Implication of Laser Technology than that of Shape Memory Alloy [NiTinol] in Angioplasty

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Abstract

Modern Angioplasty is an alternative to bypass heart surgery because of safety and validity. As we know that the Heart diseases has risen to become that number of deaths in most of the developing or developed countries due to the high increase rates of obesity, drug dependence, and diabetes. Stents are used throughout the body but the most critical area being coronary arteries. Convention Material like Stainless Steel 316LN is used before, now a day's Smart Materials like Nitinol is having wider application in Angioplasty. This paper presents the comparison and limitations of the Shape memory alloy [Nitinol] technology with that of Laser technology. The several materials used in angioplasty for stenting are Stainless steel 316LN, Titanium and Nitinol. Laser technology finds more beneficial due to its rapid growth in technology and also more advantageous because of the alloys used are resistant to corrosion, yet the corrosion occurs when two dissimilar surfaces are in contact and this happens in almost all alloys These devices have been used for only a few years and, although initial results look promising, long-term effects have not been fully investigated. It's important to note that, if restenosis recur there is no good method to simply remove the blockage, and follow-up treatments may require laser surgery or localized drug delivery using other angioplasty devices.

Keywords: Angioplasty, Laser technology, Restenosis, Metallosis, Excimer Laser.

1. INTRODUCTION

Laser Technology in Angioplasty presents the wide usage and comparison of the advanced technology of materials with that Convention Material Technology, Smart Material Technology. As we know that the Heart diseases has risen and also become the major cause of death in most countries due to the high increase rates of obesity, drug dependence, and diabetes. Recent studies show that most of them die every year from heart failure and the numbers are constantly increasing. As time passes the symptoms of coronary heart disease can rapidly develop and will continue until intervention is carried out. Coronary heart disease may take years to develop but if proper care is not taken it is capable of ending one's life. Since 1977 [1], the Percutaneous Transluminal Coronary Angioplasty (PTCA) procedure has become the most widely used form of intervention and has led to endless research. It has been found that, as the body ages, lipids undergo an oxidation process which leads them to become harmful to the walls of the arterial vessels. As they pass through the artery vessel, the walls become damaged and the damaged walls are repaired with fatty substances which leave a scar. Calcium and oxidized, cholesterol are incorporated into the resulting scar tissue as they pass. The resulting lesion is called atherosclerotic plaque and this disease process is known as atherosclerosis. With atherosclerosis, as the years pass, calcium deposits build up, and calcified atherosclerotic plaque forms, lining the walls of the arterial vessels. This plaque is composed of various lipids, foam cells, scar tissue, and overgrown smooth muscles cells from the artery wall. In many people, this process begins in early childhood and progresses over time. The exact content of the plaques is determined by the individual diets, exercise regiment, antioxidant intake, and duration of the plaque formation process. High cholesterol levels will induce fatty deposits into the bloodstream and hasten the plaque formation process. The plaque develops different material properties due to the various lifestyles and environments. However, it is certain that as the size of the blockage increases, less and less oxygen is delivered to the most important organ of the human body, the heart.

2. CORONARY ARTERIES

The coronary artery's function is to deliver blood and oxygen to the heart muscle, and is divided into two main branches. The left coronary artery supplies oxygen rich blood into the heart ventricles and the left atrium. The right coronary artery is split between the right posterior artery and a larger marginal branch, which delivers blood to the ventricles, right atrium and sinoatrial node. The sinoatrial node is a cluster of cells located in the right atrial wall which regulates the rate at which the heart pumps. A significant decrease in oxygen leads to an increase in blood pressure and heart rate as the heart begins to work harder to supply the body with the necessary blood and oxygen supply.

FIGURE 1 shows the layout of the coronary arteries in the heart muscle.

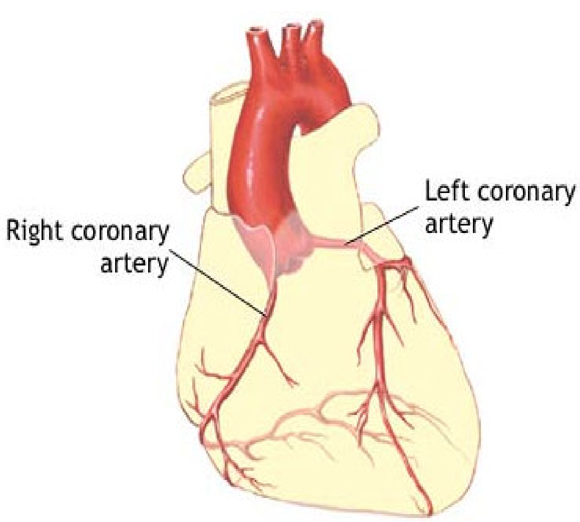

FIGURE 1 Anatomy of the coronary arteries

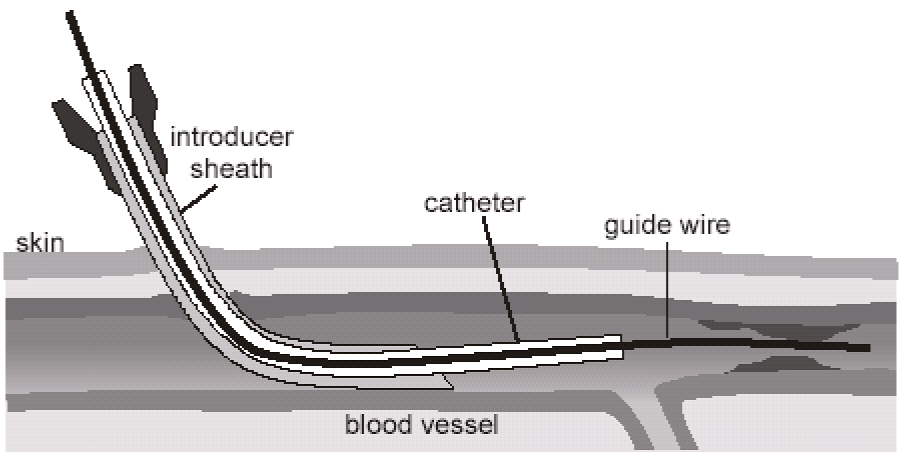

FIGURE 2 Catheter introduced into the blood vessel

3. ANGIOPLASTY

Angioplasty is performed on awaken patient who receive local anesthesia, and begins as a pencil-sized plastic tube, called a sheath, is inserted into an artery that runs below the skin. The sheath may be inserted through the artery that runs down the left leg and is typically inserted into this artery via an incision in the groin area as shown in figure 2. Though more painful, it can also be inserted through an artery in the left shoulder. Regardless of the insertion point, it is imperative to monitor the artery and blockage during the procedure. In order to produce images of the artery, an iodine based dye is injected into the blood stream, so that doctors can clearly view the progression of blood flow during the operation. Through these arteries, differently shaped catheters can be passed towards the heart. Through this catheter, an ultra-thin wire is threaded across the blockage region in the coronary artery. Over this wire, a thin, expandable balloon is passed to the blockage, where it is then inflated to several atmospheres of pressure. As the balloon expands, the plaque is forced up against the walls of the artery and broken up to allow for a restoration of blood flow. Typically, the blockage in an artery can be reduced from 70% to 90% to about 20% to 30%. This type of procedure, known as PTCA, is by far the most widely used type of angioplasty. Figure 3 shows the process of PTCA [2, 3].

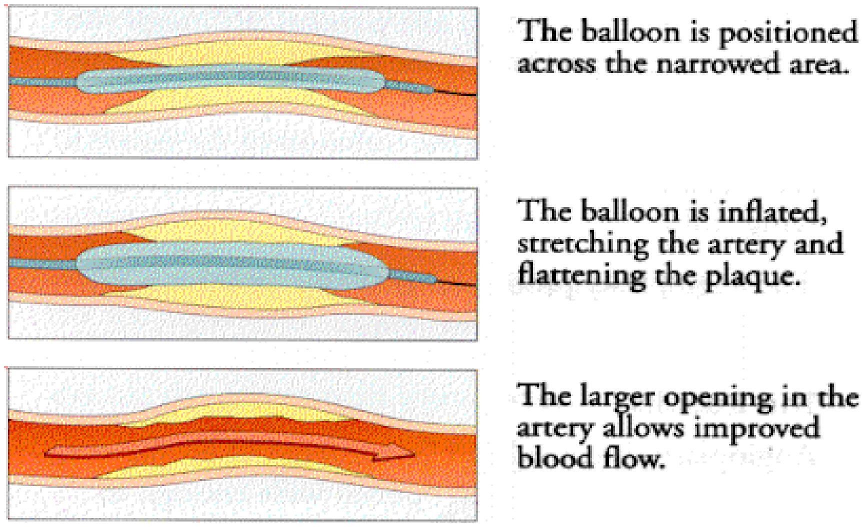

FIGURE 2 Model of Balloon insertion and inflation

Although angioplasty has proven to have a high success rate, it is a surgical procedure that carries a risk for complications. Some of the more prevalent complications include:

1. Bleeding at the site of sheath insertion. This commonly leads to a small "bruise" in the groin area and, in rare cases, to more serious internal bleeding.
2. Infection at the site of sheath insertion
3. Damage to blood vessels and Allergic reaction
4. Kidney damage or kidney failure
5. Stroke and Heart attack

Rarely, during the angioplasty procedure, inflating the angioplasty balloon within the coronary artery can cause a tear (dissection) in the artery. If this occurs, it may block the flow of blood in the artery and cause a heart attack, necessitating emergency bypass surgery. The risk for death during angioplasty depends on many factors, including the location of the blockage in the coronary artery, how difficult the blockage is to treat, whether other blockages are present in the coronary arteries, whether the patient has had prior heart attacks, and how well the patient's heart is pumping. Otherwise the healthy patients undergo a routine angioplasty.

4. CORROSION IN METAL ALLOYS USED IN ANGIOPLASTY

The metallic surface in contact with body's fluids corrodes the stents which are transplanted. The surface dissolves and the dissolved metals enter the circulation. The concentration of the metals like Stainless steel, Cobalt, Chromium, Titanium and Nickel in the blood increases. Most of the alloys used are resistant to corrosion, yet the corrosion occurs when two dissimilar surfaces are in contact this happens in almost all alloys. The corroded metal surface will releases many small particles of metal alloys. These small particles dissolve in the body fluids. As a result of these processes, the concentrations of Stainless steel, Cobalt, Chromium, Titanium and Nickel in the blood and urine of patients increases and also the Mechanical Characteristics of some of the alloys used in Angioplasty is shown in table 1. The trace-metals Cobalt and Chromium are a part of body's enzyme system, but these metals have caused cancer in workers exposed to large concentrations of these metals. However the question of the long-term effects of metallic stents on patients is not answerable. As most of the materials used are highly Biocompatible (means well tolerated by bone and other tissues) but even these metals corrode and release metallic ions in to the blood stream. Metallic wear particles in the soft tissues paint the tissues black, this is called metallosis.

Characteristics	Stainless steel	Cobalt-Chrome	Titanium	NiTinol
Stiffness	High	Medium	Low	High
Strength	Medium	Medium	High	Medium
Corrosion Resistance	Low	Medium	High	High
Biocompatibility	Low	Medium	High	High

TABLE 1: Mechanical Characteristics of Alloys used in Angioplasty

5. OTHER TYPES OF ANGIOPLASTY

The other types of angioplasty in practice include rotoblation angioplasty and laser angioplasty. Rotoblation utilizes a small diamond tipped drill on the end of the catheter and allows the surgeon to drill through the plaque. The laser procedure allows the surgeon to burn through the blockage. These are fairly new operations and have not had the time to develop as much as the balloon angioplasty has.

6. LASER MEDICAL CATHETERS AND ANGIOPLASTY DEVICES

Laser technology is used in the mechanical industry is for more than 25 years, and their use in the manufacturing environment is growing significantly. This is particularly true in the medical product industry, where the use of lasers to manufacture devices is relatively recent and where the possibilities for future use in various areas seem unlimited. Three principal laser types are used in most manufacturing environments. These are the carbon dioxide (CO_2) laser, the solid-state (primarily Nd:YAG) laser, and the Excimer laser. Each has its own distinct advantages and disadvantages when being considered for manufacturing purpose [4].

Lasers were introduced into the interventional cardiology armamentarium in the late 1980s and were initially met with enthusiasm. However, there were soon significant concerns regarding laser related complications, mainly dissections [5] and perforations [6]. Because of this, there was a drastic decline in the number of laser angioplasty procedures performed in the early 1990s. However, over the past several years due to an improvement both in equipment and in technique there has been a renewed interest in laser angioplasty. The current generations of xenon chloride excimer lasers are being used for coronary and peripheral angioplasty, pacemaker and implantable cardioverter/defibrillator lead extractions, and transmyocardial revascularization (Table 2). This review summarizes the current state of excimer laser angioplasty.

Medical devices incorporating laser-based processing as a step in their production are becoming increasingly common, especially as industry demands smaller feature sizes that may be impossible or uneconomical to realize using traditional manufacturing techniques. It is fair to say that a large percentage of the processing applications involve punching small holes into some type of plastic or organic material. The material, hole sizes, hole patterns, and other parameters change with the individual application. Typical applications include orifices for drug delivery, liquid or material removal, inflation devices, and analytical devices. Each has its own set of unique requirements and constraints, and, as in all industrial situations, technical objectives must be balanced with fiscal considerations.

Laser angioplasty was initially met with enthusiasm by the interventional cardiology community, but this enthusiasm waned due to concerns over disssections and perforations. However, due to an improvement in catheter design and operator technique there has been a resurrection of the excimer laser in cardiovascular medicine. Current cardiovascular applications include coronary and peripheral angioplasty, pacemaker and implantable cardioverter/defibrillator lead extraction, and transmyocardial revasculanzation. Coronary "niches"for the excimer laser angioplasty include saphenous vein grafts, aorto ostial lesions, undilatable or uncrossable (with balloon) lesions, total occlusions with a guidewire, and in stent restenosis. Several ongoing trials will better delineate the place of the excimer laser in cardiovascular medicine.

The idea for a "laser" was first conceived by Albert Einstein in 1905. The terms "excimer" and "laser" are acronyms. Excimer is an acronym for excited dimer, while laser stands for light amplification by stimulated emission of radiation. Laser energy from the xenon chloride laser is produced when HCl gas is excited by electrical energy and emits monochromatic, coherent light at a wavelength of 308 nm. This laser energy ablates inorganic material by photochemical mechanisms that involve the breaking of molecular bonds without the generation of heat.(1) The exact mechanisms for tissue ablation are unclear but probably consist of a combination of photochemical, localized thermal, and mechanical effects[4].

The wavelengths of emission for these lasers are 10 µm (CO2), 1 µm (Nd:YAG), and 0.2 µm (Excimer). It is generally true that thermal considerations in the processing become more important with increasing laser wavelength, and penetration depths are generally greater, allowing for faster bulk material removal at longer wavelengths. Because achievable resolutions become smaller at shorter wavelengths, it is fair to say that longer-wavelength lasers should be used where bulk material removal considerations outweigh either precision or quality requirements, but shorter-wavelength lasers must be used when the highest precision or process quality is required. The comparison of commonly used industrial lasers are illustrates in table 2.
The two issues of primary importance when determining the applicability of any lasers to specific tasks are the material's ability to absorb the wavelength of light used and to carry away excess thermal energy efficiently without causing secondary problems. In general, if the material does not show a fairly strong absorption of the desired wavelength of light, the best course of action is to find a suitable wavelength that does absorb strongly—assuming one can be found. Teflon, for instance, does not really laser machine well at any of the wavelengths under discussion, but it machines well at 157 nm (F2 laser) and can be processed if fillers are added that retain the initial desirable characteristics of Teflon while promoting absorption of the photons [7,8].

	CO_2	**Nd:YAG**	**Excimer**
Processing plane	Focal	Focal	Image
Relative operating cost per photon	Low	Low	High
Wavelength (µm)	9.6–10.6	1.06	0.19–0.35
Average power	0.3 to 20 kW	0.1 to 2 kW	<200 W
Penetration depth (µm)	>10	1 to 10	0.1 to 1
Penetration depth (µm)	>10	1 to 10	0.1 to 1
Ultimate feature resolution (µm)	10	>1	0.2
Practical feature resolution (µm)	~ 50	~ 25	~ 1
Material interaction	Thermal	Thermal	Photochemical/thermal
Types	CW, pulsed	CW, q-switched, pulsed	Pulsed

TABLE2: Comparison of commonly used industrial lasers.

Many plastics absorb all wavelengths of interest, but their low thermal conductivity prevents the use of longer-wavelength lasers for processing because the heat-affected zone exhibits symptoms of charring, melting, or cracking. This is also true of materials like glass. On the other hand, some ceramics absorb fairly well at all the wavelengths under discussion, and the choice of laser in these cases is dictated by speed, feature resolution, and quality.

It should also be noted that there are optical frequency–altering techniques commercially available for use with solid-state lasers that will double, triple, or quadruple the fundamental laser frequency. This frequency enhancement comes at the cost of losing some of the original output energy and stability, but provides an alternative way to make "green" and UV photons. In many cases, these new frequency-converted lasers particularly at the UV wavelengths achieved when frequency tripling or quadrupling may replace other UV sources in some applications, especially those requiring single-hole drilling of small, round orifices in soft material. As the technology for generating shorter-wavelength light from solid-state sources matures, the relative ease of use and low cost compared to other short-wavelength sources will be quite attractive to potential users.

7. ANGIOPLASTY-RELATED APPLICATIONS

Angioplasty operations are performed on patients who have suffered a major blockage to vessels in the circulatory system. The procedure typically involves inflating a balloon in the area of the blockage, which breaks up the accumulated plaque and opens the vessel. While this technique works well in the short term, 30 to 50% of all angioplasty operations performed will need follow-up treatment within six months. This is due to incomplete plaque removal and the formation of scar tissue as a result of irritation of the vessel, known as restenosis. There has been a tremendous push in the health-care industry over the last few years to combat restenosis because repeat operations are expensive, inconvenient, and potentially life threatening. Lasers play an important role in several of the new technologies being developed, specialized high-tech firms. Most surgeons performing angioplasty operations today insert these stents as a matter of course, since initial results seem promising. These stents are usually machined in intricate patterns to make them more flexible while still maintaining the mechanical rigidity necessary to keep the vessel walls from closing. The devices are also used to minimize the problem of arterial blockage caused by plaque falling into the vessel after inflation.

Such metal stents are usually made from small-diameter, stainless-steel tubing using a Nd:YAG laser. Other methods used to manufacture the metal stents with high precision include Electrodischarge machining (EDM) and etch techniques, but these methods have significant drawbacks and the laser process is the method of choice.

These devices have been used for only a few years and, although initial results look promising, long-term effects have not been fully investigated. It's important to note that, if restenosis recur there is no good method to simply remove the blockage, and follow-up treatments may require laser surgery or localized drug delivery using other angioplasty devices.

Because of these potential problems with metal stents, some researchers are looking at polymeric or even biodegradable ones. These materials usually require processing with an excimer laser to avoid thermal problems and heated-affected zones. In some cases stents have even been inserted after being coated in a restenosis inhibitor such as heparin.

An alternative to metal stents is the use of catheters with orifices located near the insertion end. These orifices are generally drilled using UV photons (in most cases from an excimer laser, although frequency-converted solid-state lasers appear to be a good alternative), the idea in this instance is to inject small amounts of a restenosis inhibiting drug locally. Heparin, usually used as an anticoagulant or blood thinner, has been found to be effective in controlling restenosis when used in high concentrations in localized areas. Since this drug is already well known in industry and among regulatory agencies, it has been used as a test case for localized delivery and proof of concept. Other drugs being investigated are more costly and are not as well documented, and systemic delivery can in some cases be toxic at the levels necessary for successful retardation.

8. OTHER CATHETER-RELATED APPLICATIONS OF LASER

A large number of high-tech applications for laser-manufactured devices involve angioplasty in some way, but there are also other applications that use lasers in the manufacturing process. One example is the use of CO2 lasers to drill large holes in simple catheters for liquid and material removal. Because quality in these applications is not as great a concern as functionality and low manufacturing cost, these devices can be made in high volumes at low cost.

Another use of lasers is in the manufacture of analytical catheters or devices that are inserted into the body and whose primary purpose is to give analytical feedback these devices are being manufactured for precise monitoring of vital organs and body functions at unprecedented levels of accuracy all made possible by the application of laser technology.

9. CORONARY LASER ANGIOPLASTY

The excimer laser was based on results of the Excimer Laser Coronary Angioplasty (ELCA). There was no difference in success rate or complications for long lesions, total occlusions crossable with a guidewire, saphenous vein grafts, and aorto ostial lesions, suggesting that selected complex lesions could be treated with ELCA. Risk factors for dissection included the use of larger ELCA catheters, high energy per pulse, lesion length > 10 mm, and the presence of a side branch. The incidence of perforation was higher in women, total occlusions, bifurcation lesions, and when the target vessel size was < 0.1 mm than the laser catheter.

Currently there are approved coronary applications for the excimer laser. They are saphenous vein grafts, total occlusions crossable with a guidewire, ostial lesions, long lesions, balloon dilatation failures, and moderately calcified lesions. Currently available catheters include both concentric and eccentric rapid exchange catheters. The Vitesse C catheters are 1.4 mm, 1.7 mm, and 2.0 mm concentric devices while the Vitesse E eccentric catheters are available in 1.7 mm and 2.0 mm sizes.

A major advance in excimer laser angioplasty occurred in 1995 with the advent of the saline infusion technique.[6] In blood or radiographic contrast media ultraviolet laser energy is avidly absorbed, inducing significant acoustic effects, tissue disruption, and dissection. The saline infusion technique eliminates blood and contrast from the laser field, resulting in a significant decrease in dissections from 24% to 7%. Currently, laser angioplasty is felt to have the most clinical benefit in the following applications: saphenous vein graft lesions, aorto ostial lesions, undilatable or uncrossable (with balloon) lesions, total occlusions crossable with a guidewire, and in stent restenosis.

10. CONSLUSION & FUTURE WORK

It is clear that the number of applications involving the use of lasers in the manufacturing process is increasing rapidly as advances are made in laser technology as well as in other technologies associated with medical device manufacturing. Two of the largest ongoing efforts by today's scientists and engineers are to "engineer life" (medical and biotechnology) and to make engineered devices more lifelike (microelectronics, robotics, artificial intelligence).5 These two efforts seem to converge on a microscopic scale, if anywhere, and both require novel micromachining capabilities that, in many cases, lasers can provide.

Two of the largest industrial users of precision micromachining lasers are the microelectronics and medical industries. This article has covered only angioplasty and catheter applications for laser technology; there are many more medical applications where devices are already in production or in initial engineering phases.

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