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Optimization Of The Fatigue Resistance Of Nitinol Stents Through Shot Peening

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Abstract

"Nitinol" (NiTi) is an intermetallic alloy of approximately equal atomic percentages of nickel and titanium that is widely used in less invasive and self-expanding implantable medical devices such as cardiovascular stents, due to its superelastic, shape memory and biocompatibility properties. Most of its applications in the medical industry involve the application of repeated stresses or strain cycles that drive the need of increasing the fatigue and fracture resistance of this alloy. The Nitinol stent supporting a biological heart valve prosthesis is considered one such example and is the critical structural component in many of the heart valve prostheses. Continuous effort is made to increase the fatigue resistance of these cardiac devices through experimenting with various manufacturing and surface treatment techniques. This study proves that the shot peening (SP) process improves the fatigue resistance of Nitinol stents and also describes the effect of different peening intensities on the treated surfaces, through the application of the Almen test.

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Keywords: Nitinol stents; Bioprosthetic heart valves; Fatigue resistance; Shot peening; Almen test

1. Introduction

Nitinol is a unique metal alloy composed of nickel and titanium at approximately equal atomic percentages, that exhibits extraordinary material properties, with its highlights being its superelasticity and shape memory effects (Stoeckel, 1998). In other words, it shows superior elasticity under stress, approximately 10 to 20 times more than

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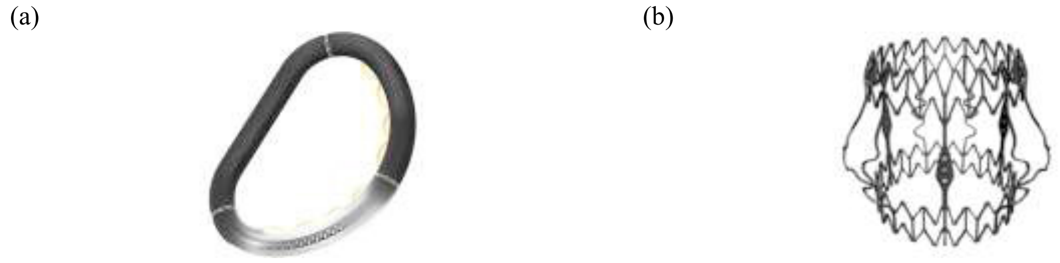


Fig. 1. (a) Memo 3D annuloplasty ring, by Sorin Group Italia Srl; (b) Nitinol stent of heart valve prosthesis Perceval, by Sorin Group Italia Srl.

that of any ordinary metal, and it can spring back with strain as high as 11% in addition to remembering its original shape and retaining it when heated above its transformation temperature (Kwok et al., 2011). Nitinol, because of its biocompatibility properties, is widely used in the medical device industry (Stoeckel et al., 2004). Some of its applications include annuloplasty rings (Fig. 1a) and heart valve prostheses (Fig. 1b), devices that are subjected to cyclic biomechanical stresses.

Due to the fact that Nitinol exhibits extraordinary material capabilities, it is often used in demanding applications requiring enormous flexibility and motion. Therefore, fatigue damage is the most common failure of Nitinol components. A relevant example is the stent, that during handling and following deployment into the body, is subjected to cyclic loading e.g. from the expansion and contraction of the blood vessels, which can result in fatigue failure (Robertson et al., 2004). Hassel (2004) highlights a number of surface treatment methods that exist for Nitinol used in medical applications for material removal, using mechanical procedures. Some of the processes he mentioned include deburring or grinding, minimization of corrosion or nickel ion release through surface oxidation, increase of the material's biocompatibility with the application of coatings, and improvement of fatigue resistance through thermal, electrochemical and mechanical processes. Some relevant examples of these processes are currently applied in the manufacturing of the Nitinol stent at Sorin Group Italia Srl, involving heat shaping, electropolishing and shot peening. Robertson et al. (2004) has made a thorough investigation on heat shaping techniques for Nitinol that can lead to an increase of its fatigue life, while Shabalovskaya et al. (2008) has performed an extensive research on Nitinol surfaces that have been electropolished, and has also compared this process with other electrochemical surface treatments. Nonetheless, none or few studies might exist regarding the effect of SP on the Nitinol surface. Surface treatment of engineering components by SP is a very effective and widely used technique for improving the fatigue resistance of metals. SP can prevent premature part failure by developing uniform layers of residual compressive stresses through bombarding the surface of the component with small spherical shots that impart a dimple on the surface. This act causes the surface to yield in tension, while below the surface, the compressed grains try to restore the surface to its original shape, producing a hemisphere of cold worked metal highly stressed in compression (Breuer, 1995, Innoue, 2002).

An example of fatigue resistance optimization of a metal through SP has been demonstrated by Torres and Voorwald (2002), who evaluated the effect of the particular process on the fatigue life of AISI 4340 steel, which is widely used in the aircraft industry for fabrication of structural components. The results of their study show that there is an improvement in the metal's fatigue life as a result of the compressive stress field induced by SP. However, the relationship between the fatigue life of AISI 4340 and the peening intensity is unclear, since their results indicate that an increase in the peening intensity, and consequently the increase of the original compressive residual stress field, does not necessarily lead to an increase the fatigue life of AISI 4340 steel. Another example of the SP effect on metals that we can consider is the study that Chen et al. (2013) performed and proved that this treatment has a positive impact on the fatigue resistance of the Ti-6Ai-4V alloy and also manages to make a comparison between the dry and wet SP process. Rios et al. (1999) adds that SP may also arrest cracks in ageing components , hence leading to healing fatigue damage.

Currently at Sorin Group Italia Srl, various surface treatments are applied on the Nitinol stent after it has been laser-cut from a raw tube, in order to remove any contaminants, and subsequently prepare it for the heat treatment process. Following the heat treatment process, the SP process is performed. It is the intention of the company to further study how this mechanical surface treatment can optimize the fatigue life of the Nitinol stent by investigating the contributing parameters at different levels using the Almen test method. This measuring system involves standardized thin plates, called Almen strips, that go under the same treatment as the treated component, which in our case is the Nitinol stent. This treatment induces residual stresses in the plates, consequently deforming them. The resulting deflected shape of the strip is called Almen intensity, and its value is appropriate to quantify the SP intensity (Schiffner et al., 2010, Li et al. 1991).

2. Experimental methods

2.1. Materials and sample preparation

The Nitinol fatigue properties are mainly depending on material and surface conditions, and are based on a strain normalization approach due to the nonlinear nature of the mechanical behavior of Nitinol, whereby the total strain is a combination of elastic, martensitic phase transformation, and plasticity. According to Pelton, Gong and Duerig (2004), the unique non-linear shape of the monotonic stress-strain curve of superelastic Nitinol lends itself to strain-control tests. The fatigue threshold of Nitinol is determined by analyzing the strain amplitude vs. fatigue data (strain-life). In order to simulate the single “V strut” of the Perceval Nitinol stent, the fatigue testing was performed on diamond shaped (DS) samples, following the same approach used by Pelton et al. (2004). To focus the analysis on the SP process, the diamond samples were not subjected to electropolishing, which normally is used for the Perceval stent. The test specimens were laser machined from the same Nitinol tube that is used for the fabrication of the stents. Subsequently they were expanded, mechanical and thermally shape-set into their final dimensions, in order to represent, as closely as possible, the material properties and relative geometry of the actual stent. The Nitinol phase transition temperature of the tube and a specimen was investigated by means of Differential Scanning Calorimetry (DSC).

Two experiments were carried out for the purpose of this study: experiment A examined if the SP process does in fact increase the number of cycles of the DS samples. Experiment B involved the study of the SP intensity to achieve maximum fatigue resistance at the lowest peening duration with the use of the Almen test.

2.2. Experiment A

Ten DS specimens were used for the first experiment in which, only five of them were peened while the other five were kept untreated. None of these ten samples were electropolished. The SP process was performed on the five samples using the same parameters applied on the Nitinol stent of Perceval. Specifically, the SP process was performed manually where the operator holds both the sample and the SP gun. The nozzle of the gun has an internal diameter of 8 mm and impacts the sample’s surface with glass microspheres in the size range of 50-150 μm in diameter, at a pressure of 4 bar. In order to achieve the ideal range of weight loss percentage, the SP duration applied in the standard preparation of DS specimens, was 150 seconds approximately, while the distance between the nozzle and the specimen was in the range of 30 to 40 mm.

The fatigue testing was performed using two calibrated test machines (MTS 858 MiniBionix), equipped with heating systems and temperature controllers, that are able to apply the required displacements on the samples at the desired temperature and frequency. The samples were placed in mixed positions in the machines regardless the treatment they underwent. This ensured that the machine would not be a factor in the determination of the variability of the experiment. The test was performed using a displacement of 2.08 ± 0.42 mm corresponding to a strain cycle of 3.77% ± 0.42 at 37 ^{o}C and at a frequency of 10 Hz. Prior to the initiation of the testing, all the specimens were preloaded in order to simulate the collapsing of the stent, needed to implant the valve.

(a) (b)

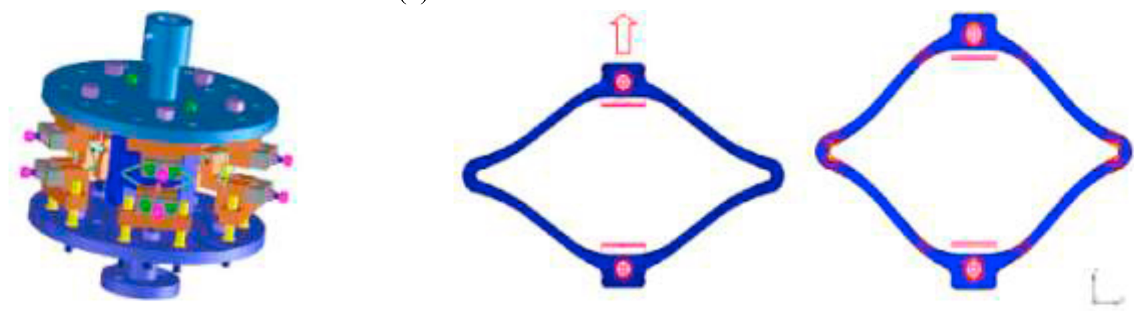


Fig. 2. (a) Specimen grip mechanism; (b) loading mode on the Nitinol specimens. (Copyright **Sorin Group Italia Srl**)

Each testing machine was equipped with a custom grip mechanism in order to allow simultaneous testing of five specimens. The grip mechanism shown in Figure 2(a) is fastened to the MTS actuator in order to apply a vertical displacement and create tensile-compressive areas in the diamond structure at a constant amplitude strain level. It is worth mentioning that while an increasing mean strain tends to decrease the fatigue life of linear-elastic engineering materials, at constant amplitude, for Nitinol, if the mean strain is higher than 1.5%, the fatigue life increases with increasing mean strain. This unusual behavior might be a result of the stress-induced martensite (Pelton et. al, 2008).

2.3. Experiment B

A first evaluation of the Almen test was made in order obtain some preliminary results regarding the SP intensity. SP intensity is the measure of the energy of the shot stream that is directly related to the compressive stress imparted into a component (Shot Peener, 2009). Six Type N Almen strips were peened on one side only, at a 90^{o} orientation to the shot stream. It was important that the orientation angle remained constant for all the strips as different angles could affect the final arc height. The treated strips were then mounted on the digital Almen gauge in order to measure the arc height that was induced by the residual stresses. The requested intensity was then verified through the establishment of an intensity saturation curve (Fig. 3). The graph shows that with increasing time of exposure to media impacts, the curving eventually diminishes to the point that curvature no longer increases. It is the aim of this study to obtain the respective saturation curve for the Nitinol specimens and find a correlation between the SP intensity and the fatigue life of the tested components.

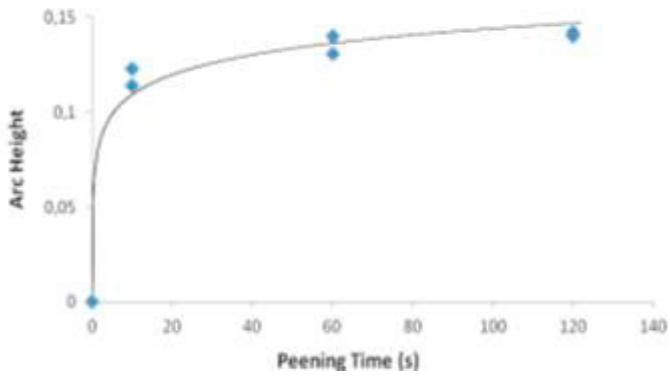


Fig. 3. Intensity saturation curve.

For this experimental part, eight DS Nitinol specimens were prepared according to the same process described in paragraph 2.1. After being heat shaped, the specimens were shot peened at different durations but using the same distance between the nozzle and the target specimen (20 mm), same orientation angle (90^o) and same pressure (4 bar). The specimens were then mounted on the fatigue testing systems and set to run until failure using the exact same parameters described in paragraph 2.2.

3. Results

3.1. Experiment A

The fatigue testing ran until failure for all the specimens. The graph in Figure 8 compares the average number of cycles to failure of the five non-peened specimens with that of the five peened ones. The results show that there is a difference of 30,000 cycles approximately, proving subsequently that under the current applied parameters, there is a slight increase of fatigue life thanks to the SP process. This leads to a further investigation on how this surface treatment can be used more efficiently, which is discussed in detail in the next experiment.

Furthermore, a high dispersion exists between the samples, especially in the non-peened ones where the standard deviation is close to 12,000 while for the peened samples it is approximately 8,500. Although this is quite common in fatigue data, another reason is the small number of samples used in the fatigue testing. However, these numbers can be considered as the maximum limits of dispersion, since with the increased number of samples to be used in future fatigue testings, a decrease in error percentage is expected.

The fracture surfaces of a non-peened and a peened DS specimen were further explored using Scanning Electron Microscopy (SEM). For the non-peened one (Fig. 4a), the crack initiation is on the top of side D with the overload fracture appearing at an early stage due to the high forces applied. This result was expected since the surface had not undergone any treatment, consequently leading to a limited fatigue life. On the other hand, for the peened specimen (Fig. 5b), the crack initiation is clearer and it starts in the corner of side D of the specimen, and progressively propagates through to side C, with the overload fracture being established approximately in the middle of the distance between sides C and D. Moreover, the fracture point for the peened sample matches with the FEA simulation of both the stent and the diamond sample (Fig. 6).

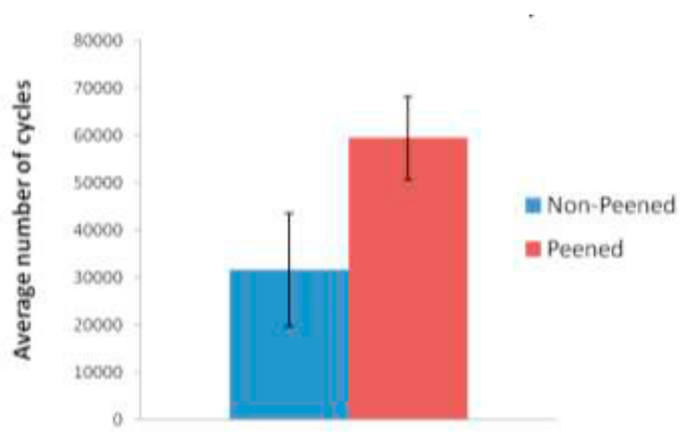


Fig. 4. Comparison between peened and non-peened specimens. Error bars correspond to data standard deviation

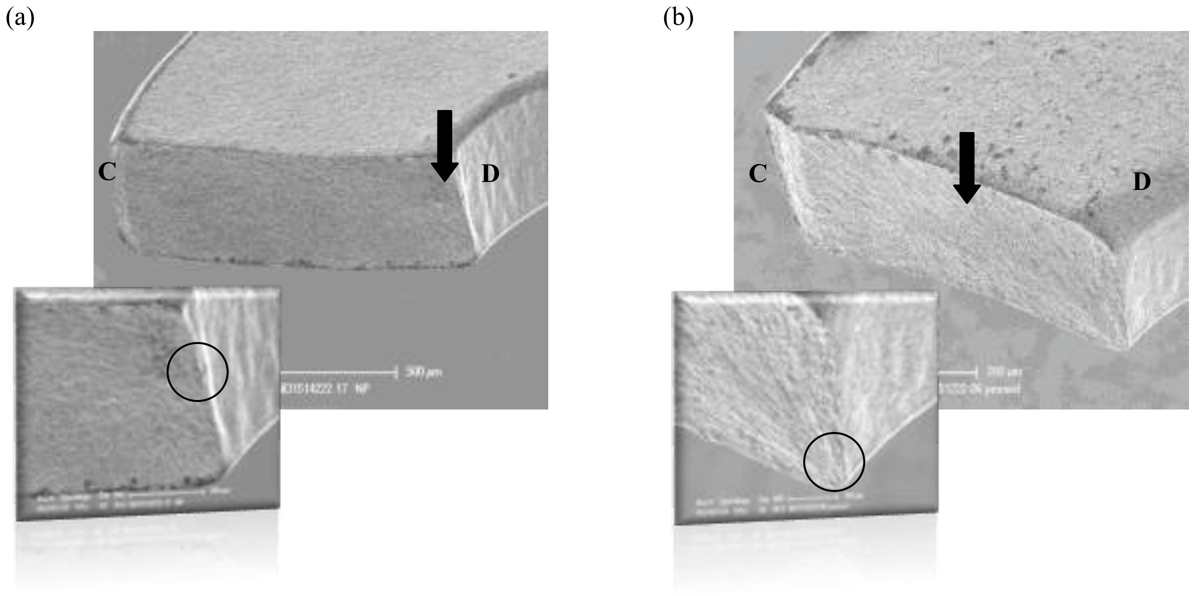


Fig. 5. (a) Fracture on a non-peened sample; (b) fracture on a peened sample.

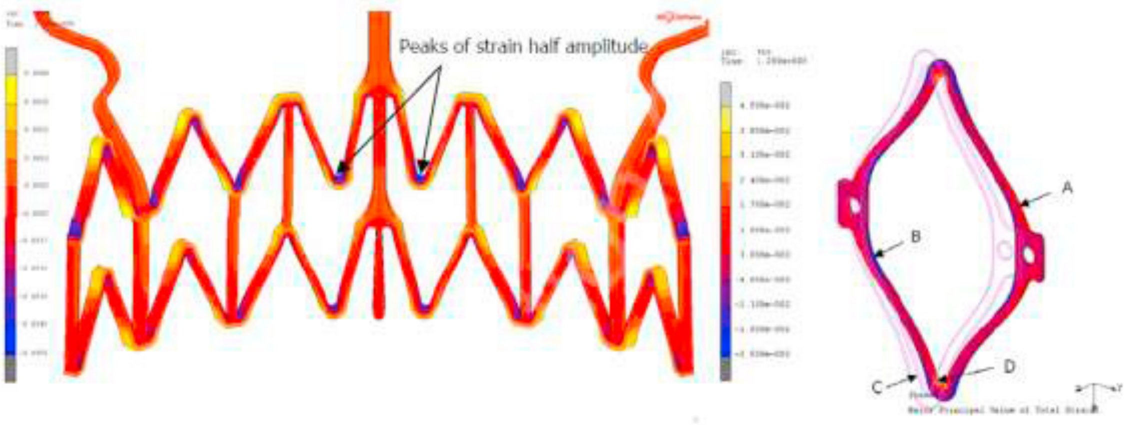


Fig. 6. Simulated strain pattern in stent inflow elements (left) and diamond sample (right). (Copyright **Sorin Group Italia Srl**)

3.2. Experiment B

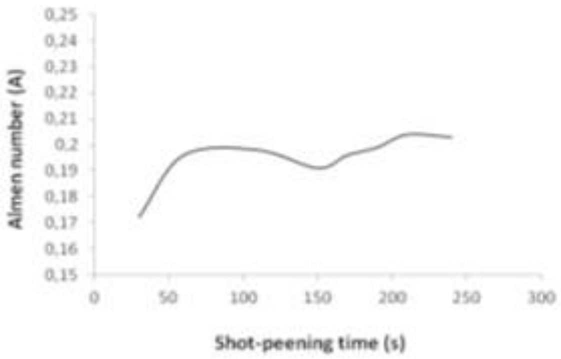
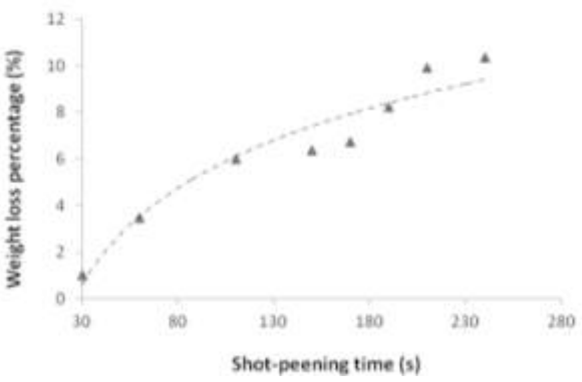


Fig. 7. Almen Test.

The saturation curve obtained from the Almen test is shown in Figure 7. It appears that there is a relatively small inconsistency on the curve, however there seems to be a trend that eventually leads to a saturation point. Such errors might exist due to differences in the impingement angle, coverage, hardness of the Almen strip or a combination of all of them (Biggs et al. 2004). Since the SP process was performed manually where both the target sample and the nozzle were not at a fixed position, such results can be expected.

An additional comparison was made on the diamond samples before and after SP (Fig. 8a). This comparison was necessary since the Almen test was performed with Almen strips made of carbon steel (SAE 1070) and not Nitinol. But even with the Nitinol samples, it appears that there is a tendency towards saturation, even though the long exposure to SP surpasses the required weight loss percentage. At this point it should be mentioned again that the impact angle applied was 90^{o}, since the material loss, also called erosion by solid particles, increases rapidly with decreasing peening angle. This erosion loss can also depend upon the heat treatment conditions, which in our case is fixed for all the samples and representative of the manufacturing process of the Nitinol stent at Sorin Group Italia Srl (Vempoort, 1989). The main objective of this study was to obtain a graph that shows a potential relationship between the SP duration and the number of cycles while keeping constant the other SP parameters (impingement angle, pressure, coverage, etc.)(Fig. 8b). Disregarding one of the specimens that fractured earlier than expected, a saturating trend can be observed. This trend concludes to the thought that after a specific SP duration, there will be no or slight increase in the number of cycles.

(a)



(b)

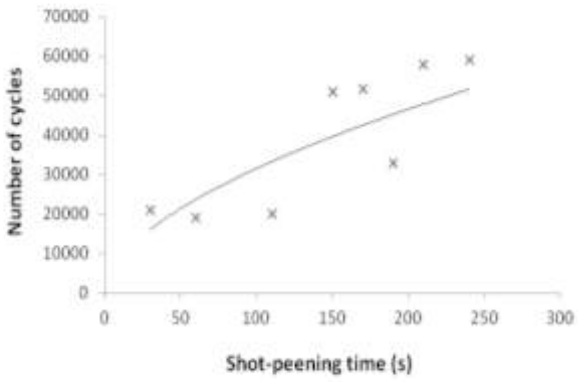


Fig. 8. (a) SP duration versus weight loss percentage of DS samples; (b) relationship between number of cycles and SP duration

4. Conclusion

A first attempt has been made to identify the potential of improving the fatigue life of Nitinol stents through SP. In this study few samples were used to obtain the aforementioned results (experiment A), therefore more iterations need to be performed in order to acquire a better understanding of the behavior of the SP process and the potential errors that might occur as they did in the Almen test (experiment B). Additional experiments will provide a clearer overview of the effect of the SP process on Nitinol stents and an optimized saturation curve. Other factors that affect the SP intensity will have to be considered as well, such as pressure, impingement angle, and distance between the sample and the nozzle. In general, peened samples performed better than the non-peened ones in terms of fatigue resistance, therefore SP is a surface treatment worth adding in the manufacturing process of stents.

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