

# Coronary Artery Stent Design Using Rapid Prototyping

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## Abstract

Each year numerous balloon angioplasties (percutaneous transluminal coronary angioplasties – PTCA) are performed on patients to alleviate the narrowing (stenosis) of their arteries. Limitations of PTCA include acute occlusion or restenosis of the artery. To help prevent these side effects from occurring, stents are placed within the artery following PTCA. A stent is an expandable, tubular, wire mesh device placed in the arteries to hold them open and restore normal blood flow. The objective of this research was to determine the feasibility of designing coronary artery stent prototypes using rapid prototyping (RP). If the design of a stent were feasible, the prototype of the stent would be designed larger than its actual proportions so that the geometries and shape of the stent could be more clearly seen in a three-dimensional model. Rapidly prototyped stents could be a powerful tool for researchers in determining new stent geometries and the attachment of drugs to stents. Both non-deployed and deployed Palmaz-Schatz stent models were created using RP. Through investment casting, the models were then cast in Everdur and electroplated to obtain a silver finish. A second stent design with movable parts was also made to show the movement of the stent in one model.

**Keywords:** Coronary artery stent, stent prototype, rapid prototyping, stereolithography, investment casting

## 1. Introduction

Dotter first proposed stenting of arterial arteries in 1969, but studies of stents in animals did not begin until the late 1980s. The first stents were made of memory metal and in the shape of a coil; when certain torque was applied their diameter could change and allow for the delivery of the stent into the artery. Palmaz introduced the concept of a stent mounted on a balloon and catheter and had initial results of balloon-mounted stents in humans in 1985. The premise of having stents placed in arteries was to reduce the acute occlusions (closures) and restenosis rates associated with balloon angioplasties [1].

### 1.1 background

Stenosis of an artery is the narrowing or constriction of the vessel's diameter. Within the coronary arteries this is usually caused by a build-up of fatty deposits (plaque) along the sides of the arteries' walls. This leads to reduced blood flow and a loss of oxygen and nutrients arriving at the heart. This reduction of blood flow to the heart can result in coronary artery disease, myocardial infarctions, or other heart problems. The stenosis of the arteries can be reduced with a variety of methods, two options being balloon angioplasty and stent insertion.

#### *1.1.1 percutaneous transluminal coronary angioplasty*

Balloon angioplasty (percutaneous transluminal coronary angioplasty - PTCA) relieves the narrowing of the coronary arteries. Fluoroscopy allows the physician to observe the flow of blood throughout the heart by injecting a dye into the patient's blood that is visible by x-ray scanners. A guide wire is then inserted and its path is navigated to the stenosis of the artery with the use of fluoroscopy before PTCA is performed.

Once the guide wire is at the location of the stenosis, a balloon and catheter are inserted along the wire and navigated to the stenosis (Figure 1A). The balloon is inflated to its rated atmospheric pressures for a designated

amount of time (Figure 1B). During inflation of the balloon the patient may feel some pressure in their chest, similar to that of a heart attack, or no pain may be felt at all. As the balloon is inflated it compresses the plaque, which has a waxy consistency, up against the walls of the artery so that the blood can once again flow to the heart. The balloon is deflated and the pressure is alleviated as the balloon is then removed from the patient. (Figure 1C) [2].

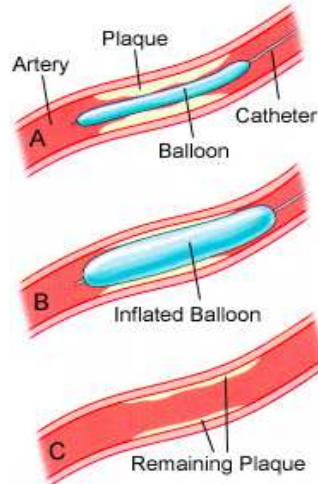


Figure 1 Percutaneous Transluminal Coronary Angioplasty [2]

Some drawbacks to PTCA are the occurrences of abrupt occlusion of the artery within 24 hours in approximately 3% - 5% of patients and restenosis within several months in 20% - 40% of patients [3]. These results have led to the use of stents in arteries that have become occluded due to a build up of plaque.

### 1.1.2 stent and stent insertion

A stent is often placed in an artery following PTCA to help eliminate some of the drawbacks of the procedure. A stent is an expandable, tubular, wire mesh device placed in the arteries to hold them open and restore normal blood flow. Figure 2 illustrates a non-deployed (top) and deployed (bottom) stent. The stent is inserted using the same procedure as PTCA; the only difference is that the stent is crimped onto the balloon prior to the balloon and catheter's deployment (Figure 3A). At the site of the stenosis, the balloon is expanded at a pressure that subsequently stretches the metal of the stent to its elastic limit. The stent is then able to remain open once the balloon is deflated and removed from the artery (Figure 3B). The stent is left in place to hold open the artery and allow the blood to flow normally through the vessel (Figure 3C) [2].

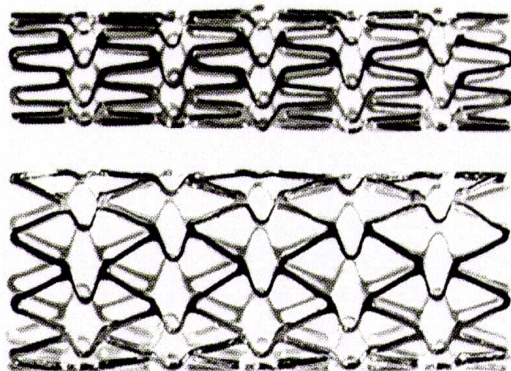


Figure 2 Stent: Non-deployed and Deployed [4]

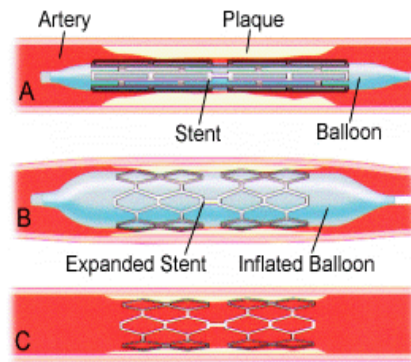


Figure 3 Stent Insertion [2]

## 1.2 rapid prototyping

Rapid prototyping (RP) is a process that allows for the creation of a prototype from a three-dimensional computer model. One type of RP technology is the stereolithography apparatus (SLA). In this process a UV (ultraviolet) laser is used to create successive cross sections of a three-dimensional model. A platform is placed into a vat of liquid photopolymer (epoxy resin). Each layer of the model is cured by the UV laser and as each layer is cured the platform drops down as the part is built layer upon layer, following a three-dimensional computer file (Figure 4). The SLA is highly accurate, the dimensions of models varying 0.002 to 0.005 inches, and is used for parts that contain complex geometries and intricate details in their design [5].

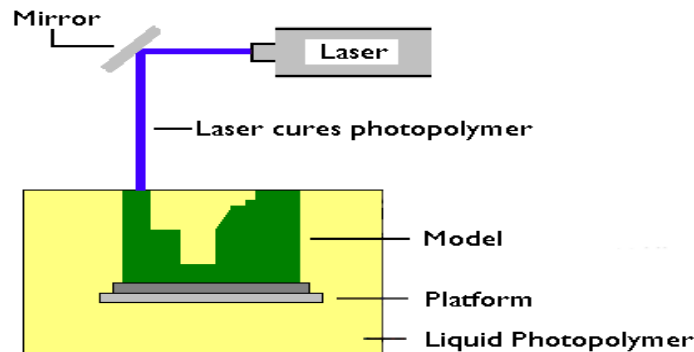


Figure 4 SLA Process

## 1.3 investment casting

Investment casting allows the manufacture of intricate designs using metals that may not be possible on a rapid prototyping machine. A mold is first made of a material that can be melted away, such as wax; this part is dipped into slurry that coats the mold and is allowed to dry. This process is repeated until the original part has a significant amount of coating surrounding it. Once this thickness is achieved, the part is placed in an oven and the inner wax is melted out. Into the void created by the melted wax, the desired metal is then poured into the slurry mold that remains. Once the metal has cooled, the outer slurry is broken and the original wax part is cast in a specific metal [6].

## 1.4 objective

The objective of this research was to determine the feasibility of designing coronary artery stent prototypes using RP. If the design of a stent were feasible, the prototype of the stent would be designed larger than its actual proportions so that the geometries and shape of the stent could be more clearly seen in a three-dimensional model.

## 2. Stent Properties

While no ideal stent has been created, there are some characteristics that all stents must achieve. These characteristics include biocompatibility, mechanical properties, safety, and compatible deployment [7]. At this time all these characteristics cannot be obtained simultaneously due to conflicts between some of the properties. Throughout the years, the characteristics have become more achievable with drug-coated and drug-eluting stents, but some complications remain.

### 2.1 biocompatibility

A stent needs to be biocompatible, especially with blood, and should not have an adverse reaction to the body once it is implanted into the patient; ideally the stent is biologically inert. This biocompatibility depends upon the stent's composition and surface characteristics, texture, and chemistry. The biocompatibility ensures non-thrombogenicity (no blood clots) and no intimal proliferation (increase/build up in the number of cells of the endothelial layer) [7].

## 2.2 mechanical properties

A stent needs to have enough elasticity, flexibility, and trackability to be navigated to the coronary arteries so that it does not become lodged in the arteries and induce arterial kinking, which can lead to abrupt closure [7]. Stainless steel and nitinol are common metal alloys that are used for stents; they are chosen due to their flexibility and a high mechanical stability that ensures that the stents can be crimped onto the balloon and successfully expanded in the artery to withstand elastic recoil [8].

An incorrect stent/artery ratio can lead to intimal proliferation and thus leads to late restenosis of the stented artery. Once inserted into the artery, the stent needs to have the correct expansion ratio and radial strength to withstand the pressures induced by the blood flowing through the coronary arteries [7]. Also a consideration is the actual size of the stent, which varies depending upon the arteries in which it is being placed. Stent are usually only a few millimeters in length, due to the small size of coronary arteries. Figure 5 displays a stent in relation to a penny.



Figure 5 Stent and Penny

## 2.3 safety

Stents are used to prevent the restenosis of arteries; to ensure this, the stent needs to be thin enough so it does not disrupt the smooth intimal lining of the arteries. The internal diameter of the stent needs to be maintained so long-term patency of the coronary arteries is achieved. This patency allows for the restoration of normal blood flow in the stented artery [7].

## 2.4 compatible deployment

A stent needs to be navigable along the guide catheter to the site of the stenosis and must be easily and precisely inserted through the blood vessels leading to the heart. The stent needs to be deployable on a low-profile catheter system (balloon and catheter used for PTCA) with minor adaptations to the current apparatus. The stent must be precisely delivered to the site of the stenosis and accurately deployed once there. The expansion of the stent needs to have a diameter suitable to the size of the artery (stent/artery ratio) so that it will be a stable support for the artery without the risk of migration of the stent within the vessel [7].

## 3. Stent Prototypes

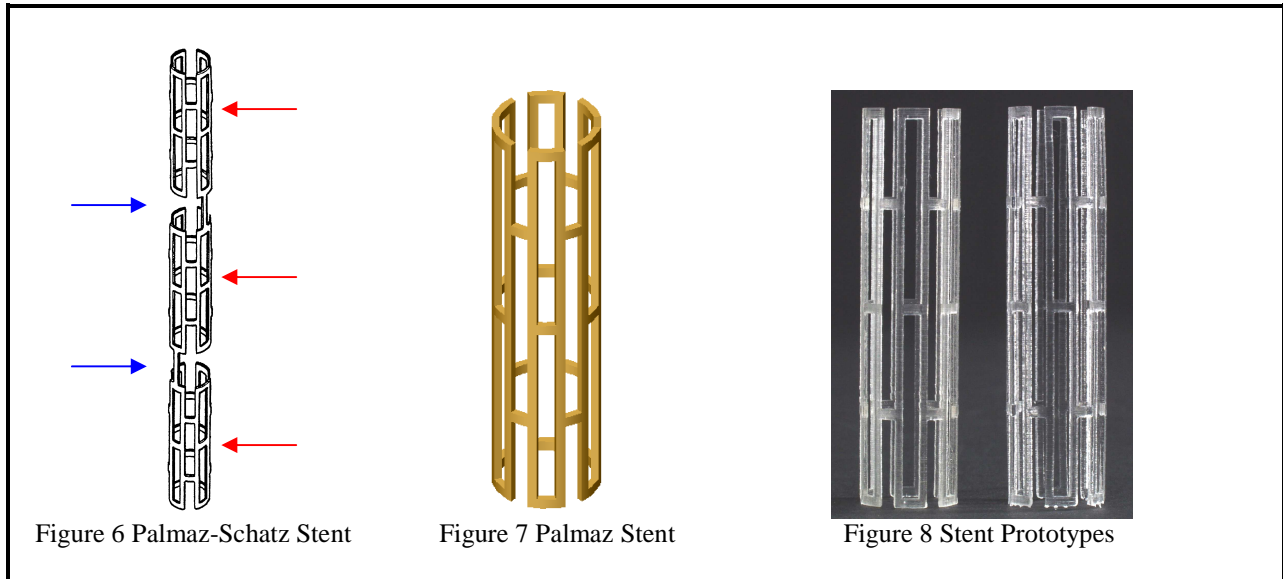
In researching different types of coronary artery stents, a Palmaz-Schatz stent was chosen to be modeled due to its widespread use in hospitals and to numerous journal articles pertaining to studies conducted on this particular stent.

### 3.1 SLA prototypes

To begin the process of creating a stent, a three-dimensional computer file needed to be created with the design of the stent. It was decided to have two different stent models, depicting both the non-deployed and deployed state of the Palmaz-Schatz stent. Since the shape of the stent differs in the two different states, one model would not be sufficient to show the change in shape of the stent after its deployment into a coronary artery. The two different models could more accurately portray the change of the stent's shape as it was deployed into patients' coronary arteries. The SLA machine was chosen to create the prototypes due to its high accuracy with intricate details and complex geometries, much like those associated with stent designs.

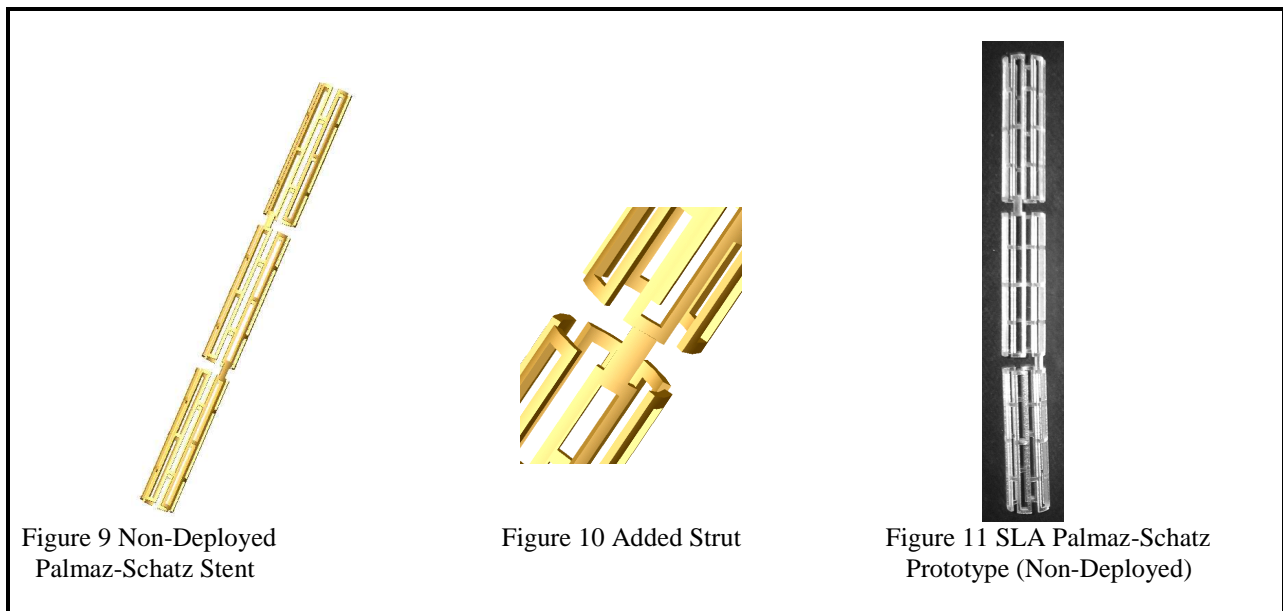
### 3.1.1 Palmaz stent prototype

A Palmaz-Schatz stent is merely three Palmaz stents connected by two struts. The red arrows in Figure 6 indicate the Palmaz stents and the blue arrows indicate the struts. Since a prototype of a stent had never been made on the SLA, just one section (a Palmaz stent) was first designed as a sample for fabrication (Figure 7). The two prototypes created on the SLA are shown in Figure 8. The prototypes were sized at 2 inches by 0.5 inches in diameter.



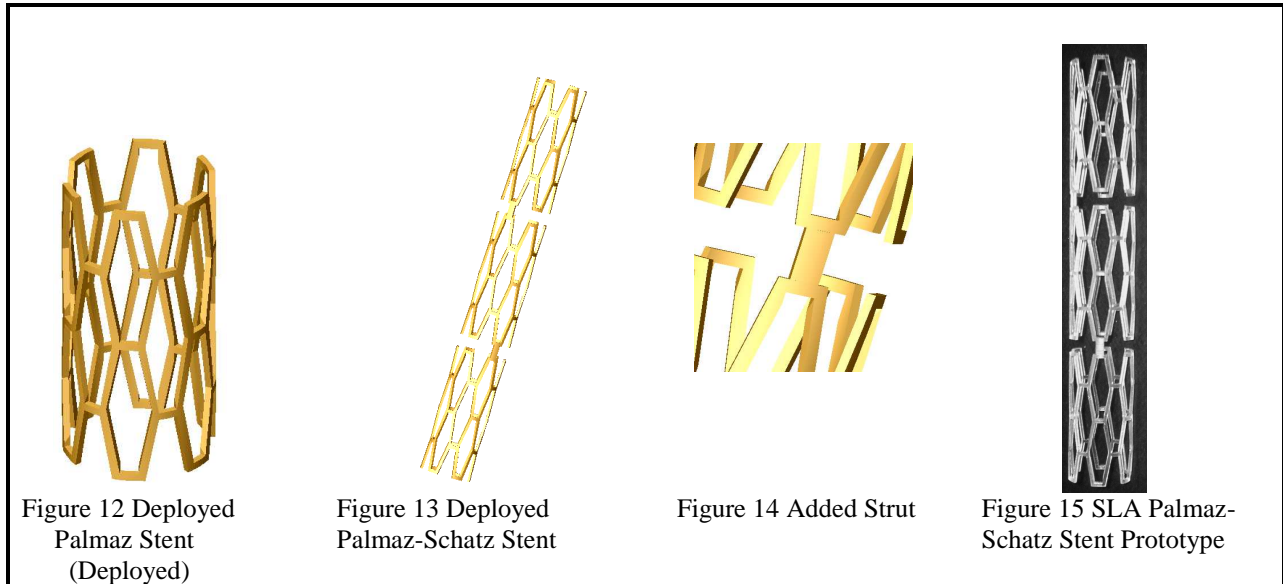
### 3.1.2 non-deployed Palmaz-Schatz prototype

Once the non-deployed Palmaz models were successfully created, files were designed with the entire non-deployed Palmaz-Schatz stent (Figure 9). An enlarged view of one of the added struts is shown in Figure 10. The non-deployed model was scaled so that each Palmaz stent portion was 3 and 1/3 inches and each strut was 1/3 inches in length; overall the stent was 10 and 2/3 inches by 5/6 inches in diameter. The SLA prototype is shown in Figure 11.



### 3.1.3 deployed Palmaz-Schatz prototype

A file was then created for the deployed Palmaz stent since the geometry of the stent changed from rectangular segments to hexagonal segments (Figure 12). A file was then created with the entire deployed Palmaz-Schatz stent (Figure 13). An enlarged view of one of the added struts is shown in Figure 14. The non-deployed model was scaled so that each Palmaz stent portion was 3.3 inches and each strut was 0.167 inches in length; overall the stent was 10.234 inches by 1 and 1/3 inches in diameter. The SLA prototype is shown in Figure 15.



### 3.1.4 movable Palmaz prototype

In addition to the non-deployed and deployed models of the Palmaz-Schatz stent, a movable model was designed. The impetus for this creation was to be able to demonstrate the movement of the stent, rather than just the form before and after deployment in the coronary arteries (Figure 16). This model would be able to move from the non-deployed to the deployed shape of a Palmaz stent.

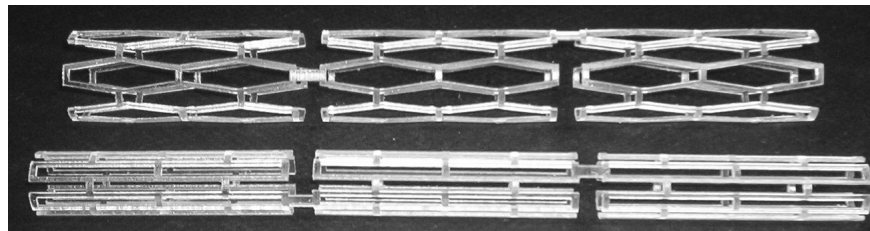
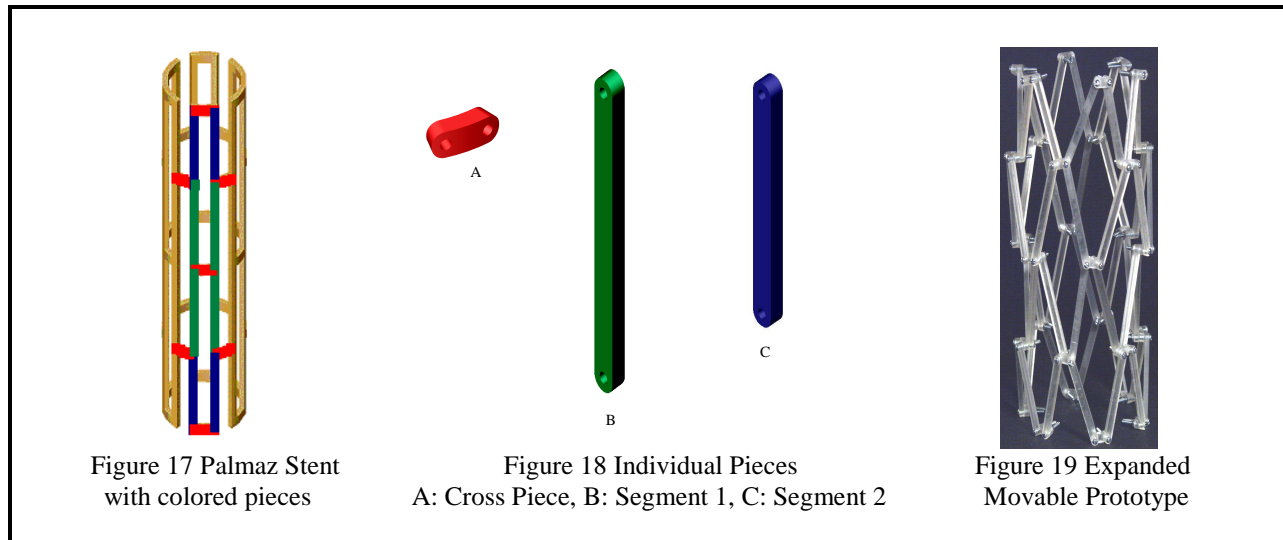


Figure 16 Non-Deployed (bottom) and Deployed (top) SLA Palmaz-Schatz Prototypes

A Palmaz stent was made to determine if the movable prototype would work and the stent would bend appropriately at the joints. Figure 17 illustrates the Palmaz stent with the three parts of the movable model indicated by the colors red, blue, and green. Figure 18 shows the individual pieces that were used to create the movable stent, which consisted of a cross piece and two different length segments. The cross piece (Figure 18A) is 0.2125 inches high and 0.556 inches long at a curvature of 30 degrees. Segment 1 (Figure 18B) has a width of 0.2125 inches and a height of 2.44375 inches. Segment 2 (Figure 18C) has a width of 0.2125 inches and a height of 2.125 inches. All pieces had a thickness of 0.1445 inches. The overall size of the stent is 8.5 inches by 2.125 inches in diameter to maximize the ability to see the movement of the stent. The movement of the stent is due to a screw and nut holding together each intersection of the various pieces. The movable stent is shown in its expanded form in Figure 19.



### 3.2 Investment Casting

Many tubular stents, such as the Palmaz-Schatz stent are made of stainless steel. Therefore, it was decided to cast the SLA non-deployed and deployed stent prototypes in metal to make them stronger and more durable. The stents are currently being cast by the Rapid Prototyping Center. They will be cast in Everdur, a copper-silicon alloy that is corrosive resistant and has high strength and resilience [9]. Due to Everdur's copper coloring, the stent prototypes will then be electroplated to obtain a silver finish to represent a stent made of stainless steel.

### 4. Conclusions

The feasibility of creating a coronary artery stent using RP was proven with the successful creation of the coronary artery stent prototypes. Both non-deployed and deployed stent prototypes of the Palmaz-Schatz stent were made using the SLA and these parts are currently being cast in Everdur and electroplated. There was the successful creation of a movable Palmaz stent. With larger samples of the stents, doctors would be able to show their patients what was placed into their arteries and how the stent would hold their arteries open. The larger models may also be useful for researchers in determining new geometries for the stents and what patterns of the stent may be more efficient for attaching drugs to the drug-coated and drug-eluting stents.

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### 6. References

- [1] Ruygrok, Peter N. and Patrick W. Serruys. "Intracoronary Stenting: From Concept to Custom." *Circulation*. 94.5 (1996). 882-890.
- [2] "Coronary Artery Disease." *Texas Heart Institute: Leading with the Heart*. Texas Heart Institute. 16 Jun. 2003 <[www.tmc.edu/thi/cad.html](http://www.tmc.edu/thi/cad.html)>.
- [3] Haas, Ruth. "Implantation and Imaging of Coronary Stents." *Radiologic Technology*. 67 (1996). 233-44.

- [4] "Open and Closed Stent." Online image. 30 Jun. 2003 <<http://www.ne.jp/asahi/ueda/stroke/stent.html>>
- [5] "Rapid Prototyping Machines: Stereolithography." 21 Feb. 2003. Milwaukee School of Engineering. 30 Jun. 2003 <<http://www.msOE.edu/rpc/sla.shtml>>.
- [6] "Investment Casting." EfundA: Engineering Fundamentals. 11 Jun. 2003 <[http://www.efunda.com/processes/metal\\_processing/invest\\_casting.cfm](http://www.efunda.com/processes/metal_processing/invest_casting.cfm)>.
- [7] Peng, Tao et al. "Role of polymers in improving the results of stenting in coronary arteries." *Biomaterials*. 17.7 (1996). 685-684.
- [8] Hehrlein, Christoph et al. "Influence of surface texture and charge on the biocompatibility of endovascular stents." *Coronary Artery Disease*. 6.7 (1995). 581-586.
- [9] "Bronze and Metals Information." 5 Aug. 2003 <<http://www.nbm-houston.com/bronze/everdur655.html>>.

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