Rev Bras Cir Cardiovasc 2013;28(2):217-23

Pulsatile stent graft: a new alternative in chronic ventricular assistance

Stent aórtico pulsátil: uma nova alternativa na assistência ventricular crônica

José Honório Palma[1], Diego Felipe Gaia[2], Guido Caputi[3], Guilherme Agreli[4], João Roberto Breda[5], Domingo M. Braile[6], Enio Buffolo[7]

DOI: 10.5935/1678-9741.20130031

RBCCV 44205-1460

Abstract

Objective: **Heart failure is currently one of the most common hospitalization causes. Several chronic circulatory assist devices have been tested and are highly complex. The objective is the description of a pulsatile endoprosthesis capable of applying a chronic pulse within the descending aorta, similar to that produced by intra-aortic balloon.**

Methods: **Pulsatile stents composed of nickel-titanium were built and positioned to engage latex tubes simulating the aorta. Different electric currents were applied to units connected in series in order to cause structure contraction and displacement of a liquid column. There were two sequence tests: first composed of two metallic cages and the second composed of five cages. At first sequence tests was applied a voltage of 16.3 volts and a current of 5 amperes. In the second, voltage of 15 volts and current of 07 amperes.**

Results: **In the first sequence was obtained the pulsatile effect of stent, with contraction of the tube and displacement of the water column sufficient to validate the pulsating effect of the endoprosthesis. The two structures ejected a volume of 2.6 ml per cycle, with a range of 29 mm in height of the column of water equivalent to 8% shrinkage during the pulse. In the second sequence, it reachead a variation of 7.4 mL per cycle.**

Conclusion: **The results obtained confirm the stent pulsatile contractility activated by electrical current. The continuity of the study and material improvement are necessary to obtain more efficient model from the point of view of energy and pulse, to allow ejection volumes comparable with the intra-aortic balloons.**

Descriptors: **Heart failure. Aorta. Stents.**

Resumo

Objetivo: **A insuficiência cardíaca é uma das causas mais comuns de internação. Dispositivos para assistência circulatória crônica foram testados e, em sua maioria, são de alta complexidade. O objetivo deste estudo é a descrição de uma endoprótese contrátil com capacidade de pulsação crônica no interior da aorta descendente, de maneira semelhante à produzida pelo balão intra-aórtico.**

Métodos: **Endopróteses pulsáteis compostas de níquel-titânio foram posicionadas de forma a envolver tubos de látex, simulando a aorta. Diferentes correntes elétricas foram aplicadas a unidades ligadas em série, de modo a causar contração da estrutura e deslocamento de uma coluna líquida. Foram realizadas duas sequências de testes: a primeira com**

1. Associate professor at Federal University of São Paulo (UNIFESP), São Paulo, SP, Brazil. Project coordination, data analaysis and review.
2. PhD, Adjunct professor of the Cardiovascular Surgery Discipline (UNIFESP), São Paulo, SP, Brazil. Results analysis and writing.
3. PhD, Cardiovascular surgeron at UNIFESP, São Paulo, SP, Brazil. Data analysis.
4. Graduation in Medical Physics, manager of the Endovascular Division of Braile Biomédica, São José do Rio Preto, SP, Brazil. Experimental procedures fulfilment and data analysis.
5. PhD, cardiovascular surgeon at UNIFESP, São Paulo, SP, Brazil. Review and writing.
6. Emeritus professor at State Medical School of Rio Preto and Senior professor at Medical Sciences Faculty of the State University of Campinas (UNICAMP), Editor of the Brazilian Journal of Cardiovascular Surgery, São José do Rio Preto, SP, Brazil. Results analysis.
7. Titular professor of the Cardiovascular Surgery Discipline of UNIFESP, São Paulo, SP, Brazil. Review and data analysis.

This study was carried out at Federal University of São Paulo (UNIFESP), São Paulo, SP, Brazil.

Correspondence address:
Diego Felipe Gaia
Universidade Federal de São Paulo – Disciplina de Cirurgia Cardiovascular
Rua Napoleão de Barros 715 – 3º andar – Vila Clementino – São Paulo, SP, Brazil – Zip code: 04024-002
E-mail: drgaia@terra.com.br

Article received on December 6th, 2012
Article accepted on April 28th, 2013

Abbreviations, acronyms and symbols	
ATP	Adenosine triphosphate
Nitinol	(Nickel Titanium Naval Ordinance Laboratory)
PVC	Polyvinyl chloride
SMA	(shape memory alloy)

duas gaiolas metálicas e a segunda com cinco gaiolas. Na primeira sequência de testes, aplicou-se tensão de 16,3 volts e corrente de 5 amperes e, na segunda sequência, tensão de 15 volts e corrente de 7 amperes.

Resultados: **Na primeira sequência de testes, obteve-se o efeito pulsátil dos 2 stents, havendo contração do tubo e deslocamento da coluna d'água suficientes para validar o efeito pulsátil da endoprótese. As duas estruturas ejetaram um volume de 2,6 mL por ciclo, com uma variação de 29 mm na altura da coluna de água, equivalente a 8% de contração durante a pulsação. Na segunda sequência, conseguiu-se uma variação de 7,4 mL por ciclo.**

Conclusão: **Os resultados obtidos comprovam a contratilidade da endoprótese pulsátil ativada pela aplicação de corrente elétrica. Continuidade do estudo e aperfeiçoamento do material se fazem necessários para obtenção de modelo mais eficiente do ponto de vista energético e com maior pulsação, para permitir volumes de ejeção comparáveis aos de balões intra-aórticos.**

Descritores: **Insuficiência cardíaca. Aorta. Stents.**

INTRODUCTION

Heart failure is currently one of the most common causes of cardiac hospital stay, and also causes significant morbidity and mortality [1].

Several chronic circulatory assist devices have been tested in recent years, and in most cases are often highly complex, and devices difficult to control which implantation depends on major procedures. The devices are also designed to be definitive or temporary, serving as a bridge to heart transplantation [2-4].

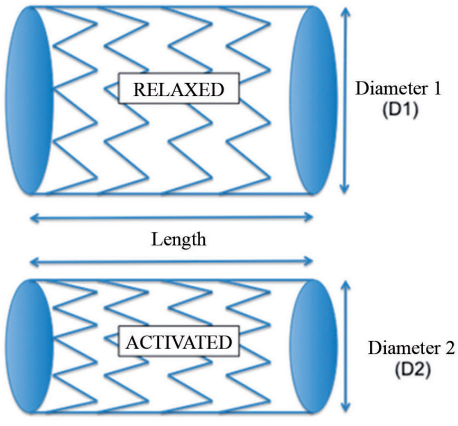
In recent years, the alloy NITINOL (Nickel Titanium Naval Ordinance Laboratory) initially used for various applications in the naval branch recognized for being "smart material" or SMA (shape memory alloy), has been used in medicine, in several areas, as orthopedic, cardiac, urological and gastrointestinal prostheses and orthodontic devices. This alloy behaves like a biological system that converts electrical or thermal energy in contraction and movement simulating a "natural muscle" [5-9].

Nitinol has the characteristic of retrieving a defined geometric shape after change in temperature. This ability is due to the modification of the alloy crystalline structure after stimulation. This material exhibits two-phase crystal structure: martensite, which has almost elastic properties, allowing deformation of the material without structural damage, and austenite phase, which has a more rigid and defined structure [10,11].

The aim of this study was to decribe an endoprosthesis contractile made with nitinol frame, still in "*in-vitro*" laboratory testing, whose function is to apply a chronic pulse inside the descending aorta, similar to that produced by an intra-aortic balloon, being synchronized with the cardiac cycle for outpatient non-invasive chronic circulatory support.

METHODS

The principle of the device is to change the structure of the stent between two states: relaxed (martensitic structure) and activated (austenitic structure), where the change of the diameter of the stent results in changing the volume of the sample, causing ejection of the resulting difference between the two conditions (Figure 1).



Endoprosthesis relaxed volume: $V_1 = \frac{D_1^2}{4}\pi C$

Endoprosthesis activated volume: $V_2 = \frac{D_2^2}{4}\pi C$

Volume difference between the two situations: $V_1 - V_2 = \frac{(D_1^2 - D_2^2)}{4}\pi C$

Fig. 1 - Schematic of the variation in volume between the two states of the contractile prosthesis: relaxed and activated

The endoprosthesis pulsatile tested was constructed with a metal strut of nickel and titanium designed as independent Gianturco Z-endoprostheses with 13.5 mm in height and 10 vertices. The metal structure involved a natural rubber latex tubular membrane, flexible and waterproof, 0.4 mm thick and 28 mm in diameter. The wire comprising nickel and titanium alloy had the following thermoelectric characteristics:

Resistivity: ρ^e=76μΩ.cm
Density ρ^m=6,5g/cm^3
Boiling point: $T_{fusão}$=1310ºC
Temperature of total transformation to the austenitic phase: A_f=60ºC
Coefficient of linear expansion: dl/dT=6,6.10^{-6}/ºC

Changing the stent was caused by the application of electrical current in metallic structures, which promoted heating and induced the shape change. When stimulated by temperature or by electricity, the league turns from its martensitic form (relaxed) and returns to its austenitic phase (activated), with its defined geometric shape and can be deformed again without structural damage.

Initially, the stent structure is shaped with a diameter of 10 mm and then, upon cooling up to room temperature, expanded to 28 mm in diameter. The cycle shown in Figure 2 illustrates the deformation experienced by the stent. In the first cycle, the structure undergoes forced expansion at low temperatures, from 10 mm to 28 mm in diameter, at room temperature. In the cycle II, with the application of current, the structure temperature rises and the return to the initial diameter in which the stent was molded occurrs. The cycle is then divided in steps relaxation (I) and activation (II). The pulsatile endoprosthesis was connected to a polyvinyl chloride (PVC) tube of 12.5 mm in internal diameter and 500 mm in length. The system was mounted vertically and filled with saline solution with blue dye at room temperature into a column of 400 mm (400 mm H_2O pressure equivalent to 30 mmHg) (Figure 3).

Cages produced with nickel and titanium wire were connected in series and connected to a pulse controller and an oscilloscope to view the profile of the electric current. This system was connected to a voltage source which supplied up to 7 amps of current, with voltage up to 220 Volts Figure 4.

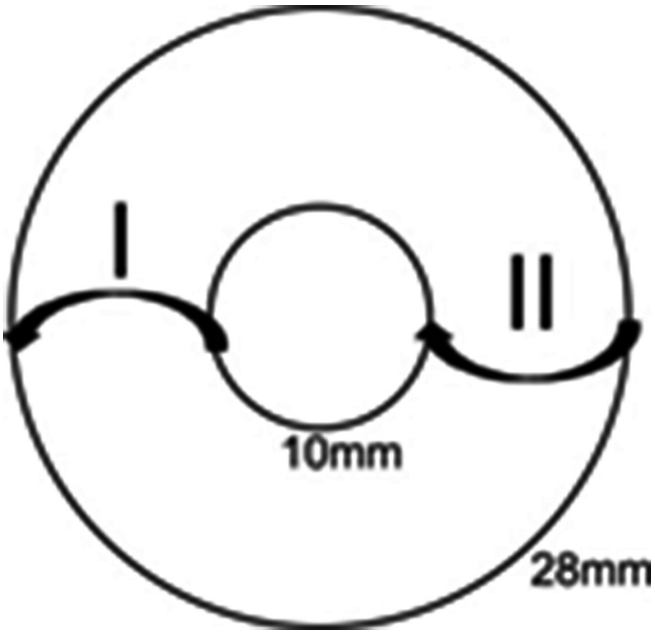


Fig. 2 - Illustration of the cycle relaxation (I) / activation (II) to which the pulsatile stent is subjected

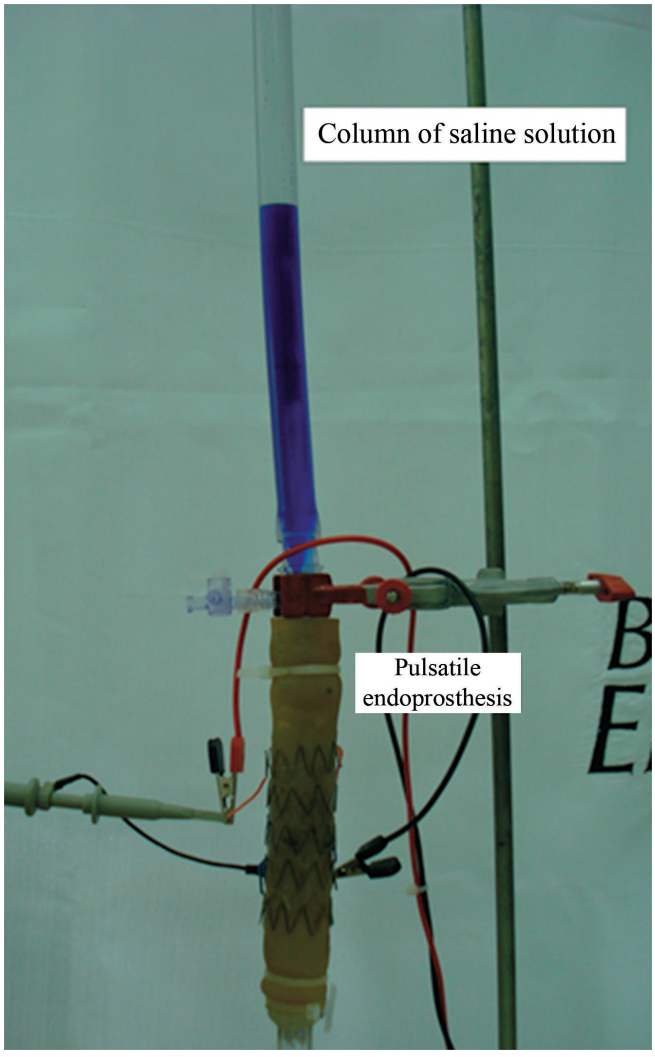


Fig. 3 - Mounting the pulsatile endoprosthesis with 5 stents connected in series in system of pulse generator, oscilloscope and current source

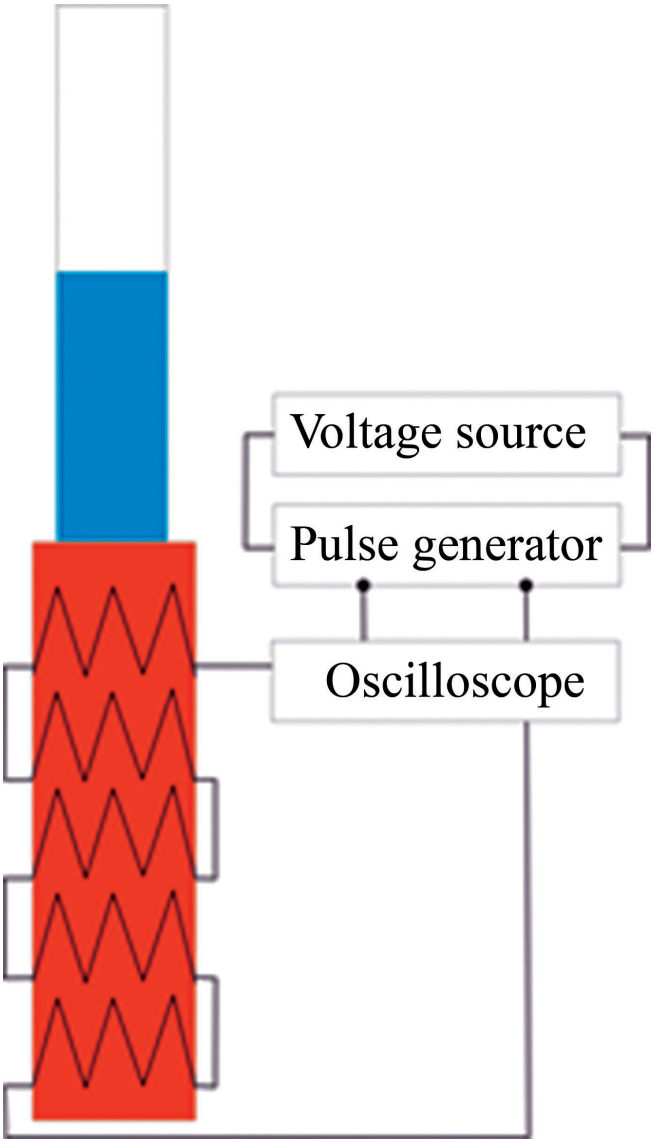


Fig. 4 - Illustration showing experimental mouting

The PVC tube was graduated in order to measure the movement of water caused by the contraction of the pulsatile stent. With the variation in the water column we can calculate the displaced volume during contraction.

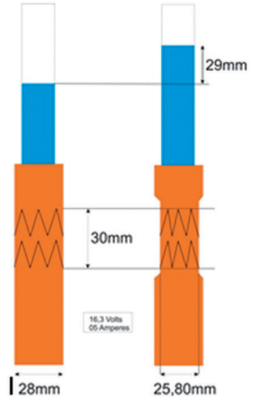
Temperature and relative humidity were, respectively, 21.2°C and 58.3%. There were performed two test sequences: the first sequence with a montage of 2 cages covering the latex membrane and the second sequence with 5 cages. In the first series, with only two cages (length 30 mm) we applied a voltage of 16.3 volts and a current of 5 amperes, with pulses of 1 second at intervals of 0.23 second. Stents were connected in series with the control and power supply system.

In a second test sequence, we used five stents connected in series, coating 80mm of the latex tubular membrane. For this system, we used a voltage of 15 volts, 7 amps current, pulse interval of 2.88 seconds, 7.12 seconds between pulses.

RESULTS

In the first test sequence was obtained pulsatile effect of two stents, with contraction of the tube and displacement of the water column sufficient to validate the endoprosthesis pulsating effect. The time intervals set in the pulse controller allowed the contraction of the frames, as well as their relaxation in the intervals between pulses. In this condition, the two structures ejected volume of 2.6 ml per cycle, with a range of 29 mm for the height of the water column and the variation in diameter of 2.2 mm (initial diameter 28 mm, end diameter of 25.8 mm in the 30 mm in length of the prosthesis), equivalent to 8% of contraction during pulsation (Figure 5).

In the second test sequence (5 stents) we obtained range of 61 mm in the column and a 7.4 mL volume per cycle (initial diameter 28 mm, 25.8 mm end diameter in 80 mm of the prosthesis) equivalent to 8% contraction during pulsation (Figure 6).



Shrinkage: 25.8.28 = 0.92 -> 8% variation in diameter in each cycle

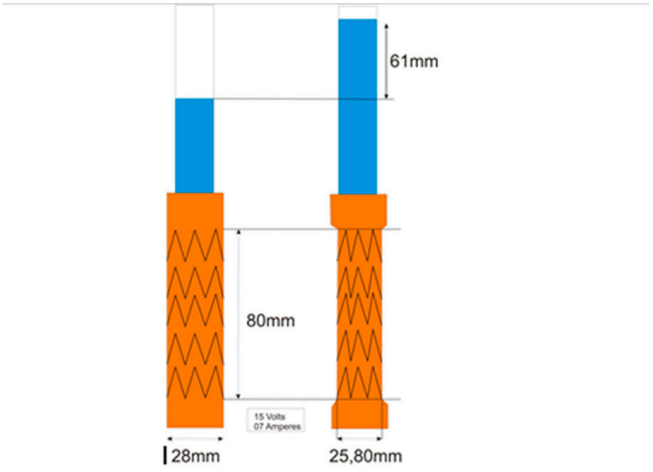
Ejected volume = volume relaxed - activated volume

Relaxed volume = (28x28) * PI * 30/4 = 18,472.56 mm ^ 3 = 18.47mL

Activated volume = (25.8x25.8) * PI * 30/4 = 3 = ^ 15683.77mm 15.68

Ejected volume = 18:47 - 15.68 = 2.6mL per cycle

Fig. 5 - Schematic of the first test sequence



Shrinkage: 25.8.28 = 0.92 -> 8% variation in diameter in each cycle

Ejected volume = volume relaxed - activated volume

Relaxed volume = (28x28) * PI * 30/4 = 18,472.56 mm ^ 3 = 18.47mL

Activated volume = (25.8x25.8) * PI * 30/4 = 3 = ^ 15683.77mm 15.68ml

Ejected volume = 18:47 - 15.68 = 2.6mL per cycle

Fig. 6 - Scheme of the second test sequence

DISCUSSION

The contractile stent is an initial prototype for cardiac assist, based on "smarts materials" technology, for the treatment of chronic heart failure. The circulatory assist devices for the treatment of chronic heart failure currently available present great complexity of handling, both at the time of implantation and in outpatient. Unlike the engines used in these devices, the called artificial muscles are light and consume little power. The use of nickel-titanium alloy for making assist devices such as artificial muscle opens new horizons in this field.

Various materials have been tested and are used in various areas of medicine, and one important class of these are the shape memory polymers that have, or that is, those that return to their shape when stimulated, in adittion to be also biocompatible. This property allows them to be released in a compact form and minimally invasive manner. These polymers are used in orthopedic prostheses and embolization coil for treatment of cerebral aneurysms [12-15].

Each one of some other materials that could be used for these devices present a restriction. The gel polymer, abandoned by high energy expenditure, as well as cobalt-based alloys or stainless steel, present major limitation which is the small deformity, limited to around 1%.

One of the main reasons for the choice of alloy nitinol for construction of artificial muscles is due to the fact that the energy used seems to be more efficient. In addition, the nitinol alloy presents superelastic or pseudoelastic property, which allows a deformity of more than 10% [11].

The advantages and qualities of the use of nickel-titanium in medicine are known since 1970, when the first ventricular assist devices were manufactured. At that time, however, major problems could not be solved, such as material fatigue, heating and energy source for their stimulation, but the league continued to be widely used as self-expandable stents in the treatment of aneurysms and dissections.

Today, one of the first studies using this technology in cardiology is a prosthesis developed with the aim of helping the atrial contraction. In this study, attention is drawn to the fact that there is no need to use an engine because the league contracts alone. In the field of atrial fibrillation, the device already is a reality, proving that actually generates atrial output for ventricular fibrillation, and can even be used to support two biatrial assistant devices. The auxiliary device improves the right atrial ejection fraction in 7% during rapid stimulation, simulating an atrial contraction [16].

The device tested, according the parameters observed in the laboratory, allows researches to continue, because the ejected volume obtained was 7.4 mL per cycle, which leads us to predict a volume of 595.2 mL when adjusted to a frequency of 80 beats per minute. This corresponds to 10% of the approximate cardiac output of a normal adults. These measurements were made with the use of a stent of 80 mm in length and 28 mm in diameter with a contraction of only 8%.

Example:
7.44mL x 80bpm = 595.2 mL/min
Cardiac output = 70 mL per beat x 80 bpm = 5600 mL/min
Assistance: 595.2 mL/5600mL = 10.6% aid

The amplitude of the material contraction depends on the choice of the ratio between nickel and titanium in the alloy, the thickness of the wire used, the geometry of the stent and the endoprosthesis length to be implanted. All these characteristics influence the efficiency of the device and the energy required for the operation depends on these factors.

The biological motor system was so successful during evolution that has been adopted by all types of striated muscle (skeletal muscle and heart). In the sarcomere, the muscle fibers contract from the sliding of actin and myosin, unlike the contraction generated by the proposed alloy, where shortening occurs by changing the molecular structure of the material. The maximum mechanical performance of all natural muscle varies between 40 and 200 watts per kilogram

of muscle, and the performance efficiency in relation to the consumption of adenosine triphosphate (ATP) is about 50%. In these tests, we obtained efficiency in converting electrical energy into fluid ejection quite low, approximately 1%. The low efficiency is due to the alloy used, which should have its temperature raised to 80°C to have a shape memory enabled. With the use of an alloy with processing at temperatures of about 43°C, the required amount of power falls drastically reducing energy consumption and enhancing efficiency, which will be performed in future tests.

The allow stimulation necessary to present contraction is another important point of discussion, because the energy required should ideally be provided by a generator similar to our known pacemaker or defibrillator. In the studies performed for making atrial contraction prosthesis, we used intermittent electrical current of 10 volts, 300 mA and 100 ms. Ont the other hand, in esophageal contractile prosthesis [11], the stimulus was 500 mA at 5 volts. In this study, we used the largest currents and voltages (16V and 5A) due to the characteristic of the alloy tested and its activation at 80°C.

Another point to be questioned when we think of using these devices is the durability of the material being subjected to fatigue (contraction) in the long-term. In the state-of-the-art aortic stents made of nickel-titanium, there is no fracture of the material even when observed that there is a pulsatile movement of the stent following the movement of the aortic wall. The post-implant contractile property can also be changed in view of the same prosthesis interaction with the aortic wall and its consequent inflammatory reaction and long-term change of the alloy crystalline structure, with loss of ability to move. Future tests will probably include a coating.

For the contractile function of the stent is similar to an intraaortic balloon of 40cc, it is necessary to optimize the design with the use of a composition of a shape memory alloy which is more efficient from the standpoint of energy for working physiological temperature, which offers greater structural rigidity in its activated form to achieve greater contraction. As an example, a stent of 28 mm in diameter when relaxed and with 130 mm in length has to contract to 17 mm, representing a 40% compliance. It is still possible to synchronize the functioning of individual pulsatile stents comprising the prosthesis to allow it to be unidirectional or bidirectional, directing blood flow to the coronary and carotid arteries or dividing them between visceral and supra-aortic and coronary arteries.

CONCLUSION

The results obtained confirm the pulsatile stent contractility activated by the application of electric current. The continued study and refinement of the material are needed to obtain a more efficient model from the point of view of energy and greater pulse, in order to allow ejection volumes comparable to intra-aortic balloons used in routine care for circulatory support.

If the expectation is confirmed, we have a non-invasive outpatient circulatory assist, with indications and effectiveness of intra-aortic balloon.

REFERENCES

1. Roger VL, Go AS, Lloyd-Jones DM, Benjamin EJ, Berry JD, Borden WB, et al; American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics: 2012 update: a report from the American Heart Association. Circulation. 2012;125(1):e2-e220.

2. Jokinen JJ, Mildh L, Hämmäinen P, Taal G, Raivio P, Suojaranta-Ylinen R, et al. Mechanical support for the heart and circulation in adults. Duodecim. 2011;127(19):2045-53.

3. Louis LB 4th, Sun B. Advances in mechanical circulatory support. Curr Opin Organ Transplant. 2008;13(5):522-5.

4. Delgado RM 3rd, Bergheim M. Management of acute and chronic heart failure with left ventricular assist devices. Am Heart Hosp J. 2005;3(3):153-60.

5. Babighian G, Fontana M, Caltran S, Ciccolella M, Amadori M, De Zen M. The heat-activated stapes prosthesis 'SMart' Piston: technique and preliminary results. Adv Otorhinolaryngol. 2007;65:190-6.

6. Carosio S, Monero A. Smart and hybrid materials: perspectives for their use in textile structures for better health care. Stud Health Technol Inform. 2004;108:335-43.

7. Roosli C, Schmid P, Huber AM. Biocompatibility of nitinol stapes prosthesis. Otol Neurotol. 2011;32(2):265-70.

8. Schaub MC. Artificial muscle: facts and fiction. Swiss Med Wkly. 2011;141:w13319.

9. Tarniţă D, Tarniţă DN, Hacman L, Copiluş C, Berceanu C. In vitro experiment of the modular orthopedic plate based on Nitinol, used for human radius bone fractures. Rom J Morphol Embryol. 2010;51(2):315-20.

10. Dotter CT, Buschmann RW, McKinney MK, Rösch J. Transluminal expandable nitinol coil stent grafting: preliminary report. Radiology. 1983;147(1):259-60.

11. Stoeckel D, Pelton A, Duerig T. Self-expanding nitinol stents: material and design considerations. Eur Radiol. 2004;14(2):292-301.

12. Sokolowski W, Metcalfe A, Hayashi S, Yahia L, Raymond J. Medical applications of shape memory polymers. Biomed Mater. 2007;2(1):S23-7.

13. Lendlein A, Rehahn M, Buchmeiser MR, Haag R. Polymers in biomedicine and electronics. Macromol Rapid Commun. 2010;31(17):1487-91.

14. Lendlein A, Shastri VP. Stimuli-sensitive polymers. Adv Mater. 2010;22(31):3344-7.

15. Lendlein A, Pierce BF, Ambrosio L, Grijpma DW. Advanced functional polymers for medicine. Macromol Biosci. 2011;11(12):1621-4.

16. Tozzi P, Hayoz D, Thévenaz P, Roulet JY, Salchli F, von Segesser LK. Atria assist device to restore transport function of fibrillating atrium. Eur J Cardiothorac Surg. 2008;33(2):263-7.