause of death by 2020 [1]. COPD is a lung disease which is mainly caused by smoking and long-term exposure to air pollution, dust, and chemical fumes. It causes the airways in your lungs to inflame and thicken. The chronic airflow limitation that is characteristic of COPD is caused by chronic bronchitis and emphysema. Chronic inflammation makes the airways structural changes by narrowing the airways and destroying the lung parenchyma, that leads to loss of elastic recoil of alveolar. Moreover, these changes decrease the ability of the airways to exhale and remain open during expiration [2]. Emphysema also the main cause of excessive breathing difficulty. The exercise also decreased. In case of severity of the disease increase, even basic daily activity can make the patient feel tired all the time [3].

Nowadays Emphysema can be treated with many methods such as using Lung Volume Reduction Surgery (LVRS), etc. It is known that LVRS is one of the potential ways to treat emphysema, but the process of surgery requires a long time. On the other hand, Endobronchial valve (EBV) is another solution for Emphysema treatment, which is a minimally invasive treatment option for emphysema [4].



EBV consists of NiTi frame which is made from Superelastic NiTi shape memory alloy (Nitinol) wires. Inside NiTi frame is attached with duckbill one-way valve to control airflow out of damaged lobe and block airflow into damaged lobe [5]. As a result of implanted EBV, the lung can reduce in volume and make damaged lung tissue can be healthier.

From above mentioned, since EBV is a new innovation for emphysema treatment and there is no publication report yet on the design and fabrication of EBV, it is a great challenge to study on design and fabrication of EBV, especially the locally made one which can be utilized physiologically for Asian people. This study focuses on the initial study of the effect of heat-treatment temperatures and braiding conditions on mechanical properties in order to fabricate superelastic EBV frame.

2. Materials and methods

NiTi with Ni-content of 50.8at% wires with diameters of 0.2 mm were used in this study as a raw material. Heat-treatment are carried out at temperature of 450 °C, 500 °C and 550 °C for 10 min, respectively in vacuum furnace followed by rapidly quenching into cold water. DSC was conducted in order to obtain transformation temperature of specimen with different heat-treatment temperature. Load-unloading test was carried out with 'Mecmesin MultiTest 2.5i' testing machine with a 100 N load cell under temperature of human body temperature (37 °C). Moreover, The NiTi frame was fabricated by braiding 12 NiTi wires together and forming into a tube shape with two difference cross-section, according to the human respiratory anatomy as shown in Table 1 [6].

Table 1. Cross-sectional area of airways.

Generation	Diameter (cm)
Trachea	1.80
Bronchi	1.22
Bronchioles	0.83
Terminal bronchioles	0.06

The braiding conditions for fabricating EBV frame are shown in Table 2. After braiding process, NiTi frame was constrained shape by heat-treatment process. Moreover, radial force of EBV frame was evaluated by Mylar film test. Figure 1 illustrates the fabricated EBV frame.

Table 2. Braiding conditions for fabrication EBV frame.

Wire numbers	Carrier speed (rad/sec)	Take up speed (mm/sec)
12	25	10
12	25	15
12	25	20
12	25	25

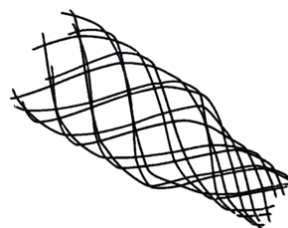


Figure 1. EBV frame from braiding process.

3. Results and discussion

Figure 2 reveals cooling and heating curves under constant cooling and heating rate of all specimens heat-treated at 3 difference temperature during DSC measurement. Two step transformation between Austenite phase, R-phase (Rhombohedral phase) and Martensite phase (Monoclinic phase) were clearly confirmed in specimens heat-treated at 450 °C and 500 °C while specimen heat-treated at 550 °C shows the single step transformation between Austenite and Martensite phase. This R-phase formation can be explained by the residual stress during cold-work process in material manufacturing. R-phase disappears with increasing heat-treatment temperature above recrystallization temperature which is approximately 526 °C. Although A_f temperature is not shown here, it is confirmed that A_f temperature of all specimens are below than 37 °C or human body temperature which means that superelasticity can be confirmed.

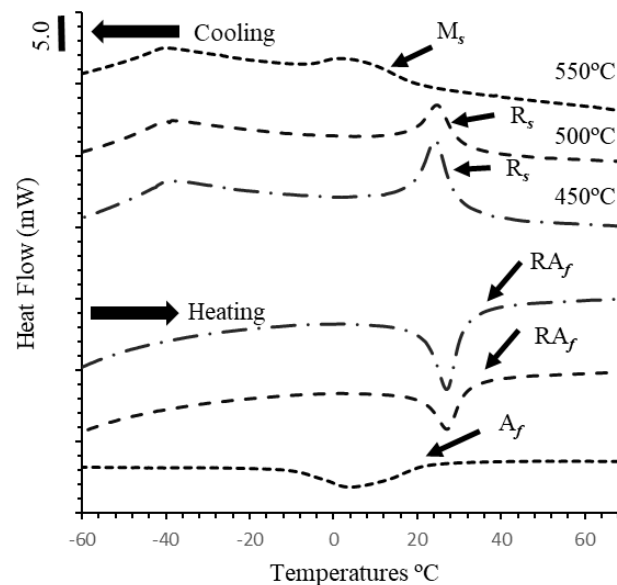


Figure 2. Cooling and heating curve of DSC measurement from specimens with difference heat-treatment temperature.

Table 3. Transformation temperature of specimens with difference heat-treatment temperature.

Heat treatment temperature (°C)	Transformation temperature(°C)			
	R_s	RA_f	M_s	A_f
450	29.60	16.5	-	-
500	30	17	-	-
550	-	-	-6	19

Figure 3 shows the stress obtained from load-unloading test of specimen with difference heat-treatment temperature. The upper and lower plateau stress are plotted against heat-treatment temperature. It is seen that upper plateau stress reveals maximum value at heat treatment of 500 °C while lower plateau stress slightly decreases with increasing of heat-treatment temperature. From this result, heat-treatment at 500 °C is selected to use as frame fabrication temperature since maximum stress can support the structure when the mass is similar.

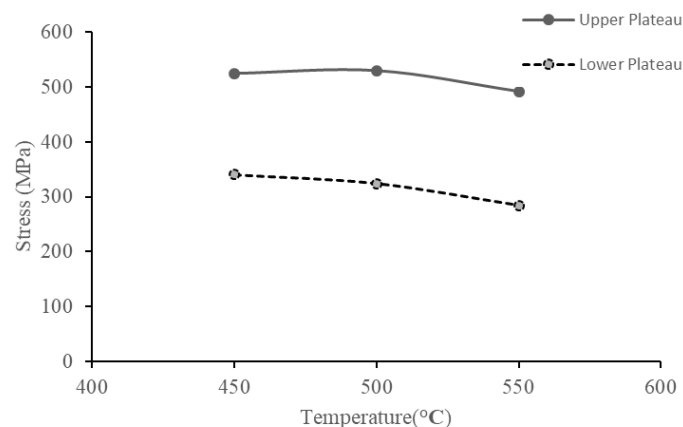


Figure 3. Upper and lower plateau stress of each specimen.

EBV frame was fabricated by braiding machine under various take up speeds, in the other word, various braiding angles. The braiding angle is observed with an optical microscope. Table 4 shows the relationship between take up speed and braiding angle. It is seen that braiding angle decreases with increasing take up speed. It is noted that NiTi frame can be constructed only when take up speed are higher than 10 mm/sec and lower than 25 mm/sec. Otherwise, shape will not be able to form.

Table 4. Braiding conditions with difference braiding angle.

Take up speed (mm/sec)	Braiding angle (Degree °)	Remarks
10	None	Cannot fabricate
15	45	
20	36	
25	26	Cannot fabricate

The Radial force of NiTi frame is performed by Mylar film test in order to obtain Radial Resistive Force (RRF) and Chronic Outward Force (COF) [7]. It is very important to evaluate the performance of NiTi frame under compression force from bronchial while implanted, also performance to return to the original shape of NiTi frame. Figure 4 shows the radial force obtained against braiding condition. It is obviously seen that RRF and COF significantly decrease with increasing of take up speed. Based on this data, the radial force of take up speed of 15 mm/sec will be designed and developed.

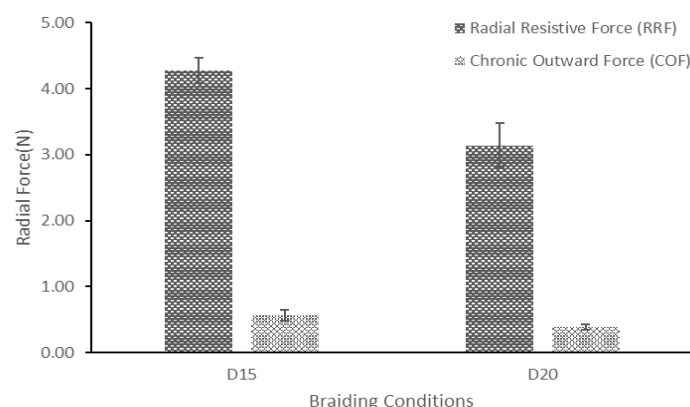


Figure 4. RRF and COF obtained from Mylar test of EBV frame with different braiding condition

4. Conclusion

In order to design and fabricate EBV frame from NiTi shape memory alloy wire, heat-treatment and braiding condition were investigated. It is able to summarize that heat-treatment at 500 °C for 10 minutes should be the optimum condition since the maximum stress was obtained. Moreover, with increasing of take up speed braiding angle and radial force of NiTi frame decrease. The optimal take up speed for fabricating NiTi frame is 15 mm/sec with equivalent to 45 °braiding angle. The further study on optimal force design of EBV device will be required.

5. References

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Acknowledgments

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