PROCESS TO INSERT NITINOL STENTS INTO THE PERIPHERAL VENOUS CATHETER

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1. Introduction

In the European Union the most often reason of deaths is the disease of the cardiovascular system. The so called stent is a biocompatible metal mesh which is inserted in the narrowed section of the artery to dilate and prop up its wall; hereby it ensures continuous flow of blood, inhibiting for example the formation of stroke [1]. In pursuance of our research stents made of shape memory Ni-Ti alloy (nitinol) were investigated which can be exceedingly applied in peripheral arteries exploiting the special features of nitinol.

2. Experimental

These stents were developed, cut out, etched and electro-polished by our research group and implanted into the carotid artery of rats by a physician group to examine how they act in biological organism. The stent is put in the artery by the help of a peripheral venous catheter. Before the implantation, the stent with 1 mm outside diameter must be inserted in the thin tube of the catheter, which inner diameter is 0.3 mm. The physicians push the stent out of this tube to the rat artery by means of a needle where it dilates to its initial size. The finishing temperature of austenite transformation of nitinol must be adjusted under body temperature to ensure the entire dilatation; furthermore the sufficient mechanical properties of the stent at body temperature must be satisfying to the sufficient working of the stent.

The first emerging problem while the stent was inserted in the catheter was the tiny size of stent. This problem manifested that the developing process must be the simplest as far as possible considering nippers must be used to the simple grip of the stent paying attention to the intact of struts. The next problem stemmed from the insurance of needed under -10°C temperature for reversible strain and from the convenient deformation of stent. The solution was searched in special features of nitinol, because of austenite-martensite transformation of nitinol due to thermal effect evolving so called single way shape memory feature and superplastic behaviour of nitinol in martensite phase was exploited. The kernel of single way shape memory phenomena is that if nitinol is cooled under finishing temperature of martensite transformation, where it can be deformed superplastic thanks to less symmetry of martensite phase, than warming it back it is taken on its initial shape transforming into more symmetrical austenite phase (Fig 1) [2,3].

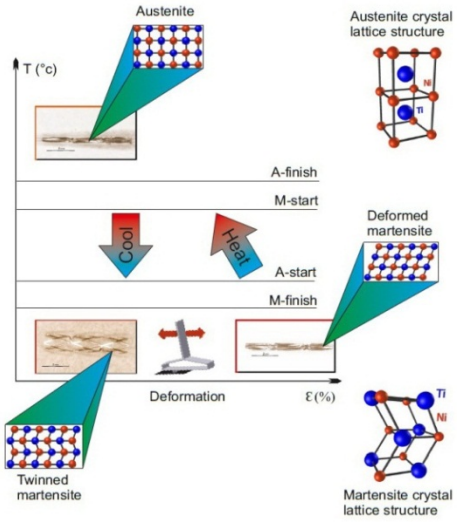

Fig.1: The process of lattice structure

There are different ways to the transformation into martensite phase but the reconformation into austenite phase can happen only one way; accordingly in deformed material from phase transformation and from deformation stemmed stress is dissolved due to a warming effect while retransforming into austenite phase it is able to recover its initial structure [2,3].

During the deformation the full martensite structure of stent must be ensured by constant under -10°C temperature. For this a chemically

harmless (in the aspect of stent and human) vehicle was needed which is convenient to carry the insert in it out and its melting point is low enough. Ethanol proved eligible (melting point is: -114°C), approximately 500 ml of it was cooled to -25°C by fluid nitrogen then poured into a 12×20×10 (mm) sized and with Styrofoam thermal isolated pot made of PP. The warming intensity of this system was 1°C/min according to our observation: the temperature of ethanol was continuously checked by a thermometer (Fig. 2).

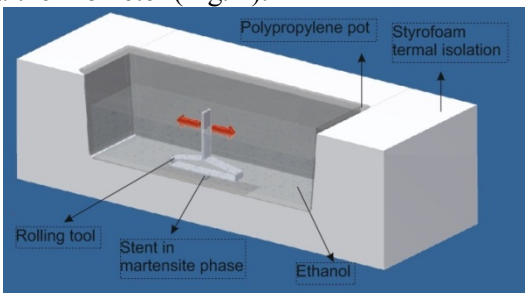

Fig. 2: Ethanol bath

The sufficient deformation of stent plays an important role by the insert. According to our earlier experiments it was determined that an equable, reversible and almost 70 percentage radial deformation is needed which ensures the intact of struts and cylindrical shape of stent by the process. The deformations of the struts have a limit because of the properties of nitinol.

The meshed structure of stent results high degree of radial deformation. The above mentioned deformation can be successfully performed by a rolling process. During this process the diameter of the stent reducing while the length of the stent is increasing. In the course of this process, the rolling terms of the stent must be met; hence to compensate the reduced friction conditions because of the ethanol, an abrasive paper (P600) was fit on the surface of the rolling tool.

After the deformation process, the stent can be placed into the venipuncture. The difficulty of the process arise from the location of the tube, which located 10 mm farther from the proximal end of the venipuncture and during the pushing movement the stent can flare out. To eliminate this problem, a cone-shaped tunnel was produced, fixed and centralised to the entrance of the venipuncture. The advantage of the cone-shape is that the stent can be easily placed even in the ethanol bath and this narrowing cross-section can help further reduce in the diameter of stent. The stent was pushed through in this cone-shaped tunnel with a metal guide catheter (its OD is less, than 0.3 mm), into the venipuncture distal tube (Fig 3). The insertion was smooth and quick.

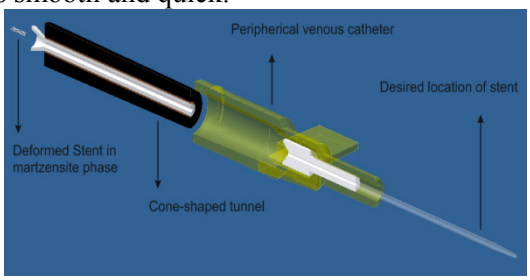

Fig. 3: Process of insertion

3. Experimental Results

Our aim was to work out such a reproducible and reliable method, through which the stents, manufactured by our research group can be placed into the venipuncture without damage. The success of this step is important and decisive in the aspect of the whole research. The problem was investigated, resolved and the method is worked out. Using this method, altogether twenty stents were put into the venipuncture.

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