

MECHANICS BIOMATERIALS:STENTS¹

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Abstract – Airways and coronary arteries can be obstructed by a variety of diseases. Airways are mainly obstructed by lung cancer, scar inflammation or weakening of the airway wall. The main cause of coronary artery obstruction is the high levels of cholesterol in the human body. Stents are devices that can keep open the obstructed passageway. They have emerged as effective treatments mainly for the obstruction of airways and coronary arteries. Although their success has been outstanding, the patients that have received stents are vulnerable to thrombosis and restenosis. This paper presents four different materials that are used for the design and manufacture of stents. These are: Cobalt Chromium, NiTinol (Nickel-Titanium), Tantalum and 316 L Stainless Steel. The materials are selected based on their stress, strain, resistance, modulus of elasticity, and biocompatibility, etc.

Key Words – Stents, Chromium Cobalt, NiTinol, Stainless Steel, stress, strain, struts and resistance.

INTRODUCTION

Stents are generally used instead of – or along with – angioplasty. It is collapsed into a small diameter and put over a balloon catheter. It is moved into the area of the blockage. When the balloon is inflated, the stent expands, locks in place and forms a scaffold. Stents need to be resistant and elastic to be able to fulfill the said procedure. Stents also need to be made of certain materials that cause none or little side effects to the patient. That is why the materials used to design a stent have to be chosen after a thorough study. There are many different type of stents: coated, un-coated, metallic, plastics etc. The four main biomaterials that are used to make stents are Stainless Steel, Cobalt Chromium, Tantalum and Nitinol. The purpose of this article is to study these different materials.

RESEARCH ADVANCES

Drug-eluting Stent

A stent is a spring-like device that is temperature sensitive. Compressed and supercooled, it is inserted into an artery, routed through the body and deployed at the point of an aneurysm, at which time it expands to its desired diameter and supports the walls of the artery.

The numbers in brackets refer to bibliography.

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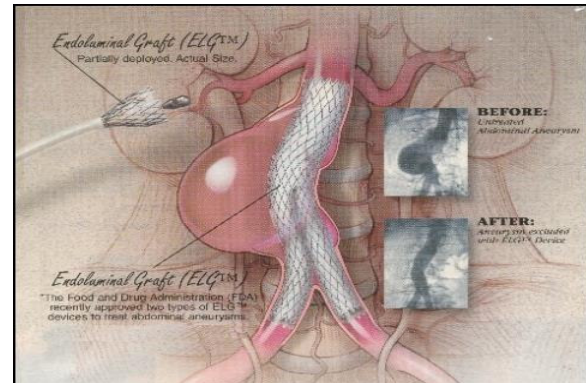


Figure 1. Drug eluting stent [15].

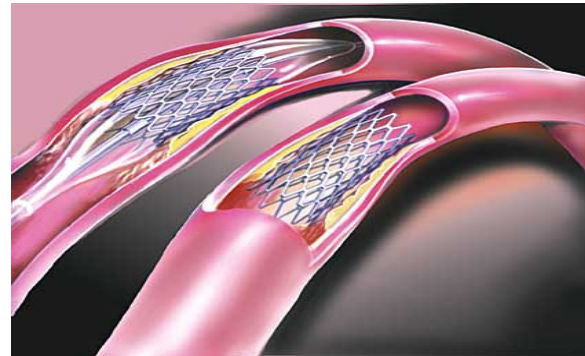


Figure 2. Drug eluting stent [15].



Figure 3. Drug eluting stent [24].

It is necessary to ensure that the stents expand at the proper rate and to the proper size within available ranges. A mistake could be life threatening.

Many types of technologies have been researched over the years to help solve the problem of restenosis. Currently there is increasing interest in a technology that brings together a drug and a stent. The drug is placed on the stent with a process that allows the drug to be released over time. This is called a drug-eluting stent, (Figure 1 to 3).

A drug-eluting stent is coated with a drug that is designed to control the release of a drug into surrounding tissue. The intention of this time-release process is to slow down the growth of unwanted cells (restenosis) and allow the vessel to heal.

Approximately 15-30 percent of stented arteries re-block (restenosis) within the first year due to the build up of scar tissue within the stented segment. These patients must be treated again with a procedure such as repeat angioplasty or bypass surgery. Drug-eluting stents have been shown to reduce the restenosis rate by 80 percent [27].

"Development of stents was a significant milestone in the treatment of blocked coronary arteries, but the problem of restenosis has continued to be an issue," said Stephen H. Hindman, M.D. "Sirolimus-coated stents will deter the scar tissue from forming [4]."

"We have been waiting for new technology which will improve the quality of lives of patients suffering from clogged arteries. This is an important advancement for cardiologists in the treatment of coronary artery blockages. Patients who receive these devices will need fewer repeat operations," said Judy Henderson, RN, director of Baptist Cardiovascular Diagnostics [3].

Radioactive Stents [24]

Radioactive stents have been shown to inhibit recurrent blockage of arteries (restenosis) following angioplasty. This article investigates alternative methods to produce a calibration technique for the stents related to national standards. In order to provide accurate clinical dosimetry, calibration of these sources is required. Air kerma strength is calculated after charge is collected in an ionization chamber at consecutive distances from a stationary source, known as the "seven distance technique". This technique has been extended to a Low Dose Rate (LDR) ^{192}Ir source in preparation to measure the ^{198}Au stents. The emitted gamma ray energies are similar for these two isotopes, (^{198}Au $E(\gamma) = 405$ keV and ^{192}Ir $E(\gamma) = 397$ keV) so this should be an effective calibration tool for ^{198}Au radioactive stents.

Radioactive Stents for the Prevention of Restenosis [24]

Currently available stems use P-32 with a half-life much longer than the acute cellular proliferation phase, and too short to provide long-term inhibition.

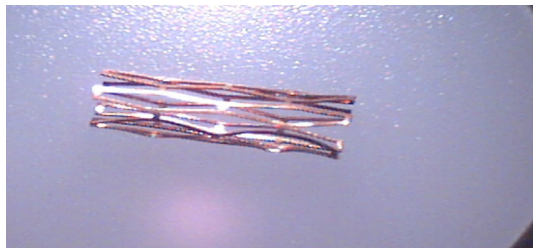


Figure 4. Radioactive stent [5].

The authors have been experimenting with other radionuclides, such as reactor-produced Au-198, that may better fit the biological characteristics. The first requirement is consistent calibration procedures that apply to all radionuclides. The basis for this calibration would be a concentric cylindrical extrapolation chamber. The second requirement is a methodology for calculating the dose distribution delivered from a deployed stent to surrounding tissues. This calculation will use intravascular ultrasound to determine the actual geometry, and sum the contributions of the parts of the stent in each image. Monte Carlo simulations will determine the contribution from small parts of the stent. This project also addresses tailoring the source distribution along the stent to produce the optimal dose distribution.

Fabrication of radioactive stents by ion implantation [8]

A tubular stainless steel mesh (stent) is implanted to mechanically support the injured vessel. Restenosis, an abundant complication (20%–30%) can be prevented, if the vessel is treated with ionizing radiation. Stents can deliver radiation if they are made radioactive. The radio isotope ^{32}P is well suited when ion implanted. Radioactive ions sources require high efficiency to keep the radioactive inventory small. Reliability, ease of operation, and maintenance are mandatory. A small emittance is important to minimize losses during mass separation and beam transport. A 2.45 GHz ECR source was developed for the implantation of ^{32}P . The source consists of two coils for the axial and a permanent hexapole for the radial confinement. The microwaves are fed in radially by a loop connected to a silver plated brass tube surrounding the plasma chamber. The plasma chamber is made from Pyrex. Neutron activated phosphorus, containing 30 ppm ^{32}P , is introduced from the rear end on a rod. As support gas D_2 is used. By this $^{32}\text{P}^+$ can be separated from $(^{31}\text{PD})^+$. The extraction is done in two steps: 60 kV–30 kV–ground. Mass separation is accomplished by a double focusing 90° magnet (radius 500 mm). During four years of operation about 1000 radioactive stents per year have been provided for animal experiments and clinical trials. It takes only one maintenance to exchange the extraction system due to degradation of high voltage stability was required so far.

PAST, PRESENT AND FUTURE SCOPE OF THE MATERIALS [7, 20, 28, 29]

The concept of the stent grew directly out of interventional cardiologist's experience with angioplasty balloons in the first decade of use (1977-87). Sometimes the wall of the coronary artery became weakened after balloon dilatation. Although the artery would be opened successfully using a balloon, in a small percentage of cases, the artery would collapse after the balloon was deflated.

A second problem soon became evident as well. Approximately 30% of all coronary arteries began to close up again after balloon angioplasty. By the mid-80's various radiologists and cardiologists were working on solutions to these problems.

One such device was the stent -- a metal tube or "scaffold" that was inserted after balloon angioplasty to provide structural support for newly opened channels, Julio Palmaz and Richard Schatz were working on such a stent in the United States; others in Europe were developing their own designs. In 1986, working in Toulouse, France, Jacques Puel and Ulrich Sigwart inserted the first stent into a human coronary artery. In 1994 the first Palmaz-Schatz stent was approved for use in the United States.

Stents virtually eliminated many of the complications of abrupt artery closure, but restenosis persisted. The solution moved away from the purely mechanical devices of the 90's and toward pharmacologic advances that were being made. Physicians and companies began testing a variety of drugs that were known to interrupt the biological processes that caused restenosis. Stents were coated with these drugs, sometimes imbedded in a thin polymer for time-release, and clinical trials were begun. A stent that seriously reduces the risk of restenosis could make angioplasty a better choice for patients who are at especially high risk for re-blocked vessels, such as diabetics or those whose blocked vessels are small. If so, the result could be a cut in the number of heart-bypass operations.

An immunosuppressant drug that inhibits proliferation of vascular smooth-muscle cells, named Sirolimus is manufactured by Wyeth-Ayerst (it is found in the soil of Easter Island) and Johnson & Johnson / Cordis has coated their CYPHER™ Stent with it. The CYPHER™ Sirolimus-Eluting Coronary Stent was approved in April of 2003 for patients undergoing angioplasty procedures to open clogged coronary arteries. It consists of a stainless steel coronary stent with a thin coating of drug (sirolimus) on its surfaces. The drug is located within a polymer (plastic) coating. The sirolimus drug on the stent is released over several days and interrupts the normal proliferation of scar tissue cells. It does not kill cells and instead allows the stent to be covered with the layer of smooth cells that normally line blood vessels. Without the growth of this smooth cell layer, the stent might cause a deadly blood clot.

The SIRIUS trial has shown extremely positive results with 8-month followup, recently reporting an in-stent restenosis rate of only 3.2% -- a 91% reduction over the control group. In the future these druged stents could also be combined with genetic medicine.

In only a few years, stent placement, as a minimally invasive intervention to treat a variety of diseases, has developed into a virtually routine procedure. Conditions in which stents are absolutely essential are stenotic coronary or peripheral arteries caused by severe arteriosclerosis, and even abdominal aorta aneurysms. Stents are frequently used in conjunction with balloon dilation of constricted vessels, to keep the newly opened stenotic vessel patent over the long term. The material properties of conventional stents (e.g. their metallic structure and hardness) make them particularly prone to damage the vessel wall. This, in turn, may result in re-occlusion of the vessel (restenosis).

Guidant is beginning development of another stent, using everolimus, but that won't be available until 2005. Meanwhile Medtronic has just begun a preliminary study (ENDEAVOR) in Australia, using a drug and polymer-coating from Abbott, but that product is also a few years off.

Preliminary study suggests polymer is safe and has fewer secondary effects than metal. Metallic stents can be lifesavers, opening up arteries that have been blocked by atherosclerotic plaques. But the downside can be thrombogenesis and restenosis. A Japanese study appearing in the July 25 issue of *Circulation: Journal of the American Heart Association* suggest that biodegradable stents made out of poly-l-lactic acid may offer a safer, but just as effective, alternative to the metallic versions [38]. The restenosis rate was only 10.5% in patients with biodegradable stents, a "very low and encouraging number", compared to the 20-30% seen in studies of metallic stents. No one knows the long-term, more than 10 years, effect of metallic stents in human coronary arteries. Biodegradable stents will be gradually absorbed and disappear in human coronary arteries within 2 years, which may resolve these problems.

The interest in the use of biodegradable stent has diminished in recent times. To be effective, the drug-releasing biodegradable stent must be biocompatible, must not evoke inflammatory reaction and must provide sufficient initial support to oppose the retracting force exerted by the diseased vessel. One such model is the Duke Biodegradable stent, this was the first biodegradable stent to be designed. Various biodegradable polymers were tested, with poly-L-lactic acid (PLLA) showing the most promise for further experimentation.

For the first time, a biodegradable stent has been implanted in a human being with great results in the Cardiology Department of Shiga, Japan. One of the most important characteristics is that this biodegradable stent reduces the inflammation of the vessels wall.

On February 4th of 2004 the London government authorized the use of the Cypher Stent, the ultimate device of Johnson & Johnson, soon after being debating how much will they pay for the stent for approximately two years. In the United States the companies can start selling soon after the Food and Drug Administration (FDA) authorize them, for Europe this is only the beginning. Then, the Europe government decides which will be the price. These delays stop the medicines to get there and the sellers decide to look for gain in the United States.

James Moore, founding partner of the Cardiovascular Engineering Center (CVEC) at Florida International University, has conducted research, which focuses on the mechanics of the cardiovascular system and the interaction with the biological tissues, which make up the arterial walls. Analyzing changes in blood flow patterns created by the placement of stents in arteries and developing new stent designs to alleviate these flow disturbances. Moore

designed recently a new stent that is made of a nickel-titanium alloy that is more flexible at its ends, thereby retarding the formation of new arterial tissue at those points. This common problem, which often follows stent insertion, requires additional surgery or an angioplasty to eliminate any new blockages. Moore considers that in order to develop good work in this field, it's essential to collaborate with medical doctors, biologists and other scientists; this will provide a valuable perspective on one's work and can help to create new alternatives.

The ideal stent might be one that is cheap to manufacture, easy to deploy, rigid enough to resist radial force, able to deliver therapeutic agents locally, and that disappears after treatment without leaving behind harmful materials. Polymer devices have this capability, although we have by no means unleashed their true potential. Biodegradable polymers such as polyesters, polyorthoesters, and polyanhydrides show great potential for this application. Another potential advantage of biodegradable stents is that they may have the potential to deliver medications that prevent restenosis to a specific area of the artery.

To be used in an endovascular stent, materials need to exhibit certain properties lending themselves to structural support, biocompatibility, biointegration, and most importantly, desirable hemodynamics. Biodegradable drug delivery systems make use of polymers that exhibit degradation, permeability, and moderate tensile strength.

FRICITION IN STENTS

Friction is a component in stents that can be an advantage and a disadvantage. First because friction can be good so that it doesn't slide from its specific place in the artery. Friction can also be a disadvantage because it is very difficult to deploy it in the artery.

In the deployment of a stent it is difficult to advance a balloon catheter as more friction between the wire and the vessel wall exists in a small vessel, very low profile balloons are frequently used. Deployment of stents in small vessels may be more challenging. Friction is higher and stent advancement is more difficult. The lesions may be localized in more distal segments of after tortuous segments [30].

In vitro experiments have shown that stents without side holes, those made with material with a low coefficient of friction or containing a hydrophilic coating, resist bacterial colonization at sites of surface irregularity and sludge formation because they are not as smooth as one would like [43].

Coated stents have low coefficient of friction that may increase stent longevity. The coating provides maximum friction reduction, which aids the passage of the catheter through lesions in blood vessels [42].

To reduce friction and thrombogenicity, Teflon heparin coatings are used. Hydrophilic polymer coating further

reduces friction to advance catheters more easily into peripheral vessel branches [6].

COMPUTATIONAL FLUID DYNAMICS SIMULATE BLOOD FLOW IN THE HEART [23]

The Bloodsim project was started in September 1998 and lasted for 36 months. The partners formed a multidisciplinary team consisting of experts in both stress analysis and computational fluid dynamics, clinical scientists as well as dedicated end-users. The latter group was used to deal with cardiac prostheses in clinical practice. In the past years, the delicate issue of mechanical heart valve failure in the patient's body has often been in the news. Profound research has brought to light that incidents of this type are caused by a faltering opening and closing mechanism of the disc occluder. The project team therefore worked on a better understanding of the quantitative factor in the behaviour of existing disc valves.

As a result, the partners offered the essential analytical facility to provide designers of new prostheses with the missing link in their concept. The search for a computational solution automatically lead to other domains in the cardiovascular discipline. These require urgent attention, such as the interaction of the blood flow with implanted devices, artificial vessels or even with a complete mechanical heart. Use of the simulation tool might even be extended to different areas within the human body, that are submitted to similar kinds of problems. The aim is to create a commercially available CFD code as well as an authoritative stress analysis package for the health care market, which integrate the complementary functions to tackle all current cardiovascular complications in a simulation environment.

Cardiovascular simulation not only relates to the behavior of the blood as a heterogeneous, anisotropic and non-Newtonian fluid, but also to the typical boundaries of the flow, which are constituted by the flexibility of the arteries, veins and heart. This means that the use of simulated rigid walls and fixed approximations of probable boundary motion are out of the question in order to predict the course of the blood. Indeed, it often occurs that the flexible natural boundaries have a pronounced effect on the flow. The simulation tool therefore has to take in account all these factors to offer clinicians a genuine insight in the different mechanisms, that are involved in the cardiac process, and to help manufacturers in the design of perfectly functioning prostheses.

Turbulence modeling for pulsatile transitional flows [23]

A major difficulty in the prediction of the flows in the carotid arteries lies in correctly accounting for their transitional nature. Ad-hoc treatments of natural transition that have proved effective elsewhere (e.g. prescribing the location of the transition point as a function of Re_{θ}) are inappropriate in these confined flows, especially when

stenoses - leading to the formation of free jets - are involved. This paper presents a progress report on ongoing efforts to develop a viable method for the treatment of transition in arterial flows within the framework of two-equation models of turbulence. One strand of this effort involves coupling a low Reynolds number k - ϵ model to an equation governing the transport of intermittency. Alternative proposals for closing this equation are assessed in relation to data from fully-developed pipe flow in the transitional regime. Further, a time-dependent flow rate is prescribed having a waveform characteristic of that found in a severely stenotic artery. Conclusions are drawn regarding the validity of this approach, and its ability to reproduce observed variations in wall shear stresses.

Effects of stents on blood flow patterns [22]

The placement of a stent in an artery affects the details of flow adjacent to the artery wall, as well as the overall flow patterns in the artery. A typical stent strut is approximately 0.15 mm in thickness, and stents are deployed into arteries at least 3 mm in diameter. Thus, the direct effects of stent strut protrusion into the lumen are confined to a region close the artery wall. The effects on overall flow patterns stem from structural aspects of the stent/artery wall interaction. The degrees to which these factors affect flow patterns depend strongly on stent design. The importance of understanding how stent-design dependent flow phenomena stems from observations that the artery wall reaction depends on the stent strut configuration.

The protrusion of the stent strut into the lumen of the artery corresponds to well-known flow situations from aerodynamics classified as flow over backward or forward facing steps. In a backward facing step flow, the momentum of the fluid flowing over the step carries the fluid past the corner of the step, creating a region of flow separation. Under steady flow conditions, the fluid contained in this region does not mix with the fluid in the mainstream, thus there are implications on the transfer of blood-borne substances in these regions adjacent to stent struts. In a forward facing step flow situation, the step inhibits the forward movement of the fluid adjacent to the strut, creating a separation zone. The separation zones associated with forward facing steps are typically smaller than those associated with backward facing steps.

The placement of a stent against the artery wall creates a series of adjacent backward and forward facing steps that may interact with one another. It is important to note that the stent struts are covered with thrombus within a few hours or days following implantation. Thus, the use of backward and forward facing steps to describe blood flow over stents is only applicable in the acute stages of implantation. There is some evidence, however, that the stent geometry is still represented in the neointimal development patterns even weeks after implantation. The effects of stent strut spacing on blood flow patterns adjacent to the artery wall have been studied using computational flow dynamics ~CFD! techniques. These techniques have the advantage of producing accurate information on all flow variables ~velocity, pressure, shear

stress, etc.! very close to the artery wall. Experimental techniques such as laser Doppler anemometry, particle imaging velocimetry, and Doppler ultrasound all suffer from significant uncertainties when measurements are being taken within the small distances close to the wall that correspond to stent struts.

The flow patterns near the struts of a wallstent were found to depend strongly on the strut spacing. The wallstent is a braided wire mesh self-expanding design. Using a commercially available CFD software package, a two-dimensional model of the wire crossover points was constructed. The bottom stent wire was assumed to be embedded by 30% of its diameter into the artery wall. Physiologic flow conditions corresponding to resting and mild exercise in the coronary arteries were applied. The flow patterns were demonstrated by plotting instantaneous streamlines and shear rate contours. Within the range of geometric parameters used to construct actual Wallstents for clinical use, the flow patterns were found to vary tremendously. With smaller stent wire spacings ~less than six wire diameters!, the stagnation regions from adjacent struts merged together for the entire cardiac cycle, creating one single stagnation region. For wire spacings larger than six wire diameters, the stagnation regions were split for at least some portion of the cardiac cycle, with the flow reattaching in between.

The strong dependence of flow stagnation on stent strut spacing was also observed by Henry using a computational model. For a stent strut spacing of three strut heights, the wall shear stress between the struts was less than 18% of the smooth wall value. For a stent strut spacing of 12 strut heights, the flow reattached between the stent struts, and the wall shear stress was approximately 90% of the smooth wall value between the struts. He also included a simple model for arterial wall compliance, but the rigid wall results were not markedly affected. It is important to note that the strut shape did not affect the nature of the near-wall flow patterns. Berry employed a two-dimensional representation of overlapping circular wire struts, while Henry employed 500 J. E. MOORE, JR. and J. L. BERRY a rectangular cross section. In an earlier report of preliminary results, Xu and Collins⁶⁰ constructed semicircular models of stent struts. Their velocity vectors and wall shear stress profiles agreed well with the subsequent studies of Berry and Henry.

This general behavior of flow stagnation associated with stent deployment was recently confirmed in a combined experimental/computational flow study by other investigators. However, the construction of their model was completely different from the models presented earlier. Their cylindrical model of flow over stent struts featured the protrusion of the artery wall between the stent struts as the primary protrusion into the flow stream. The tops of the stent struts were thus the local "low points" in the wall profile, with the struts completely embedded in the wall. The vessel wall between the struts was assumed to protrude 0.2 mm into the lumen past the tops of the stent struts in a 2.8 mm diameter artery. No justification for the use of this degree of protrusion was given. Similar patterns of flow

stagnation to those described earlier above were noted, although there were no studies of the effects of stent strut spacing. The geometric variation that was included was a representation of the acute stage ~so-called “sharp stented vessel”! and a latter stage when some neointima had formed ~“smooth stented vessel”!. Very little difference in flow patterns was noted.

The effects of flow patterns associated with backward facing steps on vascular endothelial cells have been the subject of several studies, although none directly related to stents. Depaola noted that confluent endothelial cells migrated away from the flow reattachment point in an in vitro flow chamber. Truskey demonstrated that subconfluent endothelial cells aligned with the flow direction near the flow reattachment point. Confluent cells, however, showed no preferential alignment in this region. Heidekker employed fluoroscopic techniques to quantify endothelial cell proliferation rate in a backward facing step flow chamber. It was found that cellular proliferation was higher near the flow reattachment point than in adjacent regions. These studies demonstrate quite clearly that the flow stagnation patterns produced by stent strut protrusion into the flow stream have an effect on endothelial cell behavior.

Perhaps the most important aspect of endothelial cell behavior with regard to stents is their ability to regrow over the denuded artery wall, stent, and neointima. In an in vitro experiment with a stainless steel strut embedded flush into a gel surface, Sprague demonstrated a clear dependence of endothelial cell migration on wall shear stress. They found that the stainless steel surface was 59% covered with endothelial cells after 7 days under static conditions, compared to 87% coverage with a shear stress of 15 dyn/cm² at the same time point. Walsh have reported results of endothelial cell regrowth patterns in simulated stented flow chambers in which the stent struts protruded into the flow stream. While no growth of the cells over the stent struts was observed over the experimental period of 7 days, lateral migration of endothelial cells was observed to occur at growth rates of approximately 15 mm/h. The initial growth of the cells appeared to be along the stent strut in the flow stagnation zone, with preferential alignment with the stent strut. Once the cells became confluent, the 501 Stented Artery Mechanics and Restenosis direction of preferential alignment was with the direction of flow.

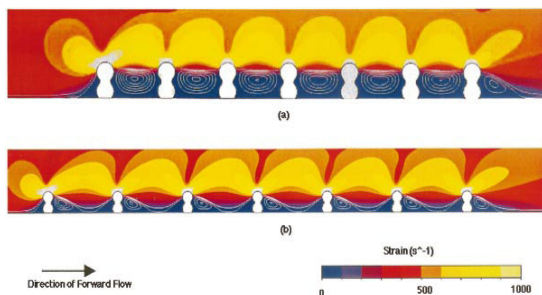


Figure 5. Stented artery mechanics and restenosis [22].

Simon noted that the largest areas devoid of endothelial cells were located downstream of trapezoidal surface obstacles intended to simulate stent struts. They also noted that the tops of the obstacles exhibited no overgrowth of endothelial cells when the obstacles were more than 175 mm in height.

The effects of stents on arterial flow patterns may extend beyond the region very close to the stent struts, depending on a host of associated mechanical factors. The imposition of the stent geometry on the artery wall affects the overall vessel geometry, as well as the compliance of the artery. When a straight, balloonexpandable stent is deployed into a curved artery, the stent will tend to straighten the artery. This geometric change was quantified, and its effects on steady flow wall shear stress, were quantified by Wentzel et al. The actual stent mesh geometry was not represented in their study. The increases in curvature at the proximal and distal ends of the stent led to significant changes in the shear stresses from the base line ~no stent! case. The spatial maximum in shear stress at the proximal end of the stent increased by as much as 113% with stent deployment. At the distal end of the stent, the maximum wall shear stress increased by 30%, while the minimum shear stress was 54% lower.

The compliance mismatch that occurs at the proximal and distal ends of the stent also affect overall blood flow patterns. The abrupt changes in mechanical properties at the ends of the stent create sites of propagating pressure wave reflection. These pressure wave reflections, in addition to the abrupt changes in cross-sectional area, lead to large-scale flow disturbances. Using dye injection flow visualization, vortices were seen to form during flow deceleration. These vortices were comparable in size to the diameter of the tube, thus much larger than the stent strut thickness. Oversizing the stent by 10% did not change this behavior appreciably.

These observations led to the design of a stent that provides a smoother transition in compliance at the ends of the stent. Prototypes of this stent, termed the compliance matching stent ~CMS! were machined and deployed in the same in vitro flow visualization system as used in Berry. The development of large-scale vortices was virtually eliminated.

Stents have also been demonstrated to produce small flow disturbances resembling turbulence as assessed by wall-mounted hot film probes. In this case, Palmaz and coil wire stents were deployed into a pulsatile flow producing apparatus. Under resting conditions, no flow disturbances were noted distal to the stents. The turbulent bursts appeared under simulated exercise conditions, and were greatest when stenoses were placed proximal or distal to multiple stents. Their experimental method did not allow for the measurement of flow disturbances within the stent. The production of flow disturbances by stents may also occur if the stent is deployed near a branch point and partially protrudes into the lumen due to inaccurate positioning. Stanek showed that wallstents placed across the ostium of the external carotid artery created additional

flow disturbance and resistance. These phenomena could result in important clinical failures as thrombus begins to form on the stent. Fabregues noted that flow disturbances of this type were reduced if the end of the stent that protruded into the parent vessel could be beveled and positioned appropriately. The thrombogenic properties of stents may also play a role in embolus formation from adjacent stenoses, as demonstrated by Sukavaneshvar.

DESIGN REQUIREMENTS

Stents

Stents are tiny mesh tubes that are implanted into a blood vessel and hold the vessel wall open to prevent from becoming blocked. Coronary stents are often used with traditional PTCA (balloon angioplasty) to prevent restenosis and improve the functioning of coronary arteries.

Deployment

The stent is introduced into the blood vessel on a balloon catheter and advanced to the blocked area of the artery. The balloon is inflated, causing the stent to expand until it fits the inner wall of the vessel, conforming to the contours as needed. The balloon is then deflated and withdrawn. The stent stays in place permanently, holding the vessel open and improving the flow of blood.

Design requirements

A cardiovascular stent must be flexible easy to track in order to be able to be deployed to small and possibly curved vessels. Flexibility is primarily dependent on mechanical configuration of the stent, although the yield stress of the material should be high enough to avoid or minimize plastic deformation. On the other hand the yield stress of the stent material should be low enough to allow balloon expansion of the stent to occur at pressures that are low enough to avoid vessel damage. The yield stress and fatigue resistance of the expanded stent must be high to withstand the stresses imposed by expansion and contraction of the blood vessel.

The design process for stents typically involves balancing conflicting mechanical requirements. For example, a compliant design that provides good radial support often leads to significant elastic recoil in deployment, a design that minimizes compaction diameter often sacrifices structural strength, a stiff design that assures secure contact with the vessel may cause damage to the vessel and restenosis.

STENT MATERIALS

Intracoronary stents are frequently used materials made of stainless steel, tantalum and nitinol. Of these stainless steel is the most used material. It is durable and has a relatively high radiopacity, a property of the material that prevents the passage of x-rays or any other radiation. Tantalum has a better radiopacity than steel. Nitinol is a nickel-titanium

alloy with unique self-expanding properties. This property allows the stent to expand into the walls of the blood vessel and acquire a better grip.

1. Cobalt Chromium Stents [10]

Cobalt chromium technology allows to reduce strut thickness and total stent volume while maintaining excellent radial strength and radiopacity.

This material is stronger and more radiopaque than stainless steel, so a cobalt chromium stent can have similar strength and visibility as a conventional stainless steel stent with struts that are only 0.0032" thick. Thinner struts make this kind of stent extremely deliverable. Clinical research has shown that thinner struts are linked to lower restenosis rates. Stents are usually made of stainless steel but recently different superalloys had been used. There are two types of CoCr alloys (Table 1).

a. CoCrMo – (typically cast into desired form)

- Used for many years in dental implants
- More recently used in artificial joints
- Good corrosion resistance

b. CoNiCrMo – (normally hot forged)

- Typically used for stems of highly loaded implants, such as hip and knee arthroplasty
- High degree of corrosion resistance in salt water when under stress
- Cold-working can increase strength by more than 100 %, but is impractical for large structures such as femoral stems
- Poor frictional properties with itself or any other material - Any bearing surface, such as the one in articulating joints.
- Higher fatigue and ultimate tensile strength than CoCrMo
- Good for components with long service life requirements
- Modulus of elasticity does not change with variations in ultimate tensile strength (220-234 GPa).

When multiple stents are required, stent materials should be of similar composition. Placing multiples stents of different metals in contact with each other may increase the potential for corrosion. The risk of in vivo corrosion does not appear to increase based on in vitro corrosion tests using a CoCr alloy stent in combination with a stainless steel alloy stent.

Table 1. Cobalt-Chromium alloy properties [10].

Type	Condition	Tensile Strength MPa	Yield Strength MPa	Elongation %
Cast CoCrMo (F76)		655	450	8
Wrought CoNiCrMo (F562)	Solution Annealed	795-1000	240 - 655	50
	Cold-worked	1790	1585	8
	Fully Annealed	600	276	50

Table 2. Stainless steel properties [14].

Type	Condition	Ultimate Tensile Strength MPa	Yield Strength MPa	Elongation %
316	Annealed	515	205	40
	Cold-finished	620	310	35
	Cold-worked	860	690	12
316L	Annealed	505	195	40
	Cold-finished	605	295	34
	Cold-worked	860	690	12

2. Stainless Steel Stent [14]

a. Progression of use.

- Vanadium steel.
- 302 stainless - stronger and more corrosion resistant.
- 316 - addition of molybdenum to improve corrosion resistance in salt water.
- 316L - reduced carbon content from 0.08 wt% to 0.03 wt% to further improve corrosion resistance in chloride solutions.

b. Chromium is a component of stainless steel alloy.

- Chromium alloys can be pacified to give excellent corrosion resistance.
- Oxidizes to form transparent film on surface of material, sealing surface and preventing other oxidants from reaching the metal.

- Minimum effective concentration for this effect is 11 wt%

c. Stainless steels 316 and 316L (Table 2)

- Austenitic category - contain fcc iron.
- Not hardenable by heat treatment, but can be hardened by cold working.
- Non-magnetic.
- Contain Iron, chromium, nickel, molybdenum, manganese, silicon, carbon, phosphorous, and sulfur. Last four elements are trace elements, with a maximum concentration of 0.75 wt% each.
- Young's modulus about 210 GPa.

3. Ni-Ti stent alloys

Because of Ni-Ti's unique super-elastic and shape memory properties, a stent of this alloy may be a viable alternative to the present standard of stainless steel available in the U.S. market. By taking advantage of Ni-Ti's shape memory, the thermally activated stent becomes self-expanding and there is no need for a balloon to deploy the stent, as with stainless steel designs. The Ni-Ti stent is deployed using a mechanical pullback catheter and self-expands to a known diameter with in the artery. The nature of the pumping heart causes the arteries to constrict and expand with the systolic and diastolic pressures, respectively, resulting in circumferential forces on the stent.

TEST METHODS FOR STENTS [14]

The human adult has average arterial pressures of 120 mm Hg systolic and 80 mmHg diastolic, creating a "pressure-pulse" of 40 mm Hg. In order to accurately test the fatigue life of the stent it needs to be tested under similar physical conditions along with an increased cycling rate to reduce overall testing time. Thus, the fatigued cycled stents were subjected to an accelerated circumferential pulsatile fatigue test at 45 Hz in 37°C saline solution to simulate the physiological conditions within the arteries.

To evaluate any differences in mechanical stiffness after fatigue cycling, the stents are flat plate and radial hoop tested. The results of both tests are compared to a control group of the same stent type with zero-cycles.

It was observed through the latex tubing the control stents (stainless steel) would first structurally fail, then because of their weakened mechanical integrity, migrate axially in the tube. However, migration of the stent may contribute to failures not directly related to the circumferential cyclic fatigue

Table 3. Stent fatigue test survival summary [21].

Stent Type	Fatigue Cycles	"Human Time"	Quantity	
			Tested	Passed
Ni-Ti	1 x 10 ⁶	12 days	6	6
SS	1 x 10 ⁶	12 days	2	2
Ni-Ti	10 x 10 ⁷	4 mths.	6	6
SS	10 x 10 ⁷	4 mths.	2	0
Ni-Ti	40 x 10 ⁶	16 mths.	6	6
SS	40 x 10 ⁶	16 mths.	2	1
Ni-Ti	100 x 10 ⁶	2.5 years	12	11
SS	100 ⁶	2.5 years	4	0

The only Ni-Ti failure occurred on a stent, which migrated, after approximately 60 million cycles, and was physically stopped by the brass port where the latex tube is fixed. The failure occurred at an intersection on the end of the stent, which came into direct contact with the port. SEM inspection photos at 500X indicate a general starting point of the failure probably originated at a corner. In a cross-sectional view this would be the outer most fiber at the intersection's radius. A possible cause for failure, other than the circumferential cyclic stresses alone, is from the stents impact against the port. However, this theory has very little physical evidence to support it. The SEM photos do not show a distinct contact area. Damage to the surface of the stent would be expected if failure were immediate upon contact. Also, both the port and stent have round ends and initial contact would be between the two flush surfaces, making it difficult to sever any portion of the stent.

One of the most notable effects of fatigue is a change in the affected material's surface, such as crack propagation. For this reason, the fatigue-tested stents were inspected using a scanning electron microscope (SEM) the results were compared to the surface of a zero-cycled control group. Also SEM may aid in determining a failure due to fatigue by magnifying the fracture surface to allow study of any patterns indicative of fatigue type failures.

After studying the location of the stents, which failed, there appears to be no correlation between the location of the stent's placement in the tube and it's failure.

FUNCTIONAL REQUIREMENTS

1. Stainless Steel [38]

Stainless steels are regularly used by the medical, chemical, and pharmaceutical industries because of their corrosion resistance, biocompatibility, and ability to withstand elevated temperatures. They offer superior corrosion resistance compared with other steels and aluminum. Compared with titanium and cobalt alloys, stainless steels are readily available and relatively inexpensive.

Material Performance

Even though the balloon extends approximately 0.3 mm beyond the stent ends to ensure full expansion of the stent during the deployment, a stainless steel stent does not expand uniformly which causes significant arterial wall injury and vascular necrosis predisposes the development of thrombosis. It exhibits spring back towards a smaller, undeformed shape after the balloon is deflated.

Strength

The strength of stainless steel is defined by the intensity of the allowable stress. There are four different mechanical properties for stainless steel: martensitic and ferritic-martensitic, ferritic, ferritic-austenitic, austenitic. Figure 6 shows a stress and strain diagram for stainless steel. The yield stress for stainless steel is shown in figure 7. The yield stress varies with the exposure temperature to which the material is exposed to.

Reliability and Safety

In reality no stent material is ever 100% safe, because many difficulties may occur in the process of implantation and after. Biological complications due to stainless steel stents may result from its insufficient mechanical and tribological properties.

Human Reaction to the material

The reactions to the material depend on the ability of the stainless steel to corrode. Contrary to common beliefs, stainless steel may not be the most inert substance. The research has shown that stainless steel coronary stents may trigger allergic reactions to substances such as nickel, molybdenum, or chromium, which are released. These allergic reactions may be a major factor in causing in-stent restenosis.

2. Cobalt Chromium, CoCr [10]

Material Performance

The use of cobalt chromium alloy allows for a thinner strut design and a lower profile, which enables physicians to access challenging coronary blockages. It also maintains excellent radial strength and radiopacity.

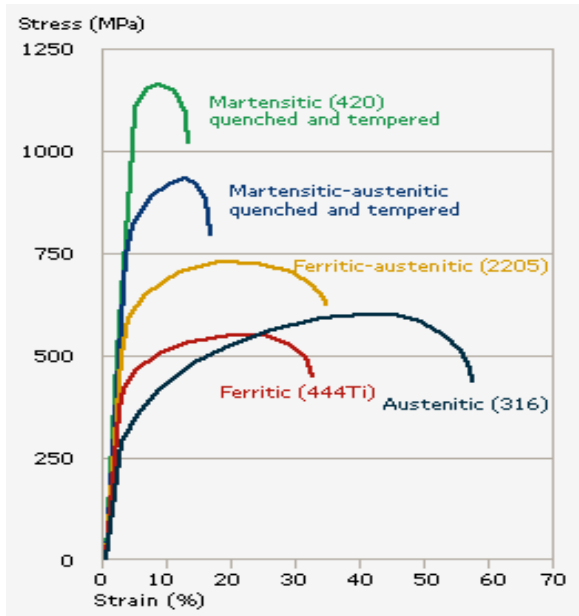


Figure 6. Stress and strain diagram for stainless steel [3].

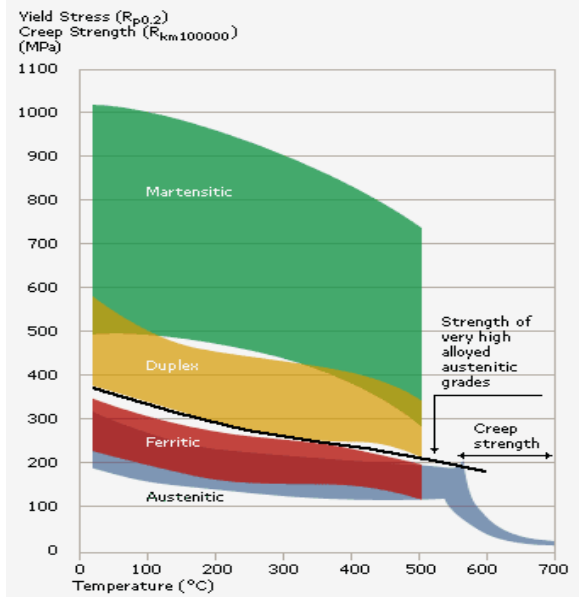


Figure 7. Yield stress versus temperature [3].

Strength

Cobalt Chromium is said to be stronger and more radiopaque than stainless steel. Cobalt-based alloys are extremely resistant to corrosion and especially to assaults by chloride within a fracture. As in all extremely alloyed metals in the body environment, galvanic corrosion can occur. Cobalt-based alloys are somewhat resistant to fatigue and to cracking caused by corrosion, and these are not brittle, since they have a minimum of 8% elongation. However, as is true of other alloys, cobalt based alloys may

fail because of fatigue fracture but less often than stainless steel stems.

Reliability and Safety

Cobalt Chromium has thinner struts that make it deliverable, and clinical research has shown that thinner struts are linked to lower restenosis rates. They offer less vessel injury and astonishing results.

Human Reaction to the material

Cobalt Chromium stents usually carry the associated risk of subacute thrombosis, vascular complications and bleeding effects. Persons allergic to the Cobalt Chromium alloy may suffer an allergic reaction to the implant.

3. Nitinol (Nickel-Titanium)

Material Performance [36]

Nitinol has 8% available elastic strain due to its superelastic transformation. Nitinol stents (Figure 8) would be inserted into the body and would be self-expanding as a result of the super elastic effect. They do not need to be embedded into the arterial wall by permanent deformation, and it is expected that they have longer fatigue life and that the risk of failure would be greatly reduced.

When open, the Nitinol stent is in its relaxed state by design. As the stent is compressed into a guide catheter, the device is loaded up the superelastic plateau. After the stent is deployed, it opens and the stress is reduced to a value along the unloading plateau. While gentle pressure is maintained to keep the artery open, any contraction, or blood vessel diameter reduction, would result in a higher resistance to loading and therefore giving the rise to biased stiffness.

Strength

The stress and strain diagram for Nitinol is compared with other materials in Figure 9.

Reliability and Safety

Nitinol has the ability to recover strains to the order of 8%. It also has the ability to be deformed at room temperature.

Keeping the device cool in the delivery system keeps the device in the soft phase in a lower force state. After deployment, the device warms to its new surroundings, recovers its “programmed” shape and becomes superelastic. This characteristic of Nitinol keeps the stent from migrating through the passage way, [34].



Figure 8. Nitinol material [36].

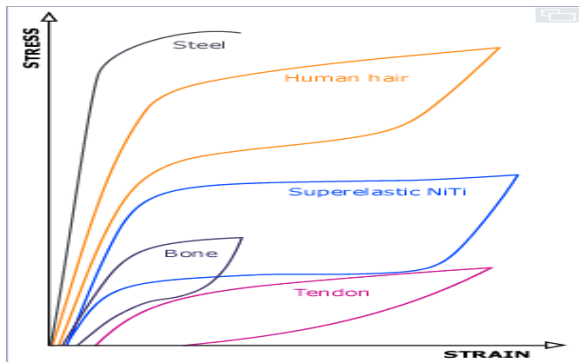


Figure 9. Stress and strain for Nitinol [36].

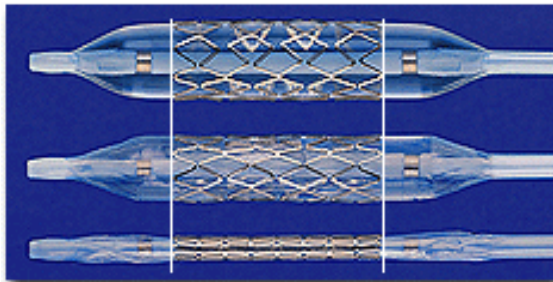


Figure 10. Model of stent manufactured with stainless Steel [18].

MECHANICAL PROPERTIES

Through the years the materials that are used to make stents have been changing. These advances in the discovery of new materials for the production of stents are moving very quickly. In almost every biomechanical product the use of stainless steel is the main choice (Figure 9). Other materials excluding stainless steel are the Nickel – Titanium (Nitinol), Silicon, Cobalt chromium. According to different sources and different companies and what products they offer stainless steel is most use. In a second perspective we find the nitinol. This material is very popular in the market because of his capability of self –

expanding. This process is interesting because the process of the angioplasty is not necessary. Other materials are not as frequently use in the marketplace because of their recent introduction to the public. Some are like the silicone and cobalt chromium. As a way to look always for the new things and finding out what is new and effective we compare what is new in the market and what is already well established. Mechanical properties for biomaterials are compared in table 4.

1. Cobalt chromium

For the chromium cobalt there is a lot of ambiguity in the field of the construction of stents because of their early introduction to the world. This material is also used for other biomechanical devices like hip replacement. The modulus of elasticity is defined by Hooke's law. For the stainless steel the value is 193 Gpa compare to the 235 Gpa found normally in the using of the material. When doing an analysis of the value in a stress – strain diagram we found that if the modulus is higher means that the slope of the curve in the linear elasticity part is steepest. Meaning that is need a bigger stress to develop a considerable strain.

2. Nickel – Titanium alloy (Nitinol)

This material is more frequently used like we stated earlier. We compare this material with stainless steel under the topic of efficiency. The Nitinol has it down side comparing with the stainless steel because the shape memory of this material also can be easily affected by the temperature and it does not happen with the stainless steel. Figure 12 shows that strength of the material under pressure is affected by stent diameter.

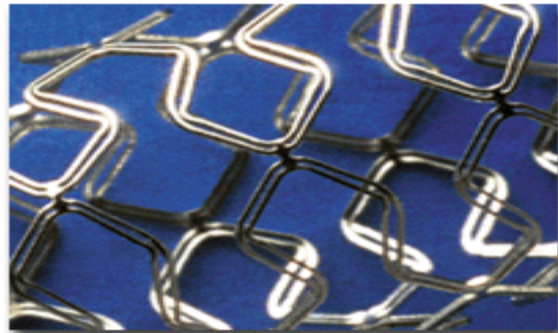


Figure 11. Up close photo of stainless steel stent [17].

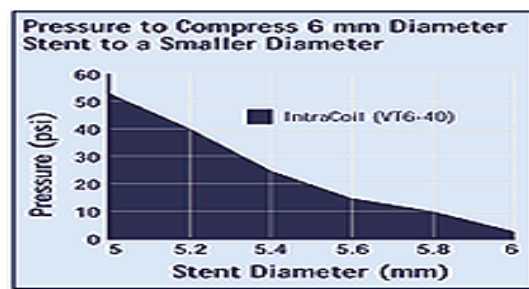


Figure 12. Graph for an specific model of stent [17].

Table 4. Mechanical properties of biomaterials for stents [32]

Property	Units	Nitinol*		Tantalum	SS 316 L	Cobalt Chromium
		High	Low			
Poisson's Ratio		0.3	0.3	0.35	-----	-----
Hardness	Vickers	----	----	100	199	410-545
Young's Modulus	GPa	75	28	186	193	235
Shear Modulus	GPa	29	11	69	-----	-----
Yield Strength	Tensile MPa	560	100	-----	330	707
Ultimate Strength	Tensile MPa	754-960	754-960	450	585	940
Elongation at Break	%	15.5	15.5	-----	45	1
Heat Capacity	J/g-°C	.32	.32	.153	0.5	-----
Thermal Conductivity	W/m-K	10	10	54.4	-----	14.7
Thermal Expansion Coefficient	10 ⁻⁶ /F 10 ⁻⁶ /C	----	----	-----	9.6 – 10.4 17.3 – 18.8	5.6 9.1

*High and Low temperature phases



Figure 13. Tantalum in wire form [40].

3. Tantalum

The modulus of elasticity is 193 GPa for stainless steel and 186 GPa for Tantalum. It shows the heavier strain is needed when trying to move a piece of stainless steel than with the tantalum. This capacity of the tantalum stent is an advantage when stent is trying to bend around the human circulatory system. Tantalum can be found in different shapes (Figure 13).

RECOMMENDATIONS

The medical innovations are being discovered at a seriously high pace. New materials beside the ones that we mentioned before are being tested to get better results with less money without falling into a decrease of quality of the product.

SUMMARY

One cannot put any type of material in the human body. Biocompatibility must be evaluated first for any kind of material. Each of the material has its up sides and down sides. The majority of stents that we see in the market are of stainless steel, however, there are several materials that have been used in human body.

ACKNOWLEDGEMENTS

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GLOSSARY

Alloy: A homogeneous mixture or solid solution of two or more metals, the atoms of one replacing or occupying interstitial positions between the atoms of the other.

Angioplasty: non surgical procedure that is a technique used to widen the narrowing in your artery without surgery. The basic idea of angioplasty is to position a catheter with a small inflatable balloon on the end within the narrowed section of the artery. The balloon is then inflated, which pushes outward against the narrowing and surrounding wall of the artery. The inflated balloon opens the narrowed artery by splitting and compressing the plaque and slightly stretching the wall of the artery.

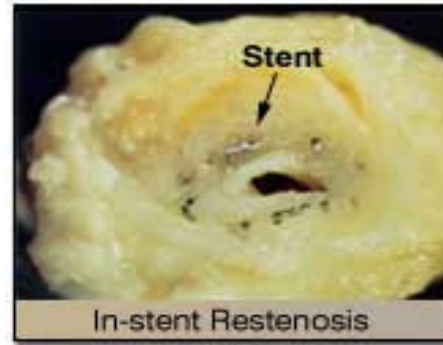
blood clots may also develop in abnormal situations, resulting in obstruction of veins or arteries. Veins carry blood that have given oxygen to the tissues of the body. Arteries carry blood away from the heart and lungs delivering oxygen to the tissues of the body.

Drug-eluting stents: a stent coated with a drug that is designed to control the release of a drug into surrounding tissue.

FCC: abbreviation for the term “face center cubic” structure. This structure is the arrangement that the atoms of a material follow when forming their composition. If this structure is altered or it is already then this also changes the mechanical properties of the material.

Radioactive stent: a stent ionized with radiation.

Restenosis: re-narrowing or blockage of an artery at the same site where treatment, such as an angioplasty or stent procedure, has already taken place. If restenosis occurs within a stent that has been placed in an artery, it technically called “in-stent restenosis”, the end result being a narrowing in the artery caused by a build-up of substances that may eventually block the flow of blood.



Stent: Stents are mesh like devices that look similar to the spring in a pen. Stents are delivered into the coronary artery on a catheter during a PCI procedure. They are then 'deployed' in the artery by either expansion by a balloon or by a unique 'self expanding' delivery design. They serve as a scaffold to prop the inside of the artery (the lumen) open which increases blood flow to the heart muscle. They are permanently deployed devices that stay in the artery. They are not removed. They ultimately become covered with cells and in essence become part of the artery over time.

Strut: Any part of a machine or structure, of which the principal function is to hold things apart; a brace subjected to compressive stress; -- the opposite of stay, and tie.

Thrombosis: The body's normal response to bleeding or damage of a blood vessel is to form clots. Formation of blood clots is necessary in certain circumstances.

APPENDIX I: NUMERICAL EXERCISES

TENSION, COMPRESSION AND SHEAR



A Nitinol stent has a diameter of 0.092 inches (2.3368 mm). When the stent is stretched by axial forces P, its diameter decreases by 0.000092 inches (0.002337mm). Find the magnitude of P considering the stent as a round bar. The mechanical properties of Nitinol are listed as follows [16]

- E = 80 GPa
- $\nu = 0.30$
- $\sigma_y = 290 \text{ MPa}$

SOLUTION:

Lateral Strain:

$$\epsilon' = \Delta d/d = -0.000092 / 2.3368 \text{ mm} = -0.0000394$$

Axial Strain:

$$\epsilon = -\epsilon' / \nu = -(-0.0000394) / 0.3 = 0.0001313$$

Axial stress:

$$\sigma = E\epsilon = (80 \text{ GPa}) * (0.0001313) = 10.5 \text{ MPa (tension)}$$

Tensile force:

$$P = \sigma A = (10.5 \text{ MPa}) * (\pi/4) * (2.3368 \text{ mm})^2 = 4.5 \text{ KN (Tensile force)}$$

AXIALLY LOAD MEMBERS



A stainless steel bar with diameter $d = 20 \text{ mm}$ is subjected to a tensile load $P = 22 \text{ kN}$. The original length of the bar is 2.4 m . [16]

- (a) What is the elongation of the bar if $E = 210 \text{ GPa}$?
(b) What is the stress in the bar?

SOLUTION:

(a)

$$\delta = PL/EA$$

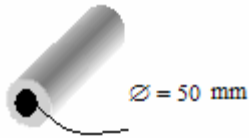
$$\delta = [(22 \text{ KN}) (2.4\text{m})] / [(210 \text{ GPa}) (\pi/4) (20^2\text{mm}^2)]$$

$$\delta = 8.0 \text{ mm}$$

(b)

$$\sigma = P/A$$

$$\sigma = (22\text{KN}) / [(\pi/4)(0.020\text{m})^2] = 7.0 \times 10^7 \text{ Pa}$$



A Nitinol tube has an inside diameter $d_1 = 50\text{mm}$, shear modulus of elasticity at low temperature of $G = 28\text{ GPa}$, and torque $T = 4.0\text{ KNm}$. The allowable shear stress in Nitinol is 50 MPa and the allowable normal strain is 900×10^{-6} . Determine the required outside diameter [16].

SOLUTION: $\tau_{\text{allowable}} = 50\text{ MPa}$

Allowable shear stress based on normal strain

$$\epsilon_{\text{max}} = \gamma/2 = T/2G$$

$$\text{then } \tau_{\text{max}} = 2 G \epsilon_{\text{max}} = 2 * 28\text{ GPa} * 900 * 10^{-6}$$

$$\tau = .0504\text{ GPa}$$

To find the value of d_2

$$\tau_{\text{max}} = \frac{T(\frac{d}{2})}{I_p}$$

$$0.0504 = \frac{(4000)(\frac{d}{2})}{\frac{\pi}{32}[d_2^4 - (0.050)^4]}$$

$$((\frac{\pi}{32}d_2^4 - \frac{\pi}{32}(0.050)^4)0.0504\text{ GPa} = 4000\text{ N-m}(d^2/2)$$

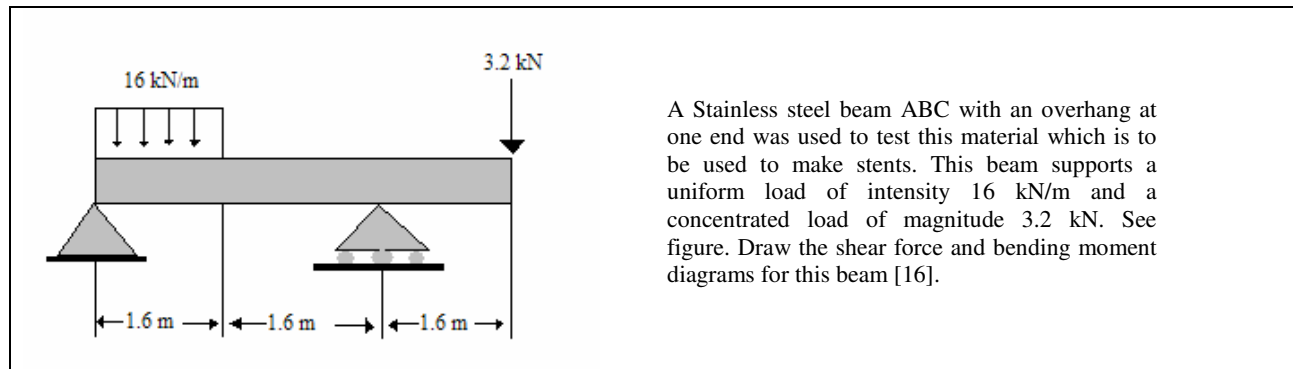
$$d_2^4 = (2000 d_2 = 30.9251) / 4.948 \times 10^7$$

$$d_2 - 0.00004 d_2 - 6.25 \times 10^{-6} = 0$$

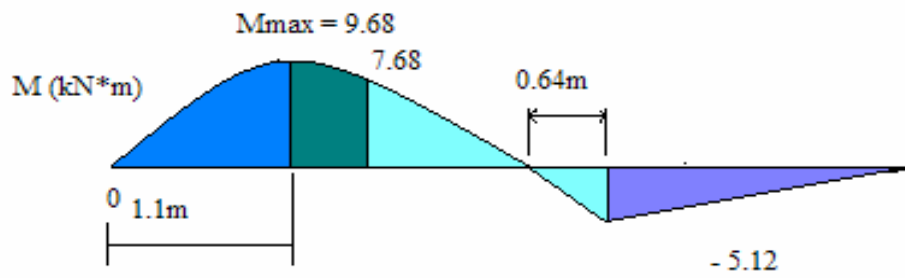
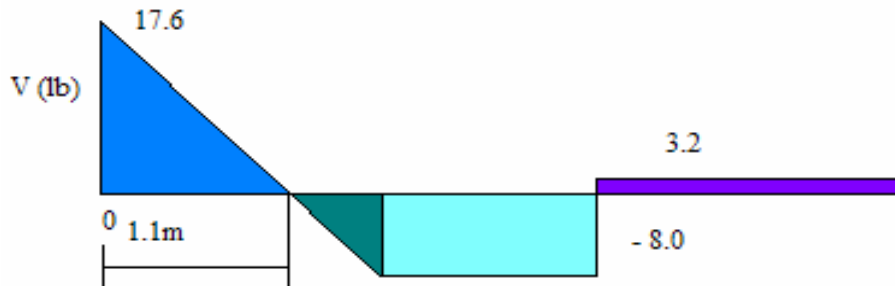
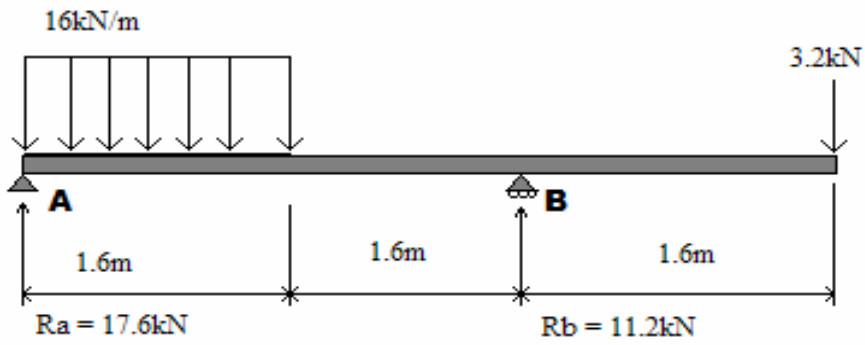
$$d_2 = 0.053841\text{ m}$$

$$d_2 = 53.8\text{ mm}$$

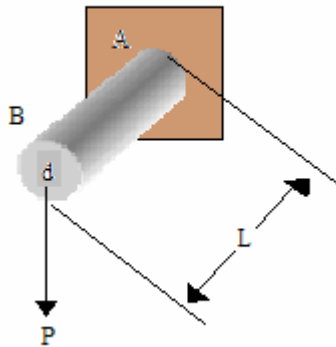
SHEAR FORCES AND BENDING MOMENTS



PROBLEM 4 CONTINUED:



STRESSES IN BEAMS



A cantilever beam AB of circular cross-section and $L = 500\text{mm}$ is used to test which diameter should be used to make a stent out of Nitinol. This beam supports a load $P = 200\text{ N}$ acting at a free end. Nitinol has an allowable bending stress of $\sigma_{\text{allow}} = 75\text{ MPa}$ and $\gamma = 72\text{kN/m}^3$. Determine the required diameter of the beam considering the effect of the beam's own weight. Then divide this diameter by 10 to get the required diameter for a stent [16].

SOLUTION:

q = weight of beam per unit length

$$q = \gamma (\pi d^2)/32 \quad S = \pi d^3 / 32$$

$$M_{\max} = PL + qL^2 / 2 = PL + (\pi \gamma d^2 L^2) / 8 = \sigma_{\text{allow}} S$$

Rearranging the equation to equal 0 we have the following:

$$PL + (\pi \gamma d^2 L^2) / 8 - \sigma_{\text{allow}} (\pi d^3 / 32) = 0$$

$$(76 \text{ MPa})d^3 - 4 (72.0 \text{ KN/m}^3)(0.5\text{m})^2d^2 - 32 (200\text{N})(0.5\text{m}) / \pi = 0$$

$$(76,000)d^3 - 72.0 d^2 - 1.01859 = 0$$

Solving the equation:

$$d = 0.024074 \text{ m} = 24.074 \text{ mm}$$

$$d_{\text{stent}} = 2.4 \text{ mm}$$