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A Review on Nickel Titanium and it's Biomedical Applications

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Abstract - *NiTinol is a super alloy that has influenced tremendous change in science and technology, since its inception in 1959. It has provided novel solutions to our pre-existing challenges and has affected many fields in our scientific community bringing funding for research and positively impacting many industries to help in their development. One such impact is in the bio medical industry. The bio medical industry is the most fast paced section of our scientific community and sees a lot of development in a short span of time. This review provides an understanding of the history, manufacturing methods, shape memory effect and the use of NiTinol in biomedicine & orthodontics; how NiTinol has helped improve pre-existing solutions to medical problems that affect a large demographic and how NiTinol has helped in dental corrections and orthodontic repairs.*

***Key Words*: Nitinol, Biomedicine, Shape Memory, Pseudoelasticity, Superelasticity**

1. INTRODUCTION

Mechanical Engineering is a vast discipline with a range of activities and functions that derives its spread from the need to design, manufacture and provide efficient solutions in development of processes and products. The application of principles of STEM in the field of Medicine has yielded Bioengineering having a great potential to treat patients better.

1.1 Shape Memory Alloys

Smart Materials are materials that are able to respond to external force and then undergo some property changes. SMAs (Shape Memory Alloys) are one among many varieties of Smart materials. SMAs are relatively new kind of metals that will show unique ability of "retaining'' it's set shape and a practical phenomenon of shape shifting. Deformation occurs at a relatively low temperature, whereas shape memory effect (SME) occurs on heating. Nickel–titanium alloys (was named Nitinol, Nickel-Titanium Naval Ordnance Laboratory), some copper-base alloys (Cu–Zn–Al and Cu–Al–Ni alloys) and some other materials have been found to be capable of showing shape memory effect up to good extent of deformations. The accidental discovery of the unique behaviour of SMAs is a story in itself. All though Early research into SMAs took place in the 1930s, In 1932 Swedish chemist Arne Ölander first observed the pseudoelastic property in gold-cadmium alloys and the formation and disappearance of martensitic phase observed by decreasing and increasing the temperature for a Cu-Zn alloy. Use of SMAs have been seen greatly in Advance Fields like Aeronautics and Biomedicine. Modern Medicine has accepted and acknowledged the usage of Shape Memory Alloys. Industrial and commercial applications of SMA haven't been exploited still but rather given trivial importance. This paper pertains only to Nitinol, Its properties and its applications in the field of Biomedical Engineering.

1.2 An Overview about the Material Science of Nickel-Titanium Alloy

William J. Buehler along with Frederick Wang, discovered the SME of Nitinol and its properties during research at the Naval Ordnance Laboratory in 1959. Different types of Nitinol can be obtained by varying its composition. Majority of the Nitinol that is being used has Nickel and Titanium in 50:50 ratio however most of the Biomedical applications of Nitinol have minor increase in nickel. The composition of Nitinol depends on its internal energy(U). Nitinol alloys exhibit two closely related and unique properties: shape memory effect (SME) and superelasticity (SE); also called pseudoelasticity, (PE). Shape memory is the ability of nitinol to undergo deformation at one temperature, then recover its original, undeformed shape upon heating above its "transformation temperature". Superelasticity occurs at a narrow temperature range just above its transformation temperature without any need for heating and the material exhibits enormous elasticity. SME of Nitinol involves phase transformations between the two unique temperature dependent crystal structures (phases) named Martensite phase (lower Temperature phase) and Austenite phase (the higher temperature parent phase). Body centered cubic (BCC) structure is found in the Austenitic Nitinol. Upon cooling, the austenite transforms spontaneously to a martensite phase. This Transformation is diffusionless and involves an orderly shift of large groups of atoms, very rapidly. The degree of transformation depends on temperature. The crystals in Martensite phase have Face Centred Cubic structure (FCC). There are two types of martensite transformations: the temperature-induced transformation which causes the SME and the stress-induced transformation which results in SE [1]. Shear Mechanisms are responsible for these transformations. The transformation temperatures are denoted as follows:

M_s : Martensite start temperature upon cooling;
M_f : Martensite finish temperature upon cooling;
A_s : Austenite start temperature upon heating;
A_f : Austenite finish temperature upon heating.

When Nitinol is heated starting at room temperature, it starts to change into Austenite Phase at temperature A_s and this transformation is completed at A_f temperature. In the similar fashion when it is cooled from Austenite phase, it starts to transform into Martensite at M_s temperature and completes this transition at temperature M_f. Crystals in Martensite phase can have different variants (orientations in which they can shear). Variants of Nitionol assemble either by Twinned Martensitic structure and Detwinned martensitic structure. Figure 1 shows the highly twinned Martensitic Structure of Nitinol. Growing and Shrinking of Twin Boundaries occurs dur to the applied external stress. Furthermore, under the removal of the applied external stress, the deformed shape is retained at this temperature. Lastly, upon subsequent heating to the initial temperature, the material reverts back to its original size and shape (stage 4). This process is accompanied by a phase transformation from the deformed martensite to the original high-temperature austenite phase. For these shape-memory alloys, the martensite-to-austenite transformation occurs over a temperature range, between temperatures A_s and A_f.

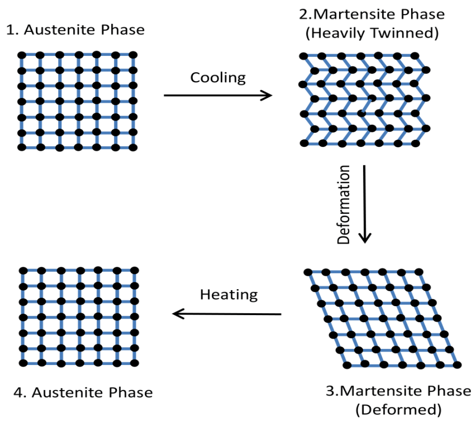

Figure 1 Diagram illustrates the SME of Nitinol and Schematic representations of the crystal structure at the four stages.

The original shape (the shape given initially) is created by heating to well above the A_f temperature and then restraining the material to the desired memory shape for a sufficient time period. For example, for Nitinol alloys, a one-hour treatment at 773.15K is necessary [2].

2. Material Processing of Nitinol

Nitinol is very much dependant on its internal grain structure and the purity of the materials used since it gets its shape memory attributes by them. Any small inclusions in the raw materials or during the manufacturing may result in the final product being weaker or may affect the temperatures at which the shape memory effect take place. Since nitinol contains a high percentage of titanium it is known to react with air and also air may cause for inclusion of foreign bodies during manufacturing therefore it is desirable for a process that eliminates air and which takes place in a closed environment. Nitinol ingots are melted using combinations of vacuum induction melting (VIM) and vacuum arc remelting (VAR) . Subtle adjustments in the ratio of the two elements can make a large difference in the properties of the NiTi alloy, particularly its transformation temperatures. If there is any excess nickel over the 50:50 ratio, one sees a dramatic decrease in the transformation temperatures and an increase in the austenite yield strength. Increasing the nickel-to-titanium ratio to 51:49 causes the active A_f to drop by over 373.15K [3]. Other non-conventional methods used are electro beam melting (EBM) and plasma arc melting (PAM). Undeniably, every machining process has its benefits and limitations and hence a suitable process must be selected according to the application.

The process of alloying of nickel – titanium is a very tactful process. VIM ensures control over the elements that the molten metals may come in contact with but the inclusion of oxides or carbides is very hard to control in VIM. It prevents the interaction of melted titanium with reactants in air preventing the formation of oxides and carbides. VIM is the most widely used process for the commercial production of NiTi alloys [4]. Carbon contamination is a major issue since graphite crucible is used , carbon is highly soluble in nickel and titanium reacts with carbon to form carbides, but research on VIM of nitinol from 2000-2005 has found better practices to get less inclusions and maintain relative high purity. VAR is a secondary process which improves the purity of the pre-cast.

In VAR the feedstock materials are pressed into a large compact, which is fed as a consumable electrode downward onto a hearth, where an electrical arc is struck; sufficient current is passed to continuously melt the electrode and, as molten metal is formed, the hearth is slowly moved downward as the metal freezes at the bottom of the pool. The molten pool is contained by a water-cooled copper collar, which forms a frozen skull on the outside of the pool, preventing any contamination of the melt by a crucible. This keeps the purity of the material at the highest level possible. [5]

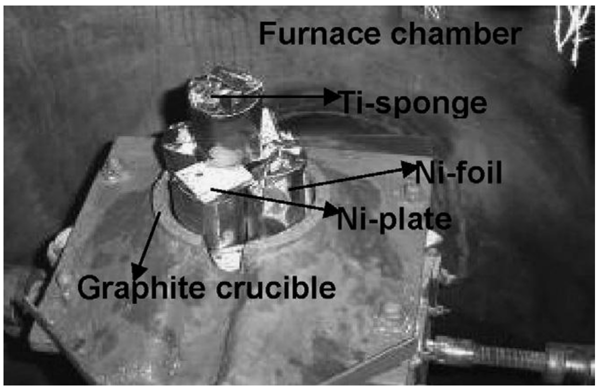

Figure 2 Photograph showing the charging of nickel plates and Titanium sponge rods in graphite crucible [6]

Electro beam melting is a process that guarantees a high purity end product, it requires an expensive setup and has limited scalability that prevents its use in mass production. By using EBM, the carbon contamination is completely eliminated due to melting in a water-cooled copper crucible, and oxygen contamination is minimized due to operation in high vacuum (better than 10-20 Pa). Therefore, the carbon and oxygen contents in the final product depend mainly on their levels in the initial raw material [7]. There is need for extensive research here as pure alloys will crucially benefit Biomedicine for better quality of Apparatus and implants. After the ingots are casted and have undergone a secondary melting to remove inclusions, they are subjected to hot/cold forging to form a cylindrical shape and then they are hot/cold drawn to a suitable diameter. By weighing the pros and cons of hot or cold methods we can assume the best method which has a minimal impact on the life of the end product and does not affect the shape memory effect in a negative way. By exposing nitinol to high temperatures, we risk the inclusion of oxides in the product, which may induce brittleness and shorten the life of the product. Finally, the product is cold worked and annealed at 873.15 – 1073.15 K. A combination of cold working and ageing treatments is necessary in order to achieve optimal superelastic performance. [8]

Table 1 : Strengths and limitations of casting/melting manufacturing methods of nitinol.

Method	Strengths	Limitations
VIM	Easy operation, flexibility due to small batch sizes, graphite crucibles are inexpensive and easy to handle, good melt chemical homogeneity	High processing costs, TiC and carbon particles present increasing Ni concentration and thus depressing phase transformation temperatures, extreme melt reactivity and segregation possible, rapid grain growth.
VAR	No need for a crucible, superior purity compared to VIM	Susceptible to presence of small inclusions, remelting can result in carbon and oxygen pick-up in case of vacuum leak, extreme melt reactivity and segregation possible, rapid grain growth
PAM	High energy concentration, high plasma flow velocity, quick heat transfer hence quick melting.	Low melted metal degassing, insufficient homogeneity; multiple torches required for homogeneity
EBM	No further carbon contamination, carbon content is 4–10 times lower than in VIM.	[Small volume production, poor chemical composition control

Table 2 : Comparison based on suitability to machine nitinol for medical applications.

Method	Determining factors and their allowable ranges. Values exceeding recommended range are shown in **bold**	Suitability rating
VIM	Carbon content: (300–**700** ppm against a ≤500 ppm recommended , Can reach **0.22** wt.-% (recommended ≤0.05 wt.%) on first crucible use) Oxygen content: ≈0.025 wt.% (recommended ≤0.05 wt.%) , Homogeneity: good due to electrodynamic stirring , Inclusions: 5–40 μm	Good
VAR	Carbon content: (≤100 ppm against a ≤500 ppm recommended ,Oxygen content: 0.03 wt.% (recommended ≤0.05 wt.%) Inclusions: ≈ 17 μm (≤39 μm recommended)	Excellent
PAM	Carbon content: 0.0094 wt.% (recommended ≤0.05 wt.%), Oxygen content: 0.031 (recommended ≤0.05 wt.%) Inclusions lesser than 5 μm, **poor homogeinity** as compared to VIM	Good
EBM	Carbon content: 0.012–0.016 wt.% (recommended ≤0.05 wt.%) , Oxygen content: 0.01 wt.% (recommended ≤0.05 wt.%), **poor chemical composition**	Good

3. PROPERTIES OF NITINOL DESIRABLE IN BIOMEDICINE

3.1 Corrosion and Surface Properties

All the studies of surface modifications of Nitinol have been aimed at improving its corrosion behavior and It has been shown that localized corrosion resistance of bare Nitinol may vary significantly, depending on its surface state. However, in scratch corrosion tests when surface damage is caused mechanically, the ability of Nitinol happens to be inferior to that of pure Ti, though comparable with the scratch healing ability of stainless steel. The potentials of NiTi determined in scratch tests are low (from 150 to 300 mV) compared with PD and PS polarization, and this is the problem to be targeted in the development of Nitinol surface modifications [9]. When Nitinol implants receive appropriate surface treatment through electropolishing and passivation, they develop a passive titanium oxide layer, which forms a barrier that will prevent corrosion and release of toxic Ni ions into the bloodstream.

3.2 Fatigue in Nitinol based Biomedical Devices

It was wrongly thought that nitinol is poor in fatigue resistance because of the non fatal fractures reported during the end of 20th century. There was a wrong notion that fatigue was not an issue for superelasticity as the material could recover from large strains with negligible residual stresses. These medical devices started being used clinically without even enough knowledge about the fatigue in nitinol and the effect of the environment of use on the device.

Nitinol being a superelastic material also has its own drawbacks and limitations. Like the property of superelasticity provides high fatigue performance even in the condition where the amplitude of force is high and strain is high. But the minimum threshold after which fatigue crack growth starts is lower than most metal which are used today in the devices with medical application. Since there is no prior material degradation like plastic deformation or strain hardening prior to the fracture, it is therefore difficult to observe and detect fatigue in nitinol. Longer fatigue cycles, higher confidence levels on fatigue limits and more specific device fatigue tests and fatigue failure modes must be evaluated. "Although the thermodynamics and phase transformations of the shape-memory and superelastic effects have been widely studied, currently, there is a lack of information and understanding of the micromechanisms that contribute to the fracture resistance of Nitinol. At present, there are only very limited data in the literature which describe crack propagation in Nitinol alloys under monotonic or cyclic loading [9-11]; furthermore, none of the data in these studies characterizes the fatigue behavior of superelastic Nitinol." "Thus, it is critical that the crack-propagation rates in superelastic NiTi are known in order to determine expected device lifetimes and provide a rational design against failure." "In order to analyze the lifetime of a device subjected to both a cyclic and static strain, a modified Goodman diagram may be used (Fig) [10]. First a strain approach is used in the constructing the axes. But then, as one might expect based on the shape of stress-strain curves, the line itself is non-linear, departing from the endurance limit along a tangent to the first yield, then finishing at a second yield." [11]

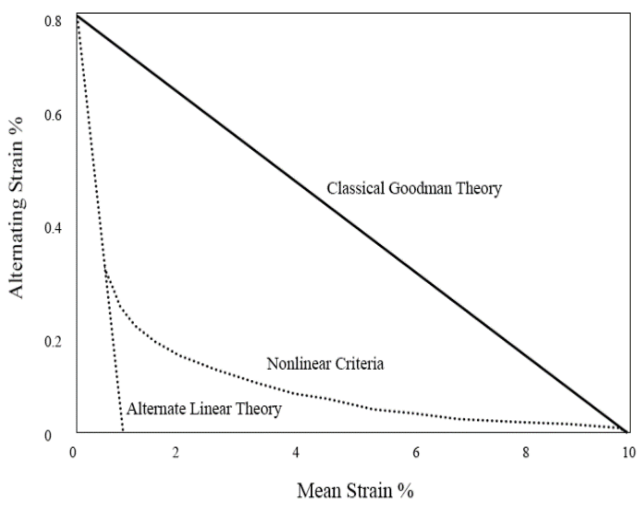

Figure 3: Modified Goodman diagram may be used to analyze the effects of mean strains on fatigue lifetime NiTi.

3.3 Biocompactibility

Any material used for biomedical use must be biocompatible, so as to avoid the induction of immune responses, resist corrosion, and be radio-opaque. Biologically inert stent material is of atmost importance to avoid all problems and safety. Biocompatibility is defined as the ability of a material to perform with an appropriate host response in a specific application [Williams, 1987]. An important aspect of the biocompatibility of implant devices is their ability to perform desirable functions in close contact with body tissues. The major criteria for traditional medical alloys were high strength and corrosion resistance. The higher the elastic modulus of an implant material, however, the higher the stress level exerted onto a bone. Thus, good mechanical compatibility required carefully matching an implant's elastic modulus to that of the elastic modulus of a specific bone. The elastic modulus of cortical bone is 15– 30 GPa, while that of cancellous bone is 0.1–1.5 GPa [Cooke, 1996]. Nitinol has a low elastic modulus that, in the presence of porous material, can be reduced to even lower values (0.1–1.5 GPa), thereby making it a suitable match for either bone type [Assad, 2003a]. Another approach to the design of biomaterials, which is based on a concept of biomechanical compatibility, is rooted in the knowledge of the mechanical behaviour of body tissues [Fung, 1991, Gunther, 2000]. A functional implant material should be similar in its mechanical behaviour to that of living tissue.

Patterns of nickel release from Nitinol is a central issue in Nitinol biocompatibility. Our understanding of the patterns of Ni release from Nitinol evolved significantly. Observations on Ti–Ni alloys prepared in laboratories [Ryhänen, 1997, Wever, 1998, Michiardi, 2006a] showed that Ni release from Nitinol might be higher than from SS during the first days of exposure to biological solutions, even though it dropped to almost undetectable levels after 10–14 days. Studies of Ni release from commercial material, however, pointed at different patterns, where an increase was noted at the beginning of exposure and its stabilization was observed only after a few months [Cisse, 2002, Kobayashi, 2005, Sui, 2006, Clarke, 2006]. The amount of released Ni differed significantly [Clarke, 2006], pointing at the effects of processing, which is in agreement with variable Ni surface concentrations reported for Nitinol wires (0.4–15 at.%) [Shabalovskaya, 2003a]. High-temperature treatments, which promote the formation of a thicker external TiO_2 layer, result in Ni accumulation in the internal surface layers. These buried layers can be easily activated due to surface damage.

3.4 Kink Resistance

Nitinol is known to have good kink resistance. It is evident from its stress-strain curve due to the presence of the plateau. When strains are locally increased beyond the plateau, stresses increase noticeably. Resulting in strain partition in the areas of lower strain, uniformly distributing the peak strain itself. Thus a more uniform strain is realised, preventing kinking.

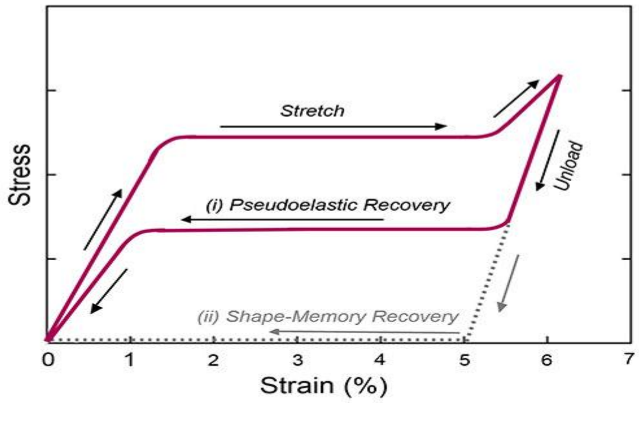

Figure 4 : Presence of plateau region indicates high kink resistance

3.5 Thermal Deployment

One of the characteristic feature of Nitinol is shape memory effect which means that increase in the temperature will trigger the pre set shape of it. One example is the Simon vena cave filter, this is preloaded into the delivery system in the martensitic state flushed with chilled saline then positioned and released. The flowing blood will trigger the shape memory motion to return to its original shape or pre-set shape so that it can rather large embolized blood clots. One more example is osteosynthesis plates and staples, these can be inserted and placed in the body. Then after heating it can help closure the facture of the bones. [12] [13] [14]

3.6 Elastic Deployment

One of the reasons to use nitinol in medical device is that with one or two small incisions will be certainly more appealing than the patient undergoing surgery with a long scars and other complications that result from traditional surgery. With using nitinol devices, it can be inserted through small openings and then expand to the desired size and function. The concept of making a curved device through a straight needle is probably the most common use of Nitinol in medical instrumentation. One of the first products was Homer Mammalok (shown in the figure below), which radiologists use to 'mark' the location of a breast tumour. It has a Nitinol wire hook inside a Stainless Steel annulated needle. [12], [13], [14]

Figure 5 : Homer Mammalok Nitinol wire needle localizer.

4. BIOMEDICAL APPLICATIONS OF NITINOL

4.1 Nitinol Stents for Coronary Treatments

Coronary Artery Disease (CAD) and Peripheral artery disease (PAD) are the narrowing of the arteries in the heart and near the limbs respectively caused by the build-up of fat and Calcium deposits called plaque. Apart from the bypass surgery, Baloon Angioplasty and Coronary artery stenting are sought out treatments. Dotter [15] was the pioneer in the interventional cardiovascular world. He opened the way for intravascular stenting at the end of the 1980s. Subsequently, the field of Intravascular stenting has seen stupendous progress due to advances in Material Science and stent design. The composition of the stent influences many of its properties, including radial strength, deliverability and potential for restenosis. Conventionally stents are made of metals and alloys. The use of Alloys helps in achieving desirable stent properties much easily. Originally Bare metal stents (MBS) were made up of stainless steel alloy 316L SS which possessed excellent mechanical properties like Youngs modulus, Yield strength, tensile strength and corrosion resistance. Unfortunately, It was found that it lacks radio opaqueness. Inclusion of other metals for mitigation has not proved beneficial. Cobalt-chromium Alloy has higher density, Young's modulus, yield strength, tensile strength and overcomes the limitations of stainless steel as it possesses better radio-opacity and better overall strength. These properties have enabled stent struts to become thinner and still have the same ability to resist deformation as a thicker strut with a lower elastic modulus [16]. Thinner struts improve the flexibility, increase the inner diameter of the stent and mainly decreases the potential injuries.

The mechanical properties of the superelastic Nitinol alloy have played a major role in the explosion of CAD and PAD stenting, with modern stents demonstrating reasonable resilience and durability. The majority of nitinol stents are of the self-expanding type. Self-expandable vascular stents made up of Nitinol exploits its pseudoelasticity property. The stenting procedure using a Nitinol stent consists of: (i) setting the stent in open condition i.e. austenitic phase (Af is lower than body temperature), (ii) compressing and inserting the stent into the catheter (iii) removal of the sheath and expansion of the stent. The inverse transformation from martensite to austenite occurs during this, which is due to the martensitic instability at a temperature higher than Af. Hence avoiding the usage of balloon and minimizing inflation problems caused by the forces exerted by the cardiovascular tissues. The Biocompactibility of Nitinol stents are exceptional compared to other MBS. However the mechanical behaviour of Nitinol under multiaxial conditions remains poorly understood and hence the deformation and fracture behaviour for long term safe use is still to be researched.

4.2 Nitinol in Orthodontics

Nitinol alloy in orthodontics was a revolutionary feat of engineering as it allowed for newer research, faster and easier ways to make dental corrections. George F Andrearson was a determined researcher in this field a published numerous articles in the 1970's. He mainly focused on nitinol's use in dental archwire. Archwire is used along with metal brackets to align the teeth to make a person look cosmetically appealing. They also help to align disfigured or even impacted teeth so as to make them more functional or to prevent future misalignment. in orthodontics an archwire also helps in conforming to the alveolar or dental arch that can be used with dental braces as a source of force in correcting irregularities in the position of the teeth. An archwire can also be used to maintain existing dental positions; in this case it has a retentive purpose [17]. Levelling is the process in which the incisal edges of the anterior teeth and the buccal cusps of the posterior teeth are placed on the same horizontal level; and alignment is the lining up of teeth of an arch in order to achieve normal contact point relationships [18]. Wires used in this initial phase in an orthodontic treatment requires them to have low stiffness, high strength and long working range. The ideal wires to use in this phase of treatment is a Nickel-Titanium archwires. Low stiffness will allow small forces to be produced when the wire is engaged in the bracket slots of teeth. High strength would prevent any permanent deformation when the wire is engaged in teeth which are severely crowded [19].

The use of NiTi alloy in this field also demands for higher grade and pure nickel-titanium as any inclusions that are not suitable may result in undesired effects or even medical complications. Nitinol is preferred overall for orthodontic use as it has general corrosion resistance as compared to stainless steel wires that have shown to corrode after some use. Nitinol is also found to have high working range compared to stainless steel or twist flex wires shown in a study by Andrearson. In his study he mentions in conclusion "the time-linked performance of one 0.019 inch cobalt unannealed nitinol wire will approximate that of having to change two to four single strands of round levelling wire with the slope of the curve following Hooks' law to the elastic limit of approximately a 0.014 inch round stainless steel wire" [20].

4.3 Clinical Instruments

There is a growing market for nitinol in clinical instruments. Instruments that are steerable, hingeless, kink resistant, highly flexible and that provide constant force have all been developed. These include: Biopsy forceps tissue ablators hingeless graspers and retrieval baskets for laparoscopy. [21]

4.4 Magnetic Resonance Imagining

Magnetic Resonance Imagining (MRI) is a non-invasive imaging technology which is used as a diagnostic procedure to get high quality results in the form of pictures. MRI scanners use strong magnetic fields to generate the images of the organs in the body. Stainless steel is susceptible to magnetic fields and as a result interferes with the image to the point where it is unrecognizable. Nitinol is very much less sensitive to magnetic resonance and therefore yields a much better results. [21]

5. CONCLUSIONS

Our review has ventured far into the understanding of NiTinol and its biomedical uses, but it is evident that far more research can be done with regards to this super alloy and we expect it to provide solutions to problems we might not know yet. Research about NiTinol in the field of Bio-medicine has many uses as discussed above and further more in surgical tools and self tightening stitches that are still under development and require further research .Our review has exhibited the ways in which NiTinol has improved pre-existing solutions by showcasing its material properties which has yielded the name super alloy .NiTinol has proven itself to be a robust, versatile and progressive super alloy that will bring forth a monumental change in science and technology in the future.

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